Drug Utilization Review Board

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

Wednesday
February 11, 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 – February 11, 2009**

DATE: February 5, 2009

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

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

30 Day Notice to Prior Authorize Advair® and Symbicort® – **See Appendix C.**

Action Item – Annual Review of Fibric Acid Derivative PBPA Category and 30 Day Notice to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™ – **See Appendix D.**

Action Item – Annual Review of Nasal Allergy PBPA Category and 30 Day Notice to Prior Authorize Astepro® – **See Appendix E.**

Action Item – Annual Review of Ocular Allergy PBPA Category – **See Appendix F.**

Utilization Review of Anti-Ulcer / GERD Medication for Children **– See Appendix G.**

Hydrocodone Product Evaluation – **See Appendix H.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – February 11, 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. Meece, Vice-Chair:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. Meece, Vice-Chair:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Meece, Vice-Chair:

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

A. January 14, 2009 DUR Minutes – Vote
B. January 15, 2009 DUR Recommendation Memorandum

Items to be presented by Dr. Keast, Dr. Meece, Vice-Chair:

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

A. Retrospective Drug Utilization Review for November 2008
B. Retrospective Drug Utilization Review Responses for September 2008
C. Medication Coverage Activity Audit for January 2009
D. Help Desk Activity Audit for January 2009

Items to be presented by Dr. Le, Dr. Meece, Vice-Chair:

5. 30 Day Notice to Prior Authorize Advair® and Symbicort® – See Appendix C.

A. COP Recommendations

Items to be presented by Dr. Le, Dr. Meece, Vice-Chair:

6. Action Item – Annual Review of Fibric Acid Derivative PBPA Category and 30 Day Notice to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™ – See Appendix D.

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

Items to be presented by Dr. Robinson, Dr. Meece, Vice-Chair:

7. Action Item – Annual Review of Nasal Allergy PBPA Category and 30 Day Notice to Prior Authorize Astepro™ – See Appendix E.

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

Items to be presented by Dr. Chonlahan, Dr. Keast, Dr. Meece, Vice-Chair:

8. Action Item – Annual Review of Ocular Allergy PBPA Category – See Appendix F.

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

Items to be presented by Dr. Moore, Dr. Meece, Vice-Chair:

9. Utilization Review of Anti-Ulcer / GERD Medication for Children – See Appendix G.

A. Product Overview
B. Utilization Review

Items to be presented by Dr. Keast, Dr. Meece, Vice-Chair:

10. Hydrocodone Product Evaluation – See Appendix H.

A. Hydrocodone Utilization Review
B. Carisoprodol Utilization Review
C. Current Hydrocodone Restrictions
D. COP Recommendations

Items to be presented by Dr. Graham, Dr. Meece, Vice-Chair:

11. FDA and DEA Updates – See Appendix I.

12. Future Business

A. Annual Reviews
B. Utilization Review of Anti-emetics
C. Utilization Review of Anti-migraine products
D. New Product Reviews

13. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JANUARY 14, 2009

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	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	
Paul Preslar, D.O.	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: Victoria Randall, Raymond Young		

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:

David Williams, Forest Labs Inc	Donna Erwin, Bristol-Myers Squibb	John Harris, Abbott Labs
Tracy Copeland, Daiichi Sankyo	Randy Clifton, Amgen	Susan Stone, Allergan
Rich Waldrop, Eisai	Linda Cantu, BMS	Jorge Nassar, BMS
Richard Ponder, J&J	Derek Salyer, Lilly	Mark DeClerk, Lilly
Aaron Mays, Alcon	Jim Fowler, Astra Zeneca	David Barton, Schering Plough
Lance Stewart, Merck	Jim Dunlap, Lilly	Rebecca King, Taro
Janie Huff, Takeda	Joseph Medina, Sepracor	

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 7 Pam Sardo, Pharm.D.; Abbott

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

1A: Roll Call

Dr. McNeill called the meeting to order. Dr. Paul Preslar was introduced as a new Board member. Roll call by Dr. Graham established a quorum.

ACTION: NONE REQUIRED

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

Dr. McNeill recognized the speaker for public comment.

ACTION: NONE REQUIRED

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

3A: December 10, 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: October 2008
4B: Retrospective Drug Utilization Review Responses: August 2008
4C: Medication Coverage Activity Audit: December 2008
4D: Help Desk Activity Audit: December 2008

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **UPDATE ON SUPPLEMENTAL REBATES**

Update presented by Lynn Rambo-Jones, J.D.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE TOVIAZ®**

Materials included in agenda packet; presented by Drs. Le, Chonlahan.

Dr. Gourley moved to approve placement of Toviaz® in Tier 2; seconded by Dr. Meece.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE SIMCOR® AND UPDATE STATIN PBPA CATEGORY**

For Public Comment, Pam Sardo, Pharm.D.: Good evening. I'm Pam Sardo. I'm a government regional clinical executive with Abbott Laboratories and I want to thank you very much for the opportunity to appear before you tonight on behalf of the patients who might have an appropriate need for Simcor. It is well documented that hyperlipidemia is a medical problem and the desire to reduce cardiovascular disease risk is important with many populations including women and diabetics. And trials using statins to lower LDL have consistently shown reductions in major cardiovascular events and can even lower LDL levels by 30 to 40% or greater. However despite the LDL lowering, residual coronary heart disease risk does remain, some of which may be modifiable. While the NCEP ATP-3 guidelines do clearly recommend LDL as a primary target of treatment for hyperlipidemia, it also refers to non-HDL as a parameter or secondary target of therapy for unmet need and appropriate patients if the triglycerides are high. So Simcor is a combination of simvastatin and extended release niaspan and it is indicated as an adjunct to diet to reduce elevated total cholesterol, LDL, non-HDL FOB triglycerides and to improve HDL in patients where treatment with the simvastatin or the niaspan monotherapies are considered inadequate. So it does provide a possible choice for combination therapy to assist compliance and convenience in patients where that might be appropriate. The SEACOAST study which was published in the *American Journal of Cardiology* in 2008 did describe greater reductions in non-HDL levels with Simcor over simvastatin 20 and the OCEAN study which was published in the *American Journal of Cardiovascular Drugs* in 2008 did demonstrate longterm safety up to 52 weeks with Simcor treatment. And in SEACOAST study, flushing was reported and did result in study discontinuation for only 6% of the patients. Simcor is contraindicated in patients with active liver disease or persistent elevations of transaminases or active peptic ulcer disease or in women who may be pregant or may become pregnant or arterial bleeding. In conclusion, I will be giving some time back to the committee and want to thank you for your consideration of Simcor for appropriate patients in Oklahoma. I'll be happy to answer any questions you may have. Thank you.

Materials included in agenda packet; presented by Dr. Le.
Dr. Meece moved to approve recommendations as submitted; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE LAMISIL® GRANULES**
Materials included in agenda packet; presented by Dr. Moore.
Dr. Kuhls moved to approve with the removal of criteria "restrict to children 12 years and younger" and change to "unable to take tablets"; seconded by Dr. Gourley.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF OPHTHALMIC ANTI-INFECTIVE PBPA CATEGORY**
Materials included in agenda packet; presented by Dr. Patel.
Dr. Gourley moved to create three tiers for the antibiotic liquids and two tiers for the ointments. Move ciprofloxacin, levofloxacin, and ofloxacin to Tier 2, and move moxifloxacin, gatifloxacin and azithromycin to Tier 3. No supplemental rebates will be requested in the future. Seconded by Dr. Meece.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **UTILIZATION REVIEW OF ASTHMA MEDICATIONS AND ANNUAL REVIEW OF BROVANA®**
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **LOCK-IN REPORT**
Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **FUTURE BUSINESS**
Materials included in agenda packet; submitted by Dr. Graham.
12A: Hydrocodone Utilization Review
12B: Pediatric Anti-Ulcer Utilization Review
12C: Annual Reviews
12D: New Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ADJOURNMENT**
The meeting was adjourned at 7:45 p.m.

THE UNIVERSITY OF OKLAHOMA
Health Sciences Center
College of Pharmacy
Department of Pharmacy Clinical & Administrative Sciences

Pharmacy Management Consultants
ORI W-4403; P.O. Box 26901; Okla. City, OK 73126-0901
PHONE: 405-271-9039 FAX: 405-271-2615

Memorandum

Date: January 15, 2009

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 January 14, 2009

Recommendation 1: Vote to Prior Authorize Toviaz™

MOTION CARRIED by majority approval.

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

Recommendation 2: Vote to Prior Authorize Simcor® and Update Statin PBPB Category

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends dividing the HMG-CoA Reductase Inhibitors (Statins) PBPA category into two subcategories and addition of a third tier with modification of criteria as shown below. The College also recommends a quantity limit 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.

Recommendation 3: Vote to Prior Authorize Lamisil® Granules

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorizing Lamisil® granules.

Approval Criteria:

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

Recommendation 4: Annual Review of Ophthalmic Anti-infectives

MOTION CARRIED by majority approval.

The DUR Board recommended the following change to the Ophthalmic Anti-infective PBPA Category.

Criteria for a Tier 2 medication:

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

Criteria for a Tier 3 medication:

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

Ophthalmic Antibiotics: Liquids		
Tier 1	**Tier 2**	**Tier 3**
Gentak (Gentamicin)	Ciloxan Solution (Ciprofloxacin)	Vigamox (Moxifloxacin)
AK-Tob (Tobramycin)	Quixin (Levofloxacin)	Zymar (Gatifloxacin)
Bleph-10, Sodium Sulamyd (Sodium Sulfacetamide)	Ocuflox (Ofloxacin)	Azasite (Azithromycin)
Viroptic (Trifluridine)		
Natacyn (Natamycin)		
Polytrim (PolymyxinB/Trimethoprim)		
AK-Spore (Neomycin/PolymyxinB/Gramacidin)		

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

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for November 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	42,098	60,653	1,111,246	31,814
Limits which were applied	Established, Major, Males and Females, Age 57-65	Males and Females, Age 5-6, Antihistamines	Contraindicated, Females, Age 22-65, Pregnancy	Dose and Duration, Nuvaring®, Males and Females 0-150
Total # of messages after limits were applied	82	99	776	64
Total # of members reviewed after limits were applied	82	94	678	64

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
52		45	

Retrospective Drug Utilization Review Report

Claims Reviewed for September 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 41-50	Antihistamines, Males and Females, Age 0-2	Contraindicated, Arrhythmia, Males and Females, Age 0-150	High Dose only, Amphetamines, Males and Females, Age 0-9

Response Summary (Prescriber)
Letters Sent: 80
Response Forms Returned: 64

The response forms returned yielded the following results:

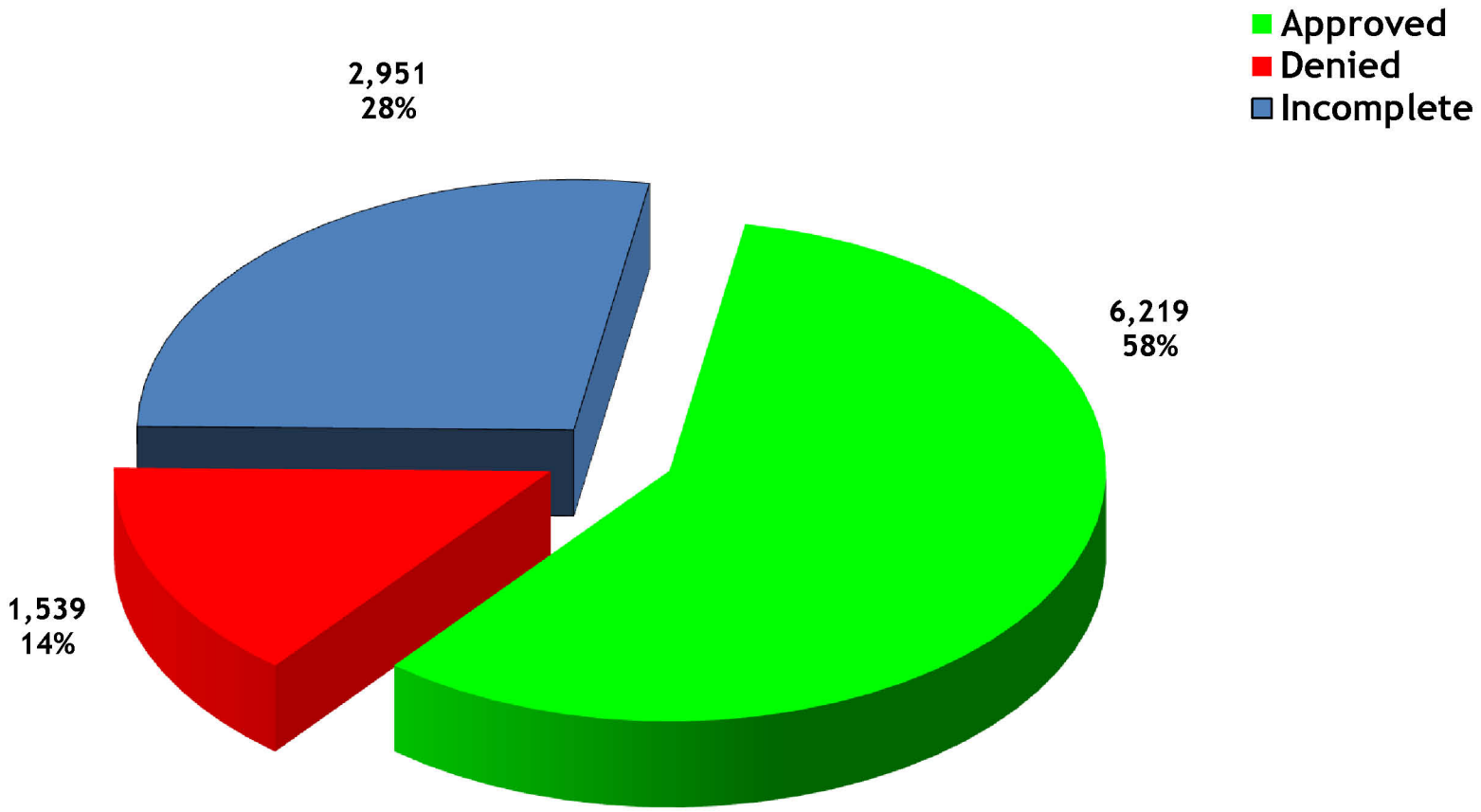
4 (6%)	*Record Error—Not my patient.*
3 (5%)	*No longer my patient.*
5 (8%)	*Medication has been changed prior to date of review letter.*
15 (23%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
23 (36%)	*I am aware of this situation and will plan to continue monitoring therapy.*
14 (22%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 71
Response Forms Returned: 37

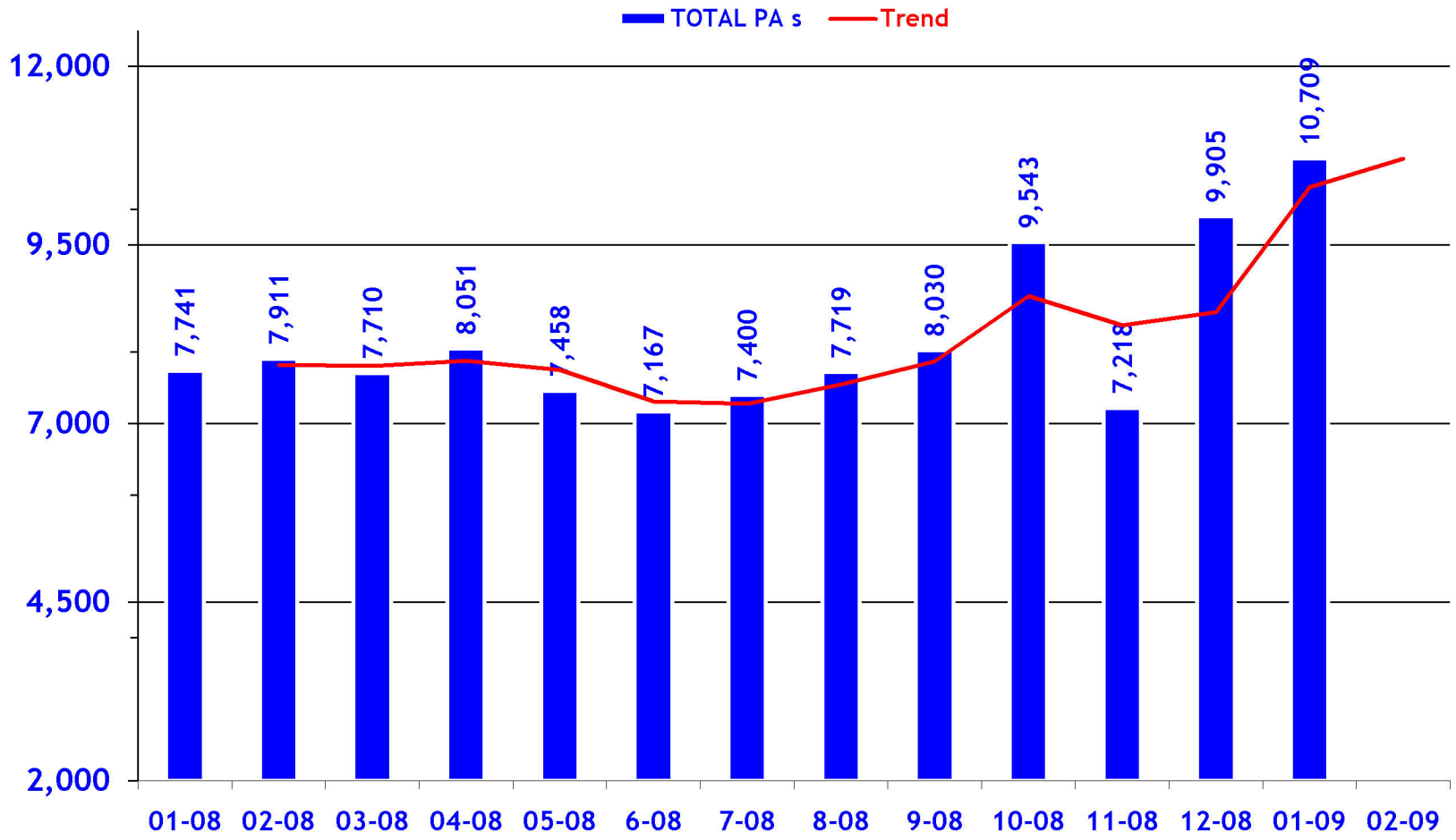
The response forms returned yielded the following results:

1 (3%)	*Record Error—Not my patient.*
1 (3%)	*No longer my patient.*
2 (5%)	*Medication has been changed prior to date of review letter.*
9 (24%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
19 (51%)	*I am aware of this situation and will plan to continue monitoring therapy.*
5 (14%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
January 2009



PRIOR AUTHORIZATION REPORT
January 2008 – January 2009



Activity Audit for

1/1/2009 Through 1/31/2009

	Average Length of Approvals in Days	Approved	Denied	Incomplete	Total
ACE Inhibitors	23	9	0	2	11
Angiotensin Receptor Antagonist	362	32	38	56	126
Antidepressant	276	214	107	219	540
Antihistamine	262	162	89	144	395
Antiulcers	37	13	1	5	19
Anxiolytic	89	2,757	201	436	3,394
Calcium Channel Blockers	101	4	0	3	7
Growth Hormones	162	35	0	9	44
HTN Combos	244	3	3	8	14
Insomnia	126	43	36	51	130
Nsaids	306	44	26	38	108
Plavix	358	101	2	42	145
Stimulant	206	561	100	275	936
Others	217	2,235	936	1,663	4,834
Emergency PAs		6	0	0	6
Total		**6,219**	**1,539**	**2,951**	**10,709**

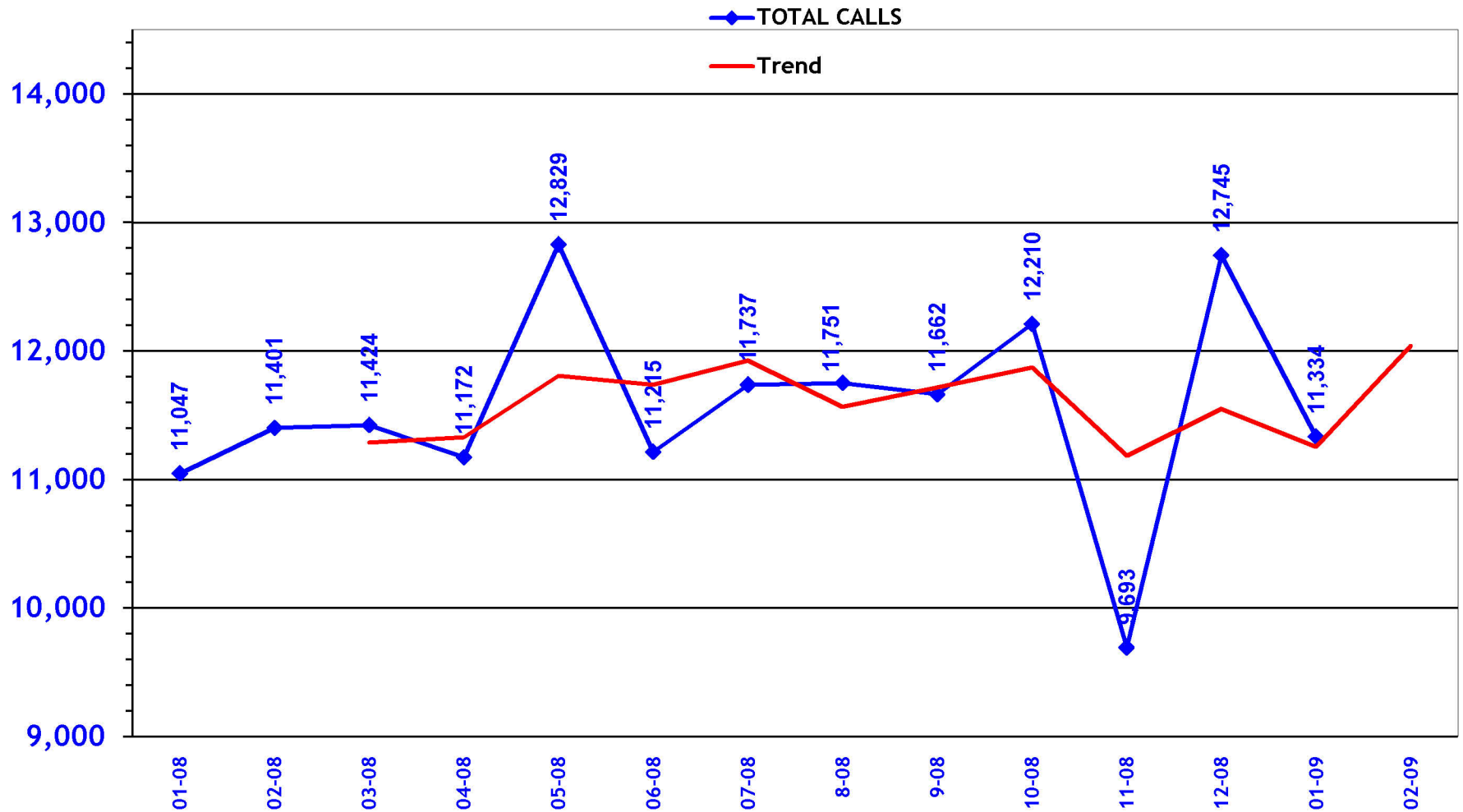
Overrides					
AF	5	1	0	0	1
Brand	250	34	9	12	55
Dosage Change	15	326	10	18	354
High Dose	31	3	0	1	4
Lost/Broken Rx	8	73	2	2	77
Nursing Home Issue	10	38	0	0	38
Other	11	31	2	6	39
Quantity vs. Days Supply	242	372	85	139	596
Stolen	3	5	2	0	7
Overrides Total		**882**	**110**	**178**	**1,170**

Denial Reasons	
Lack required information to process request.	2,700
Unable to verify required trials.	1,224
Does not meet established criteria.	203
Not an FDA approved indication/diagnosis.	114
Considered duplicate therapy. Member has a prior authorization for similar medication.	71
Requested dose exceeds maximum recommended FDA dose.	60
Member has active PA for requested medication.	28
Drug Not Deemed Medically Necessary	9
Medication not covered as pharmacy benefit.	7

Duplicate Requests: 691

Changes to existing PAs: 731

CALL VOLUME MONTHLY REPORT
January 2008 – January 2009



Appendix C

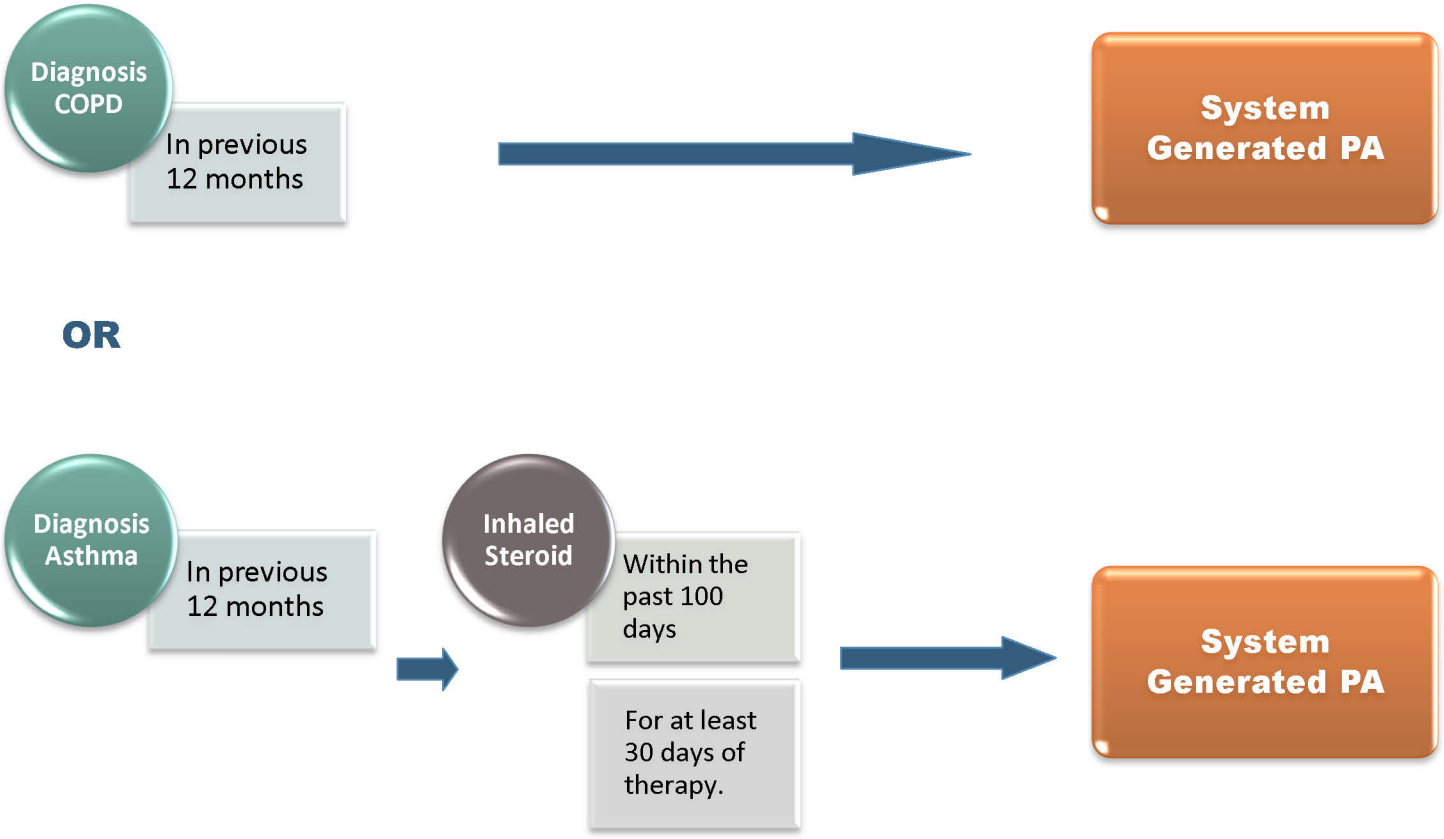
30 Day Notice to Prior Authorized Advair® and Symbicort®

Oklahoma Health Care Authority, February 2009

Recommendation

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

Automated Prior Authorization Criteria



Non-Automated Prior Authorization Criteria

For members who do not meet the automated criteria the following will apply when a petition is submitted:

- **Diagnosis of COPD: Approve for one year.**
- **Diagnosis of 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
  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.)

Appendix D

Annual Review of Fibric Acid Derivatives and 30 Day Notice to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™

Oklahoma Health Care Authority

February 2009

Approval criteria for Tier 2 Medication:

1. Laboratory documented failure with a tier one medication after 6 months trial with a tier one medication.
2. Documented adverse effect, drug interaction, or contraindication to tier-1 products.
3. Prior stabilization on the tier-2 medication documented within the last 100 days.

Fibric Acid Derivatives*	
Tier One	*Tier Two*
Fenofibrate (Lofibra® Caps)	Fenofibrate (Antara® Caps)
Fenofibrate (Fenoglide™ Tabs)	Fenofibrate (Lipofen® Caps)
Fenofibrate (Tricor® Tabs)	Fenofibrate (Triglide® Tabs)
Fenofibrate (Trilipix™ Tabs)	
Gemfibrozil (Lopid® Tabs)	
Clofibrate (Atromid-S® Caps)	

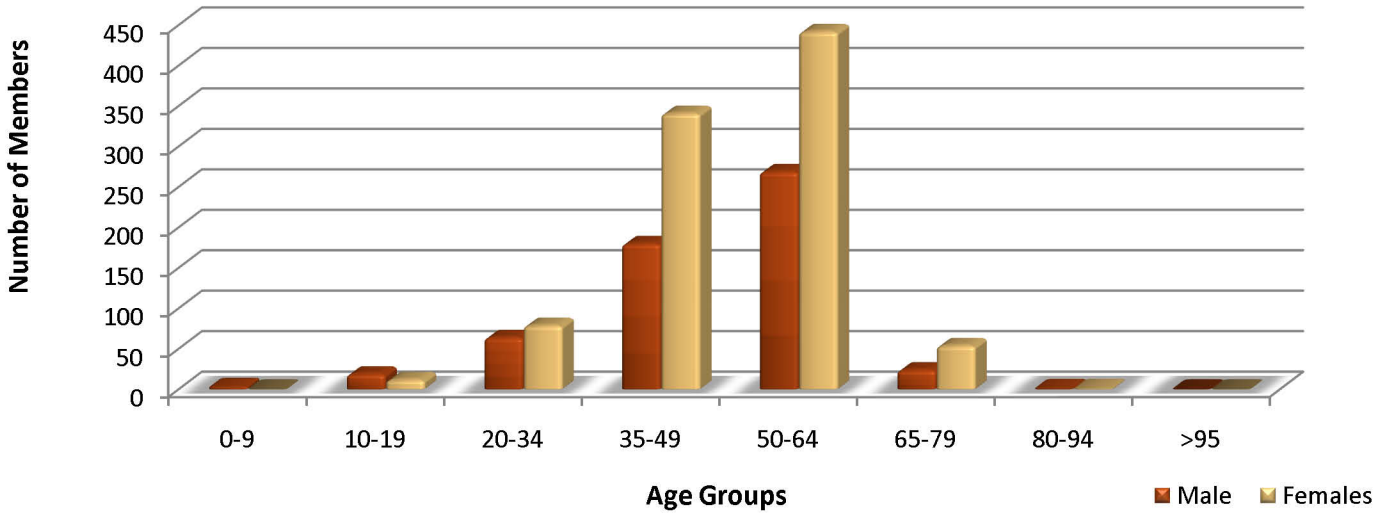
*Mandatory Generic Plan applies

Blue color indicates supplemental rebate participation

Utilization Trends of Fibric Acid Derivatives

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2007	1,395	5,530	$372,435.76	$67.35	$1.80	300,842	207,298
2008	1,533	6,523	$447,028.46	$68.53	$1.82	359,689	245,876
Change	138	993	$74,592.70	$1.18	$0.02	58,847	38,578
% Change	9.9%	18%	20%	1.8%	1.1%	19.6%	18.6%

Demographics of Members Utilizing Fibric Acid Derivatives: FY 2008



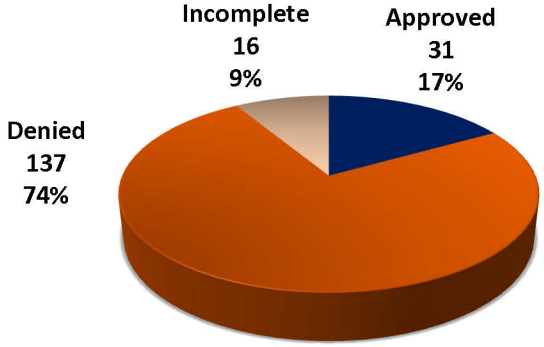
Utilization Details for Fiscal Year 2008

BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	PERDIEM	% COST
GEMFIBROZIL TAB 600MG	3,546	230,788	119,287	888	$51,783.67	1.93	$0.43	11.58%
TRICOR TAB 145MG	2,157	94,156	93,754	505	$334,022.63	1	$3.56	74.72%
TRICOR TAB 48MG	443	18,463	16,628	110	$21,969.28	1.11	$1.32	4.91%
TRIGLIDE TAB 160MG	87	3,600	3,600	31	$12,482.06	1	$3.47	2.79%
ANTARA CAP 130MG	74	3,632	3,632	19	$13,403.17	1	$3.69	3.00%
FENOFIBRATE CAP 134MG	63	2,710	2,710	16	$3,520.33	1	$1.30	0.79%
FENOFIBRATE CAP 200MG	54	2,060	2,060	12	$3,816.59	1	$1.85	0.85%
FENOFIBRATE TAB 160MG	49	2,430	2,445	23	$4,309.72	0.99	$1.76	0.96%
TRIGLIDE TAB 50MG	18	540	540	7	$685.19	1	$1.27	0.15%
FENOFIBRATE CAP 67MG	15	510	450	4	$339.78	1.13	$0.76	0.08%
FENOFIBRATE TAB 54MG	13	580	580	4	$420.68	1	$0.73	0.09%
LIPOFEN CAP 150MG	2	60	60	1	$135.50	1	$2.26	0.03%
LOFIBRA CAP 134MG	1	100	100	1	$124.95	1	$1.25	0.03%
TOTALS	**6,522**	**359,629**	**245,846**	**1,532**	**$447,013.55**	**1.46**	**$1.82**	**100%**

Prior Authorization of Fibric Acid Derivatives

During fiscal year 2008 there were a total of 184 prior authorizations received for fibric acid derivatives. The following table shows the status of the petitions received.

Prior Authorization of Fibric Acid Derivatives: FY08



New products in this category includes:

- **Fenoglide™ Tabs –fenofibrate, available as 40mg and 120mg oral tablets with MeltDose Technology** (designed to enhance absorption by incorporating soluble forms of the drug in a tablet matrix.)
- **Lipofen® Caps – fenofibrate, available as 50mg and 150mg oral capsules.**
- **Trilipix™ Caps – fenofibrate, available as 45mg and 135mg delayed release oral capsules.**

Conclusion and Recommendation

The College of Pharmacy recommends the addition of the new products to Tier 2 of the Fibric Acid Derivative PBPA category.

Appendix E

Fiscal Year 2008 Annual Review of Nasal Allergy Drugs and 30 Day Notice to Prior Authorize Astepro™ (azelastine hydrochloride)

Oklahoma Health Care Authority
February 2009

Current Prior Authorization of Nasal Allergy Drugs

1. The following criteria are required for approval of a Tier 2 product (or a Tier 3 product if no Tier 2 exists):
    a. Documented adverse effect or contraindication to the preferred products.
    b. Failure with at least two Tier 1 medications defined as no beneficial response after at least two weeks use of each during which time the drug has been titrated to the recommended dose. All available Tier 1 corticosteroids should be tried prior to approval of higher Tiered products).
2. The following criteria are required for approval of a Tier 3 product:
    a. All Tier 2 criteria must be met.
    b. Failure with all available Tier 2 products defined as no beneficial response after at least two weeks use of each during which time the drug has been titrated to the recommended dose.
3. Approvals will be for the duration of three months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

All products also have quantity limits in place, based on the FDA approved maximum dose.

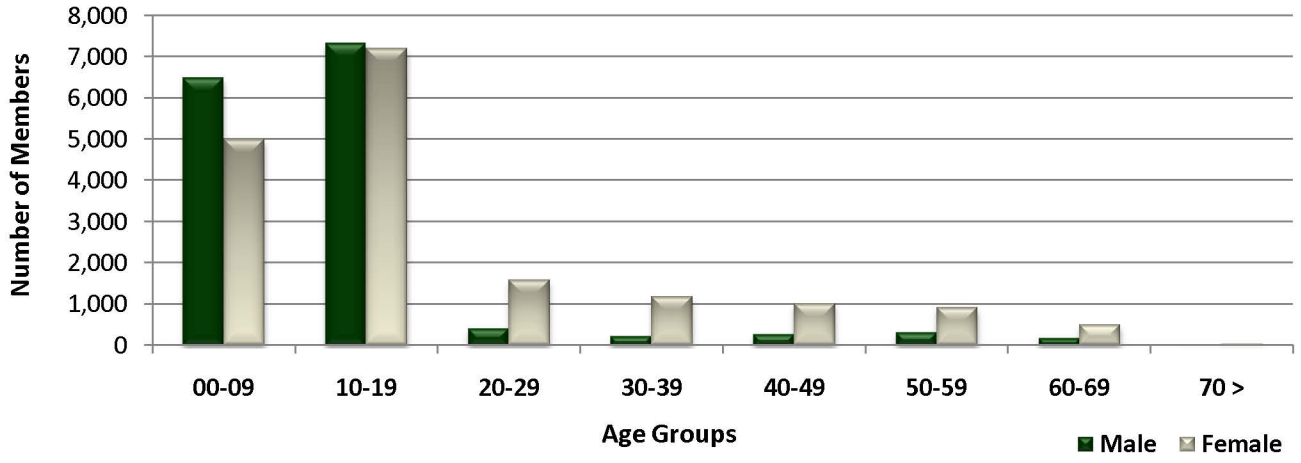
Nasal Allergy Products	
Tier 1*	***Tier 2***
Corticosteroids	**Corticosteroids**
Fluticasone (Flonase®)	Budesonide (Rhinocort AQ®)
Flunisolide (Nasalide®, Nasarel™)	Ciclesonide (Omnaris™)
Fluticasone (Veramyst™)	Mometasone (Nasonex®)
Beclomethasone (Beconase® AQ)	
Triamcinolone (Nasacort® AQ)	
Other	**Other**
Azelastine (Astelin®)	
Azelastine (Astepro™)	
Olapatadine (Patanase®)	
Ipratropium bromide (Atrovent®)	

*Mandatory Generic Plan Applies.
Blue color indicates supplemental rebate program participation.

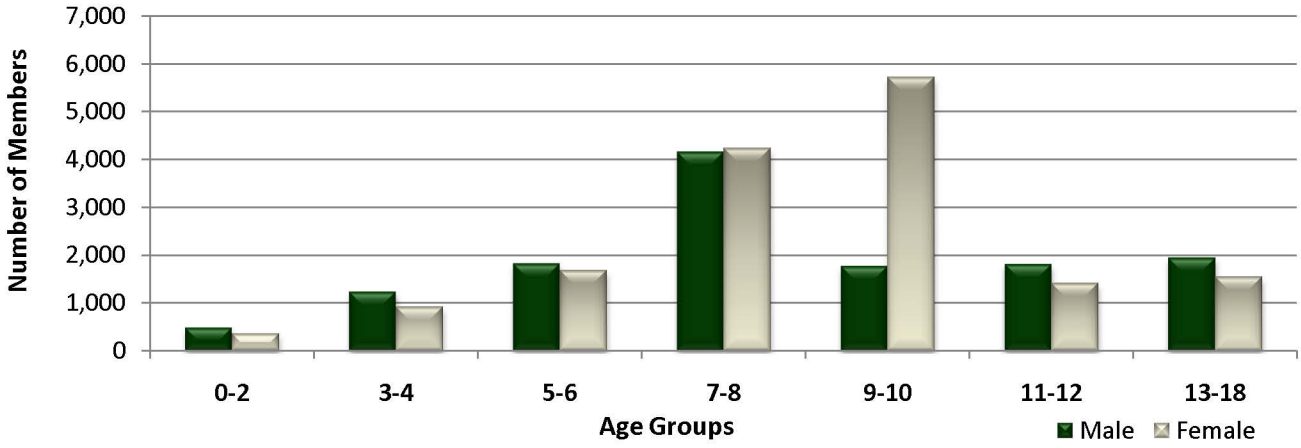
Trends in Utilization

Fiscal Year	Members	Claims	Cost	Cost/ Claim	Per-Diem	Units	Days
2007	30,733	62,016	$4,327,729.64	$69.78	$2.13	1,010,508	2,034,056
2008	32,955	66,102	$4,365,360.63	$66.04	$2.00	1,052,787	2,177,431
% Change	6.7%	6.2%	0.86%	-5.3%	-4.9%	4.0%	6.6%
Change	2,222	4,086	$37,630.99	-$3.74	-$0.11	42,279	143,375

Member Demographics for Fiscal Year 2008



Demographics of Select Age Groups for Fiscal Year 2008



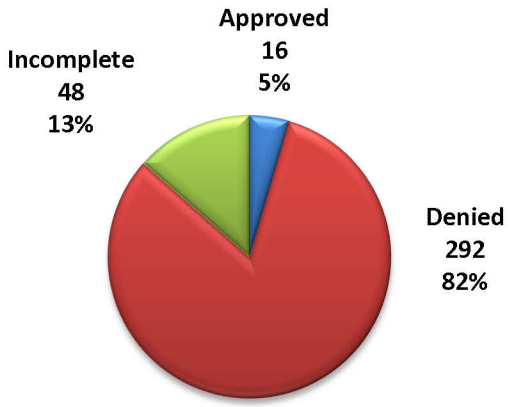
Utilization Details of Nasal Allergy Products for Fiscal Year 2008

Chemical Name	Brand Name	Claims	Members	Cost	Claims/ Member	Cost/ Day	Percent Cost
Fluticasone	FLUTICASONE SPR 50MCG	21,417	10,687	$625,385.01	2	$0.88	14.33%
Mometasone	NASONEX SPR 50MCG/AC	19,792	10,786	$1,703,680.33	1.83	$2.52	39.03%
Fluticasone	VERAMYST SPR 27.5MCG	8,522	5,644	$742,099.68	1.51	$2.78	17.00%
Budesonide	RHINOCORT SUS AQUA	5,896	3,096	$525,366.71	1.9	$2.66	12.03%
Triamcinolone	NASACORT AQ AER 55MCG/AC	5,406	2,554	$482,493.48	2.12	$2.80	11.05%
Azelastine	ASTELIN NASA SPR 137MCG	2,147	1,279	$177,931.66	1.68	$2.61	4.08%
Flunisolide	FLUNISOLIDE SPR 0.025%	1,732	1,075	$52,471.11	1.61	$0.97	1.20%
Ipratropium	IPRATROPIUM SPR 0.06%	396	298	$6,744.97	1.33	$0.66	0.15%
Ipratropium	IPRATROPIUM SPR 0.03%	334	249	$6,618.24	1.34	$0.63	0.15%
Beclomethasone	BECONASE AQ SUS 0.042%	227	75	$28,251.50	3.03	$4.00	0.65%
Flunisolide	FLUNISOLIDE SPR 29MCG	123	94	$5,949.32	1.31	$1.51	0.14%
Ciclesonide	OMNARIS SPR	47	39	$4,060.61	1.21	$2.96	0.09%
Olopatadine	PATANASE SPR 0.6%	31	27	$2,334.71	1.15	$2.68	0.05%
Flunisolide	NASAREL SPR 29MCG	30	21	$1,830.84	1.43	$1.88	0.04%
Fluticasone	FLONASE SPR 0.05%	1	1	$87.52	1	$2.92	0.00%
Beclomethasone	VANCENASE AQ SPR .084% DS	1	1	$54.94	1	$7.85	0.00%
FY 2008	**Totals**	**66,102**	**32,955**	**$4,365,360.63**	**2.01**	**$2.00**	**100%**

Prescribers of Nasal Allergy Products: FY 2008

Specialty	Total Claims	Total Cost	Comparison By Number of Claims
Family Practitioner	19,042	$1,178,323.21	
General Pediatrician	18,907	$1,311,568.13	
Nurse Practitioner (Other)	6,041	$449,490.54	
General Practitioner	4,397	$285,569.35	
Physician Assistant	3,113	$221,480.43	
Unknown	3,027	$159,334.67	
Internist	2,720	$155,363.37	
Otologist, Laryngologist, Rhinologist	2,185	$160,727.97	
Allergist	1,671	$132,442.99	
DDSD-NFM	1,067	$64,984.47	

Prior Authorization of Nasal Allergy Products: FY 2008



Market Changes

Azelastine, an H_1 receptor antagonist, is now available under the name brand Astepro™ for intranasal use. It is indicated for use in patients 12 years of age or older for the relief of seasonal allergic rhinitis symptoms. The usual starting dose is 1 to 2 sprays per nostril twice daily. It is available in a 30ml bottle containing 200 metered sprays with 137 mcg of azelastine hydrochloride in each spray.

Recommendations

The College of Pharmacy recommends the addition of Astepro™ to the Nasal Allergy Product Based Prior Authorization category as a Tier 2 product. The existing prior authorization criteria for this category will apply.

Astepro™ Product Details

Manufacturer: MEDA Pharmaceuticals, Inc.
Classification: H_1 receptor antagonist
Status: Prescription only

Summary
Astepro™ (azelastine hydrochloride) received FDA approval in October 15, 2008. Astepro™ is a prescription medicine used to treat symptoms of seasonal (not perennial) allergic rhinitis in patients 12 years of age and older. It helps prevent the release of histamine from mast cells and prevents it from binding to receptors if any is released. It is a reformulation of Astelin® with a less bitter taste and less nasal discomfort.

The recommended dose is one or two sprays in each nostril twice daily for a total dose of four to eight sprays per day. Each spray has a volume of 0.317 ml containing 137mcg of azelastine hydrochloride.

Pregnancy Risk Factor C

Contraindications

There are no contraindications to using Astepro™.

Precautions

- If pregnant or thinking of becoming pregnant
- Breastfeeding
- Have any allergies to food, dyes or preservatives

Common Adverse Effects

- Bitter taste
- Nosebleeds
- Headaches

Less Common Adverse effects

- Fatigue
- Drowsiness
- Nasal discomfort

Serious Side Effects

- Excessive drowsiness
- Irregular heart rhythm
- Feelings of a rapid or forcefull beating heart
- Confusion
- Signs of allergic reaction to the medication (unexplained rash or swelling, hives or itching

Drug Interactions

Concurrent use of alcohol or central nervous system depressants with Astepro™ could reduce alertness and impair central nervous system performance (driving or operating machinery).

When taken with Cimetidine (400mg twice daily), the Cmax and AUC of oral azelastin (4mg twice daily) increased by almost 6%.

Ketoconazole (200mg twice daily) interfered with the measurement of azelastine plasma concentrations but showed no effect on QTc.

Patient Information

- Use caution in driving, operating machinery, or doing other dangerous activities
- Drinking alcohol or using other medications that cause drowsiness while using Astepro™ may intensity the effect.

REFERENCE

Astepro(TM) (azelastine hydrochloride) Product Information. MEDA. www.astepro.com
Http://allergies.emedtv.com

Appendix F

Prior Authorization Annual Review - Fiscal Year 2008
Ocular Allergy Medications
Oklahoma Health Care Authority
February 2009

Prior Authorization Criteria

- FDA approved diagnosis
- A trial of at least one Tier 1 product of a similar type for a minimum of two weeks in the last 30 days (ie: cromolyn sodium prior to use of a mast cell stabilizer product or OTC Zaditor® prior to use of a tier two in the same category)
- Documentation of clinical need for Tier 2 product over Tier 1 should be noted on the petition
- Clinical exceptions granted for products with allergic reaction or contraindication

Ocular Allergy Medications*	
Tier 1	*Tier 2*
cromolyn sodium (Opticrom®)	nedocromil sodium (Alocril®)
ketotifen fumarate (Zaditor® OTC)	lodoxamide tromethamine (Alomide®)
ketotifen fumarate (Alaway™)	pemirolast potassium (Alamast®)
azelastine (Optivar®)	emedastine difumarate (Emadine®)
epinastine (Elestat®)	olopatadine (Pataday™)
olopatadine (Patanol®)	loteprednol etabonate (Alrex®)

*Mandatory Generic Plan Applies
Blue Color Indicates Participication in Supplemental Rebate Program

Utilization

For the period of July 2007 through June 2008, a total of 4,711 members received ocular allergy products through the SoonerCare program.

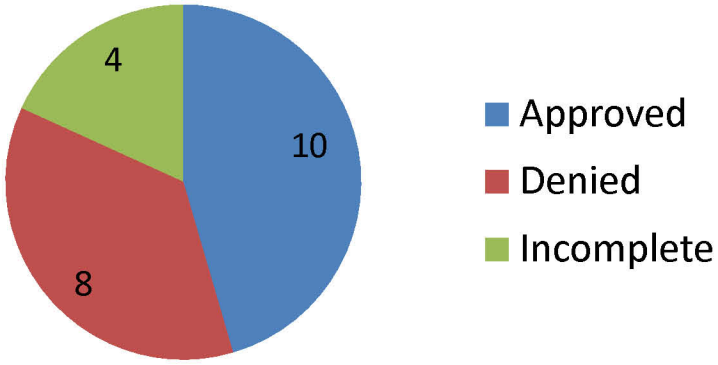
FY 2007 versus FY 2008			% Change
Cost FY '08		***$608,932.06**	**11.9%↑**
	Cost FY '07	*$544,542.16*	
Claims FY '08		**7,210**	**7.8%↑**
	Claims FY '07	*6,691*	
Per Diem FY '08		**$2.94**	**23.8%↓**
	Per Diem FY '07	*$3.86*	
Members FY '08		**4,711**	**6.6 ↑**
	Members FY '07	4,401	

*Does not include supplemental rebate information

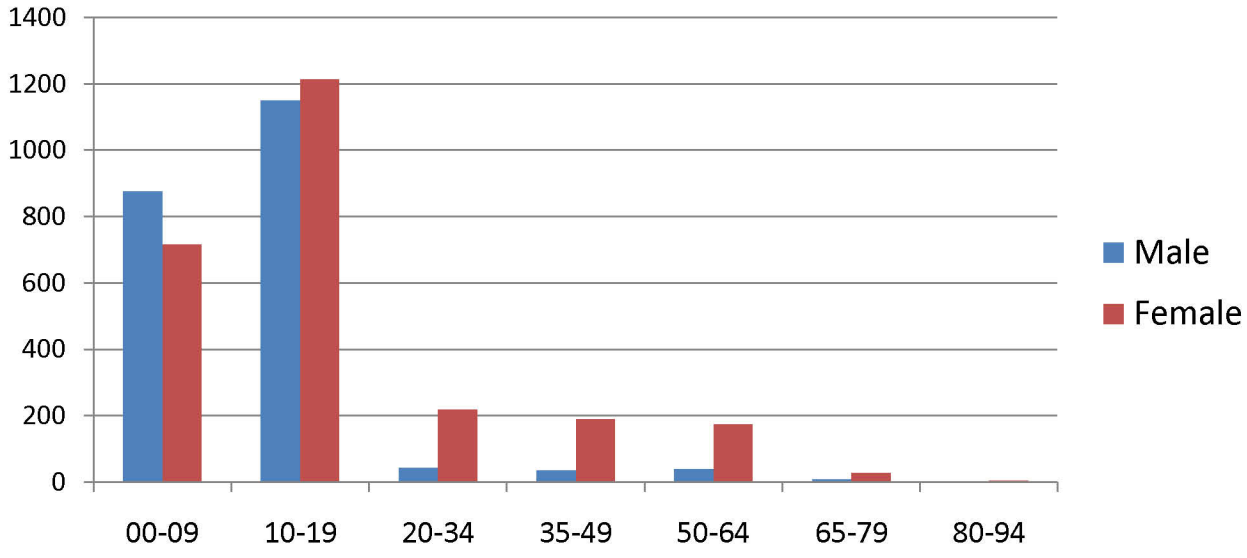
Utilization Details: FY08

Chemical Name	Brand Name	Claims	Units	Days	Members	Cost	Claims/ Mem	Cost/ Day
Olopatadine	PATANOL SOL 0.1% OP	3,657	18,495	105,018	2,415	$312,565.33	1.51	$2.98
Olopatadine	PATADAY SOL	1,960	5,040	55,131	1,380	$170,966.04	1.42	$3.10
Epinastine HCl	ELESTAT DRO 0.05%	717	3,585	20,731	480	$59,849.54	1.49	$2.89
Azelastine HCl	OPTIVAR DRO 0.05%	589	3,526	18,356	425	$53,079.69	1.39	$2.89
Ketotifen Fum	ZADITOR SOL 0.025%OP	86	460	2,579	64	$2,673.93	1.34	$1.04
Ketotifen Fum	KETOTIFEN SOL FUMARATE	79	403	2,219	66	$4,233.96	1.2	$1.91
Cromolyn	CROMOLYN SOD SOL 4%	61	600	1,732	40	$688.99	1.53	$0.40
Nedocromil	ALOCRIL SOL 2%	50	250	1,339	26	$4,267.00	1.92	$3.19
Pemirolast	ALAMAST DRO 0.1%	5	50	150	2	$410.40	2.5	$2.74
Ketotifen	ALAWAY DRO 0.025%OP	4	25	40	3	$34.68	1.33	$0.87
Lodoxamide	ALOMIDE SOL 0.1% OP	2	20	60	2	$162.50	1	$2.71
Totals		**7,210**	**32,454**	**207,355**		**$608,932.06**	**1.52**	**$2.94**

Total petitions submitted for this category during FY08: 22



Age and Gender FY08



Recommendations

The College of Pharmacy recommends no changes at this time and will continue to monitor and evaluate the ocular allergy medication category.

Appendix G

Utilization Review of Anti-Ulcer/GERD Medications for Children
Oklahoma Health Care Authority
February 2009

H2's and PPI's that are FDA approved for treatment of GERD in children

Medication	Age Range	Dosing Range
Famotidine susp, 40mg/5ml, ODT 20mg, 40mg	<3 mo, 3-12 mo, 1-16 yrs	0.5-2 mg/kg/day, divided
Ranitidine syrup, 15mg/ml, Effervescent tabs 25mg	1 mo to 16 yrs	5 to 10 mg/kg/day, divided
Nizatidine oral solution 15mg/ml	12 yr and older	150 mg bid x 8 wks
Cimetidine tabs 200mg, 300mg, 400mg	≥16 years	1600mg ORALLY per day in 2-4 divided doses
Prevacid® (**lansoprazole**) caps, Solutabs 15mg, 30mg	1-11 yrs, 12-17 yrs	15-30mg daily, may BID if needed
Nexium® (**esomeprazole**) suspension pkt, 10mg,20mg, 40mg	1-11 yrs, 12 & older	10-40 mg daily
Omeprazole cap, 20mg	2-16 yrs	Weight-based: 5-20 mg qd
Zegerid® pkt (**omeprazole/sodium bicarbonate**) 20/1100, 40/1100, 20/1680, 40/1680	No pediatric Indication	<20kg - 10 mg per day or 0.6-0.7 mg/kg qd-bid >20 kg – 20 mg per day or 0.6-0.7 mg/kg qd-bid

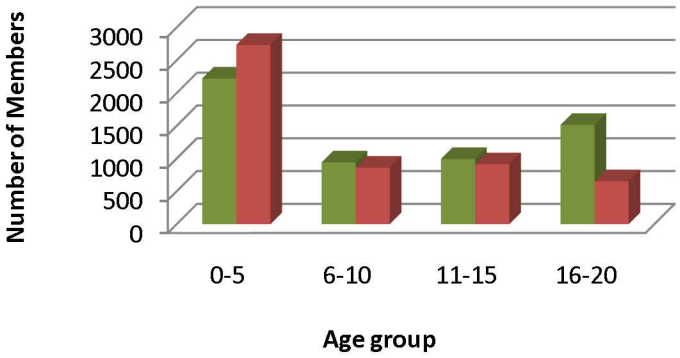
The following chart shows the different medications approved for use at various ages:

Comparison of Demographics

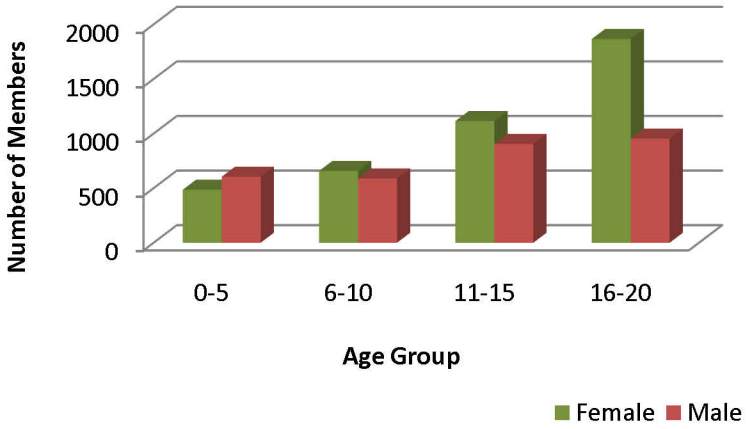
H2 Blockers		
Age	Female	Male
0-5	2,221	2,735
6-10	943	862
11-15	995	915
16-20	1,515	654

PPIs		
Age	Female	Male
0-5	486	605
6-10	658	589
11-15	1,115	905
16-20	1,867	954

H2 Blocker Use by Age/Gender



PPI Use by Age/Gender



Utilization data - FY 2008

H2 Blockers	Claims	Units	Days	Members	Cost	Per-diem
Cimetidine tab 200 mg	20	1,130	567	11	$214.11	$0.38
Cimetidine tab 300 mg	131	7,400	3,706	64	$1,360.01	$0.37
Cimetidine tabs 400 mg	305	17,660	9,024	156	$3,039.39	$0.34
Cimetidine tab 800 mg	124	4,729	3,592	74	$1,148.31	$0.32
Cimetidine sol'n 300mg/5ml	460	75,075	12,222	289	$5,741.16	$0.47
Ranitidine tab 150 mg	7,323	363,988	217,884	3,364	$53,167.13	$0.24
Ranitidine tab 300	404	15,579	12,502	177	$3,036.60	$0.24
*Zantac effervescent tab 25 mg	9	1,020	270	3	$2,949.56	$10.92
Ranitidine syrup 15 mg/ml	9,463	1,244,945	277,116	4,567	$682,643.68	$2.46
Zantac syrup 15 mg/ml	2	105	60	2	$83.27	$1.39
Ranitidine inj 150 mg/6ml	40	1,506	295	4	$2,297.90	$7.79
Ranitidine inj 50 mg/2ml	14	481	260	12	$920.52	$3.54
Zantac inj 25 mg/ml	5	68	34	5	$140.15	$4.12
Zantac inj 50 mg/50 ml	3	150	3	2	$28.05	$9.35
Famotidine tab 20 mg	1,480	63,909	39,167	826	$12,933.57	$0.33
Famotidine tab 40 mg	104	5,055	3,838	57	$1,020.89	$0.27
Pepcid susp 40 mg/5ml	963	68,150	25,139	320	$150,809.45	$6.00
Famotidine inj 10 mg/ml	7	360	313	5	$166.05	$0.53
Nizatidine cap 150 mg	88	5,200	2,735	44	$2,209.82	$0.81
Nizatidine cap 300 mg	3	148	88	2	$219.95	$2.50
Axid sol'n 15 mg/ml	3,421	388,458	103,259	1,551	$236,638.83	$2.29
TOTAL	24,369	2,265,116	712,074	10,840**	$1,160,768.40	$1.63

*Prior Authorization Required for Use.
**unduplicated members

Proton Pump Inhibitors	Claims	Unit	Days	Members	Cost	Per-Diem
*Nexium granules 20 mg	4	120	120	1	$616.14	$5.13
*Nexium cap 20 mg	144	4,729	4,564	45	$24,221.01	$5.31
*Nexium cap 40 mg	1,086	34,999	33,934	243	$179,014.06	$5.28
*Nexium inj 40 mg	13	32	32	1	$879.30	$27.48
*Prevacid granules 15 mg	120	3,295	3,555	61	$16,852.40	$4.74
*Prevacid granules 30 mg	16	480	465	6	$2,517.65	$5.41
Prevacid cap 15 mg	4,526	135,167	133,987	1,548	$689,930.74	$5.15
Prevacid cap 30 mg	7,959	252,651	238,909	2,534	$1,231,614.65	$5.16
*Prevacid solutab 15 mg	976	29,064	30,252	370	$117,248.89	$3.88
*Prevacid solutab 30 mg	171	5,650	5,445	47	$23,310.61	$4.28
Omeprazole cap 10 mg	250	8,256	7,763	103	$8,798.79	$1.13
Omeprazole cap 20 mg	6,144	250,434	191,976	2,530	$141,239.88	$0.74
*Prilosec cap 40 mg	16	1,710	435	5	$3,189.38	$7.33
†Prilosec OTC tab 20 mg	5	157	129	5	$113.17	$0.88
*Pantoprazole tab 20 mg	5	210	210	4	$551.25	$2.63
*Protonix tab 20 mg	72	2,244	2,124	33	$9,167.27	$4.32
*Pantoprazole tab 40 mg	462	14,623	14,423	206	$47,655.37	$3.30
*Protonix tab 40 mg	1,013	33,073	32,972	511	$132,766.21	$4.03
*Protonix inj 40 mg	5	13	13	3	$192.35	$14.80
*Aciphex tab 20 mg	258	8,010	7,800	62	$40,847.34	$5.24
*Zegerid cap 20-1100	22	645	660	12	$2,535.55	$3.84
*Zegerid cap 40-1100	179	5525	5,504	80	$23,346.45	$4.24
*Zegerid pkt 20-1680	198	5670	6,330	62	$27,555.09	$4.35
*Zegerid pkt 40-1680	25	749	749	9	$3,635.69	$4.85
TOTAL	23,669	797,506	722,351	7,179**	$2,727,799.24	$3.78

*Prior Authorization Required for Use.
† Product no longer covered.
**unduplicated members

Analysis

- Use of H2 blockers is higher in the younger pediatric population and tapers down, while the use of PPI's is lower in the same population, and increases with age.

Appendix H

Utilization Review of Hydrocodone Compound Products

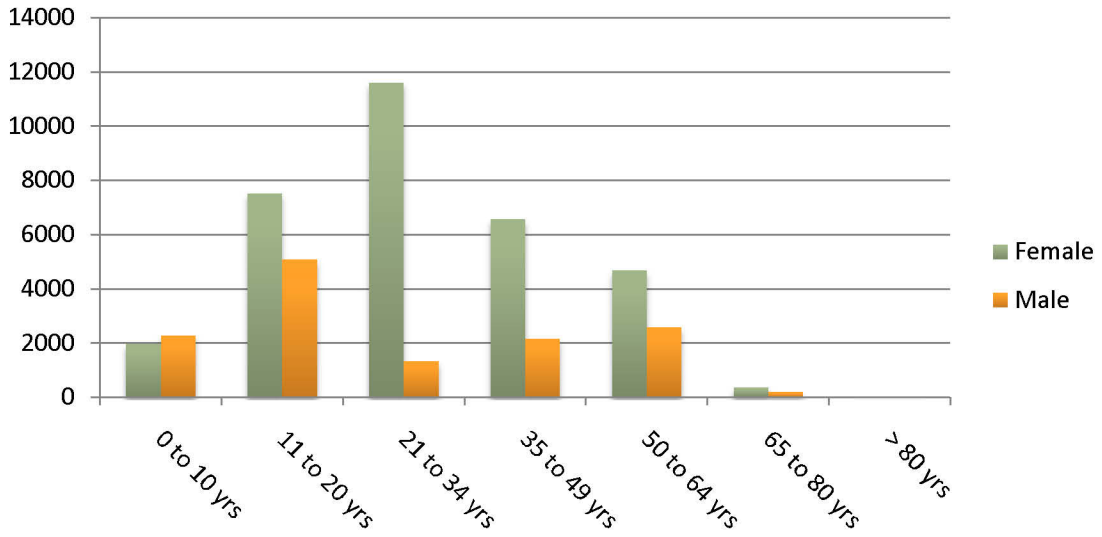
Oklahoma Health Care Authority
February 2009

Utilization Data for January 1, 2008 to June 30, 2008

RANK CLAIMS	RANK COST	BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS /DAY	CLAIMS /CLIENT	COST /DAY	% COST
1	2	HYDROCO/APAP TAB 7.5-500	44,491	2,011,563	510,881	20,831	$438,420.35	3.94	2.14	$0.86	30.10
2	3	HYDROCO/APAP TAB 5-500MG	24,847	706,123	164,225	16,666	$143,234.38	4.3	1.49	$0.87	9.84
3	1	HYDROCO/APAP TAB 10-500MG	24,812	2,110,341	527,330	7,159	$467,606.53	4	3.47	$0.89	32.11
4	5	HYDROCODONE/ SOL APAP	6,823	1,633,672	47,784	5,319	$85,938.07	34.19	1.28	$1.80	5.90
5	4	HYDROCO/APAP TAB 10-325MG	4,954	484,700	102,616	1,494	$125,761.77	4.72	3.32	$1.23	8.64
6	6	HYDROCO/APAP TAB 10-650MG	3,756	308,975	79,530	1,227	$57,961.33	3.89	3.06	$0.73	3.98
7	8	HYDROCO/APAP TAB 7.5-325	2,445	125,413	26,143	1,361	$39,534.01	4.8	1.80	$1.51	2.71
8	9	HYDROCO/APAP TAB 5-325MG	1,900	68,692	14,201	1,328	$21,644.03	4.84	1.43	$1.52	1.49
9	7	HYDROCOD/IBU TAB 7.5-200	1,482	81,015	20,635	710	$39,677.00	3.93	2.09	$1.92	2.72
10	10	HYDROCO/APAP TAB 7.5-650	1,402	63,683	16,486	656	$13,591.36	3.86	2.14	$0.82	0.93
11	11	HYDROCO/APAP TAB 7.5-750	736	32,769	9,140	433	$7,012.16	3.59	1.70	$0.77	0.48
12	12	HYDROCO/APAP TAB 2.5-500	441	14,708	3,801	333	$4,772.21	3.87	1.32	$1.26	0.33
13	13	HYCET SOL 7.5-325	76	17,258	438	58	$3,945.97	39.4	1.31	$9.01	0.27
14	20	LORTAB 5 TAB	42	1,057	217	38	$238.80	4.87	1.11	$1.10	0.02
15	16	HYDROCO/APAP TAB 10-750MG	36	1,455	324	24	$909.41	4.49	1.50	$2.81	0.06
16	18	HYDROCO/APAP TAB 10-660MG	30	1,855	510	18	$514.63	3.64	1.67	$1.01	0.04
17	14	XODOL TAB 10-300MG	23	1,720	607	6	$2,483.01	2.83	3.83	$4.09	0.17
18	15	LORTAB 10 TAB	7	1,440	197	2	$1,728.84	7.31	3.50	$8.78	0.12
19	19	XODOL TAB 7.5-300	6	195	50	5	$251.70	3.9	1.20	$5.03	0.02
20	17	LORTAB 7.5 TAB	6	540	180	1	$635.62	3	6.00	$3.53	0.04
21	24	STAGESIC CAP 500-5MG	6	217	40	5	$62.32	5.42	1.20	$1.56	0.00
22	21	XODOL TAB 5-300MG	5	160	19	3	$172.93	8.42	1.67	$9.10	0.01
23	23	REPREXAIN TAB 7.5-200	3	140	36	2	$66.22	3.89	1.50	$1.84	0.00
24	22	IBUDONE TAB 5-200MG	1	150	30	1	$116.83	5	1.00	$3.89	0.01
25	25	LORTAB 2.5 TAB	1	30	10	1	$10.61	3	1.00	$1.06	0.00
26	26	HYDROCO/APAP CAP 5-500MG	1	30	5	1	$9.98	6	1.00	$2.00	0.00
27	27	HY-PHEN TAB 500-5MG	1	20	4	1	$4.82	5	1.00	$1.21	0.00
			118,333	**7,667,921**	**1,525,439**	***46,872**	**$1,456,304.89**	**5.03**	**2.52**	**$0.95**	

*Unduplicated Members

Member Demographics



Number of Claims by Physician Specialty

Specialty	Number of Claims	Total Amount Paid
Family Practitioner	34,163	$462,270.29
General Practitioner	10,414	$152,611.76
Internist	9,511	$153,798.78
General Dentistry Practitioner	9,208	$54,856.81
Orthopedic Surgeon	7,332	$94,154.73
Obstetrician/Gynecologist	6,370	$51,538.67
Unknown	5,379	$70,953.57
Emergency Medicine Practitioner	4,741	$29,309.20
General Surgeon	3,983	$39,646.20
Otologist, Laryngologist, Rhinologist	3,431	$46,431.96
Physician Assistant	3,140	$27,524.87
DDSD-NFM	2,666	$33,336.30
Oral Surgeon	2,307	$16,502.88
General Pediatrician	2,220	$26,908.65
Nurse Practitioner (Other)	2,087	$17,147.97
Anesthesiologist	1,960	$41,245.84
Physical Medicine and Rehabilitation	1,890	$37,323.09

Averages per Member for Members greater than 20 Years of Age*

Age Group	Cost per Member	Claims per Member	Units per Member	Day Supply per Member	Units per Day per Member
21 to 34 yrs	$22.58	2.35	92.13	21.35	5.69
35 to 49 yrs	$50.08	3.53	228.21	57.86	4.85
50 to 64 yrs	$64.35	4.07	301.7	76.49	4.62
65 to 80 yrs	$54.07	3.62	266.01	67.59	4.55
> 80 yrs	$22.08	2.39	158.83	35.58	4.88

*Solid dosage forms only

Number of Members by Number of Claims – Calendar Year 2008

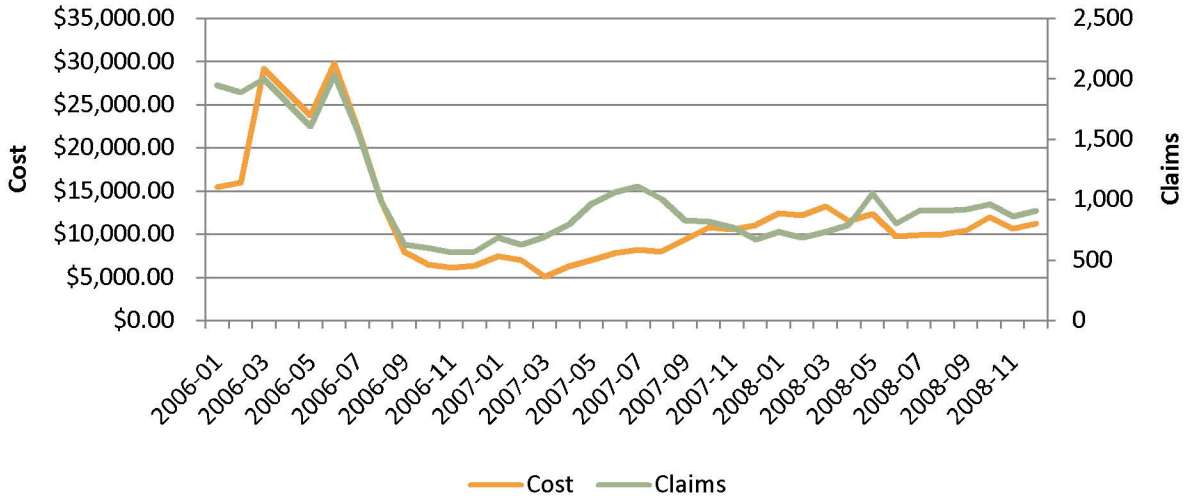
Total Claims	Members	Percent
1	25,141	53.64
2	7,620	16.26
3	3,474	7.41
4	2,313	4.93
5	1,975	4.21
6	2,822	6.02
7	1,505	3.21
8	712	1.52
9	410	0.87
10	252	0.54
11	176	0.38
12	116	0.25
>12	356	0.75

Roughly 75% of members had 3 claims or less during Calendar Year 2008. Ninety percent of the members had 9 claims or less and 95% of members had 12 claims or less. The average number of claims for all members was 3.18.

Comparison of Other Medications with Abuse Potential

In August of 2006, an edit was put in place to only allow 90 days of carisoprodol products every 365 days. This has caused an approximate 50% decrease in the cost of carisoprodol and a 60% decrease in utilization. There is a cyclical increase in claims every August as the 90 days reset.

Carisoprodol Utilization Before and After Intervention



A similar edit could be placed on hydrocodone. The following tables indicate the number of members that would be affected by various limit cut-offs. A three claim limit would result in 18,164 members requiring prior authorization. A 90 day supply cut-off would result in 10,114 members requiring prior authorization.

Three Claim Limit

Age Group	# of Members	Mean Claims
≤ 10	421	7.12
11 to 20	1,672	6.21
21 to 34	4,925	8.08
35 to 49	5,551	9.61
50 to 64	5,276	10.26
65 to 80	307	9.15
> 80	12	10.08

90 Day Supply Limit

Age Group	# of Members	Mean Days
≤ 10	161	188.22
11 to 20	211	189.66
21 to 34	1,708	210.58
35 to 49	3,747	236.5
50 to 64	4,062	250.45
65 to 80	218	235.33
> 80	7	190.71

Current Restrictions

1. Quantity limit of a maximum of 4 gm of acetaminophen per product per day.
2. Ingredient duplication module set to deny claims from different prescribers.

Recommendation

The College of Pharmacy recommends continuation of current restrictions along with increased frequency of review of overall utilization for possible referrals to the Lock-In program. The College of Pharmacy also offers the following suggestions to the DUR Board for review for further restrictions:

1. Introduce a claim or day supply limit similar to the carisoprodol restrictions with exceptions for oncology related diagnoses or other chronic pain conditions.
2. Only allow 5 to 10 days supply per specific period such as 30, 60, or 90 days.
3. Refer members with non-oncology related chronic pain conditions to care management for pain management.

Appendix I

Early Communication about an Ongoing Safety Review of clopidogrel bisulfate (marketed as Plavix)

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a cause and effect relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available

The FDA is aware of published reports that clopidogrel (marketed as Plavix) is less effective in some patients than it is in others. Differences in effectiveness may be due to genetic differences in the way the body metabolizes clopidogrel,[1, 2] or that using certain other drugs with clopidogrel can interfere with how the body metabolizes clopidogrel.[3]

Clopidogrel is an antiplatelet drug that is used to prevent blood clots that could lead to heart attacks or strokes in patients at risk for these problems. The drug clopidogrel is a "pro-drug" which means that it has to be metabolized by the body before it can be biologically active and have the effect of preventing blood clots. Understanding that there are differences in how the body metabolizes clopidogrel and there are effects that other drugs may have on its metabolism is important because decreases in the effectiveness of clopidogrel might be avoided, in part, by using other drugs with clopidogrel that do not interfere with its metabolism.

One class of drugs commonly used with clopidogrel is proton pump inhibitors (PPIs). Some reports suggest that use of certain PPIs may make clopidogrel less effective[3, 4] by inhibiting the enzyme that converts clopidogrel to the active form of the drug. Other reports do not suggest this effect.[5, 6] Proton pump inhibitors decrease stomach acid and are used to treat frequent heartburn and stomach ulcers. Clopidogrel can irritate the stomach so PPIs are commonly used with clopidogrel to help reduce this irritation. PPIs include omeprazole (Prilosec, Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), rabeprazole (Aciphex), and esomeprazole (Nexium), which are all available by prescription. Omeprazole (Prilosec OTC) is also sold without a prescription (over-the-counter) for frequent heartburn.

Currently, we have no evidence that other drugs that reduce stomach acid, such as H2

blockers (e.g., Zantac, Pepcid, Tagamet and Axid) or antacids interfere with the antiplatelet activity of clopidogrel.

The makers of Plavix, Sanofi-Aventis and Bristol-Myers Squibb, have agreed to work with FDA to conduct studies to obtain additional information that will allow us to better understand and characterize the effects of genetic factors and other drugs (especially the PPIs) on the effectiveness of clopidogrel. This information should lead to a better understanding about how to optimize the use of clopidogrel. The FDA recognizes the importance of obtaining these data promptly. The drug manufacturers have agreed to a timeline for completing the studies. The FDA will review the new information expeditiously upon receipt from the drug manufacturers and will communicate its conclusions and any recommendations to the public at that time. It could take several months to complete the studies and analyze the results.

Until further information is available FDA recommends the following:

- Healthcare providers should continue to prescribe and patients should continue to take clopidogrel as directed, because clopidogrel has demonstrated benefits in preventing blood clots that could lead to a heart attack or stroke.
- Healthcare providers should re-evaluate the need for starting or continuing treatment with a PPI, including Prilosec OTC, in patients taking clopidogrel.
- Patients taking clopidogrel should consult with their healthcare provider if they are currently taking or considering taking a PPI, including Prilosec OTC.

This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs.

The FDA urges both healthcare professionals and patients to report side effects from the use of clopidogrel to the FDA's MedWatch Adverse Event Reporting program

- online at www.fda.gov/medwatch/report.htm;
- by returning the postage-paid FDA form 3500 available in PDF format at www.fda.gov/medwatch/getforms.htm to 5600 Fishers Lane, Rockville, MD 20852-9787;
- faxing the form to 1-800-FDA-0178; or
- by phone at 1-800-332-1088

[1] Frere C et al, Effect of cytochrome P450 polymorphisms on platelet reactivity after treatment with clopidogrel in acute coronary syndrome. Am J Cardiol 2008; 101:1088-93.

[2] Trenk et al. Cytochrome P450 2C19 681G A polymorphism and high on-clopidogrel platelet reactivity associated with adverse 1-year clinical outcome of elective percutaneous coronary intervention with drug eluting or bare-metal stents. J Am Coll Cardiol 2008; 51: 1925-34.

[3] Gilard M et al. Influence of omeprazole on the antiplatelet action of clopidogrel associated with aspirin: the randomized, double-blind OCLA (Omeprazole Clopidogrel Aspirin) Study. J Am Coll Cardiol 2008: 51:256-60.

[4] Gilard M et al. Influence of omeprazole on the antiplatelet action of clopidogrel associated to aspirin. J Thromb Haemost 2006; 4:2508-9.

[5] Small DS et al. Effects of the proton pump inhibitor lansoprazole on the pharmacokinetics and pharmacodynamics of prasugrel and clopidogrel. J Clin Pharmacol 2008; 48: 475-484.

[6] Siller-Matula JM et al. Effects of pantoprazole and esomeprazole on platelet inhibition by clopidogrel. Am Heart J 2009; 157:148e1-148.e5.

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Date created: January 26, 2009

Update of Safety Review
Follow-up to the March 27, 2008, Communication about the Ongoing Safety Review of Montelukast (Singulair)

This information reflects FDA's current analysis of available data concerning this drug.

On March 27, 2008, FDA announced that it was reviewing safety data that raised concerns about a possible association between the use of montelukast and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide.

FDA requested manufacturers of products indicated for the treatment of asthma and/or allergic rhinitis that act through the leukotriene pathway (montelukast, zafirlukast, zileuton) to submit adverse event data for suicidality adverse events as well as mood and behavioral-related adverse events from all available placebo-controlled clinical trials. (Early Communication About an Ongoing Safety Review of Montelukast (Singulair), http://www.fda.gov/cder/drug/early_comm/montelukast.htm). FDA stated at the time that it expected its preliminary review to take about 9 months and that it would communicate its conclusions and any resulting recommendations to the public at the completion of its review.

FDA requested that Merck, Astra Zeneca, and Cornerstone Therapeutics use the Columbia Classification Algorithm of Suicide Assessment (C-CASA) to classify suicidal events. Merck submitted results from 41 placebo-controlled clinical trials in patients 6 years of age and older, of which 9929 were treated with montelukast and 7780 were treated with a placebo. One adult patient (0.01%) out of 9929 patients treated with montelukast had suicidal ideation and there were no completed suicides. No patients in the placebo group had suicidal ideation or suicide. Astra Zeneca submitted results from 45 placebo-controlled clinical trials in patients 5 years of age and older, of which 7540 were treated with zafirlukast and 4659 were treated with a placebo. No patients treated with zafirlukast had suicidal ideation or completed suicide. Two patients in the placebo group (0.04%) had suicidality (one suicide attempt and one suicidal ideation). Cornerstone Therapeutics submitted results from 11 placebo-controlled clinical trials in patients 12 years of age and older, of which 1745 were treated with zileuton and 1063 were treated with a placebo. No patients treated with zileuton or placebo had suicidal ideation or completed suicide. Although these data do not suggest that montelukast, zafirlukast, or zileuton are associated with suicide or suicidal behavior, these clinical trials were not designed specifically to examine neuropsychiatric events. As a result, some events may not have been reported.

FDA is continuing to review *clinical trial data* to assess other neuropsychiatric events, (mood and behavioral adverse events) related to drugs that act through the leukotriene pathway (montelukast, zafirlukast, zileuton). As a result, FDA has not yet reached a definitive conclusion regarding the clinical trial data on mood and behavioral adverse events associated with montelukast, zafirlukast, and zileuton. We will communicate our conclusions and any resulting recommendations to the public at the conclusion of the review, which may take months to complete.

Post-marketing reports of neuropsychiatric events associated with montelukast, zafirlukast and zileuton have been reported to FDA's Adverse Event Reporting System (AERS). Most of the reports of neuropsychiatric events are associated with montelukast, currently the most commonly prescribed drug that acts through the leukotriene pathway. The clinical details of some reports involving montelukast are consistent with a drug-induced effect. Because of the paucity of reports involving zafirlukast and zileuton, assessment of a drug–induced effect with these is limited. Accordingly, at this time, patients and prescribers should monitor for the possibility of neuropsychiatric events associated with these agents.

Singulair (montelukast) is a medicine in the drug class known as leukotriene receptor antagonists. Leukotriene receptor antagonists work by blocking substances in the body called leukotrienes. Leukotrienes are chemicals the body releases in response to an inflammatory stimulus, such as when a person breathes in an allergen. Singulair is used to treat asthma and the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose) and to prevent exercise-induced asthma. Accolate (zafirlukast) is also a medicine in the drug class known as leukotriene receptor antagonists. Accolate is used to treat asthma. Zyflo and Zyflo CR (zileuton) are medicines in the drug class known as leukotriene synthesis inhibitors. Leukotriene synthesis inhibitors work by stopping the formation of certain natural substances that cause swelling, tightening, and mucus production in the airways. Zyflo and Zyflo CR are used to treat asthma.

The FDA urges both healthcare professionals and patients to report side effects from the use of Singulair, Accolate, Zyflo, and Zyflo CR to the FDA's MedWatch Adverse Event Reporting program

- online at www.fda.gov/medwatch/report.htm
- by returning the postage-paid FDA form 3500 available in PDF format at www.fda.gov/medwatch/getforms.htm to 5600 Fishers Lane, Rockville, MD 20852-9787
- faxing the form to 1-800-FDA-0178
- by phone at 1-800-332-1088

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Date created: January 13, 2009

Update of Safety Review
Follow-up to the January 25, 2008 Early Communication about an Ongoing Data Review for Ezetimibe/Simvastatin (marketed as Vytorin), Ezetimibe (marketed as Zetia), and Simvastatin (marketed as Zocor)

This information reflects FDA's current analysis of available data concerning these drugs.

On January 25, 2008, FDA announced that it would be reviewing data from the ENHANCE trial (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia). (http://www.fda.gov/cder/drug/early_comm/ezetimibe_simvastatin.htm). Preliminary results from this trial had indicated that there was no significant difference between Vytorin and simvastatin-treated patients in the thickness of the carotid (neck) arteries despite greater lowering of LDL (bad) cholesterol with Vytorin compared to simvastatin. The thickness of the carotid arteries, also known as carotid intima-media thickness or cIMT, is a marker of risk for cardiovascular disease. The preliminary results from the ENHANCE trial raised several questions, some of which involve the relationship of cIMT to LDL cholesterol levels and the role of cIMT in drug development.

The FDA has completed its review of the final clinical study report of ENHANCE. Following two years of treatment, carotid artery thickness increased by 0.011 mm in the Vytorin group and by 0.006 mm in the simvastatin group. The difference in the changes in carotid artery thickness between the two groups was **not** statistically significant. However, the levels of LDL cholesterol decreased by 56% in the Vytorin group and decreased by 39% in the simvastatin group. The difference in the reductions in LDL cholesterol between the two groups **was** statistically significant.

The results from ENHANCE do not change FDA's position that an elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. Based on current available data, patients should not stop taking Vytorin or other cholesterol lowering medications and should talk to their doctor if they have any questions about Vytorin, Zetia, or the ENHANCE trial.

ENHANCE was a randomized, double-blind, active-controlled trial conducted in patients with heterozygous familial hypercholesterolemia (HeFH). A total of 725 patients were randomized 1:1 to receive either Vytorin 10/80 (ezetimibe 10 mg plus simvastatin 80 mg) or simvastatin 80 mg for 2 years. The primary efficacy outcome was the change in ultrasound-determined carotid artery thickness (or cIMT).

Based on data from a previously-conducted cIMT study[1] and the anticipated degree of cholesterol lowering with Vytorin and simvastatin, it was projected that 2 years of treatment with Vytorin in ENHANCE would lead to a *decrease* in cIMT of approximately 0.03 mm whereas treatment with simvastatin would lead to an *increase* in cIMT of approximately 0.02 mm. There are several possible explanations for why the larger reduction in LDL cholesterol observed in the Vytorin group did not translate into significant improvement in cIMT. These include:

- enrollment of a patient population who had received prior lipid-altering or statin therapy and had relatively normal cIMT values at baseline which may make it harder to demonstrate a reduction or improvement in cIMT with Vytorin compared with simvastatin therapy
- the 2-year duration of ENHANCE which may have been too short to see a favorable effect of cholesterol lowering on cIMT
- some other unknown properties of ezetimibe that may negate the beneficial effects of LDL lowering on cIMT.

An ongoing trial known as IMPROVE-IT (Improved Reduction of Outcomes: Vytorin Efficacy International Trial) is examining whether treatment with Vytorin reduces the risk for *cardiovascular events (*composite endpoint of CV death, major coronary events, and stroke*)* compared with simvastatin alone. This trial of 18,000 patients is scheduled to be completed in 2012. IMPROVE-IT will provide additional data regarding Vytorin's effect on the risk for cardiovascular disease.

Pending the results from IMPROVE-IT, patients should not stop taking Vytorin or other cholesterol lowering medications and should talk to their doctor if they have any questions about these medications.

Ezetimibe (Zetia) is an inhibitor of intestinal cholesterol absorption approved to reduce LDL cholesterol levels. Simvastatin (Zocor) is a lipid-lowering drug ("statin") approved to reduce LDL (bad) cholesterol and increase HDL (good) cholesterol levels and reduce the risk of cardiovascular events such as heart attack and stroke. Vytorin is a combination of ezetimibe and simvastatin approved for reducing LDL and increasing HDL cholesterol levels.

This follow-up communication is in keeping with FDA's commitment to informing the public about its ongoing safety reviews of drugs.

The FDA urges both healthcare professionals and patients to report side effects from the use of lipid lowering drugs to the FDA's MedWatch Adverse Event Reporting program

- on-line at www.fda.gov/medwatch/report.htm
- by returning the postage-paid FDA form 3500 (available in PDF format at www.fda.gov/medwatch/getforms.htm) to 5600 Fishers Lane, Rockville, MD 20852-9787
- faxing the form to 1-800-FDA-0178

- by phone at 1-800-332-1088

[1] Smilde T, et al. Effect of aggressive versus conventional lipid lowering on atherosclerosis progression in familial hypercholesterolemia (ASAP): a prospective, randomized double-blind study; *Lancet* 2001;357:577-581.

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Date created: January 8, 2009
