

## Print Annual Reviews for Fiscal Year 2013

Count	Category/Medication	Time Period of Review	Pharmacist
1.	Alzheimer's Meds	Fiscal Year	Michyla
2.	Antiemetics	Fiscal Year	Michyla
3.	Benlysta	Fiscal Year	Ashley
4.	Colcrys/Uloric	Fiscal Year	Michyla
5.	Daliresp	Fiscal Year	Brandy
6.	Elidel / Protopic	Fiscal Year	Brandy
7.	<b>Fibric Acid Derivatives</b>	<b>Calendar Year</b>	<b>Brandy</b>
8.	<b>Growth Hormone</b>	<b>Calendar Year</b>	<b>Bethany</b>
9.	<b>HFA Rescue Meds</b>	<b>Calendar Year</b>	<b>Brandy</b>
10.	<b>Xopenex Nebulizer Solution</b>	<b>Calendar Year</b>	<b>Brandy</b>
11.	Horizant, Gralise	Fiscal Year	Michyla
12.	Metozolv	Fiscal Year	Brandy
13.	Misc ABX (oral)	Fiscal Year	Ashley
14.	Mozbl, Nplate, Arcalyst, Ilaris	Fiscal Year	Brandy
15.	<b>Ocular Allergy Products</b>	<b>Calendar Year</b>	<b>Ashley</b>
16.	Ocular Antibiotics	Fiscal Year	Ashley
17.	<b>Osteo Meds</b>	<b>Calendar Year</b>	<b>Brandy</b>
18.	Otic Antibiotics	Fiscal Year	Michyla
19.	Qutenza	Fiscal Year	Ashley
20.	Ribavirin Caps, sol, dospks	Fiscal Year	Ashley
21.	Singulair & Zyflo CR	Fiscal Year	Ashley
22.	Misc Butalbital Products	Fiscal Year	Bethany
23.	Neupro, Requip XL, and Mirapex ER	Fiscal Year	Bethany

**Fiscal Year** = July 1, 2012 – June 30, 2013

**Calendar Year** = January 1, 2013 – December 31, 2013

# Annual Review of Alzheimer's Medications

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Current Prior Authorization Criteria

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
  - a. Member must have a documented reason why the special formulation is clinically necessary over the regular formulation.
2. An age restriction for ages 0-50 years applies to all products with the following approval criteria:
  - a. An FDA approved diagnosis.
  - b. Other patient specific, clinically significant information may be considered.

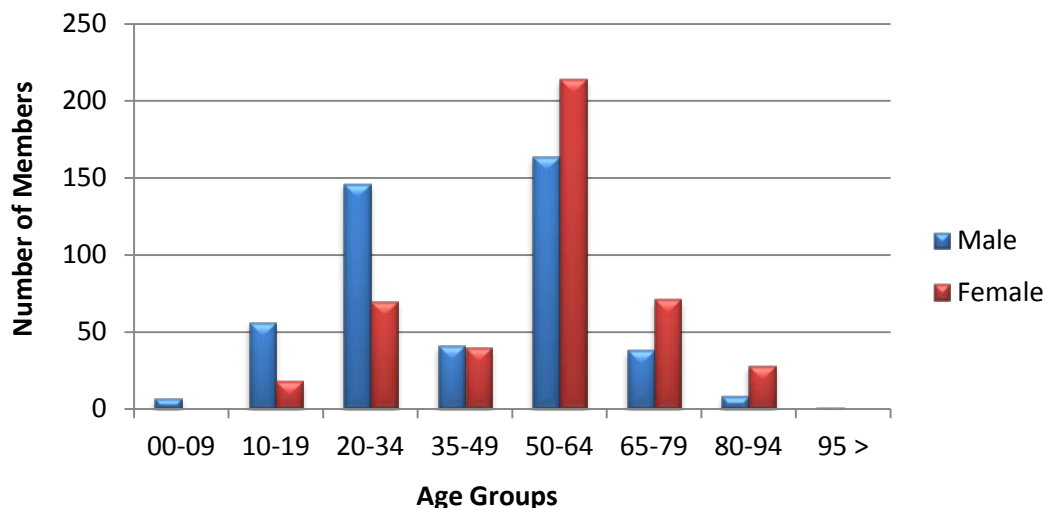
## Utilization of Alzheimer's Medications

### Comparison of Fiscal Years

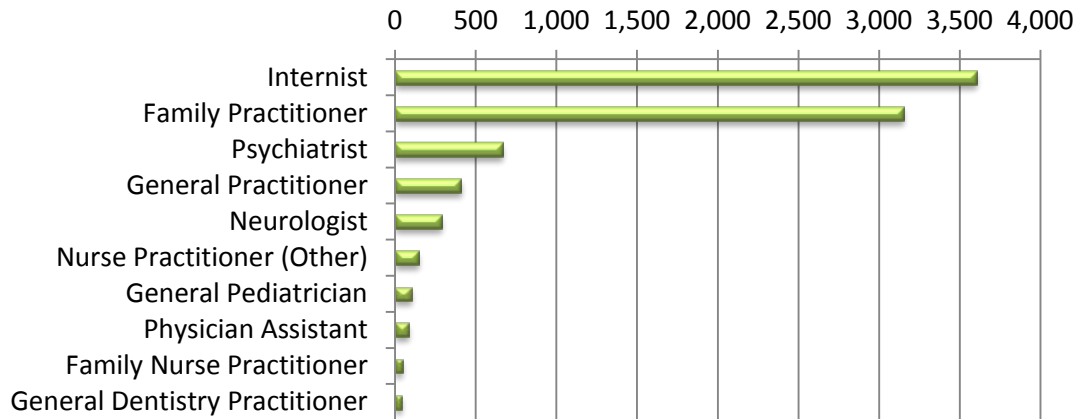
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2012	890	8,044	\$1,221,865.17	\$151.90	\$5.03	405,507	242,815
2013	902	8,678	\$1,522,839.95	\$175.48	\$5.94	429,100	256,412
% Change	1.30%	7.90%	24.60%	15.50%	18.10%	5.80%	5.60%
Change	12	634	\$300,974.78	\$23.58	\$0.91	23,593	13,597

\*Total number of unduplicated members

### Demographics of Members Utilizing Alzheimer's Medications



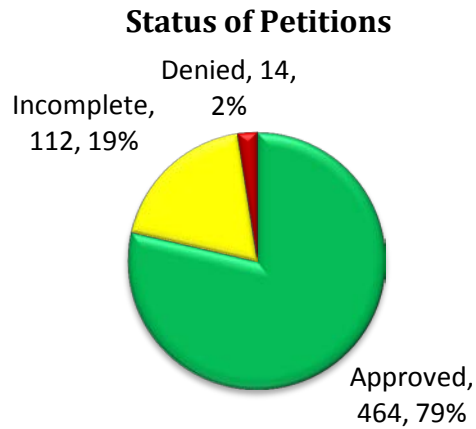
## Top Prescriber Specialties of Alzheimer's Medications by Number of Claims



## Prior Authorization of Alzheimer's Medications

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There was a total of 590 petitions submitted for Alzheimer's medications during fiscal year 2013. The following chart shows the status of the submitted petitions.



## Market News and Updates

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### Anticipated Patent Expirations:

- Namenda® (memantine) tablets & oral solution- 04/2015
- Exelon® (rivastigmine) transdermal patches- 01/2019
- Aricept® (donepezil) orally disintegrating tablets (ODTs)- 6/2022
- Aricept® (donepezil) 23mg tablets- 10/2026
- Namenda XR® (memantine) extended-release capsules- 3/2029

## New Medications:

Namenda XR® (memantine) extended-release capsules (dosed once daily) were approved by the FDA in June 2010, but did not become available on the market until June 2013. Since the availability of once daily Namenda XR®, Forest Pharmaceuticals, Inc. have announced the plan to discontinue the sale of Namenda® regular-release tablets (dosed twice daily) in August 2014. Namenda® oral solution and Namenda XR® will remain on the market.

The current FDA-approved medications to treat Alzheimer's disease support the communication network in the brain, either by inhibiting acetylcholinesterase (donepezil, galantamine, and rivastigmine) or by regulating the activity of glutamate by acting as an N-methyl-D-aspartate (NMDA) receptor antagonist (memantine). These medications treat the symptoms of Alzheimer's, temporarily helping memory and thinking problems in about half of the people who take them, but do not treat the underlying causes of Alzheimer's. There are multiple medications currently in development that aim to modify the disease process itself, by impacting one or more of the many wide-ranging brain changes that Alzheimer's causes. Targets for new drug therapies include beta-amyloid (and amyloid precursor protein), tau protein, insulin resistance in the brain, and inflammation of the brain. Three medications (gantenerumab, solanezumab, and MK-8931) are currently in Phase 3 Clinical Trials and are targeting amyloid precursor protein (APP) and amyloid-related compounds. One medication (TRx0237) is currently in Phase 3 Clinical Trials targeting the tau protein. Research and development of new medications to treat Alzheimer's disease is ongoing and provides a hopeful outlook for this progressive disease.<sup>1, 2, 3, 4, 5</sup>

## Recommendations

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The College of Pharmacy recommends no changes at this time.

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<sup>1</sup> FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm>. Last revised 5/1/14. Last accessed 5/2/14.

<sup>2</sup> Drugs@FDA: FDA Approved Drug Products. Available online at: [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search\\_Drug\\_Name](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name). Last revised 5/1/14. Last accessed 5/2/14.

<sup>3</sup> Micromedex 2.0: Drug Information. Available online at: <http://www.micromedexsolutions.com/micromedex2/librarian/>. Last revised 4/29/14. Last accessed 5/5/14.

<sup>4</sup> Alzforum: Therapeutics: Alzheimer's Medications in the Pipeline. Available online at: [http://www.alzforum.org/therapeutics/search?fda\\_statuses\[0\]=183&target\\_types\[0\]=170](http://www.alzforum.org/therapeutics/search?fda_statuses[0]=183&target_types[0]=170). Last accessed 5/5/14.

<sup>5</sup> Alzheimer's Association Research Center: Treatment Horizon. Available online at: [http://www.alz.org/research/science/alzheimers\\_treatment\\_horizon.asp](http://www.alz.org/research/science/alzheimers_treatment_horizon.asp). Last accessed 5/5/14.

## Utilization Details of Alzheimer's Medications

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/DAY	COST/CLAIM	PERCENT COST
<b>MEMANTINE PRODUCTS</b>						
NAMENDA TAB 10MG	5,620	629	\$1,347,884.80	\$8.34	\$239.84	88.51%
NAMENDA TAB 5MG	493	93	\$106,599.04	\$7.42	\$216.23	7.00%
NAMENDA SOL	6	1	\$1,651.60	\$9.18	\$275.27	0.11%
NAMENDA TAB 5-10MG	2	1	\$422.94	\$7.55	\$211.47	0.03%
<b>SUBTOTAL</b>	<b>6,121</b>	<b>692*</b>	<b>\$1,456,558.38</b>	<b>\$8.27</b>	<b>\$237.96</b>	<b>95.65%</b>
<b>DONEPEZIL PRODUCTS</b>						
DONEPEZIL TAB 10MG	1,766	250	\$13,825.77	\$0.25	\$7.83	0.91%
DONEPEZIL TAB 5MG	542	134	\$4,814.27	\$0.28	\$8.88	0.32%
ARICEPT TAB 23MG	14	2	\$4,219.22	\$10.05	\$301.37	0.28%
<b>SUBTOTAL</b>	<b>2,322</b>	<b>337*</b>	<b>\$22,859.26</b>	<b>\$0.31</b>	<b>\$9.84</b>	<b>1.50%</b>
<b>RIVASTIGMINE PRODUCTS</b>						
EXELON DIS 9.5MG/24	88	11	\$24,366.75	\$9.46	\$276.89	1.60%
RIVASTIGMINE CAP 3MG	43	8	\$5,663.21	\$4.65	\$131.70	0.37%
RIVASTIGMINE CAP	36	5	\$4,901.48	\$4.63	\$136.15	0.32%
EXELON DIS 4.6MG/24	18	5	\$2,985.80	\$5.55	\$165.88	0.20%
RIVASTIGMINE CAP	12	2	\$1,102.35	\$3.06	\$91.86	0.07%
RIVASTIGMINE CAP 6MG	7	2	\$969.00	\$4.61	\$138.43	0.06%
EXELON DIS 13.3/24	6	1	\$1,901.64	\$10.56	\$316.94	0.12%
<b>SUBTOTAL</b>	<b>210</b>	<b>29*</b>	<b>\$41,890.23</b>	<b>\$6.82</b>	<b>\$199.48</b>	<b>2.75%</b>
<b>GALANTAMINE PRODUCTS</b>						
GALANTAMINE TAB 4MG	13	1	\$797.13	\$2.04	\$61.32	0.05%
GALANTAMINE TAB 8MG	12	2	\$734.95	\$2.04	\$61.25	0.05%
<b>SUBTOTAL</b>	<b>25</b>	<b>3*</b>	<b>\$1,532.08</b>	<b>\$2.04</b>	<b>\$61.28</b>	<b>0.10%</b>
<b>TOTAL</b>	<b>8,678</b>	<b>902*</b>	<b>\$1,522,839.95</b>	<b>\$5.94</b>	<b>\$175.48</b>	<b>100.00%</b>

\*Total number of unduplicated members

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# Annual Review of Antiemetic Medications

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## Oklahoma Health Care Authority Fiscal Year 2013 Print Review

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### Current Prior Authorization Criteria

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#### **Granisetron (Kytril® and Sancuso®), Dolasetron (Anzemet®), and Aprepitant (Emend®)**

##### **Approval Criteria:**

1. An FDA approved diagnosis; and
2. A recent (within the past 6 months) trial of ondansetron used for at least 3 days or one cycle that resulted in inadequate response; and
3. Approval length will be based on duration of need.
4. Existing quantity limits apply (see chart below).

#### **Cannabinoids – Dronabinol (Marinol®) and Nabilone (Cesamet®) Approval Criteria:**

1. Approval can be granted for 6 months for the diagnosis of HIV related loss of appetite.
2. The diagnosis of chemotherapy induced nausea and vomiting requires the following:
  - a. A recent (within the past 6 months) trial of ondansetron used for at least 3 days or one cycle that resulted in inadequate response.
3. Approval length will be based on duration of need.
4. A quantity limit of 60 capsules per 30 days will apply.

#### **Zuplenz™ (Ondansetron) Approval Criteria:**

1. An FDA approved diagnosis; and
2. Must provide a clinically significant reason why the member cannot take all other available formulations of generic ondansetron.

#### **Diclegis® (Doxylamine/Pyridoxine) Approval Criteria:**

1. An FDA approved diagnosis of nausea and vomiting associated with pregnancy; and
2. Trials with at least two non-pharmacological therapies that have failed to relieve nausea and vomiting; and
3. Trials with at least three prescription medications that have failed to relieve nausea and vomiting (must include a trial of ondansetron); and
4. A patient-specific, clinically significant reason why member cannot use OTC doxylamine and OTC Vitamin B-6 (pyridoxine).

Antiemetic Medications			
Drug	Quantity Limits	Comments	FDA Daily Max
Aprepitant ( <b>Emend</b> ®) capsules in convenience packs (1-125 mg capsule & 2-80 mg cap)	2 packs per 30 days	125 mg day 1, 80 mg days 2 & 3 for CINV	125mg
Aprepitant ( <b>Emend</b> ®) 80 mg capsules	4 capsules per 30 days	125 mg day 1, 80 mg days 2 & 3 for CINV	80mg
Aprepitant ( <b>Emend</b> ®) 125 mg capsules	2 capsules per 30 days	125 mg day 1, 80 mg days 2 & 3 for CINV	125mg
Aprepitant ( <b>Emend</b> ®) 40 mg capsules	5 capsules per 30 days	1 caps pre-surgical procedure	-
Dolasetron ( <b>Anzemet</b> ®) 50 and 100 mg tablets	10 tablets per 30 days	100mg once for CINV 100mg once for PONV	100mg
Drug	Quantity Limits	Comments	
Granisetron ( <b>Kytril</b> ®) 1mg tablets	20 tablets per 30 days	2mg 1 hour before chemo/1mg all others	
Ondansetron ( <b>Zofran</b> ®, <b>Zofran</b> ® ODT) 4, 8, and 24 mg tablets and orally disintegrating tablets	24 mg: 1 tablet per 30 days 4 mg or 8 mg: 12 tablets per 30 days	CINV: 8mg Q12 hr x 2-3 days or 24 mg once; RINV: 8mg Q8 hr x 2-3 days PONV: 16mg once	
Palonosetron ( <b>Aloxi</b> ®) 0.25mg / 5 mL vial	4 vials per 28 days	Maximum dose is 0.25 mg before chemotherapy every 7 days	
Doxylamine/pyridoxine ( <b>Diclegis</b> ®) 10/10mg DR tablets	60 tablets per 30 days	Maximum dose is 4 tablets per day	

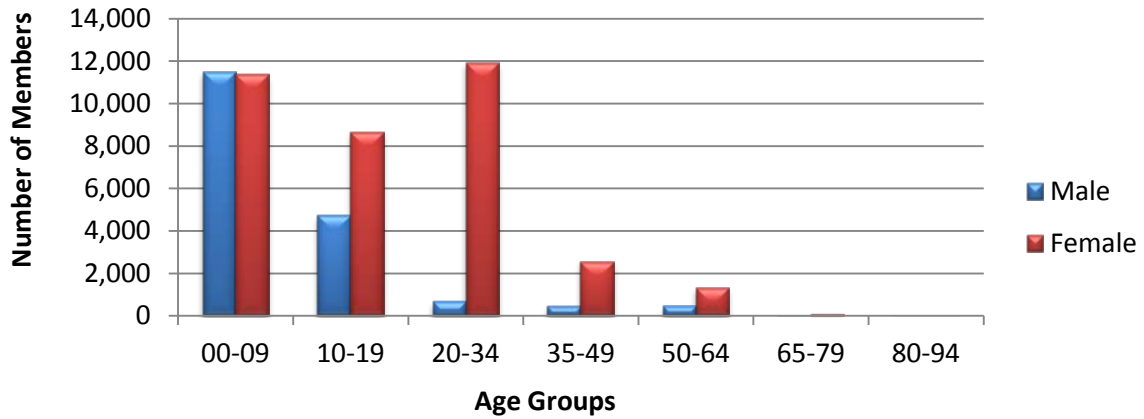
## Utilization of Antiemetic Medications

### Comparison of Fiscal Years

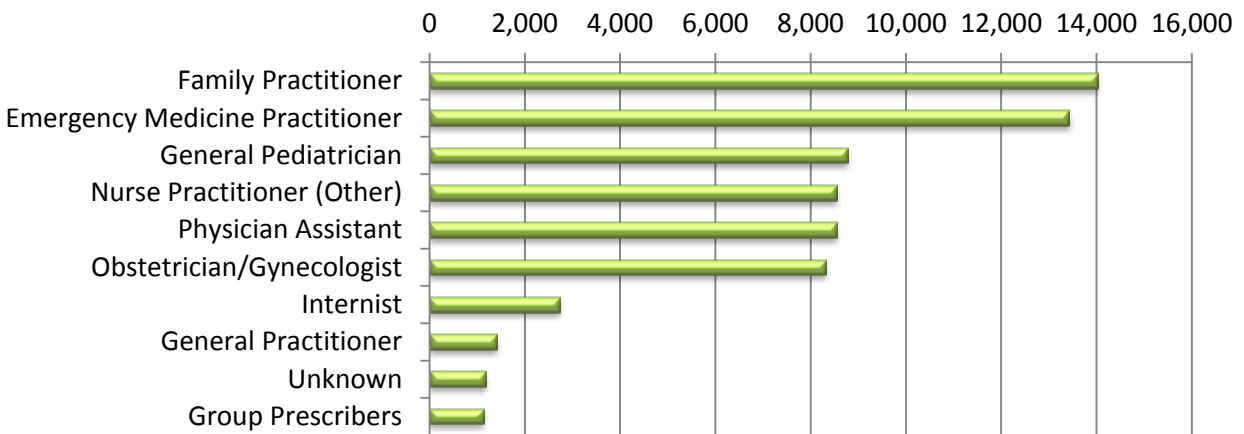
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Per-Diem Cost	Total Units	Total Days
2012	38,499	51,950	\$742,455.89	\$14.29	\$0.56	586,662	1,320,850
2013	53,948	72,712	\$1,006,582.52	\$13.84	\$0.54	831,778	1,852,040
% Change	40.10%	40.00%	35.60%	-3.10%	-3.60%	41.80%	40.20%
Change	15,449	20,762	\$264,126.63	-\$0.45	-\$0.02	245,116	531,190

\*Total number of unduplicated members.

### Demographics of Members Utilizing Antiemetic Medications



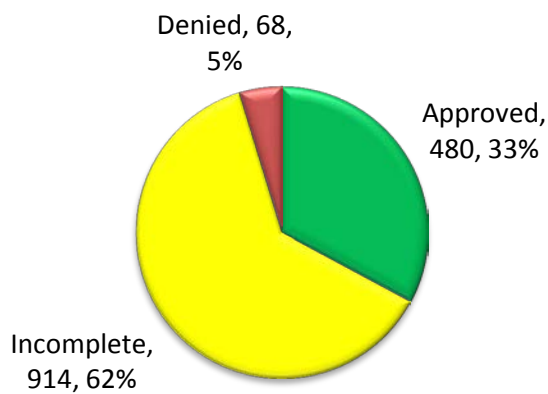
### Top Prescriber Specialties of Antiemetic Medications by Number of Claims



### Prior Authorization of Antiemetic Medications

There was a total of 1,462 petitions submitted for this category during fiscal year 2013. The following chart shows the status of the submitted petitions.

#### Status of Petitions





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

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### Anticipated Patent Expirations

- Diclegis<sup>®</sup> (doxylamine/pyridoxine)- 6/2021
- Sancuso<sup>®</sup> (granisetron)- 10/2024
- Emend<sup>®</sup> (aprepitant)- 9/2027
- Zuplenz<sup>™</sup> (ondansetron mucous membrane film)- 11/2029

## **Recommendations**

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

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<sup>6</sup> 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 4/10/14. Last accessed 4/11/14.

## Utilization Details of Antiemetic Medications: Fiscal Year 2013

Product Utilized	Total Claims	Total Members	Total Cost	Cost/Day	Cost/Claim	Percent Cost
<b>ONDANSETRON PRODUCTS</b>						
ONDANSETRON TAB 4MG ODT	38,724	32,768	\$282,567.62	\$0.30	\$7.30	28.07%
ONDANSETRON TAB 4MG	12,866	10,223	\$85,783.63	\$0.25	\$6.67	8.52%
ONDANSETRON TAB 8MG ODT	10,509	7,602	\$123,874.23	\$0.44	\$11.79	12.31%
ONDANSETRON TAB 8MG	6,096	4,268	\$44,477.92	\$0.26	\$7.30	4.42%
ONDANSETRON SOL 4MG/5ML	3,945	3,565	\$252,742.71	\$2.88	\$64.07	25.11%
ONDANSETRON INJ 4MG/2ML	64	39	\$789.73	\$1.89	\$12.34	0.08%
ONDANSETRON INJ 40/20ML	29	13	\$2,272.41	\$4.85	\$78.36	0.23%
ZOFRAN TAB 4MG	4	4	\$24.56	\$0.23	\$6.14	0.00%
<b>SUBTOTAL</b>	<b>72,237</b>	<b>53,901*</b>	<b>\$792,532.81</b>	<b>\$0.43</b>	<b>\$10.97</b>	<b>78.74%</b>
<b>APREPITANT PRODUCTS</b>						
EMEND PAK 80 & 125	180	66	\$79,940.97	\$23.68	\$444.12	7.94%
EMEND CAP 80MG	5	3	\$1,077.52	\$107.75	\$215.50	0.11%
EMEND CAP 125MG	1	1	\$519.53	\$34.64	\$519.53	0.05%
<b>SUBTOTAL</b>	<b>186</b>	<b>70*</b>	<b>\$81,538.02</b>	<b>\$23.97</b>	<b>\$438.38</b>	<b>8.10%</b>
<b>DRONABINOL PRODUCTS</b>						
DRONABINOL CAP 5MG	94	25	\$47,441.01	\$18.23	\$504.69	4.71%
DRONABINOL CAP 2.5MG	86	29	\$16,733.24	\$7.41	\$194.57	1.66%
DRONABINOL CAP 10MG	68	11	\$51,738.58	\$25.12	\$760.86	5.14%
MARINOL CAP 5MG	2	1	\$2,941.90	\$49.03	\$1,470.95	0.29%
<b>SUBTOTAL</b>	<b>250</b>	<b>59*</b>	<b>\$118,854.73</b>	<b>\$99.79</b>	<b>\$475.42</b>	<b>11.81%</b>
<b>GRANISETRON PRODUCTS</b>						
GRANISETRON TAB 1MG	28	9	\$2,799.89	\$6.36	\$100.00	0.28%
SANCUSO DIS 3.1MG	10	3	\$10,779.13	\$41.62	\$1,077.91	1.07%
GRANISOL SOL 2MG/10ML	1	1	\$77.94	\$7.79	\$77.94	0.01%
<b>SUBTOTAL</b>	<b>39</b>	<b>13*</b>	<b>\$13,656.96</b>	<b>\$19.26</b>	<b>\$350.18</b>	<b>1.36%</b>
<b>TOTAL</b>	<b>72,712</b>	<b>53,948*</b>	<b>\$1,006,582.52</b>	<b>\$0.54</b>	<b>\$13.84</b>	<b>100.00%</b>

\*Total number of unduplicated members

# Annual Review of Benlysta® (Belimumab)

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

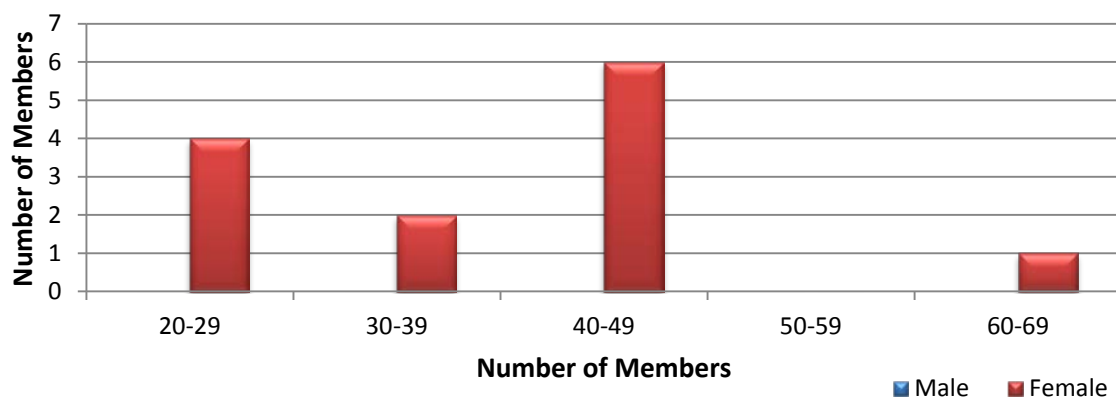
## Current Prior Authorization Criteria

1. FDA approved indication of adults with active, autoantibody-positive, systemic lupus erythematosus already receiving standard therapy.
2. Documented inadequate response to at least two of the following medications:
  1. High-dose oral corticosteroids
  2. Methotrexate
  3. Azathioprine
  4. Mycophenolate
  5. Cyclophosphamide
3. Member must not have severe active lupus nephritis or severe active central nervous system lupus.
4. No combination use with biologic therapies or intravenous cyclophosphamide.

## Utilization of Benlysta®

Drug	Claims	Units	Members	Cost	Claims/Member	Cost/Claims
Benlysta®	78	7294	13	\$246,979.43	6	\$3,166.40

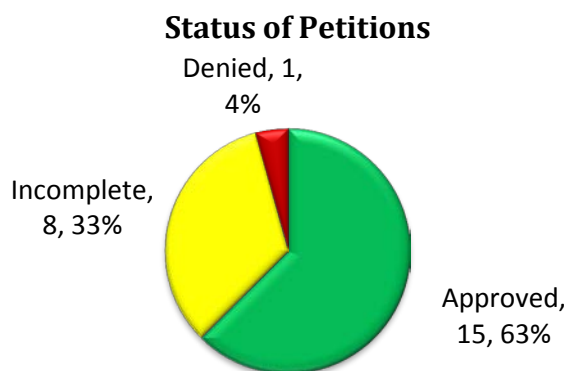
### Demographics of Members



## Prior Authorization of Benlysta®

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There were a total of 24 petitions submitted for this category during calendar year 2013. The following chart shows the status of the submitted petitions.



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

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**FDA Update:** December 2013, Acute hypersensitivity reactions, including anaphylaxis and death, have been reported in association with Benlysta®. These events generally occurred within hours of the infusion; however they may occur later. Non-acute hypersensitivity reactions including rash, nausea, fatigue, myalgia, headache, and facial edema, have been reported and typically occurred up to a week following the most recent infusion. Hypersensitivity, including serious reactions, has occurred in patients who have previously tolerated infusions of Benlysta®

## Recommendations

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The College of Pharmacy recommends no changes to this category at this time.

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<sup>7</sup> FDA: Safety: Benlysta. Available online at: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm299628.htm>. Last revised:01/10/2014. Last accessed: 04/10/2014.

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# Annual Review of Uloric® (Febuxostat) and Colcryst® (Colchicine)

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Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

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## Prior Authorization Criteria

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### 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 is not a viable option for the member.
3. A quantity limit of 30 tablets per 30 days will apply.

### Colcryst® (Colchicine) Approval Criteria:

Colcryst® will have a free floating 2 days supply of 6 tablets per 365 days.

Long term use of Colcryst® will require a petition and the following 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 colchicine/probenecid would not be a viable option for the member.
3. A Quantity limit of 60 tablets per 30 days will apply for gout.
4. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

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## Utilization of Uloric® and Colcryst®

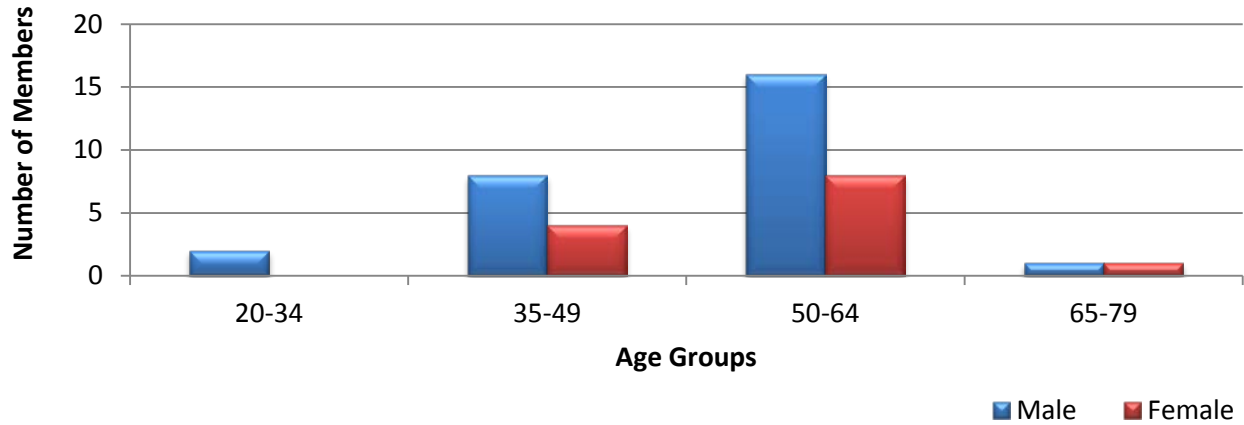
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### Comparison of Fiscal Years: Uloric®

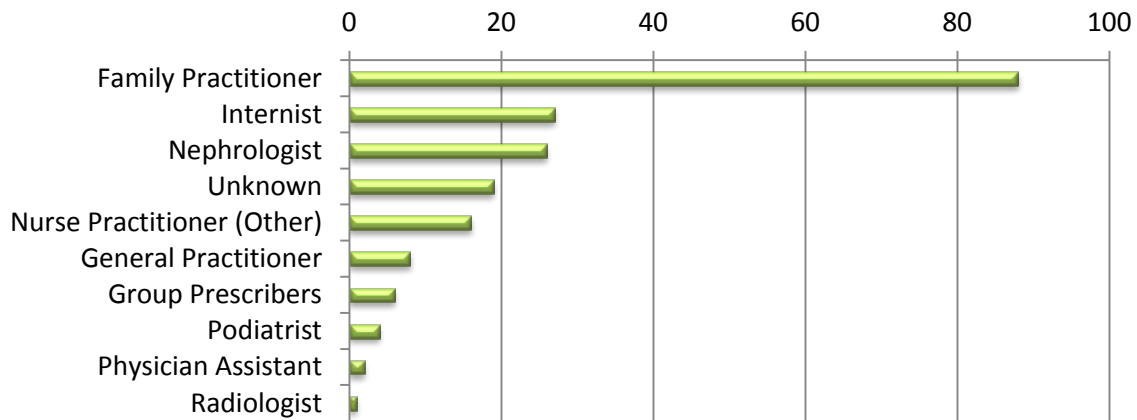
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Per-Diem Cost	Total Units	Total Days
2012	70	308	\$50,256.95	\$163.17	\$5.38	9,190	9,340
2013	40	197	\$35,756.75	\$181.51	\$5.93	5,850	6,030
% Change	-42.90%	-36.00%	-28.90%	11.20%	10.20%	-36.30%	-35.40%
Change	-30	-111	-\$14,500.20	\$18.34	\$0.55	-3,340	-3,310

\*Total number of unduplicated members.

### Demographics of Members Utilizing Uloric®



### Top Prescriber Specialties of Uloric® by Number of Claims

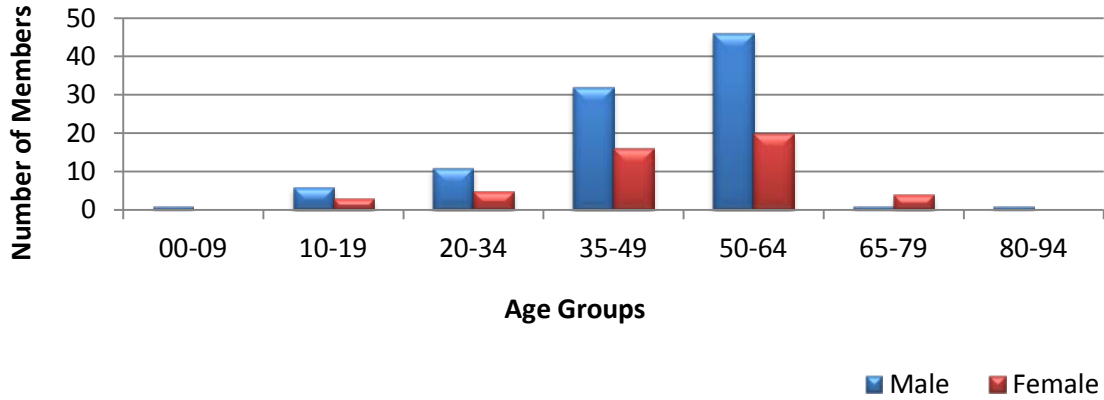


### Comparison of Fiscal Years: Colcrys®

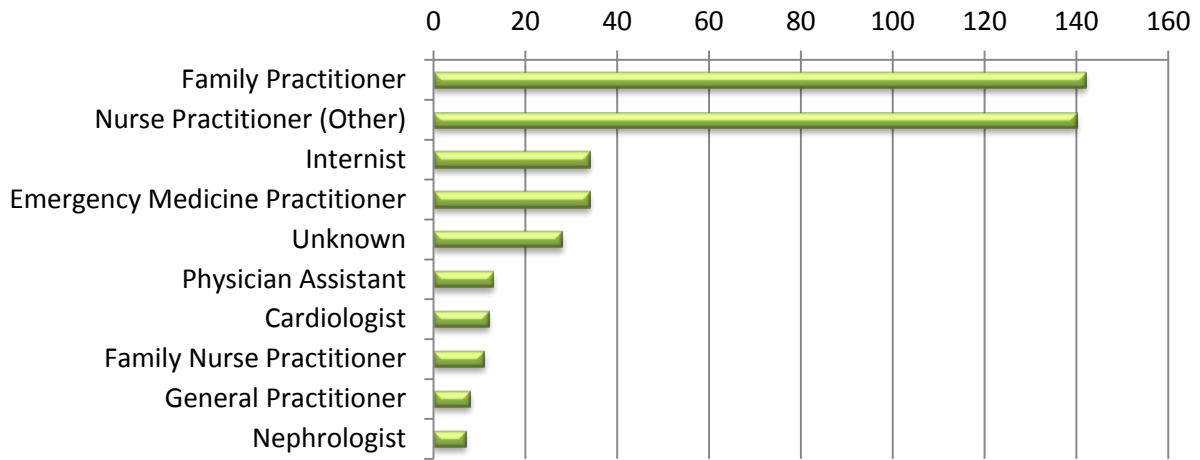
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Per-Diem Cost	Total Units	Total Days
2012	215	466	\$79,078.04	\$169.70	\$8.34	15,481	9,482
2013	146	461	\$27,890.59	\$60.50	\$7.50	5,284	3,719
% Change	-32.10%	-1.10%	-64.70%	-64.30%	-10.10%	-65.90%	-60.80%
Change	-69	-5	-\$51,187.45	-\$109.20	-\$0.84	-10,197	-5,763

\*Total number of unduplicated members.

### Demographics of Members Utilizing Colcrys®



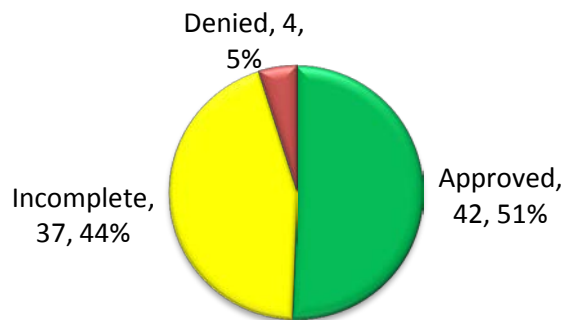
### Top Prescriber Specialties of Colcrys® by Number of Claims



### Prior Authorization of Uloric® and Colcrys®

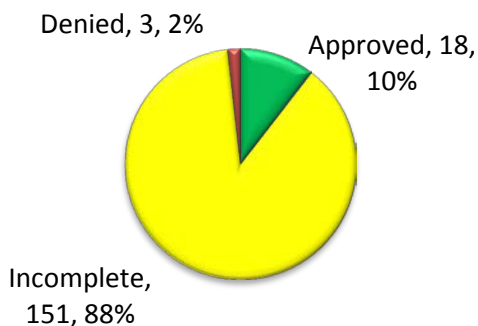
There was a total of 83 petitions submitted for Uloric® during fiscal year 2013. The following chart shows the status of the submitted petitions.

#### Status of Petitions: Uloric®



There was a total of 172 petitions submitted for Colcrys® during fiscal year 2013. Colcrys® has a free floating 2 days supply of 6 tablets per 365 days. The following chart shows the status of the submitted petitions.

### Status of Petitions: Colcrys®



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

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### Anticipated Patent Expirations

- Colcrys® (colchicine)- 2/2029
- Uloric® (febuxostat)- 9/2031

<sup>8</sup> 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 4/4/14. Last accessed 4/7/14.

<sup>8</sup> Arcalyst® Drug Information. Micromedex 2.0. Available online at: <http://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch>. Last revised 3/3/14. Last accessed 4/7/14.

<sup>8</sup> Pipeline: Arcalyst® (rilonacept). Regeneron Pharmaceuticals, Inc. Available online at: <http://www.regeneron.com/rilonacept>. Last accessed 4/7/14.

<sup>8</sup> Clinical trials.gov: Arcalyst®. Available online at: <http://www.clinicaltrials.gov/ct2/results?term=arcalyst&Search=Search>. Last accessed 4/7/14.

<sup>8</sup> Cryopyrin Associated Periodic Syndrome (CAPS) Overview. CAPS Community. Available online at: [http://www.capscommunity.com/caps\\_fact\\_caps\\_md.html](http://www.capscommunity.com/caps_fact_caps_md.html). Last accessed 4/7/14.

<sup>8</sup> AstraZeneca Press Release: AstraZeneca Announces Top-line Results from Phase III Monotherapy Study of Lesinurad in Gout Patients. Available online at: <http://www.astrazeneca.com/Media/Press-releases/Article/13122013--astrazeneca-announces-topline-results-from-phase-iii>. Last revised 12/13/13. Last accessed 4/7/14.

<sup>8</sup> The Wall Street Journal: AstraZeneca Gets Good News on Diabetes, Gout Drugs. Available online at: <http://online.wsj.com/news/articles/SB10001424052702304477704579255902377009382>. Last revised 12/13/13. Last accessed 4/7/14.

<sup>8</sup> Clinical trials.gov: lesinurad. Available online at: <http://www.clinicaltrials.gov/ct2/results?term=lesinurad&Search=Search>. Last accessed 4/7/14.

<sup>8</sup> Solvo Biotechnology: URAT1 Uptake Transporter Assay. Available online at: <http://www.solvobiotech.com/transporters/urat1>. Last accessed 4/7/14.



Regeneron Pharmaceuticals, Inc. has one medication, Arcalyst® (rilonacept), which is being clinically evaluated for the prevention of gout flare in patients who are initiating uric acid-lowering therapy. Rilonacept is an Interleukin-1 (IL-1) blocker (also known as an “IL-1 Trap”) that is a fusion protein that incorporates parts of the IL-1 receptor and was designed to attach to the pro-inflammatory protein IL-1 before IL-1 can bind to cell-surface receptors and generate signals that trigger inflammation. Arcalyst® is a subcutaneous injection that is currently FDA approved to treat Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children age 12 years and older. CAPS are a group of rare, inherited, auto inflammatory diseases with the same genetic basis and overlapping symptomatology; symptoms common to most patients with CAPS include recurrent rash, fever/chills, arthralgia, conjunctivitis, and fatigue.

AstraZeneca has one medication, lesinurad, which is currently in Phase 3 Clinical Trials. Lesinurad is an investigational agent being studied as a selective uric acid reabsorption inhibitor (SURI) that inhibits the URAT1 transporter, normalizing uric acid excretion and reducing serum uric acid (sUA). URAT1 is a transporter, predominately expressed in the kidneys, that mediates the reabsorption of uric acid, thereby regulating blood uric acid concentrations. Phase 3 Clinical Trials are investigating lesinurad as monotherapy in gout patients who are intolerant to, or otherwise cannot take, one or both of the xanthine oxidase inhibitors (allopurinol and febuxostat), in combination with allopurinol in patients not reaching target sUA levels on allopurinol alone, and in combination with febuxostat in patients with tophaceous gout. The results of these studies are expected by mid-2014, with regulatory submission of a New Drug Application (NDA) expected the second half of 2014.

## Recommendations

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

## Utilization Details of Uloric® and Colcrys®: Fiscal Year 2013

Product Utilized	Total Claims	Total Members	Total Cost	Cost/Day	Cost/Claim	Percent COST
<b>COLCHICINE PRODUCTS</b>						
Colcrys® 0.4mg	461	146	\$27,890.59	\$7.50	\$60.50	43.82%
<b>SUBTOTAL</b>	<b>461</b>	<b>146*</b>	<b>\$27,890.59</b>	<b>\$7.50</b>	<b>\$60.50</b>	<b>43.82%</b>
<b>FEBUXOSTAT PRODUCTS</b>						
Uloric® 40mg	126	28	\$22,691.16	\$6.00	\$180.09	35.65%
Uloric® 80mg	71	17	\$13,065.59	\$5.81	\$184.02	20.53%
<b>SUBTOTAL</b>	<b>197</b>	<b>40*</b>	<b>\$35,756.75</b>	<b>\$5.93</b>	<b>\$181.51</b>	<b>56.18%</b>
<b>TOTAL</b>	<b>658</b>	<b>182*</b>	<b>\$63,647.34</b>	<b>\$6.53</b>	<b>\$96.73</b>	<b>100.00%</b>

\*Total number of unduplicated members

## Annual Review of Daliresp® (Roflumilast)

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

### Current Prior Authorization Criteria

Daliresp® (Roflumilast) Approval Criteria:

1. Diagnosis of Chronic Obstructive Pulmonary Disease (COPD) with history of chronic bronchitis; and
2. Forced Expiratory Volume (FEV)  $\leq$  50% of predicted; and
3. Inadequately controlled on long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months)

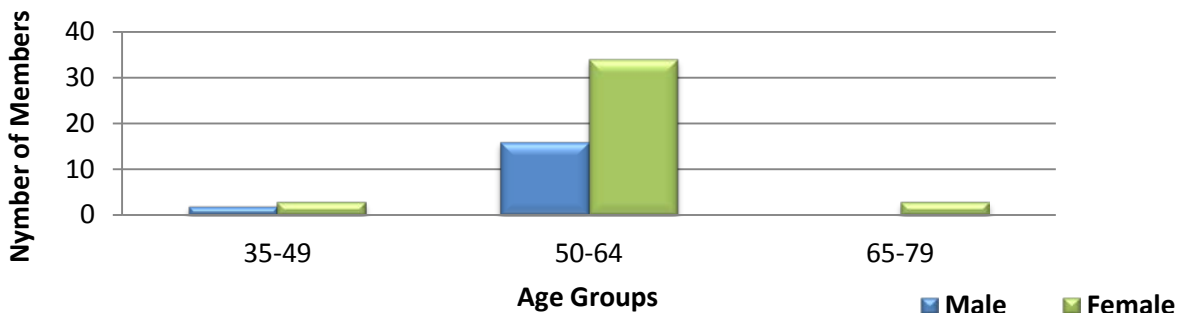
### Utilization of Daliresp® (Roflumilast)

#### Comparison of Fiscal Years

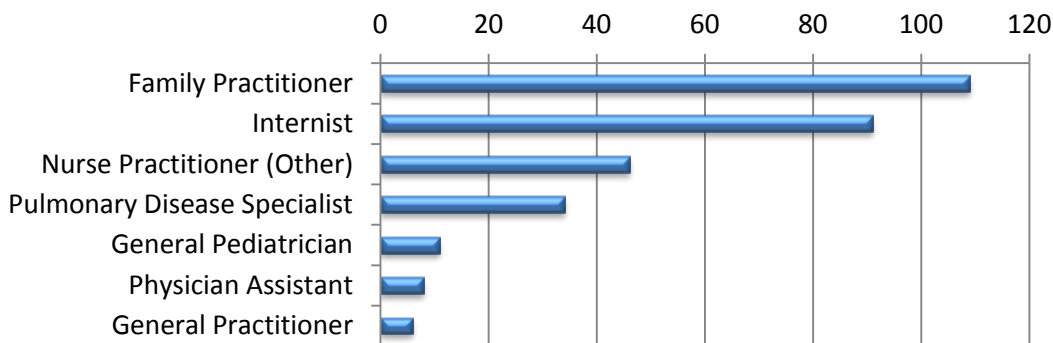
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
<b>2012</b>	43	153	\$27,857.60	\$182.08	\$6.11	4,563	4,563
<b>2013</b>	58	305	\$58,879.10	\$193.05	\$6.62	8,900	8,900
<b>% Change</b>	<b>34.90%</b>	<b>99.30%</b>	<b>111.40%</b>	<b>6.00%</b>	<b>8.30%</b>	<b>95.00%</b>	<b>95.00%</b>
<b>Change</b>	<b>15</b>	<b>152</b>	<b>\$31,021.50</b>	<b>\$10.97</b>	<b>\$0.51</b>	<b>4,337</b>	<b>4,337</b>

\*Total number of unduplicated members

#### Demographics of Members Utilizing Daliresp® (roflumilast)



### Top Prescriber Specialties of Daliresp® by Number of Claims

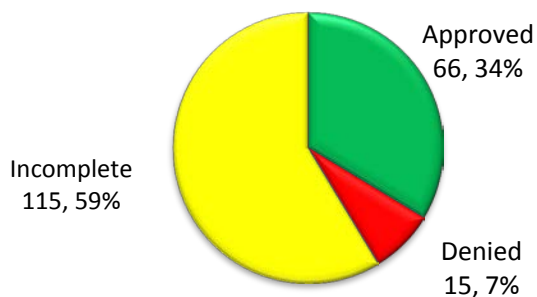


### Prior Authorization of Daliresp® (roflumilast)

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There was a total of 196 petitions submitted for Daliresp® during fiscal year 2013. The following chart shows the status of the submitted petitions.

#### Status of Petitions



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

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- August 2013: The FDA added a new warning and precaution to Daliresp®. This warning stated that cases of suicidal ideation and behavior, including completed suicide, have been observed in the post-marketing setting in patients with or without a history of depression.
- Daliresp® (roflumilast) patent expiration: March 2024

### Recommendations

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

<sup>9</sup> "FDA Safety Information" *Daliresp® (Roflumilast) Tablets*. Available online at: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm368228.htm>. Last accessed 12/16/2013.

### Utilization Details for Daliresp® (Roflumilast): Fiscal Year 2013

MEDICATION NAME	CLAIMS	MEMBERS*	COST	COST/ CLAIM	COST/ DAY	% COST
DALIRESP 500MCG	305	58	\$58,897.10	\$193.05	\$6.62	100%
TOTAL:	305	58	\$58,897.10	\$193.05	\$6.62	100%

\*Total number of unduplicated members.

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## Annual Review of Elidel® (Pimecrolimus Topical) and Protopic® (Tacrolimus Topical)

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Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

### Current Prior Authorization Criteria

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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 will be granted with documentation of one trial at least 6 weeks induration 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. Clinical Diagnosis:
  - a. Elidel® and Protopic®: short-term and intermittent treatment for mild to moderate atopic dermatitis (eczema)
2. Age Restrictions:
  - a. Elidel® 1%  $\geq$  2 years of age
  - b. Protopic® 0.03% for  $\geq$  2 years of age
  - c. Protopic® 0.1% for  $\geq$  15 years of age (approved for adult-use only)

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. Prescription by dermatologist.

Clinical exceptions for children not meeting age restriction:

1. Prescription by dermatologist

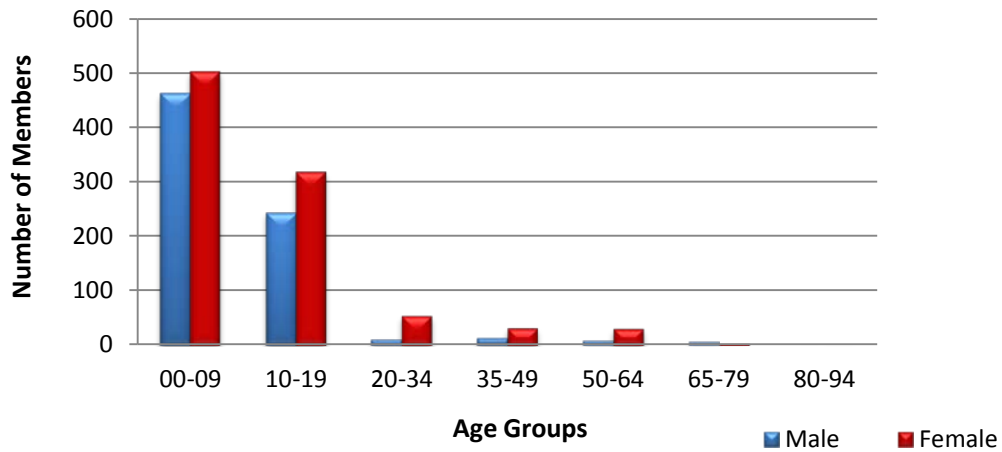
## Utilization of Elidel® and Protopic®

### Comparison of Fiscal Years

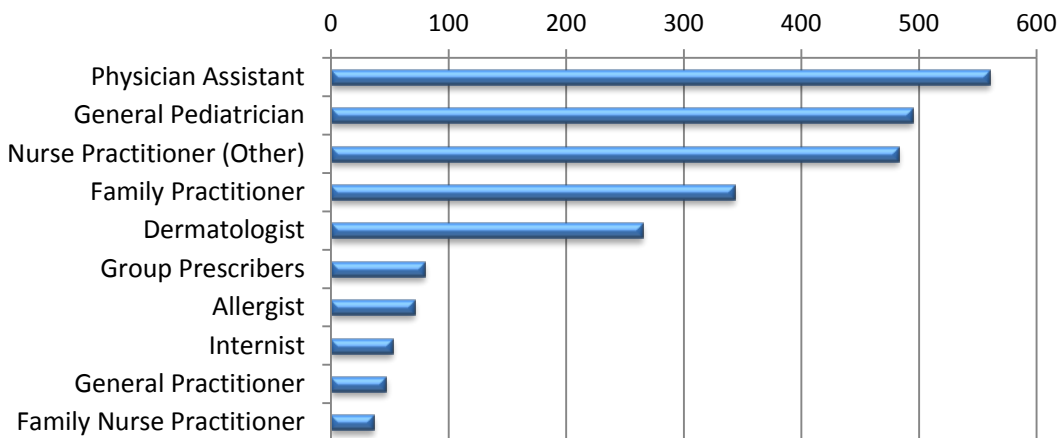
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
2012	1,754	2,543	\$589,963.59	\$232.00	\$7.60	129,866	77,599
2013	1,683	2,510	\$637,877.06	\$254.13	\$7.84	116,310	81,345
% Change	-4.00%	-1.30%	8.10%	9.50%	3.20%	-10.40%	4.80%
Change	-71	-33	\$47,913.47	\$22.13	\$0.24	-13,556	3,746

\*Total number of unduplicated members

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



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

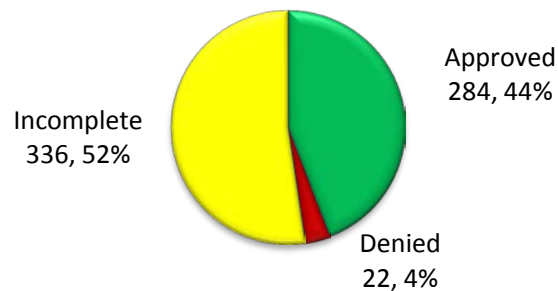


## Prior Authorization of Elidel® and Protopic®

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There was a total of 684 petitions submitted for Elidel® and Protopic® during fiscal year 2013. The following chart shows the status of the submitted petitions.

**Status of Petitions**



## Market News and Updates

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### Anticipated Patent Expirations

- Protopic® (tacrolimus topical)- 09/2014
- Elidel® (pimecrolimus topical)- 06/2018

## Recommendations

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

## Utilization Details for Elidel® and Protopic® Fiscal Year 2013

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MEDICATION NAME	CLAIMS	MEMBERS*	COST	COST/ CLAIM	COST/ DAY	% COST
PROTOPIC OINT 0.03%	1,188	788	\$328,049.61	\$276.14	\$9.02	51.43%
PROTOPIC OINT 0.1%	177	131	\$53,214.47	\$300.65	\$9.52	8.34%
<b>SUBTOTAL</b>	<b>1,365</b>	<b>919</b>	<b>\$381,264.08</b>	<b>\$279.31</b>	<b>\$9.27</b>	<b>59.77%</b>
ELIDEL CREAM 1%	1,145	790	\$256,612.98	\$224.12	\$6.51	40.23%
<b>SUBTOTAL</b>	<b>1,145</b>	<b>790</b>	<b>\$256,612.98</b>	<b>\$224.12</b>	<b>\$6.51</b>	<b>40.23%</b>
<b>TOTAL</b>	<b>2,510</b>	<b>1,683</b>	<b>\$637,877.06</b>	<b>\$266.97</b>	<b>\$7.84</b>	<b>100%</b>

\*Total number of unduplicated members.

## Annual Review of Fibric Acid Derivatives

### Oklahoma Health Care Authority Calendar Year 2013 Print Review

#### Current Prior Authorization Criteria

Fibric Acid Tier-2 Approval Criteria:

1. Documented trial of a Tier-1 medication with inadequate results after a 6 month trial; or
2. Documented adverse effect, drug interaction, or contraindication to Tier-1 medications;  
or
3. Documented prior stabilization on the Tier-2 medication within the last 100 days.

Fibric Acid Derivatives	
Tier One	Tier Two
Fenofibrate (Lofibra <sup>®</sup> Caps)	Fenofibrate (Antara <sup>®</sup> Caps)
Fenofibrate (Trilipix <sup>®</sup> Tabs)	Fenofibrate (Triglide <sup>®</sup> Tabs) 50mg, 160mg
Fenofibrate (Tricor <sup>®</sup> Tabs)	Fenofibrate (Lipofen <sup>®</sup> Caps)
Gemfibrozil (Lopid <sup>®</sup> Tabs)	Fenofibrate (Fenoglide <sup>®</sup> Tabs)
Clofibrate (Atromid-S <sup>®</sup> Caps)	

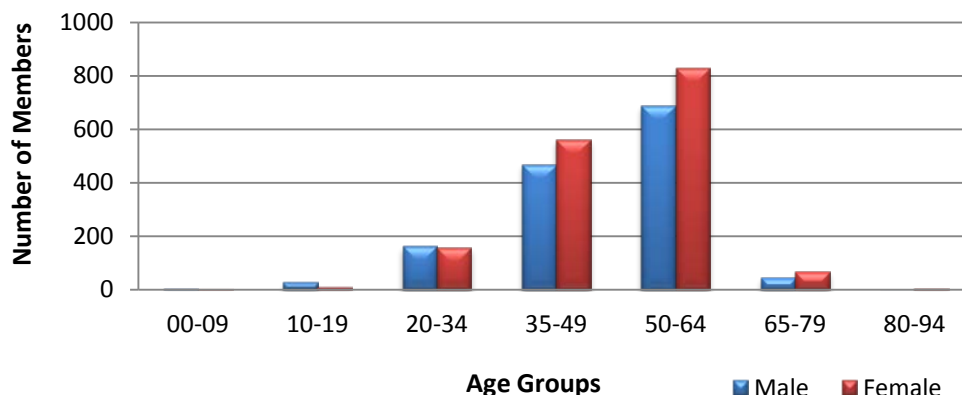
#### Utilization of Fibric Acid Derivatives

##### Comparison of Calendar Years

Calendar Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
2012	3,007	13,162	\$1,310,994.91	\$99.60	\$2.67	645,539	491,240
2013	3,061	13,670	\$1,202,060.11	\$87.93	\$2.32	671,338	517,859
% Change	1.80%	3.90%	-8.30%	-11.70%	-13.10%	4.00%	5.40%
Change	54	508	-\$108,934.80	-\$11.67	-\$0.35	25,799	26,619

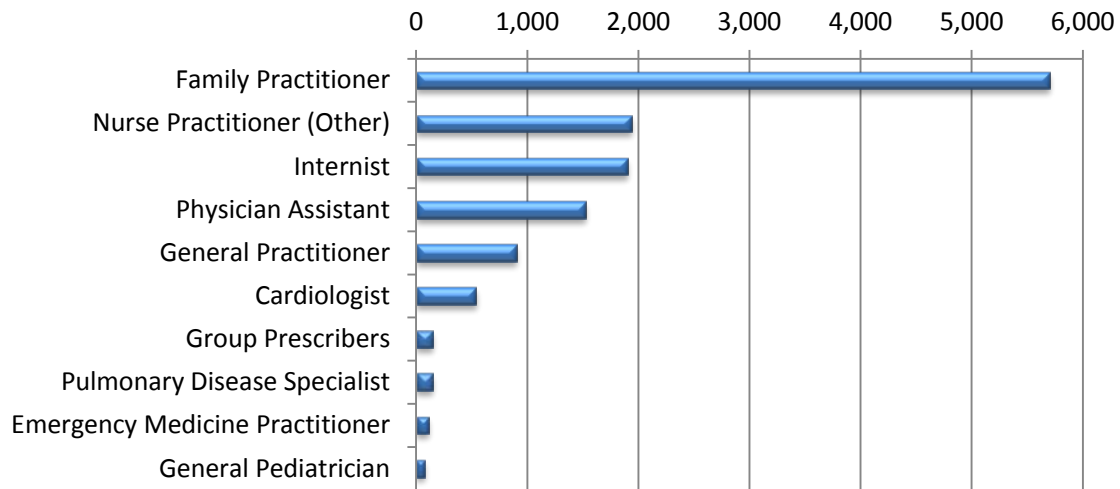
\*Total number of unduplicated members

##### Demographics of Members Utilizing Fibric Acid Derivatives





## Top Prescriber Specialties of Fibric Acid Derivatives by Number of Claims

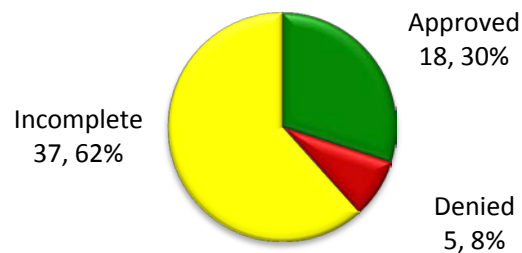


## Prior Authorization of Fibric Acid Derivatives

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There was a total of 60 petitions submitted for the Fibric Acid Derivatives category during calendar year 2013. The following chart shows the status of the submitted petitions.

### Status of Petitions



## Market News and Updates

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### Anticipated Patent Expirations

- Lipofen® (fenofibrate)- 01/2015
- Triglide® (fenofibrate)- 09/2021
- Trilipix® (fenofibrate)- 01/2025
- Fenoglide® (fenofibrate)- 12/2024

## Recommendations

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The College of Pharmacy recommends no changes.

## Utilization Details for Fibric Acid Derivatives: Calendar Year 2013

Chemical Name	Product Utilized	Claims	Members	Cost	Cost/Day	% Cost	Cost/Claim
Gemfibrozil	GEMFIBROZIL TAB 600MG	5,121	1,149	\$72,671.59	\$0.44	6.05%	\$14.19
<b>SUBTOTAL</b>		<b>5,121</b>	<b>1,149</b>	<b>\$72,671.59</b>	<b>\$0.44</b>	<b>6.05%</b>	<b>\$14.19</b>
Fenofibrate	FENOFIBRATE TAB 145MG	2,718	695	\$491,910.13	\$4.25	40.92%	\$180.98
Fenofibrate	TRICOR TAB 145MG	166	64	\$38,961.21	\$5.82	3.24%	\$234.71
Fenofibrate	FENOFIBRATE TAB 48MG	464	141	\$27,196.30	\$1.48	2.26%	\$58.61
Fenofibrate	TRICOR TAB 48MG	58	27	\$3,825.17	\$1.97	0.32%	\$65.95
<b>SUBTOTAL</b>		<b>3,406</b>	<b>927</b>	<b>\$561,892.81</b>	<b>\$3.38</b>	<b>46.74%</b>	<b>\$164.97</b>
Choline Fenofibrate	TRILIPIX CAP 135MG	1,137	333	\$264,275.33	\$5.71	21.99%	\$232.43
Choline Fenofibrate	FENOFIBRIC CAP 135MG DR	538	235	\$104,052.56	\$4.37	8.66%	\$193.41
Choline Fenofibrate	TRILIPIX CAP 45MG	278	81	\$20,517.69	\$1.94	1.71%	\$73.80
Choline Fenofibrate	FENOFIBRIC CAP 45MG DR	99	46	\$6,820.09	\$1.51	0.57%	\$68.89
<b>SUBTOTAL</b>		<b>2,052</b>	<b>695</b>	<b>\$395,665.67</b>	<b>\$3.38</b>	<b>32.93%</b>	<b>\$192.82</b>
Fenofibrate	LOFIBRA TAB 160MG	2	2	\$142.74	\$1.19	0.01%	\$71.37
Fenofibrate	FENOFIBRATE TAB 54MG	482	126	\$14,552.59	\$0.82	1.21%	\$30.19
Fenofibrate	FENOFIBRATE CAP 134MG	469	115	\$30,493.31	\$1.48	2.54%	\$65.02
Fenofibrate	FENOFIBRATE CAP 67MG	65	16	\$1,896.21	\$0.84	0.16%	\$29.17
Fenofibrate	FENOFIBRATE CAP 200MG	241	43	\$20,112.04	\$2.29	1.67%	\$83.45
<b>SUBTOTAL</b>		<b>1,259</b>	<b>302</b>	<b>\$67,196.89</b>	<b>\$1.32</b>	<b>5.59%</b>	<b>\$53.37</b>
<b>TIER-1 SUBTOTAL</b>		<b>6,717</b>	<b>3,073</b>	<b>\$1,097,426.96</b>	<b>\$2.13</b>	<b>85.26%</b>	<b>\$163.38</b>
Fenofibrate	FENOFIBRATE TAB 160MG	1,673	431	\$92,588.69	\$1.30	7.70%	\$55.34
Fenofibrate	TRIGLIDE TAB 160MG	125	31	\$5,767.30	\$1.54	0.48%	\$46.14
Fenofibrate	TRIGLIDE TAB 50MG	10	3	\$2,104.84	\$7.02	0.18%	\$210.48
<b>SUBTOTAL</b>		<b>1,808</b>	<b>465</b>	<b>\$100,460.83</b>	<b>\$3.28</b>	<b>8.36%</b>	<b>\$55.56</b>
Fenofibrate	LIPOFEN CAP 150MG	13	2	\$1,594.98	\$4.09	0.13%	\$122.69
<b>SUBTOTAL</b>		<b>13</b>	<b>2</b>	<b>\$1,594.98</b>	<b>\$4.09</b>	<b>0.13%</b>	<b>\$122.69</b>
Fenofibrate	FENOFIBRATE CAP 130MG	8	2	\$2,019.27	\$5.61	0.17%	\$252.41
Fenofibrate	ANTARA CAP 130MG	3	1	\$558.07	\$6.20	0.05%	\$186.02
<b>SUBTOTAL</b>		<b>11</b>	<b>3</b>	<b>\$2,577.34</b>	<b>\$5.91</b>	<b>0.22%</b>	<b>\$234.30</b>
<b>TIER-2 SUBTOTAL</b>		<b>1,832</b>	<b>470</b>	<b>\$104,633.15</b>	<b>\$4.42</b>	<b>8.71%</b>	<b>\$57.11</b>
<b>TOTAL</b>		<b>13,670</b>	<b>3,061*</b>	<b>\$1,202,060.11</b>	<b>\$2.32</b>	<b>100%</b>	<b>\$87.93</b>

\*Total number of unduplicated members.

# Annual Review of Growth Hormone

## Oklahoma Health Care Authority Calendar Year 2013 Print Review

### Current Prior Authorization Criteria

#### Covered indications (prior to epiphyseal closure):

- 1) Classic human growth hormone (hGH) deficiency as determined by childhood hGH stimulation tests.
- 2) Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, irradiation, hemorrhage, or infarction or a congenital anomaly, and
  - a.  $\geq 3$  pituitary hormones deficient and IGF-1  $\leq 2.5$  standard deviation (SD) below the mean.
  - b. 0, 1, or 2 hormones deficient and IGF-1  $< 50^{\text{th}}$  percentile (midline) and failure of a growth hormone stimulation test.
- 3) Panhypopituitarism in children with height  $< 2.25$  SD below mean for age and MRI evidence for empty sella, pituitary stalk agenesis, or ectopic posterior pituitary "bright spot."
- 4) Short stature associated with Prader-Willi Syndrome.
- 5) Short stature associated with chronic renal insufficiency (pre-transplantation).
- 6) History of intrauterine growth restriction who have not reached a normal height ( $\geq 2.25$  SD below mean for age/gender) by age 2 years.
- 7) Idiopathic short stature (ISS) who are  $\geq 2.25$  SD below mean for height and are unlikely to catch up in height.
- 8) Turner syndrome or 45X, 46XY mosaicism.
- 9) Hypoglycemia with evidence for hGH deficiency.
- 10) SHOX deficiency (with genetic evidence for short stature homeobox-containing gene deficiency).
- 11) Other evidence for hGH deficiency submitted for panel review and decision.

Tier 1*	Tier 2
<b>Genotropin</b> <sup>®</sup> (Pfizer) - Cartridge, MiniQuick	<b>Nutropin</b> <sup>®</sup> and <b>Nutropin AQ</b> <sup>®</sup> (Genentech) – vials, Pen Cartridge
	<b>Humatrope</b> <sup>®</sup> (Eli Lilly) - Vials, Cartridge kits
	<b>Norditropin</b> <sup>®</sup> (NovoNordisk) - NordiPen cartridges, NordiFlex pens, FlexPro pens
	<b>Omnitrope</b> <sup>®</sup> (Sandoz) - Vials, Cartridge
	<b>Saizen</b> <sup>®</sup> (EMD Serono) - Vials, Cartridges for Easypod, Cool.click, Click.easy
	<b>Serostim</b> <sup>®</sup> (EMD Serono) - Vials
	<b>Zorbitive</b> <sup>®</sup> (EMD Serono) - Vials
	<b>Tev-Tropin</b> <sup>®</sup> (Gate/Teva) - Vials

\*Supplemental rebate (All products contain the identical 191 amino acid sequence found in pituitary-derived hGH.)

**Tier-2 Approval Criteria:**

1. Documented allergic reaction to non-active components of all available Tier 1 medications.
2. Clinical exception applies to members with a diagnosis of AIDS wasting syndrome, in which case Serostim can be used, regardless of its current Tier status.

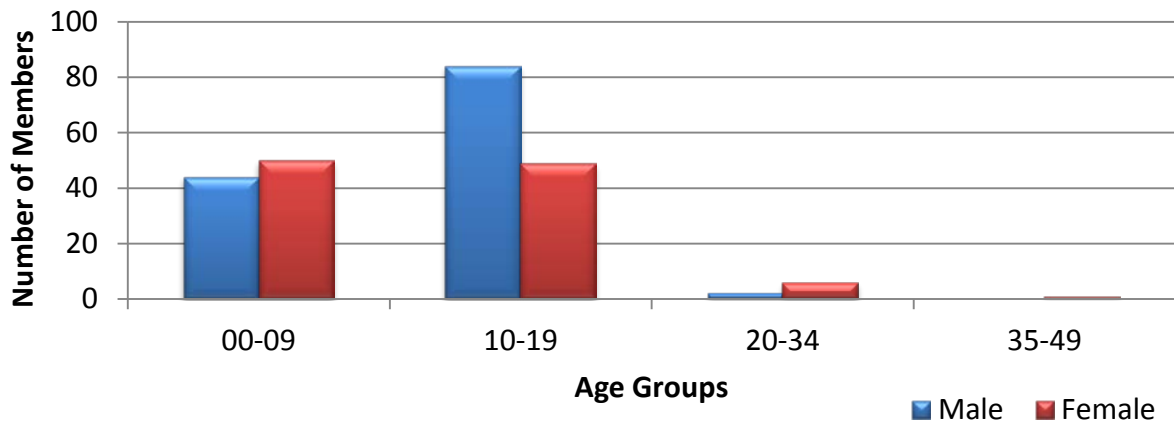
**Utilization of Growth Hormone**

**Comparison of Calendar Years**

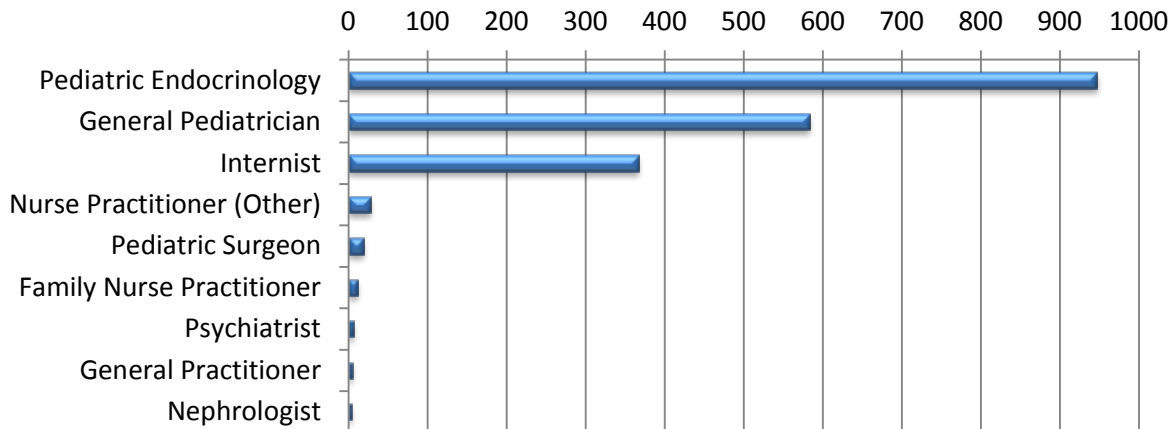
Calendar Year	*Total Members	Total Claims	Total Cost	Cost per Claim	Per-Diem Cost	Total Units	Total Days
2012	226	1,951	\$4,608,969.88	\$2,362.36	\$85.49	11,097	53,912
2013	236	1,971	\$5,535,173.09	\$2,808.31	\$97.72	19,358	56,643
% Change	4.40%	1.00%	20.10%	18.90%	14.30%	74.40%	5.10%
Change	10	20	\$926,203.21	\$445.95	\$12.23	8,261	2,731

\*Total number of unduplicated members

**Demographics of Members Utilizing Growth Hormone**



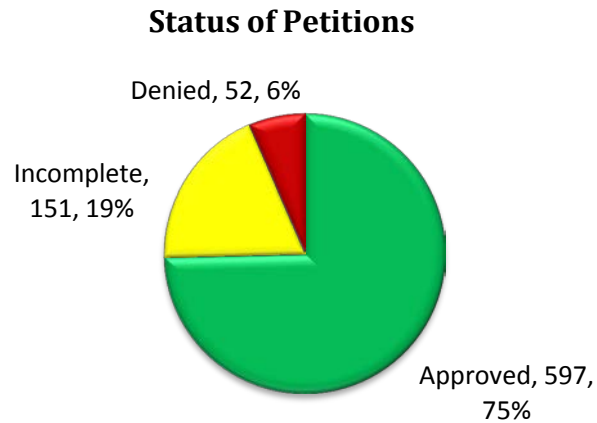
**Top Prescriber Specialties of Growth Hormone by Number of Claims**



## Prior Authorization of Growth Hormone

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There was a total of 800 petitions submitted for growth hormone during calendar year 2013. The following chart shows the status of the submitted petitions.



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

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### Patent Expirations

- Nutropin<sup>®</sup> AQ – June 2015
- Norditropin<sup>®</sup> – December 2015
- Saizen<sup>®</sup> - April 2016
- Serostim<sup>®</sup> - April 2016
- Genotropin<sup>®</sup> - November 2018

## Recommendations

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

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<sup>10</sup> FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://orange-book.findthebest.com/>. Last revised: 03/18/14. Last accessed 04/10/2014.

## Utilization Details of Growth Hormone

Product Utilized	Total Claims	Total Members	Total Cost	Units/Day	Cost/Day	Cost/Claim	Percent Cost
<b>Genotropin Products</b>							
GENOTROPIN INJ 5MG	921	130	\$1,918,536.35	0.17	\$72.06	\$2,083.10	34.66%
GENOTROPIN INJ 12MG	432	55	\$2,135,821.07	0.16	\$168.92	\$4,944.03	38.59%
GENOTROPIN INJ 1MG	87	20	\$238,111.62	1	\$94.45	\$2,736.92	4.30%
GENOTROPIN INJ 0.8MG	75	12	\$163,447.50	0.99	\$75.04	\$2,179.30	2.95%
GENOTROPIN INJ 0.6MG	60	10	\$91,506.20	0.99	\$56.59	\$1,525.10	1.65%
GENOTROPIN INJ 1.2MG	56	11	\$181,635.36	1	\$113.24	\$3,243.49	3.28%
GENOTROPIN INJ 0.4MG	47	8	\$45,061.49	1	\$33.98	\$958.76	0.81%
GENOTROPIN INJ 0.2MG	35	6	\$18,837.37	1	\$19.07	\$538.21	0.34%
GENOTROPIN INJ 2MG	28	6	\$154,172.07	1.02	\$194.66	\$5,506.15	2.79%
GENOTROPIN INJ 1.4MG	11	2	\$40,409.52	0.91	\$118.85	\$3,673.59	0.73%
GENOTROPIN INJ 1.6MG	7	2	\$30,295.44	0.96	\$148.51	\$4,327.92	0.55%
GENOTROPIN INJ 1.8MG	5	1	\$24,342.75	1	\$173.88	\$4,868.55	0.44%
<b>Subtotal</b>	<b>1,764</b>	<b>222</b>	<b>\$5,042,176.74</b>	<b>0.36</b>	<b>\$98.91</b>	<b>\$2,858.38</b>	<b>91.09%</b>
<b>Tier-1 Subtotal</b>	<b>1,764</b>	<b>222</b>	<b>\$5,042,176.74</b>	<b>0.36</b>	<b>\$98.91</b>	<b>\$2,858.38</b>	<b>91.09%</b>
<b>Nutropin Products</b>							
NUTROPIN AQ INJ 10MG/2ML	94	51	\$233,166.28	0.21	\$89.85	\$2,480.49	4.21%
NUTROPIN AQ INJ NUSPIN 5	46	31	\$67,074.96	0.25	\$52.08	\$1,458.15	1.21%
NUTROPIN AQ INJ 20MG/2ML	24	14	\$129,540.95	0.22	\$193.06	\$5,397.54	2.34%
NUTROPIN INJ 10MG	4	3	\$13,933.15	0.14	\$124.40	\$3,483.29	0.25%
<b>Subtotal</b>	<b>168</b>	<b>99</b>	<b>\$443,715.34</b>	<b>0.22</b>	<b>\$95.10</b>	<b>\$2,641.16</b>	<b>8.01%</b>
<b>Norditropin Products</b>							
NORDITROPIN INJ 10/1.5ML	11	3	\$24,167.20	0.14	\$80.02	\$2,197.02	0.44%
NORDITROPIN INJ 15/1.5ML	11	2	\$23,759.31	0.18	\$83.37	\$2,159.94	0.43%
NORDITROPIN INJ 30/3ML	7	1	\$575.00	0.26	\$3.57	\$82.14	0.01%
<b>Subtotal</b>	<b>29</b>	<b>6</b>	<b>\$48,501.51</b>	<b>0.18</b>	<b>\$64.84</b>	<b>\$1,672.47</b>	<b>0.88%</b>
<b>Omnitrope Products</b>							
OMNITROPE INJ 5/1.5ML	10	1	\$779.50	0.18	\$3.12	\$77.95	0.01%
<b>Subtotal</b>	<b>10</b>	<b>1</b>	<b>\$779.50</b>	<b>0.18</b>	<b>\$3.12</b>	<b>\$77.95</b>	<b>0.01%</b>
<b>Tier-2 Subtotal</b>	<b>207</b>	<b>106</b>	<b>\$492,996.35</b>	<b>0.21</b>	<b>\$87.04</b>	<b>\$2,381.62</b>	<b>8.9%</b>
<b>Total</b>	<b>1,971</b>	<b>236*</b>	<b>\$5,535,173.09</b>	<b>0.34</b>	<b>\$97.72</b>	<b>\$2,808.31</b>	<b>100%</b>

\*Total Number of Unduplicated Members.

## Annual Review of Rescue HFA Inhalers

### Oklahoma Health Care Authority Calendar Year 2013 Print Review

#### Current Prior Authorization Criteria

Tier-2 Approval Criteria:

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

Short Acting Beta-2 Agonists	
Tier 1	Tier 2
ProAir® HFA	Xopenex® HFA*
Proventil® HFA	Ventolin® HFA

\*Xopenex® authorization requests should document why the member is unable to use racemic albuterol. If prescribed for asthma, member should also be utilizing inhaled corticosteroid therapy for long-term control. Dose of levalbuterol requested cannot be less than the racemic equivalent documented on the prior authorization request.

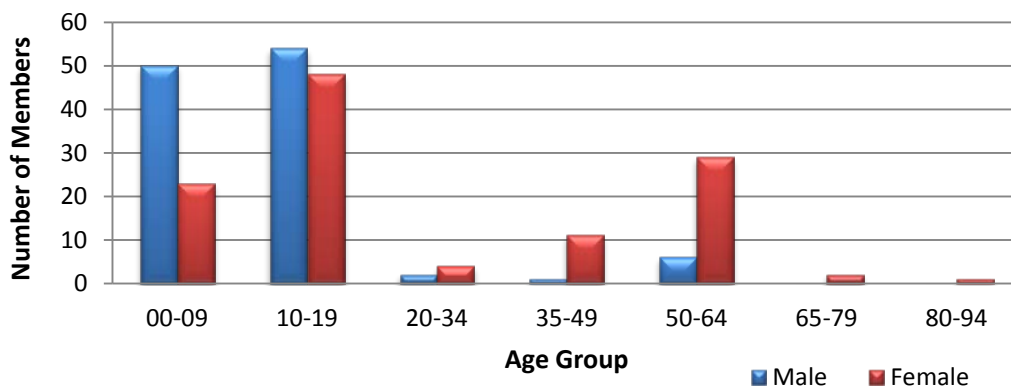
#### Utilization of Rescue HFA Inhalers

##### Comparison of Calendar Years

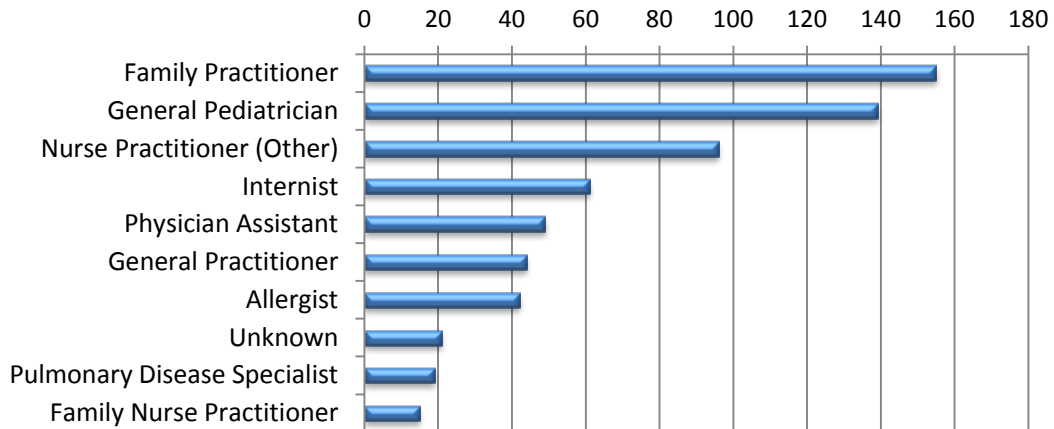
Calendar Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
<b>2012</b>	84,728	181,744	\$9,817,246.52	\$54.02	\$2.25	1,919,054	4,372,218
<b>2013</b>	81,453	174,665	\$10,355,578.34	\$59.29	\$2.43	1,740,781	4,260,402
<b>% Change</b>	<b>-3.90%</b>	<b>-3.90%</b>	<b>5.50%</b>	<b>9.80%</b>	<b>8.00%</b>	<b>-9.30%</b>	<b>-2.60%</b>
<b>Change</b>	<b>-3,275</b>	<b>-7,079</b>	<b>\$538,331.82</b>	<b>\$5.27</b>	<b>\$0.18</b>	<b>-178,273</b>	<b>-111,816</b>

\*Total number of unduplicated members

##### Demographics of Members Utilizing Rescue HFA Inhalers



## Top Prescriber Specialties of Rescue HFA Inhalers by Number of Claims

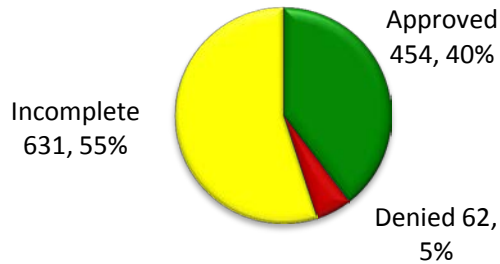


## Prior Authorization of Rescue HFA Inhalers

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There was a total of 1,147 petitions submitted for the Rescue HFA Inhaler category during calendar year 2013. The following chart shows the status of the submitted petitions.

### Status of Petitions



## Market News and Updates

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### Anticipated Patent Expirations

- Proventil®- 06/2015
- Xopenex HFA®- 11/2015
- Proair® - 12/2017
- Ventolin®- 12/2016

## Recommendations

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



### Utilization Details for Rescue HFA Inhalers: Calendar Year 2013

MEDICATION NAME	CLAIMS	MEMBERS*	COST	COST/ CLAIM	COST/ DAY	% COST
PROAIR HFA AER	145,929	70,383	\$8,519,094.61	\$58.38	\$2.39	82.27%
PROVENTIL AER HFA	26,458	13,131	\$1,707,047.89	\$64.52	\$2.66	16.48%
<b>TIER-1 SUBTOTAL</b>	<b>172,387</b>	<b>83,514</b>	<b>\$10,226,142.50</b>	<b>\$59.32</b>	<b>\$2.52</b>	<b>98.75%</b>
VENTOLIN HFA AER	1,627	355	\$88,637.87	\$54.48	\$2.24	0.86%
XOPENEX HFA AER	651	231	\$40,797.97	\$62.67	\$2.36	0.39%
<b>TIER-2 SUBTOTAL</b>	<b>2,278</b>	<b>586</b>	<b>\$129,435.84</b>	<b>\$56.82</b>	<b>\$2.30</b>	<b>1.25%</b>
<b>TOTAL:</b>	<b>174,665</b>	<b>81,453*</b>	<b>\$10,355,578.34</b>	<b>\$60.01</b>	<b>\$2.43</b>	<b>100%</b>

\*Total number of unduplicated members.

## Annual Review of Xopenex® (Levalbuterol) Nebulizer Solution

Oklahoma Health Care Authority  
Calendar Year 2013 Print Review

### Current Prior Authorization Criteria

Xopenex® (Levalbuterol) Approval Criteria:

1. Patient specific, clinically significant reason why member is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the NAEPP guidelines.
2. Also, the need for use of this product over an albuterol MDI should be stated.
3. Clinical exceptions will be made for members with COPD.
4. Quantity limit of 288mls per 30 days will also apply.

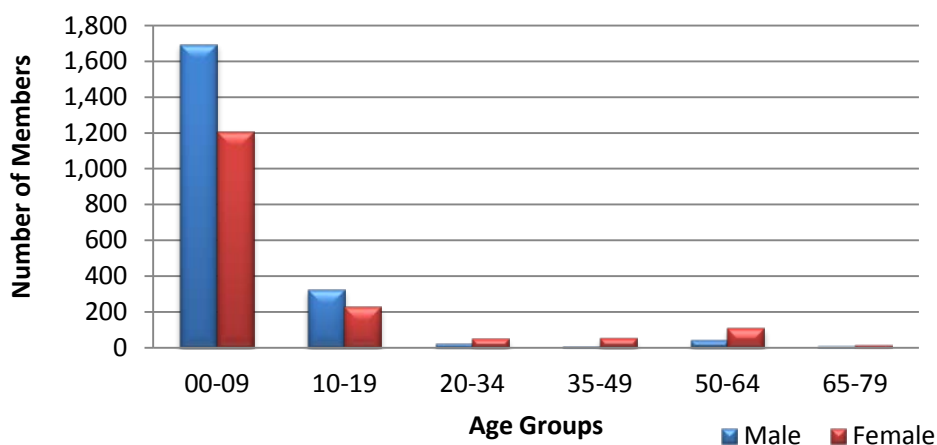
### Utilization of Xopenex® Nebulizer Solution

#### Comparison of Calendar Years

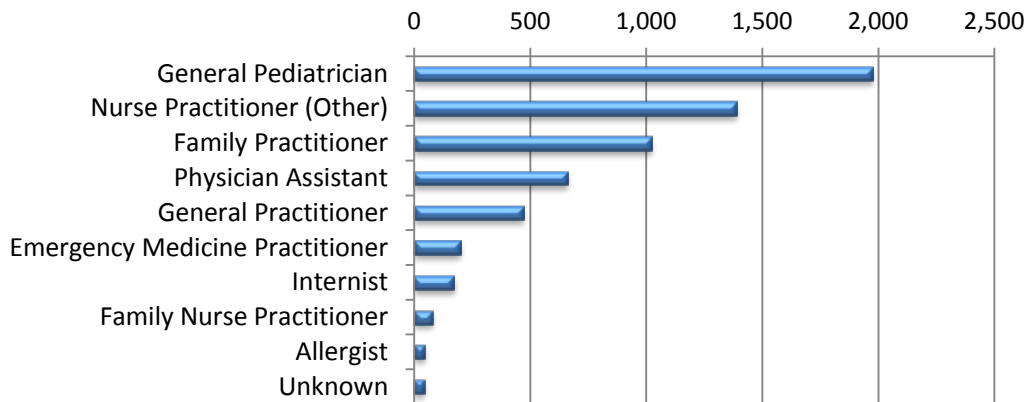
Calendar Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
<b>2012</b>	4,652	7,611	\$1,976,031.59	\$259.63	\$15.21	994,838	129,916
<b>2013</b>	3,766	6,256	\$1,545,953.18	\$247.12	\$14.24	815,438	108,530
<b>% Change</b>	<b>-19.00%</b>	<b>-17.80%</b>	<b>-21.80%</b>	<b>-4.80%</b>	<b>-6.40%</b>	<b>-18.00%</b>	<b>-16.50%</b>
<b>Change</b>	<b>-886</b>	<b>-1,355</b>	<b>-\$430,078.41</b>	<b>-\$12.51</b>	<b>-\$0.97</b>	<b>-179,400</b>	<b>-21,386</b>

\*Total number of unduplicated members

#### Demographics of Members Utilizing Xopenex® Nebulizer Solution



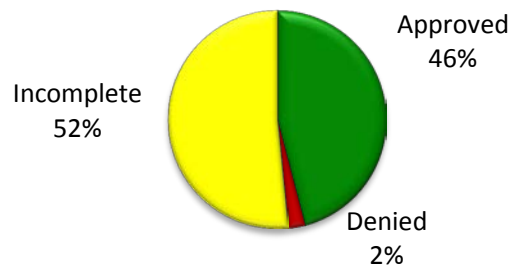
## Top Prescriber Specialties of Xopenex® Nebulizer Solution by Number of Claims



## Prior Authorization of Xopenex® Nebulizer Solution

There was a total of 359 petitions submitted for the Xopenex® Nebulizer Solution category during calendar year 2013. The following chart shows the status of the submitted petitions.

### Status of Petitions



## Recommendations

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

## Utilization Details for Xopenex® Nebulized Solution: Calendar Year 2013

MEDICATION NAME	CLAIMS	MEMBERS*	COST	COST/CLAIM	COST/DAY	% COST
LEVALBUTEROL NEB 0.63MG	2,848	1,871	\$672,704.28	\$236.20	\$13.68	43.51%
LEVALBUTEROL NEB 0.31MG	1,373	1,000	\$300,682.81	\$219.00	\$13.65	19.45%
LEVALBUTEROL NEB 1.25MG	1,617	873	\$432,117.74	\$267.23	\$14.65	27.95%
LEVALBUTEROL NEB 1.25/0.5	16	8	\$3,448.83	\$215.55	\$13.37	0.22%
XOPENEX NEB 0.63MG	200	101	\$74,188.90	\$370.94	\$19.68	4.80%
XOPENEX NEB 1.25/3ML	116	58	\$43,174.22	\$372.19	\$16.95	2.79%
XOPENEX NEB 0.31MG	84	67	\$19,041.66	\$226.69	\$15.61	1.23%
XOPENEX CONC NEB 1.25/0.5	2	2	\$594.74	\$297.37	\$16.07	0.04%
<b>TOTAL:</b>	<b>6,256</b>	<b>3,766*</b>	<b>\$1,545,953.18</b>	<b>\$275.65</b>	<b>\$14.24</b>	<b>100%</b>

\*Total number of unduplicated members.

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# Annual Review of Gralise™ and Horizant® (Gabapentin Extended-Release)

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Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Prior Authorization Criteria

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### Gralise™ (Gabapentin ER) Approval Criteria:

1. An FDA-approved indication of postherpetic neuralgia; and
2. Member must be 18 years or older; and
3. Must provide documented treatment attempts at recommended dosing or contraindications to at least one agent from two of the following drug classes:
  - a. Tricyclic antidepressants
  - b. Anticonvulsants
  - c. Topical or oral analgesics
4. Must also provide a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin.

### Horizant® (Gabapentin Enacarbil ER) Approval Criteria:

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

## Utilization of Gralise™ and Horizant®

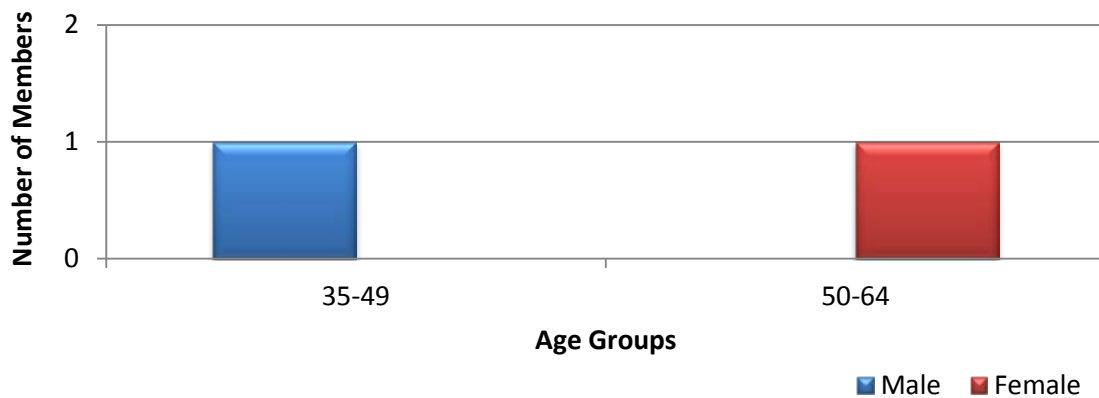
There was no utilization of Gralise™ or Horizant® during fiscal year 2012.

### Utilization Details of Gralise™ and Horizant®: Fiscal Year 2013

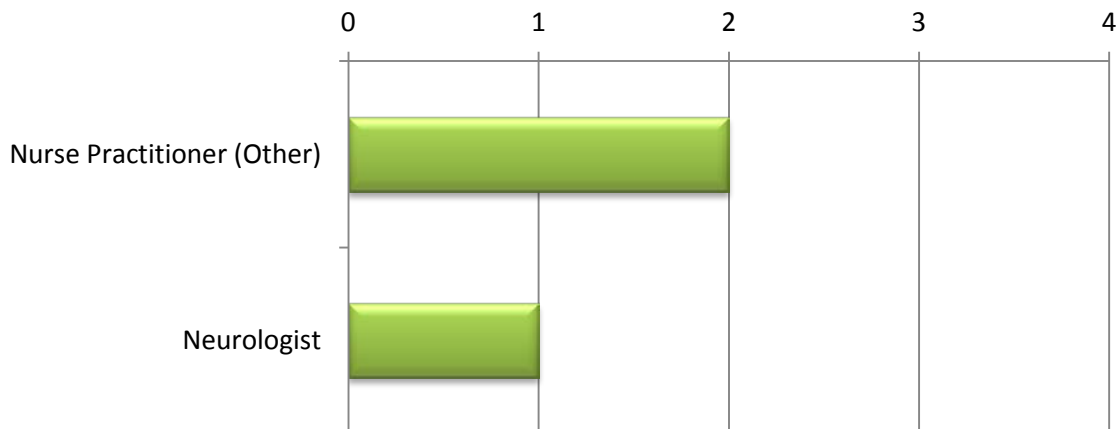
Product Utilized	Total Claims	Total Members	Total Cost	Cost/Day	Cost/Claim	Percent Cost
<b>GABAPENTIN EXTENDED-RELEASE PRODUCTS</b>						
Gralise™ 600mg	2	1	\$428.72	\$7.15	\$214.36	78.88%
Horizant® 600mg	1	1	\$114.81	\$3.83	\$114.81	21.12%
<b>TOTAL</b>	<b>3</b>	<b>2*</b>	<b>\$543.53</b>	<b>\$6.04</b>	<b>\$181.18</b>	<b>100.00%</b>

\*Total number of unduplicated members.

### Demographics of Members Utilizing Gralise™ and Horizant®



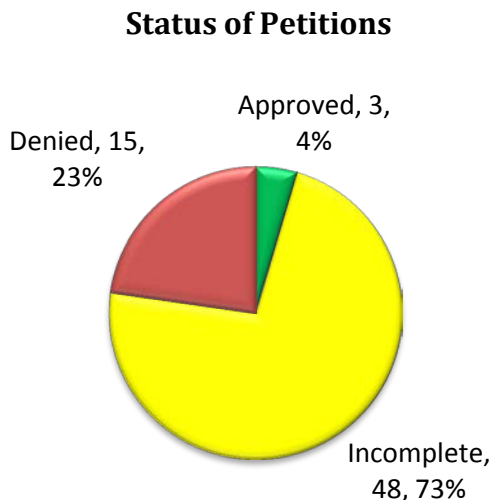
### Top Prescriber Specialties of Gralise™ and Horizant® by Number of Claims



## **Prior Authorization of Gralise™ and Horizant®**

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There was a total of 66 petitions submitted for Gralise™ and Horizant® during fiscal year 2013. The following chart shows the status of the submitted petitions.



## **Market News and Updates<sup>11</sup>**

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### Anticipated Patent Expirations

- Gralise™ (gabapentin ER)- 2/2024
- Horizant® (gabapentin enacarbil ER)- 11/2026

## **Recommendations**

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

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<sup>11</sup> 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 4/10/14. Last accessed 4/11/14.

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## **Annual Review of Metozolv® (Metoclopramide HCL ODT Tablets)**

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**Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review**

### **Current Prior Authorization Criteria**

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#### **Metozolv® (Metoclopramide HCL ODT Tablets) Approval Criteria:**

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

### **Utilization of Metozolv® (Metoclopramide HCL ODT tablets)**

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There was no utilization of Metozolv during fiscal year 2013.

### **Market News and Updates**

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#### **Anticipated Patent Expirations**

- Metozolv® (metoclopramide HCL ODT tablets)- 07/2017

### **Recommendations**

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

## Annual Review of Miscellaneous Antibiotics

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

### Current Prior Authorization Criteria

#### Miscellaneous Antibiotics Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

Miscellaneous Antibiotics	
Tier 1	Tier 2
Immediate release formulations	amoxicillin/clavulanate potassium extended-release tablet (Augmentin XR®)
	doxycycline hyclate delayed-release tablet (Doryx®)
	cephalexin 750mg capsule (Keflex® 750mg)
	amoxicillin extended release 775mg tablet (Moxatag®)
	doxycycline monohydrate extended-release 40mg capsule (Oracea®)
	minocycline extended-release tablet (Solodyn®)
	Amoxicillin tablet 500mg (Amoxil®)

#### Doxycycline Monohydrate Approval Criteria

1. Member must have a patient specific, clinically significant reason why the hyclate formulation cannot be used.

### Utilization of Miscellaneous Antibiotics

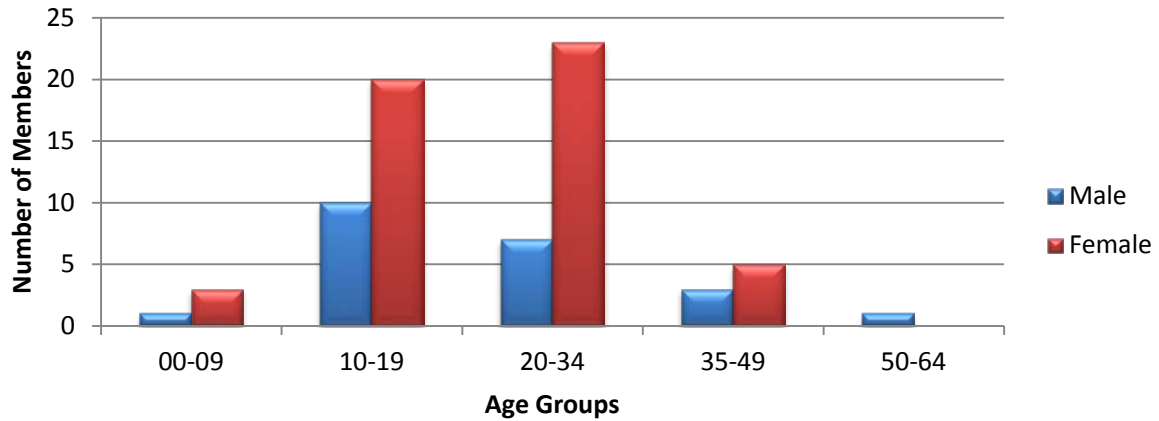
#### Comparison of Fiscal Years

Fiscal Year	Total Members*	Total Claims	Total Cost	Cost / Claim	Cost/ Day	Total Units	Total Days
2012	188	208	\$12,746.08	\$61.28	\$5.87	4,969	2,170
2013	73	84	\$2,904.01	\$34.57	\$3.06	2,172	948
% Change	-61.20%	-59.60%	-77.20%	-43.60%	-47.90%	-56.30%	-56.30%
Change	-115	-124	\$9,842.07	\$26.71	\$2.81	-2,797	-1,222

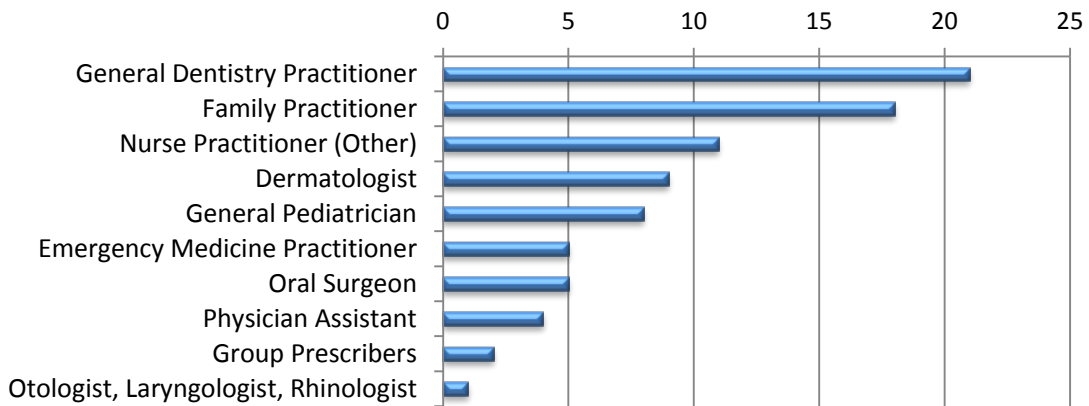
\*Total number of unduplicated members.



### Demographics of Members Utilizing Miscellaneous Antibiotics

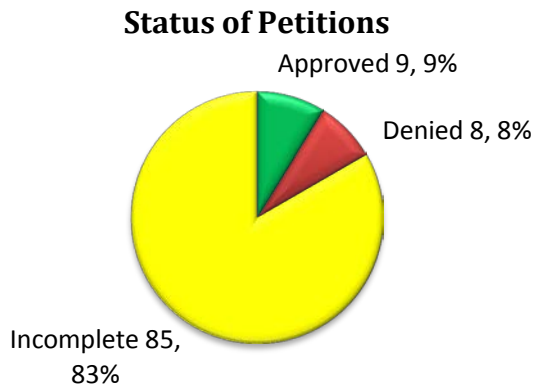


### Top Prescriber Specialties of Miscellaneous Antibiotic by Number of Claims



### Prior Authorization of Miscellaneous Antibiotics

There was a total of 102 petitions submitted for the miscellaneous antibiotic category during fiscal year 2013. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>12</sup>

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### Anticipated Patent Expirations

- Oracea® (doxycycline monohydrate extended-release) - 08/2016
- Solodyn® (minocycline extended-release)- 02/2018
- Augmentin XR®( amoxicillin/clavulanate potassium extended-release)- 04/2020
- Moxatag® (amoxicillin extended release)- 10/2020

### FDA Update

- FDA Safety Update January 2013: Drug Interaction with oral anticoagulants. Abnormal prolongation of prothrombin time (increased international normalized ratio) has been reported in patients receiving amoxicillin and oral anticoagulants.

### Recommendations

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

### Utilization of Miscellaneous Antibiotics

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Chemical Name	Product Utilized	Total Claims	Total Members	Total Cost	Claims/Member	% Cost	Cost/Claim
Amoxicillin	AMOXICILLIN TAB 500MG	71	66	\$561.98	1.08	19.35%	\$7.92
<b>SUBTOTAL</b>		<b>71</b>	<b>66</b>	<b>\$561.98</b>	<b>1.08</b>	<b>19.35%</b>	<b>\$7.92</b>
Doxycycline	DOXYCYCL HYC TAB 150MG DR	7	2	\$1,161.13	3.5	39.98%	\$165.88
<b>SUBTOTAL</b>		<b>7</b>	<b>2</b>	<b>\$1,161.13</b>	<b>3.5</b>	<b>39.98%</b>	<b>\$165.88</b>
Amoxicillin K Clav	AMOX/CLAV TAB ER 1000-62.5MG	3	3	\$263.77	1	9.08%	\$87.92
Amoxicillin K Clav	AUGMENTIN XR TAB 12HR	1	1	\$69.05	1	2.38%	\$69.05
<b>SUBTOTAL</b>		<b>4</b>	<b>4</b>	<b>\$332.82</b>	<b>1</b>	<b>11.46%</b>	<b>\$83.21</b>
Doxycycline	ORACEA CAP 40MG	2	1	\$848.08	2	29.20%	\$424.04
<b>SUBTOTAL</b>		<b>2</b>	<b>1</b>	<b>\$848.08</b>	<b>2</b>	<b>29.20%</b>	<b>\$424.04</b>
<b>Total</b>		<b>84</b>	<b>73</b>	<b>\$2,904.01*</b>	<b>1.15</b>	<b>100 %</b>	<b>\$34.57</b>

\*Total number of unduplicated members.

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<sup>12</sup> FDA: Safety Information. Available online at: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm338263.htm>. Last revised: 02/08/13. Last accessed: 04/14/14

<sup>12</sup> 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: 4/10/14. Last accessed: 4/11/14.

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## Annual Review of Mozobil® (Plerixafor), Nplate® (Romiplostim), Arcalyst® (Rilonacept), and Ilaris® (Canakinumab)

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### Oklahoma Health Care Authority Fiscal Year 2013 Print Review

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*Under Oklahoma state law, the OHCA DUR Board must review and make recommendations for any drug subject to prior authorization, whether covered under the pharmacy benefit, the medical benefit, or both. Accordingly, physician administered drugs are brought through the same DUR process as those dispensed by pharmacies.*

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### Current Prior Authorization Criteria

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#### **Mozobil® (Plerixafor, J2562) Approval Criteria:**

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

#### **Nplate® (Romiplostim, J2796) Approval Criteria:**

1. An FDA approved indication of chronic immune (idiopathic) thrombocytopenia purpura (ITP).
2. Previous insufficient response with at least two of the following treatments:
  - a. corticosteroids, immunoglobulins, or splenectomy
3. Recent platelet count of  $< 50 \times 10^9/L$
4. Dosing (requires recent body weight in kilograms):
  - a. Initial dosing of 1 mcg/kg once weekly as a subcutaneous injection
5. Continuation criteria:
  - a. Weekly CBCs with platelet count and peripheral blood smears until stable platelet count ( $\geq 50 \times 10^9/L$  for at least 4 weeks without dose adjustment) has been achieved; then obtain monthly thereafter
  - b. Dosing adjustments:
    - i. Platelets  $< 50 \times 10^9/L$ , increase dose by 1 mcg/kg.
    - ii. Platelets  $> 200 \times 10^9/L$  for 2 consecutive weeks, reduce dose by 1 mcg/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 1 mcg/kg.
6. Discontinuation criteria:
  - a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum weekly dose of 10 mcg/kg
7. Approval period will be for an initial duration of four weeks, and then quarterly.

**Arcalyst® (Riloncept, J2793) Approval Criteria:**

1. FDA approved indication of Cryopyrin-Associated Periodic Syndromes (CAPS) verified by genetic testing. This includes Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.
2. The member should not be using a tumor necrosis factor blocking agent (e.g. adalimumab, etanercept, and infliximab) or anakinra
3. Should not be initiated in patients with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis.
4. Dosing should not be more often than once weekly.
5. Approved dosing schedule for adults 18 and over:
  - a. Initial treatment: loading dose of 320 mg delivered as two (2 mL) subcutaneous injections of 160 mg each given on the same day at two different injection sites.
  - b. Continued treatment is one 160 mg injection given once weekly.
6. Approved dosing schedule for pediatric patients aged 12-17 years (requires recent weight in kilograms):
  - a. Initial treatment: loading dose of 4.4 mg/kg, up to a maximum of 320 mg, delivered as one or two subcutaneous injections with a maximum single-injection volume of 2mL.
  - b. Continued treatment is 2.2 mg/kg, up to a maximum of 160 mg, given once weekly.
7. Approval period is for the duration of one year.

**Ilaris® (Canakinumab, J0638) 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 4 and older.
2. The member should not be using a tumor necrosis factor blocking agent (e.g. adalimumab, etanercept, and infliximab) or anakinra
3. Should not be initiated in patients with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis.
4. Dosing should not be more often than once every 8 weeks.
5. Dosing (requires recent weight in kilograms):
  - a. Body weight  $>40$  kg: 150mg
  - b. Body weight 15 kg – 40 kg: 2mg/kg. If inadequate response, may be increased to 3mg/kg
6. Approval period is for the duration of one year.

## Utilization of Physician-Administered Drugs

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### Medical Claims for Fiscal Year 2013

Drug	Members	Claims	Cost	Cost/Claim	Units
Nplate®	1	6	\$6,835.14	\$1,139.19	143

### Prescriber Specialties of Physician Administered Drugs by Number of Claims

- Internal medicine

### Market News and Updates:

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1. Mozobil®- FDA Label Revision 6/4/2013.
  - Contraindication in patients with history of hypersensitivity to Mozobil®.
  - Warnings and Precautions: Anaphylactic shock and hypersensitivity reactions
2. Ilaris®- New FDA approved indication 05/09/2013
  - Juvenile Idiopathic Arthritis
  - Warning and Precaution added: Macrophage Activation Syndrome
  - October 2012- FDA Safety labeling change including neutropenia as a possible side effect in patient information.
3. Nplate®- FDA Safety Labeling Changes 11/2012
  - Hypersensitivity and angioedema added to adverse reactions after post-marketing experience.
4. Arcalyst®- FDA decision on supplemental biologics license application 07/2012
  - FDA did not approve the supplemental application for gout flares in patients initiating uric-acid lowering therapy.
  - FDA asked in response letter for more data.

### Recommendations

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

# Annual Review of Ocular Allergy Products

## Oklahoma Health Care Authority Calendar Year 2013 Print Review

### Prior Authorization Criteria

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

1. An FDA approved diagnosis; and
2. 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
3. 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. Contraindication to all lower tiered medications.

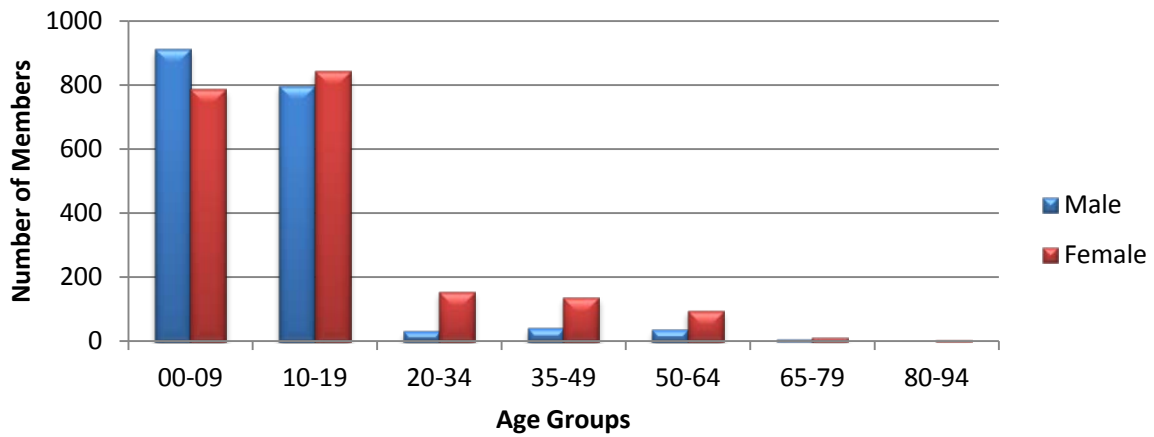
Ocular Allergy Products		
Tier 1	Tier 2	Tier 3
cromolyn (Crolom®) ketotifen (Alaway®, Zaditor OTC®)	olopatadine (Patanol®) olopatadine (Pataday®)	nedocromil (Alocril®) pemirolast (Alamast®) emedastine (Emadine®) loteprednol (Alrex®) lodoxamide (Alomide®) epinastine (Elestat®) azelastine (Optivar®) bepotastine besilate (Bepreve™) alcaftadine (Lastacast™)

### Comparison of Calendar Years

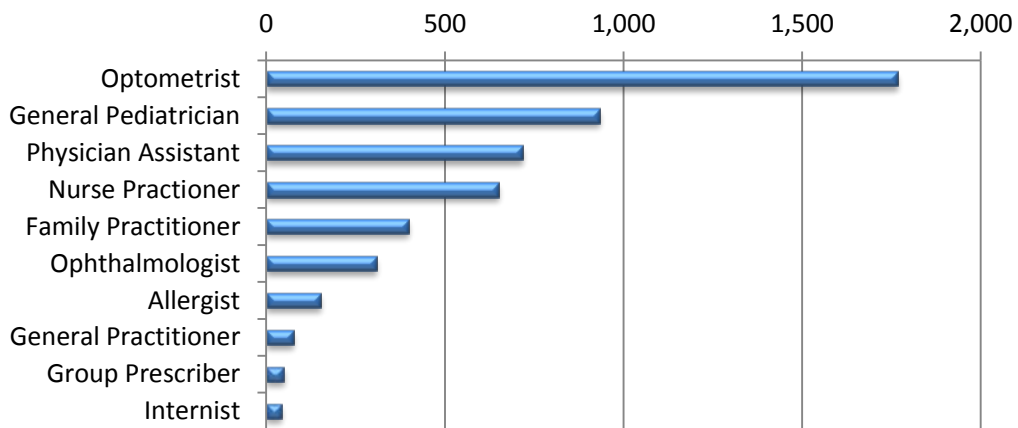
Calendar Year	*Total Members	Total Claims	Total Cost	Cost / Claim	Cost/ Day	Total Units	Total Days
2012	3,874	5,308	\$119,304.26	\$22.48	\$0.70	37,399	170,538
2013	3,853	5,273	\$116,309.94	\$22.06	\$0.71	36,304	164,625
% Change	-0.50%	-0.70%	-2.50%	-1.90%	1.40%	-2.90%	-3.50%
Change	-21	-35	\$2,994.32	\$0.42	\$0.01	-1,095	-5,913

\*Total number of unduplicated members

### Demographics of Members Utilizing Ocular Allergy Medications



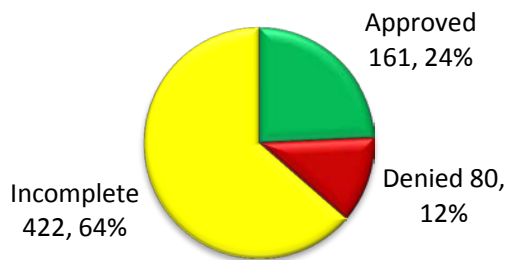
### Top Prescriber Specialties of Ocular Allergy Medications by Number of Claims



### Prior Authorization of Ocular Allergy Medications

There was a total of 663 petitions submitted for ocular allergy medications during calendar year 2013. The following chart shows the status of the submitted petitions.

#### Status of Petitions



## **Market News and Updates<sup>13</sup>**

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### Anticipated Patent Expirations

- Emadine® (emedastine)- 12/2013
- Patanol®(olopatadine)- 6/2015
- Pataday®(olopatadine)- 6/2015
- Lastacraft™ (alcaftadine)- 7/2015
- Bepreve™ (bepotastine besilate)- 12/2017

## **Recommendations**

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

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<sup>13</sup> 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: 4/10/14. Last accessed: 4/11/14.



## Utilization of Ocular Allergy Products

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	CLAIMS/ CLIENT	% COST	COST/ CLAIM
Ketotifen	KETOTIFEN FUM 0.025%	1,868	1,405	\$24,316.11	1.33	20.91%	\$13.02
Ketotifen	ALAWAY 0.025%	1,162	930	\$14,764.20	1.25	12.69%	\$12.71
Ketotifen	EYE ITCH RELIEF 0.025%	535	428	\$6,938.54	1.25	5.97%	\$12.97
Ketotifen	ZADITOR 0.025%	451	376	\$6,405.84	1.2	5.51%	\$14.20
Ketotifen	ALLERGY EYE 0.025%	14	13	\$153.15	1.08	0.13%	\$10.94
Ketotifen	ALAWAY CHILD 0.025%	8	7	\$85.76	1.14	0.07%	\$10.72
Ketotifen	ITCHY EYE 0.025%	6	4	\$71.58	1.5	0.06%	\$11.93
<b>Subtotal</b>		<b>4,044</b>	<b>3,163</b>	<b>\$52,735.18</b>	<b>1.31</b>	<b>45.34%</b>	<b>\$13.04</b>
Cromolyn	CROMOLYN SOL 4%	872	714	\$13,232.83	1.22	11.38%	\$15.18
<b>Subtotal</b>		<b>872</b>	<b>714</b>	<b>\$13,253.83</b>	<b>1.22</b>	<b>11.38%</b>	<b>\$15.18</b>
<b>Tier-1 Subtotal</b>		<b>4,916</b>	<b>34,554</b>	<b>\$65,968.01</b>	<b>1.31</b>	<b>56.72%</b>	<b>\$13.42</b>
Olopatadine	PATADAY SOL 0.2%	20	8	\$2,644.29	2.5	2.27%	\$132.22
<b>Subtotal</b>		<b>20</b>	<b>8</b>	<b>\$2,644.29</b>	<b>2.5</b>	<b>2.27%</b>	<b>\$132.22</b>
Olopatadine	PATANOL SOL 0.1% OP	324	123	\$45,866.18	2.63	39.43%	\$141.56
<b>Subtotal</b>		<b>324</b>	<b>123</b>	<b>\$45,866.18</b>	<b>2.63</b>	<b>39.43%</b>	<b>\$141.56</b>
<b>Tier-2 Subtotal</b>		<b>344</b>	<b>131</b>	<b>\$48,510.47</b>	<b>2.65</b>	<b>41.70%</b>	<b>\$141.20</b>
Epinastine	EPINASTINE DRO 0.05%	4	1	\$290.01	4	0.25%	\$72.50
<b>Subtotal</b>		<b>4</b>	<b>1</b>	<b>\$290.01</b>	<b>4</b>	<b>0.25%</b>	<b>\$72.50</b>
Bepotastine	BEPREVE DRO 1.5%	2	2	\$559.69	1	0.48%	\$279.85
<b>Subtotal</b>		<b>2</b>	<b>2</b>	<b>\$559.69</b>	<b>1</b>	<b>0.48%</b>	<b>\$279.85</b>
Azelastine	AZELASTINE DRO 0.05%	2	2	\$127.55	1	0.11%	\$63.78
<b>Subtotal</b>		<b>2</b>	<b>2</b>	<b>\$127.55</b>	<b>1</b>	<b>0.11%</b>	<b>\$63.78</b>
Alcaftadine	LASTACFT SOL 0.25%	1	1	\$128.31	1	0.11%	\$128.31
<b>Subtotal</b>		<b>1</b>	<b>1</b>	<b>\$128.31</b>	<b>1</b>	<b>0.11%</b>	<b>\$128.31</b>
Loteprednol	ALREX SUS 0.2%	4	3	\$725.90	1.33	0.62%	\$181.48
<b>Subtotal</b>		<b>4</b>	<b>3</b>	<b>\$725.90</b>	<b>1.33</b>	<b>0.62%</b>	<b>\$181.48</b>
<b>Tier-3 Subtotal</b>		<b>13</b>	<b>9</b>	<b>\$1,831.46</b>	<b>0.21</b>	<b>1.57%</b>	<b>\$140.88</b>
<b>Total</b>		<b>5,273</b>	<b>4,017*</b>	<b>\$116,309.94</b>	<b>1.37</b>	<b>100 %</b>	<b>\$22.07</b>

\*Total number of unduplicated members.

# Annual Review of Ocular Antibiotic Products

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Prior Authorization Criteria

### Ocular Antibiotic Tier-2 Approval Criteria:

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

### Ocular Antibiotic Tier-3 Approval Criteria:

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

Ophthalmic Antibiotics: Liquids		
Tier 1	Tier 2	Tier 3
Gentak (Gentamicin)	Ciloxan Solution (Ciprofloxacin)	Azasite (Azithromycin)
AK-Tob (Tobramycin)	Ocuflox (Ofloxacin)	Besivance (besifloxacin HCL)
Bleph-10, Na Sulamyd (Na Sulfacetamide)		Iquix (Levofloxacin)
Polytrim (PolymyxinB/Trimethoprim)		Quixin (Levofloxacin)
AK-Spore (Neo/PolyB/Gramacidin)		Moxeza (moxifloxacin)
		Vigamox (moxifloxacin)
		Zymaxid (Gatifloxacin)

Ophthalmic Antibiotics: Ointments	
Tier 1	Tier 2
AK-Tracin (Bacitracin)	Ciloxan Ointment (Ciprofloxacin)
AK-Poly-Bac (Bacitracin/PolymyxinB)	
Tobrex (Tobramycin)	
Neosporin (Neomycin/Polymyxin B/Bacitracin)	
A/T/S, Ilotycin, Roymicin (Erythromycin)	
Gentak (Gentamicin)	
Bleph-10, Sodium Sulamyd (Sodium Sulfacetamide)	

**Antibiotic/Steroid Combination Product Approval Criteria:**

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

<b>Ophthalmic Antibiotic-Steroid Combination Products</b>	
<b>Tier 1</b>	<b>Tier 2</b>
	Tobradex (Tobramycin/Dexamethasone) Susp & Oint
	Zylet (Tobramycin/Loteprednol) Suspension
	Blephamide (Sulf/Prednisolone) Susp & Oint
	Pred-G (Gentamicin/Prednisolone) Susp & Oint
	Poly-Pred (Neo/Poly/Prednisolone) Susp
	Cortisporin (Neo/Poly/Hydrocortisone) Susp
	Maxitrol (Neo/Poly/Dexamethasone) Susp & Oint
	Bac/Poly/Neo/Hydrocortisone Ointment
	Neo/Poly/Bac/Hydrocortisone Ointment

**Utilization of Ocular Antibiotic Products****Comparison of Fiscal Years****Ointments**

<b>Fiscal Year</b>	<b>Total Members*</b>	<b>Total Claims</b>	<b>Total Cost</b>	<b>Cost / Claim</b>	<b>Cost/ Day</b>	<b>Total Units</b>	<b>Total Days</b>
<b>2012</b>	9,838	10,773	\$209,800.17	\$19.47	\$2.36	38,940	88,863
<b>2013</b>	10,112	11,073	\$203,443.70	\$18.37	\$2.23	39,664	91,193
<b>% Change</b>	<b>2.80%</b>	<b>2.80%</b>	<b>-3.00%</b>	<b>-5.60%</b>	<b>-5.50%</b>	<b>1.90%</b>	<b>2.60%</b>
<b>Change</b>	<b>274</b>	<b>300</b>	<b>-\$6,356.47</b>	<b>\$1.10</b>	<b>-\$0.13</b>	<b>724</b>	<b>2,330</b>

**Liquids**

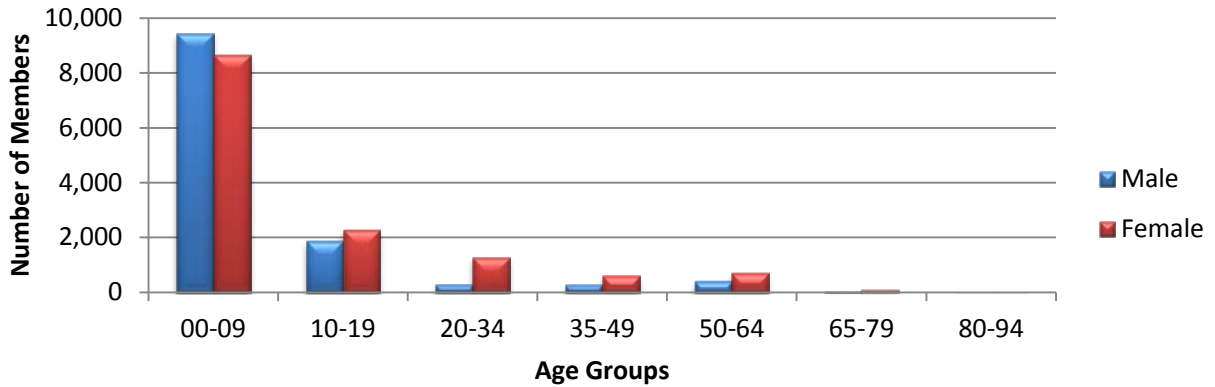
<b>Fiscal Year</b>	<b>Total Members*</b>	<b>Total Claims</b>	<b>Total Cost</b>	<b>Cost / Claim</b>	<b>Cost/ Day</b>	<b>Total Units</b>	<b>Total Days</b>
<b>2012</b>	15,991	17,881	\$336,240.87	\$18.80	\$1.75	93,742	191,983
<b>2013</b>	15,254	17,029	\$313,616.60	\$18.42	\$1.75	88,328	178,908
<b>% Change</b>	<b>-4.60%</b>	<b>-4.80%</b>	<b>-6.70%</b>	<b>-2.00%</b>	<b>0.00%</b>	<b>-5.80%</b>	<b>-6.80%</b>
<b>Change</b>	<b>-737</b>	<b>-852</b>	<b>-\$22,624.27</b>	<b>\$0.38</b>	<b>\$0.00</b>	<b>-5,414</b>	<b>-13,075</b>

## Combinations

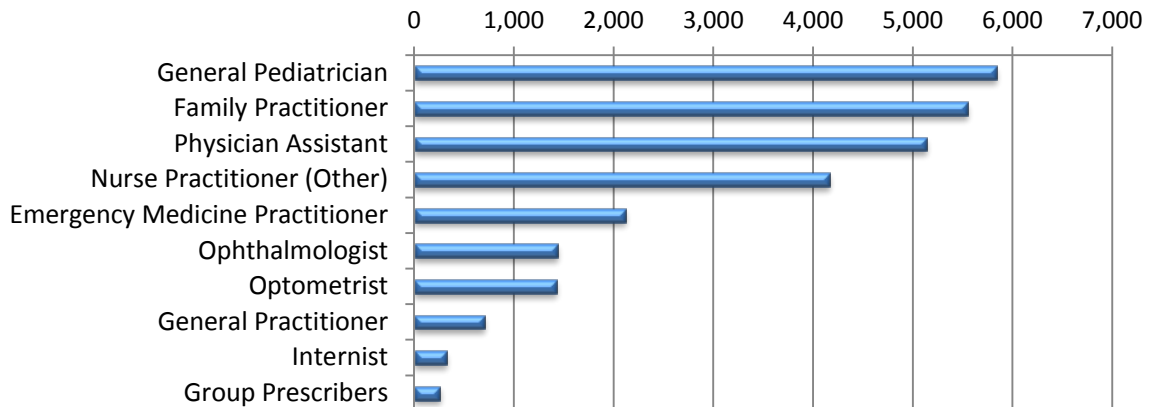
Fiscal Year	Total Members*	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2012	2,035	2,395	\$127,421.59	\$53.20	\$4.70	10,764	27,088
2013	1,962	2,288	\$125,624.95	\$54.91	\$4.48	10,435	28,043
% Change	-3.60%	-4.50%	-1.40%	3.20%	-4.70%	-3.10%	3.50%
Change	-73	-107	-\$1,796.64	\$1.71	-\$0.22	-329	955

\*Total number of unduplicated members.

## Demographics of Members Utilizing Ophthalmic Antibiotics

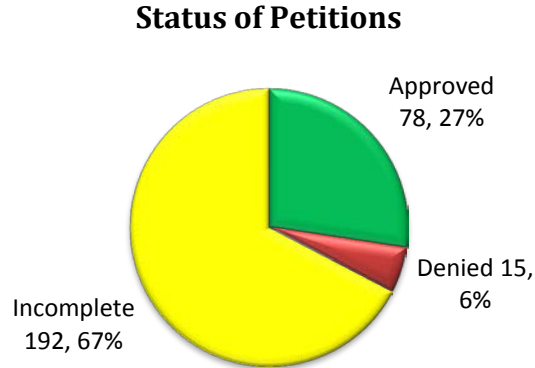


## Top Prescriber Specialties of Ocular Antibiotics by Number of Claims



## Prior Authorization of Ocular Antibiotics

There was a total of 285 petitions submitted for ocular antibiotics during fiscal year 2013. The following chart shows the status of the submitted petitions.



## Recommendations

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

## Utilization of Ocular Allergy Products

### Ophthalmic Antibiotic Ointment Utilization

CHEMICAL NAME	PRODUCT UTILIZED	CLAIMS	MEMBERS	COST	COST/DAY	% COST	COST/CLAIM
Erythromycin	ERYTHROMYCIN OIN	9,452	8,712	\$142,566.52	\$1.83	70.08%	\$15.08
Erythromycin	ILOTYCIN OIN	8	8	\$73.20	\$1.59	0.04%	\$9.15
<b>Subtotal</b>		<b>9,460</b>	<b>8,720</b>	<b>\$142,639.72</b>	<b>\$1.71</b>	<b>70.12%</b>	<b>\$15.08</b>
Gentamicin	GENTAK OIN 0.3% OP	1,147	1,072	\$22,283.30	\$2.53	10.95%	\$19.43
Gentamicin	GENTAMICIN OIN 0.3% OP	8	7	\$161.22	\$2.83	0.08%	\$20.15
<b>Subtotal</b>		<b>1,155</b>	<b>1,079</b>	<b>\$22,444.52</b>	<b>\$2.68</b>	<b>11.03%</b>	<b>\$19.43</b>
Tobramycin	TOBEX OIN 0.3% OP	241	232	\$23,448.34	\$11.20	11.53%	\$97.30
Bacitracin	BACITRACIN OIN OP	197	166	\$12,155.34	\$6.11	5.97%	\$61.70
<b>Tier-1 Subtotal</b>		<b>11053</b>	<b>10,197</b>	<b>\$200,688.00</b>	<b>\$4.35</b>	<b>98.65%</b>	<b>\$18.16</b>
Ciprofloxacin	CILOXAN OIN 0.3% OP	20	13	\$2,755.78	\$13.85	1.35%	\$137.79
<b>Tier-2 Subtotal</b>		<b>20</b>	<b>13</b>	<b>\$2,755.78</b>	<b>\$13.85</b>	<b>1.35%</b>	<b>\$137.79</b>
<b>Total</b>		<b>11,073</b>	<b>10,210</b>	<b>\$203,443.70</b>	<b>\$2.23</b>	<b>100%</b>	<b>\$18.37</b>

\*Total number of unduplicated members.

## Ophthalmic Antibiotic Liquid Utilization

CHEMICAL NAME	PRODUCT UTILIZED	CLAIMS	MEMBERS	COST	COST/DAY	% COST	COST/CLAIM
Gentamicin	GENTAMICIN SOL 0.3% OP	8,299	7,699	\$91,117.24	\$1.11	29.05%	\$10.98
Tobramycin	TOBRAMYCIN SOL 0.3% OP	6,643	6,197	\$93,818.74	\$1.40	29.92%	\$14.12
<b>Tier-1 Subtotal</b>		<b>14,942</b>	<b>13,896</b>	<b>\$184,935.98</b>	<b>\$1.26</b>	<b>58.97%</b>	<b>\$12.38</b>
Ofloxacin	OFLOXACIN DRO 0.3% OP	544	445	\$5,462.34	\$0.65	1.74%	\$10.04
Ciprofloxacin	CIPROFLOXACIN SOL 0.3% OP	362	335	\$4,802.88	\$1.18	1.53%	\$13.27
<b>Tier-2 Subtotal</b>		<b>906</b>	<b>780</b>	<b>\$10,265.22</b>	<b>\$0.92</b>	<b>3.27%</b>	<b>\$11.33</b>
Moxifloxacin	MOXEZA SOL 0.5%	8	8	\$701.90	\$6.32	0.22%	\$87.74
Moxifloxacin	VIGAMOX DRO 0.5%	746	553	\$73,758.39	\$7.60	23.52%	\$98.87
<b>Subtotal</b>		<b>754</b>	<b>561</b>	<b>\$74,460.29</b>	<b>\$6.96</b>	<b>23.72%</b>	<b>\$98.75</b>
Besifloxacin	BESIVANCE SUS 0.6%	240	186	\$24,274.08	\$5.31	7.74%	\$101.14
Azithromycin	AZASITE SOL 1%	113	73	\$11,991.09	\$6.08	3.82%	\$106.12
Gatifloxacin	ZYMAXID SOL 0.5%	72	56	\$7,576.34	\$8.04	2.42%	\$105.23
Levofloxacin	LEVOFLOXACIN SOL 0.5%	2	2	\$113.60	\$11.36	0.04%	\$56.80
<b>Tier-3 Total</b>		<b>1181</b>	<b>878</b>	<b>\$118,415.40</b>	<b>\$7.45</b>	<b>37.76%</b>	<b>\$100.27</b>
<b>Total</b>		<b>17,029</b>	<b>15,554*</b>	<b>\$313,616.60</b>	<b>\$1.75</b>	<b>100%</b>	<b>\$18.42</b>

\*Total number of unduplicated members.

## Ophthalmic Antibiotic Combination Utilization

CHEMICAL NAME	PRODUCT UTILIZED	CLAIMS	MEMBERS	COST	COST/DAY	% COST	COST/CLAIM
Tobramycin-Dexamethasone	TOBRA/DEXAME SUS 0.3-0.1%	838	781	\$70,089.09	\$6.52	55.79%	\$83.64
Tobramycin-Dexamethasone	TOBRADEX OIN 0.3-0.1%	198	174	\$31,619.56	\$15.19	25.17%	\$159.69
Tobramycin-Dexamethasone	TOBRADEX ST SUS 0.3-0.05	58	55	\$7,196.40	\$9.13	5.73%	\$124.08
<b>Subtotal</b>		<b>1,094</b>	<b>1,010</b>	<b>\$108,905.05</b>	<b>\$10.28</b>	<b>86.69%</b>	<b>\$99.55</b>
Neomycin-Polymyxin-Dexamethasone	NEO/POLY/DEX SUS 0.1% OP	715	656	\$9,718.12	\$1.02	7.74%	\$13.59
Neomycin-Polymyxin-Dexamethasone	NEO/POLY/DEX OIN 0.1% OP	474	395	\$6,853.61	\$1.41	5.46%	\$14.46
Neomycin-Polymyxin-HC	NEO/POLY/HC SUS OP	1	1	\$19.89	\$1.33	0.02%	\$19.89
<b>Subtotal</b>		<b>1,190</b>	<b>1,052</b>	<b>\$16,591.62</b>	<b>\$1.25</b>	<b>13.22%</b>	<b>\$13.94</b>
Gentamicin-Prednisolone Acetate	PRED-G SUS OP	3	3	\$91.40	\$1.87	0.07%	\$30.47
Gentamicin-Prednisolone Acetate	PRED-G S.O.P OIN OP	1	1	\$36.88	\$5.27	0.03%	\$36.88
<b>Subtotal</b>		<b>4</b>	<b>4</b>	<b>\$128.28</b>	<b>\$3.57</b>	<b>0.10%</b>	<b>\$32.07</b>
<b>Tier-2 Total and Total</b>		<b>2,288</b>	<b>1,962*</b>	<b>\$125,624.95</b>	<b>\$4.48</b>	<b>100%</b>	<b>\$54.91</b>

\*Total number of unduplicated members.

# Annual Review of Osteoporosis Medications

Oklahoma Health Care Authority  
Calendar Year 2013 Print Review

## Current Prior Authorization Criteria

Osteoporosis Medications		
Tier 1*	Tier 2	Special PA
Alendronate (Fosamax®) Calcium + Vitamin D	Alendronate + D (Fosamax®+D) Ibandronate (Boniva®) Risedronate (Actonel®)	Zoledronic acid (Reclast®) Teriparatide (Forteo®) Denosumab (Prolia®) <sup>o</sup> Risedronate ER (Atelvia®) Ibandronate (Boniva® IV) Alendronate (Binosto™) Risedronate 30mg Tabs (Actonel®)

### Tier-2 Approval Criteria:

1. A trial of at least one Tier 1 medication, compliantly used for at least 6 months concomitantly with calcium + vitamin D, that failed to prevent fracture, or improve BMD scores; or
2. Hypersensitivity to or intolerable adverse effects with all Tier-1 products.

### Special Prior Authorization Approval Criteria:

1. **Teriparatide (Forteo®)**
  - a. A Bone Mineral Density test (T-score at or below -2.5) within the last month; and
  - b. A minimum 12 month trial with a bisphosphonate plus adequate calcium and vitamin D; or
  - c. A 12 month trial of Prolia™ (Denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results.
  - d. The diagnosis of non-healing fracture may be approved for six months.
  - e. Approval will be for a maximum duration of 2 years of therapy.
2. **Prolia™, Reclast®, Boniva® IV requires:**
  - a. A minimum 12 month trial with a Tier-1 or Tier-2 bisphosphonate plus adequate calcium and vitamin D; or
  - b. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 products.
  - c. Clinical exceptions may apply for members with
    - i. Severe esophageal disease (e.g., ulcerations, strictures)
    - ii. Inability to take anything by mouth
    - iii. Inability to sit or stand for prolonged periods
    - iv. Inability to take bisphosphonates orally for other special medical circumstances that justify the method of administration

### 3. Atelvia™, Binosto™, and Actonel® 30mg Tabs

- a. Patient specific, clinically significant reason why member cannot use all other available Tier 1 and Tier 2 products.
- b. Members with diagnosis in history of Paget’s disease will not require prior authorization.

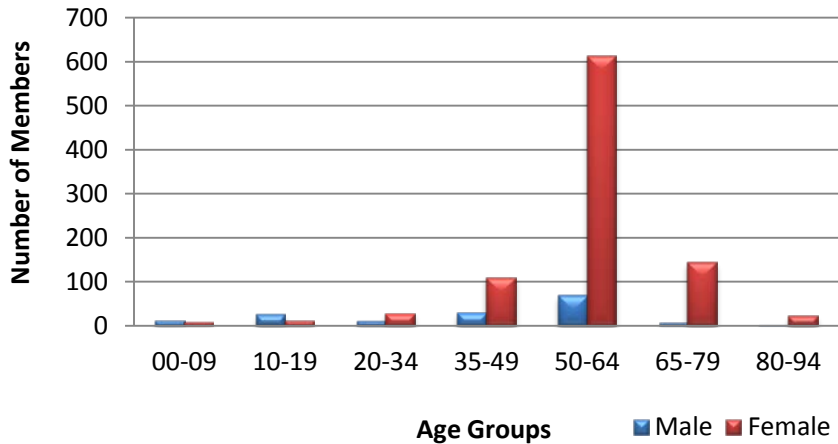
## Utilization of Osteoporosis Medications

### Comparison of Calendar Years

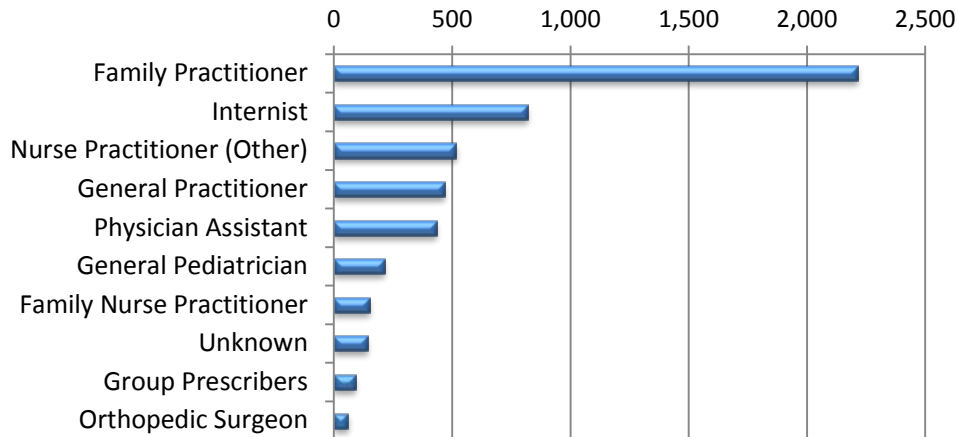
Calendar Year	Total Members*	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2012	1,169	6,164	\$283,837.93	\$46.05	\$1.60	44,994	177,150
2013	1,099	5,384	\$305,420.93	\$56.73	\$1.93	37,940	158,472
% Change	-6.00%	-12.70%	7.60%	23.20%	20.60%	-15.70%	-10.50%
Change	-70	-780	\$21,583.00	\$10.68	\$0.33	-7,054	-18,678

\*Total number of unduplicated members

### Demographics of Members Utilizing Osteoporosis Medications



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

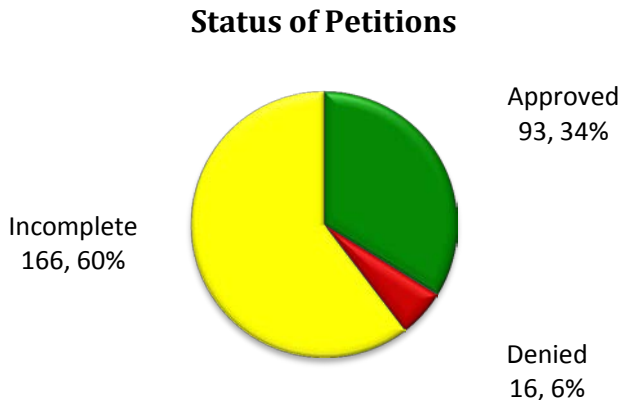




## **Prior Authorization of Osteoporosis Medications**

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There was a total of 275 petitions submitted for the Osteoporosis Medications category during calendar year 2013. The following chart shows the status of the submitted petitions.



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

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### **April 2013:**

- Label changes to Bisphosphonate drugs now include precaution for osteonecrosis of the jaw (ONJ) and postmarketing adverse reaction of asthma exacerbations.
- Boniva® (Ibandronate) injections product label changed to add anaphylaxis, including fatal events, and musculoskeletal pain to warnings and precautions. Asthma exacerbation and anaphylactic reaction were also added to adverse reactions after postmarketing experience.

## **Recommendations**

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

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<sup>14</sup> FDA Safety Information. Available online at: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm351740.htm> . Last revised 12/31/2013. Last accessed 01/03/2014.

## Utilization Details for Osteoporosis Medications: Calendar Year 2013

MEDICATION NAME	CLAIMS	MEMBERS	COST	COST/ CLAIM	COST/ DAY	% COST
<b>ALENDRONATE PRODUCTS</b>						
ALENDRONATE TAB 70MG	3,522	728	\$20,840.18	\$5.92	\$0.21	6.82%
ALENDRONATE TAB 35MG	502	119	\$2,609.55	\$5.20	\$0.18	0.85%
ALENDRONATE TAB 10MG	92	21	\$833.52	\$9.06	\$0.30	0.27%
ALENDRONATE TAB 5MG	61	10	\$485.38	\$7.96	\$0.27	0.16%
ALENDRONATE TAB 40MG	14	5	\$1,464.97	\$104.64	\$2.63	0.48%
<b>SUBTOTAL</b>	<b>4,191</b>	<b>883</b>	<b>\$26,233.60</b>	<b>\$6.26</b>	<b>\$0.72</b>	<b>8.58%</b>
<b>CALCITONIN PRODUCTS</b>						
FORTICAL SPR 200/ACT	42	14	\$1,953.56	\$46.51	\$1.55	0.64%
CALCITONIN SPR 200/ACT	167	45	\$9,370.56	\$56.11	\$1.87	3.07%
<b>SUBTOTAL</b>	<b>209</b>	<b>59</b>	<b>\$11,324.12</b>	<b>\$54.18</b>	<b>\$1.71</b>	<b>3.71%</b>
<b>PAMIDRONATE PRODUCTS</b>						
PAMIDRONATE INJ 30/10ML	282	45	\$10,419.43	\$36.95	\$30.47	3.41%
PAMIDRONATE INJ 90/10ML	10	1	\$399.13	\$39.91	\$39.91	0.13%
<b>SUBTOTAL</b>	<b>292</b>	<b>46</b>	<b>\$10818.56</b>	<b>\$37.05</b>	<b>\$35.19</b>	<b>3.54%</b>
<b>TIER-1 SUBTOTAL</b>	<b>4,692</b>	<b>988</b>	<b>\$48,376.28</b>	<b>\$10.31</b>	<b>\$12.54</b>	<b>15.83%</b>
<b>RISEDRONATE PRODUCTS</b>						
ACTONEL TAB 35MG	167	18	\$24,319.14	\$145.62	\$5.16	7.96%
ACTONEL TAB 5MG	28	3	\$3,525.76	\$125.92	\$4.39	1.15%
ACTONEL TAB 30MG	15	2	\$13,920.28	\$928.02	\$20.90	4.56%
ACTONEL TAB 150MG	1	1	\$150.99	\$150.99	\$5.03	0.05%
<b>SUBTOTAL</b>	<b>211</b>	<b>24</b>	<b>\$41,916.17</b>	<b>\$198.65</b>	<b>\$8.87</b>	<b>13.72%</b>
<b>IBANDRONATE PRODUCTS</b>						
BONIVA TAB 150MG	6	1	\$858.60	\$143.10	\$4.77	0.28%
IBANDRONATE TAB 150MG	314	66	\$40,086.08	\$127.66	\$2.84	13.12%
<b>SUBTOTAL</b>	<b>320</b>	<b>67</b>	<b>\$40,944.68</b>	<b>\$127.95</b>	<b>\$3.81</b>	<b>13.40%</b>
<b>TIER-2 SUBTOTAL</b>	<b>531</b>	<b>91</b>	<b>\$82,860.85</b>	<b>\$156.05</b>	<b>\$6.34</b>	<b>27.12%</b>
<b>ALENDRONATE PRODUCTS</b>						
BINOSTO TAB 70MG	12	1	\$1,729.27	\$144.11	\$5.15	0.57%
<b>IBANDRONATE PRODUCTS</b>						
BONIVA INJ 3MG/3ML	7	2	\$3,215.38	\$459.34	\$6.28	1.05%
<b>TERIPARATIDE PRODUCTS</b>						
FORTEO SOL 600/2.4	99	20	\$130,981.88	\$1,323.05	\$46.81	42.89%
<b>DENOSUMAB PRODUCTS</b>						
PROLIA SOL 60MG/ML	38	25	\$33,368.72	\$878.12	\$5.00	10.93%
<b>ZOLEDRONIC ACID PRODUCTS</b>						
RECLAST INJ 5/100ML	2	2	\$2,251.34	\$1,125.67	\$3.08	0.74%
ZOLEDRONIC INJ 5/100ML	3	3	\$2,637.21	\$879.07	\$2.41	0.86%
<b>SUBTOTAL</b>	<b>5</b>	<b>5</b>	<b>\$4,888.55</b>	<b>\$977.71</b>	<b>\$2.75</b>	<b>1.60%</b>
<b>SPECIAL PA SUBTOTAL</b>	<b>161</b>	<b>53</b>	<b>\$174,183.80</b>	<b>\$1,081.89</b>	<b>\$13.27</b>	<b>57.04%</b>
<b>TOTAL</b>	<b>5,384</b>	<b>1,099*</b>	<b>\$305,420.93</b>	<b>\$321.09</b>	<b>\$1.93</b>	<b>100%</b>

\*Total number of unduplicated members.

# Annual Review of Otic Antibiotics

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Current Prior Authorization Criteria

Otic Antibiotics		
Tier-1	Tier-2	Special PA
acetic acid ( <b>VoSol®</b> , <b>Acetasol®</b> )	chloroxylenol/benzocaine/HC ( <b>Trioxin®</b> )	acetic acid/HC ( <b>Acetasol® HC</b> , <b>VoSol® HC</b> )
neomycin/polymyxin B/ HC ( <b>Cortisporin®</b> , <b>Pediotic®</b> )	chloroxylenol/pramoxine/zinc/ glycerin ( <b>Zinotic®</b> , <b>Zinotic® ES</b> )	antipyrine/benzocaine/glycerin/ zinc ( <b>Neotic®</b> )
ofloxacin ( <b>Floxin® Otic</b> )*	ciprofloxacin ( <b>Cetraxal®</b> )	
	ciprofloxacin/dexamethasone ( <b>Ciprodex®</b> )	
	ciprofloxacin/HC ( <b>Cipro® HC</b> )	
	neomycin/colistin/HC/ thonzonium ( <b>Cortisporin® TC</b> , <b>Coly-Mycin® S</b> )	

\*Dexamethasone 0.1% ophthalmic solution is available without prior authorization for members who require concomitant steroid therapy.

HC = hydrocortisone

### Tier-2 Approval Criteria:

1. Member must have an adequate 14-day trial of at least two Tier-1 medications; or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 products or infection by organism not known to be covered by any of the Tier-1 agents.
3. A ciprofloxacin combination product may be approved after a recent 7 to 10 day trial of ofloxacin and dexamethasone 0.1% solution.
  - a. Dexamethasone 0.1% ophthalmic solution is available without prior authorization for members who require concomitant steroid therapy.

### Acetasol® HC, Vosol® HC, and Neotic® Approval Criteria:

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

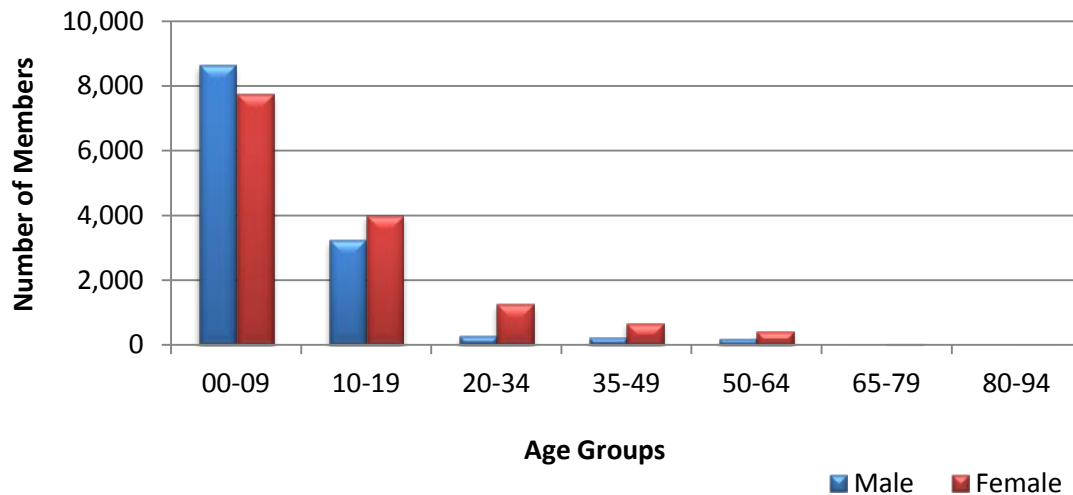
## Utilization of Otic Antibiotics

### Comparison of Fiscal Years

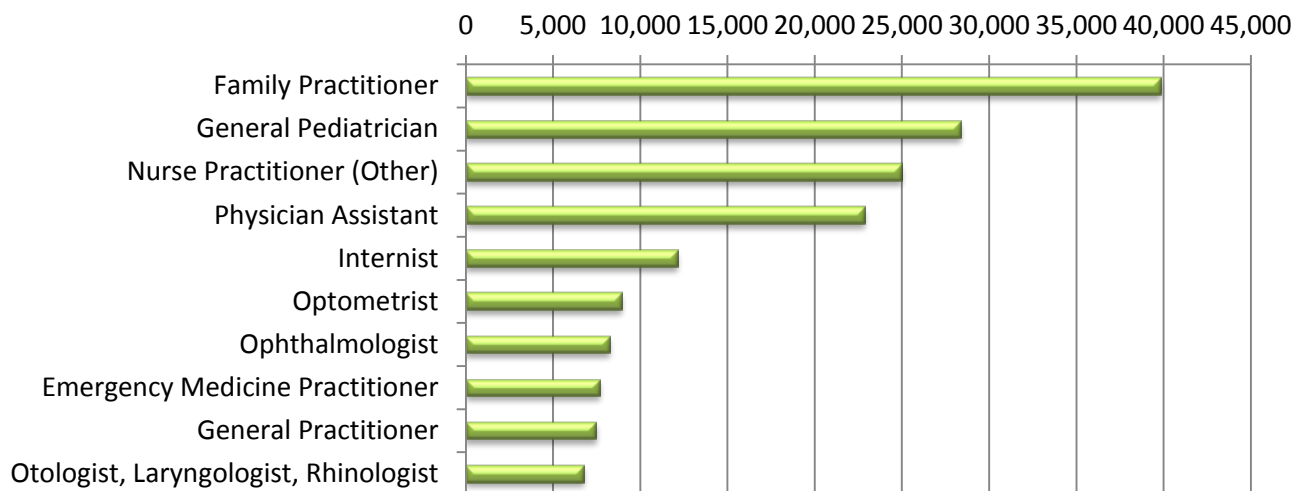
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2012	27,391	35,003	\$693,736.68	\$19.82	\$2.00	299,429	347,066
2013	26,716	34,367	\$697,322.16	\$20.29	\$2.05	291,429	339,949
% Change	-2.50%	-1.80%	0.50%	2.40%	2.50%	-2.70%	-2.10%
Change	-675	-636	\$3,585.48	\$0.47	\$0.05	-8,000	-7,117

\*Total number of unduplicated members

### Demographics of Members Utilizing Otic Antibiotics



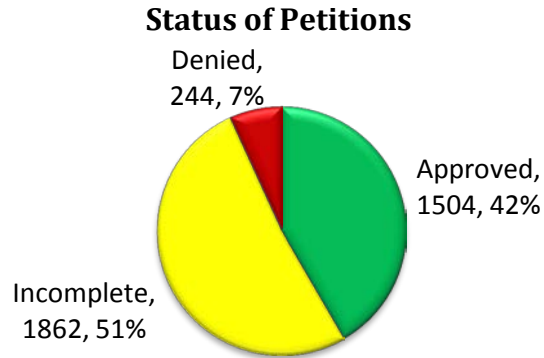
### Top Prescriber Specialties of Otic Antibiotics by Number of Claims



## Prior Authorization of Otic Antibiotics

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There was a total of 3,610 petitions submitted for otic antibiotics during fiscal year 2013. The following chart shows the status of the submitted petitions.



## Market News and Updates<sup>15</sup>

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### Anticipated Patent Expirations:

- Cipro<sup>®</sup> HC (ciprofloxacin/hydrocortisone)- 06/2015
- Ciprodex<sup>®</sup> (ciprofloxacin/dexamethasone)- 08/2020

## Recommendations

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The College of Pharmacy recommends no changes at this time.

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<sup>15</sup> FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm>. Last revised 5/5/14. Last accessed 5/6/14.

<sup>15</sup> Drugs@FDA: FDA Approved Drug Products. Available online at: [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search\\_Drug\\_Name](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name). Last revised 5/5/14. Last accessed 5/6/14.

<sup>15</sup> Micromedex 2.0: Drug Information. Available online at: <http://www.micromedexsolutions.com/micromedex2/librarian/>. Last revised 4/17/14. Last accessed 5/6/14.

## Utilization Details of Otic Antibiotics

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
<b>OFLOXACIN PRODUCTS</b>						
OFLOXACIN DRO	21,620	16,711	\$361,781.85	\$1.79	\$16.73	51.88%
<b>SUBTOTAL</b>	<b>21,620</b>	<b>16,711*</b>	<b>\$361,781.85</b>	<b>\$1.79</b>	<b>\$16.73</b>	<b>51.88%</b>
<b>NEOMYCIN/POLYMYXIN B/HYDROCORTISONE PRODUCTS</b>						
NEO/POLY/HC SUS 1%	7,491	6,971	\$193,221.74	\$2.47	\$25.79	27.71%
NEO/POLY/HC SOL 1%	4,864	4,582	\$109,694.83	\$2.15	\$22.55	15.73%
<b>SUBTOTAL</b>	<b>12,355</b>	<b>11,289*</b>	<b>\$302,916.57</b>	<b>\$2.34</b>	<b>\$24.52</b>	<b>43.44%</b>
<b>ACETIC ACID PRODUCTS</b>						
ACETIC ACID SOL 2%	208	169	\$5,825.18	\$0.92	\$28.01	0.84%
<b>SUBTOTAL</b>	<b>208</b>	<b>169*</b>	<b>\$5,825.18</b>	<b>\$0.92</b>	<b>\$28.01</b>	<b>0.84%</b>
<b>TIER-1 SUBTOTAL</b>	<b>34,183</b>	<b>26,688*</b>	<b>\$670,523.60</b>	<b>\$1.98</b>	<b>\$19.62</b>	<b>96.16%</b>
<b>CIPROFLOXACIN PRODUCTS</b>						
CIPRODEX SUS 0.3-0.1%	165	132	\$24,485.18	\$13.06	\$148.40	3.51%
CIPRO HC SUS OTIC	12	9	\$1,750.84	\$14.12	\$145.90	0.25%
CIPROFLOXACN SOL	2	2	\$185.74	\$6.63	\$92.87	0.03%
<b>SUBTOTAL</b>	<b>179</b>	<b>143*</b>	<b>\$26,421.76</b>	<b>\$13.03</b>	<b>\$147.61</b>	<b>3.79%</b>
<b>NEOMYCIN/COLISTIN/HYDROCORTISONE/THONZONIUM PRODUCTS</b>						
CORTISPORIN SUS -TC	2	2	\$154.08	\$12.84	\$77.04	0.02%
COLY-MYCIN S SUS OTIC	2	2	\$127.84	\$9.13	\$63.92	0.02%
<b>SUBTOTAL</b>	<b>4</b>	<b>4*</b>	<b>\$281.92</b>	<b>\$10.84</b>	<b>\$70.48</b>	<b>0.04%</b>
<b>TIER-2 SUBTOTAL</b>	<b>183</b>	<b>146*</b>	<b>\$26,703.68</b>	<b>\$13.01</b>	<b>\$145.92</b>	<b>3.83%</b>
<b>ACETIC ACID/HYDROCORTISONE PRODUCTS</b>						
HC/ACET ACID SOL OTIC	1	1	\$94.88	\$9.49	\$94.88	0.01%
<b>SUBTOTAL</b>	<b>1</b>	<b>1*</b>	<b>\$94.88</b>	<b>\$9.49</b>	<b>\$94.88</b>	<b>0.01%</b>
<b>TIER-3 SUBTOTAL</b>	<b>1</b>	<b>1*</b>	<b>\$94.88</b>	<b>\$9.49</b>	<b>\$94.88</b>	<b>0.01%</b>
<b>TOTAL</b>	<b>34,367</b>	<b>26,716*</b>	<b>\$697,322.16</b>	<b>\$2.05</b>	<b>\$20.29</b>	<b>100.00%</b>

\*Total number of unduplicated members

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

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### Oklahoma Health Care Authority Fiscal Year 2013 Print Report

#### Current Prior Authorization Criteria

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Qutenza® (J7335) is applied by a physician, or other health care professional under close physician supervision, and left in place for one hour. Up to four patches may be used per treatment and may be repeated after three months. A topical anesthetic should be applied to the area prior to placing the Qutenza® patch. Cleansing gel is included with the patch to clear any residue once the patch has been removed.

#### 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
  - b. Anticonvulsants
  - c. Topical lidocaine; and
3. Qutenza® must be administered by a healthcare provider.
4. A quantity limit of no more than 4 patches per treatment every 90 days will apply.

#### Utilization of Qutenza®

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There was no utilization of Qutenza® in fiscal year 2013.

# Annual Review of Ribavirin Products

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Current Prior Authorization Criteria

### RibaPak® and Rabetrol® (Ribavirin Solution) Approval Criteria:

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

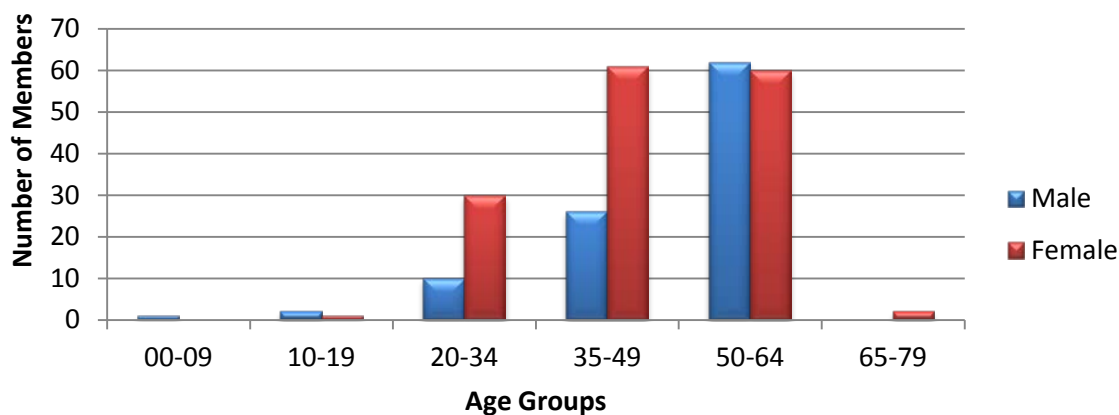
## Utilization of Ribavirin Products

### Comparison of Fiscal Years

Fiscal Year	Total Members*	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2012	295	1,155	\$197,796.27	\$171.25	\$5.96	187,515	33,170
2013	255	961	\$132,253.53	\$137.62	\$4.82	145,014	27,454
% Change	-13.60%	-16.80%	-33.10%	-19.60%	-19.10%	-22.70%	-17.20%
Change	-40	-194	\$65,542.74	-\$33.63	-\$1.14	-42,501	-5,716

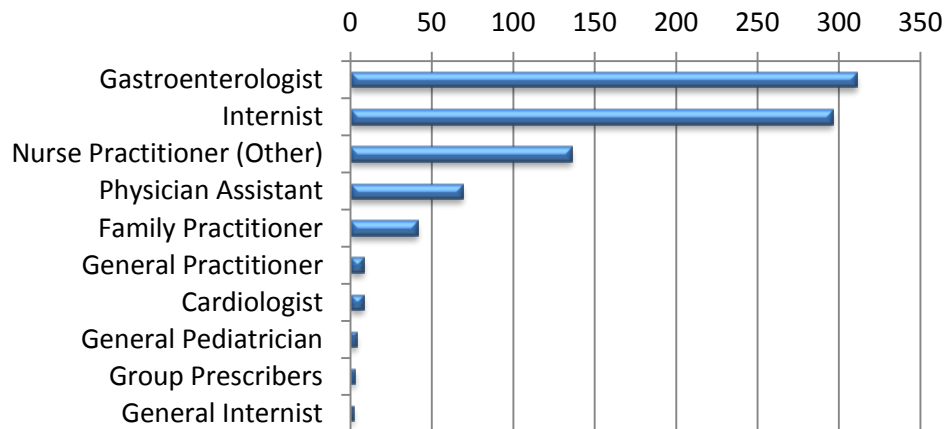
\*Total number of unduplicated members.

### Demographics of Members Utilizing Ribavirin





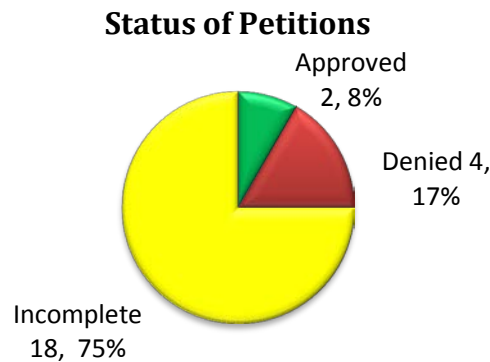
### Top Prescriber Specialties of Ribavirin by Number of Claims



### Prior Authorization of Ribavirin Products

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There were a total of 24 petitions submitted for ribavirin products during fiscal year 2013. The following chart shows the status of the submitted petitions.



### Market News and Updates<sup>16</sup>

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#### Anticipated Patent Expirations

- Rebetol® (ribavirin oral solution)- 2023

### Recommendations

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The College of Pharmacy recommends no changes at this time.

<sup>16</sup> 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: 4/10/14. Last accessed: 4/11/14.

## Utilization of Ribaviron

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Chemical Name	Product Utilized	Total Claims	Total Members	Total Cost	Claims/Member	% Cost	Cost/Claim
Ribavirin	RIBASPHERE CAP 200MG	137	41	\$22,450.91	3.34	16.98%	\$163.88
Ribavirin	RIBAVIRIN CAP 200MG	81	26	\$15,915.44	3.12	12.03%	\$196.49
Ribavirin	RIBAVIRIN TAB 200MG	460	127	\$57,338.47	3.62	43.35%	\$124.65
Ribavirin	RIBASPHERE TAB 200MG	283	82	\$36,548.71	3.45	27.64%	\$129.15
<b>Total</b>		<b>961</b>	<b>255*</b>	<b>\$132,253.53</b>	<b>3.77</b>	<b>100 %</b>	<b>\$137.62</b>

\*Total number of unduplicated members.

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# Annual Review of Singulair® (Montelukast), Accolate® (Zafirlukast), and Zyflo CR® (Zileuton)

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Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

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## Current Prior Authorization Criteria

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### Singulair® (Montelukast) Approval Criteria:

1. For members under 21 years of age montelukast tablets and chewable tablets are available without prior authorization
2. For members 21 years of age and older a prior authorization is required with the following criteria:
  - a. A diagnosis of asthma (mild or moderate persistent asthma, and/or exercise induced asthma); or
  - b. A diagnosis of allergic rhinitis with a re recent trial of an oral antihistamine of 14 day duration within the last 30 days.
3. For Ensure Oklahoma members a prior authorization is required. This medication is not covered for a diagnosis of allergic rhinitis for those members.
4. A prior authorization is required for the granule formulation of montelukast
  - a. Use of the granule formulation requires a patient-specific, clinically significant reason why member cannot use montelukast tablets or chewable tablets.

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

1. Member must be 12 year and older; and
2. An FDA approved diagnosis of mild or moderate persistent asthma or allergic rhinitis; and
  - a. For a diagnosis of asthma the member must meet the following:
    - i. A trial of an inhaled corticosteroid and corticosteroid/LAB<sub>2</sub>A therapy within the previous 6 months and reason for trial failure; and
    - ii. A recent trial with at least one other available leukotriene modifier that did not yield adequate response.
  - b. For a diagnosis of allergic rhinitis the member must meet the following:
    - i. A trial of an oral antihistamine, 14 days in duration within the past 30 days that has failed to relieve allergic rhinitis symptoms.

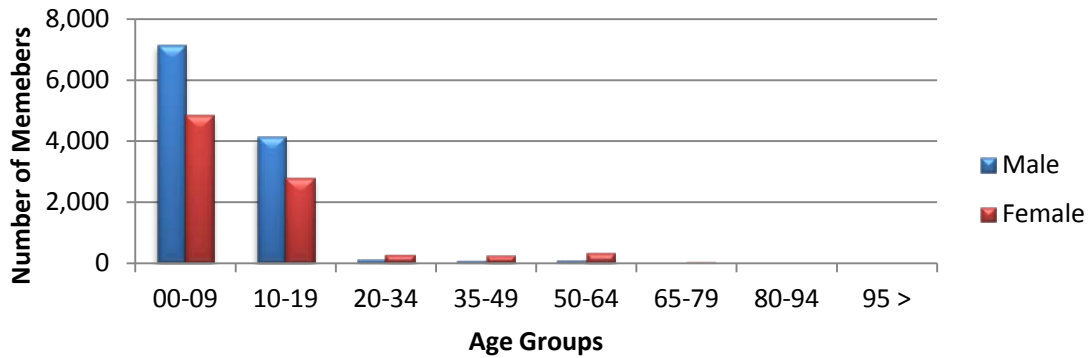
## Utilization of Singulair®, Accolate®, and Zyflo CR®

### Comparison of Fiscal Years

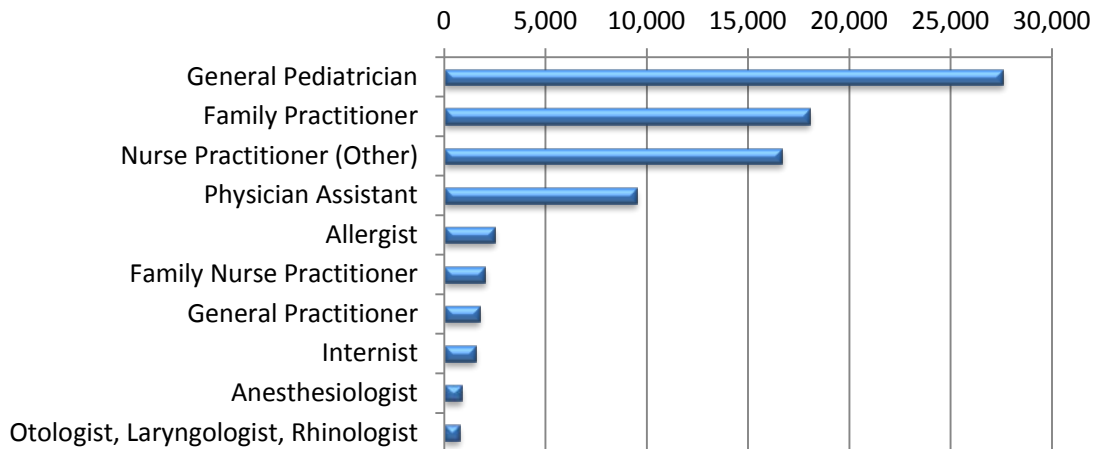
Fiscal Year	Total Members*	Total Claims	Total Cost	Cost / Claim	Cost/ Day	Total Units	Total Days
2012	19,456	85,457	\$13,387,460.83	\$156.66	\$5.23	2,575,934	2,561,455
2013	20,145	85,014	\$3,578,424.99	\$42.09	\$1.40	2,564,865	2,547,757
% Change	3.50%	-0.50%	-73.30%	-73.10%	-73.20%	-0.40%	-0.50%
Change	689	-443	-\$9,809,035.84	\$114.57	\$3.83	-11,069	-13,698

\*Total number of unduplicated members.

### Demographics of Members Utilizing Singulair®, Accolate®, and Zyflo CR®



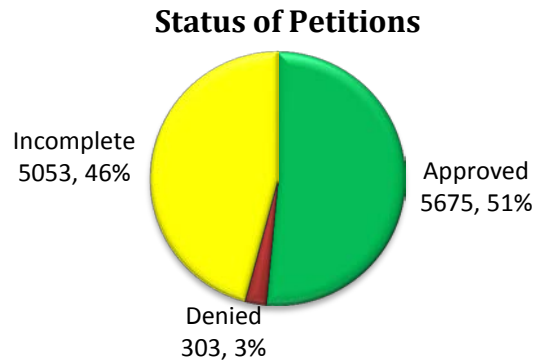
### Top Prescriber Specialties of Singulair®, Accolate®, and Zyflo CR® by Number of Claims



## **Prior Authorization of Singulair<sup>®</sup>, Accolate<sup>®</sup>, and Zflo CR<sup>®</sup>**

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There was a total of 11,031 petitions submitted for Singulair<sup>®</sup> and Zflo CR<sup>®</sup> during fiscal year 2013. The following chart shows the status of the submitted petitions.



## **Market News and Updates<sup>17</sup>**

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### **FDA Update:**

- June 2012: The FDA reports that due to the risk of hepatotoxicity, use of Zflo CR<sup>®</sup> in pediatric patients under the age of 12 years is not recommended.
- September 2012: Pulmonary eosinophilia was added to the adverse reaction section of labeling of Singulair<sup>®</sup>.
- December 2013: Stevens-Johnson syndrome and toxic epidermal necrolysis were added to the adverse reaction section of labeling of Singulair<sup>®</sup>.

## **Recommendations**

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The college of pharmacy does not recommend any changes at this time.

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<sup>17</sup>FDA: Safety Update. Available online at: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm285264.htm>. Last revised: 01/10/14. Last accessed:04/15/14.

## Utilization Details of Singulair®, Accolate®, and Zyflo CR®

CHEMICAL NAME	PRODUCT UTILIZED	CLAIMS	MEMBERS	COST	% COST	COST/CLAIM
Montelukast	MONTELUKAST CHW 5MG	33,062	8,725	\$697,393.97	19.49%	\$21.09
Montelukast	MONTELUKAST CHW 4MG	20,566	5,896	\$428,968.86	11.99%	\$20.86
Montelukast	MONTELUKAST TAB 10MG	18,131	4,588	\$365,286.12	10.21%	\$20.15
Montelukast	SINGULAIR CHW 5MG	4,490	3,607	\$717,654.06	20.06%	\$159.83
Montelukast	SINGULAIR CHW 4MG	2,786	2,273	\$446,170.64	12.47%	\$160.15
Montelukast	SINGULAIR TAB 10MG	2,580	1,999	\$419,317.09	11.72%	\$162.53
Montelukast	MONTELUKAST GRA 4MG	1,754	884	\$249,802.10	6.98%	\$142.42
Montelukast	SINGULAIR GRA 4MG	959	549	\$157,232.33	4.39%	\$163.95
Montelukast	MONTELUKAST TAB 10MG	12	12	\$181.07	0.01%	\$15.09
<b>Subtotal</b>		<b>84,978</b>	<b>28,533</b>	<b>\$3,482,006.24</b>	<b>97.32%</b>	<b>\$40.98</b>
Zafirlukast	ZAFIRLUKAST TAB 20MG	509	112	\$35,444.55	0.99%	\$69.64
Zafirlukast	ZAFIRLUKAST TAB 10MG	128	47	\$8,493.11	0.24%	\$66.35
Zafirlukast	ACCOLATE TAB 10MG	1	1	\$124.18	0.00%	\$124.18
<b>Subtotal</b>		<b>638</b>	<b>160</b>	<b>\$44,061.84</b>	<b>1.23%</b>	<b>\$69.06</b>
Zileuton	ZYFLO CR TAB 600MG	28	7	\$40,184.19	1.12%	\$1,435.15
Zileuton	ZYFLO TAB 600MG	8	3	\$12,172.72	0.34%	\$1,521.59
<b>Subtotal</b>		<b>36</b>	<b>10</b>	<b>\$52,356.91</b>	<b>1.46%</b>	<b>\$1,454.36</b>
<b>Total</b>		<b>85,014</b>	<b>22,703*</b>	<b>\$3,578,424.99</b>	<b>100 %</b>	<b>\$42.09</b>

\*Total number of unduplicated members.

# Annual Review of Butalbital Products

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Current Prior Authorization Criteria

Butalbital Products	
Tier 1	Tier 2
Butalbital/acetaminophen/caffeine standard dosage forms (50mg-325mg-40mg)	Dolgic Plus® (butalbital-acetaminophen-caffeine, 50-750-40 mg) Phrenilin Forte® (butalbital-acetaminophen 50-650 mg) Orbivan® (butalbital-acetaminophen-caffeine 50-300-40 mg) Orbivan® CF (butalbital-acetaminophen 50-300 mg) Esgic-Plus® (butalbital-acetaminophen-caffeine 50-500-40 mg)

### Tier-2 Butalbital Products Approval Criteria:

1. FDA approved indication for the treatment of tension-type headache; and
2. Member must be 12 years of age or older; and
3. Failure within the previous 60 days of the following:
  - a. All available formulations of butalbital/acetaminophen products that do not require prior authorization (Products available without prior authorization contain butalbital/acetaminophen/caffeine in the standard 50mg-325mg-40mg dose); and
  - b. At least two NSAIDs, unless contraindicated
4. Approval of Fioricet with Codeine® (butalbital/APAP/Caffeine/Codeine 30-300mg) requires a patient-specific, clinically significant reason why member cannot take the product containing 325mg of acetaminophen.

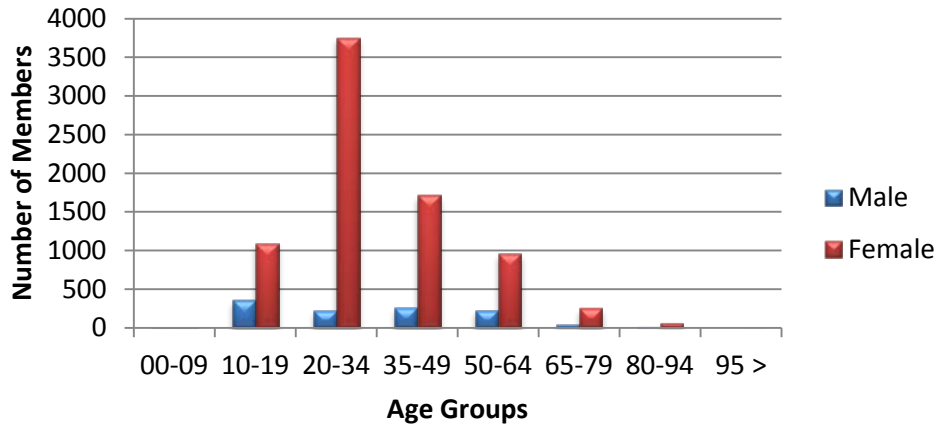
## Utilization of Butalbital Products

### Comparison of Fiscal Years

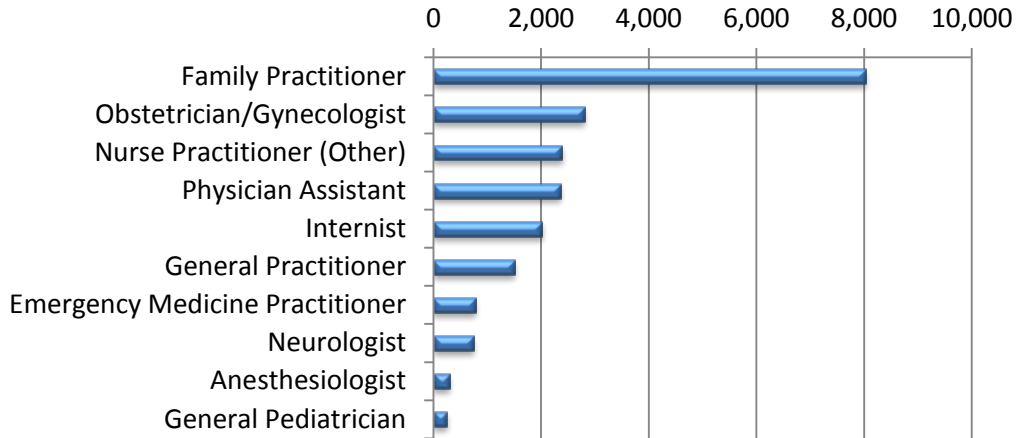
Fiscal Year	Total Members*	Total Claims	Total Cost	Cost / Claim	Cost/ Day	Total Units	Total Days
2012	9,223	23,554	\$316,478.66	\$13.44	\$1.09	1,184,201	291,304
2013	8,989	22,654	\$341,580.63	\$15.08	\$1.18	1,129,399	289,313
% Change	-2.50%	-3.80%	7.90%	12.20%	8.30%	-4.60%	-0.70%
Change	-234	-900	\$25,101.97	\$1.64	\$0.09	-54,802	-1,991

\*Total number of unduplicated members.

### Demographics of Members Utilizing Butalbital Products



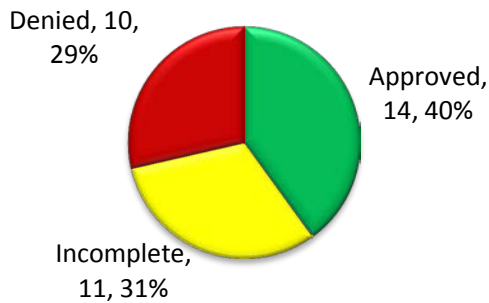
### Top Prescriber Specialties of Butalbital Products by Number of Claims



### Prior Authorization of Butalbital Products

There was a total of 35 petitions submitted for butalbital products during fiscal year 2013. The following chart shows the status of the submitted petitions.

#### Status of Petitions





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

### FDA Update:

- January 2011: FDA asked manufacturers of prescription products that contain acetaminophen to limit the amount of acetaminophen to no more than 325mg in each tablet or capsule.

### Recommendations

The college of pharmacy does not recommend any changes at this time.

### Utilization Details of Butalbital Products

CHEMICAL NAME	PRODUCT UTILIZED	CLAIMS	MEMBERS	COST	UNITS/ DAY	% COST	COST/ CLAIM
BUT/APAP/CAF	BUT/APAP/CAF 50-325-40MG TAB	18,608	7,784	\$240,968.21	3.96	70.55%	\$12.95
BUT/APAP/CAF/COD	BUT/APAP/CAF/COD 50-325-40-30MG CAP	930	392	\$19,186.51	3.69	5.62%	\$20.63
BUT/APAP/CAF	BUT/APAP/CAF 50-500-40MG TAB	719	277	\$11,141.34	3.48	3.26%	\$15.50
BUT/APAP	BUT/APAP 50-325MG TAB	148	59	\$3,160.15	4.15	0.93%	\$21.35
BUT/APAP/CAF	BUT/APAP/CAF 50-325-40MG CAP	80	58	\$1,905.29	4.6	0.56%	\$23.82
BUT/APAP/CAF	ZEBUTAL 50-500-40MG CAP	77	45	\$4,155.61	2.65	1.22%	\$53.97
BUT/APAP/CAF	ESGIC 50-325-40MG CAP	9	9	\$190.34	4.53	0.06%	\$21.15
BUT/APAP	BUPAP 50-650MG TAB	4	3	\$50.05	4.82	0.01%	\$12.51
BUT/APAP/CAF	CAPACET 50-325-40MG CAP	2	1	\$39.64	4.29	0.01%	\$19.82
BUT/APAP	CEPHADYN 50-650MG TAB	1	1	\$17.94	5	0.01%	\$17.94
<b>Subtotal</b>		<b>20,578</b>	<b>8,629</b>	<b>\$280,815.08</b>	<b>4.11</b>	<b>82.22%</b>	<b>\$13.65</b>
BUT/ASA/CAF	BUT/ASA/CAF 50-325-40MG CAP	1,168	494	\$28,000.45	3.76	8.20%	\$23.97
BUT/ASA/CAF/COD	ASCOMP/COD 50-325-40-30MG CAP	360	156	\$13,118.81	3.8	3.84%	\$36.44
BUT/ASA/CAF/COD	BUT/ASA/CAF/COD 50-325-40-30MG CAP	290	126	\$8,652.50	3.27	2.53%	\$29.84
BUT/ASA/CAF	BUT/ASA/CAFF 50-325-40MG TAB	196	102	\$2,808.09	3.99	0.82%	\$14.33
BUT/ASA/CAF	BUTALBITAL TAB 50-325-40MG TAB	25	16	\$306.88	3.19	0.09%	\$12.28
<b>Subtotal</b>		<b>2,039</b>	<b>894</b>	<b>\$52,886.73</b>	<b>3.60</b>	<b>15.48%</b>	<b>\$25.94</b>
<b>Tier-1 Subtotal</b>		<b>22,167</b>	<b>9,523</b>	<b>\$333,701.81</b>	<b>3.86</b>	<b>97.70%</b>	<b>\$14.75</b>
BUT/APAP/CAF	DOLGIC PLUS 50-750-40MG TAB	22	14	\$5,116.91	2.93	1.50%	\$232.59
BUT/APAP	PHRENILIN FORTE 50-650MG CAP	15	9	\$2,761.91	3.29	0.81%	\$184.13
<b>Subtotal</b>		<b>37</b>	<b>23</b>	<b>\$7,878.82</b>	<b>3.11</b>	<b>2.31%</b>	<b>\$212.94</b>
<b>Total</b>		<b>22,654</b>	<b>8,989*</b>	<b>\$341,580.63</b>	<b>3.90</b>	<b>100 %</b>	<b>\$15.08</b>

\*Total number of unduplicated members.

<sup>18</sup> FDA: FDA limits acetaminophen in prescription combination products. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239894.htm>. Last revised: 01/13/2011. Last accessed: 04/16/14.

# Annual Review of Neupro® (Rotigotine Transdermal), Requip XL™ (Ropinirole Extended-Release), and Mirapex® ER™ (Pramipexole Extended-Release)

Oklahoma Health Care Authority  
Fiscal Year 2013 Print Review

## Current Prior Authorization Criteria

### Neupro® (Rotigotine Transdermal) Approval Criteria:

Parkinson's Disease:

1. FDA approved indication for the treatment of signs and symptoms of Parkinson's Disease
2. Must be 18 years old or older
3. Failed treatment, intolerance, or clinically significant reason why member cannot use oral dopamine agonists

Restless Leg Syndrome:

1. FDA approved indication of Restless Leg Syndrome.
2. Must be 18 years or older.
3. Must provide documented treatment attempts at recommended dose with at least two of the following that did not yield adequate relief:
  - a. carbidopa/levodopa
  - b. pramipexole
  - c. ropinirole

### Requip XL™ (ropinirole) and Mirapex® ER™ (pramipexole) Approval Criteria:

1. Must have FDA approved indication for the treatment of signs and symptoms of Parkinson's Disease; and
2. A patient-specific, clinically significant reason why the immediate release products cannot be utilized.

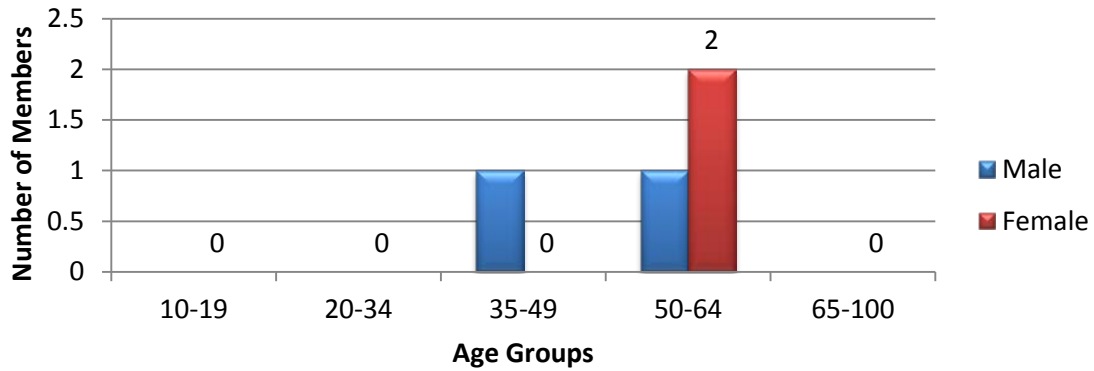
## Utilization of Neupro®, Requip XL™, and Mirapex® ER™

### Comparison of Fiscal Years

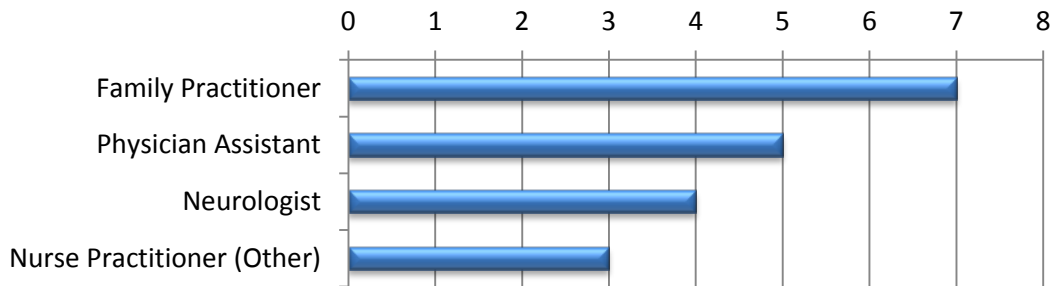
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Per-Diem Cost	Total Units	Total Days
2012	3	7	\$4,034.77	\$576.40	\$11.21	360	360
2013	4	8	\$3,304.72	\$413.09	\$9.18	360	360
% Change	33.30%	14.30%	-18.10%	-28.30%	-18.10%	0.00%	0.00%
Change	1	1	-\$730.05	-\$163.31	-\$2.03	0	0

\*Total number of unduplicated members.

**Demographics of Members Utilizing Neupro®, Requip XL™, and Mirapex® ER™**

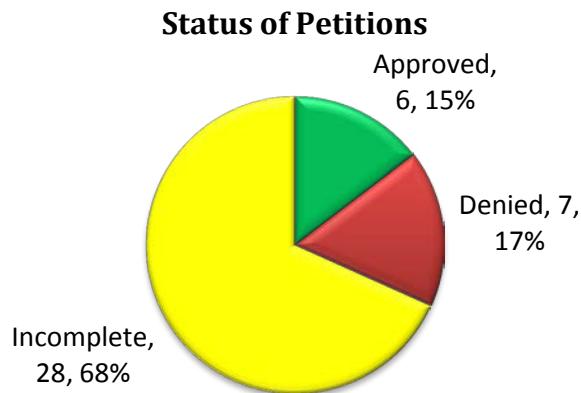


**Top Prescriber Specialties of Neupro®, Requip XL™, and Mirapex® ER™ by Number of Claims**



**Prior Authorization of Neupro®, Requip XL™, and Mirapex® ER™**

There was a total of 41 petitions submitted for this category during fiscal year 2013. The following chart shows the status of the submitted petitions.



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

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### Anticipated Patent Expirations

- Neupro® (rotigotine)- 09/2027
- Mirapex® ER™ (pramipexole extended-release)- 4/2028

### Recommendations

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

### Utilization Details of Neupro®, Requip XL™, and Mirapex® ER™: Fiscal Year 2013

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Product Utilized	Total Claims	Total Members	Total Cost	Cost/Day	Cost/Claim	Percent Cost
<b>ROPINIROLE PRODUCTS</b>						
ROPINIROLE TAB 12MG ER	4	1	\$2,710.50	\$11.29	\$677.63	82.02%
<b>SUBTOTAL</b>	<b>4</b>	<b>1</b>	<b>\$2,710.50</b>	<b>\$11.29</b>	<b>\$677.63</b>	<b>82.02%</b>
<b>ROTIGOTINE PRODUCTS</b>						
NEUPRO DIS 2MG/24HR	3	2	\$459.06	\$5.10	\$153.02	13.89%
NEUPRO DIS 1MG/24HR	1	1	\$135.16	\$4.51	\$135.16	4.09%
<b>SUBTOTAL</b>	<b>4</b>	<b>3</b>	<b>\$594.22</b>	<b>\$4.95</b>	<b>\$148.56</b>	<b>17.98%</b>
<b>TOTAL</b>	<b>8</b>	<b>4</b>	<b>\$3,304.72</b>	<b>\$9.18</b>	<b>\$413.09</b>	<b>100%</b>

\*Total number of unduplicated members

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<sup>19</sup> 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 4/10/14. Last accessed 4/11/14.