Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

January 11, 2006 @ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Gorman, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – January 11, 2006**

DATE: January 4, 2006

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

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

Call to Order

Public Comment Forum

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

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

30 Day Notice to Prior Authorize Nasal Allergy Products – **See Appendix C.**

60 Day Notice to Prior Authorize Muscle Relaxant Products – **See Appendix D.**

Action Item – Annual Review of Antidepressant (SSRI) PBPA Category – **See Appendix E.**

Action Item – Annual Review of Anxiolytics/Hypnotics – **See Appendix F.**

Action Item – Annual Review of ADHD PBPA Category – **See Appendix G.**

Review and Discuss Antiepileptic Utilization – **See Appendix H.**

New Product Reviews and Notices – **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – January 11, 2006 @ 6:00p.m.

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

AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

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

A. December 14, 2005 DUR Minutes – Vote
B. Memorandum of December 14, 2005 DUR Recommendations
C. Memorandum of 2006 DUR Meeting Dates

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

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

A. Retrospective Drug Utilization Review for September 2005
B. Medication Coverage Activity Audit for December 2005
C. Help Desk Activity Audit for December 2005
D. Pharmacotherapy Management Report 2nd Quarter FY06

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

5. 30 Day Notice to Prior Authorize Nasal Allergy Products – See Appendix C.

A. Product Summary
B. COP Recommendations

Items to be presented by Dr. Le, Dr. Gorman, Dr. Whitsett, Chairman:

6. 60 Day Notice to Prior Authorize Muscle Relaxants Products – See Appendix D.

A. Recommendations
B. Potential Economic Impact

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

7. Action Item – Annual Review of Antidepressants/SSRIs – See Appendix E.

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

Items to be presented by Dr. Browning, Dr. Whitsett, Chairman:

8. Action Item – Annual Review Anxiolytic/Hypnotics – See Appendix F.

A. Current Prior authorization Criteria
B. Utilization Review
C. Market Changes to Class
D. COP Recommendations

Items to be presented by Dr. Moore, Dr. Whitsett, Chairman:

9. Action Item – Annual Review of ADHD PBPA Category – See Appendix G.

A. Current Prior authorization Criteria
B. Utilization Review
C. Market Changes to Class
D. COP Recommendations

Items to be presented by Dr. Chonlahan, Dr. Whitsett, Chairman:

10. Review and Discuss Antiepileptic Utilization – See Appendix H.

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

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

11. New Product Reviews and Notices – See Appendix I.

A. New Product Summaries

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Contraceptive Utilization Review
B. Antidiabetic Utilization Review
C. Antiinfectives Utilization Review
D. Analgesic/Narcotic Utilization Review
E. Annual Reviews
F. New Product Reviews
G. OTC Formulary

14. Adjournment

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of DECEMBER 14, 2005

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Dorothy Gourley, D.Ph.	X	
Anetta Harrell, D.Ph.	X	
Kyle Hrdlicka, D.O.		X
Dan McNeill, Ph.D., PA-C	X	
Clif Meece, D.Ph.	X	
James Rhymer, D.Ph	X	
Dick Robinson, D.Ph., Vice-Chair		X
Thomas Whitsett, M.D., Chair	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	X	
Carol Moore, Pharm.D. Clinical Pharmacist	X	
Neeraj Patel, Pharm.D., Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.	X	
Visiting Pharmacy Students: **n/a**		

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 Governmental & Public Affairs		X
Lynn Mitchell, M.D., M.P.H/Director of Medical Services	X	
Nancy Nesser, D.Ph., 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:

Jonathan Klock, GSK	Aaron Walker, Schering Plough	Chris Caggiano, TAP
Jim Dunlap, Eli Lilly	Fran Kaiser, Merck	Aliza Tomlinson, OMJ
Jim Fowler, AstraZeneca	Justin Springfield, Sepracor	Jason Heiderschadt, P&G
Steve Higgins, TAP	Lance Stewart, Merck	Mark Declerk, Eli Lilly
Juliet Fritz	Richard Ponder, J&J	Fred Garfinkel, MD; Hillcrest Medical Ctr.

PRESENT FOR PUBLIC COMMENT:

Fred Garfinkel, MD; Hillcrest Medical Ctr. Agenda Item 5

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

1A: Roll Call

Dr. Whitsett called the meeting to order and introduced new Board Member, Dr. Anetta Harrell. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED.

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

2A: Acknowledgement of Speakers and Agenda Item

Dr. Whitsett acknowledged speaker for Public Comment.

ACTION: NONE REQUIRED.

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

3A: November 9, 2005 DUR Minutes

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

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report for August 2005

4B: Medication Coverage Activity Report: November 2005

4C: Help Desk Activity Report: November 2005

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE XOPENEX HFA™**

For Public Comment, Dr. Fred Garfinkel: *Thank you very much. I was asked to give some information on I believe, Albuterol and I think this is a privilege because I think this is critically important to the management of the obstructive airways diseases. What I'm quickly going to do is give you a summary of the demographics of the obstructive airways diseases, show you how the understanding of the physiology of the diseases has changed, is changing in the 2000's, some clinical outcomes and then a conclusion. And quickly, the most important thing, asthma represents an inflammatory disease of over 20 million people. The current understanding as of 2000, for 2005, that it's mediated by inflammatory cytokines, predominantly interleukins 4, 5 and 13 and major inflammatory media is involved in airway hyper reactivity and airway remodelling, which is the scarring of the airways. As of 2005 in the United States, COPD is recognized as the fourth leading cause of morbidity and mortality. It is expected to become the third leading cause of mortality. It affects over 24 million people, therefore asthma and COPD represent somewhere between 40 and 50 million patients and the important thing out of this very recently published article, COPD is among the most important disease of our lifetime and the lifetimes of our children. Current mortality data on the six leading causes of death, if you notice, all are flat or are significantly decreasing except for COPD which has an increasing death rate, despite our "knowledge of how to treat it" over the last thirty to forty years. Current literature, this came out of 2001, beta agonists, first line therapy recommended by most COPD treatment guidelines. Importantly 2005 COPD is recognized as a systemic disease. It is a systemic disease because of the inflammatory media that is released from the lung into the systemic circulation and as a systemic disease, it is now recognized that the leading cause of death in COPD is cardiovascular, approximately 50% of all deaths are cardiovascular. COPD has a higher CRP level than even ischemic heart disease due to the release of IL-6 into the circulation from the lung. Current literature from 2005, Il-6, IL-8 (unintelligible) factor are major systemic inflammatory mediators in COPD and that is emphasized in this article by Wunders showing that if you give anti IL-8 you actually decrease the inflammatory properties of the produced sputum and you decrease some of the inflammatory conditions in the lung. If we look at American Journal of Respiratory Critical Care Medicine 2004, asthma is characterized also as an inflammatory disease, both in terms of airway hyper reactivity and airway remodelling, mediated by IL-4, IL-5, IL-9 and IL-13. Why am I emphasizing these inflammatory cytokines? In 2002, an article published by Bronke in the Journal of Allergy and Clinical Immunology and we're going to focus on interferon and this should be gamma, IL-13 and IL-5, three of the inflammatory mediators definitely involved in COPD and asthma, and what you see is, if you give the R-isomer alone, levalbuterol and Xopenex compared to control, you reduce the inflammatory mediators. If you raise the concentration, you reduce them further. If you add S-isomer at the same concentration, these numbers go back up towards control. If you add S-isomer at a higher concentration, they go up to or above control. The conclusion of this study was that the R-isomers have antiinflammatory properties, the R-isomer of albuterol, levalbuterol. The S-isomer actually causes inflammation. It's pro-inflammatory and interestingly, the inflammatory mediators that it*

produces are the same ones that are now listed as the cause of the disease. This is data on what else the S-isomer does. It causes uptake of calcium into the smooth muscle cell. That is responsible for bronchomotor tone. The reason anticholinergic therapy works is by blocking this effect. It is accepted now in COPD as anticholinergic therapy may be better than beta-agonist therapy because of blocking this. If you don't have it all, you don't have to block it. This is a quick summary of the S-isomer and the R-isomer. The S-isomer basically I wanted to point out, augments inflammation by increasing the production of the inflammatory mediators. The R-isomer has been shown to decrease the production of the inflammatory mediators. That's a very quick summary. Here is some clinical data. This was a prospective study by Nowak out of emergency rooms and asthma patients in Detroit, and what he showed is if you give levalbuterol compared to racemic albuterol, single isomer, R and S together, first dose you get better bronchodilator response. After three hours in the emergency room you still have much better bronchodilator response, statistically highly significant. They then looked at S-isomer levels in the blood and their admissions. This is quartiles, the lowest amount of S, the highest amount of S. The higher the S, admissions were lineally related. Why is this so important? They had almost a 25% admission rate for asthma in the ER, exactly the published national ER admission rate. When they treated their patients prospectively with levalbuterol alone, no S-isomer, not racemic albuterol, their admission rate went down below 5% Is that unique? This was a double-blind, a blinded prospective study, the largest study on beta-agonists ever published in the world by Karl. It came out in the Journal of Pediatrics out of Rainbow Babies in Cleveland. This was their admissions giving racemic albuterol, their admissions giving single isomer levalbuterol or Xopenex. They reduced their admissions by almost 9.5% They have a higher admission rate because they kept patients for two hours and then they were admitted or sent home. But the important thing is highly significant reduction in ER admissions. If you just take this number of decreased admissions of every emergency room in the United States would follow using Xopenex, the country would save over $300 million based on current published statistics. My experience at Hillcrest in Tulsa, the year before to the year after we switched to Xopenex, total respiratory treatments went down by almost 25% Treatments per patient went down by 22% As importantly, mistreatments as drug errors, total mistreatments went down by over 30% and if you look just at those that were due to lack of therapist time, went down almost 50% We were able to get better results, fewer treatments and therefore fewer drug errors. The summary I don't have to give. I'm going to take right out of the literature. This was published by Regis McFadden in the American Journal of Respiratory and Critical Care Medicine. At the end of 2003 he was asked to write the state of the art review of the reactive airways diseases. This man is dogmatic. Unless he and his group did the research, he doesn't believe in it. What he said was the S-isomer is pro-inflammatory, the R-isomer alone gets better bronchodilation with fewer side effects, and his conclusion, not mine, it produces better bronchodilation at lower cost than giving the racemic drug. Lower cost because you get better outcomes, fewer complications, fewer hospital admissions. I've said my thing .... thank you.
Materials included in agenda packet; presented by Dr. Flannigan.
Motion made by Dr. Gourley to approve COP recommendations; seconded by Dr. Meece.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE DARVOCET A500™ AND BALACET 325™**
Materials included in agenda packet; presented by Dr. Moore.
Dr. McNeill moved to approve COP recommendations as submitted; seconded by Dr. Meece.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **60-DAY NOTICE TO PRIOR AUTHORIZE NASAL ALLERGY PRODUCTS**
Materials included in agenda packet; presented by Dr. Flannigan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **REVIEW AND DISCUSS MUSCLE RELAXANT UTILIZATION**
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS**
Materials included in agenda packet; presented by Dr. Patel.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS**
Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **ANNUAL REVIEW OF FORTEO® AND OSTEOPOROSIS UTILIZATION REVIEW**
Materials included in agenda packet; presented by Dr. Browning.
Dr. Meece moved to approve quantity limit on Boniva® (3 tablets/84 days); seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

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

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

AGENDA ITEM NO. 14: **FUTURE BUSINESS**
14A: **Antipsychotic Utilization Review**
14B: **Anticonvulsant Review**
14C: **Contraceptive Utilization Review**
14D: **Antidiabetic Utilization Review**
14E: **Antiinfectives Utilization Review**
14F: **Analgesic/Narcotic Utilization Review**
14G: **Annual Reviews**
14H: **New Product Reviews**
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

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

The University of Oklahoma College of Pharmacy

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

Memorandum

Date: December 15, 2005

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 December 14, 2005.

Recommendation 1: Vote to Prior Authorize Xopenex HFA™

MOTION CARRIED by unanimous approval.

- Use of this product in excess of 90 days of therapy in a 360 day period will require prior authorization.
  - In the prior authorization request, the prescriber should explain why the client is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the NAEPP guidelines. Also the need for use of this product over an albuterol MDI should be stated.
  - Clinical exceptions will be made for clients with COPD.
- A quantity limit of 30 g (2 units) every 30 days will also apply.

Recommendation 2: Vote to Prior Authorize Darvocet A500 and Balacet 325™

MOTION CARRIED by unanimous approval.

- Prior authorize Darvocet A500™ and Balacet 325™
  - Criteria:
    - Documented need to restrict acetaminophen use
    - Concurrent use of acetaminophen-containing products
    - Documented renal insufficiency or hepatic impairment
- Place a quantity limit of 180/30 on each of the products.

Recommendation 3: Annual Review of Forteo® and Osteoporosis Utilization Review

MOTION CARRIED by unanimous approval.

A quantity limit be placed on Boniva® of 3 tablets every 84 days.

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: January 4, 2006

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

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

Subject: DUR Board Meeting Dates for 2006

January 11, 2006

February 8, 2006

March 8, 2006

April 12, 2006

May 10, 2006

June 14, 2006

July 12, 2006

August 9, 2006

September 13, 2006

October 11, 2006

November 8, 2006

December 13, 2006

APPENDIX B

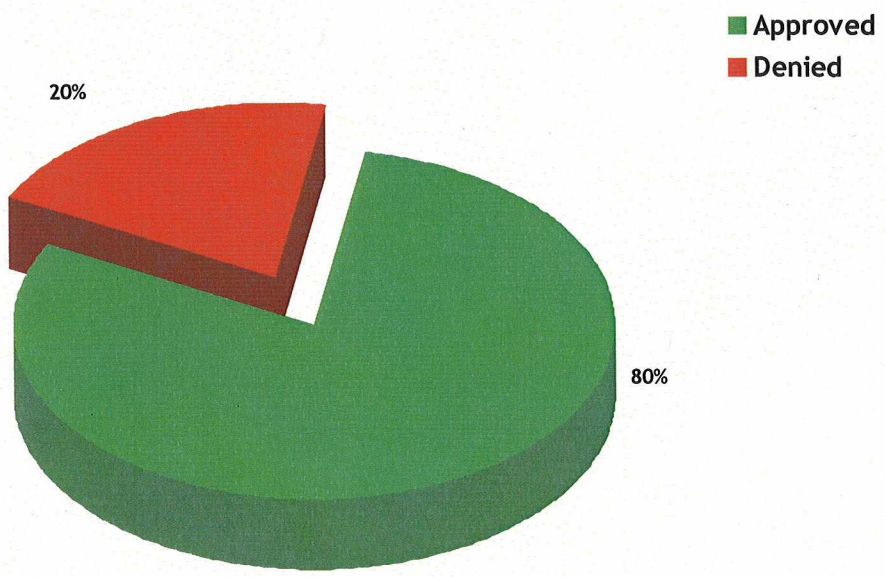
Retrospective Drug Utilization Review Report

Claims Reviewed for September 2005

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	110,264	111,618	891,231	50,124
Limits which were applied	Established, Major, Females 22-45	Antidepressants-SSRI, Age 0-21, no abuse potential	Contraindicated, age 0-21, with Asthma	High dose, Statins
Total # of messages after limits were applied	38	148	43	57
Total # of clients reviewed after limits were applied	68	138	39	57

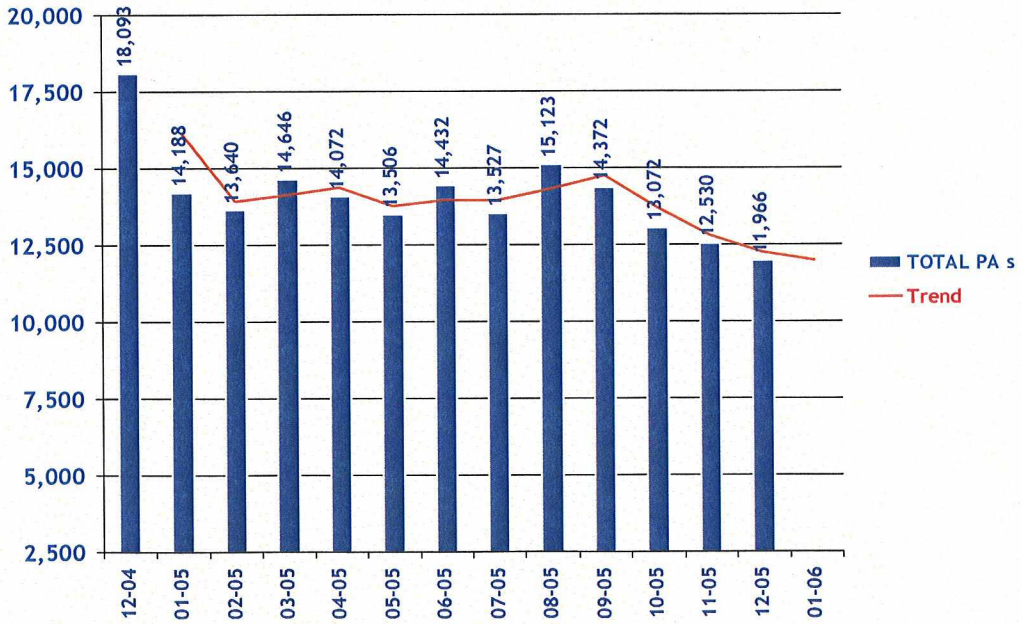
LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
74	N/A	40	N/A

PRIOR AUTHORIZATION ACTIVITY REPORT
December 2005



PHARMACY Management Consultants

PRIOR AUTHORIZATION REPORT
December 2004 - December 2005



PHARMACY Management Consultants

Activity Audit for

December 01 2005 Through December 31 2005

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
App.	23		2826		1071		39		743		197		40		11		100		636		24		303		
Den.		4		179		494		1		166		194		57		0		145		27		4		183	
Average Length of Approvals in Days	28		93		88		161		192		126		71		74		110		134		50		126		

Changes to existing PA's	1007
Total (Previous Year)	18093

*** Denial Codes**

762 = Lack of clinical information	10.02%
763 = Medication not eligible	1.52%
764 = Existing PA	1.62%
772 = Not qualified for requested Tier	9.31%
773 = Requested override not approved	17.66%

SUPER PA's

Admitted to Nursing Home	175
Early Refill Attempts	45811
Dosing Change	592
High Dose	21
Lost/Broken Rx	137
Stolen	16
Other	75
Wrong D.S. on Previous Rx	12
Quantity vs. Days Supply	1498
Brand	198
– Approved	104
– Denied	42

Monthly Totals

	Number	Percent of Total
Approved	7840	65.52%
Additional PA's	8	0.07%
Emergency PA's	10	0.08%
Duplicates	512	4.28%
Incompletes	1620	13.54%
Denied *	1976	16.51%
Total	11966	100.00%

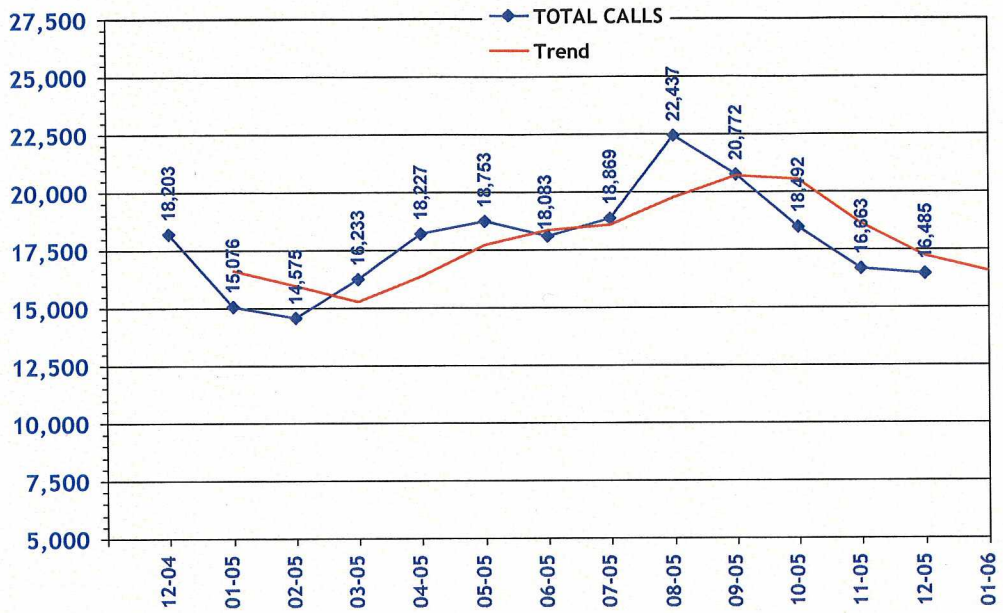
Daily Average of 543.91 for 22 Days

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

Additional PA's: Done by the help desk (doctor letter responses, PA ran for the wrong person)

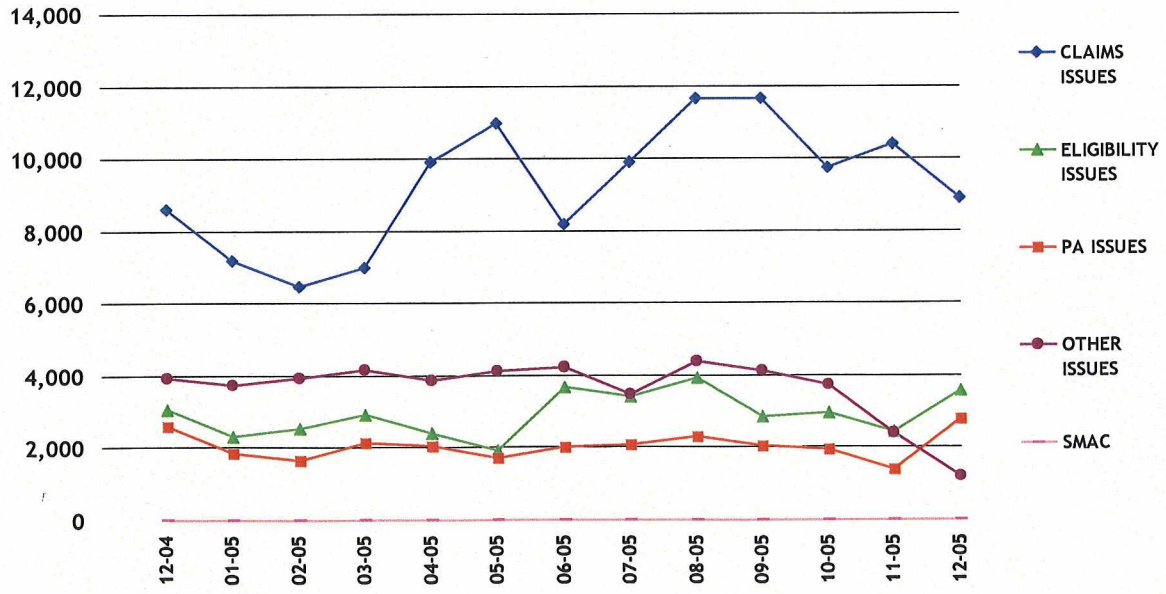
Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

CALL VOLUME MONTHLY REPORT
December 2004 - December 2005



PHARMACY management consultants

CALL VOLUME ISSUES
December 2004 - December 2005



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Pharmacotherapy Management Program
Quarterly Report FY'06
July 2005 – December 2005
Oklahoma Medicaid

	CLIENT PROFILES REVIEWED		PRIOR AUTHORIZATIONS				COMMUNICATIONS	
Month	New Clients	Established Clients	Total	Approved	Denied	Incomplete	Letters	Calls
July 2005	94	47	818	540	44	234	357	29
Aug 2005	103	73	830	585	38	257	482	45
Sept 2005	73	32	962	643	45	274	230	37
Oct 2005	25	28	805	561	53	191	152	37
Nov 2005	28	66	848	634	29	185	236	47
Dec 2005	31	52	861	648	39	550	156	29
Jan 2006								
Feb 2006								
March 2006								
April 2006								
May 2006								
June 2006								
Totals								
1st Quarter	270	152	2,660	1,768	127	765	1,069	111
2nd Quarter	84	146	2,514	1,843	121	550	554	113
3rd Quarter								
4th Quarter								
Totals	354	298	5,174	3,611	248	1,315	1,623	224

APPENDIX C

30 Day Notice to Prior Authorize Nasal Anti-Allergic Products

Oklahoma Medicaid
January 2006

Available Nasal Products

Anticholinergics: This category is most effective for treatment of severe vasomotor symptoms. Ipratropium bromide 0.03% is approved for symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children 6 years of age and over, while the 0.06% is approved for symptomatic relief of rhinorrhea associated with the common cold for adults and children 12 years of age and over (and its safety for greater than 4 days has not been established). The most frequently reported adverse events are epistaxis and nasal dryness.

Antihistamines: Azelastine is approved for treatment of the symptoms of seasonal allergic rhinitis in children 5 years of age and over and for treatment of the symptoms of vasomotor rhinitis in adults and children 12 years of age and over. The primary adverse effects were altered taste and nasal burning.

Corticosteroids: These agents are the most effective agents for treating allergic rhinitis and are considered first line therapy. Regular use is required for maximum benefit. These products are generally well tolerated. The most common side effects include sneezing, stinging, and local irritation. The aqueous formulations may be preferred as they are less irritating.

* Approved for children 3 years of age and over: Mometasone furoate (Nasonex).
* Approved for children 4 years of age and over: Fluticasone (Flonase).
* Approved for children 6 years of age and over. Beclomethasone (Beconase, Vancenase), Flunisolide (Nasarel), Budesonide (Rhinocort), and Triamcinolone (Nasacort).

Recommendation

The College of Pharmacy recommends the addition of the Nasal Allergy class to the Product Based Prior Authorization program. The following Tier-1 Drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of clients. The College of Pharmacy recommends this list to the Drug Utilization Review Board for consideration before approval and referral to the Oklahoma Healthcare Authority for final limitations or additions based on cost effectiveness.

Skeletal Muscle Relaxants	
*Tier One**	*Tier Two*
Flonase®	Nasonex®
flunisolide	Beconase® AQ
Ipratropium bromide	Nasacort® AQ
	Rhinocort® AQ
	Astelin®

*Brand products are subject to the Brand Name Override where generic is available.

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

1. Documented adverse effect or contraindication to the preferred products.
2. Failure with at least one tier one medication defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
3. Approvals will be for the duration of three months, except for clients with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

APPENDIX D

60 Day Notice to Prior Authorize Skeletal Muscle Relaxants

Oklahoma Medicaid
January 2006

The College of Pharmacy recommends the addition of the Skeletal Muscle Relaxant class to the Product Based Prior Authorization program. The following Tier-1 Drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of clients. The College of Pharmacy recommends this list to the Drug Utilization Review Board for consideration before approval and referral to the Oklahoma Healthcare Authority for final limitations or additions based on cost effectiveness.

Skeletal Muscle Relaxants	
*Tier One**	*Tier Two*
Cyclobenzaprine (Flexeril®) Baclofen (Lioresal®) Tizanidine(Zanaflex®) Methocarbamol (Robaxin®) Chlorzoxazone (Parafon Forte®, Paraflex®) Orphenadrine (Norflex®)	Carisoprodol (Soma®) Metaxolone (Skelaxin®)

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

1. Documented adverse effect or contraindication to the preferred products.
2. Failure with at least two tier one medications defined as no beneficial response after at least two week of use during which time the drug has been titrated to the recommended dose.
3. Approvals will be for the duration of three months, except for clients with chronic diseases such as multiple sclerosis, in which case authorizations will be for the duration of one year.

Total Reimbursed for Muscle Relaxant Products – 4th Qtr FY '05

Product	Total Claims	Total Reimbursement
Baclofen	3,793	$ 122,605.61
Carisoprodol	9,315	$ 69,709.48
Chlorzoxazone	540	$ 3,799.02
Cyclobenzaprine	12,030	$ 206,069.71
Metaxolone	1,888	$ 278,831.93
Methocarbamol	1,350	$ 13,728.05
Orphenadrine	450	$ 16,505.38
Tizanidine	3,180	$ 66,049.79
Total	**32,546**	**$ 777,298.97**
Total Non-Duals	**17,797**	**$ 401,509.23**

Non-Dual Client Demographics - 4th Qtr FY '05

Age	Female	Male	Totals
0 to 9	84	100	184
10 to 19	895	566	1,461
20 to 34	2,208	342	2,550
35 to 49	2,488	716	3,204
50 to 64	1,426	588	2,014
65 to 79	57	23	80
80 to 94	19	3	22
95 and over	2	1	3
Totals	**7,179**	**2,339**	**9,518**

Market Share and Cost for Non-Duals

Product	Total Claims	Total Days	Total Reimbursement	% Market Share	% Cost
Baclofen	1,831	196,655	$ 60,323.08	16.4 %	15.0 %
Carisoprodol	5,200	396,841	$ 37,681.22	33.0 %	9.4 %
Chlorzoxazone	255	17,245	$ 1,755.65	1.4 %	0.4 %
Cyclobenzaprine	7,176	356,001	$ 120,264.19	29.6 %	30.0 %
Metaxolone	965	54,485	$ 138,241.93	4.5 %	34.4 %
Methocarbamol	721	54,743	$ 7,109.50	4.6 %	1.8 %
Orphenadrine	252	10,579	$ 8,867.40	0.9 %	2.2 %
Tizanidine	1,397	114,993	$ 27,266.26	9.6 %	6.8 %
Total	**17,797**	**1,201,542**	**$ 401,509.23**	**100.0 %**	**100.0 %**

Anticipated Market Changes

- The patent exclusivity for Flexeril® 5mg is anticipated to expire February 2006.

Potential Administrative Costs

Based on a potential shift of proposed Tier-2 products to a Tier-1 product of 50%, it is estimated that approximately 2,000 to 3,000 petitions would be required annually. The proposed tier changes would affect approximately 15% of the total population for this PBPA category.

Previously, it has been theorized that total cost per petition to the healthcare system (includes cost to physicians, pharmacists, and program) is between $6.75 and $12.97. Total cost to the healthcare system for implementation of this PBPA category is estimated to be between $20,250 and $38,910. Anticipated actual administrative cost to the program is projected to be less than $20,000.

Potential Program Savings

Potential savings to the program based on recommended tiers and a potential shift of 50% of market share from tier two to tier one is estimated to be $22,870 annually. This is the net *ingredient* cost savings after accounting for current rebates and dispensing fees. While the potential savings is relatively low, patient outcomes may be improved by using the Tier-1 medications. Additional clinical and utilization data requested will be presented at the 30 day notice.

Total Potential Savings

Potential Savings:	$ 22,870.00		$ 22,870.00
Potential Administrative Cost:	20,250.00		38,910.00
Total Potential Program Savings:	**$ 2,620.00**	**to**	**$ -16,040.00**

APPENDIX E

Prior Authorization Annual Review - Fiscal Year 2005

Antidepressants (including fluoxetine and Prozac® Weekly)

Oklahoma Medicaid
January 2006

Definition of Antidepressant Product Based Prior Authorization Category

The following Tier-1 drug lists are recommended as a clinically acceptable combination for use as initial therapy for the majority of the clients.

SSRIs (Selective Serotonin Reuptake Inhibitors)	
Tier 1	*Tier 2*
Citalopram (generic only)	Citalopram (Celexa tabs and liquid)
Escitalopram (Lexapro liquid and tabs)	Fluoxetine (Sarafem and Prozac weekly)
Fluoxetine (Prozac)	Fluoxetine-all tablets and 40mg capsules
Fluvoxamine (Luvox)	
Paroxetine (Paxil, Paxil CR, Pexeva*)	
Sertraline (Zoloft)	

*will not be subject to DAW rule

The following criteria have been approved for authorization of a tier-2 product:

1. Approval of tier-2 medication after a recent 4 week trial on a tier one medication with inadequate results. Tier-1 selection can be from any tier-1 anti-depressant classification.
2. Approval of tier-2 medication if there is a documented adverse effect, drug interaction, or contraindication to tier-1 products.
3. Approval of tier-2 medication if there is prior stabilization on the tier-2 medication documented within the last 100 days.
4. Approval of tier-2 medication if there is a unique FDA-approved indication not covered by any tier-1 products.
5. A petition for a tier-2 medication may be submitted for consideration when a unique client specific situation exists.

Current Definition of Miscellaneous Antidepressant Prior Authorization Categories

Fluoxetine 10 and 20 mg Tablet and 40 mg Capsule

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

Prozac® Weekly

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

Utilization

For the period of July 2004 through June 2005, a total of 51,969 clients received antidepressant (SSRI) products through the Medicaid fee-for-service program.

Product		# of Claims	Total Units	Total Days	Units/Day	Total Cost	Per Diem
Tier 1	*Liquids*	1,285	221,711	34,153	6.49	$ 91,589.12	2.68
	Solids	250,857	10,529,230	8,946,266	1.18	$ 18,243,989.41	2.04
Tier 2	*Liquids*	299	88,275	7,658	11.53	$ 39,854.95	5.20
	Solids	1,893	60,693	61,464	0.99	$ 73,020.70	1.19
All Products		**254,334**	**10,899,909**	**9,049,541**		**$ 18,448,454.18***	**2.04**

*Before supplemental rebates.

Total Cost FY '05 **$ 18,448,454.18**
Total Cost FY '04 *$ 18,413,822.44*
Total Claims FY '05 **254,334**
Total Claims FY '04 *215,651*
Per Diem FY '05 **$ 2.04**
Per Diem FY '04 *$ 2.38*

Market share for select products.

Brand Name*	Total Days/ Brand FY '05	% Share/ Brand FY '05	Total Days/ Brand FY '04	% Share/ Brand FY '04
citalapram	801,837	8.86 %	1,006,715	13.02 %
Lexapro®	2,098,619	23.19 %	1,271,424	16.45 %
fluoxetine	1,577,916	17.44 %	1,306,825	16.91 %
fluvoxamine	139,302	1.54 %	128,754	1.67 %
paroxetine	1,818,064	20.09 %	1,813,938	23.47 %
Zoloft®	2,613,803	28.88 %	2,201,607	28.48 %

*Includes brand and generic products where applicable.

Total petitions submitted in for this category during FY04: 4,843.

Approved	*2,388*
Denied	1,823
Incomplete	632
Super PAs	846

*723 denied or incomplete petitions were subsequently approved

Age/Gender FY05

Age	Female	Male	Totals
0 to 10	547	1,030	1,577
11 to 20	5,132	3,775	8,907
21 to 34	8,469	1,645	10,114
35 to 49	7,502	2,896	10,398
50 to 64	6,369	2,355	8,724
65 to 79	5,113	1,584	6,697
80 to 94	4,329	875	5,204
≥95	309	39	348
Totals	**37,770**	**14,199**	**51,969**

	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
*Duals**	21,469	129,083	5,501,100	4,646,144	$ 9,523,233.90	2.05
Non-Duals	30,500	125,251	5,398,810	4,403,397	$ 8,925,220.28	2.03

Changes to the Antidepressant Product Based Prior Authorization Category

On October 1, 2005, dual-acting antidepressants were added to the PBPA category. This group will not undergo review until the FY06 annual review.

The patent for Zoloft® was set to expire December 2005. Potential for generic product availability in 2006.

Recommendations

The College of Pharmacy recommends continuation of the current criteria and tier-structure for this category.

APPENDIX F

Prior Authorization Annual Review - Fiscal Year 2005
Anxiolytics/Hypnotics
Oklahoma Medicaid
January 2006

Definition of Prior Authorization Category for FY '05

With respect to the anxiolytic/hypnotic medications:

- Clients may receive two medications in this category if one is used during the day for one diagnosis and the other is used at night as a hypnotic agent; or if they are using two different strengths to reach a target dose not available in a single unit.
- Clarification of dosing schedule and diagnosis are important to assure that the client is not receiving duplicate therapy (e.g. an anxiolytic and hypnotic both dosed at bedtime).
- Additional information regarding recent attempts at dose reductions should be requested on recurrent petitions for high dose anxiolytics and hypnotic medications.
- There are currently quantity limits on Lunesta®, Sonata® and Ambien®.

Utilization

41,641 clients received benzodiazepines/hypnotics through the Medicaid fee-for-service program for fiscal year 2005.

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Alprazolam 0.25mg	13,601	771,520	324,307	2.38	$91,045.49	4,252	$0.30
Xanax 0.25mg	12	678	233	2.91	$563.72	9	$2.42
Alprazolam 0.5mg	22,684	1,549,345	593,544	2.61	$181,795.24	6,306	$0.31
Xanax 0.5mg	36	2,825	1,040	2.72	$2,851.91	25	$2.74
Alprazolam 1mg	22,545	1,811,521	625,581	2.89	$223,341.33	5,244	$0.36
Xanax 1mg	48	3,494	1,439	2.43	$4,694.23	22	$3.26
Alprazolam 2mg	8,125	653,908	222,148	2.94	$136,609.73	1,768	$0.61
Xanax 2mg	4	318	123	2.56	$869.75	4	$7.07
Alprazolam 1mg/ml	1	30	30	1.00	$61.42	1	$2.05
Xanax XR 0.5mg	10	315	195	1.62	$637.91	5	$3.27
Xanax XR 1mg	56	1,992	1,597	1.25	$4,933.52	15	$3.09
Xanax XR 2mg	36	1,210	1,029	1.18	$3,988.98	10	$3.88
Xanax XR 3mg	10	360	300	1.20	$1,735.82	3	$5.79
CDP 5mg	334	19,131	8,469	2.26	$2,955.46	99	$0.35
CDP 10mg	1,095	75,285	29,078	2.59	$9,321.66	314	$0.32

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Librium 10mg	2	60	30	2.00	$10.69	1	$0.36
CDP 25mg	941	62,352	22,709	2.75	$8,392.73	315	$0.37
Cloraze DIP 3.75mg	1,644	112,105	47,305	2.37	$23,064.36	322	$0.49
Tranxene 3.75mg	5	270	150	1.80	$348.74	2	$2.32
Cloraze Dip 7.5mg	1,838	122,146	52,172	2.34	$28,747.16	415	$0.55
Tranxene 7.5mg	46	3,896	1,391	2.80	$9,816.37	9	$7.06
Cloraze Dip 15mg	350	25,571	10,664	2.40	$8,287.57	72	$0.78
Tranxene T 15mg	41	3,080	1,152	2.67	$7,207.53	15	$6.26
Tranxene-SD 11.25mg	1	10	10	1.00	$60.80	1	$6.08
Tranxene-SD 22.5mg	20	1,760	532	3.31	$13,212.84	3	$24.84
Diazepam 2mg	2,330	112,937	47,764	2.36	$12,534.43	1,009	$0.26
Diazepam 5mg	12,174	685,265	283,187	2.42	$67,123.90	4,411	$0.24
Diazepam 10mg	12,087	857,838	320,009	2.68	$83,538.76	3,258	$0.26
Diazepam 5mg/ml con	42	2,717	892	3.05	$2,335.75	16	$2.62
Diazepam 1mg/ml sol	227	39,992	3,667	10.91	$5,164.65	92	$1.41
Diazepam 5mg/ml inj	118	1,516	629	2.41	$1,639.76	88	$2.61
Ativan 0.5mg	16	1,170	530	2.21	$1,032.48	6	$1.95
Lorazepam 0.5mg	15,338	812,322	349,460	2.32	$106,085.44	4,535	$0.30
Ativan 1mg	46	4,041	1,311	3.08	$2,873.09	18	$2.19
Lorazepam 1mg	15,054	906,460	366,694	2.50	$135,381.58	4,403	$0.37
Ativan 2mg	3	205	68	3.01	$247.26	2	$3.64
Lorazepam 2mg	3,927	248,047	102,736	2.41	$52,569.93	1,070	$0.51
Lorazepam 2m/ml Con	158	4,344	2,076	2.10	$6,509.80	91	$3.13
Ativan 2mg/ml inj	601	2,232	1,319	1.70	$15,383.90	336	$11.66
Lorazepam 2mg/ml inj	492	4,926	1,527	3.23	$11,024.15	282	$7.22
Lorazepam 4mg/ml	1	60	5	12	$150.00	1	$30.00
Oxazepam 10mg	394	29,277	10,008	2.93	$10,599.93	91	$1.06
Oxazepam 15mg	463	36,812	10,022	3.67	$18,267.13	95	$1.82
Oxazepam 30mg	51	3,350	1,278	2.62	$3,774.63	12	$2.95
Estazolam 1mg	154	4,337	4,245	1.02	$1,914.59	37	$0.45
Estazolam 2mg	203	6,105	6,183	1.00	$3,042.27	46	$0.49
Prosom 2mg	3	58	58	1.00	$75.09	2	$1.29
Flurazepam 15mg	138	4,638	3,802	1.22	$862.84	66	$0.23
Dalmane 30mg	1	30	30	1.00	$6.45	1	$0.22
Flurazepam 30mg	405	12,746	12,596	1.01	$2,604.19	120	$0.21
Doral 7.5mg	2	60	60	1.00	$181.92	1	$3.03
Doral 15mg	4	225	240	0.94	$756.89	3	$3.15
Restoril 7.5mg	1,545	45,887	42,977	1.07	$111,346.36	495	$2.59
Temazepam 7.5	18	585	585	1.00	$405.14	7	$0.69
Restoril 15mg	7	210	195	1.08	$518.22	4	$2.66
Temazepam 15mg	8,411	275,187	241,006	1.14	$56,300.83	3,014	$0.23
Restoril 30mg	14	455	424	1.07	$1,154.55	10	$2.72
Temazepam 30mg	8,865	287,521	280,755	1.02	$67,682.47	2,679	$0.24
Triazolam 0.125mg	114	3,467	2,825	1.23	$1,032.30	52	$0.36
Halcion 0.25mg	35	1,287	967	1.33	$1,087.53	21	$1.12
Triazolam 0.25mg	1,083	32,326	24,649	1.31	$11,860.08	505	$0.48
Lunesta 1mg	59	1,759	1,609	1.09	$5,902.17	44	$3.67
Lunesta 2mg	235	6,238	6,353	1.00	$20,599.32	193	$3.24
Lunesta 3mg	222	6,351	6,351	1.00	$20,974.68	169	$3.30
Sonata 5mg	273	7,414	7,217	1.03	$17,438.26	122	$2.42

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Sonata 10mg	1,075	34,815	30,874	1.13	$97,356.13	390	$3.15
Ambien 5mg	9,262	259,060	248,343	1.04	$644,675.21	3,391	$2.60
Ambien 10mg	21,319	587,366	594,249	1.00	$1,768,787.23	6,337	$2.98
Total	**190,454**	**10,554,820**	**4,965,003**		**$4,137,356**	**41,641***	**$0.83****

*Total unduplicated clients for FY04.
**Total cost/total days.

Total Cost FY '05 **$4,137,356.00**
Total Cost FY '04 *$3,061,942.17*
Total Claims FY '05 **190,454**
Total Claims FY '04 *141,804*
Total Clients FY '05 **41,641**
Total Clients FY '04 *35,249*
Per Diem FY '05 **$0.83**
Per Diem FY '04 *$0.83*

Total petitions submitted in for this category during specified time period:

Approved 46,719
Denied 7,028*
Incomplete ..... 3,039 *
Supers..... 675

*Of the 10,067 petitions that were denied or incomplete, 9,175 were later approved.

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

FY '05 all clients

Age	Female	Male	Totals
0 to 9	355	480	835
10 to 19	1416	909	2325
20 to 34	5101	1240	6341
35 to 49	6690	3122	9812
50 to 64	6087	2880	8967
65 to 79	5809	1954	7763
80 to 94	4299	904	5203
95 and Over	351	44	395
Totals	**30,108**	**11,533**	**41,641**

Non Dual Clients

Age	Female	Male	Totals
0 to 9	354	480	834
10 to 19	1414	904	2318
20 to 34	4528	748	5276
35 to 49	4486	1429	5915
50 to 64	2840	1392	4232
65 to 79	244	116	360
80 to 94	222	77	299
95 and Over	19	3	22
Totals	**14,107**	**5,149**	**19,256**

Hypnotic claims for FY 05

	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	6,064	21,199	605,588	599,902	$1,710,173.86	$2.85
Non-Duals	4,582	11,246	297,415	295,094	$865,559.14	$2.93

Cost Comparison

	Estimated Acquisition Cost (EAC)	State Maximum Allowable Cost (SMAC)	Recommended Daily Dose	Monthly Cost (30 day supply) w/o dispensing fee
Lunesta® 3 mg	$3.26/tab	N/A	3 mg	$ 97.80
Ambien® 10 mg	$3.11/tab	N/A	10 mg	$ 93.30
Ambien CR®	$2.83/tab	N/A	12.5	$84.90
Rozerem®	$2.25/tab	N/A	8 mg	$67.50
Sonata® 10 mg	$3.14/cap	N/A	10 mg	$ 94.20
temazepam 30 mg	$0.75/cap	$0.11	30 mg	$ 3.30

Comparison on Current Non-Benzodiazepine Products

	FY 05		FY 04		
Product	# of Claims	Total Cost	# of Claims	Total Cost	% Change
Lunesta 1mg	59	$5,902.17			
Lunesta 2mg	235	$20,599.32			
Lunesta 3mg	222	$20,974.68			
Sonata® 5mg	273	$17,438.26	258	$16,105.17	7.6 ↑
Sonata® 10mg	1,075	$97,356.13	1,049	$91,709.27	5.8 ↑
Ambien® 5mg	9,262	$644,675.21	7,898	$505,938.95	21.5 ↑
Ambien® 10mg	21,319	$1,768,787.23	14,979	$1,236,749.78	30.1 ↑

Market Changes for FY 05

Ambien CR® is an extended-release bi-layered tablet formulation of Ambien. It has a two stage drug delivery system. The first one dissolves quickly to help induce sleep, the second is more gradual to help with continuous sleep. It was approved September 2005.

Rozerem® is a selective MT_1/MT_2 receptor agonist that was approved by the FDA in July 2005 for insomnia.

Recommendations

The college of pharmacy recommends tightening up the criteria on this category (age, quantities, dosing vs diagnosis) and doing a follow up report in about 6 months to see usage in dual eligibles. We will no longer cover the hypnotics for dual eligibles (Lunesta, Sonata, and Ambien). We will continue to cover benzodiazepines for the dual eligible's whose insurance does not cover this category.

APPENDIX G

Prior Authorization Annual Review - Fiscal Year 2005
ADHD/Narcolepsy Drugs
Oklahoma Medicaid
January 2006

Product Based Prior Authorization

There are two tiers of medications in this therapeutic category. A trial with a tier-1 ADHD medication or a clinical exception to a tier-1 trial is required before a tier-2 ADHD medication can be approved.

Category	Medications	Age Groups	PA Requirements
First	Ritalin, Ritalin SR, Adderall, Adderall XR Dexedrine, Dexedrine Spansule, Concerta*, Focalin*, Focalin XR*,	Children up to 21 years old	No PA required
		Adults	PA required – Diagnosis of ADHD or narcolepsy.
Second	Ritalin LA, Metadate CD, Strattera	Children and Adults	PA Required – Requires failed trial with one first category drug. Diagnosis of ADHD or narcolepsy.
Third	Desoxyn* and Cylert	Children and Adults	PA Required – Requires failed trial with two first category drugs. Diagnosis of ADHD or narcolepsy.

* See changes for FY05 and FY06

Provigil - Prior Authorization Criteria

Provigil will be approved for clients who have any of the following diagnoses:

- FDA approved indications:
  - Narcolepsy
  - Obstructive sleep apnea/hypopnea syndrome
  - Shift work sleep disorder
- Off-label uses:
  - Depression
  - Fatigue associated with multiple sclerosis
  - Fatigue associated with fibromyalgia
  - Daytime sleepiness in patients with myotonic dystrophy
  - Alcoholic organic brain syndrome during the early phase of abstinence
  - Drug-induced somnolence
- Quantity Limit of 30 units for 30 days supply is applied based on information in the FDA-approved product labeling.

Fiscal Year '05 Changes

- When a pharmacy submits a claim for a tier-2 stimulant for a client age 20 or under, the computer system has been programmed to detect tier-1 trials in Medicaid claims in the previous 12 months. If a tier-1 trial is found, the computer allows the tier-2 stimulant claim to pay without requiring manual prior authorization. Strattera continues to require PA for all ages as a means to monitor for concurrent use of stimulants and Strattera.
- In order to prevent the computer from automatically allowing claims for high dose tier-2 stimulants, quantity limits have been applied which trigger a PA requirement if the daily dose on the claim exceeds the FDA approved maximum. Effective 6/15/2005
- Brand name Cylert was voluntarily removed from the market by Abbott in May 2005 because of increased risk of liver toxicity.
- Effective November 1st, 2004 a prior authorization was required for brand name drugs that have a federal or state maximum allowable cost (FUL or SMAC). Currently this affects Dexedrine®, Ritalin®, Ritalin SR®, and Adderall®.

Fiscal Year '06 Changes

- Effective October 2005, manufacturers of generic pemoline will no longer sell or market their products once existing supplies are exhausted.
- In September, Focalin XR was added to tier-2.
- Effective October 1, Concerta ®, Focalin®, and Focalin XR® moved to Tier-1 after supplemental rebate agreement.

Utilization

Total Cost FY '05		**$9,868,738.46**
	Total Cost FY '04	*$7,046,294.17*
Total Claims FY '05		**128,963**
	Total Claims FY '04	*94,093*
Total Clients FY '05		**20,090**
	Total Clients FY '04	*16,816*
Per Diem FY '05		**$2.49**
	Per Diem FY '04	*$2.45*

Totals do not include Provigil

For the period of July 2005 through June 2006, a total of 20,090 clients received anorexiant/stimulant drugs through the Medicaid fee-for-service program. 885 clients received Provigil.

All Claims

Product	# of claims	Total Units	Total Days	Units/day	Total Cost	Total Clients	Per Diem
Tier 1	53,654	3,349,356	1,641,438	2.04	$1,921,669.95	11972	$1.17
Tier 2	75,309	2,710,906	2,329,398	1.16	$7,947,068.51	12740	$3.41
Total	**128,963**	**6,060,262**	**3,970,836**	**1.53**	**$9,868,738.46**	**20,090***	**$2.49**

*Total unduplicated clients for FY05

Non-Duals

Product	# of claims	Total Units	Total Days	Units/day	Total Cost	Total Clients	Per Diem
Tier 1	52,149	3,234,626	1,594,532	2.02	$1,847,575.69	11,709	$1.16
Tier 2	74,821	2,684,999	2,313,596	1.16	$7,879,287.46	12,642	$3.41
Total	**126,970**	**5,919,625**	**3,908,128**	**1.51**	**$9,726,863.15**	**19,754***	**2.49**

Total unduplicated clients for FY05

Duals

Product	# of claims	Total Units	Total Days	Units/day	Total Cost	Total Clients	Per Diem
Tier 1	1,505	114,730	46,906	2.45	$74,094.26	363	1.58
Tier 2	488	36,907	15,802	2.33	$67,781.05	98	4.29
Total	**1,993**	**140,637**	**62,708**	**2.24**	**$141,875.31**	**336***	**2.26**

Total unduplicated clients for FY05

Provigil

Clients	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
Duals	2,063	71,570	63,585	1.13	$417,641.28	443	$6.57
Non-Dual	1678	58,804	52,103	1.13	$341,713.35	442	$6.56
Total	**3,741**	**130,374**	**115,688**	**1.13**	**$759,354.63**	**885**	**$6.56**

Total unduplicated clients for FY05

Prior authorization activity

A total of 22,919 petitions were submitted for this category during FY2005. These totals include Provigil.

Total Approved	= 16,012
Total Denied	= 4,972
Total Incomplete	= 1,935
Total D/I approved	= 5,130

Demographics

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

	All		Dual		Non Dual	
Age	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**
0 to 9	2369	6338	0	0	2369	6338
10 to 19	2846	7691	0	1	2846	7690
20 to 34	240	145	41	43	199	102
35 to 49	195	86	64	55	131	31
50 to 64	79	37	43	29	36	8
65 to 79	26	15	26	13	0	2
80 to 94	17	5	16	4	1	1
95 & over	1	0	1	0	0	0
Totals	**5,773**	**14,317**	**191**	**145**	**5,582**	**14,172**

In the News

- Modafinil, the active ingredient in Provigil®, will be available in a new formulation (Sparlon™) for the treatment of ADHD in adolescents and children, pending FDA approval. Marketing is expected to begin in early '06. The drug was previously known as Attenace, but concern by the FDA prompted the name change

Recommendations

The college of pharmacy has the following recommendation(s) for Fiscal Year 2006:

Move Sparlon™ into Tier-2 upon its entry into the market.

APPENDIX H

Review Antiepileptics

Oklahoma Medicaid
January 2006

Introduction

With respect to the anti-convulsant medications it becomes necessary to adequately distinguish the difference between seizures and epilepsy.

Seizures originate from abnormal electrical activity in the brain which subsequently leads to unusual mental behavior and involuntary body movements. This clinical manifestation results from abnormal and excessive excitation of neurons in the brain. Seizures are the common symptom associated with epilepsy.

Epilepsy is a group of neurological disorders usually characterized by recurrent episodes of transient seizures caused by an unprovoked disturbance in brain activity and function. Individuals who experience episodes of seizures exhibit the hallmark symptom of epilepsy but do not necessarily have the neurological disorder.

According to the World Health Organization (WHO), approximately 50 million people will be affected by epilepsy worldwide[4,7]. In the United States, 3 million people will be affected by this relatively common condition[4,7]. About 9% of Americans will have one seizure during their lifetime. This neurological disorder may occur at any age but it is most often diagnosed before age 20 and after age 60[4]. Children are more commonly affected than young adults. The incidence is two to three times higher than children in patients greater than 70 years of age. Likewise, males predominantly are affected more often when compared to females[4].

Early diagnosis becomes critical in reducing the morbidity and mortality of seizures. It is important for the clinician to accurately diagnosis ***both*** the type of epilepsy and the type of seizure a patient is experiencing. Again, seizures are only a symptom of epilepsy. Therefore, delineation of the numerous types of seizures and epileptic disorders will lead to appropriate treatment selection and prevent disease progression.

The majority of patients with new onset of epilepsy respond to their first antiepileptic drug therapy. Approximately 70% achieve a seizure free outcome, while 30% may require alternative monotherapy or adjunctive polytherapy[4,6]. Some severe cases may require other non-pharmacological therapy. Therapeutic drug selection depends on seizure type or disorder, patient medical history and comorbid conditions, tolerability issues, as well as compliance and costs.

People affected by epilepsy are vulnerable to significant emotional, social, and economical burdens. Direct medical costs are estimated at $1.7 billion and indirect loss of productivity has been estimated at $10.8 billion.

Etiology[5]

Non-epileptic Seizures:

1. No abnormal electrical activity
2. Emotional stress or other psychosocial factor

Provoked Seizures:

1. Trauma (tumors)
2. Hypoglycemia
3. Hyponatremia
4. High fever (CNS infections and febrile seizures)
5. Alcohol/Drug Abuse
6. Psychiatric disorders (dementia)
7. Sleep disorders
8. Toxic/Poison
9. Cardiovascular (Cerebrovascular Disease, Stroke)
10. Syncope
11. Congenital disorders

Epilepsy (Seizure Disorders):

1. Idiopathic (primary)
2. Symptomatic (secondary)

Types of Seizures[6]

Partial (focal) Seizures	Primarily Generalized Seizures
Simple Partial Seizures • No loss of consciousness • Motor symptoms • Paraethesias • GI upset	**Absence (Petit Mal)** • Typical (3 Hz spike EEG) • Atypical (4.5 Hz polyspike EEG) • Brief staring • <30 sec • Confusion
Complex Partial Seizures (focal) • Loss of consciousness (staring) • Aura (déjà vu, smell) • Automatisms (oral, manual) • Motor symptoms • Amnesia • 30 sec to 3 min duration	**Myoclonic** • Head/Upper Torso jerking • Bilateral • Consciousness preserved • Precipitated at onset of sleep or awakening • Tonic/Clonic seizure • Neurologic deterioration • Juvenile Myoclonic Epilepsy (JME) • Progressive Myoclonic Epilepsies
Partial Seizure(Simple or Complex) with Secondary Generalization • Originate as simple partial or complex partial • Variable tonic (stiffening) and clonic (jerking) activity • 15 sec to 60 sec (tonic) • 60 sec to 120 sec (clonic) • > 5 min: possible status epilepticus • Confusion • Somnolence	**Clonic, Tonic, Tonic/Clonic (Grand Mal), Atonic** • Atonic patients increased risk of falls due to loss of postural tone • Tonic/Clonic presents with loss of consciousness, excessive salivation, confusion, agitation, bladder/bowel incontinence

Other Types of Seizure Disorders[6]

- Lennox-Gestaut Syndrome
- West Syndrome
- Juvenile Myoclonic Epilepsy
- Infantile Spasms
- Febrile Seizures
- Atonic Seizures
- Benign Myoclonic Epilepsy
- Neonatal Seizures
- Childhood Absence
- Juvenile Absence
- Rolandic Epilepsy

Comorbid seizure disorder syndromes[6]

- Down's Syndrome
- Prader-Willi Syndrome
- Fragile X Syndrome
- Sturge-Weber Disease
- Cerebral Palsy
- Rett's Syndrome
- Tuberous Sclerosis

Refractory Epilepsy[4]

- Traditionally defined by a failure of 3 or more AEDs.
- Approximately **30%** of children and adults with epilepsy
- Contributing risk factors: noncompliance, neoplasms, complex partial seizures, brain trauma, symptomatic seizures, atypical absence seizures, neurologic mental deficits.

Comparative Chart of AEDs[1,3,8]

	Indication	Dosing/Daily Cost	Serious Adverse Effects	Drug Interactions	Comments
1st Generation AEDs					
Carbamazepine (Tegretol)	-Partial seizures with complex sx -Generalized tonic-clonic (grand mal), mixed patterns	**Adults**: 800mg start 2400mg max **Child**:10mg/kg/day 35mg/kg/day **Cost**: $1.40/day Dosed: **TID to QID**	Syncope, blood dyscrasias, visual difficulties, hepatitis, rash, Steven-Johnson, pancreatitis	CCB's, clarithromycin, clozapine, contraceptives, cyclosporine, CYP3A4 inhibitors, danazol, diclofenac, doxycycline, erythromycin, haloperidol, imatinib, isoniazid, lamotrigine, mebendazole, methadone, nefazodone, phenytoin, propofol, propoxyphene, protease inhibitors, quinidine, SSRIs, warfarin	-New diagnosis, new onset, refractory epilepsy **-4 to 12 mcg/ml** **-LFTs** -Pregnancy Risk **D** -Other FDA approved indications: trigeminal neuralgia, Bipolar disorder
Ethosuximide (Zarontin)	-General absence, control of absence (petit mal)	**Adults**: 500mg start 1500mg max **Child**: 3-6yr 15 mg 40mg/kg/day max titrate q 4-7days **Cost**: $6.55/day Dosed: **BID**	Blood dyscrasias, lupus, Stevens-Johnson, aggression	Azole antifungals, clarithromycin, diclofenac, isoniazid, nefazodone, nicardipine, propofol, protease inhibitors, quinidine, telithromycin	-New diagnosis, new onset, refractory epilepsy **-40 to 100 mcg/ml** **-LFTs** -Pregnancy Risk **C**
Methsuximide (Celontin)	-Absence (petit mal)	**Adults**: 300mg start 1200mg max **Child**: 15 mg/kg/day 30mg/kg/day max **Cost**: $4.58/day Dosed: **TID to QID**	Hyperemia, ataxia, drowsiness, Steven-Johnson, photophobia, blood dyscrasias, rash, anorexia, anorexia	Phenobarbital, phenytoin, fluconaole, omeprazole, fluvoxamine, gemfibrozil, rifampin, ticlopidine, systemic lupus erythematosus	-Prenancy Risk **C** -No generic
Phenobarbital (Luminal)	-Generalized onset myoclonic -Partial onset, generalized onset tonic clonic	**Adults**: 120mg start 300mg max **Child**: 2mg/kg/day 8mg/kg/day **Cost**: $0.24/day Dosed: **BID to TID**	Rash, Steven-Johnson, blood dyscrasias, angioedema	Azole antifungals, CCB's, chloramphenicol, clomipramine, contraceptives, cyclosporine, disopyramide, doxycycline, gemfibrozil, isoniazid, lamotrigine, methadone, methoxyflurane, modafinil, NNRTs, omeprazole, quinidine, telithromycin, ticlopidine, tricyclic antidepressant, warfarin	-New diagnosis, new onset, refractory epilepsy **-15 to 40 mcg/ml** -Pregnancy Risk **D** -Other FDA approved indications: sedative

1st Generation AEDs					
Phenytoin (Dilantin, Phenytek)	-Partial simple or complex onset -Generalized onset tonic-clonic	**Adults:** 4mg/kg/day 6mg/kg/day max **Child:** 4mg/kg/day 6mg/kg/day max **Cost:** $0.80/day Dosed: **BID to TID**	Hepatotoxicity, blood dyscrasias, rash, Steven-Johnson, osteomalacia, lupus, lymphoma	Azole antifungals, CCB's, carbamazepine, chloramphenicol, cimetidine, contraceptives, cyclosporine, disopyramide, disulfuram, doxycycline, felbamate, flurbiprofen, gemfibrozil, HMGCoA reductase inhibitors, ibuprofen, indomethacin, isoniazid, lamotrigine, mefenamic acid, modafinil, nucleoside reverse transcriptase inhibitors, pioglitazone, piroxicam, quinidine, rifabutin, rifampin, siroliumus, SSRIs, ticlopidine, warfarin, telithromycin, warfarin, non-phenobarbital	-New diagnosis, new onset, refractory epilepsy **-15 to 40mcg/ml** -Pregnancy Risk **D** -High protein binding -loading dose 15-20mg/kg
Primidone (Mysoline)	-Partial onset -Generalized onset tonic-clonic, grand mal, psychomotor, focal seizures	**Adults:** 100mg start 2000mg max **Child:** 10-25mg/kg/day **Cost:** $3.90/day Dosed: **TID to QID**	Thrombocytopenia, anemia, dyspnea, lupus-like	Lamotrigine, quinidine	-Newly diagosis, new onset, refractory -Adult dose renal impairment **-5 to 12 mcg/ml.** -Pregnancy Risk **D**
Valproic acid (Depakene, Depacon)	-Generalized absence -Generalized onset myclonic -Partial onset mono or adjuvant -Generalized onset tonic-clonic, complex partial seizures, absence seizures (simple and complex) as mono or adjuvant therapy	**Adults:** 10mg/kg/day 60mg/kg/day max **Child: not recommended** **Cost:** $7.52/day Dosed: **QD up to QID**	Hepatotoxicity, pancreatitis, blood dyscrasias, rash, Steven-Johnson, hyperammonemia, anaphylaxis, psychosis	Felbamate, lamotrigine, macrolides **-No interaction with oral contraceptives**	-New diagnosis, new-onset, refractory epilepsy **-50-100mcg/ml** **-LFTs** -Pregnancy Risk **D** -High protein binding

2nd Generation AEDs					
Ethotoin (Peganone)	-Generalized tonic-clonic -Complex partial seizures	**Adults:** 250mg start 3gm max **Child:** same **Cost:** $12.13 Dosed: **QID**	Arrythmias, ataxia, psychiatric changes, rash, Steven-Johnson, constipation, Leukopenia, parathesia	CYPC19 (weak)	-Pregnancy Risk **D**
Divalproex Sodium (Depakote)	See Valproic acid **-Acute Manic or Mixed Bipolar** (Depakote ER)	See Valproic acid Cost: $5.20/day Dosed: **BID (E.R)**	See Valproic Acid	See Valproic Acid **-No interaction with oral contraceptives**	-See Valproic Acid -No generic in sprinkles -Other Dx: Bipolar, migraine
Felbamate (Felbatol)	-Monotherapy or adjunct partial seizures adults -Adjunct generalized or partial assoc. with Lennox-Gastaut	**Adults:** 1200mg start 3600mg max **Child:** 15mg/kg/day 45mg/kg/day max **Cost:** $11.99/day Dosed: **TID to QID**	Aplastic anemia, liver failure	Azole antifungals, calcium channel blockers, contraceptives, diclofenac, isoniazid, macrolide antibiotics, nefazodone, phenytoin, propofol, protease inhibitors, quinidine, valproic acid	-Refractory epilepsy **-LFTs** -Pregnancy Risk **C** **-Not first Line**
Fosphenytoin (Cerebryx)	-Generalized status epilepticus -acute therapy prophylaxis during surgery	**Adults:**20 mg/kgload 6mg/kgmaint. **Child: Off-label** Dosed: IM and IV	Nystagmus, dizziness, rash, hypotension, stupor, nausea, diplopia, tinnitus	Substrate: CYP2C8/9, 2C19, 3A4 Inducer: CYP2B6, 2C8/9, 2C19, 3A4	-Pregnancy Risk **D** ->5 day treatment not studied
Gabapentin (Neurontin)	-Adjunct partial seizures with or without secondary generalization **over 12 yrs old** -Adjunct partial seizures in age **3-12 yrs old**	**Adults:** 300mg start 3600mg max **Child:** 10mg/kg/day 50mg/kg/day max **Cost:** $15.60/day Dosed: **TID**	Agression	None **-No interaction with oral contraceptives**	-New diagnosis, new-onset, refractory -Level A monotherapy new diagnosis partial/mixed -Pregnancy Risk **C** -Other Dx: Post-herpetic neuralgia
Lamotrigine (Lamictal)	-Adjunct partial seizures **>/= 2yrs old** -Adj. general seizures of Lennox-Gastaut **>/= 2yrs old** -Convert to mono-therapy adults partial seizures	**Adults:** 50mg start 500mg max **Child:** 0.3mg/kg/day 8mg/kg/day max **Cost:** $15.83/day Dosed: **BID**	Rash, Steven-Johnson, toxic epidermal necrosis, allergic rxn: hepatic and renal failure, coagulation, arthritis	Barbiturates, carbamazepine, contraceptives, phenytoin, primidone, quinidine, valproic acid	-New diagnosis, new onset, refractory -Level A monotherapy new diagnosis partial/mixed -Level B add-on new diagnosis of absence seizures in children -Pregnancy Risk **C** -Other Dx: Bipolar

2nd Generation AEDs					
Levetiracetam (Keppra)	-Adjunct partial onset seizures in adults	**Adults:** 500mg start 3000mg max **Child: Off-label** **Cost:** $12.40/day Dosed: **BID**	Psychosis, blood dyscrasias, **suicide attempts**	None **-No interaction with oral contraceptives**	-Refractory epilepsy -Pregnancy Risk **C**
Oxcarbazepine (Trileptal)	-Monotherapy or adjunct in partial seizures in adults and children **(4 to 16 yrs)**	**Adults:** 300mg start 2400mg max **Child:** 8mg/kg/day 10mg/kg/day max **Cost:** $14.66/day Dosed: **BID**	Hyponatremia, Rash **(April 2005 "Dear Healthcare Professional" Advisory)** due to Steven-Johnson and toxic epidermal necrosis	Contraceptives	-New diagnosis, new onset, refractory **-Monitor hyponatremia** -Pregnancy Risk **C**
Tiagabine (Gabitril)	-Adjunct in adults and children **> 12 yrs old** partial seizures	**Adults:** 4mg start 56mg max **Child:**0.25mg/kg/day 5mg/kg/day max **Cost** $8.60/day Dosed: **BID to QID**	Nonconvulsive status epilepticus, stupor, **Public Health Advisory 02/2005**: Seizure occurrence in nonepileptics reported	Azole antifungals, CCBs, diclofenac, isoniazid, macrolides, nefazodone, propofol, protease inhibitors, quinidine -Don't affect oral contraceptives	-Refractory epilepsy **-Monitor: blood counts, LFTs, renal fxn, blood chem.** -Pregnancy Risk **C**
Topiramate (Topamax)	-Adjunct adults and children**(2-16 yrs old)** partial onset seizures, or primary generalized tonic-clonic, adjunct Lennox-Gastaut **(>2 yrs old)**	**Adults:** 25mg start 1600mg max **Child:** 1mg/kg/day 9mg/kg/day max **Cost:** $39.18/day Dosed: **BID**	Nephrolithiasis, open angle glaucoma, hypohidrosis, depression, psychosis, metabolic acidosis	Contraceptives	-New diagnosis, new onset, refractory, Level A monotherapy new diagnosis partial/mixed, Level A refractory partial epilepsy **-Monitor sodium bicarbonate** -Pregnancy Risk **C** -Migraine Prophylaxis
Zonisamide (Zonegran)	-Adjunct partial seizures in adults	**Adults:** 100mg start 600mg max **Child:** 2mg/kg/day 12mg/kg/day max **Cost:** $12.60/day Dosed: **QD**	Rash, renal calculi, hypohidrosis	Azole antifungals, CCBs, diclofenac, isoniazid, macrolide, nefazodone, propofol, protease inhibitors, quinidine	-Refractory epilepsy **-20 to 30mcg/ml** **-Renal fxn tests** -Pregnancy Risk **C**
Pregabalin (Lyrica)	-Adjunct partial seizures adults	**Adults:** 150mg/day 600mg/day max **Cost:** $3.96/day **TID**	Edema, blurred vision, dizziness, weight gain, euphoria, abnormal thinking, dry mouth	Thiazolidinedione (increased weight gain and edema)	-Refractory epilepsy **-Schedule V** -Pregnancy Risk **C** -Other dx: PHN & DPN

Utilization

For the period of July 2004 through June 2005, a total of 37,157 clients received antiepileptic products through the Medicaid fee-for-service program.

FY 2004 versus FY 2005			% Change
Cost FY '05		**$ 29,425,080.47***	29.0 ↑
	Cost FY '04	*$ 22,811,393.32*	
Claims FY '05		**357,477**	54.0 ↑
	Claims FY '04	*232,089*	
Per Diem FY '05		**$ 3.39**	4.0 ↑
	Per Diem FY '04	*$ 3.26*	
Clients FY '05		**37,157**	16.2 ↑
	Clients FY '04	31,982	

*Does not include barbiturates

AED Products	# of Claims	Total Units	Total Days	% of claims	Total Cost	Per Diem
Dilantin 50mg Chew.	3,792	424,534	116,547		$127,701.97	1.10
Dilantin 125mg/5ml	4,961	1,664,263	757		$235,078.72	310.50
Phenytoin Inj. 50mg/ml	4	50	8		$95.76	11.97
Dilantin 30mg cap	683	48,738	22,888	~11.8	$14,609.09	0.64
Dilantin 100mg cap	33,179	3,705,683	993,684		$1,079,067.25	1.09
Phenytoin prompt cap	43	4,830	1,308		$1,165.77	0.89
Phenytek 200mg cap	431	28,137	14,585		$17,200.02	1.18
Phenytek 300mg cap	667	29,694	24,119		$27,197.59	1.13
Ethosuximide 250mg cap	598	61,719	17,910	<1	$54,865.39	3.06
Ethosuximide 250mg/ml	218	84,207	6,244	<1	$14,915.95	2.39
Celontin 150mg cap	1	28	7	<1	$19.10	2.73
Celontin 300mg cap	73	5,647	2,243	<1	$5,864.10	2.61
Depakote 125mg tab	2,208	203,459	66,738		$127,525.63	1.91
Depakote 125mg spr cap	7,883	1,384,057	226,954	~10.9	$834,166.16	3.68
Depakote 250mg tab	14,723	1,492,416	447,087		$1,760,372.99	3.94
Depakote 500 mg tab	16,451	1,468,000	512,225		$3,171,022.06	6.19
Depakene 250mg/5ml	3,874	2,475,646	94,755	~2.5	$98,646.77	1.04
Depakene 250m cap	5,053	733,184	150,244		$287,834.71	1.92
Carbamazepine 200mg tb	17,034	1,784,244	521,942		$262,228.95	0.50
Carbamazepine 100mg ch	5,479	645,240	163,810		$122,357.00	0.75
Carbamazepine 100mg/5ml	2133	1,413,679	55,189		$95,967.77	1.74
Carbatrol 100mg cap	123	11,138	3,551		$11,108.29	3.13
Carbatrol 200mg cap	1,742	168,317	53,959	~9.3	$159,629.29	2.96
Carbatrol 300mg cap	1,754	142,407	55,136		$138,638.82	2.51
Tegretol XR 100mg tab	767	89,509	24,963		$28,633.74	1.15
Tegretol XR 200mg tab	1,977	220,162	61,125		$132,367.63	2.17
Tegretol XR 400mg tab	1,602	129,059	51,745		$154,542.52	2.99
Felbatol 400mg tab	146	22,360	4,141	<1	$38,091.66	9.20
Felbatol 600mg tab	299	41,343	9,058	<1	$76,973.12	8.50
Felbatol 600mg/5ml	144	71,633	4,080	<1	$55,773.32	13.67
Gabitril 2mg tab	436	35,328	13,652	<1	$56,434.13	4.13
Gabitril 4mg tab	1,899	162,343	61,437	<1	$258,526.11	4.21

Cont. AED Products	# of Claims	Total Units	Total Days	% of claims	Total Cost	Per Diem
Gabitril 12mg tab	251	16,861	9,473	<1	$35,036.15	3.70
Gabitril 16mg tab	143	8,882	5,853	<1	$23,921.74	4.09
Peganone 250mg tab	4	360	120	<1	$250.21	2.09
Cerebryx 50mg/ml inj.	4	310	40	<1	$2,184.98	54.62
Gabapentin 100mg cap	8,755	790,698	263,747	~16.7	$361,523.61	1.37
Gabapentin 300mg cap	28,239	2,662,085	889,929		$2,854,774.28	3.21
Gabapentin 400mg cap	4,914	567,044	150,122		$735,612.38	4.90
Gabapentin 100mg tab	602	50,243	17,715		$22,645.06	1.28
Gabapentin 300mg tab	2,047	195,486	62,152		$208,684.27	3.36
Gabapentin 400mg tab	316	37,443	9,666		$47,951.09	4.96
Gabapentin 600mg tab	9,956	949,906	319,950		$1,907,716.72	5.96
Gabapentin 800mg tab	3,246	323,499	99,312		$769,024.19	7.74
Neurontin 250mg/5ml	217	99,119	5,309		$19,115.78	3.60
Lamictal 25mg tab	2,856	255,460	87,003	<1	$800,031.20	9.20
Lamictal 100mg tab	4,673	349,802	155,826	1.3	$1,150,560.81	7.38
Lamictal 150mg tab	1,483	101,961	47,598	<1	$348,753.60	7.33
Lamictal 200mg tab	2,586	175,911	88,107	<1	$627,920.84	7.13
Lamictal Kit	15	735	381	<1	$2,500.10	6.56
Lamictal 5mg chew	159	23,431	4,761	<1	$67,562.00	14.19
Lamictal 25mg chew	417	48,160	11,882	<1	$143,891.81	12.11
Keppra 250mg tab	1,118	99,446	33,062	<1	$175,279.07	5.30
Keppra 500mg tab	6,152	664,454	186,445	1.7	$1,405,326.22	7.54
Keppra 750mg tab	1,290	121,604	39,231	<1	$353,895.38	9.02
Keppra 100mg/ml	1,209	346,428	34,535	<1	$146,533.00	4.24
Trileptal 150mg tab	2,547	186,483	79,021	<1	$205,652.94	2.60
Trileptal 300mg tab	6,101	495,370	187,235	1.7	$972,169.30	5.19
Trileptal 600mg tab	2,005	142,491	62,735	<1	$513,774.48	8.19
Trileptal 300mg/5ml	936	237,221	25,815	<1	$97,284.21	3.77
Mysoline 50mg tab	1711	1,932	54,741	<1	$71,175.70	1.30
Mysoline 250mg tab	1,932	163,982	61,264	<1	$92,861.37	1.52
Topamax 25mg tab	4,824	495,074	145,688	~5.1	$790,503.45	5.43
Topamax 50mg tab	1,015	70,791	33,636		$227,980.02	6.78
Topamax 100mg tab	6,427	480,874	211,726		$2,007,521.13	9.48
Topamax 200mg tab	3,135	243,572	101,348		$1,185,158.92	11.69
Topamax 15mg cap	376	34,807	12,476		$53,039.35	4.25
Topamax 25mg cap	411	65,049	12,476		$118,942.05	9.53
Zonegran 25mg cap	105	10,300	3,074	<1	$5,751.54	1.87
Zonegran 50mg cap	146	10,926	4,357	<1	$11,944.19	2.74
Zonegran 100mg cap	2,075	195,811	63,896	<1	$398,172.42	6.23
Totals*					**28,411,246.94**	

*Excludes (Benzodiazepines and Barbiturates)

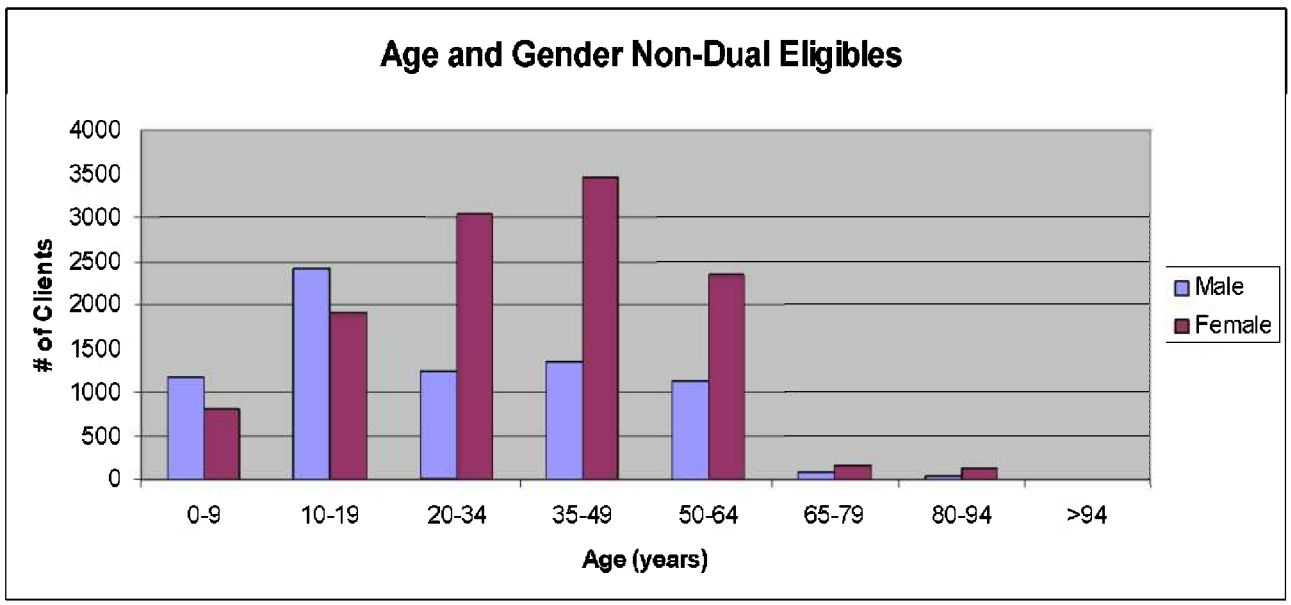
Age/Gender FY05

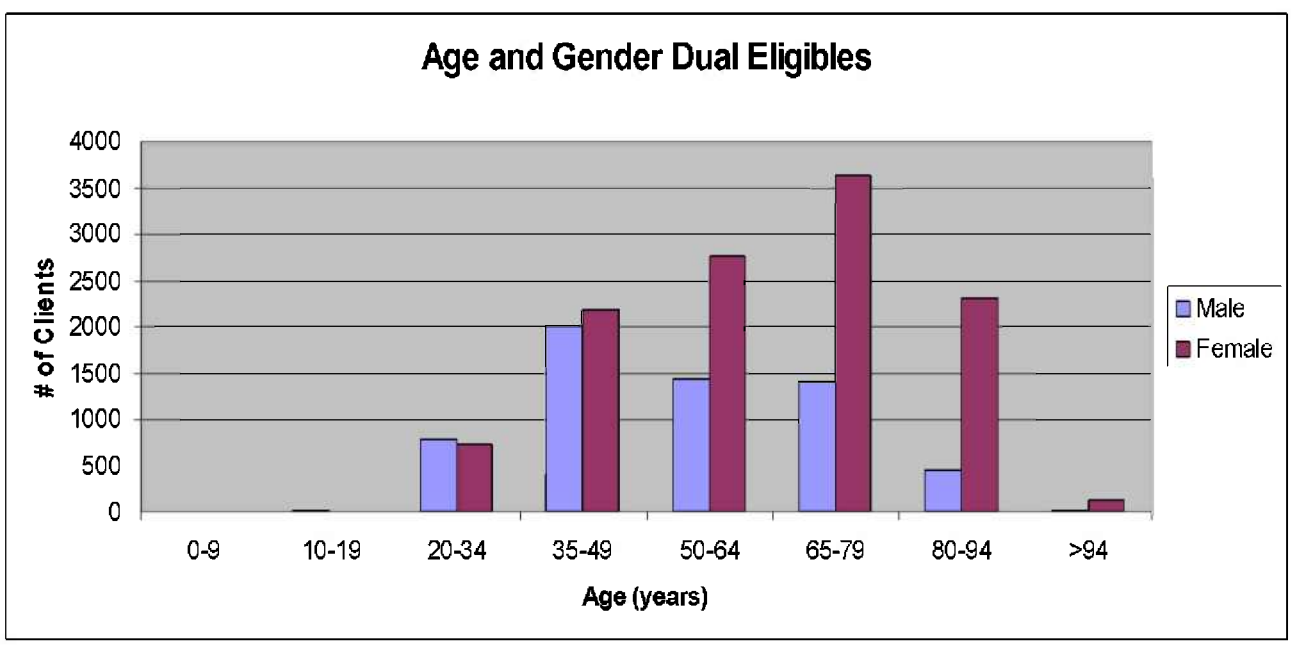
Age	Female	Male	Totals
0 to 9	796	1,166	1,962
10 to 19	1,913	2,437	4,350
20 to 34	3,772	2,010	5,782
35 to 49	5,642	3,349	8,991
50 to 64	5,107	2,568	7,675
65 to 79	3,808	1,493	5,301
80-94	2,432	497	2,929
>94	142	25	167
Totals	**23,612**	**13,545**	**37,157***

*unduplicated clients

Medicaid-Medicare Dual-Eligibles FY05

FY 2005	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	17,885	218,933	16,535,395	4,507,583	14,040,964.47	3.11
Non-Duals	19,272	138,544	15,988,128	4,163,048	15,384,116.00	3.70





Antiepileptic Barbiturate and Benzodiazepine Utilization

	# of Clients		Total Cost*
	Duals	NonDuals	
Barbiturates	902	1,133	$121,737.09
Benzodiazepines	4,093	5,187	$1,013,833.53

*Excludes (supplemental rebate information)

Non-Pharmacologic Treatments[4]

- Ketogenic Diet (ie. Atkins Diet)
- Vagus Nerve Stimulation (VNS)
- Epileptic Surgery
- Brain Cooling (hypothermia)

Current News and Safety News

April 2005-FDA request pharmaceutical companies to reexamine clinical trial data to assess if anticonvulsant medications potentially increase suicidal thoughts and behaviors.

December 2004-FDA approved pregabalin for pain associated with diabetic peripheral neuropathy; post-herpetic neuralgia; adjunctive therapy for partial onset seizure disorder in adults.

December 2005-Depakote ER approved: Acute Manic or Mixed Bipolar Disorder

Recommendations

The College of Pharmacy recommends consideration of establishing a product-based prior authorization category for the antiepileptic medications to assure appropriate utilization according to current evidenced-based guidelines and because of recent safety concerns surrounding these medications for approved and off-label indications.

Reference

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2. Website: **The Medical Letter: Treatment Guidelines Drugs for Epilepsy**. Online. Internet. 2005. Available: http://www.medicalletter.org.

3. Woelfel JA. **Comparison of FDA-approved Antiepileptic Drugs.** Pharmacist's Letter, Vol 20. December 2004. Number 201213.

4. Wilner AN. **The Epilepsy Continuum: From Age to Age.** Medscape. Internet. 2004. Available: http://medscape.com/viewprogram/3454_pnt.

5. Website: **American Epilepsy Society: Treatment Guidelines**. Online. Internet. 2005. Available: http://www.aesnet.org/Visitors/PatientsPractice/AESandAANAntiepilepticDrugGuidelines.cfm.

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APPENDIX I

New Product Summaries

Oklahoma Medicaid
January 2006

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP/ unit
Asmanex® (mometasone furoate) inhaler	Schering	Maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.	**Depends upon previous therapy Bronchodilators or ICS**: 220mcg daily q pm up to 440mcg daily or divided bid **Oral Steroids**: 440mcg twice a day. Once oral steroid dose is reduced, memetasone dose should be reduced to lowest effective dose	Headache, allergic rhinitis, pharyngitis, upper respiratory infection, sinusitis, oral candidiasis, musculoskeletal pain, dyspepsia, myalgia, abdominal pain, nausea	In the primary treatment of status asthmaticus. Hypersensitivity to any of the ingredients of the preparation	No	$103 for 30 and 60 inhalations; $160 for 120 inhalations

APPENDIX J

FDA News

FOR IMMEDIATE RELEASE
P05-114
December 28, 2005

Media Inquiries:
Rae Jones, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves New Treatment for Myelodysplastic Syndrome (MDS)

The Food and Drug Administration (FDA) has approved the drug Revlimid (lenalidomide) for the treatment of patients with a subtype of Myelodysplastic Syndrome (MDS). The subtype is MDS patients with deletion 5q cytogenetic abnormality.

MDS is a collection of disorders in which the bone marrow does not function normally and the body does not make enough normal blood cells. Patients with MDS may need blood and platelet transfusions and antibiotic therapy for infections. In clinical trials, patients treated with Revlimid no longer needed transfusions, with most patients becoming independent of transfusion by three months. The transfusion-free period lasted for an average of 44 weeks.

"This new product will offer a much needed treatment option for patients suffering from this rare illness that, in some cases, has been found to progress to fatal forms of leukemia," said Dr. Steven Galson, M.D., Director of FDA's Center for Drug Evaluation and Research (CDER).

MDS can develop following treatment with drugs or radiation therapy for other diseases, or it can develop without any known cause. Some forms of MDS can progress to acute myeloid leukemia (AML), a type of cancer in which too many white blood cells are made.

An estimated 7,000 to12,000 new cases of MDS are diagnosed yearly in the United States. Although MDS occurs in all age groups, the highest prevalence is in people over 60 years of age. Typical symptoms include weakness, fatigue, infections, easy bruising, bleeding, and fever

Revlimid is structurally similarto thalidomide, a drug known to cause severe birth defects. Additional studies are ongoing in animals to address whether there is a risk that Revlimid will also cause birth defects when taken during pregnancy. While these studies are under way, the company is marketing Revlimid under a risk management plan called RevAssist, designed to prevent fetal exposure.

Under RevAssist, only pharmacists and prescribers registered with the program will prescribe and dispense Revlimid. The program requires patients, including female patients undergoing mandatory pregnancy testing, to give informed consent before starting Revlimid. Physicians are to check pregnancy tests, limit prescriptions to a one-month mail supply, and report any pregnancies to FDA. FDA and the manufacturer will re-evaluate the risk management plan when results of further animal testing for birth defects are completed.

The labeling for Revlimid will include a Black Box Warning and a Medication Guide regarding the prevention of fetal exposure. Additional Black Box Warnings include the potential need to lower the dose due to suppressed blood counts and increased risk of blood clots. Common side effects reported with Revlimid include thrombocytopenia (low platelet count), neutropenia (low white blood cell count), diarrhea, pruritis (itch), rash, and fatigue.

Revlimid is distributed by Celgene Corporation of Summit, N.J.

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FDA News

FOR IMMEDIATE RELEASE
P05-97
December 8, 2005

Media Inquiries:
Susan Cruzan, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Advising of Risk of Birth Defects with Paxil
Agency Requiring Updated Product Labeling

The Food and Drug Administration today is alerting health care professionals and patients about early results of new studies for Paxil (paroxetine) suggesting that the drug increases the risk for birth defects, particularly heart defects, when women take it during the first three months of pregnancy. Paxil is approved for the treatment of depression and several other psychiatric disorders. FDA is currently gathering additional data and waiting for the final results of the recent studies in order to better understand the higher risk for birth defects that has been seen with Paxil.

FDA is advising health care professionals to discuss the potential risk of birth defects with patients taking Paxil who plan to become pregnant or are in their first three months of pregnancy. Health care professionals should consider discontinuing Paxil (and switching to another antidepressant if indicated) in these patients. In some patients, the benefits of continuing Paxil may be greater than the potential risk to the fetus. FDA is advising health care professionals not to prescribe Paxil in women who are in the first three months of pregnancy or are planning pregnancy, unless other treatment options are not appropriate.

FDA is advising patients that this drug should usually not be taken during pregnancy, but for some women who have already been taking Paxil, the benefits of continuing may be greater than the potential risk to the fetus. Women taking Paxil who are pregnant or plan to become pregnant should talk to their physicians about the potential risks of taking the drug during pregnancy. Women taking Paxil should not stop taking it without first talking with their physician.

The early results of two studies showed that women who took Paxil during the first three months of pregnancy were about one and a half to two times as likely to have a baby with a heart defect as women who received other antidepressants or women in the general population. Most of the heart defects reported in these studies were atrial and ventricular septal defects (holes in the walls of the chambers of the heart). In general, these types of defects range in severity from those that are minor and may resolve without treatment to those that cause serious symptoms and may need to be repaired surgically.

In one of the studies, the risk of heart defects in babies whose mothers had taken Paxil early in pregnancy was about 2 percent, compared to a 1 percent risk in the whole population. In the other study, the risk of heart defects in babies whose mothers had taken Paxil in the first three months of pregnancy was 1.5 percent, compared to 1 percent in babies whose mothers had taken other antidepressants in the first three months of pregnancy.

FDA has asked the manufacturer, Glaxo Smith Kline (GSK), to change the pregnancy category from C to D, a stronger warning. Category D means that studies in pregnant women (controlled or observational) have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risks to the fetus.

Based on results of the preliminary data, GSK updated the drug's labeling in September 2005 to add data from one study. As additional data have become available, the label has now been changed to reflect the latest data from the two studies and to change the pregnancy category.

FDA News

FOR IMMEDIATE RELEASE
P05-107
December 20, 2005

Media Inquiries:
Kristen Neese, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves New Treatment for Advanced Kidney Cancer

The Food and Drug Administration (FDA) today approved Nexavar (sorafenib tosylate), a new anti-cancer medicine used to treat adults with advanced renal cell carcinoma, the most common type of kidney cancer.

"The approval of Nexavar to treat advanced kidney cancer brings a much needed option for this group of cancer patients," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research (CDER). "FDA is working hard to support the development of new and effective treatments for patients with cancer and other serious illnesses who have limited alternatives."

In the United States, kidney cancer accounts for approximately 3 percent of all adult cancers. According to the American Cancer Society, about 32,000 new cases are diagnosed and about 12,000 people die from the disease annually. Kidney cancer occurs most often in people between the ages of 50 and 70, affects men almost twice as often as women and, if detected early enough, may be curable surgically. However, tumors that are advanced (i.e., cannot be surgically removed or have spread to other parts of the body) are difficult to treat.

Two studies in patients with advanced kidney cancer have shown that patients treated with Nexavar had more time before tumor progression or death. In the larger study, most patients had previously received treatment with interleukin-2 or interferon. The median time to tumor progression or death in the Nexavar treated arm was 167 days compared to 84 days in people not treated with the drug.

Some common temporary side effects reported with Nexavar are rash, diarrhea, increases in blood pressure, and redness, pain swelling, or blisters on the palms of the hands or soles of the feet.

Nexavar will be distributed and marketed by Bayer Pharmaceuticals Corporation of Westhaven, CT.

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FDA Alert for Healthcare Professionals

Clarithromycin (in the CLARICOR Study)

FDA ALERT [12/2005]:

FDA has learned of a placebo controlled study of patients in Denmark with heart disease (the CLARICOR Study), reporting increased mortality in patients treated with clarithromycin (14 days) compared with patients who received a placebo (http://bmj.bmjjournals.com/cgi/rapidpdf/bmj.38666.653600.55v1). The observed difference in mortality became apparent after patients had been followed for one year or longer after the study drug was given. A mechanism by which two-weeks of clarithromycin could cause increased mortality measured after one year or longer is not clear. Previous trials of antibacterial drugs to prevent heart disease and other trials of clarithromycin have not shown a statistically significant effect on mortality. Considering the results from the CLARICOR study and the results from previous studies of antibacterial drugs to prevent heart disease, the FDA is not recommending any specific changes to the use of clarithromycin at this time. FDA has discussed these findings with the Danish Medicines Agency (DMA) and the FDA recommendation is consistent with that of the DMA. The FDA is providing the summary below to physicians and patients so that they can be aware of the information currently available. The FDA is attempting to get more information regarding the CLARICOR study and its findings.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about this information. 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 at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

- Healthcare providers should be aware of the information summarized below regarding the CLARICOR study. This information may also be helpful in addressing questions from patients about the CLARICOR study and clarithromycin (an antibiotic marketed as BIAXIN® and BIAXIN® XL).
- No specific changes in the product labeling for clarithromycin are being recommended at this time.

Summary

The following provides a more detailed description of the available information about the CLARICOR study and other published trials of antibacterial drugs in patients with heart disease.

The CLARICOR Study

FDA Alert for Healthcare Professionals

Clarithromycin (in the CLARICOR Study)

An article published by the *British Medical Journal* (available online at http://bmj.bmjjournals.com/cgi/rapidpdf/bmj.38666.653600.55v1), describes the findings of the CLARICOR study,[1] a study of clarithromycin for the prevention of heart disease. The study, conducted by academic investigators in Denmark, was designed to evaluate whether treatment with clarithromycin could prevent another event ("heart attack", unstable angina, or death) in patients with stable coronary artery (heart) disease (CAD). In this study, over 4300 people with stable CAD received either clarithromycin (500 mg once daily) or a placebo for two weeks. The results for the primary endpoint ("heart attack", unstable angina or death, whichever occurred first) did not achieve statistical significance ($p = 0.08$). There were 344 primary endpoint events in the clarithromycin group (15.8%) and 307 events in the placebo group (13.8%). Analysis of all cause mortality found that there were 212 deaths in the clarithromycin group and 172 deaths in the placebo group. The hazard ratio and 95% confidence interval for all-cause mortality was 1.27 (1.03 to 1.54) ($p = 0.03$).

The observed differences in deaths became apparent about one year or longer after the study drug was given. The finding of a higher mortality rate occurring beyond one year of follow-up after a single two-week course of clarithromycin was an unexpected finding. Most of these deaths were attributed to heart disease. When the analysis was limited to cardiovascular deaths, the difference in mortality between treatment groups was still present. There is no clear explanation for how clarithromycin would lead to more deaths than placebo and no biological mechanism to account for deaths occurring one year or longer after a single two-week treatment course of clarithromycin in the CLARICOR study. The authors' conclusions regarding this study are that even a brief course of clarithromycin given to patients with stable CAD may be associated with more deaths compared to similar patients given a placebo. The authors recommend further study of the long term effects of clarithromycin (and other antibacterial agents) in patients with coronary artery disease to further investigate the results of the CLARICOR study.

At this point in time, the FDA has not had access to the primary data for the CLARICOR study to perform an independent review of the study and its results. It is possible that further evaluation of the study will help in understanding the observed results. We also cannot exclude the possibility that other factors or chance could have contributed to the observed mortality difference. For example, the authors note that they would like to know about New York Heart Association class, ejection fraction at baseline and medical treatment and lifestyle during the study period.

FDA has reviewed analyses prepared by Abbott Laboratories of their clarithromycin clinical trials database. The analyses evaluate the available clinical trial data for clarithromycin to

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[1] Jespersen, CM, Als-Nielsen, B, Damgaard, M., et al. "Randomised placebo controlled multicenter trial to assess short term clarithromycin for patients with stable coronary heart disease: CLARICOR trial." *BMJ*, DOI 10.1136/bmj.38666.653600.55

examine whether there are differences in death rates or adverse events related to heart disease between clarithromycin and other antibacterial drug comparators. These analyses do not show significant differences in the adverse events or death rates, but most of these studies ended after a few weeks or months. They do not continue for long enough to be able to see whether the difference in deaths reported in the CLARICOR trial would occur.

Previous Studies of Antibacterial Drugs for Prevention of Heart Disease

Some investigators have reported the presence of *Chlamydophila pneumoniae* in atherosclerotic plaques and there is some evidence of an association between *C. pneumoniae* antibodies and CAD. These findings have led investigators to perform clinical trials with antibacterial drugs active against *C. pneumoniae* (such as clarithromycin) in patients with CAD. The hypothesis of these trials has been that antibacterial therapy against *C. pneumoniae* would prevent progression of coronary artery disease and subsequent coronary events (e.g., heart attacks).

Two studies of clarithromycin (prior to CLARICOR) for the prevention of heart disease have been published. In one of these studies,[2] 148 patients with stable CAD were given clarithromycin or placebo for three months. After a year, there were four deaths in the clarithromycin group and one death in the placebo group. The number of patients in the study was too small to draw any conclusions about the death rates in this study. A second study[3] involved 473 patients undergoing surgery for heart disease. Patients received clarithromycin or placebo until their surgery (an average of 16 days of treatment). After two years of follow-up, there were 10 deaths in the clarithromycin group and 9 deaths in the placebo group. These two smaller studies do not show the same statistically significant difference in death rates shown in the CLARICOR study.

Several other antibacterial drugs have been studied for the prevention of heart disease.[4, 5] Antibacterial drugs with activity against *Chlamydophila pneumoniae* did not prevent subsequent cardiac events in patients with coronary artery disease. None of these other studies have shown statistically significant differences, either beneficial or harmful, in the rates of death for antibacterial-treated compared with placebo-treated patients.

[2] Sinisalo J and the Clarithromycin in Acute Coronary Syndrome Patients in Finland (CLARIFY) Study Group. "Effect of 3 Months of Antimicrobial Treatment with Clarithromycin in Acute Non-Q-wave Coronary Syndrome" Circulation (April 2, 2002) 105(13): 1555-1560.

[3] Berg et al. "Treatment with Clarithromycin Prior to Coronary Artery Bypass Graft Surgery Does Not Prevent Subsequent Cardiac Events" CID 40: 358-65 (February 1, 2005).

[4] Andraws R et al., "Effects of Antibiotic Therapy on Outcomes of Patients With Coronary Artery Disease – A Meta-analysis of Randomized Controlled Trials" JAMA (June 1, 2005) 293(21): 2641-2647.

[5] O'Connor CM et al., "Azithromycin for the Secondary Prevention of Coronary Heart Disease Events – The WIZARD Study: A Randomized Controlled Trial" JAMA (September 17, 2003) 290(11): 1459-1466.

FDA Alert for Healthcare Professionals

Clarithromycin (in the CLARICOR Study)

What the FDA is Doing

The FDA is taking the following steps in response to the preliminary findings reported from the CLARICOR study:

- FDA is providing this information to healthcare providers and patients via this Alert.
- FDA has discussed these findings with the Danish Medicines Agency (DMA) and is working with the DMA to obtain additional information regarding the CLARICOR study and its results. Through these efforts, FDA hopes to further investigate the findings reported from the CLARICOR study.
- FDA's Office of New Drugs and Office of Drug Safety are collaborating to evaluate available sources of post-marketing data for patients receiving clarithromycin.
- As information becomes available from continued analysis of the CLARICOR study or other sources, appropriate further steps will be determined.

We are providing this statement regarding the results of the CLARICOR study so that physicians and patients are aware of this information. FDA is not recommending any specific changes in the product labeling for clarithromycin (marketed as BIAXIN® and BIAXIN® XL) at this time. Physicians and patients should weigh the benefits and risks of any drug treatment, including clarithromycin.

The FDA will continue to notify healthcare providers and patients as new information becomes available.

Additional information regarding the CLARICOR study is also available on the Danish Medicines Agency website. (http://www.dkma.dk/) (http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=7597)

The FDA urges health care providers and patients to report adverse event information to FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by the Internet at http://www.fda.gov/medwatch/index.html.