Drug Utilization Review Board

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1A
Oklahoma City, Oklahoma 73107
Ponca Room

Wednesday
May 9, 2012
6:00 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Keast, Pharm.D., M.S.

SUBJECT: Packet Contents for Board Meeting – May 9, 2012

DATE: May 3, 2012

NOTE: The DUR Board will meet at 6:00 p.m. The meeting will be held in the Ponca Room at the Oklahoma Health Care Authority Offices in Shepherd Mall. (North Entrance)

Enclosed are the following items related to the May meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote on New Citalopram Safety Alert Limitations – See Appendix C.

Action Item – Annual Review of Atypical Antipsychotics – See Appendix D.

Action Item – Annual Review of Miscellaneous Anti-Infectives and 30 Day Notice to Prior Authorize Keflex® – See Appendix E.

Action Item – Annual Review of Non-Steroidal Anti-Inflammatory Drugs and 30 Day Notice to Prior Authorize Duexis® – See Appendix F.

Action Item – Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Zioptan™ – See Appendix G.

Utilization Review of Gonadotropin Releasing Products – See Appendix H.

FDA and DEA Updates – See Appendix I.

Future Business

Adjournment

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Oklahoma Health Care Authority
Drug Utilization Review Board

(DUR Board)

Meeting – May 9, 2012 @ 6:00 p.m.

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1-A
Oklahoma City, Oklahoma 73107
Ponca Room (North Entrance)

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call To Order

A. Roll Call – Dr. Cothran

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. Muchmore, Chairman:

3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.

A. April 11, 2012 DUR Minutes – Vote
B. April 12, 2012 DUR Recommendation Memorandum

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman:

4. Update on DUR / Medication Coverage Authorization Unit – See Appendix B.

A. Retrospective Drug Utilization Review for January 2012
B. Retrospective Drug Utilization Review Response for November 2011
C. Medication Coverage Activity for April 2012
D. Pharmacy Help Desk Activity for April 2012

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman

5. Action Item – Vote on New Citalopram Safety Alert Limitations – See Appendix C.

A. Background
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman

6. Action Item – Annual Review of Atypical Antipsychotics – See Appendix D.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorization Review
D. Poly-Pharmacy Review
E. Market Update
F. MEDNET Update
G. COP Recommendations
H. Utilization Details

Items to be presented by Dr. Sipols, Dr. Muchmore, Chairman

7. Action Item – Annual Review of Miscellaneous Anti-Infectives and 30 Day Notice to Prior Authorize Keflex® – See Appendix E.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorization Review
D. Market News and Updates
E. COP Recommendations
F. Utilization Details

Items to be presented by Dr. Sipols, Dr. Muchmore, Chairman

8. Action Item – Annual Review of Non-Steroidal Anti-Inflammatory Drugs and 30 Day Notice to Prior Authorize Duexis® – See Appendix F.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorization Review
D. Market News and Updates
E. COP Recommendations
F. Utilization Details
G. Duexis® Product Details

Items to be presented by Dr. Moore, Dr. Muchmore, Chairman

9. Action Item – Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Zioptan™ – See Appendix G.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorization Review
D. Market News and Updates
E. COP Recommendations
F. Utilization Details
G. Zioptan™ Product Details

Items to be presented by Dr. Moore, Dr. Muchmore, Chairman

10. Utilization Review of Gonadotropin Releasing Products – See Appendix H.

A. Central Precocious Puberty Overview
B. Treatment Options
C. Utilization Details
D. COP Recommendations

Items to be presented by Dr. Cothran, Dr. Muchmore, Chairman

11. FDA and DEA Updates – See Appendix I.

12. Future Business

A. Utilization Review of Botulinum Toxin Products
B. Annual Review of Synagis®
C. New Product Reviews
D. Medical Product Reviews

13. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of APRIL 11, 2012

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.	X	
Anetta Harrell, Pharm.D.	X	
Evelyn Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.		X
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.	X	
Bruna Varalli-Claypool, MHS, PA-C	X	
Eric Winegardener, D.Ph.	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Shellie Keast, Pharm.D, M.S.; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Coordinator	X	
Mark Livesay, Operations Manager	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator		X
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Graduate Students: Amany Hussein, Manish Mittal	X	
Visiting Pharmacy Student(s): Brian Golden, Jo Nel Weber	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer	X	
Garth Splinter, M.D., M.B.A.; Director of Medicaid/Medical Services	X	
Rebecca Pasternik-Ikard, Deputy State Medicaid Director		X
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Lynn Rambo-Jones, J.D.; Deputy General Counsel III	X	
Carter Kimble, MPH/Public Affairs- Information Rep.		X
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	
Stacey Hale, Pharmacy Research Analyst	X	

OTHERS PRESENT:		
Stephen Curry, Meda	Toby Thompson, Pfizer	Eric Gardner, Vertex
Sandra Manning, BMS	Don Kempin, NovoNordisk	Tom O Donnell, Genentech
Warren Tayes, Merck	Janie Huff, Takeda	Jim Chapman, Abbott
Brian Maves, Pfizer	Dana Koehn, Baxter	

PRESENT FOR PUBLIC COMMENT:

AGENDA ITEM NO. 1: CALL TO ORDER

1A: Roll Call

Dr. Muchmore called the meeting to order. Roll call by Dr. Cothran established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

There were no speakers for public comment.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: March 14, 2012 DUR Minutes

Dr. Harrell moved to approve as submitted; seconded by Dr. Preslar.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON DUR/MEDICATION COVERAGE AUTHORIZATION UNIT

4A: Retrospective Drug Utilization Review: December 2011

4B: Retrospective Drug Utilization Review Response: October 2011

4C: Medication Coverage Activity Audit: March 2012

Reports included in agenda packet; presented by Dr. Keast.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: GENETIC TECHNOLOGIES IN HEALTH CARE

Guest Speaker: Alison Adams Martinez, Ph.D.; OHCA Clinical Data Analyst

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE KALYDECO™

Materials included in agenda packet; presented by Dr. Le.

Ms. Varalli-Claypool moved to approve as submitted; seconded by Dr. Rhymer.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF GROWTH HORMONES

Materials included in agenda packet; presented by Dr. Moore.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: FY 2011 ANNUAL REVIEW

Materials included in agenda packet; presented by Dr. Keast.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: QUESTIONS REGARDING ANNUAL REVIEW OF REQUIP XL® AND MIRAPEX ER®

Materials included in agenda packet; presented by Dr. Le.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: QUESTIONS REGARDING ANNUAL REVIEW OF METAZOLV®

Materials included in agenda packet; presented by Dr. Sipols.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: FDA & DEA UPDATES

Materials included in agenda packet; presented by Dr. Cothran.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: FUTURE BUSINESS

Materials included in agenda packet; submitted by Dr. Cothran.

A: Annual Review of Atypical Antipsychotics

B: Annual Review of NSAIDs

C: New Product Reviews

D: Medical Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: ADJOURNMENT

The meeting was adjourned at 7:00 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: April 12, 2012

To: Nancy Nesser, Pharm.D., J.D.
Pharmacy Director
Oklahoma Health Care Authority

From: Shellie Keast, Pharm.D., M.S.
Drug Utilization Review Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of April 11, 2012

Recommendation 1: Vote to Prior Authorize Kalydeco™ (ivacaftor)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Kalydeco™ (ivacaftor) with the following criteria:

1. FDA approved indication of Cystic Fibrosis with a G551D mutation in the CFTR gene detected by genetic testing.
2. Age of 6 years or older.
3. Quantity limit of two tablets per day, #60 per 30 days will apply.
4. Initial approval will be for 6 months, after which time, compliance and information regarding efficacy, such as improvement in $FEV_{1,}$ will be required for continued approval.

Recommendation 2: Annual Review of Growth Hormone Products

NO ACTION REQUIRED.

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

Recommendation 3: Annual Review of Requip XL® (ropinirole extended release) and Mirapex ER® (pramipexole dihydrochloride extended release)

NO ACTION REQUIRED.

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

Recommendation 4: Annual Review of Metazolv® ODT (metoclopramide)

NO ACTION REQUIRED.

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

Appendix B

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT
January 2012

MODULE	DRUG INTERACTION	DUPLICATION OF THERAPY	DRUG-DISEASE PRECAUTIONS	DOSING & DURATION
Total # of messages	63,255	84,114	1,121,369	38,267
Limits applied	Established, Major, Males and Females, Age 36-50	Duplication of Benzodiazepines, Males and Females, Age 35-45	Contraindicated, Ulcer, Males and Females, Ages 0-150	High Dose, Duration, NSAIDs, Males and Females, age 0-2
Total # of messages after limits were applied	90	415	48	65
Total # of members reviewed	90	373	25	65

LETTERS

Category	Prescribers	Pharmacies	Total Letters
Drug Interaction	2	0	2
Duplication of Therapy	130	47	177
Drug-Disease Precautions	4	0	4
Dosing & Duration	0	2	2
Total Letters Sent	136	49	185

Retrospective Drug Utilization Review Report

Claims Reviewed for November 2011

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 61-150	Duplication of Atypical Antipsychotics, Males and Females, Age 14-16	Contraindicated, Drug Dependence, Males and Females, Age 0-150	High Dose, Duration, Proton Pump Inhibitors, Females, Age 13-14

Response Summary (Prescriber)
Letters Sent: 109
Response Forms Returned: 54

The response forms returned yielded the following results:

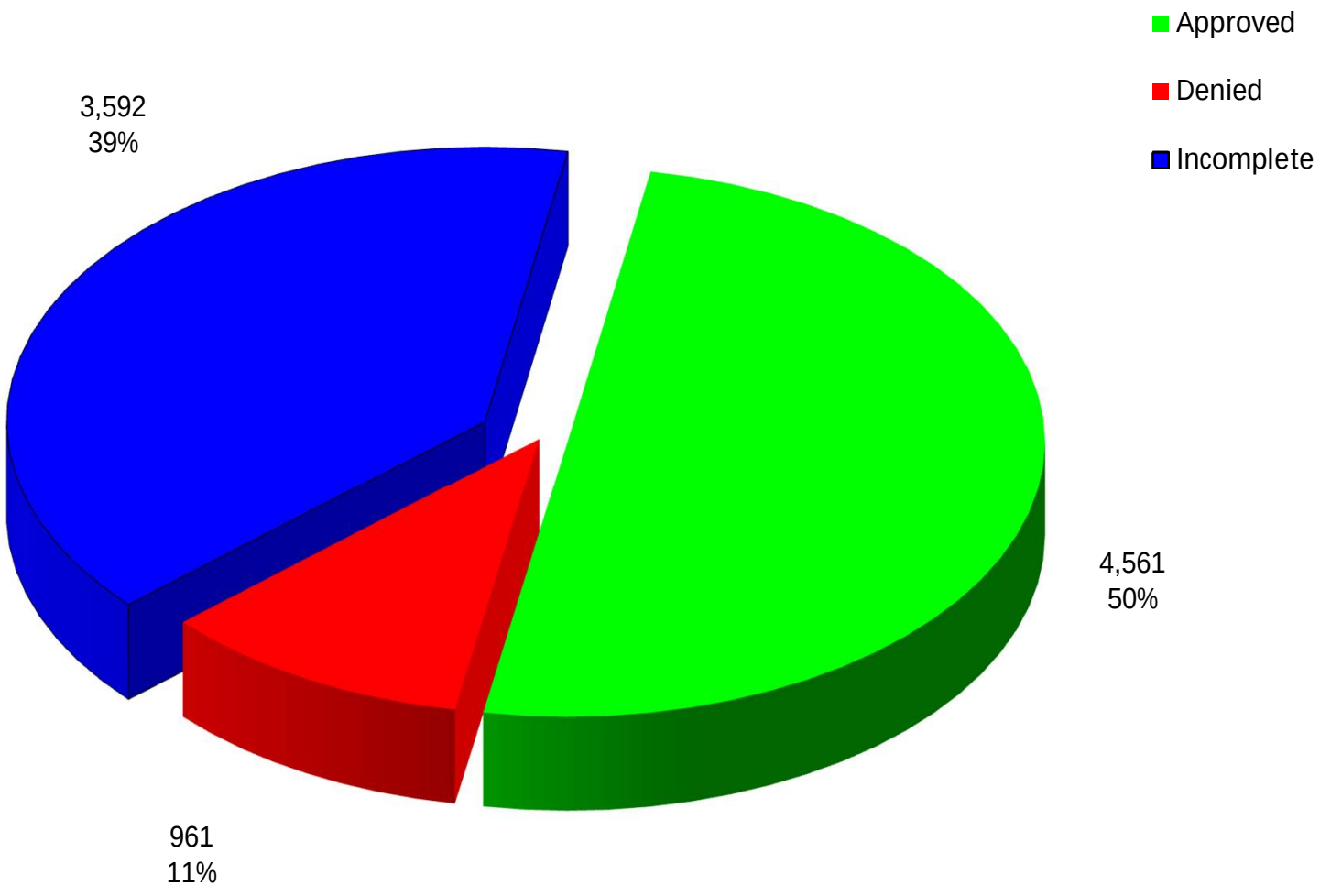
1 (2%)	*Record Error—Not my patient.*
5 (9%)	*No longer my patient.*
3 (6%)	*Medication has been changed prior to date of review letter.*
3 (6%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
39 (72%)	*I am aware of this situation and will plan to continue monitoring therapy.*
3 (6%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 0
Response Forms Returned: 0

The response forms returned yielded the following results:

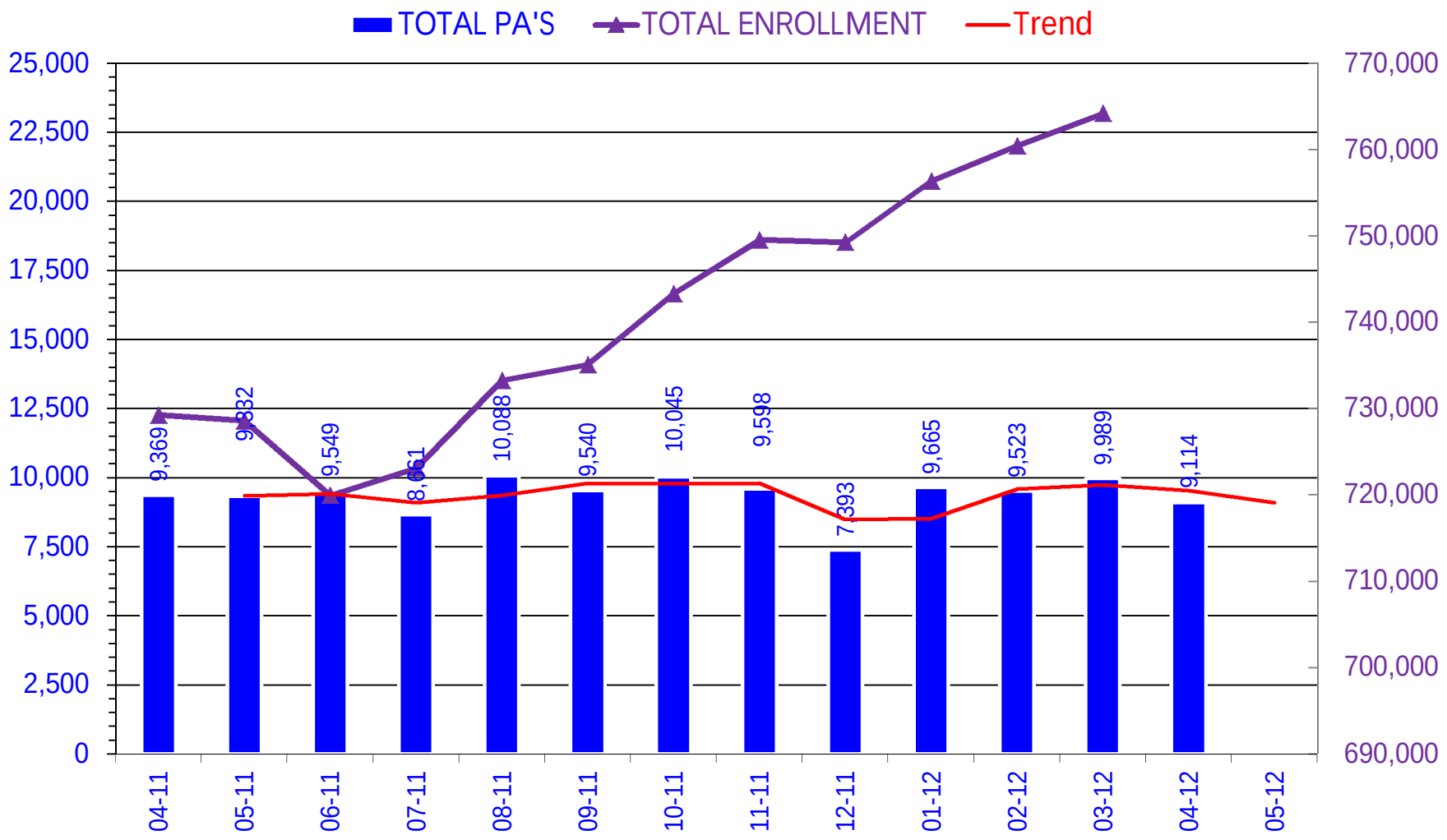
0	*Record Error—Not my patient.*
0	*No longer my patient.*
0	*Medication has been changed prior to date of review letter.*
0	*I was unaware of this situation & will consider making appropriate changes in therapy.*
0	*I am aware of this situation and will plan to continue monitoring therapy.*
0	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: April 2012



PA totals include overrides

PRIOR AUTHORIZATION REPORT: April 2011 – April 2012



PA totals include overrides

Prior Authorization Activity

4/1/2012 Through 4/30/2012

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	349	152	25	172	356
Amitiza	19	6	4	9	178
Anti-Ulcer	398	113	125	160	107
Antidepressant	306	105	17	184	347
Antihistamine	255	166	10	79	340
Antihypertensives	58	14	9	35	319
Antimigraine	70	24	10	36	349
Atypical Antipsychotics	696	296	28	372	347
Benign Prostatic Hypertrophy	3	1	1	1	365
Benzodiazepines	72	48	1	23	248
Biologics	22	16	0	6	345
Bladder Control	64	17	9	38	359
Brovana (Arformoterol)	4	1	1	2	362
Byetta	9	3	1	5	360
Elidel/Protopic	45	15	5	25	103
ESA	128	85	7	36	98
Fibric Acid Derivatives	9	2	1	6	363
Fibromyalgia	170	42	41	87	321
Fortamet/Glumetza	7	1	0	6	365
Forteo	1	1	0	0	365
Glaucoma	10	1	0	9	365
Growth Hormones	57	30	2	25	163
HFA Rescue Inhalers	159	27	48	84	301
Insomnia	73	18	12	43	163
Insulin	10	2	0	8	122
Misc Analgesics	43	6	31	6	147
Multiple Sclerosis	9	6	0	3	270
Muscle Relaxant	131	46	52	33	48
Nasal Allergy	245	49	91	105	106
NSAIDS	158	33	31	94	286
Ocular Allergy	102	13	24	65	146
Ocular Antibiotics	56	18	7	31	18
Opioid Analgesic	310	164	23	123	249
Other	1,085	473	114	498	294
Otic Antibiotic	32	5	1	26	9
Pediculicides	130	39	12	79	13
Plavix	213	158	0	55	331
Prenatal Vitamins	29	0	0	29	0
Singulair	888	500	39	349	240
Smoking Cessation	63	26	3	34	24
Statins	143	88	3	52	350
Stimulant	608	359	46	203	324
Suboxone/Subutex	161	124	5	32	77
Symlin	1	1	0	0	360
Synagis	17	6	5	6	117
Topical Antibiotics	4	0	1	3	0
Topical Antifungals	20	3	2	15	49
Topical Corticosteroids	88	1	35	52	13
Ultram ER and ODT	8	3	1	4	299
Xolair	22	4	10	8	293
Xopenex Nebs	35	19	2	14	315
Zetia (Ezetimibe)	19	6	1	12	360
Emergency PAs	7	7	0	0	
Total	**7,621**	**3,343**	**896**	**3,382**	

Overrides					
Brand	46	35	2	9	270
Dosage Change	523	509	1	13	7
High Dose	4	3	0	1	271
Ingredient Duplication	7	4	0	3	4
Lost/Broken Rx	102	100	2	0	4
NDC vs Age	8	8	0	0	280
Nursing Home Issue	68	65	0	3	17
Other	22	16	0	6	6
Quantity vs. Days Supply	700	466	60	174	274
Stolen	11	11	0	0	7
Wrong D.S. on Previous Rx	2	1	0	1	91
Overrides Total	**1,493**	**1,218**	**65**	**210**	
Total Regular PAs + Overrides	9,114	4,561	961	3,592	

Unable to verify required trials.	3,114
Does not meet established criteria.	934
Lack required information to process request.	581
Drug Not Deemed Medically Necessary	3
Drug Deemed Medically Necessary	2

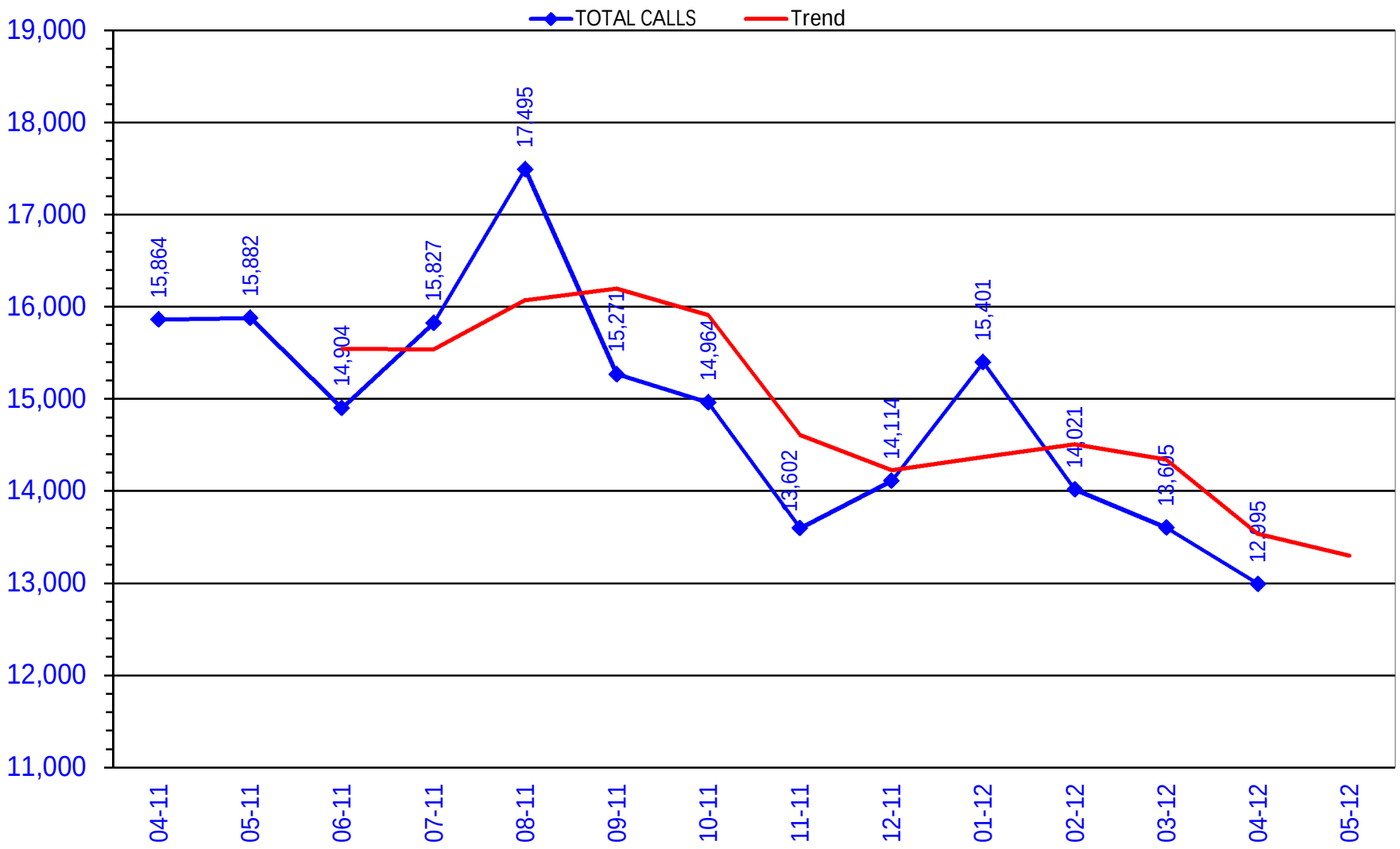
Duplicate Requests: 706

Letters: 2,293

No Process: 386

Changes to existing PAs: 503

CALL VOLUME MONTHLY REPORT:
April 2011 – April 2012



Appendix C

Vote on New Citalopram Safety Alert Limitations

Oklahoma HealthCare Authority, May 2012

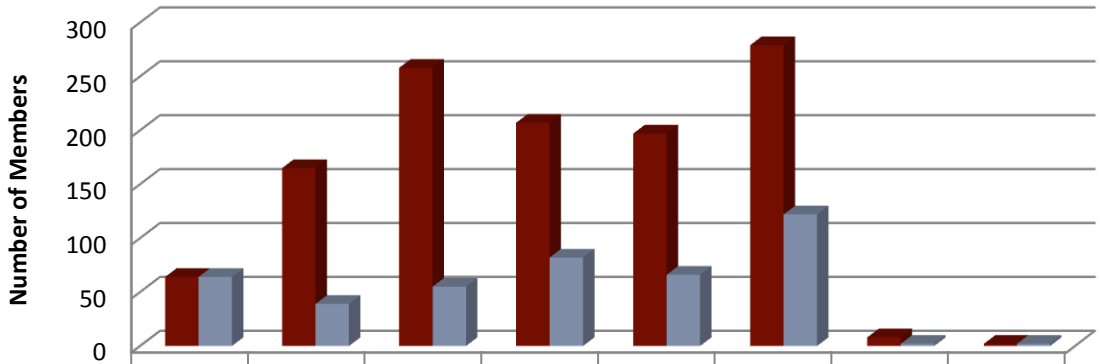
Background

In March 2012, FDA updated the Drug Safety Communication (DSC) regarding citalopram. The update stated that citalopram should no longer be used at doses greater than **40mg/day** because it could cause potentially dangerous abnormalities in the electrical activity of the heart. Prolongation of the QT interval of the electrocardiogram (ECG) can lead to a risk of an abnormal heart rhythm called Torsade de Pointes, which can be fatal. Citalopram use at any dose is discouraged in patients with certain conditions because of the risk of QT prolongation.

A maximum dose of **20mg/day** is recommended for those with the following conditions:

- Hepatic impairment
- Older than 60 years of age
- CYP 2C19 poor metabolizers
- Taking a CYP2C19 inhibitor

Calendar Year 2011 Utilization of Citalopram Dosed Greater than 40 mg for Age Less than 60 or Greater than 20 mg for Age 60 and Over



	0 to 19	20 to 29	30 to 39	40 to 49	50 to 59	60 to 69	70 to 79	>/= 80
Female	64	165	258	207	197	279	8	2
Male	64	39	55	82	66	122	2	2

Recommendations

The College of Pharmacy recommends placement of a quantity limit of one tablet daily on all strengths of citalopram. An additional age restriction will also be placed on the 40 mg tablet to require a prior authorization for members age 60 years or greater. Citalopram will also be placed in the Ingredient Duplication module of the Prospective DUR point-of-sale system to block any use of 20 mg and 40 mg concurrently without prior authorization.

References:

U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: Revised recommendations for Celexa (citalopram hydrobromide) related to a potential risk of abnormal heart rhythms with high doses. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2012. Available from URL:http://www.fda.gov/Drugs/DrugSafety/ucm297391.htm. As accessed 2012-04-23.

Appendix D

Annual Review of Atypical Antipsychotics

Oklahoma Health Care Authority, May 2012

CY 2011 Prior Authorization and Approval Criteria

Atypical Antipsychotics[a]		
Tier 1	**Tier 2[b]**	**Tier 3[c]**
risperidone **(Risperdal®)**[d] clozapine **(Clozaril®)**	aripiprazole **(Abilify®)** iloperidone **(Fanapt™)** quetiapine ER **(Seroquel XR®)** asenapine **(Saphris®)**	olanzapine **(Zyprexa®)** quetiapine **(Seroquel®)**[e] paliperidone **(Invega®)** clozapine **(Fazaclo®)** olanzapine/fluoxetine **(Symbyax®)** lurasidone **(Latuda®)** ziprasidone **(Geodon®)**

[a]Mandatory Generic Plan Applies
[b]Suplemental rebate products
[c]May be rebated to Tier 2 status only
[d]Includes Risperdal Consta
[e]Moved to Tier 1 on April 5, 2012, when SMAC was applied.

Approval Criteria for Tier 2 Medication:

1. A trial of risperidone, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Tier 3 Medication:

1. A trial of risperidone, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
2. A trial of two Tier 2 medications, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Use as Depression Adjunct:

1. For **aripiprazole and quetiapine extended release, or olanzapine/fluoxetine**: a diagnosis of depression requires current use of an antidepressant, and previous trials with at least two other antidepressants. Tier structure still applies.

Clinical Exceptions:

1. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
2. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
3. Members being released from a hospital and stabilized on a higher tiered medication will be approved.

Utilization Review

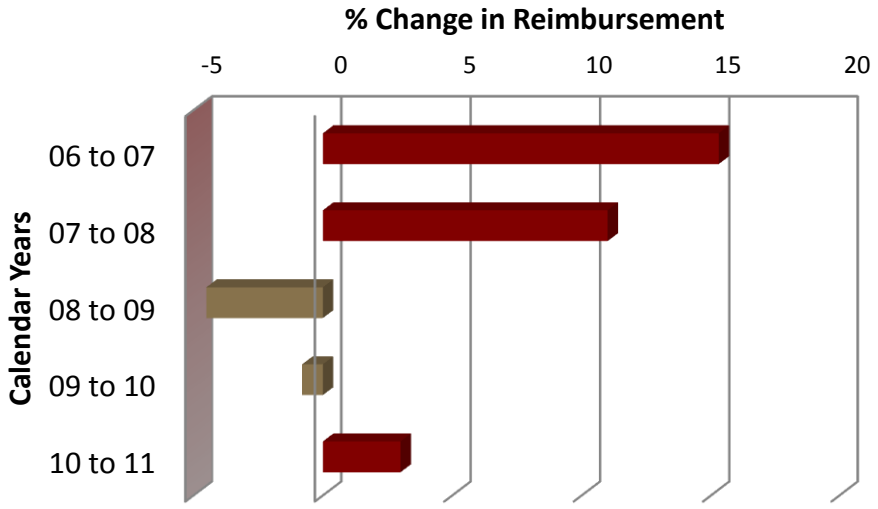
This category was first implemented on April 1, 2010. The first annual review was done based on pre-post implementation dates. This review is based on calendar year 2011, keep in mind that for calendar year 2010 data, the first quarter of 2010 is pre-implementation.

Calendar Year Comparison

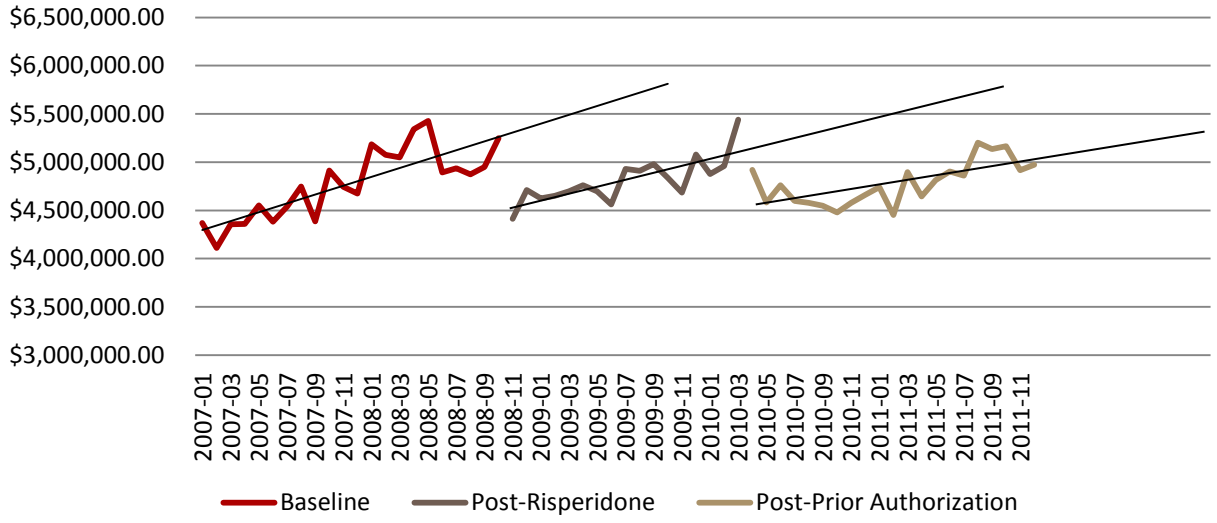
Calendar Year	Total Members*	Total Claims	Total Cost	Cost per Claim	Per-Diem Cost	Total Units	Total Days
2009	25,017	171,910	$57,412,745.73	$333.97	$10.89	7,128,695	5,274,240
2010	24,633	173,023	$56,980,166.38	$329.32	$10.79	7,175,086	5,279,606
2011	24,712	175,255	$58,701,982.88	$334.95	$11.08	7,265,061	5,300,303
Percent Change**	**0.3%**	**1.3%**	**3.0%**	**1.7%**	**2.7%**	**1.3%**	**0.4%**
Absolute Change**	**79**	**2,232**	**$1,721,816.50**	**$5.63**	**$0.29**	**89,975**	**20,697**

*Unduplicated members for each year
**Change from 2010 to 2011

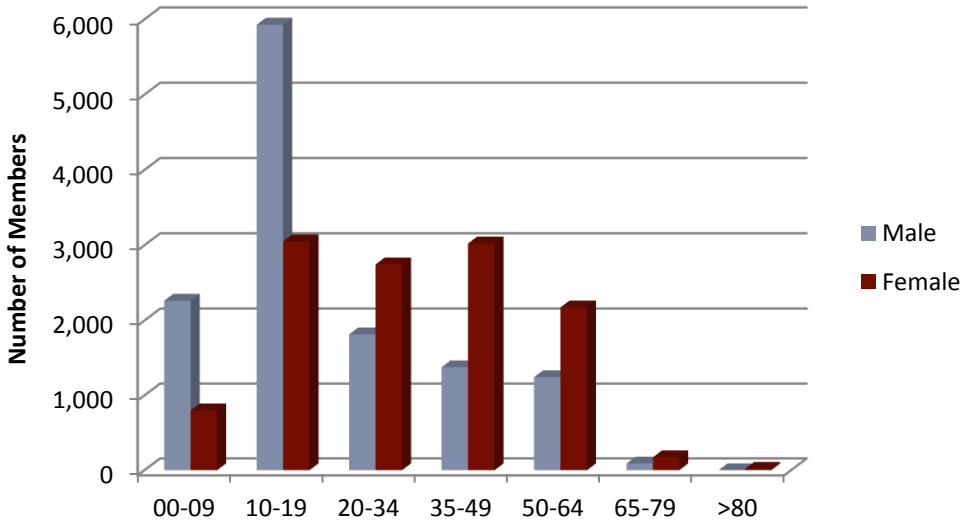
Between CY08 and CY09 this category saw a -4.5% decrease in pharmacy reimbursement due to the introduction of generic risperidone in November 2009. CY09 to CY10 saw a total decrease of 0.8% due to the implementation of the PBPA program in April 2010. The estimated total savings for the first year of the PBPA program for this category was just over $9 million based on the difference between the projected monthly trend without the new PBPA program and the actual monthly cost in the post period.



Trends in Utilization for Atypical Antipsychotics (Monthly Reimbursement)



Member Demographics

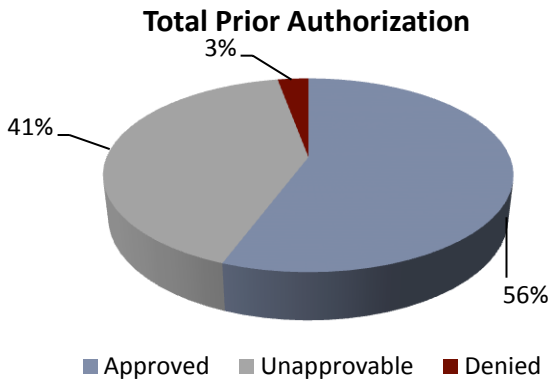


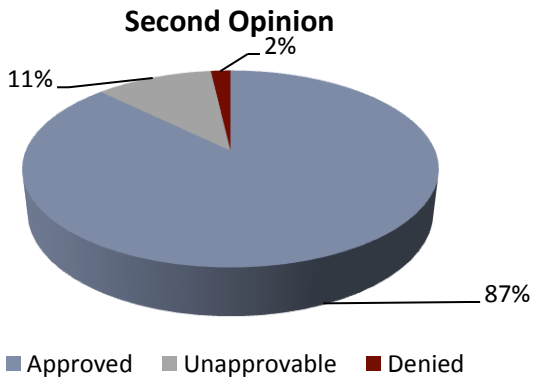
Prior Authorizations

During the review period a total of 9,537 petitions were submitted for this category including step-therapy requests and quantity limit overrides. The point-of-sale system is set to look for claims for lower-tiered products and allow movement to higher tiers when appropriate without manual prior authorization. A total of 5,315 petitions were approved, 3,946 were incomplete, and 276 were denied.

Second Opinion Prior Authorizations

A total of 165 prior authorization requests were submitted for children 4 years of age or less. 144 requests were approved, 3 were denied, and 18 were sent back for additional information. 114 unique members in this age group were approved for atypical antipsychotics.



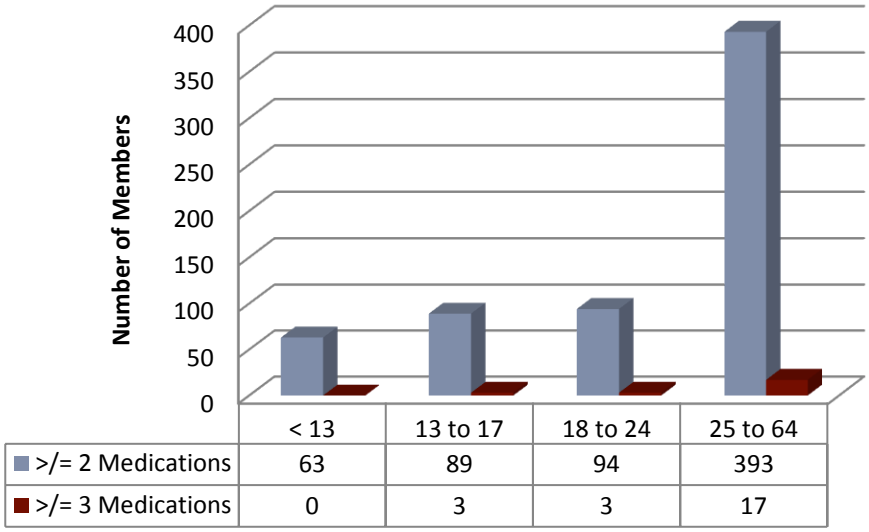


Review of Poly-Pharmacy

A review of concurrent product use (poly-pharmacy) was done for the period of January 1, 2012 through March 31, 2012. To be included in the review, the members had to be eligible for the entire three month period, receive at least one paid pharmacy claim for an atypical antipsychotic, and were less than 65 years of age. Injectable products were not included in the review. If a member had overlapping medications for greater than 90 days, then they were considered to have poly-pharmacy.

	# of Members	Percent (N=10,149)
Greater Than or Equal to 2 Medications	639	6.30 %
Greater Than or Equal to 3 Medications	23	0.23 %

Number of Members Overlapping Medications by Age



Market Update

The following patent expirations are anticipated:

- **Seroquel®**: Generic currently available – SMAC applied
- **Zyprexa®**: Generic currently available
- **Geodon®**: Generic currently available
- **Abilify®**: 2014

MEDNET Update

MEDNET is a collaborative workgroup between California, Maine, Missouri, Oklahoma, Texas and Washington with the goal of improving quality in prescribing of atypical antipsychotics. The workgroup is based out of the Rutgers' Institute for Health, Health care Policy and Aging Research and funded by a grant from the Agency for Healthcare Research and Quality. As part of this workgroup, Oklahoma has established a stakeholder group and has set a primary outreach goal of improving dosing of atypical antipsychotics and appropriate diagnosis/use in children 5 to 14 years of age. As a first step in reaching this goal, in the next few months an outreach will be initiated to prescribers of atypical antipsychotics who have members on doses greater than 1.5 times the FDA approved maximum and/or members who have no diagnosis on file that is consistent with receipt of an atypical antipsychotic.

Recommendations

The College of Pharmacy recommends continuation of the Atypical Antipsychotic Product Based Prior Authorization Program. The College recommends continued movement of Tier 3 products to Tier 1 as generics become available and SMAC pricing is applied (olanzapine will only be available as a Tier 2 product due to metabolic issues).

Proposed changes in January 2013:

Atypical Antipsychotics[a]		
Tier 1	**Tier 2[b]**	**Tier 3[c]**
risperidone **(Risperdal®)**[d] quetiapine (**Seroquel®**) **ziprasidone (Geodon®)** clozapine **(Clozaril®)**	aripiprazole **(Abilify®)**[b] iloperidone **(Fanapt™)**[b] quetiapine ER **(Seroquel XR®)**[b] asenapine **(Saphris®)**[b] olanzapine **(Zyprexa®)**	paliperidone **(Invega®)** clozapine **(Fazaclo®)** olanzapine/fluoxetine **(Symbyax®)** lurasidone **(Latuda®)**

[a]**Mandatory Generic Plan Applies**
[b]**Suplemental rebate products or Tier 2 generics. Brand products may change each year due to changes in supplemental rebates.**
[c]**May be rebated to Tier 2 status only**
[d]**Includes Risperdal Consta**

Approval Criteria for Tier 2 Medication:

1. A trial of ~~risperidone~~ two available Tier 1 products, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
2. Clozapine is available without prior authorization, but does not count towards a Tier 1 trial.

Approval Criteria for Tier 3 Medication:

1. A trial of ~~risperidone~~ two available Tier 1 products (not including clozapine), at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
2. A trial of two Tier 2 medications, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Use as Depression Adjunct:

1. For **aripiprazole and quetiapine extended release, or olanzapine/fluoxetine**: a diagnosis of depression requires current use of an antidepressant, and previous trials with at least two other antidepressants. Tier structure still applies.

Clinical Exceptions:

1. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
2. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
3. Members being released from a hospital and stabilized on a higher tiered medication will be approved.

Utilization Details for Calendar Year 2011

RANK CLAIMS	RANK COST	PRODUCT NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
109	111	ABILIFY INJ 9.75MG	2	4	9	2	$57.16
70	65	ABILIFY SOL 1MG/ML	122	17,130	3,706	26	$61,411.07
4	1	ABILIFY TAB 10MG	8,513	260,963	263,355	2,295	$4,473,370.84
8	7	ABILIFY TAB 15MG	5,865	174,480	185,062	1,475	$3,003,262.84
12	6	ABILIFY TAB 20MG	4,381	137,727	138,235	988	$3,343,772.63
21	12	ABILIFY TAB 2MG	2,537	78,432	77,863	771	$1,347,041.38
16	8	ABILIFY TAB 30MG	3,454	113,853	114,457	649	$2,759,381.39
5	3	ABILIFY TAB 5MG	8,272	248,091	254,776	2,350	$4,240,534.40
83	77	ABILIFY DISC TAB 10MG	42	1,127	1,217	11	$23,276.09
97	84	ABILIFY DISC TAB 15MG	17	570	510	6	$11,834.96
		Total Aripiprazole	**33,205**	**1,032,377**	**1,039,190**		**$19,263,942.76**
20	40	CLOZAPINE TAB 100MG	2,705	224,011	54,339	219	$225,358.56
76	93	CLOZAPINE TAB 200MG	68	3,058	1,630	13	$6,742.82
57	88	CLOZAPINE TAB 25MG	299	14,189	5,211	38	$7,571.38
65	96	CLOZAPINE TAB 50MG	159	4,250	1,860	19	$4,365.27
74	60	CLOZARIL TAB 100MG	83	11,383	2,413	10	$81,738.71
		Total Clozapine	**3,314**	**256,891**	**65,453**		**$325,776.74**
92	104	FANAPT PAK	25	200	176	23	$2,046.86
75	67	FANAPT TAB 10MG	80	4,732	2,366	24	$47,649.22
62	52	FANAPT TAB 12MG	200	11,630	5,914	46	$112,527.69
81	78	FANAPT TAB 1MG	47	2,271	1,371	24	$23,104.77
69	62	FANAPT TAB 2MG	129	7,064	3,725	39	$70,257.13
64	58	FANAPT TAB 4MG	173	9,698	5,072	60	$92,349.11
44	35	FANAPT TAB 6MG	535	30,033	15,752	177	$304,413.95
56	46	FANAPT TAB 8MG	299	17,491	8,932	85	$169,336.83
		Total Iloperidone	**1,488**	**83,119**	**43,308**		**$821,685.56**
18	22	FAZACLO TAB 100MG	2,788	162,748	46,078	211	$948,978.80
35	29	FAZACLO TAB 150MG	1,060	45,491	16,278	114	$389,581.87
43	36	FAZACLO TAB 200MG	677	25,633	11,152	73	$293,189.48
40	55	FAZACLO TAB 25MG	801	44,526	13,209	81	$98,186.67
		Total Clozapine ODT	**5,326**	**278,398**	**86,717**		**$1,729,936.82**
37	34	GEODON CAP 20MG	941	42,664	28,472	273	$324,429.17
27	25	GEODON CAP 40MG	1,847	87,749	56,343	440	$667,744.87
25	21	GEODON CAP 60MG	2,043	105,931	62,033	468	$976,033.99
14	10	GEODON CAP 80MG	4,197	234,403	131,022	743	$2,150,326.63
100	101	GEODON INJ 20MG	15	193	128	14	$3,065.93
		Total Ziprasidone	**9,043**	**470,940**	**277,998**		**$4,121,600.59**
89	82	INVEGA TAB 1.5MG	32	868	883	14	$12,301.08
38	27	INVEGA TAB 3MG	925	28,769	28,238	211	$447,041.99
23	11	INVEGA TAB 6MG	2,383	90,342	74,235	422	$1,391,662.17
34	23	INVEGA TAB 9MG	1,143	36,895	36,655	200	$857,548.06
49	37	INVEGA SUST INJ 117/0.75	363	273	10,370	79	$290,316.54
36	20	INVEGA SUST INJ 156MG/ML	949	949	27,328	277	$1,033,961.86
42	18	INVEGA SUST INJ 234/1.5	702	1,052	20,144	239	$1,140,140.59
111	108	INVEGA SUST INJ 39/0.25	1	0	29	1	$277.28
96	83	INVEGA SUST INJ 78/0.5ML	22	11	626	7	$12,019.04
		Total Paliperidone	**6,520**	**159,159**	**198,508**		**$5,185,268.61**
55	47	LATUDA TAB 40MG	302	11,070	9,971	135	$165,917.49
52	45	LATUDA TAB 80MG	350	11,103	10,821	111	$172,600.11
		Total Lurasidone	**652**	**22,173**	**20,792**		**$338,517.60**
93	94	RISPERDAL INJ 12.5MG	24	43	602	8	$5,493.27
45	42	RISPERDAL INJ 25MG	465	801	11,274	91	$202,294.21
47	39	RISPERDAL INJ 37.5MG	393	617	8,715	56	$228,935.91
32	19	RISPERDAL INJ 50MG	1,187	2,078	29,102	166	$1,053,234.52
95	87	RISPERDAL SOL 1MG/ML	22	1,770	661	2	$8,149.47
103	103	RISPERDAL TAB 0.25MG	9	450	270	1	$2,223.78
77	99	RISPERDAL TAB 0.5MG	59	2,145	1,770	8	$3,323.70

RANK CLAIMS	RANK COST	PRODUCT NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
87	92	RISPERDAL TAB 1MG	34	1,986	1,023	8	$7,018.82
104	98	RISPERDAL TAB 2MG	5	450	150	1	$4,267.60
78	73	RISPERDAL TAB 3MG	53	3,540	1,617	5	$34,167.41
110	110	RISPERDAL TAB 4MG	1	50	27	1	$153.54
101	102	RISPERDAL M TAB 0.5MG	10	540	300	2	$3,019.79
102	97	RISPERDAL M TAB 1MG	10	660	300	3	$4,267.85
108	105	RISPERDAL M TAB 2MG	2	112	56	1	$1,193.92
39	64	RISPERIDONE SOL 1MG/ML	910	63,950	28,366	163	$62,540.98
105	106	RISPERIDONE TAB 0.25 ODT	5	210	150	3	$726.62
7	59	RISPERIDONE TAB 0.25MG	6,313	294,036	189,814	1,762	$85,987.07
2	43	RISPERIDONE TAB 0.5MG	16,276	708,148	489,916	4,578	$192,735.72
59	81	RISPERIDONE TAB 0.5MG OD	240	10,008	7,029	87	$12,837.47
1	33	RISPERIDONE TAB 1MG	22,466	983,469	685,520	6,118	$324,847.11
48	69	RISPERIDONE TAB 1MG ODT	388	17,885	11,212	122	$42,208.42
3	41	RISPERIDONE TAB 2MG	13,349	564,701	412,132	3,793	$212,032.56
54	74	RISPERIDONE TAB 2MG ODT	325	13,842	9,416	104	$33,391.86
6	51	RISPERIDONE TAB 3MG	6,749	300,968	212,782	1,550	$118,197.10
72	75	RISPERIDONE TAB 3MG ODT	92	4,456	2,834	43	$28,299.44
15	63	RISPERIDONE TAB 4MG	3,654	164,646	121,036	866	$68,051.85
80	79	RISPERIDONE TAB 4MG ODT	48	2,390	1,444	16	$21,805.79
		Total Riperidone	**73,089**	**3,143,951**	**2,227,518**		**$2,761,405.78**
50	44	SAPHRIS SUB 10MG	359	19,724	10,927	110	$192,674.66
63	56	SAPHRIS SUB 5MG	195	9,936	5,883	77	$95,631.61
		Total Asenapine	**554**	**29,660**	**16,810**		**$288,306.27**
9	13	SEROQUEL TAB 100MG	5,124	232,848	160,570	1,052	$1,314,879.56
11	9	SEROQUEL TAB 200MG	4,558	206,787	142,997	906	$2,174,401.68
28	38	SEROQUEL TAB 25MG	1,671	86,558	51,390	352	$280,928.11
10	4	SEROQUEL TAB 300MG	5,050	254,689	158,096	967	$3,547,911.09
13	5	SEROQUEL TAB 400MG	4,315	211,094	135,360	732	$3,455,180.22
19	24	SEROQUEL TAB 50MG	2,740	128,593	85,106	593	$690,734.99
30	31	SEROQUEL XR TAB 150MG	1,265	39,416	38,850	446	$341,940.43
33	32	SEROQUEL XR TAB 200MG	1,148	35,853	35,263	359	$341,380.60
22	16	SEROQUEL XR TAB 300MG	2,404	99,196	74,507	669	$1,250,890.63
26	14	SEROQUEL XR TAB 400MG	2,033	88,219	62,709	486	$1,307,528.17
41	48	SEROQUEL XR TAB 50MG	743	30,371	22,471	286	$149,083.78
		Total Quetiapine	**31,051**	**1,413,624**	**967,319**		**$14,854,859.26**
79	71	SYMBYAX CAP 12-25MG	48	1,930	1,930	9	$40,201.25
82	68	SYMBYAX CAP 12-50MG	43	2,070	1,590	8	$43,085.37
94	91	SYMBYAX CAP 3-25MG	24	720	720	5	$7,211.06
73	70	SYMBYAX CAP 6-25MG	86	2,983	2,983	18	$41,533.59
84	80	SYMBYAX CAP 6-50MG	40	1,243	1,243	7	$17,189.11
		Total Olanzepine/Fluoxetine	**241**	**8,946**	**8,466**		**$149,220.38**
88	95	ZYPREXA INJ 10MG	33	143	109	13	$5,385.51
24	15	ZYPREXA TAB 10MG	2,219	74,161	72,122	480	$1,303,549.11
29	17	ZYPREXA TAB 15MG	1,306	46,921	42,068	273	$1,240,851.64
53	54	ZYPREXA TAB 2.5MG	342	10,486	10,442	76	$100,636.66
17	2	ZYPREXA TAB 20MG	3,402	120,236	113,927	584	$4,268,147.13
31	26	ZYPREXA TAB 5MG	1,209	39,957	38,835	272	$465,743.84
61	57	ZYPREXA TAB 7.5MG	206	6,459	6,399	43	$92,802.07
60	49	ZYPREXA ZYDI TAB 10MG	228	7,477	7,078	62	$142,204.58
71	50	ZYPREXA ZYDI TAB 15MG	108	4,462	3,232	27	$124,530.92
51	28	ZYPREXA ZYDI TAB 20MG	355	11,461	11,116	62	$410,189.07
67	66	ZYPREXA ZYDI TAB 5MG	154	4,744	4,639	49	$58,528.96
106	107	ZYPREXA ZYDIS 5MG TAB	2	60	60	1	$709.72
107	109	OLANZAPINE INJ 10MG	2	6	3	2	$218.40
58	53	OLANZAPINE TAB 10MG	274	8,795	8,795	198	$103,305.62
90	85	OLANZAPINE TAB 10MG ODT	30	965	935	23	$10,795.27
68	61	OLANZAPINE TAB 15MG	145	4,599	4,354	107	$79,369.77
98	89	OLANZAPINE TAB 15MG ODT	16	480	480	10	$7,563.48

RANK CLAIMS	RANK COST	PRODUCT NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
85	90	OLANZAPINE TAB 2.5MG	40	1,179	1,179	26	$7,533.06
46	30	OLANZAPINE TAB 20MG	464	15,470	14,959	308	$359,878.58
86	76	OLANZAPINE TAB 20MG ODT	37	1,260	1,230	25	$26,682.37
66	72	OLANZAPINE TAB 5MG	155	5,109	4,899	104	$40,005.89
99	100	OLANZAPINE TAB 5MG ODT	15	433	403	10	$3,126.00
91	86	OLANZAPINE TAB 7.5MG	30	960	960	18	$9,704.86
		Total Olanzepine	**10772**	**365823**	**348224**		**$8,861,462.51**
		Grand Totals	**175,255**	**7,265,061**	**5,300,303**	**24,712***	**$58,701,982.88**

*Unduplicated Members

Appendix E

Annual Review of Miscellaneous Anti-Infectives and 30 Day Notice to Prior Authorize Keflex® (cephalexin) 750 mg

Oklahoma HealthCare Authority, May 2012

Current Prior Authorization Criteria

Moxatag® (extended-release amoxicillin trihydrate)
Augmentin XR® (amoxicillin/clavulanate potassium)
Oracea® (extended-release doxycycline monohydrate 40mg)
Doryx® (extended-release doxycycline)
Solodyn® (extended-release minocycline)

Approval Criteria:
For all these formulations member must have a clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

Oravig® (miconazole buccal tablets) Criteria:

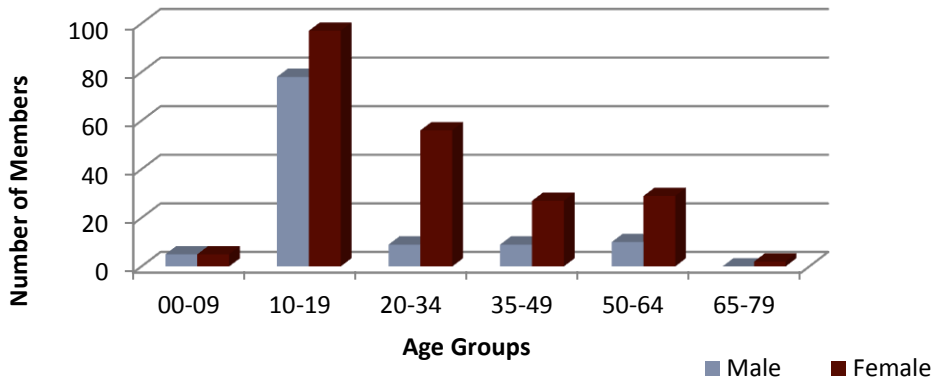
1. FDA-approved diagnosis of oropharyngeal candidiasis in adults age 18 and older.
2. Recent trials (within the last month) of the following medications at recommended dosing and duration of therapy:
    a. Clotrimazole troches, AND
    b. Nystatin suspension, AND
    c. Fluconazole tablets
3. Contraindication(s)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

Utilization of Miscellaneous Anti-Infectives

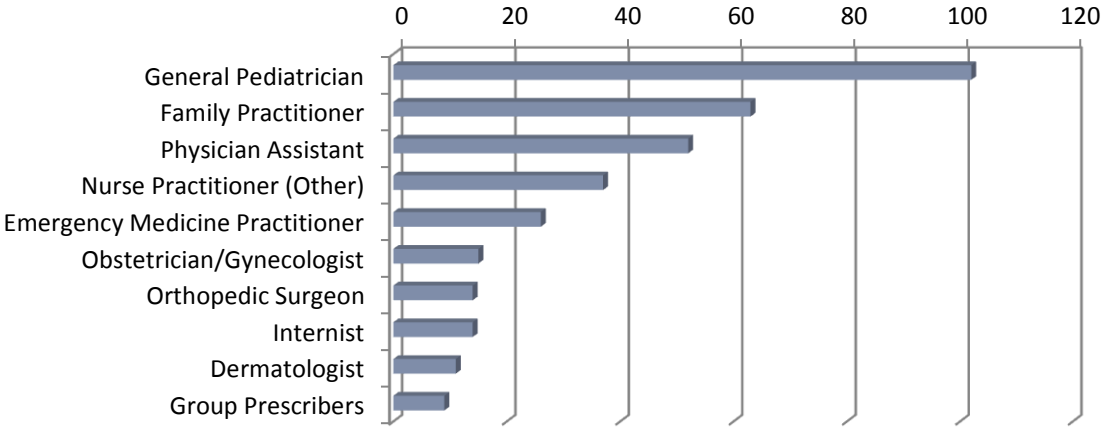
Comparison of Fiscal Years

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2010	879	1,016	$89,561.79	$88.15	$8.57	23,579	10,447
2011	327	389	$35,885.76	$92.25	$8.17	9,193	4,391
Percent Change	**-62.80%**	**-61.70%**	**-59.90%**	**4.70%**	**-4.70%**	**-61.00%**	**-58.00%**
Change	**-552**	**-627**	**-$53,676.03**	**$4.10**	**-$0.40**	**-14,386**	**-6,056**

Demographics of Members Utilizing Miscellaneous Anti-Infectives: FY 2011



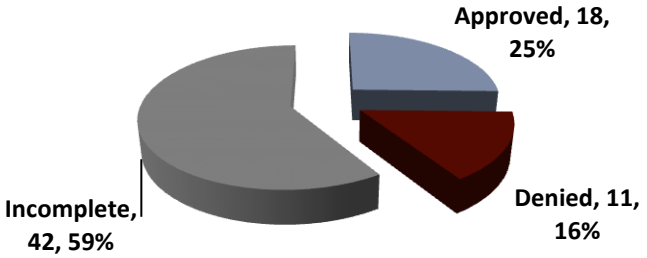
Top Ten Prescribers of Miscellaneous Anti-Infectives by Number of Claims: FY 2011



Prior Authorization of Miscellaneous Anti-Infectives

There were a total of 71 petitions submitted for this PBPA category during fiscal year 2011. The following chart shows the status of the submitted petitions.

Status of Petitions for Miscellaneous Anti-Infectives: FY 2011



Market News and Updates

Upcoming Patent Expirations :

- **Moxatag®:** October 2020
- **Augmentin XR®:** April 2020
- **Oracea®:** December 2027
- **Doryx®:** December 2020
- **Solodyn®:** March 2027
- **Oravig®:** September 2022
- **Keflex®:** all patents have expired but no generic for the 750 mg capsules is available

Conclusion and Recommendations

The College of Pharmacy recommends continuation of the current criteria for these products. The College also recommends the addition of Keflex® 750 mg to the miscellaneous anti-infectives category with the current criteria.

Utilization Details of Miscellaneous Anti-Infectives: Fiscal Year 2011

BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
KEFLEX CAP 750MG	158	3,045	1,672	128	$11,419.71	1.82	1.23	$6.83	31.82%
AMOX-POT CLA TAB ER	147	3,905	1,552	129	$12,747.13	2.52	1.14	$8.21	35.52%
AUGMENTIN XR TAB 12HR	68	1,763	687	64	$6,490.79	2.57	1.06	$9.45	18.09%
ORACEA CAP 40MG	16	480	480	7	$5,228.13	1	2.29	$10.89	14.57%
TOTALS:	**389**	**9,193**	**4,391**	**327***	**$35,885.76**	**2.09**	**1.19**	**$8.17**	**100.00%**

Total number of unduplicated members

Appendix F

Annual Review of Non-Steroidal Anti-Inflammatory Drugs and 30-day Notice to Prior Authorize Duexis® (ibuprofen/famotidine)

Oklahoma HealthCare Authority, May 2012

Current Prior Authorization Criteria

Criteria for the non-steroidal, anti-inflammatory drugs in Tier 2 are demonstrated by the following conditions:

1. Previous use of at least two Tier 1 NSAIDs (from different product lines) plus a PPI.
2. For those with prior GI bleed who must have an NSAID, then a Tier 2 product may be approved (Celebrex should also be taken with a PPI).

Criteria for the NSAIDS in the Special PA Category are:

1. Special indications, such as the diagnosis of gout for indomethacin, OR
2. Previous use of at least two Tier 1 NSAIDs (from different product lines) AND
3. Reason why a special formulation is needed over a Tier 1 product.

(History of severe ulcers or GI bleed may receive topical NSAIDs if currently on PPI.)

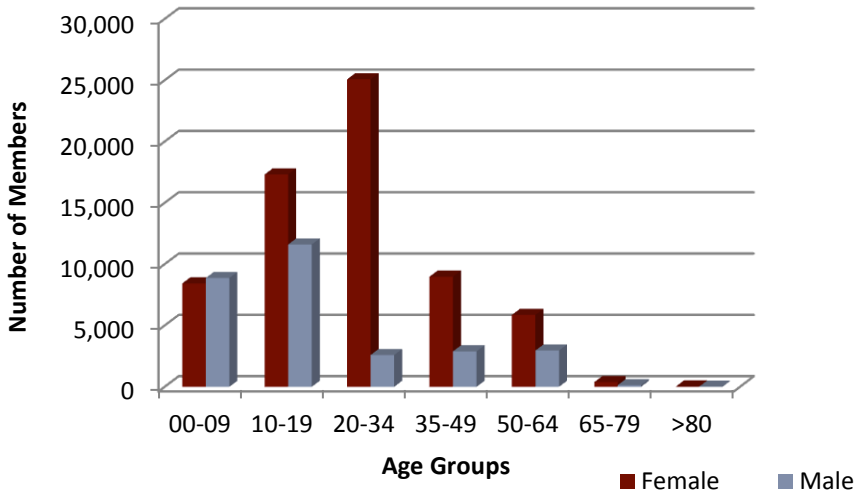
NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)		
Tier 1	**Tier 2**	**Special PA**
diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®)	diclofenac epolamine (Flector® patch)
diclofenac pot (Cataflam®)	diclofenac sodium/misoprostol (Arthrotec®)	diclofenac potassium (Zipsor® capsule)
diclofenac sodium (Voltaren®)	fenoprofen (Nalfon®)	diclofenac sodium (Voltaren Gel®)
etodolac (Lodine®)		diclofenac potassium (Cambia® pk)
etodolac ER (Lodine® XL)		diclofenac sodium (Pennsaid® drops)
flurbiprofen (Ansaid®)		indomethacin (Indocin®)+
ibuprofen (Motrin®)		mefanamic acid (Ponstel®)
ketoprofen (Orudis®)		naproxen sodium (Naprelan®)
ketoprofen ER (Oruvail®)		piroxicam (Feldene®)
meclofenamate (Meclomen®)		naproxen/esomeprazole (Vimovo®)
meloxicam (Mobic®)		
nabumetone (Relafen®)		
naproxen (Naprosyn®)		
naproxen sodium (Anaprox®)		
naproxen EC (Naprosyn® EC)		
oxaprozin (Daypro®)		
sulindac (Clinoril®)		
tolmetin (Tolectin®)		

Utilization of NSAIDs

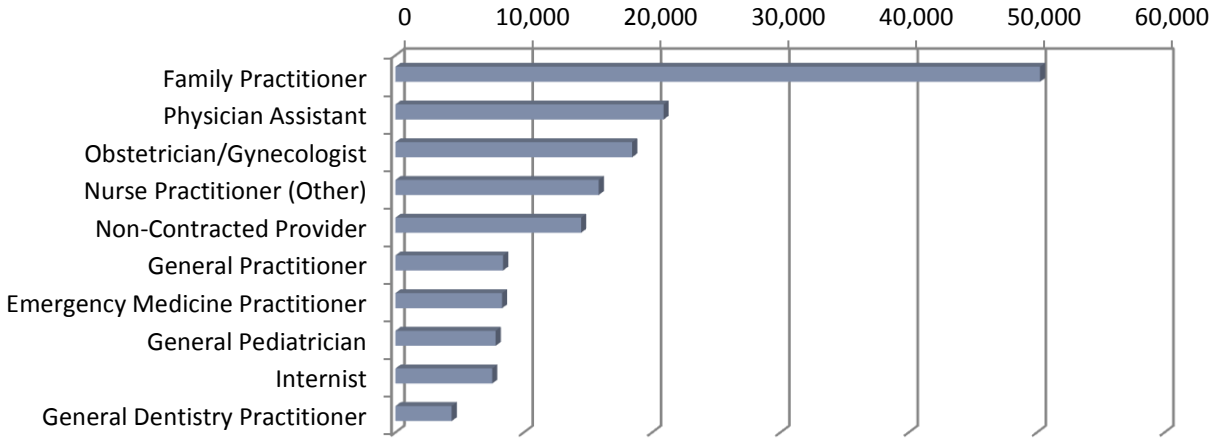
Comparison of Fiscal Years

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2010	85,282	149,988	$1,831,227.23	$12.21	$0.60	8,918,205	3,074,260
2011	95,176	176,096	$1,889,938.32	$10.73	$0.51	10,217,252	3,677,745
% Change	**11.60%**	**17.40%**	**3.20%**	**-12.10%**	**-15.00%**	**14.60%**	**19.60%**
Change	**9,894**	**26,108**	**$58,711.09**	**-$1.48**	**-$0.09**	**1,299,047**	**603,485**

Demographics of Members Utilizing NSAIDs: FY 2011



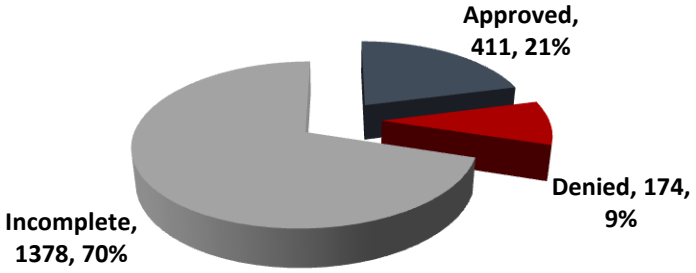
Top Ten Prescribers of NSAIDs by Number of Claims: FY 2011



Prior Authorization of NSAIDs

There were a total of 1,963 petitions submitted for this PBPA category during fiscal year 2011. The following chart shows the status of the submitted petitions.

Status of Petitions for NSAIDs: FY 2011



Market News and Updates

Upcoming Patent Expirations :

- **Celebrex® (celecoxib):** December 2015
- **Arthrotec® (diclofenac sodium /misoprostol):** February 2014
- **Flector Patch® (diclofenac epolamine):** April 2014

New Product :

- **Duexis® (ibuprofen/famotidine):** April 2011 (EAC: $1.72 each)

Conclusion and Recommendations

The College of Pharmacy recommends continuation of the current PBPA category. The College also recommends the addition of Duexis® (ibuprofen/famotidine) to the current NSAID product based prior authorization criteria and placement into the special prior authorization category.

Utilization Details of NSAIDs: Fiscal Year 2011

BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
ARTHROTEC 50 TAB	36	1,964	977	11	$5,131.20	2.01	3.27	$5.25	0.27%
ARTHROTEC 75 TAB	77	4,470	2,305	22	$12,115.39	1.94	3.5	$5.26	0.64%
CELEBREX CAP 100MG	198	10,882	6,242	53	$27,102.84	1.74	3.74	$4.34	1.43%
CELEBREX CAP 200MG	1,962	93,039	71,609	459	$371,415.69	1.3	4.27	$5.19	19.65%
CELEBREX CAP 400MG	5	390	390	2	$2,378.32	1	2.5	$6.10	0.13%
CHILD ADVIL DRO 50/1.25	54	810	365	48	$429.84	2.22	1.13	$1.18	0.02%
CHILD ADVIL SUS 100/5ML	355	42,298	5,077	306	$2,966.92	8.33	1.16	$0.58	0.16%
CHLD IBUPRFN DRO 40MG/ML	647	10,110	9,126	533	$6,367.75	1.11	1.21	$0.70	0.34%
CHLD IBUPROF SUS 100/5ML	10,919	1,300,879	159,639	8,441	$94,966.61	8.15	1.29	$0.59	5.02%
DICLOFEN POT TAB 50MG	756	39,348	16,685	468	$9,480.83	2.36	1.62	$0.57	0.50%
DICLOFENAC TAB 100MG ER	250	10,252	7,791	110	$4,860.97	1.32	2.27	$0.62	0.26%
DICLOFENAC TAB 100MG XR	88	4,072	3,182	28	$1,816.03	1.28	3.14	$0.57	0.10%
DICLOFENAC TAB 25MG EC	25	1,656	734	11	$2,035.01	2.26	2.27	$2.77	0.11%
DICLOFENAC TAB 50MG DR	433	22,997	9,834	316	$10,285.20	2.34	1.37	$1.05	0.54%
DICLOFENAC TAB 50MG EC	471	26,738	11,349	304	$11,957.64	2.36	1.55	$1.05	0.63%
DICLOFENAC TAB 50MG EC	31	1,650	815	12	$807.22	2.02	2.58	$0.99	0.04%
DICLOFENAC TAB 75MG DR	4,788	269,481	136,083	2,636	$92,457.20	1.98	1.82	$0.68	4.89%
DICLOFENAC TAB 75MG EC	212	11,693	6,049	99	$5,214.28	1.93	2.14	$0.86	0.28%
DICLOFENAC TAB 75MG EC	2	60	60	1	$28.82	1	2	$0.48	0.00%
ETODOLAC CAP 200MG	130	5,672	2,392	102	$1,917.26	2.37	1.27	$0.80	0.10%
ETODOLAC CAP 300MG	446	24,070	10,135	300	$9,351.86	2.37	1.49	$0.92	0.49%
ETODOLAC ER TAB 400MG	193	10,127	6,060	92	$7,795.97	1.67	2.1	$1.29	0.41%
ETODOLAC ER TAB 500MG	117	5,945	3,388	53	$4,490.10	1.75	2.21	$1.33	0.24%
ETODOLAC ER TAB 600MG	93	4,073	3,018	50	$5,417.33	1.35	1.86	$1.80	0.29%
ETODOLAC TAB 400MG	2,611	134,722	64,320	1,500	$34,902.46	2.09	1.74	$0.54	1.85%
ETODOLAC TAB 500MG	864	47,598	24,329	427	$13,802.74	1.96	2.02	$0.57	0.73%
FENOPROFEN TAB 600MG	1	100	50	1	$142.53	2	1	$2.85	0.01%
FLECTOR DIS 1.3%	8	240	165	8	$1,311.00	1.45	1	$7.95	0.07%
FLURBIPROFEN TAB 100MG	111	4,541	2,343	55	$1,188.63	1.94	2.02	$0.51	0.06%
FLURBIPROFEN TAB 50MG	3	240	75	3	$47.79	3.2	1	$0.64	0.00%
IBU TAB 400MG	6	232	51	6	$37.14	4.55	1	$0.73	0.00%
IBU TAB 600MG	24	892	247	22	$149.51	3.61	1.09	$0.61	0.01%
IBU TAB 800MG	26	2,022	656	20	$216.99	3.08	1.3	$0.33	0.01%
IBU-DROPS DRO 40MG/ML	149	2,250	2,390	130	$1,414.83	0.94	1.15	$0.59	0.07%
IBU-DROPS DRO INFANTS	54	1,561	950	45	$638.55	1.64	1.2	$0.67	0.03%

BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
IBUPROF CHLD SUS 100/5ML	3,840	458,706	75,410	2,874	$29,746.57	6.08	1.34	$0.39	1.57%
IBUPROFEN DRO INFANTS	147	4,395	2,390	126	$1,490.33	1.84	1.17	$0.62	0
IBUPROFEN POW	1	30	30	1	$11.93	1	1	$0.40	0.00%
IBUPROFEN SUS 100/5ML	9,376	1,195,471	96,418	6,987	$82,219.59	12.4	1.34	$0.85	4.35%
IBUPROFEN SUS INFANTS	369	6,420	4,379	317	$3,013.01	1.47	1.16	$0.69	0.16%
IBUPROFEN TAB 400MG	6,757	309,393	93,126	4,345	$49,380.07	3.32	1.56	$0.53	2.61%
IBUPROFEN TAB 600MG	14,093	630,330	192,622	10,581	$95,350.28	3.27	1.33	$0.50	5.05%
IBUPROFEN TAB 800MG	48,576	2,534,026	848,138	31,894	$322,569.71	2.99	1.52	$0.38	17.07%
INDOCIN SUP 50MG	3	90	50	1	$837.66	1.8	3	$16.75	0.04%
INDOCIN SUS 25MG/5ML	8	1,323	238	3	$1,170.67	5.56	2.67	$4.92	0.06%
INDOMETHACIN CAP 25MG	54	3,426	1,562	16	$937.53	2.19	3.38	$0.60	0.05%
INDOMETHACIN CAP 50MG	78	5,530	1,894	36	$1,481.35	2.92	2.17	$0.78	0.08%
INDOMETHACIN CAP 75MG ER	50	1,698	1,419	11	$3,600.68	1.2	4.55	$2.54	0.19%
KETOPROFEN CAP 200MG ER	214	70,200	7,750	80	$16,184.83	9.06	2.68	$2.09	0.86%
KETOPROFEN CAP 50MG	823	36,607	11,149	647	$8,123.71	3.28	1.27	$0.73	0.43%
KETOPROFEN CAP 75MG	2,170	68,093	25,723	1,728	$18,230.58	2.65	1.26	$0.71	0.96%
KETOPROFEN POW	163	12,413	4,163	103	$5,859.82	2.98	1.58	$1.41	0.31%
KETOROLAC INJ 15MG/ML	1	10	3	1	$18.80	3.33	1	$6.27	0.00%
KETOROLAC INJ 30MG/ML	31	209	349	23	$382.78	0.6	1.35	$1.10	0.02%
KETOROLAC INJ 60MG/2ML	25	204	305	20	$246.91	0.67	1.25	$0.81	0.01%
KETOROLAC INJ 60MG/2ML	3	42	11	2	$36.73	3.82	1.5	$3.34	0.00%
KETOROLAC TAB 10MG	2,135	33,604	15,276	1,751	$14,420.41	2.2	1.22	$0.94	0.76%
MECLOFEN SOD CAP 100MG	6	370	317	5	$640.93	1.17	1.2	$2.02	0.03%
MECLOFEN SOD CAP 50MG	22	1,340	526	8	$1,386.95	2.55	2.75	$2.64	0.07%
MEDI-PROFEN SUS 100/5ML	38	4,548	281	32	$367.75	16.19	1.19	$1.31	0.02%
MEFENAM ACID CAP 250MG	5	145	36	5	$1,928.78	4.03	1	$53.58	0.10%
MELOXICAM SUS 7.5/5ML	111	8,733	3,417	32	$5,509.40	2.56	3.47	$1.61	0.29%
MELOXICAM TAB 15MG	18,354	658,566	646,062	8,305	$94,235.36	1.02	2.21	$0.15	4.99%
MELOXICAM TAB 7.5MG	9,175	381,637	286,638	4,639	$57,304.55	1.33	1.98	$0.20	3.03%
NABUMETONE TAB 500MG	1,369	80,533	38,197	635	$24,927.37	2.11	2.16	$0.65	1.32%
NABUMETONE TAB 750MG	1,937	114,606	57,855	820	$39,881.37	1.98	2.36	$0.69	2.11%
NAPRELAN TAB 375MG CR	34	1,744	1,019	19	$6,598.08	1.71	1.79	$6.48	0.35%
NAPRELAN TAB 500MG CR	115	4,533	3,070	61	$19,619.64	1.48	1.89	$6.39	1.04%
NAPROXEN DR TAB 375MG	141	6,938	3,587	87	$1,461.37	1.93	1.62	$0.41	0.08%
NAPROXEN DR TAB 500MG	881	42,319	21,104	550	$9,633.59	2.01	1.6	$0.46	0.51%
NAPROXEN SOD TAB 275MG	161	5,772	2,650	109	$1,500.30	2.18	1.48	$0.57	0.08%
NAPROXEN SOD TAB 550MG	2,577	93,324	46,039	1,946	$23,735.16	2.03	1.32	$0.52	1.26%

BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
NAPROXEN SUS 125/5ML	458	110,249	7,855	274	$9,671.74	14.04	1.67	$1.23	0.51%
NAPROXEN TAB 250MG	1,186	53,855	23,788	816	$9,550.10	2.26	1.45	$0.40	0.51%
NAPROXEN TAB 375MG	2,532	113,444	57,710	1,583	$16,431.53	1.97	1.6	$0.28	0.87%
NAPROXEN TAB 500MG	20,240	962,570	486,327	12,160	$132,703.85	1.98	1.66	$0.27	7.02%
OXAPROZIN TAB 600MG	375	19,625	10,596	194	$5,530.53	1.85	1.93	$0.52	0.29%
PENNSAID SOL 1.5%	4	600	120	3	$613.18	5	1.33	$5.11	0.03%
PIROXICAM CAP 10MG	2	120	60	1	$17.44	2	2	$0.29	0.00%
PIROXICAM CAP 20MG	28	1,080	1,072	9	$1,793.40	1.01	3.11	$1.67	0.09%
SM IBUPROFEN SUS INFANTS	667	14,640	9,255	586	$5,868.58	1.58	1.14	$0.63	0.31%
SULINDAC TAB 150MG	100	5,164	2,880	47	$1,161.27	1.79	2.13	$0.40	0.06%
SULINDAC TAB 200MG	387	25,603	12,897	191	$6,743.71	1.99	2.03	$0.52	0.36%
TOLMETIN SOD CAP 400MG	15	1,430	470	3	$1,048.80	3.04	5	$2.23	0.06%
TOLMETIN SOD TAB 200MG	1	60	30	1	$43.62	2	1	$1.45	0.00%
TOLMETIN SOD TAB 600MG	5	210	150	2	$331.78	1.4	2.5	$2.21	0.02%
VOLTAREN GEL 1%	108	34,200	2,451	56	$9,741.79	13.95	1.93	$3.97	0.52%
TOTALS:	**176,096**	**10,217,252**	**3,677,745**	**95,176***	**$1,889,938.32**	**2.78**	**1.85**	**$0.51**	**100.00%**

Total number of unduplicated members

Appendix G

Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Tafluprost (Zioptan®)

Oklahoma HealthCare Authority, May 2012

Current Prior Authorization Criteria

Ophthalmic Glaucoma Medications	
Tier 1	**Tier 2**
Beta-Blockers	
betaxolol (Betoptic® 0.5%)	betaxolol (Betoptic-S®)
carteolol (Ocupress®)	brimonidine/timolol (Combigan®)
dorzolamide/timolol (Cosopt®)	timolol maleate (Timoptic® 0.5% dropperette)
levobunolol (Betagan®)	
metipranolol (OptiPranolol®)	
timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic Ocudose®, Timoptic-XE®)	
Prostaglandin Analogs	
travoprost (Travatan®, Travatan-Z®)*	bimatoprost (Lumigan®)
	latanoprost (Xalatan®)
Adrenergic Agonists	
dipivefrin (Propine®)	
Alpha-2 Adrenergic Agonists	
brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%)
	apraclonidine (Iopidine® 1%)
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®)	brinzolamide (Azopt®)
dorzolamide (Trusopt®)	
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto Carpine®, Pilopine HS®, 0.5%, 1%, 2%, 4%, 6%)	carbachol (Isopto®, Miostat® 1.5%, 3%)
	echothiophate iodide (Phospholine Iodide®)

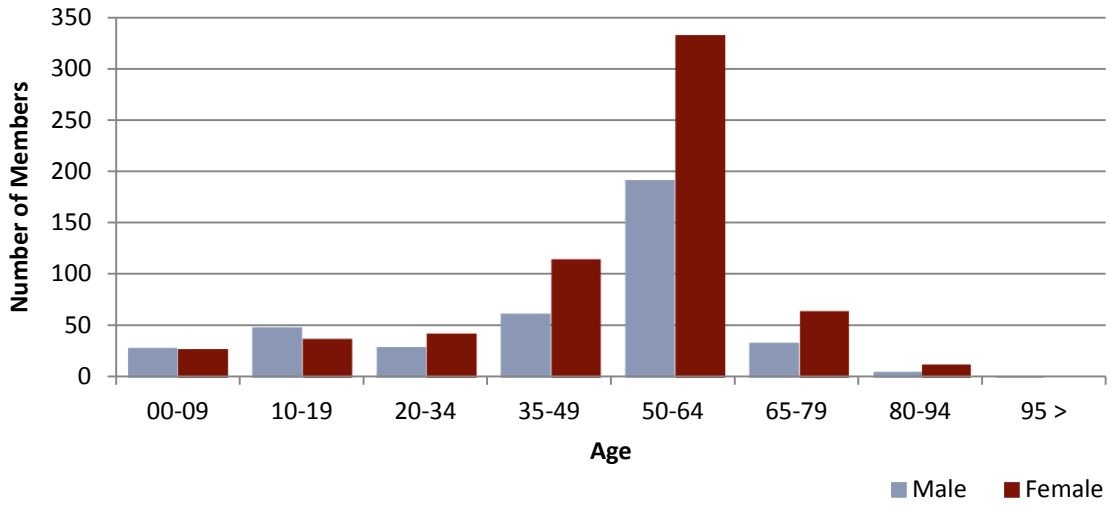
*Supplemental Rebate

1. FDA approved diagnosis.
2. Member must attempt at least one Tier 1 trial of a minimum of 4 weeks duration within the last 90 days. Tier 1 trial may be from any pharmacologic class.
3. Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to Tier 1 products.
4. Approval may be granted if there is a unique FDA approved indication not covered by Tier 1 products.
5. Member must have had a comprehensive dilated eye exam within the last 365 day period as recommended by the National Institute of Health.
6. Approval duration will be for 1 year.

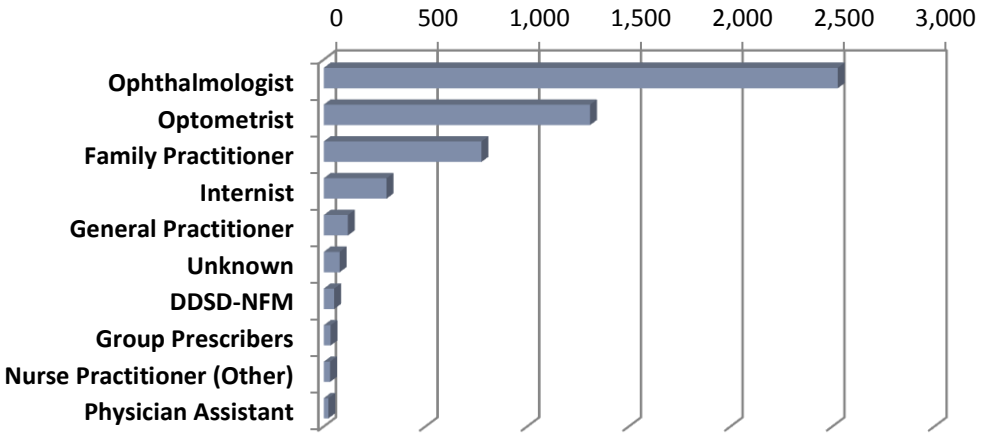
Utilization Comparison: Calendar Year 2010 and 2011

Calendar Year	Total Members	Total Claims	Total Paid	Paid/ Claim	Per-Diem	Total Units	Total Days
2010	1,016	5,302	$445,149.77	$83.96	$2.85	30,562	156,252
2011	1,036	5,374	$426,579.61	$79.38	$2.61	30,113	163,677
% Change	2.0%	1.4%	-4.2%	-5.5%	-8.4%	-1.5%	4.8%
Change	20	72	-$18,570.16	-$4.58	-$0.24	-449	7,425

Demographics of Members Utilizing Glaucoma Medications CY2011

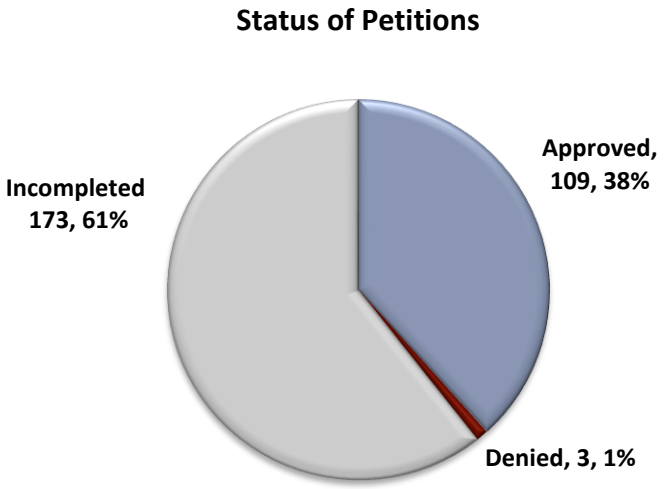


Top Ten Prescribers of Glaucoma Medications CY2011



Prior Authorization Totals

There were a total of 285 petitions submitted for this PBPA category during calendar year 2011. Computer edits are in place to detect tier-1 medications in member's recent claims history and generate automated prior authorization where possible. The following chart shows the status of the submitted petitions.



Market News and Update

- **Anticipated patent expiration**:
  - **Azopt®** (brinzolamide) – 4/2012
  - **Travatan Z®** (travoprost) - 5/2012
  - **Lumigan®** (bimatoprost) 0.03% - 9/2012
  - **Lumigan®** (bimatoprost) 0.01% - 9/2012
  - **Alphagan P®** (brimonidine) - 6/2012

- Effective 3/30/11, Xalatan® (latanoprost) generic was approved. Bottle cost is ~$12

- Zioptan® (tafluprost) 0.0015% ophthalmic solution was approved by the FDA February 2012 for ocular hypertension and open-angle glaucoma. It is the first preservative-free prostaglandin analog ophthalmic solution.

Recommendations

The College of Pharmacy recommends the following changes:

- Zioptan® (tafluprost) to be added to Tier 2
- Xalatan® (latanoprost) to be moved to Tier 1.

Ophthalmic Glaucoma Medications	
Tier 1	**Tier 2**
Beta-Blockers	
betaxolol (Betoptic® 0.5%)	betaxolol (Betoptic-S®)
carteolol (Ocupress®)	brimonidine/timolol (Combigan®)
dorzolamide/timolol (Cosopt®)	timolol maleate (Timoptic® 0.5% dropperette)
levobunolol (Betagan®)	
metipranolol (OptiPranolol®)	
timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic Ocudose®, Timoptic-XE®)	
Prostaglandin Analogs	
travoprost (Travatan®, Travatan-Z®)*	bimatoprost (Lumigan®)
latanoprost (Xalatan®)	**tafluprost (Zioptan®)**
Adrenergic Agonists	
dipivefrin (Propine®)	
Alpha-2 Adrenergic Agonists	
brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%)
	apraclonidine (Iopidine® 1%)
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®)	brinzolamide (Azopt®)
dorzolamide (Trusopt®)	
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto Carpine®, Pilopine HS®, 0.5%, 1%, 2%, 4%, 6%)	carbachol (Isopto®, Miostat® 1.5%, 3%)
	echothiophate iodide (Phospholine Iodide®)

*Supplemental Rebate

Utilization Details of Glaucoma Medications for Calendar Year 2011

BRAND NAME	CLAIMS	DAYS	MEMBERS	COST	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
ALPHAGAN P SOL 0.1%	143	4,135	40	$15,026.46	3.58	$3.63	3.52%
ALPHAGAN P SOL 0.15%	69	1,972	14	$8,313.73	4.93	$4.22	1.95%
AZOPT SUS 1% OP	162	5,482	46	$18,589.27	3.52	$3.39	4.36%
BETAXOLOL SOL 0.5% OP	3	130	2	$222.24	1.5	$1.71	0.05%
BETIMOL SOL 0.25%	6	164	3	$289.26	2	$1.76	0.07%
BETIMOL SOL 0.5%	11	620	4	$1,219.44	2.75	$1.97	0.29%
BETOPTIC-S SUS 0.25% OP	16	646	6	$2,395.71	2.67	$3.71	0.56%
BRIMONIDINE SOL 0.15%	190	4,962	42	$19,869.62	4.52	$4.00	4.66%
BRIMONIDINE SOL 0.2% OP	293	8,226	103	$4,703.66	2.84	$0.57	1.10%
COMBIGAN SOL 0.2/0.5%	342	9,352	77	$33,033.48	4.44	$3.53	7.74%
COSOPT SOL 2-0.5%OP	6	360	1	$1,479.60	6	$4.11	0.35%
DORZOL/TIMOL SOL 2-0.5%OP	449	15,049	134	$22,473.57	3.35	$1.49	5.27%
DORZOLAMIDE SOL 2% OP	93	2,983	28	$3,053.02	3.32	$1.02	0.72%
ISTALOL SOL 0.5% OP	1	25	1	$149.89	1	$6.00	0.04%
LATANOPROST SOL 0.005%	660	19,530	167	$11,976.33	3.95	$0.61	2.81%
LEVOBUNOLOL SOL 0.25% OP	6	72	1	$57.91	6	$0.80	0.01%
LEVOBUNOLOL SOL 0.5% OP	33	885	8	$502.50	4.13	$0.57	0.12%
LUMIGAN SOL 0.01%	69	2,273	20	$7,927.64	3.45	$3.49	1.86%
LUMIGAN SOL 0.03%	315	10,964	82	$46,350.31	3.84	$4.23	10.87%
PHOSPHOLINE SOL 0.125%OP	4	60	2	$299.28	2	$4.99	0.07%
PILOCARPINE SOL 1% OP	10	404	7	$166.68	1.43	$0.41	0.04%
PILOCARPINE SOL 2% OP	3	105	2	$71.10	1.5	$0.68	0.02%
PILOCARPINE SOL 4% OP	7	247	2	$195.41	3.5	$0.79	0.05%
TIMOLOL GEL SOL 0.25% OP	5	230	2	$153.03	2.5	$0.67	0.04%
TIMOLOL GEL SOL 0.5% OP	82	2,519	29	$3,409.24	2.83	$1.35	0.80%
TIMOLOL MAL SOL 0.25% OP	59	1,919	13	$409.19	4.54	$0.21	0.10%
TIMOLOL MAL SOL 0.5% OP	378	13,356	158	$3,470.04	2.39	$0.26	0.81%
TRAVATAN DRO 0.004%	7	162	6	$817.94	1.17	$5.05	0.19%
TRAVATAN Z DRO 0.004%	1,745	50,679	482	$198,601.10	3.62	$3.92	46.56%
XALATAN SOL 0.005%	207	6,166	112	$21,352.96	1.85	$3.46	5.01%
	5,374	**163,377**	***1,036**	**$426,579.61**	**5.19**	**$2.61**	**100%**

*Total number of unduplicated members

PRODUCT DETAILS OF ZIOPTAN™ (TAFLUPROST OPHTHALMIC SOLUTION) FDA-APPROVED IN FEBRUARY 2012

INDICATIONS:

- Elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE FORMS:

- Zioptan™ is supplied as an ophthalmic solution containing tafluprost 0.015 mg/mL.

ADMINISTRATION:

- The recommended dose is one drop of Zioptan™ in the conjunctival sac of the affected eye(s) once daily in the evening.
- The dose should not exceed once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the intraocular pressure lowering effect.
- Reduction of the intraocular pressure starts approximately 2 to 4 hours after the first administration with the maximum effect reached after 12 hours.
- Zioptan™ may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic product is being used, each one should be administered at least 5 minutes apart.

CONTRAINDICATIONS:

- None.

SPECIAL POPULATIONS:

- **Pregnancy:** Pregnancy Category C. In embryo-fetal development animal studies, tafluprost administered intravenously was teratogenic. Tafluprost caused increases in post-implantation losses and reductions in fetal body weights. Tafluprost also increased the incidence of vertebral skeletal abnormalities and the incidence of skull, brain and spine malformations. There are no adequate and well-controlled studies in pregnant woman. Although animal reproduction studies are not always predictive of human response, Zioptan™ should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Women of childbearing age/potential should have adequate contraceptive measures in place.

- **Nursing Mothers:** A study in lactating rats demonstrated that radio-labeled tafluprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zioptan™ is administered to a nursing woman.

- **Pediatrics**: Use in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

- **Geriatrics:** No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

WARNINGS AND PRECAUTIONS:

- **Pigmentation:** Tafluprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as

tafluprost is administered. After discontinuation of tafluprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue has been reported to be reversible in some patients. The long-term effects of increased pigmentation are not known. Iris color change may not be noticeable for several months to years. While treatment with Zioptan™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

- **Eyelash changes:** Zioptan™ may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, color, thickness, shape and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

- **Intraocular Inflammation:** Zioptan™ should be used with caution in patients with active intraocular inflammation (e.g., iritis/uveitis) because the inflammation may be exacerbated.

- **Macular edema:** Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2α analogs. Zioptan™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

ADVERSE REACTIONS:

- **Common adverse reactions:** The most commonly observed adverse reaction associated with the use of tafluprost was conjunctival hyperemia.

- **Other adverse reactions:** Stinging/irritation, ocular pruritus including allergic conjunctivitis, cataract, dry eye, ocular pain, eyelash darkening, growth of eyelashes, blurred vision, headache, common cold, cough, urinary tract infection, and lid changes including deepening of the eyelid sulcus.

DRUG INTERACTIONS:

- None.

PATIENT COUNSELING INFORMATION:

- Patients should be advised to not exceed once daily dosing since more frequent administration may decrease the intraocular pressure lowering effect of tafluprost.

- Patients should be advised that tafluprost is a sterile solution that does not contain a preservative. The solution from one individual unit is to be used immediately after opening. Since sterility cannot be maintained after the individual unit is opened, the remaining contents should be discarded immediately after administration.

- Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of tafluprost.

- Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with tafluprost. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

- Patients should be advised that if they develop a new ocular condition (eg, trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their health care provider's advice concerning the continued use of tafluprost.

- If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

REFERENCES:

1. Zioptan™ Prescribing Information. Zioptan™ (tafluprost ophthalmic solution) 0.0015%. Merck & Co., Inc. Available online at: http://zioptan.com/zioptan/hcp/secure/index.html. Last revised: February 2012; Accessed Mar 8, 2012.

Appendix H

Drug Utilization Review of Gonadotropin-Releasing Hormone Analogs

Oklahoma Health Care Authority, May 2012

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

Central Precocious puberty (CPP), neurogenic or idiopathic[1,2]

Precocious puberty is a condition in which physiologically normal pituitary-gonadal function appears at an early age. By convention, it is defined as the onset of androgen secretion and spermatogenesis before the age of 9 or 10 years in boys or the onset of estrogen secretion and cyclic ovarian activity before age 7 or 8 in girls. Central precocious puberty is caused by disturbed CNS function, which may or may not have an identifiable structural basis. Etiologies include idiopathic, hypothalamic tumor including hamartomas, arachnoid cyst, hydrocephalus, head trauma, perinatal asphyxia, cerebral palsy, sex chromosome abnormalities, nonspecific seizure disorder or mental retardation. Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). This disorder is about ten times more common in girls than in boys. They also show a significantly advanced bone age that can result in diminished adult height attainment.

Treatment Options[3]

The standard of care for treatment of CPP is Gonadotropin Releasing Hormone (Gn-RH) analogs. Gn-RH analogs are synthetic derivatives of the native hypothalamic peptide. These products cause inhibition of gonadotropin secretion through suppression of testicular and ovarian steroidogenesis. Initial administration of the drug causes a rise in luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels, but with repeated administration, the levels are reduced through downregulation of the pituitary Gn-RH receptors.

Other Clinical Indications of Gn-RH[2]

Because of their action of suppressing gonadal production, Gn-RH analogs are used clinically for several conditions for which estrogen suppression is necessary, including endometriosis, uterine leiomyoma, polycystic ovary syndrome, premenstrual syndrome and breast cancer. Similarly, in men with late-stage prostate cancer, testosterone suppression results in improvement.

Available treatments

Depot formulations may be billed through pharmacies but are administered by a healthcare professional.

Medication	Dosing	FDA-Approved Indications
Rapid-Acting Formulations of GnRH		
Nafarelin (Synarel®)	1600 mcg intranasally daily 800 mcg intranasally daily	CPP Endometriosis
Leuprolide, 5 mg/ml subcu	50 mcg /kg/day subcu 1 mg subcu daily 1.88 mg subcu on cycle days 21 or 23 or 0m5 mg/day on cycle days 21-23.	CPP Prostate Cancer (palliation) In vitro fertilization

Depot GnRHa Formulations		
Goserelin (Zoladex® LA)	3.6 mg every month or 10.8 mg every 3 months	Endometriosis Breast Cancer Prostate Cancer
Leuprolide (Lupron® depot PED)	7.5, 11.25, or 15 mg every month (0.2–0.3 mg/kg per mo) or 11.25 mg every 3 mo	CPP
Leuprolide (Lupron® depot)	3.75 mg every month or 11.25 mg every 3 months	Endometriosis Uterine leiomyoma Prostate Cancer
Leuoprolide (Eligard®)	7.5 mg every month 22.5 mg every 3 months 30 mg every 4 months 45 mg every 5 months	Prostate Cancer
Triptorelin (Trelstart®)	3 or 3.75 mg every month or 11.25 mg every 3 months	Prostate Cancer
Histrelin (Supprelin® LA)	50 mg implant every year	CPP

Cost Comparison of Central Precocious Puberty Therapy

	EAC/unit	Cost per month or per treatment *
Supprelin LA®	$16,484.00/kit	$1,373.67/mo
Lupron Depot* (monthly)	$926.77 – $1,853.14/mo	$926.77 – $1,853.14/mo
Lupron Depot (3 month kit)	$5,047.62 - $5,559.42 per kit	$1,682.54 – $1,853.14/mo
Synarel 2mg/ml	$147.40/ml	$4,716.80/mo

*weight based dosing, administration costs not included

Fiscal Year Comparison - Pharmacy – All indications

Fiscal Year	Total Members	Total Claims	Total Cost	Cost per Claim	Per-Diem Cost	Total Units	Total Days
2010	159	608	$716,468.74	$1,178.40	$34.41	672	20,819
2011	172	655	$850,924.17	$1,299.12	$38.60	662	22,042
% Change	8.20%	7.70%	18.80%	10.20%	12.20%	-1.50%	5.90%
Change	13	47	$134,455.43	$120.72	$4.19	-10	1,223

FY 2011 Utilization Details – Pharmacy

BRAND NAME	CLAIMS	MEMBERS	COST	CLAIMS/ MEMBER	COST/DAY	% COST	UNITS/DAY
LUPRON DEPOT INJ 3.75MG	196	72	$140,675.02	2.72	$25.85	16.53%	0.04
LUPR DEP-PED INJ 15MG	154	21	$252,339.96	7.33	$60.98	29.65%	0.04
LUPR DEP-PED INJ 11.25MG	135	24	$205,257.37	5.63	$51.26	24.12%	0.03
LUPRON DEPOT INJ 11.25MG	76	41	$158,482.87	1.85	$29.53	18.62%	0.01
LUPR DEP-PED INJ 7.5MG	55	8	$45,908.29	6.88	$29.62	5.40%	0.04
LUPRON DEPOT INJ 7.5MG	29	7	$25,855.06	4.14	$31.15	3.04%	0.04
LUPRON DEPOT INJ 22.5MG	6	3	$15,294.68	2	$28.97	1.80%	0.01
LUPRON DEPOT INJ 30MG	2	2	$6,434.76	1	$41.78	0.76%	0.01
LEUPROLIDE INJ 1MG/0.2	2	1	$676.16	2	$24.15	0.08%	0.07
Totals	**655**	**172***	**$850,924.17**	**3.81**	**$38.60**		**0.03**

***Total Number of Unduplicated Members**

FY 2011 Pharmacy Claims with Central Precocious Puberty ICD-9 CM code (259.1)

Drug	Claims	Members	Units	Days	Cost
Lupron Depot Inj 7.5 mg	25	5	26	651	$21,189.78
Lupron Depot Inj 11.25 mg	17	4	17	476	$35,845.15
Lupron Depot-Ped inj 7.5 mg	297	39	297	8,013	$444,729.38
Totals	**339**	**48***	**340**	**9140**	**$501,764.31**

***Total Number of Unduplicated Members**

FY 2011 Utilization Details – Outpatient/Medical

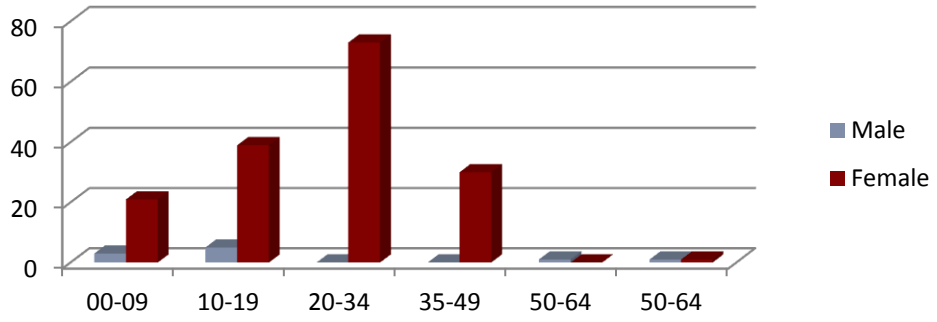
BRAND NAME	CLAIMS	MEMBERS	COST	UNITS
J1950 – Lupron Depot Inj 3.75MG	15	12	$17,762.76	35
J9217 – Lupron Suspension 7.5 mg depot	138	57	$74,946.00	391
J9218 – Lupron 1 mg	44	43	$1,311.39	59
Totals	**197**	**112***	**$94,020.15**	**485**

***Total Number of Unduplicated Members**

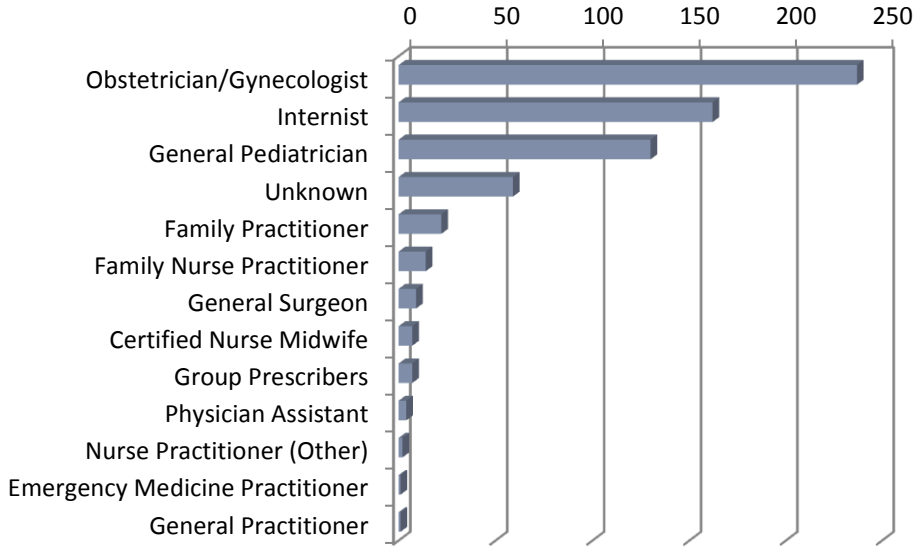
FY 2011 Utilization Details – Outpatient/Medical with Central Precocious Puberty ICD-9 CM code

BRAND NAME	CLAIMS	MEMBERS	COST	UNITS
J1950 - Lupron Depot Inj 3.75MG	3	1	$6,206.36	12
J9218 – Lupron 1 mg	19	19	$83.94	19
Totals	**22**	**20**	**$6,290.30**	**31**

Member Demographics for FY 2011 (Pharmacy - 172 Total)



Prescribers Specialties by Number of Pharmacy Claims: FY 2011



Recommendations

The College of Pharmacy recommends medical and pharmacy prior authorization of this category for the diagnosis of central precocious puberty

Criteria for Approval

1. FDA approved indication – central precocious puberty (ICD-9 –CM Diagnosis Code 259.1)
    - Documentation of onset of symptoms at ages less than 8 years of age in females and 9 years of age in males
    - Bone age
    - Abnormal levels of total sex hormones
        - Luteinizing hormone
        - Follicle stimulating hormone
2. Failed trial of lower tiered products or FDA approved indication not covered by a lowered tiered product.

Tier 1	Tier 2	Tier 3
Lupron®	Supprelin LA®	Synarel® 2mg/ml

References

1. Melmed S. Williams Textbook of Endocrinology, 12th ed. Elsevier 2011
2. Casper, R. Clinical uses of gonadotropin-releasing hormone analogues. Can Med Assoc J 10991 144(2)
3. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics 2009; 123:e752.

Appendix I

FDA & DEA Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA News Release:

For Immediate Release: April 27, 2012
FDA approves Stendra for erectile dysfunction
The U.S. Food and Drug Administration today approved Stendra (avanafil), a new drug to treat erectile dysfunction.
Stendra belongs to a class of drugs called phosphodiesterase type 5 (PDE5) inhibitors, which are used to help increase blood flow. As with other PDE5 inhibitors, Stendra should not be used by men who also take nitrates, commonly used to treat chest pain (angina), because the combination can cause a sudden drop in blood pressure.

For Immediate Release: April 26, 2012
FDA approves Afinitor for non-cancerous kidney tumors caused by rare genetic disease
The U.S. Food and Drug Administration today approved Afinitor (everolimus), the first drug approved specifically to treat non-cancerous kidney tumors (renal angiomyolipomas) not requiring immediate surgery in patients with tuberous sclerosis complex (TSC).
TSC is a rare genetic disease that causes the growth of various non-cancerous tumors in the brain, kidney and other vital organs. It affects as many as 40,000 patients in the United States, with an estimated 70 to 80 percent developing kidney problems. TSC generally causes multiple tumors in both kidneys that compress normal kidney tissues as they increase in size, leading to kidney failure and bleeding.
A pill taken once daily, Afinitor blocks the uncontrolled activity of a certain protein, the mTOR kinase, which plays a critical role in the development and growth of the various non-cancerous tumors occurring in patients with TSC.
The FDA granted Afinitor orphan drug designations to treat renal angiomyolipomas and a certain type of brain tumor called subependymal giant cell astrocytoma (SEGA) in patients with TSC in 2009. An orphan designation is given to a drug intended to treat a disease or condition affecting fewer than 200,000 patients in the United States and for which the drug, based on supporting data, has shown promise in the treatment of the disease.

For Immediate Release: April 27, 2012
FDA approves new antibacterial treatment for plague
The U.S. Food and Drug Administration today approved Levaquin (levofloxacin) to treat patients with plague, a rare and potentially deadly bacterial infection. The agency also approved the drug to reduce the risk of getting plague after exposure to Yersinia pestis, the bacterium that causes the disease.
Plague is extremely rare in most parts of the world, including the United States, with 1,000 to 2,000 cases worldwide each year. The three most common forms of plague are bubonic plague (infection of the lymph nodes), pneumonic plague (infection of the lungs), and septicemic plague (infection of the blood).
Primarily an animal disease, plague can be spread to humans through bites from infected fleas, contact with infected animals or humans, or laboratory exposure. Yersinia pestis also is considered a biological threat agent, which could potentially be used as a bioterrorism agent.
The FDA approved Levaquin for plague under the agency's Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to be used in cases where it is not feasible or ethical to conduct trials in humans. Because plague is such a rare disease, it would not be possible to conduct adequate efficacy trials in humans.

FDA Drug Safety Communication: Updated information on drug interactions between Victrelis (boceprevir) and certain boosted HIV protease inhibitor drugs

Safety Announcement

[4-26-2012] The U.S. Food and Drug Administration (FDA) is notifying the public that co-administration of Victrelis (boceprevir), a hepatitis C virus (HCV) protease inhibitor, along with certain ritonavir-boosted human immunodeficiency virus (HIV) protease inhibitors, is not recommended at this time because of the possibility of reducing the effectiveness of the medicines, permitting the amount of HCV or HIV virus in the blood (viral load) to increase. Ritonavir-boosted HIV protease inhibitors include ritonavir-boosted Reyataz (atazanavir), ritonavir-boosted Prezista (darunavir), and Kaletra (lopinavir/ritonavir).

Current Drug Shortages:

- Drug Shortages: Current Drug Shortages: Alfentanil Injection[19] (updated)
- Drug Shortages: Current Drug Shortages: Amino Acid Products[20] (updated)
- Drug Shortages: Current Drug Shortages: AsmanexTwisthaler[21]
- Drug Shortages: Current Drug Shortages: Calcitriol 1 mcg/mL Injection[22] (updated)
- Drug Shortages: Current Drug Shortages: Diphenhydramine Hydrochloride Injection[23] (updated)
- Drug Shortages: Current Drug Shortages: Diltiazem Injection[24] (updated)
- Drug Shortages: Current Drug Shortages: Epinephrine Injection[25]
- Drug Shortages: Current Drug Shortages: Fentanyl Citrate Injection[26] (updated)
- Drug Shortages: Current Drug Shortages: Fluorouracil Injection[27] (updated)
- Drug Shortages: Current Drug Shortages: Methotrexate Injection[28] (updated)
- Drug Shortages: Current Drug Shortages: Methylphenidate HCl[29] (updated)
- Drug Shortages: Current Drug Shortages: Mitomycin Powder for Injection[30] (updated)
- Drug Shortages: Current Drug Shortages: Phytonadione Injectable Emulsion (Vitamin K)[31] (updated)
- Drug Shortages: Current Drug Shortages: Sufentanil Injection[32] (updated)
- Drug Shortages: Current Drug Shortages: Ammonul (sodium phenylacetate and sodium benzoate) Injection 10%/10%[42] (updated)
- Drug Shortages: Current Drug Shortages: Dexrazoxane Injection[43] (updated)
- Drug Shortages: Current Drug Shortages: Bupivacaine Hydrochloride Injection[52] (updated)
- Drug Shortages: Current Drug Shortages: Etoposide solution for injection[53] (updated)
- Drug Shortages: Current Drug Shortages: Ondansetron Injection 2 mg/mL[54] (updated)
- Drug Shortages: Current Drug Shortages: Paclitaxel Injection[55] (updated)
- Drug Shortages: Current Drug Shortages: Sodium Acetate Injection[56] (updated)
- Drug Shortages: Current Drug Shortages: Tobramycin Solution for Injection[57] (updated)
- Drug Shortages: Current Drug Shortages: Calcium Chloride Injection[59] (updated)
- Drug Shortages: Current Drug Shortages: Desmopressin Injection[60] (updated)
- Drug Shortages: Current Drug Shortages: Fosphenytoin Sodium Injection[61] (updated)
- Drug Shortages: Current Drug Shortages: Leucovorin Calcium Lyophilized Powder for Injection[62] (updated)
- Drug Shortages: Current Drug Shortages: Vasopressin Injection[64] (updated)
- Drug Shortages: Current Drug Shortages: Atropine Sulfate Injection[96] (updated)
- Drug Shortages: Current Drug Shortages: Etomidate Injection[98] (updated)
- Drug Shortages: Current Drug Shortages: Isoniazid Tablets[99] (updated)
- Drug Shortages: Current Drug Shortages: Nefazodone Tablets[100]
- Drug Shortages: Current Drug Shortages: Naloxone Injection[101] (updated)
- Drug Shortages: Current Drug Shortages: Naltrexone Oral Tablets[102] (updated)
- Drug Shortages: Current Drug Shortages: Ondansetron Injection[103] (updated)
- Drug Shortages: Current Drug Shortages: Paclitaxel Injection[104] (updated)
- Drug Shortages: Current Drug Shortages: Protonix (pantoprazole) Injection[105] (updated)
- Drug Shortages: Current Drug Shortages: Vecuronium Injection[107] (updated)