Print Annual Reviews for Fiscal Year 2017

Count	Category/Medication	Review Period
1.	Actinic Keratosis Medications	Fiscal Year
2.	Antidepressant Medications	Fiscal Year
3.	Antifungals (systemic)	Fiscal Year
4.	Antihistamines (oral)	Fiscal Year
5.	Arcalyst® (rilonacept)	Fiscal Year
6.	Benzodiazepines	Fiscal Year
7.	Benign Prostatic Hypertrophy Medications	Fiscal Year
8.	Butalbital Products	Fiscal Year
9.	Cholbam® (cholic acid)	Fiscal Year
10.	Chorionic Gonadotropin Medications	Fiscal Year
11.	Daraprim® (pyrimethamine)	Fiscal Year
12.	Diabetic Supplies	Fiscal Year
13.	Fibromyalgia	Fiscal Year
14.	Gattex® (Teduglutide [rDNA origin])	Fiscal Year
15.	Gaucher Disease medications	Fiscal Year
16.	H.P. Acthar® Gel (repository corticotropin injection)	Fiscal Year
17.	Heart Failure Medications	Fiscal Year
18.	Idiopathic Pulmonary Fibrosis Medications	Fiscal Year
19.	Inhaled Cystic Fibrosis Medications	Fiscal Year
20.	Inhaled Short-Acting $Beta_2$ Agonists	Fiscal Year
21.	Keveyis® (dichlorphenamide)	Fiscal Year
22.	Lidoderm® (lidocaine patch)/Synera® (lidocaine/tetracaine)	Fiscal Year
23.	Mozobil® (plerixafor)	Fiscal Year
24.	Muscle Relaxant Medications	Fiscal Year
25.	Myalept® (metreleptin)	Fiscal Year
26.	Mytesi® (crofelemer) [formerly Fulyzaq®]	Fiscal Year
27.	Naloxone Medications	Fiscal Year
28.	Nasal Allergy Medications	Fiscal Year
29.	Northera® (droxidopa)	Fiscal Year
30.	Ocular Antibiotics	Fiscal Year
31.	Pediculocides	Fiscal Year
32.	Prednisolone Special Formulations	Fiscal Year
33.	Prenatal Vitamins	Fiscal Year
34.	Procysbi® (cysteamine bitartrate)	Fiscal Year
35.	Pulmonary Hypertension Medications	Fiscal Year
36.	Qualaquin® (quinine sulfate)	Fiscal Year
37.	Qutenza® (capsaicin 8% patch)	Fiscal Year
38.	Ravicti® (glycerol phenylbutyrate)	Fiscal Year
39.	Retisert® (fluocinolone intravitreal implant)	Fiscal Year
40.	Singulair® (montelukast)/Zyflo CR® (Zileuton Extended-Release)	Fiscal Year

Count	Category/Medication	Review Period
41.	Smoking Cessation	Fiscal Year
42.	Strensiq® (asfotase alfa)	Fiscal Year
43.	Symlin® (pramlintide)	Fiscal Year
44.	Sylvant® (siltuximab)	Fiscal Year
45.	Testosterone Products	Fiscal Year
46.	Topical Antibiotics	Fiscal Year
47.	Topical Antifungals	Fiscal Year
48.	Ulcerative Colitis and Crohn's Disease Medications	Fiscal Year
49.	Vasomotor Symptom Medications	Fiscal Year
50.	Xgeva® (denosumab)	Fiscal Year
51.	Xiaflex® (collagenase clostridium histolyticum)	Fiscal Year
52.	Xuriden™ (uridine triacetate)	Fiscal Year

Fiscal Year = July 1, 2016 – June 30, 2017
Calendar Year = January 1, 2017 – December 31, 2017

Coverage and Policy Updates Impacting the Following Reports:

- Due to new federal regulations, SoonerCare implemented a new pricing methodology for pharmacy claims reimbursement on January 3, 2017. Ingredient reimbursement changed from an estimated acquisition cost (EAC) to an actual acquisition cost (AAC). In addition, the professional dispensing increased from $3.60 in 2016 to $10.55 effective January 2017; professional dispensing fees are included in the reimbursement totals in the following reports. The impact of the pricing methodology and dispensing fee change are estimated to be budget neutral. This change in reimbursement should be considered when evaluating reimbursement changes from year to year. Medications with a very low cost per claim and large volume of claims will appear to increase in price due to the increase in dispensing fee; however, these increases will be neutralized by changes in ingredient reimbursement for higher cost medications.
- Effective October 1, 2017 non-prescription products for adult members were limited to insulin, smoking cessation products, family planning products, and diabetic testing supplies only. Other over-the-counter (OTC) medications are no longer a covered benefit for adult members; however, the fiscal year runs from July 1, 2016 to June 30, 2017 and the change in coverage policies for adult members is not reflected in the utilization data for these reports.

Fiscal Year 2017 Annual Review of Actinic Keratosis Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Carac® (Fluorouracil 0.5% Cream) Approval Criteria:

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

Picato® (Ingenol Mebutate Gel) Approval Criteria:

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

Solaraze® (Diclofenac 3% Gel) Approval Criteria:

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

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

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

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

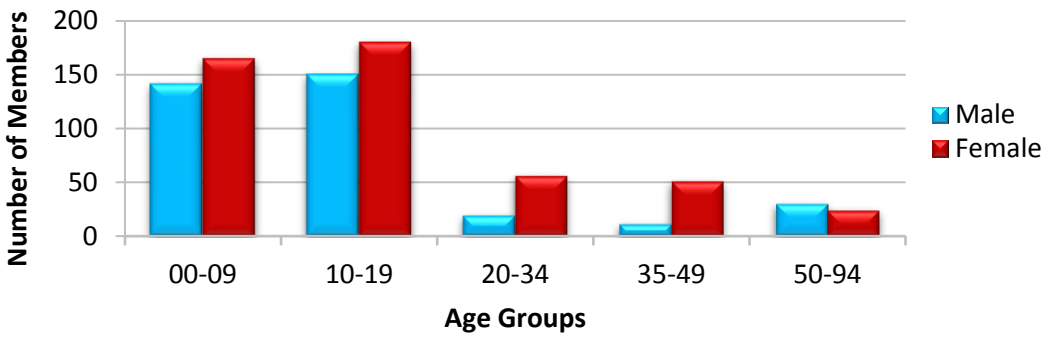
Utilization of Actinic Keratosis Medications: Fiscal Year 2017

Comparison of Fiscal Years

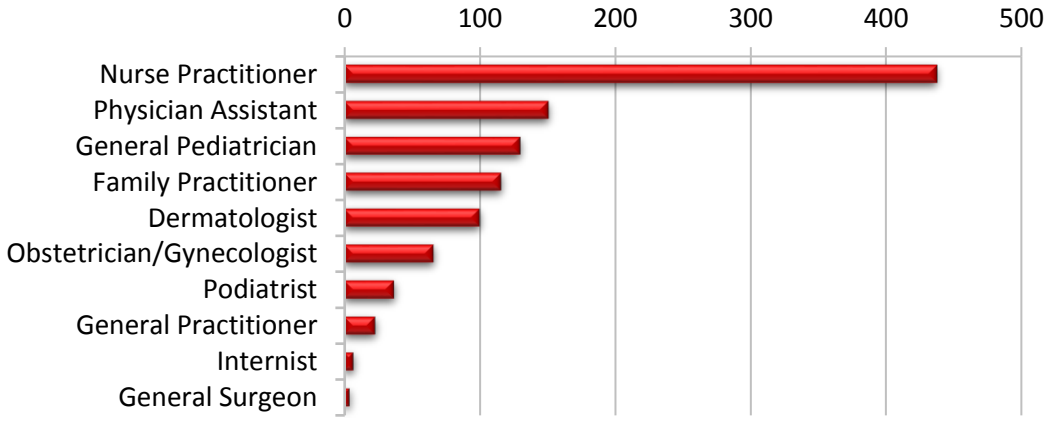
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	768	967	$108,941.74	$112.66	$3.01	16,969	36,134
2017	827	1,090	$83,261.37	$76.39	$2.07	17,211	40,150
% Change	**7.70%**	**12.70%**	**-23.60%**	**-32.20%**	**-31.20%**	**1.40%**	**11.10%**
Change	**59**	**123**	**-$25,680.37**	**-$36.27**	**-$0.94**	**242**	**4,016**

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

Demographics of Members Utilizing Actinic Keratosis Medications

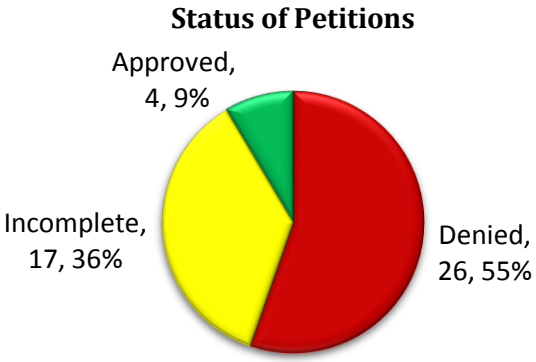


Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims



Prior Authorization of Actinic Keratosis Medications

There were 47 prior authorization requests submitted for actinic keratosis medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[1]

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

Recommendations

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

Utilization Details of Actinic Keratosis Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
IMIQUIMOD PRODUCTS						
IMIQUIMOD CRE 5%	1,016	769	$62,192.31	$1.61	$61.21	74.70%
SUBTOTAL	**1,016**	**769**	**$62,192.31**	**$1.61**	**$61.21**	**74.70%**
FLUOROURACIL PRODUCTS						
FLUOROURACIL CRE 5%	59	50	$8,584.38	$7.23	$145.50	10.31%
FLUOROURACIL CRE 0.5%	8	8	$11,106.56	$84.78	$1,388.32	13.34%
FLUOROURACIL SOL 2%	2	2	$81.97	$2.22	$40.99	0.10%
FLUOROURACIL SOL 5%	1	1	$66.17	$2.21	$66.17	0.08%
SUBTOTAL	**70**	**61**	**$19,839.08**	**$14.31**	**$283.42**	**23.83%**
DICLOFENAC PRODUCTS						
DICLOFENAC GEL 3%	4	3	$1,229.98	$10.25	$307.50	1.47%
SUBTOTAL	**4**	**3**	**$1,229.98**	**$10.25**	**$307.50**	**1.47%**
TOTAL	**1,090**	**827***	**$83,261.37**	**$2.07**	**$76.39**	**100.00%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2017. Last accessed 10/12/2017.

Fiscal Year 2017 Annual Review of Antidepressant Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			fluoxetine 10mg, 20mg (Sarafem®) & 60mg tabs
escitalopram (Lexapro®)			fluoxetine DR (Prozac® Weekly™)
fluoxetine 10mg, 20mg, 40mg caps (Prozac®)			fluvoxamine CR (Luvox CR®)
fluvoxamine (Luvox®)			paroxetine CR (Paxil CR®)
paroxetine (Paxil®)			paroxetine (Pexeva®)
sertraline (Zoloft®)			
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)	vilazodone (Viibryd®)	levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron® SolTab™)		nefazodone (Serzone®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)			trazodone 300mg tabs (Desyrel®)
venlafaxine (Effexor®, Effexor XR® capsules)			~~trazodone ER (Oleptro®)~~
			venlafaxine ER tabs (Effexor XR® tabs)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		Vortioxetine (Trintellix®)	

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

Antidepressant Medications Tier-2 Approval Criteria:

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

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

Antidepressant Medications Tier-3 Approval Criteria:

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

Antidepressant Medications Special Prior Authorization (PA) Approval Criteria:

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

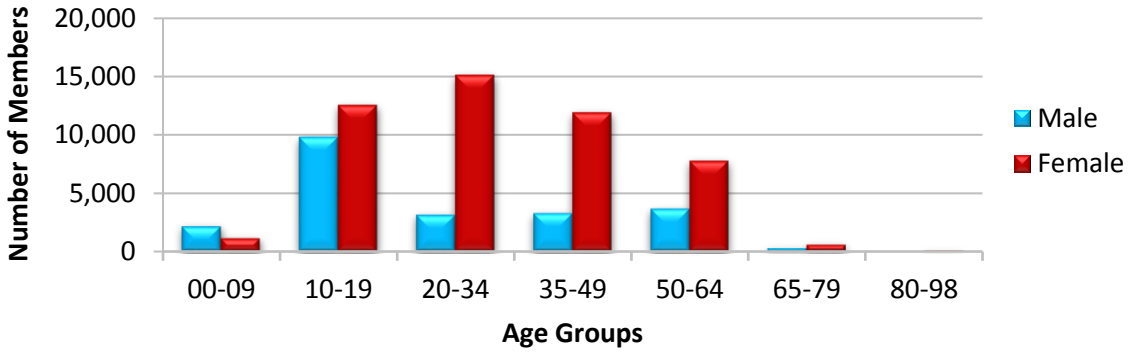
Utilization of Antidepressants: Fiscal Year 2017

Comparison of Fiscal Years

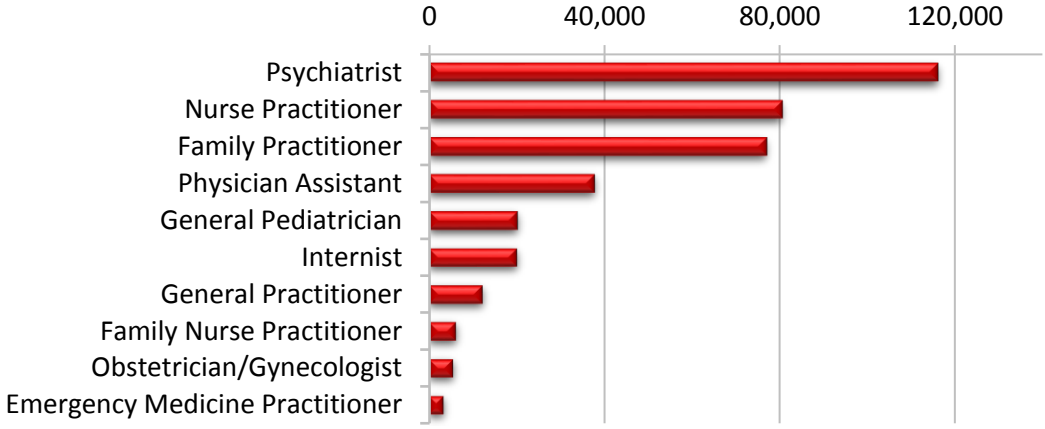
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	68,529	371,834	$5,032,750.73	$13.53	$0.41	14,354,661	12,357,138
2017	71,297	395,350	$6,271,372.75	$15.86	$0.47	15,339,148	13,242,847
% Change	**4.00%**	**6.30%**	**24.60%**	**17.20%**	**14.60%**	**6.90%**	**7.20%**
Change	**2,768**	**23,516**	**$1,238,622.02**	**$2.33**	**$0.06**	**984,487**	**885,709**

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

Demographics of Members Utilizing Antidepressants

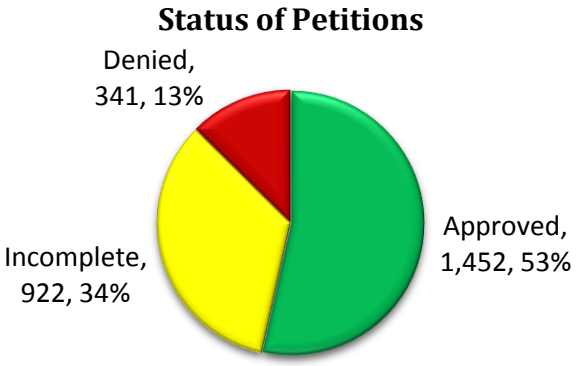


Top Prescriber Specialties of Antidepressants by Number of Claims



Prior Authorization of Antidepressants

There were 2,715 prior authorization requests submitted for antidepressants during fiscal year 2017. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[2]

- Emsam® [selegiline extended-release (ER) transdermal patches]: June 2018
- Viibryd® (vilazodone tablets): June 2022
- Pexeva® (paroxetine tablets): May 2025
- Aplenzin® (bupropion ER tablets): June 2026
- Forfivo XL® (bupropion ER tablets): June 2027
- Trintellix® (vortioxetine tablets): June 2031
- Fetzima® (levomilnacipran ER capsules): May 2032

News:

- **Oleptro™ (trazodone ER):** Oleptra™ (trazodone ER) 150mg and 300mg tablets have been discontinued. The Federal Register determined that the product was not discontinued or withdrawn for safety or efficacy reasons.[3]

Pipeline:

- **ALKS 5461:** Alkermes announced the initiation of its rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), seeking marketing approval of ALKS 5461, a once-daily, oral investigational medicine with a novel mechanism of action, for the adjunctive treatment of major depressive disorder (MDD). The company expects to complete the submission of the NDA for this Fast Track designated medicine by year-end 2017. ALKS 5461 consists of samidorphan and buprenorphine. It is designed to rebalance brain function through endogenous opioid modulation.[4]
- **Brexanolone:** In November 2017, Sage Therapeutics announced positive top-line results from two Phase 3 clinical trials with its proprietary intravenous (IV) formulation of brexanolone**.** Brexanolone provided a rapid and durable reduction over 30 days in

[2] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 10/2017. Last accessed 12/08/2017.
[3] U.S. Food and Drug Administration (FDA) Drugs@FDA: FDA Approved Drug Products. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=022411. Last revised 11/16/2017. Last accessed 12/11/2017.
[4] Alkermes. Alkermes Initiates Rolling Submission of ALKS 5461 New Drug Application for Major Depressive Disorder. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20170821005216/en/Alkermes-Initiates-Rolling-Submission-ALKS-5461-New. Issued 08/21/2017. Last accessed 12/11/2017.

depressive symptoms in patients with severe and moderate postpartum depression as measured by Hamilton Rating Scale for Depression (HAM-D) in both placebo-controlled multi-center trials. Patients treated with brexanolone demonstrated mean reductions from baseline in HAM-D total scores of 14 to 20 points at 60 hours maintained to 30 days in both trials (P=0.0242, P=0.0011).[5]

- **Esketamine:** Janssen Pharmaceutical Companies announced that the FDA has granted a Breakthrough Therapy Designation for esketamine, an investigational antidepressant medication, for the indication of MDD with imminent risk for suicide. If approved by the FDA, esketamine would be one of the first new approaches to treat MDD available to patients in the last 50 years. Esketamine was first granted this designation for treatment-resistant depression in November 2013. Esketamine is a non-competitive and subtype non-selective activity-dependent N-methyl-D-aspartate (NMDA) receptor antagonist for intranasal administration.[6]
- **SAGE-217:** In December 2017, Sage Therapeutics announced positive top-line results from the Phase 2, double-blind, placebo-controlled clinical trial of SAGE-217 in the treatment of 89 adult patients with moderate-to-severe MDD. In the trial, treatment for 14 days with SAGE-217 was associated with a statistically significant mean reduction in the HAM-D total score from baseline to Day 15 (the time of the primary endpoint) of 17.6 points for SAGE-217, compared to 10.7 for placebo (P<0.0001). The majority of patients (64%) achieved remission at Day 15 as determined by a HAM-D total score less than or equal to 7 (compared with 23% of patients who received placebo, P=0.0005). SAGE-217 is a novel, highly potent and selective, next generation $GABA_A$ receptor positive allosteric modulator.[7]

Recommendations

The College of Pharmacy recommends the removal of Oleptro™ (trazodone ER) from the Special Prior Authorization (PA) Tier of the Antidepressants Product Based Prior Authorization (PBPA) category based on its discontinuation. Changes can be seen in red in the *Current Prior Authorization Criteria* section at the beginning of this report.

[5] Sage Therapeutics: Investors & Media. Sage Therapeutics Announces Brexanolone Achieves Primary Endpoints in Both Phase 3 Clinical Trials in Postpartum Depression. Available online at: http://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-announces-brexanolone-achieves-primary. Issued 11/09/2017. Last accessed 12/18/2017.

[6] Janssen Pharmaceutical Companies. *PR Newswire*. Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Major Depressive Disorder with Imminent Risk for Suicide. Available online at: https://www.prnewswire.com/news-releases/esketamine-receives-breakthrough-therapy-designation-from-us-food-and-drug-administration-for-major-depressive-disorder-with-imminent-risk-for-suicide-300313633.html. Issued 08/16/2016. Last accessed 12/18/2017.

[7] Sage Therapeutics: Investors & Media. Sage Therapeutics Reports Positive Top-line Results from Phase 2 Placebo-Controlled Trial of SAGE-217 in Major Depressive Disorder. Available online at: http://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-reports-positive-top-line-results-phase-2. Issued 12/07/2017. Last accessed 12/18/2017.

Utilization Details of Antidepressants: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 MEDICATIONS					
SERTRALINE PRODUCTS					
SERTRALINE TAB 100MG	30,434	7,260	$282,555.57	$0.28	$9.28
SERTRALINE TAB 50MG	28,492	10,257	$255,495.74	$0.27	$8.97
SERTRALINE TAB 25MG	12,623	4,685	$118,090.56	$0.29	$9.36
SERTRALINE CON 20MG/ML	533	141	$31,244.16	$1.78	$58.62
ZOLOFT TAB 100MG	4	1	$1,544.36	$12.87	$386.09
ZOLOFT TAB 50MG	2	1	$524.98	$8.75	$262.49
SUBTOTAL	**72,088**	**22,345**	**$689,455.37**	**$0.29**	**$9.56**
TRAZODONE PRODUCTS					
TRAZODONE TAB 50MG	28,364	8,477	$223,928.30	$0.25	$7.89
TRAZODONE TAB 100MG	21,146	5,852	$197,818.19	$0.29	$9.35
TRAZODONE TAB 150MG	12,685	3,196	$164,002.49	$0.39	$12.93
SUBTOTAL	**62,195**	**17,525**	**$585,748.98**	**$0.29**	**$9.42**
FLUOXETINE PRODUCTS					
FLUOXETINE CAP 20MG	28,377	8,866	$210,061.88	$0.22	$7.40
FLUOXETINE CAP 40MG	14,577	3,862	$165,729.34	$0.33	$11.37
FLUOXETINE CAP 10MG	12,038	4,398	$93,839.07	$0.25	$7.80
FLUOXETINE SOL 20MG/5ML	1,211	285	$14,710.57	$0.41	$12.15
PROZAC CAP 20MG	18	3	$18,849.39	$24.17	$1,047.19
PROZAC CAP 20MG	15	2	$20,968.43	$46.60	$1,397.90
SUBTOTAL	**56,236**	**17,416**	**$524,158.68**	**$0.28**	**$9.32**
CITALOPRAM PRODUCTS					
CITALOPRAM TAB 20MG	19,516	6,727	$139,006.21	$0.20	$7.12
CITALOPRAM TAB 40MG	10,962	3,110	$75,489.39	$0.18	$6.89
CITALOPRAM TAB 10MG	8,631	2,954	$70,370.87	$0.25	$8.15
CITALOPRAM SOL 10MG/5ML	197	44	$8,690.23	$1.53	$44.11
SUBTOTAL	**39,306**	**12,835**	**$293,556.70**	**$0.21**	**$7.47**
ESCITALOPRAM PRODUCTS					
ESCITALOPRAM TAB 10MG	17,188	6,099	$173,042.56	$0.30	$10.07
ESCITALOPRAM TAB 20MG	16,848	4,176	$176,841.25	$0.31	$10.50
ESCITALOPRAM TAB 5MG	2,105	812	$22,004.01	$0.33	$10.45
ESCITALOPRAM SOL 5MG/5ML	162	36	$19,064.25	$4.17	$117.68
LEXAPRO TAB 20MG	14	5	$8,567.34	$10.20	$611.95
LEXAPRO TAB 10MG	6	2	$2,050.23	$13.06	$341.71
SUBTOTAL	**36,323**	**11,130**	**$401,569.64**	**$0.33**	**$11.06**
BUPROPION PRODUCTS					
BUPROPN HCL TAB 150MG XL	7,722	2,930	$174,145.96	$0.66	$22.55
BUPROPN HCL TAB 300MG XL	6,892	1,853	$175,192.71	$0.70	$25.42
BUPROPION TAB 150MG SR	5,130	1,786	$76,087.31	$0.47	$14.83
BUPROPION TAB 100MG	2,103	728	$59,770.95	$0.92	$28.42

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
BUPROPION TAB 100MG SR	1,922	788	$30,660.15	$0.51	$15.95
BUPROPION TAB 75MG	1,844	672	$40,823.67	$0.72	$22.14
BUPROPION TAB 150MG ER	1,408	624	$21,499.78	$0.48	$15.27
BUPROPION TAB 200MG SR	1,021	250	$23,174.29	$0.72	$22.70
BUPROPION TAB 100MG ER	569	278	$9,277.09	$0.51	$16.30
BUPROPION TAB 200MG ER	207	76	$4,459.25	$0.71	$21.54
WELLBUTRIN TAB XL 150MG	22	4	$52,972.49	$73.57	$2,407.84
WELLBUTRIN TAB XL 300MG	9	1	$13,847.32	$51.29	$1,538.59
SUBTOTAL	**28,849**	**9,990**	**$681,910.97**	**$0.71**	**$23.64**
DULOXETINE PRODUCTS					
DULOXETINE CAP 60MG	17,554	4,325	$394,408.14	$0.63	$22.47
DULOXETINE CAP 30MG	8,583	3,367	$185,595.29	$0.65	$21.62
DULOXETINE CAP 20MG	1,378	599	$37,997.29	$0.86	$27.57
CYMBALTA CAP 60MG	9	2	$4,011.67	$14.86	$445.74
SUBTOTAL	**27,524**	**8,293**	**$622,012.39**	**$0.65**	**$22.60**
MIRTAZAPINE PRODUCTS					
MIRTAZAPINE TAB 15MG	12,056	3,672	$125,406.33	$0.33	$10.40
MIRTAZAPINE TAB 30MG	6,928	1,986	$77,803.65	$0.35	$11.23
MIRTAZAPINE TAB 45MG	3,317	756	$52,045.20	$0.45	$15.69
MIRTAZAPINE TAB 7.5MG	794	271	$43,581.32	$1.80	$54.89
MIRTAZAPINE TAB 15MG ODT	211	72	$6,349.86	$0.97	$30.09
MIRTAZAPINE TAB 30MG ODT	142	49	$4,680.86	$0.97	$32.96
MIRTAZAPINE TAB 45MG ODT	39	11	$1,193.42	$0.95	$30.60
SUBTOTAL	**23,487**	**6,817**	**$311,060.64**	**$0.41**	**$13.24**
VENLAFAXINE PRODUCTS					
VENLAFAXINE CAP 150MG ER	8,062	2,040	$103,220.13	$0.35	$12.80
VENLAFAXINE CAP 75MG ER	6,524	2,429	$75,238.33	$0.33	$11.53
VENLAFAXINE CAP 37.5MG ER	2,471	1,258	$27,887.10	$0.35	$11.29
VENLAFAXINE TAB 75MG	2,253	717	$45,737.76	$0.63	$20.30
VENLAFAXINE TAB 37.5MG	838	390	$15,516.86	$0.61	$18.52
VENLAFAXINE TAB 100MG	505	118	$12,210.18	$0.77	$24.18
VENLAFAXINE TAB 50MG	189	65	$3,821.09	$0.66	$20.22
VENLAFAXINE TAB 25MG	152	65	$2,715.80	$0.60	$17.87
EFFEXOR XR CAP 150MG	40	4	$27,378.95	$22.82	$684.47
EFFEXOR XR CAP 75MG	22	3	$14,869.22	$22.53	$675.87
SUBTOTAL	**21,056**	**7,089**	**$328,595.42**	**$0.45**	**$15.61**
PAROXETINE PRODUCTS					
PAROXETINE TAB 20MG	5,529	2,186	$46,875.64	$0.24	$8.48
PAROXETINE TAB 40MG	3,848	1,006	$43,296.91	$0.30	$11.25
PAROXETINE TAB 10MG	2,296	953	$20,199.05	$0.26	$8.80
PAROXETINE TAB 30MG	1,821	496	$20,042.72	$0.31	$11.01
PAXIL SUS 10MG/5ML	35	12	$6,730.03	$7.02	$192.29
PAXIL TAB 40MG	5	1	$2,837.92	$6.31	$567.58

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	**13,534**	**4,654**	**$139,982.27**	**$0.29**	**$10.34**
FLUVOXAMINE PRODUCTS					
FLUVOXAMINE TAB 100MG	1,424	283	$28,851.74	$0.66	$20.26
FLUVOXAMINE TAB 50MG	1,064	262	$16,320.31	$0.50	$15.34
FLUVOXAMINE TAB 25MG	319	86	$4,444.93	$0.43	$13.93
SUBTOTAL	**2,807**	**631**	**$49,616.98**	**$0.57**	**$17.68**
TIER-1 SUBTOTAL	**383,405**	**118,725**	**$4,627,668.04**	**$0.36**	**$12.07**
TIER-2 MEDICATIONS					
VILAZODONE PRODUCTS					
VIIBRYD TAB 40MG	831	169	$184,063.30	$7.35	$221.50
VIIBRYD TAB 20MG	357	132	$77,792.26	$7.35	$217.91
VIIBRYD TAB 10MG	76	47	$14,064.22	$7.12	$185.06
SUBTOTAL	**1,264**	**348**	**$275,919.78**	**$7.33**	**$218.29**
DESVENLAFAXINE PRODUCTS$^{\Delta}$					
PRISTIQ TAB 50MG	188	56	$81,446.71	$10.35	$433.23
PRISTIQ TAB 100MG	174	40	$73,621.49	$10.77	$423.11
DESVENLAFAX TAB 50MG ER	50	30	$3,738.47	$1.84	$74.77
DESVENLAFAX TAB 100MG ER	45	26	$4,739.54	$2.52	$105.32
PRISTIQ TAB 25MG	18	4	$5,386.79	$10.48	$299.27
DESVENLAFAX TAB 25MG ER	9	3	$378.08	$1.48	$42.01
SUBTOTAL	**484**	**159**	**$169,311.08**	**$8.73**	**$349.82**
TIER-2 SUBTOTAL	**1,748**	**507**	**$445,230.86**	**$7.81**	**$254.71**
TIER-3 MEDICATIONS					
VORTIOXETINE PRODUCTS^{+}					
TRINTELLIX TAB 20MG	237	58	$78,864.88	$11.12	$332.76
TRINTELLIX TAB 10MG	156	64	$59,423.30	$11.71	$380.92
BRINTELLIX TAB 10MG	10	9	$3,331.80	$11.29	$333.18
TRINTELLIX TAB 5MG	8	6	$2,719.92	$11.33	$339.99
BRINTELLIX TAB 20MG	8	3	$2,689.14	$11.20	$336.14
BRINTELLIX TAB 5MG	2	2	$679.16	$11.32	$339.58
SUBTOTAL	**421**	**142**	**$147,708.20**	**$11.36**	**$350.85**
LEVOMILNACIPRAN PRODUCTS$^{¥}$					
FETZIMA CAP 80MG	135	34	$43,079.45	$10.64	$319.11
FETZIMA CAP 40MG	113	34	$35,639.97	$10.59	$315.40
FETZIMA CAP 120MG	53	13	$16,878.33	$10.62	$318.46
FETZIMA CAP 20MG	22	11	$7,137.32	$11.59	$324.42
FETZIMA CAP TITRATION	2	2	$596.94	$10.66	$298.47
SUBTOTAL	**325**	**94**	**$103,332.01**	**$10.68**	**$317.94**
NEFAZODONE PRODUCTS					
NEFAZODONE TAB 200MG	22	3	$1,357.41	$2.06	$61.70
NEFAZODONE TAB 100MG	17	2	$1,157.94	$2.38	$68.11
NEFAZODONE TAB 150MG	10	1	$791.89	$2.64	$79.19
NEFAZODONE TAB 250MG	9	1	$1,092.73	$2.80	$121.41

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	**58**	**7**	**$4,399.97**	**$2.40**	**$75.86**
DESVENLAFAXINE PRODUCTS					
DESVENLAFAX TAB 100MG ER	13	3	$1,920.83	$4.93	$147.76
DESVENLAFAX TAB 50MG ER	12	5	$1,790.57	$4.97	$149.21
SUBTOTAL	**25**	**8**	**$3,711.40**	**$4.95**	**$148.46**
SELEGILINE PRODUCTS					
EMSAM DIS 6MG/24HR	6	2	$9,103.62	$50.58	$1,517.27
EMSAM DIS 12MG/24H	5	1	$7,854.88	$52.37	$1,570.98
SUBTOTAL	**11**	**3**	**$16,958.50**	**$51.39**	**$1,541.38**
TRANYLCYPROMINE PRODUCTS					
TRANYLCYPROM TAB 10MG	2	1	$474.42	$11.57	$237.21
SUBTOTAL	**2**	**1**	**$474.42**	**$11.57**	**$237.21**
TIER-3 SUBTOTAL	**842**	**255**	**$276,584.50**	**$10.79**	**$328.49**
SPECIAL PA MEDICATIONS					
FLUOXETINE PRODUCTS∞					
FLUOXETINE TAB 10MG	4,135	1,364	$116,216.13	$0.89	$28.11
FLUOXETINE TAB 20MG	2,481	914	$156,626.40	$1.93	$63.13
FLUOXETINE CAP 90MG DR	34	8	$4,488.05	$4.70	$132.00
FLUOXETINE TAB 60MG	13	2	$3,391.28	$8.70	$260.87
SUBTOTAL	**6,663**	**2,288**	**$280,721.86**	**$1.32**	**$42.13**
VENLAFAXINE PRODUCTS					
VENLAFAXINE TAB 225MG ER	998	236	$350,039.60	$9.41	$350.74
VENLAFAXINE TAB 150MG ER	165	49	$19,287.00	$2.97	$116.89
VENLAFAXINE TAB 75MG ER	52	25	$5,923.28	$3.22	$113.91
VENLAFAXINE TAB 37.5MG ER	41	13	$4,386.56	$3.16	$106.99
SUBTOTAL	**1,256**	**323**	**$379,636.44**	**$8.09**	**$302.26**
PAROXETINE PRODUCTS					
PAROXETINE TAB 25MG ER	461	104	$66,731.26	$4.31	$144.75
PAROXETIN ER TAB 37.5MG	186	47	$30,854.86	$4.12	$165.89
PAROXETIN ER TAB 12.5MG	124	51	$14,783.53	$3.65	$119.22
PEXEVA TAB 20MG	9	2	$6,578.32	$11.54	$730.92
PAXIL CR TAB 37.5MG	8	1	$1,512.49	$6.30	$189.06
PEXEVA TAB 40MG	1	1	$1,095.05	$12.17	$1,095.05
SUBTOTAL	**789**	**206**	**$121,555.51**	**$4.35**	**$154.06**
TRAZODONE PRODUCTS€					
TRAZODONE TAB 300MG	392	130	$46,469.40	$3.30	$118.54
SUBTOTAL	**392**	**130**	**$46,469.40**	**$3.30**	**$118.54**
FLUVOXAMINE PRODUCTS					
FLUVOXAMINE CAP 100MG ER	133	24	$55,504.70	$13.40	$417.33
FLUVOXAMINE CAP 150MG ER	118	27	$37,589.47	$9.36	$318.55
SUBTOTAL	**251**	**51**	**$93,094.17**	**$11.41**	**$370.89**
DULOXETINE PRODUCTS					
DULOXETINE CAP 40MG	4	2	$411.97	$3.43	$102.99

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	4	2	$411.97	$3.43	$102.99
SPECIAL PA SUBTOTAL	9,355	3,000	$921,889.35	$2.97	$98.55
TOTAL	395,350	71,297*	$6,271,372.75	$0.47	$15.86

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

[Δ]Desvenlafaxine (Pristiq®) moved to from Tier-3 to Tier-2 on October 4, 2017. The utilization above occurred during fiscal year 2017, but is shown under the Tier-2 products to reflect the current tier placement.

[+]The FDA approved a brand name change for Brintellix® (vortioxetine) to Trintellix® in May 2016; therefore, the product was still available as Brintellix® for part of fiscal year 2017, as is reflected in the utilization details above.

[¥]The levomilnacipran products moved from Tier-2 to Tier-3 on January 1, 2017. The utilization above occurred during fiscal year 2017, and is shown under the Tier-3 products to reflect the current tier placement.

[∞]Fluoxetine 10mg and 20mg tablets were moved to the Special PA Tier October 4, 2017. The utilization above occurred during fiscal year 2017, but is shown under the Special PA Tier products to reflect the current tier placement.

[€]Trazodone 300mg tablets were moved to the Special PA Tier October 4, 2017. The utilization above occurred during fiscal year 2017, but is shown under the Special PA Tier products to reflect the current tier placement.

Fiscal Year 2017 Annual Review of Antifungal Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

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

Ketoconazole Oral Tablets Approval Criteria:

Consideration for approval requires the following:

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

Lamisil® Oral Granules (Terbinafine) Approval Criteria:

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

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
    a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy; or

b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole; or
2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization; and
4. For the diagnosis of OPC, only the oral suspension may be used.

Onmel® (Itraconazole Oral Tablets) Approval Criteria:

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

Oravig® (Miconazole Buccal Tablets) Approval Criteria:

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

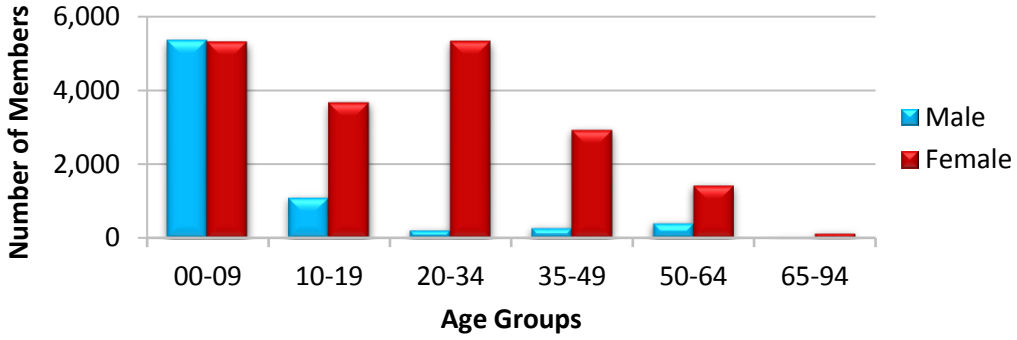
Utilization of Antifungal Medications: Fiscal Year 2017

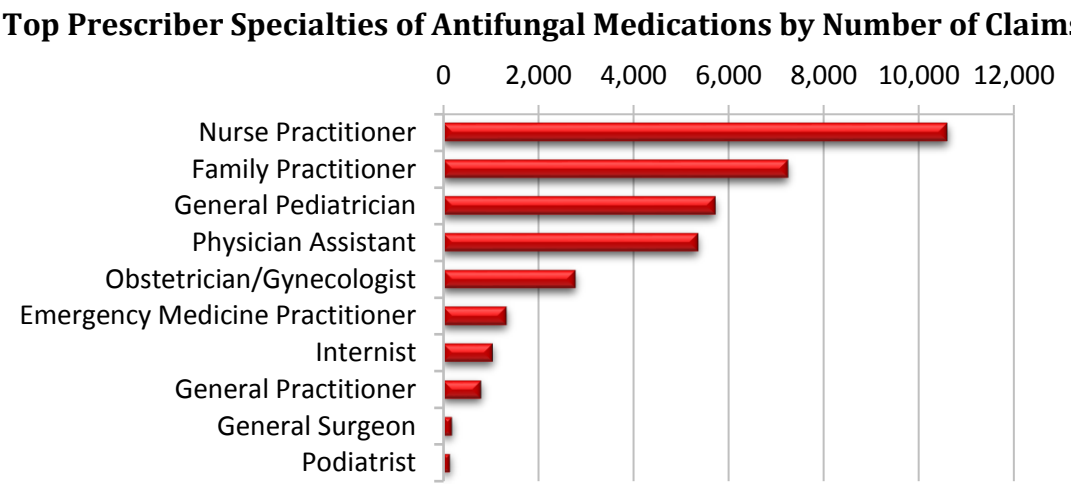
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	26,511	37,406	$1,231,478.18	$32.92	$2.94	2,184,457	419,540
2017	26,148	37,256	$1,223,598.21	$32.84	$2.89	2,141,264	423,692
% Change	**-1.40%**	**-0.40%**	**-0.60%**	**-0.20%**	**-1.70%**	**-2.00%**	**1.00%**
Change	**-363**	**-150**	**-$7,879.97**	**-$0.08**	**-$0.05**	**-43,193**	**4,152**

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

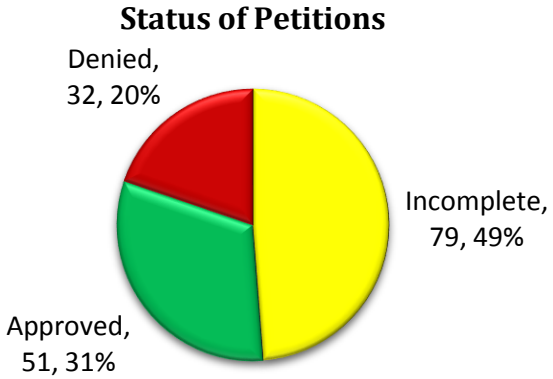
Demographics of Members Utilizing Antifungal Medications





Prior Authorization of Antifungal Medications

There were 162 prior authorization requests submitted for antifungal medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[8]

- Sporanox® (itraconazole solution): June 2019
- Noxafil® (posaconazole tablet): July 2019
- Cresemba® (isavuconazonium): October 2020
- Noxafil® (posaconazole suspension): April 2022
- Oravig® (miconazole): September 2022
- Onmel® (itraconazole tablet): October 2028

[8] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2017. Last accessed 10/17/2017.

News:

- **March 2017:** Alembic Pharmaceuticals launched a generic formulation of Sporanox® (itraconazole) capsules, and will offer the drug in a 100mg dosage strength. Alembic joins several other generic manufacturers in supplying this medication.[9]

Recommendations

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

Utilization Details of Antifungal Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
FLUCONAZOLE PRODUCTS					
FLUCONAZOLE TAB 150MG	14,576	10,347	$140,953.81	$2.52	$9.67
FLUCONAZOLE TAB 200MG	1,927	1,423	$37,398.26	$1.74	$19.41
FLUCONAZOLE TAB 100MG	1,910	1,468	$30,162.64	$1.57	$15.79
FLUCONAZOLE SUS 40MG/ML	1,540	1,257	$58,624.69	$3.33	$38.07
FLUCONAZOLE SUS 10MG/ML	1,448	1,204	$30,047.93	$1.82	$20.75
FLUCONAZOLE INJ 400MG	32	9	$1,240.23	$5.39	$38.76
FLUCONAZOLE TAB 50MG	16	13	$225.19	$1.53	$14.07
FLUCONAZOLE INJ 200MG	9	1	$466.32	$20.27	$51.81
SUBTOTAL	**21,458**	**15,722**	**$299,119.07**	**$2.28**	**$13.94**
NYSTATIN PRODUCTS					
NYSTATIN SUSP 100000 U/ML	10,061	8,407	$152,927.28	$1.26	$15.20
NYSTATIN TAB 500000 UNITS	61	28	$2,410.98	$1.61	$39.52
SUBTOTAL	**10,122**	**8,435**	**$155,338.26**	**$1.26**	**$15.35**
GRISEOFULVIN PRODUCTS					
GRISEOFULVIN SUS 125MG/5ML	1,898	1,444	$124,258.34	$2.70	$65.47
GRISEOFULVIN MICRO 500MG	436	358	$102,631.48	$7.98	$235.39
GRISEOFULVIN ULTRA 250MG	308	229	$63,616.93	$7.15	$206.55
GRISEOFULVIN ULTRA 125MG	74	57	$13,169.06	$5.41	$177.96
SUBTOTAL	**2,716**	**2,088**	**$303,675.81**	**$4.33**	**$111.81**
TERBINAFINE PRODUCTS					
TERBINAFINE TAB 250MG	2,355	1,649	$25,016.16	$0.29	$10.62
SUBTOTAL	**2,355**	**1,649**	**$25,016.16**	**$0.29**	**$10.62**
ITRACONAZOLE PRODUCTS					
ITRACONAZOLE CAP 100MG	266	137	$79,656.16	$12.26	$299.46
SPORANOX SOL 10MG/ML	94	61	$60,491.66	$29.61	$643.53
SUBTOTAL	**360**	**198**	**$140,147.82**	**$16.41**	**$389.30**
VORICONAZOLE PRODUCTS					
VORICONAZOLE TAB 200MG	60	17	$39,654.83	$25.82	$660.91

[9] Berk, B. Alembic Debuts Sporanox Generic. *Drug Store News*. Available online at: http://www.drugstorenews.com/article/alembic-debuts-sporanox-generic. Issued 03/15/2017. Last accessed 10/23/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
VORICONAZOLE SUS 40MG/ML	20	6	$26,939.49	$64.14	$1,346.97
VORICONAZOLE TAB 50MG	5	2	$3,608.11	$22.84	$721.62
VFEND IV INJ 200MG	5	2	$14,037.81	$179.97	$2,807.56
VORICONAZOLE INJ 200MG	3	3	$1,983.41	$20.03	$661.14
SUBTOTAL	**93**	**30**	**$86,223.65**	**$37.64**	**$927.14**
CLOTRIMAZOLE PRODUCTS					
CLOTRIMAZOLE LOZ 10MG	60	45	$1,944.61	$2.77	$32.41
CLOTRIMAZOLE TRO 10MG	18	15	$438.73	$2.91	$24.37
SUBTOTAL	**78**	**60**	**$2,383.34**	**$2.79**	**$30.56**
POSACONAZOLE PRODUCTS					
NOXAFIL TAB 100MG	27	6	$146,040.61	$194.72	$5,408.91
NOXAFIL SUS 40MG/ML	4	1	$5,224.14	$43.53	$1,306.04
SUBTOTAL	**31**	**7**	**$151,264.75**	**$173.87**	**$4,879.51**
AMPHOTERICIN B PRODUCTS					
AMBISOME INJ 50MG	19	5	$59,579.82	$428.63	$3,135.78
AMPHOTERICIN POW B	10	8	$417.10	$2.32	$41.71
AMPHOTERICIN INJ 50MG	2	1	$7.90	$0.40	$3.95
SUBTOTAL	**31**	**14**	**$60,004.82**	**$177.01**	**$1,935.64**
MICONAZOLE PRODUCTS					
MICONAZOLE POWDER	11	10	$413.45	$1.56	$37.59
SUBTOTAL	**11**	**10**	**$413.45**	**$1.56**	**$37.59**
KETOCONAZOLE PRODUCTS					
KETOCONAZOLE TAB 200MG	1	1	$11.08	$1.58	$11.08
SUBTOTAL	**1**	**1**	**$11.08**	**$1.58**	**$11.08**
TOTAL	**37,256**	**26,148***	**$1,223,598.21**	**$2.89**	**$32.84**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2017 Annual Review of Oral Antihistamine Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

Oral Antihistamine Tier-1 Approval Criteria:

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

Oral Antihistamine Tier-2 Approval Criteria:

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

Oral Antihistamine Tier-3 Approval Criteria:

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

Utilization of Oral Antihistamines: Fiscal Year 2017

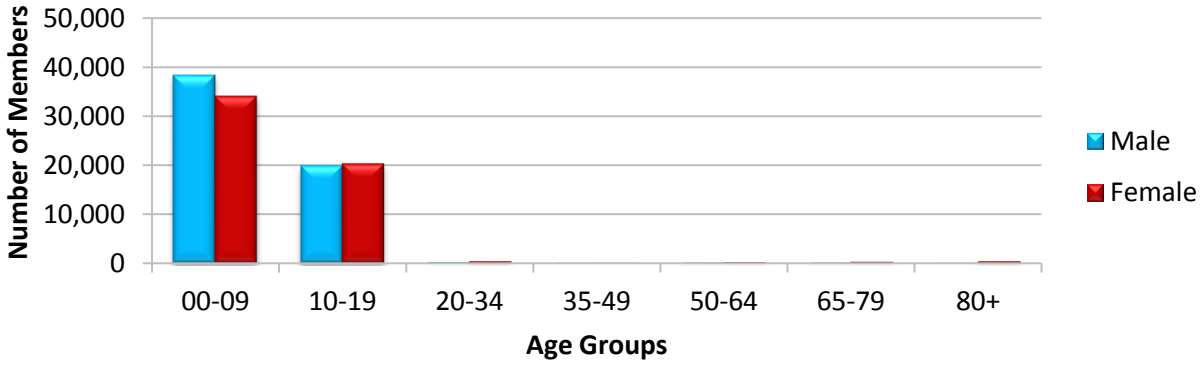
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	116,005	282,633	$2,184,334.83	$7.73	$0.25	25,174,693	8,631,140
2017	114,836	281,315	$2,592,243.82	$9.21	$0.30	24,901,980	8,626,845
% Change	**-1.00%**	**-0.50%**	**18.70%**	**19.10%**	**20.00%**	**-1.10%**	**0.00%**
Change	**-1,169**	**-1,318**	**$407,908.99**	**$1.48**	**$0.05**	**-272,713**	**-4,295**

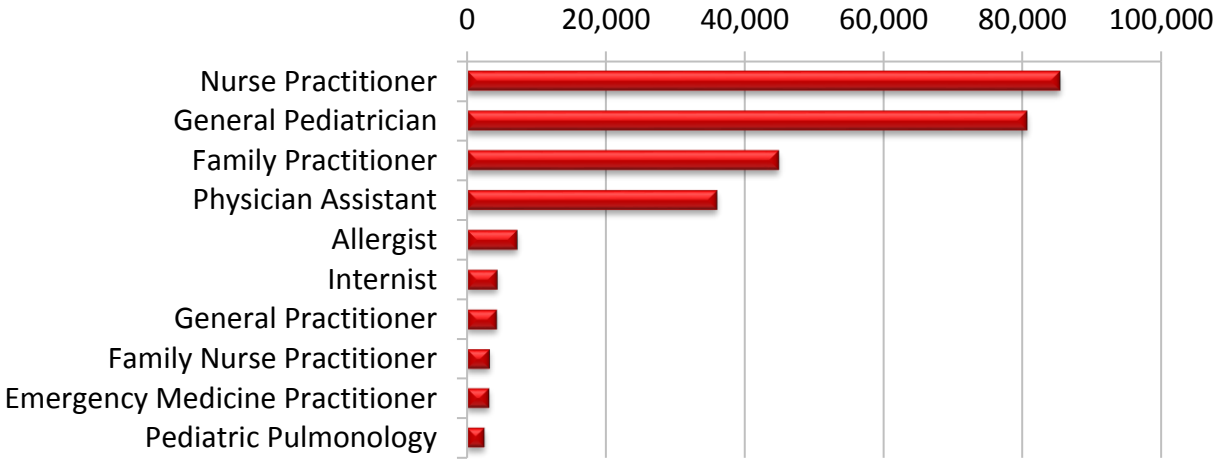
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- Effective 10/01/2017 non-prescription products for adult members were limited to insulin, smoking cessation products, family planning products, and diabetic testing supplies only. Oral antihistamines are no longer a covered benefit for adult members; however, the fiscal year runs from 07/01/2016 to 06/30/2017 and the change in coverage policies for adult members is not reflected in the utilization data for this report.

Demographics of Members Utilizing Oral Antihistamine Medications

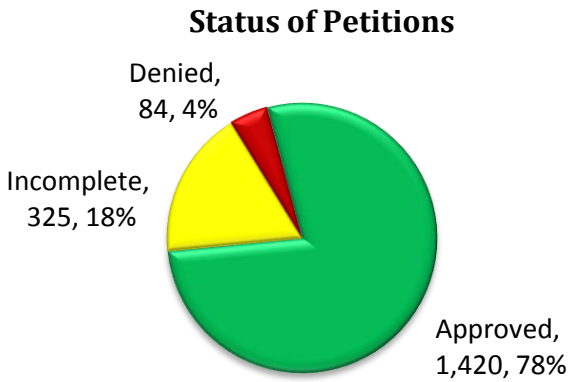


Top Prescriber Specialties of Oral Antihistamine Medications by Number of Claims



Prior Authorization of Oral Antihistamine Medications

There were 1,829 prior authorization requests submitted for the oral antihistamine medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[10]

- Clarinex® (desloratadine solution): June 2018
- Clarinex® (desloratadine tablets): July 2019

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

- **February 2017:** The FDA approved Xyzal® Allergy 24HR (levocetirizine) as an OTC treatment for the relief of symptoms associated with seasonal and year-round allergies. The FDA approved two formulations for OTC use – 5mg tablets for ages 6 years and older and a 0.5mg/mL oral solution for ages 2 years and older.[11]

Recommendations

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

Utilization Details of Oral Antihistamine Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
CETIRIZINE PRODUCTS					
CETIRIZINE SYP 1MG/ML	104,159	51,189	$1,054,351.47	2.03	$10.12
CETIRIZINE TAB 10MG	84,368	32,858	$570,982.48	2.57	$6.77
CETIRIZINE SOL 5MG/5ML	17,598	11,614	$207,604.54	1.52	$11.80
CETIRIZINE TAB 5MG	4,718	2,082	$43,663.75	2.27	$9.25
ALL DAY ALLG TAB 10MG	3,372	1,416	$28,326.54	2.38	$8.40
ALL DAY ALLG SOL 5MG/5ML	758	465	$8,790.01	1.63	$11.60
ALLERGY COMP SOL 1MG/ML	330	240	$2,993.49	1.38	$9.07

[10] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2017. Last accessed 10/16/2017.

[11] Sanofi. Sanofi's Xyzal® Allergy 24HR Approved for Over-the-Counter Use in the United States. *PRNewswire*. Available online at: http://www.prnewswire.com/news-releases/sanofis-xyzal-allergy-24hr-approved-for-over-the-counter-use-in-the-united-states-300400145.html. Issued 02/01/2017. Last accessed 10/09/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
ALL DAY ALLG SOL 1MG/ML	261	139	$3,074.08	1.88	$11.78
ALL DAY ALLG SYP 1MG/ML	139	94	$1,241.64	1.48	$8.93
GNP ALL DAY TAB ALLERGY	49	23	$460.20	2.13	$9.39
CETIRIZINE SYP 1MG/ML	34	19	$316.92	1.79	$9.32
SM ALL DAY TAB ALLERGY	14	10	$112.60	1.4	$8.04
ALLERGY RELF SOL 5MG/5ML	4	4	$38.87	1	$9.72
SUBTOTAL	**215,804**	**93,002**	**$1,921,956.59**	**2.32**	**$8.91**
LORATADINE PRODUCTS					
LORATADINE TAB 10MG	36,530	13,876	$298,888.70	2.63	$8.18
LORATADINE SOL 5MG/5ML	22,507	12,129	$270,679.56	1.86	$12.03
LORATADINE SYP 5MG/5ML	4,182	2,536	$53,052.00	1.65	$12.69
ALLERGY TAB 10MG	624	294	$5,635.54	2.12	$9.03
ALLERGY RELF TAB 10MG	401	178	$3,677.67	2.25	$9.17
ALLERGY RELF SYP 5MG/5ML	316	174	$4,081.85	1.82	$12.92
LORATADINE TAB 10MG	29	15	$511.47	1.93	$17.64
ALLERGY RELF TAB 10MG	23	5	$407.64	4.6	$17.72
ALLERGY CHLD SYP 5MG/5ML	16	14	$229.60	1.14	$14.35
ALLERGY TAB 10MG	1	1	$9.30	1	$9.30
SUBTOTAL	**64,629**	**28,137**	**$637,173.33**	**2.3**	**$9.86**
TIER-1 SUBTOTAL	**280,433**	**114,724**	**$2,559,129.92**	**2.44**	**$9.13**
LEVOCETIRIZINE PRODUCTS					
TIER-2 UTILIZATION					
LEVOCETIRIZI TAB 5MG	536	127	$6,703.11	4.22	$12.51
LEVOCETIRIZI SOL 2.5/5ML	308	83	$19,504.63	3.71	$63.33
TIER-2 SUBTOTAL	**844**	**205**	**$26,207.74**	**4.12**	**$31.05**
DESLORATADINE PRODUCTS					
TIER-3 UTILIZATION					
DESLORATADIN TAB 5MG	20	3	$452.00	6.67	$22.60
CLARINEX SYP 0.5MG/ML	18	2	$6,454.16	9	$358.56
TIER-3 SUBTOTAL	**38**	**4**	**$6,906.16**	**9.5**	**$181.74**
TOTAL	**281,315**	**114,836***	**$2,592,243.82**	**2.45**	**$9.21**

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

Fiscal Year 2017 Annual Review of Arcalyst® (Rilonacept)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Arcalyst® (rilonacept) Approval Criteria:

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

Utilization of Acralyst®: Fiscal Year 2017

There were no pharmacy or medical claims for Arcalyst® (rilonacept) during fiscal year 2017.

Prior Authorization of Acralyst®

There were no prior authorization requests submitted for Arcalyst® (rilonacept) during fiscal year 2017.

Recommendations

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

Fiscal Year 2017 Annual Review of Benzodiazepine Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

1. Currently there are no prior authorization criteria; however, quantity limits are set at maximum of 3 units per day for most products.
2. Approval for dosing greater than 3 times daily requires a chronic physical diagnosis; for these diagnoses the maximum allowed dosing would be 4 times daily.
3. A member may receive more than three units per day if the following criteria exists:
    a. The number of units per day is greater than 3, but less than the maximum daily dose for the product (or for a total daily dosing 3 times daily); and
    b. The member has a chronic diagnosis and a clinical reason for excessive units has been provided.

Benzodiazepine Approval Criteria for Members Younger Than 19 Years of Age:

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

Niravam™ (Alprazolam Orally Disintegrating Tablets) Approval Criteria:

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

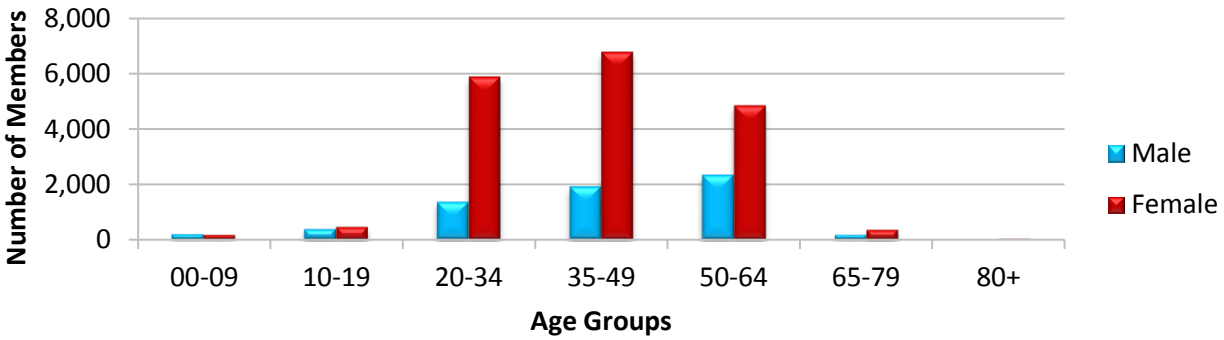
Utilization of Benzodiazepine Medications: Fiscal Year 2017

Comparison of Fiscal Years

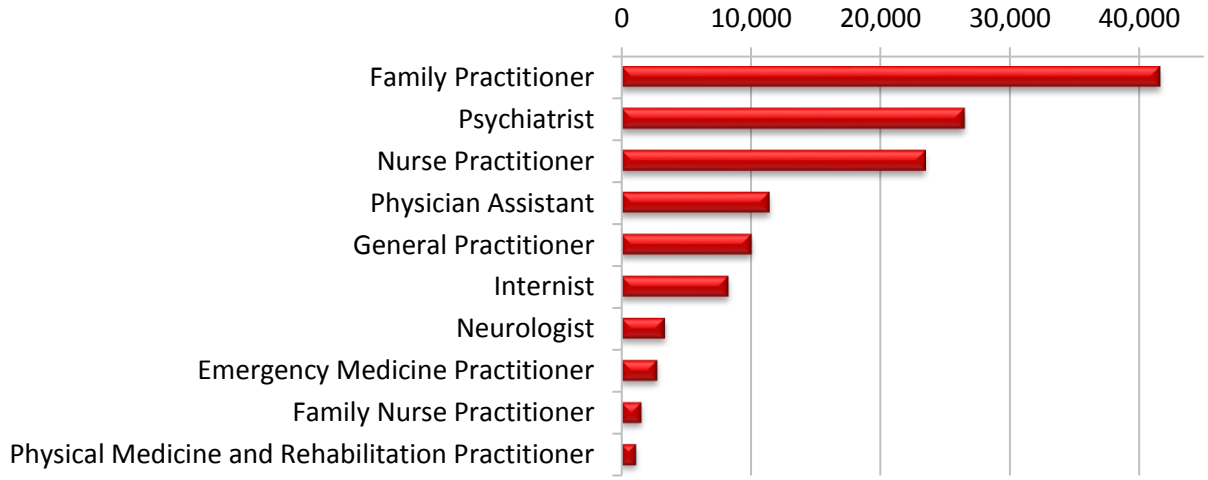
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	26,768	150,273	$850,799.54	$5.66	$0.20	9,592,092	4,205,567
2017	24,731	138,528	$1,191,073.29	$8.60	$0.31	8,709,031	3,866,093
% Change	**-7.60%**	**-7.80%**	**40.00%**	**51.90%**	**55.00%**	**-9.20%**	**-8.10%**
Change	**-2,037**	**-11,745**	**$340,273.75**	**$2.94**	**$0.11**	**-883,061**	**-339,474**

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

Demographics of Members Utilizing Benzodiazepine Medications



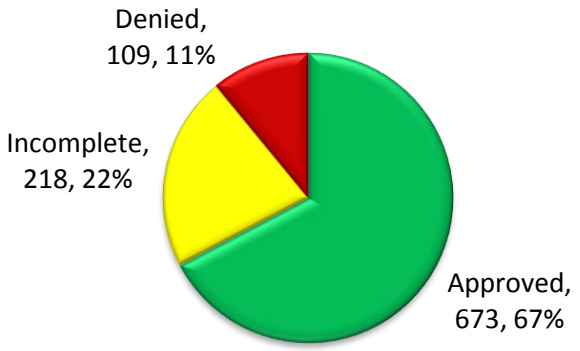
Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



Prior Authorization of Benzodiazepine Medications

There were 1,000 prior authorization request submitted for benzodiazepine medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2107.

Status of Petitions



Recommendations

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

Utilization Details of Benzodiazepine Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
ALPRAZOLAM PRODUCTS					
ALPRAZOLAM TAB 1MG	30,248	5,276	$226,888.05	5.73	$7.50
ALPRAZOLAM TAB 2MG	14,936	2,268	$130,972.74	6.59	$8.77
ALPRAZOLAM TAB 0.5MG	14,160	3,711	$102,384.24	3.82	$7.23
ALPRAZOLAM TAB 0.25MG	3,436	1,231	$23,961.71	2.79	$6.97
ALPRAZOLAM TAB 2MG ER	192	58	$3,842.88	3.31	$20.02
ALPRAZOLAM TAB 1MG ER	168	58	$2,659.89	2.9	$15.83
ALPRAZOLAM TAB 3MG ER	161	34	$3,715.09	4.74	$23.08
ALPRAZOLAM TAB 0.5MG ER	72	38	$875.38	1.89	$12.16
ALPRAZOLAM TAB 2MG XR	23	8	$529.60	2.88	$23.03
ALPRAZOLAM TAB 1MG XR	22	8	$343.18	2.75	$15.60
ALPRAZOLAM TAB 0.5MG XR	14	5	$179.96	2.8	$12.85
ALPRAZOLAM TAB 3MG XR	11	2	$247.51	5.5	$22.50
ALPRAZOLAM CON 1 MG/ML	5	3	$491.95	1.67	$98.39
ALPRAZOLAM TAB 0.5MG ODT	1	1	$17.80	1	$17.80
SUBTOTAL	**63,449**	**10.617**	**$497,109.98**	**5.98**	**$7.83**
CHLORDIAZEPOXIDE PRODUCTS					
CHLORDIAZEP CAP 25MG	277	169	$2,186.44	1.64	$7.89
CHLORDIAZEP CAP 10MG	172	66	$1,505.70	2.61	$8.75
CHLORDIAZEP CAP 5MG	50	30	$473.96	1.67	$9.48
SUBTOTAL	**499**	**250**	**$4,166.10**	**2.42**	**$8.35**
CLONAZEPAM PRODUCTS					
CLONAZEPAM TAB 1MG	18,210	3,897	$134,713.78	4.67	$7.40
CLONAZEPAM TAB 0.5MG	13,499	3,730	$94,969.97	3.62	$7.04
CLONAZEPAM TAB 2MG	5,342	1,030	$43,638.70	5.19	$8.17

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
CLONAZEP ODT TAB 0.25MG	814	264	$37,838.33	3.08	$46.48
CLONAZEP ODT TAB 0.5MG	461	138	$21,332.47	3.34	$46.27
CLONAZEP ODT TAB 0.125MG	399	130	$17,180.35	3.07	$43.06
CLONAZEP ODT TAB 1MG	215	64	$8,664.33	3.36	$40.30
CLONAZEP ODT TAB 2MG	50	16	$1,487.56	3.13	$29.75
KLONOPIN TAB 2MG	12	1	$2,866.16	12	$238.85
KLONOPIN TAB 1MG	11	1	$2,780.91	11	$252.81
SUBTOTAL	**39,013**	**7,959**	**$365,472.56**	**4.9**	**$9.37**
CHORAZEPATE PRODUCTS					
CLORAZ DIPOT TAB 7.5MG	416	77	$31,433.26	5.4	$75.56
CLORAZ DIPOT TAB 3.75MG	218	44	$14,212.39	4.95	$65.19
CLORAZ DIPOT TAB 15MG	119	20	$17,371.25	5.95	$145.98
SUBTOTAL	**753**	**121**	**$63,016.90**	**6.22**	**$83.69**
DIAZEPAM PRODUCTS					
DIAZEPAM TAB 10MG	11,629	2,684	$80,816.39	4.33	$6.95
DIAZEPAM TAB 5MG	8,191	2,552	$53,388.99	3.21	$6.52
DIAZEPAM TAB 2MG	1,306	478	$9,315.81	2.73	$7.13
DIAZEPAM SOL 1MG/ML	172	56	$4,775.73	3.07	$27.77
DIAZEPAM INJ 5MG/ML	21	8	$3,323.63	2.63	$158.27
DIAZEPAM SOL 5MG/5ML	16	2	$1,358.69	8	$84.92
DIAZEPAM CON 5MG/ML	16	4	$1,207.01	4	$75.44
SUBTOTAL	**21,351**	**5,182**	**$154,186.25**	**4.12**	**$7.22**
LORAZEPAM PRODUCTS					
LORAZEPAM TAB 1MG	6,562	2,047	$47,107.12	3.21	$7.18
LORAZEPAM TAB 0.5MG	4,650	1,590	$33,078.14	2.92	$7.11
LORAZEPAM TAB 2MG	2,020	480	$17,468.46	4.21	$8.65
LORAZEPAM CON 2MG/ML	139	42	$4,235.93	3.31	$30.47
LORAZEPAM INJ 2MG/ML	23	11	$304.45	2.09	$13.24
SUBTOTAL	**13,394**	**3,767**	**$102,194.10**	**3.56**	**$7.63**
OXAZEPAM PRODUCTS					
OXAZEPAM CAP 10MG	30	8	$1,099.24	3.75	$36.64
OXAZEPAM CAP 30MG	23	3	$2,827.50	7.67	$122.93
OXAZEPAM CAP 15MG	16	5	$1,000.66	3.2	$62.54
SUBTOTAL	**69**	**16**	**$4,927.40**	**4.31**	**$7.41**
TOTAL	**138,528**	**24,731**	**$1,191,073.29**	**5.6**	**$8.60**

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

Fiscal Year 2017 Annual Review of Benign Prostatic Hypertrophy (BPH) Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

BPH Medications Tier-2 Prior Authorization Criteria:

1. An FDA approved diagnosis; and
2. A 4-week trial of two Tier 1 medications from different pharmacological classes within 90 days; or
3. Documented adverse effect, drug interaction, or contraindication to all available Tier 1 medication(s).

BPH Medications Tier-3 Prior Authorization Criteria:

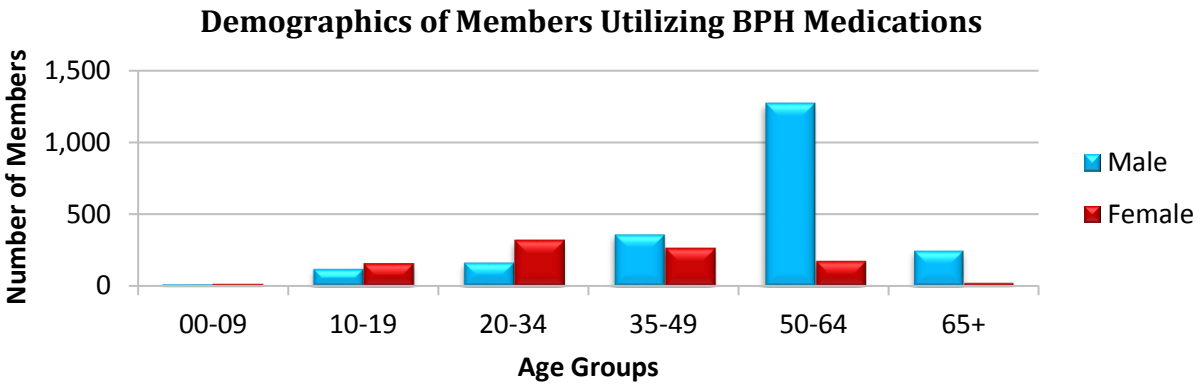
1. An FDA approved diagnosis of BPH; and
2. A trial of at least two Tier-1 medications from different pharmacological classes; and
3. A 4-week trial of each Tier-2 medication within the past 5 months; or
4. Documented adverse effect, drug interaction, contraindication, or lack of efficacy to all available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

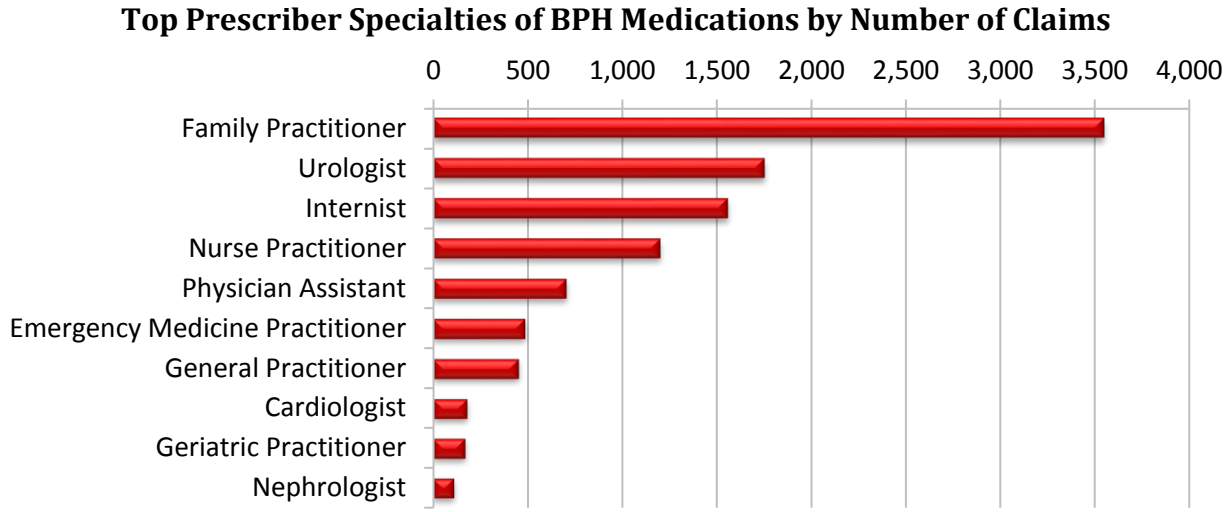
Utilization of BPH Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	2,830	9,784	$195,760.33	$20.01	$0.52	412,924	375,051
2017	3,128	10,722	$183,684.72	$17.13	$0.45	455,385	412,169
% Change	**10.50%**	**9.60%**	**-6.20%**	**-14.40%**	**-13.50%**	**10.30%**	**9.90%**
Change	**298**	**938**	**-$12,075.61**	**-$2.88**	**-$0.07**	**42,461**	**37,118**

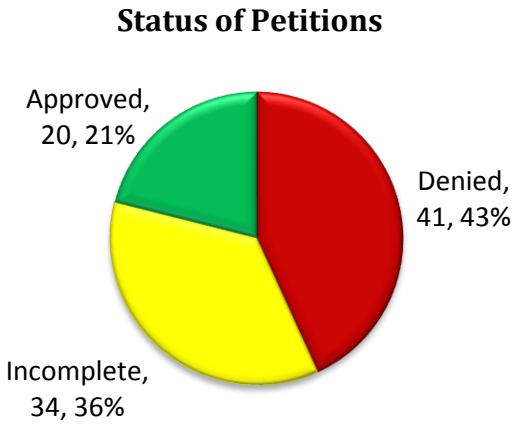
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Benign Prostatic Hypertrophy Medications

There were 95 prior authorization requests submitted for BPH medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Patent Expiration(s):[12]

- Cialis (tadalafil): November 2017
- Rapaflo® (silodosin): December 2018

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

- **March 2017:** The FDA approved the first generic for Rapaflo® (silodosin) for the treatment of the signs and symptoms of BPH.[13]

Recommendations

The College of Pharmacy recommends the following changes to the BPH medication Product Based Prior Authorization (PBPA) category:

1. Move dutasteride (Avodart®) capsules into Tier-1 based on low net cost.

The proposed changes can be seen in red in the following Tier chart:

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

Utilization Details of Benign Prostatic Hypertrophy Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
TAMSULOSIN CAP 0.4MG	7,593	2,571	$103,524.89	2.95	$13.63
FINASTERIDE TAB 5MG	806	209	$9,144.72	3.86	$11.35
DOXAZOSIN TAB 4MG	578	141	$12,048.49	4.1	$20.85
DOXAZOSIN TAB 2MG	387	107	$8,836.60	3.62	$22.83
DOXAZOSIN TAB 8MG	252	63	$5,508.14	4	$21.86
DOXAZOSIN TAB 1MG	188	66	$4,500.59	2.85	$23.94
ALFUZOSIN TAB 10MG ER	163	38	$2,142.68	4.29	$13.15
TERAZOSIN CAP 2MG	152	41	$1,306.73	3.71	$8.60
TERAZOSIN CAP 5MG	146	43	$962.08	3.4	$6.59
TERAZOSIN CAP 1MG	145	44	$965.81	3.3	$6.66

[12] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2017. Last accessed 10/16/2017.

[13] FDA: First Generic Drug Approvals. Available online at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/. Last revised 10/04/2017. Last accessed 10/16/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TERAZOSIN CAP 10MG	109	25	$896.85	4.36	$8.23
TIER-1 SUBTOTAL	**10,519**	**3,117**	**$149,837.58**	**3.37**	**$14.24**
TIER-2 UTILIZATION					
DUTASTERIDE CAP 0.5MG	85	18	$1,946.99	4.72	$22.91
RAPAFLO CAP 8MG	64	9	$15,225.78	7.11	$237.90
DUTAST/TAMSU CAP 0.5-0.4	21	2	$2,542.56	10.5	$121.07
CARDURA XL TAB 4MG	5	2	$1,979.98	2.5	$396.00
RAPAFLO CAP 4MG	1	1	$225.98	1	$225.98
TIER-2 SUBTOTAL	**176**	**32**	**$21,921.29**	**5.5**	**$124.55**
TIER-3 UTILIZATION					
CIALIS TAB 5MG	27	3	$11,925.85	9	$441.70
TIER-3 SUBTOTAL	**27**	**3**	**$11,925.85**	**9**	**$441.70**
TOTAL	**10,722**	**3,128**	**$183.684.72**	**3.43**	**$17.13**

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

Fiscal Year 2017 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Butalbital Medications Approval Criteria:

1. An FDA approved indication for the treatment of tension-type headache; and
2. Member must be 12 years of age or older; and
3. Failure within the previous 60 days of the following:
    a. All available formulations of butalbital/acetaminophen medications that do not require prior authorization (medications available without prior authorization contain butalbital/acetaminophen/caffeine in the standard 50mg-325mg-40mg dose); and
    b. At least two nonsteroidal anti-inflammatory drugs (NSAIDs), unless contraindicated.
4. Esgic® capsules (butalbital/acetaminophen/caffeine 50mg/325mg/40mg) will require prior authorization with the following criteria:
    a. A patient-specific, clinically significant reason why the member cannot use Fioricet® tablets (butalbital/acetaminophen/caffeine 50mg/325mg/40mg).

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

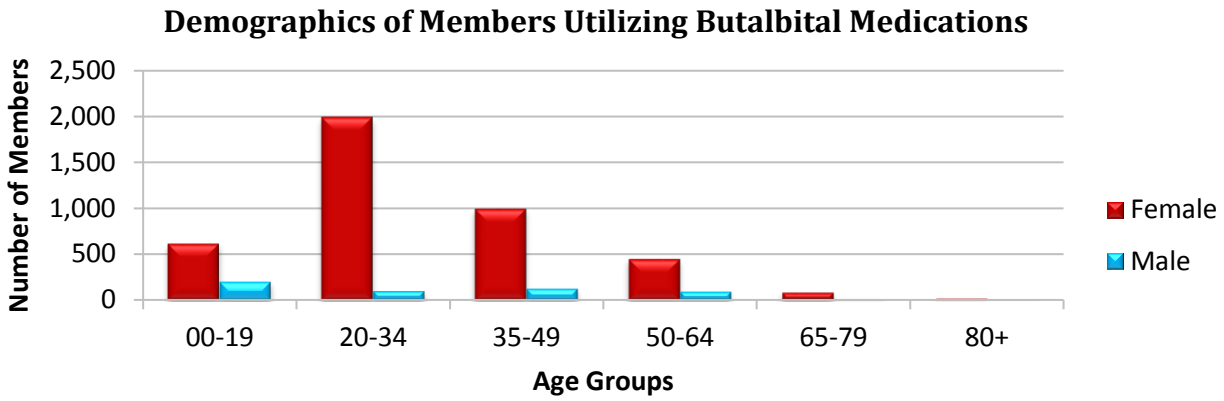
1. An FDA approved indication for the treatment of symptom complex of tension (or muscle contraction) headache; and
2. A patient-specific, clinically significant reason why a liquid formulation is needed in place of the generic tablets even when the tablets are crushed; and
3. Members with other solid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

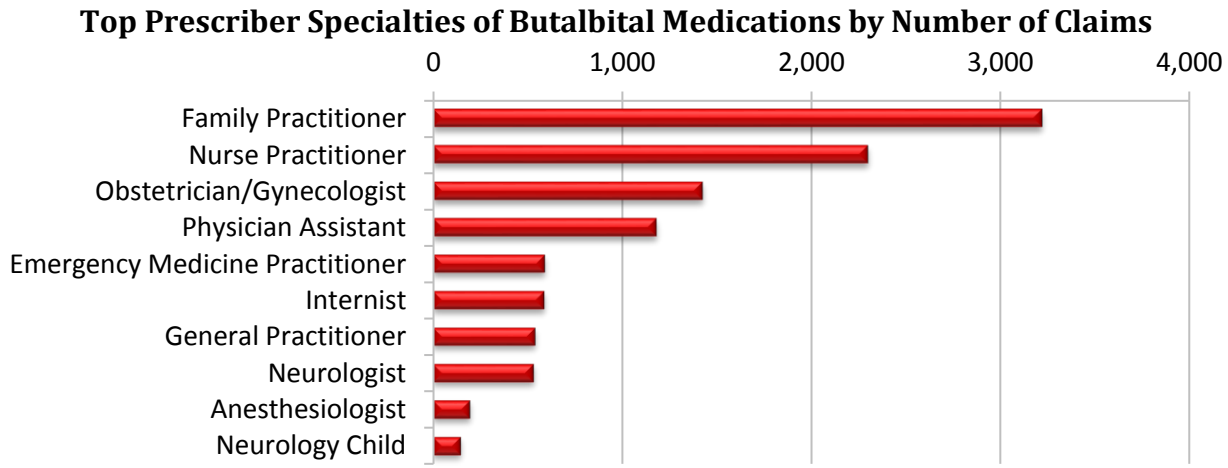
Utilization of Butalbital Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	5,022	11,770	$528,844.58	$44.93	$2.90	573,074	182,620
2017	4,683	11,363	$518,898.78	$45.67	$2.94	571,783	176,322
% Change	**-6.80%**	**-3.50%**	**-1.90%**	**1.60%**	**1.40%**	**-0.20%**	**-3.40%**
Change	**-339**	**-407**	**-$9,945.80**	**$0.74**	**$0.04**	**-1,291**	**-6,298**

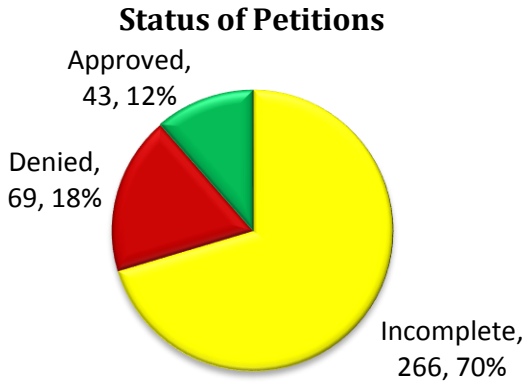
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Butalbital Medications

There were 378 prior authorizations submitted for butalbital medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Recommendations

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

Utilization Details of Butalbital Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
BUTALBITAL/APAP PRODUCTS					
BUT/APAP/CAF TAB 50-325-40MG	9,209	4,071	$313,948.60	2.26	$34.09
BUT/APAP/CAF CAP 50-325-40MG	100	69	$6,541.30	1.45	$65.41
BUT/APAP TAB 50-325MG	65	27	$5,615.38	2.41	$86.39
VANATOL LQ SOL 50-325-40MG/15ML	29	20	$52,041.71	1.45	$1,794.54
MARGESIC CAP 50-325-40MG	1	1	$47.50	1	$47.50
CAPACET CAP 50-325-40MG	1	1	$32.05	1	$32.05
SUBTOTAL	**9,405**	**4,147**	**$378,226.54**	**2.27**	**$40.22**
BUTALBITAL/APAP/CAFFEINE/CODEINE PRODUCTS					
BUT/APAP/CAF/COD CAP 50-325-40-30MG	864	305	$57,321.42	2.83	$66.34
SUBTOTAL	**864**	**305**	**$57,321.42**	**2.83**	**$66.34**
BUTALBITAL/ASA PRODUCTS					
BUT/ASA/CAFF CAP 50-325-40MG	738	343	$44,107.42	2.15	$59.77
SUBTOTAL	**738**	**343**	**$44,107.42**	**2.15**	**$59.77**
BUTALBITAL/ASA/CAFFEINE/CODEINE PRODUCTS					
BUT/ASA/CAF/ COD CAP 50-325-40-30MG	248	70	$29,455.23	3.54	$118.77
ASCOMP/COD CAP 50-325-40-30MG	108	45	$9,788.17	2.4	$90.63
SUBTOTAL	**356**	**102**	**$39,243.40**	**3.49**	**$110.23**
TOTAL	**11,363**	**4,683**	**$518,898.78**	**2.43**	**$45.67**

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

Fiscal Year 2017 Annual Review of Cholbam™ (Cholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Cholbam™ (Cholic Acid) Approval Criteria:

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

Utilization of Cholbam™ (Cholic Acid): Fiscal Year 2017

- There was no utilization or prior authorization requests for Cholbam™ (cholic acid) during fiscal year 2017.

Market News and Updates[14]

Anticipated Patent Expiration(s):

- Cholbam™ (Cholic Acid): March 2022

Recommendations

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

[14] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 08/2017. Last accessed 10/13/2017.

Fiscal Year 2017 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

Utilization of Chorionic Gonadotropin Medications: Fiscal Year 2017

There were no pharmacy or medical claims for chorionic gonadotropin medications during fiscal year 2017.

Prior Authorization of Chorionic Gonadotropin Medications

There were no prior authorization requests submitted for chorionic gonadotropin medications during fiscal year 2017.

Recommendations

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

Fiscal Year 2017 Annual Review of Daraprim® (Pyrimethamine)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Review

Introduction[15,16,17,18,19]

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

Daraprim® (pyrimethamine) was approved by the U.S. Food and Drug Administration (FDA) in 1953; however, no generic products are available. Pyrimethamine is a folic acid antagonist that is highly selective against plasmodia and *Toxoplasma gondii.* Pyrimethamine is indicated for the treatment of toxoplasmosis when used concomitantly with a sulfonamide, as synergism exists with this combination. Pyrimethamine is the only FDA approved medication for the treatment of toxoplasmosis.

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

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

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[15] Toxoplasmosis. *Mayo Clinic*. Available online at: http://www.mayoclinic.org/diseases-conditions/toxoplasmosis/basics/definition/con-20025859. Last revised 01/31/2017. Last accessed 12/20/2017.
[16] Toxoplasmosis in Patients with HIV: Basic Facts. *Infectious Disease Society of America (IDSA).* Available online at: http://www.hivma.org/uploadedFiles/HIVMA/News_Announcements/Toxo%20The%20Basics_FINAL.pdf. Last revised 09/23/2015. Last accessed 12/20/2017.
[17] Gandhi RT. Toxoplasmosis in HIV-Infected Patients. *UpToDate®*. Available online at: http://www.uptodate.com/contents/toxoplasmosis-in-hiv-infected-patients?source=machineLearning&search=toxoplasmosis&selectedTitle=1%7E150&sectionRank=1&anchor=H21#H21. Last revised 07/21/2016. Last accessed 12/20/2017.
[18] Daraprim® (Pyrimethamine) Prescribing Information. Vyera Pharmaceuticals LLC. Available online at: http://www.daraprimdirect.com/Content/downloads/DAR2017062-Portrait-201708-PI.PDF. Last revised 08/2017. Last accessed 12/20/2017.
[19] Daraprim® (Pyrimethamine) Package Insert. MedLibrary.org. Available online at: https://medlibrary.org/lib/rx/meds/daraprim-6/. Last revised 08/31/2017. Last accessed 12/20/2017.

Current Prior Authorization Criteria

Daraprim® (Pyrimethamine) Approval Criteria:

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

Utilization of Daraprim® (Pyrimethamine): Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	1	3	$17,422.91	$5,807.64	$139.38	22	125
2017	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**
Change	**-1**	**-3**	**-$17,422.91**	**-$5,807.64**	**-$139.38**	**-22**	**-125**

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

- There was no SoonerCare utilization in fiscal year 2017 of Daraprim® (pyrimethamine).

Prior Authorization of Daraprim® (Pyrimethamine)

There were no prior authorization requests submitted for Daraprim® (pyrimethamine) during fiscal year 2017.

Recommendations

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

Fiscal Year 2017 Annual Review of Diabetic Supplies

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

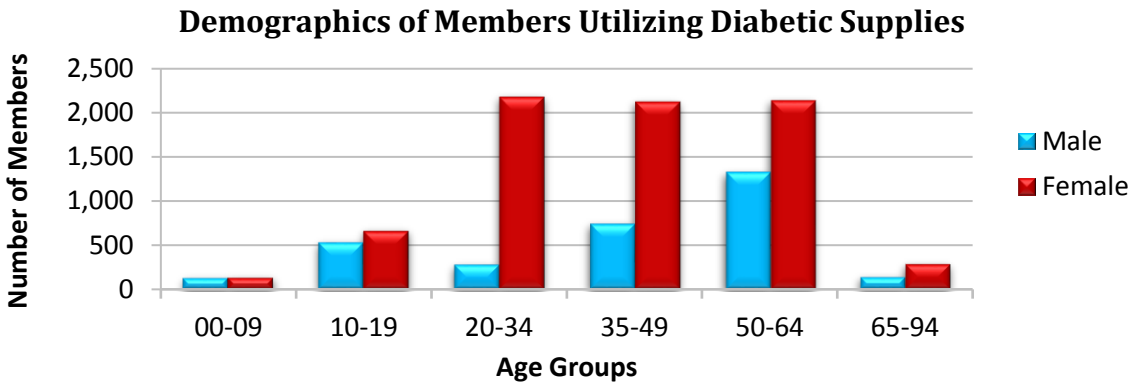
- The preferred brands for SoonerCare members are OneTouch®, FreeStyle™, and Precision™ test strips and meters. Other brands of strips and meters are not covered.
- In addition to strips and meters, lancets, syringes, pen needles, and control solution are also covered in the pharmacy claims system. Supplies for insulin pumps remain durable medical equipment (DME) claims.
- Meters are limited to one per member per year. Strips are limited to 100 strips per 30 days for members using insulin and 100 strips per 90 days for members using oral medications. Members diagnosed with gestational diabetes are limited to 150 strips per 30 days.
- Diabetic supplies are a zero copay and do not count against the monthly prescription limit.
- An automated prior authorization process looks for insulin and other diabetic medications in the member's claims history. If the medication is not found in claims history or if the quantity submitted exceeds the maximum allowed, the claim will deny for prior authorization.
- Automated refills of diabetic supplies are not allowed. Refills should be ordered by the member or the member's representative.

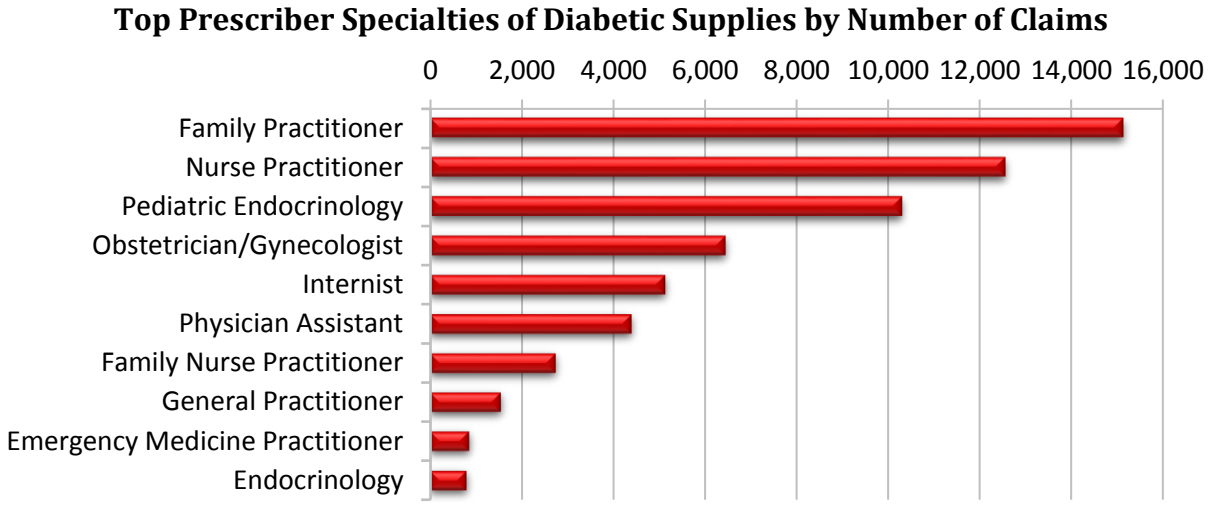
Utilization of Diabetic Supplies: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	10,506	61,285	$4,741,759.98	$77.37	$2.01	6,803,548	2,353,293
2017	10,655	62,304	$5,013,813.39	$80.47	$2.05	7,175,763	2,450,674
% Change	**1.42%**	**1.66%**	**5.74%**	**4.00%**	**1.99%**	**5.47%**	**4.14%**
Change	**149**	**1,019**	**$272,053.41**	**$3.10**	**$0.04**	**372,215**	**97,381**

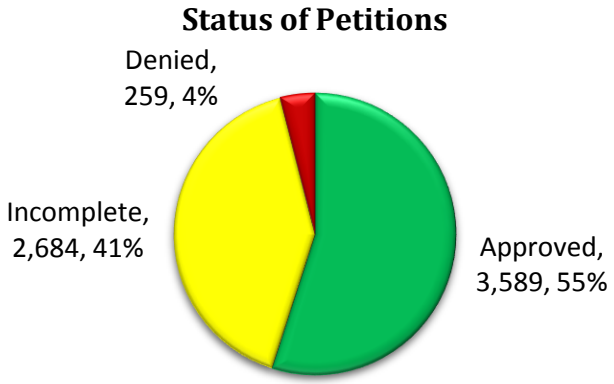
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Diabetic Supplies

There were 6,532 prior authorization requests submitted for diabetic supplies during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates[20,21]

News:

- **June 2017:** Study results from a randomized controlled trial of nearly 500 patients, presented at the American Diabetes Association (ADA) 77th Scientific Sessions, showed the use of structured self-monitoring of blood glucose (SMBG) provided significant benefits in terms of glycemic control with a mean reduction of 0.9 percentage points [95% confidence interval (CI) -1.18 to -0.62, P=<0.001] between the combined SMBG groups compared with the control group. The researchers randomized the participants to one of three groups: a control group receiving usual diabetes care, structured SMBG with clinical review every 3 months, and a structured SMBG with additional monthly telecare support. The mean hemoglobin A1c (HbA1c) for all participants at randomization was 8.6%, and among the 323 participants who attended the final visit at 12 months, mean HbA1c levels were all significantly lower than at baseline: 8.3% (P<0.01), 7.4% (P<0.001), and 7.3% (P<0.001) for groups one, two, and three, respectively. While there was not a large difference between the SMBG groups, there was evidence of the benefit of telemedicine. Telemedicine in the early phase of blood glucose monitoring appears to have a positive impact on SMBG.
- **July 2017:** *The Journal of the American Medical Association (JAMA)* published the results of a randomized clinical trial designed to determine if SMBG levels is effective for people with non-insulin-treated type 2 diabetes in terms of improving either HbA1c levels or health-related quality of life (HRQOL) in primary care practice. These results were also presented at the ADA 77th Scientific Sessions. The study included 450 patients randomized to 1 of 3 groups: no SMBG, once-daily SMBG, and once-daily SMBG with enhanced patient feedback (automatic tailored messages delivered via the meter). There were no significant differences in glycemic control across all groups, nor were there significant differences found in HRQOL.

Recommendations

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

Utilization Details of Diabetic Supplies: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
DIABETIC TEST STRIPS						
FREESTYLE TES LITE	13,097	4,311	$2,550,814.89	$5.05	$194.76	421.11
ONETOUCH TES ULTRA BL	11,154	3,779	$1,460,923.53	$3.15	$130.98	320.79
CONTOUR TES NEXT	1,822	408	$122,177.90	$2.11	$67.06	730.88

[20] Bachert A. ADA: SMBG May Tighten Glycemic Control in Type 2 Diabetes. *MedPage Today*. Available online at: https://www.medpagetoday.com/mastery-of-medicine/mastery-in-diabetes-management/65937. Issued 06/11/2017. Last accessed 11/14/2017.

[21] Young LA, Buse JB, Weaver MA, et al. Glucose Self-monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings. *JAMA Intern Med*. 2017; 177(7):920-929.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
FREESTYLE TES INSULINX	592	196	$127,033.96	$5.97	$214.58	437.24
FREESTYLE TES	488	199	$85,531.23	$4.86	$175.27	303.77
PRECISION TES XTRA	190	76	$27,359.91	$3.71	$144.00	250.66
ONETOUCH TES VERIO	160	95	$19,463.73	$3.66	$121.65	201.32
EASYMAX TES	18	6	$580.77	$0.51	$32.27	358.33
PRODIGY NO TES CODING	6	3	$134.33	$0.57	$22.39	116.67
FREESTYLE TES INSULINX	234	90	$49,128.21	$6.14	$209.95	368.89
FREESTYLE TES LITE	3	2	$53.64	$0.54	$17.88	125.00
SUBTOTAL	**27,764**	**9,165**	**$4,443,202.10**	**$4.08**	**$160.03**	**386.92**
GLUCOMETERS						
FREESTYLE MIS LITE	1,712	1,669	$25,432.34	$0.43	$14.86	1.03
ONETOUCH KIT ULTRA 2	1,245	1,227	$18,399.58	$0.39	$14.78	1.01
ONETOUCH KIT ULT MINI	670	661	$9,925.68	$0.44	$14.81	1.01
FREESTYLE KIT FREEDOM	258	253	$3,834.00	$0.44	$14.86	1.02
FREESTYLE KIT INSULINX	54	53	$2,023.90	$1.03	$37.48	1.02
PRECISION MIS XTRA	38	38	$566.00	$0.50	$14.89	1.00
ONETOUCH KIT VERIO	13	13	$190.93	$0.33	$14.69	1.00
ONETOUCH KIT VERIO FL	9	8	$135.00	$0.50	$15.00	1.13
ONETOUCH KIT VERIO IQ	8	8	$183.75	$0.77	$22.97	1.00
FREESTYLE KIT FREEDOM	258	253	$3,834.00	$0.44	$14.86	1.02
FREESTYLE KIT INSULINX	54	53	$2,023.90	$1.03	$37.48	1.02
SUBTOTAL	**4,319**	**4,236**	**$66,549.08**	**$0.44**	**$15.41**	**1.02**
LANCETS & LANCING DEVICES						
FREESTYLE MIS LANCETS	4,675	2,350	$9,344.49	$0.05	$2.00	261.87
ONETOUCH MIS LANCETS	1,903	1,046	$3,231.48	$0.04	$1.70	206.56
ONETOUCH MIS 30G	731	491	$1,158.83	$0.03	$1.59	161.10
EASY TOUCH MIS LANC/30G	583	216	$953.55	$0.04	$1.64	288.89
EASY TOUCH MIS LANC/32G	420	231	$677.12	$0.03	$1.61	192.60
TRUPLUS LANC MIS 33G	399	237	$668.40	$0.03	$1.68	188.82
ONETOUCH US MIS LANCETS	319	190	$634.70	$0.04	$1.99	220.79
MICROLET MIS LANCETS	271	127	$587.08	$0.06	$2.17	313.39
EASY TOUCH MIS LANC/33G	266	138	$414.54	$0.03	$1.56	197.83
TRUPLUS LANC MIS 28G	251	147	$419.54	$0.03	$1.67	188.10
TRUPLUS LANC MIS 30G	247	151	$417.06	$0.03	$1.69	182.78
EASY TOUCH MIS	227	226	$512.83	$0.05	$2.26	1.44
FASTCLIX MIS LANCETS	123	37	$287.91	$0.09	$2.34	512.14
LANCET ULTRA MIS THIN 30G	86	48	$141.63	$0.04	$1.65	189.58
SURE COMFORT MIS LANCETS	81	39	$193.91	$0.06	$2.39	325.64
EASY TOUCH MIS LANC/28G	66	34	$119.42	$0.03	$1.81	226.47
BAYER MICRLT MIS LANCETS	65	39	$156.34	$0.07	$2.41	261.56
LANCETS ULTR MIS THIN	61	35	$104.34	$0.04	$1.71	191.43
COMFORTOUCH MIS LANCET	48	13	$94.40	$0.04	$1.97	461.54
GNP LANCETS MIS 21G	43	19	$71.95	$0.04	$1.67	236.84

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
EMBRACE LANC MIS THIN 30G	34	17	$54.30	$0.03	$1.60	205.88
TECHLITE MIS LANCETS	25	11	$57.60	$0.04	$2.30	336.36
PRODIGY MIS 28G	24	17	$37.99	$0.03	$1.58	141.18
BD LANCET UF MIS 33G	22	7	$41.62	$0.07	$1.89	385.71
ULTRA THIN MIS 31G	19	11	$29.28	$0.05	$1.54	172.73
UNILET GP 28 MIS ULT THIN	18	7	$35.38	$0.05	$1.97	314.29
THIN LANCETS MIS 30G	18	13	$30.93	$0.03	$1.72	153.85
SURE COMFORT MIS LANC PEN	18	18	$40.84	$0.09	$2.27	1.00
LANCETS MIS 28G	16	11	$34.24	$0.05	$2.14	210.91
ACCU-CHEK MIS MLTICLIX	14	10	$30.03	$0.07	$2.15	193.60
LANCETS MIS 33G	13	8	$20.57	$0.05	$1.58	175.00
LANCETS MIS	13	10	$19.84	$0.04	$1.53	130.00
TRUPLUS LANC MIS 26G	12	5	$27.23	$0.06	$2.27	360.00
BD LANCET UF MIS 30G	10	4	$18.42	$0.05	$1.84	300.00
ASSURE CMFRT MIS 30G	10	9	$17.23	$0.05	$1.72	122.22
ONETOUCH MIS LANC DEV	9	9	$17.76	$0.06	$1.97	1.00
PRODIGY MIS LANC DEV	9	8	$21.88	$0.10	$2.43	1.13
LANCING DEVI MIS	8	8	$18.96	$0.06	$2.37	1.00
UNILET EX II MIS 28G	7	4	$15.12	$0.05	$2.16	250.00
ULTRA THIN MIS LANC 30G	7	3	$11.09	$0.05	$1.58	233.33
GNP LANCETS MIS	7	2	$11.55	$0.07	$1.65	350.00
SIMPLE DIAG MIS LANCING	5	5	$11.80	$0.04	$2.36	1.00
GNP LANCETS MIS THIN 26G	5	3	$5.91	$0.03	$1.18	200.00
LANCETS MIS 23G	4	2	$11.55	$0.10	$2.89	350.00
LANCETS MIS 30G	3	3	$6.37	$0.04	$2.12	133.33
LANCETS THIN MIS	3	3	$6.60	$0.04	$2.20	133.33
ACCU-CHEK KIT FASTCLIX	3	3	$10.08	$3.36	$3.36	1.33
LANCET STAND MIS 21G	3	2	$4.95	$0.04	$1.65	150.00
EASY TOUCH MIS LANC/26G	3	1	$4.95	$0.05	$1.65	300.00
SOFTCLIX MIS LANCETS	3	3	$4.72	$0.06	$1.57	100.00
ULTILET MIS 30G	3	1	$4.26	$0.05	$1.42	300.00
RELION KIT LANCING	2	2	$4.64	$0.06	$2.32	1.00
AUTOLET LANC MIS DEVICE	2	2	$4.64	$2.32	$2.32	1.00
SM LANCETS MIS 33G	2	1	$6.60	$0.11	$3.30	400.00
GLOBAL 28G MIS LANCETS	2	1	$2.84	$0.05	$1.42	200.00
GLOBAL 30G MIS LANCETS	2	2	$2.84	$0.02	$1.42	100.00
RELION LANCE MIS THIN 30G	2	2	$2.84	$0.06	$1.42	100.00
ULTRA THIN MIS LANC 28G	2	2	$3.30	$0.06	$1.65	100.00
CVS LANCETS MIS THIN 33G	2	1	$3.30	$0.07	$1.65	200.00
FINGERSTIX MIS LANCETS	1	1	$3.30	$0.11	$3.30	200.00
CVS LANCING MIS DEVICE	1	1	$2.52	$2.52	$2.52	1.00
BAYER MICRLT MIS LANC DVC	1	1	$2.52	$2.52	$2.52	1.00
LANCET MICRO MIS THIN 33G	1	1	$1.42	$0.01	$1.42	100.00

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
SM LANCETS MIS THIN 30G	1	1	$1.42	$0.04	$1.42	100.00
E-Z JECT MIS THIN 26G	1	1	$1.65	$0.06	$1.65	100.00
GNP LANCETS MIS SUP THIN	1	1	$1.65	$0.02	$1.65	100.00
COMFORT MIS LANCETS	1	1	$1.65	$0.05	$1.65	100.00
UNISTIK 2 MIS NORMAL	1	1	$10.52	$0.12	$10.52	100.00
GNP LANCETS MIS MICRO	1	1	$1.42	$0.03	$1.42	100.00
CVS LANCETS MIS 30G	1	1	$3.30	$0.11	$3.30	200.00
SUBTOTAL	**11,240**	**6,056**	**$20,914.94**	**$0.04**	**$1.86**	**221.33**
PEN NEEDLES						
BD PEN NEEDL MIS 32GX4MM	3,121	1,016	$118,991.77	$1.10	$38.13	473.56
BD PEN NEEDL MIS 31GX3/16	1,622	667	$52,727.87	$0.84	$32.51	309.34
BD PEN NEEDL MIS 31GX5/16	1,175	542	$35,576.51	$0.74	$30.28	255.52
NOVOFINE MIS 32GX6MM	490	196	$16,733.49	$0.96	$34.15	350.00
PEN NEEDLES MIS 32GX4MM	423	171	$10,071.83	$0.67	$23.81	337.78
PEN NEEDLES MIS 31GX8MM	409	179	$7,234.67	$0.45	$17.69	237.15
PEN NEEDLES MIS 31GX6MM	407	188	$6,890.88	$0.39	$16.93	219.31
UNFINE PNTP MIS 32GX4MM	367	130	$6,402.97	$0.47	$17.45	372.31
EASY TOUCH MIS 31GX3/16	351	113	$5,410.11	$0.42	$15.41	384.96
RELION PEN MIS 32GX4MM	323	152	$5,833.80	$0.49	$18.06	216.12
RELION PEN MIS 31GX8MM	290	117	$4,832.96	$0.40	$16.67	233.76
UNIFINE PNTP MIS 31GX8MM	255	97	$3,760.65	$0.35	$14.75	270.52
EASY TOUCH MIS 31GX5/16	238	98	$3,312.40	$0.35	$13.92	254.39
COMFORT EZ MIS 32GX4MM	226	51	$10,307.92	$1.45	$45.61	784.31
RELION PEN MIS 31GX6MM	209	89	$3,406.20	$0.37	$16.30	213.37
SURE COMFORT MIS 31GX5/16	189	67	$5,466.15	$0.66	$28.92	316.42
UNIFINE PNTP MIS 31GX3/16	189	74	$3,098.61	$0.42	$16.39	289.59
NOVOFINE PLS MIS 32GX4MM	175	68	$6,171.23	$0.86	$35.26	361.91
UNIFINE PNTP MIS 31GX6MM	167	79	$2,632.60	$0.37	$15.76	233.80
SURE COMFORT MIS 31GX3/16	161	64	$4,674.79	$0.80	$29.04	285.94
NOVOTWIST MIS 32GX5MM	158	53	$7,271.95	$1.38	$46.03	533.96
EASY TOUCH MIS 32GX5MM	142	55	$2,603.70	$0.56	$18.34	357.45
COMFORT EZ MIS 31GX6MM	136	25	$5,590.00	$1.29	$41.10	860.00
NOVOFINE MIS 30GX8MM	135	60	$3,630.65	$0.60	$26.89	240.83
EASY TOUCH MIS 31GX1/4"	134	57	$2,115.74	$0.43	$15.79	280.53
SURE COMFORT MIS 32GX5/32	128	44	$4,750.89	$1.11	$37.12	434.09
COMFORT EZ MIS 31GX8MM	124	32	$4,464.00	$1.28	$36.00	537.50
COMFORT EZ MIS 31GX5MM	123	34	$4,808.42	$1.17	$39.09	550.00
BD PEN NEEDL MIS 29GX1/2"	110	50	$3,097.95	$0.69	$28.16	242.00
EASY TOUCH MIS 32GX6MM	75	33	$1,355.16	$0.45	$18.07	251.21
PEN NEEDLES MIS 31GX3/16	64	28	$2,042.00	$0.74	$31.91	282.14
PEN NEEDLES MIS 31GX5/16	64	33	$1,500.14	$0.54	$23.44	227.27
PEN NEEDLES MIS 31GX1/4"	59	22	$1,013.72	$0.47	$17.18	301.36
UNIFINE PNTP MIS 31GX5MM	57	18	$961.36	$0.40	$16.87	361.11

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
PEN NEEDLES MIS 31GX5MM	56	23	$2,046.50	$1.08	$36.54	386.96
RELION PEN MIS 29GX12MM	37	12	$621.00	$0.43	$16.78	287.50
CLICKFINE MIS 31GX1/4"	34	10	$815.33	$0.78	$23.98	350.00
UNIFINE PNTP MIS 29GX12MM	33	14	$483.70	$0.31	$14.66	241.43
PEN NEEDLES MIS 29GX12MM	31	17	$525.10	$0.51	$16.94	170.59
UNIFINE PNTP MIS 32GX4MM	24	10	$589.18	$0.74	$24.55	380.00
NOVOFINE AUT MIS 30GX8MM	24	8	$644.80	$0.42	$26.87	310.00
AUTOSHIELD MIS 30GX3/16	22	4	$572.00	$0.97	$26.00	550.00
INSUPEN ULTR MIS 31GX6MM	21	11	$487.79	$0.63	$23.23	227.27
SURE COMFORT MIS 32GX6MM	21	11	$756.80	$1.22	$36.04	272.73
SURE COMFORT MIS 30GX5/16	19	8	$618.98	$0.74	$32.58	300.00
UNIFINE PNTP MIS 32GX5/32	13	8	$452.29	$0.81	$34.79	250.00
INSUPEN SENS MIS 32GX6MM	12	3	$390.00	$0.94	$32.50	500.00
UNIFINE PNTP MIS 31GX5/16	11	2	$276.01	$0.50	$25.09	550.00
PEN NEEDLE MIS 29GX1/2"	10	5	$260.00	$0.75	$26.00	200.00
PEN NEEDLES MIS 29GX12.7	8	3	$107.72	$0.32	$13.47	266.67
PEN NEEDLES MIS 29GX1/2"	7	3	$99.47	$0.54	$14.21	213.33
SURE COMFORT MIS 29GX1/2"	7	7	$169.29	$0.50	$24.18	100.00
CLICKFINE MIS 31GX5/16	6	4	$129.67	$0.59	$21.61	150.00
INSUPEN MIS 32GX4MM	5	2	$166.50	$1.11	$33.30	450.00
INSUPEN ULTR MIS 30GX8MM	3	2	$78.00	$0.86	$26.00	150.00
PENTIPS MIS 31GX5MM	2	1	$49.40	$0.75	$24.70	400.00
PENTIPS MIS 32GX4MM	2	2	$24.70	$0.21	$12.35	100.00
INSUPEN ULTR MIS 31GX8MM	1	1	$19.50	$0.22	$19.50	100.00
EASY COMFORT MIS 31GX1/4"	1	1	$26.00	$0.52	$26.00	100.00
NOVOTWIST MIS 30GX8MM	1	1	$26.00	$0.52	$26.00	100.00
EASY TOUCH MIS 29GX1/2"	1	1	$13.72	$0.55	$13.72	100.00
SUBTOTAL	**12,708**	**4,876**	**$369,192.54**	**$0.77**	**$29.05**	**339.45**
INSULIN SYRINGES						
INSULIN SYRG MIS 1ML/31G	1,094	378	$22,695.34	$0.56	$20.75	317.30
INSULIN SYRG MIS 0.5/31G	961	357	$18,188.53	$0.51	$18.93	282.32
INSULIN SYRG MIS 0.3/31G	730	316	$15,431.32	$0.52	$21.14	262.41
INSULIN SYRG MIS 1ML/30G	411	149	$7,168.20	$0.45	$17.44	295.44
INSULIN SYRG MIS 0.5/30G	345	113	$5,588.61	$0.45	$16.20	338.58
INSULIN SYRG MIS 1ML/30G	222	69	$5,247.60	$0.77	$23.64	348.41
INSULIN SYRG MIS 1ML/29G	218	96	$3,807.96	$0.46	$17.47	237.92
INSULIN SYRG MIS 0.3/31G	176	81	$5,403.15	$0.68	$30.70	263.95
INSULIN SYRG MIS 0.5/30G	166	67	$3,965.42	$0.61	$23.89	259.70
INSULIN SYRG MIS 0.5/31G	153	61	$4,416.34	$0.72	$28.86	279.84
INSULIN SYRG MIS 0.5/29G	111	58	$1,836.41	$0.42	$16.54	195.34
INSULIN SYRG MIS 1ML/31G	108	50	$2,984.67	$0.74	$27.64	245.60
INSULIN SYRG MIS 0.3/30G	96	46	$1,558.76	$0.44	$16.24	210.00
INSULIN SYRG MIS 0.3/29G	50	27	$830.04	$0.46	$16.60	183.33

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	UNITS/ MEMBER
INSULIN SYRG MIS 0.3/30G	34	19	$732.00	$0.45	$21.53	181.05
INSULIN SYRG MIS 1ML/28G	27	7	$613.76	$0.59	$22.73	408.57
INSULIN SYRG MIS 0.5/28G	12	6	$245.14	$0.69	$20.43	186.67
INSULIN SYR MIS 0.3/31G	7	7	$100.64	$0.28	$14.38	114.29
INSULIN SYRG MIS 28GX1/2"	7	3	$62.37	$0.16	$8.91	233.33
INSULIN SYRG MIS 1ML/25G	2	2	$52.27	$0.83	$26.14	110.00
INSULIN SYRG MIS 1ML/27G	2	2	$45.64	$0.35	$22.82	95.00
INSULIN SYRG MIS 1ML/25G	1	1	$26.00	$0.26	$26.00	100.00
SUBTOTAL	**4,933**	**1,915**	**$101,000.17**	**$0.54**	**$20.47**	**280.06**
GLUCOMETER CONTROL SOLUTION						
ONETOUCH SOL ULT CONT	41	39	$223.99	$0.17	$5.46	2.13
FREESTYLE LIQ CONTROL	11	11	$46.07	$0.14	$4.19	1.64
SUBTOTAL	**52**	**50**	**$270.06**	**$0.16**	**$5.19**	**2.02**
KETONE STRIPS						
KETOSTIX TES STRIP	997	448	$8,689.37	$0.27	$8.72	166.23
KETOCARE TEST	239	128	$1,887.61	$0.25	$7.90	132.42
PRECISN XTRA TES KETONE	32	12	$1,924.93	$4.23	$60.15	31.67
KETONE TEST	18	15	$159.03	$0.26	$8.84	90.00
RELION TEST KETONE	2	2	$23.56	$0.51	$11.78	100.00
SUBTOTAL	**1,288**	**605**	**$12,684.50**	**$0.31**	**$9.85**	**154.30**
TOTAL	**62,304**	**10,655***	**$5,013,813.39**	**$2.05**	**$80.47**	**266.73**

*Total number of unduplicated members.

Fiscal Year 2017 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Review

Current Prior Authorization Criteria

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

*Tier-2 will include supplemental rebated medications. If no medications rebate to Tier-2, Tier-2 will include the lowest net cost Tier-3 product(s).
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Fibromyalgia Medications Tier-2 Approval Criteria:

1. A documented, recent (within the last six months) trial of two Tier-1 medications (must include one trial with duloxetine) at least three weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication.
4. Clinical Exceptions include:
    a. Diagnosis of seizures or postherpetic neuralgia for Lyrica® (pregabalin).

Fibromyalgia Medications Tier-3 Approval Criteria:

1. A documented, recent (within the last six months) trial of two Tier-1 medications (must include one trial with duloxetine) and all available Tier-2 medications at least three weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-3 medication.

Lyrica® (Pregabalin) Approval Criteria [Diabetic Neuropathy Diagnosis]:

1. For the diagnosis of diabetic neuropathy, a trial of duloxetine and a trial of gabapentin at least three weeks in duration or a patient-specific, clinically significant reason why duloxetine or gabapentin cannot be used must be provided.
2. Clinical exceptions for Lyrica® (pregabalin) include:
    a. Diagnosis of seizures or postherpetic neuralgia.

Utilization of Fibromyalgia Medications: Fiscal Year 2017

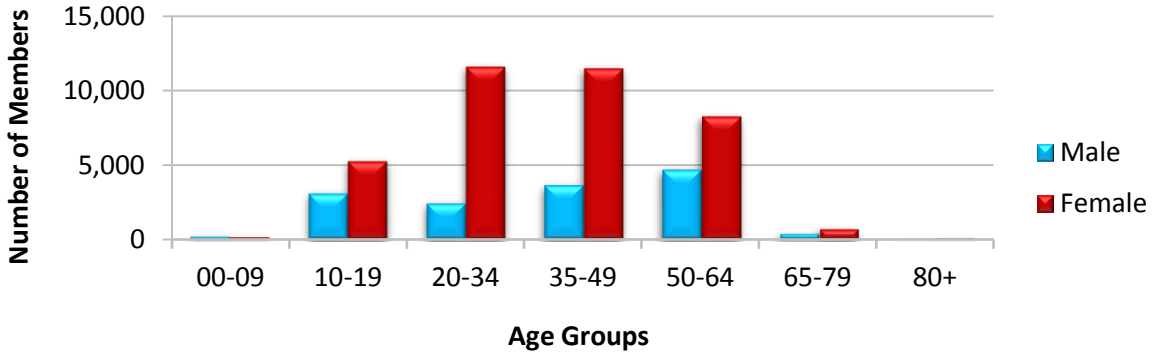
The following utilization data includes fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years for Fibromyalgia Medications

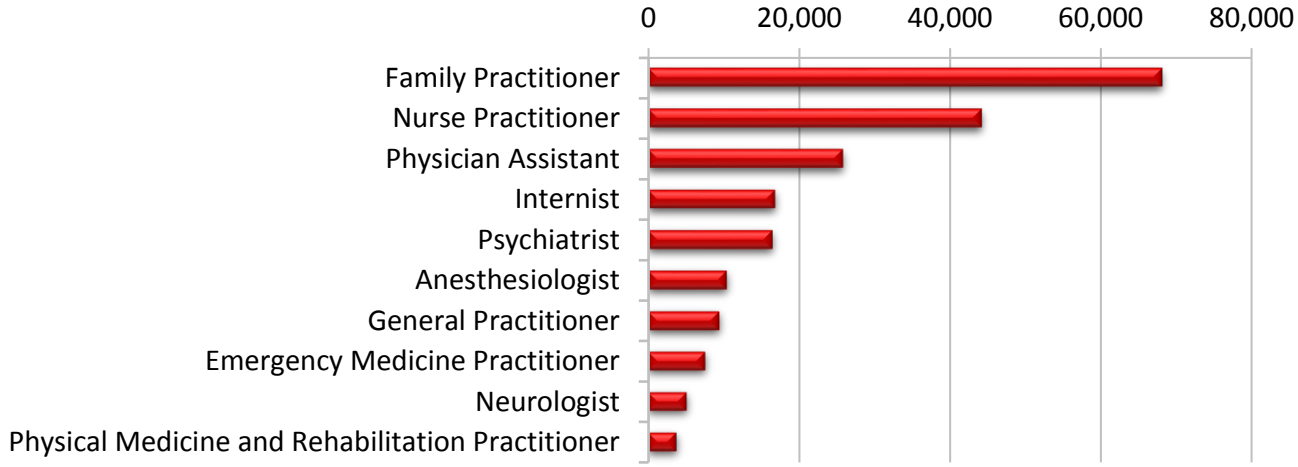
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	52,357	223,442	$7,402,581.40	$33.13	$1.20	16,400,050	6,179,538
2017	51,734	230,571	$7,213,411.25	$31.28	$1.11	17,215,742	6,499,960
% Change	**-1.20%**	**3.20%**	**-2.60%**	**-5.60%**	**-7.50%**	**5.00%**	**5.20%**
Change	**-623**	**7,129**	**-$189,170.15**	**-$1.85**	**-$0.09**	**815,692**	**320,422**

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

Demographics of Members Utilizing Fibromyalgia Medications



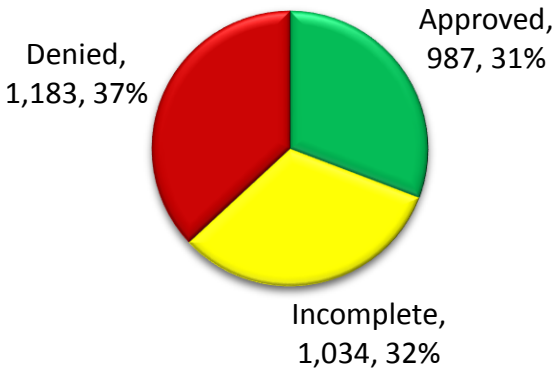
Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims



Prior Authorization of Fibromyalgia Medications

There were 3,204 prior authorization requests submitted for fibromyalgia medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):

- Lyrica® (pregabalin): December 2018[22]

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

- **April 2016:** The FDA approved an Abbreviated New Drug Application (ANDA) for the first generic version of Savella® (milnacipran) for the treatment of fibromyalgia. Four additional pharmaceutical companies have submitted ANDAs to market generic milnacipran and are awaiting approval from the FDA. The anticipated release date and cost information for generic milnacipran are not currently available.[23]
- **October 2017:** The FDA approved a New Drug Application (NDA) for Lyrica® CR (pregabalin extended-release tablets) as once-daily therapy for the management of neuropathic pain associated with diabetic peripheral neuropathy and the management of postherpetic neuralgia. Lyrica® CR did not receive FDA approval for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures. A full review of Lyrica® CR will be completed within the annual review of special formulations. [24,25]

Recommendations

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

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[22]U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2017. Last accessed 12/27/2017.

[23] FDA. ANDA Approval: Milnacipran Oral Tablets. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205081. Issued 04/22/2016. Last accessed 12/27/2017.

[24] FDA. NDA Approval: Lyrica® CR (Pregabalin Extended-Release Oral Tablets). Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209501. Issued 10/11/2017. Last accessed 12/27/2017.

[25] Pfizer News Release: U.S. FDA Approves Lyrica® CR (Pregabalin) Extended-Release Tablets CV. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_approves_lyrica_cr_pregabalin_extended_release_tablets_cv. Issued 10/12/2017. Last accessed 12/27/2017.

Utilization Details of Fibromyalgia Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ DAY	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	36,391	11,134	$374,733.72	$10.30	$0.31	5.19%
GABAPENTIN TAB 600MG	23,220	4,974	$459,374.97	$19.78	$0.64	6.37%
GABAPENTIN TAB 800MG	14,891	2,641	$340,297.29	$22.85	$0.76	4.72%
GABAPENTIN CAP 100MG	9,194	3,605	$79,054.57	$8.60	$0.29	1.10%
GABAPENTIN CAP 400MG	5,733	1,651	$69,347.35	$12.10	$0.40	0.96%
GABAPENTIN SOL 250/5ML	674	132	$38,873.20	$57.68	$1.93	0.54%
NEURONTIN CAP 300MG	12	1	$4,610.17	$384.18	$12.81	0.06%
NEURONTIN TAB 800MG	12	1	$10,557.59	$879.80	$29.33	0.15%
GABAPENTIN SOL 300/6ML	2	2	$145.82	$72.91	$2.43	0.00%
SUBTOTAL	**90,129**	**24,141**	**$1,376,994.68**	**$15.28**	**$0.49**	**19.09%**
TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	44,135	17,393	$342,092.55	$7.75	$0.40	4.74%
TRAMADOL HCL TAB 200MG	5	1	$438.24	$87.65	$2.92	0.01%
TRAMADOL HCL TAB 100MG	4	2	$260.84	$65.21	$2.17	0.00%
SUBTOTAL	**44,144**	**17,396**	**$342,791.63**	**$7.77**	**$0.40**	**4.75%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPR TAB 10MG	33,628	15,808	$232,320.76	$6.91	$0.30	3.22%
CYCLOBENZAPR TAB 5MG	6,696	4,378	$51,074.27	$7.63	$0.40	0.71%
SUBTOTAL	**40,324**	**20,186**	**$283,395.03**	**$7.03**	**$0.31**	**3.93%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	17,554	4,325	$394,408.14	$22.47	$0.63	5.47%
DULOXETINE CAP 30MG	8,583	3,367	$185,595.29	$21.62	$0.65	2.57%
DULOXETINE CAP 20MG	1,378	599	$37,997.29	$27.57	$0.86	0.53%
CYMBALTA CAP 60MG	9	2	$4,011.67	$445.74	$14.86	0.06%
DULOXETINE CAP 40MG	4	2	$411.97	$102.99	$3.43	0.01%
SUBTOTAL	**27,528**	**8,295**	**$622,424.36**	**$22.61**	**$0.65**	**8.63%**
AMITRIPTYLINE PRODUCTS						
AMITRIPTYLIN TAB 25MG	6,096	2,340	$76,855.89	$12.61	$0.37	1.07%
AMITRIPTYLIN TAB 50MG	4,463	1,462	$92,265.69	$20.67	$0.58	1.28%
AMITRIPTYLIN TAB 10MG	3,474	1,342	$37,439.73	$10.78	$0.33	0.52%
AMITRIPTYLIN TAB 100MG	2,606	634	$104,272.62	$40.01	$1.08	1.45%
AMITRIPTYLIN TAB 150MG	1,022	231	$66,975.18	$65.53	$1.65	0.93%
AMITRIPTYLIN TAB 75MG	883	248	$27,661.57	$31.33	$0.80	0.38%
SUBTOTAL	**18,544**	**6,257**	**$405,470.68**	**$21.87**	**$0.62**	**5.62%**
PREGABALIN PRODUCTS						
LYRICA CAP 150MG	3,089	540	$1,323,406.22	$428.43	$14.51	18.35%
LYRICA CAP 100MG	1,808	350	$831,636.53	$459.98	$15.31	11.53%
LYRICA CAP 75MG	1,637	400	$698,412.34	$426.64	$14.15	9.68%
LYRICA CAP 300MG	1,060	158	$409,625.29	$386.44	$12.87	5.68%
LYRICA CAP 200MG	856	130	$333,170.91	$389.22	$13.17	4.62%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ DAY	% COST
LYRICA CAP 50MG	751	223	$325,528.72	$433.46	$14.53	4.51%
LYRICA CAP 225MG	325	53	$143,822.17	$442.53	$14.75	1.99%
LYRICA CAP 25MG	83	28	$31,983.21	$385.34	$13.13	0.44%
LYRICA SOL 20MG/ML	2	1	$805.95	$402.98	$13.43	0.01%
SUBTOTAL	**9,611**	**1,883**	**$4,098,391.34**	**$426.43**	**$14.30**	**56.82%**
MILNACIPRAN PRODUCTS						
SAVELLA TAB 100MG	123	22	$38,158.96	$310.24	$10.35	0.53%
SAVELLA TAB 50MG	104	37	$29,685.67	$285.44	$9.67	0.41%
SAVELLA MIS TITR PAK	27	26	$7,596.25	$281.34	$9.80	0.11%
SAVELLA TAB 25MG	22	14	$6,072.48	$276.02	$9.59	0.08%
SAVELLA TAB 12.5MG	15	10	$2,430.17	$162.01	$10.39	0.03%
SUBTOTAL	**291**	**109**	**$83,943.53**	**$288.47**	**$9.99**	**1.16%**
TOTAL	**230,571**	**51,734***	**$7,213,411.25**	**$31.28**	**$1.11**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
The utilization details above include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Fiscal Year 2017 Annual Review of Gattex® (Teduglutide)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Gattex® (Teduglutide) Approval Criteria:

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

Utilization of Gattex® (Teduglutide): Fiscal Year 2017

There was no utilization of Gattex® during fiscal year 2017.

Prior Authorization of Gattex® (Teduglutide)

There was one prior authorization request submitted for Gattex® (teduglutide) during fiscal year 2017. The status of the submitted prior authorization was denied.

Market News and Updates

Anticipated Patent Expiration(s):

- Gattex® (teduglutide): November 2025[26]

Other News:

- **February 2017:** Outcomes from a 12-week, open-label, multicenter clinical trial of teduglutide in pediatric short bowel syndrome (SBS) were published in *The Journal of Pediatrics*. Patients 1 to 17 years of age with intestinal failure associated with short bowel syndrome (SBS-IF) who required parenteral nutrition (PN) and showed minimal or no advance in enteral nutrition (EN) feeds were enrolled in the study. Patients were sequentially enrolled into three teduglutide cohorts (0.0125mg/kg/day, 0.025mg/kg/day, 0.05mg/kg/day) or received standard of care (SOC). All patients enrolled in the study experienced one or more treatment-emergent adverse events and

[26] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2017. Last accessed 10/02/2017.

most were mild or moderate. There were no serious teduglutide-related treatment-emergent adverse events. Between baseline and week 12, prescribed PN volume and calories changed by a median of -41% and -45%, respectively, with 0.025mg/kg/day teduglutide, and by -25% and -52% with 0.05mg/kg/day teduglutide. In patients on 0.0125mg/kg/day teduglutide PN volume and calories changes by 0% and -6%, respectively, and by 0% and -0.1% with SOC. The reported study limitations included its short-term, open-label design, and small sample size. The authors concluded that teduglutide was well tolerated in pediatric patients with SBS-IF. Teduglutide 0.025 or 0.05mg/kg/day was associated with trends toward reductions in PN requirements and advancements in EN feeding in children with SBS-IF.[27]

- **July 2017:** The results of a retrospective cohort study to evaluate the safety and efficacy of teduglutide in patients with Crohn's disease (CD) and SBS were published in the *Journal of Clinical Gastroenterology*. Due to the rarity of SBS, real-world safety or efficacy data are not available for patients with CD and SBS treated with teduglutide. This study was conducted at three tertiary centers in the United States between 2012 and 2014. A total of 13 patients with CD were included and 8 of the patients were on concomitant immunosuppression. The median duration of teduglutide therapy was 365 days and 9 of the 13 patients remain on therapy. At initiation of teduglutide, 69% of the patients were on PN. At conclusion of follow-up, one patient was on PN. All patients were on intravenous (IV) fluids prior to teduglutide; six patients ceased IV fluids. Adverse events attributed to teduglutide included obstructive symptoms (N=1), pancreatitis (N=1), asymptomatic lipase and amylase elevation (N=1), nausea (N=1), and abdominal pain (N=1). The authors stated that teduglutide appeared to be safe and the majority of patients were weaned off parenteral support. [28]

Recommendations

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

[27] Carter BA, Cohran VC, Cole CR, et al. Outcomes From a 12-Week, Open-Label, Multicenter Clinical Trial of Teduglutide in Pediatric Short Bowel Syndrome. *The Journal of Pediatrics*. 2017;181:102-111.

[28] Kochar B, Long MD, Shelton E, et al. Safety and Efficacy of Teduglutide (Gattex) in Patients with Crohn's Disease and Need for Parenteral Support Due To Short Bowel Syndrome-Associated Intestinal Failure. *Journal of Clinical Gastroenterology*. 2017;51(6):508-511.

Fiscal Year 2017 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

Cerdelga® (Eliglustat) Approval Criteria:

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

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved indication of mild/moderate Type 1 Gaucher disease (GD1); and
2. A patient-specific, clinically significant reason why the member cannot use one of the following enzyme replacement therapies:
    a. Cerezyme® (imiglucerase); or
    b. Elelyso® (taliglucerase alfa); or
    c. Vpriv® (velaglucerase alfa); and
3. Prescriber must verify that the member will not take Zavesca® concurrently with another therapy for GD1.
4. A quantity limit of 90 capsules per 30 days will apply.
5. Approvals will be for the duration of six months, at which time the prescriber must verify the patient is responding to the medication.

Utilization of Gaucher Disease Medications: Fiscal Year 2017

Gaucher Disease Medications Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	5	51	$905,265.06	$17,750.30	$619.20	2,100	1,462
2017	5	48	$707,064.65	$14,730.51	$528.05	2,351	1,339
% Change	**0.00%**	**-5.90%**	**-21.90%**	**-17.00%**	**-14.70%**	**12.00%**	**-8.40%**
Change	**0**	**-3**	**-$198,200.41**	**-$3,019.79**	**-$91.15**	**251**	**-123**

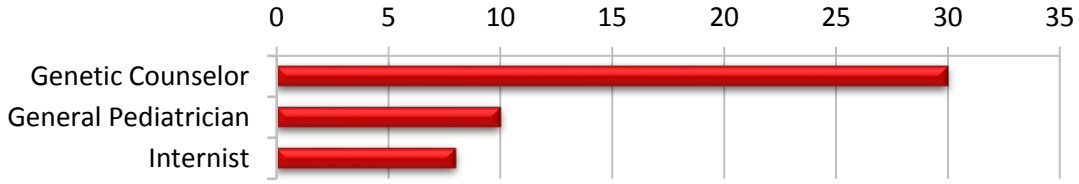
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- There were no pharmacy claims for Cerdelga® (eliglustat), Elelyso® (taliglucerase alfa), or Vpriv® (velaglucerase alfa) during fiscal year 2017.
- There were no medical claims for Elelyso® (taliglucerase alfa) or Cerezyme® (imiglucerase) during fiscal year 2017. Details of medical claims for Vpriv® (velaglucerase alfa) during fiscal year 2017 can be found in the *Utilization Details* section at the end of the report.

Demographics of Members Utilizing Gaucher Disease Medications

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

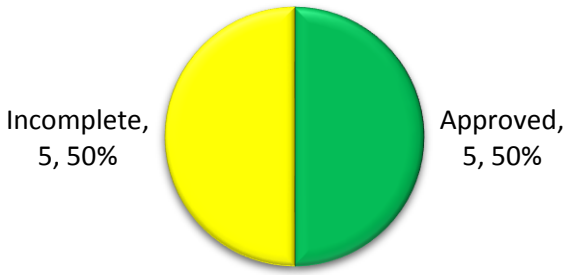
Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims



Prior Authorization of Gaucher Disease Medications

There were 10 prior authorization requests submitted for Gaucher disease medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates[29]

Patent Expiration(s):

- Cerezyme® (imiglucerase), Vpriv® (velaglucerase alfa), and Zavesca® (miglustat) are not available generically, but have no unexpired patents or exclusivities
- Cerdelga® (eliglustat): April 2022
- Elelyso® (taliglucerase alfa): October 2025

Recommendations

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

Utilization Details of Gaucher Disease Medications: Fiscal Year 2017

Fiscal Year 2017: Pharmacy Claims

Product Utilized	Total Claims	Total Members	Total Cost	Cost/ Day	Cost/ Claim	% Cost
CEREZYME INJ 400UNIT	30	3	$706,515.15	$884.25	$23,550.51	99.92%
ZAVESCA CAP 100MG	18	2	$549.50	$1.02	$30.53	0.08%
Total	**48**	**5***	**$707,064.65**	**$528.05**	**$14,730.51**	**100.00%**

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

Fiscal Year 2017: Medical Claims

Product Utilized	J-code	Total Claims	Total Members	Total Cost	Cost/Claim
VPRIV INJ 400 UNIT	J3385	52	2	$403,421.52	$7,758.11
Total	**J3385**	**52**	**2***	**$403,421.52**	**$7,758.11**

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

[29]U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 08/2017. Last accessed 10/03/2017.

Fiscal Year 2017 Annual Review of H.P. Acthar® Gel (Corticotropin Injection)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis of infantile spasms; and
    a. Member must be two years of age or younger; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist; or
2. An FDA approved diagnosis of multiple sclerosis (MS); and
    a. Member is experiencing an acute exacerbation; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist or a physician that specializes in MS; and
    c. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., IV methylprednisolone); and
    d. Therapy will be limited to five weeks per approval (three weeks of treatment, followed by taper). Additional approval, beyond the initial five weeks, will require prescriber documentation of response to initial treatment and need for continued treatment; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce a diuresis or a remission of proteinuria; and
    a. Must be prescribed by, or in consultation with, a nephrologist or an advanced care practitioner with a supervising prescriber that is a nephrologist; and
    b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone); or
4. An FDA approved diagnosis of the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous states; and
    a. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy.

Utilization of H.P. Acthar® Gel (Corticotropin Injection): Fiscal Year 2017

Comparison of Fiscal Years

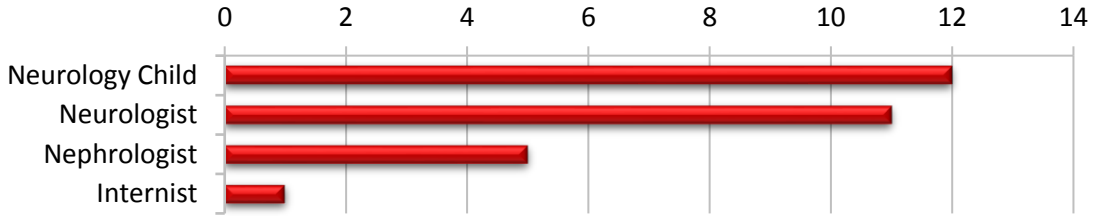
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	15	48	$2,568,844.91	$53,517.60	$2,695.54	370	953
2017	14	29	$1,721,095.62	$59,348.12	$3,401.37	245	506
% Change	**-6.70%**	**-39.60%**	**-33.00%**	**10.90%**	**26.20%**	**-33.80%**	**-46.90%**
Change	**-1**	**-19**	**-$847,749.29**	**$5,830.52**	**$705.83**	**-125**	**-447**

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

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

- Due to the small number of members utilizing H.P. Acthar® Gel (corticotropin injection) during fiscal year 2017, detailed demographic information could not be provided.

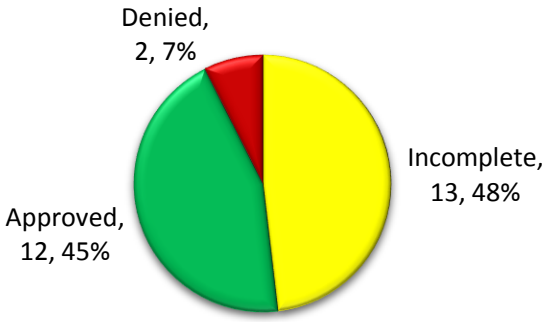
Top Prescriber Specialties of H.P. Acthar® Gel (Corticotropin Injection) by Number of Claims



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

There were 27 prior authorization requests submitted for H.P. Acthar® Gel (corticotropin injection) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017. The prior authorization criteria went into effect on November 3, 2016.

Status of Petitions



Market News and Updates

News:

- **March 2017:** Researchers from Oregon Health and Science University presented findings on an investigation into how much Medicare was spending on H.P. Acthar® Gel at the Americas Committee for Treatment and Research in Multiple Sclerosis 2017 Forum. With support from the National Multiple Sclerosis Society, the researchers looked at publicly available Medicare Part D data and found that fewer than one out of 100 clinicians prescribed Acthar® Gel in 2013 and 2014. They found that 274 neurologists, nephrologists, and rheumatologists were responsible for about 40 percent of Medicare's expenditures on Acthar® Gel. Dr. Daniel Hartung, PharmD, one of the researchers, stated that "we question why a small number of physicians are prescribing this extremely expensive drug when there are much cheaper alternatives," noting the lack of evidence that Acthar® Gel is superior to lower-cost corticosteroids for treating multiple sclerosis episodes. The other researcher, Dr. Dennis Bourdette, MD, concluded that "physicians should stop prescribing Acthar® Gel for anything other than infantile spasms."[30]
- **June 2017:** Mallinckrodt enrolled its first patient in a Phase 2B trial of H.P. Acthar® Gel for treatment of amyotrophic lateral sclerosis (ALS).[31]
- **July 2017:** Mallinckrodt announced it will conduct a Phase 4 trial of H.P. Acthar® Gel for treatment of symptomatic sarcoidosis. Enrollment of its first subject is expected in early 2018.[32]

Recommendations

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

[30] Henriques C. Acthar Gel of Dubious Value in Treating MS Despite its $34,000-Per-Vial Cost, Study Finds. *Multiple Sclerosis News Today*. Available online at: https://multiplesclerosisnewstoday.com/2017/03/01/medicare-spent-more-than-650-million-in-two-years-on-a-drug-prescribed-by-less-than-1-percent-of-physicians-study/. Issued 03/01/2017. Last accessed 10/18/2017.
[31] Reuters Staff. BRIEF-Mallinckrodt Enrolls First Patient in Phase 2B Trial of H.P. Acthar Gel. Reuters. Available online at: http://www.reuters.com/article/brief-mallinckrodt-enrolls-first-patient/brief-mallinckrodt-enrolls-first-patient-in-phase-2b-trial-of-h-p-acthar-gel-idUSASA09TWV. Issued 06/14/2017. Last accessed 10/18/2017.
[32] Reuters Staff. BRIEF-Mallinckrodt to Conduct Phase 4 Trial of H.P. Acthar Gel. Reuters. Available online at: http://www.reuters.com/article/brief-mallinckrodt-to-conduct-phase-4-tr/brief-mallinckrodt-to-conduct-phase-4-trial-of-h-p-acthar-gel-idUSASB0BMDL. Issued 10/09/2017. Last accessed 10/18/2017.

Fiscal Year 2017 Annual Review of Heart Failure Medications [Corlanor® (Ivabradine) and Entresto® (Sacubitril/Valsartan)]

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Corlanor® (Ivabradine) Approval Criteria:

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

Entresto® (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of chronic heart failure (NYHA Class II, III, or IV); and
2. The prescriber must verify that the member has a left ventricular ejection fraction ≤40%; and
3. The member must be on a maximally tolerated dose of a beta-blocker or have a contraindication to beta-blocker therapy; and
4. The member must not take an ACE inhibitor while taking Entresto® as concomitant use is contraindicated; and
5. Members with a diagnosis of diabetes must not be taking aliskiren while taking Entresto® as concomitant use is contraindicated; and
6. A quantity limit of 60 tablets per 30 days will apply.

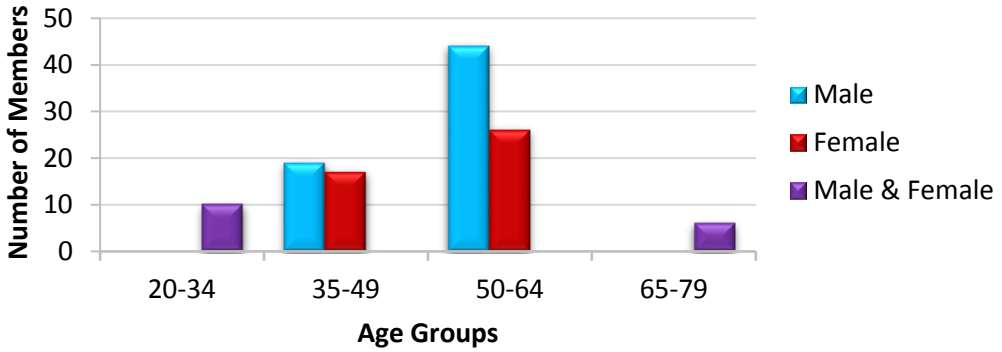
Utilization of Corlanor® and Entresto®: Fiscal Year 2017

Comparison of Fiscal Years

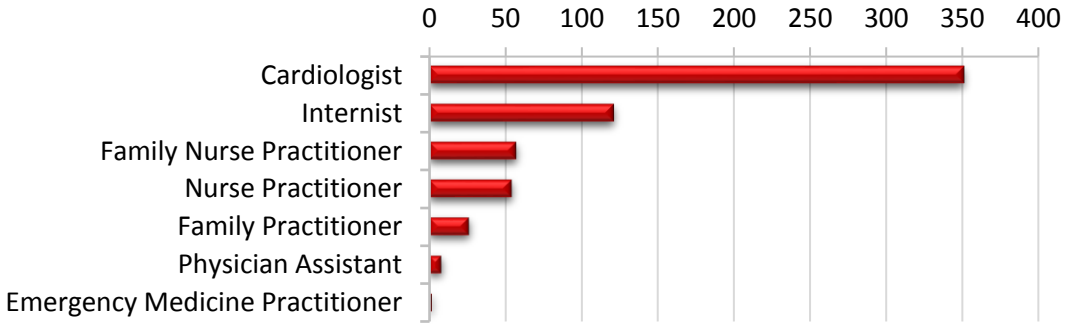
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	48	153	$60,697.14	$396.71	$13.22	9,180	4,590
2017	122	619	$250,867.21	$405.28	$13.54	36,850	18,532
% Change	**154.20%**	**304.60%**	**313.30%**	**2.20%**	**2.40%**	**301.40%**	**303.70%**
Change	**74**	**466**	**$190,170.07**	**$8.57**	**$0.32**	**27,670**	**13,942**

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

Demographics of Members Utilizing Corlanor® and Entresto®



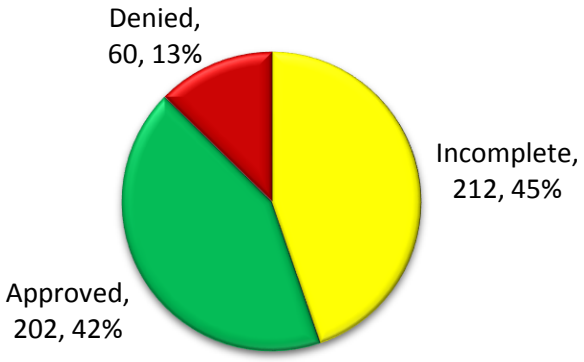
Top Prescriber Specialties of Corlanor® and Entresto® by Number of Claims



Prior Authorization of Corlanor® and Entresto®

There were 474 prior authorization requests submitted for Corlanor® and Entresto® during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[33]

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

Other News:

- **November 2016:** The results of a new analysis have demonstrated that in patients with heart failure (HF) and a reduced ejection fraction (rEF), Entresto® (sacubitril/valsartan) reduced the risk of all events, including first and repeat HF hospitalizations as well as cardiovascular (CV) deaths that followed HF hospitalization, compared with enalapril. The findings are from a *post hoc* analysis of PARADIGM-HF. The investigators found that, compared to enalapril, Entresto® demonstrated a risk reduction of between 20% and 24% for all events. Additional *post hoc* analyses from the PARADIGM-HF study further supported the safety and efficacy of Entresto® compared with enalapril. The analyses found that treatment with Entresto® was associated with fewer diuretic dose increases and more dose reductions compared to enalapril, treatment with Entresto® and a mineralcorticoid receptor antagonist (MRA) had a lower risk of severe hyperkalemia compared with those receiving an MRA and enalapril, and Entresto® demonstrated a consistent benefit in patients with severe HF symptoms [New York Heart Association (NYHA) functional class IV].[34]
- **March 2017:** Novartis announced results of a new *post hoc* analysis in a subgroup of patients with HFrEF and diabetes, which suggests that Entresto® improved glycemic control as assessed by hemoglobin A1c (HbA1c) testing. The analysis found that Entresto® decreased HbA1c levels by 0.26% during the first year of follow-up, compared to a 0.16% reduction with enalapril (p=0.0023). HbA1c levels remained persistently lower in patients with Entresto® compared to enalapril over three years, with an overall reduction of 0.14% [95% confidence interval (CI) (0.06, 0.23); P=0.005]. New use of insulin therapy or oral diabetes agents was also reduced in the Entresto® group. In the patients treated with Entresto®, 29% fewer patients initiated insulin therapy to achieve glycemic control compared to enalapril-treated patients.[35]

Pipeline:

- **CXL-1427:** Bristol-Myers Squibb's candidate HF medication, CXL-1427, works as a donor of nitric oxide to help increase intracellular cyclic guanosine monophosphate (cGMP). CXL-1427's targeted indication is HFrEF patients experiencing acute decompensation. In a Phase 1 dose-escalation study, 70 healthy patients received a 48-hour infusion of CXL-

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[33] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 10/18/2017.

[34] Novartis. Entresto Data Show Long-Term Benefits of Heart Failure Readmissions. *Managed Care*. Available online at: https://www.managedcaremag.com/news/entresto-data-show-long-term-benefits-heart-failure-readmissions. Issued 11/16/2016. Last accessed 12/14/2017.

[35] Novartis. New Analysis Shows Novartis Entresto Improves Glycemic Control in Reduced Ejection Fraction Heart Failure Patients with Diabetes. *P&T Community*. Available online at: https://www.ptcommunity.com/wire/new-analysis-shows-novartis-entresto-improves-glycemic-control-reduced-ejection-fraction-heart. Issued 03/18/2017. Last accessed 12/14/2017.

1427. The medication was well tolerated, with headache and nausea being the most common adverse effects at doses up to 10mcg/kg per minute. The results of a dose-finding Phase 2a trial have not yet been published and a Phase 2b efficacy trial, STANDUP-AHF, is currently enrolling participants with an anticipated completion date of spring 2019. CXL-1427 would launch in 2024, contingent on successful Phase 3 trials and U.S. Food and Drug Administration (FDA) approval, as an adjunct therapy to loop diuretics in the treatment of acute decompensated HF. [36]

- **Omecamtiv Mecarbil:** Cytokinetics' candidate HF medication, omecamtiv mecarbil (OM), is a novel, small molecule, direct activator of cardiac adenosine triphosphatase. OM is being developed for use in patients with HFrEF following an acute exacerbation. The use of OM results in increased left ventricular ejection time and stroke volume while not affecting a patient's systolic blood pressure (SBP). A Phase 2 trial, ATOMIC-AHF, was completed in 2013 and evaluated the dosing, efficacy, and safety of a 48-hour infusion of OM. In the trial, 606 patients with an acute HF exacerbation and a left ventricular ejection fraction (LVEF) of ≤40% were evaluated. There was no overall statistical difference seen in the primary outcome (improvement in dyspnea) when comparing OM to placebo. However, in patients receiving the highest OM dose the dyspnea response rate was 51% vs. 37% (P=0.034) compared with placebo. In the Phase 2 trial, COSMIC-HF, patients received either oral OM in doses of 25mg or 50mg twice daily for up to 20 weeks. All endpoints, including improved stroke volume, improved systolic ejection time, and reductions in heart rate, were significantly improved in the 50mg OM group compared with placebo (P<0.05). Amgen and Cytokinetics have partnered to continue Phase 3 development of OM. Enrollment in GALACTIC-HF is under way. The anticipated launch is 2022, pending successful results in Phase 3 trials and FDA approval.[4]
- **RT-100:** Renova Therapeutics' drug candidate, RT-100, is a novel approach to treating HF patients through gene transfer therapy. RT-100 targets human adenylyl cyclase type 6, a protein downregulated in some HF patients. RT-100 is a one-time therapy administered via cardiac catheterization and delivered to the site by an adenovirus type 5 vector. A Phase 2 trial involving 56 patients with chronic HFrEF demonstrated significantly improved LVEF at four weeks in patients treated with RT-100 compared with baseline (36.3% vs. 29.7%; P<0.004); however, RT-100 was unable to maintain a statistical difference at the 12-week evaluation (34.2% vs. 29.7%; P=0.16). A Phase 3 trial is set to begin enrollment at the end of 2017. The anticipated launch is 2024, pending FDA approval, and is positioned to be the first gene therapy on the market for HF.[4]
- **Vericiguat:** Bayer HealthCare and Merck's candidate, vericiguat, is a soluble guanylyl cyclase activator that targets patients with HFrEF and worsening disease. The Phase 3 trial, VICTORIA, is expected to be complete in January 2020. The trial will enroll 4,800 patients with a LVEF <45%, NYHA class II-IV disease, and a hospitalization in the previous six months. The primary endpoint is a composite of CV death or hospitalization for HF. The Phase 2 trial, SOCRATES-Reduced, showed vericiguat had no impact on N-terminal

[36] Kish, Troy. New Heart Failure Medications Aim to Fill Significant Gaps in Treatment. *Pharmacy and Therapeutics* 2017; *42*(12): 764-766.

pro-BNP, CV death, or positive changes in left ventricular function. However, secondary analysis of the results suggested a positive relationship between increasing dose and improved N-terminal pro-BNP reduction. Vericiguat anticipated launch is 2021, pending FDA approval. The agent would be added to standard therapy in patients who have recently experienced a disease exacerbation.[4]

- **Cimaglermin:** According to a study published in the *Journal of American College of Cardiology: Basic to Translational Science*, the recombinant growth factor, cimaglermin alfa, may enhance cardiac function in left ventricular systolic dysfunction (LVSD). The safety, tolerability, and exploratory efficacy of an intravenous (IV) infusion of cimaglermin alfa were examined in a Phase 1 study involving 40 patients with HF and LVSD. A dose-dependent improvement was seen in LVEF, which lasted 90 days after the infusion. Treatment with cimaglermin was generally well tolerated, except for transient nausea and headache, in patients on optimal guideline-directed medical therapy. At the highest planned dose, dose-limiting toxicity was noted. [37]
- **Tafamidis:** Pfizer announced in June 2017 that the FDA granted Fast Track designation to tafamidis, the company's investigational treatment for transthyretin cardiomyopathy (TTR-CM). TTR-CM is associated with progressive HF and is universally fatal. Tafamidis is currently in Phase 3 development for TTR-CM and is being evaluated for its potential to reduce mortality and CV-related hospitalizations. Tafamidis, trade name Vyndaqel®, is a novel specific TTR stabilizer that was first approved by the European Union (EU) in 2011 for the treatment of transthyretin familial amyloid polyneuropathy (TTR-FAP) in adult patients with early-stage symptomatic polyneuropathy to delay peripheral neurologic impairment. Vyndaqel® is currently approved for TTR-FAP in 40 countries. It is not approved in the United States.[38]

New Safety Information and Update(s):

- **October 2016:** Entresto® (sacubitril/valsartan) was added to the FDA watch list of drugs with possible safety issues for risk of rhabdomyolysis with concomitant use of statin therapy. The FDA is evaluating the need for regulatory action. [39]

Recommendations

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

[37] Lenihan DJ, Anderson SA, Lenneman CG, et al. A phase I, single ascending dose study of cimaglermin alfa (Neuregulin 1β3) in patients with systolic dysfunction and heart failure. *JACC Basic Transl Sci*. 2016;7(1). doi:10.1016/j.jacbts.2016.09.005.

[38] Pfizer Press Release. Pfizer Receives FDA Fast Track Designation for Tafamidis for Transthyretin Cardiomyopathy. Issued 06/06/2017. Last accessed 12/26/2017.

[39] Lowes R. New FDA Watch List Cover 27 Drugs and Drug Classes. *Medscape*. Available online at: https://www.medscape.com/viewarticle/869815. Issued 10/04/2016. Last accessed 12/14/2017.

Utilization Details of Corlanor® and Entresto®: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
IVABRADINE PRODUCTS					
CORLANOR TAB 5MG	88	20	$35,940.02	$13.61	$408.41
CORLANOR TAB 7.5MG	24	7	$9,963.07	$12.30	$415.13
SUBTOTAL	**112**	**27**	**$45,903.09**	**$13.31**	**$409.85**
SACUBITRIL/VALSARTAN PRODUCTS					
ENTRESTO TAB 24-26MG	205	64	$82,231.68	$13.52	$401.13
ENTRESTO TAB 49-51MG	162	41	$66,720.52	$13.73	$411.86
ENTRESTO TAB 97-103MG	140	33	$56,011.92	$13.53	$400.09
SUBTOTAL	**507**	**138**	**$204,964.12**	**$13.59**	**$404.27**
TOTAL	**619**	**122***	**$250,867.21**	**$13.54**	**$405.28**

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

Fiscal Year 2017 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Review

Introduction[40,41,42]

Idiopathic pulmonary fibrosis (IPF) is a chronic, incurable lung condition that is characterized by varying degrees of fibrosis, collagen deposits, and distortion of the pulmonary architecture. Clinical manifestations of IPF include progressive symptoms of dyspnea, cough, and worsening pulmonary function. Over time, fibrosis of the lungs increases until the lungs can no longer provide enough oxygen to the body's organs and tissues. The prognosis of IPF is poor, with a median survival of approximately three years after diagnosis. It is estimated that IPF affects approximately 100,000 individuals in the United States, with 30,000 to 40,000 new cases being diagnosed each year.[1] IPF is usually diagnosed in adults over the age of 50 years and is more common in men than in women.

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

Current Prior Authorization Criteria

Ofev® (Nintedanib) Approval Criteria:

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

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and

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[40] National Library of Medicine. Genetics Home Reference: Idiopathic Pulmonary Fibrosis. Available online at: http://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis. Last revised 04/2015. Last accessed 12/28/2017.
[41] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2017. Last accessed 12/28/2017.
[42] Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with Add-On Pirfenidone in Idiopathic Pulmonary Fibrosis: Results of the INJOURNEY Trial. *Am J Respir Crit Care Med* 2017; doi: 10.1164/rccm.201706-1301OC.

2. Member must be 18 years of age or older; and
3. Medication must be prescribed by a pulmonologist or pulmonary specialist; and
4. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 801mg strength tablets.

Utilization of IPF Medications: Fiscal Year 2017

Comparison of Fiscal Years for IPF Medications

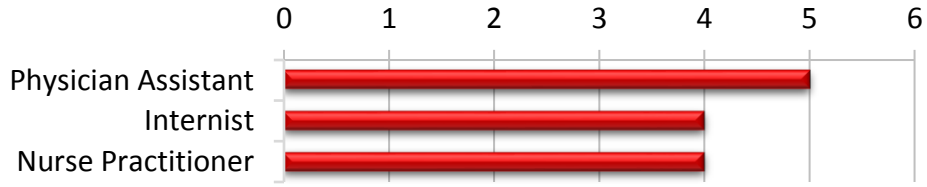
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	7	42	$350,664.96	$8,349.17	$278.31	7,350	1,260
2017	4	13	$113,103.64	$8,700.28	$290.01	1,830	390
% Change	**-42.90%**	**-69.00%**	**-67.70%**	**4.20%**	**4.20%**	**-75.10%**	**-69.00%**
Change	**-3**	**-29**	**-$237,561.32**	**$351.11**	**$11.70**	**-5,520**	**-870**

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

Demographics of Members Utilizing IPF Medications

- Due to the limited number of members utilizing IPF medications during fiscal year 2017, detailed demographic information could not be provided.

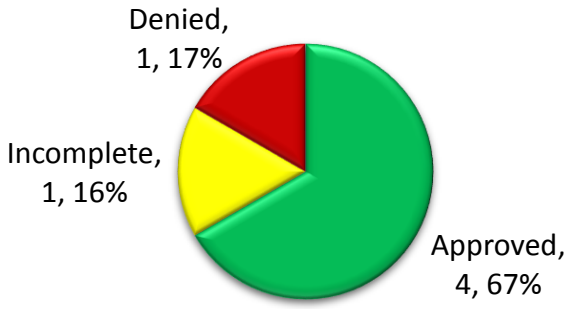
Top Prescriber Specialties of IPF Medications by Number of Claims



Prior Authorization of IPF Medications

There were 6 prior authorization requests submitted for IPF medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[2]

- Ofev® (nintedanib): April 2024
- Esbriet® (pirfenidone): August 2033

News:

- **September 2017:** Results were published from a clinical study investigating safety, tolerability, pharmacokinetic, and exploratory efficacy endpoints in patients treated with nintedanib and add-on pirfenidone versus nintedanib alone. Patients with IPF and forced vital capacity (FVC) ≥50% predicted at screening who completed a 4 to 5 week run-in with nintedanib 150mg twice daily without dose reduction or treatment interruption were randomized to nintedanib 150mg twice daily with add-on pirfenidone (titrated to 801mg three times daily), or nintedanib 150mg twice daily alone, open-label for 12 weeks. The primary endpoint was the percentage of patients with on-treatment gastrointestinal (GI) adverse events from baseline to week 12. On-treatment GI adverse events were reported in 37 of 53 patients (69.8%) treated with nintedanib with add-on pirfenidone and 27 of 51 patients (52.9%) treated with nintedanib alone. Pre-dose plasma trough concentrations of nintedanib were similar when it was administered alone or with add-on pirfenidone. Mean changes from baseline in FVC at week 12 were -13.3mL and -40.9mL in patients treated with nintedanib with add-on pirfenidone (n=48) and nintedanib alone (n=44), respectively. Nintedanib with add-on pirfenidone had a manageable safety and tolerability profile in patients with IPF, in line with the adverse event profiles of each drug; therefore, these data support further research into combination regimens in the treatment of IPF.[43,44]
- **September 2017:** Results were reported from a post-hoc analysis of data from Phase 3 studies showing that pirfenidone can significantly reduce the incidence of disease progression events in patients with IPF, including respiratory-related hospitalizations, decline in lung function and physical capacity, and the risk of death, compared to placebo. The analysis pooled data from three trials, involving a total of 1,247 IPF patients randomly assigned to receive either pirfenidone (2,403mg/day) or placebo daily for up to 52 weeks. Among the 623 patients given pirfenidone, significantly fewer progressive events were recorded compared to the 624 patients on placebo. Progressive events were defined as a relative decline in percent-predicted FVC ≥10% (as a measure of lung function), an absolute decline of 50 meters or more in the 6-minute walk distance test (assessing physical capacity), respiratory-related hospitalizations, or death from any cause. Over the 12 months, treatment with pirfenidone, compared to placebo, was seen to lessen the number of events marking a decline in lung function by 34%, events marking hospitalizations for respiratory problems by 38%, and events marking a decline in physical capacity by 24%. Furthermore, 6.3% of patients in the placebo-

[43] Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with Add-On Pirfenidone in Idiopathic Pulmonary Fibrosis: Results of the INJOURNEY Trial. *Am J Respir Crit Care Med* 2017; doi: 10.1164/rccm.201706-1301OC.

[44] Mumal I. Ofev®-Esbriet® Combo is as Safe as Individual Components as a Pulmonary Fibrosis Therapy, Trial Indicates. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/09/12/trial-shows-that-ofev-and-esbriet-combo-is-as-safe-an-ipf-therapy-as-its-individual-components/. Issued 09/12/2017. Last accessed 01/04/2018.

treated group died during the study period after at least one progressive event, compared to 2.1% in the pirfenidone group. The reduced mortality following one progressive event when patients were treated with pirfenidone compared to placebo support the continuation of treatment with pirfenidone even in the event of disease progression.[45]

- **November 2017:** Results from a Phase 3b clinical trial of nintedanib show that nintedanib slows the progression of lung scarring, according to high-resolution scans used in the trial. Computed tomography (CT) imaging demonstrated for the first time that nintedanib could reduce the progression of patients' lung fibrosis lesions, compared with placebo. Researchers presented the Phase 3b trial results at the Pulmonary Fibrosis Foundation Summit 2017 in November 2017. In the trial, investigators used high-resolution CT scans to evaluate nintedanib's ability to slow fibrosis and included 113 patients with IPF who received either nintedanib 150mg or placebo twice daily. After six months, the average CT lung fibrosis score for the nintedanib-treated patients was 11.4%, versus 14.6% for the placebo-treated patients. A lower percentage indicates less fibrosis progression. Nintedanib-treated patients also experienced less lung function decline than placebo-treated patients, researchers said, using FVC as a measure of lung function.[46]

Pipeline:

- **July 2017:** The FDA granted Orphan Drug designation to SM04646, a therapy developed by Samumed to treat IPF. SM04646, given as a nebulized inhalation solution, was previously found to be well tolerated and safe in a Phase 1 clinical trial. Previously, in preclinical studies with an animal model of lung fibrosis, researchers found that aerosolized SM04646 reduced fibrosis-like alterations in lungs with compared to control treatment. Moreover, SM04646 showed more anti-fibrotic activity than the two already approved therapies for IPF, pirfenidone and nintedanib. Samumed presented results of preclinical studies of SM04646, which demonstrated anti-fibrotic properties in numerous *in vitro* and *in vivo* studies. SM04646 is believed to exert its anti-fibrotic action by decreasing the expression of genes related to fibrosis development. It has the potential for a dual application, either as monotherapy or combined with currently approved oral medications, including pirfenidone and nintedanib.[47,48]
- **October 2017:** The FDA granted Fast Track designation to PBI-4050, Prometic Life Sciences' potential treatment for IPF. Regulators recently approved Prometic's

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[45] Melão A. Esbriet® Seen to Offer Significant Benefits to IPF Patients in Pooled Analysis of Phase 3 Trials. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/09/22/esbriet-seen-to-delay-ipf-progression-in-pooled-analysis-of-phase-3-trials-plus-interview/. Issued 09/22/2017. Last accessed 01/04/2018.

[46] Melão A. Ofev® Slows Progression of Fibrosis, Lung Imaging in Phase 3b Trial Shows. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/11/13/phase-3b-trial-shows-ofev-slows-lung-scarring-in-pulmonary-fibrosis/. Issued 11/13/2017. Last accessed 01/04/2018.

[47] Inacio P. FDA Grants Orphan Drug Designation to Samumed's Investigational SM04646 for IPF Treatment. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/07/25/samumed-receives-orphan-drug-designation-from-fda-for-sm04646-as-a-treatment-for-idiopathic-pulmonary-fibrosis-ipf/. Issued 07/25/2017. Last accessed 01/04/2018.

[48] Samumed News Release: Samumed Successfully Completed Phase I Study for Potential Treatment of Idiopathic Pulmonary Fibrosis. Available online at: https://www.samumed.com/medium/image/samumed-successfully-completed-phase-1-study-for-the-potential-treatment-of-idiopathic-pulmonary-fibrosis_134/view.aspx. Issued 07/17/2017. Last accessed 01/04/2018.

Investigational New Drug Application for PBI-4050 and the company's design for pivotal Phase 2/3 clinical trials of the therapy. PBI-4050 is designed to regulate lung inflammation and tissue scarring. It reduces levels of cytokines that promote scarring and also inhibits two other processes involved in scarring, or fibrosis: fibrocyte differentiation and microfibroblast activation. A number of studies have demonstrated that PBI-4050 can inhibit fibrosis in key organs, including the lungs, kidneys, heart, and liver. The results of a Phase 2 trial of PBI-4050 were presented at the 2017 American Thoracic Society International Conference in May 2017 and showed that PBI-4050 was safe and well tolerated. Patients received the therapy alone or in combination with either nintedanib or pirfenidone, which are FDA approved to treat IPF. The pirfenidone combination offered little benefit, researchers said, but the nintedanib combination led to less lung function decline than in the placebo-treated group. Researchers used FVC to measure lung function. [49]

- **December 2017:** The FDA granted Orphan Drug designation to Prometic's Ryplazim™ (plasminogen) as a treatment for IPF. Plasminogen is a naturally occurring protein that is synthesized by the liver and circulates in the blood; activated plasminogen, plasmin, is a fundamental component of the fibrinolytic system and is crucial for wound healing. Prometic believes plasminogen can reduce IPF flare-ups. Plasminogen was as effective as FDA-approved drugs in animal studies, and plasminogen-treated animals had significantly less lung tissue scarring than untreated animals, indicating the potential for providing clinically significant improvement and stabilization in lung function. Prometic is planning clinical trials to see what benefits plasminogen may offer IPF patients, including stabilizing their lung function during acute exacerbations or flare-ups.[50,51]

Recommendations

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

[49] Henriques C. FDA Grants Fast Track Designation to Prometic's Potential IPF Therapy PBI-4050. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/10/31/fda-grants-fast-track-status-to-pulmonary-fibrosis-therapy-candidate-pbi-4050/. Issued 10/31/2017. Last accessed 01/04/2018.

[50] Stewart J. FDA Grants Orphan Drug Status to Prometic's Pulmonary Fibrosis Therapy Ryplazim™. *Pulmonary Fibrosis News*. Available online at: https://pulmonaryfibrosisnews.com/2017/12/22/fda-grants-orphan-drug-status-to-prometics-pulmonary-fibrosis-therapy-ryplazim/. Issued 12/22/2017. Last accessed 01/04/2018.

[51] Prometic News Release: Prometic's Plasminogen (Ryplazim™) Granted Orphan Drug Designation for the Treatment of Idiopathic Pulmonary Fibrosis (IPF). Available online at: http://www.prometic.com/prometics-plasminogen-ryplazim-granted-orphan-drug-designation-for-the-treatment-of-idiopathic-pulmonary-fibrosis-ipf/. Issued 12/18/2017. Last accessed 01/04/2018.

Utilization Details of IPF Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
NINTEDANIB PRODUCTS						
OFEV CAP 150MG	8	3	$71,097.96	2.7	$8,887.25	62.86%
SUBTOTAL	**8**	**3**	**$71,097.96**	**2.7**	**$8,887.25**	**62.86%**
PIRFENIDONE PRODUCTS						
ESBRIET CAP 267MG	5	1	$42,005.68	5	$8,401.14	37.14%
SUBTOTAL	**5**	**1**	**$42,005.68**	**5**	**$8,401.14**	**37.14%**
TOTAL	**13**	**4***	**$113,103.64**	**3.25**	**$8,700.28**	**100%**

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

Fiscal Year 2017 Annual Review of Inhaled Cystic Fibrosis (CF) Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

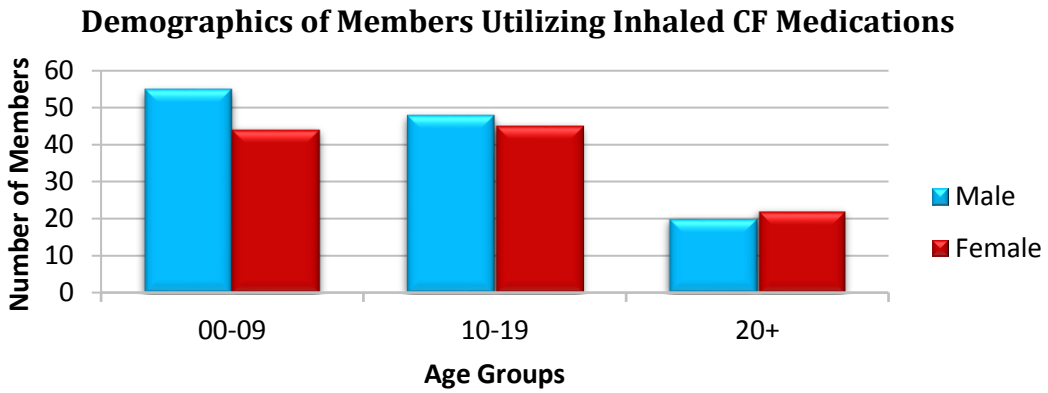
1. Use of inhaled tobramycin products, Pulmozyme® (dornase alfa), and Cayston® (aztreonam) is reserved for members who have a diagnosis of cystic fibrosis (CF).
    a. Authorization of Tobi® Podhaler™ requires a trial of tobramycin nebulized solution or a patient-specific, clinically significant reason why tobramycin nebulized solution is not appropriate for the member.
    b. Tobramycin nebulized solution (including Bethkis®, Kitabis™ Pak, and generic nebulized solution), dornase alfa, and aztreonam inhalation will not require a prior authorization and claims will pay at the point of sale if member has a reported diagnosis of CF within the past 12 months of claims history.
    c. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration.
2. Use of inhaled tobramycin products and Cayston® (aztreonam) is restricted to 28 days of therapy per every 56 days to ensure cycles of 28 days on therapy followed by 28 days off therapy.
    a. Use outside of this recommended regimen may be considered for coverage via a manual prior authorization submission with a patient-specific, clinically significant reason why the member would need treatment outside of the FDA approved dosing.
    b. Pharmacies should process the prescription claim with a 56 day supply.

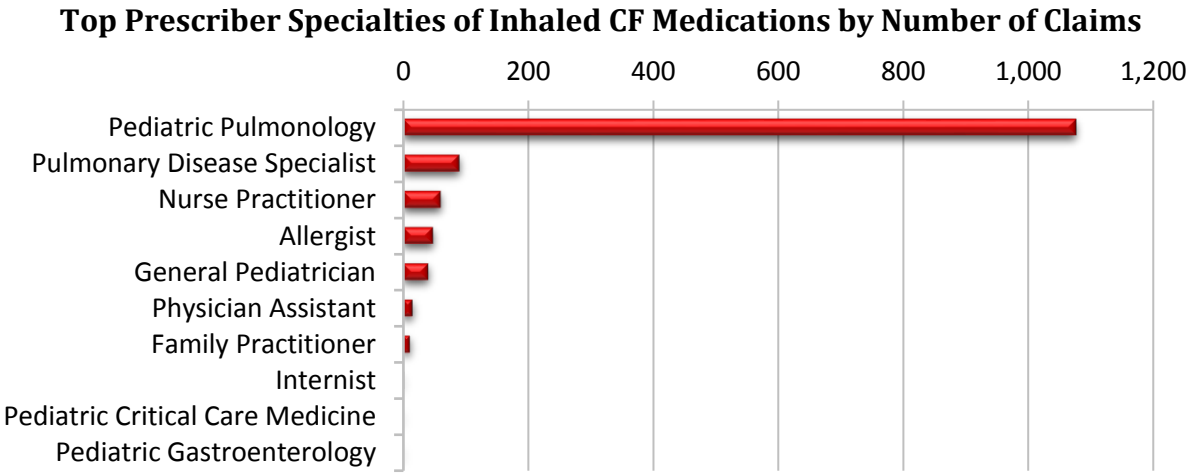
Utilization of Inhaled CF Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	202	1,249	$4,708,016.97	$3,769.43	$103.33	155,097	45,565
2017	234	1,343	$5,087,066.64	$3,787.84	$100.27	169,406	50,734
% Change	**15.80%**	**7.50%**	**8.10%**	**0.50%**	**-3.00%**	**9.20%**	**11.30%**
Change	**32**	**94**	**$379,049.67**	**$18.41**	**-$3.06**	**14,309**	**5,169**

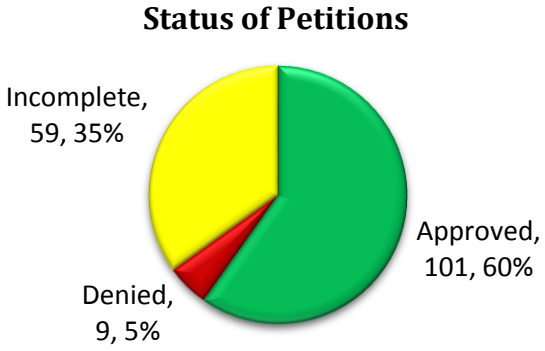
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Inhaled CF Medications

There were 169 prior authorization requests submitted for inhaled CF medications during fiscal year 2017. Computer edits are in place to detect a cystic fibrosis diagnosis in a member's recent diagnosis claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



Market News and Updates[52]

Patent Expiration(s):

- Tobi® (tobramycin solution inhalation): there are no unexpired patents for the nebulized solution formulation of Tobi®. Generic nebulized tobramycin formulations are currently available.
- Cayston® (aztreonam inhalation): December 2021
- Bethkis® (tobramycin solution inhalation): March 2023
- Tobi® Podhaler™ (tobramycin powder inhalation): October 2025

Recommendations

The College of Pharmacy does not recommend any changes to the inhaled CF medication criteria at this time.

Utilization Details of Inhaled CF Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DORNASE ALFA PRODUCTS					
PULMOZYME SOL 1MG/ML	917	167	$3,037,127.57	5.49	$3,312.03
SUBTOTAL	**917**	**167**	**$3,037,127.57**	**5.49**	**$3,312.03**
TOBRAMYCIN NEBULIZED PRODUCTS					
TOBRAMYCIN NEB 300MG/5ML	282	105	$852,329.68	2.69	$3,022.45
BETHKIS NEB 300MG/4ML	5	2	$29,671.15	2.5	$5,934.23
SUBTOTAL	**287**	**106**	**$882,000.83**	**2.71**	**$3,073.17**
TOBRAMYCIN POWDER PRODUCTS					
TOBI PODHALR CAP 28MG	53	23	$501,884.63	2.3	$9,469.52
SUBTOTAL	**53**	**23**	**$501,884.63**	**2.3**	**$9,469.52**
AZTREONAM PRODUCTS					
CAYSTON INH 75MG	86	32	$666,053.61	2.69	$7,744.81
SUBTOTAL	**86**	**32**	**$666,053.61**	**2.69**	**$7,744.81**
TOTAL	**1,343**	**234***	**$5,087,066.64**	**5.74**	**$3,787.84**

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

[52] U.S. Food and Drug Adminstration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2017. Last accessed 01/22/2018.

Fiscal Year 2017 Annual Review of Inhaled Short-Acting Beta$_2$ Agonists (SABAs)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

Rescue Inhalers Tier-2 Approval Criteria:

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

Rescue Inhalers	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA)	albuterol HFA (Ventolin® HFA)
albuterol HFA (Proventil® HFA)	albuterol sulfate (ProAir® RespiClick®)
levalbuterol HFA (Xopenex® HFA)*	

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

Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:

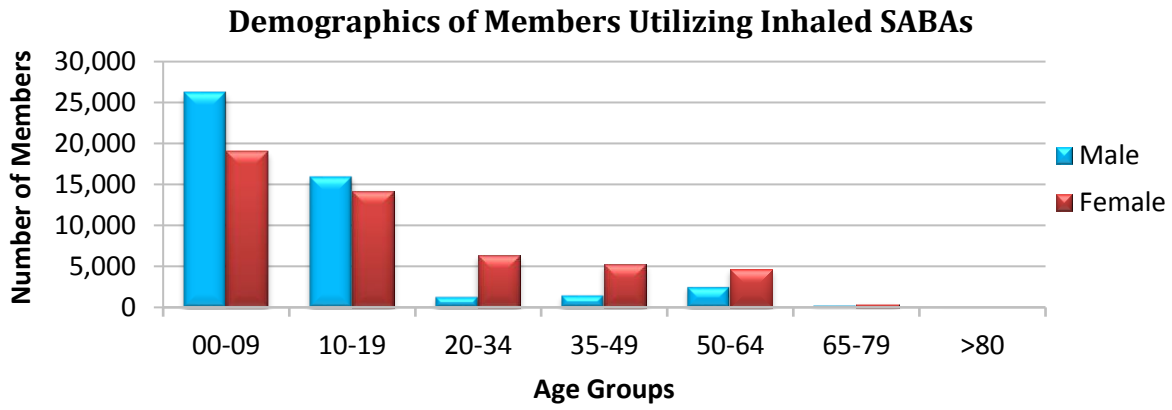
1. A patient-specific, clinically significant reason why the member is unable to use long-acting bronchodilators and/or inhaled corticosteroids (ICS) therapy for long-term control as recommended in the National Asthma Education and Prevention Program (NAEPP) guidelines; and
2. A patient-specific, clinically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

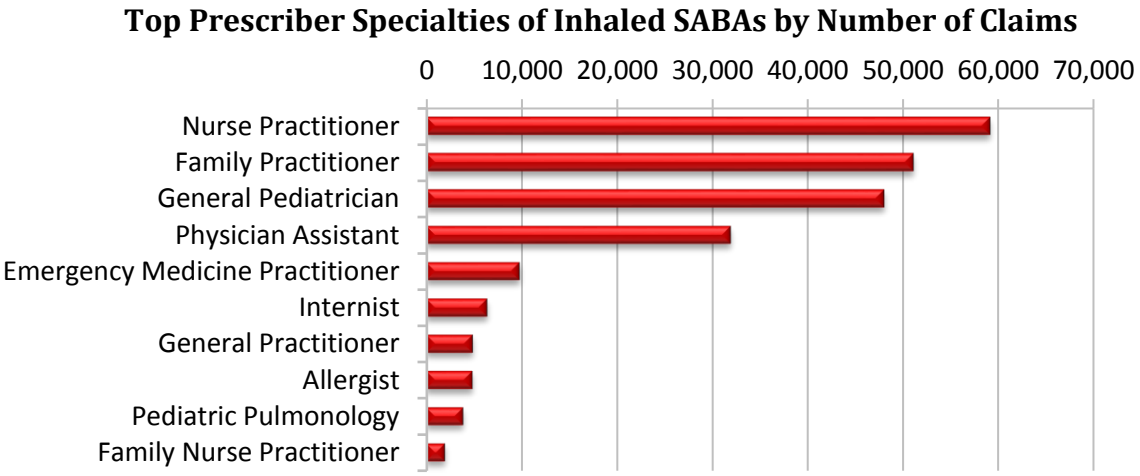
Utilization of Inhaled SABAs: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	108,586	254,618	$14,538,638.68	$57.10	$2.65	13,371,714	5,477,922
2017	103,732	247,361	$16,878,395.19	$68.23	$3.19	12,238,992	5,285,770
% Change	**-4.50%**	**-2.90%**	**16.10%**	**19.50%**	**20.40%**	**-8.50%**	**-3.50%**
Change	**-4,854**	**-7,257**	**$2,339,756.51**	**$11.13**	**$0.54**	**-1,132,722**	**-192,152**

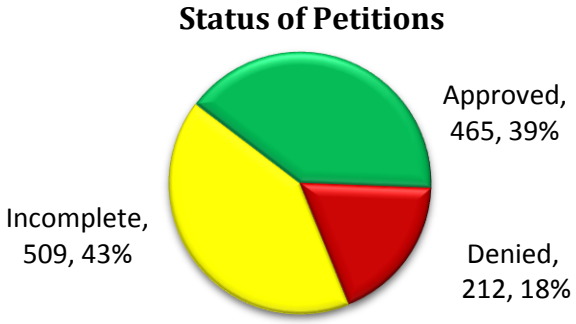
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





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

There were 1,186 prior authorization requests submitted for inhaled SABAs during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[53]

- Proventil® (albuterol HFA): December 2016
- Xopenex® (levalbuterol HFA): October 2024

[53] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 11/17/2017.

- Ventolin® (albuterol HFA): August 2026
- ProAir® (albuterol HFA): May 2031
- ProAir Respiclick® (albuterol sulfate inhalation powder): January 2032

News:

- **December 2016:** Amphastar Pharmaceuticals, Inc. announced the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) to its wholly-owned subsidiary, Armstrong Pharmaceuticals, Inc. regarding the New Drug Application (NDA) for Primatene® Mist (epinephrine inhalation aerosol). The CRL requested further modifications to the drug label and packaging of Primatene® Mist and to conduct another Human Factor validation study to assess consumers' ability to use the product without the guidance of a physician or pharmacist. The new Primatene® Mist is made with the same active ingredient, epinephrine that was used in the original Primatene® Mist. However, the product's new inhalation delivery system no longer includes chlorofluorocarbons (CFCs), which were phased out of various products worldwide as part of an international environmental treaty. Amphastar intends to continue to work with the FDA to address the CRL concerns and bring Primatene® Mist to the over-the-counter (OTC) market as soon as possible.[54]
- **October 2017:** Teva Pharmaceuticals announced the launch of levalbuterol tartrate 45mcg/actuation inhalation aerosol, the generic version of Sunovion's Xopenex® HFA. Brand name Xopenex® HFA is preferred by Soonercare at this time due to net cost.[55]

Recommendations

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

Utilization Details of Inhaled SABAs: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
PROAIR HFA AER	149,120	69,037	$10,813,370.11	$3.05	$72.51	75.99%
PROVENTIL AER HFA	16,870	8,827	$1,677,656.35	$3.91	$99.45	11.79%
XOPENEX HFA AER	310	141	$27,536.20	$3.18	$88.83	0.19%
SUBTOTAL	**166,300**	**78,005**	**$12,518,562.66**	**$3.14**	**$75.28**	**87.97%**
TIER-2 PRODUCTS						
VENTOLIN HFA AER	187	22	$15,026.96	$3.19	$80.36	0.11%
PROAIR RESPICLICK AER	14	8	$1,108.82	$3.36	$79.20	0.01%
SUBTOTAL	**201**	**30**	**$16,135.78**	**$3.20**	**$80.28**	**0.12%**
NEBULIZER SOLUTION PRODUCTS						

[54] Amphastar Pharmaceuticals, Inc. Amphastar Pharmaceuticals Receives Complete Response Letter for Primatene® Mist. Available online at: http://ir.amphastar.com/releasedetail.cfm?ReleaseID=1005509. Issued 12/2016. Last accessed 12/18/2017.
[55] Teva Pharmaceutical Industries Ltd. Teva Launches Generic Xopenex HFA. MPR. Available online at: http://www.empr.com/generics-news/teva-launches-generic-xopenex-hfa/article/566901/. Issued 10/2016. Last accessed 11/20/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ALBUTEROL NEB 0.083%	39,650	24,169	$553,631.87	$0.93	$13.96	3.89%
ALBUTEROL NEB 1.25MG/3	12,056	8,863	$488,866.82	$3.41	$40.55	3.44%
ALBUTEROL NEB 0.63MG/3	7,895	5,860	$332,025.21	$3.43	$42.06	2.33%
LEVALBUTEROL NEB 0.63MG	2,129	1,326	$163,965.04	$5.07	$77.02	1.15%
LEVALBUTEROL NEB 1.25MG	911	521	$80,496.80	$5.23	$88.36	0.57%
LEVALBUTEROL NEB 0.31MG	589	436	$42,150.34	$4.88	$71.56	0.30%
ALBUTEROL NEB 0.5%	478	290	$10,944.13	$1.20	$22.90	0.08%
LEVALBUTEROL AER 45/ACT	144	78	$10,639.08	$2.93	$73.88	0.07%
LEVALBUTEROL NEB 1.25/0.5	13	11	$5,601.91	$21.63	$430.92	0.04%
XOPENEX NEB 1.25/3ML	10	1	$6,579.86	$26.32	$657.99	0.05%
XOPENEX NEB 0.63MG	2	1	$461.07	$28.82	$230.54	0.00%
SUBTOTAL	**63,877**	**41,556**	**$1,695,362.13**	**$1.87**	**$26.54**	**11.92%**
TOTAL	**230,378**	**97,547***	**$14,230,060.57**	**$2.91**	$61.77	**100%**

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

Fiscal Year 2017 Annual Review of Keveyis® (Dichlorphenamide)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Keveyis® (Dichlorphenamide) Approval Criteria:

7. An FDA approved indication for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants; and
8. Prescriber documentation that all non-pharmacological treatments failed including the following:
    a. Hyperkalemic periodic paralysis:
        i. Acute attacks can be aborted with sugar or mild exercise
        ii. Avoiding foods rich in potassium
        iii. Avoiding fasting
        iv. High-carbohydrate diet
        v. Avoiding strenuous activity
        vi. Avoiding prolonged cold exposure
    b. Hypokalemic periodic paralysis:
        i. Low-carbohydrate diet (avoiding carbohydrate loading)
        ii. Avoiding vigorous exercise (some mild attacks can be aborted by low level exercise)
9. Prescriber documentation of frequent and severe attacks requiring pharmacological treatment (at least one attack per week but no more than three attacks per day); and
10. A four-week trial within the last 90 days of acetazolamide in combination with
    a. Spironolactone or triamterene in hypokalemic periodic paralysis; or
    b. Hydrochlorothiazide in hyperkalemic periodic paralysis
11. A quantity limit of four tablets per day will apply.

Utilization of Keveyis® (Dichlorphenamide): Fiscal Year 2017

- There has been no utilization or prior authorization requests for Keveyis® (dichlorphenamide) since it was approved by the U.S. Food and Drug Administration (FDA) in August 2015 to current date.

Market News and Updates

Anticipated Exclusivity Expiration(s):[56]

- Keveyis® (dichlorphenamide): August 2022

[56] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 12/04/2017.

News:

- **May 2016:** Taro Pharmaceuticals announced Keveyis® (dichlorphenamide) will now be available to distributors at no cost for the treatment of primary periodic paralysis. As a result, Taro ceased commercial sales and related promotional activities for Keveyis® and will bear all costs associated with its manufacture. Although Taro expected to treat only a few hundred patients with Keveyis®, it became clear that reaching such a small pool of people is more difficult than previously anticipated. Among the 5,000 people estimated to be living with periodic paralysis (PP) in the United States, less than 1,500 are believed to be diagnosed. Among these patients, a mix of lifestyle modifications and medicines prescribed off-label are often used to manage their disease. Taro reports sales have been less than one million dollars since launch. Given the high costs and resources required to identify and reach a limited number of viable patients, Taro decided that it cannot sustain its current level of investment. Based on these learnings, Taro now believes that it can better serve all stakeholders, including patients, by ceasing commercial sales and related promotional activities for Keveyis®.[57]
- **December 2016:** Taro Pharmaceutical Industries announced the sale of rights for Keveyis® (diclorphenamide) to Strongbridge Biopharma for $8.5 million and additional future payments upon the achievement of certain sales unit milestones. Strongbridge expects to commercially launch Keveyis® in the United States in April 2017. Taro has agreed to continue to manufacture Keveyis® for Strongbridge, under an exclusive supply agreement at least for the period of Keveyis® orphan exclusivity.[58]
- **November 2017:** Strongbridge announced Keveyis® net product sales of $2.5 million during the third quarter of 2017, a 67% increase, compared to $1.5 million in the second quarter of 2017. Within the first two quarters of the Strongbridge Keveyis® launch, Strongbridge cumulatively generated more than 80 new patient start forms (prescriptions for Keveyis®). The company has launched free genetic testing for the disease state and plans to expand the Keveyis® sells force. In addition, the company plans to build upon PP disease-state education programs and Keveyis® branded promotional initiatives, and support the recent national launch of the *Uncovering Periodic Paralysis* genetic testing program.[59]

Recommendations

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

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[57] Taro Pharmaceutical Industries Inc. Taro to Make Keveyis™ Available to Distributors Free of Cost. Available online at: http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-newsArticle&ID=2163726. Issued 05/2016. Last accessed 12/04/2017.

[58] Taro Pharmaceutical Industries. Taro Announces Sale of U.S. Rights to Keveyis® to Strongbridge BioPharma plc. *BusinessWire*. Available online at: http://www.businesswire.com/news/home/20161223005197/en/Taro-Announces-Sale-U.S.-Rights-Keveyis%C2%AE-Strongbridge. Issued 12/2016. Last accessed 12/04/2017.

[59] Strongbridge Biopharma Plc. Strongbridge Biopharma Plc Provides Corporate Update and Reports Third Quarter 2017 Financial Results. Available online at: https://globenewswire.com/news-release/2017/11/14/1185758/0/en/Strongbridge-Biopharma-plc-Provides-Corporate-Update-and-Reports-Third-Quarter-2017-Financial-Results.html. Issued 11/2017. Last accessed 12/04/2017.

Fiscal Year 2017 Annual Review of Lidoderm® (Lidocaine 5% Patch) & Synera® (Lidocaine/Tetracaine Patch)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Lidoderm® (Lidocaine 5% Patch) Approval Criteria:

1. An FDA approved indication for the treatment of postherpetic neuralgia; and
2. Documented treatment attempts at recommended dosing or contraindication to at least one agent from two of the following drug classes:
   a. Tricyclic antidepressants; or
   b. Anticonvulsants; or
   c. Topical or oral analgesics; and
3. A quantity limit of no more than three patches per day with a maximum of 90 patches per month will apply.

Synera® (Lidocaine/Tetracaine Patch) Approval Criteria:

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

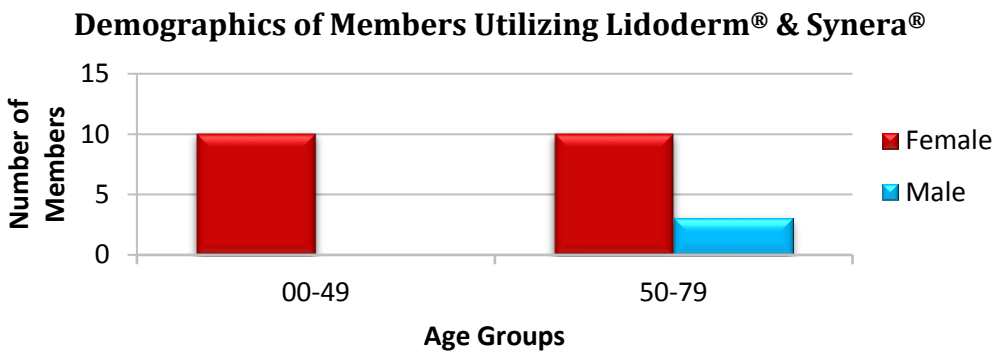
Utilization of Lidoderm® & Synera®: Fiscal Year 2017

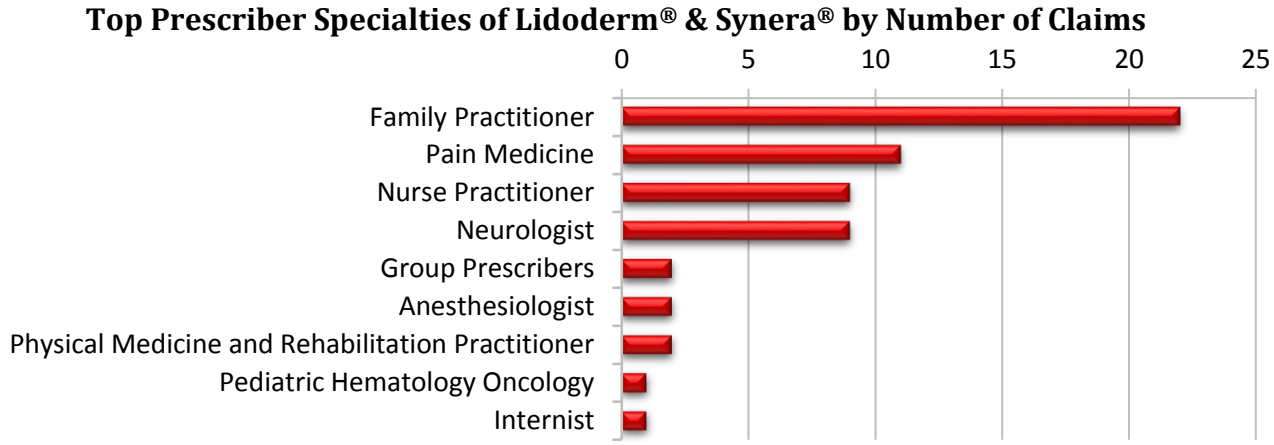
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	25	51	$14,548.84	$285.27	$9.86	2,411	1,475
2017	23	59	$8,150.34	$138.14	$4.82	2,112	1,692
% Change	**-8.00%**	**15.70%**	**-44.00%**	**-51.60%**	**-51.10%**	**-12.40%**	**14.70%**
Change	**-2**	**8**	**-$6,398.50**	**-$147.13**	**-$5.04**	**-299**	**217**

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

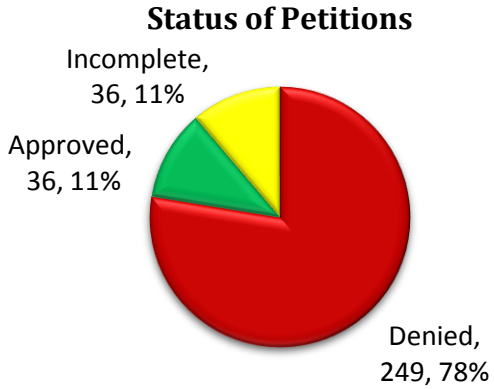
- There was no utilization of no Synera® (lidocaine/tetracaine patch) during fiscal year 2017.





Prior Authorization of Lidoderm® & Synera®

There were 321 prior authorization requests submitted for Lidoderm® and Synera® during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[60]

- Synera® (lidocaine/tetracaine patch): July 2020

[60] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 11/13/2017.

News:

- **March 2016:** The makers of Blue-Emu® (Gregory Pharmaceutical Holdings, Inc.) announced the launch of Lidocare™. Lidocare™ is the first lidocaine patch available over-the-counter (OTC). It contains lidocaine 4%, the maximum strength available without a prescription, and offers up to 8 hours of pain relief. It is the only water-free lidocaine patch, making it ultra-flexible, sweat resistant, and highly durable according to the manufacturer.[61]
  - As of 11/14/2017, the cost found on Walgreens.com for a 3-count box of Lidocare™ was $18.99.
- **October 2016:** Hisamitsu America announced the launch of Salonpas® Lidocaine 4% Pain Relieving Gel-Patch. The patch features the maximum strength lidocaine available without a prescription. This Salonpas® patch uses a proprietary hydro-gel technology, which ensures precise and even delivery of medicine at the site of pain to provide temporary relief of minor aches and pains.[62]
  - As of 11/14/2017, the cost found on Walgreens.com for a 6-count box of Salonpas® Lidocaine 4% Pain Relieving Gel-Patch was $12.99.

Recommendations

The College of Pharmacy does not recommend any changes to the Lidoderm® (lidocaine 5% patch) and Synera® (lidocaine/tetracaine patch) prior authorization criteria at this time.

Utilization Details of Lidoderm® & Synera®: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
LIDOCAINE PRODUCTS						
LIDOCAINE PAD 5%	59	23	$8,150.34	$4.82	$138.14	100.00%
TOTAL	**59**	**23***	**$8,150.34**	**$4.82**	**$138.14**	**100.00%**

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

[61] Gregory Pharmaceutical Holdings, Inc. Blue-Emu® to extend product line to include first OTC Lidocaine Pain Relief patch - Lidocare™. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/blue-emu-to-extend-product-line-to-include-first-otc-lidocaine-pain-relief-patch--lidocare-300241876.html. Issued 03/28/2016. Last accessed 11/14/2017.
[62] Hisamitsu America. Hisamitsu America, the Global Leader of Topical Pain Patches, Introduces the Salonpas® Lidocaine 4% Pain Relieving Gel-Patch. *Marketwired*. Available online at: http://www.marketwired.com/press-release/hisamitsu-america-global-leader-topical-pain-patches-introduces-salonpasr-lidocaine-2166943.htm. Issued 10/17/2016. Last accessed 11/14/2017.

Fiscal Year 2017 Annual Review of Mozobil® (Plerixafor)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Mozobil® (Plerixafor) Approval Criteria:

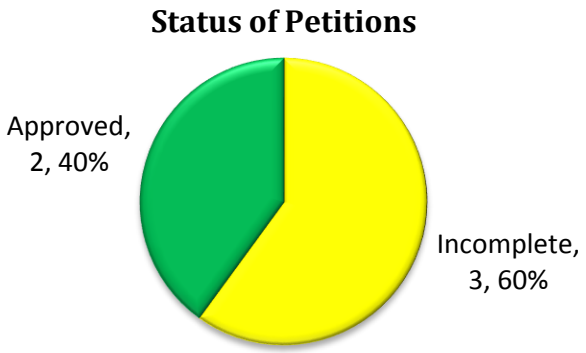
1. An FDA approved indication for use in combination with a granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM); and
2. Member must have a cancer diagnosis of non-Hodgkins's lymphoma (NHL) or multiple myeloma (MM); and
3. Mozobil® must be prescribed by an oncologist or a midlevel practitioner with a supervising prescriber who is an oncologist; and
4. Member must be 18 years of age or older; and
5. Mozobil® must be given in combination with a G-CSF [e.g., Neupogen® (filgrastim)]; and
6. Approvals will be based on FDA approved dosing recommendations; and
7. Approvals will be for the duration of two months.

Utilization of Mozobil® (Plerixafor): Fiscal Year 2017

There were no pharmacy or medical claims for Mozobil® (plerixafor) during fiscal year 2017.

Prior Authorization of Mozobil® (Plerixafor)

There were 5 prior authorizations submitted for Mozobil® (plerixafor) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Recommendations

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

Fiscal Year 2017 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA**
baclofen (Lioresal®)	metaxalone (Skelaxin®)	carisoprodol 250mg (Soma®)
chlorzoxazone (Parafon Forte®)		carisoprodol 350mg (Soma®)
cyclobenzaprine (Flexeril®)		carisoprodol with aspirin
methocarbamol (Rovaxin®)		carisoprodol/ASA/codeine
orphenadrine (Norflex®)		chlorzoxazone (Lorzone®) 375mg and 750mg tablets
tizanidine tablets (Zanaflex®)		cyclobenzaprine 7.5mg (Fexmid®)
		cyclobenzaprine ER (Amrix®)
		tizanidine capsules (Zanaflex®)

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

Muscle Relaxant Medications Tier-2 Criteria:

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

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

1. A cumulative 90 therapy day window per 365 days will be in place for these medications, further approval will be based on the following:
    a. An additional approval for 1 month will be granted to allow titration or change to a Tier-1 muscle relaxant. Further authorizations will not be granted.
    b. Clinical exceptions may be made for members with the following diagnosis and approvals will be granted for the duration of one year: multiple sclerosis, cerebral palsy, muscular dystrophy, or paralysis.
2. A quantity limit of 120 per 30 days will apply.

Carisoprodol (Soma®) 250mg Approval Criteria:

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

Chlorzoxazone (Lorzone®) 375mg and 750mg Approval Criteria:

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

Cyclobenzapirine (Fexmid®) and Cyclobenzaprine ER (Amrix®) Approval Criteria:

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

Tizanidine Capsules (Zanaflex®) Approval Criteria:

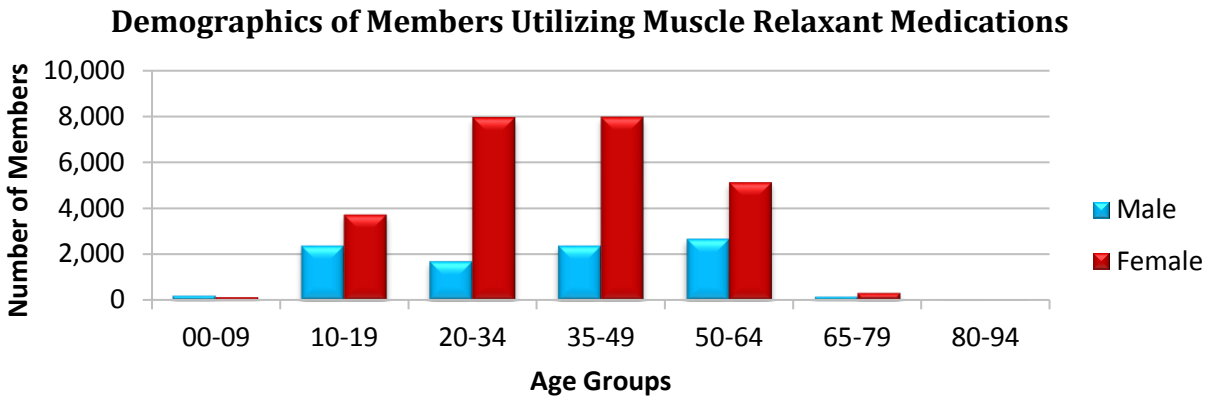
1. Tizanidine tablets must be tried prior to consideration of the capsules; and
2. The capsules may be considered for authorization if there is supporting information as to why the member cannot take the tablets.

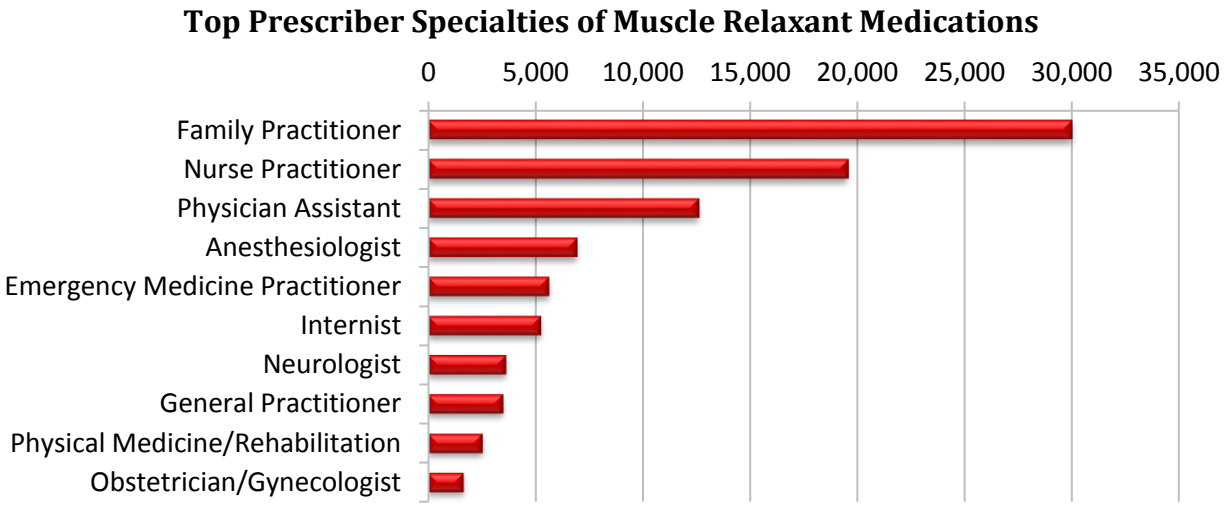
Utilization of Muscle Relaxant Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	35,199	102,117	$1,345,070.72	$13.17	$0.53	7,162,630	2,530,193
2017	34,597	101,924	$1,456,303.40	$14.29	$0.58	7,107,489	2,523,429
% Change	**-1.70%**	**-0.20%**	**8.30%**	**8.50%**	**9.40%**	**-0.80%**	**-0.30%**
Change	**-602**	**-193**	**$111,232.68**	**$1.12**	**$0.05**	**-55,141**	**-6,764**

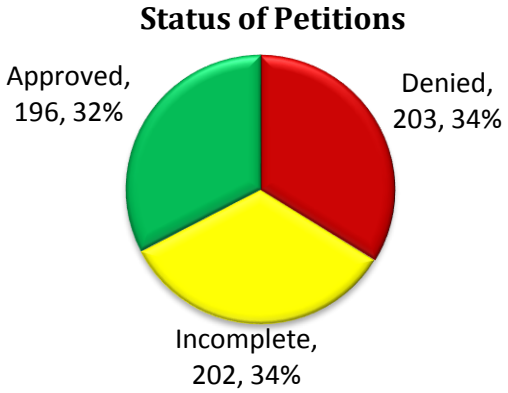
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Muscle Relaxant Medications

There were 601 prior authorization requests for muscle relaxant medications submitted during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Recommendations

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

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
TIER-1 UTILIZATION					
BACLOFEN PRODUCTS					
BACLOFEN TAB 10MG	12,602	3,928	$211,543.92	3.21	$16.79
BACLOFEN TAB 20MG	6,536	1,481	$191,156.47	4.41	$29.25
BACLOFEN POW	267	48	$2,915.27	5.56	$10.92
GABLOFEN INJ 40000/20	21	4	$17,672.97	5.25	$841.57
LIORESAL INT INJ 40MG/20	8	1	$14,194.88	8	$1,774.36
LIORESAL INT INJ 10MG/20	2	1	$448.19	2	$224.10
SUBTOTAL	**19,436**	**5,167**	**$437,931.70**	**3.76**	**$22.53**
CHLORZOXAZONE PRODUCTS					
CHLORZOXAZON TAB 500MG	1,479	670	$29,420.23	2.21	$19.89
SUBTOTAL	**1,479**	**670**	**$29,420.23**	**2.21**	**$19.89**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR TAB 10MG	33,625	15,806	$232,283.30	2.13	$6.91
CYCLOBENZAPR TAB 5MG	6,696	4,378	$51,074.27	1.53	$7.63
SUBTOTAL	**40,321**	**19,556**	**$283,357.57**	**2.06**	**$7.03**
METHOCARBAMOL PRODUCTS					
METHOCARBAM TAB 500MG	4,086	2,132	$43,133.14	1.92	$10.56
METHOCARBAM TAB 750MG	4,047	1,800	$48,887.11	2.25	$12.08
SUBTOTAL	**8,133**	**3,815**	**$92,020.25**	**2.13**	**$11.31**
ORPHENADRINE PRODUCTS					
ORPHENADRINE TAB 100MG ER	2,698	1,740	$53,011.78	1.55	$19.65
SUBTOTAL	**2,698**	**1,740**	**$53,011.78**	**1.55**	**$19.65**
TIZANIDINE PRODUCTS					
TIZANIDINE TAB 4MG	23,653	7,118	$418,248.07	3.32	$17.68
TIZANIDINE TAB 2MG	2,746	1,096	$42,662.37	2.51	$15.54
SUBTOTAL	**26,399**	**8,023**	**$460,910.44**	**3.29**	**$17.46**
TIER-1 SUBTOTAL	**98,466**	**33,711**	**$1,356,651.97**	**2.92**	**$13.78**
TIER-2 UTILIZATION					
METAXALONE PRODUCTS					
METAXALONE TAB 800MG	309	114	$64,854.09	2.71	$209.88
METAXALONE TAB 400MG	3	2	$1,030.66	1.5	$343.55
TIER-2 SUBTOTAL	**312**	**116**	**$65,884.75**	**2.69**	**$211.17**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
CARISOPRODOL PRODUCTS					
CARISOPRODOL TAB 350MG	3,142	1,433	$31,780.13	2.19	$10.11
SUBTOTAL	**3,142**	**1,433**	**$31,780.13**	**2.19**	**$10.11**
CHLORZOXAZONE PRODUCTS					
LORZONE TAB 375MG	4	1	$1,986.55	4	$496.64
SUBTOTAL	**4**	**1**	**$1,986.55**	**4**	**$496.64**
SPECIAL PA SUBTOTAL	**3,146**	**1,434**	**$33,766.68**	**2.19**	**$10.73**
TOTAL	**101,924**	**34,597**	**$1,456,303.40**	**2.95**	**$14.29**

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

Fiscal Year 2017 Annual Review of Myalept® (Metreleptin)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Myalept® (Metreleptin) Approval Criteria:

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

Utilization of Myalept® (Metreleptin): Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	1	13	$1,174,044.90	$90,311.15	$3,010.37	330	390
2017	1	12	$447,505.38	$37,292.11	$1,243.07	120	360
% Change	**0.00%**	**-7.70%**	**-61.90%**	**-58.70%**	**-58.70%**	**-63.60%**	**-7.70%**
Change	**0**	**-1**	**-$726,539.52**	**-$53,019.04**	**-$1,767.30**	**-210**	**-30**

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

Demographics of Members Utilizing Myalept® (Metreleptin)

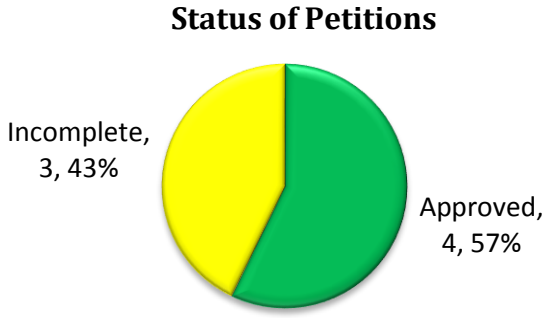
- Due to the small number of members utilizing Myalept® (metreleptin), detailed demographic information could not be provided.

Top Prescriber Specialties of Myalept® (Metreleptin)

- The only prescriber specialty list on paid claims for Myalept® (metreleptin) during fiscal year 2017 was pediatric endocrinology.

Prior Authorization of Myalept® (Metreleptin)

There were 7 prior authorization request submitted for Myalept® (metreleptin) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Recommendations

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

Fiscal Year 2017 Annual Review of Mytesi® (Crofelemer) [Formerly Known As Fulyzaq®]

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

Utilization of Mytesi® (Crofelemer): Fiscal Year 2017

There was no utilization of Mytesi® (crofelemer) during fiscal year 2017.

Prior Authorization of Mytesi® (Crofelemer)

There were no prior authorization requests submitted for Mytesi® (crofelemer) during fiscal year 2017.

Market News and Updates[63]

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

Recommendations

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

[63] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 11/28/2017.

Fiscal Year 2017 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

Evzio® (Naloxone Auto-Injector) Approval Criteria:

1. An FDA approved diagnosis of potential or risk for opioid overdose; and
2. A patient-specific, clinically significant reason why the member cannot use other formulations of naloxone.

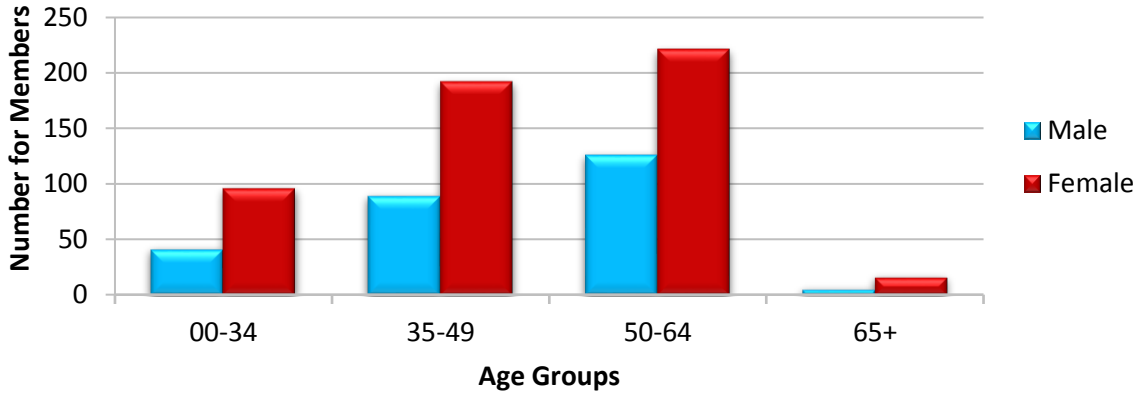
Utilization of Naloxone Medications: Fiscal Year 2017

Comparison of Fiscal Years

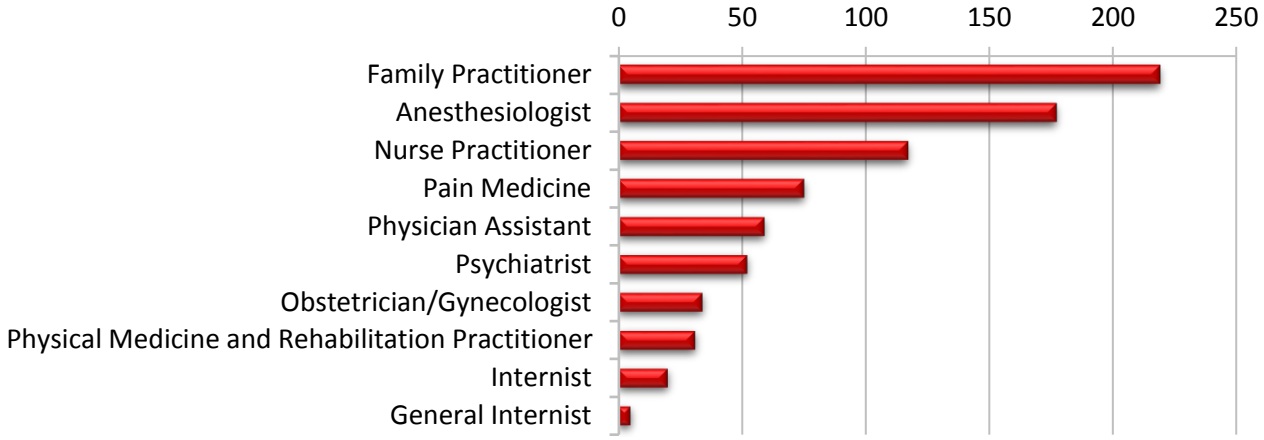
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2015	258	258	$22,852.10	$88.57	$3.56	589	6,415
2016	786	796	$89,081.43	$111.91	$3.76	1,633	23,703
% Change	**204.70%**	**208.50%**	**289.80%**	**26.40%**	**5.60%**	**177.20%**	**269.50%**
Change	**528**	**538**	**$66,229.33**	**$23.34**	**$0.20**	**1,044**	**17,288**

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

Demographics of Members Utilizing Naloxone Medications



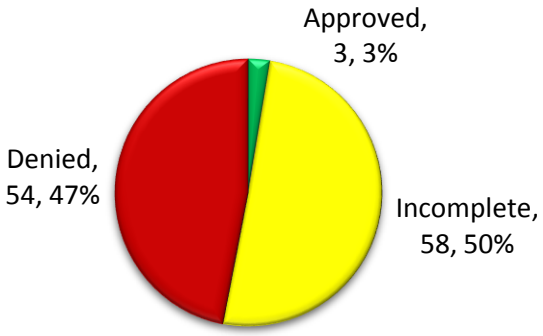
Top Prescriber Specialties of Naloxone Medications by Number of Claims



Prior Authorization of Naloxone Medications

There were 115 prior authorization requests submitted for naloxone medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates[64]

Anticipated Patent Expiration(s):

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

Recommendations

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

[64] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2017. Last accessed 01/22/2018.

Utilization Details of Naloxone Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
NARCAN SPR 4MG/0.1ML	560	554	$71,666.30	$4.16	$127.98
NALOXONE INJ SYR 1MG/ML	231	229	$9,271.04	$1.45	$40.13
EVZIO INJ 0.4MG/0.4ML	2	2	$7,923.20	$132.05	$3,961.60
NALOXONE INJ CART 0.4MG/ML	2	2	$198.45	$8.27	$99.23
NALOXONE INJ 0.4MG/ML	1	1	$22.44	$1.50	$22.44
TOTAL	**796**	**786***	**$89,081.43**	**$3.76**	**$111.91**

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

Fiscal Year 2017 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Nasal Allergy Medications*		
Tier-1	**Tier-2**	**Tier-3**
beclomethasone (Beconase® AQ)	azelastine 0.1% (Astelin®)	azelastine 0.15% (Astepro®)
Fluticasone propionate (Flonase®)	beclomethasone (Qnasl® 80mcg)	azelastine/fluticasone (Dymista®)
		beclomethasone (Qnasl® 40mcg)
		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		fluticasone furoate (Veramyst®)
		mometasone (Nasonex®)
		olopatadine (Patanase®)

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

Nasal Allergy Medications Tier-2 Approval Criteria:

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

Nasal Allergy Medications Tier-3 Approval Criteria:

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

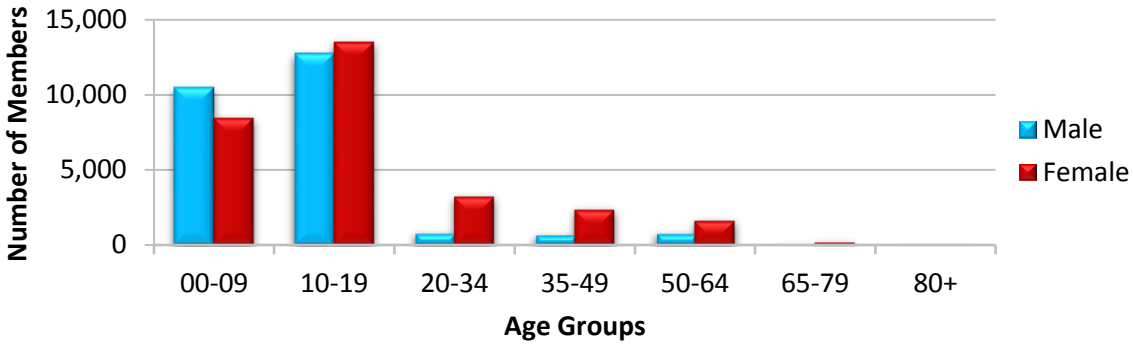
Utilization of Nasal Allergy Medications: Fiscal Year 2017

Comparison of Fiscal Years

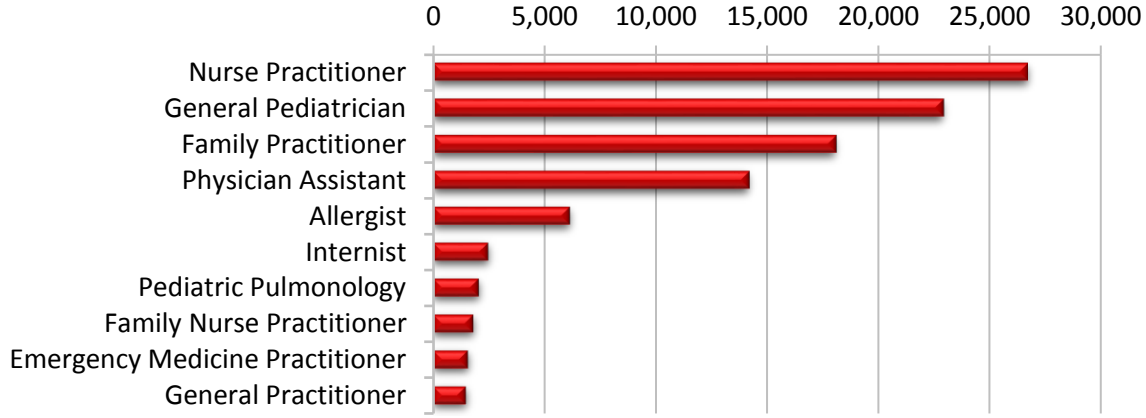
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	55,200	101,137	$1,264,594.47	$12.50	$0.35	1,627,282	3,593,113
2017	54,846	100,878	$1,463,269.74	$14.51	$0.39	1,625,880	3,704,984
% Change	**-0.60%**	**-0.30%**	**15.70%**	**16.10%**	**11.40%**	**-0.10%**	**3.10%**
Change	**-354**	**-259**	**$198,675.27**	**$2.01**	**$0.04**	**-1,402**	**111,871**

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

Demographics of Members Utilizing Nasal Allergy Medications



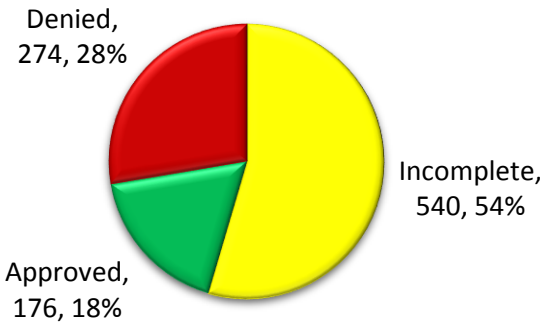
Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims



Prior Authorization of Nasal Allergy Medications

There were 990 prior authorization requests submitted for the Nasal Allergy Product Based Prior Authorization (PBPA) category during fiscal year 2017. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[65]

- Zetonna® (ciclesonide): May 2018
- Patanase® (olopatadine): August 2023
- Dymista® (azelastine/Fluticasone): August 2026
- Qnasl® 40mcg (beclomethasone): January 2027
- Omnaris® (ciclesonide): February 2028
- Astepro® (azelastine): June 2028

FDA Update(s):

- **February 2016:** McNeil Consumer Healthcare launched over-the-counter (OTC) Rhinocort® Allergy Spray.[66]
- **April 2016:** Bayer Consumer Healthcare launched OTC ClariSpray™ (fluticasone propionate).[67]
- **August 2016:** The FDA approved OTC Flonase® Sensimist™ (fluticasone furoate). Fluticasone furoate was previously available by prescription as Veramyst®, which is being discontinued.[68]
- **November 2017:** Innovus Pharma launched OTC FlutiCare™ (fluticasone propionate).[69]

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[65] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm?resetfields=1. Last revised 11/2017. Last accessed 12/28/2017.

[66] Johnsen, Michael. Another Nasal Corticosteroid Enters the OTC Market. *Drug Store News*. Available online at: http://www.drugstorenews.com/article/another-nasal-corticosteroid-enters-otc-market. Issued 02/08/2016. Last accessed 12/28/2017.

[67] Bulik, Beth Snyder. Bayer Leans on Claritin Brand Strength for Allergy Spray Launch. *FiercePharma*. Available online at: https://www.fiercepharma.com/marketing/bayer-leans-claritin-brand-strength-for-allergy-spray-launch. Issued 05/25/2016. Last accessed 12/28/2017.

[68] GSK Consumer Healthcare. FDA Approves Flonase® Sensimist™ Allergy Relief. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-flonase-sensimist-allergy-relief-300308201.html. Issued 08/03/2016. Last accessed 11/08/2017.

[69] Innovus Pharmaceuticals, Inc. Innovus Pharma Launches FlutiCare™ OTC Nasal Allergy Relief in the U.S. *BusinessWire*. Available online at: https://www.businesswire.com/news/home/20171114005563/en/Innovus-Pharma-Launches-FlutiCare%E2%84%A2-OTC-Nasal-Spray. Issued 11/14/2017. Last accessed 12/28/2017.

Guideline Update(s):[70,71]

- **November 2017:** An update of recommendations for the treatment of seasonal allergic rhinitis (SAR) were published in the *Annals of Allergy, Asthma, and Immunology*. The updated recommendations were issued by members of the Joint Task Force on Practice Parameters (JTFPP) and include changes to initial treatment strategies and aims to reduce unnecessary cost to patients. The update addressed three clinical scenarios:
  - For patients aged 12 years and older, nasal symptoms of SAR should be treated at least initially with an intranasal corticosteroid (INCS) alone rather than the INCS-oral antihistamine combination.
  - For initial treatment of patients 15 years of age and older with moderate-to-severe SAR, the clinician should recommend an INCS over a leukotriene receptor antagonist (LTRA).
  - The clinician may recommend combination therapy with an intranasal antihistamine (INAH) and INCS over either monotherapy. The working group noted combination therapy will come with increased cost and some increased risk of side effects.

Recommendations

The College of Pharmacy recommends the following changes to the Nasal Allergy Product Based Prior Authorization (PBPA) category:

1. Move Dymista® (azelastine/fluticasone) from Tier-3 to Tier-2 based on net costs after rebates.
2. Remove Rhinocort AQ® (budesonide) and Veramyst® (fluticasone furoate) from the Nasal Allergy PBPA category due to the availability of over-the-counter formulations and product discontinuations.

Nasal Allergy Medications*		
Tier-1	**Tier-2**	**Tier-3**
beclomethasone (Beconase® AQ)	azelastine 0.1% (Astelin®)	azelastine 0.15% (Astepro®)
fluticasone propionate (Flonase®)	**azelastine/fluticasone (Dymista®)**	beclomethasone (Qnasl® 40mcg)
	beclomethasone (Qnasl® 80mcg)	~~**budesonide (Rhinocort AQ®)**~~
		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		~~**fluticasone furoate (Veramyst®)**~~
		mometasone (Nasonex®)
		olopatadine (Patanase®)

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

[70] PL Detail-Document, Nasal Sprays for Allergic Rhinitis. P*harmacist's Letter/Prescriber's Letter*. April 2016.
[71] Harrison, Pam. New Guidelines for Allergic Rhinitis Change Treatment. *Medscape*. Available online at: https://www.medscape.com/viewarticle/888269?nlid=119013_745&src=WNL_mdplsfeat_171114_mscpedit_phar&uac=255225HG&spon=30&impID=1483168&faf=1#vp_2. Issued 11/09/2017. Last accessed 12/28/2017.

Utilization Details of Nasal Allergy Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 UTILIZATION						
FLUTICASONE SPR 50MCG	99,317	54,445	$1,189,896.82	$0.33	$11.98	81.32%
BECONASE AQ SUS 0.042%	668	441	$183,812.29	$7.79	$275.17	12.56%
TIER-1 SUBTOTAL	**99,985**	**54,886**	**$1,373,709**	**$0.37**	**$13.74**	**93.88%**
TIER-2 UTILIZATION						
AZELASTINE SPR 0.1%	103	65	$2,849.29	$0.76	$27.66	0.19%
QNASL AER 80MCG	40	19	$6,670.38	$4.71	$166.76	0.46%
TIER-2 SUBTOTAL	**143**	**84**	**$9,519.67**	**$1.85**	**$66.57**	**0.65%**
TIER-3 UTILIZATION						
FLUNISOLIDE SPR 0.025%	411	242	$23,548.93	$1.66	$57.30	1.61%
DYMISTA SPR 137-50MCG	91	24	$16,039.43	$5.63	$176.26	1.10%
MOMETASONE SPR 50MCG	85	30	$13,412.18	$4.38	$157.79	0.92%
VERAMYST SPR 27.5MCG	56	12	$11,129.48	$6.51	$198.74	0.76%
OLOPATADINE SPR 0.6%	46	6	$6,575.54	$4.66	$142.95	0.45%
QNASL CHILD SPR 40MCG	36	7	$6,466.47	$5.99	$179.62	0.44%
AZELASTINE SPR 0.15%	18	5	$1,613.55	$2.52	$89.64	0.11%
NASONEX SPR 50MCG/AC	4	3	$994.85	$6.63	$248.71	0.07%
BUDESONIDE SUS 32MCG	3	3	$260.53	$2.89	$86.84	0.02%
TIER-3 SUBTOTAL	**750**	**332**	**$80,040.96**	**$3.18**	**$106.72**	**5.48%**
TOTAL	**100,878**	**54,846***	**$1,463,269.74**	**$0.39**	**$14.51**	**100%**

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

Fiscal Year 2017 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Northera® (Droxidopa) Approval Criteria:

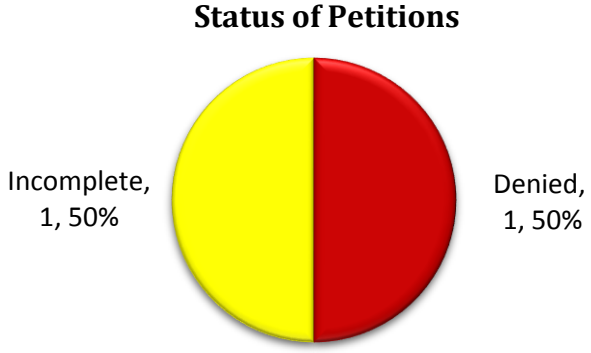
1. An FDA approved diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (i.e., Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; and
2. Member must be 18 years of age or older; and
3. Member must have tried and failed two of the following medications at recommended dosing within the last 90 days:
    a. Midodrine; or
    b. Fludrocortisone; or
    c. Pyridostigmine; or
    d. Have a contraindication to all preferred medications.
4. Initial approval will be for the duration of two weeks of treatment only.
5. Continued approval will require the prescriber to provide information regarding improved member response/effectiveness of this medication to determine whether Northera® is continuing to provide a benefit.
6. Continued approval will be for the duration of three months. Each approval will require prescriber documentation of member response/effectiveness to Northera®.

Utilization of Northera® (Droxidopa): Fiscal Year 2017

There were no paid claims for Northera® (droxidopa) during fiscal year 2017.

Prior Authorization of Northera® (Droxidopa)

There were 2 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Exclusivity Expiration(s):[72]

- Northera® (droxidopa): February 2021

Recommendations

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

[72] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 12/06/2017.

Fiscal Year 2017 Annual Review of Ocular Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

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

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

Ocular Antibiotic Tier-2 Approval Criteria:

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

Ocular Antibiotic Tier-3 Approval Criteria:

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

Antibiotic/Steroid Combination Tier-2 Approval Criteria:

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

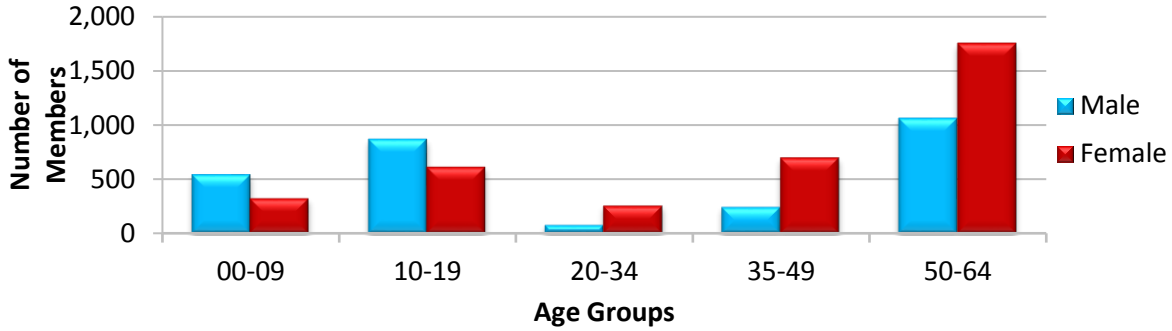
Utilization of Ocular Antibiotic Products: Fiscal Year 2017

Comparison of Fiscal Years

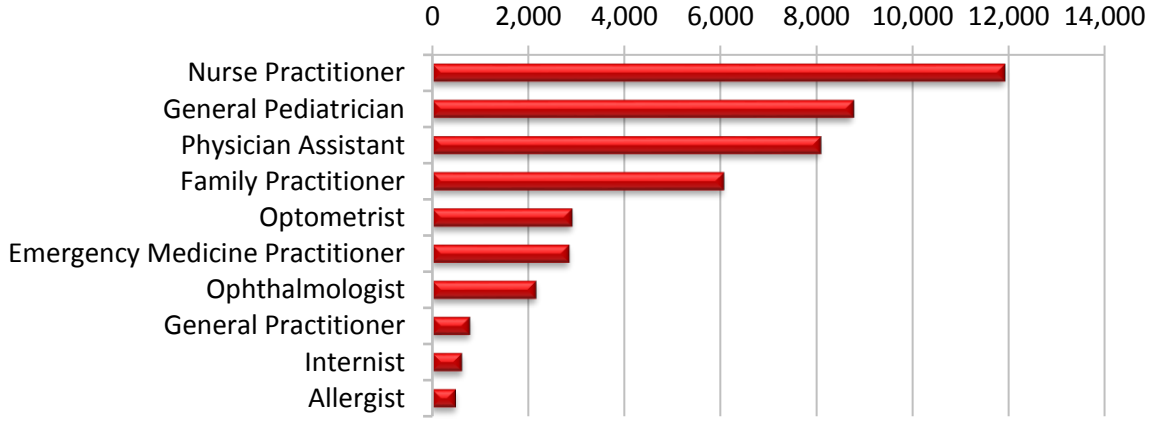
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	43,269	51,065	$921,827.55	$18.05	$1.57	345,301	587,574
2017	39,619	46,519	$945,890.70	$20.33	$1.71	309,707	552,073
% Change	**-8.40%**	**-8.90%**	**2.60%**	**12.60%**	**8.90%**	**-10.30%**	**-6.00%**
Change	**-3,650**	**-4,546**	**$24,063.15**	**$2.28**	**$0.14**	**-35,594**	**-35,501**

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

Demographics of Members Utilizing Ocular Antibiotic Products

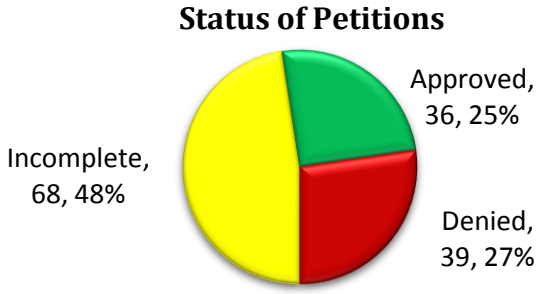


Top Prescriber Specialties of Ocular Antibiotic Products by Number of Claims



Prior Authorization of Ocular Antibiotic Products

There were 143 prior authorization requests submitted for the ocular antibiotic products during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expirations: [73]

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

New(s):

- **July 2017:** Generic versions of Alcon's Vigamox® (moxifloxacin 0.5% ophthalmic solution) were launched by two different manufacturers.[74]

Recommendations

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

Utilization Details of Ocular Antibiotic Products: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OCULAR ANTIBIOTIC LIQUIDS						
OCULAR ANTIBIOTIC LIQUIDS: TIER-1						
POLYMYXIN B/ SOL TRIMETHP	11,354	10,819	$140,691.76	$0.78	$12.39	14.87%
OFLOXACIN DRO 0.3% OP	7,164	6,514	$168,336.44	$2.08	$23.50	17.80%
TOBRAMYCIN SOL 0.3% OP	5,064	4,793	$66,279.20	$1.36	$13.09	7.01%
GENTAMICIN SOL 0.3% OP	4,743	4,478	$57,103.19	$1.12	$12.04	6.04%
CIPROFLOXACN SOL 0.3% OP	2,046	1,914	$24,082.31	$1.18	$11.77	2.55%
SOD SULFACET SOL 10% OP	1,611	1,567	$59,844.22	$2.11	$37.15	6.33%

[73] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 11/2017. Last accessed 12/22/2017.

[74] OptumRx Clinical Services Department. Vigamox® (moxifloxacin) first time generic. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_vigamox_2017-0705.pdf. Issued 2017. Last accessed 12/22/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
GENTAK OIN 0.3% OP	705	679	$14,280.21	$2.49	$20.26	1.51%
TRIMETHOPRIM SOL POLYMYXN	460	453	$6,567.65	$1.00	$14.28	0.69%
NEO/POLY/GRA SOL OP	455	436	$22,062.42	$3.38	$48.49	2.33%
SULFACET SOD SOL 10% OP	376	371	$14,927.34	$2.44	$39.70	1.58%
BLEPH-10 SOL 10% OP	16	15	$456.21	$3.04	$28.51	0.05%
NEOSPORIN SOL OP	1	1	$47.99	$16.00	$47.99	0.01%
SUBTOTAL	**33,995**	**32,040**	**$574,678.94**	**$1.32**	**$16.90**	**60.77%**
OCULAR ANTIBIOTIC LIQUIDS: TIER-2						
LEVOFLOXACIN SOL 0.5%	2	2	$89.88	$3.60	$44.94	0.01%
SUBTOTAL	**2**	**2**	**$89.88**	**$3.60**	**$44.94**	**0.01%**
OCULAR ANTIBIOTIC LIQUIDS: TIER-3						
VIGAMOX DRO 0.5%	350	264	$56,273.54	$12.49	$160.78	5.95%
BESIVANCE SUS 0.6%	112	87	$15,857.99	$6.30	$141.59	1.68%
GATIFLOXACIN SOL 0.5%	54	47	$4,776.03	$7.39	$88.45	0.50%
AZASITE SOL 1%	28	16	$4,595.82	$6.65	$164.14	0.49%
MOXEZA SOL 0.5%	8	8	$1,235.94	$10.30	$154.49	0.13%
SUBTOTAL	**552**	**422**	**$82,739.32**	**$9.76**	**$149.89**	**8.75%**
OCULAR ANTIBIOTIC OINTMENTS						
OCULAR ANTIBIOTIC OINTMENTS: TIER-1						
ERYTHROMYCIN OIN OP	7,800	7,333	$103,223.97	$1.67	$13.23	10.91%
ERYTHROMYCIN OIN 5MG/GM	629	576	$10,980.97	$2.22	$17.46	1.16%
TOBREX OIN 0.3% OP	219	213	$43,937.83	$23.72	$200.63	4.65%
BACIT/POLYMY OIN OP	182	163	$3,319.68	$2.23	$18.24	0.35%
POLYCIN OIN OP	38	37	$753.69	$2.22	$19.83	0.08%
NEO-POLYCIN OIN OP	32	19	$1,236.62	$4.46	$38.64	0.13%
NEO/BAC/POLY OIN OP	30	29	$1,280.50	$4.71	$42.68	0.14%
GENTAMICIN OIN 0.3% OP	11	11	$204.94	$1.38	$18.63	0.02%
AK-POLY-BAC OIN OP	3	3	$48.67	$2.12	$16.22	0.01%
NEO/POLY/BAC OIN /HC 1% OP	1	1	$54.65	$6.83	$54.65	0.01%
SUBTOTAL	**8,945**	**8,385**	**$165,041.52**	**$2.32**	**$18.45**	**17.46%**
OCULAR ANTIBIOTIC OINTMENTS: TIER-2						
BACITRACIN OIN OP	158	140	$15,630.45	$10.25	$98.93	1.65%
CILOXAN OIN 0.3% OP	10	5	$2,055.45	$23.90	$205.55	0.22%
SUBTOTAL	**168**	**145**	**$17,685.90**	**$10.98**	**$105.27**	**1.87%**
OCULAR ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
OCULAR ANTIBIOTIC/STEROID COMBINATIONS: TIER-1						
NEO/POLY/DEX SUS 0.1% OP	1,558	1,404	$29,861.69	$1.44	$19.17	3.16%
NEO/POLY/DEX OIN 0.1% OP	588	506	$9,993.02	$1.86	$16.99	1.06%
SULF/PRED NA SOL OP	2	2	$43.58	$1.61	$21.79	0.00%
SUBTOTAL	**2,148**	**1,912**	**$39,898.29**	**$1.52**	**$18.57**	**4.22%**
OCULAR ANTIBIOTIC/STEROID COMBINATIONS: TIER-2						
TOBRA/DEXAME SUS 0.3-0.1%	579	535	$40,157.41	$4.57	$69.36	4.25%
TOBRADEX OIN 0.3-0.1%	81	63	$15,786.11	$20.85	$194.89	1.67%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ZYLET SUS 0.5-0.3%	36	34	$7,649.07	$11.22	$212.47	0.81%
TOBRADEX ST SUS 0.3-0.05	9	9	$1,672.04	$17.98	$185.78	0.18%
NEO/POLY/HC SUS OP	2	2	$240.74	$10.47	$120.37	0.03%
BLEPHAMIDE SUS OP	2	1	$251.48	$4.19	$125.74	0.03%
SUBTOTAL	**709**	**644**	**$65,756.85**	**$6.33**	**$92.75**	**6.97%**
TOTAL	**46,519**	**39,619***	**$945,890.70**	**$1.71**	**$20.33**	**100%**

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

Fiscal Year 2017 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

- Over-the-counter (OTC) treatments for lice are a covered benefit for pediatric members. A prescription is required for coverage, and prescriptions are limited to one individual package size for a seven day supply.

Pediculicide Medications Tier-2 Approval Criteria:

1. Trials with all available Tier-1 medication(s) with inadequate response or adverse effect; and
2. Requested medication must be age-appropriate.
3. A clinical exception to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

The following restrictions also apply for each individual product based on U.S. Food and Drug Administration (FDA) approval information:

1. **Crotamiton (Eurax®) Cream & Lotion:**
   a. Diagnosis of scabies; and
   b. Member must be at least 18 years of age; and
   c. Member must have used permethrin 5% cream in the past seven to fourteen days with inadequate results; and
   d. A quantity limit of 60 grams per 30 days will apply.
2. **Ivermectin (Sklice®) Lotion:**
   a. Member must be at least six months of age; and
   b. A quantity limit of 117mL per seven days will apply.
3. **Lindane Shampoo:**
   a. Member must be at least 13 years of age or weigh at least 110 pounds; and
   b. A quantity limit of 60mL per seven days will apply; and
   c. One seven day supply per 30 days maximum.
4. **Malathion (Ovide®) Lotion:**
   a. Member must be at least six years of age; and
   b. A quantity limit of 60mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.

5. **Spinosad (Natroba™) Suspension:**
   a. Member must be at least six months of age; and
   b. A quantity limit of 120mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.

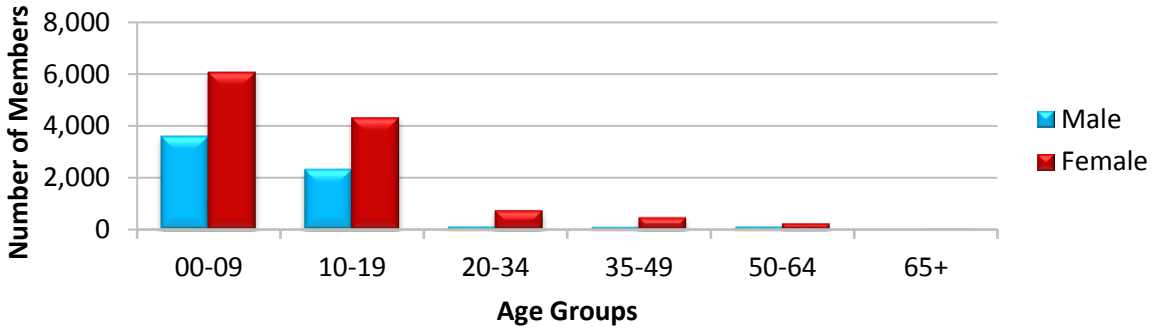
Utilization of Pediculicide Medications: Fiscal Year 2017

Comparison of Fiscal Years

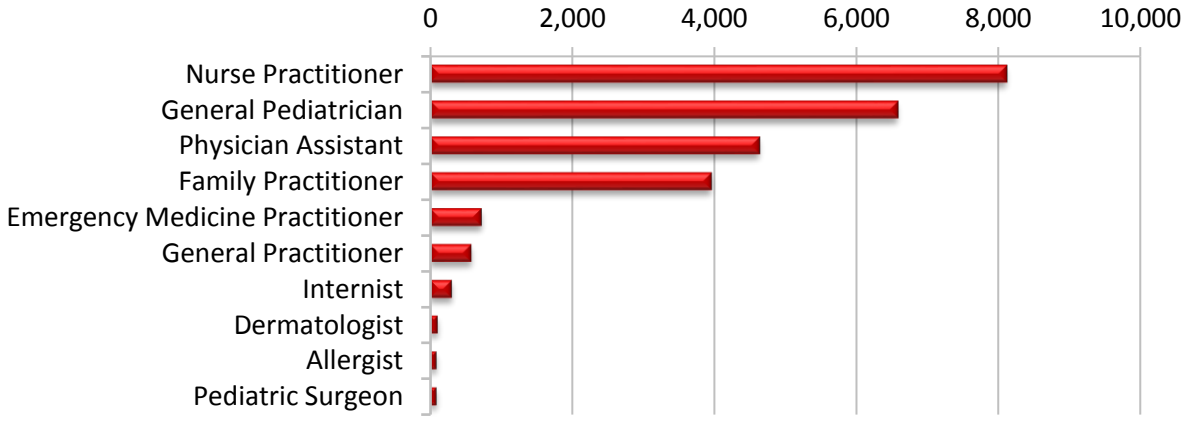
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	17,810	24,788	$2,279,593.31	$91.96	$9.05	1,872,136	251,822
2017	18,102	25,722	$3,859,513.95	$150.05	$16.39	2,114,248	235,428
% Change	**1.60%**	**3.80%**	**69.30%**	**63.20%**	**81.10%**	**12.90%**	**-6.50%**
Change	**292**	**934**	**$1,579,920.64**	**$58.09**	**$7.34**	**242,112**	**-16,394**

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

Demographics of Members Utilizing Pediculicide Medications



Top Prescriber Specialties of Pediculicide Medications by Number of Claims

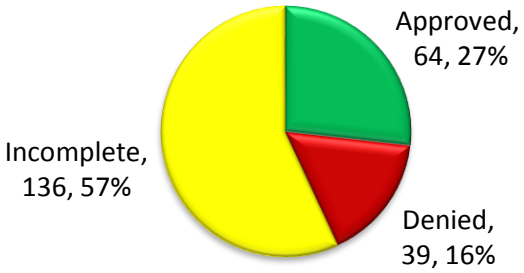


Prior Authorization of Pediculicide Medications

There were 239 prior authorization requests submitted for pediculicide medications during fiscal year 2017. Computer edits are in place to detect lower tiered medications in a member's

recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[75]

Anticipated Patent Expiration(s):

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

Recommendations

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

Utilization Details of Pediculicide Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 PRODUCTS					
PERMETHRIN PRODUCTS					
PERMETHRIN CRE 5%	13,616	10,611	$965,126.84	1.28	$70.88
LICE TREATMT LOT 1%	1,269	897	$17,420.23	1.41	$13.73
LICE TRTMNT LIQ 1%	864	628	$11,259.22	1.38	$13.03
PERMETHRIN LOT 1%	275	218	$3,558.63	1.26	$12.94
LICE TREATME LOT 1%	61	51	$639.65	1.2	$10.49
SM LICE LOT TREATMNT 1%	41	35	$522.62	1.17	$12.75
SUBTOTAL	**16,126**	**12,198**	**$998,527.19**	**1.32**	**$61.92**
IVERMECTIN PRODUCTS					
SKLICE LOT 0.5%	8,811	6,140	$2,693,211.37	1.44	$305.66
SUBTOTAL	**8,811**	**6,140**	**$2,693,211.37**	**1.44**	**$305.66**
SPINOSAD PRODUCTS					
SPINOSAD SUS 0.9%	540	437	$107,373.49	1.24	$198.84
NATROBA SUS 0.9%	235	190	$57,783.31	1.24	$245.89
SUBTOTAL	**775**	**616**	**$165,156.80**	**1.26**	**$213.11**

[75] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2017. Last accessed 01/23/2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 SUBTOTAL	**25,712**	**18,098**	**$3,856,895.36**	**1.42**	**$150.00**
TIER-2 PRODUCTS$^{\Delta}$					
BENZYL ALCOHOL PRODUCTS					
ULESFIA LOT 5%	3	2	$532.95	1.5	$177.65
SUBTOTAL	**3**	**2**	**$532.95**	**1.5**	**$177.65**
MALATHION PRODUCTS					
MALATHION LOT 0.5%	1	1	$221.14	1	$221.14
SUBTOTAL	**1**	**1**	**$221.14**	**1**	**$221.14**
LINDANE PRODUCTS					
LINDANE SHA 1%	3	3	$353.99	1	$118.00
SUBTOTAL	**3**	**3**	**$353.99**	**1**	**$118.00**
TIER-2 SUBTOTAL	**7**	**6**	**$1,108.08**	**1.17**	**$158.30**
CROTAMITON PRODUCTS					
EURAX LOT 10%	2	2	$1,014.67	1	$507.34
EURAX CRE 10%	1	1	$495.84	1	$495.84
SUBTOTAL	**3**	**3**	**$1,510.51**	**1**	**$503.50**
TOTAL	**25,722**	**18,102***	**$3,859,513.95**	**1.42**	**$150.05**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

$^{\Delta}$The manufacturer of Ulesfia® (benzyl alcohol lotion) no longer has a federal drug rebate agreement and is no longer covered. It is shown in the table above to accurately reflect pediculicide utilization for fiscal year 2017.

Fiscal Year 2017 Annual Review of Prednisolone Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

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

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

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

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

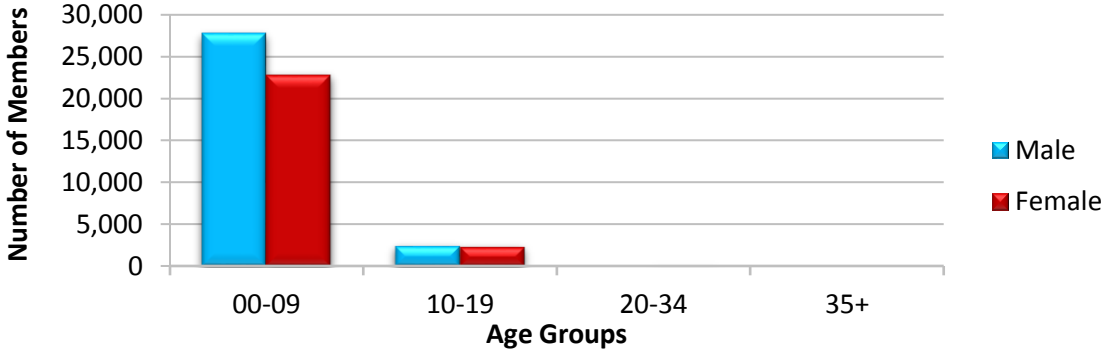
Utilization of Prednisolone Special Formulations: Fiscal Year 2017

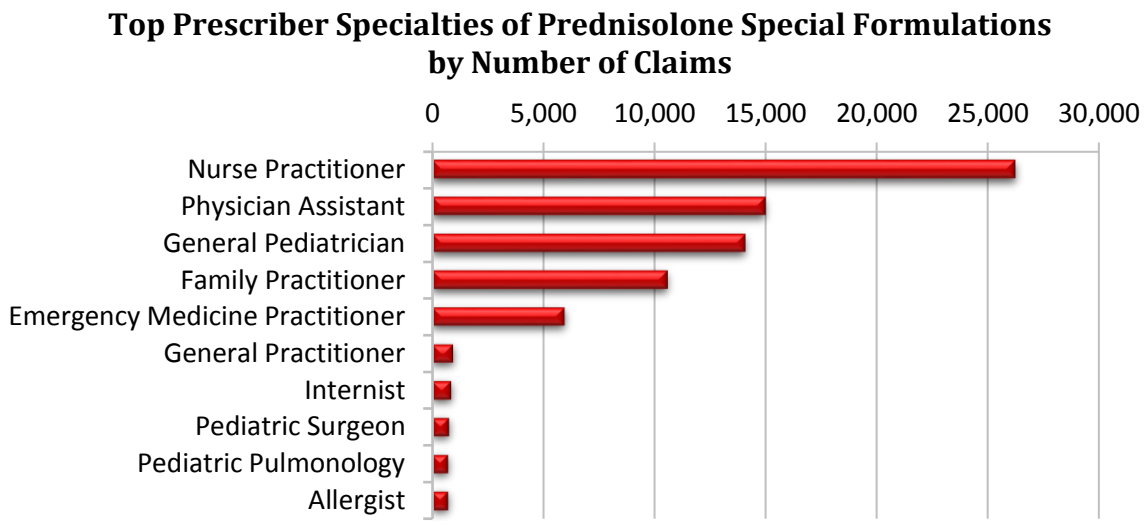
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	58,834	83,189	$1,460,466.51	$17.56	$3.20	3,152,038	456,897
2017	55,485	78,031	$1,074,880.58	$13.78	$2.55	2,878,102	421,223
% Change	**-5.70%**	**-6.20%**	**-26.40%**	**-21.50%**	**-20.30%**	**-8.70%**	**-7.80%**
Change	**-3,349**	**-5,158**	**-$385,585.93**	**-$3.78**	**-$0.65**	**-273,936**	**-35,674**

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

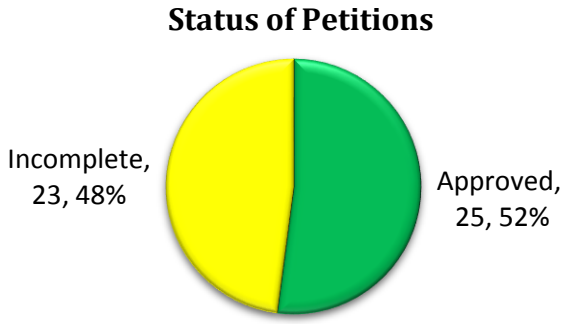
Demographics of Members Utilizing Prednisolone Special Formulations





Prior Authorization of Prednisolone Special Formulations

There were 48 prior authorization requests submitted for prednisolone special formulations during fiscal year 2017. The following chart shows the status of the submitted petitions.



Recommendations

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

Utilization Details of Prednisolone Special Formulations: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISOLONE ORALLY DISINTEGRATING PRODUCTS					
PREDNISOLONE TAB 15MG ODT	1,160	976	$121,754.58	1.19	$104.96
PREDNISOLONE TAB 30MG ODT	467	408	$50,660.60	1.14	$108.48
PREDNISOLONE TAB 10MG ODT	458	376	$38,824.57	1.22	$84.77
SUBTOTAL	**2,085**	**1,720**	**$211,239.75**	**1.21**	**$101.31**
PREDNISOLONE ORAL SOLUTION AND POWDER PRODUCTS					
PREDNISOLONE SOL 15MG/5ML	37,132	28,901	$379,262.64	1.28	$10.21
PREDNISOLONE SOL 15MG/5ML	22,632	18,984	$194,994.21	1.19	$8.62
PREDNISOLONE SYP 15MG/5ML	12,240	10,859	$135,622.17	1.13	$11.08

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PRED SOD PHO SOL 5MG/5ML	2,395	2,175	$90,589.72	1.1	$37.82
PREDNISOLONE SOL 25MG/5ML	1,527	1,314	$62,344.49	1.16	$40.83
PREDNISOLONE POW SOD PHOS	20	1	$827.60	20	$41.38
SUBTOTAL	**75,946**	**54,358**	**$863,640.83**	**1.4**	**$11.37**
TOTAL	**78,031**	**55,485***	**$1,074,880.58**	**1.41**	**$13.78**

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

Fiscal Year 2017 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Prenatal Vitamins Approval Criteria:

- Most brand formulation prenatal vitamins require prior authorization for SoonerCare members. Preferred products do not require prior authorization. Products that are not listed on the preferred product list are non-preferred, and require prior authorization.
- Updated versions of the preferred products list can be downloaded from www.okhca.org/providers/rx.
- The SoonerCare prenatal vitamin category is modified throughout the fiscal year and adjusted for price fluctuations and supplemental rebate participation.

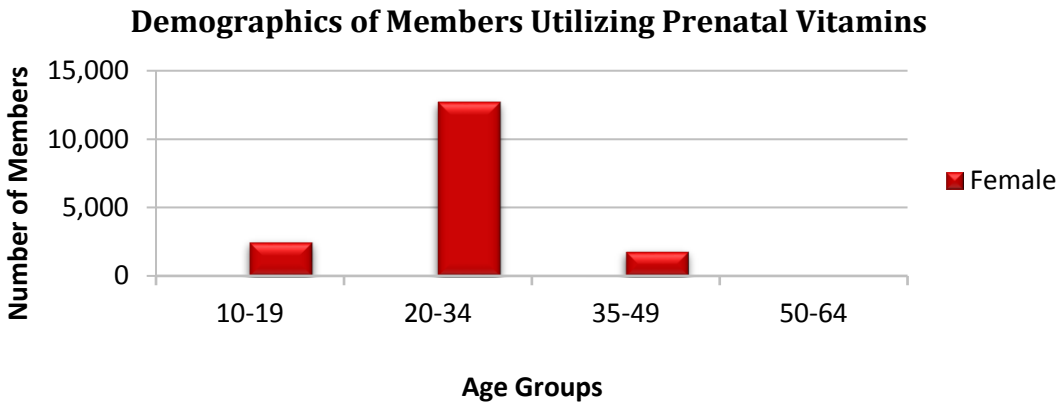
Utilization of Prenatal Vitamins: Fiscal Year 2017

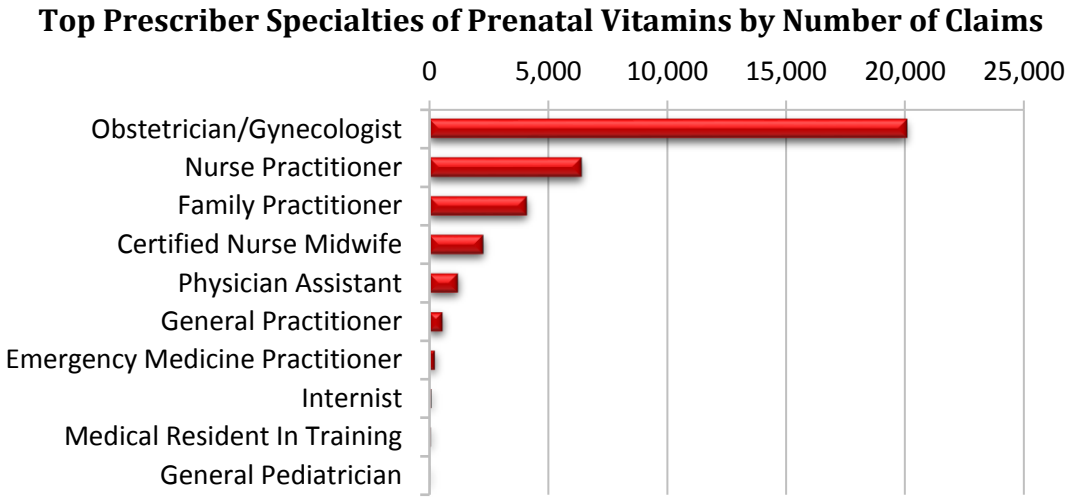
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	17,134	34,849	$1,785,266.71	$51.23	$1.18	1,743,393	1,507,519
2017	16,882	35,288	$2,226,259.37	$63.09	$1.47	1,698,290	1,509,554
% Change	**-1.50%**	**1.30%**	**24.70%**	**23.20%**	**24.60%**	**-2.60%**	**0.10%**
Change	**-252**	**439**	**$440,992.66**	**$11.86**	**$0.29**	**-45,103**	**2,035**

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

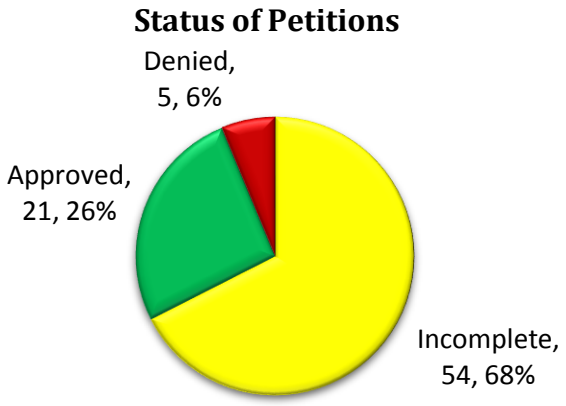
- Based on the decline in the percentage of members utilizing prenatal vitamins compared to the number of deliveries, in November 2016 the College of Pharmacy presented an update on the drug utilization review of prenatal vitamins to the Drug Utilization Review board. The College of Pharmacy recommendeded incorporating regular prenatal education, based on previous successful interventions, into its work-flow to maintain increased utilization of prenatal vitamins. Additionally, opportunities for new interventions are sought wherever possible. Starting in March 2017, a message was implemented to be utilized when evaluating prior authorizations for Soon To Be Sooners (STBS) members to encourage use of prenatal vitamins when there are no paid claims in the members history.





Prior Authorization of Prenatal Vitamins

There were 80 prior authorization requests submitted for prenatal vitamins during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Recommendations

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

Utilization Details of Prenatal Vitamins: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
CONCEPT DHA CAP	5,781	2,858	$221,038.85	$0.93	$38.24	2.02
VITAFOL CAP ULTRA	4,098	1,883	$536,894.21	$3.72	$131.01	2.18
PNV PRENATAL TAB PLUS	3,572	2,093	$51,634.72	$0.30	$14.46	1.71
CITRANATAL MIS 90 DHA	3,319	1,519	$339,855.37	$3.27	$102.40	2.18
CITRANATAL HARMONY	2,661	1,138	$335,330.07	$3.38	$126.02	2.34
FOLIVANE-OB CAP	2,292	1,348	$75,930.14	$0.78	$33.13	1.7
TARON-C DHA CAP	1,696	888	$59,971.32	$0.84	$35.36	1.91
CONCEPT OB CAP	1,676	959	$61,463.27	$0.80	$36.67	1.75
VOL-PLUS TAB	1,649	1,257	$57,367.26	$0.40	$34.79	1.31
PRENAT PLUS TAB 27-1MG	1,420	947	$18,599.27	$0.27	$13.10	1.5
CITRANATAL PAK DHA	1,043	461	$101,868.55	$3.17	$97.67	2.26
CITRANATAL PAK ASSURE	921	411	$94,915.13	$3.36	$103.06	2.24
PRENATAL VIT LOW IRON	795	473	$7,060.90	$0.18	$8.88	1.68
VITAFOL-NANO TAB	679	327	$88,524.40	$3.66	$130.37	2.08
PROVIDA OB CAP	573	318	$31,668.41	$1.02	$55.27	1.8
VITAFOL FE+ CAP	523	259	$54,733.98	$3.27	$104.65	2.02
PRENATAL TAB 27-1MG	383	255	$4,976.94	$0.29	$12.99	1.5
SE-NATAL 19 TAB	336	186	$7,479.11	$0.54	$22.26	1.81
CITRANATAL MIS B-CALM	310	179	$25,702.40	$2.30	$82.91	1.73
PREPLUS TAB 27-1MG	236	135	$3,132.25	$0.28	$13.27	1.75
COMPLETE NAT PAK DHA	230	103	$6,121.39	$0.87	$26.61	2.23
NIVA-PLUS TAB	191	159	$3,900.72	$0.25	$20.42	1.2
VIRT-C DHA CAP	151	102	$5,816.08	$0.90	$38.52	1.48
COMPLETENATE CHW	146	84	$3,395.23	$0.59	$23.26	1.74
PRENATA CHW 29-1MG	125	88	$2,017.90	$0.30	$16.14	1.42
TRINATAL RX TAB 1	123	95	$2,851.43	$0.27	$23.18	1.29
SE-NATAL 19 CHW	80	61	$2,414.40	$0.66	$30.18	1.31
VITAFOL CHW GUMMIES	76	53	$6,755.57	$2.44	$88.89	1.43
CITRANATAL TAB RX	48	32	$6,573.57	$2.44	$136.95	1.5
VOL-TAB RX TAB	48	37	$1,319.23	$0.41	$27.48	1.3
VITAFOL-OB PAK +DHA	21	17	$2,575.66	$3.73	$122.65	1.24
PRENATAL VIT TAB PLUS	20	15	$247.64	$0.26	$12.38	1.33
VIRT NATE TAB	15	12	$457.29	$0.38	$30.49	1.25
ENBRACE HR CAP	13	2	$2,412.55	$4.23	$185.58	6.5
VP-GGR-B6 TAB PRENATAL	10	6	$265.04	$0.66	$26.50	1.67
VIRT-ADVANCE 90-1MG	10	9	$157.03	$0.24	$15.70	1.11
PNV TABS TAB 29-1MG	10	9	$170.66	$0.44	$17.07	1.11
ULTIMATECARE CAP ONE	3	2	$113.05	$0.75	$37.68	1.5

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
PRENATE CHW 0.6-0.4	3	1	$492.81	$5.48	$164.27	3
PRENATAL PLS MV + DHA	1	1	$30.05	$1.00	$30.05	1
VIRT-VITE GT TAB 90-1MG	1	1	$25.52	$0.28	$25.52	1
TOTAL	**35,288**	**16,882***	**$2,226,259.37**	**$1.47**	**$63.09**	**2.09**

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

Fiscal Year 2017 Annual Review of Procysbi® (Cysteamine Bitartrate)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Procysbi® (Cysteamine Bitartrate) Approval Criteria:

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

Utilization of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	1	2	$4,478.49	$2,239.24	$74.64	360	60
2017	1	1	$2,307.17	$2,307.17	$76.91	60	30
% Change	**0.00%**	**-50.00%**	**-48.50%**	**3.00%**	**3.00%**	**-83.30%**	**-50.00%**
Change	**0**	**-1**	**-$2,171.32**	**$67.93**	**$2.27**	**-300**	**-30**

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

Demographics of Members Utilizing Procysbi® (Cysteamine Bitartrate)

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

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

- The only prescriber specialty listed on paid pharmacy claims for Procysbi® (cysteamine bitartrate) during fiscal year 2017 was a general pediatrician.

Prior Authorization of Procysbi® (Cysteamine Bitartrate)

There were 6 prior authorization requests submitted for Procysbi® (cysteamine bitartrate) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions

Market News and Updates[76]

Anticipated Patent Expiration(s):

- Procysbi® (cysteamine bitartrate): June 2034

Recommendations

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

[76] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 12/06/2017.

Fiscal Year 2017 Annual Review of Pulmonary Arterial Hypertension (PAH) Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Revatio® (Sildenafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist.
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

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

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; and
4. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of PAH must have previous failed trials of at least one of each of the following categories:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP); and
5. Female members and all healthcare professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® REMS program.
6. A quantity limit of 90 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Previous failed trials of at least one of each of the following categories:
   a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of 90 tablets per 30 days will apply.

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Previous failed trials of at least one of each of the following categories:
   a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Female members and all healthcare professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® REMS program.
5. A quantity limit of 30 tablets per 30 days will apply.

Uptravi® (Selexipag) Tablets Approval Criteria:

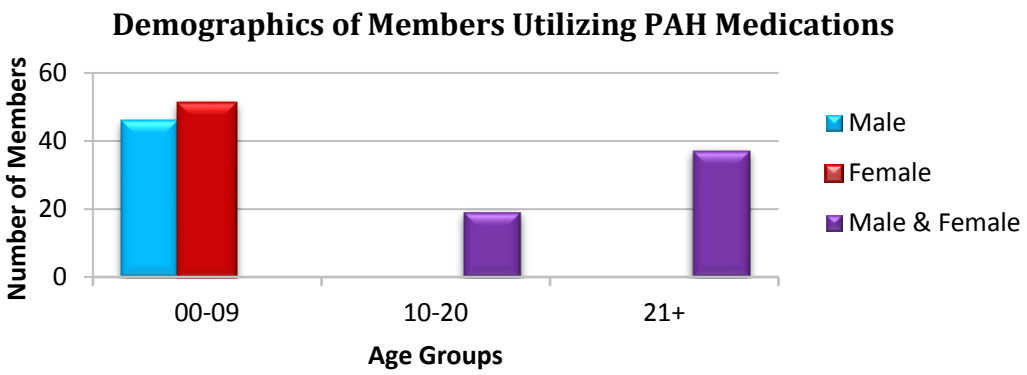
1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Previous failed trials of at least one of each of the following categories (alone or in combination):
   a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
   b. Letairis®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

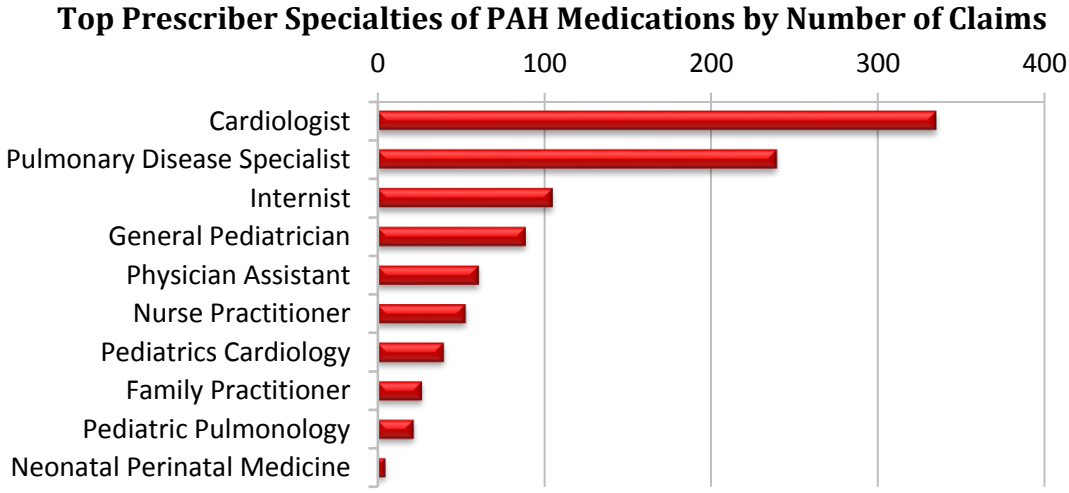
Utilization of PAH Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	116	762	$3,385,214.21	$4,442.54	$145.68	58,877	23,237
2017	133	991	$5,546,472.80	$5,596.84	$187.80	85,521	29,534
% Change	**14.70%**	**30.10%**	**63.80%**	**26.00%**	**28.90%**	**45.30%**	**27.10%**
Change	**17**	**229**	**$2,161,258.59**	**$1,154.30**	**$42.12**	**26,644**	**6,297**

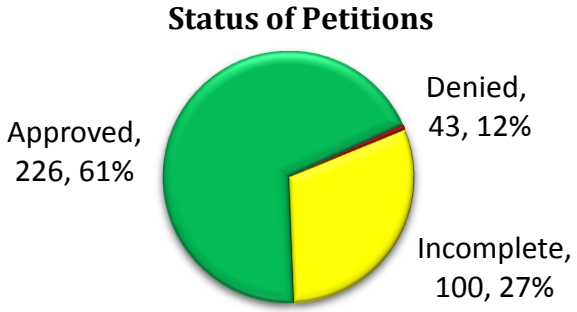
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of PAH Medications

There were 369 prior authorization requests submitted for PAH medications during fiscal year 2017. The following chart shows the status of the submitted petitions during fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[77]

- Adcirca® (tadalafil): May 2021
- Adempas® (riociguat): April 2023

[77] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 11/2017. Last accessed 12/21/2017.

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

New(s):

- **September 2017:** The FDA has expanded the approved age for bostentan (Tracleer®) from adults to include ages 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR) which is expected to result in an improvement in exercise ability. Bosentan is an endothelin receptor antagonist and is the first FDA-approved medication for children with PAH. In addition to the 62.5mg and 125mg doses available, a new 32mg strength tablet will be available that is scored to allow weight-based dose adjustments for younger patients. The new formulation can also be dispersed in a teaspoon of water before administered orally.[78]

Pipeline(s):

- **October 2017:** Arena Pharmaceuticals' next-generation PAH therapy, ralinepag (APD811), showed significant improvements in PVR and the 6-minute walk distance (6MWD) demonstrating increased blood flow and exercise capacity compared to placebo in a Phase 2 clinical trial. Ralinepag is a selective prostacyclin receptor agonist causing increased vasodilation. Based on these positive results, Arena is planning a Phase 3 clinical trial program with ralinepag.[79]

Recommendations

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

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PHOSPHODIESTERASE-5 INHIBITORS (PDE-5)						
SILDENAFIL TAB 20MG	289	53	$13,110.24	$1.55	$45.36	0.24%
REVATIO SUS 10MG/ML	226	51	$1,771,521.82	$251.10	$7,838.59	31.94%
ADCIRCA TAB 20MG	173	24	$328,365.90	$62.38	$1,898.07	5.92%
SUBTOTAL	**688**	**128**	**$2,112,997.96**	**$101.82**	**$3,071.22**	**38.10%**
SOLUABLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	3	1	$27,622.95	$306.92	$9,207.65	0.50%
SUBTOTAL	**3**	**1**	**$27,622.95**	**$306.92**	**$9,207.65**	**0.50%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						

[78] Brown, T. FDA Approves First Medication for Pediatric PAH, Bosentan. *Medscape.* Available online at: https://www.medscape.com/viewarticle/885342. Issued 09/2017. Last accessed 01/03/2018.

[79] Steward, J. Arena Pharmaceutical's Ralinepag Shows Promise in Treating PAH in Phase 2 Clinical Trial. *Pulmonary Hypertension News*. Available online at: https://pulmonaryhypertensionnews.com/2017/10/20/arena-pharmaceuticals-announces-late-breaking-presentation-of-positive-phase-2-results-with-ralinepag-in-patients-with-pulmonary-arterial-hypertension-at-the-american-college-of-chest-physicians-2017/. Issued 10/2016. Last accessed 01/03/2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TRACLEER TAB 62.5MG	63	9	$212,034.44	$117.80	$3,365.63	3.82%
LETAIRIS TAB 10MG	56	9	$496,911.65	$295.78	$8,873.42	8.96%
OPSUMIT TAB 10MG	43	7	$341,854.52	$271.53	$7,950.11	6.16%
LETAIRIS TAB 5MG	11	3	$158,346.40	$479.84	$14,395.13	2.85%
TRACLEER TAB 125MG	4	1	$39,066.16	$325.55	$9,766.54	0.70%
SUBTOTAL	**177**	**29**	**$1,248,213.17**	**$240.55**	**$7,052.05**	**22.49%**
PROSTACYCLIN VASODILATORS						
ORENITRAM TAB 2.5MG	24	4	$818,217.65	$1,144.36	$34,092.40	14.75%
TYVASO REFIL SOL 0.6MG/ML	20	2	$298,211.14	$532.52	$14,910.56	5.38%
UPTRAVI TAB 800MCG	14	2	$194,649.55	$499.10	$13,903.54	3.51%
FLOLAN INJ 1.5MG	12	1	$101,206.23	$276.52	$8,433.85	1.82%
REMODULIN INJ 10MG/ML	12	1	$432,714.10	$1,201.98	$36,059.51	7.80%
UPTRAVI TAB 200MCG	10	3	$182,819.66	$816.16	$18,281.97	3.30%
ORENITRAM TAB 0.25MG	10	5	$23,971.95	$84.11	$2,397.20	0.43%
ORENITRAM TAB 0.125MG	9	3	$8,341.54	$31.84	$926.84	0.15%
ORENITRAM TAB 1MG	7	4	$34,701.17	$165.24	$4,957.31	0.63%
REMODULIN INJ 5MG/ML	3	1	$30,621.30	$437.45	$10,207.10	0.55%
UPTRAVI TAB 200/800MCG	1	1	$22,999.28	$766.64	$22,999.28	0.41%
REMODULIN INJ 2.5MG/ML	1	1	$9,185.15	$306.17	$9,185.15	0.17%
SUBTOTAL	**123**	**28**	**$2,157,638.72**	**$616.12**	**$17,541.78**	**38.90%**
TOTAL	**991**	**133***	**$5,546,427.80**	**$187.80**	**$5,596.84**	**100%**

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

Fiscal Year 2017 Annual Review of Qualaquin® (Quinine Sulfate)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Qualaquin® (Quinine Sulfate) Approval Criteria:

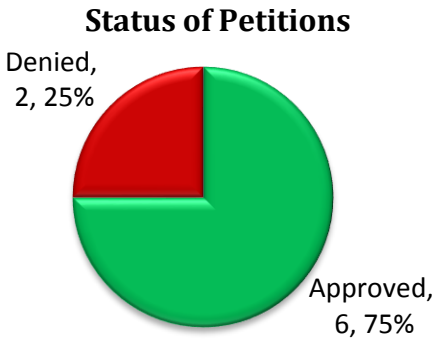
1. An FDA approved diagnosis of malaria.
2. Off-label use for the prevention/treatment of leg cramps and other related conditions will not be covered.

Utilization of Qualaquin® (Quinine Sulfate): Fiscal Year 2017

There was no utilization of Qualaquin® (quinine sulfate) during fiscal year 2017.

Prior Authorization of Qualaquin® (Quinine Sulfate)

There were 8 prior authorization requests submitted for Qualaquin® (quinine sulfate) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates[80]

Patent Expiration(s):

- There are no unexpired patents for Qualaquin® (quinine sulfate) and multiple generic formulations are available.

Recommendations

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

[80] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 02/2018. Last accessed 04/05/2018.

Fiscal Year 2017 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Qutenza® (Capsaicin 8% Patch) Approval Criteria:

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

Utilization of Qutenza® (Capsaicin 8% Patch): Fiscal Year 2017

There was no utilization of Qutenza® (capsaicin 8% patch) during fiscal year 2017.

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were no prior authorization requests submitted for Qutenza® (capsaicin 8% patch) during fiscal year 2017.

Market News and Updates[81]

Anticipated Patent Expiration(s):

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

Recommendations

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

[81] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 11/14/2017.

Fiscal Year 2017 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Review

Introduction[82,83,84,85,86]

Urea cycle disorders (UCDs) are inherited deficiencies of enzymes or transporters necessary for the synthesis of urea from ammonia. Absence of these enzymes or transporters results in the accumulation of toxic levels of ammonia in the blood, with possible complications of confusion and eventually disorientation, swelling of the brain, brain damage, coma, and death. UCDs occur in 1 in 30,000 newborns in the United States and are often diagnosed when the child is still an infant. Signs may include abnormal amino acids in blood and urine, abnormal level(s) of orotic acid in blood or urine, or high blood ammonia level. Within the first week after birth, the baby may develop symptoms of confusion, decreased food intake, disliking protein-containing foods, increased sleepiness, difficulty waking, nausea, and vomiting. Neonatal onset UCDs are caused by severe enzyme deficiencies or complete absence of enzyme function. Individuals with childhood or adult onset disease have partial enzyme deficiencies. The percentage of enzyme function, and therefore ability to rid the body of ammonia varies widely between individuals with partial enzyme deficiencies.

The treatment of UCDs consists of dietary protein management to limit ammonia production in conjunction with medications and/or supplements which provide alternative pathways for the removal of ammonia from the bloodstream. There are two medications approved by the U.S. Food and Drug Administration (FDA) for chronic management of UCDs, both of which are "ammonia scavengers", providing alternative pathways for removal of ammonia from the bloodstream and helping to prevent hyperammonemia. Buphenyl® (sodium phenylbutyrate) was FDA approved in 1996 and is available as an oral powder and oral tablets. Sodium phenylbutyrate is dosed based on body surface area (BSA), three to six times daily with food. The oral powder may be mixed with solid food, liquid food, or water prior to administration. Buphenyl® contains 125mg sodium per gram of sodium phenylbutyrate, which, at a maximum dose of 20g sodium phenylbutyrate per day, results in 2,500mg of sodium per day. Ravicti® (glycerol phenylbutyrate) was FDA approved in 2013 and is available as an oral solution. Glycerol phenylbutyrate should be given in three equally divided doses, each rounded up to the

[82] Hereditary Urea Cycle Abnormality. *Medline Plus*. Available online at: http://www.nlm.nih.gov/medlineplus/ency/article/000372.htm. Last revised 10/27/2015. Last accessed 01/23/2018.
[83] Lee, B. Urea Cycle Disorders: Management. *UpToDate*. Available online at: http://www.uptodate.com/contents/urea-cycle-disorders-management?search=urea+cycle+disorder&source=search_result&selectedTitle=2%7E53. Last revised 01/09/2018. Last accessed 01/23/2018.
[84] Urea Cycle Disorders Treatment Guidelines. Rare Clinical Diseases Research Network. Available online at: http://rarediseasesnetwork.epi.usf.edu/ucdc/physicians/guidelines-main.htm. Last revised 2005. Last accessed 12/17/2018.
[85] Buphenyl® (Sodium Phenylbutyrate) Package Insert. MedLibrary.org. Available online at: https://medlibrary.org/lib/rx/meds/buphenyl-3/. Last revised 05/26/2016. Last accessed 01/23/2018.
[86] Ravicti® (Glycerol Phenylbutyrate) Package Insert. MedLibrary.org. Available online at: https://medlibrary.org/lib/rx/meds/ravicti-1/. Last revised 10/07/2015. Last accessed 01/23/2018.

nearest 0.5mL, and should be taken with food. Glycerol phenylbutyrate dosing is based on BSA, previous dose of sodium phenylbutyrate, residual urea synthetic capacity, dietary protein requirements, and/or diet adherence, and the maximum total daily dosage is 17.5mL (19g). These medications are administered multiple times per day in order to ensure continual removal of toxic ammonia from the bloodstream. When optimal management fails, or in the case of neonatal onset of the UCDs, carbamyl phosphate synthetase (CPS) or ornithine transcarbamylase (OTC) deficiency, liver transplantation becomes a treatment option.

Current Prior Authorization Criteria

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

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

Utilization of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2017

Comparison of Fiscal Years for Ravicti® (Glycerol Phenylbutyrate)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	3	32	$470,850.61	$14,714.08	$510.68	3,025	922
2017	8	42	$865,562.10	$20,608.62	$742.33	5,325	1,166
% Change	**166.70%**	**31.30%**	**83.80%**	**40.10%**	**45.40%**	**76.00%**	**26.50%**
Change	**5**	**10**	**$394,711.49**	**$5,894.54**	**$231.65**	**2,300**	**244**

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

Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- There were 8 unique members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2017, and all members were in the 0 to 9 year age group.

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

- The only prescriber specialty listed on paid claims for Ravicti® (glycerol phenylbutyrate) during fiscal year 2017 was genetic counselor. Upon further research, all prescribers were also classified as general pediatricians specializing in medical genetics and clinical genetics.

Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

There were 19 prior authorization requests submitted for Ravicti® (glycerol phenylbutyrate) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):[87]

- Ravicti® (glycerol phenylbutyrate): March 2032

New FDA Approval(s):

- **April 2017:** The FDA approved a supplemental New Drug Application (sNDA) for Ravicti® (glycerol phenylbutyrate) to expand the indication for the treatment of UCDs to include children two months of age and older who have UCDs that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Glycerol phenylbutyrate was first FDA approved in 2013 for use in adults and children two years of age and older.[88]

Recommendations

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

[87] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2017. Last accessed 01/23/2018.

[88] Horizon Pharma News Release: Horizon Pharma plc Announces FDA Approval to Expand the Age Range for Ravicti® (Glycerol Phenylbutyrate) Oral Liquid to People with Urea Cycle Disorders Two Months of Age and Older. Available online at: https://globenewswire.com/news-release/2017/05/01/974919/0/en/Horizon-Pharma-plc-Announces-FDA-Approval-to-Expand-the-Age-Range-for-RAVICTI-glycerol-phenylbutyrate-Oral-Liquid-to-People-with-Urea-Cycle-Disorders-Two-Months-of-Age-and-Older.html. Issued 05/01/2017. Last accessed 01/23/2018.

Fiscal Year 2017 Annual Review of Retisert® (Fluocinolone Intravitreal Implant)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria:

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

Utilization of Retisert® (Fluocinolone Intravitreal Implant): Fiscal Year 2017

There was no utilization of Retisert® (fluocinolone intravitreal implant) during fiscal year 2017.

Prior Authorization of Retisert® (Fluocinolone Intravitreal Implant)

There were no prior authorization requests submitted for Retisert® (fluocinolone intravitreal implant) during fiscal year 2017.

Market News and Updates

Anticipated Patent Expiration(s):[89]

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

Recommendations

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

[89] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 11/2017. Last accessed 12/19/2017.

Fiscal Year 2017 Annual Review of Singulair® (Montelukast) and Zyflo CR® (Zileuton Extended-Release)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Singulair® (Montelukast)Approval Criteria:

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

Zyflo CR® [Zileuton Extended-Release (ER)] Approval Criteria:

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

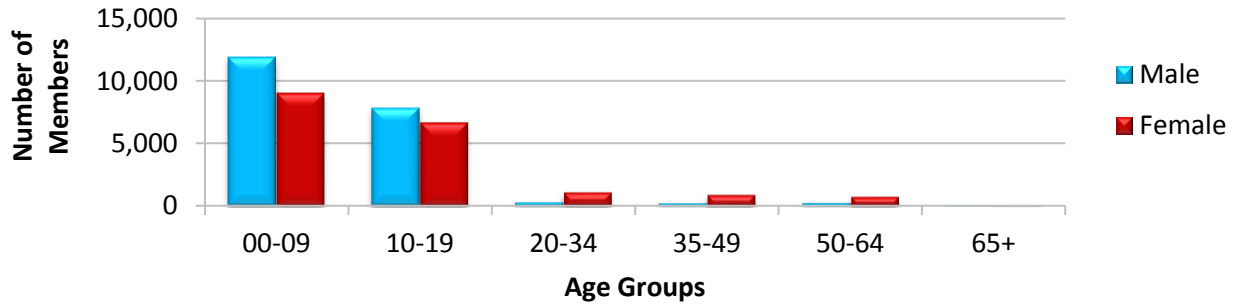
Utilization of Singulair® and Zyflo CR®: Fiscal Year 2017

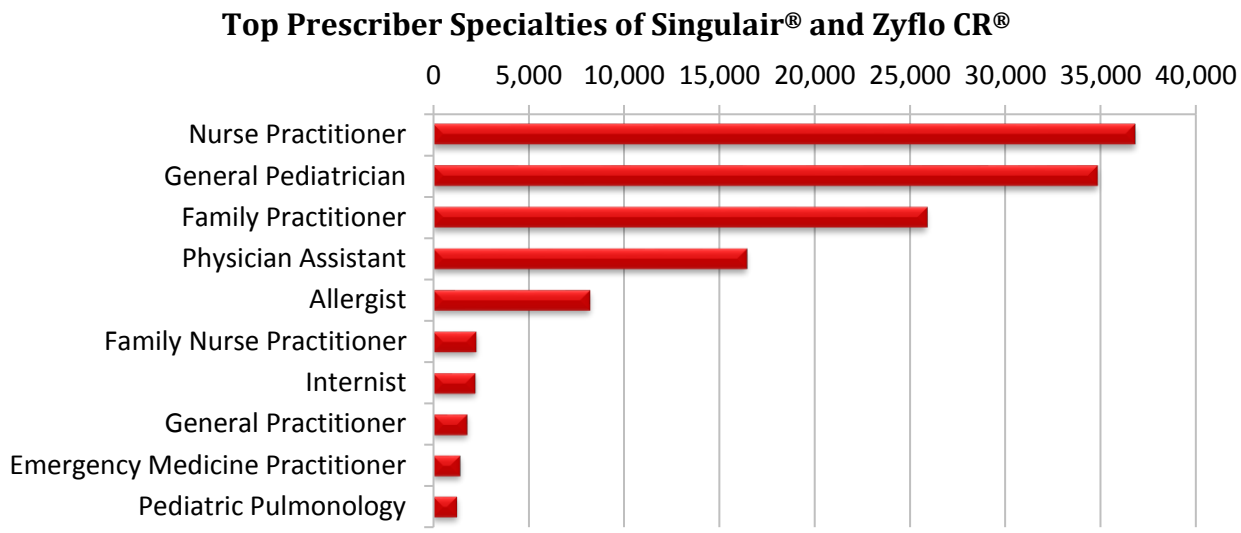
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	36,079	124,184	$1,832,605.11	$14.76	$0.49	3,717,912	3,725,809
2017	39,078	134,728	$2,120,204.48	$15.74	$0.52	4,031,563	4,038,681
% Change	**8.30%**	**8.50%**	**15.70%**	**6.60%**	**6.10%**	**8.40%**	**8.40%**
Change	**2,999**	**10,544**	**$287,599.37**	**$0.98**	**$0.03**	**313,651**	**312,872**

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

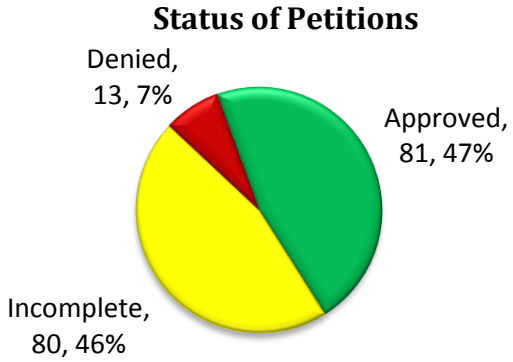
Demographics of Members Utilizing Singulair® and Zyflo CR®





Prior Authorization of Singulair® and Zyflo CR®

There were 174 prior authorization requests submitted for Singular® and Zyflo CR® during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

FDA Approval(s):[90]

- **March 2017:** The U.S. Food and Drug Administration (FDA) approved the first generic for Zyflo CR® (zileuton extended-release) for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Recommendations

The College of Pharmacy does not recommend any changes to the Singulair® (montelukast) and Zyflo CR® (zileuton extended-release) prior authorization criteria at this time.

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[90] U.S. Food and Drug Administration (FDA): First Generic Drug Approvals. Available online at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/. Last revised 10/04/2017. Last accessed 10/16/2017.

Utilization Details of Singulair® and Zyflo CR®: Fiscal Year 2017

Product Utilized	Total Claims	Total Members*	Total Cost	Claims/ Client	Cost/ Claim
MONTELUKAST PRODUCTS					
MONTELUKAST CHW 5MG	54,164	15,605	$748,364.51	3.47	$13.82
MONTELUKAST TAB 10MG	39,302	11,839	$419,136.18	3.32	$10.66
MONTELUKAST CHW 4MG	37,697	12,037	$546,993.81	3.13	$14.51
MONTELUKAST GRA 4MG	3,562	1,768	$395,505.77	2.01	$111.03
SUBTOTAL	**134,725**	**39,077**	**$2,110,000.27**	**3.45**	**$15.66**
ZILEUTON PRODUCTS					
ZYFLO TAB 600MG	3	2	$10,204.21	1.5	$3,401.40
SUBTOTAL	**3**	**2**	**$10,204.21**	**1.5**	**$3,401.40**
TOTAL	**134,728**	**39,078**	**$2,120,204.48**	**3.45**	**$15.74**

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

Fiscal Year 2017 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Smoking Cessation Products Coverage Criteria:

1. All nicotine replacement products (patches, gum, lozenges, and inhalers), Zyban® (bupropion), and Chantix® (varenicline) do not require prior authorization.
2. Effective March 2016, the duration of therapy limit of 180 days was removed for smoking cessation products excluding Chantix® (varenicline). Chantix® (varenicline) may only be used for up to 180 days per calendar year.
3. Smoking cessation products do not count against the six prescription limit per month.
4. Smoking cessation products are available without a co-pay.

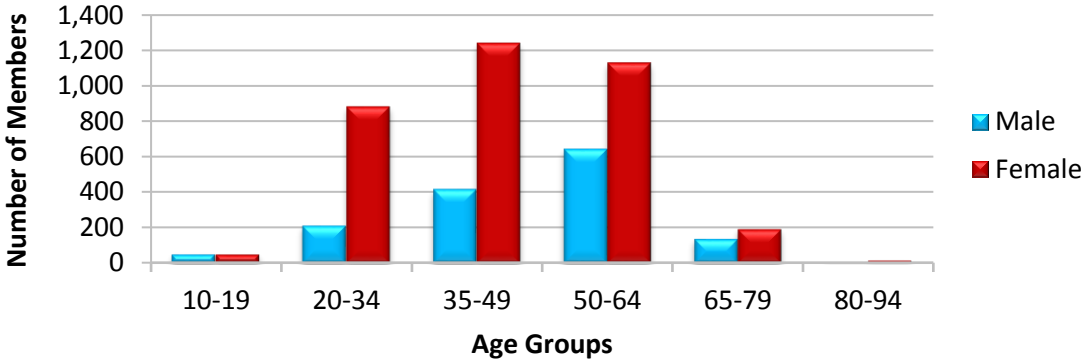
Utilization of Smoking Cessation Products: Fiscal Year 2017

Comparison of Fiscal Years

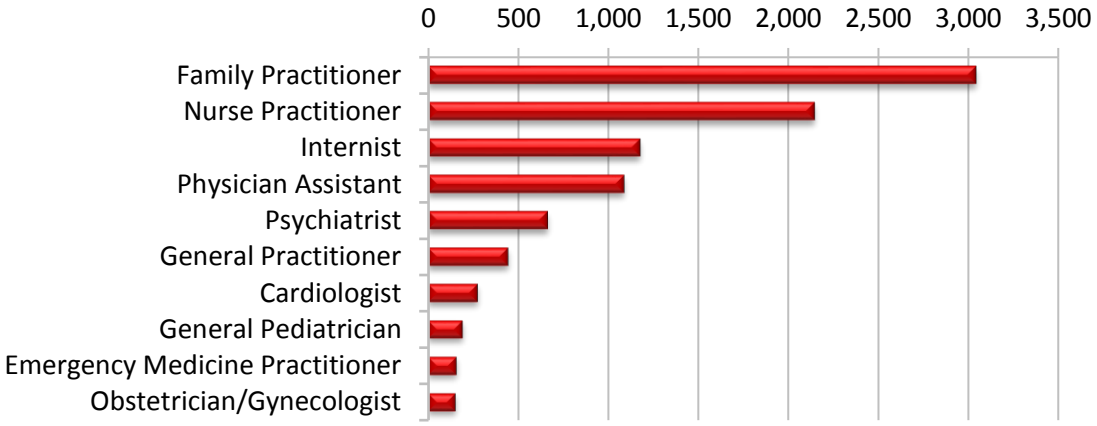
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	4,336	8,587	$1,368,100.30	$159.32	$6.56	426,077	208,407
2017	4,972	10,004	$1,761,945.38	$176.12	$7.23	475,362	243,633
% Change	**14.70%**	**16.50%**	**28.80%**	**10.50%**	**10.20%**	**11.60%**	**16.90%**
Change	**636**	**1,417**	**$393,845.08**	**$16.80**	**$0.67**	**49,285**	**35,226**

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

Demographics of Members Utilizing Smoking Cessation Products



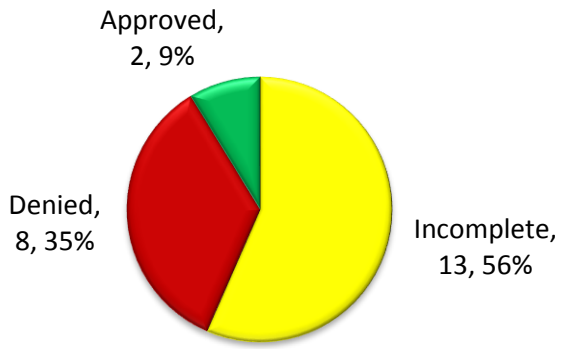
Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 23 prior authorization requests submitted for smoking cessation products during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017,

Status of Petitions



Market News and Updates[91,92]

Anticipated Patent Expiration(s):

- Chantix® (varenicline tablets): August 2022

News:

- **December 2016:** The U.S. Food and Drug Administration (FDA) announced the removal of the Boxed Warning from the Chantix® (varenicline) drug label. Based on the review of a large clinical trial that the FDA required the drug companies to conduct, it was

[91] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 11/15/2017.

[92] FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings. Available online at: https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm. Issued 12/16/2016. Last accessed 11/15/2017.

determined that the risk of serious side effects on mood, behavior, or thinking from Chantix® (varenicline) is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines. Zyban® (bupropion), another smoking cessation medication, was also included in this trial and its label underwent the same revision.

Recommendations

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

Utilization Details of Smoking Cessation Products: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24H	1,740	1,132	$82,120.14	$2.07	$47.20	1.54
NICOTINE TD DIS 14MG/24H	1,108	656	$46,088.37	$2.14	$41.60	1.69
NICOTINE TD DIS 7MG/24HR	469	318	$19,352.01	$2.15	$41.26	1.47
NICOTINE TD DIS 7MG/24HR	287	223	$18,640.98	$2.68	$64.95	1.29
SM NICOTINE DIS 21MG/24HR	241	136	$12,750.58	$2.40	$52.91	1.77
NICODERM CQ DIS 14MG/24HR	183	148	$10,293.61	$2.56	$56.25	1.24
NICOTINE DIS 21MG/24HR	156	122	$7,775.78	$2.10	$49.84	1.28
NICOTINE POL LOZ 4MG MINT	127	41	$6,312.64	$5.15	$49.71	3.1
NICOTROL INH	105	83	$39,566.63	$16.01	$376.83	1.27
HM NICOTINE DIS 14MG/24HR	79	62	$4,266.37	$2.44	$54.00	1.27
SM NICOTINE DIS 14MG/24HR	77	57	$4,356.64	$2.35	$56.58	1.35
NICORETTE LOZ 4MG MINT	77	29	$4,567.96	$4.32	$59.32	2.66
NICODERM CQ DIS 7MG/24HR	75	56	$4,180.00	$2.65	$55.73	1.34
NICOTINE DIS 14MG/24HR	69	56	$3,202.57	$2.11	$46.41	1.23
HM NICOTINE GUM 4MG MINT	63	16	$4,466.33	$4.35	$70.89	3.94
NICOTINE POL LOZ 2MG MINT	62	18	$2,961.36	$3.48	$47.76	3.44
SM NICOTINE DIS 7MG/24HR	48	40	$1,985.87	$2.54	$41.37	1.2
SM NICOTINE GUM 2MG MINT	38	17	$1,635.93	$3.96	$43.05	2.24
NICORELIEF GUM 2MG MINT	33	30	$4,253.98	$4.39	$128.91	1.1
HM NICOTINE LOZ 2MG MINT	31	9	$1,099.97	$2.26	$35.48	3.44
NICOTINE POL GUM 4MG MINT	30	20	$1,778.65	$3.15	$59.29	1.5
NICORETTE GUM 4MG MINT	29	21	$2,130.07	$3.89	$73.45	1.38
NICOTROL NS SPR 10MG/ML	29	16	$14,191.59	$23.15	$489.37	1.81
SM NICOTINE GUM 2MG	24	7	$582.79	$2.56	$24.28	3.43
NICOTINE POL GUM 4MG	24	14	$1,337.80	$2.42	$55.74	1.71
HM NICOTINE LOZ 4MG MINT	24	11	$1,157.49	$2.76	$48.23	2.18
SM NICOTINE GUM 4MG	23	16	$1,011.08	$3.87	$43.96	1.44

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
NICOTINE DIS 7MG/24HR	21	20	$927.65	$1.97	$44.17	1.05
SM NICOTINE GUM 4MG MINT	21	8	$1,156.03	$2.25	$55.05	2.63
NICORETTE GUM 4MG FRUIT	19	12	$1,089.59	$4.05	$57.35	1.58
NICORELIEF GUM 4MG MINT	17	9	$884.18	$2.16	$52.01	1.89
NICOTINE POL GUM 2MG MINT	16	11	$642.05	$2.63	$40.13	1.45
GNP NICOTINE LOZ 4MG MINT	15	4	$652.38	$2.72	$43.49	3.75
NICOTINE POL GUM 2MG CINN	15	10	$655.20	$2.25	$43.68	1.5
NICORETTE GUM 2MG MINT	14	13	$753.09	$2.87	$53.79	1.08
NICOTINE POL GUM 4MG ORIG	13	9	$798.97	$3.55	$61.46	1.44
SM NICOTINE LOZ 4MG MINT	13	10	$590.15	$4.19	$45.40	1.3
NICORETTE LOZ 2MG MINT	12	10	$852.05	$3.35	$71.00	1.2
NICOTINE POL GUM 2MG ORIG	12	12	$410.00	$2.32	$34.17	1
SM NICOTINE LOZ 2MG MINT	11	5	$499.38	$3.24	$45.40	2.2
NICORETTE GUM 2MG CINN	11	7	$581.99	$2.92	$52.91	1.57
GNP NICOTINE DIS 21MG/24HR	8	6	$421.50	$2.11	$52.69	1.33
GNP NICOTINE GUM 4MG MINT	8	4	$711.36	$3.91	$88.92	2
NICOTINE POL GUM 2MG	7	6	$198.13	$2.54	$28.30	1.17
NICORETTE GUM 2MG FRUIT	7	6	$278.96	$3.17	$39.85	1.17
NICORETTE ST GUM 2MG ORIG	6	2	$288.96	$3.25	$48.16	3
NICORETTE GUM 2MG ORIG	6	5	$419.14	$3.81	$69.86	1.2
NICORETTE ST GUM 2MG MINT	6	5	$480.83	$3.88	$80.14	1.2
SM NICOTINE DIS 21MG	5	5	$376.93	$2.69	$75.39	1
NICORELIEF GUM 2MG ORIG	4	4	$290.22	$4.03	$72.56	1
HM NICOTINE GUM 2MG MINT	4	4	$229.25	$3.14	$57.31	1
GNP NICOTINE GUM 2MG MINT	4	3	$91.96	$1.03	$22.99	1.33
NICORELIEF GUM 4MG ORIG	3	3	$97.47	$1.39	$32.49	1
NICORETTE ST GUM 4MG ORIG	1	1	$52.75	$4.40	$52.75	1
NICORETTE GUM 4MG ORIG	1	1	$66.35	$2.21	$66.35	1
NICORETTE LOZ 2MG CHRY	1	1	$41.27	$1.38	$41.27	1
NICORETTE LOZ 4MG CHRY	1	1	$39.10	$1.30	$39.10	1
NICORETTE GUM 4MG CINN	1	1	$48.16	$1.61	$48.16	1
GNP NICOTINE GUM 2MG ORIG	1	1	$45.62	$3.26	$45.62	1
GNP NICOTINE LOZ MINI 2MG	1	1	$35.86	$3.59	$35.86	1
SUBTOTAL	**5,536**	**3,554**	**$316,773.72**	**$2.76**	**$57.22**	**1.56**
VARENICLINE PRODUCTS						
CHANTIX PAK 0.5MG & 1MG	2,062	1,786	$698,211.36	$11.67	$338.61	1.15
CHANTIX PAK 1MG	1,167	682	$394,213.65	$11.78	$337.80	1.71
CHANTIX TAB 1MG	932	479	$310,559.41	$11.54	$333.22	1.95
CHANTIX TAB 0.5MG	133	98	$36,552.47	$10.68	$274.83	1.36
SUBTOTAL	**4,294**	**3,045**	**$1,439,536.89**	**$11.64**	**$335.24**	**1.41**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG	174	110	$5,634.77	$1.06	$32.38	1.58
SUBTOTAL	**174**	**110**	**$5,634.77**	**$1.06**	**$32.38**	**1.58**
TOTAL	**10,004**	**4,972***	**$1,761,945.38**	**$7.23**	**$176.12**	**2.01**

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

Fiscal Year 2017 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Strensiq® (Asfotase Alfa) Approval Criteria:

5. An FDA approved indication for the treatment of patients with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
6. Confirmed diagnosis by laboratory testing of:
   a. Low age-adjusted ALP activity; and
   b. Elevated pyridoxal 5'-phophate (PLP) levels; and
7. Member's weight (kg) must be provided and have been taken within the last four weeks to ensure accurate weight-based dosing; and
8. The 80mg/0.8mL vial should not be used in pediatric patients weighing less than 40kg.

Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	2	16	$326,488.76	$20,405.55	$728.77	110	448
2017	5	42	$1,268,376.77	$30,199.45	$1,078.55	477	1,176
% Change	**150.00%**	**162.50%**	**288.50%**	**48.00%**	**48.00%**	**333.60%**	**162.50%**
Change	**3**	**26**	**$941,888.01**	**$9,793.90**	**$349.78**	**367**	**728**

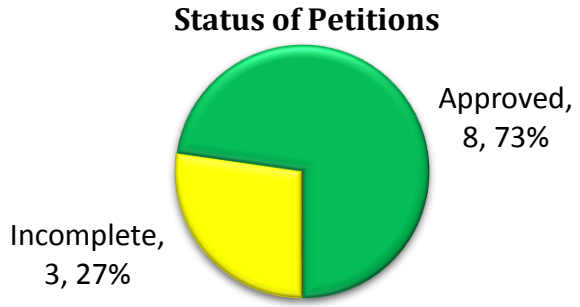
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

Top Prescriber Specialties of Strensiq® (Asfotase Alfa) by Number of Claims

- The only prescriber specialites listed on paid pharmacy claims for Strensiq® (asfotase alfa) during fiscal year 2017 was a general pediatrician and genetic counselor.

Prior Authorization of Strensiq® (Asfotase Alfa)

There were 11 prior authorization requests submitted for Strensiq® (asfotase alfa) during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

News:

- **May 2017:** Alexion Pharmaceuticals, Inc. announced that the final data from the extension phase of a randomized, open-label, dose-ranging Phase 2 trial of Strensiq® (asfotase alfa) showed that the rapid benefits achieved in adolescents and adults (ages 13 to 66 years at study entry) with hypophosphatasia (HPP) within the first 6 months were sustained through 5 years of treatment. The results were presented at the European Calcified Tissue Society (ECTS) Congress in Austria and demonstrate a reduction in two key biomarkers of HPP disease activity, as well as improvements in physical function in patients treated with Strensiq®, as observed in tests to measure walking distance, running speed and agility, and muscle strength.[93]

Recommendations

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

[93] Alexion Pharmaceuticals, Inc. Long-term Data Confirm Benefits of Treatment with Strensiq® (asfotase alfa) in Adolescents and Adults with Hypophosphatasia (HPP) Through Five Years. *Business Wire*. Available online at: https://www.businesswire.com/news//home/20170515005433/en/Long-term-Data-Confirm-Benefits-Treatment-Strensiq%C2%AE-asfotase. Issued 05/15/2017. Last accessed 12/19/2017.

Fiscal Year 2017 Annual Review of Symlin® (Pramlintide)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a healthcare professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (Pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. HbA1c >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past six months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric patients 15 years of age or younger.

Utilization of Symlin® (Pramlintide): Fiscal Year 2017

There was no utilization of Symlin® (pramlintide) during fiscal year 2017.

Prior Authorization of Symlin® (Pramlintide)

There were no prior authorization requests submitted for Symlin® (pramlintide) during fiscal year 2017.

Market News and Updates

Anticipated Patent Expiration(s):[94]

- Symlin® (pramlintide): March 2019

Recommendations

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

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[94] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2017. Last accessed 10/16/2017.

Fiscal Year 2017 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Sylvant® (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of Multicentric Castleman's Disease (also known as giant lymph node hyperplasia); and
2. Member must be Human Immunodeficiency Virus (HIV) and Human Herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
    a. 11 mg/kg via intravenous (IV) infusion every three weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status); and
5. Sylvant™ must be administered in a clinical setting able to provide resuscitation equipment, medications, and trained personnel; and
6. The prescriber must verify that a complete blood count (CBC) will be done prior to each dose for the first 12 months and for an additional three doses thereafter; and
7. Approvals will be for the duration of six months.

Utilization of Sylvant® (Siltuximab): Fiscal Year 2017

There was no utilization of Sylvant® (siltuximab) during fiscal year 2017.

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2017.

Recommendations

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

Fiscal Year 2017 Annual Review of Testosterone Products

Oklahoma Health Care Authority
Fiscal Year 2017 Print Review

Current Prior Authorization Criteria

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
methyltestosterone powder	testosterone nasal gel (Natesto®)	fluoxymesterone oral tab (Androxy®)
testosterone cypionate inj (Depo-Testosterone®)	testosterone patch (Androderm®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate inj	testosterone topical gel (Fortesta®, Testim®, Vogelxo™)	testosterone buccal tablet (Striant®)
testosterone topical gel (Androgel®)+	testosterone topical sol (Axiron®)	testosterone pellets (Testopel®)
	testosterone undecanoate inj (Aveed®)	

inj = injection; tab = tablet; cap = capsule; sol = solution
*Tier-1 products include generic injectable products and supplementally rebated topical products.
+Brand name preferred
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of one of the following:
   a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy; or
   b. Idiopathic gonadotropin or luteinizing-hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
   c. Delayed puberty; or
   d. Advanced inoperable metastatic mammary cancer in females one to five years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor; and
2. Must include two labs showing pre-medication, morning testosterone (total testosterone) levels below 300ng/dL; and
3. Must include one lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
4. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

5. Approvals will be for the duration of one year.

Testosterone Products Tier-2 Authorization Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A trial of at least two Tier-1 products (must include at least one injectable and one topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 medications; or
4. Prior stabilization on a Tier-2 medication (within the past 180 days).
5. Approvals will be for the duration of one year.

Testosterone Products Special Prior Authorization (PA) Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone.
3. Approvals will be for the duration of one year.

Utilization of Testosterone Products: Fiscal Year 2017

Comparison of Fiscal Years for Testosterone Products: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	155	541	$146,050.75	$269.96	$5.40	29,500	27,053
2017	144	535	$119,622.19	$223.59	$4.80	22,131	24,925
% Change	**-7.10%**	**-1.11%**	**-18.10%**	**-17.18%**	**-11.12%**	**-24.98%**	**-7.87%**
Change	**-11**	**-6**	**-$26,428.56**	**-$46.37**	**-$0.60**	**-7,369**	**-2,128**

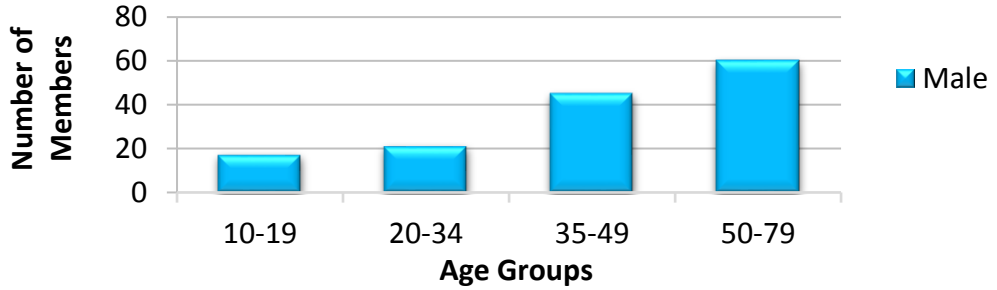
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

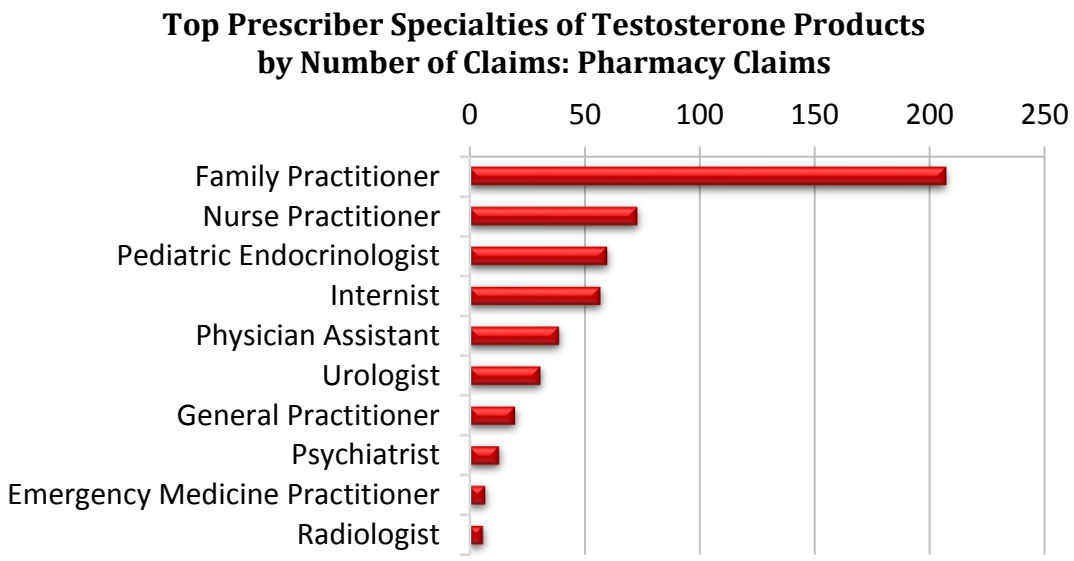
Fiscal Year 2017 Utilization of Testosterone Products: Medical Claims

*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
149	852	$2,933.83	$3.44	5.7

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

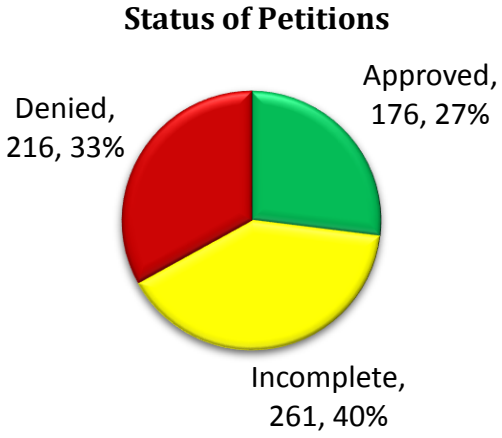
Demographics of Members Utilizing Testosterone Products: Pharmacy Claims





Prior Authorization of Testosterone Products

There were 653 prior authorization requests submitted for testosterone products during fiscal year 2017. All products regardless of tier status require prior authorization in order to evaluate submitted labs. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[95]

- Fortesta® (testosterone topical gel): November 2018
- Striant® (testosterone buccal tablets): August 2019
- Natesto® (testosterone nasal gel): February 2024
- Testim® (testosterone topical gel): January 2025
- Aveed® (testosterone undecanoate injection): March 2027
- Vogelxo™ (testosterone topical gel): February 2034

[95] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2017. Last accessed 02/13/2018.

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

- **February 2017:** The FDA approved an Abbreviated New Drug Application (ANDA) for the first generic version of Axiron® (testosterone topical solution). Two additional pharmaceutical companies received FDA approval to market generic testosterone topical solution in October 2017 and January 2018. The College of Pharmacy will continue to monitor net costs of generic testosterone topical solution in comparison to the lower tiered products.[96]
- **July 2017:** The FDA approved an ANDA for the first generic version of Androgel® 1.62% (testosterone topical gel packets). Two additional pharmaceutical companies have submitted ANDAs to market generic testosterone topical gel packets but have not yet received FDA approval. The College of Pharmacy will continue to monitor net costs of generic testosterone topical gel packets in comparison to the branded product and other lower tiered products.[97]

News:

- **February 2017:** Although testosterone replacement is increasingly being used clinically, the cardiovascular benefits and risks of testosterone administration to older men with age-related decline in testosterone levels remain uncertain, as studies of the effects of testosterone on clinical cardiovascular outcomes are conflicting. Results of the Cardiovascular Trial, a study to examine whether testosterone treatment increases cardiovascular risk and one of the seven National Institute of Health (NIH) Testosterone Trials (TTrials) to assess the efficacy of testosterone treatment in older men with low testosterone levels, were published in the *Journal of the American Medical Association* (*JAMA*). The double-blind, placebo-controlled trial included 170 men aged 65 years or older with an average of two serum testosterone levels less than 275ng/dL and symptoms suggestive of hypogonadism. The primary outcome was noncalcified coronary artery plaque volume, as determined by coronary computed tomographic angiography. Of the 170 men who were enrolled, 138 men (73 receiving testosterone gel and 65 receiving placebo gel) completed the study and were available for primary analysis. Among the 138 men, the mean age was 71.2 years. At baseline, 70 men (50.7%) had a coronary artery calcification score higher than 300 Agatston units, reflecting severe atherosclerosis. For the primary outcome, testosterone treatment compared with placebo was associated with a significantly greater increase in coronary artery noncalcified plaque volume from baseline to 12 months; however, larger studies are needed to understand the clinical implications of this finding. No major adverse cardiovascular events occurred in either group.[98]

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[96] U.S. FDA. ANDA Approval: Testosterone Topical Solution. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204255. Issued 02/28/2017. Last accessed 02/20/2018.

[97] U.S. FDA. ANDA Approval: Testosterone 1.62% Topical Gel Packets. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205781. Issued 07/12/2017. Last accessed 03/01/2018.

[98] Budoff MJ, Ellenberg SS, Lewis CE, et al. Testosterone Treatment and Coronary Artery Plaque Volume in Older Men with Low Testosterone. *JAMA* 2017; 317(7):708-716.

- **February 2017:** Aging is associated with declines in some cognitive functions, including verbal and visual memory, executive function, and spatial ability and is also associated with a reduction in serum testosterone, raising the possibility that reduced circulating testosterone concentration may contribute to age-related cognitive decline. Results of the Cognitive Function Trial, a study to determine if testosterone treatment may improve these cognitive functions and one of the seven NIH TTrials, were published in *JAMA*. The placebo-controlled trial included 493 men aged 65 years or older with a serum testosterone level less than 275ng/dL and symptoms suggestive of hypogonadism and who met criteria for age-associated memory impairment (AAMI) based on baseline subjective memory complaints and objective memory performance. The primary outcome was the mean change from baseline to 6 months and 12 months for delayed paragraph recall among men with AAMI. Of the 493 men who were enrolled, 492 men (247 receiving testosterone gel and 245 receiving placebo gel) completed the memory study. There was no significant mean change from baseline to 6 months and 12 months in delayed paragraph recall score among men with AAMI in the testosterone and placebo groups. Testosterone was also not associated with significant differences in visual memory, executive function, or spatial ability (all secondary outcomes). Therefore, among older men with low testosterone and AAMI, treatment with testosterone for one year compared with placebo was not associated with improved memory or other cognitive functions.[99]
- **April 2017:** A large study of more than 9,000 men has established harmonized reference ranges for total testosterone in men, that when applied to assays that have been appropriately calibrated, will effectively enable clinicians to make a correct diagnosis of hypogonadism. The correct diagnosis and effective treatment and prevention of hypogonadism as well as many other diseases depend on accurate measurement of hormones, but lack of both defined references ranges of testosterone and standardization of hormone assays has made diagnosing hypogonadism a difficult task. In this study, researchers obtained serum testosterone samples from men who had already had their testosterone levels assayed locally. The samples were sent to the Centers for Disease Control and Prevention's (CDC) Clinical Standardization Programs at the National Center for Environmental Health where testosterone concentrations were measured using a higher order liquid chromatography tandem mass spectrometry method. Researchers used the results from both measurements to generate harmonized values, which were in turn used to derive standardized, age-specific reference ranges overall. These new findings offer, for the first time, a reliable baseline for total testosterone levels. The harmonized normal range for testosterone in a non-obese population of European and American men, ages 19 to 39 years, was 264 to 916ng/dL, while that for all men aged 19 to 39 years, including those who were obese, was 228 to 895ng/dL. As testosterone levels decline with age, the researchers then generated reference ranges stratified by

[99] Resnick SM, Matsumoto AM, Stephens-Shields AJ, et al. Testosterone Treatment and Cognitive Function in Older Men with Low Testosterone and Age-Associated Memory Impairment. *JAMA* 2017; 317(7):717-727.

decade of age. For older age groups, among all men (including the obese), the age-specific estimates for normal reference ranges of testosterone were:

- Age 40 to 49 years: 208 to 902ng/dL
- Age 50 to 59 years: 192 to 902ng/dL
- Age 60 to 79 years: 190 to 902ng/dL
- Age 80 to 99 years: 119 to 902ng/dL[100]

Pipeline:

- **June 2017:** Clarus Therapeutics resubmitted a New Drug Application (NDA) to the FDA for Jatenzo™ (formerly Rextoro™), the company's oral testosterone replacement product for the treatment of low testosterone in hypogonadal men. The new submission addresses all points raised by the FDA in the Complete Response Letter (CRL) issued to Clarus following the NDA submission for Rextoro™ in 2014. Clarus conducted a new Phase 3 clinical investigation of Jatenzo™ (the "inTUne" trial) in which 87% of men treated with Jatenzo™ achieved average circulating levels of testosterone in the normal range based on the primary efficacy analysis mandated by the FDA. The safety profile of Jatenzo™ in the inTUne trial was consistent with data generated in two earlier Phase 3 trials and the general safety profiles for testosterone replacement products as a therapeutic class. Jatenzo™ is a proprietary softgel capsule that contains a testosterone prodrug, testosterone undecanoate, formulated to foster absorption via the intestinal lymphatic system and is dosed twice daily. If approved, Jatenzo™ would offer a safe and effective oral testosterone-replacement option that would eliminate the risk of testosterone transfer to others associated with testosterone topical gels.[101,102]
- **August 2017:** Lipocine resubmitted an NDA to the FDA for Tlando™, the company's oral testosterone product candidate for testosterone replacement therapy in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The new submission addresses all points raised by the FDA in the 2016 CRL issued to Lipocine following the NDA submission for Tlando™. Lipocine conducted a new dose validation study to confirm the efficacy of Tlando™ with a fixed dose regimen without need for dose adjustment. Tlando™ was well tolerated upon 52-week exposure with no reports of drug related serious adverse events. Tlando™ is a novel oral prodrug of testosterone, testosterone undecanoate, and is dosed twice daily to help restore normal testosterone levels in hypogonadal men. Lipocine has another product in development, LPCN 1111, which is a novel oral prodrug of

[100] Travison TG, Vesper HW, Orwoll E, et al. Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe. *J Clin Endocrinol Metab* 2017; 102(4):1161-1173.

[101] Clarus Therapeutics News Release: Clarus Re-Submits Jatenzo™ NDA Following Positive Results of inTUne Trial. Available online at: http://www.clarustherapeutics.com/content/investors-and-media/releases/062617.htm. Issued 06/26/2017. Last accessed 02/15/2018.

[102] Clarus Therapeutics News Release: Clarus Therapeutics Reports FDA Advisory Committees Vote on Rextoro™ for Low Testosterone in Men. Available online at: http://www.clarustherapeutics.com/content/investors-and-media/releases/091814.htm. Issued 09/18/2014. Last accessed 02/15/2018.

testosterone with the potential for once daily dosing and is currently in Phase 2 trials.[103,104]

- **October 2017:** The FDA declined to approve Antares Pharma's NDA for testosterone enanthate in a proprietary autoinjector (Xyosted™, formerly QuickShot™ Testosterone) and raised two safety concerns: first, that Xyosted™ could cause a clinically meaningful increase in blood pressure and second, concern about occurrence of depression and suicidality. The CRL did not cite any chemistry, manufacturing and controls, device, or efficacy issues. In 2015, the FDA asked Antares Pharma for additional safety data after a patient developed hives in a midstage trial. The company eventually submitted the NDA for review in December 2016 under the product name QuickShot™ Testosterone, which was renamed Xyosted™. Xyosted™ autoinjector is designed to allow rapid subcutaneous self-administration of testosterone using high spring pressure through a fine gauge needle. Antares Pharma scheduled a formal meeting with the FDA in February 2018 to discuss the CRL received for Xyosted™ and to determine a path forward for re-submission of the Xyosted™ NDA.[105,106]
- **January 2018:** An FDA advisory committee voted against recommending the approval of two new oral testosterone products for the treatment of hypogonadism in adult males. The two products, Jatenzo™ and Tlando™, are both oral testosterone undecanoate capsules, and both pharmaceutical companies were seeking an indication for the class of approved therapies for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The FDA advisory committee voted against the approval of the two products due to cardiovascular safety concerns as well as potential, inappropriate off-label use. Although they are not required to, the FDA often follows the advisory committee's recommendations. The FDA has not yet made the decision on whether or not to approve Jatenzo™ or Tlando™.[107]

Recommendations

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

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[103] Lipocine Inc. News Release: Lipocine Announces FDA Acknowledgement of Tlando™ ("LPCN 1021") NDA Resubmission; PDUFA Goal Date, February 8, 2018. Available online at: http://ir.lipocine.com/Lipocine-Announces-FDA-Acknowledgement-of-TLANDO-TM-LPCN-1021-NDA-Resubmission-PDUFA-Goal-Date-February-8-2018. Issued 08/14/2017. Last accessed 02/20/2018.

[104] Lipocine Inc. News Release: Lipocine Receives Complete Response Letter (CRL) for LPCN 1021 From U.S. Food and Drug Administration. Available online at: http://ir.lipocine.com/Lipocine-Receives-Complete-Response-Letter-CRL-for-LPCN-1021-From-U-S-Food-and-Drug-Administration. Issued 06/29/2016. Last accessed 02/20/2018.

[105] Antares Pharma. News Release: Antares Receives Complete Response Letter from the FDA for Xyosted™. Available online at: https://www.antarespharma.com/investors/press?year=2017. Issued 10/20/2017. Last accessed 03/01/2018.

[106] Antares Pharma. News Release: Antares Pharma Provides Xyosted™ Regulatory Update. Available online at: https://www.antarespharma.com/investors/press?year=2018. Issued 01/16/2018. Last accessed 03/01/2018.

[107] Monaco K. FDA Panel: Two Thumbs Down for New Oral Testosterone Drugs. *MedPage Today*. Available online at: https://www.medpagetoday.com/endocrinology/generalendocrinology/70432. Issued 01/10/2018. Last accessed 02/15/2018.

Utilization Details of Testosterone Products: Fiscal Year 2017

Testosterone Products: Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	300	92	$17,283.95	3.3	$57.61	14.45%
TESTOST CYP INJ 100MG/ML	14	8	$699.01	1.8	$49.93	0.58%
DEPO-TESTOST INJ 200MG/ML	14	5	$1,075.87	2.8	$76.85	0.90%
TESTOST ENAN INJ 200MG/ML	12	6	$1,101.82	2	$91.82	0.92%
DEPO-TESTOST INJ 100MG/ML	2	2	$154.65	1	$77.33	0.13%
SUBTOTAL	**342**	**113**	**$20,315.30**	**3**	**$59.40**	**16.98%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1.62%	108	23	$66,031.32	4.7	$611.40	55.20%
TESTOSTERONE GEL 1%(50MG)	38	8	$12,847.49	4.8	$338.09	10.74%
ANDROGEL GEL 1%(50MG)	17	2	$7,867.15	8.5	$462.77	6.58%
ANDROGEL GEL 1.62%	11	4	$3,569.62	2.8	$324.51	2.98%
AXIRON SOL 30MG/ACT	9	2	$5,332.04	4.5	$592.45	4.46%
TESTOSTERONE GEL PUMP 1%	7	2	$2,130.67	3.5	$304.38	1.78%
NATESTO GEL 5.5MG	2	2	$954.35	1	$477.18	0.80%
ANDROGEL GEL 1.62%	1	1	$574.25	1	$574.25	0.48%
SUBTOTAL	**193**	**44**	**$99,306.89**	**4.4**	**$514.54**	**83.02%**
TOTAL	**535**	**144***	**$119,622.19**	**3.7**	**$223.59**	**100%**

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

Testosterone Products: Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	852	149	$2,933.83	$3.44	5.7
TOTAL	**852**	**149***	**$2,933.83**	**$3.44**	**5.7**

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

Fiscal Year 2017 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Topical Antibiotic Products	
Tier-1	**Tier-2**
Bactroban® (mupirocin) ointment 2%	Altabax® (retapamulin) ointment 1%
Cortisporin® (neomycin/polymyxin B sulfates/hydrocortisone) cream 0.5%	Bactroban® (mupirocin) cream 2%
Cortisporin® (neomycin/polymyxin B sulfates/ bacitracin zinc/hydrocortisone) ointment 1%	Bactroban® (mupirocin) nasal ointment 2%
Garamycin® (gentamicin) cream 0.1%	Centany® (mupirocin) kit 2%
Garamycin® (gentamicin) ointment 0.1%	
Gentamicin powder	

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

Topical Antibiotic Tier-2 Approval Criteria:

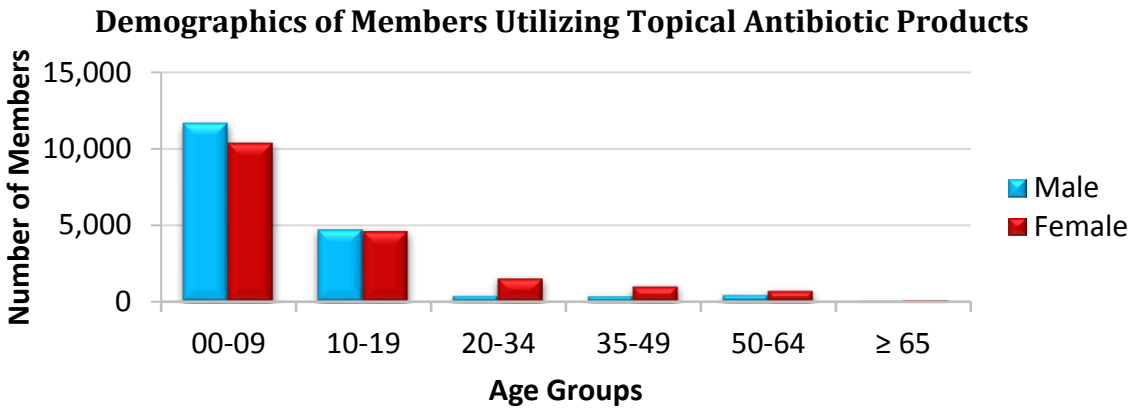
1. Documented five-day trial of a Tier-1 product within the last 30 days.
2. Clinical exceptions apply for adverse effects with all Tier-1 products, or a unique indication not covered by Tier-1 products.
3. Approvals will be for the duration of ten days.

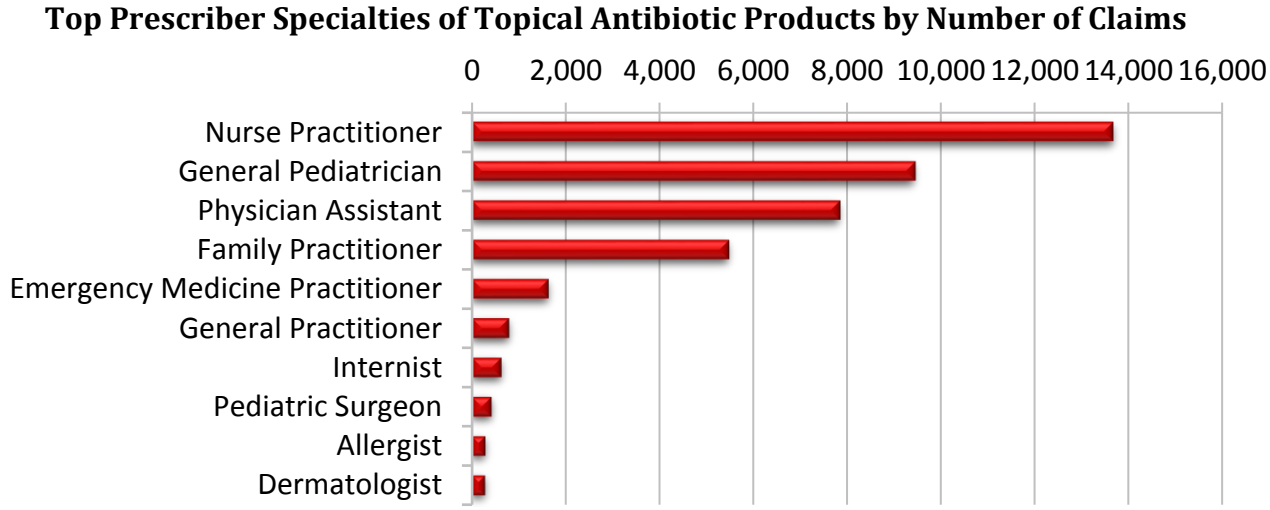
Utilization of Topical Antibiotic Products: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	32,422	38,247	$522,410.31	$13.66	$1.26	903,472	415,717
2017	35,706	41,965	$633,252.38	$15.09	$1.42	973,306	445,468
% Change	**10.10%**	**9.70%**	**21.20%**	**10.50%**	**12.70%**	**7.70%**	**7.20%**
Change	**3,284**	**3,718**	**$110,842.07**	**$1.43**	**$0.16**	**69,834**	**29,751**

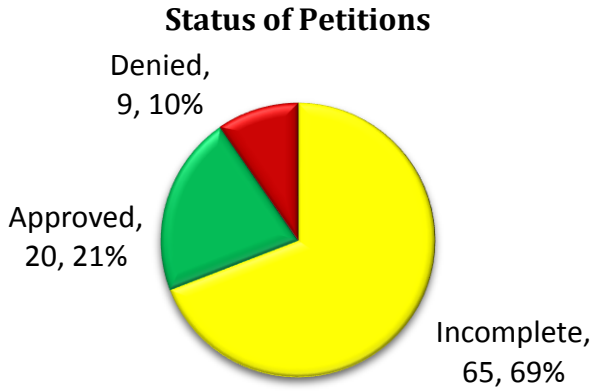
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.





Prior Authorization of Topical Antibiotic Products

There were 94 prior authorization requests submitted for topical antibiotic products during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates

Anticipated Patent Expiration(s):[108]

- Altabax® (retapamulin): February 2027

Recommendations

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

Utilization Details of Topical Antibiotic Products: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ DAY	% COST
TIER-1 PRODUCTS						
MUPIROCIN OINT 2%	41,519	35,496	$593,256.22	$14.29	$1.35	93.68%
GENTAMICIN OINT 0.1%	240	156	$18,701.60	$77.92	$6.75	2.95%
GENTAMICIN CRE 0.1%	88	55	$4,913.31	$55.83	$3.79	0.78%
CORTISPORIN CRE 0.5%	57	39	$5,700.16	$100.00	$8.61	0.90%
CORTISPORIN OINT 1%	17	15	$2,268.94	$133.47	$14.09	0.36%
SUBTOTAL	**41,921**	**35,761**	**$624,840.23**	**$14.91**	**$1.40**	**98.67%**
TIER-2 PRODUCTS						
MUPIROCIN CRE 2%	39	28	$7,364.27	$188.83	$14.36	1.16%
ALTABAX OINT 1%	5	5	$1,047.88	$209.58	$19.41	0.17%
SUBTOTAL	**44**	**33**	**$8,412.15**	**$191.19**	**$14.84**	**1.33%**
TOTAL	**41,965**	**35,706***	**$633,252.38**	**$15.09**	**$1.42**	**100%**

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

[108] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 11/21/2017.

Fiscal Year 2017 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
ketoconazole cream, shampoo	econazole cream	
nystatin cream, ointment, powder	ketoconazole foam (Extina®)	
terbinafine (OTC)* cream	ketoconazole gel (Xolegel®)	
tolnaftate (OTC)* cream	luliconazole cream (Luzu®)	
	miconazole/zinc oxide/white petrolatum (Vusion®)	
	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Over the counter (OTC) antifungal medications are covered for pediatric members 0 to 20 years of age without prior authorization; OTC antifungal medications require a prescription to be covered at the pharmacy.

Topical Antifungal Tier-2 Approval Criteria:

1. Documented, recent trials with at least two Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-2 (e.g., foams, shampoos, sprays, kits).
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/betamethasone lotion requires a patient-specific, clinically significant reason why the member cannot use the individual components separately, or in the case of clotrimazole/betamethasone lotion why the Tier-1 cream cannot be used.

4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

Jublia® (Efinaconazole) and Kerydin® (Tavaborole) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*; and
2. A trial of oral antifungals (12 weeks for toenails); and
3. A patient-specific, clinically significant reason why member cannot use Penlac® (ciclopirox solution); and
4. A clinically significant reason the member requires treatment for onychomycosis (cosmetic reasons will not be approved).

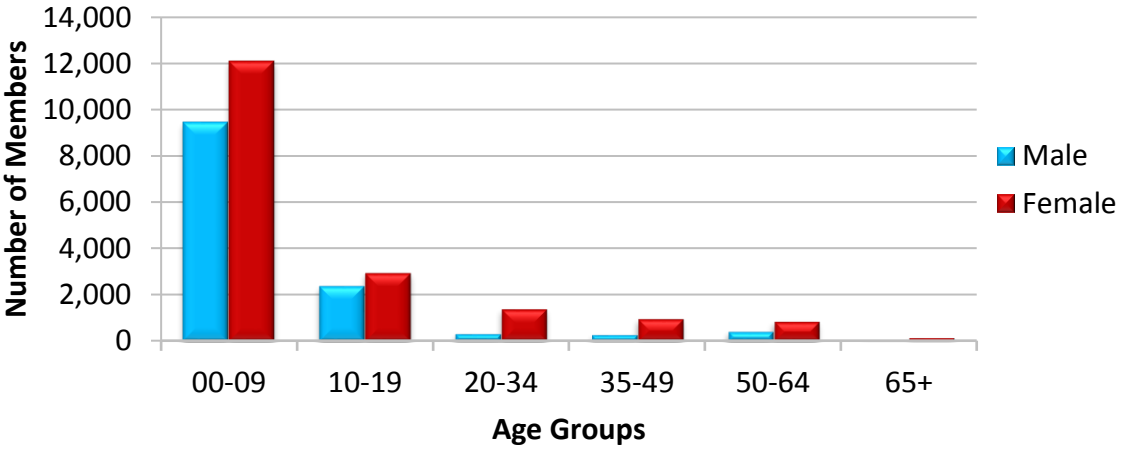
Utilization of Topical Antifungal Products: Fiscal Year 2017

Comparison of Fiscal Years

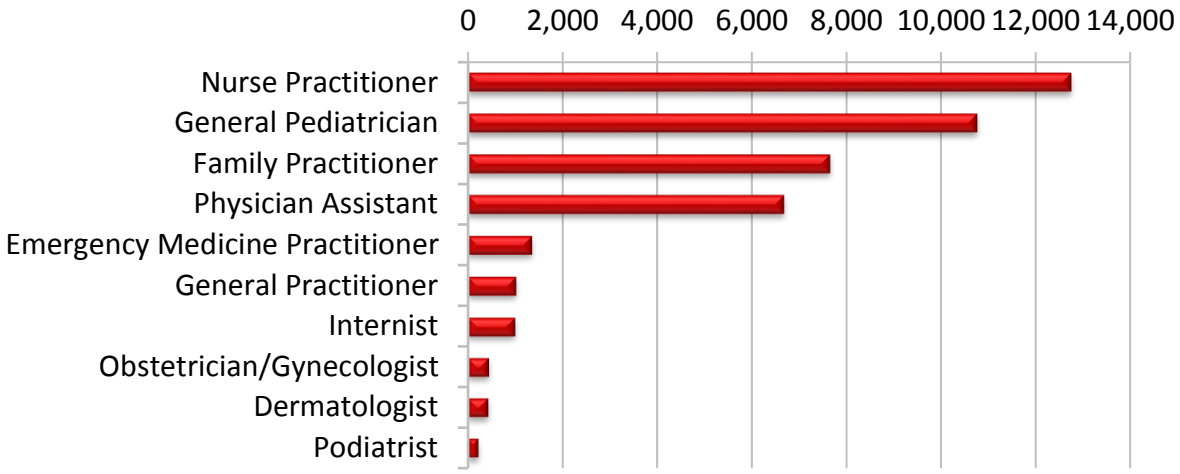
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	30,986	44,228	$1,086,765.84	$24.57	$1.68	1,645,010	648,614
2017	31,249	43,973	$993,620.24	$22.60	$1.54	1,647,505	647,244
% Change	**0.80%**	**-0.60%**	**-8.60%**	**-8.00%**	**-8.30%**	**0.20%**	**-0.20%**
Change	**263**	**-255**	**-$93,145.60**	**-$1.97**	**-$0.14**	**2,495**	**-1,370**

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

Demographics of Members Utilizing Topical Antifungal Products



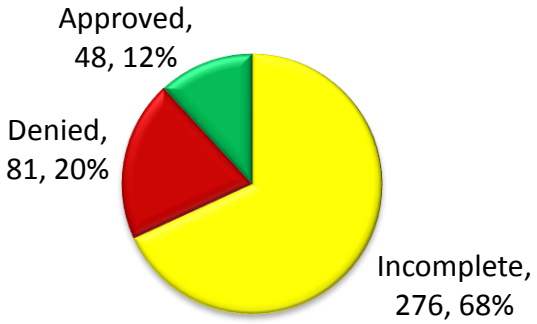
Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 405 prior authorization requests submitted for topical antifungal products during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[109]

- Extina® (ketoconazole foam): October 2018
- Xolegel® (ketoconazole gel): November 2020
- Kerydin® (tavaborole): May 2027
- Vusion® (miconazole/zinc oxide/white petrolatum): March 2028
- Naftin® (naftifine gel 2%): January 2033
- Luzu® (luliconazole cream): April 2034
- Jublia® (efinaconazole): October 2034

[109] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 11/21/2017.

Generic Availability:

- **March 2016:** The U.S. Food and Drug Administration (FDA) approved the first generic of Oxistat® (oxiconazole) 1% cream.[110]

New Indication(s):

- **November 2016:** The FDA expanded the indication of Naftin® (naftifine) 2% cream to include children 2 years of age and older with tinea corporis. Previously, the safety and effectiveness of naftifine 2% cream were not established in patients younger than 12 years of age. The expanded indication was based on a safety and efficacy study conducted in 184 patients with tinea corporis. Pediatric patients 2 to 17 years of age received naftifine cream or vehicle. The primary efficacy endpoint was the proportion of patients with a complete cure at day 21. A complete cure was achieved in 46% of patients treated with naftifine and 28% of patients treated with vehicle. Naftin® is also available as 1% and 2% gels and generically as 1% cream.[111]

Recommendations

The College of Pharmacy recommends the following changes to the Topical Antifungal PBPA category:

1. Move econazole nitrate 1% cream from Tier-2 to Tier-1 based on decreases in costs.

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole cream	ketoconazole foam (Extina®)	
ketoconazole cream, shampoo	ketoconazole gel (Xolegel®)	
nystatin cream, ointment, powder	luliconazole cream (Luzu®)	
terbinafine (OTC)* cream	miconazole/zinc oxide/white petrolatum (Vusion®)	
tolnaftate (OTC)* cream	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	

[110] U.S. Food and Drug Administration (FDA). FDA Approves First Generic of Oxistat Cream, 1% for Athlete's Foot, Jock Itch and Ringworm. *Healio Dermatology*. Available online at: https://www.healio.com/dermatology/practice-management/news/online/%7B57babfff-90c2-43d8-b230-5542a74f414c%7D/fda-approves-first-generic-of-oxistat-cream-1-for-athletes-foot-jock-itch-and-ringworm. Issued 03/11/2016. Last accessed 12/11/2017.

[111] Naftin® (Naftifine) 2% Cream – Expanded Indication. OptumRx. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdates_naftin_2016-1118.pdf. Issued 11/10/2016. Last accessed 12/26/2017.

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Over the counter (OTC) antifungal medications are covered for pediatric members 0 to 20 years of age without prior authorization; OTC antifungal medications require a prescription to be covered at the pharmacy.

Utilization Details of Topical Antifungal Products: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 UTILIZATION							
CICLOPIROX PRODUCTS¥							
CICLOPIROX CRE 0.77%	555	7,939	432	$11,088.66	$1.40	$19.98	1.12%
CICLOPIROX SUS 0.77%	6	117	6	$192.68	$1.65	$32.11	0.02%
SUBTOTAL	**561**	**8,056**	**438**	**$11,281.34**	**$1.40**	**$20.11**	**1.14%**
CLOTRIMAZOLE PRODUCTS							
CLOTRIMAZOLE CRE 1%	7,703	104,647	6,514	$133,824.58	$1.28	$17.37	13.47%
ATHLETE FOOT CRE 1%	20	244	19	$176.08	$0.72	$8.80	0.02%
CLOTRIMAZOLE POW	7	210	6	$82.14	$0.39	$11.73	0.01%
SUBTOTAL	**7,730**	**105,101**	**6,539**	**$134,082.80**	**$1.28**	**$17.35**	**13.50%**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS¥							
CLOTRIM/BETA CRE DIPROP	1,254	17,681	1,079	$30,021.13	$1.70	$23.94	3.02%
CLOTRIM/BETA CRE 1-0.05%	265	3,987	227	$6,345.18	$1.59	$23.94	0.64%
SUBTOTAL	**1,519**	**21,668**	**1,306**	**$36,366.31**	**$1.68**	**$23.94**	**3.66%**
KETOCONAZOLE PRODUCTS							
KETOCONAZOLE CRE 2%	4,850	79,636	4,043	$222,611.22	$2.80	$45.90	22.40%
KETOCONAZOLE SHA 2%	3,295	100,135	2,058	$53,972.87	$0.54	$16.38	5.43%
SUBTOTAL	**8,145**	**179,771**	**6,101**	**$276,584.09**	**$1.54**	**$33.96**	**27.83%**
NYSTATIN PRODUCTS							
NYSTATIN CRE 100000	14,495	181,104	11,482	$229,853.58	$1.27	$15.86	23.13%
NYSTATIN OIN 100000	6,547	80,986	5,343	$135,195.25	$1.67	$20.65	13.61%
NYSTOP POW 100000	1,949	26,200	1,301	$44,369.16	$1.69	$22.77	4.47%
NYSTATIN POW 100000	1,389	20,630	919	$35,613.47	$1.73	$25.64	3.58%
NYAMYC POW 100000	530	6,767	275	$14,294.69	$2.11	$26.97	1.44%
SUBTOTAL	**24,910**	**315,687**	**19,320**	**$459,326.15**	**$1.46**	**$18.44**	**46.23%**
TERBINAFINE PRODUCTS							
TERBINAFINE CRE 1%	483	6,802	433	$7,042.47	$1.04	$14.58	0.71%
ATHLETE FOOT CRE 1%	34	417	33	$541.44	$1.30	$15.92	0.05%
LAMISIL AT CRE 1%	21	300	21	$346.47	$1.15	$16.50	0.03%
ATHLETE FOOT CRE AF	8	114	8	$144.81	$1.27	$18.10	0.01%
SUBTOTAL	**546**	**7,633**	**495**	**$8,075.19**	**$1.06**	**$14.79**	**0.80%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TOLNAFTATE PRODUCTS							
TOLNAFTATE CRE 1%	14	221	11	$161.49	$0.73	$11.54	0.02%
SM ANTIFUNGL CRE 1%	6	97	6	$62.91	$0.65	$10.49	0.01%
ANTIFUNGAL CRE 1%	1	7	1	$8.01	$1.14	$8.01	0.00%
SUBTOTAL	**21**	**325**	**18**	**$232.41**	**$0.72**	**$11.07**	**0.03%**
TIER-1 SUBTOTAL	**43,432**	**638,241**	**34,217**	**$925,948.29**	**$1.45**	**$21.32**	**93.19%**
TIER-2 UTILIZATION							
CICLOPIROX PRODUCTS							
CICLOPIROX SHA 1%	5	105	2	$417.67	$3.98	$83.53	0.04%
CICLOPIROX SOL 8%	4	127	4	$114.21	$0.90	$28.55	0.01%
SUBTOTAL	**9**	**232**	**6**	**$531.88**	**$2.29**	**$59.10**	**0.05%**
CLOTRIMAZOLE PRODUCTS$^{\Delta}$							
CLOTRIMAZOLE SOL 1%	111	2,225	86	$6,830.84	$3.07	$61.54	0.69%
SUBTOTAL	**111**	**2,225**	**86**	**$6,830.84**	**$3.07**	**$61.54**	**0.69%**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS							
CLOTRIM/BETA LOT DIPROP	3	90	1	$309.65	$3.44	$103.22	0.03%
SUBTOTAL	**3**	**90**	**1**	**$309.65**	**$3.44**	**$103.22**	**0.03%**
ECONAZOLE PRODUCTS$^{\Delta}$							
ECONAZOLE CRE 1%	389	6,017	306	$53,743.55	$8.93	$138.16	5.41%
SUBTOTAL	**389**	**6,017**	**306**	**$53,743.55**	**$8.93**	**$138.16**	**5.41%**
NAFTIFINE PRODUCTS							
NAFTIN GEL 2%	2	40	1	$1,001.70	$25.04	$500.85	0.10%
SUBTOTAL	**2**	**40**	**1**	**$1,001.70**	**$25.04**	**$500.85**	**0.10%**
NYSTATIN/TRIAMCINOLONE PRODUCTS							
NYSTAT/TRIAM CRE	16	202	11	$2,326.75	$11.52	$145.42	0.23%
NYSTAT/TRIAM OIN	6	89	6	$635.09	$7.14	$105.85	0.06%
SUBTOTAL	**22**	**291**	**17**	**$2,961.84**	**$10.18**	**$134.63**	**0.29%**
OXICONAZOLE PRODUCTS							
OXICONAZOLE CRE NITRATE	4	78	3	$1,728.75	$22.16	$432.19	0.17%
SUBTOTAL	**4**	**78**	**3**	**$1,728.75**	**$22.16**	**$432.19**	**0.17%**
TIER-2 SUBTOTAL	**540**	**8,973**	**420**	**$67,108.21**	**$7.48**	**$124.27**	**6.74%**
SPECIAL PA UTILIZATION							
EFINACONAZOLE PRODUCTS							
JUBLIA SOL 10%	1	30	1	$563.74	$18.79	$563.74	0.06%
SPECIAL PA SUBTOTAL	**1**	**30**	**1**	**$563.74**	**$18.79**	**$563.74**	**0.06%**
TOTAL	**43,973**	**647,244**	**31,249***	**$993,620.24**	**$1.54**	**$22.60**	**100%**

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated members.

$^{\Delta}$Econazole nitrate 1% cream and clotrimazole 1% solution moved from Tier-1 to Tier-2 on October 12, 2016 due to increases in net cost. The utilization in the table occurred during fiscal year 2017. They are shown under the Tier-2 products to reflect the current tier placement.

$^{¥}$Ciclopirox suspension and clotrimazole/betamethasone cream moved from Tier-2 to Tier-1 in October 2016 due to decreases in net cost. The utilization in the table occurred during fiscal year 2017. They are shown under the Tier-1 products to reflect the current tier placement.

Fiscal Year 2017 Annual Review of Ulcerative Colitis (UC) and Crohn's Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Apriso® (Mesalamine Extended-Release Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Asacol® HD (Mesalamine Delayed-Release Tablets) Approval Criteria:

1. An FDA approved indication of the treatment of moderately active ulcerative colitis (UC); and
2. A patient-specific, clinically significant reason why the member cannot use other available mesalamine products that do not require prior authorization must be provided; and
3. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 180 tablets per 30 days will apply.

Canasa® (Mesalamine Suppositories) Quantity Limit Approval Criteria:

1. A quantity limit of 30 suppositories per 30 days will apply.
2. The first six weeks of treatment would not require prior authorization.
3. After six weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Colazal® (Balsalazide Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 270 capsules per 30 days will apply.
2. The first twelve weeks of treatment would not require prior authorization.
3. After twelve weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.
4. An age restriction of five years and older will apply.

Delzicol® (Mesalamine Delayed-Release Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 180 capsules per 30 days will apply.

Dipentum® (Olsalazine Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Giazo® (Balsalazide) Approval Criteria:

1. An FDA approved diagnosis of mildly-to-moderately active ulcerative colitis (UC); and
2. Member must be 18 years of age or older; and

3. Member must be male (effectiveness of Giazo® was not demonstrated in female patients in clinical trials); and
4. A patient-specific, clinically significant reason why the member cannot use generic balsalazide 750mg capsules or other products available without prior authorization* must be provided; and
5. Approvals will be for the duration of eight weeks. After eight weeks of treatment the prescriber must document a patient-specific, clinically significant reason the member needs a longer duration of treatment.

***The following medications do not require prior authorization:** sulfasalazine 500mg tablets, sulfasalazine delayed-release 500mg tablets, Rowasa® (mesalamine) rectal suspension enemas, Lialda® (mesalamine) delayed-release capsules, Colazal® (balsalazide) capsules, Dipentum® (olsalazine) capsules, Pentasa® (mesalamine) 250mg controlled-release capsules, Canasa® (mesalamine) suppositories, Apriso® (mesalamine) extended-release capsules, Delzicol® (mesalamine) delayed-release capsules, and hydrocortisone enemas.

Lialda® (Mesalamine Delayed-Release Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 60 capsules per 30 days will apply.
2. For quantity limit requests for greater than two capsules per day:
    a. An FDA approved indication for the induction of remission in patients with active, mild-to-moderate ulcerative colitis (UC); and
    b. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that are indicated to induce remission that do not require prior authorization must be provided; and
    c. Approvals will be for the duration of eight weeks in accordance with manufacturer recommended duration of therapy; and
    d. A maximum approval of 120 capsules per 30 days will apply.

Pentasa® (Mesalamine 250mg Controlled-Release Capsules) Quantity Limit Approval Criteria:

1. A quantity limit of 480 capsules per 30 days will apply.
2. The first eight weeks of treatment would not require prior authorization.
3. After eight weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Pentasa® (Mesalamine 500mg Controlled-Release Capsules) Approval Criteria:

1. An FDA approved indication for the induction of remission or for the treatment of patients with mildly-to-moderately active ulcerative colitis (UC); and
2. A patient-specific, clinically significant reason the member cannot use Pentasa® 250mg controlled-release capsules or other available mesalamine products that do not require prior authorization must be provided; and
3. Approvals will be for the duration of eight weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 240 capsules per 30 days will apply.

Rowasa® (Mesalamine Rectal Suspension Enema) Approval Criteria:

1. The first three weeks of treatment would not require prior authorization.

2. An FDA approved indication for the treatment of active, mild-to-moderate, distal ulcerative colitis (UC), proctosigmoiditis, or proctitis; and
3. A patient-specific, clinically significant reason the member cannot use Canasa® (mesalamine suppositories) which do not require prior authorization must be provided; and
4. Provider documentation that member is still having active symptoms after three weeks of treatment; and
5. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy; and
6. A quantity limit of 30 enemas (1,800mL) per 30 days will apply.

Uceris® (Budesonide Extended-Release Tablets) Approval Criteria:

1. An FDA approved diagnosis of induction of remission in patients with active, mild-to-moderate ulcerative colitis (UC); and
2. Previous failure of at least two of the following:
   a. Oral aminosalicylates; or
   b. Topical mesalamine; or
   c. Topical corticosteroids; or
   d. A contraindication to all preferred medications; and
3. A patient-specific, clinically significant reason why the member cannot use other oral corticosteroids available without prior authorization; must be provided; and
4. Approvals will be for the duration of eight weeks in accordance with manufacturer maximum recommended duration of therapy.
5. A quantity limit of 30 tablets per 30 days will apply.

Uceris® (Budesonide Rectal Foam) Approval Criteria:

1. An FDA approved diagnosis of induction of remission in patients with active, mild-to-moderate, distal ulcerative colitis (UC) extending up to 40cm from the anal verge; and
2. A patient-specific, clinically significant reason why the member cannot use oral aminosalicylates, topical mesalamine, or other topical (rectally administered) corticosteroids available without prior authorization must be provided; and
3. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy.
4. A quantity limit of 133.6 grams per 42 days will apply.

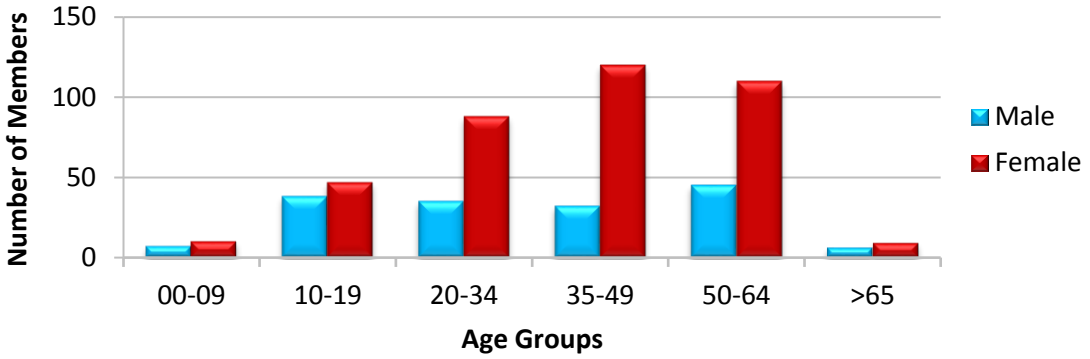
Utilization of UC and Crohn's Disease Medications: Fiscal Year 2017

Comparison of Fiscal Years

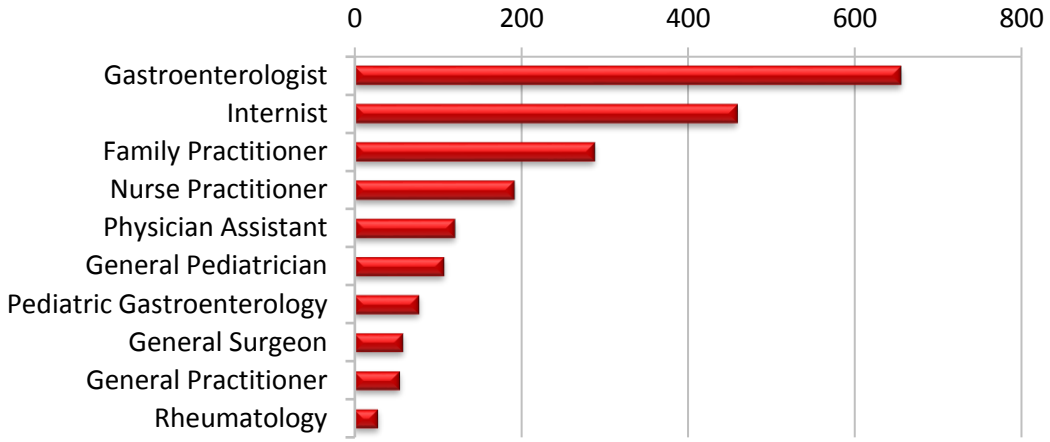
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	588	2,276	$916,590.51	$402.72	$13.60	330,146	67,379
2017	547	2,049	$688,228.03	$335.88	$11.27	267,087	61,094
% Change	**-7.00%**	**-10.00%**	**-24.90%**	**-16.60%**	**-17.10%**	**-19.10%**	**-9.30%**
Change	**-41**	**-227**	**-$228,362.48**	**-$66.84**	**-$2.33**	**-63,059**	**-6,285**

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

Demographics of Members Utilizing UC and Crohn's Disease Medications



Top Prescriber Specialties of UC and Crohn's Disease Medications by Number of Claims



Prior Authorization of UC and Crohn's Disease Medications

There were 300 prior authorization requests submitted for UC and Crohn's Disease medications during fiscal year 2017. The following chart shows the status of the submitted petitions during fiscal year 2017.

Status of Petitions

Market News and Updates

Patent Expiration(s):[112]

- Pentasa® [mesalamine controlled-release (CR) tablets], Dipentum® (olsalazine capsules), and Cortifoam® (10% hydrocortisone rectal aerosol foam): There are no unexpired patents; however, no generic formulations are available at this time.
- Delzicol® [mesalamine delayed-release (DR) tablets]: April 2020
- Lialda® (mesalamine DR tablets): June 2020
- Asacol® HD (mesalamine DR tablets): November 2021
- Canasa® (mesalamine suppositories): June 2028
- Apriso® [mesalamine extended-release (ER) tablets]: May 2030
- Giazo® (balsalazide tablets): June 2031

New(s):

- **December 2016:** Allergan Pharmaceuticals announced a settlement with Zydus Pharmacetuicals and Cadila Healthcare Limited regarding Allergan's product, Delzicol® (mesalamine). As a result of the settlement, if approved by the FDA, Zydus and Cadila may be able to market their generic version of Delzicol® in the United States as of March 1, 2020 or earlier under certain circumstances not disclosed. Delzicol® has a patent expiration date of April 13, 2020 per the Orange Book.[1,113]

Recommendations

The College of Pharmacy does not recommend any changes to the UC and Crohn's disease medications prior authorization criteria at this time.

Utilization Details of UC and Crohn's Disease Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SULFASALAZINE PRODUCTS						
SULFASALAZIN TAB 500MG	633	185	$16,087.63	$0.87	$25.41	2.34%
SULFASALAZIN TAB 500MG	325	107	$10,449.98	$1.07	$32.15	1.52%
SUBTOTAL	**958**	**292**	**$26,537.61**	**$0.94**	**$27.70**	**3.86%**
MESALAMINE PRODUCTS						
LIALDA TAB 1.2GM	385	93	$253,891.99	$21.55	$659.46	36.89%
DELZICOL CAP 400MG	180	44	$85,176.21	$15.59	$473.20	12.38%
PENTASA CAP 250MG CR	125	49	$84,685.15	$22.55	$677.48	12.30%
APRISO CAP 0.375GM	107	22	$45,424.92	$14.11	$424.53	6.60%
CANASA SUP 1000MG	44	31	$31,234.25	$22.23	$709.87	4.54%

[112] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 11/2017. Last accessed 12/20/2017.

[113] Allergan Pharmaceuticals. Allergan Announces Settlement of a Delzicol® (mesalamine) Patent Litigation. Available online at: https://www.allergan.com/news/news/thomson-reuters/allergan-announces-settlement-of-a-delzicol-mesal. Issued 12/2016. Last accessed 12/20/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PENTASA CAP 500MG CR	17	5	$18,266.58	$36.10	$1,074.50	2.65%
MESALAMINE ENE 4GM	8	6	$1,781.81	$9.58	$222.73	0.26%
ASACOL HD TAB 800MG	6	5	$4,895.57	$29.67	$815.93	0.71%
MESALAMINE TAB 800MG DR	4	3	$2,284.74	$19.04	$571.19	0.33%
SUBTOTAL	**876**	**258**	**$527,641.22**	**$19.83**	**$602.33**	**76.66%**
BALASALAZIDE PRODUCTS						
BALSALAZIDE CAP 750MG	12	4	$974.65	$2.71	$81.22	0.14%
SUBTOTAL	**12**	**4**	**$974.65**	**$2.71**	**$81.22**	**0.14%**
BUDESONIDE PRODUCTS						
BUDESONIDE CAP 3MG DR	176	55	$108,975.66	$20.56	$619.18	15.83%
UCERIS TAB 9MG	14	5	$22,764.14	$54.20	$1,626.01	3.31%
SUBTOTAL	**190**	**60**	**$131,739.80**	**$23.03**	**$693.37**	**19.14%**
HYDROCORTISONE PRODUCTS						
HYDROCORT ENE 100MG	8	5	$884.37	$5.98	$110.55	0.13%
COLOCORT ENE 100MG	5	4	$450.38	$7.51	$90.08	0.07%
SUBTOTAL	**13**	**9**	**$1,334.75**	**$6.42**	**$102.67**	**0.20%**
TOTAL	**2,049**	**547***	**$688,228.03**	**$11.27**	**$335.88**	**100%**

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

Fiscal Year 2017 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Member must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reasoning why a SSRI or SNRI is not appropriate for the member must be provided; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For a diagnosis of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least seven moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For a diagnosis of prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate) or Reclast® (zoledronic acid) compliantly used for at least six months concomitantly with calcium + vitamin D, that failed to prevent fracture or improve BMD scores; or
    b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and
5. Member must not have any of the contraindications for use of Duavee®; and
6. Members older than 65 years of age will generally not be approved without supporting information.
7. Approvals will be for the duration of six months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible.
8. A quantity limit of 30 tablets per 30 days will apply.

Elestrin® (Estradiol Gel 0.06%) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms due to menopause; and
2. Member must not have any contraindications for use of Elestrin®; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of six months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. A quantity limit of 52 grams per 30 days will apply.

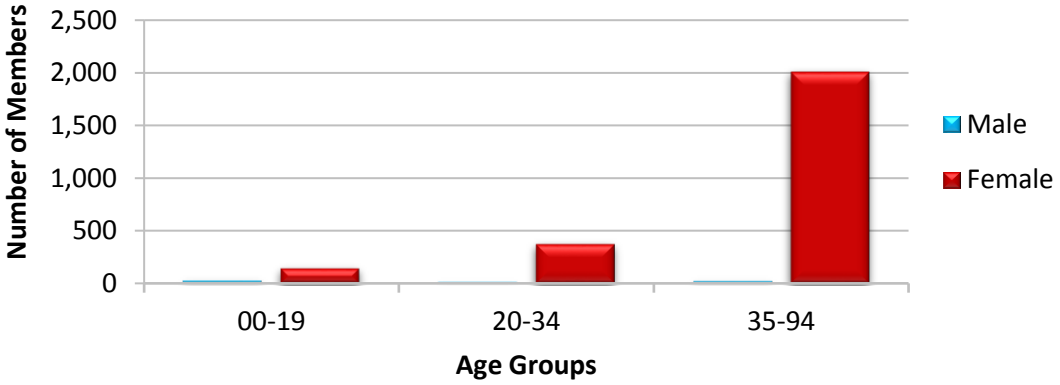
Utilization of Vasomotor Symptom Medications: Fiscal Year 2017

Comparison of Fiscal Years

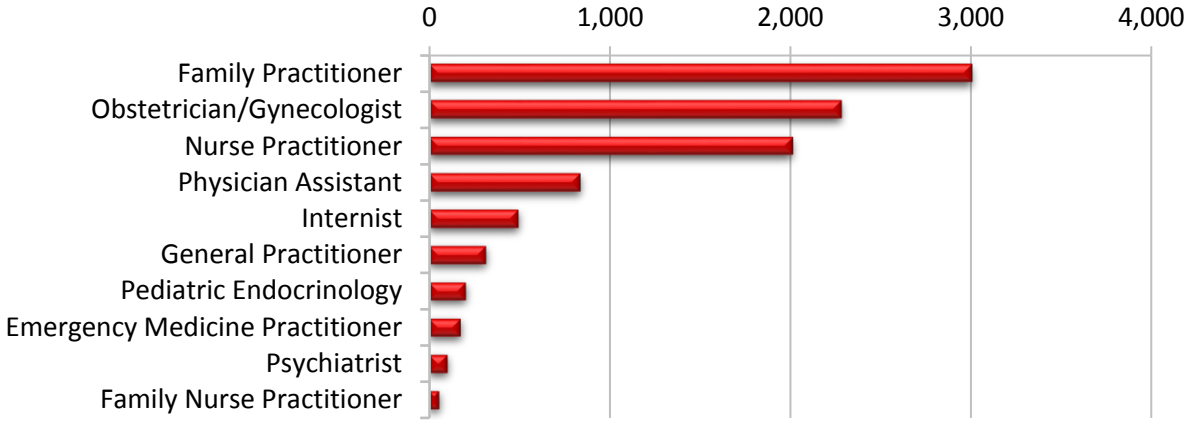
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	2,659	10,014	$908,691.41	$90.74	$2.15	380,934	423,093
2017	2,569	9,802	$954,689.40	$97.40	$2.31	377,223	413,937
% Change	**-3.40%**	**-2.10%**	**5.10%**	**7.30%**	**7.40%**	**-1.00%**	**-2.20%**
Change	**-90**	**-212**	**$45,997.99**	**$6.66**	**$0.16**	**-3,711**	**-9,156**

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

Demographics of Members Utilizing Vasomotor Symptom Medications



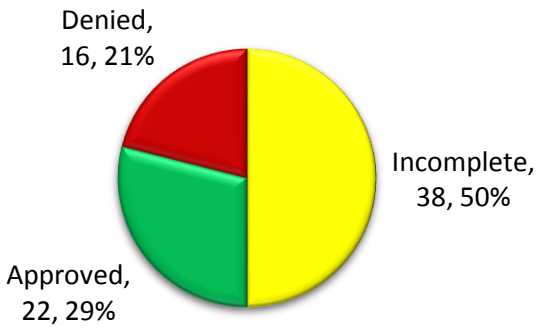
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 76 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates

Anticipated Patent Expirations:[114]

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

[114] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 10/2017. Last accessed 11/27/2017.

News:

- **July 2017:** The North American Menopause Society (NAMS) published a position statement to update the 2012 NAMS Hormone Therapy Position Statement. The key recommendations regarding vasomotor symptoms include the following:
  - Systemic hormone replacement therapy (HRT) is the most effective treatment for vasomotor symptoms (VMS).
  - Systemic HRT has the most favorable benefit-risk ratio in women who are younger than 60 years of age or within 10 years of the onset of menopause. This ratio is optimal in women who do not have a uterus and are eligible for estrogen monotherapy.
  - For women 60 years of age or older or greater than 10 years from the onset of menopause, the benefit-risk ratio of HRT is less favorable because of the greater absolute risk for coronary heart disease, stroke, venous thromboembolism, and dementia.
  - No evidence supports the routine discontinuation of HRT at a specific age (e.g., 65 years of age).
  - For systemic HRT, type, dose, duration, and route of administration should be individualized; shared decision making is recommended.
  - When prescribing systemic estrogen for women with an intact uterus, progestin or bazedoxifene is also recommended to prevent the development of endometrial hyperplasia or cancer.[115]
- **August 2017:** The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) published an updated position statement regarding menopause treatment. The recommendations outlined in the AACE/ACE 2011 clinical practice guideline did not change; however, new recommendations were added as follows:
  - The use of HRT in symptomatic postmenopausal women should be based on consideration of all risk factors for cardiovascular disease, age, and time from menopause.
  - The use of transdermal estrogen preparations should be considered as less likely to produce thrombotic risk, and perhaps the risk for stroke and coronary artery disease (CAD).
  - When the use of progesterone is necessary, micronized progesterone is considered the safer alternative.
  - HRT is not recommended for the prevention of diabetes.
  - In women with previously diagnosed diabetes, the use of HRT should be individualized, taking in to account age and metabolic and cardiovascular risk factors.
  - AACE does not recommend use of bioidentical hormone therapy.

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[115] Barbieri RL. North American Menopause Society Updates Its Position Statement on Hormone Therapy: 2017. *NEJM Journal Watch*. Available online at: https://www.jwatch.org/na44455/2017/07/11/north-american-menopause-society-updates-its-position. Issued 07/11/2017. Last accessed 11/28/2017.

- In symptomatic menopausal women who are at significant risk from the use of HRT, the use of selective serotonin reuptake inhibitors (SSRI's) and possibly other non-hormonal agents may offer significant symptom relief.
- AACE fully supports the recommendations of the Comité de l'Évolution des Pratiques en Oncologie regarding the management of menopause in women with breast cancer.[116]

Pipeline:

- **MLE4901:** Millendo Therapeutics is currently advancing the development of MLE4901 for the treatment of polycystic ovary syndrome (PCOS) and VMS. It leverages recent biological insights that brought to light the central regulator of reproductive hormonal signaling, the KNDy (kisspeptin/neurokinin B/dynorphin) neuron. MLE4901 is a potent and reversible antagonist of the human neurokinin 3 receptor (NK3R). Hyperactivity of KNDy neurons due to low estrogen levels is believed to initiate the process that causes VMS. By inhibiting NK3R signaling on KNDy neurons, MLE4901 is intended to reduce KNDy neuron hyperactivity. MLE4901 is in Phase 2 clinical development for VMS.[117]

Recommendations

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

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ORAL ESTROGEN PRODUCTS					
ESTRADIOL TAB 1MG	2,090	684	$19,856.36	$0.23	$9.50
ESTRADIOL TAB 2MG	1,597	489	$17,939.02	$0.25	$11.23
PREMARIN TAB 0.625MG	993	264	$211,001.48	$5.14	$212.49
PREMARIN TAB 1.25MG	811	212	$200,400.49	$5.16	$247.10
ESTRADIOL TAB 0.5MG	731	257	$6,441.21	$0.20	$8.81
PREMARIN TAB 0.3MG	415	107	$87,592.03	$5.01	$211.07
PREMARIN TAB 0.9MG	194	55	$44,914.35	$5.08	$231.52
PREMARIN TAB 0.45MG	165	42	$32,301.58	$5.10	$195.77
ESTROPIPATE TAB 0.75MG	61	11	$1,410.09	$0.59	$23.12
ESTROPIPATE TAB 1.5MG	42	11	$1,083.12	$0.54	$25.79
MENEST TAB 0.625MG	37	6	$2,889.34	$2.05	$78.09
MENEST TAB 1.25MG	25	8	$2,945.26	$2.85	$117.81
ESTROPIPATE TAB 3MG	10	2	$624.01	$1.16	$62.40
ENJUVIA TAB 0.45MG	3	2	$523.71	$3.88	$174.57

[116] Rodriguez T. AACE/ACE Updated Position Statement on Menopause. *Endocrinology Advisor*. Available online at: http://www.endocrinologyadvisor.com/androgen-and-reproductive-disorders/aaceace-updated-position-statement-on-menopause/article/683904/. Issued 08/23/2017. Last accessed 11/28/2017.

[117] Millendo Therapeutics. First-in-class mechanism of action leveraging novel biology. Available online at: http://www.millendo.com/our-programs/mle4901.php. Last accessed 11/28/2017.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
MENEST TAB 0.3MG	2	1	$99.06	$1.65	$49.53
PREMARIN INJ 25MG	1	1	$298.71	$9.96	$298.71
SUBTOTAL	**7,177**	**2,152**	**$630,319.82**	**$2.02**	**$87.82**
TOPICAL ESTROGEN PRODUCTS					
ESTRADIOL DIS 0.1MG	271	86	$15,079.44	$1.98	$55.64
ESTRADIOL DIS 0.1MG	264	55	$19,629.89	$2.59	$74.36
ESTRADIOL DIS 0.05MG	129	41	$7,730.82	$2.12	$59.93
ESTRADIOL DIS 0.05MG	125	37	$9,130.28	$2.57	$73.04
ESTRADIOL DIS 0.075MG	70	17	$5,078.17	$2.51	$72.55
ESTRADIOL DIS 0.025MG	69	22	$5,031.12	$2.26	$72.91
ESTRADIOL DIS 0.025MG	64	21	$3,598.07	$1.99	$56.22
ESTRADIOL DIS 0.0375MG	58	11	$3,655.37	$2.24	$63.02
ESTRADIOL DIS 0.0375MG	50	17	$3,638.06	$2.53	$72.76
MINIVELLE DIS 0.1MG	50	12	$3,884.06	$2.71	$77.68
DIVIGEL GEL 1MG/GM	33	9	$5,236.00	$4.59	$158.67
ESTRADIOL DIS 0.075MG	29	10	$1,937.90	$2.36	$66.82
MINIVELLE DIS 0.075MG	22	5	$1,782.85	$2.80	$81.04
MINIVELLE DIS 0.05MG	19	4	$1,247.30	$2.34	$65.65
EVAMIST SPR 1.53MG	18	8	$2,099.73	$2.26	$116.65
DIVIGEL GEL 0.5MG	17	5	$1,897.85	$3.84	$111.64
MINIVELLE DIS 0.025MG	14	5	$1,139.43	$2.76	$81.39
MENOSTAR DIS 14MCG	12	1	$1,651.91	$4.92	$137.66
VIVELLE-DOT DIS 0.1MG	9	2	$704.46	$2.77	$78.27
ALORA DIS 0.025MG	6	2	$521.52	$3.09	$86.92
ESTRADIOL DIS 0.06MG	5	3	$338.10	$2.38	$67.62
DIVIGEL GEL 0.25MG	4	3	$391.09	$3.31	$97.77
ALORA DIS 0.075MG	3	1	$237.57	$2.83	$79.19
VIVELLE-DOT DIS 0.05MG	3	1	$212.12	$2.53	$70.71
MINIVELLE DIS 0.0375MG	1	1	$81.12	$2.90	$81.12
CLIMARA DIS 0.025MG	1	1	$68.05	$2.43	$68.05
SUBTOTAL	**1,346**	**380**	**$96,002.28**	**$2.45**	**$71.32**
ORAL ESTROGEN/PROGESTIN PRODUCTS					
PREMPRO TAB 0.625-2.5MG	263	60	$66,496.61	$6.24	$252.84
PREMPRO TAB 0.3-1.5MG	170	51	$42,305.03	$6.23	$248.85
PREMPRO TAB 0.45-1.5MG	87	22	$21,292.42	$6.23	$244.74
PREMPRO TAB 0.625-5MG	80	18	$16,543.97	$6.29	$206.80
ESTRA/NORETH TAB 0.5-0.1MG	67	18	$8,106.03	$2.81	$120.99
ESTRA/NORETH TAB 1-0.5MG	54	11	$7,058.74	$3.15	$130.72
MIMVEY TAB 1-0.5MG	52	11	$6,378.83	$3.35	$122.67
JINTELI TAB 1MG-5MCG	30	6	$1,952.83	$2.21	$65.09
PREMPHASE TAB 0.625-5MG	16	4	$4,196.46	$6.24	$262.28
NORETH/ETHIN TAB 0.5-2.5MG	13	5	$1,136.54	$3.12	$87.43
MIMVEY LO TAB 0.5-0.1MG	10	3	$1,221.79	$3.12	$122.18

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
PREFEST TAB 1-0.09MG	4	1	$496.32	$4.14	$124.08
LOPREEZA TAB 0.5-0.1MG	3	1	$270.63	$3.22	$90.21
NORETH/ETHIN TAB 1MG-5MCG	2	1	$116.96	$2.09	$58.48
JEVANTIQUE LO TAB 0.5-2.5MCG	1	1	$80.35	$2.87	$80.35
ANGELIQ TAB 0.25-0.5MG	1	1	$140.66	$5.02	$140.66
ANGELIQ TAB 0.5-1MG	1	1	$426.06	$5.07	$426.06
FYAVOLV TAB 0.5-2.5MCG	1	1	$276.46	$3.07	$276.46
SUBTOTAL	**855**	**216**	**$178,496.69**	**$5.36**	**$208.77**
INJECTABLE ESTROGEN PRODUCTS					
DEPO-ESTRADI INJ 5MG/ML	253	133	$22,664.20	$1.01	$89.58
ESTRAD VAL INJ 20MG/ML	12	8	$1,393.13	$0.88	$116.09
ESTRAD VAL INJ	5	3	$953.98	$2.94	$190.80
SUBTOTAL	**270**	**144**	**$25,011.31**	**$1.03**	**$92.63**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS					
CLIMARA PRO DIS WEEKLY	40	15	$6,866.41	$6.13	$171.66
COMBIPATCH DIS 0.05/0.25MG	26	5	$4,129.31	$5.60	$158.82
COMBIPATCH DIS 0.05/0.14MG	26	6	$4,078.38	$5.57	$156.86
SUBTOTAL	**92**	**26**	**$15,074.10**	**$5.82**	**$163.85**
ESTROGEN POWDER PRODUCTS					
ESTRADIOL POW	19	6	$894.35	$1.57	$47.07
ESTRADIOL POW	13	5	$473.43	$1.10	$36.42
SUBTOTAL	**32**	**11**	**$1,367.78**	**$1.37**	**$42.74**
ESTROGEN/SERM PRODUCTS					
DUAVEE TAB 0.45-20MG	17	3	$2,757.55	$5.41	$162.21
SUBTOTAL	**17**	**3**	**$2,757.55**	**$5.41**	**$162.21**
VAGINAL ESTROGEN PRODUCTS					
FEMRING MIS 0.1MG/24HR	13	4	$5,659.87	$4.89	$435.37
SUBTOTAL	**13**	**4**	**$5,659.87**	**$4.89**	**$435.37**
TOTAL	**9,802**	**2,569***	**$954,689.40**	**$2.31**	**$97.40**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2017 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Dupuytren's Contracture Diagnosis]:

1. An FDA approved indication of Dupuytren's contracture with palpable cord, functional impairment, and fixed-flexion contractures of the metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint of 30 degrees or more; and
2. Member must be 18 years of age or older; and
3. The member must not be a candidate for needle aponeurotomy; and
4. The prescriber must be trained in the treatment of Dupuytren's contracture and injections of the hand; and
5. A quantity limit of three doses (one dose per four weeks) per cord will apply.

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Peyronie's Disease Diagnosis]:

1. A diagnosis of stable Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy; and
2. Member must be 18 years or older; and
3. Member must have pain outside the circumstances of intercourse that is refractory to other available treatments; and
4. Peyronie's plaques must not involve the penile urethra; and
5. Member must have intact erectile function (with or without the use of medications); and
6. Prescriber must be certified to administer Xiaflex® through the Xiaflex® REMS program; and
7. A maximum of eight injection procedures will be approved.

Utilization of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2017

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

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2016	1	4	$13,699.80	$3,424.95	360
2017	1	2	$7,407.00	$3,703.50	180
% Change	**0.00%**	**-50.00%**	**-45.93%**	**8.13%**	**-50.00%**
Change	**0**	**-2**	**-$6,292.80**	**$278.55**	**-180**

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

- There were no pharmacy claims for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2017.

Demographics of Members Utilizing Xiaflex® (Collagenase Clostridium Histolyticum)

- Due to the limited number of members utilizing Xiaflex® (collagenase clostridium histolyticum), detailed member demographics information cannot be provided.

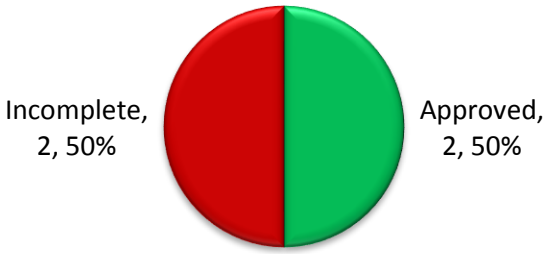
Top Prescriber Specialties of Xiaflex® (Collagenase Clostridium Histolyticum) by Number of Claims

- The only prescriber specialty listed on paid claims for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2017 was urologist.

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 4 prior authorization requests submitted Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2017. The following chart shows the status of the submitted petitions.

Status of Petitions



Recommendations

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

Fiscal Year 2017 Annual Review of Xuriden™ (Uridine Triacetate)

Oklahoma Health Care Authority
Fiscal Year 2017 Print Report

Current Prior Authorization Criteria

Xuriden™ (Uridine Triacetate) Approval Criteria:

1. An FDA approved diagnosis of Hereditary Orotic Aciduria defined by at least one of the following:
    a. Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patients erythrocytes showing deficiency in both enzymes; or deficiency in orotidylic acid decarboxylase alone; or
    b. Evidence of megaloblastic anemia:
        i. Shown not to improve with iron supplements; and
        ii. Normal serum folate and vitamin B12 levels and no evidence of Transcobalamine II deficiency; or
    c. Orotic acid crystals visualized in the urine via microscopy; and
2. Current weight of member must be provided on the prior authorization request; and
    a. Weights should be reassessed every six months to ensure proper dosing and effectiveness; or
    b. Prescriber can indicate urine orotic acid levels are within normal ranges and dosing remains appropriate; and
3. The prescriber must verify that the patient/caregiver is able to properly measure and administer medication; and
4. A quantity limit of four packets per day will apply.

Utilization of Xuriden™ (Uridine Triacetate): Fiscal Year 2017

There was no utilization of Xuriden™ (uridine triacetate) during fiscal year 2017.

Prior Authorization of Xuriden™ (Uridine Triacetate)

There were no prior authorization requests submitted for Xuriden™ (uridine triacetate) during fiscal year 2017.

Market News and Updates

Anticipated Patent Expiration(s):[118]

- Xuriden™ (uridine triacetate): July 2018

[118] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 02/2018. Last accessed 04/06/2018.

Recommendations

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