Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

Wednesday

November 14, 2007

@ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Gorman, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – November 14, 2007**

DATE: November 8, 2007

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

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

Call to Order

Public Comment Forum

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

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

Action Item – Cough and Cold Coverage Update – **See Appendix C.**

Action Item – Vote to Prior Authorize Xyzal® and Vote to Update Oral Allergy PBPA Category – **See Appendix D.**

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

Action Item – Vote on Changes to Ingredient Duplication ProDUR Module **– See Appendix F.**

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

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

30 Day Notice to PA Soma® 250mg **– See Appendix I.**

Action Item – Annual Review of Muscle Relaxants – **See Appendix J.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – November 14, 2007 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. McNeill, Chairman:

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

A. October 10, 2007 DUR Minutes – Vote
B. October 18, 2007 DUR Recommendations Memorandum

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

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

A. Retrospective Drug Utilization Review for July 2007
B. Retrospective Drug Utilization Review Response for April 2007
C. Medication Coverage Activity Audit for October 2007
D. Help Desk Activity Audit for October 2007

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

5. Action Item – Cough and Cold Coverage Update – See Appendix C.

A. Current Policy
B. Utilization Review
C. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Xyzal® and Vote to Update Oral Allergy PBPA Category– See Appendix D.

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

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

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

A. Product Summary
B. COP Recommendations

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

8. Action Item – Vote on Changes to Ingredient Duplication ProDUR Module – See Appendix F

A. Current Settings
B. COP Recommendations

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

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

A. Product Summary
B. COP Recommendations

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

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

A. Product Summary
B. COP Recommendations

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

11. 30 Day Notice to Prior Authorize Soma® 250mg – See Appendix I.

A. Product Summary
B. COP Recommendations

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

11. Action Item – Annual Review of Muscle Relaxants – See Appendix J.

A. Current Guidelines
B. Utilization Review
C. COP Recommendations

12. FDA and DEA Updates – See Appendix K.

13. Future Business

A. Narcotic Utilization Follow-Up
B. Erythropoiesis-Stimulating Agents Follow-Up
C. Osteoporosis Utilization Review
D. Elidel/Protopic Annual Review
E. Amitiza® Annual Review
F. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of OCTOBER 10, 2007

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

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph.; PA Coordinator	X	
Metha Chonlahan, D.Ph.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Kelly Flannigan, Pharm.D.; Operations Manager		X
Shellie Gorman, Pharm.D.; DUR Manager	X	
Ronald Graham, D.Ph.; Pharmacy Director	X	
Chris Le, Pharm.D.; Clinical Pharmacist/Coordinator	X	
Carol Moore, Pharm.D.; Clinical Pharmacist		X
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Principal Investigator	X	
Pharmacy Graduate Student: Sabyasachi Ghosh	X	
Visiting Pharmacy Students: Katy Jordan; Neal Cast	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Alex Easton, M.B.A.; Pharmacy Operations Manager		X
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer		X
Nico Gomez; Director of Gov't and Public Affairs		X
Lynn Mitchell, M.D., M.P.H,; Director of Medical Services		X
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.; Director of Legal Services		X
Lynn Rambo-Jones, J.D.; Deputy General Counsel III		X
Rodney Ramsey; Drug Reference Coordinator	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	

OTHERS PRESENT:

Mark DeClerk, Lilly	Perry Johnson, Graceway	Jim Dunlap, Lilly
Rachelle Wan, Amgen	Pat Trahan, Taro	Toby Thompson, Pfizer
Brian Mares, Pfizer	Scott Clemens, UCB Pharma	Donna Erwin, BMS
M. Patty Laster, Benentech	David L. Dude, BMS	Jim Fowler, Astra Zeneca
Rebecca King, Taro	Joseph Medina, Sepracor	

PRESENT FOR PUBLIC COMMENT:

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

1A: Roll Call

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

ACTION: NONE REQUIRED.

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

There were no speakers for Public Comment.

ACTION: NONE REQUIRED.

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

3A: September 12, 2007 DUR Minutes

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

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: June 2007

4B: Retrospective Drug Utilization Review Response: March 2007

4C: Medication Coverage Activity Audit: September 2007

4D: Help Desk Activity Audit: September 2007

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE LIDODERM®**

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **COUGH AND COLD UTILIZATION REVIEW**

Dr. Gourley moved to table to the November 2007 meeting; seconded by Dr. Bell.

ACTION: TABLED TO NOVEMBER 2007.

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF ANTIHYPERTENSIVES**

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF ULTRAM® ER AND ODT**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **30-DAY NOTICE TO PRIOR AUTHORIZE XYZAL®**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE NUVIGIL™**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **60-DAY NOTICE TO PRIOR AUTHORIZE TOPICAL ANTIFUNGALS**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **FDA & DEA UPDATES**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **FUTURE BUSINESS**

13A: Narcotic Utilization Follow-Up
13B: Erythropoiesis-Stimulating Agents Follow-Up
13C: Osteoporosis Utilization Review
13D: Carisoprodol Annual Review
13E: Amitiza® Annual Review
13F: New Product Reviews
13G: Annual Reviews

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 14: **ADJOURNMENT**

The meeting was declared adjourned.

The University of Oklahoma College of Pharmacy

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

Memorandum

Date: October 18, 2007

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

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

Subject: DUR Board Recommendations from Meeting of October 10, 2007.

Recommendation 1: Vote to Prior Authorize Lidoderm®

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Lidoderm® with the following criteria:

1. FDA approved diagnosis.
2. Provide documented treatment attempts at recommended dosing or contraindication to at least one agent from two of the following drug classes:
    a. Tricyclic antidepressants
    b. Anticonvulsants
    c. Topical or Oral Analgesics
3. Quantity limit of no more than 3 patches per day with a maximum of 90 patches in a month.

Recommendation 2: Vote on Changes to Cough and Cold Coverage

MOTION TABLED by unanimous approval.

The College of Pharmacy has the following recommendations for the Cough and Cold products:

1. Either discontinue OTC coverage for children less than 2 years of age ***or*** require a prior authorization.
2. Only allow a maximum of 5 claims per year for this category.

Recommendation 3: Annual Review of Antihypertensives

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Antihypertensive PBPA category.

To qualify for a **Tier-2** medication (or Tier-3 medication when no Tier-2 medications) exist there must be

- documented inadequate response to two Tier-1 medications in the class, or
- previous stabilization on the Tier-2 drug a unique indication for which the Tier-1 drugs lack

To qualify for a **Tier-3** medication there must be

- documented inadequate response to two Tier-1 medications and documented inadequate response to all available tier-2 medications, or
- previous stabilization on the Tier-3 drug
- a unique indication for which the lower tiered drugs lack

CCB MEDICATIONS		
Tier 1	**Tier 2**	**Tier 3**
amlodipine (Norvasc)	(Supplemental rebated Tier 3)	amlodipine/atorvastatin (Caduet)
diltiazem (Cardizem)		bepridil (Vascor)
diltiazem (Tiazac, Taztia XT)		diltiazem (Cardizem LA)
diltiazem CD (Cardizem CD)		isradipine (Dynacirc)
diltiazem ER (Cartia XT, Diltia XT)		nicardipine (Cardene SR)
diltiazem SR (Cardizem SR)		nimodipine (Nimotop)
diltiazem XR (Dilacor XR)		nisoldipine (Sular)
felodipine (Plendil)		verapamil (Covera HS)
isradipine (Dynacirc CR)		verapamil (Verelan PM)
nicardipine (Cardene)		
nifedipine (Adalat, Procardia)		
nifedipine CC (Adalat CC)		
nifedipine XL (Nifedical XL, Procardia XL)		
verapamil (Calan, Isoptin, Verelan)		
verapamil SR (Calan SR, Isoptin SR)		
ACE INHIBITORS		
benazepril (Lotensin)	(Supplemental rebated Tier 3)	perindopril (Aceon)
captopril (Capoten)		ramipril (Altace)
enalapril (Vasotec)		trandolapril (Mavik)
enalaprilat (Vasotec IV)		
fosinopril (Monopril)		
lisinopril (Prinivil, Zestril)		
moexipril (Univasc)		
quinapril (Accupril)		
ACE/CCB COMBINATIONS		
Tier-1 ACEI + Tier-1 CCB	(Supplemental rebated Tier 3)	benazepril/amlodipine (Lotrel)
		enalapril/felodipine (Lexxel)
		trandolapril/verapamil (Tarka)
ACEI/HCTZ COMBINATIONS		
benazepril/HCTZ (Lotensin HCT)	(Supplemental rebated Tier 3)	quinapril/HCTZ (Accuretic)
captopril/HCTZ (Capozide)		moexipril/HCTZ (Uniretic)
enalapril/HCTZ (Vasoretic)		
fosinopril/HCTZ (Monopril HCT)		
lisinopril/HCTZ (Prinzide, Zestoretic)		
ARB AND ARB/HCTZ COMBINATION		
Tier-1 ACE inhibitor	(Supplemental rebated Tier 3)	All other ARBs & ARB combos
DIRECT RENIN INHIBITORS		
Tier-1 ACE inhibitor + diuretic	ARB or ARB combo	Aliskiren (Tekturna)

Recommendation 4: Annual Review of Ultram ER and Ultram ODT

NO ACTION REQUIRED.

The College of Pharmacy does not recommend any changes at this time.

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for July 2007

Module	**Drug Interaction**	**Duplication of Therapy**	**Drug-Disease Precautions**	**Dosing & Duration**
Total # of messages returned by system when no limits were applied	38,337	57,614	948,882	29,947
Limits which were applied	Established, Major, Males and Females, Age 19-40	Antiplatelet agents, males and females, 0-150 years old	Contraindicated, Males and Females, 0-150, Chronic Kidney Disease	High Dose only, Digitalis, 0-150 years old
Total # of messages after limits were applied	66	24	20	1
Total # of members reviewed after limits were applied	66	22	20	1

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
55		42	

Retrospective Drug Utilization Review Report

Claims Reviewed for April 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 56-65	Amphetamines/Stimulants, Males and Females, Age 0-9, Duplication in extended release products only	Contraindicated, Pregnancy, Females, Age 0-16	Duration, Heparins, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 32
Response Forms Returned: 16

The response forms returned yielded the following results:

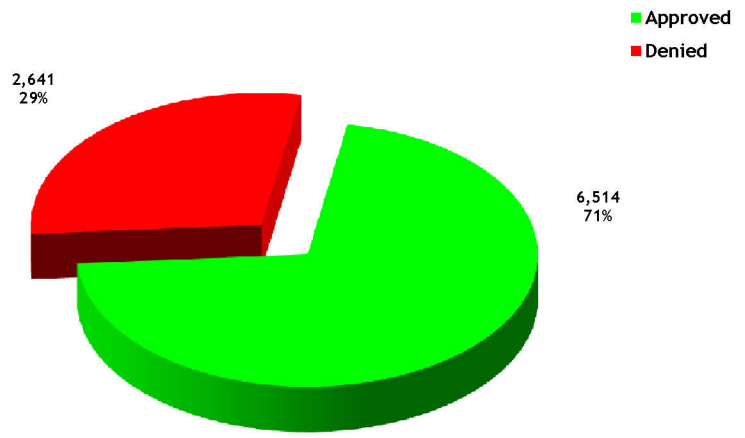
1 (6%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
1 (6%)	*Medication has been changed prior to date of review letter.*
2 (13%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
12 (75%)	*I am aware of this situation and will plan to continue monitoring therapy.*
0 (0%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 31
Response Forms Returned: 19

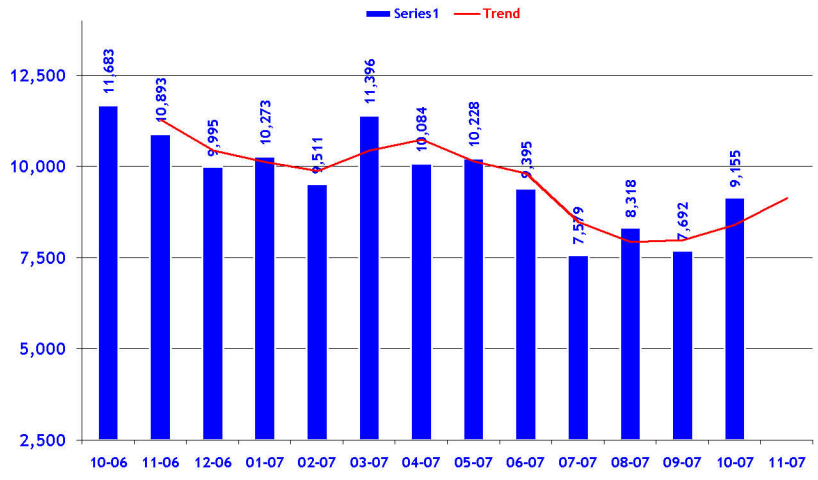
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
2 (11%)	*No longer my patient.*
1 (5%)	*Medication has been changed prior to date of review letter.*
0 (0%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
15 (79%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (5%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
October 2007



PRIOR AUTHORIZATION REPORT
October 2006 – October 2007



Activity Audit for

October 01, 2007 Through October 31, 2007

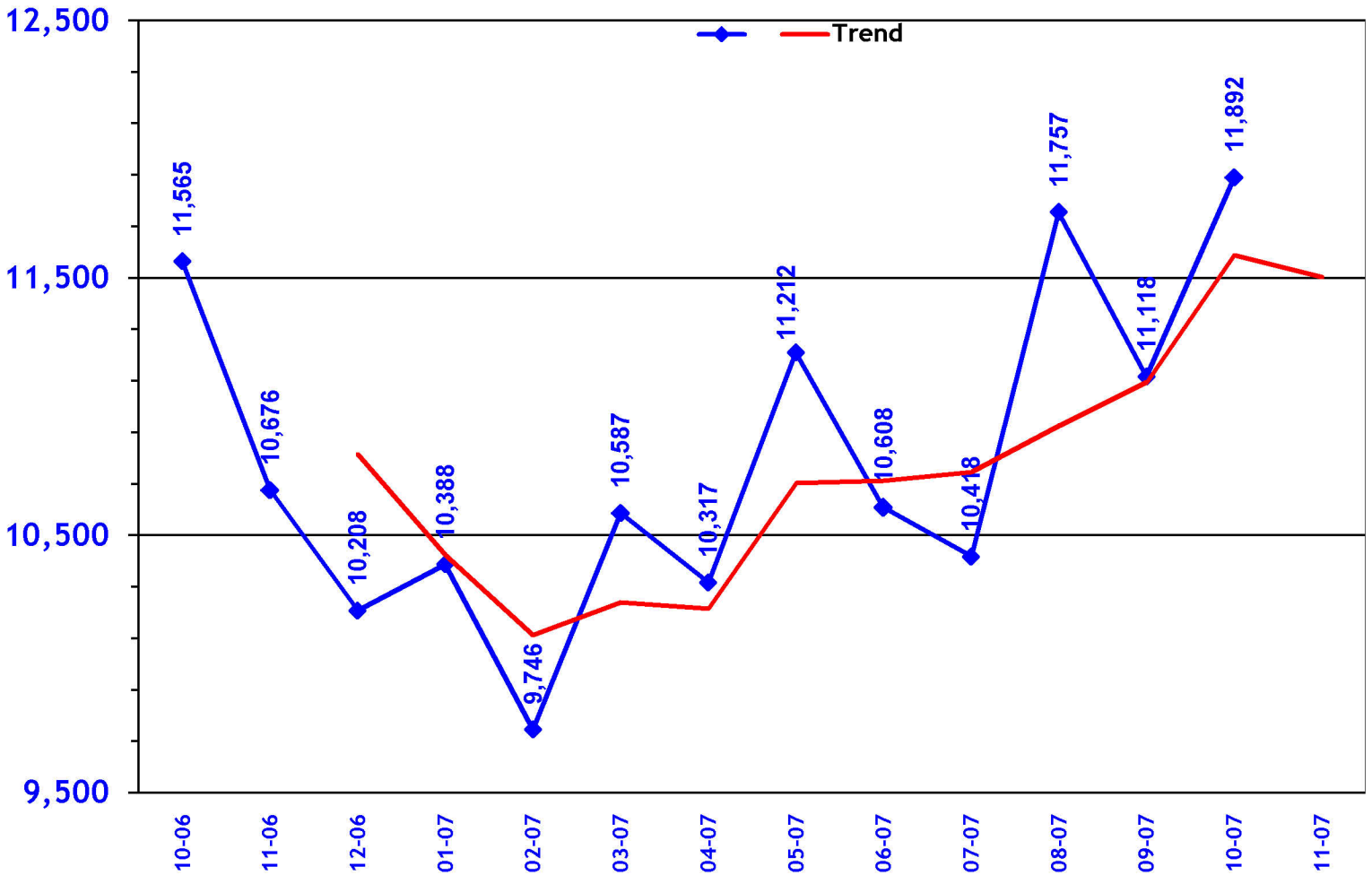
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	121	10	12	22
Angiotensin Receptor Antagonist	351	27	48	75
Antidepressant	301	231	381	612
Antihistamine	105	519	477	996
Antiulcers	47	18	7	25
Anxiolytic	100	3,035	350	3,385
Calcium Channel Blockers	63	8	2	10
Growth Hormones	179	39	3	42
HTN Combos	328	10	16	26
Insomnia	112	35	48	83
Nsaids	249	34	73	107
Plavix	171	157	20	177
Stimulant	236	1,041	214	1,255
Others	117	1,350	990	2,340
Emergency PAs		0	0	0
Total		**6,514**	**2,641**	**9,155**
Overrides				
Brand	297	21	17	38
Dosage Change	16	409	31	440
High Dose	365	1	0	1
Lost/Broken Rx	18	85	6	91
Nursing Home Issue	23	76	3	79
Other	54	41	20	61
Quantity vs. Days Supply	213	221	138	359
Stolen	3	4	3	7
Overrides Total		**858**	**218**	**1,076**

Denial Reasons

Lack required information to process request.	2,577
Unable to verify required trials.	923
Does not meet established criteria.	227
Not an FDA approved indication/diagnosis.	129
Considered duplicate therapy. Member has a prior authorization for similar medication.	99
Requested dose exceeds maximum recommended FDA dose.	49
Member has active PA for requested medication.	22
Medication not covered as pharmacy benefit.	8
Duplicate Requests	510
* Changes to existing	755

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

CALL VOLUME MONTHLY REPORT
October 2006 – October 2007



04-06 thru 03-07: corrected totals

Appendix C

Cough and Cold Coverage Update

Oklahoma Health Care Authority *November 14, 2007*

Current Policy

Selected non-prescription cough and cold products are covered for children less than 21 years of age.

Generally, products covered

- Are liquid formulations
- Do not contain antihistamines
- May contain APAP, cough suppressants, expectorants, and/or decongestants
- Must have a federal drug rebate contract on file.

Since these products are covered only for children, ***there is no copay and they do not count against the monthly prescription limit.***

There is no requirement for a prescription from a prescribing practitioner. Pharmacist recommendation and approval are all that is necessary to submit the claim.

The prescriber name "OTC" and prescriber number 1000001 should be submitted on the claim for payment.

Utilization

From November 28, 2006 through September 18, 2007 a total of 13,802 SoonerCare members under 21 years of age received OTC Cough and Cold medications. The following table is a summary of usage based on the first product ingredient listed. Forty-two percent of all claims were for children 2 years of age or less. A complete table is included at the end of this report.

GCN Description	Total Paid	Total Claims	Total Quantity	Total Days	Mean Paid	Mean Qty	Mean Days	Mean Age
ACETAMINOPHEN	$ 80,401.21	10,493	983,448	107,936	7.66	93.72	10.29	3.97
DEXTROMETHORPHAN	$ 43,161.22	4,476	431,794	47,728	9.64	96.47	10.66	5.87
GUAIFENESIN	$ 66,033.27	8,191	1,144,781	83,454	8.06	139.76	10.19	5.52
IBUPROFEN	$ 2,659.59	310	41,876	3,715	8.58	135.08	11.98	3.25
PSEUDOEPHEDRINE	$ 9,437.64	1,383	107,905	13,759	6.82	78.02	9.95	3.55
	$ 201,692.93	**24,853**	**2,709,804**	**256,592**	**8.12**	**109.03**	**10.32**	**4.43**

Delsym Utilization

According to the DEA Office of Diversion Control, dextromethorphan is often abused by adolescents. Abusers report a heightened sense of perceptual awareness, altered time perception and visual hallucinations. Because of concerns raised during both RetroDUR and In-House reviews over excessive use of this product, Delsym was removed from the covered products in August 2007. It has the third highest number of claims and second highest cost.

Delsym (2,603 Claims)	Sum	Mean	Min	Max
Total Paid	$ 29,000.75	11.14	2.14	25.57
Quantity	272,632	104.74	15	355
Day Supply	28,650	11.01	1	180
Claims / Member	-	1.24	1	12
Age	-	6.72	0	20

Other Overutilization Issues

Because these products can be purchased without a prescription, further review was conducted of all products. There appears to be issues of overutilization by some members across more than one drug category. Several of the 107 members with 10 or more claims belong to the same family unit.

Number of Claims	Number of Members
10 or More	107
5 to 9	728
Less than 5	8,619

Other Concerns

FDA issued a public health advisory regarding the use of cough and cold products on August 15, 2007. Some of the items mentioned are:

- Do ***not*** use cough and cold products in children under 2 years of age UNLESS given specific directions to do so by a healthcare provider.
- If other medicines (over-the-counter or prescription) are being given to a child, the child's healthcare provider should review and approve their combined use.

An FDA Advisory panel recommended, on October 19, 2007, that cough and cold products should not be given to children under 6 years of age, the recommendation included combinations of decongestants, antihistamines, and cough suppressants. Prior to this several manufacturers voluntarily recalled their infant formulations.

Recommendations

The College of Pharmacy has the following recommendations for the Cough and Cold products:

1. Either discontinue OTC coverage for children less than 6 years of age ***or*** require a prior authorization. Single ingredient ibuprofen and acetaminophen products would still be covered.
2. Only allow a maximum of 5 claims per year for this category.

Utilization by GCN Description

GCN Description	Total Paid	Total Claims	Total Quantity	Total Days	Mean Paid	Mean Qty	Mean Days	Mean Age
ACETAMINOPHEN ORAL 100MG/ML DROPS	$3,763.15	544	10,203	4,801	6.92	18.76	8.83	0.34
ACETAMINOPHEN ORAL 100MG/ML DROPS SUSP	$2,711.98	470	9,508	5,444	5.77	20.23	11.58	0.74
ACETAMINOPHEN ORAL 160MG/5ML ELIXIR	$9,803.33	1,332	161,215	12,008	7.36	121.03	9.02	4.46
ACETAMINOPHEN ORAL 160MG/5ML GEL	$8.43	1	120	10	8.43	120.00	10.00	1.00
ACETAMINOPHEN ORAL 160MG/5ML LIQUID	$625.85	94	13,645	715	6.66	145.16	7.61	5.17
ACETAMINOPHEN ORAL 160MG/5ML ORAL SUSP	$43,949.03	5,704	712,978	62,110	7.70	125.00	10.89	5.03
ACETAMINOPHEN ORAL 160MG/5ML SOLUTION	$134.10	24	2,952	322	5.59	123.00	13.42	5.25
ACETAMINOPHEN ORAL 167MG/5ML LIQUID	$780.90	96	24,378	894	8.13	253.94	9.31	13.27
ACETAMINOPHEN ORAL 80MG/0.8ML DROPS SUSP	$18,624.44	2,228	48,449	21,632	8.36	21.75	9.71	0.51
DEXTROMETHORPHAN HBR ORAL 10MG/5ML LIQUID	$13.22	2	238	16	6.61	119.00	8.00	5.50
DEXTROMETHORPHAN HBR ORAL 15MG/5ML SYRUP	$525.59	76	8,996	755	6.92	118.37	9.93	7.46
DEXTROMETHORPHAN HBR ORAL 30MG/5ML LIQUID	$29,000.75	2,603	272,632	28,650	11.14	104.74	11.01	6.72
DEXTROMETHORPHAN HBR ORAL 5MG/5ML SYRUP	$11.81	2	240	25	5.91	120.00	12.50	1.50
DEXTROMETHORPHAN HBR ORAL 7.5MG/5ML GEL	$8.43	1	120	6	8.43	120.00	6.00	18.00
DEXTROMETHORPHAN HBR ORAL 7.5MG/5ML SYRUP	$1,823.53	259	30,467	2,621	7.04	117.63	10.12	4.46
DEXTROMETHORPHN/ACETAMINOPH/CP ORAL 5-160-1/5 ORAL SUSP	$63.25	8	960	57	7.91	120.00	7.13	3.38
D-METHORPHAN HB/ACETAMINOPHEN ORAL 5-160MG/5 ORAL SUSP	$2,801.97	389	46,584	4,218	7.20	119.75	10.84	5.37
D-METHORPHAN HB/P-EPHED HCL ORAL 10-20MG/5 ELIXIR	$44.42	7	896	70	6.35	128.00	10.00	8.00
D-METHORPHAN HB/P-EPHED HCL ORAL 15-30MG/5 LIQUID	$190.49	24	3,341	184	7.94	139.21	7.67	6.21
D-METHORPHAN HB/P-EPHED HCL ORAL 2.5-7.5/.8 DROPS	$5,211.64	661	11,246	5,791	7.88	17.01	8.76	0.86
D-METHORPHAN HB/P-EPHED HCL ORAL 7.5-15MG/5 SYRUP	$2,890.39	368	47,436	4,488	7.85	128.90	12.20	4.65
D-METHORPHAN/PE/ACETAMINOPHEN ORAL 5-325MG/15 LIQUID	$105.91	14	2,925	129	7.57	208.93	9.21	11.21
D-METHORPHAN/P-EPHED/ACETAMINP ORAL 20-60-650 SOLUTION	$13.10	2	297	30	6.55	148.50	15.00	1.00
D-METHORPHAN/P-EPHED/ACETAMINP ORAL 30-60-1000 LIQUID	$60.72	9	1,560	102	6.75	173.33	11.33	7.11
D-METHORPHAN/P-EPHED/ACETAMINP ORAL 30-60-650 SOLUTION	$20.97	4	592	82	5.24	148.00	20.50	8.00
D-METHORPHAN/P-EPHED/ACETAMINP ORAL 5-15-160MG DROPS	$206.09	25	420	294	8.24	16.80	11.76	0.56
D-METHORPHAN/P-EPHED/ACETAMINP ORAL 7.5-15-160 LIQUID	$168.94	22	2,844	210	7.68	129.27	9.55	5.59
GUAIFEN/D-METHORPHAN HB/PE ORAL 100-10-5MG LIQUID	$4,009.04	527	82,627	5,583	7.61	156.79	10.59	5.81
GUAIFEN/DM HB/P-EPHEDRINE ORAL 100-10-30 SYRUP	$3,604.47	526	78,253	5,505	6.85	148.77	10.47	6.18
GUAIFEN/DM HB/P-EPHEDRINE ORAL 40-6-2/ML DROPS	$29.60	5	150	60	5.92	30.00	12.00	0.80
GUAIFEN/DM HB/P-EPHEDRINE ORAL 5-15MG/2.5 DROPS	$431.51	46	1,545	744	9.38	33.59	16.17	1.39
GUAIFEN/DM/P-EPHED/ACETAMINOPH ORAL 10-30-324 EXPECT.	$13.56	2	360	20	6.78	180.00	10.00	4.00

GUAIFENESIN/ACETAMINOPHEN ORAL 200-500/15 SOLUTION	$387.56	50	11,880	448	7.75	237.60	8.96	10.82
GUAIFENESIN/D-METHORPHAN HB ORAL 100-10MG/5 LIQUID	$520.49	62	8,764	565	8.40	141.35	9.11	6.39
GUAIFENESIN/D-METHORPHAN HB ORAL 100-10MG/5 SYRUP	$21,899.43	2,998	474,967	31,952	7.30	158.43	10.66	6.40
GUAIFENESIN/D-METHORPHAN HB ORAL 100-5/2.5 DROPS	$2,047.71	259	8,038	2,455	7.91	31.03	9.48	0.78
GUAIFENESIN/D-METHORPHAN HB ORAL 100-5MG/5 LIQUID	$11,906.81	1,221	146,491	12,003	9.75	119.98	9.83	5.39
GUAIFENESIN/D-METHORPHAN HB ORAL 200-10MG/5 LIQUID	$18.87	3	356	30	6.29	118.67	10.00	0.33
GUAIFENESIN/D-METHORPHAN HB ORAL 200-10MG/5 SYRUP	$575.96	81	9,400	877	7.11	116.05	10.83	5.70
GUAIFENESIN/D-METHORPHAN HB ORAL 200-30MG/5 LIQUID	$22.24	3	358	24	7.41	119.33	8.00	14.00
GUAIFENESIN/D-METHORPHAN HB ORAL 66.7-6.7/5 ELIXIR	$46.56	8	960	42	5.82	120.00	5.25	6.88
GUAIFENESIN ORAL 100MG/5ML LIQUID	$9,152.27	981	117,232	8,594	9.33	119.50	8.76	5.82
GUAIFENESIN ORAL 100MG/5ML SYRUP	$3,935.15	569	99,180	6,078	6.92	174.31	10.68	6.57
GUAIFENESIN/P-EPHED HCL ORAL 100-30MG/5 SYRUP	$734.30	118	15,341	1,491	6.22	130.01	12.64	5.80
GUAIFENESIN/P-EPHED HCL ORAL 50-15MG/5 SYRUP	$525.67	66	7,932	666	7.96	120.18	10.09	5.14
GUAIFENESIN/PHENYLEPHRINE HCL ORAL 100-5MG/5 LIQUID	$6,112.07	657	79,873	6,227	9.30	121.57	9.48	6.76
GUAIFN/DM/PHENYLEPH/ACETAMINOP ORAL 10-5-325/5 LIQUID	$60.00	9	1,074	90	6.67	119.33	10.00	5.44
IBUPROFEN ORAL 100MG/5ML GEL	$8.43	1	120	10	8.43	120.00	10.00	2.00
IBUPROFEN/PSEUDOEPHEDRINE HCL ORAL 100-15MG/5 ORAL SUSP	$2,651.16	309	41,756	3,705	8.58	135.13	11.99	4.50
PSEUDOEPHEDRINE HCL ORAL 15MG/5ML LIQUID	$2,662.10	347	42,920	3,235	7.67	123.69	9.32	5.67
PSEUDOEPHEDRINE HCL ORAL 15MG/5ML SYRUP	$9.86	2	236	37	4.93	118.00	18.50	3.00
PSEUDOEPHEDRINE HCL ORAL 30MG/5ML SYRUP	$3,347.83	583	54,890	5,649	5.74	94.15	9.69	4.61
PSEUDOEPHEDRINE HCL ORAL 9.4MG/ML DROPS	$3,417.85	451	9,859	4,838	7.58	21.86	10.73	0.93
TOTALS	**$201,692.93**	**24,853**	**2,709,805**	**256,592**				

Members with More than 10 Claims

Number	Claims	Gender	Age	Comments
1	88	M	3	Multiple Family Members on List
2	84	M	8	Multiple Family Members on List
3	40	M	1	
4	32	M	6	Multiple Family Members on List
5	29	F	5	
6	25	M	3	
7	24	F	7	
8	20	M	5	Multiple Family Members on List
9	19	M	6	
10	19	M	5	Multiple Family Members on List
11	19	M	4	Multiple Family Members on List
12	19	F	3	
13	19	M	3	
14	19	M	1	Multiple Family Members on List
15	18	M	1	
16	17	F	8	
17	17	F	3	
18	17	F	3	
19	17	F	2	Multiple Family Members on List
20	17	M	1	
21	16	M	15	
22	16	M	8	
23	16	M	13	Multiple Family Members on List
24	16	M	7	Multiple Family Members on List
25	16	M	7	
26	16	F	7	Multiple Family Members on List
27	16	M	13	
28	16	F	1	
29	16	F	1	Multiple Family Members on List
30	15	F	6	Multiple Family Members on List
31	15	M	2	
32	15	M	2	
33	15	F	1	
34	15	M	1	
35	14	M	7	
36	14	M	1	
37	14	M	1	
38	14	M	1	
39	14	M	1	
40	14	F	1	
41	13	M	19	Multiple Family Members on List
42	13	F	7	Multiple Family Members on List
43	13	M	5	
44	13	M	5	
45	13	M	6	
46	13	F	19	
47	13	M	7	Multiple Family Members on List
48	13	F	8	Multiple Family Members on List
49	12	F	8	Multiple Family Members on List
50	12	M	3	
51	12	F	1	Multiple Family Members on List
52	12	M	1	Multiple Family Members on List
53	12	M	3	

54	12	M	1	
55	12	F	0	
56	11	M	15	Multiple Family Members on List
57	11	M	15	
58	11	M	12	
59	11	M	9	
60	11	F	7	
61	11	F	12	
62	11	M	7	
63	11	M	6	
64	11	F	5	
65	11	F	3	
66	11	M	3	
67	11	M	12	
68	11	M	3	
69	11	F	2	
70	11	M	2	
71	11	M	2	
72	11	M	2	
73	11	M	1	
74	11	M	5	
75	11	M	1	
76	11	M	3	Multiple Family Members on List
77	11	F	1	Multiple Family Members on List
78	10	M	15	
79	10	M	12	
80	10	F	18	
81	10	F	11	Multiple Family Members on List
82	10	F	11	
83	10	F	9	
84	10	M	8	Multiple Family Members on List
85	10	M	8	
86	10	M	7	
87	10	M	6	Multiple Family Members on List
88	10	M	6	
89	10	M	6	
90	10	M	5	Multiple Family Members on List
91	10	M	4	Multiple Family Members on List
92	10	F	3	
93	10	M	3	Multiple Family Members on List
94	10	F	3	
95	10	F	2	
96	10	M	2	
97	10	M	1	
98	10	M	1	
99	10	F	1	
100	10	F	1	
101	10	M	1	Multiple Family Members on List
102	10	F	2	
103	10	F	1	
104	10	M	1	
105	10	F	1	
106	10	F	1	
107	10	F	4	

Appendix D

Vote to Prior Authorize XYZAL® (levocetirizine dihydrochloride)
Vote to Update Oral Allergy Product PBPA Category

Oklahoma Health Care Authority
November 2007

Manufacturer	UCB, Inc
Classification	H1 receptor antagonist antihistamine
Status:	Prescription Only

Summary

XYZAL® is the R-enantiomer of cetirizine. It is available as a white, oval, scored 5mg tablet. It is indicated for the following conditions:

- The relief of symptoms associated with allergic rhinitis (seasonal and perennial) in adults and children 6 years of age and older.
- The treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

Dosing

Recommended dose is 5mg once daily in the evening for adults and children 12 years of age and older. The recommended dose for children 6 to 11 years of age is 2.5mg (1/2 tablet) once daily in the evening. A daily dose above 2.5mg for children 6 to 11 years of age is not recommended.

Commonly Reported Adverse Effects

Subjects >12 years of age*	Children 6-12 years of age*
Somnolence 6%	Pyrexia 4%
Nasopharyngitis 4%	Cough 3%
Fatigue 4%	Somnolence 3%
Dry Mouth 2%	Epistaxis 2%
Pharyngitis 1%	

*dose of 5mg/day

Cost Comparison

	Per Diem (based on EAC or SMAC)
Loratadine OTC 10mg	$0.50975
Fexofenadine 180mg	$1.44300
Zyrtec® 10mg	$2.44200
XYZAL® 5mg	$2.47504
Clarinex® 5mg	$3.04260

PA Criteria For Children Under 21 Years of Age

- Tier 2 oral allergy products are covered after previous trials with an over-the-counter antihistamine. A 14 day trial of over-the-counter loratadine is required prior to coverage of a Tier 2 product for all age groups.
  - Trials should have been in the last month and be of adequate dose and duration,
  - Over-the-counter loratadine is a covered product for members under 21 years of age without prior authorization, and
  - For members 21 years of age and older, loratadine is available with prior authorization AFTER documented trial of a non-loratadine OTC product.
- For members six months to two years of age, cetirizine and desloratadine syrup is available without prior authorization.
- Diagnosis must be for a chronic allergic condition.
- Clinical exceptions include asthma and COPD. Prior authorization will not be approved for a time period greater than 90 days for members without a diagnosis which requires continuous coverage.

Tier 1	Tier 2
• Over-the-counter loratadine • Cetirizine and desloratadine syrup for members 6 months to 2 years of age	• Cetirizine • Desloratadine • Fexofenadine

Recommendations

The College of Pharmacy recommends the following:

I. Restructuring of Category

Tier 1	Tier 2	Tier 3
• Over-the-counter loratadine* • Zyrtec and Clarinex syrup for members 6 months to 2 years of age	• Fexofenadine Tabs	• Zyrtec • Clarinex • Allegra • Xyzal

* For members 21 years of age and older, loratadine is available with prior authorization AFTER documented trial of a non-loratadine OTC product.

Criteria:

- A 14 day trial of OTC loratadine within the last month is required before a Tier 2 medication can be approved.
- OTC loratadine and a Tier 2 product must be tried for 14 days each within the last 60 days before a Tier 3 medication can be approved.
- Diagnosis must be for a chronic allergic condition.
- Clinical exception for members with asthma.
- Prior authorization will be for 90 days, except for members with asthma. Authorization for members with asthma will be for 360 days.

II. Prior Authorization of XYZAL®
Placing XYZAL® in the PBPA as a tier-3 agent. In addition to current tier-3 criteria, member must also be greater than 6 years of age.

REFERENCE

XYZAL® Product Information. UCB Inc. May 2007.

Appendix E

Vote to Prior Authorize Nuvigil™ (armodafinil)
Oklahoma Health Care Authority
November 2007

Manufacturer	Cephalon, Inc.
Classification	FDA classification: C-IV Status: prescription only

Summary

Nuvigil™ (armodafinil) is an oral wakefulness-promoting medication which is the longer-lived R-enantiomer of modafinil (Provigil®). It is available in 50mg, 150mg and 250mg strengths and is indicated for obstructive sleep apnea/hypopnea syndrome (OSAHS), narcolepsy, or shift work sleep disorder. In OSAHS, it is indicated as an adjunct to standard treatment. Its effectiveness has not been studied in placebo-controlled trials for use longer than 12 weeks and has no indication for use in pediatric patients.

Recommendatations

The College of Pharmacy recommends placing Nuvigil™ into the ADHD/Narcolepsy PBPA category as a Tier 3. Approval would require a diagnosis of obstructive sleep apnea/hypopnea syndrome (with documentation of prior attempts and continuation of standard treatment, i.e. CPAP), narcolepsy or shift work sleep disorder. A quantity limit of 30 units for a 30 day supply and age restriction of 18 or older would also be applied. If approved, the initial approval would be for 3 months, beyond that additional information from the physician about the member's response to the medication would be required for long term authorization.

References

Nuvigil™, Product Information. Cephalon, Inc. 2007.

Appendix F

Vote on Changes to the Ingredient Duplication ProDUR Module

Oklahoma Health Care Authority, November 2007

Prospective Drug Utilization Review – Ingredient Duplication:

Current Settings

The ingredient duplication module for the point-of-sale Prospective DUR is currently set to warn dispensing pharmacist when two overlapping claims for the same ingredient are being processed. For example, if a member has a claim for Lortab® 5 mg at a different pharmacy and this pharmacy is attempting to dispense a claim for Lortab® 7.5 mg then the new claim would send out a flag. The complete list of ingredients which are active is included in the appendix.

Recommended Changes

The College of Pharmacy recommends reconfiguring the module to review only claims for duplication of hydrocodone with acetaminophen. Because this is the single most utilized product for the current SoonerCare population, this ingredient will be targeted.

The module can be changed to check only hydrocodone with acetaminophen products AND set to deny a duplicate hydrocodone claim when a paid claim already exists within a certain time period, or for which the previous days supply has not been exhausted. Members, through their pharmacy providers, may petition for an override for issues such as an increased dose. By making these changes, members would be able to fill only one strength of hydrocodone with acetaminophen at any time, without prior approval.

Appendix – Ingredient Duplication Module

Currently Monitored Ingredients

Therapy Class (HIC4)	Description
Anti-Ulcer Preparations	
Histamine H2-Receptor Inhibitors	
Z2DA	Cimetidine
Z2DB	Ranitidine
Z2DC	Famotidine
Z2DD	Nizatidine
Proton-Pump Inhibitors	
D4JA	Omeprazole
D4JB	Lansoprazole
D4JC	Pantoprazole
D4JD	Rabeprazole
D4JE	Esomeprazole Miscellaneous
D4EA	Sucralfate
Anxiolytic, Sedative-Hypnotics	
Barbiturates	
H2DA	Barbital
H2DB	Phenobarbital
H2DC	Amobarbital
H2DD	Butarbarbital
H2DE	Pentobarbital
H2DH	Secobarbital
H2DJ	Mephobarbital
H2DP	Butalbital
Sedative-Hypnotics, Non-Barbiturate	
H2EB	Chloral Hydrate
H2ET	Zolpidem
H2EZ	Zaleplon
Anti-Anxiety Drugs	
H2FF	Temazepam
H2FJ	Chlordiazepoxide

Anxiolytic, Sedative-Hypnotics, Cont.

H2FK	Clorazepic Acid
H2FM	Lorazepam
H2FN	Diazepam
H2FO	Estazolam
H2FP	Oxazepam
H2FQ	Flurazepam
H2FR	Alprazolam
H2FT	Triazolam
H2FU	Midazolam

ADHD/Narcolepsy

H2VA	Methylphenidate
H2VE	Amphetaminil
H2VF	Dexmethylphenidate
H7FA	Atomoxetine

Skeletal Muscle Relaxants

H6HC	Methocarbamol
H2HE	Chlorzoxazone
H2HF	Carisoprodal
H2HL	Baclofen
H2HM	Cyclobenzaprine
H6HN	Orphenadrine

Narcotic Analgesics

H3AA	Meperidine
H3AD	Morphine
H3AE	Hydromorphone
H3AF	Oxymorphone
H3AH	Codeine
H3AJ	Hydrocodone
H3AK	Dihydrocodeine
H3AL	Oxycodone
H3AR	Methadone
H3AT	Fentanyl
H3AU	Propoxyphene
H3AY	Opium
H3AZ	Buprenorphine

Narcotic Analgesics, Cont.

H3BH	Tramadol
H3BL	Butorphanol
H3BM	Pentazocine

NSAIDs and Salicylates

S2BF	Tolmetin
S2BG	Naproxen
S2BH	Flurbiprofen
S2BL	Sulindac
S2BM	Meclofenamic Acid
S2BN	Piroxicam
S2BQ	Diclofenac
S2BS	Ketorolac
S2BT	Etodolac
S2BU	Nabumetone
S2BZ	Ketoprofen
S2DF	Mefenamic Acid
S2EG	Tolfenamic Acid
S2EI	Meloxicam
S2EP	Bromfenac

NSAIDs, Cyclooxygenase 2 Inhibitor Type

S2LA	Celecoxib
S2LB	Rofecoxib
S2LC	Valdecoxib
S2LE	Etoricoxib

Analgesics/Antipyretics, Salicylates

H3DA	Salicylate
H3DB	Aspirin
H3DQ	Salsalate
H3DT	Diflunisal

Appendix G

30 Day Notice and Potential Economic Impact for Product Based Prior Authorization of Topical Antifungals
Oklahoma Health Care Authority
November 2007

Recommendations

The College of Pharmacy recommends including the Topical Antifungals in the Product Based Prior Authorization (PBPA) 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 members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

Tier 1	Tier 2
Ciclopirox	Ciclopirox sol, shampoo, & gel **(Penlac® and Loprox®)**
Clotrimazole and Clotrimazole/Betamethasone	Miconazole/Zinc Oxide/White petrolatum **(Vusion®)**
Econazole	Oxiconazole **(Oxistat®)**
Ketoconazole	Sertaconazole nitrate **(Ertaczo®)**
Nystatin and Nystatin/Triamcinolone	Butenafine **(Mentax®)**
Hydrocortisone/Iodoquinol	Ketoconazole gel **(Xolegel™)**
All available generic antifungal products	Ketoconazole gel + 1% pyrithione zinc shampoo **(Xolegel™ DUO)**
	Naftifine **(Naftin®)**
	Sulconazole **(Exelderm®)**
	Terbinafine **(Lamisil® Spray)**
	Clotrimazole **(Lotrimin Lotion 1%)**
	Ketoconazole Foam 2% **(Extina®)**

Approval Criteria:

1. Approval of a branded antifungal product will be granted following trials of at least two Tier 1 topical antifungal products within the last 30 days.
2. For treatment of Onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required before approval of Penlac®

Medication	Claims	Members	Units	Days	Cost	Perdiem
CLOTRIM/BETA CRE DIPROP	7,058	5,273	263,686	82,100	$164,729.83	$2.01
KETOCONAZOLE CRE 2%	2,685	2,131	93,891	33,751	$65,598.01	$1.94
NYSTATIN CRE 100000	9,925	7,611	321,011	96,672	$64,391.72	$0.67
CLOTRIMAZOLE CRE 1%	2,909	2,321	100,753	35,831	$64,200.19	$1.79
ECONAZOLE CRE 1%	1,413	1,098	61,700	18,204	$55,692.54	$3.06
CICLOPIROX CRE 0.77%	896	741	34,407	11,811	$44,094.76	$3.73
NYAMYC POW 100000	66	45	31,545	633	$39,989.48	$63.17
KETOCONAZOLE SHA 2%	1,475	844	186,118	24,156	$39,786.70	$1.65
NYSTAT/TRIAM CRE	4,883	3,835	181,776	55,269	$34,073.80	$0.62
NYSTATIN POW 100000	546	408	26,355	5,300	$33,602.17	$6.34
NYSTOP POW 100000	1,023	599	24,480	10,703	$31,735.30	$2.97
PENLAC SOL 8%	222	149	1,474	5,472	$31,431.87	$5.74
CICLOPIROX SUS 0.77%	354	251	19,320	5,573	$27,193.30	$4.88
MENTAX CRE 1%	372	293	10,215	4,394	$26,022.99	$5.92
OXISTAT CRE 1%	446	359	14,970	5,823	$24,554.88	$4.22
NYSTATIN OIN 100000	2,708	2,139	96,035	28,462	$19,721.25	$0.69
ALCORTIN GEL	267	198	12,197	3,598	$17,083.14	$4.75
MONISTAT CRE DERM 2%	218	163	10,238	2,568	$13,267.99	$5.17
CLOTRIM/BETA LOT DIPROP	365	273	13,135	5,192	$12,997.25	$2.50
LOPROX SHA 1%	152	79	19,770	2,771	$12,233.82	$4.41
LOPROX GEL TOPICAL	117	93	4,720	1,624	$10,506.27	$6.47
ERTACZO CRE 2%	92	52	3,480	1,413	$6,217.85	$4.40
NYSTAT/TRIAM OIN	647	505	20,359	6,617	$4,287.68	$0.65
NAFTIN CRE 1%	79	60	3,030	1,215	$4,247.76	$3.50
NAFTIN GEL 1%	33	19	1,480	651	$2,271.34	$3.49
EXELDERM CRE 1%	75	55	2,445	1,171	$1,978.82	$1.69
SPECTAZOLE CRE 1%	31	31	1,160	373	$1,628.07	$4.36
PEDI-DRI POW 100000	19	13	1,084	246	$1,376.28	$5.59
CLOTRIMAZOLE SOL 1%	78	30	2,350	595	$1,258.31	$2.11
LAMISIL SPR 1%	15	11	450	115	$1,224.20	$10.65
HYDROCORT/ CRE IODOQUIN	66	38	2,617	784	$1,043.45	$1.33
OXISTAT LOT 1%	16	14	480	242	$765.59	$3.16
NIZORAL SHA 2%	20	18	2,640	252	$670.76	$2.66
VUSION OIN	11	10	330	173	$611.38	$3.53
NYSTATIN POW USP	11	10	808	185	$238.84	$1.29
EXELDERM SOL 1%	6	6	210	90	$201.37	$2.24
NYSTAT-RX POW 50MU	2	2	59	30	$135.48	$4.52
NYSTAT-RX POW 500MU	1	1	86	15	$120.56	$8.04
HYDROC IODO CRE 1%	6	5	227	67	$120.06	$1.79
CLOTRIMAZOLE POW	5	5	374	80	$103.55	$1.29
LOTRIMIN LOT 1%	3	3	90	27	$90.44	$3.35
NYSTATIN POW 50MU	2	2	45	8	$58.21	$7.28
VERSICLEAR LOT	2	2	240	45	$41.62	$0.92
LOTRIMIN AF CRE 1%	1	1	120	10	$6.84	$0.68
MYCOGEN II OIN	1	1	15	10	$5.61	$0.56
NAFTIN-MP CRE 1%	1	1	1	1	$5.44	$5.44
Totals	**39,323**	**26,651***	**1,571,976**	**454,322**	**$861,616.77**	**$1.90**

*Total number of unduplicated members

Appendix H

30 Day Notice to Prior Authorize Azor™ (amlodipine/olmesartan)

Oklahoma Health Care Authority
November 2007

Manufacturer Daiichi Sankyo, Inc
Classification FDA classification: Oral Antihypertensive
Status: prescription only

Summary

Azor™ is a dihydropyridine calcium channel blocker and angiotensin II receptor blocker (ARB) combination product indicated for once daily treatment of hypertension, alone, or with other antihypertensive agents.

Cost comparison

	EAC/unit	SMAC/Unit	$/Month (30 day supply)
Azor™ tab 5/20 mg	$2.34		$70.20
Azor™ tab 10/20 mg	$2.65		$79.50
Azor™ tab 5/40 mg	$2.97		$89.10
Azor™ tab 10/40 mg	$3.37		$101.10
Amlodipine tab 5 mg		$0.29	$8.70
Amlodipine tab 10 mg		$0.30	$9.00
Benicar® tab 20 mg	$1.70		$51.00
Benicar® tab 40 mg	$1.98		$59.40
Lisinopril tab 10 mg		$0.14	$4.20
Lisinopril tab 20 mg		$0.15	$4.50
Benazepril tab 10 mg		$0.11	$3.30
Benazepril tab 20 mg		$0.09	$2.70

Recommendations

The College of Pharmacy recommends placing Azor™ in the PBPA program as a Tier 3 ARB. A Quantity limit of one unit per day would be applied.

ARB AND ARB COMBINATIONS		
Tier 1	**Tier 2**	**Tier 3**
Tier-1 ACE inhibitor	**(Supplemental rebated Tier 3)**	**All other ARBs and ARB combos**

To qualify for a Tier-2 medication (or Tier-3 medication when no Tier-2 medications) exist there must be
- documented inadequate response to two Tier-1 medications in the class, or
- previous stabilization on the Tier-2 drug
- a unique indication for which the Tier-1 drugs lack

To qualify for a **Tier-3** medication there must be
- documented inadequate response to two Tier-1 medications and documented inadequate response to all available tier-2 medications, or
- previous stabilization on the Tier-3 drug
- a unique indication for which the Tier-1 drugs lack

REFERENCES

1. Azor™ Product information, Daiichi Sankyo, Inc

Appendix I

30 Day Notice to Prior Authorize Soma® 250mg

Oklahoma Healthcare Authority
November 2007

Manufacturer: **MedPointe Pharmaceuticals**
Classification: **Skeletal Muscle Relaxant, Centrally Acting**

Summary

Carisoprodol has been on the market for almost 50 years, first marketed as brand name Soma® 350mg and later widely used when it was available as the generic carisoprodol 350mg. During September of this year MedPointe Pharmaceuticals began marketing of brand name Soma® 250mg. It is the same chemical compound and formulation as the carisoprodol 350mg, but at a lower dosage.

Soma® 250mg is currently being marketed with the following points:

- Short term relief of back pain comparable to that of the 350mg dosage.
- Better tolerability, i.e. less drowsiness.

However, the clinical trial results showed the following rates for adverse effects with no p-values listed, therefore, it is unknown if the differences are significant.

	Placebo (n=560)	*Soma® 250mg (n=548)*	*Soma® 350mg (n=279)*
Drowsiness	31 (6%)	73 (13%)	47 (17%)
Dizziness	11 (2%)	43 (8%)	19 (7%)
Headache	11 (2%)	26 (5%)	9 (3%)

Adapted from Table 1 of Soma® 250 Prescribing Information

The following is a comparison of cost based on estimated acquisition costs of Soma 250mg and other commonly used skeletal muscle relaxants.

	EAC per Dose*	*Typical Regimen*	*Cost per Month*
Soma® 250mg	$2.48	QID	$297.60
Carisoprodol 350mg	$0.10	QID	$12.00
Cyclobenzaprine 10mg Tabs	$0.14	TID	$12.60
Tizanidine 4mg Tabs	$0.12	2 TID	$21.60

*Estimated Acquisition Cost

Conclusion and Recommendations

The College of Pharmacy recommends the prior authorization of Soma® 250mg with the following criteria:

1. A specific reason member cannot be drowsy for even a short time period. Member must not have other sedating medications in current claims history.
2. A diagnosis of acute musculoskeletal pain, in which case, the approval will be for 30 days per acute event. Conditions requiring chronic use will not be approved.

Medication Details[i]

Pharmacology and Pharmacodynamics

The mechanism of action of carisoprodol in relieving discomfort associated with acute painful musculoskeletal conditions has not been clearly identified. Carisoprodol is a centrally acting skeletal muscle relaxant that does not directly relax skeletal muscles. A metabolite of carisoprodol, meprobamate, has anxiolytic and sedative properties. The degree to which these properties of meprobamate contribute to the safety and efficacy of carisoprodol is unkown.

Pharmacokinetics

- **Absorption:** Absolute bioavailability of carisoprodol has not been determined. The mean time to peak plasma concentrations (Tmax) of carisoprodol was approximately 1.5 to 2 hours. Soma® may be administered with or without food.
- **Metabolism:** The major pathway of carisoprodol metabolism is via the liver by CYP2C19 to form meprobamate.
- **Elimination:** Carisoprodol is eliminated by both renal and non-renal routes with a terminal elimination half-life of approximately 2 hours. The half-life of meprobamate is approximately 10 hours.

Indications and Usage

Soma® is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults. Soma® should only be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration.

Dosing and Administration

The recommended dose of Soma® is 250 mg to 350 mg three times a day and at bedtime. The recommended maximum duration of Soma® use is up to two or three weeks.

Contraindications

Soma® is contraindicated in patients with a history of acute intermittent porphyria or a hypersensitivity reaction to a carbamate such as meprobamate.

Warnings and Precautions

- **Sedation** - may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery. Sedative effects of Soma® and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive.
- **Drug Dependence, Withdrawal, and Abuse**-abuse have been reported with prolonged use. Withdrawal symptoms have been reported following abrupt cessation after prolonged use. To reduce the chance of Soma® dependence, withdrawal, or abuse, Soma® should be used with caution in addiction prone patients and in patients taking other CNS depressants including alcohol, and Soma® should not be used more than two to three weeks for the relief of acute musculoskeletal discomfort. One of the metabolites of Soma®, meprobamate, may cause dependence.
- **Seizures-**there have been post-marketing reports of seizures in patients who received Soma®. Most of these cases have occurred in the setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol.)

Adverse Effects

- Drowsiness
- Dizziness
- Headache

Drug Interactions

- CNS Depressants
- CYP2C19 inducers (i.e. rifampin) and inhibitors (i.e. omeprazole and fluvoxamine) may increase or decrease exposure to carisoprodol.

Populations

- **Pregnancy**-Category C
- **Pediatric**- The efficacy, safety, and pharmacokinetics of Soma® in pediatric patients less than 16 years of age have not been established.
- **Geriatric**- The efficacy, safety, and pharmacokinetics of Soma® in patients over 65 years old have not been established.
- **Renal Impairment-**The safety and pharmacokinetics of Soma® in patients with renal impairment have not been evaluated. Since Soma® is excreted by the kidney, caution should be exercised if Soma® is administered to patients with impaired renal function. Soma® is dialyzable by hemodialysis and peritoneal dialysis.
- **Hepatic Impairment-**The safety and pharmacokinetics of Soma® in patients with hepatic impairment have not been evaluated. Since Soma® is metabolized in the liver, caution should be exercised if Soma® is administered to patients with impaired hepatic function.
- **Patients with Reduced CYP2C19 Activity**- Soma® should be used with caution in patients with reduced CYP2C19 activity. Published studies indicate that patients who are poor CYP2C19 metabolizers have a 4-fold increase in exposure to carisoprodol, and concomitant 50% reduced exposure to meprobamate compared to normal CYP2C19 metabolizers. The prevalence of poor metabolizers in Caucasians and African Americans is approximately 3-5% and in Asians is approximately 15-20%.
- **Gender**-Exposure of carisoprodol is higher in female than in male subjects (approximately 30-50% on a weight adjusted basis). Overall exposure of meprobamate is comparable between female and male subjects.

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[i] Medpointe Pharmaceuticals. Soma 250mg Prescribing information. Accessed at: http://www.soma250.com/pdf/full_prescribing_info.pdf. Last modified 9/2007.

Appendix J

Annual Review of Skeletal Muscle Relaxants

Oklahoma HealthCare Authority

November 2007

Introduction

In March of 2006, the DUR Board voted for the addition of the Skeletal Muscle Relaxants to the Product Based Prior Authorization Category. The current tier structure and approval criteria are as follows:

Skeletal Muscle Relaxants+		
Tier-1	*Tier-2*	*Hard PA*
Cyclobenzaprine (Flexeril®)		Carisoprodol (Soma®)
Baclofen (Lioresal®)		Carisoprodol w Aspirin
Tizanidine (Zanaflex®)		Carisoprodol, ASA, Codeine
Methocarbamol (Robaxin®)		Tizanidine (Zanaflex®) Caps
Chlorzoxazone (Parafon Forte®, Paraflex®)		Cyclobenzaprine ER (Amrix®) Caps
Orphenadrine (Norflex®)		Cyclobenzaprine 7.5mg (Fexmid®) Tabs
*Metaxolone (Skelaxin®)		

+Brand products are subject to the Brand Name Override where generic is available.
***Tier one due to Supplemental Rebate Participation**

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

1. FDA approved indication. Skeletal muscle relaxants are recommended as adjunct to rest, and/or physical therapy for the relief of musculoskeletal pain.
2. Documentation of failed withdrawal attempt within past three months defined as increase in pain and debilitating symptoms when medication was discontinued.
3. Failure with at least two Tier-1 medications within the past 90 days defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
4. Approvals will be for the duration of three months, except for clients with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of one year.

Carisoprodol or Carisoprodol combination products:

A cumulative 90 therapy day window per 365 days will be in place for these products, further approval will be based on the following:

1. An additional approval for 1 month will be granted to allow titration or change to a Tier-1 muscle relaxant, further authorizations will not be granted, or
2. Indication of multiple sclerosis, cerebral palsy, muscular dystrophy, and/or paralysis with approvals granted for the duration of one year.

Zanaflex® Capsules -Tizanidine tablets must be tried prior to consideration of the capsules. The capsules may be considered for approval if there is supporting information as to why the member cannot take the tablets.

Amrix® and Fexmid® - Approval is based on clinical documentation of inability to take other generically available forms of cyclobenzaprine tabs. Quantity limits are also set on both products.

Utilization

Trends in Utilization

	Fiscal Year 2006	Fiscal Year 2007	Percent Change	
Cost	$2,489,741.21	$1,543,693.40	Decreased	38.0%
Claims	104,835	71,621	Decreased	31.7%
Member	31,900	25,368	Decreased	20.5%
Units	7,446,002	4,633,191	Decreased	37.8%
Days	2,545,058	1,610,611	Decreased	36.7%
Per-diem	$0.98	$0.96	Decreased	2.0%

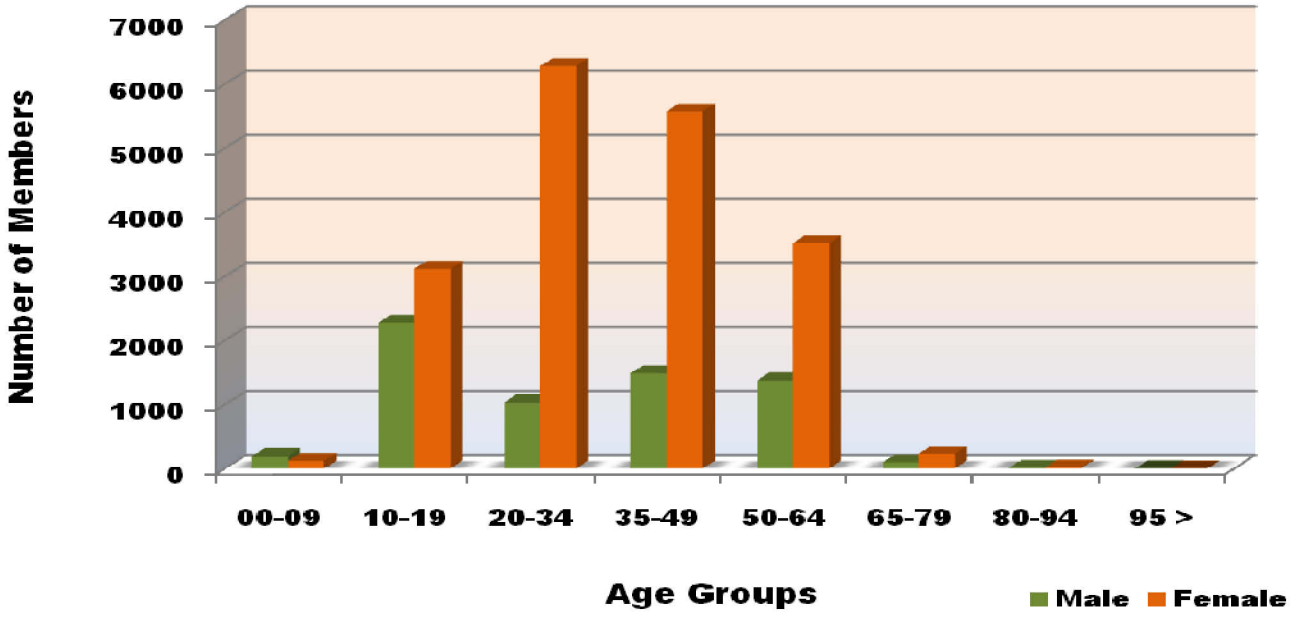
	Fiscal Year 2006 (Non-Duals)	Fiscal Year 2007	Percent Change	
Cost	$1,668,760.22	$1,543,693.40	Decreased	7.5%
Claims	71,966	71,621	Decreased	0.5%
Member	22,010	25,368	Increased	15.3%
Units	4,840,620	4,633,191	Decreased	4.3%
Days	1,681,289	1,610,611	Decreased	4.2%
Per-diem	$0.99	$0.96	Decreased	3.4%

Utilization trends of Carisoprodol Products

		Fiscal Year 2006*	Fiscal Year 2007	Percent Change	
Carisoprodol	Cost	$209,403.00	$96,727.64	Decreased	53.8%
	Claims	20,872	9,752	Decreased	53.3%
	Member	4053	4,383	Increased	8.1%
	Units	1,638,395	672,505	Decreased	59.0%
	Days	563,183	241,307	Decreased	57.2%
	Per-diem	$0.37	$0.40	Increased	7.8%
Car/aspirin	Cost	$3,320.76	$692.67	Decreased	79.1%
	Claims	234	53	Decreased	77.4%
	Member	63	41	Decreased	34.9%
	Units	14,767	2,553	Decreased	82.7%
	Days	5,233	875	Decreased	83.3%
	Per-diem	0.63	$0.79	Increased	25.4%
Car/asa/cod	Cost	$3,179.71	$1,600.86	Decreased	49.7%
	Claims	35	23	Decreased	34.3%
	Member	16	12	Decreased	25.0%
	Units	2,353	1,180	Decreased	49.9%
	Days	706	390	Decreased	44.8%
	Per-diem	4.50	$4.10	Decreased	8.9%

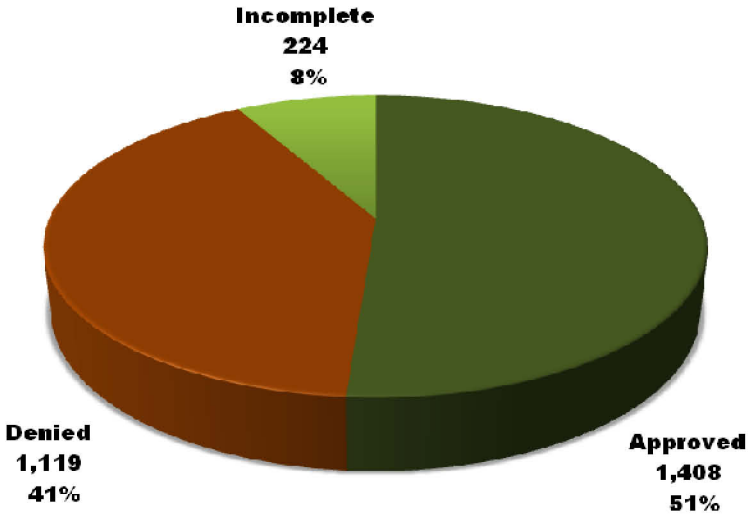
*Non-Dual utilization

Demographics of Members
Utilizing Skeletal Muscle Relaxants: FY 2007



Prior Authorization for the Class of Skeletal Muscle Relaxants

There were a total of 2,751 petitions submitted for this category during fiscal year 2007. This number includes regular petitions, Brand Name Override petitions, Quantity Limits and refill too soon overrides. The PA on Zanaflex® capsules has just been implemented recently in early 2007 so Carisoprodol products account for the majority of the petitions received in the class. The following shows the status of prior authorizations received:



Conclusion and Recommendations

The College of Pharmacy recommends the following:

- Continuation of the current criteria for the class of Skeletal Muscle Relaxants.
- Prior Authorization of Soma® 250mg (see 30 Day Notice to Prior Authorize Soma® 250mg).

Utilization of Skeletal Muscle Relaxants: FY 2007

MEDICATION	CLAIMS	MEMBERS	UNITS	DAYS	COST	PERDIEM
CYCLOBENZAPR TAB 10MG	31,678	14,942	1,636,139	647,526	$295,183.53	$0.46
CARISOPRODOL TAB 350MG	9,752	4,383	672,505	241,307	$96,727.64	$0.40
TIZANIDINE TAB 4MG	6,320	1,911	508,759	169,642	$74,580.38	$0.44
BACLOFEN TAB 10MG	5,875	1,380	561,420	165,947	$99,242.15	$0.60
SKELAXIN TAB 800MG	4,377	2,468	248,619	89,008	$685,533.11	$7.70
CYCLOBENZAPR TAB 5MG	3,360	2,150	136,413	52,771	$36,422.58	$0.69
BACLOFEN TAB 20MG	2,546	488	336,977	74,697	$78,161.77	$1.05
METHOCARBAM TAB 750MG	2,523	1,341	193,244	50,167	$26,681.22	$0.53
METHOCARBAM TAB 500MG	1,308	647	100,184	28,434	$13,430.32	$0.47
CHLORZOXAZON TAB 500MG	1,302	641	86,796	29,530	$9,994.36	$0.34
ORPHENADRINE TAB 100MG ER	1,280	744	53,007	26,954	$43,232.60	$1.60
TIZANIDINE TAB 2MG	944	334	73,559	25,839	$15,563.47	$0.60
ZANAFLEX CAP 4MG	152	93	11,292	3,815	$22,608.80	$5.93
ZANAFLEX CAP 6MG	95	39	6,831	2,441	$21,800.88	$8.93
ZANAFLEX CAP 2MG	32	15	2,390	864	$3,961.05	$4.58
BACLOFEN POW	19	7	1,579	616	$289.77	$0.47
SOMA TAB 350MG	13	1	1,560	390	$6,810.69	$17.46
LIORESAL INT INJ 40MG/20	11	3	55	91	$11,986.56	$131.72
FLEXERIL TAB 5MG	11	11	332	146	$572.84	$3.92
SKELAXIN TAB 400MG	9	9	330	96	$480.78	$5.01
CHLORZOXAZON TAB 250MG	9	1	900	225	$91.11	$0.40
CYCLOBENZAPR POW HCL	3	3	239	70	$33.96	$0.49
ORPHENADRINE TAB 100MG CR	1	1	60	30	$56.80	$1.89
LIORESAL INT INJ 10/20ML	1	1	1	5	$247.03	$49.41
TOTALS	**71,621**	**25,368**	**4,633,191**	**1,610,611**	**$1,543,693.40**	**$0.96**

Carisoprodol Combination Products

MEDICATION	CLAIMS	MEMBERS	UNITS	DAYS	COST	PERDIEM
CARISO/ASA TAB 200-235	53	2,553	875	41	$692.67	$0.79
CARISO/ASA/COD TAB	23	1,180	390	12	$1,600.86	$4.10

Utilization of Skeletal Muscle Relaxants: FY 2006

MEDICATION	CLAIMS	MEMBERS	UNITS	DAYS	COST	PERDIEM
CYCLOBENZAPR TAB 10MG	26,298	12624	1,325,894	528,782	$299,532.57	0.57
CARISOPRODOL TAB 350MG	20,872	4053	1,638,395	563,183	$209,403.00	0.37
BACLOFEN TAB 10MG	5,015	1120	519,996	142,830	$121,840.06	0.85
TIZANIDINE TAB 4MG	4,984	1483	413,852	133,784	$86,191.33	0.64
SKELAXIN TAB 800MG	3,715	2170	202,502	74,110	$536,178.54	7.23
FLEXERIL TAB 5MG	2,121	1488	85,876	32,969	$135,611.58	4.11
BACLOFEN TAB 20MG	2,044	368	205,897	60,117	$81,878.34	1.36
METHOCARBAM TAB 750MG	1,830	971	140,784	36,313	$21,475.56	0.59
ORPHENADRINE TAB 100MG ER	1,130	675	45,540	23,442	$39,229.45	1.67
CYCLOBENZAPR TAB 5MG	1,129	822	44,461	17,081	$62,223.09	3.64
CHLORZOXAZON TAB 500MG	986	508	69,751	23,242	$7,915.62	0.34
METHOCARBAM TAB 500MG	923	474	76,447	19,517	$10,941.65	0.56
TIZANIDINE TAB 2MG	707	209	55,396	20,834	$11,261.36	0.54
ZANAFLEX CAP 4MG	67	54	4,998	1,809	$8,418.15	4.65
ZANAFLEX CAP 6MG	41	18	3,312	1,233	$9,388.45	7.61
SKELAXIN TAB 400MG	36	36	1,923	487	$2,732.75	5.61
ZANAFLEX CAP 2MG	29	16	2,468	886	$3,539.31	3.99
BACLOFEN POW	13	4	2,084	247	$1,551.90	6.28
LIORESAL INT INJ 40MG/20	8	3	18	60	$16,073.84	267.90
SOMA TAB 350MG	6	1	720	180	$2,940.03	16.33
CYCLOBENZAPR POW HCL	5	5	62	61	$107.62	1.76
ORPHENADRINE TAB 100MG CR	4	4	230	115	$181.73	1.58
ORPHENADRINE INJ 30MG/ML	3	2	14	7	$144.29	20.61
TOTALS	**71,966**	**22,010**	**4,840,620**	**1,681,289**	**$1,668,760.22**	**$0.99**

Carisoprodol Combination Products*

MEDICATION	CLAIMS	MEMBERS	UNITS	DAYS	COST	PERDIEM
CARISO/ASA TAB 200-235	234	14,767	5,233	63	$3,320.76	$0.63
CARISO/ASA/COD TAB	35	2,353	706	16	$3,179.71	$4.50

*Non-Dual Utilization

Appendix K

FDA News

FOR IMMEDIATE RELEASE
November 5, 2007

Media Inquiries:
Peper Long, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Requests Marketing Suspension of Trasylol

The U.S. Food and Drug Administration (FDA) today announced that, at the agency's request, Bayer Pharmaceuticals Corp. has agreed to a marketing suspension of Trasylol, a drug used to control bleeding during heart surgery, pending detailed review of preliminary results from a Canadian study that suggested an increased risk for death.

FDA requested the suspension in the interest of patient safety based on the serious nature of the outcomes suggested in the preliminary data. FDA has not yet received full study data but expects to act quickly with Bayer, the study's researchers at the Ottawa Health Research Institute, and other regulatory agencies to undertake a thorough analysis of data to better understand the risks and benefits of Trasylol.

There are not many treatment options for patients at risk for excessive bleeding during cardiac surgery. Thus, FDA is working with Bayer to phase Trasylol out of the marketplace in a way that does not cause shortages of other drugs used for this purpose.

Until FDA can review the data from the terminated study it is not possible to determine and identify a population of patients undergoing cardiac surgery for which the benefits of Trasylol outweigh the risks. Understanding that individual doctors may identify specific cases where benefit outweighs risk, FDA is committed to exploring ways for those doctors to have continued, limited access to Trasylol.

Two weeks ago, FDA was notified that researchers with the Ottawa Health Institute stopped a study on Trasylol because the drug appeared to increase the risk for death compared to two other antifibrinolytic drugs used in the study. Antifibrinolytic drugs help slow the breakdown of blood clots and subsequent excessive bleeding. The preliminary data from this terminated study also suggested that fewer patients receiving the drug experienced serious bleeding events.

On Oct. 26, FDA issued an Early Communication about an Ongoing Safety Review of Trasylol in response to the Canadian study's termination. In 2006, FDA revised the labeling for Trasylol to strengthen its safety warning and limit its approved usage to patients at an increased risk for blood loss and blood transfusion during coronary bypass graft surgery.

#

Exenatide (marketed as Byetta) Information

FDA ALERT [10/2007]: FDA has reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta, a drug used to treat adults with type 2 diabetes. An association between Byetta and acute pancreatitis is suspected in some of these cases.

Healthcare professionals should instruct patients taking Byetta to seek prompt medical care if they experience unexplained persistent severe abdominal pain which may or may not be accompanied by vomiting. If pancreatitis is suspected, Byetta should be discontinued. If pancreatitis is confirmed, Byetta should not be restarted unless an alternative etiology is identified.

FDA has asked and the maker of Byetta, Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA is not advising practitioners to discontinue prescribing the product. FDA intends to update this sheet when additional information or analyses become available.

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

Healthcare Professional Information

- Information for Healthcare Professionals (10/16/2007)
- Labeling for Exenatide from Drugs@FDA

Patient Information

- Patient Information Sheet (5/2005)

Report Adverse Events to MedWatch

Back to Top Back to Drug Information

PDF requires the free Adobe Acrobat Reader

Date created: October 16, 2007

FDA News

FOR IMMEDIATE RELEASE

October 18, 2007

Media Inquiries:
Rita Chappelle, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Announces Revisions to Labels for Cialis, Levitra and Viagra

Potential risk of sudden hearing loss with ED drugs to be displayed more prominently

The U.S. Food and Drug Administration has approved labeling changes for erectile dysfunction (ED) drugs in the class that includes Cialis, Levitra, and Viagra, to display more prominently the potential risk of sudden hearing loss, and to guide consumers on what to do if they experience sudden problems with their hearing.

In addition, the FDA plans to require the same changes in labeling for the drug Revatio, also a member of this drug class known as phosphodiesterase type 5 (PDE5) inhibitors. Revatio is used to treat pulmonary arterial hypertension (PAH). PAH is a serious medical condition in which continuous high blood pressure in arteries of the lungs weakens the heart muscle and often leads to right heart failure and death.

The FDA asked manufacturers of these drugs to revise product labeling after a very small number of patients taking the PDE5 inhibitors reported sudden hearing loss, sometimes accompanied by ringing in the ears and dizziness.

“Because some level of hearing loss is usually associated with the aging process, patients on these drugs may not think to talk to their doctor about it,” said Janet Woodcock, M.D., FDA’s deputy commissioner for scientific and medical programs, chief medical officer, and acting director of its Center for Drug Evaluation and Research.

Patients taking Cialis, Levitra, or Viagra who experience sudden hearing loss should immediately stop taking the drug and seek prompt medical attention. Those using Revatio should continue taking their medication but should contact their health care provider for further evaluation. Because Revatio is used to treat a potentially life-threatening condition, the FDA does not recommend patients abruptly stop taking this medication but should consult their physician if they experience sudden problems with their hearing.

A case report in the April 2007 issue of the Journal of Laryngology & Otology involving sudden hearing loss in a man taking Viagra prompted the FDA to search the FDA’s Adverse Events Reporting System for instances of hearing loss and PDE5 inhibitors. The FDA found a total of 29 postmarketing reports of sudden hearing loss, both with and without accompanying ringing in the ears, vertigo, or dizziness. In most of the cases, the hearing loss involved one ear. The hearing loss was either a partial or complete loss of usual hearing. In approximately one third of cases, the event was temporary. In the remainder, the hearing loss was ongoing at the time of the report or the final outcome was not described.

Although no causal relationship has been demonstrated, the strong relationship between the use of these drugs and sudden hearing loss in these cases warrants revisions to the product labeling for this drug class.

Product Web sites, marketing and educational materials, and advertisements for PDE5 inhibitors will reflect the revised product labeling. The label revisions can be viewed at:

FDA News

Generic Initiative for Value and Efficiency (GIVE) Page

FOR IMMEDIATE RELEASE
October 4, 2007

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

FDA Announces Initiative to Bolster Generic Drug Program

Effort will streamline generic drug approval process; provide more options for consumers, health professionals

En Español

The U.S. Food and Drug Administration today outlined a program aimed at increasing the number and variety of generic drug products available to consumers and health care providers. Generic drugs generally cost less than their brand-name counterparts and competition among generics has been a key factor in lowering drug prices. The Generic Initiative for Value and Efficiency, or GIVE, will help the FDA modernize and streamline its generic drug approval process.

The agency approved or tentatively approved a record of 682 generic drugs products in fiscal year 2007, over 30 percent more than the previous year.

"To keep pace with the increasing number of generic drug applications, FDA will implement some changes to the generic drug approval process," said Gary Buehler, director of FDA's Office of Generic Drugs. "The GIVE plan outlines ways to maximize the use of our resources so that FDA can review and approve even more high quality generic drugs during the upcoming fiscal year than it did in 2007."

As part of the GIVE efforts, FDA is revising the review order for certain drug applications. For example, first generic products, for which there are no blocking patents or exclusivity protections on the reference listed drug, are identified at the time of submission for expedited review. This will mean that these products, for which there are currently no generic products on the market, may reach the consumer much faster.

FDA now has about 215 full-time staff working on the review of generic drug applications. Under GIVE, FDA will hire and train new generic drug reviewers and focus on enhanced use of electronic programs for handling drug submissions and internal documents. When possible, resources from other FDA departments will be engaged in the effort. As well, FDA will increase its communications with generic drug manufacturers and provide training on proper application submission to the industry in meetings and Webcasts.

Generic drugs undergo a rigorous scientific review to ensure that they are of high quality, safe, and effective. Generic drug manufacturers must demonstrate that a generic drug has the same dosage form, strength, route of administration, and conditions of use as the approved brand-name product. Generic drug manufacturers also must demonstrate bioequivalence, meaning they show that the drug delivers the same amount of its active ingredient in the same amount of time as the brand-name counterpart. Bioequivalence is a critical requirement for concluding that the original and generic drugs will produce the same therapeutic results.

VIDEO

Windows Media Player
56K | 150K | 300K

Real Player
56K | 150K | 300K

Audio Only (MP3)

Broadcast quality video for television stations only [238 MB]

Generic Initiative for Value and Efficiency

HTML | PDF (330K)
A diagram of how FDA is making generic drugs available more quickly.

PDF documents may be read

FDA's New GIVE Initiative

www.fda.gov/consumer/updates/GIVE_diagram100407.html

On Oct. 4, FDA announced the Generic Initiative for Value and Efficiency (GIVE), a new program aimed at optimizing the generic drug review process to increase efficiency. It was spurred by recent developments affecting FDA's generic drugs approval process.

1984

ABBREVIATED APPLICATIONS ALLOWED

The Drug Price Competition and Patent Term Restoration Act of 1984 put in place a process allowing generic-drug producers to submit abbreviated new drug applications to FDA's Office of Generic Drugs (OGD).

Qualifying generic drugs would be approved after a stringent review process.

2000–2007

INCREASE IN NUMBER OF GENERIC DRUG APPLICATIONS

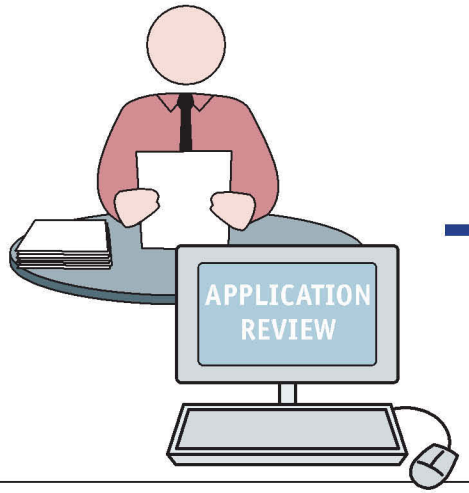
Factors such as advancements in medical science and a growing need and market for less expensive medications lead to a dramatic increase in the number of generic-drug producers, and in the number of new products they propose.

The number of abbreviated new drug applications submitted to OGD jumps.

OGD responds with various process improvements. These help it approve a record number of applications during fiscal years 2006 and 2007.

TODAY

'GIVE' IMPROVES FDA REVIEW PROCESS



Process improvements are combined into GIVE, a harmonized activity that will implement process improvements throughout OGD's entire system.

GIVE is focused on 3 main areas:

- Mobilizing staff efforts to increase review productivity.
- Optimizing the capacity and capability of all assets within OGD and leveraging wherever possible resources from other FDA components.
- Using every avenue possible to recruit, hire and train reviewers for our critical needs areas.

END RESULT

MORE APPROVED GENERIC DRUGS AVAILABLE

Consumers have timely access to more generic drugs.

Roche

IMPORTANT DRUG WARNING

October 2007

Subject: Important Changes in the CellCept® (mycophenolate mofetil) Prescribing Information – Use of CellCept is Associated with Increased Pregnancy Loss and Congenital Malformations/Change from Pregnancy Category C to Pregnancy Category D

Dear Health Care Professional:

Roche Laboratories Inc. would like to inform you that use of CellCept during pregnancy is associated with increased pregnancy loss and congenital malformations. This new important safety information in the CellCept Prescribing Information includes:

Boxed WARNING and WARNINGS:

- Increased risk of first trimester pregnancy loss and increased risk of congenital malformations, especially external ear and facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney.

PRECAUTIONS/Pregnancy:

- Changed to Pregnancy Category D based on positive evidence of fetal risk observed in postmarketing data and from the United States National Transplantation Pregnancy Registry, similar to malformations seen in animal reproductive toxicology studies.

PRECAUTIONS/Information for Patients:

- Informing females of childbearing potential about risks (pregnancy loss/malformations) associated with CellCept use during pregnancy.
- Requiring that female patients of childbearing potential must receive contraceptive counseling and must use effective contraception.
- Advising that a patient who is planning a pregnancy should not use CellCept unless she cannot be successfully treated with other immunosuppressant drugs.

The pregnancy category for CellCept has been changed from Category C (Risk of Fetal Harm Cannot be Ruled Out) to Category D (Positive Evidence of Fetal Risk). This change is a result of postmarketing data from the United States National Transplantation Pregnancy Registry (NTPR), and additional postmarketing data collected in women exposed to systemic MMF during pregnancy.

Roche Laboratories Inc. 340 Kingsland Street
Nutley, New Jersey 07110-1199

Based on postmarketing data from the NTPR and Roche worldwide adverse event reporting system, use of CellCept during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations, especially external ear and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney. In December 2006, the NTPR published data from prospective cases where 24 female transplant patients reported 33 pregnancies exposed to mycophenolate mofetil-containing regimens. There were 15 spontaneous abortions (45%) and 18 live-born infants. Four of these 18 infants had structural malformations (22%). In postmarketing data (collected from 1995 to 2007) on 77 women exposed to systemic MMF during pregnancy, 25 had spontaneous abortions and 14 had a malformed infant or fetus. Six of 14 malformed offspring had ear abnormalities. Because these postmarketing data are reported voluntarily, it is not always possible to reliably estimate the frequency of particular adverse outcomes. Similar structural malformations have been observed in preclinical animal reproductive toxicology studies.

During the development of CellCept, animal reproductive toxicology studies were performed to assess the potential for birth defects, and there were increased rates of fetal resorptions and malformations in the absence of maternal toxicity. Female rats and rabbits received mycophenolate mofetil doses equivalent to 0.02 to 0.9 times the recommended human dose for renal and cardiac transplant patients, based on body surface area conversions. In rat offspring, malformations included anophthalmia, agnathia, and hydrocephaly. In rabbit offspring, malformations included ectopia cordis, ectopic kidneys, diaphragmatic hernia, and umbilical hernia.

Women of childbearing potential should have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL within 1 week prior to beginning therapy. CellCept therapy should not be initiated until a negative pregnancy test is obtained. Women of childbearing potential (including pubertal girls and peri-menopausal women) taking CellCept must receive contraceptive counseling and use effective contraception. The patient should begin using her two chosen methods of contraception 4 weeks prior to starting CellCept therapy, unless abstinence is the chosen method. She should continue contraceptive use during therapy and for 6 weeks after stopping CellCept. Patients should be aware that CellCept reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness. A patient who is planning pregnancy should not use CellCept unless she cannot be successfully treated with other immunosuppressant drugs.

National Transplantation Pregnancy Registry: To monitor fetal outcomes of pregnant women exposed to CellCept, a National Transplantation Pregnancy Registry has been established. Physicians are encouraged to register patients by calling 1-877-955-6877.

Roche Laboratories will continue to monitor the safety of CellCept through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. You can assist us in monitoring the safety of CellCept by reporting adverse reactions to us at 1-800-526-6367, by FAX at 1-800-532-3931, or to FDA at www.fda.gov/medwatch, or by mail to MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20851.

Important Information about CellCept® (mycophenolate mofetil)

Indications:

CellCept is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. CellCept should be used concomitantly with cyclosporine and corticosteroids.

Contraindications:

Allergic reactions to CellCept have been observed; therefore, CellCept is contraindicated in patients with a hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product. CellCept Intravenous is contraindicated in patients who are allergic to Polysorbate 80 (TWEEN).

Important Safety Information:

WARNING:

Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Female users of childbearing potential must use contraception. Physicians should inform female patients that CellCept use during pregnancy is associated with increased rates of pregnancy loss and congenital malformations.

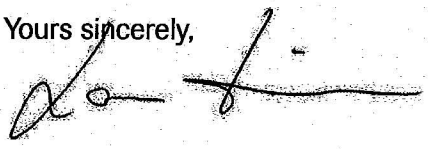
- Patients receiving immunosuppressive regimens involving combinations of drugs, including CellCept, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin.
- Oversuppression of the immune system can also increase susceptibility to infection, including opportunistic infections, and sepsis.
- CellCept can cause fetal harm when administered to a pregnant woman. A patient who is planning a pregnancy should not use CellCept unless she cannot be successfully treated with other immunosuppressant drugs. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patients should be apprised of the potential hazard to the fetus.
- Women of childbearing potential (including pubertal girls and peri-menopausal women) taking CellCept must receive contraceptive counseling and use effective contraception. The patient should begin using her chosen contraceptive method 4 weeks prior to starting CellCept therapy. She should continue contraceptive use during therapy and for 6 weeks after stopping CellCept. Two reliable forms of contraception must be used simultaneously unless abstinence is the chosen method. Patients should be aware that CellCept reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness.

- Severe neutropenia [absolute neutrophil count (ANC) <0.5 x 10^3/μL] developed in up to 2.0% of renal, up to 2.8% of cardiac, and up to 3.6% of hepatic transplant patients receiving CellCept 3 g daily. Patients receiving CellCept should be monitored for neutropenia. If neutropenia develops (ANC <1.3 x 10^3/μL), dosing with CellCept should be interrupted or the dose reduced, appropriate diagnostic tests performed, and the patient managed appropriately (see the **DOSAGE AND ADMINISTRATION** section of the CellCept Prescribing Information).
- Gastrointestinal bleeding (requiring hospitalization) has been observed in approximately 3% of renal, in 1.7% of cardiac, and in 5.4% of hepatic transplant patients treated with CellCept 3 g daily.
- Common adverse events that were reported in ≥20% of patients in CellCept group in controlled studies in prevention of renal, cardiac or hepatic allograft rejection are listed in Table 8 of the **ADVERSE REACTIONS** section of the CellCept Prescribing Information.

Please see the enclosed CellCept complete Prescribing Information, which includes additional information for Warnings, Precautions, and Dosage and Administration.

If you have any questions or require additional information regarding the use of CellCept, please contact the Roche Pharmaceuticals Service Center at 1-800-526-6367 from 8:30 AM to 6:00 PM Eastern Standard Time, Monday through Thursday, and 8:30 AM to 5:00 PM on Friday.

Yours sincerely,



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Vice President
Medical Affairs