Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

Wednesday

July 11, 2007

@ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Gorman, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – July 11, 2007**

DATE: July 3, 2007

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

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

Call to Order

Public Comment Forum

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

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

Action Item – Vote to Prior Authorize Ophthalmic Glaucoma Products – **See Appendix C.**

Action Item – Vote to Prior Authorize Tovalt™ ODT – **See Appendix D.**

30 Day Notice to Prior Authorize Brovana™ **– See Appendix E.**

30 Day Notice to Prior Authorize Exforge® – **See Appendix F.**

30 Day Notice to Prior Authorize Ophthalmic Anti-Infectives **– See Appendix G.**

30 Day Notice to Prior Authorize Omnaris™ and Veramist™ – **See Appendix H.**

Utilization Review of Erythropoiesis Stimulating Agents – **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – July 11, 2007 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. McNeill, Chairman:

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

A. June 13, 2007 DUR Minutes – Vote
B. June 18, 2007 DUR Recommendations Memorandum

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

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

A. Retrospective Drug Utilization Review for March 2007
B. Retrospective Drug Utilization Review Response for October 2006
C. Medication Coverage Activity Audit for June 2007
D. Help Desk Activity Audit for June 2007

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

5. Action Item – Vote to Prior Authorize Ophthalmic Glaucoma Products – See Appendix C.

A. COP Recommendations
B. PA Criteria

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

6. Action Item – Vote to Prior Authorize Tovalt™ ODT – See Appendix D.

A. Product Summary
B. COP Recommendations

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

7. 30 Day Notice to Prior Authorize Brovana™ – See Appendix E.

A. Product Summary
B. Place in Therapy
C. COP Recommendations

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

8. 30 Day Notice to Prior Authorize Exforge® – See Appendix F.

A. Product Summary
B. COP Recommendations

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

9. 30 Day Notice to Prior Authorize Ophthalmic Anti-Infectives – See Appendix G.

A. Introduction
B. COP Recommendations

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

10. 30 Day Notice to Prior Authorize Omnaris™ and Veramist™ – See Appendix H.

A. Product Summary
B. COP Recommendations

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

11. Utilization Review of Erythropoiesis Stimulating Agents – See Appendix I.

A. Background
B. Utilization Review

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Utilization Review of Narcotics
B. Utilization Review of Antifungals
C. Annual Reviews
D. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JUNE 13, 2007

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

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

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

OTHERS PRESENT:

Michael Mason, Alcon	Aliza Tomlinson, OMJ	Walter Seratin, MGI Pharma
Toby Thompson, Pfizer	Rebecca King, Tavo	Valerie Pennington, Novartis
Bobby White, UCB	Lance Stewart, Merck	Jim Dunlap, Eli Lilly
Joseph Medina, Sepracor	Chaney Horn, Alcon	Pat Traham, Tavo
Vince Morrison, Forest	Valerie Pennington, Novartis	Jim Fowler, Astra Zeneca
James McAdams, Daiichi Sankyo	Holly Jaques, Merck	

PRESENT FOR PUBLIC COMMENT:

Justin Springfield, Sepracor	Agenda Item No. 7
Lucas Trigler, Dean McGee/for Alcon	Agenda Item No. 9

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

1A: Roll Call

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

ACTION: NONE REQUIRED.

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

Dr. McNeill acknowledged speakers for Public Comment.

ACTION: NONE REQUIRED.

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

3A: May 9, 2007 DUR Minutes

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

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: January 2007

4B: Retrospective Drug Utilization Review Report: February 2007

4C: Medication Coverage Activity Report: May 2007

4D: Help Desk Activity Report: May 2007

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

ACTION: NONE REQUIRED.

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

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE AMRIX® AND FEXMID™**

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **VOTE ON CHANGES TO XOPENEX® PRIOR AUTHORIZATION**

For Public Comment, Justin Springfield: Hello, good to see everyone again. It's been awhile since we last spoke and as you know, I'm Justin Springfield, an account rep with Sepracor Pharmaceuticals. Here tonight to talk for a couple of comments in support of the current PA criteria, the 90-day PA criteria for Xopenex. I believe for the most part that most of you (unintelligible) product of spirited debate and in 2004 I witnessed this committee and a lot of members which still sit in the room today, wrestle with the various issues surrounding trying to put a PA on a rescue medication that's used in an acute emergency situation. And together this committee collaborated with the Oklahoma OU School of Pharmacy and came up with a 90-day PA criteria that in my job, I've traveled most of the country, and I've seen this criteria replicated in other Medicaid states. I've seen it imitated in HMO organizations across the country, and you know imitation is really the sincerest form of flattery and the current PA criteria makes so much sense because it controls utilization, it protects the patient and it's good policy. The evidence of controlled utilization is in your claims data. The average patient only gets 2.1 prescriptions per year. So we're talking about a drug that a patient's only going to get two prescriptions per year and you guys actually allow three months' worth of the drug, so the patient could get three prescriptions per year if they wanted to, but the average number of prescriptions per year is 2.1. That tells me that the patient's not abusing their bronchodilator, they're not using it in place of their controller medication and in order to get any medicine beyond the three months, the patient has to be documented and is taking their controller medication, being managed appropriately. And I say it protects the patient because it almost assures that the patient will never leave the pharmacy without their rescue medication. It would never be in a situation in a rural state like Oklahoma where most patients do not live close to a hospital. If you go to get a prescription filled at night or on the weekend when the PA lines are closed, it insures that that patient is at least going to be able to get a prescription and go home and get themselves through the weekend because, again, the average number of prescriptions is only 2.1 per year, and you guys allow

three prescriptions per year. So I think we've all, you know, based on the last conversation we've had about this thing, we can all agree that the emergency 72-hour supply law is not a viable avenue to protect patients. And my third point about being good policy. It's good public policy. The asthma patient population is an at risk patient population. These patients are disproportionally minority; they're economically and educationally disadvantaged. So it's good policy when you say we're going to make sure that you at least have access to a medication if you use it in an acute situation. And in the case of a pediatric patient, a little human, in the outpatient department, there are only two widely prescribed drugs for a pediatric patient to use on an outpatient setting to save their life when they're in the middle of an asthma exacerbation. Xopenex is one of those drugs. I would ask this committee to, I mean if it's not broke, don't fix it. I don't think anyone ever said the current policy was broken. It's great policy, it controls utilization and it protects the patient. So I would ask you to vote no on the recommended changes and keep current policy, which is good policy. It was the result of a great collaboration of the OU School of Pharmacy and this committee. Thank you for your time and attention, and I'd be honored to entertain any questions.

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

Dr. Kuhls: First of all ..... I don't know where to start. First of all let's look at this since you have it up. So you're telling me that the State of Oklahoma just by nebulization alone, right?, spent $2.2 million on Xopenex in 2006? If there was no Xopenex, OK, absolutely none, and everything was just albuterol, regular albuterol, OK, how much is the cost of albuterol? And the nebulizations?

Dr. Gorman: The per diem was over a dollar, a couple of bucks, I think.

Dr. Kuhls: So we're talking about $2 per day for 2006, right?

Dr. Flannigan: Correct, roughly.

Dr. Kuhls: So we're talking about probably a third of that, right? So that's $700,000 a year, right? So what you're telling me is that there's about $1.4 million of taxpayers' money being used because of Xopenex compared to if everybody just used albuterol.

Dr. Flannigan: That would be correct if there was no Xopenex.

Dr. Kuhls: I just want to get those numbers straight.

Dr. Flannigan: I see where your logic is coming from.

Dr. Kuhls: Second of all, my second question is these recommendations are different than last time's, isn't that correct?

Dr. Flannigan: Correct.

Dr. Kuhls: Why were there changes, what were the, can you review for me what the recommendations were the last time?

Dr. Flannigan: The recommendations last time were a part of PA period with the same, one and two were saying there was a clause in there that said if it was prescribed by an asthma allergy specialist or pulmonologist, they would get the automatic approval.

Dr. Kuhls: So my question is why did we, why did we change, why the College changed their recommendations to the newer 30-day limit.

Dr. Flannigan: The discussion around the table was rather in favor of something not quite that hard, that stringent.

Dr. Kuhls: Because I remember the discussion, maybe I'm wrong, so you guys can chime in, but I remember the discussion, there was a lot of talk that the scientific data shows that there's really no increased efficacy and the change in the discussion was what happens to the patient in an emergency , who gets a Xopenex script, right?, goes to the pharmacy and then told it's PA'd, go home without a script and then they get sicker, right? So tell me how your new recommendation differs in the patient who's had, say, one prescription for Xopenex filled already this year. They go in for the second, they're still going to go ahead and go home without a script the second time, right?

Dr. Knisely: Is the 30 days concurrent? Or, so what he said, someone bumps up against a 30-day, it'll kick out?

Dr. Flannigan: They've had one filled for 14 days previously and you come back and include it for another 14 days, they're good.

Dr. Graham: The discussion was on the emergency.

Dr. Kuhls: I understand but I'm just, my problem is that I think we're all concerned about that, but I'm not so sure that fixes the problem, except for somebody who's never had Xopenex for a whole year and then they come in their first time, then they don't get PA'd and they are sent home, but systems wise the new recommendations in my mind don't fix the patient who's already had one and comes in for a refill.

Dr. Flannigan: So what would then, in your professional opinion as a physician, be something that would be helpful? Because the 90-day you thought was a little too loosey-goosey, a little too 'give 'em too much'. I'm trying to find a balance.

Dr. Kuhls: I'm sure and I'm not sure there's a, I'm not sure, I believe that the original recommendations are such, okay, that they're just as good as these recommendations and if I'm measuring the numbers right, you're going to save approximately $500,000 here when you should be possibly saving a million dollars a year, which to me is big dollars. Correct?

Dr. McNeill: I think if I'm not mistaken, where you're, what I'm understanding you say is that you have to have a mechanism when they leave the ER to be able to get the meds. What you're looking to prevent is maintenance on Xopenex for a fourth of the year. That 30-day, maintenance doesn't address emergency rescue like Mr. Springfield was talking about. It ...

Dr. Kuhls: That's my whole point.

Dr. McNeill: Yeah, exactly.

Dr. Kuhls: It doesn't fix the problem.

Dr. McNeill: The only thing the 30-days does is to prevent you from using it as a maintenance med rather than a true rescue med.

Dr. Kuhls: Exactly. So if we had the initial criteria, right?, of PA'ing everything except for giving one dose out or two doses out, and then PA'ing it from then, that would take care of the emergency situation, because you would automatically be able to

dispense I don't care how many albuterol, or how many Xopenex things, but you only give a day's, why can't you just give a day's therapy and PA it on Monday?
Dr. Feightner: What about multiple visits to the ER? What if they .....
Dr. Kuhls: I'm not talking about, let's just talk about the nebulizations first, because that's where your big dollars are. OK? And I think, I'm glad you separated these out because how much does a pro-air HFA cost? We'll get to that. That was one of my other questions. But I'm just dealing with where the big dollars are of $2.2 million, OK?, to begin with, alright? Why can't we have everything being PA'd but we give out a day's worth of rescue medication when a Xopenex script is written and then it's PA'd down the line?
Dr. Flannigan: What would we do on the next day? The system right now, the computer system, does not allow for such unless you use the emergency PA, which then allows for three days' supply. The computer, the point-of-sale system is not able to distinguish just because you put in one inhaler for a one day supply that would also go to quantity limit. There's no way the computer can do .....
(unintelligible, multiple speakers)
Dr. Kuhls: Do three days, give them out three days but I don't think this 30-day, you do a 3-day and then it's a PA. Because the next doctor will get the message that the next time he's going to have to prescribe albuterol.
Dr. Nesser: Maybe he's going to get the message. He's in the ER .....
Dr. Bell: But you know, we're putting up, OK we've got people who are spending $3.50 a gallon on gas and we're setting, it's getting more and more complicated .... you know. These are people we don't, there's just so many roadblocks you need to put up.
Dr. Nesser: Right.
Dr. Kuhls: But this is a drug that when you look at all the studies, OK?, there's no better effectiveness. That was shown the last time when we went through all the studies. And a drug that cost three times, OK?, as much. And in, I would guess, less than 10%, you guys can use the number 20%, I don't care what it is. But almost all patients, kids tolerate the albuterol very well. I don't personally use any of Xopenex. I don't have any patients on Xopenex because all my asthmatics are taking albuterol and do fine. So that there are some patients out there, granted, and those can be PA'd, but why is the taxpayer, this is $2.2 million when it should be $700,000. Talking about $1.4 million and $1.4 million buys a lot of gas at $3.50 a gallon.
Dr. Feightner: My only question is what, on the 3-day rule, OK, they get Xopenex, they go to the ER, OK? Come out, OK, go to doctor whatever, and then they get a maintenance of albuterol. Then they go back in the ER two months later, get another prescription for Xopenex. The ER doc writes for Xopenex. Come to the pharmacy, get another 3-day? Do they get another 3-day emergency? Yes or no? Currently the way it's set, currently the way it's set up today, do they get the 3-day emergency. I think, to me that sounds good. To allow the 3-day.
Dr. Knisely: Do all pharmacists, are they cognizant and able to do the emergency thing? I mean, I know that's probably extra paperwork or extra hassle for them. Do you find that they need to do it, or they can do it if they need to do it in a situation like this?
Dr. Gorman: It's a phone call, that one is simple. Just a phone call
Dr. Feightner: Help Desk being called, I don't there's visibility of this rule out there. I really don't. I don't think there's enough visibility and if this goes passed, we need to give visibility to the pharmacies that this is .....
Dr. Kuhls: Huge amount of information to emergency room doctors that albuterol is the preferred drug, to all the physicians that, I mean we're going to need a whole lot .....
Dr. Nesser: Uh-huh .... a lot of education.
Dr. Flannigan: They're going to do a mailout too to prescribers that say "did you know"
Dr. Gorman: There is one...when DUR-plus comes on board in a couple of months, it could be set to do a 3-day supply as long as they haven't had any in the last 30 days, and that would be an automatic process, wouldn't require any phone calls or .....
Dr. McNeill: But that's not good enough.
Dr. Feightner: I don't like that idea. If they have a script for Xopenex we don't, a rescue script, we're wanting to convert from Xopenex to albuterol. The conversion is what we're after, to get that person off the Xopenex to albuterol. That's essentially what we're after.
Dr. Gorman: It would sort of be the same as emergency only there wouldn't be any phone call and they couldn't get any more for 27 more days, so some call would have to happen to get something for the rest of the month. Now if they're just needing a 3-day supply and they're fine, then they could get that every month theoretically, so .....
Dr. Kuhls: Well, then they need a phone call.
Dr. Graham: That gives you a false sense of being able to get it too, unless that's communicated to that patient sometimes.
Dr. Kuhls: Yeah, but doctors ..... the ER is a different group, a different breed, OK? And that's going to have to be thought out but the regular doctor's going to get tired of writing the scripts over and over and over again. That's going to get fixed for mostly clinicians. The ER ..... just going to keep on writing and writing and writing, and that is going to have to be fixed.
Dr. Knisely: When you guys mail, I mean mail out something to physicians, because the ER docs, like you said, you know, are they even going to be on those lists? A lot of times they're not. Because they float from place to place and they work for the agencies .....
Dr. Kuhls: Each hospital, yeah, you have to send it, ER specifically.
Dr. Flannigan: We would send it ... well a lot of times if the ER physician, they have their name on it, so they actually get attached to the prescription, their prescriber ID, so we'd send it not only to that, but also to the facility so that way the nurse practitioners and PAs could also be educated.
Dr. Knisely: What's the clinical exception made for members with COPD? Is that handled through the prior auth or how is that handled?

Dr. Flannigan: That's handled through the prior auth. When they submit their prior authorization they note that they're COPD just because the GOLD guidelines do allow around-the-clock for short acting. And now if it was in the population where they felt that there were adverse effects of accumulation of S-levalbuterol they would be the ones that would see it. And we don't have a lot of COPD.
Dr. Knisely: I wouldn't think you do, lost most of those, yeah.
Dr. Feightner: We will make efforts to send out educational materials to the pharmacies about the 3-day with this when it's, when it's .....?
Dr. Flannigan: Pharmacies and prescribers.
Dr. Feightner: Pharmacies, what typically happens is they're going to say in the majority of the cases, we can't fill this, it requires prior authorization, we need to do paperwork. And that happens a lot of them and the patients are OK and they walk out the door. That's what we want to prevent. So education needs to go on there to the pharmacies.
Dr. Muchmore: Are you recommending that we change this to a hard PA with no 30-day supply because the 3-day ....
Dr. Kuhls: Hard, hard, hard PA with a 3-day emergency. You can always get three days' emergency meds no matter what ....
Dr. Muchmore: Do I understand correctly that this is dispensed in unit dose packs? Is that what this means?
Dr. Feightner: Two different ways. A box or a metered dose inhaler.
Dr. Muchmore: When it says HFA inhaler, it's separate.
(unintelligible, multiple speakers)
Dr. Muchmore: But the pharmacist can dispense just certain number of units of .....
Dr. Feightner: It kind of depends on the pharmacy I think, they would either dispense ..... what do you guys .....
(unintelligible, multiple speakers)
Dr. Muchmore: What's in a box?
Dr. Gorman: The official 3-day emergency would unless they wanted to do the other .....
(unintelligible, multiple speakers)
Dr. Graham: How long have you been giving out stuff that you don't know whether you're going to get paid on it?
Dr. Meece: Forever.
Dr. Graham: That's what I'm saying, Most pharmacists do that and I know you do it too, so it goes on all the time. It's not anything unusual; however I do think there needs to be a precedent set that it will be paid if it is in that vein, you know where it's an emergency dispense.
Dr. Muchmore: A box of 24 would be more than a 3-day supply, so that's .....
(unintelligible, multiple speakers)
Dr. Kuhls: I think what's going to happen is that the ER is going to continue to be a problem, but doctors aren't going continue to write scripts after scripts after scripts. A lot of this stuff is two to three claims and this is going to be cutting down chronic .... if we get this...educated the physician side to pharmacy side I think that we're going to do OK with this.
Dr. Knisely: Xopenex is being used more and more in the hospitals. That's becoming more, you know on the brain. Well the hospitals that I am associated with, I'm seeing more and more Xopenex use, so that's what they're kind of, you know, the mindset, that this is what we're going to write for.
Dr. Muchmore: Not at my hospital.
Dr. Knisely: At Saints it is.
Dr. Kuhls: Yeah but Xopenex isn't even on the formulary at Norman. A lot of hospitals it is.
Dr. Muchmore: There are a lot of very prestigious institutions and asthma clinics that use none.
Dr. Kuhls: Can we switch then and talk about nebulization, do you just want to just do nebulization separately, or do you want to switch to .....
Dr. McNeill: Do you want to keep them combined in one ..... well, let's switch them out. Let's switch them out.
Dr. Kuhls: In HFA, you are negotiating ..... what does that mean?
Dr. Nesser: That means there's an offer on the table that we are considering.
Dr. Kuhls: So that would make all this moot to talk about?
Dr. Gorman: But you should probably decide on how you want it, should that no longer be the case.
Dr. Kuhls: Well I think we need to be hard then on that.
Dr. Feightner: So all PA's then, they can still use the 3-day emergency?
Dr. Muchmore: Now are we going to define a 3-day as 12 packets? Twelve units?
Dr. Bell: Yes, we're not going to do full boxes out.
(unintelligible, multiple speakers)
Dr. Feightner: How much money is it going to cost us to give the extra twelve? Really?
Dr. McNeill: It would probably cost you more to deal with half of box, or a third of a box than a box. I've never written a prescription for albuterol nebulizer and noted half a box.
Dr. McNeill: I don't agree with the half box.
Dr. Kuhls: Well but the point is that if you don't use the half box, you're really not given three days. And if you're not given three days, when anybody writes a script you're going to be giving them three days' worth, OK? And then the next time, three days, and then, so you're going to get as many boxes as you want if you don't just get three days' worth. You see what I'm saying?
Dr. Feightner: One more time.
Dr. Kuhls: With a 3-day emergency, you get three days' worth and that's it, so somebody's got to write a new script for maintenance. But if you have a 3-day emergency you'll give three days' worth, after those three days the next time it's written, it's only three days, so you have to keep writing scripts. But this way if you give a whole box, you've given a number of other

days that they can be used till the end and write another three days, so you're really not PA'ing it at all if you're giving more than three days' emergency therapy, because you've got a whole box left over to keep on using maintenance.
Dr. Feightner: If you give a box, you give one box, it's actually a 6-day therapy, they have essentially six days to contact their physician or go and see the primary care physician to get regular albuterol.
Dr. Kuhls: Then at day seven, the way the system's going to be is if they just write another Xopenex script, it will keep on doing that. Not the way it's set up?
Dr. Feightner: They could do another emergency, is that correct?
Dr. Flannigan: They could call and try get another emergency, but we would probably look in their history and go you've just had one three days ago, six days ago.
Dr. Kuhls: Well if you have a way not to do that and get six days and it's easier for everybody, I don't have a problem with that, but that's got to be monitored because that could be abused very quickly. If you have a way where you can stop that emergency-wise, that's probably OK then. To make you guys happier, but at the same time you have to be real careful with your emergency people looking up things and making sure that it's real.
(unintelligible, multiple speakers)
Dr. McNeill: OK, let me throw out one more thing here, another thing. I agree with what you guys are saying, but in listening to Dr. Bell's comments earlier, if the two physicians that cover the ER in Grove write Xopenex, and I don't know who the physicians are in Grove and don't go back to them and say, hey McNeill said bad things about you, but if they are Xopenex writers, are we going to be able to reach them so that if physician A prescribes Xopenex on day one, the kid comes back two weeks later to the ER, using the ER as a primary care clinic, and physician B writes another script for Xopenex, are they going to be able to get Xopenex if they indeed need a rescue and it's Saturday night at 11:00?
Dr. Feightner: Yes.
Mr. Springfield: No. They'll hand it to the tech. The tech won't know about the emergency 72-hour supply law .....
Dr. Feightner: That's where the education comes in. That's where we have to educate the pharmacists.
Dr. Bell: But that was my concern last time, is they never see a pharmacist. You see a tech.
Dr. Meece: I think most of my emergency room doctors, there's such a rotation of them in Sallisaw that if I just sent it back and said hey, they can't have Xopenex or if I just call them, they'd ..... just because they write Xopenex because they've heard about it and maybe they've written it somewhere else in another emergency room ..... they're pretty freewheeling.
Dr. Knisely: Yeah, but you're going to make the call. I'm concerned about the busy people that don't make the call and it .....
Dr. Feightner: What about messaging? Can we message back when we transmit?
Dr. Nesser: I don't know the answer to that question. I don't think we can message very specifically, and even if we can, I don't know which systems receive those messages because we send out a lot of messages now that nobody ever sees, so you can't give a flat answer on .....
Dr. Feightner: Can we look at that? I think that's a big communication tool. Because that's the way a lot of the PBMs communicate to pharmacies today and explain, that's right in front of your face, you know, as soon as the transmission's done, it's right on your brain. It's right there. The messaging is, to me is a huge part of the communication that needs to go one. And the education that needs to go on. So if you send a claim for Xopenex, it comes back and says you know, denied, you know, 3-day therapy excepted. PBMs do this all the time. Current PBMs do this. And send it back, you can get a 3-day therapy, PCS does it. You know, you get a "X-day" number of therapy, resubmit using override code blah-blah-blah-blah-blah for your 3-day therapy. That goes on today. But that messaging I think is critical to let the pharmacy tech know, the tech know that there is a way to get this medicine with a 3-day override.
Dr. Graham: Is that message, do the techs pick up on that or do they follow up?
Dr. Feightner: Yes, they do. Oh yeah, because it comes back. There's two different types. There's foreground and background processing. Systems that have foreground processing see the transmission as it comes back. You see that. Background processing, it just rejects it and they have to go look at it. There's two different systems out there. But I feel the majority are on foreground and they see it when it comes back and they look up, they can look up the details and see what was wrong and see what to do. And you put like a code in there of prior authorization number, 9999 or 7777 or whatever you want to come up with and that allows the three, that prevents the call, don't have to make a phone call, OK, and it goes through, and you guys know it's a 3-day therapy. The claim goes through and the education can then go to the customer, OK, you know, we can only give you one box even though your doctor wrote for seven boxes, you know. Why'd I only get one box? You can only get one box because you need to contact your primary care physician.
Dr. Meece: So will that message come back at 11:00 at night?
Dr. Feightner: Yes. That's the nice thing is that the Help Desk doesn't have to be there.
(unintelligible, multiple speakers)
Dr. Feightner: The majority of pharmacies, the techs handle a lot of billing. They handle all the billing issues and input. I think we need to look into messaging.
Dr. Muchmore: Do we have a mechanism in place when we see somebody writing a lot of whatever prescription for getting back to them and saying, you know this is a PA medicine. You can't just write it on Saturday night.
Dr. Nesser: We don't have a mechanism like that. I think that this is maybe a good place to start.
Dr. Muchmore: This is a $2 million reason to think about that.
Dr. Feightner: Can we explore that?
Dr. Nesser: Yeah, we can look at it. We can send the messages. My concern is that the stores that are open until 11:00 on Saturday night, without naming any names, are the systems that don't see those messages.
Dr. Muchmore: You mean their system doesn't show it to them or they look at them?

Dr. Nesser: Both. The system doesn't make it obvious like you know, flashing red, here's what you do to fix this. I mean, even when it comes back it just says "rejected". It doesn't give all the background messaging that we send back that says you know, whatever the problem is.
Dr. Feightner: Most pharmacies now, NCPDP 5.1 compliant and that allows for transmission of messages as far as from what I can remember. Allows for transmission of messages to the pharmacies. If we transmit it, it's there. I think anything we can do to improve education to the pharmacies and to get them to buy off on a 3-day if they need it, needs to be done. If only 30% of the pharmacies get it, I still think it's worth doing, because I don't know what the cost is to you guys, I would expect it to be minimal but I don't know the cost .....
Dr. Nesser: Oh, to send a message back? Yeah, it's, that's just part of the transaction.
Dr. Meece: Everything it rejects sends a message back.
Dr. Nesser: Right, right. And it sends more than just rejected. It shows some other stuff but that's the thing. They only show just the main .....
Dr. Muchmore: Can they drill down and see why if they want to?
Dr. Nesser: Some systems can. All theoretically should, but it's whether they've been trained or not.
Dr. Feightner: Yeah, foreground and background processing. Foreground, you send it and you can't move onto the next one until that one's done. Background processing, you send it and then it goes away and then the next one comes up, but it's still working in the back. See it still works in the back sending the claim. Background processing a little bit more efficient, you know, I guess that way, but foreground .....
Dr. Bell: Are we going to solve this tonight?
Dr. McNeill: I think Dr. Kuhls has a solution?
Dr. Kuhls: My recommendation is remove the 30 days to make this a hard PA with the emergency PA available and one box, and nebulizers send out one inhaler but there has to be observation that if you start seeing people using a lot a lot it just means they're not doing very well, good therapy anyways. So I'd kind of go back to where you were. I think your initial ideas were better.
Dr. Muchmore: I have one question. On this HFA inhaler it says 30 units. I don't quite understand. I thought it was a metered dose inhaler.
Dr. Flannigan: Unit in this case is a gram, one inhaler is 15 grams.
Dr. Feightner: Most inhalers are 200. Is HFA 200? Two hundred inhalations? I knew albuterol is, I hadn't looked at HFA. Two hundred inhalations per metered dose inhaler.
Dr. Muchmore: So you're going to dispense one of those?
Dr. Feightner: If they write for metered dose inhaler it would be 200 units. It would be 200 doses. They're filled on grams of the liquid.
Dr. Muchmore: I didn't understand that 30 units.
Dr. Feightner: One inhaler instead .....
Dr. Flannigan: One inhaler for emergencies, that quantity is for two inhalers for those people, we do have a COPD patient that is using it around the clock. They could in theory in a 30-day time span need two inhalers, otherwise one inhaler for 25 days.
Dr. Muchmore: Dispense two inhalers? Oh, oh if they say take it qid, you'd only give 15 units.
Dr. Graham: (repeating motion) Hard PA went from 30 days. We also have twelve, on nebulizers, 12 units or one box and then a one box on the HFA inhaler, and work on system changes.
Dr. Nesser: Yeah, it's not going to be implemented, I'll tell you that, until we get the system, because this is too dangerous to our patients until we get ..... to leave them out in the cold basically with a hard PA without a lot of education to physicians and pharmacists, I'm not, I'm not doing that to these kids. But I mean, we'll work on getting there but it's not going to be next month or .....
Dr. Kuhls: When were you talking timetable?
Dr. Nesser: I don't know, because I've got to check on systems issues, we've got to get education, we've got to see who is writing these scripts and get them educated right away to know that they're not going to get filled, the 3-day thing is problematic, the 3-day emergency PA is problematic. We have some other ways around that but you all were not interested in us doing that, and so I'm very concerned about just what I've stated. That I know that there are, that we send messages and they're not received now. So I know that because of calls that we get back in. So just because the message goes out doesn't mean it's received, so .....
Dr. Kuhls: Well it's kind of amazing to me that other PBMs .....
Dr. Nesser: Other PBMs don't have people below poverty line with no education .... yeah. I mean if my PBM wants to do it, that's fine.
Dr. Kuhls: Well for $1.4 dollars you should be hiring so many people to try to figure out your systems problems so quick . . . to start to getting your education down .....
Dr. Nesser: It's not just our systems problems. It's the systems on the other end. I can't hire people to fix their system.
Dr. Kuhls: Well there's a lot of places, a lot of PBMs that don't have Xopenex as first tier.
Dr. Nesser: Right. And those people have money to buy Xopenex. Our clients don't have the option of buying Xopenex or paying the third tier copay .....
Dr. Kuhls: No, they use albuterol because it's first tier in their system.
Dr. McNeill: The big issue is the 3-day. That's got to get out to pharmacies .....
Dr. Nesser: Right. There's a lot of education.
Dr. McNeill: Don't worry about the computer system, it's, telephone is just ..... you've got three days. You'll get paid for this.
Dr. Nesser: Three days.

Dr. Muchmore: Actually, one HFA is a month.
Dr. Feightner: The computer system I think is essential. I think it's essential. That's your communication tool.
Dr. McNeill: Well yeah, it is, but I mean, you know, first you've got to get ... if you don't have the computer system the three days is there.
Dr. Feightner: In the Medicare Part D world it is going more to rejections and is becoming primary, one of the primary communication tools ..... we have to get to the point to where we can. Like I said, spending $1.4 million to get there, whatever it takes and pharmacies can get there. The messaging tool they should be able, all pharmacies should be able to receive it because there's a standard. NCPDP 5.1 was implemented in pharmacies as far as communication. It's the standard all pharmacies had to go to. And it should be there. Every pharmacy should be able to read the messaging that comes back to them.
Dr. McNeill: I appreciate that concerning this. But we have passed a lot of stuff in here over the past ten years under the assumption that a patient has access to three days of emergency meds. Lot of different drug classes and if that ain't working . . .
Dr. Knisely: How many of those do you fill? Have you guys done numbers on that?
Dr. Nesser: It's in the packet every month how many emergency supplies ..... you know one of the other problems is if they don't see that message that says you can get three days, whatever, all they're going to get is a rejection. They're not necessarily going to know to just cut it back to a 3-day supply and submit it and get paid. Or to even call. And then they've got to cut it back. The way we do it right now, also emergency PAs, you don't get a dispensing fee, so the pharmacist isn't going to get a dispensing fee on this. They're only going to get paid for the cost of the drug, and that's a lot of work to do to not get a dispensing fee.
(unintelligible, multiple speakers)
Dr. Feightner: I don't look at, the majority of the pharmacists don't see that contract information, but independents do, or the pharmacy does, but the majority of the pharmacists don't see that ..... they're wanting to get it filled for the customer, get it out the door, get them happy. I agree education's huge, I agree, I'm with you. It's huge, huge, huge.
Dr. Nesser: Right. I mean this can't just be implemented right away. I know it's a lot of money but it's also a lot of money for these kids to have to go back to the ER because they can't get their med. Because they can't get whatever it is. Some pharmacists are willing to call the ER and say, Hey I need you to change the script. Some are not. Some ERs are responsive and some are not. So .....
Dr. Kuhls: This is insane. This is insane. This is saying we don't have a good system so we're going to pay a lot more money because the system doesn't work.
Dr. Nesser: No, I'm not saying that our system, Medicaid system, it's the whole health care system that's messed up. It's not our system. We send the messages. Like I said, we have the ability. But we don't have the ability to go through the computer and make them read it.
Dr. Kuhls: I think that's not true.
Dr. Nesser: I challenge you to spend an hour in a pharmacy.
Multiple participants: Discussion regarding Medicare Part D, health care systems, Medicaid, educating pharmacies.
Dr. Graham: (repeating motion) Hard PA we approve for 30 days. We also have twelve, on nebulizers, 12 units or one box and then a one box on the HFA inhaler, and work on system changes and education.
Dr. Kuhls moved to approve; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: VOTE ON CHANGES TO ANXIOLYTICS PRIOR AUTHORIZATION

Materials included in agenda packet; presented by Dr. Gorman.
Dr. Bell moved to approve; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 9: 60-DAY NOTICE TO PRIOR AUTHORIZE OPTHALMIC ANTI-INFECTIVES AND STEROID COMBINATIONS

For Public Comment, Dr. Lucas Trigler: Thank you for having me tonight. My name is Lucas Trigler. I'm a pediatric ophthalmologist at the Dean McGee Eye Institute as well as I have a clinical appointment at the University of Oklahoma, and my partner and myself both run the pediatric ophthalmology section for Children's Hospital of Oklahoma. And so I have a particular interest in the healthcare needs of this population and services that are available for them. Approximately about 70+% of my practice is insured by SoonerCare. One of the common conditions that affect children is pediatric conjunctivitis. This is seen in primary care physicians' offices all the time, pediatrician, family practitioner, and also I see it in my office on occasion, particularly cases that may be treated but there's further question and is referred on. Unlike adult conjunctivitis, pediatric conjunctivitis is more commonly bacterial in origin. Viral pinkeye is more common in adults. Some reports show that 80% of pediatric conjunctivitis is actually bacterial in origin. In some cases bacterial conjunctivitis can cause very serious damage to the eye and most common pathogens encountered in bacterial conjunctivitis are staph, strep pneumo, haemophilus, moraxella and also in strep and haemophilus organisms are more commonly seen in children. So it is my opinion that these patients require a very broad spectrum topical antibiotic that acts quickly to eradicate the infection of these most common pathogens affecting pediatric conjunctivitis. Additionally this antibiotic should be designed in a way that would allow decreased

resistance to develop to the antibiotic, and in my opinion, the newer fourth generation fluoroquinolone topical antibiotics are fulfilling these needs today. In my practice I prefer moxifloxacin or Vigamox over other fourth generation fluoroquinolones for several reasons. The first, when compared to competitors including the fourth generation but also the older third generation fluoroquinolones, moxifloxacin or Vigamox has been proven to show much higher concentrations in the conjunctival tissues and much faster, or the fastest eradication times for the most common infecting agents. It is one of the broadest spectrums of activity against a multitude of aerobic and anaerobic gram positive and gram negative atypical organisms. The antibiotic Vigamox also provides protection against multi drug resistant strains of the most common bacteria that cause conjunctivitis and the bacteriocidal activity is very important, obviously, but there's also less potential for the development of resistance because Vigamox acts at two sites on the bacteria. The older fluoroquinolones will act at the DNA gyrase but Vigamox and fourth generation fluoroquinolones will act at both DNA gyrase as well as topoisomerase IV. Therefore in my opinion, Vigamox provides an ideal situation in regards to quick eradication of common pathogens and less potential for resistance. Just in kind of my clinical experience, I routinely instruct patients that I see with bacterial conjunctivitis to contact my office within a day or two after starting Vigamox if their symptoms are not significantly improved. I expect that sort of rapid response to treatment with this medication. I think this is critical for daycare situations and school situations because daycare and school policies often exclude children from those situations when they have pinkeye, and so as a result, the parents are unable to attend work, the children are out of school for longer, they can't get back to school or the daycare setting, parents can't get back to work. So I think it is critical to have a drug that acts this quickly on such a broad spectrum. Also I feel that the quick time to eradication allows primary care physicians to better make decisions regarding the possible need for referral. If this drug is started in a child with pediatric conjunctivitis and the child is not improving within a day or two, I think that the diagnosis may need to be reconsidered. Is this a HSV keratitis. Is this something else more devastating to the eye, potentially. So I think that this allows the primary care, the pediatrician, the family practitioner to make a better decision with regard to the need for referral or seeking further opinion. Other things with regard to the clinical use of this drug, it has a simple three times a day dosing for seven days. Very straightforward. The other competitor fourth generation fluoroquinolone requires Q2-hour dosing for eight doses a day for two days followed by four times a day dosing for a total of seven days. Much more complicated dosing, Much more medication to administer to the eye and we all know that children do not like eye drops. The other third reason I like this drug is that it has a neutral pH and does not contain benzalkonium chloride, which is a preservative agent that's used in many ophthalmics and can cause a stinging effect and also has known to be toxic to the eye when used in frequent administration. So I think that this promotes better acceptance in children who typically don't like these drops, possibly less stinging with this medication. Hopefully they'll use it more frequently, or use it as directed. Last and of particular importance, particularly people seeing children of course, this drug has been FDA approved for the use in children down to twelve months of age. No other fluoroquinolone has that indication or the competing fourth generation fluoroquinolone. Additionally, this drug has been studied in neonates. This drug has been studied at BID dosing for three days in neonates and has shown excellent results for treating neonatal conjunctivitis on BID dosing for three days. Given the well known compliance issues with any medication, I think this suggests that if parents miss a drop or two at times, the infection is still likely to be completely treated if this is truly a bacterial conjunctivitis. So in conclusion, I feel that the pediatrician, the family practitioners, primary care physicians of this state, as well as the eye care providers should have a fourth generation fluoroquinolone available to them to use. I feel that Vigamox has distinct advantages over other fluoroquinolones and for the reason that I described, and that's why I prefer it in my practice.

Dr. Kuhls: I have a couple of comments. First of all, a couple of years ago I went to a CME that you presented at Children's on a Saturday morning and you .... sort of a potpourri. And you talked about using tobramycin drops because as your routine conjunctivitis treatment. Now that was before Vigamox got approved, I think, but that was your routine treatment.

Dr. Trigler: Actually I was routinely using Polytrim actually in a lot of kids that had nasolacrimal duct obstruction and other things. But since Vigamox has come on board, obviously intraocular surgery and other things I use Vigamox for, for other reasons, it treats very high concentrations intraocularly as well. So that's, but I see where you're, I understand your comment and but for me, I really do feel that the rapid time to eradication and the very quick treatment of this provides a benefit to the patient, the parent, the social situation, the economic situation, the work situation, school, whatever you want to look at; significant advantage over the other agents.

Dr. Kuhls: You have data that says, not looking at killing times, because I think that falsely predicts in the routine garden variety bacterial conjunctivitis in children, OK. We're talking about not what you do a lot of, but what the usual family practitioner does and the pediatrician. Do you have studies that compare directly, not looking at killing times, but effectiveness in treatment of bacterial conjunctivitis to show that it works better than tobramycin or sulfa drugs or whatever drug that's less expensive?

Dr. Trigler: With regard to duration of treatment?

Dr. Kuhls: Yeah, with a three, four, five day treatment course, blinded control.

Dr. Trigler: The only study I can cite with regard to this drug would be the fact that in neonates it was used on BID dosing for 72 hours.

Dr. Kuhls: So the garden variety, there's no data that says that in the garden variety bacterial conjunctivitis and Vigamox is better than tobramycin or Sulamyd or whatever you want to pick as a drug?

Dr. Trigler: Well I think that it depends on, what do you mean by garden variety? I mean if . . .

Dr. Kuhls: Well I mean the outpatient, what Dr. McNeill sees and what I take care of in my pediatric practice, and I don't want to talk about intraocular surgery because I can understand the necessity for broad spectrum high coverage, but I'm talking about the usual garden variety treatment of outpatient not sent to the ophthalmologist for conjunctivitis.

Dr. Trigler: I think what, the only data that I could, off the top of my head, give you that would be accurate without looking into this further, would be the things in terms of the studies regarding time to eradication, killing times.

Dr. Kuhls: Which makes me, I'm not sure that equates to effectiveness.

Dr. Trigler: In my clinical practice, I mean, I've seen a number of kids who have been treated with a multitude of agents, sulfacetamide, tobra, gentamicin, you know, erythromycin, any number of drugs that have come to my office on referral for questioning why isn't this getting better. And of course then, I culture it and then I, because this has been treated, we'll see what's going on, is there something atypical about this, but then start them on Vigamox. And in my experience, these kids have been adequately treated with Vigamox after they come to me for second opinion on the fact that they've been less than adequately treated on referral. That's my clinical experience.
Dr. Kuhls: All those sulfa, or pretty much all the agents that you talked about is very active against pretty much all those agents as well as tobramycin and the eye, even for staphococci and everything else.
Dr. Trigler: We know that certainly those agents kill these bugs, there's no doubt.
Dr. Kuhls: They kill those organisms, so the second quick question I have is a little more theoretical but concerning to me, tremendous in children. Are you aware of all the increasing, I know you're talking about two modes of mechanisms, gyrase, OK. But are you aware of all the increasing studies in the least infectious diseases literature, talking about increasing resistance rates of pneumococci to even extended fluoroquinolones?
Dr. Trigler: I know there's a concern about development of resistance with any drugs and certainly .....
Dr. Kuhls: And there's more and more reports, especially in pneumococci of even resistance to moxifloxacin, to resistance to gatifloxacin. And it's very concerning to me that we just use, because bacterial conjunctivitis in children is much more common, that outpatient physicians, not so much ophthalmologists, I think you're in a different ballpark, but the routine family practice guy, the routine pediatrician, is just using extended fluoroquinolones in kids and it goes down the tear duct and then sooner or later, we're going to have increasing resistance rates of extended fluoroquinolones which are an extremely important medication in terms of community acquired pneumonia.
Dr. Feightner: Resistance will happen. Resistance is going .....
Dr. Kuhls: It already has. And if we just use this as a first line agent in everybody, that we're just going ..... feeding ourselves for resistance so that when we need the drugs for pneumonia, when we need the drugs for your patients, OK, that we're already going to have resistance for that drug.
Dr. Trigler: I think that's a good point and I agree with your point that resistance will happen. Resistance is going to happen and already has happened to many third generation fluoroquinolones and other drugs, of course. Isolates that are resistant to tobra, sulfacetamide, gent, erythromycin, other third generation fluoroquinolones are eradicated by this drug in many situations. This drug has been shown to kill bacteria that are resistant to those other drugs. So one other way of looking at this is saying, well here's a drug, and this is one of the ways that I look at this, here's a drug that when placed in the eye, kills 99% of the pathogens within 45 minutes in the conjunctiva. So it acts very rapidly. The DNA have less time to mutate, and if they've already been, if the bug is resistant to third generation fluoroquinolones that have the DNA gyrase activity, this bug, this drug is going to knock it out.
Dr. Kuhls: Well I don't want to argue with it then. I'm a pediatric ID person, so I kind of understand that argument because that comes from the pharmaceutical companies but already we're seeing extended fluoroquinolone resistance. So I'm not sure I buy that. And the real question is do we just use this, you know. The theory is, the real question is this, do you believe that using the broadest spectrum antibiotic that is ever available should be used in everybody's eyes because that way for the first time we're going to treat it good the first time and get rid of it so that in five years from now, we don't have that drug anymore. That's the real juxt of the question.
Dr. Feightner: You can't control the dosing. You can't control them once they leave your office if they don't dose it appropriately. They just do it once a day. They don't, they get rid of all the weak bugs and then those strong bugs die, that's the way, if drugs, antibiotics, were taken as prescribed, today, and eradicate the entire bug, then we all know resistance would be less. But you can't. That's where the resistance comes. You can't control every patient leaving your office and they're not going to always do what you say, so that brings in resistance to the drug.
Dr. Muchmore: That's why we have drug resistant TB.
Dr. Trigler: That's actually one of the reasons why I, one of the reasons why I've started using Vigamox, because obviously there are compliance issues and I think there's reasonable data to suggest that even if they, even if it is once or two times a day dosing, that the majority of the pathogens are knocked out.
Continued discussion between Dr. Trigler and Board members regarding drug resistance, drug costs per diem, and treatment options.
Materials included in agenda packet; presented by Drs. Gorman and Le.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE OPTHALMIC ANTI-GLAUCOMA PRODUCTS**

Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **30-DAY NOTICE TO PRIOR AUTHORIZE TOVALT ™ ODT**

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

ACTION: NONE REQUIRED.

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

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

ACTION: NONE REQUIRED.

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

13A: Utilization Review of Narcotics

13B: Utilization Review of ESAs

13C: Review of New Nasal Allergy Products

13D: New Products

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 14: **ADJOURNMENT**

The meeting was declared adjourned.

The University of Oklahoma College of Pharmacy

Pharmacy Management Consultants
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Memorandum

Date: June 18, 2007

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

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

Subject: DUR Board Recommendations from Meeting of June 13, 2007.

Recommendation 1: Vote to Prior Authorize Tekturna®

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Tekturna® (aliskiren) to the Antihypertensive PBPA category with the following approval criteria:

1. FDA approved indication.
2. Recent trial, within the previous 6 months and at least 4 weeks in duration, of an ACE Inhibitor (or an ARB if previous trial of an ACEI) and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control.
3. Aliskiren may be used in either monotherapy or combination therapy.

Recommendation 2: Vote to Prior Authorize Amrix® and Fexmid™

MOTION CARRIED by majority approval.

The College of Pharmacy recommends prior authorization of Amrix® and Fexmid™. Approval based on clinical documentation of inability to take other generically available forms of cyclobenzaprine hydrochloride. A quantity limit of 30 capsules for 30 days would be placed on Amrix® and 90 tablets for 30 days on the Fexmid™.

Recommendation 3: Vote to Prior Authorize Xopenex®

MOTION CARRIED by majority approval.

The College of Pharmacy recommends the following change to the Xopenex® prior authorization criteria:

Xopenex® (levalbuterol) nebulizer and HFA will require prior authorization with a 3 day* emergency supply allowance. If long-term authorization is needed, the following criteria must be met:

1. In the prior authorization request, the prescriber should document why the member is unable to use racemic albuterol. For those members with asthma, members should also be utilizing inhaled corticosteroid (ICS) therapy for long-term control per NAEPP guidelines.
2. Dose of levalbuterol requested cannot be less than the racemic equivalent documented on the prior authorization request.

Quantity limits apply as follows:

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

Additionally, educational materials should be sent to the providers and prescribers prior to implementation. Appropriate system changes for point-of-sale messaging should be also pursued.

*Up to 72 mL of solution or 1 HFA unit (15 gm).

Recommendation 4: Vote on Changes to Anxiolytic Prior Authorize Category

MOTION CARRIED by unanimous approval.

Drug Grouping:

1	2	3
14 Days – No Pa	14 Days – No Pa	Hard PA
Chlordiazepoxide	Alprazolam	Alprazolam XR
Clorazepate	Diazepam	Niravam
Oxazepam	Lorazepam	
Clonazepam		
Midazolam		

Approval Criteria:

1. DUR+ Criteria:
    a. Long-Term (PA Exempt) Diagnosis = Automatic Paid Claim.
    b. No Long-Term Diagnosis (Group 1 and 2) and claim is for 14 day supply or less:
        i. No benzodiazepine claim in last 90 days *AND*
        ii. Member between 19 and 64 years old or less than 19 and prescription is from a psychiatrist *AND*
        iii. No concurrent ADHD medications (except Strattera) *AND*
        iv. No contraindicated indications *AND*
        v. Total units do not exceed 4 per day = Automatic Paid Claim.

2. Manual Prior Authorization Criteria (All Groups):
    a. Diagnosis from the long-term behavioral health list *AND*
    b. Documentation of recent (past 90 days) SSRI or other non-benzodiazepine treatment when appropriate, including treatment outcome and reason benzodiazepine is required *AND*
    c. If Group 2, reason must be given for not using a Group 1 medication – if Group 3, clinical documentation and previous trial information must be given to support the use of a Group 3 drug instead of a Group 1 or Group 2 medication *OR*
    d. Prescription by a Psychiatrist.

3. Limitations to Prior Authorization:
    a. Review by pharmacy Lock-In Program staff for members using Group 2 or Group 3 medications if other controlled substances are utilized.
    b. Approval granted for 90 days per authorization.
    c. Up to TID dosing if a hypnotic is being used concurrently; up to QID otherwise.

Current Prior Authorized Members:

1. Continue current regimen unless a 90 day therapy gap exists.
    a. If gap exists, member will be subject to "New Start" criteria.
2. Review by pharmacy Lock-In Program staff for members using Group 2 or Group 3 medications if other controlled substances are utilized.
3. Request downward dosage titration every 180 days.
4. Approval granted for 90 days per authorization.
5. Up to TID dosing if a hypnotic is being used concurrently; up to QID otherwise.
6. No concurrent ADHD medications.

Long-Term (**PA Exempt**) Diagnoses:

For these physical medicine diagnoses, *DUR +* will automatically generate a yearly approval:

- Seizures,
- Epilepsy,
- Paralysis,
- MS,
- CP, and
- Muscular Dystrophy

Contra-Indicated Co-Morbid Conditions:

- History of Substance Abuse/Dependence including Alcoholism.
- Antisocial Personality Disorder
- Cigarette Use

Long-Term Behavioral Health Diagnoses:

- Post Traumatic Stress Disorder
- Panic Disorder
- Obsessive Compulsive Disorder
- Social Phobia
- Severe Generalized Anxiety Disorder
- Major Depression Recurrent
- Bipolar Disorder

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for March 2007

Module	**Drug Interaction**	**Duplication of Therapy**	**Drug-Disease Precautions**	**Dosing & Duration**
Total # of messages returned by system when no limits were applied	40,792	61,925	122,325	35,478
Limits which were applied	Established, Major, Males and Females, Age 46-55	Antianxiety Agents, Males and Females, age 66-150 years	Contraindicated, Males and Females 0-35 years, Diabetes	High dose, Strattera, Males and Females, 11-150 years
Total # of messages after limits were applied	86	124	20	11
Total # of members reviewed after limits were applied	86	122	11	11

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
36		30	

Retrospective Drug Utilization Review Report

Claims Reviewed for October 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 0-21	Anti-anxiety Agents, Males and Females, Age 43-50	Contraindicated, Hypothyroidism, Males and Females, Age 0-150	High dose, Digitalis, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 97
Response Forms Returned: 42

The response forms returned yielded the following results:

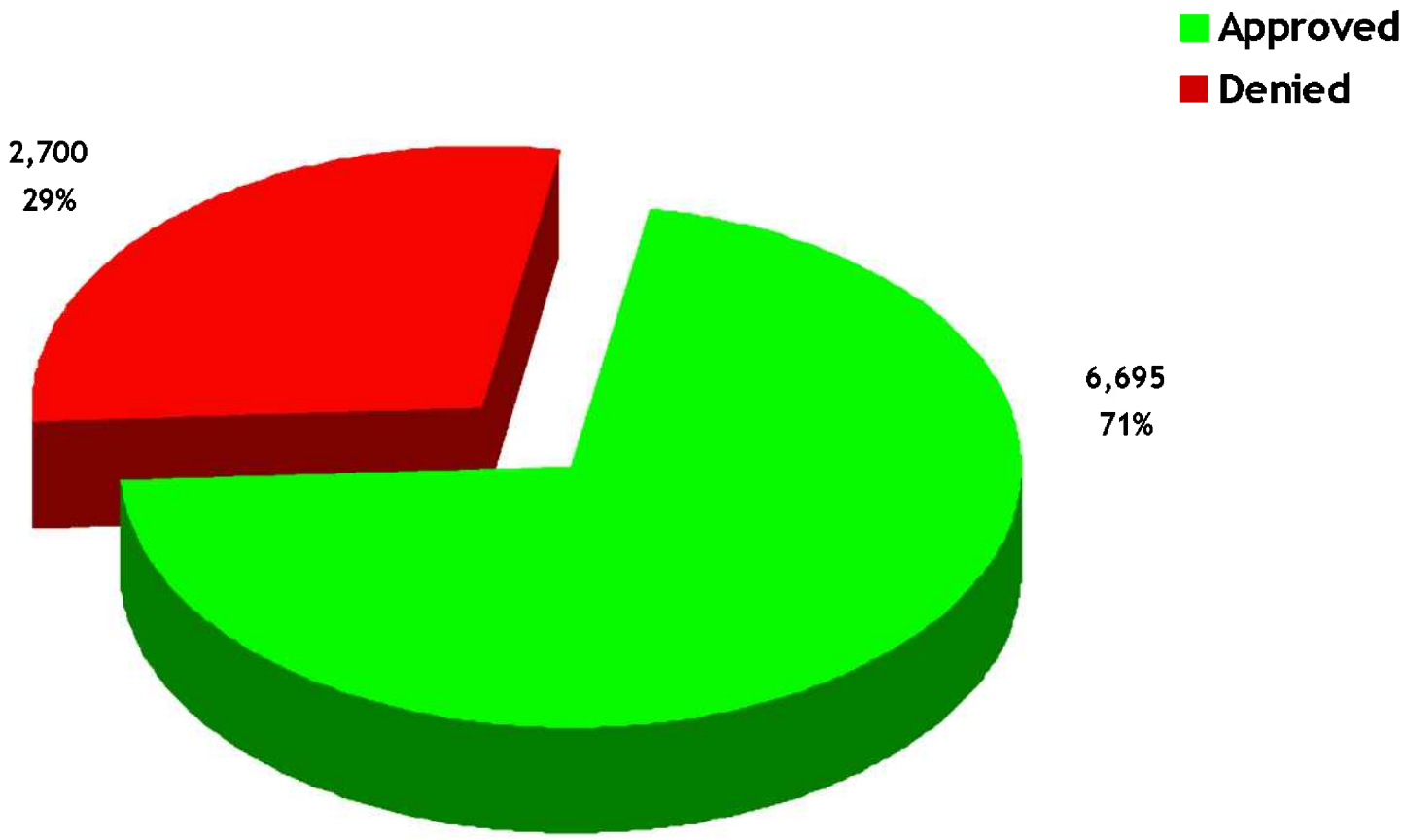
2 (5%)	*Record Error—Not my patient.*
10 (24%)	*No longer my patient.*
2 (5%)	*Medication has been changed prior to date of review letter.*
8 (19%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
10 (24%)	*I am aware of this situation and will plan to continue monitoring therapy.*
10 (24%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 69
Response Forms Returned: 31

The response forms returned yielded the following results:

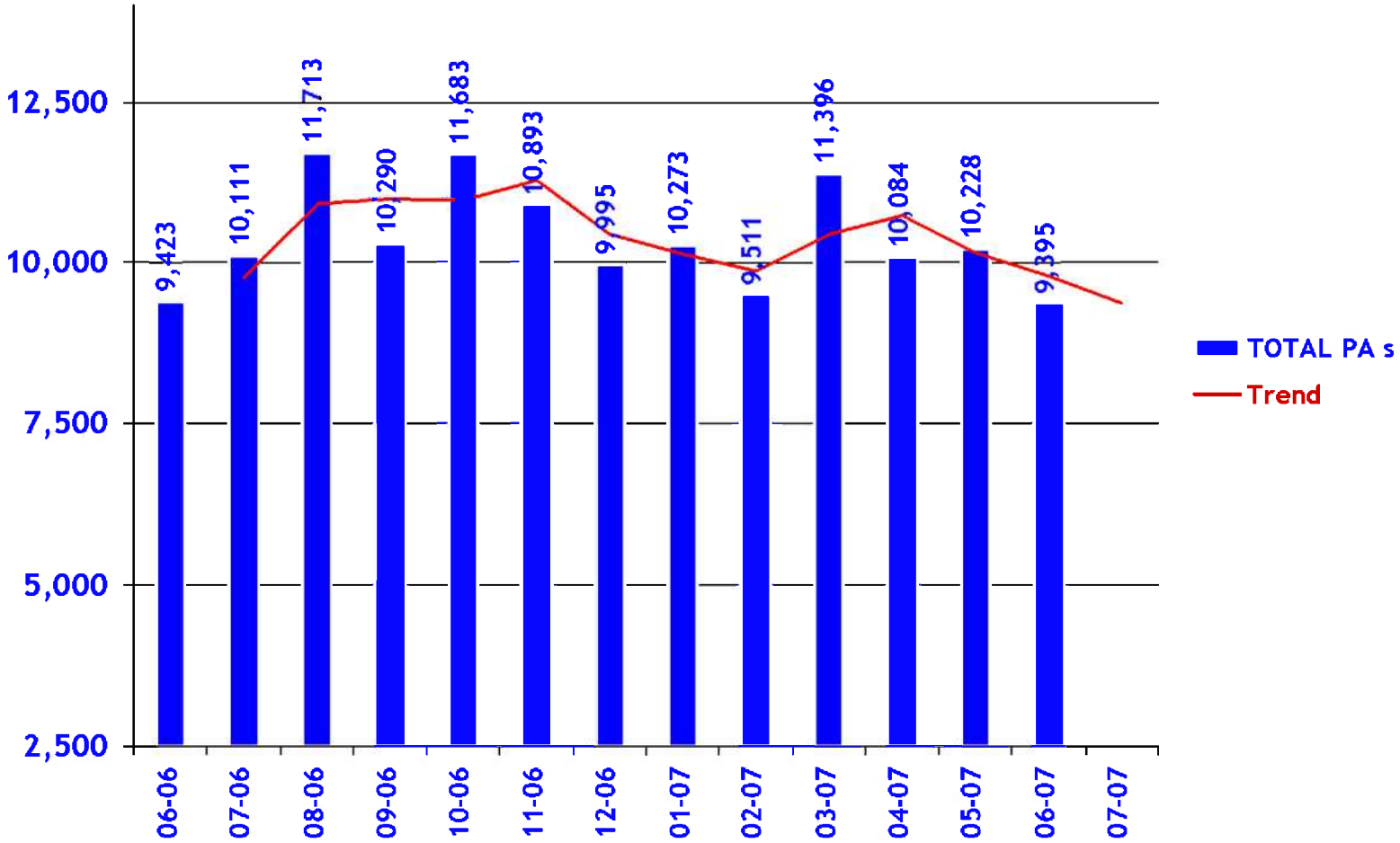
0 (0%)	*Record Error—Not my patient.*
4 (13%)	*No longer my patient.*
3 (10%)	*Medication has been changed prior to date of review letter.*
2 (6%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
15 (48%)	*I am aware of this situation and will plan to continue monitoring therapy.*
7 (23%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
June 2007



PHARMACY Management consultants

PRIOR AUTHORIZATION REPORT
June 2006 - June 2007



PHARMACY Management consultants

Activity Audit for
June 01, 2007 Through June 30, 2007

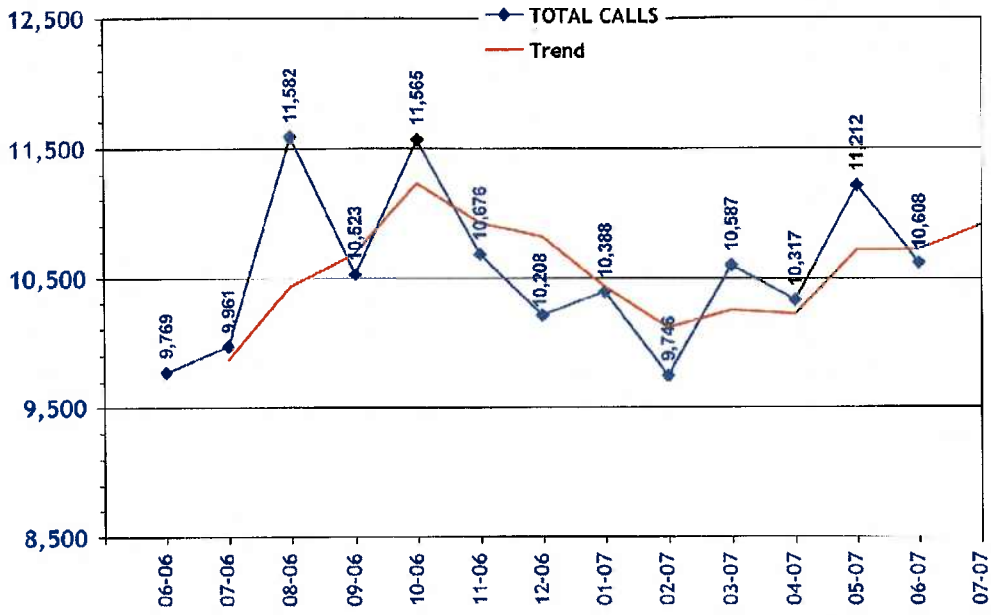
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	173	11	13	24
Angiotensin Receptor Antagonist	338	39	65	104
Antidepressant	274	218	394	612
Antihistamine	98	1,097	578	1,675
Antiulcers	18	14	14	28
Anxiolytic	94	3,225	412	3,637
Calcium Channel Blockers	97	6	3	9
Growth Hormones	124	63	1	64
HTN Combos	323	8	14	22
Hypnotics	92	344	120	464
Nsaids	201	28	66	94
Plavix	347	166	14	180
Stimulant	203	568	187	755
Others	112	908	819	1,727
Emergency PAs		0	0	0
Total		6,695	2,700	9,395
Overrides				
Brand	231	23	32	55
Dosage Change	15	303	16	319
High Dose	81	3	0	3
Lost/Broken Rx	11	85	12	97
Nursing Home Issue	11	47	0	47
Other	22	20	21	41
Quantity vs. Days Supply	198	231	153	384
Stolen	14	7	0	7
Wrong D.S. on Previous Rx	3	1	5	6
Overrides Total		720	239	959

Denial Reasons

Lack required information to process request.	2,952
Unable to verify required trials.	781
Not an FDA approved indication/diagnosis.	127
Considered duplicate therapy. Member has a prior authorization for similar medication.	71
Requested dose exceeds maximum recommended FDA dose.	54
Does not meet established criteria.	51
Member has active PA for requested medication.	40
Medication not covered as pharmacy benefit.	9
Duplicate Requests	541
* Changes to existing	745

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

CALL VOLUME MONTHLY REPORT
June 2006 - June 2007



04-06 thru 03-07: corrected totals

PHARMACY Management Consultants

Appendix C

Vote to Prior Authorize Ophthalmic Anti-Glaucoma Products

Oklahoma Health Care Authority

July 2007

The College of Pharmacy recommends the addition of the Ophthalmic Anti-Glaucoma class to the Product Based Prior Authorization program. The following Tier-1 Drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of members. The College of Pharmacy will also provide member outreach to ensure a high standard of vision care is provided to those diagnosed and treated for glaucoma.

PA Criteria

1. FDA approved diagnosis.
2. Member must attempt at least one Tier 1 trial of a minimum of 4 weeks duration within the last 90 days. Tier 1 trial may be from any pharmacologic class.
3. Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to Tier 1 products.
4. Approval may be granted if there is a unique FDA approved indication not covered by Tier 1 products.
5. Member must have had a comprehensive dilated eye exam within the last 365 day period as recommended by the National Institute of Health.
6. Approval duration will be for 1 year.

Tier 1	Tier 2
Beta-Blockers	
Betagan 0.25%,0.5% (Levobunolol) Optipranolol 0.3% (Metipranolol) Timoptic, Betimol, Istalol, Timoptic Ocudose, Timoptic XE 0.25,0.5% (Timolol Maleate) Cartrol, Ocupress 1% (Carteolol) Betoptic-S 0.5% (betaxolol)	Betoptic-S (betaxolol) Cosopt (Dorzolamide and Timolol)* Timoptic 0.5% Dropperette
Prostaglandin Analogs	
Xalatan (Latanoprost)**	Lumigan (Bimatoprost) Travatan, Travatan Z (Travoprost)
Adrenergic Agonists#	
Propine (Dipivefrin)	
Alpha-2 Adrenergic Agonists	
Brimonidine 0.2%	Alphagan P 0.1, 0.15% (Brimonidine) Iopidine 1% Apraclonidine
Carbonic Anhydrase Inhibitor@	
	Azopt (Brinzolamide) Trusopt (Dorzolamide) Cosopt (Dorzolamide and Timolol)*
Cholinergic Agonists[1]/Cholinesterase Inhibitors[2]	
Isopto Carpine, Pilopine HS 0.5,1,2,4,6 %(Pilocarpine)	Isopto, Miostat 1.5, 3% (Carbachol) Phospholine Iodide (Echothiophate Iodide)[2]

@ Oral formulations of Carbonic Anhydrase Inhibitors also available as Tier-1 *Combination product.

**Tentative generic approval by FDA 03/09/2007; current portfolio supplemental rebate agreement participation

Drugname	Mechanism/Indication	Dosing	Generic	Other
Beta-Blockers*				
Betagan 0.25%, 0.5% (levobunolol)	Lower IOP in chronic open-angle glaucoma or Ocular HTN	1 drop daily or twice daily	Y	
Optipranolol 0.3% (metipranolol)	Lower IOP in chronic open-angle glaucoma	1 drop twice daily	Y	
Timoptic, Betimol, Istalol, Timoptic Ocudose, Timoptic XE 0.25%, 0.5% (timolol)	Lower IOP in glaucoma or ocular hypertension	1 drop daily or twice daily	Y	Available in combination with Dorzolamide. 1 drop bid ≥2 *yrs. old*
Cartrol, Ocupress 1% (Carteolol)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop twice daily	Y	
Betoptic-S (betaxolol)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily or twice daily	Y	Oral dosage form available.
Prostaglandin Analogs*				
Lumigan (Bimatoprost)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily	N	More than once daily decrease effectiveness
Xalatan (Latanoprost)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily	N	More than once daily decrease effectiveness
Travatan, Travatan Z (Travoprost)	*Lower IOP in chronic open-angle glaucoma and Ocular HTN after failure of other IOP-lowering medication*	1 drop daily	N	Travatan Z uses non Benzalkonium Chloride preservative
Adrenergic Agonists				
Propine (Dipivefrin)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop twice daily	Y	Prodrug of epinephrine
Alpha-2 Adrenergic Agonists				
Alphagan P, Alphagan 0.1%, 0.15%, 0.2% (brimonidine)	Lower IOP in chronic open-angle glaucoma and Ocular HTN ≥2 *years old*	1 drop three times daily	Y (only 0.2%)	Alphagan P uses non Benzalkonium chloride preservative
Iopidine 0.5%, 1% (apraclonidine)	*Prevention and treatment of postsurgical IOP, short-term adjunctive*	1-2 drop three times daily (0.5%); 1 drop prior and after surgery (1%)	N	
Carbonic Anhydrase Inhibitor				
Azopt (Brinzolamide)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop three times daily	N	
Trusopt (Dorzolamide)	Lower IOP in chronic open-angle glaucoma and Ocular HTN *(children and adults)*	1 drop three times daily	N	Available in combination with timolol. 1 drop bid ≥2 *years old*
Cholinergic Agonists/Cholinesterase Inhibitors				
Isopto Carpine, Pilopine HS 0.5,1,2,4,6% (Pilocarpine)	Management of chronic and acute angle-closure glaucoma	1-2 drops up to six times daily; Apply 0.5 in. ribbon at bedtime	Y	
Isopto, Miostat 1.5%, 3% (Carbachol)	Lower IOP in glaucoma; *miosis during surgery*	1-2 drops three times daily	N	Miostat used during surgery. DUR+ check ICD-9
Phospholine Iodide (Echothiophate Iodide)	*Miotic in chronic open-angle glaucoma; post-cataract surgery; accommodative estropia; used where surgery refused/contraindicated*	1 drop daily or twice daily (1 dose at bedtime) or every other day; 1 drop twice daily for 2-3 weeks (estropia) then treat once or every other day thereafter	N	

*Recommended 1st Line

Appendix D

Vote to Prior Authorize Tovalt™ ODT (zolpidem tartrate)

Oklahoma Health Care Authority
July 2007

Manufacturer Bioavail Pharmaceuticals, Inc
Classification FDA classification: Non-benzodiazepine hypnotic
Status: prescription only

Summary

Tovalt® ODT is an orally disintegrating tablet. It is a non-benzodiazepine hypnotic of the imidazopyridine class available in 5mg and 10mg strengths. Tovalt™ (zolpidem tartrate) orally disintegrating tablets are bioequivalent to Ambien® tablets. It is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Revised Tier Table

Tier 1	Tier 2	Tier 3
estazolam temazepam flurazepam triazolam zolpidem Ambien CR® Rozerem® Lunesta®	Sonata Restoril® 7.5 and 22.5 mg	Tovalt ODT

Supplemental rebate participation

Recommendations

The College of Pharmacy recommends placing Tovalt® into the Hynpotic PBPA category as a Tier 3. Approval would require a diagnosis of insomnia and an additional diagnosis indicating that the member has a condition that prevents him/her from swallowing tablets.

REFERENCE

Tovalt™ Product Information. Bioavail Pharmaceuticals, Inc. 2007

Appendix E

30 Days Notice to Prior Authorize Brovana™ (arformoterol tartrate) Inhalation Solution

Oklahoma Health Care Authority
July 2007

Manufacturer	Sepracor Inc	
Classification	FDA classification:	Long Acting Beta$_2$ Agonist
	Status:	Prescription Only

Summary

Brovana™ is the (R,R)-enantiomer of the long-acting beta$_2$-agonist formoterol. It is available as a 15mcg/2ml inhaled solution. It is indicated for the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Dosing

Recommended dose is 15mcg twice a day (morning and evening) by nebulization. A total daily dose greater than 30mcg is not recommended and does not provide sufficient additional benefit to support use.

Pharmacokinetic Comparison

	Delivered Dose	Onset	Duration	Indications
Arformoterol Nebs	15mcg	20min*/6.7min†	12h	COPD only
Salmeterol DPI	44mcg	120min*/31.9min†	12h	Asthma, EIB, and COPD
Formoterol DPI	12mcg	5min†	12h	Asthma, EIB, and COPD

*Defined as a mean FEV1 increase of 12% or more and at least 200ml after dosing in patients with COPD.
†Defined as a mean FEV1 increase of 15% or more from baseline after doing in patients with COPD.
EIB = exercise induced bronchospasm

Warnings

- Black Box Warning for class about increased risk of asthma-related death.
- Brovana™ is not indicated for treatment of acute episodes of bronchospasm.
- Brovana™ should not be initiated in patients with acutely deteriorating COPD.
- COPD is not a disease that occurs in children. Brovana™ should not be used in children as the safety and efficacy have not been established.
- Brovana™ should not be use in conjunction with other inhaled, long-acting beta$_2$-agonists.
- The drug compatibility (physical and chemical), efficacy, and safety of Brovana™ when mixed in the nebulizer with other drugs (e.g. inhaled corticosteroids) have not been established.

Brovana™ Place in Therapy

1. In those patients unable to utilize hand held delivery devices due to inability to coordinate hand movement or deep inhalations.
2. In those patients that have observed objective improvement with nebulized therapy.

<table>
<tr><th colspan="6">Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2006
Therapy According to COPD Stage</th></tr>
<tr><th></th><th>0: At Risk</th><th>I: Mild</th><th>II: Moderate</th><th>III: Severe</th><th>IV: Very Severe</th></tr>
<tr><td>Characteristics</td><td>• Chronic Symptoms
• Exposure to Risk Factors
• Normal spirometry</td><td>• FEV_1/FVC < 70%
• $FEV_1 \geq$ 80% predicted
• With or without symptoms</td><td>• FEV_1/FVC < 70%
• 50% ≤ FEV_1 < 80% predicted
• With or without symptoms</td><td>• FEV_1/FVC < 70%
• 30% ≤ FEV_1 < 50% predicted
• With or without symptoms</td><td>• FEV_1/FVC < 70%
• FEV_1 <30% or FEV_1 < 50% predicted plus chronic respiratory failure</td></tr>
<tr><td rowspan="4"></td><td colspan="5">Avoidance of risk factor(s); smoking cessation; influenza vaccination</td></tr>
<tr><td rowspan="3"></td><td colspan="4">Add short-acting bronchodilator when needed</td></tr>
<tr><td rowspan="2"></td><td colspan="3">Add regular treatment with one or more long-acting bronchodilators
Add rehabilitation</td></tr>
<tr><td rowspan="2"></td><td colspan="2">Add ICS if repeated exacerbations</td></tr>
<tr><td></td><td>Add long-term oxygen if chronic respiratory failure
Consider surgical options</td></tr>
</table>

Cost Summary

	Per Diem (based on EAC)
Brovana™ 15mcg/2ml Solution	$10.14
Serevent Diskus® 50mcg DPI	$4.00
Foradil® 12mcg DPI	$3.60

Recommendations

The College of Pharmacy recommends prior authorization and the following restrictions of Brovana™.

1. Member must be over 18 years of age and have one of the following diagnoses: COPD, chronic bronchitis, or emphysema.
2. Member must have previous trial with Advair®, Serevent® or Foradil® in the past 45 days. A clinical exception will be given for those members who are unable to effectively use hand-actuated devices.
3. Quantity limit of 120ml for a 30 day supply.

REFERENCE

Brovana™ Product Dossier. Sepracor Inc. May 2007.

Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Bethesda (MD): Global Initiative for Chronic Obstructive Lung Disease, World Health Organization, National Heart, Lung and Blood Institute; 2006.

Appendix F

30 Day Notice to Prior Authorize Exforge® (amlodipine(CCB)/valsartan(ARB)
Oklahoma Health Care Authority
July 2007

Manufacturer Novartis Pharmaceuticals
Classification FDA classification: antihypertensive
Status: prescription only

Summary
Exforge® is a combination of Diovan® (valsartan) and Norvasc® (amlodipine) in a single pill. It is indicated for the treatment of hypertension when blood pressure is not adequately controlled by either medication alone. It is not for initial therapy. It is available in four different strength combinations (5/160, 10/160, 5/320 or 10/320) with 5 or 10 mg of amlodipine and 160 or 320 mg of valsartan.

Revised Tier Table

ANTI-HYPERTENSIVE MEDICATIONS	
ARB AND ARB/HCTZ COMBINATION	
Tier 1	**Tier 2**
All Tier 1 ACEIs	All other ARBs and ARB combos
Avalide	Exforge®

Supplemental Rebate Agreement

Recommendations
The College of Pharmacy recommends placing Exforge® in the PBPA program as a Tier 2 ARB. A quantity limit of one unit per day would be applied. Existing ARB criteria (as follows) would apply.

In order to get a Tier 2 ARB, client must meet one of the following criteria:
- Tier 1 drug failure (i.e. inadequate clinical response or adverse effect), or
- contraindication to the Tier 1 drugs , or
- already stabilized on the Tier 2 drug, or
- using the Tier 2 drug for a unique indication which the Tier 1 drugs lack

REFERENCE

Exforge®, Product Information. Novartis Pharmaceuticals, 2007.

Appendix G

30 Day Notice to Prior Authorize Ophthalmic Anti-Infectives & Steroid-Antibiotic Combination Products

Oklahoma HealthCare Authority

July 2007

Recommendations

The College of Pharmacy recommends the addition of the Ophthalmic Anti-infective Class to the Product Based Prior Authorization program. The following Tier 1 drug lists have been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

Ophthalmic Anti-infectives: Liquids	
Tier 1	**Tier 2**
Ciloxan Solution (Ciprofloxacin)	Vigamox (Moxifloxacin)
Quixin (Levofloxacin)	Zymar (Gatifloxacin)
Gentak (Gentamicin)	Azasite (Azithromycin)
Ocuflox (Ofloxacin)	
AK-Tob (Tobramycin)	
Bleph-10, Sodium Sulamyd (Sodium Sulfacetamide)	
Viroptic (Trifluridine)	
Natacyn (Natamycin)	
Polytrim (PolymyxinB/Trimethoprim)	
AK-Spore (Neomycin/PolymyxinB/Gramacidin)	

Ophthalmic Anti-infectives: Ointments	
Tier 1	**Tier 2**
AK-Tracin (Bacitracin)	
AK-Poly-Bac (Bacitracin/PolymyxinB)	
Ciloxan Ointment (Ciprofloxacin)	
Tobrex (Tobramycin)	
Neosporin (Neomycin/Polymyxin B/Bacitracin)	
A/T/S, Ilotycin, Roymicin (Erythromycin)	
Gentak (Gentamicin)	
Bleph-10, Sodium Sulamyd (Sodium Sulfacetamide)	

Approval Criteria:

1. Approved indication/suspected infection by organism not known to be covered by tier one antibiotics.
2. Known contraindication to indicated tier one medication.
3. Prescription by optometrists/ophthalmologists or when used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic–Steroid Combination Products	
Tier 1	**Tier 2**
	Tobradex (Tobramycin/Dexamethasone) Susp & Oint
	Zylet (Tobramycin/Loteprednol) Suspension
	Blephamide (Sulf/Prednisolone) Susp & Oint
	Pred-G (Gentamicin/Prednisolone) Susp & Oint
	Poly-Pred (Neo/Poly/Prednisolone) Susp
	Cortisporin (Neo/Poly/Hydrocortisone) Susp
	Maxitrol (Neo/Poly/Dexamethasone) Susp & Oint
	Bac/Poly/Neo/Hydrocortisone Ointment
	Neo/Poly/Bac/Hydrocortisone Ointment

Approval Criteria:

1. Prescription by optometrists/ophthalmologists or when used for pre/post-operative prophylaxis.

Appendix H

30 Day Notice to Prior Authorize Veramyst™ (fluticasone furoate) Nasal Spray and Omnaris™ (ciclesondide) Nasal Spray

Oklahoma Health Care Authority
July 2007

Veramyst™ GlaxoSmithKline	Omnaris™ Altana Pharma US, Inc.
Veramyst™ is a corticosteroid nasal spray. It is indicated for treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children ≥ 2 years of age. Starting dosage is 2 sprays per nostril once daily for adults and 1 spray per nostril once daily for children.	Omnaris™ is the pro-drug of the corticosteroid des-ciclesonide. It is indicated for treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older. The recommended dose is 2 sprays in each nostril once daily.
EAC: $ 83.40 for 10g vial (120 sprays)	**No current release date**

Recommendations

The College of Pharmacy recommends inclusion of Veramyst™ and Omnaris™ with the Tier 2 Nasal Allergy Products.

Nasal Allergy Products

*Tier 1**	*Tier 2*
Fluticasone (Flonase®)	Veramyst™
flunisolide	Omnaris™
Ipratropium bromide	
Nasonex®	
Beconase® AQ	
Nasacort® AQ	
Rhinocort® AQ	
Astelin®	

*Brand products are subject to the Brand Name Override where generic is available.
Blue color indicated supplemental rebate participation.

Criteria for approval of a Tier 2 product:

1. Documented adverse effect or contraindication to the preferred products.
2. Failure with at least one Tier 1 medication defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
3. Approvals will be for the duration of three months, except for clients with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

REFERENCE

Veramyst™ Prescribing Information. GlaxoSmithKline. 2007.
Omnaris™ Prescribing Information. Altana Pharma US, Inc. Rev. 19-Oct-06 draft. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed June 12, 2007.

Appendix I

ERYTHROPOIESIS-STIMULATING AGENTS UTILIZATION REVIEW

Oklahoma Health Care Authority
July 2007

Prevalence[1,2,3,4]

- Anemia affects 3.4 million Americans; it is the most common blood disorder in the US.
- 20 million Americans – 1 in 9 US adults – have Chronic Kidney Disease (CKD) and another 20 million are at increased risk. Anemia develops early in the course of CKD and is nearly universal in patients with CKD stage 5
- Approximately 1.4 million Americans are currently diagnosed with cancer. The development of chemotherapy-associated anemia is characteristically an insidious and delayed complication of treatment

Evidence-based Guidelines for ESA's[2,4]

- National Kidney Foundation's 2006 KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, updated 2007
    - Defines anemia as: Hb <13.5 g/dL in adult males and <12.0 g/dL in adult females.
    - In patients with CKD target range for hemoglobin (Hb) should be in the range of 11.0 to 12.0 g/dl.
    - Target Hb should not exceed 13.0 g/dL in ESA-treated patients.
- Clinical Practice Guidelines of the American Society of Clinical Oncology and the American Society of Hematology, updated Nov 2006
    - Epoetin is recommended for patients with chemotherapy-associated anemia whose Hb is <10 g/dl at a starting dose of 150U/kg three times a week for 4 weeks. Dosing weekly with 40,000U is also acceptable.
    - Target Hb range should not exceed 12 g/dl.
    - For patients whose Hb level fails to respond to adequate doses after 6-8 weeks, continued treatment with epoetin does not appear to be of benefit

Current Issues[5,6]

- Recent studies have shown that using epoetin to achieve a target Hb level of >13.5 g/dl leads to increased risk of complications including death, myocardial infarctions, strokes, hospitalization for congestive heart failure in patients with chronic kidney disease with or without dialysis, compared to a target Hb level of 11.3 g/dl. No incremental increase in quality of life was demonstrated with the higher hemoglobin.
- March 2007, FDA issued a public health advisory, with resultant black box warning:

WARNINGS: Erythropoiesis-Stimulating Agents
Use the lowest dose of (epoetin) that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion (see DOSAGE AND

ADMINISTRATION). (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 g/dL (see WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events).
Cancer Patients: Use of ESAs shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a hemoglobin of greater than 12 g/dL; shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target a hemoglobin of greater than 12 g/dL;
• increased the risk of death when administered to target a hemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy nor radiation therapy. ESAs are not indicated for this population.

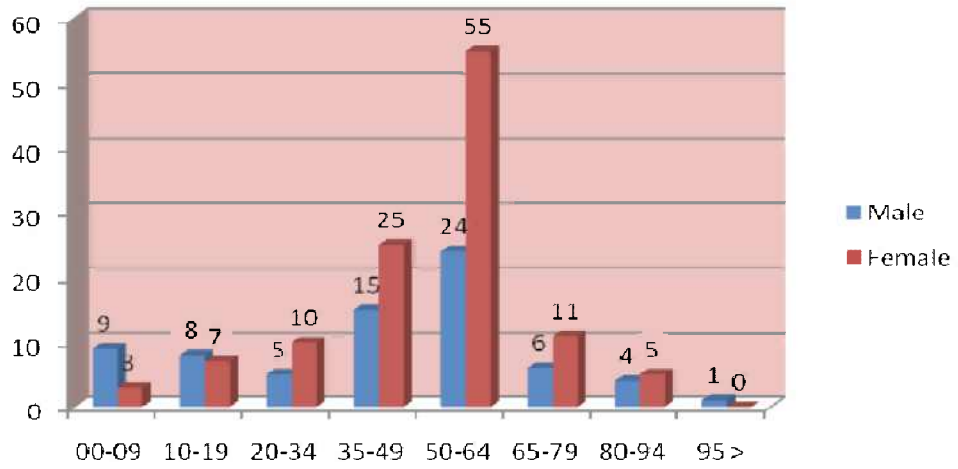
(See WARNINGS: Increased Mortality and/or Tumor Progression)

Patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving (epoetin)® who were not receiving prophylactic anticoagulation. Antithrombotic prophylaxis should be strongly considered when EPOGEN® is used to reduce allogeneic red blood cell transfusions (see WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events).

Utilization of ESA's for Calendar Year 2006*

BRAND NAME	CLAIMS	UNITS	DAYS	CLIENTS	COST	COST/ DAY
Aranesp	131	190	2809		$217,329.48	$77.37
Epogen	121	902	3,560	45	$161,616.05	$45.40
Procrit	515	2505	13,630	150	$586,126.05	$43.00
	767	**3,597**	**19,999**	**188**	**$965,071.58**	

*All data reflects pharmacy claims only, hospital or physician's office claims not included.



BRAND NAME	CLAIMS	UNITS	DAYS	MEMEBERS	COST	COST/ DAY
Procrit (epoetin alfa) INJ 40000/ML	128	469	3,319	36	$247,520.51	$74.58
Procrit (epoetin alfa) INJ 20000/ML	134	788	4,042	48	$210,553.71	$52.09
Procrit (epoetin alfa) INJ 10000/ML	196	850	5,132	47	$112,975.66	$22.01
Epogen (epoetin alfa) INJ 20000/ML	51	344	1,441	17	$96,358.01	$66.87
Aranesp (darbepoetin alfa) INJ 200MCG	22	22	548	7	$51,984.08	$94.86
Aranesp (darbepoetin alfa) INJ 100MCG	56	51	875	8	$50,086.52	$57.24
Epogen (epoetin alfa) INJ 10000/ML	32	240	768	15	$31,445.91	$40.95
Aranesp (darbepoetin alfa) INJ 500MCG	3	12	84	1	$29,350.05	$349.41
Epogen (epoetin alfa) INJ 40000/ML	10	41	303	4	$22,540.34	$74.39
Aranesp (darbepoetin alfa) INJ 200MCG	11	22	160	4	$21,544.29	$134.65
Aranesp (darbepoetin alfa) INJ 100MCG	11	38	299	6	$18,615.93	$62.26
Aranesp (darbepoetin alfa) INJ 40MCG	13	24	436	2	$11,967.25	$27.45
Aranesp (darbepoetin alfa) INJ 200MCG	6	5	174	3	$11,750.34	$67.53
Aranesp (darbepoetin alfa) INJ 500MCG	1	4	28	1	$9,783.35	$349.41
Epogen (epoetin alfa) INJ 4000/ML	17	154	434	3	$8,040.15	$18.53
Procrit (epoetin alfa) INJ 4000/ML	16	114	296	6	$6,168.88	$20.84
Aranesp (darbepoetin alfa) INJ 150MCG	2	2	56	1	$5,873.06	$104.88
Procrit (epoetin alfa) INJ 2000/ML	32	202	611	10	$5,554.90	$9.09
Procrit (epoetin alfa) INJ 3000/ML	9	82	230	3	$3,352.39	$14.58
Epogen (epoetin alfa) INJ 2000/ML	11	123	614	6	$3,231.64	$5.26
Aranesp (darbepoetin alfa) INJ 300MCG	1	2	30	1	$2,936.51	$97.88
Aranesp (darbepoetin alfa) INJ 60MCG	3	3	63	3	$2,649.30	$42.05
Aranesp (darbepoetin alfa) INJ 25MCG/ML	1	4	28	1	$493.22	$17.62
Aranesp (darbepoetin alfa) INJ 60MCG/ML	1	1	28	1	$295.58	$10.56
	767	**3,597**	**19,999**	**188***	**$965,071.58**	**$48.26**

**Unduplicated Number of Members*

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3. American Cancer Society
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Appendix J

FDA News

FOR IMMEDIATE RELEASE
July 2, 2007

Media Inquiries:
Catherine McDermot, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet

Practice Puts Consumers at Risk and May Be More Expensive than Domestic Purchasing

The U.S. Food and Drug Administration continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by the FDA show that consumers who are trying to save money on prescription drugs don't need to take chances by buying prescription drugs from foreign Internet sites, because low-cost generic versions are available in the United States. This finding also may be an indication that some consumers are likely buying foreign drugs this way to avoid getting a prescription from their doctor or health care professional, since many Web sites do not require a prescription.

Safety Concerns
The use of prescription drugs without a prescription is an intrinsically unsafe practice. FDA urges consumers to have a prescription from their doctor or other health care professional before using prescription drugs. The agency also urges consumers to review www.fda.gov for important information before making such purchases.

Consumers should be aware of safety concerns of drugs purchased from unregulated Internet sellers since some of these drugs might:

- require careful dosing and monitoring;
- not have adequate labeling for safe use;
- be inappropriately packaged, therefore product integrity is uncertain;
- have been withdrawn from the U.S. market for safety or efficacy reasons;
- may carry risks that require initial screening and/or periodic patient monitoring;
- cause harm—such as a controlled substance (narcotic), whose use should be supervised by a doctor or health care professional due to abuse potential; and
- have clinically significant drug-drug interactions.

Recent examinations of a sample of drugs shipped to U S. consumers found several drugs are associated with higher risks and are more dangerous to the consumer if used without the supervision of a doctor or health care professional. For example, warfarin (an anticoagulant or blood thinner) is a medication that requires very close monitoring to prevent stroke or death. Another example is amoxicillin and other antibiotics that should not be used for self treatment to reduce the risk of antibiotic-resistant infections. Levothyroxine, a thyroid replacement hormone, also requires close monitoring to ensure effective treatment. Another blood thinner, clopidogrel, may pose increased risk of cardiac events, such as heart attack if used in sub-optimal doses, which might be found in imported tablets. (See more examples in Table 2).

Consumers are also at risk if the drugs are not properly labeled for safe and effective use. For example, alendronate sodium, which is used to treat and prevent osteoporosis, should include information warning patients of significant side effects if it is not taken appropriately. Imported eye drop preparations may not have been manufactured under proper conditions to ensure sterility, leaving patients susceptible to contamination that may result in serious infections. These are only a few examples demonstrating the importance of obtaining FDA-approved drugs and health care provider monitoring.

Cost Concerns

The examination of foreign mail shipments also found that about 45 percent of the imported products already are available in the United States as an FDA-approved generic drug (see Table 1). About half of these generic drugs are available through national pharmacy chain programs that offer generic prescriptions at a cost of $4 each. This cost is usually significantly less than the cost of drugs charged by Internet sellers.

FDA has documented problems with imported drug products and has taken action when possible against foreign Web sites selling counterfeit products. Some examples follow.

- FDA Updates its Nationwide Alert on Counterfeit Blood Glucose Test Strips (October 23, 2006)
  www.fda.gov/bbs/topics/NEWS/2006/NEW01497.html
- FDA Warns Consumers Not to Buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products (August 30, 2006)
  www.fda.gov/bbs/topics/NEWS/2006/NEW01441.html
- Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor (August 31, 2005)
  www.fda.gov/bbs/topics/news/2005/new01228.html
- FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs (December 01, 2004)
  www.fda.gov/bbs/topics/news/2004/NEW01142.html
- FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico (July 30, 2004)
  www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html
- FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products Are Fake and Substandard (July 13, 2004)
  www.fda.gov/bbs/topics/news/2004/NEW01087.html
- FDA Takes Action Against Foreign Websites Selling Counterfeit Contraceptive Patches (February 12, 2004)
  www.fda.gov/bbs/topics/NEWS/2004/NEW01023.html
- FDA and Johnson & Johnson Warn Public About Counterfeit Contraceptive Patches Sold Through Foreign Internet Site (February 04, 2004)
  www.fda.gov/bbs/topics/NEWS/2004/NEW01017.html
- FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments (September 29, 2003)
  www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html

TABLE 1: Examples of intercepted drugs available as low-cost generic products in the U.S.

Drug Product	Common Intended Medical Use
Amoxicillin Capsules	Antibiotic
Atenolol Tablets	High blood pressure

Fluoxetine Capsule	Depression
Hydrochlorothiazide (HCTZ) Tablets	High blood pressure (diuretic)
Isotretinoin Capsules	Oral anti-acne
Levothyroxine Tablets	Thyroid hormone replacement
Lisinopril Tablets	High blood pressure
Meloxicam Tablets	Inflammation
Metformin Tablets	Diabetes (blood sugar levels)
Metoprolol Tartrate Tablets	High blood pressure
Methotrexate Tablets	Anti-cancer
Nifedipine ER (extended release) Tablets	High blood pressure
Paroxetine Tablets	Depression
Phenytoin Capsules	Anti-seizure
Prednisone Tablets	Inflammation (steroid)
Simvastatin Tablets	High cholesterol
Tamoxifen Tablets	Anti-cancer
Warfarin Tablets	Blood thinner

TABLE 2: Examples of intercepted drugs with particular associated risks	
Drug Product	**Common Intended Medical Use**
Alendronate sodium Tablets	Osteoporosis

Amoxicillin Capsules	Antibiotic
Celecoxib Capsules	Osteo- and Rheumatoid Arthritis
Clopidogrel Tablets	Blood thinner
Isotretinoin Capsules	Oral anti-acne
Levothyroxine Tablets	Thyroid hormone replacement
Methotrexate Tablets	Anti-cancer
Prednisone Tablets	Inflammation (steroid)
Phenytoin Capsules	Anti-seizure
Warfarin Tablets	Blood thinner
Zolpidem Tablets	Insomnia

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FDA News

FOR IMMEDIATE RELEASE
July 2, 2007

Media Inquiries:
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Consumer Inquiries:
888-INFO-FDA

FDA Approves First Generic Versions of Lamisil Tablets

Agency also approves over-the-counter terbinafine cream to treat athlete's foot

The U.S. Food and Drug Administration today approved the first generic versions of prescription Lamisil (terbinafine hydrochloride) tablets, used to treat nail fungus infection (onychomycosis). Such infections occur when fungi invade a fingernail or toenail or the skin underneath the nail.

"This approval offers Americans additional alternatives when choosing medications to treat nail fungus infections," said Gary J. Buehler, R.Ph., director of FDA's Office of Generic Drugs.

FDA approved applications from multiple generic drug manufacturers for terbinafine hydrochloride tablets in 250-milligram formulations. Manufacturers include: Amneal Pharmaceuticals, Apotex Corp., Aurobindo Pharma USA Inc., Dr. Reddy's Laboratories Ltd., Gedeon Richter USA Inc., Genpharm Inc., Glenmark Pharmaceuticals Inc., InvaGen Pharmaceuticals Inc., Mylan Pharmaceuticals Inc., Orgenus Pharma Inc., Roxane Laboratories Inc., TEVA Pharmaceuticals USA, Watson Laboratories Inc., Wockhardt USA Inc.

The remaining patent or exclusivity for Lamisil expired on June 30, 2007.

According to the online trade magazine, *Drug Topics*, Lamisil tablets are the 57th highest selling brand-name prescription drug by retail dollars in the United States.

In addition to terbinafine tablets, FDA also approved an application for a generic version of over-the-counter Lamisil cream (terbinafine hydrochloride,1 percent) to treat athlete's foot, a skin disease caused by a fungus that usually occurs between the toes. The cream is manufactured by Taro Pharmaceuticals U.S.A. Inc.

The FDA's Office of Generic Drugs ensures that generic drugs are safe and effective through a thorough scientific and regulatory process.

For more information:
Office of Generic Drugs
www.fda.gov/cder/consumerinfo/generic_equivalence.htm.

Generic Drugs: What You Need to Know
www.fda.gov/fdac/features/2002/502_generic.html.

FDA monthly reports for first-time generics
www.fda.gov/cder/ogd/approvals/

FDA News

FOR IMMEDIATE RELEASE
P07-104
June 15, 2007

Media Inquiries:
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888-INFO-FDA

FDA Approves New Orphan Drug for Treatment of Pulmonary Arterial Hypertension

The U.S. Food and Drug Administration (FDA) today approved Letairis (ambrisentan) for the treatment of pulmonary arterial hypertension, a rare, life-threatening condition characterized by continuous high blood pressure within the arteries of the lungs.

"Letairis represents a valuable addition to the treatment alternatives for this orphan disease," said John Jenkins, M.D., director of FDA's Office of New Drugs. "Letairis is similar to an existing drug, but offers the potential for fewer drug interactions."

In pulmonary arterial hypertension, the small arteries in the lungs become narrowed or blocked, and the heart must work harder to pump the blood through them. Over time, the overworked heart muscle may become weak and lose its ability to pump enough blood through the lungs. Symptoms include shortness of breath, fatigue, chest pain, dizzy spells and fainting. About 100,000 people in the United States have pulmonary arterial hypertension.

Letairis, a new drug not previously approved in the United States, was granted a priority review by FDA. A priority review designation is intended for those products that address unmet medical needs. For priority drug applications, FDA sets a target date of six months after the date of receipt for the agency to complete all aspects of a review and to take action.

The safety and effectiveness of Letairis were demonstrated in two international clinical trials involving 393 patients. Letairis significantly improved physical activity capacity compared with a placebo, as shown by a six-minute walk, a standard test. Letairis also delayed the worsening of the pulmonary hypertension.

The most common side effects in patients using Letairis included swelling of legs and ankles, nasal congestion, sinusitis, and getting red in the face (flushing).

Letairis should not be used by women who are pregnant or may become pregnant because the drug may cause birth defects. Patients taking Letairis must have monthly blood tests to check for potential liver injury.

Letairis will be available in five-milligram and 10-milligram once-daily tablets.

Letairis was granted orphan drug status by FDA because it treats a rare disease and meets other criteria. Orphan designation qualifies the drug's sponsor for a tax credit and marketing incentives.

Letairis is manufactured by Gilead Sciences, Inc., Foster City, Calif. Gilead acquired the U.S.

rights to ambrisentan when it acquired Myogen, Inc. in 2006. GlaxoSmithKline holds rights to ambrisentan outside of the United States.

For more information:

The Orphan Drug Act
www.fda.gov/orphan/

National Heart Lung and Blood Institute – What is Pulmonary Arterial Hypertension?
www.nhlbi.nih.gov/health/dci/Diseases/pah/pah_what.html

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Propofol (marketed as Diprivan and as generic products) Information

FDA ALERT [6/15/2007] - FDA is issuing this alert to inform healthcare professionals about several clusters of patients who have experienced chills, fever, and body aches shortly after receiving propofol for sedation or general anesthesia. FDA has tested multiple units of propofol vials and lots used in patients who have experienced these symptoms and to date, these tests have not identified any vials contaminated with bacteria or endotoxins.

FDA recommends that healthcare professionals who administer propofol for sedation or general anesthesia carefully follow the recommendations for handling and use found in the current product labeling.

In addition, please report to the MedWatch program patients who have received propofol for sedation or general anesthesia and subsequently experienced fever, chills, and body aches or other symptoms of an acute febrile reaction (see MedWatch reporting information at the bottom of this page). Patients who develop these symptoms shortly after receiving propofol should be evaluated for bacterial sepsis.

The FDA is working closely with the Centers for Disease Control and Prevention (CDCP) to investigate possible reasons for the patients' illnesses following propofol administration. The FDA will provide more information as it becomes available.

This information reflects FDA's current analysis of available data concerning this drug. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug product and the emerging drug safety issue. Nor does it mean that FDA is advising practitioners to discontinue prescribing the product. FDA is considering, but has not reached a conclusion about, whether this information warrants any regulatory action. FDA intends to provide updated information when it becomes available.

- **Healthcare Professional Information**
  - Information for Healthcare Professionals[PDF] or [HTML]
  - Prescribing (labeling) Information from Drugs@FDA

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Date created: June 15, 2007