Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

January 10, 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 – January 10, 2007**

DATE: January 3, 2007

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

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

Call to Order

Public Comment Forum

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

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

Action Item – Vote on Insomnia Product Based Prior Authorization – **See Appendix C.**

Action Item – Required Annual Review of Forteo® – **See Appendix D.**

Action Item – Required Annual Review of Elidel®/Protopic® – **See Appendix E.**

Action Item – Required Annual Review of Xopenex®/ Xopenex HFA® – **See Appendix F.**

Utilization Review of Asthma Medications – **See Appendix G.**

Disease Management ProgramUpdate – **See Appendix H.**

Lock-In Program Update and Study Information – **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – January 10, 2007 @ 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. December 13, 2006 DUR Minutes – Vote
B. December 13, 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 August 2006
B. Retrospective Drug Utilization Review Response for June 2006
C. Medication Coverage Activity Audit for December 2006
D. Help Desk Activity Audit for December 2006

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

5. Action Item – Vote on Insomnia Product Based Prior Authorization – See Appendix C.

A. Background
B. Product Comparison
C. COP Recommendations

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

6. Action Item – Required Annual Review of Forteo® – See Appendix D.

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

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

7. Action Item – Required Annual Review of Elidel®/Protopic® – See Appendix E.

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

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

8. Action Item – Required Annual Review of Xopenex® – See Appendix F.

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

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

9. Utilization Review of Asthma Medications – See Appendix G.

A. Background
B. Utilization Review
C. Emergency Department Utilization
D. COP Recommendations

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

10. Disease Management Program Update – See Appendix H.

A. Program Summary
B. Health Inventory Charts
C. Education Initiatives

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

11. Lock-In Program Update and Study Information – See Appendix I.

A. Background
B. Program Update
C. Study Information

12. FDA and DEA Updates – See Appendix J.

13. Future Business

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

14. Adjournment

APPENDIX A

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

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Mark Feightner, D.Ph.	X	
Dorothy Gourley, D.Ph.	X	
Kyle Hrdlicka, D.O.		X
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.	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: n/a		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Alex Easton, M.B.A./ Pharmacy Operations Manager		X
Mike Fogarty, J.D., M.S.W./Chief Executive Officer	X	
Nico Gomez, Director of 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	
Jill Ratterman, D.Ph./Pharmacy Specialist		X

OTHERS PRESENT:

Alan Blakeney, Inspire Pharm
David Williams, Forest
Jim Dunlap, Eli Lilly
Ron Schnare, Abbott
Paul Sparks, Allergan
Debbie Hayes, Sanofi-Aventis
Aliza Tomlinson, OMI
Jonathan Klock, GSK
Steve Higgins, TAP Pharmaceuticals
Mary Beth Webb, Boehringer-Ingelheim
Laura Mitchell, Purdue Pharma
Kay Ruble, FKG
Scott Mullins, Sanofi

PRESENT FOR PUBLIC COMMENT:

Dan Garcia, Pharm.D., Takeda Pharmaceuticals	Agenda Item 8
Stanley Muenzler, M.D.; Muenzler Opthamalogy PA	Agenda Item 11

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

1A: Roll Call

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

ACTION: NONE REQUIRED.

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

Dr. McNeill acknowledged speakers for Public Comment for Agenda Items 8 and 11.

ACTION: NONE REQUIRED.

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

3A: November 8, 2006 DUR Minutes

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 4: **APPROVAL OF 2007 DUR MEETING DATES**

4A: Approval of 2007 DUR Meeting Dates

DUR Board Meetings will be held the second Wednesday of each month, except for the February 2007 meeting which will be held on Thursday, February 15, 2007.

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

ACTION: MOTION CARRIED.

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

5A: Retrospective Drug Utilization Review Report: July 2006

5B: Retrospective Drug Utilization Review Response: May 2006

5C: Medication Coverage Activity Report: November 2006

5D: Help Desk Activity Report: November 2006

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF PLAVIX®**

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF BLADDER PRODUCTS**

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF BENZODIAZEPINES/HYPNOTICS**

For Public Comment, Dan Garcia, Pharm.D.. Good evening. I'm Dr. Daniel Garcia and I'm a regional scientific manager for Takeda Pharmaceuticals. It's good to see familiar faces. I have presented this before but felt that I should probably present again because Rozerem is a unique product. Unlike the other hypnotics that are on the market, it is the only non-benzodiazepine receptor agonist on the market. Everything else is Schedule IV because they are agonists. Rozerem on the other hand, is a melatonin MT1, MT2 receptor agonist which makes it unique. There's really not another product out there and I think consumers, physicians may get a little confused because everything kind of gets lumped into sedative of nights and you know, as we all know, sedative hypnotics, really the only difference is in dose. Because if you take a sedative, if you go to a higher dose, you will, the patient will go to sleep. There's no doubt about that. So that is the reason that I'm here today to emphasize some of these main differences. I think it's important to talk about Rozerem or ramelteon is, but also what it's not. And it certainly does not fit into the regular category. Now when Takeda had got approval for this product, it's approval was only as a hypnotic. And also interestingly enough, it is not listed as a sedative. It is only listed as a hypnotic. The FDA recognizes that this product is different. Studies are under way to possibly get another indication for it, possibly for circadian rhythm dysfunction, but that is not on the table tonight. That is something that might happen or may not, as the FDA says, until we approve it it's not a drug until we prove that you can't use it for this indication, or you should use it with extreme care. So I just wanted to bring out some of those things. As you know, it is metabolized in cytochrome 1A2 system and strong inhibitors of this system such as fluvoxamine should not

be combined with remalteon because you've got a much higher apparent effect from this drug. However in other 1A2 inhibitors such as some of the antidepressants such as fluoxetine, no such effects occurred, so it is not a class effect. One of the other nice things about Rozerem or ramelteon is that it's a one dose, 8 mg for all patients. It can be used in patients that have renal impairment, including patients that are on hemodyalysis; however cannot be used, should be used in caution with patients that have severe hepatic impairment. It is OK to use in mild to moderate impairment. And it has proven its' efficacy. It's been on the market for a little over a year now and it, one of the things that many patients, many physicians like about it is that it has no abuse potential. It was tested at doses of 160 mg which is twenty times the dose that's normally given to patients, and they found no residual effect. They found patients didn't like it any better than placebo. There was no drug seeking for this drug. There was tests like balance the next day proved that it was equal to efficacy, to placebo, as opposed to increasing doses alprazolam. So it clearly has a unique place in the armament of physicians. Are there any questions? Could I ask a question? I noticed that one of the recommendations that was presented for you to, paper that I have here, that recommendation was to split the categories into benzodiazepines, non-benzodiazepine hypnotics was the one category, and the other one was a non-hypnotic benzodiazepine anxiolytic and like I said earlier, all drugs in this category, it's just a matter of dose. So I'm a little confused by that and maybe we'll get some clarification because all these areas are hypnotics at doses. And I wanted to also bring up one other idea, and that was that ramelteon or Rozerem is a unique drug. It doesn't fit the standard classification. However, within the very near future there will be another melatonin agonist that will be hopefully approved by the FDA, and shortly after that will be an H1 antagonist also on the market, that will be marketed as hypnotic. And then after that, there will be an indirect gamma agonist on the market, so just for consideration, obviously I'm not making any recommendations as to how the committee should do. I mean it's your committee. I'm just here to give testimony, but just for consideration. Thank you very much.
Materials included in agenda packet; presented by Dr. Browning.
Dr. Meece moved to table to January or February 2007; seconded by Dr. Bell.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF NON-SEDATING ANTIHISTAMINES**
Materials included in agenda packet; presented by Dr. Patel.
Dr. Meece moved to approve as submitted; seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 10: **ANNUAL REVIEW OF FENOFIBRATES**
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **UTILIZATION REVIEW OF OCULAR ALLERGY PRODUCTS**
For Public Comment, Stanley Muenzler, M.D.: Thank you very much. I'm Dr. Stan Muenzler. I'm a private practice ophthalmologist in Oklahoma City with a special interest in external disease of the eye. I'm also a medical professor of ophthalmology at the University of Oklahoma and Dean A. McGee Eye Institute. (unintelligible) interest and appreciate your allowing us to be here this evening. I'm here speaking on behalf of Inspire Pharmaceutical Company which you may or may not know is a very small, research primarily, company in the Research Triangle, Durham, North Carolina. Most of their research has been centered around cystic fibrosis. As a result of that, they've come out with their only product for eye, which is a combination of antihistamine, mast cell stabilizer and anti-inflammatory drug. They also are centered around research for dry eye and other products eventually. They are a small company having only 64 sales reps across the whole country. This is in contrast to what I was told the other day from someone from Pfizer that said they had 222 reps in Oklahoma. Very small company that has a product that is the number two selling prescription drop for ocular allergy. Ocular allergy seems like it's benign, but in a large scale, there are millions of work hours lost from allergies in general and the people that have allergies in general, 70-80% of them have ocular allergies that can be very debilitating. So this is an important subject and I'm here primarily to request that this committee consider removing the request for prior authorization for Elestat for reasons that hopefully, when I've told you, are obvious. There are products that are becoming over the counter that one drug has been prescription, Zaditor, which is now going to be over the counter. All of the drugs except a drug manufactured by Alcon Laboratories in Fort Worth which is a $4.4 billion dollar ocular and ear, nose and throat company only are insufficient mast cell stabilizers in the eye. They stabilize mast cells (unintelligible), where all this happens. There are 50 million mast cells in the (unintelligible) of the eye and if those aren't stabilized, this process continues to go on and on and on. The Elestat drug is relatively new in the market, released I think only three or four years ago and yet it's in second place as far as prescriptions are concerned and this is in spite of a very small sales force, very little advertising, etc., etc. The number one drug is Patonol. It's the second largest selling prescription drug in the world for opthamic use, number one being Xalatan, an anti-glaucoma drug. So this is kind of why we're here and hopefully we can, I'd be happy to answer questions about this and I feel this .....
Dr. Kuhls: I have a question. Do you have, since you're talking for a small research company today, do you have any comparative data and good clinical controlled trials looking at Elestat versus any of these other products to show that your product is better?
Dr. Muenzler: Yes.
Dr. Kuhls: Or is all your studies looking comparative versus placebo?
Dr. Muenzler: No, they're all versus other, all the other drugs that are available. None of the present over the counter drugs have been compared. All of the other prescription drugs .....

Dr. Kuhls: So Elestat's been compared in large clinical trials to which one of these?
Dr. Muenzler: I don't know where you're (unintelligible) available.
Dr. Kuhls: Ophthalmic that are there.
Dr. Muenzler: Elestat has been compared to I believe, I know for certain it's been compared to Optivar, Zaditor, to Emadine, to Livostin, not the bottom four. They've banned Patanol, and Patanol since it was the very first prescription drug for allergies, has had more clinical trials than any of the other drugs all together.
Dr. Kuhls: And you have data that's saying that your product is clinically better?
Dr. Muenzler: Yes. Better in terms of more comfort, more rapid relief of itching, redness, watering, swelling, etc. All of the symptoms of allergy in the eye. We have a handout if you wish to look at some of this information.
Dr. McNeill: Yes, could we? Could we get a copy of this? Any other questions from the Board?
Dr. Muchmore: Yeah, why have we abandoned cromolyn sodium? Years ago, it was highly effective for allergic conjunctivitis.
Dr. Muenzler: Well, it no longer is and I've been around doing this for over thirty years. I've seen all these things come and go. The problem with allergy is everything works for a little while and over the long term, the reason these drugs, the reason Zaditor is going to go over the counter is because the company cannot document the fact that this drug is superior to any of the other products, the two primarily prescribed products. It can't go through the FDA and show in clinical trials that it's beneficial. It is not an adequate ocular mast cell stabilizer; this is the main issue in these drugs. Things like Naphcon-A, Vasacon-A and those drugs that have been around for a long time, these are vasoconstrictors and antihistamines and make the eye feel better for a little while. Visine gets the red out, same thing. But in the long run, patients have rebound. Their eyes become redder. All of these products have preservatives in them and they're not (unintelligible). So they cause a lot of toxicity to the ocular surface.
Dr. Kuhls: I would like just to make a comment. Of the handouts that you did hand out, the one, only trial that I see in here looking at it, compared to Optivar and Zaditor, you know, showed that maybe it was a little more comfortable but it hasn't shown anything that I see that was tremendously more effective.
Dr. Muenzler: There are other papers. I'm not, I didn't compile this and there are other papers that I've reviewed.
Dr. Kuhls: And that acutally this study was only forty patients.
Dr. Muenzler: Well, very few of these, there are very few clinical studies that have involved thousands of patients, in fact none.
Dr. Kuhls: Right, but that's my concern is that since there's not large clinical studies comparatively, you know the statement that sits there and says this product is so much better that we need to use it and not look at cost. If we have a product that's more effective than another product and it's more expensive, I'd rather use the more expensive better product. But in a situation where we got a trial of forty people saying that maybe it's a little bit more comfortable and it's more expensive, and we don't have true definite efficacy data, then it's hard for me to sit there and say we need to pick that, based on forty patients.
Dr. Muenzler: Well, I agree with you. I wouldn't, I didn't put this together and wouldn't have put it together. I think it's a naive group of papers. There are other papers that I have reviewed that do indeed show this superior to the products that are mentioned. And most of these clinical trials, clinical trials have been Zaditor, Elestat and (unintelligible) challenge, allergy challenge model, a CAP model for them.
Dr. Kuhls: Well I'm not interested in looking at CAP model data and comparing the amount of patients that are being treated with it, so, thank you.
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **NEW FOR 2007**
Materials included in agenda packet; presented by Dr. Flannigan.
ACTION: NONE REQUIRED.

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

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

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

The University of Oklahoma College of Pharmacy

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

Memorandum

Date: January 3, 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 December 13, 2006.

Recommendation 1: Vote on 2007 DUR Meeting Dates

MOTION CARRIED by unanimous approval.

Meetings are held the second Wednesday of each month.

January 10, 2007
February 15, 2007*
March 14, 2007
April 11, 2007
May 09, 2007
June 13, 2007
July 11, 2007
August 08, 2007
September 12, 2007
October 10, 2007
November 14, 2007
December 12, 2007

*This meeting will be held on Thursday.

Recommendation 2: Annual Review of Plavix®

No Action Required

At this time, the College of Pharmacy does not recommend any changes to the prior authorization of Plavix®.

Recommendation 3: Annual Review of Bladder Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends moving extended-release oxybutynin to Tier 1 when a SMAC is applied.

Recommendation 4: Annual Review of Benzodiazepines/Hypnotics

TABLED by majority approval.

1. Split category into:
   a) benzodiazepine/non-benzodiazepine hypnotics and
   b) non-hypnotic benzodiazepine anxiolytics.

2. Develop new criteria for both categories.

Recommendation 5: Annual Review of Oral Allergy Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Allegra® Suspension to the Tier 2 category once it becomes available.

Recommendation 6: Annual Review of Fenofibrates

No Action Required

The College of Pharmacy recommends continued monitoring of this PBPA category.

APPENDIX B

Retrospective Drug Utilization Review Report

Claims Reviewed for August 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	42,839	54,654	679,562	29,180
Limits which were applied	Established, Major, Males 41-150 years	Antianxiety Agents, Males and Females, age 22-32 years	Contraindicated, Males and Femalesm, Age 22-45 years, Drug Dependence/Abuse	High dose, Duration, Oxazolidinones, Statins, Males and Females, Age 0-150
Total # of messages after limits were applied	54	167	29	31
Total # of members reviewed after limits were applied	100	147	23	31

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
137		71	

Retrospective Drug Utilization Review Report

Claims Reviewed for June 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females Age 0-20	Narcotics, Females, Age 49-51	Contraindicated, Age 30-31, Pregnancy	High dose, Carbamates, Tingabine, Hydantoins, Oxazolidinedions, Succinimides, Valproic Acid, Miscellaneous Anticonvulsants, Males and Females, Age 66-150

Response Summary (Prescriber)
Letters Sent: 138
Response Forms Returned: 79

The response forms returned yielded the following results:

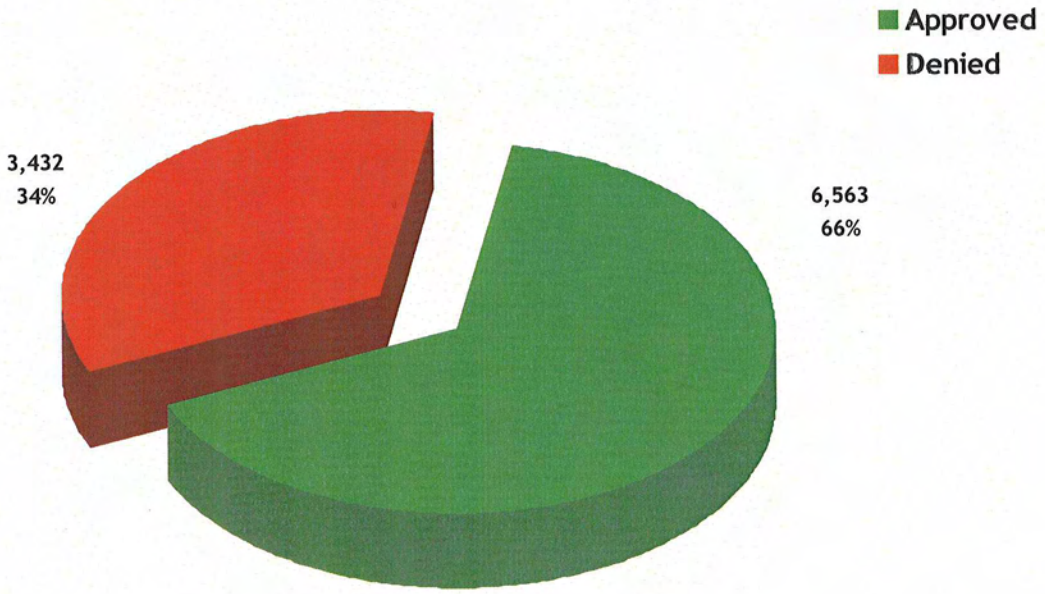
12 (15%)	*Record Error—Not my patient.*
14 (18%)	*No longer my patient.*
6 (8%)	*Medication has been changed prior to date of review letter.*
14 (18%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
18 (23%)	*I am aware of this situation and will plan to continue monitoring therapy.*
15 (19%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 115
Response Forms Returned: 87

The response forms returned yielded the following results:

2 (2%)	*Record Error—Not my patient.*
10 (11%)	*No longer my patient.*
6 (7%)	*Medication has been changed prior to date of review letter.*
26 (30%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
31 (36%)	*I am aware of this situation and will plan to continue monitoring therapy.*
12 (14%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
December 2006



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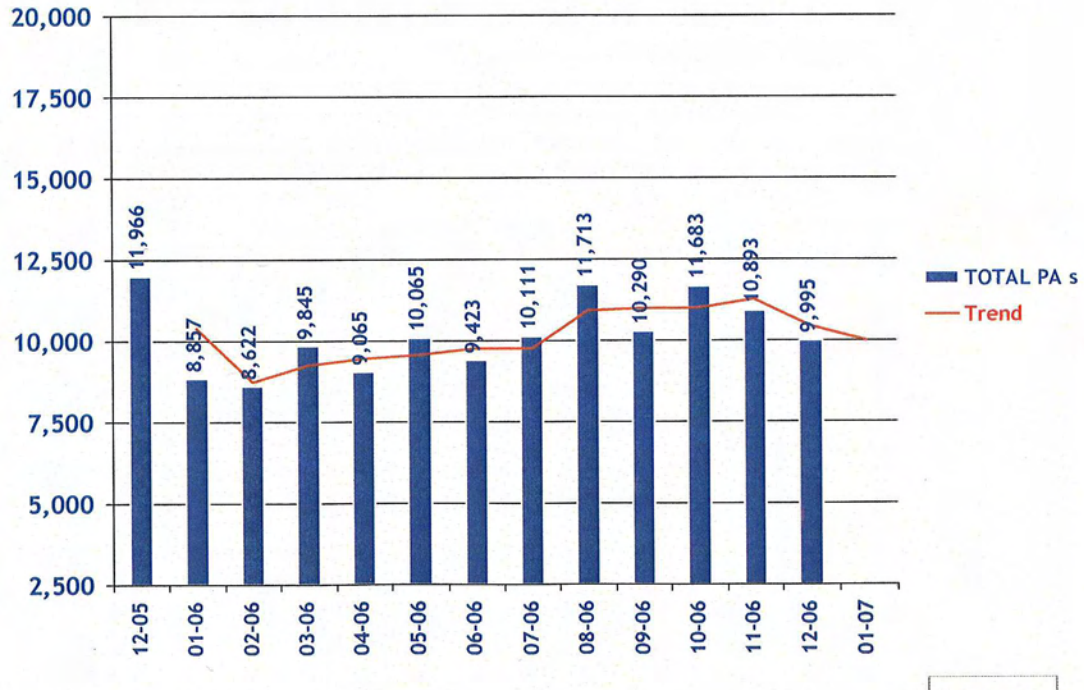
PRIOR AUTHORIZATION REPORT
December 2005 - December 2006



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

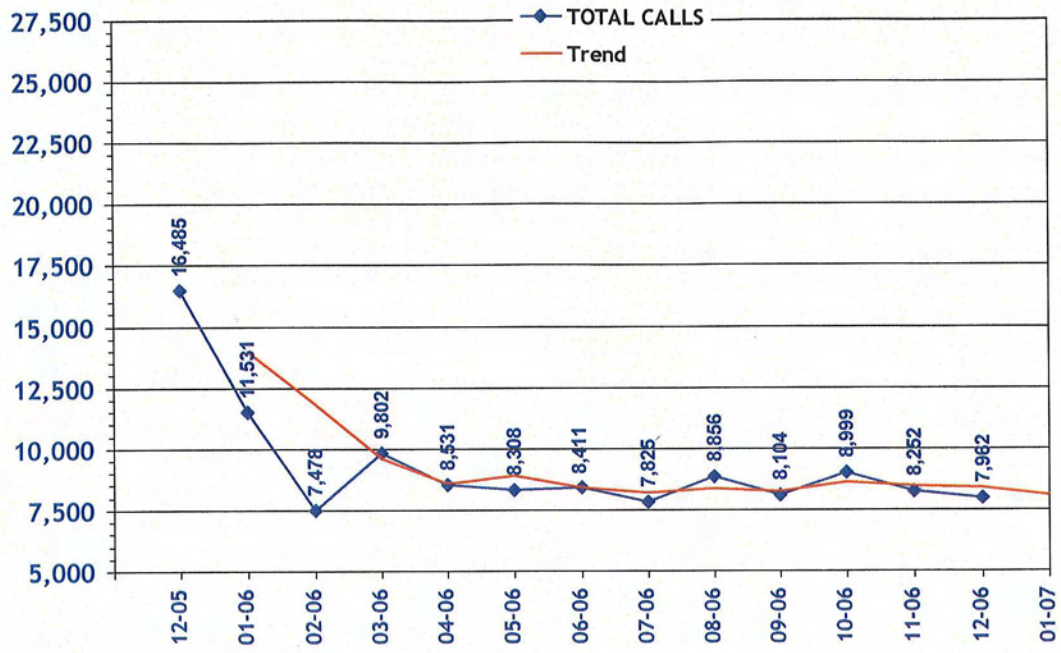
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	123	13	12	25
Angiotensin Receptor Antagonist	365	23	52	75
Antidepressant	284	205	493	698
Antihistamine	98	905	542	1447
Antiulcers	19	10	14	24
Anxiolytic	92	3043	518	3561
Calcium Channel Blockers	205	21	67	88
Growth Hormones	171	27	5	32
HTN Combos	319	12	15	27
Hypnotics	89	378	146	524
Nsaids	289	26	54	80
Plavix	361	203	32	235
Stimulant	209	717	312	1029
Others	115	976	1170	2146
Emergency PAs		4	0	4
Total		**6563**	**3432**	**9995**
Overrides				
Brand	263	28	25	53
Dosage Change	6	259	32	291
High Dose	3	1	0	1
Lost/Broken Rx	10	84	6	90
Nursing Home Issue	4	16	0	16
Other	2	36	20	56
Quantity vs. Days Supply	178	208	166	374
Stolen	2	2	1	3
Wrong D.S. on Previous Rx	3	1	6	7
Overrides Total		**635**	**256**	**891**

Denial Reasons

Lack required information to process request.	2720
Unable to verify required trials.	1228
Not an FDA approved indication/diagnosis.	210
Does not meet established criteria.	175
Member has active PA for requested medication.	153
Considered duplicate therapy. Member has a prior authorization for similar medication.	145
Requested dose exceeds maximum recommended FDA dose.	77
Medication not covered as pharmacy benefit.	34
Duplicate Requests	639
* Changes to existing	889

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

CALL VOLUME MONTHLY REPORT
December 2005 - December 2006



PHARMACY Management Consultants

APPENDIX C

Vote on Insomnia Product Based Prior Authorization

Oklahoma Health Care Authority
January 2007

Background

Current insomnia product criteria:

- The first 90 therapy days of insomnia medication is covered without prior authorization.
- After the first 90 days, members may continue to receive an insomnia medication if daytime dosing of benzodiazepines does not exceed three times daily. Prior authorization is granted every 90 days as long as the above criterion is met.
- There are currently quantity limits on temazepam, Lunesta®, Rozerem®, Sonata®, Ambien® and Ambien CR®.

As of January 1, 2006, all Dual Eligible members are covered under Medicare Part D except for excluded categories like the benzodiazepines which continue to be covered by Medicaid. Non-benzodiazepine insomnia medications are no longer covered by Medicaid, but fall under Part D coverage.

Product Comparison

Recently there have been two major evidence based reviews of insomnia products by health care research organizations: National Institute for Clinical Excellence (NICE) (United Kingdom) performed by the University of Liverpool in 2003 and the Oregon Evidence-based Practice Center, Oregon Health and Science University in 2006.

NICE has made the following guidance recommendations about the use of zaleplon, zolpidem and zopiclone to treat insomnia[1].

- When, after due consideration of the use of nonpharmacological measures, hypnotic drug therapy is considered appropriate for the management of severe insomnia interfering with normal daily life, it is recommended that hypnotics should be prescribed for short periods of time only, in strict accordance with their licensed indications.
- It is recommended that, because of the lack of compelling evidence to distinguish between zaleplon, zolpidem, zopiclone or the shorter-acting benzodiazepine hypnotics, the drug with the lowest purchase cost (taking into

account daily required dose and product price per dose) should be prescribed.

- It is recommended that switching from one of these hypnotics to another should only occur if a patient experiences adverse effects considered to be directly related to a specific agent. These are the only circumstances in which the drugs with the higher acquisition costs are recommended.
- Patients who have not responded to one of these hypnotic drugs should not be prescribed any of the others.

Oregon reviewed 181 publications (including 8 head-to-head trials). The table below summarizes their findings for the newer insomnia drugs. There is some data comparing newer drugs to benzodiazepines. Zolpidem was more effective than flurazepam, but similar to temazepam and triazolam. Zaleplon was similar in efficacy to triazolam[2].

Summary of Short-Term Efficacy by Drug and Outcome[a]

	Outcome	Shorter Sleep Latency	Longer Sleep Duration	Fewer Number of Awakenings	Improved Sleep Quality	Daytime Alertness	Less Rebound Insomnia
Eszopiclone	**Direct Evidence[b]**	Similar to zolpidem[d]		Similar to zolpidem[d]		Similar to zolpidem	
	Indirect Evidence[c]	Similar to zolpidem	Better than zolpidem				
Zaleplon	**Direct Evidence**	Better than zolpidem		Similar to zolpidem		Similar to zolpidem	Better than zolpidem
	Indirect Evidence	Better than zolpidem					
Zolpidem	**Direct Evidence**	Similar to eszopiclone[d]	Better than zaleplon	Similar to zaleplon	Better than zaleplon	Similar to zaleplon and eszopiclone	
	Indirect Evidence	Similar to eszopiclone					
Zolpidem Extended Release	**Direct Evidence**						
	Indirect Evidence						
Ramelteon	**Direct Evidence**						
	Indirect Evidence	Similar to zolpidem[d] and eszopiclone[d]					

[a] Adapted from: Carson S, Yen P-Y, McDonagh MS. Drug Class Review on Newer Drugs for Insomnia, pg 31. 2006. Available at: http://www.ohsu.edu/drugeffectiveness/reports/final.crm.
[b] Data from head-to-head trials. [c] Data from active- and placebo-controlled trials. [d] **Measured via PSG in a sleep laboratory.**

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[1] National Institute of Clinical Excellence. Zaleplon, zolpidem and zopiclone for the short-term management of insomnia. April 2004. Available at: http://www.nice.org.uk/page.aspx?o=ta077guidance.

[2] Carson S, Yen P-Y, McDonagh MS. Drug Class Review on Newer Drugs for Insomnia. 2006. Available at: http://www.ohsu.edu/drugeffectiveness/reports/final.crm.

Recommendations

The College of Pharmacy recommends the following changes to the current anxiolytic/hypnotic prior authorization category:

1. Split category into
   a) benzodiazepine/non-benzodiazepine insomnia products and
   b) non-hypnotic benzodiazepine anxiolytics.

2. New Insomnia Product Based Prior Authorization category:

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

Tier 1[a]	Tier 2	Tier 3
Estazolam[b] temazepam[b] flurazepam[b] zolpidem[c]	Lunesta® Sonata® Rozerem® triazolam Restoril® 7.5 and 22.5 mg	Ambien CR®

[a]Brand products would still require a brand name override.
[b]Covered for Dual-Eligible members.
[c]Tier 1 once generic becomes available.

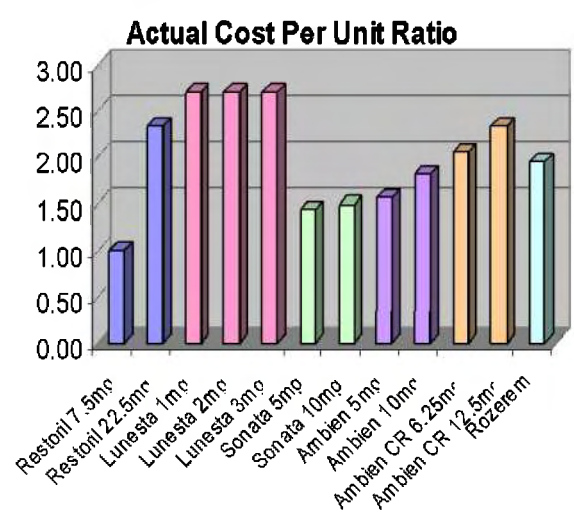
Tier 2 Insomnia Approval Criteria:
1. Minimum of 30 day trial with at least two Tier 1 products (including zolpidem once generic is available) and clinical documentation of attempts to correct any primary cause for insomnia.
2. FDA approved diagnosis.
3. No concurrent anxiolytic benzodiazepine therapy greater than TID dosing and no concurrent ADHD medications.
4. Approvals granted for 6 months.

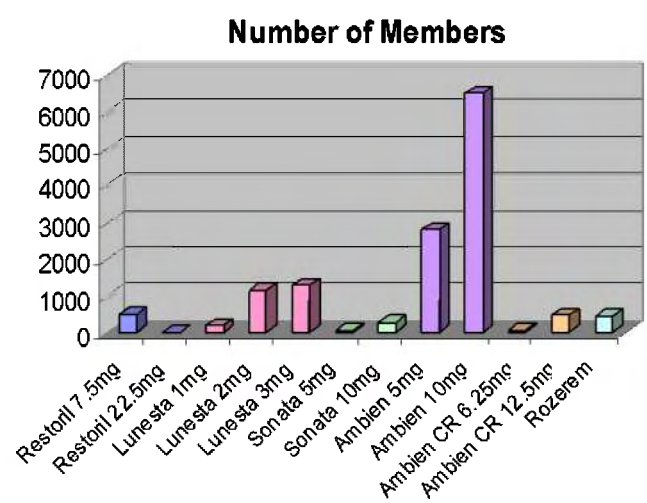
Tier 3 Insomnia Approval Criteria:
1. Minimum of 30 day trial with at least two Tier 2 products and clinical documentation of attempts to correct any primary cause for insomnia.
2. FDA approved diagnosis.
3. No concurrent anxiolytic benzodiazepine therapy greater than TID dosing and no concurrent ADHD medications.
4. Approvals granted for 6 months.

Also, age limits placed based on FDA approved limits and quantity limits of 30 units for a 30 day supply.

Utilization FY06

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Members	Per Diem
Estazolam 1mg	97	3,087	2,533	1.22	$1,248.14	36	$0.50
Estazolam 2mg	225	6,693	6,768	1.00	$3,583.21	66	$0.53
Flurazepam 15mg	150	4,915	3,940	1.25	$913.89	54	$0.23
Flurazepam 30mg	448	14,055	13,922	1.01	$2,541.46	140	$0.18
Doral 15mg	8	600	600	1.00	$2,217.79	2	$3.70
Restoril 7.5mg	1,679	49,674	47,459	1.05	$145,868.03	501	$3.07
Temazepam 7.5	18	675	575	1.17	$465.91	8	$0.81
Temazepam 15mg	9,691	323,031	280,425	1.15	$60,527.04	3,198	$0.22
Restoril 22.5mg	11	390	390	1.00	$1,163.68	6	$2.98
Temazepam 30mg	11,683	384,474	371,008	1.04	$79,624.41	3,037	$0.21
Triazolam 0.125mg	93	2,909	2,084	1.40	$972.10	44	$0.47
Halcion 0.25mg	10	600	300	2.00	$905.82	1	$3.02
Triazolam 0.25mg	1,417	42,612	32,451	1.31	$15,662.99	610	$0.48
Lunesta 1mg	449	12,027	12,049	1.00	$40,878.58	213	$3.40
Lunesta 2mg	2,324	62,985	63,515	1.00	$214,776.72	1,173	$3.38
Lunesta 3mg	3,210	91,840	92,054	1.00	$312,225.20	1,295	$3.40
Sonata 5mg	175	4,752	4,777	1.00	$12,553.90	83	$2.63
Sonata 10mg	794	24,800	21,182	1.17	$76,368.11	273	$3.61
Ambien 5mg	6,671	183,107	177,837	1.03	$554,742.56	2,818	$3.12
Ambien 10mg	19,750	540,391	546,863	1.00	$1,735,463.25	6,512	$3.17
Ambien CR 6.25mg	132	3,556	3,556	1.00	$11,414.92	88	$3.21
Ambien CR 12.5mg	892	25,252	25,282	1.00	$80,021.63	483	$3.16
Rozerem	768	21,872	22,029	1.00	$56,239.59	453	$2.55
Total	**60,695**	**1,804,297**	**1,731,599**		**$3,410,378.93**		**$1.97**





Reflects ratios of cost per unit after rebates, not representative of any actual dollar amounts.

APPENDIX D

Required Annual Review of Forteo®

Fiscal Year 2006

Oklahoma Health Care Authority
January 2007

Current Prior Authorization Criteria

- Postmenopausal women at high risk for fractures, or that cannot tolerate, are allergic to, or have failed to improve while on other agents.
- Men with primary or hypogonadal osteoporosis.
- Appropriate ICD-9 code (733.00, 733.01, etc).
- No concurrent use of Forteo® with other agents until more information is available regarding the safety and efficacy of such use.
- Minimum 3 month trial with one other agent (Fosamax®, Evista®, estrogen, Calcimar® or Miacalcin® unless contraindicated, intolerant, or allergic) ending in the past 30 days.
- PA approval for one month's supply per fill for duration of 1 year, with a maximum duration of 2 years.

Product Summary

Forteo® - approved December 2002 and available since January 2003.

- The first agent approved for the treatment of osteoporosis that stimulates new bone formation.
- Administered 20mcg/dose SQ once per day.
- Increases BMD, reconstructs bone architecture and has the same effects on the bone and kidney as endogenous parathyroid hormone.
- FDA labeled indications:
  - men with primary or hypogonadal osteoporosis,
  - postmenopausal women with osteoporosis, and
  - both men and women who
    - are at high risk for fractures,
    - have a history of fractures,
    - have multiple risk factors for the development of fractures,
    - cannot tolerate other therapies, or
    - have failed other therapies.
- Adverse effects similar to other osteoporosis medications.

Utilization

For the period of July 2005 through June 2006, a total of 138 members received Forteo®.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Members	Per Diem
Forteo® 750 sol	**514**	**1,601**	**14,752**	**0.11**	**$328,431.01**	**138**	**$22.26**

244 total petitions were submitted for Forteo® during specified time period for 94 members:

Approved 107
Denied 65
Incomplete 72
65 denied or incomplete petitions were subsequently approved.

	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Members	Per Diem
Duals	**451**	**1,412**	**13,043**	**0.11**	**$290,911.29**	**120**	**$22.30**
Non-Duals	**63**	**199**	**1,709**	**0.12**	**$ 37,519.72**	**18**	**$21.95**

Total Cost FY '06	**$328,431.01**
Total Cost FY '05	*$391,804.75*
Total Claims FY '06	**514**
Total Claims FY '05	*631*
Total Members FY '06	**138**
Total Members FY '05	*117*
Per Diem FY '06	**$22.26**
Per Diem FY '05	*$22.79*

FY '06 All Members

Age	Female	Male	Totals
0 to 9	0	0	0
10 to 19	0	0	0
20 to 34	1	1	2
35 to 49	10	3	13
50 to 64	30	5	35
65 to 79	42	0	42
80 to 94	43	2	45
95 and Over	1	0	1
Totals	**127**	**11**	**138**

Non Dual Members FY '06

Age	Female	Male	Totals
0 to 9	0	0	0
10 to 19	0	0	0
20 to 34	1	0	1
35 to 49	2	1	3
50 to 64	8	2	10
65 to 79	2	0	2
80 to 94	2	0	2
95 and Over	0	0	0
Totals	**15**	**3**	**18**

Recommendations

The College of Pharmacy recommends continuation of current prior authorization criteria.

APPENDIX E

Required Annual Review of Elidel®/Protopic® - Fiscal Year 2006

Oklahoma Health Care Authority
January 2007

Product Based Prior Authorization

With respect to the immunomodulator topical medications there are two products in this therapeutic category. Both are immunosuppressants classified as topical calcineurin inhibitors.

- The first 90 days of a 12 month period will be covered without a prior authorization if member meets age requirement.
- After the initial period, authorization will be granted with documentation of one trial of a topical corticosteroid for six weeks duration within the past 90 days.
- Therapy will be approved only once each 90 day period to ensure appropriate short-term and intermittent utilization as advised by the FDA.
- Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas.
- Authorizations will be restricted to those patients who are not immunocompromised.

Approved Clinical Diagnosis:

- **Elidel®** for short-term and intermittent treatment for mild to moderate *atopic dermatitis (eczema)*
- **Protopic®** for short-term and intermittent treatment for moderate to severe *atopic dermatitis (eczema)*

Age Restriction:

- **Elidel® 1% Cream** ≥ 2 years of age
- **Protopic® 0.03% Cream** ≥ 2 years of age
- **Protopic® 0.1% Cream** ≥ 15 years of age

Clinical exceptions for topical corticosteroid trials are the following:

- Documented adverse effect, drug interaction, or contraindication to topical corticosteroid products.
- Atopic dermatitis on the face, neck, or groin where physician does not want to use topical corticosteroids *(regardless of age).*
- Prescription by allergist or dermatologist *(regardless of age).*

Utilization in Oklahoma SoonerCare

During the period between July 2005 and June 2006 a total of 7,156 members had claims for topical immunosuppressant drugs paid through the Medicaid Fee-for-Service program.

FY 2005 versus FY 2006*			% Change
Cost FY '06		**$ 1,511,208.17**	**19.7 ↓**
	Cost FY '05	*$ 1,882,906.97*	
Claims FY '06		**12,859**	**30.5 ↓**
	Claims FY '05	*18,505*	
Per Diem FY '06		**$ 7.08**	**6.9 ↑**
	Per Diem FY '05	*$ 6.62*	
Members FY '06		**7,156**	**27.5 ↓**
	Members FY '05	9,877	

*Totals represent only 6 month utilization of Dual-Eligibles

Individual Products Utilization FY '06

Drugname	Total Claims	Total Units	Total Days	Members	Total Paid
Elidel Cream 1%	11,346	678,700	186,946	6,437	$1,312,939.21
Protopic Ointment 0.03%	838	48,570	14,743	500	$ 102,558.69
Protopic Ointment 0.1%	675	43,280	11,876	416	$ 95,710.27
TOTAL	**12,859**	**770,550**	**213,565**	**7,156***	**$1,511,208.17**

*Unduplicated members for time period.

Age and Gender FY '06

Age	Female	Male	Total
0 to <2	745	945	1,690
2 to 15	2,302	2,092	4,394
16 to 49	434	155	589
50 to 64	118	71	189
65 to 79	117	57	174
80 to 94	96	17	113
≥95	7	0	7
Total	**3,819**	**3,337**	**7,156**

Elidel® and Protopic® are approved for children 2 years of age and older.

Member < 2 years of age	FY 2006	FY 2005
Female	745	908
Male	945	1,268
Total	**1,690**	**2,166**

Dual and Non-Dual Eligibles FY '06

	Members	Total Expenditures
Duals	474	$ 93,175.92
Non-Duals	6,682	$ 1,418,032.25*

*16.2% decrease from FY '05 expenditures

Prescriber Specialty FY '06

Prescriber Specialty	# of Providers	% of Total
General Pediatrician	2423	35.2
Family Practice	2138	31.0
General Practitioner	639	9.3
Dermatologist	367	5.3
Nurse Pract.	310	4.5

Market and Safety News

FDA Advisory – March 11, 2005; Updated January, 2006

The Food and Drug Administration (FDA) has issued a public health advisory concerning two drugs used in the treatment of eczema. Pimecrolimus (Elidel®) and tacrolimus (Protopic®) are topically-applied calcineurin inhibitors. Based on data from animal studies, case reports, and the known pharmacology of these agents, they may increase the risk of developing cancer. Although this risk is uncertain, the FDA advisory emphasizes that Elidel® or Protopic® should be used according to the product labeling. In particular, these agents are considered second-line therapies, and should be limited to use in patients who have failed treatment with other therapies.

FDA has approved labeling changes, including a **"black-box" warning**, for these products to warn about the potential risk of cancers. A Medication Guide **(MedGuide)** is also available for use by patients and/or caregivers. The MedGuide should be distributed at the time of dispensing for each new prescription or refill.

An FDA-approved medication guide must be distributed when dispensing an outpatient prescription (new or refill) where this medication is to be used without direct supervision of a healthcare provider.

Medication guides are available at
http://www.fda.gov/cder/Offices/ODS/medication_guides.htm

Recommendations

The College of Pharmacy recommends no changes at this time. In the meantime, we will continue to monitor and evaluate this category.

APPENDIX F

Prior Authorization Annual Review – FY'06

Xopenex® and Xopenex HFA® (levalbuterol)

Oklahoma Health Care Authority
January 2007

Category Criteria for FY'06

Xopenex® (levalbuterol) use in excess of 90 days of therapy in a floating 360-day period will require prior authorization.

1. In the prior authorization request, the prescriber should explain why the member is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control per NAEPP guidelines.
2. Clinical exceptions will be made for members with COPD.

Quantity limits apply as follows:

- For nebulizations – 288units/30 day supply
- For HFA inhaler – 30units/30 day supply

Utilization

For the 2006 fiscal year, 9,452 members received Xopenex® through the *SoonerCare* program.

Product	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Xopenex Neb 0.31mg/3ml	3,098	452,382	60,485	$404,430.23	6.69
Xopenex Neb 0.63mg/3ml	9,558	1,380,832	182,762	$1,240,165.31	6.79
Xopenex Neb 1.25mg/3ml	5,237	833,712	104,742	$734,529.65	7.01
Xopenex Neb 1.25/0.5ml	8	300	117	$835.22	7.14
Xopenex HFA	839	29,758	19,920	$45,672.91	2.29
Total	*18,740*	*2,696,984*	*368,026*	*$ 2,425,633.32*	*6.59*

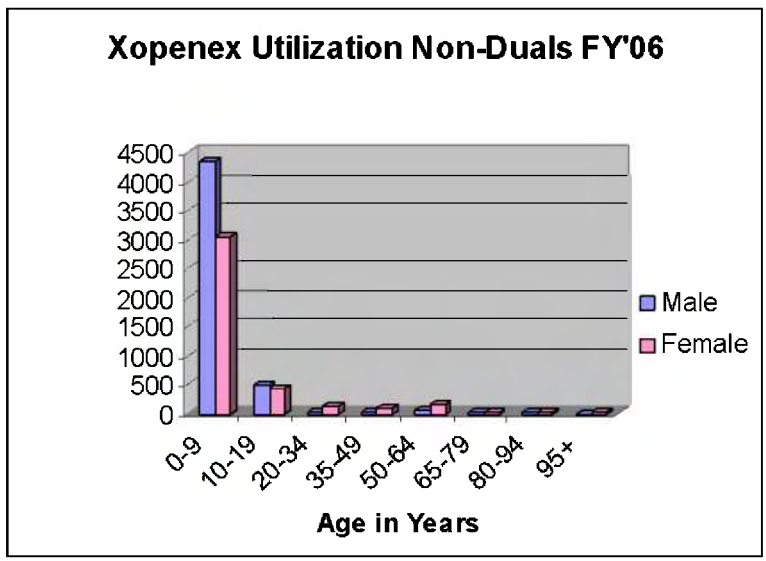
	# of Members	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	598	1,575	252,683	29,893	$211,842.40	7.09
Non-Duals	8,854	17,165	2,444,301	338,133	$2,213,790.92	6.55

	Fiscal Year 2005	*Fiscal Year 2006*	*Percent Change*
Total Cost	**$2,238,495.86**	**$2,425,633.32**	**+8.4%**
Total Claims	**16,967**	**18,740**	**+10.4%**
Total Members	**7,919**	**9,452**	**+19.4%**
Per Diem	**$6.61**	**$6.59**	**- 0.3%**

	Non-Duals FY'05	*Non-Duals FY'06*	*Percent Change*
Total Cost	**$ 1,925,192.60**	**$ 2,213,790.92**	**+ 15.0%**
Total Claims	**14,550**	**17,165**	**+ 18.0%**
Total Members	**7,103**	**8,854**	**+ 24.7%**
Per Diem	**$6.54**	**$6.55**	**+ 0.2%**

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

Approved	*155*
Denied	70
Incomplete	65
Number of denied/incomplete petitions later approved	45



Recommendations

The College of Pharmacy recommends adding the following to the prior authorization criteria:

- Please explain why the member is unable to use albuterol.

APPENDIX G

Utilization Review of Asthma Medications

Oklahoma HealthCare Authority

January 2007

Prevalence[1]

- An estimated 20 million Americans suffer from asthma (1 in 15 Americans)
- Asthma is the most common chronic condition among children
- Asthma is more common among children (7 to 10%) than adults (3 to 5%)
- Asthma is more common among male children, but is more prevalent in adult women than adult men.
- Asthma is slightly more prevalent among African Americans than Caucasians.
- Ethnic differences in asthma prevalence, morbidity and mortality are highly correlated with poverty, urban air quality, indoor allergens, and lack of patient education and inadequate medical care.
- In the SoonerCare population, approximately 6-8 percent of the members are diagnosis with asthma.

NAEPP Asthma Guidelines

- The National Asthma Education and Prevention Program (NAEPP) guidelines were last revised in July 2002.
- This revision made inhaled corticosteroids the preferred treatment for long-term control of all types of asthma, except for mild intermittent asthma.
- Bronchodilators, theophylline, and leukotriene modulators are recommended as either adjunctive or alternate choices.
- There has been no further updates to the guidelines as of yet.

Utilization

For the period of July 2005 through June 2006, a total of 96,420 members received an asthma medication. The following charts outline the trends in utilization.

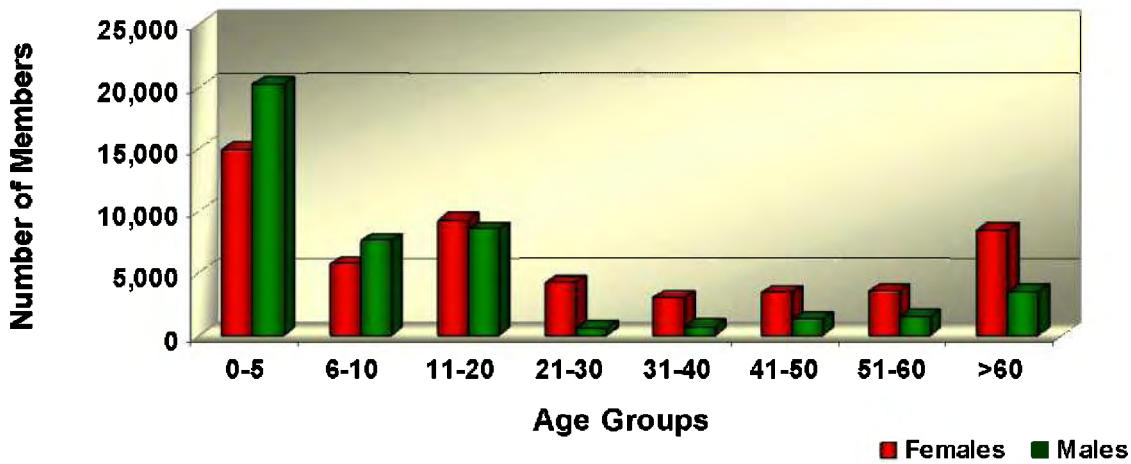
Utilization of Asthma Medications for FY 2006

ALL	CLAIMS	UNITS	DAYS	MEMBERS	COST	PERDIEM
Anticholinergics	15,687	1,262,571	437,250	5,060	$1,341,387.34	$3.07
Anti-Inflammatory Agents	1,139	118,904	30,593	492	$62,037.17	$2.03
Sympathomimetics	276,782	19,341,954	6,427,099	81,374	$16,017,333.06	$2.49
Xanthines	5,811	469,966	199,527	1,421	$130,400.60	$0.65
Inhaled Steroids	43,532	1,769,681	1,232,907	16,618	$6,041,563.28	$4.90
Leukotriene Modulators	122,636	3,694,380	3,671,205	31,681	$11,588,194.78	$3.16
Combination Products	229	39,979	2,272	161	$4,019.80	$1.77
TOTALS	465,816	26,697,435	12,000,853	96,420	$35,184,936.03	$2.93

Trends in Utilization of Asthma Medications

	Fiscal Year 2005	Fiscal Year 2006	Percent Change	
Total Cost	$33,348,105.58	$35,184,936.03	Increased	5.51 %
Total Claims	481,166	465,816	Decreased	3.19 %
Total Members	104,627	96,420	Decreased	7.84 %
Perdiem	$2.69	$2.93	Increased	8.92 %

Demographics of Members Utilizing Asthma Medications



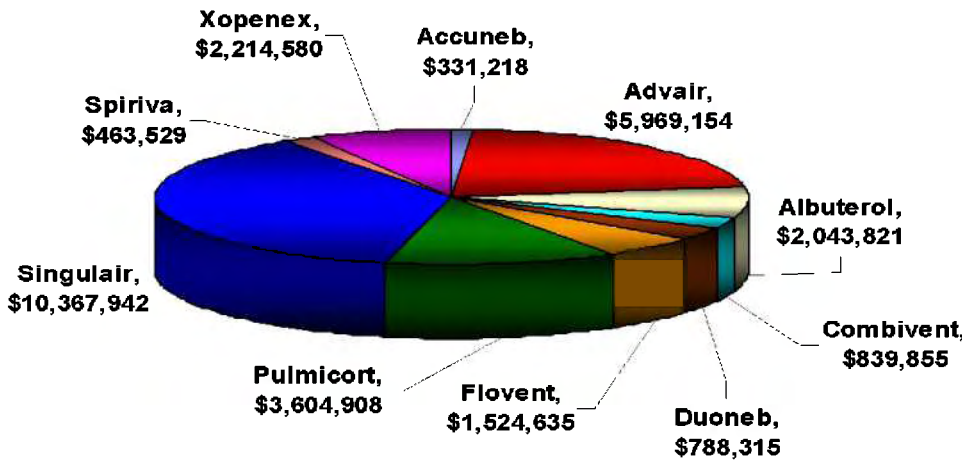
Comparison of Duals vs. Non-Dual Utilization

	Client	Claims	Units	Days	Cost	Perdiem
Non-Duals	81,272	395,740	22,305,447	10,100,649	$29,502,309.34	$2.92
Duals	14,551	70,076	4,391,990	1,900,204	$5,682,626.69	$2.99

Costs of Non-Duals vs. Dual Eligible

Drug Class	Non-Duals	Duals	Totals
Anticholinergics	$678,477.37	$662,909.97	$1,341,387.34
Anti-Inflammatory Agents	$59,382.95	$2,654.22	$62,037.17
Sympathomimetics	$12,681,294.55	$3,336,038.51	$16,017,333.06
Xanthines	$54,140.66	$76,259.94	$130,400.60
Inhaled Steroids	$5,607,310.25	$434,253.03	$6,041,563.28
Leukotriene Modulators	$10,418,643.46	$1,169,551.32	$11,588,194.78
Combination Products	$3,060.10	$959.70	$4,019.80
TOTALS FY 2006	$29,502,309.34	$5,682,626.69	$35,184,936.03
TOTALS FY 2005	$24,272,775.59	$9,055,329.99	$33,348,105.58

Top 10 Agents by Cost



Evaluation of Asthma Related Emergency Department Utilization

During the period from January through June of 2006 there were 52,301 asthma related medical/hospital claims. There were a total of 2,287 emergency department visits that were asthma related. Of these, 1,398 members had just one visit, while 370 members had two or more visits. The following table shows the key asthma medication usage within these populations during the specified timeframe.

1,398 Members with ONE visit*

Medication	Claim for Medication	No Claim for Medication
Sympathomimetics	1,139	259
Inhaled Corticosteroids	332	1,066
Leukotriene Modulators	375	1,023
Xanthines	9	1,389

Of the 1,398 members with an ER visit, 217 members did not have a claim for any asthma medication.

370 Members with TWO or more visits*

Medication	Claim for Medication	No Claim for Medication
Sympathomimetics	329	41
Inhaled Corticosteroids	99	271
Leukotriene Modulators	123	247
Xanthines	1	369

Of the 370 members with 2 or more ER visits, 37 members did not have a claim for any asthma medication.

Change in Pharmaceutical Market

- The combination of fluticasone/salmeterol is currently available in a metered dosed inhalation form marketed as Advair® HFA. The product comes in a 12g canister containing 45/21, 115/21, or 233/21 mcg of fluticasone/salmeterol and is priced similar to the corresponding Advair® Diskus.

- Symbicort®, the combination of budesonide/formoterol, in an oral inhalation form, is expected to be available in the U.S. market the first quarter of 2007.

- Arformoterol tartrate, the (R,R) enantiomer of formoterol is anticipated to be marketed the second quarter of 2007 as Brovana®, a nebulized inhalation solution.

- Products under development:
    - Ciclesonide – a new generation inhaled corticosteroid currently in phase III clinical trials.
    - Roflumilast – a PDE (phosphodiesterase)-4-inhibitor currently in phase III clinical trials is being investigated for the treatment of asthma and chronic obstructive pulmonary disease.

Conclusion and Recommendation

The College of Phamacy has the following recommendations for the class of Asthma medications:

- Consider member based education initiatives for select members with multiple ER visits.

- Evaluate the comparative cost-effectiveness of Brovana® vs. formoterol and/or other long acting inhaled beta2-agonists once it's marketed.

- Evaluate the comparative cost-effectiveness of Symbicort® vs. Advair® and/or other single agent inhalation products once it's marketed.

Utilization Details

Anticholinergics

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
IPRATROPIUM SOL INHAL	5,318	948,398	106,485	1949	$102,459.30
IPRATROPIUM POW BROMIDE	96	5,891	2,880	23	$7,192.65
ATROVENT INH AER 18MCG/AC	1,951	35,965	54,372	797	$171,473.21
ATROVENT HFA AER 17MCG	728	13,223	19,567	359	$77,470.25
SPIRIVA CAP HANDIHLR	7,594	259,094	253,946	2659	$982,791.93
TOTALS	**15,687**	**1,262,571**	**437,250**	**5,060***	**$1,341,387.34**

* Unduplicated members

Anti-Inflammatory Agents

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
CROMOLYN NEB 20MG/2ML	690	112,821	18,424	369	$20,420.60
INTAL INH AER 800MCG	415	5,370	11,399	181	$38,393.73
TILADE AER 1.75/ACT	34	713	770	12	$3,222.84
TOTALS	**1,139**	**118,904**	**30,593**	**492***	**$62,037.17**

* Unduplicated members

Xanthines

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
AMINOPHYLLIN TAB 200MG	16	2,070	471	4	$169.85
ELIXOPHYLLIN ELX 80/15ML	45	33,497	751	10	$5,893.96
THEOPHYLLINE ELX 80/15ML	2	1,925	38	2	$28.73
THEOPHYLLINE CAP 125MG ER	25	2,710	770	6	$898.25
THEOPHYLLINE CAP 200MG ER	**248**	**18,829**	**8,102**	**77**	**$6,879.99**
THEOPHYLLINE CAP 300MG ER	**468**	**34,536**	**15,966**	**145**	**$13,898.73**
THEO-24 CAP 100MG CR	**15**	**1,540**	**590**	**4**	**$706.79**
THEO-24 CAP 200MG CR	**78**	**4,838**	**2,546**	**24**	**$3,335.39**
THEO-24 CAP 300MG CR	147	8,583	5,521	51	$7,265.15
THEO-24 CAP 400MG ER	126	7,866	5,532	40	$9,048.53
THEOPHYLLINE TAB 100MG CR	76	7,300	2,440	22	$1,149.02
THEOPHYLLINE TAB 100MG ER	45	2,702	1,428	14	$480.52
THEOCHRON TAB 200MG CR	**39**	**3,452**	**1,254**	**8**	**$599.74**
THEOPHYLLINE TAB 200MG CR	**817**	**60,779**	**26,800**	**241**	**$10,887.36**
THEOPHYLLINE TAB 200MG ER	**707**	**57,488**	**23,409**	**212**	**$9,982.58**
THEOPHYLLINE TAB 200MG TD	**4**	**240**	**120**	**1**	**$45.80**
THEO-DUR TAB 300MG ER	1	100	50	1	$19.88
THEOCHRON TAB 300MG CR	55	4,800	2,040	15	$968.32
THEOPHYLLINE TAB 300MG CR	1,511	113,530	51,704	400	$23,221.29
THEOPHYLLINE TAB 300MG ER	1,107	86,469	38,546	322	$17,873.93
THEOPHYLLINE TAB 300MG TD	**5**	**600**	**150**	**1**	**$114.90**
THEOPHYLLINE TAB 450MG ER	**55**	**4,400**	**2,121**	**15**	**$2,206.63**
UNIPHYL TAB 400MG CR	**133**	**7,808**	**5,664**	**41**	**$8,517.99**
UNIPHYL TAB 600MG CR	**86**	**3,904**	**3,514**	**20**	**$6,207.27**
TOTALS	**5,811**	**469,966**	**199,527**	**1,421***	**$130,400.60**

* Unduplicated members

Sypathomimetics

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
ALBUTEROL AER 90MCG	115,527	2,345,115	2,703,732	50159	$1,290,460.39
ALBUTEROL TAB 2MG	359	25,979	8,849	153	$3,487.46
ALBUTEROL TAB 4MG	556	42,269	16,777	194	$6,713.17
ALBUTEROL SYP 2MG/5ML	10,369	1,363,087	137,164	8171	$68,333.75
ALBUTEROL NEB 0.083%	**34,494**	**6,218,491**	**582,700**	**18160**	**$447,795.86**
ALBUTEROL NEB 0.5%	**4,163**	**120,577**	**77,363**	**2061**	**$37,769.48**
ALBUTEROL NEB 1.25MG/3	**1,971**	**297,784**	**31,728**	**1328**	**$152,041.37**
ALBUTEROL POW SULFATE	**424**	**43,359**	**12,780**	**73**	**$26,032.12**
ALBUTEROL AER HFA	4,981	51,407	120,535	3124	$211,140.27
PROVENTIL AER 90MCG	21	527	495	6	$1,231.84
PROVENTIL RE TAB 4MG ER	2	107	45	2	$87.96
PROVENTIL NEB 0.083%	1	72	6	1	$59.06
PROVENTIL AER HFA	**1,748**	**14,514**	**42,912**	**978**	**$89,036.93**
ACCUNEB NEB 0.63MG/3	**2,952**	**387,327**	**41,570**	**1,897**	**$215,072.78**
ACCUNEB NEB 1.25MG/3	**1,480**	**216,891**	**22,876**	**933**	**$119,300.52**
VENTOLIN HFA AER	**298**	**5,579**	**7,210**	**235**	**$11,240.48**
VOSPIRE ER TAB 4MG	788	53,360	25,607	212	$54,282.10
VOSPIRE ER TAB 8MG	183	13,178	6,644	43	$26,101.67
FORADIL CAP AEROLIZE	1,826	109,201	55,587	557	$174,698.02
XOPENEX NEB 0.31MG	3,098	452,382	60,485	1,960	$404,430.23
XOPENEX NEB 0.63MG	**9,558**	**1,380,832**	**182,762**	**5,094**	**$1,240,165.31**
XOPENEX NEB 1.25/3ML	**5,237**	**833,712**	**104,742**	**2,428**	**$734,529.65**
XOPENEX CONC NEB 1.25/0.5	**8**	**300**	**117**	**3**	**$835.22**
XOPENEX HFA AER	**839**	**29,758**	**19,920**	**627**	**$45,672.91.23**
METAPROTER TAB 10MG	12	1,485	325	4	$424.79
METAPROTER SYP 10MG/5ML	241	36,285	3,081	188	$1,939.62
METAPROTER NEB 0.4%	10	1,763	220	3	$285.86
METAPROTER NEB 0.6%	5	475	104	4	$111.02
ALUPENT INH AER 0.65/ACT	**238**	**3,710**	**5,842**	**84**	**$9,372.19**
MAXAIR AUTOH AER 200MCG	**1,046**	**14,658**	**34,431**	**517**	**$95,575.48**
SEREVENT AER 21MCG/AC	**7**	**164**	**222**	**6**	**$1,027.43**
SEREVENT DIS AER 50MCG	**1,477**	**91,802**	**43,795**	**480**	**$155,903.31**
BRETHINE TAB 2.5MG	1	60	10	1	$31.79
BRETHINE INJ 1MG/ML	10	420	255	2	$11,732.14
TERBUTALINE TAB 2.5MG	1,015	55,760	16,502	709	$24,722.24
TERBUTALINE TAB 5MG	761	43,083	13,948	510	$25,740.30
TERBUTALINE INJ 1MG/ML	**1**	**20**	**30**	**1**	**$272.33**
TERBUTALINE POW SULFATE	**3**	**130**	**90**	**1**	**$797.58**
ADRENALIN INJ 1MG/ML	**7**	**140**	**140**	**1**	**$371.92**
EPINEPHRINE INJ 1MG/ML	**21**	**113**	**375**	**17**	**$96.94**
DUONEB SOL	7,650	1,870,769	159,533	3045	$1,227,230.75
COMBIVENT AER	14,675	296,789	409,061	4967	$1,592,320.13
ADVAIR DISKU MIS 100/50	20,863	1,249,708	633,406	7499	$2,689,054.29
ADVAIR DISKU MIS 250/50	22,212	1,330,353	671,731	7824	$3,575,959.54
ADVAIR DISKU MIS 500/50	5,644	338,459	171,392	1756	$1,243,844.86
TOTALS	**276,782**	**19,341,954**	**6,427,099**	**81,374***	**$16,017,333.06**

* Unduplicated members

Inhaled Corticosteroids

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
QVAR AER 40MCG	1,527	11,516	39,607	749	$90,381 09
VANCERIL AER 42MCG	1	17	11	1	$48.07
QVAR AER 80MCG	706	5,425	19,299	323	$52,383.58
PULMICORT SUS 0.25MG/2	9,271	765,401	238,722	4940	$1,784,737.40
PULMICORT SUS 0.5MG/2	8,337	709,770	212,824	3847	$1,800,334.22
PULMICORT INH 200MCG	1,043	1,041	46,019	630	$162,235.35
AEROBID AER 250MCG	507	4,163	13,159	240	$46,093.99
AEROBID-M AER 250MCG	285	2,346	7,916	119	$25,107.89
FLOVENT AER 44MCG/AC	477	6,312	14,145	374	$32,132.11
FLOVENT AER 110MCG/A	641	8,803	20,481	442	$58,818.29
FLOVENT AER 220MCG/A	204	2,917	6,674	135	$29,262.31
FLOVENT ROTA AER 50MCG	2	120	60	2	$92.78
FLOVENT HFA AER 44MCG	8,925	97,543	260,245	4012	$676,409.84
FLOVENT HFA AER 110MCG	7,189	88,946	213,239	3132	$718,442.04
FLOVENT HFA AER 220MCG	1,265	16,274	37,775	561	$195,262.68
ASMANEX 120 AER 220MCG	31	7	950	25	$4,430.13
ASMANEX 14 AER 220MCG	3	1	90	2	$139.02
ASMANEX 30 AER 220MCG	485	357	14,339	244	$70,477.91
ASMANEX 60 AER 220MCG	433	527	14,294	224	$62,855.76
AZMACORT AER 100MCG	2,200	48,195	73,058	1096	$231,918.82
TOTALS	**43,532**	**1,769,681**	**1,232,907**	**16,618***	**$6,041,563.28**

* Unduplicated members

Leukotriene Modulators

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
ZYFLO TAB 600MG	21	2,340	630	11	$4,131.97
SINGULAIR TAB 10MG	46,353	1,377,231	1,383,453	13647	$4,320,831 95
SINGULAIR CHW 4MG	29,344	876,207	879,646	9626	$2,796,706.07
SINGULAIR CHW 5MG	41,785	1,253,921	1,251,754	12169	$3,999,305.09
SINGULAIR GRA 4MG	3,946	118,280	120,185	2198	$378,664.88
ACCOLATE TAB 10MG	51	2,730	1,440	17	$3,613.96
ACCOLATE TAB 20MG	1,136	63,671	34,097	222	$84,940.86
TOTALS	**122,636**	**3,694,380**	**3,671,205**	**31,681***	**$11,588,194.78**

* Unduplicated members

Miscellaneous Combination Products

DRUG	CLAIMS	UNITS	DAYS	MEMBERS	COST
COPD TAB 200-200	5	383	111	5	$103.01
DYPHYLLIN-GG TAB 200-200	4	380	110	3	$239.18
DYPHYLLIN/GG TAB 200-200	18	1,406	407	12	$574.24
DILEX-G 400 TAB	7	360	140	6	$204.45
DY-G LIQ 100-100	87	20,266	681	67	$1,226.80
DYPHYLLIN-GG ELX 100-100	4	654	48	4	$25.44
PANFIL-G SYP	103	16,470	745	91	$1,606.90
QUIBRON CAP 150-90	1	60	30	1	$39.78
TOTALS	**229**	**39,979**	**2,272**	**161***	**$4,019.80**

* Unduplicated members

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1 Asthma and Allergy Foundation of America (AAFA). Asthma Facts and Figures. Website available at: http://www.aafa.org/display.cfm?id=8&sub=42#fast

APPENDIX H

Disease Management Initiative

Oklahoma Health Care Authority
January 2007

Summary of Program

Starting July 10, 2006, Pharmacy Management Consultants and the Oklahoma Health Care Authority implemented a Disease Management Initiative. While this initiative is not all-inclusive, OHCA is developing a comprehensive disease management program that will launch later this year. The mission of the current initiative is to assist SoonerCare members and providers to improve clinical outcomes by providing educational interventions. The current focus of the Disease Management Initiative is diabetes.

Diabetic members thought to be at high risk for complications are contacted via mail to introduce them to the initiative and let them know that we will be calling them. During these calls, the members are asked specific questions about their diabetes and their answers direct the flow of the conversation. After the call, an educational mailing is sent to the member that reinforces the telephonic discussion. The initiative encourages members to take an active role in their treatment and to engage their providers for additional individual education. Calls and mailings are performed quarterly. Examples of the educational newsletters can be found at the end of this section.

Select SoonerCare providers received correspondence outlining the initiative, its mission, and evidence based guidelines and chart flowsheets. Examples of the guidelines and flowsheets can be found at the end of this section.

Call Topics and Educational Newsletters Focus

Call 1 – Introduction and Health Inventory
- What is Diabetes?

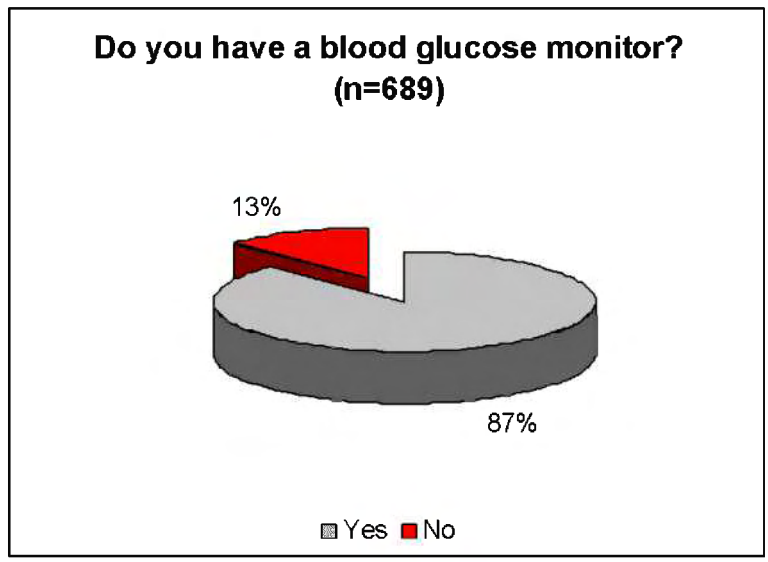
Call 2 – Medication Adherence; Building Relationship with Provider
- About Diabetes Medications
- Blood Sugar Chart and Lab Chart

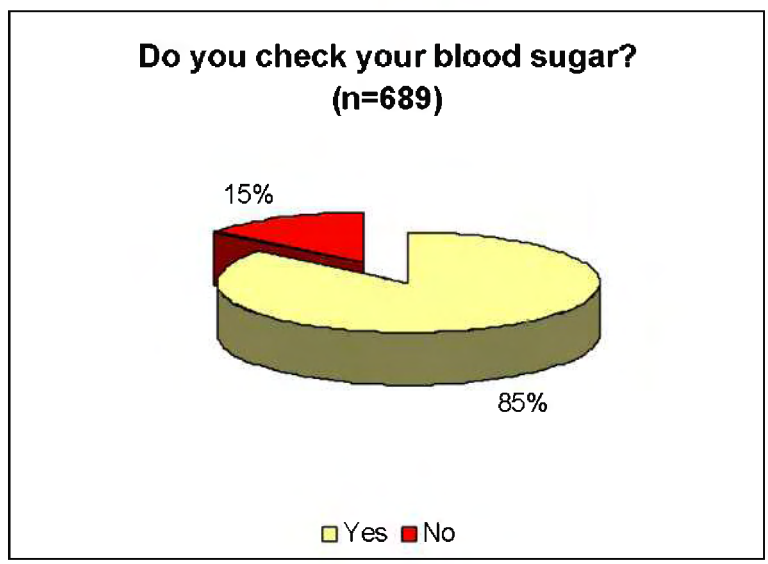
Call 3 – Complications of Diabetes
- Eye Problems & Diabetes
- Foot Problems & Diabetes
- High Blood Pressure & Diabetes

Call 4 – Diet and Exercise
- Healthy Eating
- Weight Loss and Exercise

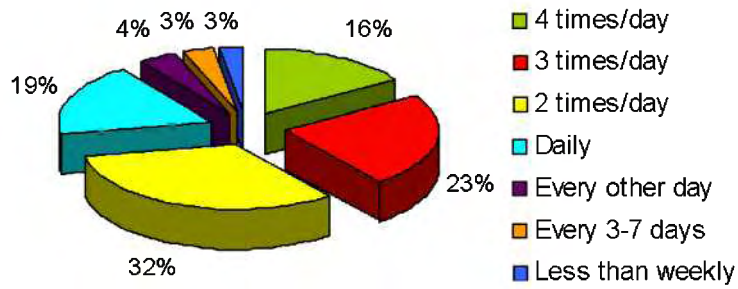
Call 5 – Exit Health Inventory

Questions and Answers from the Health Inventory

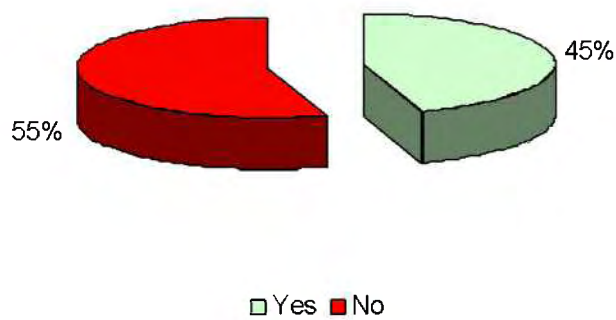




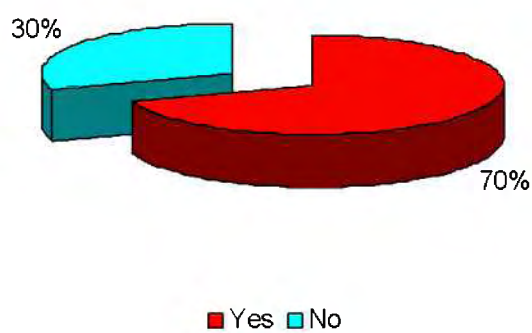
If you check your blood sugar, how often do you check it? (n=589)

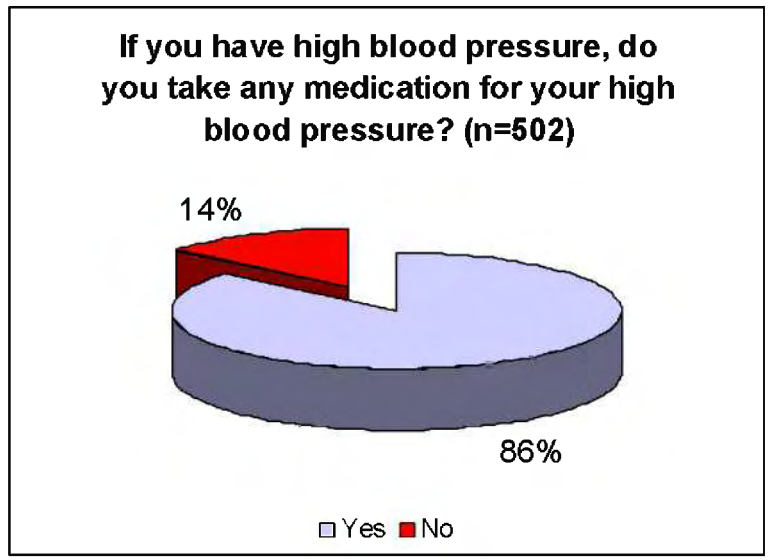


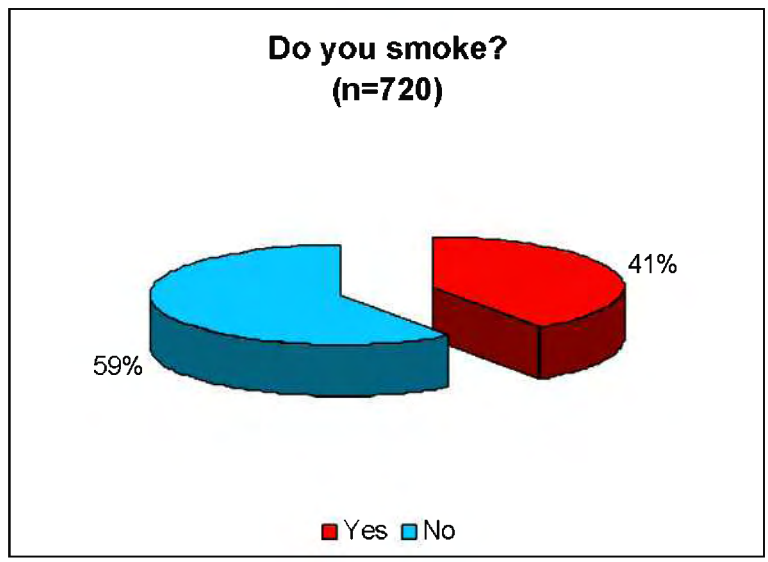
Do you take an aspirin every day? (n=721)

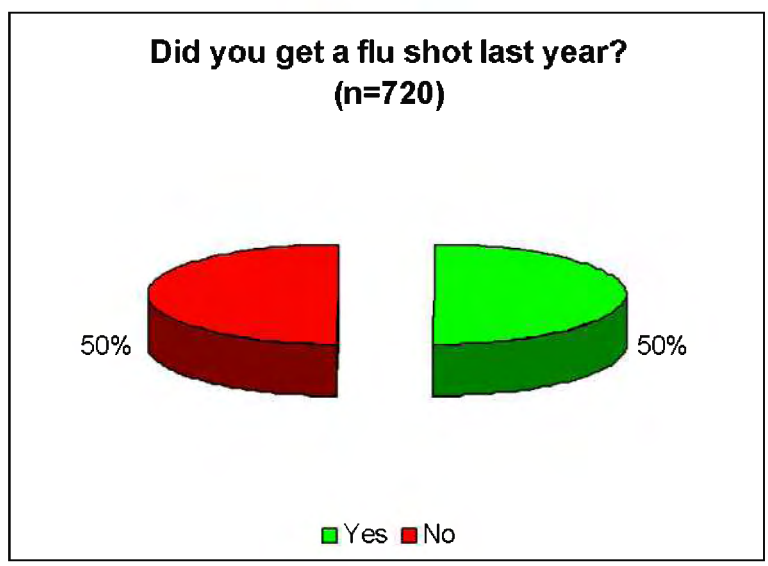


Have you ever been told that you have high blood pressure? (n=721)




If you have high blood pressure, do you take any medication for your high blood pressure? (n=502)
14%
86%
Yes
No


Do you smoke?
(n=720)
41%
59%
Yes
No


Did you get a flu shot last year?
(n=720)
50%
50%
Yes
No

oklahoma health care authority

Diabetes & Your Health

Staying Healthy

There are a number of things you can do to help control your diabetes and stay healthy:

- See your doctor regularly.
- Talk to your doctor about a diabetes meal plan.
- Enjoy at least 30 minutes of physical activity each day.
- Take medications as directed by your doctor.
- Test your blood sugar as directed & write the number in your log book after each test.
- Do not smoke or use tobacco products.
- Avoid alcoholic beverages.

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

What Is Diabetes?

Diabetes is often called sugar diabetes. It is a disease in which the body does not produce insulin or cannot use insulin properly. Insulin is a hormone that is needed to convert the food we eat into energy the body can use.

The cause of diabetes is unknown, but both family history and factors such as being overweight and not getting enough physical activity appear to play roles.

What Are the Major Types of Diabetes?

Type 1 Diabetes

Type 1 Diabetes results when the body fails to produce insulin. Insulin is the hormone that allows glucose (blood sugar) to enter the body's cells and fuel them. People with Type 1 diabetes use insulin injections and proper diet to control their blood sugar.

Type 2 Diabetes

Most Americans who are diagnosed with diabetes have Type 2 diabetes. Type 2 Diabetes develops when the body does not use insulin properly, or produce enough insulin. A balanced diet and regular physical activity help many people control Type 2 diabetes. Some people may also need pills or shots to help control their blood sugar.

Pre-Diabetes

Pre-Diabetes is a condition that occurs when a person's blood sugar levels are higher than normal, but not high enough for a diagnosis of diabetes. It is a warning sign that you might develop diabetes. People with pre-diabetes may be able to prevent diabetes by changing their diets and increasing their physical activity.

Diabetes in Pregnancy (Gestational Diabetes)

Gestational Diabetes is a temporary type of diabetes that some women develop during pregnancy; It usually goes away after the baby is born. With treatment, most women can control their blood sugar and give birth to healthy babies. If diabetes is not controlled during pregnancy, it can cause babies to grow too large or to be born with low blood sugar.

Source: The American Diabetes Association

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Diabetes & Your Health

About Diabetes Medications

If you take shots or pills to control your diabetes, ask your doctor how these medicines work. It is important for you to know how and when to take your diabetes medicines.

If you take other medicines, ask your doctor if they will affect your diabetes. You should ask your doctor about all other medicines you take, even the ones you can buy without a prescription, like cold medicine or aspirin.

When you take insulin shots or diabetes pills, your blood sugar can get too low. Ask your doctor how keep your blood sugar from getting too low or too high.

If you get sick, you should keep taking your diabetes medicines and call your doctor.

If you take insulin shots, ask your doctor:

- How to give yourself shots
- When you need to change your insulin dose
- How to safely throw away needles

Write Down Your Test Results

It is important to keep a written record of your test results. It may also be a good idea to set goals for future doctor visits.

You can use the charts on the next page to keep track of your blood sugar, blood pressure, weight, and other important parts of your diabetes control plan.

Checking Your Blood Sugar

If you have diabetes, checking your blood sugar regularly is one of the most important parts of staying healthy. Check your blood sugar as doctor recommends. If you do not know how often you should check, ask your doctor.

Each time you check your blood sugar, write the results in a log book. Take your log book with you when you see your doctor.

You should have a blood test called an A1C several times each year. The A1C test shows your average blood sugar over a two to three month period. It is an important test for your doctor to use in helping you manage your diabetes.

Fill in the chart on the next page each time you go to the doctor. It will help you to keep track of your goals and results.

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

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Every Doctor Visit

Date						
Blood Glucose						
A1c Test / Goal						
Weight / Goal						
Blood Pressure / Goal						
Foot Check						

Every Year

Date						
Flu Shot						
Urine Protein						
Total Cholesterol						
HDL Cholesterol						
LDL Cholesterol						
Triglycerides						
Tobacco Use						
Eye Exam						

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Diabetes & Your Health

Signs of Diabetic Eye Disease

You may have diabetic eye disease even if your vision is good.

Regular eye exams are important so that any problems can be found early.

You may have eye problems if:

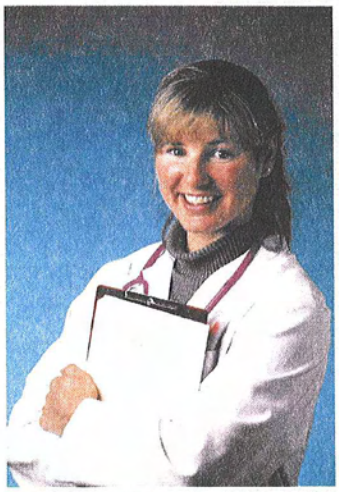
- You are having trouble reading
- Your vision is blurred
- You are seeing dark spots
- You are seeing rings around lights
- You see flashing lights

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

Eye Problems & Diabetes



Many people with diabetes develop diabetic eye disease, also called diabetic retinopathy. It is a serious problem that damages the small blood vessels in the eye. Diabetic eye disease can lead to poor vision, and sometimes even blindness.

If you have diabetes, it is important to have regular eye exams. Finding and treating eye problems early can help save your eyesight. Keeping your blood sugar and blood pressure under control are very important.

How Can I Protect My Vision?

Although diabetic eye disease is a serious problem, there are several things that people can do to help protect their vision:

Get Regular Eye Exams

Even if you can see well, you still need to get regular eye exams. Find an eye doctor who cares for people with diabetes. If you have lost your sight from diabetic eye disease, you still need to have regular eye care.

You should have a yearly eye exam if :

- You have had Type 1 diabetes for five years or longer
- You have Type 2 diabetes
- You have diabetes and you are pregnant or planning to become pregnant

Keep Your Blood Sugar Under Control

If your blood sugar is too high, it can damage your vision over time. Work with your doctor to keep your blood sugar as close to normal as possible. If you do not have a diabetes meal plan, talk to your doctor. Also, ask your doctor about what kind of exercise is right for you.

Keep Your Blood Pressure Under Control

High blood pressure can also damage your eyes. Have your blood pressure checked every time you see your doctor. If you take blood pressure medicine, be sure to take it according to your doctor's directions.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

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Order additional copies on the OHCA Web site www.okhca.org.

oklahoma health care authority

Diabetes & Your Health

Foot Problems & Diabetes

Nerve damage, blood flow problems, and infections can cause serious foot problems for people with diabetes. When you have nerve damage, you can lose feeling and pain in your feet. Nerve damage can also deform or change the shape of your feet, causing blisters, sores, or ulcers. Poor blood flow can make these injuries slow to heal.

Signs of Foot Problems

If you have any of the symptoms listed below, you should see your doctor.

- Your feet tingle, burn, or hurt
- Your feet can not feel heat, cold, or touch
- Loss of hair on feet, toes, or lower legs
- Dry or cracked skin on your feet
- Toenails turn thick and yellow
- Blisters, sores, ulcers, infected corns, and ingrown toenails

How Can I Protect My Feet?

- Keep your blood sugar as close to normal as possible.
- Do not smoke or use tobacco.
- Ask your doctor to check your feet at every visit.
- Ask your doctor how to care for your feet.
- Check your feet each day for scratches, cracks, cuts, or blisters. Call your doctor if you have a sore on your foot.
- Wash your feet daily. Dry them carefully, especially between the toes.
- Rub lotion or cream on the tops and bottoms of your feet, but not between the toes. Ask your doctor what kind of lotion to use.
- Do not soak your feet—this can dry them out and lead to infections.

Vaccines & Diabetes

Vaccines can prevent illnesses that are very serious for people with diabetes. You should ask your doctor about:

Influenza Vaccine (also known as Flu Vaccine or Flu Shot)

The flu is a serious illness, especially for people with diabetes. It can lead to pneumonia, or even death. You can help avoid catching the flu by getting a flu shot every year in October or early November.

Pneumococcal Vaccine (also known as PPV)

Pneumococcal disease is a major cause of illness and death. It can cause serious infections in the lungs, the blood, and the covering of the brain. Getting a shot can help prevent these infections. Most people have to take the shot only once in their lives.

Tetanus / Diphtheria (Td) Toxoid

Tetanus and diphtheria are serious diseases that can be prevented with a combined shot called Td toxoid. Adults should get one every ten years.

Other Vaccines

Ask your doctor if you need any of these vaccines: Measles/Mumps/Rubella, Hepatitis A & B, Varicella (chicken pox), Polio

For more information, contact:

SoonerCare Disease Management Services
(405) 123-4567
(800) 123-4567

or talk to your doctor.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

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Diabetes & Your Health

Aspirin & Heart Health

Studies have shown that taking a low-dose aspirin every day can lower the risk for heart attack and stroke.

Aspirin can help those who are at high risk of heart attack, such as people who have diabetes or high blood pressure.

Aspirin can also help people with diabetes who have already had a heart attack or a stroke, or who have heart disease.

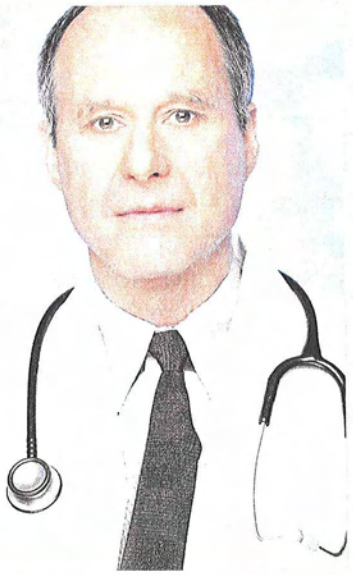
Taking an aspirin a day is not safe for everyone. Ask your doctor if taking aspirin would be right for you.

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

High Blood Pressure & Diabetes



Did you know as many as two out of three adults with diabetes have high blood pressure? High blood pressure is a serious problem. It can raise your chances of stroke, heart attack, eye problems, and kidney disease.

Many people do not know they have high blood pressure because they do not have any symptoms. That is why it is often called "the silent killer."

The only way to know if you have high blood pressure is to have it checked. If you have diabetes, you should have your blood pressure checked every time you see the doctor. People with diabetes should try to keep their blood pressure lower than 130 over 80.

Cholesterol & Diabetes

Keeping your cholesterol and other blood fats, called lipids, under control can help you prevent diabetes problems. Cholesterol and blood lipids that are too high can lead to heart attack and stroke. Many people with diabetes have problems with their cholesterol and other lipid levels.

You will not know that your cholesterol and blood lipids are at dangerous levels unless you have a blood test to have them checked. Everyone with diabetes should have cholesterol and other lipid levels checked at least once per year. Some people will need to have them checked more often.

How Can I Control My Blood Pressure & Cholesterol?

- Quit smoking. Do not use any tobacco products.
- If you take blood pressure medicine or cholesterol medicine, be sure to take it like your doctor told you.
- Enjoy regular physical activity.
- Lose weight if you are overweight.
- Eat a healthy diet with lots of vegetables.
- Eat a diet that is low in salt, saturated fat, and cholesterol.
- Have your cholesterol and other blood lipids checked at least once per year.

Sources: American Diabetes Association, American Heart Association

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Diabetes & Your Health

Foods Not to Eat

- Sugar or honey
- Alcoholic drinks
- Syrup
- Candy
- Jelly or jam
- Cakes or cookies
- Doughnuts
- Brownies
- Ice Cream
- Sherbet
- Pies
- Pudding

Healthy Snacks

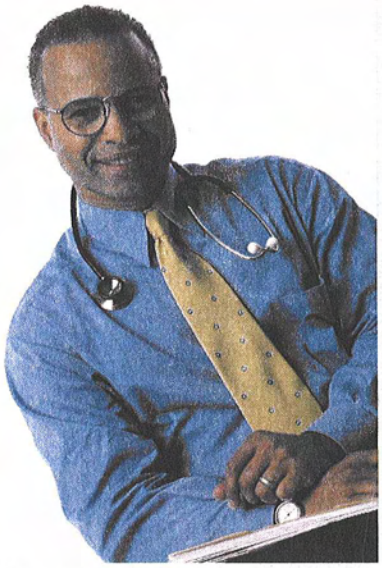
- 1 low-fat granola bar
- 1/2 cup fresh fruit
- 1/2 cup sugar-free pudding
- 5 vanilla wafers
- 6 to 12 tortilla chips with salsa
- 5 whole wheat crackers with a little peanut butter or low-fat cheese

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

Healthy Eating Makes a Difference



People who have diabetes need to pay attention to what they eat and drink. Making good choices about what you eat and drink is a very important part of living with diabetes. Combined with exercise, healthy eating helps to manage diabetes, as well as blood pressure and cholesterol.

Healthy Eating Tips

- Eat 3 well balanced meals a day and never skip meals.
- Eat a wide variety of foods and smaller helpings for a healthy diet.
- Eat 3 to 5 servings of non-starchy vegetables every day.
- Eat more foods that are high in fiber such as oatmeal, bran cereal, brown rice, canned or dry beans, and raw vegetables.
- Limit lean meat, fish, and poultry to 6 or 7 ounces per day.
- Limit starchy foods to 1 or 2 servings per meal.
- Limit fruits to 1 small piece with lunch or dinner. Don't eat fruit at breakfast.
- Limit milk to 2 cups of skim or fat free milk per day.
- Use sugar substitutes like Equal™, Splenda™, or Sweet n' Low™.
- Avoid high fat foods such as bacon, sausage, fried foods, bologna, mayonnaise, and regular cheese.

Portion Size Guide

- Grains, Beans, & Starchy Vegetables: *1/2 cup portion (size of a fist)*
- Non-Starchy Vegetables: *1/2 cup of cooked vegetables (size of a fist) or 1 cup of raw vegetables (size of two fists)*
- Fruits: *1 small orange or apple (size of a baseball)*
- Dairy: *1 cup of yogurt, 1 cup skim or fat free milk (size of a baseball)*
- Meats: *3 ounces of lean meat, poultry, or fish (size of a deck of cards)*
- Fats: *1 teaspoon of butter, oil, or margarine*

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

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oklahoma health care authority

Diabetes & Your Health

Benefits of Fitness

Weight loss & exercise improve your health in the following ways:

- Lowers blood sugar by helping insulin work better
- Lowers cholesterol
- Lowers blood pressure
- Makes your heart stronger, and lowers the risk of heart disease, kidney disease, and stroke
- Gives you more energy
- Makes muscles stronger
- Makes bones stronger
- Improves blood flow
- May reduce the need for medicines
- Reduces stress and helps you relax
- Makes you feel better

For more information, contact:

SoonerCare Disease Management Services
(405) 522-6205
(800) 522-0114

or talk to your doctor.

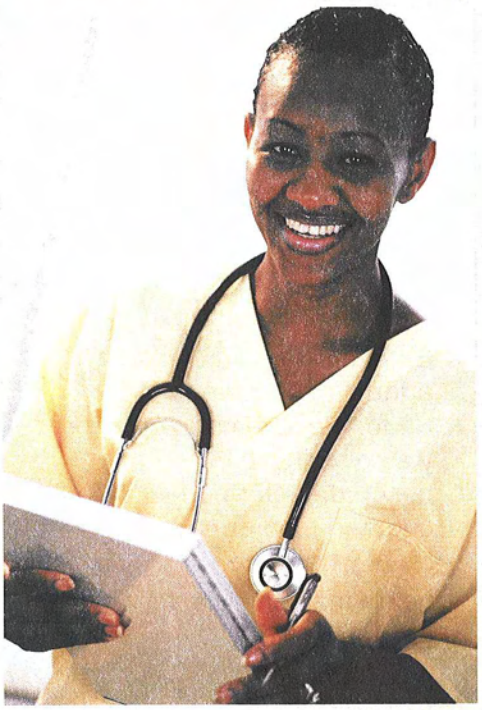
Weight Loss Helps Control Diabetes

Did you know that nine out of ten people with type 2 diabetes are overweight?

People who are overweight and have diabetes are more likely to have high blood pressure, which can lead to heart disease, stroke, and kidney disease.

If you are overweight and have diabetes, losing weight can:

- Help lower your blood sugar
- Help lower your blood pressure
- Improve your health
- Make you feel better



Sometimes when people with Type 2 diabetes lose weight, they no longer need to use insulin or take medicine for their diabetes.

You should talk to your doctor before starting a weight loss plan. If you change your diet, you will need to pay special attention to your blood sugar, insulin, and medicines.

Importance of Exercise

Enjoying physical activity regularly is an important part of controlling diabetes. Exercise does not have to be hard. It can be any activity that gets you moving, like walking. Getting enough exercise helps you lose weight; It makes you feel better both physically and mentally.

Exercise Tips

- Ask your doctor what kind of exercise program is right for you.
- Try to exercise 30 minutes every day.
- Keep active during the day.
- Wait at least 30 minutes to an hour after eating before you exercise.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

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DIABETES CARE FLOWSHEET

Visit Frequency: 2x/year if meeting treatment goals, 4x or more/year if not meeting treatment goals

Patient Provider		DOB Height			MR#				
Date of Visit									
EACH VISIT	Diabetes Medications & Doses (Insulin and/or Oral Agents)								
	Weight/BMI: Goal <25 Value								
	B/P: Goal <130/80								
	Tobacco Use: Yes or No								
	Smoking Cessation: Offered (O), Provided (P), Declined (D)								
	HbA1C every 3-6 months: Target < 7%								
	Aspirin Use: Yes, No, or Contraindicated								
	Self Management Education & Nutrition								
	Fasting/Random Blood Glucose: Goal <140 fasting, <160 random								
	Review Blood Glucose Records								
	Visual Foot Exam								

		2006	2007	2008	2009
YEARLY	Flu Vaccine				
	Microalbumin (if urine neg for protein)				
	Serum Creatinine				
	Dilated Eye Exam Date				
	Fasting Lipid Profile: Date/Value LDL goal <100mg/dl HDL goal >40mg/dl M; >50mg/dl F Triglycerides goal < 150mg/dl Total Cholesterol <200mg/dl	LDL: HDL: TG: TC:	LDL: HDL: TG: TC:	LDL: HDL: TG: TC:	LDL: HDL: TG: TC:
	Monofilament Lower Extremity Exam				
PER CDC[§]	Pneumococcal Vaccine Date				
	Tetanus, Diphtheria Vaccine Date				

[§]For CDC immunization schedules, see: http://www.cdc.gov/nip/menus/vaccines.htm#Schedules

SoonerCare Disease Management Services
405-522-6205 or 800-522-0114

SoonerCare Guidelines for Diabetes Care

Abnormal physical or lab findings should result in appropriate interventions. For particular references and details for each specific area, please refer to the most recent clinical practice guidelines at http://www.diabetes.org/for-health-professionals-and-scientists/cpr.jsp .

Measure	Consensus Guidelines (Frequency)	Treatment Goals
Height/Weight	Weight taken at every visit Height, if needed to calculate BMI	Counseling for maintaining ideal body weight*
Glycosylated hemoglobin (A1C)	Twice a year, 3 months or more apart, in stable patients Quarterly in patients that are not meeting goal or have changed therapy	A1C < 7.0
Microalbumin	Annually	< 30mg/24hr; >30mg/24hr start treatment with ACE/ARB
Dilated eye exam	Type 1 – Within 3-5 years of diagnosis, then annually Type 2 – At diagnosis, then annually	
Foot exam	Visual foot exam with every visit; Monofilament exam annually	
Lipid profile	At least annually, more often if not at goal	Cholesterol <200mg/dl LDL <100mg/dl HDL >40mg/dl (men) >50mg/dl (women) Triglycerides <150mg/dl
Blood pressure measurement	Every visit	<130/80 mmHg (antihypertensive of choice ACE or ARB)
Smoking	Counsel to stop at every visit	
Aspirin therapy (for patients > 20 years of age)	Daily, if not contraindicated	81-162mg aspirin daily
Self management education & medical nutrition therapy	Initially and at clinician's discretion	
Immunizations**		
Influenza Vaccine	Annually	
Pneumococcal Vaccine	As per CDC recommendation/schedule for patient age	
Tetanus, Diphtheria Vaccine	Children – as per CDC schedule; Adults – every 10 years	

*BMI < 25 for adults; for children age 2 to 20 years, BMI for age <85th percentile. For calculating children's BMI, see: http://www.cdc.gov/nccdphp/dnpa/growthcharts/bmi_tools.htm

** For CDC immunization schedules, see: http://www.cdc.gov/nip/menus/vaccines.htm#Schedules

Criteria for Diagnosis of Pre-Diabetes		
Measure	**Diagnosis**	**Treatment Goals**
Fasting Plasma Glucose Test (FPG) – 100-125mg/dl	Pre-Diabetes – Impaired Fasting Glucose (IFG)	Moderate Physical activity (e.g. walking 30 minutes 5x per week); Diet Modification; Weight Loss, if overweight, at least 5-7% of current body weight; Test Glucose Annually
Oral Glucose Tolerance Test (OGTT) – 140-199 mg/dl (2 hour plasma glucose following a 75gm oral glucose load)	Pre-Diabetes – Impaired Glucose Tolerance (IGT)	

Adapted from American Diabetes Association Clinical Practice Guidelines 2006

These guidelines were developed to provide guidance to primary care providers and are not intended to replace or preclude clinical judgment.

SoonerCare Disease Management Services
405-522-6205 or 800-522-0114

APPENDIX I

Lock-In Program Update and Study Information

Oklahoma Health Care Authority
January 2007

Background

On January 1, 2006 the program for reducing the incidence of fraud and abuse of narcotic medications for the Oklahoma SoonerCare population was transferred from the Oklahoma Health Care Authority's (OHCA) direct management to Pharmacy Management Consultants.

The profiles of members identified as exhibiting potentially abusive or fraudulent behavior are reviewed by a Clinical Pharmacist and the members are then monitored, sent a warning letter, or "locked in" to a single pharmacy for their SoonerCare prescription claims. Members who have been locked in are periodically reviewed to determine if they should continue in the program.

Program Update

2006 Lock-In Pharmacy Program Results

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total in Database	461	496	534	569	613	640	681	731	896	959	1026	1026
Total Locked-In	224	225	224	212	207	207	206	212	210	216	212	209
Total Reviewed	52	122	77	89	109	86	75	122	152	172	100	105
Results of Reviews												
Extended Lock-in	0	2	2	3	0	1	5	5	1	1	0	2
In Lock-In process	0	14	2	4	2	6	18	8	1	6	4	2
Warned	7	10	9	16	21	9	7	17	5	12	11	9
Completed Lock-In	1	0	16	4	4	7	5	12	0	10	3	2

During 2006 referrals were made by pharmacists and physicians in the community or OHCA and PMC staff members. Beginning in 2007 a new pharmacy claims review system will be tested. This system is designed to generate a pool of members for review based on current pharmacy claim activity.

Study Information

Because outcomes for this program have never been assessed a study is being performed on the Lock-In program. The overall objective of this evaluation study is to assess the impact of the Lock-In Pharmacy Program on the Oklahoma SoonerCare Population.

One goal of the program is to reduce the number of narcotic medication claims for members identified as being potentially abusive or fraudulent. Members who are identified are then locked in to a pharmacy of their choice and are required to fill all prescriptions at this designated pharmacy.

Often the members that fall into this area use multiple physicians and frequently are seen in the emergency room. A second goal of this program is to reduce the incidence of physician and emergency room visits. Additionally it could be theorized that reduced utilization across all areas will result in a decreased net cost to OHCA.

The scope of this study will be to determine if these goals are being achieved with the current program and suggest any areas for improvement that may become apparent.

Data collection has begun on members enrolled in the program from January 1, 2006 through October 31, 2006 and will continue until August 31, 2007. Data analysis should begin in late 2007.

Demographics

Members Locked-In January though October 2006

Age	Female	Male	# Warned
0 – 12	1	3	0
13 – 20	2	2	0
21 – 34	12	9	7
35 – 49	15	5	6
50 - 64	2	4	3
> 65	0	0	0

Conclusion

Updates on the Lock-In Pharmacy Program will continue to be reported to the DUR Board. The results of the evaluation study will also be reported once the study has been completed.

APPENDIX J

FDA News

FOR IMMEDIATE RELEASE
P06-208
December 20, 2006

Media Inquiries:
Press Office, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves New Drug for Schizophrenia

The Food and Drug Administration (FDA) today approved Invega (paliperidone) extended-release tablets for the treatment of schizophrenia. Paliperidone is a new molecular entity, which means this medication contains an active substance that has never before been approved for marketing in any form in the United States. Paliperidone is the principal active metabolite of risperidone, a marketed drug for treating schizophrenia.

"Schizophrenia can be a devastating illness requiring lifelong medication and professional counseling," said Douglas Throckmorton, MD, Deputy Director of FDA's Center for Drug Evaluation and Research. "Today's approval adds to the treatment options for patients with this condition."

Schizophrenia is a chronic, disabling mental disorder that affects more than two million Americans. Symptoms include hallucinations, delusions, disordered thinking, movement disorders, social withdrawal and cognitive deficits (e.g., difficulty with perception, memory or abstract thinking that interferes with one's ability to learn; impaired judgment, inattentiveness, impulsiveness or impairment of speech and language).

The effectiveness of Invega in the acute treatment of schizophrenia was established in three 6-week, placebo-controlled trials conducted in North America, Europe and Asia. The 1665 participating adults were evaluated for the full array of signs and symptoms of schizophrenia. In the three studies using doses ranging from three milligrams (mg) to 15 mg a day, the effectiveness of Invega at relieving symptoms of schizophrenia was superior to the placebo treatment. The recommended dose range for Invega is three mg to 12 mg a day.

Among the commonly reported adverse events were restlessness, extrapyramidal symptoms (movement disorders), rapid heart beat and sleepiness. Invega is a member of a class of drugs called atypical antipsychotics that have an increased rate of death compared with placebo in elderly patients with dementia-related psychosis. Invega is not approved for dementia-related psychosis.

The effectiveness of Invega has not been evaluated in placebo-controlled trials for longer than six weeks, and patients who use the drug for extended periods should be periodically reevaluated by a physician.

Invega is manufactured by ALZA Corp. in Mountain View, CA. for Janssen, L.P. in Titusville, NJ.

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RSS Feed for FDA News Releases [what's this?]

FDA News

FOR IMMEDIATE RELEASE
P06-210
December 20, 2006

Media Inquiries:
Karen Riley, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves Treatment for Children and Teens With Mildly to Moderately Active Ulcerative Colitis

The Food and Drug Administration (FDA) today approved Colazal (balsalazide disodium) for the treatment of mildly to moderately active ulcerative colitis in patients 5 to 17 years of age. The condition is a type of inflammatory bowel disease which causes inflammation of the colon and rectum and affects about 5 per 100,000 pediatric patients in the United States each year. Pediatric use of Colazal was granted orphan drug status under FDA's Orphan Drug program, which provides financial incentives for firms that develop therapies for diseases affecting fewer than 200,000 patients a year.

"Ulcerative colitis is a debilitating and frequently painful disease for which there has been no satisfactory pediatric treatment," said Dr. Douglas C. Throckmorton, Deputy Director of FDA's Center for Drug Evaluation and Research. "Today's approval is another example of the great benefits that the Orphan Drug program provides for patient populations that are too small to justify the large investment in new drug development."

Colazal had been previously approved for use in adult patients with mildly to moderately active ulcerative colitis. The drug's safety and effectiveness in children 5 to 17 years of age with mildly to moderately active ulcerative colitis was demonstrated in a multicenter study in 68 patients who were randomized to receive either 6.75 grams or 2.25 grams of Colazal per day for a total of 8 weeks of treatment. In this study, 45% of the children on the higher dose and 37% on the lower dose showed clinical improvement in rectal bleeding and the appearance of the gastrointestinal mucosa.

The most common adverse events associated with the use of Colazal were headache, and symptoms referrable to the gastrointestinal tract, such as abdominal pain, vomiting and diarrhea. The overall rate of drug-related adverse events was higher in the low-dose group as compared to the high-dose group. This may have been due to the lower efficacy seen in the low-dose group.

Colazal is manufactured by Salix Pharmaceuticals, Inc., Morrisville, NC.

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FDA Public Health Advisory

Life-threatening Brain Infection in Patients with Systemic Lupus Erythematosus After Rituxan (Rituximab) Treatment

FDA has received reports of the death of two patients who were treated with Rituxan for systemic lupus erythematosus (SLE). Both patients developed a life-threatening viral infection of the brain. This infection is called progressive multifocal leukoencephalopathy (PML). PML is caused by the JC virus and is usually fatal. There are no known effective treatments for PML.

The signs of PML include confusion, dizziness or loss of balance, difficulty talking or walking, and vision problems. Recognition of these warning signs of PML may be obscured by the fact that they are also associated with the underlying diseases for which Rituxan may b prescribed.

- Patients who have been treated with Rituxan should contact their doctor if they experience any warning signs like those listed above--to find out the exact cause of their warning signs and to be checked for PML.
- Physicians who are thinking about treating a patient with Rituxan for any condition should inform their patient about the chance of PML with Rituxan treatment because there is no known effective treatment for PML.
- Patients who are taking or are considering taking Rituxan should be aware of the chance of developing PML and discuss it with their doctor.

Rituxan is a powerful medication that is used to suppress the immune system. It works by blocking the effect of specific immune cells in the blood, known as B cells, for up to six to nine months. Rituxan is approved for use only in patients with certain types of cancer called non-Hodgkin's lymphoma and for rheumatoid arthritis when other treatments have failed. Rituxan is not approved for the treatment of SLE. The sponsor estimates that approximately 10,000 patients with SLE have been treated with Rituxan.

In February 2006, the labeling for Rituxan was updated to include information about reports of several different types of viral infections, including PML, that had become active again or worsened in cancer patients taking Rituxan. FDA is working to gather more information about Rituxan and PML and to strengthen the Warnings about PML in the Rituxan product label.

More details about Rituxan and PML can be found in FDA's Information for Healthcare Professionals at http://www.fda.gov/cder/drug/InfoSheets/HCP/rituximab.pdf

The FDA asks health care professionals and patients to report possible cases of PML to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at http://www.fda.gov/medwatch.

Back to Top Back to Rituxibam Information

FDA News

FOR IMMEDIATE RELEASE
P06-204
December 15, 2006

Media Inquiries:
Press Office, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

Celebrex Approved to Treat Juvenile Rheumatoid Arthritis

The U.S. Food and Drug Administration (FDA) today approved Celebrex (celecoxib) for a new use – the relief of the signs and symptoms of Juvenile Rheumatoid Arthritis (JRA) in patients two years of age and older. Today's approval follows the November 29 meeting of FDA's Arthritis Advisory Committee, in which the committee voted 15 to 1 in favor of approval of this product.

JRA is an autoimmune disease that affects approximately 30,000 to 60,000 children in the United States. The disease is associated with joint swelling, pain, decreased range of motion and abnormalities of growth and development. In some cases, systemic complications may occur including uveitis, a chronic inflammation of the eye. In severe, uncontrolled cases, permanent disability may occur due to progressive joint damage.

"JRA is often a devastating disease," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. "While there are other medicines approved for the treatment of this disorder, for some children they may have limited effectiveness or cause intolerable side effects. Celebrex will be a needed additional treatment option for children."

A 24-week study of Celebrex involving 242 patients between the ages of two and 17 years demonstrated its effectiveness in treating JRA. The most commonly reported side effects were cough, cold, upper respiratory tract infection, abdominal pain, headache, fever, nausea, diarrhea and vomiting.

Celebrex has not been studied in patients under the age of two years, in patients who weigh less than 22 pounds, or in patients showing signs of having "systemic onset JRA", a more serious type of JRA associated with high fever and rash. Celebrex should be used only with caution in patients with systemic onset JRA due to the risk for serious adverse reactions, including abnormal clotting tests, which can be associated with the clinical condition known as disseminated intravascular coagulation (DIC). DIC is a serious condition in which the body's blood clotting mechanisms are activated throughout the body instead of being localized to an area of injury.

Safety and efficacy were not studied beyond six months, and experience with adults suggests the possibility of longer term cardiovascular problems. As part of the approval of Celebrex, the drug's manufacturer has agreed to conduct two Phase 4 postmarketing studies: a short-term controlled trial to evaluate high blood pressure, and a several-year registry study to further evaluate long-term safety issues, including renal toxicity, high blood pressure, and cardiovascular events.

Celebrex, a COX-2 selective non-steroidal anti-inflammatory drug (NSAID), was originally approved in l998 for the relief of signs and symptoms of rheumatoid arthritis and

osteoarthritis in adults. Celebrex is manufactured by Pfizer Inc. of New York, NY.

For more information on Celebrex and COX-2 drugs, please see
http://www.fda.gov/cder/drug/infopage/COX2/default.htm

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kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, December 11, 2006

Prescription Drugs

FDA Advisory Panel Recommends More Warnings About Drug-Eluting Stents

FDA should warn doctors and patients that the safety of drug-eluting stents has not been established for relatively high-risk patients for whom the stents are not approved, a group that accounts for the majority of stenting procedures, an agency advisory panel said Friday, the *Washington Post* reports (Stein, *Washington Post*, 12/9). Drug-coated stents, which are sold in the U.S. by Boston Scientific and Johnson & Johnson, are designed to prevent scar tissue from forming in arteries after angioplasty. However, recent studies have suggested the devices might increase the risk of blood clots compared with bare-metal stents. Drug-coated stents are approved by FDA for use in patients with simple artery blockages, but the agency estimates that at least 60% of procedures involving the devices are performed in patients with more complex conditions, such as heart attacks, multiple blockages requiring more than one stent or blockages in more than one branch of an artery. FDA asked the advisory panel to examine the risks of blood clots, heart attack and death for approved and off-label uses of drug-coated stents compared with bare-metal stents. On Thursday, the panel said there is no conclusive evidence that drug-eluting stents increase the risk of heart attack or death when used within the scope of their FDA approval (*Kaiser Daily Health Policy Report*, 12/8). After reviewing research on off-label use of drug-coated stents, the panel on Friday said that such use appears to raise the risk of blood clots, heart attack and death. The panel said it is unclear whether the increased risk is caused by the drug-coated stents or if it is a result of the poorer health of the higher-risk patients. Until that effect can be determined, FDA should warn doctors and patients of the potential risks, the panel said (*Washington Post*, 12/9).

Anticlotting Drugs

The panel also said that patients should take an anticlotting medication, such as Bristol-Myers Squibb's Plavix, and aspirin for at least one year after receiving a drug-coated stent. Currently, the label for J&J's Cypher stent recommends that patients take anticlotting drugs for three months, and the label for Boston Scientific's Taxus stent recommends use of the drugs for six months. According to the *New York Times*, it is "unclear" how FDA will respond to the recommendations. The agency "cannot require the companies to recommend a drug program on their labels for an unapproved use of the device," and BMS "is not allowed to market the drug for off-label stent use," the *Times* reports.

FDA

Daniel Schultz, head of the Center for Devices and Radiological Health at FDA, said, "What I heard loud and clear is that we need to do a better job communicating to doctors and patients the best and latest information." He said it is too soon to discuss what specific actions FDA might take (Feder, *New York Times*, 12/9). "There may be things that can be done relatively quickly," Schultz said, adding that the options include a label change or a letter to doctors and patients.

Comments

Panel Chair William Maisel of Beth Israel Deaconess Medical Center said, "If you use the device outside [the approved] indication, you're going to have a higher incidence of complications." Panel member Steven Nissen of the Cleveland Clinic said, "Do we have evidence that the safety-efficacy balance might be different in the off-label [use]? I think we've heard enough to suggest that that's the case" (*Washington Post*, 12/9). Panel member Robert Harrington of Duke University said, "It's really a societal question. What do you do when you have a technology that is potentially so transforming that it will be used in virtually everybody, even though it has only been studied in a minority of people?" (Sternberg, *USA Today*, 12/11).

Additional Coverage

In related news, the *Wall Street Journal* on Saturday examined how some cardiologists "already are changing the way they treat patients" with drug-coated stents. According to the *Journal*, such doctors are "rethinking when to use the devices and how to alter follow-up care." Some cardiologists are concerned about extended use of Plavix, which costs about $6 per day and can interfere with certain medical procedures. Christopher Cannon, a cardiologist at Brigham & Women's Hospital and Harvard Medical School, said, "I wouldn't see necessarily a big shift away from drug-eluting stents, adding, "But a more thoughtful and discriminate approach does seem useful" (Winslow/Wilde Mathews/*Wall Street Journal*, 12/9).

Broadcast Coverage

APM's "Marketplace" on Friday included an interview with Heather Won Tesoriero, a reporter for the *Wall Street Journal* who has been covering the FDA panel's consideration of stent safety (Ryssdal, "Marketplace," APM, 12/8).

A transcript and audio of the segment are available online.