Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

Wednesday

May 14, 2008

@ 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 14, 2008**

DATE: May 7, 2008

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 Allegra® Syrup and ODT Tablets and Update PBPA Category – **See Appendix C.**

Action Item – Vote to Update ADHD PBPA Criteria – **See Appendix D.**

Action Item – Vote on Criteria for Grandfathering – **See Appendix E.**

Utilization Review of Asthma Medications and 30 Day Notice to Prior Authorize Singulair® – **See Appendix F.**

30 Day Notice to Prior Authorize Plavix® 300mg – **See Appendix G**

30 Day Notice to Prior Authorize Osteoporosis Medications – **See Appendix H.**

30 Day Notice to Prior Authorize Topical Antibiotics **– See Appendix I.**

30 Day Notice to Prior Authorize Auralgan™ **– See Appendix J.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – May 14, 2008 @ 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 9, 2008 DUR Minutes – Vote
B. April 10, 2008 DUR Recommendations Memorandum

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

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

A. Retrospective Drug Utilization Review for January 2008
B. Retrospective Drug Utilization Review Responses for September 2007
C. Retrospective Drug Utilization Review Responses for October 2007
D. Medication Coverage Activity Audit for April 2008
E. Help Desk Activity Audit for April 2008

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

5. Vote to Prior Authorize Allegra® Syrup and ODT Tablets and Update PBPA Category – See Appendix C.

A. COP Recommendations

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

6. Vote to Update ADHD PBPA Criteria – See Appendix D.

A. COP Recommendations

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

7. Vote on Criteria for Grandfathering – See Appendix E.

A. Overview
B. COP Recommendations

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

8. Utilization Review of Asthma Medications and 30 Day Notice to Prior Authorize Singulair® – See Appendix F.

A. Utilization Review
B. COP Recommendations
C. Cost Comparison

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

9. 30 Day Notice to Prior Authorize Plavix® 300mg – See Appendix G.

A. Current PA Criteria
B. COP Recommendations

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

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

A. COP Recommendations
B. Current Forteo Criteria

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

11. 30 Day Notice to Prior Authorize Topical Antibiotics – See Appendix I.

A. COP Recommendations

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

12. 30 Day Notice to Prior Authorize Auralgan™ – See Appendix J.

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

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

13. FDA and DEA Updates – See Appendix K.

14. Future Business

A. Hemophilia Review
B. Antidepressant Review
C. Oral Antifungals Review
D. New Product Reviews

15. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of APRIL 9, 2008

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

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	
Shellie Keast, 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.; Principal Investigator	X	
Visiting Pharmacy Students: Ashley Ison	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
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
Kerri Wade, Senior Pharmacy Financial Analyst	X	

OTHERS PRESENT:

George Stambouligh, Cephalon	Jim Chapman, Abbott	Vince Morrison, Forest
Jacque Collier, Abbott	James Lieurance, Endo	Jack Rockett, Abbott
Sheryl Clark, Abbott	Jim Graham, Johnson and Johnson	Pam Davis, MHAT
Laura Mitchell, Purdue Pharma	Melton Edminsten, OBN	Donna Erwin, BMS
Linda Cantu, BMS	Jorge Nassar, BMS	Mark Woodward, OBN
Lance Stewart, Merck	Juan Avila, Endo	Jason Easley, Abbott
Jason Russell, Novartis	John Omick, Novartis	Joe McIntosh, Novartis
Jeff Knappen, Allergan	David Williams, Forest	

PRESENT FOR PUBLIC COMMENT:

S.A. Dean Drouty, M.D.; Abbott	(not specified)
Juan Avila; Endo	Agenda Item No. 6
Ed Zastawny; Novartis	Agenda Item No. 7
Maria Posa-Kane, M.D.	Agenda Item No. 10
Pam Sardo, Pharm.D.; Abbott	(not specified)

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

1A: Roll Call

Dr. Meece called the meeting to order. Roll call by Dr. Graham established a quorum.

ACTION: NONE REQUIRED.

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

Dr. McNeill recognized the speakers for public comment.

Pam Sardo, Pharm.D.; Abbott	comment regarding Simcor®, not on agenda
S.A. Dean Drouty, M.D.; Abbott	comment regarding Simcor®, not on agenda
Juan Avila; Endo	Agenda Item No. 6
Ed Zastawny; Novartis	Agenda Item No. 7
Maria Posa-Kane, M.D.	Agenda Item No. 10

ACTION: NONE REQUIRED.

Comments regarding Simcor® (not an agenda item):

For Public Comment, Dr. Drouty: For the record, I'm Dr. Drouty. I'm an internist. I practice internal medicine at, on the Mercy campus. I have accepted honoraria before from this company when I was functioning on their speaker's bureau. This is my first time doing this, so I'll keep it short and sweet because I don't know what to do. Zocor is a drug that is in Simcor. It's known to you as simvastatin. It's a drug that has a proven track record in preventing heart attacks in patients with established heart disease. It has now gone generic. Niaspan is the drug that Abbott made for many years and now it's been (unintelligible) the drug Zocor generic and put it together with niaspan so it's known as Simcor. It comes in three doses which replicate a study that was 164 patients (unintelligible) that got a lot of press several years ago because it showed that the addition of niaspan or (unintelligible) to Zocor reduced heart attacks (unintelligible) more than just Zocor, which is a statin. Statins typically they use the first heart attack, 37% of patients with (unintelligible) heart disease and by about 37-42% of patients who have heart disease. The addition of niaspan in doses similar to what Simcor would do or has done, reduced risk of heart attack by another 53%. Now this was a small study, four small groups, but it did attain significance. It is our hope as a practitioner that because this drug would be a one pill that contains basically equal to five pills (unintelligible) in this case, and one simvastatin, only one pill, it would meet with better patient acceptance and that your clients, the Medicaid folks, would hopefully comply better and avoid their first and second heart attack. That's all I want to say because I've never done this before.

For Public Comment, Dr. Sardo: Good evening to the committee. My name is Pam Sardo. I'm a government regional clinical executive with Abbott Laboratories and I don't know if you take conflict of interest because I work for Abbott and made that clear. Tonight I just wanted to share with you a little brief information regarding Simcor, a brand new FDA approved product and I understand that there was a recent article in the Journal of Clinical Lipidiology which talked about the fact that number of patients with multiple lipid abnormalities is increasing, as well as an article in the American Journal of Cardiovascular Drugs published in 2008, which also discussed the fact that statins do fail to prevent approximately two-thirds of the cardiovascular events. So just to make you aware of the combination product, the SEACOAST study, I just thought it was apropos tonight to talk about SEACOAST and OCEANS ..... maybe there should be a study called "NOAH'S ARK". But anyway, with the weather tonight. SEACOAST study was in 641 patients which did look at and the researchers identified significantly greater reductions in non-HDL with these patients in both the Simcor 2000/20 and the Simcor 1000/20 dose compared to simvastatin monotherapy 20 mg. There was a separate study called the OCEANS study which was an open label study mostly to look at the safety profile of these two agents which have been on the market independently. In the study, 520 patients, the OCEANS study, at least one episode of flushing did occur in about 70% of the patients; however, the intensity of the flushing was mild to moderate in intensity and only 7% of the patients discontinued, based on the side effect of flushing. It was well tolerated in these patients. in SEACOAST, the flushing occurred in 59% of the patients; however, discontinuation rates were only 6% in those patients. And as you're well aware, Simcor is contraindicated in patients with liver disease and elevated transaminases as well as active peptic ulcer disease, ulterior bleeding, and patients who want to become pregnant or are pregnant. And so I just appreciate the opportunity to come for you tonight and I'm happy to answer any questions that you may have about this new product that's now on the market for the patients in the State of Oklahoma. Thank you very much.

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

3A: March 12, 2008 DUR Minutes

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

ACTION: MOTION CARRIED.

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

4A: Retrospective Drug Utilization Review Report: December 2007

4B: Medication Therapy Management Services: July-December 2007

4C: Medication Coverage Activity Audit: March 2008

4D: Help Desk Activity Audit: March 2008

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

ACTION: NONE REQUIRED.

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

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE NARCOTIC ANALGESICS**

Mark Woodward of Oklahoma Bureau of Narcotics (OBN): Thank you and I appreciate the opportunity to visit with you all tonight about something at the Bureau of Narcotics that we're very excited about. My name is Mark Woodward. I'm the public information and education office for the Bureau of Narcotics and this is chief agent Melton Edmonstein who is the chief over our diversion section which handles a lot of the prescription fraud and abuse that we're dealing with here in Oklahoma. And I just wanted to give you a real kind of a quick overview of what we're seeing and what we're finding. I've had a lot of people ask me how bad is the prescription drug problem and I think this kind of says it, this Tulsa World headline, pretty clearly. We're number one in a lot of things in Oklahoma. This is not something to be proud of. We are number one in the consumption of prescription drugs per capita in terms of the non-medical use of prescription drugs, specifically painkillers. Estimated behind marijuana as the second biggest drug problem in the United States. It's just not ugly or violence. You don't see it on the 6:00 news, but we have an estimated 87,000 people using medications for non-medical use here in Oklahoma. That tops methamphetamine, cocaine and heroin combined. I get about 25 autopsy reports a month in Oklahoma on drug-related deaths that we have. Of those 25 a month, on average about 20 of them, or 80%, were prescription accidental overdoses. We have a lot more people dying from prescription drugs than we do street drugs. But again, it's something that has for years kind of flown under the radar at the Bureau of Narcotics. We've had a tracking program, but we started back in 1990 tracking Schedule II drugs, but the problem is obviously the early '90's to the late '90's, the number one drug became hydrocodone and that was a Schedule III, so it's harder to track. Three years ago we went to the Legislature and got permission to expand our OSTAR system to start tracking Schedule II – V, and that system called PMP, or Prescription Monitoring Program, it was launched in July of 2006. It has been a tremendous tool that we're very proud of and I know we've got a lot of feedback on doctors and pharmacists and law enforcement around the state where they are finally saying, look, I oftentimes have somebody sitting in my clinic, sitting in my ER in the middle of the night, their story just doesn't add up, but I do not have concrete evidence that this person's scamming me. And now there's a system in place where they can query our system. For example, if I'm the patient, they can check my medical history. They can see with the click of a mouse how many other doctors am I seeing. How often am I seeing them and what am I getting? And it's a tool for medical professionals and pharmacists so that they can intervene on the front lines so we don't have to get involved. It's not about catching more people, the criminals who are scamming and stealing and involved in fraud, it's about stopping them getting them to realize they've got a problem. When their doctor confronts them face to face, or a pharmacist stops them right there at the counter, suddenly that becomes the wakeup call that a lot of them need to say I've got a problem. This system has really helped us identify how bad the problem is. We've got several hundred Oklahomans who are seeing more than ten doctors in Oklahoma. Obviously these doctors don't know about the other doctor. We've got one, our poster child right now, that's seeing 66 different doctors in the state of Oklahoma, and if those doctors aren't checking this system, this guy's going to keep flying under the radar feeding an addiction. And we're not talking about somebody with just a small problem. Most of these people are eating anywhere from on the low end, maybe 25, but on the high end, 125 hydrocodone per day. No doctor's going to keep feeding that. That's why they're going to multiple doctors, to get this. And it's a great tool to have for doctors who can check these scammers, drug seekers we call them. They know the ERs better than a lot of the ER doctors do. They know when the shift changes are. They know who's on duty on a Friday night and a Thursday, and who's easier to get drugs from. They know when they're the most crowded and when to hit them and now doctors are saying it's great to have a system in place where if I'm suspicious, I'll have this guy sit in the waiting room and I can check this system and I can see how many other doctors (unintelligible). And it may show that in the last six months I'm at the same ER, multiple ERs, every Friday and Saturday night between midnight and 2:00 a.m., here's how much I'm getting, so it's a great system to have in place. We've really partnered with a lot of the regulatory boards around the State of Oklahoma, the Medical board, D.O. board, Dental board, and we've recently partnered here with the Health Care Authority to help you all because we know that a lot of these people, it's Medicaid and Medicare fraud that they're using in order to help feed an addiction. So we're really excited about the partnership that we have with the Health Care Authority to be able to again stop another avenue or potential loophole somebody's doing or using to try to feed an addiction, so we're very excited about that. We would encourage anybody that has questions about how our system works, demonstrations. Maybe as a doctor you've not used the system yet and maybe need some assistance or want to know just kind of how it works, feel free to call. The Bureau of Narcotics will gladly walk you through. Thank you all very much for letting me share some of this with you.

For Public Comment, Juan Avila: Hello everyone. My name's Juan Avila and I'm with Endo Pharmaceuticals. I'm their clinical affairs manager. I want to keep this very brief. I didn't really bring up any slides but the information with oxymorphone or Opana® ER, extended release formulation, has been out there for a period of time now. There's not a lot of new clinical data with it, but I do want to inform you that there's some new dosage strengths that just came out to make it a little easier to titrate patients, to start them on a lower dose then come up. The dosage strengths are 7.5 mg, 15 mg and 30 mg. So it kind of fits in with just broadening a little bit, making it a little bit easier to tailor the correct dosage for an individual patient. Because one of the things that we're finding is that, you know it's important to have a multitude of different medications to treat patients because we do know, just like with other class of medications like NSAIDs that some patients, not every patient responds to the same opiate in the same manner. So some people may have a better response than others and if the patient does not respond to one opiate, changes in that opiate make sense. A different chemical or molecule. And so that's why this product is out there available now. And it is available in both the IR form and the ER form. Are there any questions that I can try to answer from anyone right now about Opana?
Dr. Kuhls: Can I just ask, probably Dr. Mitchell needs to answer this question, but how is the Health Care Authority working with OBD that, how are you picking up these individuals? What are you doing quality assurance wise, to make sure that people are not getting meds, or what's on the back end that the Health Care Authority's doing quality assurance wise to make sure that we're doing something about all these individuals? Who are 87,000 individuals, many of them are abusing drugs, how is the Health Care Authority getting these people treatment or getting them off your program, or what are you guys doing as a quality assurance group to take care of that?
Dr. Mitchell: And Nancy can speak to that as well, and that's why we think partnering with the other agency is going to be so effective, and we're just beginning that relationship. But we primarily have looked from the standpoint of the providers, and we do regular routine runs looking at provider prescriptive habits and then we intervene on, traditionally the provider half of this equation, and work with the provider from the standpoint of when we see what we consider inappropriate prescribing going on. We do work with members that obviously have issues related to narcotic usage or other usage of medications, and we typically do that with our member services as well as we have care management. Coordinators actually call those members and offer them services from the standpoint of our behavioral health services, etc., etc. But we traditionally in the past have primarily approached it from the standpoint of providers.
Dr. Kuhls: Right, but that doesn't .....
Dr. Graham: We also have the lock-in program, too.
Dr. Kuhls: That's working well?
Dr. Graham: Oh yeah.
Dr. Nesser: It does what it does.
Dr. Mitchell: It does what it does. We would like to be able to do more aggressive with that program, but we obviously run that under some federal guidelines.
Dr. Kuhls: Because the real problem is what's on the back end? Obviously identifying them is important, but what's on the back end as far as taking care of the problem?
Mr. Woodward: A lot of times what we find is simply having a doctor or us, for example, notifying a doctor that they've got a particular patient that's a red flag, or contacting an ER and letting them know that a particular patient has been red-flagged by our system. They are looking to look out for them and able to confront them and sometimes just that's all it takes right then, kind of the wakeup call that many of them need. We don't want to have to intervene in terms of making it a criminal matter and in many cases, they do take their own steps to seek help, once somebody has kind of shed light on their problem.
Dr. Graham: Mark could I ask you a question? Do you guys find that there's more abuse with forged prescriptions or false pretenses under that, or is it due to stealing like grandparents' medications and things like that? What are you finding as far as?
Mr. Woodward: The big problem is just obtaining it by fraud, by going to multiple doctors, fill out, and then they ask, are you seeing another doctor and they're all checking "no". You always want to take their word for it but again, that's why this system will really help them if they are suspicious about their story, but most of it is simply going to multiple doctors. It is a tremendous problem when it comes to stealing it out of the homes, more from a perspective rather than professional, but if you're as a parent or grandparent, about eight out of ten calls that we get from Oklahoma's high schools and junior high is about the drugs they found on campus, whether it's in a locker or in a kid's pocket. It's not a street drug, it's mom and dad's pain pills and grandma's Xanax that they have stolen or what they call "farmed". They farmed it out of the house and some of them eat it to get a high but most of these kids are trading it or selling it and that answers the question I get from a lot of parents, is how do these kids afford marijuana and alcohol and some of the other things that they're doing. They're selling hydrocodone for $10 and oxycontin for $50 apiece.
Dr. Kuhls: I just, the reason why I bring it up is just that in my teenage population, because that's what I deal with with this problem, trying to find services for a kid as an adolescent for substance abuse is brutal. Psychiatrists don't want to do it, it's just very difficult to get. The back end's so important but the services are just incredibly brutal to get kids in and I'm sure the adult population is the same way. You've got huge numbers, relatively small .....
Mr. Woodward: Right now, the Department of Mental Health has a 900 member waiting list.
Dr. Kuhls: That's what I'm saying.
Mr. Woodward: Of treatment bed.
Dr. Kuhls: We just need to make sure that we identify, I know you work on provider side, but we need to find out when we find individuals that are being, that are abusing drugs, it's easy just to go to the next doctor. And so, we need to make sure that those people are identified to at least get those individuals into programs, too, from that side. Because you're right, it's the ERs and it's everything else. I just think it's extremely important. It's beyond the DUR Board.

Dr. Mitchell: We totally concur and we realize it's a huge issue. We've had a budget request in now for several years for enhancing some of our substance abuse treatment services that we're able to provide to our SoonerCare members and so we would welcome any help from that standpoint on bringing additional dollars into our service package to be able to provide additional services. But we do obviously take this very seriously. It's a very large issue. We very much appreciate you all reviewing it tonight to be able to add another, hopefully, link to the chain and our partnership as well, to be able to try to get a handle on an issue that affects a lot of our members and quite frankly, affects a lot of our providers.
Dr. McNeill: Does Commissioner White have any comment on this?
Dr. Mitchell: Commissioner White would have lots of comments if she was here. But she would, I'm sure she would love to come and spend some time. It's certainly one of her issues that she is committed heartily on, and she would very eloquently discuss this with you if the DUR would want to have her come and do that.
Dr. McNeill: That would be nice. Commissioner, Department of Mental Health and Substance Abuse.
Dr. Kuhls: What currently is covered with SoonerCare as far as rehabilitation? Anything?
Dr. Mitchell: Primarily out-patient services that are currently covered. And there is some, there are detox services covered dependent on obviously, what the issue is, but there are out-patient services.
Dr. Kuhls: For a certain length of time?
Dr. Mitchell: With prior authorization. I mean, it depends on what is proposed treatment plan, etc., etc. And we'd be happy to have any of our behavioral health folks come and speak to that. Or maybe they're ..... Glenn's here. Glenn. Glenn's hiding behind the pillar back there. Glenn from our behavioral health division is here. Glenn, do you know off the top of your head ...
Glenn: Lynn, you did a pretty good job of covering what we covering right now, but as far as time limits go, it just depends on what the treatment (unintelligible).
Dr. McNeill: When you stop and look at it though, from cost to this agency and where Oklahoma fits in, behavioral health diseases and substance abuse, those two together have to be the biggest part of our health care budget overall. In different agencies. It's just amazing.
Dr. Kuhls: I'm just tired of being number one when we should be 47, and we're number 47 when we should be number one.
Dr. Graham: We had Dr. Vorse here, you know, here awhile back, to talk about the detox center and all of that. One of his comments that shocked me was that even for all the detox docs that we've had, I mean, there's not that many, but there's several. They're so booked up that, you know, I mean, it's like, what are we going to do with these people, you know? It's, they're just overwhelmed with the numbers.
Materials included in agenda packet; presented by Dr. Keast.
Motion No. 1: Dr. Feightner moved to approve as submitted; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED.
Motion No. 2: Dr. Feightner moved to allow supplemental rebates for this category; seconded by Dr. Muchmore.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: **60-DAY NOTICE TO PRIOR AUTHORIZE OSTEOPOROSIS MEDICATIONS**

Materials included in agenda packet; presented by Dr. Keast.
For Public Comment, Ed Zastawny, Novartis: My name's Ed Zastawny. I'm a medical science liaison for Novartis Pharmaceuticals. I'm here to talk a little bit about Reclast or zoledronic acid, once a year IV infusion for postmenopausal osteoporosis. There's been two studies published in the New England Journal regarding the use of zoledronic acid for postmenopausal osteoporosis. The first one was the HORIZON trial, also known as the Pivotal Fracture Trial or PFT. Seventy-seven postmenopausal women age 65 to 89 randomized to either once annual IV zoledronic acid 5 mg, or to placebo. There was two strata in here that were asked when they were randomized if they wanted to be on the active treatment or not or did they want treatment. If they wanted treatment with a biphosphonate, they were excluded from the trial and then were treated, but they could be in strata two on concurrent therapy with either hormones, a serum like Evista calcitonin or randomized to one of the other. Everybody, as Dr. Muchmore mentioned, got calcium and vitamin D as part of the trial. This has been the only biphosphonate to-date that has shown statistically significant decreases in both hip fractures, vertebral fractures and non-vertebral fractures at three years. There is an on-going 3-year extension and we'll look to see after, what they've done with that group is the people that were on it for three years were randomized either to be off of it for three years or to continue getting it for three more years and we'll see where that ends up. The other study that was published in November-December in the New England Journal was another HORIZON trial but the RFT, the Recurrent Fracture Trial. This was study of about 2,200 men and women, age 50 and above, had a surgical repair of hip fracture within 90 days status post hip fracture repair, were randomized to either placebo or 5 mg once a year of zoledronic acid. It was an event driven trial, so even though it was planned to go for three years, whenever you hit the number of events that they calculated, they ended it about 1.9 years, almost two years, showed a significant decrease in the incidence of clinical fractures, non-vertebral fractures and vertebral fractures. There was a numerical difference in hip fracture reduction of 30%, but that was not statistically significant. The interesting thing about that trial, though, is it showed a 28% decrease in mortality in people status post hip fracture. I can't give you any details as to why that is, we can only hypothesize was that loss of mobility or lack of loss of mobility was appeased whatever. We're in the enviable position of trying to explain why we saved people's lives at 28%. There was a switch trial and it looked at people that had been on once a week, 70 mg of alendronate for post menopausal osteoporosis, and is it safe and effective to switch people then to once a year. There was a one year trial of about a little over 200 patients. People who had been on 70 mg were either continued on that and got an IV placebo infusion, or off of that but placebo oral tablet once a week like they would their Fosamax and got the once a year Reclast. (unintelligible) it was a non-inferiority trial. All the bone markers,

bone and mineral density, all those things, were equivalent so it was well tolerated, showed similar efficacy and they did a survey afterwards and asked patients, would you prefer oral, would you prefer IV. About 80% of them all preferred on the survey that they would prefer a once a year IV product. I'd be happy to answer any questions if you have them.
Dr. Kuhls: What's your literature say about recommendation of calcium and vitamin D post treatment? I mean that you give out to patients and stuff, what does it say?
Mr. Zastawny: That was a requirement and it was 800 to 1,000 of vitamin D and about a 1,000 of calcium every day. In the first trial, the the Pivotal Fracture Trial, that was all they got. You didn't measure vitamin D's, they didn't do anything else. An amendment to the second trail besides giving the standard course of calcium and vitamin D, they gave them a loading dose if they were measured to be deficient. And it was either 50,000 units orally or they actually got a single IM shot before they went on with the rest of them. But certainly as you mentioned, vitamin D is rampant, vitamin D deficiency is rampant and without supplementing those people, at least getting them to 30 or above, so that's the recommendation. And again, I think the new daily requirement is going up to a 1,000 units a day.
Dr. Muchmore: It looks like all your multivitamins will have more soon.
Mr. Zastawny: I think it's still 400 but I think they'll all be going up.
Dr. Muchmore: Do you give out any literature pamphlets to the patient or the physician that prescribes the zoledronic acid, saying remind your patient to continue to take calcium and vitamin D?
Mr. Zastawny: Part of my job is making sure doctors know that, but I think there are patient education guides out there to remind them of all those things. If there are no more questions, thank you for your time.
Dr. McNeill: Thank you sir. (to Dr. Keast) . . . on the Reclast coverage guidelines on page 27, did we take the bone mineral density out of the other criteria, does it need to come out of here?
Dr. Keast: ..... need to come out of both?
Dr. McNeill: Take it out of both ..... right? On page 27 under the secondary coverage guidelines, take it out of there too.
Dr. Knisely: So where does Forteo fit in?
Dr. Keast: It's already PA'ed. It's separate.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **60-DAY NOTICE TO PRIOR AUTHORIZE TOPICAL ANTIBIOTICS**
Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **30-DAY NOTICE TO PRIOR AUTHORIZE ALLEGRA® ODT AND SYRUP AND UPDATE PBPA CATEGORY**
Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE PRISTIQ™ AND UPDATE PBPA CATEGORY**
For Public Comment, Maria Posa-Kane, M.D.: I'm Dr. Maria Kane. I'm a psychiatrist here in Oklahoma City in private practice, strictly for patient private practice. It has come to my attention today that there has been (unintelligible) here today about the prior authorization for (unintelligible) antidepressants. Right now we're doing prior authorization of the Tier 2 antidepressant after they have failed one of the Tier 1 and the generic (unintelligible). So from what I have gathered today it's that there will be a requirement now for the patient to fail (unintelligible) or two of the generics before they could be started on one of the newer antidepressants or the Tier 2 antidepressant, so I thought I probably would come here and then giving my two cents worth because as a psychiatrist who's been in practice for, since 1977, it has really become quite difficult here recently having to do all these prior authorizations and usually occupies, obviously, quite a bit of time. At the end of the day it's about a two hour process. But too, also the whole process of having to fail generic medication is already a long period of time, but to have to fail two will almost have to take a two month period since most of the patients (unintelligible) and insurance is (unintelligible) so titrates to once a month. And that will really prolong that whole process to almost a two month period. And as we all know, just too many things could happen within the two month period. And besides, from old experience that we've had because I know that the psychiatrists are not the only ones who prescribe SSRIs or any of the other psychotropic medications, but I think we all know that two medications or those that are non-generic or the newer ones, basically are just more tolerated, are just more efficacious and also have just a better side effect profile. And in case of SSRIs, I think we also know that most of the very intolerable side effects that (unintelligible) have difficulty staying on their medication because of the GI sometimes which normally consists of the gastric (unintelligible) or just the nausea, vomiting, but also the diarrhea, some of the other, some of these SSRIs, and then there's the sexual dysfunctions that is also associated with it and all other side effects basically, so I guess at this point failure of (unintelligible) generics is already quite difficult, both for the physicians and the patient because as it is, failing twice, in my opinion anyway, tend to probably erode already the physician/patient relationship and obviously the long period that is required then you know, many things would happen and just the difficulty of having to take medications that don't really agree with them and basically prolonging their agony that way, but yet too you

know, they could exacerbate and decompensate. Even the ones shows up that they require inpatient treatment and (unintelligible) and also some fatal consequences of you know, that happens. So I thought I'd just come here and put in my two cents worth because I understand that Dr. Bell was not here and I was talking to some of my colleagues this afternoon and we thought that probably somebody should come here just to kind of express some of our own concerns about having to go through two trials before they could go to a Tier 2 medication, and also the whole issue of what we're hearing about possibly even creating a Tier 3. And I guess just knowing that the newer medications are the ones that are classified under the Tier 2 are much (unintelligible) in terms of efficacy and tolerability and it's not really a matter of us using the newer drugs, but also as we know, we have medications that we use for depression that are from the (unintelligible) or the (unintelligible) category, so we still use quite a bit of trazodone and (unintelligible) and amitriptyline and so I guess it's just truly a matter of how good a medication is or how well tolerated they are, or how efficacious they are and after all, I guess, they're all out in the market because they all work, but then we have to look at dose (unintelligible) criteria, side effect profile and efficacy and tolerability I think, that we know that well, the newer they are and the cleaner versions there are, and also when they have a better delivery system utilized in these newer medications, not only for antidepressants but also for antipsychotics, I think then we tend to use those for our patients just to I guess give them what we feel is best for them. So that's basically just my point.

Dr. Kuhls: I'd like to make a comment. I think that looking at this new drug, I think this is an, I agree with you totally. I think this is an important time that we have a brand new class review of these drugs looking at efficacy, looking at side effects, looking at stuff and to re-review these in terms of talking about tiers, OK? Instead of just adding this to a tier, I think this is a good time to reexamine what we got and see what the class one and class two. I think what's really important though when we look at that and maybe you can help the Health Care Authority, you made some statements that some of these Tier 2 drugs clearly have well controlled trials compared to some of the generics showing that one, that they're more effective. You need to let the Health Care Authority look at those studies, look at tolerability compared, I don't want to just see a report, but we need to look at comparative randomized controlled trials, comparing those versus the generics, to clearly show that one's better than the, that Tier 2's are better than the Tier 1's, and that we should all look at that and then re-examine this as a class.

Dr. Kane: Well this was unsure (unintelligible) just asking about this and I found out Dr. Bell is not going to be here, so I volunteered to come and I've never done this before.

Dr. Kuhls: We're not, I mean I think it's a good time. That we need to review things, look at med by med analysis, making sure that there aren't some drugs that are better than the others and to do that to make some decisions.

Dr. McNeill: I think there are a couple of things that should be looked at. One of them is that the efficacy issue. The other is tweaking a molecule before it goes off patent into another formulation to make it more expensive and to prolong the patent. You compare the Tier 1's and Tier 3's here .....

Dr. Kuhls: Wait, wait, wait ..... I don't necessarily, I just think right now we need to keep this open and to review and show that, I want to see that these Tier 3's are more effective than the generics and you agree with me totally.

Dr. McNeill: I agree with you, I agree with you, yes.

Dr. Kuhls: And you agree with that?

Dr. Kane: Yes.

Dr. Kuhls: And so let's look at it as a class and I understand what you said. I think it's a great time to re-look at that, to review everything and to make sure we're doing everything right.

Dr. Kane: Yeah because like I said, we use a lot of generics, especially from those in the '70's and the '80', you know, those tricyclics and heterocyclics that I've known (unintelligible) and amitriptyline.

Dr. Kuhls: I know, I know. And we clearly have Tier 1 SSRIs and so let's review it, look at it, look at effect, and if you could get those studies that you're talking about showing that some of these Tier 2 SSRIs that are out, that we have down here are more effective, then bring those to them and so we can look at that too.

Dr. Feightner: Doctor, this number 5, "petition for a Tier 2 medication may be submitted for consideration when a unique member specific situation exists or prescription by a psychiatrist", that is a prescription by a psychiatrist goes to Tier 2 or Tier 3 if no Tier 2 is available. So your patients if they are not doing well on Tier 1, if they submit for a PA the next month, my reading of this, it goes automatically to a Tier 3. So you're not having to wait for two months, you're not waiting two months.

Dr. Kane: Right, but most of the patients are not covered (unintelligible) they cannot do multiple doses but just once a month. And basically of course, I guess there has got to be some time, some period of time that you have to do a trial to take effect, at least the (unintelligible). So .....

Dr. Feightner: My point is you don't need to, my point is coming from, if you present a unique specific situation, the way it currently is today, the way I read it, present a specific situation, sexual dysfunction, OK? As a specific situation, the way I read it is you can go from after a trial of, one trial with one medication, you can go from Tier 1 to Tier 3. Is that the way that, is that wrong?

Dr. Le: No, that's not wrong. Just to clarify how it is right now and that fifth criteria is put in when we first looked at it, was for the concern that Dr. Kane brought up, for patients with unique medications or for considerations that they must have a specific agent, we put that in so the doctor wouldn't have to spend that time and put the patient at risk for a trial. Whenever there is a unique indication, unique situation a psychiatrist can submit a PA and they can request .....

Dr. Kuhls: OK, and this says "or a prescription by a psychiatrist", so that doesn't have to go through the PA process.

Dr. Kane: Right now, there is one trial, but my understanding, there is a proposal currently that we'll have to, that a patient has to fail two trials before they could go to a Tier 2.

Dr. Kuhls: The way I read it is not that case, because of number 5, that's the way I read it.

Dr. Muchmore: It's like our ophthalmic drugs, if prescribed by an ophthalmologist. The same thing, the psychiatrist can do directly up a tier.

Dr. Kuhls: But I, I think you're right, we need to review it because I don't ..... we need to review it all because I don't necessarily agree with opening the whole .....
Dr. Muchmore: We need to look at everything. We need to look at the whole class and re-do this whole thing.
Dr. Graham: Are you specifically talking about Medicaid patients or are you talking about all your patients with insurance?
Dr. Kane: Well not all the patients, but Medicaid patients especially are disadvantaged in a way because they're only allowed one visit.
Dr. Graham: Medicaid patients are only allowed one visit?
Dr. Mitchell: That's not the case, so we need to follow up with you about what specifically is .....
Dr. Kane: Right, but also .....
Dr. Mitchell: Medicaid patients actually can self-refer for some services and you as a physician, would not be limited to one visit a month, so I don't know what .....
Dr. Rhymer: Are they paid for more than one visit a month?
Dr. Kuhls: We need to re-do, re-look at this, look at the class, look at the meta-analysis, look at everything. If you have studies showing all that, they'd be happy to take a look at those.
Dr. Kane: Yes. Well like I said, you know, this was a (unintelligible) today, so I know that the more intense discussion of this issue will be on your next meeting so I just thought I'd come in and at least .....
Dr. Feightner: Doc, leave knowing that that's there, OK? That, that is there and that should be the way (unintelligible) .....
Dr. McNeill: Do we need to take care of Pristiq tonight with the knowledge that we're going to come back and re-do the whole thing?
Dr. Nesser: It's a 30-day, so it's OK. Yeah, and it's treated as a higher tier when it first comes in anyway, so we can take as long as we want.
Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **FUTURE BUSINESS**
Materials included in agenda packet; submitted by Dr. Graham.
12A: Oral Antifungals
12B: Methylphenidate Follow-Up
12C: Asthma Utilization Review
12D: Hemophilia
12E: New Product Reviews
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 13: **ADJOURNMENT**
The meeting was adjourned at 7:40 p.m.

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 10, 2008

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

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

Subject: DUR Board Recommendations from Meeting of April 9, 2008

Recommendation 1: Vote to Prior Authorize Tekturna HCT

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends adding Tekturna HCT® to the PBPA category as a Tier 3 agent with the following criteria, similar to Tekturna®:

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

Recommendation 2: Vote to Prior Authorize Narcotic Analgesics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends adding the Narcotic Analgesics to the Product Based Prior Authorization Program.

Tier 1	Tier 2	Tier 3	Oncology Only
All Immediate Release Narcotics Not Listed in Higher Tier*	**Long-Acting**		
	Morphine ER* Duragesic® Patches†	Kadian® Avinza® Opana® ER Oxycontin®	
	Short-Acting		
	Xodol® Opana®		Actiq® Fentora®

*Branded products will require a brand name override.
†Product would move to Tier 3 if current manufacturer's federal rebate status changes.

Recommended Criteria:

1. Tier 2 agents will only be approved after:
    a. A minimum 30 day documented trial/titration period of at least two Tier 1 agents in the past 90 days or
    b. Clinically appropriate pain therapy requiring time-released medication.

    In either case, diagnosis should be for pain related to a chronic condition.
2. Tier 3 agents will only be approved after:
    a. A minimum 30 day documented trial period of at least two Tier 2 agents in different classes in the past 90 days or
    b. Documented allergy or contraindication to all Tier 2 agents.
3. Members with an oncology related diagnosis will be exempt from the prior authorization process, quantity and dosage limits would still apply.
4. Actiq® and Fentora® are only approved for oncology related diagnoses.
5. Only 1 long-acting and 1 short-acting agent can be used concurrently regardless of diagnosis (methadone is included in this criteria).

Additionally the category was approved for inclusion in the Supplemental Rebate Program for Tier 3 Long-Acting Products and Tier 2 Short-Acting Products.

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for January 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	32,850	69,130	1,069,574	36,908
Limits which were applied	Established, Major, Males and Females, Age 38-55	Narcotics, Males and Females, Age 24-26	Contraindicated, Males and Females, Age 43-46, Asthma	High Dose only, 0-6 year old, male and females,Miscellaneous Anticonvulsants
Total # of messages after limits were applied	110	155	84	26
Total # of members reviewed after limits were applied	110	115	52	26

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
112		36	

Retrospective Drug Utilization Review Report

Claims Reviewed for September 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 51-65	Narcotics, Males and Females, Age 11-15	Contraindicated, Asthma, Males and Females, Age 0-15	High Dose, Androgens and Anabolic Steroids, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 90
Response Forms Returned: 64

The response forms returned yielded the following results:

6 (9%)	*Record Error—Not my patient.*
7 (11%)	*No longer my patient.*
8 (13%)	*Medication has been changed prior to date of review letter.*
8 (13%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
22 (34%)	*I am aware of this situation and will plan to continue monitoring therapy.*
13 (20%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 60
Response Forms Returned: 36

The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
3 (8%)	*No longer my patient.*
5 (14%)	*Medication has been changed prior to date of review letter.*
6 (17%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
17 (47%)	*I am aware of this situation and will plan to continue monitoring therapy.*
5 (14%)	*Other*

Retrospective Drug Utilization Review Report

Claims Reviewed for October 2007

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 66-150	Narcotics, Males and Females, Age 16-18	Contraindicated, Asthma, Males and Females, Age 16-21	High Dose, Abilify and Geodon, Males and Females, Age 0-21

Response Summary (Prescriber)
Letters Sent: 111
Response Forms Returned: 77

The response forms returned yielded the following results:

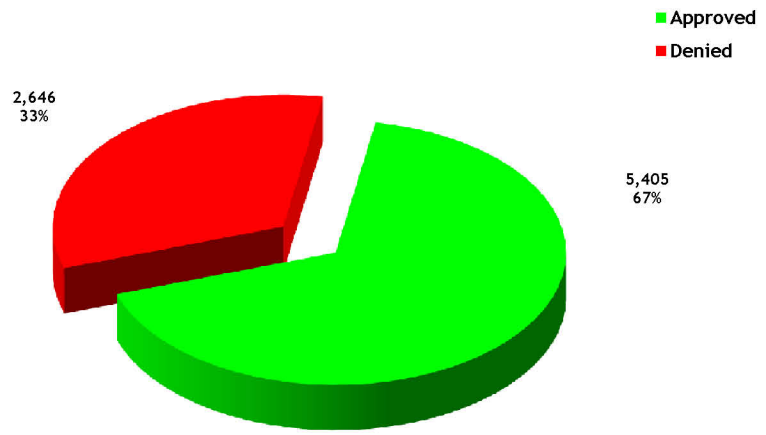
8 (10%)	*Record Error—Not my patient.*
8 (10%)	*No longer my patient.*
6 (8%)	*Medication has been changed prior to date of review letter.*
22 (29%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
14 (18%)	*I am aware of this situation and will plan to continue monitoring therapy.*
19 (25%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 29
Response Forms Returned: 17

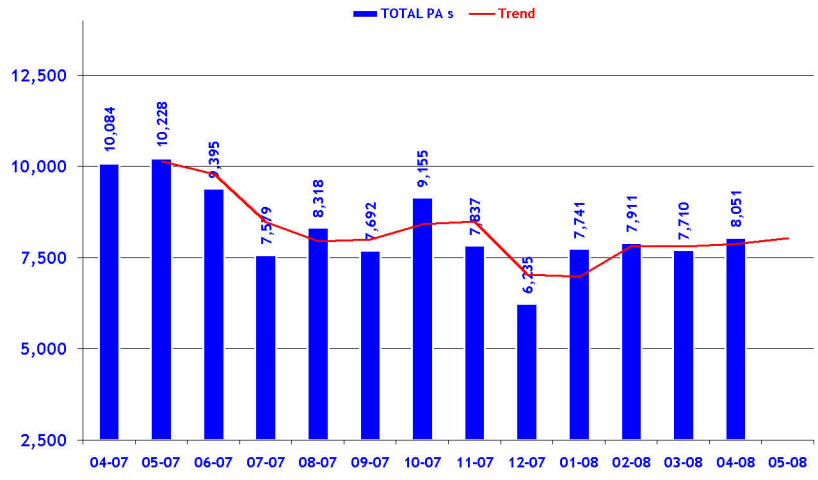
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
1 (6%)	*Medication has been changed prior to date of review letter.*
1 (6%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
9 (53%)	*I am aware of this situation and will plan to continue monitoring therapy.*
6 (35%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
April 2008



PRIOR AUTHORIZATION REPORT
April 2007 – April 2008



Activity Audit for

April 01, 2008 Through April 30, 2008

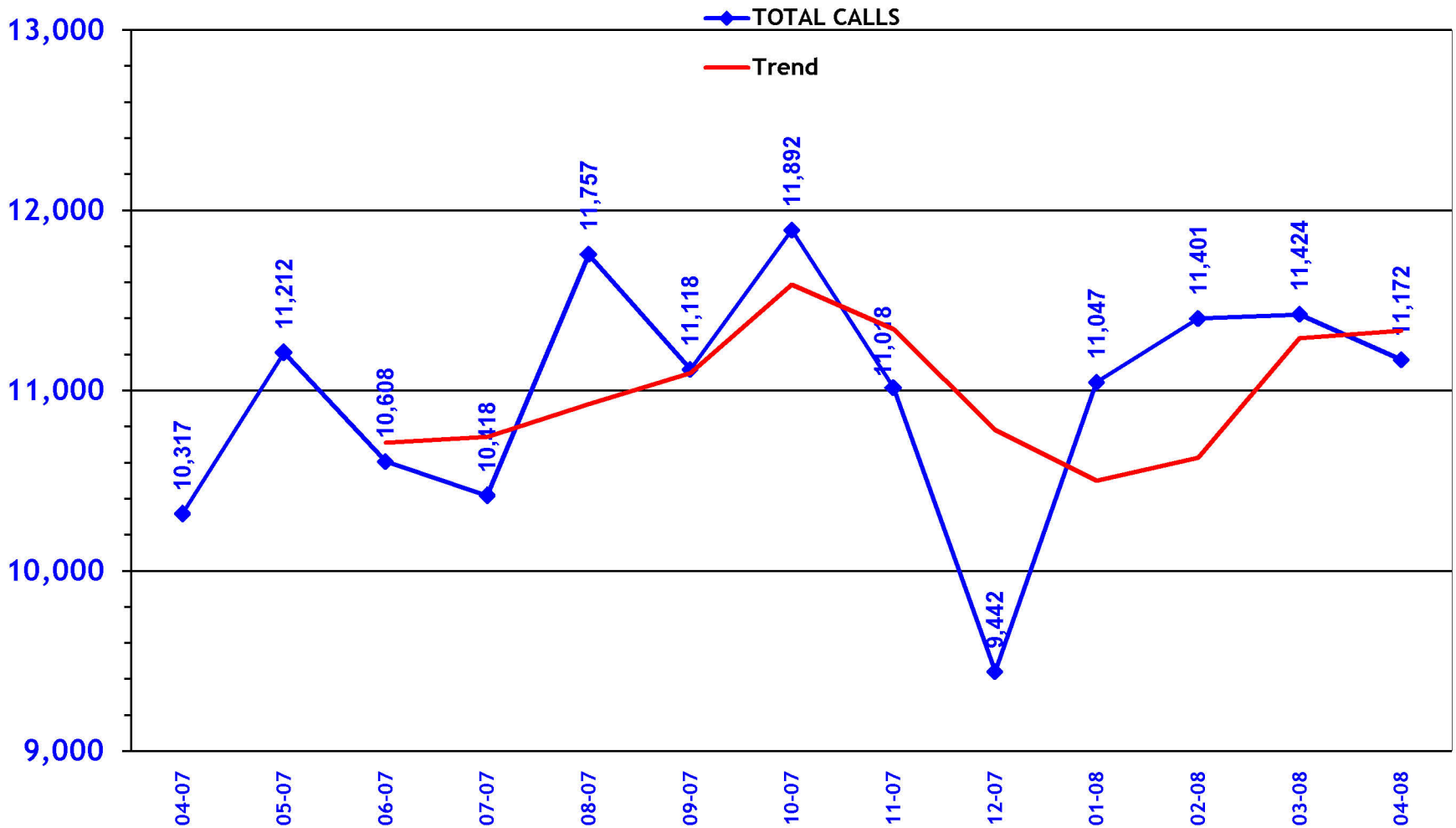
	Average Length of Approvals in Days	Approved	Denied	Total
ACE Inhibitors	188	11	6	17
Angiotensin Receptor Antagonist	345	39	94	133
Antidepressant	260	163	303	466
Antihistamine	98	401	398	799
Antiulcers	6	8	5	13
Anxiolytic	95	2,988	326	3,314
Calcium Channel Blockers	127	6	1	7
Growth Hormones	177	36	4	40
HTN Combos	202	6	18	24
Hypnotics	92	1	2	3
Insomnia	81	33	32	65
Nsaids	275	32	70	102
Plavix	112	161	20	181
Stimulant	205	603	312	915
Others	83	917	1,055	1,972
Emergency PAs		0	0	0
Total		**5,405**	**2,646**	**8,051**
Overrides				
Brand	174	41	30	71
Dosage Change	14	361	39	400
High Dose	0	0	1	1
Ingredient Duplication	10	16	3	19
Lost/Broken Rx	14	87	6	93
Nursing Home Issue	9	60	1	61
Other	14	42	7	49
Quantity vs. Days Supply	153	47	60	107
Stolen	9	4	0	4
Overrides Total		**642**	**144**	**786**

Denial Reasons

Lack required information to process request.	2,218
Unable to verify required trials.	1,217
Not an FDA approved indication/diagnosis.	236
Considered duplicate therapy. Member has a prior authorization for similar medication.	108
Does not meet established criteria.	69
Requested dose exceeds maximum recommended FDA dose.	59
Member has active PA for requested medication.	22
Medication not covered as pharmacy benefit.	8
Duplicate Requests	491
* Changes to existing	619

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

CALL VOLUME MONTHLY REPORT
April 2007 – April 2008



Appendix C

Vote to Prior Authorize Allegra Syrup and ODT Tablets and Update PBPA Category

Oklahoma Health Care Authority

May 2008

Recommendations

ORAL ALLERGY MEDICATIONS		
Tier 1	**Tier 2**	**Tier 3**
OTC loratadine*	fexofenadine (generic tabs)	desloratadine (Clarinex)
OTC cetirizine*		fexofenadine (Allegra)†
		levocetirizine (Xyzal)‡
* For members 21 years and older, OTC loratadine and OTC cetirizine are available with prior authorization. OTC loratadine and OTC cetirizine do not require PA for members under age 21. †Includes new Allegra syrup and ODT formulations. ‡Xyzal not covered for members under age 6.		

Approval Criteria:

- A 14 day trial each of OTC loratadine and cetirizine within the last month is required before a Tier 2 medication can be approved.
- All Tier 2 products must be tried for 14 days each within the last 60 days before a Tier 3 medication can be approved.
- Diagnosis must be for a chronic allergic condition or asthma.
- Prior authorization will be for 360 days.

Appendix D

VOTE TO UPDATE ADHD PBPA CRITERIA

OKLAHOMA HEALTH CARE AUTHORITY, MAY 2008

DISCUSSION

After implementation of new criteria in February 2008, several physicians requested continued access to immediate release methylphenidate for multi-daily dosing for their patients. As a result, the cap on the once daily dosing was lifted for the immediate release methylphenidate products.

RECOMMENDATION

The College of Pharmacy recommends moving methylphenidate IR to Tier 1 for doses up to TID, however it will not be counted as a Tier 1 trial (changes in red below).

Tier 1	*Tier 2*	*Tier 3*
methylphenidate SR, ER, and CR *dexmethylphenidate IR (Focalin)* *methylphenidate IR** *Focalin XR* *Concerta* *Adderall XR* *Vyvanse*	*Metadate CD* *Ritalin LA* *Strattera* *amphetamine salt combos†*	*Daytrana* *Desoxyn* *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.
*Doses greater than TID will require prior authorization. Does not count as a Tier 1 trial.
†No PA will be required for a once daily dosing of these medications. Doses greater than once daily will require prior authorization.

For Tier 2 Products:

- ☑ Trial with <u>one</u> 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.
- ☑ Clinical exception for Strattera if tics or substance abuse is present.
- ☑ Only use of one long-acting 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 E

Vote on Criteria for Grandfathering

Oklahoma Health Care Authority

May 2008

Recommendations

Currently, there are no specific guidelines applying to each Product Based Prior Authorization (PBPA) category regarding the grandfathering of medications. Grandfathering refers to the choice to allow current continuous utilizers of tier-2 and higher to remain on the higher tiered drugs after the category is implemented. For clarification purposes and to increase the efficiency in the administration of the PBPA categories the College of Pharmacy recommends the following:

Criteria for Grandfathering of PBPA Categories

1. A member is considered stabilized on a medication when claims history suggests a minimum compliance rate of 80% in the past 100 days.
2. On categories voted to be grandfathered, the member that is currently stabilized on a medication will still be eligible to receive that medication if it is moved to a higher tier.
3. PBPA categories will not be grandfathered unless the DUR Board votes to apply the grandfathering rule to the category.

Medications	Titration Required	Recommendation on Grandfathering
Antidepressants	Yes	Yes
Antihistamines	No	No
Antihypertensives	Yes	Yes
Anti-Ulcer Medications	No	No
Bladder Control Meds	No	No
Fibric Acid Derivatives	No	No
Insomnia Meds	No	No
Muscle Relaxants (excluding Special PAs)	No	No
NSAIDs	No	No
Nasal Allergy Medications	No	No
Ophthalmic Allergy Products	No	No
Ophthalmic Antibiotics	No	No
Ophthalmic Glaucoma Agents	Yes	Yes
ADHD Medications	Yes	Yes
Statins	Yes (not extensive)	No

Appendix F

Drug Utilization Review of Asthma Medications and 30 Day Notice to Prior Authorize Singulair®

Oklahoma Health Care Authority
May 2008

Introduction

Asthma is a highly prevalent disease, affecting more people in the United States than cancer and coronary heart disease, combined. It is more prevalent in children than adults, and more common in adult women than in men. Since the SoonerCare population has a higher percentage of females and children, asthma is expected to have a higher impact on this population.

Utilization

The anti-asthmatics class of medications is the second leading pharmaceutical class in expenditures for Calendar Year 2007 incurring a total cost of $44,257,596.36, which is roughly 15% of the total pharmacy expenditure.

Utilization of Asthma Medications for Calendar Year 2007

Drug Class	Claims	Members	Days	Cost	% Cost	Perdiem	Claims/ Member
Leukotriene Rec. Modifiers	151,891	42,875	4,633,844	$15,825,942.62	35.8%	$3.42	3.5
Sympathomimetics	231,013	86,860	4,854,798	$9,837,447.04	22.2%	$2.03	2.7
Sympathomimetics/Steroids	54,493	16,130	1,602,186	$9,117,251.12	20.6%	$5.69	3.4
Inhaled Steroids	52,912	21,246	1,509,595	$8,071,286.29	18.2%	$5.35	2.5
Anticholinergic	12,053	3,352	331,020	$1,083,713.92	2.4%	$3.27	3.6
Omalizumab	92	13	2,608	$192,268.11	0.4%	$73.72	7.1
Mast Cell Stabilizer	1,086	477	30,302	$67,818.76	0.2%	$2.24	2.3
Xanthines	2,379	594	73,329	$61,868.50	0.1%	$0.84	4.0
Totals	**505,919**	**109,810**	**13,037,682**	**$44,257,596.36**	**100.0%**	**$3.39**	**4.6**

Trends in Utilization of Asthma Medications

Calendar Year	Members	Claims	Cost	Cost/Claim	Perdiem	Days
2006	94,982	425,915	$33,644,105.54	$78.99	$3.09	10,893,588
2007	109,810	505,919	$44,257,596.36	$87.48	$3.39	13,037,682
Change	**14,828**	**80,004**	**$10,613,490.82**	**$8.49**	**$0.30**	**2,144,094**
Percent Change	**15.6%**	**18.8%**	**31.5%**	**10.7%**	**9.7%**	**19.7%**

Members

Medication Class	Calendar Year 2006	Calendar Year 2007	Percent Change
Leukotriene Receptor Modifiers	35,429	42,875	21.02
Sympathomimetics	74,981	86,860	15.84
Sympathomimetics/Steroids	15,437	16,130	4.49
Inhaled Steroids	18,199	21,246	16.74
Anticholinergic	3,071	3,352	9.15
Omalizumab	7	13	85.71
Mast Cell Stabilizer	476	477	0.21
Xanthines	605	594	-1.82
Totals	94,982	109,810	15.61

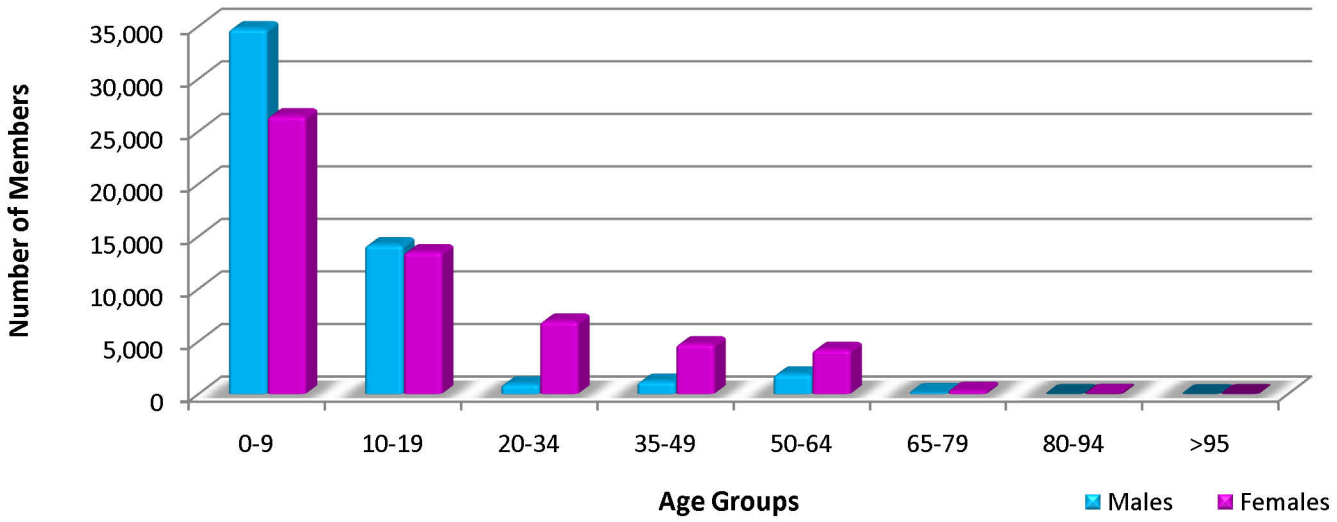
Claims

Medication Class	Calendar Year 2006	Calendar Year 2007	Percent Change
Leukotriene Receptor Modifiers	122,706	151,891	23.78
Sympathomimetics	193,946	231,013	19.11
Sympathomimetics/Steroids	52,212	54,493	4.37
Inhaled Steroids	43,343	52,912	22.08
Anticholinergic	10,250	12,053	17.59
Omalizumab	69	92	33.33
Mast Cell Stabilizer	1,018	1,086	6.68
Xanthines	2,371	2,379	0.34
Totals	425,915	505,919	18.78

Cost

Medication Class	Calendar Year 2006	Calendar Year 2007	Percent Change
Leukotriene Receptor Modifiers	$11,899,632.14	$15,825,942.62	33.00
Sympathomimetics	$6,501,885.86	$9,837,447.04	51.30
Sympathomimetics/Steroids	$7,996,157.27	$9,117,251.12	14.02
Inhaled Steroids	$6,124,298.86	$8,071,286.29	31.79
Anticholinergic	$867,724.78	$1,083,713.92	24.89
Omalizumab	$134,367.07	$192,268.11	43.09
Mast Cell Stabilizer	$61,390.62	$67,818.76	10.47
Xanthines	$58,648.94	$61,868.50	5.49
Totals	$33,644,105.54	$44,257,596.36	31.55

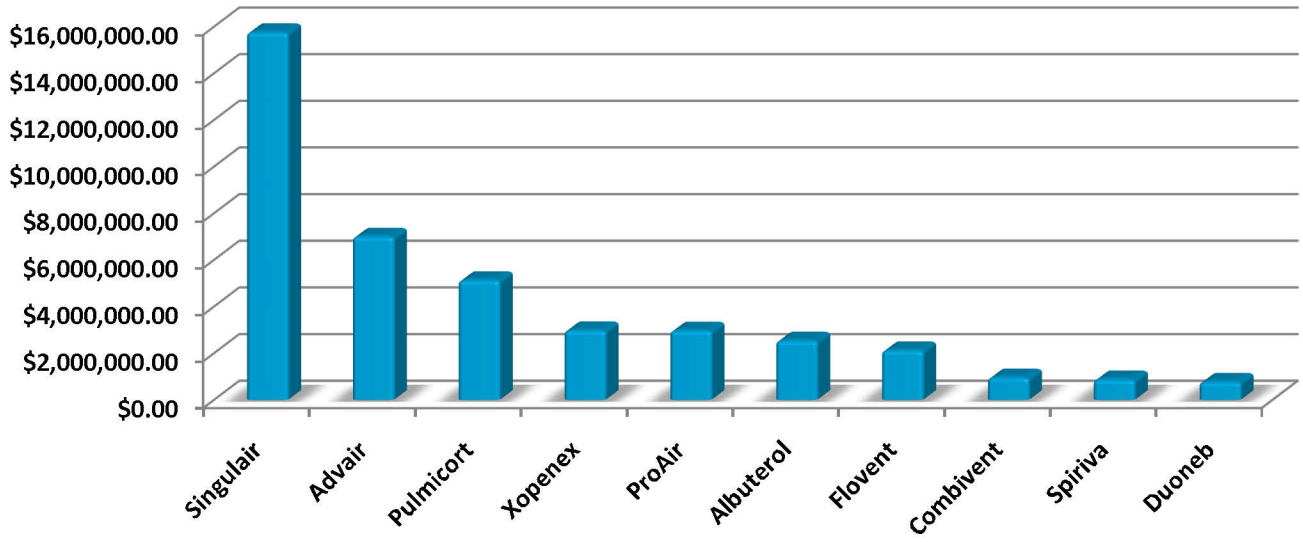
Demographics of Members Utilizing Anti-Asthmatics



	0-9	10-19	20-34	35-49	50-64	65-79	80-94	>95
Males	34,778	14,209	963	1,209	1,903	175	15	0
Females	26,491	13,547	6,944	4,786	4,248	351	38	5

A total of 109,810 members received an anti-asthmatic medication during calendar year 2007. This is approximately 15% of the SoonerCare population. However, only 44,020 (40%) of these members had a diagnosis of asthma in their medical or hospital claims. 65,790 members received an anti-asthmatic medication, but did not have a diagnosis for asthma in their medical or hospital claims.

Top 10 Agents by Cost



Leukotriene Receptor Modulators Utilization

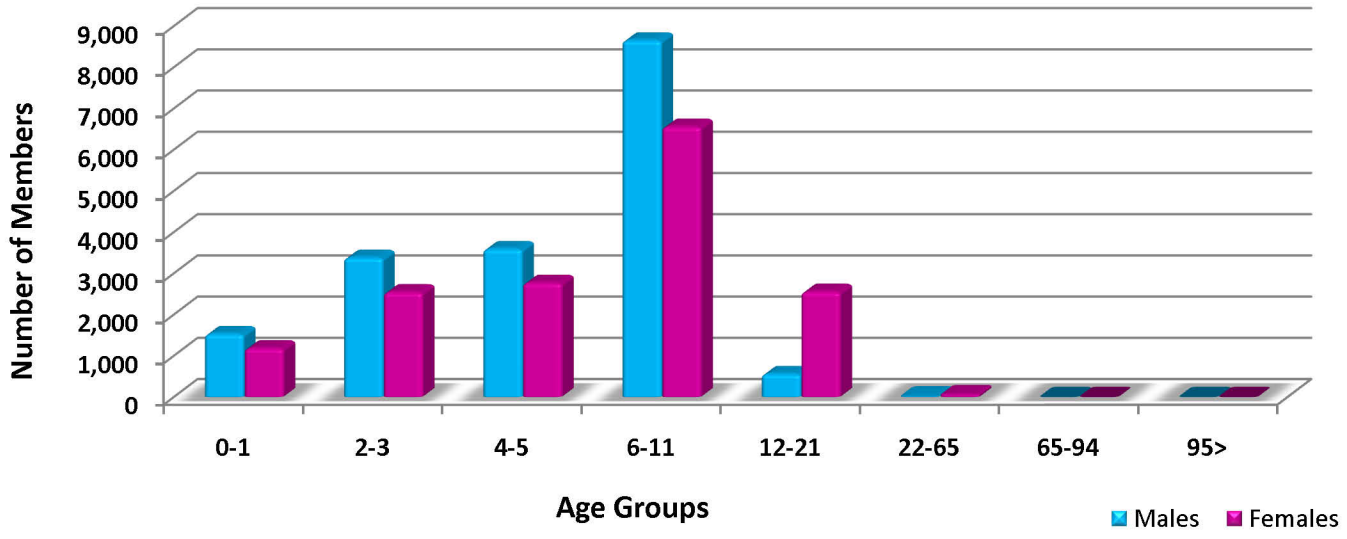
The utilization data shows over 99% of the claims and cost for the leukotriene receptor modulators are incurred by the product Singulair®. Singulair® is available in several dosage forms including tablets, chewable tablets, and granules. The following are the indications, maximum FDA recommended doses for each indication, and the age it's indicated for:

- **Asthma, chronic:** max of 10 mg orally in the evening, 12 months and older
- **Exercise-induced asthma; Prophylaxis**: max of 10 mg orally as a single dose at least 2 hours before exercise, no additional doses should be taken within 24 h of previous dose, 15 years and older
- **Perennial allergic rhinitis:** max of 10 mg orally once daily, 6 months and older
- **Seasonal allergic rhinitis:** max of 10 mg orally in the evening, 2 years and older

Utilization of Leukotriene Receptor Modulators

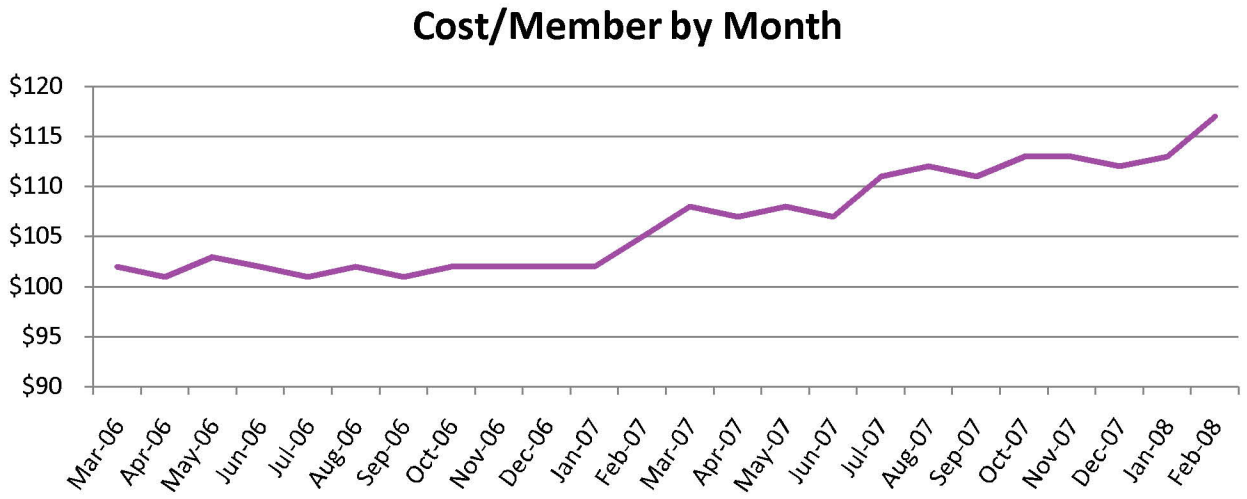
Brand Name	Claims	Units	Days	Members	Cost	Units/ Day	Claims/ Member	Perdiem
SINGULAIR® CHW 5MG	58,029	1,767,592	1,765,888	16,451	$6,060,887.84	1	3.53	$3.43
SINGULAIR® TAB 10MG	44,832	1,372,901	1,380,869	13,118	$4,675,034.80	0.99	3.42	$3.39
SINGULAIR® CHW 4MG	41,147	1,244,794	1,247,351	12,668	$4,283,933.48	1	3.25	$3.43
SINGULAIR® GRA 4MG	7,339	220,604	223,147	3,632	$755,354.47	0.99	2.02	$3.39
ACCOLATE® TAB 20MG	463	26,574	14,199	83	$38,880.70	1.87	5.58	$2.74
ACCOLATE® TAB 10MG	42	2,415	1,260	7	$3,288.87	1.92	6	$2.61
ZYFLO® TAB 600MG	39	3,860	1,130	9	$8,562.46	3.42	4.33	$7.58
Totals	**151,891**	**4,638,740**	**4,633,844**	**42,875**	**$15,825,942.62**	**1**	**3.54**	**$3.42**

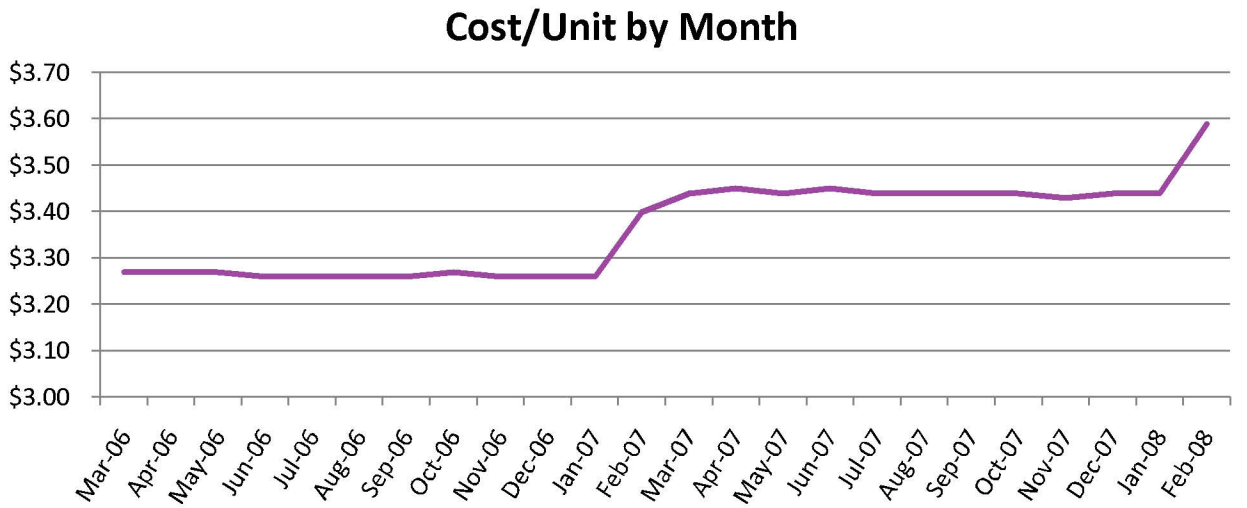
Demographics of Members Utilizing Singulair®

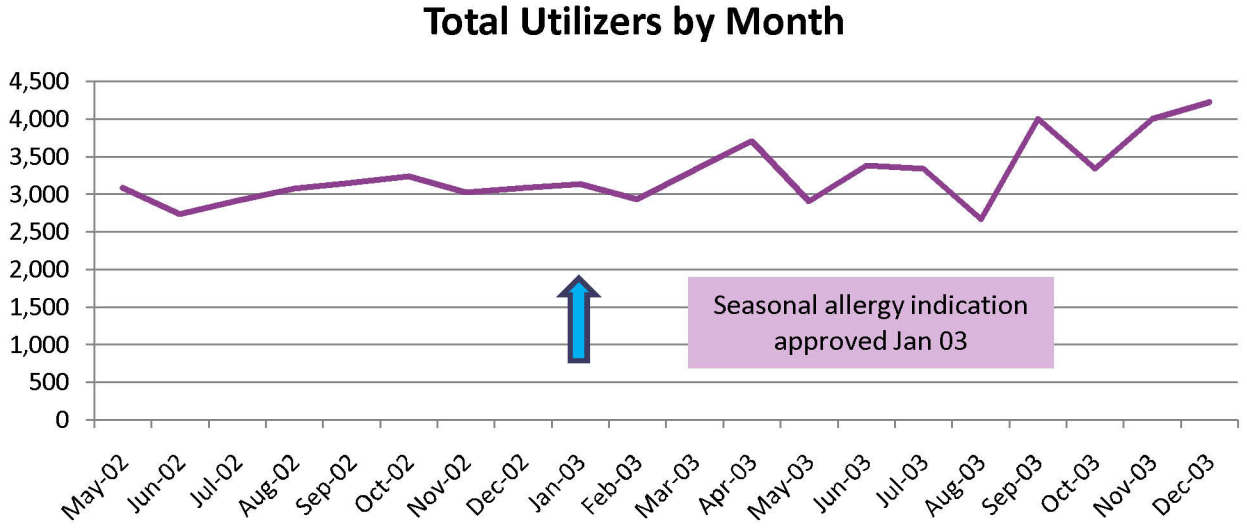


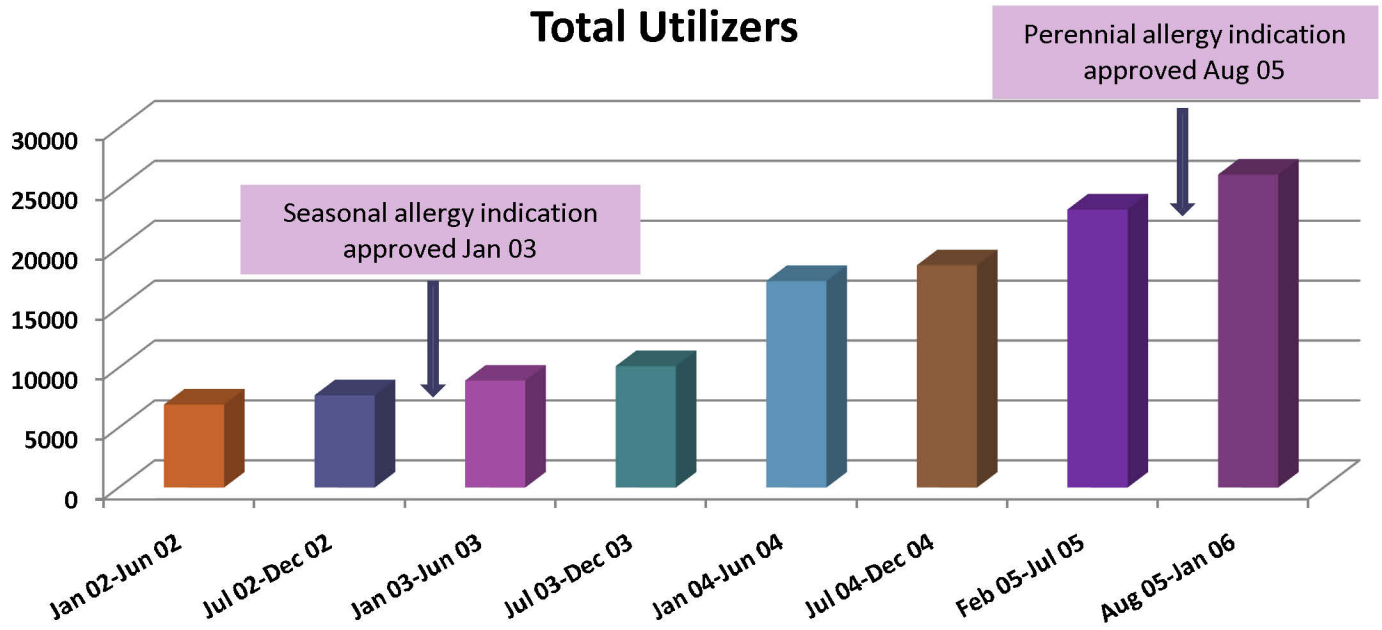
	0-1	2-3	4-5	6-11	12-21	22-65	65-94	95>
Males	1,532	3,382	3593	8,657	563	27	0	0
Females	1,186	2,547	2,775	6,562	2,559	73	0	0

Of a total of 42,792 members who had at least one claim for Singulair® in calendar year 2007, only 40% (18,140) of the members had a diagnosis code of Asthma in their medical/hospital claims. The following tables show the trends in utilization of Singulair® .









Place in Therapy of Singulair®

The efficacy of Singulair® has been evaluated in two diseases, asthma and allergic rhinits. According to the National Asthma Education and Prevention Program (NAEPP) guidelines, Singulair® is recommended as an alternative to low-dose inhaled corticosteroids in the stepwise approach for the management of mild persistent asthma. Singulair® is not recommended in the management of intermittent asthma. There are few published guidelines for the management of allergic rhinitis, and of those that are available, Singulair® is not widely recommended.[1,2] For treatment of symptoms associated with allergic rhinits the recommendations are as follows:

- Avoidance of allergens
- OTC decongestants
- Intranasal corticosteroids
- Oral antihistamines
- Various other agents such as cromolyn, anticholinergics, leukotriene receptor modulators, or ophthalmic preparations.

Intranasal corticsteroids and oral antihistamines have the most efficacy data. Efficacy data from randomized clinical trials of Singulair® for the symptomatic treatment of allergic rhinitis from the product insert showed the following results:

Effects of Singulair® on **daytime nasal allergy symptoms score*** in a placebo- and active control trial in patients with **Seasonal Allergic Rhinitis.**

Treatment Group (N)	Baseline Mean Score	Mean Change from Baseline	Diff between Treatment and Placebo (95% CI) Least Square Means.
Singulair® 10mg (344)	2.09	-0.39	-0.13‡ (-0.21,-0.06)
Placebo (351)	2.10	-0.26	N/A
Loratadine 10mg† (599)	2.06	-0.46	-0.24‡ (-0.31,-0.17)

*Avg of individual scores of nasal congestion, rhinorrhea, nasal itching, sneezing as assessed by patients on a 0-3 categorical scale.
†The study was not designed for statistical comparison between Singulair® and the active control (Loratadine).
‡Statistically different from placebo (p≤0.001)

Effects of Singulair® on **daytime nasal allergy symptoms score*** in a placebo controlled trial in patients with **Perennial Allergic Rhinitis.**

Treatment Group (N)	Baseline Mean Score	Mean Change from Baseline	Diff between Treatment and Placebo (95% CI) Least Square Means.
Singulair® 10mg (344)	2.09	-0.42	-0.08‡ (-0.12, -0.04)
Placebo (351)	2.10	-0.35	N/A

*Avg of individual scores of nasal congestion, rhinorrhea, nasal itching, sneezing as assessed by patients on a 0-3 categorical scale.
‡Statistically different from placebo (p≤0.001)

Conclusions

- Overall utilization data shows that Singulair® is the major cost driver for the category of anti-asthmatic medications and in the individual class of leukotriene receptor modulators.
- The increase in cost of Singulair® could be attributed to an increase in utilizers, an annual increase in cost of the medication, and the addition of the allergic rhinitis indications.
- Published guidelines and efficacy data does not support the use of Singulair® as one of the first line agents in the management of allergic rhinitis.

Recommendations

The College of Pharmacy recommends prior authorization of Singulair®. The College recommends an edit be put in place to detect a diagnosis of asthma and at least one claim for a rescue medication within a member's previous year's claims history. If a diagnosis is found, the claim for Singulair® will trigger a system-generated prior authorization for one year. For all other claims a manual prior authorization will be required and the following criteria will apply:

- Members with a diagnosis of asthma and at least one claim for a rescue medication within the previous year will receive approval for the duration of one year.
- Members with a diagnosis of Allergic Rhinitis must also have:
    1. Trials with Loratadine, Cetirizine, and Fexofenadine, each 14 days in duration, that has failed to provide adequate relief of allergic symptoms, and
    2. Two trials of an intranasal corticosteroid, each 14 days in duration, that has failed to provide adequate relief of allergic symptoms (applies only to members 2 years of age or older)
    3. Petitions with a diagnosis of perennial allergic rhinitis may be approved for the duration of one year, and petitions with a diagnosis of seasonal allergic rhinitis may be approved for the duration of 3 months.

[1] Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of respiratory illness in children and adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jan. 71 p. [176 references] Available at **http://www.guideline.gov/summary/summary.aspx?doc_id=10622&nbr=005564&string=rhinitis**

[2] Agency for Healthcare Research and Quality. Department of Health and Human Services. **Management of Allergic and Nonallergic Rhinitis.** Available at **http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1.chapter.117840**

Sympathomimetics	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
PROAIR® HFA AER	72,022	33,570	724,426	1,678,746	$2,981,033.28	$41.39	$1.78	2.15	0.43	30.30%
XOPENEX® NEB 0.63MG	10,260	5,728	1,423,492	188,792	$1,403,235.18	$136.77	$7.43	1.79	7.54	14.26%
XOPENEX® NEB 1.25/3ML	4,689	2,459	728,959	94,154	$710,062.54	$151.43	$7.54	1.91	7.74	7.22%
ALBUTEROL AER 90MCG	26,576	13,672	529,828	611,592	$637,294.72	$23.98	$1.04	1.94	0.87	6.48%
ALBUTEROL AER 90MCG	25,273	13,887	513,586	592,052	$605,830.50	$23.97	$1.02	1.82	0.87	6.16%
ALBUTEROL NEB 0.083%	31,459	17,070	5,819,950	549,811	$594,910.52	$18.91	$1.08	1.84	10.59	6.05%
XOPENEX® NEB 0.31MG	4,288	2,575	521,247	72,916	$516,830.81	$120.53	$7.09	1.67	7.15	5.25%
ACCUNEB® NEB 0.63MG/3	4,772	2,810	668,921	72,461	$388,143.29	$81.34	$5.36	1.7	9.23	3.95%
ALBUTEROL NEB 1.25MG/3	5,193	3,238	733,663	77,155	$375,287.55	$72.27	$4.86	1.6	9.51	3.81%
XOPENEX® HFA AER	6,837	4,159	115,954	175,086	$360,536.33	$52.73	$2.06	1.64	0.66	3.66%
PROVENTIL® AER HFA	7,380	4,551	54,541	185,096	$334,587.08	$45.34	$1.81	1.62	0.29	3.40%
ALBUTEROL NEB 0.083%	9,193	5,868	1,441,148	139,604	$159,393.17	$17.34	$1.14	1.57	10.32	1.62%
ACCUNEB® NEB 1.25MG/3	1,574	981	256,907	26,693	$148,195.29	$94.15	$5.55	1.6	9.62	1.51%
FORADIL® CAP AEROLIZE	1,047	346	62,406	31,679	$113,235.09	$108.15	$3.57	3.03	1.97	1.15%
MAXAIR® AUTOH AER 200MCG	718	337	10,473	24,076	$76,729.65	$106.87	$3.19	2.13	0.43	0.78%
VENTOLIN® HFA AER	1,817	1,363	37,718	43,962	$75,736.19	$41.68	$1.72	1.33	0.86	0.77%
ALBUTEROL SYP 2MG/5ML	9,317	7,300	1,203,095	125,033	$66,627.62	$7.15	$0.53	1.28	9.62	0.68%
ALBUTEROL NEB 0.63MG/3	940	707	122,898	15,563	$62,588.84	$66.58	$4.02	1.33	7.9	0.64%
SEREVENT® DIS AER 50MCG	458	136	29,114	13,846	$61,286.05	$133.81	$4.43	3.37	2.1	0.62%
ALBUTEROL NEB 0.5%	3,805	1,783	119,674	74,516	$37,513.42	$9.86	$0.50	2.13	1.61	0.38%
TERBUTALINE TAB 2.5MG	1,183	835	71,701	17,584	$28,468.17	$24.06	$1.62	1.42	4.08	0.29%
TERBUTALINE TAB 5MG	819	559	46,447	11,909	$24,343.50	$29.72	$2.04	1.47	3.9	0.25%
TERBUTALINE INJ 1MG/ML	35	6	3,390	561	$16,536.81	$472.48	$29.48	5.83	6.04	0.17%
VOSPIRE® ER TAB 4MG	140	43	8,524	4,021	$10,782.90	$77.02	$2.68	3.26	2.12	0.11%
VOSPIRE® ER TAB 8MG	57	14	3,986	1,812	$9,640.90	$169.14	$5.32	4.07	2.2	0.10%
BROVANA® NEB 15MCG	34	14	3,000	930	$7,714.26	$226.89	$8.29	2.43	3.23	0.08%
ALUPENT® INH AER 0.65/ACT	154	40	2,367	4,180	$6,746.82	$43.81	$1.61	3.85	0.57	0.07%
ALBUTEROL TAB 8MG ER	35	9	2,162	1,066	$4,444.25	$126.98	$4.17	3.89	2.03	0.05%
ALBUTEROL TAB 4MG	333	127	21,630	8,608	$3,631.15	$10.90	$0.42	2.62	2.51	0.04%
ALBUTEROL TAB 4MG ER	40	17	2,454	1,247	$2,724.54	$68.11	$2.18	2.35	1.97	0.03%
XOPENEX® CONC NEB 1.25/0.5	18	14	922	308	$2,720.47	$151.14	$8.83	1.29	2.99	0.03%
Totals	**231,013**	**86,860**	**15,329,250**	**4,854,798**	**$9,837,447.04**	**$42.58**	**$2.03**	**2.66**	**3.16**	**100%**

Sympathomimetics (Cont'd)	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
PROVENTIL® AER 90MCG	52	35	1,139	1,386	$2,704.58	$52.01	$1.95	1.49	0.82	0.03%
ALBUTEROL TAB 2MG	215	90	15,247	4,885	$2,060.54	$9.58	$0.42	2.39	3.12	0.02%
METAPROTEREN SYP 10MG/5ML	202	160	22,654	2,087	$1,661.80	$8.23	$0.80	1.26	10.85	0.02%
ALBUTEROL TAB 4MG ER	23	12	1,460	680	$1,587.76	$69.03	$2.33	1.92	2.15	0.02%
PROVENTIL® NEB 0.083%	6	2	1,524	87	$1,306.86	$217.81	$15.02	3	17.52	0.01%
PERFOROMIST® NEB 20MCG	1	1	120	30	$310.92	$310.92	$10.36	1	4	0.00%
ALBUTEROL POW SULFATE	2	2	211	40	$247.01	$123.51	$6.18	1	5.27	0.00%
METAPROTEREN NEB 0.4%	6	3	1,063	162	$202.36	$33.73	$1.25	2	6.56	0.00%
METAPROTEREN TAB 20MG	1	1	400	100	$169.17	$169.17	$1.69	1	4	0.00%
EPINEPHRINE INJ 1MG/ML	25	24	60	84	$120.21	$4.81	$1.43	1.04	0.71	0.00%
ADRENALIN® INJ 1MG/ML	3	1	30	30	$92.97	$30.99	$3.10	3	1	0.00%
METAPROTEREN NEB 0.6%	2	2	288	60	$60.70	$30.35	$1.01	1	4.79	0.00%
METAPROTEREN TAB 10MG	5	1	100	50	$50.45	$10.09	$1.01	5	2	0.00%
AIRET® NEB 0.083%	2	2	360	55	$47.68	$23.84	$0.87	1	6.55	0.00%
EPINEPHRINE INJ 0.1MG/ML	2	2	11	3	$13.14	$6.57	$4.38	1	3.67	0.00%
Totals	**231,013**	**86,860**	**15,329,250**	**4,854,798**	**$9,837,447.04**	**$42.58**	**$2.03**	**2.66**	**3.16**	**100%**

Sympathomimetics/Steroids	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
ADVAIR® DISKU MIS 250/50	17,716	6,034	1,071,414	541,388	$3,292,003.84	$185.82	$6.08	2.94	1.98	36.11%
ADVAIR® DISKU MIS 100/50	16,302	5,781	984,697	501,610	$2,456,381.04	$150.68	$4.90	2.82	1.96	26.94%
ADVAIR® DISKU MIS 500/50	3,912	1,183	238,775	120,911	$993,761.22	$254.03	$8.22	3.31	1.97	10.90%
COMBIVENT® AER	8,299	2,562	155,259	232,757	$968,118.38	$116.65	$4.16	3.24	0.67	10.62%
DUONEB® SOL	4,401	1,751	1,108,859	99,872	$782,921.24	$177.90	$7.84	2.51	11.1	8.59%
IPRATRO-ALBU 2.5-0.5/3 SO	1,098	620	240,121	22,061	$154,014.72	$140.27	$6.98	1.77	10.88	1.69%
ADVAIR® HFA AER 115/21	750	332	8,997	23,110	$132,417.39	$176.56	$5.73	2.26	0.39	1.45%
ALBUTEROL/ SOL IPRATROP	654	352	175,056	16,068	$112,932.19	$172.68	$7.03	1.86	10.89	1.24%
ADVAIR® HFA AER 45/21	633	329	7,656	20,400	$91,354.18	$144.32	$4.48	1.92	0.38	1.00%
SYMBICORT® AER 160-4.5	325	215	3,405	11,135	$55,591.11	$171.05	$4.99	1.51	0.31	0.61%
ADVAIR® HFA AER 230/21	168	73	2,064	5,220	$43,480.12	$258.81	$8.33	2.3	0.4	0.48%
SYMBICORT® AER 80-4.5	235	166	2,377	7,654	$34,275.69	$145.85	$4.48	1.42	0.31	0.38%
Totals	**54,493**	**16130**	**3,998,680**	**1,602,186**	**$9,117,251.12**	**$167.31**	**$5.69**	**3.38**	**2.5**	**100%**

Inhaled Corticosteroids	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
PULMICORT® SUS 0.5MG/2	10,520	4,803	879,180	276,113	$2,476,635.30	$235.42	$8.97	2.19	3.18	30.68%
PULMICORT® SUS 0.25MG/2	12,351	6,552	986,647	314,069	$2,424,476.71	$196.30	$7.72	1.89	3.14	30.04%
FLOVENT® HFA AER 110MCG	8,380	3,442	102,606	255,202	$966,541.24	$115.34	$3.79	2.43	0.4	11.98%
FLOVENT® HFA AER 44MCG	10,567	4,592	114,649	309,153	$937,473.35	$88.72	$3.03	2.3	0.37	11.61%
AZMACORT® AER 75MCG	1,452	731	30,731	51,703	$191,465.37	$131.86	$3.70	1.99	0.59	2.37%
ASMANEX® 30 AER 220MCG	1,781	612	430	53,697	$179,256.59	$100.65	$3.34	2.91	0.01	2.22%
FLOVENT® HFA AER 220MCG	866	405	10,870	26,064	$154,578.49	$178.50	$5.93	2.14	0.42	1.92%
PULMICORT® INH 200MCG	936	483	940	40,204	$153,003.96	$163.47	$3.81	1.94	0.02	1.90%
ASMANEX ®60 AER 220MCG	1,303	523	311	40,839	$131,988.51	$101.30	$3.23	2.49	0.01	1.64%
QVAR® AER 40MCG	1,910	933	14,412	53,860	$122,445.17	$64.11	$2.27	2.05	0.27	1.52%
FLOVENT® HFA AER 220MCG	381	215	4,788	12,036	$71,438.39	$187.50	$5.94	1.77	0.4	0.89%
PULMICORT® 180MCG INH POW	585	382	608	20,267	$68,844.74	$117.68	$3.40	1.53	0.03	0.85%
QVAR® AER 80MCG	826	361	6,288	23,829	$66,472.88	$80.48	$2.79	2.29	0.26	0.82%
ASMANEX® 120 AER 220MCG	196	77	46	8,143	$29,462.93	$150.32	$3.62	2.55	0.01	0.37%
PULMICORT® SUS 1MG/2ML	78	62	5,580	2,541	$27,291.08	$349.89	$10.74	1.26	2.2	0.34%
AEROBID® AER 250MCG	288	115	2,262	8,017	$26,983.43	$93.69	$3.37	2.5	0.28	0.33%
AEROBID-M® AER 250MCG	238	115	1,708	6,220	$19,624.86	$82.46	$3.16	2.07	0.27	0.24%
PULMICORT® INH 90MCG	203	115	217	6,001	$19,091.21	$94.05	$3.18	1.77	0.04	0.24%
FLOVENT® DISK AER 50MCG	45	26	2,700	1,474	$3,627.52	$80.61	$2.46	1.73	1.83	0.04%
AZMACORT® AER 100MCG	4	4	105	105	$406.63	$101.66	$3.87	1	1	0.01%
ASMANEX® 14 AER 220MCG	2	2	0	58	$177.93	$88.97	$3.07	1	0.01	0.00%
Totals	**52,912**	**21,246**	**2,165,078**	**1,509,595**	**$8,071,286.29**	**$152.54**	**$5.35**	**2.49**	**1.43**	**100%**

Anticholinergics	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
SPIRIVA® CAP HANDIHLR	6,166	1,604	201,135	200,490	$888,081.31	$144.03	$4.43	3.84	1	81.95%
ATROVENT® HFA AER 17MCG	1,216	442	18,770	33,223	$122,594.17	$100.82	$3.69	2.75	0.56	11.31%
IPRATROPIUM SOL INHAL	4,641	1,541	829,412	96,505	$70,773.51	$15.25	$0.73	3.01	8.59	6.53%
ATROVENT® INH AER 18MCG/AC	30	21	431	802	$2,264.93	$75.50	$2.82	1.43	0.54	0.21%
Totals	**12,053**	**3,352**	**1,049,748**	**331,020**	**$1,083,713.92**	**$89.91**	**$3.27**	**3.6**	**3.17**	**100%**

Xanthines	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
THEOPHYLLINE TAB 300MG ER	1,002	192	78,254	32,419	$20,916.93	$20.88	$0.65	5.22	2.41	33.81%
ELIXOPHYLLIN ELX 80/15ML	57	15	46,377	1,243	$7,765.37	$136.23	$6.25	3.8	37.31	12.55%
THEOPHYLLINE TAB 200MG CR	326	95	24,250	10,618	$4,468.91	$13.71	$0.42	3.43	2.28	7.22%
THEOPHYLLINE TAB 200MG ER	214	59	18,075	7,261	$3,219.57	$15.04	$0.44	3.63	2.49	5.20%
THEOPHYLLINE CAP 300MG ER	92	28	6,322	3,102	$3,082.92	$33.51	$0.99	3.29	2.04	4.98%
THEO-24® CAP 400MG ER	36	8	2,157	1,707	$2,916.39	$81.01	$1.71	4.5	1.26	4.71%
UNIPHYL® TAB 600MG CR	29	10	1,532	1,502	$2,683.87	$92.55	$1.79	2.9	1.02	4.34%
THEOPHYLLINE CAP 200MG ER	83	24	6,222	2,606	$2,645.37	$31.87	$1.02	3.46	2.39	4.28%
UNIPHYL® TAB 400MG CR	33	6	1,738	1,283	$2,118.66	$64.20	$1.65	5.5	1.35	3.42%
THEO-24® CAP 300MG CR	35	10	2,155	1,273	$2,066.77	$59.05	$1.62	3.5	1.69	3.34%
THEOPHYLLINE TAB 300MG CR	90	17	7,340	3,033	$2,045.85	$22.73	$0.67	5.29	2.42	3.31%
DY-G® LIQ 100-100	132	100	23,619	975	$1,504.68	$11.40	$1.54	1.32	24.22	2.43%
THEOPHYLLINE TAB 450MG ER	38	7	2,870	1,540	$1,400.60	$36.86	$0.91	5.43	1.86	2.26%
PANFIL-G® SYP	70	50	9,366	530	$1,138.77	$16.27	$2.15	1.4	17.67	1.84%
THEOPHYLLINE TAB 100MG CR	32	14	4,290	1,001	$700.49	$21.89	$0.70	2.29	4.29	1.13%
THEO-24® CAP 100MG CR	12	4	1,130	705	$613.02	$51.09	$0.87	3	1.6	0.99%
THEOPHYLLINE TAB 400MG ER	5	2	540	210	$581.33	$116.27	$2.77	2.5	2.57	0.94%
THEO-24® CAP 200MG CR	14	9	690	555	$531.06	$37.93	$0.96	1.56	1.24	0.86%
THEOPHYLLINE TAB 100MG ER	23	6	1,630	693	$319.06	$13.87	$0.46	3.83	2.35	0.52%
THEOCHRON® TAB 300MG CR	13	2	1,060	393	$283.54	$21.81	$0.72	6.5	2.7	0.46%
DILEX-G® 400 TAB	7	4	460	150	$269.80	$38.54	$1.80	1.75	3.07	0.44%
THEOPHYLLINE TAB 600MG ER	1	1	100	100	$157.76	$157.76	$1.58	1	1	0.25%
DYPHYLLIN-GG® ELX 100-100	20	18	2,371	150	$136.53	$6.83	$0.91	1.11	15.81	0.22%
JAY-PHYL® SYP	2	2	480	24	$95.60	$47.80	$3.98	1	20	0.15%
DILEX-G® 200 SYP	3	1	360	48	$53.94	$17.98	$1.12	3	7.5	0.09%
THEOPHYLLINE ELX 80/15ML	3	3	3,750	78	$51.87	$17.29	$0.67	1	48.08	0.08%
THEOPHYLLINE CAP 125MG ER	2	1	60	20	$31.76	$15.88	$1.59	2	3	0.05%
THEO-DUR® TAB 300MG ER	1	1	60	30	$22.31	$22.31	$0.74	1	2	0.04%
COPD® TAB 200-200	2	1	60	20	$20.42	$10.21	$1.02	2	3	0.03%
THEOCHRON® TAB 200MG CR	1	1	60	30	$12.87	$12.87	$0.43	1	2	0.02%
THEO-DUR® TAB 100MG ER	1	1	60	30	$12.48	$12.48	$0.42	1	2	0.02%
Totals	**2,379**	**594**	**247,438**	**73,329**	**$61,868.50**	**$26.01**	**$0.84**	**4.01**	**3.37**	**100%**

Mast Cell Stabilizers	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
INTAL® INH AER 800MCG	439	170	5,446	12,444	$42,963.10	$97.87	$3.45	2.58	0.44	63.35%
CROMOLYN SOD NEB 20MG/2ML	605	309	105,066	16,890	$20,435.21	$33.78	$1.21	1.96	6.22	30.13%
TILADE® AER 1.75/ACT	42	11	794	968	$4,420.45	$105.25	$4.57	3.82	0.82	6.52%
Totals	**1,086**	**477**	**111,306**	**30,302**	**$67,818.76**	**$62.45**	**$2.24**	**2.28**	**3.67**	**100%**

Omalizumab	Claims	Members	Units	Days	Cost	Cost/Claim	Perdiem	Claims/Mem	Units/Day	% Cost
XOLAIR® SOL 150MG	92	13	356	2,608	$192,268.11	$2,089.87	$73.72	7.08	0.14	100 %
Totals	**92**	**13**	**356**	**2,608**	**$192,268.11**	**$2,089.87**	**$73.72**	**7.08**	**0.14**	**100 %**

Appendix G

30 Day Notice to Prior Authorize Plavix 300mg

Oklahoma Health Care Authority
May 2008

Current Prior Authorization Criteria

Plavix® (clopidogrel) requires prior authorization for all members. Plavix® therapy will be approved for members meeting approved diagnostic criteria that have failed aspirin therapy (due to either side effects or event recurrence), or have a documented aspirin allergy, or use Plavix® (clopidogrel) concomitantly with aspirin. Members are approved for 12 months of therapy per authorization. The approved diagnoses are as follows:

- Recent stroke
- Recent myocardial infarction
- Established peripheral artery disease
- Acute coronary syndrome (unstable angina/non-Q-wave MI)
- Percutaneous coronary intervention with stent placement (aspirin trial not required)
- Transient ischemic attacks

Plavix 300mg

Plavix® 300mg tablet was approved for use as a loading dose for patients with non-ST-segment elevation acute coronary syndrome and ST segment elevated acute myocardial infarction. As these events are usually diagnosed in an institutional setting, it is anticipated that the loading dose would be administered in the institution and billed on a medical claim. It is not anticipated that the 300mg loading dose would be billed routinely through the point-of-sale system.

Recommendations

The College of Pharmacy recommends prior authorization of Plavix® 300mg. Approval Criteria is as follows:

- FDA approved diagnosis of non-ST-segment elevated acute coronary syndrome or ST segment elevated acute myocardial infarction.
- Approval will be for only one dose of 300mg.

Appendix H

30 Day Notice to Prior Authorize Osteoporosis Medications

Oklahoma Health Care Authority
May 2008

This category was introduced for possible inclusion in the Product Based Prior Authorization program in March 2008. See the March and April DUR packets for a more complete discussion of the category. This notice is presented to meet the statutory requirements of 63 O.S. Sec. 5030.5.

Recommendations

The College of Pharmacy recommends adding the Osteoporosis Medications to the Product Based Prior Authorization Program.

Tier 1*	Tier 2	Tier 3
Alendronate (Fosamax)	Alendronate + D (Fosamax+D)	Zoledronic acid (Reclast)
Calcium + Vitamin D†	Ibandronate (Boniva)	Teriparatide (Forteo)
	Risedronate (Actonel)	

*Branded products will require a brand name override. Calcitonin and raloxifene are not included as Tier 1 trials.
†Must be used at recommended doses in conjunction with Tier 1 bisphosphonate for trial to be accepted unless member has a recent laboratory result showing adequate Vitamin D or member is unable to tolerate calcium. OTC Calcium and Vitamin D are only covered for members with osteoarthritis.

Recommended Criteria for Moving to Higher Tiers:

1. Treatment failure with all lower tiered products, or
2. Contraindication to all lower tiered products, or
3. Allergic reaction to all lowered tiered products, or
4. Specific indication not covered by a lower tiered product.
5. No concomitant use of bisphosphonate therapy will be approved. No additional bisphosphonate may be approved for 365 days following zoledronic acid infusion.
6. Clinical Exceptions:
   a. Risedronate may be approved for members with high risk for gastric side effects.
   b. Zoledronic acid will be exempt from prior authorization for a diagnosis of Paget's disease or for osteoporosis if secondary diagnosis meets criteria (see Attachment 2).

Appendix 1

Reclast Coverage Guidelines

Reclast will be covered for postmenopausal osteoporosis in women who have the following secondary diagnoses:

- Severe esophageal disease (e.g., ulcerations, strictures):
  - ICD-9 codes 530.0, 530.20-530.21, 530.3 and 710.1
- Inability to take anything by mouth:
  - ICD-9 codes 530.87, V44.1, V45.72 and V45.75
- Inability to sit or stand for prolonged periods.
  - ICD-9 code V49.84.
- Inability to take an oral bisphosphonate for other special medical circumstances that justify the method of administration:
  - ICD-9 codes 995.29 and V12.79.

http://www.trailblazerhealth.com/Tools/Local%20Coverage%20Determinations/Default.aspx?ID=2084

Appendix 2

Current Forteo Criteria

1. Postmenopausal women at high risk for fractures (T-score at or below -2.5), or that cannot tolerate, are allergic to, or have failed to improve while on other agents.
2. Men with primary or hypogonadal osteoporosis (T-score at or below -2.5), or that cannot tolerate, are allergic to, or have failed to improve while on other agents.
3. No concurrent use of Forteo® with other osteoporosis agents.
4. Minimum 12 month trial with one other agent (unless contraindicated, intolerant, or allergic) and a BMD (T-score at or below -2.5) test within the last month.
5. PA approval for one month's supply per fill for duration of 1 year, with a maximum duration of 2 years.

Appendix 3

Dietary Reference Intakes for Vitamin D (Based on absence of adequate exposure to sunlight.)				
	Life Stage Group	RDA/AI (IU)	UL (IU)	Adverse effects of excessive consumption
Infants	0-6 mo	200	1000	Elevated plasma 25 (OH) D concentration causing hypercalcemia
	7-12 mo	200	1000	
Children	1-3 yrs	200	2000	
	4-8 yrs	200	2000	
Males	9-13	200	2000	
	14-18	200	2000	
	19-30	200	2000	
	31-50	200	2000	
	50-70	400	2000	
	> 70	600	2000	
Females	9-13	200	2000	
	14-18	200	2000	
	19-30	200	2000	
	31-50	200	2000	
	50-70	400	2000	
	>70	600	2000	
Pregnant or Lactating	≤18	200	2000	
	19-30	200	2000	
	31-50	200	2000	

Dietary Reference Intakes for Calcium				
	Life Stage Group	RDA/AI (mg)	Upper Limit (mg)	Adverse Effects of excessive consumption
Infants	0-6 months	210	ND	Kidney stones, hypercalcemia, renal insufficiency, milk alkali syndrome, possible CV risks
	7-12 months	270	ND	
Children	1-3 yrs	500	2500	
	4-8 yrs	800	2500	
Males	9-13 yrs	1300	2500	
	14-18 yrs	1300	2500	
	19-30 yrs	1000	2500	
	31-49 yrs	1000	2500	
	50-70 yrs	1200	2500	
	> 70 yo	1200	2500	
Females	9-13 yrs	1300	2500	
	14-18 yrs	1300	2500	
	19-30 yrs	1000	2500	
	31-50 yrs	1000	2500	
	50-70 yrs	1200	2500	
	>70 yrs	1200	2500	
Pregnant or Lactating	≤18 yrs	1300	2500	
	19-30 yrs	1000	2500	
	31-50 yrs	1000	2500	

United States Department of Agriculture. Dietary Reference Intake Tables. United States Department of Agriculture. http://www.iom.edu/Object.File/Master/7/294/0.pdf. http://www.iom.edu/Object.File/Master/7/296/webtablevitamins.pdf. Published 2001. Accessed March 13, 2008.

Appendix I

30 Day Notice to Prior Authorize Topical Antibiotics

Oklahoma HealthCare Authority, May 2008

Recommendations:

The College of Pharmacy recommends creating a prior authorization category for this group of medications with the following tier structure and criteria:

Tier 1*	Tier 2	Tier 3
Mupirocin Oint 2%	Supplemental Rebated Tier 3	Bactroban Cream 2%*
Gentamicin Oint 0.1%		Bactroban Nasal Ointment 2%
Gentamicin Cream 0.1%		Centany Kit 2%
Gentamicin Powder		Altabax Oint 1%
Cortisporin Oint 1%†		
Cortisporin Cream 0.5%†		

*Branded products will require a Brand Name Override when generic versions are available.
†Products will remain Tier 1 as long as federal rebate does not change.

Criteria:

- A 5-day trial of a Tier 1 medication within the last month is required before a Tier 2 medication can be approved.
- Member must have a 5-day trial with a Tier 1 and a Tier 2 medication prior to receiving authorization for a Tier 3 medication.
- Clinical exception for drug allergy or unique indication.
- Prior authorization will be for 10 days.

Appendix J

30 Day Notice to Prior Authorize Auralgan™

Oklahoma Health Care Authority
May 2008

Manufacturer Deston Therapeutics, LLC.
Classification Miscellaneous Otic Preparations
Status Prescription only

Summary[1]

Auralgan, an otic solution containing 1.4% benzocaine, 5.4% antipyrine, 0.01% acetic acid, 0.01% polycosanol, and glycerin, is the reformulation of the original Auralgan by Ayerst, which contained only antipyrine and benzocaine. The new formulation is being marketed for the relief of pain associated with acute otitis externa, removal of cerumen, and as an adjunct to systemic antibiotic to relieve pain and reduce inflammation of acute otitis media.

Dosing

- Pain: 2-4 drops every 1 to 2 hours as needed.
- Cerumen removal: 2-4 drops tid x 2-3 days.

Auralgan is available in a 14 mL container with dropper.

Neither this formulation nor the original Auralgan has FDA approval, so there are no officially approved generics therapeutic equivalents. Generic substitution is not allowed.

Product comparison

While the manufacturer claims that the addition of acetic acid and polycosanol provides added benefits and may even decrease the need for systemic antibiotics, there is no documentation to support these claims. A cost comparison has been compiled and is shown below:

	EAC*/unit	SMAC*/Unit	Cost/container
Auralgan (14mL)	$11.23/ml		$161.37
Benzocaine, Antipyrine, Glycerin (10 or 15mL)		$0.43/ml	$8.45/10 ml $10.60/15 ml
Acetasol (2% acetic acid solution) (15 ml)		$1.83/ml	$31.60
Acetasol HC **2% Acetic acid/1% hydrocortisone (10mL)**		$1.66/ml	$20.75

*Estimated Acquisition Cost, [+]State Maximum Allowable Cost

Recommendations

The College of Pharmacy recommends prior authorization of this product with approval after a trial of the generically available product, benzocaine/antipyrine/glycerin, and 2 trials of an oral pain reliever within the last 30 days that has failed to produce adequate pain relief.

1. Pharmacist Letter, May 2008 Vol. 24, Detail-Document 240502,

Appendix K

AMGEN
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Wyeth
P.O. Box 8299
Philadelphia, PA 19101-8299

IMPORTANT DRUG WARNING

SUBJECT: Tuberculosis and Infections with Enbrel® (etanercept)

March 14, 2008

Dear Health Care Professional:

Amgen Inc. and Wyeth Pharmaceuticals have added a BOXED WARNING to the ENBREL US Prescribing Information (US PI) to further strengthen and clarify information regarding the risk of infections, including tuberculosis (TB) in patients taking ENBREL; namely the new recommendation to screen for latent tuberculosis infection before beginning Enbrel. The complete BOXED WARNING is as follows:

WARNING
RISK OF INFECTIONS
Infections, including serious infections leading to hospitalization or death, have been observed in patients treated with ENBREL® (see **WARNINGS** and **ADVERSE REACTIONS**). Infections have included bacterial sepsis and tuberculosis. Patients should be educated about the symptoms of infection and closely monitored for signs and symptoms of infection during and after treatment with ENBREL®. Patients who develop an infection should be evaluated for appropriate antimicrobial treatment and, in patients who develop a serious infection, ENBREL® should be discontinued.

Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation) has been observed in patients receiving TNF-blocking agents, including ENBREL®. Tuberculosis may be due to reactivation of latent tuberculosis infection or to new infection. Data from clinical trials and preclinical studies suggest that the risk of reactivation of latent tuberculosis infection is lower with ENBREL® than with TNF-blocking monoclonal antibodies. Nonetheless, postmarketing cases of tuberculosis reactivation have been reported for TNF blockers, including ENBREL®. Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to initiating ENBREL® and during treatment. Treatment of latent tuberculosis infection should be initiated prior to therapy with ENBREL®. Treatment of latent tuberculosis in patients with a reactive tuberculin test reduces the risk of tuberculosis reactivation in patients receiving TNF blockers. Some patients who tested negative for latent tuberculosis prior to receiving ENBREL® have developed active tuberculosis. Physicians should monitor patients receiving ENBREL® for signs and symptoms of active tuberculosis, including patients who tested negative for latent tuberculosis infection.

The **ADVERSE REACTIONS: Infections** section of the US PI has also been updated to include the following information: "In global clinical studies of 20,070 patients (28,308 patient-years of therapy), tuberculosis was observed in approximately 0.01% of patients. In 15,438 patients (23,524 patient-years of therapy) from clinical studies in the US and Canada, tuberculosis was observed in approximately 0.007% of patients. These studies include reports of pulmonary and extra-pulmonary tuberculosis (see **WARNINGS**)."

The ENBREL Patient Package Insert (PPI) is being converted to a Medication Guide. The Medication Guide is designed to provide important patient safety information and increase the awareness about the proper use of ENBREL. The Medication Guide will be distributed when a prescription for ENBREL is dispensed in the US.

A copy of the revised US PI is enclosed. Following approval by the FDA the Medication Guide will be available on Enbrel.com. We encourage you to review the full prescribing information and discuss the safety information with your patients.

To report adverse patient experiences or request further safety information on ENBREL, please contact Amgen's Medical Information Connection™ at 1-800-77-AMGEN. Alternatively, adverse events may be reported to FDA's MedWatch reporting system:

- by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178),
- online (https://www.accessdata.fda.gov/scripts/medwatch/) or
- mailed, using the MedWatch for FDA 3500 postage paid form, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787

Sincerely,

Sean E. Harper, MD
Senior Vice President, Global Development
and Chief Medical Officer
Amgen, Inc.

Bruce Freundlich, M.D.
Multi-Therapeutic Area Head
Inflammation/Musculo-
Skeletal Diseases
Global Medical Affairs
Wyeth

Update to Healthcare Facilities and Healthcare Professionals about Heparin and Heparin-containing Medical Products

The Food and Drug Administration is summarizing important information relating to medical products that contain potentially contaminated heparin and is seeking assistance from healthcare facilities and providers in identifying and reporting adverse events related to these products.

Recommendations and Considerations

- Be aware of recent recalls of injectable heparin and heparin flushes and of life-threatening reactions which have been reported in association with contaminated heparin. Current recall information is available at http://www.fda.gov/cder/drug/infopage/heparin/default.htm#recalls and will be updated when new information becomes available. Additional information on reported adverse events can be found at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm.

- Report any adverse patient reactions that may be associated with injectable heparin and heparin lock flush solutions. In addition, we are asking you to report heparin-related adverse reactions associated with use of other medical products which contain or are coated with heparin. This includes a wide variety of medical devices and diagnostic products as described below. Instructions for reporting these adverse events are also provided below.

Background on heparin and heparin-containing medical products

Heparin is an anticoagulant (blood thinner) that is commonly administered intravenously or subcutaneously. It is used in patients undergoing kidney dialysis, certain types of cardiac surgery, and treatment or prevention of other serious medical conditions, including deep venous thrombosis (DVT) and pulmonary emboli. These products are typically sold in concentrations of 1000 U/mL or greater. Heparin lock flush solutions, which are generally used to maintain the patency of intravenous catheters and are considered to be medical devices, are manufactured at concentrations of 100 U/mL or less.

A variety of other medical devices and diagnostic products may also contain or be coated with heparin, including certain intravascular catheters, oxygenators, pumps, filters, and blood reservoirs used during cardiac procedures, vascular stents/grafts, and blood collection tubes. A list of specific medical devices containing heparin is provided at http://www.fda.gov/cdrh/safety/heparin-device-list.html. This is not an inclusive list of all firms that manufacture or distribute heparin-containing devices or a complete list of medical devices that contain or are coated with heparin. This list will be updated as additional information becomes available.

Adverse Events, Product Recalls, and FDA Actions

There has been an increase in the number of adverse events, including deaths, reported in association with the use of injectable heparin products. In particular, FDA has seen an increase in events consistent with an anaphylactic-type reaction and/or acute hypotension. Information on these events is available at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm. To date, only a small number of similar events have been reported for heparin lock flush solutions.

FDA scientists have identified a contaminant in the heparin – an oversulfated chondroitin sulfate. The contaminant mimics heparin activity so closely that it was not recognized by routine testing. FDA now has in vitro and animal data demonstrating a solid mechanistic link between the oversulfated chondroiton sulfate and the adverse events observed after bolus dosing. Our data demonstrate that the compound directly activates the kinin-kallikrein pathway in human plasma, which can lead to the generation of bradykinin (a potent vasoactive mediator) and C3a and C5a (potent anaphylatoxins). These data were recently published in the New England Journal of Medicine.

Several manufacturers and distributors of heparin products have initiated recalls of their products based on reports of adverse events associated with their product(s) or as a precaution after testing revealed that they were supplied with contaminated lots of heparin. Further information on these recalls may be found at http://www.fda.gov/cder/drug/infopage/heparin/default.htm#recalls.

The Center for Drug Evaluation and Research (CDER) has received commitments from the major US heparin manufacturers/suppliers to perform the recommended screening tests on all heparin active pharmaceutical ingredient (API) that is received (http://www.fda.gov/cder/drug/infopage/heparin/default.htm#screening). In addition, FDA's Center for Devices and Radiological Health (CDRH) has issued a letter requesting medical device manufacturers and distributors to determine if they market unfinished or final form products that contain heparin or utilize heparin in their processing, and if so, to ensure that the products are contaminant-free before they are released for distribution (http://www.fda.gov/cdrh/safety/heparin-notice.html).

Reporting Heparin-Related Adverse Events

FDA continues to actively monitor its post-market safety database for cases of heparin-related adverse events. Because we believe that it is essential to learn of new events as soon as possible, we are asking you to report any

significant adverse events that may be *heparin-related*, whether the product is a drug or a heparin-containing medical device.

In particular we are asking you to report:

- events with signs or symptoms consistent with anaphylactic-type reactions, acute hypotension, and/or acute gastrointestinal distress.
- any other serious reaction which may be attributed to the heparin in a medical product. These may include, but are not limited to
    - unexplained thrombocytopenia;
    - excessive anticoagulation or hemorrhage;
    - inadequate anticoagulation;
    - unexplained or premature thrombosis of a heparin-coated device; or
    - spurious results of in-vitro diagnostic tests that utilize heparin either as part of the assay or as part of the specimen collection.

To assist us in learning as much as possible about the adverse events, please include the following information in your reports, if available:

- The specific name of the product and its manufacturer;
- The lot number of the product;
- A description of the patient's characteristics, co-morbid conditions, and the reason for use of the product (diagnosis);
- A list of the patient's concomitant medications, therapies, and allergies;
- The route of administration, concentration and total amount of heparin given or on/in the device;
- The nature of the adverse event, the interventions required to address or correct it, and the clinical outcome;
- The time to event after heparin administration or device use;
- An explanation of why you believe the injectable heparin drug or the heparin component of the medical device was responsible for, or contributed to, the adverse event; and
- In the case of medical devices, whether systemic or subcutaneous heparin was administered concomitantly along with the device (and if so, the concentration and total amount given).

Please submit your reports to FDA as follows:

Healthcare providers should report adverse events to the FDA's MedWatch Adverse Event Reporting program either

- online at www.fda.gov/medwatch/report.htm;
- by returning the postage-paid Voluntary Form FDA 3500 (available in PDF format at www.fda.gov/medwatch/getforms.htm) to 5600 Fishers Lane, Rockville, MD 20852-9787;
- by faxing the Voluntary Form FDA 3500 form to 1-800-FDA-0178; or
- by reporting the event by phone at 1-800-332-1088

User facilities such as hospitals and nursing homes are required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and medical device-related serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. Again, please note that heparin lock flush solutions and in vitro diagnostic tests are considered medical devices and are therefore subject to these reporting requirements. These reports must be made on the MedWatch Mandatory Form FDA 3500A (available at www.fda.gov/medwatch/getforms.htm). Reports should be sent to Food and Drug Administration, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

Although user facilities are not required by law to report drug-related adverse events to FDA, we are asking that when you become aware of any such event related to use of a heparin injectable drug, you submit a Voluntary Report Form FDA 3500 directly to us. You can obtain the form at www.fda.gov/medwatch/getforms.htm. These reports should be provided to FDA using the methods described above for **healthcare providers**.

If your facility participates in **FDA's Medical Product Safety Network (MedSun)** program, please submit your reports for both device and drug-related heparin reactions to the MedSun website, as you currently do for your device reports. MedSun will forward your heparin-related drug reports to the Center for Drug Evaluation and Research for you.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek® (digoxin tablets, USP) as precaution

Contact:
Stericycle customer service
1-888-276-6166

FOR IMMEDIATE RELEASE -- Morristown, NJ -- April 25, 2008 -- Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than it appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6166 with representatives available Monday through Friday, 8 am to 5 pm EST. Additional information about the voluntary recall can also be found at www.actavis.us.

Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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FDA News

FOR IMMEDIATE RELEASE
April 29, 2008

Media Inquiries:
Rita Chappelle, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves Amitiza for IBS-C

Only drug available in United States for irritable bowel syndrome with constipation

This release contains revisions posted April 30, 2008

The U.S. Food and Drug Administration today approved Amitiza (lubiprostone) for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adult women aged 18 and over. There is currently no prescription drug therapy for IBS-C. With this approval, Amitiza becomes the only FDA-approved medical treatment for IBS-C available in the United States.

Irritable bowel syndrome is a disorder characterized by cramping, abdominal pain, bloating, constipation, and diarrhea. IBS causes a great deal of discomfort and distress to its sufferers. It affects at least twice as many women as men.

"For some people IBS can be quite disabling, making it difficult for them to fully participate in everyday activities," said Julie Beitz, M.D., director of the Office of Drug Evaluation III, Center for Drug Evaluation and Research, FDA. "This drug represents an important step in helping to provide medical relief from their symptoms."

The safety and efficacy of Amitiza was established in two major studies involving 1,154 patients diagnosed with IBS-C. The majority of the patients studied were women (approximately 8 percent were men). Patients enrolled in the studies were experiencing at least mild abdominal discomfort or pain that was associated with at least two of the following additional symptoms: 1) fewer than 3 spontaneous bowel movements per week (that did not result from laxative use); 2) hard stools; or 3) moderate or severe straining with bowel movements. In the studies some patients received Amitiza and others were given a placebo. More patients treated with Amitiza reported that their IBS symptoms were moderately or significantly relieved over a 12 week treatment period than patients who received placebo. The safety of long term treatment was assessed in a study in which all patients were treated with Amitiza for a duration that ranged 9 to 13 months.

The efficacy of Amitiza in men was not conclusively demonstrated for IBS-C.
Amitiza, like most prescription medications, is accompanied by some side effects. Common side effects of Amitiza include nausea, diarrhea, and abdominal pain. Other rare side effects include urinary tract infections, dry mouth, syncope (fainting), peripheral edema (swelling of the extremities), dyspnea (difficulty breathing), and heart palpitations.

Amitiza should be taken twice-a-day in 8 microgram doses with food and water. Patients and their health care professionals should periodically assess the need for continued therapy.

Amitiza is not approved for use in children and men. It is not to be administered to patients suffering from severe diarrhea or patients with known or suspected bowel obstructions. Its safety and efficacy has not been established in patients with renal or hepatic impairment, pregnant, or nursing mothers.

Amitiza is also approved for the treatment of chronic idiopathic constipation (CIC), but the dose for that indication is higher, 24 micrograms twice a day.

Amitiza is manufactured by Sucampo Pharmaceuticals, Bethesda, MD, and will be jointly marketed by Sucampo and Takeda Pharmaceuticals America, Inc., Deerfield, IL. As with all FDA-approved products, the agency will monitor Amitiza throughout its life cycle. Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

For more information about Irritable Bowel Syndrome, visit:

National Institute of Diabetes and Digestive and Kidney Diseases—Irritable Bowel Syndrome
http://digestive.niddk.nih.gov/ddiseases/pubs/ibs/

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Rx-to-OTC Switch List

January 1 through March 31, 2008

There are no switches for this period of time.

January 1 through December 31, 2007

NDA	Drug Name	Purpose	Approval Date
NDA 21-887	Orlistat	Weight Loss Aid	2-7-2007
NDA 21-150/S-007	Zyrtec-D	Antihistamine and Nasal Decongestant	11-9-2007
NDA 22-155	Children's Zyrtec Allergy and Children's Zyrtec Hives Relief (syrup)	Antihistamine	11-16-2007
NDA 21-621/S-005	Children's Zyrtec Allergy and Children's Zyrtec Hives Relief (chewable tablets)	Antihistamine	11-16-2007
NDA 19-835/S-022	Zyrtec Allergy and Zyrtec Hives Relief (tablets)	Antihistamine	11-16-2007

January 1 through December 31, 2006

NDA	Drug Name	Purpose	Approval Date
NDA 21-958	Lamisil Derm Gel	Topical Antifungal	7-24-2006
NDA 21-045	Plan B	Emergency Contraceptive	8-24-2006
NDA 22-015	MiraLax	Laxative	10-6-2006
NDA 21-066	Zaditor	Antihistamine Eye Drop	10-19-2006
NDA 21-698	Zantac 150	Acid reducer	8-21-2004

January 1 through December 31, 2004

NDA	Drug Name	Purpose	Approval Date
NDA 21-620[1]	Mucinex DM ER Tablet	Expectorant/Cough Suppressant	4-29-2004

NDA 21-585[1]	Mucinex D ER Tablet	Expectorant/Decongestant	6-22-2004
NDA 21-698	Zantac 150	Acid reducer	8-21-2004

January 1 through December 31, 2003

NDA	Drug Name	Purpose	Approval Date
NDA 21-229	Prilosec OTC	Acid reducer/PPI	6-20-2003
NDA 20-325/S-015	Pepcid AC Maximum Strength	Acid Reducer/H2 blocker	9-23-2003
NDA 19-658	Claritin Tablets	Antihistamine	11-19-2003

January 1 through December 31, 2002

NDA	Drug Name	Purpose	Approval Date
NDA 20-150	Nicotrol TD	Smoking Cessation	3-21-2002
NDA 21-282[1]	Mucinex ER Tablet	Expectoran	7-12-2002
NDA 20-641	Claritin Syrup	Antihistamine	11-27-2002
NDA 20-704	Claritin Reditabs	Antihistamine	11-27-2002
NDA 19-670	Claritin-D	Antihistamine/Decongestant	11-27-2002
NDA 20-470	Claritin-D 24-hour	Antihistamine/Decongestant	11-27-2002

January 1 through December 31, 2001

NDA	Drug Name	Purpose	Approval Date
NDA 21-261	Monistat 3 combo pk	Vaginal Antifungal	2-2-2001
NDA 21-308	Monistat 1 (supp)	Vaginal Antifungal	6-29-2001
NDA 21-307	Lotrimin Ultra	Topical Antifungal	12-07-2001

[1]These NDAs are not **true** switches because these products were marketed as prescription products without an approved NDA prior to being approved for OTC marketing under an NDA.

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Date created: April 24, 2008