Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

July 12, 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 – July 12, 2006**

DATE: July 5, 2006

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

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

Utilization Review of Antiretrovirals – **See Appendix C.**

Overview of Pharmacy Program and DUR – **See Appendix D.**

Action Item – Vote to Prior Authorize Chantix™ – **See Appendix E.**

Action Item – Review of Anti-migraine Utilization –**See Appendix F.**

30 Day Notice to Prior Authorize Antiemetics –**See Appendix G.**

30 Day Notice to Prior Authorize Pediculicides – **See Appendix H.**

Addition of OTC Cough and Cold Drugs to Children's Pharmacy Benefit Package – **See Appendix I.**

New Products and Notices – **See Appendix J.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – July 12, 2006 @ 6:00p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. McNeill, Chairman:

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

A. June 14, 2006 DUR Minutes – Vote
B. June 14, 2006 DUR Recommendations Memorandum

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

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

A. Retrospective Drug Utilization Review for March 2006
B. Retrospective Drug Utilization Review Response for January 2006
C. Medication Coverage Activity Audit for June 2006
D. Help Desk Activity Audit for June 2006

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

5. Utilization Review of Antiretrovirals – See Appendix C.

A. **Guest Speaker, R. Chris Rathbun, Pharm.D., BCPS**
B. Epidemiology
C. Utilization of Antiretrovirals
D. Conclusions and Recommendations

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

6. Overview of Pharmacy Program and DUR – See Appendix D.

A. Medicaid Pharmacy Program Background
B. DUR Plus

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

7. Action Item – Vote to Prior Authorize Chantix™ – See Appendix E.

A. Product Summary
B. COP Recommendations
C. Cost Comparison

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

8. Action Item – Review of Anti-migraine Utilization – See Appendix F.

A. Current Quantity Limits
B. Utilization Review
C. COP Recommendations

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

9. 30 Day Notice to Prior Authorize Antiemetics – See Appendix G.

A. Introduction
B. Cost and Utilization Update
C. COP Recommendations

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

10. 30 Day Notice to Prior Authorize Pediculicides – See Appendix H.

A. Introduction
B. COP Recommendations

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

11. Addition of OTC Cough and Cold Drugs to Children's Pharmacy Benefit Package – See Appendix I.

A. Introduction
B. Recommended Covered Products
C. Potential Economic Impact

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

12. New Product Reviews and Notices – See Appendix J.

13. FDA and DEA Updates – See Appendix K.

14. Future Business

A. Beta-Blocker Utilization Review
B. Antipsychotic Utilization Review
C. Heart Failure Utilization Review
D. Flu Medication Review
E. Annual Reviews
F. New Product Reviews and 30 Day Notices

15. Adjournment

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JUNE 14, 2006

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.		X
Mark Feightner, 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	
John Muchmore, M.D.	X	
James Rhymer, D.Ph		X

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./PA Coordinator	X	
Metha Chonlahan, D.Ph./Clinical Pharmacist	X	
Karen Egesdal, D.Ph./SMAC-ProDUR Coordinator/OHCA Liaison		X
Kelly Flannigan, Pharm.D../Operations Manager	X	
Shellie Gorman, Pharm.D./DUR Manager	X	
Ronald Graham, D.Ph./Pharmacy Director	X	
Chris Le, Pharm.D., Clinical Pharmacist/Coordinator	X	
Carol Moore, Pharm.D., Clinical Pharmacist	X	
Neeraj Patel, Pharm.D., Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.	X	
Visiting Pharmacy Students: Sarah Grode, Mai Pham	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Alex Easton, M.B.A./ Pharmacy Operations Manager		X
Mike Fogarty, J.D., M.S.W./Chief Executive Officer		X
Lynn Mitchell, M.D., M.P.H/Director of Medical Services	X	
Nancy Nesser, Pharm.D., J.D./Pharmacy Director	X	
Howard Pallotta, J.D./Director of Legal Services		X
Lynn Rambo-Jones, J.D./Deputy General Counsel III	X	
Rodney Ramsey/Drug Reference Coordinator	X	
Jill Ratterman, D.Ph./Pharmacy Specialist		X

OTHERS PRESENT:

Donna Erwin, BMS	Aliza Tomlinson, OMJ	Janie Turnbull, Ruble and Associates
Brian Leugs, PhRMA	Bobby White, UCB Pharma	Jorge Nassar, BMS
Sandy Ruble, Ruble & Assoc.	Jonathan Klock, GSK	Jim Dunlap, Eli Lilly
Patty Laster, Genentech	Steve Higgins, TAP Pharmaceuticals	Lana Stewart, Merck

PRESENT FOR PUBLIC COMMENT: n/a

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

1A: Roll Call

Roll call by Dr. Graham established the presence of a quorum. The Board proceeded to elect the new Chair and Vice Chair, whereupon the meeting was called to order.

ACTION: NONE REQUIRED.

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

There were no speakers for Public Comment.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: **VOTE ON NEW DUR BOARD CHAIR AND VICE CHAIR**

Dr. Gourley moved to elect Dr. Dan McNeill as Chair and Dr. Cliff Meece as Vice Chair, by acclamation; seconded by Dr. Feightner. Dr. Nesser introduced new Board members Dr. John Muchmore and Dr. Mark Feightner.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 4: **APPROVAL OF DUR BOARD MINUTES**

4A: May 10, 2006 DUR Minutes

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 5: **UPDATE ON DUR/MCAU PROGRAM**

5A: Retrospective Drug Utilization Review Report: February 2006
5B: Retrospective Drug Utilization Review Response: December 2005
5C: Medication Coverage Activity Report: May 2006
5D: Help Desk Activity Report: May 2006

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

ACTION: NONE REQUIRED.

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

Materials included in agenda packet; presented by Dr. Gorman.
The board members discussed the potential of abuse for this product.
Dr. Gourley moved to approve as submitted; seconded by Dr. Meece.

ACTION: MOTION CARRIED.

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

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **60-DAY NOTICE TO PRIOR AUTHORIZE PEDICULICIDES**

Materials included in agenda packet; presented by Drs. Patel and Gorman.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **60-DAY NOTICE TO PRIOR AUTHORIZE ANTIEMETICS**

Materials included in agenda packet; presented by Drs. Chonlahan and Gorman.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **REVIEW OF ANTIBIOTIC UTILIZATION**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **FOLLOW-UP OF STIMULANT UTILIZATION**
Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **GENERIC ADHERENCE**
Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **NEW PRODUCT REVIEWS AND NOTICES**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 14: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 15: **FUTURE BUSINESS**
15A: Antimigraine Utilization Review
15B: Antipsychotic Utilization Review
15C: New Product Reviews and 30-Day Notices
15D: OTC Formulary
15E: HIV Utilization Review
15F: Annual Reviews
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 16: **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: June 23, 2006

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

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

Subject: DUR Board Recommendations from Meeting of June 14, 2006.

Recommendation 1: Vote to On New Chair and Vice-Chair

MOTION CARRIED by unanimous approval.

A motion was made by member Dorothy Gourley to elect by acclamation member Dan McNeill as Chairman and Clif Meece as Vice-Chair of the DUR Board.

Recommendation 2: Vote to Prior Authorize Daytrana™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends including Daytrana™ as a Tier-2 medication in the ADHD Product Based Prior Authorization program. A quantity limit of 30 patches for 30 days is also recommended.

Tier	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, Daytrana	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.

*Tier 1 due to supplemental rebate agreement.

APPENDIX B

Retrospective Drug Utilization Review Report

Claims Reviewed for March 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	45,109	54,764	735,229	31,583
Limits which were applied	Established, Major, Males and Females, 22-42 years	Narcotics, Females, age 38-41 years	Contraindicated, Female Age 16-19 years, Pregnancy	High dose, Carbamates, Tingabine, Hydantoins, Oxazolidinedions, Succinimides, Valproic Acid, Misc. Anticonvulsants. Males and Females, Age 16-21
Total # of messages after limits were applied	44	361	150	25
Total # of members reviewed after limits were applied	69	250	102	24

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
157		138	

Retrospective Drug Utilization Review Report

Claims Reviewed for January 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females Age 66-150	Narcotics, Males, Age 31-40	Contraindicated, Age 66-150, Asthma	High dose, Centrally acting SMR, Males and Females, Age 22-40

Response Summary (Physician)
Letters Sent: 106
Response Forms Returned: 58

The response forms returned yielded the following results:

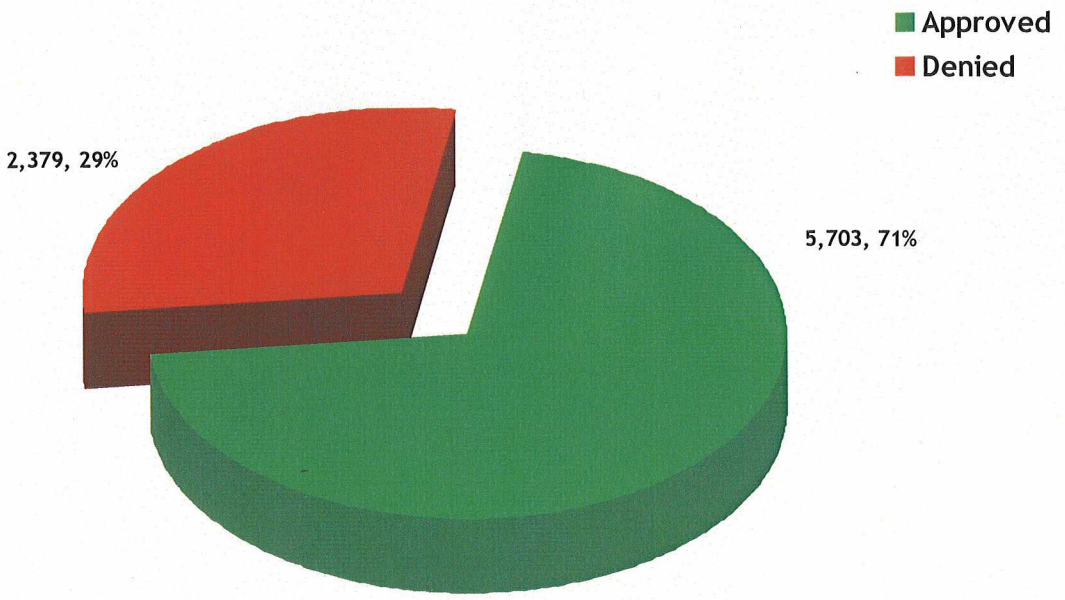
7 (12%)	*Record Error—Not my patient.*
14 (24%)	*No longer my patient.*
2 (3%)	*Medication has been changed prior to date of review letter.*
11 (19%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
18 (31%)	*I am aware of this situation and will plan to continue monitoring therapy.*
6 (10%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 84
Response Forms Returned: 54

The response forms returned yielded the following results:

1 (2%)	*Record Error—Not my patient.*
11 (20%)	*No longer my patient.*
2 (4%)	*Medication has been changed prior to date of review letter.*
13 (24%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
20 (37%)	*I am aware of this situation and will plan to continue monitoring therapy.*
7 (13%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
June 2006



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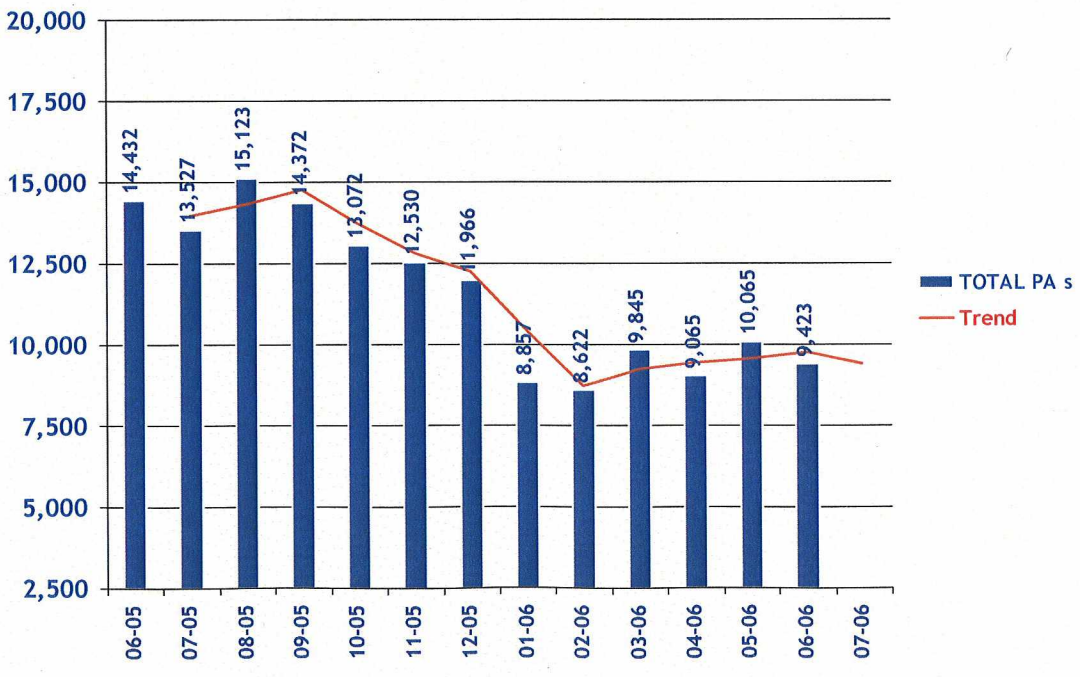
PRIOR AUTHORIZATION REPORT
June 2005 - June 2006



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Activity Audit for

June 01 2006 Through June 30 2006

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.	13		2867		985		36		628		30		13		0		27		149		5		171		
Den.		6		407		546		0		192		146		14		0		62		21		2		176	
Average Length of Approvals in Days	30		94		95		177		202		258		123		0		286		358		184		209		

Changes to existing PA's	543
Total (Previous Year)	14432

* Denial Codes	
762 = Lack of clinical Information	33.33%
763 = Medication not eligible	0.88%
764 = Existing PA	2.06%
772 = Not qualified for requested Tier	4.88%
773 = Requested override not approved	13.45%

SUPER PA's	
Admitted to Nursing Home	25
Early Refill Attempts	25689
Dosing Change	352
High Dose	9
Lost/Broken Rx	104
Stolen	16
Other	52
Wrong D.S. on Previous Rx	10
Quantity vs. Days Supply	867
Brand	97
-- Approved	25
-- Denied	21

Monthly Totals

	Number	Percent of Total
Approved	5702	60.51%
Additional PA's	0	0.00%
Emergency PA's	1	0.01%
Duplicates	400	4.24%
Incompletes	941	9.99%
Denied *	2379	25.25%
Total	9423	100.00%

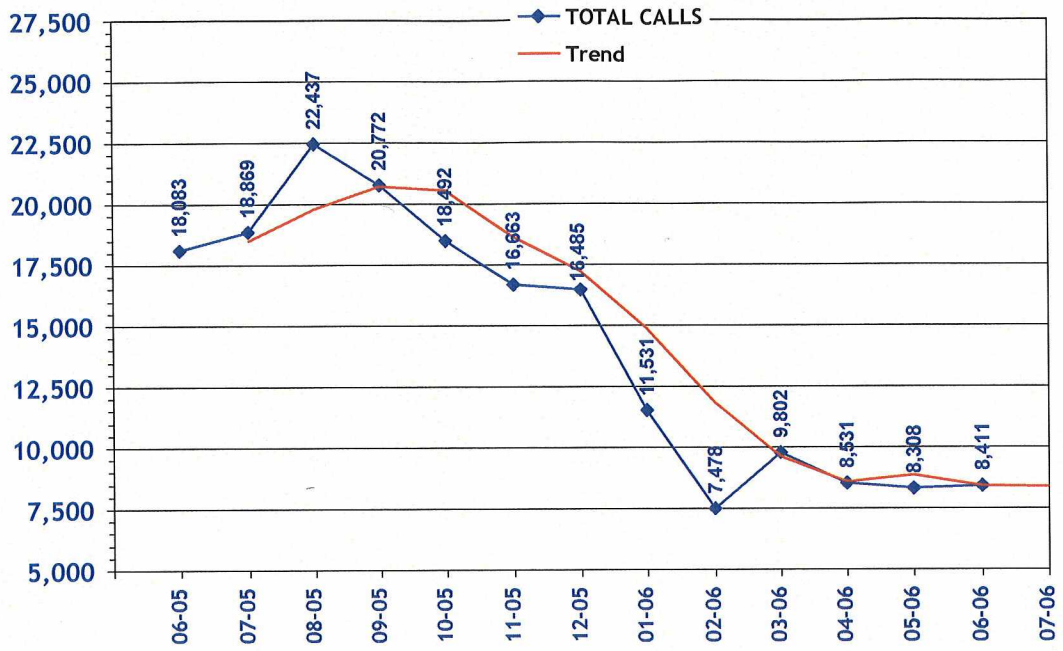
Daily Average of 428.32 for 22 Days

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
June 2005 - June 2006



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APPENDIX C

Utilization Review of Antiretrovirals

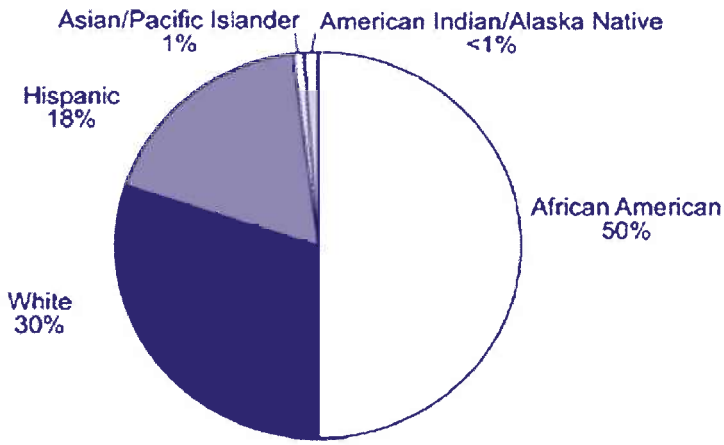
Oklahoma HealthCare Authority

June 2006

Epidemiology[1]

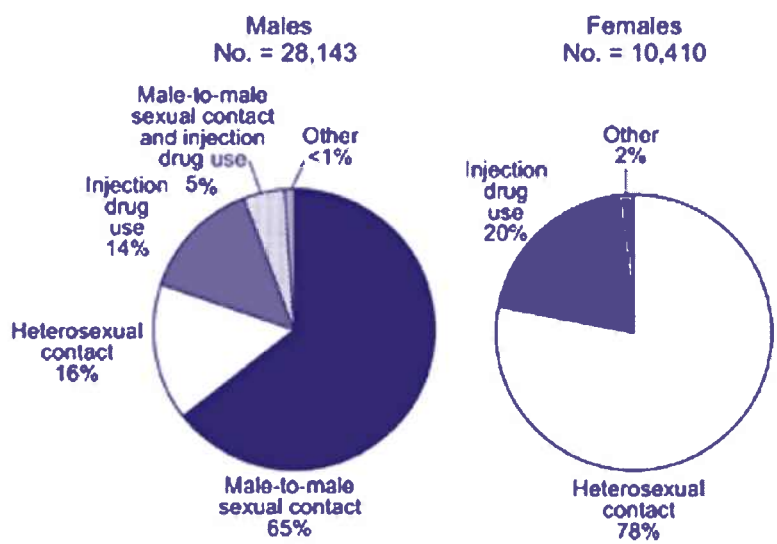
The National Centers for Disease Control reports an estimated 1.2 million people in the U.S. were living with HIV/AIDS in 2003. Every year approximately 40,000 people become infected with HIV, of which, almost 75% are male adolescents or adults. The following charts show other national epidemiologic data collected by the CDC.

Race/ethnicity of persons (including children) with HIV/AIDS diagnosed during 2004



No. = 38,730

Transmission categories of adults and adolescents with HIV/AIDS diagnosed during 2004



Trends in Diagnosis and Deaths

In the earlier stages of the AIDS epidemic, a diagnosis of HIV infection was an impending death sentence. However, during the mid-to-late 1990s, advances in treatment slowed the progression of HIV infection to AIDS and led to dramatic decreases in the number of AIDS-related deaths. The overall improvement and advancements in antiretroviral therapy has allowed HIV to become, to some extent, a chronic disease. People diagnosed with HIV may live up to 10 or more years with currently available treatments.

Although the decrease in the estimated number of AIDS deaths continues, it's also countered by an increase in HIV diagnosis. This results in an increase in the number of persons in the United States who are living with AIDS. From 2000 through 2004, the estimated number of persons in the United States living with AIDS increased by 30%.

Estimated numbers of AIDS diagnoses, deaths, and persons living with AIDS, 2000–2004[2]

	2000	2001	2002	2003	2004	Cumulative
AIDS diagnosis	39,513	39,206	40,267	41,831	42,514	944,306
AIDS Death	17,139	17,611	17,544	17,849	15,798	529,113
Living with AIDS	320,177	341,773	364,496	388,477	415,193	415,193

Oklahoma HIV/AIDS Epidemiology[3]

The following data on HIV/AIDS prevalence in Oklahoma has been collected and reported by the Oklahoma Department of Health.

Diagnosed HIV Infection and AIDS cases, Cumulative through 12/31/2005

Cases	Oklahoma HIV		Oklahoma AIDS	
	Number	Deaths	Number	Deaths
Adult/Adolescent	2,544	330	4,400	2,527
Pediatric (<13 years)	28	1	23	17
Total	2,572	331	4,423	2,544
Race	**Number**	**Percent**	**Number**	**Percent**
White	1,666	65%	3,075	70%
Black	594	23%	799	18%
Asian/Pacific Islander	13	0.5%	22	0.5%
American Indian	157	6%	316	7%
Multi-race	15	1%	14	0.3%
Unknown/Other	127	5%	197	5%
Gender	**Number**	**Percent**	**Number**	**Percent**
Male	2,131	83%	3,915	89%
Female	441	17%	508	11%

The Pre-1987 Definition refers to the original list of "opportunistic infections" established by the Centers for Disease Control and Prevention (CDC), any one of which was necessary for an AIDS diagnosis.
The 1987 Definition refers to additions to that list, including such diagnoses as AIDS-related dementia and the wasting syndrome. Because all conditions are not necessarily infections, the new term for AIDS-defining conditions is "indicator disease"
The 1993 Definition expands the CDC definition to include the following: invasive cervical cancer, pulmonary tuberculosis, recurrent pneumonia, or a CD4+ lymphocyte count of less than 200 :l/dl or less than 14% of total lymphocytes. This update of the definition is applicable only to adults and adolescents aged 13 or older, and continues to include the fact that the person exhibiting the disease must also be diagnosed as having HIV infection.

Available Antiretroviral Agents

The following chart shows the classification of the currently available agents. Treatment consists of a combination of agents that targets different aspects of viral replication.

Class	Drug		Dosage
Nucleoside Reverse Transcriptase Inhibitors	Zidovudine (AZT)	Retrovir® *†	200mg q8h or 300mg q12h
	Didanosine (ddI)	Videx®	>60kg: 200mg (tablets) or 250mg (powder) q12h, 400mg q24h (tablets or EC capsules)
			<60kg: 125mg (tablets) or 167mg (powder) q12h; 250mg q24h (tablets or EC capsules)
	Zalcitabine (ddC)	Hivid®	0.75mg q8h
	Lamivudine (3TC)	Epivir® *†	>50kg: 150mg q12h
			<50kg: 2mg/kg q12h
	Stavudine (d4T)	Zerit®	>60kg: 40mg q12h
			<60kg: 30mg q12h
	Abacavir (ABC)	Ziagen® †	300mg q12h
	Emtricitabine	Emtriva® #	Caps: 200mg QD, oral solution: 240 mg (ml) QD
	Abacavir/Lamivudine	Epzicom ®	(ABC 600mg + 3TC 300mg) QD
Nucleotide reverse transcriptase inhibitors	Tenofovir	Viread® #	300mg q24h
Non-nucleoside reverse transcriptase inhibitors	Delavirdine (DLV)	Rescriptor®	400mg q8h
	Nevirapine (NVP)	Viramune®	200mg q24h for 2–4 weeks, then 200mg q12h
	Efavirenz (EFV)	Sustiva®	600mg q24h
Protease inhibitors	Saquinavir (SAQ)	Invirase® (HGC) ‡	HGC: 400mg q12h, to be used only with ritonavir
		Fortovase® (SGC) §	SGC: 1200mg q8h
	Ritonavir (RTV)	Norvir®	300mg q12h, escalate to 600mg q12h in 2 weeks
	Indinavir (IDV)	Crixivan®	800mg q8h
	Nelfinavir (NFV)	Viracept®	750mg q8h or 1250mg q12h
	Amprenavir (APV)	Agenerase®	>50kg: 1200mg q12h
			<50kg: 20mg/kg q12h (max. 2400mg daily total)
	Lopinavir (LPV)	Kaletra® ¶	400mg lopinavir + 100mg ritonavir q12h
	Atazanavir	Reyataz®	300mg-400mg QD
	Fosamprenavir	Lexiva®	700mg BID, or 1400mg QD
	Tipranavir	Aptivus®	500mg BID
Fusion Inhibitor	Enfuvirtide	Fuzeon® Kit	90mg SQ BID

Adapted from **TABLE 139-1** -- Antiretroviral drugs available for highly active antiretroviral therapy combination regimens.[4]
* Also available (300mg AZT+ 150mg 3TC) as Combivir®.
† Also available (300mg AZT+ 150mg 3TC+ 300mg ABV) as Trizivir®.
‡ Hard-gel capsule.
§ Soft-gel capsule.
¶ Only available as Kaletra® (133.3mg lopinavir + 33.3mg ritonavir).
# Also available (Emtricitabine 200mg + Tenofovir 300mg) as Truvada®

Utilization of Antiretrovirals

The following chart shows the trends in utilization of the Antiretroviral class of medications between calendar years 2004 and 2005.

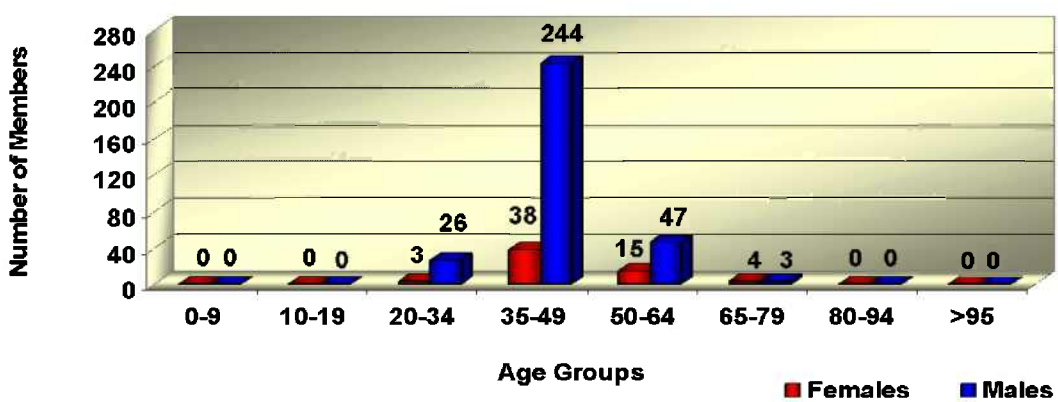
Trends in Utilization

	Calendar Year 2004	Calendar Year 2005	Percent Change	
Total Cost	$ 5,967,233.68	$ 7,376,040.56	Increased	23.6 %
Total Claims	12,320	13,747	Increased	11.6 %
Total Members	679	734	Increased	8.10 %
Cost/Claim	$ 484.35	$ 536.56	Increased	10.8 %
Cost/Member	$ 8,788.27	$ 10,049.10	Increased	14.3 %

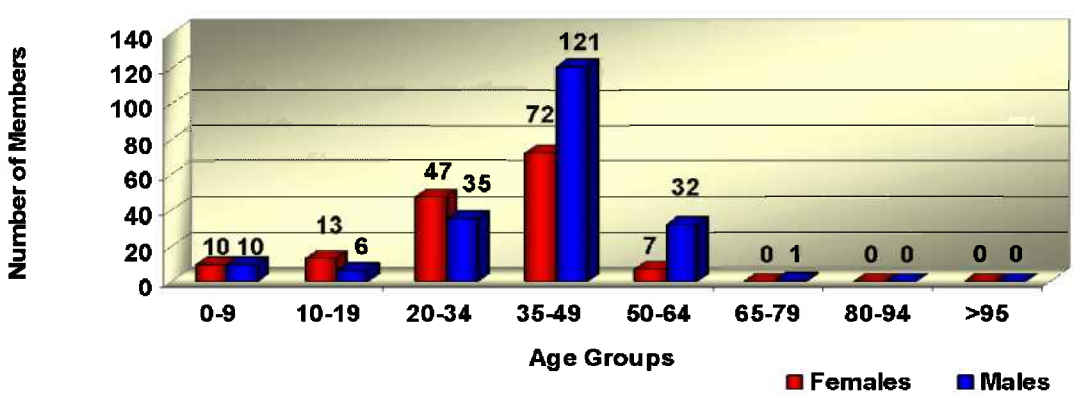
Dual vs. Non-Dual Member Utilization in 2005

	Claims	Units	Days	Members	Cost
Duals	8,219	628,374	250,646	380	$ 4,446,699.91
Non-Duals	5,528	494,535	169,082	354	$ 2,929,340.65
All Members	13,747	1,122,909	419,728	734	$ 7,376,040.56

Dual Eligible Members Utilizing Antiretrovirals in 2005



Non-Dual Eligible Members Utilizing Antiretrovirals in 2005



Non-Dual Utilization of Antiretrovirals in Calendar Year 2005

DRUGNAME	CLAIMS	UNITS	DAYS	MEMBERS	COST
FUZEON KIT	10	10	298	3	$18,069.18
AGENERASE CAP 150MG	7	1,860	186	1	$2,646.21
REYATAZ CAP 100MG	1	90	30	1	$1,180.79
REYATAZ CAP 150MG	115	6,900	3,450	27	$90,382.11
REYATAZ CAP 200MG	96	5,770	2,885	16	$75,474.22
LEXIVA TAB 700MG	101	6,494	3,067	18	$62,811.25
CRIXIVAN CAP 200MG	26	4,530	755	3	$6,406.27
CRIXIVAN CAP 400MG	103	16,960	3,227	21	$47,604.47
VIRACEPT TAB 250MG	94	22,860	2,841	12	$50,374.38
VIRACEPT TAB 625MG	124	14,880	3,720	28	$80,813.39
NORVIR CAP 100MG SG	265	15,404	8,102	76	$145,164.81
NORVIR SOL 80MG/ML	19	4,890	570	4	$32,355.33
FORTOVASE CAP 200MG	44	15,000	1,284	9	$19,440.87
INVIRASE CAP 200MG	2	360	37	1	$795.02
APTIVUS CAP 250MG	7	780	210	3	$6,413.15
ZIAGEN TAB 300MG	170	10,180	5,180	30	$69,431.08
ZIAGEN SOL 20MG/ML	2	1,800	60	1	$777.22
VIDEX BUFFER CHW 50MG	2	300	60	1	$345.82
VIDEX BUFFER CHW 100MG	45	2,985	1,346	4	$6,863.06
VIDEX BUFFER CHW 200MG	23	990	690	3	$4,507.18
VIDEX EC CAP 125MG	20	750	600	3	$2,459.19
VIDEX EC CAP 200MG	28	840	840	5	$4,099.82
VIDEX EC CAP 250MG	155	4,870	4,870	45	$29,734.04
VIDEX EC CAP 400MG	86	2,820	2,820	24	$26,112.80
EMTRIVA CAP 200MG	112	3,568	3,583	23	$35,316.49
EPIVIR HBV TAB 100MG	34	1,065	1,020	10	$6,799.15
EPIVIR TAB 150MG	250	14,302	7,795	40	$73,166.71
EPIVIR TAB 300MG	33	990	990	7	$10,110.00
EPIVIR SOL 10MG/ML	41	17,190	1,185	6	$5,948.91
HIVID TAB 0.75MG	3	180	90	1	$462.99
ZERIT CAP 20MG	21	1,240	610	3	$6,536.71
ZERIT CAP 30MG	37	2,220	1,110	7	$12,386.89
ZERIT CAP 40MG	149	9,010	4,565	26	$50,684.11
ZERIT SOL 1MG/ML	38	34,200	1,051	3	$10,900.12
RETROVIR CAP 100MG	20	2,352	509	7	$4,704.07
ZIDOVUDINE TAB 300MG	68	3,944	2,107	17	$23,252.31
ZIDOVUDINE SYR 50MG/5ML	46	28,540	1,044	15	$5,818.13
VIREAD TAB 300MG	465	14,668	14,772	85	$219,578.10
RESCRIPTOR TAB 200MG	2	360	60	1	$561.08
SUSTIVA CAP 100MG	12	1,080	360	1	$2,674.40
SUSTIVA CAP 200MG	31	2,800	933	6	$13,669.64
SUSTIVA TAB 600MG	578	18,519	18,459	99	$271,141 19
VIRAMUNE TAB 200MG	194	11,979	5,946	26	$78,124.96
VIRAMUNE SUS 50MG/5ML	23	14,360	683	3	$5,140.07
EPZICOM TAB	50	1,500	1,500	13	$35,788.07
TRUVADA TAB	376	11,627	11,650	83	$290,868.65
COMBIVIR TAB	671	40,733	20,494	122	$447,659.68
KALETRA CAP	515	91,900	15,089	95	$331,260.52
KALETRA TAB 200-50MG	24	2,835	672	19	$16,615.87
KALETRA SOL	40	12,000	1,152	11	$24,164.62
TRIZIVIR TAB	150	9,050	4,525	21	$161,745.55
TOTALS	**5,528**	**494,535**	**169,082**	**354***	**$ 2,929,340.65**

*Unduplicated Non-Dual Eligible Members

Future of HIV Therapy

Over the past two decades there have been considerable strides made in the recognition of HIV/AIDS through awareness campaigns and educational initiatives. The medical community has also responded with a burst of research and development, and in the process, has discovered novel therapies to slow the progression of this disease. In 1995 there were only 6 agents in the HIV armamentarium. This number has quadrupled in the past 10 years.

Research is ongoing and new treatments are highly anticipated within this community as evident by the recent FDA approval of Prezista®. The drug, also known as darunavir, is a member of the protease inhibitor class of drugs. The major side effects of this class of drugs are high cholesterol and blood-sugar levels, as well as lipidystrophy.

Prezista® is meant for use in patients who hasn't responded to treatment with other antiretroviral drugs. The FDA approved Prezista® to be taken with a low-dose of ritonavir (Norvir®), a protease inhibitor, in combination with other HIV drugs. Ritonavir slows the metabolism of Prezista®, resulting in an increased effect of Prezista®.

Currently, there are over one hundred new HIV medications in development[5]. Roughly 38% of these agents are from the main classes of HIV inhibitors already in use. About 27% are entry inhibitors, like Fuzeon®, though many of them target different binding, fusion or entry mechanisms than the one currently available. The remaining 35% represent new classes of medications that are not currently available commercially. These classes include integrase inhibitors, maturation inhibitors and other types of HIV antagonists. Obviously, not all of the medications in development will become FDA approved, but they are some of the most promising research to date.

Conclusion and Recommendations

Due to the severity and complexity of this disease, treatment is often initiated and monitored by health care providers who are specialized in the treatment of HIV/AIDS. As is the nature of the disease, utilization of healthcare resources dramatically increases as the disease progresses due to concomitant infections and other illnesses the patient may succumb to. The cost of treatment also increases during disease progression as multiple agents have to be combined and newer treatments must be used when the virus is no longer susceptible to initial agents.

The College of Pharmacy recommends no actions at this time for the class of Antiretrovirals. Members are treated and monitored by trained healthcare providers at special HIV or infectious diseases clinics which minimize the overall risk for inappropriate use and/or abuse of medications. It appears from the utilization that the increases in utilization and costs may be in part due to the nature of the disease and the treatment of this disease.

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[1] Centers for Disease Control and Prevention. A Glance at HIV/AIDS Epidemic. April 2006. Available online at http://www.cdc.gov/HIV/resources/factsheets/At-A-Glance.htm.
[2] Ibid.
[3] Oklahoma State Department of Health. HIV/STD Statistics. Available online: http://www.health.state.ok.us/program/hivstd/epi/1205_1.pdf
[4] **Cohen & Powderly: Infectious Diseases, 2nd ed.**, Copyright © 2004
[5] Pujol, G. HAART Turns 10. Article available online: http://www.thebody.com/asp/janfeb06/haart10.html

APPENDIX D

Oklahoma Medicaid Pharmacy Overview and DUR Plus

February 2006

Medicaid Pharmacy Program Background

Medicaid was enacted in 1965 as a program designed to provide health care to low income individuals who receive cash assistance payments from the government. Since that time, it has been expanded to include individuals with disabilities and those in long term care facilities.

Forty years ago, prescription drugs were not included in the list of mandatory services that states must provide in order to receive federal financial participation for the Medicaid program. Today, in spite of the prevalence of pharmaceutical care and the apparent benefits which can be derived from them, drug coverage is still optional under state Medicaid plans. However, all states currently provide a pharmacy benefit for their Medicaid recipients because of the evidence supporting the use of prescription drugs for treatment and prevention of illness, disease, and complications.

Until 1991, states had little incentive to provide prescription drugs to their Medicaid recipients. Many states, including Oklahoma, provided a very limited pharmacy benefit for clients, covering such things as heart and blood pressure medications, cancer chemotherapy, pain relievers, and antibiotics. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) changed all that by setting requirements for Medicaid pharmacy programs and tying those requirements to a drug rebate program with pharmaceutical manufacturers.

The Medicaid Drug Rebate Program guarantees that the Medicaid program is given the "best price" for all pharmaceutical products. In exchange for this best price, Medicaid programs are required to cover most drugs of participating manufacturers. Drugs in the following therapeutic category are exempt from this requirement:

1) Drugs for weight loss or weight gain
2) Fertility
3) Cosmetic or hair growth
4) Symptomatic relief of cough and colds
5) Smoking cessation
6) Prescription vitamins and minerals, other than prenatal preparations and fluoride
7) Barbiturates
8) Benzodiazepines

All states currently cover at least some of these drugs. Oklahoma Medicaid covers both prescription and non-prescription products used to assist clients with

tobacco cessation and covers barbiturates and benzodiazepines for treatment of seizures and behavioral health conditions.

Since OBRA 90 took effect 15 years ago, Medicaid pharmacy programs have been through a series of changes. Although states are free to design their own benefit structures, many of the programs implement similar measures to ensure that medications are used appropriately.

Prior authorization programs are used in Medicaid programs as well as in commercial health plans. These programs have frequently been chastised as looking only at the cost of a particular medication or category and not at the benefit provided by the drug therapy. The task of the Oklahoma DUR Board is to balance the need for the medication with the potential for inappropriate use.

In 2000, OHCA implemented one of the first Medicaid preferred drug programs in the nation. Although we call it the Product Based Prior Authorization (PBPA), it is a forerunner to the current Preferred Drug List (PDL) programs which are prevalent in pharmacy benefit design. The categories included in the PBPA are listed below:

Anti-Ulcer
NSAIDs
ACE Inhibitors
ARBs
Calcium Channel Blockers
ADHD/Narcolepsy Treatment
Antidepressants
Statins
Fenofibrate
Bladder Control
Nasal steroids/anti-allergy sprays
Skeletal Muscle Relaxants

For each of these categories, the DUR Board has designated first and second tier drugs. First tier drugs are available without prior authorization. Second tier drugs require the use of a first tier drug in a step therapy protocol or a prior authorization. Each category has unique clinical criteria for the approved use of a Tier 2 product.

As an extension of the PBPA, in 2004, OHCA began offering manufacturers an opportunity to participate in Supplemental Rebates as a way to make their Tier 2 products more cost-effective and remove the prior authorization requirement. Currently we have manufacturers participating in most of the categories listed above.

Before the PBPA program was implemented, OHCA used prior authorizations based on scope and/or utilization. Currently we have several single drug products in this type of program, as well as several drug categories, such as the non-sedating antihistamines, benzodiazepines, and smoking cessation products.

All drugs which are subject to prior authorization must be reviewed at least annually according to state law. These reviews are spread out over the year, but typically there is a concentration of these reviews in the first few months of the calendar year.

Other utilization programs include quantity limits, age or sex restriction, days supply limits and Prospective Drug Utilization Review edits. These edits will alert the pharmacy to situations of potential danger to the patient including drug-drug interaction, drug-disease interaction, early refill, and high dose warnings.

The monthly prescription limit for adults in Oklahoma Medicaid is capped at six, and of those, up to three may be brand name drugs. Children under age 21 are not subject to a monthly prescription limit. Adults in long term care settings are also not limited. Clients who are eligible for one of the Home and Community Based Waiver programs have the six regular prescriptions, plus seven extra generics. For HCBW clients who require more than three branded drugs or more than thirteen total drugs per month, there is a program called Pharmacotherapy Management which reviews their medications and checks for duplicate therapy, contraindicated therapy, or ways to consolidate treatment. If the review determines that there is medical necessity for the additional drug products, prior authorizations can be granted.

With the implementation in January 2006 of the Medicare Part D pharmacy benefit, approximately 80,000 Medicaid clients no longer receive their prescriptions through the Medicaid program. Although they represent only about 15% of the Medicaid population, their pharmacy spending represented 45-50% of total drug spend. The clients who are eligible for the new Medicare Part D benefit include most of the elderly who reside in long term care facilities and many of the disabled adults who participate in the HCBW programs.

DUR PLUS

Medicare Part D provides OHCA with an opportunity to streamline some of the prior authorization processes by automating the approval process. Several states have been using system applications which are integrated into their claims processing. Because OHCA has not only pharmacy claims, but also medical and hospital claims in our system, the application can be configured to search for diagnosis codes, procedure codes, levels of care, and previous medication usage to determine whether a prior authorization should be approved.

EDS, the OHCA claims processing contractor, has developed an application called DUR Plus which incorporates these prior authorization determinations into the claims processor. This eliminates the need for paper authorization forms to be faxed to and from pharmacies and physicians offices. For some prior authorizations, the documentation requirement will dictate that the authorization request be handled as it is currently, but a large number of the requests can be handled electronically.

In addition to the PA processing, DUR Plus will integrate ProDUR edits, quantity limits, age and gender restrictions, total daily dose calculations, and other features that are not currently available in the OHCA claims processing system. DUR Plus is tentatively scheduled to be implemented in early 2007.

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APPENDIX E

Vote to Prior Authorize Chantix™ (varenicline)

Oklahoma Health Care Authority
July 2006

Manufacturer Pfizer Inc.
Classification *FDA classification*: Smoking Cessation
Status: prescription only

Summary

Chantix™ is the first medication to be approved in over a decade for the purpose of smoking cessation that does not contain any nicotine. It is available in two strengths (0.5mg and 1mg) with a maximum dose of 1mg twice a day. It is a partial agonist that is selective for $\alpha_4\beta_2$ nicotinic acetylcholine receptor subtypes. It binds to $\alpha_4\beta_2$ neuronal nicotinic acetylcholine receptors and stimulates receptor-mediated activity but at a level lower than nicotine. Varenicline blocks nicotine's ability to activate the receptors which won't allow the central nervous mesolimbic dopamine system to be stimulated.

Recommendations:

As with all other smoking cessation products, allow 12 weeks of therapy with out a prior authorization, followed by an additional 12 weeks with a prior authorization. Place a quantity limit of no more than 2 tablets per day of either strength.

Cost comparison

	Average Wholesaler Price (AWP)	Daily Dose*	Monthly Dose (30 day supply)	Length of therapy
Chantix™	$112.00/56	2mg	$120.00	3-6 months
Bupropion SR 150mg	$149.19/100	300mg	$89.51	3 months
Commit® 4mg	$32.81/72	variable	$179.39	3 months
Nicotine patches	$3.49/1	1/day	$97.72	2.5 months
Nicotrol® Inh	$146.94/168	6-16	$236.74	6 months

REFERENCES

1. Chantix™ Package Insert (www.Pfizer.com)

APPENDIX F

Review of Anti-migraine Utilization

January 2005 to December 2005

Oklahoma Health Care Authority
July 2006

Current Anti-migraine Quantity Limits

Drug	Quantity Limit
Migranal® nasal spray amps 1ml	8 amps per 30 days
Axert® tabs 6.25mg, 12.5mg	12 tabs per 30 days
Relpax® tabs 20mg, 40mg	8 tabs per 30 days
Frova® tabs 2.5mg	12 tabs per 30 days
Amerge® tabs 1mg, 2.5mg	9 tabs per 30 days
Maxalt® or Maxalt-MLT® tabs 5mg, 10mg	12 tabs per 30 days
Imitrex® tabs 25mg, 50mg, 100mg	18 tabs per 30 days
Imitrex® autoinjector 6mg/0.5ml	4 kits per 30 days
Imitrex® vials 6mg/0.5ml	8 vials per 30 days
Imitrex® nasal spray 5mg, 20mg	12 nasal units per 30 days
Zomig® or Zomig ZMT® tabs	2.5mg – 12 tabs per 30 days 5mg – 6 tabs per 30 days
Zomig® nasal spray	6 units per 30 days

Utilization – January 2005 to December 2005

For the period of January 2005 to December 2005, a total of 4,082 members received anti-migraine medications.

Product	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Ergotamine SL Tab 2mg	2	40	8	$70.90	8.86
Dihydroergot Inj 1mg/ml	37	248	382	$8,365.47	21.90
Migranal® Nasal Amp	77	380	1,213	$12,572.03	10.36
Axert® Tab 6.25mg	49	377	429	$6,580.68	15.34
Axert® Tab 12.5mg	392	3,310	3,683	$58,376.29	15.85
Relpax® Tab 20mg	416	3,700	5,093	$59,493.46	11.68
Relpax® Tab 40mg	1,405	11,603	16,616	$185,260.10	11.15
Frova® Tab 2.5mg	240	2,098	3,099	$34,946.71	11.28
Amerge® Tab 1mg	2	15	30	$296.57	9.89
Amerge® Tab 2.5mg	163	1,432	1,990	$27,846.38	13.99
Maxalt® Tab 5mg	140	1,342	1,318	$23,489.36	17.82
Maxalt® Tab 10mg	647	5,940	8,365	$103,352.74	12.36
Maxalt-MLT® Tab 5mg	182	1,420	1,921	$24,868.08	12.95
Maxalt-MLT® Tab 10mg	940	8,030	10,571	$136,014.37	12.87

Imitrex® Spr 5mg/act	134	816	2,069	$20,833.24	10.07
Imitrex® Spr 20mg/act	217	1,506	3,781	$37,704.662	9.97
Imitrex® Tab 25mg	1,038	11,755	14,063	$221,435.79	15.75
Imitrex® Tab 50mg	1,462	16,327	21,122	$285,365.74	13.51
Imitrex® Tab 100mg	1,862	19,935	23,316	$348,608.77	14.95
Imitrex® Inj 6mg/0.5ml	28	117	459	$12,925.71	28.16
Imitrex® Kit Ref	335	888	4,008	$105,405.68	26.30
Zomig® Tab 2.5mg	350	2,961	5,645	$47,568.63	8.43
Zomig® Tab 5mg	417	2,775	4,545	$50,207.83	11.05
Zomig® Spr 5mg	131	786	1,404	$18,995.38	13.53
Zomig ZMT® 2.5mg	124	1,051	1,617	$16,874.89	10.44
Zomig ZMT® 5mg	113	663	1,428	$12,188.33	8.54
Isometh/APAP/Dichlor	17	527	126	$267.44	2.12
Ergotam/Caff Tab 1/100	147	4,516	2,656	$5,156.02	1.94
Ergotam/Caf Supp 2/100	11	125	247	$258.48	1.05
Ergot/Bellad/Pheno Tab	434	27,082	13,975	$6,231.61	0.45
All Products	**11,512**	**131,764**	**155,179**	**$ 1,871,561.30**	**12.06**

	Calendar Year 2004	*Calendar Year 2005*	*Percent Change*
Total Cost	**$ 1,671,668.44**	**$ 1,871,561.30**	**+ 12.0%**
Total Claims	**9,309**	**11,512**	**+ 23.7%**
Total Members	**3,451**	**4,082**	**+ 18.3%**
Per Diem	**$ 16.02**	**$12.06**	**- 24.7%**

Calendar Year 2005

	# of Members	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	784	2,972	43,911	45,286	$ 483,099.71	10.67
Non-Duals	3,298	8,540	87,853	109,893	$ 1,388,461.59	12.63

Claims were reviewed to determine the age of the members.

All Members			
Age	Female	Male	Total
0 to 9	45	70	115
10 to 19	739	391	1,130
20 to 34	1,175	84	1,259
35 to 49	895	109	1,004
50 to 64	397	41	438
65 to 79	94	12	106
80 to 94	27	2	29
95 and over	0	1	1
Totals	**3,372**	**710**	**4,082**

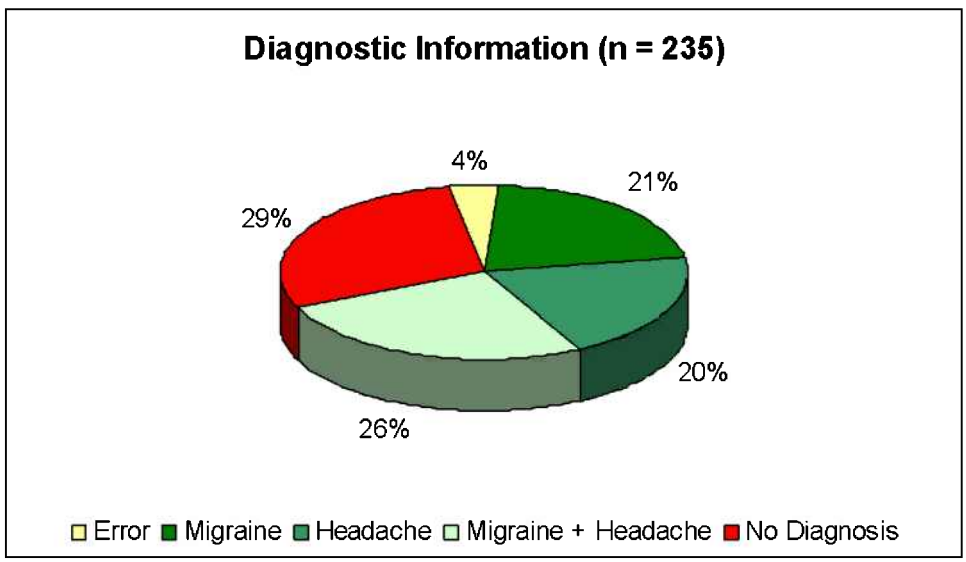
Non-Dual Members			
Age	Female	Male	Total
0 to 9	45	70	115
10 to 19	737	390	1,127
20 to 34	1,062	54	1,116
35 to 49	659	46	705
50 to 64	199	31	230
65 to 79	4	0	4
80 to 94	1	0	1
95 and over	0	0	0
Totals	**2,707**	**591**	**3,298**

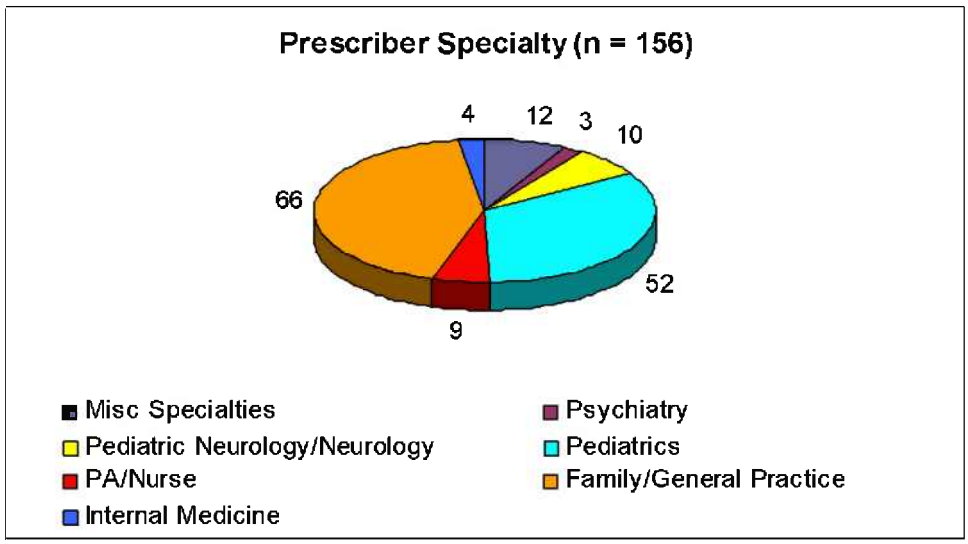
Triptans and the Pediatric and Adolescent Population

None of the triptans currently available on the market are indicated for use in children. There have been studies looking at various compounds in the child and adolescent population (6-17 years of age) with mixed results. In December 2004, the American Academy of Neurology[1] published a paper outlining the treatment of migraine headaches in children and adolescents. The paper made the following treatment recommendations:

1. Ibuprofen is effective and should be considered for the acute treatment of migraine in children.
2. Acetaminophen is probably effective and should be considered for the acute treatment of migraine in children.
3. Sumatriptan nasal spray is effective and should be considered for the acute treatment of migraine in adolescents.
4. There are not data to support or refute the use of any oral triptan preparations in children or adolescents.
5. There are inadequate data to make a judgment on the efficacy of subcutaneous sumatriptan.

Triptan Utilization in Children 11 years of age or less





While the off-label use of this class of medication in this population appears to be of concern, there are several factors to consider. When looking at the entire non-dual population with triptan claims, only 7.4% of the members are age 11 and under. Sixty-seven percent (67%) of these members had a diagnosis of headache, migraine, or both headache and migraine in medical claims history during the review period. Forty percent (40%) of the prescribers were pediatricians or neurology specialists.

Of the fourteen children 5 years of age or less receiving triptans, nine had a diagnosis of migraine. Six of the fourteen were seen by a neurologist or pediatric neurologist. Five of the fourteen were seen by a pediatrician.

Six member IDs have been turned over to OHCA to investigate possible fraud.

This is a group of members that might benefit from possible prior authorization once the new DUR+ system is in place. The system could be programmed to check for age, diagnosis, and/or specialty prescribers and automatically generate a PA for those meeting the approved criteria. Manual PA review would be needed for those not meeting the selected criteria. A three day emergency PA would be available, if needed.

Recommendations

The College of Pharmacy has several recommendations for this category.

1. Add quantity limits for the following:

Ergotamine 2mg sublingual tab	25 tabs/30 days
Ergotamine/Caffeine 1-100mg tab	50 tabs/30 days
Ergotamine/Caffeine Supp 2-100mg	25 supp/30 days
Ergotamine/Belladonna/Phenobarb tab	60 tabs/30 days

2. A possible PA for child members when the DUR+ system is in place. The system could check the member's records for age, diagnosis, and/or prescriber specialty.
3. Monitor this category over the next year to gauge the effect of the change in member population upon utilization patterns.

References

1. Lewis D, Ashwal S, Hershey A, et al. Practice Parameter: Pharmacological treatment of migraine headache in children and adolescents. Neurology 2004;63:2215-2224.

APPENDIX G

30 Day Notice to Prior Authorize Antiemetics

Oklahoma Health Care Authority
July 2006

Introduction

The high cost of select groups of antiemetics has led to the development of consensus guidelines which have been implemented in many hospitals and clinics to assist in appropriate cost-effective management of nausea and vomiting according to patient risk factors and evidence based medicine.

Prevention is always the preferred treatment over therapy of established nausea and vomiting. Various non-pharmacologic and pharmacologic treatment modalities exist to alleviate symptoms of nausea and vomiting and improve quality of life.

Several guidelines have been developed for management of CINV*, RINV*, PONV*, and management of nausea and vomiting in pregnancy. The inadequate or excessive use of antiemetics may lead to refractory episodes and unnecessary medical expenses due to wasted drug or rescue therapy.

Overall efficacy has been shown to be equal across the class, but drug selection requires individual patient history which includes, but is not limited to: other illness/disease risk factors, individual diet restrictions, side-effect profile, drug-drug interaction profiles and medication costs.

*Chemotherapy induced nausea and vomiting (CINV), Radiation induced nausea and vomiting (RINV), Post-operative nausea and vomiting (PONV)

Cost and Utilization Update

In a 2004 drug utilization review, 5-HT3 receptor antagonists accounted for only 30% of claims, yet incurred 88% of the medication costs. Ninety-three percent of 5-HT3 claims were for the product, Zofran®. The review revealed possible inappropriate utilization of these antiemetics. Quantity limits were implemented in June 2004 on select antiemetic medications. In fiscal year 2005, the 5HT3 receptor antagonists accounted for only 25% of claims but incurred 75% of the costs.

Recommendations

The College of Pharmacy recommends consideration of prior authorization for 5HT3 antagonists, substance P antagonists, and cannabinoids to ensure appropriate utilization. Quantity limits already established will remain in effect.

Purpose: Ensure appropriate utilization of antiemetic medication.

Why: Antiemetic prescription claims accounted for 19,932 prescription drug claims, totaling $2,255,605.12, for the period of July 01, 2004 thru June 30, 2005. The 5HT3 receptor antagonists accounted for only 25% of claims but incurred 75% of the cost. Analysis of relevant ICD-9 diagnosis indicates about 34% of members using 5HT3 antagonists had a diagnosis of pregnancy and 24% for non-specific nausea and vomiting. Due to the shift to Part D for dual eligible members, the relative frequency of use of these medications in the remaining population for non-oncology related diagnoses is expected to increase. Aprepitant is approved in combination with other antiemetic medications. Dronabinol should only be used as a third-line antiemetic agent.

Criteria for Approval:

1. *FDA approved diagnosis.*
2. *Clinical supporting information on failure or contraindication with conventional antiemetic drug therapies at maximum FDA approved daily dose with dates and dosages.*

Clinical Exceptions:

1. *Approval granted through the Point-of-Sale system for members undergoing chemotherapy, radiation therapy or surgery for cancer related diagnosis or prescriptions written by an oncologist or radiology oncologist.*
2. *Documented adverse effect, drug interaction, or contraindication to tier-1 products.*
3. *Approval granted for hyperemesis gravidarum with supporting documentation listing*
    a. *week of gestation,*
    b. *presence of weight loss (loss of ≥ 5% pre-pregnancy body weight)*
    c. *recent hospitalizations or emergency room visits due to hyperemesis, or*
    d. *history of hyperemesis gravidarum with previous pregnancies.*
4. *Approval granted if there is a unique FDA-approved indication not covered by any other products.*

No PA	PA Required
Corticosteroids	**5HT3 Antagonist**
Dexamethasone, methylprednisolone, cortisone, prednisone, prednisolone	Dolasetron Ondansetron
Antidopaminergic	
Thiethylperazine	Granisetron
Antihistaminic	
Meclizine, hydroxyzine	Palonosetron
Cyclizine	**Appetite stimulant/Antiemetic**
Promethazine	Dronabinol
Anticholinergic	
Scopolamine, trimethobenzamide,	
Prokinetic	**Substance P/Neurokinin Antagonist**
Metoclopramide	Aprepitant (In combination with corticosteroid or 5HT3 antagonist)
Antipsychotic	**Cannabinoids**
Droperidol	Nabilone
Chlorpromazine	
Prochlorperazine	
Perphenazine, prochlorperazine, fluphenazine, mesoridazine, thioridazine, trifluoperazine	

APPENDIX H

30 Day Notice to Prior Authorize Pediculicides

Oklahoma Health Care Authority
July 2006

Introduction

Pediculosis (or lice) is an infestation of the hairy parts of the human body or clothing with eggs, larvae, or adult lice. There are two species of lice that infest humans: *Pediculus humanus* and *Phthirius pubis*. *Pediculus humanus* is further divided into subspecies, *P humanus capitis* (head louse) and *P humanus corporis* (body louse).[1]The head and body louse have similar morphology but have different ecological niches and clinical manifestations. Pediculosis capitis (head louse) is the most common type of pediculosis in the world, infecting about 6-12 million people annually in the United States alone.[1] Scabies is an intensely pruritic and highly contagious infestation of the skin cause by *Sarcoptes scabiei*.[1] There are various treatments available to treat these conditions, including OTC products. The Oklahoma Health Care Authority would like to establish a list of OTC products for first-line treatment of these conditions.

Recommendations:

The College of Pharmacy recommends prior authorization of prescription-only pediculicides and payment for OTC pediculicides as first line treatment. The criteria for prescription only pediculicides would be as follows:

1. Coverage of OTC Permethrin and Pyrethrin products (for body or hair - including kits) will require a prescription (written or called in).

2. Lindane lotion and shampoo available only after first-line treatment with OTC permethrin or pyrethrin products has failed. At point-of-sale the pharmacy clinical edit will search history for paid claims to identify the following criteria:
   - Member must be ≥13 years old
   - Must have trial of OTC Permethrin or Pyrethrin
   - Quantity limit of 60ml for 7 days. Claim will deny if there is a Lindane prescription in history during the previous 30 days

3. Ovide® lotion available only after treatment with OTC product and Lindane have failed. At point-of-sale the pharmacy clinical edit will search history for paid claims to identify the following criteria:
   - Member must be ≥ 6 years old
   - Quantity limit of 60ml for 7 days; may be repeated once if needed for current infestation after 7 days of date of service of the original fill.

4. Prior authorization required for Eurax
    - Must have a trial of Permethrin 1% or 5%

5. Clinical exception if known resistance to OTC Permethrin and Pyrethrin.

Reference:

1 Elston D. Pediculosis. American Academy of Dermatology.2004;10:1-12

APPENDIX I

Addition of OTC Cough and Cold Drugs to Children's Pharmacy Benefit Package

Oklahoma Health Care Authority
July 2006

Introduction

In order to provide a more comprehensive pharmacy benefit for children under 21 who are members of the SoonerCare program, a list of covered Over-the-Counter (OTC) cough and cold products is being proposed. This drug list would include decongestant, cough suppressant, antipyretic and expectorant OTC products whose manufacturers participate in the Federal Medicaid Drug Rebate program.

Covered OTC Products

1. Dextromethorphan
2. Guaifensin
3. Pseudoephedrine
4. Phenylephrine
5. Ibuprofen
6. Acetaminophen
7. Covered combination products would be limited to those containing only the listed ingredients. For example, a combination product with pseudoephedrine and chlorpheniramine would not be covered, but a combination of dextromethorphan and pseudoephedrine would be covered.
8. Only syrup, elixir, suspension and drop dosage forms would be covered.

Criteria

1. Prescription must be written or called-in for covered OTC product.
2. Quantity limit of the manufacturer's recommended maximum per product for a 15 day supply.
3. Prior authorization required if greater than 60 therapy days dispensed in a 90 day period.

Potential Economic Impact

For calendar year 2005 there were approximately 220,000 non-dual members under the age of 21 who received an antibiotic claim. Approximately 400,000 antibiotic claims were filled for these members. At a price range of $2.99 to $12.99 per packaged OTC formulary products, and a dispensing fee of $2.00, the projected pharmacy *reimbursement* for this formulary could range from $1.0 to $5.9 million. Based on the average reimbursement for products in the category, the cost would be approximately $2.7 million. However, if only 25% of prescriptions written for antibiotics could be avoided by giving the prescriber the option to instead prescribe only symptom relief, a minimum of $7 million in pharmacy reimbursement could be saved, netting a savings of $4.3 million.

Example Covered Products

Guaifenesin / Pseudophedrine 50-15 mg / 5 ml Syrup
Dextromethorphan 7.5 mg / 5 ml Syrup
Pseudophedrine 9.4 mg / ml Drops
Pseudophedrine 15 mg / 5 ml Syrup
Ibuprofen 100 mg / 5 ml Suspension
Ibuprofen 40 mg / ml Suspension Drops
Guaifenesin / Dextromethorphan / 100-5 mg / 2.5 ml Drops
Guaifensin / Dextromethorphan / Pseudophedrine 100-10-30 mg / 5 ml Syrup
Guaifenesin / Dextromethorphan / 100-10 mg / 5 ml Syrup
Guaifensin / Pseudophedrine 100-30 mg / 5 ml Syrup
Dextromethorphan / Pseudophedrine / Acetamenophen 7.5-15-160 Liquid
Ibuprofen / Pseudophedrine 100-15 mg / 5 ml Suspension
Dextromethorphan / Pseudophedrine 2.5-7.5 / 0.8 ml Drops
Dextromethorphan / Pseudophedrine 7.5-7.5 / 0.8 ml Drops

APPENDIX J

New Product Summaries

Oklahoma Medicaid
July 2006

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP/ unit
Oracea™ (doxycycline, USP) capsules	CollaGenex Pharmaceuticals, Inc.	Indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. NOT for treatment of infections.	Once daily in the morning on an empty stomach, preferably at least one hour prior to or two hours after meals. Efficacy beyond 16 weeks and safety beyond 9 months have not been established.	Nasopharyngitis, pharyngolaryngeal Pain, Sinusitis, Nasal Congestion, Fungal Infection, Influenza, Diarrhea, Abdominal Pain/Distention, Dry Mouth, Hypertension, Blood Glucose Increase, Anxiety, pain, Sinus Headache	Contraindicated in persons who have shown hypersensitivity to doxycycline or any of the other tetracyclines.	No	N/A
Solodyn™ (minocycline, USP) extended release tablets	AAIPharma, Inc. for Medicis Pharmaceutical Corporation	Indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. NOT been evaluated for treatment of infections.	Once daily tablet based on patient's weight to achieve approximately 1 mg/kg dosage without any loading dose: 99-131 lbs = 45 mg; 132-199 lbs = 90 mg; 200-300 lbs = 135 mg. Recommended duration is 12 weeks.	Headache, Fatigue, Dizziness, Pruritus, Malaise, Mood Alteration, Somnolence, Urticaria, Tinnitus, Arthalgia, Vertigo, Dry Mouth, Myalgia	Contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.	No	N/A

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP/ unit
Prevista™ (darunavir) tablets	Tibotec, Inc. (Tibotec Therapeutics, Division of Ortho bitotech Products, L.P.)	Indicated for the treatment of human immuno-deficiency virus (HIV) infection in antiretroviral treatment-experienced adult patients, such as those with HIV-A strains resistant to more than one protease inhibitor.	Adults: 600 mg twice daily taken with ritonavir 100 mg twice daily with food. Pediatric: safety and efficacy not established.	Most common adverse events: diarrhea, nausea, headache, and nasopharyngitis.	Contraindicated in patients with known hypersensitivity to any of the ingredients in this product, with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events.	Yes	N/A
Opana® and Opana® ER (Oxymorphone HCl) tablets and extended-release tablets	Endo Pharmaceuticals, Inc.	Indicated for the relief of moderate to severe pain. Opana® ER is NOT indicated for pain in the immediate post-operative period, or if the pain is mild, or not expected to persist for an extended period of time.	See prescribing information for details and conversion charts.	Constipation, Somnolence, Nausea, Dizziness, Headache, Pruritus	Contraindicated in patients with known hypersensitivity to oxymorphone or any of the other ingredients, or with known hypersensitivity to morphine analogs, patients with respiratory depression, acute or severe bronchial asthma or hypercarbia, paralytic ileus, or moderate to severe hepatic impairment.	No	N/A

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP/ unit
Advair® HFA (fluticasone propionate and salmeterol) inhalation aerosol	GlaxoSmithKline	Indicated for the long-term, twice daily maintenance treatment of asthma in patients 12 years of age and older. NOT for the relief of acute bronchospasm.	Administered by orally inhaled route only in patients 12 yrs of age and older. 2 inhalations twice daily every day. Available strengths (fluticasone/ salmeterol): 45 mcg/ 21 mcg, 115 mcg/ 21 mcg; 230 mcg/ 21 mcg.	Long-acting beta2-adrenergic agonists, such as salmeterol, may increase the risk of asthma-related death. Common side effects: URI, LRI, headaches, dizziness, nausea, vomiting, pain.	Contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Hypersensitivity to any of the ingredients of these preparations.	No	N/A

APPENDIX K

FDA News

FOR IMMEDIATE RELEASE
P06-92
June 30, 2006

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FDA Commemorates a Century of Protecting and Promoting Public Health

The U.S. Food and Drug Administration (FDA) today will celebrate the centennial of the Pure Food and Drugs Act of 1906 at an event dedicated to the agency's past, present and future service to the nation.

The ceremony, which will be held at the FDA's Harvey W. Wiley federal building, will feature U.S. Health and Human Services Secretary Michael O. Leavitt and Acting FDA Commissioner Andrew C. von Eschenbach, M.D. Also in attendance will be senior leaders of the agency, and scores of current and former FDA employees and special guests including former Commissioners of Food and Drugs, representatives of consumer and trade groups, and descendants of Dr. Harvey W. Wiley, the scientist whose early support of food and drug regulations earned him the title of "Father of the Pure Food and Drugs Act." Dr. Wiley served as the first director of the Bureau of Chemistry of the United States Department of Agriculture, which later became the FDA.

In addition to presentations by Secretary Leavitt and Acting Commissioner Dr. von Eschenbach, the program's highlights include an overview of the coming public health opportunities and challenges by FDA's Deputy Commissioners and other senior leaders of the agency. Sean K. Sullivan, Associate Publisher of Good Housekeeping magazine, will speak about Dr. Wiley's work following government service as Director of the Bureau of Foods, Sanitation and Health for Good Housekeeping magazine.

The modern FDA dates its origin to June 1906, when President Theodore Roosevelt signed the Food and Drugs Act and Congress embarked on a policy of continuous strengthening of public health protections and of their enforcement, first by the Bureau of Chemistry, and later by the FDA. Since then, Americans have benefited from increasingly comprehensive, science-based safeguards for a myriad products essential for health, survival and high quality of life.

Today, these products represent almost 25% of all U.S. consumer spending and include 80% of the national food supply as well as all human drugs, vaccines, blood products, medical devices, tissues for transplantation, radiation-emitting equipment, and animal drugs and feed.

The FDA's centennial celebration, which include conferences and special forums in cities from coast to coast, have the following aims:

Observe FDA's role -- past, present and future -- domestically and internationally in protecting and promoting the health of the public;
Inspire future efforts to advance science, innovation, and public health through partnerships and alliances with key FDA stakeholders;
Attract new generations of regulatory scientists; and
Salute the contributions of FDA employees, alumni, legislators, academicians, industry, consumer groups, and public health leaders to fulfilling FDA's mission.

Today's ceremony will be held at the Harvey W. Wiley Federal Building at 5100 Paint Branch Parkway at River Road in College Park, MD., from 1:00 p.m. to 3:00 p.m. For full details of the

event's program, see http://www.fda.gov/centennial/program/program.html

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FDA News

FOR IMMEDIATE RELEASE
P06-93
June 30, 2006

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FDA Approves First Generic Sertraline

As part of the Food and Drug Administration's (FDA) on-going efforts to increase the available generic drug alternatives for American consumers, the agency today approved the first generic version of Zoloft tablets (sertraline), as well as a liquid concentrate (sertraline hydrochloride) version of the product.

Sertraline tablets are indicated for the treatment of major depressive disorder (MDD) in adults and the liquid concentrate is approved for the treatment of MDD and some anxiety related disorders. In 2005, Zoloft was the sixth highest-selling brand-name drug in the United States, with retail sales totaling $2,561,069,000.

"Generic drugs are safe and effective alternatives to brand name prescription products and can provide for significant cost savings for the American public," said Gary J. Buehler, Director, Office of Generic Drugs. "Our office is committed to increasing the number of approved generic alternatives as quickly as possible."

The economic benefits of FDA's generic drug approval program are significant because generics can cost a fraction of the price of the brand name drugs and generic drugs represent about two-thirds of total prescription doses sold in the United States in 2004, according to IMS data on U.S. retail sales. Competition from generic drugs that are safe and effective alternatives may quickly lead to reductions in spending. The savings would likely increase as more competitors enter the market (See http://www.fda.gov/cder/ogd/generic_competition.htm).

FDA's Office of Generic Drugs (OGD) continues working expeditiously to review and take action on generic drug applications. For more information on other first generic versions, please see http://www.fda.gov/cder/ogd/approvals/1stgen0506.htm.

For additional information related to FDA's Office of Generic Drugs, please go to: http://www.fda.gov/cder/consumerinfo/generic_equivalence.htm.

The oral concentrate is manufactured by Roxane Laboratories, Inc and tablets are manufactured by IVAX Pharmaceuticals.

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FDA News

FOR IMMEDIATE RELEASE
P06-90
June 29, 2006

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FDA Completes Safety Assessment of Ketek New Safety Information to be Added to Product Labeling

The Food and Drug Administration (FDA) today completed its safety assessment of Ketek (telithromycin) and is advising health practitioners and patients to be aware of rare but potentially serious health risks. Ketek is the first FDA-approved antibiotic of the ketolide class. It is indicated for the treatment of acute exacerbation of chronic bronchitis; acute bacterial sinusitis; and community acquired pneumonia of mild to moderate severity, including pneumonia caused by resistant strep infections. The drug has been associated with rare cases of serious liver injury and liver failure with four reported deaths and one liver transplant after the administration of the drug. The manufacturer is revising the drug labeling to address this safety concern.

Although it is difficult to determine the exact frequency of Ketek-associated adverse events on the basis of FDA's mandatory and voluntary reporting systems, the agency has concluded that the drugs' benefit to patients for the approved indications outweighs its risk, including the rare risk of liver failure, and supports its continued availability.

"We are advising both patients taking Ketek and their doctors to be on the alert for signs and symptoms of liver problems," said Dr. Steven Galson, Director for FDA's Center for Drug Evaluation and Research. "Patients experiencing such signs or symptoms should discontinue Ketek and seek medical evaluation, which may include tests for liver function." The signs and symptoms of liver failure include fatigue, malaise, loss of appetite, nausea, yellow skin and dark-colored urine.

The warning, which Ketek's manufacturer is adding to the drug's labeling, results from FDA's vigilant monitoring of all drugs after their introduction to the market. When the agency approved the drug in 2004, based on data in the marketing application, the risk of liver injury with Ketek was similar to that of other marketed antibiotics. A safety evaluation conducted one year after approval was consistent with this. However, as the product entered into wider use, FDA's adverse event monitoring system received some reports of serious liver problems in patients taking Ketek, including some cases of acute liver failure leading to death or requiring liver transplantation.

Following receipt of these reports, FDA conducted a rigorous and thorough assessment of existing data, and continued to engage in U.S. and ex-U.S. monitoring of additional post market events. This work involved efforts by experts in the agency's Office of Surveillance and Epidemiology and the Office of New Drugs, as well as by recognized external liver disease experts. FDA tracked reports of adverse events associated with Ketek via MedWatch and also had the benefit of three case reports described in the February '06 issue of *Annals of Internal Medicine*. FDA has now completed its evaluation of this information and determined that additional warnings are required.

FDA will continue to evaluate Ketek-associated safety issues and take further actions if warranted. It is important to note that negative effects on liver function are a known and potential complication with some antibiotics, including Ketek, and as drug usage becomes more widespread, it is expected that rare adverse events may be detected or reported in greater numbers.

Ketek is manufactured by Sanofi Aventis.

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This press release was revised June 15, 2006, to clarify information in the table.

FDA News

FOR IMMEDIATE RELEASE
P06-80
June 14, 2006

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FDA and ISMP Launch Campaign to Reduce Medication Mistakes Caused by Unclear Medical Abbreviations

The U S. Food and Drug Administration (FDA) and the Institute for Safe Medication Practices (ISMP) today launched a nationwide health professional education campaign aimed at reducing the number of common but preventable sources of medication mix-ups and mistakes caused by the use of unclear medical abbreviations.

"Some abbreviations, symbols and dose designations are frequently misinterpreted and lead to mistakes that result in patient harm," said FDA Acting Commissioner Andrew C. von Eschenbach, M.D. "This joint campaign will promote safe practices among those who communicate medical information to help avoid serious and even potentially fatal consequences of medication errors."

According to the Institute of Medicine (IOM) of the National Academies, there are more than 7,000 deaths a year due to medication errors. Mistakes can occur anywhere in the medication-use system, from prescribing to administering a drug in a variety of settings (hospitals, outpatient clinics, nursing homes, home care, etc.)

FDA and ISMP's educational campaign focuses on eliminating the use of potentially confusing abbreviations by healthcare professionals, medical students, medical writers, the pharmaceutical industry and FDA staff. The campaign will address the use of mistake-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens and commercial medication labeling, packaging and advertising.

"We recommend that ISMP's list of abbreviations, symbols and dose designations http://www.ismp.org/PDF/ErrorProne.pdf most often associated with medication errors be considered whenever medical information is communicated," said Michael Cohen, ISMP President. "ISMP's list includes abbreviations that have been associated with medication errors reported to the USP-ISMP Medication Errors Reporting Program."

Examples of common error-prone notations that the campaign will seek to eliminate include:

Abbreviation	Reason
U	Mistaken for zero, number four, cc (write as "unit")
IU	Mistaken for IV, number ten (write as "international unit")
Trailing zero	Decimal point is missed (five milligrams should be presented as "5 mg" and not "5.0 mg") SHOULD use leading zeroes before decimal points (e.g., use "0.5 mg" instead of ".5 mg")
MSO4 and MgSO4	Can be confused for one another (write as "morphine sulfate" or "magnesium sulfate")

FDA and ISMP's campaign materials promote ISMP's list and include: 1) a brochure to be

distributed to medical professionals, the pharmaceutical industry and medical publishing professionals; 2) a print public service ad that will be sent to professional trade publications; 3) posters with reminders about commonly used error-prone abbreviations for healthcare facilities; 4) an online toolkit of materials, including PowerPoint slides for presentations at conferences and meetings; and 5) a patient safety video. All of these materials are available on the Web at www.fda.gov/cder/drug/MedErrors and www.ismp.org/tools/abbreviations.

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