Drug Utilization Review Board

Oklahoma Health Care Authority
4545 North Lincoln Boulevard, Suite 124
Oklahoma City, Oklahoma 73105
OHCA Board Room

Wednesday
January 14, 2009
6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

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

SUBJECT: **Packet Contents for Board Meeting – January 14, 2009**

DATE: January 8, 2009

NOTE: **THE DUR BOARD WILL MEET AT 6:00 P.M.**

Enclosed are the following items related to the January 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.**

Update on Supplemental Rebates

Action Item – Vote to Prior Authorize Toviaz® – **See Appendix C.**

Action Item – Vote to Prior Authorize Simcor® and update Statin PBPA Category – **See Appendix D.**

Action Item – Vote to Prior Authorize Lamisil® Granules – **See Appendix E.**

Action Item – Annual Review of Ophthalmic Anti-infective PBPA Category – **See Appendix F.**

Action Item - Utilization Review of Asthma Medications and Annual Review of Brovana® **– See Appendix G.**

Lock-In Report – **See Appendix H.**

FDA and DEA Updates – **See Appendix I.**

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – January 14, 2009 @ 6:00 p.m.

Oklahoma Health Care Authority
4545 N. Lincoln Suite 124
Oklahoma City, Oklahoma 73105
Oklahoma Health Care Authority Board Room

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. McNeill, Chairman:

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

A. December 10, 2008 DUR Minutes – Vote
B. December 11, 2008 DUR Recommendation Memorandum

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

4. Update on DUR/MCAU Program – See Appendix B.

A. Retrospective Drug Utilization Review for October 2008
B. Retrospective Drug Utilization Review Responses for August 2008
C. Medication Coverage Activity Audit for December 2008
D. Help Desk Activity Audit for December 2008

Items to be presented by Lynn Rambo-Jones, J.D., Dr. McNeill, Chairman:

5. Update on Supplemental Rebates

Items to be presented by Dr. Le, Dr. Chonlahan, Dr. McNeill, Chairman

6. Action Item – Vote to Prior Authorize Toviaz® – See Appendix C.

A. Product Summary
B. COP Recommendations
C. Utilization Review

Items to be presented by Dr. Le, Dr. McNeill, Chairman

7. Action Item – Vote to Prior Authorize Simcor® and Update Statin PBPA Category – See Appendix D.

A. COP Recommendations

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

8. Action Item – Vote to Prior Authorize Lamisil® Granules – See Appendix E.

A. Product Summary
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Patel, Dr. McNeill, Chairman

9. Action Item – Annual Review of Ophthalmic Anti-Infective PBPA Category – See Appendix F.

A. Current PA Criteria
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Le, Dr. McNeill, Chairman

10. Action Item – Utilization Review of Asthma Medications and Annual Review of Brovana® – See Appendix G.

A. Utilization Review of Anti-Asthmatics
B. Market Update
C. COP Recommendations
D. Annual Review of Brovana®

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

11. Lock-In Report – See Appendix H.

Items to be presented by Dr. Graham, Dr. McNeill, Chairman

12. FDA and DEA Updates – See Appendix I.

13. Future Business

A. Hydrocodone Utilization Review
B. Pediatric Anti-Ulcer Utilization Review
C. Annual Reviews
D. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of DECEMBER 10, 2008

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Jay D. Cunningham, D.O.		X
Mark Feightner, Pharm.D.		X
Dorothy Gourley, D.Ph.		X
Evelyn Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.	X	
Dan McNeill, Ph.D., PA-C; Chairman	X	
Cliff Meece, D.Ph.; Vice-Chairman	X	
John Muchmore, M.D., Ph.D.	X	
James Rhymer, D.Ph	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Metha Chonlahan, D.Ph.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison		X
Ronald Graham, D.Ph.; Pharmacy Director	X	
Shellie Keast, Pharm.D.; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Pharmacist/Coordinator	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
Visiting Pharmacy Students: **n/a**		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer	X	
Nico Gomez; Director of Gov't and Public Affairs		X
Lynn Mitchell, M.D., M.P.H,; Director of Medicaid/Medical Services	X	
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.; Director of Legal Services		X
Lynn Rambo-Jones, J.D.; Deputy General Counsel III	X	
Rodney Ramsey; Drug Reference Coordinator	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	

OTHERS PRESENT:

Kim Greenberg, Amylin	John Harris, Abbott	David Williams, Forest Labs
Pat Trahan, Taro	Rebecca King, Taro	Lon Lowrey, Novartis
Jason Russell, Novartis	Janie Huff, Takeda	John Frey, Santarus
Jim Graham, Johnson & Johnson	Carl Rose, Sepracor	Kim Elston, Novo Nordisk
Randy Clifton, Amgen	David Barton, Schering Plough	Bobby White, UCB
Mark DeClerk, Lilly	Ron Schnare, Shire	Jim Fowler, AZ
William Dozier, Gilead	Linda Cantu, BMS	Lana Stewart, Merck

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 5	Mike Ketcher, Pharm.D.; Novartis
Agenda Item No. 7	Carla Nikkel, Amylin

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: Roll Call

Dr. McNeill called the meeting to order. Roll call by Dr. Graham established a quorum.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

Dr. McNeill recognized the speakers for public comment.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MINUTES**

3A: November 12, 2008 DUR Minutes

Dr. Meece moved to approve as submitted; seconded by Dr. Kuhls.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON DUR/MCAU PROGRAM**

4A: Retrospective Drug Utilization Review: September 2008

4B: Retrospective Drug Utilization Review Responses: July 2008

4C: Medication Coverage Activity Audit: November 2008

4D: Help Desk Activity Audit: November 2008

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **ANNUAL REVIEW OF BLADDER CONTROL PBPA CATEGORY AND 30-DAY NOTICE TO PRIOR AUTHORIZE TOVIAZ®**

For Public Comment, Mike Ketcher, Pharm.D.: Good evening ladies and gentlemen. My name is Mike Ketcher. I'm a clinical pharmacist for Novartis Pharmaceuticals. I work at our medical affairs research and development division. I just want to say a few comments on Enablex. Enablex, the generic name's Darifenacin. As you all know, it's approved or indicated for the treatment of overactive bladder with symptoms of urge, urinary incontinence, urgency and frequency. Just a couple of things that I wanted to mention on Enablex. We have studies ranging from 12-week trials out to two years of data. In some of our long-term trials, particularly the open label 2-year data, about half the patients have a 90% reduction in their incontinence episodes and that approaches what we've defined or call as continent. It is a muscarinic receptor antagonist at the M3 receptor and we have done several studies. I'm looking at cognitive function, cardiac changes or visual changes. We see so causation of Enablex producing any of those adverse effects relative to other agents that we studied against or placebo. We've even done some cardiac safety studies upwards of 75 mg of the drug with no effect on QT prolongation. So I just wanted to update the committee on where we're at. We still have some other on-going safety studies with Enablex. It's been used by almost half a million patients worldwide and it is effective in both treatment naive and non-naive patients. We also have data when you switch from one agent whether it be a generic or branded agent over to Enablex where we maintain fairly good efficacy and don't fall off over that period of time. We also have some quality of life parameters, social parameters, physical limitations, that have also been approved in patients who have received Enablex relative to control therapies. We think that Enablex provides safe and effective treatment for overactive bladder. Not that it matters to the committee, but we have done trials in patients over age 65 and upwards beyond age 75 and we've also done some specific studies in patients that may have a propensity to have impaired cognition and we see no adverse effects of Enablex added into that population. So what we'd like from Novartis' perspective to ask the committee is that if the pricing or contracting is somewhat close or favorable that we would maintain our current status or at least be on equal status with other branded agents provided contracting works itself out. That's all I wanted to say.

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF STATINS/ZETIA® PBPA CATEGORY AND 30-DAY NOTICE TO PRIOR AUTHORIZE SIMCOR®**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF SYMLIN® AND BYETTA®**

For Public Comment, Carla Nikkel: Good evening. Thank you for letting me come tonight. My name's Carla Nikkel and I am a medical science liaison with Amylin Pharmaceuticals, and first of all I just wanted to take a few minutes to give you a brief update of what has been going on over the last year with both Byetta and Symlin. Most recently last week, published in *Diabetes Care*, there was a new consensus from the American Diabetes Association and from the European Association for the Study of Diabetes in regards to the medical management of hyperglycemia in patients with Type 2 diabetes. In this consensus, there's an algorithm that gives guidance to those healthcare professionals that look to it for the initiation and for the adjustments of diabetes therapies. This year a change was made to the algorithm to include a new Tier 2 step for newer therapies such as Byetta that although they are less well validated as mentioned in the algorithm, for patients that fail diet and exercise or Metformin. And so we are very happy to see Byetta is now included in this algorithm for the treatment of patients with Type 2 diabetes that have hyperglycemia. In addition, throughout this consensus, they frequently mention the need to provide compounds to patients that are durable and that also offer weight loss. Over this last year we have offered many studies showing that Byetta has shown durability for now over three years, so maintaining these A1c reductions. In addition, during this time, these patients have lost and been able to keep off 12 pounds of weight, which there's no other diabetes agent that can offer that type of combination, so we've really had some nice scientific disclosures over the last year for Byetta. In regards to Symlin over the last year, we've also launched a new Symlin pen, which I saw was referenced in the appendix, and this has made it easier for patients on Symlin as far as the dosing and the titration and has helped with compliance to help get them to goal. So with that said, I just wanted to be brief. I will take any questions or if not, we just respectfully ask that you continue to allow the utilization of both Symlin and Byetta for patients with diabetes here in Oklahoma.

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

Dr. Bell moved to approve; seconded by Dr. Kuhls.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **UTILIZATION REVIEW OF ORAL ANTIFUNGALS AND 30-DAY NOTICE TO APPLY AGE RESTRICTION TO LAMISIL® GRANULES**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **UTILIZATION REPORT FOR FIRST QUARTER FISCAL YEAR 2009 AND FISCAL YEAR 2008 ANNUAL REVIEW**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **RETROSPECTIVE DRUG UTILIZATION REVIEW PROGRAM DEMONSTRATION**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **FDA & DEA UPDATES**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **FUTURE BUSINESS**

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

12A: Lock-In Report
12B: Annual Review of Ocular Antibiotics
12C: Annual Review of Brovana®
12D: New Product Reviews

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **ADJOURNMENT**

The meeting was adjourned at 7:25 p.m.

The University of Oklahoma College of Pharmacy

Pharmacy Management Consultants
ORI W-4403; PO Box 26901
Oklahoma City, OK 73190
(405)-271-9039

Memorandum

Date: December 11, 2008

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 December 10, 2008

Recommendation 1: Annual Review of Bladder Control PBPA Category

No Action Required

Recommendation 2: Annual Review of Statins/Zetia PBPA Category

No Action Required

Recommendation 3: Annual Review of Byetta® and Symlin®

MOTION CARRIED by unanimous approval.

The DUR Board recommended the following changes to the Symlin® approval criteria:

Members with type 1 and 2 diabetes using insulin must:

1. be using a basal-bolus insulin regimen (basal insulin plus rapid acting with meals);
2. have failed to achieve adequate glycemic control (on basal-bolus regimen) or are gaining excessive weight (on basal-bolus regimen);
3. are receiving ongoing care under the guidance of a health care professional.

Members meeting the following criteria should **NOT** be considered for Symlin® therapy:

1. Poor compliance with insulin regimen
2. Poor compliance with self-blood glucose monitoring
3. HbA1c> 9%
4. Recurrent severe hypoglycemia requiring assistance in past 6 months
5. Presence of hypoglycemia unawareness
6. Diagnosis of gastroparesis
7. Require use of drugs that stimulate GI motility
   ~~Anticholinergics (e.g. Atropine)~~
   ~~Glyset® (Miglitol)~~
   ~~Precose® (Acarbose)~~
8. Pediatric patients (≤ 15 years old)

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for October 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	45,443	67,924	1,181,325	33,701
Limits which were applied	Established, Major, Males and Females, Age 51-56	Males and Females, Age 3-4, Antihistamines	Contraindicated, Females, age 0-21, Pregnancy	High Dose and Duration, Males and Females, 0-150 years old, Zyvox®
Total # of messages after limits were applied	65	80	739	3
Total # of members reviewed after limits were applied	65	79	671	3

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
25		4	

Retrospective Drug Utilization Review Report

Claims Reviewed for August 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 19-40	Antiarrhythmics, Males and Females, Age 0-150	Contraindicated, Drug Abuse, Males and Females, Age 0-150	High Dose only, Substance P/Neurokinin 1 Antagonist (Emend), Males and Females, Age 0-18

Response Summary (Prescriber)
Letters Sent: 72
Response Forms Returned: 35

The response forms returned yielded the following results:

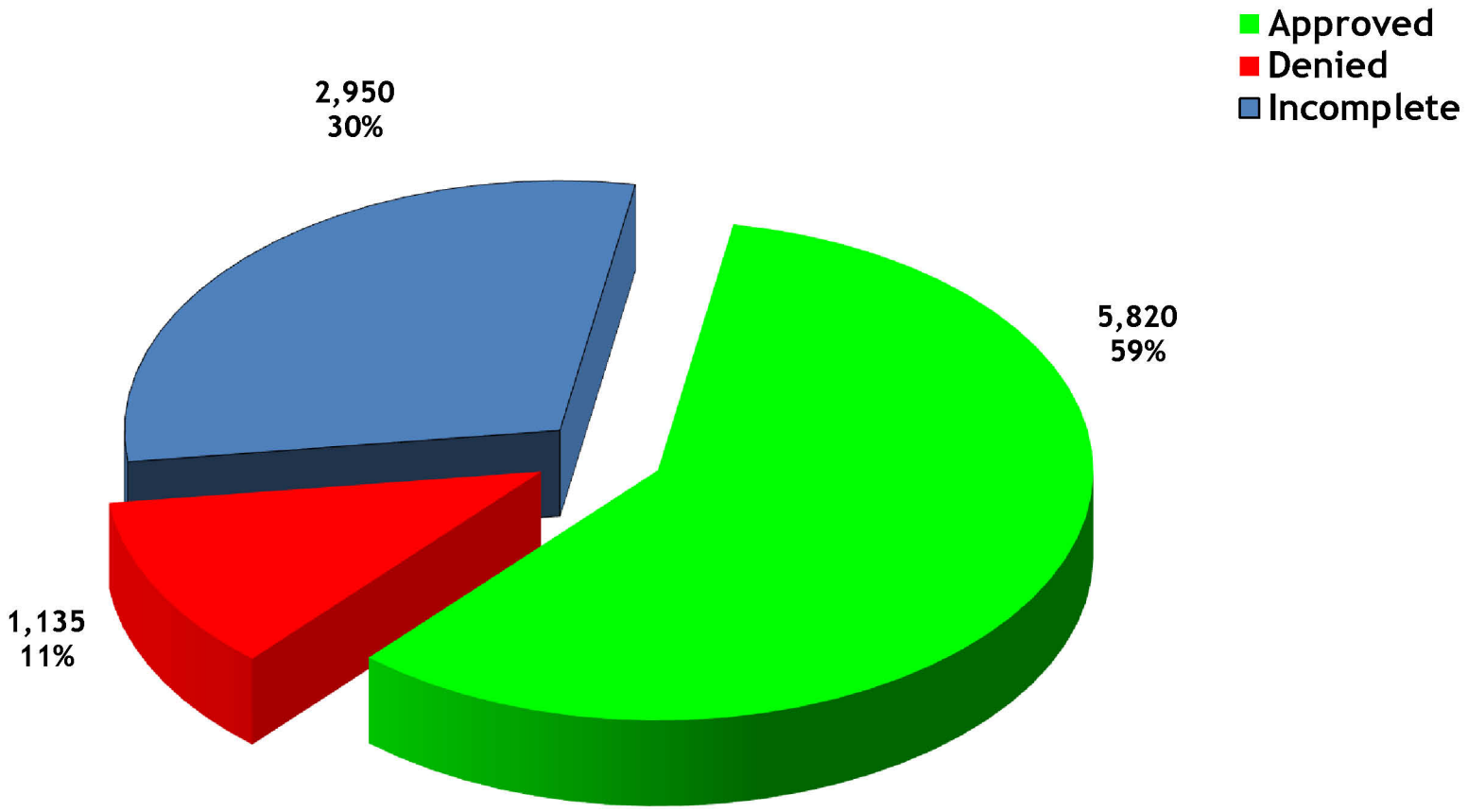
5 (14%)	*Record Error—Not my patient.*
6 (17%)	*No longer my patient.*
2 (6%)	*Medication has been changed prior to date of review letter.*
4 (11%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
14 (40%)	*I am aware of this situation and will plan to continue monitoring therapy.*
4 (11%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 56
Response Forms Returned: 26

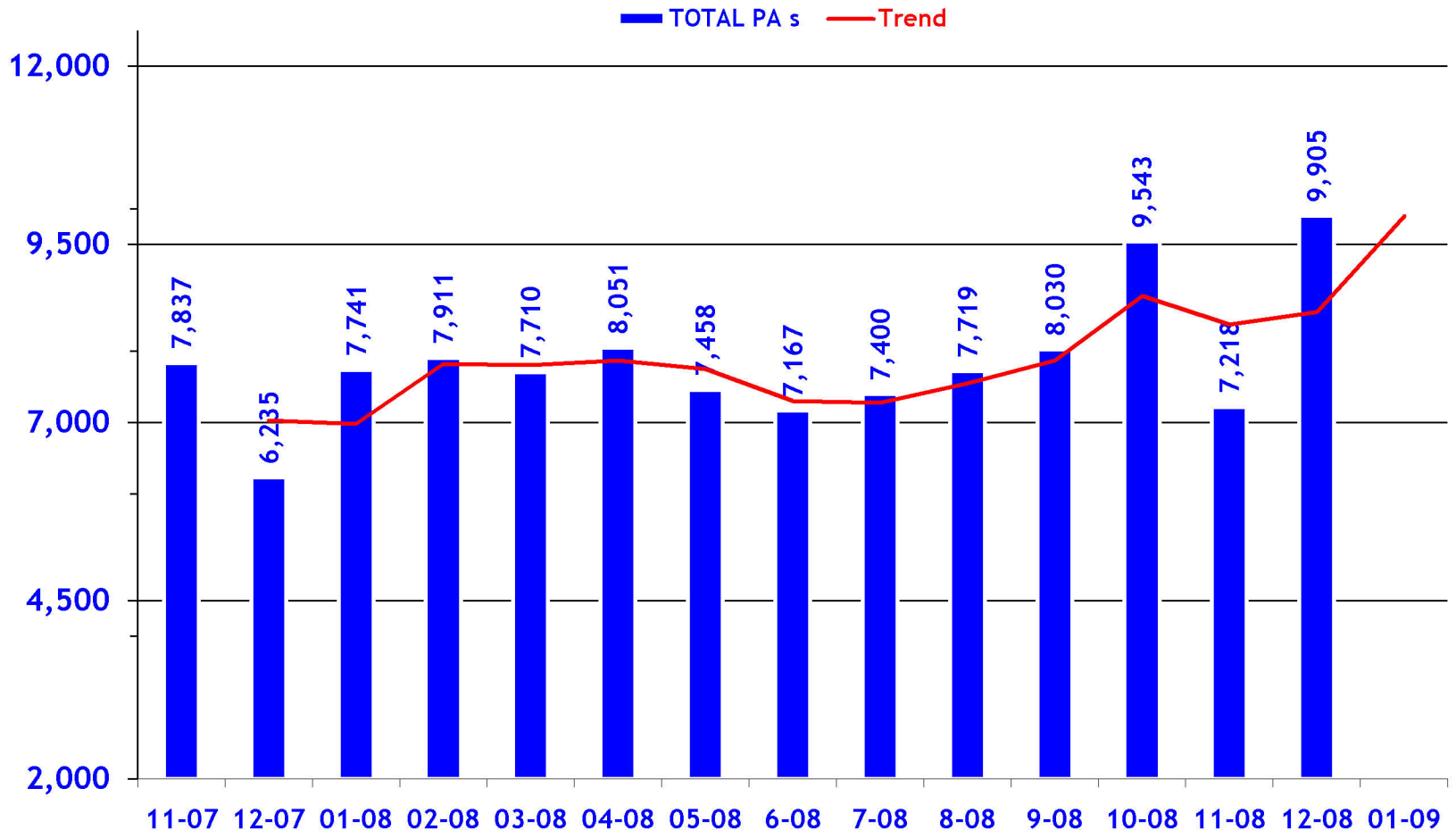
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
11 (42%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
14 (54%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (4%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
December 2008



PRIOR AUTHORIZATION REPORT
December 2007 – December 2008



Activity Audit for
December 01, 2008 Through December 31, 2008

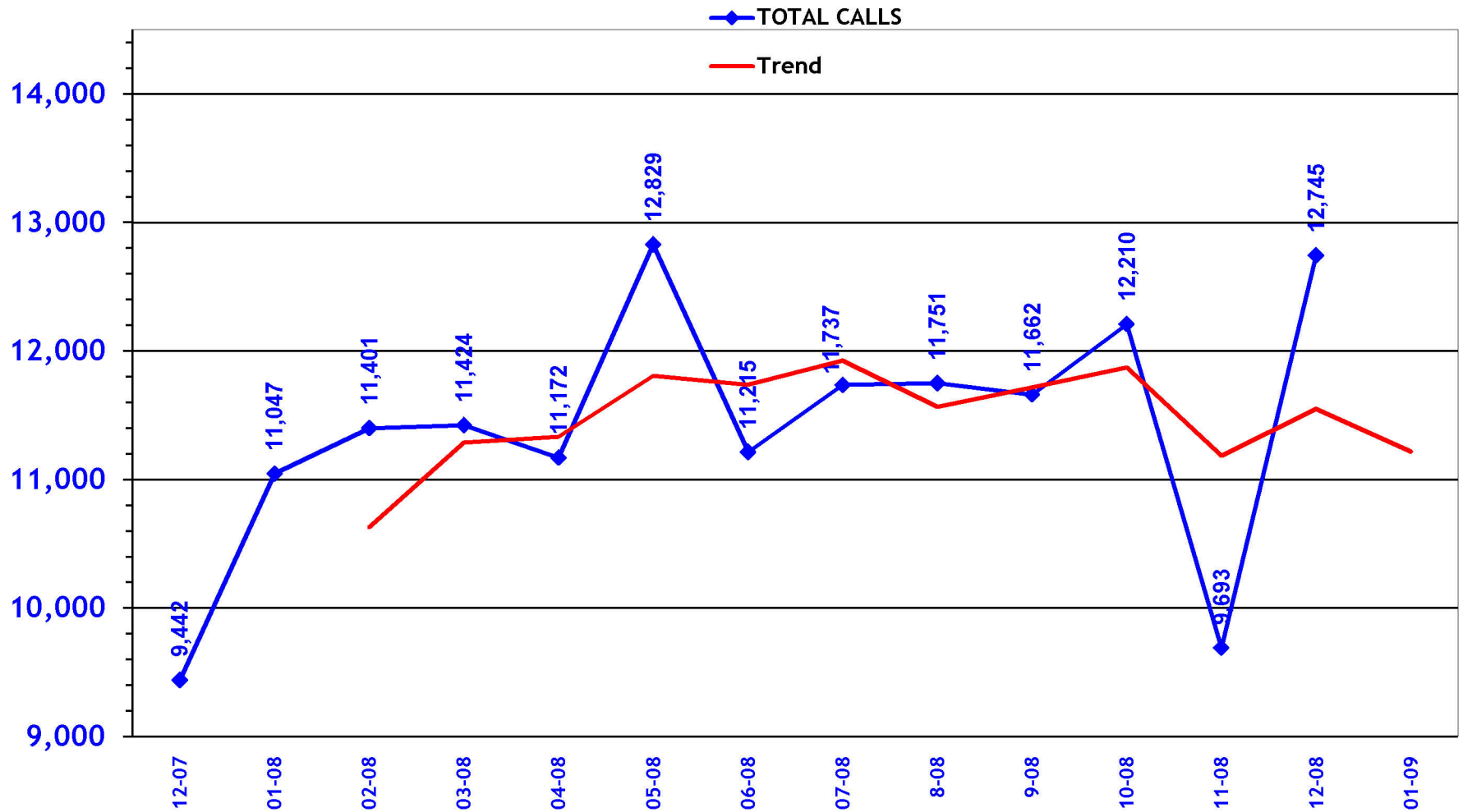
	Average Length of Approvals in Days	Approved	Denied	Incomplete	Total
ACE Inhibitors	62	11	0	2	13
Angiotensin Receptor Antagonist	336	22	46	37	105
Antidepressant	286	291	96	267	654
Antihistamine	292	217	74	178	469
Antiulcers	3	14	0	1	15
Anxiolytic	90	2,872	204	517	3,593
Calcium Channel Blockers	3	3	1	3	7
Growth Hormones	174	27	0	4	31
HTN Combos	107	7	6	16	29
Insomnia	119	61	49	82	192
Nsaids	333	31	16	51	98
Plavix	357	77	5	56	138
Stimulant	215	630	111	340	1,081
Others	137	1,554	527	1,396	3,477
Emergency PAs		3	0	0	3
Total		**5,820**	**1,135**	**2,950**	**9,905**
Overrides					
Brand	295	22	6	22	50
Dosage Change	10	345	11	22	378
High Dose	134	7	0	2	9
Lost/Broken Rx	6	101	7	4	112
Nursing Home Issue	4	44	0	1	45
Other	27	16	5	2	23
Quantity vs. Days Supply	269	741	122	294	1,157
Stolen	12	6	0	0	6
Wrong D.S. on Previous Rx	365	1	0	0	1
Overrides Total		**1,283**	**151**	**347**	**1,781**

Denial Reasons

Lack required information to process request.	3183
Unable to verify required trials.	580
Does not meet established criteria.	142
Considered duplicate therapy. Member has a prior authorization for similar medication.	50
Not an FDA approved indication/diagnosis.	47
Requested dose exceeds maximum recommended FDA dose.	37
Member has active PA for requested medication.	15
Drug Not Deemed Medically Necessary	7
Medication not covered as pharmacy benefit.	6
Duplicate Requests	620
* Changes to existing	781

** Changes to existing PA's: Backdates, changing units, end dates, etc.*

CALL VOLUME MONTHLY REPORT
December 2007 – December 2008



Appendix C

Vote to Prior Authorize Toviaz™ (fesoterodine fumarate)

Oklahoma Health Care Authority

January 2009

Manufacturer	Pfizer
Classification	Anticholinergic Agent
Status	Prescription only

Summary

Toviaz(TM) (fesoterodine fumarate) received FDA approval in October 2008. Toviaz[1] is a used in adults to treat symptoms of overactive bladder, including urinary incontinence, urinary urgency, and urinary frequency.

The recommended starting dose is 4mg once a day with a maximum of 8mg a day. Toviaz should be taken whole with liquid and with or without food.

Recommendations

The College of Pharmacy recommends placement of Toviaz(TM) (fesoterodine) in Tier 2 of the Bladder Control PBPA category.

Incontinence Medications*	
Tier 1	*Tier 2*
Darifenacin (Enablex®)	**Oxybutinin Extended-Release** (Ditropan XL®)
Flavoxate (Urispas®)	**Oxybutynin** (Oxytrol®)
Oxybutynin (Ditropan®)	**Trospium** (Sanctura®, Sanctura XR®)
Solifenacin (VESIcare®)	**Fesoterodine** (Toviaz™)
Tolterodine Extended-Release (Detrol LA®)	
Tolterodine (Detrol®)	

*Hyoscyamine can be used as adjuvant therapy only. By itself, it will not count as a Tier 1 trial.

In order to get a Tier 2 drug, member must meet one of the following criteria:

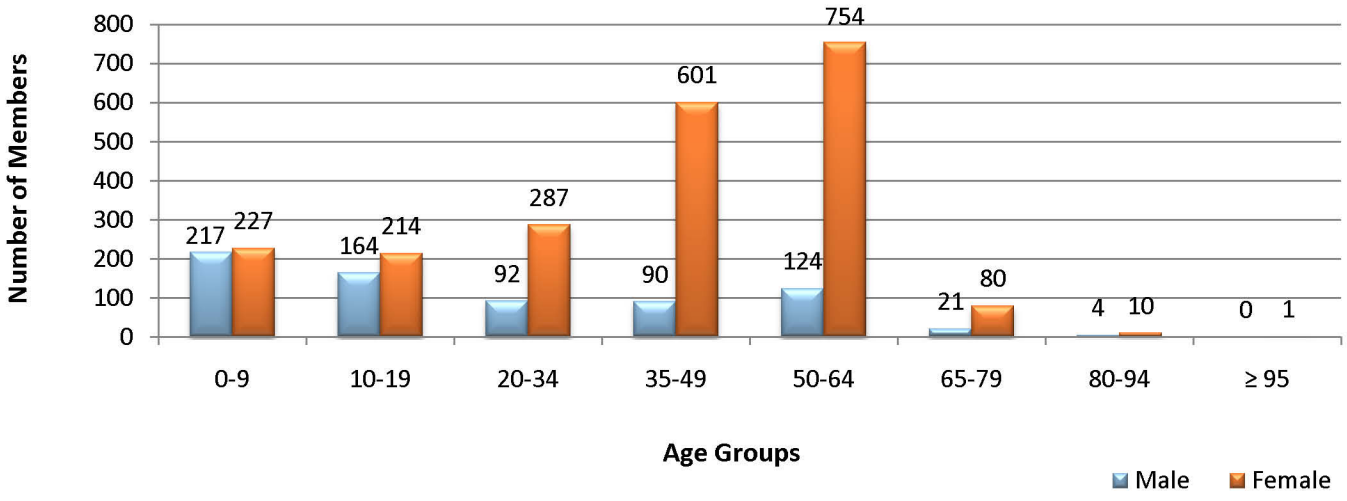
- Tier 1 drug failure (i.e. inadequate clinical response or adverse effect), or
- Contraindication to the Tier 1 drugs , or
- Stabilization on the Tier 2 drug, or
- A unique indication which the Tier 1 drugs lack.

Utilization of Bladder Control Medications in Select Pediatric Population

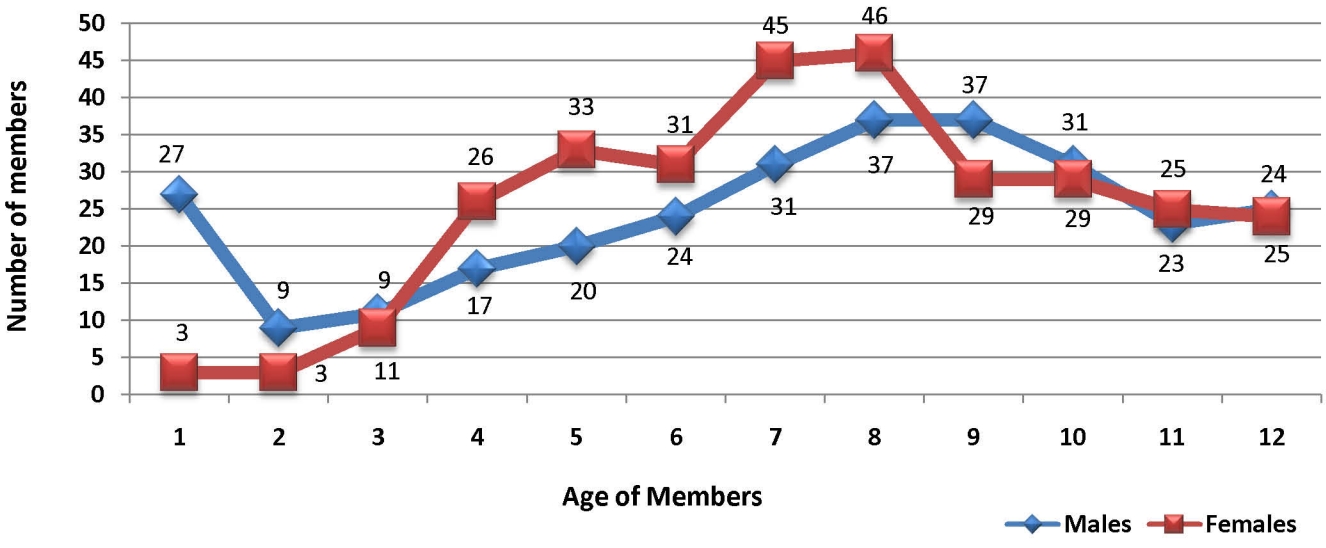
The following table shows agents with pediatric indications and youngest approved age.

Incontinence Medications approved for Adults	
Tier 1	*Tier 2*
Darifenacin **Enablex**®	Oxybutinin ER **Ditropan XL**®
Flavoxate **Urispas**® ***(> 12 yrs)***	Oxybutynin **Oxytrol** ***(≥ 1 yr)***
Oxybutynin **Ditropan**® ***(≥ 1 yr)***	Trospium **Sanctura**®**, Sanctura XR**®
Solifenacin **VESIcare**®	Fesoterodine **Toviaz**™
Tolterodine ER **Detrol LA**®	
Tolterodine **Detrol**®	

Demographics of All Members Utilizing Bladder Control Medications



Demographics of Members Less than 13 Years of Age*



*25 members with unknown age or sex codes

Utilization Details of Members Less than 13 Years of Age

Medication	Claims	Units	Days	Members	Cost	Per-diem	% Claims	% Cost
ENABLEX® TAB 7.5MG	3	90	90	2	$254.94	$2.83	0.16	0.38
ENABLEX® TAB 15MG	9	330	330	4	$1,232.78	$3.74	0.49	1.86
FLAVOXATE TAB 100MG	12	560	210	8	$561.92	$2.68	0.66	0.85
OXYTROL® DIS 3.9MG/24	4	32	116	1	$410.16	$3.54	0.22	0.62
OXYBUTYNIN TAB 5MG	639	37,591	20,088	241	$5,081.38	$0.25	34.92	7.67
OXYBUTYNIN SYP 5MG/5ML	709	182,219	18,922	283	$8,708.31	$0.46	38.74	13.14
DITROPAN XL® TAB 5MG	5	150	150	3	$522.98	$3.49	0.27	0.79
OXYBUTYNIN TAB 5MG ER	26	915	780	11	$2,138.18	$2.74	1.42	3.23
OXYBUTYNIN TAB 10MG ER	99	3,885	3,065	21	$8,430.12	$2.75	5.41	12.72
OXYBUTYNIN TAB 15MG ER	23	750	690	2	$1,921.47	$2.78	1.26	2.90
VESICARE® TAB 5MG	46	1,410	1,390	14	$5,424.20	$3.90	2.51	8.19
VESICARE® TAB 10MG	74	3,120	2,302	18	$11,847.91	$5.15	4.04	17.88
DETROL® TAB 1MG	19	780	570	9	$1,562.36	$2.74	1.04	2.36
DETROL® TAB 2MG	61	2,530	1,830	23	$5,130.96	$2.80	3.33	7.74
DETROL LA® CAP 2MG	23	1,136	866	11	$4,087.66	$4.72	1.26	6.17
DETROL LA® CAP 4MG	76	2,340	2,340	29	$8,715.20	$3.72	4.15	13.15
SANCTURA XR® CAP 60MG	2	60	60	1	$221.70	$3.70	0.11	0.33
TOTALS	**1,830**	**237,898**	**53,799**	**620***	**$66,252.23**	**$1.23**	**100.00**	**100.00**

*Total of 620 members unduplicated members

Diagnosis and Concomitant DDAVP Utilization

Members Age 0-12	Members with Nocturnal Enuresis	Members with DDAVP Use
620	147	99

Conclusion and Recommendations

The College of Pharmacy recommends no further action at this time as the data analyzed showed the majority of the pediatric utilization in this category was due to utilization of oxybutynin, which has a pediatric indication for children as young as one year of age.

REFERENCE

Toviaz(TM) (fesoterodine) Product Information. Pfizer. **www.toviaz.com** Accessed 2008.

Appendix D

Vote to Prior Authorize simvastatin/Niaspan® (Simcor®) and Vote to Update Statin PBPA Category

Oklahoma HealthCare Authority
January 2009

Recommendation

The College of Pharmacy recommends dividing the HMG-CoA Reductase Inhibitors (Statins) PBPA category into two subcategories and adding a third tier with modification of criteria as shown below. The College also recommend quantity limits be placed on all strengths Advicor® and Simcor®.

HMG-CoA Reductase Inhibitors (Statins)		
Tier One	*Tier Two*	*Tier Three*
Fluvastatin (Lescol® & Lescol® XL)	Atorvastatin (Lipitor®)	Lovastatin (brand Altoprev®)
Lovastatin (Mevacor®)	Rosuvastatin (Crestor®)	Pravastatin/Aspirin (Pravaguard®)
Pravastatin (Pravachol®)		Simvastatin/Ezetimibe (Vytorin®)
Simvastatin (Zocor®)		Ezetemibe (Zetia®)
Statin/Niaspan® Combination Products		
Tier 1 Statins and/or Niaspan®	Lovastatin/Niacin CR (Advicor®)	
	Simvastatin/Niacin CR (Simcor®)	

Mandatory generic plan in effect where generic is available.

Criteria for Authorization

To qualify for a Tier 2 medication, there must be:

1. A trial, defined by at least 8 weeks of continuous therapy titrated to recommended dose, of a Tier 1 medication that did not yield adequate LDL reduction.
2. Documented adverse effect or contraindication to all available lower tiered products.
3. Clinical exception for atorvastatin 80mg: members hospitalized for recent acute myocardial infarction or acute coronary syndrome.

To qualify for a Tier 3 medication, there must be:

1. A trial, defined by at least 8 weeks of continuous therapy titrated to recommended dose, of a Tier 2 medication that did not yield adequate LDL reduction.
2. Documented adverse effect or contraindication to all available lower tiered products.
3. Clinical exceptions for Ezetimibe:
    a. Documented active liver disease.
    b. Documented unexplained, persistent elevations of serum transaminases.
    c. Documented statin related myopathy.

Appendix E

Vote to PA Lamisil® Granules

Oklahoma Health Care Authority
January 2009

Introduction[1]

Tinea capitis is a dermatophyte infection of the scalp hair shaft and is the most common superficial fungal infection in children. Prevalence rates of tinea capitis are estimated to be 3% to 8% in the United States with the highest incidence seen in children from ages three to seven. *Trichophyton* and *Microsporum* are the species of dermatophytes that cause tinea capitis

The most common etiology of tinea capitis is *Trichophyton tonsurans.* In North America and the United Kingdom, *T. tonsurans* accounts for more than 95% of tinea capitis cases. A small percentage of cases are caused by *Microsprum canis,* which is contracted from household dogs and cats.

Product Comparison[2, 3]

GENERIC NAME	TRADE NAME	COMMON FDA INDICATIONS	DOSAGE FORMS AVAILABLE	AGE RANGE	PEDIATRIC DOSING RANGE PER DAY DURATION OF THERAPY	SPECIAL INSTRUCTIONS
Griseofulvin Microsize **Griseofulvin Ultramicrosize**	Fulvicin P/G® Gris-PEG®	-Tinea capitis	Tabs, Caps, Suspension	>2 years	**Griseofulvin Microsize:** 10-20 mg/kg/day in single or divided doses for 4 to 6 weeks **Griseofulvin Ultramicrosize:** 5-15 mg/kg/day in single dose or 2 divided doses (maximum: 750 mg/day) for 4 to 6 weeks	Oral: Administer w/ fatty meal (peanut butter or ice cream to increase absorption), or with food or milk to avoid GI upset; shake suspension well before use. Ultramicrosize tablets may be swallowed whole or crushed and sprinkled onto 1 tablespoonful of applesauce and taken immediately without chewing.
Terbinafine	Lamisil®	-Tinea capitis	Granules	≥4 years	**<25 kg:** 125 mg once daily for 6 weeks **25-35 kg:** 187.5 mg once daily for 6 weeks **>35 kg:** 250 mg once daily for 6 weeks	Granules should be taken with food; sprinkle on a spoonful of nonacidic food (eg, pudding, mashed potatoes); do not use applesauce or fruit-based foods; swallow granules whole without chewing.

Common Adverse Events Profile[4]

Lamisil® Granules (%) N=1,042	Griseofulvin Oral Suspension (%) N=507
Nasopharyngitis – 10 Headache – 7 Pyrexia – 7 Cough – 6 Vomiting – 5 URI – 5 Upper abdominal pain – 4 Diarrhea – 3	Nasopharyngitis – 11 Headache – 8 Pyrexia - 6 Cough –5 Vomiting – 5 URI – 5 Upper abdominal pain – 4 Diarrhea – 4

Primary Efficacy Results by Dermatophyte Species[4]

	Study 1		Study 2	
Species	**Terbinafine**	**Griseofulvin**	**Terbinafine**	**Griseofulvin**
All Dermatophytes Complete Cure	(N=411) 190 (46.2%)	(N=197) 67 (34.0%)	(N=411) 194 (44.0%)	(N=237) 103 (43.5%)
T.tonsurans Complete Cure	(N=264) 148 (56.1%)	(N=131) 45 (34.4%)	(N=243) 116 (47.7%)	(N=126) 46 (36.5%)
M. canis Complete Cure	(N=80) 10 (23.8%)	(N=37) 13 (35.1%)	(N=72) 22 (30.6%)	(N=45) 23 (51.1%)
Other* Complete Cure	(N=67) 23 (34.2%)	(N=29) 9 (31.0%)	(N=126) 56 (44.4%)	(N=66) 34 (51.5%)

**T. violaceum, M. audiuinii, T. menagrophytes, M. gypseum, and M. vanbreuseghemii*

Contraindications, Warnings, and Precautions[3]

	Lamisil® Granules	Griseofulvin
Contraindications	History of or allergic reaction to oral terbinafine	Hypersensitivity to griseofulvin or any component; severe liver disease, porphyria (interferes with porphyrin metabolism); pregnant women (may cause fetal harm)
Warnings	Although rare, **Stevens-Johnson syndrome** and toxic epidermal necrolysis have been reported with oral use; discontinue therapy if progressive skin rash occurs. **Pancytopenia and neutropenia** have been reported rarely with oral use; discontinuation of therapy may be required. Monitor CBCs in patients with pre-existing immunosuppression if use to continue >6 weeks. Rare cases of **hepatic failure** (including fatal cases) have been reported following oral treatment; not recommended for use in patients with active or chronic liver disease. Pretreatment hepatic enzymes tests are recommended for patients receiving oral therapy. Discontinue if symptoms or signs of hepatobiliary dysfunction or cholestatic hepatitis develop. Use of oral therapy not recommended in patients with hepatic cirrhosis; clearance is reduced. **Changes in the ocular lens and retina** have been reported with oral use; discontinuation of therapy may be required. Precipitation or exacerbation of **cutaneous or systemic lupus erythematosus** has been observed with oral therapy; discontinue if signs and/or symptoms develop. Use of oral therapy not recommended in patients with renal dysfunction (Cl_{cr} ≤50 mL/minute); clearance is reduced by approximately 50%.	**Lupus erythematosus** or lupus-like syndromes have been reported in patients receiving griseofulvin.
Precautions	Use with caution in patients sensitive to allylamine antifungals (eg, naftifine, butenafine); cross sensitivity to terbinafine may exist	Avoid exposure to intense sunlight to prevent photosensitivity reactions; use with caution in patients with penicillin hypersensitivity since cross-reactivity with griseofulvin is possible
Monitoring Parameters	Oral therapy: AST/ALT prior to initiation, repeat if used >6 weeks; CBC	Periodic renal, hepatic, and hematopoietic function tests

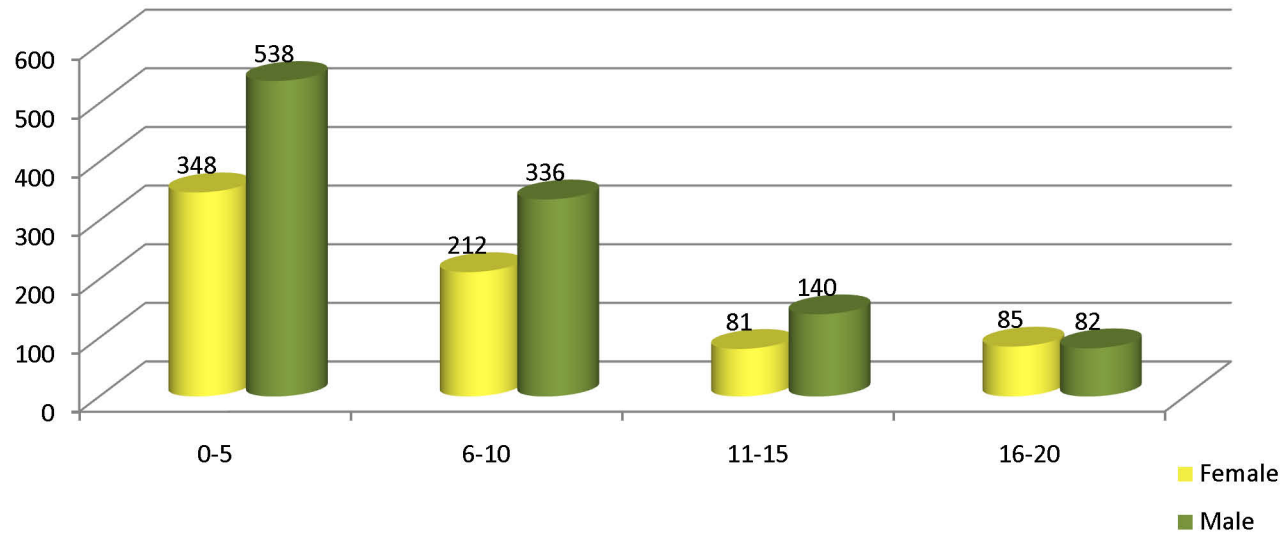
Utilization data – April 2008 – October 2008

Drug	Claims	Units	Days	Members	Cost/ Claim	Cost/ Member	Cost
GRIFULVIN V TAB 500MG	220	6,805	6,518	176	$105.51	$123.40	$21,718.90
GRISEOFULVIN SUSP 125/5ML	1,831	497,378	45,112	1,265	$66.15	$71.79	$90,819.04
GRIS-PEG® TAB 125MG	28	1,506	580	21	$91.30	$93.16	$1,956.36
GRIS-PEG® TAB 250MG	175	7,347	5,143	139	$98.98	$106.59	$14,815.88
TERBINAFINE TAB 250MG	406	12,357	13,471	289	$100.35	$12.96	$3,745.94
LAMISIL® GRANULES 125MG	23	820	782	15	$279.19	$353.59	$5,303.92
LAMISIL® GRANULES 187.5MG	29	1,082	1,085	11	$320.42	$1,047.93	$11,527.20
TOTALS	**2,712**	**527,295**	**72,691**	**1916**	**$940.18**	**$78.23**	**$149,887.24**

*Unduplicated Members

Demographic Data for Children Prescribed Griseofulvin and Terbinafine

April - October 2008



Prescribed Lamisil Granules

Nineteen children had paid claims for Lamisil Granules between April 1 and October 31, 2008. The status of the children is as follows.

Treatment	Number of Members
Lamisil® Granules only	**13**
Griseofulvin before Lamisil®	**4**
Griseofulvin after Lamisil®	**2**

Recommendations

The College of Pharmacy recommends prior authorizing Lamisil® granules.

Approval Criteria

- FDA approved indication of tinea capitis
- No improvement after at least 3 weeks of therapy with griseofulvin
- Intolerance or hypersensitivity to griseofulvin or penicillin
- Restrict to children 12 years and younger

References

1. Swanson A, Elewski B. The Role of the Pharmacist in Managing Patients with Tinea Capitis. Available online at Powerpak: http://www.powerpak.com/index.asp?page=courses/105573/disclaimer.htm&lsn_id=105573
2. Facts & Comparisons 4.0, 2008 Wolters Kluwer Health, Inc. Available online at http://online.factsandcomparisons.com/index.aspx
3. Lexi-Comp Copyright © 1978 - 2008 Lexi-Comp, Inc. Available online at http://www.crlonline.com/crlsql/servlet/crlonline
4. Lamisil® Granules Package Insert. Available online at http://www.pharma.us.novartis.com/product/pi/pdf/Lamisil_Oral_Granules.pdf

Appendix F

Prior Authorization Annual Review - Fiscal Year 2008
Ophthalmic Anti-Infectives and Steroid-Antibiotic Combination Products

Oklahoma Health Care Authority
January 2009

CURRENT CRITERIA FOR OPHTHALMIC ANTIBIOTICS

1. Approved indication/suspected infection by organism not known to be covered by tier one antibiotics.
2. Known contraindication to all indicated tier one medication.
3. Prescription written by optometrists/ophthalmologists, or
4. When used for pre/post-operative prophylaxis.

Ophthalmic Antibiotics: Liquids	
Tier 1	**Tier 2**
Vigamox (Moxifloxacin)	
Zymar (Gatifloxacin)	
Azasite (Azithromycin)	
Ciloxan Solution (Ciprofloxacin)	
Quixin (Levofloxacin)	
Gentak (Gentamicin)	
Ocuflox (Ofloxacin)	
AK-Tob (Tobramycin)	
Bleph-10, Sodium Sulamyd (Sodium Sulfacetamide)	
Viroptic (Trifluridine)	
Natacyn (Natamycin)	
Polytrim (PolymyxinB/Trimethoprim)	
AK-Spore (Neomycin/PolymyxinB/Gramacidin)	

Blue indicates tier-1 due to supplemental rebate participation

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

CURRENT CRITERIA FOR ANTIBIOTIC-STEROID COMBINATION PRODUCTS

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

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

Utilization – Fiscal Year 2008

For the period of July 2007 through June 2008, a total of 37,491 members received Ophthalmic Antibiotics: Liquid, Ointments or Steroid Combinations through the Oklahoma Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Total Cost	Total Members	Cost/ Member	Cost/ Claim	Per-diem
Liquids & Ointments	41,940	252,922	428,819	$ 1,047,505.93	34,282	$ 30.55	$24.98	$2.44
Steroid Combos	4,841	26,662	54,923	$ 251,778.81	4,125	$ 61.04	$52.01	$4.58
Total	46,781	279,584	483,742	$1,299,284.74	38,407*	$33.83	$27.77	$2.69

*Total unduplicated members for FY08

Total Cost FY '08		**$1,299,284.74**
	Total Cost FY '07	*$1,149,660.26*
Total Claims FY '08		**279,584**
	Total Claims FY '07	*267,480*
Total Members FY '08		**37,491**
	Total Clients FY '07	*35,392*
Per Diem FY '08		**$2.69**
	Per Diem FY '07	*$2.58*

Demographics

Claims were reviewed to determine the age/gender of the members on Ophthalmic Antibiotics:

Age	Female	Male	Totals
0 to 9	12,891	14,236	27,127
10 to19	3,796	2,833	6,629
20 to 34	1,505	244	1,749
35 to 49	600	193	793
50 to 64	654	302	956
65 to 79	98	53	151
80 to 94	11	5	16
95 and Over	0	1	1
Totals	**19,555**	**17,867**	**37,422***

*69 members no longer eligible, therefore, a total of 37,491 members

Prior Authorizations

Prior Authorizations (Ophthalmic Antibiotics: Liquids & Ointments)	No. of Petitions FY07	No. of Petitions FY08
Approved	15	27
Denied	0	3
Incomplete	9	6
Totals	24	36

Prior Authorizations (Ophthalmic Antibiotics: Steroid Combos)	No. of Petitions FY07	No. of Petitions FY08
Approved	2	24
Denied	0	19
Incomplete	6	5
Totals	8	48

Top 10 Prescriber Specialties for Ophthalmic Antibiotics

Specialty	Number of Claims	Total Amount Paid
General Pediatrician	13,059	$486,522.54
Family Practitioner	12,097	$218,100.58
General Practitioner	3,251	$69,737.94
Nurse Practitioner (Other)	3,025	$86,170.49
Optometrist	2,498	$114,888.98
Physician Assistant	2,330	$57,366.85
Emergency Medicine Practitioner	1,833	$25,836.23
Unknown	1,830	$35,396.15
Ophthalmologist	1,779	$75,717.26
Internist	1,469	$31,941.98

Recommendations

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

Ingredient	Brand Name	Claims	Units	Days	Members	Cost	Units/ Day	Claims/ Mem	Perdiem	% Cost
Moxifloxacin	VIGAMOX DRO 0.5%	9,843	30,303	102,524	8,664	$627,249.80	0.3	1.14	$6.12	48.28%
Erythromycin	ERYTHROMYCIN OIN OP	6,533	23,489	50,656	5,978	$44,527.94	0.46	1.09	$0.88	3.43%
Gentamicin	GENTAMICIN SOL 0.3% OP	4,285	24,167	40,726	3,844	$27,879.23	0.59	1.11	$0.68	2.15%
Sulfacetamide Sodium	SOD SULFACET SOL 10% OP	3,796	56,660	51,104	3,569	$21,878.81	1.11	1.06	$0.43	1.68%
Tobramycin	TOBRAMYCIN SOL 0.3% OP	3,451	17,904	35,134	3,170	$23,093.87	0.51	1.09	$0.66	1.78%
Polymyxin B-Trimethoprim	POLYMYXIN B/ SOL TRIMETHP	2,338	23,458	31,371	2,202	$18,519.37	0.75	1.06	$0.59	1.43%
Ciprofloxacin	CIPROFLOXACN SOL 0.3% OP	2,144	10,797	20,482	1,923	$35,797.37	0.53	1.11	$1.75	2.76%
Tobramycin-Dexamethasone	TOBRADEX SUS OP	1,868	10,027	22,290	1,616	$143,037.09	0.45	1.16	$6.42	11.01%
Polymyxin B-Trimethoprim	TRIMETHOPRIM SOL POLYMYXN	1,624	16,185	17,247	1,555	$15,670.17	0.94	1.04	$0.91	1.21%
Ofloxacin	OFLOXACIN SOL 0.3% OP	1,291	8,339	13,068	1,121	$17,364.21	0.64	1.15	$1.33	1.34%
Neo-PolyB-Gram	NEO/POLY/GRA SOL OP	1,263	12,603	15,931	1,161	$30,346.15	0.79	1.09	$1.90	2.34%
Azithromycin	AZASITE SOL 1%	962	2,470	8,188	786	$61,354.66	0.3	1.22	$7.49	4.72%
Neomycin-Polymyxin-HC	NEO/POLY/HC SUS OP	953	7,347	11,592	891	$51,202.53	0.63	1.07	$4.42	3.94%
Neo-Poly-Dexamethasone	NEO/POLY/DEX SUS 0.1% OP	857	4,439	9,569	769	$7,884.80	0.46	1.11	$0.82	0.61%
Sulfacetamide Sodium	SULFACET SOD SOL 10% OP	706	10,484	7,561	675	$4,386.68	1.39	1.05	$0.58	0.34%
Gatifloxacin	ZYMAR DRO 0.3%	645	3,253	8,629	525	$39,898.99	0.38	1.23	$4.62	3.07%
Gentamicin	GENTAK OIN 0.3% OP	412	1,478	3,261	387	$7,291.62	0.45	1.06	$2.24	0.56%
Neo-Poly-Dexamethasone	NEO/POLY/DEX OIN 0.1% OP	401	1,425	3,729	337	$2,729.87	0.38	1.19	$0.73	0.21%
Bacitracin-Polymyxin B	BACIT/POLYMY OIN OP	372	1,317	2,947	339	$4,413.91	0.45	1.10	$1.50	0.34%
Tobramycin-Dexamethasone	TOBRADEX OIN OP	359	1,267	3,342	323	$29,064.95	0.38	1.11	$8.70	2.24%
Gentamicin	GENTAK SOL 0.3% OP	302	1,600	2,966	282	$2,083.62	0.54	1.07	$0.70	0.16%
Tobramycin	TOBREX OIN 0.3% OP	298	1,088	2,437	262	$19,776.68	0.45	1.14	$8.12	1.52%
Bacitracin	BACITRACIN OIN OP	286	1,247	2,595	225	$2,178.18	0.48	1.27	$0.84	0.17%
Ciprofloxacin	CILOXAN OIN 0.3% OP	249	968	2,076	178	$18,197.24	0.47	1.40	$8.77	1.40%
Neo-Bac-Polymyx	NEO/BAC/POLY OIN OP	231	828	1,810	214	$2,292.84	0.46	1.08	$1.27	0.18%
Sulfacetamide Sodium	BLEPH-10 SOL 10% OP	213	1,130	1,577	197	$1,031.29	0.72	1.08	$0.65	0.08%
Gentamicin	GENTAMICIN OIN 0.3% OP	173	623	1,339	163	$3,067.42	0.46	1.06	$2.29	0.24%
Levofloxacin	QUIXIN SOL 0.5%	128	670	1,497	118	$7,931.78	0.45	1.08	$5.30	0.61%
Sulfacetamide /Prednisolone	BLEPHAMIDE SUS OP	121	820	1,593	109	$7,432.43	0.51	1.11	$4.67	0.57%
Bacitracin-Polymyxin B	AK-POLY-BAC OIN OP	100	349	773	92	$1,186.23	0.45	1.09	$1.53	0.09%
Sulfacetamide Sodium	SULFACET SOD OIN 10% OP	96	353	709	86	$746.65	0.5	1.12	$1.05	0.06%
Trifluridine Ophth	TRIFLURIDINE SOL 1% OP	87	661	1,373	60	$7,099.62	0.48	1.45	$5.17	0.55%
Neo-Bac-Polymyx	BAC/NEO/POLY OIN OP	69	243	488	64	$681.68	0.5	1.08	$1.40	0.05%
Loteprednol-Tobramycin	ZYLET SUS 0.5-0.3%	68	350	740	54	$5,411.56	0.47	1.26	$7.31	0.42%
Bac-Poly-Neo-HC	BAC/POLY/NEO OIN /HC OP1%	66	238	585	60	$682.23	0.41	1.10	$1.17	0.05%
Sulfacetamide/Prednisolone	SULF/PRED NA SOL OP	55	385	508	37	$1,056.42	0.76	1.49	$2.08	0.08%
Sulfacetamide-Prednisolone	BLEPHAMIDE OIN S.O.P.	47	165	385	43	$2,446.56	0.43	1.09	$6.35	0.19%
Bac-Poly-Neo-HC	NEO/POLY/BAC OIN /HC OP1%	27	99	284	24	$286.19	0.35	1.13	$1.01	0.02%
	Totals	**46,781**	**279,584**	**483,742**	**37,491**	**$1,299,284.74**	**0.58**	**1.25**	**$2.69**	**100**

Ingredient (Cont'd)	Brand Name	Claims	Units	Days	Members	Cost	Units/ Day	Claims/ Mem	Perdiem	% Cost
Tobramycin	AK-TOB SOL 0.3% OP	21	105	151	20	$154.81	0.7	1.05	$1.03	0.01%
Levofloxacin	IQUIX SOL 1.5%	15	75	104	14	$986.25	0.72	1.07	$9.48	0.08%
Gentamicin-Prednisolone	PRED-G SUS OP	10	50	106	8	$288.40	0.47	1.25	$2.72	0.02%
Neo-Poly-Prednisolone	POLY-PRED SUS OP	7	35	127	5	$196.56	0.28	1.40	$1.55	0.02%
Neo-Poly B-Gram	NEOSPORIN SOL OP	4	40	45	4	$77.56	0.89	1.00	$1.72	0.01%
Sulfacet -Fluorometholone	FML-S SUS LIQUIFLM	2	15	73	1	$59.22	0.21	2.00	$0.81	0.00%
Natamycin	NATACYN SUS 5% OP	2	30	40	1	$334.30	0.75	2.00	$8.36	0.03%
Gentamicin	GENOPTIC SOL 0.3% OP	1	5	10	1	$7.00	0.5	1.00	$0.70	0.00%
Totals		**46,781**	**279,584**	**483,742**	**37,491**	**$1,299,284.74**	**0.58**	**1.25**	**$2.69**	

*Total number of unduplicated members.

Appendix G

Drug Utilization Review of Asthma Medication
Annual Review of Brovana

Oklahoma Health Care Authority, January 2009

Utilization of Anti-Asthmatics

Utilization of Different Classes of Asthma Medications: FY2008

Medication Class	Members	Claims	Cost	Cost/Claim	Perdiem
Leukotriene Receptor Antagonists	43,467	152,050	$16,471,282.71	$108.33	$3.50
Beta Agonists	88,757	231,775	$10,157,513.19	$43.82	$2.10
Sympathomimetic Combo	16,169	55,059	$9,445,000.73	$171.54	$5.78
Inhaled Corticosteroids	21,512	53,897	$8,666,152.45	$160.79	$5.64
Anticholinergic Bronchodilators	3,434	12,187	$1,214,808.93	$99.68	$3.58
Omalizumab	12	85	$169,950.08	$1,999.41	$70.64
Mast Cell Stabilizer	407	905	$56,941.17	$62.92	$2.23
Xanthine Derivatives	555	2,173	$56,714.43	$26.10	$0.83
Epinephrine	27	27	$153.59	$5.69	$3.20
Totals	**111,867***	**508,158**	**$46,238,517.28**	**$90.99**	**$3.52**

*Unduplicated members.
Red color indicate restrictions apply.

Utilization of Inhaled Corticosteroids

Inhaled corticosteroids are recommended by the NAEPP/NHLBI Guidelines and various other international guidelines as the first-line therapy for long-term control of persistent asthma symptoms in both children and adults. There are several agents available. Although there are differences in potency, no definitive clinical evidence exists that shows greater efficacy for any of the inhaled corticosteroids when administered in their relative equipotent dosages. As a result guidelines do not recommend one agent over others. The following table shows the available products arranged from the least potent to most potent.

Ingredient	Brand Name	Formulation and Lowest Age Indicated	Dosing
Flunisolide	AEROBID® (M)	Inhaler 6 years of age	2-4 puffs BID
Triamcinolone	AZMACORT®	Inhaler 6 years of age	1-2 puffs TID-QID or 4 puffs BID
Beclomethasone	QVAR®	Inhaler 5 years of age	2-8 Puffs BID
Mometasone	ASMANEX®	Inhaler 4 years of age	1-4 Puffs QD-BID
Budesonide	PULMICORT®	Nebulizer 1-8 years old, Inhaler 6 years of age	1-4 Puffs QD-BID
Fluticasone	FLOVENT®	Inhaler 4 years and older	2-4 Puffs BID

Utilization Trends

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem
2007	19,798	48,494	$7,102,850.44	$146.47	$5.16
2008	21,512	53,897	$8,666,152.45	$160.79	$5.64
Percent Change	8.70%	11.10%	22.00%	9.80%	9.30%
Change	1,714	5,403	$1,563,302.01	$14.32	$0.48

Utilization Details

Ingredient	Brand Name	Claims	Members	Cost	Perdiem	% Cost	Claims/ Member
Budesonide	PULMICORT® SUS 0.25MG/2	12,396	6,435	$2,569,372.47	$8.19	29.65%	1.93
Budesonide	PULMICORT® SUS 0.5MG/2	10,666	4,965	$2,685,325.49	$9.67	30.99%	2.15
Budesonide	PULMICORT® SUS 1MG/2ML	393	247	$152,925.71	$12.52	1.76%	1.59
Budesonide	PULMICORT® INH 180MCG	1,120	586	$149,877.77	$3.77	1.73%	1.91
Budesonide	PULMICORT ®INH 200MCG	320	215	$53,426.86	$3.83	0.62%	1.49
Budesonide	PULMICORT® INH 90MCG	405	199	$38,710.03	$3.21	0.45%	2.04
Fluticasone	FLOVENT® DISK AER 50MCG	109	47	$9,091.71	$2.69	0.10%	2.32
Fluticasone	FLOVENT® HFA AER 44MCG	10,890	4,613	$984,235.12	$3.07	11.36%	2.36
Fluticasone	FLOVENT® HFA AER 110MCG	8,409	3,456	$987,878.39	$3.86	11.40%	2.43
Fluticasone	FLOVENT® HFA AER 220MCG	1,185	492	$219,027.12	$5.96	2.53%	2.41
Mometasone	ASMANEX® 14 AER 220MCG	5	2	$441.37	$2.98	0.01%	2.5
Mometasone	ASMANEX® 30 AER 220MCG	1,798	594	$202,615.73	$3.73	2.34%	3.03
Mometasone	ASMANEX® 60 AER 220MCG	1,277	490	$139,611.47	$3.45	1.61%	2.61
Mometasone	ASMANEX® 120 AER 220MCG	185	68	$28,196.14	$3.66	0.33%	2.72
Triamcinolone	AZMACORT® AER 75MCG	1,537	790	$207,009.26	$3.59	2.39%	1.95
Beclomethasone	QVAR® AER 40MCG	1,922	914	$129,705.89	$2.35	1.50%	2.1
Beclomethasone	QVAR® AER 80MCG	841	364	$70,844.48	$2.91	0.82%	2.31
Flunisolide	AEROBID® AER 250MCG	220	94	$20,028.36	$3.36	0.23%	2.34
Flunisolide	AEROBID-M® AER 250MCG	219	103	$17,829.08	$3.20	0.21%	2.13
FY 2008	Totals	53,897	21,512*	$8,666,152.45	$5.64	100%	2.51

*Unduplicated members.

Demographics for all Steroids

FY 08	Male	Female
00-09	9,346	6,049
10-19	2,469	1,989
20-34	105	428
35-49	90	382
50-64	152	406
65-79	19	50
80-94	2	0

Demographics for Pulmicort®

FY 08	Male	Female
00-09	6,152	3,987
10-19	624	478
20-34	33	100
35-49	20	71
50-64	21	87
65-79	8	12
80-94	2	0

Demographics for Flovent®

FY08	Male	Female
00-09	3,036	1,943
10-19	1,312	1,023
20-34	39	204
35-49	35	173
50-64	60	174
65-79	6	20
80-94	0	0

Utilization of Sympathomimetic Combination Agents

This category consists of long acting and short acting beta agonists in combination with other agents such as a corticosteroid or ipratropium. Advair and Symbicort are indicated as adjunctive therapy for management of persistent asthma uncontrolled on inhaled corticosteroids. They are also used in chronic obstructive pulmonary disease (COPD). Inhaled anticholinergics are considered as quick-relief medications and may offer some additive benefit to inhaled beta-2 agonists in severe acute asthma exacerbations, but evidence is lacking for a role in long-term management of asthma.

Utilization Trends

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem
2007	15,490	52,981	$8,475,182.98	$159.97	$5.50
2008	16,169	55,059	$9,445,000.73	$171.54	$5.78
Percent Change	4.40%	3.90%	11.40%	7.20%	5.10%
Change	679	2,078	$969,817.75	$11.57	$0.28

Utilization Details

Ingredient	Brand Name	Claims	Members	Cost	Perdiem	% Cost	Claims/ Member
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 250/50	17,953	6,007	$3,456,125.99	$6.24	36.59%	2.99
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 100/50	15,074	5,353	$2,338,169.51	$5.02	24.75%	2.82
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 500/50	3,971	1,187	$1,052,990.77	$8.49	11.15%	3.35
Fluticasone-Salmeterol	ADVAIR® HFA AER 115/21	1,117	447	$205,547.55	$6.04	2.18%	2.5
Fluticasone-Salmeterol	ADVAIR® HFA AER 230/21	348	126	$92,035.72	$8.59	0.97%	2.76
Fluticasone-Salmeterol	ADVAIR® HFA AER 45/21	794	365	$123,802.20	$4.89	1.31%	2.18
Ipratropium-Albuterol	COMBIVENT® AER	8,225	2,478	$992,068.03	$4.24	10.50%	3.32
Ipratropium-Albuterol	DUONEB® SOL	1,234	630	$234,341.46	$7.79	2.48%	1.96
Ipratropium-Albuterol	IPRATROPIUM/ ALBUTER SOL	4,625	1,956	$657,519.27	$6.46	6.96%	2.36
Budesonide-Formoterol	SYMBICORT® AER 160-4.5	1,030	548	$186,318.22	$5.61	1.97%	1.88
Budesonide-Formoterol	SYMBICORT® AER 80-4.5	695	384	$107,290.74	$4.87	1.14%	1.81
FY 2008	Totals	55,066	16,170*	$9,446,209.46	$5.78		3.41

*Unduplicated members.

Demographics for Advair®

FY 08	Male	Female
00-09	1,299	779
10-19	3,241	2,424
20-34	214	928
35-49	234	1,076
50-64	570	1,280
65-79	80	112
80-94	2	6
95 >	0	2

Demographics for Alb/Iprat

FY 08	Male	Female
00-09	793	476
10-19	482	389
20-34	134	482
35-49	338	1,074
50-64	923	1,518
65-79	186	264
80-94	13	21
95 >	1	1

Demographics for Symbicort®

FY08	Male	Female
00-09	124	77
10-19	205	192
20-34	13	69
35-49	21	86
50-64	31	67
65-79	6	6
80-94	0	1
95 >	0	1

Market Update[i]

On November 18, 2005, FDA alerted health care professionals and patients that several long-acting bronchodilator medicines have been associated with possible increased risk of worsening wheezing (bronchospasm) in some people, and requested that manufacturers update warnings in their existing product labeling. This information has now been included in updated labeling.

Starting March 2, 2006, FDA required black box warnings and Medication Guides for all products containing a long acting beta2 agonist:

- **Serevent Diskus®** (salmeterol xinafoate)
- **Advair Diskus®** and **Advair® HFA** (fluticasone propionate; salmeterol xinafoate)
- **Foradil®** (formoterol fumarate)
- **Symbicort®** Inhalation Aerosol (budesonide; formoterol fumarate dehydrate
- **Perforomist®** Inhalation Solution (formoterol fumarate)

In January 2008, FDA requested manufacturers of Advair Diskus®, Advair HFA®, Brovana® Inhalation Solution, Foradil® Aerolizer, Perforomist® Inhalation Solution, Serevent® Diskus, and Symbicort® Inhalation Aerosol to provide information regarding controlled clinical studies conducted with these products in order to further evaluate the safety of LABAs when treating asthma.

In November 2008, a U.S. Food and Drug Administration panel concluded that Serevent and Foradil should not be used for treating asthma. The panel ruled that Advair® and Symbicort® should continue to be used as asthma treatments. The panel is working on final recommendations to be made to the FDA.

Conclusions

Inhaled Corticosteroids

Claims data indicate an increase in utilization of the inhaled corticosteroid category. Inhaled corticosteroids have been shown to prevent exacerbations, reduce the need for systemic corticosteroids, emergency department care, hospitalizations, and deaths due to asthma hence they are the recommended first-line therapy for long-term control of persistent asthma symptoms. An increase in appropriate utilization of this category is desired to decrease potential overall healthcare expenditures.

The cost driver for this category is Pulmicort® Respules: a unique formulation that is useful in the very young members of the SoonerCare population. The patent for this formulation is anticipated to expire in approximately one year. The other products differ slightly from each other and current guidelines do not recommend one agent over others.

Sympathomimetic Combination Agents

Claims data shows an increase in utilization due to increase in members using this class. The final recommendations to the FDA may cause an increase in the utilization of the combination agents if the LABA single ingredient agents are taken off the market.

Recommendation

The College of Pharmacy recommends prior authorization of Advair® and Symbicort® with the following criteria.

A computer edit will be put in place to exempt members who have a diagnosis of COPD or asthma and a paid claim for an inhaled corticosteroid. All others will require a prior authorization with the following criteria:

Asthma

1. Member must be 4 years of age or older, and
2. Have used inhaled corticosteroid for at least one month immediately prior, and be
3. Considered uncontrolled by provider (required rescue medication > 2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids.)

Utilization Details for Inhaled Corticosteroids: FY 2007

Ingredient	Brand Name	Claims	Members	Cost	Perdiem	% Cost	Claims/ Member
Budesonide	PULMICORT® SUS 0.25MG/2	11,322	6,018	$2,171,424.93	$7.60	30.57%	1.88
Budesonide	PULMICORT® SUS 0.5MG/2	9,663	4,318	$2,133,826.42	$8.44	30.04%	2.24
Budesonide	PULMICORT® INH 180MCG	72	67	$8,375.24	$3.82	0.12%	1.07
Budesonide	PULMICORT® INH 200MCG	1,327	684	$212,271.65	$3.74	2.99%	1.94
Budesonide	PULMICORT® INH 90MCG	19	16	$1,630.26	$3.02	0.02%	1.19
Fluticasone	FLOVENT® HFA AER 44MCG	9,554	4,416	$807,741.25	$2.89	11.37%	2.16
Fluticasone	FLOVENT® HFA AER 110MCG	7,846	3,266	$868,115.49	$3.66	12.22%	2.4
Fluticasone	FLOVENT® HFA AER 220MCG	1,186	484	$204,333.62	$5.76	2.88%	2.45
Fluticasone	FLOVENT® AER 110MCG/A	92	81	$8,262.87	$2.67	0.11%	1.11
Fluticasone	FLOVENT® AER 220MCG/A	19	16	$2,530.22	$4.11	0.04%	1.19
Mometasone	ASMANEX® 120 AER 220MCG	147	68	$22,095.77	$4.11	0.31%	2.16
Mometasone	ASMANEX® 14 AER 220MCG	3	3	$176.19	$2.00	0.00%	1
Mometasone	ASMANEX® 30 AER 220MCG	1,602	601	$154,341.37	$3.20	2.17%	2.67
Mometasone	ASMANEX® 60 AER 220MCG	1,175	502	$114,173.48	$3.11	1.61%	2.34
Triamcinolone	AZMACORT ®AER 75MCG	1,337	628	$172,984.61	$3.78	2.44%	2.13
Triamcinolone	AZMACORT® AER 100MCG	40	19	$2,721.63	$2.45	0.04%	2.11
Beclomethasone	QVAR® AER 40MCG	1,809	903	$112,140.15	$2.25	1.58%	2
Beclomethasone	QVAR ®AER 80MCG	753	333	$58,969.18	$2.75	0.83%	2.26
Flunisolide	AEROBID® AER 250MCG	316	128	$29,276.86	$3.45	0.41%	2.47
Flunisolide	AEROBID-M®AER 250MCG	211	107	$17,413.18	$3.06	0.25%	1.97
Beclomethasone	VANCERIL® AER 42MCG	1	1	$46.07	$4.19	0.00%	1
	Totals	**48,494**	**19,798***	**$7,102,850.44**	**$5.16**	**100 %**	**2.45**

*Unduplicated members.

Utilization Details for Sympathomimetic Combination Agents: FY 2007

Ingredient	Brand Name	Claims	Members	Cost	Perdiem	% Cost	Claims/ Member
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 250/50	17,123	5,816	$3,030,799.90	$5.85	35.76%	2.94
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 100/50	17,223	5,936	$2,452,341.12	$4.67	28.94%	2.9
Fluticasone-Salmeterol	ADVAIR® DISKU MIS 500/50	3,866	1,147	$929,635.34	$7.91	10.97%	3.37
Fluticasone-Salmeterol	ADVAIR® HFA AER 115/21	288	150	$49,169.78	$5.62	0.58%	1.92
Fluticasone-Salmeterol	ADVAIR® HFA AER 230/21	46	27	$11,083.48	$8.03	0.13%	1.7
Fluticasone-Salmeterol	ADVAIR® HFA AER 45/21	287	169	$38,792.44	$4.25	0.46%	1.7
Ipratropium-Albuterol	COMBIVENT® AER	8,202	2,570	$940,797.78	$4.09	11.10%	3.19
Ipratropium-Albuterol	DUONEB® SOL	5,944	2,253	$1,022,394.78	$7.76	12.06%	2.64
Ipratropium-Albuterol	IPRATROPIUM/ ALBUTER SOL	4,625	1,956	$657,519.27	$6.46	6.96%	2.36
Budesonide-Formoterol	SYMBICORT® AER 80-4.5	2	1	$168.36	$2.81	0.00%	2
	Totals	**52,981**	**15,490***	**$8,475,182.98**	**$5.50**	**100 %**	**3.42**

*Unduplicated members.

Annual Review of Brovana™ (arformoterol tartrate) Inhalation Solution

The prior authorization of Brovana™ inhalation solution was implemented in November 2007 with the following criteria:

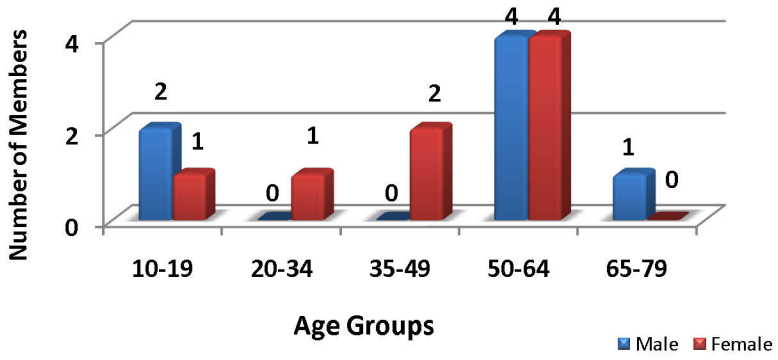
Approval Criteria:

- Member must be age 18 or older
- Diagnosis of COPD, chronic bronchitis, or emphysema
- Prior trial with Advair®, Serevent®, or Foradil® within the past 45 days
- Clinical exception for members who are unable to effectively use hand-actuated devices or are stable on nebulized therapy.
- Quantity limit of 120 ml for a 30 day supply also applies.

Utilization Trend and Details

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2007	8	12	$2,776.94	$231.41	$8.05	1,080	345
2008	15	31	$7,347.38	$237.01	$8.59	3,000	855
Percent Change	87.50%	158.30%	164.60%	2.40%	6.70%	177.80%	147.80%
Change	7	19	$4,570.44	$5.60	$0.54	1,920	510

Demographics of Members Utilizing Brovana™



Prior Authorization of Brovana™

Approved	8
Denied	13
Incomplete	2
Total	23

Prescribers of Brovana™

Specialty	Claims	Cost
Pulmonary Disease Specialist	10	$2,364.80
General Pediatrician	9	$1,405.89
General Practitioner	4	$1,255.82
Internist	3	$766.77
Family Practitioner	3	$941.54
Physician Assistant	2	$612.56

Recommendations

The College of Pharmacy recommends no changes at this time.

[i] FDA. Center for Drug Evaluation and Research. Available at: **http://www.fda.gov/CDER/Drug/infopage/LABA/default.htm**

Appendix H

Lock-In Report

Calendar Year 2008

Current Program Details

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total in Database	2,031	2056	2087	2135	2197	2241	2340	2396
Total Locked-In	147	144	143	139	148	148	157	158
Total Reviewed	111	126	148	143	87	161	145	130

Results of Reviews

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Extended Lock-in	4	4	3	2	2	1	2	5
In Lock-In process	10	8	18	9	5	13	18	4
Warned	6	7	28	24	17	20	14	6
Completed Lock-In	10	5	3	10	10	12	3	4

Retrospective Study of Oklahoma SoonerCare Lock-In Program

Oklahoma Health Care Authority
January 2009

Background

In January 2006, PMC began management of the Lock- In program for Oklahoma Medicaid's SoonerCare members. Prior to that time, the Lock-In program was managed by the SURS unit at OHCA. The goal of the Lock-In program is to promote appropriate utilization of health care resources for those members identified with misuse of resources or potentially fraudulent behavior. The Lock-In program provides a mechanism to detect misuse of narcotic and other medications and a procedure to "lock-in" the member to one pharmacy thereby limiting the opportunity for inappropriate behavior within the SoonerCare system. This is the first analysis of outcomes data for the Lock-In program since it began.

Objective

The objective of this research was to study the association of member enrollment in the Lock-In program on their utilization of narcotics, maintenance medications, and emergency room visits; number of pharmacies and physicians used each month; and expenditures for pharmacy and emergency departments. A review of outcomes for these members is necessary to determine the effectiveness of the program in reducing utilization and costs and optimizing medication utilization.

Lock-In Procedure

Generally, to be eligible for lock-in, a member must be currently eligible to receive pharmacy benefits from Oklahoma SoonerCare and meet at least three out of the following eight test criteria.

1. Number of emergency room visits (3 or greater).
2. Number of different pharmacies (3 or greater).
3. Number of different prescribers/physicians (5 or greater) (combined).
4. Total monthly day supply of narcotics, anxiolytics, antidepressants etc.

5. Diagnosis of drug dependency/ other diagnosis.
6. Number of hospital discharges (3 or greater).
7. Other information from past reviews.
8. Safety concerns.

The final decision to lock-in the member is made by the clinical pharmacist reviewing the case. Actual enrollment in the Lock-In program is performed by the staff at PMC. A diagnosis such as cancer may exclude a member from enrollment even though other criteria are met. Members are given notice of their lock-in status and are allowed to appeal the decision with OHCA. Prior to being locked-in, members may be warned that their claims activity is being monitored to allow for self-correction. The clinical pharmacists involved in the lock-in process were not involved in the study data collection or analysis in order to eliminate the chance for bias.

Study Population

A total of 55 members were enrolled in the Lock-in program during the study period and 52 of those members met the inclusion criteria for this study.

Inclusion Criteria

1. Be newly enrolled in the LI program between January 1, 2006 and October 31, 2006.
2. Be successfully locked-in through the MMIS system.
3. Have at least one month of eligibility in the pre and post lock-in periods.

Table 1: Demographics of SoonerCare Members Included in the Study

	Number of Enrollees	% of Study Population	p-value
Male	21	40.38%	0.1655
Age (mean ± SD)	(33.37 ± 12.13)		0.001†
≤ 20	7	13.46%	
21-40	31	59.62%	
41-64	10	19.23%	
≥ 65	4	7.69%	
Warned			0.001†
None	37	71.15%	
OHCA	11	21.15%	
PMC	4	7.69%	

†Significant at the 0.05 level.

Table 1 shows the demographic information for the SoonerCare members enrolled in the study. Overall the total Oklahoma SoonerCare population consists of children (69 %) with the adult population being largely female (71 %). This study subgroup has a higher percentage of adults (59.6 %) compared to the overall SoonerCare population (31 %). The percentage of the subgroup that was male is also higher in the study subgroup than in the total SoonerCare population. The majority of the members enrolled in the study were not warned by either OHCA or PMC prior to being locked in and this variable was not a significant source of interaction (p. 0.3820) for the monthly narcotic utilization.

Research Objectives

There were four specific research questions to be answered in this study:

1. Is enrollment in a "lock-in" pharmacy program associated with a decrease in utilization and program costs of narcotic medication?
2. Is enrollment in a "lock-in" pharmacy program associated with a decrease in multiple pharmacy, physician, or emergency room utilization?
3. Is enrollment in a "lock-in" pharmacy program associated with an effect in utilization of maintenance medications or overall pharmacy claims?
4. Is enrollment in a "lock-in" pharmacy program associated with an effect on expenditures for both pharmacy and emergency medical care?

Results

Table 2 shows the results of the T-tests performed on the mean monthly averages for each of the variables of interest in the study. There was a statistically significant decrease in the average number of monthly narcotic claims (-0.84, p. <0.0001), monthly pharmacy claims (-1.40, p. <0.0001), emergency department visits (-0.45, p. 0.0008), number of monthly pharmacies (-1.16, p. <0.0001) number of prescribers seen monthly (-0.85, p. <0.0001), overall emergency department costs (-$224.14, p. 0.0011), and combined emergency department and pharmacy costs ($259.25, p. 0.0019). Although there was a slight increase in the number of maintenance medications (+0.02) and a decrease in both narcotic (-$12.78) and total pharmacy costs ($30.58), the differences were not statistically significant.

Regression analyses using a mixed model were also performed on the variables of interest. The results are similar to the T-tests. **Table 3** shows the mean value for each dependent variable the month immediately prior to the point of lock-in and the month of lock-in. There is a statistically significant decrease in all variables except for maintenance medications (-0.06, p. 0.162) and emergency department visits (-0.11, p. 0.169).

Table 2. Results of T-Tests for Mean Monthly Averages per Member Pre and Post Lock-In

Variable (Monthly)	Pre Lock-In Mean	Post Lock-In Mean	Difference	p-value
Narcotics Claims	2.16	1.32	-0.84	<0.0001†
Maintenance Med Claims	0.37	0.39	+0.02	0.7784
All Pharmacy Claims	4.86	3.46	-1.40	<0.0001†
Emergency Dept Visits	1.26	0.81	-0.45	0.0008†
# of Pharmacies	2.05	0.89	-1.16	<0.0001†
# of Prescribers	2.48	1.63	-0.85	<0.0001†
Narcotic Cost	$83.19	$70.41	-$12.78	0.5380
Pharmacy Cost	$256.83	$226.25	-$30.58	0.5601
Emergency Dept Costs	$288.99	$64.85	-$224.14	0.0011†
Pharmacy and Emergency Dept Costs	$550.15	$290.90	-$259.25	0.0019†

†Significant at the 0.05 level.

Table 3. Results of Regression Analyses for Month Prior to and Month of Lock-In

Variable (Monthly)	Pre Lock-In Mean	Post Lock-In Mean	Difference	p-value
Narcotics Claims	2.47	1.67	-0.80	<0.001†
Maintenance Med Claims	0.41	0.35	-0.06	0.162
All Pharmacy Claims	5.45	3.75	-1.70	<0.001 †
Emergency Dept Visits	1.07	0.96	-0.11	0.169
# of Pharmacies	2.39	1.03	-1.36	<0.001†
# of Prescribers	2.76	1.89	-0.87	<0.001†
Narcotic Cost	$99.28	$56.07	-$43.21	<0.001†
Pharmacy Cost	$275.33	$214.17	-$61.16	0.025†
Emergency Dept Costs	$286.19	$63.48	-$227.71	0.019†
Pharmacy and Emergency Dept Costs	$583.49	$267.72	-$315.77	0.005†

†Significant at the 0.05 level.

Table 4 has the results of the trend analyses performed using the mixed regression model on data 21 months prior to the lock-in and 21 months after the lock-in. These results indicate that the post lock-in monthly trend differs from the pre lock-in monthly trend for several of the key dependent variables. Monthly mean narcotic claims (-0.09, p. <0.0001), pharmacy claims (-0.11, p. <0.0001), emergency department visits (-0.05, p. 0.0007), and number of pharmacies and prescribers (-0.07, p. <0.0001) all had a negative trend after being locked-in. Emergency department costs also had a negative trend after lock-in, however this trend was not statistically significant (-$4.63, p. 0.2916). While there was not a statistically significant change in the trend for maintenance medications, there was a slight increase in trend after lock-in (+0.01). There was also a non-significant increase in trend for overall pharmacy costs (+$1.72).

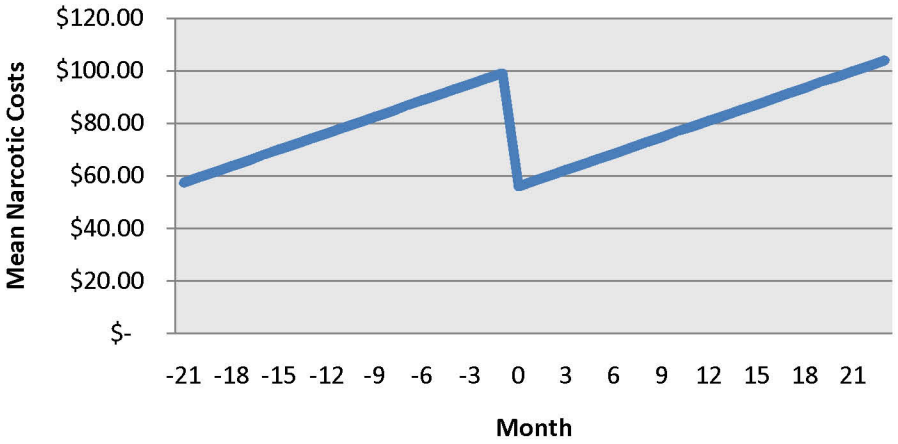
Table 4. Results of Monthly Trend Pre and Post Lock-In

Variable (Monthly)	Pre Lock-In Monthly Trend	Post Lock-In Monthly Trend	Difference	p-value
Narcotics Claims	+0.05	-0.04	-0.09	<0.0001†
Maintenance Med Claims	0.00	+0.01	+0.01	0.6867
All Pharmacy Claims	+0.08	-0.03	-0.11	<0.0001†
Emergency Dept Visits	+0.01	-0.04	-0.05	0.0007†
# of Pharmacies	+0.05	-0.02	-0.07	<0.0001†
# of Prescribers	+0.04	-0.03	-0.07	<0.0001†
Narcotic Cost	+$2.23	+$1.95	-$0.28	0.8323
Pharmacy Cost	+$1.39	+$3.11	+$1.72	0.6162
Emergency Dept Costs	+$5.66	-$4.63	-$10.29	0.2916
Pharmacy and Emergency Dept Costs	+$7.59	+$1.88	-$5.71	0.6295

†Significant at the 0.05 level.

The most unusual finding was for the mean monthly narcotic costs which had a statistically significant drop at the point of lock-in (-$43.21, p. <0.001), but did not have a statistically significant decrease in overall mean monthly costs (-$12.78) or monthly trend after lock-in ($-0.28). **Chart 1** illustrates the effect of the lock-in program on the mean monthly narcotic costs. At the point of lock-in the trend is reduced by $43, however it continues its positive trend at approximately the same rate of $2 per month thereafter. This causes the overall mean for the two time periods to appear to be equal, although the total cost for the post time period is reduced.

Chart 1. Predicted Mean for Monthly Narcotic Costs



Conclusion

While this analysis appears to show an overall positive change in the behavior of the members enrolled in the Lock-In program, the utilization of pharmacy benefits are limited to those claims which were reimbursed by the SoonerCare program. Members who were locked-in may have chosen to pay for certain prescriptions on their own and these prescriptions would not be captured for this analysis.

Overall, the results of these analyses point to an association of the Lock-In program with a decrease in utilization of narcotic medications, multiple pharmacies and physicians, and overall emergency department visits. It also appears that there was not an association between enrollment and the use of maintenance medications for these members which might indicate that therapies for chronic conditions were not affected by the Lock-In program. However, the Lock-In program did appear to be associated with an effect on total pharmacy claims, but whether this effect was due to the decrease in narcotic claims only and not related to any discontinuation of needed maintenance therapies, was not determined. Finally, there appears to be an association between the Lock-In program and overall costs for emergency department visits as well as the combined costs for pharmacy and emergency departments. The final results indicate that the Lock-In program was successful in reaching its goal of promoting appropriate utilization of health care resources and reducing narcotic utilization and costs.

Appendix I

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

ETHEX Corporation Initiated Nationwide Voluntary Recall of a Single Lot of Hydromorphone HCl 2 mg Tablets Due to Potential for Oversized Tablet

Contact:
Ann McBride
1-800-748-1472

FOR IMMEDIATE RELEASE -- St. Louis, MO – December 23, 2008 – ETHEX Corporation announced today that it has voluntarily recalled to the consumer level, a single production lot of Hydromorphone HCl 2 mg tablets (Lot #90219, Exp: 03/2010; NDC #58177-0620-04), as a precaution, due to the possibility it may contain oversized tablets. Hydromorphone is a drug used for pain management and is packaged under the ETHEX label in 100-count bottles.

If someone were to take a higher than expected dose of Hydromorphone, the risk of adverse effects known to be associated with the drug may be increased, including respiratory depression (difficulty or lack of breathing), low blood pressure, and sedation.

There are other companies in the United States producing and marketing versions of Hydromorphone HCl tablets and consumers and their caregivers are encouraged to check their prescriptions to determine the source of their tablets. Hydromorphone HCl 2 mg tablets marketed by ETHEX are a blue, round tablet with a script "E" on one side and a "2" on the other side.

ETHEX Corporation has initiated recall notifications to wholesalers and retailers nationwide who have received any inventory of the recalled lot of this product with instructions for returning the recalled product and, if they have not already done so, they are urged to contact ETHEX as provided below regarding procedures for returning the recalled product. If consumers have any questions about the recall, they should call the telephone number below or their physician, pharmacist, or other health care provider.

Any customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-748-1472 or fax to ETHEX Customer Service at 314-646-3751, or e-mail to customer-service@ethex.com. Representatives are available Monday through Friday, 8 am to 5 pm CST. Consumers who experience any adverse reactions to this drug should contact their physician and/or healthcare provider immediately. Any adverse reactions experienced with the use of this product, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

The Hydromorphone HCl recall announcement is posted on www.kvpharmaceutical.com and www.fda.gov/opacom/7alerts.html. It includes step-by-step details on how to return affected product to KV Pharmaceutical. The Company web site also includes a list of the drugs affected by the suspension.

The parent company of ETHEX Corporation, KV Pharmaceutical has advised the U.S. Food and Drug Administration that, effective midnight Dec. 19, 2008, the company voluntarily suspended

shipments of all FDA-approved drug products in tablet form. This action is being taken as a precautionary measure, to allow KV to expeditiously address manufacturing issues that have come to management's attention, to review and enhance comprehensively the company's quality systems, and to implement efficiency improvements in its production facilities. KV is keeping the FDA informed about the Company's plans.

This recall and suspension are being conducted with the knowledge of the FDA. At this time, the company is unable to determine when distribution of tablet form products will resume, or estimate what the financial impact of the recall and suspension will be.

#

kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, January 05, 2009

Medicaid

States Consider Further Cuts to Medicaid Programs Amid Continuing Recession

The *Washington Post* recently examined how many states "are being forced to curtail" Medicaid services "as they struggle to cope with the deteriorating economy." Medicaid, which provided health coverage to 50 million U.S. residents in 2007, is the largest or second-largest expense in every U.S. state, the *Post* reports. According to the *Post*, 19 states have lowered payments to hospitals and nursing homes, eliminated coverage for some treatments and excluded some beneficiaries from the program completely. Eighteen of these states, as well as six others, are considering additional reductions for fiscal year 2010 in preparation for the possibility that additional money will not be available, the *Post* reports.

Many states are suspending coverage for services not required by the federal government, such as physical therapy, eyeglasses, hearing aids and hospice care, and a few states are requiring that beneficiaries pay a larger portion of the cost of their care. The *Post* also examined financial issues facing the Medicaid programs of California, Maryland, Rhode Island, South Carolina, Virginia and Washington, D.C.

Diane Rowland, executive vice president of the Kaiser Family Foundation and executive director of the Foundation's Commission on Medicaid and the Uninsured, said the financial crises facing Medicaid programs are exacerbated because of a milder recession earlier in the decade, when states implemented many "cuts that were making the program more efficient." She added, "Now they are making ... cuts to the core."

According to the *Post*, governors and state legislators "have been pleading with Congress" and President-elect Barack Obama's administration for financial help with Medicaid. Congressional Democrats and Obama have proposed providing additional funding to the state Medicaid programs in an economic stimulus package. Lawmakers have suggested $100 billion for the programs, which would increase the portion funded by the federal government over the next two years. In addition, some lawmakers also are considering allowing people who have recently lost their jobs to enroll in Medicaid, with the federal government paying for the entire cost of their coverage (Goldstein, *Washington Post*, 12/26/08).

THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, January 05, 2009

Prescription Drugs

FDA Approves More New Drugs in '08 Compared With Last Three Years

FDA approved 24 new drugs in 2008, more than in any of the prior three years, the *Wall Street Journal* reports. The agency approved 18 drugs in 2007, 22 in 2006 and 20 in 2005. According to the *Journal*, the agency's high 2008 approval rate is "a consolation of sorts to an industry struggling with greater scrutiny, thousands of layoffs and thinning drug pipelines."

A standard drug review takes 10 months, while a priority review takes six months and is given to drugs FDA deems are an advance over existing treatments. FDA does not have a goal for the number of drugs approved each year, according to agency spokesperson Sandy Walsh. She said it is difficult to compare one year's figures to another because applications are received on a rolling basis. "The primary factor driving new drug approval is the quality of the application and the data that support the drug's safety and efficacy," she said.

Year of Delays

Industry analysts say that despite the high rate of approvals, 2008 will be remembered more for delays in the approval process. FDA sets a goal of reaching a final decision on 90% of applications within the six- to 10-month time frame. However, FDA said it missed deadlines on 32 out of 159 drug applications, or 20%, through Oct. 31, 2008.

John Jenkins, director of FDA's office of new drugs, recently told an industry conference that the agency has "been struggling to meet (drug approval) goals for the past several years" and made a "management decision" earlier last year that it could not meet all of its deadlines given the workload and a staff shortage. According to the *Journal*, one factor contributing to the missed deadlines is a requirement that all new drug applications be reviewed by agency advisory committees made up of outside medical experts.

Jenkins said that the agency in 2008 hired more than 800 employees, but added that training the new employees has taken time. Jenkins said that in 2009 the agency hopes to come closer to its 90% goal. Ira Loss, a senior health care analyst at Washington Analysis, said that the new employees should improve the speed of the agency's approval process by mid-2009 (Favole/Corbett Dooren, *Wall Street Journal*, 1/2).

kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, January 05, 2009

Prescription Drugs

Pharmaceutical Research and Manufacturers of America Enacts New Voluntary Guidelines on Physician Gifting Practices

New guidelines by the Pharmaceutical Research and Manufacturers of America to address conflicts of interest that "illuminated the once-shadowy financial dealings" between pharmaceutical companies and physicians took effect Thursday, the *Boston Herald* reports. Compliance with the set of guidelines, which the lobbying group titled, "Code on Interactions with Healthcare Professionals," is voluntary. PhRMA plans to produce a directory of companies that comply with the guidelines, according to the *Herald* (McConville, *Boston Herald*, 1/2).

Under the new code, pharmaceutical companies are barred from distributing office supplies, clothes and other gifts with company logos or product brand names to physicians and clinics, the *Houston Chronicle* reports. The new code also prohibits the companies from paying for physicians' meals, including those during medical education events, and requires that all grant money allocated for continuing medical education programs be handled by personnel who are not from sales and marketing departments.

The new code does not address the issue of the "amount drugmakers pay doctors to hit the speaking circuit for their products," according to the *Chronicle*. The amount has not yet been capped but the companies have been told to keep a record of the consulting fees they pay to each physician (Cook, *Houston Chronicle*, 1/1). According to the *New York Times*, the voluntary moratorium on supplying branded gifts and trinkets to physicians seeks to "counter the impression that gifts to doctors are intended to unduly influence medicine."

However, while some physicians "applaud the gift ban, others seem offended by the insinuation that a ballpoint pen could turn their heads," the *Times* reports, adding that "skeptics deride the voluntary ban as a superficial measure that does nothing to curb the far larger amounts drug companies spend each year on various other efforts to influence physicians" (Singer, *New York Times*, 12/31/08).

Editorials

- *Las Vegas Sun*: "Although the new guidelines are a step in the right direction, there is reason to believe pharmaceutical manufacturers exert considerable influence over physicians in a bid to get them to prescribe certain drugs," a *Sun* editorial states. The editorial continues that "drug companies still ply doctors with free meals, often expensive ones, while delivering their sales pitches" and "many manufacturers also pay doctors tens of thousands of dollars annually to serve as consultants." According to the *Sun*, "There is nothing wrong with physicians seeking information from manufacturers to learn as much as they can about a drug," but "it is unethical when doctors prescribe certain medications simply because a pharmaceutical company encouraged them to do so" (*Las Vegas Sun*, 1/5).

- *New York Times*: "The updated rules are the [pharmaceutical] industry's latest attempt to restore public confidence that doctors are prescribing medicines in the patient's interest,"

but the code "still has too many loopholes," a *Times* editorial states. According to the *Times*, "Congress needs to pass legislation that would force all drug and medical device companies to report a wide range of payments to doctors through a national registry so that all conflicts are known." The editorial states, "This is a reform that the industry itself now seems willing to accept," adding, "Better yet, the medical profession needs to wean itself almost entirely from its pervasive dependence on industry money" (*New York Times*, 1/5).

Letter to the Editor

The *Times* article published on Dec. 31, 2008, "portrays the pharmaceutical industry's voluntary moratorium on 'goodies for doctors' as an honest effort by drug manufacturers to curb doctors' 'deep financial ties with the drugmakers,'" but "[n]othing could be further from the truth," David Edelson, an assistant clinical professor of medicine at Albert Einstein College of Medicine, writes in a *Times* letter to the editor. According to Edelson, the "simple fact" is that the practice of giving gifts is "not cost-effective." He continues, "Furthermore, industry leaders realize that doctors don't even determine what drugs are prescribed to their patients anymore -- managed care formularies have taken over that function." Edelson adds, "Having done the math and realizing that $1 billion could be better spent elsewhere, they cleverly packaged this ban as a step to the higher moral ground." Edelson concludes that gifts from the pharmaceutical companies "is the least of our worries" because physicians "will be facing a significant increase in office supply costs on top of already skyrocketing office overhead, malpractice insurance costs and 15 years of falling reimbursements" (Edelson, *New York Times*, 1/4).