Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

Wednesday

September 12, 2007

@ 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 – September 12, 2007**

DATE: September 6, 2007

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

Enclosed are the following items related to the September 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 Ophthalmic Anti-Infective Products – **See Appendix C.**

Action Item – Vote to Prior Authorize Omnaris™ and Veramyst™ – **See Appendix D.**

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

Action Item – Vote to Prior Authorize Brovana™ – **See Appendix F.**

Action Item – Vote to Approve Updated Maintenance Drug List – **See Appendix G.**

Action Item – Narcotic Utilization Review – **See Appendix H.**

30 Day Notice to Prior Authorize Lidoderm®– **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – September 12, 2007 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. McNeill, Chairman:

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

A. July 11, 2007 DUR Minutes – Vote
B. July 13, 2007 DUR Recommendations Memorandum

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 April 2007
B. Retrospective Drug Utilization Review for May 2007
C. Retrospective Drug Utilization Review Response for January 2007
D. Retrospective Drug Utilization Review Response for February 2007
E. Medication Coverage Activity Audit for July 2007
F. Medication Coverage Activity Audit for August 2007
G. Help Desk Activity Audit for July 2007
H. Help Desk Activity Audit for August 2007
I. Pharmacotherapy Management Annual Report FY 2007

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

5. Action Item – Vote to Prior Authorize Ophthalmic Anti-Infective Products – See Appendix C.

A. COP Recommendations
B. PA Criteria

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

6. Action Item – Vote to Prior Authorize Omnaris™ and Veramyst™ – See Appendix D.

A. Product Summary
B. COP Recommendations
C. PA Criteria

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

7. Action Item – Vote to Prior Authorize Exforge® – See Appendix E.

A. Product Summary
B. COP Recommendations
C. PA Criteria

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

8. Action Item – Vote to Prior Authorize Brovana™ – See Appendix F.

A. Product Summary
B. COP Recommendations
C. PA Criteria

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

9. Action Item – Vote to Approve Updated Maintenance Drug List – See Appendix G.

A. Introduction
B. Recommended Maintenance Drug List

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

10. Action Item – Narcotic Utilization Review – See Appendix H.

A. Utilization Review
B. Current Restrictions
C. Market Changes
D. COP Recommendations

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

11. 30 Day Notice to Prior Authorize Lidoderm® – See Appendix I

A. Product Summary
B. Utilization Review
C. COP Recommendations
D. PA Criteria

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Utilization Review of Antifungals
B. Utilization Review of Osteoporosis Products
C. Annual Reviews
D. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JULY 11, 2007

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

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
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.; Principal Investigator	X	
Visiting Pharmacy Students: Mai Nguyen, Michelle Coady	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:

Burt Matthews	Randy McGinley, Bayer	Jay Schafer, Bayer
Lon Lowrey, Novartis	John Omick, Novartis	Jim Maxsun, EMD Serono
Chaney Horn, Alcon	Janie Huff, TAP	Paul Sparks, Allergen
Edward DePaz, Shire	Aliza Tomlinson, OMJPS	Richard Ponder, J&J
Laura Mitchell, Purdue	Michael Mason, Alcon	Aaron Walker, Schering-Plough
Jim Dunlap, Eli Lilly	Vince Morrison, Forest	Tim Hambacher, Abbott Diabetes Care
Brian Shank, Aztra Zeneca	Justin Springfield, Sepracor	

PRESENT FOR PUBLIC COMMENT:	
Patrick Harvey, Sepracor	Agenda Item No. 7
John Omick, Novartis	Agenda Item No. 8
William Chapman, Alcon	Agenda Item No. 9

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

1A: Roll Call

Dr. McNeill 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**

Dr. McNeill acknowledged speakers for Public Comment.

ACTION: NONE REQUIRED.

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

3A: June 13, 2007 DUR Minutes

Dr. Meece moved to approve minutes as submitted; seconded by Dr. Muchmore.

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: March 2007

4B: Retrospective Drug Utilization Review Response: October 2006

4C: Medication Coverage Activity Report: June 2007

4D: Help Desk Activity Report: June 2007

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE OPHTHALMIC GLAUCOMA PRODUCTS**

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

Dr. Meece moved to approve; seconded by Dr. Muchmore.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE TOVALT™ ODT**

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

Dr. Muchmore moved to approve; seconded by Dr. Gourley.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **30-DAY NOTICE TO PRIOR AUTHORIZE BROVANA™**

For Public Comment, Patrick Harvey: Thank you for allowing me to come today. I'm a clinical pharmacist for Sepracor and I'd like to thank the school of pharmacy for their work on the review of Brovana . . . you're aware. You can see in your folder is it's the only, the first and only available long acting nebulized beta-2 agonist at this time. The school of pharmacy did a good job on the review. The one comment I would like to make is on the recommendation number two where it is recommending the member must have a previous trial of Advair, Serevent or Foradil in the past 45 days. This product is in a nebulized form and as such, we're marketing this product as for those according to the GOLD guidelines which would be for moderate to severe to very severe COPD that are already on a nebulized solution. We have prepared this not to take away utilization . . . already on Advair, Serevent or Foradil. It's for those that are unable to manipulate maybe a metered dose inhaler or have reached or progressed to a point where they're already on the nebulized solution. This solution by being a 12-hour action allows those people a little more freedom to get out of the house and maybe do some grocery shopping or shopping, maybe work parttime or something, which they're not tied to a nebulized solution for that time. According to the GOLD guidelines this is just for those with the moderate to severe, you're only talking about, according to IMS there's only about 25% of your COPD'ers that are on a nebulized solution already, so according to CMS, they just reviewed this for Medicare Part B, their recommendation is to have a failure of a short-acting beta agonist for those that are on a regular four time a day use of a short acting beta agonist instead of Advair, Serevent or Foradil, so that's basically all that I had to add to this. If anybody's got any questions I'd be glad to try to guarantee you the answer for those.

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

ACTION: NONE REQUIRED.

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

For Public Comment, John Omick: Good evening. My name's John Omick. I'm not a doctor. I'm a regional account manager with Novartis. That made Evie laugh. She is a doctor and she reminds me of it every day. As a regional account manager of Novartis, I just thought I'd come up to say a few words about our newest product for the treatment of hypertension. That's Exforge. I just passed out to each of you a product fax sheet. I know you have information in your packets about Exforge, but I thought I'd just cover a couple of key points about what this product actually is. Exforge is a line extension of the Diovan family. It combines valsartan and amlodipine into one pill in a fixed dose combination of 5-160, 10-160, 5-320 and 10-320. It is for the treatment of hypertension specifically as our indication. We don't have any other indications other than that. That's one point I wanted to speak about with regards to the recommendations from the College of Pharmacy. Keeping in mind studies have shown that many patients need more than one product to control hypertension. Many times it's two, three, maybe even four and low fixed dose combinations may be the answer to help them obtain their goal. Diovan in the line of families we have, as you know we have Diovan HCT and now Exforge. If you take a look at the last page of the product fact sheet, the WAC price shows that Exforge is actually priced along with Diovan HCT. We're trying to make it very affordable for the patient and for the Oklahoma Health Care Authority for utilization. With regards to the College of Pharmacy recommendation we would agree that as a product that should be used after independent products such as amlodipine, an ARB, an ACE inhibitor or a calcium channel blocker does not bring your patient to goal but Exforge will be made available for that patient, so ... the fourth item that you have though, is an indication other than hypertension. That really wouldn't apply to Exforge, so I just wanted to make sure that was clear. And I would be glad to answer any questions with regards to Exforge as long as they're not from Evie Knisely. That was a joke.

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **30-DAY NOTICE TO PRIOR AUTHORIZE OPTHALMIC ANTI-INFECTIVES**

For Public Comment, William Chapman: I'm here to talk about Vigamox between ..... I'm a ..... first of all, my name is William Chapman. I'm a pediatrician and I worked for 20 some years. Private practice . . . see a lot of Medicaid patients, about 60% of the practice is that ..... can you hear me in the back? OK. And the situation we have here with the effective medications to be pre-approved in a situation where it just adds more load to the office staff and makes patients wait for effective treatment, and actually complicates life a little more. By the way on the nursing sides when she has to call this in, and also because you have to get a lot more phone calls from patients and parents where you have to use medication four times a day with babies who won't let you do that, and it's not as easy and also because they are not getting better and three or four days later their eyes are worse and that's pretty (unintelligible) they end up going to emergency room from something that could have been just real easily taken care of with an effective medication. They might also end up going to specialty, seeing the specialty eye doctor for something that could have been easily handled at the pediatrics office with a very effective medication. And so my point is that we keep this medication more available for us to use on a primary care basis without having to delay the patient right to use it would be very good for the patients (unintelligible).

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE OMNARIS™ AND VERAMIST™**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **UTILIZATION REVIEW OF ERYTHROPOIESIS STIMULATING AGENTS**

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

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**

13A: Utilization Review of Narcotics

13B: Utilization Review of Antifungals

13C: Annual Reviews

13D: New Product Reviews

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 14: **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: July 13, 2007

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 July 11, 2007.

Recommendation 1: Vote to Prior Authorize Ophthalmic Glaucoma Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Ophthalmic Glaucoma Products to the PBPA program with the following approval criteria:

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

Tier 1	Tier 2
Beta-Blockers	
Betagan 0.25%,0.5% (Levobunolol) Optipranolol 0.3% (Metipranolol) Timoptic, Betimol, Istalol, Timoptic Ocudose, Timoptic XE 0.25,0.5% (Timolol Maleate) Cartrol, Ocupress 1% (Carteolol) Betoptic-S 0.5% (betaxolol)	Betoptic-S (betaxolol) Cosopt (Dorzolamide and Timolol)* Timoptic 0.5% Dropperette
Prostaglandin Analogs	
Xalatan (Latanoprost)*	Lumigan (Bimatoprost) Travatan, Travatan Z (Travoprost)
Adrenergic Agonists	
Propine (Dipivefrin)	
Alpha-2 Adrenergic Agonists	
Brimonidine 0.2%	Alphagan P 0.1, 0.15% (Brimonidine) Iopidine 1% Apraclonidine
Carbonic Anhydrase Inhibitor	
Available Oral Products: Acetazolamide (Diamox®) Dichlorphenamide (Daranide®) Methazolamide (Neptazane®)	Azopt (Brinzolamide) Trusopt (Dorzolamide) Cosopt (Dorzolamide and Timolol)*
Cholinergic Agonists/Cholinesterase Inhibitors	
Isopto Carpine, Pilopine HS 0.5,1,2,4,6 %(Pilocarpine)	Isopto, Miostat 1.5, 3% (Carbachol)[1] Phospholine Iodide (Echothiophate Iodide)[2]

* Current portfolio supplemental rebate agreement participation

Recommendation 2: Vote to Prior Authorize Tovalt ODT™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Tovalt ODT™ as a third tier in the Insomnia PBPA category. Approval based on a diagnosis of insomnia and an additional diagnosis indicating member has a condition that prevents them from swallowing crushed regular release tablets. All other PBPA category criteria apply. A quantity Limit of 30 units for 30 days will also be applied.

Tier 1	Tier 2	Tier 3
estazolam temazepam flurazepam triazolam zolpidem Ambien CR® Rozerem® Lunesta®	Sonata® Restoril® 7.5 and 22.5 mg	Tovalt ODT™

Supplemental rebate participation.

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for April 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	39,727	59,673	614,110	31,178
Limits which were applied	Established, Major, Males and Females, Age 56-65	Amphetamines/ Stimulants, Males and Females, age 0-9, Duplication in extended release products only.	Contraindicated, Males and Females 0-16 years, Pregnant	Duration, Heparins, Males and Females, age 0-150
Total # of messages after limits were applied	29	135	25	80
Total # of members reviewed after limits were applied	29	135	21	80

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
32		31	

Retrospective Drug Utilization Review Report

Claims Reviewed for May 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	40,653	59,981	608,148	31,933
Limits which were applied	Established, Major, Males and Females, Age 66-150	Amphetamines/ Stimulants,Males and Females, age 10-15 years old, Duplication in extended release products only.	Contraindicated, Males and Females 17-18 years, Pregnant	High dose only, Benzodiazepine, 0-18 years old
Total # of messages after limits were applied	3	286	43	1
Total # of members reviewed after limits were applied	3	286	37	1

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
53		70	

Retrospective Drug Utilization Review Report

Claims Reviewed for January 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 22-35	Anti-anxiety Agents, Males and Females, Age 51-57	Contraindicated, Hyperthyroidism, Males and Females, Age 0-150	High dose, Strattera, Males and Females, Age 0-7

Response Summary (Prescriber)
Letters Sent: 71
Response Forms Returned: 31

The response forms returned yielded the following results:

1 (3%)	*Record Error—Not my patient.*
7 (23%)	*No longer my patient.*
1 (3%)	*Medication has been changed prior to date of review letter.*
8 (26%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
12 (39%)	*I am aware of this situation and will plan to continue monitoring therapy.*
2 (6%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 17
Response Forms Returned: 8

The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
2 (25%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
2 (25%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
3 (38%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (13%)	*Other*

Retrospective Drug Utilization Review Report

Claims Reviewed for February 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 36-45	Anti-anxiety Agents, Males and Females, Age 58-65	Contraindicated, Glaucoma, Males and Females, Age 0-150	High dose, Strattera, Males and Females, Age 8-10

Response Summary (Prescriber)
Letters Sent: 59
Response Forms Returned: 42

The response forms returned yielded the following results:

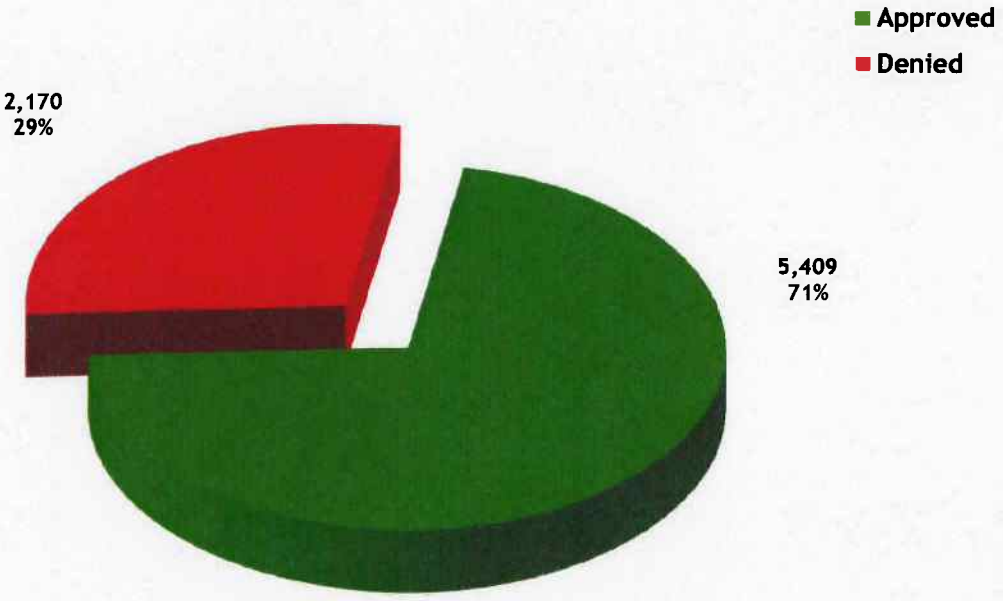
6 (14%)	*Record Error—Not my patient.*
2 (5%)	*No longer my patient.*
1 (2%)	*Medication has been changed prior to date of review letter.*
5 (12%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
22 (52%)	*I am aware of this situation and will plan to continue monitoring therapy.*
6 (14%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 25
Response Forms Returned: 19

The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
1 (5%)	*No longer my patient.*
2 (11%)	*Medication has been changed prior to date of review letter.*
2 (11%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
10 (53%)	*I am aware of this situation and will plan to continue monitoring therapy.*
4 (21%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
July2007



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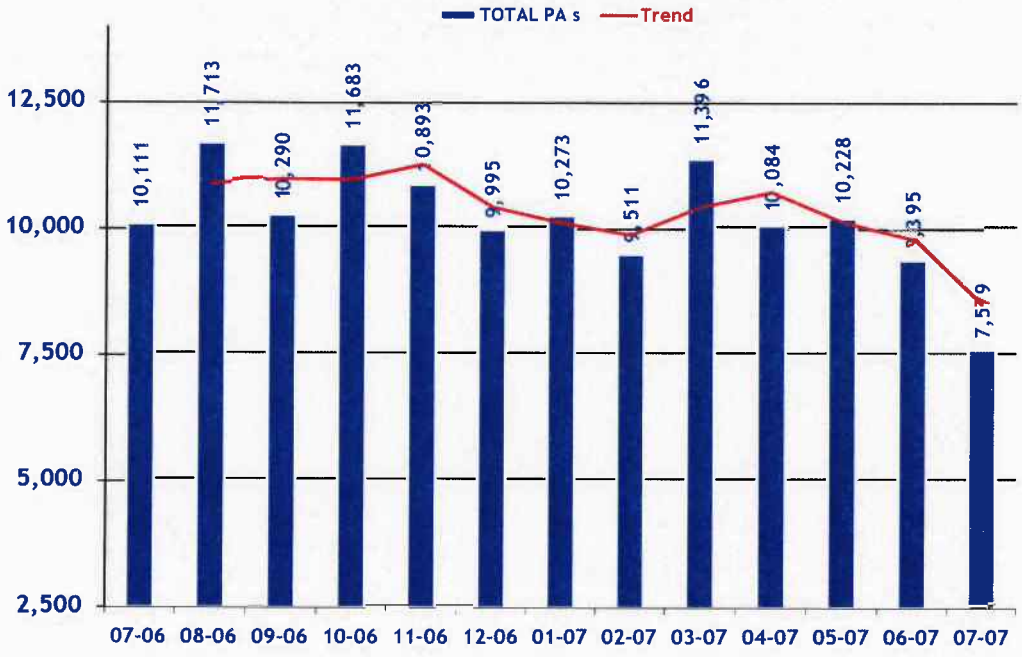
PRIOR AUTHORIZATION REPORT
July2006 - July2007



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Activity Audit for

July 01, 2007 Through July 31, 2007

	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	106	13	3	16
Angiotensin Receptor Antagonist	331	32	42	74
Antidepressant	258	199	381	580
Antihistamine	102	457	322	779
Antiulcers	13	11	6	17
Anxiolytic	94	2,956	357	3,313
Calcium Channel Blockers	170	7	0	7
Growth Hormones	162	31	1	32
HTN Combos	365	4	9	13
Insomnia	94	122	102	224
Nsaids	263	19	81	100
Plavix	355	152	24	176
Stimulant	214	559	170	729
Others	108	845	672	1,517
Emergency PAs		2	0	2
Total		**5,409**	**2,170**	**7,579**
Overrides				
Brand	256	20	12	32
Dosage Change	13	278	18	296
High Dose	0	0	1	1
Lost/Broken Rx	19	84	11	95
Nursing Home Issue	17	74	8	82
Other	18	38	14	52
Quantity vs. Days Supply	218	208	132	340
Stolen	3	2	6	8
Wrong D.S. on Previous Rx	0	0	5	5
Overrides Total		**704**	**207**	**911**

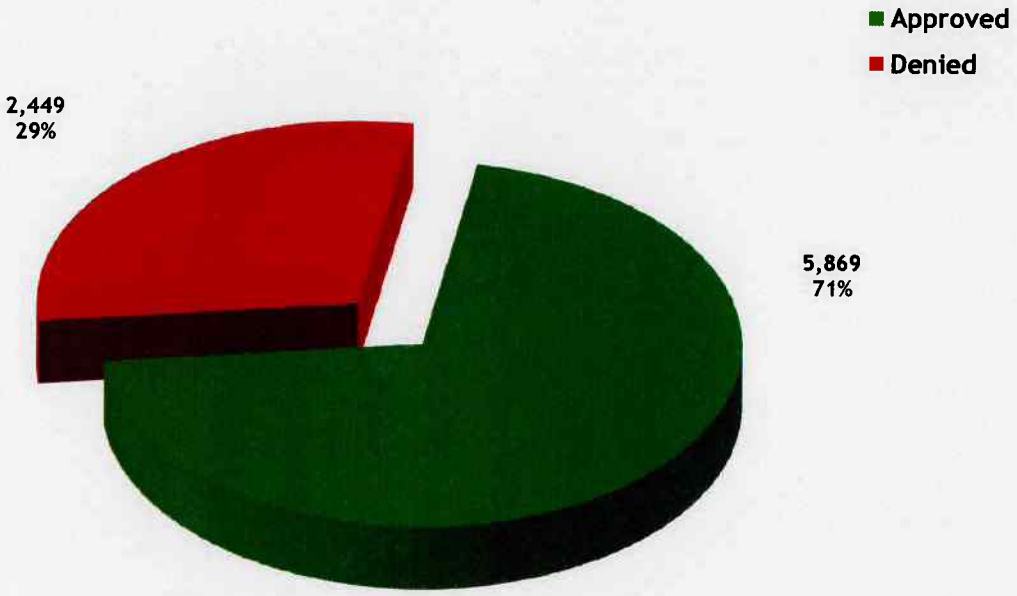
Denial Reasons

Lack required information to process request.	2,013
Unable to verify required trials.	874
Not an FDA approved indication/diagnosis.	113
Considered duplicate therapy. Member has a prior authorization for similar medication.	98
Does not meet established criteria.	88
Requested dose exceeds maximum recommended FDA dose.	68
Member has active PA for requested medication.	35
Medication not covered as pharmacy benefit.	14
Duplicate Requests	369
* Changes to existing	751

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

Tuesday, September 4, 2007

PRIOR AUTHORIZATION ACTIVITY REPORT
August 2007



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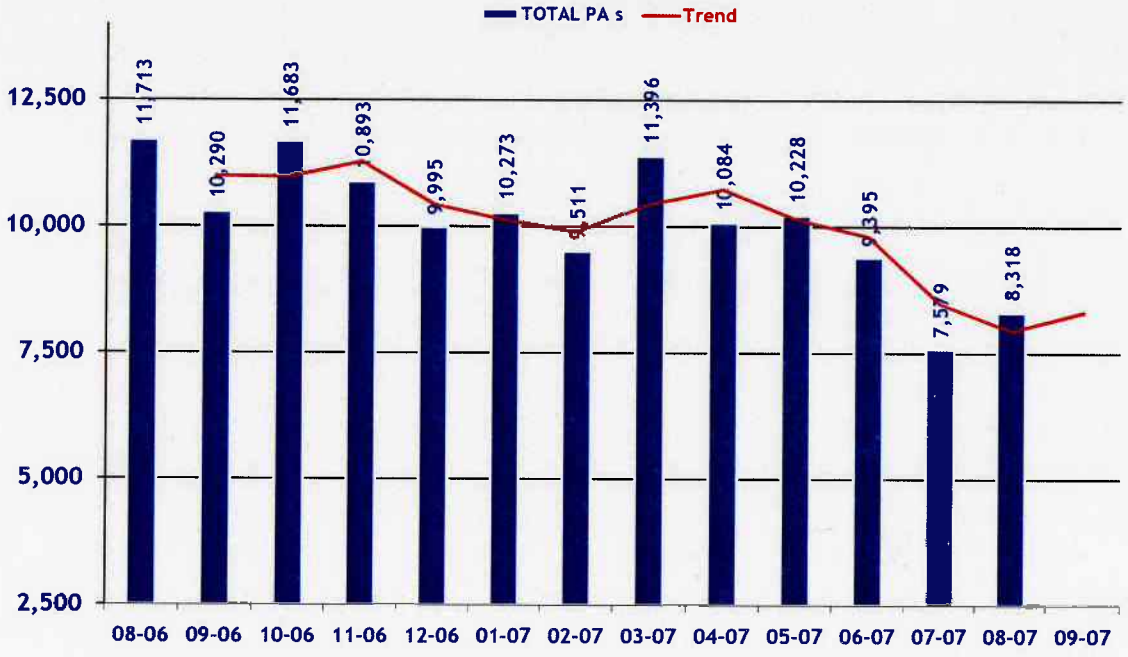
PRIOR AUTHORIZATION REPORT
August 2006 - August 2007



PHARMACY management consultants

Activity Audit for

August 01, 2007 Through August 31, 2007

	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	46	15	7	22
Angiotensin Receptor Antagonist	314	46	59	105
Antidepressant	255	194	400	594
Antihistamine	96	484	425	909
Antiulcers	5	13	6	19
Anxiolytic	94	2,976	386	3,362
Calcium Channel Blockers	148	6	8	14
Growth Hormones	167	30	2	32
HTN Combos	284	12	21	33
Insomnia	102	69	62	131
Nsaids	296	18	70	88
Plavix	351	145	21	166
Stimulant	228	885	220	1,105
Others	113	975	762	1,737
Emergency PAs		1	0	1
Total		**5,869**	**2,449**	**8,318**
Overrides				
Brand	323	28	12	40
Dosage Change	20	341	22	363
High Dose	0	0	2	2
Lost/Broken Rx	13	97	7	104
Nursing Home Issue	10	77	3	80
Other	16	31	11	42
Quantity vs. Days Supply	200	246	185	431
Stolen	21	3	3	6
Wrong D.S. on Previous Rx	0	0	2	2
Overrides Total		**823**	**247**	**1,070**

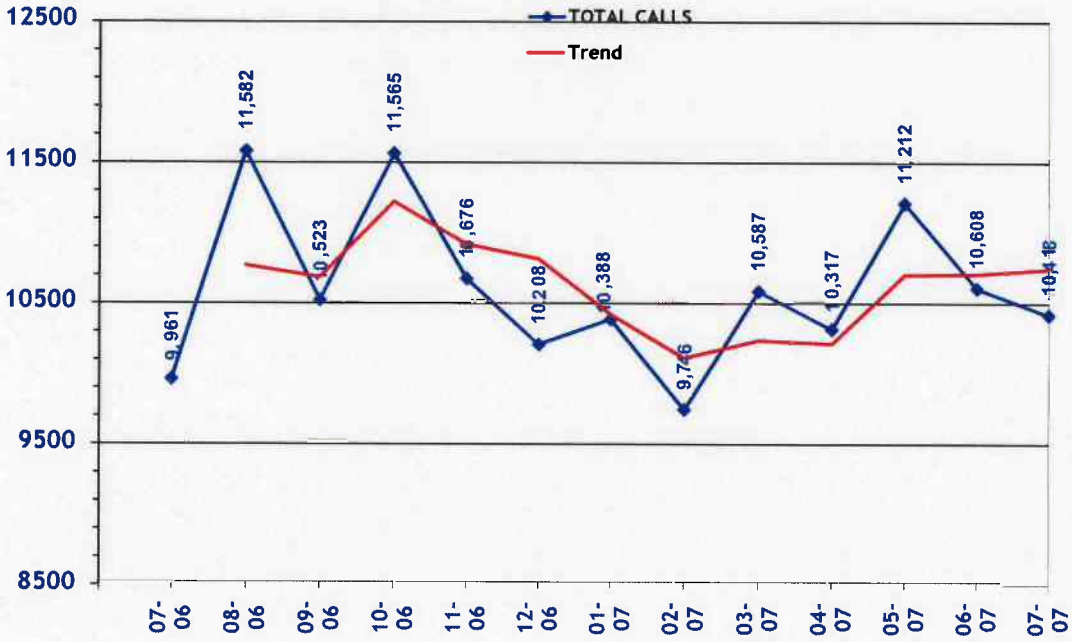
Denial Reasons

Lack required information to process request.	2,462
Unable to verify required trials.	799
Not an FDA approved indication/diagnosis.	115
Considered duplicate therapy. Member has a prior authorization for similar medication.	110
Does not meet established criteria.	77
Requested dose exceeds maximum recommended FDA dose.	55
Member has active PA for requested medication.	26
Medication not covered as pharmacy benefit.	6
Duplicate Requests	414
* Changes to existing	647

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

Wednesday, September 5, 2007

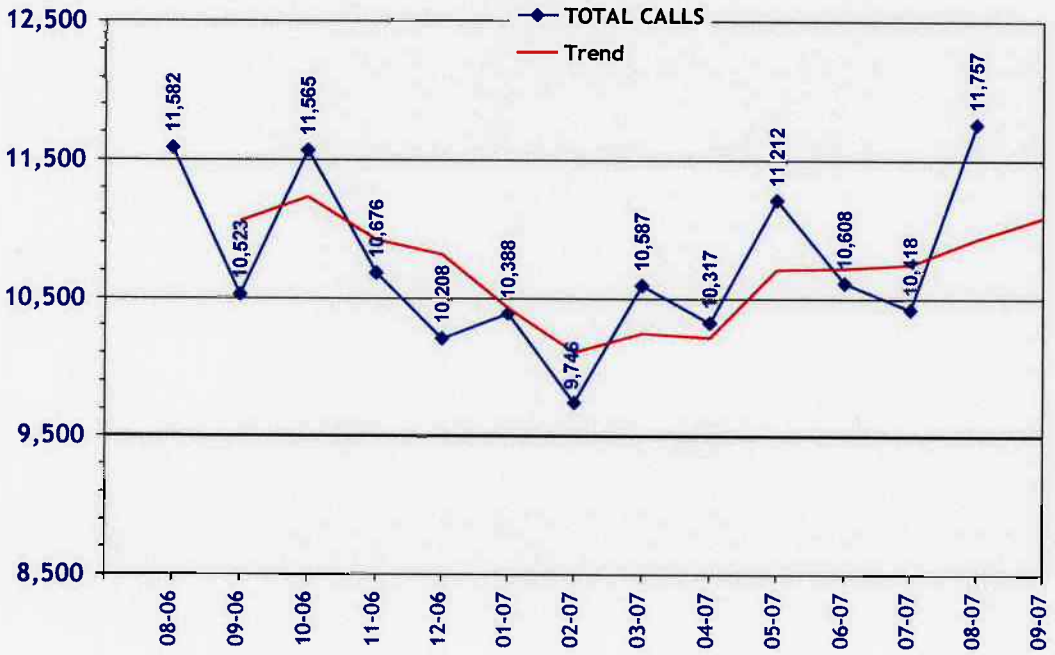
CALL VOLUME MONTHLY REPORT
July 2006 - July 2007



04-06 thru 03-07: corrected totals

PHARMACY Management consultants

CALL VOLUME MONTHLY REPORT
August 2006 - August 2007



04-06 thru 03-07: corrected totals

PHARMACY Management consultants

Pharmacotherapy Management Program
Report FY'07
July 2006 – June 2007
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	11	20	271	156	19	96	80	31
Nov 2006	25	0	221	105	36	80	54	13
Dec 2006	25	5	212	118	27	67	48	11
Jan 2007	18	12	249	154	23	72	70	9
Feb 2007	13	68	197	109	47	41	215	20
March 2007	26	8	354	197	34	123	92	29
April 2007	25	7	229	130	24	75	53	13
May 2007	20	12	250	143	22	85	62	12
June 2007	10	18	251	130	13	108	48	11
Totals	234	212	2930	1,631	313	986	1,028	241
1st Quarter	61	62	696	389	68	239	306	92
2nd Quarter	61	25	704	379	82	243	182	55
3rd Quarter	57	88	800	460	104	236	377	58
4th Quarter	55	37	730	403	59	268	163	36
Totals	234	212	2930	1,631	313	986	1,028	241

Appendix C

Vote to Prior Authorize Ophthalmic Anti-Infectives and Steroid-Antibiotic Combination Products

Oklahoma HealthCare Authority

September 2007

Recommendations

The College of Pharmacy recommends the addition of the Ophthalmic Anti-infective Class to the Product Based Prior Authorization program. The following Tier-1 drug lists have been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

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

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

Approval Criteria:

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

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

Approval Criteria:

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

Appendix D

Vote to Prior Authorize Veramyst™ (fluticasone furoate) Nasal Spray and Omnaris™ (ciclesondide) Nasal Spray

Oklahoma Health Care Authority
September 2007

Veramyst™ GlaxoSmithKline	Omnaris™ Altana Pharma US, Inc.
Veramyst™ is a corticosteroid nasal spray. It is indicated for treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children ≥ 2 years of age. Starting dosage is 2 sprays per nostril once daily for adults and 1 spray per nostril once daily for children.	Omnaris™ is the pro-drug of the corticosteroid des-ciclesonide. It is indicated for 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 2 sprays in each nostril once daily.
EAC: $ 83.40 for 10g vial (120 sprays)	**No current release date**

Recommendations

The College of Pharmacy recommends inclusion of Veramyst™ and Omnaris™ with the Tier 2 Nasal Allergy Products.

Nasal Allergy Products

*Tier 1**	*Tier 2*
Corticosteroids	Veramyst™
Fluticasone (Flonase®)	Omnaris™
flunisolide	
Nasonex®	
Beconase® AQ	
Nasacort® AQ	
Rhinocort® AQ	
Other	
Astelin®	
Ipratropium bromide	

*Brand products are subject to the Brand Name Override where generic is available.
Blue color indicated supplemental rebate participation.

Criteria for approval of a Tier 2 product:

1. Documented adverse effect or contraindication to the preferred products.
2. Failure with at least two Tier 1 medications defined as no beneficial response after at least two weeks each of use during which time the drug has been titrated to the recommended dose (at least one trial must be a corticosteroid).
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.

REFERENCE

Veramyst™ Prescribing Information. GlaxoSmithKline. 2007.

Omnaris™ Prescribing Information. Altana Pharma US, Inc. Rev. 19-Oct-06 draft. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed June 12, 2007.

Appendix E

Vote to Prior Authorize Exforge® (amlodipine(CCB)/valsartan(ARB)
Oklahoma Health Care Authority
September 2007

Manufacturer Novartis Pharmaceuticals
Classification FDA classification: antihypertensive
Status: prescription only

Summary

Exforge® is a combination of Diovan® (valsartan) and Norvasc® (amlodipine) in a single pill. It is indicated for the treatment of hypertension when blood pressure is not adequately controlled by either medication alone. It is not for initial therapy. It is available in four different strength combinations (5/160, 10/160, 5/320 or 10/320) with 5 or 10 mg of amlodipine and 160 or 320 mg of valsartan.

Revised Tier Table

ANTI-HYPERTENSIVE MEDICATIONS	
ARB AND ARB/HCTZ COMBINATION	
Tier 1	**Tier 2**
All Tier 1 ACEIs	All other ARBs and ARB combos
Avalide	Exforge®

Supplemental Rebate Agreement

Recommendations

The College of Pharmacy recommends placing Exforge® in the PBPA program as a Tier 2 ARB. A quantity limit of one unit per day would be applied.

Existing ARB criteria (as follows) would apply.

In order to get a Tier 2 ARB, client must meet **one** of the following criteria:

- Tier 1 ACEI drug failure (i.e. inadequate clinical response or adverse effect), or
- contraindication to the Tier 1 ACEI drugs , or
- already stabilized on the Tier 2 drug, or
- using the Tier 2 drug for a unique indication which the Tier 1 ACEI drug lacks.

REFERENCE

Exforge®, Product Information. Novartis Pharmaceuticals, 2007.

Appendix F

Vote to Prior Authorize Brovana™ (arformoterol tartrate) Inhalation Solution

Oklahoma Health Care Authority
September 2007

Manufacturer	Sepracor Inc
Classification	Long Acting Beta$_2$ Agonist
Status:	Prescription Only

Summary
Brovana™ is the (R,R)-enantiomer of the long-acting beta$_2$-agonist formoterol. It is available as a 15mcg/2ml inhaled solution. It is indicated for the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Dosing
Recommended dose is 15mcg twice a day (morning and evening) by nebulization. A total daily dose greater than 30mcg is not recommended and does not provide sufficient additional benefit to support use.

Cost Comparison

	Per Diem (based on EAC)
Brovana™ 15mcg/2ml Solution	$10.14
Serevent Diskus® 50mcg DPI	$4.00
Foradil® 12mcg DPI	$3.60
Spiriva® 18mcg DPI	$4.27

Recommendations

The College of Pharmacy recommends prior authorization and the following restrictions of Brovana™.

1. Member must be over 18 years of age and have one of the following diagnoses: COPD, chronic bronchitis, or emphysema.
2. Member must have previous trial with Advair®, Serevent® or Foradil® in the past 45 days. A clinical exception will be given for those members who are unable to effectively use hand-actuated devices or are stable on nebulized therapy.
3. Quantity limit of 120ml for a 30 day supply.

REFERENCE

Brovana™ Product Dossier. Sepracor Inc. May 2007.

Appendix G

Maintenance Drug List (solid oral dose forms)

Oklahoma Health Care Authority
September 2007

The Oklahoma Health Care Authority has selected drugs from certain disease states that are considered maintenance medications because they are taken on a regular schedule to treat chronic conditions. Daily dosage quantity limits still apply. Items in red are additions to the original list approved at the July 2004 DUR Board Meeting.

Anticoagulation:

- anagrelide
- aspirin/dipyridamole
- cilostazol
- clopidogrel
- pentoxifylline
- ticlopidine
- warfarin

Antidepressants:

- bupropion
- citalopram
- duloxetine
- escitalopram
- fluoxetine
- fluvoxamine
- mirtazapine
- paroxetine
- sertraline
- trazodone
- venlafaxine

Asthma:

- albuterol

Cardiovascular:

- acebutolol
- aliskiren
- amiloride
- amiodarone
- amlodipine
- amlodipine/atorvastatin
- amlodipine/benazepril
- atenolol
- atenolol/chlorthalidone
- atorvastatin
- benazepril
- benazepril/hydrochlorothiazide
- betaxolol
- bisoprolol
- bisoprolol/hydrochlorothiazide
- bosentan
- bumetanide
- candesartan
- candesartan/hydrochlorothiazide
- captopril
- captopril/hydrochlorothiazide
- carvedilol
- chlorothiazide
- clofibrate
- clonidine
- digoxin
- diltiazem
- disopyramide
- doxazosin

- enalapril
- enalapril/felodipine
- enalapril/hydrochlorothiazide
- eplerenone
- eprosartan
- eprosartan/hydrochlorothiazide
- ethacrynic acid
- ezetimibe
- ezetimibe/simvastatin
- felodipine
- fenofibrate
- flecainide
- fluvastatin
- fosinopril
- furosemide
- gemfibrozil
- guanfacine
- hydralazine
- hydralazine/hydrochlorothiazide
- hydrochlorothiazide
- hydrochlorothiazide/spironolactone
- hydrochlorothiazide/triamterene
- indapamide
- irbesartan
- irbesartan/hydrochlorothiazide
- isosorbide dinitrate
- isosorbide mononitrate
- isradipine
- labetalol
- lisinopril
- lisinopril/hydrochlorothiazide
- losartan
- losartan/hydrochlorothiazide
- lovastatin
- methyldopa
- methyldopa/hydrochlorothiazide
- metolazone
- metoprolol
- metoprolol/hydrochlorothiazide
- mexiletine
- minoxidil
- moexipril
- moexipril/hydrochlorothiazide
- nadolol
- niacin/lovastatin
- nicardipine
- nifedipine
- nimodipine
- nisoldipine
- nitroglycerin
- olmesartan
- olmesartan/hydrochlorothiazide
- perindopril
- pindolol
- pravastatin
- prazosin
- procainamide
- propranolol
- propranolol/hydrochlorothiazide
- quinapril
- quinapril/hydrochlorothiazide
- quinidine
- ramipril
- reserpine
- rosuvastatin
- simvastatin
- sotalol
- spironolactone
- telmisartan
- telmisartan/hydrochlorothiazide
- terazosin
- timolol
- torsemide
- trandolapril
- trandolapril/verapamil
- triamterene
- valsartan
- valsartan/hydrochlorothiazide
- verapamil

Diabetic:

- acarbose
- acetohexamide
- chlorpropamide
- glimepiride
- glipizide
- glipizide/metformin
- glyburide
- glyburide/metformin
- metformin
- nateglinide
- pioglitazone
- pioglitazone/metformin
- repaglinide
- rosiglitazone
- rosiglitazone/glimepiride
- rosiglitazone/metformin
- sitagliptin
- sitagliptin/metformin
- tolbutamide
- vildagliptin

Hormone:

- conjugated estrogens
- estradiol
- estropipate
- medroxyprogesterone
- tamoxifen

Thyroid:

- levothyroxine
- liotrix
- liothyronine
- methimazole
- propylthiouracil
- thyroid

Others:

- allopurinol
- carbamazepine
- colchicine
- felbamate
- folic acid
- isoniazid
- oxcarbazepine
- phenobarbital
- phenytoin
- potassium
- prednisone
- pregabalin
- prenatal vitamins
- primidone
- rifampin
- tiagabine
- topiramate
- valproic acid
- zonisamide

Appendix H

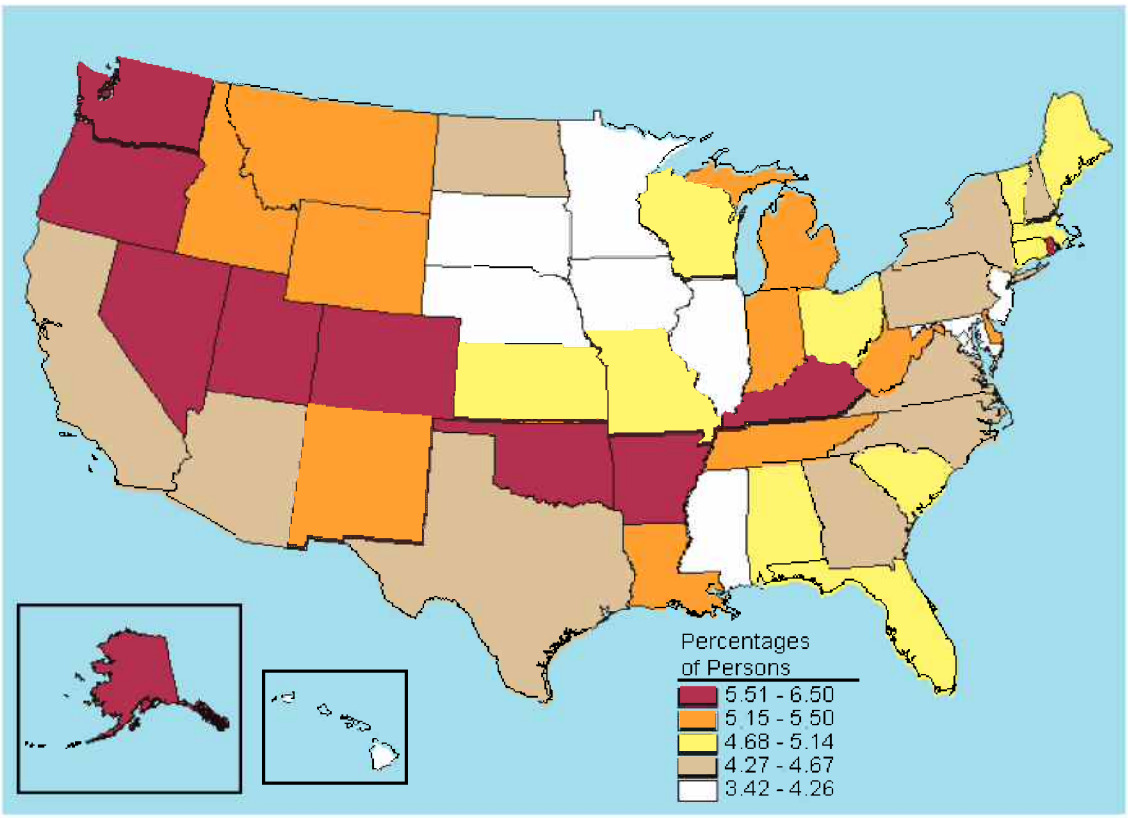
Utilization Review of Narcotic Analgesics

Oklahoma HealthCare Authority, September 2007

Introduction:

The topic of narcotic drug use and abuse has been an issue of debate in recent years. Patients with diseases involving chronic pain have relied on these medications to ease their pain and increase their quality of life. However, the nonmedical use of prescription pain relievers has been on the rise. The National Survey of Drug Use and Health (NSDUH) estimates that 439,000 Oklahomans over the age of 12 have used prescription pain relievers for nonmedical uses in their lifetime, with an estimated 153,000 Oklahomans using them in the past year.

Nonmedical Use of Pain Relievers in Past Year among Persons Aged 12 or Older, by State: Percentages, Annual Averages Based on 2004 and 2005 NSDUHs



Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2004 and 2005.
Available at: http://oas.samhsa.gov/2k5State/Ch2.htm#Fig2.28. Downloaded on 7/27/2007.

Utilization Review:

Calendar Year Comparison

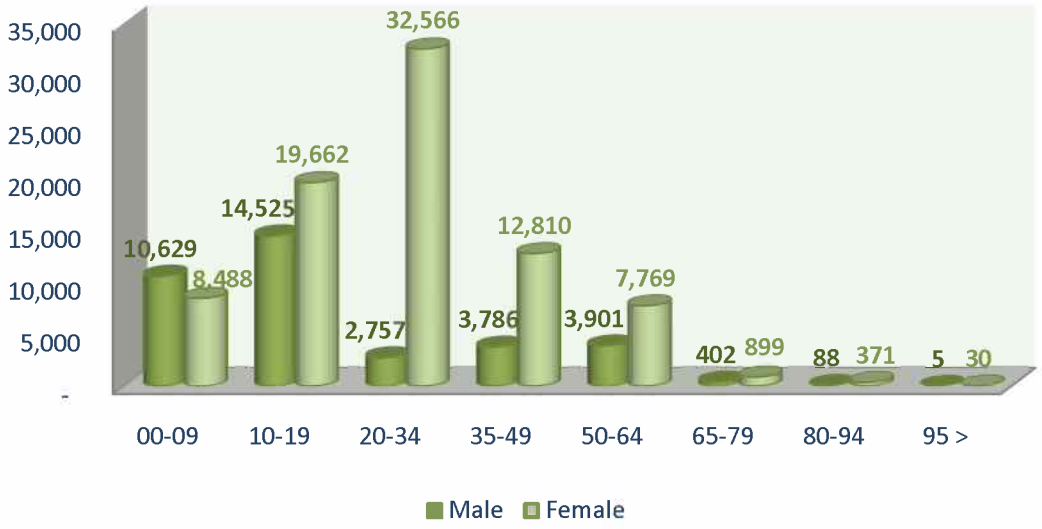
Year	Totals Members	Total Claims	Total Cost	Cost/ Claim	Per-Diem	Total Units	Total Days
2005							
	153,535	671,423	$26,155,095.84	$38.95	$2.62	43,629,032	9,976,522
2006*							
	118,843	403,659	$11,093,285.84	$27.48	$2.16	24,478,427	5,126,517
% Change	-22.60%	-39.90%	-57.60%	-29.40%	-17.60%	-43.90%	-48.60%
	-34,692	-267,764	-$15,061,810.00	-$11.47	-$0.46	-19,150,605	-4,850,005

*Loss of Dual Eligibles

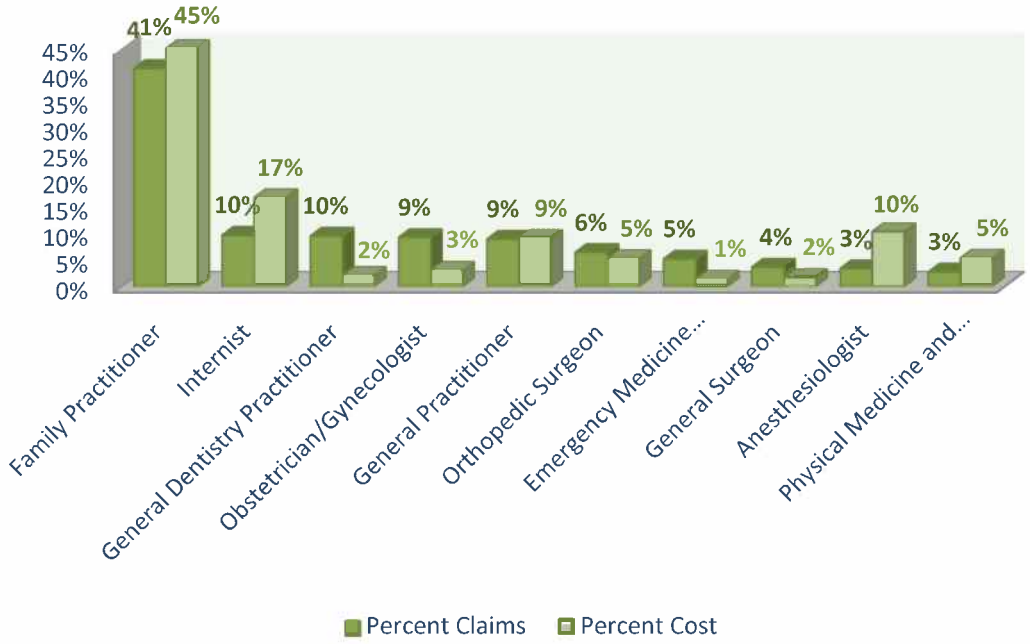
Calendar Year 2006 Utilization

Drug Class	Total Claims	Total Units	Total Days	Total Members	Total Paid
Narcotic Agonists	72,815	4,978,794	1,582,663	26,263	$6,951,333.02
Narcotic Partial Agonists	2,126	78,393	31,623	838	$115,715.62
Narcotic Combinations	32,659	1,574,326	329,082	22,523	$731,869.04
Analgesic Sedatives	40,521	2,935,061	242,226	31,308	$338,523.84
Dihydrocodeine Combinations	1,821	58,229	13,284	1,302	$67,905.32
Hydrocodone Combinations	215,416	13,111,028	2,526,783	92,687	$2,387,550.58
Propoxyphene Combinations	32,650	1,361,129	322,696	17,734	$267,703.30
Meperidine Combinations	323	12,043	2,928	250	$4,550.78
Pentazocine Combinations	312	18,438	3,991	160	$14,299.56
Tramadol Combinations	5,016	350,985	71,241	2,722	$213,834.78
Totals	**403,659**	**24,478,426**	**5,126,517**		**$11,093,285.84**

Age and Gender for Calendar Year 2006



Prescriber Specialties



Current Restrictions:

Prior Authorized Medications

Darvocet A500 (propoxyphene napsylate 100 mg / acetaminophen 500 mg)
Balacet 325 (propoxyphene napsylate 100 mg / acetaminophen 325 mg)

- Approved for members with documented need to restrict acetaminophen use or documented renal insufficiency or hepatic impairment.
- A quantity limit of 180/30 on each of the products also applies.

Ultram ER

- Approved for members with a diagnosis indicating a condition that requires extended pain treatment with an around-the-clock dosing schedule and a reason immediate release tramadol is inappropriate.
- The maximum covered dose is 300 mg daily with a quantity limit of 30 units for 30 days.

Ultram ODT

- Diagnosis indicating that the member has a condition that prevents them from swallowing tablets,
- A quantity limit of 240 units for 30 days for the ODT.

Quantity Limits Only

Drug	Restriction
Butorphanol (**Stadol**) nasal spray	10mL per 30 days (four 2.5 mL bottles = 100 sprays total)
Fentanyl transdermal (**Duragesic**) 12.5, 25, 50, 75, & 100 mcg/hr patches	12.5, 25, 50, & 75 mcg- 10 patches per 30 days 100 mcg – no limit
Fentanyl oral transmucosal (**Actiq**) 200, 400, 600, 800, 1200, 1600 mcg lozenges	120 lozenges per 30 days
Hydromorphone (**Dilaudid**)2, 4, & 8 mg immediate release tablets	2 or 4 mg – 180 tablets per 30 days 8 mg – 120 tablets per 30 days
Meperidine (**Demerol**) 50 & 100 mg tablets	60 tablets per 30 days
Methadone (**Dolophine**) 5, 10, & 40 mg tablets	240 tablets per 30 days
Morphine sulfate (**Avinza**) 30, 60, 90, & 120 mg extended release capsules	30 capsules per 30 days
Morphine sulfate (**Kadian**) 20, 30, 50, 60, 80, 100 & 200 mg sustained release capsules	60 capsules per 30 days
Oxycodone / ibuprofen (**Combunox**) 5 / 400 mg tablets	28 tablets per 30 days
Oxycodone (**Oxy IR**) 5, 15, & 30 mg immediate release tablets & capsules	240 tablets/capsules per 30 days
Oxycodone (**OxyContin**) 10, 20, 40, & 80 mg controlled release tablets	10, 20, 40 mg – 60 tabs per 30 days 80 mg – no limit
Tramadol (**Ultram**) 50 mg tablets	240 tablets per 30 days

Market Changes:

- Kadian - two new strengths:
  - 80 mg – October 2006
  - 200 mg – February 2007

- Fentora Tabs – fentanyl buccal tablet:
  - September 2006

- Opana IR and ER – oxymorphone hydrochloride:
  - June 2006

- Oxycontin:
  - October 2006 – Purdue settles patent lawsuit and Teva agrees to stop selling generic version by March 31, 2007.
  - May 2007 - Purdue pleads guilty to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused.

Recommendations:

The college of pharmacy recommends adding quantity limits to the following products:

Drug	Restriction
Fentanyl buccal (**Fentora**) 100, 200, 400, 600, 800 mcg buccal tablets	120 tablets per 30 days
Oxymorphone (**Opana IR**) 5 & 10 mg tablets	5 mg – 120 per 30 days 10 mg – 240 per 30 days
Oxymorphone (**Opana ER**) 5, 10, 20, & 40 mg tablets	5, 10 & 20 mg – 60 per 30 days 40 mg – 120 per 30 days
Pentazocine (**Talwin Cpd, Talwin NX, Talacen**) tablets	12.5 mg / Aspirin 325 mg – 240 tablets per 30 days 50 mg / Naloxone 0.5 mg – 360 tablets per 30 days 25 mg / APAP 650 mg – 180 tablets per 30 days
All product combinations containing acetaminophen (**Lortab, Percocet, Tylenol w/Codeine**, **Darvocet**, etc)	Maximum of 4 gms of APAP per day for 30 days (or as product labeling indicates)
All product combinations containing aspirin (**Percodan, Fiorinal**, etc)	Maximum of 4 gms of ASA per day for 30 days (or as product labeling indicates)
All product combinations containing ibuprofen (**Vicoprofen, Reprexain**)	150 tablets per 30 days

Appendix

Hydrocodone Combinations

RANK CLAIMS	RANK COST	BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
1	2	HYDROCO/APAP TAB 7.5-500	86,423	3,734,771	918,328	34,207	$654,347.90	4.07	2.53	$0.71	27.41%
2	3	HYDROCO/APAP TAB 5-500MG	50,791	1,416,326	316,574	30,468	$281,716.18	4.47	1.67	$0.89	11.80%
3	1	HYDROCO/APAP TAB 10-500MG	38,288	3,139,994	761,708	8,721	$744,835.27	4.12	4.39	$0.98	31.20%
4	7	HYDROCODONE/ SOL APAP	10,075	2,776,438	61,464	7,683	$111,124.24	45.17	1.31	$1.81	4.65%
5	5	HYDROCO/APAP TAB 10-650MG	8,941	734,005	180,856	2,287	$127,566.34	4.06	3.91	$0.71	5.34%
6	4	HYDROCO/APAP TAB 10-325MG	6,966	654,438	137,859	1,945	$199,118.28	4.75	3.58	$1.44	8.34%
7	6	HYDROCOD/IBU TAB 7.5-200	3,097	150,789	40,045	1,457	$123,472.67	3.77	2.13	$3.08	5.17%
8	10	HYDROCO/APAP TAB 7.5-650	3,013	153,038	38,510	1,210	$27,244.44	3.97	2.49	$0.71	1.14%
9	8	HYDROCO/APAP TAB 7.5-325	2,509	120,566	26,406	1,315	$46,630.57	4.57	1.91	$1.77	1.95%
10	9	HYDROCO/APAP TAB 5-325MG	2,282	68,821	13,291	1,556	$27,475.62	5.18	1.47	$2.07	1.15%
11	11	HYDROCO/APAP TAB 7.5-750	1,536	72,194	18,101	820	$11,682.21	3.99	1.87	$0.65	0.49%
12	13	HYDROCO/APAP TAB 2.5-500	907	30,618	7,669	649	$7,279.83	3.99	1.4	$0.95	0.30%
13	12	HYCET SOL 7.5-325	158	37,958	954	102	$7,751.00	39.79	1.55	$8.12	0.32%
14	14	XODOL TAB	143	7,796	2,216	73	$6,893.12	3.52	1.96	$3.11	0.29%
15	16	HYDROCO/APAP TAB 10-750MG	92	2,472	467	83	$2,186.27	5.29	1.11	$4.68	0.09%
16	21	LORTAB 5 TAB	63	1,648	331	56	$321.76	4.98	1.13	$0.97	0.01%
17	19	HYDROCO/APAP TAB 10/660MG	45	1,929	552	19	$663.82	3.49	2.37	$1.20	0.03%
18	15	LORTAB 10 TAB	24	4,340	624	3	$4,482.32	6.96	8	$7.18	0.19%
19	18	REPREXAIN TAB	22	744	151	7	$956.54	4.93	3.14	$6.33	0.04%
20	20	XODOL TAB 5-300MG	13	374	73	11	$338.03	5.12	1.18	$4.63	0.01%
21	17	LORTAB 7.5 TAB	11	990	330	1	$982.40	3	11	$2.98	0.04%
22	22	ZYDONE TAB 10-400MG	5	366	141	3	$298.22	2.6	1.67	$2.12	0.01%
23	23	ANEXSIA TAB 5-325MG	3	117	33	3	$42.49	3.55	1	$1.29	0.00%
24	25	ANEXSIA TAB 7.5-325	3	90	19	2	$37.85	4.74	1.5	$1.99	0.00%
25	27	STAGESIC CAP 500-5MG	2	84	36	2	$22.62	2.33	1	$0.63	0.00%
26	28	ZYDONE TAB 5-400MG	1	12	2	1	$10.15	6	1	$5.08	0.00%
27	29	LORTAB 2.5 TAB	1	20	3	1	$7.21	6.67	1	$2.40	0.00%
28	26	MHYDROCOD/IBU TAB 7.5-200	1	30	10	1	$24.51	3	1	$2.45	0.00%
29	24	STAGESIC-10 TAB 10/250	1	60	30	1	$38.72	2	1	$1.29	0.00%
			215,416	**13,111,028**	**2,526,783**		**$2,387,550.58**	**6.9**	**2.39**	**$2.49**	

Oxycodone Combinations

RANK CLAIMS	RANK COST	BRAND NAME	CLAIMS	UNITS	DAYS	CLIENTS	COST	UNITS/ DAY	CLAIMS/ CLIENT	COST/ DAY	PERCENT COST
1	2	OXYCOD/APAP TAB 5-325MG	15,624	540,124	90,002	12,430	$107,038.41	6	1.26	$1.19	14.63%
2	3	OXYCOD-APAP TAB 7.5-325	2,665	119,015	24,069	1,900	$90,576.78	4.94	1.4	$3.76	12.38%
3	1	OXYCODO-APAP TAB 10-325	2,517	223,751	48,528	1,030	$148,035.13	4.61	2.44	$3.05	20.23%
4	9	OXYCOD/APAP CAP 5-500MG	2,402	100,964	19,713	1,833	$22,697.60	5.12	1.31	$1.15	3.10%
5	12	ENDOCET TAB 5-325MG	1,868	75,705	17,125	1,401	$13,647.12	4.42	1.33	$0.80	1.86%
6	5	ENDOCET TAB 10-325MG	1,288	131,666	29,123	446	$86,959.90	4.52	2.89	$2.99	11.88%
7	4	ENDOCET TAB 10-650MG	1,287	112,104	30,201	401	$88,618.67	3.71	3.21	$2.93	12.11%
8	14	ROXICET TAB 5-325MG	1,233	39,764	12,272	913	$7,930.68	3.24	1.35	$0.65	1.08%
9	7	OXYCO/APAP TAB 7.5-500	1,167	66,720	17,078	650	$39,265.72	3.91	1.8	$2.30	5.37%
10	6	OXYCO/APAP TAB 10-650	743	60,988	16,023	322	$48,542.13	3.81	2.31	$3.03	6.63%
11	8	ENDOCET TAB 7.5-325M	656	39,594	8,844	405	$28,590.43	4.48	1.62	$3.23	3.91%
12	10	ENDOCET TAB 7.5-500M	481	31,332	8,508	250	$17,987.97	3.68	1.92	$2.11	2.46%
13	13	COMBUNOX TAB 5/400MG	333	6,663	2,282	306	$10,234.30	2.92	1.09	$4.48	1.40%
14	11	OXYCOD/ASA TAB	304	19,761	4,238	167	$16,150.45	4.66	1.82	$3.81	2.21%
15	15	ENDODAN TAB	49	2,944	697	36	$2,511.37	4.22	1.36	$3.60	0.34%
16	16	PERCOCET TAB 2.5-325	30	791	157	24	$1,180.42	5.04	1.25	$7.52	0.16%
17	19	ROXICET SOL 5-325/5	6	1,540	42	6	$148.10	36.67	1	$3.53	0.02%
18	17	PERCOCET TAB 10-325MG	3	360	90	1	$1,082.13	4	3	$12.02	0.15%
19	18	PERCODAN TAB	3	540	90	2	$671.73	6	1.5	$7.46	0.09%
			32,659	**1,574,326**	**329,082**		**$731,869.04**	**6.1**	**1.78**	**$3.66**	

Narcotic Agonists

RANK CLAIMS	RANK COST	BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
1	8	TRAMADOL HCL TAB 50MG	28,475	1,923,643	437,527	12,225	$246,789.39	4.4	2.33	$0.56	3.55%
2	3	OXYCODONE TAB 40MG CR	4,270	249,313	125,713	947	$705,686.55	1.98	4.51	$5.61	10.15%
3	6	OXYCODONE TAB 20MG CR	3,790	216,398	109,140	1,070	$324,873.01	1.98	3.54	$2.98	4.67%
4	1	OXYCODONE TAB 80MG CR	3,164	250,677	92,799	545	$1,323,128.67	2.7	5.81	$14.26	19.03%
5	4	FENTANYL DIS 50MCG/HR	2,004	19,225	57,372	669	$339,104.78	0.34	3	$5.91	4.88%
6	37	METHADONE TAB 10MG	1,883	251,556	53,169	421	$26,523.41	4.73	4.47	$0.50	0.38%
7	2	FENTANYL DIS 100MCG/H	1,816	21,961	52,089	380	$773,651.07	0.42	4.78	$14.85	11.13%
8	40	OXYCODONE CAP 5MG	1,613	142,761	33,096	554	$21,490.42	4.31	2.91	$0.65	0.31%
9	15	MORPHINE SUL TAB 30MG ER	1,584	105,489	44,427	505	$93,099.29	2.37	3.14	$2.10	1.34%
10	11	FENTANYL DIS 25MCG/HR	1,387	12,600	37,767	614	$129,321.93	0.33	2.26	$3.42	1.86%
11	24	OXYCODONE TAB 10MG CR	1,367	75,553	38,968	533	$60,554.58	1.94	2.56	$1.55	0.87%
12	12	OXYCODONE TAB 30MG	1,301	165,784	30,926	188	$127,178.02	5.36	6.92	$4.11	1.83%
13	5	FENTANYL DIS 75MCG/HR	1,260	12,451	36,031	382	$328,790.55	0.35	3.3	$9.13	4.73%
14	45	OXYCODONE TAB 5MG	1,161	121,835	25,548	414	$18,363.87	4.77	2.8	$0.72	0.26%
15	25	OXYCODONE TAB 15MG	1,137	133,072	27,215	285	$58,431.41	4.89	3.99	$2.15	0.84%
16	58	MORPHINE SUL TAB 15MG	1,046	95,497	21,816	368	$10,194.60	4.38	2.84	$0.47	0.15%
17	49	PROPOXY HCL CAP 65MG	1,003	57,029	15,064	408	$15,810.15	3.79	2.46	$1.05	0.23%
18	14	MORPHINE SUL TAB 60MG ER	947	69,577	27,849	252	$107,726.58	2.5	3.76	$3.87	1.55%
19	48	MEPERIDINE TAB 50MG	927	33,832	9,124	616	$16,042.78	3.71	1.5	$1.76	0.23%
20	53	METHADOSE TAB 10MG	861	112,366	25,018	254	$11,835.20	4.49	3.39	$0.47	0.17%
21	38	MORPHINE SUL TAB 15MG ER	793	48,421	21,625	318	$23,817.70	2.24	2.49	$1.10	0.34%
22	59	MEPERIDINE SOL 50MG/5ML	769	33,069	1,577	615	$8,433.49	20.97	1.25	$5.35	0.12%
23	13	OXYCODONE TAB 40MG ER	743	43,825	21,661	261	$125,253.81	2.02	2.85	$5.78	1.80%
24	23	OXYCODONE TAB 20MG ER	736	42,229	21,487	283	$65,169.00	1.97	2.6	$3.03	0.94%
25	56	MORPHINE SUL TAB 30MG	701	79,566	15,674	189	$11,299.81	5.08	3.71	$0.72	0.16%
26	47	METHADOSE TAB 40MG	638	53,970	18,411	132	$16,919.05	2.93	4.83	$0.92	0.24%
27	51	HYDROMORPHON TAB 4MG	621	66,292	13,853	209	$12,505.85	4.79	2.97	$0.90	0.18%
28	17	MORPHINE SUL TAB 100MG ER	422	39,163	12,566	93	$90,067.75	3.12	4.54	$7.17	1.30%
29	55	DISKETS TAB 40MG	384	36,596	10,892	87	$11,325.97	3.36	4.41	$1.04	0.16%
30	28	AVINZA CAP 60MG CR	347	10,474	10,234	127	$56,200.70	1.02	2.73	$5.49	0.81%
31	20	AVINZA CAP 90MG CR	319	9,752	9,277	86	$77,319.65	1.05	3.71	$8.33	1.11%
32	81	HYDROMORPHON TAB 2MG	299	17,683	3,911	195	$2,954.56	4.52	1.53	$0.76	0.04%
33	31	KADIAN CAP 30MG CR	262	11,966	7,350	89	$35,589.99	1.63	2.94	$4.84	0.51%
34	32	KADIAN CAP 20MG CR	260	12,559	7,087	113	$34,261.88	1.77	2.3	$4.83	0.49%
35	9	OXYCONTIN TAB 80MG CR	233	19,867	6,844	77	$187,320.53	2.9	3.03	$27.37	2.69%
36	43	AVINZA CAP 30MG CR	228	6,674	6,644	114	$18,840.67	1	2	$2.84	0.27%
37	27	KADIAN CAP 50MG CR	209	11,894	6,203	52	$57,708.67	1.92	4.02	$9.30	0.83%
38	21	AVINZA CAP 120MG CR	205	7,530	6,090	55	$71,337.89	1.24	3.73	$11.71	1.03%
39	65	MORPHINE SUL SOL 20MG/ML	199	17,415	2,548	98	$6,711.49	6.83	2.03	$2.63	0.10%
40	39	HYDROMORPHON TAB 8MG	193	24,975	5,434	49	$22,406.05	4.6	3.94	$4.12	0.32%
41	68	MEPERIDINE TAB 100MG	191	8,731	2,563	75	$5,760.58	3.41	2.55	$2.25	0.08%

42	89	METHADOSE TAB 5MG	191	15,847	5,359	90	$1,535.16	2.96	2.12	$0.29	0.02%
43	91	METHADONE TAB 5MG	179	14,868	4,978	97	$1,449.90	2.99	1.85	$0.29	0.02%
44	66	OXYCODONE TAB 10MG ER	146	8,023	4,144	84	$6,692.47	1.94	1.74	$1.61	0.10%
45	61	DARVON-N TAB 100MG	145	6,802	1,459	53	$7,809.14	4.66	2.74	$5.35	0.11%
46	16	KADIAN CAP 100MG CR	137	10,687	4,056	30	$90,734.01	2.63	4.57	$22.37	1.31%
47	30	KADIAN CAP 60MG CR	124	6,708	3,625	29	$35,768.50	1.85	4.28	$9.87	0.51%
48	7	ACTIQ LOZ 800MCG	108	11,068	3,195	15	$289,768.42	3.46	7.2	$90.69	4.17%
49	52	DURAGESIC-12 DIS 12.5MCG	104	937	2,822	38	$11,901.87	0.33	2.74	$4.22	0.17%
50	71	MORPHINE SUL TAB 30MG CR	103	6,437	2,952	54	$4,906.92	2.18	1.91	$1.66	0.07%
51	57	ORAMORPH SR TAB 30MG	98	11,408	2,748	27	$10,375.77	4.15	3.63	$3.78	0.15%
52	22	ACTIQ LOZ 400MCG	92	3,674	1,533	36	$66,246.80	2.4	2.56	$43.21	0.95%
53	92	MEPERITAB TAB 50MG	83	2,930	785	58	$1,436.63	3.73	1.43	$1.83	0.02%
54	107	DEMEROL INJ 50MG/ML	74	637	257	44	$644.47	2.48	1.68	$2.51	0.01%
55	41	ACTIQ LOZ 200MCG	72	1,240	658	41	$19,543.19	1.88	1.76	$29.70	0.28%
56	34	OXYCODONE TAB 80MG ER	71	5,927	2,135	31	$30,495.81	2.78	2.29	$14.28	0.44%
57	36	OXYCONTIN TAB 40MG CR	68	5,224	2,072	9	$26,721.13	2.52	7.56	$12.90	0.38%
58	18	ACTIQ LOZ 600MCG	56	4,360	1,626	11	$86,696.05	2.68	5.09	$53.32	1.25%
59	80	ETH-OXYDOSE CON 20MG/ML	54	30,060	932	27	$3,010.14	32.25	2	$3.23	0.04%
60	73	ULTRAM ER TAB 100MG	52	1,512	1,469	44	$4,386.23	1.03	1.18	$2.99	0.06%
61	67	MORPHINE SUL SOL 10MG/5ML	50	11,928	713	21	$6,061.50	16.73	2.38	$8.50	0.09%
62	69	MORPHINE SUL TAB 60MG CR	46	3,836	1,245	19	$5,072.10	3.08	2.42	$4.07	0.07%
63	42	OXYCODONE CON 20MG/ML	46	29,458	1,134	15	$19,436.43	25.98	3.07	$17.14	0.28%
64	29	MORPHINE SUL TAB 200MG ER	46	8,424	1,346	12	$47,647.20	6.26	3.83	$35.40	0.69%
65	95	CODEINE SULF TAB 30MG	46	2,526	700	26	$1,178.79	3.61	1.77	$1.68	0.02%
66	111	METHADONE SOL 5MG/5ML	39	4,250	790	24	$439.48	5.38	1.63	$0.56	0.01%
67	102	MEPERITAB TAB 100MG	35	1,355	446	10	$915.48	3.04	3.5	$2.05	0.01%
68	85	MORPHINE SUL SOL 20MG/5ML	33	19,545	579	10	$2,350.06	33.76	3.3	$4.06	0.03%
69	10	ACTIQ LOZ 1600MCG	33	3,100	955	6	$129,445.03	3.25	5.5	$135.54	1.86%
70	76	ULTRAM ER TAB 200MG	33	848	848	20	$4,095.99	1	1.65	$4.83	0.06%
71	87	MORPHINE SUL INJ 10MG/ML	32	1,536	479	10	$1,718.89	3.21	3.2	$3.59	0.02%
72	44	DURAGESIC DIS 100MCG/H	31	330	930	5	$18,501.78	0.35	6.2	$19.89	0.27%
73	72	OPANA ER TAB 10MG	30	1,631	816	18	$4,810.13	2	1.67	$5.89	0.07%
74	62	OPANA TAB 10MG	28	1,886	607	13	$7,223.57	3.11	2.15	$11.90	0.10%
75	112	MSIR TAB 30MG	28	2,340	440	11	$362.13	5.32	2.55	$0.82	0.01%
76	105	MORPHINE SUL TAB 15MG CR	26	1,810	720	20	$739.91	2.51	1.3	$1.03	0.01%
77	19	ACTIQ LOZ 200MCG	26	2,694	684	6	$84,204.42	3.94	4.33	$123.11	1.21%
78	33	DILAUDID-HP INJ 10MG/ML	25	8,650	356	4	$33,577.00	24.3	6.25	$94.32	0.48%
79	64	OPANA ER TAB 20MG	25	1,379	690	16	$6,946.69	2	1.56	$10.07	0.10%
80	109	MORPHINE SUL TAB 10MG	24	1,674	240	22	$571.23	6.97	1.09	$2.38	0.01%
81	46	MS CONTIN TAB 60MG CR	24	4,890	720	3	$17,754.68	6.79	8	$24.66	0.26%
82	74	ULTRAM ER TAB 300MG	23	626	626	11	$4,180.86	1	2.09	$6.68	0.06%
83	78	DURAGESIC DIS 25MCG/HR	22	230	645	4	$3,524.10	0.36	5.5	$5.46	0.05%
84	60	OXYCONTIN TAB 20MG CR	20	2,910	600	3	$8,390.89	4.85	6.67	$13.98	0.12%
85	90	CODEINE SULF TAB 60MG	20	1,880	498	2	$1,457.84	3.78	10	$2.93	0.02%
86	114	DEMEROL INJ 100MG/ML	19	203	73	9	$306.03	2.78	2.11	$4.19	0.00%
87	83	MORPHINE SUL TAB 100MG CR	17	1,420	512	8	$2,488.02	2.77	2.13	$4.86	0.04%
88	99	OPANA ER TAB 5MG	16	598	314	13	$950.16	1.9	1.23	$3.03	0.01%

89	115	MORPHINE SUL INJ 2MG/ML	16	209	48	11	$270.08	4.35	1.45	$5.63	0.00%
90	63	OPANA ER TAB 40MG	14	714	342	9	$6,971.18	2.09	1.56	$20.38	0.10%
91	50	MS CONTIN TAB 200MG CR	13	1,310	393	2	$12,814.00	3.33	6.5	$32.61	0.18%
92	35	MORPHINE POW SULFATE	13	4,306	215	5	$29,302.19	20.03	2.6	$136.29	0.42%
93	106	MORPHINE SUL TAB 30MG	12	1,200	306	8	$692.25	3.92	1.5	$2.26	0.01%
94	130	DEMEROL SYP 50MG/5ML	11	138	16	11	$68.70	8.63	1	$4.29	0.00%
95	26	OXYCODONE POW HCL	10	3,267	222	2	$57,877.50	14.71	5	$260.71	0.83%
96	77	DURAGESIC DIS 75MCG/HR	9	90	270	2	$3,775.72	0.33	4.5	$13.98	0.05%
97	121	OXYCODONE SOL 5MG/5ML	9	2,140	73	6	$172.72	29.32	1.5	$2.37	0.00%
98	98	HYDROMORPHON POW HCL	9	53	153	5	$951.76	0.35	1.8	$6.22	0.01%
99	124	DEMEROL INJ 25MG/ML	8	110	47	7	$109.88	2.34	1.14	$2.34	0.00%
100	79	DURAGESIC DIS 50MCG/HR	8	110	224	4	$3,063.67	0.49	2	$13.68	0.04%
101	75	FENTANYL OT LOZ 400MCG	8	195	105	5	$4,111.33	1.86	1.6	$39.16	0.06%
102	122	CODEINE SULF TAB 15MG	7	335	43	6	$149.92	7.79	1.17	$3.49	0.00%
103	117	ROXICODONE SOL 5MG/5ML	7	2,340	79	2	$230.48	29.62	3.5	$2.92	0.00%
104	103	OPANA TAB 5MG	7	400	84	7	$856.05	4.76	1	$10.19	0.01%
105	119	METHADONE TAB DSP 40MG	6	580	184	3	$181.75	3.15	2	$0.99	0.00%
106	101	ROXICODONE TAB 15MG	6	1,080	180	1	$926.70	6	6	$5.15	0.01%
107	134	DEMEROL INJ 75MG/ML	6	24	10	4	$46.86	2.4	1.5	$4.69	0.00%
108	133	MSIR TAB 15MG	5	410	95	5	$46.93	4.32	1	$0.49	0.00%
109	129	ASTRAMORPH INJ 1MG/ML	5	10	5	5	$68.96	2	1	$13.79	0.00%
110	97	LEVORPHANOL TAB 2MG	5	1,000	153	1	$954.55	6.54	5	$6.24	0.01%
111	84	MORPHINE SUL INJ 50MG/ML	5	5,010	81	2	$2,370.74	61.85	2.5	$29.27	0.03%
112	93	MORPHINE SUL INJ 5MG/ML	5	2,300	72	2	$1,380.15	31.94	2.5	$19.17	0.02%
113	94	ROXICODONE TAB 30MG	5	750	150	1	$1,302.09	5	5	$8.68	0.02%
114	131	MORPHINE SUL INJ 1MG/ML	4	123	96	4	$57.21	1.28	1	$0.60	0.00%
115	132	MEPERIDINE INJ 50MG/ML	4	39	7	4	$48.66	5.57	1	$6.95	0.00%
116	123	METHADOSE CON 10MG/ML	4	1,440	120	1	$141.12	12	4	$1.18	0.00%
117	120	CODEINE PHOS TAB SOL 30MG	3	222	53	3	$179.39	4.19	1	$3.38	0.00%
118	118	MEPERIDINE INJ 25MG/ML	3	220	13	1	$188.50	16.92	3	$14.50	0.00%
119	125	MORPHINE SUL TAB 15MG	3	246	50	3	$101.74	4.92	1	$2.03	0.00%
120	136	ORAMORPH SR TAB 15MG	3	70	40	3	$40.43	1.75	1	$1.01	0.00%
121	108	HYDROMORPHON INJ 2MG/ML	3	1,220	20	2	$621.22	61	1.5	$31.06	0.01%
122	113	MORPHINE SUL INJ 25MG/ML	2	1,604	31	2	$316.83	51.74	1	$10.22	0.00%
123	104	DEMEROL TAB 100MG	2	432	60	1	$818.80	7.2	2	$13.65	0.01%
124	100	MORPHINE SUL TAB 200MG CR	2	222	64	1	$936.16	3.47	2	$14.63	0.01%
125	135	MSIR CAP 15MG	2	120	25	2	$45.58	4.8	1	$1.82	0.00%
126	127	MORPHINE SUL INJ 4MG/ML	2	62	21	2	$71.59	2.95	1	$3.41	0.00%
127	128	OXYFAST CON 20MG/ML	2	90	60	2	$70.19	1.5	1	$1.17	0.00%
128	70	FENTORA TAB 600MCG	2	180	60	1	$4,954.30	3	2	$82.57	0.07%
129	54	FENTANYL OT LOZ 1600MCG	2	240	60	1	$11,712.88	4	2	$195.21	0.17%
130	126	ORAMORPH SR TAB 60MG	1	64	32	1	$92.81	2	1	$2.90	0.00%
131	116	KADIAN CAP 80MG	1	30	30	1	$239.75	1	1	$7.99	0.00%
132	137	DEPODUR INJ 15/1.5ML	1	60	1	1	$35.27	60	1	$35.27	0.00%
133	138	DILAUDID INJ 2MG/ML	1	10	1	1	$19.90	10	1	$19.90	0.00%
134	139	RMS SUP 20MG	1	10	2	1	$19.23	5	1	$9.62	0.00%
135	140	MEPERIDINE INJ 100MG/ML	1	20	5	1	$17.67	4	1	$3.53	0.00%

136	141	DILAUDID INJ 1MG/ML	1	10	1	1	$17.49	10	1	$17.49	0.00%
137	142	MORPHINE SUL SUP 10MG	1	10	4	1	$15.40	2.5	1	$3.85	0.00%
138	143	MEPERIDINE INJ 300MG	1	30	30	1	$14.53	1	1	$0.48	0.00%
139	144	METHADONE SOL 10MG/5ML	1	10	1	1	$4.33	10	1	$4.33	0.00%
140	96	FENTORA TAB 100MCG	1	84	28	1	$969.05	3	1	$34.61	0.01%
141	110	FENTANYL OT LOZ 200MCG	1	30	8	1	$498.58	3.75	1	$62.32	0.01%
142	88	FENTANYL OT LOZ 600MCG	1	60	30	1	$1,542.85	2	1	$51.43	0.02%
143	86	FENTORA TAB 400MCG	1	90	30	1	$1,904.36	3	1	$63.48	0.03%
144	82	FENTANYL OT LOZ 800MCG	1	90	30	1	$2,666.69	3	1	$88.89	0.04%
			72,815	**4,978,795**	**1,582,663**		**$6,951,333.02**	**6.67**	**2.74**	**$17.21**	

Appendix I

30-Day Notice to Prior Authorize Lidoderm® Patches

Oklahoma Health Care Authority

September 2007

Manufacturer	Endo Pharmaceuticals, Inc.
Classification	Topical Anesthetic/Analgesic
Status	Prescription Only

Summary

Lidoderm® patch is FDA approved for relief of pain in individuals with post-herpetic neuralgia[1] (PHN). Lidocaine, is an amide-type local anesthetic agent, which is the active ingredient in the transdermal patch. The mechanism of action is suggested to be the stabilization of neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of neuronal impulses. The penetration of lidocaine through intact skin is sufficient to cause an analgesic effect without complete sensory block. The amount of lidocaine absorbed is directly proportional to the duration of application and total surface area over which the patch is applied. Each patch contains 700mg of lidocaine (50mg per gram adhesive) in an aqueous base. Lidoderm® patch is recommended for use on intact skin to cover the areas with the most pain. Up to three patches may be applied for a maximum of 12 hours duration in a 24-hour period. Patches may be cut into smaller pieces if necessary.

Recommended Pharmacologic Agents for Postherpetic Neuralgia

- Tricyclic Antidepressants
- Anticonvulsants
- Opioid Analgesics
- Capsaicin Products
- Anesthetic Agents

Comparison of Agents used in Post-Herpetic Neuralgia (PHN)#

Class	Examples	Safety	Clinical Evidence
Tri-Cyclic[6] Antidepressants	Amitriptyline, Nortriptyline, Desipramine **(Treat concomitant depression)**	Contraindicated in patients with myocardial infarction, cardiac arrhythmias or hepatic disease. Lesser extent with Nortriptyline and desipramine[6]	Watson CPN et. al.[2] Dubinsky RM et.al.[6]
Anticonvulsants[6]	Gabapentin, Pregabalin **(Also improve sleep and mood)**	Somnolence and dizziness	Rowbotham MC et. al.[3] Dubinsky RM et.al.[6]
Opioid Analgesics[5]	Oxycodone SR	Contraindicated in acute respiratory depression, acute alcoholism and risk of paralytic ileus. Constipation, sedation, & nausea may occur.	Watson CPN et. al.[4] Dubinsky RM et.al.[6]
Capsaicin Products[5] (AWP 60gram/$16.71)	Zostrix HP 0.075% **(reduce substance P)**	Local pain, burning, stinging and redness (~9% patients)	Watson CPN et. al.[5]
Topical Anesthetic Agents	Lidocaine containing agents (i.e. patches)	(See Adverse Effects and Safety)	(See Adverse Effects and Safety)
Other	Tramadol, ice packs, acupuncture[6]	n/a	n/a

#AAN=American Academy of Neurology

Note: Antiviral medications may reduce the risk of developing PHN if treated in the early stages of a shingles outbreak and in the developing stages of reactivation of varicella zoster virus.

Cost Comparison

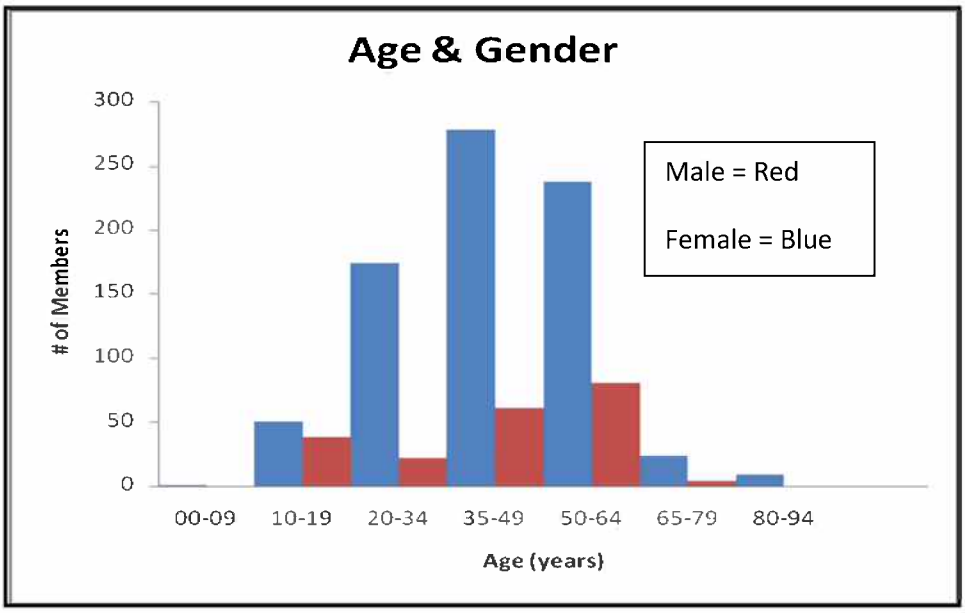
Product	EAC Cost /Unit	Maximum Dose	Monthly Cost@	Dosage Form
Lidocaine patch	$6.71	3 patches/day	$608.05	Patch
Lidocaine Cr(85gm)	$0.56	2 to 3 times/day	$51.75	Cream
Gabapentin	$0.38	3600 mg/day	$72.55	Tablet
Pregabalin	$1.92	600mg/day	$177.22	Capsule
Amitriptyline	$0.09	75 mg/day	$6.85	Capsule
Capsaicin Cr(60gm)	$0.28	3 to 4 times/day	$16.81	Cream
Oxycodone CR	$2.43	60 mg/day	$222.85	Tablet

@EAC + $4.15 dispensing fee

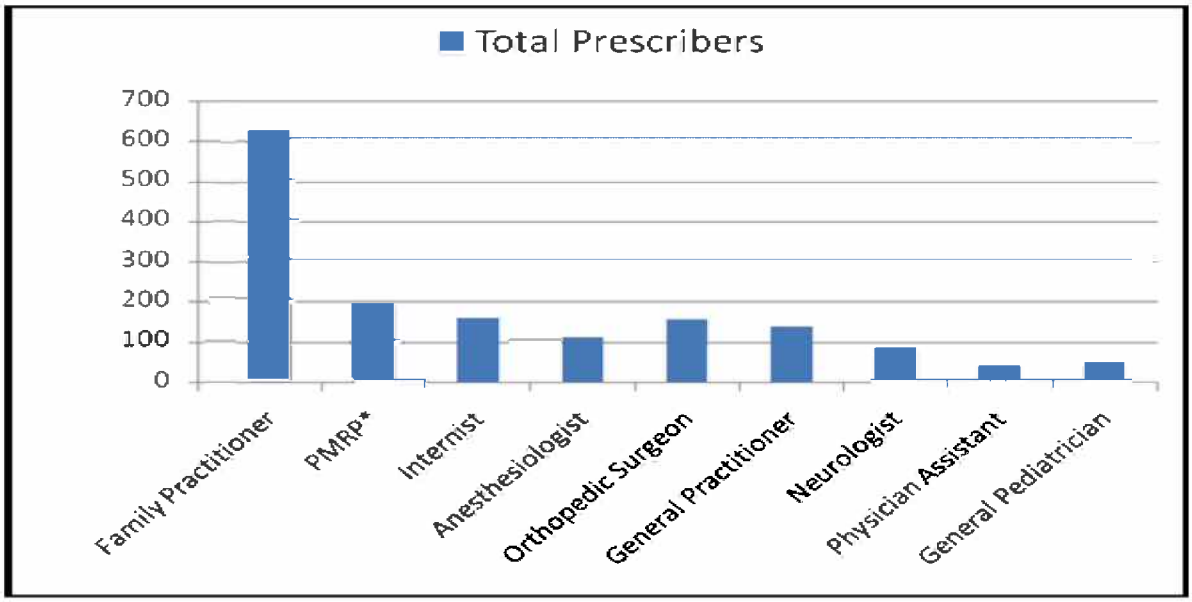
SoonerCare Utilization and Costs: CY '06

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS*	COST*	UNITS/DAY	COST/MEMBER	COST/DAY
LIDODERM DIS 5%	2,283	94,397	60,898	992	$536,742.55	1.55	$541.07	$8.81

*CY 05 Total Costs = $1,175,890.81; Total Members (Dual and Non-Dual) = 1,942



Prescriber CY '06



*PMRP = Physical Medicine and Rehabilitation Practioner

Utilization and Diagnosis Coding relevant to PHN CY '06

ICD-9 Diagnosis: Post-Herpetic Neuropathy

Members with diagnosis = 294

Members without diagnosis = 698

Off-label use has been associated with osteoarthritis, low back pain, and diabetic neuropathy.

Market News

January 2007 – Manufacturer of the lidocaine patch was issued a subpoena from the U.S.Department of Health and Human Services regarding sales and promotional practices for off label uses.

February 2007 – FDA Public Health Advisory regarding appropriate use and safety of topical anesthetics.

Public Health Advisory – February 2007

Topical application can result in high systemic levels and lead to toxic effects (eg, irregular heart beats, seizures, coma, respiratory depression, death). At risk are consumers, particularly those without the supervision of trained professionals, who apply large amounts of anesthetics (or cover large areas of the skin), leave these products on for long periods of time, or use materials, wraps, or dressings to cover the skin after anesthetic application. Application to areas of skin irritation, rash, and broken skin may also increase the risk of systemic absorption. The degree of systemic exposure following topical application is highly variable between patients; however, all of these practices listed may increase the degree of systemic absorption and should be avoided. The FDA is aware of two fatalities (presenting initially as seizures and then coma) following use of highly concentrated compounded topical anesthetics applied to legs and subsequently wrapped with plastic wrap to lessen pain of laser hair removal. The FDA is recommending that if topical anesthetics are needed prior to medical or cosmetic procedures, consumers ask their healthcare provider for instructions on safe use of these products, use only FDA-approved products, and use products with the lowest amount of anesthetic while applying the least amount possible to relieve pain. If a high degree of pain is expected that is not controlled by appropriate amounts of topical anesthetics, consumers should ask their healthcare provider for alternative techniques for pain control.

Recommendations

The College of Pharmacy recommends prior authorization of Lidoderm to ensure safe and appropriate use of this medication for FDA approved indications as advised by the FDA and as supported by current treatment guidelines.

PA Criteria

1. FDA approved diagnosis.

2. Provide documented treatment attempts at recommended dosing or contraindication to at least one agent in ALL of the following drug classes:
    a. Tricyclic antidepressants
    b. Anticonvulsants
    c. Topical or Oral Analgesics

3. Quantity limit of no more than 3 patches per day with a maximum of 90 patches in a month.

Indication and Usage

Relief of pain associated with post-herpetic neuralgia.

Postherpetic neuralgia is a chronic pain syndrome experienced by a minority of patients (9 to 34 %) after healing of herpes zoster rash (shingles). The elderly are more susceptible than younger individuals. About 50% with PHN over the age of 70 will have pain at 1 year. Patients <50 years have about 10% incidence. The pain associated to the local area affected by rash ranges from burning, throbbing, sharp, or shooting pain.

Bioavailability and Pharmacokinetics

- *Absorption*

  The amount of lidocaine absorbed is directly proportional to the duration of application and the surface area being treated. When used correctly, only 3 ±2% of the dose applied is expected to be absorbed. About 95% (665mg) of lidocaine is not absorbed in a used patch. Mean blood concentrations is about 0.13 ug/mL which is about one/tenth of the concentration needed to treat cardiac arrhythmias. Studies have shown that mean blood concentration does not increase when used at the recommended maximum daily dose of three patches applied simultaneously for up to 12 hours for 3 days.

- Distribution

  When applied topically, lidocaine is about 70% bound to plasma proteins. At much higher plasma concentrations than the recommended dosing schedule, protein binding becomes plasma concentration dependent. Lidocaine can cross the placental and blood brain barrier.

- Metabolism

  Lidocaine is metabolized rapidly in the liver resulting in active and less potent metabolites.

- Excretion

  Lidocaine is primarily excreted in the kidneys with less than 10% excreted unchanged. Half-life of lidocaine following IV administration is 81 to 149 minutes.

Dosage Forms (AWP $6.71 ea.)

Patches are approximately 10 cm x 14 cm in size which are available in 30-count carton. The product may be stored at room temperature. (NDC# 63481-687-06)

Dosing and Administration

Lidoderm Patch should only be applied to intact skin to cover the most painful affected areas. Up to 3 patches may be applied for a maximum of 12-hours within a 24-hour period. Patches may be cut into smaller sizes prior to application.

Remove patch if there is irritation or burning during application. Reapply when irritation subsides.

Excessive dosing may occur by applying to larger areas, using more than recommended number of patches, application on smaller patients, impaired route of elimination, application on broken or inflamed skin, or application for longer periods of time. Higher lidocaine plasma concentrations may lead to serious adverse effects.

Plasma concentrations should be monitored for patients with impaired renal or hepatic function.

Adverse Effects

Application site

- Blisters
- Bruising
- Burning Sensation
- Depigmentation
- Dermatitis
- Discoloration
- Edema
- Erythema
- Exfoliation
- Irritation
- Papules
- Petechia
- Pruritis
- Vesicles
- Abnormal Sensation

Systemic

- Light-headedness
- Nervousness
- Apprehension
- Euphoria
- Confusion
- Dizziness
- Drowsiness
- Tinnitus
- Blurred or Double Vision
- Vomiting
- Sensations of heat, cold or numbness
- Twitching
- Tremors
- Convulsions
- Unconsciousness
- Respiratory Depression and arrest
- Bradycardia
- Hypotension
- Cardiac Arrest

Precautions and Safety

- Approved for adult use.
- Pregnancy risk factor B.
- Contraindicated in patients with known hypersensitivity to local anesthetics.
- Important to store and dispose of patches out of the reach of children and pets.
- Wash hands after the handling of patches.
- Eye contact with patches should be avoided.
- Used patches should be folded so that adhesive side sticks to itself and safely discarded.

Drug Interactions

Antiarrhythmic Drugs

- Patches should be used with caution in patients using Class I antiarrhythmic drugs. Toxic effects are additive and possibly synergistic.

Local Anesthetics

- Higher absorption and plasma concentration may result with concomitant use of other anesthetic agents.

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Appendix J

FDA News

FOR IMMEDIATE RELEASE
August 22, 2007

Media Inquiries:
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Consumer Inquiries:
888-INFO-FDA

FDA Approves Risperdal for Two Psychiatric Conditions in Children and Adolescents

The U.S. Food and Drug Administration today approved Risperdal (risperidone) for the treatment of schizophrenia in adolescents, ages 13 to 17, and for the short-term treatment of manic or mixed episodes of bipolar I disorder in children and adolescents ages 10 to 17. This is the first FDA approval of an atypical antipsychotic drug to treat either disorder in these age groups.

Until now, there has been no FDA-approved drug for the treatment of schizophrenia for pediatric use and only lithium is approved for the treatment of bipolar disorder in adolescents ages 12 and up.

“The pediatric studies of Risperdal provided an opportunity to assess the effectiveness, proper dose, and safety of using this product in the pediatric population,” said Dianne Murphy, M.D., director of FDA’s Office of Pediatric Therapeutics. “These data have permitted the identification of the effective pediatric dose ranges and have provided an evidence-based approach for treating these disorders in pediatric patients.”

The FDA first approved Risperdal in 1993 for the treatment of schizophrenia in adults. The drug later was approved for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults and the treatment of irritability associated with autistic disorder in children and adolescents 5 to 16 years old.

Evidence to support this approval was collected through studies the FDA requested as part of its pediatric drug development initiatives.

The efficacy of Risperdal in the treatment of schizophrenia in adolescents was demonstrated in two short-term (6 to 8 weeks), double-blind, controlled trials. All patients were experiencing an acute episode of schizophrenia at the time of enrollment. Treated patients generally had fewer symptoms, including a decrease in hallucinations, delusional thinking, and other symptoms of their illness.

The efficacy of Risperdal in the treatment of manic or mixed episodes in children or adolescents with bipolar I disorder was demonstrated in a three-week, randomized, double-blind, placebo-controlled, multicenter trial in patients who were experiencing a manic or mixed episode. Treated patients generally had fewer symptoms, including a decrease in their elevated mood and hyperactivity, and other symptoms of their illness.

Drowsiness, fatigue, increase in appetite, anxiety, nausea, dizziness, dry mouth, tremor, and rash were among the most common side effects reported.

Schizophrenia is a serious and disabling psychiatric disorder. Symptoms may include hallucinations, delusions, and disorganized thinking. Bipolar disorder, also known as manic-depressive illness, is a serious psychiatric disorder that causes wide shifts in a person's mood, energy, and ability to function.

Risperdal is manufactured by Janssen, L.P. of Titusville, N.J.

For more information:

FDA Office of Pediatric Therapeutics
www.fda.gov/oc/opt/default.htm

National Institute of Mental Health—Schizophrenia
www.nimh.nih.gov/healthinformation/schizophreniamenu.cfm

National Institute of Mental Health—Bipolar Disorder
www.nimh.nih.gov/healthinformation/bipolarmenu.cfm

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Public Health Advisory

Nonprescription Cough and Cold Medicine Use in Children

August 15, 2007

Federal Register Meeting Notice

FDA announced today that, in October, the Nonprescription Drugs Advisory Committee will discuss the safety and effectiveness of cough and cold drug product use in children. Questions have been raised about the safety of these products and whether the benefits justify any potential risks from the use of these products in children, especially in children under 2 years of age. In preparation for the meeting, FDA is reviewing safety and efficacy data for the ingredients of these products.

Some reports of serious adverse events associated with the use of these products appear to be the result of giving too much of these medicines to children. An over-the-counter cough and cold medicine can be harmful if more than the recommended amount is used, if it is given too often, or if more than one cough and cold medicine containing the same active ingredient are being used. To avoid giving a child too much medicine, parents must carefully follow the directions for use of the product in the "Drug Facts" box on the package label.

What should parents know about using cough and cold products in children?

- Do ***not*** use cough and cold products in children under 2 years of age UNLESS given specific directions to do so by a healthcare provider.
- Do not give children medicine that is packaged and made for adults. Use only products marked for use in babies, infants or children (sometimes called "pediatric" use).
- Cough and cold medicines come in many different strengths. If you are unsure about the right product for your child, ask a healthcare provider.
- If other medicines (over-the-counter or prescription) are being given to a child, the child's healthcare provider should review and approve their combined use.
- Read all of the information in the "Drug Facts" box on the package label so that you know the ***active ingredients*** and the ***warnings***.
- Follow the ***directions*** in the "Drug Facts" box. Do not give a child medicine more often or in greater amounts than is stated on the package.
- Too much medicine may lead to serious and life-threatening side effects, particularly in children aged 2 years and younger.
- For liquid products, parents should use the measuring device (dropper, dosing cup or dosing spoon) that is packaged with each different medicine formulation and that is marked to deliver the recommended dose. A kitchen teaspoon or tablespoon is not an appropriate measuring device for giving medicines to children.
- If a measuring device is not included with the product, parents should purchase one at the pharmacy. Make sure that the dropper, dosing cup or dosing spoon has markings on it that match the dosing that is in the ***directions*** in the "Drug Facts" box on the

package label, or is recommended by the child's health care provider.

- If you DO NOT UNDERSTAND the instructions on the product, or how to use the dosing device (dropper, dosing cup or dosing spoon), DO NOT USE the medicine. Consult your healthcare provider if you have questions or are confused.
- Cough and cold medicines only treat the symptoms of the common cold such as runny nose, congestion, fever, aches, and irritability. They do not cure the common cold. Children get better with time.
- If a child's condition worsens or does not improve, stop using the product and immediately take the child to a health care provider for evaluation.

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Date created: August 15, 2007

FDA News

FOR IMMEDIATE RELEASE
August 14, 2007

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Consumer Inquiries:
888-INFO-FDA

Manufacturers of Some Diabetes Drugs to Strengthen Warning on Heart Failure Risk

Companies Will Include Boxed Warning on Drug Label

The U.S. Food and Drug Administration today announced manufacturers of certain drugs approved to treat Type 2 diabetes have agreed to add a stronger warning on the risk of heart failure, a condition that occurs when the heart does not adequately pump blood. The information will be included in the form of a "boxed" warning—FDA's strongest form of a warning. The upgraded warning emphasizes that the drugs may cause or worsen heart failure in certain patients.

After a review of postmarketing adverse event reports, FDA determined that an updated label with a boxed warning on the risks of heart failure was needed for the entire thiazolidinedione class of antidiabetic drugs. This class includes Avandia (rosiglitazone), Actos (pioglitazone) Avandaryl (rosiglitazone and glimepiride), Avandamet (rosiglitazone and metformin), and Duetact (pioglitazone and glimepride). These drugs are used in conjunction with diet and exercise, to improve blood sugar control in adults with type 2 (non-insulin-dependent) diabetes. FDA had asked the drug's manufacturers, GlaxoSmithKline and Takeda, to address these concerns.

"Under FDA's postmarketing surveillance program, we carefully monitor new safety information for marketed drugs and take appropriate action when necessary to inform patients and health care providers of new information," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "This new boxed warning addresses FDA's concerns that despite the warnings and information already listed in the drug labels, these drugs are still being prescribed to patients without careful monitoring for signs of heart failure."

FDA's review of adverse event reports found cases of significant weight gain and edema—warning signs of heart failure. In some reports, FDA noted, continuation of therapy has been associated with poor outcomes, including death.

The strengthened warning advises health care professionals to observe patients carefully for the signs and symptoms of heart failure, including excessive, rapid weight gain, shortness of breath, and edema after starting drug therapy. Patients with these symptoms who then develop heart failure should receive appropriate management of the heart failure and use of the drug should be reconsidered. People who have questions should contact their health care providers to discuss alternative treatments.

The warning also states that these drugs should not be used by people with serious or severe heart failure who have marked limits on their activity and who are comfortable only at rest or who are confined to bed or a chair.

FDA's review of Avandia and possible increased risk of heart attacks is ongoing. On July 30, 2007, FDA's Endocrine and Metabolic Advisory Committee and the Drug Safety and Risk Management Advisory Committee recommended that Avandia continue to be marketed, and further recommended that information be added to the labeling for risk of heart attacks (ischemic risks).

For more information, visit:
Rosiglitazone maleate (marketed as Avandia, Avandamet, and Avandaryl) Information
Pioglitazone HCl (marketed as Actos and Duetact) Information

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Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.

Early Communication About an Ongoing Safety Review

Omeprazole (Prilosec)
Esomeprazole (Nexium)

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 causal 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.

FDA has received and is reviewing new safety data about Prilosec (omeprazole) and Nexium (esomeprazole). On May 29, 2007, AstraZeneca, the manufacturer of Prilosec (omeprazole) and Nexium (esomeprazole), sent FDA and other regulatory authorities world-wide their preliminary review of new data from two small long-term clinical studies in patients with severe gastroesophageal reflux disease (GERD). In both studies, patients were to be randomly assigned to receive treatment with a drug (either omeprazole or esomeprazole) or to have surgery to control their GERD. The results from the study of Prilosec and analyses from an ongoing study of Nexium raised concerns that long-term use of Prilosec or Nexium may have increased the risk of heart attacks, heart failure, and heart-related sudden death in those patients taking either one of the drugs compared to patients who received surgery.

Since May 29, the company has provided FDA with a large amount of additional data, including more information on patient follow-up from the two long-term studies mentioned above, and pooled analyses of other controlled clinical studies, including placebo-controlled trials of up to two-year's duration. At this time, FDA's preliminary conclusion is that collectively, these data do not suggest an increased risk of heart problems for patients treated with omeprazole or esomeprazole. Therefore, FDA does not believe that healthcare providers or patients should change either their prescribing practices or their use of these products at this time.

This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. FDA plans to complete its review within three months, and will communicate its conclusions and any resulting recommendations to the public at that time.

What does FDA know now about these data?

A 14-year study comparing treatment with the drug omeprazole to surgery in patients with severe GERD found that more patients treated with omeprazole had heart attacks, heart failure, and heart-related sudden death than did the patients who had surgery. The difference between the two groups of patients was seen within the first year of the study, and continued over time. A second, still ongoing, study comparing esomeprazole to surgery had five year follow-up information on patients. While the initial data from this study suggested a difference between treatments in the rate of cardiovascular events, an updated report submitted by AstraZeneca found that the number of patients who experienced heart problems was similar in both treatment groups.

While both of these studies collected safety data, the study protocols did not specify how heart problems, such as heart attacks, were to be defined or documented. As a result,

evaluating the information that has been gathered about the safety of either drug in these studies is difficult.

Also, many of the patients who were randomized to the group that was to have surgery withdrew from the study without ever undergoing the surgical procedure. The patients who did undergo surgery tended to be younger, and less likely to have a past history of heart problems or risk factors for heart problems, than those who were treated with one of the drugs. These differences between the two groups of patients could have biased and significantly influenced the safety data from these studies.

Finally, FDA's preliminary conclusion about the information from these two studies is further supported by an additional analysis of 14 comparative studies of omeprazole, of which four were placebo-controlled. Patients in these studies were treated for up to two years. In these studies, there were fewer heart attacks or other heart problems reported in the patients treated with omeprazole compared to patients that were given a placebo. Although these studies were not specifically conducted to assess the risk of heart problems, and patient follow-up is incomplete, they do not suggest an increased risk of heart problems with the use of omeprazole. FDA will continue its review of all available data.

Based on everything we know now, FDA's preliminary conclusion is that the observed difference in risk of heart attacks and other heart related problems seen in early analyses of the two small long-term studies is not a true effect.

Prilosec and Nexium are members of a class of drugs called proton pump inhibitors (PPIs) and work by reducing the amount of acid produced by the stomach. Both drugs are used for the treatment of gastroesophageal reflux disease (GERD) including a condition where the lining of the esophagus wears away (erosions), and for maintenance of healing erosions of the esophagus. They are also used for the treatment of ulcers. Prilosec (omeprazole) and Nexium (esomeprazole) are available by prescription. Prilosec is also sold over-the-counter for frequent heartburn.

Report serious adverse events to
FDA's MedWatch reporting system by completing a form on line at
http://www.fda.gov/medwatch/report/hcp.htm, by faxing (1-800-FDA-0178),
by mail using the postage-paid address form provided online
(5600 Fishers Lane, Rockville, MD 20853-9787),
or by telephone (1-800-FDA-1088)

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Date created: August 9, 2007

FDA News

FOR IMMEDIATE RELEASE
July 27, 2007

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888-INFO-FDA

FDA Permits Restricted Use of Zelnorm for Qualifying Patients

The U.S. Food and Drug Administration announced that it is permitting the restricted use of Zelnorm (tegaserod maleate) under a treatment investigational new drug (IND) protocol to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in women younger than 55 who meet specific guidelines.

In some instances, patients with a serious or life-threatening disease or condition who are not enrolled in a clinical trial may be treated with a drug not approved by the FDA. Generally, such use is allowed within guidelines called a treatment IND, when no comparable or satisfactory alternative drug or therapy is available.

In addition to the age and gender restrictions, the IND protocol for Zelnorm limits use of the drug to those with IBS-C or CIC whose physicians decide the drug is medically necessary. Patients must sign consent materials to ensure they are fully informed of the potential risks and benefits of Zelnorm.

On March 30, 2007, the FDA asked Novartis, the manufacturer of Zelnorm, to suspend its U.S. marketing and sales because a safety analysis found a higher chance of heart attack, stroke, and unstable angina (heart/chest pain) in patients treated with Zelnorm compared with treatment with an inactive substance (placebo).

At that time, the FDA indicated that there might be patients for whom the benefits of Zelnorm treatment outweigh the risks and for whom no other treatment options were available. FDA committed to work with Novartis to allow access to Zelnorm for those patients through a special program. That work yielded this IND protocol.

"These patients must meet strict criteria and have no known or pre-existing heart problems and be in critical need of this drug," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research (CDER). "Zelnorm will remain off the market for general use."

Irritable bowel syndrome is a disorder characterized most commonly by cramping, abdominal pain, bloating, constipation, and diarrhea. IBS causes a great deal of discomfort and distress, but it does not permanently harm the intestines and does not lead to disease. For some people, however, IBS can be disabling. They may be unable to work, attend social events, or even travel short distances.

Patients are considered to have chronic constipation if they have fewer than three complete spontaneous bowel movements per week and at least one of the following symptoms for at least 25 percent of those bowel movements: straining, hard stools, incomplete evacuation.

Physicians with IBS-C or CIC patients who meet the IND criteria should contact Novartis at 888-669-6682 or 866-248-1348. Those who do not qualify for the Zelnorm treatment protocol may contact FDA's Division for Drug Information about other options at 888-463-6332.

For more information:

Novartis Zelnorm Web page
www.zelnorm.com

National Institute of Diabetes and Digestive and Kidney Diseases—Irritable Bowel Syndrome
http://digestive.niddk.nih.gov/ddiseases/pubs/ibs/

International Foundation for Functional Gastrointestinal Disorders
www.iffgd.org

FDA Center for Drug Evaluation and Research
www.fda.gov/cder

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FDA News

FOR IMMEDIATE RELEASE
July 2, 2007

Media Inquiries:
Sandy Walsh, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves First Generic Versions of Lamisil Tablets

Agency also approves over-the-counter terbinafine cream to treat athlete's foot

The U.S. Food and Drug Administration today approved the first generic versions of prescription Lamisil (terbinafine hydrochloride) tablets, used to treat nail fungus infection (onychomycosis). Such infections occur when fungi invade a fingernail or toenail or the skin underneath the nail.

"This approval offers Americans additional alternatives when choosing medications to treat nail fungus infections," said Gary J. Buehler, R.Ph., director of FDA's Office of Generic Drugs.

FDA approved applications from multiple generic drug manufacturers for terbinafine hydrochloride tablets in 250-milligram formulations. Manufacturers include: Amneal Pharmaceuticals, Apotex Corp., Aurobindo Pharma USA Inc., Dr. Reddy's Laboratories Ltd., Gedeon Richter USA Inc., Genpharm Inc., Glenmark Pharmaceuticals Inc., InvaGen Pharmaceuticals Inc., Mylan Pharmaceuticals Inc., Orgenus Pharma Inc., Roxane Laboratories Inc., TEVA Pharmaceuticals USA, Watson Laboratories Inc., Wockhardt USA Inc.

The remaining patent or exclusivity for Lamisil expired on June 30, 2007.

According to the online trade magazine, *Drug Topics*, Lamisil tablets are the 57th highest selling brand-name prescription drug by retail dollars in the United States.

In addition to terbinafine tablets, FDA also approved an application for a generic version of over-the-counter Lamisil cream (terbinafine hydrochloride,1 percent) to treat athlete's foot, a skin disease caused by a fungus that usually occurs between the toes. The cream is manufactured by Taro Pharmaceuticals U.S.A. Inc.

The FDA's Office of Generic Drugs ensures that generic drugs are safe and effective through a thorough scientific and regulatory process.

For more information:
Office of Generic Drugs
www.fda.gov/cder/consumerinfo/generic_equivalence.htm

Generic Drugs: What You Need to Know
www.fda.gov/fdac/features/2002/502_generic.html

FDA monthly reports for first-time generics
www.fda.gov/cder/ogd/approvals/

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Information for Healthcare Professionals

Omalizumab (for Subcutaneous Use) (marketed as Xolair)

The full prescribing information (product labeling) for Xolair was updated on July 2, 2007 with important new safety information—see summary below.

FDA ALERT [2/2007, updated 7/2007]: This Alert highlights important revisions to the full prescribing information for Xolair. The updated full prescribing information for Xolair (July 2007) includes a new Boxed WARNING, updated WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS--Postmarketing Spontaneous Reports. A New Medication Guide about the risk of anaphylaxis following administration of Xolair is to be distributed with each dose of Xolair. These revisions address the risk of anaphylaxis following treatment with Xolair. The implications of this new labeling for healthcare professionals who administer Xolair are summarized below. Xolair is approved to treat adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

The Xolair product label now includes a Boxed Warning, new Warnings and Precautions and an Adverse Reactions section that address the risk of anaphylaxis following administration of Xolair. Xolair also has a new Medication Guide for distribution with each Xolair prescription.

Recommendations and considerations for healthcare professionals:

- Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue has been reported to occur after administration of Xolair.
- Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond one year after beginning regular treatment with Xolair.
- Due to the risk of anaphylaxis, Xolair should only be administered to patients in a healthcare setting under direct medical supervision by providers who:
  - Are prepared to identify and treat anaphylaxis after Xolair treatment
  - Know anaphylaxis can occur after any dose of Xolair, even if past doses were well tolerated
  - Know the onset of anaphylaxis can be delayed after administration
  - Observe patients for an appropriate period of time following each Xolair injection

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  - Have trained personnel, medications, and equipment for the treatment of life-threatening anaphylaxis available when administering Xolair. Medical personnel administering Xolair should be prepared to recognize and treat anaphylaxis
- Inform patients receiving Xolair treatment of their chance of developing anaphylaxis (including anaphylaxis delayed for 24 hours or more following Xolair treatment) and how to treat it if it occurs. The "Information for the patient" section below provides more detail.
  - Give patients the Medication Guide for Xolair and instruct them to read it before starting treatment with Xolair and before each subsequent dose
  - Inform patients of the signs and symptoms of anaphylaxis
  - Instruct patients to seek immediate care should such symptoms occur
- Discontinue Xolair in patients who experience a severe hypersensitivity reaction
- Report patients who have adverse events including anaphylaxis or hypersensitivity to the FDA's MedWatch program (see reporting information at the bottom of this page)
- Periodically reassess the need for continued Xolair therapy based upon the patient's disease severity and level of asthma control

Information for the patient: *Physicians who are prescribing Xolair should discuss with their patients:*

- Because of the chance of anaphylaxis with Xolair, patients should receive Xolair treatment in a doctor's office and be observed for an appropriate period of time after each treatment
- Anaphylaxis can be serious and life-threatening. Signs and symptoms of anaphylaxis include:
  - Wheezing, shortness of breath, cough, chest tightness, or trouble breathing
  - Low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of "impending doom"
  - Swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing
  - Flushing, itching, hives, or feeling warm
- Anaphylaxis can occur with the first dose or after any dose of Xolair
- Anaphylaxis can begin 24 hours or more after Xolair treatment
- To tell your healthcare provider right away if you have symptoms of anaphylaxis after receiving Xolair, and
- To get emergency medical attention immediately if any symptoms of anaphylaxis appear after leaving the doctor's office

Report serious adverse events to FDA's MedWatch reporting system by completing a form on line at http://www.fda.gov/medwatch/report/hcp.htm, by faxing (1-800-FDA-0178), by mail using the postage-paid address form provided on line (HF-2, 5600 Fishers Lane, Rockville, MD 20853-9787), or by telephone (1-800-FDA-1088).
Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov

Information for Healthcare Professionals

Omalizumab (for Subcutaneous Use) (marketed as Xolair)

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- Carry medical contact information and be fully prepared to begin treatment for anaphylaxis
- You should not receive Xolair if you have ever had an allergic reaction to a Xolair injection
- Do not change or stop taking any of your other asthma medications unless otherwise instructed to do so by a healthcare provider
- Patients may not see immediate improvement in their asthma after beginning Xolair therapy

Background Information and Data

Clinical trial experience

Three cases of anaphylaxis were identified among the 3,507 subjects exposed to Xolair in premarketing clinical trials. Reports of anaphylaxis were based on investigator judgment in relationship to the study drug. The time to onset of anaphylaxis after administration of Xolair in these three patients was:

- 90 minutes in two patients
- 2 hours in one patient.

In addition to these three cases, there were two cases of dyspnea and/or wheezing with urticaria that were not reported as anaphylaxis, but met the diagnostic criteria for anaphylaxis that were used to define the postmarketing cases (see below). One of these patients developed localized urticaria, dyspnea, coughing, and wheezing after receiving the first dose of Xolair. The second patient experienced urticaria, dyspnea, and hot flushes the day after receiving the third dose of Xolair.

Postmarketing Cases

Based on a review of 124 spontaneous case reports and an estimated exposure of about 57,300 patients from June 2003 to December 2006, the frequency of anaphylaxis attributed to Xolair use was estimated to be at least 0.2% of treated patients. Because adverse reactions are reported voluntarily, the actual frequency of anaphylaxis and percent of patients with onset during specific time periods after administration of Xolair may differ from these estimates and this case series. The case definition of anaphylaxis used for this review included either skin or mucosal tissue involvement, and, either airway compromise, and/or reduced blood pressure with or without associated symptoms; and a temporal relationship with Xolair administration with no other identifiable cause.

Symptoms and signs of anaphylaxis in these reported cases included bronchospasm, hypotension, syncope, urticaria, angioedema of the throat or tongue, dyspnea, cough, chest tightness, cutaneous angioedema, and generalized pruritus. Some patients required oxygen and parenteral medications. Pulmonary involvement, including bronchospasm, dyspnea, cough, or chest tightness, was reported in

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89% of the cases. Hypotension or syncope was reported in 14% of cases. Fifteen percent of patients required hospitalization. A previous history of anaphylaxis unrelated to Xolair was reported in 24% of the cases. The list below provides information about the time to onset of anaphylaxis following Xolair administration for these patients.

- 30 minutes or less 35%
- Greater than 30 to 60 minutes 16%
- Greater than 60 to 90 minutes 2%
- Greater than 90 to 120 minutes 6%
- Greater than 2 hours to 6 hours 5%
- Greater than 6 to 12 hours 14%
- Greater than 12 to 24 hours 8%
- Greater than 24 hours (up to 4 days) 5%
- Unknown 9%.

Of the reported cases of anaphylaxis, 39% occurred after the first dose of Xolair, 19% occurred with the second dose, 10% occurred with the third dose, and the rest after subsequent doses. One case occurred after 39 doses (after 19 months of continuous therapy, anaphylaxis occurred when treatment was restarted following a 3 month gap). Twenty-three patients who experienced anaphylaxis were re-challenged with Xolair; among them, 18 had a recurrence of similar symptoms of anaphylaxis. Four patients who experienced urticaria and not anaphylaxis were re-challenged with Xolair and developed anaphylaxis upon re-challenge.