THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – April 13, 2004**

DATE: April 8, 2004

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

Enclosed are the following items related to the April 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 New Prior Authorization Criteria for Anti-Ulcers - See Appendix C.

Intent to Prior Authorize Synagis™ – **See Appendix D.**

Intent to Prior Authorize Caduet™ - **See Appendix E.**

Intent to Prior Authorize Provigil™ – **See Appendix F.**

Review and Discuss Antiretroviral Medications for HIV – **See Appendix G.**

Pharmacoeconomic Review of the Statins – **See Appendix H.**

Review and Discuss Tamiflu™ - **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – April 13, 2004 @ 6:00p.m.

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

AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

1. **Call To Order**
   A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

2. **Public Comment Forum**
   A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

3. **Action Item - Approval of DUR Board Meeting Minutes – See Appendix A.**
   A. March 9, 2004 DUR Minutes
   B. Memorandum of March 9, 2004

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

4. **Update on DUR/MCAU Program - See Appendix B.**
   A. Medication Coverage Activity Audit for March 2004
   B. Help Desk Activity Audit for March 2004

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

5. **Action Item – Vote on New PA Criteria for Anti-Ulcers - See Appendix C.**
   A. COP Recommendations

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

6. **Intent to Prior Authorize Synagis™ – See Appendix D.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

7. **Intent to Prior Authorize Caduet™ - See Appendix E.**
   A. COP Recommendations

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

8. **Intent to Prior Authorize Provigil™ – See Appendix F.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

9. Review and Discuss Antiretroviral Medications for HIV – See Appendix G.

A. Oklahoma Medicaid Utilization
B. COP Recommendations

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

10. Pharmacoeconomic Review of the Statins – See Appendix H.

A. Oklahoma Medicaid Utilization and Economic Review
B. COP Recommendations

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

11. Review and Discuss Tamiflu™ - See Appendix I.

A. Oklahoma Medicaid Utilization
B. COP Recommendations

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Hepatitis C Agents Review
B. Maintenance Drug List
C. Epogen / Procrit Review
D. SSRI's Economic and Utilization Review
E. Benzo/Ambien™ Follow-up Review
F. Annual Review of Antihypertensives
G. Review of Anti-asthmatics
H. Consultant Pharmacist Presentation

14. Adjournment

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of MARCH 9, 2004

BOARD MEMBERS:	PRESENT	ABSENT
Rick G. Crenshaw, D.O.	X	
Dorothy Gourley, D.Ph.	X	
Cathy Hollen, D.Ph.	X	
Thomas Kuhls, M.D.	X	
Dan McNeill, Ph.D., PA-C	X	
Cliff Meece, D.Ph.	X	
Dick Robinson, D.Ph., Vice-Chair		X
James M. Swaim, D.Ph.	X	
Greg Tarasoff, M.D.	X	
Thomas Whitsett, M.D., Chair	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./Clinical Pharmacist	X	
Jack Coffey, Assistant Dean, College of Pharmacy		X
Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison	X	
Kelly Flannigan, D.Ph./Clinical Pharmacist	X	
Shellie Gorman, Pharm.D./Clinical Pharmacist	X	
Ronald Graham, D.Ph., Manager, Operations/DUR	X	
Elgene Jacobs, Ph.D.; Manager, Research		X
Chris Kim Le, Pharm.D.; Clinical Pharmacist	X	
Ann McIlvain, Pharm.D.; Clinical Pharmacist	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Lester Reinke, Ph.D.; College of Pharmacy	X	
Douglas Voth, MD./Dean , College of Pharmacy		X
Visiting Pharmacy Student: Labinot Avdiu	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Kristall Bright; Pharmacy Financial Analyst		X
Alex Easton, M.B.A.; Pharmacy Operations Manager	X	
Mike Fogarty, C.E.O	X	
Lynn Mitchell, M.D., M.P.H, Medical Director	X	
Nancy Nesser, D.Ph., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.		X
Lynn Rambo-Jones, J.D.	X	
Rodney Ramsey; Pharmacy Claims Specialist	X	

OTHERS PRESENT:

David Dude, Bristol-Myers Squibb	Andi Moore, Takeda	Scott Mullins, Sanofi-Synthelabo
Woodie Zachry, Eli Lilly	Chris Carllson, Eli Lilly	Rebecca Waldrop, Sanofi-Synthelabo
Candie Phipps, Boehringer Ingelheim	Darryl Davy, Pfizer	Kay Kaut, Amylin Pharma
Greg Hoke, Wyeth	Meg Propis, Eli Lilly	Pat Evans, Bristol-Myers Squibb
Mark DeClerk, Eli Lilly	Aliza Tomlinson, Janssen	Jack Jones, Eli Lilly
Jeff Ekyzyn, Eli Lilly	Brett Spencer, Purdue Pharma	Roger Enix, Merck
Charlene Kaiser, Wyeth	Sandra Cahill, IVAX	Marvin Stacy, Amylin Pharma
Tammie Kilpatrick, Kilpatrick Consulting		

PRESENT FOR PUBLIC COMMENT:

Dr. Marguerite Enlow; BMS

Scott Mullins; Sanofi-Synthelabo

AGENDA ITEM NO. 1: CALL TO ORDER

1A: Roll Call

Dr. Whitsett 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

2A: Acknowledgement of Speakers and Agenda Item

Dr. Whitsett acknowledged Dr. Marguerite Enlow, public comment for Agenda Item No. 7.

Dr. Whitsett acknowledged Scott Mullins, public comment for Agenda Item no. 8.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: February 10, 2004 DUR Minutes

Dr. Meece moved to approve minutes; motion seconded by Dr. Tarasoff .

ACTION: MOTION CARRIED.

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

4A: Medication Coverage Activity Report: February 2004

The February 2004 activity audit noted total number of petitions submitted was 14,188 including super-PA's and special circumstance PA's. Approval/denial/duplicate percentages were indicated on the reports included in the agenda packet for this meeting. Reports were included in agenda packet; presented by Dr. Browning.

4B: Help Desk Activity Report: February 2004

Total calls for February 2004 numbered 16,857 (82% pharmacies, 8.9% clients, 1.3% physicians, 7.4% other). Reports included in agenda packet; presented by Dr. Browning.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: VOTE ON PRIOR AUTHORIZATION OF FORTEO™

Materiel included in agenda packet; presented by Dr. Browning. Dr. Kuhls requested a clarification for use in children. It is not to be used in children.

Dr. Crenshaw moved to approve; motion seconded by Dr. Meece .

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: ANNUAL REVIEW OF NON-SEDATING ANTIHISTAMINES (NSA) UTILIZATION

Materials included in agenda packet; presented by Dr. Gorman. Dr. Swaim requested that a criteria update be placed on the OHCA website or presented to providers. Dr. Kuhls suggested that we look at a PDL for the brand name non-sedating antihistamines when generic loratidine cannot be used.

ACTION: NONE REQUIRED.

AGENDA ITEM No. 7: ANNUAL REVIEW OF PLAVIX™ UTILIZATION

Dr. Marguerite Enlow, Bristol-Myers Squibb for Public Comment: *Good evening. I'm Marguerite Enlow and I'm a Pharm.D. with Bristol-Myers Squibb in the medical department. I'm a scientific liaison for Oklahoma and Kansas and tonight I appreciate the opportunity to review some of the clinical data with Plavix /clopidigrel as you are reviewing the drug utilization of that product. First of all I just wanted to say a few words about the mechanism of action of clopidigrel as compared to aspirin. Both are anti-platelet agents and both are involved in locking the activation of the platelet and therefore platelet aggregation. However the mechanism of action is different with*

aspirin working at the cycloxygenase, blocking that conversion to thromboxin A and that pathway to activation of the platelet and Plavix working as an ADP blocker and that process of activation. This is important just to provide the rationale for the dual antiplatelet therapy that we've seen has increased benefit over aspirin alone. The CURE trial is Clopidogrel in Unstable Angina to Prevent Recurrent Events *and this study was in over 12,000 patients that presented with acute coronary syndrome with an onset of symptoms less than 24 hours. Patients were randomized to received a loading dose of 300 mg of clopidogrel followed by 75 mg daily or placebo loading dose followed by placebo daily, both in addition to aspirin and standard therapy. The followup period was for up to 12 months and what was found was a 20% relative risk reduction in the primary endpoint, very serious cardiovascular endpoints composite of myocardial infarction, ischemic stroke and cardiovascular death. The interesting thing about this was that the Kaplan-Meier curve separated early and there was a dual primary endpoint that also included refractory ischemia and it was actually statistically significantly better within 24 hours. The combination of aspirin plus clopidogrel as opposed to aspirin alone. And this just points out the importance of the combination treatment to be started early with a loading dose followed uninterrupted in patients who have had acute coronary syndrome. That included both patients who were managed medically and those who received percutaneous interventions, stent or no stent. The bleeding results did, however, as expected, show us an increase in patients in major and minor bleeding in the combination of aspirin plus clopidogrel as compared to aspirin alone. However, an interesting point about that was that the bleeding rate actually went up as the aspirin dose went up, so that aspirin alone at 325 mg had a higher incidence of bleeding than the combination of low dose aspirin plus clopidogrel. The result of the CURE trial was that it actually had an impact on the standard of care of patients with acute coronary syndrome and in fact the American College of Cardiology, American Heart Association guidelines for the treatment of unstable angina non ST segment elevated MI was changed based on the results of the CURE trial. The Class I recommendations are that antiplatelet therapy should be initiated promptly. Aspirin administered as soon as possible after presentation and continued indefinitely. And in hospitalized patients whom a non-interventional approach is planned that would be medically managed, aspirin should be added . . . clopidogrel should be added to aspirin as soon as possible upon admission, administered for at least one month and up to nine. And in patients in whom a PCI is planned, clopidogrel should be started, continued for a month and up to nine months in patients who are not at risk for bleeding. The nine months also came from the CURE trial because that was the mean duration of therapy in that trial. The other clinical trial upon which the indications were based was the CAPRIE trial, and this stands for* Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events. *CAPRIE was given to patient who presented with a recent onset of myocardial infarction, ischemic stroke or peripheral arterial disease. This included over 19,000 patients who were followed for up to three years, a mean duration of 2.5 years. This was a head-to-head comparison of clopidogrel against aspirin and showed a significant relative risk reduction in the patients who received clopidogrel in the composite endpoint of, again, myocardial infarction, ischemic stroke and vascular death. The safety profile in this trial was comparable between the two groups with numerically slightly increased GI hemorrhage, hospitalization due to GI hemorrhage, GI ulcer and intercranial hemorrhage in the aspirin . . . OK, that didn't reach statistical significance. Severe neutropenia was slightly more for patients in the clopidogrel group and, too in the aspirin group. This resulted in a change in the ADA consensus statement on peripheral arterial disease which stated, in summary, patients with diabetes should be on an antiplatelet agent, either aspirin or clopidogrel, according to current guidelines. Those with diabetes and peripheral arterial disease may benefit more by taking clopidogrel. So, in summary, I want to thank you for letting me be here today. I know a lot of you have heard this data before. I appreciate the opportunity to put the clinical data into perspective today, along with your utilization review data. Thank you.*

Dr. McNeill asked about the PA approval rates for Plavix. Dr. Gourley asked for clarification on the word "recent" within the criteria. Dr. Kuhls wanted to know if there are differences in efficacy of the other drugs compared to Plavix. Dr. Flannigan explained the different indications of the other drugs. Dr. Kuhls wanted to know why the drug has increased in cost so much. Dr. Tarasoff wanted to know what the recommended dose of aspirin was now for a failed trial in order to move on to Plavix.

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

ACTION: NONE REQUIRED.

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

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

Dr. McNeill wanted to know how many elderly people over 65 years old were taking anxiolytics and hypnotics. Dr. Gourley wants to know specifically what the Ambien™ use is in the nursing home patient. Dr. Tarasoff would like the DUR Board to look at capping the dosage of these two categories at the FDA maximum. Dr. Tarasoff requested the Board to also look at the utilization of Provigil™ and the benzo's. Dr. Tarasoff recommended the Board look

very hard at duration of hypnotics (short-term versus long-term use). Dr. Whitsett suggested that the COP bring back more utilization information on hypnotic use in the nursing home population and also look at the efficacy of using these products. Dr. Tarasoff suggested we look at the use of these anxiolytics and hypnotics in the pediatric population. Dr. Whitsett wants the Board to pursue the prescribing habits in these two populations specifically.

Scott Mullins, Sanofi-Synthelabo for Public Comment: *I basically just wanted, I mean I think everybody's pretty familiar with Ambien and I just wanted to give an opportunity if anybody had any particular questions to address.*

Dr. Whitsett: *Well, the question . . . talking about, the duration of therapy, what does the package insert say now, what's your approval for?*

Scott Mullins: *It says that if it's to be taken for more than two to three weeks, reevaluation is recommended so it doesn't prohibit you from prescribing it longer than . . .*

Dr. Whitsett: *What would that look like, if you were to reevaluate?*

Scott Mullins: *You're supposed to technically reevaluate after every two to three weeks.*

Dr. Whitsett: *So what would it look like if I were to reevaluate one of my patients after three weeks of Ambien? What would I do?*

Scott Mullins: *It doesn't say specifically but typically just ask them, you know, what's the root of their . . . what's causing the insomnia, for example say if you have a depressed patient, find out, you know, was their medicine causing the insomnia . . . primary insomnia.*

Dr. Whitsett: *OK.*

Dr. Hollen: *Do you have any studies with the long term use or use over those 14 days, safety wise?*

Scott Mullins: *We do. Technically I'm not supposed to talk off-label, but there is a study that's a 360 day study.*

Dr. Whitsett: *Has it been published?*

Scott Mullins: *It's published.*

Dr. Hollen: *Was it found to be safe and effective?*

Scott Mullins: *Yeah. There was no rebound, there was no withdrawal at the end of the 360 days and patients maintained, the medication maintained its' efficacy during the study.*

Dr. Hollen: *Average age of the patients in the study?*

Scott Mullins: *I don't know that specifically.*

Dr. Tarasoff: *So if there was no, again, we're talking about a study that's off-label that none of us have seen, but if there's no withdrawal then at that duration, it would seem reasonable that a trial withdrawal from the medications every two weeks or three weeks to see if the patient sleep cycle had normalized would be reasonable, prudent care.*

Scott Mullins: *Right.*

Dr. Kuhls: *How long of a length of time is that?*

Dr. Tarasoff: *Two weeks, three weeks.*

Dr. Kuhls: *So two weeks on, two weeks off.*

Dr. Tarasoff: *That would be probably reasonable. I mean sleep cycles depending on what's disrupting could take a lot longer to stabilize.*

Scott Mullins: *And also, depending on what their . . . if it is a psychiatric patient, for example, depending on what their Axis I disorder is, you know, if they're bipolar. I think if you ask most psychiatrists what happens if the patient doesn't sleep well, most will say that their depression gets worse. They may go into a manic phase or their anxiety gets worse, or what have you. So I think because it is predictable, I think that helps out a lot but . . .*

Dr. Whitsett: *What do we know about the usage pattern in our population and in general? Do doctors follow that recommendation or do the majority of the patients, 80+% take it day in, day out?*

Scott Mullins: *I find that in a primary care setting, it seems to be used more short term. In a psychiatric setting it seems to be used for a longer term.*

Dr. Tarasoff: *Well, what does our data show? I mean when we get scripts, are they for 2 weeks with no refills, or are they for a month with 5 refills?*

Dr. Browning: *They're either 30 a month refill or 90. Lots of times they're filling either 90 or 100 since 100 is . . they'll fill 90 or 34-days supply, whichever is greater, so they're writing for 100.*

Dr. Whitsett: *My guess is long term care facilities probably never miss a dose. Probably pretty compliant and we might look at that to see usage patterns and what age groups and settings.*

Dr. Browning: *Nursing homes sends them in like clockwork.*

Dr. Whitsett: *Yes, that would be my suspicion.*

Dr. Graham: *We could look at Ambien next . . .*

Dr. Whitsett: *I think that would be interesting to see because we right now use a lot and someone can locate that study, if there's other studies out there, we want to know that.*

Dr. Kuhls: *In my other duties, in hearing discussions about these drugs, can you comment to me about dosage in terms of using it in the elderly?*

Scott Mullins: *Generally, 5 mg is where you would start, 10 mg seems to be in a lot of cases, too much. Does that answer your question?*
Dr. Browning: *What about the use of 20?*
Scott Mullins: *20? We see . . . it's not very common in a general population, psychiatric population it seems like there's, I've seen it. A lot of practices, psychiatry, you have maybe one or two patients on 20, so it's not real common, but they will swear that the patient can't sleep if they don't have 20, but it's uncommon.*
Dr. Kuhls: *Are there good studies in the elderly looking at 5 versus 10 and looking at efficacy versus adverse effects, cognition, and those kind of things?*
Dr. Tarasoff: *For Ambien, I don't know. I don't know that.*
Scott Mullins: *And also I noticed and I think it was on page 37 of the agenda, a lot of more commonly used sedative hypnotics. Ambien I think had the lowest, on that page, the lowest units per day, which I think is a testament to it's low abuse potential, so you don't see people using 2 pills a night, generally.*
Dr. Graham: *It's because we cut them off – we don't let them have it.*
Scott Mullins: *But it is a non-benzodiazepine so it is on the omega-1 only, so you don't see the anxiolytic effects, you don't see the minor relaxant effects that you would with a benzodiazepine such as a Xanax or temazopine or something of that nature, so it is a non-benzo, so it is very specific.*
Dr. Hollen: *So the benefits of using Ambien over some of these other agents in the long term care or elderly population in your opinion, would be what?*
Scott Mullins: *Well, I think because the long term care facility, the patients are on so many medications already so, you know, if it runs into a brick wall it's got another pathway it can go given all the medications that they're already on.*
Dr. Hollen: *So there are no contraindications with other meds?*
Scott Mullins: *Correct. There can be some additive effects with imipramine, alcohol, there's going to be some additive effects but there's no . . . it's got a very favorable drug interaction profile.*
Dr. Tarasoff: *Which again in a controlled setting where you're starting at low doses anyway, clinically, it doesn't change a lot of what we do. If you've got a drug interaction, you lower the dose. If you're using something that can affect cognition or sleep, you're going to monitor fairly closely anyway, so you know again, in the lab and what we see in the test tube may or may not, doesn't necessarily translate into the clinician on the floor making a decision of one agent versus another.*
Scott Mullins: *I think because Ambien has been out for so long I think that people know it well and it really allows you to do no harm first, because you don't see patients falling over, it's got a 2 ½ hour half life so patients don't feel slain when they wake up in the morning. You see half lifes of other medications, temazepam I think has a half life of close to 15 hours, trazodone is very commonly used, that's a half life of between 9 and 12 hours I believe, so you can see how this really, I think it makes a patient higher functioning. When they wake up, they don't feel hung over and I think it helps them.*
Dr. Whitsett: *Halcion has a short half life, right?*
Scott Mullins: *Correct.*
Dr. Whitsett: *We still have a fair amount of that that's used.*
Dr. Tarasoff: *On the side of cost issue, it's the ones that are really indicated for sleep alone, Sonata and the Ambien, the non-benzodiazepines and I think if we kind of look at those, again one of the indications, how long are they being used for, and we've heard and I think we have read independently that prudent medical care requires to reevaluate after 2 weeks, 3 weeks, certainly 4 weeks at the latest, to reevaluate and so writing a prescription for 100 with refills doesn't make a whole lot of sense in terms of what we're trying to treat with these medications. The others may be some leeway there if you're treating for anxiety as well, though again, there are other agents, other combinations. Certainly in those two age groups that can't speak for themselves, we're very careful about what we're allowing in terms of multiple months of dosing.*
Scott Mullins: *We generally don't hear about people prescribing it for 100 days at a time. Because it is a non-benzo, patients will not get physically addicted to it and I think that's definitely a benefit over benzodiazepine like Valium or Xanax, so it's limited potential for addiction is a very strong (inaudible) for Ambien.*
Dr. Whitsett: *Questions? If not we may want to consider taking a look at this in more specifics . . . roll over some of the long term care patients in this program.*
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: REVIEW & DISCUSS SYNAGIS™ UTILIZATION
Materials included in agenda packet; presented by Dr. Moore.

Dr. Kuhls recommended that this drug require PA using multiple criteria such as AAP guidelines, date restrictions, no coverage in September and May, no more than seven vials in a season, no coverage for any client over 2 years old unless they turn three years old after starting drug, special emphasis on not starting Synagis™ after age 1 unless there is documentation of significant lung disease based on being hospitalized or chronically on oxygen or evidence they have had problems within the first year since they were a premature baby, every client in this group should be looked at carefully. COP's PA recommendations to be presented to Board at the April 2004 meeting.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **FDA & DEA UPDATES**
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 11: **FUTURE BUSINESS**
11A: Antiviral Utilization Review
11B: Hepatitis C Agents Review
11C: Anti-Asthmatics Review
11D: Tamiflu Review
11E: Epogen/Procrit Review
11F: Annual Review of Antihypertensives
Materials included in agenda packet; submitted by Dr. Graham. Dr. Whitsett requested more follow-up on nursing home clients with dementia using Zyprexa™ and Riperdal™. Dr. Kuhls recommended that the Board keep the antipsychotics on the priority list for future business. Dr. McNeill suggested that the Board look into the 1.5 times the maximum dosage restriction for other drugs and not just the stimulants. Dr. Whitsett acknowledged Dr. Tarasoff's last Board meeting and for his service on this Board. Dr. Tarasoff will be leaving the state for another career opportunity.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 12: **ADJOURNMENT**
The meeting was declared adjourned.

The University of Oklahoma College of Pharmacy

Pharmacy Management Consultants
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Memorandum

Date: March 18, 2004

To: Nancy Nesser, DPh, JD
Pharmacy Director
Oklahoma Health Care Authority

From: Ron Graham, DPh
Operations Coordinator / DUR Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of March 9, 2004.

Recommendation 1: Discussion and Vote on Prior Authorization of Forteo™.

Prior Authorization Criteria:

- Osteoporosis, men with primary or hypogonadal osteoporosis or postmenopausal women with osteoporosis who are at high risk for fracture.
- No concurrent use of Forteo™ with other agents until more information is available.
- Minimum 12 month trial with any one other agent (unless contraindicated, intolerant, or allergic) and a BMD (T-score at or below -2.5) test within the last month (results indicated on petition).
- PA approval for one month's supply per fill for duration of 1 year, with a maximum renewal period of 2 years.
- No approved coverage for use in children.
  MOTION CARRIED.

APPENDIX B

Activity Audit for

March 01 2004 Through March 31 2004

Date	Antiulcers		Anxiolytic/ Hypnotics		Antihistamine		Growth Hormones		Stimulant		Smoking Cess.		Nsaids		ACE Inhibitors		HTN Combos		Calcium Channel Blockers		Plavix		NPA		Misc		Daily Total
	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	
1	1	39	102	15	12	15	0	0	47	12	0	0	3	11	1	4	2	0	2	9	36	5	20	0	0	3	339
2	10	68	206	40	41	37	1	0	98	25	0	0	17	37	4	6	3	4	4	18	59	6	30	5	0	5	724
3	18	70	208	40	31	36	0	0	84	25	0	0	17	47	5	12	4	5	4	24	36	18	8	0	0	4	696
4	9	59	134	17	23	45	0	0	88	26	0	0	23	27	5	7	2	3	8	13	34	7	12	1	0	3	546
5	14	40	165	26	19	28	2	0	74	28	0	0	10	32	5	14	2	1	6	8	50	13	4	2	0	4	547
6	4	27	49	7	4	7	0	0	20	8	0	0	3	8	0	4	2	1	1	5	10	2	7	0	0	1	170
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	6	49	151	18	38	30	0	0	83	18	0	0	22	27	1	2	7	6	6	11	47	5	9	1	0	7	544
9	7	35	108	17	31	30	0	0	55	20	0	0	8	25	1	7	1	3	5	14	26	6	7	0	0	1	407
10	3	56	169	21	36	37	0	1	104	24	0	0	11	39	4	9	2	1	2	10	38	12	14	0	1	1	595
11	1	48	106	27	19	25	1	0	83	17	1	0	10	26	1	8	0	5	5	11	22	7	24	0	1	4	452
12	3	63	241	30	26	40	10	0	119	49	0	0	17	36	1	12	1	2	5	13	62	5	15	1	0	5	756
13	9	10	40	7	7	9	0	0	26	16	0	0	2	10	1	2	0	2	2	1	8	5	4	0	0	0	161
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	9	19	124	9	19	14	0	0	40	7	0	0	5	19	2	4	1	2	5	8	25	7	10	0	0	2	331
16	8	61	151	20	30	47	1	0	77	32	0	0	11	41	1	4	1	3	5	20	39	9	13	0	0	3	577
17	6	57	145	23	24	53	0	0	88	29	0	0	12	33	3	3	3	3	4	15	31	10	12	0	0	2	556
18	4	23	89	9	18	11	0	0	52	23	0	0	6	15	2	4	1	4	2	10	13	5	13	0	0	0	304
19	6	60	113	27	36	47	0	1	62	26	0	0	5	28	2	8	3	5	4	14	32	8	15	1	0	10	513
20	2	18	50	19	8	4	0	0	18	12	0	0	10	9	0	3	0	2	1	4	11	0	1	0	0	1	173
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	3	28	75	9	16	16	0	0	35	18	0	0	6	11	2	2	1	0	1	5	24	6	6	0	1	2	267
23	2	56	198	21	48	42	0	0	92	30	0	0	15	27	2	9	2	2	9	12	35	9	30	1	0	9	651
24	8	59	144	15	28	51	1	0	73	36	0	0	17	22	3	9	1	2	5	15	39	7	29	2	0	4	570
25	4	50	145	23	40	42	5	0	86	37	0	0	14	26	1	11	2	2	3	12	22	5	10	0	1	6	547
26	4	53	133	16	28	45	1	0	48	26	0	0	11	33	1	4	2	3	2	9	32	12	24	0	1	7	495
27	0	15	15	2	8	15	0	0	40	5	0	0	2	9	1	0	0	0	1	4	3	0	4	0	0	0	124
28	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
29	5	42	136	18	30	25	0	0	42	15	0	0	13	10	1	4	1	2	5	9	25	5	8	1	0	3	400
30	7	41	117	21	25	40	1	0	77	39	0	0	15	30	4	8	0	1	4	13	31	13	9	0	0	1	497
31	8	54	157	26	41	40	3	0	88	33	0	0	15	18	2	8	2	4	7	18	28	8	18	0	0	7	585

Activity Audit for

March 01 2004 Through March 31 2004

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Smoking Cess. app.	Smoking Cess. den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	NPA app.	NPA den.	Misc app.	Misc den.	Daily Total
App.	161		3472		686		26		1799		1		300		56		46		108		818		356		5		
Den.		1200		523		831		2		636		0		656		168		68		305		195		15		95	
Average Length of Approvals in Days	96		93		100		135		278		92		357		348		357		339		314		221		147		

Smoking Cessation	0 PA's for Zyban	1 Total PA's Approved
	1 PA's for Nicotine Patch	1 Unique RID's

Changes to existing PA's	617
Total (Previous Year)	10358

Monthly Totals

	Number	Percent of Total
Approved	7864	48.73%
Additional PA's	12	0.07%
SUPER PA's	940	5.82%
Emergency PA's	7	0.04%
Duplicates	1041	6.45%
Incompletes	1543	9.56%
Denied *	4731	29.32%
Total	16138	100.00%

Daily Average of 597.70 for 27 Days

*** Denial Codes**

762 = Lack of clinical information	42.19%
763 = Medication not eligible	3.02%
764 = Existing PA	12.22%
772 = Not qualified for requested Tier	7.93%

SUPER PA's

Early Refill Attempts	72054
Dosing Change	656
lost/stolen/broke	101
Other	102
wrong DS	81

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

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

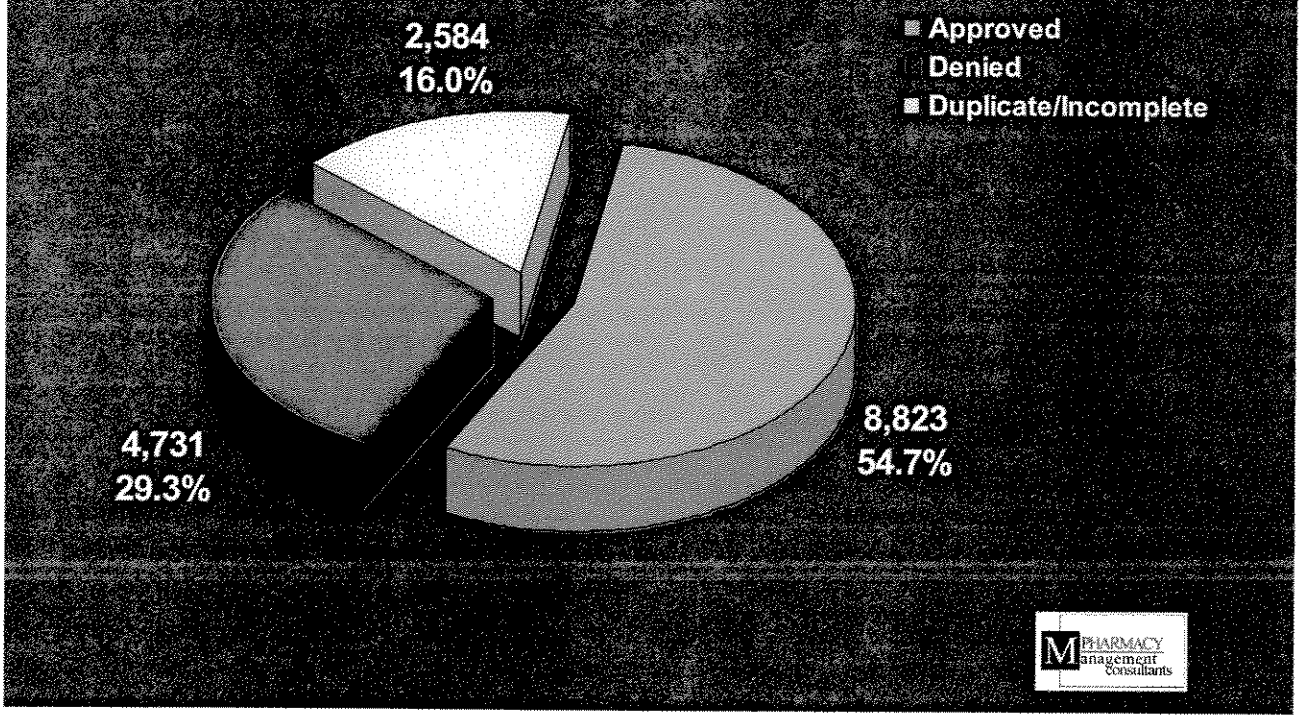
Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

PRIOR AUTHORIZATION ACTIVITY AUDIT

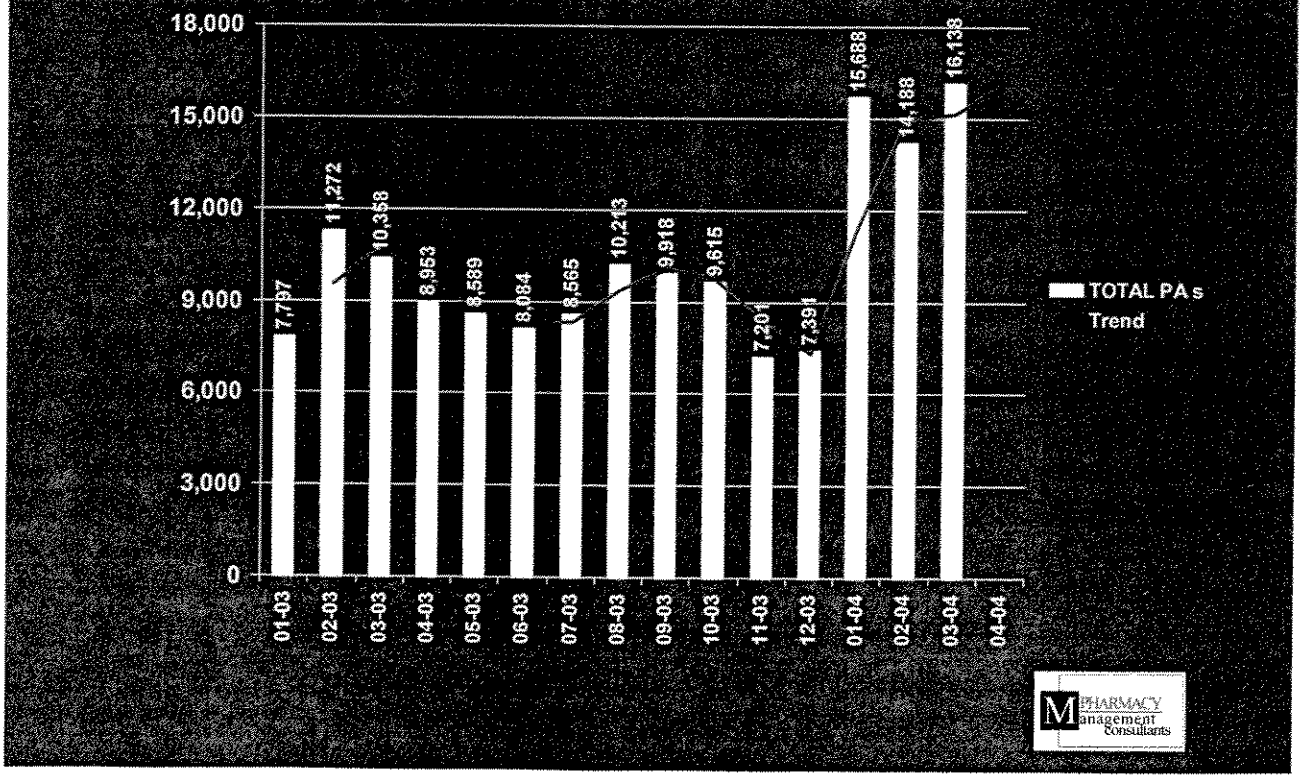
Monthly Totals

MONTH	1999 Total *(approved/ duplicates/ denied)*	2000 Total *(approved/ duplicates/ denied)*	2001 Total *(approved/ duplicates/ denied)*	2002 Total *(approved/ duplicates/ denied)*	2003 Total *(approved/ duplicates/ denied)*	2004 Total *(approved/ duplicates/ denied)*
January	4,124	8,669	9,296	8,427	7,797	15,688
February	3,542	8,077	7,194	6,095	11,272	14,188
March	3,856	7,588	7,748	6,833	10,358	16,138
April	3,867	6,390	7,676	13,381	8,953	
May	3,959	6,711	7,980	12,082	8,589	
June	3,884	6,565	7,249	8,550	8,084	
July	3,523	6,181	8,133	8,775	8,565	
August	10,676	7,183	8,195	9,353	10,213	
September	8,387	6,585	7,438	9,793	9,918	
October	3,863	6,140	7,956	11,584	9,615	
November	3,919	6,961	7,949	7,921	7,201	
December	3,953	6,206	6,385	4,867	7,391	
Calendar Year Total	**57,553**	**83,256**	**93,199**	**107,661**	**107,956**	**46,014**

PRIOR AUTHORIZATION ACTIVITY REPORT
March 2004

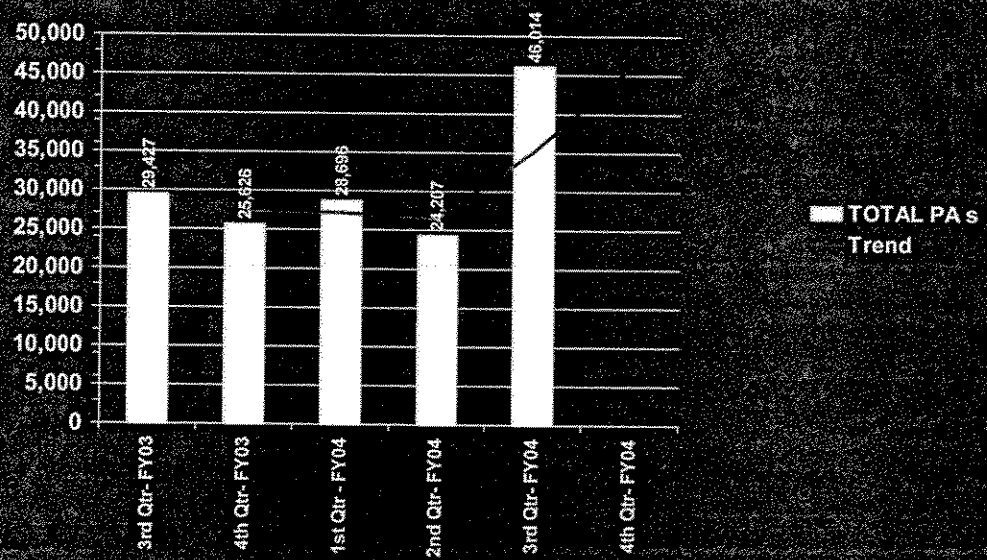


PRIOR AUTHORIZATION REPORT
March 2003 – March 2004



PRIOR AUTHORIZATION QUARTERLY REPORT

3rd Quarter SFY03 thru 3rd Quarter SFY04

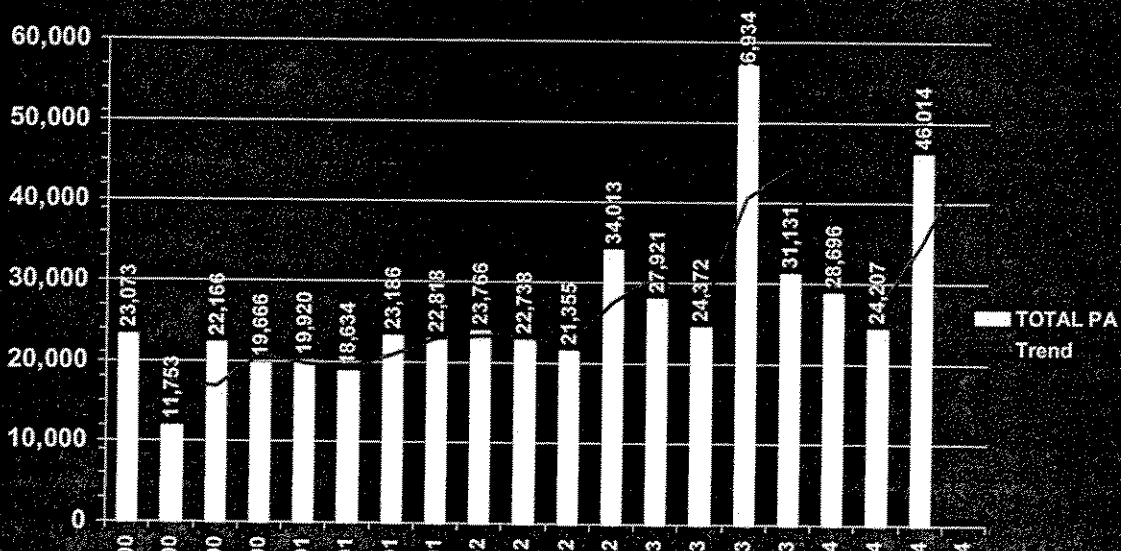


PHARMACY Management Consultants

PRIOR AUTHORIZATION QUARTERLY REPORT

FY00 through FY04

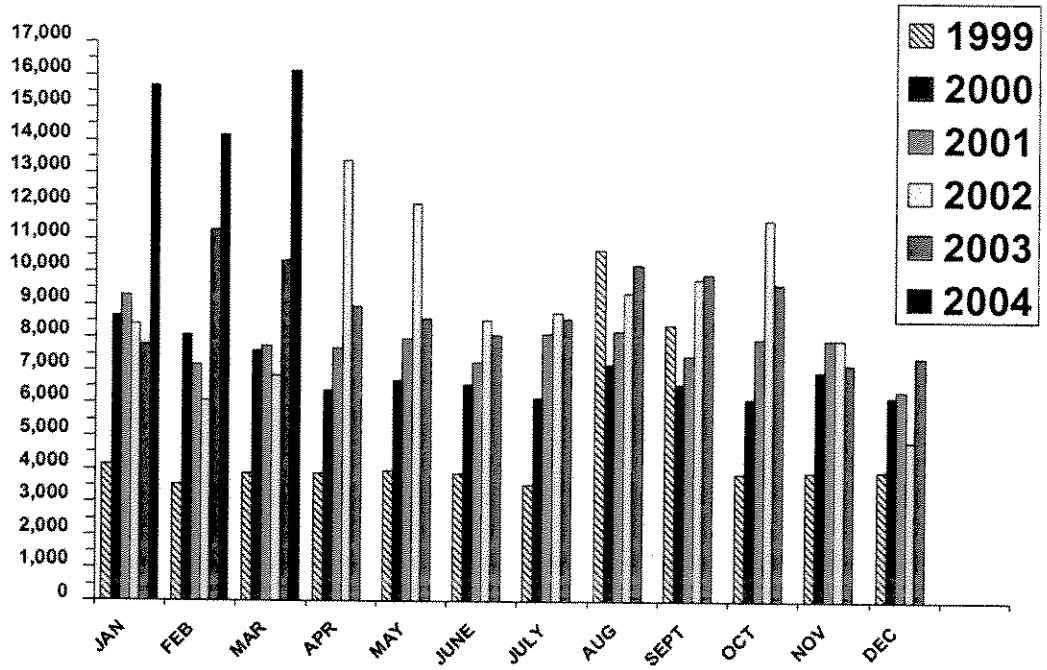
(July 1999 – March 2004)



PHARMACY Management Consultants

Monthly PA Activity

Calendar Years 2000-2004



Monthly PA Activity

Calendar Years 2000-2004

CALL VOLUME - MARCH 2004

MARCH 04	CALLER					ISSUE					TYPE OF CALL							RESOLUTION						
																				Resolved				
	Call Volume	Physician	Pharmacies	Clients	Other	Eligibility	Claims	PA Issue	SMAC	Other	Regular	Callback	Transferred Pharmacist	Transferred Supervisor	Proactive	ProDUR	Other	Helpdesk Resolved	Helpdesk PA	OHCA	Reversals/ Adjustments	EDS	Customer Service	Provider Contracts
1	1014	9	898	61	46	213	622	89	0	90	948	30	1	1	4	19	11	1002	2	0	6	0	4	0
2	964	9	852	78	25	179	581	84	0	120	916	8	1	2	0	26	11	952	0	2	9	0	1	0
3	799	22	578	74	125	172	295	198	3	131	653	117	4	1	4	14	6	790	4	1	4	0	0	0
4	788	14	628	62	84	142	389	137	0	120	680	76	0	0	3	17	12	785	2	0	1	0	0	0
5	771	15	594	63	99	130	386	160	2	93	638	85	0	1	1	24	22	769	1	1	0	0	0	0
6	155	1	151	2	1	21	104	6	0	24	150	4	0	0	0	0	1	155	0	0	0	0	0	0
7	58	0	57	1	0	11	32	3	0	12	58	0	0	0	0	0	0	58	0	0	0	0	0	0
8	826	15	652	81	78	205	391	158	0	72	713	72	2	1	0	27	11	820	6	0	0	0	0	0
9	760	10	663	72	15	179	423	81	0	77	706	3	1	1	1	30	18	753	3	4	0	0	0	0
10	834	14	706	77	37	200	415	106	2	111	765	25	2	0	4	24	14	822	8	4	0	0	0	0
11	788	18	571	59	140	170	274	195	4	145	622	125	3	1	2	19	16	784	4	0	0	0	0	0
12	721	22	534	74	91	145	250	171	2	153	575	84	3	0	4	33	22	709	5	3	4	0	0	0
13	185	0	169	9	7	37	91	10	0	47	177	7	0	0	1	0	0	184	1	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	849	15	648	75	111	162	313	200	2	172	686	102	2	1	2	40	16	843	1	1	1	1	1	1
16	760	9	625	79	47	186	323	103	0	148	656	44	4	1	1	29	25	725	30	1	2	0	1	1
17	724	17	572	64	71	159	256	155	0	154	617	56	4	0	0	24	23	713	3	1	5	0	2	0
18	783	14	645	71	53	160	352	123	5	143	684	33	3	2	3	33	25	768	2	1	3	0	9	0
19	667	23	530	48	66	145	263	118	2	139	556	43	6	0	9	28	25	661	3	1	2	0	0	0
20	176	1	167	4	4	33	86	11	0	46	167	2	0	0	1	5	1	175	0	1	0	0	0	0
21	58	0	54	3	1	13	31	4	0	10	56	1	0	0	0	0	1	58	0	0	0	0	0	0
22	885	20	725	59	81	171	458	143	1	112	753	66	1	0	4	27	34	872	4	3	5	0	1	0
23	824	28	664	69	63	168	359	155	0	142	724	41	3	1	1	27	27	820	0	2	1	0	1	0
24	735	13	590	71	61	136	335	161	2	101	631	53	2	0	0	36	13	691	43	1	0	0	0	0
25	657	18	529	77	33	159	260	120	1	117	576	36	6	1	2	20	16	657	0	0	0	0	0	0
26	741	17	610	65	49	136	340	149	1	115	659	45	3	1	0	18	15	739	1	1	0	0	0	0
27	183	0	170	6	7	31	97	17	0	37	168	13	0	0	2	0	0	183	0	0	0	0	0	0
28	56	1	50	5	0	8	28	5	0	15	56	0	0	0	0	0	0	56	0	0	0	0	0	0
29	827	18	673	86	50	196	379	148	1	103	739	47	3	1	1	23	13	814	1	1	6	1	2	2
30	792	22	656	68	46	172	377	114	0	129	709	35	1	1	2	24	20	748	22	3	7	1	11	0
31	852	24	705	79	44	190	412	140	0	110	779	31	4	1	1	20	16	847	1	0	3	0	1	0
Total	**19,232**	**389**	**15,666**	**1,642**	**1,535**	**4,029**	**8,922**	**3,264**	**28**	**2,988**	**16,817**	**1,284**	**59**	**18**	**53**	**587**	**414**	**18,953**	**147**	**32**	**59**	**3**	**34**	**4**
Percentage	**100.00%**	**2.02%**	**81.46%**	**8.54%**	**7.98%**	**20.95%**	**46.39%**	**16.97%**	**0.15%**	**15.54%**	**87.44%**	**6.68%**	**0.31%**	**0.09%**	**0.28%**	**3.05%**	**2.15%**	**98.55%**	**0.76%**	**0.17%**	**0.31%**	**0.02%**	**0.18%**	**0.02%**

CALL VOLUME

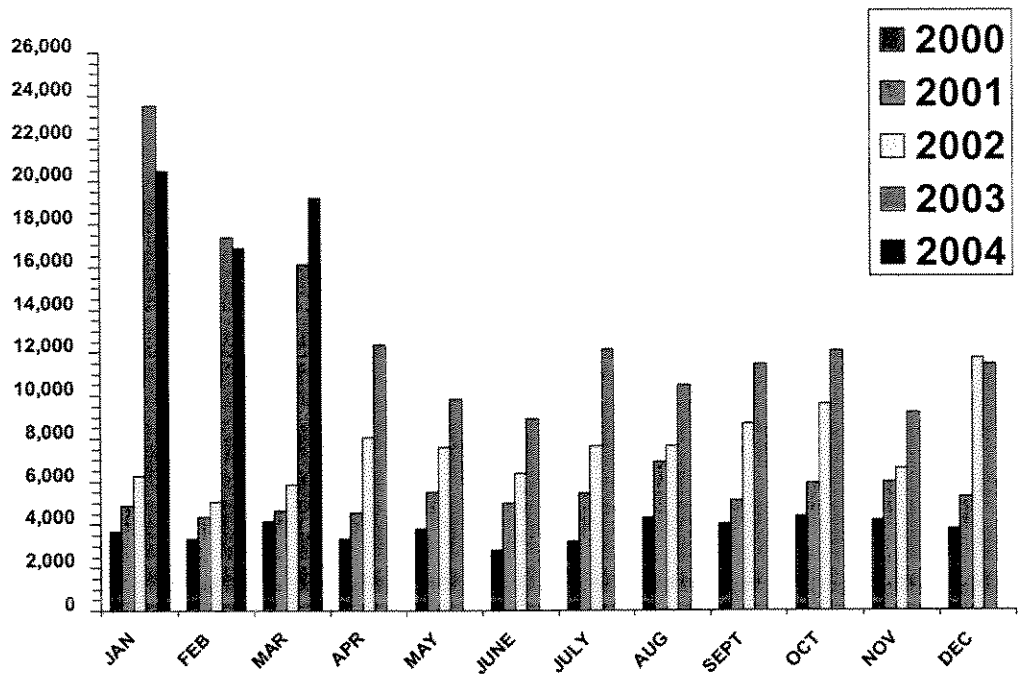
Monthly Totals

MONTH	1999 Total	2000 Total	2001 Total	2002 Total	2003 Total	2004 Total
January	* 0	3,697	4,905	6,295	23,499	20,498
February	* 0	3,335	4,393	5,049	17,354	16,857
March	* 0	4,157	4,668	5,858	16,081	19,232
April	* 0	3,337	4,556	8,047	12,378	
May	* 0	3,804	5,540	7,586	9,836	
June	* 0	2,820	4,982	6,368	8,917	
July	* 0	3,242	5,465	7,651	12,126	
August	3,883	4,333	6,881	7,629	10,454	
September	2,360	4,015	5,145	8,664	11,449	
October	1,963	4,398	5,912	9,608	12,102	
November	1,721	4,216	6,011	6,627	9,178	
December	2,475	3,804	5,314	11,710	11,461	
Calendar Year Total	**12,402**	**45,158**	**63,772**	**91,092**	**154,835**	**56,587**

* Help Desk Call Center implemented in August 1999.

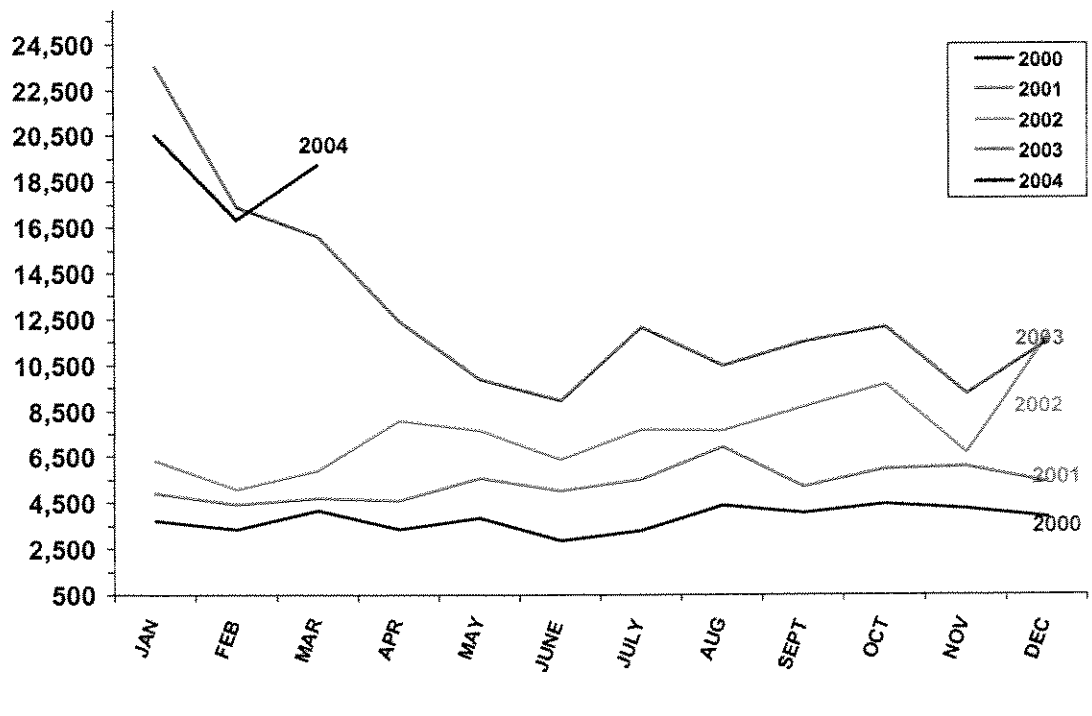
Monthly Call Volume

Calendar Years 2000-2004

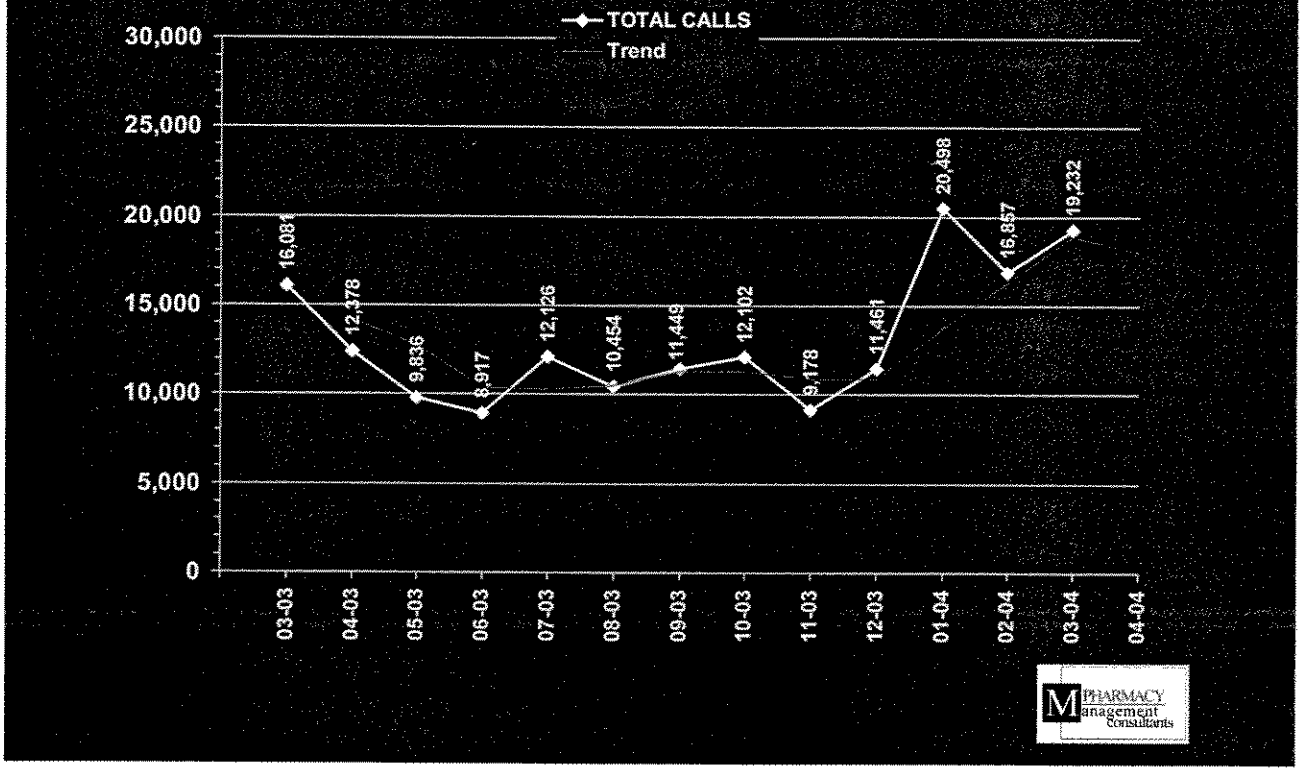


Monthly Call Volume

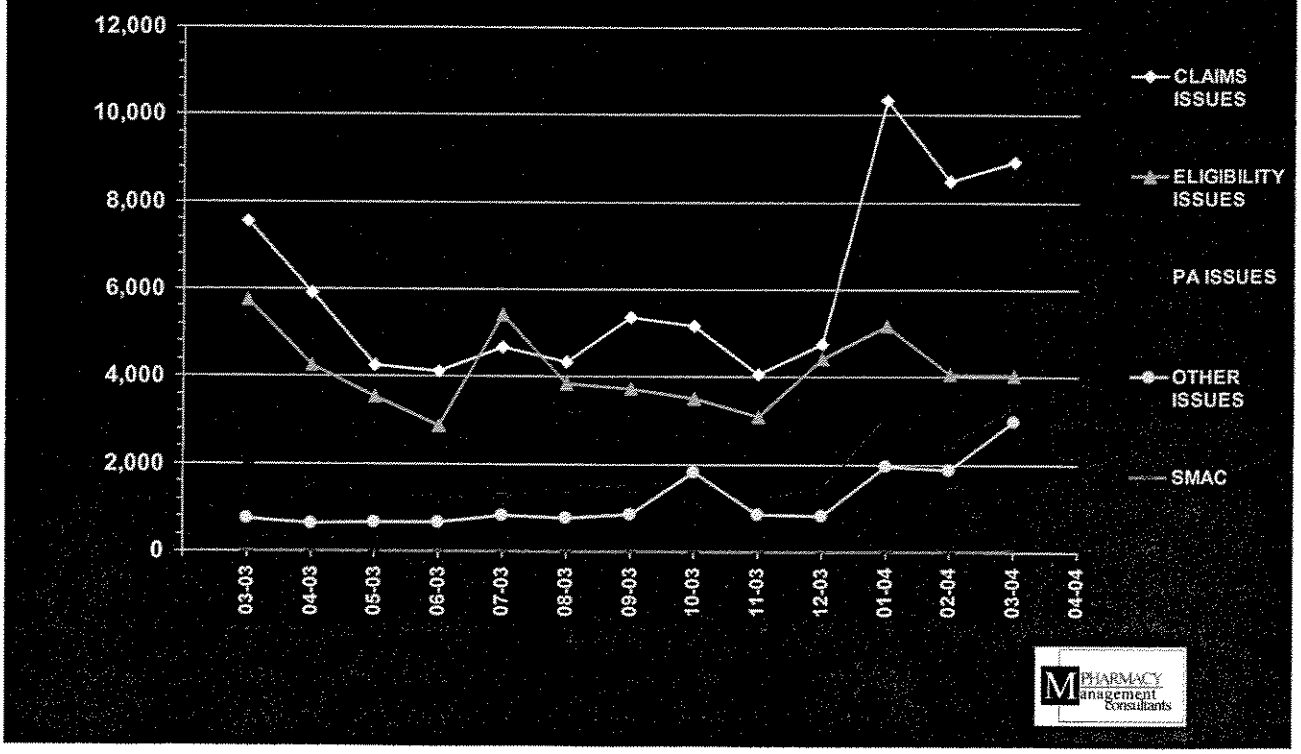
Calendar Years 2000-2004



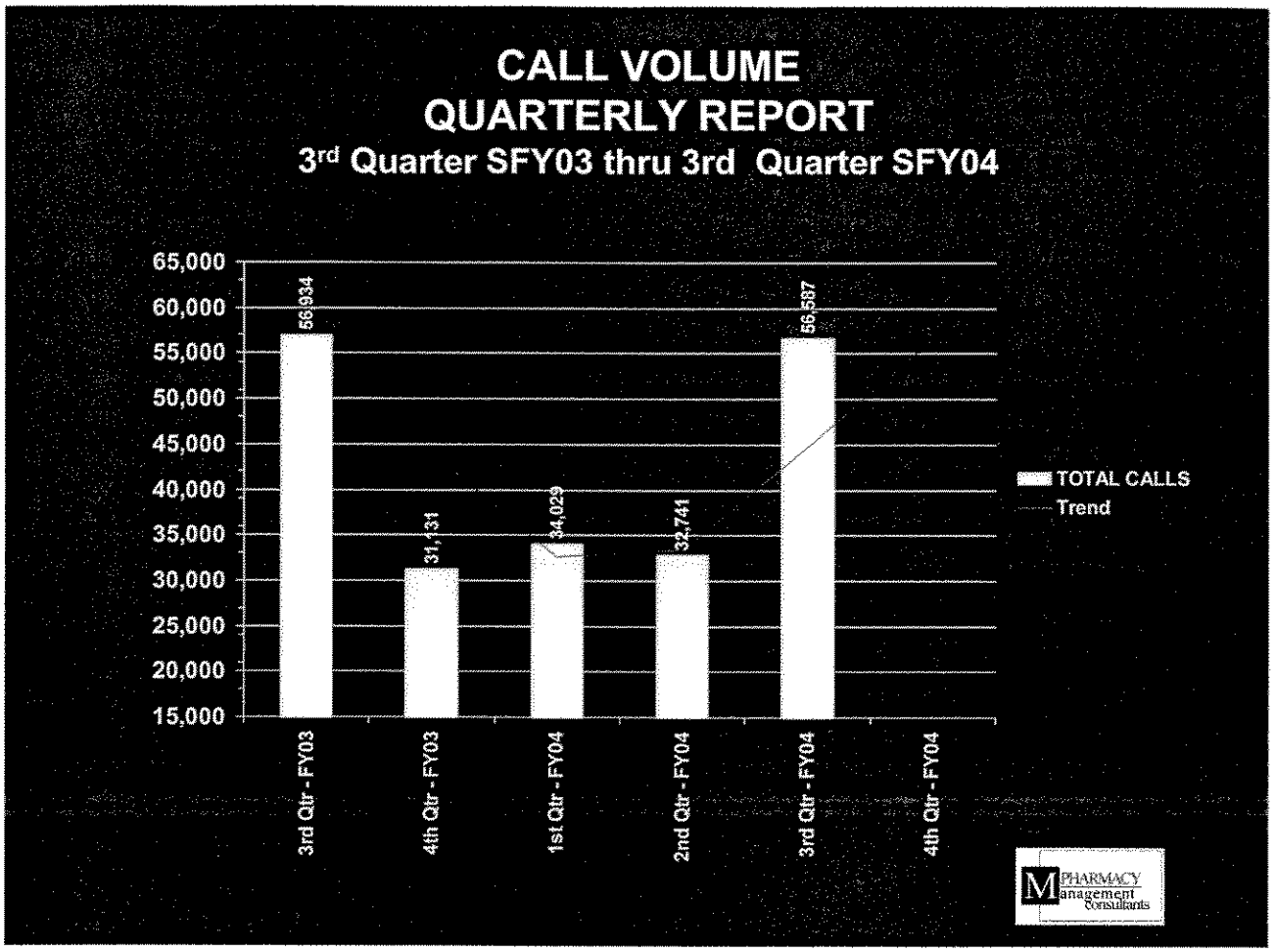
CALL VOLUME MONTHLY REPORT
March 2003 – March 2004



CALL VOLUME ISSUES
March 2003 – March 2004



CALL VOLUME
QUARTERLY REPORT
3rd Quarter SFY03 thru 3rd Quarter SFY04



APPENDIX C

Vote to Change Prior Authorization Criteria for
Anti-Ulcer Medications
Oklahoma Medicaid
April 2004

Product Based Prior Authorization – the college of pharmacy recommends the following prior authorization criteria for anti-ulcer medications:

Tier-1 Medications

1. Prilosec™ OTC
2. Rx Omeprazole (generic and brand)

Tier-2 Medications

1. Ranitidine (Zantac™) capsules and other forms besides tablets
2. Rabeprazole sodium (Aciphex™)
3. Esomeprazole magnesium (Nexium™)
4. Lansoprazole (Prevacid™)
5. Pantoprazole sodium (Protonix™)

Criteria

1. Tier-1 medications do not require prior authorization.
2. A **14** day trial of Prilosec OTC 40mg or Rx Omeprazole 40mg daily within the last **60** days is required before a Tier-2 medication can be authorized.
3. There will be no grandfathering after the current prior authorization expires.

APPENDIX D

SYNAGIS (palivizumab)
Intent to Prior Authorize

Oklahoma Medicaid

April, 2004

Prior Authorization Criteria

A. Must meet one of the following criteria*: (age at the beginning of RSV season)
   1) Infants and children less than 2 years of age with Chronic Lung Disease (CLD) who have required medical treatment (O_2, bronchodilator, diuretic, or corticosteroid therapy) for CLD in the 6 months prior to RSV season.
   2) Infants less than 12 months of age, born at 28 weeks gestation or earlier
   3) Infants less than 6 months of age, born at 29-32 weeks gestation.
   4) Infants, up to 6 months old at the start of RSV season, born at 32-36 weeks gestation, who have 2 or more of the following risk factors:
      a. Child care attendance
      b. School-aged siblings
      c. Exposure to environmental air pollutants (Tobacco smoke exposure can be controlled by the family, so is not a risk factor for Synagis prophylaxis)
      d. Congenital abnormalities of the airway
      e. Severe neuromuscular disease
   5) Children up to 24 months old with hemodynamically significant cyanotic and acyanotic congenital heart disease.
   6) Infants up to 12 month with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.
   7) Other. Specify_____

   * Treatment should continue through the entire RSV season.

B. To be given only during RSV season, approximately October 1 through April 30 (as determined by Oklahoma State Health Department).

C. The number of units authorized is to be calculated as the closest number of full vials necessary to provide the dose based on 15mg/kg per month.

D. Treating multiple patients from a single vial is discouraged due to risk of contamination.

APPENDIX E

Caduet® (Atorvastatin/Amlodipine)
Intent to Prior Authorize
Oklahoma Medicaid
April, 2004

Introduction
- Caduet is a combination drug for the treatment of hypertension and hyperlipidemia.
- It combines atorvastatin (Lipitor), an HMG-CoA reductase inhibitor, and amlodipine (Norvasc), a calcium channel blocker (CCB).
- For use in patients for whom both drugs are indicated

FDA Approved Indications
- Amlodipine component – Hypertension, Chronic stable angina, Vasospastic angina (Prinzmetal's or variant angina)
- Atorvastatin component - Primary dysbetalipoproteinemia, Hypertriglyceridemia, Hypercholesterolemia, Mixed dyslipidemia. Also indicated for heterozygous familial and nonfamilial hypercholesterolemia, and homozygous familial hypercholesterolemia.

Product Information
- Caduet is available as 8 dose combinations.
- Amlodipine/atorvastatin: 5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40, 10/80

Dosing information
- The once daily dose is individualized to effectiveness of each component.
- The FDA maximum daily dose of amlodipine is 10 mg, for atorvastatin, 80mg.

Contraindications
- Hypersensitivity to any component of this medication
- Active liver disease or unexplained persistent elevations of serum transaminases
- During pregnancy and while nursing

Warnings/Precautions
- CCB component can cause increased angina and/or myocardial infarction
- HMG-CoA component associated with liver dysfunction, with elevation of transaminases. These should be monitored during therapy.
- Rhabdomyolysis with acute renal failure due to myoglobinuria has been reported in patients taking atorvastatin.

Adverse effects
- The most common side effects reported by Caduet patients were fluid retention, headache, dizziness, abdominal pain and weakness, and were characterized as mild to moderate.
- With any statin, patients should promptly report muscle pain, tenderness, or weakness. This could be a sign of serious side effects.

Oklahoma Medicaid Utilization - January-December 2003

Norvasc (All Strengths):

Total Recipients 4,048
Total Claims 21,308
Total Units 985,727
Total Cost $1,602,165.13

Lipitor (All Strengths):

Total Recipients 8,440
Total Claims 37,729
Total Units 1,711,853
Total Cost $4,625,815.54

Lipitor and Norvasc (All Strengths):

Total Recipients 614
Total Claims 5,802
Total Units 287,567
Total Cost $618,120.51

Drug Name	Total Clients	# of Claims	Total Units	Total $
Norvasc 2.5 mg	255	1,322	59,435	**$84,351.55**
Norvasc 5 mg	2,226	11,379	532,242	**$742,677.73**
Norvasc 10 mg	1,836	8,607	394,050	**$775,135.85**
Lipitor 10 mg	4,426	20,016	872,652	**$1,904,902.63**
Lipitor 20 mg	3,019	11,656	541,135	**$1,754,710.30**
Lipitor 40 mg	1,358	4,984	245,245	**$795,230.36**
Lipitor 80 mg	343	1,073	52,821	**$170,972.25**

Cost of Caduet versus Norvasc and Lipitor

	5mg/10mg	5mg/20mg	5mg/40mg	5mg/80mg	10mg/10mg	10mg/20mg	10mg/40mg	10mg/80mg
Amlodipine Equivalent (mg)	5	5	5	5	10	10	10	10
Atorvastatin Equivalent (mg)	10	20	40	80	10	20	40	80
EAC cost (Caduet)	$3.16	$4.33	$4.33	$4.33	$3.16	$4.33	$4.33	$4.33
EAC cost Norvasc/Lipitor	1.45+2.27 = 3.72	1.45+3.30 = 4.75	1.45+3.30 = 4.75	1.45+3.30 = 4.75	1.99+2.27 = 4.26	1.99+3.30 = 5.29	1.99+3.30 = 5.29	1.99+3.30 = 5.29

Cost Comparison - 30 day supply:

Caduet 5/10 & 10/10: $94.80 + $4.15 = $98.95
Norvasc 5/Lipitor 10: $43.50 + $4.15 + $68.10 + $4.15 = $119.90
Norvasc 10/Lipitor 10: $59.70 + $4.15 + $68.10 + $4.15 = $136.10

Caduet 5/20, 5/40, 5/80, 10/20, 10/40, & 10/80: $129.90 + $4.15 = $134.05
Norvasc 5/Lipitor 20, 5/40, 5/80: $43.50 + $4.15 + $99.00 + $4.15 = $150.80
Norvasc 10/Lipitor 20, 10/40, 10/80: $59.70 + $4.15 + $99.00 + $4.15 = $167.00

Recommendations

The College of Pharmacy recommends placing Caduet in the Product Based Prior Authorization program as a tier-2 calcium channel blocker. Approval would require:

- An FDA approved diagnosis from each drug category (CCB and HMG-CoA Reductase inhibitor)
- A failed trial of a tier-1 CCB (diltiazem, verapamil, nicardipine, or nifedipine).
- Concurrent use of an HMG-CoA reductase inhibitor.
- Patients currently using both Norvasc and Lipitor will be encouraged to switch to the appropriate strength of Caduet.

APPENDIX F

Provigil® (modafinil)
Intent to Prior Authorize

Oklahoma Medicaid
April 2004

Utilization

For the period of Jan 2002 through Dec 2003, a total of 290 clients received modafinil through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Total Cost
Provigil 100 mg tablet	278	11,846	9,651	$45,801.68
Provigil 200 mg tablet	775	36,147	28,731	$193,528.83
Total	**1,053**	**47,993**	**38,382**	**$239,330.51**

Recommendations

The College of Pharmacy recommends that the board discuss this issue at the next DUR board meeting and consider whether prior authorization should be required for Provigil prescriptions.

Prior authorization criteria could include:

- Coverage of Provigil only for FDA approved indications
- Maximum covered dosing 200 mg daily
- Quantity limitation of 30 tablets per 30 days
- Provigil not covered if the patient is taking daytime benzodiazepines concurrently

APPENDIX G

Antiretroviral Drugs for HIV

Drug Utilization Review: 11/1/02 – 10/31/03

Oklahoma Medicaid
April 2004

Background

State Medicaid programs are the single largest source of public financing for HIV/AIDS care in the United States. According to the Kaiser Family Foundation, state Medicaid programs provided 43% of spending on HIV/AIDS in FY 2000, but HIV/AIDS represented only about 2% of total Medicaid spending nationwide.
(From: http://www.kff.org/hivaids/upload/13367_1.pdf)

Utilization

For the period of November 2002 through October 2003, a total of 467 clients received antiretroviral agents through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Per Diem
Protease Inhibitors						
Amprenavir (AGENERASE)	63	14,940	1,657	9.02	$18,767.27	$11.33
Atazanavir (REYATAZ)	12	720	360	2.00	$8,752.73	$24.31
Fosamprenavir (LEXIVA)	0	0	0	0	$0.00	$0.00
Indinavir (CRIXIVAN)	376	57,570	10,905	5.28	$150,388.46	$13.79
Nelfinavir (VIRACEPT)	422	124,940	12,613	9.91	$267,974.16	$21.25
Ritonavir (NORVIR)	216	27,190	6,534	4.16	$50,000.45	$7.65
Saquinavir (FORTOVASE, INVIRASE)	96	27,630	2,836	9.74	$37,232.31	$13.13
Lopinavir/Ritonavir (KALETRA)	855	171,464	25,135	6.82	$556,386.87	$22.14
Nucleotide Analog Reverse Transcriptase Inhibitor						
Tenofovir (VIREAD)	487	15,611	15,391	1.01	$199,629.31	$12.97
Nucleoside Reverse Transcriptase Inhibitors						
Abacavir (ZIAGEN)	243	15,070	7,535	2.00	$93,118.55	$12.36
Didanosine (VIDEX)	679	23,974	21,663	1.11	$178,251.52	$8.23
Emtricitabine (EMTRIVA)	6	180	180	1.00	$1,606.54	$8.93
Lamivudine (EPIVIR)	774	59,332	23,883	2.48	$204,004.82	$8.54
Stavudine (ZERIT)	805	61,097	24,738	2.47	$247,946.68	$10.02
Zalcitabine (HIVID)	0	0	0	0	$0.00	$0.00
Zidovudine (RETROVIR)	180	28,516	5,370	5.31	$52,117.86	$9.71
Abacavir/Lamivudine/ Zidovudine (TRIZIVIR)	174	10,410	5,205	2.00	$168,357.01	$32.35
Lamivudine/ Zidovudine (COMBIVIR)	952	58,344	28,796	2.03	$576,736.19	$20.03
Non-Nucleoside Reverse Transcriptase Inhibitors						
Delavirdine (RESCRIPTOR)	34	7,020	1,020	6.88	$9,542.36	$9.36
Efavirenz (SUSTIVA)	760	36,140	23,402	1.54	$309,023.68	$13.21
Nevirapine (VIRAMUNE)	339	21,944	10,247	2.14	$120,186.75	$11.73
Fusion Inhibitor						
Enfuvirtide (FUZEON)	5	5	144	0.03	$9,172.85	$63.70
Total	**7,478**	**762,097**	**227,614**	**3.35**	**$3,259,196.37**	**$14.32**

Total Cost 11/1/02 – 10/31/03	**$3,259,196.37**
Total Cost 11/1/01 – 10/31/02	*$3,087,834.50*
Total Claims 11/1/02 – 10/31/03	**7,478**
Total Claims 11/1/01 – 10/31/02	*8,040*
Total Clients 11/1/02 – 10/31/03	**467**
Total Clients 11/1/01 – 10/31/02	*463*
Per Diem 11/1/02 – 10/31/03	**$14.32**
Per Diem 11/1/01 – 10/31/02	*$12.88*

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

Age	Female	Male	Totals
0 to 9	8	6	14
10 to 19	2	4	6
20 to 34	20	52	72
35 to 49	64	254	318
50 to 64	13	38	51
65 to 79	1	5	6
80 to 94	0	0	0
95 and Over	0	0	0
Totals	**108**	**359**	**467**

Claims were reviewed to determine the total number of claims per client:

Claim Count	# of Clients	% of Clients
1 to 5	124	26.5
6 to 10	74	15.9
11 to 15	50	10.7
16 to 20	48	10.3
21 and over	171	36.6
Totals	**467**	**100**

Controversial Issues

Ritonavir (Norvir):

- Recent five-fold price increase (100 mg capsule: AWP on 12/1/03 was $1.88; on 12/4/03 AWP increased to $10.72).
- Patients generally use the drug in small doses as a pharmacokinetic enhancer for other protease inhibitors (PI's), but some patients still use the drug at higher doses as a stand-alone PI.
- Public programs will be protected from the price increase until June 2005. However, many states must pay the new price up front and get the difference back later as a manufacturer's rebate.

Enfuvirtide (Fuzeon):

- New drug, injected SQ twice daily every day. Yearly cost is about $20,000.00.
- Currently only available in the U.S. through one central pharmacy.
- Is only indicated for treatment-experienced patients. Has not been tested in antiretroviral naïve patients.
- At least 2 state Medicaid programs have already placed a prior authorization requirement on this drug: Florida and Massachussetts.

Recommendations

The college of pharmacy has the following recommendation:

Consider placing a prior authorization requirement on coverage of Fuzeon.

Antiretroviral Drugs for HIV – Appendix

Comparisons of HIV regimens:

Comparison of sequential three-drug regimens as initial therapy for HIV-1 infection.[see comment].
Authors
Robbins GK. De Gruttola V. Shafer RW. Smeaton LM. Snyder SW. Pettinelli C. Dube MP. Fischl MA. Pollard RB. Delapenha R. Gedeon L. van der Horst C. Murphy RL. Becker MI. D'Aquila RT. Vella S. Merigan TC. Hirsch MS. AIDS Clinical Trials Group 384 Team.
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Comments
Comment in: N Engl J Med. 2003 Dec 11;349(24):2351-2; PMID: 14668462
Source
New England Journal of Medicine. 349(24):2293-303, 2003 Dec 11.
Abstract
BACKGROUND: The optimal sequencing of antiretroviral regimens for the treatment of infection with human immunodeficiency virus type 1 (HIV-1) is unknown. We compared several different antiretroviral treatment strategies. **METHODS:** This multicenter, randomized, partially double-blind trial used a factorial design to compare pairs of sequential three-drug regimens, starting with a regimen including zidovudine and lamivudine or a regimen including didanosine and stavudine in combination with either nelfinavir or efavirenz. The primary end point was the length of time to the failure of the second three-drug regimen. **RESULTS:** A total of 620 subjects who had not previously received antiretroviral therapy were followed for a median of 2.3 years. Starting with a three-drug regimen containing efavirenz combined with zidovudine and lamivudine (but not efavirenz combined with didanosine and stavudine) appeared to delay the failure of the second regimen, as compared with starting with a regimen containing nelfinavir (hazard ratio for failure of the second regimen, 0.71; 95 percent confidence interval, 0.48 to 1.06), as well as to delay the second virologic failure (hazard ratio, 0.56; 95 percent confidence interval, 0.29 to 1.09), and significantly delayed the failure of the first regimen (hazard ratio, 0.39) and the first virologic failure (hazard ratio, 0.34). Starting with zidovudine and lamivudine combined with efavirenz (but not zidovudine and lamivudine combined with nelfinavir) appeared to delay the failure of the second regimen, as compared with starting with didanosine and stavudine (hazard ratio, 0.68), and significantly delayed both the first and the second virologic failures (hazard ratio for the first virologic failure, 0.39; hazard ratio for the second

virologic failure, 0.47), as well as the failure of the first regimen (hazard ratio, 0.35). The initial use of zidovudine, lamivudine, and efavirenz resulted in a shorter time to viral suppression. **CONCLUSIONS:** The efficacy of antiretroviral drugs depends on how they are combined. The combination of zidovudine, lamivudine, and efavirenz is superior to the other antiretroviral regimens used as initial therapy in this study. Copyright 2003 Massachusetts Medical Society

Comparison of four-drug regimens and pairs of sequential three-drug regimens as initial therapy for HIV-1 infection.[see comment].

Authors
Shafer RW. Smeaton LM. Robbins GK. De Gruttola V. Snyder SW. D'Aquila RT. Johnson VA. Morse GD. Nokta MA. Martinez AI. Gripshover BM. Kaul P. Haubrich R. Swingle M. McCarty SD. Vella S. Hirsch MS. Merigan TC. AIDS Clinical Trials Group 384 Team.
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Comments
Comment in: N Engl J Med. 2003 Dec 11;349(24):2351-2; PMID: 14668462
Source
New England Journal of Medicine. 349(24):2304-15, 2003 Dec 11.
Abstract
BACKGROUND: It is unclear whether **therapy for** human immunodeficiency virus type 1 (**HIV-1**) should be initiated with a four-drug or two sequential three-drug regimens. **METHODS:** In this multicenter trial we compared initial therapy involving four-drug regimens containing efavirenz and nelfinavir in combination with either didanosine and stavudine or zidovudine and lamivudine with therapy involving two consecutive three-drug regimens the first of which contained either efavirenz or nelfinavir. **RESULTS:** A total of 980 subjects were followed for a median of 2.3 years. There was no significant difference in the occurrence of regimen failures between the group that received the four-drug regimen containing didanosine, stavudine, nelfinavir, and efavirenz and the groups that received the three-drug regimens beginning with didanosine, stavudine, and nelfinavir (hazard ratio for regimen failure, 1.24) or didanosine, stavudine, and efavirenz (hazard ratio, 1.01). There was no significant difference between the group that received the four-drug regimen containing zidovudine, lamivudine, nelfinavir, and efavirenz and the groups that received the three-drug regimens beginning with zidovudine, lamivudine, and nelfinavir (hazard ratio, 1.06) or zidovudine, lamivudine, and efavirenz (hazard ratio, 1.45). A four-drug regimen was associated with a longer time to the first regimen failure than the three-drug regimens containing didanosine, stavudine, and nelfinavir (hazard ratio for a first regimen failure, 0.55); didanosine, stavudine, and efavirenz (hazard ratio, 0.63); or zidovudine, lamivudine, and nelfinavir (hazard ratio, 0.49), but not the three-drug regimen containing zidovudine, lamivudine, and efavirenz (hazard ratio, 1.21).
CONCLUSIONS: There was no significant difference in the duration of successful HIV-1 treatment between a single four-drug regimen and two consecutive three-drug regimens. Among these treatment strategies, initiating therapy with the three-drug regimen of zidovudine, lamivudine, and efavirenz is the optimal choice. Copyright 2003 Massachusetts Medical Society

Guidelines:

CDC Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents - November 10, 2003

Developed by the Panel on Clinical Practices for Treatment of HIV Infection convened by the Department of Health and Human Services (DHHS).
These guidelines are available at the following website:
http://www.aidsinfo.nih.gov/guidelines/adult/AA_111003.html
The following page is an excerpt of these guidelines.

Table 12a. Antiretroviral Regimens Recommended for Treatment of HIV-1 Infection in Antiretroviral Naïve Patients

This table is a guide to treatment regimens for patients who have no previous experience with HIV therapy. Regimens should be individualized based on the advantages and disadvantages of each combination such as pill burden, dosing frequency, toxicities, and drug-drug interactions, and patient variables, such as pregnancy, co-morbid conditions, and level of plasma HIV-RNA. Clinicians should refer to **Table 12b** to review the pros and cons of different components of a regimen and to **Tables 15–18** for adverse effects and dosages of individual antiretroviral agents. Preferred regimens are in bold type; regimens are designated as "preferred" for use in treatment naïve patients when clinical trial data suggests optimal and durable efficacy with acceptable tolerability and ease of use. Alternative regimens are those where clinical trial data show efficacy, but it is considered alternative due to disadvantages compared to the preferred agent, in terms of antiviral activity, demonstrated durable effect, tolerability or ease of use. In some cases, based on individual patient characteristics, a regimen listed as an alternative regimen in the table may actually be the preferred regimen for a selected patient. Clinicians initiating antiretroviral regimens in the HIV-1-infected pregnant patient should refer to "*Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*", at **http://www.aidsinfo.nih.gov/guidelines/**.

NNRTI-Based Regimens		**# of pills per day**
Preferred Regimens	**efavirenz + lamivudine + (zidovudine or tenofovir DF or stavudine*) – except for pregnant women or women with pregnancy potential****	**3–5**
Alternative Regimens	efavirenz + emtricitabine + (zidovudine or tenofovir DF or stavudine*) – except for pregnant women or women with pregnancy potential**	3–4
	efavirenz + (lamivudine or emtricitabine) + (didanosine or abacavir) - except for pregnant women or women with pregnancy potential**	3-5
	nevirapine + (lamivudine or emtricitabine) + (zidovudine or stavudine* or didanosine or abacavir) [Note: High incidence (11%) of symptomatic hepatic events observed in women with pre-nevirapine CD4+ T cell count > 250 cells/mm³ and men with CD4 > 400 cells/mm³ (6.3%). Use with caution in these patients, with close clinical and laboratory monitoring, especially during the first 18 weeks of therapy.]	4–5
PI-Based Regimens		**# of pills per day**
Preferred Regimens	**lopinavir/ritonavir (co-formulated as Kaletra®) + lamivudine + (zidovudine or stavudine*)**	**8–10**
Alternative Regimens	atazanavir + (lamivudine or emtricitabine) + (zidovudine or stavudine* or abacavir)	4-5
	fosamprenavir + (lamivudine or emtricitabine) + (zidovudine or stavudine* or abacavir)	6–8
	fosamprenavir/ritonavir† + (lamivudine or emtricitabine) + (zidovudine or stavudine* or abacavir)	6–8
	indinavir/ritonavir†+(lamivudine or emtricitabine)+(zidovudine or stavudine* or abacavir)	8-11
	lopinavir/ritonavir (co-formulated as Kaletra®) + emitricitabine + (zidovudine or stavudine* or abacavir)	8-9
	lopinavir/ritonavir (co-formulated as Kaletra®) + lamivudine + abacavir	8-9
	nelfinavir§ + (lamivudine or emtricitabine) + (zidovudine or stavudine* or abacavir)	12-14
	saquinavir (sgc or hgc)ϕ/ritonavir† + (lamivudine or emtricitabine) + (zidovudine or stavudine* or abacavir)	14-16
Triple NRTI Regimen – Only when a preferred or alternative NNRTI- or a PI-based regimen cannot or should not be used as first line therapy		**# of pills per day**
	abacavir + lamivudine + zidovudine (or stavudine*)	2–6

* Higher incidence of lipoatrophy, hyperlipidemia, and mitochondrial toxicities reported with stavudine than with other NRTIs.

** Women with child bearing potential implies women who want to conceive or those who are not using effective contraception

† Low-dose (100–200 mg) ritonavir

ϕ sgc = soft gel capsule; hgc = hard gel capsule

APPENDIX H

Pharmacoeconomic Review of the Statins

Oklahoma Medicaid
April 2004

Background

Introduction

Cardiovascular disease is the leading cause of death for both men and women in the United States and worldwide. It was the reported cause of 60% of total mortality in 2001, an average of 1 death every 34 seconds. Data from the Healthcare Cost and Utilization Project showed the 1st and 2nd most costly diagnosis treated in U.S. hospitals were cardiovascular disease and associated events.[1] Hyperlipidemia is a major risk factor for developing cardiovascular diseases. There is an increased awareness for the risks associated with cardiovascular diseases and more emphasis is being placed on prevention of cardiovascular disease and its associated mortality and morbidity.

In 1985 a new class of anticholesterol medication known as 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, otherwise known as the statins, was introduced to the market. HMG-CoA reductase is the rate-limiting enzyme in de novo cholesterol synthesis. HMG-CoA reductase inhibitors have been found to reduce the production of mevalonic acid from HMG-CoA, resulting in a reduction in hepatic cholesterol synthesis. This in turn results in a compensatory increase in the expression of high affinity low-density lipoprotein (LDL) receptors on hepatocyte membranes and stimulation of LDL catabolism.[2]

Hyperlipidemia

The National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol meets periodically to determine the guidelines for treatment of dyslipidemias in adults. The panel consists of representatives from various medical practices, associations, and federal agencies who last convened in 2002 to assemble the guideline's latest update, known as the NCEP Adult Treatment Panel III (ATPIII) guidelines. According to these guidelines, 50% of the population ages 20 and older have elevated cholesterol levels.

	LDL (mg/dL)	Triglycerides (mg/dL)	HDL
Desired	<100	<150	>60
Borderline High	100-129	150-199	
High	130-159	200-499	
Very High	>160	>500	

Treatment

Low density lipoprotein (LDL) cholesterol is the primary target of treatment as a result of clinical studies that have indicated elevated LDL cholesterol as a major cause of coronary heart disease. A number of large randomized clinical trials have shown that reduction of LDL

cholesterol significantly reduces the incidence of cardiovascular events. As a result, treatment guidelines use LDL values as the indicator for initiation and the target for treatment.[3]

Pharmacologic Treatments of Hyperlipidemia[4, 5]

Pharmacologic Class	LDL-C	Triglycerides	HDL-C
Bile acid-binding resins	↓ 10-30%	↑ 3-10%	Unchanged
Fibric acid derivatives	↓ 5-10%*	↓ 30-60%	↑ 5-10%
Nicotinic acid derivatives	↓ 10-25%	↓ 5-30%	↑ 15-25%
HMG-CoA reductase inhibitors	↓ 20-40%	↓ 10-30%	↑ 5-15%

* Fenofibrate may increase LDL-C levels.

New Studies and Guidelines

Due to the many large scale randomized clinical trials that show cholesterol lowering therapy with HMGCo-A reductase inhibitors reduces the mortality and/or cardiovascular events regardless of age, gender, and history of coronary artery disease, the statins are currently the pharmacologic class of choice for treatment of elevated LDL levels per NCEP guidelines.[6]

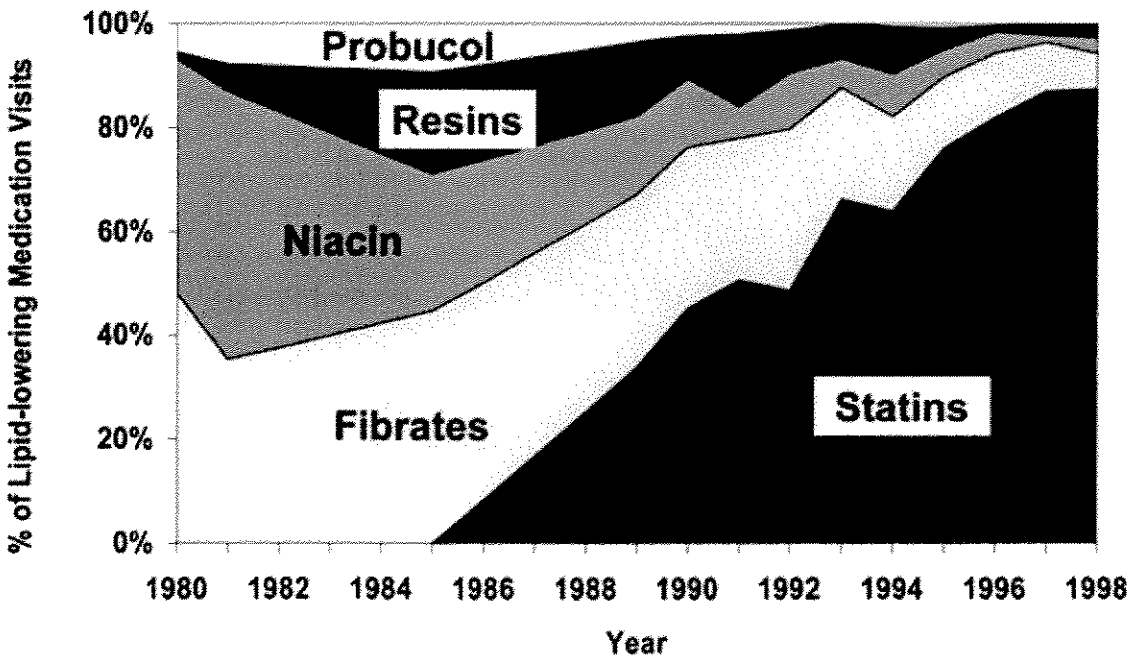


Figure 1 of Wang TJ et al. Annual proportion of medication classes among all visits by patients taking cholesterol-lowering medications.[7]

New studies and guideline changes are expected to further increase the use of this class of anticholesterol medication. Recent findings of clinical trials such as the Heart Protection Study[8] and the PROVE IT[9] Study show that patients with normal LDL values according to the NCEP guidelines benefit just as much as those with high LDL cholesterol in terms of reduction of coronary events and that reduction of LDL cholesterol below the recommended values provide additional risk reduction in terms of events and deaths. The new update of NCEP ATP III guidelines call for more aggressive diagnosis and treatment of hypercholesterolemia, which will substantially increase the number of individuals in the United States considered to be at risk for heart disease, and expand the number of people who will receive drug treatment with statins.

Currently Available Statins

Generic Name	*Brand Name*	*Dosage Forms Available*	*Usual Adult Dose*	*CNS Penetration*	*Comments*
Lovastatin	Mecacor® Altocor®	10, 20, 40 mg Tabs 10, 20, 40, 60 mg XR Tabs	10-80 mg QHS or divided doses	Yes	Take with food
Pravastatin	Pravachol®	10, 20, 40, 80 mg Tabs	10-40 mg QHS	No	Metabolized by Sulfation
Fluvastatin	Lescol® Lescol XL®	20, 40 mg Caps 80 mg XL Tabs	20-80 mg QHS or divided doses	No	
Simvastatin	Zocor®	5, 10, 20, 40, 80 mg Tabs	5-80 mg QHS	Yes	
Atorvastatin	Lipitor®	10, 20, 40, 80 mg Tabs	10-80 mg QD	No	14 hr half life
Rosuvastatin	Crestor®	5, 10, 20, 40 mg Tabs	10-40 mg QD	No	19 hr half life 10% metabolized

- Statins are contradindicated in pregnant women or women who may become pregnant and in patients with active or chronic liver disease.
- Statins are metabolized by the CYP-450 enzyme system and are susceptible to drug interactions that may increase risk of myopathy. Caution should be taken when statins are administered concomitantly with medications sharing the same metabolic pathway.
- The combination of statins and fibric acid derivatives may increase risk for myopathy.
- Statins have similar low adverse effect profiles and are generally well tolerated with the most common adverse effects being GI symptoms and muscle aches. Elevated liver function tests occur in < 2% and are usually reversible upon lowering the dose or discontinuation of the statin. The increase is generally not seen with a re-challenge or trial with another statin.

Monitoring in Statin Therapy[10]

- Upon initiation of a statin, followup visits should be made every 6-8 weeks to assess efficacy and titrate dose to achieve LDL goal. Thereafter follow-up visits should be every 4-6 months.
- It is recommended that liver function tests be performed before and at 12 weeks following both the initiation of therapy and any elevation of dose, then periodically thereafter (e.g. semi-annually).
- Creatine kinase levels should be obtained initially and when muscle soreness, tenderness, or pain is reported. Statins should be discontinued if CK levels exceed 10 times the upper limit of normal in a patient with myalgias. Myalgias are generally reported in 5% of patients in clinical trials and are not usually associated with myotoxicity.
- Due to rhabdomyolysis, a severe but rare adverse event that can occur with statins, patients should be advised to report any muscle weakness, discomfort, or brown urine immediately.

New Anticholesterol Products

Zetia® (ezetimibe)

- First of a new anticholesterol class called 2-azetidinones which inhibits absorption of cholesterol at the brush border of the small intestines.
- Marketed as an adjunct to statin therapy in cases when lipid goals are not met with maximal statin therapy or for patients with contraindications to statin.
- Lowers LDL-C approximately 18% as monotherapy and when combined with a statin, contributes an additional 25% in LDL reduction over statins alone.[11]

Advicor®

- Combination of lovastatin and niacin extended release.
- Maximum reduction of LDL-C is 45%, triglycerides is 44%, and increases HDL by 30%, which is better than either product alone.[12]
- Increased risk for myopathy and LFT abnormality with combination drug.

Pravigard PAC®

- Pravastatin and aspirin tablets packaged side by side on a blister card.
- For patients in which both pravastatin and aspirin are indicated.
- Available doses are 20/81mg, 20/325mg, 40/81mg, and 40/325mg (blister cards with both tabs.)

Caduet®

- Combination of Norvasc® (amlodipine) and Lipitor® (atorvastatin).
- Available doses and cost* between Caduet® versus combined cost of Lipitor® and Norvasc®.
- This product will be discussed during the Antihypertensive Annual Review.

Utilization and Cost Comparison of Statins

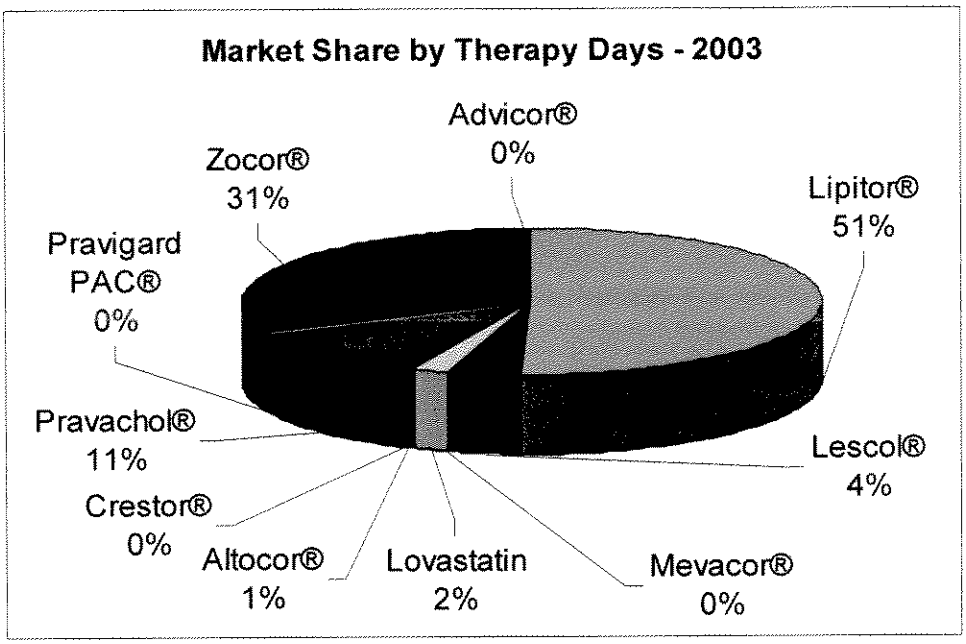
Utilization

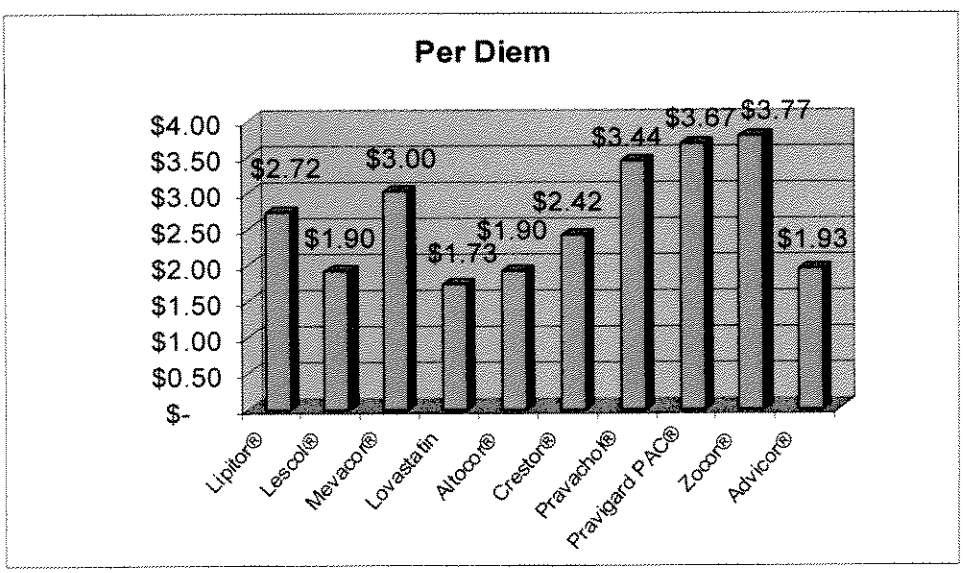
For the period of January 2003 through December 2003, a total of 18,490 clients received statins and statin combination products through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Unit/ Day	Total Cost	Total Clients	Per Diem**
LOVASTATIN TAB 10MG*	65	3,004	2,614	1.15	$ 2,549.83	15	$ 0.98
LOVASTATIN TAB 20MG*	1,030	48,365	43,731	1.10	$ 61,263.85	211	$ 1.40
LOVASTATIN TAB 40MG*	414	2,413	2,302	1.05	$ 4,739.64	24	$ 2.06
MEVACOR® TAB 20MG*	35	20,684	18,894	1.09	$ 49,286.95	120	$ 2.61
MEVACOR® TAB 40MG*	50	2,396	2,194	1.09	$ 8,757.03	17	$ 3.99
ALTOCOR CR® TAB 20MG	2	120	120	1.00	$ 194.38	2	$ 1.62
ALTOCOR CR® TAB 40MG	36	1,278	1,350	0.95	$ 2,184.95	14	$ 1.62
ALTOCOR CR® TAB 60MG	413	16,707	16,647	1.00	$ 32,001.26	193	$ 1.92
ADVICOR® TAB 500-20MG	186	9,477	7,847	1.21	$ 14,902.68	63	$ 1.90
ADVICOR® TAB 750-20MG	11	430	430	1.00	$ 812.90	5	$ 1.89
ADVICOR® TAB 1000-20	18	988	868	1.14	$ 1,962.02	7	$ 2.26
PRAVACHOL® TAB 10MG	527	22,925	21,280	1.07	$ 62,155.75	94	$ 2.92
PRAVACHOL® TAB 20MG	3,590	169,985	163,724	1.04	$ 466,964.27	786	$ 2.85
PRAVACHOL® TAB 40MG	3,520	161,924	159,491	1.02	$ 649,395.26	833	$ 4.07
PRAVACHOL® TAB 80MG	328	17,157	18,363	0.93	$ 68,900.79	110	$ 3.75
PRAVIGARD PAC® 81-20MG	2	90	60	1.50	$ 248.26	2	$ 4.14
PRAVIGARD PAC® 325-20MG	1	100	100	1.00	$ 273.22	1	$ 2.73
PRAVIGARD PAC® 81-40MG	3	150	150	1.00	$ 603.14	2	$ 4.02
PRAVIGARD PAC® 325-40MG	1	30	30	1.00	$ 121.49	1	$ 4.05
LESCOL® CAP 20MG	778	36,337	34,333	1.06	$ 60,005.89	150	$ 1.75
LESCOL® CAP 40MG	1,153	56,115	51,996	1.09	$ 92,230.14	256	$ 1.77
LESCOL XL® TAB 80MG	1,108	51,384	50,367	1.02	$ 107,827.83	279	$ 2.14
ZOCOR® TAB 5MG	292	12,824	11,800	1.09	$ 23,069.89	69	$ 1.96
ZOCOR® TAB 10MG	2,697	122,789	119,493	1.03	$ 286,320.63	713	$ 2.40
ZOCOR® TAB 20MG	10,140	476,298	471,882	1.01	$ 1,940,206.38	2,612	$ 4.11
ZOCOR® TAB 40MG	7,058	323,975	334,848	0.97	$ 1,323,040.49	1,970	$ 3.95
ZOCOR® TAB 80MG	2,166	103,324	120,902	0.85	$ 421,796.31	677	$ 3.49
LIPITOR® TAB 10MG	20,016	872,652	859,248	1.02	$ 1,904,902.63	4,426	$ 2.22
LIPITOR® TAB 20MG	11,656	541,135	537,764	1.01	$ 1,754,710.30	3,019	$ 3.26
LIPITOR® TAB 40MG	4,984	245,245	245,699	1.00	$ 795,230.36	1,358	$ 3.24
LIPITOR® TAB 80MG	1,073	52,821	56,137	0.94	$ 170,972.25	343	$ 3.05
CRESTOR® TAB 5MG	11	462	333	1.39	$ 1,104.72	6	$ 3.32
CRESTOR® TAB 10MG	126	5,569	5,486	1.02	$ 13,157.86	90	$ 2.40
CRESTOR® TAB 20MG	21	1,000	1,030	0.97	$ 2,358.13	16	$ 2.29
CRESTOR® TAB 40MG	7	375	390	0.96	$ 883.30	6	$ 2.26
Total	**73,518**	**3,380,528**	**3,361,903**		**$ 10,325,134.78**	**18,490†**	**$ 3.07**

*SMAC pricing implemented on 11/03/2003
**Total cost/total days
†Total unduplicated clients

Total Cost Calendar Year '03	**$10,325,134.78**
Total Cost Calendar Year '02	*$8,974,612.79*
Total Claims Calendar Year '03	**73,518**
Total Claims Calendar Year '02	*82,295*
Total Clients Calendar Year '03	**18,490**
Total Clients Calendar Year '02	*17,796*
Total Days Calendar Year '03	**3,361,903**
Total Days Calendar Year '02	*3,282,369*
Per Diem Calendar Year '03	**$3.07**
Per Diem Calendar Year '02	*$2.73*





Crestor® may not be accurately comparable based on short use history.

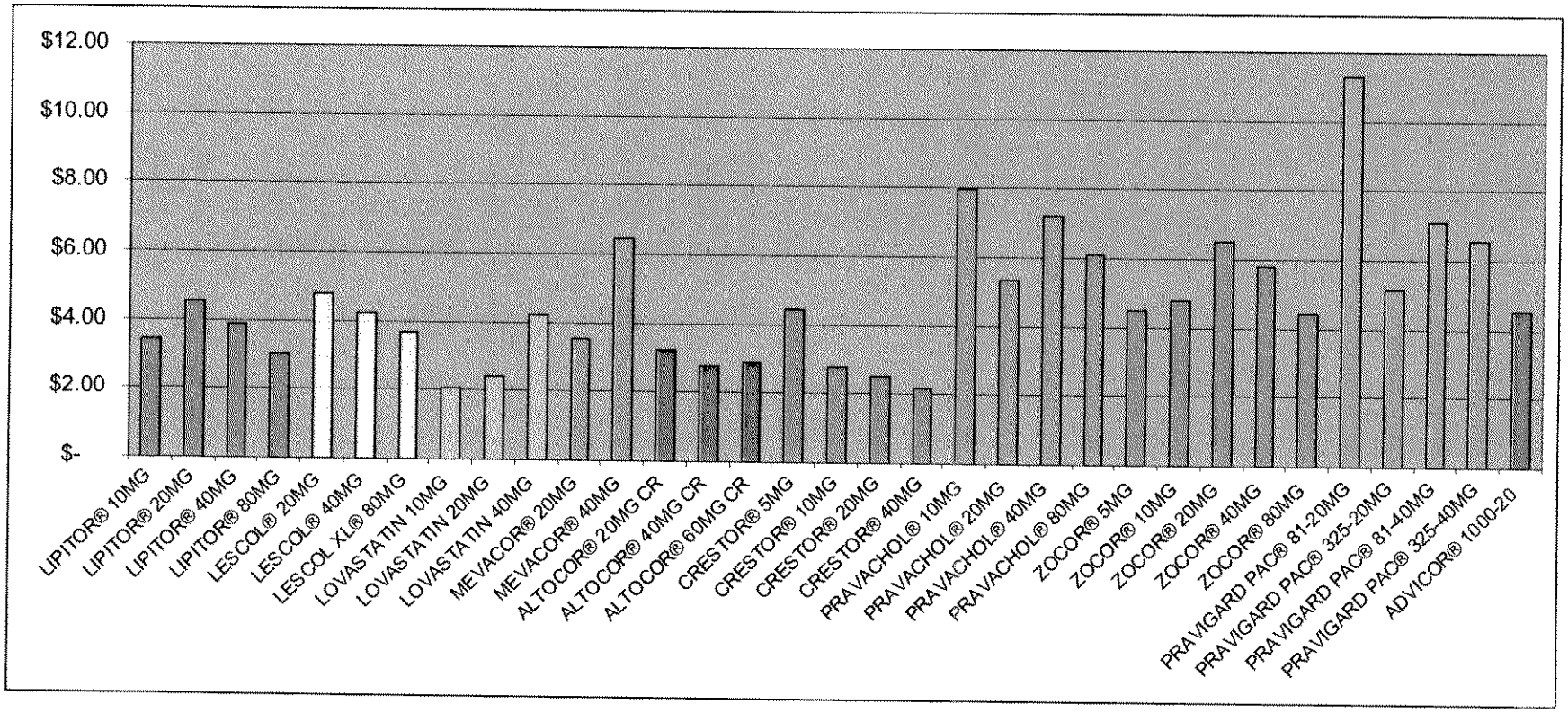
Cost Comparison by Percent LDL Reduction Capacity

Statin	% LDL Reduction	Cost per % LDL Reduced**
LOVASTATIN TAB 10MG	28	$ 2.10
LOVASTATIN TAB 20MG	35	$ 2.40
LOVASTATIN TAB 40MG	37	$ 4.23
MEVACOR® TAB 20MG	35	$ 3.53
MEVACOR® TAB 40MG	37	$ 6.47
ALTOCOR CR® TAB 20MG*	30	$ 3.24
ALTOCOR CR® TAB 40MG*	35	$ 2.77
ALTOCOR CR® TAB 60MG*	40	$ 2.88
ADVICOR® TAB 500-20MG	Titration purposes (< 30)	-
ADVICOR® TAB 750-20MG	Titration purposes (< 30)	-
ADVICOR® TAB 1000-20MG	30	$ 4.52
PRAVACHOL® TAB 10MG	22	$ 7.96
PRAVACHOL® TAB 20MG	32	$ 5.34
PRAVACHOL® TAB 40MG	34	$ 7.18
PRAVACHOL® TAB 80MG	37	$ 6.08
PRAVIGARD PAC® 81-20MG*	22	$ 11.29
PRAVIGARD PAC® 325-20MG*	32	$ 5.11
PRAVIGARD PAC® 81-40MG*	34	$ 7.09
PRAVIGARD PAC® 325-40MG*	37	$ 6.08
LESCOL® CAP 20MG	22	$ 4.77
LESCOL® CAP 40MG	25	$ 4.20
LESCOL XL® TAB 80MG	35	$ 3.03
ZOCOR® TAB 5MG	26	$ 4.52
ZOCOR® TAB 10MG	30	$ 4.80
ZOCOR® TAB 20MG	38	$ 6.49
ZOCOR® TAB 40MG	41	$ 5.78
ZOCOR® TAB 80MG	47	$ 4.46
LIPITOR® TAB 10MG	39	$ 3.42
LIPITOR® TAB 20MG	43	$ 4.55
LIPITOR® TAB 40MG	50	$ 3.89
LIPITOR® TAB 80MG	60	$ 3.05
CRESTOR® TAB 5MG*	45	$ 4.43
CRESTOR® TAB 10MG*	52	$ 2.77
CRESTOR® TAB 20MG*	55	$ 2.50
CRESTOR® TAB 40MG*	63	$ 2.15

*Data may not be accurately comparable due to short claims history.
**Cost comparison based on 60 days of treatment with each drug once daily. (60 x cost per diem) / %LDL reduction)

This chart shows a relative comparison of the per diem cost of each agent, taking into account their different LDL lowering capacities. 60 days is used as the timeframe because a statin's maximal LDL reduction can be seen in approximately 6-8 weeks. LDL reduction percentages are based on the listed values from the prescribing information and do not reflect actual values achieved by individual clients.

Comparison by Cost Per Percent LDL Reduction



Cost Comparison by Indication[13]

Indication	Atorvastatin	Fluvastatin	Lovastatin	Lovastatin/Niacin	Pravastatin	Simvastatin	Rosuvastatin
Primary hypercholesterolemia	√[1]	√[1]	√[1]	√[1]	√[1]	√[1]	√[1]
Mixed dyslipidemia	√[2]	√[2]	√[2]	√[2]	√[2]	√[2]	√[2]
Hypertriglyceridemia	√[3]				√[3]	√[3]	√[3]
Primary dysbetalipoproteinemia	√[4]				√[4]	√[4]	
Homozygous familial hyperlipidemia	√					√	√
Primary prevention coronary events			√		√		
Secondary prevention cardiovascular event(s)		√	√		√	√	
Product and Average Per Diem for All Strengths	Lipitor® $2.72	Lescol® $1.76 Lescol XL® $2.14	Mevacor® $3.00 Lovastatin $1.73 Altocor® $1.90	Advicor® $1.93	Pravachol® $3.44 Pravigard®[5] $3.67	Zocor® $3.77	Crestor® $2.42

[1]Includes heterozygous familial and nonfamilial hypercholesterolemia.
[2]Includes Fredrickson types IIa and IIb.
[3]Includes Fredrickson type IV.
[4]Includes Fredrickson type III.
[5]Indications for aspirin not included.

Options for Board Consideration

Preferred Drug List for Statins

Option 1

Preferred Drugs
- Lipitor®
- Lescol®
- Mevacor®
- Lovastatin

Non-Preferred Drugs
- Altocor®
- Crestor®
- Pravachol®
- Pravigard®
- Zocor®
- Advicor®

Option 2

Preferred Drugs
- Lescol®
- Mevacor®
- Crestor®
- Lovastatin

Non-Preferred Drugs
- Lipitor®
- Altocor®
- Pravachol®
- Pravigard®
- Zocor®
- Advicor®

As SMAC pricing is implemented on future generics, these products will be moved to preferred status.

Prior Authorization of Zetia

Total Cost for 2003	$	127,269.43
Current EAC	$	2.38

Will be reviewed and discussed next month if Board would like to consider prior authorization.

[1] American Heart Association. *Heart Disease and Stroke Statistics — 2004 Update*. American Heart Association; 2003. ©2003, American Heart Association.
[2] Website: MICROMEDEX(R) Healthcare Series Vol. 120. Online. Internet 2004. http://www.Micromedex.com
[3] Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) *Clinical Guidelines/Evidence Reports* - 2001 May.
[4] Dorland's Illustrated Medical Dictionary 29th edition. W.B. Saunders, Philadelphia, 2003; 853.

[5] Website: US Food and Drug Administration. Online. Internet. 2003. Available: http://www.fda.gov/cder
[6] Website: National Institutes of Health. Online. Internet. 2003. Available: http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm
[7] Wang Tj, Randall RS. Randomized clinical trials and recent patterns in the use of statins. *American Heart Journal* 2003; 14: 957-963.
[8] Heart Protection Study Collaborative Study Group. Heart protection study of cholesterol lowering with simvastatin in 20,536 high risk individuals: a randomized placebo-controlled trial. *Lancet* 2002; 360: 7-22.
[9] Cannon, CP et al. Comparison of intensive and moderate lipid lowering with statins after acute coronary syndromes. *New England Journal of Medicine* 2004; 350; 15.
[10] Pasternak RC, Grundy SM, et al. ACC/AHA/NHLBI Clinical advisory on the use and safety of Statins. Journal of the American College of Cardiology 2002; 40:567-572.
[11] Merck/Schering-Plough Pharmaceuticals. Package literature Zetia®. March 2003.
[12] Kos Pharmaceuticals, Inc. Package literature Advicor®. August 2002.
[13] Adapted from Website: Facts and Comparison. Online. Internet. 2004. Available: http//www.factsandcomparison.com

APPENDIX I

Tamiflu and other Influenza Medications

Fiscal Year 2003

Oklahoma Medicaid
April 13, 2004

Tamiflu

- treatment of influenza types A and B in adults & children one year and older.
- prophylaxis in adults and children 13 years and older.

Relenza

- treatment of influenza type A and B in adults and children 7 years and older.

Symmetrel

- treatment and prophylaxis of influenza type A in adults and children 1 year old and older.

Flumadine

- treatment of influenza type A in patients 14 years and older
- prophylaxis in adults and children 1 year old and older.

Utilization

For the period of July 2002 through June 2003:

- 2,375 clients received Flu medications (Tamiflu, Flumadine, or Relenza)
- 1,059 received Amantadine (don't know if all were for flu diagnosis) through the Medicaid fee-for-service program.
- Approximately 10,000 claims were found of clients receiving the flu shot.
- Only 31 were found to have gotten the flu shot and a script for Tamiflu.
- The majority of prescriptions for Tamiflu were filled for a quantity equal to five days of therapy.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
*Amantadine 100mg***	2,759	155,207	79,778	1.95	$58,733.53	1,059	$0.74
Flumadine 100mg	67	933	813	1.15	$2,067.55	59	$2.54
Rimantadine 100mg	41	629	504	1.25	$1,142.06	36	$2.27
Flumadine 50mg/5ml	50	4272	383	11.15	$933.03	46	$2.44
Tamiflu 75mg	1,133	11,948	6,171	1.94	$76,015.11	1,102	$12.32
Tamiflu 12mg/ml	1,179	50,013	7,151	7	$64,539.74	1,109	$9.03
Relenza	23	460	158	3	$1,156.51	23	$7.32
Total	**2,493**	**68,255**	**15,180**		**$145,854.00**	**2,375**	

*Total unduplicated clients for FY03
**Amantadine figures are not added into overall totals.

Total Cost FY '03	**$145,854.00**
Tamiflu Cost FY03	*$140,554.85*
Total Claims FY '03	**2,493**
Tamiflu Claims FY03	*2,312*
Total Clients FY 03	***2,375***
Tamiflu Clients FY03	*2,211*

Claims were reviewed to determine the age/gender of the clients.
FY03

Age	Female	Male	Totals
0 to 9	572	561	1133
10 to 19	505	395	900
20 to 34	75	16	91
35 to 49	58	16	74
50 to 64	36	18	54
65 to 79	34	5	39
80 to 94	36	7	43
95 and Over	1	0	1
Totals	**1,317**	**1,018**	**2,335**

Recommendations:

The college of pharmacy has the following recommendation(s) for Fiscal Year 2004:

Continue to do regular reviews of the medication and as soon as generics become available place a SMAC value on them.

APPENDIX J

Statins After Ischemic Stroke and Transient Ischemic Attack

An Advisory Statement From the Stroke Council, American Heart Association and American Stroke Association

The Stroke Council

Based on results of numerous large-scale randomized trials, the vast majority of patients with a history of ischemic stroke or transient ischemic attack could benefit from statin use.

Although prevention of second stroke was not the primary aim of any completed study, some studies included subjects whose primary reason for entry was stroke. Multiple studies have shown that statins reduce risk of stroke in those with coronary artery disease and elevated total or low-density lipoprotein (LDL) cholesterol. Recently, the Heart Protection Study showed that simvastatin 40 mg/day reduced the risk of stroke by 25% among patients with coronary artery disease, other occlusive arterial disease, or diabetes.[1] In the subgroup enrolled with prior ischemic stroke or transient ischemic attack but no coronary artery disease, the risk of major vascular events (coronary events, stroke, or revascularization) was reduced by 21% (absolute risk reduction, 1% per year; number needed to treat 102 to prevent 1 event each year). Benefits persisted in those with LDL <116 mg/dL or total cholesterol <193 mg/dL. A meta-analysis also shows that the benefits of statins in reducing the rates of stroke and cardiovascular events is independent of cholesterol levels and occur with other statins.[2] Given early benefits in trials of acute coronary syndromes, statin initiation during hospitalization for first ischemic stroke of atherosclerotic origin is probably justified and may increase rates of long-term use. Results of the ongoing SPARCL trial[3] will provide additional information about the role of statins in the minority of patients with prior stroke but no history of coronary heart disease, other occlusive arterial disease, or diabetes.

References

1. Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet*. 2002;360:7–22.
2. Corvol JC, Bouzamondo A, Sirol M, Hulot JS, Sanchez P, Lechat P. Differential effects of lipid-lowering therapies on stroke prevention: a meta-analysis of randomized trials. *Arch Intern Med*. 2003;163:669–676.
3. Amarenco P, Bogousslavsky J, Callahan AS, Goldstein L, Hennerici M, Sillsen H, Welch MA, Zivin J, SPARCL Investigators. Design and baseline characteristics of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study. *Cerebrovasc Dis*. 2003;16:389–395.

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on January 12, 2004. To purchase reprints call 410-528-4121, fax 410-528-4264, or e-mail kgray@lww.com. Ask for reprint No. 71-0282. To make photocopies for personal or educational use, call the Copyright Clearance Center, 978-750-8400.

(*Stroke* 2002;35:1023.)

***Stroke* is available at http://www.strokeaha.org**

DOI: 10.1161/01.STR.0000122762.96972.DD

March 22, 2004

Subject: WORSENING DEPRESSION AND SUICIDALITY IN PATIENTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS

Today the Food and Drug Administration (FDA) asked manufacturers of the following antidepressant drugs to include in their labeling a Warning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality. The drugs that are the focus of this new Warning are: Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine).

Warning Information

- Health care providers should carefully monitor patients receiving antidepressants for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases. Although FDA has not concluded that these drugs cause worsening depression or suicidality, health care providers should be aware that worsening of symptoms could be due to the underlying disease or might be a result of drug therapy.

- Heath care providers should carefully evaluate patients in whom depression persistently worsens, or emergent suicidality is severe, abrupt in onset, or was not part of the presenting symptoms, to determine what intervention, including discontinuing or modifying the current drug therapy, is indicated.

- Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although FDA has not concluded that these symptoms are a precursor to either worsening of depression or the emergence of suicidal impulses, there is concern that patients who experience one or more of these symptoms may be at increased risk for worsening depression or suicidality. Therefore, therapy should be evaluated, and medications may need to be discontinued, when symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

- If a decision is made to discontinue treatment, certain of these medications should be tapered rather than stopped abruptly (see labeling for individual drug products for details).

- Because antidepressants are believed to have the potential for inducing manic episodes in patients with bipolar disorder, there is a concern about using antidepressants alone in this population. Therefore, patients should be adequately screened to determine if they are at risk for bipolar disorder before initiating antidepressant treatment so that they can be appropriately monitored during treatment. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

- Health care providers should instruct patients, their families and their caregivers to be alert for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality and worsening depression, and to report such symptoms immediately to their health care provider.

Background

Among antidepressants, only Prozac (fluoxetine) is approved for the treatment of pediatric major depressive disorder. Prozac (fluoxetine), Zoloft (sertraline), and Luvox (fluvoxamine) are approved for pediatric obsessive compulsive disorder. None of these drugs is approved as monotherapy for use in treating bipolar depression, either in adults or children.

The requested labeling changes are consistent with recommendations made to the Agency at a meeting of the Psychopharmacological Drugs Advisory Committee (PDAC) and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee (Peds AC), held on February 2, 2004. The possibility of suicidality associated with the use of antidepressant drug products in the pediatric population was also the subject of two previous FDA communications (FDA Talk Paper on June 19, 2003, and FDA Public Health Advisory on October 27, 2003).

FDA is continuing to review available clinical trial data for pediatric patients with depression and other psychiatric disorders to try to determine whether there is evidence that some or all antidepressants increase the risk of suicidality. Later this summer, the FDA plans to update the PDAC and Peds AC about the results of this review.

FDA plans to work closely with each of the nine manufacturers of the antidepressants that are the subject of today's request to continue investigating how to optimize the safe use of these drugs and implement the proposed labeling changes and other safety communications in a timely manner.

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U.S. Food and Drug Administration

Department of Health and Human Services

MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

2004 Safety Alert: Zyprexa (olanzapine)

The following information is from Eli Lilly and Company. Contact the company for a copy of any referenced enclosures.

March 1, 2004

Re: Safety data on Zyprexa ® (olanzapine) – Hyperglycemia and Diabetes

Dear Doctor,

Eli Lilly and Company would like to inform you of important labeling changes regarding Zyprexa (olanzapine). The Food and Drug Administration (FDA) has asked all manufacturers of atypical antipsychotic medications, including Lilly, to add a Warning statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including Zyprexa. In addition to Zyprexa, the atypical antipsychotic class includes Clozaril ® (clozapine, Novartis), Risperdal ® (risperidone, Janssen), Seroquel ® (quetiapine, AstraZeneca), Geodon ® (ziprasidone, Pfizer), and Abilify ® (aripiprazole, Bristol Myers Squibb and Otsuka American Pharmaceutical). Accordingly, the Zyprexa prescribing information has been updated with the following information:

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes

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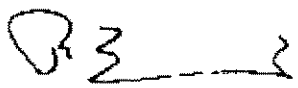
mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Should you have any questions or concerns regarding this important safety information, please contact your Eli Lilly and Company sales representative or contact the Lilly medical department at 1-800-Lilly-Rx . Please refer to the full prescribing information for Zyprexa included with this letter. As always, we request that serious adverse events be reported to Lilly at 1-800-Lilly-Rx or to the FDA MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178) or by email (www.fda.gov/medwatch).

Sincerely,



Dr. Paul Eisenberg
Vice President, Global Product Safety
Eli Lilly and Company

Return to 2004 Safety Summary

FDA Issues Statement on Generic Oxycodone Hydrochloride Extended Release Tablets

ROCKVILLE, MD -- March 24, 2004 -- The Food and Drug Administration today released the following statement on its approval of generic oxycodone hydrochloride extended-release tablets:

Oxycodone hydrochloride extended-release products, such as OxyContin and its generic versions, are important options for the management of moderate-to-severe chronic pain, such as that associated with cancer and various other illnesses. FDA's approval of two generic oxycodone hydrochloride products should make this safe and effective medicine available at a lower cost to patients suffering from moderate to severe chronic pain.

At the same time, FDA recognizes that oxycodone extended-release tablets present a potential for abuse, misuse, and diversion. That is why FDA has secured the agreement of the manufacturers of the generic products to have in place, prior to marketing, risk management plans that are consistent with the innovator product's plan.

Decades of experience with generic drug approvals suggest that, when the first generic versions of an innovator drug reach the market, the use of that drug does not increase overall. Rather, demand tends to remain steady, with an increasing proportion of market share being held by the generic versions.

Earlier this month, the Office of National Drug Control Policy, the DEA, and FDA announced a coordinated strategy to confront the illegal diversion and abuse of prescription drugs. This coordinated strategy includes:

- Careful consideration of labeling and commercial promotion of opiate drug products;

- Ensuring wider dissemination of education and training on appropriate pain management and opioid treatment procedures for physicians authorized to prescribe controlled substances;

- Increasing the number of state Prescription Monitoring Programs, which detect suspicious prescriptions and individuals redeeming prescriptions from multiple physicians ("doctor shopping") to identify abusers; and

- Using web crawler/data mining technology to identify, investigate and prosecute "pill mills" - Internet pharmacies that provide controlled substances illegally.

Today's announcement incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies, as well as increased investigation and enforcement activities.

When used correctly, opioids play a very important role in the management of pain. FDA's job is to maximize the potential benefits that patients receive from these drugs, while, at the same time, minimizing the risks associated with these products. FDA takes its responsibility in meeting this challenge very seriously.

In approving these generic products, FDA is seeking to balance the need for effective pain management therapies -- for the more than 10 million Americans who suffer from chronic pain -- with the prevention of misuse, abuse, and diversion of prescription drugs.

Source: The Food and Drug Administration