Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

November 8, 2006

@ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Gorman, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – November 08, 2006**

DATE: November 01, 2006

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

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

Call to Order

Public Comment Forum

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

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

Action Item – Vote to Prior Authorize Fortament® and Glumetza™ – **See Appendix C.**

Action Item – Vote to Prior Authorize Exubera® – **See Appendix D.**

Action Item – Annual Review of Statins – **See Appendix E.**

Action Item – Annual Review of NSAIDs – **See Appendix F.**

Action Item – Annual Review of Antidepressants – **See Appendix G.**

Utilization Review of Suboxone® – **See Appendix H.**

New Products – **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – November 08, 2006 @ 6:00p.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. October 11, 2006 DUR Minutes – Vote
B. October 11, 2006 DUR Recommendations Memorandum
C. Provider Correspondence

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

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

A. Retrospective Drug Utilization Review for June 2006
B. Retrospective Drug Utilization Review Response for April 2006
C. Medication Coverage Activity Audit for October 2006
D. Help Desk Activity Audit for October 2006
E. Pharmacotherapy Management Quarterly Report

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

5. Action Item – Vote to Prior Authorize Fortamet® and Glumetza™ – See Appendix C.

A. Product Summaries
B. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Exubera™ – See Appendix D.

A. Product Summary
B. COP Recommendations

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

7. Action Item – Annual Review of Statins – See Appendix E.

A. Current Prior Authorization Criteria
B. Utilization Review
C. COP Recommendations

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

8. Action Item – Annual Review of NSAIDs – See Appendix F.

A. Current Prior Authorization Criteria
B. Utilization Review
C. COP Recommendations

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

9. Action Item - Annual Review of Antidepressants – See Appendix G.

A. Current Prior Authorization Criteria and Quantity Limits
B. Utilization Review
C. Market Changes
D. COP Recommendations

Items to be presented by Dr. Flannigan, Dr. Gorman, Dr. McNeill, Chairman

10. Utilization Review of Suboxone® – See Appendix H.

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

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

11. New Product Reviews – See Appendix I.

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Annual Reviews
B. Hemophilia Utilization Review
C. Topical Products Utilization Review
D. New Product Reviews and 30 Day Notices

14. Adjournment

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of SEPTEMBER 13, 2006

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Mark Feightner, D.Ph.	X	
Dorothy Gourley, D.Ph.	X	
Kyle Hrdlicka, D.O.		X
Dan McNeill, Ph.D., PA-C; Chairman		X
Cliff Meece, D.Ph., Vice-Chairman	X	
John Muchmore, M.D.		X
James Rhymer, D.Ph	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./PA Coordinator	X	
Metha Chonlahan, D.Ph./Clinical Pharmacist	X	
Karen Egesdal, D.Ph./SMAC-ProDUR Coordinator/OHCA Liaison	X	
Kelly Flannigan, Pharm.D../Operations Manager	X	
Shellie Gorman, Pharm.D./DUR Manager	X	
Ronald Graham, D.Ph./Pharmacy Director	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.	X	
Visiting Pharmacy Students: Katie Dill, Phong Nguyen	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Alex Easton, M.B.A./ Pharmacy Operations Manager		X
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 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

OTHERS PRESENT:

Rob Flory, UCB Pharma	Paul Sparks, Allergen	Fred Morse, BMS
Ron Schnare, Abbott	Steve Higgins, TAP Pharmaceuticals	M. Patty Laster, Genentech Inc.
Greg Hoke, Wyeth	Cathy Hollen, Lilly	David Dude, BMS
Aaron Walker, BMS	Sandy Ruble	Lon Lowrey, Novartis
Jim Turner, Astellas	Toby Thompson, Pfizer	Mark DeClerk, Lilly

PRESENT FOR PUBLIC COMMENT:

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

1A: Roll Call

Dr. Meece called the meeting to order. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED.

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

ACTION: NONE REQUIRED.

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

3A: September 13, 2006 DUR Minutes

Dr. Bell moved to approve minutes as submitted; seconded by Dr. Rhymer.

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: May 2006

4B: Retrospective Drug Utilization Review Response: March 2006

4C: Medication Coverage Activity Report: September 2006

4D: Help Desk Activity Report: September 2006

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ZORBTIVE™ AND OMNITROPE™**

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

Dr. Gourley moved to approve as submitted; seconded by Dr. Bell.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE INCRELEX™ AND IPLEX™**

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

Dr. Feightner moved to approve as submitted; seconded by Dr. Gourley.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ZANAFLEX CAPSULES™**

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

Dr. Bell moved to approve as submitted; seconded by Dr. Rhymer.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: **30-DAY NOTICE TO PRIOR AUTHORIZE FORTAMET®**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF ANTI-ULCER / PPIs**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **UTILIZATION REVIEW OF BETA-BLOCKERS**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **UTILIZATION REVIEW OF FLU MEDICATIONS**
Materials included in agenda packet; presented by Dr. Flannigan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **NEW PRODUCT REVIEWS**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 14: **FUTURE BUSINESS**
14A: Hemophilia Utilization Review
14B: Topical Products Utilization Review
14C: Annual Reviews
14D: New Product Revices and 30-Day Notices
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 15: **ADJOURNMENT**
The meeting was declared adjourned.

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: October 18, 2006

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

From: Shellie Gorman, Pharm.D.
Drug Utilization Review Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of October 11, 2006.

Recommendation 1: Vote to Prior Authorize Omnitrope™ and Zorbtive™

MOTION CARRIED by unanimous approval.

As with all other growth hormones, the College of Pharmacy recommends prior authorization of these two drugs. The criteria are based on the specific indications of each drug.

Omnitrope™

- Criteria established for Classic hGH deficiency for pediatric and adult members

Zorbtive™

- Diagnosis of Short Bowel Syndrome
- Under the care of gastroenterologist
- Documentation of specialized nutritional support (may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences. Nutritional supplements may be added according to the discretion of the treating physician.)
- Used in conjunction with optimal management of SBS may include dietary adjustments, enteral feedings, parenteral nutrition, fluids, and micronutrient supplements as needed.
- Daily dose not to exceed 8 mg
- Approval for 4 weeks of treatment (administration for greater than 4 weeks has not been adequately studied)

Recommendation 2: Vote to Prior Authorize IGF-1 Analog Products Increlex™ and Iplex™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization with the criteria based on the following FDA approved indications for use as listed below.

- Initiation of therapy
  - Therapy initiated by an endocrinologist
  - Diagnosis of Primary IGF-1 Deficiency with all of the following:
    - Height >3 SD below the mean
    - Basal IGF-1 >3 SD below the mean
    - Normal or elevated GH
  - Documentation of mutation in GH receptor (GHR) or mutation in post-GHR signaling pathway or IGF-1 gene defects (Laron Syndrome)
  - Not approved for use in secondary IGF-1 deficiencies related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

- Discontinue therapy

  Therapy may be discontinued when one of the following criteria is met:
  - Epiphyses closed
  - Covered height (165.1 cm. in males, 152.4 cm in females) is reached
  - Sensitivity to mecasermin
  - Member is noncompliant

Recommendation 3: Vote to Prior Authorize Zanaflex Capsules™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Zanaflex Capsules™. Tizanidine tablets must be tried prior to consideration of the capsules. The capsules may be considered for authorization if there is supporting information as to why the member cannot take the tablets.

From: Meyer, Cheryl D. (HSC) [mailto:Cheryl-Meyer@ouhsc.edu]
Sent: Wednesday, November 01, 2006 10:59 AM
To: Nancy Nesser
Subject: Regarding Inhaled Insulin

Dear Ms. Nesser,

It is my understanding that Exubera, inhaled insulin, is under discussion by the Oklahoma Pharmacy board that advises on Medicaid coverage of medications. As a diabetes educator and nurse for many years, the greatest obstacle I have found with Type 2 diabetes patients is the reluctance to start insulin. The phobia of needles and the misunderstanding of what starting insulin means, has frequently resulted in the patients being very ill or suffering severe complications of diabetes before agreeing to using insulin. Instead of prolonging this fear, the inhaled insulin seems to relieve the patients of anxiety and increases compliancy. With increased compliancy, there is less hospital costs and co-morbidity costs of complications due to patient's refusal to take injections. Also, when the cost of multiple oral diabetes medications versus insulin is evaluated, insulin is cheaper.

Every patient that has seen the insulin inhaler has liked the idea and has requested this option be available to them for insulin administration. With the increasing numbers of diabetes in Oklahoma and the increased use of insulin, I feel everyone should have a choice of medication method of administration. If Type 2 patients would start insulin earlier, the risk of complications would be improved and compliancy would be better.

Please consider adding Exubera to the Medicaid pharmacy approved list for the sake of patients and long term financial gains in health care cost Oklahomans would receive.

Thank you for your consideration in this matter.

Cheryl Meyer, RN, CDE
Diabetes Clinician, Insulin Pump Coordinator
Oklahoma Diabetes Center - OUHSC
920 Stanton L. Young Blvd., WP 1345
Oklahoma City, Ok. 73104
www.oklahomadiabetescenter.com
w3.ouhsc.edu/endocrinology/
ph# (405) 271-5896
fax# (405) 271- 7522

APPENDIX B

Retrospective Drug Utilization Review Report

Claims Reviewed for June 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	42,409	51,830	735,448	28,050
Limits which were applied	Established, Major, Males and Females, 0-20 years	Narcotics, Females, age 49-51 years	Contraindicated, Female Age 30-31 years, Pregnancy	High dose, Carbamates, Tingabine, Hydantoins, Oxazolidinedions, Succinimides, Valproic Acid, Misc. Anticonvulsants. Males and Females, Age 66-150
Total # of messages after limits were applied	30	280	170	3
Total # of members reviewed after limits were applied	30	196	106	3

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
138		115	

Retrospective Drug Utilization Review Report

Claims Reviewed for April 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females Age 43-65	Narcotics, Females, Age 42-44	Contraindicated, Age 35-50, Pregnancy	High dose, Carbamates, Tingabine, Hydantoins, Oxazolidinedions, Succinimides, Valproic Acid, Miscellaneous Anticonvulsants, Males and Females, Age 22-40

Response Summary (Prescriber)
Letters Sent: 223
Response Forms Returned: 136

The response forms returned yielded the following results:

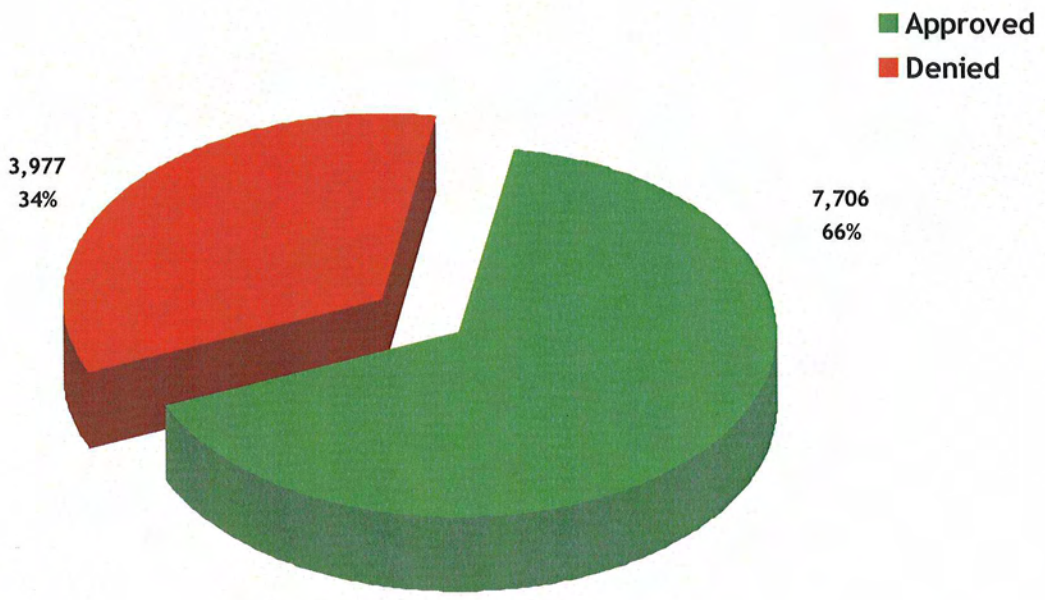
18 (13%)	*Record Error—Not my patient.*
13 (10%)	*No longer my patient.*
7 (5%)	*Medication has been changed prior to date of review letter.*
31 (23%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
40 (29%)	*I am aware of this situation and will plan to continue monitoring therapy.*
27 (20%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 181
Response Forms Returned: 133

The response forms returned yielded the following results:

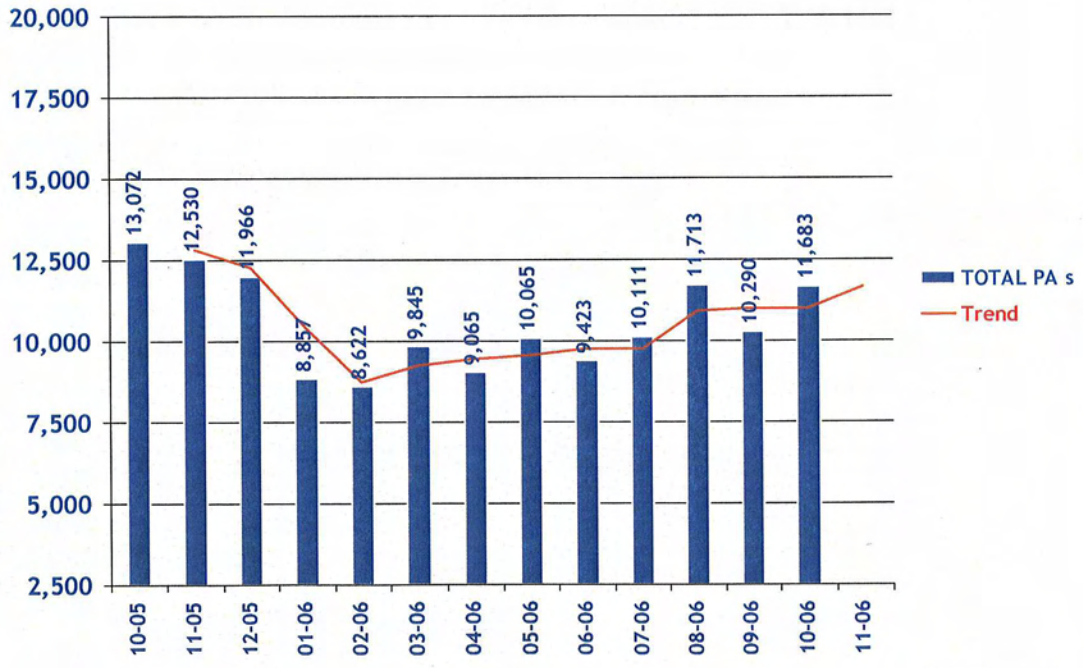
0 (0%)	*Record Error—Not my patient.*
16 (12%)	*No longer my patient.*
4 (3%)	*Medication has been changed prior to date of review letter.*
28 (21%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
61 (46%)	*I am aware of this situation and will plan to continue monitoring therapy.*
24 (18%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
October 2006



PHARMACY Management Consultants

PRIOR AUTHORIZATION REPORT
October 2005 - October 2006



PHARMACY Management Consultants

Activity Audit for
October 01, 2006 Through October 31, 2006

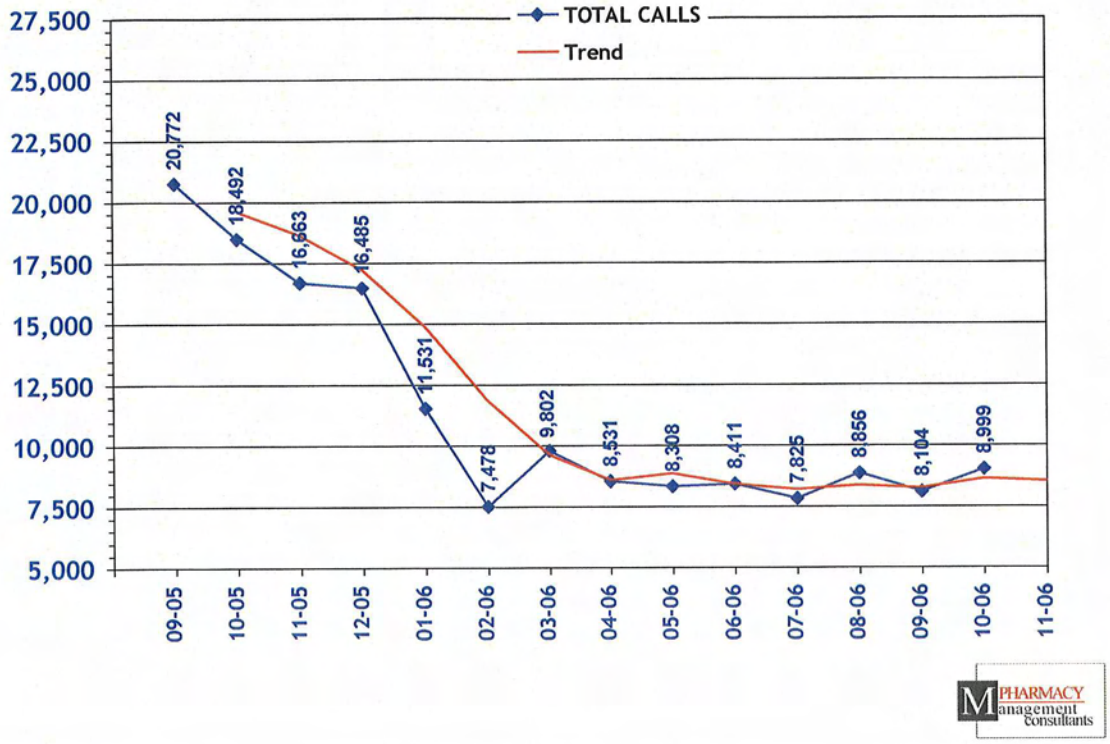
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	157	17	12	29
Angiotensin Receptor Antagonist	133	3	5	8
Antidepressant	225	172	282	454
Antihistamine	108	1141	761	1902
Antiulcers	14	15	4	19
Anxiolytic	107	3448	446	3894
Calcium Channel Blockers	286	19	63	82
Growth Hormones	162	27	0	27
HTN Combos	31	2	0	2
Hypnotics	100	367	167	534
Nsaids	266	30	80	110
Plavix	359	215	44	259
Stimulant	195	769	352	1121
Others	126	1477	1761	3238
Emergency PAs		4	0	4
Total		**7706**	**3977**	**11683**
Overrides				
Brand	254	27	29	56
Dosage Change	13	333	30	363
High Dose	137	2	0	2
Lost/Broken Rx	11	95	10	105
Nursing Home Issue	13	36	2	38
Other	7	29	16	45
Quantity vs. Days Supply	200	239	261	500
Stolen	2	5	6	11
Wrong D.S. on Previous Rx	2	4	8	12
Overrides Total		**770**	**362**	**1132**

Denial Reasons

Lack required information to process request.	3449
Unable to verify required trials.	1117
Does not meet established criteria.	374
Member has active PA for requested medication.	178
Not an FDA approved indication/diagnosis.	158
Considered duplicate therapy. Member has a prior authorization for similar medication.	123
Requested dose exceeds maximum recommended FDA dose.	57
Medication not covered as pharmacy benefit.	47
Duplicate Requests	702
* Changes to existing	947

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

CALL VOLUME MONTHLY REPORT
October 2005 - October 2006



PHARMACY management consultants

Pharmacotherapy Management Program
Quarterly Report FY'07
July 2006 – September 2006
Oklahoma Health Care Authority

	MEMBER PROFILES REVIEWED		PRIOR AUTHORIZATIONS				COMMUNICATIONS	
Month	New Members	Established Members	Total	Approved	Denied	Incomplete	Letters	Calls
July 2006	26	13	211	138	20	53	88	34
Aug 2006	27	47	256	136	21	99	187	42
Sept 2006	8	2	229	115	27	87	31	16
Oct 2006								
Nov 2006								
Dec 2006								
Jan 2007								
Feb 2007								
March 2007								
April 2007								
May 2007								
June 2007								
Totals	61	62	696	389	68	239	306	92
1st Quarter	61	62	696	389	68	239	306	92
2nd Quarter								
3rd Quarter								
4th Quarter								
Totals	61	62	696	389	68	239	306	92

APPENDIX C

Vote to Prior Authorize Fortamet® and Glumetza™ (metformin hydrochloride) Extended Release Tablets

Oklahoma Health Care Authority
November 2006

Glumetza™ Depomed, Inc	Fortamet® Andrx Labs, Inc
Glumetza™ is an extended release metformin hydrochloride tablet indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes (monotherapy). It may also be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults. It utilizes the AcuForm™ Deliver Technology which lengthens the time of the drug in the stomach.	Fortamet® is an extended-release form of metformin hydrochloride designed for once daily administration using the Single-Composition Osmotic Technology (SCOT®) which provides a constant rate of delivery of metformin as long as there is undissolved drug in the core. Fortamet® is indicated for monotherapy as adjunct to diet and exercise and concomitantly with a sulfonylurea or insulin to improve glycemic control in adults.

Cost Comparison

	EAC / unit	SMAC / unit	Average Daily Dose[2]	$ / Month (30 day supply)
Glumetza™ (tablet) 500 mg	$ 1.10		1000 mg QD	$ 66.00
Fortamet® (tablet) 500 mg	$ 1.16		1000 mg QD	$ 69.60
Fortamet® (tablet) 1000 mg	$ 2.74		1000 mg QD	$ 82.20
Metformin ER (tablet) 500 mg	N/A	$ 0.23	1000 mg QD	$ 13.80
Metformin (tablet) 1000 mg	N/A	$ 0.12	1000 mg BID	$ 7.20

Recommendations

The College of Pharmacy recommends prior authorization of Fortamet® and Glumetza™ with approval to be based on clinical documention of inability to take other forms of generic metformin ER.

Reference

Glumetza™ Product Information. Depomed Inc. 2006.
Fortamet® Product Information. Andrx Labs, Inc. 2003.

APPENDIX D

Vote to Prior Authorize Exubera® (insulin human [rDNA origin]) Inhalation Powder

Oklahoma Health Care Authority
November 2006

Manufacturer Pfizer Inc.
Classification FDA classification: Human Insulin Inhalation Powder
Status: prescription only

Summary
Exubera® is an inhaled powder form of recombinant human insulin. It has FDA approval for treatment of adults with type 1 and type 2 diabetes. Efficacy is comparable to subcutaneously injected regular insulin. Onset of action is similar to rapid-acting analogs, however duration of action is the same as regular insulin. Because of this, Exubera® should be given within 10 minutes of a meal. Exubera® is not indicated for monotherapy and does not eliminate the need for longer-acting insulin in patients with type 1 diabetes.

Exubera® is contraindicated in smokers or patients who have discontinued smoking in the past 6 months, or in patients with unstable or poorly controlled lung disease. Pulmonary function should be assessed prior to initiating therapy. Exubera® will be available in 1 mg and 3 mg blisters. Dosing of three 1 mg blisters does not equal a single 3 mg blister (also see equivalent dosing chart below). The Exubera® release unit must be replaced every 2 weeks. Each blister must be administered as a separate inhalation.

Because Exubera® does not require a self-injection, its proposed place in therapy is for patients who delay initiation of insulin therapy due to fear of self-injection. Earlier initiation of insulin therapy could have a positive impact on long-term outcomes. Packaging is based on average dosing of 12 or 15 mgs daily. Variation in dosing may cause issues with wasting or unnecessary purchasing of both strengths.

Approximate guidelines for Initial, Pre-Meal Exubera® Weight-Based Dose

Patient Wt (lb)	Initial Dose per Meal	Number of 1 mg Exubera® Blisters PER Dose	Number of 3 mg Exubera® Blisters PER Dose
66 – 87 lb	1 mg per meal	1	-
88 – 132 lb	2 mg per meal	2	-
133 – 176 lb	3 mg per meal	-	1
177 – 220 lb	**4 mg per meal**	**1**	**1**
221 – 264 lb	**5 mg per meal**	**2**	**1**
265 – 308 lb	6 mg per meal	-	2

Adapted from Exubera® Inhaler Product Dossier, June 2006.

Approximate Equivalent IU Dose of Regular Insulin

Dose (mg)	Approximate Regular Insulin SC Dose (IU)	Number of 1 mg Exubera® Blisters PER Dose	Number of 3 mg Exubera® Blisters PER Dose
1 mg	3	1	-
2 mg	6	2	-
3 mg	8	-	1
4 mg	**11**	**1**	**1**
5 mg	**14**	**2**	**1**
6 mg	16	-	2

Adapted from Exubera® Inhaler Product Dossier, June 2006.

Cost Comparison

	EAC or Fee/ bill unit	SMAC / unit	Average Daily Dose[2]	$ / Month (30 day supply)
Exubera® Kit (1 Inh, 1 Replacement Chamber, 1mg X 180, 3mg X 90, 2 RUs[1]) (Each)	$ 0.61		5 mg TID	$ 164.70
Exubera® Combo Pack 12 (1mg X 90, 3mg X 90, 2 RUs) (Each)	$ 0.68		4 mg TID	$ 122.40
Exubera® Combo Pack 15 (1mg X 180, 3mg X 90, 2 RUs) (Each)	$ 0.57		5 mg TID	$ 153.90
Exubera® Release Units (2 Each)	$ 2.75			$ 5.50
Spirometry[3]	$ 34.27			
Regular Insulin 10 ml	$ 3.32		14 IU TID	$ 41.83
Humalog® 10 ml	$ 7.37		14 U TID	$ 92.86
Humalog® 3 ml Disposable Device	$ 9.49		14 U TID	$ 119.57
Humalog® 3 ml Cartridges	$ 9.55		14 U TID	$ 120.33
Syringes 100 count	$ 0.29			$ 29.00
Pen Needles 100 count	$ 0.89			$ 89.00
Alchohol Swabs 1 box	$ 2.50			$ 2.50
Byetta® 10 mg (2.4 ml)	$ 83.81		10 mg BID	$ 201.14
Avandia® 8 mg (tablet)	$ 5.77		8 mg QD	$ 173.10
Metformin (tablet) 1000 mg	N/A	$ 0.12	1000 mg BID	$ 7.20
Metformin ER (tablet) 500 mg	N/A	$ 0.23	1000 mg QD	$ 13.80

[1]RUs = Release Units
[2]Insulin dosing based on equivalent inhaled dosing of 15 mg.
[3]Average Payment

Recommendations
The College of Pharmacy has the following recommendations for Exubera®:

PRODUR EDITS

1. A quantity limit based on the manufacturer's packaging per 30 days.
2. Members must be 18 years of age or older.

PRIOR AUTHORIZATION

Prior Authorization with criteria as outlined below or as determined by the DUR Board:

Type II Diabetics:

1. Inability to maintain HbA1c levels at or below 7% after a minimum of six months of oral therapy, *and*
2. Diagnosis of injection-phobia, provided no additional injectable medications (including other forms of insulin) are being utilized.
3. *Or* member currently using injectable insulin and experiencing severe persistent problems with injection sites, such as lipohypertrophy.

Type I Diabetics:

1. Currently using injectable insulin and experiencing severe persistent problems with injection sites, such as lipohypertrophy. (Exubera® is not approved as monotherapy in type 1 diabetics.)

For both types:
Patients must not be smokers or have discontinued smoking in the past 6 months, or have unstable or poorly controlled lung disease (asthma, COPD, etc). Pulmonary function must be assessed prior to initiating therapy.

Approval for 6 months with a follow up HbA1c. If HbA1c has not decreased by a minimum of 1% or if not at or below 7%, further renewal will not be granted without supporting information for continued use of the product.

All members who are approved for Exubera® will be enrolled in the Diabetes Disease Management Program, if not already participating.

REFERENCES

1. Exubera® Inhaler Product Dossier. Pfizer Inc. June 2006.
2. Insulin Human Inhaled. In: Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, Colorado (Vol. 129 expires [9/2006]).

APPENDIX E

Annual Review of HMG-CoA Reductase Inhibitors

Oklahoma Health Care Authority
November 2006

Current Prior Authorization Criteria of HMG-CoA Reductase Inhibitors

The class of HMG-CoA Reductase Inhibitors (Statins) was included in the Product Based Prior Authorization program during fiscal year 2004.

HMG-CoA Reductase Inhibitors (Statins)*	
Tier One	*Tier Two*
lovastatin fluvastatin (Lescol® and Lescol XL®) atorvastatin (Lipitor®)	rosuvastatin (Crestor®) pravastatin (Pravachol®) pravastatin/aspirin (Pravagard®) simvastatin (Zocor®) ezetimibe/simvastatin (Vytorin®) lovastatin (Mevacor® Altoprev®) lovastatin/Niacin (Advicor®)

*Tiers as of October 2006

Currently Approved Criteria for Authorization

To qualify for a tier-2 medication, there must be:

1. Previous failure to achieve desired LDL reduction with a preferred statin - defined by at least 6-8 weeks of continuous therapy at standard to high dose.
2. Previous stabilization on non-preferred medication.
3. Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
4. Documented adverse effect or contraindication to the preferred products.

Utilization of Statins

Trends in Utilization of Statins

	Fiscal Year 2006	*Fiscal Year 2005*	*Percent Change*	
Total Cost	$13,088,957.42	$16,859,495.49	Decreased	22.4 %
Total Claims	91,108	118,055	Decreased	22.8 %
Total Clients	26,416	25,354	Increased	4.2 %
Total Days	3,994,114	5,265,562	Decreased	24.1 %
Per-Diem	$3.28	$3.20	Increased	2.5 %

Utilization of Statins by 26,416 Clients during Fiscal Year 2006

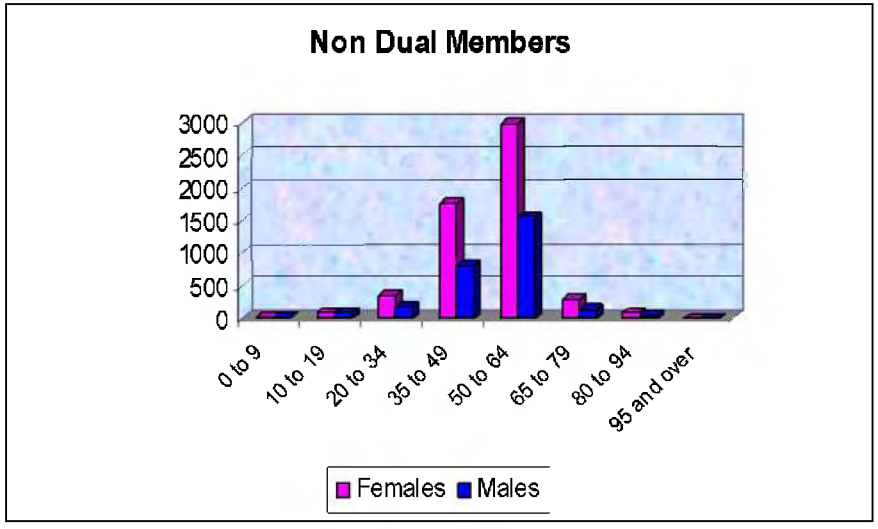
Name of Drug	Total Claims	Total Units	Total Days	Total Costs	Units/Day	PerDiem
atorvastatin (Lipitor®)	45,699	1,991,139	1,996,326	$6,127,679.39	1.00	3.07
simvastatin (Zocor®)	23,789	1,002,575	1,035,845	$4,353,224.08	0.97	4.20
pravastatin (Pravachol®)	4,032	190,628	187,594	$748,220.28	1.02	3.99
rosuvastatin (Crestor®)	5,494	245,359	245,881	$677,315.38	1.00	2.75
lovastatin (generic, Mevacor® Altoprev®)	3,433	152,857	143,656	$155,743.87	1.06	1.08
fluvastatin (Lescol® and Lescol XL®)	1,587	72,499	70,804	$163,566.66	1.02	2.31
lovastatin/niacin (Advicor®)	300	15,244	12,337	$36,973.25	1.24	3.00
pravastatin/aspirin (Pravagard®)	2	180	180	$815.62	1.00	4.53
ezetimibe/simvastatin (Vytorin®)	6,772	300,447	301,491	$825,418.89	1.00	2.74
TOTALS	**91,108**	**3,970,928**	**3,994,114**	**$13,088,957.42**	**0.99**	**3.28**

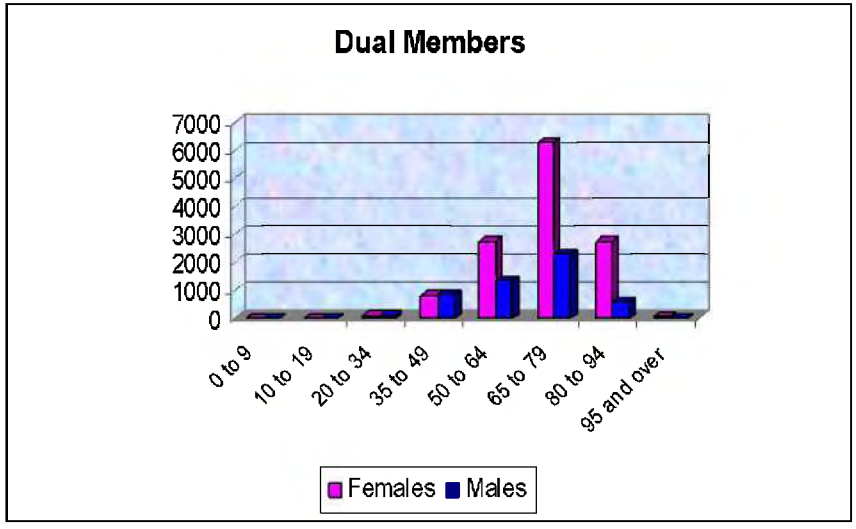
Utilization of Statins by 8,397 Non-Dual Eligible Clients

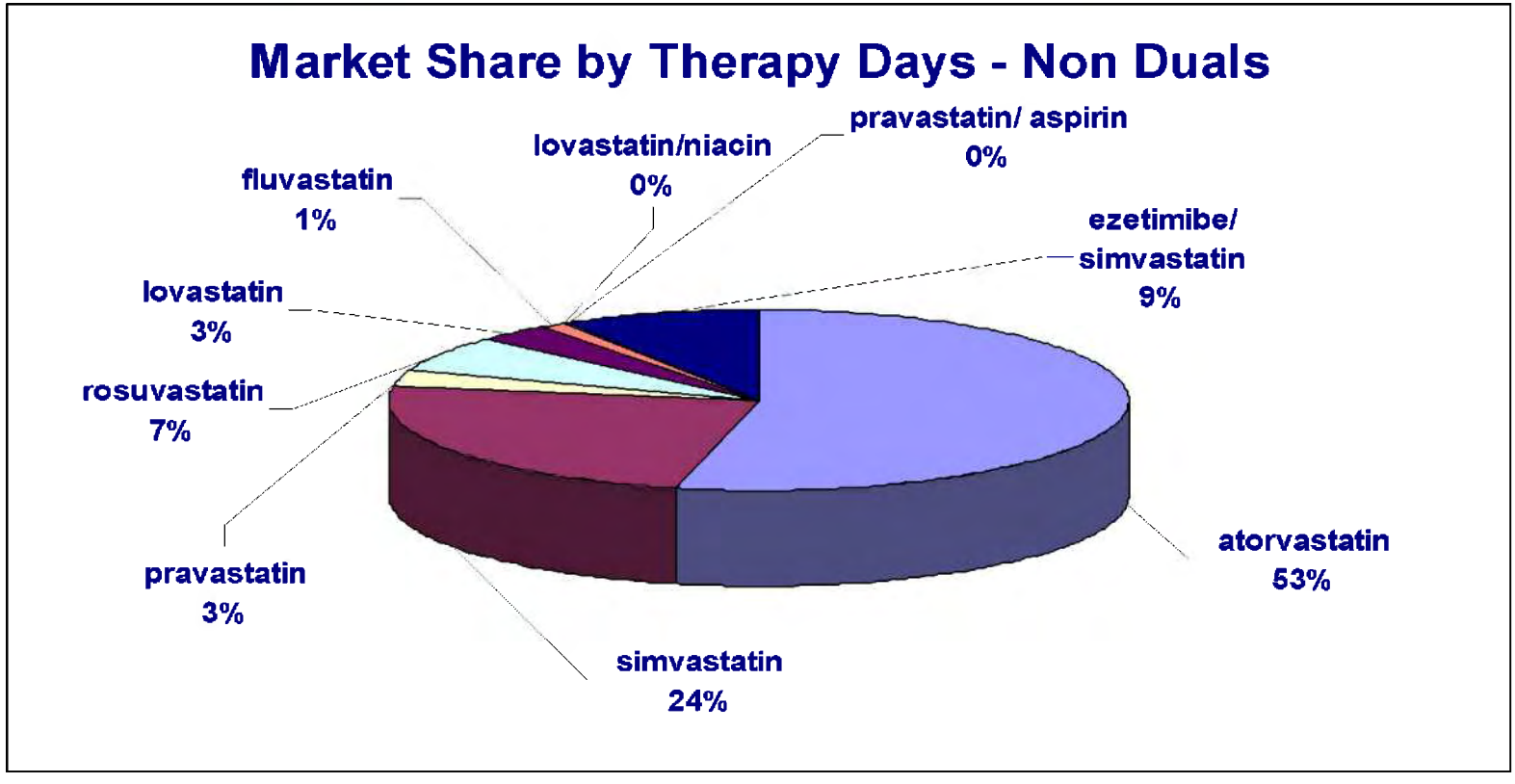
Name of Drug	Total Claims	Total Units	Total Days	Total Costs	Units/Day	PerDiem
atorvastatin (Lipitor®)	19,043	832,846	834,214	$2,629,949.76	1.00	3.15
simvastatin (Zocor®)	8,687	355,234	369,769	$1,579,982.14	0.96	4.27
pravastatin (Pravachol®)	947	45,225	44,384	$182,908.61	1.02	4.12
rosuvastatin (Crestor®)	2,297	101,135	102,970	$287,342.76	0.98	2.79
lovastatin (generic, Mevacor® Altoprev®)	1,071	49,600	46,716	$50,191.25	1.06	1.07
fluvastatin (Lescol® and Lescol XL®)	340	16,481	15,897	$37,918.83	1.04	2.39
lovastatin/niacin (Advicor®)	85	4,290	3,680	$10,418.31	1.17	2.83
pravastatin/aspirin (Pravagard®)	0	0	0	0	0.00	0.00
ezetimibe/simvastatin (Vytorin®)	3,009	135,395	135,753	$373,006.72	1.00	2.75
TOTALS	**35,479**	**1,540,206**	**1,553,383**	**$5,151,748.38**	**0.99**	**3.32**

Utilization of Statins by 18,019 Dual Eligible Clients

Name of Drug	Total Claims	Total Units	Total Days	Total Costs	Units/Day	PerDiem
atorvastatin (Lipitor®)	26,656	1,158,294	1,162,112	$3,497,729.63	1.00	3.01
simvastatin (Zocor®)	15,102	647,341	666,076	$2,773,241.94	0.97	4.16
pravastatin (Pravachol®)	3,085	145,403	143,210	$565,311.67	1.02	3.95
rosuvastatin (Crestor®)	3,197	144,224	142,911	$389,972.62	1.01	2.73
lovastatin (generic, Mevacor® Altoprev®)	2,362	103,257	96,940	$105,552.62	1.07	1.09
fluvastatin (Lescol® and Lescol XL®)	1,247	56,018	54,907	$125,617.83	1.02	2.29
lovastatin/niacin (Advicor®)	215	10,954	8,657	$26,554.94	1.27	3.07
pravastatin/aspirin (Pravagard®)	2	180	180	$815.62	1.00	4.53
ezetimibe/simvastatin (Vytorin®)	3,763	165,052	165,738	$452,412.17	1.00	2.73
TOTALS	**55,629**	**2,430,722**	**2,440,731**	**$7,937,209.04**	**1.00**	**3.25**


Non Dual Members
3000
2500
2000
1500
1000
500
0
0 to 9
10 to 19
20 to 34
35 to 49
50 to 64
65 to 79
80 to 94
95 and over
Females
Males


Dual Members
7000
6000
5000
4000
3000
2000
1000
0
0 to 9
10 to 19
20 to 34
35 to 49
50 to 64
65 to 79
80 to 94
95 and over
Females
Males


Market Share by Therapy Days - Non Duals
pravastatin/ aspirin
0%
lovastatin/niacin
0%
fluvastatin
1%
ezetimibe/
simvastatin
9%
lovastatin
3%
rosuvastatin
7%
pravastatin
3%
simvastatin
24%
atorvastatin
53%

Current and Anticipated Changes in the Class of Cholesterol Lowering Medications

HDL Elevator

Human trials are well under way and the late stage research and development of torcetrapib/Lipitor®, a combination CETP inhibitor/statin, are near completion.

Patent Expirations

Patents have expired on Zocor® and Pravachol® and both products are available generically.

Conclusion and Recommendation

The College of Pharmacy recommends the following tier changes to the HMG-CoA Reductase Inhibitor Class:

HMG-CoA Reductase Inhibitors (Statins)*	
Tier One	*Tier Two*
lovastatin fluvastatin (Lescol® and Lescol XL®) **simvastatin (generic only)←** **pravastatin (generic only)←**	rosuvastatin (Crestor®) **→atorvastatin (Lipitor®)** pravastatin (Pravachol®) pravastatin/aspirin (Pravagard®) simvastatin (Zocor®) ezetimibe/simvastatin (Vytorin®) lovastatin (Mevacor® Altoprev®) lovastatin/Niacin (Advicor®)

Criteria for Authorization

To qualify for a tier-2 medication, there must be:

1. Previous failure to achieve desired LDL reduction with a Tier-1 statin - defined by at least **8-12** weeks of continuous therapy at standard to high dose.
2. Previous stabilization with Tier-2 medication.
3. Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
4. Documented adverse effect or contraindication to the Tier-1 products.

Product Comparison

% LDL Reduction Target[1]	Generic Name	Brand Name	Dosage Forms Available	Usual Adult Dose	Indications	% LDL Reduction	% 2006 Market Share
High to Moderate	Rosuvastatin	Crestor®	5, 10, 20, 40 mg Tabs	10-40 mg QD	1-3, 5	45 - 63	6.63
	Atorvastatin	Lipitor®	10, 20, 40, 80 mg Tabs	10-80 mg QD	1-5	39 - 60	53.70
	Simvastatin/Ezetimibe	Vytorin®	10/10, 20, 40, 80 mg Tabs	10/10-10/80 mg QD	1,5	45-60	8.74
	Simvastatin	Zocor®	5, 10, 20, 40, 80 mg Tabs	5-80 mg QHS	1-5,7	26 - 47	23.80
		Simvastatin	5, 10, 20, 40, 80 mg Tabs	5-80 mg QHS	1-5,7	26 - 47	0.00
Moderate to Low		Altoprev®	10, 20, 40, 60 mg ER Tabs	10-60 mg QD	1-2, 6-7	23 - 40	0.25
	Lovastatin[1]	Lovastatin	10, 20, 40 mg Tabs	10-80 mg QHS or divided doses	1-2, 6-7	28 - 37	2.76
		Pravachol®	10, 20, 40, 80 mg Tabs	40-80 mg QD	1-4,6,7	22 - 37	2.86
	Pravastatin[2]	Pravastatin	10, 20, 40, 80 mg Tabs	40-80 mg QD	1-4,6,7	22 - 37	0.00
Low	Lovastatin/Niacin	Advicor®	20/500, 750, 1000 mg Tabs	20/1000 mg QHS	1-2	30	0.24
	Fluvastatin	Lescol® & Lescol XL®	20, 40 mg Caps & 80 mg XL Tabs	20-80 mg QHS or divided doses	1-2,7	22 - 35	1.02

[1] Mevacor® and Altocor® had no utilization for January 2006 through June 2006.
[2] Pravigard PAC® had no utilization for January 2006 through June 2006.

Indications:
1. Primary hypercholesterolemia (Includes heterozygous familial and nonfamilial hypercholesterolemia)
2. Mixed dyslipidemia (Includes Fredrickson types IIa and IIb)
3. Hypertriglyceridemia (Includes Fredrickson type IV)
4. Primary dysbetalipoproteinemia (Includes Fredrickson type III)
5. Homozygous familial hyperlipidemia
6. Primary prevention coronary events
7. Secondary prevention cardiovascular event(s)

APPENDIX F

Prior Authorization Annual Review - Fiscal Year 2006
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
Oklahoma Medicaid
November 2006

Product Based Prior Authorization

With respect to the non-steroidal, anti-inflammatory drugs (NSAIDs), there are two tiers of drugs in this therapeutic classification.

(A) Tier-2 NSAIDs are approved if the individual has had two tier-1 NSAIDs within the current continuous NSAID therapy. This consists of all NSAID claims that have been sequentially acquired within 120 days of each other and provide medication coverage for the current date. The current continuous NSAID therapy shall then be retrospectively reviewed up to a maximum of 360 days for tier-1 NSAIDs.

(B) After an individual has received tier-2 NSAID coverage, the individual has tier-1 and tier-2 coverage for the duration of their continuous NSAID therapy.

(C) Individuals who have not acquired an NSAID for 120 days will be considered to have discontinued their continuous NSAID therapy and the previous approval will no longer be in effect.

The clinical exceptions for the non-steroidal, anti-inflammatory drugs in tier-2 are demonstrated by the following conditions:

(A) history of upper GI bleeding; or
(B) history of NSAID-induced ulcer, or
(C) active peptic ulcer disease, or
(D) concurrent use of warfarin, or
(E) concurrent chronic use of oral corticosteroids, or
(F) chronic NSAID therapy in elderly or debilitated patients, or
(G) diagnosis of gout – indomethacin only.

These clinical conditions are demonstrated by the documentation sent by the prescribing physician and pharmacist.

NSAIDS	
(Arthritis Medications or Non-Steroidal Anti-Inflammatory Drugs)	
Tier 1	Tier 2
diclofenac ER (Voltaren XR®)	diclofenac sodium/misoprostol (Arthrotec®)
diclofenac potassium (Cataflam®)	celecoxib (Celebrex®)
diclofenac sodium (Voltaren®)	indomethacin (Indocin®)
etodolac (Lodine®)	naproxen sodium (Naprelan®)
etodolac ER (Lodine XL®)	piroxicam (Feldene®)
fenoprofen (Nalfon®)	lansoprazole/naproxen (Prevacid® NapraPAC™)
flurbiprofen (Ansaid®)	meloxicam (Mobic®)
ibuprofen (Motrin®)	
ketoprofen (Orudis®)	
ketoprofen ER (Oruvail®)	
meclofenamate (Meclomen®)	
mefanamic acid (Ponstel®)	
nabumetone (Relafen®)	
naproxen (Naprosyn®)	
naproxen sodium (Anaprox®)	
naproxen EC (Naprosyn EC®)	
oxaprozin (Daypro®)	
sulindac (Clinoril®)	
tolmetin (Tolectin®)	

Changes for Fiscal Year 2006

July 1, 2005: meloxicam (Mobic®) was moved back to tier-2 status (generic available after July 2006) after discontinuation of supplemental rebate agreement.

Utilization – Fiscal Year 2006

For the period of July 2005 through June 2006, a total of 65,912 members received non-steroidal, anti-inflammatory drugs through the Oklahoma Medicaid fee-for-service program.

Tier	# of Claims	Total Units	Total Days	Units /Day	Total Cost	Total Clients	Cost /Client	Cost /Claim
Tier-1	129,082	8,063,728	3,019,158	2.67	$2,786,480.26	63,210	$ 44.08	$ 21.60
Tier-2	13,097	669,476	469,375	1.43	$1,590,679.84	3,741	$ 425.20	$ 121.45
Total	**142,179**	**8,733,204**	**3,488,533**	**2.50**	**$4,377,160.10**	**65,951***	**$ 65.38**	**$ 30.79**

*Total unduplicated clients for FY06

Total Cost FY '06	**$4,377,160.10**
Total Cost FY '05	*$7,808,652.05*
Total Claims FY '06	**142,179**
Total Claims FY '05	*189,663*
Total Clients FY '06	**65,914**
Total Clients FY '05	*71,158*
Per Diem FY '06	**$1.25**
Per Diem FY '05	*$1.55*

Claims were reviewed to determine the age/gender of the clients.

Age	Female	Male	Totals
0 to 9	1,386	1,522	2908
10 to19	11,336	6,737	18073
20 to 34	15,944	1,292	17236
35 to 49	7,369	2,398	9767
50 to 64	6,203	2,625	8489
65 to 79	5,949	2,540	5952
80 to 94	2,814	492	3306
95 and Over	166	17	183
Totals	**49,455**	**16,459**	**65,914**

Claims were also divided into the two tiers and reviewed by age and gender

Number of Members with Tier 1 Claims

Age	Female	Male	Totals
0 to 9	1,383	1,519	2,902
10 to19	11,322	6,728	18,050
20 to 34	15,911	1,267	17,178
35 to 49	7,220	2,304	9,514
50 to 64	5,486	2,364	7,850
65 to 79	3,789	1,305	5,094
80 to 94	2,107	390	2,497
95 and Over	111	14	125
Totals	**47,319**	**15,891**	**63,210**

Tier 2 Claims

Age	Female	Male	Totals
0 to 9	4	3	7
10 to19	43	14	57
20 to 34	103	39	142
35 to 49	343	150	493
50 to 64	722	264	986
65 to 79	878	207	1,085
80 to 94	797	112	909
95 and Over	59	3	62
Totals	**2,949**	**792**	**3,741**

	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Tier -1 Duals	38,129	2,603,300	1,132,904	$1,277,579.33	$1.13
Tier-1 Non-Duals	90,953	5,460,428	1,886,254	$1,508,900.93	$0.80
	129,082	8,063,728	3,019,158	$2,786,480.26	$0.92
Tier-2 Duals	9,030	446,887	324,027	$1,084,889.44	$3.35
Tier-2 Non Duals	4,067	222,589	145,348	$505,790.40	$3.48
	13,097	669,476	469,375	$1,590,679.84	$3.39

Prior Authorizations

Prior Authorizations	No. of Petitions
Approved	1,317
Denied	2,001
Incomplete	822
Denied/Incomplete → Approved	516
	4,140

Type of PA	No. of PA's
Regular	3,922
Super	89
Therapy Management	129
	4,140

Recommendations

The College of Pharmacy recommends moving Meloxicam to tier 1 once a SMAC has been placed on it.

APPENDIX G

Annual Review of Antidepressants

Oklahoma HealthCare Authority

November 2006

Introduction

Four classes of antidepressant medications were included in the Product Based Prior Authorization program during fiscal year 2006. The classes are as follows:

- Dual Acting Antidepressants
- Selective Serotonin Re-Uptake Inhibitors (SSRIs)
- Tricyclic and Tetracyclic Antidepressants (TCAs)
- Monoamine Oxidase Inhibitors (MAOIs)

The following tier-1 drug list is recommended as a clinically acceptable combination for use as initial therapy for the majority of individuals. Tier 2 drugs should be reserved for second line treatment in most cases.

Antidepressants*	
Tier-1	*Tier-2*
Dual Acting Antidepressants	
Mirtazapine (Remeron ,Remeron Soltab)	Duloxetine (Cymbalta)
Trazodone (Desyrel®)	Nefazodone (Serzone®)***
Bupropion (Wellbutrin, Wellbutrin SR®, Wellbutrin XL®)	Venlafaxine (Effexor®, Effexor XR®)
Selective Serotonin Re-Uptake Inhibitors**	
Fluoxetine (Prozac®)	Fluoxetine (Sarafem® and Prozac® weekly) Fluoxetine 10mg and 20mg Tabs and 40 mg Capsules
Citalopram (generic Tabs only)	Citalopram (Celexa®) brand name Tabs and Liquid
Fluvoxamine (Luvox®)	Escitalopram (Lexapro®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)	Sertraline (Zoloft®)
Tricyclics and Tetracyclics	
Desipramine (Norpramin®)	
Nortriptyline (Pamelor®)	
Protriptyline (Vivactil®)	
Amitriptyline (Elavil®)	
Clomipramine (Anafranil®)	
Doxepine (Sinequan®)	
Imipramine (Tofranil-PM®)	
Trimipramine (Surmontil®)	
Amoxapine (Asendin®)	
Maprotiline (Ludiomil®)	
Monoamine Oxidase Inhibitors	
	Phenelzine (Nardil®)
	Tranylcypromine (Parnate®)
	Selegiline (Eldepryl®)

* Mandatory generic plan applies
** Current SSRI tiers based on Supplemental Rebate participation
*** Serzone® has been link to hepatic toxicity.

The following criteria are recommended for approval of a tier-2 product:

1. Approval of tier-2 medication after a recent (within 6 months) 4 week trial and failure on a tier-1 medication. Tier-1 selection can be from any tier-1 anti-depressant classification.
2. Approval of tier-2 medication with a documented adverse effect, drug interaction, or contraindication to tier-1 products.
3. Approval of tier-2 medication with prior stabilization on the tier-2 medication documented within the last 100 days.
4. Approval of tier-2 medication for a unique FDA-approved indication not covered by any tier-1 products.
5. A petition for a tier-2 medication may be submitted for consideration when a unique member specific situation exists or with a prescription written by a psychiatrist.

Quantity Limits

Antidepressants			
Drug	**Quantity Limits**	**Comments**	**FDA Daily**
Mirtazapine (**Remeron**®) Tabs and SolTabs	100 tablets per 100 days	15-45mg QD	45mg
Bupropion (**Wellbutrin**®) Tabs	102 tablets per 34 days	100mg BID – 150mg TID	450mg
Bupropion (**Wellbutrin® SR**) Tabs	100 tablets per 50 days	150mg - 200mg BID	400mg
Bupropion (**Wellbutrin® XL**) sustained release Tabs	100 tablets per 100 days	150mg – 300mg QD	450mg
Venlafaxine (**Effexor®**) Tabs	102 tablets per 34 days	25mg -200mg QD	200mg
Venlafaxine (**Effexor® XR**) Caps	100 capsules per 100 days	37.5mg -225 mg QD	225mg
Duloxetine (**Cymbalta®**)	100 tablets per 100 days	20mg-60mg QD	60mg
Citalopram (**Celexa®**) Tabs	100 tablets per 34 days	20mg-40mg QD	60mg
Escitalopram (**Lexapro®**) Tabs	100 tablets per 66 days	10mg-20mg QD	20mg
Fluoxetine (**Prozac®**) Caps/ Tabs	100 capsules/tablets per 34 days	20mg-80mg QD	80mg
Fluoxetine (**Prozac® Weekly**)	4 caps (1 pack) per 28 days	Half life ~ 7 days	90mg weekly
Fluvoxamine (**Luvox®**) tablets	25mg – 100 tablets per 100 days 50mg – 100 tablets per 50 days 100mg - 102 tablets per 34 days	50mg-300mg QD	300mg
Paroxetine (**Paxil®**) Tabs	10, 20mg - 100 tabs per 100 days 30mg – 100 tabs per 50 days 40mg – 100 tabs per 66 days	20mg-50mg QD	50mg
Paroxetine (**Paxil® CR**) Tabs	100 tablets per 100 days	12.5mg-75mg QD	75mg
Sertraline (**Zoloft®**) Tabs	100 tablets per 50 days	25mg-200mg QD	200mg

Miscellaneous Antidepressant Prior Authorization Categories

1. Fluoxetine 10 and 20 mg Tablet and 40 mg Capsule

- Fluoxetine 10 and 20 mg **tablets** and fluoxetine 40 mg **capsules** require a prior authorization.
- Fluoxetine 10 and 20 mg capsules are a covered benefit with **no** prior authorization required.
- No PA is required for members 12 years of age or under for the fluoxetine 10 and 20 mg tablets.

2. Prozac® Weekly

- The quantity limit for Prozac® Weekly is 3 packs of 4 tablets each (12 week supply).
- Members currently stabilized on Prozac® Weekly should be continued.
- New start members must meet all of the following criteria:
  - Member must have been stabilized on 20 mg daily of fluoxetine for at least 12 weeks.
  - Start date should be 7 days after the last daily dose.
  - Member must have a compelling clinical reason for use of this convenience only product. This product should not be approved for patients in nursing homes or assisted living centers (because medications are administered to patients, so compliance/convenience should not be an issue).
  - Prior authorization can be given for a 12 week supply per petition.

Utilization

For the period of July 2005 through June 2006, a total of 74,034 members received antidepressant medications from the PBPA categories. The following charts outline the trends in utilization:

Utilization Trends of Antidepressants

	Fiscal Year 2005	Fiscal Year 2006	Percent Change	
Total Clients	76,930	74,034	Decreased	3.76 %
Total Claims	495,137	361,919	Decreased	26.9 %
Total Cost	$29,458,361.17	$21,788,867.80	Decreased	26.0 %
Total Days	16,170,173	12,664,242	Decreased	21.7 %
Per Diem	$1.82	$1.72	Decreased	5.49 %

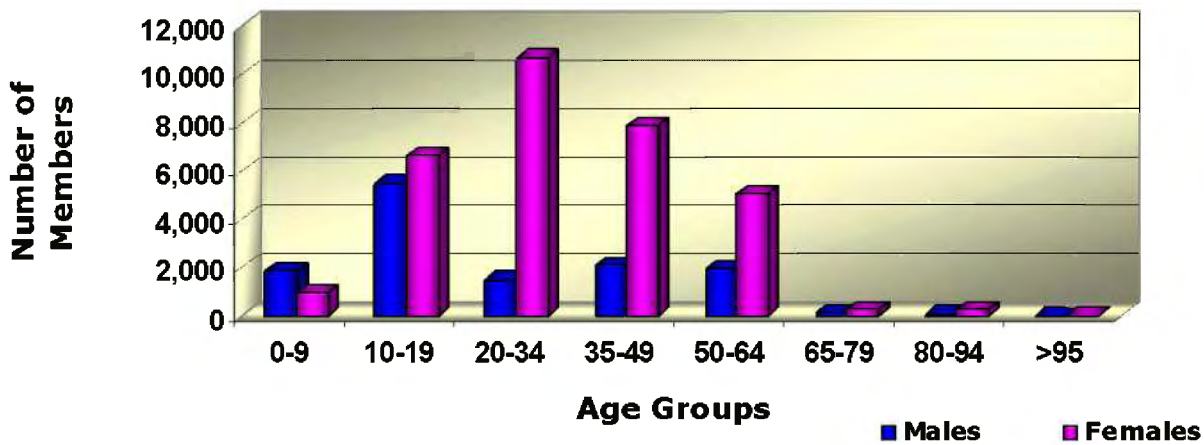
Utilization Comparison between Classes of Antidepressants

	Total Claims	Total Cost	Cost/Claim
Dual Acting Antidepressants	125,195	$8,678,571.96	$69.32
SSRIs	198,868	$12,698,594.72	$63.85
TCAs	37,814	$408,450.97	$10.80
MAOIs	42	$3,250.15	$77.38

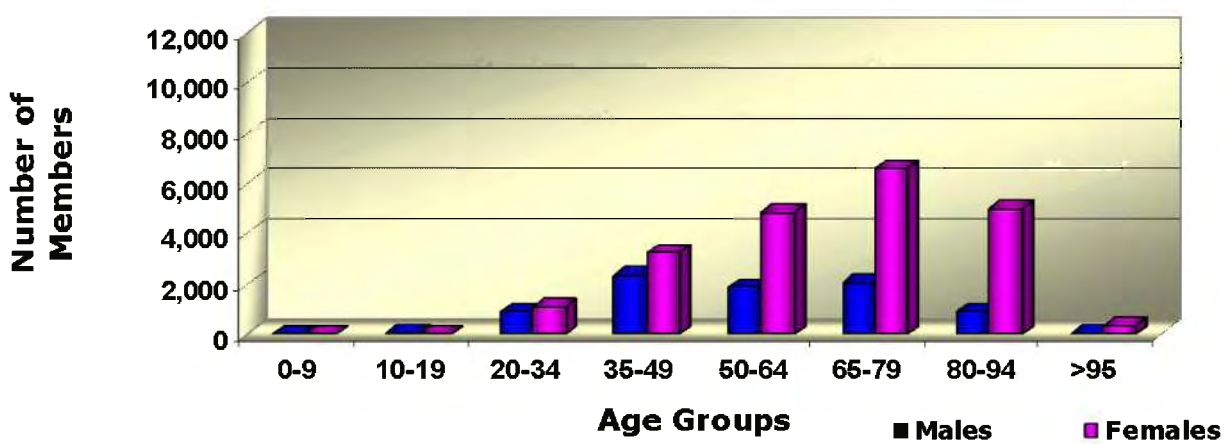
Comparison of Duals vs. Non-Dual Utilization

Groups	Non-Duals	Duals	Total Cost
Dual Acting Antidepressants	$5,600,563.35	$3,078,008.61	$8,678,571.96
SSRIs	$8,062,258.74	$4,636,335.98	$12,698,594.72
TCAs	$270,687.16	$137,763.81	$408,450.97
MAOIs	$680.21	$2,569.94	$3,250.15
Totals FY 2006	$13,934,189.46	$7,854,678.24	$21,788,867.80
Totals FY 2005	$14,121,492.78	$15,336,868.39	$29,458,361.17

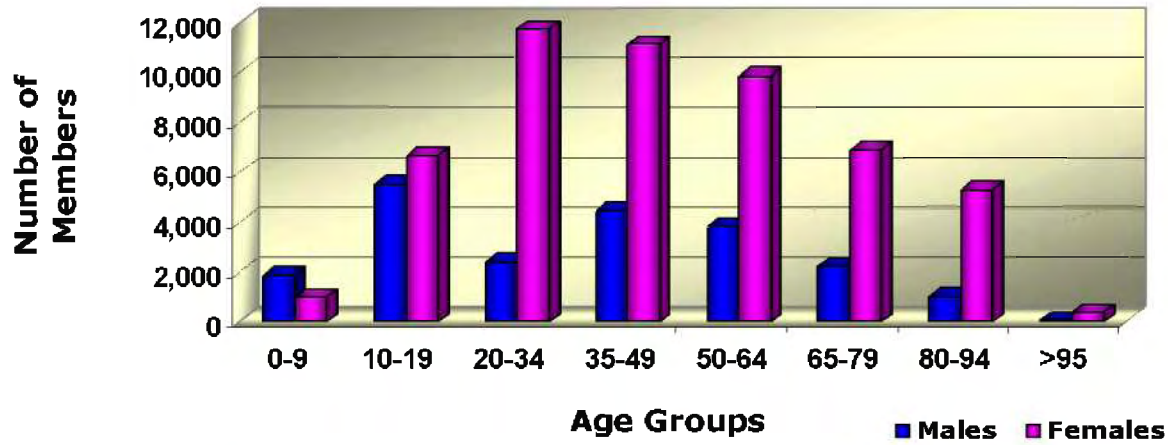
Demographics of Non-Dual Eligible Members Utilizing Antidepressants



Demographics of Dual Eligible Members Utilizing Antidepressants



Demographics of Members Utilizing Antidepressants

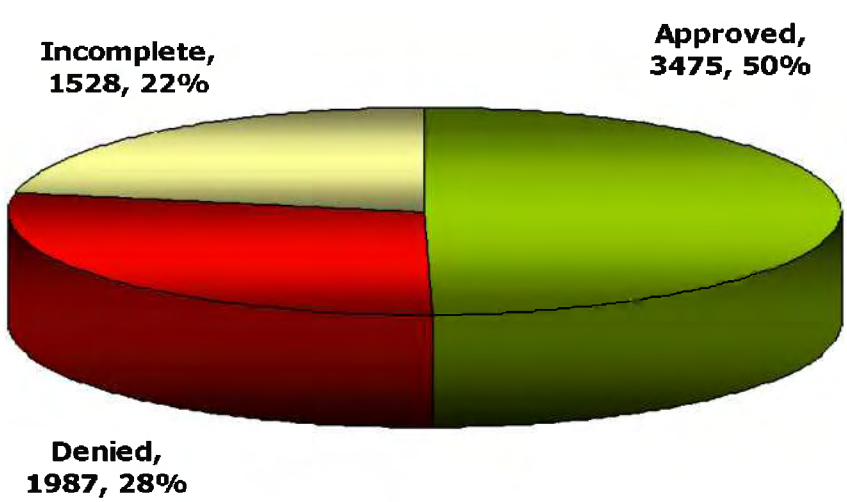


Prior Authorization of Antidepressants

Of the 74,034 members utilizing antidepressants, 4,563 members submitted a total of 6,990 prior authorization requests during fiscal year 2006. The details are as follows:

	Petitions	*Members*
Regular Petitions	**2,396**	**1,637**
Early Refill, Quantity Limit, or High Dose	**4,074**	**2,874**
Therapy Management Petitions	**520**	**367**
TOTALS	***6,990***	***4,563***

Prior Authorization for the Class of Antidepressants



Of the 3,515 petitions that were initially incompleted or denied, 1,406 were eventually approved.

Changes in the Antidepressant Market

- Sertraline (Zoloft®) and immediate release venlafaxine (Effexor®) are now available in generic.
- The MAOI selegiline is now marketed as Emsam® and is available as 6mg/24hr, 9mg/24hr, and 12mg/24hr transdermal patch.
- An NDA has been filed for desvenlafaxine SR in December 2005 and phase III clinical trials have been completed. Desvenlafaxine is a salt form of the isolated major active metabolite of venlafaxine (Effexor®). The patent for venlafaxine ER (Effexor XR®) is expected to expire the 2nd quarter of 2008.
- Novel antidepessants currently in phase III clinical trials include:
  - Agomelatine - melatonin receptor agonist and selective serotonin antagonist
  - Gepirone ER - serotonin 5-HT_{1A} partial agonist
  - Nemifitide - pentapeptide compound adminstered by subcutaneous or needleless injection.
  - Saredutant - neurokinin-2 receptor antagonist
  - Vilazodone - dual selective SSRI and partial 5-HT_{1A} receptor agonist
  - SR 58611 - $beta_3$ adrenorecptor agonist
- The following drugs are in the process of attaining new indications for use as sole or adjunctive treatment of depression or bipolar depresson:
  - Ziprasidone - Geodon®
  - Quetiapine - Seroquel® and Seroquel SR®
  - Lamotrigine - Lamictal®
  - Aripiprazole - Abilify®
  - Divalproex ER - Depakote ER®
  - Ropinirole Cr – Requip® (adjunctive treatment)
  - Olanzapine/fluoxetine – Symbyax® (treatment resistant depression or depression without psychotic features.)

Conclusion and Recommendation

The College of Pharmacy has the following recommendation(s) for Fiscal Year 2007:

- Vote to move the generic sertraline and venlafaxine to tier-1.
- Vote to continue to move drugs from Tier-2 to Tier-1 as they become available as generic and have a SMAC applied.
- Vote to prior authorize Emsam® with the following criteria:

  1. Recent and continuous 4 week trial with at least one agent from each of the other antidepressant classes (the dual acting antidepressants, the SSRIs, and a tricyclic antidepressant) and
  2. A diagnosis indicating that the client has a condition that prevents him/her from swallowing tablet medications.

Utilization Details of Dual Acting Antidepressants

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
MIRTAZAPINE TAB 7.5MG	30	802	817	12	$1,937.47
MIRTAZAPINE TAB 15MG	8,916	264,982	286,757	2632	$138,810.11
MIRTAZAPINE TAB 30MG	6,883	235,707	234,270	1901	$140,700.46
MIRTAZAPINE TAB 45MG	1,556	58,552	58,378	425	$44,127.49
MIRTAZAPINE TAB 15MG ODT	**1,427**	**43,748**	**44,501**	**430**	**$88,509.96**
MIRTAZAPINE TAB 30MG ODT	**1,052**	**34,718**	**33,742**	**321**	**$71,350.12**
MIRTAZAPINE TAB 45MG ODT	**273**	**9,717**	**9,582**	**83**	**$24,341.60**
REMERON TAB 30MG	**22**	**1,090**	**730**	**4**	**$3,508.65**
REMERON SLTB TAB 15MG	2	60	60	1	$160.70
REMERON SLTB TAB 30MG	8	252	252	2	$680.61
REMERON SLTB TAB 45MG	56	1,740	1,740	13	$5,003.53
NEFAZODONE TAB 50MG	12	654	484	8	$319.64
NEFAZODONE TAB 100MG	**174**	**12,302**	**5,914**	**43**	**$5,951.57**
NEFAZODONE TAB 150MG	**174**	**12,509**	**5,701**	**40**	**$6,420.26**
NEFAZODONE TAB 200MG	**175**	**12,166**	**5,724**	**35**	**$5,959.63**
NEFAZODONE TAB 250MG	**28**	**1,737**	**797**	**5**	**$858.01**
DESYREL TAB 50MG	3	360	90	1	$694.80
DESYREL TAB 150MG	3	300	300	3	$869.97
TRAZODONE TAB 50MG	16,475	707,201	534,225	5402	$88,901.54
TRAZODONE TAB 100MG	12,899	637,979	444,150	3923	$94,501.23
TRAZODONE TAB 150MG	**9,674**	**436,244**	**340,218**	**2906**	**$113,109.19**
TRAZODONE TAB 300MG	**339**	**15,539**	**14,320**	**123**	**$57,281 75**
CYMBALTA CAP 20MG	**575**	**27,414**	**17,530**	**233**	**$83,326.80**
CYMBALTA CAP 30MG	**2,585**	**89,912**	**83,715**	**1145**	**$307,102.16**
CYMBALTA CAP 60MG	9,063	324,212	321,664	2737	$1,101,268.00
EFFEXOR TAB 25MG	104	5,453	3,441	30	$9,798.60
EFFEXOR TAB 37.5MG	649	29,103	21,094	287	$53,068.76
EFFEXOR TAB 50MG	79	4,421	2,557	32	$8,125.79
EFFEXOR TAB 75MG	**1,833**	**91,332**	**60,409**	**695**	**$177,957.36**
EFFEXOR TAB 100MG	**110**	**6,757**	**3,515**	**37**	**$14,195.73**
EFFEXOR XR CAP 37.5MG	**1,772**	**57,130**	**54,888**	**861**	**$163,558.57**
EFFEXOR XR CAP 75MG	**9,815**	**400,181**	**365,262**	**3683**	**$1,260,801.35**
EFFEXOR XR CAP 150MG	12,799	593,801	481,256	3464	$2,030,304.09
BUPROPION TAB 75MG	948	43,217	28,008	351	$12,558.79
BUPROPION TAB 100MG	1,348	88,358	43,538	547	$27,319.10
BUPROPION TAB 100MG SR	1,357	60,652	43,536	450	$60,492.46
BUPROPION TAB 150MG SR	**5,646**	**320,863**	**189,207**	**2253**	**$452,726.62**
BUPROPION TAB 200MG SR	**819**	**44,415**	**28,936**	**239**	**$103,355.15**
BUDEPRION TAB 100MG SR	**236**	**11,895**	**8,468**	**89**	**$11,871.80**
BUDEPRION TAB 150MG SR	**2,430**	**134,969**	**79,922**	**1056**	**$189,458.63**
WELLBUTRIN TAB 150MG SR	17	1,140	720	4	$2,646.17
WELLBUTRIN TAB 200MG SR	7	420	210	1	$1,734.71
WELLBUTRIN TAB XL 150MG	5,966	207,645	200,295	2482	$666,405.82
WELLBUTRIN TAB XL 300MG	6,856	249,029	248,967	2158	$1,046,497.21
TOTALS	**125,195**	**5,280,675**	**4,309,890**	**29,632**	**$8,678,571.96**

Utilization Details of Selective Serotonin Re-uptake Inhibitors

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
CITALOPRAM TAB 10MG	1,163	39,591	38,238	404	$11,450.79
CITALOPRAM TAB 20MG	8,041	304,988	289,476	2564	$83,073.07
CITALOPRAM TAB 40MG	6,336	248,130	239,001	1733	$65,332.14
CITALOPRAM SOL 10MG/5ML	53	10,520	1,558	12	$4,647.40
CELEXA TAB 10MG	9	520	520	2	$1,362.49
CELEXA TAB 20MG	8	358	298	3	$920.46
CELEXA TAB 40MG	34	1,636	1,267	7	$4,545.30
CELEXA SOL 10MG/5ML	29	9,000	812	10	$4,526.25
LEXAPRO TAB 5MG	607	19,195	18,892	222	$44,444.41
LEXAPRO TAB 10MG	30,137	1,032,124	1,034,338	10332	$2,441,043.60
LEXAPRO TAB 20MG	21,269	756,815	747,632	6028	$1,866,853.43
LEXAPRO SOL 5MG/5ML	140	35,715	3,428	33	$16,647.63
FLUOXETINE CAP 10MG	5,452	200,431	175,441	1856	$32,398.94
FLUOXETINE CAP 20MG	30,585	1,552,501	1,066,976	8679	$212,572.15
FLUOXETINE CAP 40MG	212	10,984	7,039	83	$12,614.02
FLUOXETINE TAB 10MG	502	14,732	15,566	195	$3,758.73
FLUOXETINE TAB 20MG	16	1,095	480	6	$790.48
FLUOXETINE SOL 20MG/5ML	604	76,510	16,711	161	$10,849.28
PROZAC CAP 10MG	12	760	430	2	$3,195.96
PROZAC CAP 20MG	88	6,672	3,301	17	$28,942.09
PROZAC CAP 40MG	35	1,750	1,190	6	$15,131.06
PROZAC WEEKL CAP 90MG	218	912	6,272	40	$21,648.35
FLUVOXAMINE TAB 25MG	406	15,720	12,760	102	$8,964.70
FLUVOXAMINE TAB 50MG	1,356	61,426	43,523	297	$33,002.10
FLUVOXAMINE TAB 100MG	1,735	106,960	57,097	311	$54,995.62
PAROXETINE TAB 10MG	3,209	110,178	110,235	1031	$90,475.77
PAROXETINE TAB 20MG	12,682	476,475	476,203	4156	$391,597.97
PAROXETINE TAB 30MG	3,142	134,485	115,051	840	$115,512.76
PAROXETINE TAB 40MG	6,805	268,834	263,933	1865	$248,094.50
PAXIL TAB 20MG	14	580	490	6	$1,696.34
PAXIL TAB 30MG	6	378	234	3	$1,115.31
PAXIL TAB 40MG	19	850	642	2	$2,726.02
PAXIL SUS 10MG/5ML	139	45,335	3,772	37	$26,421.30
PAXIL CR TAB 12.5MG	1,533	53,034	52,576	737	$146,638.25
PAXIL CR TAB 25MG	2,961	114,175	107,626	1153	$329,584.91
PAXIL CR TAB 37.5MG	1,277	46,438	46,108	396	$138,353.69
PEXEVA TAB 10MG	19	574	574	3	$1,288.89
PEXEVA TAB 20MG	62	1,910	1,925	31	$4,069.36
PEXEVA TAB 30MG	9	270	300	4	$602.39
PEXEVA TAB 40MG	71	2,586	2,436	24	$6,131.63
ZOLOFT TAB 25MG	4,643	151,209	144,593	1664	$410,992.23
ZOLOFT TAB 50MG	24,810	898,917	857,145	8469	$2,425,203.12
ZOLOFT TAB 100MG	28,254	1,250,811	1,032,718	7552	$3,357,754.36
ZOLOFT CON 20MG/ML	160	14,507	4,938	44	$15,543.15
SARAFEM CAP 10MG	4	112	112	1	$439.36
SARAFEM CAP 20MG	2	168	168	1	$642.96
TOTALS	**198,868**	**8,080,869**	**7,004,025**	**49,562**	**$12,698,594.72**

Utilization Details of Tricyclics and Tetracyclic Antidepressants

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
AMITRIPTYLIN TAB 10MG	2,960	151,354	99,939	1158	$14,903.51
AMITRIPTYLIN TAB 25MG	9,325	501,434	332,133	3516	$47,303.41
AMITRIPTYLIN TAB 50MG	5,791	307,088	221,181	1980	$31,114.86
AMITRIPTYLIN TAB 75MG	1,299	65,723	51,374	380	$8,342.07
AMITRIPTYLIN TAB 100MG	**3,135**	**160,524**	**124,133**	**879**	**$22,763.18**
AMITRIPTYLIN TAB 150MG	**952**	**46,905**	**41,978**	**242**	**$8,499.23**
AMOXAPINE TAB 25MG	**10**	**1,080**	**285**	**2**	**$256.79**
AMOXAPINE TAB 50MG	**31**	**2,526**	**1,008**	**7**	**$2,169.61**
AMOXAPINE TAB 100MG	29	1,502	1,013	6	$2,015.78
CLOMIPRAMINE CAP 25MG	208	15,686	6,681	63	$2,206.27
CLOMIPRAMINE CAP 50MG	406	32,160	12,653	87	$5,954.23
CLOMIPRAMINE CAP 75MG	90	6,977	2,987	22	$2,027.38
ANAFRANIL CAP 50MG	**11**	**1,100**	**363**	**1**	**$6,505.61**
DESIPRAMINE TAB 10MG	**25**	**1,606**	**665**	**12**	**$372.67**
DESIPRAMINE TAB 25MG	**116**	**8,591**	**3,701**	**37**	**$1,495.86**
DESIPRAMINE TAB 50MG	**154**	**10,217**	**5,179**	**35**	**$4,592.02**
DESIPRAMINE TAB 75MG	25	777	741	6	$514.72
DESIPRAMINE TAB 100MG	59	3,131	1,770	8	$2,438.72
DESIPRAMINE TAB 150MG	19	637	637	4	$717.77
NORPRAMIN TAB 50MG	12	2,160	360	1	$3,347.12
DOXEPIN HCL CAP 10MG	**402**	**21,374**	**12,264**	**163**	**$2,587.61**
DOXEPIN HCL CAP 25MG	**1,304**	**87,749**	**42,475**	**430**	**$10,389.57**
DOXEPIN HCL CAP 50MG	**1,136**	**75,873**	**39,342**	**344**	**$10,852.59**
DOXEPIN HCL CAP 75MG	**350**	**21,033**	**12,159**	**96**	**$3,825.91**
DOXEPIN HCL CAP 100MG	884	51,147	31,927	230	$10,951.22
DOXEPIN HCL CAP 150MG	322	16,459	13,137	90	$6,294.75
DOXEPIN HCL CON 10MG/ML	24	7,794	685	7	$640.07
IMIPRAM HCL TAB 10MG	929	52,694	29,699	318	$13,590.33
IMIPRAM HCL TAB 25MG	**2,848**	**159,780**	**91,445**	**856**	**$45,461.17**
IMIPRAM HCL TAB 50MG	**1,907**	**110,204**	**63,223**	**506**	**$41,122.17**
TOFRANIL TAB 25MG	**9**	**1,068**	**270**	**1**	**$2,672.35**
TOFRANIL-PM CAP 75MG	**126**	**5,348**	**4,420**	**44**	**$39,024.62**
TOFRANIL-PM CAP 100MG	54	2,160	1,680	13	$14,895.02
TOFRANIL-PM CAP 150MG	26	1,154	824	7	$7,524.02
NORTRIPTYLIN CAP 10MG	480	24,167	15,638	190	$2,960.89
NORTRIPTYLIN CAP 25MG	1,319	75,318	43,481	509	$8,998.81
NORTRIPTYLIN CAP 50MG	**727**	**37,911**	**25,715**	**221**	**$5,479.06**
NORTRIPTYLIN CAP 75MG	**167**	**8,185**	**7,050**	**48**	**$1,411.68**
NORTRIPTYLIN SOL 10MG/5ML	**22**	**3,488**	**648**	**5**	**$485.06**
PAMELOR CAP 50MG	**5**	**380**	**126**	**1**	**$3,933.02**
VIVACTIL TAB 10MG	30	2,380	980	10	$3,323.74
SURMONTIL CAP 25MG	8	380	230	3	$433.75
SURMONTIL CAP 50MG	17	690	510	3	$1,311.40
SURMONTIL CAP 100MG	3	210	210	1	$553.65
MAPROTILINE TAB 25MG	**20**	**1,011**	**756**	**6**	**$360.61**
MAPROTILINE TAB 50MG	**26**	**2,730**	**845**	**7**	**$1,352.92**
MAPROTILINE TAB 75MG	**12**	**710**	**460**	**4**	**$474.17**
TOTALS	**37,814**	**2,092,575**	**1,348,980**	**11,174**	**$408,450.97**

Utilization Details of Monoamine Oxidase Inhibitors

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
NARDIL TAB 15MG	38	5,110	1,223	6	$2,892.22
PARNATE TAB 10MG	4	430	124	3	$357.93
TOTALS	**42**	**5540**	**1347**	**9**	**$3,250.15**

APPENDIX H

Suboxone® (buprenorphine HCl/naloxone HCl) Utilization July 2005 to June 2006

Oklahoma Health Care Authority
November 2006

Summary[1]

Suboxone® is indicated for the treatment of opioid dependence.

Under the Drug Addiction Treatment Act of 2000 (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements and have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product. Physicians certified to prescribe Suboxone for the treatment of opioid dependence are issued a special DEA waiver and an "X" DEA number. Physicians should write their "X" DEA number on all Suboxone® prescriptions.

Suboxone® contains buprenorphine and naloxone at a ratio of 4:1. Buprenorphine is a partial agonist of the μ-opioid receptor and an antagonist at the κ-opioid receptor. Naloxone is a μ-opioid receptor antagonist.

Comparisons of buprenorphine with full agonists suggest that sublingual buprenorphine produces typical opioid effects but is limited by a ceiling effect. When administered in the sublingual Suboxone® formulation, naloxone has no clinically significant effects although blood levels of naloxone were measurable.

Because Suboxone® contains naloxone, if the tablet is crushed and injected it will produce intense withdrawal symptoms in those patients dependant on opioids such as heroin, morphine, oxycodone, or methadone.

The most commonly reported side effects for Suboxone® include headache (36% vs. 22% placebo), withdrawal syndrome (25% vs. 37% placebo), pain (22% vs. 19% placebo), nausea (15% vs. 11% placebo), insomnia (14% vs. 16% placebo), and sweating (14% vs. 10% placebo).

The recommended target dose of Suboxone® is 16mg/day. The dosage should be progressively titrated in increments/decrements of 2mg or 4mg to a level that holds the patient in treatment and suppresses opioid withdrawal effects. This is likely to be in the range of 4mg to 24mg per day depending on the individual.

Utilization – July 2005 to June 2006

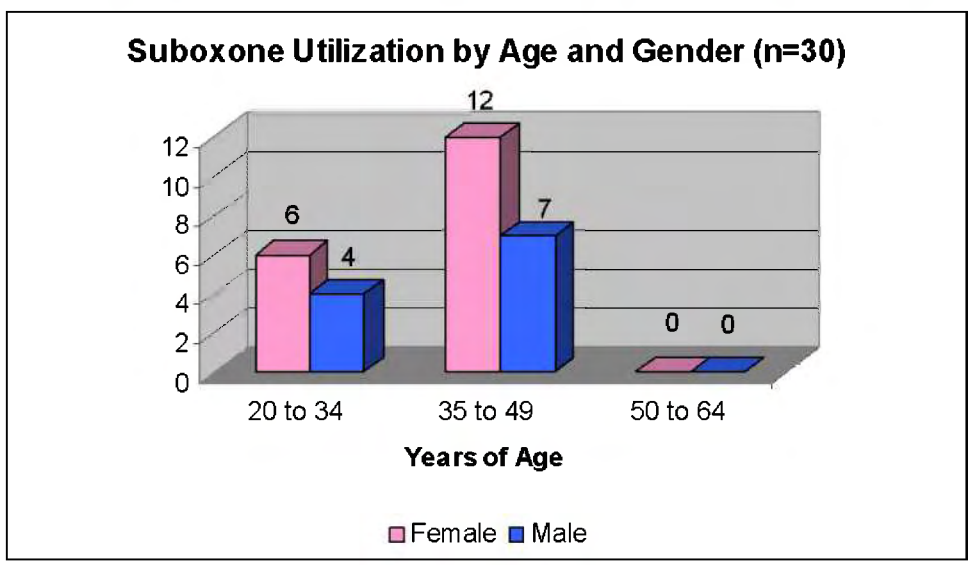
For the period of July 2005 to June 2006, thirty (30) *SoonerCare* members had paid claims for Suboxone®.

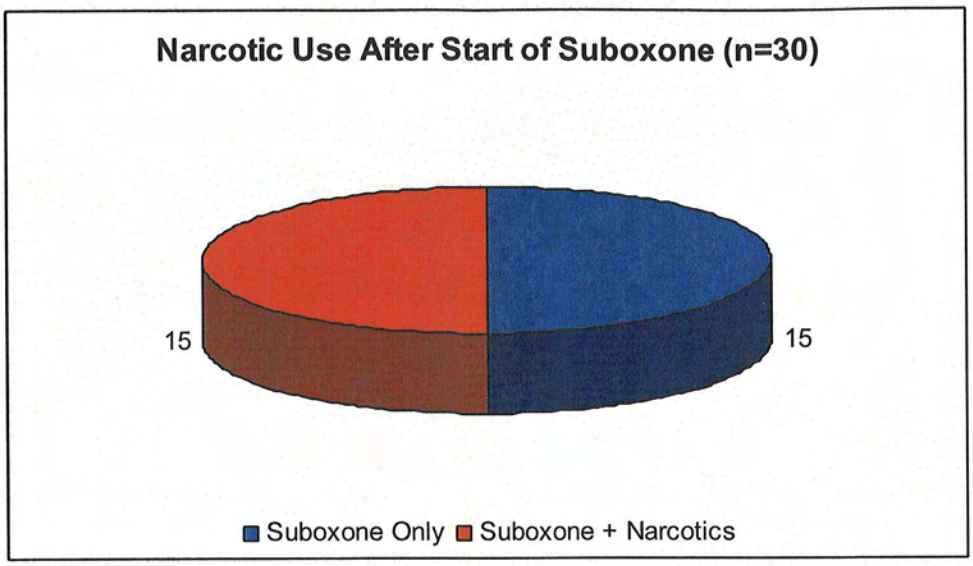
Product	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Suboxone® Sub 2-0.5mg	49	3,270	1,320	$8,684.81	$6.58
Suboxone® Sub 8-2mg	30	1,110	756	$5,201.65	$6.88
	79	**4,380**	**2,076**	**$13,886.46**	**$6.69**

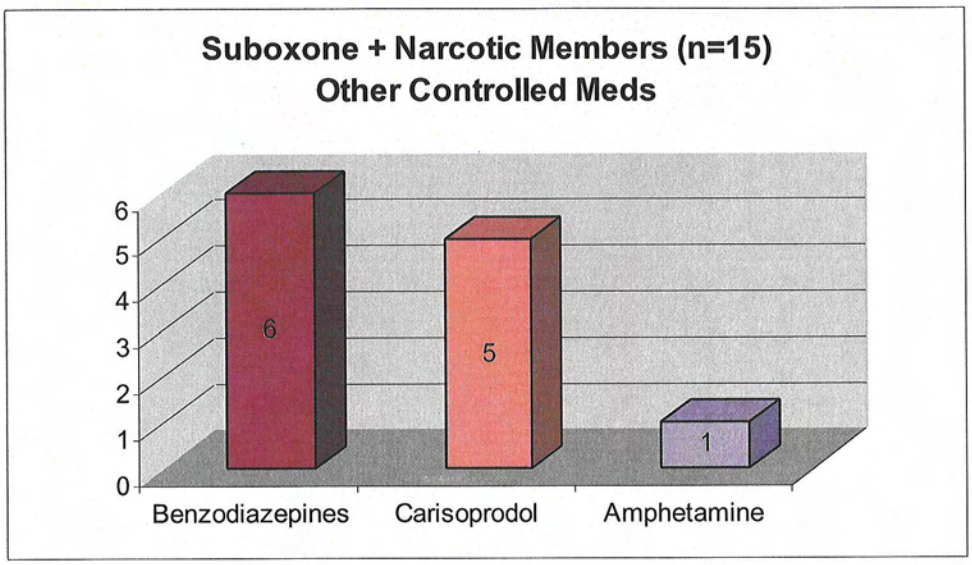
	Fiscal Year 2005	*Fiscal Year 2006*	*Percent Change*
Total Cost	**$3,486.50**	**$13,886.46**	**+ 298%**
Total Claims	**20**	**79**	**+ 295%**
Total Members	**8**	**30**	**+ 275%**
Per Diem	**$ 6.11**	**$ 6.69**	**+ 9.5%**

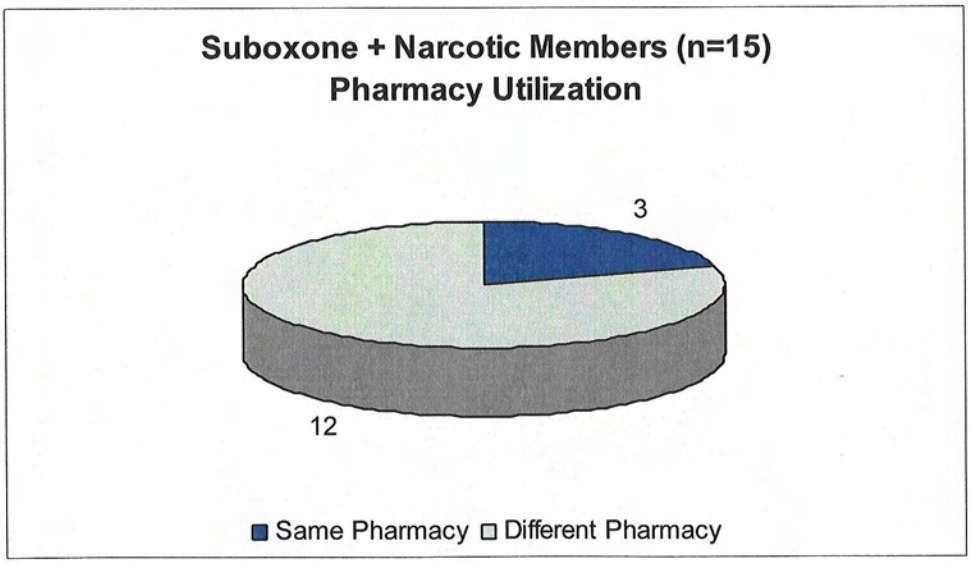
Fiscal Year 2006

	# of Members	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	1	1	28	14	$75.91	5.42
Non-Duals	29	78	4,352	2,062	$13,810.55	6.70

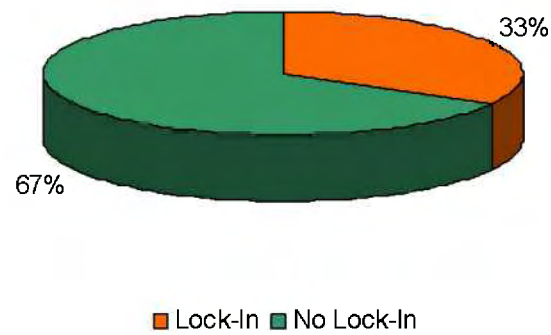



Narcotic Use After Start of Suboxone (n=30)
15
15
Suboxone Only
Suboxone + Narcotics

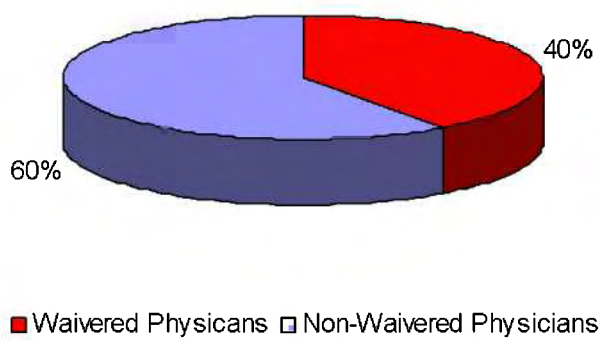

Suboxone + Narcotic Members (n=15)
Other Controlled Meds
6
5
1
0
1
2
3
4
5
6
Benzodiazepines
Carisoprodol
Amphetamine


Suboxone + Narcotic Members (n=15)
Pharmacy Utilization
3
12
Same Pharmacy
Different Pharmacy

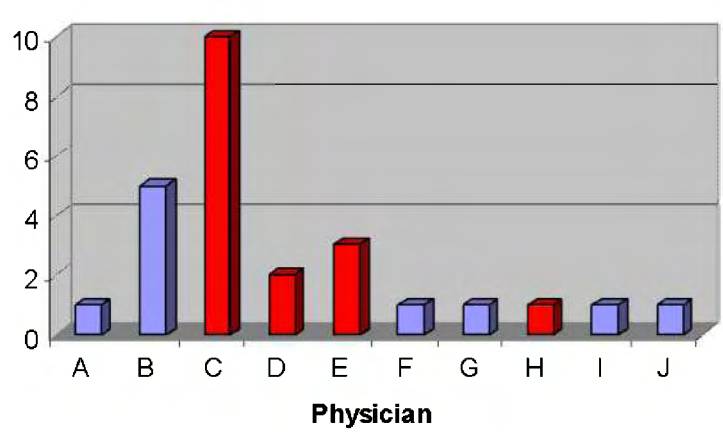
Suboxone + Narcotics Members (n=15)
Lock-In Status



DEA Waivered vs. Non-Waivered Prescribers (n=10)



Members per Physician



Recommendations

The College of Pharmacy has the following recommendations for this category.

1. Refer members receiving Suboxone® to the Lock-In Program for evaluation of narcotic over-utilization issues.
2. Educate pharmacies about Suboxone® prescribing and verifying that the prescribing physician is certified if the medication is to be used for the outpatient treatment of opioid dependence.

Reference

1. Suboxone Product Information. Reckitt Benckiser Pharmaceuticals, Inc. 2005.

APPENDIX I

New Product Summaries

Oklahoma Health Care Authority
November 2006

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP / unit
Omnaris™ (ciclesonide) nasal spray	Altana Pharma US, Inc.	For the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.	The recommended dose is 200 mcg per day administered as 2 sprays (50 mcg/spray) in each nostril once daily. Maximum total dosage should not exceed 2 sprays in each nostril.	Headache (6.0%), epistaxis (4.9%), nasopharyngitis (3.7), ear pain (2.2).	Contraindicated in patients with a hypersensitivity to any of its ingredients	Yes	N/A
Januvia™ (sitagliptin phosphate) tablets	Merck & co., Inc.	It is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. It is indicated for monotherapy, or in combination therapy with metformin or TZDs when the single agent does not provide adequate glycemic control. Not approved for type 1 diabetes or treatment of diabetic ketoacidosis.	100mg Once Daily as monotherapy or as combination therapy with metformin or a TZD.	Abdominal pain (2.3%), nausea (1.4%), diarrhea (3.0%), headache, upper respiratory infection, stuffy or runny nose and sore throat.	None	Yes	N/A

APPENDIX J

FDA News

FOR IMMEDIATE RELEASE
P06-175
October 25, 2006

Media Inquiries:
Laura Alvey, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves New Treatment for Chronic Hepatitis B in Adults

The Food and Drug Administration (FDA) today approved Tyzeka (telbivudine) for the treatment of adults with chronic hepatitis B (HBV), a serious viral infection that attacks the liver and can cause lifelong infection, scarring of the liver (cirrhosis), and eventually liver cancer, liver failure, and death. Tyzeka is a new molecular entity, which is a term used by the FDA to describe a medication containing an active substance that has never before been approved for marketing in any form in the United States.

"In a typical year, an estimated 70,000 Americans become infected with chronic HBV, and some 5,000 of them will die of the complications caused by the disease," said Dr. Steven Galson, Director of the Center for Drug Evaluation and Research. "Tyzeka offers prescribers another option for treating these patients."

Tyzeka was studied in a year-long international clinical trial in 1,367 patients with chronic HBV. Three-quarters of the trial participants were male, and all were 16 years of age or older. The trial produced evidence of antiviral effectiveness, including the suppression of hepatitis B virus, and improvement in liver inflammation comparable to Epivir-HBV (lamivudine), one of five other medications approved to treat patients with chronic HBV.

HBV is spread when blood from an infected person enters the body of a person who is not infected, sometimes by sexual contact or blood contamination. Tyzeka is not a cure for hepatitis B, and long-term treatment benefits of this drug are not known. Use of Tyzeka has not been shown to reduce the risk of transmission of HBV to others through sexual contact or blood contamination.

In clinical studies Tyzeka was generally well tolerated, and most reported adverse events were mild to moderate. The most common side effects were elevated CPK (creatinine phosphokinase, an enzyme that is present in muscle tissue and is a marker for breakdown of muscle tissue), upper respiratory tract infection, fatigue, headache, abdominal pain and cough.

Also, after several weeks to months of Tyzeka use, some patients developed symptoms ranging from transient muscle pain to muscle weakness. Those who developed muscle weakness experienced significant improvement in their symptoms when Tyzeka was discontinued.

Patients should only stop Tyzeka after a careful discussion with their doctor. As has happened with other forms of treatment for hepatitis B, some patients who discontinued Tyzeka experienced a sudden and severe worsening of their hepatitis B. Therefore, patients who discontinue Tyzeka should be closely monitored by their doctor for at least several months.

Among drugs in the same class as Tyzeka, some cases of lactic acidosis (too much acid in the body due to buildup of lactic acid) and severe enlargement and accumulation of fat in the liver, including fatal cases, have been reported.

Tyzeka is manufactured by Novartis Pharma Stein AG, Stein, Switzerland and marketed and distributed by Idenix Pharmaceuticals, Inc., Cambridge, MA.

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FDA News

FOR IMMEDIATE RELEASE
P06-174
October 23, 2006

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888-INFO-FDA

FDA Updates its Nationwide Alert on Counterfeit Blood Glucose Test Strips

On October 13, 2006, the U.S. Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the United States for use with various models of LifeScan, Inc., One Touch Brand Blood Glucose Monitors. These test strips are used by people with diabetes to measure their blood glucose. Today's announcement provides two additional lot numbers that are included in the distribution of counterfeit products, along with descriptions of how to identify them.

The counterfeit test strips are:

- One Touch Basic®/Profile® (lot #272894A, 2619932, 2606340, and 2615211 **(new)**) test strips; and,
- One Touch Ultra® (lot #2691191 and 2691261 **(new)**) test strips.

The counterfeit test strips potentially could give incorrect blood glucose values--either too high or too low--which might result in a patient taking either too much or too little insulin and lead to serious injury or death.

LifeScan alerted FDA of the counterfeit test strips. The FDA continues to investigate the matter, including whether there have been any adverse events associated with this counterfeit product.

Consumers who have the counterfeit test strips should stop using them, replace them immediately and contact their physician. Consumers with questions may contact Lifescan, Inc. at 1-866-621-4855. Consumers who have discarded the outer box or do not know the lot number of their test strips should stop using those test strips and replace them.

The counterfeit test strips were distributed to pharmacies and stores nationwide by various distributors.

How to Identify

For complete information on how to identify the counterfeit test strips, please check Lifescan's web site at www.lifescan.com/company/about/press/counterfeit/.

The following characteristics may help to identify the counterfeit test strips:

Counterfeit One Touch Basic/Profile Test Strips, lot numbers 272894A, 2619932, and 2606340

- The lot number 272894A, 2619932, or 2606340 appears on the outer carton and on the inner container (vial).
- The outer carton is written in multiple languages including English, Greek and Portuguese.
- The outer carton is labeled as 50-Count One Touch (Basic/Profile) Test Strip packages
- The bottom of the outer carton does not include an NDC number.

Counterfeit One Touch Basic/Profile Test Strips, lot number 2615211

- The lot number 2615211 appears on the outer carton and on the inner container (vial).
- The outer carton is written in English.
- The outer carton is labeled as 50-Count One Touch (Basic/Profile) Test Strip packages.
- A picture of a hand appears on the test strip displayed on the outer carton.
- The inner container is labeled as "plasma-calibrated".

Counterfeit One Touch Ultra Test Strips, lot numbers 2691191 and 2691261

- The lot number 2691191 or 2691261 appears on the outer carton and on the inner container (vial).
- The outer carton and the inside container (vial) are written in both English and French.
- The outer carton is labeled as 50-Count One Touch Ultra Test Strip packages.
- The bottom of the outer carton does not include an NDC number.

On October 13, 2006, LifeScan alerted the public via a press release and notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advised customers to contact their original source of supply for restitution. For more information, visit: www.Lifescan.com.

On October 13, 2006, FDA alerted its Counterfeit Alert Network partners, a coalition of healthcare professional, consumer and trade associations, who have agreed to further disseminate this important information in a timely and effective manner. For more information about this and other counterfeit products, visit: www.fda.gov/counterfeit/.

Any adverse reactions experienced with the use of this product, and/or quality problems should 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, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787, or through the MedWatch Web site at www.fda.gov/medwatch.

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FDA Press Release (Oct. 13, 2006)

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