Print Annual Reviews for Fiscal Year 2018

Count	Category/Medication	Review
1.	Actinic Keratosis Medications	Fiscal Year
2.	Allergen Immunotherapies	Fiscal Year
3.	Alpha$_1$-Proteinase Inhibitor Medications	Fiscal Year
4.	Alzheimer's Medications	Fiscal Year
5.	Antidepressant Medications	Fiscal Year
6.	Antifungals (systemic)	Fiscal Year
7.	Antihistamines (oral)	Fiscal Year
8.	Anti-Parasitic Medications	Fiscal Year
9.	Anti-Ulcer Medications	Fiscal Year
10.	Antiviral Medications	Fiscal Year
11.	Arcalyst® (rilonacept)	Fiscal Year
12.	Benlysta® (belimumab)	Fiscal Year
13.	Benzodiazepines	Fiscal Year
14.	Benign Prostatic Hypertrophy Medications	Fiscal Year
15.	Brineura® (cerliponase alfa)	Fiscal Year
16.	Butalbital Medications	Fiscal Year
17.	Cholbam® (cholic acid)	Fiscal Year
18.	Chorionic Gonadotropin Medications	Fiscal Year
19.	Daraprim® (pyrimethamine)	Fiscal Year
20.	Defitelio® (defibrotide)	Fiscal Year
21.	Diabetic Supplies	Fiscal Year
22.	Elaprase® (idursulfase)	Fiscal Year
23.	Fibric Acid Derivatives	Fiscal Year
24.	Fibromyalgia	Fiscal Year
25.	Gattex® [Teduglutide (rDNA origin)]	Fiscal Year
26.	Gaucher Disease medications	Fiscal Year
27.	Heart Failure Medications	Fiscal Year
28.	Idiopathic Pulmonary Fibrosis Medications	Fiscal Year
29.	Inhaled Short-Acting Beta$_2$ Agonists	Fiscal Year
30.	Insomnia Medications	Fiscal Year
31.	Iron Chelating Agents	Fiscal Year
32.	Kanuma® (sebelipase alfa)	Fiscal Year
33.	Keveyis® (dichlorphenamide)	Fiscal Year
34.	Leukotriene Modulators	
35.	Lidocaine Topical Medications	Fiscal Year
36.	Lumizyme® (alglucosidase alfa)	Fiscal Year
37.	Mozobil® (plerixafor)	Fiscal Year
38.	Muscle Relaxant Medications	Fiscal Year
39.	Myalept® (metreleptin)	Fiscal Year
40.	Mytesi® (crofelemer) [formerly Fulyzaq®]	Fiscal Year
41.	Naloxone Medications	Fiscal Year

Count	Category/Medication	Review
42.	Nasal Allergy Medications	Fiscal Year
43.	Nonsteroidal Anti-Inflammatory Drugs (NSAIDs; systemic)	Fiscal Year
44.	Northera® (droxidopa)	Fiscal Year
45.	Ocaliva® (obeticholic acid)	Fiscal Year
46.	Ophthalmic Allergy Medications	Fiscal Year
47.	Ophthalmic Antibiotics	Fiscal Year
48.	Otic Anti-Infective Medications	Fiscal Year
49.	Pancreatic Enzymes	Fiscal Year
50.	Pediculocides	Fiscal Year
51.	Phosphate Binders	Fiscal Year
52.	Prednisolone Special Formulations	Fiscal Year
53.	Prenatal Vitamins	Fiscal Year
54.	Procysbi® (cysteamine bitartrate)	Fiscal Year
55.	Pulmonary Hypertension Medications	Fiscal Year
56.	Qualaquin® (quinine sulfate)	Fiscal Year
57.	Qutenza® (capsaicin 8% patch)	Fiscal Year
58.	Radicava® (edaravone)	Fiscal Year
59.	Ravicti® (glycerol phenylbutyrate)	Fiscal Year
60.	Retisert® (fluocinolone intravitreal implant)	Fiscal Year
61.	Smoking Cessation	Fiscal Year
62.	Soliris® (eculizumab)	Fiscal Year
63.	Strensiq® (asfotase alfa)	Fiscal Year
64.	Sylvant® (siltuximab)	Fiscal Year
65.	Symlin® (pramlintide)	Fiscal Year
66.	Topical Acne Products	Fiscal Year
67.	Topical Antibiotics	Fiscal Year
68.	Topical Antifungals	Fiscal Year
69.	Ulcerative Colitis and Crohn's Disease Medications	Fiscal Year
70.	Vasomotor Symptom Medications	Fiscal Year
71.	Vesicular Monoamine Transporter-2 Medications	Fiscal Year
72.	Vimizim® (elosulfase alfa)	Fiscal Year
73.	Xgeva® (denosumab)	Fiscal Year
74.	Xiaflex® (collagenase clostridium histolyticum)	Fiscal Year
75.	Xuriden™ (uridine triacetate)	Fiscal Year
76.	Zinplava™ (bezlotoxumab)	Fiscal Year

Fiscal Year = July 1, 2017 – June 30, 2018

Coverage and Policy Updates Impacting the Following Reports:

- Due to new federal regulations, SoonerCare implemented a new pricing methodology for pharmacy claims reimbursement on January 3, 2017. Ingredient reimbursement changed from an estimated acquisition cost (EAC) to an actual acquisition cost (AAC). In addition, the professional dispensing increased from $3.60 in 2016 to $10.55 effective January 2017; professional dispensing fees are included in the reimbursement totals in the following reports. The impact of the pricing methodology and dispensing fee change are estimated to be budget neutral. This change in reimbursement should be considered when evaluating reimbursement changes from year to year. Medications with a very low cost per claim and large volume of claims will appear to increase in price due to the increase in dispensing fee; however, these increases will be neutralized by changes in ingredient reimbursement for higher cost medications.
- Effective October 1, 2017 non-prescription products for adult members were limited to insulin, smoking cessation products, family planning products, and diabetic testing supplies only. Other over-the-counter (OTC) medications are no longer a covered benefit for adult members.

Fiscal Year 2018 Annual Review of Actinic Keratosis Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 adults; 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.

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.

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.

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 adults or topical treatment of external genital and perianal warts/condyloma acuminate (EGW) in patients 12 years and older; and
2. Member must be 12 years 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%.

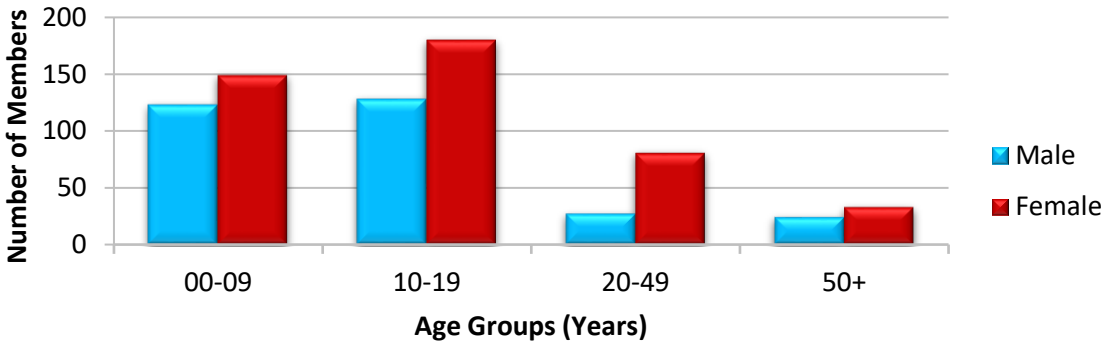
Utilization of Actinic Keratosis Medications: Fiscal Year 2018

Comparison of Fiscal Years

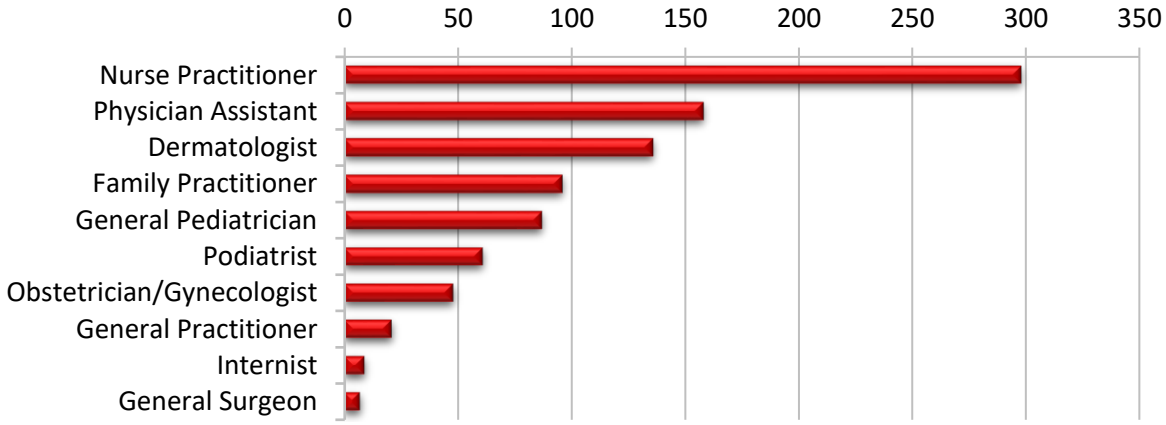
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	826	1,087	$83,101.26	$76.45	$2.07	17,609	40,060
2018	745	945	$43,210.72	$45.73	$1.19	16,276	36,454
% Change	**-9.80%**	**-13.10%**	**-48.00%**	**-40.20%**	**-42.50%**	**-4.60%**	**-9.00%**
Change	**-81**	**-142**	**-$39,890.54**	**-$30.72**	**-$0.88**	**-793**	**-3,606**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Actinic Keratosis Medications



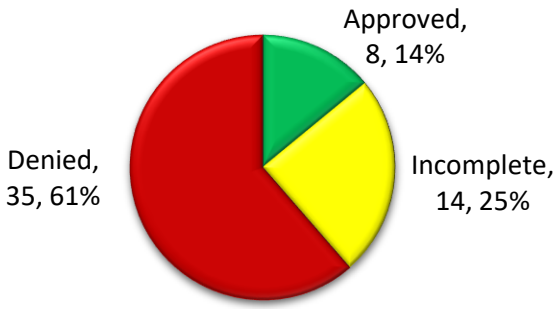
Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims



Prior Authorization of Actinic Keratosis Medications

There were 57 prior authorization requests submitted for actinic keratosis medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



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:

- **Feburary 2019:** Athenex, Inc. announced that they would be presenting an abstract reporting the results from 2 Phase 3 studies of KX2-391 ointment for the treatment of actinic keratosis at the Late-Breaking Research Program at the 2019 American Academy of Dermatology Annual Meeting in Washington, DC. KX2-391 is a novel dual Src Kinase inhibitor and tubulin polymerization inhibitor. Currently there is also development of an oral formulation of the drug for the treatment of solid and liquid tumors.[2,3]

Recommendations

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

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[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 02/28/2019.

[2] Anthenex, Inc. Athenex Announces Late-Breaking Oral Presentation of KX2-391 Ointment in Two Phase III Studies at the American Academy of Dermatology Annual Meeting. *Globe Newswire*. Available online at: http://ir.athenex.com/phoenix.zhtml?c=254495&p=irol-newsArticle&ID=2385847. Issued 02/04/2019. Last Accessed 03/01/2019.

[3] Src Kinase Inhibition. Anthenex, Inc. Available online at: http://www.athenex.com/oncology-innovation/src-kinase-inhibitors/. Last Accessed 03/01/2019.

Utilization Details of Actinic Keratosis Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
IMIQUIMOD PRODUCTS					
IMIQUIMOD CRE 5%	851	671	$31,427.66	$0.92	$36.93
SUBTOTAL	**851**	**671**	**$31,427.66**	**$0.92**	**$36.93**
FLUOROURACIL PRODUCTS					
FLUOROURACIL CRE 5%	86	69	$10,191.20	$4.59	$118.50
FLUOROURACIL SOL 5%	4	4	$200.48	$2.11	$50.12
SUBTOTAL	**90**	**73**	**$19,839.08**	**$14.31**	**$283.42**
DICLOFENAC PRODUCTS					
DICLOFENAC GEL 3%	3	2	$437.81	$4.86	$145.94
SUBTOTAL	**3**	**2**	**$437.81**	**$4.86**	**$145.94**
INGENOL PRODUCTS					
INGENOL MEBUTATE GEL 0.015%	1	1	$953.57	$317.86	$953.57
SUBTOTAL	**1**	**1**	**$953.57**	**$317.86**	**$953.57**
TOTAL	**945**	**745***	**$43,210.72**	**$1.19**	**$45.73**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Grastek® (Timothy Grass Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or in vitro testing for pollen specific IgE antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of the grass pollen season (November 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to one of the 5 grass pollens contained in Oralair®; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and

5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

Ragwitek® (Short Ragweed Pollen Allergen Extract) Approval Criteria:

1. Member must be 18 years to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis symptoms; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and

9. Initial approvals will be for the duration of six months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as “allergy shots”; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

Odactra™ (House Dust Mite Allergen Extract) Approval Criteria:

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    b. **Montelukast:** (1) 14-day trial in combination with an antihistamine; and
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician’s office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as “allergy shots”; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and
10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the patient is responding well to Odactra™ therapy. Additionally, compliance will be evaluated for continued approval.

Utilization of Allergen Immunotherapies: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2	17	$5,504.21	$323.78	$10.79	510	510
2018	1	1	$263.40	$263.40	$8.78	30	30
% Change	**-50.00%**	**-94.10%**	**-95.20%**	**-18.60%**	**-18.60%**	**-94.10%**	**-94.10%**
Change	**-1**	**-16**	**-$5,240.81**	**-$60.38**	**-$2.01**	**-480**	**-480**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Allergen Immunotherapies

- Due to the small number of members utilizing allergen immunotherapies during fiscal year 2018, detailed demographic information could not be provided.

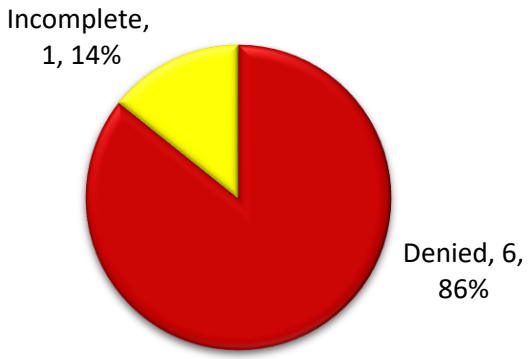
Top Prescriber Specialties of Allergen Immunotherapies by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for allergen immunotherapies during fiscal year 2018 was an allergist.

Prior Authorization of Allergen Immunotherapies

There were 7 prior authorization requests submitted for allergen immunotherapies during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

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

- **November 2018:** Stallergenes Greer announces that it FDA approval for a label expansion for Oralair® to treat patients 5 years of age and older for grass pollen-induced allergic rhinitis. Previously Oralair® was approved in patients 10 years of age and older.[4]

Pipeline:

- **AR101:** Aimmune Therapeutics, Inc. presented data on AR101, an oral immunotherapy for peanut allergy, at the 2019 American Academy of Asthma, allergy and Immunology (AAAAI) annual meeting. This treatment is aimed at training the immune system to decrease the severity of an allergic reaction with accidental exposure to peanuts. In a Phase 3 trial published in the *New England Journal of Medicine,* 67.2% of patients

[4] Stallergenes Greer. Stallergenes Greer Announces U.S. FDA Approval of Pediatric Indication Extension for Oralair® Sublingual Immunotherapy Tablet for the Treatment of Grass Pollen Allergy. *BioSpace*. Available online at: https://www.biospace.com/article/releases/stallergenes-greer-announces-u-s-fda-approval-of-pediatric-indication-extension-for-oralair-sublingual-immunotherapy-tablet-for-the-treatment-of-grass-pollen-allergy/. Issued 11/14/2018. Last accessed 03/01/2019.

treated with AR101 were able to ingest 600mg or more of peanut protein with only mild symptoms after 24 weeks (difference of 63.2% compared to placebo).[5,6]

Recommendations

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

[5] Aimmune Therapeutics, Inc. Aimmune Therapeutics to Present AR101, OIT and Peanut Allergy Data at 2019 AAAAI Annual Meeting. *APNews*. Available online at: https://www.apnews.com/397f051e58b0484cac4174a085720d38. Issued 02/04/2019. Last accessed: 03/01/2019.

[6] PALISADE. "AR101 Oral Immunotherapy for Peanut Allergy." *N Engl J Med* 2018; 379:1991-2001.

Fiscal Year 2018 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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.

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; 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.

Utilization of Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	11	88	$814,410.28	$9,254.66	$330.52	1,704,383	2,464
2018	8	70	$648,360.52	$9,262.29	$334.38	1,374,846	1,939
% Change	**-27.30%**	**-20.50%**	**-20.40%**	**0.10%**	**1.20%**	**-19.30%**	**-21.30%**
Change	**-3**	**-18**	**-$166,049.76**	**$7.63**	**$3.86**	**-329,537**	**-525**

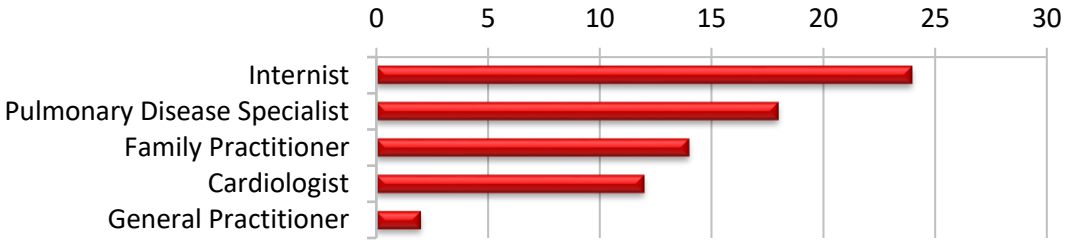
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- There were no paid medical claims for alpha$_1$-proteinase inhibitors during fiscal year 2018.

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.

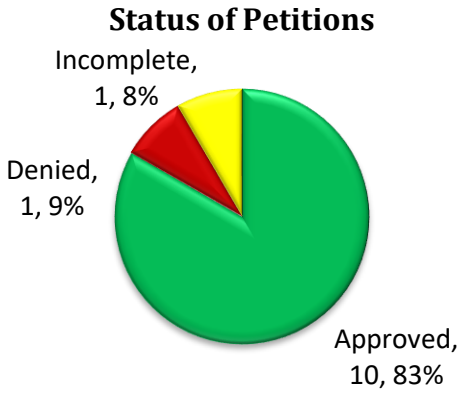
Top Prescriber Specialties of Alpha$_1$-Proteinase Inhibitors by Number of Claims



- 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 12 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



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 2018

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
PROLASTIN-C INJ 1000MG	68	7	$631,087.05	$335.15	$9,280.69	97.34%
ZEMAIRA INJ 1000MG	2	1	$17,273.47	$308.45	$8,636.74	2.66%
TOTAL	**70**	**8***	**$648,360.52**	**$334.38**	**$9,262.29**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Alzheimer's Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 ER Capsules) Approval Criteria:

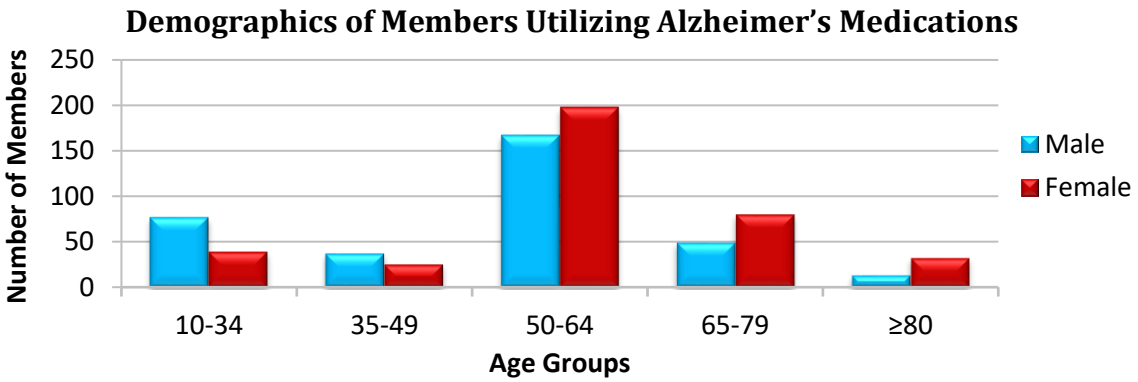
1. An FDA approved diagnosis for the treatment of moderate-to-severe Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use memantine immediate-release tablets.

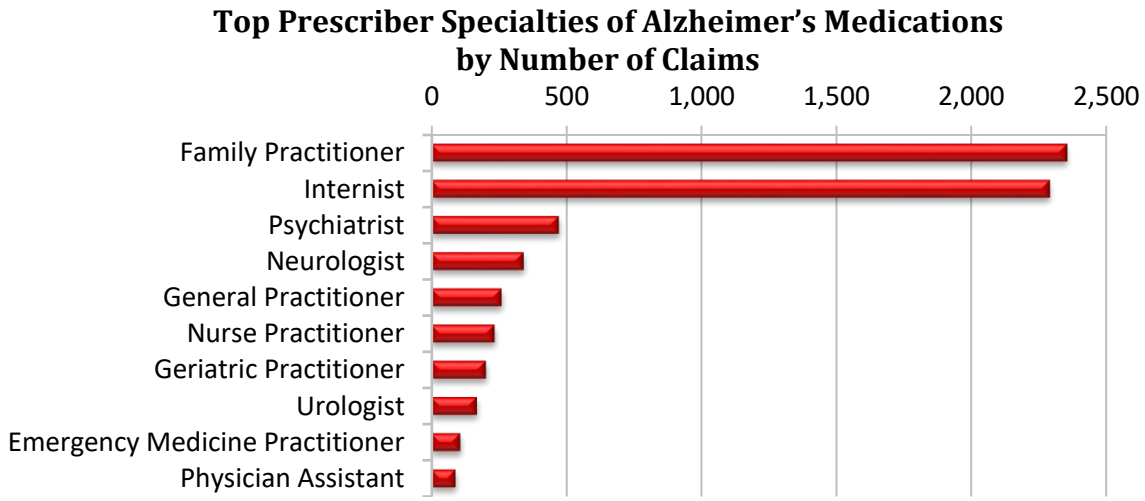
Utilization of Alzheimer's Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	742	7,025	$648,244.87	$92.28	$3.11	301,197	208,769
2018	717	6,683	$421,045.24	$63.00	$2.04	309,129	206,511
% Change	**-3.40%**	**-4.90%**	**-35.00%**	**-31.70%**	**-34.40%**	**2.60%**	**-1.10%**
Change	**-25**	**-342**	**-$227,199.63**	**-$29.28**	**-$1.07**	**7,932**	**-2,258**

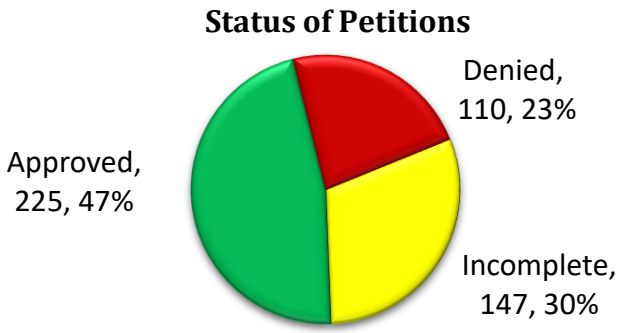
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Alzheimer's Medications

There were 482 prior authorization requests submitted for Alzheimer's medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s):[7]

[7] 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 12/2018. Last accessed 01/23/2019.

- Namenda XR® [memantine extended-release (ER) capsules]: September 2029, however, after litigation settlements, generic versions are currently available in the U.S. [8,9]
- Namzaric™ (memantine ER/donepezil): December 2029

Pipeline:

- **June 2018:** AstraZeneca and Eli Lilly and Company are discontinuing the global Phase 3 clinical trials of lanabecestat, an oral beta secretase cleaving enzyme (BACE) inhibitor, for the treatment of Alzheimer's disease (AD). The decision is based on recommendations by an independent data monitoring committee (IDMC), which concluded that both the AMARANTH trial, in early AD, and the DAYBREAK-ALZ trial, in mild AD dementia, were not likely to meet their primary endpoints upon completion and therefore should be stopped for futility. As a result of this decision, the related AMARANTH extension trial will also be discontinued. [10]
- **July 2018:** NeuroActiva, Inc. announced results from a Phase 2A clinical study of NA-831 at the Alzheimer's Association International Conference (AAIC) 2018. The study was a randomized, double-blind, placebo-controlled, parallel-group, 24-week Phase 2A clinical study of NA-831, conducted in patients with mild cognitive impairment (MCI), or patients with mild and moderate AD. Clinical efficacy was evaluated using the Brief Cognitive Rating Scale (BCRS), and the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog-13). Based on the BCRS, NA-831-treated paitents showed significant improvement (P=0.001) in the following areas: fatigue, anxiety, irritability, affective lability, disturbance to waking, daytime drowsiness, headache, and nocturnal sleep. After 24 weeks of treatment for patients with mild and moderate AD, NA-831 showed a significant improvement in ADAS-Cog score change (average of 4.1) as compared to the placebo (P=0.01). This represented a 47% slowing in the rate of decline for the NA-831 arm which was considered to be clinically important. NA-831 was well-tolerated at. There were no serious adverse events observed; 4 patients in the mild and moderate AD cohort reported having minor headaches and diarrhea. While the study was not powered to show statistical significance compared to placebo on clinical symptoms, the results suggest that NA-831 could slow decline in cognitive function of patients with MCI due to AD or mild to moderate dementia due to AD.[11]
- **July 2018:** Alzheon, Inc. presented data at the AAIC highlighting new responder analyses that focus on APOE4/4 homozygous patients with mild AD at baseline, a genetically-defined population that has previously shown the largest clinical efficacy

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[8] Allergan. Allergan Issues Statement on Namenda XR Patent Litigation Following Announcement of ANDA Approvals. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/allergan-issues-statement-on-namenda-xr-patent-litigation-following-announcement-of-anda-approvals-300336497.html. Issued 09/29/2016. Last accessed 01/23/2019.

[9] Namenda XR® (Memantine) - First-time Generic. OptumRx®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_namendaxr_2018-0222.pdf. Issued 2018. Last accessed 01/23/2019.

[10] AstraZeneca. Update on Phase III Clinical Trials of Lanabecestat for Alzheimer's Disease. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2018/update-on-phase-iii-clinical-trials-of-lanabecestat-for-alzheimers-disease-12062018.html. Issued 06/12/2018. Last accessed 01/23/2019.

[11] NeuroActiva, Inc. NeuroActiva, Inc. Announced Results from Phase 2A Clinical Trial of NA-831 in Patients with Mild Cognitive Impairment and Mild and Moderate Alzheimer's Disease at the AAIC 2018 Conference in Chicago. Available online at: http://www.neuroactiva.com/news.html. Issued 07/30/2018. Last accessed 01/23/2019.

signals in the North American Phase 3 study of oral tramiprostate. Tramiprosate is the active agent in ALZ-801, Alzheon's Phase 3-ready drug candidate that is being developed as a potential disease-modifying treatment for AD. ALZ-801 is a novel, oral, anti-amyloid drug candidate that is an optimized prodrug of tramiprosate, which has shown promising results in analyses of clinical data and therapeutic mechanism of action (MOA). ALZ-801 received Fast Track designation by the U.S. Food and Drug Administration (FDA) in October 2017. ALZ-801 acts through a novel MOA blocking the formation of toxic amyloid oligomers associated with the development and progression of AD. The initial Phase 3 program for ALZ-801 will focus on patients with the homozygous APOE4/4 genotype at the mild stage of AD, with the potential for future expansion to additional Alzheimer's populations.[12]

- **July 2018:** Results of a randomized, double-blind clinical trial suggest that nabilone, a synthetic cannabinoid, may be effective in treating agitation in people with AD and was presented at the 2018 AAIC. Nabilone (Cesamet™) is currently approved for the treatment of chemotherapy-related nausea and vomiting. The oral agent offered clinically and statistically significant improvements in agitation compared with placebo measured by the Cohen-Mansfield Agitation Inventory [treatment difference -4.0, 95% confidence interval (CI) -6.5 to -1.5, P=0.003). Nabilone also significantly improved overall behavioral symptoms compared to placebo, as measured by the Neuropsychiatric Inventory (P=0.004). The researchers also observed small benefits in cognition and nutrition during the study. More people in the study experienced sedation on nabilone (45%) compared to placebo (16%). The findings suggest that nabilone may be an effective treatment for agitation, however, the risk of sedation may need to be carefully monitored. [13,14]
- **October 2018:** Biogen presented results at the Clinical Trials on Alzheimer's Disease (CTAD) meeting, in Barcelona, Spain, from recent 36- and 48-month analyses of the Phase 1b study of aducanumab, an investigational treatment for MCI due to AD and mild AD. A late-breaking oral presentation and poster included data from patients treated with aducanumab for up to 36 and 48 months. Data from both analyses showed a reduction in amyloid plaque levels in a dose- and time-dependent manner, as measured by positron emission tomography (PET). In addition, analyses of exploratory clinical endpoints, Clinical Dementia Rating Sum of Boxes (CDR-SB) and the Mini-Mental State Examination (MMSE), suggested a continued slowing of clinical decline over 36 months and 48 months. The results in each dosing arm were generally consistent with previously reported analyses of this study, and there were no changes to the risk-benefit

[12] Alzheon. Alzheon Present New Finding in APOE4/4 Homozygous Patients with Mild Alzheimer's Disease, Further Supporting Precision Medicine Approach and Planned Confirmatory Clinical Trial with ALZ-801. Available online at: https://alzheon.com/alzheon-presents-new-findings-in-apoe4-4-homozygous-patients-with-mild-alzheimers-disease-further-supporting-precision-medicine-approach-and-planned-confirmatory-clinical-trial-with-alz-801/. Issued 07/23/2018. Last accessed 01/23/2019.

[13] Alzheimer's Association. New Research Focuses on Treating Non-Cognitive Symptoms of People with Dementia. Available online at: https://www.alz.org/aaic/releases_2018/AAIC18-Tues-non-cognitive-symptoms.asp. Issued 07/24/2018. Last accessed 01/23/2019.

[14] Monaco, K. Nabilone Effective for Easing Agitation in Alzheimer's. *MedPage Today*. Available online at: https://www.medpagetoday.com/meetingcoverage/aaic/74214. Issued 07/25/2018. Last accessed 01/23/2019.

profile of aducanumab. Aducanumab is a human monoclonal antibody (mAb) derived from a de-identified library of B-cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform called Reverse Translational Medicine (RTM). As of October 2017, Biogen and Eisai Co., Ltd. are collaborating on the development and commercialization of aducanumab globally.[15]

New(s):

- **February 2018:** The FDA published the industry guidance draft *Early Alzheimer 's Disease: Developing Drugs for Treatment*. This guidance revises the draft guidance for industry *Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease* issued in February 2013. This revision addresses the FDA's current thinking regarding the selection of patients with early AD for enrollment into clinical trials and the selection of endpoints for clinical trials in these populations. In general, the FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required. As the scientific understanding of AD has evolved, efforts have been made to incorporate in clinical trials, to varying degrees, the use of biomarkers reflecting underlying AD pathophysiological changes and the enrollment of patients with AD at earlier stages of the disease, stages in which there may be no functional impairment or even no detectable clinical abnormality. These efforts are particularly important because of the opportunity to intervene very early in the disease process that AD provides, given the development of characteristic pathophysiological changes that greatly precede the development of clinically evident findings and the slowly progressive course of AD. It is obvious that delaying, or preferably, halting or reversing the pathophysiological process that will lead to the initial clinical deficits of AD is the ultimate goal of presymptomatic intervention, and that treatment directed at this goal must begin before there are overt clinical symptoms. This opportunity carries with it the need to understand the optimum manner in which to assess treatment benefit in these earlier stages of disease.[16]
- **July 2018**: The Alzheimer's Association previewed its first-ever clinical practice guidelines for primary care physicians evaluating AD, dementia, and neurodegenerative cognitive behavioral syndromes. The Alzheimer's Association convened a Best Clinical Practices Guidelines (CPG) Workgroup consisting of multidisciplinary clinician experts in dementia care and research. The CPG workgroup was charged to evaluate relevant

[15] Biogen. Biogen and EISAI Announce Presentation of Detailed Analyses from the Phase 1B Long-term Extension Study of Aducanumab at Clinical Trials on Alzheimer's Disease (CTAD). Available online at: http://investors.biogen.com/news-releases/news-release-details/biogen-and-eisai-announce-presentation-detailed-analyses-phase. Issued 10/26/2018. Last accessed 01/23/2019.

[16] U.S. Food and Drug Administration (FDA). Early Alzheimer's Disease: Developing Drugs for Treatment Guidance for Industry. Available online at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM596728.pdf. Issued February 2018. Last accessed 01/23/2019.

literature, delineate gaps, and integrate evidence and clinical experience to provide consensus recommendations for the clinical evaluation of cognitive behavioral syndromes (CBS) and AD dementia clinical spectrums. The CPG workgroup aimed to delineate best practice points and provide practical and specific guidelines that were multi-tiered in approach and relevant to both primary and specialty settings. The results of 20 consensus best CPG recommendations for primary and specialty care settings were developed and graded for the evaluation of CBS and AD dementia clinical spectrums. The recommendations delineate utilization of tiers of assessments and tests based on individual presentation, risk factors, and profile to first establish the presence and characteristics of a CBS; second, to investigate possible causes and contributing factors to arrive at an etiologic diagnosis based on established disease criteria; and third, to appropriately educate, communicate findings, and disclose the syndromic and etiologic diagnosis(es), and ensure ongoing management, care and support.[17,18]

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	2,935	395	$54,691.52	$0.63	$18.63	12.99%
NAMENDA XR CAP 28MG	761	116	$268,653.52	$12.85	$353.03	63.81%
MEMANTINE TAB HCL 5MG	457	96	$8,275.54	$0.59	$18.11	1.97%
MEMANTINE HC CAP 28MG ER	93	27	$25,286.83	$9.52	$271.90	6.01%
NAMENDA XR CAP 14MG	21	4	$6,256.36	$12.87	$297.92	1.49%
MEMANTINE HC SOL 2MG/ML	17	2	$7,262.14	$14.24	$427.18	1.72%
NAMENDA XR CAP 21MG	14	4	$5,345.61	$12.73	$381.83	1.27%
NAMENDA XR CAP 7MG	10	2	$3,814.78	$12.93	$381.48	0.91%
MEMANTINE HC CAP 7MG ER	3	1	$954.90	$10.61	$318.30	0.23%
NAMENDA XR CAP TITRATIO	1	1	$351.81	$12.56	$351.81	0.08%
SUBTOTAL	**4,312**	**648**	**$380,893.01**	**$3.01**	**$88.33**	**90.48%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,749	284	$20,524.81	$0.35	$11.74	4.87%
DONEPEZIL TAB 5MG	508	134	$5,813.36	$0.33	$11.44	1.38%
SUBTOTAL	**2,257**	**418**	**$26,338.17**	**$0.34**	**$11.67**	**6.25%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 1.5MG	29	4	$1,382.16	$1.65	$47.66	0.33%

[17] George, J. Alzheimer's Guidelines for Primary Care Announced. *MedPage Today*. Available online at: https://www.medpagetoday.com/meetingcoverage/aaic/74147. Issued 07/22/2018. Last accessed 01/25/2019.
[18] Alzheimer's Association. First Practice Guidelines for Clinical Evaluation of Alzheimer's Disease and Other Dementias for Primary and Specialty Care. Available online at: https://www.alz.org/aaic/downloads2018/Sun-clinical-practice-guidelines.pdf. Issued 07/22/2018. Last accessed 01/25/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
RIVASTIGMINE CAP 6MG	13	2	$721.62	$1.85	$55.51	0.17%
RIVASTIGMINE CAP 3MG	12	1	$547.78	$1.52	$45.65	0.13%
RIVASTIGMINE CAP 4.5MG	9	1	$792.71	$2.94	$88.08	0.19%
RIVASTIGMINE DIS 13.3/24	8	1	$1,770.27	$7.38	$221.28	0.42%
RIVASTIGMINE DIS 9.5MG/24	4	1	$872.41	$7.27	$218.10	0.21%
EXELON DIS 13.3/24	1	1	$631.71	$21.06	$631.71	0.15%
SUBTOTAL	**76**	**11**	**$6,718.66**	**$2.99**	**$88.40**	**1.60%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	16	2	$525.74	$1.10	$32.86	0.12%
GALANTAMINE TAB 8MG	6	3	$316.80	$1.93	$52.80	0.08%
SUBTOTAL	**22**	**5**	**$842.54**	**$1.31**	**$38.30**	**0.20%**
MEMANTINE/DONEPEZIL PRODUCTS						
NAMZARIC CAP 28-10MG	16	3	$6,252.86	$13.03	$390.80	1.49%
SUBTOTAL	**16**	**3**	**$6,252.86**	**$13.03**	**$390.80**	**1.49%**
TOTAL	**6,683**	**717***	**$421,045.24**	**$2.04**	**$63.00**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Antidepressants

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			fluoxetine tabs
escitalopram (Lexapro®)			fluoxetine DR (Prozac® Weekly™)
fluoxetine caps (Prozac®)			fluvoxamine CR (Luvox CR®)
fluvoxamine (Luvox®)			paroxetine CR (Paxil CR®)
paroxetine (Paxil®)			paroxetine (Pexeva®)
sertraline (Zoloft®)			
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron® SolTab™)		nefazodone (Serzone®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	trazodone 300mg tabs (Desyrel®)
venlafaxine (Effexor®, Effexor XR® capsules)			venlafaxine ER tabs (Effexor XR® tabs)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
CR = controlled-release; DR = delayed-release; ER = extended-release; tabs = tablets; caps = capsules

Antidepressant Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial of 2 Tier-1 medications at least 4 weeks in duration each and titrated to recommended dosing, that

did not provide an adequate response. Tier-1 selection must include at least 1 medication from the SSRI category and 1 trial with duloxetine; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressant Medications Tier-3 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (1 medication from the SSRI category and 1 trial with duloxetine) and a trial of a Tier-2 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressant Medications Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists.
3. Tier structure rules still apply.
4. **Irenka™ (Duloxetine 40mg) Approval Criteria [Non-Depression Diagnosis]:**
    a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
    b. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules; and
    c. A quantity limit of 30 capsules per 30 days will apply.
    d. Tier structure rules still apply.
5. **Marplan® (Isocarboxazid) Approval Criteria:**
    a. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan®. Tier structure rules still apply.
6. **Desyrel® (Trazodone 300mg Tablets) Approval Criteria:**
    a. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose.

7. **Fluoxetine Tablets Approval Criteria:**

a. Fluoxetine capsules will be available without a prior authorization. The tablet formulation will require prior authorization and reasoning why the tablet formulation is required in place of the capsule formulation.

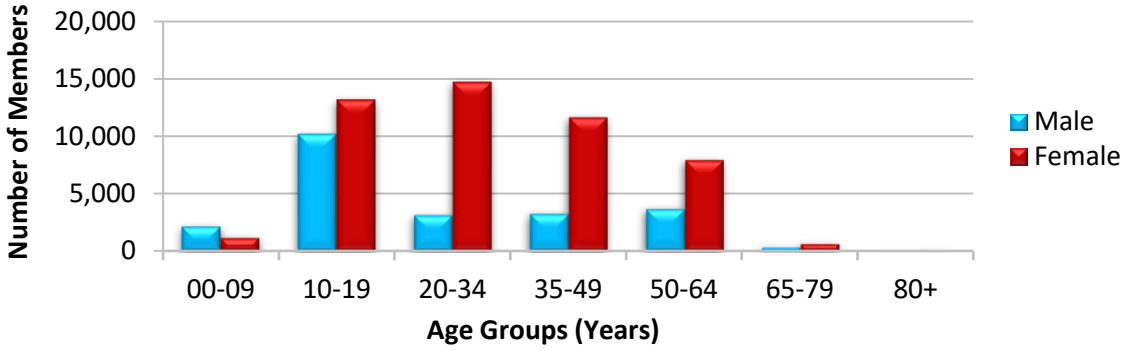
Utilization of Antidepressants: Fiscal Year 2018

Comparison of Fiscal Years

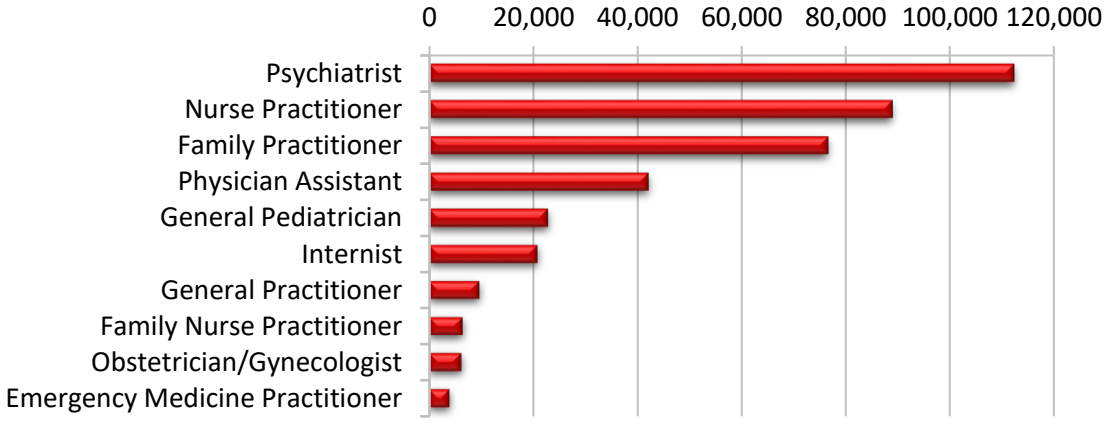
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	71,294	395,316	$6,270,666.29	$15.86	$0.47	15,330,276	13,242,058
2018	72,101	401,886	$6,544,002.56	$16.28	$0.48	15,807,672	13,660,181
% Change	**1.10%**	**1.70%**	**4.40%**	**2.60%**	**2.10%**	**3.10%**	**3.20%**
Change	**807**	**6,570**	**$273,336.27**	**$0.42**	**$0.01**	**477,396**	**418,123**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Antidepressants



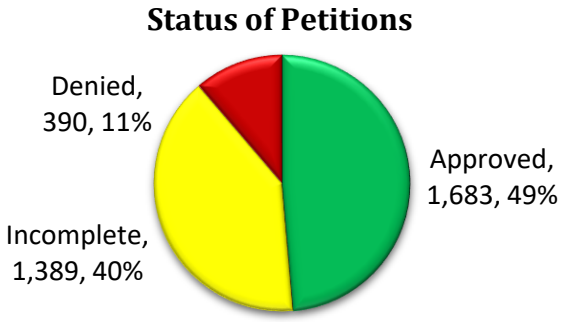
Top Prescriber Specialties of Antidepressants by Number of Claims



Prior Authorization of Antidepressants

There were 3,462 prior authorization requests submitted for antidepressants during fiscal year 2018. 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 2018.



Market News and Updates

Anticipated Patent Expiration(s):[19]

- Viibryd® (vilazodone tablets): June 2022
- Pexeva® (paroxetine tablets): May 2025
- Aplenzin® [bupropion extended-release (ER) tablets]: June 2026
- Forfivo XL® (bupropion ER tablets): June 2027
- Trintellix® (vortioxetine tablets): March 2032
- Fetzima® (levomilnacipran ER capsules): May 2032

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

- **May 2018:** The FDA approved a supplemental New Drug Application (sNDA) for Trintellix® (vortioxetine) to update the prescribing information with new data showing improvement in processing speed, an important aspect of cognitive function that may be impaired in adult patients with major depressive disorder (MDD). The label was updated with data from 2 clinical studies, FOCUS and CONNECT, which were both 8-week, randomized, double blind, placebo-controlled studies conducted to evaluate the effect of vortioxetine on the Digit Symbol Substitution Test (DSST) during the treatment of acute MDD. The DSST is a neuropsychological test that most specifically measures processing speed. The studies showed that vortioxetine had a positive effect on processing speed. Comparative studies have not been conducted to demonstrate a therapeutic advantage over other antidepressants on the DSST. Trintellix® was first FDA approved in 2013 for the treatment of MDD in adults.[20]

Pipeline:

- **Spravato™ (Esketamine):** In February 2019, 2 FDA panels jointly recommended approval of an esketamine 28mg single-use nasal spray device for treatment-resistant depression.

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[19] 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 01/16/2019.

[20] Takeda News Release. Trintellix® (Vortioxetine) Prescribing Information Now Includes New Data Showing Improvement in Processing Speed, an Important Aspect of Cognitive Function in Acute Major Depressive Disorder (MDD). Available online at: https://www.takeda.com/newsroom/newsreleases/2018/trintellix-label-update/. Issued 05/01/2018. Last accessed 02/15/2019.

The 2 panels together voted that the benefits outweigh the risks for esketamine on the basis of research findings to date. Esketamine, the s-enantiomer of ketamine, is a non-competitive and subtype non-selective activity-dependent N-methyl-D-aspartate (NMDA) receptor antagonist for intranasal administration. One advantage of esketamine is that it is fast acting, which means that patients can get symptom relief more quickly and potentially avoid self-injury, such as suicide. Esketamine has a novel mechanism of action and if approved by the FDA, esketamine would be one of the first new approaches to treat MDD available to patients in the last 50 years. Esketamine was previously granted Breakthrough Therapy designations by the FDA for treatment-resistant depression and for MDD with imminent risk of suicide. Janssen submitted a New Drug Application (NDA) to the FDA for Spravato™ (esketamine) in September 2018, which has a target Prescription Drug User Fee Act (PDUFA) action date of March 2019.[21]

- **ALKS 5461:** In February 2019, the FDA issued a Complete Response Letter (CRL) to Alkermes regarding the NDA for ALKS 5461, citing the need for additional data to prove the effectiveness of the drug for the adjunctive treatment of MDD. This decision comes months after an advisory panel to the FDA strongly voted against the drug and raised questions on its safety and efficacy. ALKS 5461 is an investigational, once daily oral medication that is a fixed-dose combination of samidorphan, a mu-opioid receptor antagonist, and buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist. ALKS 5461 is designed to rebalance brain function through endogenous opioid modulation. Alkermes plans to meet with the FDA to discuss the contents of the CRL and potential next steps for ALKS 5461.[22]
- **SAGE-217:** In January 2019, Sage Therapeutics announced top-line results from the Phase 3 ROBIN study evaluating the effect of SAGE-217 30mg on depressive symptoms in women with postpartum depression (PPD). In the study, a statistically significant reduction was observed in depressive symptoms compared to placebo in women with PPD, and SAGE-217 was well tolerated with a rapid onset of statistically significant effect (day 3) through 2 weeks and maintained for 4 weeks after treatment. SAGE-217 is a novel, highly potent, selective, next generation $GABA_A$ receptor positive allosteric modulator that is intended for daily oral dosing. Sage Therapeutics is currently developing SAGE-217 for MDD, PPD, and other mood disorders.[23]
- **Zulresso™ (Brexanolone):** In November 2018, Sage Therapeutics announced notification of a PDUFA extension for the Priority Review of the NDA for brexanolone for the treatment of PPD. The previous December 2018 target PDUFA action date for brexanolone was extended by the FDA by 3 months to March 19, 2019. Following a

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[21] Johnson & Johnson News Release. FDA Advisory Committee Recommends Approval of Spravato™ (Esketamine) Nasal Spray CIII for Adults with Treatment-Resistant Depression. Available online at: https://www.jnj.com/fda-advisory-committee-recommends-approval-of-spravatotm-esketamine-nasal-spray-ciii-for-adults-with-treatment-resistant-depression. Issued 02/12/2019. Last accessed 02/15/2019.

[22] Alkermes News Release. Alkermes Receives Complete Response Letter from the U.S. Food and Drug Administration for ALKS 5461 New Drug Application. Available online at: http://phx.corporate-ir.net/phoenix.zhtml?c=92211&p=irol-newsArticle&ID=2385782. Issued 02/01/2019. Last accessed 02/15/2019.

[23] Sage Therapeutics News Release. Sage Therapeutics Announces SAGE-217 Meets Primary and Secondary Endpoints in Phase 3 Clinical Trial in Postpartum Depression. Available online at: https://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-announces-sage-217-meets-primary-and-secondary. Issued 01/07/2019. Last accessed 02/16/2019.

positive FDA Advisory Committee meeting, Sage submitted a proposed REMS program with Elements to Ensure Safe Use (ETASU) in response to the FDA's request; the PDUFA was extended by the FDA for submission of a risk evaluation and mitigation strategy (REMS) with ETASU that was not submitted in the original NDA. The FDA has not requested any additional clinical data or any additional information from Sage as part of the extension. Brexanolone is an allosteric modulator of both synaptic and extrasynaptic $GABA_A$ receptors that is intended for intravenous (IV) administration.[24]

- **Psilocybin:** In October 2018, COMPASS Pathways' psilocybin therapy received Breakthrough Therapy designation from the FDA for treatment-resistant depression. In August 2018, the FDA approved COMPASS' planned Phase 2b dose-ranging clinical trial to test psilocybin therapy in patients with treatment-resistant depression, the first large-scale psilocybin therapy clinical trial. Psilocybin is the active ingredient in psychoactive mushrooms, and psilocybin therapy has been a frequent, if not controversial, investigative treatment for psychiatric conditions since the 1950s.[25]

Recommendations

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

Utilization Details of Antidepressants: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SERTRALINE PRODUCTS						
SERTRALINE TAB 100MG	30,896	7,267	$361,809.91	$11.71	4.3	5.53%
SERTRALINE TAB 50MG	28,901	10,142	$332,333.17	$11.50	2.8	5.08%
SERTRALINE TAB 25MG	14,086	5,195	$169,614.52	$12.04	2.7	2.59%
SERTRALINE CON 20MG/ML	607	155	$38,475.72	$63.39	3.9	0.59%
ZOLOFT TAB 25MG	1	1	$320.32	$320.32	1.0	0.00%
SUBTOTAL	**74,491**	**22,760**	**$902,553.64**	**$12.12**	**3.3**	**13.79%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	28,794	8,623	$304,774.71	$10.58	3.3	4.66%
TRAZODONE TAB 100MG	21,883	5,945	$263,534.90	$12.04	3.7	4.03%
TRAZODONE TAB 150MG	13,133	3,204	$196,309.59	$14.95	4.1	3.00%
SUBTOTAL	**63,810**	**17,772**	**$764,619.20**	**$11.98**	**3.6**	**11.68%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	30,164	9,223	$293,484.99	$9.73	3.3	4.48%

[24] Sage Therapeutics News Release. Sage Therapeutics Receives Notification of PDUFA Extension for Zulresso™ (Brexanolone) Injection. Available online at: https://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-receives-notification-pdufa-extension. Issued 11/20/2018. Last accessed 02/16/2019.

[25] COMPASS Pathways News Release. COMPASS Pathways Receives FDA Breakthrough Therapy Designation for Psilocybin Therapy for Treatment-Resistant Depression. Available online at: https://compasspathways.com/compass-pathways-receives-fda-breakthrough-therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression/. Issued 10/23/2018. Last accessed 02/18/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUOXETINE CAP 40MG	15,344	4,091	$189,710.75	$12.36	3.8	2.90%
FLUOXETINE CAP 10MG	14,835	5,306	$150,173.06	$10.12	2.8	2.29%
FLUOXETINE SOL 20MG/5ML	1,359	336	$19,557.59	$14.39	4.0	0.30%
PROZAC CAP 20MG	19	2	$19,747.01	$1,039.32	9.5	0.30%
PROZAC CAP 40MG	15	2	$19,706.09	$1,313.74	7.5	0.30%
SUBTOTAL	**61,736**	**18,960**	**$692,379.49**	**$11.22**	**3.3**	**10.58%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	17,955	6,359	$217,022.46	$12.09	2.8	3.32%
ESCITALOPRAM TAB 20MG	17,810	4,353	$223,251.31	$12.54	4.1	3.41%
ESCITALOPRAM TAB 5MG	2,451	988	$31,220.01	$12.74	2.5	0.48%
ESCITALOPRAM SOL 5MG/5ML	196	50	$22,849.69	$116.58	3.9	0.35%
LEXAPRO TAB 20MG	28	4	$13,137.60	$469.20	7.0	0.20%
SUBTOTAL	**38,440**	**11,754**	**$507,481.07**	**$13.20**	**3.3**	**7.75%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	17,211	5,928	$163,099.11	$9.48	2.9	2.49%
CITALOPRAM TAB 40MG	10,059	2,844	$93,253.25	$9.27	3.5	1.43%
CITALOPRAM TAB 10MG	8,181	2,850	$89,793.52	$10.98	2.9	1.37%
CITALOPRAM SOL 10MG/5ML	212	51	$9,373.83	$44.22	4.2	0.14%
SUBTOTAL	**35,663**	**11,673**	**$355,519.71**	**$9.97**	**3.1**	**5.43%**
BUPROPION PRODUCTS						
BUPROPN HCL TAB 150MG	8,570	3,183	$196,881.30	$22.97	2.7	3.01%
BUPROPN HCL TAB 300MG	7,459	1,962	$174,387.17	$23.38	3.8	2.66%
BUPROPION TAB 150MG SR	6,807	2,437	$118,971.04	$17.48	2.8	1.82%
BUPROPION TAB 100MG SR	2,610	957	$46,228.25	$17.71	2.7	0.71%
BUPROPION TAB 75MG	1,781	644	$41,066.54	$23.06	2.8	0.63%
BUPROPION TAB 100MG	1,558	542	$43,829.68	$28.13	2.9	0.67%
BUPROPION TAB 200MG SR	1,264	312	$28,460.25	$22.52	4.1	0.43%
WELLBUTRIN TAB XL 150MG	22	2	$52,992.73	$2,408.76	11.0	0.81%
WELLBUTRIN TAB XL 300MG	9	1	$14,207.15	$1,578.57	9.0	0.22%
SUBTOTAL	**30,080**	**10,040**	**$717,024.11**	**$23.84**	**3.0**	**10.96%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	18,297	4,481	$339,422.48	$18.55	4.1	5.19%
DULOXETINE CAP 30MG	10,002	3,778	$191,540.28	$19.15	2.6	2.93%
DULOXETINE CAP 20MG	1,557	702	$32,074.00	$20.60	2.2	0.49%
CYMBALTA CAP 60MG	8	2	$3,048.02	$381.00	4.0	0.05%
SUBTOTAL	**29,864**	**8,963**	**$566,084.78**	**$18.96**	**3.3**	**8.65%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	12,062	3,590	$147,405.45	$12.22	3.4	2.25%
MIRTAZAPINE TAB 30MG	6,689	1,847	$89,554.40	$13.39	3.6	1.37%
MIRTAZAPINE TAB 45MG	3,105	728	$53,021.66	$17.08	4.3	0.81%
MIRTAZAPINE TAB 7.5MG	970	308	$51,720.40	$53.32	3.1	0.79%
MIRTAZAPINE TAB 15MG	265	78	$7,868.43	$29.69	3.4	0.12%
MIRTAZAPINE TAB 30MG	128	46	$3,858.11	$30.14	2.8	0.06%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MIRTAZAPINE TAB 45MG	52	14	$1,781.85	$34.27	3.7	0.03%
SUBTOTAL	**23,271**	**6,611**	**$355,210.30**	**$15.26**	**3.5**	**5.43%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE CAP 150MG ER	8,306	2,015	$127,362.51	$15.33	4.1	1.95%
VENLAFAXINE CAP 75MG ER	6,683	2,400	$93,853.02	$14.04	2.8	1.43%
VENLAFAXINE CAP 37.5 ER	2,722	1,369	$37,606.29	$13.82	2.0	0.57%
VENLAFAXINE TAB 75MG	2,076	621	$41,997.48	$20.23	3.3	0.64%
VENLAFAXINE TAB 37.5MG	675	317	$12,997.95	$19.26	2.1	0.20%
VENLAFAXINE TAB 100MG	471	110	$11,250.09	$23.89	4.3	0.17%
VENLAFAXINE TAB 50MG	248	71	$5,264.54	$21.23	3.5	0.08%
VENLAFAXINE TAB 25MG	143	62	$2,677.96	$18.73	2.3	0.04%
EFFEXOR XR CAP 75MG	19	2	$16,786.94	$883.52	9.5	0.26%
EFFEXOR XR CAP 150MG	10	2	$4,252.35	$425.24	5.0	0.06%
SUBTOTAL	**21,353**	**6,969**	**$354,049.13**	**$16.58**	**3.1**	**5.41%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	5,139	2,088	$54,212.31	$10.55	2.5	0.83%
PAROXETINE TAB 40MG	3,749	984	$51,211.02	$13.66	3.8	0.78%
PAROXETINE TAB 10MG	2,248	1,010	$24,816.92	$11.04	2.2	0.38%
PAROXETINE TAB 30MG	1,732	487	$23,599.78	$13.63	3.6	0.36%
PAXIL SUS 10MG/5ML	79	20	$17,633.10	$223.20	4.0	0.27%
PAXIL TAB 40MG	4	1	$2,328.52	$582.13	4.0	0.04%
SUBTOTAL	**12,951**	**4,590**	**$173,801.65**	**$13.42**	**2.8**	**2.66%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	1,654	307	$38,591.90	$23.33	5.4	0.59%
FLUVOXAMINE TAB 50MG	1,144	281	$21,497.46	$18.79	4.1	0.33%
FLUVOXAMINE TAB 25MG	321	92	$5,691.92	$17.73	3.5	0.09%
SUBTOTAL	**3,119**	**680**	**$65,781.28**	**$21.09**	**4.6**	**1.01%**
TIER-1 SUBTOTAL	**394,778**	**71,504***	**$5,454,504.36**	**$13.82**	**5.5**	**83.35%**
TIER-2 MEDICATIONS						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAX TAB 50MG ER	440	155	$16,853.16	$38.30	2.8	0.26%
DESVENLAFAX TAB 100MG ER	365	87	$15,082.70	$41.32	4.2	0.23%
DESVENLAFAX TAB 25MG ER	57	28	$2,051.73	$36.00	2.0	0.03%
PRISTIQ TAB 100MG	21	5	$8,035.30	$382.63	4.2	0.12%
PRISTIQ TAB 50MG	21	6	$7,955.25	$378.82	3.5	0.12%
SUBTOTAL	**904**	**281**	**$49,978.14**	**$55.29**	**3.2**	**0.76%**
TIER-2 SUBTOTAL	**904**	**231***	**$49,978.14**	**$55.29**	**3.9**	**0.76%**
TIER-3 MEDICATIONS						
VILAZODONE PRODUCTS						
VIIBRYD TAB 40MG	791	142	$183,725.84	$232.27	5.6	2.81%
VIIBRYD TAB 20MG	362	103	$82,926.99	$229.08	3.5	1.27%
VIIBRYD TAB 10MG	71	28	$14,642.92	$206.24	2.5	0.22%
SUBTOTAL	**1,224**	**273**	**$281,295.75**	**$229.82**	**4.5**	**4.30%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	306	64	$108,403.69	$354.26	4.8	1.66%
TRINTELLIX TAB 10MG	261	84	$99,686.80	$381.94	3.1	1.52%
TRINTELLIX TAB 5MG	30	14	$9,959.07	$331.97	2.1	0.15%
BRINTELLIX TAB 5MG	1	1	$324.71	$324.71	1.0	0.00%
SUBTOTAL	**598**	**163**	**$218,374.27**	**$365.17**	**3.7**	**3.34%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 80MG	74	13	$21,994.36	$297.22	5.7	0.34%
FETZIMA CAP 40MG	61	19	$20,141.61	$330.19	3.2	0.31%
FETZIMA CAP 120MG	54	11	$17,640.07	$326.67	4.9	0.27%
FETZIMA CAP 20MG	3	2	$1,029.61	$343.20	1.5	0.02%
FETZIMA CAP TITRATION PACK	2	2	$603.72	$301.86	1.0	0.01%
SUBTOTAL	**194**	**47**	**$61,409.37**	**$316.54**	**4.1**	**0.94%**
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 200MG	22	3	$1,411.04	$64.14	7.3	0.02%
NEFAZODONE TAB 100MG	16	5	$1,185.62	$74.10	3.2	0.02%
NEFAZODONE TAB 250MG	8	1	$1,162.16	$145.27	8.0	0.02%
NEFAZODONE TAB 150MG	6	1	$480.58	$80.10	6.0	0.01%
NEFAZODONE TAB 50MG	2	1	$153.05	$76.53	2.0	0.00%
SUBTOTAL	**54**	**11**	**$4,392.45**	**$81.34**	**4.9**	**0.07%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAX TAB 50MG ER	8	3	$1,108.58	$138.57	2.7	0.02%
DESVENLAFAX TAB 100MG ER	3	2	$800.43	$266.81	1.5	0.01%
SUBTOTAL	**11**	**5**	**$1,909.01**	**$173.55**	**2.2**	**0.03%**
SELEGILINE PRODUCTS						
EMSAM DIS 12MG/24HR	4	1	$5,855.84	$1,463.96	4.0	0.09%
SUBTOTAL	**4**	**1**	**$5,855.84**	**$1,463.96**	**4.0**	**0.09%**
TIER-3 SUBTOTAL	**2,085**	**394***	**$573,236.69**	**$274.93**	**5.3**	**8.76%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	1,832	776	$53,389.58	$29.14	2.4	0.82%
FLUOXETINE TAB 20MG	775	406	$50,572.99	$65.26	1.9	0.77%
FLUOXETINE CAP 90MG DR	28	6	$3,634.94	$129.82	4.7	0.06%
FLUOXETINE TAB 60MG	3	2	$891.05	$297.02	1.5	0.01%
SUBTOTAL	**2,638**	**1,190**	**$108,488.56**	**$41.13**	**2.2**	**1.66%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE TAB 225MG ER	520	118	$202,323.64	$389.08	4.4	3.09%
VENLAFAXINE TAB 150MG ER	81	25	$9,907.93	$122.32	3.2	0.15%
VENLAFAXINE TAB 75MG ER	30	11	$3,110.47	$103.68	2.7	0.05%
VENLAFAXINE TAB 37.5 ER	17	6	$1,691.23	$99.48	2.8	0.03%
SUBTOTAL	**648**	**160**	**$217,033.27**	**$334.93**	**4.1**	**3.32%**
PAROXETINE PRODUCTS						
PAROXETINE ER TAB 25MG	265	56	$31,950.49	$120.57	4.7	0.49%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PAROXETINE ER TAB 37.5MG	161	29	$18,989.87	$117.95	5.6	0.29%
PAROXETINE ER TAB 12.5MG	77	20	$8,293.27	$107.70	3.9	0.13%
PEXEVA TAB 20MG	10	1	$3,668.50	$366.85	10.0	0.06%
PAXIL CR TAB 37.5MG	6	1	$1,554.53	$259.09	6.0	0.02%
SUBTOTAL	**519**	**107**	**$64,456.66**	**$124.19**	**4.9**	**0.98%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE CAP 100MG ER	93	19	$31,714.18	$341.01	4.9	0.48%
FLUVOXAMINE CAP 150MG ER	84	18	$26,999.89	$321.43	4.7	0.41%
SUBTOTAL	**177**	**37**	**$58,714.07**	**$331.72**	**4.8**	**0.90%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	128	73	$15,834.87	$123.71	1.8	0.24%
SUBTOTAL	**128**	**73**	**$15,834.87**	**$123.71**	**1.8**	**0.24%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	8	2	$1,486.52	$185.82	4.0	0.02%
SUBTOTAL	**8**	**2**	**$1,486.52**	**$185.82**	**4.0**	**0.02%**
ISOCARBOXAZID PRODUCTS						
MARPLAN TAB 10MG	1	1	$269.42	$269.42	1.0	0.00%
SUBTOTAL	**1**	**1**	**$269.42**	**$269.42**	**1.0**	**0.00%**
SPECIAL PA SUBTOTAL	**4,119**	**1,516***	**$466,283.37**	**$113.20**	**2.7**	**7.13%**
TOTAL	**401,886**	**72,101***	**$6,544,002.56**	**$16.28**	**5.6**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Antifungal Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 Tablets 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.
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Lamisil® Oral Granules (Terbinafine) Approval Criteria:

1. An FDA approved indication of tinea capitis or onychomychosis; and
2. No improvement after at least 3 weeks of therapy with griseofulvin; or
3. Intolerance or hypersensitivity to griseofulvin or penicillin; and
4. Member is unable to swallow tablets.

Please note: The manufacturer of Lamisil® granules no longer has a drug rebate agreement with the federal government; therefore, it is no longer a covered product. If the manufacturer chooses to reinstate the drug rebate agreement, the previous drug utilization review (DUR) board-voted criteria will apply as shown.

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 Tablets) Approval Criteria:

1. An FDA approved diagnosis of onychomychosis 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 Tablets) Approval Criteria:

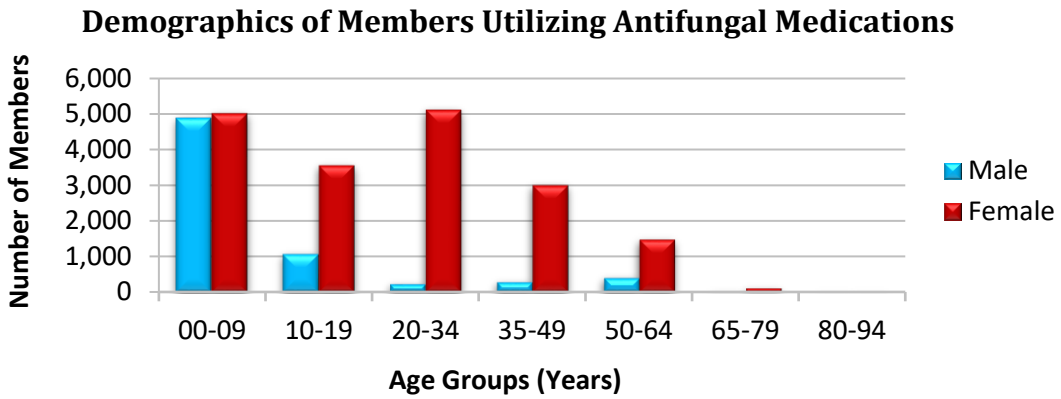
1. An FDA-approved diagnosis of oropharyngeal candidiasis in adults 18 years of age and older; and
2. Recent trials (within the last month) of the following medications at the recommended dosing and duration of therapy:
   a. Clotrimazole troches; and
   b. Nystatin suspension; and
   c. Fluconazole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

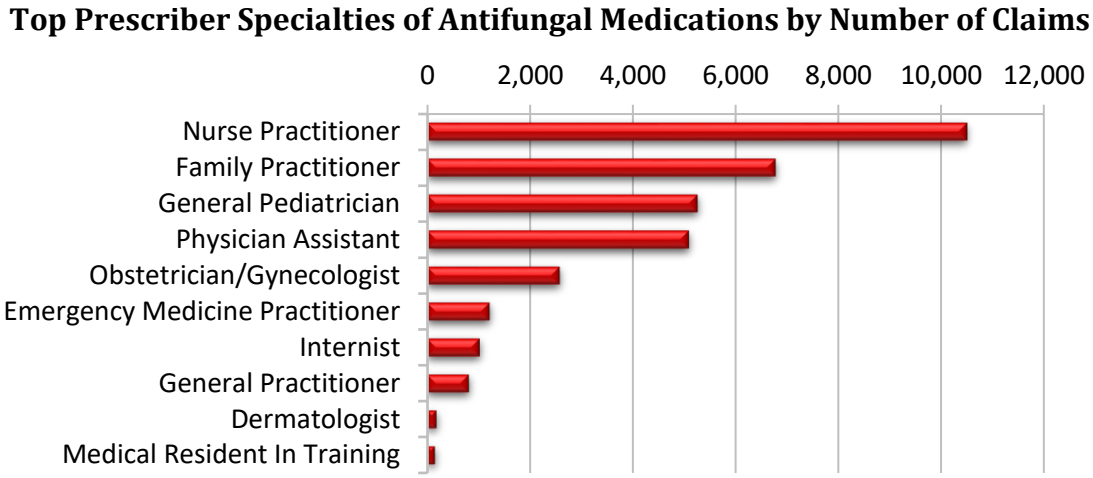
Utilization of Antifungal Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	26,148	37,256	$1,223,611.93	$32.84	$2.89	2,141,416	423,692
2018	25,165	35,638	$1,167,460.99	$32.76	$2.91	2,139,726	400,699
% Change	**-3.80%**	**-4.30%**	**-4.60%**	**-0.20%**	**0.70%**	**-0.10%**	**-5.40%**
Change	**-983**	**-1,618**	**-$56,150.94**	**-$0.08**	**$0.02**	**-1,690**	**-22,993**

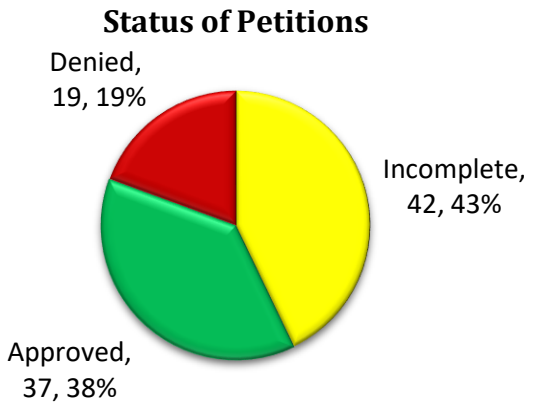
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Antifungal Medications

There were 98 prior authorization requests submitted for antifungal medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates[26]

Anticipated Patent Expiration(s):

- Sporanox® (itraconazole oral solution): June 2019
- Noxafil® (posaconazole tablet): July 2019
- 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

Recommendations

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

Utilization Details of Antifungal Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
FLUCONAZOLE PRODUCTS					
FLUCONAZOLE TAB 150MG	14,127	10,074	$159,842.85	$2.90	$11.31
FLUCONAZOLE TAB 200MG	1,833	1,432	$37,473.95	$1.88	$20.44
FLUCONAZOLE TAB 100MG	1,779	1,408	$29,744.82	$1.71	$16.72
FLUCONAZOLE SUS 10MG/ML	1,416	1,159	$34,009.61	$2.18	$24.02
FLUCONAZOLE SUS 40MG/ML	1,373	1,146	$53,871.90	$3.37	$39.24
FLUCONAZOLE TAB 50MG	25	21	$449.38	$1.44	$17.98
FLUCONAZOLE INJ 200MG	6	3	$493.57	$10.50	$82.26
FLUCONAZOLE INJ 400MG	5	3	$115.79	$3.99	$23.16
SUBTOTAL	**20,564**	**15,246**	**$316,001.87**	**$2.54**	**$15.37**
NYSTATIN PRODUCTS					
NYSTATIN SUSP 100000 U/ML	9,710	7,995	$171,784.05	$1.47	$17.69
NYSTATIN TAB 500000 UNITS	33	19	$1,454.62	$1.95	$44.08
SUBTOTAL	**9,743**	**8,014**	**$173,238.67**	**$1.48**	**$17.78**
GRISEOFULVIN PRODUCTS					
GRISEOFULVIN SUS 125MG/5ML	1,750	1,363	$134,697.31	$3.00	$76.97
GRISEOFULVIN MICRO 500MG	468	356	$104,569.97	$7.88	$223.44
GRISEOFULVIN ULTRA 250MG	224	171	$41,163.88	$6.32	$183.77
GRISEOFULVIN ULTRA 125MG	51	41	$9,169.44	$6.59	$179.79
SUBTOTAL	**2,493**	**1,931**	**$289,600.60**	**$4.38**	**$116.17**
TERBINAFINE PRODUCTS					

[26] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 11/2018. Last accessed 01/11/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TERBINAFINE TAB 250MG	2,244	1,619	$27,860.99	$0.35	$12.42
SUBTOTAL	**2,244**	**1,619**	**$27,860.99**	**$0.35**	**$12.42**
ITRACONAZOLE PRODUCTS					
ITRACONAZOLE CAP 100MG	285	141	$66,226.73	$9.72	$232.37
SPORANOX SOL 10MG/ML	86	54	$68,053.24	$36.12	$791.32
SUBTOTAL	**371**	**195**	**$134,279.97**	**$15.45**	**$361.94**
VORICONAZOLE PRODUCTS					
VORICONAZOLE TAB 200MG	64	25	$23,161.62	$13.71	$361.90
VORICONAZOLE SUS 40MG/ML	14	7	$20,023.64	$91.43	$1,430.26
VORICONAZOLE TAB 50MG	9	4	$6,313.99	$29.23	$701.55
VORICONAZOLE INJ 200MG	1	1	$2,208.01	$315.43	$2,208.01
VFEND IV INJ 200MG	1	1	$161.93	$11.57	$161.93
SUBTOTAL	**89**	**38**	**$51,869.19**	**$24.18**	**$582.80**
CLOTRIMAZOLE PRODUCTS					
CLOTRIMAZOLE LOZ 10MG	54	47	$1,523.83	$2.61	$28.22
CLOTRIMAZOLE TRO 10MG	12	12	$338.85	$2.75	$28.24
SUBTOTAL	**66**	**59**	**$1,862.68**	**$2.63**	**$28.22**
POSACONAZOLE PRODUCTS					
NOXAFIL TAB 100MG	29	8	$142,726.16	$175.34	$4,921.59
NOXAFIL SUS 40MG/ML	5	1	$8,638.39	$100.45	$1,727.68
SUBTOTAL	**34**	**9**	**$151,364.55**	**$168.18**	**$4,451.90**
AMPHOTERICIN B PRODUCTS					
AMBISOME INJ 50MG	11	3	$15,984.22	$89.80	$1,453.11
AMPHOTERICIN POW B	10	8	$803.59	$4.00	$80.36
AMPHOTERICIN INJ 50MG	1	1	$43.98	$3.14	$43.98
SUBTOTAL	**22**	**12**	**$16,831.79**	**$42.83**	**$765.08**
MICONAZOLE PRODUCTS					
MICONAZOLE POWDER	11	10	$274.42	$0.87	$24.95
SUBTOTAL	**11**	**10**	**$274.42**	**$0.87**	**$24.95**
ISAVUCONAZONIUM PRODUCTS					
CRESEMBA CAP 186 MG	1	1	$4,276.26	$194.38	$4,276.26
SUBTOTAL	**1**	**1**	**$4,276.26**	**$194.38**	**$4,276.26**
TOTAL	**35,638**	**25,165***	**$1,167,460.99**	**$2.91**	**$32.76**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Antihistamines

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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

+For members 21 years and younger, prior authorization is necessary for Tier-1 products, but no previous trials required.
*Xyzal® tablets are not covered for members younger than 6 years of age.
*Xyzal® solution is available for children 6 months to 6 years of age.

Oral Antihistamine Tier-1 Approval Criteria:

1. An FDA-approved diagnosis.
2. Member must be 21 years of age or younger. Over-the-counter (OTC) oral antihistamines are not a covered pharmacy benefit for adult SoonerCare members.

Oral Antihistamine Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. A trial of all Tier-1 products which meet the following:
   a. Trials should have been within the last 30 days; and
   b. Trials should have been attempted for 14 days or documented adverse effects.

Oral Antihistamine Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. A trial of all Tier-2 products which meet the following:
   a. Trials should have been within the last 60 days; and
   b. Trials should have been attempted for 14 days or documented adverse effects.

Utilization of Oral Antihistamines: Fiscal Year 2018

Comparison of Fiscal Years

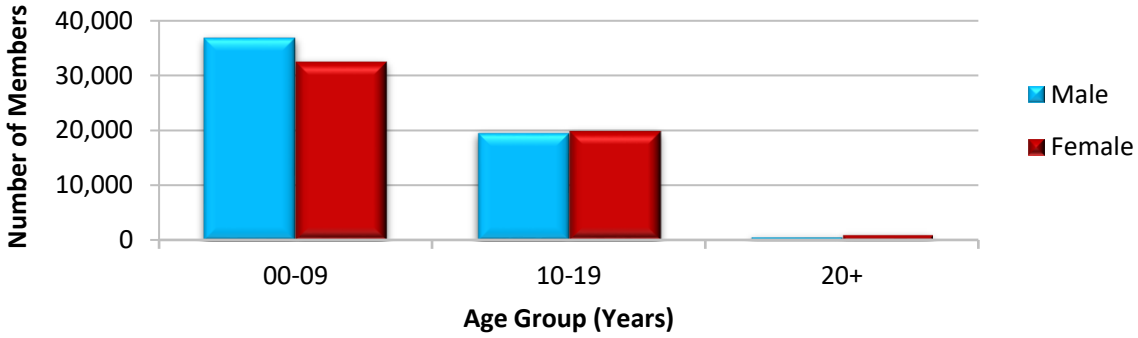
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	114,835	281,313	$2,592,222.49	$9.21	$0.30	24,901,785	8,626,791
2018	110,257	267,874	$3,082,528.76	$11.51	$0.37	24,418,325	8,327,521
% Change	**-4.00%**	**-4.80%**	**18.90%**	**25.00%**	**23.30%**	**-1.90%**	**-3.50%**
Change	**-4,578**	**-13,439**	**$409,306.27**	**$2.30**	**$0.07**	**-483,460**	**-299,270**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

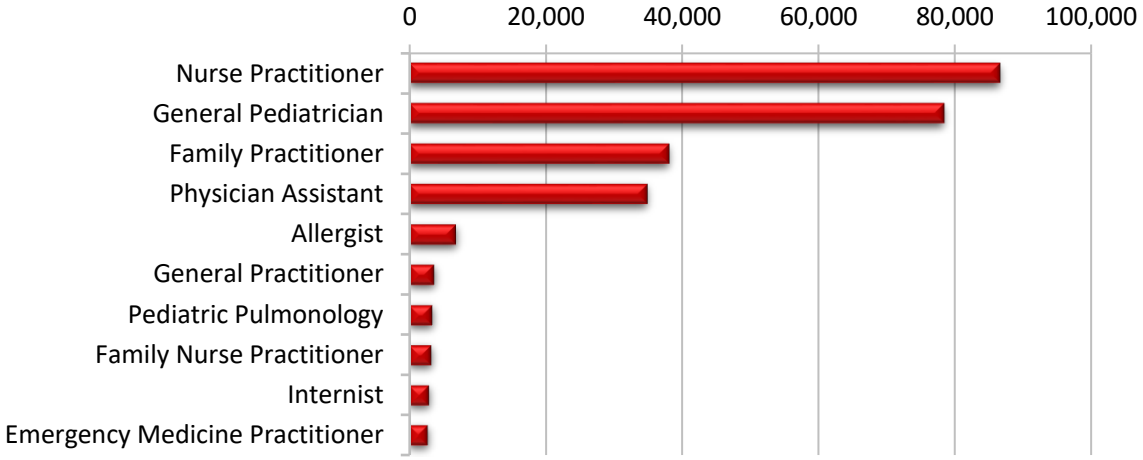
- Effective 10/01/2017 non-prescription products for adult members were limited to insulin, smoking cessation products, family planning products, and diabetic testing

supplies only. Oral antihistamines are no longer a covered benefit for adult members; however, the fiscal year runs from 07/01/2017 to 06/30/2018 and the change in coverage policies for adult members is reflected in the utilization data for this report.

Demographics of Members Utilizing Oral Antihistamine Medications



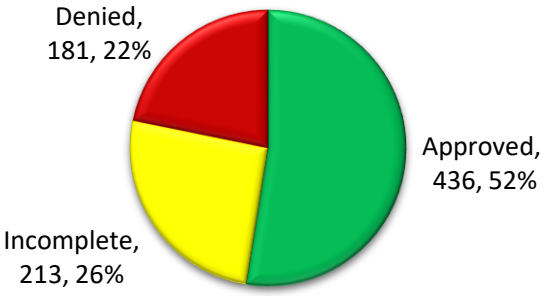
Top Prescriber Specialties of Oral Antihistamine Medications by Number of Claims



Prior Authorization of Oral Antihistamine Medications

There were 830 prior authorization requests submitted for the oral antihistamine medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Recommendations

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

Utilization Details of Oral Antihistamine Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
CETIRIZINE PRODUCTS					
CETIRIZINE SOL 1MG/ML	97,740	47,104	$1,256,065.06	2.07	$12.85
CETIRIZINE TAB 10MG	81,057	32,153	$685,350.90	2.52	$8.46
CETIRIZINE SOL 5MG/5ML	24,901	14,323	$339,110.06	1.74	$13.62
CETIRIZINE TAB 5MG	4,726	2,032	$56,110.52	2.33	$11.87
ALL DAY ALLG TAB 10MG	3,148	1,515	$37,754.18	2.08	$11.99
ALL DAY ALLG SOL 5MG/5ML	529	303	$7,698.95	1.75	$14.55
ALL DAY ALLG SOL 1MG/ML	259	129	$4,346.87	2.01	$16.78
ALLERGY COMP SOL 1MG/ML	75	42	$756.26	1.79	$10.08
CETIRIZINE SYP 1MG/ML	21	15	$240.29	1.4	$11.44
GNP ALL DAY TAB ALLERGY	5	5	$67.58	1	$13.52
SUBTOTAL	**212,461**	**97,621**	**$2,387,500.67**	**2.33**	**$11.24**
LORATADINE PRODUCTS					
LORATADINE TAB 10MG	28,769	11,664	$314,651.28	2.47	$10.94
LORATADINE SOL 5MG/5ML	20,947	11,050	$280,374.31	1.9	$13.38
LORATADINE SYP 5MG/5ML	3,588	2,216	$52,739.15	1.62	$14.70
ALLERGY TAB 10MG	875	401	$9,870.11	2.18	$11.28
SM LORATADIN TAB 10MG	140	67	$1,742.57	2.09	$12.45
ALLERGY CHLD SYP 5MG/5ML	119	68	$1,857.17	1.75	$15.61
ALLERGY RELF TAB 10MG	117	49	$1,429.68	2.39	$12.22
ALLERGY RELF SYP 5MG/5ML	33	27	$532.76	1.22	$16.14
SUBTOTAL	**54,588**	**25,542**	**$663,197.03**	**2.23**	**$12.15**
TIER-1 SUBTOTAL	**267,049**	**123,163**	**$3,050,697.70**	**2.17**	**$11.42**
LEVOCETIRIZINE PRODUCTS					
TIER-2 UTILIZATION					
LEVOCETIRIZI TAB 5MG	493	125	$7,387.67	3.94	$14.99
LEVOCETIRIZI SOL 2.5/5ML	298	74	$20,339.34	4.03	$68.25
TIER-2 SUBTOTAL	**791**	**199**	**$27,727.01**	**4.02**	**$35.05**
DESLORATADINE PRODUCTS					
TIER-3 UTILIZATION					
DESLORATADIN TAB 5MG	25	4	$593.16	6.25	$23.73
CLARINEX SYP 0.5MG/ML	8	1	$3,500.89	8	$437.61
TIER-3 SUBTOTAL	**33**	**5**	**$4,094.05**	**6.6**	**$124.06**
TOTAL	**267,873**	**110,257***	**$3,082,518.76**	**2.43**	**$11.51**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Anti-Parasitic Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Albenza® (Albendazole) Approval Criteria:

1. A quantity of 6 tablets will process for the brand formulation or authorized generic formulation without prior authorization.
2. For infections requiring additional doses, a prior authorization will need to be submitted and the following criteria will apply:
    a. An FDA approved diagnosis of 1 of the following:
        i. Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*.
        ii. Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.
3. For requests for the generic formulation (other than the authorized generic formulation), a prior authorization will need to be submitted and the following criteria will apply:
    a. An FDA approved diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use the brand formulation must be provided.

Emverm® (Mebendazole) Approval Criteria:

3. An FDA approved diagnosis of any of the following:
    a. Treatment of *Enterobius vermicularis* (pinworm); or
    b. Treatment of *Trichuris trichiura* (whipworm); or
    c. Treatment of *Ascaris lumbricoides* (roundworm); or
    d. Treatment of *Ancylostoma duodenale* (hookworm); or
    e. Treatment of *Necator americanus* (hookworm); and
4. For the treatment of *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (hookworm), or *Necator americanus* (hookworm), a patient-specific, clinically significant reason why a more cost-effective anthelmintic therapy, such as albendazole or pyrantel pamoate, cannot be used must be provided.
5. The following quantity limits will apply:
    a. *Enterobius vermicularis (*pinworm): 2 tablets per approval
    b. *Trichuris trichiura* (whipworm): 6 tablets per approval
    c. *Ascaris lumbricoides* (roundworm): 6 tablets per approval
    d. *Ancylostoma duodenale* (hookworm): 6 tablets per approval
    e. *Necator americanus* (hookworm): 6 tablets per approval

Impavido® (Miltefosine) Approval Criteria:

1. An FDA approved indication for treatment of:
    1. Visceral leishmaniasis due to *Leishmania donovani*; or
    2. Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*; or
    3. Mucosal leishmaniasis due to *Leishmania braziliensis*; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members must be willing to use effective contraception while on therapy and for 5 months after completion of therapy; 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.
4. A quantity limit of 84 capsules per 28 days will apply.

Benznidazole Tablets Approval Criteria:

1. An FDA approved diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*; and
2. Benznidazole must be prescribed by, or in consultation with, an infectious disease specialist; and
3. Female members of reproductive potential must have a pregnancy test prior to treatment with benznidazole; and
4. Female members of reproductive potential must be willing to use effective contraception during treatment with benznidazole tablets and for 5 days after the last dose; and
5. Member must not have taken disulfiram within the last 2 weeks; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug. The approval duration will be for 60 days of therapy.

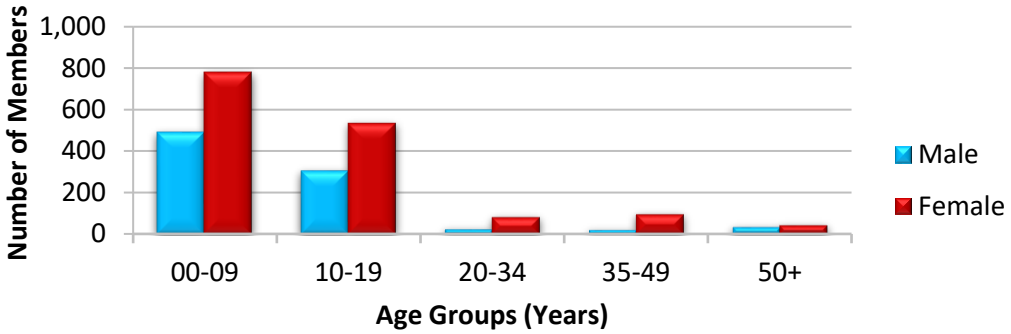
Utilization of Anti-Parasitic Medications: Fiscal Year 2018

Anti-Parasitic Medications Comparison of Fiscal Years: Pharmacy Claims

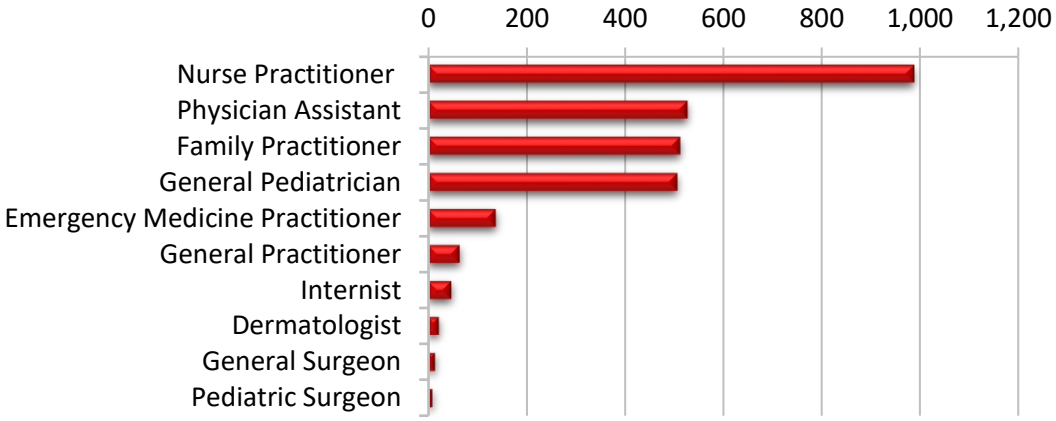
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2,850	3,417	$1,011,430.31	$296.00	$36.02	14,999	28,080
2018	2,415	2,888	$971,938.10	$336.54	$42.40	11,300	22,924
% Change	**-15.30%**	**-15.50%**	**-3.90%**	**13.70%**	**17.70%**	**-24.70%**	**-18.40%**
Change	**-435**	**-529**	**-$39,492.21**	**$40.54**	**$6.38**	**-3,699**	**-5,156**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Anti-Parasitic Medications



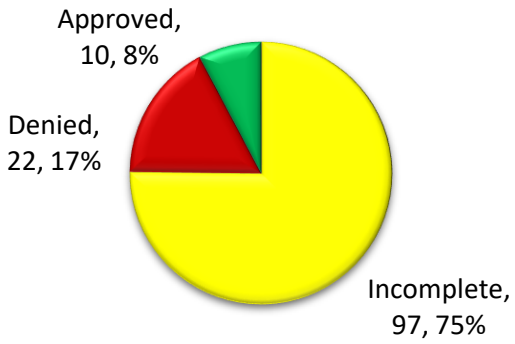
Top Prescriber Specialties of Anti-Parasitic Medications by Number of Claims



Prior Authorization of Anti-Parasitic Medications

There were 129 prior authorization requests submitted for anti-parasitic medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

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

- **June 2018:** Medicines Development for Global Health (MDGH) and the World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR)

announced that the FDA approved moxidectin for the treatment of onchocerciasis (river blindness) due to *Onchocerca volvulus* in patients 12 years of age and older. MDGH is the first not-for-profit company to register a medicine through the tropical disease Priority Review Voucher (PRV) program.[27]

- **September 2018:** An AB-rated generic version of Albenza® (albendazole) was launched.[28]

Recommendations

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

Utilization Details of Anti-Parasitic Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
ALBENZA TAB 200MG	1,649	1,457	$935,458.62	1.13	$567.29	96.25%
IVERMECTIN TAB 3MG	1,221	979	$31,904.76	1.25	$26.13	3.28%
BILTRICIDE TAB 600MG	16	13	$3,735.47	1.23	$233.47	0.38%
EMVERM CHW 100MG	2	2	$839.25	1	$419.63	0.09%
TOTAL	**2,888**	**2,415**	**$971,938.10**	**1.2**	**$336.54**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[27] Medicines Development for Global Health. U.S. FDA Approves Moxidectin for the Treatment of River Blindness. Available online at: https://www.medicinesdevelopment.com/news-180613.htm. Issued 06/13/2018. Last accessed 03/25/2019.
[28] Albenza® (albendazole) – First-time generic. *OptumRx*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_albenza_2018-0925.pdf. Last accessed 03/12/2019.

Fiscal Year 2018 Annual Review of Anti-Ulcer Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
omeprazole (Prilosec® caps)	dexlansoprazole (Dexilant® caps)	esomeprazole (Nexium® caps, IV)	aspirin/omeprazole (Yosprala™ DR tabs)
pantoprazole (Protonix® tabs)	esomeprazole (Nexium® packets)	esomeprazole strontium caps	cimetidine (Tagamet® tabs)
	lansoprazole (Prevacid® caps, ODT)	dexlansoprazole (Dexilant® SoluTab)	esomeprazole kit (ESOMEP-EZS™)
	pantoprazole (Protonix® IV)	omeprazole (Prilosec® susp, powder)	famotidine (Pepcid® susp)
	rabeprazole sodium (Aciphex® tabs)	pantoprazole (Protonix® susp)	nizatidine (Axid® caps, sol)
		rabeprazole sodium (Aciphex® Sprinkles)	omeprazole/sodium bicarbonate (Zegerid®)
			ranitidine caps
			sucralfate susp unit dose cups

ODT = orally disintegrating tablets; caps = capsules; tabs = tablets; IV = intravenous; susp = suspension; DR = delayed-release
*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reason(s) for use.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

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; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reason(s) for use.

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, 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.

Special Prior Authorization Approval Criteria:

1. **Pepcid® suspension (famotidine):**
    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 capsules:** A patient-specific, clinically significant reason why the member cannot use ranitidine tablets must be provided.
4. **Sucralfate suspension unit dose cups:** A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.
5. **Tagamet® (cimetidine tablets):** 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 capsules):** 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 tablets):** 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.

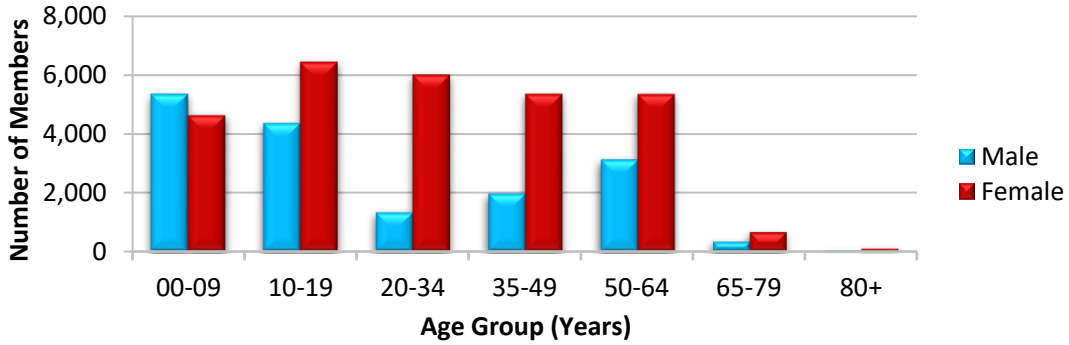
Utilization of Anti-Ulcer Medications: Fiscal Year 2018

Comparison of Fiscal Years

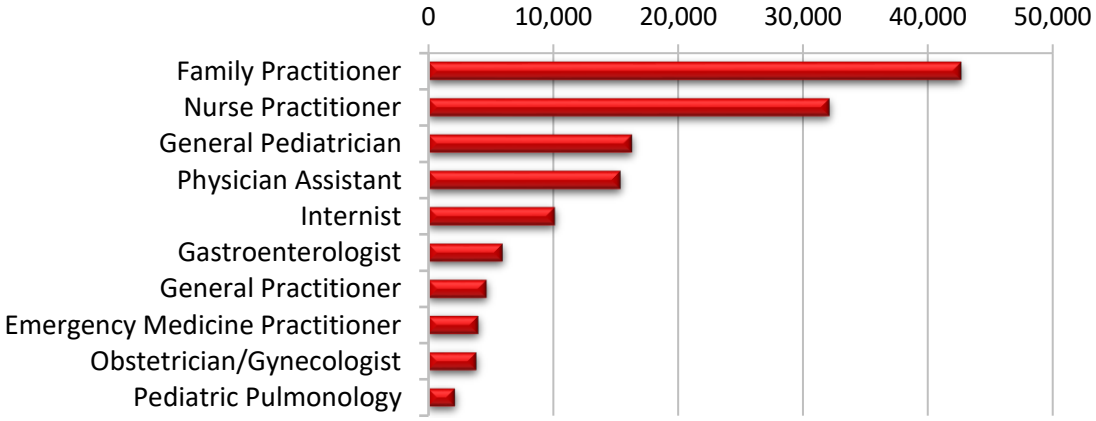
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	47,558	161,039	$3,295,145.44	$20.46	$0.61	10,228,915	5,401,379
2018	44,963	149,700	$3,507,361.67	$23.43	$0.67	9,952,215	5,260,095
% Change	**-5.50%**	**-7.00%**	**6.40%**	**14.50%**	**9.80%**	**-2.70%**	**-2.60%**
Change	**-2,595**	**-11,339**	**$212,216.23**	**$2.97**	**$0.06**	**-276,700**	**-141,284**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Anti-Ulcer Medications

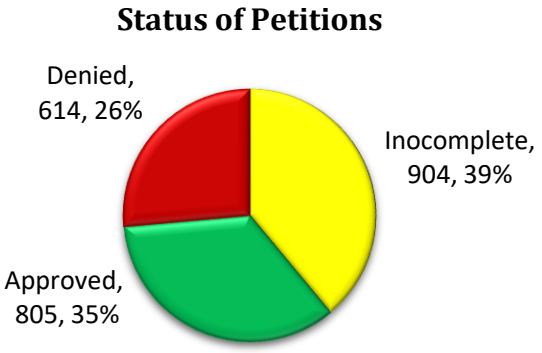


Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 2,323 prior authorization requests submitted for anti-ulcer medications during fiscal year 2018. 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 2018.



Market News and Updates

Anticipated Patent Expiration(s):[29]

- Prevacid® [lansoprazole orally disintegrating tablet (ODT)]: November 2019
- Prilosec® (omeprazole suspension): November 2019
- Nexium® (esomeprazole suspension): May 2020
- Protonix® [pantoprazole intravenous (IV)]: May 2022
- Protonix® (pantoprazole suspension): December 2026
- Dexilant® (dexlansoprazole orally disintegrating tablets [ODT]): March 2029
- Dexilant® (dexlansoprazole capsules): March 2030
- Yosprala™ (aspirin/omeprazole tablets): March 2033

News: [30,31]

- **October 2017:** An article published in *Gut* evaluated the potential link between long-term proton pump inhibitor (PPI) therapy and gastric cancer. This study was a retrospective look at a health database in Hong Kong. The study included 63,397 subjects who were treated for *H. pylori* and achieved eradication prior to continuing on long-term PPI therapy. The study found that after successful *H. pylori* eradication, patients who used long-term PPIs had a 2.4-fold increase in the risk of gastric cancer comparted to non-users. The study also found that patients that who took PPIs for ≥3 years were at the highest risk of gastric cancer [hazard ratio (HR) 8.34].
- **August 2018:** A randomized trial published in *The Lancet* looked at the use of esomeprazole and aspirin in Barrett's esophagus. Patients in the trial were randomized 1:1:1:1 to receive high-dose (40mg twice-daily) or low-dose (20mg once-daily) esomperazole, with or without aspirin (300mg per day in the UK or 325mg per day in Canada) for at least 8 years. A total of 2,557 patients were included in the study. The primary composite endpoint was time to all-cause mortality, esophageal adenocarcinoma, or high-grade dysplasia. High-dose PPI was superior to low-dose PPI

[29] 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 03/04/2019.
[30] Cheung KS, Chan EW, Wong AYS, et al. Long-term proton pump inhibitors and risk of gastric cancer development after treatment for *Helicobacter pylori*: a population-based study. *Gut* 2018; 67:28-35.
[31] Jankowski J, de Caestecker J, Love S, et al. Esomeprazole and aspirin in Barrett's oesophagus (AspECT): a randomised factorial trial. *The Lancet* 2018; 392(10145);400-408.

[139:1,270 vs. 174:1,265; time ratio (TR) 1.27, P=0.038]. The use of aspirin was not significantly better than no aspirin (P=0.068), but the use of high-dose PPI with aspirin had the strongest effect compared to low-dose PPI without aspirin (TR 1.59, P=0.0068). Only 28 (1%) patients reported a study related serious adverse event.

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
CIMETIDINE PRODUCTS					
CIMETIDINE SOL 300MG/5ML	291	203	$7,676.67	1.43	$26.38
SUBTOTAL	**291**	**203**	**$7,676.67**	**1.43**	**$26.38**
FAMOTIDINE PRODUCTS					
FAMOTIDINE TAB 20MG	7,764	3,040	$84,214.87	2.55	$10.85
FAMOTIDINE TAB 40MG	1,459	621	$18,232.14	2.35	$12.50
FAMOTIDINE INJ 20MG/2ML	14	2	$186.34	7	$13.31
FAMOTIDINE INJ 200/20ML	13	4	$300.51	3.25	$23.12
FAMOTIDINE INJ 40MG/4ML	7	3	$120.75	2.33	$17.25
SUBTOTAL	**9,257**	**3,670**	**$103,054.61**	**2.55**	**$11.13**
OMEPRAZOLE PRODUCTS					
OMEPRAZOLE CAP 20MG	39,258	12,733	$441,001.09	3.08	$11.23
OMEPRAZOLE CAP 40MG	23,173	7,470	$296,523.60	3.1	$12.80
OMEPRAZOLE CAP 10MG	2,377	857	$40,830.85	2.77	$17.18
SUBTOTAL	**64,808**	**21,060**	**$778,355.54**	**3.22**	**$12.01**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE TAB 40MG	21,645	6,831	$252,123.15	3.17	$11.65
PANTOPRAZOLE TAB 20MG	3,825	1,273	$48,402.68	3	$12.65
PANTOPRAZOLE TAB 40MG DR	17	15	$201.54	1.13	$11.86
SUBTOTAL	**25,487**	**8,119**	**$300,727.37**	**3.22**	**$11.80**
RANITIDINE PRODUCTS					
RANITIDINE SYP 75MG/5ML	17,652	8,160	$242,701.29	2.16	$13.75
RANITIDINE TAB 150MG	15,202	6,361	$182,146.38	2.39	$11.98
RANITIDINE TAB 300MG	1,865	765	$23,588.93	2.44	$12.65
RANITIDINE SYP 15MG/ML	781	526	$10,921.87	1.48	$13.98
RANITIDINE SYP 150/10ML	4	4	$59.49	1	$14.87
RANITIDINE INJ 150/6ML	1	1	$196.20	1	$196.20
SUBTOTAL	**35,505**	**15,817**	**$459,614.16**	**2.3**	**$12.95**
SUCRALFATE PRODUCTS					
SUCRALFATE TAB 1GM	4,372	2,340	$111,808.04	1.87	$25.57
CARAFATE SUS 1GM/10ML	1,516	798	$398,798.97	1.9	$263.06
CARAFATE TAB 1GM	1	1	$68.87	1	$68.87
SUBTOTAL	**5,889**	**3,139**	**$510,675.88**	**1.88**	**$86.72**
TIER-1 SUBTOTAL	**141,237**	**52,008**	**$2,160,104.23**	**2.72**	**$15.29**
TIER-2 UTILIZATION					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DEXLANSOPRAZOLE PRODUCTS					
DEXILANT CAP 60MG DR	1,908	287	$499,515.63	6.65	$261.80
DEXILANT CAP 30MG DR	311	61	$82,489.23	5.1	$265.24
SUBTOTAL	**2,219**	**348**	**$582,004.86**	**6.55**	**$262.28**
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE CAP 30MG DR	1,953	255	$30,784.51	7.66	$15.76
PREVACID TAB 15MG STB	589	116	$240,523.33	5.08	$408.36
PREVACID TAB 30MG STB	393	61	$156,654.20	6.44	$398.61
LANSOPRAZOLE CAP 15MG DR	244	53	$5,714.58	4.6	$23.42
LANSOPRAZOLE TAB 15MG	56	26	$20,314.45	2.15	$362.76
LANSOPRAZOLE TAB 30MG	49	21	$17,923.26	2.33	$365.78
SUBTOTAL	**3,284**	**532**	**$471,914.33**	**6.81**	**$143.70**
RABEPRAZOLE PRODUCTS					
RABEPRAZOLE TAB 20MG	388	62	$8,469.43	6.26	$21.83
ACIPHEX TAB 20MG	5	1	$2,554.15	5	$510.83
SUBTOTAL	**393**	**63**	**$11,023.58**	**6.34**	**$28.05**
ESOMEPRAZOLE PRODUCTS					
NEXIUM GRA 10MG DR	76	21	$20,779.97	3.62	$273.42
NEXIUM GRA 20MG DR	47	9	$14,196.50	5.22	$302.05
NEXIUM GRA 40MG DR	30	7	$7,554.55	4.29	$251.82
NEXIUM GRA 2.5MG DR	20	7	$5,419.82	2.86	$270.99
NEXIUM GRA 5MG DR	14	9	$3,566.01	1.56	$254.72
SUBTOTAL	**187**	**53**	**$51,516.85**	**3.74**	**$275.49**
PANTOPRAZOLE PRODUCTS					
PROTONIX INJ 40MG	68	5	$2,157.30	13.6	$31.73
SUBTOTAL	**68**	**5**	**$2,157.30**	**13.6**	**$31.73**
TIER-2 SUBTOTAL	**6,151**	**1,001**	**$1,118,616.92**	**6.14**	**$181.86**
TIER-3 UTILIZATION					
ESOMEPRAZOLE PRODUCTS					
ESOMEPRA MAG CAP 40MG DR	317	40	$8,825.04	7.93	$27.84
NEXIUM CAP 40MG	24	2	$5,949.54	12	$247.90
ESOMEPRA MAG CAP 20MG DR	17	4	$669.68	4.25	$39.39
SUBTOTAL	**358**	**46**	**$15,444.26**	**7.78**	**$43.14**
RABEPRAZOLE PRODUCTS					
ACIPHEX SPR CAP 10MG	2	1	$1,066.60	2	$533.30
SUBTOTAL	**2**	**1**	**$1,066.60**	**2**	**$533.30**
OMEPRAZOLE PRODUCTS					
PRILOSEC POW 2.5MG	64	20	$18,047.77	3.2	$282.00
PRILOSEC POW 10MG	50	12	$13,261.93	4.17	$265.24
SUBTOTAL	**114**	**32**	**$31,309.70**	**3.56**	**$274.65**
PANTOPRAZOLE PRODUCTS					
PROTONIX PAK	57	6	$23,127.96	9.5	$405.75
SUBTOTAL	**57**	**6**	**$23,127.96**	**9.5**	**$405.75**
TIER-3 SUBTOTAL	**531**	**85**	**$70,948.52**	**6.25**	**$133.61**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
FAMOTIDINE PRODUCTS					
FAMOTIDINE SUS 40MG/5ML	51	26	$3,285.35	1.96	$64.42
SUBTOTAL	**51**	**26**	**$3,285.35**	**1.96**	**$64.42**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NIZATIDINE PRODUCTS					
NIZATIDINE SOL 15MG/ML	1,170	457	$135,397.76	2.56	$115.72
NIZATIDINE CAP 150MG	39	11	$872.75	3.55	$22.38
NIZATIDINE CAP 300MG	1	1	$29.52	1	$29.52
SUBTOTAL	**1,210**	**469**	**$136,300.03**	**2.59**	**$112.64**
CIMETIDINE PRODUCTS					
CIMETIDINE TAB 400MG	241	132	$8,890.45	1.83	$36.89
CIMETIDINE TAB 300MG	126	88	$3,501.82	1.43	$27.79
CIMETIDINE TAB 200MG	93	53	$2,801.50	1.75	$30.12
CIMETIDINE TAB 800MG	60	41	$2,912.85	1.46	$48.55
SUBTOTAL	**520**	**314**	**$18,106.62**	**1.66**	**$34.82**
SPECIAL PA SUBTOTAL	**1,781**	**809**	**$157,692.00**	**2.20**	**$88.54**
TOTAL	**149,700**	**44,963***	**$3,507,361.67**	**3.33**	**$23.43**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Antiviral Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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

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

Prevymis™ (Letermovir Tablets and Injection) Approval Criteria:

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

RibaPak® (Ribavirin Dose Pack), Rebetol® (Ribavirin Solution), and Ribasphere® (Ribavirin 400mg and 600mg Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the 200mg tablets or 200mg capsules in place of the unique dosage formulations must be provided.

Zovirax® (Acyclovir Ointment) Approval Criteria:

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

Zovirax® (Acyclovir Suspension) Approval Criteria:

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

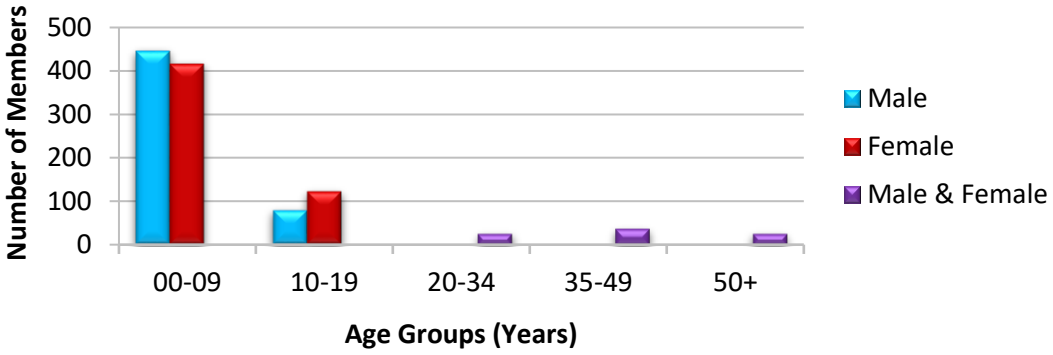
Utilization of Antiviral Medications: Fiscal Year 2018

Comparison of Fiscal Years

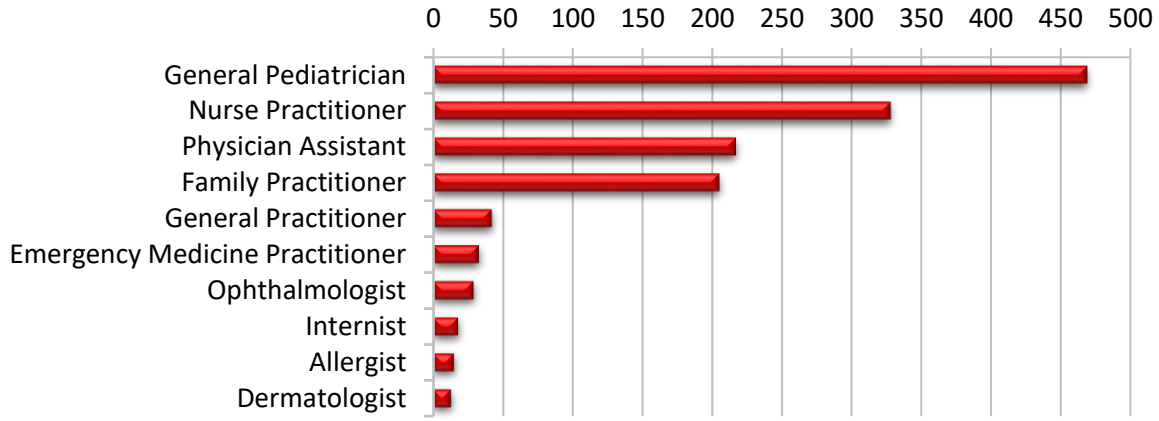
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1,867	2,373	$514,476.72	$216.80	$19.31	274,717	26,649
2018	1,146	1,455	$205,366.21	$141.15	$12.89	227,339	15,931
% Change	**-38.60%**	**-38.70%**	**-60.10%**	**-34.90%**	**-33.20%**	**-17.20%**	**-40.20%**
Change	**-721**	**-918**	**-$309,110.51**	**-$75.65**	**-$6.42**	**-47,378**	**-10,718**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Antiviral Medications



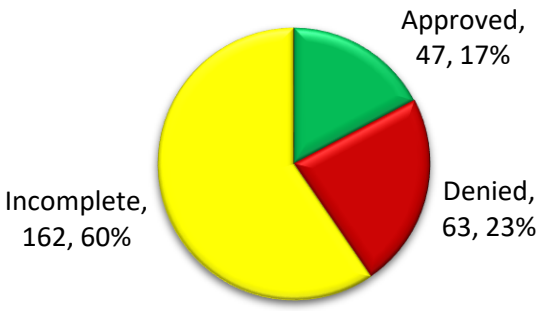
Top Prescriber Specialties of Antiviral Medications by Number of Claims



Prior Authorization of Antiviral Medications

There were 272 prior authorization requests submitted for antiviral medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Recommendations

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

Utilization Details of Antiviral Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ DAY	COST/ CLAIM
ACYCLOVIR PRODUCTS						
ACYCLOVIR SUS 200MG/5ML	1,140	869	$131,289.52	1.31	$11.06	$115.17
ACYCLOVIR OIN 5%	297	271	$59,431.74	1.1	$16.64	$200.11
SUBTOTAL	**1,437**	**1,129**	**$190,721.26**	**1.27**	**$12.35**	**$132.72**
PENCICLOVIR PRODUCTS						
DENAVIR CRE 1%	15	14	$11,129.85	1.07	$24.73	$741.99
SUBTOTAL	**15**	**14**	**$11,129.85**	**1.07**	**$24.73**	**$741.99**
ACYCLOVIR/HYDROCORTISONE PRODUCTS						
XERESE CRE 5-1%	3	3	$3,515.10	1	$83.69	$1,171.70
SUBTOTAL	**3**	**3**	**$3,515.10**	**1**	**$83.69**	**$1,171.70**
TOTAL	**28,145**	**23,191***	**$5,448,231.85**	**1.21**	**$17.81**	**$193.58**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Arcalyst® (Rilonacept)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Arcalyst® (rilonacept) Approval Criteria:

1. FDA approved indication of Cryopyrin-Associated Periodic Syndromes (CAPS) verified by genetic testing. This includes Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.
2. The member should not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Arcalyst® should not be initiated in patients with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once weekly; and
5. Approvals will be based on FDA approved dosing schedules for age and weight; and
6. Approvals will be for the duration of 1 year.

Utilization of Acralyst®: Fiscal Year 2018

There were no pharmacy or medical claims for Arcalyst® (rilonacept) during fiscal year 2018.

Prior Authorization of Acralyst®

There were no prior authorization requests submitted for Arcalyst® (rilonacept) during fiscal year 2018.

Recommendations

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

Fiscal Year 2018 Annual Review of Benlysta® (Belimumab)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Benlysta® (Belimumab) Approval Criteria:

1. The intravenous (IV) formulation will be covered as a medical claim only benefit while the subcutaneous (sub-Q) formulation will be covered as a pharmacy only benefit; and
2. An FDA approved indication of the treatment of adults with active, autoantibody-positive, systemic lupus erythematosus (SLE) already receiving standard therapy; and
3. Documented inadequate response to at least 2 of the following medications:
    a. High-dose oral corticosteroids; or
    b. Methotrexate; or
    c. Azathioprine; or
    d. Mycophenolate; or
    e. Cyclophosphamide; and
4. Member must not have severe active lupus nephritis or severe active central nervous system lupus; and
5. Benlysta® will not be approved for combination use with biologic therapies or IV cyclophosphamide.

Utilization of Benlysta® (Belimumab): Fiscal Year 2018

Fiscal Year 2018 Utilization of Benlysta® (Belimumab): Pharmacy Claims

*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
5	16	$56,934.71	$3,558.42	3.2

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, the subcutaneous formulation of Benlysta® was approved by the U.S. Food and Drug Administration (FDA) in July 2017; therefore, there was no pharmacy utilization of Benlysta® during fiscal year 2017 (07/01/2016 to 06/30/2017).

Fiscal Year 2018 Utilization of Benlysta® (Belimumab): Medical Claims

*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
20	136	$411,972.10	$3,029.21	6.8

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Benlysta® (Belimumab)

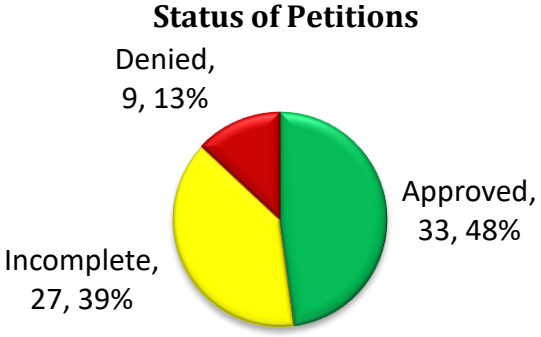
- There were 22 unique members utilizing Benlysta® (belimumab) during fiscal year 2018, and all members were female and in the 20 to 64 year old age group. There were 3 members that had both medical and pharmacy claims for Benlysta® (all 3 members switched from the IV formulation to the sub-Q formulation).

Top Prescriber Specialties of Benlysta® (Belimumab) by Number of Claims

- The only prescriber specialties listed on paid claims for Benlysta® (belimumab) during fiscal year 2018 was rheumatologist, physician assistant, and nurse practitioner. Upon further research, the supervising physician for the physician assistants and the nurse practitioner was a rheumatologist.

Prior Authorization of Benlysta® (Belimumab)

There were 69 prior authorization requests submitted for 31 unique members for Benlysta® (belimumab) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

News:

- **March 2018:** GSK announced the start of a Phase 3 study investigating Benlysta® (belimumab) in combination with rituximab in adult patients with systemic lupus erythematosus (SLE). Belimumab and rituximab have different but potentially complementary mechanisms of action; this study will assess whether co-administration enhances the treatment effect of belimumab and provided sustained disease control, which could lead to clinical remission. This pivotal Phase 3 study (BLISS-BELIEVE) is a multi-center, 3-arm, randomized, double-blind, placebo-controlled, 104-week superiority study in at least 200 adult patients with SLE to evaluate the efficacy and safety of belimumab administered in combination with a single cycle of rituximab. Patients will be randomized to receive either belimumab plus rituximab-placebo, plus standard therapy (control arm); belimumab plus rituximab, plus standard therapy (combination arm); or belimumab plus standard therapy (reference arm).[32]
- **November 2018:** Using Benlysta® (belimumab) as a maintenance therapy after Rituxan® (rituximab) leads to similar kidney function in patients with lupus nephritis compared with rituximab alone, according to a Phase 2 study. Two randomized trials studying rituximab have failed to meet their goals in patients with lupus and lupus nephritis; one possible explanation is the elevated B-cell-activating factor (BAFF) levels seen in lupus patients after treatment with rituximab. BAFF is essential for the survival of B-cells and

[32] GSK News Release. GSK Starts Phase III Study of Benlysta® and Rituximab Combination in Systemic Lupus Erythematosus. Available online at: https://www.gsk.com/en-gb/media/press-releases/gsk-starts-phase-iii-study-of-benlysta-and-rituximab-combination-in-systemic-lupus-erythematosus/. Issued 03/20/2018. Last accessed 03/04/2019.

an increase in this factor is thought to favor the expansion of autoreactive B cells, which produce antibodies against the body's own tissues, leading to lupus flares. The Phase 2 study (CALIBRATE) intended to explore this hypothesis, to assess whether adding the anti-BAFF immunosuppressant, belimumab, could improve the clinical effects of rituximab, and to determine the safety of the combination therapy. The open-label study included 43 patients with active, proliferative lupus nephritis despite standard treatment. All patients received rituximab IV 1,000mg, cyclophosphamide 750mg, and methylprednisolone 200mg at the start of the study and at week 2, as well as an initial daily prednisone dose of 40mg, which was progressively lowered to 10mg by week 12. At week 4, patients were randomized to belimumab (10mg/kg at weeks 4, 6, and 8, and then every 4 weeks thereafter) plus prednisone (21 patients) or prednisone alone (22 patients). At week 48, the rates of renal response were similar between the groups. Future analyses at week 96 will further reveal the effects of belimumab on B cells and longer-term clinical outcomes.[33]

Recommendations

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

Utilization Details of Benlysta® (Belimumab): Fiscal Year 2018

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BENLYSTA SUBQ INJ 200MG/ML PREFILLED SYRINGE	8	3	$28,488.92	$3,561.12	2.7
BENLYSTA SUBQ INJ 200MG/ML AUTO-INJECTOR	8	3	$28,445.79	$3,555.72	2.7
TOTAL	**16**	**5***	**$56,934.71**	**$3,558.42**	**3.2**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, the sub-Q formulation of Benlysta® is covered as a pharmacy only benefit; the IV formulation is covered as a medical claim only benefit.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BELIMUMAB 10MG INJ (J0490)	136	20	$411,972.10	$3,029.21	6.8
TOTAL	**136**	**20***	**$411,972.10**	**$3,029.21**	**6.8**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, the IV formulation of Benlysta® is covered as a medical claim only benefit; the sub-Q formulation is covered as a pharmacy only benefit.

[33] Marques Lopes J. Benlysta® Maintenance Does Not Change Kidney Function of Lupus Nephritis Patients, Phase 2 Trial Shows. *Lupus News Today.* Available online at: https://lupusnewstoday.com/2018/11/21/no-change-kidney-function-benlysta-maintenance-lupus-nephritis-patients-phase-2-trial/. Issued 11/21/2018. Last accessed 03/04/2019.

Fiscal Year 2018 Annual Review of Benzodiazepine Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Benzodiazepine 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; 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; and
    a. A member may receive more than 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 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 or younger will have the same criteria and the prescription must be originally written by a psychiatrist or neurologist.

Niravam™ (Alprazolam Orally Disintegrating Tablets) 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.
4. Dosing regimens that involve splitting of tablets will not be covered.

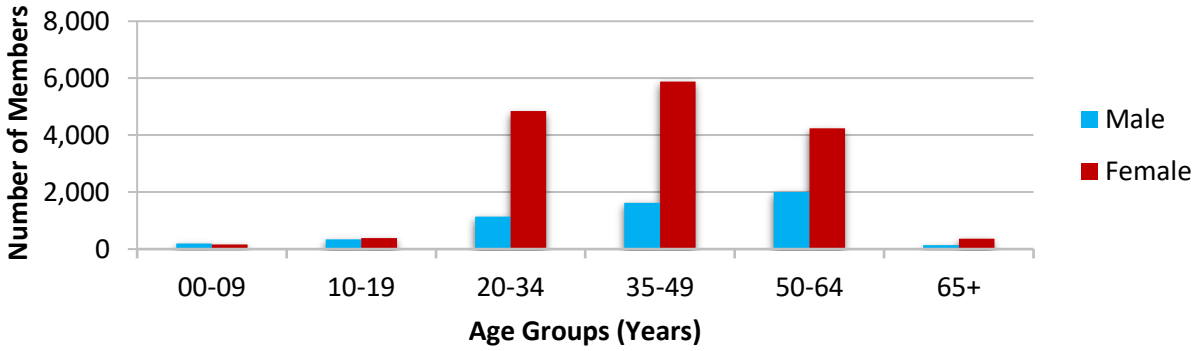
Utilization of Benzodiazepine Medications: Fiscal Year 2018

Comparison of Fiscal Years

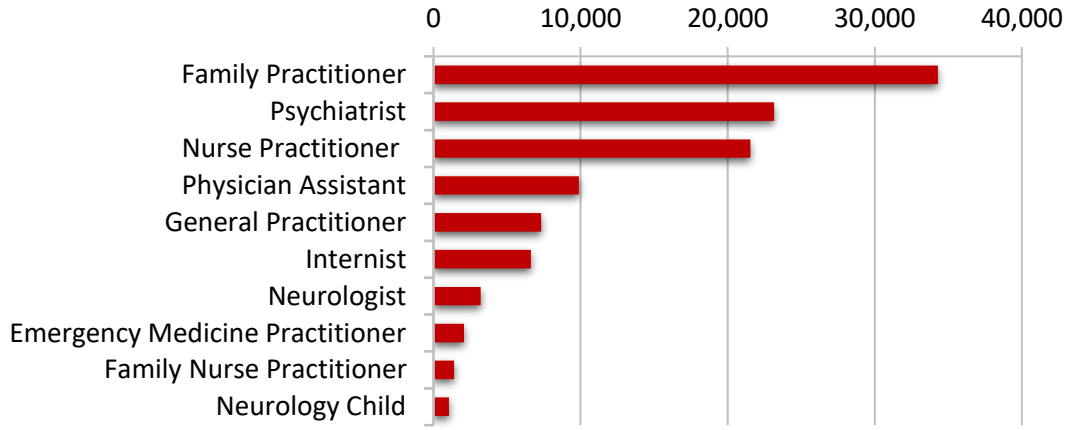
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	24,702	138,316	$1,188,825.35	$8.59	$0.31	8,668,776	3,860,312
2018	21,323	116,729	$1,312,630.03	$11.25	$0.41	7,191,325	3,240,097
% Change	**-13.70%**	**-15.60%**	**10.40%**	**31.00%**	**32.30%**	**-17.00%**	**-16.10%**
Change	**-3,379**	**-21,587**	**$123,804.68**	**$2.66**	**$0.10**	**-1,477,451**	**-620,215**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Benzodiazepine Medications



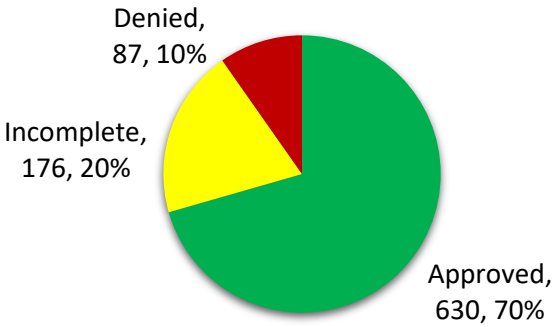
Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



Prior Authorization of Benzodiazepine Medications

There were 893 prior authorization request submitted for benzodiazepine medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

News:

- **May 2018:** A guideline for deprescribing benzodiazepines was published in *the Canadian Family Physician*. The evidence-based guideline was created to help clinicians decide when and how to safely taper and stop benzodiazepines. The guideline recommends tapering benzodiazepines slowly for elderly adults (≥65 years) regardless of duration of use. The guidelines also recommend tapering adults 18 to 64 years of age when they have been on benzodiazepines longer than 4 weeks. These recommendations also apply to benzodiazepines used for primary insomnia or comorbid insomnia where potential underlying comorbidities are effectively managed.[34]
- **May 2018:** The data from a nationwide case-control study in Finland was published in the *Acta Psychiatria Scandinavica*. The study evaluated Finish community-dwelling patients who received a diagnosis of Alzheimer's disease from 2005 to 2011. The study found that benzodiazepine use was associated with a modestly increased risk of Alzheimer's disease [adjusted odds ratio (OR) 1.06, 1.04 to 1.08]. There was no difference between different subcategories of benzodiazepines. [35]

Recommendations

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

Utilization Details of Benzodiazepine Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
ALPRAZOLAM PRODUCTS					
ALPRAZOLAM TAB 1MG	25,213	4,466	$248,956.30	5.65	$9.87
ALPRAZOLAM TAB 2MG	12,874	1,898	$144,743.15	6.78	$11.24
ALPRAZOLAM TAB 0.5MG	11,914	3,151	$116,340.03	3.78	$9.76

[34] Pottie K, Thompson W, et al. Deprescribing benzodiazepine receptor agonists: Evidence-based clinical practice guideline. *Can Fam Physician* 2018; 64(5):339-351.
[35] Tapiainen V, Taipale H, Tanskanen A, Tiihonen J, Hartikainen S, Tolppanen A-M. The risk of Alzheimer's disease associated with benzodiazepines and related drugs: a nested case–control study. *Acta Psychiatr Scand* 2018; 138(2): 91-100.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
ALPRAZOLAM TAB 0.25MG	3,104	1,085	$29,511.29	2.86	$9.51
ALPRAZOLAM TAB 2MG ER	153	41	$3,460.45	3.73	$22.62
ALPRAZOLAM TAB 1MG ER	149	51	$2,815.09	2.92	$18.89
ALPRAZOLAM TAB 3MG ER	123	20	$3,536.09	6.15	$28.75
ALPRAZOLAM TAB 0.5MG ER	55	24	$856.23	2.29	$15.57
ALPRAZOLAM TAB 1MG XR	35	8	$652.45	4.38	$18.64
ALPRAZOLAM TAB 0.5MG XR	19	4	$280.45	4.75	$14.76
ALPRAZOLAM TAB 2MG XR	11	3	$265.09	3.67	$24.10
ALPRAZOLAM TAB 1MG ODT	1	1	$118.17	1	$118.17
SUBTOTAL	**53,651**	**10,752**	**$551,534.79**	**6.01**	**$10.28**
CHLORDIAZEPOXIDE PRODUCTS					
CHLORDIAZEP CAP 25MG	213	139	$2,356.22	1.53	$11.06
CHLORDIAZEP CAP 10MG	167	53	$2,038.86	3.15	$12.21
CHLORDIAZEP CAP 5MG	44	28	$560.34	1.57	$12.74
SUBTOTAL	**424**	**220**	**$4,955.42**	**2.02**	**$11.69**
CLONAZEPAM PRODUCTS					
CLONAZEPAM TAB 1MG	15,470	3,267	$157,042.94	4.74	$10.15
CLONAZEPAM TAB 0.5MG	12,440	3,318	$122,254.93	3.75	$9.83
CLONAZEPAM TAB 2MG	4,373	828	$46,463.00	5.28	$10.62
CLONAZEP ODT TAB 0.25MG	941	295	$34,052.56	3.19	$36.19
CLONAZEP ODT TAB 0.5MG	511	152	$24,459.62	3.36	$47.87
CLONAZEP ODT TAB 0.125MG	427	154	$16,735.61	2.77	$39.19
CLONAZEP ODT TAB 1MG	241	77	$10,636.81	3.13	$44.14
CLONAZEP ODT TAB 2MG	62	19	$2,512.00	3.26	$40.52
KLONOPIN TAB 2MG	12	1	$2,890.66	12	$240.89
KLONOPIN TAB 1MG	4	1	$1,040.77	4	$260.19
SUBTOTAL	**34,481**	**8,112**	**$418,088.90**	**4.91**	**$12.13**
CHORAZEPATE PRODUCTS					
CLORAZ DIPOT TAB 3.75MG	242	40	$17,583.02	6.05	$72.66
CLORAZ DIPOT TAB 7.5MG	234	42	$21,601.54	5.57	$92.31
CLORAZ DIPOT TAB 15MG	138	23	$17,313.90	6	$125.46
SUBTOTAL	**614**	**105**	**$56,498.46**	**6.82**	**$92.02**
DIAZEPAM PRODUCTS					
DIAZEPAM TAB 10MG	8,117	1,937	$78,591.12	4.19	$9.68
DIAZEPAM TAB 5MG	6,717	2,163	$62,442.49	3.11	$9.30
DIAZEPAM TAB 2MG	1,190	432	$11,750.36	2.75	$9.87
DIAZEPAM SOL 5MG/5ML	217	66	$7,268.38	3.29	$33.49
DIAZEPAM INJ 5MG/ML	14	3	$2,281.08	4.67	$162.93
DIAZEPAM CON 5MG/ML	4	3	$150.96	1.33	$37.74
SUBTOTAL	**16,259**	**4,604**	**$162,484.39**	**3.89**	**$9.99**
LORAZEPAM PRODUCTS					
LORAZEPAM TAB 1MG	5,588	1,742	$54,286.11	3.21	$9.71
LORAZEPAM TAB 0.5MG	3,891	1,308	$38,270.33	2.97	$9.84
LORAZEPAM TAB 2MG	1,600	389	$17,572.70	4.11	$10.98

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
LORAZEPAM CON 2MG/ML	130	42	$4,263.45	3.1	$32.80
LORAZEPAM INJ 2MG/ML	29	10	$406.26	2.9	$14.01
SUBTOTAL	**11,238**	**3,491**	**$114,798.85**	**3.55**	**$10.22**
OXAZEPAM PRODUCTS					
OXAZEPAM CAP 10MG	24	4	$1,008.49	6	$42.02
OXAZEPAM CAP 15MG	21	3	$1,088.04	7	$51.81
OXAZEPAM CAP 30MG	17	3	$2,172.69	5.67	$127.81
SUBTOTAL	**62**	**10**	**$4,269.22**	**6.2**	**$68.86**
TOTAL	**116,729**	**21,323**	**$1,312,630.03**	**5.47**	**$8.60**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Benign Prostatic Hypertrophy (BPH) Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 4-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 medication(s).

BPH Medications Tier-3 Prior Authorization Criteria:

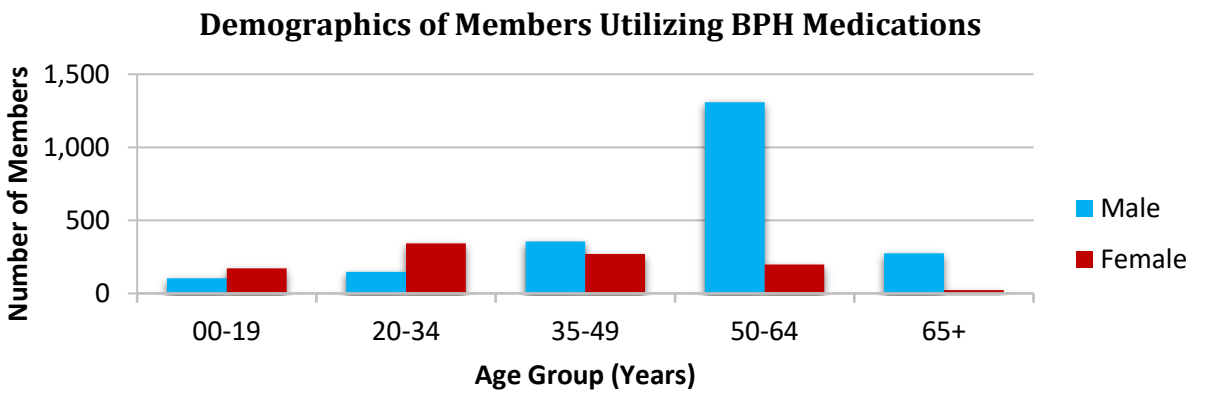
1. An FDA approved diagnosis of BPH; and
2. A trial of at least 2 Tier-1 medications from different pharmacological classes; and
3. A 4-week trial of each Tier-2 medication within the past 5 months; or
4. Documented adverse effect, drug interaction, contraindication, or lack of efficacy to all available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

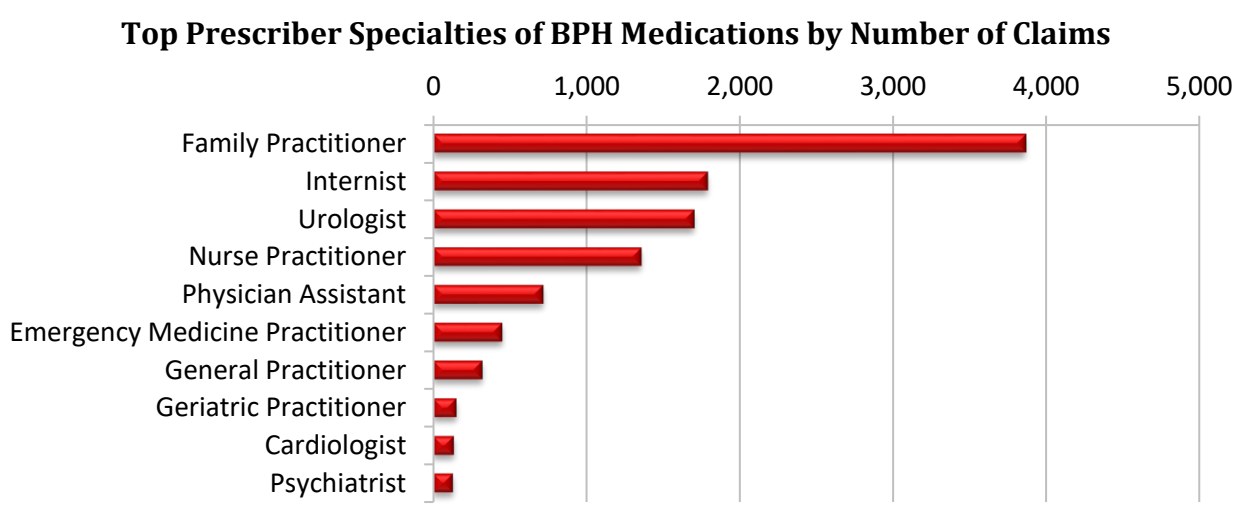
Utilization of BPH Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	3,128	10,718	$181,221.96	$16.91	$0.44	454,731	412,007
2018	3,192	11,282	$183,144.61	$16.23	$0.41	485,304	441,948
% Change	**2.00%**	**5.30%**	**1.10%**	**-4.00%**	**-6.80%**	**6.70%**	**7.30%**
Change	**64**	**564**	**$1,922.65**	**-$0.68**	**-$0.03**	**30,573**	**29,941**

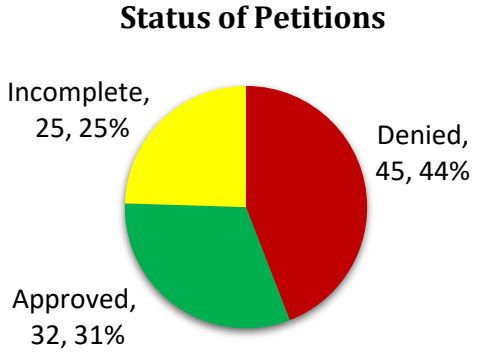
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Benign Prostatic Hypertrophy Medications

There were 102 prior authorization requests submitted for BPH medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s):[36]

- Cialis (tadalafil): August 2021

Recommendations

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

Utilization Details of Benign Prostatic Hypertrophy Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
ALFUZOSIN TAB 10MG ER	135	32	$1,960.54	4.22	$14.52
DOXAZOSIN TAB 4MG	739	151	$14,710.11	4.89	$19.91
DOXAZOSIN TAB 2MG	412	106	$9,147.53	3.89	$22.20
DOXAZOSIN TAB 8MG	282	61	$5,941.47	4.62	$21.07
DOXAZOSIN TAB 1MG	177	68	$4,183.51	2.6	$23.64
FINASTERIDE TAB 5MG	893	230	$11,277.05	3.88	$12.63
TAMSULOSIN CAP 0.4MG	7,966	2,647	$107,942.33	3.01	$13.55
TERAZOSIN CAP 2MG	160	43	$1,793.74	3.72	$11.21
TERAZOSIN CAP 1MG	156	52	$1,670.22	3	$10.71
TERAZOSIN CAP 5MG	94	29	$1,077.45	3.24	$11.46
TERAZOSIN CAP 10MG	83	20	$889.18	4.15	$10.71
DUTASTERIDE CAP 0.5MG	99	23	$1,905.17	4.3	$19.24
TIER-1 SUBTOTAL	**11,196**	**3,462**	**$162,498.30**	**3.23**	**$14.51**
TIER-2 UTILIZATION					
CARDURA XL TAB 8MG	8	1	$1,300.15	8	$162.52
DUTAST/TAMSU CAP 0.5-0.4MG	10	1	$1,187.96	10	$118.80
RAPAFLO CAP 8MG	50	6	$11,479.62	8.33	$229.59
RAPAFLO CAP 4MG	1	1	$444.40	1	$444.40
TIER-2 SUBTOTAL	**69**	**9**	**$14,412.13**	**7.29**	**$208.87**
TIER-3 UTILIZATION					
CIALIS TAB 5MG	17	3	$6,234.18	5.67	$366.72
TIER-3 SUBTOTAL	**17**	**3**	**$6,234.18**	**5.67**	**$366.72**
TOTAL	**11,282**	**3,192***	**$183,144.61**	**3.53**	**$16.23**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[36] 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 03/11/2019.

Fiscal Year 2018 Annual Review of Brineura® (Cerliponase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2018 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 at least 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 two 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 2018

There were no paid pharmacy or medical claims for Brineura® (cerliponase alfa) during fiscal year 2018.

Prior Authorization of Brineura® (Cerliponase Alfa)

There were no prior authorization requests submitted for Brineura® (cerliponase alfa) during fiscal year 2018.

Market News and Updates[37]

Pipeline:

- **January 2019:** Spark Therapeutics announced 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 TPP1 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.

[37] 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 02/18/2019.

Fiscal Year 2018 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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.
4. Esgic® capsules (butalbital/acetaminophen/caffeine 50mg/325mg/40mg) will require prior authorization with the following criteria:
   a. A patient-specific, clinically significant reason why the member cannot use Fioricet® tablets (butalbital/acetaminophen/caffeine 50mg/325mg/40mg).

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

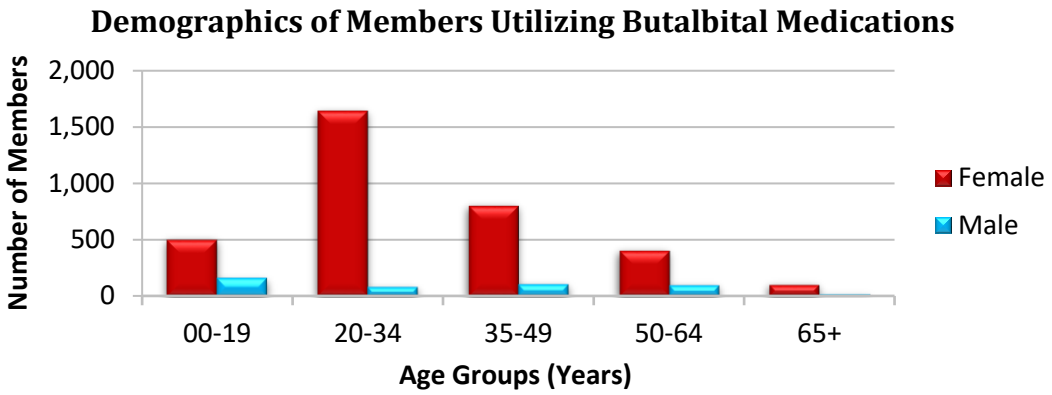
1. An FDA approved indication for the treatment of symptom complex of tension (or muscle contraction) headache; and
2. A patient-specific, clinically significant reason why a liquid formulation is needed in place of the generic tablets even when the tablets are crushed; and
3. Members with other solid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

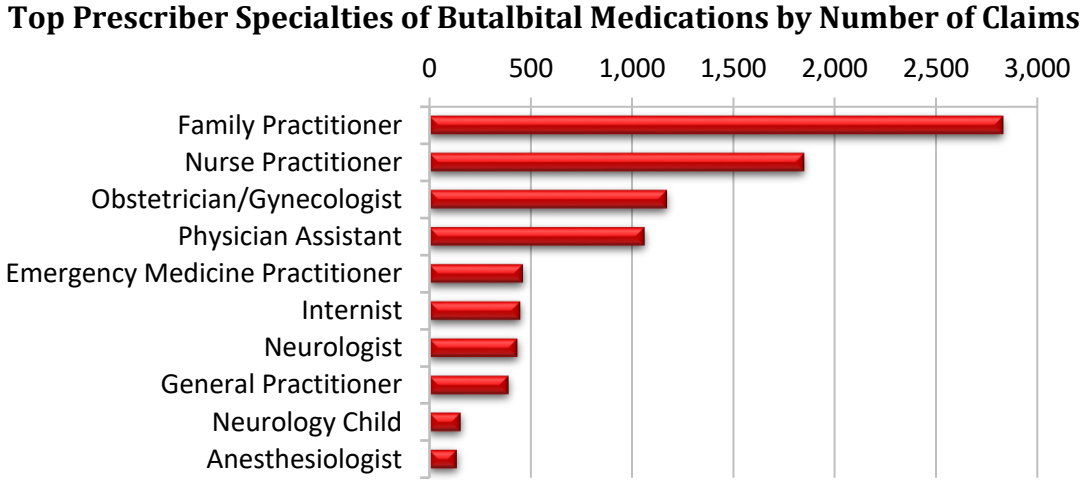
Utilization of Butalbital Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	4,683	11,363	$518,898.78	$45.67	$2.94	571,783	176,322
2018	3,892	9,468	$381,196.78	$40.26	$2.55	473,515	149,206
% Change	**-16.90%**	**-16.70%**	**-26.50%**	**-11.80%**	**-13.30%**	**-17.20%**	**-15.40%**
Change	**-791**	**-1,895**	**-$137,702.00**	**-$5.41**	**-$0.39**	**-98,268**	**-27,116**

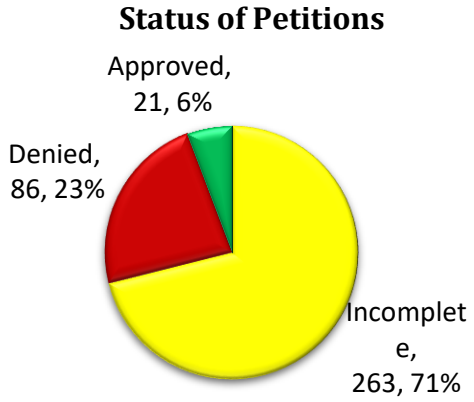
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Butalbital Medications

There were 370 prior authorization requests submitted for butalbital medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

U.S. Food and Drug Administration (FDA) Safety Updates:

- **January 2018:** The FDA required safety labeling changes to cough and cold medications that contain codeine or hydrocodone. The FDA label changes limit the use of codeine

and hydrocodone cough and cold medications to adults 18 years of age or older due to the risk of slowed breathing in children. Additional labeling changes included adding information about abuse, overdose, addiction, and difficultly breathing to the *Boxed Warning* for these medications.[38]

Recommendations

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

Utilization Details of Butalbital Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
BUTALBITAL/APAP PRODUCTS					
BUT/APAP/CAFF TAB 50-325-40MG	7,775	3,416	$225,282.22	2.28	$28.98
BUT/APAP TAB 50-325MG	57	19	$5,059.00	3	$88.75
VANATOL LQ SOL 50-325-40MG/15ML	18	16	$34,394.68	1.13	$1,910.82
SUBTOTAL	**7,850**	**3,451**	**$264,735.90**	**2.27**	**$33.72**
BUTALBITAL/APAP/CAFFEINE/CODEINE PRODUCTS					
BUT/APAP/CAFF/COD CAP 50-325-40-30MG	626	241	$39,483.72	3.36	$63.07
SUBTOTAL	**626**	**241**	**$39,483.72**	**3.36**	**$63.07**
BUTALBITAL/ASA PRODUCTS					
BUT/ASA/CAFF CAP 50-325-40MG	616	265	$35,953.10	2.79	$58.37
SUBTOTAL	**616**	**265**	**$35,953.10**	**2.79**	**$58.37**
BUTALBITAL/ASA/CAFFEINE/CODEINE PRODUCTS					
BUT/ASA/CAFF/COD CAP 50-325-40-30MG	255	65	$30,993.79	3.92	$121.54
ASCOMP/COD CAP 50-325-40-30MG	121	40	$10,030.27	3.03	$82.89
SUBTOTAL	**376**	**105**	**$41,024.06**	**3.58**	**$109.11**
TOTAL	**9,468**	**3,892***	**$381,196.78**	**2.43**	**$40.26**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
APAP = acetaminophen; ASA = aspirin; CAFF = caffeine; COD = Codeine; BUT = butalbital

[38] U.S. Food and Drug Administration (FDA) Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older Available online at: https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm. Issued 01/11/2018. Last accessed 09/11/2018.

Fiscal Year 2018 Annual Review of Cholbam® (Cholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved diagnosis of:
    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 patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
2. 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.
3. 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
4. Initial approval will be for 3 months to monitor for compliance and liver function tests; and
5. Continuation approvals will be granted for the duration of 1 year; and
6. 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 2018

There were not paid pharmacy claims for Cholbam® (cholic acid) during fiscal year 2018.

Prior Authorization of Cholbam® (Cholic Acid)

There were no prior authorization requests for Cholbam® (cholic acid) during fiscal year 2018.

Market News and Updates

Anticipated Exclusivity Expiration(s):[39]

- Cholbam® (cholic acid): March 2022

Recommendations

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

[39] 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 12/2018. Last accessed 01/25/2019.

Fiscal Year 2018 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 member must be 4 to 10 years of age; or
5. For the diagnosis of hypogonadotropic hypogonadism member must be of peripubertal age; and
    a. Patient-specific, clinically significant reason why testosterone therapy is not appropriate

Utilization of Chorionic Gonadotropin Medications: Fiscal Year 2018

There were no paid pharmacy or medical claims for chorionic gonadotropin medications during fiscal year 2018.

Prior Authorization of Chorionic Gonadotropin Medications

There was 1 prior authorization request submitted for chorionic gonadotropin medications during fiscal year 2018. The request was approved.

Recommendations

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

Fiscal Year 2018 Annual Review of Daraprim® (Pyrimethamine)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Introduction[40,41,42]

Toxoplasmosis is a disease that results from infection with the *Toxoplasma gondii* parasite, which is one of the world's most common parasites. Toxoplasmosis only progresses to illness in individuals with compromised immune systems, such as Human Immunodeficiency Virus (HIV) and cancer, and in pregnant women because their immune system is unable to control the parasite. Severe toxoplasmosis can cause brain and organ damage and can result in blindness.

Daraprim® (pyrimethamine 25mg tablet) was approved by the U.S. Food and Drug Administration (FDA) in 1953; however, no generic products are available. Pyrimethamine is a folic acid antagonist that is highly selective against plasmodia and *Toxoplasma gondii.* Pyrimethamine is indicated for the treatment of toxoplasmosis when used concomitantly with a sulfonamide, as synergism exists with this combination. Pyrimethamine is the only FDA approved medication for the treatment of toxoplasmosis. The recommended adult starting dose of pyrimethamine for toxoplasmosis is 50 to 75mg daily, taken with 1 to 4g daily of a sulfonamide. This dosage is typically continued for 1 to 3 weeks, depending on patient response and tolerance to therapy. The dosage may then be reduced to about half of the previous dose (for each drug) and continued for an additional 4 to 5 weeks.

Pyrimethamine is also indicated for the treatment of acute malaria, but should not be used as monotherapy. Concurrent use of pyrimethamine with a sulfonamide will initiate transmission control and suppression of susceptible strains of plasmodia. Lastly, pyrimethamine is indicated for the chemoprophylaxis of malaria due to susceptible strains of plasmodia. However, resistance to pyrimethamine is prevalent worldwide; therefore, it is not suitable as a prophylactic agent for travelers to most areas.

In August 2015, Daraprim® increased in price by more than 5,000%, from an estimated acquisition cost (EAC) of $14.31 to $792.00 per tablet, as a result of acquisition of Daraprim® by Turing Pharmaceuticals. The Drug Utilization Review (DUR) Board voted to prior authorize Daraprim® in December 2015. The current wholesale acquisition cost (WAC) of Daraprim® is $750.00 per tablet.

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[40] Centers for Disease Control and Prevention (CDC). Parasites – Toxoplasmosis (Toxoplasma Infection). Available online at: https://www.cdc.gov/parasites/toxoplasmosis/. Last revised 08/29/2018. Last accessed 03/05/2019.
[41] Gandhi RT. Toxoplasmosis in HIV-Infected Patients. *UpToDate*. Available online at: http://www.uptodate.com/contents/toxoplasmosis-in-hiv-infected-patients?source=machineLearning&search=toxoplasmosis&selectedTitle=1%7E150&sectionRank=1&anchor=H21#H21. Last revised 04/24/2018. Last accessed 03/05/2019.
[42] Daraprim® (Pyrimethamine) Prescribing Information. Vyera Pharmaceuticals LLC. Available online at: https://www.daraprimdirect.com/Content/downloads/DAR2017062-Portrait-201708-PI.PDF. Last revised 08/2017. Last accessed 03/05/2019.

Current Prior Authorization Criteria

Daraprim® (Pyrimethamine) Approval Criteria:

1. An FDA approved indication for the treatment of toxoplasmosis; or
2. An FDA approved indication for the treatment of susceptible strains of acute malaria; and
3. Member must take Daraprim® concomitantly with a sulfonamide; and
4. Approval length will be based on recommended dosing regimen specific to the member's diagnosis.

Utilization of Daraprim® (Pyrimethamine): Fiscal Year 2018

Fiscal Year 2018 Utilization of Daraprim® (Pyrimethamine)

*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
1	1	$6,006.55	$6,006.55	1

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, there was no SoonerCare utilization of Daraprim® (pyrimethamine) during fiscal year 2017 (07/01/2016 to 06/30/2017).

Demographics of Members Utilizing Daraprim® (Pyrimethamine)

- Due to the limited number of members utilizing Daraprim® (pyrimethamine) during fiscal year 2018, detailed demographic information could not be provided.

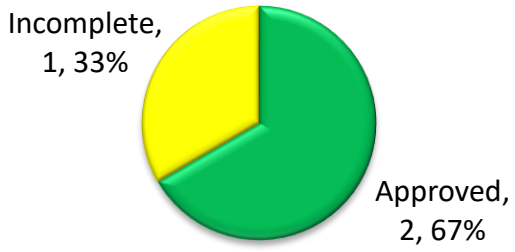
Top Prescriber Specialties of Daraprim® (Pyrimethamine) by Number of Claims

- The only prescriber specialty listed on paid claims for Daraprim® (pyrimethamine) during fiscal year 2018 was internist.

Prior Authorization of Daraprim® (Pyrimethamine)

There were 3 prior authorization requests submitted for 2 unique members for Daraprim® (pyrimethamine) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Recommendations

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

Fiscal Year 2018 Annual Review of Defitelio® (Defibrotide)

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

There were no paid claims for Defitelio® (defibrotide) during fiscal year 2018.

Prior Authorization of Defitelio® (Defibrotide): Fiscal Year 2018

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2018.

Market News and Updates

Anticipated Exclusivity Expiration(s):[43]

- 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.

[43] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2018. Last accessed 12/24/2018.

Fiscal Year 2018 Annual Review of Diabetic Supplies

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

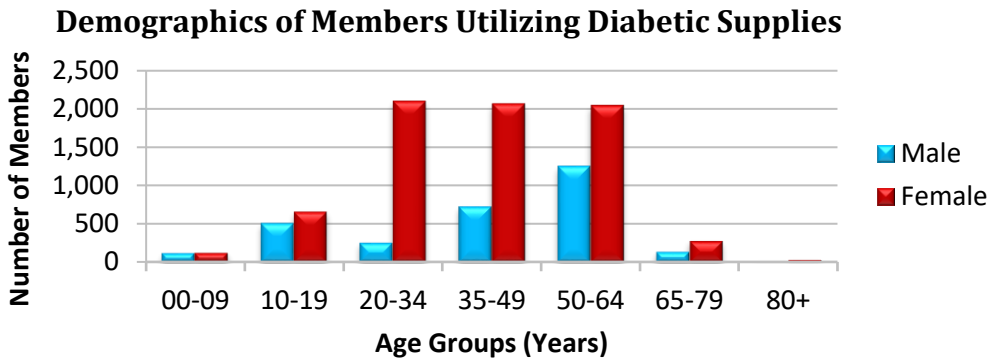
- The preferred brands for SoonerCare members are OneTouch®, FreeStyle™, and Precision™ test strips and meters. Other brands of test strips and glucometers are not covered.
- In addition to test strips and glucometers, lancets, syringes, pen needles, and control solution are also covered in the pharmacy claims system. Supplies for insulin pumps remain durable medical equipment (DME) claims.
- Glucometers are limited to 1 meter per member per year. Test strips are limited to 100 strips per 30 days for members using insulin and 100 strips per 100 days for members using oral medications. Members diagnosed with gestational diabetes are limited to 150 strips 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.
- Automated refills of diabetic supplies are not allowed. Refills should be ordered by the member or the member's representative.

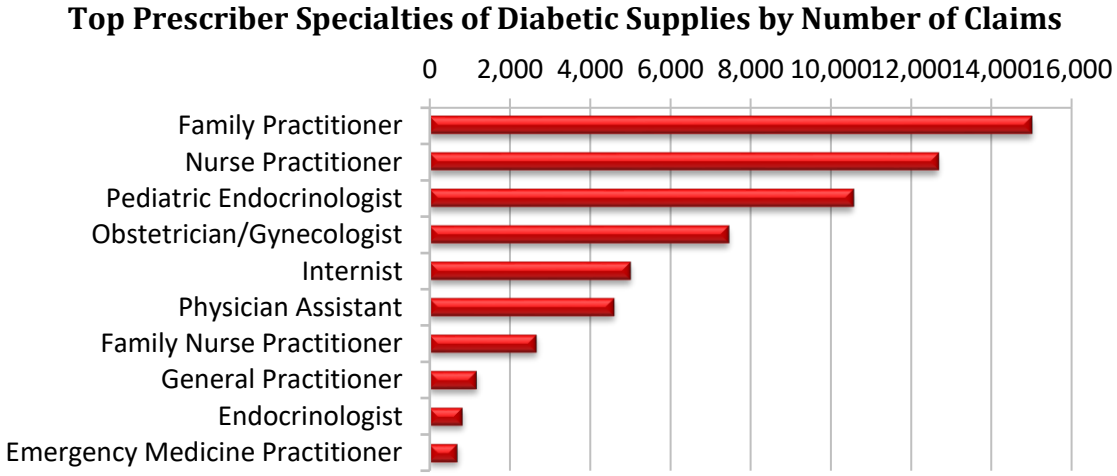
Utilization of Diabetic Supplies: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	10,276	61,745	$4,958,835.09	$80.31	$2.04	7,144,569	2,431,972
2018	10,276	63,242	$5,052,435.81	$79.89	$2.04	7,252,252	2,476,837
% Change	**0.00%**	**2.40%**	**1.90%**	**-0.50%**	**0.00%**	**1.50%**	**1.80%**
Change	**0**	**1,497**	**$93,600.72**	**-$0.42**	**$0.00**	**107,683**	**44,865**

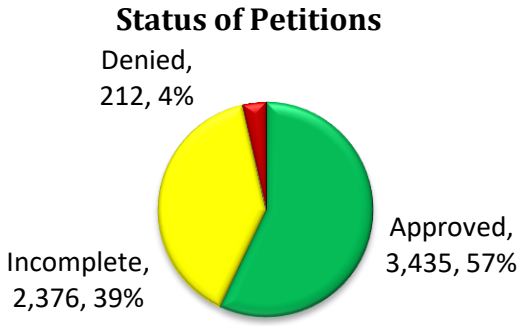
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Diabetic Supplies

There were 6,023 prior authorization requests submitted for 2,703 unique members for diabetic supplies during fiscal year 2018. 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 2018.



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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DIABETIC TEST STRIPS						
FREESTYLE TES LITE	13,007	4,209	$2,415,374.79	$185.70	3.1	47.81%
ONETOUCH TES ULTRA BL	10,394	3,419	$1,346,808.70	$129.58	3.0	26.66%
CONTOUR TES NEXT	1,913	441	$319,931.52	$167.24	4.3	6.33%
ONETOUCH TES VERIO	1,403	583	$151,426.50	$107.93	2.4	3.00%
FREESTYLE TES INSULINX	542	141	$122,420.85	$225.87	3.8	2.42%
FREESTYLE TES	458	188	$80,370.46	$175.48	2.4	1.59%
PRECISION TES XTRA	125	51	$16,771.72	$134.17	2.5	0.33%
EASYMAX TES	16	6	$492.40	$30.78	2.7	0.01%
PRODIGY NO TES CODING	13	8	$402.99	$31.00	1.6	0.01%
SUBTOTAL	**27,871**	**8,643***	**$4,453,999.93**	**$159.81**	**3.2**	**88.16%**
GLUCOMETERS						
FREESTYLE MIS LITE	1,963	1,923	$29,212.00	$14.88	1.0	0.58%
ONETOUCH KIT ULTRA 2	1,147	1,133	$16,849.67	$14.69	1.0	0.33%
ONETOUCH KIT ULT MINI	509	503	$7,511.05	$14.76	1.0	0.15%
FREESTYLE KIT FREEDOM	233	230	$3,457.00	$14.84	1.0	0.07%
ONETOUCH KIT VERIO	132	127	$1,923.75	$14.57	1.0	0.04%
ONETOUCH KIT VERIO FL	57	56	$838.93	$14.72	1.0	0.02%
PRECISION MIS XTRA	38	38	$570.00	$15.00	1.0	0.01%
ONETOUCH KIT VERIO IQ	21	21	$480.00	$22.86	1.0	0.01%
FREESTYLE KIT INSULINX	16	16	$608.00	$38.00	1.0	0.01%
PRODIGY AUTO KIT MONITOR	2	2	$15.90	$7.95	1.0	0.00%
SUBTOTAL	**4,118**	**3,992***	**$61,466.30**	**$14.93**	**1.0**	**1.22%**
GLUCOMETER CONTROL SOLUTION						
ONETOUCH SOL ULT CONT	15	14	$66.98	$4.47	1.1	0.00%
FREESTYLE LIQ CONTROL	6	6	$20.28	$3.38	1.0	0.00%
SUBTOTAL	**21**	**20***	**$87.26**	**$4.16**	**1.1**	**0.00%**
LANCETS AND LANCING DEVICES						
FREESTYLE MIS LANCETS	4,577	2,227	$8,221.24	$1.80	2.1	0.16%
ONETOUCH MIS LANCETS	2,238	1,116	$3,599.24	$1.61	2.0	0.07%
ONETOUCH MIS 30G	903	526	$1,330.33	$1.47	1.7	0.03%
EASY TOUCH MIS LANC/32G	456	261	$700.06	$1.54	1.7	0.01%
EASY TOUCH MIS LANC/30G	384	171	$579.70	$1.51	2.2	0.01%
TRUPLUS LANC MIS 33G	340	205	$512.86	$1.51	1.7	0.01%
ONETOUCH US MIS LANCETS	289	167	$479.82	$1.66	1.7	0.01%
TRUPLUS LANC MIS 30G	287	154	$433.10	$1.51	1.9	0.01%
MICROLET MIS LANCETS	238	119	$475.70	$2.00	2.0	0.01%
EASY TOUCH MIS LANC/33G	229	99	$345.06	$1.51	2.3	0.01%
TRUPLUS LANC MIS 28G	214	111	$354.97	$1.66	1.9	0.01%
EASY TOUCH MIS	180	174	$432.45	$2.40	1.0	0.01%
FASTCLIX MIS LANCETS	139	36	$289.85	$2.09	3.9	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SURE COMFORT MIS LANCETS	81	30	$171.82	$2.12	2.7	0.00%
BAYER MICRLT MIS LANCETS	68	36	$153.36	$2.26	1.9	0.00%
LANCET ULTRA MIS THIN 30G	47	26	$78.10	$1.66	1.8	0.00%
EMBRACE LANC MIS THIN 30G	39	18	$59.64	$1.53	2.2	0.00%
LANCETS ULTR MIS THIN	39	22	$56.80	$1.46	1.8	0.00%
EASY TOUCH MIS LANC/28G	34	17	$59.64	$1.75	2.0	0.00%
PRODIGY MIS 28G	32	15	$48.28	$1.51	2.1	0.00%
GLOBAL 30G MIS LANCETS	31	20	$45.44	$1.47	1.6	0.00%
LANCETS MIS 33G	30	12	$46.86	$1.56	2.5	0.00%
COMFORTOUCH MIS LANCET	28	10	$56.80	$2.03	2.8	0.00%
UNILET GP 28 MIS ULT THIN	28	15	$42.60	$1.52	1.9	0.00%
TRUPLUS LANC MIS 26G	25	20	$34.08	$1.36	1.3	0.00%
AQUALANCE MIS 30G	23	8	$32.66	$1.42	2.9	0.00%
GNP LANCETS MIS 21G	23	9	$46.86	$2.04	2.6	0.00%
LANCING DEVI MIS	20	20	$42.40	$2.12	1.0	0.00%
SURE COMFORT MIS LANC PEN	18	18	$38.16	$2.12	1.0	0.00%
THIN LANCETS MIS 30G	16	13	$24.14	$1.51	1.2	0.00%
TECHLITE MIS LANCETS	15	8	$24.14	$1.61	1.9	0.00%
LANCETS MIS 28G	14	12	$23.85	$1.70	1.2	0.00%
SOFTCLIX MIS LANCETS	13	11	$21.30	$1.64	1.2	0.00%
ONETOUCH MIS LANC DEV	13	13	$277.20	$21.32	1.0	0.01%
LANCETS MIS	11	7	$18.46	$1.68	1.6	0.00%
ACCU-CHEK MIS MLTICLIX	11	6	$26.10	$2.37	1.8	0.00%
EASY COMFORT MIS 30G	9	6	$12.78	$1.42	1.5	0.00%
LANCETS MIS 30G	8	4	$12.78	$1.60	2.0	0.00%
PRODIGY MIS LANC DEV	8	8	$16.96	$2.12	1.0	0.00%
BD LANCET UF MIS 30G	6	1	$17.04	$2.84	6.0	0.00%
ULTILET MIS 30G	6	2	$8.52	$1.42	3.0	0.00%
BD LANCET UF MIS 33G	6	4	$9.94	$1.66	1.5	0.00%
ULTRA THIN MIS LANC 30G	5	2	$7.10	$1.42	2.5	0.00%
STERILANCE MIS TL 30G	4	3	$5.68	$1.42	1.3	0.00%
ADV LANCING MIS DEVICE	4	4	$8.48	$2.12	1.0	0.00%
MICROLET MIS NEXT	3	3	$8.48	$2.83	1.0	0.00%
AUTOLET LANC MIS DEVICE	3	3	$6.36	$2.12	1.0	0.00%
LANCETS THIN MIS	3	2	$7.10	$2.37	1.5	0.00%
ULTRA THIN MIS 31G	3	2	$4.26	$1.42	1.5	0.00%
GNP LANCETS MIS THIN 26G	2	2	$2.84	$1.42	1.0	0.00%
RELION LANCE MIS THIN 30G	2	2	$2.84	$1.42	1.0	0.00%
UNILET EX II MIS 28G	2	2	$2.84	$1.42	1.0	0.00%
SOFT TOUCH MIS LANCETS	2	1	$2.84	$1.42	2.0	0.00%
RELION ULTRA MIS THIN PLS	2	2	$2.84	$1.42	1.0	0.00%
EASY MINI MIS EJECT	1	1	$2.12	$2.12	1.0	0.00%
ULTILET MIS 26G	1	1	$2.84	$2.84	1.0	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLOBAL 28G MIS LANCETS	1	1	$1.42	$1.42	1.0	0.00%
ADVOCATE MIS LANCETS	1	1	$1.42	$1.42	1.0	0.00%
SM LANCETS MIS THIN 30G	1	1	$1.42	$1.42	1.0	0.00%
LANCING MIS DEVICE	1	1	$2.12	$2.12	1.0	0.00%
SUBTOTAL	**11,217**	**5,185***	**$19,334.09**	**$1.72**	**2.2**	**0.38%**
		PEN NEEDLES				
BD PEN NEEDL MIS 32GX4MM	3,472	1,098	$131,725.86	$37.94	3.2	2.61%
BD PEN NEEDL MIS 31GX5MM	1,618	655	$49,705.57	$30.72	2.5	0.98%
BD PEN NEEDL MIS 31GX8MM	1,158	501	$33,916.01	$29.29	2.3	0.67%
PEN NEEDLES MIS 32GX4MM	580	206	$14,508.73	$25.02	2.8	0.29%
RELION PEN MIS 32GX4MM	485	211	$9,286.80	$19.15	2.3	0.18%
UNFINE PNTP MIS 32GX4MM	441	141	$7,442.51	$16.88	3.1	0.15%
PEN NEEDLES MIS 31GX8MM	395	114	$7,532.28	$19.07	3.5	0.15%
NOVOFINE MIS 32GX6MM	373	154	$13,308.00	$35.68	2.4	0.26%
PEN NEEDLES MIS 31GX6MM	357	129	$6,679.45	$18.71	2.8	0.13%
RELION PEN MIS 31GX6MM	345	135	$5,692.60	$16.50	2.6	0.11%
RELION PEN MIS 31GX8MM	345	138	$5,361.60	$15.54	2.5	0.11%
EASY TOUCH MIS 31GX3/16	310	117	$4,723.76	$15.24	2.6	0.09%
EASY TOUCH MIS 31GX5/16	253	100	$3,378.05	$13.35	2.5	0.07%
UNIFINE PNTP MIS 31GX8MM	233	91	$3,259.75	$13.99	2.6	0.06%
NOVOTWIST MIS 32GX5MM	219	62	$10,522.00	$48.05	3.5	0.21%
SURE COMFORT MIS 31GX3/16	216	87	$5,838.76	$27.03	2.5	0.12%
UNIFINE PNTP MIS 31GX3/16	206	76	$3,500.90	$16.99	2.7	0.07%
SURE COMFORT MIS 31GX5/16	202	73	$5,565.81	$27.55	2.8	0.11%
NOVOFINE PLS MIS 32GX4MM	195	88	$6,518.00	$33.43	2.2	0.13%
SURE COMFORT MIS 32GX5/32	182	73	$6,321.49	$34.73	2.5	0.13%
COMFORT EZ MIS 32GX4MM	176	53	$7,848.00	$44.59	3.3	0.16%
PEN NEEDLES MIS 31GX5MM	161	60	$5,540.77	$34.41	2.7	0.11%
COMFORT EZ MIS 31GX5MM	151	40	$5,486.00	$36.33	3.8	0.11%
BD PEN NEEDL MIS 29GX12.7	150	68	$4,025.08	$26.83	2.2	0.08%
UNIFINE PNTP MIS 31GX6MM	147	75	$2,181.02	$14.84	2.0	0.04%
EASY TOUCH MIS 31GX1/4"	143	43	$2,096.38	$14.66	3.3	0.04%
EASY TOUCH MIS 32GX5MM	124	41	$2,132.56	$17.20	3.0	0.04%
NOVOFINE MIS 30GX8MM	121	53	$3,398.00	$28.08	2.3	0.07%
EASY TOUCH MIS 32GX6MM	114	41	$2,197.52	$19.28	2.8	0.04%
EASY COMFORT MIS 31GX3/16	114	62	$3,852.95	$33.80	1.8	0.08%
PEN NEEDLES MIS 31GX5/16	109	44	$2,941.18	$26.98	2.5	0.06%
EASY COMFORT MIS 32GX5/32	101	54	$3,775.87	$37.38	1.9	0.07%
COMFORT EZ MIS 31GX8MM	93	22	$3,008.00	$32.34	4.2	0.06%
COMFORT EZ MIS 31GX6MM	71	27	$2,730.00	$38.45	2.6	0.05%
BD PEN NEEDL MIS 32GX6MM	68	41	$1,844.02	$27.12	1.7	0.04%
PEN NEEDLES MIS 31GX3/16	59	21	$1,775.48	$30.09	2.8	0.04%
EASY COMFORT MIS 31GX5/16	53	30	$1,366.00	$25.77	1.8	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EASY COMFORT MIS 31GX1/4"	47	26	$1,582.00	$33.66	1.8	0.03%
UNIFINE PNTP MIS 31GX5MM	46	11	$779.00	$16.93	4.2	0.02%
AUTOSHIELD MIS 30GX5MM	43	9	$1,794.00	$41.72	4.8	0.04%
RELION PEN MIS 29GX12MM	34	18	$518.00	$15.24	1.9	0.01%
INSUPEN ULTR MIS 31GX6MM	29	9	$653.10	$22.52	3.2	0.01%
UNIFINE PNTP MIS 32GX4MM	28	16	$629.90	$22.50	1.8	0.01%
UNIFINE PNTP MIS 29GX12MM	26	12	$389.20	$14.97	2.2	0.01%
CLICKFINE MIS 31GX1/4"	21	9	$474.97	$22.62	2.3	0.01%
PEN NEEDLES MIS 29GX12MM	21	6	$502.10	$23.91	3.5	0.01%
SURE COMFORT MIS 30GX5/16	18	7	$450.92	$25.05	2.6	0.01%
PEN NEEDLES MIS 31GX1/4"	17	5	$297.39	$17.49	3.4	0.01%
UNIFINE PNTP MIS 32GX5/32	16	8	$596.82	$37.30	2.0	0.01%
INSUPEN SENS MIS 32GX6MM	15	5	$468.00	$31.20	3.0	0.01%
UNIFINE PNTP MIS 31GX5/16	14	2	$402.32	$28.74	7.0	0.01%
EASY TOUCH MIS 32GX5/32	13	4	$271.83	$20.91	3.3	0.01%
PEN NEEDLES MIS 29GX12.7	10	1	$131.00	$13.10	10.0	0.00%
PEN NEEDLES MIS 29GX1/2"	9	4	$133.24	$14.80	2.3	0.00%
NOVOFINE AUT MIS 30GX8MM	9	3	$260.00	$28.89	3.0	0.01%
CLICKFINE MIS 31GX5/16	9	3	$210.00	$23.33	3.0	0.00%
SURE COMFORT MIS 32GX6MM	7	4	$204.00	$29.14	1.8	0.00%
COMFORT EZ MIS 32GX5MM	7	3	$364.00	$52.00	2.3	0.01%
SURE COMFORT MIS 29GX1/2"	7	5	$169.66	$24.24	1.4	0.00%
PEN NEEDLE MIS 29GX1/2"	4	2	$104.00	$26.00	2.0	0.00%
PENTIPS MIS 31GX5MM	4	2	$61.75	$15.44	2.0	0.00%
PRO COMFORT MIS 32GX6MM	4	1	$104.00	$26.00	4.0	0.00%
INSUPEN ULTR MIS 30GX8MM	2	2	$52.00	$26.00	1.0	0.00%
NOVOTWIST MIS 30GX8MM	2	1	$52.00	$26.00	2.0	0.00%
1ST TIER UNI MIS 29GX12MM	1	1	$25.00	$25.00	1.0	0.00%
INSUPEN ULTR MIS 31GX8MM	1	1	$19.50	$19.50	1.0	0.00%
PENTIPS MIS 32GX4MM	1	1	$12.35	$12.35	1.0	0.00%
EASY TOUCH MIS 29GX1/2"	1	1	$12.99	$12.99	1.0	0.00%
COMFORT EZ MIS 32GX6MM	1	1	$26.00	$26.00	1.0	0.00%
PEN NEEDLES MIS 33GX4MM	1	1	$26.00	$26.00	1.0	0.00%
PRO COMFORT MIS 32GX5MM	1	1	$52.00	$52.00	1.0	0.00%
COMFORT EZ MIS 29GX12MM	1	1	$26.00	$26.00	1.0	0.00%
SUBTOTAL	**14,010**	**4,196***	**$402,841.80**	**$28.75**	**3.3**	**7.97%**
INSULIN SYRINGES						
INSULIN SYRG MIS 1ML/31G	1,146	379	$24,843.73	$21.68	3.0	0.49%
INSULIN SYRG MIS 0.5/31G	989	354	$20,451.56	$20.68	2.8	0.40%
INSULIN SYRG MIS 0.3/31G	816	316	$17,842.91	$21.87	2.6	0.35%
INSULIN SYRG MIS 1ML/30G	246	84	$4,759.20	$19.35	2.9	0.09%
INSULIN SYRG MIS 0.3/31G	230	91	$6,435.82	$27.98	2.5	0.13%
INSULIN SYRG MIS 0.5/31G	213	91	$5,390.33	$25.31	2.3	0.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INSULIN SYRG MIS 1ML/31G	191	92	$4,146.12	$21.71	2.1	0.08%
INSULIN SYRG MIS 1ML/30G	179	68	$3,798.89	$21.22	2.6	0.08%
INSULIN SYRG MIS 0.5/30G	171	64	$3,128.67	$18.30	2.7	0.06%
INSULIN SYRG MIS 1ML/29G	157	73	$3,112.61	$19.83	2.2	0.06%
INSULIN SYRG MIS 0.5/30G	155	55	$3,621.20	$23.36	2.8	0.07%
INSULIN SYRG MIS 0.5/29G	134	61	$2,389.95	$17.84	2.2	0.05%
INSULIN SYRG MIS 0.3/30G	73	33	$1,639.46	$22.46	2.2	0.03%
INSULIN SYRG MIS 0.3/30G	49	25	$936.67	$19.12	2.0	0.02%
INSULIN SYRG MIS 0.3/29G	35	20	$660.83	$18.88	1.8	0.01%
INSULIN SYRG MIS 1ML/28G	10	6	$190.91	$19.09	1.7	0.00%
INSULIN SYRG MIS 0.5/28G	8	6	$191.95	$23.99	1.3	0.00%
BD U-500 MIS 31GX6MM	4	3	$116.64	$29.16	1.3	0.00%
INSULIN SYRG MIS 1ML/27G	3	1	$156.00	$52.00	3.0	0.00%
INSULIN SYRG MIS 28GX1/2"	1	1	$8.70	$8.70	1.0	0.00%
SUBTOTAL	**4,810**	**1,492***	**$103,822.15**	**$21.58**	**3.2**	**2.05%**
KETONE TEST STRIPS						
KETOSTIX TES STRIP	722	378	$7,051.83	$9.77	1.9	0.14%
KETOCARE TES	432	174	$3,455.49	$8.00	2.5	0.07%
KETONE TEST TES	32	19	$306.28	$9.57	1.7	0.01%
RELION TES KETONE	8	6	$58.90	$7.36	1.3	0.00%
RELION KETON TES	1	1	$11.78	$11.78	1.0	0.00%
SUBTOTAL	**1,195**	**528***	**$10,884.28**	**$9.11**	**2.3**	**0.22%**
TOTAL	**63,242**	**10,276***	**$5,052,435.81**	**$79.89**	**6.2**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Elaprase® (Idursulfase)

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	8	$511,580.96	$63,947.62	$2,283.84	492	224
2018	1	10	$752,704.70	$75,270.47	$2,688.23	720	280
% Change	**0.00%**	**25.00%**	**47.10%**	**17.70%**	**17.70%**	**46.30%**	**25.00%**
Change	**0**	**2**	**$241,123.74**	**$11,322.85**	**$404.39**	**228**	**56**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Elaprase® (Idursulfase)

- Due to the small number of members utilizing Elaprase® (idursulfase) during fiscal year 2018, 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 2018 was general pediatrician.

Market News and Updates

News:

- **December 2017:** Shire announced top-line results from its Phase 2/3 study evaluating SHP609, an investigational formulation of idursulfase administered intrathecally for a new potential indication for the treatment of pediatric patients with Hunter syndrome (mucopolysaccharidosis II or MPS II) and cognitive impairment. Elaprase® (idursulfase) is

approved by the U.S. Food and Drug Administration (FDA) for the treatment of Hunter syndrome and is administered intravenously; however, it does not cross the blood-brain barrier in clinically relevant amounts. Approximately 2 out of 3 patients with Hunter syndrome are also affected with progressive cognitive decline. SHP609 was specifically developed to be administered into the cerebrospinal fluid as a means of delivering the drug to the central nervous system. The primary endpoint of the clinical trial of SHP609 was the difference in cognition between the SHP609-treated and control groups, as measured by change from baseline in General Conceptual Ability (GCA) scores in children with Hunter syndrome after 12 months of treatment. The key secondary endpoint was the difference between the SHP609-treated and control groups as measured by the change from baseline in Adaptive Behavior Composite (ABC) score. The primary endpoint and key secondary endpoint were not met in the SHP609 study.[44]

Recommendations

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

[44] Shire Pharmaceuticals Group. Shire Announces Top-Line Results for Phase II/III Clinical Trial in Children with Hunter Syndrome and Cognitive Impairment. *Globe Newswire*. Available online at: https://globenewswire.com/news-release/2017/12/19/1266050/0/en/Shire-Announces-Top-Line-Results-for-Phase-II-III-Clinical-Trial-in-Children-with-Hunter-Syndrome-and-Cognitive-Impairment.html. Issued 12/19/2017. Last accessed 12/24/2018.

Fiscal Year 2018 Annual Review of Fibric Acid Derivative Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Fibric Acid Derivative Medications	
Tier-1	**Tier-2**
choline fenofibrate delayed-release (Trilipix® capsules) 45mg	choline fenofibrate delayed-release (Trilipix® capsules) 135mg
fenofibrate (Tricor® tablets)	fenofibrate (Fenoglide® tablets)
fenofibrate (Triglide® tablets)	fenofibrate (Lipofen® capsules)
fenofibrate micronized (Lofibra® capsules) 67mg, 134mg	fenofibrate micronized (Antara® capsules)
fenofibric acid (Fibricor® tablets) 35mg	fenofibrate micronized (Lofibra® capsules) 200mg
gemfibrozil (Lopid® tablets)	fenofibric acid (Fibricor® tablets) 105mg

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

Fibric Acid Derivative Tier-2 Approval Criteria:

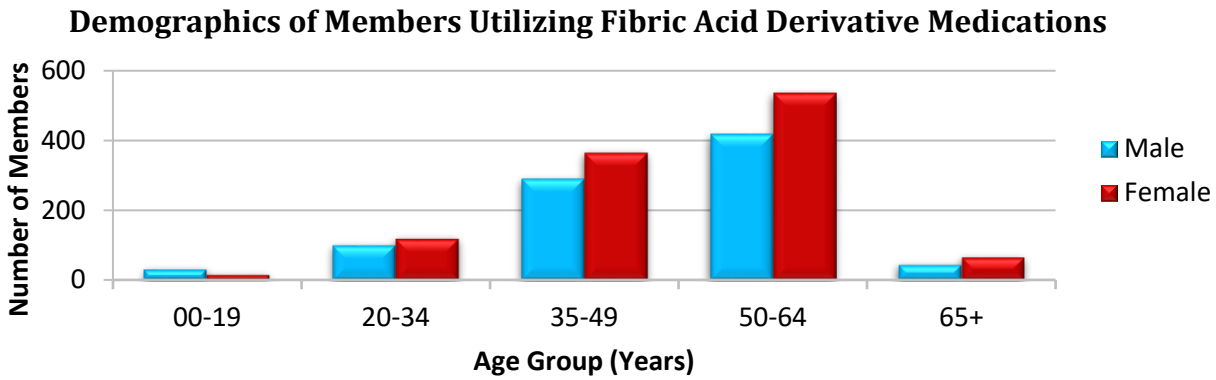
1. Laboratory documented failure with a Tier-1 medication after a 6-month trial; or
2. Documented adverse effect, drug interaction, or contraindication to all Tier-1 medication(s); or
3. Prior stabilization on the Tier-2 medication documented within the last 100 days.

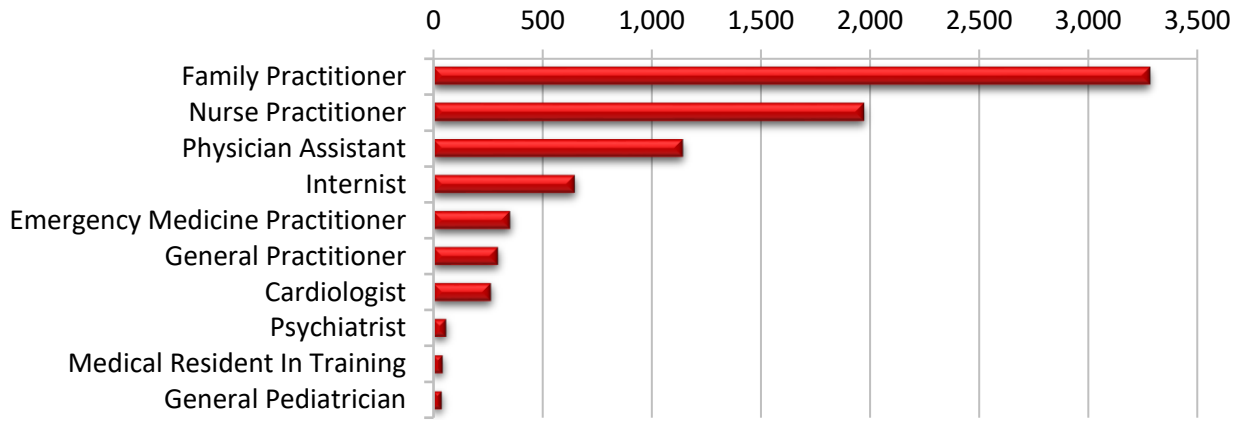
Utilization of Fibric Acid Derivative Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2,149	8,881	$323,698.67	$36.45	$0.89	457,520	365,679
2018	1,983	8,321	$250,382.78	$30.09	$0.71	440,163	353,178
% Change	**-7.70%**	**-6.30%**	**-22.60%**	**-17.40%**	**-20.20%**	**-3.80%**	**-3.40%**
Change	**-166**	**-560**	**-$73,315.89**	**-$6.36**	**-$0.18**	**-17,357**	**-12,501**

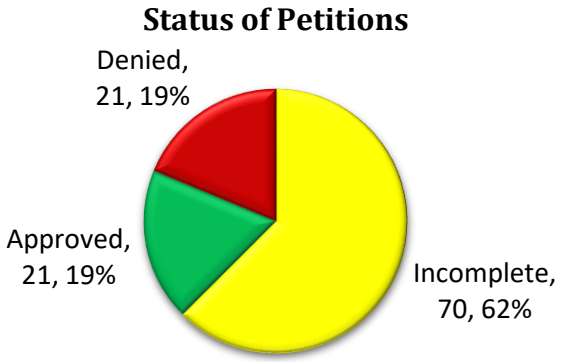
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Fibric Acid Derivative Medications

There were 112 prior authorization requests for fibric acid derivative medications during calendar year 2018. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Patent Expiration(s)[45]:

- Tricor® (fenofibrate): February 2020

[45] 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 01/2019. Last accessed 03/11/2019.

- Triglide® (fenofibrate): September 2021
- Fenoglide® (fenofibrate): December 2024
- Trilipix® (choline fenofibrate delayed-release): January 2025
- Antara® (micronized fenofibrate): April 2025
- Fibricor® (fenofibric acid): August 2027

Pipeline Update(s)[46]:

- **Pemafibrate:** The results from a multi-centered, randomized, double-blind, placebo/active drug-controlled, parallel group comparison Phase 3 trial comparing pemafibrate with fenofibrate was published in the *Journal of Atherosclerosis and Thrombosis*. The results from the study showed non-inferiority of pemafibrate 0.4mg/day and 0.2mg/day to fenofibrate 200mg/day as well as non-inferiority and superiority of pemafibrate to fenofibrate 100mg/day for reducing triglyceride levels. The incidence of adverse events for all pemafibrate doses was similar to fenofibrate 100mg/day.

Recommendations

The College of Pharmacy does not recommend any changes to the current fibric acid derivative medication criteria at this time.

Utilization Details of Fibric Acid Derivative Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 PRODUCTS					
GEMFIBROZIL TAB 600MG	2,823	680	$38,292.11	4.15	$13.56
FENOFIBRATE TAB 145MG	1,944	497	$59,171.02	3.91	$30.44
FENOFIBRATE TAB 160MG	1,280	309	$35,021.11	4.14	$27.36
FENOFIBRATE TAB 48MG	570	162	$13,720.91	3.52	$24.07
FENOFIBRATE TAB 54MG	367	95	$9,321.61	3.86	$25.40
FENOFIBRATE CAP 134MG	317	85	$15,132.40	3.73	$47.74
FENOFIBRIC CAP 45MG DR	178	33	$6,914.15	5.39	$38.84
FENOFIBRATE TAB 160	135	59	$4,500.78	2.29	$33.34
FENOFIBRATE CAP 67MG	47	10	$1,643.30	4.7	$34.96
FENOFIBRIC TAB 35MG	1	1	$80.89	1	$80.89
SUBTOTAL	**7,662**	**1,931**	**$183,798.28**	**3.97**	**$23.99**
TIER-2 PRODUCTS					
FENOFIBRIC CAP 135MG DR	517	122	$43,084.82	4.24	$83.34
FENOFIBRATE CAP 200MG	108	20	$7,761.51	5.4	$71.87
FENOFIBRATE CAP 150MG	14	5	$3,819.33	2.8	$272.81
FENOFIBRATE CAP 43MG	10	1	$474.06	10	$47.41
FENOFIBRATE TAB 120MG	6	3	$10,580.48	2	$1,763.41

[46] Arai H, Yamashita S, Yokote K, et al. Efficacy and Safety of Pemafibrate Versus Fenofibrate in Patients with High Triglyceride and Low HDL Cholesterol Levels: A Multicenter, Placebo-Controlled, Double-Blind, Randomized Trial. *J Atheroscler Thromb* 2018; 25(6):521-538.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
FENOFIBRATE TAB 40MG	3	2	$773.40	1.5	$257.80
FENOFIBRATE CAP 50MG	1	1	$90.90	1	$90.90
SUBTOTAL	**659**	**154**	**$66,584.50**	**4.28**	**$101.04**
TOTAL	**8,321**	**1,983***	**$250,382.78**	**4.20**	**$30.09**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Review

Current Prior Authorization Criteria

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

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.

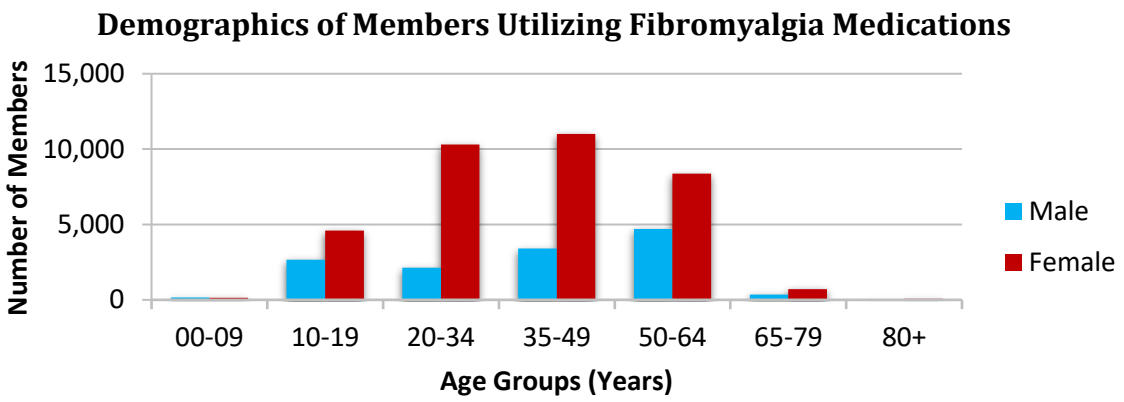
Utilization of Fibromyalgia Medications: Fiscal Year 2018

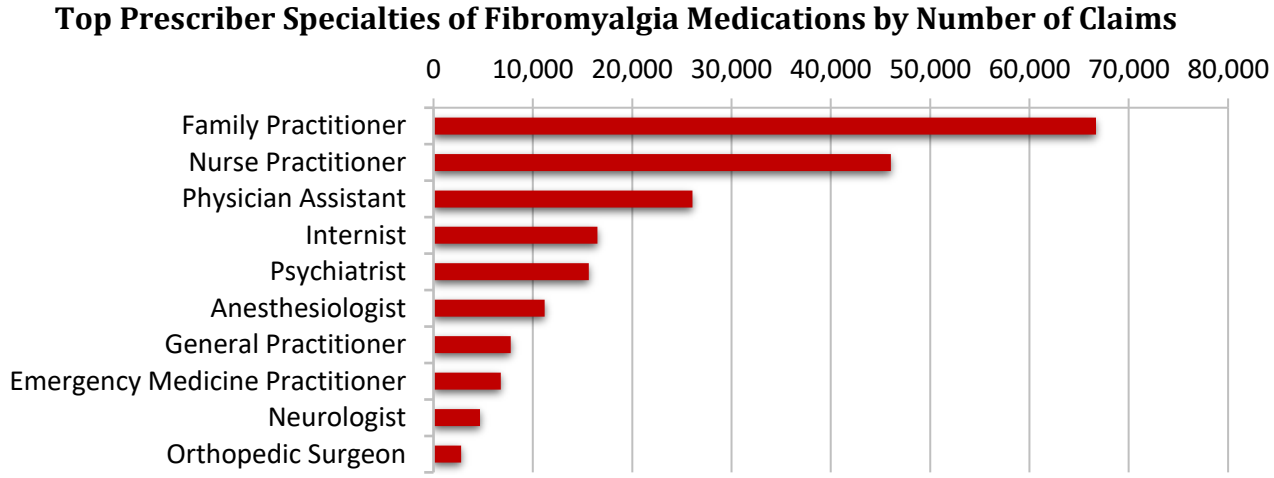
The following utilization data includes fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years for Fibromyalgia Medications

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	51,732	230,553	$7,212,512.96	$31.28	$1.11	17,211,620	6,499,473
2018	48,639	226,854	$7,318,380.12	$32.26	$1.12	17,143,586	6,554,978
% Change	**-6.00%**	**-1.60%**	**1.50%**	**3.10%**	**0.90%**	**-0.40%**	**0.90%**
Change	**-3,093**	**-3,699**	**$105,867.16**	**$0.98**	**$0.01**	**-68,034**	**55,505**

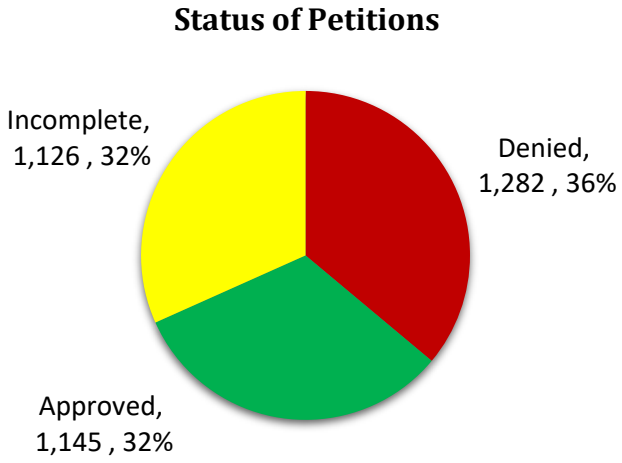
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Fibromyalgia Medications

There were 3,553 prior authorization requests submitted for fibromyalgia medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
GABAPENTIN PRODUCTS					
GABAPENTIN CAP 300MG	36,936	10,967	$462,538.64	$0.37	$12.52
GABAPENTIN TAB 600MG	24,281	5,048	$442,554.58	$0.59	$18.23
GABAPENTIN TAB 800MG	17,394	2,929	$368,106.10	$0.71	$21.16
GABAPENTIN CAP 100MG	9,468	3,661	$105,788.99	$0.37	$11.17
GABAPENTIN CAP 400MG	6,112	1,662	$86,955.41	$0.47	$14.23
GABAPENTIN SOL 250/5ML	642	123	$33,509.18	$1.77	$52.19
NEURONTIN CAP 300MG	11	1	$4,859.92	$14.73	$441.81
NEURONTIN TAB 800MG	11	1	$11,070.91	$33.55	$1,006.45
GABAPENTIN SOL 300/6ML	1	1	$110.54	$3.68	$110.54
SUBTOTAL	**94,856**	**24,393**	**$1,515,494.27**	**$0.51**	**$15.98**
TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 50MG	38,503	14,718	$381,718.37	$0.49	$9.91
SUBTOTAL	**38,503**	**14,718**	**$381,718.37**	**$0.49**	**$9.91**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR TAB 10MG	30,535	13,991	$276,463.80	$0.39	$9.05
CYCLOBENZAPR TAB 5MG	6,484	4,031	$63,540.40	$0.51	$9.80
SUBTOTAL	**37,019**	**18,022**	**$340,004.20**	**$0.40**	**$9.18**
DULOXETINE PRODUCTS					
DULOXETINE CAP 60MG	18,297	4,481	$339,422.48	$0.51	$18.55
DULOXETINE CAP 30MG	10,002	3,778	$191,540.28	$0.57	$19.15
DULOXETINE CAP 20MG	1,557	702	$32,074.00	$0.65	$20.60
CYMBALTA CAP 60MG	8	2	$3,048.02	$11.95	$381.00
DULOXETINE CAP 40MG	8	2	$1,486.52	$6.64	$185.82
SUBTOTAL	**29,872**	**8,965**	**$567,571.30**	**$0.54**	**$19.00**
AMITRIPTYLINE PRODUCTS					
AMITRIPTYLIN TAB 25MG	5,958	2,255	$85,013.21	$0.41	$14.27
AMITRIPTYLIN TAB 50MG	4,253	1,384	$93,467.24	$0.60	$21.98
AMITRIPTYLIN TAB 10MG	3,527	1,307	$45,307.42	$0.39	$12.85
AMITRIPTYLIN TAB 100MG	2,455	600	$92,846.29	$0.99	$37.82
AMITRIPTYLIN TAB 150MG	946	212	$60,734.74	$1.62	$64.20
AMITRIPTYLIN TAB 75MG	877	278	$28,464.71	$0.84	$32.46
SUBTOTAL	**18,016**	**6,036**	**$405,833.61**	**$0.63**	**$22.53**
PREGABALIN PRODUCTS					
LYRICA CAP 150MG	2,815	457	$1,405,698.66	$16.92	$499.36
LYRICA CAP 100MG	1,582	303	$841,459.41	$17.66	$531.90
LYRICA CAP 75MG	1,300	313	$596,220.19	$15.38	$458.63

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
LYRICA CAP 300MG	1,025	143	$429,390.33	$14.07	$418.92
LYRICA CAP 200MG	744	128	$323,279.14	$14.80	$434.51
LYRICA CAP 50MG	549	157	$281,389.34	$17.27	$512.55
LYRICA CAP 225MG	264	42	$125,215.13	$15.94	$474.30
LYRICA CAP 25MG	69	19	$31,502.54	$15.41	$456.56
LYRICA SOL 20MG/ML	3	2	$3,189.15	$34.66	$1,063.05
SUBTOTAL	**8,351**	**1,564**	**$4,037,343.89**	**$16.27**	**$483.46**
MILNACIPRAN PRODUCTS					
SAVELLA TAB 50MG	100	29	$29,192.82	$9.89	$291.93
SAVELLA TAB 100MG	87	17	$27,019.73	$10.41	$310.57
SAVELLA MIS TITR PAK	25	22	$7,070.28	$10.00	$282.81
SAVELLA TAB 25MG	23	13	$6,784.38	$10.58	$294.97
SAVELLA TAB 12.5MG	2	2	$347.27	$9.92	$173.64
SUBTOTAL	**237**	**83**	**$70,414.48**	**$10.16**	**$297.11**
TOTAL	**226,854**	**48,639***	**$7,318,380.12**	**$1.12**	**$32.26**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
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.

Fiscal Year 2018 Annual Review of Gattex® (Teduglutide)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Gattex® (Teduglutide) 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, and 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): Fiscal Year 2018

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	1	$37,024.06	$37,024.06	$1,234.14	1	30

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Gattex® (Teduglutide)

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

Top Prescriber Specialties of Gattex® (Teduglutide) by Number of Claims

- The only prescriber specialty listed on paid claims for Gattex® (teduglutide) during fiscal year 2018 was gastroenterologist.

Prior Authorization of Gattex® (Teduglutide)

There were 3 prior authorization requests submitted for Gattex® (teduglutide) during fiscal year 2018 for 1 member.

Market News and Updates

Anticipated Patent Expiration(s):[47]

- Gattex® (teduglutide): November 2025

News:

- **November 2018:** Shire announced the that U.S. Food and Drug Administration (FDA) has accepted for filing the supplemental New Drug Application (sNDA) to extend the indication of Gattex® (teduglutide) to pediatric patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support. Gattex® is indicated for the treatment of adult patients with SBS who are dependent on parenteral support. Shire submitted the sNDA to the FDA in September 2018 and the FDA is expected to reach a decision in March 2019.[48]

Recommendations

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

[47] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2018. Last accessed 12/24/2018.

[48] Shire Plc. U.S. FDA Accepts for Filing Shire's Supplemental New Drug Application for Gattex® (teduglutide [rDNA origin]) for Children with Short Bowel Syndrome. Globe Newswire. Available online at: https://globenewswire.com/news-release/2018/11/13/1650275/0/en/U-S-FDA-Accepts-for-Filing-Shire-s-Supplemental-New-Drug-Application-for-GATTEX-teduglutide-rDNA-origin-for-Children-with-Short-Bowel-Syndrome.html. Issued 11/13/2018. Last accessed 12/24/2018.

Fiscal Year 2018 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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.

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.

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 2018

Gaucher Disease Medications Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	5	48	$707,064.65	$14,730.51	$528.05	2,351	1,339
2018	5	48	$492,729.00	$10,265.19	$355.50	2,512	1,386
% Change	**0.00%**	**0.00%**	**-30.30%**	**-30.30%**	**-32.70%**	**6.80%**	**3.50%**
Change	**0**	**0**	**-$214,335.65**	**-$4,465.32**	**-$172.55**	**161**	**47**

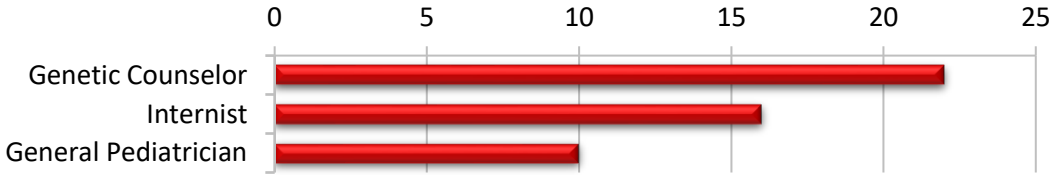
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- There were no pharmacy claims for Cerdelga® (eliglustat) or Elelyso® (taliglucerase alfa) during fiscal year 2018.
- There were no medical claims for Elelyso® (taliglucerase alfa) or Cerezyme® (imiglucerase) during fiscal year 2018. Details of medical claims for Vpriv® (velaglucerase alfa) during fiscal year 2018 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.

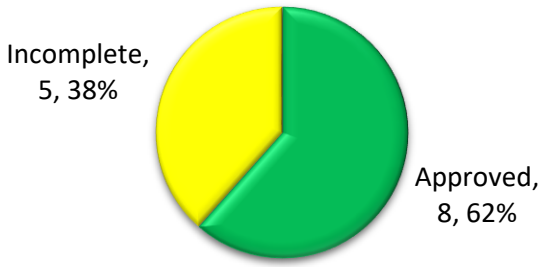
Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims



Prior Authorization of Gaucher Disease Medications

There were 13 prior authorization requests submitted for Gaucher disease medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Patent Expiration(s):[49]

- Cerezyme® (imiglucerase) and Vpriv® (velaglucerase alfa) are not available generically, but have no unexpired patents or exclusivities.
- Elelyso® (taliglucerase alfa): October 2025
- Cerdelga® (eliglustat): June 2026

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

- **April 2018:** Final approval was granted to an Abbreviated New Drug Application (ANDA) for miglustat 100mg capsules for the treatment of adult patients with mild-to-moderate Type 1 Gaucher disease (GD) for whom enzyme replacement therapy is not an option. This is the first ANDA to be approved as a generic equivalent to Actelion Pharmaceuticals' drug, Zavesca®.[50]

News:

- **July 2018:** A study published in *Nature Medicine* showed mice fetuses with GD who received a gene therapy injection were able to express the missing enzyme associated with GD. The animals treated with gene therapy lived for 4.5 months after birth compared to 15 days for untreated mice. The approach is still a long way from being testing in humans, but underscores the potential of using gene therapy to prevent and cure diseases in humans in utero.[51]

Pipeline:[52]

- **Lucerastat:** Lucerastat is a substrate reduction therapy being investigated for the treatment of GD. Safety, tolerability, and pharmacokinetics were investigated in 2 randomized, double-blind, placebo-controlled studies. No severe or serious adverse effects were observed.
- **Pharmacological Chaperone Therapy (PCT):** PCT, also known as enzyme enhancement therapy, uses chemicals to stabilize or reactivate misfolded GCase within cells. One of these agents is ambroxol, an over-the-counter expectorant used in many part of the world to treat a variety of airway infections. In laboratory studies, ambroxol was found to increase the enzymatic activity of various misfolded mutant forms of GCase in the endoplasmic reticulum. Ambroxol can cross the blood-brain barrier, therefore it is a promising option for Type 3 GD. High-dose amboxol in a study of 5 patients produced improvement in neuronological symptoms, including reduction of myoclonus seizures and pupillary light reflex dysfunction.

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[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/default.cfm?resetfields=1. Last revised 11/2018. Last accessed 12/26/2018.

[50] Shanley M. First Generic Version of Miglustat Approved by FDA. *Rare Disease Report*. Available online at: https://www.raredr.com/news/generic-miglustat-approved. Issued 04/23/2018. Last accessed 12/26/2018.

[51] Burik A. Deadly brain disease could be treated in the womb with gene therapy. *Genetic Literacy Project*. Available online at: https://geneticliteracyproject.org/2018/07/25/deadly-disease-could-be-treated-in-womb-with-gene-therapy/. Issued 07/25/2018. Last accessed 12/26/2018.

[52] Bennett L, Fellner C. Pharmacotherapy of Gaucher Disease: Current and Future Options. *P&T Community* 2018;43(5): 274-280, 309.

Recommendations

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

Utilization Details of Gaucher Disease Medications: Fiscal Year 2018

Fiscal Year 2018: Pharmacy Claims

Product Utilized	Total Claims	Total Members*	Total Cost	Cost/ Day	Cost/ Claim	% Cost
CEREZYME INJ 400UNIT	22	2	$368,760.10	$598.64	$16,761.82	74.84%
ZAVESCA CAP 100MG	21	2	$0.00	$0.00	$0.00	0.00%
VPRIV INJ 400UNIT	5	1	$123,968.90	$885.49	$24,793.78	25.16%
Total	**48**	**5**	**$492,729.00**	**$355.50**	**$10,265.19**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Claims included may contain claims for which SoonerCare is not the primary payer.

Fiscal Year 2018: Medical Claims

Product Utilized	J-code	Total Claims	Total Members	Total Cost	Cost/Claim
VPRIV INJ 400 UNIT	J3385	50	2	$411,954.72	$8,239.09
Total	**J3385**	**50**	**2***	**$411,954.72**	**$8,239.09**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Heart Failure Medications [Corlanor® (Ivabradine) and Entresto® (Sacubitril/Valsartan)]

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Corlanor® (Ivabradine) Approval Criteria:

1. An FDA approved diagnosis of symptomatic, stable, chronic worsening heart failure; and
2. The prescriber must verify that the member has left ventricular ejection fraction ≤35%; and
3. The prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute; and
4. The member must be on maximal/maximally tolerated doses of beta-blockers or have a contraindication to beta-blockers; and
5. A quantity limit of 60 tablets per 30 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.

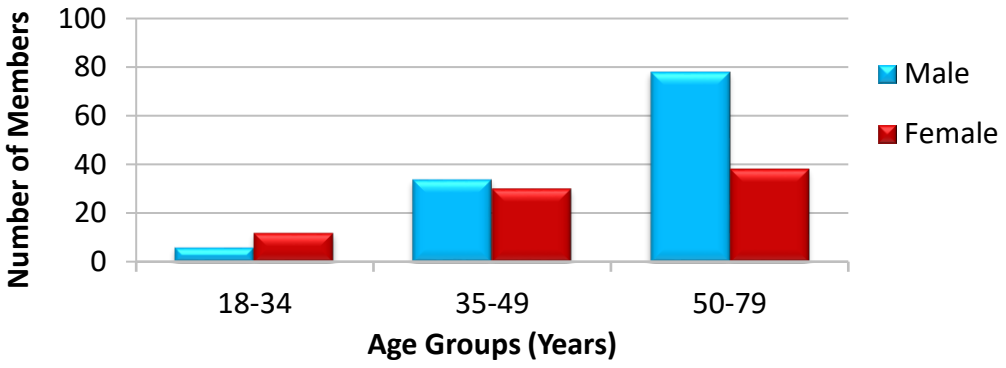
Utilization of Heart Failure Medications: Fiscal Year 2018

Comparison of Fiscal Years

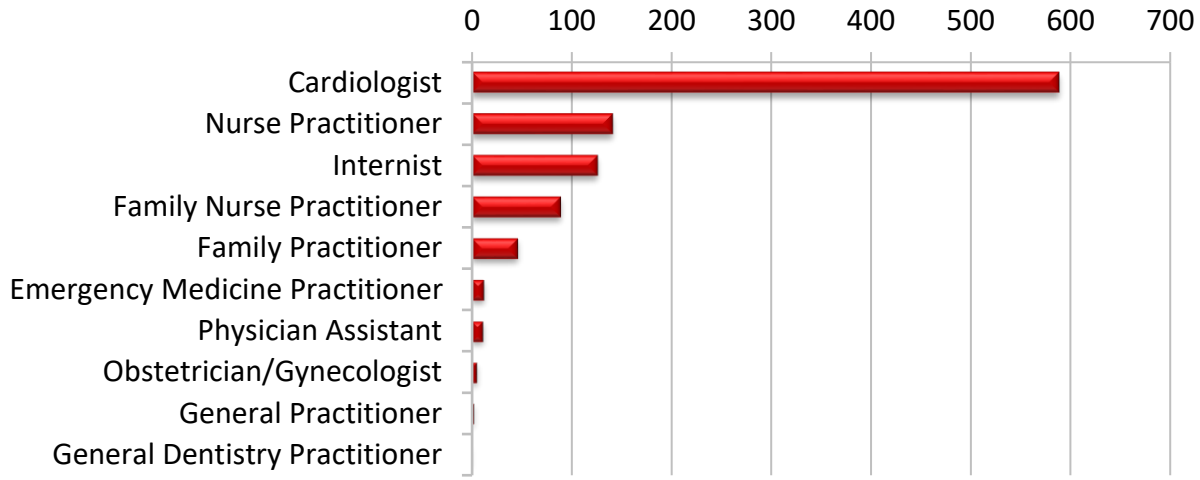
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	122	619	$250,867.21	$405.28	$13.54	36,850	18,532
2018	198	1,022	$439,609.18	$430.15	$14.39	60,948	30,554
% Change	**62.30%**	**65.10%**	**75.20%**	**6.10%**	**6.30%**	**65.40%**	**64.90%**
Change	**76**	**403**	**$188,741.97**	**$24.87**	**$0.85**	**24,098**	**12,022**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Heart Failure Medications



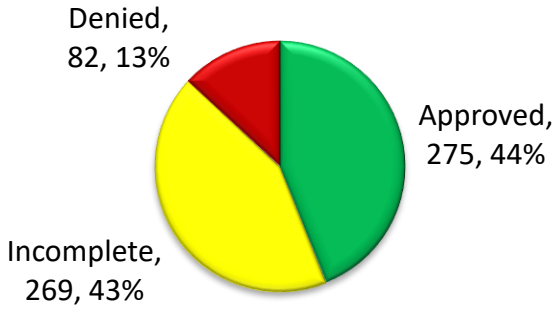
Top Prescriber Specialties of Heart Failure Medications by Number of Claims



Prior Authorization of Heart Failure Medications

There were 626 prior authorization requests submitted for 246 unique members for heart failure medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[53]

- Corlanor® (ivabradine): February 2026
- Entresto® (sacubitril/valsartan): May 2027

Pipeline:

- **Cimaglermin (GGF2):** According to a study published in the *Journal of the American College of Cardiology,* a single infusion of cimaglermin appears to result in a sustained improvement in left ventricular ejection fraction (LVEF) over a 90-day period at higher

[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 02/2019. Last accessed 03/21/2019.

doses. Neuregulin is an endogenous protein that is essential for cardiac repair; cimaglermin is recombinant neuregulin and is currently in early phase clinical trials.[54]

- **Serelaxin (RLX030):** Novartis announced that a Phase 3 study with serelaxin did not meet the primary endpoints of reduced cardiovascular (CV) death or worsening heart failure in patients with acute heart failure. Additionally, according to a systematic review and meta-analysis of serelaxin, compared with other heart failure treatments, serelaxin did not significantly decrease mortality, and had no remarkable improvement in dyspnea. erelaxin is a recombinant form of the naturally-occurring human relaxin-2 hormone, which has vasodilatory and end-organ protective effects. Human relaxin-2 is present in both men and women, and elevated levels in pregnant women are thought to help the body cope with the additional CV demands during pregnancy.[55,56]
- **Tafamidis:** In January 2018, Pfizer submitted 2 New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for tafamidis for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM). The 2 NDAs for tafamidis are based on 2 forms of tafamidis: meglumine salt and free acid. Tafamidis is the only product to complete a Phase 3 trial evaluating its efficacy, safety, and tolerability in patients with ATTR-CM, a rare, fatal, and underdiagnosed condition. The tafamidis meglumine form (20mg capsule) has been granted Priority Review and has a target Prescription Drug User Fee Act (PDUFA) action date of July 2019. The tafamidis free acid form (61mg capsule) will be under standard review; this form is bioequivalent to the 80mg tafamidis meglumine dose, which was administered as (4) 20mg capsules in the pivotal Phase 3 clinical trial. The tafamidis free acid form was developed for patient convenience to enable a single capsule for daily administration and has a target PDUFA action date of November 2019. Tafamidis is currently approved in Europe under brand name Vyndaqel®.[57]
- **RT-100:** Renova Therapeutics is currently developing RT-100 for the treatment of heart failure, a first-in-class, single-dose gene therapy candidate designed to safely improve heart function. It was discovered that adenylyl cyclase type 6 (AC6) was downregulated in the hearts of patients with heart failure; AC6 is a protein found in heart muscle cells that regulates heart function. The basis for RT-100 is a method of gene transfer designed to upregulate AC6 content in the heart. RT-100 is infused during cardiac catherization, directly into the arteries that feed the heart, and is aimed at improving overall heart function. Rather than slow progression or minimize symptoms of heart failure, it is thought that RT-100 has the potential to halt and reverse the heart failure-induced remodeling of the heart, enabling it to pump more efficiently. RT-100 has been granted

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[54] Lenihan DJ, Koren M, Eisen A, et al. Sustained Improvement of Left Ventricular Ejection Fraction with Intravenous Cimaglermin in Patients with Symptomatic Systolic Dysfunction. *J Am Coll Cardiol* 2018; 71(11 supp): A667. doi: 10.1016/S0735-1097(18)31208-7.

[55] Novartis News Release. Novartis Provides Update on Phase III Study of RLX030 (Serelaxin) in Patients with Acute Heart Failure. Available online at: https://www.novartis.com/news/media-releases/novartis-provides-update-phase-iii-study-rlx030-serelaxin-patients-acute-heart. Issued 03/22/2017. Last accessed 03/22/2019.

[56] Yu L, Cao L, Sun J, et al. Serelaxin, Recombinant Human Relaxin-2, for Heart Failure Patients: A Systematic Review and Meta-Analysis. *Medicine (Baltimore)* 2018; 97(25): e11010. doi: 10.1097/MD.0000000000011010.

[57] Pfizer News Release. U.S. FDA Accepts Regulatory Submissions for Review of Tafamidis to Treat Transthyretin Amyloid Cardiomyopathy. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/us_fda_accepts_regulatory_submissions_for_review_of_tafamidis_to_treat_transthyretin_amyloid_cardiomyopathy. Issued 01/14/2019. Last accessed 03/22/2019.

Fast Track designation by the FDA and is in late-stage clinical development, with a Phase 3 trial estimated to start in June 2019.[58]

- **Praliciguat (IW-1973):** Ironwood Pharmaceuticals is currently developing praliciguat for the treatment of heart failure with preserved ejection fraction (HFpEF) and was granted Fast Track designation by the FDA in September 2018. Praliciguat is an investigational, orally administered soluble guanylate cyclase (sGC) stimulator currently in Phase 2 clinical trials, with topline data expected in the second half of 2019.[59]

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24-26MG	429	102	$184,613.10	$430.33	4.2	41.99%
ENTRESTO TAB 97-103MG	260	49	$111,864.70	$430.25	5.3	25.45%
ENTRESTO TAB 49-51MG	231	62	$100,274.28	$434.09	3.7	22.81%
SUBTOTAL	**920**	**188***	**$396,752.08**	**$431.25**	**4.9**	**90.25%**
IVABRADINE PRODUCTS						
CORLANOR TAB 5MG	82	16	$34,451.76	$420.14	5.1	7.84%
CORLANOR TAB 7.5MG	20	5	$8,405.34	$420.27	4.0	1.91%
SUBTOTAL	**102**	**21***	**$42,857.10**	**$420.17**	**4.9**	**9.75%**
TOTAL	**1,022**	**198***	**$439,609.18**	**$430.15**	**5.2**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[58] Renova Therapeutics. Therapies: RT-100 (AC6 Gene Transfer). Available online at: https://renovatherapeutics.com/therapies/rt-100-congestive-heart-failure/. Last accessed 03/22/2019.
[59] Ironwood Pharmaceuticals News Release. Ironwood Pharmaceuticals Announces FDA Fast Track Designation for Praliciguat for the Treatment of Heart Failure with Preserved Ejection Fraction (HFpEF). Available online at: http://news.ironwoodpharma.com/news-releases/news-release-details/ironwood-pharmaceuticals-announces-fda-fast-track-designation. Issued 09/13/2018. Last accessed 03/22/2019.

Fiscal Year 2018 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Introduction[60,61,62]

Idiopathic pulmonary fibrosis (IPF) is a chronic, incurable lung condition that is characterized by varying degrees of fibrosis, collagen deposits, and distortion of the pulmonary architecture. Clinical manifestations of IPF include progressive symptoms of dyspnea, cough, and worsening pulmonary function. Over time, fibrosis of the lungs increases until the lungs can no longer provide enough oxygen to the body's organs and tissues. The prognosis of IPF is poor, with a median survival of approximately 3 years after diagnosis. It is estimated that IPF affects approximately 100,000 individuals in the United States, with 30,000 to 40,000 new cases being diagnosed each year. IPF is usually diagnosed in adults older than 50 years of age and is more common in men than in women.

Pharmacologic treatments for IPF are limited. The U.S. Food and Drug Administration (FDA) approved 2 products for the treatment of IPF, Ofev® (nintedanib) and Esbriet® (pirfenidone), in October 2014. Prior to the FDA approval of nintedanib and pirfenidone, no medications were approved for the treatment of IPF. Traditional approaches to treat IPF have included prednisone, azathioprine, and N-acetylcysteine, either alone or in combination; however, there is not adequate evidence to support the use of these medications. Treatment has predominantly been limited to supportive care (e.g., oxygen therapy, pulmonary rehabilitation), with lung transplantation as an option for selected patients.

Current Prior Authorization Criteria

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist; and
4. A quantity limit of 60 capsules per 30 days will apply.

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[60] U.S. National Library of Medicine: Genetics Home Reference. Idiopathic Pulmonary Fibrosis. Available online at: http://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis. Last revised 04/2015. Last accessed 03/11/2019.
[61] Raghu G, Mikacenic C. Pathogenesis of Idiopathic Pulmonary Fibrosis. *UpToDate®*. Available online at: http://www.uptodate.com/contents/pathogenesis-of-idiopathic-pulmonary-fibrosis?search=idiopathic+pulmonary+fibrosis&sectionRank=2&anchor=H26&source=machineLearning&selectedTitle=3%7E104#H26. Last revised 11/28/2018. Last accessed 03/11/2019.
[62] King TE. Treatment of Idiopathic Pulmonary Fibrosis. *UpToDate®*. Available online at: http://www.uptodate.com/contents/treatment-of-idiopathic-pulmonary-fibrosis?search=idiopathic+pulmonary+fibrosis&sectionRank=3&anchor=H48&source=machineLearning&selectedTitle=1%7E104#H48. Last revised 11/19/2018. Last accessed 03/11/2019.

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist; and
4. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 801mg strength tablets.

Utilization of IPF Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	4	13	$113,103.64	$8,700.28	$290.01	1,830	390
2018	1	5	$28,786.87	$5,757.37	$191.91	879	150
% Change	**-75.00%**	**-61.50%**	**-74.50%**	**-33.80%**	**-33.80%**	**-52.00%**	**-61.50%**
Change	**-3**	**-8**	**-$84,316.77**	**-$2,942.91**	**-$98.10**	**-951**	**-240**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing IPF Medications

- Due to the limited number of members utilizing IPF medications during fiscal year 2018, detailed demographic information could not be provided.

Top Prescriber Specialties of IPF Medications by Number of Claims

- The only prescriber specialties listed on paid claims for IPF medications during fiscal year 2018 was pulmonary disease specialist and internal medicine. Upon further research, all prior authorization requests for IPF medications during fiscal year 2018 were submitted by a pulmonary disease specialist.

Prior Authorization of IPF Medications

There were 6 prior authorization requests submitted for 1 unique member for IPF medications during fiscal year 2018.

Market News and Updates

Anticipated Patent Expiration(s):[63]

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

[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 01/2019. Last accessed 03/06/2019.

News:

- **August 2018:** Results of a 24-week, single-arm, open-label Phase 4 clinical study assessing the safety and tolerability of treatment with nintedanib added to pirfenidone in patients with IPF were published in the *European Respiratory Journal*. Before initiating nintedanib, patients had received pirfenidone for ≥16 weeks and tolerated a stable dose of ≥1,602mg/day for ≥28 days. The primary endpoint was the proportion of patients who completed treatment on pirfenidone (1,602 to 2,403mg/day) and nintedanib (200 to 300mg/day). Combined pirfenidone and nintedanib use for 24 weeks was tolerated by the majority of patients with IPF and associated with a similar pattern of treatment-emergent adverse effects expected for either treatment alone. These results encourage further study of combination treatment with pirfenidone and nintedanib in patients with IPF.[64]
- **September 2018:** Clinical practice guidelines for the diagnosis of IPF were released through a collaborative effort between the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and Latin American Thoracic Society. Previously defined patterns of usual interstitial pneumonia (UIP) were refined to patterns of UIP, probably UIP, indeterminate for UIP, and alternate diagnosis, and recommendations were made for patients with newly detected interstitial lung disease (ILD) based on their high-resolution computed tomography scan pattern. Additional recommendations included a conditional recommendation for multidisciplinary discussion and a strong recommendation against measurement of serum biomarkers for the sole purpose of distinguishing IPF from other ILDs.[65]
- **January 2019:** Treatment of IPF with pirfenidone increased 5-year survival and also resulted in less decline in lung function at 2 years, according to a real-world patient cohort study from the Czech Republic. The study compared 383 IPF patients that received pirfenidone to 218 IPF patients that received no antifibrotic treatment. The 2- and 5-year overall survival, forced vital capacity (FVC), and diffusing lung capacity for carbon monoxide (DL_{CO}) were investigated at treatment initiation and at 6, 12, 18, and 24 months' follow-up. During a 2-year follow-up, less than a quarter of the patients progressed on pirfenidone as assessed by the decline of ≥10% FVC (17%) and ≥15% DL_{CO} (14.3%). The DL_{CO} decline showed higher predictive value for mortality than FVC decline; DL_{CO} decline of ≥10% showed potential as a mortality predictor in IPF patients on pirfenidone and should be routinely evaluated during follow-up examinations. Pirfenidone increased 5-year overall survival over no antifibrotic treatment (55.9% vs. 31.5% alive, P=0.002).[66]

Pipeline:

- **Nintedanib:** The FDA granted Fast Track designation to nintedanib for the treatment of systemic sclerosis with associated ILD (SSc-ILD). Systemic sclerosis, also known as

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[64] Flaherty KR, Fell CD, Huggins JT, et al. Safety of Nintedanib Added to Pirfenidone Treatment for Idiopathic Pulmonary Fibrosis. *Eur Respir J* 2018; 52(2):1800230. doi:10.1183/13993003.00230-2018.

[65] Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. *Am J Respir Crit Care Med* 2018; 198(5):e44-e68. doi:10.1164/rccm.201807-1255ST.

[66] Zurkova M, Kriegova E, Kolek V, et al. Effect of Pirfenidone on Lung Function Decline and Survival: 5-yr Experience from a Real-Life IPF Cohort from the Czech EMPIRE Registry. *Respir Res* 2019; 20(1):16. doi:10.1186/s12931-019-0977-2.

scleroderma, is a rare disease characterized by the thickening and scarring of connective tissue of multiple organs in the body. Most people with systemic sclerosis develop some degree of lung scarring or ILD. Nintedanib is currently in Phase 3 clinical studies for the treatment of SSc-ILD.[67]

- **Nintedanib + Sildenafil:** A Phase 3 clinical study evaluating the safety and effectiveness of the combination treatment with nintedanib and sildenafil showed no added benefit in IPF patients with poor lung function. The study included 274 patients with IPF and a DL_{CO} ≤35% of the predicted value, and patients were randomly assigned to nintedanib plus sildenafil or nintedanib plus placebo for 24 weeks. No significant differences were seen between the combination therapy and nintedanib alone in terms of health-related quality of life at week 12 or week 24.[68]
- **PRM-151:** Promedior plans to begin Phase 3 testing of its investigational therapy, PRM-151, for the treatment of IPF. PRM-151 is an engineered form of pentraxin 2, an antifibrotic protein that can resolve fibrosis by blocking further inflammation; lower levels of pentraxin 2 in IPF patients are associated with increased fibrotic damage.[69]
- **PBI-4050:** Results from a Phase 2 study demonstrated the safety of PBI-4050, an oral, low-molecular weight 3-pentylbenzeneacetic acid sodium salt, alone or in combination with nintedanib or pirfenidone in patients with IPF. PBI-4050 was well tolerated and associated with no serious adverse events during the 12-week treatment period.[70]
- **PLN-74809:** The FDA granted Orphan Drug designation to PLN-74809 for the treatment of IPF. PLN-74809 works as a dual selective inhibitor of αVβ1 and αVβ6 integrins, which are specific to tissues implicated in fibrosis; by modulating these integrins, PLN-74809 aims to block the activation of transforming growth factor beta (TGF-β), preventing the growth of fibrotic tissues within organs. PLN-74809 is currently in Phase 1 studies.[71]
- **SM04646:** Samumed entered into an exclusive license agreement with United Therapeutics Corporation for North American rights to SM04646, which is being developed for the treatment of IPF. SM04646 is administered as a nebulized inhalation solution and is believed to exert its antifibrotic action by decreasing the expression of genes related to fibrosis development. SM04646 is currently in Phase 2 clinical studies.[72]

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[67] Boehringer Ingelheim News Release. FDA Grants Fast Track Designation to Nintedanib for the Treatment of Systemic Sclerosis with Associated Interstitial Lung Disease. Available online at: https://www.boehringer-ingelheim.us/press-release/fda-grants-fast-track-designation-nintedanib-treatment-systemic-sclerosis-associated. Issued 03/19/2018. Last accessed 03/12/2019.

[68] Pena A. Ofev®, Sildenafil Combo Shows No Added Benefit in IPF Patients with Poor Lung Function, Study Shows. *Pulmonary Fibrosis News.* Available online at: https://pulmonaryfibrosisnews.com/2018/10/03/ofev-sildenafil-combo-no-added-benefit-ipf-poor-lung-function/. Issued 10/03/2018. Last accessed 03/12/2019.

[69] Iyer V. Promedior's Experimental IPF Therapy PRM-151 to Enter Phase 3 Stage. *Pulmonary Fibrosis News.* Available online at: https://pulmonaryfibrosisnews.com/2019/01/08/prm-151-enter-phase-3-trials/. Issued 01/08/2019. Last accessed 03/12/2019.

[70] May B. New Idiopathic Pulmonary Fibrosis Treatment Safe, Likely Effective. *Pulmonary Advisor.* Available online at: https://www.pulmonologyadvisor.com/home/topics/restrictive-lung-disease/new-idiopathic-pulmonary-fibrosis-treatment-safe-likely-effective/. Issued 01/24/2019. Last accessed 03/12/2019.

[71] Pena A. FDA Names PLN-74809, Potential IPF Treatment, Orphan Drug to Speed Its Development. *Pulmonary Fibrosis News.* Available online at: https://pulmonaryfibrosisnews.com/2018/08/08/fda-names-pln-74809-by-pliant-orphan-drug-to-speed-development-as-ipf-treatment/. Issued 08/08/2018. Last accessed 03/12/2019.

[72] United Therapeutics Corporation News Release. Samumed and United Therapeutics Announce North American License Agreement for Samumed's IPF Drug Candidate. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/samumed-and-united-therapeutics-announce-north-american-license-agreement-for-samumeds-ipf-drug-candidate-300713382.html. Issued 09/17/2018. Last accessed 03/12/2019.

- **X-165:** The FDA approved X-Rx's Investigational New Drug (IND) application for it's IPF therapy candidate, X-165, to start Phase 1 clinical studies. X-165 is a highly potent, small molecule inhibitor of the enzyme autotaxin. Autotaxin is responsible for the production of lysophosphatidic acid, a lipid molecule that triggers the release of pro-inflammatory molecules; increased levels of autotaxin and lysophosphatidic acid have been reported in lung cells and bronchoalveolar lavage (BAL) of patients with IPF and in animal models of pulmonary fibrosis. By inhibiting the action of autotaxin, X-165 is expected to block the production of lysophosphatidic acid and restrict inflammation and tissue scarring.[73]

Recommendations

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

Utilization Details of IPF Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ESBRIET TAB 267MG	5	1	$28,786.87	$5,757.37	5
TOTAL	**5**	**1***	**$28,786.87**	**$5,757.37**	**5**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, there was no SoonerCare utilization of Ofev® (nintedanib) during fiscal year 2018.

[73] Pena A. FDA Clears Way for First Trials of IPF Treatment Candidate X-165. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2019/02/04/fda-clears-way-for-first-clinical-trials-x-165-ipf-treatment-x-rx/. Issued 02/04/2019. Last accessed 03/12/2019.

Fiscal Year 2018 Annual Review of Inhaled Short-Acting Beta$_2$ Agonists

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Tier-1 products are covered with no prior authorization necessary.

Inhaled Short-Acting Beta2 Agonists Tier-2 Approval Criteria:

1. A FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications.
3. Approval of generic levalbuterol HFA or the generic formulation of ProAir® HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

Inhaled Short-Acting Beta$_2$ Agonists	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA) brand formulation	albuterol HFA (ProAir® HFA) generic formulation
albuterol HFA (Proventil® HFA)	albuterol sulfate (ProAir® Respiclick®)¥
albuterol HFA (Ventolin® HFA)	levalbuterol HFA (Xopenex® HFA) generic formulation
levalbuterol HFA (Xopenex® HFA) brand formulation	

¥ FDA approved for ages 12 and older.
Tier structure based on supplemental rebate participation ,and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC is unavailable.

Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:

1. A patient-specific, clinically significant reason why the member is unable to use long-acting bronchodilators and/or inhaled corticosteroids (ICS) therapy for long-term control as recommended in the National Asthma Education and Prevention Program (NAEPP) guidelines; and
2. A patient-specific, clinically significant reason why the member cannot use an albuterol metered-dose inhaler (MDI).
3. Clinical exceptions will be made for clients with chronic obstructive pulmonary disease (COPD).
4. A quantity limit of 288mL per 30 days will apply.

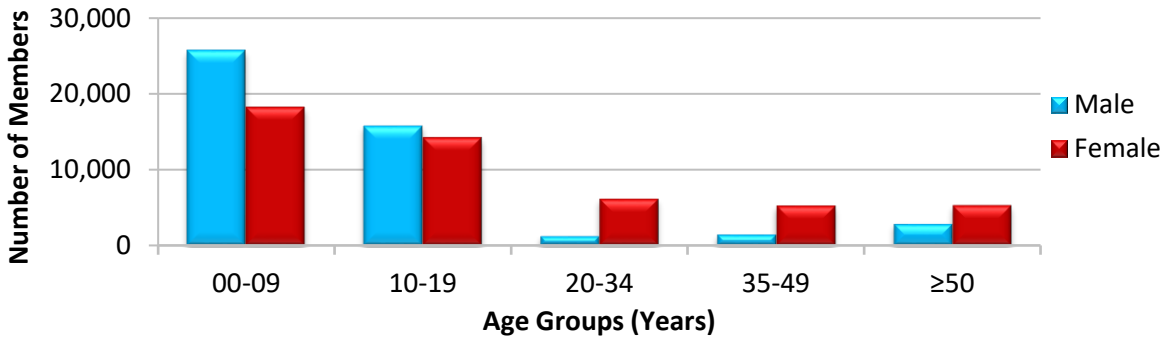
Utilization of Inhaled Short-Acting Beta$_2$ Agonists: Fiscal Year 2018

Comparison of Fiscal Years

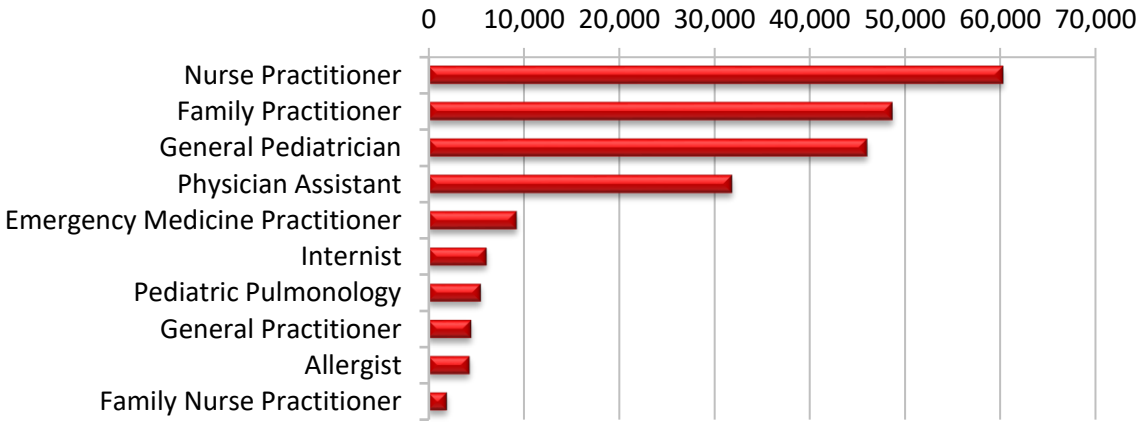
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	97,540	230,365	$14,229,443.49	$61.77	$2.91	11,477,182	4,896,488
2018	95,816	228,287	$15,077,181.83	$66.04	$3.11	10,907,656	4,848,808
% Change	**-1.80%**	**-0.90%**	**6.00%**	**6.90%**	**6.90%**	**-5.00%**	**-1.00%**
Change	**-1,724**	**-2,078**	**$847,738.34**	**$4.27**	**$0.20**	**-569,526**	**-47,680**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Inhaled Short-Acting Beta$_2$ Agonists

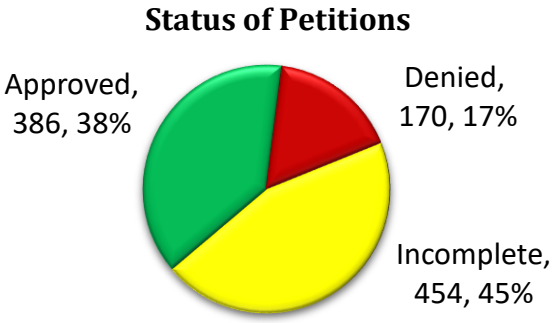


Top Prescriber Specialties of Inhaled Short-Acting Beta$_2$ Agonists by Number of Claims



Prior Authorization of Inhaled Short-Acting Beta$_2$ Agonists

There were 1,010 prior authorization requests submitted for inhaled short-acting beta$_2$ agonists during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Patent Expiration(s):[74]

- Xopenex® (levalbuterol HFA): October 2024, however, authorized generics are currently available as of October 2016.[75]
- Ventolin® (albuterol HFA): August 2026
- ProAir Respiclick® (albuterol sulfate inhalation powder): January 2032

Over-The-Counter (OTC) Approval(s):

- **November 2018:** Primatene® MIST (epinephrine inhalation aerosol) was approved by the U.S. Food and Drug Administration (FDA) to provide temporary relief of symptoms of mild, intermittent asthma. This OTC drug is approved only for those who have been diagnosed with asthma by a health care provider. The former OTC Primatene® MIST was taken off the market in 2011 because it contained chlorofluorocarbon (CFC) propellants, which are known to deplete the ozone layer. This new version contains hydrofluoroalkane (HFA) propellants, which are permitted under current law. Primatene® MIST is not a covered SoonerCare product.[76]

New(s):

- **May 2018:** Perrigo Company announced that it expects to receive a Complete Response Letter (CRL) from the FDA regarding its Abbreviated New Drug Application (ANDA) for its generic version of ProAir® (albuterol sulfate) Inhalation Aerosol. The FDA issues a CRL to indicate that the review cycle for an ANDA is complete and that the application is not ready for approval. Upon receipt of the CRL, the Perrrigo will evaluate the FDA's comments and how to best address them.[77]

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[74] 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 12/2018. Last accessed 01/23/2019.

[75] Xopenex HFA® (Levalbuterol Tartrate) First Time Generic. OptumRX®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_xopenexhfa_2016-1003.pdf. Issued 2016. Last accessed 01/28/2019.

[76] Gottlieb S, Woodcock J. Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Wookcock, M.D., Director of the Center for Drug Evaluation and Research, on Approval of OTC Primatene® MIST to Treat Mild Asthma. Available online at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625338.htm. Issued 11/08/2018. Last accessed 01/28/2019.

[77] Perrigo Company. Perrigo Expects Complete Response Letter On Generic Version of ProAir®. Available online at: https://www.prnewswire.com/news-releases/perrigo-expects-complete-response-letter-on-generic-version-of-proair-300647185.html. Issued 05/11/2018. Last accessed 01/28/2019.

Recommendations

The College of Pharmacy does not recommend any changes to the current inhaled short-acting beta$_2$ agonists' prior authorization criteria at this time.

Utilization Details of Inhaled Short-Acting Beta$_2$ Agonists: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
PROAIR HFA AER	150,444	68,496	$11,782,425.28	$3.26	$78.32	78.15%
PROVENTIL AER HFA	15,373	8,247	$1,590,271.53	$4.13	$103.45	10.55%
XOPENEX HFA AER	308	147	$26,169.94	$3.17	$84.97	0.17%
SUBTOTAL	**166,125**	**76,890**	**$13,398,866.75**	**$3.35**	**$174.26**	**88.87%**
TIER-2 PRODUCTS						
VENTOLIN HFA AER	162	23	$12,916.07	$3.04	$79.73	0.09%
PROAIR RESPI AER	17	6	$1,170.51	$2.85	$68.85	0.01%
SUBTOTAL	**179**	**29**	**$14,086.58**	**$3.03**	**$78.70**	**0.10%**
NEBULIZER SOLUTION PRODUCTS						
ALBUTEROL NEB 0.083%	38,764	23,475	$615,588.89	$1.12	$15.88	4.08%
ALBUTEROL NEB 1.25MG/3ML	12,010	8,752	$486,678.51	$3.53	$40.52	3.23%
ALBUTEROL NEB 0.63MG/3ML	7,960	5,814	$342,303.75	$3.63	$43.00	2.27%
LEVALBUTEROL NEB 0.63MG	1,468	889	$101,995.40	$4.07	$69.48	0.68%
LEVALBUTEROL NEB 1.25MG	741	378	$51,288.43	$3.83	$69.22	0.34%
LEVALBUTEROL NEB 0.31MG	471	359	$31,495.01	$4.28	$66.87	0.21%
ALBUTEROL NEB 0.5%	377	241	$10,790.85	$1.50	$28.62	0.07%
LEVALBUTEROL AER 45MCG/ACT	168	73	$12,612.80	$2.92	$75.08	0.08%
LEVALBUTEROL NEB 1.25MG/0.5ML	14	7	$4,591.32	$19.96	$327.95	0.03%
XOPENEX NEB 1.25MG/3ML	10	1	$6,883.54	$27.53	$688.35	0.05%
SUBTOTAL	**61,983**	**39,989**	**$1,664,228.50**	**$1.98**	**$26.85**	**11.04%**
TOTAL	**228,287**	**95,816***	**$15,077,181.83**	**$3.11**	$66.04	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Insomnia Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	suvorexant (Belsomra®)	doxepin (Silenor®)
eszopiclone (Lunesta®)			tasimelteon (Hetlioz®)+
flurazepam (Dalmane®)			temazepam (Restoril®) 7.5mg and 22.5mg
ramelteon (Rozerem®)			zolpidem SL tablets (Edluar®)
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Intermezzo®)
triazolam (Halcion®)			zolpidem oral spray (Zolpimist®)
zaleplon (Sonata®)			
zolpidem (Ambien®)			

CR = controlled release; SL = sublingual
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Unique dosage formulations require a special reason for use in place of Tier-1 formulations.
+Individual criteria specific to tasimelteon.

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

Insomnia Medications Tier-2 Approval Criteria:

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

Insomnia Medications Tier-3 Approval Criteria:

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

Hetlioz® (Tasimelteon) Approval Criteria:

1. An FDA approved diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24); and
2. Member must be 18 years of age or older; and
3. Member must be totally blind; and
4. A failed trial of appropriately timed doses of melatonin; and
5. A failed trial of Rozerem® (ramelteon); and
6. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.
7. A quantity limit of 30 capsules for 30 days will apply.

Utilization of Insomnia Medications: Fiscal Year 2018

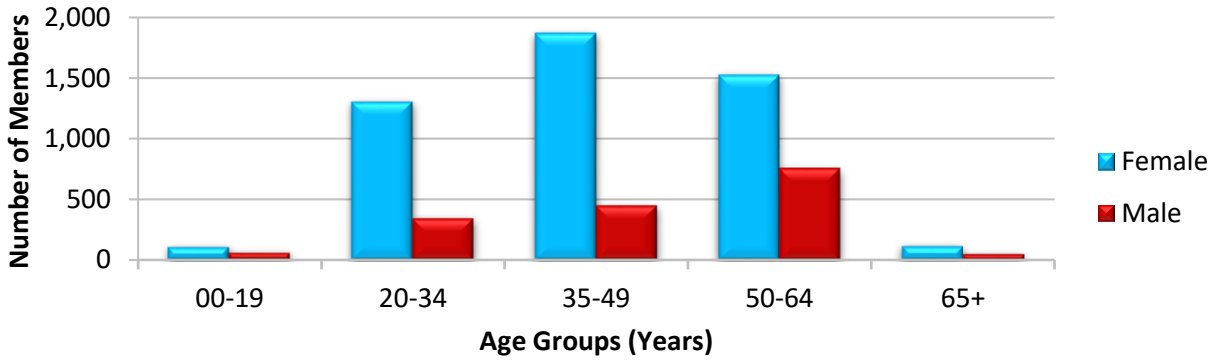
Comparison of Fiscal Years

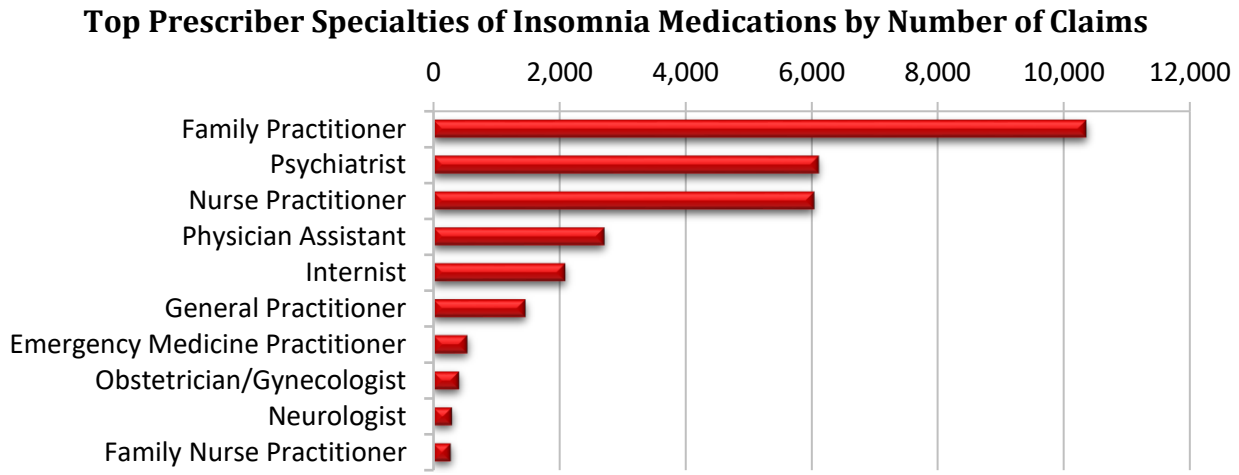
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	7,758	37,258	$587,178.66	$15.76	$0.54	1,091,163	1,089,237
2018	6,593	31,787	$886,512.93	$27.89	$0.95	931,901	928,841
% Change	**-15.00%**	**-14.70%**	**51.00%**	**77.00%**	**75.90%**	**-14.60%**	**-14.70%**
Change	**-1,165**	**-5,471**	**$299,334.27**	**$12.13**	**$0.41**	**-159,262**	**-160,396**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

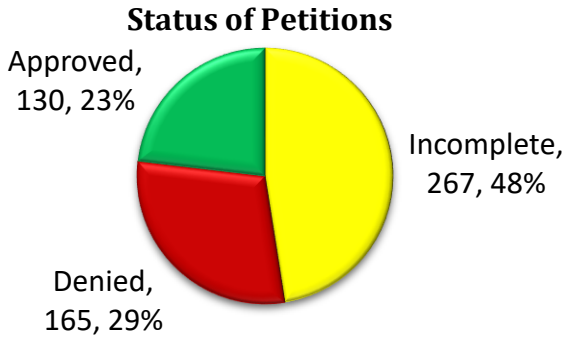
Demographics of Members Utilizing Insomnia Medications





Prior Authorization of Insomnia Medications

There were 562 prior authorization requests submitted for insomnia medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s)[78]:

- Rozerem® (ramelteon tablets): November 2021
- Edluar® (zolpidem sublingual tablets): April 2027
- Silenor® (doxepin tablets): June 2029
- Intermezzo® (zolpidem sublingual tablets): August 2029
- Zolpimist® (zolpidem oral spray): August 2032
- Belsomra® (suvorexant tablets): May 2033
- Hetlioz® (tasimelteon capsules): February 2035

News:

- **July 2018:** A study presented at the Alzheimer's Association International Conference (AAIC) 2018 found that hypnotic Z drugs increase overall fracture risk by 40% and hip fracture risk by 59% in patients with dementia.[79]

[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/. Last revised 02/2019. Last accessed 03/13/2019.

Pipeline Update(s):

- **December 2018:** The U.S. Food and Drug Administration (FDA) extended the review period for the New Drug Application (NDA) submitted by Jazz Pharmaceuticals for solriamfetol, a treatment to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA). The FDA determined that an NDA submission made by Jazz during the course of discussions regarding draft labeling for solriamfetol constitutes a major amendment to the NDA, resulting in a 3-month extension of the Prescription Drug User Fee Act (PDUFA) goal date to provide time for a full review of the submission.[80]
- **March 2019:** The U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for lemborexant, an orexin receptor antagonist being studied for the treatment of insomnia. Eisai and Purdue Pharma are jointly developing lemborexant. The NDA was based on the data from 2 Phase 2 studies, Sunrise 1 and Sunrise 2.[81]

Recommendations

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

Utilization Details of Insomnia Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
ZOLPIDEM TAB 10MG	16,031	3,266	$147,960.02	4.91	$9.23
TEMAZEPAM CAP 30MG	3,859	828	$40,770.14	4.66	$10.56
ZOLPIDEM TAB 5MG	3,476	1,230	$33,300.00	2.83	$9.58
TEMAZEPAM CAP 15MG	2,404	757	$25,680.87	3.18	$10.68
ESZOPICLONE TAB 3MG	1,734	400	$27,991.68	4.34	$16.14
TRIAZOLAM TAB 0.25MG	684	331	$23,743.89	2.07	$34.71
ESZOPICLONE TAB 2MG	663	220	$11,047.90	3.01	$16.66
ZALEPLON CAP 10MG	500	135	$8,348.14	3.7	$16.70
ROZEREM TAB 8MG	423	148	$146,430.57	2.86	$346.17
ESZOPICLONE TAB 1MG	243	117	$5,065.24	2.08	$20.84
FLURAZEPAM CAP 30MG	100	17	$2,323.66	5.88	$23.24

[79] Anderson, P. 'Z' Drugs Significantly Boost Fracture Risk in Dementia Patients. *Medscape*. Available online at: https://www.medscape.com/viewarticle/899792. Issued 07/25/2018. Last accessed 03/13/2019.

[80] Jazz Pharmaceuticals PLC. Jazz Pharmaceuticals Receives New PDUFA Goal Date for Solriamfetol for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea. PRNewswire. Available online at: https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-receives-new-pdufa-goal-date-for-solriamfetol-for-excessive-daytime-sleepiness-associated-with-narcolepsy-or-obstructive-sleep-apnea-300770117.html. Issued 12/21/2018. Last accessed 03/13/2019.

[81] Eisai Inc. Eisai and Imbrium Therapeutics Announce U.S. FDA Filing Acceptance of New Drug Application for Lemborexant for the Treatment of Insomnia. PRNewswire. Available online at: https://www.prnewswire.com/news-releases/eisai-and-imbrium-therapeutics-announce-us-fda-filing-acceptance-of-new-drug-application-for-lemborexant-for-the-treatment-of-insomnia-300809862.html. Issued 03/11/2019. Last accessed 03/13/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ZALEPLON CAP 5MG	93	47	$1,490.07	1.98	$16.02
FLURAZEPAM CAP 15MG	29	8	$511.40	3.63	$17.63
ESTAZOLAM TAB 2MG	26	9	$616.75	2.89	$23.72
ESTAZOLAM TAB 1MG	22	4	$518.90	5.5	$23.59
TRIAZOLAM TAB 0.125MG	18	12	$603.39	1.5	$33.52
TIER-1 SUBTOTAL	**30,305**	**7,529**	**$476,402.62**	**4.03**	**$15.72**
TIER-2 UTILIZATION					
ZOLPIDEM ER TAB 12.5MG	1,226	214	$37,331.96	5.73	$30.45
ZOLPIDEM ER TAB 6.25MG	120	36	$4,229.86	3.33	$35.25
AMBIEN CR TAB 12.5MG	19	2	$9,301.58	9.5	$489.56
TIER-2 SUBTOTAL	**1,365**	**252**	**$50,863.40**	**5.42**	**$37.26**
TIER-3 UTILIZATION					
BELSOMRA TAB 20MG	32	10	$9,830.01	3.2	$307.19
BELSOMRA TAB 10MG	24	10	$7,560.44	2.4	$315.02
BELSOMRA TAB 15MG	15	4	$4,632.83	3.75	$308.86
TIER-3 SUBTOTAL	**71**	**24**	**$22,023.28**	**2.96**	**$310.19**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
HETLIOZ CAP 20MG	24	3	$334,671.74	8	$13,944.66
TEMAZEPAM CAP 7.5MG	18	5	$1,597.49	3.6	$88.75
ZOLPIDEM TAR SUB 3.5MG	4	1	$954.40	4	$238.60
SPECIAL PA SUBTOTAL	**46**	**9**	**$337,223.63**	**5.11**	**$7,330.95**
TOTAL	**31,787**	**6,593***	**$886,512.93**	**4.82**	**$28.89**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2018 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.

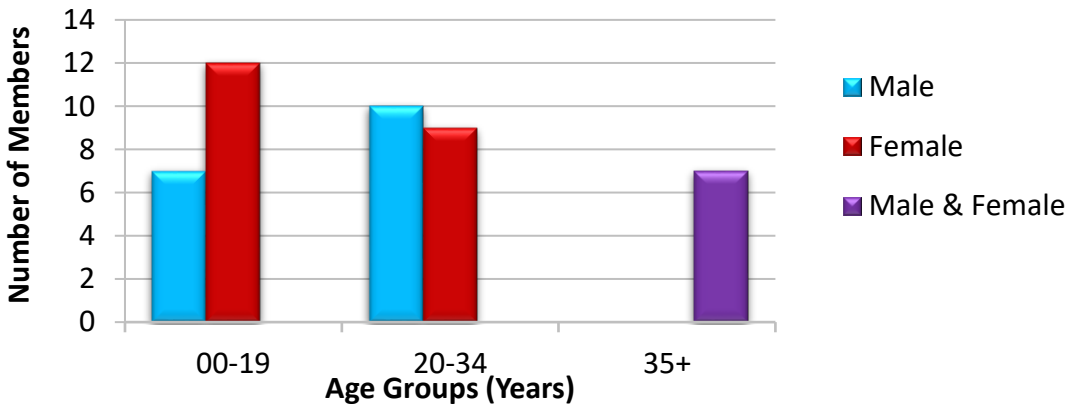
Utilization of Iron Chelating Agents: Fiscal Year 2018

Comparison of Fiscal Years

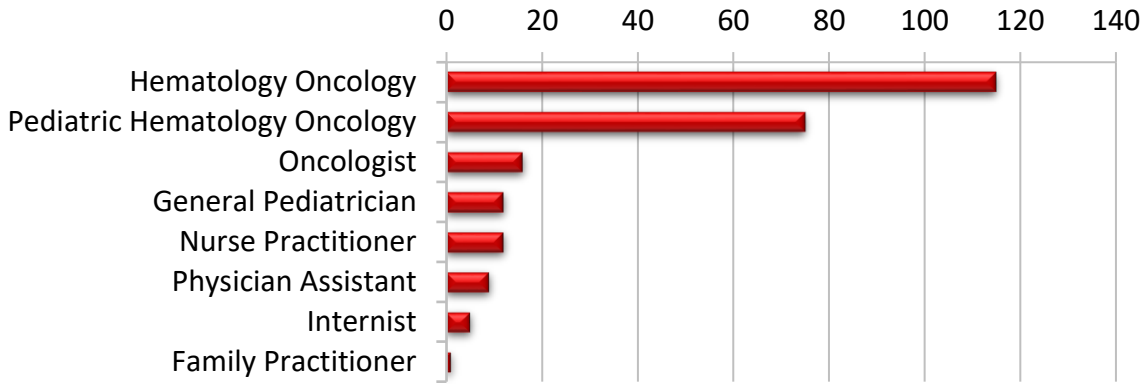
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	39	216	$1,771,728.92	$8,202.45	$269.59	16,617	6,572
2018	45	245	$2,480,406.06	$10,124.11	$324.96	20,110	7,633
% Change	**15.40%**	**13.40%**	**40.00%**	**23.40%**	**20.50%**	**21.00%**	**16.10%**
Change	**6**	**29**	**$708,677.14**	**$1,921.66**	**$55.37**	**3,493**	**1,061**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Iron Chelating Agents



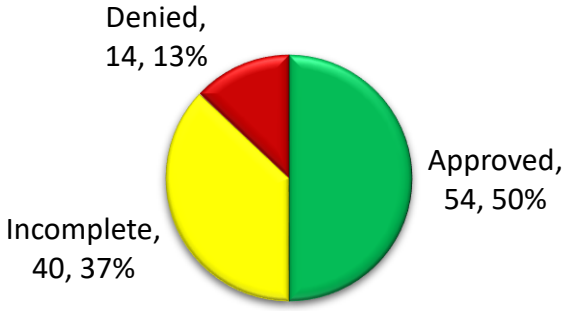
Top Prescriber Specialties of Iron Chelating Agents by Number of Claims



Prior Authorization of Iron Chelating Agents

There were 108 prior authorization requests submitted for 45 unique members for iron chelating agents during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[82]

- Exjade® (deferasirox): April 2019
- Ferriprox® (deferiprone): October 2029
- Jadenu® (deferasirox): November 2034

Recommendations

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

[82] 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 03/12/2019.

Utilization Details of Iron Chelating Agents: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
JADENU TAB 360MG	144	30	$1,659,472.95	$11,524.12	4.8	66.90%
EXJADE TAB 500MG	49	12	$538,624.25	$10,992.33	4.1	21.72%
JADENU TAB 90MG	26	5	$58,722.27	$2,258.55	5.2	2.37%
EXJADE TAB 250MG	6	3	$13,712.46	$2,285.41	2	0.55%
JADENU TAB 180MG	5	3	$11,571.27	$2,314.25	1.7	0.47%
JADENU SPRKL GRA 180MG	3	1	$10,588.53	$3,529.51	3	0.43%
EXJADE TAB 125MG	1	1	$7,481.93	$7,481.93	1	0.30%
SUBTOTAL	**234**	**44***	**$2,300,173.66**	**$9,829.80**	**5.3**	**92.73%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 500MG	11	1	$180,232.40	$16,384.76	11	7.27%
SUBTOTAL	**11**	**1***	**$180,232.40**	**$16,384.76**	**11**	**7.27%**
TOTAL	**245**	**45***	**$2,480,406.06**	**$10,124.11**	**5.4**	**100.00%**

*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 2018 Annual Review of Kanuma® (Sebelipase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Kanuma® (Sebelipase Alfa) Approval Criteria:

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

Utilization of Kanuma® (Sebelipase Alfa): Fiscal Year 2018

There were no paid claims for Kanuma® (sebelipase alfa) during fiscal year 2018.

Prior Authorization of Kanuma® (Sebelipase Alfa): Fiscal Year 2018

There were no prior authorization requests submitted for Kanuma® (sebelipase alfa) during fiscal year 2018.

Market News and Updates

News:

- **February 2018:** Alexion Pharmaceuticals, Inc. announced that the combined interim data from 2 ongoing open-label studies, VITAL and CL-08, show a 3-year survival estimate of 68% in infants with rapidly progressive lysosomal acid lipase deficiency (LAL-D) treated with Kanuma® (sebelipase alfa). Of the 19 infants who were enrolled in the studies, 7 infants are surviving and have reached 3 years of age, while an additional 6 infants have not yet reached 3 years of age. The infants in the study also benefited from improvements in other key parameters including markers of liver disease and function, as well as weight gain. There were no discontinuations due to adverse events.[83]

Recommendations

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

[83] Alexion Pharmaceuticals, Inc. Data Presented at WORLD Symposium™ 2018 Show Survival To 3 Years Of Age And Improvements In Liver Function In Infants With Lysosomal Acid Lipase Deficiency Treated With Kanuma® (Sebelipase Alfa). *Business Wire*. Available online at: https://news.alexionpharma.com/press-release/product-news/data-presented-worldsymposium-2018-show-survival-3-years-age-and-improvem. Issued 02/06/2018. Last accessed 12/24/2018.

Fiscal Year 2018 Annual Review of Keveyis® (Dichlorphenamide)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Keveyis® (Dichlorphenamide) Approval Criteria:

7. An FDA approved indication for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants; and
8. 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
        ii. Avoiding foods rich in potassium
        iii. Avoiding fasting
        iv. High-carbohydrate diet
        v. Avoiding strenuous activity
        vi. Avoiding prolonged cold exposure
    b. Hypokalemic periodic paralysis:
        i. Low-carbohydrate diet (avoiding carbohydrate loading)
        ii. Avoiding vigorous exercise (some mild attacks can be aborted by low level exercise); and
9. 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
10. A 4-week trial within the last 90 days of acetazolamide in combination with
    a. Spironolactone or triamterene in hypokalemic periodic paralysis; or
    b. Hydrochlorothiazide in hyperkalemic periodic paralysis; and
11. A quantity limit of 4 tablets per day will apply.

Utilization of Keveyis® (Dichlorphenamide): Fiscal Year 2018

There were no paid claims for Keveyis® (dichlorphenamide) during fiscal year 2018.

Prior Authorization of Keveyis® (Dichlorphenamide)

There were no prior authorization requests submitted for Keveyis® (dichlorphenamide) during fiscal year 2018.

Market News and Updates

Anticipated Exclusivity Expiration(s):[84]

- Keveyis® (dichlorphenamide): August 2022

New(s):

- **May 2016:** Taro Pharmaceuticals announced Keveyis® (dichlorphenamide) will now be available to distributors at no cost for the treatment of primary periodic paralysis (PPP). As a result, Taro ceased commercial sales and related promotional activities for Keveyis® and will bear all costs associated with its manufacturing. Although Taro expected to treat only a few hundred patients with Keveyis®, it became clear that reaching such a small pool of people is more difficult than previously anticipated. Among the 5,000 people estimated to be living with PPP in the United States, <1,500 are believed to be diagnosed. Among these patients, a mix of lifestyle modifications and medicines prescribed off-label are often used to manage their disease. Taro reports sales have been <$1 million dollars since launch. Given the high costs and resources required to identify and reach a limited number of viable patients, Taro decided that it cannot sustain its current level of investment. Based on these learnings, Taro now believes that it can better serve all stakeholders, including patients, by ceasing commercial sales and related promotional activities for Keveyis®.[85]
- **December 2016:** Taro Pharmaceutical Industries announced the sale of United States rights for Keveyis® (diclorphenamide) to Strongbridge Biopharma for upfront and deferred payments of $8.5 million in 2 installments and additional future payments upon the achievement of certain sales unit milestones. Strongbridge expects to commercially launch Keveyis® in the United States in April 2017. Taro has agreed to continue to manufacture Keveyis® for Strongbridge, under an exclusive supply agreement at least for the period of Keveyis® orphan exclusivity, subject to certain commercial terms and conditions, including minimum supply purchases.[86]
- **November 2017:** Strongbridge announced Keveyis® net product sales of $2.5 million during the third quarter of 2017, a 67% increase, compared to $1.5 million in the second quarter of 2017. Within the first 2 quarters of the Strongbridge Keveyis® launch, Strongbridge cumulatively generated more than 80 new patient start forms (prescriptions for Keveyis®). The company has launched free genetic testing for the disease state and plans to expand the Keveyis® sells force increasing from 12 to 21 sales representatives with the addition of 3 regional business directors and 3 patient access managers, build upon PPP disease-state education programs and Keveyis® branded

[84] 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 12/2018. Last accessed 01/28/2019.

[85] Taro Pharmaceutical Industries. Taro Announces Sale of U.S. Rights to Keveyis® to Strongbridge BioPharma plc. *BusinessWire*. Available online at: http://www.businesswire.com/news/home/20161223005197/en/Taro-Announces-Sale-U.S.-Rights-Keveyis%C2%AE-Strongbridge. Issued 12/2016. Last accessed 01/28/2019.

[86] Strongbridge Biopharma, Plc. Strongbridge Biopharma Plc Provides Corporate Update and Reports Third Quarter 2017 Financial Results. *Globe Newswire*. Available online at: https://globenewswire.com/news-release/2017/11/14/1185758/0/en/Strongbridge-Biopharma-plc-Provides-Corporate-Update-and-Reports-Third-Quarter-2017-Financial-Results.html. Issued 11/2017. Last accessed 01/28/2019.

promotional initiatives, and support the recent national launch of the *Uncovering Periodic Paralysis* genetic testing program.[87]

- **March 2018:** Strongbridge announced that new clinical analyses to validate the overall clinical profile of Keveyis® (dichlorphenamide) was presented at the 70th American Academy of Neurology (AAN) Annual Meeting from April 21 to 27, 2018 in Los Angeles, California. A post-hoc analysis of a Phase 3, placebo-controlled, cross-over trial comparing the effects of dichlorphenamide in adolescent and adult patients with PPP was presented in a poster presentation entitled, "Efficacy and Safety of Dichlorphenamide in Adolescent Patients with Primary Periodic Paralysis". Dichlorphenamide treatment resulted in median changes from baseline in weekly attack rate of -0.96 [confidence interval (CI): -1.63, -0.88] in adolescents versus -0.83 (CI: -2.75, -0.26) in adults. The results show that adolescents had similar improvements in short-term attack rates and similar side effects as adults. A pooled analysis of efficacy data from 2 Phase 3 placebo-controlled trials evaluating dichlorphenamide in 138 patients with PPP was also presented in an oral poster presentation entitled, "Efficacy of Dichlorphenamide in Primary Periodic Paralysis: Pooled-Data Analysis of Two Phase 3 Clinical Trials". The results add to the growing body of clinical evidence to support Keveyis® efficacy across disease variants by measuring changes from baseline in weekly attack rates.[88]
- **May 2018:** Strongbridge reported first quarter 2018 financial results which included net product sales for Keveyis® of $3.9 million in the first quarter of 2018, a 30% increase compared to $3.0 million in the fourth quarter of 2017.[89]

Recommendations

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

[87] Taro Pharmaceutical Industries Inc. Taro to Make Keveyis™ Available to Distributors Free of Cost. Available online at: http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-newsArticle&ID=2163726. Issued 05/2016. Last accessed 01/28/2019.

[88] Strongbridge Biopharma, Plc. Strongbridge Biopharma plc to Present Keveyis® (dichlorphenamide) Primary Periodic Paralysis Data at the 2018 American Academy of Neurology Annual Meeting. *Globe Newswire*. Available online at: https://globenewswire.com/news-release/2018/03/05/1414763/0/en/Strongbridge-Biopharma-plc-to-Present-KEVEYIS-dichlorphenamide-Primary-Periodic-Paralysis-Data-at-the-2018-American-Academy-of-Neurology-Annual-Meeting.html. Issued 03/05/2018. Last accessed 01/28/2019.

[89] Strongbridge Biopharma, Plc. Strongbridge Biopharma plc Reports First Quarter 2018 Financial Results and Provides Corporate Update. *Globe Newswire*. Available online at: https://investors.strongbridgebio.com/news-releases/news-release-details/strongbridge-biopharma-plc-reports-first-quarter-2018-financial. Issued 05/10/2018. Last accessed 01/28/2019.

Fiscal Year 2018 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority
Fiscal Year 2018 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 Extended-Release (ER)] Approval Criteria:

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

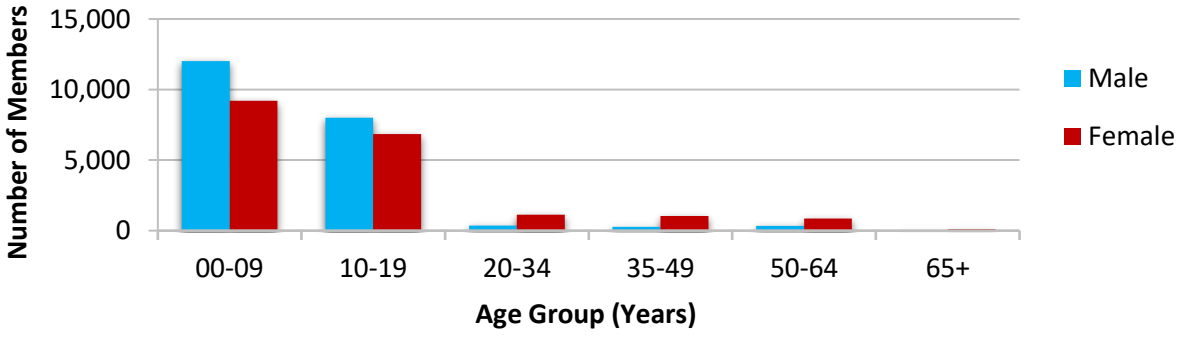
Utilization of Leukotriene Modulators: Fiscal Year 2018

Comparison of Fiscal Years

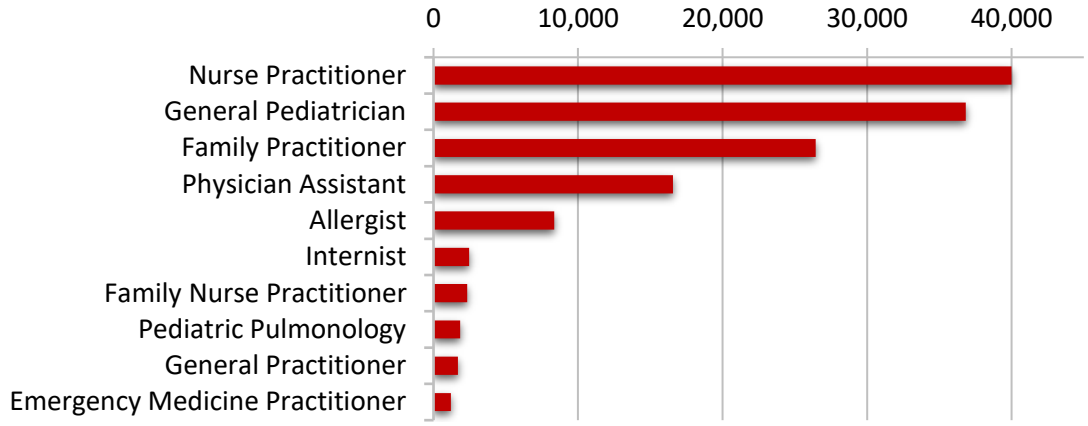
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	39,099	134,905	$2,134,424.47	$15.82	$0.53	4,041,277	4,044,018
2018	40,204	141,638	$2,332,183.98	$16.47	$0.55	4,240,971	4,244,873
% Change	**2.80%**	**5.00%**	**9.30%**	**4.10%**	**3.80%**	**4.90%**	**5.00%**
Change	**1,105**	**6,733**	**$197,759.51**	**$0.65**	**$0.02**	**199,694**	**200,855**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Leukotriene Modulators



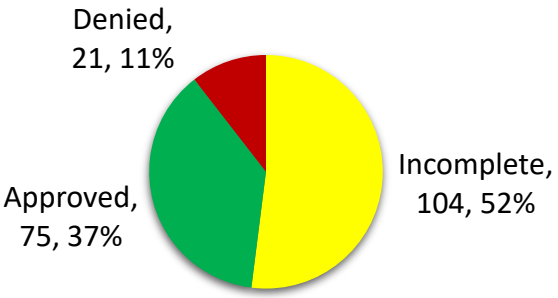
Top Prescriber Specialties of Leukotriene Modulators by Number of Claims



Prior Authorization of Leukotriene Modulators

There were 200 prior authorization requests submitted for leukotriene modulators during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Recommendations

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

Utilization Details of Leukotriene Modulators: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
MONTELUKAST PRODUCTS					
MONTELUKAST CHW 5MG	56,149	15,927	$826,874.56	3.53	$14.73
MONTELUKAST TAB 10MG	41,316	12,053	$503,656.95	3.43	$12.19
MONTELUKAST CHW 4MG	40,258	12,535	$611,779.54	3.21	$15.20
MONTELUKAST GRA 4MG	3,739	1,720	$365,629.90	2.17	$97.79
SINGULAIR CHW 4MG	4	1	$936.40	4	$234.10
SINGULAIR CHW 5MG	1	1	$233.15	1	$233.15
SUBTOTAL	**141,467**	**42,237**	**$2,309,110.50**	**3.35**	**$16.32**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
ZILEUTON PRODUCTS					
ZYFLO TAB 600MG	2	1	$7,360.18	2	$3,680.09
ZILEUTON ER TAB 600MG	1	1	$2,706.79	1	$2,706.79
SUBTOTAL	**3**	**2**	**$10,066.97**	**1.5**	**$3,355.66**
ZAFIRLUKAST PRODUCTS					
ZAFIRLUKAST TAB 20MG	153	28	$11,916.78	5.46	$77.89
ZAFIRLUKAST TAB 10MG	15	6	$1,089.73	2.5	$72.65
SUBTOTAL	**168**	**34**	**$13,006.51**	**4.94**	**$77.42**
TOTAL	**141,638**	**40,204***	**$2,322,183.98**	**3.52**	**$16.47**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Lidocaine Topical Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

- The prior authorization for Lidoderm® (lidocaine 5% patch) was removed in May 2018.

Synera® (Lidocaine/Tetracaine Patch) Approval Criteria:

2. Member must be 3 years of age or older; and
3. Member must have an FDA approved need for local dermal analgesia for superficial venous access or superficial dermatological procedures; and
4. 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
5. The total number of procedures must be provided on the prior authorization request; and
6. 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 patch(es), 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 Medications: Fiscal Year 2018

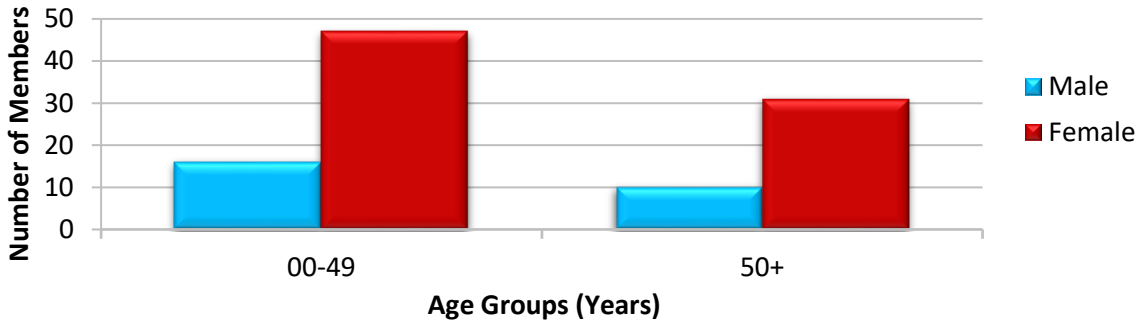
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	23	59	$8,150.34	$138.14	$4.82	2,112	1,692
2018	104	133	$13,215.29	$99.36	$3.89	4,213	3,399
% Change	**352.20%**	**125.40%**	**62.10%**	**-28.10%**	**-19.30%**	**99.50%**	**100.90%**
Change	**81**	**74**	**$5,064.95**	**-$38.78**	**-$0.93**	**2,101**	**1,707**

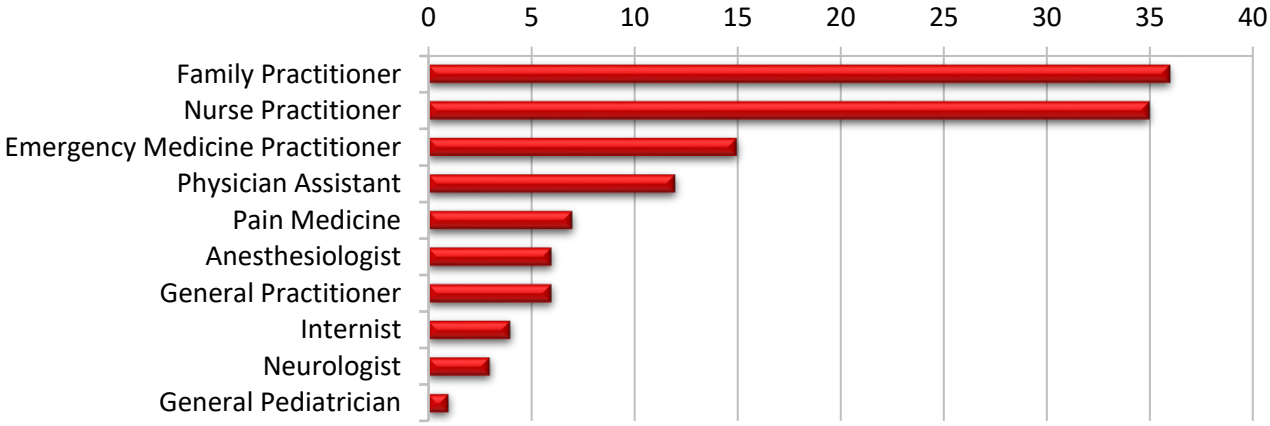
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- There was no paid claims for Synera® (lidocaine/tetracaine patch) or ZTlido™ (lidocaine 1.8% topical system) during fiscal year 2018.

Demographics of Members Utilizing Lidocaine Topical Medications



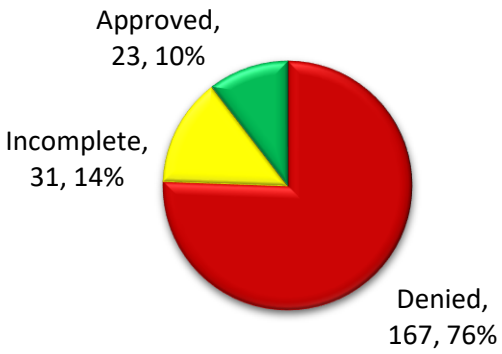
Top Prescriber Specialties of Lidocaine Topical Medications by Number of Claims



Prior Authorization of Lidocaine Topical Medications

There were 221 prior authorization requests submitted for lidocaine topical medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[90]

- 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 medications prior authorization criteria at this time.

Utilization Details of Lidocaine Topical Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
LIDOCAINE PRODUCTS					
LIDOCAINE PAD 5%	133	104	$13,215.29	1.28	$99.36
TOTAL	**133**	**104***	**$13,215.29**	**1.28**	**$99.36**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[90] 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 02/2019. Last accessed 03/31/2019.

Fiscal Year 2018 Annual Review of Lumizyme® (Alglucosidase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2018 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 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 have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at that 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 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	13	$360,996.95	$27,769.00	$1,071.21	468	337
2018	1	1	$30,170.55	$30,170.55	$1,077.52	40	28
% Change	**0.00%**	**-92.30%**	**-91.60%**	**8.60%**	**0.60%**	**-91.50%**	**-91.70%**
Change	**0**	**-12**	**-$330,826.40**	**$2,401.55**	**$6.31**	**-428**	**-309**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Lumizyme® (Alglucosidase Alfa)

- Due to the limited number of members utilizing Lumizyme® (alglucosidase alfa) detailed demographic information could not be provided.

Top Prescriber Specialties of Lumizyme® (Alglucosidase Alfa) by Number of Claims

- The only prescriber specialty listed on paid claims for Lumizyme® (alglucosidase alfa) during fiscal year 2018 was genetic counseleor.

Prior Authorization of Lumizyme® (Alglucosidase Alfa)

There were 2 prior authorization requests submitted for Lumizyme® (alglucosidase alfa) during fiscal year 2018, both of which were approved.

Market News and Updates[91]

Pipeline:

- **January 2019:** Spark Therapeutics announced it is investigating, SPK-3006 as an investigational liver-directed adeno-associated viral (AAV) gene therapy for Pompe disease. SPK-3006 has been engineered to produce a modified enzyme that is secreted from the liver, which may sustain acid alpha-glucosidase (GAA) plasma levels and lower immunogenicity to GAA to potentially provide greater uptake in muscle tissue. The transgene was in-licensed in 2017 from Genethon, a non-profit research and development organization dedicated to the development of gene therapies for orphan genetic diseases from research to clinical validation. Spark Therapeutics retains global commercialization rights to SPK-3006.

Recommendations

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

[91] 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 02/18/2019.

Fiscal Year 2018 Annual Review of Mozobil® (Plerixafor)

Oklahoma Health Care Authority
Fiscal Year 2018 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: Creatinine clearance ≤50 mL/min: 0.16mg/kg, maximum of 27mg/day; and
7. Approvals will be for the duration of 2 months.

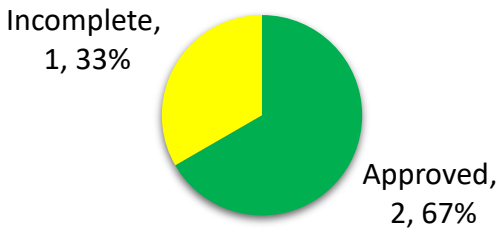
Utilization of Mozobil® (Plerixafor): Fiscal Year 2018

There were no paid pharmacy or medical claims for Mozobil® (plerixafor) during fiscal year 2018.

Prior Authorization of Mozobil® (Plerixafor)

There were 3 prior authorizations submitted for Mozobil® (plerixafor) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Recommendations

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

Fiscal Year 2018 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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 tablets (Zanaflex®)		chlorzoxazone (Lorzone®)
		cyclobenzaprine 7.5mg (Fexmid®)
		cyclobenzaprine ER (Amrix®)
		tizanidine capsules (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 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.
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.
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.

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

1. A cumulative 90 therapy day window per 365 days will be in place for these medications, further approval will be based on the following:
   a. An additional approval for 1 month will be granted to allow titration or change to a Tier-1 muscle relaxant. Further authorizations will not be granted.
   b. 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, or paralysis.
2. A quantity limit of 120 per 30 days will apply.

Soma® (Carisoprodol 250mg) Approval Criteria:

1. Must provide detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and specific reason member cannot be drowsy for even a short time period. Member must not have other sedating medications in current claims history.
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.

Lorzone® (Chlorzoxazone) Approval Criteria:

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone™; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. A quantity limit of 120 tablets per 30 days will apply.

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

1. Clinical documentation of inability to take other generically available forms of cyclobenzaprine tabs; and
2. The following quantity limits apply:
   a. Amrix®: 30 capsules per 30 days
   b. Fexmid®: 90 tablets per 30 days

Zanaflex® (Tizanidine Capsules) Approval Criteria:

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

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.

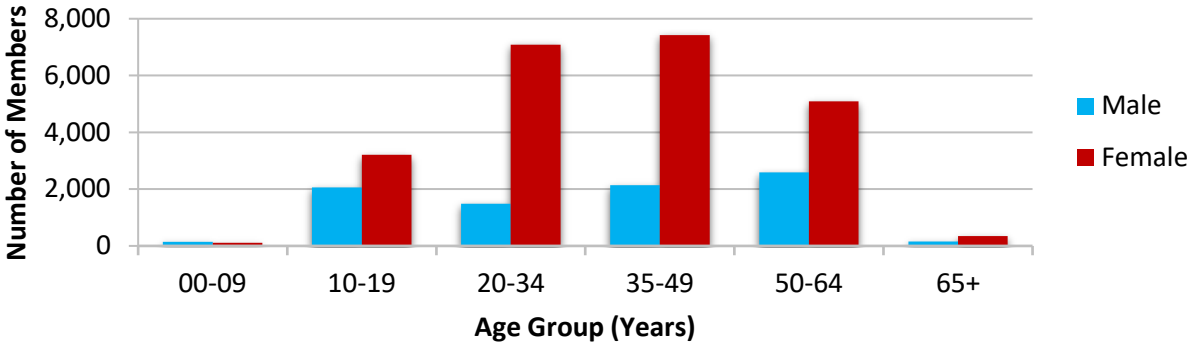
Utilization of Muscle Relaxant Medications: Fiscal Year 2018

Comparison of Fiscal Years

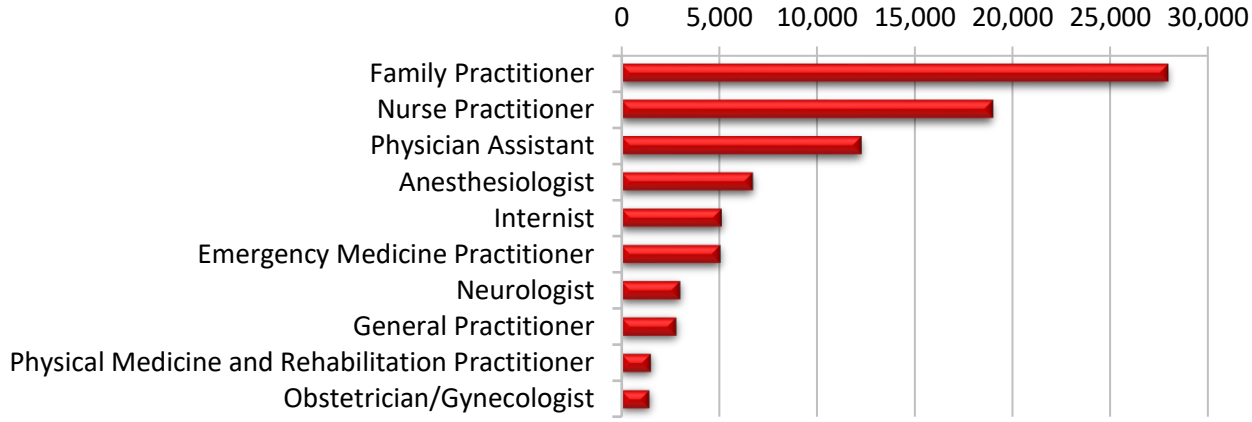
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	34,501	101,021	$1,438,400.06	$14.24	$0.58	6,893,264	2,498,985
2018	31,821	94,915	$1,429,807.72	$15.06	$0.60	6,423,476	2,364,786
% Change	**-7.80%**	**-6.00%**	**-0.60%**	**5.80%**	**3.40%**	**-6.80%**	**-5.40%**
Change	**-2,680**	**-6,106**	**-$8,592.34**	**$0.82**	**$0.02**	**-469,788**	**-134,199**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Muscle Relaxant Medications



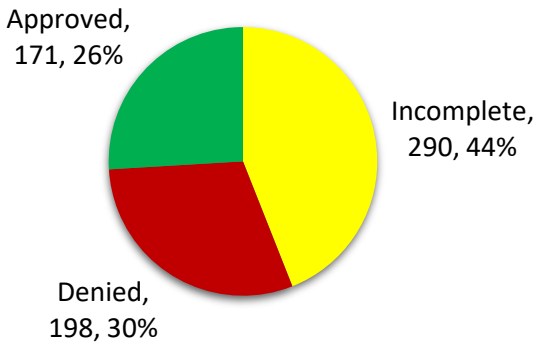
Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 659 prior authorization requests for muscle relaxant medications submitted during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[92]

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

Pipeline:

- **November 2018**: Ontinua™ ER is an extended-release formulation of arbaclofen, the R isomer of baclofen, which is currently being studied for the treatment of spasticity related to multiple sclerosis. Enrollment for second Phase 3 trial was completed in November 2018, and the trial is estimated to be competed in 2019. The trial is a randomized, double-blind, placebo-controlled parallel group study with 536 participants enrolled, and is intended to compare 2 doses of arbaclofen ER (40mg and 80mg) twice daily to placebo. The primary endpoint is the total numeric-transformed modified Ashworth Scale score of the most affected limb, which is a clinical measure of muscle spasticity in subjects with neurological conditions. If the trial results are positive Osmotica Pharmaceuticals plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2019.[93,94,95]

Recommendations

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

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
BACLOFEN PRODUCTS					
BACLOFEN TAB 10MG	12,143	3,647	$206,293.73	3.33	$16.99
BACLOFEN TAB 20MG	6,160	1,390	$173,142.77	4.43	$28.11
GABLOFEN INJ 40000/20	13	4	$11,542.45	3.25	$887.88
LIORESAL INT INJ 40MG/20	9	1	$16,054.29	9	$1,783.81
SUBTOTAL	**18,325**	**5,042**	**$407,033.24**	**3.63**	**$22.21**
CHLORZOXAZONE PRODUCTS					
CHLORZOXAZON TAB 500MG	1,321	574	$30,497.13	2.3	$23.09

[92] 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 03/2019. Last accessed 04/23/2019.

[93] Osmotica Pharmaceuticals plc. Research and Development: Arbaclofen ER. Available online at: https://www.osmotica.com/pipeline/research-and-development/. Last revised 01/2019. Last Accessed 04/23/2019.

[94] Osmotica Pharmaceuticals plc. Osmotica Pharmaceuticals plc Reports Third Quarter 2018 Results. Globe Newswire. Available online at: https://www.globenewswire.com/news-release/2018/11/08/1648473/0/en/Osmotica-Pharmaceuticals-plc-Reports-Third-Quarter-2018-Results.html. Issued 11/08/2018. Last Accessed 04/23/2019.

[95] Osmotica Pharmaceutical US, LLC. A Study to Investigate the Safety and Effectiveness of Arbaclofen Extended-Release Tablets for Patients With MS. ClinicalTrials.gov. Available online at: https://clinicaltrials.gov/ct2/show/NCT03290131. Last updated 01/18/2019. Last accessed 04/23/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
SUBTOTAL	**1,321**	**574**	**$30,497.13**	**2.3**	**$23.09**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR TAB 5MG	6,484	4,031	$63,540.40	1.61	$9.80
CYCLOBENZAPR TAB 10MG	30,535	13,991	$276,463.80	2.18	$9.05
SUBTOTAL	**37,019**	**18,022**	**$340,004.20**	**2.05**	**$9.18**
METHOCARBAMOL PRODUCTS					
METHOCARBAM TAB 500MG	3,963	2,064	$51,577.99	1.92	$13.01
METHOCARBAM TAB 750MG	3,826	1,581	$56,579.79	2.42	$14.79
SUBTOTAL	**7,789**	**3,645**	**$108,157.78**	**2.14**	**$13.89**
ORPHENADRINE PRODUCTS					
ORPHENADRINE TAB 100MG ER	2,733	1,812	$56,972.97	1.51	$20.85
SUBTOTAL	**2,733**	**1,812**	**$56,972.97**	**1.51**	**$20.85**
TIZANIDINE PRODUCTS					
TIZANIDINE TAB 4MG	22,554	6,683	$376,626.98	3.37	$16.70
TIZANIDINE TAB 2MG	2,853	1,221	$45,917.45	2.34	$16.09
SUBTOTAL	**25,407**	**7,904**	**$422,544.43**	**3.21**	**$16.63**
TIER-1 SUBTOTAL	**92,594**	**36,999**	**$1,365,209.75**	**2.50**	**$14.74**
TIER-2 UTILIZATION					
METAXALONE PRODUCTS					
METAXALONE TAB 800MG	269	83	$36,406.00	3.24	$135.34
METAXALONE TAB 400MG	5	4	$1,893.08	1.25	$378.62
TIER-2 SUBTOTAL	**274**	**87**	**$38,299.08**	**3.15**	**$139.78**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
CARISOPRODOL PRODUCTS					
CARISOPRODOL TAB 350MG	2,044	970	$25,989.16	2.11	$12.71
CARISOPRODOL TAB 250MG	2	2	$134.08	1.00	$67.04
SUBTOTAL	**2,046**	**972**	**$26,123.24**	**2.10**	**$12.77**
TIZANIDINE PRODUCTS					
TIZANIDINE CAP 6MG	1	1	$175.65	1	$175.65
SUBTOTAL	**1**	**1**	**$175.65**	**1**	**$175.65**
SPECIAL PA SUBTOTAL	**2,047**	**973**	**$26,298.89**	**2**	**$12.85**
TOTAL	**94,915**	**31,821***	**$1,429,807.72**	**2.49**	**$15.06**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Myalept® (Metreleptin)

Oklahoma Health Care Authority
Fiscal Year 2018 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.
   a. Baseline HbA1c, fasting glucose, and fasting triglycerides must be stated on 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 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	12	$447,505.38	$37,292.11	$1,243.07	120	360
2018	1	12	$482,908.20	$40,242.35	$1,341.41	120	360
% Change	**0.00%**	**0.00%**	**7.90%**	**7.90%**	**7.90%**	**0.00%**	**0.00%**
Change	**0**	**0**	**$35,402.82**	**$2,950.24**	**$98.34**	**0**	**0**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Myalept® (Metreleptin)

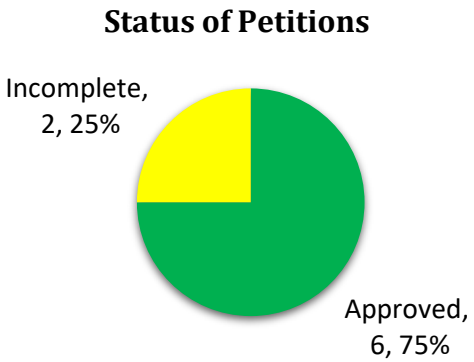
- Due to the small number of members utilizing Myalept® (metreleptin), detailed demographic information could not be provided.

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

- The only prescriber specialty list on paid claims for Myalept® (metreleptin) during fiscal year 2018 was pediatric endocrinology.

Prior Authorization of Myalept® (Metreleptin)

There were 8 prior authorization request submitted for Myalept® (metreleptin) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Recommendations

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

Fiscal Year 2018 Annual Review of Mytesi® (Crofelemer) [Formerly Known As Fulyzaq®]

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

There were no paid pharmacy claims for Mytesi® (crofelemer) during fiscal year 2018.

Prior Authorization of Mytesi® (Crofelemer)

There were no prior authorization requests submitted for Mytesi® (crofelemer) during fiscal year 2018

Market News and Updates

Anticipated Patent Expiration(s):

- Mytesi® (crofelemer): October 2031[96]

Recommendations

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

[96] 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 11/2018. Last accessed 01/11/2019.

Fiscal Year 2018 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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

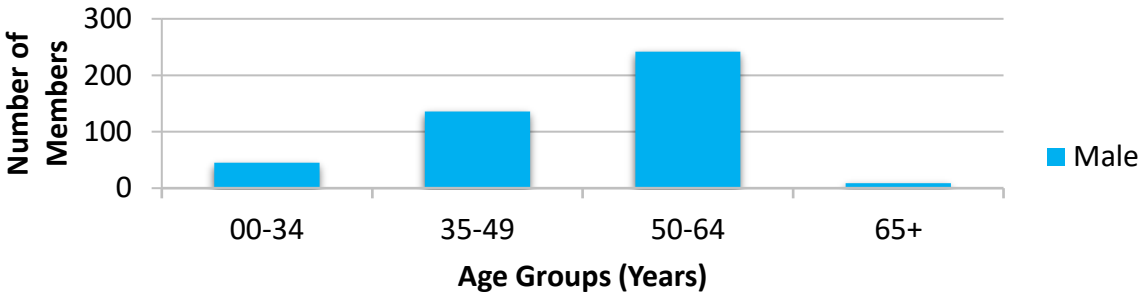
Utilization of Naloxone Medications: Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	783	793	$89,003.40	$112.24	$3.76	1,625	23,643
2018	1,356	1,394	$159,385.28	$114.34	$3.76	2,859	42,380
% Change	**73.20%**	**75.80%**	**79.10%**	**1.90%**	**0.00%**	**75.90%**	**79.20%**
Change	**573**	**601**	**$70,381.88**	**$2.10**	**$0.00**	**1,234**	**18,737**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

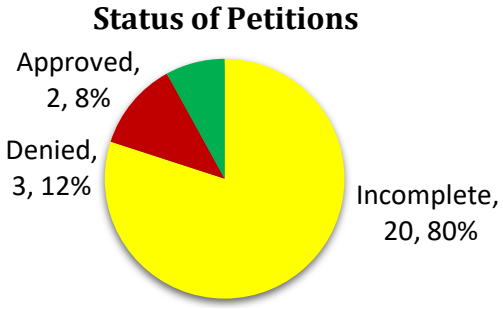
Demographics of Members Utilizing Naloxone Medications



Top Prescriber Specialties of Naloxone Medications by Number of Claims

Prior Authorization of Naloxone Medications

There were 25 prior authorization requests submitted for naloxone medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s)[97]:

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

News:

- **December 2018:** Kaléo, Inc. announced that they will be offering an authorized generic formulation of Evzio® (naloxone HCL injections). Kaléo, Inc. is the current manufacturer of Evzio®, and will make the authorized generic with the same formulation and packaging with a different label. The authorized generic is set to be available midyear 2019, with an estimated list price of $178 per carton of 2 auto-injectors.[98]

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
NARCAN SPR 4MG/0.1ML	1,168	1,138	$149,096.14	$4.06	$127.65
NALOXONE INJ 1MG/ML	208	206	$9,652.26	$1.79	$46.41
NALOXONE INJ 0.4MG/ML	16	16	$452.94	$2.87	$28.31
NALOXONE INJ 0.4MG/ML	2	2	$183.94	$2.02	$91.97
TOTAL	**1,394**	**1,356***	**$159,385.28**	**$3.76**	**$114.34**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[97] 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 12/2018. Last accessed 01/22/2018.

[98] Kaléo, Inc. Authorized Generic for EVZIO® (naloxone HCl injection) to be Available at a Reduced List Price of $178. 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 2018 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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; and
3. No grandfathering of Tier-2 or Tier-3 medications will be allowed for this category; and
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; and
5. 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; and
4. No grandfathering of Tier-2 or Tier-3 medications will be allowed for this category.
5. 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; and
6. 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 2018

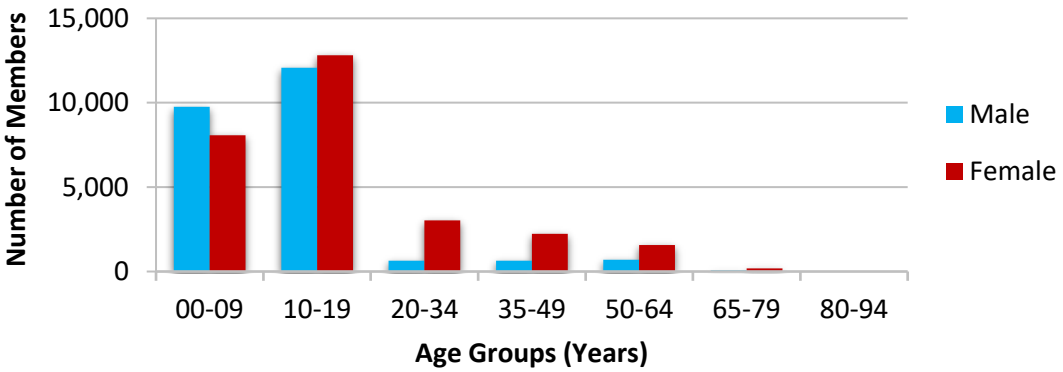
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	54,849	100,880	$1,463,028.60	$14.50	$0.39	1,625,874	3,705,044
2018	51,829	98,767	$1,720,589.93	$17.42	$0.47	1,591,933	3,659,326
% Change	**-5.50%**	**-2.10%**	**17.60%**	**20.10%**	**20.50%**	**-2.10%**	**-1.20%**
Change	**-3,020**	**-2,113**	**$257,561.33**	**$2.92**	**$0.08**	**-33,941**	**-45,718**

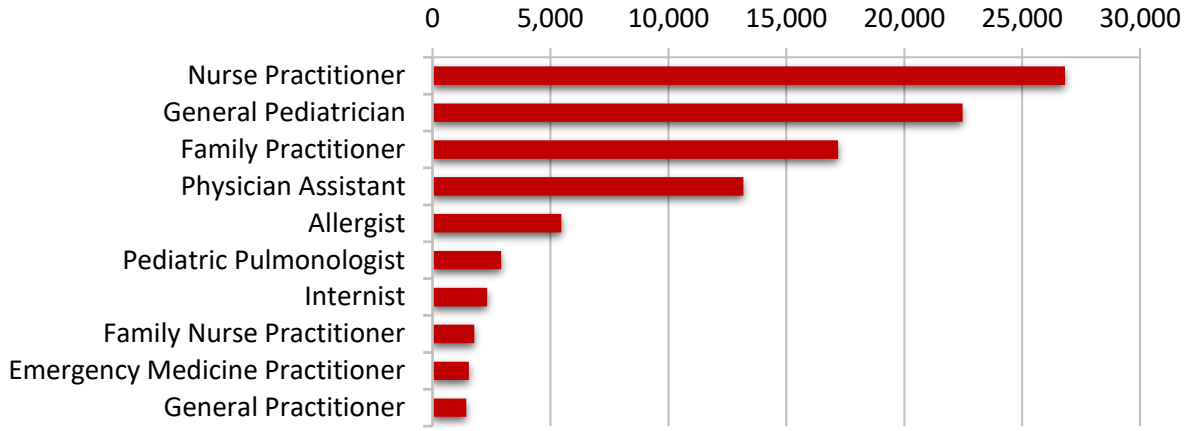
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- Please note, due to new federal regulations, a new pricing methodology for pharmacy claims reimbursement was implemented by SoonerCare on January 3, 2017. Ingredient reimbursement changed from an estimated acquisition cost (EAC) to an actual acquisition cost (AAC). In addition, the professional dispensing fee increased from $3.60 in 2016 to $10.55 effective January 2017; professional dispensing fees are included in the reimbursement totals in the following report. The impact of the pricing methodology and dispensing fee change are estimated to be budget neutral. This change in reimbursement should be considered when evaluating reimbursement changes from year to year. Medications with a very low cost per claim and large volume of claims will appear to increase in price due to the increase in dispensing fee; however, these increases will be neutralized by changes in ingredient reimbursement for higher cost medications.

Demographics of Members Utilizing Nasal Allergy Medications



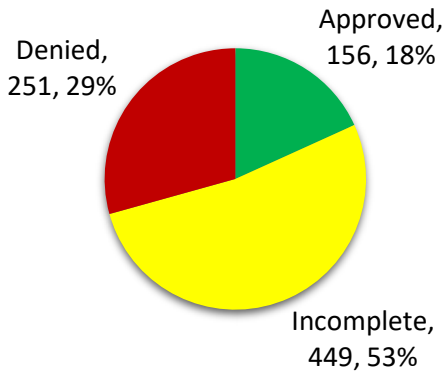
Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims



Prior Authorization of Nasal Allergy Medications

There were 856 prior authorization requests submitted for nasal allergy medications during fiscal year 2018. 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 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[99]

- 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): October 2034

[99] 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 03/15/2019.

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
FLUTICASONE SPR 50MCG	97,234	51,447	$1,375,476.97	$14.15	1.9	79.94%
BECONASE AQ SUS 0.042%	1,021	500	$287,620.37	$281.70	2.0	16.72%
SUBTOTAL	**98,255**	**51,757***	**$1,663,097.34**	**$16.93**	**1.9**	**96.66%**
TIER-2 PRODUCTS						
AZELASTINE SPR 0.1%	146	87	$3,541.27	$24.26	1.7	0.21%
QNASL AER 80MCG	97	26	$18,524.85	$190.98	3.7	1.08%
SUBTOTAL	**243**	**110***	**$22,066.12**	**$90.81**	**2.2**	**1.28%**
TIER-3 PRODUCTS						
DYMISTA SPR 137MCG-50MCG	84	14	$14,627.07	$174.13	6.0	0.85%
QNASL CHILD SPR 40MCG	48	11	$9,590.84	$199.81	4.4	0.56%
MOMETASONE SPR 50MCG	42	19	$2,856.43	$68.01	2.2	0.17%
FLUNISOLIDE SPR 0.025%	32	7	$1,959.30	$61.23	4.6	0.11%
OLOPATADINE SPR 0.6%	32	5	$3,492.91	$109.15	6.4	0.20%
AZELASTINE SPR 0.15%	25	6	$1,617.68	$64.71	4.2	0.09%
VERAMYST SPR 27.5MCG	4	3	$778.70	$194.68	1.3	0.05%
NASONEX SPR 50MCG/ACT	2	1	$503.54	$251.77	2.0	0.03%
SUBTOTAL	**269**	**64***	**$35,426.47**	**$131.70**	**4.2**	**2.06%**
TOTAL	**98,767**	**51,829***	**$1,720,589.93**	**$17.42**	**1.9**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
Fiscal Year 2018 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
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release; EC = enteric coated; caps = capsules; tabs = tablets; susp = suspension; PA = prior authorization
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 2 celecoxib 200mg capsules to achieve a 400mg dose.

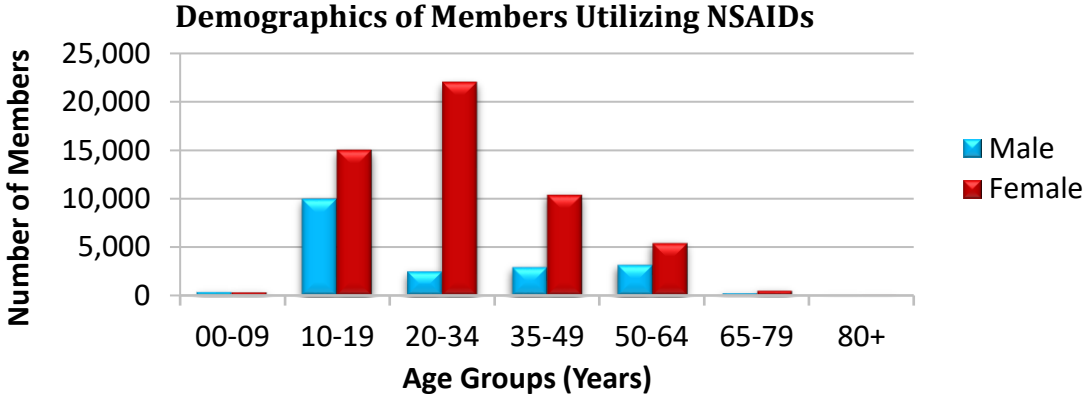
Utilization of NSAIDs: Fiscal Year 2018

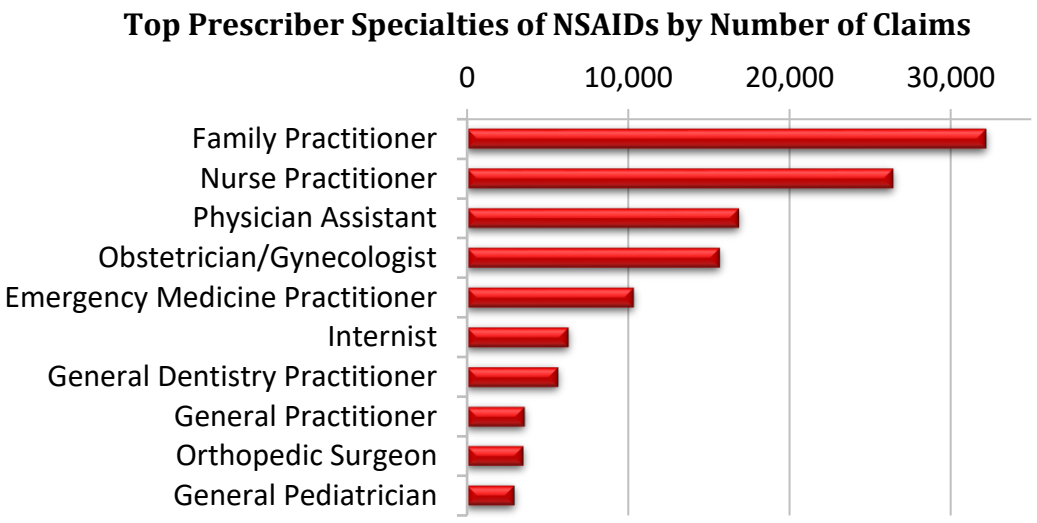
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	75,045	141,219	$1,632,226.65	$11.56	$0.51	6,773,456	3,223,286
2018	72,538	136,757	$1,827,085.23	$13.36	$0.59	6,560,679	3,123,174
% Change	**-3.30%**	**-3.20%**	**11.90%**	**15.60%**	**15.70%**	**-3.10%**	**-3.10%**
Change	**-2,507**	**-4,462**	**$194,858.58**	**$1.80**	**$0.08**	**-212,777**	**-100,112**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

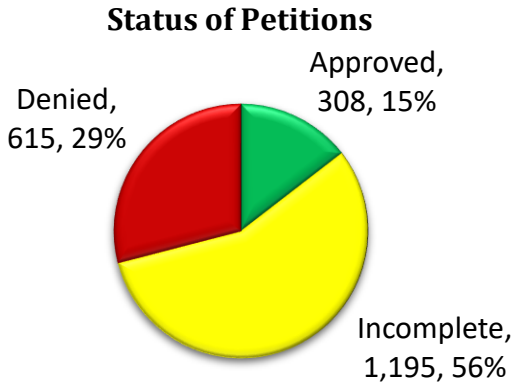
- Please note, due to new federal regulations, a new pricing methodology for pharmacy claims reimbursement was implemented by SoonerCare on January 3, 2017. Ingredient reimbursement changed from an estimated acquisition cost (EAC) to an actual acquisition cost (AAC). In addition, the professional dispensing fee increased from $3.60 in 2016 to $10.55 effective January 2017; professional dispensing fees are included in the reimbursement totals in the following report. The impact of the pricing methodology and dispensing fee change are estimated to be budget neutral. This change in reimbursement should be considered when evaluating reimbursement changes from year to year. Medications with a very low cost per claim and large volume of claims will appear to increase in price due to the increase in dispensing fee; however, these increases will be neutralized by changes in ingredient reimbursement for higher cost medications.





Prior Authorization of NSAIDs

There were 2,118 prior authorization requests submitted for NSAIDs during fiscal year 2018. 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 2018.



Market News and Updates

Anticipated Patent Expiration(s):[100]

- Flector® (diclofenac epolamine topical patches): April 2019
- Cambia® (diclofenac potassium powder packs): June 2026
- Duexis® (ibuprofen/famotidine tablets): July 2026
- Dyloject™ (diclofenac sodium for injection): March 2027
- Zipsor® (diclofenac potassium capsules): February 2029
- Tivorbex® (indomethacin capsules): April 2030
- Zorvolex® (diclofenac capsules): April 2030

[100] 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 02/2019. Last accessed 03/29/2019.

- Pennsaid® (diclofenac sodium 2% topical drops): August 2030
- Vimovo® (naproxen/esomeprazole tablets): October 2031
- Vivlodex® (meloxicam capsules): March 2035

News:

- **June 2018:** A systemic review and meta-analysis published in *Alimentary Pharmacology and Therapeutics* found no consistent overall association between worsening inflammatory bowel disease (IBD) and acetaminophen (APAP), NSAIDs, or cyclooxygenase 2 (COX-2) inhibitors. These findings are contrary to the prevailing thought that NSAIDs may exacerbate Crohn's disease (CD) and ulcerative colitis (UC), as clinicians generally advise against the use of NSAIDs in patients with established IBD. Researchers caution against any changes in current practice as significantly more work is required to examine the safety of APAP and NSAIDs in patients with CD and UC, and they plan to design large prospective cohort studies that will systematically examine the link between IBD and the use of APAP and NSAIDs, as well as aspirin.[101]

Pipeline:

- **Parecoxib:** A poster was presented 2018 World Congress of Pain in Boston regarding the use of parecoxib for postoperative pain following oral surgery (surgical extraction of at least 2 ipsilateral affected third molars that required bone removal). In the study, patients were randomly assigned to receive placebo, ketorolac, or parecoxib and were assessed over a 24-hour period for onset analgesia and time-specific pain levels. The onset of analgesia was found to be faster in patients administered parecoxib and ketorolac versus placebo, and the analgesic effect appeared to last longer in patients who received parecoxib versus ketorolac. Nausea and vomiting were less common in patients who received parecoxib compared with ketorolac and placebo. Parecoxib is an injectable COX-2 inhibitor that is a prodrug to valdecoxib. The U.S. Food and Drug Administration (FDA) rejected Pfizer's New Drug Application (NDA) for parecoxib in 2005 as "nonapprovable". At the time, Pfizer was to meet with the FDA to discuss the concerns; however, an NDA has not been resubmitted and parecoxib has not been approved by the FDA.[102, 103]

Recommendations

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

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[101] Moninuola OO, Milligan W, Lochhead P, et al. Systematic Review with Meta-Analysis: Association Between Acetaminophen and Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and Risk of Crohn's Disease and Ulcerative Colitis Exacerbation. *Aliment Pharmacol Ther* 2018; 47(11): 1428-1439.

[102] Salomon I, Wallentin A, Salomon P, et al. Parecoxib for the Treatment of Postoperative Pain After Oral Surgery: A Pooled, Post-Hoc Analysis. *Clinical Pain Advisor.* Available online at: https://www.clinicalpainadvisor.com/home/conference-highlights/iasp-2018/parecoxib-may-be-superior-to-ketorolac-for-oral-surgery-associated-pain/. Issued 09/13/2018. Last accessed 03/29/2019.

[103] Gandey A. FDA Rejects Parecoxib, Only Injectable COX-2 Inhibitor. *Medscape.* Available online at: https://www.medscape.com/viewarticle/538344. Issued 09/20/2005. Last accessed 03/29/2019.

Utilization Details of NSAIDs: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	39,036	27,125	$428,117.69	$10.97	1.4	23.43%
IBUPROFEN TAB 600MG	10,088	8,402	$101,604.62	$10.07	1.2	5.56%
IBU TAB 800MG	6,959	4,849	$86,608.85	$12.45	1.4	4.74%
IBUPROFEN TAB 400MG	2,853	2,196	$31,103.54	$10.90	1.3	1.70%
IBU TAB 600MG	2,068	1,653	$25,125.42	$12.15	1.3	1.38%
IBU TAB 400MG	706	508	$8,657.54	$12.26	1.4	0.47%
IBUPROFEN SUS 100/5ML	5	2	$134.85	$26.97	2.5	0.01%
SUBTOTAL	**61,715**	**44,735**	**$681,352.51**	**$11.04**	**1.4**	**37.29%**
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	18,962	8,749	$159,440.02	$8.41	2.2	8.73%
MELOXICAM TAB 7.5MG	9,030	4,719	$78,467.76	$8.69	1.9	4.29%
SUBTOTAL	**27,992**	**13,468**	**$237,907.78**	**$8.50**	**2.1**	**13.02%**
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	19,912	13,202	$206,928.97	$10.39	1.5	11.33%
NAPROXEN TAB 375MG	2,462	1,870	$27,081.52	$11.00	1.3	1.48%
NAPROXEN TAB 250MG	1,913	1,293	$22,986.33	$12.02	1.5	1.26%
NAPROXEN DR TAB 500MG	744	434	$13,711.60	$18.43	1.7	0.75%
NAPROXEN SUS 125/5ML	514	312	$90,776.98	$176.61	1.6	4.97%
NAPROXEN SOD TAB 550MG	151	91	$8,210.80	$54.38	1.7	0.45%
NAPROXEN DR TAB 375MG	137	84	$2,190.54	$15.99	1.6	0.12%
NAPROXEN SOD TAB 275MG	20	12	$1,092.71	$54.64	1.7	0.06%
SUBTOTAL	**25,853**	**17,298**	**$372,979.45**	**$14.43**	**1.5**	**20.41%**
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 75MG DR	5,647	2,805	$72,074.09	$12.76	2.0	3.94%
DICLOFENAC TAB 50MG DR	1,950	1,072	$34,114.65	$17.49	1.8	1.87%
DICLOFEN POT TAB 50MG	967	526	$34,709.60	$35.89	1.8	1.90%
DICLOFENAC GEL 1%	306	148	$18,586.11	$60.74	2.1	1.02%
DICLOFENAC TAB 100MG ER	290	139	$5,780.40	$19.93	2.1	0.32%
DICLOFENAC TAB 25MG DR	30	13	$1,475.35	$49.18	2.3	0.08%
VOLTAREN GEL 1%	12	7	$1,341.04	$111.75	1.7	0.07%
PENNSAID SOL 2%	4	3	$8,966.93	$2,241.73	1.3	0.49%
FLECTOR DIS 1.3%	3	3	$1,090.87	$363.62	1.0	0.06%
CAMBIA POW 50MG	2	2	$1,055.75	$527.88	1.0	0.06%
SUBTOTAL	**9,211**	**4,718**	**$179,194.79**	**$19.45**	**2.0**	**9.81%**
NABUMETONE PRODUCTS						
NABUMETONE TAB 500MG	1,369	684	$24,734.83	$18.07	2.0	1.35%
NABUMETONE TAB 750MG	1,301	486	$27,488.16	$21.13	2.7	1.50%
SUBTOTAL	**2,670**	**1,170**	**$52,222.99**	**$19.56**	**2.3**	**2.86%**
KETOROLAC PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
KETOROLAC TAB 10MG	2,531	2,194	$64,080.03	$25.32	1.2	3.51%
KETOROLAC INJ 60MG/2ML	40	13	$662.45	$16.56	3.1	0.04%
KETOROLAC INJ 30MG/ML	8	6	$175.44	$21.93	1.3	0.01%
KETOROLAC INJ 15MG/ML	1	1	$13.35	$13.35	1.0	0.00%
SUBTOTAL	**2,580**	**2,214**	**$64,931.27**	**$25.17**	**1.2**	**3.55%**
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	1,586	849	$57,587.58	$36.31	1.9	3.15%
ETODOLAC TAB 500MG	606	283	$27,049.62	$44.64	2.1	1.48%
ETODOLAC CAP 300MG	109	70	$6,054.98	$55.55	1.6	0.33%
ETODOLAC CAP 200MG	79	49	$3,606.08	$45.65	1.6	0.20%
ETODOLAC ER TAB 400MG	29	11	$2,312.26	$79.73	2.6	0.13%
ETODOLAC ER TAB 600MG	22	5	$2,467.81	$112.17	4.4	0.14%
ETODOLAC ER TAB 500MG	2	2	$195.03	$97.52	1.0	0.01%
SUBTOTAL	**2,433**	**1,269**	**$99,273.36**	**$40.80**	**1.9**	**5.43%**
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	1,804	683	$42,087.58	$23.33	2.6	2.30%
CELECOXIB CAP 100MG	522	191	$12,882.54	$24.68	2.7	0.71%
CELECOXIB CAP 50MG	13	10	$380.40	$29.26	1.3	0.02%
CELEBREX CAP 200MG	10	1	$6,708.55	$670.86	10.0	0.37%
SUBTOTAL	**2,349**	**885**	**$62,059.07**	**$26.42**	**2.7**	**3.40%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	413	254	$5,592.97	$13.54	1.6	0.31%
INDOMETHACIN CAP 25MG	306	223	$3,311.81	$10.82	1.4	0.18%
INDOCIN SUS 25MG/5ML	43	7	$28,411.05	$660.72	6.1	1.55%
INDOMETHACIN CAP 75MG	19	8	$832.72	$43.83	2.4	0.05%
SUBTOTAL	**781**	**492**	**$38,148.55**	**$48.85**	**1.6**	**2.09%**
KETOPROFEN PRODUCTS						
KETOPROFEN CAP 75MG	531	471	$11,175.03	$21.05	1.1	0.61%
KETOPROFEN CAP 50MG	135	112	$2,818.34	$20.88	1.2	0.15%
SUBTOTAL	**666**	**583**	**$13,993.37**	**$21.01**	**1.1**	**0.77%**
SULINDAC PRODUCTS						
SULINDAC TAB 200MG	191	82	$3,593.07	$18.81	2.3	0.20%
SULINDAC TAB 150MG	95	44	$1,611.25	$16.96	2.2	0.09%
SUBTOTAL	**286**	**126**	**$5,204.32**	**$18.20**	**2.3**	**0.28%**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	93	44	$2,626.78	$28.24	2.1	0.14%
FLURBIPROFEN TAB 50MG	12	4	$234.53	$19.54	3.0	0.01%
SUBTOTAL	**105**	**48**	**$2,861.31**	**$27.25**	**2.2**	**0.16%**
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 75-0.2MG	42	12	$5,251.95	$125.05	3.5	0.29%
DICLO/MISOPR TAB 50-0.2MG	6	4	$604.07	$100.68	1.5	0.03%
SUBTOTAL	**48**	**16**	**$5,856.02**	**$122.00**	**3.0**	**0.32%**
FENOPROFEN PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FENOPROFEN CAP 400MG	23	8	$6,362.57	$276.63	2.9	0.35%
FENOPROFEN TAB 600MG	5	2	$831.79	$166.36	2.5	0.05%
NALFON CAP 400MG	2	2	$555.61	$277.81	1.0	0.03%
SUBTOTAL	**30**	**12**	**$7,749.97**	**$258.33**	**2.5**	**0.42%**
PIROXICAM PRODUCTS						
PIROXICAM CAP 20MG	10	5	$492.66	$49.27	2.0	0.03%
PIROXICAM CAP 10MG	4	2	$261.97	$65.49	2.0	0.01%
SUBTOTAL	**14**	**7**	**$754.63**	**$53.90**	**2.0**	**0.04%**
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	14	3	$1,151.54	$82.25	4.7	0.06%
SUBTOTAL	**14**	**3**	**$1,151.54**	**$82.25**	**4.7**	**0.06%**
MECLOFENAMATE PRODUCTS						
MECLOFEN SOD CAP 50MG	7	1	$768.74	$109.82	7.0	0.04%
SUBTOTAL	**7**	**1**	**$768.74**	**$109.82**	**7.0**	**0.04%**
TOLMETIN PRODUCTS						
TOLMETIN SOD CAP 400MG	2	1	$443.02	$221.51	2.0	0.02%
TOLMETIN SOD TAB 600MG	1	1	$232.54	$232.54	1.0	0.01%
SUBTOTAL	**3**	**2**	**$675.56**	**$225.19**	**1.5**	**0.04%**
TOTAL	**136,757**	**72,538***	**$1,827,085.23**	**$13.36**	**1.9**	**100%**

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

Fiscal Year 2018 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2018 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 (Parkinson's disease, multiple system atrophy, and 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.
4. Initial approval will be for the duration of 2 weeks of treatment only.
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.
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 2018

There was one paid claim for Northera® (droxidopa) during fiscal year 2018 (see *Utilization Details* section at the end of this report for additional details).

Demographics of Members Utilizing Northera® (Droxidopa)

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

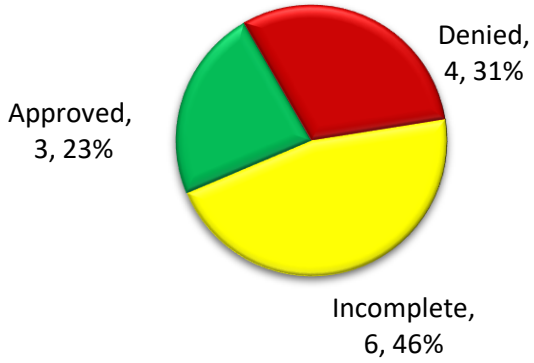
Top Prescriber Specialties of Northera® (Droxidopa) by Number of Claims

- The only prescriber specialty list on paid claims for Northera® (droxidopa) during fiscal year 2018 was a cardiologist.

Prior Authorization of Northera™ (Droxidopa)

There were 13 prior authorization requests submitted for Northera™ (droxidopa) for 3 unique members during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Exclusivity Expiration(s):[104]

- 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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
NORTHERA CAP 100MG	1	1	$1,012.91	3	$1,012.91	100%
TOTAL	**1**	**1***	**$1,012.91**	**3**	**$1,012.91**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

[104] 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 12/2018. Last accessed 01/28/2019.

Fiscal Year 2018 Annual Review of Ocaliva® (Obeticholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2018 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 daily will apply.

Utilization of Ocaliva® (Obeticholic Acid): Fiscal Year 2018

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	4	$22,826.20	$5,706.55	$190.22	120	120
2018	1	12	$73,611.60	$6,134.30	$204.48	360	360
% Change	**0.00%**	**200.00%**	**222.50%**	**7.50%**	**7.50%**	**200.00%**	**200.00%**
Change	**0**	**8**	**$50,785.40**	**$427.75**	**$14.26**	**240**	**240**

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.

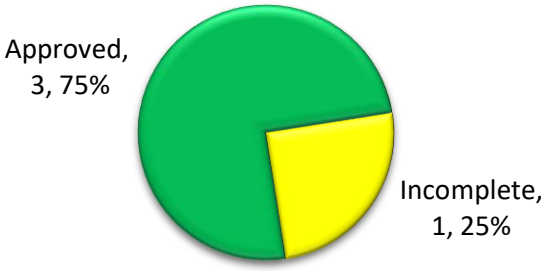
Top Prescriber Specialties of Ocaliva® (Obeticholic Acid) by Number of Claims

- The only prescriber specialty listed on paid claims for Ocaliva® (obeticholic acid) during fiscal year 2018 was a gastroenterologist.

Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 4 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Exclusivity Expiration(s):[105]

- 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. 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 new *Boxed Warning*, the FDA's most prominent warning, to highlight this information in the prescribing information of the drug label. The FDA is also requiring a Medication Guide for patients to inform them about this issue. As a condition of approval, the FDA required the manufacturer of Ocaliva®, Intercept Pharmaceuticals, to continue studying the medicine in patients with advanced PBC. These clinical trials are currently ongoing and the FDA expects to receive results in 2023. The FDA is adding the additional warnings to the drug label after receiving 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. The FDA will continue to monitor this medicine and will update the public if new information becomes available.[106]

Recommendations

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

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[105] 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 01/2019. Last accessed 02/26/2019.

[106] FDA Drug Safety Communication. Ocaliva® (obeticholic acid): Drug Safety Communication Boxed Warning Added to Highlight Correct Dosing. Available online at: https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm594901.htm. Issued 02/01/2018. Last accessed 02/26/2019.

Utilization Details of Ocaliva® (Obeticholic Acid): Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OCALIVA TAB 10MG	12	1	$73,611.60	$204.48	$6,134.30	100%
TOTAL	**12**	**1**	**$73,611.60**	**$204.48**	**$6,134.30**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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™)
		emedastine (Emadine®)
		lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine 0.2% (Pataday®)
		olopatadine 0.7% (Pazeo®)

OTC = over-the-counter
OTC products are not covered for adult members.
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 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 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.

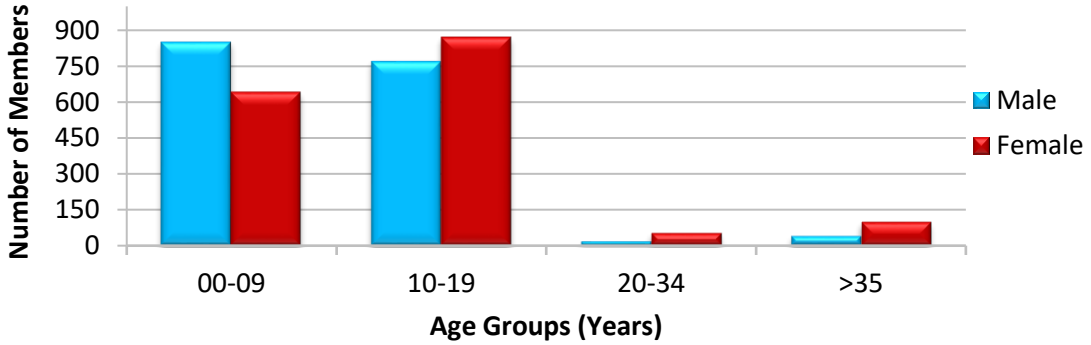
Utilization of Ophthalmic Allergy Medications: Fiscal Year 2018

Comparison of Fiscal Years

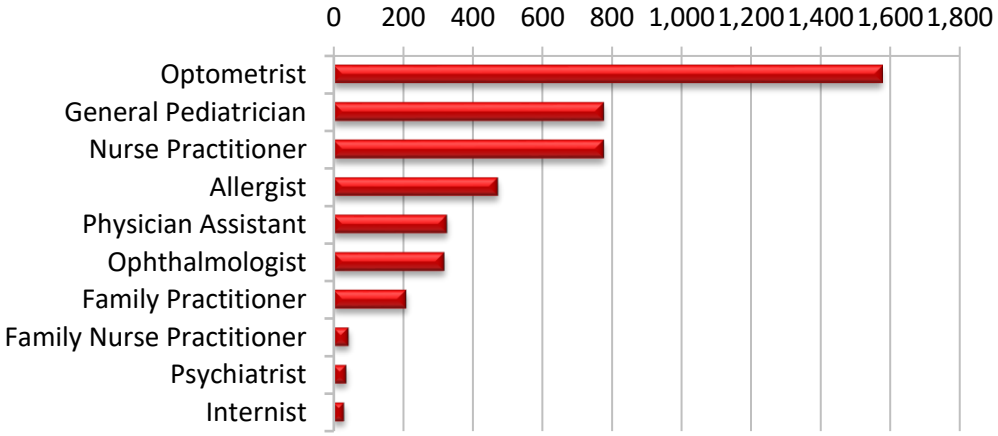
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	3,629	5,419	$99,785.69	$18.41	$0.57	35,882	174,346
2018	3,339	4,686	$93,393.85	$19.93	$0.61	31,236	153,907
% Change	**-8.00%**	**-13.50%**	**-6.40%**	**8.30%**	**7.00%**	**-12.90%**	**-11.70%**
Change	**-290**	**-733**	**-$6,391.84**	**$1.52**	**$0.04**	**-4,646**	**-20,439**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Ophthalmic Allergy Medications



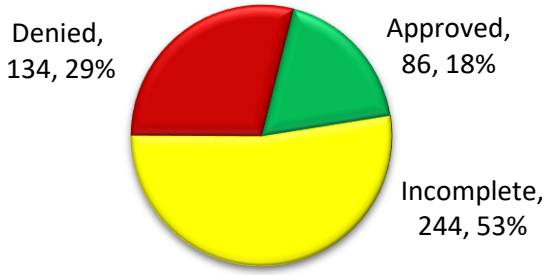
Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 464 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2018. 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.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[107]

- Pataday® (olopatadine 0.2%): May 2024
- Bepreve® (bepotastine): September 2024
- Lastacaft® (alcaftadine): December 2027
- Pazeo® (olopatadine 0.1%): May 2032
- Zerviate™ (cetirizine): January 2033

Recommendations

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

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
CROMOLYN PRODUCTS					
CROMOLYN SOD SOL 4%	388	304	$5,902.68	$0.45	$15.21
SUBTOTAL	**388**	**304**	**$5,902.68**	**$0.45**	**$15.21**
KETOTIFEN PRODUCTS					
KETOTIF FUM DRO 0.025%	2,715	2,083	$40,775.32	$0.48	$15.02
ALAWAY DRO 0.025%	1,232	886	$18,365.50	$0.40	$14.91
ALAWAY CHILD DRO 0.025%	13	13	$209.62	$0.54	$16.12
EYE ITCH SOL RELIEF 0.025%	6	6	$106.81	$0.59	$17.80
EYE ITCH REL DRO 0.025%	2	2	$34.93	$0.58	$17.47
SUBTOTAL	**3,968**	**2,990**	**$59,492.18**	**$0.45**	**$14.99**
TIER-1 SUBTOTAL	**4,356**	**3,294**	**$65,394.86**	**$0.45**	**$15.01**
TIER-2 PRODUCTS					
AZELASTINE PRODUCTS					
AZELASTINE DRO 0.05%	39	19	$927.10	$0.77	$23.77

[107] 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 01/2019. Last accessed 02/26/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	**39**	**19**	**$927.10**	**$0.77**	**$23.77**
OLOPATADINE PRODUCTS					
OLOPATADINE SOL 0.1%	171	65	$5,324.75	$1.09	$31.14
SUBTOTAL	**171**	**65**	**$5,324.75**	**$1.09**	**$31.14**
EPINASTINE PRODUCTS					
EPINASTINE DRO 0.05%	2	2	$88.97	$1.48	$44.49
SUBTOTAL	**2**	**2**	**$88.97**	**$1.48**	**$44.49**
TIER-2 SUBTOTAL	**212**	**86**	**$6,340.82**	**$1.03**	**$29.91**
TIER-3 PRODUCTS					
ALCAFTADINE PRODUCTS					
LASTACAFT SOL 0.25%	3	1	$615.53	$6.84	$205.18
SUBTOTAL	**3**	**1**	**$615.53**	**$6.84**	**$205.18**
BEPOTASTINE PRODUCTS					
BEPREVE DRO 1.5%	1	1	$388.52	$12.95	$388.52
SUBTOTAL	**1**	**1**	**$388.52**	**$12.95**	**$388.52**
OLOPATADINE PRODUCTS					
PAZEO DRO 0.7%	99	30	$19,490.32	$6.55	$196.87
OLOPATADINE SOL 0.2%	15	2	$1,163.80	$2.74	$77.59
SUBTOTAL	**114**	**32**	**$20,654.12**	**$6.07**	**$181.18**
TIER-3 SUBTOTAL	**118**	**34**	**$21,658.17**	**$6.15**	**$183.51**
TOTAL	**4,686**	**3,339***	**$93,393.85**	**$0.61**	**$19.93**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
Fiscal Year 2018 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/polymyxin B/gramicidin (AK-Spore®)		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™, Roymcin®)	ciprofloxacin (Ciloxan®)
gentamicin (Gentak®)	sodium sulfacetamide (Bleph-10®, Sodium Sulamyd®)
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

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

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

Ocular Antibiotic Tier-2 Approval Criteria:

1. An approved indication/suspected infection by 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.

Ocular Antibiotic Tier-3 Approval Criteria:

1. An approved indication/suspected infection by 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.

Antibiotic/Steroid Combination Tier-2 Approval Criteria:

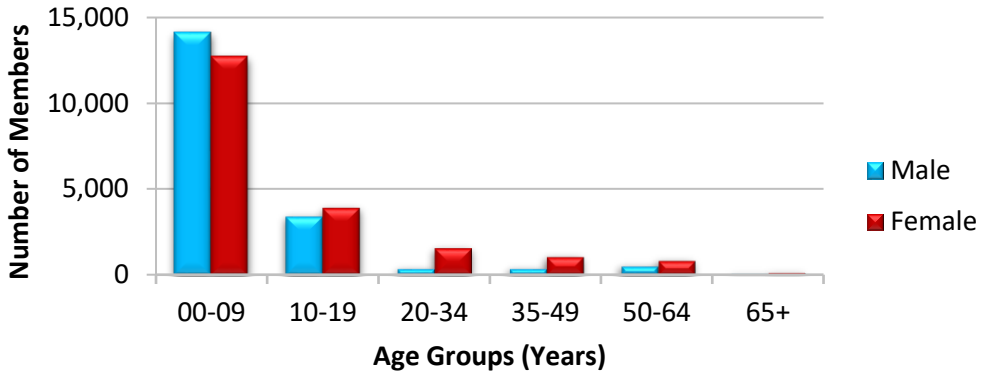
1. Prescription written by optometrists/ophthalmologists; or
2. When requested medication is being used for pre/post-operative prophylaxis.

Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2018

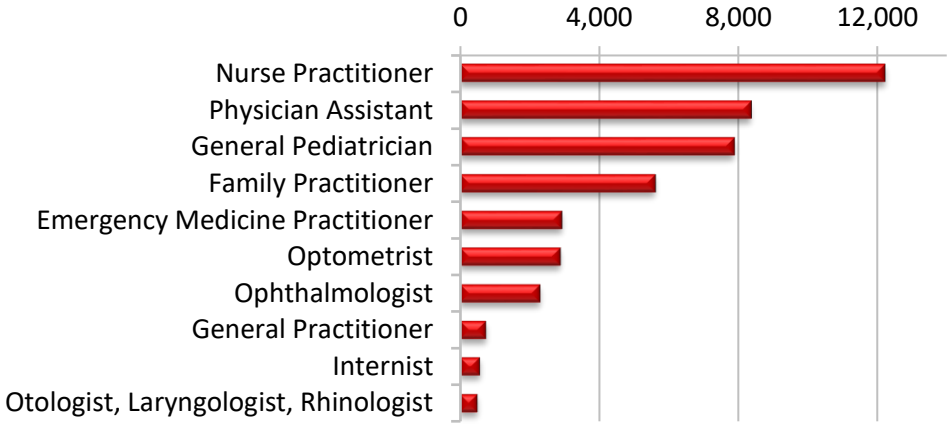
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	39,618	46,518	$945,792.23	$20.33	$1.71	309,703	552,066
2018	39,020	45,840	$928,167.11	$20.25	$1.63	303,134	570,909
% Change	**-1.50%**	**-1.50%**	**-1.90%**	**-0.40%**	**-4.70%**	**-2.10%**	**3.40%**
Change	**-598**	**-678**	**-$17,625.12**	**-$0.08**	**-$0.08**	**-6,569**	**18,843**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Ophthalmic Antibiotic Medications



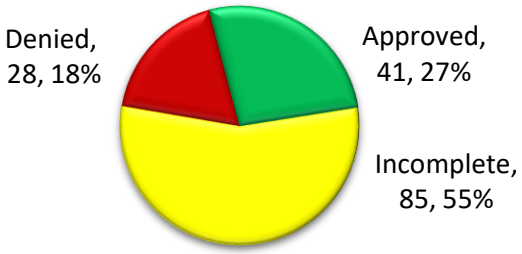
Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims



Prior Authorization of Ophthalmic Antibiotic Medications

There were 154 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[108]

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

Recommendations

The College of Pharmacy does not recommend any changes to the current Ophthalmic Antibiotics/Steroid Combination Products Product Based (PBPA) criteria.

[108] 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 01/2019. Last accessed 02/26/2019.

Utilization Details of Ophthalmic Antibiotic Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OCULAR ANTIBIOTIC LIQUIDS						
TIER-1						
POLYMYXIN B/ SOL TRIMETHP	12,113	11,516	$166,536.52	$0.82	$13.75	17.94%
OFLOXACIN DRO 0.3% OP	6,986	6,370	$179,283.35	$2.17	$25.66	19.32%
TOBRAMYCIN SOL 0.3% OP	4,610	4,297	$65,259.03	$1.32	$14.16	7.03%
GENTAMICIN SOL 0.3% OP	4,383	4,124	$58,339.36	$1.20	$13.31	6.29%
CIPROFLOXACN SOL 0.3% OP	2,023	1,912	$28,187.74	$1.36	$13.93	3.04%
SULFACET SOD SOL 10% OP	1,054	1,022	$43,852.46	$1.99	$41.61	4.72%
SOD SULFACET SOL 10% OP	522	512	$22,940.87	$2.77	$43.95	2.47%
TRIMETHOPRIM SOL POLYMYXN	313	308	$5,003.20	$1.23	$15.98	0.54%
NEO/POLY/GRA SOL OP	205	197	$10,338.06	$3.73	$50.43	1.11%
TOBREX OIN 0.3% OP	124	122	$25,357.68	$24.01	$204.50	2.73%
BLEPH-10 SOL 10% OP	26	26	$715.54	$1.74	$27.52	0.08%
TOBREX SOL 0.3% OP	2	2	$213.68	$3.89	$106.84	0.02%
SUBTOTAL	**32,361**	**30,408**	**$606,027.49**	**$1.37**	**$18.73**	**65.29%**
TIER-2						
LEVOFLOXACIN SOL 0.5%	3	3	$123.16	$2.28	$41.05	0.01%
SUBTOTAL	**3**	**3**	**$123.16**	**$2.28**	**$41.05**	**0.01%**
TIER-3						
MOXIFLOXACIN SOL HCL 0.5%	310	218	$18,791.43	$4.51	$60.62	2.02%
BESIVANCE SUS 0.6%	140	115	$21,850.35	$7.28	$156.07	2.35%
GATIFLOXACIN SOL 0.5%	58	49	$4,477.50	$7.41	$77.20	0.48%
VIGAMOX DRO 0.5%	28	27	$4,401.51	$12.47	$157.20	0.47%
MOXEZA SOL 0.5%	21	16	$3,504.01	$10.55	$166.86	0.38%
AZASITE SOL 1%	19	7	$3,325.83	$6.63	$175.04	0.36%
SUBTOTAL	**576**	**432**	**$56,350.63**	**$6.29**	**$97.83**	**6.06%**
OCULAR ANTIBIOTIC OINTMENTS						
TIER-1						
ERYTHROMYCIN OIN OP	8,653	8,052	$127,449.40	$1.86	$14.73	13.73%
ERYTHROMYCIN OIN 5MG/GM	401	358	$5,972.87	$1.89	$14.89	0.64%
GENTAK OIN 0.3% OP	282	271	$6,215.73	$2.62	$22.04	0.67%
BACIT/POLYMY OIN OP	119	107	$2,435.34	$2.39	$20.47	0.26%
POLYCIN OIN OP	34	31	$692.41	$2.36	$20.37	0.07%
NEO-POLYCIN OIN OP	28	19	$895.73	$3.27	$31.99	0.10%
NEO/BAC/POLY OIN OP	23	21	$773.47	$3.28	$33.63	0.08%
AK-POLY-BAC OIN OP	1	1	$21.43	$2.14	$21.43	0.00%
SUBTOTAL	**9,541**	**8,860**	**$144,456.38**	**$1.90**	**$15.14**	**15.55%**
TIER-2						
BACITRACIN OIN OP	103	76	$9,830.61	$9.30	$95.44	1.06%
CILOXAN OIN 0.3% OP	16	5	$3,375.27	$18.24	$210.95	0.36%
PRED-G S.O.P OIN OP	1	1	$149.24	$21.32	$149.24	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	**120**	**82**	**$13,355.12**	**$10.69**	**$111.29**	**1.44%**
OCULAR ANTIBIOTIC/STEROID COMBINAITON PRODUCTS						
		TIER-1				
NEO/POLY/DEX SUS 0.1% OP	2,049	1,850	$41,339.38	$1.49	$20.18	4.45%
NEO/POLY/DEX OIN 0.1% OP	604	521	$11,380.61	$2.05	$18.84	1.23%
TOBRA/DEXAME SUS 0.3-0.1%	482	461	$34,280.78	$4.70	$71.12	3.69%
TOBRADEX SUS 0.3-0.1%	12	11	$1,868.57	$12.13	$155.71	0.20%
SULF/PRED NA SOL OP	2	2	$42.64	$2.03	$21.32	0.00%
SUBTOTAL	**3,149**	**2,845**	**$88,911.98**	**$2.18**	**$28.23**	**9.57%**
		TIER-2				
TOBRADEX OIN 0.3-0.1%	53	49	$11,256.70	$19.01	$212.39	1.21%
ZYLET SUS 0.5-0.3%	19	15	$4,141.97	$12.36	$218.00	0.45%
TOBRADEX ST SUS 0.3-0.05	12	12	$2,704.11	$15.54	$225.34	0.29%
BLEPHAMIDE SUS OP 10-0.2%	4	4	$604.26	$11.40	$151.07	0.07%
NEO/POLY/HC SUS OP	2	2	$235.31	$12.38	$117.66	0.03%
SUBTOTAL	**90**	**82**	**$18,942.35**	**$16.15**	**$210.47**	**2.05%**
TOTAL	**45,840**	**39,020***	**$928,167.11**	**$1.63**	**$20.25**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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-infectives cannot be used must be provided; and
5. A quantity limit of 1 vial per treatment course will apply.

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)	finafloxacin (Xtoro®)	
neomycin/colistin/HC/ thonzonium (Coly-Mycin® S)	neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	
	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.

Utilization of Otic Anti-Infective Medications: Fiscal Year 2018

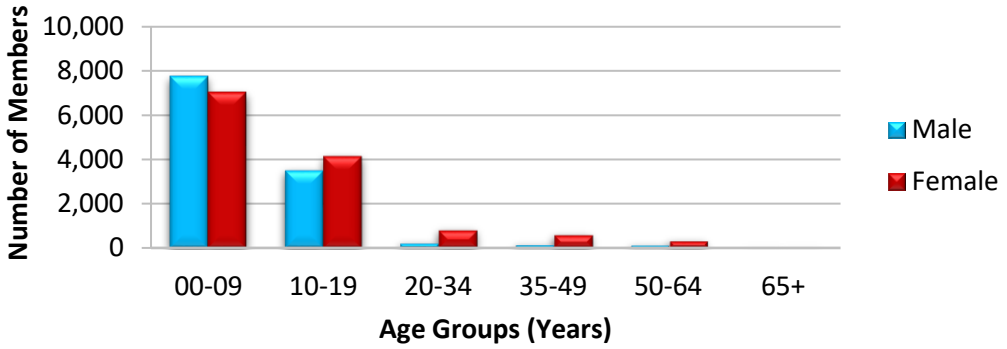
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	23,073	27,985	$5,450,716.84	$194.77	$17.61	216,309	309,579
2017	24,547	29,805	$6,036,607.96	$202.54	$18.83	228,171	320,530
% Change	**6.40%**	**6.50%**	**10.70%**	**4.00%**	**6.90%**	**5.50%**	**3.50%**
Change	**1,474**	**1,820**	**$585,891.12**	**$7.77**	**$1.22**	**11,862**	**10,951**

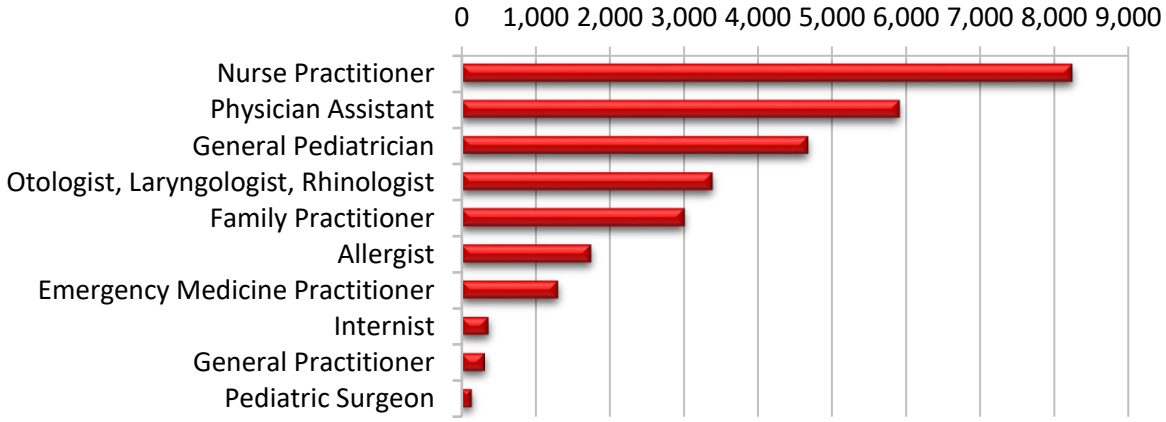
Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

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

Demographics of Members Utilizing Otic Anti-Infective Medications

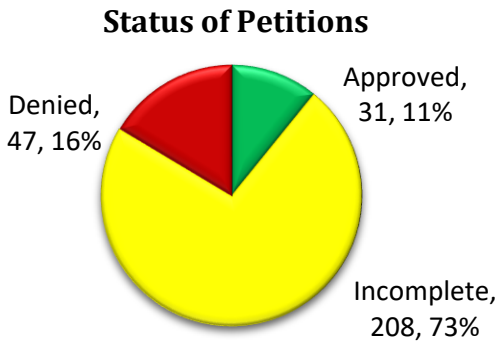


Top Prescriber Specialties of Otic Anti-Infective Medications by Number of Claims



Prior Authorization of Otic Anti-Infective Medications

There were 286 prior authorization requests submitted for otic anti-infective medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates[109]

Anticipated Patent Expiration(s):

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Xtoro® (finafloxacin): November 2033
- Otiprio® (ciprofloxacin): July 2035

Recommendations

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

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS						
CIPRODEX SUS 0.3-0.1% OTIC	28,619	23,675	$5,814,284.09	1.21	$19.52	$203.16
CIPRO HC SUS 0.2-1% OTIC	589	562	$165,461.48	1.05	$18.23	$280.92
ACETIC ACID SOL 2% OTIC	344	319	$10,416.60	1.08	$0.98	$30.28
COLY-MYCIN S SUS OTIC	225	207	$44,699.36	1.09	$16.85	$198.66
TIER-1 SUBTOTAL	**29,777**	**24,538**	**$6,034,861.53**	**1.21**	**$18.85**	**$202.67**
TIER-2 PRODUCTS						
OFLOXACIN DRO 0.3% OTIC	13	12	$787.11	1.08	$4.95	$60.55
NEO/POLY/HC SUS 1% OTIC	8	8	$543.83	1	$6.11	$67.98
NEO/POLY/HC SOL 1% OTIC	6	6	$339.81	1	$5.86	$56.64
TIER-2 SUBTOTAL	**27**	26	**$1,670.75**	**1.04**	**$5.46**	$61.88
SPECIAL PA PRODUCTS						
HC/ACET ACID SOL 1-2% OTIC	1	1	$75.68	1	$5.05	$75.68
SPECIAL PA SUBTOTAL	**1**	**1**	**$75.68**	**1**	**$5.05**	**$75.68**
TOTAL	**29,805**	**24,547***	**$6,036,607.96**	**1.21**	**$18.83**	**$202.54**

*Total number of unduplicated members.
Tier-1 products may participate in supplemental rebates; therefore, costs shown do not reflect net costs.

[109] 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 11/2018. Last accessed 01/11/2019.

Fiscal Year 2018 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2018 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®.

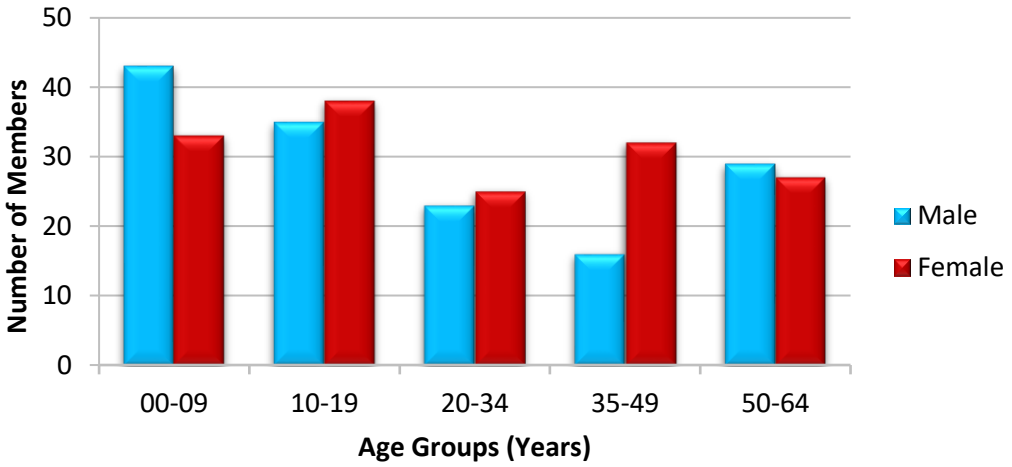
Utilization of Pancreatic Enzymes: Fiscal Year 2018

Pancreatic Enzymes Comparison of Fiscal Years: Pharmacy Claims

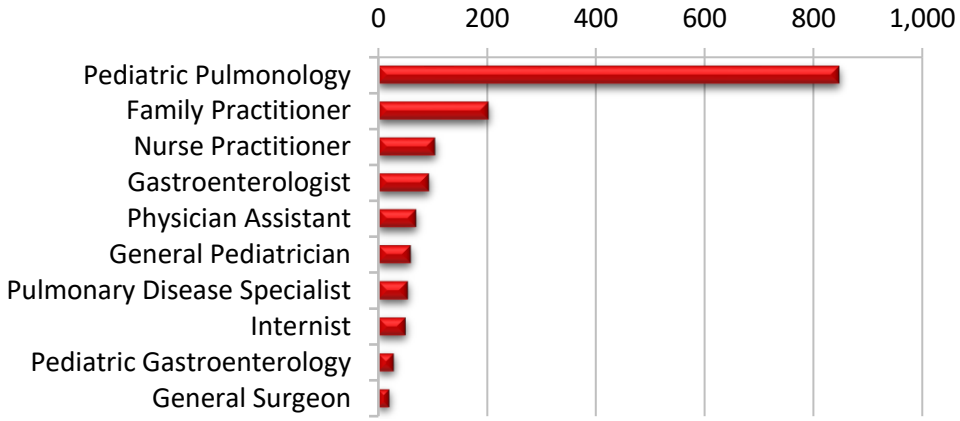
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	322	1,614	$2,469,781.19	$1,530.22	$52.93	546,541	46,659
2018	301	1,596	$2,594,038.12	$1,625.34	$56.97	539,492	45,532
% Change	**-6.50%**	**-1.10%**	**5.00%**	**6.20%**	**7.60%**	**-1.30%**	**-2.40%**
Change	**-21**	**-18**	**$124,256.93**	**$95.12**	**$4.04**	**-7,049**	**-1,127**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Pancreatic Enzymes



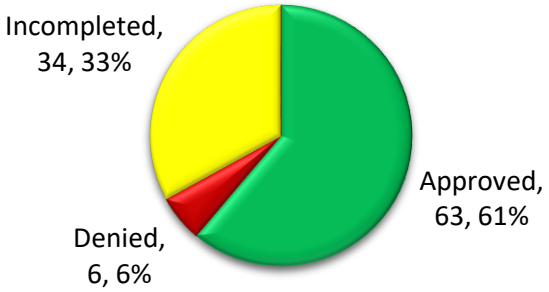
Top Prescriber Specialties of Pancreatic Enzymes by Number of Claims



Prior Authorization of Pancreatic Enzymes

There were 103 prior authorization requests submitted for pancreatic enzymes during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Patent Expiration(s):[110]

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

Recommendations

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

[110] 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 03/06/2019.

Utilization Details of Pancreatic Enzymes: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
CREON®						
CREON CAP 24000 UNIT	315	76	$590,745.35	$65.63	$1,875.38	22.77%
CREON CAP 36000 UNIT	254	63	$565,226.26	$77.48	$2,225.30	21.79%
CREON CAP 12000 UNIT	217	57	$191,444.26	$30.60	$882.23	7.38%
CREON CAP 6000 UNIT	74	16	$27,726.45	$13.43	$374.68	1.07%
CREON CAP 3000 UNIT	16	9	$2,515.98	$6.18	$157.25	0.10%
SUBTOTAL	**876**	**221**	**$1,377,658.30**	**$55.06**	**$1,572.67**	**53.11%**
ZENPEP®						
ZENPEP CAP 20000 UNIT	85	15	$156,345.86	$63.66	$1,839.36	6.03%
ZENPEP CAP 25000 UNIT	83	19	$231,965.41	$97.34	$2,794.76	8.94%
ZENPEP CAP 5000 UNIT	82	23	$30,315.90	$13.71	$369.71	1.17%
ZENPEP CAP 10000 UNIT	67	14	$42,491.82	$22.70	$634.21	1.64%
ZENPEP CAP 15000 UNIT	66	15	$90,319.83	$49.06	$1,368.48	3.48%
ZENPEP CAP 40000 UNIT	38	11	$85,768.45	$74.45	$2,257.06	3.31%
ZENPEP CAP 40000 UNIT	23	10	$74,827.11	$112.18	$3,253.35	2.88%
ZENPEP CAP 25000 UNIT	16	10	$35,961.76	$82.29	$2,247.61	1.39%
ZENPEP CAP 3000 UNIT	5	3	$2,198.99	$16.29	$439.80	0.08%
SUBTOTAL	**465**	**120**	**$750,195.13**	**$57.03**	**$1,613.32**	**28.92%**
PERTZYE®						
PERTZYE CAP 16000 UNIT	176	30	$336,352.55	$66.00	$1,911.09	12.97%
PERTZYE CAP 8000 UNIT	43	11	$34,912.75	$28.16	$811.92	1.35%
PERTZYE CAP 24000 UNIT	20	5	$86,975.80	$157.28	$4,348.79	3.35%
SUBTOTAL	**239**	**46**	**$458,241.10**	**$66.52**	**$1,917.33**	**17.67%**
VIOKACE®						
VIOKACE TAB 10440 UNIT	9	1	$6,119.47	$22.66	$679.94	0.24%
VIOKACE TAB 20880 UNIT	1	1	$1,054.17	$35.14	$1,054.17	0.04%
SUBTOTAL	**10**	**2**	**$7,173.64**	**$23.91**	**$717.36**	**0.28%**
PANCREAZE®						
PANCREAZE CAP 4200 UNIT	6	1	$769.95	$4.67	$128.33	0.03%
SUBTOTAL	**6**	**1**	**$769.95**	**$4.67**	**$128.33**	**0.03%**
TOTAL	**1,596**	**301**	**$2,594,038.12**	**$56.97**	**$1,625.34**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Pediculicide Medications	
Tier-1	**Tier-2**
Covered OTC Lice Medications	lindane shampoo
Sklice® (ivermectin lotion)	Ovide® (malathion)
Natroba® (spinosad suspension)	

Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
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 one individual package size for a 7-day supply.

Pediculicide Medications Tier-2 Approval Criteria:

1. Trials with all available Tier-1 medication(s) with inadequate response or adverse effect; and
2. Requested medication must be age-appropriate.
3. 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®) Cream & Lotion:**
   a. Diagnosis of scabies; and
   b. Member must be at least 18 years of age; and
   c. Member must have used permethrin 5% cream in the past 7 to 14 days with inadequate results; and
   d. For authorization of Crotan® a patient-specific, clinically significant reason why the member cannot use Eurax® is required; and
   e. 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.
   c. The brand formulation is preferred. Member's requesting the generic formulation of Natroba® (spinosad) require a patient-specific, clinically significant reason why the brand formulation cannot be used.

Utilization of Pediculicide Medications: Fiscal Year 2018

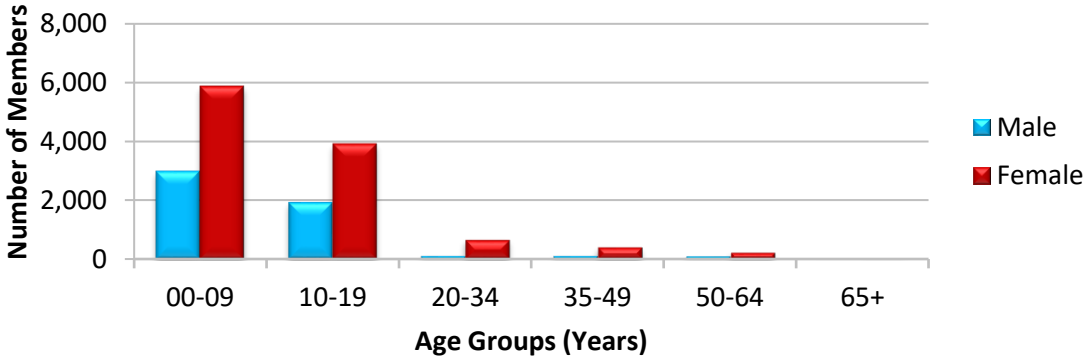
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	18,102	25,722	$3,859,513.95	$150.05	$16.39	2,114,248	235,428
2018	16,309	23,231	$4,081,424.56	$175.69	$19.03	2,075,248	214,459
% Change	**-9.90%**	**-9.70%**	**5.70%**	**17.10%**	**16.10%**	**-1.80%**	**-8.90%**
Change	**-1,793**	**-2,491**	**$221,910.61**	**$25.64**	**$2.64**	**-39,000**	**-20,969**

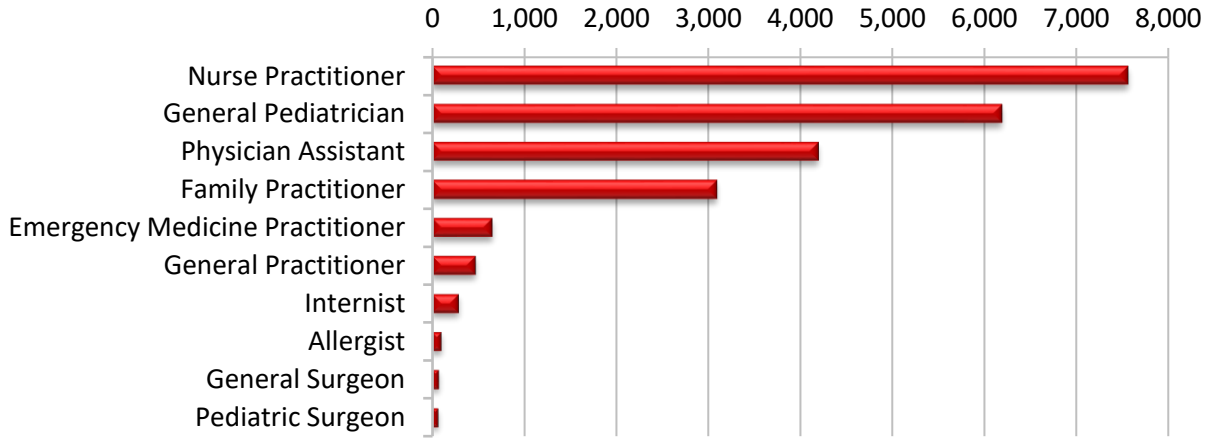
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

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

Demographics of Members Utilizing Pediculicide Medications



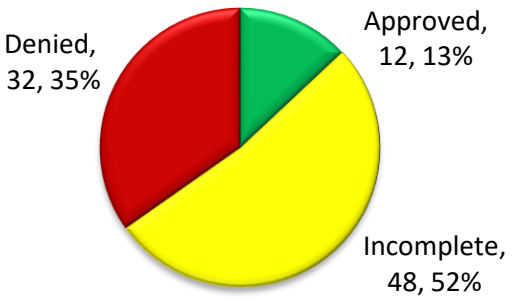
Top Prescriber Specialties of Pediculicide Medications by Number of Claims



Prior Authorization of Pediculicide Medications

There were 92 prior authorization requests submitted for pediculicide medications during fiscal year 2018. 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.

Status of Petitions



Market News and Updates[111,112]

Anticipated Patent Expiration(s):

- Natroba® (spinosad): July 2023
- Ovide® (malathion): August 2026
- Sklice® (ivermectin): October 2027

Pipeline:

- **Xeglyze® (abametapir):** Abametapir, a metalloproteinase enzyme inhibitor, has shown efficacy in 2 unpublished, randomized, double-blind, vehicle-controlled 2016 trials. A single treatment with abametapir lotion 0.74% was 81 to 88% effective in eradicating

[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 11/2018. Last accessed 01/14/2019.

[112] Medical Letter Staff. Drugs for Head Lice. *The Medical Letter*. 2016; 58(1508) 150-152.

lice. In a study of ovicidal efficacy, 100% of abametapir-treated eggs failed to hatch. Metalloproteinase enzymes are needed for both egg development and survival of hatched lice. No updates are available on product submission to the U.S. Food and Drug Administration (FDA).

Recommendations

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

Utilization Details of Pediculicide Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 PRODUCTS					
PERMETHRIN PRODUCTS					
PERMETHRIN CRE 5%	10,372	7,965	$535,645.58	1.3	$51.64
LICE TREATMENT LIQ 1%	661	502	$10,791.61	1.32	$16.33
LICE TREATMENT LOT 1%	491	359	$7,094.68	1.37	$14.45
SUBTOTAL	**11,524**	**8,753**	**$553,531.87**	**1.32**	**$48.03**
IVERMECTIN PRODUCTS					
SKLICE LOT 0.5%	8,761	6,187	$2,894,794.20	1.42	$330.42
SUBTOTAL	**8,761**	**6,187**	**$2,894,794.20**	**1.42**	**$330.42**
SPINOSAD PRODUCTS					
SPINOSAD SUS 0.9%	2,168	1,628	$437,360.21	1.33	$201.73
NATROBA SUS 0.9%	775	617	$195,072.01	1.26	$251.71
SUBTOTAL	**2,943**	**2,206**	**$632,432.22**	**1.33**	**$214.89**
TIER-1 SUBTOTAL	**23,228**	**16,307**	**$4,080,758.29**	**1.42**	**$175.68**
TIER-2 PRODUCTS					
MALATHION PRODUCTS					
MALATHION LOT 0.5%	3	3	$666.27	1	$222.09
SUBTOTAL	**3**	**3**	**$666.27**	**1**	**$222.09**
TIER-2 SUBTOTAL	**3**	**3**	**$666.27**	**1**	**$222.09**
TOTAL	**25,722**	**18,102***	**$3,859,513.95**	**1.42**	**$150.05**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

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

Fiscal Year 2018 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Generic calcium acetate containing products, Fosrenol® (lanthanum carbonate 500mg and 750mg chewable tablets), PhosLo® (calcium acetate gelcaps), Phoslyra® (calcium acetate oral solution), Renagel® (sevelamer hydrochloride tablets), and Renvela® (sevelamer carbonate tablets and packets 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; 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.
3. A quantity limit of 12 tablets per day will apply based on maximum recommended dose.

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.
3. For Auryxia®, a quantity limit of 12 tablets per day will apply.

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

1. An FDA approved diagnosis of hyperphosphatemia in 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; 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.

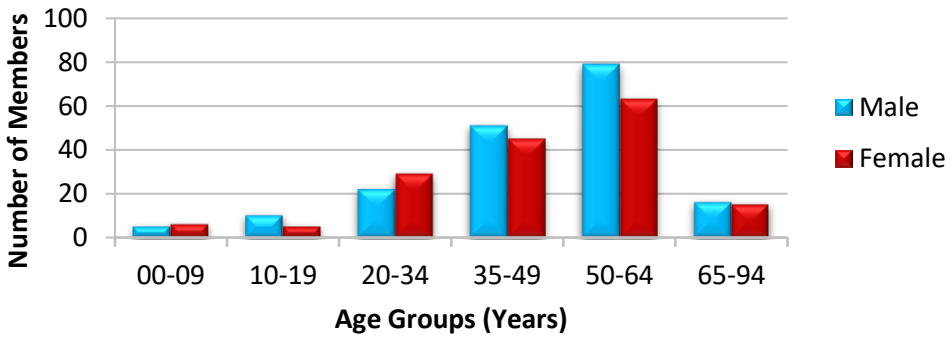
Utilization of Phosphate Binders: Fiscal Year 2018

Phosphate Binders Comparison of Fiscal Years

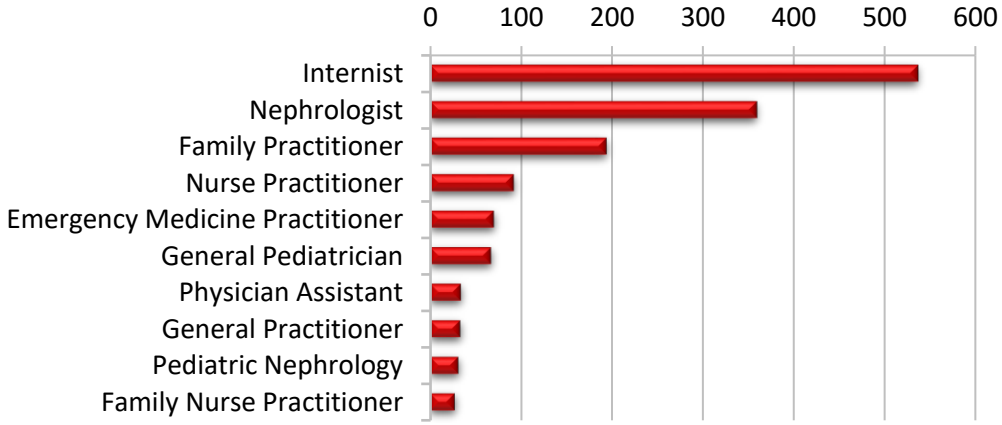
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	341	1,470	$1,239,441.01	$843.16	$29.43	350,973	42,116
2018	346	1,502	$914,991.72	$609.18	$21.25	365,075	43,066
% Change	**1.50%**	**2.20%**	**-26.20%**	**-27.80%**	**-27.80%**	**4.00%**	**2.30%**
Change	**5**	**32**	**-$324,449.29**	**-$233.98**	**-$8.18**	**14,102**	**950**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Phosphate Binders



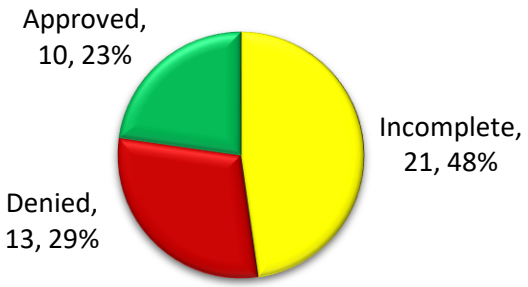
Top Prescriber Specialties of Phosphate Binders by Number of Claims



Prior Authorization of Phosphate Binders

There were 44 prior authorization requests submitted for phosphate binders during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Patent Expiration(s):[113]

- Renagel® (sevelamer hydrochloride): October 2020
- PhosLo® (calcium acetate): July 2021
- Velphoro® (sucroferric oxyhydroxide): January 2030
- Phoslyra® (calcium acetate): February 2030
- Auryxia® (ferric citrate): July 2030
- Fosrenol® (lanthanum carbonate): December 2030
- Renvela® (sevelamer carbonate): December 2030

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

- **February 2019:** The FDA approved the first generic formulation of Renagel® (sevelamer hydrochloride) to control serum phosphorus in patients with chronic kidney disease on dialysis.[114]

Recommendations

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

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[113] 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 03/06/2019.

[114] Renagel® (sevelamer hydrochloride) – First-time generic. *OptumRx*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_renagel_2019-0213.pdf. Last accessed 03/11/2019.

Utilization Details of Phosphate Binders: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
SEVELAMER CARBONATE PRODUCTS						
SEVELAMER TAB 800MG	485	143	$292,261.40	$20.87	$602.60	31.94%
RENVELA TAB 800MG	178	68	$285,054.57	$55.56	$1,601.43	31.15%
SEVELAMER POW 2.4GM	37	8	$38,126.78	$41.58	$1,030.45	4.17%
SEVELAMER POW 0.8GM	20	9	$46,497.49	$71.21	$2,324.87	5.08%
RENVELA POW 2.4GM	16	6	$26,314.51	$55.40	$1,644.66	2.88%
RENVELA POW 0.8GM	6	4	$8,025.63	$38.22	$1,337.61	0.88%
SUBTOTAL	**742**	**238**	**$696,280.38**	**$32.56**	**$938.38**	**76.10%**
CALCIUM ACETATE PRODUCTS						
CALC ACETATE CAP 667MG	609	173	$33,788.48	$1.91	$55.48	3.69%
CALC ACETATE TAB 667MG	15	13	$1,071.61	$2.44	$71.44	0.12%
PHOSLYRA SOL 667MG/5ML	14	2	$4,354.82	$12.10	$311.06	0.48%
SUBTOTAL	**638**	**188**	**$39,214.91**	**$2.12**	**$61.47**	**4.29%**
LANTHANUM CARBONATE PRODUCTS						
FOSRENOL CHW 500MG	22	3	$25,122.01	$126.24	$1,141.91	2.75%
LANTHANUM CHW 500MG	10	3	$19,585.80	$65.29	$1,958.58	2.14%
LANTHANUM CHW 750MG	3	1	$7,803.48	$86.71	$2,601.16	0.85%
FOSRENOL CHW 1000MG	2	1	$3,475.54	$57.93	$1,737.77	0.38%
LANTHANUM CHW 1000MG	1	1	$1,629.68	$54.32	$1,629.68	0.18%
SUBTOTAL	**38**	**9**	**$57,616.51**	**$84.85**	**$1,516.22**	**6.30%**
FERRIC CITRATE PRODUCTS						
AURYXIA TAB 210MG	31	5	$29,497.91	$31.45	$951.55	3.22%
SUBTOTAL	**31**	**5**	**$29,497.91**	**$31.45**	**$951.55**	**3.22%**
SUCROFERRIC OXYHYDROXIDE PRODUCTS						
VELPHORO CHW 500MG	27	10	$55,093.77	$68.02	$2,040.51	6.02%
SUBTOTAL	**27**	**10**	**$55,093.77**	**$68.02**	**$2,040.51**	**6.02%**
SEVELAMER HYDROCHLORIDE PRODUCTS						
RENAGEL TAB 800MG	25	8	$37,236.74	$51.29	$1,489.47	4.07%
RENAGEL TAB 400MG	1	1	$51.50	$25.75	$51.50	0.01%
SUBTOTAL	**26**	**9**	**$37,288.24**	**$51.22**	**$1,434.16**	**4.08%**
TOTAL	**1,502**	**346***	**$914,991.72**	**$21.25**	**$609.18**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Prednisolone Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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).

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

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

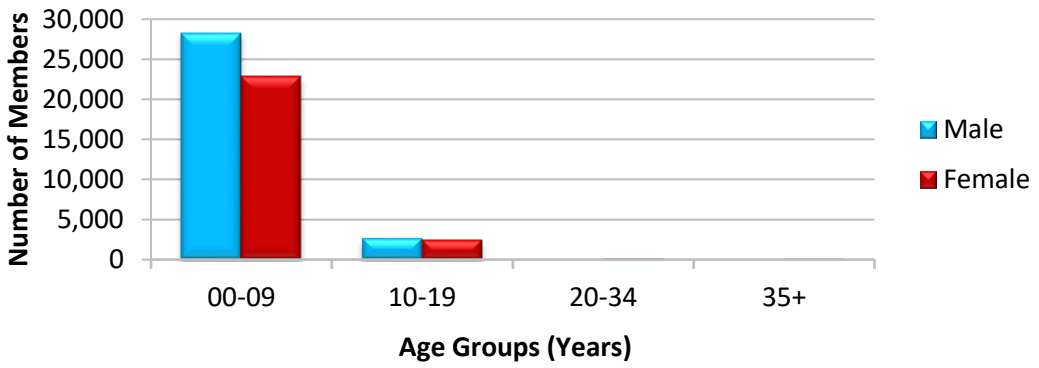
Utilization of Prednisolone Special Formulations: Fiscal Year 2018

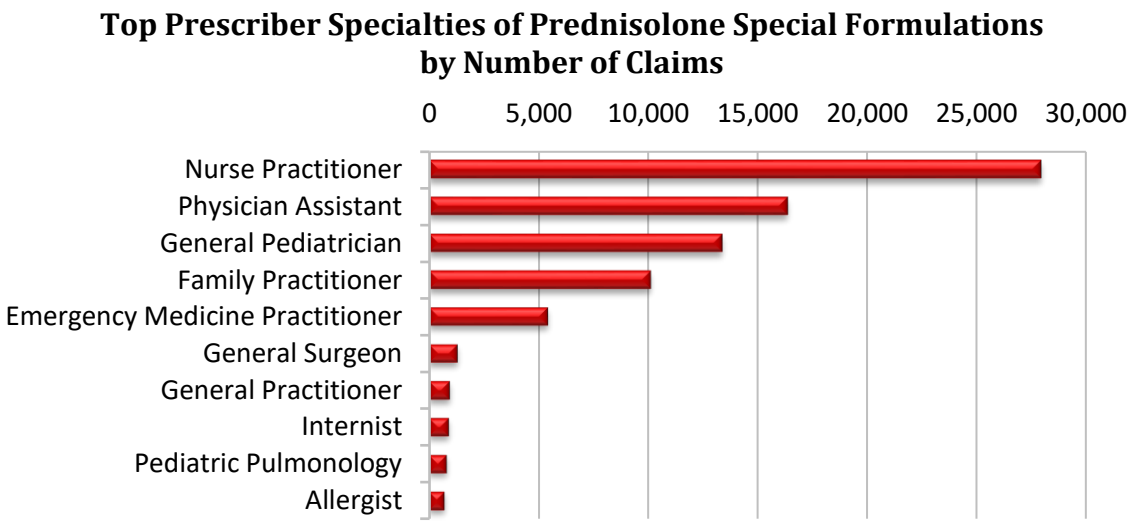
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	55,485	78,031	$1,074,880.58	$13.78	$2.55	2,878,102	421,223
2018	56,478	80,635	$1,291,605.13	$16.02	$3.00	2,850,902	431,079
% Change	**1.80%**	**3.30%**	**20.20%**	**16.30%**	**17.60%**	**-0.90%**	**2.30%**
Change	**993**	**2,604**	**$216,724.55**	**$2.24**	**$0.45**	**-27,200**	**9,856**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

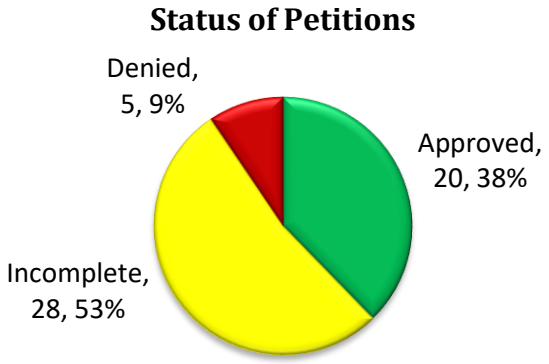
Demographics of Members Utilizing Prednisolone Special Formulations





Prior Authorization of Prednisolone Special Formulations

There were 53 prior authorization requests submitted for prednisolone special formulations during fiscal year 2017. The following chart shows the status of the submitted petitions.



Recommendations

The College of Pharmacy recommends does not recommend any changes to the current prednisolone special formulation prior authorization criteria at this time.

Utilization Details of Prednisolone Special Formulations: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISOLONE ORALLY DISINTEGRATING PRODUCTS					
PREDNISOLONE TAB 15MG ODT	1,186	983	$118,069.42	1.21	$99.55
PREDNISOLONE TAB 10MG ODT	516	421	$41,232.54	1.23	$79.91
PREDNISOLONE TAB 30MG ODT	410	356	$43,412.83	1.15	$105.88
SUBTOTAL	**2,112**	**1,690**	**$202,714.79**	**1.25**	**$95.98**
PREDNISOLONE ORAL SOLUTION AND POWDER PRODUCTS					
PREDNISOLONE SOL 15MG/5ML	34,573	26,783	$429,315.78	1.29	$12.42

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISOLONE SYP 15MG/5ML	26,634	21,509	$311,067.03	1.24	$11.68
PREDNISOLONE SOL 15MG/5ML	12,302	10,303	$147,274.75	1.19	$11.97
PREDNISOLONE SOL 25MG/5ML	2,866	2,346	$117,614.82	1.22	$41.04
PRED SOD PHO SOL 5MG/5ML	2,148	1,955	$83,617.96	1.1	$38.93
SUBTOTAL	**78,523**	**55,387**	**$1,088,890.34**	**1.42**	**$13.87**
TOTAL	**80,635**	**56,478***	**$1,291,605.13**	**1.43**	**$16.02**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
Fiscal Year 2018 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/providers/rx.
- The SoonerCare prenatal vitamin category is modified throughout the fiscal year and adjusted for price fluctuations and supplemental rebate participation.

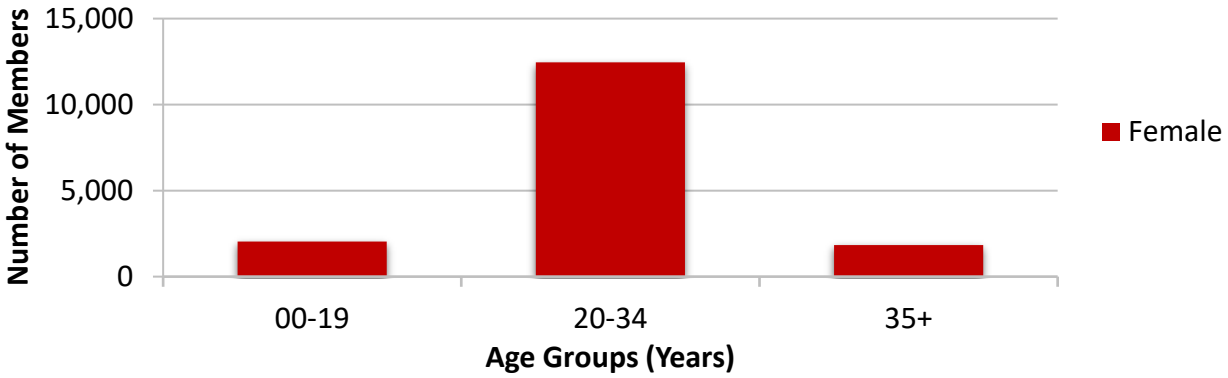
Utilization of Prenatal Vitamins: Fiscal Year 2018

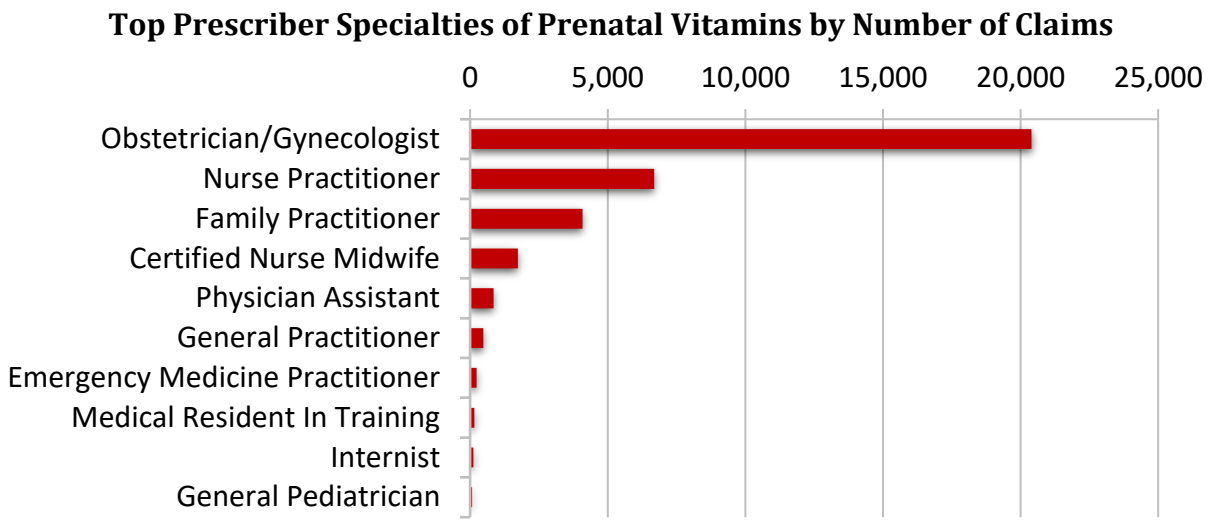
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	16,881	35,287	$2,226,148.25	$63.09	$1.47	1,698,230	1,509,524
2018	16,339	35,005	$2,743,347.85	$78.37	$1.84	1,684,347	1,493,396
% Change	**-3.20%**	**-0.80%**	**23.20%**	**24.20%**	**25.20%**	**-0.80%**	**-1.10%**
Change	**-542**	**-282**	**$517,199.60**	**$15.28**	**$0.37**	**-13,883**	**-16,128**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

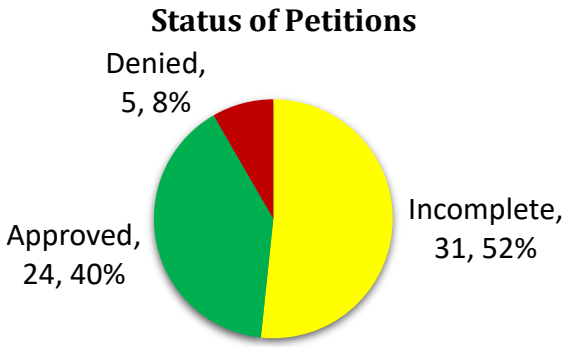
Demographics of Members Utilizing Prenatal Vitamins





Prior Authorization of Prenatal Vitamins

There were 60 prior authorization requests submitted for prenatal vitamins during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Recommendations

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

Utilization Details of Prenatal Vitamins: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
VITAFOL CAP ULTRA	7,496	3,294	$1,128,754.48	$3.94	$150.58	2.28
CONCEPT DHA CAP	5,637	2,822	$244,877.68	$1.02	$43.44	2.00
PNV PRENATAL TAB PLUS	3,712	2,129	$47,304.15	$0.29	$12.74	1.74
CITRANATAL MIS 90 DHA	2,672	1,256	$284,638.70	$3.44	$106.53	2.13
VOL-PLUS TAB	2,306	1,645	$63,495.87	$0.34	$27.54	1.40
CITRANATAL CAP HARMONY	2,175	962	$287,464.09	$3.57	$132.17	2.26
FOLIVANE-OB CAP	1,890	1,138	$74,483.08	$0.82	$39.41	1.66
TARON-C DHA CAP	1,474	745	$49,837.39	$0.86	$33.81	1.98

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
CONCEPT OB CAP	1,344	813	$60,815.97	$0.86	$45.25	1.65
VITAFOL CHW GUMMIES	891	458	$97,892.28	$2.95	$109.87	1.95
VITAFOL FE+ CAP	853	415	$94,965.39	$3.52	$111.33	2.06
CITRANATAL PAK ASSURE	782	333	$85,397.48	$3.55	$109.20	2.35
VIRT-C DHA CAP	525	299	$18,836.81	$0.87	$35.88	1.76
CITRANATAL PAK DHA	516	246	$54,083.39	$3.41	$104.81	2.10
PRENATAL VIT TAB LOW IRON	498	297	$4,528.32	$0.20	$9.09	1.68
VITAFOL-NANO TAB	362	167	$51,087.81	$4.09	$141.13	2.17
PROVIDA OB CAP	324	173	$14,750.45	$1.11	$45.53	1.87
PRENATAL TAB 27-1MG	291	162	$3,753.28	$0.33	$12.90	1.80
CITRANATAL MIS B-CALM	237	140	$20,507.11	$2.09	$86.53	1.69
COMPLETE NAT PAK DHA	197	76	$5,999.73	$0.98	$30.46	2.59
SE-NATAL 19 TAB	174	109	$5,169.41	$0.60	$29.71	1.60
VITAFOL-OB PAK +DHA	141	55	$17,095.19	$3.93	$121.24	2.56
PRENATA CHW 29-1MG	90	66	$1,602.57	$0.29	$17.81	1.36
CITRANATAL TAB RX	70	39	$7,746.89	$2.56	$110.67	1.79
COMPLETENATE CHW	63	45	$2,213.14	$0.60	$35.13	1.40
PREPLUS TAB 27-1MG	58	48	$897.56	$0.25	$15.48	1.21
SE-NATAL 19 CHW	50	31	$1,526.20	$0.76	$30.52	1.61
TRINATAL RX TAB 1	32	18	$623.35	$0.40	$19.48	1.78
VITAFOL-ONE CAP	31	25	$4,807.30	$4.11	$155.07	1.24
VOL-TAB RX TAB	25	10	$564.45	$0.50	$22.58	2.50
VITAFOL-OB TAB 65-1MG	24	18	$4,305.67	$3.88	$179.40	1.33
VP-GGR-B6 TAB PRENATAL	20	13	$995.49	$0.65	$49.77	1.54
PRENATAL PLS MIS MV + DHA	16	9	$345.47	$0.68	$21.59	1.78
VIRT NATE TAB	12	9	$416.64	$0.40	$34.72	1.33
SELECT-OB CHW	4	2	$507.00	$4.22	$126.75	2.00
NIVA-PLUS TAB	4	4	$89.40	$0.30	$22.35	1.00
ULTIMATECARE CAP ONE	4	1	$118.44	$0.99	$29.61	4.00
ENBRACE HR CAP	3	2	$706.60	$4.71	$235.53	1.50
SELECT-OB+ PAK DHA	1	1	$125.31	$4.18	$125.31	1.00
PNV TABS TAB 29-1MG	1	1	$18.31	$0.61	$18.31	1.00
TOTAL	**35,005**	**16,339***	**$2,743,347.85**	**$1.84**	**$78.37**	**2.14**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Procysbi® (Cysteamine Bitartrate)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Procysbi® (Cysteamine Bitartrate) Approval Criteria:

7. An FDA approved diagnosis of nephropathic cystinosis; and
8. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation Cystagon® (cysteamine bitartrate).

Utilization of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2018

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	1	$2,307.17	$2,307.17	$76.91	60	30
2018	1	2	$5,749.89	$2,874.94	$95.83	360	60
% Change	**0.00%**	**100.00%**	**149.20%**	**24.60%**	**24.60%**	**500.00%**	**100.00%**
Change	**0**	**1**	**$3,442.72**	**$567.77**	**$18.92**	**300**	**30**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Procysbi® (Cysteamine Bitartrate)

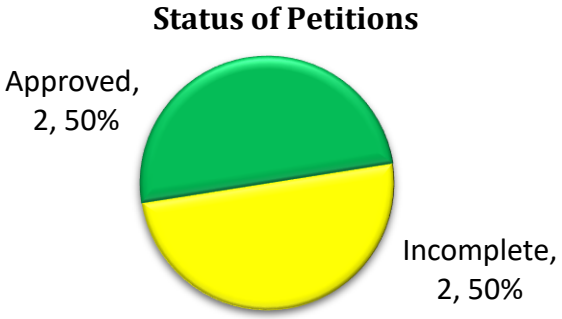
- Due to the limited number of members utilizing Procysbi® (cysteamine bitartrate) during fiscal year 2018, detailed demographic information could not be provided.

Top Prescriber Specialties of Procysbi® (Cysteamine Bitartrate) by Number of Claims

- The only prescriber listed on paid pharmacy claims for Procysbi® (cysteamine bitartrate) during fiscal year 2018 was a general pediatrician.

Prior Authorization of Procysbi® (Cysteamine Bitartrate)

There were 4 prior authorization requests submitted for Procysbi® (cysteamine bitartrate) during fiscal year 2018. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Exclusivity Expiration(s):[115]

- Procysbi® (cysteamine bitartrate): August 2036

Recommendations

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

[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/default.cfm?resetfields=1. Last revised 01/2019. Last accessed 02/28/2019.

Fiscal Year 2018 Annual Review of Pulmonary Hypertension Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Revatio® (Sildenafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist.
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 members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation.
4. A quantity limit of 224mL per 30 days (2 bottles) will apply.

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; 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; and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 of each of the following categories:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of chronic thromboembolic pulmonary hypertension (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.
6. A quantity limit of 90 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Previous failed trials of at least 1 of 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 of 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.
5. A quantity limit of 30 tablets per 30 days will apply.

Uptravi® (Selexipag) Tablets Approval Criteria:

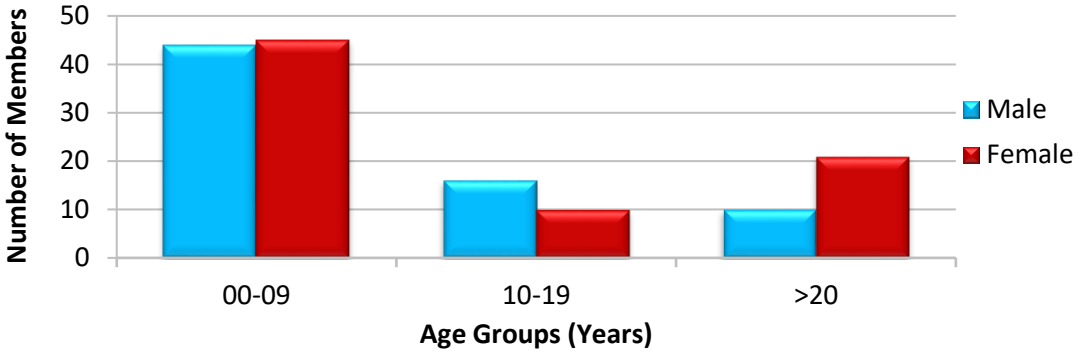
1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Previous failed trials of at least 1 of each of the following categories (alone or in combination):
    a. Revatio® (sildenafil), Adcirca® (tadalafil), or Adempas® (riociguat); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    c. Orenitram® (treprostinil); and
4. Medical supervision by a pulmonary specialist and/or cardiologist; and
5. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Utilization of Pulmonary Hypertension Medications: Fiscal Year 2018

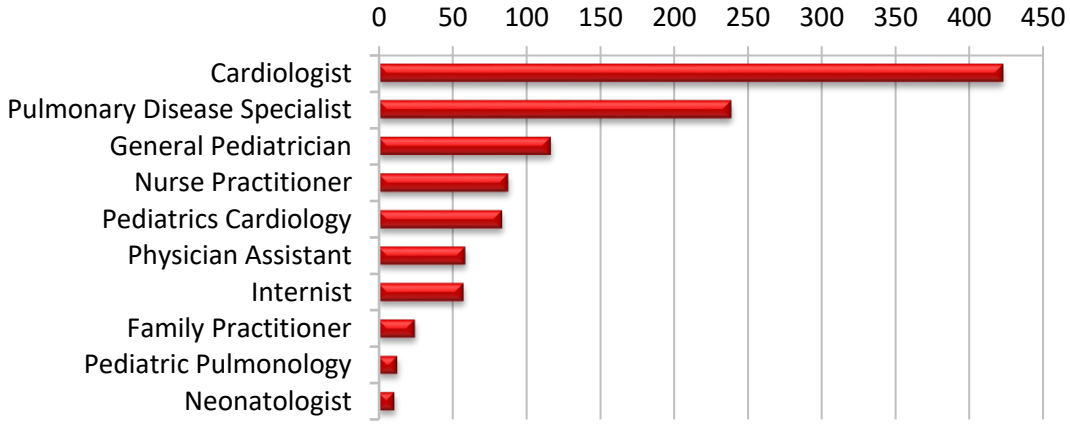
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	134	993	$5,546,598.80	$5,585.70	$187.42	85,541	29,594
2018	146	1,123	$6,546,381.40	$5,829.37	$192.67	96,537	33,977
% Change	**9.00%**	**13.10%**	**18.00%**	**4.40%**	**2.80%**	**12.90%**	**14.80%**
Change	**12**	**130**	**$999,782.60**	**$243.67**	**$5.25**	**10,996**	**4,383**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

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 435 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):[116]

- Adcirca® (tadalafil): May 2021

[116] 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 01/2019. Last accessed 03/01/2019.

- Adempas® (riociguat): December 2026
- Opsumit® (macitentan): April 2029
- Uptravi® (selexipag): August 2030
- Orenitram® (treprostinil): January 2031
- Letairis® (ambrisentan): October 2031

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

- **September 2017**: The FDA approved a new 32mg tablet for oral suspension for Tracleer® (bosentan) to support a new indication for use in pediatric patients 3 years of age and older with idiopathic pulmonary atrial hypertension (PAH), to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability. The tablet can be dispersed in a teaspoon of water before oral administration. The lower dosage and score lines on the tablets are designed to allow physicians to vary the prescribed dose by the weight of the patient. Tracleer® is also available in 62.5mg and 125mg film-coated oral tablets. [117]
- **August 2018:** The FDA approved Medtronic's Implantable System for Remodulin® (treprostinil), or ISR, to deliver Remodulin® to patients with PAH. Many patients are administered Remodulin® intravenously (IV) through the use of external infusion pumps. ISR is a fully implantable device designed to reduce patient burden and reduce complications such as infections. The FDA's approval of the pump and delivery device was based on data collected from the DelIVery for PAH clinical trial, which was conducted at 10 sites in the United States with 60 PAH patients successfully implanted with the device. Results from the trial indicated the device was effective at delivering Remodulin®, with a low rate of catheter-related complications and a high rate of patient satisfaction.[118]

Generic [Abbreviated New Drug Application (ANDA)] Approval(s):

- **August 2018:** The FDA approved the first generic version of Adcirca® (tadalafil) 20mg tablets. Mylan Pharmaceuticals received final approval for its ANDA and was awarded 180 days of marketing exclusivity.[119]

Pipeline:

- **August 2018:** The FDA granted Orphan Drug designation to Livantra® (trimetazidine) for the treatment of PAH. Livantra® (trimetazidine) is already an approved treatment outside the United States for treatment of angina pectoris. In March 2018, Livantra® also received Orphan Drug designation for the treatment of acute or chronic liver

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[117] Actelion Pharmaceuticals Inc. Actelion Receives FDA Approval of Tracleer® (Bosentan) for Use In Pediatric Patients with Pulmonary Arterial Hypertension. Available online at: https://www.jnj.com/media-center/press-releases/actelion-receives-fda-approval-of-tracleer-bosentan-for-use-in-pediatric-patients-with-pulmonary-arterial-hypertension. Issued 09/06/2017. Last accessed 03/06/2019.

[118] Mumal I. FDA Approves Medtronic's Implantable System for Remodulin® for Treatment of PAH. Pulmonary Hypertension News. Available online at: https://pulmonaryhypertensionnews.com/2018/08/01/fda-approves-medtronics-implantable-system-for-remodulin-treatment-pah/. Issued 08/01/2018. Last accessed 03/06/2019.

[119] Mylan Pharmaceuticals. Mylan Launches First Generic for Adcirca® Tablets. Available online at: http://newsroom.mylan.com/2018-08-13-Mylan-Launches-First-Generic-for-Adcirca-R-Tablets. Issued 08/13/2018. Last accessed 03/06/2019.

failure. Trimetazidine restores the activity of the enzyme pyruvate dehydrogenase, which has low levels in PAH. By doing so, the treatment induces a shift in the metabolism of glucose which prevents excessive cell growth proliferation inside blood vessels and restores cellular homeostasis. Trimetazidine's potential for treating PAH has been supported by preclinical studies in 2 mouse models of PAH, the drug was seen to significantly decrease pulmonary arterial pressure, reduced right heart ventricle thickness, and improve exercise capacity.[120]

- **October 2018:** Arena Pharmaceuticals announced positive data from a planned interim analysis of the ongoing open-label extension of a Phase 2 trial of its investigational drug candidate ralinepag, a next-generation, oral, selective, and potent prostacyclin receptor agonist in development for the treatment of PAH. The study was an open-label extension study evaluating the long-term safety, tolerability and efficacy of ralinepag in 45 patients who completed the Phase 2 randomized study. In the extension study, patients originally randomized to ralinepag continued on active therapy (N=30); patients randomized to placebo switched to ralinepag (N=15). Key efficacy measurements include PVR and 6-minute walk distance (6MWD). Patients who continued on ralinepag in the open-label extension had a median treatment duration of 1.8 years (range 1.2 to 3.4 years) at the time of right heart catheterization (RHC). In these patients, sustained improvements from baseline in the original study were observed for PVR (219 $dyn*s*cm^{-5}$ median reduction, P=0.002) and 6MWD (49.8 meters mean improvement; P=0.003). Patients switching from placebo to active drug had a median ralinepag treatment duration of 1.4 years (range 0.9 to 2.3 years) at the time of RHC. In these patients, a similar magnitude of improvement was observed for PVR (214 $dyn*s*cm^{-5}$ median reduction, P=0.206) and 6MWD (69.8 meters mean improvement; P=0.010). In both groups, these long-term changes in PVR and 6MWD were observed in a population where the majority of patients were already receiving dual combination PAH background therapy. In January 2019, Arena closed on the global license agreement with United Therapeutics.[121,122]
- **November 2018:** Tenax Therapeutics announced the Stanford University School of Medicine is the first clinical site for a Phase 2 trial testing levosimendan as a potential treatment for pulmonary hypertension (PH) associated with heart failure and preserved ejection fracture. 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). The therapy is not yet approved for use in the United States; however, in more than 60 other countries, levosimendan is used for the treatment of

[120] Pena A. FDA Grants Orphan Drug Status to Livantra® Repurposed for Treatment of PAH. *Pulmonary Hypertension News*. Available online at: https://pulmonaryhypertensionnews.com/2018/08/16/livantra-fda-orphan-drug-status-repurposed-for-pah-treatment/. Issued 08/16/2018. Last accessed 03/06/2019.

[121] Arena Pharmaceuticals. Arena Pharmaceuticals Reports Positive Long-Term Data from the Ongoing Open-Label Extension of the Phase 2 Trial Evaluating Ralinepag for Treatment of Pulmonary Arterial Hypertension. Available online at: http://invest.arenapharm.com/news-releases/news-release-details/arena-pharmaceuticals-reports-positive-long-term-data-ongoing. Issued 10/02/2018. Last accessed 03/04/2019.

[122] Arena Pharmaceuticals. Arena Pharmaceuticals Announces Closing of Global Licensure Agreement with United Therapeutics for Ralinepag. Available online at: http://invest.arenapharm.com/news-releases/news-release-details/arena-pharmaceuticals-announces-closing-global-license-agreement. Issued 01/24/2019. Last accessed 03/04/2019.

acute heart failure in hospitalized patients. The Phase 2 trial, HELP, is expected to recruit a total of 36 patients at about 12 to 15 different research institutions across the United States.[123]

Guideline Update(s):

- **January 2019:** Best practice recommendations (BPR) for the safe use of pharmacotherapies and a description of the pharmacist's role in the care of patients with PH titled *Development of best practice recommendations for the safe use of pulmonary hypertension pharmacotherapies using a modified Delphi method* was published in the *American Journal of Health-System Pharmacy*. The panel of PH experts reached consensus on 26 BPRs and accepted 25 of these with a strong level of recommendation. Categorized into 5 separate practice domains, the BPRs encompass inpatient practice, inpatient formulary management, ambulatory care practice, diagnostic and procedural areas, and PAH accreditation processes. The BPRs identify situations for which delineated procedures should exist to optimize PH medication safety and access but allow for individual sites to develop their own processes given differences in resources and personnel that exist at PAH-accredited centers of comprehensive care, regional clinical programs, and nonaccredited centers.[124,125]

Recommendations

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

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PHOSPHODIESTERASE-5 INHIBITOR (PDE-5)						
REVATIO SUS 10MG/ML	338	73	$2,901,797.19	$271.20	$8,585.20	44.33%
SILDENAFIL TAB 20MG	277	49	$8,609.31	$1.05	$31.08	0.13%
ADCIRCA TAB 20MG	165	19	$389,260.58	$76.55	$2,359.16	5.95%
SUBTOTAL	**780**	**141**	**$3,299,667.08**	**$137.49**	**$4,230.34**	**50.41%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
TRACLEER TAB 62.5MG	79	10	$271,336.55	$119.27	$3,434.64	4.14%
OPSUMIT TAB 10MG	63	7	$549,501.15	$290.74	$8,722.24	8.39%
LETAIRIS TAB 10MG	52	7	$481,006.97	$308.34	$9,250.13	7.35%
LETAIRIS TAB 5MG	20	3	$268,594.69	$447.66	$13,429.73	4.10%
TRACLEER TAB 32MG	10	3	$63,578.00	$227.06	$6,357.80	0.97%

[123] Iyer V. First Clinical Site Announced for Phase 2 Trial Testing Levosimendan for PH Linked to Heart Disease. *Pulmonary Hypertension News*. Available online at: https://pulmonaryhypertensionnews.com/2018/11/28/first-site-announced-levosimendan-phase-2-trial-ph-linked-heart-disease/. Issued 11/28/2018. Last accessed 03/11/2019.

[124] Smith Z, et al. Development of Best Practice Recommendations for the Safe Use of Pulmonary Hypertension Pharmacotherapies using a modified Delphi Method. *Am J Health Syst Pharm.* 2019; 76(3): 153-165.

[125] Best Practices for Safe Use of Pulmonary Hypertension Pharmacotherapies. Pulmonology Advisor. Available online at: https://www.pulmonologyadvisor.com/home/topics/pulmonary-hypertension/best-practices-for-safe-use-of-pulmonary-hypertension-pharmacotherapies/. Issued 02/19/2019. Last accessed 03/01/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TRACLEER TAB 125MG	2	1	$21,775.10	$362.92	$10,887.55	0.33%
SUBTOTAL	**226**	**31**	**$1,655,792.46**	**$248.43**	**$7,326.52**	**25.28%**
PROSTACYCLIN VASODILATORS						
ORENITRAM TAB 0.125MG	14	4	$20,479.85	$49.23	$1,462.85	0.31%
ORENITRAM TAB 0.25MG	14	3	$26,811.29	$65.55	$1,915.09	0.41%
REMODULIN INJ 10MG/ML	14	2	$488,999.00	$1,178.31	$34,928.50	7.47%
ORENITRAM TAB 2.5MG	13	3	$232,474.09	$596.09	$17,882.62	3.55%
UPTRAVI TAB 800MCG	12	1	$189,360.60	$526.00	$15,780.05	2.89%
FLOLAN INJ 1.5MG	11	1	$84,844.97	$271.07	$7,713.18	1.30%
TYVASO REFIL SOL 0.6MG/ML	9	2	$137,434.95	$545.38	$15,270.55	2.10%
ORENITRAM TAB 5MG	8	1	$289,483.90	$1,206.18	$36,185.49	4.42%
REMODULIN INJ 1MG/ML	7	2	$11,902.58	$79.88	$1,700.37	0.18%
VELETRI INJ 1.5MG	4	1	$8,448.88	$93.88	$2,112.22	0.13%
ORENITRAM TAB 1MG	4	1	$30,693.20	$255.78	$7,673.30	0.47%
REMODULIN INJ 5MG/ML	3	1	$29,735.35	$407.33	$9,911.78	0.45%
TYVASO START SOL 0.6MG/ML	2	2	$34,337.10	$613.16	$17,168.55	0.52%
REMODULIN INJ 2.5MG/ML	2	1	$5,916.10	$197.20	$2,958.05	0.09%
SUBTOTAL	**117**	**25**	**$1,590,921.86**	**$480.21**	**$13,597.62**	**24.29%**
TOTAL	**1,123**	**146***	**$6,546,381.40**	**$192.67**	**$5,829.37**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Qualaquin® (Quinine Sulfate)

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

There was no paid claims for Qualaquin® (quinine sulfate) during fiscal year 2018.

Prior Authorization of Qualaquin® (Quinine Sulfate)

There were 2 prior authorization requests submitted for Qualaquin® (quinine sulfate) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

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 2018 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

There were no paid claims for Qutenza® (capsaicin 8% patch) during fiscal year 2018.

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were no prior authorization requests submitted for Qutenza® (capsaicin 8% patch) during fiscal year 2018.

Market News and Updates[126]

Anticipated Patent Expiration(s):

- Qutenza® (capsaicin 8% patch): June 2021

Recommendations

The College of Pharmacy does not recommend any changes to the current Qutenza® (capsaicin 8% patch) prior authorization criteria at this time.

[126] 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 02/2019. Last accessed 03/31/2019.

Fiscal Year 2018 Annual Review of Radicava® (Edaravone)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Introduction[127,128,129]

Amyotrophic lateral sclerosis (ALS; Lou Gehrig's disease) is a rapidly progressive neurodegenerative disease that affects motor neurons in the brain and spinal cord that control voluntary muscle movement. With voluntary muscle action progressively affected, people with ALS may lose the ability to speak, eat, move, and breathe. Most people with ALS die from respiratory failure, usually within 3 to 5 years from the onset of symptoms. The prevalence, or number of people living with ALS, varies among geographic regions worldwide; however, it is estimated that approximately 16,500 people in the United States have ALS, with an estimated prevalence of 5.2 cases per 100,000 population. ALS affects people of all races and ethnic backgrounds. Symptoms of ALS most commonly develop between the ages of 55 and 75 years, and men are slightly more likely than women to develop ALS. There is currently no cure for ALS, and treatment typically consists of symptomatic and supportive care.

Radicava® (edaravone) was approved by the U.S. Food and Drug Administration (FDA) in May 2017 as an Orphan Drug for the treatment of ALS. Edaravone is a free radical scavenger that is thought to reduce oxidative stress, a likely factor in the onset and progression of ALS. Radicava® is supplied for intravenous (IV) infusion in 30mg/100mL single-dose bags. The initial dosing cycle should consist of daily dosing (60mg) for 14 days, followed by a 14-day drug-free period. Subsequent dosing cycles should consist of daily dosing (60mg) for 10 days out of 14-day periods, followed by 14-day drug-free periods. The Wholesale Acquisition Cost (WAC) of Radicava® is $1,108 per infusion, resulting in an annual cost of $144,040, based on 13 treatment cycles of maintenance dosing (10 infusions per 28-day treatment cycle).

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 or less (for initial approval); and

[127] National Institutes of Health. National Institute of Neurological Disorders and Stroke: Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. Available online at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet#Treatment. Last revised 08/09/2018. Last accessed 03/06/2019.
[128] Centers for Disease Control and Prevention (CDC). Prevalence of Amyotrophic Lateral Sclerosis - United States, 2015. Available online at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6746a1.htm. Last revised 11/21/2018. Last accessed 03/06/2019.
[129] Radicava® (Edaravone) Prescribing Information. Mitsubishi Tanabe Pharma Corporation. Available online at: https://www.radicava.com/assets/dist/pdfs/radicava-prescribing-information.pdf. Last revised 08/2018. Last accessed 03/06/2019.

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.

Utilization of Radicava® (Edaravone): Fiscal Year 2018

There was no SoonerCare utilization of Radicava® (edaravone) during fiscal year 2018.

Prior Authorization of Radicava® (Edaravone)

There were no prior authorization requests submitted for Radicava® (edaravone) during fiscal year 2018.

Market News and Updates

Anticipated Patent Expiration(s):[130]

- Radicava® (edaravone): November 2020

Pipeline:

- **November 2018:** Biohaven Pharmaceuticals submitted a New Drug Application (NDA) to the FDA for BHV-0223, a novel sublingual delivery form of riluzole, for the treatment of ALS. BHV-0223 is a sublingually administered, orally dissolving tablet that is designed to be placed under the tongue where it dissolves in seconds and is absorbed by the vasculature, thereby eliminating the need for swallowing. Riluzole was first approved by the FDA in 1995 and is currently available as oral tablets and oral suspension. In clinical trials of patients with ALS and dysphagia, BHV-0223 was generally well tolerated and reported by patients to be easy to use. Biohaven was previously granted Orphan Drug designation from the FDA for BHV-0223 in the treatment of ALS.[131]

Recommendations

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

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[130] 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 03/06/2019.

[131] Biohaven Pharmaceuticals News Release. Biohaven Announces FDA Acceptance of 505(b)(2) NDA Filing for BHV-0223, a Novel Sublingual Delivery Form of Riluzole for the Treatment of Amyotrophic Lateral Sclerosis (ALS). Available online at: https://www.biohavenpharma.com/investors/news-events/press-releases/11-26-2018. Issued 11/26/2018. Last accessed 03/06/2019.

Fiscal Year 2018 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Introduction[132,133,134,135]

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.

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[132] 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 03/07/2019.

[133] 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 03/07/2019.

[134] Buphenyl® (Sodium Phenylbutyrate) Prescribing Information. Horizon Pharma. Available online at: https://www.horizonpharma.com/wp-content/uploads/2017/07/BUPHENYL_PI_April-2016.pdf. Last revised 04/2016. Last accessed 03/07/2019.

[135] Ravicti® (Glycerol Phenylbutyrate) Prescribing Information. Horizon Pharma. Available online at: https://hznp.azureedge.net/public/ravicti_1-1g-ml_vial_pi_effective_us.PDF. Last revised 12/2018. Last accessed 03/07/2019.

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 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member	Total Units	Total Days
2017	8	42	$865,562.10	$20,608.62	5.25	5,325	1,166
2018	6	63	$1,547,010.90	$24,555.73	10.50	8,800	1,765
% Change	**-25.00%**	**50.00%**	**78.70%**	**19.20%**	**100.00%**	**65.30%**	**51.40%**
Change	**-2**	**21**	**$681,448.80**	**$3,947.11**	**5.25**	**3,475**	**599**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- Due to the limited number of members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2018, detailed demographic information could not be provided.

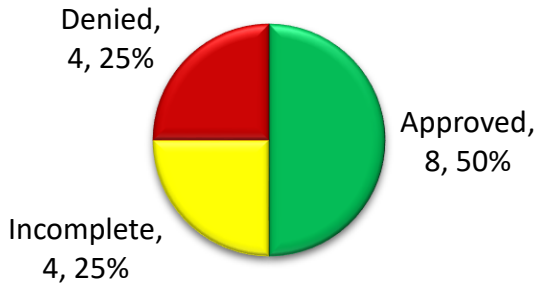
Top Prescriber Specialties of Ravicti® (Glycerol Phenylbutyrate) by Number of Claims

- The only prescriber specialty listed on paid claims for Ravicti® (glycerol phenylbutyrate) during fiscal year 2018 was genetic counselor.

Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

There were 16 prior authorization requests submitted for 6 unique members for Ravicti® (glycerol phenylbutyrate) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[136]

- Ravicti® (glycerol phenylbutyrate): March 2032

FDA Approval(s):

- **December 2018:** The FDA expanded the indication of Ravicti® (glycerol phenylbutyrate) for the treatment of UCDs to include adults and children of all ages who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. This expanded age range was based on study results demonstrating the safety, efficacy, and pharmacokinetics in pediatric patients with UCDs 2 months of age and younger. Ravicti® was first FDA approved in 2013 for this indication in patients 2 years of age and older and was then expanded to patients 2 months of age and older in 2017.[137]

Recommendations

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

[136] 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 03/07/2019.

[137] Horizon Pharma News Release. Horizon Pharma plc Announces FDA Approval to Expand the Age Range for Ravicti® (Glycerol Phenylbutyrate) Oral Liquid to Include Newborns. Available online at: http://ir.horizon-pharma.com/news-releases/news-release-details/horizon-pharma-plc-announces-fda-approval-expand-age-range-0. Issued 12/27/2018. Last accessed 03/07/2019.

Fiscal Year 2018 Annual Review of Retisert® (Fluocinolone Intravitreal Implant)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis.

Utilization of Retisert® (Fluocinolone Intravitreal Implant): Fiscal Year 2018

There were no paid claims for Retisert® (fluocinolone intravitreal implant) during fiscal year 2018.

Prior Authorization of Retisert® (Fluocinolone Intravitreal Implant)

There were no prior authorization requests submitted for Retisert® (fluocinolone intravitreal implant) during fiscal year 2018.

Market News and Updates

Anticipated Patent Expiration(s):[138]

- Retisert® (fluocinolone intravitreal implant): March 2019.

Recommendations

The College of Pharmacy does not recommend any changes to the current Retisert® (fluocinolone intravitreal implant) 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/default.cfm?resetfields=1. Last revised 01/2019. Last accessed 02/28/2019.

Fiscal Year 2018 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2018 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.

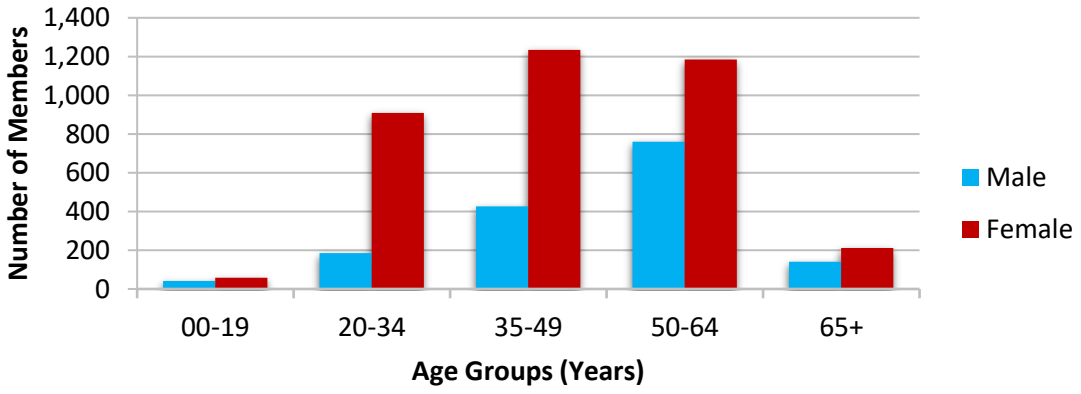
Utilization of Smoking Cessation Products: Fiscal Year 2018

Comparison of Fiscal Years

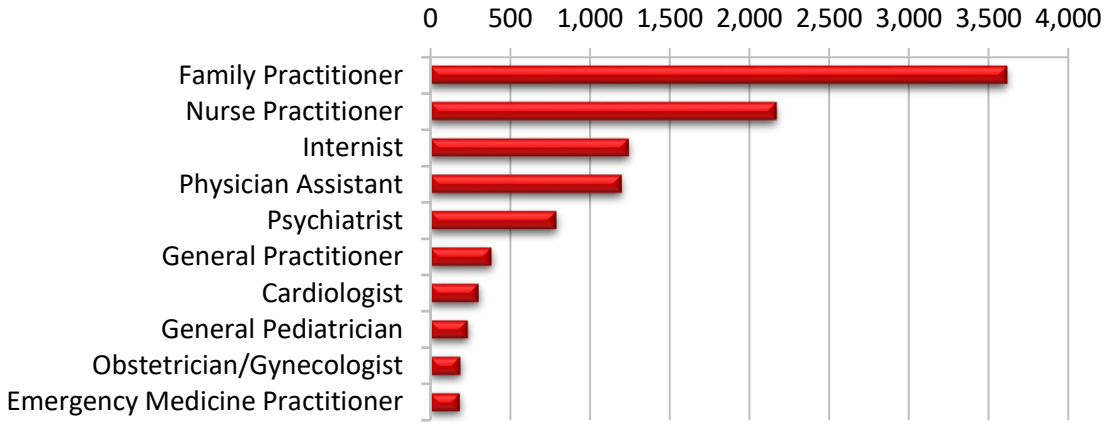
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	4,972	10,004	$1,761,945.38	$176.12	$7.23	475,362	243,633
2018	5,152	10,894	$2,085,827.32	$191.47	$7.96	500,929	262,037
% Change	**3.60%**	**8.90%**	**18.40%**	**8.70%**	**10.10%**	**5.40%**	**7.60%**
Change	**180**	**890**	**$323,881.94**	**$15.35**	**$0.73**	**25,567**	**18,404**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Smoking Cessation Products



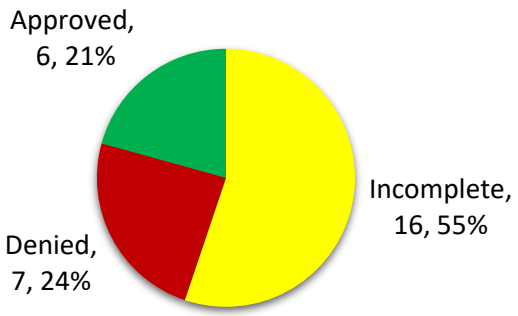
Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 29 prior authorization requests submitted for smoking cessation products during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[139]

- Chantix® (varenicline tablets): February 2023

News:

- **March 2018:** Pfizer, Inc. released results of their Phase 4 study evaluating the safety and efficacy of Chantix® (varenicline) for smoking cessation in nicotine dependent adolescents 12 to 19 years of age. The study was a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging multicenter study evaluating varenicline, along with age-appropriate counseling, for smoking cessation in adolescents. The study did not meet its primary endpoint of the 4-week continuous abstinence rate at weeks 9 to

[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 02/2019. Last accessed 03/31/2019.

12 compared to placebo. The adverse event profile observed in the study was similar to the adverse event profile of varenicline studies in adults.[140]

- **May 2018:** A double-blind, randomized, triple-dummy, placebo- and active-controlled trial evaluating the cardiovascular safety of smoking cessation medications was published in the *Journal of the American Medical Association* (*JAMA*). Smokers, with or without established psychiatric diagnoses, were included in the study. The primary endpoint was time to development of a major adverse cardiovascular event (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) during treatment. The study concluded that there was no evidence that the use of smoking cessation pharmacotherapies increase the risk of serious cardiovascular adverse events.[141]

Recommendations

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

Utilization Details of Smoking Cessation Products: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24HR	2,257	1,314	$104,533.05	$2.11	$46.32	1.72
NICOTINE TD DIS 14MG/24HR	1,226	741	$53,414.45	$2.17	$43.57	1.65
NICOTINE TD DIS 7MG/24HR	581	372	$24,114.62	$2.20	$41.51	1.56
NICODERM CQ DIS 21MG/24HR	271	184	$12,605.34	$2.12	$46.51	1.47
SM NICOTINE DIS 21MG/24HR	197	120	$9,228.37	$2.14	$46.84	1.64
NICODERM CQ DIS 14MG/24HR	184	131	$8,190.86	$2.14	$44.52	1.4
NICOTINE POL LOZ 4MG MINT	111	40	$6,592.06	$4.53	$59.39	2.78
NICODERM CQ DIS 7MG/24HR	103	65	$4,064.35	$2.26	$39.46	1.58
NICOTROL INH	103	77	$43,336.23	$17.54	$420.74	1.34
NICOTINE POL GUM 4MG	94	28	$3,300.24	$4.02	$35.11	3.36
NICORETTE LOZ 4MG MINT	81	30	$4,919.13	$4.32	$60.73	2.7
HM NICOTINE DIS 14MG/24HR	63	50	$3,196.42	$2.10	$50.74	1.26
NICOTINE POL LOZ 2MG MINT	61	28	$2,532.06	$3.55	$41.51	2.18
NICOTINE POL GUM 4MG ORIG	60	32	$2,329.64	$4.34	$38.83	1.88
HM NICOTINE GUM 2MG MINT	44	12	$1,972.10	$2.92	$44.82	3.67
NICORETTE GUM 4MG MINT	44	23	$2,109.58	$2.70	$47.95	1.91
NICOTROL NS SPR 10MG/ML	43	16	$28,439.07	$25.67	$661.37	2.69
SM NICOTINE DIS 7MG/24HR	42	31	$1,460.09	$2.42	$34.76	1.35
SM NICOTINE DIS 14MG/24HR	41	31	$2,110.10	$2.11	$51.47	1.32

[140] Pfizer, Inc. Pfizer Reports Top-Line Results from a Study of CHANTIX®/CHAMPIX® (varenicline) in Adolescent Smokers. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer_reports_top_line_results_from_a_study_of_chantix_champix_varenicline_in_adolescent_smokers. Issued 03/23/2018. Last accessed 03/31/2019.

[141] Benowitz NL, Pipe A, West R, et al. Cardiovascular Safety of Varenicline, Bupropion, and Nicotine Patch in Smokers: A Randomized Clinical Trial. *JAMA Intern Med* 2018; 178(5):622–631.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
SM NICOTINE GUM 4MG MINT	40	10	$2,169.38	$2.72	$54.23	4
NICOTINE POL GUM 2MG MINT	27	17	$867.50	$2.81	$32.13	1.59
NICOTINE POL GUM 4MG MINT	26	21	$1,018.50	$2.79	$39.17	1.24
HM NICOTINE GUM 4MG MINT	21	9	$1,191.36	$3.78	$56.73	2.33
HM NICOTINE LOZ 4MG MINT	21	10	$1,518.41	$3.22	$72.31	2.1
NICOTINE POL GUM 2MG	20	18	$688.29	$2.42	$34.41	1.11
NICOTINE POL GUM 2MG CINN	19	16	$720.70	$2.20	$37.93	1.19
NICOTINE POL GUM 2MG ORIG	19	15	$541.30	$3.02	$28.49	1.27
SM NICOTINE GUM 2MG	18	12	$453.26	$2.78	$25.18	1.5
NICORETTE LOZ 2MG MINT	18	15	$1,225.69	$4.09	$68.09	1.2
SM NICOTINE LOZ 4MG MINT	17	8	$1,772.34	$4.78	$104.26	2.13
NICORETTE GUM 4MGFRUIT	17	11	$846.05	$2.17	$49.77	1.55
NICORETTE GUM 2MGFRUIT	16	10	$786.75	$1.99	$49.17	1.6
NICORETTE GUM 4MG CINN	14	6	$949.35	$3.03	$67.81	2.33
GNP NICOTINE DIS 21MG/24HR	12	12	$640.02	$2.08	$53.34	1
SM NICOTINE GUM 4MG	11	8	$389.67	$2.15	$35.42	1.38
NICOTINE LOZ 2MG MINT	10	7	$399.15	$2.08	$39.92	1.43
NICORETTE GUM 2MG MINT	9	7	$404.79	$1.69	$44.98	1.29
NICORELIEF GUM 2MG MINT	8	4	$274.17	$3.34	$34.27	2
NICORELIEF GUM 2MG ORIG	8	8	$205.06	$2.36	$25.63	1
NICORETTE GUM 2MG CINN	8	5	$410.60	$2.35	$51.33	1.6
NICORELIEF GUM 4MG MINT	7	5	$218.22	$1.46	$31.17	1.4
SM NICOTINE GUM 2MG MINT	5	4	$185.28	$3.43	$37.06	1.25
NICORETTE GUM 4MG ORIG	5	2	$331.75	$9.76	$66.35	2.5
SM NICOTINE LOZ 2MG MINT	5	4	$335.85	$2.38	$67.17	1.25
HM NICOTINE LOZ 2MG MINT	4	4	$327.29	$3.31	$81.82	1
NICORELIEF GUM 4MG ORIG	4	2	$116.97	$1.44	$29.24	2
GNP NICOTINE LOZ MINI 2MG	4	2	$152.29	$4.76	$38.07	2
NICORETTE GUM 2MG ORIG	3	3	$214.29	$2.86	$71.43	1
NICORETTE ST GUM 4MG ORIG	3	3	$240.47	$3.21	$80.16	1
NICORETTE LOZ 2MG CHRY	2	2	$116.16	$1.94	$58.08	1
GNP NICOTINE GUM 2MG MINT	2	2	$54.10	$1.59	$27.05	1
NICORETTE ST GUM 2MG MINT	1	1	$52.75	$3.10	$52.75	1
NICORETTE LOZ 4MG CHRY	1	1	$43.25	$14.42	$43.25	1
NICORETTE LOZ 2MG ORIG	1	1	$41.27	$1.72	$41.27	1
GNP NICOTINE LOZ 4MG MINT	1	1	$36.60	$12.20	$36.60	1
NICOTINE SYS KIT TRANSDER	1	1	$95.84	$1.71	$95.84	1
SUBTOTAL	**6,014**	**3,592**	**$338,482.48**	**$2.76**	**$56.28**	**1.67**
VARENICLINE PRODUCTS						
CHANTIX PAK 0.5& 1MG	2,301	2,041	$869,265.23	$13.10	$377.78	1.13
CHANTIX PAK 1MG	1,259	731	$475,041.44	$13.07	$377.32	1.72
CHANTIX TAB 1MG	962	500	$360,944.09	$12.82	$375.20	1.92
CHANTIX TAB 0.5MG	114	76	$33,875.67	$12.15	$297.16	1.5
SUBTOTAL	**4,636**	**2,475**	**$1,739,126.43**	**$13.01**	**$375.14**	**1.87**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
BUPROPION PRODUCTS						
BUPROPION TAB 150MG	244	119	$8,218.41	$1.09	2.05	$33.68
SUBTOTAL	**244**	**119**	**$8,218.41**	**$1.09**	**2.05**	**$33.68**
TOTAL	**10,894**	**5,152***	**$2,085,827.32**	**$7.96**	**$191.47**	**2.11**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Soliris® (Eculizumab)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria or Atypical Hemolytic Uremic Syndrome Diagnosis]:

1. Member must have an established diagnosis of paroxysmal nocturnal hemoglobinuria or atypical hemolytic uremic syndrome via international classification of disease (ICD) coding in the member's medical claims history; and
2. An age restriction of 18 years and older will apply; and
3. For members younger than 18 years of age, approval can be granted with a documented diagnosis of atypical hemolytic uremic syndrome.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Positive serologic test for anti-acetylcholine receptor (AchR) antibodies; and
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
6. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Utilization of Soliris® (Eculizumab): Fiscal Year 2018

Soliris® (Eculizumab) Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	4	79	$1,711,063.67	$21,659.03	$1,565.47	17,990	1,093
2018	5	80	$1,888,266.53	$23,603.33	$1,800.06	18,100	1,049
% Change	**25.00%**	**1.30%**	**10.40%**	**9.00%**	**15.00%**	**0.60%**	**-4.00%**
Change	**1**	**1**	**$177,202.86**	**$1,944.30**	**$234.59**	**110**	**-44**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Soliris® (Eculizumab) Fiscal Year Comparison: Medical Claims

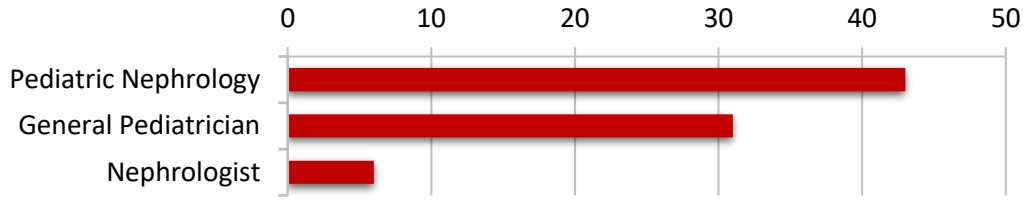
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2017	7	40	$1,449,643.80	$36,241.10	5,927
2018	7	29	$1,176,895.50	$40,582.60	7,110
% Change	**0.00%**	**-27.50%**	**-18.81%**	**11.98%**	**19.96%**
Change	**0**	**-11**	**-$272,748.30**	**$4,341.50**	**1,183**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Soliris® (Eculizumab)

- Due to the small number of members utilizing Soliris® (eculizumab) during fiscal year 2018, detailed demographic information cannot be provided.

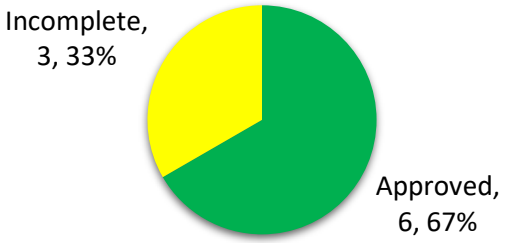
Top Prescriber Specialties of Soliris® (Eculizumab) by Number of Claims: Pharmacy Claims



Prior Authorization of Soliris® (Eculizumab)

There were 9 prior authorization requests submitted for Soliris® (eculizumab) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

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

- **Ultomiris™ (Ravulizumab-cwvz):** In December 2018, the FDA approved ravulizumab injection for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). PNH is a rare acquired disorder that leads to the rupture or destruction of red blood cells (RBCs) or hemolysis. Patients with PNH are missing glycosylphosphatidylinositol (GPI), a protein that normally protects RBCs from being destroyed by the patient's immune system. Patients with PNH have sudden, recurring

episodes where RBCs are prematurely destroyed which may be triggered by stresses on the body (e.g., infections or physical exertion). During these episodes, symptoms may include severe anemia, profound fatigue, shortness of breath, intermittent episodes of dark colored urine, kidney disease, or recurrent pain. PNH can occur at any age, although it is most often diagnosed in young adulthood. Ravulizumab is a long-acting complement inhibitor that prevents hemolysis. Ravulizumab is dosed every 8 weeks as compared to the current standard of care Soliris® (eculizumab), which is dosed every 2 weeks. The efficacy of ravulizumab was studied in a clinical trial of 246 patients who previously had not been treated for PNH, who were randomized to be treated with ravulizumab or eculizumab. The results of the trial demonstrated that ravulizumab was non-inferior to eculizumab. Study participants did not receive a transfusion and had a similar incidence of hemolysis. Ravulizumab was studied in a second clinical trial of 195 patients with PNH who were clinically stable after having been treated with eculizumab for at least the past 6 months. Patients were randomly selected to be treated with ravulizumab or to continue eculizumab. Ravulizumab was again found to be non-inferior to eculizumab based on hemolysis and avoiding transfusion.[142,143]

Pipeline:

- **Soliris® (Eculizumab) for Neuromyelitis Optica Spectrum Disorder (NMOSD):** In September 2018, Alexion Pharmaceuticals, Inc. announced positive topline results from the Phase 3 PREVENT study of eculizumab in patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD. NMOSD is a rare, complement-mediated disorder of the central nervous system (CNS) characterized by relapses. Each relapse results in stepwise accumulation of disability, including blindness and paralysis, and sometimes premature death. Patients who have anti-AQP4 auto-antibodies represent approximately 3 quarters of all patients with NMOSD. There are currently no approved therapies for NMOSD. The study met its primary endpoint of time to first adjudicated on-trial relapse, demonstrating that treatment with eculizumab reduced the risk of NMOSD relapse by 94.2% compared to placebo (P<0.0001). At 48 weeks, 97.9% of patients receiving eculizumab were free of relapse compared to 63.2% of patients receiving placebo.[144]

Recommendations

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

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[142] U.S. Food and Drug Administration (FDA). FDA approves new treatment for adult patients with rare, life-threatening blood disease. Available online at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629022.htm. Issued 12/21/2018. Last accessed 01/14/2019.

[143] Brodsky RA. Pathogenesis of paroxysmal nocturnal hemoglobinuria. *UpToDate*. Available online at: https://www.uptodate.com/contents/pathogenesis-of-paroxysmal-nocturnal-hemoglobinuria?search=pnh&source=search_result&selectedTitle=2~71&usage_type=default&display_rank=2#H13962299. Last revised 11/15/2017. Last accessed 01/14/2019.

[144] Alexion Pharmaceuticals, Inc. Alexion Announces Successful Phase 3 PREVENT Study Of Soliris® (Eculizumab) In Patients With Neuromyelitis Optica Spectrum Disorder (NMOSD). *Business Wire*. Available online at: https://news.alexionpharma.com/press-release/product-news/alexion-announces-successful-phase-3-prevent-study-soliris-eculizumab-pat. Issued 09/24/2018. Last accessed 01/14/2019.

Fiscal Year 2018 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Strensiq® (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of members with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by laboratory testing of:
   a. Low age-adjusted alkaline phosphatase (ALP) activity; and
   b. Elevated pyridoxal 5'-phosphate (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 members weighing <40kg.

Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2018

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	5	42	$1,268,376.77	$30,199.45	$1,078.55	477	1,176
2018	3	36	$1,272,955.80	$35,359.88	$1,262.85	451	1,008
% Change	**-40.00%**	**-14.30%**	**0.40%**	**17.10%**	**17.10%**	**-5.50%**	**-14.30%**
Change	**-2**	**-6**	**$4,579.03**	**$5,160.43**	**$184.30**	**-26**	**-168**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Strensiq® (Asfotase Alfa)

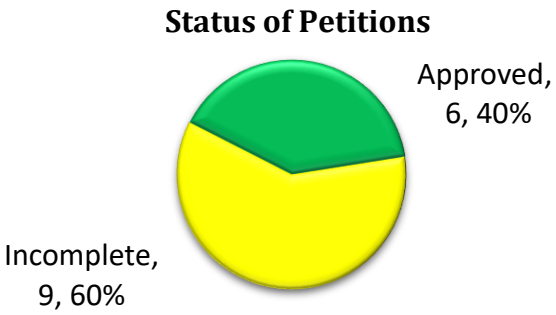
- Due to the limited number of members utilizing Strensiq® (asfotase alfa) during fiscal year 2018, detailed demographic information could not be provided.

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 2018 were general pediatrician and genetic counselor.

Prior Authorization of Strensiq® (Asfotase Alfa)

There were 15 prior authorization requests submitted for Strensiq® (asfotase alfa) during fiscal year 2018. The following chart shows the status of the submitted petitions.



Recommendations

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

Fiscal Year 2018 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Sylvant® (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of Multicentric Castleman's Disease (also known as giant lymph node hyperplasia); and
2. Member must be Human Immunodeficiency Virus (HIV) and Human Herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
    a. 11 mg/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 2018

There was no SoonerCare paid claims for Sylvant® (siltuximab) during fiscal year 2018.

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2018.

Recommendations

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

Fiscal Year 2018 Annual Review of Symlin® (Pramlintide)

Oklahoma Health Care Authority
Fiscal Year 2018 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 healthcare 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. HbA1c >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past six 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 2018

Fiscal Year 2018 Utilization of Symlin® (Pramlintide)

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

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Symlin® (Pramlintide)

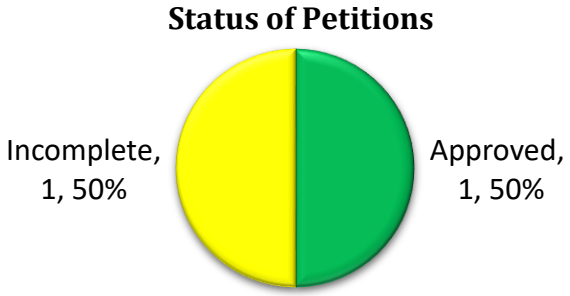
- Due to the limited number of members utilizing Symlin® (Pramlintide) during fiscal year 2018, detailed demographic information could not be provided.

Top Prescriber Specialties of Symlin® (Pramlintide) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Symlin® (Pramlintide) during fiscal year 2018 was endocrinology.

Prior Authorization of Symlin® (Pramlintide)

There were 2 prior authorization requests submitted for Symlin® (pramlintide) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s):[145]

- Symlin® (pramlintide): March 2019

Recommendations

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

[145] 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 02/2019. Last accessed 03/31/2019.

Fiscal Year 2018 Annual Review of Topical Acne Products

Oklahoma Health Care Authority
Fiscal Year 2018 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; 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.

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 a 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% gel, 0.05% cream, and 0.1% gel will not require prior authorization for members 20 years of age or younger; and
5. A quantity limit of 60 grams per 30 days will apply.

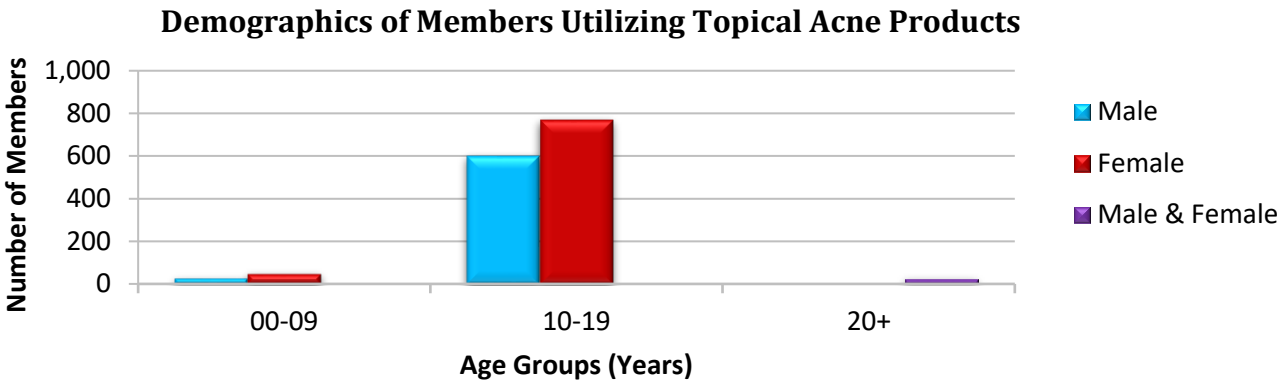
Utilization of Topical Acne Products: Fiscal Year 2018

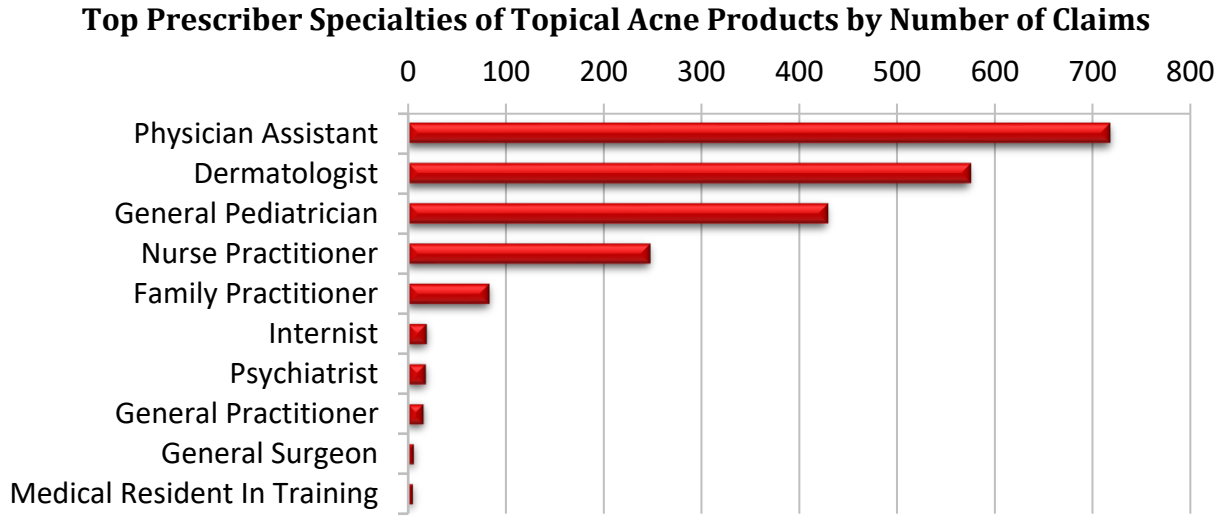
Comparison of Fiscal Years: Topical Acne Products

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2,117	3,326	$1,509,883.30	$453.96	$18.30	138,340	82,507
2018	1,467	2,125	$906,152.01	$426.42	$16.65	83,295	54,435
% Change	**-30.70%**	**-36.10%**	**-40.00%**	**-6.10%**	**-9.00%**	**-39.80%**	**-34.00%**
Change	**-650**	**-1,201**	**-$603,731.29**	**-$27.54**	**-$1.65**	**-55,045**	**-28,072**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

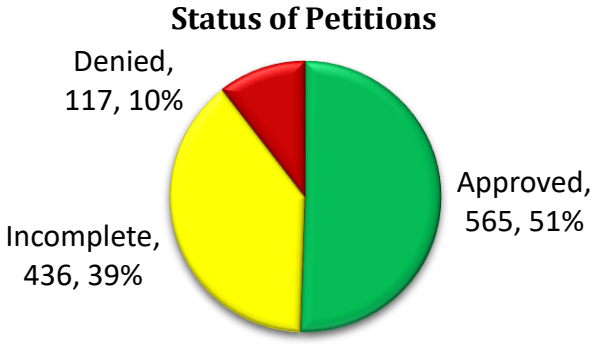
- Please note, Aczone® and Tazorac® both have significant federal rebates and costs included in this report do not reflect rebated prices or net costs.





Prior Authorization of Topical Acne Products

There were 1,118 prior authorization requests submitted for topical acne products during fiscal year 2018. The following chart shows the status of the submitted petitions for calendar year 2018.



Market News and Updates

Anticipated Patent Expiration(s):[146]

- Aczone® (dapsone 7.5% gel): November 2033

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TAZAROTENE PRODUCTS					
TAZORAC CRE 0.05%	1,258	931	$551,833.05	1.35	$438.66
TAZAROTENE CRE 0.1%	309	243	$103,187.04	1.27	$333.94
TAZORAC GEL 0.05%	200	148	$79,981.87	1.35	$399.91
TAZORAC GEL 0.1%	193	142	$84,104.25	1.36	$435.77
TAZORAC CRE 0.1%	142	103	$75,343.57	1.38	$530.59
SUBTOTAL	**2,102**	**1,454***	**$894,449.78**	**1.45**	**$425.52**
DAPSONE PRODUCTS					
ACZONE GEL 7.5%	18	14	$9,721.07	1.29	$540.06
DAPSONE GEL 5%	4	4	$1,401.08	1	$350.27
ACZONE GEL 5%	1	1	$580.08	1	$580.08
SUBTOTAL	**23**	**19***	**$11,702.23**	**1.21**	**$508.79**
TOTAL	**2,125**	**1,467***	**$906,152.01**	**1.45**	**$426.42**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- Please note, Aczone® and Tazorac® both have significant federal rebates and costs included in this report do not reflect rebated prices or net costs.

[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. Last revised 03/2018. Last accessed 04/19/2018.

Fiscal Year 2018 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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

Tier structure 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 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 a unique indication not covered by Tier-1 products.
3. Approvals will be for the duration of 10 days.

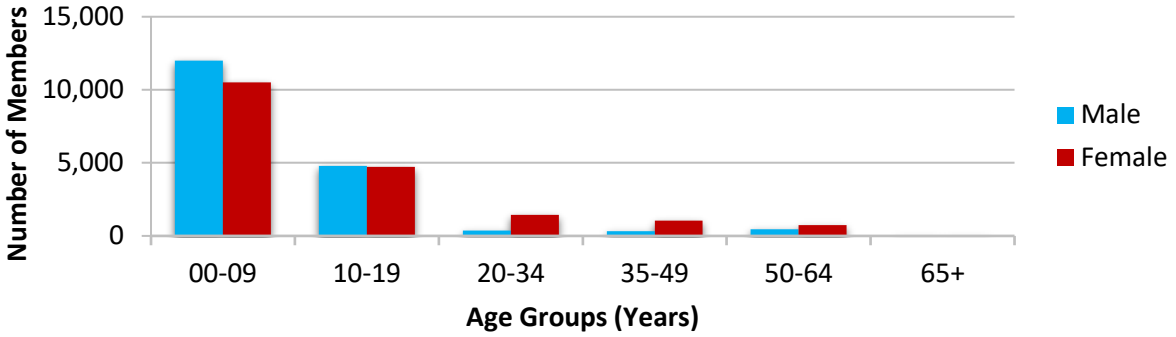
Utilization of Topical Antibiotic Products: Fiscal Year 2018

Comparison of Fiscal Years

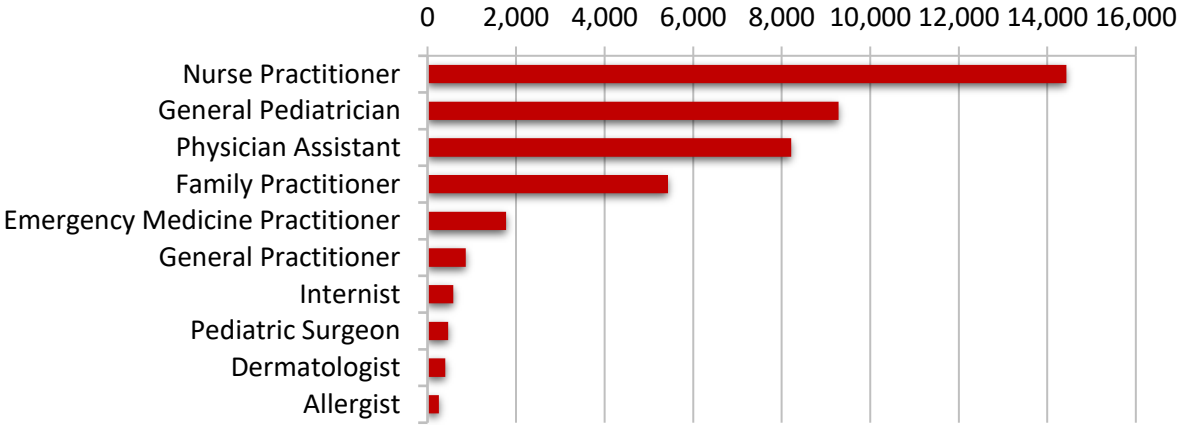
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	35,615	41,859	$630,715.49	$15.07	$1.42	969,973	442,984
2018	36,505	43,176	$699,380.51	$16.20	$1.54	997,946	453,237
% Change	**2.50%**	**3.10%**	**10.90%**	**7.50%**	**8.50%**	**2.90%**	**2.30%**
Change	**890**	**1,317**	**$68,665.02**	**$1.13**	**$0.12**	**27,973**	**10,253**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Topical Antibiotic Products



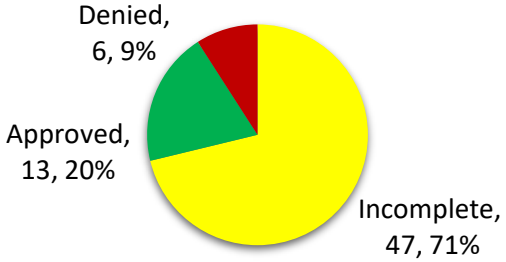
Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims



Prior Authorization of Topical Antibiotic Products

There were 66 prior authorization requests submitted for topical antibiotic products during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[147]

- Altabax® (retapamulin): February 2027

[147] 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 02/2019. Last accessed 03/31/2019.

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 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
MUPIROCIN OIN 2%	42,782	36,312	$662,369.53	$1.48	$15.48
GENTAMICIN OIN 0.1%	187	130	$13,676.74	$6.01	$73.14
GENTAMICIN CRE 0.1%	111	68	$6,603.50	$3.22	$59.49
CORTISPORIN CRE 0.5%	29	16	$3,326.79	$9.45	$114.72
CORTISPORIN OIN 1%	28	23	$4,448.30	$14.40	$158.87
SUBTOTAL	**43,137**	**36,549**	**$690,424.86**	**$1.52**	**$16.01**
TIER-2 PRODUCTS					
MUPIROCIN CRE 2%	39	30	$8,955.65	$19.60	$229.63
SUBTOTAL	**39**	**30**	**$8,955.65**	**$19.60**	**$229.63**
TOTAL	**43,176**	**36,505***	**$699,380.51**	**$1.54**	**$16.20**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
ketoconazole cream, shampoo	econazole cream	
nystatin cream, ointment, powder	ketoconazole foam (Extina®)	
terbinafine (OTC)* cream	ketoconazole gel (Xolegel®)	
tolnaftate (OTC)* cream	luliconazole cream (Luzu®)	
	miconazole/zinc oxide/white petrolatum (Vusion®)	
	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.
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 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., foams, shampoos, sprays, kits).
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/ betamethasone lotion requires a patient-specific, clinically significant reason why the member cannot use the individual components separately, or in the case of clotrimazole/betamethasone lotion why the Tier-1 cream cannot be used.
4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

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

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

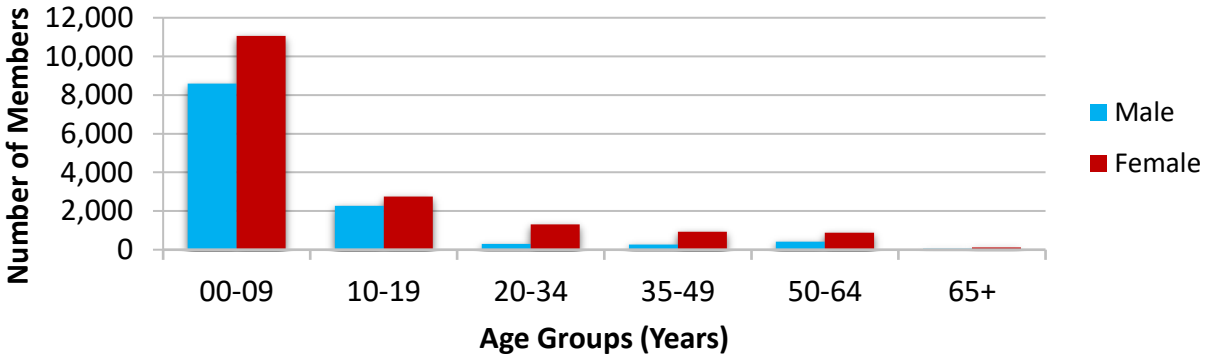
Utilization of Topical Antifungal Products: Fiscal Year 2018

Comparison of Fiscal Years

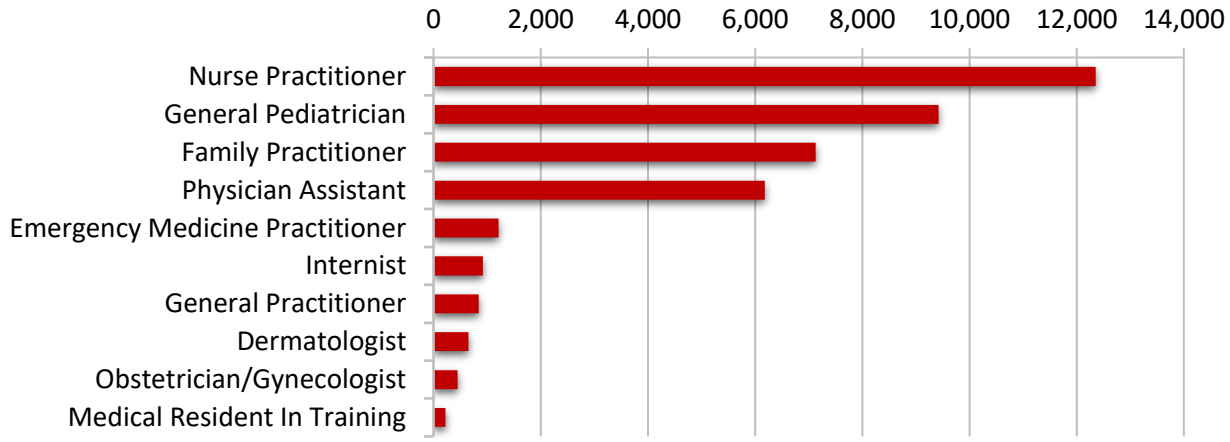
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	31,131	43,708	$987,910.84	$22.60	$1.54	1,627,172	642,526
2018	28,953	40,914	$891,604.11	$21.79	$1.46	1,570,438	608,874
% Change	**-7.00%**	**-6.40%**	**-9.70%**	**-3.60%**	**-5.20%**	**-3.50%**	**-5.20%**
Change	**-2,178**	**-2,794**	**-$96,306.73**	**-$0.81**	**-$0.08**	**-56,734**	**-33,652**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Topical Antifungal Products

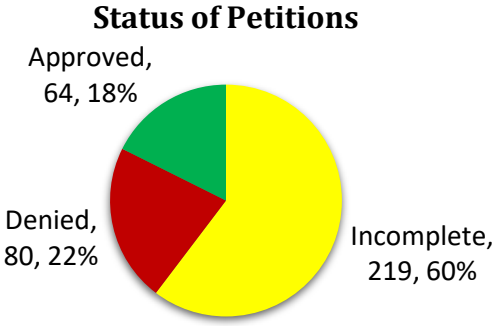


Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 363 prior authorization requests submitted for topical antifungal products during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Market News and Updates

Anticipated Patent Expiration(s):[148]

- Xolegel® (ketoconazole gel): November 2020
- Kerydin® (tavaborole solution): November 2027
- Vusion® (miconazole/zinc oxide/white petrolatum): March 2028
- Naftin® (naftifine gel): January 2033
- Luzu® (luliconazole cream): April 2034
- Jublia® (efinaconazole solution): October 2034

Recommendations

The College of Pharmacy recommends the following changes to the Topical Antifungal Product Based Prior Authorization (PBPA) category:

1. Move econazole nitrate 1% cream from Tier-2 to Tier-1 based on a decrease in cost.

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole cream	ketoconazole foam (Extina®)	
ketoconazole cream, shampoo	ketoconazole gel (Xolegel®)	
nystatin cream, ointment, powder	luliconazole cream (Luzu®)	
terbinafine (OTC)* cream	miconazole/zinc oxide/white petrolatum (Vusion®)	

[148] 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 02/2019. Last accessed 03/31/2019.

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
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.
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.

Utilization Details of Topical Antifungal Products: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 UTILIZATION						
CICLOPIROX PRODUCTS						
CICLOPIROX CRE 0.77%	436	6,459	348	$8,549.81	$1.32	$19.61
CICLOPIROX SUS 0.77%	13	309	9	$577.31	$1.87	$44.41
SUBTOTAL	**449**	**6,768**	**357**	**$9,127.12**	**$1.35**	**$20.33**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE CRE 1%	7,005	94,529	5,805	$130,531.08	$1 38	$18.63
ATHLETE FOOT CRE 1%	12	123	12	$141.17	$1.15	$11.76
SUBTOTAL	**7,017**	**94,652**	**5,817**	**$130,672.25**	$1.38	**$18.62**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOT/BETA CRE 1-0.05%	332	5,108	269	$7,072.63	$1.38	$21.30
CLOT/BETA CRE DIP 1-0.05%	1,397	19,960	1,164	$28,970.32	$1.45	$20.74
SUBTOTAL	**1,729**	**25,068**	**1,433**	**$36,042.95**	**$1.44**	**$20.85**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE CRE 2%	4,795	77,403	3,985	$192,756.74	$2.49	$40.20
KETOCONAZOLE SHA 2%	3,638	110,651	2,240	$65,203.11	$0.59	$17.92
SUBTOTAL	**8,433**	**188,054**	**6,225**	**$257,959.85**	**$1.37**	**$30.59**
NYSTATIN PRODUCTS						
NYSTATIN CRE 100000	13,193	164,076	10,536	$219,576.75	$1.34	$16.64
NYSTATIN OIN 100000	5,869	72,203	4,835	$134,747.86	$1.87	$22.96
NYSTOP POW 100000	1,745	23,234	1,193	$38,452.32	$1.66	$22.04
NYSTATIN POW 100000	1,183	17,492	808	$27,382.53	$1.57	$23.15
NYAMYC POW 100000	628	6,893	323	$14,324.06	$2.08	$22.81
SUBTOTAL	**22,618**	**283,898**	**17,695**	**$434,483.52**	**$1.53**	**$19.21**
TERBINAFINE PRODUCTS						
TERBINAFINE CRE 1%	467	6,500	431	$ 7,387.06	$1.14	$15.82
ATHLETE FOOT CRE 1%	44	610	44	$ 806.45	$1.32	$18.33
LAMISIL AT CRE 1%	16	246	16	$ 231.36	$0.94	$14.46

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ATHLETE FOOT CRE AF 1%	7	127	5	$ 115.42	$0.91	$16.49
SUBTOTAL	**534**	**7,483**	**496**	**$8,540.29**	**$1.14**	**$15.99**
TOLNAFTATE PRODUCTS						
SM ANTIFUNGL CRE 1%	7	79	5	$90.31	$1.14	$12.90
ANTIFUNGAL CRE 1%	2	14	2	$19.09	$1.36	$9.55
TOLNAFTATE CRE 1%	2	22	2	$22.40	$1.02	$11.20
SUBTOTAL	**11**	**115**	**9**	**$131.80**	**$1.15**	**$11.98**
TIER-1 SUBTOTAL	**40,791**	**606,038**	**32,032**	**$876,957.78**	**$1.45**	**$21.50**
TIER-2 UTILIZATION						
BUTENAFINE PRODUCTS						
MENTAX CRE 1%	2	24	2	$413.32	$17.22	$206.66
SUBTOTAL	**2**	**24**	**2**	**$413.32**	**$17.22**	**$206.66**
CICLOPIROX PRODUCTS						
CICLOPIROX SHA 1%	8	225	3	$548.47	$2.44	$68.56
CICLOPIROX SOL 8%	4	120	4	$106.47	$0.89	$26.62
SUBTOTAL	**12**	**345**	**7**	**$654.94**	**$1.90**	**$54.58**
CLOTRIMAZOLE PRODUCTS$^{\Delta}$						
CLOTRIMAZOLE SOL 1%	36	1,131	25	$1,977.43	$1.75	$54.93
SUBTOTAL	**36**	**1,131**	**25**	**$1,977.43**	**$1.75**	**$54.93**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOT/BETA LOT DIPROP 1-0.05%	17	231	4	$1,645.22	$7.12	$96.78
SUBTOTAL	**17**	**231**	**4**	**$1,645.22**	**$7.12**	**$96.78**
ECONAZOLE PRODUCTS$^{\Delta}$						
ECONAZOLE CRE 1%	18	507	6	$1,707.34	$3.37	$94.85
SUBTOTAL	**18**	**507**	**6**	**$1,707.34**	**$3.37**	**$94.85**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE AER 2%	4	120	1	$2,685.52	$22.38	$671.38
SUBTOTAL	**4**	**120**	**1**	**$2,685.52**	**$22.38**	**$671.38**
NAFTIFINE PRODUCTS						
NAFTIN GEL 2%	3	60	1	$799.56	$13.33	$266.52
SUBTOTAL	**3**	**60**	**1**	**$799.56**	**$13.33**	**$266.52**
NYSTATIN/TRIAMCINOLONE PRODUCTS						
NYSTAT/TRIAM CRE	18	208	14	$1,092.18	$5.25	$60.68
NYSTAT/TRIAM OIN	6	50	5	$386.79	$7.74	$64.47
SUBTOTAL	**24**	**258**	**19**	**$1,478.97**	**$5.73**	**$61.62**
OXICONAZOLE PRODUCTS						
OXICONAZOLE CRE NITRATE 1%	4	70	1	$1,606.56	$22.95	$401.64
SUBTOTAL	**4**	**70**	**1**	**$1,606.56**	**$22.95**	**$401.64**
TIER-2 SUBTOTAL	**120**	**2,746**	**66**	**$12,968.86**	**$4.72**	**$108.07**
SPECIAL PA UTILIZATION						
EFINACONAZOLE PRODUCTS						
JUBLIA SOL 10%	3	90	2	$1,677.47	$18.64	$559.16

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SPECIAL PA SUBTOTAL	3	90	2	$1,677.47	$18.64	$559.16
TOTAL	40,914	608,874	28,953*	$891,604.11	$1.46	$21.79

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated members.

Fiscal Year 2018 Annual Review of Ulcerative Colitis (UC) and Crohn's Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis of induction of remission in members with active, mild-to-moderate ulcerative colitis; 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; 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 members with active, mild-to-moderate, distal ulcerative colitis 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; 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.

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

1. An FDA approved indication for 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; 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.

Pentasa® (Mesalamine 500mg Controlled-Release Capsules) 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; 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 would not require prior authorization.
2. An FDA approved indication for the treatment of active, mild-to-moderate, distal ulcerative colitis, proctosigmoiditis, or proctitis; and
3. A patient-specific, clinically significant reason the member cannot use Canasa® (mesalamine suppositories) which do not require prior authorization; and
4. Provider documentation that member is still having active symptoms after 3 weeks of treatment; and
5. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
6. A quantity limit of 30 enemas (1,800mL) per 30 days will apply.

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

1. A quantity limit of 60 capsules per 30 days will apply.
2. For quantity limit requests for >2 capsules per day:
    a. An FDA approved indication for the induction of remission in members with active, mild-to-moderate ulcerative colitis; 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; 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.

Colazal® (Balsalazide Capsules) Quantity Limit Approval Criteria:

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

Dipentum® (Olsalazine Capsules) Quantity Limit Approval Criteria:

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

Pentasa® (Mesalamine 250mg Controlled-Release Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 480 capsules per 30 days will apply.
2. The first 8 weeks of treatment would not require prior authorization.

3. After 8 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Canasa® (Mesalamine Suppositories) Quantity Limit Approval Criteria:

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

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

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

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

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

Giazo® (Balsalazide) Approval Criteria:

1. An FDA approved diagnosis of mildly-to-moderately active ulcerative colitis; and
2. Member must be 18 years of age or older; and
3. Member must be male (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; 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.

The following medications do not require prior authorization: sulfasalazine 500mg tablets, sulfasalazine delayed-release 500mg tablets, Rowasa® (mesalamine) rectal suspension enemas, Lialda® (mesalamine) delayed-release capsules, Colazal® (balsalazide) capsules, Dipentum® (olsalazine) capsules, Pentasa® (mesalamine) 250mg controlled-release capsules, Canasa® (mesalamine) suppositories, Apriso® (mesalamine) extended-release capsules, Delzicol® (mesalamine) delayed-release capsules, and hydrocortisone enemas.

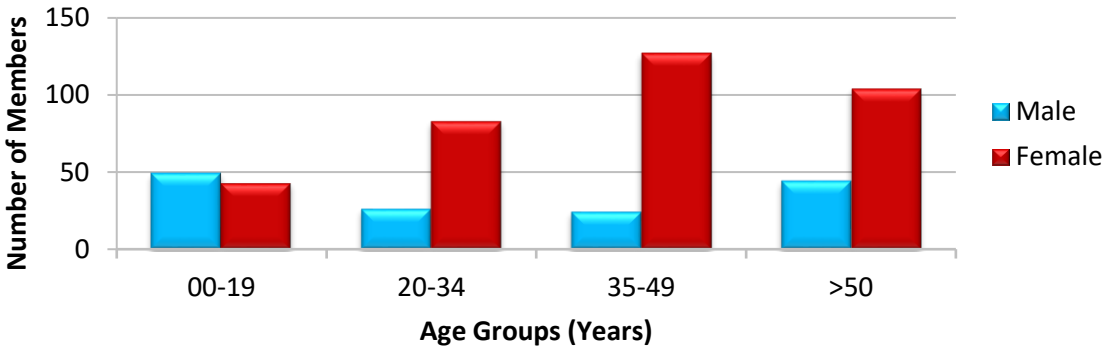
Utilization of UC and Crohn's Disease Medications: Fiscal Year 2018

Comparison of Fiscal Years

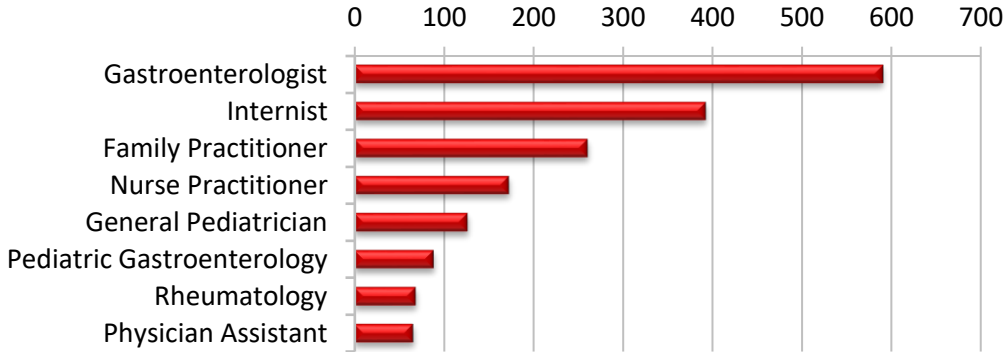
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	547	2,049	$688,228.03	$335.88	$11.27	267,087	61,094
2018	500	1,921	$585,833.54	$304.96	$10.20	247,941	57,440
% Change	**-8.60%**	**-6.20%**	**-14.90%**	**-9.20%**	**-9.50%**	**-7.20%**	**-6.00%**
Change	**-47**	**-128**	**-$102,394.49**	**-$30.92**	**-$1.07**	**-19,146**	**-3,654**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing UC and Crohn's Disease Medications



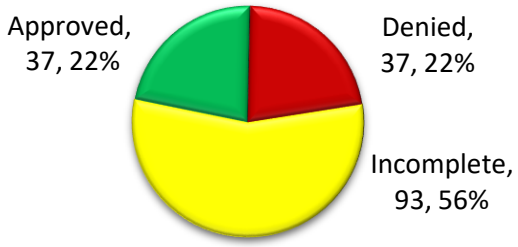
Top Prescriber Specialties of UC and Crohn's Disease Medications by Number of Claims



Prior Authorization of UC and Crohn's Disease Medications

There were 167 prior authorization requests submitted for UC and Crohn's disease medications during fiscal year 2018. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[149]

- Pentasa® (mesalamine controlled-release tablets), Dipentum® (olsalazine capsules), and Cortifoam® (10% hydrocortisone rectal aerosol foam): There are no unexpired patents; however, no generic formulations are available at this time.

[149] 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 01/2019. Last accessed 03/04/2019.

- Delzicol® (mesalamine delayed-release tablets): April 2020
- Lialda® (mesalamine delayed-release tablets): June 2020
- Asacol® HD (mesalamine delayed-release tablets): November 2021
- Canasa® (mesalamine suppositories): June 2028
- Apriso® (mesalamine extended-release tablets): May 2030
- Giazo® (balsalazide tablets): June 2031

News:

- **July 2018:** Teva Pharmaceuticals announced the launch of a generic version of Uceris® (budesonide) extended-release 9mg tablets in the United States. Budesonide extended-release tablets are a glucocorticosteroid indicated for the induction of remission in patients with active, mild-to-moderate ulcerative colitis.[150]

Recommendations

The College of Pharmacy does not recommend any changes to the current UC and Crohn's disease medications prior authorization criteria at this time

Utilization Details of UC and Crohn's Disease Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SULFASALAZINE PRODUCTS						
SULFASALAZIN TAB 500MG	568	166	$15,425.48	$0.91	$27.16	2.63%
SULFASALAZIN TAB 500MG	376	123	$13,085.95	$1.16	$34.80	2.23%
SUBTOTAL	**944**	**289**	**$28,511.43**	**$1.01**	**$30.20**	**4.86%**
MESALAMINE PRODUCTS						
MESALAMINE TAB 1.2GM	212	65	$129,310.75	$20.69	$609.96	22.07%
DELZICOL CAP 400MG	145	31	$79,687.48	$17.76	$549.57	13.60%
APRISO CAP 0.375GM	112	26	$50,120.09	$14.88	$447.50	8.56%
LIALDA TAB 1.2GM	109	38	$79,402.25	$24.11	$728.46	13.55%
PENTASA CAP 250MG CR	85	30	$68,501.97	$27.43	$805.91	11.69%
CANASA SUP 1000MG	32	25	$21,980.16	$24.64	$686.88	3.75%
MESALAMINE TAB 800MG DR	19	2	$4,453.14	$7.81	$234.38	0.76%
PENTASA CAP 500MG CR	13	3	$15,290.58	$33.98	$1,176.2	2.61%
MESALAMINE ENE 4GM	11	8	$2,340.00	$8.13	$212.73	0.40%
SUBTOTAL	**738**	**228**	**$451,086.42**	**$20.42**	**$611.23**	**76.99%**
BALSALAZIDE PRODUCTS						
BALSALAZIDE CAP 750MG	26	10	$2,397.40	$2.79	$92.21	0.41%
SUBTOTAL	**26**	**10**	**$2,397.40**	**$2.79**	**$92.21**	**0.41%**
BUDESONIDE PRODUCTS						
BUDESONIDE CAP 3MG DR	188	50	$73,574.92	$13.03	$391.36	12.56%
UCERIS TAB 9MG	18	3	$29,473.33	$54.58	$1,637.4	5.03%

[150] Teva Pharmaceutical Inc. Teva Announces Launch of a Generic Version of Uceris® in the United States. Available online at: https://www.tevapharm.com/news/teva_announces_launch_of_a_generic_version_of_uceris_in_the_united_states_07_18.aspx. Issued 07/09/2018. Last accessed 03/04/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	**206**	**53**	**$103,048.25**	**$16.66**	**$500.23**	**17.59%**
HYDROCORTISONE PRODUCTS						
HYDROCORT ENE 100MG	5	5	$614.56	$6.27	$122.91	0.10%
COLOCORT ENE 100MG	2	2	$175.48	$5.01	$87.74	0.03%
SUBTOTAL	**7**	**7**	**$790.04**	**$5.94**	**$112.86**	**0.13%**
TOTAL	**1,921**	**500***	**$585,833.54**	**$10.20**	**$304.96**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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 prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For a 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 a diagnosis of prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate) or Reclast® (zoledronic acid) compliantly used for at least 6 months concomitantly with calcium + vitamin D, that failed to prevent fracture or improve 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.
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.
8. A quantity limit of 30 tablets per 30 days will apply.

Elestrin® (Estradiol Gel 0.06%) 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 2018

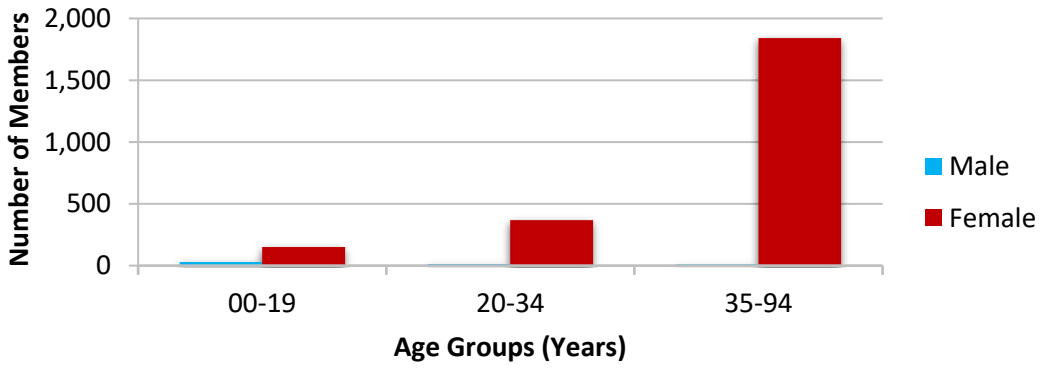
The following utilization data includes vasomotor symptom medications used for all diagnoses and does not differentiate between vasomotor symptom diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

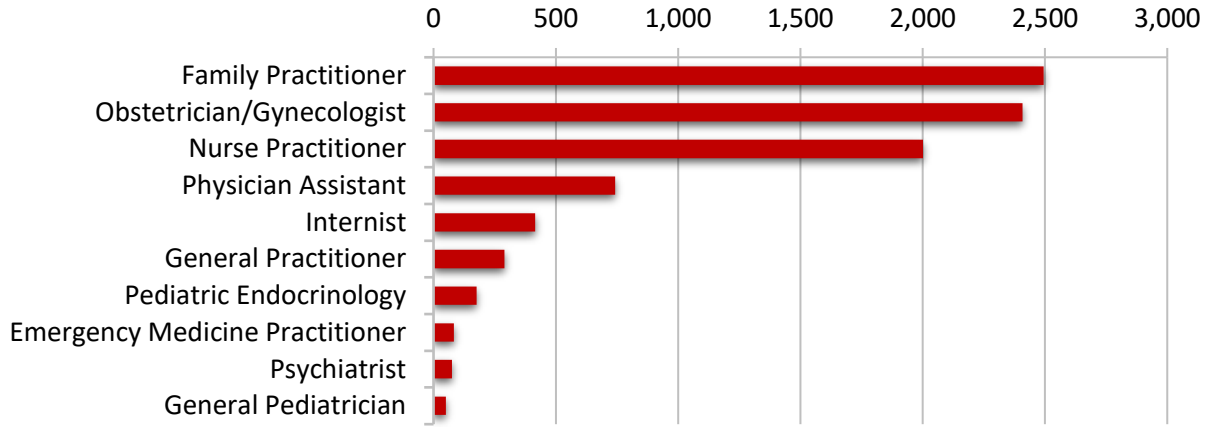
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2,561	9,770	$953,321.62	$97.58	$2.31	376,535	412,937
2018	2,411	9,008	$875,893.20	$97.24	$2.29	347,420	382,099
% Change	**-5.90%**	**-7.80%**	**-8.10%**	**-0.30%**	**-0.90%**	**-7.70%**	**-7.50%**
Change	**-150**	**-762**	**-$77,428.42**	**-$0.34**	**-$0.02**	**-29,115**	**-30,838**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Vasomotor Symptom Medications



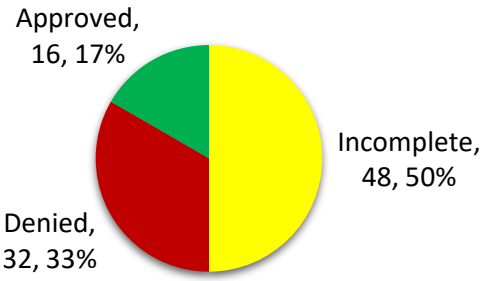
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 96 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Anticipated Patent Expirations:[151]

- Elestrin® (estradiol gel): June 2022
- Evamist® (estradiol transdermal spray): July 2022
- Duavee® (conjugated estrogens/bazedoxifene tablets): March 2027
- Brisdelle® (paroxetine capsules): April 2029
- Minivelle® (estradiol transdermal system): July 2030
- Angeliq® (drospirenone/estradiol tablets): October 2031

News:

- **December 2017:** The U.S. Preventive Services Task Force (USPSTF) made a final recommendation statement over the use of hormone replacement therapy in

[151] 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 02/2019. Last accessed 03/31/2019.

postmenopausal women for the primary prevention of chronic conditions. The recommendations regarding vasomotor symptoms include the following:

- The USPSTF recommends against the use of combined estrogen and progestin for the primary prevention of chronic conditions in postmenopausal women.
- The USPSTF recommends against the use of estrogen alone for the primary prevention of chronic conditions in postmenopausal women who have had a hysterectomy.[152]

- **March 2018:** In a study published the *Journal of the American Medical Association (JAMA) Internal Medicine* found that the mean total score on the Female Sexual Function Index had similar improvements when comparing estradiol to placebo (5.4, 4.0 to 6.9 vs. 4.5, 2.8 to 6.1, P=0.64) and moisturizer compared with placebo (3.1, 1.7 to 4.5 vs. 4.5, 2.8 to 6.1; P=0.17). The trial included 302 postmenopausal women, 102 of whom were randomized to receive Vagifem® 10mcg estradiol tablet daily for 2 weeks and twice weekly thereafter in addition to placebo gel, 100 women who received a placebo tablet plus the over-the-counter vaginal moisturizer Replens®, and 100 women who received dual placebo.[153]

Pipeline:

- **NT-814:** KaNDy Therapeutics announced the initiation of their Phase 2b clinical trial to evaluate NT-814 in women with troublesome symptoms from menopause. NT-814 is a dual mechanism neurokinin (NK)-1,3 receptor antagonist. Hyperactivity of KNDy neurons due to low estrogen levels is believed to initiate the process that causes vasomotor symptoms. The NK-3 receptor system has a controlling influence on at least 2 major pathways: the heat dissipating thermoregulatory pathway and the gonadotropin-releasing hormone (GnRH) pathway. The KNDy neurons have also been shown to express NK-1 receptors and its ligand substance P, suggesting this receptor system may be involved in the functioning of this neuronal circuitry. The combination of NK-1 and NK-3 receptor antagonism could treat multiple symptoms of menopause.[154]

Recommendations

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

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[152] US Preventive Services Task Force. Hormone Therapy for the Primary Prevention of Chronic Conditions in Postmenopausal Women: US Preventive Services Task Force Recommendation Statement. *JAMA* 2017;318(22):2224–2233.
[153] Manaco, K. Vaginal Estradiol Offers Little Help for Postmenopausal Symptoms. *MedPage Today*. Available online at: https://www.medpagetoday.com/obgyn/hrt/71840. Issued 03/19/2018. Last accessed 03/31/2019.
[154] Kandy Therapeutics. KaNDy Therapeutics announces initiation of Phase 2b trial of NT-814 for the treatment of troublesome post-menopausal symptoms. *GlobeNewswire.* Available online at: https://www.globenewswire.com/news-release/2018/12/11/1664832/0/en/KaNDy-Therapeutics-announces-initiation-of-Phase-2b-trial-of-NT-814-for-the-treatment-of-troublesome-post-menopausal-symptoms.html. Issued 12/11/2018. Last accessed 03/31/2019.

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ORAL ESTROGEN PRODUCTS					
ESTRADIOL TAB 1MG	1,959	657	$23,867.73	$0.28	$12.18
ESTRADIOL TAB 2MG	1,529	491	$20,334.13	$0.30	$13.30
PREMARIN TAB 0.625MG	829	209	$183,756.55	$5.28	$221.66
PREMARIN TAB 1.25MG	729	189	$185,991.72	$5.39	$255.13
ESTRADIOL TAB 0.5MG	695	259	$7,681.69	$0.25	$11.05
PREMARIN TAB 0.3MG	355	99	$76,869.50	$5.13	$216.53
PREMARIN TAB 0.9MG	139	44	$33,797.24	$4.95	$243.15
PREMARIN TAB 0.45MG	136	34	$28,838.73	$5.23	$212.05
ESTROPIPATE TAB 0.75MG	53	10	$1,334.43	$0.75	$25.18
ESTROPIPATE TAB 1.5MG	49	9	$1,434.02	$0.72	$29.27
MENEST TAB 0.625MG	28	8	$2,695.84	$2.40	$96.28
MENEST TAB 1.25MG	16	6	$2,133.71	$3.05	$133.36
ESTROPIPATE TAB 3MG	2	1	$59.50	$0.99	$29.75
MENEST TAB 0.3MG	1	1	$147.66	$1.64	$147.66
SUBTOTAL	**6,520**	**2017**	**$568,942.45**	**$1.99**	**$87.26**
TOPICAL ESTROGEN PRODUCTS					
ESTRADIOL DIS 0.1MG	293	50	$22,994.40	$2.77	$78.48
ESTRADIOL DIS 0.1MG	246	80	$14,753.31	$2.10	$59.97
ESTRADIOL DIS 0.05MG	174	43	$13,469.87	$2.67	$77.41
ESTRADIOL DIS 0.05MG	145	36	$8,467.55	$2.07	$58.40
ESTRADIOL DIS 0.075MG	92	22	$6,980.92	$2.67	$75.88
ESTRADIOL DIS 0.025MG	86	26	$6,300.58	$2.09	$73.26
ESTRADIOL DIS 0.025MG	94	36	$5,990.73	$2.22	$63.73
ESTRADIOL DIS 0.0375MG	55	10	$3,613.87	$2.30	$65.71
ESTRADIOL DIS 0.0375MG	40	12	$2,499.77	$2.23	$62.49
ESTRADIOL DIS 0.075MG	25	11	$1,634.34	$2.33	$65.37
MINIVELLE DIS 0.1MG	26	7	$2,279.48	$3.13	$87.67
MINIVELLE DIS 0.025MG	18	4	$1,536.56	$2.79	$85.36
DIVIGEL GEL 1MG/GM	24	6	$5,146.48	$5.36	$214.44
DIVIGEL GEL 0.5MG	21	8	$3,064.43	$4.09	$145.93
EVAMIST SPR 1.53MG	21	14	$2,708.12	$2.22	$128.96
MINIVELLE DIS 0.05MG	14	4	$1,189.06	$3.03	$84.93
DIVIGEL GEL 0.25MG	13	6	$1,836.61	$4.08	$141.28
ESTRADIOL DIS 0.06MG	9	3	$558.99	$2.22	$62.11
MINIVELLE DIS 0.0375MG	8	1	$680.96	$3.04	$85.12
MENOSTAR DIS 14MCG	8	1	$1,201.62	$5.36	$150.20
VIVELLE-DOT DIS 0.1MG	7	1	$564.13	$2.82	$80.59
CLIMARA DIS 0.025MG	6	2	$390.85	$2.33	$65.14
MINIVELLE DIS 0.075MG	5	4	$418.70	$2.93	$83.74
ALORA DIS 0.025MG	5	3	$426.60	$3.00	$85.32

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
VIVELLE-DOT DIS 0.05MG	1	1	$73.98	$2.55	$73.98
SUBTOTAL	**1,436**	**391**	**$108,781.91**	**$2.55**	**$75.75**
ORAL ESTROGEN/PROGESTIN PRODUCTS					
PREMPRO TAB .625-2.5	235	56	$63,955.68	$6.40	$272.15
PREMPRO TAB 0.3-1.5	95	32	$23,306.68	$6.35	$245.33
PREMPRO TAB 0.45-1.5	88	19	$19,082.46	$6.12	$216.85
PREMPRO TAB 0.625-5	67	17	$16,914.99	$6.35	$252.46
ESTRA/NORETH TAB 0.5-0.1	93	22	$9,393.16	$2.65	$101.00
ESTRA/NORETH TAB 1-0.5MG	47	12	$4,842.29	$2.93	$103.03
MIMVEY TAB 1-0.5MG	26	9	$2,723.58	$2.85	$104.75
JINTELI TAB 1MG-5MCG	19	4	$1,344.34	$2.01	$70.75
PREMPHASE TAB 0.625-5MG	15	4	$4,118.17	$7.00	$274.54
MIMVEY LO TAB 0.5-0.1MG	1	1	$243.94	$2.90	$243.94
NORETH/ETHIN TAB 0.5-2.5MG	11	3	$949.30	$3.06	$86.30
PREFEST TAB 1-0.09MG	12	1	$1,488.96	$4.14	$124.08
NORETH/ETHIN TAB 1MG-5MCG	3	3	$282.08	$1.91	$94.03
JEVANTIQUE L TAB 0.5-2.5MCG	3	2	$231.11	$2.75	$77.04
ANGELIQ TAB 0.5-1MG	3	2	$1,520.13	$6.03	$506.71
ANGELIQ TAB 0.25-0.5MG	2	2	$698.35	$6.24	$349.18
SUBTOTAL	**720**	**189**	**$151,095.22**	**$5.36**	**$209.85**
INJECTABLE ESTROGEN PRODUCTS					
DEPO-ESTRADI INJ 5MG/ML	221	113	$24,062.04	$1.19	$108.88
ESTRAD VAL INJ 20MG/ML	7	6	$763.05	$1.01	$109.01
DELESTROGEN INJ 10MG/ML	5	3	$598.22	$1.95	$119.64
DELESTROGEN INJ 40MG/ML	1	1	$320.86	$2.29	$320.86
SUBTOTAL	**234**	**123**	**$25,744.17**	**$1.20**	**$110.02**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS					
CLIMARA PRO DIS WEEKLY	33	10	$6,194.24	$6.69	$187.70
COMBIPAT DIS 0.05-0.25MG	11	4	$1,797.17	$3.95	$163.38
COMBIPAT DIS 0.05-0.14MG	25	5	$4,128.24	$5.90	$165.13
SUBTOTAL	**69**	**19**	**$12,119.65**	**$5.82**	**$175.65**
ESTROGEN/SERM PRODUCTS					
DUAVEE TAB 0.45-20MG	13	2	$2,142.10	$5.49	$164.78
SUBTOTAL	**13**	**2**	**$2,142.1**	**$5.49**	**$164.78**
VAGINAL ESTROGEN PRODUCTS					
FEMRING MIS 0.1MG/24H	11	5	$4,946.41	$5.03	$449.67
FEMRING MIS 0.05/24H	5	2	$2,121.29	$4.71	$424.26
SUBTOTAL	**16**	**7**	**$7,067.7**	**$4.93**	**$441.73**
TOTAL	**9,008**	**2,411***	**$875,893.20**	**$2.29**	**$97.24**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
SERM = selective estrogen receptor modulator

Fiscal Year 2018 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
Fiscal Year 2018 Print Report

Current Prior Authorization Criteria

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, 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 they are 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.

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, 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 they are 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.

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. Member must not be at significant risk for suicidal or violent behavior and must not have unstable psychiatric symptoms; 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 monoamine oxidase inhibitors (MAOIs); and
7. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
8. 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
9. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
10. Female members must not be pregnant or breastfeeding; and
11. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
12. A quantity limit of 1 capsule per day will apply; and
13. 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.

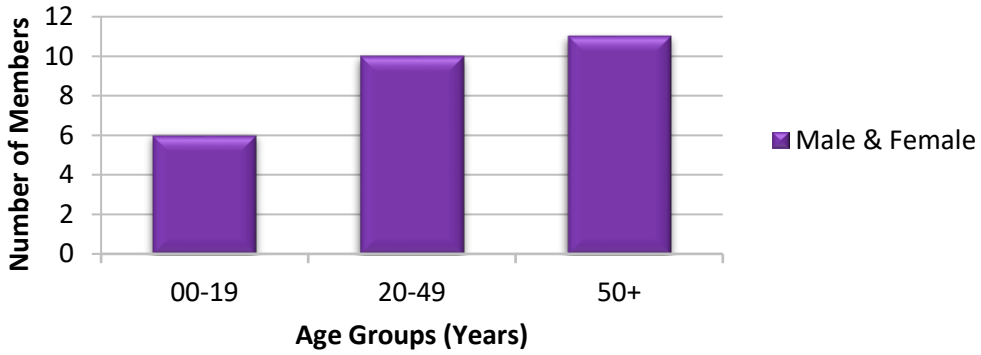
Utilization of VMAT2 Inhibitor Medications: Fiscal Year 2018

Comparison of Fiscal Years

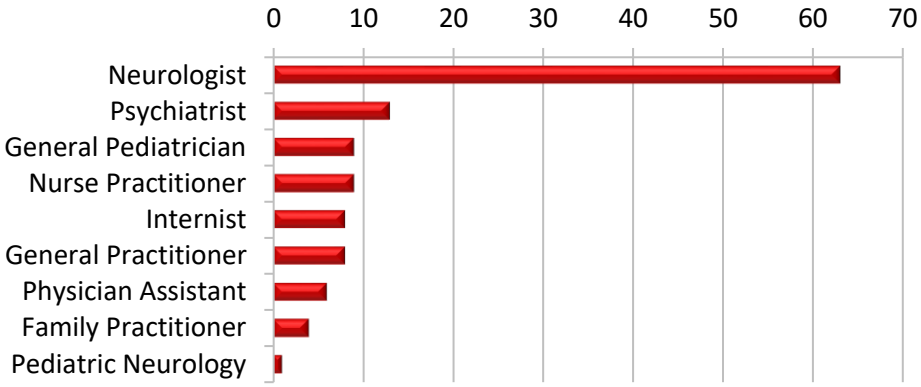
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	11	79	$801,022.00	$10,139.52	$329.10	5,678	2,434
2018	27	121	$940,041.02	$7,768.93	$269.43	6,230	3,489
% Change	**145.50%**	**53.20%**	**17.40%**	**-23.40%**	**-18.10%**	**9.70%**	**43.30%**
Change	**16**	**42**	**$139,019.02**	**-$2,370.59**	**-$59.67**	**552**	**1,055**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing VMAT2 Inhibitor Medications



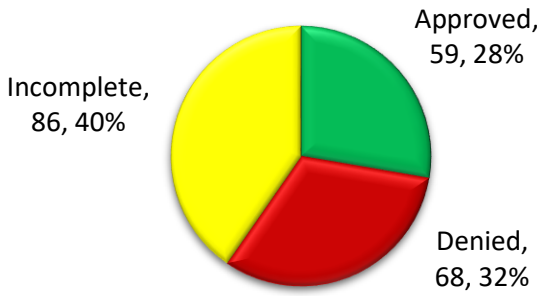
Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 213 prior authorization requests submitted for VMAT2 inhibitor medications during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.

Status of Petitions



Market News and Updates

Patent Expiration(s):[155]

- Austedo® (deutetrabenazine): September 2033
- Ingrezza® (valbenazine): October 2036

Pipeline:

- **IONIS-HTT$_{Rx}$:** In August 2018, Ionis Pharmaceuticals, Inc. announced that the European Medicines Agent (EMA) had granted Priority Medicines designation to IONIS-HTT$_{Rx}$ for the treatment of people with Huntington's disease (HD). This is the first drug to demonstrate a reduction of mutant huntingtin protein (mHTT), the underlying cause of HD. In a Phase 1/2 study, IONIS-HTT$_{Rx}$ demonstrated a significant reduction in mHTT, which breaks down the nerve cells in the brain. In adult patients treated with IONIS-HTT$_{Rx}$ for 3 months at the 2 highest doses, the study demonstrated a mean 40% (up to

[155] 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 03/14/2019.

60%) reduction of the specific HD protein in the cerebrospinal fluid. Roche plans to initiate a pivotal study to evaluate IONIS-HTT_{Rx} in a larger patient population to further characterize its safety and efficacy in adults with HD. IONIS-HTT_{Rx} has been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with HD.[156]

News:

- **June 2018:** Updates to the evidence-based recommendations for tardive syndromes (TS) were published in the *Journal of Neurological Sciences*. A systematic review was conducted to update the evidence-based recommendations and provide a practical treatment algorithm for the management TS. TS is an umbrella term for a variety of delayed-onset, persistent motor and nonmotor syndromes associated with use of dopamine receptor blocking agents (DRBAs). The "classic" form of TS is oral-buccal-lingual dyskinesia, often used synonymously with the term "tardive dyskinesia." The authors recommended that suppressive therapy should be considered when disabilities are at least moderate and interfere with activities of daily living (ADL) and quality of life. The new VMAT2 inhibitors, valbenazine and deutetrabenazine, were recommended as the first-line treatment options (Level A evidence), and, if valbenazine and deutetrabenazine are not available, tetrabenazine may be used (Level C evidence). Clonazepam and ginkgo biloba were listed as second-line treatment options, and combined with amantadine if symptoms are still troublesome. The authors recommended that globus pallidus interna deep brain stimulation be reserved for intractable TD.[157]
- **August 2018:** Data for a Phase 3 clinical trial of Ingrezza® (valbenazine) shows that long-term daily use of the medication leads to a clinically meaningful easing of tardive dyskinesia (TD). The results were presented at the 2018 World Congress on Parkinson's Disease and Related Disorders. At week 48, both doses (40 and 80mg) eased TD, as assessed by the Abnormal Involuntary Movement Scale (AIMS) total score, and more than 75% of participants reported a Patient Global Impression of Change (PGIC) score of 2 or under (a self-reported score meaning "much improved" or "very much improved"). Clinically meaningful long-term improvements were also observed at week 48 for both dose groups. Of note, both PGIC and Clinical Global Impression of Change-TD worsened after treatment withdrawal during the final 4 weeks of follow-up evaluation. Data showed that safety and tolerability were also favorable, with no new safety signals from previous studies. Fewer than 15% of all participants reported a serious treatment emergent adverse events (TEAEs) or a TEAE leading to discontinuation. Suicidal thoughts or behavior during treatment were reported by 6.7% of participants. The scientists

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[156] Ionis Pharmaceuticals. IONIS-HTT Rx (RG6042) Granted PRIME Designation by the European Medicines Agency for the Treatment of People with Huntington's Disease. *PRNewswire*. Available online at: http://ir.ionispharma.com/news-releases/news-release-details/ionis-htt-rx-rg6042-granted-prime-designation-european-medicines. Issued 08/02/2018. Last accessed 03/21/2019.

[157] Bhidayasiri R, Jitkritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci* 2018; 389:67-75. doi: 10.1016/j.jns.2018.02.010

stated that the worsening of TD after treatment discontinuation suggests that patients may need ongoing therapy for stable improvements.[158]

- **January 2019:** According to a recent meta-analysis, treatment with clozapine demonstrated a reduction in disease severity and symptoms in some patients with TD. The team from the Netherlands discovered 16 relevant studies to include in their analysis and the investigators sought to examine the effect of switching to clozapine in an attempt to reduce TD disease severity. Patients involved in the published studies had a diagnosis of schizophrenia or a related disorder and switched to clozapine monotherapy. Scores on a TD rating scale were reported before and after switching to clozapine. The team reported that the overall effect of switching to clozapine monotherapy produced a significant reduction in TD. The investigators also noted that clozapine did not appear to worsen TD based on what they observed from the subclinical group. They also noted that compared to those that switched to clozapine monotherapy in their clinical TD group, the effects of VMAT-2 inhibitors were smaller; however, studies of valbenazine and deutetrabenazine included a wider range of patient diagnosis than the current meta-analysis. The National Institute for Health and Care Excellence and the American Psychiatric Association guidelines suggest switching to clozapine treatment only after a partial or suboptimal response to 2 other antipsychotics, and at least 1 of those should be a second-generation antipsychotic. The study authors recommended adding moderate-to-severe TD and/or substantial discomfort from the disease as an indication for switching to clozapine to these guidelines.[159]

Recommendations

The College of Pharmacy does not recommend any changes to the current VMAT2 inhibitor medications prior authorization criteria at this time.

Utilization Details of VMAT2 Inhibitor Medications: Fiscal Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TETRABENAZINE PRODUCTS						
XENAZINE TAB 25MG	35	6	$450,982.60	$429.51	$12,885.22	47.97%
TETRABENAZIN TAB 25MG	15	5	$104,287.90	$226.71	$6,952.53	11.09%
TETRABENAZIN TAB 12.5MG	10	3	$30,409.77	$108.61	$3,040.98	3.23%
XENAZINE TAB 12.5MG	2	1	$18,775.12	$312.92	$9,387.56	2.00%
SUBTOTAL	**62**	**15**	**$604,455.39**	**$10,074.26**	**$9,749.28**	**64.29%**
VALBENAZINE PRODUCTS						
INGREZZA CAP 80MG	31	8	$190,351.55	$207.81	$6,140.37	20.25%

[158] Lopes JM. Ingrezza Eases Tardive Dyskinesia Safely and Effectively Over Long-Term, Phase 3 Trial Shows. *Parkinson's News Today*. Available online at: https://parkinsonsnewstoday.com/2018/08/21/ingrezza-eases-tardive-dyskinesia-safely-and-effectively-in-long-term-phase-3-trial-shows/. Issued 08/21/2018. Last accessed 03/21/2019.

[159] Lutz R. Clozapine Shows Reduction in Tardive Dyskinesia Symptoms. *MD Magazine*. Available online at: https://www.mdmag.com/medical-news/clozapine-shows-reduction-tardive-dyskinesia-symptoms. Issued 01/07/2019. Last accessed 03/21/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
INGREZZA CAP 40MG	11	8	$59,752.73	$228.94	$5,432.07	6.36%
SUBTOTAL	**42**	**16**	**$250,104.28**	**$212.49**	**$5,954.86**	**26.61%**
DEUTETRABENAZINE PRODUCTS						
AUSTEDO TAB 12MG	12	5	$72,592.00	$211.02	$6,049.33	7.72%
AUSTEDO TAB 6MG	3	1	$5,720.35	$85.38	$1,906.78	0.61%
AUSTEDO TAB 9MG	2	2	$7,169.00	$140.57	$3,584.50	0.76%
SUBTOTAL	**17**	**8**	**$85,481.35**	**$185.02**	**$5,028.31**	**9.09%**
TOTAL	**121**	**27***	**$940,041.02**	**$573.55**	**$7,768.93**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Fiscal Year 2018 Annual Review of Vimizim® (Elosulfase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2018 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 2018

There were no paid medical or pharmacy claims for Vimizim® (elosulfase alfa) during fiscal year 2018.

Prior Authorization of Vimizim® (Elosulfase Alfa)

There were no prior authorization requests submitted for Vimizim® (elosulfase alfa) during fiscal year 2018.

Recommendations

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

Fiscal Year 2018 Annual Review of Xgeva® (Denosumab)

Oklahoma Health Care Authority
Fiscal Year 2018 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 members with multiple myeloma and in members 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 of greater than 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 2018

Xgeva® (Denosumab) Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim
2017	57	268	$513,738.28	$1,916.93
2018	52	236	$448,939.74	$1,902.29
% Change	**-8.77%**	**-11.94%**	**-12.61%**	**-0.76%**
Change	**-5**	**-32**	**-$64,798.54**	**-$14.64**

*Total number of unduplicated members.

Demographics of Members Utilizing Xgeva® (Denosumab)

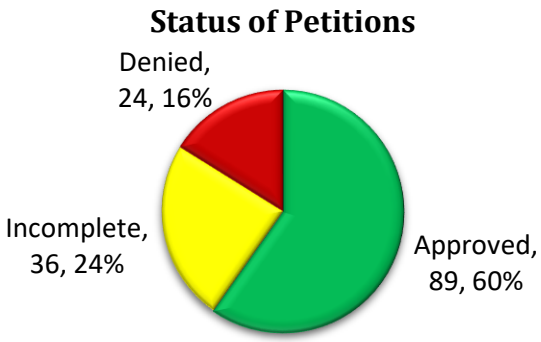
- Xgeva® (denosumab) is a medically administered drug, therefore member demographics are not provided in this report.

Top Prescriber Specialties of Xgeva® (Denosumab) by Number of Claims

- Xgeva® (denosumab) is a medically administered drug, therefore prescriber specialties are not provided in this report.

Prior Authorization of Xgeva® (Denosumab)

There were 149 prior authorization requests submitted for Xgeva® (denosumab) during fiscal year 2018. The following chart shows the status of the submitted petitions for fiscal year 2018.



Recommendations

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

Fiscal Year 2018 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2018 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]:

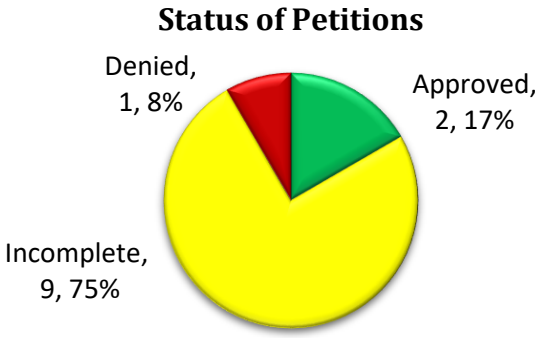
1. A diagnosis of stable Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy; and
2. Member must be 18 years of age or older; and
3. Member must have pain outside the circumstances of intercourse that is refractory 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 2018

There were no paid pharmacy or medical claims for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2018.

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 12 prior authorization requests submitted for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2018. The following chart shows the status of the submitted petitions.



Market News and Updates

Guideline Update:[160]

- In February 2018, the Canadian Urological Association updated the guideline for the diagnosis and management of Peyronie's disease and congenital penile curvature. Recommendations include no treatment for men who do not have sexual issues associated with Peyronie's disease or treatment with surgery in those who have sexual concerns and a stable deformity. For patients who have sexual concerns and active disease, intralesional therapy with Xiaflex® (collagenase clostridium hystolyticum) is recommended first-line.

Recommendations

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

[160] Bella AJ, Lee JC, Grober ED, et al. 2018 Canadian Urological Association guideline for Peyronie's disease and congenital penile curvature. *Can Urol Assoc J* 2018;12(5):E197-209.

Fiscal Year 2018 Annual Review of Xuriden® (Uridine Triacetate)

Oklahoma Health Care Authority
Fiscal Year 2018 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; or
        i. Normal serum folate and vitamin B12 levels and no evidence of transcobalamin II deficiency; or
    c. Orotic acid crystals visualized in the urine via microscopy; and
2. Current weight of member 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/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 2018

There was no SoonerCare paid claims for Xuriden® (uridine triacetate) during fiscal year 2018.

Prior Authorization of Xuriden® (Uridine Triacetate)

There were no prior authorization requests submitted for Xuriden® (uridine triacetate) during fiscal year 2018.

Market News and Updates

Anticipated Patent Expiration(s):[161]

- Xuriden® (uridine triacetate): July 2019

Recommendations

[161] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 11/2018. Last accessed 01/02/2019.

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

Fiscal Year 2018 Annual Review of Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
Fiscal Year 2018 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 or more of the following risk factors for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes 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 2018

Zinplava™ (Bezlotoxumab): Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2018	1	1	$3,800.00	$3,800.00	100

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- There was no SoonerCare utilization of Zinplava™ (bezlotoxumab) during fiscal year 2017 to allow for a fiscal year comparison.
- There were no pharmacy claims for Zinplava™ (bezlotoxumab) during fiscal year 2018.

Demographics of Members Utilizing Zinplava™ (Bezlotoxumab)

- Due to the small number of members utilizing Zinplava™ (bezlotoxumab), detailed demographic information could not be provided.

Top Prescriber Specialties of Zinplava™ (Bezlotoxumab) by Number of Claims

- The only prescriber specialty listed on paid claims for Zinplava™ (bezlotoxumab) during fiscal year 2018 was hematology/oncology.

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were 2 prior authorization requests submitted for Zinplava™ (bezlotoxumab) for 1 unique member during fiscal year 2018.

Market News and Updates

Guideline Update(s):[162]

- **February 2018:** An updated clinical practice guideline for *Clostridium difficile* infections (CDI) was published online in the journal *Clinical Infectious Diseases*. It is endorsed by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA), and is an update from the previous 2010 CDI guideline. Recommendations for treatment of CDI in adults have been revised significantly.
  - A strong recommendation from the panel, citing high-quality evidence, now favors a 10-day course of vancomycin or fidaxomicin rather than metronidazole for first-line therapy of mild/moderate CDI in adults. This is based on several clinical trials demonstrating greater cure rate and less frequent recurrence following vancomycin compared with metronidazole.
  - Treatment strategies for recurrent CDI were also revised. Following initial CDI treated with a 10-day course of vancomycin, either a several-week tapered and pulsed course of vancomycin or a 10-day course of fidaxomicin is recommended. For most patients, probiotics can be considered because of favorable cost and safety, although definitive efficacy data for probiotics to prevent recurrent CDI are still lacking.
  - For multiple recurrent CDI, correction of the patient's underlying intestinal microbiota perturbation with fecal microbiota transplantation (FMT) should be strongly considered.
  - For treatment of children with CDI, metronidazole can still be considered for treatment of an initial or first recurrence of mild/moderate CDI, but vancomycin is preferred for multiple recurrent and/or severe CDI. Fidaxomicin is currently undergoing Phase 3 investigation in children.
  - The guidelines strongly reinforce the importance of practicing good diagnostic stewardship and limiting CDI testing to patients with new-onset, unexplained, and clinically significant (i.e., at least 3 unformed stools in a 24-hour period) diarrhea.

[162] Kociolek LK. Updated *C difficile* Infection Clinical Guidance From IDSA/SHEA. *Infectious Disease Advisor*. Available online at: https://www.infectiousdiseaseadvisor.com/clostridium-difficile/updated-clostridium-difficile-infection-guidelines-from-idsa-shea/article/744927/. Issued 02/06/2018. Last accessed 02/04/2019.

Pipeline: [163,164]

- **CP101:** Crestovo's lead microbiome therapy generated from the company's Full-Spectrum Microbiota™ (FSM™) platform, CP101, is being studied for the prevention of recurrent CDI. As an encapsulated, orally-administered FSM™ therapy, CP101 contains the full complement of functional microorganisms that may help restore the microbial imbalance to a normal, functioning gut microbial community.

Recommendations

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

[163] Payesko J. Phase 2 Clinical Trial Tests CP101 in Subjects with Recurrent C. diff. *MD Magazine*. Available online at: https://www.mdmag.com/medical-news/phase-2-clinical-trial-tests-cp101-in-subjects-with-recurrent-c-diff. Issued 09/29/2017. Last accessed 02/04/2019.

[164] Crestovo. Crestovo Doses Patients in PRISM 3, a Clinical Trial of CP101, a Microbiome Therapy for the Prevention of Recurrent *Clostridium difficile* Infection. *Business Wire*. Available online at: http://www.businesswire.com/news/home/20170627005282/en/Crestovo-Doses-Patients-PRISM-3-Clinical-Trial. Issued 06/27/2017. Last accessed 01/23/2019.