Drug Utilization Review Board

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

August 10, 2005 @ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – August 10, 2005**

DATE: August 03, 2005

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

Enclosed are the following items related to the August 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 to Prior Authorize Zetia® – **See Appendix C.**

Action Item – Vote to Prior Authorize Elidel® and Protopic® – **See Appendix D.**

Action Item – Vote on Placement of ADHD PBPA Category in Supplemental Rebate Program and 30 Day Notice to Prior Authorize Focalin™ XR – **See Appendix E**

Action Item – Annual Review of Synagis® – **See Appendix F**

Review and Discuss Pulmonary Hypertension Medications and 30 Day Notice to Prior Authorize Revatio® – **See Appendix G**

30 Day Notice to Prior Authorize Fenofibrates – **See Appendix H**

30 Day Notice to Prior Authorize Byetta® – **See Appendix I.**

Review and Discuss Estrogen Medications – **See Appendix J.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – August 10, 2005 @ 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. June 14, 2005 DUR Minutes – Vote
   B. Memorandum of June 14, 2005 DUR Recommendations
   C. Provider Correspondence

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

4. **Update on DUR/MCAU Program – See Appendix B.**
   A. Retrospective Drug Utilization Review Report for April 2005
   B. Medication Coverage Activity Audit for June and July 2005
   C. Help Desk Activity Audit for June and July 2005
   D. Pharmacotherapy Management Program – Annual Report FY05

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

5. **Action Item – Vote to Prior Authorize Zetia® – See Appendix C.**
   A. COP Recommendations

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

6. **Action Item – Vote to Prior Authorize Elidel® and Protopic® – See Appendix D.**
   A. Products Summary
   B. COP Recommendations
   C. Available Topical Steroids

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

7. **Action Item – Vote on Placement of ADHD PBPA Category in Supplemental Rebate Program and 30 Day Notice to Prior Authorize Focalin™ XR – See Appendix E.**
   A. ADHD COP Recommendations
   B. Product Summary
   C. COP Recommendations

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

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

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

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

9. Review and Discuss Pulmonary Hypertension Medications and 30 Day Notice to Prior Authorize Revatio® – See Appendix G.

A. Review of Treatment guidelines for PAH
B. Utilization Review of PAH Medications
C. New Product Review - Revatio®
D. COP Recommendations

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

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

A. COP Recommendations

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

11. 30 Day Notice to Prior Authorize Byetta® – See Appendix I.

A. Product Summary
B. COP Recommendations
C. Cost Information
D. Product Review

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

12. Review and Discuss Estrogen Products – See Appendix J.

A. Clinical Trial Summary
B. Utilization Review
C. COP Recommendations

13. FDA and DEA Updates – See Appendix K.

14. Future Business

A. Antipsychotic Utilization Review
B. Pediculicides Review
C. Neurontin® Follow-Up Review
D. Renal Product Review
E. Antifungal Review
F. Annual Reviews
G. New Product Reviews

15. Adjournment

APPENDIX A

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

BOARD MEMBERS:	PRESENT	ABSENT
Dorothy Gourley, D.Ph.	X	
Cathy Hollen, D.Ph.		X
Dan McNeill, Ph.D., PA-C	X	
Clif Meece, D.Ph.	X	
Dick Robinson, D.Ph., Vice-Chair		X
Thomas Whitsett, M.D., Chair	X	

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

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

OTHERS PRESENT:

Randy McGinley, Berlex	JoAnne Hargraves, Schering	Lon Lowrey, Novartis
Jason Schwier, Amgen	Greg Hoke, Wyeth	Roger Enix, Merck
David Dude, BMS	Joe McIntosh, Novartis	Jim Dunlap, Lilly
Holly Jacques, Merck	Monte Summers, Amylin	Mark DeClerk, Lilly
Richard Ponder, J&J	John Omick, Novartis	

PRESENT FOR PUBLIC COMMENT:

Robert Cortes Jr., Schering Plough	Agenda Item No. 12
Evie Knisely; Novartis	Agenda Item No. 5, 13
Warren V. Filley, OAAC	Agenda Item No. 5
Richard Hatch, OAAC	Agenda Item No. 5

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 speakers for Public Comment.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MINUTES; VOTE TO CHANGE MEETING DATE**

3A: May 10, 2005 DUR Minutes

Corrections noted to minutes: Page 11, Paragraph 8; Dr. Gourley's statement was, "*The way I read the background information on the cause for this black box warning was the FDA wanted to establish that the drug is safe.*" Page 11, Paragraph 10, last sentence, "*But we don't know its' long-term effects.*"

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

ACTION: MOTION CARRIED.

3B: Vote to Change Meeting Date

Dr. McNeill moved to change the DUR Board Meeting date to the second Wednesday of each month, effective July 2005; seconded by Dr. Meece.

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report for March 2005

4B: Medication Coverage Activity Report: May 2005

4C: Help Desk Activity Report: May 2005

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **REVIEW & DISCUSS XOLAIR®**

For Public Comment, Dr. Warren Filley: *Thank you, I appreciate that very much. I won't take much of your time. I'm here really on behalf of the Oklahoma Allergy & Asthma Clinic. We're the large clinic down by the University. We probably see about, care for about nine to ten thousand patients a year (unintelligible) asthmatics. We have a total of like twenty patients on this drug. Two of them are approved through the Health Care Authority. So we don't use the drug very much, but we'd like to ask you to change your criteria to match the package insert for the drug which would include the fact that either moderate or severe persistent asthmatics be included and that the patient not have to have the prior authorization of two hospitalizations in a six month period of time. Certainly our clinic, it's a good idea to get them to us if they've had a hospitalization but then we try as hard as we can to keep them from going back to the hospital. So we feel like it's a malpractice instance to allow them to keep going back to the hospital just so they could get the drug that they might need. And again, it's a drug that we use sparingly when we feel the need for patients who are having a great deal of trouble. So, other than that, the other criteria that you have are all okay, at least in my opinion.*

Dr. Whitsett: *The . . . I think on the diagnosis of severe persistent asthma was according to the NAEPP guidelines that we had pulled that from. Is that . . .*

Dr. Filley: *In fact, the FDA approved package insert says "moderate to severe".*

Dr. Whitsett: *Yeah.*

Dr. Filley: *And of course there is such a trouble trying to sometimes decide if it's moderate or severe and when somebody comes in, they have had severe asthma, then they get treatment so they're a little bit better, so does somebody marked to moderate, when they really were severe before they ever took medication. And at what point did you see them and I know in reviewing the cases, that we have said to you in fact, one was labeled moderate and it probably should have been labeled as severe, but the doctor just decided to label it as moderate, knowing that that was still within the package insert guidelines and didn't think much about it.*

Dr. Whitsett: *I guess if they ask the patient, most would be severe.*

Dr. Filley: *Well not, well actually not. At lot of people perceive themselves as being more moderate and even mild and in fact they wind up being severe. If you look at studies that are done, there's a very nice study from Australia that show that children that came to the emergency room and died of their asthma, a third, the parent and the family, actually thought the child had mild*

disease; and yet that third wound up dying just like a third that were severe and a third that were moderate. So it's a sticky point and I guess a matter of semantics and sometimes it's hard to tell. And again, Xolair® is a drug that we've been using sparingly but in cases where you really feel like it's needed and in this population, you'd really like to be able to use it when the physician at the clinic sees that type of patient that would need the drug.

Dr. Whitsett: *Okay – other questions? If not, thank you very much.*

For Public Comment, Evie Knisley: *The only point I wanted to make was that with regards to cost that the national average is $12,000 to $13,000 a year. I think one of the numbers that was mentioned last time was quite a bit higher, so I wanted to share that with you. Thirty percent of patients do well on one vial per month which is five to six, so some of the patients are higher and of course it's based on their weight and their IgE level, but we did want to share that cost information with you.*

Dr. Whitsett: *Okay – thank you.*

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

Dr. Richard Hatch, Oklahoma Allergy & Asthma Clinic was in attendance to address questions posed by Board members. *"I don't really have anything to add to what Warren said other than, let me just emphasize, you can really, I think you all know, you can really break your back to keep these kids out of the ER, people out of the ER, just by really loading them up with steroids and I think to make admission a requirement for somebody for instance that's steroid dependent, comparing that to somebody who'll maybe get admitted because they haven't had the steroids, I think that's a little rigid. And I don't think that that criteria, I think the College would be inflexible about it, but I really that the hospitalization requirement probably is a little tight. That's really the only thing I'd like to add. Other than that, I think it looks reasonable."*

Dr. McNeill: *I must have missed something. I don't, the patient must have been in the ER* ***or*** *hospitalized.*

Dr. Hatch: *ER, right, ER . . .we need to keep these kids out of the ER.*

Dr. McNeill: *Is there some way to, concerning Item no. 8, for both you gentlemen, is there some way to, to document the seriousness of the asthma here, other than using Item 8 or, if you, instead of six months, if you extended it to one year, two years, I mean I don't know an asthmatic that's moderate or severe that hasn't been in the ER twice . . . what do you think about that?*

Drs. Hatch, Filley: *I know plenty. I do, too. . . hundreds.*

Dr. Filley: *But I keep them out of the emergency room and out of the hospital. I have a fellow that's retired from Tinker and believe it or not, he was in the military with asthma, he was admitted almost every year and he's only had one emergency room visit in the last 12 years since I've taken care of him, and we're keeping him out of the ER too.*

Dr. McNeill: *Is he on Xolair®?*

Dr. Filley: *No he's not. He doesn't need Xolair® at this point. He's managed with other medicines, that's why I said, I mean not all nine to ten thousand patients that we follow regularly in our office practice have asthma, but we only have like twenty patients on it, so it's not a, I mean, we do this judiciously, but there are people who, it just doesn't seem to be another way to keep them healthy. At least it's another option that we'd like to have a chance to try.*

Dr. Hatch: *The irony of this criteria is really what you want for the Xolair® people, you want compliant people, really, because they're the ones that'll come in and get their injections. The non-compliant hopefully will but you're less likely and I think one of the risk factors for, and one of the identifiers of non-compliant patients is emergency room visits and hospitalizations. I think, you know the criteria points out being on high dose steroids and I think that's reasonable, but I also, you know some of it's on systemic steroids, it's a steroid dependent asthmatic. That goes past the criteria of obviously high dose inhaled steroids but I think that's, I think maybe just as a suggestion, maybe instead of saying ER or hospitalized twice in the last six months, maybe saying "dependent" is a suggestion. Dependent on oral steroids for the last (you can determine) time period . . . three months. Let me just say first of all, I think they've been real flexible and I don't have any complaints with it. It's, I think in reality that might be what would happen anyway.*

Dr. Whitsett: *So, number 8, you would add at the end of that first sentence "or steroid dependent"?*

Dr. Hatch: *Yes. Does that sound reasonable?*

Dr. Filley: *In my opinion, if they're steroid dependent, they're on it all the time and I think like for example, the fellow I told you about that was at Tinker, he gets two or three bursts of steroids a year and that has allowed being on his feet and out of emergency rooms and out of the hospital.*

Dr. Whitsett: *But would not be steroid dependent.*

Dr. Filley: *He would be steroid dependent but since he takes it all the time. He's on high doses of everything and so,*

Dr. Whitsett: *And it works?*

Dr. Filley: *And it seems to work, but in a person, say had a person like that, of course he's an adult, he's now retired from the military, but in that individual if that stopped working for him, if we couldn't treat him and he was becoming more and more miserable and having more trouble, I would like to put that person on Xolair®. But if your criteria is he has to be in the emergency room, then I would have to basically either that or the hospital, I would have to withdraw medicine that I know has worked in order to make him sick enough to fulfill your criteria. And since it's not a criteria that's in the package insert, it makes sense to just eliminate it altogether.*

Dr. Graham: *Dr. Filley, have you had any rejected because of non-compliant on number 8?*

Dr. Filley: *Well actually there are, we have had only three patients that went through. Two have been accepted. One, the authorization was denied and it, I think it was denied because he was listed as, and it's not my patient. None of these that are currently in your system are my patients, but this one wasn't one of Dr. Hatch's either, but the person had the diagnosis of moderate persistent rather than severe persistent, so he was not allowed in. And the doctor at the clinic responsible for that patient decided not to reapply at that time. But I have had lots of other insurance companies deny Xolair® for lots of other reasons and we try to work with them. I mean you're not alone in this regard. Obviously the drug is real expensive and you know, I don't just prescribe it willy-nilly for everybody. It's something that you can't just give them a sample to take home and say try this for a couple of weeks or a month, and if it works we're going to try to get it out of the insurance company. You can't do it*

that way. This is a drug that unfortunately you've got to use it repeatedly month after month for really six or eight months to see if it's going to be effective and for some people it's extremely effective, it works well, they do, they have a much better quality of life here. The symptoms come down and such, and for other people it doesn't work that well and so those people wind up dropping out of the system. I know you all have had some trouble with physicians wanting to prescribe it for all kinds of other things, diseases that it's not approved for and we would like to just be able to try to use it for the disease that it is currently approved for which is moderate to severe persistent asthma and for people that aren't controlled with the other medicines, and there are a lot of people who are very well controlled and I can show you studies, I have some actually here that don't deal with Xolair at all, just deal with inhaled corticosteroids and long-acting (unintelligible) show that most people can be adequately controlled. Most people leaving out of course those that are not compliant like the one that was used in the emergency room all the time. That's a very much of a non-compliant patient. Just comes in willy-nilly and doesn't take medicines and wants to use your emergency room system.

Dr. Whitsett: *Last meeting we were discussing that and I'd asked if there was an endpoint which you tested the patient to see if they continued to need it. I kind of got the notion that once you start it; the routine is to continue it indefinitely. Maybe you would speak to that further. After a year do you try to wean them off of it or what's the . . .*

Dr. Hatch: *That's a tough question. I don't, this is a drug from our experience I think what you're asking is not necessarily what the package insert says and what the FDA's approved because there's really no reason to believe that if you stop it, that you'll have long lasting effects. If you're asking me what my experience is, and I don't really have enough experience with it. I don't know that anybody does to say that you can stop it at such and such a point. There are some things we could try to do in theory, like for instance maybe try to get them on allergy shots that they might not otherwise tolerate and then what do you do? I think that's a bridge we're going to have to cross when we come to it. I just don't know that I can project you know, I think it's reasonable though after a year, to say well this drug just isn't working for this person. If it's not working that's easy. If it is working then you're going to have to choose. I don't, I don't really know. You're grappling with it and trying to project something that can't be projected and I appreciate that. I think we'll do the best we can too, because I'll tell you, I don't think any of these patients, well there will be some, they're not going to love coming in for shots every two weeks, every month, and it's a pain. They'll be some people that will be wedded to it that will be afraid to stop it, but I don't think we'll have a hard time convincing people to stop it most of the time, assuming things are going okay. And it may, you know, we know that, we know that it does things other than just eliminate the IgE and the circulation. It does things to the inflammatory cells that may be long lasting and it may be that once you've subdued the IgE long enough, you get away with going out to twice or half as frequently. I don't think anybody can answer that question for you.*

Dr. Whitsett: *I trust there are studies going on to look at that and that would be a logical thing to do, at least from my point of view I don't know if the pharmaceutical company would see that logical, use less of their drug but . . .*

Dr. Filley: *Right, right, right, right. What they're looking at now too I think is getting people on immunotherapy while this is going on and try (untelligible) it's early yet.*

Dr. McNeill: *I may be wrong but it seems like when we discussed this initially, the, there was a presentation, there was a presenter that stated that there was an actual rebound elevation of IgE after this drug was stopped. Do I remember that incorrectly?*

Dr. Hatch: *Are you aware of that Warren?*

Dr. Filley: *No, the IgE levels go up because they're bound and so I . . . but they're absorbed to this molecule and so they don't just leave, but they're absorbed to it so they're inactive, but actually you'll see IgE levels rise, yet the people, cases where it works and nothing ever works for everybody all the time, but you can see people that for example as Rich said, can't take allergy shots. They're just so sensitive. Every time you try they have systemic reactions and problems and you take these people, lower their IgE level and then allow them to take that type of therapy. Children who have anaphylactic sensitivity to nuts have been given this product or one very similar and shown to be able to eat fairly large quantities of nuts without having any kind of systemic reaction, even though their IgE level to the nut is quite high. So it's bound but it's inactive. So maybe that's what (untelligible).*

Dr. Hatch: *What he's saying is that the assays that we have commercially available do not differentiate between bound and unbound IgE. I think the only people that have that assay are the pharmaceutical company that developed it. They can actually look for unbound, so it's the rest of us that we just order and IgE like we always have. It's going to show high.*

Dr. Whitsett: *Other questions? If not, thank you very much.*

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

Board members discussed removing Item 8 from recommendations (ER visits or hospitalization) and keep Items 1 through 7 as written. Consensus was to add to Item 8, " . . . twice in the past 6 months or have been judged to be steroid dependent".

Dr. McNeill moved to approve recommendations; seconded by Dr. Meece.

ACTION: MOTION CARRIED.

NOT A VOTING ITEM PER THE AGENDA – SO NOTED BY DR. WHITSETT

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ZELNORM®

Materials included in agenda packet; presented by Dr. Browning

Dr. McNeill moved to approve recommendations and add "with the exception of chronic pain therapies"; seconded by Dr. Meece.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE NIRAVAM®**
Materials included in agenda packet; presented by Dr. Browning.
Dr. McNeill moved to approve recommendations; seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE SYMLIN®**
Materials included in agenda packet; presented by Dr. Patel.
Dr. McNeill moved to approve recommendations; seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 9: **REVIEW & DISCUSS MEDICARE PART D**
Materials included in agenda packet; presented by Dr. Nesser.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **FISCAL YEAR 2004 UTILIZATION SUMMARY & COMPARISONS**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **60-DAY NOTICE TO PRIOR AUTHORIZE FENOFIBRATES**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **30-DAY NOTICE TO PRIOR AUTHORIZE ZETIA®**
For Public Comment, Robert Cortes: *Good afternoon. My name is Dr. Robert Cortes. I'm a medical science specialist with Schering Plough Pharmaceuticals. Formerly I practiced for 24 years in Texas as a family physician and I unfortunately did not have a chance to use this drug before I retired, but I wish I'd had it. It is good. Let me just read you a summary of this and I think you'll hear a more detailed approach to this in the 30 day notice but I am just going to give you a quick overview. Zetia® is administered alone or in combination with an HMG-CoA reductase inhibitor is indicated as adjunct therapy to diet for reduction of elevated total C, LDL-C, Apo B in patients with primary which includes heterozygous familial and non-familial hypercholesterolemia. The combination of Zetia® and atorvastatin or simvastatin, is indicated for the reduction of elevated total cholesterol, LDL cholesterol levels in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments, such as LDL apheresis or if such treatments are unavailable. It is also indicated as adjunct therapy for diet in reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia. Now the mode of action is that it's the first in it's' class of lipid lowering compounds that selectively inhibits the intestinal absorption of cholesterol and related hydrosterol. It does not inhibit cholesterol synthesis in the liver or increase bile acids excretion. Instead, it localizes and appears to act as the brush border, or at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol by upped regulation and it stores and an increase in clearance of cholesterol from the blood; this distinct mechanism is complementary instead of the of HMG-CoA reductase inhibitors. It is contraindicated in patients who are hypersensitive to the components of the product. It is also in combination with HMG-CoA reductase inhibitor that is contraindicated in patients with active liver disease and those who have unexplained persistent elevations in serum transaminases. All HMG-CoA reductase inhibitors are contraindicated in pregnant and nursing women. So when it's administered with the HMG-CoA reductase inhibitor in a woman of childbearing potential, then you have to refer to that pregnancy category that goes with the HMG-CoA reductase inhibitor or statin. Now clinical studies basically come in three flavors, one of which is Zetia® was added to on-going statins with therapy, the other one which is added concurrently to that and finally as monotherapy. I'll just give you a few statistics of that. In a multicenter, double-blind, placebo-controlled, 8-week study, 769 patients with primary hypercholesterolemia, known coronary heart disease or multiple cardiovascular risk factors who were already receiving statins monotherapy, but who had not met their "National Cholesterol Education Program" (NCEP) "Adult Treatment Panel"(ATP) target LDL-C goal were randomized to receive either Zetia or placebo in addition to their on-going statin therapy. And compared that to monotherapy when added on as an add-on it significantly decreased or reduced the LDL cholesterol 25 versus 4, total cholesterol 17 versus 2 Apo B, 19 versus 3 and triglycerides, 14 versus 3 and it increased the HDL cholesterol from 3 versus 1. Now when there were four, multicenter, double placebo trials, 12-week trials, with 2,382 hypercholesterolemic patients, in this case it was compared with atorvastatin 10 to 80 mg, simvastatin, the same amount, pravastatin 10 to 40, and lovastatin 10*

to 40 mg. And the full results from the trials demonstrated the following that when you combine Zetia® with atorvastatin, you've decreased total cholesterol 41 versus 32, LDL cholesterol 56 versus 44 and Apo B, 33 versus 24, with an increase of HDL-C of 7 versus 4 compared to atorvastatin alone. Now I want to quote the simvastatin to go along, to finish this out. In that study when it was done with simvastatin it significantly reduced the total cholesterol 37 versus 26, LDL 52 versus 36, ApoB of 41 versus 30, triglycerides 29 versus 20 and HDL-C 9 versus 7. In monotherapy, in two, multicenter, double-blind, placebo-controlled, 12-week studies in 1,719 patients with primary hypercholesterolemia, Zetia® or placebo was administered along. It this case they lowered total cholesterol 13 versus 0, LDL cholesterol 18 versus 1, Apo B 16 versus 2, and triglycerides 8 versus 0 with an increase of HDL of 3, change in 3% compared to placebo. Finally, looking at tolerability, it was similar to placebo with clinical adverse experience was recorded in barely 2% of patients treated with Zetia® and in incidence greater than placebo regardless of causality or fatigue, abdominal pain, diarrhea, infection, viral pharyngitis, sinusitis, arthralgia, back pain and coughing. The incidence of consecutive elevations and greater than 3 and coughing, greater than 3 (unintelligible) the number of limit of normal (unintelligible) three times the normal amount of serum transaminases was similar to (unintelligible) Zetia® placebo (unintelligible) in combination studies, the adverse experiences were similar between Zetia® and the statins and also statins alone. However, the frequency of increased transaminases was slightly higher in patients receiving Zetia® administered with a statin, that was 1.3 versus .4%. In clinical studies there was no excessive myopathy or rhabdomyolysis associated with Zetia® compared with placebo or with a statin alone. And the hypersensitive reactions were those that you'd find normally in others including edema and rash reported in during the post-marketing experience. In summary, Zetia® is a drug that can be used when the statins are not able to be used and when and that's used in monotherapy, or it is combination therapy, can be used to decrease the amount of cholesterol, especially in your secondary prevention and primary prevention as well. Thank you.
Dr. Whitsett: *Dr. Cortes, are any of those studies that have been set up and performed relative to Zetia outcome driven? Is there any evidence that it in addition to this compound will reduce myocardial infarction or stroke?*
Dr. Cortes: *At least on the label portion I can't . . . no. Now the next month you're going to have the . . . another presentation that will show some of the more recent studies in which they have actually compared them . . . compared outcomes with atorvastatin but I don't have those, that data today so that's going to be presented . . .*
Dr. Whitsett: *Other questions? If not, thank you very much.*
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **30-DAY NOTICE TO PRIOR AUTHORIZE ELIDEL® & PROTOPIC®**
For Public Comment, Evie Knisely: *I'm Evie Knisely, Scientific Operations with Novartis and I would like to very briefly address Elidel® and I want to stress again that Novartis is committed to this drug being prescribed based on the labeling and on the package insert. I want to address three things in the College of Pharmacy PA recommendations. First of all, we are currently in discussions and negotiations with the FDA, so at this time no discussion and no decision has been reached with regards to the black box warning. And I know you all have one I believe on page 69 in your agenda and that actually is premature. We have not agreed to anything and the FDA has not agreed with us to do anything, so that's premature at this point. So we would ask that your decision be postponed until final recommendations are made by the FDA. Secondly, the recommendation for two 6-week trials of steroid products before Elidel® can be used is a little restrictive. In fact, no commercial pharmacy plans or surrounding state Medicaid plans have that type of restrictive language and we would request reconsideration on the language because it is confusing. And then finally, we are concerned with the proposed quantity limits for Elidel® per year. And if you remember my testimony last month, I made the point that our data shows that we have 45 calendar days of use of Elidel® per year, so 45 calendar days in a year. And that's actually in line with the FDA advisory committee's recommendation that prescribed the use on an intermittent basis and not be used continuously. So we would ask that you wait on a decision with regards to that criteria until that can be reevaluated from some practicing dermatologist or some practicing specialist that actually do treat Medicaid patients. So to summarize, I would ask that reconsideration be made on the criteria and a decision postponed until further input from practicing physicians and until a decision is reached by the FDA.*
Materials included in agenda packet; presented by Dr. Gorman.
Dr. McNeill asked what is the minimum age for use of high potency steroids? Dr. Gourley stated nothing less than 12. Dr. Meece said that Diprolene is 12 years and Elocon has a 2 year minimum. Dr. McNeill wanted the Board to take a close look at that issue.
ACTION: NONE REQUIRED.

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

AGENDA ITEM NO. 15: **FUTURE BUSINESS**

15A: Antifungal Review
15B: Estrogen Replacement Products Review
15C: Neurontin® Follow-Up Review
15D: Renal Product Review
15E: Pediculide Product Review
15F: Synagis® Annual Review
15G: New Product Reviews
- **Byetta®**
- **Focalin XR®**
- **Revatio®**

Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 16: **ADJOURNMENT**

The meeting was declared adjourned.

The University of Oklahoma College of Pharmacy

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

Memorandum

Date: June 20, 2005

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

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

Subject: DUR Board Recommendations from Meeting of June 14, 2005.

Recommendation 1: Change Meeting Date to 2nd Wednesday of Each Month

MOTION CARRIED by unanimous approval.

Notice of new meeting dates for monthly Drug Utilization Review Board for remainder of calendar year:

Wednesday
July 13, 2005
August 10, 2005
September 14, 2005
October 12, 2005
November 9, 2005
December 14, 2005

Recommendation 2: Change to Xolair® Approval Criteria

MOTION CARRIED by unanimous approval.

The criteria are as follows:

1. Client must be between 12-75 years of age.
2. Client must have a diagnosis of severe persistent asthma (as per NAEPP guidelines).
3. Client must have a positive skin test to at least one perennial aeroallergen. Positive perennial allergens must be listed on the petition.
4. Client must have a pretreatment serum IgE level between 30-700 IU/ml.
5. Client weight must be between 30-150kg.
6. Client must have been on high dose ICS (as per NAEPP Guidelines) for at minimum the past 3 months.
7. Medication must be prescribed by either a pulmonary or an allergy/asthma specialist.
8. Client must have been in the ER or hospitalized, due to an asthma exacerbation, twice in the past 6 months (date of visits must be listed on petition), **or have been determined to be dependent on systemic steroids to prevent serious exacerbations.**

Recommendation 3: Vote to Prior Authorize Zelnorm®

MOTION CARRIED by unanimous approval.

The criteria are as follows:

1. Constipation-Predominate IBS in women.
2. Chronic Idiopathic Constipation in males and females who meet the following criteria:
   a. Patient is between 19 and 65 years of age.
   b. Have documentation that constipating therapies for other disease states (with the exception of chronic pain therapies) have been discontinued.
   c. Documented and updated Colon Screening (>50 years of age).
3. For both diagnoses, hydration and treatment attempts with a minimum of three alternate products must be documented.
4. Initial approval for 12 weeks of therapy. An additional year approval may be granted if physician documents client is responding well to treatment.

Recommendation 4: Vote to Prior Authorize Niravam®

MOTION CARRIED by unanimous approval.

The criteria are as follows:

1. Require a PA with:

    a. an FDA approved diagnosis for the use of Niravam®,
    b. a diagnosis indicating that the client has a condition that prevents them from swallowing tablets,
    c. and the physician's signature.

2. Dosing regimens that involve splitting of tablets will not be covered.

Recommendation 5: Vote to Prior Authorize Symlin®

MOTION CARRIED by unanimous approval.

The criteria are as follows:

Patients with type 1 and 2 diabetes using insulin must:
1. have failed to achieve adequate glycemic control;
2. are receiving ongoing care under the guidance of a health care professional.

Patients meeting the following criteria should **NOT** be considered for Symlin® therapy:
1. poor compliance with insulin regimen
2. poor compliance with self-blood glucose monitoring
3. HbA1c> 9%
4. recurrent severe hypoglycemia requiring assistance in past 6 months
5. presence of hypoglycemia unawareness
6. diagnosis of gastroparesis
7. require use of drugs that stimulate GI motility
8. pediatric patients (< 15 years old)

Oklahoma Allergy & Asthma Clinic
Founded 1925

(405) 235-0040

750 N.E. 13th
(2 Blocks East of Lincoln Blvd.)
Oklahoma City, Oklahoma

MERCY OFFICE:
The Plaza Physician Offices
4140 West Memorial Road, Suite 115
Oklahoma City, Oklahoma

SOUTH OFFICE:
Southwest Medical Tower
1044 S.W. 44th St., Suite 518
Oklahoma City, Oklahoma

NORMAN OFFICE:
Physicians and Surgeons Bldg.
950 North Porter, Suite 101
Norman, Oklahoma

EDMOND OFFICE:
Sycamore Square
120 North Bryant, Suite A4
Edmond, Oklahoma

MAILING ADDRESS:
Post Office Box 26827
Oklahoma City, Oklahoma 73126

SPECIALIZING IN THE EVALUATION
AND MANAGEMENT OF
ALLERGIES AND ASTHMA
IN ADULTS AND CHILDREN

Charles D. Haunschild, MD*
James H. Wells, MD*
John R. Bozalis, MD*
Warren V. Filley, MD*
James R. Claflin, MD*
Patricia I. Overhulser, MD*
Dean A. Atkinson, MD*
Richard T. Hatch, MD*

SENIOR CONSULTANTS
Lyle W. Burroughs, MD*
Robert S. Ellis, MD*

* Diplomate American Board
Allergy and Immunology

G. Keith Montgomery, MHA
Chief Operating Officer

Ruth Riddles, BSN MBA CCRC
Clinical Research

Sherry K. Hubbard, RD LD
Clinical Dietitian

Karen Gregory, MS RN RRT AE-C CNS
Pulmonary Disease Management

Member Institution of
OKLAHOMA Health Center

June 24, 2005

Oklahoma Health Care Authority
4545 N. Lincoln Blvd, Suite 124
Oklahoma City, OK 73105

TO: Pharmacy Review Committee

It has come to my attention that you are in the process of reconsidering your recommendations for the usage of topical Calcineruin inhibitors (Pimecrolimus and Tacrolimus). These drugs are indicated for the topical use of atopic dermatitis, which has not been responsive to other more conventional therapies, including low-dose topical steroids.

I hope that you are aware the Pediatric Advisory Committee of the Food & Drug Administration (FDA) met on February 15, 2005, and made recommendations for a "black box" warning for these medications. However, as of today, no black box indication has been issued.

I would hope that you would **refrain from making any changes** in your recommendations for these medicines until the FDA finishes their hearing process and decides whether or not a black box warning is indeed indicated.

I see no sense in changing your regulations or recommendations now when the Pediatric Advisory Committee should be forthcoming with its recommendations in the near future. Hopefully, you will be able to table your decision until an official FDA decision has been made.

High dose topical steroids in pediatric patients are not appropriate!

Thank you very much for your consideration in this regard.

Most Sincerely,

C D Haunschild, MD

Charles D. Haunschild, M.D.
Diplomate, American Board
Allergy and Immunology

CDH:kp

North Rock

MEDICATION CLINIC

August 1, 2005

Dr .Nancy Nesser J.D., D.Ph.
Planning Director
Oklahoma Health Care Authority
4545 North Lincoln Blvd
Oklahoma City, Ok 73105

Dear Dr. Nesser,

I would like to bring to your attention some very important issues regarding your quantity limitations on Medicaid patients.

First of all, in our mental health clinic, we see the most severely, chronically ill patients. Sometimes these patients take months or even years to stabilize on medications. Our goal is to keep patients stable, functioning in society and prevent relapses so that they do not kill themselves or others or end up in inpatient facilities, which is very expensive.

We do know the FDA recommended dosages (maximums), but these patients do not do well on recommended amounts so we have to stabilize them on higher dosages.

With this sudden decrease in the number of pills or capsules patients can receive it will cause symptoms to reappear, leading to either decompensation or relapse. Some will become violent, suicidal, or homicidal.

One example of such risk would be Quetiapine (Seroquel), FDA approved maximum is 800mg per day. There are numerous studies with up 1000 – 1600 mg per day. Now, a 2-unit limit it means a maximum of 600 mg per day. This will not help these patient psychosis, bipolar symptoms with insomnia or with high anxiety.

I would urge you to consider these factors and let us take care of these most helpless, vulnerable patients from harming themselves or others or being admitted to inpatient facilities

We always try to keep the number of meds and dosages down but this special group of patients needs some exception.

We appreciate your consideration in this extremely important matter.

Thank you,

Sincerely,

Jahangir Ghaznavy, M.D.
Medical Director North Rock Behavioral Health Medication Clinic

OKLAHOMA DEPARTMENT OF MENTAL HEALTH
AND SUBSTANCE ABUSE SERVICES
BILL WILLIS COMMUNITY MENTAL HEALTH AND SUBSTANCE ABUSE CENTER

August 2, 2005

Nancy Messer, M.D.
Oklahoma Health Care Authority
Lincoln Plaza
4545 N. Lincoln Blvd.
Oklahoma City, OK 73105-3413

Der Dr. Messer:

This letter is in regard to the recent change in the policy for the number of pills that are available for certain psychotropic medications that are paid for by the Oklahoma Health Care Authority and supplied to patients with Medicaid. Several issues have arisen out of this new policy change. The most concerning is that of patients who are on antipsychotic medications especially medicines such as Seroquel which must be dosed twice a day intent to need high doses to control serious disorders such as schizophrenia. Here at Bill Willis Community Mental Health Center we treat only severely mentally ill patients and treat mostly schizophrenia and bipolar disorder. As you may know the effective dose of Seroquel for these disorders is 600mg per day and above. Because we are treatment facility of last resort we tend To get a lot of patients who are treatment resistant and typically require high dosing just to keep them stable and allow them to remain n the community. Mot of my patients who tae Seroquel take doses above 600mg a day and these doses require more than 2 pills per day. Several of my patients are in great danger of decompensating and becoming either violent toward themselves or others. This could cause a great deal of hospitalizations which would cost the State lot more in dollars than the dollars necessary to pay for the larger doses of medications. Seroquel is only one of several medications that are causing us difficulties. We also are having difficulties with several antidepressants, which cannot be dosed at the upper limits of the FDA recommended dosing due to the restriction I, the number f pills. While I appreciate he desire to save cost and save taxpayer's money we have to recognize that there is a practicality to these things and that many times patients need to be on dosages require more than one pill a day or even 2 pills a day to get them to a therapeutic dose. If you would like to discuss this matter further you can reach me at 918-207-3042 and would be happy to talk with you about this at any time.

Sincerely,

Robert V. Hensley, D.O.
Diplomat
American Board of Psychiatry & Neurology

RVH: pjs

Oklahoma Institute Of Psychiatric Medicine

Cooper Center #106, 7100 North Classen Boulevard, Oklahoma City, OK 73116
Phone: 405-841-3337 * Fax: 405-841-3338

AMAR N. BHANDARY, MD
Diplomate: *American Board of Psychiatry and Neurology*
Clinical Fellowship:
Consultation-Liaison Psychiatry

August 2, 2005

Dr. Nancy Nesser J.D., D.Ph
Planning Director
Oklahoma Health Care Authority
4545 North Lincoln Blvd.
Oklahoma City, OK 73105

Dear Dr. Nesser,

The purpose of my correspondence today is to inform you of some concerns I have involving the new quantity limitations on Medicaid patients medications.

A large percentage of my private psychiatry practice here in Oklahoma City centers on the treatment and care of mental health patients coming from the state medicaid program. Many of my patients are chronically ill and need to be on the medications they current take to remain stable.

I am aware of the FDA recommended dosages that patients taking antidepressants and/or antipsychotics need to use. But don't understand why some of my Medicaid patients prescriptions for Citalopram (Celexa), Venlafaxine (Effexor), and Escitalopram oxalate (Lexapro) have been returned, when the requested amounts are within FDA approved guidelines? And, why patients taking Quetiapine (Seroquel) 800mg per day, now are restricted to 2-units per day that limits their dose to 600mg per day? I do understand that a second brand punch can be used for a different strength of Quetiapine to achieve a total dose of 800mg. However, my patients often need that extra punch for medications from their primary care physician. Reducing my patient dose of Quetiapine (Seroquel) to 600mg daily may jeopardize the stability of my patients; which has in many instances taken months to achieve using various agents.

I request that you allow antidepressant use within the FDA guidelines, and Quetiapine (Seroquel) availability at 800mg per day utilizing just one punch which is still within FDA guidelines.

I greatly appreciate your support of these requests.

Sincerely,
Amar N. Bhandary, MD

Amar N. Bhandary, M.D.
Oklahoma Institute of Psychiatric Medicine

APPENDIX B

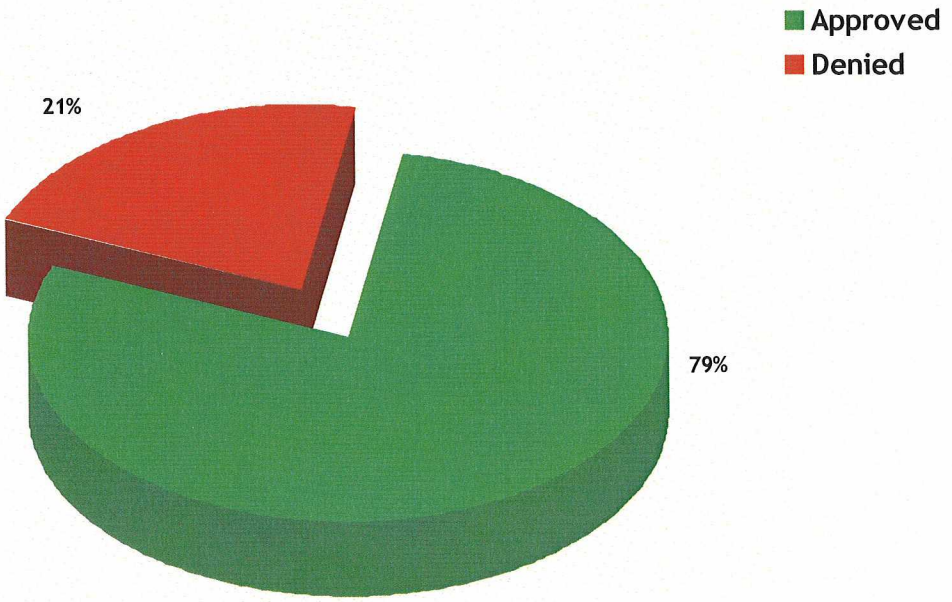
Retrospective Drug Utilization Review Report

Claims Reviewed for April 2005

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	103,691	102,429	808,269	51,209
Limits which were applied	Established, major, 0 – 21 yrs old	Osteoporosis Agents	Contraindicated, Chronic Renal Failure	High dose, Muscle Relaxants, Males
Total # of messages after limits were applied	26	302	91	145
Total # of clients reviewed after limits were applied	26	284	88	145

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
80	38	32	17

PRIOR AUTHORIZATION ACTIVITY REPORT
June 2005



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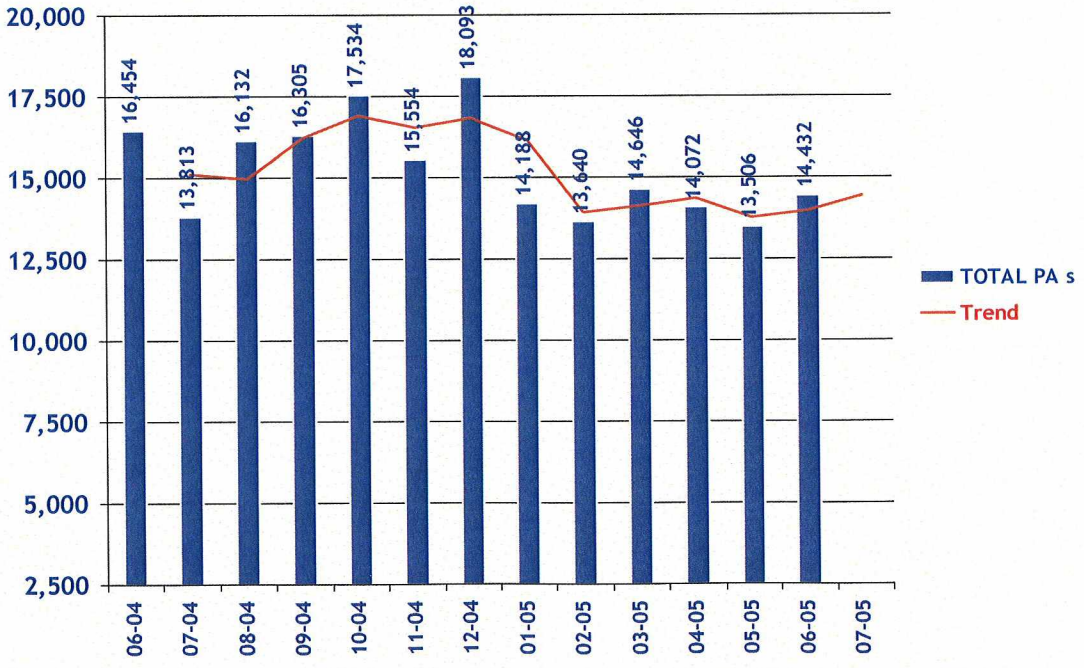
PRIOR AUTHORIZATION REPORT
June 2004 - June 2005



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Activity Audit for

June 01 2005 Through June 30 2005

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
App.	21		4351		1116		36		881		126		50		9		109		747		32		135		
Den		5		654		530		1		240		149		53		2		212		83		6		57	
Average Length of Approvals in Days	29		96		100		152		230		303		162		237		311		352		212		75		

Changes to existing PA's	1126
Total (Previous Year)	16454

*** Denial Codes**

762 = Lack of clinical information	13.80%
763 = Medication not eligible	1.35%
764 = Existing PA	6.57%
772 = Not qualified for requested Tier	5.59%
773 = Requested override not approved	14.78%

SUPER PA's

Admitted to Nursing Home	130
Early Refill Attempts	45489
Dosing Change	702
Lost/Broken Rx	161
Stolen	29
Other	84
Wrong D.S. on Previous Rx	19
Quantity vs. Days Supply	623
Brand	209
-- Approved	66
-- Denied	58

Monthly Totals

	Number	Percent of Total
Approved	8921	61.81%
Additional PA's	59	0.41%
Emergency PA's	1	0.01%
Duplicates	596	4.13%
Incompletes	2406	16.67%
Denied *	2449	16.97%
Total	14432	100.00%

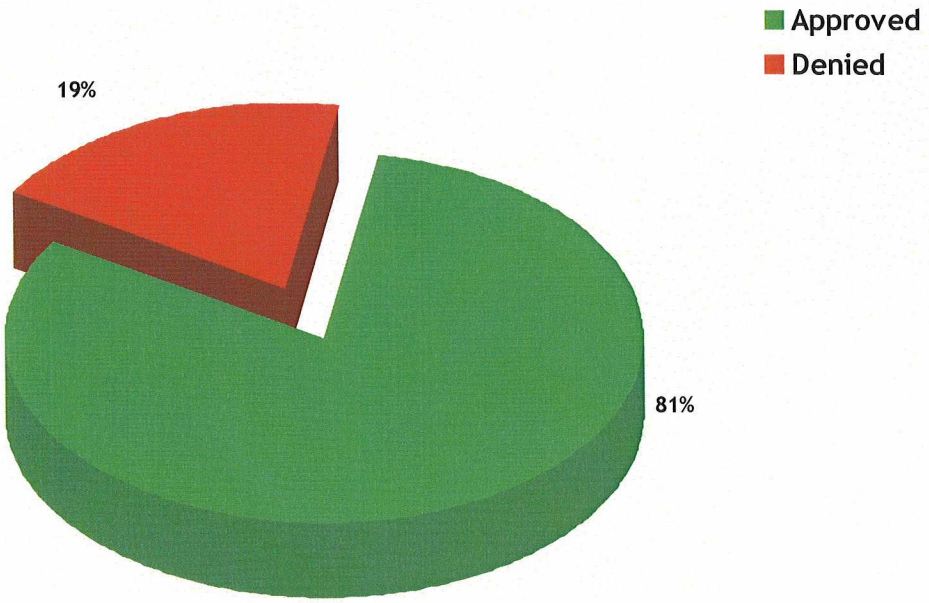
Daily Average of 555.08 for 26 Days

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

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

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

PRIOR AUTHORIZATION ACTIVITY REPORT
July 2005



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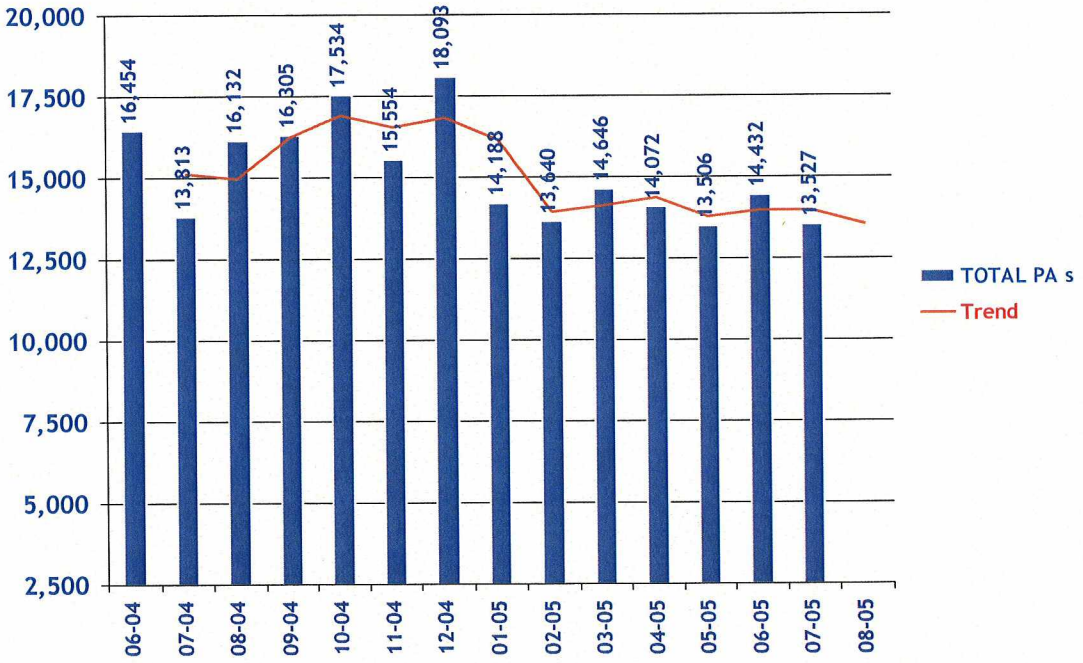
PRIOR AUTHORIZATION REPORT
June 2004 - July 2005



PHARMACY Management consultants

Activity Audit for

July 01 2005 Through July 31 2005

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
App.	19		2925		891		28		848		161		54		6		88		571		35		584		
Den		5		305		316		1		231		199		33		1		140		63		15		128	
Average Length of Approvals in Days	16		99		98		172		234		337		191		183		285		352		168		202		

Changes to existing PA's	916
Total (Previous Year)	13813

*** Denial Codes**

762 = Lack of clinical information	10.92%
763 = Medication not eligible	1.61%
764 = Existing PA	4.21%
772 = Not qualified for requested Tier	8.48%
773 = Requested override not approved	23.61%

SUPER PA's

Admitted to Nursing Home	191
Early Refill Attempts	42724
Dosing Change	582
Lost/Broken Rx	157
Stolen	29
Other	61
Wrong D.S. on Previous Rx	14
Quantity vs. Days Supply	3390
Brand	174
-- Approved	63
-- Denied	42

Monthly Totals

	Number	Percent of Total
Approved	8314	61.46%
Additional PA's	7	0.05%
Emergency PA's	8	0.06%
Duplicates	630	4.66%
Incompletes	2645	19.55%
Denied *	1923	14.22%
Total	13527	100.00%

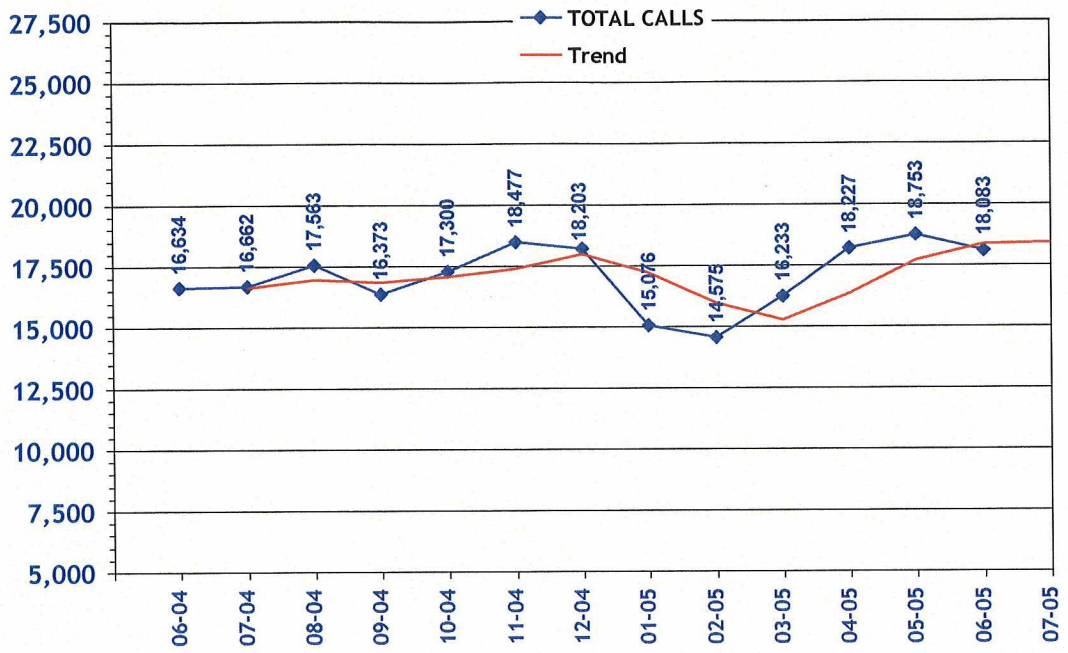
Daily Average of 541.08 for 25 Days

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

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

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

CALL VOLUME MONTHLY REPORT
June 2004 - June 2005



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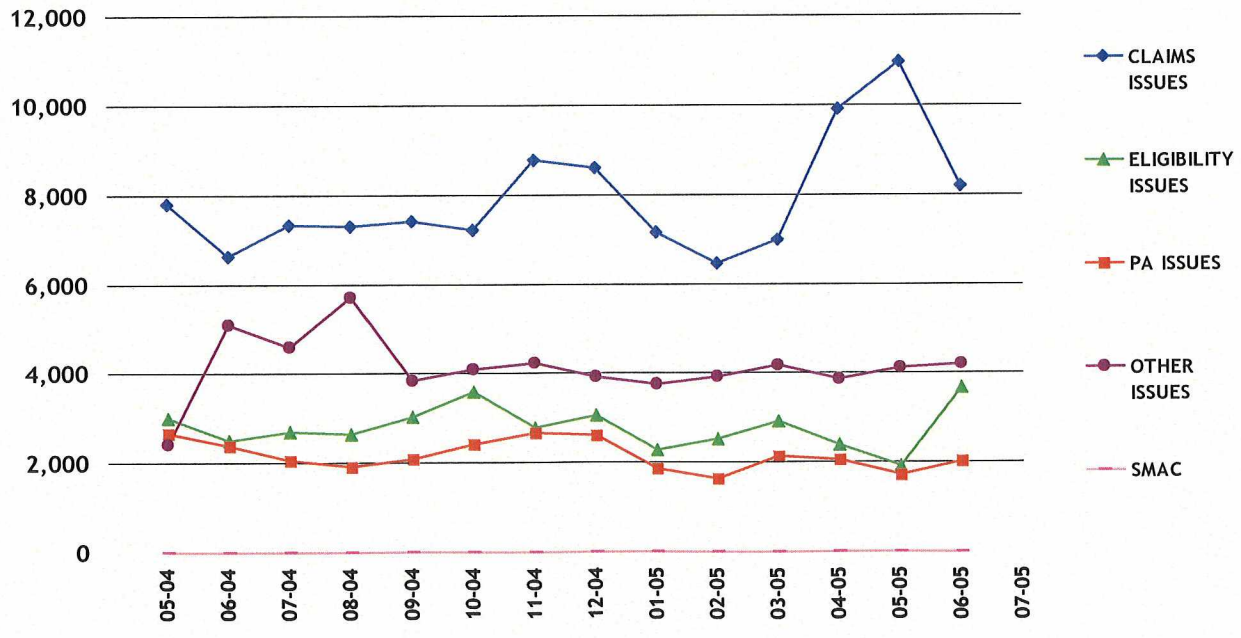
CALL VOLUME ISSUES
June 2004 - June 2005



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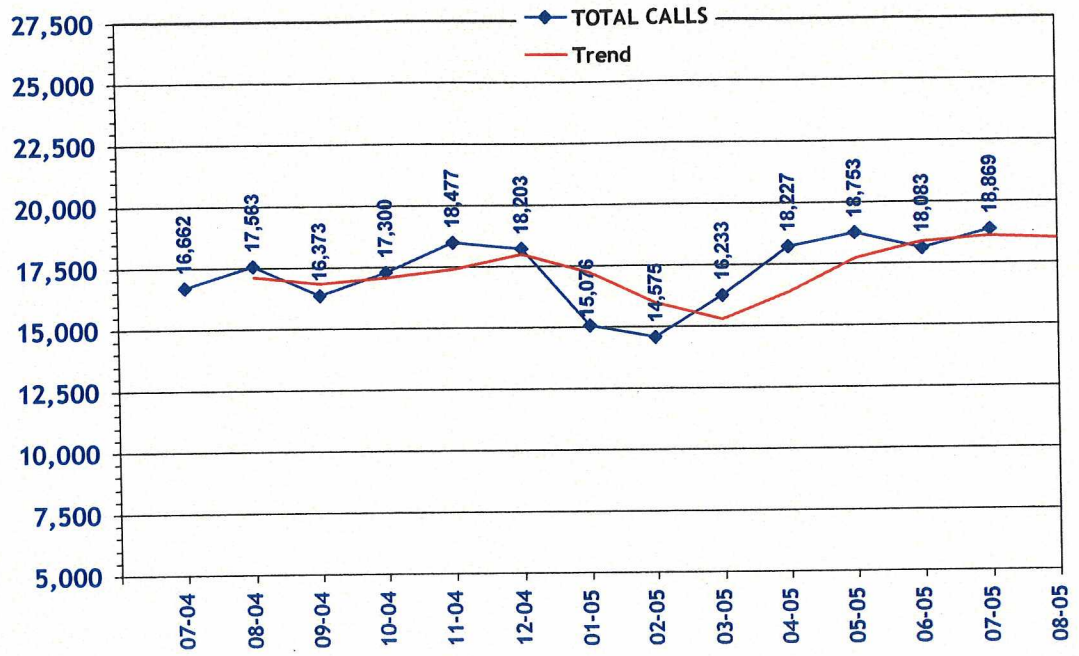
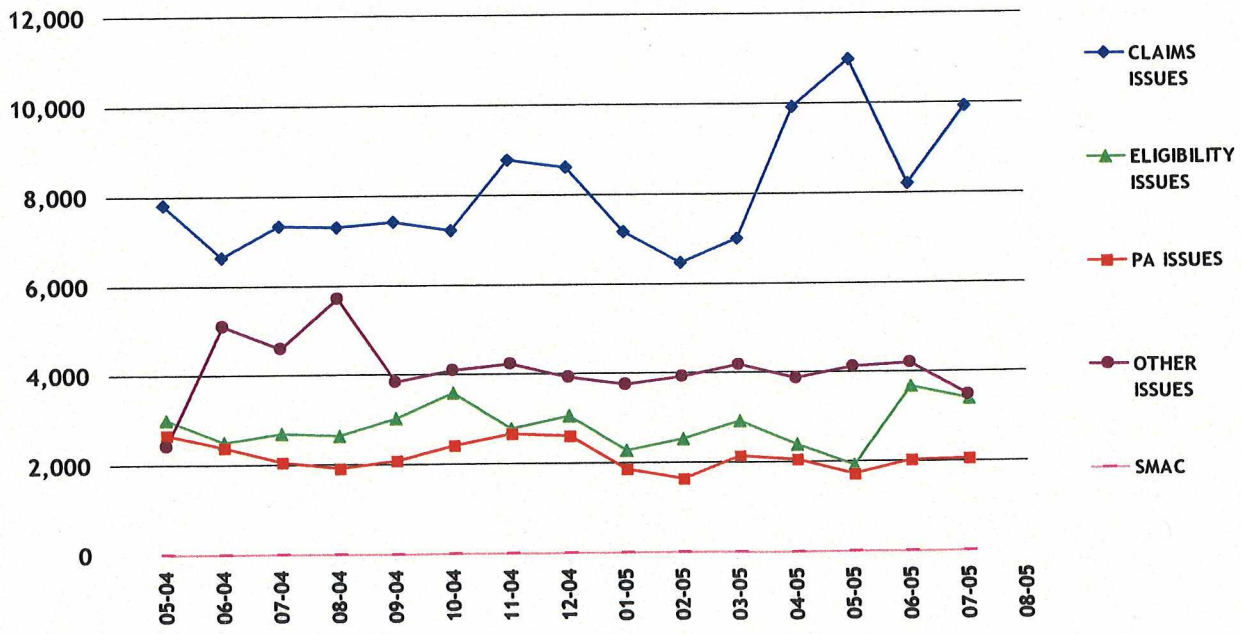
CALL VOLUME MONTHLY REPORT
July 2004 - July 2005



PHARMACY Management Consultants

CALL VOLUME ISSUES
July 2004 - July 2005



PHARMACY Management Consultants

Pharmacotherapy Management Program
Annual Report FY'05
July 2004 – June 2005
Oklahoma Medicaid

	CLIENT PROFILES REVIEWED			PRIOR AUTHORIZATIONS				COMMUNICATIONS	
Month	New Clients	Established Clients	Incomplete Information	Total	Approved	Denied	Incomplete	Letters	Calls
July 2004	80	61	26	478	290	18	170	236	32
Aug 2004	102	77	27	681	381	24	276	348	100
Sept 2004	114	46	23	714	401	44	269	234	104
Oct 2004	99	35	20	711	437	55	219	349	73
Nov 2004	87	17	15	571	342	43	186	221	66
Dec 2004	94	49	13	638	382	61	205	348	89
Jan 2005	106	37	15	727	453	60	214	344	83
Feb 2005	73	36	14	507	332	33	142	227	55
March 2005	85	73	15	729	464	43	222	345	86
April 2005	83	36	14	728	434	36	258	294	58
May 2005	71	29	15	684	404	51	229	246	41
June 2005	109	30	13	687	434	33	220	335	57
Totals	1103	526	210	7,855	4,754	501	2,610	3,527	844
1st Quarter	296	184	76	1,873	1,072	86	715	818	236
2nd Quarter	280	101	48	1,920	1,161	159	610	918	228
3rd Quarter	264	146	44	1,963	1,249	136	578	916	224
4th Quarter	263	95	42	2,099	1,272	120	707	875	156
Totals	1103	526	210	7,855	4,754	501	2,610	3,527	844

APPENDIX C

Vote to Prior Authorize Zetia®

Oklahoma Medicaid
August 2005

Recommendations

The College of Pharmacy recommends a prior authorization be placed on Zetia®. The approval criterion is as follows:

1. Diagnosis[i]:
   - Hypercholesterolemia, primary
   - Hypercholesterolemia, homozygous familial
   - Sitosterolemia, homozygous

2. Laboratory documentation that client has not met (LDL) cholesterol goals after therapeutic lifestyle changes and statin therapy for at least 6 months.

3. Not a candidate for statin therapy due to:
   - Documented active liver disease.
   - Documented unexplained, persistent elevations of serum transaminases.
   - Documented statin related myopathy.

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[i] Merck & Co., Inc. Product Literature Zetia®. March 2005. Available online at: http://www.zetia.com/zetia/shared/documents/zetia_pi.pdf

APPENDIX D

Elidel® (Pimecrolimus) and Protopic® (Tacrolimus)
Oklahoma Medicaid
August 2005

Manufacturer Elidel® (Pimecrolimus) Novartis Pharmaceutical Corp.
Protopic® (Tacrolimus) Fujisawa Healthcare, Inc.

Pharmacologic Category Calcineurin Inhibitors; Topical Immunosuppressants

Status Prescription only

Overview

Elidel® (Pimecrolimus) 1% cream has approved marketing for patients two years of age and older as second-line treatment for short-term and intermittent mild to moderate atopic dermatitis (eczema) that has been shown to be unresponsive or intolerant to conventional treatments. Protopic® (Tacrolimus 0.03% or 0.1%) has been approved for patients two years of age and older as second-line treatment for short-term and intermittent moderate to severe atopic dermatitis (eczema) that has been shown to be unresponsive or intolerable to conventional treatments. Children two years of age and older may use only the 0.03% ointment. Protopic® (Tacrolimus) 0.1% is approved for adult use ages 15 years or older. The active ingredient in Protopic® is tacrolimus and Elidel® is pimecrolimus. Both are microbial-derived macrolides with a mechanism of action similar to cyclosporine. They are believed to decrease both cytokine production and release of inflammatory mediators due to cell-mediated immune responses. The inhibitory binding consequently leads to reduced t-lymphocyte activation and immunosuppression.

Recommendations

The College of Pharmacy recommends prior authorization for topical immunosuppressants Protopic® and Elidel® with the following criteria:

- **Clinical Diagnosis:**

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

- **Adherence to Age Restrictions:**

  - Elidel® 1% ≥ 2 years of age
  - Protopic® 0.03% for ≥ 2 years of age
  - Protopic® 0.1% for ≥ 15 years of age (Approved for adult-use only)

- **Prior Authorization Criteria:**

  - Non-immunocompromised patients.
  - A failed trial of at least two tier-1 topical corticosteroids with each trial lasting 6 weeks in duration within the last 90 days (~12 weeks).
  - Limited to one authorization every 6 months to ensure appropriate short-term and intermittent utilization advised by FDA.
  - Quantity limitation per approval for all ages: 30 gram(s) maximum for face, neck, and groin areas, 100 gram(s) maximum for all other areas.
  - Approvals granted for clients undergoing treatment by an allergist or dermatologist regardless of age to ensure proper management of disease and safety concerns.

- **Clinical Exceptions:**
  - Documented adverse effect, drug interaction, or contraindication to tier-1 products.
  - Atopic Dermatitis on the face where physician does not want to use topical corticosteroids.

Evidenced-Based Pediatric Therapy with Topical Corticosteroids A= proven in well-conducted RCTs with adequate # of pts. B=case studies, low # of pts. , non-RCTs, short duration,etc... C=ineffective in well-conducted RCTs with adequate # of pts.	FDA-approved	Non-FDA approved (age,# pts, trial length)	Level of Evidence
Super-High Potency			
Diprolene®, (Betamethasone dipropionate aug.)0.05%	≥ 12 yr		
Olux®, Temovate® (Clobetasol propionate) 0.05%	≥ 12 yr	5 yr, n=30, 5 weeks	B
Psorcon® (Diflorasone diacetate) 0.05%	≥ 12 yr		
Ultravate® (Halobetasol propionate) 0.05%	≥ 12 yr	5-15 yr, n=81,14-day	B
High Potency			
Cyclocort® (Amcinonide) 0.1%	≥ 12 yr		
Topicort® (Desoximetasone) 0.05%	≥ 10 yr		
Diprolene AF® (Betamethasone dipropionate augmented)0.05%	≥ 12 yr		
Psorcon E®, Maxiflor® (Diflorasone diacetate) 0.05%	≥ 12 yr		
Lidex® (Fluocinonide) 0.05%	≥ 12 yr		
Halog E®, Halog® (Halcinonide) 0.1%	≥ 12 yr	5 mos. – 15yr, n=105, 2 weeks	B
Elocon® (Mometasone furoate) 0.1%	≥ 2 yr		
Medium-High Potency			
Aristocort A®, Kenalog®(Triamcinolone acetonide) 0.5,0.1%	> 16 yr	3 mos. – 10yr, n=101, 8-day	B
Betatrex® (Betamethasone valerate) 0.1%	≥ 12 yr		
Cutivate® (Fluticasone propionate) 0.005% ointment	≥ 17 yr		
Cyclocort® (Amcinonide) 0.1% cream, lotion	≥ 12 yr		
Alphatrex® (Betamethasone dipropionate) 0.05%	≥ 12 yr		
Maxiflor® (Diflorasone diacetate) 0.05% cream	≥ 12 yr		
Lidex E® (Fluocinonide) 0.05%	≥ 12 yr		
Medium Potency			
Luxiq® (Betamethasone valerate) 0.12%	> 16 yr		
Synalar® (Fluocinolone acetonide) 0.025%	≥ 2 yr		
Cordran® (Flurandrenolide) 0.025, 0.05%	pediatric		
Westcort® (Hydrocortisone valerate) 0.2%	pediatric		
Elocon® (Mometasone furoate) 0.1% cream, lotion	≥ 2 yr		
Aristocort A®, Kenalog®(Triamcinolone acetonide) 0.1% cream	pediatric		
Medium-Low Potency			
Desowen®, Tridesilon® (Desonide) 0.05%	> 16 yr		
Locoid® or Locoid Lipocream® (Hydrocortisone butyrate) 0.1%	pediatric		
Dermatop® (Prednicarbate) 0.1%	≥ 1 yr	≥ 2mos., n=55, 3 wks	B
Synalar® (Fluocinolone acetonide)0.025%, 0.01% cream, solution	≥ 2 yr		
Cordran SP® (Flurandrenolide) 0.025%, 0.05% cream, lotion	pediatric		
Aclovate® (Alclometasone dipropionate) 0.05%	≥ 1 yr		
Betatrex® (Betamethasone valerate) 0.025% cream	pediatric		
Cloderm® (Clocortolone) 0.1%	pediatric		
Cutivate® (Fluticasone propionate) 0.05% cream	≥ 3 mos.		
Westcort® (Hydrocortisone valerate) 0.2% cream	pediatric		
Kenalog®(Triamcinolone acetonide) 0.025%, 0.1% cream, lotion	pediatric		
Lowest Potency			
Hytone® (Hydrocortisone) 0.5, 1.0, 2.5%	pediatric		

APPENDIX E

Vote on Placement of ADHD PBPA Category in Supplemental Rebate Program

Oklahoma Medicaid
August 2005

Recommendations

The following tier table is recommended as a clinically acceptable combination for use as initial therapy for the majority of clients. The College of Pharmacy recommends the tier 2 list to the Drug Utilization Review Board for approval and referral to the Oklahoma Healthcare Authority for supplemental rebate consideration and final approval by the OHCA Board of Directors.

ADHD and Narcolepsy

PA Criteria:

First step of immediate release stimulants prior to once-daily extended release formulations.

- Dose not to exceed 1.5 times the FDA approved maximum.
- No concurrent use of multiple products from this category, ie, Strattera + Stimulant, Methylphenidate + Amphetamine
- Desoxyn & Cylert require two Tier-1 trials and are not available for supplemental rebate.
- Prior authorization is required for all products for adults age 21 and older.

Tier 1	Tier 2	Tier 3
• amphetamine salt combo (Adderall) • dextroamphetamine (Dexedrine, Dextrostat) • methylphenidate ER (Metadate ER) • methylphenidate (Ritalin) • methylphenidate SR (RitalinSR)	• amphetamine salt combo (Adderall XR) • methylphenidate ER (Concerta) • dexmethylphenidate (Focalin, Focalin XR*) • methylphenidate ER (Metadate CD, Ritalin LA) • atomoxetine (Strattera)	• pemoline (Cylert) • methamphetamine (Desoxyn)

*Focalin XR will be voted on separately.

30 Day Notice to PA Focalin™ XR (dexmethylphenidate hydrochloride)

Oklahoma Medicaid
August 2005

Manufacturer Novartis Pharmaceuticals Corporation
Classification Central Nervous System Stimulant
Status: prescription only (schedule II)

Summary*

Dexmethylphenidate hydrochloride, the more active *d*-threo-enantiomer of methylphenidate hydrochloride, is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and children over 6 years of age. Focalin™ XR has a bimodal release profile using the SODAS® (Spherical Oral Drug Absorption System) technology. It produces two distinct peaks approximately 4 hours apart. Time to first peak is similar to the immediate release at 1 ½ hours while time to second peak is slightly longer. Focalin™ XR is intended for administration once daily in the morning.

Recommendation

The College of Pharmacy recommends Focalin™ XR be included in Tier-2 of the ADHD Product Based Prior Authorization category. An inadequate response to a trial with methylphenidate and a diagnosis of ADHD is required. The College of Pharmacy also recommends a quantity limit of 30 units for a 30 day supply.

Cost Comparison

	EAC	SMAC	30 Day Supply
Methylphenidate 5 mg	N/A	0.10	$9.00 (TID)
Methylphenidate 10 mg	N/A	0.13	$11.70 (TID)
Methylphenidate 20 mg	N/A	0.34	$30.60 (TID)
Ritalin™ LA 10 mg	2.47	N/A	$74.10 (QD)
Ritalin™ LA 20mg	2.47	N/A	$74.10 (QD)
Ritalin™ LA 30 mg	2.53	N/A	$75.90 (QD)
Ritalin™ LA 40 mg	2.60	N/A	$78.00 (QD)
Focalin™ 2.5 mg	0.51	N/A	$30.60 (BID)
Focalin™ 5 mg	0.72	N/A	$43.20 (BID)
Focalin™ 10 mg	1.04	N/A	$62.40 (BID)
Focalin™ XR 5 mg	2.98	N/A	$89.40 (QD)
Focalin™ XR 10 mg	2.98	N/A	$89.40 (QD)
Focalin™ XR 20 mg	2.98	N/A	$89.40 (QD)

* Prescribing Information: Focalin™ XR (dexmethylphenidate hydrochloride) extended-release; Novartis Pharmaceuticals Corporation, East Hanover, NJ; May 2005.

APPENDIX F

Prior Authorization Annual Review - Fiscal Year 2005
Synagis®
Oklahoma Medicaid
August 2005

Definition of Prior Authorization Category for FY '05

Prior authorization is required for all clients who receive Synagis® through a pharmacy or in a physician's office. Synagis® is approved for all clients who meet the established criteria based on the 2003 American Academy of Pediatrics (AAP) guidelines.

Criteria for Prior Authorization of Synagis

A. Client Selection. Client must be included in one of the following age groups at the beginning of the RSV season:*

1) Infants and children less than 24 months old with Chronic Lung Disease (CLD) who have required medical treatment (O_2, bronchodilator, corticosteroid, or diuretic 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 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.

* Treatment should continue through the entire RSV season.

B. Length of treatment. Synagis® is approved for use only during RSV season, which is generally October 1 through April 30, as determined by Oklahoma State Dept. of Health.

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

D. Dose-pooling. To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization

For the period of October 2004 through April 2005, a total of 963 clients received Synagis® through the Medicaid fee-for-service program from a pharmacy provider or a physician's office.

Pharmacy Claims:

Product	# of Claims	Total Units	Total Days	Total Cost	Total Clients
Synagis® 50 mg vial	2,178	2,923	55,111	$1,963,946.72	706
Synagis® 100 mg vial	3,550	3,972	85,393	$4,986,723.45	795
Total	**5,728**	**6,895**	**140,504**	**$6,950,670.17**	**931***

Physician Office Claims – CPT code 90378

Product	# of Claims	Total Units	Total Days	Total Cost	Total Clients
Synagis® 50 mg increments	136	395	3,808	$265,982.54	32*

*Total unduplicated clients for 04-05

Total Cost - RSV Season 04-05	**$7,216,652.71**
Total Cost RSV Season 03-04	*$5,736,869.25*
Total Claims- RSV Season 04-05	**5,864**
Total Claims RSV Season 03-04	*4,522*
Total Clients - RSV Season 04-05	**963**
Total Clients RSV Season 03-04	*1,027*

Total petitions - RSV Season 04-05

A total of 1393 petitions were submitted for consideration of Synagis®. 522 petitions were denied for 365 unduplicated clients. Upon submission of additional information, petitions for 181 clients were subsequently approved.

Approved 1160
Denied 522
Incomplete 289

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

Age	Female	Male	Totals
0 to 1	443	511	954
1 to 2	5	4	9
Totals	**448**	**515**	**963**

Hospitalization

Hospital claims submitted only during the 2004-05 RSV season were evaluated to determine the incidence of RSV requiring medical intervention (hospitalization or emergency room visit). Claims were selected using RSV-specific ICD-9 codes (480.1, 079.6, and 466.11) as well as unspecific bronchiolitis and viral pneumonia codes (480.9, 466.1, and 466.19). These claims were compared with approval and denial data for Synagis®. 115 clients who had approval for Synagis® and presumably received the monthly injections sought treatment for RSV or a similar respiratory illness. 19 clients who were denied and did not receive the injections were treated.

	Clients	Claims	Costs
Synagis® Approved	115	185	$282,250.79
Synagis® Denied	19	26	$37,446.57

Discussion

A new liquid formulation of Synagis® has been approved and will be dispensed after the powder products have been used. This should occur in approximately November 2005.

Recommendations

The College of Pharmacy does not recommend any changes for RSV Season 2005-2006. We will continue to monitor usage of this drug.

APPENDIX G

Review and Discuss Pulmonary Arterial Hypertension and 30-day Notice to Prior Authorize Revatio® (Sildenafil)

Oklahoma Medicaid

August 2005

Introduction

Pulmonary arterial hypertension (PAH) is a rare and devastating disease which reduces quality of life and may become life-threatening for those affected if misdiagnosed and left untreated. The pulmonary artery leading from the heart to the lungs plays a vital role in the gas exchange and oxygen transport of blood throughout the body. High blood pressure in this blood vessel can lead to decreased cardiovascular functioning through vasculature remodeling and right heart enlargement. Extensive damage to endothelial cells, increase risk of blood clots, and right heart failure can lead to premature cardiovascular death. Incidence in the United States is estimated to be about 500 to 1000 new cases per year. PAH predominantly affects women between the ages of 20 and 40 years of age but males and females of all ages are susceptible to this disease with a shortened life-expectancy even with current treatment options available. The etiology of the disease is not yet fully understood but has been associated with genetic factors, concomitant diseases (i.e. Raynaud's syndrome, HIV infection, emphysema, bronchitis, scleroderma, portal hypertension, Crest Syndrome, Systemic Lupus Erythematosus) and combination drug use (i.e. diet drugs, cocaine). Clinical manisfestations of PAH include: fatigue, dyspnea, vertigo, syncope, chest pain, palpitations, cough, edema in legs, and bluish discoloration of lips and skin. There is no cure for PAH and lung transplantation becomes a treatment option when patients no longer respond to medical therapy. Early diagnosis and adequate treatment results in significant improvement of quality of life and life-expectancy by preventing disease progression.

Classification and Diagnosis

This rare and complex disease requires management and assessment by a specialist such as a cardiologist or pulmonologist to adequately diagnose and select medical treatment. Drug therapies are often chosen based on patient's functional classification and degree of disease progression. Therefore, modified versions of the New York Heart Association (table 1) and World Health Organization (table 2) functional classifications were adopted by the American College of Chest Physicians (ACCP) to categorize the current understanding of PAH pathology and progression as a basis for drug therapy selection. Approximately, 70 % are diagnosed in NYHA Class III-IV.

Table 1

New York Heart Association Functional Classification (patients with cardiovascular disease)	
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea.
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity causes fatigue, palpitation or dyspnea.
Class IV	Unable to carry out any physical activity without discomfort. Symptoms possible at rest. If physical activity is undertaken, discomfort is increased.

Table 2

Venice 2003 Revised Classification system for PAH (3rd World Symposium on Pulmonary Hypertension)	
WHO Group I	*Pulmonary arterial hypertension(PAH)*
WHO Group II	Pulmonary hypertension with left heart disease
WHO Group III	Pulmonary hypertension associated with lung diseases and/or hypoxemia
WHO Group IV	Pulmonary hypertension due to chronic throbotic and/or embolic disease
WHO Group V	Miscellaneous

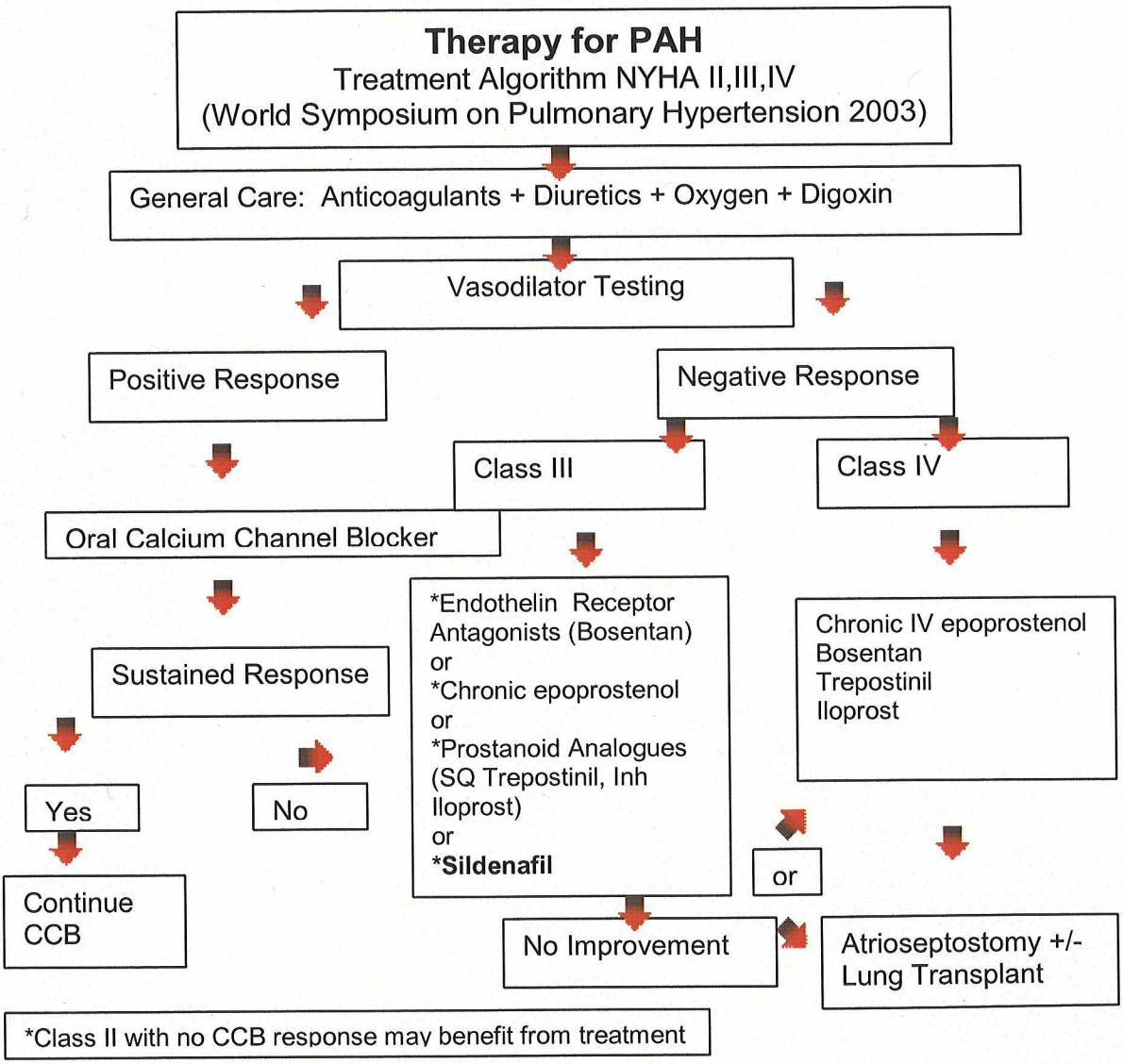
Diagnosis of PAH with unknown etiology is referred to as idiopathic pulmonary arterial hypertension (IPAH). All other known causes of PAH are referred to as familial pulmonary arterial hypertension (FPAH). Relevant causative etiologies include chronic thromboembolic disease, connective tissue disease, congenital heart disease, appetite suppressant use, and/or HIV infection. Comprehensive clinical evaluation is essential in achieving a differential diagnosis from other diseases with similar signs and symptoms. Right heart catheterization is the "gold standard" of diagnosing PAH.

Diagnostic Criteria:

- Mean Pulmonary Arterial Pressure (mPAP) is the objective measurement for PAH. Normal mPAP at rest is 14 mm Hg. mPAP > 20 mm Hg at rest or > 40 mm Hg during exercise are indicators of PAH. Cardiac output is also measured.
- EKG: elevated T-waves, P-wave
- Chest X-ray/MRI/CT: enlarged pulmonary artery (anatomical)
- Echocardiogram: enlarged right atrial or ventricular chamber (prognostic)
- Pulmonary Function testing: determine baseline function (O_2Sat)
- 6-minute walk testing: exercise capacity determined by distance walked
- Physical Exam: Heart sounds, edema, low B.P., cyanosis
- Serologic, Genetic testing, Lung Biopsy

Treatment

The choice of drug therapy is determined usually after cardiac catheterization and assessment of patient functional classification and concomitant drug/disease profile. Available drug therapies include calcium channel blockers, prostacyclins, diuretics, oxygen supplementation, digoxin, warfarin, endothelial receptor antagonists, and phosphodiesterase-5 inhibitors. Both hemodynamic and functional response to therapy is not necessarily correlated to survival rate. Approximately, one-quarter of patients with PAH respond to calcium channel blocker therapy. Combination therapy may be used in severe cases but lung transplantation is inevitable when patients no longer respond to medical therapy.



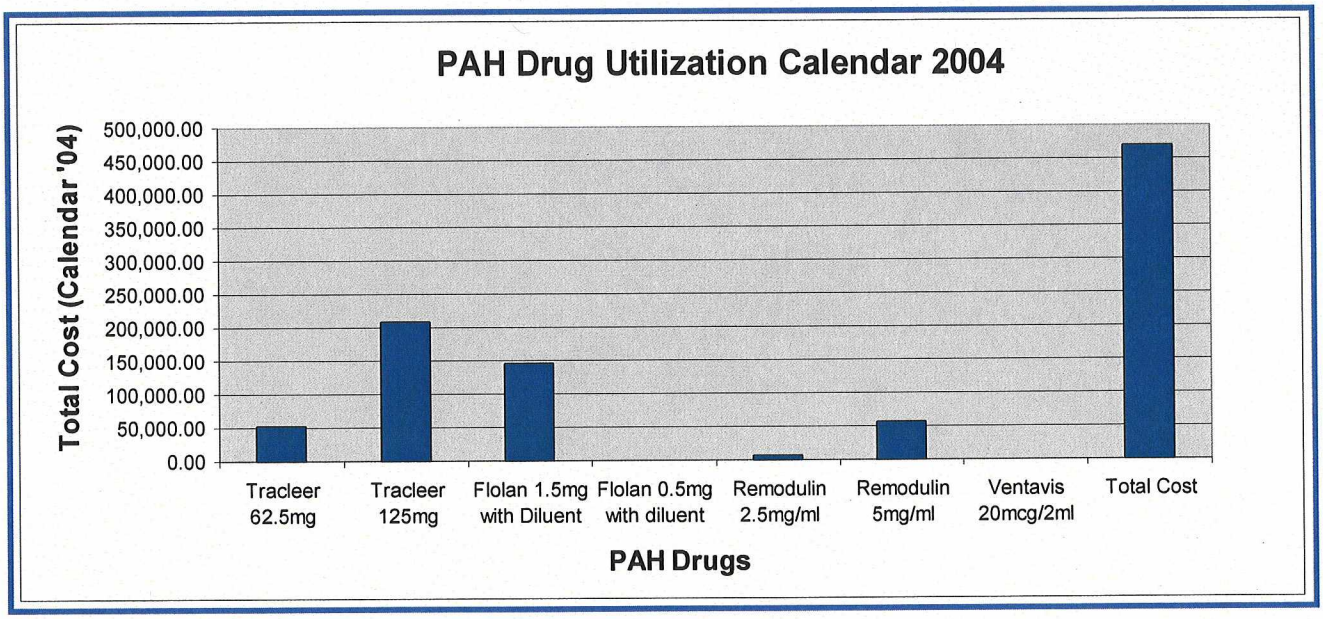
Treatment Goals: Improved hemodynamics (mPAP, PVR, CO), exercise capacity (6 minute walk test), quality of life, prevent progression, improve survival.

Oklahoma Medicaid Cost and Utilization

Drug Name	Total Claims	Total Units	Total Days	# Client	Cost Per Client	Per Day	Total Paid
Tracleer® 62.5 mg	18	1,080	540	5	10,334.66	95.69	$51,673.30
Tracleer® 125 mg	70	4,200	2,100	8	25,970.53	98.94	$207,764.20
Sterile Diluent	28	82,100	803	4	4,791.14	23.87	$19,164.57
Flolan® 1.5mg/ml	26	3,115	747	4	31,824.60	170.41	$127,298.40
Remodulin® 2.5 mg/ml	1	40	28	1	5,722.15	204.36	$5,722.15
Remodulin® 5.0 mg/ml	5	200	150	2	28,605.38	381.41	$57,210.75
TOTAL	**148**	**90,735**	**4,368**	**15***			**$468,833.37**

*Unduplicated

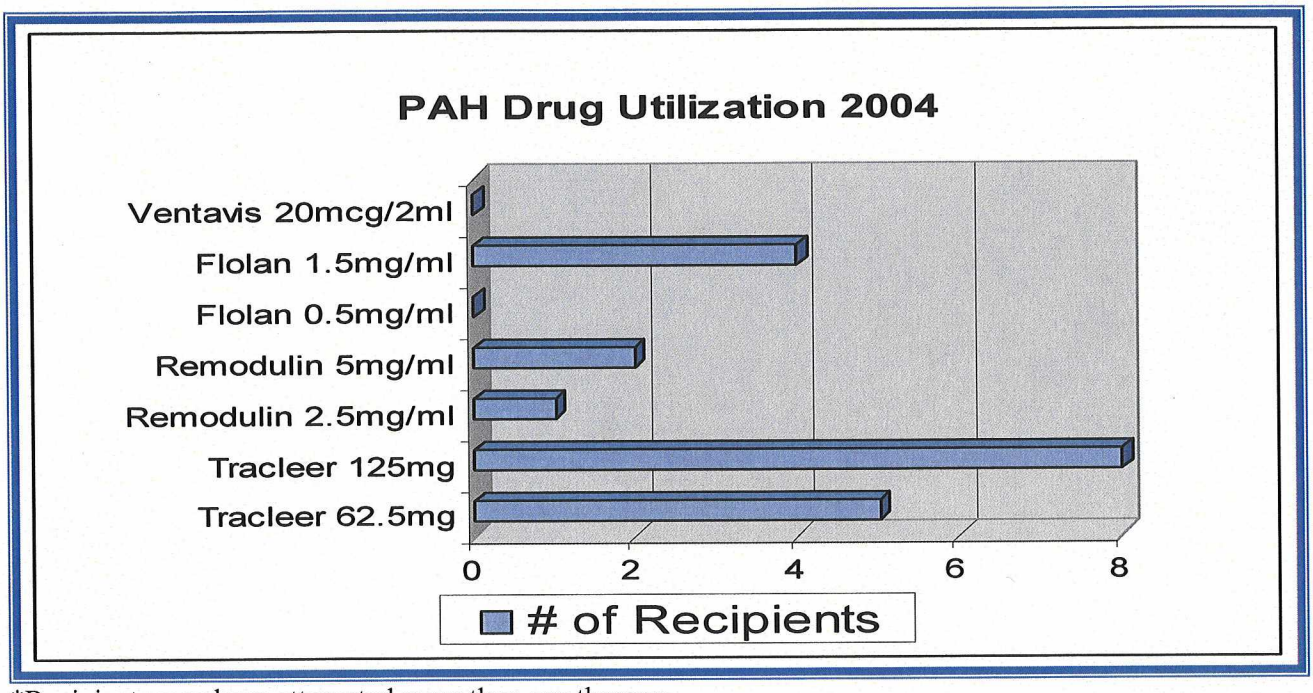
Cost and Utilization PAH Medications



Age and Gender

Age	Female	Male	Totals
10 to 19	1	0	1
20 to 34	2	2	4
35 to 49	5	0	6
50 to 64	5	0	5
Totals	**13**	**2**	**15***

Product Utilization 2004*



*Recipients may have attempted more than one therapy

Cost comparison for Pulmonary Arterial Hypertensive Drugs

Product	Route of administration	Dosage	Approximate annual cost
Nifedipine	Oral	10mg tid	$259**
Hydralazine	Oral	100mg bid	$450
Bosentan (Tracleer®) (Actelion)	Oral	62.5 mg bid X4 weeks, then 125 mg bid	$36,000
Epoprostenol (Flolan®) (GlaxoSmithKline)	Continuous IV	20 ng/kg/minute	$72,000*
Treprostinil (Remodulin®) (United Therapeutics)	Continuous IV, SC	20 ng/kg/minute	$93,000*
Illoprost (Ventavis®)	Inhalation	5mcg/dose, 6 times a day	$100,000*
Sildenafil (Revatio®)	Oral	20mg tid	$10,758

* For a 70 kg patient, including delivery systems but excluding costs of nursing care and administration
**SMAC pricing

Revatio® (Sildenafil)

Manufacturer Pfizer Inc.
Classification Phosphodiesterase-5 Enzyme Inhibitor
Status: prescription only

Pharmacological data

- Sildenafil is a phosphodiesterase type 5 (PDE-5) inhibitor. PDE-5 is involved in the deactivation of cyclic guanosine 3'-5' monophosphate (cGMP) which is responsible for vasodilation effects while in the presence of nitric oxide (NO). Sildenafil, originally approved for erectile dysfunction, has shown in clinical trials to reduce mean pulmonary arterial pressure (mPAP) and peripheral vascular resistance (PVR) by inhibiting PDE-5 degradation and sustaining the vasodilation effects of cGMP. The reduction of mPAP and PVR is vital in the management of Pulmonary Arterial Hypertension (PAH).

Therapeutic indications

- Pulmonary Arterial Hypertension NYHA Class II-III and WHO Class I to improve exercise ability.

Bioavailability/pharmacokinetics

Absorption

- It has rapid absorption with about 40% bioavailability and reaching maximum plasma concentrations in approximately 30 to 120 minutes after oral administration. High-fat meals can delay absorption to 60 minutes and reduce bioavailability to 29%.

Distribution

- Sildenafil and its metabolite N-desmethyl are about 96% protein bound.

Metabolism

- Metabolized via the cytochrome P450 isoenzymes: 3A4 (major) and 2C9 (minor). The N-desmethylation of sildenafil is the active metabolite which contributes about 20% to the pharmacologic effects of phosphodiesterase-5 enzyme (PDE5) inhibition by the parent drug. Patients diagnosed with PAH have a higher ratio of metabolite to sildenafil concentrations. Sildenafil does have a minor inhibitory effect on CYP450: 1A2, 2C9, 2C19, 2D6, 2E1 AND 3A4.

Elimination

- Both the metabolite and sildenafil have a 4 hour half-life. Eighty-percent of the elimination occurs predominantly through the feces and about thirteen percent via urine.

Dosage forms

Oral

- Tablet, 20 mg
- The formulation is a round and white tablet to minimize confusion with Viagra®

Dosage range

- 20mg three times a day; taken 4 to 6 hours apart.

Known adverse effects/toxicities

	Adverse Events			
	0 – 5 %	6 – 10 %	11 – 16 %	> 16 %
Sildenafil	Insomnia, Erythema, Rhinitis, Gastritis, Sinusitis, Paresthesia	Epistaxis, Flushing, Dyspnea, Diarrhea, Myalgia, Pyrexia	dyspepsia	Headache

Special precautions

- Caution with patients on other erectile dysfunction medications.
- In patients with anatomical deformation of penis and /or patients whom are at risk of priapism should use sildenafil with caution.
- Sildenafil has not been evaluated in combination therapy.
- No dosage adjustments based on age, gender, race and renal and hepatic function are currently recommended.
- Pregnancy risk factor: B.

Drug interactions and Contraindications

- The use of nitrates and/or alpha-blockers is contraindicated due to the potential of potentiation of hypotensive effects.
- Substantial increase in AUC and Cmax of Sildenafil occurs with coadministration with ritonavir due to CYP450 3A4 inhibition.
- Epistaxis was increased with concomitant use of vitamin K antagonists.
- Inhibitors of CYP450 3A4 and 2C9 may increase bioavailability and Cmax of Sildenafil.
- Bosentan is an inducer of CYP3A4 resulting in a decrease of Sildenafil bioavailability; in turn, sildenafil is an inhibitor of 3A4 and 2C9 which increases Bosentan bioavailability.

Recommendation

The College of Pharmacy recommends coverage of Revatio® with a prior authorization for male clients. Approvals based upon the appropriate supervision and diagnosis by a pulmonary specialist or cardiologist and meeting FDA-approved indications with respect to NYHA and WHO Classification of Pulmonary Arterial Hypertension.

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APPENDIX H

30 Day Notice of Product Based Prior Authorization of Fenofibrates

Oklahoma Medicaid
August 2005

Recommendations

The following tier table is recommended as a clinically acceptable combination for use as initial therapy for the majority of clients. The College of Pharmacy recommends this list to the Drug Utilization Review board for approval and referral to the Oklahoma Healthcare Authority for supplemental rebate consideration and final approval by the OHCA Board of Directors.

Fibric Acid Derivatives	
Tier One	***Tier Two***
Lofibra®[1] 67mg Caps	Tricor®[2] 48mg Tabs
Lofibra® 134mg Caps	Tricor® 145mg Tabs
Lofibra® 200mg Caps	Antara®[3] 43mg Caps
Gefibrozil 600mg Tabs	Antara® 87mg Caps
Clofibrate 500mg Caps	Antara® 130mg Caps
	Triglide®[4] 50mg Tabs
	Triglide® 160mg Tabs

The approval criteria for a tier-2 medication are as follows:

1. Laboratory documented failure with a tier one medication after 6 months trial with a tier one medication.
2. Documented adverse effect, drug interaction, or contraindication to tier-1 products.
3. Prior stabilization on the tier-2 medication documented within the last 100 days.

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[1] Gate Pharmaceuticals. Product Literature Lofibra®. July 2003. Available online at: http://www.gatepharma.com/Lofibra/PrescribingInfo.pdf

[2] Abbott Laboratories. Product Literature Tricor®. November 2004. Available online at: http://www.rxabbott.com/pdf/tricorpi.pdf

[3] Reliant Pharmaceuticals. Product Literature Antara®. March 2005. Available online at: http://antararx.com/PI.pdf

[4] First Horizon Pharmaceutical Corporation. Product Literature Triglide®. Jamuary 2005. Available online at: http://www.fda.gov/cder/foi/label/2005/021350lbl.pdf

APPENDIX I

30 Day Notice to Prior Authorize Byetta® (exenatide)

Oklahoma Medicaid
August 2005

Manufacturer	Amylin Pharmaceuticals
Marketed by	Amylin Pharmaceuticals and Eli Lilly and Company
Classification	FDA classification: Incretin mimetic Status: prescription only

Summary

Byetta® is the first in a new class of products called incretin mimetics, which improve glycemic control in patients with type 2 diabetes. It is indicated for patients who are already receiving metformin, a sulfonylurea, or both and have suboptimal glycemic control. [1]

Recommendations

The College of Pharmacy recommends:

- Prior authorization of Byetta®
- Patients must have Type 2 diabetes and currently taking metformin, a sulfonylurea, or a combination and have not achieved adequate glycemic control.

Cost comparison

	Average Wholesale Price (AWP)	Daily Dose	Monthly Dose (30 day supply)
Byetta®			
5mcg/0.02ml (1.2ml pen)	$183.75	5mcg bid	$183.75
10mcg/0.04ml (2.4ml pen)	$215.62	10mcg bid	$215.62
Avandia®			
4mg	$3.14	daily- bid	$94.20- $188.40
8mg	$5.82	daily	$174.60
Actos®			
15mg	$4.13	daily	$123.90
30mg	$6.60	daily	$198.00
45mg	$7.16	daily	$214.80

Pharmacological data

Incretins, such as glucagon-like-peptide-1 (GLP-1), enhance glucose dependent insulin secretion and exhibit other antihyperglycemic actions following their release into the circulation from the gut. Byetta® is an incretin mimetic that mimics the enhancement of glucose dependent insulin secretions and several other antihyperglycemic actions of incretins.[1]

Byetta® improves glycemic control by reducing both fasting and post-prandial glucose concentrations through the following effects:

- Enhancement of glucose dependent insulin secretion
- Restoration of the 1st phase insulin response
- Moderation of glucagon secretion
- Reduction of food intake
- Slowing gastric emptying

Therapeutic indications

Byetta® is indicated to improve glycemic control in patients with type 2 diabetes mellitus as an adjunctive therapy to metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea, who have failed to achieve adequate glycemic control on other oral antidiabetic drugs.

Bioavailability/pharmacokinetics

Absorption

- Following subcutaneous administration (SC), Byetta® reaches median peak plasma concentrations in 2.1 hours. Mean peak concentration (C_{max}) was 211 pg/ml. Overall mean area under the curve (AUC) was 1036 pg?h/ml following SC administration of a 10mcg dose of Byetta®.

Distribution

- The mean apparent volume of distribution of Byetta® following a single dose is 28.3L.

Metabolism and Elimination

- Byetta® is predominantly eliminated by glomerular filtration with subsequent proteolytic degradation. The mean clearance of Byetta® is 9.1L/h and the mean half-life is 2.4h.

Dosage forms

Injectable

- Byetta® is supplied as a sterile solution for subcutaneous injection containing 250mcg/ml. Byetta® is available as:
    1. 5 mcg per dose, 60 dose, 1.2ml prefilled pen
    2. 10 mcg per dose, 60 doses, 2.4ml prefilled pen

Dosage range
Byetta® should be initiated at 5mcg per dose given twice daily at any time within the 60 minute period before the morning and evening meals. It should NOT be given after meals. The dose can be increased to 10mcg twice daily after 1 month of therapy

Known adverse effects/toxicities
Hypoglycemia, nausea, vomiting, diarrhea, felling jittery, dizziness, headache, dyspepsia

Special precautions
- Byetta® is NOT to be used in patients with Type 1 diabetes or for the treatment of diabetic ketoacidosis.
- The concurrent use with insulin, thiazolidinediones, D-phenylalanine derivatives, meglitanides, or alpha-glucosidase inhibitors has not been studied.
- Byetta® is NOT recommended to be used in patients with end-stage renal disease or renal impairment (Creatinine clearance< 30ml/min).
- Byetta® is not recommended in patients with severe gastrointestinal disease.

Contraindications
Byetta® is contraindicated in patients with known hypersensitivity to the product or any of its components.

Drug interactions
- Since Byetta® slows gastric emptying; it may reduce the extent and rate of absorption of orally administered drugs. Byetta® should be used with caution in patients receiving oral medications that require rapid gastrointestinal absorption.
- Oral medications that depend on threshold concentrations for efficacy, such as contraceptives and antibiotics, patients should be advised to take those drugs at least 1 hour before Byetta® injection. If such drugs are to be administered with food, they should be taken with a meal or snack when Byetta® is not administered.

REFERENCES
1. Byetta® package insert.

APPENDIX J

HORMONE REPLACEMENT THERAPY - ESTROGEN PRODUCTS
DRUG UTILIZATION REVIEW
Oklahoma Medicaid – August 2005

Introduction

- In February 2004, the estrogen-only arm of the Women's Health Initiative (WHI) being conducted by the National Institute of Health (NIH) was stopped early when evaluation of the data indicated an increased risk of stroke, but no effect on the incidence of heart disease. While it did show a decrease in hip fractures, the benefit was not shown to outweigh the risk of stroke. Other endpoints such as venous thrombosis, colorectal or total cancer, all deaths or those for a specific cause, showed no significant difference in risk. With regard to breast cancer, the effect is uncertain.
- An additional arm of the study, Women's Health Initiative Memory Study (WHIMS), evaluated the effect of estrogen-only therapy on cognitive function. In June 2004, the data revealed a slightly greater risk for developing dementia, including Alzheimer's disease, for women taking estrogen alone versus no therapy at all. It also confirmed that estrogen alone does not prevent cognitive decline.
- The first results of the WHI were published in July 2002 when the estrogen-progestin arm of the study was stopped early. Investigators determined that there is increased risk for invasive breast cancer, cardiovascular disease, stroke, pulmonary embolism, and venous thrombosis. The benefits include decreased hip fractures, endometrial cancer, and colorectal cancer. Among the other outcomes evaluated were coronary heart disease (CHD) (nonfatal myocardial infarction and CHD death), stroke, pulmonary embolism, endometrial cancer, colorectal cancer, hip fracture, and death from other causes.
- As a result of these findings, women who must take hormone replacement therapy, estrogen alone or in combination with progesterone, are advised to use the lowest possible dose for the shortest length of time.

Oklahoma Medicaid Utilization - 2003 to 2004 and 2002 to 2003

Summary Tables

Year	Claims	Units	Days	Clients	Amount Paid	$/Day	$/Unit	$/Client
2003	35,696	1,682,446	1,676,532	9,016	$1,563,526.56	$0.93	$0.93	$173.42
2004	39,950	1,843,469	1,830,593	9,539	$1,786,851.82	$0.98	$0.97	$187.32
% Change 2003 to 2004	**11.9%**	**9.5%**	**9.2%**	**5.8%**	**14.3%**	**5.4%**	**4.3%**	**13.8%**

Year	Claims	Units	Days	Clients	Amount Paid
2002	55,310	2,375,448	2,294,666	11,568	$1,765,289.24
2003	35,696	1,682,446	1,676,532	9,016	$1,563,526.56
% Change 2002 to 2003	**-35.5%**	**-29.2%**	**-26.9%**	**-22.1%**	**-11.4%**

HORMONE REPLACEMENT THERAPY - ESTROGEN PRODUCTS
DRUG UTILIZATION REVIEW
Oklahoma Medicaid – August 2005

Medicaid Utilization by Product Type – Calendar year 2004

Product Type	Claims	Units	Days	Clients	Amount Paid	Per diem
Tabs	36,177	1,814,577	1,691,917	9844	$1,629,365.04	$0.96
Patches	2714	17962	86,363	822	$107,101.99	$1.24
Gel	7	651	163	6	$617.65	$3.79
Injectable	952	5,257	48,842	519	$45,566.95	$0.93
Powder	95	4,546	3,182	31	$3,977.33	$1.25
Emulsion	5	476	126	1	$222.86	$1.77

Medicaid Utilization by Individual Products – Calendar year 2004

Drug	Claims	Units	Days	Clients	Amount Paid	Per diem**
Alora transdermal	112	982	3,721	24	$4,466.51	$1.20
Cenestin tab	1,065	57,452	54,912	351	$62,079.41	$1.13
Climara transdermal	975	4,870	31,627	289	$41,753.18	$1.32
Delestrogen injection	182	1,043	8,954	96	$21,442.22	$2.39
Depo-Estrodiol injection	770	4,214	39,888	423	$24,124.73	$0.60
Esclim transdermal	51	504	1,824	18	$2,102.04	$1.15
Estinyl tab	3	99	90	1	$107.94	$1.20
Estrace tab	19	856	726	9	$741.68	$1.02
Estraderm transdermal	330	3,272	10,677	88	$15,181.00	$1.42
Estradiol transdermal	780	3,872	23,194	263	$24,000.72	$1.03
Estradiol powder	41	1,938	1,510	18	$1,686.08	$1.12
Estradiol tabs	4,576	210,928	205,627	1180	$24,894.37	$0.12
Estrasorb emulsion	5	476	126	1	$222.86	$1.77
Estriol powder	54	2,608	1,672	13	$2,291.25	$1.37
Estrogel gel	7	651	163	6	$617.65	$3.79
Estropipate tab	1,564	72,607	70,542	350	$18,152.72	$0.25
Gynodiol tab	26	1,900	1,900	10	$751.34	$0.40
Menest tab	707	33,834	33,846	264	$21,532.65	$0.64
Ogen tab	66	3,008	2,951	27	$2,125.81	$0.72
Ortho-Est tab	5	220	220	2	$44.31	$0.20
Premarin tab	28,146	1,433,672	1,321,103	7650	$1,498,934.81	$1.13
Vivelle transdermal	107	1,022	3,581	34	$4,283.25	$1.20
Vivelle-Dot transdermal	359	3,440	11,739	106	$15,315.29	$1.30
TOTALS	**39,950**	**1,843,469**	**1,830,593**	**9,539** *	**$1,786,851.82**	**$0.98**

* Total unduplicated recipients.
** Average of all strengths

HORMONE REPLACEMENT THERAPY - ESTROGEN PRODUCTS
DRUG UTILIZATION REVIEW
Oklahoma Medicaid – August 2005

Client Demographics - 2004

Age	Female	Male	Total
0 to 9	6	0	6
10 to 19	90	7	97
20 to 34	716	4	720
35 to 49	2446	12	2458
50 to 64	3065	20	3085
65 to 79	2301	27	2328
80 to 94	798	23	821
95 and over	24	0	24
FY 04 Total	**9446**	**93**	**9539**

Estrogen Patches - Quantity Limits – Effective 6/2004

Drug	Quantity Limits	Comments
Alora patches	8 patches per 28 days	Twice weekly
Climara patches	4 patches per 28 days	Once weekly
Combi-patch	8 patches per 28 days	Twice weekly
Esclim patches	8 patches per 28 days	Twice weekly
Estraderm patches	8 patches per 28 days	Twice weekly
Fempatch patches	4 patches per 28 days	Once weekly
Vivelle/Vivelle DOT patches	8 patches per 28 days	Twice weekly

Discussion:

- The number of clients decreased in 2002 when the results of the WHI studies were made available.
- The number of clients increased in 2004 as a result of the shift from HMO to FFS.
- Effective 6/2004, transdermal patch products became subject to Quantity Limits.
- Black Box Warning on all Estrogen and estrogen-containing products following WHI study results.

Recommendations:

The College of Pharmacy recommends the following action.

- Continue to monitor this class of drugs.

APPENDIX K

FDA News

FOR IMMEDIATE RELEASE
P05-42
July 13, 2005

Media Inquiries:
Suzanne Treviño, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Asks Purdue Pharma to Withdraw Palladone for Safety Reasons

After acquiring new information that serious and potentially fatal adverse reactions can occur when Palladone (hydromorphone hydrochloride) extended release capsules are taken together with alcohol, the U.S. Food and Drug Administration has asked Purdue Pharma L.P., the makers of the drug, to withdraw it from the market.

Palladone is a once-a-day pain management drug containing a very potent narcotic. New data gathered from a company-sponsored study testing the potential effects of alcohol use shows that when Palladone is taken with alcohol the extended release mechanism is harmed which can lead to dose-dumping. Dose-dumping is a term that describes the rapid release of the active ingredient from an extended release product into the blood stream. The consequences of dose dumping at the lowest marketed dose (12 mg.) of Palladone could lead to serious, or even fatal, adverse events in some patients and the risk is even greater for the higher strengths of the product. As a result of this potential serious safety risk, the FDA has asked Purdue Pharma, and they have agreed, to suspend all sales and marketing of Palladone in the U.S. pending further discussions with the agency.

"All powerful pain management drugs have serious risks if used incorrectly, but the current formulation of Palladone presents an unacceptably high level of patient risk" said Dr. Steven Galson, FDA Acting Director of the Center for Drug Evaluation and Research. "Although we have not received reports of serious problems, this product has so far been used in a relatively small number of patients. We are concerned that as more patients take this drug, safety problems will arise since even having one alcoholic drink could have fatal implications."

The current labeling for Palladone, approved in September, 2004, already includes the standard opioid warning against the use of alcohol and Palladone. However, the FDA does not believe that the risk of serious, and potentially fatal, adverse events can be effectively managed by label warnings alone and a risk management plan.

Patients currently taking Palladone should consult with their physicians for alternative treatments. For additional information, please go to: http://www.fda.gov/cder/drug/infopage/palladone/default.htm

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FDA Statement

FOR IMMEDIATE RELEASE
Statement
July 15, 2005

Media Inquiries:
Laura Alvey, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Issues Public Health Advisory on the Fentanyl Patch

The FDA today issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches in response to reports of deaths in patients using this potent narcotic medication for pain management. In addition, a patient information sheet and an alert to healthcare professionals were issued identifying several important safety precautions for the use of fentanyl transdermal patches. These safety precautions include but are not limited to patient education regarding signs of overdose, proper patch application, use of other medications while using the patch, safeguards for children, and proper storage and disposal.

The FDA is conducting an investigation into the deaths associated with these patches. The Agency has been examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch or factors related to the quality of the product. It is possible that some patients and their health care providers may not be completely aware of the dangers of these potent narcotic drug products and the important recommendations regarding their safe use.

The Agency is working closely with the manufacturers of fentanyl patches to fully evaluate the risks associated with their use and to develop a plan to help patients avoid accidental fentanyl overdose.

For more information, go to: http://www.fda.gov/cder/drug/infopage/fentanyl/default.htm.

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FDA News

FOR IMMEDIATE RELEASE
P05-51
July 29, 2005

Media Inquiries:
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Consumer Inquiries:
888-INFO-FDA

FDA Alerts U.S. Residents to Recall of Counterfeit "Lipitor" Sold in the United Kingdom

The Food and Drug Administration (FDA) is alerting U.S. residents to the recent recall of a batch of counterfeit "Lipitor" (atorvastatin) sold in the United Kingdom (U.K.). The medicine is used to treat high cholesterol. The counterfeit Lipitor 20mg tablets were recalled in the U.K. on July 28, 2005. Health authorities in the U.K. stated that initial results of tests performed on the counterfeit drugs do not indicate that this product poses an immediate risk to patients, however, they are advising that patients stop taking the drug and return it to the pharmacy where they obtained it. U.K. pharmacies are being advised to return all remaining stock of this batch to Pfizer Ltd., the manufacturer of Lipitor.

Consumers who purchased FDA-approved Lipitor products through legitimate U.S. pharmacies should not have received any of these counterfeit tablets and are not subject to this recall. But some U.S. residents may have obtained prescription drugs from the U.K. through on-line or storefront operations that do not supply legitimate, FDA-approved products, or through state-run drug importation programs that facilitate the purchase of unapproved foreign drugs. Consumers who purchase drugs through these arrangements may have received these counterfeit products.

"Americans need to be very careful when buying drugs outside of the U.S. drug distribution system," said FDA Commissioner Lester M. Crawford. "The American drug supply system is in fact a very safe one that consumers can count on."

The affected product is 20 mg. "Lipitor" and is sold in packages of 28 tablets. The drug packages are marked with batch number 004405K1 and an expiration date of "11 2007." The batch number can be found on the end of the box next to the expiration date and on the foil backing of the drug's blister pack. Legitimate U.K. Lipitor also has this same batch number.

Because the recalled Lipitor is fake, there is no guarantee of its quality or effectiveness. U.S. patients who have the identified U.K. drugs should stop using them and should consult their physician or pharmacist if they have any questions or concerns. Patients should resume treatment as soon as they can obtain from their doctors or pharmacists a legitimate supply of Lipitor or an equivalent medicine. When patients resume taking the drug, they should take only the daily dose prescribed and not try to make up for missed doses.

Lipitor belongs to a class of drugs known as "statins". In addition to Lipitor, a number of low-cost FDA-approved generic versions of these drugs are available to consumers. Consumers interested in these options should discuss them with their physicians.

Information on Pfizer's recall of the one batch of Lipitor can be accessed from the following links:

http://www.mhra.gov.uk/news/press_Lipitor_280705.pdf

http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/defmedsrepcen/Lipitor_EL_05_A11Final.pdf

For additional consumer information on counterfeit drugs, visit the following web sites:
FDA Consumer Education for Counterfeit Medicine

www.fda.gov/cder/consumerinfo/counterfeit_text.htm

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