

## Print Annual Reviews for Fiscal Year 2016

Count	Category/Medication	Review Period
1.	Allergy Immunotherapies	Fiscal Year
2.	Antifungals (Oral/IV)	Fiscal Year
3.	Antihistamines (Oral)	Fiscal Year
4.	Anti-Ulcer Medications	Fiscal Year
5.	Benlysta® (belimumab)	Fiscal Year
6.	Benzodiazepines	Fiscal Year
7.	Benign Prostatic Hypertrophy Medications	Fiscal Year
8.	Cholbam® (cholic acid)	Fiscal Year
9.	Diabetic Supplies	Fiscal Year
10.	Elidel™ (pimecrolimus)/Protopic® (tacrolimus)	Fiscal Year
11.	Erythropoiesis-Stimulating Agents (ESAs)	Fiscal Year
12.	Fibric Acid Derivatives	Fiscal Year
13.	Fibromyalgia	Fiscal Year
14.	Gattex® (Teduglutide [rDNA origin])	Fiscal Year
15.	Gout Medications	Fiscal Year
16.	Hereditary Angioedema Medications	Fiscal Year
17.	Horizant® (gabapentin ER)/Gralise® (gabapentin ER)	Fiscal Year
18.	Inhaled Short-Acting Beta <sub>2</sub> Agonists	Fiscal Year
19.	Insomnia Medications	Fiscal Year
20.	Leukotriene Modifiers	Fiscal Year
21.	Metozolv® ODT (metoclopramide orally disintegrating tablets)	Fiscal Year
22.	Mozobil® (plerixafor)/Nplate® (romiplostim)/Acralyst® (rilonacept)	Fiscal Year
23.	Muscle Relaxant Medications	Fiscal Year
24.	Myalept® (metreleptin)	Fiscal Year
25.	Mytesi™ (crofelemer) [Formerly Known As Fulyzaq®]	Fiscal Year
26.	Nasal Allergy Medications	Fiscal Year
27.	Northera® (droxidopa)	Fiscal Year
28.	Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	Fiscal Year
29.	Nuedexta® (dextromethorphan/quinidine)	Fiscal Year
30.	Ocular Allergy	Fiscal Year
31.	Ocular Antibiotics	Fiscal Year
32.	Ophthalmic Corticosteroids	Fiscal Year
33.	Pediculocides	Fiscal Year
34.	Prenatal Vitamins	Fiscal Year
35.	Procysbi® (cysteamine bitartrate)	Fiscal Year
36.	Qualaquin® (quinine sulfate)	Fiscal Year
37.	Qutenza® (capsaicin 8% patch)	Fiscal Year
38.	Ravicti® (glycerol phenylbutyrate)	Fiscal Year
39.	Rayos® (prednisone delayed-release)	Fiscal Year

<b>Count</b>	<b>Category/Medication</b>	<b>Review Period</b>
40.	Retisert® (fluocinolone intravitreal implant)	Fiscal Year
41.	Ribavirin Unique Dosage Formulation Products	Fiscal Year
42.	Smoking Cessation	Fiscal Year
43.	Soliris® (eculizumab)	Fiscal Year
44.	Sylvant® (siltuximab)	Fiscal Year
45.	Symlin® (pramlintide)	Fiscal Year
46.	Topical Antibiotics	Fiscal Year
47.	Topical Antifungals	Fiscal Year
48.	Vasomotor Symptom Medications	Fiscal Year
49.	Xgeva® (denosumab)	Fiscal Year
50.	Xiaflex® (collagenase clostridium histolyticum)	Fiscal Year

Fiscal Year = 07/01/2015 to 06/30/2016

ER = extended-release; IV = intravenous

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# Fiscal Year 2016 Annual Review of Allergy Immunotherapies

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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

1. Member must be 5 years of age or older; 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 two different medications for 14 days each during a previous season; and
  - b. Montelukast: One 14-day trial during a previous season in combination with an antihistamine; and
  - c. Nasal steroids: Trials of two different medications for 21 days each during a previous season; and
6. Treatment must begin greater than or equal to 12 weeks (November 15<sup>th</sup>) prior to the start of the grass pollen season 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 one 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.
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 10 years of age or older; and
2. Member must have a positive skin test or in vitro testing for pollen specific IgE antibodies to one of the five 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 two different medications for 14 days each during a previous season; and
  - b. Montelukast: One 14-day trial during a previous season in combination with an antihistamine; and
  - c. Nasal steroids: Trials of two different medications for 21 days each during a previous season; and
6. Treatment must begin greater than or equal to 16 weeks prior to the start of the grass pollen season (October 15<sup>th</sup>) 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 one tablet daily will apply; and
9. Initial approvals will be for the duration of six 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 of age or older; 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 two different medications for 14 days each during a previous season; and
  - b. Montelukast: One 14-day trial during a previous season in combination with an antihistamine; and
  - c. Nasal steroids: Trials of two different medications for 21 days each during a previous season; and
6. Treatment must begin greater than or equal to 12 weeks prior to the start of ragweed pollen season 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 one 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.
12. Prescriber must be an allergist, immunologist or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

## Utilization of Allergy Immunotherapies: Fiscal Year 2016

### Comparison of Fiscal Years\*

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	1	7	\$1,855.05	\$265.01	\$8.83	210	210

\*There was no utilization of allergy immunotherapies for fiscal year 2015; therefore, no comparison is available.

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Allergy Immunotherapies

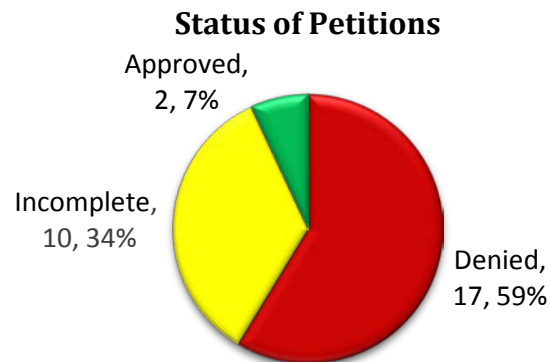
- Due to the small number of members utilizing allergy immunotherapies detailed demographic information could not be provided.

### Top Prescriber Specialties of Allergy Immunotherapies by Number of Claims

- The only prescriber listed for paid claims of allergy immunotherapies during fiscal year 2016 was an allergist.

## Prior Authorization of Allergy Immunotherapies

There were 29 prior authorization requests submitted for the allergy immunotherapies during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Recommendations

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

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# Fiscal Year 2016 Annual Review of Antifungal Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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#### **Cresemba® (Isavuconazonium Sulfate) Approval Criteria:**

1. An FDA approved diagnosis of one of the following:
  - a. Invasive mucormycosis; or
  - b. Invasive aspergillosis; 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:**

1. An FDA approved indication of systemic fungal infections with one of the following:
  - a. Blastomycosis; or
  - b. Coccidioidomycosis; or
  - c. Histoplasmosis; or
  - d. Chromomycosis; or
  - e. paracoccidioidomycosis; and
2. Member must be 3 years of age or older; and
3. Member must 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 onychomycosis; and
2. No improvement after at least three weeks of therapy with griseofulvin; or
3. Intolerance or hypersensitivity to griseofulvin or penicillin; and
4. Member is unable to swallow tablets.

#### **Noxafil® (Posaconazole) Approval Criteria:**

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

**Oravig® (Miconazole Buccal Tablets) Approval Criteria:**

1. An FDA-approved diagnosis of oropharyngeal candidiasis in adults age 18 and older; and
2. Recent trials (within the last month) of the following medications at 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 2016**

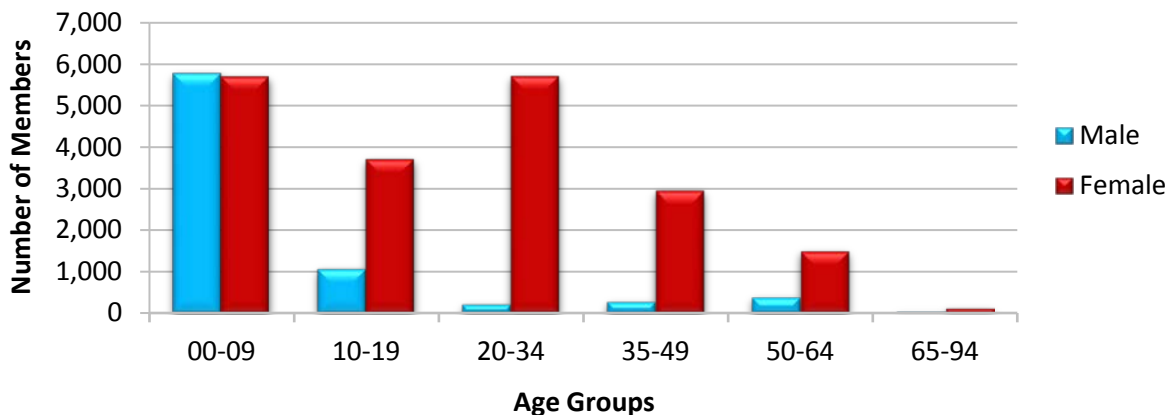
**Comparison of Fiscal Years**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	27,460	38,420	\$1,147,194.61	\$29.86	\$2.73	2,278,672	420,953
2016	27,449	38,670	\$1,260,679.33	\$32.60	\$2.90	2,254,888	434,345
% Change	0.00%	0.70%	9.90%	9.20%	6.20%	-1.00%	3.20%
Change	-11	250	\$113,484.72	\$2.74	\$0.17	-23,784	13,392

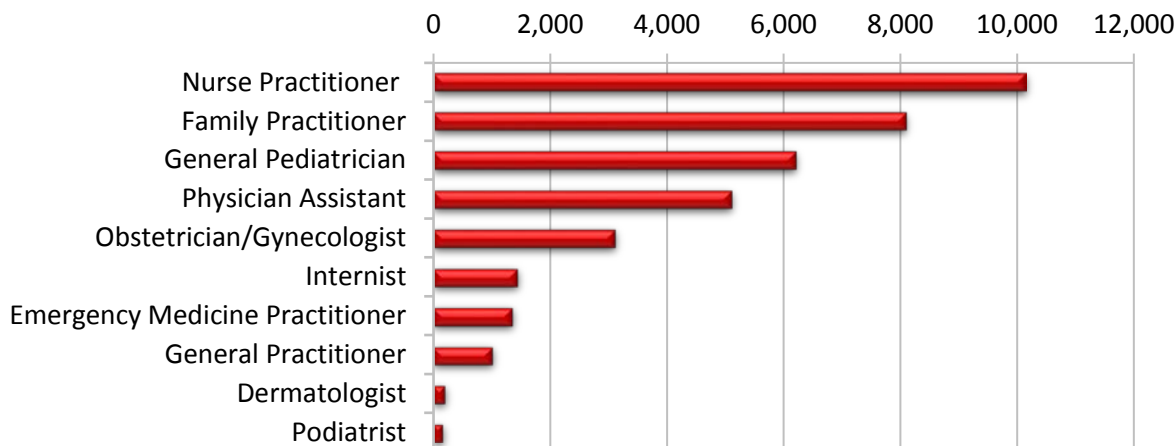
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

**Demographics of Members Utilizing Antifungal Medications**

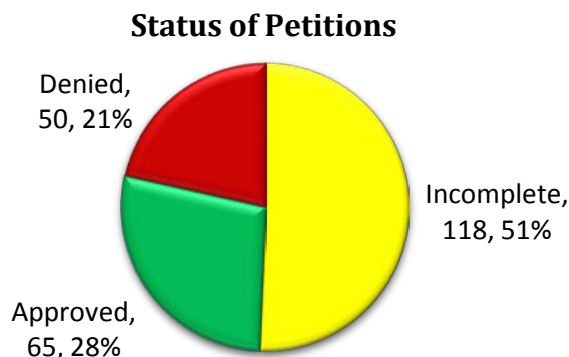


## Top Prescriber Specialties of Antifungal Medications by Number of Claims



## Prior Authorization of Antifungal Medications

There were 233 prior authorization requests submitted for the antifungal medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- Noxafil® (posaconazole): July 2019
- Cresemba® (isavuconazonium): October 2020
- Oravig® (miconazole): September 2022
- Onmel® (itraconazole): October 2028

## Recommendations

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

<sup>1</sup> 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 08/2016. Last accessed 10/2016.



## Utilization Details of Antifungal Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	% COST
<b>AMPHOTERICIN B PRODUCTS</b>						
AMBISOME INJ 50MG	37	10	\$105,706.27	\$230.80	\$2,856.93	8.38%
AMPHOTERICIN POW B	6	4	\$88.17	\$0.96	\$14.70	0.01%
AMPHOTERICIN INJ 50MG	2	1	\$54.58	\$3.64	\$27.29	0.00%
<b>SUBTOTAL</b>	<b>45</b>	<b>15</b>	<b>\$105,849.02</b>	<b>187.34</b>	<b>\$2352.20</b>	<b>8.39%</b>
<b>CLOTRIMAZOLE PRODUCTS</b>						
CLOTRIMAZOLE LOZ 10MG	61	60	\$2,161.19	\$3.02	\$35.43	0.17%
CLOTRIMAZOLE TRO 10MG	32	21	\$1,323.43	\$2.68	\$41.36	0.10%
<b>SUBTOTAL</b>	<b>93</b>	<b>81</b>	<b>\$3,484.62</b>	<b>\$2.88</b>	<b>\$37.47</b>	<b>0.27%</b>
<b>FLUCONAZOLE PRODUCTS</b>						
FLUCONAZOLE TAB 150MG	14,690	10,552	\$107,805.30	\$1.85	\$7.34	8.55%
FLUCONAZOLE TAB 200MG	2,271	1,751	\$45,906.55	\$1.94	\$20.21	3.64%
FLUCONAZOLE TAB 100MG	1,848	1,471	\$28,068.63	\$1.46	\$15.19	2.23%
FLUCONAZOLE SUS 40MG/ML	1,544	1,312	\$50,980.23	\$3.04	\$33.02	4.04%
FLUCONAZOLE SUS 10MG/ML	1,510	1,275	\$27,493.34	\$1.71	\$18.21	2.18%
FLUCONAZOLE TAB 50MG	91	82	\$768.93	\$1.56	\$8.45	0.06%
FLUCONAZOLE/ INJ 400MG	23	6	\$593.48	\$3.51	\$25.80	0.05%
FLUCONAZOLE/ INJ 200MG	3	2	\$69.39	\$7.71	\$23.13	0.01%
DIFLUCAN SUS 10MG/ML	1	1	\$10.54	\$0.75	\$10.54	0.00%
DIFLUCAN TAB 150MG	1	1	\$6.29	\$0.45	\$6.29	0.00%
<b>SUBTOTAL</b>	<b>21,982</b>	<b>16,453</b>	<b>\$261,702.68</b>	<b>\$1.95</b>	<b>\$11.91</b>	<b>20.76%</b>
<b>FLUCYTOSINE PRODUCTS</b>						
FLUCYTOSINE CAP 500MG	2	1	\$57,167.42	\$2,381.98	\$28,583.71	4.53%
<b>SUBTOTAL</b>	<b>2</b>	<b>1</b>	<b>\$57,167.42</b>	<b>\$2,381.98</b>	<b>\$28,583.71</b>	<b>4.53%</b>
<b>GRISEOFULVIN PRODUCTS</b>						
GRISEOFULVIN SUS 125/5ML	2,089	1,609	\$117,183.46	\$2.22	\$56.10	9.30%
GRISEOFULVIN MICRO 500MG	400	333	\$87,518.73	\$7.44	\$218.80	6.94%
GRISEOFULVIN ULTRA 250MG	272	196	\$68,418.01	\$8.63	\$251.54	5.43%
GRISEOFULVIN ULTRA 125MG	47	43	\$12,759.62	\$10.02	\$271.48	1.01%
GRIS-PEG TAB 250MG	17	12	\$3,014.95	\$7.65	\$177.35	0.24%
GRIS-PEG TAB 125MG	14	14	\$3,175.43	\$7.80	\$226.82	0.25%
GRIFULVIN V TAB 500MG	2	1	\$398.42	\$6.64	\$199.21	0.03%
<b>SUBTOTAL</b>	<b>2,841</b>	<b>2,208</b>	<b>\$292,468.62</b>	<b>\$3.91</b>	<b>\$102.95</b>	<b>23.20%</b>
<b>ISAVUCONAZONIUM PRODUCTS</b>						
CRESEMBA CAP 186 MG	1	1	\$4,656.56	\$155.22	\$4,656.56	0.37%
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$4,656.56</b>	<b>\$155.22</b>	<b>\$4,656.56</b>	<b>0.37%</b>
<b>ITRACONAZOLE PRODUCTS</b>						
ITRACONAZOLE CAP 100MG	214	103	\$76,409.52	\$14.17	\$357.05	6.06%
SPORANOX SOL 10MG/ML	90	61	\$49,336.04	\$25.80	\$548.18	3.91%
<b>SUBTOTAL</b>	<b>304</b>	<b>164</b>	<b>\$125,745.56</b>	<b>\$17.22</b>	<b>\$413.64</b>	<b>9.97%</b>
<b>MICONAZOLE PRODUCTS</b>						
MICONAZOLE POWDER	1	1	\$31.96	\$1.07	\$31.96	0.00%
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$31.96</b>	<b>\$1.07</b>	<b>\$31.96</b>	<b>0.00%</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	% COST
<b>NYSTATIN PRODUCTS</b>						
NYSTATIN SUSP 100000 U/ML	10,869	9,009	\$144,656.97	\$1.13	\$13.31	11.47%
NYSTATIN TAB 500000 UNITS	82	24	\$4,274.60	\$1.90	\$52.13	0.34%
<b>SUBTOTAL</b>	<b>10,951</b>	<b>9,033</b>	<b>\$148,931.57</b>	<b>\$1.14</b>	<b>\$13.60</b>	<b>11.81%</b>
<b>POSACONAZOLE PRODUCTS</b>						
NOXAFIL TAB 100MG	23	9	\$132,015.87	\$194.14	\$5,739.82	10.47%
NOXAFIL SUS 40MG/ML	7	1	\$9,133.71	\$43.49	\$1,304.82	0.72%
<b>SUBTOTAL</b>	<b>30</b>	<b>10</b>	<b>\$141,149.58</b>	<b>\$158.60</b>	<b>\$4704.99</b>	<b>11.19%</b>
<b>TERBINAFAFINE PRODUCTS</b>						
TERBINAFAFINE TAB 250MG	2,317	1,620	\$18,366.55	\$0.22	\$7.93	1.46%
LAMISIL GRAN 125MG	10	9	\$4,967.82	\$14.15	\$496.78	0.39%
LAMISIL GRAN 187.5MG	4	2	\$2,632.35	\$16.87	\$658.09	0.21%
<b>SUBTOTAL</b>	<b>2,331</b>	<b>1,631</b>	<b>\$25,966.72</b>	<b>\$0.31</b>	<b>\$11.14</b>	<b>2.06%</b>
<b>VORICONAZOLE PRODUCTS</b>						
VORICONAZOLE TAB 200MG	64	26	\$68,085.79	\$41.02	\$1,063.84	5.40%
VORICONAZOLE TAB 50MG	12	4	\$4,925.36	\$17.85	\$410.45	0.39%
VORICONAZOLE 40MG/ML	12	6	\$18,609.28	\$85.76	\$1,550.77	1.48%
VFEND IV INJ 200MG	1	1	\$1,904.59	\$634.86	\$1,904.59	0.15%
<b>SUBTOTAL</b>	<b>89</b>	<b>37</b>	<b>\$93,525.02</b>	<b>\$43.38</b>	<b>\$1,050.84</b>	<b>7.42%</b>
<b>TOTAL</b>	<b>38,670</b>	<b>27,449*</b>	<b>\$1,260,679.33</b>	<b>\$2.90</b>	<b>\$32.60</b>	<b>100%</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Oral Antihistamines

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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

OTC = over-the-counter; \*For members 21 years and older, prior authorization is necessary for Tier-1 products, but no previous trials are required. \*Xyzal® tablets are not covered for members under age six. \*Xyzal® solution is available for children six months of age to six years of age. Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

#### Antihistamines Tier-2 Approval Criteria:

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

#### Antihistamines Tier-3 Approval Criteria:

1. A diagnosis for a chronic allergic condition or asthma; and
2. A fourteen day trial of all Tier-1 and Tier-2 products within the last 60 days.
3. Approvals will be for the duration of one year.

### Utilization of Oral Antihistamines: Fiscal Year 2016

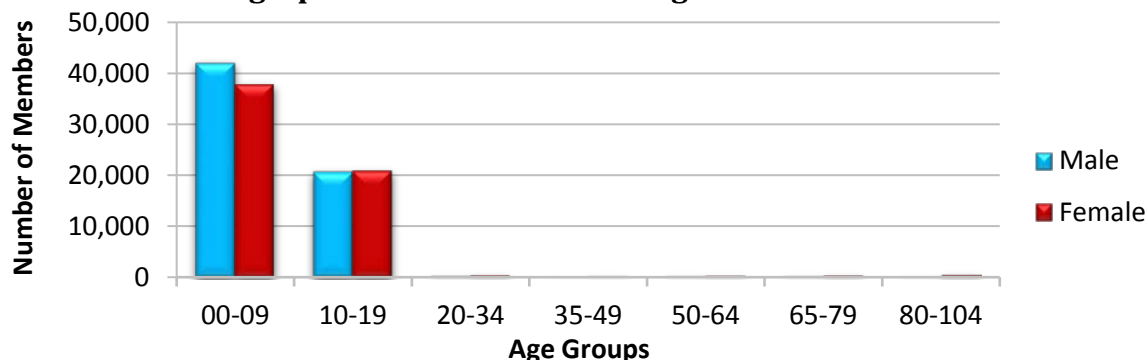
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	114,733	271,321	\$2,144,137.34	\$7.90	\$0.26	23,591,360	8,276,544
2016	123,895	300,553	\$2,335,446.95	\$7.77	\$0.26	26,619,825	9,146,589
% Change	8.00%	10.80%	8.90%	-1.60%	0.00%	12.80%	10.50%
Change	9,162	29,232	\$191,309.61	-\$0.13	\$0.00	3,028,465	870,045

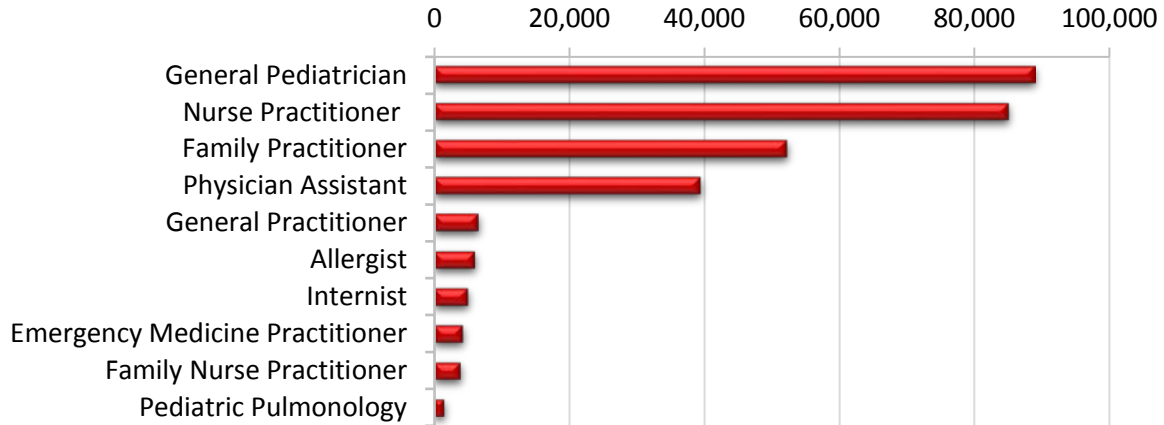
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Oral Antihistamines

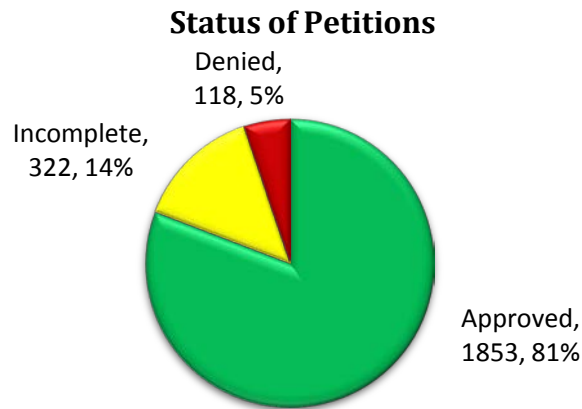


## Top Prescriber Specialties of Oral Antihistamines by Number of Claims



## Prior Authorization of Oral Antihistamines

There were 2,293 prior authorization requests submitted for the oral antihistamines during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>2</sup>

**Anticipated Patent Expiration(s):** Clarinex<sup>®</sup> (desloratadine syrup): December 2018

## Recommendations

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

<sup>2</sup> 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 08/2016. Last accessed 10/2016.

## Utilization Details of Oral Antihistamines: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>CETIRIZINE PRODUCTS</b>					
CETIRIZINE SYP 1MG/ML	121,859	59,225	\$1,070,264.25	\$0.31	\$8.78
CETIRIZINE TAB 10MG	84,604	33,679	\$452,460.06	\$0.16	\$5.35
CETIRIZINE SOL 5MG/5ML	9,378	5,347	\$89,639.67	\$0.34	\$9.56
CETIRIZINE TAB 5MG	5,191	2,245	\$38,908.19	\$0.23	\$7.50
ALL DAY ALLG TAB 10MG	3,087	1,355	\$16,727.84	\$0.16	\$5.42
ALL DAY ALLG SOL 5MG/5ML	975	488	\$9,480.15	\$0.37	\$9.72
ALLERGY COMP SOL 1MG/ML	716	460	\$6,063.62	\$0.31	\$8.47
ALL DAY ALLG SYP 1MG/ML	444	256	\$4,154.62	\$0.34	\$9.36
ALL DAY ALLG SOL 1MG/ML	329	181	\$3,354.08	\$0.37	\$10.19
GNP ALL DAY TAB ALLERGY	67	25	\$441.16	\$0.22	\$6.58
CETIRIZINE SYP 1MG/ML	49	24	\$458.63	\$0.38	\$9.36
CETIRIZINE SYP 5MG/5ML	14	12	\$153.18	\$0.38	\$10.94
ALLERGY RELF SOL 5MG/5ML	6	5	\$53.46	\$0.36	\$8.91
SM ALL DAY TAB ALLERGY	5	4	\$31.74	\$0.21	\$6.35
<b>SUBTOTAL</b>	<b>226,724</b>	<b>103,306</b>	<b>\$1,692,190.65</b>	<b>\$0.25</b>	<b>\$7.46</b>
<b>LORATADINE PRODUCTS</b>					
LORATADINE TAB 10MG	40,196	15,581	\$257,505.87	\$0.19	\$6.41
LORATADINE SOL 5MG/5ML	23,055	12,518	\$249,690.19	\$0.40	\$10.83
LORATADINE SYP 5MG/5ML	7,109	4,126	\$79,393.02	\$0.41	\$11.17
ALLERGY TAB 10MG	935	460	\$6,354.21	\$0.22	\$6.80
ALLERGY RELF TAB 10MG	783	329	\$5,175.49	\$0.20	\$6.61
ALLERGY RELF SYP 5MG/5ML	469	270	\$5,423.81	\$0.44	\$11.56
ALAVERT TAB 10MG	173	121	\$2,054.65	\$0.35	\$11.88
LORATADINE TAB 10MG	94	45	\$1,751.65	\$0.51	\$18.63
ALLERGY RELF TAB 10MG	61	35	\$835.58	\$0.42	\$13.70
ALLERGY TAB 10MG	25	16	\$317.41	\$0.46	\$12.70
<b>SUBTOTAL</b>	<b>72,900</b>	<b>33,501</b>	<b>\$608,501.88</b>	<b>\$0.27</b>	<b>\$8.35</b>
<b>TIER-1 SUBTOTAL</b>	<b>299,624</b>	<b>136,807</b>	<b>\$2,300,692.53</b>	<b>\$0.25</b>	<b>\$7.68</b>
<b>TIER-2 PRODUCTS</b>					
<b>LEVOCETIRIZINE PRODUCTS</b>					
LEVOCETIRIZINE TAB 5MG	561	107	\$6,703.26	\$0.37	\$11.95
LEVOCETIRIZINE SOL 2.5 MG/5ML	308	77	\$19,908.28	\$2.09	\$64.64
<b>SUBTOTAL</b>	<b>869</b>	<b>184</b>	<b>\$26,611.54</b>	<b>\$0.96</b>	<b>\$30.62</b>
<b>TIER-2 SUBTOTAL</b>	<b>869</b>	<b>184</b>	<b>\$26,611.54</b>	<b>\$0.96</b>	<b>\$30.62</b>
<b>TIER-3 PRODUCTS</b>					
<b>DESLOTRADINE PRODUCTS</b>					
CLARINEX SYP 0.5MG/ML	31	3	\$7,367.91	\$8.59	\$237.67
DESLOTRADIN TAB 5MG	29	4	\$774.97	\$0.89	\$26.72
<b>SUBTOTAL</b>	<b>60</b>	<b>7</b>	<b>\$8,142.88</b>	<b>\$4.71</b>	<b>\$135.71</b>
<b>TIER-3 SUBTOTAL</b>	<b>60</b>	<b>7</b>	<b>\$8,142.88</b>	<b>\$4.71</b>	<b>\$135.71</b>
<b>TOTAL</b>	<b>300,553</b>	<b>123,895*</b>	<b>\$2,335,446.95</b>	<b>\$0.26</b>	<b>\$7.77</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Anti-Ulcer Medications

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Anti-Ulcer Medications*		
Tier-1	Tier-2	Tier-3
omeprazole (Prilosec®)	dexlansoprazole (Dexilant®)	dexlansoprazole (Dexilant™SoluTab)
pantoprazole (Protonix®)	lansoprazole (Prevacid® and ODT)	esomeprazole magnesium (Nexium®)
	rabeprazole (Aciphex®)	esomeprazole strontium
		omeprazole suspension (Prilosec®)
		pantoprazole (Protonix® suspension)
		rabeprazole (Aciphex® sprinkles)

\*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.  
ODT = orally disintegrating tablet

#### Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A recent 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. A contraindication to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

#### Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A recent 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. A contraindication to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications.
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and solutions for intravenous (IV) use require patient-specific, clinically significant reasoning why the member cannot use standard dosage formulations.

#### Proton-Pump Inhibitors for Pediatric Members Approval Criteria:

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

#### Anti-Ulcer Medications Special Prior Authorization Approval Criteria:

1. Authorization of ranitidine (Zantac® Effervescent Tablets) requires a patient-specific, clinically significant reason why the member cannot use other dosage formulations.
2. Pepcid® Suspension (famotidine) is reserved for members less than 1 month of age when no other anti-ulcer medications are indicated.

- Authorization of omeprazole/sodium bicarbonate combination products requires a patient-specific, clinically significant reason for use in place of the individual components.

### Utilization of Anti-Ulcer Medications: Fiscal Year 2016

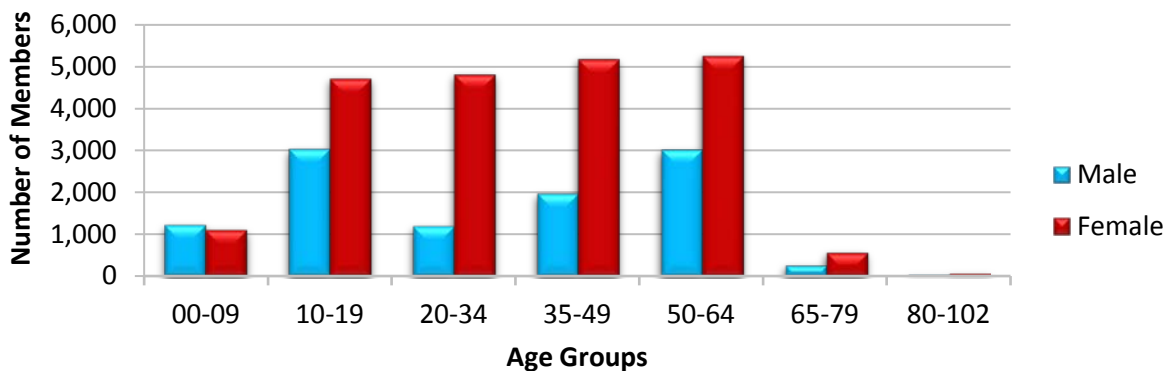
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	31,833	121,622	\$2,075,961.57	\$17.07	\$0.52	4,851,051	3,966,804
2016	32,382	121,486	\$2,180,775.83	\$17.95	\$0.53	5,051,356	4,120,064
% Change	1.70%	-0.10%	5.00%	5.20%	1.90%	4.10%	3.90%
Change	549	-136	\$104,814.26	\$0.88	\$0.01	200,305	153,260

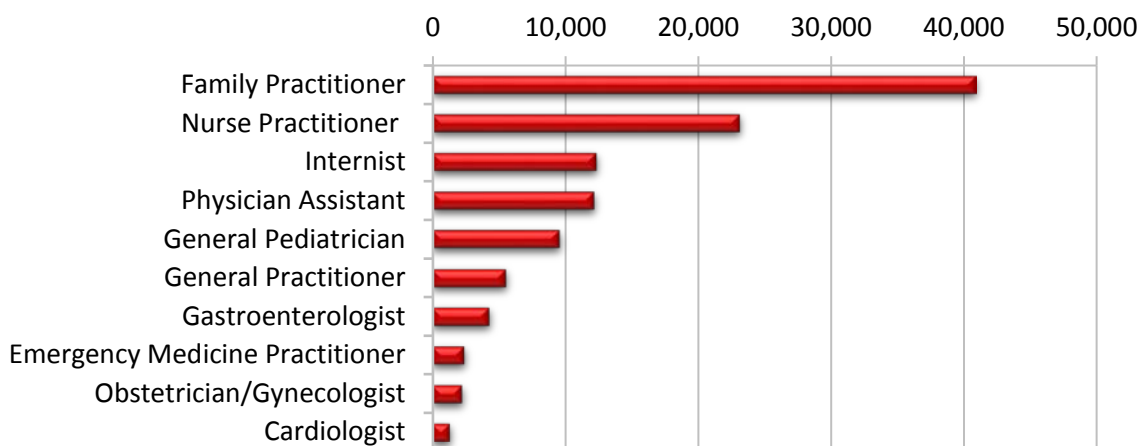
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Anti-Ulcer Medications

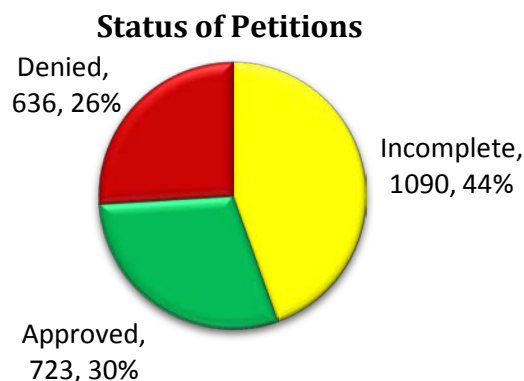


#### Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



### Prior Authorization of Anti-Ulcer Medications

There were 2,449 prior authorization requests submitted for the anti-ulcer medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>3,4</sup>

### Anticipated Patent Expiration(s):

- Prilosec® packets (omeprazole): November 2019
- Nexium® packets (esomeprazole) May 2020
- Protonix® packets (pantoprazole): December 2026
- Dexilant™ SoluTab (dexlansoprazole): March 2029
- Dexilant® capsule (dexlansoprazole): September 2030

### New Safety Information and Updates:

- **July 2016:** The journal *Current Opinion in Rheumatology* published a review to provide an update on recent advances in the evidence based on proton pump inhibitors (PPI) as a possible cause of osteoporosis and osteoporotic fractures. Overall the findings from various worldwide studies lead the authors to conclude that the association between use of PPIs and the risk of osteoporosis and fractures is if anything further strengthened by recent studies. Additionally, the authors admit the direct pathogenesis remains unclear and specific points of intervention are lacking. It is recommended that prescribers be vigilant in regard to the indication for prescribing PPIs and to use the lowest effective dose where PPIs cannot be avoided.

## Recommendations

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

## Utilization Details of Anti-Ulcer Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>OMEPRAZOLE PRODUCTS</b>					
OMEPRAZOLE CAP 20MG	55,150	17,342	\$368,149.81	\$0.19	\$6.68
OMEPRAZOLE CAP 40MG	28,250	8,528	\$268,346.24	\$0.26	\$9.50

<sup>3</sup> 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 08/2016. Last accessed 10/2016.  
<sup>4</sup> Andersen BN, Johansen PB, Abrahamsen B. Proton pump inhibitors and osteoporosis. *Current Opinion in Rheumatology* 2016; 28 (4):420-425.



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
OMEPRAZOLE CAP 10MG	2,570	1,021	\$34,776.96	\$0.46	\$13.53
<b>SUBTOTAL</b>	<b>85,970</b>	<b>26,891</b>	<b>\$671,273.01</b>	<b>\$0.22</b>	<b>\$7.81</b>
<b>PANTOPRAZOLE PRODUCTS</b>					
PANTOPRAZOLE TAB 40MG	23,771	6,532	\$156,082.53	\$0.22	\$6.57
PANTOPRAZOLE TAB 20MG	3,165	1,037	\$23,535.61	\$0.25	\$7.44
PROTONIX TAB 40MG	1	1	\$12.17	\$0.41	\$12.17
<b>SUBTOTAL</b>	<b>26,937</b>	<b>7,570</b>	<b>\$179,630.31</b>	<b>\$0.22</b>	<b>\$6.67</b>
<b>TIER-1 SUBTOTAL</b>	<b>112,907</b>	<b>34,461</b>	<b>\$750,903.32</b>	<b>\$0.22</b>	<b>\$7.54</b>
<b>TIER-2 PRODUCTS</b>					
<b>DEXLANSOPRAZOLE PRODUCTS</b>					
DEXILANT CAP 60MG DR	2,054	306	\$481,369.89	\$7.84	\$234.36
DEXILANT CAP 30MG DR	255	52	\$62,142.63	\$8.22	\$243.70
<b>SUBTOTAL</b>	<b>2,309</b>	<b>358</b>	<b>\$543,512.52</b>	<b>\$7.88</b>	<b>\$235.39</b>
<b>LANSOPRAZOLE PRODUCTS</b>					
LANSOPRAZOLE CAP 30MG DR	3,131	468	\$56,169.29	\$0.61	\$17.94
PREVACID TAB 15MG STB	629	137	\$222,303.12	\$11.68	\$353.42
PREVACID TAB 30MG STB	508	65	\$173,127.43	\$11.49	\$340.80
LANSOPRAZOLE CAP 15MG DR	388	77	\$9,719.87	\$0.83	\$25.05
LANSOPRAZOLE TAB 30MG ODT	1	1	\$153.31	\$5.11	\$153.31
<b>SUBTOTAL</b>	<b>4,657</b>	<b>748</b>	<b>\$461,473.02</b>	<b>\$3.33</b>	<b>\$99.09</b>
<b>RABEPRAZOLE PRODUCTS</b>					
RABEPRAZOLE TAB 20MG	441	74	\$10,213.16	\$0.77	\$23.16
<b>SUBTOTAL</b>	<b>441</b>	<b>74</b>	<b>\$10,213.16</b>	<b>\$0.77</b>	<b>\$23.16</b>
<b>TIER-2 SUBTOTAL</b>	<b>7,407</b>	<b>1180</b>	<b>\$1,015,198.70</b>	<b>\$4.60</b>	<b>\$137.06</b>
<b>TIER-3 PRODUCTS</b>					
<b>ESOMEPRAZOLE PRODUCTS</b>					
ESOMEPRA MAG CAP 40MG DR	443	69	\$84,914.11	\$6.29	\$191.68
NEXIUM CAP 40MG	232	34	\$71,047.21	\$10.25	\$306.24
NEXIUM GRA 10MG DR	90	20	\$27,487.00	\$10.65	\$305.41
NEXIUM I.V. INJ 40MG	49	1	\$15,078.31	\$47.72	\$307.72
NEXIUM GRA 5MG DR	41	16	\$15,783.66	\$12.83	\$384.97
NEXIUM GRA 2.5MG DR	30	8	\$8,059.13	\$8.95	\$268.64
ESOMEPRA MAG CAP 20MG DR	23	4	\$4,606.06	\$6.68	\$200.26
NEXIUM GRA 40MG DR	20	4	\$4,973.76	\$8.29	\$248.69
NEXIUM GRA 20MG DR	10	1	\$2,686.45	\$8.95	\$268.65
ESOMEPRAZOLE INJ 40MG	3	1	\$637.65	\$37.51	\$212.55
NEXIUM CAP 20MG	2	1	\$520.38	\$8.67	\$260.19
<b>SUBTOTAL</b>	<b>943</b>	<b>159</b>	<b>\$235,793.72</b>	<b>\$8.69</b>	<b>\$250.05</b>
<b>OMEPRAZOLE PRODUCTS</b>					
PRILOSEC POW 10MG	94	23	\$27,145.61	\$9.67	\$288.78
PRILOSEC POW 2.5MG	64	25	\$19,064.14	\$10.25	\$297.88
<b>SUBTOTAL</b>	<b>158</b>	<b>48</b>	<b>\$46,209.75</b>	<b>\$9.90</b>	<b>\$292.47</b>
<b>PANTOPRAZOLE PRODUCTS</b>					
PROTONIX PAK	51	8	\$19,527.04	\$13.08	\$382.88
<b>SUBTOTAL</b>	<b>51</b>	<b>8</b>	<b>\$19,527.04</b>	<b>\$13.08</b>	<b>\$382.88</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>RABEPRAZOLE PRODUCTS</b>					
ACIPHEX SPR CAP 10MG	20	2	\$13,143.30	\$21.91	\$657.17
<b>SUBTOTAL</b>	<b>20</b>	<b>2</b>	<b>\$13,143.30</b>	<b>\$21.91</b>	<b>\$657.17</b>
<b>TIER-3 SUBTOTAL</b>	<b>1172</b>	<b>217</b>	<b>314,673.81</b>	<b>\$5.59</b>	<b>\$268.49</b>
<b>TOTAL</b>	<b>121,486</b>	<b>32,382*</b>	<b>\$2,180,775.83</b>	<b>\$0.53</b>	<b>\$17.95</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Benlysta® (Belimumab)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Benlysta® (Belimumab) Approval Criteria:

1. An FDA approved diagnosis of active, autoantibody-positive, systemic lupus erythematosus, already receiving standard therapy; and
2. Member must be 18 years or older; and
3. Member must have a documented inadequate response to at least two of the following medications:
  - a. High-dose oral corticosteroids
  - b. Methotrexate
  - c. Azathioprine
  - d. Mycophenolate
  - e. Cyclophosphamide; and
4. Member must not have severe active lupus nephritis or severe active central nervous system lupus; and
5. Combination use with biologic therapies or intravenous cyclophosphamide will not be approved.

### Utilization of Benlysta® (Belimumab): Fiscal Year 2016

#### Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	24	137	\$432,338.52	\$3,155.76	11,328
2016	12	72	\$211,334.83	\$2,935.21	5,173
% Change	-50%	-47.45%	-51.12%	-6.99%	-54.33%
Change	-12	-65	-\$221,003.69	-\$220.55	-6155

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	1	1	\$1,630.96	\$1,630.96	1

Please note, there was no utilization of Benlysta® for fiscal year 2016 in pharmacy claims; therefore, no comparison is available.

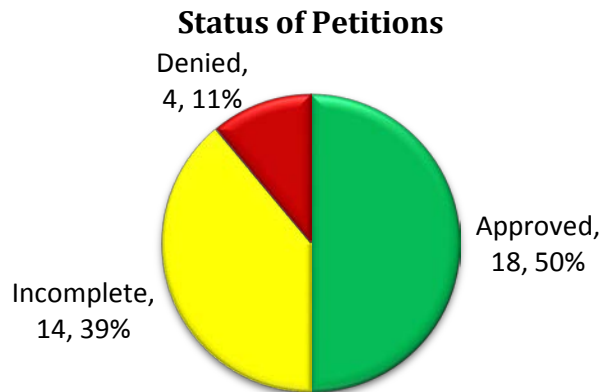
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

## **Prior Authorization of Benlysta® (Belimumab)**

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There were 36 prior authorization requests submitted for Benlysta® (belimumab) during fiscal year 2016. The following chart shows the status of the submitted petitions.



## **Recommendations**

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

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# Fiscal Year 2016 Annual Review of Benzodiazepine Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### **Benzodiazepine Approval Criteria for Members 19 Years of Age & Older:**

1. Currently there are no prior authorizations required; however, quantity limits are set at maximum of three units per day for most products.
2. Approval for dosing greater than three times daily requires a chronic physical diagnosis; for these diagnoses the maximum allowed dosing would be four times daily.
3. A member may receive more than three units per day if the following criteria exist:
  - a. The number of units per day is greater than three, but less than the maximum daily dose for the product (or for a total daily dosing of three times daily).
  - b. The member has a chronic diagnosis and a clinical reason for excessive units has been provided.

#### **Benzodiazepine Approval Criteria for Members Under 19 Years of Age:**

1. Member must have a chronic behavioral health related diagnosis or a chronic physical diagnosis.
2. Approval Criteria for a Chronic Behavior Health Related Diagnosis:
  - a. No concurrent stimulant ADHD medications; and
  - b. No contraindicated conditions; and
  - c. A maximum dosing of three times daily will apply.
3. Approval Criteria for a Chronic Physical Diagnosis:
  - a. A maximum dosing of three times daily will apply if a hypnotic medication is being used concurrently; and
  - b. A maximum dosing of four 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 2016

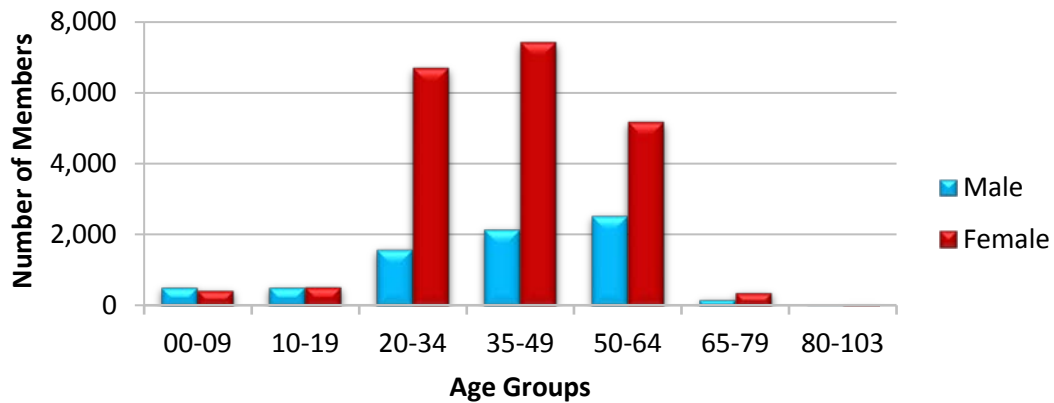
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	29,562	164,379	\$1,791,564.32	\$10.90	\$0.39	10,297,653	4,542,406
2016	28,166	154,759	\$1,776,924.29	\$11.48	\$0.41	9,719,028	4,285,592
% Change	-4.70%	-5.90%	-0.80%	5.30%	5.10%	-5.60%	-5.70%
Change	-1,396	-9,620	-\$14,640.03	\$0.58	\$0.02	-578,625	-256,814

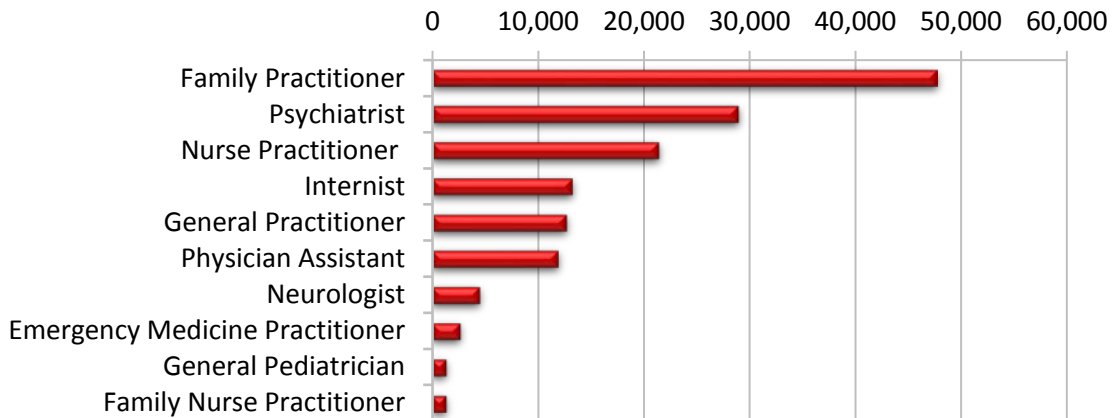
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Benzodiazepine Medications

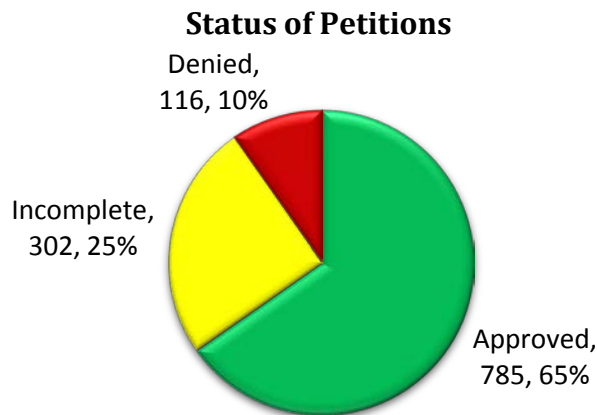


### Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



### Prior Authorization of Benzodiazepine Medications

There were 1,203 prior authorization requests submitted for benzodiazepine medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## **Market News and Updates<sup>5</sup>**

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**August 2016:** The U.S. Food and Drug Administration (FDA) announced that it is requiring class-wide changes to drug labeling to better inform health care providers and patients of the serious risks associated with combined use of opioids and benzodiazepines.

- The changes include boxed warnings and patient-focused medication guides for prescription opioids, opioid-containing cough products, and benzodiazepines.
- Data reviewed by the FDA from 2004 to 2011, showed a significant increase in emergency room visits related to non-medical use of both drug classes. Additionally, during the above time frame, overdose deaths involving both drug classes almost tripled.
- The FDA further found that physicians' rates of prescribing opioids and benzodiazepines together has also been on the rise. From 2002 to 2014, there was a 41% increase in the number of patients who were prescribed both drug classes. This increase resulted in more than 2.5 million patients receiving both an opioid analgesic and a benzodiazepine.
- If the only treatment option is the use of an opioid with a benzodiazepine, the FDA recommends limiting the dosage and duration of each medication to the minimum needed for effective treatment.

## **Recommendations**

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

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<sup>5</sup> U.S. Food and Drug Administration (FDA): FDA News Release: FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risks and Death from Combined Use. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm>. Issued 08/31/2016. Last accessed 11/02/2016.

## Utilization Details of Benzodiazepine Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>ALPRAZOLAM PRODUCTS</b>					
ALPRAZOLAM TAB 1MG	34,216	5,897	\$168,776.42	\$0.17	\$4.93
ALPRAZOLAM TAB 2MG	17,082	2,551	\$104,631.30	\$0.21	\$6.13
ALPRAZOLAM TAB 0.5MG	14,758	3,881	\$61,828.00	\$0.15	\$4.19
ALPRAZOLAM TAB 0.25MG	3,365	1,264	\$13,553.02	\$0.16	\$4.03
ALPRAZOLAM TAB 2MG ER	228	65	\$4,065.56	\$0.61	\$17.83
ALPRAZOLAM TAB 1MG ER	211	72	\$2,482.72	\$0.40	\$11.77
ALPRAZOLAM TAB 3MG ER	153	29	\$3,641.96	\$0.80	\$23.80
ALPRAZOLAM TAB 0.5MG ER	56	31	\$565.05	\$0.35	\$10.09
ALPRAZOLAM TAB 1MG XR	13	9	\$146.65	\$0.42	\$11.28
ALPRAZOLAM TAB 3MG XR	9	5	\$211.50	\$0.78	\$23.50
ALPRAZOLAM TAB 2MG XR	8	3	\$118.84	\$0.50	\$14.86
ALPRAZOLAM TAB 1MG ODT	7	1	\$423.60	\$3.14	\$60.51
ALPRAZOLAM CON 1 MG/ML	5	2	\$450.64	\$2.82	\$90.13
ALPRAZOLAM TAB 0.5MG XR	1	1	\$9.74	\$0.32	\$9.74
<b>SUBTOTAL</b>	<b>70,112</b>	<b>13,811</b>	<b>\$360,905.00</b>	<b>\$0.18</b>	<b>\$5.15</b>
<b>CHLORDIAZEPOXIDE PRODUCTS</b>					
CHLORDIAZEP CAP 25MG	320	188	\$1,512.81	\$0.26	\$4.73
CHLORDIAZEP CAP 10MG	204	87	\$1,060.65	\$0.20	\$5.20
CHLORDIAZEP CAP 5MG	68	31	\$538.08	\$0.36	\$7.91
<b>SUBTOTAL</b>	<b>592</b>	<b>306</b>	<b>\$3,111.54</b>	<b>\$0.25</b>	<b>\$5.26</b>
<b>CLONAZEPAM PRODUCTS</b>					
CLONAZEPAM TAB 1MG	20,852	4,565	\$98,578.61	\$0.16	\$4.73
CLONAZEPAM TAB 0.5MG	14,297	3,980	\$59,088.91	\$0.15	\$4.13
CLONAZEPAM TAB 2MG	5,982	1,189	\$32,348.74	\$0.18	\$5.41
CLONAZEP ODT TAB 0.25MG	720	231	\$38,283.68	\$2.20	\$53.17
CLONAZEP ODT TAB 0.5MG	425	131	\$17,355.73	\$1.71	\$40.84
CLONAZEP ODT TAB 0.125MG	322	124	\$16,389.90	\$2.27	\$50.90
CLONAZEP ODT TAB 1MG	215	61	\$10,045.86	\$1.87	\$46.72
CLONAZEP ODT TAB 2MG	68	21	\$2,924.82	\$2.33	\$43.01
KLONOPIN TAB 2MG	12	1	\$2,675.58	\$7.43	\$222.97
KLONOPIN TAB 1MG	9	1	\$2,208.39	\$8.18	\$245.38
<b>SUBTOTAL</b>	<b>42,902</b>	<b>10,304</b>	<b>\$279,900.22</b>	<b>\$0.23</b>	<b>\$6.52</b>
<b>CLORAZEPATE PRODUCTS</b>					
CLORAZ DIPOT TAB 3.75MG	348	48	\$5,745.80	\$0.57	\$16.51
CLORAZ DIPOT TAB 7.5MG	343	66	\$7,886.21	\$0.74	\$22.99
CLORAZ DIPOT TAB 15MG	122	24	\$11,313.72	\$3.16	\$92.74
<b>SUBTOTAL</b>	<b>813</b>	<b>138</b>	<b>\$24,945.73</b>	<b>\$1.02</b>	<b>\$30.68</b>
<b>DIAZEPAM PRODUCTS</b>					
DIAZEPAM TAB 10MG	13,128	3,060	\$59,916.78	\$0.17	\$4.56
DIAZEPAM TAB 5MG	9,290	2,959	\$32,831.30	\$0.14	\$3.53
DIAZEPAM GEL 10MG	1,344	740	\$537,732.49	\$67.00	\$400.10
DIAZEPAM TAB 2MG	1,266	465	\$4,485.14	\$0.14	\$3.54



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
DIAZEPAM GEL 20MG	292	159	\$137,742.08	\$68.53	\$471.72
DIAZEPAM SOL 1MG/ML	231	62	\$6,637.57	\$1.38	\$28.73
DIASAT ACDL GEL 5-10MG	170	104	\$90,913.98	\$52.70	\$534.79
DIAZEPAM GEL 2.5MG	162	103	\$73,335.28	\$43.91	\$452.69
DIASAT ACDL GEL 12.5-20	97	45	\$50,705.05	\$59.86	\$522.73
DIASAT PED GEL 2.5M GEL	44	38	\$19,927.89	\$70.42	\$452.91
DIAZEPAM CON 5MG/ML	22	9	\$1,772.85	\$2.78	\$80.58
DIAZEPAM INJ 5MG/ML	18	7	\$2,327.32	\$5.85	\$129.30
DIAZEPAM SOL 5MG/5ML	4	3	\$330.23	\$4.13	\$82.56
<b>SUBTOTAL</b>	<b>26,068</b>	<b>7,754</b>	<b>\$1,018,657.96</b>	<b>\$1.57</b>	<b>\$39.08</b>
<b>LORAZEPAM PRODUCTS</b>					
LORAZEPAM TAB 1MG	7,046	2,203	\$32,127.76	\$0.18	\$4.56
LORAZEPAM TAB 0.5MG	4,719	1,658	\$19,946.38	\$0.17	\$4.23
LORAZEPAM TAB 2MG	2,278	574	\$14,211.51	\$0.22	\$6.24
LORAZEPAM CON 2MG/ML	126	41	\$4,439.65	\$1.32	\$35.24
LORAZEPAM INJ 2MG/ML	15	6	\$89.55	\$0.48	\$5.97
ATIVAN TAB 1MG	5	1	\$12,134.09	\$80.89	\$2,426.82
<b>SUBTOTAL</b>	<b>14,189</b>	<b>4,483</b>	<b>\$82,948.94</b>	<b>\$0.23</b>	<b>\$5.85</b>
<b>OXAZEPAM PRODUCTS</b>					
OXAZEPAM CAP 15MG	43	8	\$2,643.12	\$2.13	\$61.47
OXAZEPAM CAP 30MG	28	6	\$3,564.05	\$4.24	\$127.29
OXAZEPAM CAP 10MG	12	5	\$247.73	\$0.74	\$20.64
<b>SUBTOTAL</b>	<b>83</b>	<b>19</b>	<b>\$6,454.90</b>	<b>\$2.68</b>	<b>\$77.77</b>
<b>TOTAL</b>	<b>154,759</b>	<b>28,166*</b>	<b>\$1,776,924.29</b>	<b>\$0.41</b>	<b>\$11.48</b>

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

# Fiscal Year 2016 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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

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

### Benign Prostatic Hyperplasia Medications Tier-2 Approval Criteria:

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

### Benign Prostatic Hyperplasia Medications Tier-3 Approval Criteria:

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

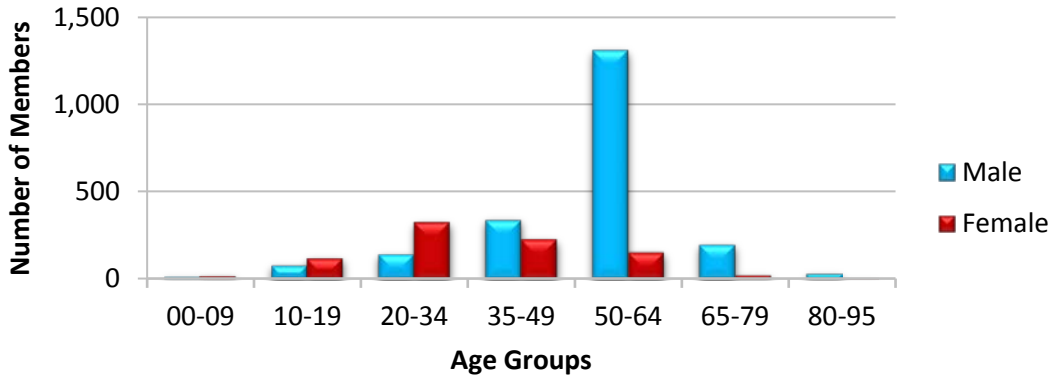
### Utilization of BPH Medications: Fiscal Year 2016

#### Comparison of Fiscal Years

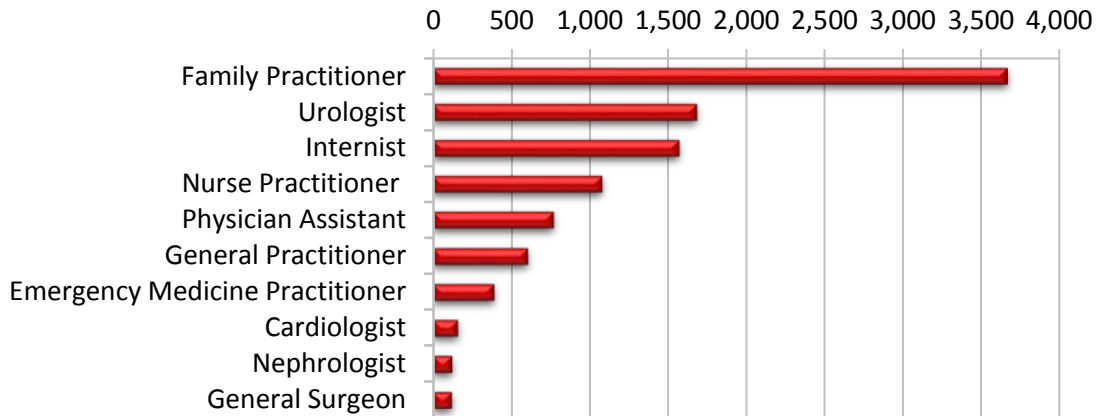
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	2,720	9,757	\$217,847.73	\$22.33	\$0.61	396,086	359,921
2016	2,994	10,489	\$208,312.32	\$19.86	\$0.52	438,883	397,320
% Change	10.10%	7.50%	-4.40%	-11.10%	-14.80%	10.80%	10.40%
Change	274	732	-\$9,535.41	-\$2.47	-\$0.09	42,797	37,399

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

### Demographics of Members Utilizing BPH Medications

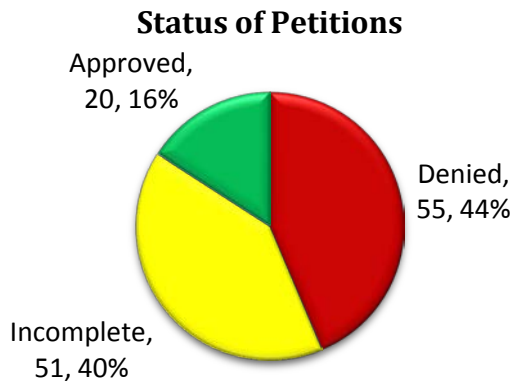


### Top Prescriber Specialties of BPH Medications by Number of Claims



### Prior Authorization of BPH Medications

There were 126 prior authorization requests submitted for the BPH Medications during fiscal year 2016. Computer edits are in place to detect lower tiered medications in members’ recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>6</sup>

### Anticipated Patent Expiration(s):

- Rapaflo® (silodosin): December 2018
- Cialis® (tadalafil): November 2020

### Recommendations

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

### Utilization Details of BPH Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>ALFUZOSIN PRODUCTS</b>					
ALFUZOSIN TAB 10MG	128	34	\$1,788.55	\$0.35	\$13.97
<b>SUBTOTAL</b>	<b>128</b>	<b>34</b>	<b>\$1,788.55</b>	<b>\$0.35</b>	<b>\$13.97</b>
<b>DOXAZOSIN PRODUCTS</b>					
DOXAZOSIN TAB 4MG	662	153	\$14,339.94	\$0.53	\$21.66
DOXAZOSIN TAB 2MG	495	133	\$10,620.06	\$0.59	\$21.45
DOXAZOSIN TAB 8MG	240	52	\$5,210.08	\$0.53	\$21.71
DOXAZOSIN TAB 1MG	203	68	\$4,843.90	\$0.61	\$23.86
CARDURA TAB 8MG	1	1	\$18.79	\$0.63	\$18.79
<b>SUBTOTAL</b>	<b>1,601</b>	<b>407</b>	<b>\$35,032.77</b>	<b>\$0.56</b>	<b>\$21.88</b>
<b>FINASTERIDE PRODUCTS</b>					
FINASTERIDE TAB 5MG	728	187	\$7,364.28	\$0.24	\$10.12
<b>SUBTOTAL</b>	<b>728</b>	<b>187</b>	<b>\$7,364.28</b>	<b>\$0.24</b>	<b>\$10.12</b>
<b>TAMSULOSIN PRODUCTS</b>					
TAMSULOSIN CAP 0.4MG	7,163	2,403	\$116,139.16	\$0.44	\$16.21
<b>SUBTOTAL</b>	<b>7,163</b>	<b>2,403</b>	<b>\$116,139.16</b>	<b>\$0.44</b>	<b>\$16.21</b>
<b>TERAZOSIN PRODUCTS</b>					
TERAZOSIN CAP 2MG	208	62	\$1,117.09	\$0.12	\$5.37
TERAZOSIN CAP 5MG	193	54	\$1,076.23	\$0.13	\$5.58
TERAZOSIN CAP 1MG	120	39	\$556.10	\$0.11	\$4.63
TERAZOSIN CAP 10MG	110	30	\$630.85	\$0.11	\$5.74
<b>SUBTOTAL</b>	<b>631</b>	<b>185</b>	<b>\$3,380.27</b>	<b>\$0.12</b>	<b>\$5.36</b>
<b>TIER-1 SUBTOTAL</b>	<b>10,251</b>	<b>3,216</b>	<b>\$163,705.03</b>	<b>\$0.42</b>	<b>\$15.97</b>
<b>TIER-2 PRODUCTS</b>					
<b>DOXAZOSIN PRODUCTS</b>					
CARDURA XL TAB 4MG	5	2	\$1,256.00	\$3.81	\$251.20
<b>SUBTOTAL</b>	<b>5</b>	<b>2</b>	<b>\$1,256.00</b>	<b>\$3.81</b>	<b>\$251.200</b>
<b>DUTASTERIDE PRODUCTS</b>					
DUTASTERIDE CAP 0.5MG	67	18	\$3,634.39	\$1.17	\$54.24

<sup>6</sup> 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 09/2016. Last accessed 11/03/2016.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
AVODART CAP 0.5MG	42	17	\$11,052.83	\$5.91	\$263.16
<b>SUBTOTAL</b>	<b>109</b>	<b>35</b>	<b>\$14,687.22</b>	<b>\$2.95</b>	<b>\$134.75</b>
<b>DUTASTERIDE/TAMSULOSIN PRODUCTS</b>					
JALYN CAP	11	3	\$1,945.20	\$5.89	\$176.84
DUTAST/TAMSU CAP 0.5-0.4	10	3	\$1,317.95	\$4.39	\$131.80
<b>SUBTOTAL</b>	<b>21</b>	<b>6</b>	<b>\$3,263.15</b>	<b>\$5.18</b>	<b>\$155.39</b>
<b>SILODOSIN PRODUCTS</b>					
RAPAFLO CAP 8MG	78	12	\$16,240.09	\$7.02	\$208.21
RAPAFLO CAP 4MG	6	1	\$1,196.76	\$6.65	\$199.46
<b>SUBTOTAL</b>	<b>84</b>	<b>13</b>	<b>\$17,436.85</b>	<b>\$7.00</b>	<b>\$207.58</b>
<b>TIER-2 SUBTOTAL</b>	<b>219</b>	<b>56</b>	<b>\$36,643.22</b>	<b>\$4.35</b>	<b>\$167.32</b>
<b>TIER-3 PRODUCTS</b>					
<b>TADALAFIL PRODUCTS</b>					
CIALIS TAB 5MG	19	3	\$7,964.07	\$13.97	\$419.16
<b>SUBTOTAL</b>	<b>19</b>	<b>3</b>	<b>\$7,964.07</b>	<b>\$13.97</b>	<b>\$419.16</b>
<b>TIER-3 SUBTOTAL</b>	<b>19</b>	<b>3</b>	<b>\$7,964.07</b>	<b>\$13.97</b>	<b>\$419.16</b>
<b>TOTAL</b>	<b>10,489</b>	<b>2,994*</b>	<b>\$208,312.322</b>	<b>\$0.52</b>	<b>\$19.86</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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## **Fiscal Year 2016 Annual Review of Cholbam™ (Cholic Acid)**

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### **Oklahoma Health Care Authority Fiscal Year 2016 Print Report**

#### **Current Prior Authorization Criteria**

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##### **Cholbam™ (Cholic Acid) Approval Criteria:**

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

#### **Utilization of Cholbam™ (Cholic Acid): Fiscal Year 2016**

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There were no pharmacy claims for Cholbam™ (cholic acid) during fiscal year 2016.

#### **Prior Authorization of Cholbam™ (Cholic Acid)**

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There were no prior authorization requests submitted for Cholbam™ (cholic acid) during fiscal year 2016.

#### **Recommendations**

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

# Fiscal Year 2016 Annual Review of Diabetic Supplies

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

- The preferred brands for SoonerCare members are OneTouch®, FreeStyle™, and Precision™ test strips and meters. Other brands of strips and meters are not covered.
- In addition to strips and meters, lancets, syringes, pen needles, and control solution are also covered in the pharmacy claims system. Supplies for insulin pumps remain DME claims.
- Meters are limited to one per member per year. Strips are limited to 100 strips per 30 days for members using insulin and 100 strips per 90 days for members using oral medications. Members diagnosed with gestational diabetes are limited to 150 strips per 30 days.
- Diabetic supplies are a zero copay and do not count against the monthly prescription limit.
- An automated prior authorization process looks for insulin and other diabetic medications on 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 2016

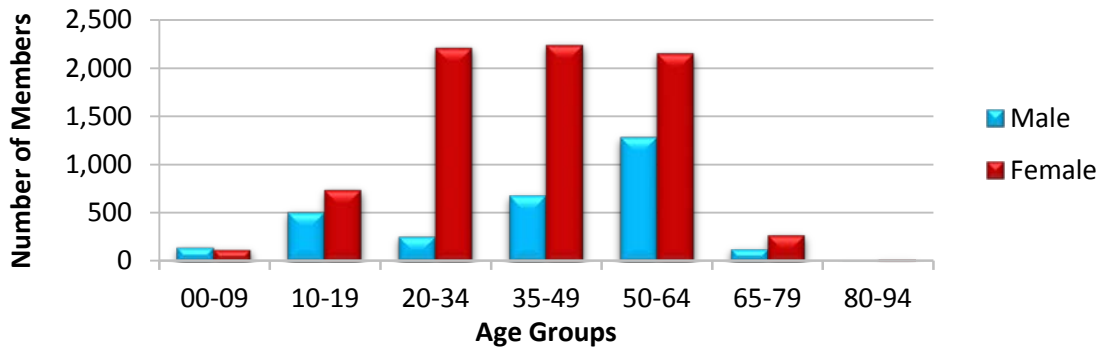
#### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	4,642	11,764	\$901,993.37	\$76.67	\$2.11	1,128,853	427,009
2016	10,766	49,445	\$4,421,907.37	\$89.43	\$2.36	5,376,073	1,870,562
% Change	131.93%	320.31%	390.24%	16.64%	11.85%	376.24%	338.06%
Change	6,124	37,681	\$3,519,914.00	\$12.76	\$0.25	4,247,220	1,443,553

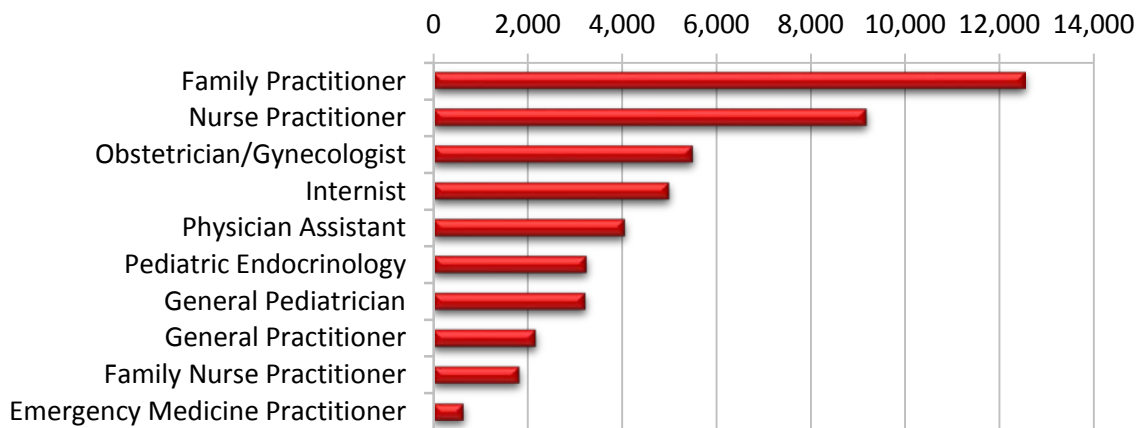
\*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.

Please note: Diabetic supplies began processing as pharmacy claims starting April 1, 2015 resulting in abbreviated data for fiscal year (FY) 2015. This is the main contributing factor for the large increase in the totals comparing FY 2015 and FY 2016.

### Demographics of Members Utilizing Diabetic Supplies

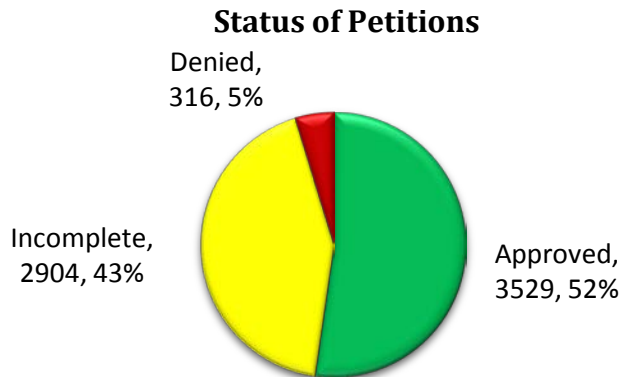


### Top Prescriber Specialties of Diabetic Supplies by Number of Claims



### Prior Authorization of Diabetic Supplies

There were 6,749 prior authorization requests submitted for diabetic supplies during fiscal year 2016. Computer edits are in place to detect claims for diabetic medications and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



### Recommendations

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



## Utilization Details of Diabetic Supplies: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	CLAIMS/MEMBER	UNITS/MEMBER
<b>DIABETIC TEST STRIPS</b>							
FREESTYLE TES LITE	12,689	4,269	\$2,419,533.20	\$5.14	\$190.68	2.97	400.64
ONETOUCH TES ULTRA BL	11,239	3,674	\$1,476,538.10	\$3.26	\$131.38	3.06	332.06
CONTOUR TES NEXT	1,453	380	\$45,328.10	\$0.97	\$31.20	3.82	617.50
PRECISION TES XTRA	864	236	\$53,454.86	\$2.00	\$61.87	3.66	335.34
FREESTYLE TES	597	233	\$102,237.29	\$4.91	\$171.25	2.56	333.26
FREESTYLE TES INSULINX	265	107	\$50,228.44	\$5.11	\$189.54	2.48	314.95
EASYMAX TES	27	6	\$749.52	\$0.89	\$27.76	4.5	600.00
FREESTYLE LITE TEST STRIP	1,623	527	\$34,882.82	\$0.73	\$21.49	3.08	319.86
FREESTYLE INSULINX	186	64	\$33,335.73	\$5.68	\$179.22	2.91	350.78
<b>SUBTOTAL</b>	<b>28,943</b>	<b>9,496</b>	<b>\$4,216,288.06</b>	<b>\$3.90</b>	<b>\$145.68</b>	<b>3.05</b>	<b>373.85</b>
<b>GLUCOMETERS</b>							
FREESTYLE MIS LITE	1,775	1,736	\$26,421.65	\$0.45	\$14.89	1.02	1.02
ONETOUCH KIT ULTRA 2	1,432	1,408	\$21,277.26	\$0.40	\$14.86	1.02	1.02
ONETOUCH KIT ULT MINI	880	869	\$12,966.88	\$0.42	\$14.74	1.01	1.01
PRECISION MIS XTRA	58	58	\$853.16	\$0.45	\$14.71	1	1.00
EASYMAX V KIT SYSTEM	2	2	\$75.00	\$0.58	\$37.50	1	1.00
FREESTYLE FREEDOM LITE	298	294	\$4,391.77	\$0.43	\$14.74	1.01	1.01
FREESTYLE INSULINX	61	61	\$2,310.00	\$1.25	\$37.87	1	1.00
<b>SUBTOTAL</b>	<b>4,506</b>	<b>4,428</b>	<b>\$68,295.72</b>	<b>\$0.44</b>	<b>\$15.16</b>	<b>1.02</b>	<b>1.02</b>
<b>LANCETS &amp; LANCING DEVICES</b>							
FREESTYLE MIS LANCETS	4,859	2,411	\$10,119.59	\$0.05	\$2.08	2.02	258.58
ONETOUCH MIS LANCETS	2,084	1,144	\$3,666.84	\$0.04	\$1.76	1.82	201.92
EASY TOUCH LANCETS	1,194	547	\$1,998.88	\$0.04	\$1.67	2.18	227.70
TRUPLUS LANC MIS 28G	666	357	\$1,179.93	\$0.04	\$1.77	1.87	201.12
TRUPLUS LANC MIS 33G	532	251	\$927.41	\$0.04	\$1.74	2.12	225.58
ONETOUCH MIS 30G	471	292	\$809.79	\$0.04	\$1.72	1.61	172.95
ONETOUCH US LANCETS	380	237	\$719.88	\$0.04	\$1.89	1.6	191.59
TRUPLUS LANC MIS 30G	260	172	\$438.26	\$0.03	\$1.69	1.51	158.49
MICROLET MIS LANCETS	242	112	\$534.41	\$0.06	\$2.21	2.16	298.21
FASTCLIX MIS LANCETS	107	34	\$260.06	\$0.09	\$2.43	3.15	467.65
BAYER MICRLT LANCETS	80	49	\$117.13	\$0.04	\$1.46	1.63	155.57
PRODIGY TWIST LANCET	62	42	\$112.20	\$0.04	\$1.81	1.48	161.90
UNILET GP LANCETS	48	24	\$99.00	\$0.04	\$2.06	2	262.50
ASSURE CMFRT MIS 30G	31	17	\$52.80	\$0.04	\$1.70	1.82	188.24
TECHLITE MIS LANCETS	21	10	\$47.85	\$0.04	\$2.28	2.1	290.00
TRUPLUS LANC MIS 26G	17	12	\$27.37	\$0.03	\$1.61	1.42	141.67
SOFTCLIX MIS LANCETS	15	9	\$37.95	\$0.06	\$2.53	1.67	255.56
ACCU-CHEK MIS MLTICLIX	13	6	\$38.74	\$0.11	\$2.98	2.17	391.00
LANCING DEVI MIS	12	12	\$30.24	\$0.05	\$2.52	1	1.00
ONETOUCH MIS LANC DEV	11	10	\$27.72	\$0.09	\$2.52	1.1	1.10
ULTRA THIN LANC 28G	8	4	\$13.20	\$0.07	\$1.65	2	200.00
ULTILET MIS LANCETS	7	3	\$11.55	\$0.03	\$1.65	2.33	233.33
ULTRA THIN LANC 30G	5	2	\$8.25	\$0.06	\$1.65	2.5	250.00
LANCETS MIS 23G	5	1	\$16.50	\$0.11	\$3.30	5	1,000.00
LANCETS MIS 28G	5	3	\$5.12	\$0.03	\$1.02	1.67	313.33
BAYER MICRLT LANC DVC	3	3	\$7.56	\$0.12	\$2.52	1	1.00
ADV LANCING MIS DEVICE	2	2	\$5.04	\$0.08	\$2.52	1	1.00
ULTILET MIS 26G	2	2	\$3.30	\$0.03	\$1.65	1	100.00

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	CLAIMS/MEMBER	UNITS/MEMBER
SAFE-T-PRO MIS LANCETS	1	1	\$3.30	\$0.11	\$3.30	1	200.00
GLUCOLET 2 MIS LANCING	1	1	\$2.52	\$0.08	\$2.52	1	1.00
LB LANCING MIS DEVICE	1	1	\$2.52	\$0.01	\$2.52	1	1.00
ACCU-CHEK KIT FASTCLIX	1	1	\$2.52	\$0.08	\$2.52	1	1.00
ONETOUCH MIS LANC DEV	1	1	\$1.65	\$0.06	\$1.65	1	100.00
ULTILET MIS 28G	1	1	\$1.65	\$0.03	\$1.65	1	100.00
SOFT TOUCH MIS LANCETS	1	1	\$1.65	\$0.02	\$1.65	1	100.00
LANCET SUPER MIS 30G	1	1	\$1.65	\$0.07	\$1.65	1	100.00
LANCET ULTRA MIS 28G	1	1	\$1.65	\$0.07	\$1.65	1	100.00
<b>SUBTOTAL</b>	<b>11,151</b>	<b>5,777</b>	<b>\$21,335.68</b>	<b>\$0.05</b>	<b>\$1.91</b>	<b>2.09</b>	<b>228.13</b>
<b>PEN NEEDLES</b>							
NOVOFINE MIS 30GX8MM	1,574	451	\$46,003.39	\$0.92	\$29.23	3.49	393.33
NOVOFINE MIS 32GX6MM	1,253	415	\$39,649.54	\$0.97	\$31.64	3.02	380.22
NOVOTWIST 32GX5MM	102	47	\$3,933.50	\$1.14	\$38.56	2.17	325.96
PEN NEEDLES 31GX1/4"	87	18	\$1,599.67	\$0.65	\$18.39	4.83	536.11
PEN NEEDLES 31GX5/16	80	37	\$1,381.98	\$0.48	\$17.27	2.16	218.92
NOVOFINE PLS 32GX4MM	51	28	\$1,624.60	\$0.67	\$31.85	1.82	225.36
NOVOFINE AUT 30GX8MM	22	10	\$553.80	\$0.49	\$25.17	2.2	213.00
PEN NEEDLES 31GX3/16	17	11	\$468.00	\$0.49	\$27.53	1.55	163.64
PEN NEEDLES 29GX1/2"	16	5	\$264.52	\$0.59	\$16.53	3.2	318.00
PEN NEEDLES 31GX6MM	9	2	\$167.31	\$0.70	\$18.59	4.5	450.00
PEN NEEDLE 29GX1/2"	1	1	\$26.00	\$0.87	\$26.00	1	100.00
<b>SUBTOTAL</b>	<b>3,212</b>	<b>1025</b>	<b>\$95,672.31</b>	<b>\$0.91</b>	<b>\$29.79</b>	<b>3.31</b>	<b>371.79</b>
<b>INSULIN SYRINGES</b>							
INSULIN SYRG 1ML/31G	119	38	\$2,548.97	\$0.62	\$21.42	3.13	322.11
INSULIN SYRG 0.5/31G	102	44	\$1,933.59	\$0.56	\$18.96	2.32	207.73
INSULIN SYRG 0.3/31G	66	29	\$1,605.55	\$0.65	\$24.33	2.28	256.21
INSULIN SYRG 1ML/30G	40	16	\$1,034.88	\$0.78	\$25.87	2.5	300.00
INSULIN SYRG 0.5/30G	32	13	\$723.88	\$0.62	\$22.62	2.46	253.85
INSULIN SYRG 0.3/30G	17	7	\$388.08	\$0.65	\$22.83	2.43	257.14
INSULIN SYRG 0.5/29G	12	7	\$146.12	\$0.23	\$12.18	1.71	157.29
INSULIN SYRG 1ML/28G	9	5	\$144.69	\$0.27	\$16.08	1.8	184.00
INSULIN SYRG 0.5/28G	7	5	\$135.83	\$0.65	\$19.40	1.4	126.00
ULTICARE SYG 0.5CC/29G	6	3	\$45.95	\$0.23	\$7.66	2	200.00
INSULIN SYRG 1ML/29G	5	2	\$61.76	\$0.41	\$12.35	2.5	250.00
INSULIN SYRG 0.3/29G	3	1	\$63.36	\$0.42	\$21.12	3	300.00
INSULIN SYRG 0.3/29G	1	1	\$14.46	\$0.43	\$14.46	1	100.00
ULTICARE SYG 0.3CC/29G	1	1	\$11.02	\$0.37	\$11.02	1	120.00
ULTICARE SYG 1CC/29G	1	1	\$9.19	\$0.31	\$9.19	1	100.00
<b>SUBTOTAL</b>	<b>421</b>	<b>173</b>	<b>\$8,867.33</b>	<b>\$0.59</b>	<b>\$21.06</b>	<b>2.58</b>	<b>249.02</b>
<b>GLUCOMETER CONTROL SOLUTION</b>							
ONETOUCH SOL ULT CONT	38	38	\$191.78	\$0.18	\$5.05	1	1.42
FREESTYLE LIQ NORMAL	20	20	\$132.00	\$0.21	\$6.60	1	1.70
<b>SUBTOTAL</b>	<b>58</b>	<b>58</b>	<b>\$323.78</b>	<b>\$0.19</b>	<b>\$5.58</b>	<b>1</b>	<b>1.52</b>
<b>KETONE STRIPS</b>							
KETOSTIX TES STRIP	895	408	\$7,188.49	\$0.25	\$8.03	2.19	152.57
KETOCARE TES	201	107	\$1,481.20	\$0.23	\$7.37	1.88	134.11
PRECISN XTRA	29	11	\$2,189.75	\$4.06	\$75.51	2.64	43.64
KETONE TEST STRIP	29	26	\$265.05	\$0.23	\$9.14	1.12	86.54
<b>SUBTOTAL</b>	<b>1154</b>	<b>552</b>	<b>\$11,124.49</b>	<b>\$0.31</b>	<b>\$9.64</b>	<b>2.10</b>	<b>143.71</b>
<b>TOTAL</b>	<b>49,445</b>	<b>10,766*</b>	<b>\$4,421,907.37</b>	<b>\$2.36</b>	<b>\$89.49</b>	<b>4.59</b>	<b>499.39</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Cost per claim may correspond to a member receiving several months of therapy in one claim.

# Fiscal Year 2016 Annual Review of Elidel™ (Pimecrolimus Topical) and Protopic® (Tacrolimus Topical)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Elidel™ (Pimecrolimus Topical) and Protopic® (Tacrolimus Topical) Approval Criteria:

1. The first 90 days of a 12 month period will be covered without prior authorization.
2. After the initial period, authorization may be granted with documentation of one trial at least six weeks in duration within the past 90 days of a Tier-1 topical corticosteroid.
3. Therapy will be approved only once each 90 day period to ensure appropriate short-term and intermittent utilization as advised by the FDA.
4. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas.
5. Authorizations will be restricted to those patients who are not immunocompromised.

#### Members Must Meet All of the Following Criteria for Authorization:

1. An FDA approved diagnosis:
  - a. Elidel™: short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema)
  - b. Protopic®: short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema)
2. Age Restrictions:
  - a. Elidel™ 1% is restricted to two years of age and older
  - b. Protopic® 0.03% is restricted to two years of age and older
  - c. Protopic® 0.1% is restricted to 15 years of age and older

#### Clinical Exceptions for Children Meeting Age Restriction:

1. Documented adverse effect, drug interaction, or contraindication to Tier-1 products; or
2. Atopic dermatitis of face or groin where physician does not want to use topical corticosteroids; or
3. Prescribed by a dermatologist.

**Clinical Exceptions for Children Not Meeting Age Restriction:** Prescribed by dermatologist.

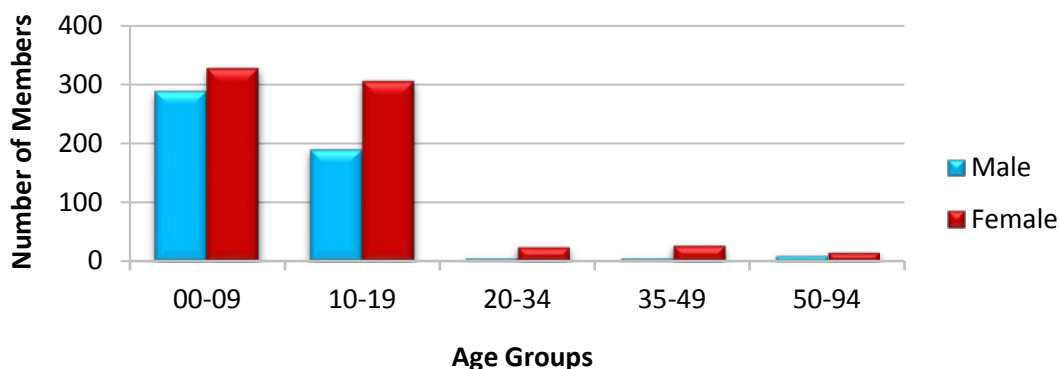
### Utilization of Elidel™ and Protopic®: Fiscal Year 2016

#### Comparison of Fiscal Years

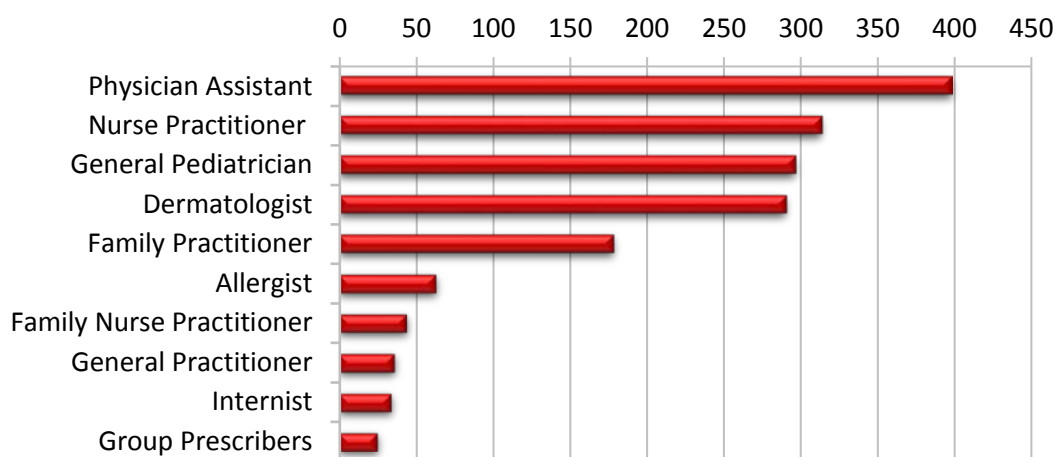
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1,225	1,720	\$560,888.66	\$326.10	\$10.22	78,210	54,896
2016	1,194	1,699	\$542,966.07	\$319.58	\$10.01	83,500	54,268
% Change	-2.50%	-1.20%	-3.20%	-2.00%	-2.10%	6.80%	-1.10%
Change	-31	-21	-\$17,922.59	-\$6.52	-\$0.21	5,290	-628

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

### Demographics of Members Utilizing Elidel™ and Protopic®

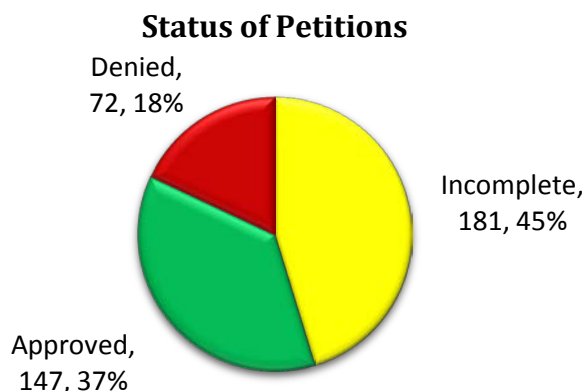


### Top Prescriber Specialties of Elidel™ and Protopic® by Number of Claims



### Prior Authorization of Elidel™ and Protopic®

There were 400 prior authorization requests submitted for Elidel™ and Protopic® during fiscal year 2016. The following chart shows the status of the submitted petitions.



### Market News and Updates<sup>7</sup>

<sup>7</sup> 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 09/2016. Last accessed 10/2016.

**Anticipated Patent Expiration(s):** Elidel™ (pimecrolimus topical): December 2018

## **Recommendations**

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The College of Pharmacy does not recommend any changes to the Elidel™ and Protopic® prior authorization criteria at this time.

## **Utilization Details of Elidel™ and Protopic®: Fiscal Year 2016**

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<b>PRODUCT UTILIZED</b>	<b>TOTAL CLAIMS</b>	<b>TOTAL MEMBERS</b>	<b>TOTAL COST</b>	<b>COST/ DAY</b>	<b>COST/ CLAIM</b>
TACROLIMUS OIN 0.03%	861	598	\$264,816.11	\$10.10	\$307.57
ELIDEL CRE 1%	718	532	\$247,072.30	\$10.13	\$344.11
TACROLIMUS OIN 0.1%	117	89	\$29,844.27	\$8.40	\$255.08
PROTOPIC OIN 0.03%	3	2	\$1,233.39	\$13.70	\$411.13
<b>TOTAL</b>	<b>1,699</b>	<b>1,194*</b>	<b>\$542,966.07</b>	<b>\$10.01</b>	<b>\$319.58</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Erythropoiesis-Stimulating Agents (ESAs)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Aranesp® (Darbepoetin Alfa) Approval Criteria:

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

#### Procrit® and Epogen® (Epoetin Alfa) Approval Criteria:

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

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### Utilization of ESA's: Fiscal Year 2016

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#### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	50	274	\$219,259.06	\$800.22	579
2016	42	231	\$241,455.72	\$1,045.26	548
% Change	-16.00%	-15.70%	10.10%	30.60%	-5.40%
Change	-8	-43	\$22,196.66	\$245.04	-31

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

## Comparison of Fiscal Years: Medical Claims

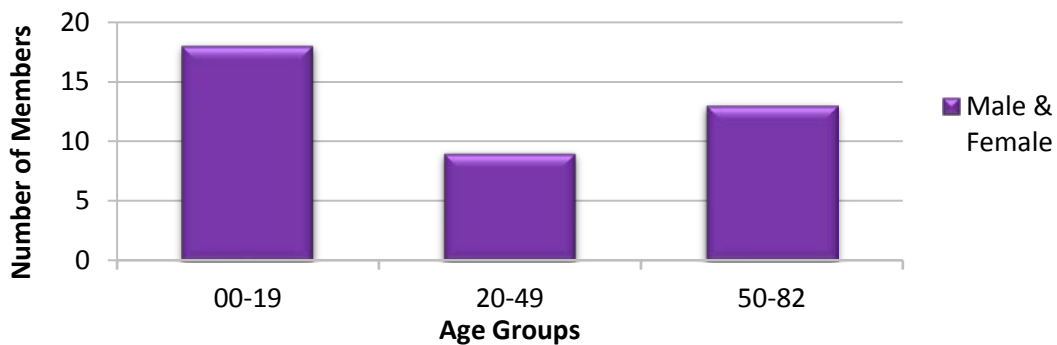
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim
2015	58	301	\$145,101.26	\$482.06
2016	38	116	\$87,147.66	\$751.27
% Change	-34.48%	-61.46%	-39.94%	\$269.21
Change	-20	-185	-\$57,953.60	55.85%

\*Total number of unduplicated members.

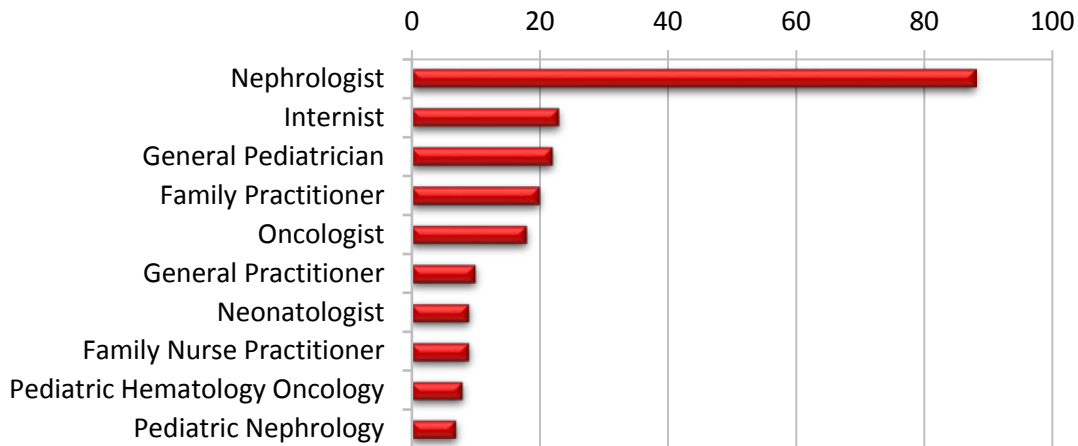
Costs do not reflect rebated prices or net costs.

Totals exclude darbepoetin alfa and epoetin alfa claims for anemia in end-stage renal disease for members on dialysis. ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately.

### Demographics of Members Utilizing ESAs

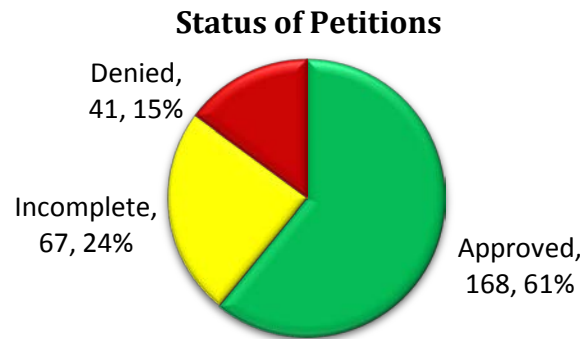


### Top Prescriber Specialties of ESAs by Number of Claims



### Prior Authorization of ESA's

There were 276 prior authorization requests submitted for ESA's during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>8</sup>

- October 2015:** It was announced that Hospira's abbreviated Biologics License Application (aBLA) for Retacrit™ (epoetin Hospira), a biosimilar to Amgen's Epogen® (epoetin alpha), was rejected by the U.S. Food and Drug Administration (FDA). Retacrit™ has been available in Europe since 2008. Pfizer, current owner of Hospira, indicated on its quarterly conference call that the aBLA may be amended and submitted to the FDA again.

## Recommendations

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

## Utilization Details of ESAs: Fiscal Year 2016

### ESAs: Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
<b>EPOETIN ALFA PRODUCTS</b>						
PROCRIT INJ 20000/ML	131	20	\$143,338.78	\$63.34	\$1,094.19	59.36%
PROCRIT INJ 10000/ML	32	8	\$22,980.34	\$27.33	\$718.14	9.52%
PROCRIT INJ 2000/ML	20	3	\$1,292.57	\$4.79	\$64.63	0.54%
EPOGEN INJ 10000/ML	15	5	\$8,951.10	\$22.21	\$596.74	3.71%
PROCRIT INJ 40000/ML	12	3	\$15,168.30	\$57.89	\$1,264.03	6.28%
EPOGEN INJ 20000/ML	6	2	\$5,911.29	\$34.98	\$985.22	2.45%
<b>SUBTOTAL</b>	<b>216</b>	<b>41</b>	<b>\$197,642.38</b>	<b>\$46.97</b>	<b>\$915.01</b>	<b>81.86%</b>
<b>DARBEPOETIN ALFA PRODUCTS</b>						
ARANESP INJ 500MCG	10	1	\$36,940.66	\$175.91	\$3,694.07	15.30%
ARANESP INJ 60MCG	3	1	\$5,403.06	\$64.32	\$1,801.02	2.24%
ARANESP INJ 25MCG	2	1	\$1,469.62	\$8.16	\$734.81	0.61%
<b>SUBTOTAL</b>	<b>15</b>	<b>3</b>	<b>\$43,813.34</b>	<b>\$92.43</b>	<b>\$2,920.89</b>	<b>18.15%</b>
<b>TOTAL</b>	<b>231</b>	<b>42*</b>	<b>\$241,455.72</b>	<b>\$51.57</b>	<b>\$1,045.26</b>	<b>100.00%</b>

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

<sup>8</sup> Big Molecule Watch: Biosimilars: FDA Rejects Hospira's Epogen Biosimilar. Available online at: <http://www.bigmoleculewatch.com/2015/10/27/fda-rejects-hospiras-epogen-biosimilar/>. Issued 10/27/2015. Last accessed 11/04/2016.



### ESAs: Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
PROCRIT INJ J0885	75	27	\$45,941.28	\$612.55
ARANESP INJ J0881	41	11	\$41,206.38	\$1,005.03
<b>TOTAL</b>	<b>116</b>	<b>38</b>	<b>\$87,147.66</b>	<b>\$751.27</b>

\*Total number of unduplicated members.

Totals exclude darbepoetin alfa and epoetin alfa claims for anemia in end-stage renal disease for members on dialysis. ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately.

# Fiscal Year 2016 Annual Review of Fibric Acid Derivative Medications

Oklahoma Health Care Authority  
Fiscal Year 2016 Print Report

## Current Prior Authorization Criteria

Fibric Acid Derivative Medications*	
Tier-1	Tier-2
fenofibrate (Lofibra® capsules)	fenofibrate (Antara® capsules)
fenofibrate (Triglide® tablets) 160mg	fenofibrate (Lipofen® capsules)
fenofibrate (Trilipix® tablets)	fenofibrate (Fenoglide® tablets)
fenofibrate (Tricor® tablets)	fenofibrate (Fibricor® tablets)
gemfibrozil (Lopid® tablets)	

\*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 Medications Tier-2 Approval Criteria:

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

## Utilization of Fibric Acid Derivative Medications: Fiscal Year 2016

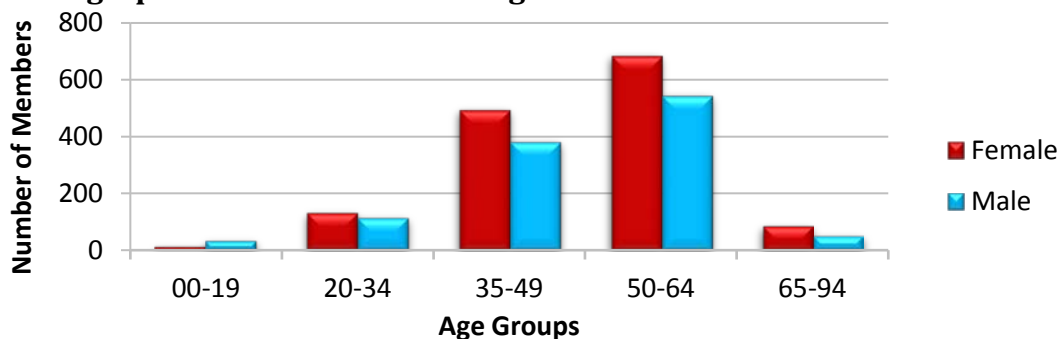
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	2,580	11,059	\$569,658.64	\$51.51	\$1.35	533,866	422,572
2016	2,527	10,892	\$457,524.63	\$42.01	\$1.08	532,394	425,457
% Change	-2.10%	-1.50%	-19.70%	-18.40%	-20.00%	-0.30%	0.70%
Change	-53	-167	-\$112,134.01	-\$9.50	\$0.27	-1,472	2,885

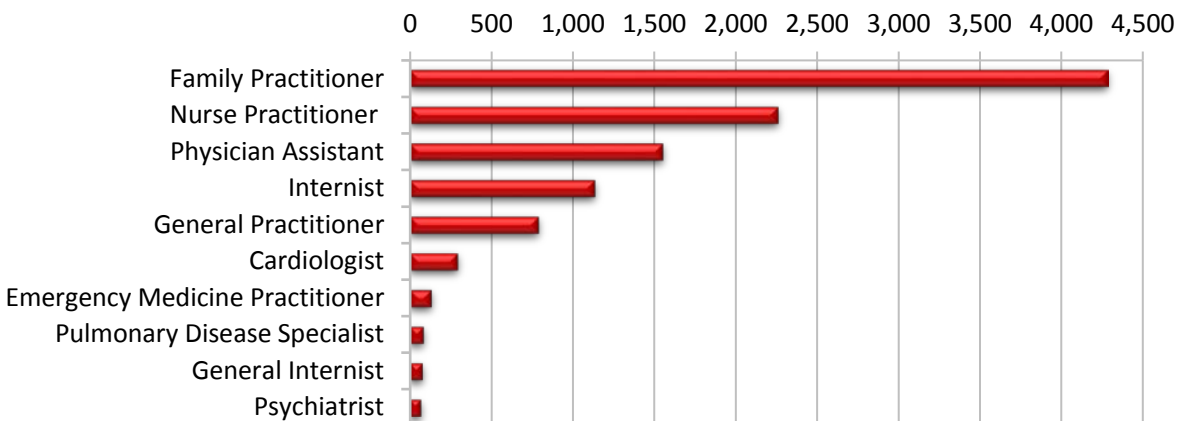
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Fibric Acid Derivative Medications

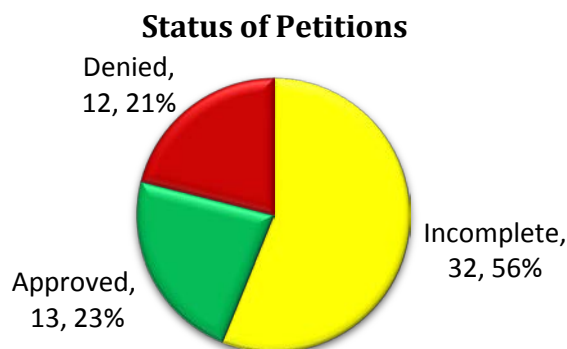


## Top Prescriber Specialties of Fibric Acid Derivative Medications by Number of Claims



## Prior Authorization of Fibric Acid Derivative Medications

There were 57 prior authorization requests submitted for the fibric acid derivative medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>9,10</sup>

### Anticipated Patent Expiration(s):

- Triglide® (fenofibrate tablets): September 2021
- Antara® (fenofibrate capsules): April 2025

### News:

- **June 2016:** Mylan received U.S. Food and Drug Administration (FDA) approval for its Abbreviated New Drug Application (ANDA) for fenofibrate 40mg and 120mg tablets (generic Fenoglide®).

<sup>9</sup> 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 09/2016. Last accessed 11/02/2016.

<sup>10</sup> U.S. Food and Drug Administration (FDA): Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process&ApplNo=204475>. Last accessed 11/03/2016.

## Recommendations

The College of Pharmacy does not recommend any changes to the fibric acid derivative medications prior authorization criteria at this time.

### Utilization Details of Fibric Acid Derivative Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
GEMFIBROZIL TAB 600MG	3,537	836	\$34,409.54	\$0.31	\$9.73
FENOFIBRATE TAB 145MG	2,497	628	\$129,136.66	\$1.18	\$51.72
FENOFIBRATE TAB 160MG	1,755	397	\$65,420.47	\$0.90	\$37.28
FENOFIBRIC CAP 135MG DR	990	236	\$121,997.50	\$2.62	\$123.23
FENOFIBRATE TAB 48MG	672	180	\$23,056.02	\$0.85	\$34.31
FENOFIBRATE TAB 54MG	467	131	\$11,355.54	\$0.65	\$24.32
FENOFIBRATE CAP 134MG	357	98	\$23,090.33	\$1.34	\$64.68
FENOFIBRIC CAP 45MG DR	251	76	\$12,946.76	\$1.25	\$51.58
FENOFIBRATE CAP 200MG	164	26	\$12,536.06	\$2.14	\$76.44
FENOFIBRATE CAP 67MG	67	12	\$2,063.50	\$0.76	\$30.80
TRILIPIX CAP 135MG	64	15	\$5,263.10	\$2.77	\$82.24
TRICOR TAB 145MG	21	7	\$818.07	\$1.30	\$38.96
TRILIPIX CAP 45MG	2	1	\$78.90	\$1.32	\$39.45
<b>TIER-1 SUBTOTAL</b>	<b>10,844</b>	<b>2643</b>	<b>\$442,172.45</b>	<b>\$1.04</b>	<b>\$40.78</b>
<b>TIER-2 PRODUCTS</b>					
FENOFIBRATE CAP 150MG	17	7	\$2,428.15	\$4.76	\$142.83
FENOFIBRATE TAB 40MG	11	2	\$3,984.02	\$8.85	\$362.18
FENOGLIDE TAB 40MG	8	2	\$2,645.07	\$11.02	\$330.63
FENOFIBRATE CAP 130MG	5	2	\$602.03	\$4.01	\$120.41
FENOFIBRIC TAB 105MG	2	1	\$456.00	\$2.53	\$228.00
FENOFIBRATE TAB 120MG	2	2	\$4,765.76	\$26.48	\$2,382.8
LIPOFEN CAP 50MG	1	1	\$287.36	\$3.19	\$287.36
FENOFIBRATE CAP 43MG	1	1	\$158.70	\$1.76	\$158.70
FENOFIBRIC TAB 35MG	1	1	\$25.09	\$0.84	\$25.09
<b>TIER-2 SUBTOTAL</b>	<b>48</b>	<b>19</b>	<b>\$15,352.18</b>	<b>\$8.00</b>	<b>\$319.84</b>
<b>TOTAL</b>	<b>10,892</b>	<b>2,527*</b>	<b>\$457,524.63</b>	<b>\$1.08</b>	<b>\$42.01</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Fibromyalgia Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Fibromyalgia Medications		
Tier-1	Tier-2*	Tier-3
amitriptyline (Elavil®)	milnacipran (Savella®)	pregabalin (Lyrica®)
cyclobenzaprine (Flexeril®)		
duloxetine (Cymbalta®)		
fluoxetine (Prozac®)		
tramadol (Ultram®)		

\*Tier-2 includes supplemental rebated medication(s). If no medications rebate to Tier-2, Tier-2 will include the lowest cost Tier-3 product(s).

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 six months) trial of two Tier-1 medications (must include one trial with duloxetine) at least three 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.
4. Clinical Exceptions include:
  - a. Diagnosis of seizures or postherpetic neuralgia for Lyrica® (pregabalin)

#### Fibromyalgia Medications Tier-3 Approval Criteria:

1. A documented, recent (within the last six months) trial of two Tier-1 medications (must include one trial with duloxetine) and all available Tier-2 medications at least three 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-3 medication.

#### Lyrica® (Pregabalin) Approval Criteria (Diabetic Neuropathy Diagnosis):

1. For the diagnosis of diabetic neuropathy, a trial of duloxetine and a trial of gabapentin or a patient-specific, clinically significant reason why duloxetine or gabapentin cannot be used must be provided.
2. Other criteria for Lyrica® (pregabalin) will continue to apply.

## Utilization of Fibromyalgia Medications: Fiscal Year 2016

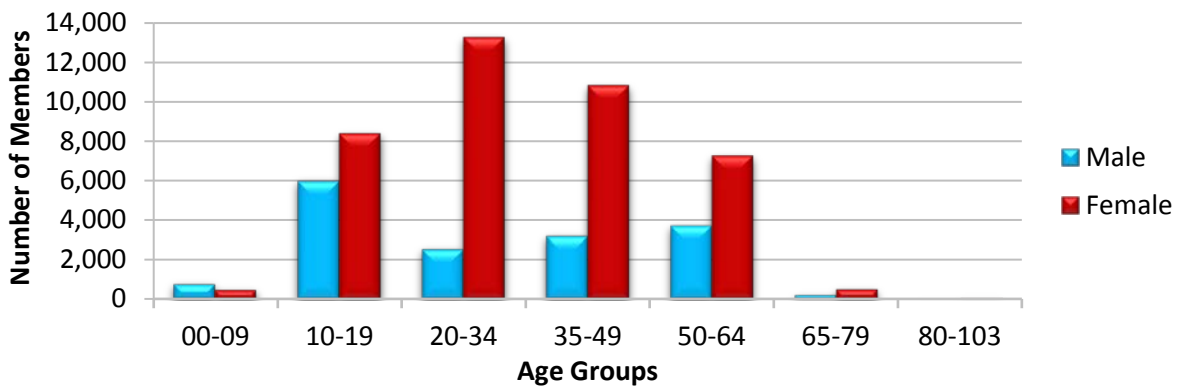
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	57,886	212,557	\$6,922,778.81	\$32.57	\$1.21	11,461,339	5,723,416
2016	57,211	213,228	\$7,144,627.70	\$33.51	\$1.22	11,489,909	5,863,923
% Change	-1.20%	0.30%	3.20%	2.90%	0.80%	0.20%	2.50%
Change	-675	671	\$221,848.89	\$0.94	\$0.01	28,570	140,507

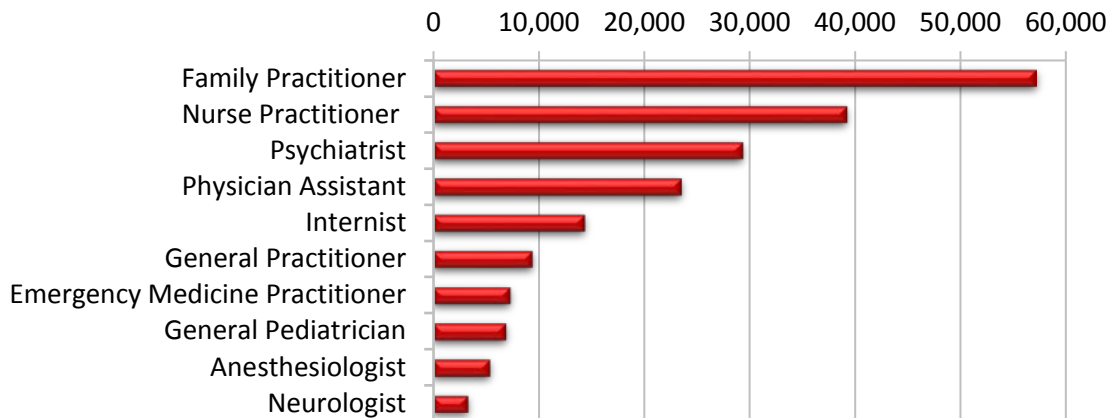
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Fibromyalgia Medications



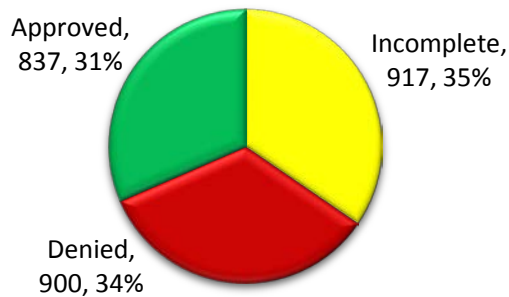
### Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims



### Prior Authorization of Fibromyalgia Medications

There were 2,654 prior authorization requests submitted for the fibromyalgia medications during fiscal year 2016. Computer edits are in place to detect Tier-1 medications in members' 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<sup>11,12,13</sup>

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### Anticipated Patent Expiration(s):

- Lyrica® (pregabalin): December 2018
- Savella® (milnacipran): September 2029

### News

- **April 2016:** The U.S. Food and Drug Administration (FDA) approved Amneal Pharmaceuticals' abbreviated New Drug Application (aNDA) for milnacipran, generic Savella®. Amneal obtained generic approval for all four strengths (12.5mg, 25mg, 50mg, and 100mg) of milnacipran. Milnacipran is not currently available and no tentative launch dates have been announced.
- **July 2016:** The *Annals of the Rheumatic Diseases* journal published the European League Against Rheumatism (EULAR) Revised Recommendations for the Management of Fibromyalgia. A multidisciplinary group from 12 countries assessed evidence with a focus on systematic reviews and meta-analyses concerned with pharmacological/non-pharmacological management for fibromyalgia. The key outcomes assessed were pain, fatigue, sleep, and daily functioning. The Grading of Recommendations Assessment, Development and Evaluation system was used for making recommendations. This is a four-point scale: strong for/weak for/weak against/strong against with the strength of recommendation based on the balance between desirable and undesirable effects, confidence in the magnitude of effects, and resource use. The only 'strong for' therapy-based recommendation to come out of this review was exercise. This was based on the findings for its effect on pain, physical function and well-being, availability, relatively low cost, and lack of safety concerns. Pharmacological options assessed included: amitriptyline, duloxetine, milnacipran, tramadol, pregabalin, and cyclobenzaprine. These medications were given a 'weak for' strength of recommendation. Additionally, monoamine oxidase inhibitors, non-steroidal anti-inflammatory drugs, and selective serotonin reuptake inhibitors were given a recommendation of 'weak against.' Based on unanimous expert opinion, EULAR recommended optimal management of fibromyalgia with prompt diagnosis and providing the patient with information. Additionally, a comprehensive assessment of pain, function, and the psychosocial context is

<sup>11</sup> U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Last revised 10/2016. Last accessed 12/08/16.

<sup>12</sup> U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Last revised 11/01/2016. Last accessed 12/08/2016.

<sup>13</sup> Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis* 2016. Available online at: <http://ard.bmj.com/content/early/2016/07/04/annrheumdis-2016-209724.full>. Issued 07/04/2016. Last accessed 12/13/2016.

recommended. Management should take the form of a graduated approach with the aim of improving health-related quality of life. Non-pharmacological modalities are the recommended first-line approach. If there is a lack of efficacy with a non-pharmacological approach, individualized therapy is recommended which may include pharmacological therapy.

## Recommendations

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

## Utilization Details of Fibromyalgia Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>AMITRIPTYLINE PRODUCTS</b>					
AMITRIPTYLIN TAB 25MG	6,923	2,576	\$83,846.30	\$0.36	\$12.11
AMITRIPTYLIN TAB 50MG	4,666	1,532	\$91,889.61	\$0.57	\$19.69
AMITRIPTYLIN TAB 10MG	3,545	1,355	\$30,532.69	\$0.27	\$8.61
AMITRIPTYLIN TAB 100MG	2,740	690	\$113,161.12	\$1.16	\$41.30
AMITRIPTYLIN TAB 150MG	1,136	242	\$69,958.08	\$1.67	\$61.58
AMITRIPTYLIN TAB 75MG	1,129	322	\$34,222.88	\$0.84	\$30.31
<b>SUBTOTAL</b>	<b>20,139</b>	<b>6,717</b>	<b>\$423,610.68</b>	<b>\$0.62</b>	<b>\$21.03</b>
<b>CYCLOBENZAPRINE PRODUCTS</b>					
CYCLOBENZAPR TAB 10MG	37,166	17,401	\$181,645.56	\$0.21	\$4.89
CYCLOBENZAPR TAB 5MG	6,896	4,502	\$39,099.28	\$0.30	\$5.67
<b>SUBTOTAL</b>	<b>44,062</b>	<b>21,903</b>	<b>\$220,744.84</b>	<b>\$0.22</b>	<b>\$5.01</b>
<b>DULOXETINE PRODUCTS</b>					
DULOXETINE CAP 60MG	15,747	4,015	\$482,781.18	\$0.85	\$30.66
DULOXETINE CAP 30MG	7,449	2,994	\$214,320.81	\$0.89	\$28.77
DULOXETINE CAP 20MG	993	421	\$37,394.67	\$1.22	\$37.66
CYMBALTA CAP 60MG	17	6	\$8,622.67	\$12.50	\$507.22
CYMBALTA CAP 30MG	13	5	\$3,355.56	\$5.33	\$258.12
<b>SUBTOTAL</b>	<b>24,219</b>	<b>7,441</b>	<b>\$746,474.89</b>	<b>\$0.89</b>	<b>\$30.82</b>
<b>FLUOXETINE PRODUCTS</b>					
FLUOXETINE CAP 20MG	28,990	8,988	\$141,847.21	\$0.15	\$4.89
FLUOXETINE CAP 40MG	13,902	3,750	\$129,482.48	\$0.27	\$9.31
FLUOXETINE CAP 10MG	11,732	4,094	\$61,297.69	\$0.17	\$5.22
FLUOXETINE TAB 10MG	3,300	1,229	\$92,848.07	\$0.90	\$28.14
FLUOXETINE TAB 20MG	1,966	749	\$101,115.61	\$1.58	\$51.43
FLUOXETINE SOL 20MG/5ML	1,163	278	\$11,369.00	\$0.33	\$9.78
PROZAC CAP 20MG	27	3	\$22,777.15	\$26.64	\$843.60
PROZAC CAP 40MG	2	1	\$2,716.08	\$45.27	\$1,358.0
<b>SUBTOTAL</b>	<b>61,082</b>	<b>19,092</b>	<b>\$563,453.29</b>	<b>\$0.28</b>	<b>\$9.22</b>
<b>TRAMADOL PRODUCTS</b>					
TRAMADOL HCL TAB 50MG	51,283	20,456	\$270,081.86	\$0.27	\$5.27



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>SUBTOTAL</b>	<b>51,283</b>	<b>20,456</b>	<b>\$270,081.86</b>	<b>\$0.27</b>	<b>\$5.27</b>
<b>TIER-1 SUBTOTAL</b>	<b>200,785</b>	<b>75,609</b>	<b>\$2,224,365.56</b>	<b>\$0.40</b>	<b>\$11.08</b>
<b>TIER-2 PRODUCTS</b>					
<b>MILNACIPRAN PRODUCTS</b>					
SAVELLA TAB 100MG	150	23	\$38,974.22	\$8.66	\$259.83
SAVELLA TAB 50MG	107	26	\$28,396.87	\$8.87	\$265.39
SAVELLA MIS TITR PAK	18	18	\$4,616.11	\$8.84	\$256.45
SAVELLA TAB 12.5MG	12	9	\$2,946.19	\$8.98	\$245.52
SAVELLA TAB 25MG	10	7	\$2,607.75	\$9.69	\$260.78
<b>SUBTOTAL</b>	<b>297</b>	<b>83</b>	<b>\$77,541.14</b>	<b>\$8.79</b>	<b>\$261.08</b>
<b>TIER-2 SUBTOTAL</b>	<b>297</b>	<b>83</b>	<b>\$77,541.14</b>	<b>\$8.79</b>	<b>\$261.08</b>
<b>TIER-3 PRODUCTS</b>					
<b>PREGABALIN PRODUCTS</b>					
LYRICA CAP 150MG	3,668	662	\$1,487,298.55	\$13.71	\$405.48
LYRICA CAP 75MG	2,520	631	\$974,767.09	\$13.08	\$386.81
LYRICA CAP 100MG	2,164	462	\$925,979.08	\$14.42	\$427.90
LYRICA CAP 300MG	1,178	174	\$436,000.17	\$12.33	\$370.12
LYRICA CAP 50MG	1,136	321	\$464,341.77	\$13.57	\$408.75
LYRICA CAP 200MG	958	166	\$350,674.52	\$12.28	\$366.05
LYRICA CAP 225MG	412	67	\$166,397.94	\$13.40	\$403.88
LYRICA CAP 25MG	109	37	\$37,186.93	\$11.34	\$341.16
LYRICA SOL 20MG/ML	1	1	\$74.95	\$2.50	\$74.95
<b>SUBTOTAL</b>	<b>12,146</b>	<b>2,521</b>	<b>\$4,842,721.00</b>	<b>\$13.41</b>	<b>\$398.71</b>
<b>TIER-3 SUBTOTAL</b>	<b>12,146</b>	<b>2,521</b>	<b>\$4,842,721.00</b>	<b>\$13.41</b>	<b>\$398.71</b>
<b>TOTAL</b>	<b>213,228</b>	<b>57,211*</b>	<b>\$7,144,627.70</b>	<b>\$1.22</b>	<b>\$33.51</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Gattex® (Teduglutide)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Gattex® (Teduglutide) Approval Criteria:

1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must require parenteral nutrition at least three times per week, every week, for the past twelve 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 six months, with removal of polyps if present; and
  - c. Gastro-intestinal malignancy has been ruled out.
4. Approval will be for the duration of three months, after which time, the prescriber must verify benefit of medication by documented reduction of at least 20% in parenteral support. Subsequent approvals will be for the duration of one year.

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### Utilization of Gattex® (Teduglutide): Fiscal Year 2016

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There was no utilization of Gattex® (teduglutide) during fiscal year 2016.

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### Prior Authorization of Gattex® (Teduglutide)

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There were no prior authorization requests submitted for Gattex® (teduglutide) during fiscal year 2016.

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### Market News and Updates<sup>14</sup>

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**Anticipated Patent Expiration(s):** Gattex® (teduglutide): November 2025

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### Recommendations

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

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<sup>14</sup> 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 10/2016. Last accessed 11/28/2016.

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# Fiscal Year 2016 Annual Review of Gout Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### **Mitigare™ (Colchicine Capsules) and Colcrys® (Colchicine Tablets) Approval Criteria:**

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

#### **Uloric® (Febuxostat) Approval Criteria:**

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

#### **Zurampic™ (Lesinurad) Approval Criteria:**

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

## Utilization of Gout Medications: Fiscal Year 2016

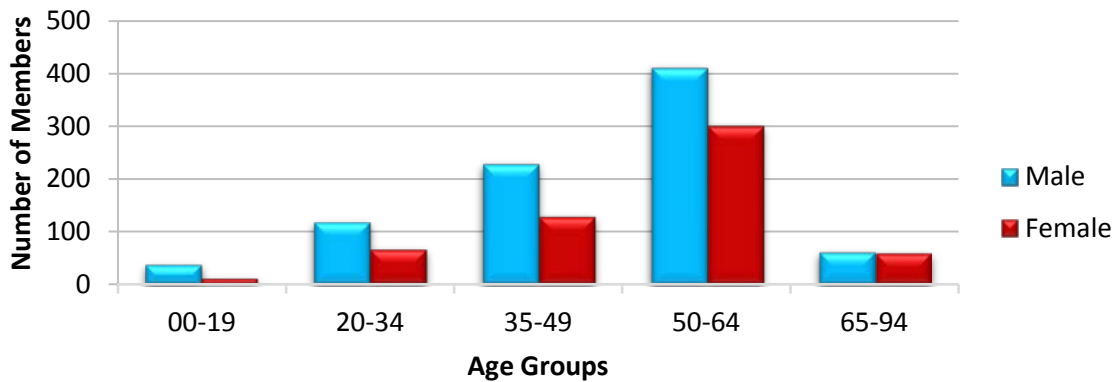
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1,400	6,205	\$131,744.51	\$21.23	\$0.58	315,995	228,493
2016	1,419	6,333	\$181,205.12	\$28.61	\$0.78	324,383	232,247
% Change	1.40%	2.10%	37.50%	34.80%	34.50%	2.70%	1.60%
Change	19	128	\$49,460.61	\$7.38	\$0.20	8,388	3,754

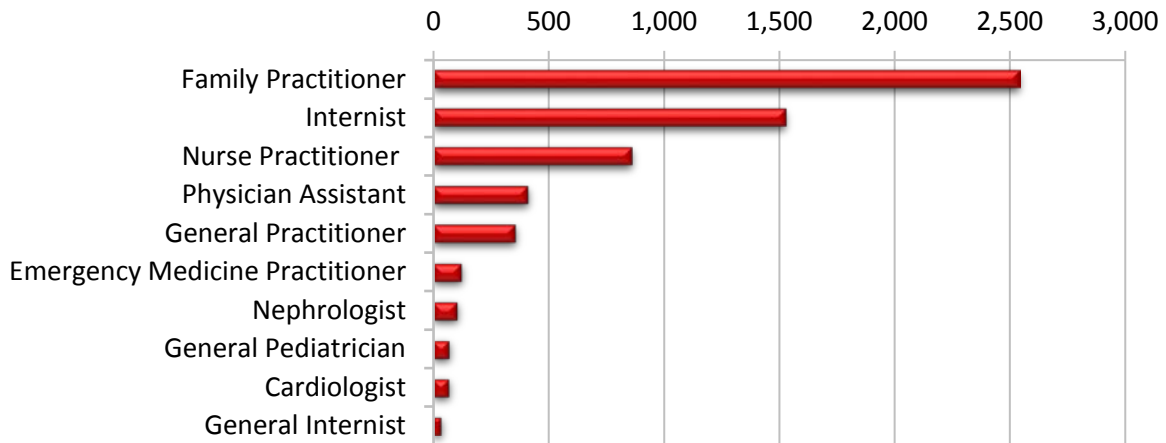
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Gout Medications



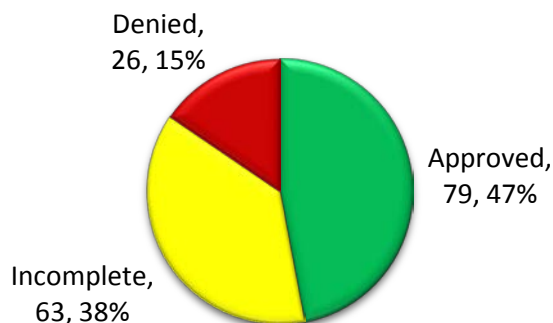
### Top Prescriber Specialties Gout Medications by Number of Claims



### Prior Authorization of Gout Medications

There were 168 prior authorization requests submitted for gout medications during fiscal year 2016. The following chart shows the status of the submitted petitions.

## Status of Petitions



## Market News and Updates<sup>15,16,17</sup>

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### Anticipated Patent Expiration(s):

- Colcyrs® (colchicine): February 2029
- Uloric® (febuxostat): September 2031
- Zurampic™ (lesinurad): February 2032
- Mitigare™ (colchicine): August 2033

### News:

- **November 2016:** The American College of Physicians (ACP) published new clinical guidelines for gout. The guidelines recommend the use of corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), or colchicine to treat patients with acute gout.
  - Corticosteroids are recommended as first-line treatment in patients without contraindications. According to the ACP, they are the most effective anti-inflammatory medications with fewer adverse effects than NSAIDs, and are less expensive than colchicine.
  - The ACP recommends use of low dose colchicine when used for acute gout. The evidence showed that lower doses are as effective as higher doses at reducing pain and are associated with fewer gastrointestinal adverse effects.
  - The ACP found insufficient evidence to determine the effectiveness of dietary changes on symptomatic outcomes for the treatment of gout.
  - For diagnosing gout, the ACP recommends that physicians use synovial fluid analysis when clinical judgement indicates that diagnostic testing is necessary in patients with possible gout. The ACP does acknowledge that most patients are seen initially by their primary care physician or an emergency room physician where synovial fluid analysis is less frequently and less easily performed. In those cases, physicians should use clinical judgement so that patients can begin treatment if gout is suspected.

<sup>15</sup> U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Last revised 10/2016. Last accessed 11/29/2016.

<sup>16</sup> American College of Physicians (ACP). ACP Newsroom. American College of Physicians releases clinical practice guidelines for acute gout. Available online at: <https://www.acponline.org/acp-newsroom/american-college-of-physicians-releases-clinical-practice-guidelines-for-acute-gout>. Issued 11/01/2016. Last accessed 12/09/2016.

<sup>17</sup> Kelly, J. Gout Doubt: Experts Challenge New ACP Guidelines. *Medscape*. Available online at: [http://www.medscape.com/viewarticle/871265#vp\\_3](http://www.medscape.com/viewarticle/871265#vp_3). Issued 11/02/2016. Last accessed 12/09/2016.

- The ACP recommends against initiating long-term uric acid-lowering therapy in most patients after a first gout attack or in patients with infrequent attacks. In cases of recurrent gout, they recommend that physicians and patients discuss the benefits, harms, costs, and individual preferences before initiating uric acid-lowering therapy.
- Further, the ACP called for the need for comparative effectiveness studies to evaluate the incremental benefits and harms of a treat-to-target strategy over a treat-to-avoid-symptoms strategy. This turn away from recent “treat-to-target” emphasis on controlling serum uric acid levels has outraged many gout experts. This guidance counters that of the American College of Rheumatology. One expert argues that hyperuricemia is not a mere 'comorbid risk factor' of gout but rather the main pathophysiologic culprit that causes flares, tophi, and joint damage; therefore, management of hyperuricemia is a key tenet of disease control. Another expert points out that the lack of randomized control trial data comparing "treat-to-target" vs "treat-to-avoid-symptoms" does not mean that no data are available to distinguish these two strategies. There is a large body of scientific knowledge other than randomized data to support a 'treat-to-target' strategy, while at the same time, the existing body of scientific knowledge raises concern regarding the 'treat-to-avoid-symptoms' approach contributing to poor outcomes in gout. Furthermore, another expert voices concern that “that the ACP recommendations are so flawed that it would be unfortunate if something as simple as getting uric acid levels done to routinely monitor serum uric acid were to be impacted at the third-party payer level.” In an editorial by a member of the ACP Clinical Guidelines Committee, it is pointed out that evidence must direct guideline recommendations, and that specifying clinical options when evidence is lacking is the role of expert consensus panels or best-practice statements.

## Recommendations

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

## Utilization Details of Gout Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>ALLOPURINOL PRODUCTS</b>					
ALLOPURINOL TAB	3,303	713	\$68,327.93	\$0.52	\$20.69
ALLOPURINOL TAB	2,220	611	\$23,361.47	\$0.27	\$10.52
<b>SUBTOTAL</b>	<b>5,523</b>	<b>1,324</b>	<b>\$91,689.40</b>	<b>\$0.42</b>	<b>\$16.60</b>
<b>COLCHICINE/PROBENECID PRODUCTS</b>					
PROBEN/COLCH TAB	85	29	\$3,701.34	\$1.39	\$43.55
<b>SUBTOTAL</b>	<b>8</b>	<b>29</b>	<b>\$3,701.34</b>	<b>\$1.39</b>	<b>\$43.55</b>
<b>COLCHICINE PRODUCTS</b>					
COLCHICINE TAB	338	148	\$19,578.61	\$6.83	\$57.92
COLCRYS TAB 0.6MG	157	66	\$8,349.94	\$7.04	\$53.18

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
COLCHICINE CAP	15	9	\$235.85	\$4.62	\$15.72
<b>SUBTOTAL</b>	<b>510</b>	<b>223</b>	<b>\$28,164.40</b>	<b>\$6.86</b>	<b>\$55.22</b>
<b>FEBUXOSTAT PRODUCTS</b>					
ULORIC TAB 40MG	125	24	\$32,463.70	\$8.84	\$259.71
ULORIC TAB 80MG	90	16	\$25,186.28	\$9.33	\$279.85
<b>SUBTOTAL</b>	<b>215</b>	<b>40</b>	<b>\$57,649.98</b>	<b>\$9.05</b>	<b>\$268.14</b>
<b>TOTAL</b>	<b>6,333</b>	<b>1,419*</b>	<b>\$181,205.12</b>	<b>\$0.78</b>	<b>\$28.61</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Hereditary Angioedema Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### **Cinryze® (C1 Esterase Inhibitor) Approval Criteria:**

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Cinryze® must be used for *prophylaxis* of hereditary angioedema; and
3. History of at least one or more abdominal or respiratory HAE attack(s) per month, or history of laryngeal attack(s), or three or more emergency medical treatments per year; and
4. Member must not be currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
5. Documented intolerance, insufficient response, or contraindication to:
  - a. Attenuated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone); and
  - b. Antifibrinolytic agents (e.g.  $\epsilon$  – aminocaproic acid, tranexamic acid); or
  - c. Recent hospitalization for severe episode of angioedema.
6. Dosing:
  - a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every three to four days, approximately two times per week, to be infused at a rate of 1mL/min.
  - b. Initial doses should be administered in an outpatient setting by a healthcare provider. Patients can be taught by their healthcare provider to self-administer Cinryze® intravenously.
  - c. A quantity limit of 8,000 units per month will apply (i.e. two treatments per week or eight treatments per month).

#### **Berinert® (C1 Esterase Inhibitor), Kalbitor® (Ecallantide), and Firazyr® (Icatibant) Approval Criteria:**

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

#### **Ruconest® (C1 Esterase Inhibitor) Approval Criteria:**

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



## Utilization of Hereditary Angioedema Medications: Fiscal Year 2016

### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	6	27	\$1,129,836.33	\$41,845.79	\$1,711.87	453	660
2016	2	14	\$1,003,742.26	\$71,695.88	\$2,586.96	370	388
% Change	-66.70%	-48.10%	-11.20%	71.30%	51.10%	-18.30%	-41.20%
Change	-4	-13	-\$126,094.07	\$29,850.09	\$875.09	-83	-272

\*Total number of unduplicated members.

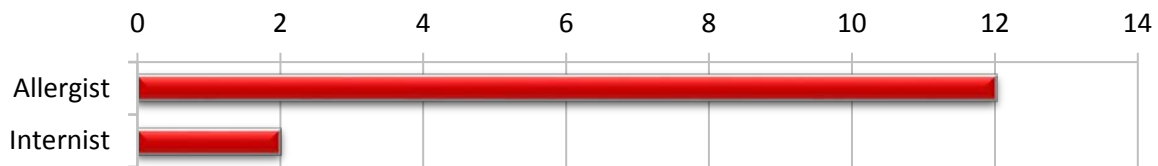
Costs do not reflect rebated prices or net costs.

- There were no paid medical claims for Berinert®, Kalbitor®, Firazyr®, or Ruconest® during fiscal year 2016.

### Demographics of Members Utilizing Hereditary Angioedema Medications

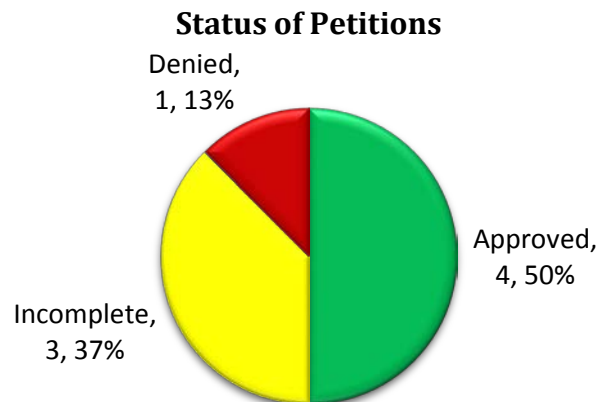
- Due to the small number of members utilizing hereditary angioedema medications, detailed demographic information could not be reported.

### Top Prescriber Specialties of Hereditary Angioedema Medications by Number of Claims



### Prior Authorization of Hereditary Angioedema Medications

There were eight prior authorization requests submitted for hereditary angioedema medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>18</sup>

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**Anticipated Patent Expiration(s):** Firazyr® (icatibant): July 2019

### Recommendations

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

### Utilization Details of Hereditary Angioedema Medications: Fiscal Year 2016

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PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/MEMBER	COST/CLAIM
CINRYZE SOL 500 UNIT	13	2	\$985,209.86	6.5	\$75,785.37
BERINERT INJ 500UNIT	1	1	\$18,532.40	1	\$18,532.40
<b>TOTAL</b>	<b>14</b>	<b>2*</b>	<b>\$1,003,742.2</b>	<b>7</b>	<b>\$71,695.88</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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<sup>18</sup> 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 10/2016. Last accessed 11/29/2016.

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# Fiscal Year 2016 Annual Review of Horizant® (Gabapentin Enacarbil Extended-Release) & Gralise® (Gabapentin Extended-Release)

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Oklahoma Health Care Authority  
Fiscal Year 2016 Print Report

## Current Prior Authorization Criteria

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### Horizant® (Gabapentin Enacarbil Extended-Release) Approval Criteria:

1. For the FDA-approved indication of restless leg syndrome:
  - a. Member must be 18 years of age or older; and
  - b. Documented treatment attempts at recommended dosing with at least two of the following that did not yield adequate relief:
    - i. Carbidopa/levodopa; or
    - ii. Pramipexole; or
    - iii. Ropinirole; and
  - c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin.
2. For the FDA-approved indication of postherpetic neuralgia:
  - a. Member must be 18 years of age or older; and
  - b. Documented treatment attempts at recommended dosing with at least one agent from two of the following drug classes that did not yield adequate relief:
    - i. Tricyclic antidepressants; or
    - ii. Anticonvulsants; or
    - iii. Topical or oral analgesics; and
  - c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin.

### Gralise® (Gabapentin Extended-Release) Approval Criteria:

1. An FDA-approved indication of postherpetic neuralgia; and
2. Documented treatment attempts at recommended dosing with at least one agent from two of the following drug classes that did not yield adequate relief:
  - a. Tricyclic antidepressants; or
  - b. Anticonvulsants; or
  - c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin.

## Utilization of Horizant® and Gralise®: Fiscal Year 2016

### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	4	10	\$4,696.02	\$469.60	\$13.04	990	360
2016	5	21	\$10,841.61	\$516.27	\$15.71	1,020	690
% Change	25.00%	110.00%	130.90%	9.90%	20.50%	3.00%	91.70%
Change	1	11	\$6,145.59	\$46.67	\$2.67	30	330

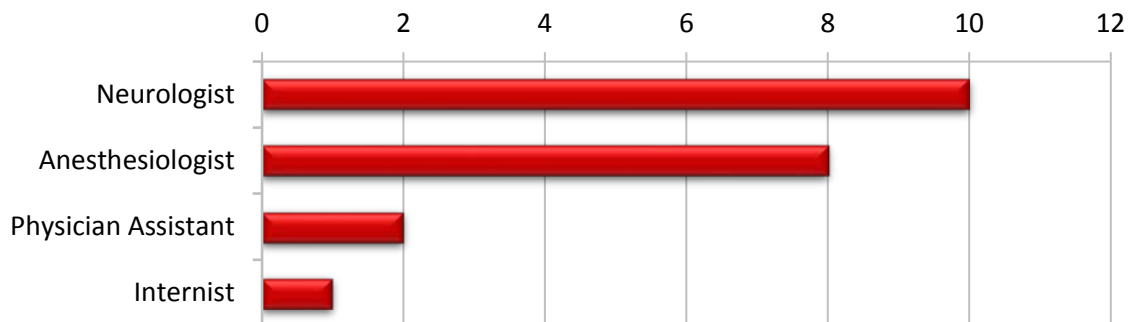
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Horizant® or Gralise®

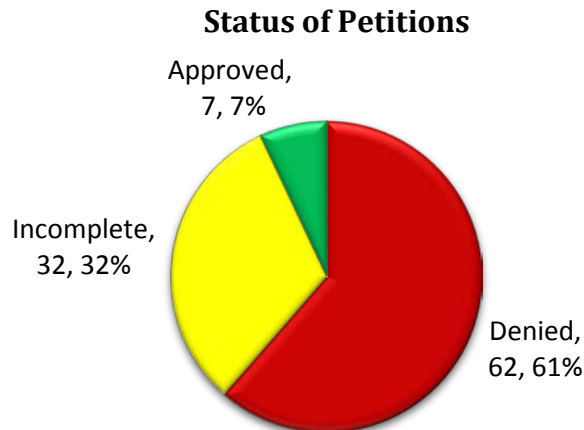
- Due to the small number of members utilizing Horizant® or Gralise® during fiscal year 2016, detailed demographic information could not be provided.

### Top Prescriber Specialties of Horizant® or Gralise® by Number of Claims



### Prior Authorization of Horizant® and Gralise®

There were 101 prior authorization requests submitted for Horizant® and Gralise® during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>19</sup>

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### Anticipated Patent Expiration(s):

- Gralise® (gabapentin extended-release tablets): February 2024
- Horizant® (gabapentin enacarbil extended-release tablets): June 2029

### Recommendations

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The College of Pharmacy does not recommend any changes to the Horizant® or Gralise® prior authorization criteria at this time.

### Utilization Details of Horizant® and Gralise®: Fiscal Year 2016

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PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
HORIZANT TAB 600MG	21	5	\$10,841.61	\$15.71	\$516.27
<b>TOTAL</b>	<b>21</b>	<b>5*</b>	<b>\$10,841.61</b>	<b>\$15.71</b>	<b>\$516.27</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

There was no utilization of Gralise® for fiscal year 2016.

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<sup>19</sup> 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 10/2016. Last accessed 12/15/2016.

# Fiscal Year 2016 Annual Review of Inhaled Short-Acting Beta<sub>2</sub> Agonists

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Tier-2 Inhaled Short-Acting Beta<sub>2</sub> Agonists Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications.

Inhaled Short-Acting Beta <sub>2</sub> Agonists	
Tier-1	Tier-2
albuterol HFA (ProAir <sup>®</sup> HFA)	albuterol HFA (Ventolin <sup>®</sup> HFA)
albuterol HFA (Proventil <sup>®</sup> HFA)	levalbuterol HFA (Xopenex <sup>®</sup> HFA)
	albuterol sulfate inhalation powder (ProAir <sup>®</sup> RespiClick)*

\*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 unavailable.

#### Xopenex<sup>®</sup> (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 corticosteroid (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<sub>2</sub> Agonists: Fiscal Year 2016

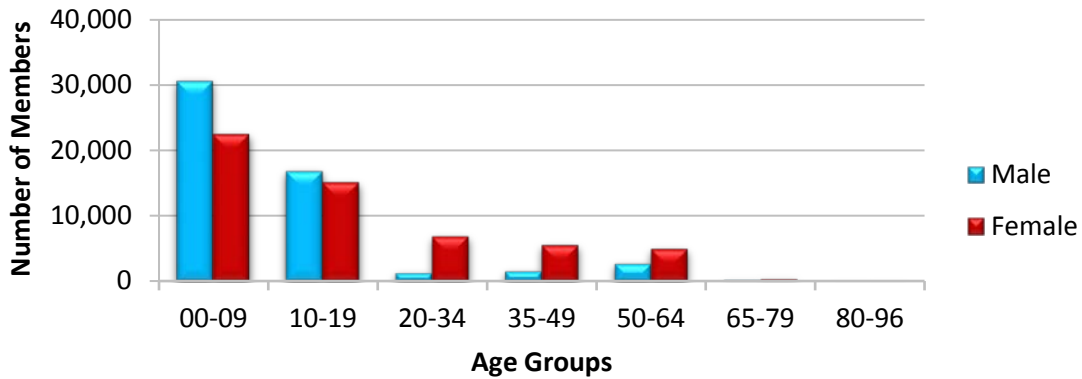
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	108,803	252,238	\$13,783,169.49	\$54.64	\$2.52	13,610,135	5,478,247
2016	108,571	254,596	\$14,537,733.25	\$57.10	\$2.65	13,369,401	5,478,350
% Change	-0.20%	0.90%	5.50%	4.50%	5.20%	-1.80%	0.00%
Change	-232	2,358	\$754,563.76	\$2.46	\$0.13	-240,734	103

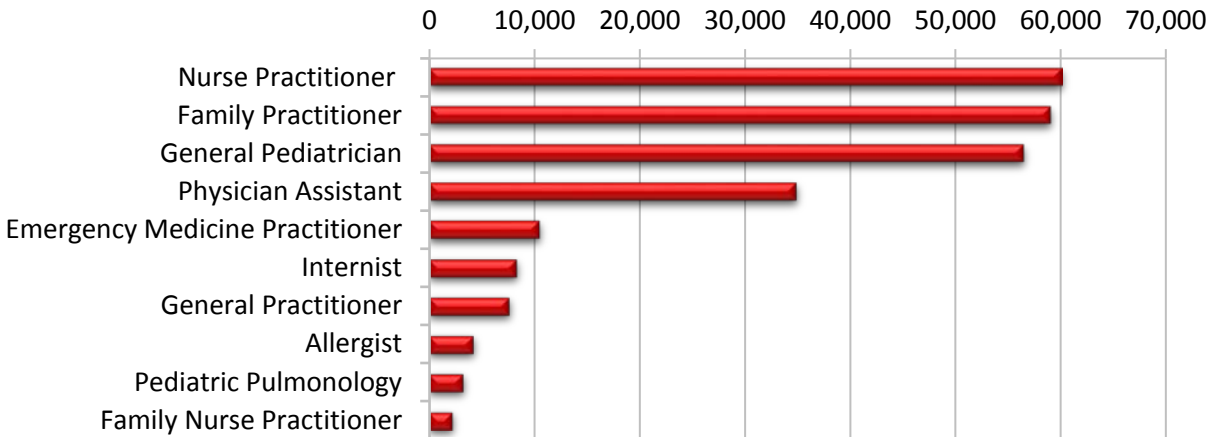
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Inhaled Short-Acting Beta<sub>2</sub> Agonists

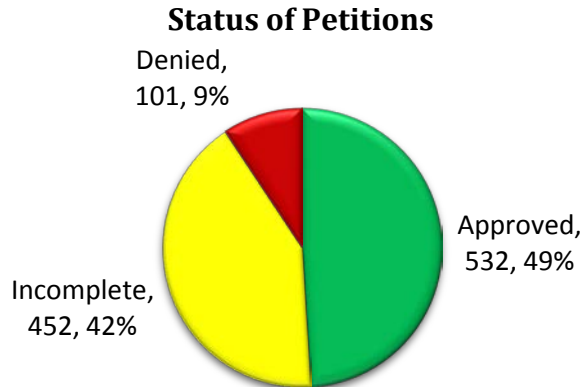


### Top Prescriber Specialties of Inhaled Short-Acting Beta<sub>2</sub> Agonists by Number of Claims



### Prior Authorization of Inhaled Short-Acting Beta<sub>2</sub> Agonists

There were 1,085 prior authorization requests submitted for the inhaled short-acting beta<sub>2</sub> agonists during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>20,21,22</sup>

### Anticipated Patent Expiration(s):

- Proventil<sup>®</sup> HFA (albuterol HFA): December 2016
- Xopenex<sup>®</sup> HFA (levalbuterol HFA): October 2024
- Ventolin<sup>®</sup> HFA (albuterol HFA): August 2026
- ProAir<sup>®</sup> HFA (albuterol HFA): May 2031
- ProAir<sup>®</sup> Respiclick (albuterol inhalation powder): January 2032

### News:

- **October 2016:** Teva Pharmaceuticals announced the launch of levalbuterol tartrate inhalation aerosol, the generic version of Sunovion's Xopenex<sup>®</sup> HFA.
- **December 2016:** Due to a settlement reached with Teva Pharmaceuticals, Perrigo Pharmaceutical Co. and Catalent Pharma Solutions LLC have a limited quantity license to launch a generic version of Proair<sup>®</sup> HFA. This license is for an initial period starting December 19, 2016 and lasting until June 2018. After this time, the limits will no longer apply.

## Recommendations

The College of Pharmacy does not recommend any changes to the inhaled short-acting beta<sub>2</sub> agonist prior authorization criteria at this time.

## Utilization Details of Short-Acting Beta<sub>2</sub> Agonists: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
PROAIR HFA AER	150,667	72,063	\$10,114,170.27	\$2.80	\$67.13
PROVENTIL AER HFA	29,216	14,569	\$2,568,874.62	\$3.50	\$87.93
<b>SUBTOTAL</b>	<b>179,883</b>	<b>86,632</b>	<b>\$12,683,044.89</b>	<b>\$2.91</b>	<b>\$70.51</b>
<b>TIER-2 PRODUCTS</b>					
XOPENEX HFA AER	618	221	\$50,463.06	\$3.17	\$81.66
VENTOLIN HFA AER	275	36	\$18,766.61	\$2.68	\$68.24
PROAIR RESPI AER	9	8	\$606.25	\$2.67	\$67.36
<b>SUBTOTAL</b>	<b>902</b>	<b>265</b>	<b>\$69,835.92</b>	<b>\$3.02</b>	<b>\$77.42</b>
<b>NEBULIZER SOLUTION PRODUCTS</b>					
ALBUTEROL NEB 0.083%	45,530	27,704	\$522,706.60	\$0.71	\$11.48
ALBUTEROL NEB 1.25MG/3	13,675	10,092	\$505,938.42	\$2.97	\$37.00
ALBUTEROL NEB 0.63MG/3	8,956	6,597	\$337,340.91	\$2.97	\$37.67
LEVALBUTEROL NEB 0.63MG	3,160	1,847	\$213,580.09	\$5.15	\$67.59

<sup>20</sup> U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Last revised 10/2016. Last accessed 12/14/2016.

<sup>21</sup> Business Wire: Teva Reaches Settlement in ProAir<sup>®</sup> HFA Patent Case. Available online at: <http://www.businesswire.com/news/home/20140620005338/en/Teva-Reaches-Settlement-ProAir%C2%AE-HFA-Patent-Case>. Issued 06/20/2014. Last accessed 12/15/2016.

<sup>22</sup> MPR News: Generic News: Teva Launches Generic Xopenex HFA. Available online at: <http://www.empr.com/generics-news/teva-launches-generic-xopenex-hfa/article/566901/>. Issued 10/19/2016. Last accessed 12/15/2016.



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
LEVALBUTEROL NEB 1.25MG	1,271	683	\$122,252.69	\$5.79	\$96.19
LEVALBUTEROL NEB 0.31MG	700	501	\$61,307.35	\$6.25	\$87.58
ALBUTEROL NEB 0.5%	496	308	\$10,681.41	\$1.20	\$21.54
LEVALBUTEROL NEB 1.25/0.5	13	9	\$4,980.77	\$21.85	\$383.14
XOPENEX NEB 1.25/3ML	10	1	\$6,064.20	\$24.26	\$606.42
<b>SUBTOTAL</b>	<b>73,811</b>	<b>47,742</b>	<b>\$1,784,852.44</b>	<b>\$1.62</b>	<b>\$24.18</b>
<b>TOTAL</b>	<b>254,596</b>	<b>108,571*</b>	<b>\$14,537,733.25</b>	<b>\$2.65</b>	<b>\$57.10</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Insomnia Medications

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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

\*Unique dosage formulations require a special reason for use in place of Tier-1 formulations. SL= sublingual

+Individual criteria specific to tasimelteon applies.

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

- Tier-1 products are available without a prior authorization for all members 18 years of age and older.
- Members 18 years or younger will be required to submit a prior authorization for consideration.
- All products have a quantity limit of 30 units per 30 days.
- Unique dosage formulations require a special reason for use in place of Tier-1 formulations.

#### Insomnia Medications Tier-2 Approval Criteria:

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

#### Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A minimum of a 30-day trial with at least two Tier-2 products; and
3. Clinical documentation of attempts to correct any primary cause for insomnia; and
4. No concurrent anxiolytic benzodiazepine therapy greater than three times daily dosing.
5. Approvals will be granted for the duration of six 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.
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.
6. A quantity limit of 30 capsules for 30 days will apply.

## Utilization of Insomnia Medications: Fiscal Year 2016

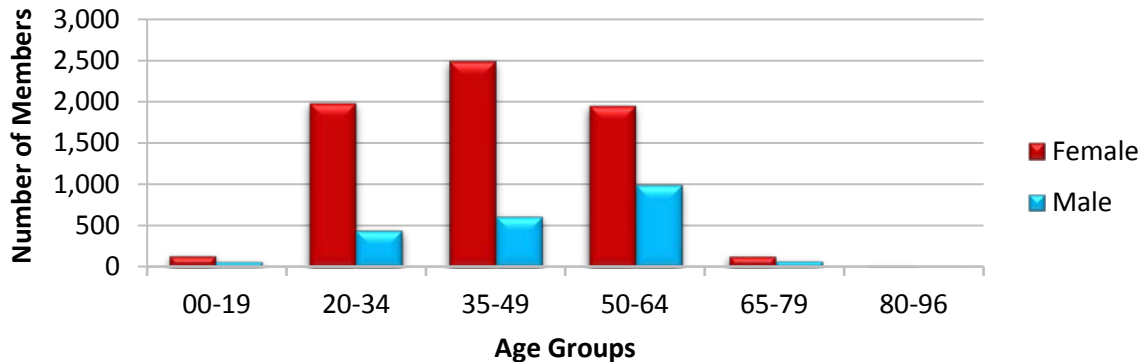
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	10,050	44,830	\$359,218.58	\$8.01	\$0.28	1,298,622	1,296,060
2016	8,859	40,821	\$367,663.88	\$9.01	\$0.31	1,192,296	1,192,183
% Change	-11.90%	-8.90%	2.40%	12.50%	10.70%	-8.20%	-8.00%
Change	-1,191	-4,009	\$8,445.30	\$1.00	\$0.03	-106,326	-103,877

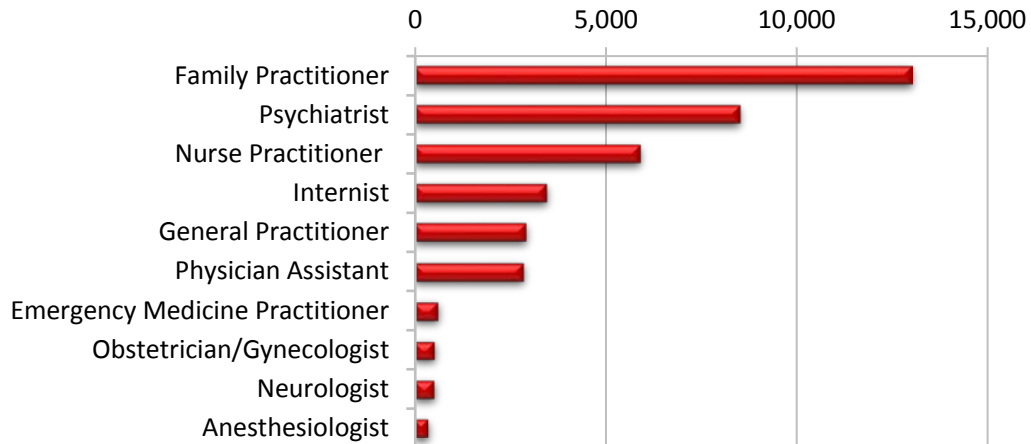
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Insomnia Medications



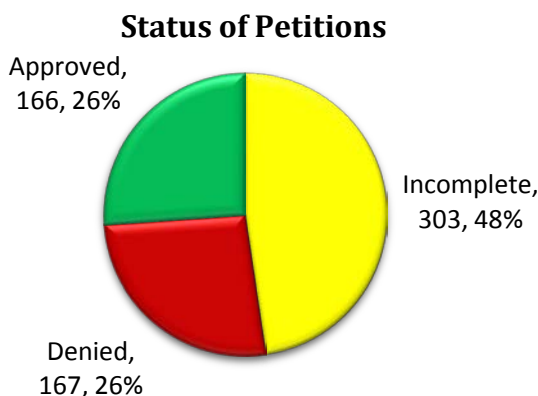
### Top Prescriber Specialties of Insomnia Medications by Number of Claims



## Prior Authorization of Insomnia Medications

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There were 636 prior authorization requests submitted for the insomnia medications during fiscal year 2016. Computer edits are in place to detect Tier-1 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.



## Market News and Updates<sup>23,24,25,26,27</sup>

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### Anticipated Patent Expiration(s):

- Rozerem® (ramelteon tablets): July 2019
- Intermezzo® (zolpidem sublingual tablets): August 2029
- Belsomra (suvorexant tablets): November 2029
- Silenor® (doxepin tablets): September 2030
- Hetlioz® (tasimelteon capsules): January 2033

### Guideline Update(s):

- In May 2016 the American College of Physicians (ACP) published new evidence-based clinical practice guidelines in the journal *Annals of Internal Medicine*. The guidelines recommend cognitive behavioral therapy for insomnia (CBT-I) as first-line treatment for adults with chronic insomnia. CBT-I consists of a combination of treatments that include cognitive therapy around sleep, behavioral interventions such as sleep restriction and stimulus control, and education such as sleep hygiene (habits for a good night's sleep). The ACP also recommends that doctors use a shared-decision making approach with patients to decide whether drug therapy should be added to treatment, if CBT-I alone is

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<sup>23</sup> 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 12/2016. Last accessed 01/23/2017.

<sup>24</sup> American College of Physicians: ACP Newsroom: ACP Recommends Cognitive Behavioral Therapy as Initial Treatment for Chronic Insomnia. Available online at: <https://www.acponline.org/acp-newsroom/acp-recommends-cognitive-behavioral-therapy-as-initial-treatment-for-chronic-insomnia>. Issued 05/03/2016. Last accessed 02/28/2017.

<sup>25</sup> Staton T. What public outcry? New year brings dozens of double-digit drug price hikes. Available online at: <http://www.fiercepharma.com/pharma/what-public-outcry-new-year-brings-dozens-of-double-digit-drug-price-hikes>. Issued 01/12/2016. Last accessed 02/28/2017.

<sup>26</sup> Lupin Pharmaceuticals Inc. Lupin Launches Generic Intermezzo® Sublingual Tablets in the US. Available online at: <http://www.lupin.com/lupin-launches-generic-intermezzo-sublingual-tablets-in-the-us.php>. Issued 04/05/2016. Last accessed 02/28/2017.

<sup>27</sup> Frisher M, Gibbons N, Bashford J, et al. Melatonin, hypnotics and their association with fracture: a matched cohort study. *Age and Ageing* 2016; 45(60): 801-806.

unsuccessful. This approach should include discussing the benefits, harms, and costs of medications. Further it is noted that medications should ideally be used for no longer than four to five weeks. Before continuing drug therapy beyond this duration, doctors should consider treatable secondary causes of insomnia such as depression, pain, enlarged prostate, substance abuse disorders, and other sleep disorders like sleep apnea and restless legs syndrome.

**News:**

- **January 2016:** It is reported that Vanda Pharmaceuticals increased the price of Hetlioz® (tasimelteon capsules), its sleep-wake disorder treatment, by 10%. This puts the price 76% higher than it was at launch in 2014. This increase results in an annual cost at around \$150,000 per year.
- **April 2016:** Lupin Pharmaceuticals Inc. launched zolpidem sublingual tablets, a generic equivalent of Purdue Pharma’s Intermezzo® Sublingual Tablets. Lupin received final approval from the U.S. Food & Drug Administration (FDA) in June 2015, as well as final clearance from the federal trade commission with 180 days of exclusivity.
- **November 2016:** Falls and fractures are a major health issue for older adults. It has been reported that more than 30% of people over 65 years of age fall each year and in half of the cases falls are recurrent. Drugs that increase the propensity to fall are therefore a cause for concern. Medicines used to treat insomnia include hypnotic benzodiazepines, non-benzodiazepine sedatives (Z-drugs), and melatonin agonists. Older people have an increased risk of hip fracture associated with anxiolytic or hypnotic drug use including short-acting benzodiazepine anxiolytics and Z-drugs. A retrospective cohort study published in the journal *Age and Ageing* found that both melatonin and the "Z-drugs" (zolpidem and zopiclone) are independently associated with increased fracture risk. This study only showed an increased risk for the large diagnostic category of fracture, and the authors address that further work could explore if the study drugs are associated with particular types of fracture that occur as a result of falling (e.g., hip fractures), which in turn may be caused by specific risk factors such as drowsiness. The authors also indicate that this study did not examine if there was a dose response relationship between the study drugs and fracture risk. In the case of melatonin, the risk was only observed for those prescribed the drug three or more times.

**Recommendations**

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

**Utilization Details of Insomnia Medications: Fiscal Year 2016**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>ESTAZOLAM PRODUCTS</b>					
ESTAZOLAM TAB 2MG	54	11	\$1,056.97	\$0.65	\$19.57
ESTAZOLAM TAB 1MG	2	2	\$24.27	\$0.40	\$12.14
<b>SUBTOTAL</b>	<b>56</b>	<b>13</b>	<b>\$1,081.24</b>	<b>\$0.64</b>	<b>\$19.31</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>ESZOPICLONE PRODUCTS</b>					
ESZOPICLONE TAB 3MG	1,207	321	\$23,510.06	\$0.65	\$19.48
ESZOPICLONE TAB 2MG	483	200	\$8,716.50	\$0.62	\$18.05
ESZOPICLONE TAB 1MG	177	101	\$3,235.87	\$0.62	\$18.28
LUNESTA TAB 3MG	2	1	\$51.98	\$0.87	\$25.99
<b>SUBTOTAL</b>	<b>1,869</b>	<b>623</b>	<b>\$35,514.41</b>	<b>\$0.64</b>	<b>\$19.00</b>
<b>FLURAZEPAM PRODUCTS</b>					
FLURAZEPAM CAP 30MG	158	35	\$2,270.82	\$0.48	\$14.37
FLURAZEPAM CAP 15MG	12	6	\$150.86	\$0.42	\$12.57
<b>SUBTOTAL</b>	<b>170</b>	<b>41</b>	<b>\$2,421.68</b>	<b>\$0.48</b>	<b>\$14.25</b>
<b>TEMAZEPAM PRODUCTS</b>					
TEMAZEPAM CAP 30MG	5,790	1,316	\$30,053.22	\$0.17	\$5.19
TEMAZEPAM CAP 15MG	3,107	1,064	\$14,919.89	\$0.16	\$4.80
<b>SUBTOTAL</b>	<b>8,897</b>	<b>2,380</b>	<b>\$44,973.11</b>	<b>\$0.17</b>	<b>\$5.05</b>
<b>TRIAZOLAM PRODUCTS</b>					
TRIAZOLAM TAB 0.25MG	988	450	\$23,076.43	\$1.17	\$23.36
TRIAZOLAM TAB 0.125MG	40	18	\$1,183.76	\$1.09	\$29.59
<b>SUBTOTAL</b>	<b>1,028</b>	<b>468</b>	<b>\$24,260.19</b>	<b>\$1.17</b>	<b>\$23.60</b>
<b>ZALEPLON PRODUCTS</b>					
ZALEPLON CAP 10MG	553	185	\$7,546.30	\$0.46	\$13.65
ZALEPLON CAP 5MG	109	53	\$1,285.49	\$0.45	\$11.79
<b>SUBTOTAL</b>	<b>662</b>	<b>238</b>	<b>\$8,831.79</b>	<b>\$0.46</b>	<b>\$13.34</b>
<b>ZOLPIDEM PRODUCTS</b>					
ZOLPIDEM TAB 10MG	21,738	4,769	\$63,719.63	\$0.10	\$2.93
ZOLPIDEM TAB 5MG	4,884	1,768	\$16,230.81	\$0.12	\$3.32
AMBIEN TAB 10MG	3	3	\$20.66	\$0.23	\$6.89
<b>SUBTOTAL</b>	<b>26,625</b>	<b>6,540</b>	<b>\$79,971.10</b>	<b>\$0.10</b>	<b>\$3.00</b>
<b>TIER-1 SUBTOTAL</b>	<b>39,307</b>	<b>10,303</b>	<b>\$197,053.52</b>	<b>\$0.17</b>	<b>\$5.01</b>
<b>TIER-2 PRODUCTS</b>					
<b>RAMELTEON PRODUCTS</b>					
ROZEREM TAB 8MG	189	47	\$60,640.39	\$10.75	\$320.85
<b>SUBTOTAL</b>	<b>189</b>	<b>47</b>	<b>\$60,640.39</b>	<b>\$10.75</b>	<b>\$320.85</b>
<b>ZOLPIDEM PRODUCTS</b>					
ZOLPIDEM ER TAB 12.5MG	1,113	191	\$56,805.89	\$1.71	\$51.04
ZOLPIDEM ER TAB 6.25MG	144	32	\$8,975.88	\$2.16	\$62.33
AMBIEN CR TAB 12.5MG	12	1	\$5,534.01	\$15.37	\$461.17
<b>SUBTOTAL</b>	<b>1,269</b>	<b>224</b>	<b>\$71,315.78</b>	<b>\$1.89</b>	<b>\$56.20</b>
<b>TIER-2 SUBTOTAL</b>	<b>1,458</b>	<b>271</b>	<b>\$131,956.17</b>	<b>\$3.05</b>	<b>\$90.50</b>
<b>TIER-3 PRODUCTS</b>					
<b>SUVOREXANT PRODUCTS</b>					
BELSOMRA TAB 10MG	20	8	\$4,565.86	\$7.61	\$228.29
BELSOMRA TAB 20MG	11	4	\$2,473.89	\$8.53	\$224.90
BELSOMRA TAB 15MG	7	1	\$2,057.27	\$9.80	\$293.90
BELSOMRA TAB 5MG	1	1	\$299.66	\$9.99	\$299.66
<b>SUBTOTAL</b>	<b>39</b>	<b>14</b>	<b>\$9,396.68</b>	<b>\$8.32</b>	<b>\$240.94</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-3 SUBTOTAL</b>	<b>39</b>	<b>14</b>	<b>\$9,396.68</b>	<b>\$8.32</b>	<b>\$240.94</b>
<b>SPECIAL PA PRODUCTS</b>					
<b>TASIMELTEON PRODUCTS</b>					
HETLIOZ CAP 20MG	2	1	\$26,082.14	\$434.70	\$13,041.07
<b>SUBTOTAL</b>	<b>2</b>	<b>1</b>	<b>\$26,082.14</b>	<b>\$434.70</b>	<b>\$13,041.07</b>
<b>TEMAZEPAM PRODUCTS</b>					
TEMAZEPAM CAP 7.5MG	6	2	\$591.83	\$3.31	\$98.64
<b>SUBTOTAL</b>	<b>6</b>	<b>2</b>	<b>\$591.83</b>	<b>\$3.31</b>	<b>\$98.64</b>
<b>ZOLPIDEM PRODUCTS</b>					
INTERMEZZO SUB 1.75MG	9	1	\$2,583.54	\$9.57	\$287.06
<b>SUBTOTAL</b>	<b>9</b>	<b>1</b>	<b>\$2,583.54</b>	<b>\$9.57</b>	<b>\$287.06</b>
<b>SPECIAL PA SUBTOTAL</b>	<b>17</b>	<b>4</b>	<b>\$29,257.51</b>	<b>\$57.48</b>	<b>\$1,721.03</b>
<b>TOTAL</b>	<b>40,821</b>	<b>8,859*</b>	<b>\$367,663.88</b>	<b>\$0.31</b>	<b>\$9.01</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Leukotriene Modifiers

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Singulair® (Montelukast) Granules Approval Criteria:

1. A patient-specific, clinically significant reason for use of the granule formulation in place of tablets or chewable tablets; and
2. Age-appropriate trials of asthma and/or allergic rhinitis medications.

#### Zyflo®, Zyflo CR® (Zileuton) Approval Criteria:

5. An FDA approved indication of mild or moderate persistent asthma; and
6. Member must be 12 years of age or older; and
7. A trial of inhaled corticosteroid and corticosteroid/long-acting beta<sub>2</sub> agonist (LABA) therapy within the previous six months, and reason for trial failure; and
8. A recent trial with at least one other available leukotriene modifier that did not yield an adequate response.

### Utilization of Leukotriene Modifiers: Fiscal Year 2016

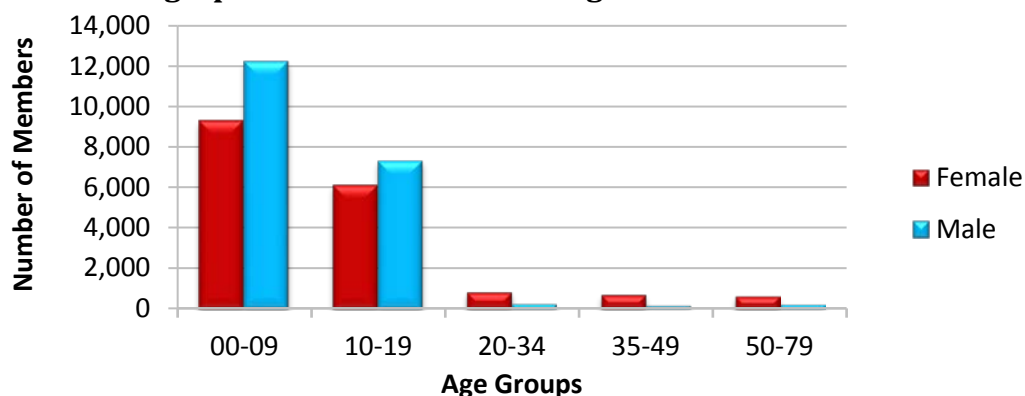
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	31,439	109,565	\$1,760,388.44	\$16.07	\$0.54	3,287,056	3,285,461
2016	37,895	129,467	\$1,920,133.42	\$14.83	\$0.49	3,880,449	3,884,173
% Change	20.5%	18.2%	9.1%	-7.7%	-9.3%	18.1%	18.2%
Change	6,456	19,902	\$159,744.98	\$1.24	\$0.05	593,393	598,712

\*Total number of unduplicated members.

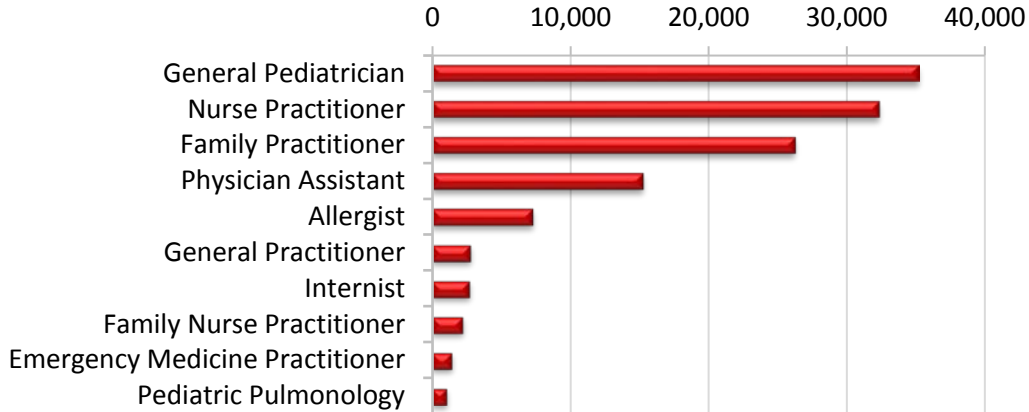
Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Leukotriene Modifiers



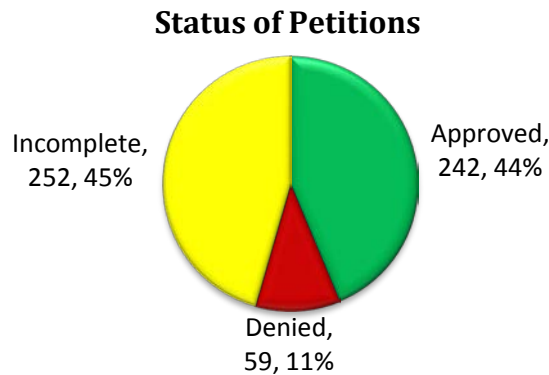


## Top Prescriber Specialties of Leukotriene Modifiers by Number of Claims



## Prior Authorization of Leukotriene Modifiers

There were 553 prior authorization requests submitted for the leukotriene modifiers during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Recommendations

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

## Utilization Details of Leukotriene Modifiers: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>MONTELUKAST PRODUCTS</b>					
MONTELUKAST CHW 5MG	53,865	15,798	\$694,674.17	\$0.43	\$12.90
MONTELUKAST CHW 4MG	37,134	11,923	\$469,457.82	\$0.42	\$12.64
MONTELUKAST TAB 10MG	34,604	10,446	\$313,662.57	\$0.30	\$9.06
MONTELUKAST GRA 4MG	3,625	1,791	\$421,886.55	\$3.87	\$116.38
SINGULAIR CHW 4MG	4	1	\$873.25	\$7.28	\$218.31
<b>SUBTOTAL</b>	<b>129,232</b>	<b>37,862</b>	<b>\$1,900,554.36</b>	<b>\$0.49</b>	<b>\$14.71</b>
<b>ZAFIRLUKAST PRODUCTS</b>					
ZAFIRLUKAST TAB 20MG	215	30	\$18,304.03	\$2.85	\$85.14
ZAFIRLUKAST TAB 10MG	20	6	\$1,275.03	\$2.68	\$63.75
<b>SUBTOTAL</b>	<b>235</b>	<b>35</b>	<b>\$19,579.06</b>	<b>\$2.84</b>	<b>\$83.32</b>
<b>TOTAL</b>	<b>129,467</b>	<b>37,895*</b>	<b>\$1,920,133.42</b>	<b>\$0.49</b>	<b>\$14.83</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Metozolv® ODT (Metoclopramide Orally Disintegrating Tablets)

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Oklahoma Health Care Authority  
Fiscal Year 2016 Print Report

## Current Prior Authorization Criteria

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### Metozolv® ODT [Metoclopramide Orally Disintegrating Tablets (ODT)] Approval Criteria:

1. Use of Metozolv® ODT requires a patient-specific, clinically significant reason why the member is unable to use the metoclopramide oral tablet formulation.

## Utilization of Metozolv® ODT (Metoclopramide ODT): Fiscal Year 2016

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There was no utilization of Metozolv® ODT (metoclopramide ODT) during fiscal year 2016.

## Prior Authorization of Metozolv® ODT (Metoclopramide ODT)

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There were no prior authorization requests submitted for Metozolv® ODT (metoclopramide ODT) during fiscal year 2016.

## Cost<sup>28</sup>

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The U.S. Food and Drug Administration (FDA) approved the generic formulation of Metozolv® ODT (metoclopramide ODT) in August 2014. The cost, however, for generic metoclopramide ODT remains high with a wholesale acquisition cost (WAC) of \$7.48 per tablet. By comparison, the national drug acquisition cost (NADAC) for the generic oral tablet formulation of metoclopramide is \$0.04 per tablet.

## Recommendations

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The College of Pharmacy does not recommend any changes to the Metozolv® ODT (metoclopramide ODT) prior authorization criteria at this time.

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<sup>28</sup> U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Last revised 02/2017. Last accessed 02/28/2017.

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# Fiscal Year 2016 Annual Review of Mozobil® (Plerixafor), Nplate® (Romiplostim), and Arcalyst® (Rilonacept)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with a 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 non-Hodgkins's lymphoma (NHL) or multiple myeloma (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 granulocyte-colony stimulating factor (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 four consecutive days.
  - b. Dosing for renal impairment: Creatinine clearance  $\leq$  50 mL/min: 0.16mg/kg, maximum of 27mg/day.
7. Approvals will be for the duration of two months.

#### Nplate® (Romiplostim) Approval Criteria:

1. An FDA approved indication of chronic immune (idiopathic) thrombocytopenia purpura (ITP); and
2. Previous insufficient response with at least two of the following treatments:
  - a. Corticosteroids; or
  - b. Immunoglobulin; or
  - c. Splenectomy; and
3. Member must have a recent platelet count of  $< 50 \times 10^9/L$ ; and
4. The following dosing restrictions will apply:
  - a. Initial dosing of 1mcg/kg once weekly as a subcutaneous injection with recent patient weight in kilograms provided; and
5. The following criteria will apply for continuation:
  - a. Weekly CBCs with platelet count and peripheral blood smears until stable platelet count ( $\geq 50 \times 10^9/L$  for at least four weeks without dose adjustment) has been achieved; then should be obtained monthly thereafter; and
  - b. Dosing adjustments:
    - i. Platelets  $< 50 \times 10^9/L$ , increase dose by 1mcg/kg
    - ii. Platelets  $> 200 \times 10^9/L$  for two consecutive weeks, reduce dose by 1mcg/kg
    - iii. Platelets  $> 400 \times 10^9/L$ , do not dose. Continue to assess platelet count weekly. When platelets  $< 200 \times 10^9/L$ , resume at a dose reduced by 1mcg/kg

6. The following criteria will apply in regards to discontinuation:
  - a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after four weeks of therapy at the maximum weekly dose of 10mcg/kg
7. Approvals will be for the duration of four weeks initially and then quarterly thereafter.

**Arcalyst® (Riloncept) Approval Criteria:**

1. An 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 years of age and older; and
2. Member should not be using a tumor necrosis factor blocking agent (e.g. adalimumab, etanercept, and infliximab) or anakinra; and
3. Arcalyst® must 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.
5. The following dosing schedule will apply for adults 18 years of age and older:
  - a. Initial treatment: loading dose of 320mg delivered as two 2mL subcutaneous injections of 160mg each given on the same day at two different injection sites.
  - b. Continued treatment is one 160mg injection given once weekly.
6. The following dosing schedule will apply for pediatric patients 12 to 17 years of age:
  - a. Initial treatment: loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as one or two subcutaneous injections with a maximum single-injection volume of 2mL.
  - b. Continued treatment is 2.2mg/kg, up to a maximum of 160mg, given once weekly.
7. Approvals will be for the duration of one year.

**Utilization of Mozobil® (Plerixafor), Nplate® (Romiplostim), and Arcalyst® (Riloncept): Fiscal Year 2016**

- There were no pharmacy or medical claims for Arcalyst® (riloncept) and no pharmacy claims for Mozobil® (plerixafor) for during fiscal year 2016.

**Mozobil® (Plerixafor) Comparison of Fiscal Years: Medical Claims**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2016	2	8	\$53,240.52	\$6,655.07	174

Please note, there was no utilization of Mozobil® for fiscal year 2015 in medical claims; therefore, no comparison is available.

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

**Nplate® (Romiplostim) Fiscal Year comparison: Medical Claims**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	1	4	\$5,646.25	\$1,411.56	500
2016	3	64	\$136,820.95	\$2,137.83	2,361
% Change	200.00%	1,500.00%	2,323.22%	51.45%	372.20%
Change	2	60	\$131,174.70	\$726.27	\$1,861.00

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

## Nplate® (Romiplostim) Fiscal Year comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	5	98	\$214,506.73	\$2,188.84	\$403.21	267	532
2016	4	44	\$101,941.63	\$2,316.86	\$392.08	68	260
% Change	-20.00%	-55.10%	-52.50%	5.80%	-2.80%	-74.50%	-51.10%
Change	-1	-54	-\$112,565.10	\$128.02	-\$11.13	-199	-272

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Nplate® (Romiplostim)

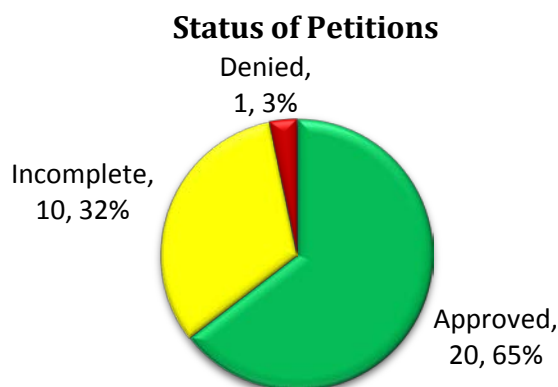
- Due to the limited number of members utilizing Nplate® (romiplostim), detailed member demographics information cannot be provided.

### Top Prescriber Specialties of Nplate® (Romiplostim) by Number of Claims

- Due to the limited number of prescribers for Nplate® (romiplostim), detailed prescriber specialty information cannot be provided.

### Prior Authorization of Mozobil® (Plerixafor), Nplate® (Romiplostim), and Arcalyst® (Rilonacept)

There were 31 prior authorization requests submitted for Mozobil® (plerixafor) and Nplate® (romiplostim) during fiscal year 2016. There were no prior authorization requests submitted for Arcalyst® (rilonacept). The following chart shows the status of the submitted petitions.



### Market News and Updates<sup>29</sup>

#### Anticipated Patent Expiration(s):

- Mozobil® (plerixafor): July 2023

### Recommendations

The College of Pharmacy does not recommend any changes to the Mozobil® (plerixafor), Nplate® (romiplostim), and Arcalyst® (rilonacept) prior authorization criteria at this time.

<sup>29</sup> 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 12/2016. Last accessed 02/2017.

**Utilization Details of Mozobil® (Plerixafor), Nplate® (Romiplostim), and Arcalyst® (Rilonacept): Fiscal Year 2016**

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**Nplate: Pharmacy Claims**

<b>PRODUCT UTILIZED</b>	<b>TOTAL CLAIMS</b>	<b>TOTAL MEMBERS</b>	<b>TOTAL COST</b>	<b>COST/ DAY</b>	<b>COST/ CLAIM</b>	<b>% COST</b>
NPLATE INJ 250MCG	43	4	\$98,982.43	\$382.17	\$2,301.92	97.10%
NPLATE INJ 500MCG	1	1	\$2,959.20	\$2,959.20	\$2,959.20	2.90%
<b>TOTAL</b>	<b>44</b>	<b>4*</b>	<b>\$101,941.63</b>	<b>\$392.08</b>	<b>\$2,316.86</b>	<b>100.00%</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Muscle Relaxant Medications

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Muscle Relaxant Medications		
Tier-1	Tier-2	Special Prior Authorization*
baclofen (Lioresal®)	metaxalone (Skelaxin®)	carisoprodol (Soma®) 250mg
chlorzoxazone (Parafon Forte®)		carisoprodol (Soma®) 350mg
cyclobenzaprine (Flexeril®)		carisoprodol/ASA
methocarbamol (Robaxin®)		carisoprodol/ASA/codeine
orphenadrine (Norflex®)		chlorzoxazone (Lorzone®)
tizanidine tablets (Zanaflex®)		cyclobenzaprine (Fexmid®)
		cyclobenzaprine ER (Amrix®)
		tizanidine capsules (Zanaflex®)

ASA = aspirin; ER = extended-release

\*Medications in the Special Prior Authorization Tier have individual criteria.

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 Medication Tier-2 Approval Criteria:

1. Failure with at least two Tier-1 medications within the past 90 days defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
2. Approvals will be for the duration of three 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 one year.
3. For repeat authorizations, there must be documentation of a failed withdrawal attempt within past three months defined as increase in pain and debilitating symptoms when medication was discontinued.

#### Soma® (Carisoprodol) 350mg and Carisoprodol Combination Products Approval Criteria:

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

**Soma® (Carisoprodol) 250mg Approval Criteria:**

1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and a specific reason why member cannot be drowsy for even a short time-period. Member must not have other sedating medications in current claims history; and
2. A diagnosis of acute musculoskeletal pain, in which case, the approval will be for the duration of 14 days per 365 day period. Conditions requiring chronic use will not be approved.

**Lorzone™ (Chlorzoxazone) Approval Criteria:**

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

**Zanaflex® (Tizanidine) Capsules Approval Criteria:**

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

**Amrix® (Cyclobenzaprine Extended-Release) and Fexmid® (Cyclobenzaprine 7.5mg Tablets):**

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

**Utilization of Muscle Relaxant Medications: Fiscal Year 2016****Comparison of Fiscal Years**

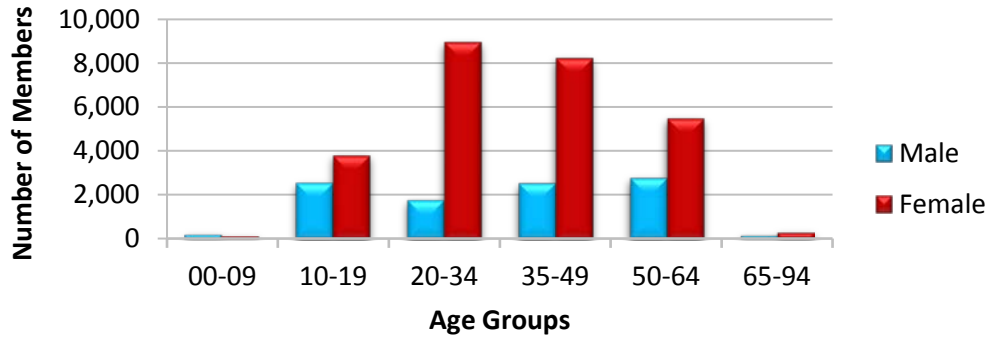
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	37,850	110,068	\$1,795,342.65	\$16.31	\$0.66	7,758,449	2,715,906
2016	36,758	106,725	\$1,398,433.18	\$13.10	\$0.53	7,437,387	2,640,189
% Change	-2.90%	-3.00%	-22.10%	-19.70%	-19.70%	-4.10%	-2.80%
Change	-1,092	-3,343	-\$396,909.47	-\$3.21	-\$0.13	-321,062	-75,717

\*Total number of unduplicated members.

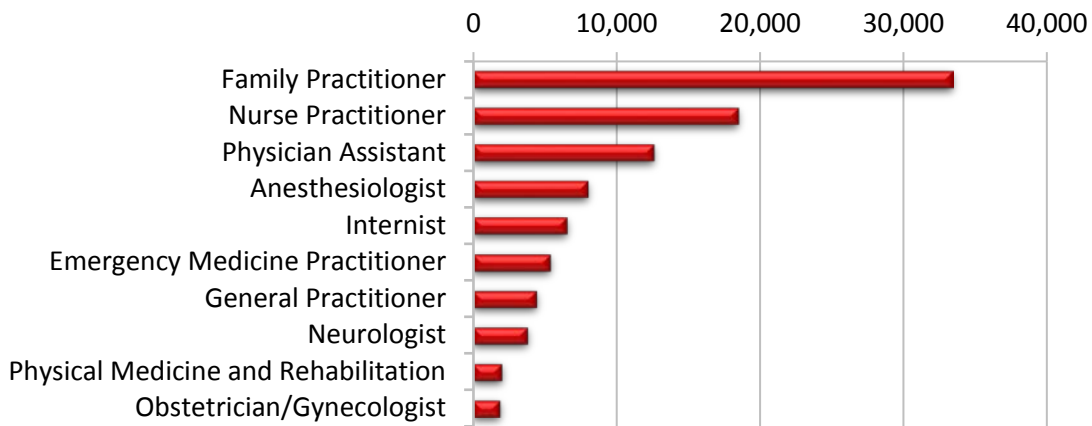
Costs do not reflect rebated prices or net costs.



### Demographics of Members Utilizing Muscle Relaxant Medications



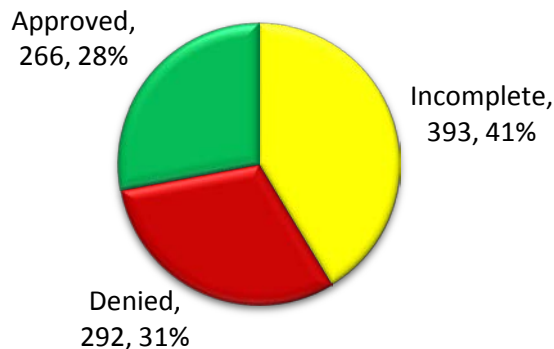
### Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



### Prior Authorization of Muscle Relaxant Medications

There were 951 prior authorization requests submitted for muscle relaxant medications during fiscal year 2016. Computer edits are in place to detect Tier-1 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



### Anticipated Patent Expiration(s):

- Amrix® (cyclobenzaprine extended-release capsules): February 2025

### FDA Generic Approval(s):

- **November 2015:** FDA approved a generic formulation of Soma® 250mg (carisoprodol).
- **November 2016:** FDA approved a generic formulation of Skelaxin® 800mg (metaxolone).

### Guideline Update:

- **January 2017:** The American College of Physicians (ACP) released updated guidelines for the noninvasive treatment of non-radicular subacute, acute, and chronic low back pain in primary care. The new guidelines emphasize conservative treatment. It is noted that acute or subacute low back pain (LBP) should improve over time regardless of treatment. Per the new guidelines, first-line therapy should include nondrug therapy, such as superficial heat, massage, acupuncture, or spinal manipulation. If nondrug therapy fails, nonsteroidal anti-inflammatory drugs (NSAIDs) or skeletal muscle relaxants should be considered. For chronic LBP, nondrug therapy, such as exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive-behavioral therapy, or spinal manipulation is recommended as first line treatment. If chronic LBP does not respond to nondrug therapy, it is recommended to consider NSAIDs as first-line therapy. For second-line therapy, consideration of tramadol or duloxetine is recommended. The guidelines strongly discourage the use of opioids. NSAIDs and skeletal muscle relaxants, with acetaminophen are no longer recommended.

### News

- **September 2015:** Osmotica Pharmaceutical Corporation announced that the U.S. Food and Drug Administration (FDA) accepted their New Drug Application (NDA) for Ontinua™ ER (arbaclofen extended-release tablets). The NDA covers the use of Ontinua™ ER for alleviation of spasticity associated with multiple sclerosis. Ontinua™ ER will be dosed twice daily and utilizes Osmotica's proprietary Osmodex® technology. This technology combines laser-drilled tablet technology with a variety of single-active and multiple-

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<sup>30</sup> 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 01/2017. Last accessed 02/23/2017.

<sup>31</sup> U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Last revised 02/2017. Last accessed 02/28/2017.

<sup>32</sup> Hackethal V. New ACP Guidelines for Nonradicular Low Back Pain. *Medscape*. Available online at: <http://www.medscape.com/viewarticle/875737>. Issued 02/13/2017. Last accessed 02/28/2017.

<sup>33</sup> Business Wire: Osmotica Announces FDA Acceptance of Filing for Ontinua ER for Alleviation of Spasticity Resulting from Multiple Sclerosis and Strong Advancement in the Clinical Program for Osmolex ER. Available online at: <http://www.businesswire.com/news/home/20150928006528/en/Osmotica-Announces-FDA-Acceptance-Filing-Ontinua-ER#.VgmYRZiFN9M>. Issued 09/28/2015. Last accessed 02/23/2017.

<sup>34</sup> Osmotica Pharmaceuticals Corp. Drug Delivery Technology. Available online at: <http://www.osmotica.com/drug-delivery-technology.aspx>. Last accessed 02/23/2017.

<sup>35</sup> Friedman BW, Dym AA, Davitt M, et al. Naproxen with Cyclobenzaprine, Oxycodone/Acetaminophen, or Placebo for Treating Acute Low Back Pain: A Randomized Clinical Trial. *JAMA* 2015; 314(15): 1572-1580.

active drug delivery devices. According to Osmotica, Osmodex® systems simplify dosing and may aid in patient compliance.

- October 2015:** LBP is responsible for 2.4% of visits to U.S. emergency departments (EDs) resulting in 2.7 million visits annually. Pain outcomes for these patients are generally poor. Given the pain and functional impairment that persists beyond an ED visit for musculoskeletal LBP and the heterogeneity in clinical care, a randomized clinical trial (RCT) was conducted to determine whether a 10-day course of muscle relaxants or opioids combined with NSAIDs is more effective than NSAID monotherapy for the treatment of non-traumatic, non-radicular LBP. The *Journal of the American Medical Association (JAMA)* published the results of this trial. The results showed that among patients with acute, non-traumatic, non-radicular LBP presenting to the ED, adding cyclobenzaprine or oxycodone/acetaminophen to naproxen alone did not improve functional outcomes or pain at 1-week follow-up. Based on these findings, use of these additional medications is not supported in this setting.

## Recommendations

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

## Utilization Details of Muscle Relaxant Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>BACLOFEN PRODUCTS</b>					
BACLOFEN TAB 10MG	13,769	4,440	\$225,088.57	\$0.58	\$16.35
BACLOFEN TAB 20MG	5,910	1,359	\$175,656.90	\$1.01	\$29.72
BACLOFEN POW	346	55	\$3,410.77	\$0.35	\$9.86
LIORESAL INT INJ 40MG/20	10	1	\$18,199.75	\$60.67	\$1,819.9
LIORESAL INT INJ 10MG/20	2	1	\$680.43	\$11.34	\$340.22
GABLOFEN INJ 40000/20	2	2	\$1,888.66	\$31.48	\$944.33
<b>SUBTOTAL</b>	<b>20,039</b>	<b>5,858</b>	<b>\$424,925.08</b>	<b>\$0.75</b>	<b>\$21.20</b>
<b>CHLORZOXAZONE PRODUCTS</b>					
CHLORZOXAZON TAB 500MG	1,676	728	\$30,164.93	\$0.71	\$18.00
<b>SUBTOTAL</b>	<b>1,676</b>	<b>728</b>	<b>\$30,164.93</b>	<b>\$0.71</b>	<b>\$18.00</b>
<b>CYCLOBENZAPRINE PRODUCTS</b>					
CYCLOBENZAPR TAB 10MG	37,168	17,403	\$181,655.04	\$0.21	\$4.89
CYCLOBENZAPR TAB 5MG	6,896	4,502	\$39,099.28	\$0.30	\$5.67
<b>SUBTOTAL</b>	<b>44,064</b>	<b>21,905</b>	<b>\$220,754.32</b>	<b>\$0.22</b>	<b>\$5.01</b>
<b>METHOCARBAMOL PRODUCTS</b>					
METHOCARBAM TAB 750MG	4,415	1,970	\$43,460.73	\$0.40	\$9.84
METHOCARBAM TAB 500MG	4,354	2,335	\$33,047.64	\$0.36	\$7.59
ROBAXIN INJ 100MG/ML	1	1	\$282.84	\$282.844	\$282.84
<b>SUBTOTAL</b>	<b>8,770</b>	<b>4,306</b>	<b>\$76,791.21</b>	<b>\$0.38</b>	<b>\$8.76</b>
<b>ORPHENADRINE PRODUCTS</b>					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
ORPHENADRINE 100MG ER	2,718	1,739	\$48,030.04	\$0.95	\$17.67
<b>SUBTOTAL</b>	<b>2,718</b>	<b>1,739</b>	<b>\$48,030.04</b>	<b>\$0.95</b>	<b>\$17.67</b>
<b>TIZANIDINE PRODUCTS</b>					
TIZANIDINE TAB 4MG	22,148	6,973	\$418,071.24	\$0.69	\$18.88
TIZANIDINE TAB 2MG	2,624	1,075	\$41,984.54	\$0.62	\$16.00
<b>SUBTOTAL</b>	<b>24,772</b>	<b>8,048</b>	<b>\$460,055.78</b>	<b>\$0.69</b>	<b>\$18.57</b>
<b>TIER-1 SUBTOTAL</b>	<b>102,039</b>	<b>42,584</b>	<b>\$1,260,721.363</b>	<b>\$0.50</b>	<b>\$12.36</b>
<b>TIER-2 PRODUCTS</b>					
<b>METAXALONE PRODUCTS</b>					
METAXALONE 800MG	378	138	\$92,812.36	\$9.49	\$245.54
METAXALONE 400MG	14	3	\$7,708.53	\$19.52	\$550.61
<b>SUBTOTAL</b>	<b>392</b>	<b>141</b>	<b>\$100,520.89</b>	<b>\$9.88</b>	<b>\$256.43</b>
<b>TIER-2 SUBTOTAL</b>	<b>392</b>	<b>141</b>	<b>\$100,520.89</b>	<b>\$9.88</b>	<b>\$256.43</b>
<b>SPECIAL PA PRODUCTS</b>					
<b>CARISOPRODOL PRODUCTS</b>					
CARISOPRODOL 350MG	4,272	1,972	\$30,862.38	\$0.28	\$7.22
CARISOPRODOL ASA/COD	5	2	\$665.15	\$6.72	\$133.03
CARISOPRODOL 250MG	2	2	\$418.23	\$6.97	\$209.12
CARISOPR/ASA 200-325MG	1	1	\$33.95	\$6.79	\$33.95
<b>SUBTOTAL</b>	<b>4,280</b>	<b>1,977</b>	<b>\$31,979.71</b>	<b>\$0.29</b>	<b>\$7.47</b>
<b>CHLORZOAZONE PRODUCTS</b>					
LORZONE TAB 750MG	6	1	\$3,974.77	\$19.87	\$662.46
LORZONE TAB 375MG	1	1	\$631.25	\$12.63	\$631.25
<b>SUBTOTAL</b>	<b>7</b>	<b>2</b>	<b>\$4,606.02</b>	<b>\$18.42</b>	<b>\$658.00</b>
<b>CYCLOBENZAPRINE PRODUCTS</b>					
AMRIX CAP 15MG	1	1	\$102.85	\$3.43	\$102.85
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$102.85</b>	<b>\$3.43</b>	<b>\$102.85</b>
<b>TIZANIDINE PRODUCTS</b>					
TIZANIDINE CAP 6MG	6	1	\$502.35	\$2.79	\$83.73
<b>SUBTOTAL</b>	<b>6</b>	<b>1</b>	<b>\$502.35</b>	<b>\$2.79</b>	<b>\$83.73</b>
<b>SPECIAL PA SUBTOTAL</b>	<b>4,294</b>	<b>1,981</b>	<b>\$37,190.93</b>	<b>\$0.33</b>	<b>\$8.66</b>
<b>TOTAL</b>	<b>106,725</b>	<b>36,758*</b>	<b>\$1,398,433.18</b>	<b>\$0.53</b>	<b>\$13.10</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Myalept™ (Metreleptin)

## Oklahoma Health Care Authority Fiscal Year 2016 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. 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 three months to evaluate compliance and ensure the prescriber is assessing continued efficacy; and
7. A quantity limit of one vial per day will apply.

### Utilization of Myalept™ (Metreleptin): Fiscal Year 2016

#### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1	8	\$618,807.66	\$77,350.96	\$2,918.90	212	212
2016	1	13	\$1,174,044.90	\$90,311.15	\$3,010.37	330	390
% Change	0.00%	62.50%	89.70%	16.80%	3.10%	55.70%	84.00%
Change	0	5	\$555,237.24	\$12,960.19	\$91.47	118	178

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

There were no medical claims for Myalept™ (metreleptin) during fiscal year 2016.

#### Demographics of Members Utilizing Myalept™ (Metreleptin)

- Due to the small number of members utilizing Myalept™ (metreleptin) during fiscal year 2016, detailed demographic information could not be provided.

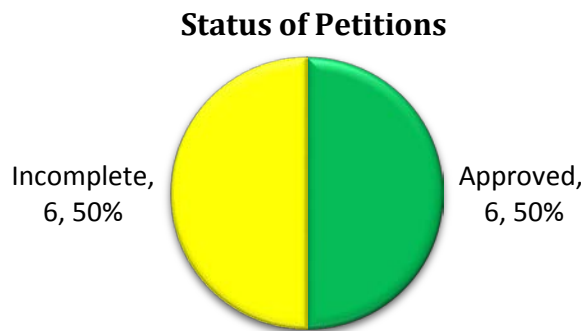
## Top Prescriber Specialties of Myalept™ (Metreleptin) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for d Myalept™ (metreleptin) during fiscal year 2016 was pediatric endocrinologist.

## Prior Authorization of Myalept™ (Metreleptin)

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There were 12 prior authorization requests submitted for Myalept™ (metreleptin) during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Recommendations

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

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# Fiscal Year 2016 Annual Review of Mytesi™ (Crofelemer) [Formerly Known As Fulyzaq®]

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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#### 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 greater than or equal to four 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
    - ii. Ova, Parasite, Cryptosporidium and/or Giardia
    - 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 approval will be for four weeks of therapy. An additional six month approval may be granted if physician documents member is responding well to treatment.

### Utilization of Mytesi™ (Crofelemer): Fiscal Year 2016

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There was no utilization of Mytesi™ (crofelemer) during fiscal year 2016.

### Prior Authorization of Mytesi™ (Crofelemer)

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There was one prior authorization request submitted for Mytesi™ (crofelemer) during fiscal year 2016. The request was incompleated for additional criteria information. No further information was provided by the prescriber.

## Market News and Updates<sup>36,37,38</sup>

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**Anticipated Patent Expiration(s):** Mytesi™ (crofelemer): October 2031

### News:

- **March 2016:** Salix Pharmaceuticals, Inc. and Napo Pharmaceuticals, Inc. announced the settlement of Napo's litigation with Salix. As part of the Settlement, the Collaboration Agreement between Salix and Napo dated December 9, 2008 has been terminated. Accordingly, Napo has regained the rights for Mytesi™ (crofelemer). Napo will assume all commercial and regulatory responsibility for Mytesi™ and is developing plans for the further development of crofelemer for other potential indications. As part of the Settlement, Napo will receive all finished product inventory and inventory used in the production of crofelemer. Crofelemer is in various stages of clinical development for the following indications: diarrhea predominant irritable bowel syndrome, acute infectious diarrhea (including cholera), and pediatric diarrhea. The U.S. Food and Drug Administration (FDA) has granted fast track status to crofelemer development for the IBS indication.
- **October 2016:** Napo Pharmaceuticals, Inc., announced the launch and general availability of Mytesi™ (crofelemer). Previously marketed as Fulyzaq®, the product launch under the Mytesi™ brand importantly included the unveiling of the Mytesi™ Copay Savings Program and NapoCares™ Patient Assistance Program to provide people with HIV/AIDS with affordable access to the drug. Currently, crofelemer is the only antidiarrheal FDA-approved for the relief of diarrhea in HIV patients.

### Recommendations

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

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<sup>36</sup> 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 10/2016. Last accessed 11/28/2016.

<sup>37</sup> Business Wire: Napo and Salix Settle Litigation. Available online at: <http://www.businesswire.com/news/home/20160307006153/en/Napo-Salix-Settle-Litigation>. Issued 03/07/2016. Last accessed 12/15/2016.

<sup>38</sup> PRNewswire: Napo Pharmaceuticals Launches Mytesi (crofelemer) as the Only FDA-Approved Treatment for Relief of Noninfectious Diarrhea in HIV+ Patients. Available online at: <http://www.prnewswire.com/news-releases/napo-pharmaceuticals-launches-mytesi-crofelemer-as-the-only-fda-approved-treatment-for-relief-of-noninfectious-diarrhea-in-hiv-patients-300343714.html>. Issued 10/13/2016. Last accessed 12/15/2016.



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# Fiscal Year 2016 Annual Review of Nasal Allergy Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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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)
		budesonide (Rhinocort AQ®)
		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		fluticasone (Veramyst®)
		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.

#### Nasal Allergy Medications Tier-2 Approval Criteria:

1. Failure with all Tier-1 medications defined as no beneficial response after at least three weeks use at the maximum recommended dose; or
2. Documented adverse effect or contraindication to all Tier-1 medications.
3. No grandfathering of Tier-2 or Tier-3 products will be allowed for this category.
4. For 2 to 4 year old members, the age-appropriate, lower-tiered generic products must be tried prior to the approval of higher tiered products.
5. Approvals will be for the duration of three 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 one year.

#### Nasal Allergy Medications Tier-3 Approval Criteria:

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

## Utilization of Nasal Allergy Medications: Fiscal Year 2016

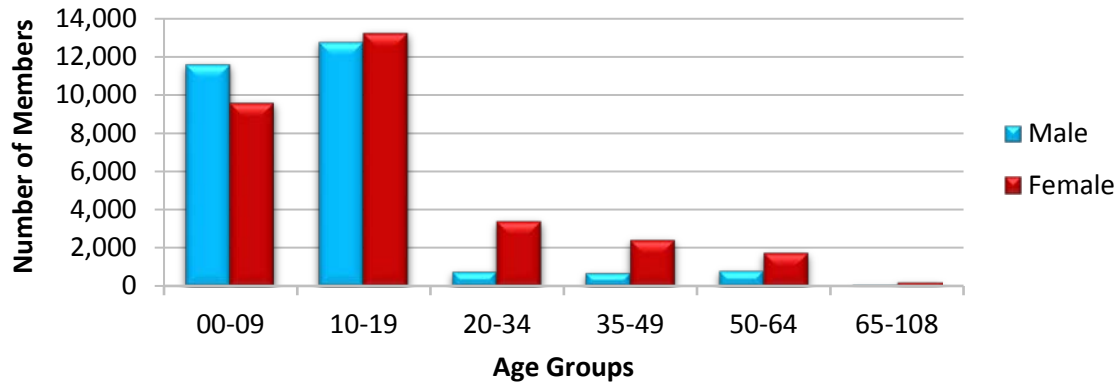
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	55,105	97,819	\$1,506,689.49	\$15.40	\$0.45	1,574,852	3,354,241
2016	57,415	104,958	\$1,307,083.08	\$12.45	\$0.35	1,688,503	3,713,332
% Change	4.20%	7.30%	-13.20%	-19.20%	-22.20%	7.20%	10.70%
Change	2,310	7,139	-\$199,606.41	-\$2.95	-\$0.10	113,651	359,091

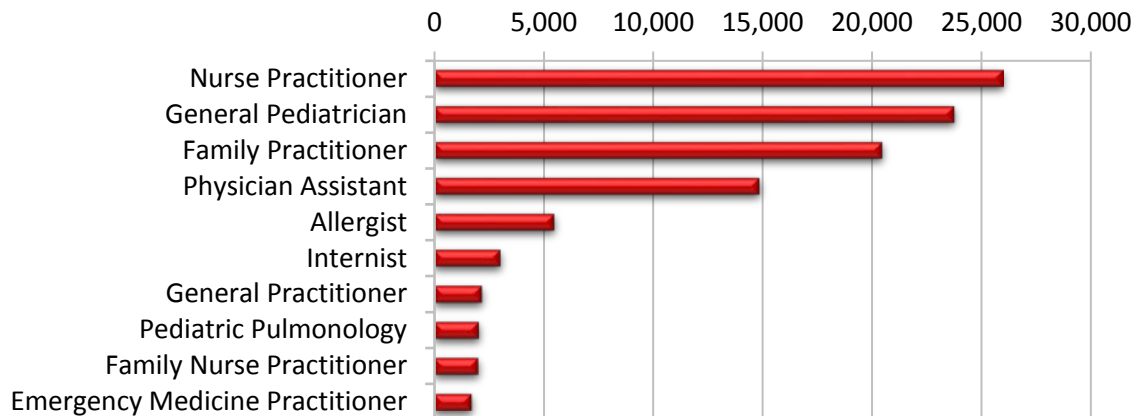
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Nasal Allergy Medications

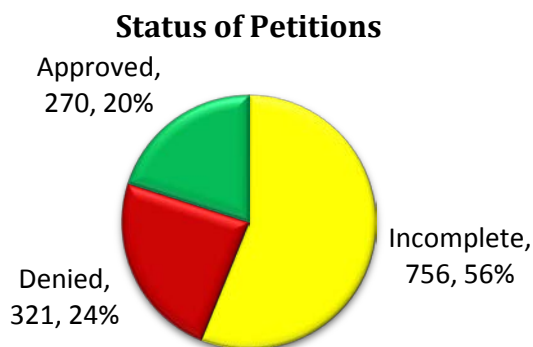


### Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims



### Prior Authorization of Nasal Allergy Medications

There were 1,347 prior authorization requests submitted for nasal allergy medications during fiscal year 2016. Computer edits are in place to detect Tier-1 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.



## Market News and Updates<sup>39,40,41,42,43</sup>

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### Anticipated Patent Expiration(s):

- Dymista® (azelastine/fluticasone): August 2026
- Qnasl® (beclomethasone): January 2027
- Omnaris® (ciclesonide): February 2028
- Zetonna® (ciclesonide): February 2028

### New Generic Approval(s):

- **March 2016:** The U.S. Food and Drug Administration (FDA) approved a generic version of Nasonex® (mometasone) nasal spray.

### FDA Update(s):

- **March 2015:** The FDA approved Rhinocort® Allergy (budesonide) nasal spray for over-the-counter (OTC) treatment of nasal allergy symptoms in patients six years of age and older. The prescription product, Rhinocort Aqua®, is approved for the treatment of nasal symptoms of seasonal or perennial allergic rhinitis in adults and children six years of age and older. The OTC approval of Rhinocort® Allergy is considered a full prescription-to-OTC switch by the FDA, as shown by the indications above. That is, all the original prescription indications were kept for the OTC approval.
- **August 2016:** GlaxoSmithKline (GSK) announced that the FDA approved Flonase® Sensimist™ Allergy Relief (fluticasone furoate, 27.5mcg spray) as an OTC treatment for symptoms associated with seasonal and perennial allergies. Previously available by prescription as Veramyst®, Flonase® Sensimist™ is the latest prescription-to-OTC switch from GSK. Flonase® Sensimist™ provides non-drowsy, 24-hour relief of both nose and eye related allergy symptoms like itchy, watery eyes, nasal congestion, runny nose, itchy nose, and sneezing. The Indication for “itchy, watery eyes” is for ages 12 years and older

<sup>39</sup> 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 01/2017. Last accessed 02/24/2017.

<sup>40</sup> U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Last revised 11/08/2016. Last accessed 02/27/2017.

<sup>41</sup> Warren, NJ. GSK Press Releases: FDA Approves FLONASE® Sensimist™ Allergy Relief Available online at: <http://us.gsk.com/en-us/media/press-releases/2016/fda-approves-flonase-sensimist-allergy-relief/>. Issued 08/02/2016. Last accessed 02/27/2017.

<sup>42</sup> Veramyst® Prescribing Information. GlaxoSmithKline. Available online at: [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Veramyst/pdf/VERAMYST-PI-PIL-COMBINED.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Veramyst/pdf/VERAMYST-PI-PIL-COMBINED.PDF). Last revised 08/2012. Last accessed 02/27/2017.

<sup>43</sup> Henderson D. New Guidelines for Allergic Rhinitis Released. *Medscape*. Available online at: <http://www.medscape.com/viewarticle/839130>. Issued 02/03/2015. Last accessed 02/27/2017.

only. This is similar to prescription Veramyst® which is indicated for treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older. Veramyst® has no age limit assigned to symptoms of itchy, watery eyes. Both Flonase® Sensimist™ and Veramyst® are dosed as two sprays in each nostril daily for adults 12 years and older. However, Flonase® Sensimist™ directs patients to taper dose to one or two sprays daily after one week and to consult a doctor if medication is needed longer than six months. For Veramyst® it is recommended to reduce the dose to one spray in each nostril once daily as it may be effective when the maximum benefit has been achieved. For children age 2 to 11 years of age, Flonase® Sensimist™ is recommended at one spray in each nostril daily for the shortest duration necessary and to consult the doctor after two months of use. Veramyst® may be increased to two sprays in each nostril daily for children not responding to initial dosing, and once symptoms have been controlled, dosage reduction is recommended.

#### Guideline Update(s):

- **February 2015:** New clinical practice guidelines for the treatment of allergic rhinitis (AR) were published in *Otolaryngology-Head and Neck Surgery* in February 2015. The guidelines suggest that clinicians should treat AR with intranasal steroids when patients' symptoms impair their quality of life, and they also suggest that clinicians should recommend second-generation oral antihistamines for patients complaining of sneezing and itching.

#### Recommendations

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

#### Utilization Details of Nasal Allergy Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
FLUTICASONE SPR 50MCG	102,676	56,623	\$1,059,708.98	\$0.29	\$10.32
BECONASE AQ SUS 0.042%	104	54	\$26,032.44	\$7.10	\$250.31
<b>TIER-1 SUBTOTAL</b>	<b>102,780</b>	<b>56,677</b>	<b>\$1,085,741.42</b>	<b>\$0.30</b>	<b>\$10.56</b>
<b>TIER-2 PRODUCTS</b>					
QNASL AER 80MCG	21	12	\$3,760.49	\$4.99	\$179.07
AZELASTINE SPR 0.1%	18	10	\$636.09	\$1.10	\$35.34
<b>TIER-2 SUBTOTAL</b>	<b>39</b>	<b>22</b>	<b>\$4,396.58</b>	<b>\$3.30</b>	<b>\$112.73</b>
<b>TIER-3 PRODUCTS</b>					
TRIAMCINOLON AER	937	737	\$96,135.99	\$3.06	\$102.60
FLUNISOLIDE SPR 0.025%	743	453	\$37,842.64	\$1.55	\$50.93
DYMISTA SPR 137-50	108	35	\$19,161.34	\$5.86	\$177.42
VERAMYST SPR 27.5MCG	102	17	\$19,043.93	\$6.10	\$186.71
NASONEX SPR 50MCG/AC	82	31	\$17,797.83	\$6.24	\$217.05
OLOPATADINE SPR 0.6%	64	19	\$11,220.14	\$4.92	\$175.31
QNASL CHILD SPR 40MCG	32	15	\$5,511.36	\$5.57	\$172.23
AZELASTINE SPR 0.15%	27	9	\$2,610.38	\$2.75	\$96.68

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
MOMETASONE SPR 50MCG	20	15	\$4,171.81	\$6.05	\$208.59
BUDESONIDE SUS 32MCG	16	10	\$1,654.74	\$3.06	\$103.42
PATANASE SPR 0.6%	5	1	\$1,342.75	\$8.95	\$268.55
OMNARIS SPR	2	1	\$429.90	\$7.17	\$214.95
FLUNISOLIDE SPR 29MCG	1	1	\$22.27	\$0.74	\$22.27
<b>TIER-3 SUBTOTAL</b>	<b>2,139</b>	<b>1,344</b>	<b>\$216,945.08</b>	<b>\$3.07</b>	<b>\$101.42</b>
<b>TOTAL</b>	<b>104,958</b>	<b>57,415*</b>	<b>\$1,307,083.08</b>	<b>\$0.35</b>	<b>\$12.45</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

- In November 2016, flunisolide (Nasarel®) moved from Tier-1 to Tier-3 of the nasal allergy medication product based prior authorization (PBPA) category, while beclomethasone (Beconase® AQ) moved from Tier-2 to Tier-1. Additionally, beclomethasone (Qnasl® 80mcg) and azelastine (Astelin®) moved from Tier-3 to Tier-2. The implemented tier changes may have affected utilization subtotals shown above as this table reflects the current tier assignments.

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# Fiscal Year 2016 Annual Review of Northera® (Droxidopa)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### 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, and non-diabetic autonomic neuropathy; and
2. Member must be 18 years of age or older; and
3. Member must have tried and failed two of the following medications at recommended dosing within the last 90 days:
  - a. Midodrine; or
  - b. Fludrocortisone; or
  - c. Pyridostigmine; or
  - d. Have a contraindication to all preferred medications; and
4. Initial approval will be for the duration of two 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 three months. Each approval will require prescriber documentation of member response/effectiveness to Northera®.

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### Utilization of Northera® (Droxidopa): Fiscal Year 2016

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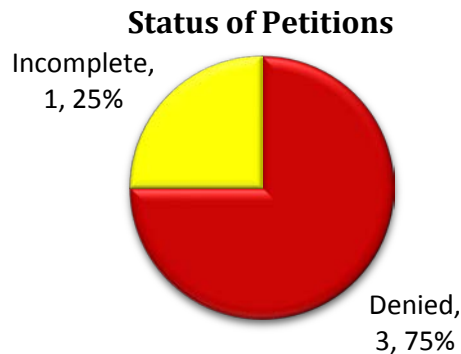
There were no pharmacy claims for Northera® (droxidopa) during fiscal year 2016.

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### Prior Authorization of Northera® (Droxidopa)

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There were 4 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2016.



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### Recommendations

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

# Fiscal Year 2016 Annual Review of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	Tier-2	Special PA
diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®)	diclofenac (Zorvolex®)
diclofenac potassium (Cataflam®)	diclofenac sodium/misoprostol (Arthrotec®)	diclofenac epolamine (Flector® patch)
diclofenac sodium (Voltaren®) 50mg and 75mg tablets	diclofenac sodium (Voltaren®) 25mg tablets	diclofenac potassium (Cambia® powder pack)
etodolac (Lodine®) 400mg and 500mg tablets	etodolac (Lodine®) 200mg and 300mg capsules	diclofenac potassium (Zipsor® capsule)
flurbiprofen (Ansaid®)	etodolac ER (Lodine® XL)	diclofenac sodium (Dyloject™)
ibuprofen (Motrin®)	fenoprofen (Nalfon®)	diclofenac sodium (Pennsaid® top drops)
indomethacin IR (Indocin®)	meclofenamate (Meclomen®)	diclofenac sodium (Voltaren Gel®)
ketoprofen (Orudis®)	naproxen sodium (Anaprox®) 275mg and 550mg tablets	ibuprofen/famotidine (Duexis®)
meloxicam (Mobic®)	oxaprozin (Daypro®)	indomethacin susp and ER capsules (Indocin®)
nabumetone (Relafen®)	piroxicam (Feldene®)	indomethacin (Tivorbex™)
naproxen (Naprosyn®)	tolmetin (Tolectin®)	ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®)
naproxen EC (Naprosyn®)		mefenamic acid (Ponstel®)
		meloxicam (Vivlodex™)
sulindac (Clinoril®)		naproxen sodium (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER= extended-release, IR = immediate-release, EC = enteric coated, top = topical, susp = suspension

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 two Tier-1 NSAID medications (from different product lines) plus a proton pump inhibitor (PPI) within the last 120 days; or
2. For those with a prior gastrointestinal (GI) bleed who must have a NSAID, a Tier-2 product may be approved (celecoxib should be taken with a PPI).

#### NSAIDs Special Prior Authorization (PA) Approval Criteria:

4. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
5. Previous use of at least two Tier-1 NSAID medications (from different product lines); and
6. A patient-specific, clinically-significant reason why a special formulation is needed over a Tier-1 product.

7. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.

## Utilization of NSAIDs: Fiscal Year 2016

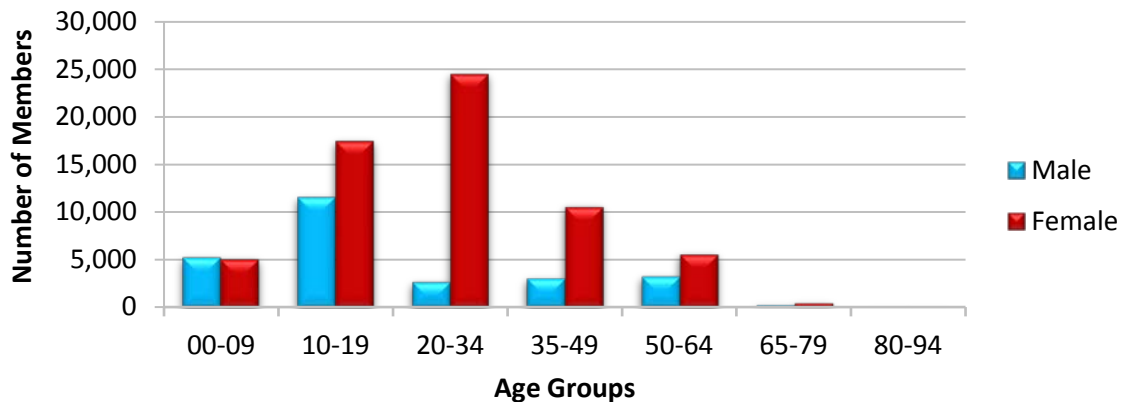
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	94,487	167,745	\$1,667,135.45	\$9.94	\$0.46	9,224,985	3,613,573
2016	89,691	159,355	\$1,594,310.65	\$10.00	\$0.46	8,684,567	3,483,145
% Change	-5.10%	-5.00%	-4.40%	0.60%	0.00%	-5.90%	-3.60%
Change	-4,796	-8,390	-\$72,824.80	\$0.06	\$0.00	-540,418	-130,428

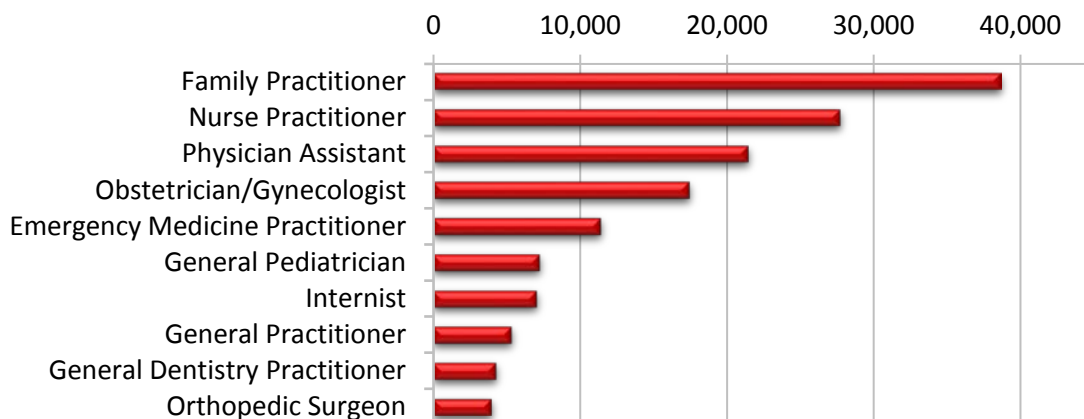
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing NSAIDs



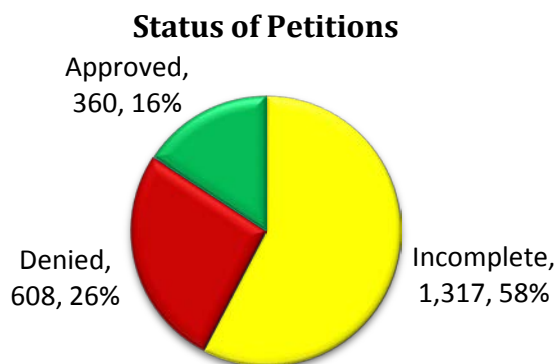
### Top Prescriber Specialties of NSAIDs by Number of Claims



## Prior Authorization of NSAIDs

There were 2,285 prior authorization requests submitted for NSAIDs during fiscal year 2016. The following chart shows the status of the submitted petitions.





## Market News and Updates<sup>44,45</sup>

### Anticipated Patent Expiration(s):

- Flector<sup>®</sup> (diclofenac epolamine) patch: April 2019
- Duexis<sup>®</sup> (ibuprofen/famotidine): July 2026
- Tivorbex<sup>™</sup> (indomethacin): April 2030
- Zorvolex<sup>®</sup> (diclofenac): April 2030
- Pennsaid<sup>®</sup> (diclofenac sodium) topical solution: August 2030
- Vimovo<sup>®</sup> (naproxen/esomeprazole): October 2031

### New Generic Approval(s):

- **February 2016:** The U.S. Food and Drug Administration (FDA) approved Bionpharma's Abbreviated New Drug Application (ANDA) for diclofenac potassium 25mg capsules, generic Zipsor<sup>®</sup>.
- **March 2016:** The FDA approved Amneal's ANDA for diclofenac sodium topical gel 1%, generic Voltaren<sup>®</sup> 1% gel.
- **May 2016:** The FDA approved Par Pharmaceutical's ANDA for diclofenac potassium 50mg powder for oral solution, generic Cambia<sup>®</sup>.

## Recommendations

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

## Utilization Details of NSAIDs: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>DICLOFENAC PRODUCTS</b>					
DICLOFENAC TAB 75MG DR	5,599	2,919	\$59,641.59	\$0.39	\$10.65
DICLOFEN POT TAB 50MG	1,378	909	\$40,603.33	\$1.24	\$29.47
DICLOFENAC TAB 50MG DR	1,321	852	\$19,231.68	\$0.57	\$14.56

<sup>44</sup> 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 01/2017. Last accessed 03/02/2017.

<sup>45</sup> U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Available online at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Last revised 03/2017. Last accessed 03/02/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
DICLOFENAC TAB 100MG ER	324	153	\$5,584.16	\$0.52	\$17.24
<b>SUBTOTAL</b>	<b>8,622</b>	<b>4,833</b>	<b>\$125,060.76</b>	<b>\$0.54</b>	<b>\$14.50</b>
<b>ETODOLAC PRODUCTS</b>					
ETODOLAC TAB 400MG	1,853	1,111	\$73,936.64	\$1.64	\$39.90
ETODOLAC TAB 500MG	695	317	\$34,714.63	\$1.75	\$49.95
<b>SUBTOTAL</b>	<b>2,548</b>	<b>1,428</b>	<b>\$108,651.27</b>	<b>\$1.68</b>	<b>\$42.64</b>
<b>FLURBIPROFEN PRODUCTS</b>					
FLURBIPROFEN TAB 100MG	79	29	\$1,531.39	\$0.77	\$19.38
<b>SUBTOTAL</b>	<b>79</b>	<b>29</b>	<b>\$1,531.39</b>	<b>\$0.77</b>	<b>\$19.38</b>
<b>IBUPROFEN PRODUCTS</b>					
IBUPROFEN TAB 800MG	47,440	32,449	\$347,896.11	\$0.40	\$7.33
IBUPROFEN TAB 600MG	13,425	10,784	\$89,528.40	\$0.47	\$6.67
IBUPROFEN SUS 100/5ML	12,291	10,692	\$117,217.84	\$0.81	\$9.54
IBUPROFEN TAB 400MG	5,907	4,293	\$41,847.62	\$0.45	\$7.08
IBUPROFEN DRO 50/1.25	66	61	\$614.35	\$0.86	\$9.31
ADVIL CHILD SUS 100/5ML	57	57	\$419.93	\$0.62	\$7.37
CHLD IBUPRFN DRO 40MG/ML	8	8	\$79.42	\$0.54	\$9.93
IBU-DROPS DRO 40MG/ML	4	3	\$38.77	\$0.51	\$9.69
INFANT ADVIL DRO 50/1.25	3	3	\$20.63	\$0.33	\$6.88
IBUPROFEN POW	3	3	\$14.11	\$0.15	\$4.70
IBU-DROPS DRO 50/1.25	2	2	\$44.66	\$2.98	\$22.33
<b>SUBTOTAL</b>	<b>79,206</b>	<b>58,355</b>	<b>\$597,721.84</b>	<b>\$0.46</b>	<b>\$7.55</b>
<b>INDOMETHACIN PRODUCTS</b>					
INDOMETHACIN CAP 50MG	96	44	\$882.46	\$0.43	\$9.19
INDOMETHACIN CAP 25MG	29	16	\$288.13	\$0.35	\$9.94
INDOMETHACIN POW	1	1	\$3.98	\$0.13	\$3.98
<b>SUBTOTAL</b>	<b>126</b>	<b>61</b>	<b>\$1,174.57</b>	<b>\$0.40</b>	<b>\$9.32</b>
<b>KETOPROFEN PRODUCTS</b>					
KETOPROFEN CAP 75MG	170	128	\$3,702.03	\$1.24	\$21.78
KETOPROFEN POW	132	98	\$13,353.37	\$3.58	\$101.16
KETOPROFEN CAP 50MG	88	71	\$1,617.28	\$1.28	\$18.38
<b>SUBTOTAL</b>	<b>390</b>	<b>297</b>	<b>\$18,672.68</b>	<b>\$2.34</b>	<b>\$47.88</b>
<b>KETOROLAC PRODUCTS</b>					
KETOROLAC TAB 10MG	2,344	2,090	\$40,969.82	\$2.56	\$17.48
KETOROLAC INJ 60MG/2ML	53	45	\$546.91	\$1.32	\$10.32
KETOROLAC INJ 30MG/ML	52	45	\$558.16	\$2.01	\$10.73
KETOROLAC INJ 15MG/ML	2	2	\$43.37	\$7.23	\$21.69
<b>SUBTOTAL</b>	<b>2,451</b>	<b>2,182</b>	<b>\$42,118.26</b>	<b>\$2.74</b>	<b>\$17.18</b>
<b>MELOXICAM PRODUCTS</b>					
MELOXICAM TAB 15MG	20,849	9,848	\$66,491.45	\$0.09	\$3.19
MELOXICAM TAB 7.5MG	10,280	5,601	\$36,740.58	\$0.12	\$3.57
MELOXICAM SUS 7.5/5ML	329	97	\$30,852.39	\$3.30	\$93.78
MOBIC SUS 7.5/5ML	9	4	\$1,722.85	\$6.36	\$191.43
<b>SUBTOTAL</b>	<b>31,467</b>	<b>15,550</b>	<b>\$135,807.27</b>	<b>\$0.13</b>	<b>\$4.32</b>
<b>NABUMETONE PRODUCTS</b>					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
NABUMETONE TAB 500MG	1,494	796	\$19,001.25	\$0.48	\$12.72
NABUMETONE TAB 750MG	1,222	532	\$18,359.66	\$0.52	\$15.02
<b>SUBTOTAL</b>	<b>2,716</b>	<b>1,328</b>	<b>\$37,360.91</b>	<b>\$0.50</b>	<b>\$13.76</b>
<b>NAPROXEN PRODUCTS</b>					
NAPROXEN TAB 500MG	20,795	13,775	\$120,345.41	\$0.26	\$5.79
NAPROXEN TAB 375MG	2,717	1,884	\$15,683.44	\$0.27	\$5.77
NAPROXEN TAB 250MG	1,631	1,183	\$10,030.57	\$0.32	\$6.15
NAPROXEN DR TAB 500MG	787	461	\$11,508.37	\$0.55	\$14.62
NAPROXEN SUS 125/5ML	372	256	\$11,721.98	\$1.95	\$31.51
NAPROXEN DR TAB 375MG	145	99	\$1,574.84	\$0.49	\$10.86
NAPROSYN TAB 500MG	1	1	\$9.56	\$0.32	\$9.56
<b>SUBTOTAL</b>	<b>26,448</b>	<b>17,659</b>	<b>\$170,874.17</b>	<b>\$0.29</b>	<b>\$6.46</b>
<b>SULINDAC PRODUCTS</b>					
SULINDAC TAB 200MG	152	77	\$1,929.05	\$0.43	\$12.69
SULINDAC TAB 150MG	68	21	\$827.03	\$0.40	\$12.16
<b>SUBTOTAL</b>	<b>220</b>	<b>98</b>	<b>\$2,756.08</b>	<b>\$0.42</b>	<b>\$12.53</b>
<b>TIER-1 SUBTOTAL</b>	<b>154,273</b>	<b>101,820</b>	<b>\$1,241,729.20</b>	<b>\$0.37</b>	<b>\$8.05</b>
<b>TIER-2 PRODUCTS</b>					
<b>CELECOXIB PRODUCTS</b>					
CELECOXIB CAP 200MG	1,170	303	\$74,593.37	\$1.83	\$63.76
CELECOXIB CAP 100MG	229	68	\$13,467.39	\$1.98	\$58.81
CELEBREX CAP 200MG	34	6	\$8,190.34	\$8.03	\$240.89
CELECOXIB CAP 50MG	11	6	\$395.97	\$1.02	\$36.00
CELECOXIB CAP 400MG	8	3	\$1,093.49	\$3.04	\$136.69
CELEBREX CAP 100MG	3	1	\$202.33	\$2.25	\$67.44
<b>SUBTOTAL</b>	<b>1,455</b>	<b>387</b>	<b>\$97,942.89</b>	<b>\$1.98</b>	<b>\$67.31</b>
<b>DICLOFENAC PRODUCTS</b>					
DICLOFENAC TAB 25MG DR	75	45	\$4,910.17	\$2.27	\$65.47
DICLO/MISOPR TAB 75-0.2MG	58	17	\$7,821.90	\$4.35	\$134.86
DICLO/MISOPR TAB 50-0.2MG	7	2	\$995.64	\$4.74	\$142.23
<b>SUBTOTAL</b>	<b>140</b>	<b>64</b>	<b>\$13,727.71</b>	<b>\$3.29</b>	<b>\$98.06</b>
<b>ETODOLAC PRODUCTS</b>					
ETODOLAC CAP 300MG	706	543	\$32,878.30	\$3.38	\$46.57
ETODOLAC CAP 200MG	196	153	\$8,485.20	\$2.56	\$43.29
ETODOLAC ER TAB 400MG	42	25	\$4,707.86	\$4.12	\$112.09
ETODOLAC ER TAB 500MG	20	8	\$3,246.04	\$4.06	\$162.30
ETODOLAC ER TAB 600MG	20	7	\$2,207.46	\$2.70	\$110.37
<b>SUBTOTAL</b>	<b>984</b>	<b>736</b>	<b>\$51,524.86</b>	<b>\$3.26</b>	<b>\$52.36</b>
<b>FENOPROFEN PRODUCTS</b>					
FENOPROFEN CAP 400MG	3	3	\$822.19	\$10.28	\$274.06
<b>SUBTOTAL</b>	<b>3</b>	<b>3</b>	<b>\$822.19</b>	<b>\$10.28</b>	<b>\$274.06</b>
<b>MECLOFENAMATE PRODUCTS</b>					
MECLOFEN SOD CAP 50MG	19	3	\$2,284.76	\$4.18	\$120.25
MECLOFEN SOD CAP 100MG	7	6	\$1,786.32	\$23.20	\$255.19
<b>SUBTOTAL</b>	<b>26</b>	<b>9</b>	<b>\$4,071.08</b>	<b>\$6.52</b>	<b>\$156.58</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>NAPROXEN PRODUCTS</b>					
NAPROXEN SOD TAB 550MG	1,889	1,521	\$106,446.52	\$3.30	\$56.35
NAPROXEN SOD TAB 275MG	214	165	\$6,726.45	\$2.25	\$31.43
<b>SUBTOTAL</b>	<b>2,103</b>	<b>1,686</b>	<b>\$113,172.97</b>	<b>\$3.21</b>	<b>\$53.82</b>
<b>OXAPROZIN PRODUCTS</b>					
OXAPROZIN TAB 600MG	81	32	\$10,485.31	\$4.31	\$129.45
<b>SUBTOTAL</b>	<b>81</b>	<b>32</b>	<b>\$10,485.31</b>	<b>\$4.31</b>	<b>\$129.45</b>
<b>PIROXICAM PRODUCTS</b>					
PIROXICAM CAP 10MG	12	1	\$354.68	\$0.99	\$29.56
PIROXICAM CAP 20MG	2	2	\$194.80	\$1.62	\$97.40
PIROXICAM POW	1	1	\$16.69	\$0.83	\$16.69
<b>SUBTOTAL</b>	<b>15</b>	<b>4</b>	<b>\$566.17</b>	<b>\$1.13</b>	<b>\$37.74</b>
<b>TOLMETIN PRODUCTS</b>					
TOLMETIN SOD CAP 400MG	12	2	\$1,609.77	\$4.97	\$134.15
TOLMETIN SOD TAB 600MG	1	1	\$231.91	\$7.73	\$231.91
<b>SUBTOTAL</b>	<b>13</b>	<b>3</b>	<b>\$1,841.68</b>	<b>\$5.20</b>	<b>\$141.67</b>
<b>TIER-2 SUBTOTAL</b>	<b>4,820</b>	<b>2,924</b>	<b>\$294,154.86</b>	<b>\$2.71</b>	<b>\$61.03</b>
<b>SPECIAL PA PRODUCTS</b>					
<b>DICLOFENAC PRODUCTS</b>					
VOLTAREN GEL 1%	151	84	\$20,825.49	\$6.01	\$137.92
DICLOFENAC GEL 1%	34	29	\$3,818.82	\$5.02	\$112.32
PENNSAID SOL 2%	7	3	\$11,836.95	\$56.37	\$1,690.99
CAMBIA POW 50MG	3	1	\$1,554.22	\$12.34	\$518.07
FLECTOR DIS 1.3%	2	2	\$587.81	\$19.59	\$293.91
DICLOFENAC SOL 1.5%	2	1	\$385.67	\$6.43	\$192.84
<b>SUBTOTAL</b>	<b>199</b>	<b>120</b>	<b>\$39,008.96</b>	<b>\$8.39</b>	<b>\$196.02</b>
<b>INDOMETHACIN PRODUCTS</b>					
INDOCIN SUS 25MG/5ML	38	5	\$12,786.69	\$11.50	\$336.49
INDOMETHACIN CAP 75MG ER	18	5	\$1,509.29	\$1.91	\$83.85
<b>SUBTOTAL</b>	<b>56</b>	<b>10</b>	<b>\$14,295.98</b>	<b>\$7.52</b>	<b>\$255.29</b>
<b>KETOPROFEN PRODUCTS</b>					
KETOPROFEN CAP 200MG ER	2	2	\$90.74	\$2.27	\$45.37
<b>SUBTOTAL</b>	<b>2</b>	<b>2</b>	<b>\$90.74</b>	<b>\$2.27</b>	<b>\$45.37</b>
<b>KETOROLAC PRODUCTS</b>					
SPRIX SPR 15.75MG	4	2	\$3,973.84	\$33.12	\$993.46
<b>SUBTOTAL</b>	<b>4</b>	<b>2</b>	<b>\$3,973.84</b>	<b>\$33.12</b>	<b>\$993.46</b>
<b>NAPROXEN PRODUCTS</b>					
NAPRELAN TAB 500MG CR	1	1	\$1,057.07	\$42.28	\$1,057.07
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$1,057.07</b>	<b>\$42.28</b>	<b>\$1,057.07</b>
<b>SPECIAL PA SUBTOTAL</b>	<b>262</b>	<b>135</b>	<b>\$58,462.59</b>	<b>\$8.23</b>	<b>\$223.00</b>
<b>TOTAL</b>	<b>159,355</b>	<b>89,691*</b>	<b>\$1,594,310.655</b>	<b>\$0.46</b>	<b>\$10.00</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Nuedexta® (Dextromethorphan/Quinidine) Approval Criteria:

1. An FDA approved diagnosis of pseudobulbar affect; and
2. Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply.
4. Approvals will be for the duration of one year.

### Utilization of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2016

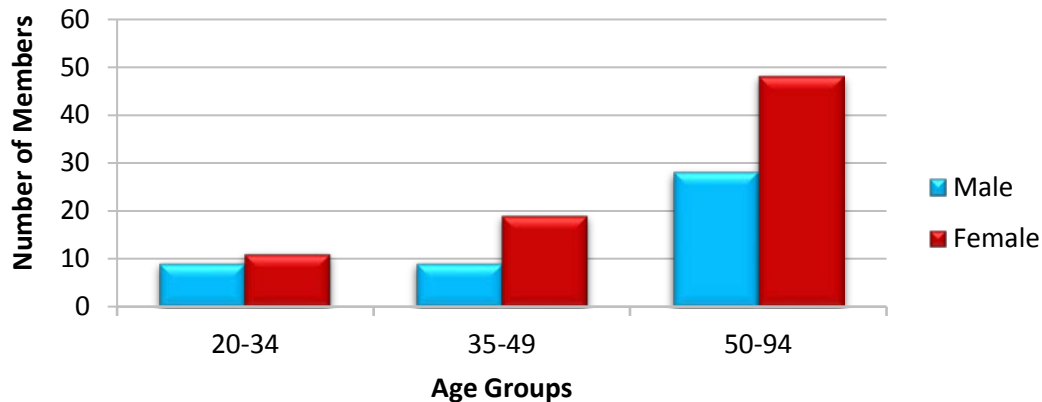
#### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	96	695	\$354,999.36	\$510.79	\$21.34	31,430	16,639
2016	124	955	\$548,729.36	\$574.59	\$23.45	45,657	23,403
% Change	29.20%	37.40%	54.60%	12.50%	9.90%	45.30%	40.70%
Change	28	260	\$193,730.00	\$63.80	\$2.11	14,227	6,764

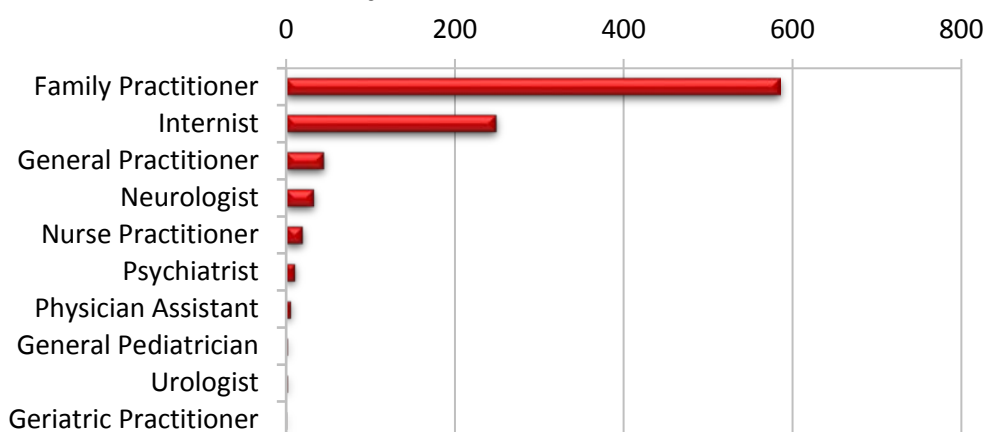
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)

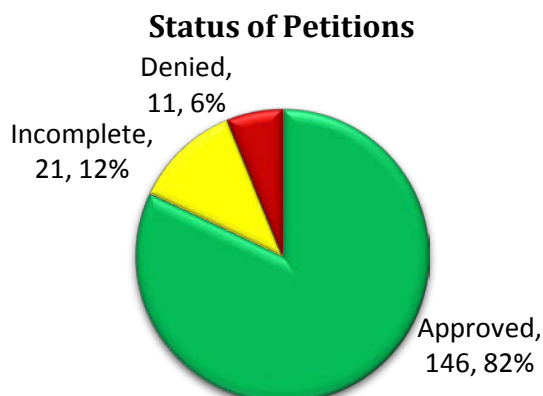


## Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



## Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 178 prior authorization requests submitted for Nuedexta® (dextromethorphan/quinidine) during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>46</sup>

**Anticipated Patent Expiration(s):** Nuedexta® (dextromethorphan/quinidine): August 2026

## Recommendations

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

<sup>46</sup> 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 01/2017. Last accessed 03/02/2017.

# Fiscal Year 2016 Annual Review of Ocular Allergy Medications

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Ocular Allergy Medications		
Tier-1	Tier-2	Tier-3
cromolyn (Crolom <sup>®</sup> )	azelastine (Optivar <sup>®</sup> )	alcaftadine (Lastacaft <sup>™</sup> )
ketotifen (Alaway <sup>®</sup> , Zaditor <sup>®</sup> OTC)	olopatadine (Pazeo <sup>®</sup> )	bepotastine (Bepreve <sup>™</sup> )
	olopatadine (Patanol <sup>®</sup> )	emedastine (Emadine <sup>®</sup> )
		epinastine (Elestat <sup>®</sup> )
		lodoxamide (Alomide <sup>®</sup> )
		loteprednol (Alrex <sup>®</sup> )
		nedocromil (Alocril <sup>®</sup> )
		olopatadine (Pataday <sup>®</sup> )

OTC = Over-the-counter

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

#### Ocular Allergy Tier-2 Approval Criteria:

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

#### Ocular Allergy Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Recent trials of one Tier-1 product and all available Tier-2 medications for a minimum of two 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 Ocular Allergy Medications: Fiscal Year 2016

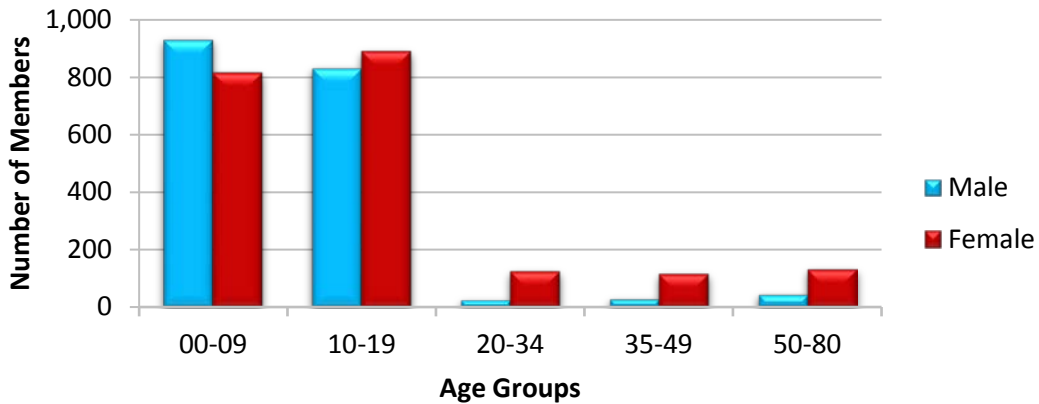
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	3,931	5,306	\$125,922.94	\$23.73	\$0.75	34,759	166,814
2016	3,934	5,808	\$102,928.78	\$17.72	\$0.55	37,976	186,439
% Change	0.10%	9.50%	-18.30%	-25.30%	26.70%	9.30%	11.80%
Change	3	502	-\$22,994.16	-\$6.01	-\$0.20	3,217	19,625

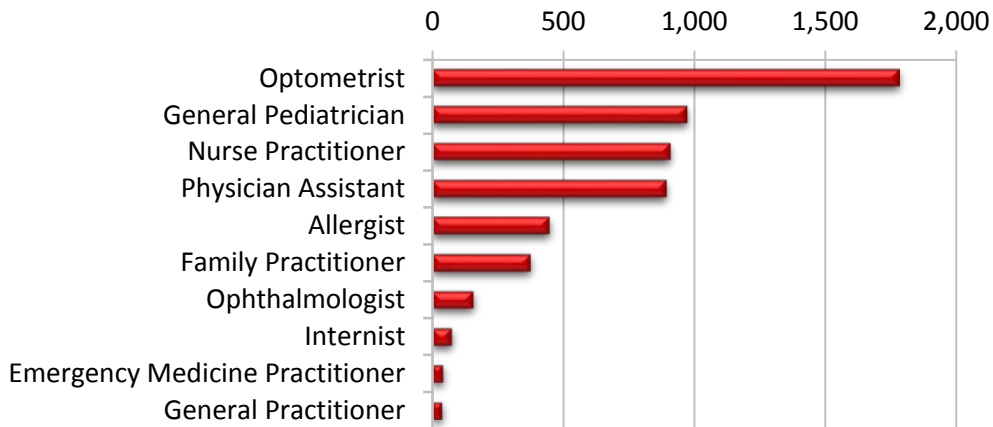
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Ocular Allergy Medications



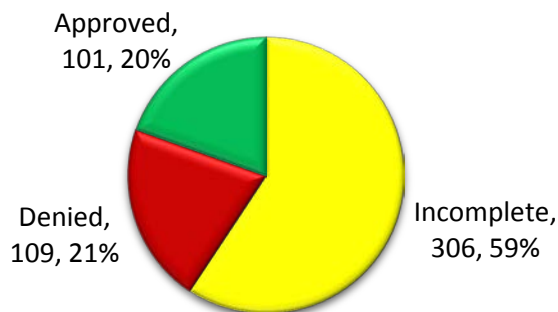
### Top Prescriber Specialties of Ocular Allergy Medications by Number of Claims



### Prior Authorization of Ocular Allergy Medications

There were 516 prior authorization requests submitted for Ocular Allergy Medications during fiscal year 2016. Computer edits are in place to detect Tier-1 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<sup>47</sup>

### Anticipated Patent Expiration(s):

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

### Recommendations

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

### Utilization Details of Ocular Allergy Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>CROMOLYN PRODUCTS</b>					
CROMOLYN SOD SOL 4% OP	550	454	\$6,454.19	\$0.36	\$11.73
<b>SUBTOTAL</b>	<b>550</b>	<b>454</b>	<b>\$6,454.19</b>	<b>\$0.36</b>	<b>\$11.73</b>
<b>KETOTIFEN PRODUCTS</b>					
KETOTIF FUM DRO 0.025%OP	3,569	2,426	\$45,169.54	\$0.42	\$12.66
ALAWAY DRO 0.025%OP	1,285	964	\$15,265.29	\$0.32	\$11.88
EYE ITCH REL DRO 0.025%OP	66	44	\$697.18	\$0.35	\$10.56
ALAWAY CHILD DRO	11	9	\$115.17	\$0.35	\$10.47
ZADITOR DRO 0.025%OP	10	10	\$135.24	\$0.45	\$13.52
ITCHY EYE DRO 0.025%OP	1	1	\$11.51	\$0.37	\$11.51
<b>SUBTOTAL</b>	<b>4,942</b>	<b>3,454</b>	<b>\$61,393.93</b>	<b>\$0.39</b>	<b>\$12.42</b>
<b>TIER-1 SUBTOTAL</b>	<b>5,492</b>	<b>3,908</b>	<b>\$67,848.12</b>	<b>\$0.38</b>	<b>\$12.35</b>
<b>TIER-2 PRODUCTS</b>					
<b>AZELASTINE PRODUCTS</b>					
AZELASTINE DRO 0.05%	106	55	\$4,426.09	\$1.35	\$41.76
<b>SUBTOTAL</b>	<b>106</b>	<b>55</b>	<b>\$4,426.09</b>	<b>\$1.35</b>	<b>\$41.76</b>
<b>OLOPATADINE PRODUCTS</b>					
OLOPATADINE DRO 0.1%	69	26	\$3,029.62	\$1.57	\$43.91
PATANOL SOL 0.1% OP	60	19	\$14,919.64	\$8.54	\$248.66
PAZEO DRO 0.7%	28	17	\$4,377.24	\$5.20	\$156.33
<b>SUBTOTAL</b>	<b>157</b>	<b>62</b>	<b>\$22,326.50</b>	<b>\$4.94</b>	<b>\$142.21</b>
<b>TIER-2 SUBTOTAL</b>	<b>263</b>	<b>117</b>	<b>\$26,752.59</b>	<b>\$3.43</b>	<b>\$101.72</b>
<b>TIER-3 PRODUCTS</b>					
<b>BEPOTASTINE PRODUCTS</b>					
BEPREVE DRO 1.5%	3	1	\$557.19	\$6.19	\$185.73
<b>SUBTOTAL</b>	<b>3</b>	<b>1</b>	<b>\$557.19</b>	<b>\$6.19</b>	<b>\$185.73</b>
<b>OLOPATADINE PRODUCTS</b>					

<sup>47</sup> 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 01/2017. Last accessed 03/03/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
PATADAY SOL 0.2%	50	13	\$7,770.88	\$5.33	\$155.42
<b>SUBTOTAL</b>	<b>50</b>	<b>13</b>	<b>\$7,770.88</b>	<b>\$5.33</b>	<b>\$155.42</b>
<b>TIER-3 SUBTOTAL</b>	<b>53</b>	<b>14</b>	<b>\$8,328.07</b>	<b>\$5.38</b>	<b>\$157.13</b>
<b>TOTAL</b>	<b>5,808</b>	<b>3,934*</b>	<b>\$102,928.78</b>	<b>\$0.55</b>	<b>\$17.72</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Ocular Antibiotic Products

Oklahoma Health Care Authority  
Fiscal Year 2016 Print Report

## Current Prior Authorization Criteria

Ocular Antibiotics: Liquids		
Tier-1	Tier-2	Tier-3
ciprofloxacin (Ciloxan®)	levofloxacin (Quixin®)	azithromycin (Azasite®)
gentamicin (Gentak®)		besifloxacin (Besivance®)
neomycin/polymyxin B/gramicidin (Neosporin®)		gatifloxacin (Zymaxid®)
ofloxacin (Ocuflax®)		moxifloxacin (Vigamox®, Moxeza®)
polymyxin B/trimethoprim (Polytrim®)		
sulfacetamide sodium (Bleph-10®)		
tobramycin (Tobrex®)		
Ocular Antibiotics: Ointments		
Tier-1	Tier-2	
bacitracin/polymyxin B (AK-Poly-Bac®)	bacitracin (AK-Tracin®)	
erythromycin (Ilotycin™, Roymcin®)	ciprofloxacin (Ciloxan®)	
gentamicin (Gentak®)	sulfacetamide sodium (Bleph-10®, Sodium Sulamyd®)	
neomycin/polymyxin B/bacitracin (Neosporin®)		
tobramycin (Tobrex®)		
Ocular Antibiotics/Steroid Combination Products		
Tier-1	Tier-2	
neomycin/polymyxin B/dexamethasone (Maxitrol®) susp & oint	bacitracin/polymyxin B/neomycin/HC oint	
sulfacetamide/prednisolone 10%-0.23% solution	gentamicin/prednisolone (Pred-G®) susp & oint	
	neomycin/polymyxin B/HC (Cortisporin®) susp	
	sulfacetamide/prednisolone 10%-0.2% (Blephamide®) susp & oint	
	tobramycin/dexamethasone (Tobradex®) susp & 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 (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

**Ocular Antibiotic Tier-2 Approval Criteria:**

- 1. An approved indication/suspected infection by an organism not known to be covered by Tier-1 products, or failure of a Tier-1 product; or
- 2. Known contraindication(s) 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 an organism not known to be covered by Tier-2 products, or failure of a Tier-2 product; or
- 2. Known contraindication(s) 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.

**Ocular 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 Ocular Antibiotic Products: Fiscal Year 2016**

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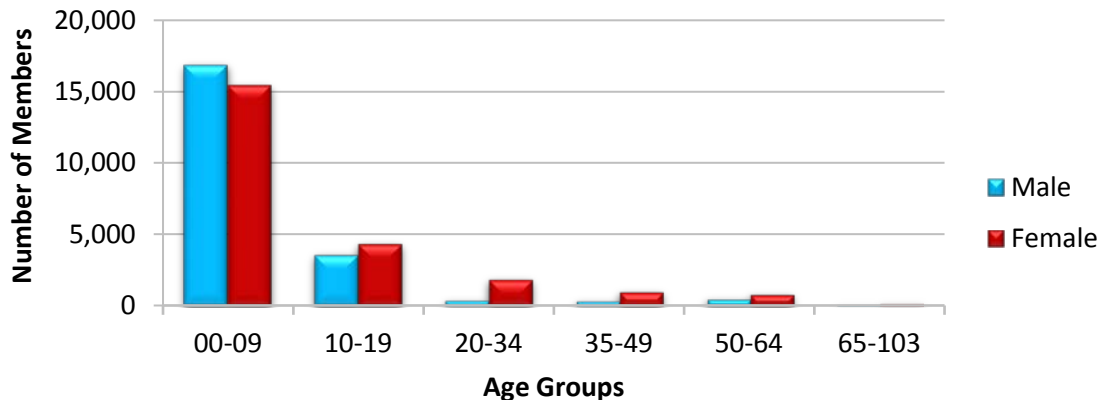
**Comparison of Fiscal Years**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	37,146	43,421	\$773,891.15	\$17.82	\$1.54	301,119	502,301
2016	45,315	53,610	\$986,867.76	\$18.41	\$1.62	360,778	610,590
% Change	22.00%	23.50%	27.50%	3.30%	5.20%	19.80%	21.60%
Change	8,169	10,189	\$212,976.61	\$0.59	\$0.08	59,659	108,289

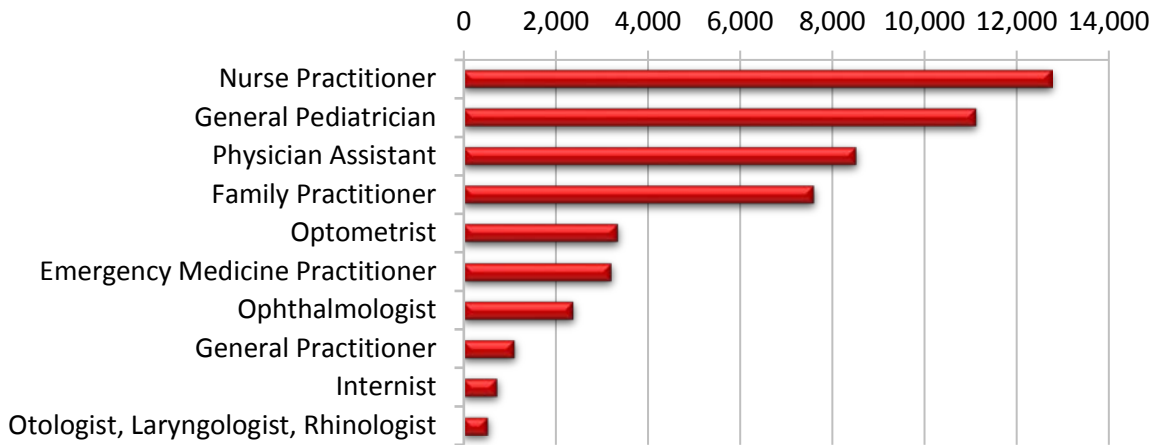
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

**Demographics of Members Utilizing Ocular Antibiotic Products**

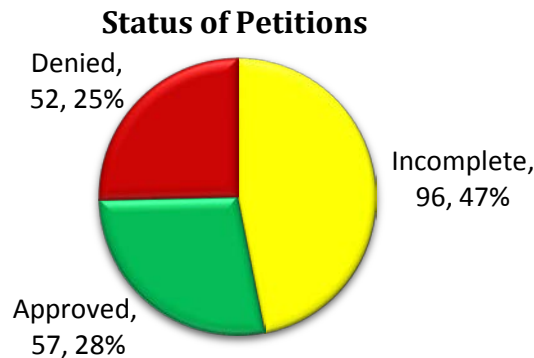


## Top Prescriber Specialties of Ocular Antibiotic Products by Number of Claims



## Prior Authorization of Ocular Antibiotic Products

There were 205 prior authorization requests submitted for ocular antibiotic products during fiscal year 2016. Computer edits are in place to detect Tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>48</sup>

### Anticipated Patent Expiration(s):

- Azasite® (azithromycin): March 2019
- Vigamox® (moxifloxacin): March 2020
- Tobradex® ST (tobramycin/dexamethasone): August 2028
- Besivance® (besifloxacin): January 2031

## Recommendations

The College of Pharmacy does not recommend any changes to the ocular antibiotic product prior authorization criteria at this time.

<sup>48</sup> 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 01/2017. Last accessed 03/06/2017.

## Utilization Details of Ocular Antibiotic Products: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>OCULAR ANTIBIOTICS LIQUIDS</b>					
<b>TIER-1 PRODUCTS</b>					
POLYMYXIN B/SOL TRIMETHP	12,474	11,865	\$135,260.14	\$0.77	\$10.84
OFLOXACIN DRO 0.3% OP	6,811	6,077	\$143,849.98	\$1.85	\$21.12
GENTAMICIN SOL 0.3% OP	6,607	6,239	\$63,953.06	\$0.93	\$9.68
TOBRAMYCIN SOL 0.3% OP	6,478	6,106	\$74,843.00	\$1.16	\$11.55
CIPROFLOXACN SOL 0.3% OP	1,955	1,845	\$18,104.35	\$0.89	\$9.26
SOD SULFACET SOL 10% OP	1,636	1,604	\$50,263.10	\$1.76	\$30.72
TRIMETHOPRIM SOL POLYMY	1,184	1,136	\$14,685.76	\$0.92	\$12.40
SULFACET SOD SOL 10% OP	1,054	1,036	\$39,329.68	\$2.73	\$37.31
NEO/POLY/GRA SOL OP	528	513	\$25,756.36	\$3.77	\$48.78
BLEPH-10 SOL 10% OP	79	76	\$1,691.80	\$2.44	\$21.42
POLYTRIM SOL OP	18	15	\$232.74	\$1.92	\$12.93
OCUFLOX DRO 0.3% OP	10	7	\$218.95	\$2.88	\$21.90
NEOSPORIN SOL OP	1	1	\$60.51	\$6.72	\$60.51
<b>TIER-1 SUBTOTAL</b>	<b>38,835</b>	<b>36,520</b>	<b>\$568,249.43</b>	<b>\$1.20</b>	<b>\$14.63</b>
<b>TIER-2 PRODUCTS</b>					
LEVOFLOXACIN SOL 0.5%	3	3	\$141.47	\$2.83	\$47.16
<b>TIER-2 SUBTOTAL</b>	<b>3</b>	<b>3</b>	<b>\$141.47</b>	<b>\$2.83</b>	<b>\$47.16</b>
<b>TIER-3 PRODUCTS</b>					
VIGAMOX DRO 0.5%	453	342	\$68,957.96	\$11.84	\$152.23
BESIVANCE SUS 0.6%	150	114	\$21,237.19	\$6.70	\$141.58
GATIFLOXACIN SOL 0.5%	76	65	\$7,299.68	\$7.07	\$96.05
AZASITE SOL 1%	29	12	\$4,428.16	\$6.16	\$152.70
MOXEZA SOL 0.5%	17	15	\$2,461.66	\$11.34	\$144.80
<b>TIER-3 SUBTOTAL</b>	<b>725</b>	<b>548</b>	<b>\$104,384.65</b>	<b>\$9.52</b>	<b>\$143.98</b>
<b>TOTAL</b>	<b>39,563</b>	<b>37,071</b>	<b>\$672,775.55</b>	<b>\$1.39</b>	<b>\$17.01</b>
<b>OCULAR ANTIBIOTICS OINTMENTS</b>					
<b>TIER-1 PRODUCTS</b>					
ERYTHROMYCIN OIN OP	9,537	8,873	\$111,697.93	\$1.46	\$11.71
GENTAK OIN 0.3% OP	832	802	\$15,199.14	\$2.15	\$18.27
ERYTHROMYCIN OIN	398	384	\$5,434.56	\$1.65	\$13.65
BACIT/POLYMY OIN OP	292	279	\$5,039.13	\$1.95	\$17.26
TOBREX OIN 0.3% OP	243	234	\$45,702.31	\$20.84	\$188.08
AK-POLY-BAC OIN OP	65	62	\$1,133.54	\$1.76	\$17.44
NEO/BAC/POLY OIN OP	35	35	\$1,407.44	\$4.36	\$40.21
GENTAMICIN OIN 0.3% OP	30	29	\$533.66	\$2.01	\$17.79
POLYCIN OIN OP	23	23	\$403.12	\$1.80	\$17.53
NEO-POLYCIN OIN OP	5	5	\$208.26	\$4.73	\$41.65
ILOTYCIN OIN OP	2	2	\$20.11	\$1.44	\$10.06
<b>TIER-1 SUBTOTAL</b>	<b>11,462</b>	<b>10,728</b>	<b>\$186,779.20</b>	<b>\$2.00</b>	<b>\$16.30</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-2 PRODUCTS</b>					
BACITRACIN OIN OP	190	181	\$17,631.47	\$9.63	\$92.80
SULFACET SOD OIN 10% OP	16	16	\$925.55	\$5.71	\$57.85
CILOXAN OIN 0.3% OP	4	4	\$773.19	\$27.61	\$193.30
<b>TIER-2 SUBTOTAL</b>	<b>210</b>	<b>201</b>	<b>\$19,330.21</b>	<b>\$9.56</b>	<b>\$92.05</b>
<b>TOTAL</b>	<b>11,672</b>	<b>10,929</b>	<b>\$206,109.41</b>	<b>\$2.16</b>	<b>\$17.66</b>
<b>OCULAR ANTIBIOTIC/STEROID COMBINATION PRODUCTS</b>					
<b>TIER-1 PRODUCTS</b>					
NEO/POLY/DEX SUS 0.1% OP	1,004	892	\$16,544.88	\$1.21	\$16.48
NEO/POLY/DEX OIN 0.1% OP	567	472	\$8,859.23	\$1.49	\$15.62
<b>TIER-1 SUBTOTAL</b>	<b>1,571</b>	<b>1,364</b>	<b>\$25,404.11</b>	<b>\$1.29</b>	<b>\$16.17</b>
<b>TIER-2 PRODUCTS</b>					
TOBRA/DEXAME SUS 0.3-0.1%	625	573	\$48,037.89	\$5.26	\$76.86
TOBRADEX OIN 0.3-0.1%	108	98	\$21,741.36	\$16.61	\$201.31
ZYLET SUS 0.5-0.3%	35	29	\$8,126.34	\$11.64	\$232.18
TOBRADEX ST SUS 0.3-0.05	18	18	\$3,015.60	\$14.09	\$167.53
TOBRADEX SUS 0.3-0.1%	10	10	\$847.95	\$7.37	\$84.80
NEO/POLY/HC SUS OP	4	4	\$480.92	\$7.63	\$120.23
NEO/POLY/BAC OIN /HC	2	2	\$92.04	\$2.30	\$46.02
BLEPHAMIDE SUS OP	1	1	\$121.74	\$17.39	\$121.74
BLEPHAMIDE OIN S.O.P.	1	1	\$114.85	\$11.48	\$114.85
<b>TIER-2 SUBTOTAL</b>	<b>804</b>	<b>736</b>	<b>\$82,578.69</b>	<b>\$7.13</b>	<b>\$102.71</b>
<b>TOTAL</b>	<b>2,375</b>	<b>2,100</b>	<b>\$107,982.80</b>	<b>\$3.46</b>	<b>\$45.47</b>
<b>GRAND TOTAL</b>	<b>53,610</b>	<b>45,315*</b>	<b>\$986,867.76</b>	<b>\$1.62</b>	<b>\$18.41</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Ophthalmic Corticosteroids

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Ophthalmic Corticosteroids	
Tier-1	Tier-2
dexamethasone sodium phosphate solution 0.1%	fluorometholone (FML Forte®) suspension 0.25%
dexamethasone (Maxidex™) suspension 0.1%	fluorometholone (FML S.O.P®) ointment 0.1%
difluprednate (Durezol®) emulsion 0.05%	loteprednol (Lotemax®) gel 0.5%
fluorometholone (FML Liquifilm®) suspension 0.1%	loteprednol (Lotemax®) ointment 0.5%
fluorometholone (Flarex®) suspension 0.1%	prednisolone acetate (Pred Forte®) suspension 1%
loteprednol (Lotemax®) suspension 0.5%	
prednisolone acetate (Omnipred®) suspension 1%	
prednisolone acetate (Pred Mild®) suspension 0.12%	
prednisolone sodium phosphate solution 1%	
rimexolone (Vexol®) suspension 1%	

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

### Ophthalmic Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower-tiered medications; or
3. A unique indication for which the Tier-1 anti-inflammatories lack.

### Utilization of Ophthalmic Corticosteroids: Fiscal Year 2016

#### Comparison of Fiscal Years

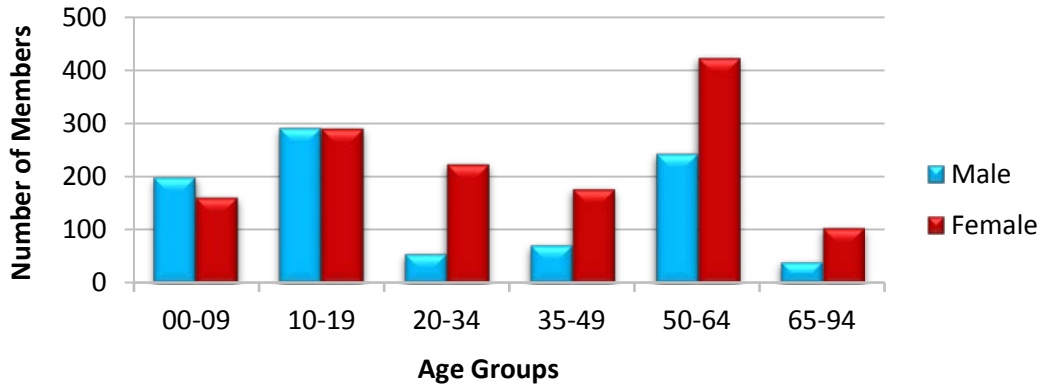
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	2,960	4,060	\$306,475.39	\$75.49	\$3.73	26,986	82,214
2016	2,274	3,289	\$310,391.75	\$94.37	\$3.96	22,547	78,409
% Change	-23.20%	-19.00%	1.30%	25.00%	6.20%	-16.40%	-4.60%
Change	-686	-771	\$3,916.36	\$18.88	\$0.23	-4,439	-3,805

\*Total number of unduplicated members.

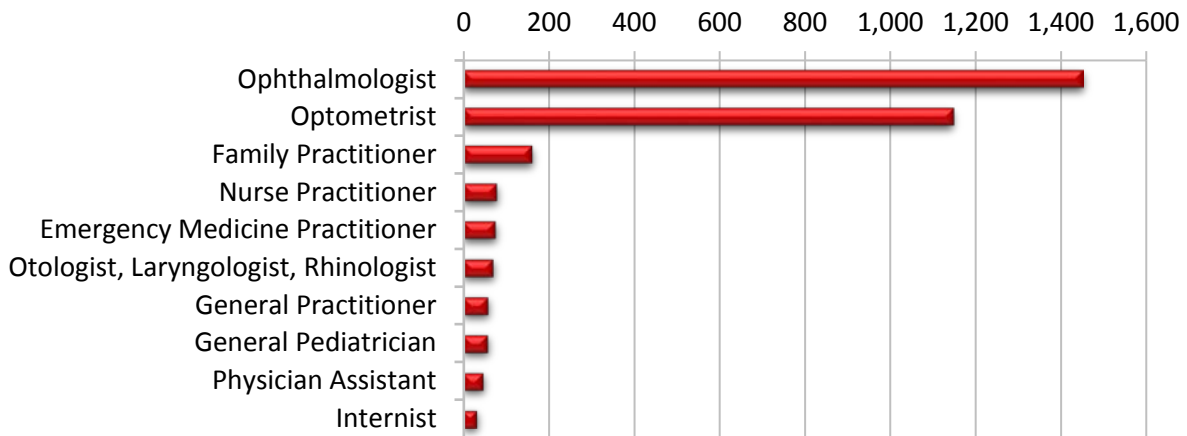
Costs do not reflect rebated prices or net costs.



### Demographics of Members Utilizing Ophthalmic Corticosteroids

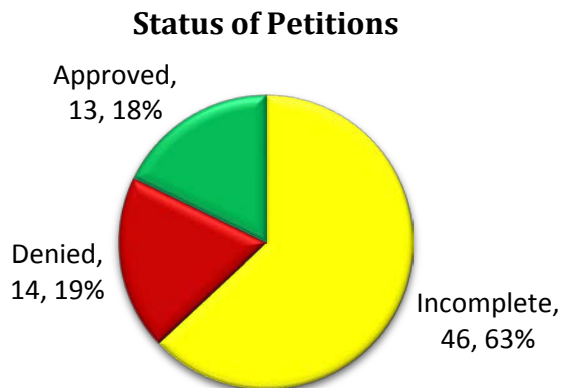


### Top Prescriber Specialties of Ophthalmic Corticosteroids by Number of Claims



### Prior Authorization of Ophthalmic Corticosteroids

There were 73 prior authorization requests submitted for ophthalmic corticosteroids during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>49,50,51,52</sup>

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### Anticipated Patent Expiration(s):

- Lotemax® (loteprednol) gel: January 2017
- Durezol® (difluprednate) emulsion: November 2019

### Pipeline:

- **DexaSite™ (ISV-303):** InSite Vision reports DexaSite™, a DuraSite formulation of 0.1% dexamethasone ophthalmic solution, is in Phase 3 clinical development. InSite Vision is conducting trials for both the treatment of ocular inflammation, such as blepharitis, and treatment of ocular pain and inflammation in cataract surgery. DuraSite is drug delivery vehicle that stabilizes small molecules in a polymeric mucoadhesive matrix. It creates a gel forming drop, which extends the residence time of the drug relative to conventional eye drops.
- **Dextenza™ (dexamethasone insert):** Ocular Therapeutix™ reports Dextenza™ is in Phase 3 clinical development for the treatment of post-surgical ocular inflammation and pain. It contains the corticosteroid dexamethasone as an active pharmaceutical ingredient in a hydrogel-based drug-eluting intracanalicular depot. In September 2015, Ocular Therapeutix™ submitted a new drug Application (NDA) to the U.S. Food and Drug Administration (FDA), for Dextenza™, and the FDA has accepted the NDA for filing. Dextenza™ is inserted non-invasively through the punctum, and resides within the canaliculus, delivering a four-week tapered release of corticosteroid to the ocular surface. The product also contains a visualization aid for retention monitoring throughout the treatment period. After therapy is complete, the hydrogel resorbs and exits the nasolacrimal system without need for removal by the physician. Dextenza™ provides a dropless option for steroid therapy.
- **EGP-437:** EyeGate Pharmaceuticals is currently in Phase 3 trials for EGP-437, a corticosteroid formulation for anterior uveitis. It is dexamethasone delivered with iontophoresis. EGP-437 is currently available for research as a simple cylindrical device that looks like a thimble and acts like a contact lens with a drug-laden sponge on it. A secondary electrode on the forehead drives that charge through the eye. EyeGate Pharmaceuticals reports medication delivery in this fashion is pain-free and brief.

## Recommendations

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

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<sup>49</sup> 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 01/2017. Last accessed 03/13/2017.

<sup>50</sup> InSite Vision: a SUN PHARMA company: Product Portfolio. Available online at: [http://www.insitevision.com/Pipeline\\_Products.html](http://www.insitevision.com/Pipeline_Products.html). Last accessed 03/20/2017.

<sup>51</sup> Ocular Therapeutix, Inc. Product Candidates: Dextenza™. Available online at: <http://www.ocutx.com/pipeline/dexamethasone-punctum-plug>. Last accessed 03/20/2017.

<sup>52</sup> Stephenson, M. In the Dry-Eye Pipeline: Slow Progress. Review® of Ophthalmology. Available online at: <https://www.reviewofophthalmology.com/article/in-the-dryeye-pipeline-slow-progress>. Issued 11/11/2014. Last accessed 03/20/2017.

## Utilization Details Ophthalmic Corticosteroids: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>DIFLUPREDNATE PRODUCTS</b>					
DUREZOL EMU 0.05%	502	294	\$85,020.16	\$7.31	\$169.36
<b>SUBTOTAL</b>	<b>502</b>	<b>294</b>	<b>\$85,020.16</b>	<b>\$7.31</b>	<b>\$169.36</b>
<b>DEXAMETHASONE PRODUCTS</b>					
DEXAMETH PHO SOL 0.1% OP	247	213	\$11,883.44	\$3.64	\$48.11
MAXIDEX SUS 0.1% OP	6	4	\$432.78	\$4.97	\$72.13
<b>SUBTOTAL</b>	<b>253</b>	<b>217</b>	<b>\$12,316.22</b>	<b>\$3.68</b>	<b>\$48.68</b>
<b>FLUOROMETHOLONE PRODUCTS</b>					
FLUOROMETHOL SUS 0.1% OP	270	200	\$24,189.56	\$4.06	\$89.59
FML LIQUIFLM SUS 0.1% OP	24	21	\$4,025.70	\$7.85	\$167.74
FLAREX SUS 0.1% OP	6	6	\$391.16	\$4.16	\$65.19
<b>SUBTOTAL</b>	<b>300</b>	<b>227</b>	<b>\$28,606.42</b>	<b>\$4.36</b>	<b>\$95.34</b>
<b>LOTEPREDNOL PRODUCTS</b>					
LOTEMAX SUS 0.5%	219	168	\$55,458.85	\$9.96	\$253.24
<b>SUBTOTAL</b>	<b>219</b>	<b>168</b>	<b>\$55,458.85</b>	<b>\$9.96</b>	<b>\$253.24</b>
<b>PREDNISOLONE PRODUCTS</b>					
PREDNISOLONE SUS 1% OP	1,952	1,415	\$120,343.89	\$2.42	\$61.65
PRED MILD SUS 0.12% OP	41	33	\$6,875.08	\$7.29	\$167.68
PRED SOD PHO SOL 1% OP	12	11	\$542.55	\$1.78	\$45.21
<b>SUBTOTAL</b>	<b>2,005</b>	<b>1,459</b>	<b>\$127,761.52</b>	<b>\$2.50</b>	<b>\$63.72</b>
<b>RIMEXOLONE PRODUCTS</b>					
VEXOL SUS 1% OP	7	4	\$658.69	\$3.66	\$94.10
<b>SUBTOTAL</b>	<b>7</b>	<b>4</b>	<b>\$658.69</b>	<b>\$3.66</b>	<b>\$94.10</b>
<b>TIER-1 SUBTOTAL</b>	<b>3,286</b>	<b>2,369</b>	<b>\$309,821.86</b>	<b>\$3.95</b>	<b>\$94.29</b>
<b>TIER-2 PRODUCTS</b>					
<b>FLUOROMETHOLONE PRODUCTS</b>					
FML OIN 0.1% OP	1	1	\$112.41	\$11.24	\$112.41
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$112.41</b>	<b>\$11.24</b>	<b>\$112.41</b>
<b>LOTEPREDNOL PRODUCTS</b>					
LOTEMAX OIN 0.5%	2	2	\$457.48	\$10.17	\$228.74
<b>SUBTOTAL</b>	<b>2</b>	<b>2</b>	<b>\$457.48</b>	<b>\$10.17</b>	<b>\$228.74</b>
<b>TIER-2 SUBTOTAL</b>	<b>3</b>	<b>3</b>	<b>\$569.89</b>	<b>\$10.36</b>	<b>\$189.96</b>
<b>TOTAL</b>	<b>3,289</b>	<b>2,274*</b>	<b>\$310,391.75</b>	<b>\$3.96</b>	<b>\$94.37</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Pediculicide Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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Pediculicide Medications	
Tier-1	Tier-2
Covered OTC Lice Products	lindane shampoo
ivermectin (Sklice®) lotion	malathion (Ovide®) brand and generic
spinosad (Natroba™) suspension	

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

Over-the-counter (OTC) treatments for lice are a covered benefit for all members. A prescription is required for coverage, and fills are limited to one individual package size for a seven 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 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 seven to fourteen days with inadequate results; and
  - d. A quantity limit of 60 grams per 30 days will apply.
2. **Ivermectin (Sklice®) Lotion:**
  - a. Member must be at least six months of age; and
  - b. A quantity limit of 117mL per seven days will apply.
3. **Lindane Shampoo:**
  - a. Member must be at least 13 years old or weigh at least 110 pounds; and
  - b. A quantity limit of 60mL per seven days will apply; and
  - c. One seven day supply per 30 days maximum.
4. **Malathion (Ovide®) Lotion:**
  - a. Member must be at least six years of age; and
  - b. A quantity limit of 60mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.
5. **Spinosad (Natroba™) Suspension:**
  - a. Member must be at least six months of age; and

- b. A quantity limit of 120mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.

## Utilization of Pediculicide Medications: Fiscal Year 2016

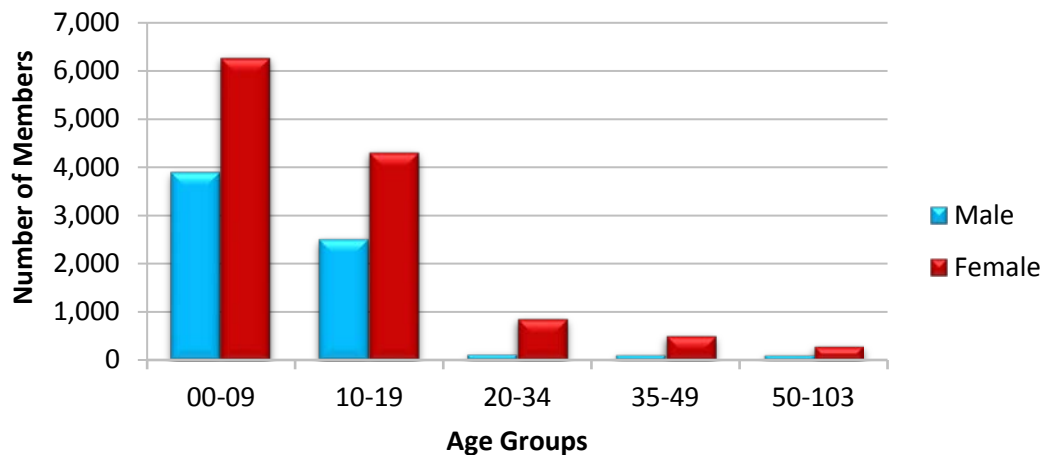
### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	18,480	26,047	\$1,575,744.28	\$60.50	\$5.93	1,867,754	265,865
2016	18,946	26,167	\$2,356,362.36	\$90.05	\$8.86	1,961,828	265,909
% Change	2.50%	0.50%	49.50%	48.80%	49.40%	5.00%	0.00%
Change	466	120	\$780,618.08	\$29.55	\$2.93	94,074	44

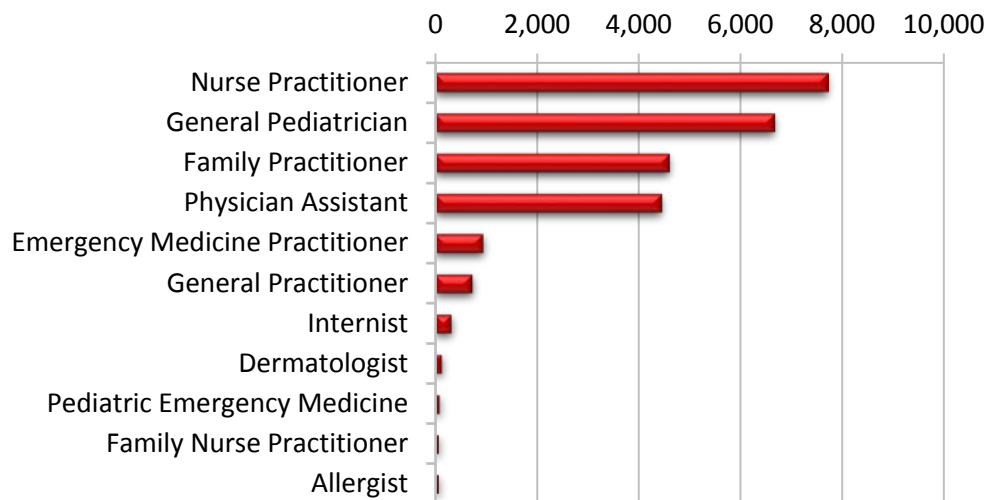
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Pediculicide Medications



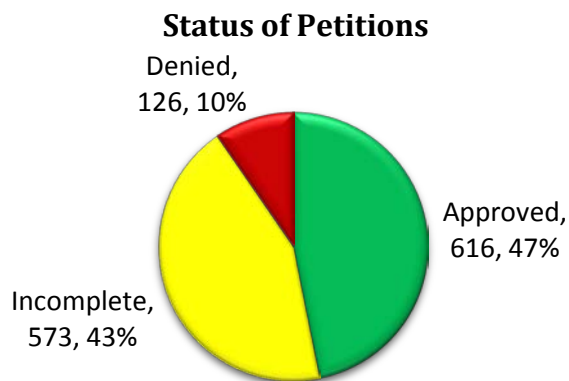
### Top Prescriber Specialties of Pediculicide Medications by Number of Claims



## Prior Authorization of Pediculicide Medications

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There were 1,315 prior authorization requests submitted for Pediculicide Medications during fiscal year 2016. Computer edits are in place to detect Tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>53,54,55</sup>

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### Anticipated Patent Expiration(s):

- Ulesfia® (benzyl alcohol): May 2024
- Sklice® (ivermectin): October 2027

### News:

- **September 2015:** Hatchtech announced the filing its New Drug Application (NDA) for Xeglyze™ (abametapir) lotion with the U.S. Food and Drug Administration (FDA). Abametapir is an inhibitor of metalloproteases, and has demonstrated both ovicidal and lousicidal activity. It offers the potential for an effective treatment using only a single application.
- **June 2016:** Wockhardt Bio AG/Morton Grove Pharmaceuticals made the decision to discontinue manufacturing lindane 1% lotion.
- **November 2016:** Akron Pharmaceuticals discontinued lindane 1% lotion and lindane 1% shampoo due to product line rationalization.

## Recommendations

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The College of Pharmacy does not recommend any changes at this time.

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<sup>53</sup> 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 02/2017. Last accessed 03/20/2017.

<sup>54</sup> U.S. Food and Drug Administration (FDA): Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Available online at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>. Last accessed 03/21/2017.

<sup>55</sup> Business Wire. Dr. Reddy's Laboratories Signs Commercialization Deal with Hatchtech. Available online at: <http://www.businesswire.com/news/home/20150914005395/en/Dr.-Reddy%E2%80%99s-Laboratories-Signs-Commercialization-Deal-Hatchtech>. Issued 09/14/2015. Last accessed 03/31/2017.

## Utilization Details of Pediculicide Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>OTC PERMETHRIN PRODUCTS</b>					
PERMETHRIN LOT 1%	4,622	3,590	\$54,581.80	\$1.16	\$11.81
LICE TREATMT LOT 1%	951	744	\$13,101.63	\$1.40	\$13.78
LICE TRTMNT LIQ 1%	443	349	\$4,837.82	\$1.20	\$10.92
SM LICE LOT TREATMNT	379	316	\$5,683.68	\$1.58	\$15.00
LICE TREATME LOT 1%	305	233	\$3,136.15	\$1.22	\$10.28
<b>SUBTOTAL</b>	<b>6,700</b>	<b>5,232</b>	<b>\$81,341.08</b>	<b>\$1.22</b>	<b>\$12.14</b>
<b>PRESCRIPTION PERMETHRIN PRODUCTS</b>					
PERMETHRIN CRE 5%	15,759	12,460	\$1,188,726.20	\$7.34	\$75.43
<b>SUBTOTAL</b>	<b>15,759</b>	<b>12,460</b>	<b>\$1,188,726.20</b>	<b>\$7.34</b>	<b>\$75.43</b>
<b>IVERMECTIN PRODUCTS</b>					
SKLICE LOT 0.5%	3,114	2,459	\$923,731.24	\$32.21	\$296.64
<b>SUBTOTAL</b>	<b>3,114</b>	<b>2,459</b>	<b>\$923,731.24</b>	<b>\$32.21</b>	<b>\$296.64</b>
<b>SPINOSAD PRODUCTS</b>					
SPINOSAD SUS 0.9%	291	238	\$65,929.88	\$20.88	\$226.56
NATROBA SUS 0.9%	45	34	\$11,188.49	\$16.43	\$248.63
<b>SUBTOTAL</b>	<b>336</b>	<b>272</b>	<b>\$77,118.37</b>	<b>\$20.09</b>	<b>\$229.52</b>
<b>TIER-1 SUBTOTAL</b>	<b>25,909</b>	<b>20,423</b>	<b>\$2,270,916.89</b>	<b>\$8.70</b>	<b>\$87.65</b>
<b>TIER-2 PRODUCTS<sup>A</sup></b>					
<b>BENZYL ALCOHOL PRODUCTS</b>					
ULESFIA LOT 5%	243	192	\$80,249.96	\$17.50	\$330.25
<b>SUBTOTAL</b>	<b>243</b>	<b>192</b>	<b>\$80,249.96</b>	<b>\$17.50</b>	<b>\$330.25</b>
<b>TIER-2 SUBTOTAL</b>	<b>243</b>	<b>192</b>	<b>\$80,249.96</b>	<b>\$17.50</b>	<b>\$330.25</b>
<b>TIER-3 PRODUCTS</b>					
<b>MALATHION PRODUCTS</b>					
MALATHION LOT 0.5%	4	4	\$762.89	\$14.13	\$190.72
<b>SUBTOTAL</b>	<b>4</b>	<b>4</b>	<b>\$762.89</b>	<b>\$14.13</b>	<b>\$190.72</b>
<b>LINDANE PRODUCTS</b>					
LINDANE SHA 1%	2	2	\$244.52	\$17.47	\$122.26
<b>SUBTOTAL</b>	<b>2</b>	<b>2</b>	<b>\$244.52</b>	<b>\$17.47</b>	<b>\$122.26</b>
<b>TIER-3 SUBTOTAL</b>	<b>6</b>	<b>6</b>	<b>\$1,007.41</b>	<b>\$14.81</b>	<b>\$167.90</b>
<b>CROTAMITON PRODUCTS</b>					
EURAX CRE 10%	6	5	\$2,802.97	\$15.57	\$467.16
EURAX LOT 10%	3	2	\$1,385.13	\$15.39	\$461.71
<b>SUBTOTAL</b>	<b>9</b>	<b>7</b>	<b>\$4,188.10</b>	<b>\$15.51</b>	<b>\$465.34</b>
<b>TOTAL</b>	<b>26,167</b>	<b>18,946*</b>	<b>\$2,356,362.36</b>	<b>\$8.86</b>	<b>\$90.05</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

<sup>A</sup>The manufacturer of Ulesfia® (benzyl alcohol lotion) no longer has a drug rebate agreement and is no longer covered. It is shown in the table above to accurately reflect pediculicide utilization for fiscal year 2016.

# Fiscal Year 2016 Annual Review of Prenatal Vitamins

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Prenatal Vitamins Approval Criteria:

- Most brand-name 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](http://www.okhca.org/providers/rx).
- The SoonerCare prenatal vitamin category is modified throughout the fiscal year and adjusted for price fluctuations.
- Preferred products are based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

### Utilization of Prenatal Vitamins: Fiscal Year 2016

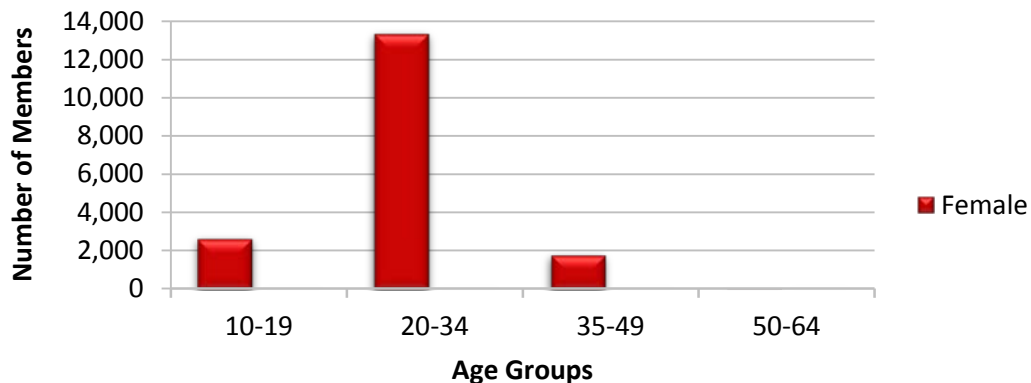
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	19,392	39,037	\$1,271,973.57	\$32.58	\$0.72	1,815,527	1,758,266
2016	17,805	35,889	\$1,805,639.69	\$50.31	\$1.15	1,810,521	1,569,887
% Change	-8.20%	-8.10%	42.00%	54.40%	59.70%	-0.30%	-10.70%
Change	-1,587	-3,148	\$533,666.12	\$17.73	\$0.43	-5,006	-188,379

\*Total number of unduplicated members.

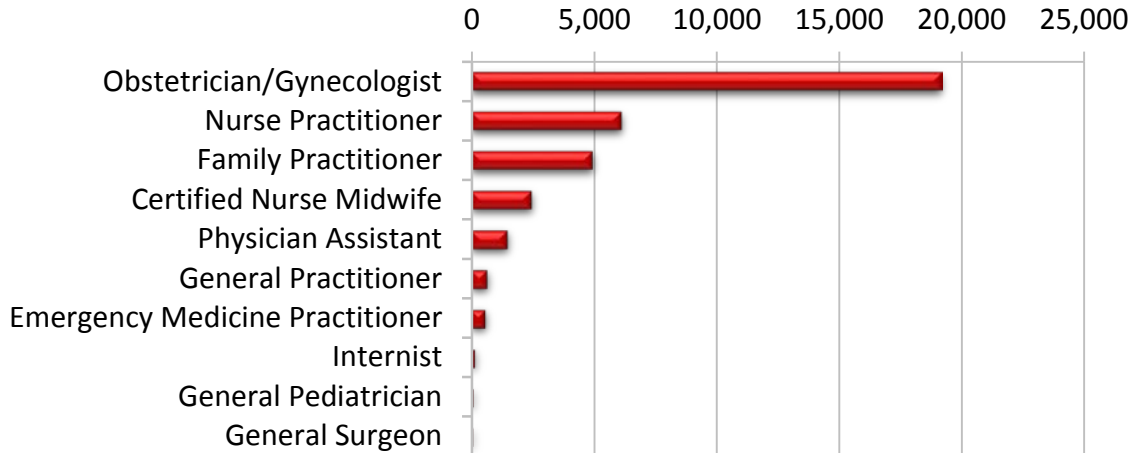
Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Prenatal Vitamins



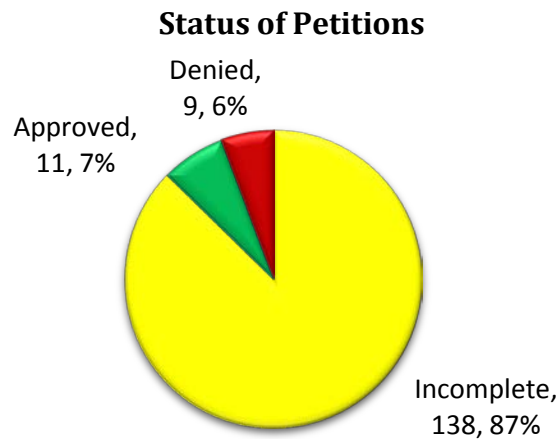


## Top Prescriber Specialties of Prenatal Vitamins by Number of Claims



## Prior Authorization of Prenatal Vitamins

There were 158 prior authorization requests submitted for prenatal vitamins during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Recommendations

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

## Utilization Details of Prenatal Vitamins: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
PNV PRENATAL TAB PLUS	4,514	2,676	\$68,240.69	\$0.32	\$15.12	1.69
CITRANATAL MIS 90 DHA	3,921	1,748	\$379,360.03	\$3.01	\$96.75	2.24
FOLIVANE-OB CAP	3,741	2,137	\$112,527.84	\$0.72	\$30.08	1.75
CONCEPT OB CAP	3,288	1,766	\$101,182.81	\$0.75	\$30.77	1.86
PRENAT PLUS TAB 27-1MG	3,171	1,823	\$49,774.56	\$0.31	\$15.70	1.74
CITRANATAL HARMONY	2,926	1,326	\$350,417.01	\$3.09	\$119.76	2.21
PREPLUS TAB 27-1MG	2,391	1,555	\$31,373.36	\$0.22	\$13.12	1.54
CONCEPT DHA CAP	2,175	1,317	\$73,487.20	\$0.77	\$33.79	1.65

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	CLAIMS/MEMBER
CITRANATAL PAK DHA	1,565	716	\$139,378.04	\$2.87	\$89.06	2.19
VOL-PLUS TAB	1,514	1,104	\$65,480.32	\$0.50	\$43.25	1.37
CITRANATAL PAK ASSURE	1,390	580	\$130,705.03	\$3.07	\$94.03	2.4
VITAFOL CAP ULTRA	878	500	\$107,527.36	\$3.38	\$122.47	1.76
TARON-C DHA CAP	777	489	\$24,035.72	\$0.74	\$30.93	1.59
CITRANATAL MIS B-CALM	698	376	\$48,881.71	\$2.04	\$70.03	1.86
COMPLETE NAT PAK DHA	368	190	\$9,039.73	\$0.80	\$24.56	1.94
SE-NATAL 19 TAB	333	190	\$8,277.62	\$0.51	\$24.86	1.75
VITAFOL-NANO TAB	283	167	\$34,003.75	\$3.43	\$120.15	1.69
SE-NATAL 19 CHW	278	158	\$6,413.48	\$0.64	\$23.07	1.76
PROVIDA OB CAP	223	170	\$12,146.49	\$0.99	\$54.47	1.31
VIRT-C DHA CAP	203	134	\$7,396.29	\$0.94	\$36.43	1.51
PRENATA CHW 29-1MG	152	97	\$1,875.76	\$0.24	\$12.34	1.57
PRENATAL TAB PLUS	151	135	\$1,502.18	\$0.27	\$9.95	1.12
COMPLETENATE CHW	148	90	\$3,778.79	\$0.51	\$25.53	1.64
CITRANATAL TAB RX	137	83	\$17,460.01	\$2.16	\$127.45	1.65
TRINATAL RX TAB 1	123	90	\$1,949.20	\$0.28	\$15.85	1.37
VITAFOL FE+ CAP	106	68	\$9,084.10	\$2.66	\$85.70	1.56
PNV TABS TAB 29-1MG	102	54	\$1,560.88	\$0.39	\$15.30	1.89
NIVA-PLUS TAB	93	73	\$1,055.37	\$0.25	\$11.35	1.27
VOL-TAB RX TAB	84	57	\$1,624.21	\$0.38	\$19.34	1.47
PRENATAL 19 CHW TAB	30	29	\$958.65	\$0.69	\$31.96	1.03
PRENATAL VIT TAB PLUS	25	16	\$224.40	\$0.27	\$8.98	1.56
PRENATABS RX TAB	15	14	\$262.47	\$0.37	\$17.50	1.07
VIRT-ADVANCE 90-1MG	15	6	\$150.42	\$0.29	\$10.03	2.5
ENBRACE HR CAP	11	3	\$2,434.83	\$3.86	\$221.35	3.67
TRINATAL GT TAB	8	2	\$72.55	\$0.30	\$9.07	4
PRENATABS FA 29-1MG	7	6	\$106.00	\$0.34	\$15.14	1.17
PRENATAL TAB 27-1MG	7	7	\$107.33	\$0.28	\$15.33	1
PNV FE FUM TAB DOC/FA	7	5	\$140.15	\$0.52	\$20.02	1.4
PRENATAL VIT LOW IRON	6	3	\$40.63	\$0.17	\$6.77	2
PRENATAL 19 TAB	5	4	\$67.48	\$0.45	\$13.50	1.25
PRENATE CAP RESTORE	4	1	\$460.88	\$3.84	\$115.22	4
SE-TAN DHA CAP	4	2	\$236.60	\$1.97	\$59.15	2
TRISTART DHA CAP	3	3	\$512.35	\$3.42	\$170.78	1
VOL-NATE TAB	2	2	\$36.38	\$0.40	\$18.19	1
TRINATE TAB	2	2	\$26.72	\$0.45	\$13.36	1
PRENAPLUS TAB	2	2	\$33.53	\$0.28	\$16.77	1
PRENATAL-U CAP 106.5-1	1	1	\$61.43	\$0.68	\$61.43	1
PRENATE DHA CAP	1	1	\$144.89	\$4.83	\$144.89	1
TRIADVANCE TAB	1	1	\$22.46	\$0.22	\$22.46	1
<b>TOTAL</b>	<b>35,889</b>	<b>17,805*</b>	<b>\$1,805,639.69</b>	<b>\$1.15</b>	<b>\$50.31</b>	<b>2.02</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Procysbi® (Cysteamine Bitartrate)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Procysbi® (Cysteamine Bitartrate) Approval Criteria:

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

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### Utilization of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2016

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#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1	10	\$154,568.47	\$15,456.85	\$515.23	2,340	300
2016	1	2	\$4,478.49	\$2,239.24	\$74.64	360	60
% Change	0.00%	-80.00%	-97.10%	-85.50%	-85.50%	-84.60%	-80.00%
Change	0	-8	-\$150,089.98	-\$13,217.61	-\$440.59	-1,980	-240

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs, additionally third party insurance altered claim reimbursement in fiscal year 2016.

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

- The only prescriber specialty listed on paid pharmacy claims for Procysbi® (cysteamine bitartrate) during fiscal year 2016 was general pediatrician.

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#### Prior Authorization of Procysbi® (Cysteamine Bitartrate)

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- There were two prior authorization requests submitted for Procysbi® (cysteamine bitartrate) during fiscal year 2016. Both requests were approved.

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#### Market News and Updates<sup>56</sup>

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**Anticipated Patent Expiration(s):** Procysbi® (cysteamine bitartrate): June 2034

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#### Recommendations

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

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<sup>56</sup>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 1/2017. Last accessed 03/2017.

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# Fiscal Year 2016 Annual Review of Qalaaquin® (Quinine Sulfate)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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#### Qalaaquin® (Quinine Sulfate) Approval Criteria:

1. An FDA approved diagnosis of malaria.
2. Off-label use for the prevention/treatment of leg cramps and other related conditions will not be approved.

### Utilization of Qalaaquin® (Quinine Sulfate): Fiscal Year 2016

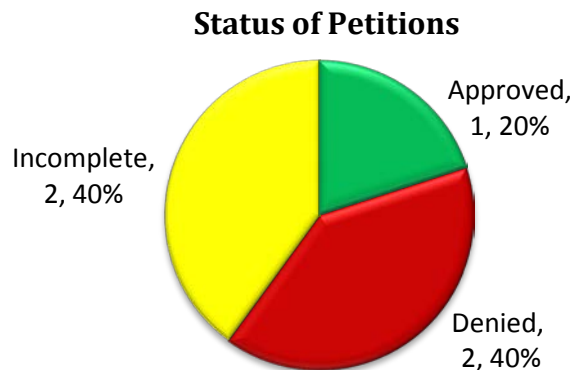
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There were no claims for Qalaaquin® (quinine sulfate) during fiscal year 2016.

### Prior Authorization of Qalaaquin® (Quinine Sulfate)

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There were five prior authorization requests submitted for Qalaaquin® (quinine sulfate) during fiscal year 2016. The approved prior authorization did not have any claim attempts. The following chart shows the status of the submitted petitions.



### Recommendations

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The College of Pharmacy does not recommend any changes to the Qalaaquin® (quinine sulfate) prior authorization criteria at this time.

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# Fiscal Year 2016 Annual Review of Qutenza® (Capsaicin 8% Patch)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Qutenza® (Capsaicin 8% Patch) Approval Criteria:

1. An FDA approved diagnosis of postherpetic neuralgia; and
2. Documented treatment attempts at recommended dosing or contraindication to at least one agent from each of the following drug classes:
  - a. Tricyclic antidepressants; or
  - b. Anticonvulsants; or
  - c. Topical lidocaine; and
3. Qutenza® must be administered by a healthcare provider.
4. A quantity limit of no more than four patches per treatment every 90 days will apply.

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### Utilization of Qutenza® (Capsaicin 8% Patch): Fiscal Year 2016

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There was no utilization of Qutenza® (capsaicin 8% patch) during fiscal year 2016.

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### Prior Authorization of Qutenza® (Capsaicin 8% Patch)

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There were no prior authorization requests submitted for Qutenza® (capsaicin 8% patch) during fiscal year 2016.

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### Market News and Updates<sup>57</sup>

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**Anticipated Patent Expiration(s):** Qutenza® (capsaicin 8% patch): November 2017

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### Recommendations

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

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<sup>57</sup>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 01/2017. Last accessed 03/03/2017.

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# Fiscal Year 2016 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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#### Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with protein restricted diet; and
3. A patient-specific, clinically significant reason why member cannot use Buphenyl® (sodium phenylbutyrate).

### Utilization of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2016

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#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1	4	\$25,476.88	\$6,369.22	\$197.50	200	129
2016	3	32	\$470,850.61	\$14,714.08	\$510.68	3,025	922
% Change	200%	700%	1,748.10%	131.00%	158.60%	1,412.50%	614.70%
Change	2	28	\$445,373.73	\$8,344.86	\$313.18	2,825	793

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- Due to the small number of members utilizing Ravicti® (glycerol phenylbutyrate), detailed demographic information cannot be provided.

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

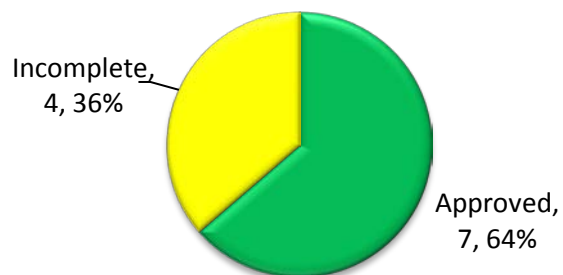
- The only prescriber specialty listed on paid pharmacy claims for Ravicti® (glycerol phenylbutyrate) during fiscal year 2016 was a genetic counselor.

### Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

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There were 11 prior authorization request submitted for Ravicti® (glycerol phenylbutyrate) during fiscal year 2016. The following chart shows the status of the submitted petitions.

### Status of Petitions



### Market News and Updates<sup>58</sup>

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**Anticipated Patent Expiration(s):** Ravicti® (glycerol phenylbutyrate): March 2032

### Recommendations

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

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<sup>58</sup>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 1/2017. Last accessed 03/03/2017.

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# Fiscal Year 2016 Annual Review of Rayos® (Prednisone Delayed-Release)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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

1. Approval requires a patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications.

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### Utilization of Rayos® (Prednisone Delayed-Release): Fiscal Year 2016

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There was no utilization of Rayos® (prednisone delayed-release) during fiscal year 2016.

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### Prior Authorization of Rayos® (Prednisone Delayed-Release)

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There was 1 prior authorization request submitted for Rayos® (prednisone delayed-release) during fiscal year 2016, which was incomplete.

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### Market News and Updates<sup>59</sup>

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#### Anticipated Patent Expiration(s):

- Rayos® (prednisone delayed-release): August 2027

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### Recommendations

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The College of Pharmacy does not recommend any changes to the Rayos® (prednisone delayed-release) prior authorization criteria at this time.

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<sup>59</sup>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 01/2017. Last accessed 03/06/2017.



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# Fiscal Year 2016 Annual Review of Retisert® (Fluocinolone Intravitreal Implant)

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Oklahoma Health Care Authority  
Fiscal Year 2016 Print Report

## Current Prior Authorization Criteria

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### 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 2016

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There was no utilization of Retisert® (fluocinolone intravitreal implant) during fiscal year 2016.

## Prior Authorization of Retisert® (Fluocinolone Intravitreal Implant)

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There were no prior authorization requests submitted for Retisert® (fluocinolone intravitreal implant) during fiscal year 2016.

## Market News and Updates<sup>60</sup>

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### Anticipated Patent Expiration(s):

- Retisert® (fluocinolone intravitreal implant): March 2019

## Recommendations

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The College of Pharmacy does not recommend any changes to the Retisert® (fluocinolone intravitreal implant) prior authorization criteria at this time.

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<sup>60</sup>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 01/2017. Last accessed 03/06/2017.

# Fiscal Year 2016 Annual Review of Ribavirin Unique Dosage Formulation Products

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

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

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

### Utilization of Ribavirin Products: Fiscal Year 2016

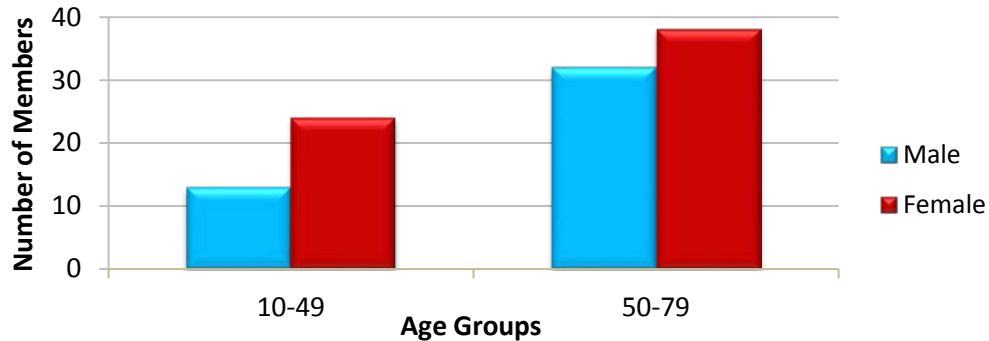
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	164	436	\$54,180.77	\$118.86	\$4.25	69,060	12,270
2016	107	309	\$33,554.48	\$108.59	\$3.91	44,728	8,592
% Change	-34.80%	-29.60%	-35.70%	-8.60%	-8.00%	-35.20%	-30.00%
Change	-57	-130	-\$18,626.29	-\$10.27	-\$0.34	-24,332	-3,678

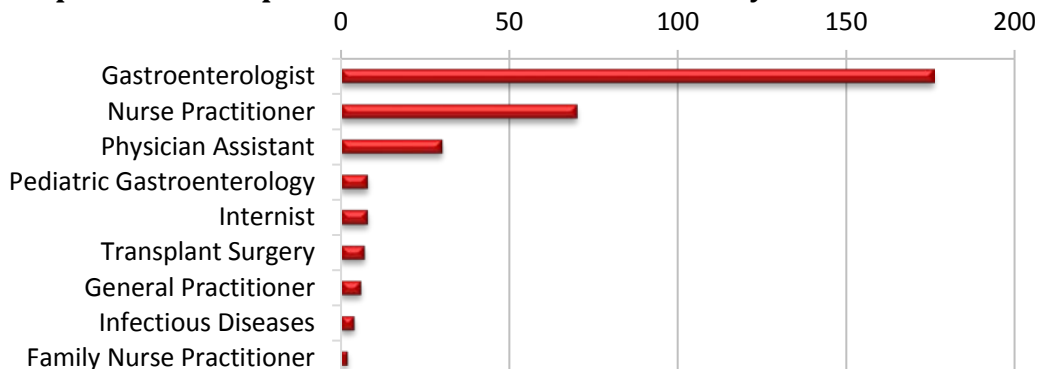
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Ribavirin Products



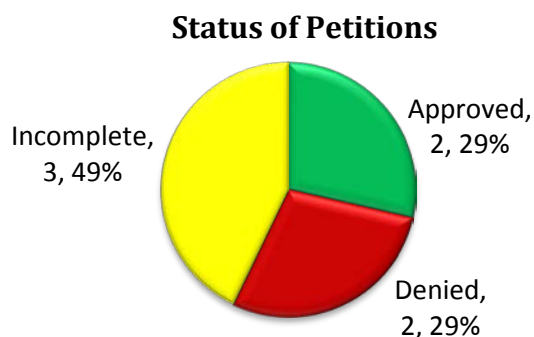
#### Top Prescriber Specialties of Ribavirin Products by Number of Claims



## Prior Authorization of Ribavirin Products

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There were 7 prior authorization requests submitted for ribavirin products during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>61</sup>

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**Anticipated Patent Expiration(s):** Rebetol® (ribavirin solution): October 2023

## Recommendations

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The College of Pharmacy does not recommend any changes to the ribavirin unique dosage formulation prior authorization criteria at this time.

## Utilization Details of Ribavirin Products: Fiscal Year 2016

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PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
RIBAVIRIN CAP 200 MG	34	11	\$5,541.92	\$5.82	\$163.00	16.51%
RIBAVIRIN TAB 200 MG	275	98	\$28,012.56	\$3.67	\$101.86	74.54%
<b>TOTAL</b>	<b>309</b>	<b>109</b>	<b>\$33,554.48</b>	<b>\$3.91</b>	<b>\$108.59</b>	<b>100%</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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<sup>61</sup> 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 01/2017. Last accessed 03/2017.

# Fiscal Year 2016 Annual Review of Smoking Cessation Products

## Oklahoma Health Care Authority Fiscal Year 2016 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. Effective March 2016, the duration of therapy limit of 180 days was removed for smoking cessation products excluding Chantix® (varenicline). Chantix® (varenicline) may only be used for up to 180 days per calendar year per member.
3. Smoking cessation products do not count against the six prescription monthly limit.
4. Smoking cessation products are available without a co-pay.

### Utilization of Smoking Cessation Products: Fiscal Year 2016

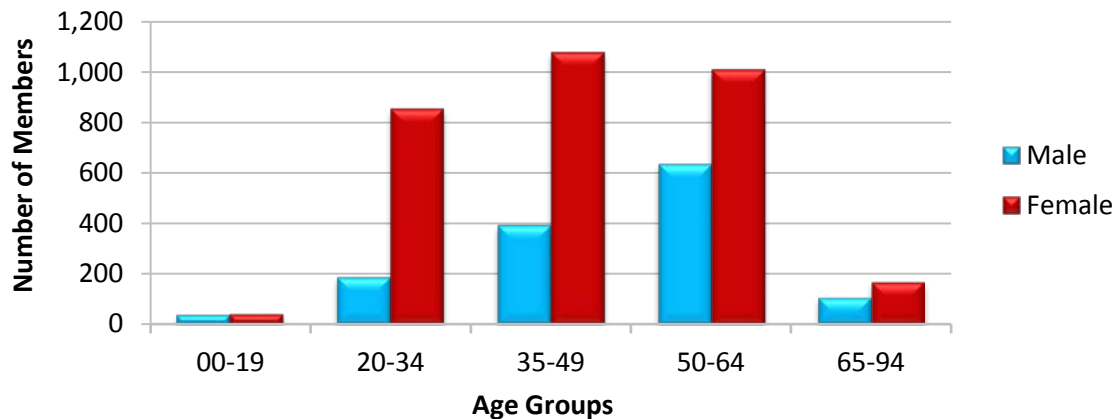
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	3,956	7,158	\$1,087,879.01	\$151.98	\$6.18	374,484	176,091
2016	4,506	8,943	\$1,411,017.29	\$157.78	\$6.54	442,831	215,623
% Change	13.90%	24.90%	29.70%	3.80%	5.80%	18.30%	22.40%
Change	550	1,785	\$323,138.28	\$5.80	\$0.36	68,347	39,532

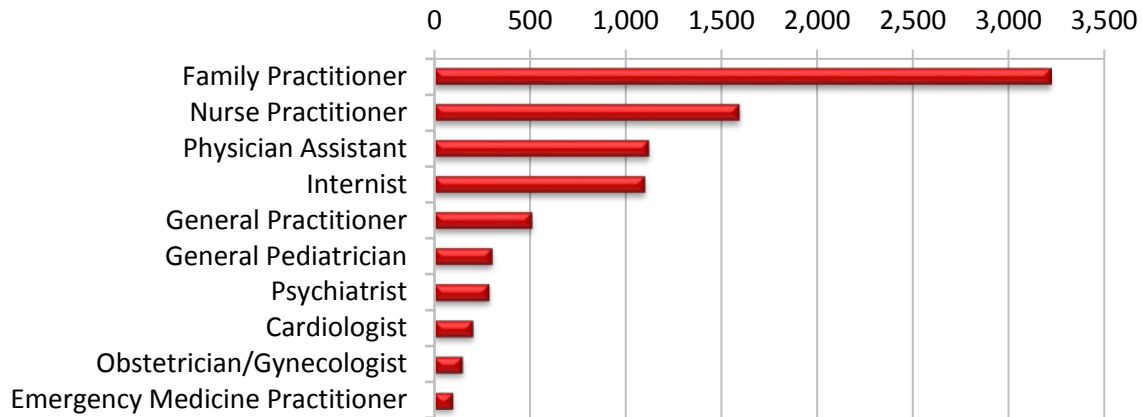
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Smoking Cessation Products

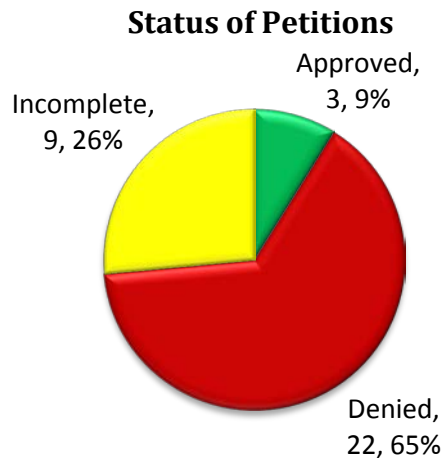


## Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



## Prior Authorization of Smoking Cessation Products

There were 34 prior authorization requests submitted for smoking cessation products during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>62,63</sup>

**Anticipated Patent Expiration(s):** Chantix® (varenicline): August 2022

### News:

- December 2016:** The U.S. Food and Drug Administration (FDA) announced the removal of the *Boxed Warning* from the Chantix® (varenicline) drug label. Based on the review of a large clinical trial the FDA required the manufacturers to conduct, it was determined that the risk of serious side effects on mood, behavior, or thinking from Chantix® (varenicline) is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for

<sup>62</sup> 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 02/2017. Last accessed 03/2017.

<sup>63</sup> FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings. Available online at: <https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm>. Issued 12/16/2016. Last accessed 03/29/2017.

mental illnesses in the past. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines. Zyban® (bupropion), another smoking cessation medication, was also included in this trial and its label underwent the same revision.

## Recommendations

The College of Pharmacy does not recommend any changes to the smoking cessation coverage criteria at this time.

## Utilization Details of Smoking Cessation Products: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
<b>BUPROPION PRODUCTS</b>					
BUPROBAN TAB 150MG	4	4	\$196.48	\$1.62	\$49.12
BUPROPION TAB 150MG	138	89	\$4,556.66	\$1.08	\$33.02
<b>SUBTOTAL</b>	<b>142</b>	<b>93</b>	<b>\$4,753.14</b>	<b>\$1.10</b>	<b>\$33.47</b>
<b>VARENICLINE PRODUCTS</b>					
CHANTIX PAK 0.5 & 1MG	1,820	1,615	\$545,768.40	\$10.32	\$299.87
CHANTIX PAK 1MG	1,021	602	\$307,891.08	\$10.57	\$301.56
CHANTIX TAB 0.5MG	83	66	\$18,595.20	\$9.93	\$224.04
CHANTIX TAB 1MG	743	378	\$223,338.45	\$10.45	\$300.59
<b>SUBTOTAL</b>	<b>3,667</b>	<b>1,990</b>	<b>\$1,095,593.13</b>	<b>\$10.41</b>	<b>\$298.77</b>
<b>NICOTINE REPLACEMENT PRODUCTS</b>					
NICORELIEF GUM 2MG ORIG	12	11	\$480.66	\$2.97	\$40.06
NICORELIEF GUM 4MG ORIG	12	6	\$395.43	\$2.15	\$32.95
NICORELIEF GUM 2MG MINT	98	78	\$15,097.74	\$5.14	\$154.06
NICORELIEF GUM 4MG MINT	13	6	\$624.44	\$2.52	\$48.03
NICORETTE GUM 2MG CINN	13	4	\$626.40	\$2.38	\$48.18
NICORETTE GUM 2MG ORIG	7	6	\$414.96	\$3.17	\$59.28
NICORETTE GUM 2MG FRUIT	8	6	\$566.56	\$3.37	\$70.82
NICORETTE GUM 4MG ORIG	1	1	\$121.45	\$4.34	\$121.45
NICORETTE GUM 2MG MINT	21	14	\$1,248.28	\$2.77	\$59.44
NICORETTE GUM 4MG CINN	18	8	\$1,135.47	\$2.51	\$63.08
NICORETTE GUM 4MG MINT	24	19	\$2,216.16	\$4.05	\$92.34
NICORETTE GUM 4MG FRUIT	21	14	\$1,049.76	\$3.32	\$49.99
NICORETTE ST GUM 2MG MINT	7	6	\$350.83	\$3.25	\$50.12
NICORETTE ST GUM 2MG ORIG	3	2	\$144.59	\$2.41	\$48.20
NICORETTE ST GUM 4MG ORIG	5	4	\$500.34	\$4.00	\$100.07
NICOTINE GUM 2MG	25	6	\$709.58	\$2.61	\$28.38
NICOTINE GUM 2MG MINT	26	11	\$1,341.33	\$5.12	\$51.59
NICOTINE GUM 4MG	186	38	\$7,861.53	\$5.82	\$42.27
NICOTINE GUM 4MG MINT	28	11	\$2,537.65	\$5.00	\$90.63
NICOTINE GUM 4MG MINT	4	4	\$253.27	\$3.38	\$63.32
NICOTINE GUM 2MG ORIG	2	2	\$81.37	\$3.70	\$40.69
NICOTINE GUM 4MG MINT	3	3	\$223.68	\$2.80	\$74.56
NICOTINE POL GUM 2MG	30	12	\$975.95	\$2.20	\$32.53

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
NICOTINE POL GUM 2MG CINN	6	5	\$372.27	\$4.33	\$62.05
NICOTINE POL GUM 2MG MINT	13	10	\$579.57	\$2.60	\$44.58
NICOTINE POL GUM 2MG ORIG	5	4	\$157.64	\$1.04	\$31.53
NICOTINE POL GUM 4MG	3	2	\$186.72	\$4.45	\$62.24
NICOTINE POL GUM 4MG MINT	19	16	\$1,189.53	\$4.31	\$62.61
NICOTINE POL GUM 4MG ORIG	16	10	\$1,179.85	\$2.99	\$73.74
NICOTINE GUM 2MG MINT	4	4	\$246.77	\$3.16	\$61.69
NICORETTE LOZ 2MG MINT	11	10	\$582.37	\$3.47	\$52.94
NICORETTE LOZ 2MG ORIG	2	1	\$105.60	\$1.89	\$52.80
NICORETTE LOZ 4MG CHRY	4	3	\$267.34	\$2.78	\$66.84
NICORETTE LOZ 4MG MINT	48	12	\$2,343.67	\$3.71	\$48.83
NICOTINE LOZ 2MG MINT	36	7	\$1,254.09	\$2.41	\$34.84
NICOTINE LOZ 2MG MINT	10	6	\$420.83	\$6.47	\$42.08
NICOTINE LOZ 4MG MINT	19	12	\$661.63	\$3.96	\$34.82
NICOTINE LOZ 4MG MINT	13	6	\$431.52	\$2.94	\$33.19
NICOTINE LOZ 2MG MINT	30	17	\$1,235.94	\$2.23	\$41.20
NICOTINE LOZ 4MG MINT	25	12	\$1,235.40	\$2.73	\$49.42
NICOTINE LOZ MINI 2MG	1	1	\$35.86	\$3.59	\$35.86
NICOTINE SYS KIT TRANSDER	4	4	\$374.79	\$1.67	\$93.70
NICOTROL INH	111	88	\$41,256.18	\$15.22	\$371.68
NICOTROL NS SPR 10MG/ML	29	27	\$12,834.59	\$18.87	\$442.57
NICODERM CQ DIS 14MG/24H	248	187	\$14,489.05	\$2.74	\$58.42
NICODERM CQ DIS 21MG/24H	480	344	\$30,991.82	\$3.00	\$64.57
NICODERM CQ DIS 7MG/24H	79	70	\$4,020.49	\$2.88	\$50.89
NICOTINE DIS 14MG/24H	92	54	\$4,986.51	\$2.69	\$54.20
NICOTINE DIS 14MG/24H	74	45	\$4,031.79	\$2.63	\$54.48
NICOTINE DIS 21MG	60	38	\$4,054.49	\$2.79	\$67.57
NICOTINE DIS 21MG/24H	198	90	\$9,971.66	\$2.63	\$50.36
NICOTINE DIS 7MG/24HR	25	18	\$1,020.63	\$2.75	\$40.83
NICOTINE DIS 14MG/24H	245	183	\$10,456.64	\$2.16	\$42.68
NICOTINE DIS 21MG/24H	482	347	\$23,614.19	\$2.09	\$48.99
NICOTINE DIS 7MG/24HR	97	76	\$4,013.12	\$2.23	\$41.37
NICOTINE TD DIS 14MG/24H	668	425	\$28,453.33	\$2.08	\$42.59
NICOTINE TD DIS 21MG/24H	1,113	742	\$53,060.77	\$2.06	\$47.67
NICOTINE TD DIS 7MG/24HR	297	216	\$11,596.94	\$2.07	\$39.05
<b>SUBTOTAL</b>	<b>5,134</b>	<b>2,546</b>	<b>\$310,671.02</b>	<b>\$2.93</b>	<b>\$60.51</b>
<b>TOTAL</b>	<b>8,943</b>	<b>4,506*</b>	<b>\$1,411,017.29</b>	<b>\$6.54</b>	<b>\$157.78</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

# Fiscal Year 2016 Annual Review of Soliris® (Eculizumab)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Soliris® (Eculizumab) Approval Criteria:

1. Established diagnosis of paroxysmal nocturnal hemoglobinuria or atypical hemolytic uremic syndrome via International Classification of Disease (ICD) coding in a member's medical claims.
2. An age restriction of 18 years and older will apply.
3. For members under 18 years of age, approval can be granted with a documented diagnosis of atypical hemolytic uremic syndrome.

### Utilization of Soliris® (Eculizumab): Fiscal Year 2016

#### Soliris® (Eculizumab) Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	5	68	\$1,344,942.33	\$19,778.56	6,840
2016	2	29	\$762,685.20	\$26,299.49	3,540
% Change	-60.00%	-57.35%	-43.29%	32.97%	-48.25%
Change	-3	-39	-\$58,2257.13	\$6,520.93	-3,300

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Soliris® (Eculizumab) Fiscal Year comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	4	83	\$1,721,852.82	\$20,745.21	\$1,538.74	11,560	1,119
2016	4	80	\$1,729,571.78	\$21,619.65	\$1,525.20	10,640	1,134
% Change	0.00%	-3.60%	0.40%	4.20%	-0.90%	-8.00%	1.30%
Change	0	-3	\$7,718.96	\$874.44	-\$13.54	-920	15

\*Total number of unduplicated members.

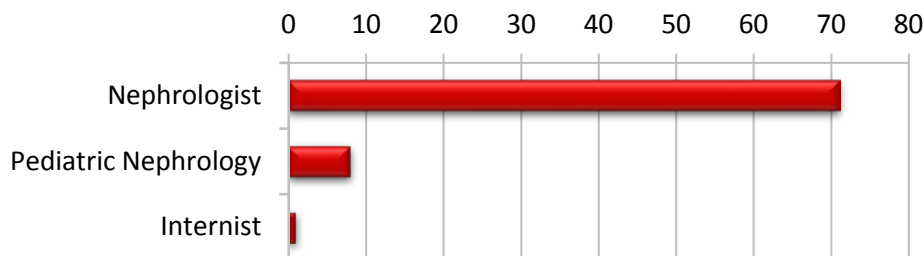
Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Soliris® (Eculizumab)

- Due to the small number of members utilizing Soliris® (eculizumab) during fiscal year 2016, detailed demographic information could not be provided.



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



### Prior Authorization of Soliris® (Eculizumab)

There were 5 prior authorization requests submitted Soliris® (eculizumab) during fiscal year 2016. All 5 prior authorization requests were approved.

### Market News & Updates<sup>64,65,66</sup>

#### News:

- **June 2016:** Alexion Pharmaceuticals, Inc. announced topline results from the REGAIN study, a Phase 3 registration trial of eculizumab (Soliris®) in patients with refractory generalized myasthenia gravis (gMG). Refractory gMG is an ultra-rare segment of MG, a debilitating, complement-mediated neuromuscular disease, in which patients have largely exhausted conventional therapy and continue to suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness, and episodes of respiratory failure. In the study, the primary efficacy endpoint of change from baseline in Myasthenia Gravis-Activities of Daily Living Profile (MG-ADL) total score, a patient-reported assessment, at week 26, did not reach statistical significance ( $p=0.0698$ ) as measured by a worst-rank analysis. However, the first three secondary endpoints and a series of prospectively defined sensitivity analyses, shows early and sustained substantial improvements over 26 weeks for patients treated with eculizumab compared to placebo. Secondary endpoints include change from baseline in Quantitative Myasthenia Gravis (QMG) total score, a physician-administered assessment of MG clinical severity, with eculizumab treatment compared to placebo at week 26. Alexion continues to analyze the data from the REGAIN study, and point out that the findings from this study underscore the pivotal role of complement inhibition in addressing the underlying pathophysiology of refractory gMG.

<sup>64</sup> Alexion Pharmaceuticals, Inc. Alexion Announces Topline Results From Phase 3 REGAIN Study of Eculizumab (Soliris®) In Patients With Refractory Generalized Myasthenia Gravis (GMG). Available online at: <http://news.alexionpharma.com/press-release/product-news/alexion-announces-topline-results-phase-3-regain-study-eculizumab-soliris>. Last revised 06/06/2016. Last accessed 03/30/2017.

<sup>65</sup> Alexion Pharmaceuticals, Inc. Alexion Announces Top-Line Results From Phase 2/3 PROTECT Study of Eculizumab (Soliris®) For The Prevention Of Delayed Graft Function (DGF) After Kidney Transplant. Available online at: <http://news.alexionpharma.com/press-release/product-news/alexion-announces-top-line-results-phase-23-protect-study-eculizumab-soli>. Last revised 12/21/2016. Last accessed 03/30/2017.

<sup>66</sup> Alexion Pharmaceuticals, Inc. FDA Accepts SBLA Filing of Soliris® (Eculizumab) As A Potential Treatment For Patients With Refractory Generalized Myasthenia Gravis (GMG). Available online at: <http://news.alexionpharma.com/press-release/product-news/fda-accepts-sbla-filing-soliris-eculizumab-potential-treatment-patients-r>. Last revised 8/8/2017. Last accessed 03/30/2017.

- **December 2016:** Alexion Pharmaceuticals, Inc. provided results from the PROTECT study, a placebo-controlled Phase 2/3 study of eculizumab for the prevention of delayed graft function (DGF) after kidney transplantation in adult recipients of a deceased donor kidney over 26 weeks with follow-up over 52 weeks (n=286). The primary endpoint of incidence of DGF, death, graft loss or loss to follow-up at 7 days post-transplant was 35.9% with a two-dose regimen of eculizumab compared to 41.7% for patients receiving placebo, which was not statistically significant (p=0.398). Eculizumab currently has orphan drug status for the prevention of DGF in renal transplant patients.
- **March 2017:** The U.S. Food and Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) to extend the indication for Soliris® (eculizumab) as a potential treatment for patients with refractory generalized myasthenia gravis (GMG) who are anti-acetylcholine receptor (AChR) antibody-positive. The FDA set a Prescription Drug User Fee Act (PDUFA) date of October 23, 2017.

## **Recommendations**

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

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## **Fiscal Year 2016 Annual Review of Sylvant® (Siltuximab)**

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### **Oklahoma Health Care Authority Fiscal Year 2016 Print Report**

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#### **Current Prior Authorization Criteria**

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##### **Sylvant® (Siltuximab) Approval Criteria:**

1. An FDA approved diagnosis of Multicentric Castlemann's Disease (also known as giant lymph node hyperplasia); and
2. Member must be Human Immunodeficiency Virus (HIV) and Human Herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
  - a. 11mg/kg via intravenous (IV) infusion every three 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 three doses thereafter; and
7. Approvals will be for the duration of six months.

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#### **Utilization of Sylvant® (Siltuximab): Fiscal Year 2016**

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There was no utilization of Sylvant® (siltuximab) during fiscal year 2016.

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#### **Prior Authorization of Sylvant® (Siltuximab)**

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There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2016.

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#### **Recommendations**

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

# Fiscal Year 2016 Annual Review of Symlin® (Pramlintide)

## Oklahoma Health Care Authority Fiscal Year 2016 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 a basal-bolus insulin regimen or be gaining excessive weight on a basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a healthcare professional.

#### Members Meeting Any of the Following Criteria Should Not be Considered for Symlin® (Pramlintide) Therapy:

1. Poor compliance with insulin regimen; or
2. Poor compliance with self-blood glucose monitoring; or
3. HbA1c > 9%; or
4. Recurrent severe hypoglycemia requiring assistance in the past six months; or
5. Presence of hypoglycemia unawareness; or
6. Diagnosis of gastroparesis; or
7. Required use of medications that stimulate gastrointestinal motility; or
8. Pediatric patients 15 years of age or younger

### Utilization of Symlin® (Pramlintide): Fiscal Year 2016

#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	1	3	\$3,900.32	\$1,300.11	\$43.34	32	90
2016	1	5	\$8,142.08	\$1,628.42	\$54.28	54	150
% Change	0%	66.70%	108.80%	41.80%	25.20%	68.80%	66.70%
Change	0	2	\$4,241.76	\$384.90	\$10.94	22	60

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Symlin® (Pramlintide)

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

#### Top Prescriber Specialties of Symlin® (Pramlintide)

- The only prescriber specialty listed on paid pharmacy claims for Symlin® (pramlintide) during fiscal year 2016 was an internist.

## **Prior Authorization of Symlin® (Pramlintide)**

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There were two prior authorization requests submitted for Symlin® (pramlintide) during fiscal year 2016, one was approved and the other was incomplete.

## **Market News and Updates<sup>67</sup>**

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**Anticipated Patent Expiration(s):** Symlin® (pramlintide): March 2019

## **Recommendations**

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

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<sup>67</sup> 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 01/2017. Last accessed 03/20/2017.

# Fiscal Year 2016 Annual Review of Topical Antibiotic Products

## Oklahoma Health Care Authority Fiscal Year 2016 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/hydrocortisone) cream 0.5%	Bactroban® (mupirocin) cream 2%
Cortisporin® (neomycin/polymyxin B sulfates/bacitracin zinc/hydrocortisone) 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.

### Topical Antibiotic Tier-2 Approval Criteria:

1. Documented five day trial of a Tier-1 product within the last 30 days.
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 ten days.

### Utilization of Topical Antibiotic Products: Fiscal Year 2016

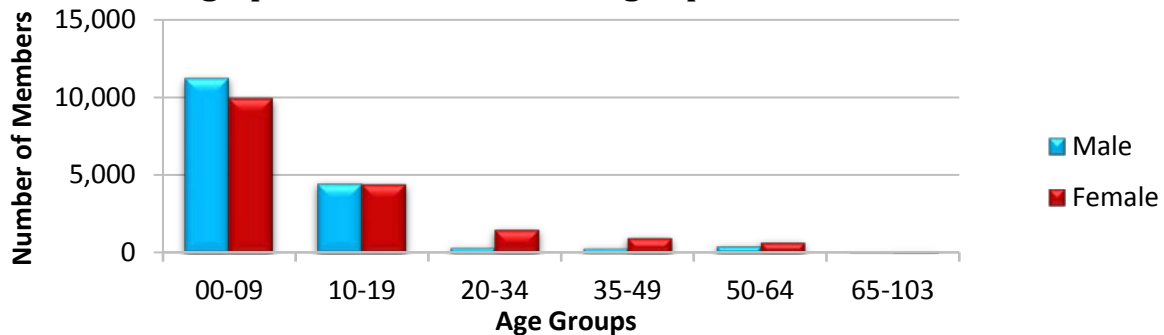
#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	30,836	36,425	\$480,746.66	\$13.20	\$1.20	890,967	401,342
2016	34,616	40,895	\$557,871.68	\$13.64	\$1.25	962,543	446,636
% Change	12.30%	12.30%	16.00%	3.30%	4.20%	8.00%	11.30%
Change	3,780	4,470	\$77,125.02	\$0.44	\$0.05	71,576	45,294

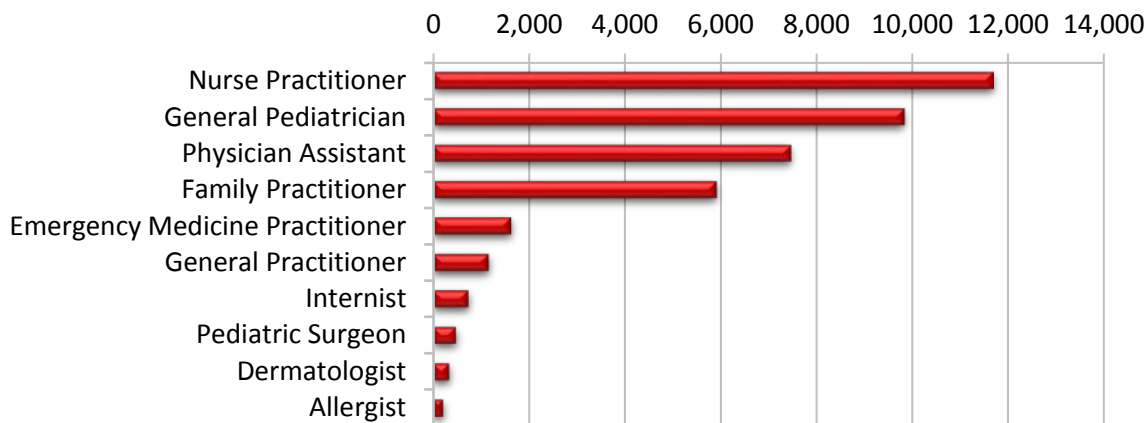
\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

### Demographics of Members Utilizing Topical Antibiotic Products

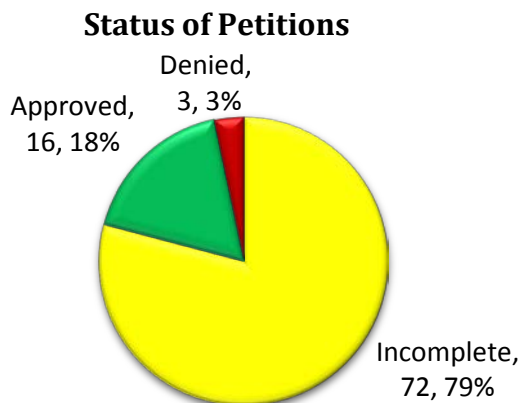


## Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims



## Prior Authorization of Topical Antibiotic Products

There were 91 prior authorization requests submitted for topical antibiotic products during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>68</sup>

### Anticipated Patent Expiration(s):

- Centany® (mupirocin) kit 2%: July 2018
- Altabax® (retapamulin): February 2027

## Recommendations

The College of Pharmacy does not recommend any changes to the topical antibiotic product prior authorization criteria at this time.

<sup>68</sup> 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 02/2017. Last accessed 03/27/2017.

## Utilization Details of Topical Antibiotic Products: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
MUPIROCIN OIN 2%	40,326	34,361	\$518,474.70	\$1.18	\$12.86
GENTAMICIN OIN 0.1%	343	176	\$23,784.44	\$6.21	\$69.34
GENTAMICIN CRE 0.1%	113	77	\$5,363.05	\$3.02	\$47.46
CORTISPORIN CRE 0.5%	51	37	\$4,233.52	\$7.29	\$83.01
CORTISPORIN OIN 1%	10	10	\$1,681.66	\$20.76	\$168.17
BACTROBAN OIN 2%	10	10	\$129.04	\$1.33	\$12.90
GENTAMICIN POW SULFATE	7	1	\$181.83	\$0.87	\$25.98
<b>TIER-1 SUBTOTAL</b>	<b>40,860</b>	<b>34,672</b>	<b>\$553,848.24</b>	<b>\$1.24</b>	<b>\$13.55</b>
<b>TIER-2 PRODUCTS</b>					
MUPIROCIN CRE 2%	32	25	\$3,777.57	\$7.26	\$118.05
ALTABAX OIN 1%	1	1	\$163.84	\$32.77	\$163.84
MUPIROCIN CA CRE 2%	1	1	\$65.93	\$9.42	\$65.93
CENTANY OIN 2%	1	1	\$16.10	\$1.61	\$16.10
<b>TIER-2 SUBTOTAL</b>	<b>35</b>	<b>28</b>	<b>\$4,023.44</b>	<b>\$7.42</b>	<b>\$114.96</b>
<b>TOTAL</b>	<b>40,895</b>	<b>34,616*</b>	<b>\$557,871.68</b>	<b>\$1.25</b>	<b>\$13.64</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.



# Fiscal Year 2016 Annual Review of Topical Antifungal Products

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

Topical Antifungal Products		
Tier-1	Tier-2	Special PA
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
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®)	

\*Over the counter (OTC) antifungal medications are covered for pediatric members 0-20 years of age without 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.

### Topical Antifungal Tier-2 Approval Criteria:

1. Documented, recent trials with at least two Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (foams, shampoos, sprays, kits, etc.).
3. Authorization of combination products (nystatin/triamcinolone cream, nystatin/triamcinolone ointment, 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 Tier-1 clotrimazole/betamethasone 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 the member cannot use Penlac® (ciclopirox solution); and
4. A clinically significant reason why the member requires treatment for onychomycosis (cosmetic reasons will not be approved).

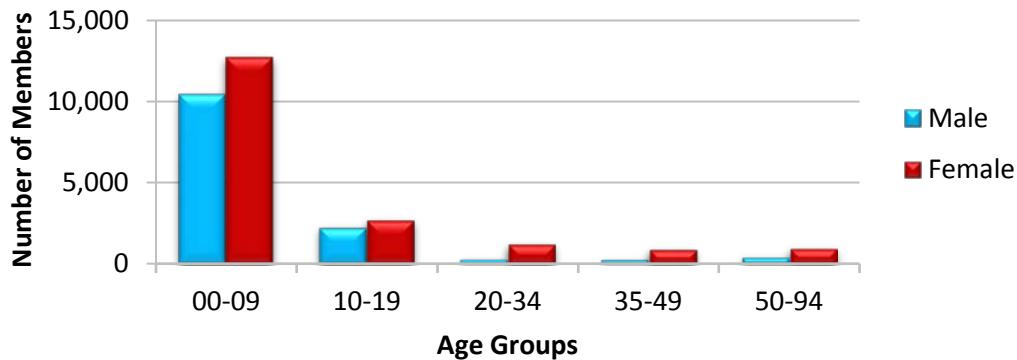
**Utilization of Topical Antifungal Products: Fiscal Year 2016**

**Comparison of Fiscal Years**

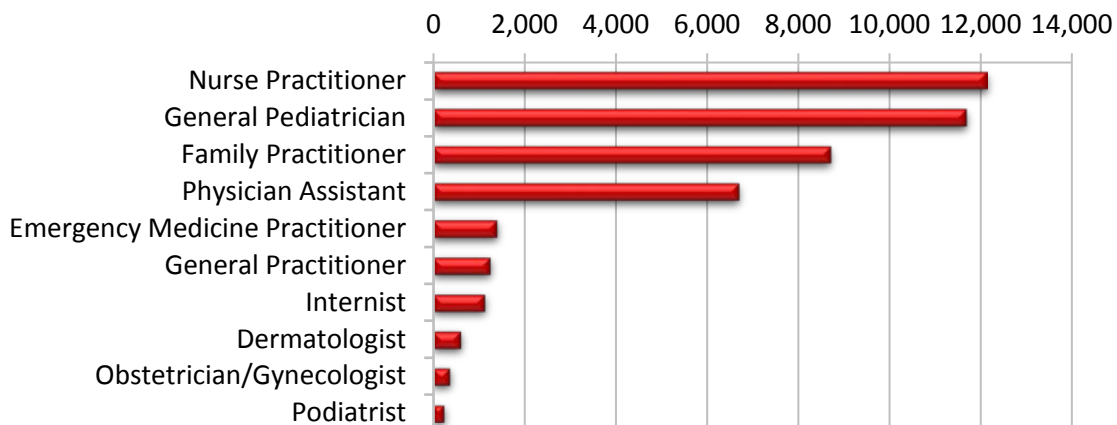
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	31,009	44,095	\$1,029,658.83	\$23.35	\$1.64	1,603,962	629,268
2016	32,167	45,813	\$1,112,623.90	\$24.29	\$1.65	1,687,267	672,747
% Change	3.70%	3.90%	8.10%	4.00%	0.60%	5.20%	6.90%
Change	1,158	1,718	\$82,965.07	\$0.94	\$0.01	83,305	43,479

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

**Demographics of Members Utilizing Topical Antifungal Products**



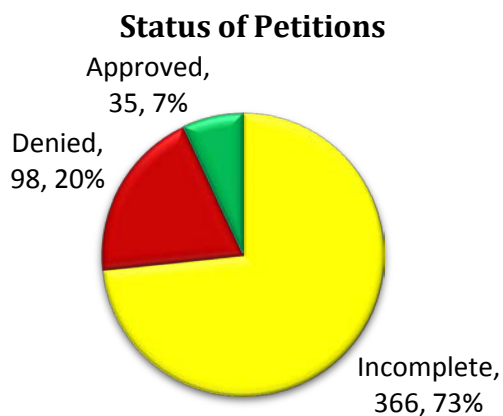
**Top Prescriber Specialties of Topical Antifungal Products by Number of Claims**



## Prior Authorization of Topical Antifungal Products

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There were 499 prior authorization requests submitted for topical antifungal products during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>69</sup>

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### Anticipated Patent Expiration(s):

- Loprox® (ciclopirox 1% shampoo): September 2017
- Loprox® (ciclopirox 0.77% gel): September 2018
- Extina® (ketoconazole foam 2%): October 2018
- Xolegel® (ketoconazole gel): November 2020
- Kerydin® (tavaborole 5% solution): May 2027
- Vusion® (miconazole/zinc oxide/white petrolatum): March 2028
- Jublia® (efinaconazole 10% topical solution): October 2030
- Naftin® (naftifine gel 2%): January 2033
- Luzu™ (luliconazole): April 2034

## Recommendations

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

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<sup>69</sup> 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 02/2017. Last accessed 03/28/2017.

## Utilization Details of Topical Antifungal Products: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>TIER-1 PRODUCTS</b>					
<b>CICLOPIROX PRODUCTS</b>					
CICLOPIROX CRE 0.77%	573	452	\$12,129.53	\$1.41	\$21.17
CICLOPIROX SUS 0.77%	5	1	\$143.23	\$1.10	\$28.65
<b>SUBTOTAL</b>	<b>578</b>	<b>453</b>	<b>\$12,272.76</b>	<b>\$1.41</b>	<b>\$21.23</b>
<b>CLOTRIMAZOLE PRODUCTS</b>					
CLOTRIMAZOLE CRE 1%	9,310	7,738	\$155,888.70	\$1.20	\$16.74
ATHLETE FOOT CRE 1%	28	27	\$206.88	\$0.74	\$7.39
CLOTRIMAZOLE POW	12	9	\$99.31	\$0.28	\$8.28
CLOTRIM/BETA CRE DIPROP	6	4	\$251.87	\$1.87	\$41.98
CLOTRIM/BETA CRE 1-0.05%	4	1	\$171.16	\$1.43	\$42.79
<b>SUBTOTAL</b>	<b>9,360</b>	<b>7,779</b>	<b>\$156,617.92</b>	<b>\$1.20</b>	<b>\$16.73</b>
<b>KETOCONAZOLE PRODUCTS</b>					
KETOCONAZOLE CRE 2%	4,374	3,663	\$187,721.54	\$2.60	\$42.92
KETOCONAZOLE SHA 2%	2,933	1,864	\$40,639.46	\$0.46	\$13.86
<b>SUBTOTAL</b>	<b>7,307</b>	<b>5,527</b>	<b>\$228,361.00</b>	<b>\$1.42</b>	<b>\$31.25</b>
<b>NYSTATIN PRODUCTS</b>					
NYSTATIN CRE 100000	15,915	12,397	\$254,557.50	\$1.28	\$15.99
NYSTATIN OIN 100000	6,521	5,429	\$136,314.22	\$1.69	\$20.90
NYSTOP POW 100000	2,263	1,562	\$56,450.17	\$1.68	\$24.94
NYSTATIN POW 100000	1,341	859	\$34,332.20	\$1.78	\$25.60
NYAMYC POW 100000	613	255	\$18,344.12	\$2.50	\$29.93
<b>SUBTOTAL</b>	<b>26,653</b>	<b>20,502</b>	<b>\$499,998.21</b>	<b>\$1.47</b>	<b>\$18.76</b>
<b>TERBINAFINE PRODUCTS</b>					
TERBINAFINE CRE 1%	451	418	\$5,976.89	\$0.87	\$13.25
ATHLETE FOOT CRE 1%	53	47	\$789.81	\$0.90	\$14.90
LAMISIL AT CRE 1%	26	23	\$403.93	\$1.10	\$15.54
ATHLETE FOOT CRE AF	8	8	\$132.07	\$1.41	\$16.51
<b>SUBTOTAL</b>	<b>538</b>	<b>496</b>	<b>\$7,302.70</b>	<b>\$0.89</b>	<b>\$13.57</b>
<b>TOLNAFTATE PRODUCTS</b>					
TOLNAFTATE CRE 1%	14	13	\$130.96	\$0.54	\$9.35
ANTIFUNGAL CRE 1%	3	3	\$25.97	\$0.44	\$8.66
SM ANTIFUNGL CRE 1%	1	1	\$8.94	\$1.28	\$8.94
<b>SUBTOTAL</b>	<b>18</b>	<b>17</b>	<b>\$165.87</b>	<b>\$0.54</b>	<b>\$9.22</b>
<b>TIER-1 SUBTOTAL</b>	<b>44,454</b>	<b>34,774</b>	<b>\$904,718.46</b>	<b>\$1.39</b>	<b>\$20.35</b>
<b>TIER-2 PRODUCTS</b>					
<b>CICLOPIROX PRODUCTS</b>					
CICLOPIROX SOL 8%	14	9	\$384.98	\$0.92	\$27.50
<b>SUBTOTAL</b>	<b>14</b>	<b>9</b>	<b>\$384.98</b>	<b>\$0.92</b>	<b>\$27.50</b>
<b>CLOTRIMAZOLE PRODUCTS</b>					
CLOTRIMAZOLE SOL 1%	187	157	\$9,694.20	\$2.77	\$51.84
CLOTRIM/BETA LOT DIPROP	1	1	\$126.99	\$18.14	\$126.99
<b>SUBTOTAL</b>	<b>188</b>	<b>158</b>	<b>\$9,821.19</b>	<b>\$2.80</b>	<b>\$52.24</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM
<b>ECONAZOLE PRODUCTS</b>					
ECONAZOLE CRE 1%	1,153	938	\$197,292.32	\$10.30	\$171.11
<b>SUBTOTAL</b>	<b>1,153</b>	<b>938</b>	<b>\$197,292.32</b>	<b>\$10.30</b>	<b>\$171.11</b>
<b>NAFTIFINE PRODUCTS</b>					
NAFTIFINE CRE HCL 1%	1	1	\$7.48	\$1.50	\$7.48
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$7.48</b>	<b>\$1.50</b>	<b>\$7.48</b>
<b>NYSTATIN/TRIAMCINOLONE PRODUCTS</b>					
NYSTAT/TRIAM CRE	2	2	\$167.48	\$6.20	\$83.74
NYSTAT/TRIAM OIN	1	1	\$231.99	\$7.73	\$231.99
<b>SUBTOTAL</b>	<b>3</b>	<b>3</b>	<b>\$399.47</b>	<b>\$7.01</b>	<b>\$133.16</b>
<b>TIER-2 SUBTOTAL</b>	<b>1,359</b>	<b>1,109</b>	<b>\$207,905.44</b>	<b>\$8.98</b>	<b>\$152.98</b>
<b>TOTAL</b>	<b>45,813</b>	<b>32,167*</b>	<b>\$1,112,623.90</b>	<b>\$1.65</b>	<b>\$24.29</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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# Fiscal Year 2016 Annual Review of Vasomotor Symptom Medications

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### **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; 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 seven 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 six 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 greater than 65 years of age will generally not be approved without supporting information.
7. Approvals will be for the duration of six 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 greater than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of six 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.

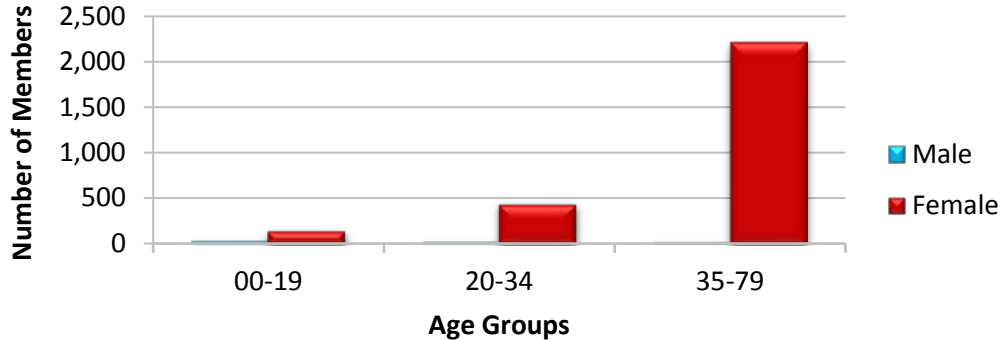
## Utilization of Vasomotor Symptom Medications: Fiscal Year 2016

### Comparison of Fiscal Years

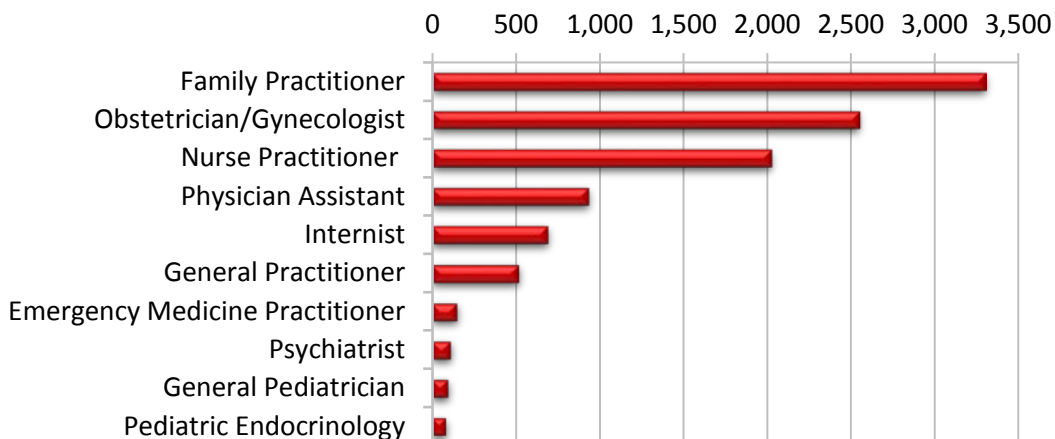
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2015	3,068	11,689	\$938,619.19	\$80.30	\$1.96	426,816	478,963
2016	2,825	10,706	\$977,462.01	\$91.30	\$2.19	402,425	445,366
% Change	-7.90%	-8.40%	4.10%	13.70%	11.70%	-5.70%	-7.00%
Change	-243	-983	\$38,842.82	\$11.00	\$0.23	-24,391	-33,597

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

### Demographics of Members Utilizing Vasomotor Symptom Medications



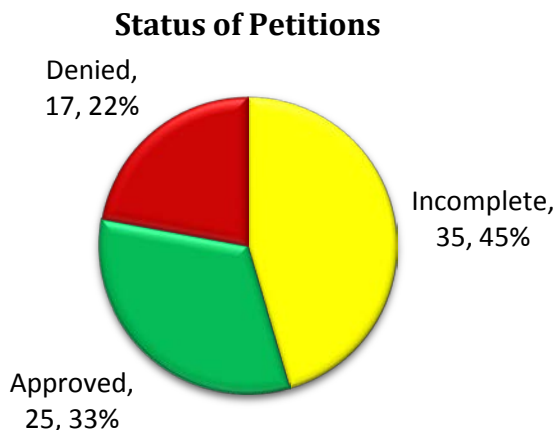
### Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



## Prior Authorization of Vasomotor Symptom Medications

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There were 77 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2016. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>70,71,72</sup>

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### Anticipated Patent Expiration(s):

- Enjuvia<sup>®</sup> (synthetic conjugated estrogen): March 2021
- Elestrin<sup>®</sup> Gel (estradiol gel): June 2022
- Evamist<sup>®</sup> (estradiol transdermal spray): July 2022
- Duavee<sup>®</sup> (conjugated estrogens/bazedoxifene): March 2027
- Brisdelle<sup>®</sup> (paroxetine): April 2029
- Minivelle<sup>®</sup> (estradiol transdermal system): July 2030
- Angeliq<sup>®</sup> (drospirenone and estradiol): October 2031

### Guideline Update:

- In 2016, the International Menopause Society (IMS) published new recommendations on women's midlife health and menopause hormone therapy (MHT) to help guide health-care professionals in optimizing their management of women in the menopause transition and beyond. For the first time, the 2016 IMS recommendations included grades of recommendations, levels of evidence, and 'good practice points', in addition to section-specific references. Included in the governing principles is that MHT remains the most effective therapy for vasomotor symptoms (VMS). Also that MHT must be individualized and tailored according to symptoms, the need for prevention, personal and family history, results of investigations, and each woman's preferences and expectations. IMS further indicated that MHT should not be recommended without a clear indication for its use, and women taking MHT should have at least an annual medical consultation. In regard to duration of treatment IMS states there are no reasons to place a mandatory limit on the duration of MHT. Dose and duration of MHT should be

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<sup>70</sup> 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/>. Last revised 11/2016. Last accessed 01/11/2017.

<sup>71</sup> Baber RJ, Panay N, Fenton A. 2016 IMS Recommendations on women's midlife health and menopause hormone therapy. *Climacteric* 2016; 19(2): 109-150.

<sup>72</sup> International Menopause Society. 2016 IMS Recommendations on women's midlife health and menopause hormone therapy. English slide show. Available online at: [http://www.imsociety.org/ims\\_recommendations.php](http://www.imsociety.org/ims_recommendations.php). Last revised 04/2016. Last accessed 02/27/2017.



consistent with treatment goals. Whether or not to continue should be decided at the discretion of the well-informed woman and her health professional. Included in the key points was that healthy women considering MHT for VMS should not be concerned that MHT will adversely affect cognitive function. Also, cognitive behavioral therapy, mindfulness training, acupuncture, hypnosis, and stellate ganglion blockade may be useful techniques to consider when treating VMS. Selective serotonin reuptake inhibitors and selective norepinephrine reuptake inhibitors (SSRIs/SNRIs) such as venlafaxine, desvenlafaxine, paroxetine, escitalopram and citalopram are effective in reducing VMS in postmenopausal women. It is also noted that gabapentin is effective in reducing VMS in higher doses but has more side-effects than the SNRIs/SSRIs.

## Recommendations

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

## Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2016

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
<b>ORAL ESTROGEN PRODUCTS</b>						
ESTRADIOL TAB 1MG	1,959	673	\$11,271.72	\$0.14	\$5.75	2.91
ESTRADIOL TAB 2MG	1,627	517	\$12,467.48	\$0.18	\$7.66	3.15
PREMARIN TAB 0.625MG	1,306	328	\$232,803.66	\$4.42	\$178.26	3.98
PREMARIN TAB 1.25MG	1,020	272	\$214,680.72	\$4.54	\$210.47	3.75
ESTRADIOL TAB 0.5MG	631	257	\$3,320.89	\$0.12	\$5.26	2.46
PREMARIN TAB 0.3MG	538	129	\$90,489.02	\$4.32	\$168.20	4.17
PREMARIN TAB 0.9MG	223	64	\$43,815.84	\$4.42	\$196.48	3.48
PREMARIN TAB 0.45MG	190	50	\$35,477.09	\$4.45	\$186.72	3.8
MENEST TAB 0.625MG	153	36	\$9,654.76	\$1.95	\$63.10	4.25
MENEST TAB 1.25MG	82	27	\$8,025.20	\$2.70	\$97.87	3.04
ESTROPIPATE TAB 0.75MG	67	14	\$1,402.28	\$0.48	\$20.93	4.79
ESTROPIPATE TAB 1.5MG	46	14	\$1,244.41	\$0.55	\$27.05	3.29
MENEST TAB 0.3MG	42	9	\$1,699.80	\$1.35	\$40.47	4.67
MENEST TAB 2.5MG	17	5	\$2,723.07	\$4.62	\$160.18	3.4
ENJUVIA TAB 1.25MG	15	5	\$1,493.44	\$2.45	\$99.56	3
ENJUVIA TAB 0.3MG	13	3	\$1,033.07	\$2.65	\$79.47	4.33
ESTROPIPATE TAB 3MG	11	2	\$684.77	\$1.20	\$62.25	5.5
ENJUVIA TAB 0.45MG	8	5	\$1,512.42	\$3.60	\$189.05	1.6
ENJUVIA TAB 0.9MG	3	1	\$239.64	\$2.66	\$79.88	3
<b>SUBTOTAL</b>	<b>7,951</b>	<b>2,411</b>	<b>\$674,039.28</b>	<b>\$2.00</b>	<b>\$84.77</b>	<b>3.61</b>
<b>TOPICAL ESTROGEN PRODUCTS</b>						
ESTRADIOL DIS 0.1MG	277	84	\$16,596.68	\$2.12	\$59.92	3.3
ESTRADIOL DIS 0.1MG	222	51	\$15,388.68	\$2.46	\$69.32	4.35
ESTRADIOL DIS 0.05MG	156	44	\$9,212.12	\$2.09	\$59.05	3.55
ESTRADIOL DIS 0.05MG	108	36	\$7,321.62	\$2.38	\$67.79	3
ESTRADIOL DIS 0.0375MG	86	16	\$5,470.29	\$2.26	\$63.61	5.38
ESTRADIOL DIS 0.075MG	70	15	\$4,468.85	\$2.27	\$63.84	4.67
ESTRADIOL DIS 0.0375MG	67	24	\$3,774.81	\$1.97	\$56.34	2.79
MINIVELLE DIS 0.1MG	62	16	\$4,487.73	\$2.54	\$72.38	3.88
ESTRADIOL DIS 0.025MG	57	21	\$2,941.42	\$1.83	\$51.60	2.71

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	CLAIMS/MEMBER
ESTRADIOL DIS 0.025MG	55	23	\$3,534.56	\$1.81	\$64.26	2.39
EVAMIST SPR 1.53MG	29	8	\$3,206.74	\$2.11	\$110.58	3.63
VIVELLE-DOT DIS 0.1MG	24	7	\$1,796.92	\$2.67	\$74.87	3.43
ALORA DIS 0.1MG	20	4	\$1,429.53	\$2.54	\$71.48	5
DIVIGEL GEL 1MG/GM	17	9	\$1,978.60	\$3.47	\$116.39	1.89
DIVIGEL GEL 0.5MG	17	8	\$1,859.87	\$3.76	\$109.40	2.13
MINIVELLE DIS 0.05MG	16	8	\$1,067.03	\$2.36	\$66.69	2
VIVELLE-DOT DIS 0.05MG	15	4	\$1,181.63	\$2.74	\$78.78	3.75
ESTRADIOL DIS 0.075MG	13	3	\$796.50	\$2.16	\$61.27	4.33
MENOSTAR DIS 14MCG	13	2	\$1,623.61	\$4.46	\$124.89	6.5
CLIMARA DIS 0.1MG	10	4	\$715.22	\$2.52	\$71.52	2.5
ALORA DIS 0.025MG	8	1	\$501.51	\$2.09	\$62.69	8
ESTRADIOL DIS 0.06MG	8	3	\$365.57	\$1.62	\$45.70	2.67
DIVIGEL GEL 0.25MG	7	3	\$731.73	\$3.48	\$104.53	2.33
CLIMARA DIS 0.025MG	6	1	\$393.80	\$2.34	\$65.63	6
ALORA DIS 0.05MG	3	3	\$239.47	\$2.85	\$79.82	1
MINIVELLE DIS 0.025 MG	3	1	\$199.86	\$2.22	\$66.62	3
CLIMARA DIS 0.075MG	2	1	\$138.08	\$2.47	\$69.04	2
ALORA DIS 0.075MG	2	1	\$133.80	\$2.39	\$66.90	2
VIVELLE-DOT DIS 0.025MG	2	2	\$129.46	\$1.54	\$64.73	1
ELESTRIN GEL 0.06%	2	1	\$370.18	\$6.17	\$185.09	2
<b>SUBTOTAL</b>	<b>1,377</b>	<b>404</b>	<b>\$92,055.87</b>	<b>\$2.29</b>	<b>\$66.85</b>	<b>4.19</b>
<b>INJECTABLE ESTROGEN PRODUCTS</b>						
DEPO-ESTRADI INJ 5MG/ML	256	128	\$17,327.02	\$0.74	\$67.68	2
ESTRAD VAL INJ 20MG/ML	14	11	\$1,731.69	\$1.03	\$123.69	1.27
ESTRAD VAL INJ 200MG/5	3	3	\$587.19	\$2.17	\$195.73	1
DELESTROGEN 20MG/ML	2	2	\$235.20	\$1.31	\$117.60	1
<b>SUBTOTAL</b>	<b>275</b>	<b>144</b>	<b>\$19,881.10</b>	<b>\$0.78</b>	<b>\$72.29</b>	<b>1.92</b>
<b>ESTROGEN POWDER PRODUCTS</b>						
ESTRIOL POW MICRONIZ	84	25	\$5,809.02	\$2.08	\$69.16	3.36
ESTRADIOL POW	25	9	\$1,099.30	\$1.52	\$43.97	2.78
ESTRADIOL MICRO POW	7	2	\$527.09	\$2.51	\$75.30	3.5
<b>SUBTOTAL</b>	<b>116</b>	<b>36</b>	<b>\$7,435.41</b>	<b>\$2.00</b>	<b>\$64.10</b>	<b>3.41</b>
<b>VAGINAL ESTROGEN PRODUCTS</b>						
FEMRING MIS 0.1MG/24	13	5	\$5,000.82	\$4.43	\$384.68	2.6
FEMRING MIS 0.05/24H	4	3	\$1,430.63	\$4.04	\$357.66	1.33
<b>SUBTOTAL</b>	<b>17</b>	<b>8</b>	<b>\$6,431.45</b>	<b>\$4.34</b>	<b>\$378.32</b>	<b>2.13</b>
<b>ORAL ESTROGEN/PROGESTIN PRODUCTS</b>						
PREMPRO TAB .625-2.5	292	67	\$58,620.68	\$5.37	\$200.76	4.36
PREMPRO TAB 0.3-1.5	177	44	\$36,576.37	\$5.41	\$206.65	4.02
PREMPRO TAB 0.625-5	79	21	\$14,238.10	\$5.39	\$180.23	3.76
ESTRA/NORETH TAB 0.5-0.1	70	17	\$9,320.27	\$3.20	\$133.15	4.12
PREMPRO TAB 0.45-1.5	69	26	\$15,788.23	\$5.46	\$228.81	2.65
ESTRA/NORETH 1-0.5MG	41	13	\$5,335.26	\$3.46	\$130.13	3.15
MIMVEY TAB 1-0.5MG	39	10	\$7,234.66	\$3.74	\$185.50	3.9
JINTELI TAB 1MG-5MCG	21	8	\$2,631.99	\$2.50	\$125.33	2.63
LOPREEZA TAB 0.5-0.1	21	3	\$2,329.27	\$3.33	\$110.92	7
ANGELIQ TAB 0.25-0.5	20	4	\$2,644.71	\$4.29	\$132.24	5
LOPREEZA TAB 1-0.5MG	15	3	\$2,553.57	\$3.65	\$170.24	5
PREMPHASE TAB	11	3	\$4,188.30	\$5.75	\$380.75	3.67
NORETH/ETHIN TAB 0.5-2.5	10	3	\$1,493.60	\$3.60	\$149.36	3.33

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	CLAIMS/MEMBER
ANGELIQ TAB 0.5-1MG	10	5	\$1,244.71	\$4.45	\$124.47	2
MIMVEY LO TAB 0.5-0.1	2	1	\$187.60	\$3.35	\$93.80	2
FEMHRT TAB 0.5-2.5	1	1	\$131.38	\$4.69	\$131.38	1
NORETH/ETHIN 1MG-5MCG	1	1	\$58.48	\$2.09	\$58.48	1
FYAVOLV TAB 0.5-2.5	1	1	\$276.46	\$3.07	\$276.46	1
<b>SUBTOTAL</b>	<b>880</b>	<b>231</b>	<b>\$164,853.64</b>	<b>\$4.81</b>	<b>\$187.33</b>	<b>4.17</b>
<b>TOPICAL ESTROGEN/PROGESTIN PRODUCTS</b>						
COMBIPATCH DIS .05/.25	42	8	\$6,041.41	\$5.07	\$143.84	5.25
COMBIPATCH DIS .05/.14	24	11	\$3,355.06	\$4.95	\$139.79	2.18
CLIMARA PRO DIS WEEKLY	14	6	\$1,953.97	\$4.91	\$139.57	2.33
<b>SUBTOTAL</b>	<b>80</b>	<b>25</b>	<b>\$11,350.44</b>	<b>\$5.00</b>	<b>\$141.88</b>	<b>3.2</b>
<b>ESTROGEN/SERM PRODUCTS</b>						
DUAVEE TAB 0.45-20	10	2	\$1,414.82	\$4.72	\$141.48	5
<b>SUBTOTAL</b>	<b>10</b>	<b>2</b>	<b>\$1,414.82</b>	<b>\$4.72</b>	<b>\$141.48</b>	<b>5</b>
<b>TOTAL</b>	<b>10,706</b>	<b>2,825*</b>	<b>\$977,462.01</b>	<b>\$2.19</b>	<b>\$91.30</b>	<b>3.79</b>

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Cost per claim may correspond to a member receiving several months of therapy in one claim.

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# Fiscal Year 2016 Annual Review of Xgeva® (Denosumab)

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## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

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### Current Prior Authorization Criteria

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#### Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of one of the following:
  - a. Prevention of skeletal-related events in patients with bone metastases from solid tumors; or
  - b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; or
    - i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity.
  - c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
    - 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.

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### Utilization of Xgeva® (Denosumab): Fiscal Year 2016

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#### Xgeva® (Denosumab) Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	46	197	\$347,648.40	\$1,764.71	8,832.86
2016	58	223	\$414,094.08	\$1,856.92	27,122
% Change	26.09%	13.20%	19.11%	5.23%	207.06%
Change	12	26	\$66,445.68	\$92.21	18,289.14

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

#### Demographics of Members Utilizing Xgeva® (Denosumab)

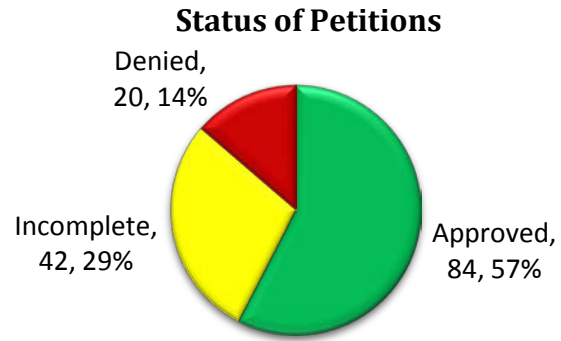
- The information provided above is from medical claims; therefore, demographic information is not available.

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### Prior Authorization of Xgeva® (Denosumab)

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There were 146 prior authorization requests submitted Xgeva® (denosumab) during fiscal year 2016. The following chart shows the status of the submitted petitions.



## **Recommendations**

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

# Fiscal Year 2016 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

## Oklahoma Health Care Authority Fiscal Year 2016 Print Report

### Current Prior Authorization Criteria

#### Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria (Dupuytren's Contracture):

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 (one dose per 4 weeks) per cord will apply.

#### Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria (Peyronie's Disease):

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 2016

#### Xiaflex® (Collagenase Clostridium Histolyticum) Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2015	1	1	\$3,457.80	\$3,457.80	90
2016	1	4	\$13,699.80	\$3,424.95	360
% Change	0.00%	300.00%	296.20%	-0.95%	300.00%
Change	0	3	\$10,242.00	-\$32.85	270

\*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

- There were no pharmacy claims for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2016.

### **Demographics of Members Utilizing Xiaflex® (Collagenase Clostridium Histolyticum)**

- Due to the small number of members utilizing Xiaflex® (collagenase clostridium histolyticum), detailed demographic information could not be provided.

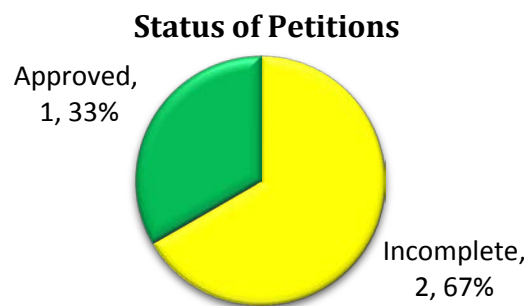
### **Top Prescriber Specialties of Xiaflex® (Collagenase Clostridium Histolyticum) by Number of Claims**

- The only prescriber specialty listed on paid claims for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2016 was urologist.

### **Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)**

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There were 3 prior authorization requests submitted for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2016. The following chart shows the status of the submitted petitions.



### **Recommendations**

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