Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

Wednesday

May 9, 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 – May 9, 2007**

DATE: May 3, 2007

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

Enclosed are the following items related to the May 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 Flector® – **See Appendix C.**

Action Item – Vote to Prior Authorize Qualaquin® – **See Appendix D.**

Action Item – Vote to Prior Authorize Ocular Allergy Products – **See Appendix E.**

Action Item – Discuss and Vote on Proposed Changes to ADHD/Narcolepsy PBPA Category and Vote on Prior Authorization of Vyvanse™ – **See Appendix F.**

60 Day Notice to Prior Authorize Ophthalmic Glaucoma Products – **See Appendix G.**

30 Day Notice to Prior Authorize Tekturna® – **See Appendix H.**

30 Day Notice to Prior Authorize Amrix® and Fexmid™– **See Appendix I.**

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

Future Business

Adjournment

Drug Utilization Review Board
(DUR Board)
Meeting – May 9, 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. April 11, 2007 DUR Minutes – Vote
B. April 11, 2007 DUR Recommendations Memorandum
C. Provider and Member Correspondence

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 October 2006
B. Retrospective Drug Utilization Review Response for September 2006
C. Medication Coverage Activity Audit for April 2007
D. Help Desk Activity Audit for April 2007

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

5. Action Item – Vote to Prior Authorize Flector® – See Appendix C.

A. Product Summary
B. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Qualaquin® – See Appendix D.

A. Product Summary
B. COP Recommendations

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

7. Action Item – Vote to Prior Authorize Ocular Allergy Products – See Appendix E.

A. Product Summary
B. COP Recommendations

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

8. Action Item – Discuss and Vote on Proposed Changes to ADHD/Narcolepsy PBPA Category and Vote on Prior Authorization of Vyvanse™ – See Appendix F.

A. Current Tier Structure
B. Proposed Tier Structure
C. Proposed Criteria

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

9. 60 Day Notice to Prior Authorize Ophthalmic Glaucoma Products – See Appendix G.

A. Utilization Review
B. Prescribing Trends
C. COP Recommendations
D. Potential Costs and Savings

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

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

A. Product Summary
B. COP Recommendations
C. Cost Comparison
D. Monograph

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

11. 30 Day Notice to Prior Authorize Amrix® and Fexmid™ – See Appendix I.

A. Product Summaries
B. Utilization Review
C. COP Recommendations

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Xopenex® Changes
B. Anxiolytics
C. Ophthalmic Anti-Infectives

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of APRIL 11, 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.	X	
James Rhymer, D.Ph	X	

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

Dale Seibt, Alcon	Michael Mason, Alcon	Juanita Green, Sepracor
Dawn Harmon, Sepracor	Joseph Medina, Sepracor	Toby Thompson, Pfizer
Fred Morse, BMS	Sam Smothers, MedImmune	Bobby White, UCB Pharma
Perry Johnson, Graceway Pharma	Paul Sparks, Allergen	Donna Erwin, BMS
Ashley McConnell, Genentech	Jim Dunlap, Lilly	Janie Huff, TAP
Janell Cyrus	Danny Farr, Sepracor	David
Sally Mathew, Sepracor	Rob Baxter, MedImmune	Heidi Corey, Sepracor
Richard Ponder, Johnson & Johnson	Brett Pharks, Genentech	

PRESENT FOR PUBLIC COMMENT:

Justin Springfield, Sepracor Inc.	Agenda Item No. 5
Scott Cyrus, D.O.; Pediatrician	Agenda Item No. 5
David Jackson, M.D., Dean McGee for Alcon	Agenda Item No. 8

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: February 15, 2007 DUR Minutes

Dr. Kuhls moved to approve minutes as submitted; seconded by Dr. Feightner.

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: August 2006

4B: Medication Coverage Activity Report: February 2007

4C: Medication Coverage Activity Report: March 2007

4D: Help Desk Activity Report: February 2007

4E: Help Desk Activity Report: March 2007

4F: Pharmacotherapy Management Quarterly Report

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **VOTE ON CHANGES TO XOPENEX® PRIOR AUTHORIZATION**

For Public Comment, Justin Springfield: I'm an account director with Sepracor Pharmaceuticals and I just want to offer a couple of comments based on the current considerations with regard to the PA criteria for Xopenex. When you guys first developed the original criteria two years ago in 2004, I was transitioning into this geography and before coming to an Oklahoma DUR meeting, I'd only been involved with states that made preferred drug list recommendations based on supplemental rebate offers and recommendations from third parties such as Provider Synergies. And what I saw that evening in this committee and I was acutally looking through some of the minutes, it was really interesting to see the thought process, and you know Dr. Whitsett, I really liked Dr. Whitsett, so I could kind of hear his voice as I read through these minutes in determining, you know, which patients are not going to respond to Albuterol and why they might need access to Xopenex. And the committee started from the basis of all asthmatics exacerbate and all asthmatic exacerbations are potentially life threatening. So since there are only two drugs that will treat a life threatening event, bronchospasm, maybe the PA criteria for bronchodilators shouldn't be the same as the PA criteria for antihistamines. Maybe you shouldn't put a PA between the patient and their ability to get the drug at the pharmacy because especially in a rural state like Oklahoma, if you're at a pharmacy at night or on the weekend and you have a prescription for a drug that you can't filled, it might be an hour drive to the nearest hospital and if you're in an acute situation, that's not a good thing. So as you guys discussed this and looked at the three different recommendations that Ms. Flannigan had laid out for you and they were all really unique and creative things that I had not seen before, and that impacted me because the recommendations as they are, they insure appropriate utilization, they positively impact patient care because when the PA is invoked at 90 days, that patient has to be on corticosteroid. That's what the guidelines say and that's what your PA, your current PA process does. It insures that the patient's on a corticosteroid and we all know corticosteroid compliance is the biggest issue with asthma therapy in this country. And the other thing that, reason it impacted me, it's good policy. It's good policy. Everyone from the National Black Caucus of Legislatures and the Asthma, Allergy and Immunology Coalition had issued policy statements saying that PA of rescue medication might not be a good thing. You know, putting access barriers to an acute rescue medication for asthma. We'd rather not see that happen. So actually I took that and I presented it to Texas, and I presented it to Scott White and different health plans that I called on and it made me, it gave me the ability to actually be a value added service to my customers because a lot of people, a lot of institutions, a lot of IDN's, a lot of managed care organizations, they experience overutilization of Xopenex, right? I mean, Albuterol works for the most part. It's not, everybody doesn't need Xopenex. But when you do need it, it's a potentially life threatening situation. So I just wanted to commend you for the current criteria that you developed, because what that criteria do or basically eliminate the possibility that a patient could leave the pharmacy without their rescue medication. But at the same time it prevents the patient from getting too much rescue medication because you can't get more than three months of the drug without justifying why you need more. If you're on three months of a rescue medication, you're on a corticosteroid, you need to go to a hospital anyway. So because of the fact that it insures appropriate utilization, it protects patients and positively impacts the quality of patient care and it's good policy, I would ask for you to vote "no" on the current recommendations because the ones you guys have put in place are so well

thought out and they're so good. They've been duplicated in Arkansas, they've been duplicated in other Medicaid states across the country and about 43 Medicaid states have open access for Xopenex because they're all into medications in the class that will save a kid's life. And I don't mean to be an alarmist, but fifteen kids do die every day in the United States from asthma exacerbation. And there's only two drugs that can treat that event when it happens, so I would ask you not to take one of those options away from the little humans in the State of Oklahoma. I thank you for your time and consideration. I'd be honored to entertain your questions.

Dr. Kuhls: I guess my only question is, I thought there was more than two drugs that you could give in emergency situations.

Mr. Springfield: For acute bronchospasms?

Dr. Kuhls: Uh-huh.

Mr. Springfield: Short acting beta agonists, I believe, is what the guidelines say.

Dr. Kuhls: I guess epinephrine's not a drug that .....

Mr. Springfield: Epinephrine's a bronchodilator.

Dr. Kuhls: So there's more than two drugs.

Mr. Springfield: Yes there are.

For Public Comment, Scott Cyrus, D.O.: My name is Scott Cyrus. I'm a pediatrician from Tulsa. I chose to sit in the chairs that you're in right now for the task force for perinatal meeting and the new child health meeting, so I know there's a lot of things that come across your desk and everything, and so I just wanted to take a little bit of time this evening. First to thank you for allowing me to come up here and talk to you, but more importantly, I take care of a lot of children with trachs. I take care of a lot of children with chronic pulmonary problems in northeast Oklahoma. According to the Oklahoma Health Care Authority, because these children have a tendency to make their way to the Medicaid system because they just outdistanced the private insurance companies, they hit their $2 million, $1 million dollar maximums. I see a lot of these kids on Medicaid and these kids respond very well to levalbuterol, there's no doubt about it. And they respond very well, obviously to your, they respond well to your racemic epinephrines. But we don't send them home on that because there's too much beta-1 activity when you start talking about racemic epinephrines and sending children home on that, and depending upon the parents to truly give this in the way that it should be given. So we have really and truly, two options. We've got albuterol and we've got levalbuterol. And so in the hospital, when I've got a nurse who's giving the medication I think that it's great. We can do racemic, we can do Atrovent, we can do different medications from that sample. But when I have to depend upon a parent to do this, it's not feasible. It's not good for the child's health and as a child advocate, I have to stand up and say we've got two drugs, we've only got two drugs. And when you talk about the waiting to try to give a child albuterol, I have a child who acts out and I've got a 7-year old who has a trach and a G-tube, and they act out in school when given albuterol. Or they have a problem with the side effects from albuterol. And so as to wait and have a prior auth applied to that, I think that all we're doing is hurting the child. We're hurting the child in multiple ways at different levels of their education, at different levels of their development, and so I have, you know, I tell you that it makes a big impact on our outpatient therapy. What you're thinking about, moving toward, is prior authing. We have a, it makes a big impact on my kids when you talking about taking from outpatient therapy and taking care of a child from an office base to having to place them inpatient because they don't respond to receiving albuterol. So I think that as you have it set up at this point in time, it works extremely well. Is it costly? Yes, medications are costly and I think that what you do, keeping a thumb on the cost of medications, is a very wise idea. But when you compare to the cost of the inpatient admissions, compared to what you see as those children who can go home with a nebulizer and with a levalbuterol, I think that you're making the wise choice. Can they go beyond 90 days? I don't mind as with my chronic patients. I have probably twenty to thirty trach patients that we do pulmonary toileting on and we have to use a short acting beta agonist. Yes we use a, we use a corticosteroid, but these children, to keep them out of pneumonia, because you've got to realize, one of my children, when my kids go to the hospital they don't go to just the floor. They go to the PICU, so you're, that creates a two and three-fold increase. If I can keep these children home using home health as merchants, it makes a huge difference, a huge impact on what we do. I mean, you can ask Mr. Fogarty. That I take care of a lot of trach patients. Really I like doing it. We've been in on a lot of discussions as far as taking care of these patients and we work very closely together as far as trying to do nursing care as far as doing medications and so on and so forth. So as far as what you're doing, I think it's a very wise idea, but the prior auth, trying to keep us having to you know, Friday afternoon, we can't use levalbuterol to try to keep these kids out of the hospital. I think it's a little restrictive. I think that it's really wise from your standpoint as far as trying to keep the cost down in the state, is to use the 90 days and allow us as pediatricians, to use our judgement and to move forward with the process that you have in place at this point in time. I know that, like you said, that access to care is a big huge issue, and we've talked about this many times and so what we have, our problem, part of our problem in northeast Oklahoma is that we've lost our pulmonologists. Okay? And one of the points that you make is that we've got a pulmonologist that can prescribe it. And that makes a barrier, because we don't have one. So you eliminate that as a possibility. So I would ask that you keep the current plan in place. It works very well for what we have. I've got a child who I've had on levalbuterol for the last four years, five years. She is a trach, she had a trach. We were able to get it out. But we do constant daily pulmonary toileting and we try to move them forward and we keep them out of the hospital. For the last three years we've been able to keep her out of the hospital, so you know, I would ask that you look at this and when you look at it, think about those kids that access a barrier as far as their care. I would entertain any questions.

Dr. Feightner: Doc, what percentage of your patients do not respond to racemic and you have to switch them to the levalbuterol. What percentage? I'm reading the studies, in one of the studies it says no significant difference, no significant difference, no significant difference. Can you tell us that you have a significant difference in your practice?

Dr. Cyrus: In my practice I don't use racemic on an outpatient basis. I don't know of in any practice that I've seen uses racemic epinephrine on an outpatient basis. We only use racemic epinephrine on an inpatient basis.

Dr. Feightner: How about albuterol?

Dr. Cyrus: I'm sorry. I was thinking racemic epinephrine. How many do not respond? I would say .....
Dr. Feightner: Percentage, give me a percent.
Dr. Cyrus: What's that?
Dr. Feightner: What percent do you have to convert from albuterol to the Xopenex?
Dr. Cyrus: I probably convert 30%.
Dr. Feightner: Because they don't respond?
Dr. Cyrus: Because they don't respond. I mean, it's to the point where I don't necessarily go to it as first line. I mean, it's kind of like saying I've got a goopy eyed child and I've got an otitis media . . . I'm going to use amoxicillin. When I know that it's H flu and I know that H flu is resistant to amoxicillin. There's a certain percentage of it. So am I going to take the chance that this child's going to be a non-responder and come back in ten days and be upset and they've got to pay another co-pay for another drug? Or do I just skip over that and say, clinically I look at it from a clinician's standpoint and say, this is the route that we're going to take. And that's typically what my parents want. They want my best judgment from my experience. And the studies that I've seen. You look at Rainbow Children's. I don't know if it's in the studies or .....
Dr. Feightner: I've got one, two, three, four, five, six .....
Dr. Kuhls: The Rainbow I think is the converse ..... well that's a very interesting study but ....
Dr. Cyrus: It is. I mean, you could make a, I mean I do research for Merck and I do, you know I'm in the middle of doing different things, and you can make the numbers, as we all say. You can make the numbers say what you want. But the experience that I've dealt with in dealing with the aged, blind and disabled population that I'm willing to take in my private practice and not send to OU and OSU so that every, you know every three years they get a new rollover of residents. What I brought in is trying to deal with the Oklahoma Health Care Authority and trying to maintain costs, keep the children out of the hospital. I mean, I've been called by the pediatric intensive care unit physicians and said, would you take this patient because every time we get a call, they come to the ER, they come to PICU because they're, because they have a cough or a cold or whatever. And so I work I mean with Lynn Mitchell, with Mr. Fogarty, I work really close trying to maintain those costs. I have my own private practice. I own my own private practice. Cost is a huge issue and I understand from what we're, what you're dealing with. I understand it on a first line basis. But this is a medication that is extremely important to my practice. I use it on a daily basis. I don't know that a third of the time, you know it would be great if I knew what third was going to fail. It would be great if I knew what third was not going to make, go forward with it. But I've got a number of patients on this medication and it is a, it's a good medication. I've seen the studies that you're talking about. Bill Banner and I have bantered back and forth if you will, with CommunityCare insurance about the levalbuterol question. But it has, there are other issues, there are places to use it.
Dr. Feightner: What's your definition of failure, too? Is it an ER visit? Is it ..... what's your definition of failure?
Dr. Cyrus: Well that's really a wide open question when you start looking at, is it an admission, is it an ER visit, is it a child who is tachycardic, is it a child who is tachypneic and the parents don't realize they're tachypneic, is it a child who is hypoxic, they don't realize the child's hypoxic? Because you won't be able to tell me a child who is 92 on a pulse/ox versus a child who is 88. But I will admit the child who is 88 and I'll send the child home who's 92. I mean when you get a call from a parent that says, you know, they are absolutely wild after their albuterol, is that a failure? I mean .....
Dr. Feightner: That's my question to you is what do you look at as a clinician?
Dr. Cyrus: Well as a clinician and as a person, as a physician who deals with parents and who deals with hospital admissions, I take care of all my own patients in the hospital and so when I look at a patient who fails, it is a hospital admission. It's a complaint, it's a problem with that patient, when they have a heart rate that's over 200 because they're tachycardic secondary to the albuterol. That is hypoxia that doesn't respond. Now can I take a racemic epinephrine, do I take a racemic epinephrine patient, or racemic albuterol patient and get them the drug, turn right around and give them an albuterol treatment in my office? No, it's one or the other. It's one or the other. Now have I had more success with levalbuterol or racemic albuterol? Levalbuterol.
Dr. Feightner: Levalbuterol dosed high enough and albuterol dosed high enough, could still bring in beta-1 effects. I mean you dose it high enough, you're going to get beta-1 effects, so saying that you get away from that, I mean, would you agree that dosing of the steroids would be the appropriate change if you know, we're not talking the life threatening situation here. Physicians should probably address it with steroids versus switching to .....
Dr. Cyrus: There's no doubt in my mind that I have given many times, have given Pulmicort and levalbuterol in the same nebulizer and given it at the same time and seen what the response is. Are they getting more response from the Pulmicort, are they getting more response from the Xopenex? The overall response is a child who can go home, not a child who can go to the hospital. Now and this is really, truly just clinical, just I mean, it really is the way I clinically treat my patients. I mean, that's just the way that, this works for me. Do I do levalbuterol and they go home? Yes, I do.
Dr. Feightner: I was a believer in the Flovent. You know you do the Flovent and Azmacort and stuff like that. I'm going to say not relying on the inhalers, not relying on, you know albuterol I think, from the studies, you know, is the effective drug if the steroids are used correctly. If you keep, you have to use it over and over and over.
Dr. Cyrus: There's no doubt about it in my mind. But when the parent comes in to you and they have a child who ...
Dr. Feightner: It puts you in a tough situation. Puts you in a difficult situation.
Dr. Cyrus: That's exactly right. And I'm in the front line, and I'm down in the ditches as I tell parents .....
Dr. Feightner: We have a 3-day emergency that .....
Dr. Cyrus: That has not worked. I will tell you right up front. That has not worked. I have tried that. I have talked to pharmacists about that, and it doesn't, that's not working. And I mean, again, I'm in the front line, I'm down in the ditches, and I'm telling you it doesn't work. What has worked is showing that when children are in trouble, it works when we have access to

levalbuterol. I mean that's just, and I know that's obviously not what the studies say, but I'm telling you, we don't live in an ivory tower. We live in Oklahoma, rural Oklahoma .....

Dr. Kuhls: Let me ask you a couple of questions. To be open and honest, to start out my conversation, what you've told me, some of the stuff really scares me. Okay? Let me tell you what scares me. I believe that the physicians . . .

Dr. Cyrus: Sorry, can I ask you a real quick question? What's your point of view coming from?

Dr. Kuhls: I'm a pediatrician. I am board certified. I have a big practice. I'm in the ditches. I dig the holes. I might not have as many trach patients as you, but I have some. I have a lot of asthmatics. I use a lot of albuterol. I'm a pediatrician, so that's where I'm coming from.

Dr. Cyrus: Okay.

Dr. Kuhls: Let's start out with what you said in terms of otitis media. If I know that there's a possibility of H flu, I want to give the drug, is that what you're telling me, that is the most broad spectrum that's going to take care of that right from the beginning?

Dr. Cyrus: If I think it's H flu, I want something that's going to attack H flu, yeah. Not necessarily broad spectrum .....

Dr. Kuhls: Despite the fact that over 70% or so of otitis medias go away by themselves and the new push in this country is not even to treat otitis media, but to sit and watch because of that fear, you're going to put everybody on the most broad spectrum, most expensive, widest thing that there is to treat this because you're down in the ditches and you don't care what the studies say, but you know . . . is that right?

Dr. Cyrus: I know that probably about 80% of them, if you look at the European studies, about 80% . . . I mean not that we want to digress . . .

Dr. McNeill: Let me interrupt. As Chair . . .

Dr. Kuhls: No, but it has to go back to the same process as how you look at albuterol.

Dr. McNeill: As Chair here, I want to stay focused and I want to wrap this up here.

Dr. Kuhls: That was stated, because now I want to shift back and use that argument to the argument in terms of using albuterol versus using Xopenex. Okay?

Dr. McNeill: Okay.

Dr. Kuhls: So on that basis I understand how you believe that since there are a few patients out there that do get side effects more from albuterol with the basic philosophy of how you treat, I can understand how you use a lot of Xopenex. And that's what you were trying to explain, right?

Dr. Cyrus: I use Xopenex because it's a drug, it is a medication that works very well. And I see side effects, I use also racemic albuterol, I mean there's no doubt about it. I do. When those parents and those patients that can tolerate racemic albuterol that show to do well on racemic albuterol, I've used it.

Dr. Kuhls: Okay, so my whole point then is that if you have a drug that works pretty well and is cheaper versus a drug that in a very few patients, some patients have side effects, that probably in good clinical practice in the trenches, that sometimes it's better to try the cheaper drug that works almost all the time and then if we have side effects, then we can start talking about Xopenex. That's fair practice?

Dr. Cyrus: That is fair practice.

Dr. Kuhls: Okay, good. Then my question is, is that in a situation where you have a PA for three days, where for the practitioner that doesn't routinely use albuterol who albuterol is used in the past and worked well, you still give them a little bit of window, but we really want to get physicians to use albuterol first and then if we have side effects, then we can PA it and do that, that's probably pretty fair practice.

Dr. Cyrus: If it worked. And I don't know as far as where you got this, I am not . . .

Dr. Kuhls: So you're saying that albuterol, so you're believing that, so you're believing that routine .....

Dr. Cyrus: I have not had to deal with the process of PA'ing it for 3 days ..... because in the process of PA for 3 days, it hasn't really worked for me. I mean, because I had discussions with the pharmacists ....

Dr. Kuhls: If the PA process worked, then the 3-day thing would work ..... is that true?

Dr. Cyrus: Yeah.

Dr. Kuhls: Okay.

Dr. Cyrus: Yeah, but if everybody responded .....

Mr. Springfield: Here's a patient in Mississippi that died because she didn't get her 3-day PA. The problem with the 3-day PA is not all pharmacists know about it, and on top of that, when you walk into a pharmacist's, you give your prescription usually to a tech who puts it into the claims adjudication system and if it says it's not covered, the tech says it's not covered. They don't say oh, I know the code for the emergency PA, I'm going to send this patient home with an emergency 3-day supply. It's a CMS law, too, to have an emergency 72-hours supply, but there's no emergency 72-hour police running around making sure pharmacists do this.

Dr. Cyrus: I just haven't dealt with it. I mean as far as, I've dealt with the parent who I have, and thank goodness, thank goodness Sepracor gives us samples, because I've dealt with the fact that I've given samples to the parents from the drug companies that gets them through the weekend so we can get the process going. Because I have patients who I've already documented four years ago have tachycardia to albuterol, racemic albuterol, that I have to go back through the process of PA'ing again because of the change in, actually the change hasn't even occurred and I can tell you right now that just two weeks ago, I already had to PA somebody who was on Xopenex who has had an adverse reaction to racemic albuterol. One of my chronic kids. And the process hasn't even gone through yet and I'm already dealing with it because we're discussing it today. And I don't know, again, I don't know that you're doing that. I know that I'm doing it. And that's the only thing I can really talk about, is just tell you that this is where I'm coming from. I'm willing to take care of these kids in an open fashion. They call me from, you know, different organizations call me all the time, and I enjoy taking care of them. But I also know that that's in my

armamentarium and it's a problem if you'll just put a halt to it. That's all I'm saying. If we just put a halt to it and even if you put in a 72-hour process, I'm just, all I'm telling you is from my point of view. I'm a humble pediatrician in Tulsa, Oklahoma that just tells you that it's a problem. It's a good drug, it works well, it should be available. I agree with you that it doesn't need to go rampant, you know. If you see it going rampant I think you need to address it. I think that the letters that I get about drugs with my children, especially my chronic kids, that I do from the Oklahoma Health Care Authority, is done in a very honest fashion. And I try to address them in a very honest fashion and I think that's a way that you can address this issue. If you start seeing, you know, somebody that has no proof of it, but to just, to put a halt to it, I think that you're changing a lot, making a big change, I really do. Any other questions? Thank you very much for your time.
Materials included in agenda packet; presented by Dr. Flannigan.
Dr. Bell moved to table; seconded by Dr. Meece.
ACTION: MOTION TABLED.

AGENDA ITEM NO. 6: ANNUAL REVIEW OF GROWTH HORMONE PRIOR AUTHORIZATION CATEGORY
Materials included in agenda packet; presented by Dr. Moore.
Dr. Kuhls moved to approve to add SHOX to PA criteria; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: ANNUAL REVIEW OF SMOKING CESSATION PRIOR AUTHORIZATION CATEGORY
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: 30-DAY NOTICE TO PRIOR AUTHORIZE OCULAR ALLERGY MEDICATIONS
For Public Comment, David Jackson, M.D.. I'm David Jackson. I am a clinical assistant professor of opthamology at the Dean McGee Eye Institute. My potential bias tonight is I was asked to speak by Michael Mason with Alcon, so I'd just like to throw that out there, but really I'm going to stay away from it and talk to you more about science in my clinical practice. I'm a researcher. I'm currently involved in both basic science and clinical research. I'm an author. I'm a teacher. I teach our residents and I'm a clinician, taking care of patients. I moved here about four and a half years ago and until then I didn't have, see more allergy, didn't have it. So we're living in the allergy belt. The current recommendations, I take a little bit of an issue with, only because it sets those patients that have to follow these recommendations aside from my normal clinical practice. I will not treat them in a similar manner that I treat my current allergy sufferers with. And based on the scientific data, and I asked Michael to just list the studies on different medications and give you each a packet of them, Cromolyn is, it's approved for vernal conjunctivitis. It's a drug that takes seven to fourteen days, seven days at the least, fourteen days typically to be effective, and is at the bottom of the efficacious ladder when you look at many of the other drugs in the mast cell stabilizer class. It's not a drug that I've written for in eight years. Not to say that it doesn't have its' good points, because it certainly does. You can stay on it for two weeks. You can minimize some of the symptoms associated with ocular allergies. But it's really for treating vernal conjunctivitis. That's what it was approved for. And the current state-of-the-art treatment for vernal doesn't put Cromolyn at the top. It's steroids and cyclosporin A. And that's really not, you know, my issues, but the point is that Cromolyn is really is an outdated ocular allergy medication. If you take me for example, I'm on two different ocular allergy drops, a nasal spray and pills. And if I had to be on a drop that took fourteen days to work, I would miss four days in the operating room and clinic time. Now I mean I know that's not the population of patients we're talking about. It's just not. But that's not the standard of care. It's not the standard of care. The standard of care really falls to the mast cell stabilizer antihistamine class. It really does. That's the current standard of care for seasonal allergies which are the most common form of allergy care in Oklahoma, well just about anywhere. I'm excluding severe allergies, vernal and atopic which can actually do corneal scarring and blindness. I'm excluding those because those are treated way differently and that's not the purpose of this recommendation, is to treat that sort of severe disease. If you look at the clinical papers, and I'll just go over the drug utilization board handout, if you just have that handout available. There are four studies. You can ignore the mast cell stabilizers. It's the second to the last page of the handout and it just kind of shows the clinical studies, plusses and minuses where drugs perform well. And the drug, I'm excluding just this whole mast cell stabilizers, and looking at the mast cell stabilizer/antihistamine combinations. The drug that has the greatest preponderance of clinical evidence for being efficacious is Patanol. It's been around the longest. It has the most scientific data behind it. And the one category that it has here with Zaditor, there's a plus/equal sort of thing. That's a ten to one scientific bias right there. The only paper I'm aware of and it's listed in the handout here, is the Ganz study that says that Zaditor is equal to or superior to Patanol and that's a very poor study. There's only about 32 patients in that study, non-ocular allergy patients were included and so, I mean, it is, you know, you can say that it was a published peer reviewed study, but it's not of a calibre of the other studies that are listed. And I would strongly say that an over the counter medication that couldn't make it as a prescription medication is not a good choice for first line ocular allergy treatment in the allergy belt. It's, I understand why the decision was made. I'm sure cost was a big factor on that and I would urge you to pressure the companies

and competively bid them. You know, that's to save money, but also to treat my patients, you know, with something that I know is going to work. That's about for it. We can get into the scientific data or I can try and answer any questions . . .
Dr. Kuhls: So that's the only study you know, Patanol versus Zaditor?
Dr. Jackson: No, that's the only study . . .
Dr. Kuhls: That says they're equal.
Dr. Jackson: Yeah, exactly.
Dr. Kuhls: How many studies are there then that say directly compare?
Dr. Jackson: In your, in your stack, there are at least five studies. There is one listed in the references here which I do not have and I have not read and I'm not aware of the results. And that study is the Avunduk study. I don't know that study. So, but and those are just the studies I know of. I'm sure that there are more out there. But it's by far the preponderance of clinical, it's not only clinical, but scientific evidence that says that Zaditor is not on the same playing field as other drugs in the class. I know there's a big cost savings there and I know that that's something you have to be very, very concerned with. But I don't see that as being a very, a very smooth route to go by. It would mean more visits, failures, and ultimately a drug that works.
Dr. Feightner: Do you believe Zaditor OTC is effective for treating the allergy symptoms? Are you saying the drug in your opinion is not effective in the allergy belt?
Dr. Jackson: What would you say are allergy symptoms?
Dr. Feightner: Itchy eyes.
Dr. Jackson: Yeah, what else?
Dr. Feightner: Runny eyes.
Dr. Jackson: Runny eyes.
Dr. Feightner: Water, tearing.
Dr. Jackson: Runny water teary eyes.
Dr. Feightner: Sneezing.
Dr. Jackson: No, no .... just eyes.
Dr. Feightner: Just eyes? Is it just out of the eyes? That'd be my two.
Dr. Jackson: And there's chemosis and, well there's four. We've got three of them. It's only approved for itching. And there is only one study that shows it's equal to olopatadine, and that study's a poor study. And in my clinical experience, it doesn't work. So I wouldn't even write the prescription, much less ask them to spend a visit with me and then go get an over the counter they could have gotten without ever seeing . . . that, that will not fly in my insured class and I don't think it's standard of care. I . . .
Board Member: I was looking as far as from a, as a first line trial before it comes to you. Before it comes to you, are you .....
Dr. Jackson: No. I mean, if you look at it like that and they go to the pharmacy, and everyone's gone to the pharmacy and tried it, and then they come to me, well that makes sense. But, I mean that's not how, it tends to not be how I see the patients.
Dr. Feightner: Cause it's easier to document Zaditor OTC, you know, if the patient said, you know, we have tried it before, over the counter, you know, and failed. The outcome to me and a patient being satisifed with the allergy symptoms is, you know, relief from that, is what we're looking at, you know. Can Zaditor produce those effects?
Dr. Jackson: Not very effectively.
Dr. Kuhls: That's scary, 'cause in my eyes they do. I think I've got Zaditor in them right now. Matter of fact, I know I do.
Dr. Jackson: Yeah, that's not just my opinion. That's the scientific evidence. I mean that really is the scientific evidence. I'm not speaking based on my opinion. I mean if you ask me my opinion, and you did, I'll tell you. But it's based on scientific evidence and my clinical practice.
Dr. Feightner: I just dispense this drug a lot and I think a lot of physicians would have pulled off of this drug and it been almost blackballed if it didn't work, efficacy in some patients, in a lot of patients. They would have pulled away from it, shyed away from it, not prescribed it at all. I'm not trying to argue . . .
Dr. Jackson: You're right and if you look back at the last drug utilization board notes, and you see what is the percentage market share of Zaditor versus the other antihistamine mast cell stabilizers, and you'll see that it's 80+% other, 75% Patanol, 5% Zaditor.
Dr. Gourley: I also think the perception that he brought up as OTC versus prescription is a very valid perception of physicians that an OTC product is not any good and a prescription product is better. I think that's a built-in bias that you have.
Dr. McNeill: Well it's the same thing we had with benadryl and Claritin.
Dr. Feightner: That doesn't make it right, though. Doesn't make it ..... correct.
Dr. Gourley: No but I think it's a perception.
Dr. Feightner: People come in to you, they want a prescription, I mean they come in to a doc . . .
Dr. Kuhls: I think it's the patients.
Dr. Gourley: Well, that too. Yeah.
Dr. Jackson: Yeah. I mean if primary care doctors were seeing everyone and trying them on OTC Zaditor and then they were coming to me, I wouldn't have any problem with that sort of scenario because it allows me to treat them to the standard of care that I treat my other patients.
Dr. Muchmore: Are you aware of any head-to-head trials between 0.1 % olopatadine and 4% Cromolyn Sodium? I don't know of any. I have not seen . . .
Dr. Jackson: There are. I think there are a couple in your packet, in fact.
Dr. Muchmore: No, not olopatadine and 4% Cromolyn. There's one with 2% which is not even marketed that I'm aware of.
Dr. Jackson: Yeah. I think the majority of the trials were with 2%. Cromolyn again is approved for, was initially approved for vernal, you know, which is a very, very serious eye disease. It leads to corneal vascularization, corneal scarring and blindness.

And Cromolyn's not even the standard of care for that disease anymore. It's steroid drops and cyclosporin A. It's a major basic protein that's released from the eosinophils that line the palpable conjunctivitis, causes horrible shield ulcers. And cyclosporin A does a wonderful job of treating that. So I intentionally excluded vernal and atopic because those tend to be much more severe diseases than seasonal, itchy, runny, watery, red eyes.

Dr. Muchmore: I'm sure you tend to see some of the more severe ocular allergies, because most of them are treated by family doctors or whatever specialist who they see, oh by the way doc, my eyes are awful itchy this spring, and they get something. The danger is, or the expense is having olopatadine be the first-line drug for these minor ocular allergies and you know, the vast majority of people that have minor ocular allergies do well with all sorts of preparations without jumping to an $80 bottle of olopatadine. This is the thing we're wrestling with. Because yes, you're going to see a biased group that have polyps under their eyelids and conjunctival edema and they really got a problem.

Dr. Jackson: There's, if you look at severe, moderate and mild, the large majority of patients aren't severe and so the large majority of patients I see aren't the vernal and atopic. It's seasonal, seasonal exacerbation. Now I do see the horrible disease as well. And I'm sure there's a percentage of patients that I don't see because they're satisfied with Naphcon-A or Visine or over the counter preparations, but I don't know how to quantify that for you. I can tell you the majority of my practice during the time of year and the fall, 30 to 50% is the moderate group. It's not severe scarring eye disease, it's I'm uncomfortable, help. You know. They have gone through over the counter, over the counter preparations or sometimes not. So I don't' know how to quantify that for you. I mean, I under . . . I understand the expense part of the equation and I don't know .....

Dr. Kuhls: That's why I think the best thing you said tonight is that the drug utilization review board needs to significantly think about how we can reduce the costs the best through the companies. I couldn't agree with you more.

Dr. Jackson: And, and I have to tell you, the companies, indigent care is a big part of our mission, you know. I mean, I, it's probably 5 to 10% lost income, you know, indigent care. It's part of our mission. The companies supply us with medications for those patients, so companies do stand to gain from this. But, you know, the, I don't see it as a, it's hard to just see it as a dollar sign. I mean, it comes down to that. I mean it does. It comes down to that . . . try to . . .

Dr. McNeill: Could I, you know I kind of view this as the years ago when we had the benadryl nonsedating antihistamine issue. This is much different than the asthma issue where a kid could go home and die over the weekend. The way we solve that if you remember, is that as long as there was documentation of a 14-day trial of something over the counter, it doesn't have to be tier-1, but why not, you know, if you've had Visine for 14 days and it didn't work, if you tried this over the counter prep and it didn't work, why would that not make you eligible for a tier-2?

Dr. Gorman: Those aren't as effective as Zaditor.

Dr. McNeill: Those are less effective, okay that's what you're telling me? Those are less effective even than Zaditor?

Dr. Gorman: I would say so, yes.

Dr. Jackson: I think that's true. I mean, because they're all short term. Short term and some with significant rebound effect.

Dr. McNeill: I was trying to help you out here.

Dr. Jackson: But I can't agree with something I don't agree with. But let me take that just a step farther and that is, why does it have to be Zaditor over the counter? Because .....

Dr. Muchmore: Well it doesn't have to be. Cromolyn Sodium is tier-1.

Dr. Jackson: Yeah, but I mean that's .....

Dr. Muchmore: Let me ask you a question. You're fairly young and olopatadine's been available your entire clinical career.

Dr. Jackson: No, well not .....

Dr. Muchmore: Have you ever ....

Dr. Jackson: Yes, I've written for Cromolyn. Patanol really wasn't well prescribed for a few years into my training.

Dr. Muchmore: And you're saying that in your clinical experience, Cromolyn Sodium is ineffective?

Dr. Jackson: No sir. I'm saying that the scientific literature, the peer reviewed publications say it's not as effective as mast cell stabilizer antihistamine combinations.

Dr. Muchmore: Well now wait a minute. I still have yet to see the study with olopatadine and 4% Cromolyn.

Dr. Jackson: That doesn't mean .....

Dr. Muchmore: That study doesn't exist so far as I know.

Dr. Jackson: That doesn't mean you can say it works and recommend it.

Dr. Muchmore: There's never any question that olopatadine works. What we're saying is that Cromolyn Sodium works very well in the vast majority of seasonal allergic conjunctivitis . . .

Dr. Jackson: Where is that paper? Where is that study? I have not seen that study. Especially when it's compared with mast cell stabilizer antihistamines. You know. I have not seen that data. That data doesn't exist.

Dr. Kuhls: Well, the Health Care Authority better fund his study, then. There you go.

Dr. Jackson: That would work. But it won't use it.

Board Member: Well, I can't name the study but I know through studies with 4% Cromolyn Sodium.

Dr. Gourley: Well, it had to be effective to get approved. It had to be proved effective.

Dr. Muchmore: See there was a period of time when nobody was manfacturing .....

Dr. Gourley: . . . be FDA approved.

Dr. Muchmore: . . . and that's when olopatadine came out and really got a heavy use because you couldn't get 4% Cromolyn for, what, six years, eight years? But before that, you know, it was a very effective treatment.

Dr. Jackson: At its' time, it was the only thing we really had.

Dr. McNeill: Any other questions from the Board? I apologize. This is not an action item tonight, so .....

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

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **30-DAY NOTICE TO PRIOR AUTHORIZE VYVANSE™**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE FLECTOR®**
Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **30-DAY NOTICE TO PRIOR AUTHORIZE QUALAQUIN®**
Materials included in agenda packet; presented by Dr. Patel.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **NEW PRODUCT REVIEWS**
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

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

AGENDA ITEM NO. 14: **FUTURE BUSINESS**
14A: ADHD Tier Changes
14B: Anxiolytics
14C: Opthalmic Anti-Infectives
14D: Glaucoma Products
14E: New Product Reviews
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

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

The University of Oklahoma College of Pharmacy

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

Memorandum

Date: April 12, 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 April 11, 2007.

Recommendation 1: Vote on changes to Xopenex Prior Authorization

TABLED by majority approval

The College of Pharmacy is to review and bring back new recommendations for this category.

Recommendation 2: Annual Review of Growth Hormone PA Category

MOTION CARRIED by unanimous approval.

Add SHOX (short stature homeobox-containing gene) deficiency to covered indications and the following criteria.

- *Chromosomal analysis diagnosing SHOX gene anomaly*
- *Height below the third percentile on growth chart*
- *Open epiphyses*
- *Normal endocrine screen*
- *No evidence of GH deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth*

Recommendation 3: Annual Review of Smoking Cessation PA Category

NO ACTION Required

The College of Pharmacy recommends continuation of current prior authorization criteria. Additionally the College recommends initiation of an educational outreach program to members starting on smoking cessation products. The DUR Board also recommends a more in-depth program be developed to further decrease smoking among the SoonerCare population.

ALLERGY & ASTHMA CENTER

Martha M. Tarpay, M.D.
Board Certified in Allergy and Immunology

4200 Memorial Rd. Suite 206
Oklahoma City, OK 73120
(405) 752-0393

April 11, 2007

Attn: Nancy Nesser, PharmD
Oklahoma Healthcare Authority

Dear Dr. Nesser,

Please do not restrict access to Xopenex for Oklahoma Medicaid patients or physicians who choose to write it. Not only Pulmonologist but Allergist are involved in the management of asthma. Pediatricians and Internist also manage their patients with this drug.

There should be open access to ALL rescue medications.

Sincerely,

Martha M. Tarpay, M.D,

Richard G. Wood, D.O.
Pulmonary Disease
Internal Medicine
Critical Care Medicine
4200 W. Memorial Rd., Suite 708
Oklahoma City, OK 73120
(405) 752-5864

Nancy Hesser PharmD

I would like to express my opinion on the restriction of rescue medications, specifically Xopenex. I feel it is not appropriate to restrict potentially lie-saving drugs from any patient group. I am pulmonologist and feel all practioners should be allowed access to rescue medications for their appropriate patients. I favor unrestricted but justified use of Xopenex.

Richard G Wood, DO

COPELAND MACHINING CORPORATION

11222 EAST PINE STREET
TULSA, OK 74116
(918) 437-3311
Fax (918) 234-0077

TO: Nancy Nesser **DATE 4/11/2007**
COMPANY: Drug Utilization Board **PAGES:** 1
FROM: Tracy Copeland **FAX:405-530-7119**
SUBJET: XOPENEX

OTHER INFORMATION:

Very Important!!!!

My son uses this emergency medicine. This would be a terrible Thing to do removing it from your approved list. There are not very many emergency meds out there as it is.

Rural areas will not have access to pulmonary specialists.

Please make the right choice and leave this medicine (xopenex) on the approved list.

Thank You
Mother and Father of a son with SEVERE ASTHMA!!!

Tracy Copeland
Steven R Copeland

AMERICAN LUNG ASSOCIATION- Asthma WALK
www.asthmawalk.org

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April 11, 2007

Nancy Nesser
OHCA
Oklahoma City, OK

Dear Ms Nesser,

It has been brought to my attention today that the DUR will be voting tonight on whether or not to keep xopenex on the Medicaid drug list.

This is a rescue inhaler that is working for many Medicaid patients when nothing else will. For example; the young man that holds the Youth Chair this year for the Asthma Walk can't use anything else without an allergic reaction. He is a Medicaid recipient. There are not that many rescue medications available; so when you restrict one of them it could mean life or death to patients who suffer from lung disease!

I have been told that it could be set up that the only way to get it paid for would be with a written script from a pulmonoligist. What about your rural areas that don't have easy access to a specialist?

Please take into consideration some of the things that I have mentioned and vote NO tonight!

Thank you!

Sincerely,

Ila Allee
Development Associate
918.747.3441 ext 204
iallee@oklung.org

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Tulsa, Oklahoma 74120

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From: Jennifer Jensen [mailto:jjosu55@sbcglobal.net]
Sent: Tuesday, April 10, 2007 3:30 PM
To: Pharmacy
Subject: xopenex

Please keep xopenex available with out a prior authorization for medicaid patients.

Thank you-
Jennifer Jensen PA-C

From: Hopper-Southern, Kim [mailto:kim.hopper_southern@okstate.edu]
Sent: Wednesday, April 11, 2007 10:12 AM
To: Pharmacy
Subject: Xopenex

I was just informed that they are trying to take Xopenex off of Soonercare. I wanted to voice my concern before the meeting you are having in regards to this matter.

I have a three year old son who is on Xopenex prn. He has been diagnosed with asthma and is hospitalized with pneumonia quite frequently. When he gets a cold it goes directly into pneumonia and he goes down hill within a matter of hours. Xopenex is the one thing that helps him feel like he can breathe. We have tried albuterol before and it made his heart race. I have seen the panic on the face of my child because he is in respiratory distress and is scared because he is unable to breath, I have also seen the relief on his face after a breathing treatment of Xopenex.

As a mother of a child who is uses this medication, and also a registered medical assistant, this is such a benefit to not only my son but many asthmatic patients; I am asking that you reconsider taking this away from the Soonercare Insurance because without it I do not know what my son and myself would do.

Thank you for listening and for your consideration of this matter.

From: Hagman, Candice C [mailto:cchagman@saintfrancis.com]
Sent: Tuesday, April 10, 2007 5:11 PM
To: Pharmacy
Subject: FW:

-----Original Message-----
From: Hagman, Candice C
Sent: Tuesday, April 10, 2007 16:58
To: 'medicaidrx@okhca.org'
Subject:

To Whom It may Concern: Xopenex is a useful B agonist for inhalation treatment for children with RAD who cannot tolerate albuteral because of its side effects. It is a useful agent on our medicaid formulary. Sincerely Mona Mange M.D.

I personally have a daughter on soonercare and she is currently on Xopenex and it has done wonders for her she is not so hyper and dysobediant as she was with the albuterol and I am so thankful for that, and the fact that it has worked with her brochospasms so much better if any medication is to stay on formulary I feel it should be Xopenex.

Candice Hagman RMA
Warren Clinic Pediartics
(918) 663-6228 ext 7099

From: Stanley Grogg [mailto:sgroggdo@travelmedicine.com]
Sent: Tuesday, April 10, 2007 8:49 PM
To: Pharmacy
Subject: Xopenex

4/10/07
Attention: Nancy Nesser, PharmD, OHCA
Re: Xopenex

Dear Dr. Nesser:

I am concerned about the DUR's restrictions on the use of Xopenex. As you are aware, childhood asthma is under diagnosed and treated. Unfortunately, for the patient and family, inappropriate medications are frequently given because of cost issues, without regard to the total costs (ER visits, hospitalizations, missed employment, etc) and side effects to the patient. Albuterol is very inexpensive as a bronchodilator, but must be used every 2-4 hrs and results in many patients developing fussiness, tachycardia and tremors. Xopenex, on the other hand, can be given every 6-8 hrs. and has few side effects. A study at Rainbow Children's hospital showed significant a decrease in hospitalization for children seen in the EM and given Xopenex versus albuterol.
I would request that the DUR reconsider the restrictions on Xopenex. If a parent cannot give a medication every 2 hours when needed or is not compliant, the child suffers as does the cost to society.
Thank you for your consideration.

Stanley E. Grogg, DO
Professor of Pediatrics, Ok State Univ-CHS
Medical Director, Osteopathic Medical Educational Consortium of Oklahoma (OMECO)
1111 W. 17th St.
Ste. 250
Tulsa, OK 74107
918-561-8401
Kelly Dipboye, Administrative Assistant
918-382-3190

From: childrensclinicowasso@cox.net
[mailto:childrensclinicowasso@cox.net]
Sent: Wednesday, April 11, 2007 2:45 PM
To: Pharmacy
Subject: Xopenex recommendations

Nancy Nesser
Oklhaoma Medicaid

Dear Ms. Nesser,

As a pediatrician in the trenches dealing with Asthma and bronchospasm, I do not want to be limited to using only Albuterol for treatment of these conditions. Albuterol has limited effectiveness for the patient who is highly susceptible to the side effects of the S isomer found in Albuterol. I have seen a marked difference in many patients who were not effectively treated with Albuterol and used Xopenex with significant improvement in symptoms and a decrease in hospitalizations and visits to the ER. Because Xopenex has such a low side effect profile, I am able to use Xopenex with Atrovent and avoid the jitteriness often associated with combination therapy in the very young patient. I also have seen the rapid onset of effectiveness of Xopenex in the MDI form when multiple doses of Albuterol were ineffective. I implore you to reconsider the proposed prior authorization recommendation of Xopenex and leave the prescribing to the physicians who know their patients very well.

Sincerely concerned,
Cheryl A Boyd, DO

From: McConnell, Wendy MD [mailto:wmcconnell@saintfrancis.com]
Sent: Wednesday, April 11, 2007 11:12 AM
To: Pharmacy
Subject: Xopenex prescribing

I take care of a number of severe asthmatics who require Xopenex. I am extremely concerned that it may no longer be available to my Medicaid and Sooner Care patients. There is definitely better therapeutic efficacy over albuterol, especially in the chronic wheezers who need frequent bronchodilator therapy. Please continue to make it readily available. Thank you Wendy McConnell MD

From: Melinda Dandridge [mailto:drdandridge@yahoo.com]
Sent: Wednesday, April 11, 2007 12:45 PM
To: Pharmacy
Subject: xopenex

Nancy,
I am writing to to ask about Xopenex. I would like to request that Xopenex continue to be easily accessible for the Soonercare patients. It will make our prescribing situation much more difficult if a prior authorization if required before we are able to utilize this drug.
I prescribe Xopenex for infants and older children as well that experience adverse side effects from Albuterol. I have several patients who report Xopenex as a much quicker acting and effective solution also.
As a pediatrician, I feel that the benefits of having Xopenex readily available for patient use is very important. This is a medicaiton used as urgent therapy, and can not wait the 3-4 day process of prior authorization approval before it can be obtained.
Thank you for your consideration.

Sincerely,

Melinda Dandridge, DO, FACOP
Jenks House Pediatrics

Melinda I Dandridge, DO

From: Kathleen Boyls [mailto:KBoyls@hillcrest.com]
Sent: Wednesday, April 11, 2007 10:07 AM
To: Pharmacy
Subject: xopenex

Dear Nancy,
This is to request that you do not remove xopenex from the Medicaid formulary. I have over 200 Sooner Care patients and would like the ability to continue to prescribe xopenex for those patients who do not do well with generic albuterol.

Thank you,
Kathleen A. Boyls, MD

From: Tracy Carson [mailto:tcarson@allergyclinicoftulsa.com]
Sent: Wednesday, April 18, 2007 8:48 AM
To: Graham, Ronald D. (HSC)
Cc: medicaidrx@lkhca.org
Subject: Patanol/Pataday as Tier 1 eyedrop

Doctor Ronald Graham
Oklahoma College of Pharmacy
Dear Sir:
We would like to ask if possible that Patanol/ Pataday be continued as a Tier 1 eyedrop. The decreased side effects, increased compliance, and efficacy are all superior to the two that are currently listed as Tier 1, Crolom and over-the-counter Zaditor.
We treat a number of pediatric patients in this office. As such, we certainly appreciate that this eyedrop would be available as a Tier 2 as a different option. However, we feel that the number of times we will be requesting to go over to the Patanol will make this process time-intensive for everyone. It would be helpful to have Patanol/Pataday available as a Tier 1 option without a prior authorization, given the number of children that we use this in.
We appreciate your consideration of continuing Patanol/Pataday as a Tier 1 eyedrop. Please feel free to contact us with any questions you may have regarding this matter. Any one of us can be reached at 918-307-1613.
Sincerely,
Jane T. Purser, M.D.
James T. Love, Jr. M.D., Ph.D.
Laudy G. Naimeh, M.D.

Allergy Clinic of Tulsa, Inc.
9311 S. Mingo Road
Tulsa, OK 74133
918-307-1613

From: Trent Pitt [mailto:trentjp13@hotmail.com]
Sent: Thursday, April 26, 2007 3:56 PM
To: Graham, Ronald D. (HSC); MedicaidRx@lkhca.org
Subject: State Medicaid Formulary-Patanol

Mr. Graham,

I am writing because I became aware that the state of Oklahoma will be reviewing whether or not Patanol and Vigamox should be on the Medicaid formulary. As an optometric physician here in Oklahoma City, I prescribe Patanol very frequently for the relief of ocular allergies because it is the gold standard for allergy eye drops. I believe that our medicaid population should have the ability to use this drop and that is why I think that it should be kept on the formulary.

Vigamox is the most powerful and effective topical antibiotic on the market.
I use it to treat all corneal ulcers and severe eye infections. I do not feel that my medicaid patients should have to use inferior antibiotics when treating sight-threatening eye infections.

Sincerely,
Trent J. Pitt, O.D.
Optometric Physician

From: Curt Massengale [mailto:cmass@swbell.net]
Sent: Monday, April 23, 2007 4:48 PM
To: Graham, Ronald D. (HSC)
Cc: MedicaidRx@lkhca.org
Subject: Patanol/Pataday/Vigamox

Dear Mr. Graham,

I am an optometric physician and have been providing eye care in Oklahoma City for the past 18 years. I have recently been made aware that there will soon be a discussion regarding the formulary for anti-allergy medications for Medicaid in Oklahoma. I also understand that Patanol and/or Vigamox are being considered for removal from the formulary.

I would like to voice my opinion about, and encouragment for, keeping these two wonderful medications on the formulary. Patanol / Pataday are the gold standard in eye care for eye allergies. The ability to effectively treat allergies would be significantly curtailed without the use of these "best choice" treatment options. As well, Vigamox is one of the top two most effective and safe antibiotics at our disposal.

Thank you for your consideration, and please pass along my sentiments to the committee.

Curt Massengale, OD

Massengale Eye Care
7000 Crossroads Blvd.
OKC, OK 73149

405-631-2020

From: Latricia Pack [mailto:packl@nsuok.edu]
Sent: Monday, April 09, 2007 12:39 PM
To: Graham, Ronald D. (HSC)
Cc: MedicaidRx@lkhca.org
Subject: OK State Medicaid Formulary

Dear Ronald,

My name is Latricia Pack. I teach Contact Lenses I and Contact Lenses II to second-year optometry students and see patients in Contact Lens Clinic, Primary Care Clinic, and Acute Care Clinic at Northeastern State University Oklahoma College of Optometry. I am aware that the state will be reviewing the anti-allergy category for OK Medicaid on April 11 and wanted to express my support for keeping this category, specifically Patanol, on the formulary. I realize there will be some discussion about Zaditor becoming an OTC product. Zaditor is a great medication; however, Zaditor will not provide the most effective treatment for all of the ocular allergy patients I see. Having other drug choices that are dosed at once or twice daily would be the best way to serve the Medicaid patients of Oklahoma. Once or twice daily dosing is ideal for ocular allergy sufferers who wish to wear contact lenses. This allows them to put one drop in before lens wear and one drop in after lens wear.

In addition, I would highly encourage the review board to keep Vigamox on the State Formulary. Although this medication is FDA-approved for treatment of bacterial conjunctivitis, I, and many of my colleagues, rely on Vigamox to treat many types of corneal ulcers. The broad-spectrum activity and chemical structure of Vigamox sets this medication apart from other anti-infective medications, even anti-infective medications within the same classification. And, it is approved for use in children down to the age of one.

Thank you for your consideration of my requests. I trust that when decisions are made about the State Medicaid Formulary, the interest of the patients will be of highest consideration.

Sincerely,
Latricia Pack

Latricia Pack, O.D., F.A.A.O.
Associate Professor
Northeastern State University
Oklahoma College of Optometry
1001 N. Grand Avenue
Tahlequah, OK 74464
(918) 456-5511 x 4044

From: Wes DeRosier O.D. [mailto:derosier@nsuok.edu]
Sent: Monday, April 09, 2007 3:17 PM
To: Graham, Ronald D. (HSC)
Cc: MedicaidRx@lkhca.org
Subject: anti-allergy category for OK Medicaid

Sir,

It is imperative that anti-allergy meds remain on the Medicaid formulary.
Many people, especially in northeast Oklahoma, suffer from ocular allergies and anti-allergy meds are essential to control their symptoms and to allow them to lead a productive and high quality life.

Anti-allergy topical agents such as Patanol and Zaditor are especially important to control ocular allergy symptoms without the risk of systemic contraindications. These medications have had a dramatic positive impact on the quality life of many of my personal patients and the numerous patients of our students and residents.

Thank you for ensuring the best care for the citizens of Oklahoma.

Sincerely,

Wes DeRosier OD FAAO
Director of Residencies
Northeastern State University
Oklahoma College of Optometry
Phone: (918) 444-4027
Fax: (918) 458-2104

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for October 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	41,587	57,542	630,138	32,366
Limits which were applied	Established, Major, Males and Females 0-21 years	Antianxiety Agents, Males and Females, age 43-50 years	Contraindicated, Males and Females 0-150 years, Hypothyroidism	High dose, Digitalis, Males and Females, 0-150 years
Total # of messages after limits were applied	26	224	56	8
Total # of members reviewed after limits were applied	26	204	47	8

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
97		69	

Retrospective Drug Utilization Review Report

Claims Reviewed for September 2006

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Females Age 0-40	Anti-anxiety Agents, Males and Females, Age 33-42	Contraindicated, Drug Dependence/Abuse, Males and Females, Age 46-150	High dose, Duration, Emend, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 73
Response Forms Returned: 31

The response forms returned yielded the following results:

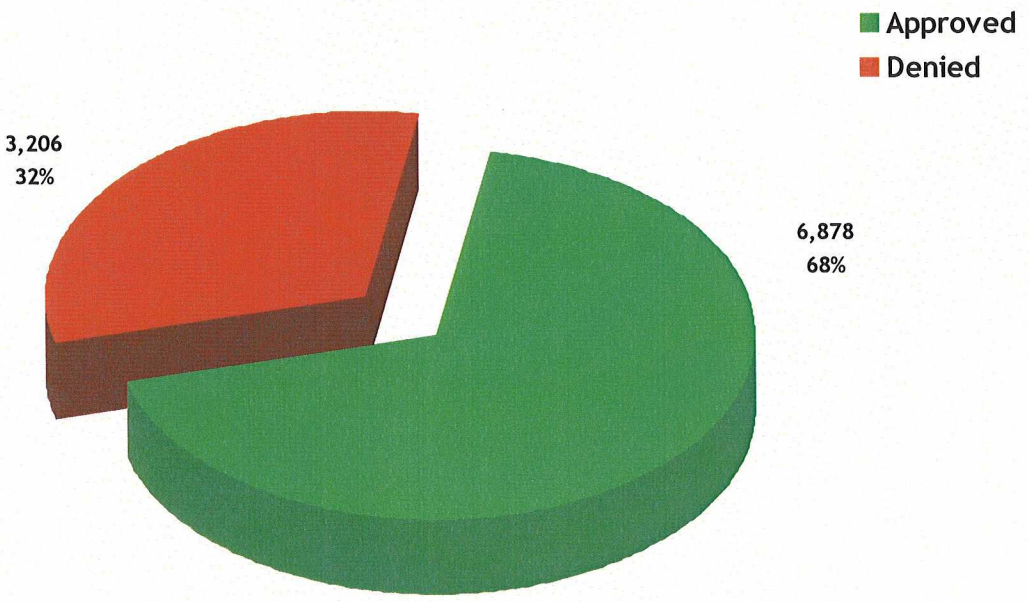
3 (10%)	*Record Error—Not my patient.*
5 (16%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
5 (16%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
14 (45%)	*I am aware of this situation and will plan to continue monitoring therapy.*
4 (13%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 34
Response Forms Returned: 26

The response forms returned yielded the following results:

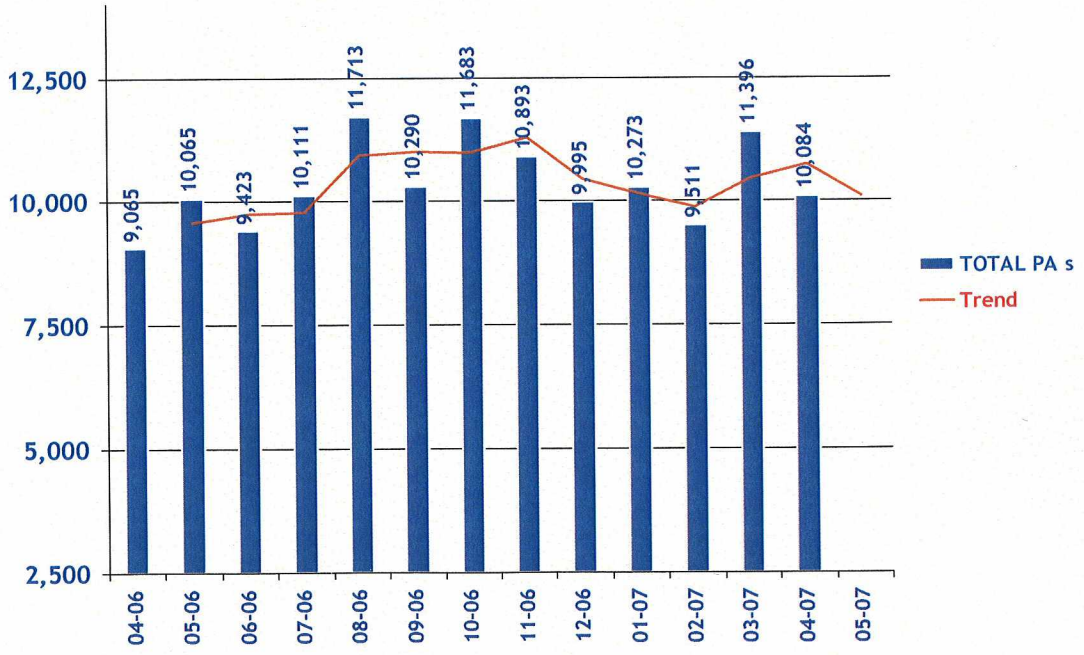
0 (0%)	*Record Error—Not my patient.*
2 (8%)	*No longer my patient.*
2 (8%)	*Medication has been changed prior to date of review letter.*
6 (23%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
13 (50%)	*I am aware of this situation and will plan to continue monitoring therapy.*
3 (12%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
April 2007



PHARMACY Management consultants

PRIOR AUTHORIZATION REPORT
April 2006 - April 2007



PHARMACY Management consultants

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

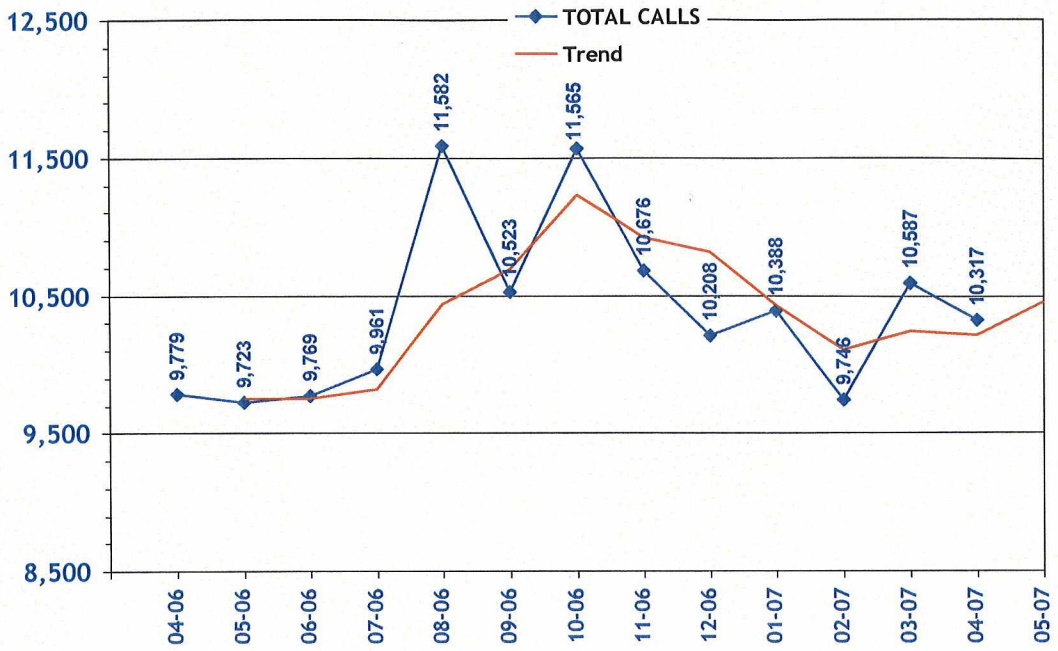
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	89	11	10	21
Angiotensin Receptor Antagonist	353	31	43	74
Antidepressant	303	216	435	651
Antihistamine	102	1,226	808	2,034
Antiulcers	22	16	4	20
Anxiolytic	92	3,143	429	3,572
Calcium Channel Blockers	120	11	29	40
Growth Hormones	161	31	4	35
HTN Combos	328	10	20	30
Hypnotics	90	350	158	508
Nsaids	257	26	87	113
Plavix	358	188	24	212
Stimulant	195	679	243	922
Others	107	936	912	1,848
Emergency PAs		4	0	4
Total		6,878	3,206	10,084
Overrides				
Brand	233	25	43	68
Dosage Change	19	329	31	360
High Dose	91	2	0	2
Lost/Broken Rx	14	83	6	89
Nursing Home Issue	18	60	3	63
Other	10	23	13	36
Quantity vs. Days Supply	183	245	174	419
Stolen	5	9	3	12
Wrong D.S. on Previous Rx	0	0	4	4
Overrides Total		776	277	1,053

Denial Reasons

Lack required information to process request.	3,179
Unable to verify required trials.	1,033
Not an FDA approved indication/diagnosis.	149
Considered duplicate therapy. Member has a prior authorization for similar medication.	102
Does not meet established criteria.	77
Member has active PA for requested medication.	75
Requested dose exceeds maximum recommended FDA dose.	49
Medication not covered as pharmacy benefit.	20
Member not approved for TB coverage and/or medication requested not associated with TB symptoms.	1
Duplicate Requests	946
* Changes to existing	779

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

CALL VOLUME MONTHLY REPORT
April 2006 - April 2007



04-06 thru 03-07: corrected totals

PHARMACY management consultants

Appendix C

Vote to Prior Authorize Flector® (diclofenac epolamine) Topical Patch

Oklahoma Health Care Authority
May 2007

Manufacturer	INST Biochem
Classification	FDA classification: Non-steroidal anti-inflammatory drug (NSAID)
Status:	prescription only

Summary

Flector® is a topical analgesic patch containing 1.3% epolamine salt of diclofenac (equivalent to 1% diclofenac sodium) designed for twice a day application which received FDA approval on January 31, 2007. Each patch contains 180mg of diclofenac epolamine in an aqueous base. The high solubility profile both in water and oily solvents and its significant release and absorption of active ingredient through the skin provides a local analgesic and anti-inflammatory effect with minor systemic exposure to diclofenac. Flector® is indicated for topical use only to treat acute pain due to minor strains, sprains and contusions.

Warnings/Adverse Effects

Similar to other NSAID products, this product requires distribution of FDA approved MEDGUIDE when dispensed.

The most common adverse events associated with the patch formulation were skin reactions at the site of treatment.

Recommendations

The College of Pharmacy recommends prior authorization of Flector® and placement with the Tier-2 NSAID products.

- Approvals will be granted with FDA approved diagnosis
- Clinical documentation supporting use for acute short-term therapy
- Quantity limit for a maximum of 28 patches for 14 days of therapy per month
- Approval based on current NSAID criteria and supporting information regarding the medical necessity of topical formulation

IMPORTANT INFORMATION ABOUT FLECTOR (diclofenac epolamine) PATCHES

1. Flector® Patch, like other NSAIDs, may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death. Although serious CV events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative sign or symptoms. Patients should be apprised of the importance of this follow-up **(WARNINGS, Cardiovascular Effects).**

2. Flector® Patch, like other NSAIDs, may cause GI discomfort and, rarely, serious GI side effects, such as ulcers and bleeding, which may result in hospitalization and even death.
Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative sign or symptoms including epigastric pain, dyspepsia, melena, and hematemesis. Patients should be apprised of the importance of this follow-up **(WARNINGS, Gastrointestinal Effects: Risk of Ulceration, Bleeding, and Perforation).**

3. Flector® Patch, like other NSAIDs, may cause serious skin side effects such as exfoliative dermatitis, SJS, and TEN, which may result in hospitalizations and even death. Although serious skin reactions may occur without warning, patients should be alert for the signs and symptoms of skin rash and blisters, fever, or other signs of hypersensitivity such as itching, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be advised to stop the drug immediately if they develop any type of rash and contact their physicians as soon as possible.

4. Patients should be instructed to promptly report signs or symptoms of unexplained weight gain or edema to their physicians **(WARNINGS, Cardiovascular Effects).**

5. Patients should be informed of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and "flulike" symptoms). If these occur, patients should be instructed to stop therapy and seek immediate medical therapy.

6. Patients should be informed of the signs of an anaphylactoid reaction (e.g. difficulty breathing, swelling of the face or throat). Patients should be instructed to seek immediate emergency help **(WARNINGS).**

7. In late pregnancy, as with other NSAIDs, Flector® Patch should be avoided because it may cause premature closure of the ductus arteriosus.

8. Patients should be advised not to use Flector® Patch if they have a aspirin-sensitive asthma. Flector@ Patch, like other NSAIDs, could cause severe and even fatal bronchospasm in these patients (see PRECAUTIONS, Preexisting asthma). Patients should discontinue use of Flector® Patch and should immediately seek emergency help if they experience wheezing or shortness of breath.

9. Patients should be informed that Flector® Patch should be used only on intact skin.

10. Patients should be advised to avoid contact of Flector® Patch with eyes and mucosa.
Patients should be instructed that if eye contact occurs, they should immediately wash out the eye with water or saline, and consult a physician if irritation persists for more than an hour.

11. Patients and caregivers should be instructed to wash their hands after applying, handling or removing the patch.

12. Patients should be informed that, if Flector® Patch begins to peel off, the edges of the patch may be taped down.

13. Patients should be instructed not to wear Flector® Patch during bathing or showering.
Bathing should take place in between scheduled patch removal and application

14. Patients should be advised to store Flector® Patch and to discard used patches out of the reach of children and pets. If a child or pet accidentally ingests Flector® Patch, medical help should be sought immediately.

REFERENCE

Flector® Product Information. FDA website: http://www fda.gov/cder/foi/label/2007/021234lbl.pdf. Accessed 2007.

Appendix D

Vote to Prior Authorize Qualaquin® (Quinine)

Oklahoma Health Care Authority
May 2007

Manufacturer	Mutual Pharmaceutical Company
Classification	FDA classification: Antimalarial Status: prescription only

Summary

Qualaquin® is the only FDA-approved quinine product available for the treatment of malaria. Numerous drug products containing quinine sulfate were marketed without approved applications for malaria and many are used off-label to treat and/or prevent nocturnal muscle leg cramps and related conditions. On February 13, 2007 the FDA ordered all firms to cease manufacturing unapproved products containing quinine, including quinine sulfate products and any other salt of quinine due to the various adverse events associated with these products.

Risks Associated with Quinine-Containing Products

Serious safety concerns, including fatalities, associated with drug products containing quinine are well documented in the literature and in adverse drug events reported. From 1969 through September 11, 2006, the FDA received 665 reports of adverse events with serious outcomes associated with the use of quinine, including 93 deaths. One of the adverse events include quinine toxicity, a cluster of symptoms that includes tinnitus, dizziness, disorientation, nausea, visual changes and auditory deficits. Serious adverse events include cardiac arrhythmias including torsades de pointes, severe skin reactions, thrombocytopenia and other hematological events, permanent visual and hearing disturbances, hypoglycemia, renal failure and generalized anaphylaxis.

Recommendations

The College of Pharmacy recommends prior authorization of Qualaquin® with approval based on an FDA approved diagnosis of malaria. Off label use for the prevention/treatment of leg cramps and other related conditions will not be covered.

Reference

FDA Updates. Available at: http://www.fda.gov/cder/drug/unapproved_drugs/quinineQA.pdf. Accessed March 26, 2007.

Appendix E

Vote to Prior Authorize Ocular Allergy Products

Oklahoma Health Care Authority
May 2007

Product Summary

Class	Product	Indication	Drops per Day
Mast Cell Stabilizer	CROMOLYN SOD SOL 4%	1	1-2 OU QID
	ALOMIDE SOL 0.1% (lodoxamide)	1	1-2 OU up to QID
	ALOCRIL SOL 2% (nedocromil)	2	1-2 OU BID
	ALAMAST DRO 0.1% (pemirolast)	3	1 OU QID
Antihistamine	EMADINE SOL 0.05% (emadastine)	4	1 OU QID
Antihistamine/ Mast Cell Stabilizer	OPTIVAR DRO 0.05% (azelastine)	2	1 OU BID
	ELESTAT DRO 0.05% (epinastine)	3	1 OU BID
	ZADITOR OTC** (ketotifen)	5	1 OU BID
	PATANOL SOL 0.1% (olopatadine)	6	1 OU BID
	PATADAY SOL 0.2% (olopatadine)	7	1 AE QD
Corticosteroid	ALREX SOL 0.2% (loteprednol)	4	1 AE QID

Indications:

1. Treatment of the ocular disorders referred to by the terms vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis.
2. Treatment of *itching* of the eye associated with **allergic conjunctivitis**.
3. Prevention of the *itching* associated with **allergic conjunctivitis**.
4. Temporary relief of the signs and symptoms of **allergic conjunctivitis**.
5. Temporary prevention of *itching* of the eye due to **allergic conjunctivitis**.
6. Treatment of the signs and symptoms of **allergic conjunctivitis**.
7. Treatment of ocular *itching* associated with **allergic conjunctivitis**.

Recommendations

The College of Pharmacy recommends the addition of the Ocular Allergy 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 recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

Tier 1	Tier 2
cromolyn sodium	Alomide Alocril® Alamast®
Zaditor OTC	Optivar Elestat® Patanol® Pataday® Ketotifen Emadine® Alrex®

Proposed Criteria for Tier 2 Products:

1. FDA approved diagnosis.
2. A trial of at least one Tier 1 product of a similar type (ie: cromolyn sodium prior to use of a mast cell stabilizer product or OTC ketotifen prior to use of an antihistamine, dual action, or corticosteroid product) for a minimum of two weeks in the last 30 days*.
3. Documentation of clinical need for Tier 2 product over Tier 1 should be noted on the petition.
4. Clinical exceptions granted for products with allergic reaction or contraindication.

* Point-of-Sale Claims system will look for Tier 1 trial and generate automatic approval for Tier 2 product if appropriate trial has been completed.

- ✓ Availability of OTC Zaditor has a potential savings of ~50% of current reimbursement.
- ✓ Manufacturers of Tier 2 products will have an opportunity to participate in the supplemental rebate program prior to the implementation of the prior authorization/step therapy of this category.

Appendix F

Discuss and Vote on Proposed Changes for ADHD/Narcolepsy PBPA Category and Vote on Prior Authorization of Vyvanse™

Oklahoma Health Care Authority
May 2007

Based on comments from the DUR Board, the following changes have been recommended to the ADHD/Narcolepsy PBPA tier structure and criteria.

Current Tier Structure

Tier	Medications	Age Groups	PA Requirements
First	Methylphenidate IR, SR, ER, and CR Concerta Focalin Focalin XR amphetamine salt combos Adderall XR dextroamphetamine Dexedrine Spansules	Children up to 21 years old	No PA required
		Adults	PA required – Diagnosis of ADHD or narcolepsy.
Second	Ritalin LA Metadate CD Strattera Daytrana Patches	Children and Adults	PA Required – Requires failed trial with one first category drug. Diagnosis of ADHD or narcolepsy.
Third	Desoxyn, pemoline	Children and Adults	PA Required – Requires failed trial with two first category drugs. Diagnosis of ADHD or narcolepsy.

Blue color denotes supplemental rebate
Brand name drugs that have SMAC applied require Brand-Only overrides
Quantity Limits are in place for the extended release products: Adderall XR, Focalin XR, Concerta, Metadate CD, and Ritalin LA.

Proposed Tier Structure

Tier 1	Tier 2	Tier 3
methylphenidate SR, ER, and CR dexmethylphenidate IR (Focalin) Focalin XR Concerta Adderall XR	Metadate CD Ritalin LA Strattera* methylphenidate IR** amphetamine salt combos**	Daytrana Desoxyn Vyvanse† dextroamphetamine Dexedrine Spansule Provigil

Blue color denotes current supplemental rebate – individual products would move to Tier 2 if manufacturer chooses to no longer participate in program.
Products can move to lower tiers based on supplemental rebate participation.
*Tier 2 due to clinical considerations, however based on pricing alone this product would be considered Tier 3.
**No PA will be required for a once daily dosing of these medications. Doses greater than once daily will require prior authorization.
†Price unavailable – may be eligible for Tier 2 status based on final price.

Proposed Criteria

For Tier 2 Product:

- ☑ Trial with one Tier 1 drug (should include a longer-acting product).
  - Trial should have been within the last 30 days.
  - Dosing up to maximum or provide information regarding side effects at higher dose.
  - If trials are not in members claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.
- ☑ Diagnosis of ADHD or Narcolepsy.
- ☑ Only use of one product (regardless of tier level) is allowed concurrently – except for a maximum of a two month titration period.
- ☑ An immediate release product of the same drug type may be used concurrently if an afternoon dose is required.

For Tier 3 Product:

- ☑ Trial with one Tier 1 drug and one Tier 2 drug **OR** two trials of either a Tier 1 or Tier 2.
  - Both trials should have been within the last 60 days.
  - Dosing of Tier 1 up to the FDA maximum or provide information regarding side effects at higher dose.
  - If trials are not in members claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.
- ☑ Diagnosis of ADHD or Narcolepsy.
- ☑ All other Tier 2 criteria apply.

For all Tiers:

- ☑ Dosing cannot exceed 1.5 times the FDA maximum.
- ☑ Prior Authorization is required for all tiers for members greater than 20 years of age. Must have a diagnosis of ADHD or Narcolepsy.

Appendix G

60-Day Notice and Potential Economic Impact of Product Based Prior Authorization of Ophthalmic Anti-Glaucoma Agents

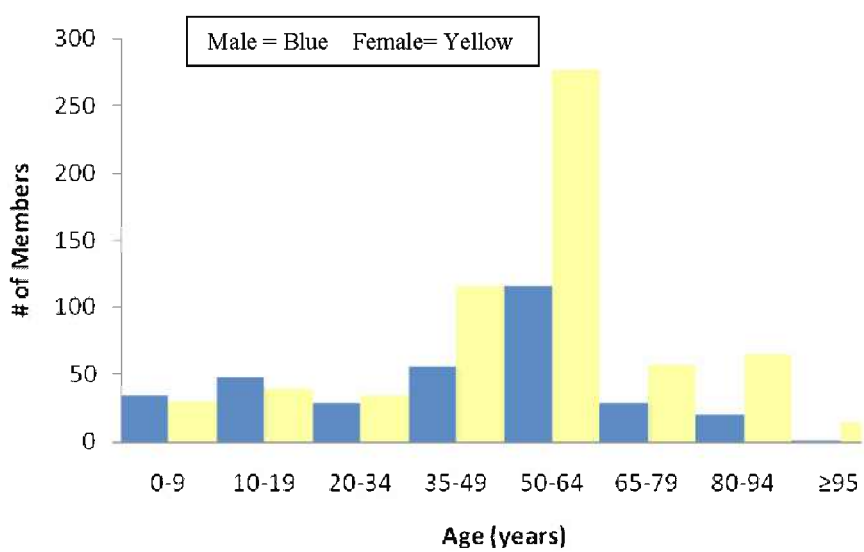
Oklahoma HealthCare Authority
May 2007

Utilization

Anti-Glaucoma Agents by Pharmacologic Class FY '06

Class	Total Claims	Total Reimbursement
Beta-Blockers	3,421	$114,943.31
Prostaglandin Analogs	9,172	$704,440.14
Adrenergic Agonists	54	$405.83
Alpha-2 Adrenergic Agonists	3,264	$245,515.68
Carbonic Anhydrase Inhibitor	916	$49,527.26
Cholinergic Agonists/ Cholinesterase Inhibitors	421	$6,729.70
Combination Product	2,073	$170,147.83
Total	**19,321**	**$1,291,709.75**

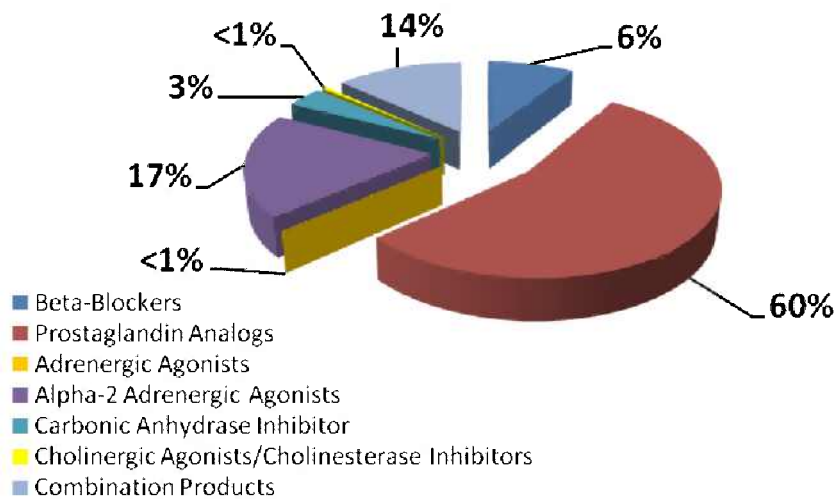
Non-Dual Member Demographics FY 06



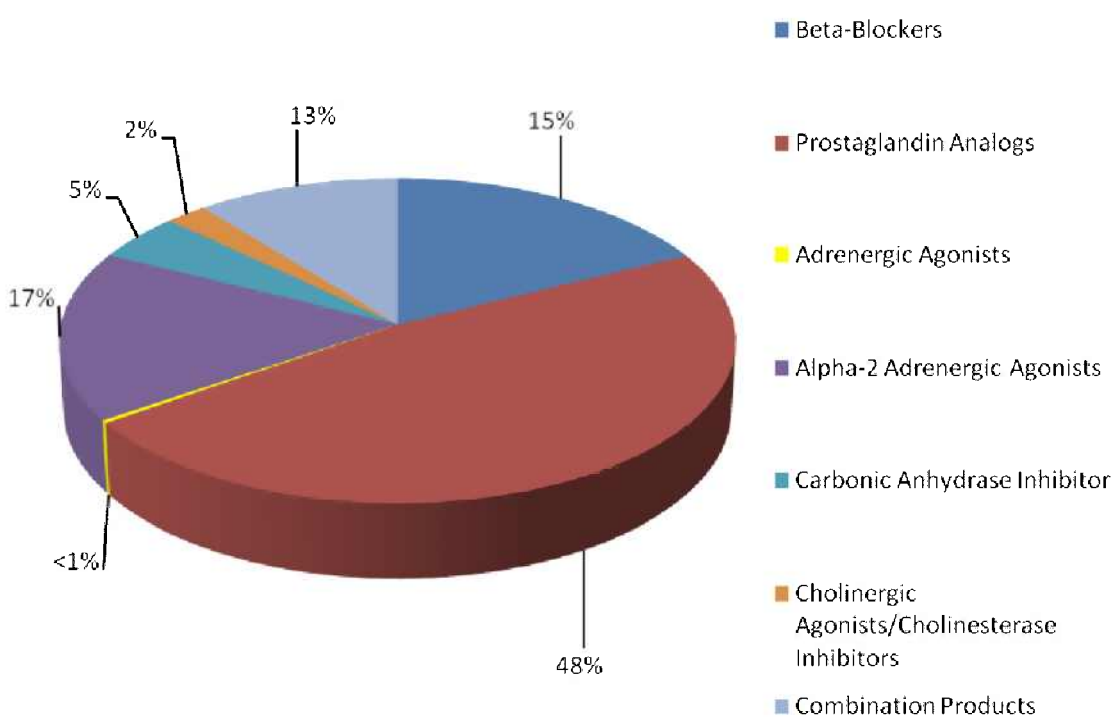
Utilization Comparison of Dual vs. Non-Dual Eligible Members FY 2006

	CLAIMS	UNITS	DAYS	MEMBERS	COST
Duals	14,574	95,346	342,211	3,532	$951,456.31
Non-Duals	4,747	31,053	121,185	964	$340,253.44

% of Total Costs Non-Duals FY 2006



% of Market Share Non-Duals FY 2006



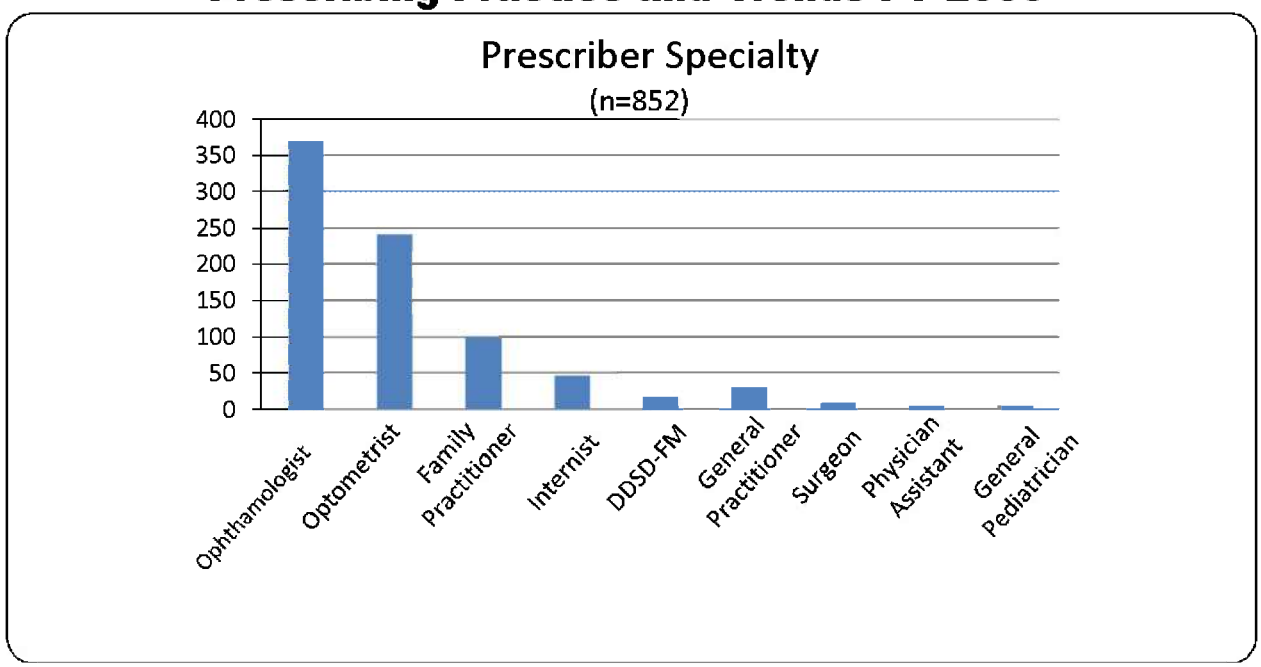
Product Cost Comparison

White = No PA required **Green** = Step-Therapy or Brand Name Override

Product	EAC	SMAC	*Per Diem
BETOPTIC-S SUS 0.25% OP	$8.97	n/a	$3.38
BETAXOLOL 0.5% OP	$4.09	$3.69	$1.39
CARTEOLOL SOL OPHTH 1%	$3.74	$1.84	$0.79
METIPRANOLOL SOL 0.3% OP	$2.92	$1.85	$0.55
LEVOBUNOLOL SOL 0.25% OP	$4.33	$0.95	$0.57
BETAGAN SOL 0.5% OP	$5.85	$0.27	$2.86
LEVOBUNOLOL SOL 0.5% OP	$2.90	$0.27	$0.19
BETIMOL SOL 0.25%	$4.17	n/a	$1.39
BETIMOL SOL 0.5%	$4.95	n/a	$1.43
TIMOLOL MAL SOL 0.25% OP	$3.18	$0.25	$0.17
TIMOLOL MAL SOL 0.5% OP	$3.89	$0.24	$0.17
TIMOPTIC SOL 0.5% OP	$3.89	$0.24	$2.47
TIMOPTIC 0.5% Dropperette	$1.92	n/a	$2.56
ISTALOL SOL 0.5% OP	$12.32	$11.20	$1.55
TIMOLOL GEL SOL 0.25% OP	$4.79	$4.20	$1.14
TIMOLOL GEL SOL 0.5% OP	$6.16	$4.99	$1.14
TIMOPTIC-XE SOL 0.5% OP	$6.16	$4.99	$1.15
COSOPT SOL 2-.5% OP	$4.79	$4.20	$3.50
COSOPT SOL 2-0.5%OP	$4.79	$4.20	$3.13
LUMIGAN SOL 0.03%	$26.28	n/a	$4.18
XALATAN SOL 0.005	$23.79	n/a	$2.49
TRAVATAN SOL 0.004%	$26.14	n/a	$3.29
ISO CARBACHO SOL 3% OP	$2.78	n/a	$0.95
PILOCARPINE SOL 0.5% OP	$0.39	n/a	$0.22
PILOCARPINE SOL 1% OP	$0.39	n/a	$0.13
ISOPTO CARP SOL 2% OP	$1.71	$0.16	$0.61
PILOCARPINE SOL 2% OP	$2.39	$0.14	$0.21
PILOCARPINE SOL 3% OP	$0.44	n/a	$2.80
PILOCARPINE SOL 4% OP	$0.44	n/a	$0.24
PILOCARPINE SOL 6% OP	$0.77	n/a	$0.28
PILOPINE HS GEL 4% OP	$0.77	n/a	$2.09
PHOSPHOLINE SOL 0.125%OP	$12.96	n/a	$2.00
DIPIVEFRIN SOL 0.1% OP	$2.44	$0.41	$0.17
IOPIDINE SOL 0.5% OP	$12.51	n/a	$6.08
ALPHAGAN P SOL 0.1%	$9.22	n/a	$4.04
ALPHAGAN P SOL 0.15%	$9.22	n/a	$3.25
BRIMONIDINE SOL 0.2% OP	$9.22	$2.28	$1.88
AZOPT 1% OP	$7.38	n/a	$2.08
TRUSOPT	$5.94	n/a	$1.99
TRUSOPT 2% OP	$5.94	n/a	$1.58

***Per diem = (Total Reimbursement – Dispensing Fees)/Days Supply**

Prescribing Practice and Trends FY 2006



Recommendations

The College of Pharmacy recommends the addition of the Anti-Glaucoma Agents to the Product Based Prior Authorization program. Drug selection would be based on individual patient characteristics which includes, but is not limited to: previous treatment failure, documented adverse effects, drug interactions, or contraindications to preferred products. Clinical information for these products will be presented as part of the 30-Day Notice. Members currently stabilized on non-preferred products will be granted approval through the point-of-sale prior authorization system. In addition, the College of Pharmacy recommends provision of both provider and member outreach through distribution of health information describing the importance of regular eye exams and compliance with therapy and to encourage appropriate use of these products for members with glaucoma.

Step-Therapy

1. FDA approved diagnosis.
2. Tier 1 trial may be from any pharmacologic class, must last at least 4 weeks and have been within the last 90 days.
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 National Institute of Health.
6. Approval duration will be for one year.

Proposed Tiers

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 0.25% (betaxolol) Cosopt (Dorzolamide & 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]

#Ocunefrin (Phenylephrine)-Available OTC

@ Oral formulations of Carbonic Anhydrase Inhibitors also available as a tier 1 medication

*Combination product

**Tentative generic approval by FDA on 03/09/2007. Once generics are established or SMAC is applied this class will be reviewed for new tier placements.

Potential Secondary Costs

Overall the products reviewed are considered safe and effective for treatment of glaucoma either as monotherapy or in combination therapy, but drug selection requires individual patient history which includes, but is not limited to: previous first-line therapy, other concomitant disease states, specific disease risk factors, and current signs and symptoms. Clinical information for these products will be presented as part of 30-day Notice.

Potential Administrative Costs

It is estimated that approximately 450 petitions would be required. The proposed product coverage changes would affect approximately 47% of the total population for this category.

Previously, it has been theorized that total cost per petition to the healthcare system (includes: cost to physicians, pharmacists, and program) is between $7.12 and $13.78. Total cost per petition to the healthcare system is estimated to be between $3,204 and $6,201. Anticipated actual administrative cost to the program is projected to be less than $6,000.

Potential Program Savings

Potential net pharmacy *ingredient* cost savings to the program based on recommended tiers is estimated to be $94,366 annually.

Total Potential Savings

Potential Savings:	$ 94,366	$ 94,366
Potential Administrative Cost:	$ - 6,201	$ - 3,204
Total Potential *Ingredient* Savings	$ 88,165 to	$ 91,162
Percent of Current *Reimbursement*	25.9% to	26.8%

Anti-Glaucoma Agents					
Drugname (Dosing schedule)	**Mechanism/Indication**	**Dosing**	**Dosage Form(s)**	**Generic**	**Other**
Beta-Blockers (Once or twice daily)					
Betagan 0.25%, 0.5% (levobunolol)	Lower IOP in chronic open-angle glaucoma or Ocular HTN	1 drop daily or Twice daily	5, 10, 15 mL	Y	
Optipranolol 0.3% (metipranolol)	Lower IOP in chronic open-angle glaucoma	1 drop Twice daily	5,10 mL	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	0.2, 2.5, 5, 10, 15 mL	Y	Available in combination with Dorzolamide.
Cartrol, Ocupress 1% (Carteolol)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop Twice daily	5, 10, 15 mL	Y	
Betoptic-S (betaxolol)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily or Twice daily	2.5, 5, 10, 15 mL	Y	Oral dosage form available.
Prostaglandin Analogs (Once daily)					
Lumigan (Bimatoprost)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily	2.5, 5, 7.5 mL	N	More than once daily decrease effectiveness
Xalatan (Latanoprost)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop daily	2.5 mL	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	2.5, 5 mL	N	Travatan Z uses non Benzalkonium Chloride preservative
Adrenergic Agonists (Twice daily)					
Propine (Dipivefrin)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop Twice daily	5, 10, 15 mL	Y	Prodrug of epinephrine
Alpha-2 Adrenergic Agonists (Three times daily)					
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	5, 10, 15 mL	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%)	1, 5, 10 mL	N	

Carbonic Anhydrase Inhibitor (Three times daily)					
Azopt (Brinzolamide)	Lower IOP in chronic open-angle glaucoma and Ocular HTN	1 drop three times daily	5, 10, 15 mL	N	
Trusopt (Dorzolamide)	Lower IOP in chronic open-angle glaucoma and Ocular HTN *(children and adults)*	1 drop Three times daily	10 mL	N	Available in combination with timolol.
Cholinergic Agonists[1]/Cholinesterase Inhibitors[2] (Daily, Twice daily, Three times daily, Six times daily)					
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	2, 15 mL; 4 gram tube	Y	
Isopto, Miostat[1] 1.5%, 3% (Carbachol)	Lower IOP in glaucoma; *miosis during surgery*	1-2 drops Three times daily	1.5, 15, 30 mL	N	Miostat used during surgery. DUR+ check ICD-9
Phospholine Iodide[2] (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	5 mL	N	
Carbonic Anhydrase Inhibitor/Beta-Blocker Combination (Twice Daily)					
Cosopt (Dorzolamide,Timolol)	Lower IOP in chronic open-angle glaucoma and Ocular HTN ≥*2 years old*	1 drop Twice daily	5, 10 mL	N	

Appendix H

Tekturna® (Aliskiren hemifumerate)

30 Day Notice of Intent to Prior Authorize

Oklahoma Healthcare Authority

May 2007

Manufacturer:	Novartis Pharmaceuticals Corp.
Classification:	Direct Renin Inhibitor
Dosage forms:	150mg and 300mg oral tablets
FDA Indications:	Treatment of hypertension, alone or in combination with other anti-hypertensive agents

Summary

Aliskiren is a potent, competitive direct inhibitor of human renin. Renin is a circulating enzyme that catalyzes the conversion of angiotensinogen to the inactive peptide angiotensin I. Angiotensin I is subsequently cleaved by angiotensin converting enzyme (ACE) to form angiotensin II. Angiotensin II is a potent vasoconstrictor and leads to the release of catecholamines from the adrenal medulla and prejunctional nerve endings. It also promotes aldosterone secretion and sodium reabsorption. Together, these effects increase blood pressure. Aliskiren is a direct renin inhibitor, decreasing plasma renin activity (PRA) and inhibiting the conversion of angiotensinogen to angiotensin I, which decreases formation of angiotensin II.

Dosage range

The usual recommended starting dose of aliskiren is 150mg daily. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 300mg. Doses above 300mg did not result in an increase in blood pressure reduction, but rather increased the rate of diarrhea. The antihypertensive effect of a given dose should be attained within approximately 2 weeks.

Place in Therapy

- Aliskiren is the first agent in a new class of Direct Renin Inhibitors.
- Aliskiren has been observed in clinical trials to lower systolic blood pressure an average of 10-15 mmHg and diastolic blood pressure an average of 5-12 mmHg.
- Aliskiren has been shown to further decrease systolic (average ~ 5-10 mmHg) and diastolic (2-4 mmHg) blood pressure when added to hydrochlorothiazide, ramipril, or valsartan.
- Currently, there are no known clinical advantages of aliskiren when compared with other agents that act upon the RAAS system.

Recommendations

The College of Pharmacy recommends 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 that did not yield adequate blood pressure control. Tekturna may be used in either monotherapy or combination therapy.

Cost Comparison

	EAC / Tab	Daily Dose	30 day supply
Tekturna® 150mg	$2.14	QD	$64.20
Tekturna® 300mg	$2.70	QD	$81.00

ACE Inhibitors

Weighted Average Perdiem = $0.34

Medication	Claims	Perdiem
BENAZEPRIL TAB 5MG*	68	$0.23
BENAZEPRIL TAB 10MG*	479	$0.26
BENAZEPRIL TAB 20MG*	481	$0.26
BENAZEPRIL TAB 40MG*	286	$0.26
LOTENSIN® TAB 20MG*	2	$2.34
LOTENSIN® TAB 40MG*	1	$1.18
CAPTOPRIL TAB 12.5MG*	621	$0.14
CAPTOPRIL TAB 25MG*	864	$0.18
CAPTOPRIL TAB 50MG*	656	$0.23
CAPTOPRIL TAB 100MG*	149	$0.29
ENALAPRIL TAB 2.5MG*	737	$0.22
ENALAPRIL TAB 5MG*	2,055	$0.20
ENALAPRIL TAB 10MG*	2,912	$0.20
ENALAPRIL TAB 20MG*	3,006	$0.24
VASOTEC® TAB 2.5MG*	13	$1.45
FOSINOPRIL TAB 10MG*	537	$0.46
FOSINOPRIL TAB 20MG*	519	$0.44
FOSINOPRIL TAB 40MG*	330	$0.47
LISINOPRIL TAB 2.5MG*	1,016	$0.20
LISINOPRIL TAB 5MG*	3,572	$0.19
LISINOPRIL TAB 10MG*	9,116	$0.21
LISINOPRIL TAB 20MG*	7,762	$0.31
LISINOPRIL TAB 30MG*	204	$0.35
LISINOPRIL TAB 40MG*	3,799	$0.42
PRINIVIL® TAB 10MG*	9	$1.04
ZESTRIL® TAB 10MG*	12	$2.36
QUINAPRIL TAB 5MG*	71	$0.98
QUINAPRIL TAB 10MG*	365	$0.96
QUINAPRIL TAB 20MG*	603	$1.04
QUINAPRIL TAB 40MG*	536	$0.93
ACCUPRIL® TAB 20MG*	3	$1.42
MOEXIPRIL TAB 7.5MG	3	$0.92
MOEXIPRIL TAB 15MG	1	$0.88
UNIVASC® TAB 7.5MG	67	$1.35
UNIVASC® TAB 15MG	88	$1.42
ACEON® TAB 4MG	27	$1.64
ACEON® TAB 8MG	18	$1.99
ALTACE® CAP 2.5MG	229	$1.59
ALTACE® CAP 5MG	294	$1.74
ALTACE® CAP 10MG	483	$2.42
MAVIK® TAB 1MG	6	$1.14
MAVIK® TAB 2MG	2	$1.23
MAVIK® TAB 4MG	9	$0.89

ARBs

Weighted Average Perdiem = $2.00

Medication	Claims	Perdiem
ATACAND® TAB 4MG	7	$1.61
ATACAND® TAB 8MG	33	$1.64
ATACAND® TAB 16MG	168	$1.74
ATACAND® TAB 32MG	198	$2.15
ATACAND HCT® TAB 16-12.5	83	$2.70
ATACAND HCT® TAB 32-12.5	174	$2.17
TEVETEN® TAB 400MG	11	$2.54
TEVETEN® TAB 600MG	56	$2.05
TEVETEN HCT® TAB 600-12.5	68	$2.06
TEVETEN HCT® TAB 600-25MG	1	$1.87
AVAPRO® TAB 75MG	71	$1.54
AVAPRO® TAB 150MG	584	$1.75
AVAPRO® TAB 300MG	542	$1.82
AVALIDE® TAB 150-12.5*	253	$2.25
AVALIDE® TAB 300-12.5*	194	$2.07
AVALIDE® TAB 300-25MG*	43	$2.37
COZAAR® TAB 25MG	175	$1.78
COZAAR® TAB 50MG	826	$1.94
COZAAR® TAB 100MG	704	$2.33
HYZAAR® TAB 50-12.5	696	$1.82
HYZAAR® TAB 100-12.5	4	$2.31
HYZAAR® TAB 100-25	941	$2.32
BENICAR® TAB 5MG	30	$2.00
BENICAR® TAB 20MG	596	$1.62
BENICAR® TAB 40MG	428	$1.76
BENICAR HCT® TAB 20-12.5	574	$1.77
BENICAR HCT® TAB 40-12.5	314	$1.92
BENICAR HCT® TAB 40-25MG	293	$2.08
MICARDIS® TAB 20MG	84	$1.72
MICARDIS® TAB 40MG	338	$1.65
MICARDIS® TAB 80MG	304	$1.71
MICARDIS HCT® TAB 40/12.5	114	$1.90
MICARDIS HCT® TAB 80/12.5	250	$2.04
MICARDIS HCT® TAB 80/25MG	51	$2.25
DIOVAN® TAB 40MG	94	$1.55
DIOVAN® TAB 80MG	1,018	$1.89
DIOVAN® TAB 160MG	892	$2.08
DIOVAN® TAB 320MG	287	$2.31
DIOVAN HCT® TAB 80/12.5	571	$2.00
DIOVAN HCT® TAB 160/12.5	695	$2.25
DIOVAN HCT® TAB 160-25MG	547	$2.48

* Indicates Tier-One Medication

Pharmacokinetics
Aliskiren is a poorly absorbed drug with an approximate accumulation half life of 24 hours. Steady-state blood levels are reached in about 7-8 days.

Absorption and Distribution
Following oral administration, peak plasma concentrations of aliskiren are reached within 1 to 3 hours. In clinical trials aliskiren was administered without requiring a fixed relation of administration to meals, however, when taken with a high fat meal, the mean AUC and C_{max} are decreased by 71% and 85%, respectively.

Metabolism and Elimination
The major enzyme responsible for metabolism, based on in vitro studies, is the CYP 3A4 system. About one fourth of the absorbed dose appears in the urine as parent drug, but the amount of drug that is metabolized remains unknown.

Known adverse effects/toxicities
- **Diarrhea** and gastrointestinal symptoms (2.3%)
- **Cough** (1.1%)
- Other rare adverse effects include rash (1%), elevated uric acid (0.4%), gout (0.2%), and renal stones (0.2%)

Special precautions
- **Angioedema** may occur at any time during treatment with aliskiren. Patients should be advised to report immediately any signs or symptoms suggesting angioedema.
- Routine **monitoring of electrolytes** and renal function is recommended. Increases in serum potassium were infrequent when aliskiren was used alone, but when used in combination with an ACE inhibitor in a diabetic population, increases in serum potassium were more frequent (5.5%.)
- Increases in **creatine kinase** >300% were recorded in about 1% of patients treated with aliskiren compared to 0.5% of patients on placebo. No cases were associated with renal dysfunction, but one case was diagnosed as subclinical rhabdomyolysis and another as myositis.

Contraindications
Drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. Aliskiren, like all medications that affect the renin angiotensin-aldosterone system (RAAS), is contraindicated in **pregnant** women.

Drug interactions
Drug interactions were detected after co-administration with the following medications:
- **Irbesartan** – reduced aliskiren C_{max} up to 50% after multiple dosing.
- **Atorvastatin** – increased C_{max} and AUC of aliskiren approximately 50% after multiple dosing.
- **Ketoconazole** – increased plasma levels of aliskiren by approximately 80%.
- **Furosemide** –AUC and C_{max} of furosemide were significantly reduced after multiple dosing with aliskiren.

Patient Populations
- Although the pharmacokinetic differences between blacks, caucasions, and Japanese are minimal, black patients tended to have slightly smaller blood pressure reductions than caucasions and asians, as has been seen with ACE inhibitors and ARBs.
- Aliskiren has not been studied in patients less than 18 years of age.
- In clinical trials, patient groups that were >65 years old and >75 years old had blood pressure responses that were similar to younger patient groups.

References

1. Novartis Pharmaceuticals Corporation. Tekturna Product Prescribing Information. Available at: http://www.pharma.us.novartis.com/product/pi/pdf/tekturna.pdf. March 2007.

Appendix I

30 Day Notice to Prior Authorize Amrix® (cyclobenzaprine hydrochloride) Extended Release Capsules and Fexmid™ (cyclobenzaprine hydrochloride) Tablets

Oklahoma Health Care Authority
May 2007

Amrix® ECR Pharmaceuticals, Inc	Fexmid™ Victory Pharmaceuticals, Inc
Amrix® is an **extended-release form** of cyclobenzaprine hydrochloride designed for once daily administration. Amrix® is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful, musculoskeletal conditions. It is available in **15mg and 30mg capsules.** Pricing not currently available.	Fexmid™ is indicated for as an adjunct to rest and physical therapy for relief of muscle spasms associated with acute, painful musculoskeletal conditions. It is available in a **7.5mg tablet**. AWP= $2.05/ea

Calendar Year 2006 Cyclobenzaprine Utilization

	Amount Paid	Days Supply	Quantity	Rx Claims Count
Cyclobenzaprine (tablet) 5 mg	$89,425.50	43,751	113,979	2,840
Flexeril® (tablet) 5 mg	$35,068.80	8,115	21,171	497
Cyclobenzaprine (tablet) 10mg	$344,869.44	604,148	1,525,866	29,786
Total	**$469,363.74**	**656,014**	**1,661,016**	**33,123**

Recommendations

The College of Pharmacy recommends prior authorization of Amrix® and Fexmid™. Approval based on clinical documentation of need for one of these products over other generically available forms of cyclobenzaprine hydrochloride. Quantity limits based on FDA approved dosages for a maximum duration of 14 days will be applied.

REFERENCE

Amrix® Product Information. ECR Pharmaceuticals, Inc. 2004.
Fexmid® Product Information. Victory Pharmaceuticals, Inc. 2007.

Appendix J

FDA News

FOR IMMEDIATE RELEASE
P07-72
April 23, 2007

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

FDA Approves First Generic Versions of Ambien (Zolpidem Tartrate) for the Treatment of Insomnia

The U.S. Food and Drug Administration (FDA) today approved the first generic versions of Ambien (zolpidem tartrate) immediate-release tablets. Zolpidem (ZOLE-pi-dem) tartrate is a sedative-hypnotic drug indicated for the short-term treatment of insomnia.

"The FDA's Office of Generic Drugs ensures that generic drugs are safe and effective for the American public through a rigorous scientific and regulatory process," said Gary J. Buehler, director, Office of Generic Drugs. "This approval offers Americans more alternatives when choosing their prescription drugs."

Zolpidem tartrate tablets in formulations of five milligrams and 10 milligrams are manufactured by multiple generic drug companies in the United States. The following 13 manufacturers have received FDA approval for zolpidem tartrate tablets: Mylan Pharmaceuticals Inc., TEVA Pharmaceuticals USA, Roxane Laboratories Inc., Watson Laboratories Inc., Ranbaxy Laboratories Ltd., Dr. Reddy's Laboratories Ltd., Apotex Inc., Synthon Pharmaceuticals Inc., Genpharm Inc., Mutual Pharmaceutical Company Inc., Caraco Pharmaceutical Laboratories Ltd., Carlsbad Technology Inc., and Lek Pharmaceuticals.

In March, FDA requested that all manufacturers of sedative-hypnotic drug products, a class of drugs used to induce and/or maintain sleep, strengthen their product labeling to include stronger language concerning potential risks. These risks include severe allergic reactions and complex sleep-related behaviors, which may include sleep-driving. Sleep driving is defined as driving while not fully awake after ingestion of a sedative-hypnotic product, with no memory of the event. For more information see www.fda.gov/bbs/topics/NEWS/2007/NEW01587.html. Generic versions of these drugs will also include this labeling.

According to the online magazine *Drug Topics*, in 2006, Ambien was the 13th highest selling brand name drug. The sanofi-aventis (formerly Sanofi-Synthelabo, Inc.) patent for zolpidem tartrate expired on April 21, 2007.

The FDA's Office of Generic Drugs (OGD) reviews and decides on approval of generic drug applications. For more information on other first generic versions, please see http://www.fda.gov/cder/ogd/approvals/.

For more information about generic drugs, please see the *FDA Consumer* article, *Generic Drugs: What You Need to Know* at www.fda.gov/fdac/features/2002/502_generic.html. For additional information related to FDA's Office of Generic Drugs, please see: www.fda.gov/cder/consumerinfo/generic_equivalence.htm.

FDA News

FOR IMMEDIATE RELEASE
P07-71
April 20, 2007

Media Inquiries:
S. Mitchell Weitzman, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Announces Audio Broadcasts on Emerging Drug Safety Information

The U.S. Food and Drug Administration (FDA) is alerting health care professionals and consumers to the availability of audio broadcasts that provide emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players.

The service is part of the agency's ongoing effort to broaden and speed its communications concerning the safety of marketed medications when unexpected adverse events are reported to FDA. The broadcasts are an addition to FDA's traditional print- and Web-based public health advisories (PHAs) and anyone can subscribe to them for free at http://www.fda.gov/cder/drug/podcast/default.htm.

"FDA's highest priority is to protect and enhance the health of the American public," said Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs. "The service contributes to this goal by providing a new venue for busy health care professionals and patients to find drug safety information, so that they don't have to look for it on FDA's Web site or read about it in print. Timely and widely available broadcasts about previously unknown potential drug risks should help ensure that these products are used safely and effectively."

Since the service was launched in February 2007, it has alerted listeners to the potential hazards of skin-numbing products used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome, and to serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients.

The American Medical Association (AMA) welcomed the FDA audio broadcast. "This innovative development can help physicians provide the best treatments to their patients and improve patient safety," said Edward Langston, M.D., an AMA Board member.

In the broadcasts, FDA asks healthcare providers and patients to report adverse side effects from medical products to MedWatch. MedWatch reports can be made by phone: at 1-800-FDA-1088; fax: 1-800-FDA-0178; or via the Internet at http://www.fda.gov/medwatch/index.html.

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ACORDA®
THERAPEUTICS

Updated Safety Information: Contraindications to the use of Tizanidine

March 5, 2007

Dear Healthcare Professional:

Acorda Therapeutics would like to inform you that concomitant use of tizanidine with fluvoxamine or ciprofloxacin (potent CYP1A2 inhibitors) is contraindicated.

The interaction between tizanidine and either fluvoxamine or ciprofloxacin, characterized by markedly and potentially dangerously elevated serum tizanidine levels, is most likely due to inhibition of CYP1A2 by fluvoxamine or ciprofloxacin. Although there have been no clinical studies evaluating the effects of other CYP1A2 inhibitors on tizanidine, other CYP1A2 inhibitors may lead to substantial increases in tizanidine blood concentrations. Therefore, concomitant use of tizanidine with other CYP1A2 inhibitors, such as zileuton, other fluoroquinolones, antiarrythmics (amiodarone, mexiletine, propafenone, and verapamil), cimetidine, famotidine, oral contraceptives, acyclovir and ticlopidine should ordinarily be avoided. If their use is clinically necessary, they should be used with caution.

Addition of two contraindications to the CONTRAINDICATIONS section of the U.S. PI:

CONTRAINDICATIONS
Concomitant use of tizanidine with fluvoxamine or with ciprofloxacin, potent inhibitors of CYP1A2, is contraindicated. Significant alterations of pharmacokinetic parameters of tizanidine including increased AUC, t1/2, Cmax, increased oral bioavailability and decreased plasma clearance have been observed with concomitant administration of either fluvoxamine or ciprofloxacin. This pharmacokinetic interaction can result in potentially serious adverse events (See WARNINGS and CLINICAL PHARMACOLOGY: Drug Interactions). Zanaflex is contraindicated in patients with known hypersensitivity to Zanaflex or its ingredients.

Addition of two WARNINGS sections to the U.S. PI:

POTENTIAL INTERACTION WITH FLUVOXAMINE OR CIPROFLOXACIN
In a pharmacokinetic study, tizanidine serum concentration was significantly increased (Cmax 12-fold, AUC 33-fold) when the drug was given concomitantly with fluvoxamine. Potentiated hypotensive and sedative effects were observed. Fluvoxamine and tizanidine should not be used together. (See CONTRAINDICATIONS and CLINICAL PHARMACOLOGY: Drug Interactions).

In a pharmacokinetic study, tizanidine serum concentration was significantly increased (Cmax 7-fold, AUC 10-fold) when the drug was given concomitantly with ciprofloxacin. Potentiated hypotensive and sedative effects were observed. Ciprofloxacin and tizanidine should not be used together (See CONTRAINDICATIONS and CLINICAL PHARMACOLOGY: Drug Interactions).

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POSSIBLE INTERACTION WITH OTHER CYP1A2 INHIBITORS
Because of potential drug interactions, concomitant use of tizanidine with other CYP1A2 inhibitors, such as zileuton, other fluoroquinolones, antiarrythmics (amiodarone, mexiletine, propafenone, and verapamil), cimetidine, famotidine, oral contraceptives, acyclovir and ticlopidine (see CLINICAL PHARMACOLOGY: Drug Interactions) should ordinarily be avoided. If their use is clinically necessary, they should be used with caution.

Pharmacokinetics and Dosing Administration Considerations

Acorda Therapeutics also would like to remind you of the pharmacokinetic differences between Zanaflex Capsules ™ (tizanidine hydrochloride) and Zanaflex® tablets (tizanidine hydrochloride) and generic tizanidine tablets. Zanaflex Capsules™ and Zanaflex® tablets are not bioequivalent when given in the fed state.

Food has complex effects on tizanidine hydrochloride pharmacokinetics. These pharmacokinetic differences may result in clinically significant differences when [1] switching administration of the tablet between the fed or fasted state, [2] switching administration of the capsule between the fed or fasted state, [3] switching between the tablet and capsule in the fed state, or [4] switching between the intact capsule and sprinkling the contents of the capsule on applesauce. These changes may result in increased adverse events or delayed/more rapid onset of activity, depending upon the nature of the switch. For this reason, the prescriber should be thoroughly familiar with the changes in kinetics associated with these different conditions.

Acorda Therapeutics is committed to ensuring that Zanaflex Capsules ™ and Zanaflex® tablets are used safely and effectively. We look forward to working in collaboration with you for the safety and well-being of all patients. You should report any adverse events to Acorda's Medical Information System by calling toll free: 1 800 367-5109 or by email at: Acorda@medcomsol.com. You can also report all cases to the FDA MedWatch program by phone at: 1 800 FDA-1088, by fax at: 1 800 FDA-0178, by website at http://www.accessdata.fda.gov/scripts/medwatch/ or by mail:

MedWatch, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

A copy of the full prescribing information for Zanaflex Capsules™ and Zanaflex® is enclosed. Prescribing healthcare professions are advised to review this information carefully. Should you have any questions or require further information please contact the Acorda Medical Information System at 1 800 367-52109.

Sincerely,

Sincerely,

Herbert R. Henney III, PharmD
Vice President, Medical Affairs

ZC00078

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FDA News

FOR IMMEDIATE RELEASE
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888-INFO-FDA

FDA Announces that Companies Must Stop Marketing Suppository Products Containing Trimethobenzamide

As part of the Food and Drug Administration's (FDA) on-going initiative to ensure that all marketed U.S. drugs have required marketing approval, the agency announced today that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride. These products are used to treat nausea and vomiting in adults and children. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. These products have been marketed under various names, including Tigan, Tebamide, T-Gen, Trimazide, and Trimethobenz.

FDA urges consumers who are using suppositories containing trimethobenzamide, and who have questions or concerns, to contact their health care provider. There are many alternative products approved to effectively treat nausea and vomiting, and that are available in a variety of forms, including tablets, capsules, solutions, injectables and suppositories. Several oral capsules and injectable products containing trimethobenzamide have been approved by FDA and are not affected by today's action.

"FDA is continuing its work to remove unapproved drugs from the market," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research (CDER). "FDA is committed to ensuring that the medicines Americans rely on when they are sick are proven to be effective and safe."

The Federal Register notice http://www.fda.gov/OHRMS/DOCKETS/98fr/78n-0224-nwl0002.pdf which outlines the agency's order to manufacturers and distributors, also concludes all outstanding issues for drugs containing trimethobenzamide, under the Drug Efficacy Study Implementation program (DESI). In 1962, Congress amended the Federal Food, Drug, and Cosmetic Act to require that drugs be shown to be effective, as well as safe. Under DESI, FDA evaluated the evidence of effectiveness for thousands of drug products previously approved for safety only, including those products marketed under the name of Tigan containing trimethobenzamide.

Because DESI findings apply to any unapproved products that are identical, related, or similar to DESI-reviewed drugs, today's notice makes the marketing of any unapproved trimethobenzamide hydrochloride suppository products unlawful.

"Prescription drugs that have not gone through the FDA approval process are of unproven safety and effectiveness," said director of CDER's Office of Compliance, Deborah M. Autor. "Today's action helps ensure that health care providers prescribe, and consumers take, only medicines shown to be effective."

Companies manufacturing or marketing trimethobenzamide hydrochloride suppository

products must cease shipping them in interstate commerce by May 9, 2007. A small amount of these products will still be available in pharmacies after that date until supplies are exhausted. Any company wishing to market a product containing trimethobenzamide in suppository form must now obtain an approved new drug application prior to marketing.

This action is the next step in a concerted FDA effort to ensure that all marketed U.S. drugs have required FDA approval. In June of last year, FDA announced its renewed emphasis on this issue and sent a clear signal to industry that FDA expects all marketed drugs to have required FDA approval, and that the agency will take action to make that happen. At that time, FDA published a Compliance Policy Guide or CPG, which is a guidance document that describes the agency's risk-based enforcement approach to marketed unapproved drugs. Completing DESI proceedings is a separate but important part of tackling the unapproved drugs problem.

For additional information regarding FDA's Unapproved Drugs Initiative visit http://www.fda.gov/cder/drug/unapproved_drugs.

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Avoiding Unintentional Opiate Poisoning

Part 1: MMWR and NCHS Article extracts
Part 2: Practice Guidelines

MMWR Weekly
February 9, 2007 / 56(05);93-96

Unintentional Poisoning Deaths — United States, 1999—2004 (Extract)

In 2004, poisoning was second only to motor-vehicle crashes as a cause of death from unintentional injury in the United States (1). Nearly all poisoning deaths in the United States are attributed to drugs, and most drug poisonings result from the abuse of prescription and illegal drugs (2). Previous reports have indicated a substantial increase in unintentional poisoning mortality during the 1980s and 1990s (2,3). To further examine this trend, CDC analyzed the most current data from the National Vital Statistics System. This report summarizes the results of that analysis, which determined that poisoning mortality rates in the United States increased each year from 1999 to 2004, rising 62.5% during the 5-year period. The largest increases were among females (103.0%), whites (75.8%), persons living in the southern United States (113.6%), and persons aged 15--24 years (113.3%). Larger rate increases occurred in states with mostly rural populations. Rates for drug poisoning deaths increased 68.3%, and mortality rates for poisonings by other substances increased 1.3%. The largest increases were in the "other and unspecified," psychotherapeutic, and narcotic drug categories. The results suggest that more aggressive regulatory, educational, and treatment measures are necessary to address the increase in fatal drug overdoses.

The number of unintentional poisoning deaths increased from 12,186 in 1999 to 20,950 in 2004. The annual age-adjusted rate increased 62.5%, from 4.4 per 100,000 population in 1999 to 7.1 in 2004. The increase among females, from 2.3 to 4.7 per 100,000 population (103.0%), was twice the increase among males, from 6.5 to 9.5 per 100,000 population (47.1%). Among males, rates among whites, American Indians/Alaska Natives, and Asians/Pacific Islanders all increased approximately 50%. Rates among black males were highest in 1999 but did not increase. Among females, rates among whites more than doubled, whereas nonwhites had smaller increases or decreased. Overall, rates increased 75.8% among whites, 55.8% among American Indians/Alaska Natives, 27.4% among Asians/Pacific Islanders, and 11.2% among blacks. Rates among non-Hispanics increased more than rates among Hispanics for both sexes. Among all sex and racial/ethnic groups, the largest increase (136.5%) was among non-Hispanic white females. Among all age groups, the largest increase occurred among persons aged 15--24 years (113.3%). In 2004, the highest rates were among persons aged 35--54 years, who accounted for 59.6% of all poisoning deaths that year.

From 1999 to 2004, rates increased by less than one third in the Northeast and West but more than doubled in the South and nearly doubled in the Midwest.† Delaware, Maryland, New York, and Rhode Island had decreases in rates, and California had the smallest increase (4.0%). States with the largest relative increases were West Virginia (550%), Oklahoma (226%), Maine

(210%), Montana (195%), and Arkansas (195%). Increases of 100% or more occurred in 23 states: 11.8% (two of 17) of states§ in the most urban tertile, 41.2% (seven of 17) of those in the middle tertile, and 82.4% (14 of 17) of those in the most rural tertile (extended Mantel-Haenszel chi-square for linear trend across the tertiles = 15.4, $p<0.001$).

Reported by: *L Paulozzi, MD, Div of Unintentional Injury Prevention; J Annest, PhD, Office of Statistics and Programming, National Center for Injury Prevention and Control, CDC.*

Editorial Note

Unintentional drug poisoning mortality rates increased substantially in the United States during 1999--2004. Previous studies, using multiple cause-of-death data, have indicated that the trend described in this report can be attributed primarily to increasing numbers of deaths associated with prescription opioid analgesics (e.g., oxycodone) and secondarily to increasing numbers of overdoses of cocaine and prescription psychotherapeutic drugs (e.g., sedatives), and cannot be attributed to heroin, methamphetamines, or other illegal drugs (3,5).

The mortality increases might be the result of greater use and abuse of potentially lethal prescription drugs in recent years, behaviors that are more common among whites than nonwhites (6,7). The substantial increase in deaths among persons aged 15--24 years is consistent with substantial recent increases in recreational prescription drug and cocaine use among adolescents and young adults (8).

Studies by state health agencies have reported recent increases in prescription-drug--poisoning mortality in rural communities (9,10), despite historically higher rates in urban areas. The South and Midwest regions, which had the largest relative and absolute increases among regions in this study, are the most rural regions of the country (4). Further research is needed to determine how differences in drug use, drug-abuse--control measures, and demographic characteristics (e.g., race/ethnicity) contribute to this pattern.

Effective response to increasing fatal drug overdoses requires strengthening regulatory measures to reduce unsafe use of drugs, increasing physician awareness regarding appropriate pharmacologic treatment of pain and psychiatric problems, supporting best practices for treating drug dependence, and potentially modifying prescription drugs to reduce their potential for abuse. State agencies that manage prescription-monitoring programs should use such systems to proactively identify 1) patients who abuse drugs and fill multiple prescriptions from different health-care providers and 2) providers whose prescribing practices are outside the standards of appropriate medical care. Both federal and state prevention measures should be evaluated periodically to determine their effectiveness.

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National Center for Health Statistics

Increases in Methadone-Related Deaths: 1999-2004

See complete report here: http://www.cdc.gov/nchs/products/pubs/pubd/hestats/methadone1999-04/methadone1999-04.htm

EXCERPT

Since 1999, between 73 and 79 percent of poisoning deaths mentioning methadone have been classified as unintentional (3,202 such deaths in 2004), with an additional 11-13 percent being of undetermined intent, 5-7 percent as suicides, less than 1 percent as homicides, and about 1 percent were injuries other than poisoning. Over this same period, only 4-6 percent of deaths where methadone was mentioned were not coded as injury deaths.

Trends

The number of all poisoning deaths increased 54 percent to 30,308 over the 1999-2004 period, while the number of poisoning deaths mentioning methadone increased 390 percent to 3,849. Poisoning deaths mentioning methadone increased from 4 percent of all poisoning deaths to 13 percent of all poisoning deaths. Most recently, all poisoning deaths increased 6 percent from 2003-04, while those mentioning methadone increased 29 percent.

Of all narcotics mentioned in poisoning deaths, methadone had the largest relative increases. The absolute number of poisoning deaths mentioning methadone was less, however, than the number of deaths mentioning cocaine or other opioids. Other opioids include pain relief drugs such as oxycodone and hydrocodone among others. The relative increase in methadone-related poisoning deaths from 1999 to 2004 was greater than for any individual substance in the T36-T65 range of codes.

PART 2: PRACTICE GUIDELINES

PRACTICE GUIDELINES

Management of Opioid Therapy for Chronic Pain
VA/DoD Clinical Practice Guideline Working Group

This guideline is presented in an algorithmic format that allows the practitioner to follow in the recognize and treat chronic pain with the use of opioids. Recommendations are made with regard to the intent to establish verifiable treatment objectives for patients with chronic pain that will lead to a reduction in pain, increase in function and quality of life.

To view the Opioid Therapy for Chronic Pain guideline, go to
http://www.oqp.med.va.gov/cpg/cot/ot_base.htm

Management of Substance Use Disorders in Primary and Specialty Care
VA/DoD Clinical Practice Guideline Working Group

The guideline consists of five modules that are designed to assist clinicians in primary care settings and specialized treatment settings with early detection of symptoms, assessment of treatment readiness, determination of the appropriate setting and intensity of treatment, and delivery of individualized interventions. The guideline also contains two appendices that provide screening and assessment instruments and a DoD clinical instruction.

To view the Substance Abuse guideline, go to.
http://www.oqp.med.va.gov/cpg/SUD/SUD_Base.htm

The above message comes from "*CDC*", who is solely responsible for its content.

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