# Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

September 14, 2005 @ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

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# MEMORANDUM

**TO:** Drug Utilization Review Board Members

**FROM:** Ron Graham, D.Ph.

**SUBJECT:** **Packet Contents for Board Meeting – September 14, 2005**

**DATE:** September 7, 2005

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

Enclosed are the following items related to the September 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 Byetta® – **See Appendix C.**

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

**Action Item** – Vote to Prior Authorize Revatio® – **See Appendix E**

**Action Item** – Vote to Prior Authorize Fenofibrates – **See Appendix F**

**Action Item** – Vote to Prior Authorize Focalin™ XR – **See Appendix G**

New Product Reviews and Notices – **See Appendix H**
30 Day Notice to Prior Authorize Rozerem® and Ambien CR™

**Action Item** – Annual Review of HMG-CoA Reductase Inhibitors – **See Appendix I.**

Review and Discuss Treatment of Head Lice – **See Appendix J.**

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

Future Business

Adjournment

# Drug Utilization Review Board

(DUR Board)

**Meeting – September 14, 2005 @ 6:00p.m.**

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

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## AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

**1. Call To Order**

A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

**2. Public Comment Forum**

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

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

A. August 10, 2005 DUR Minutes – Vote
B. Memorandum of August 10, 2005 DUR Recommendations
C. Provider Correspondence

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

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

A. Retrospective Drug Utilization Review Report for June 2005
B. Medication Coverage Activity Audit for August 2005
C. Help Desk Activity Audit for August 2005
D. Prospective Drug Utilization Review – Annual Report FFY04

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

**5. Action Item – Vote to Prior Authorize Byetta® – See Appendix C.**
**Invited Speaker – Joni Beck, Pharm.D., C.D.E., B.C.-A.D.M.**

A. Product Summary
B. COP Recommendations

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

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

A. COP Recommendations
B. Utilization Summary
C. Available Topical Steroids

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

**7. Action Item – Vote to Prior Authorize Revatio® – See Appendix E.**

A. COP Recommendations
B. Products Summary
C. Treatment Algorithm

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

**8. Action Item – Vote to Prior Authorize Fenofibrates – See Appendix F.**

A. COP Recommendations
B. Class Summary
C. Utilization Summary

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

**9. Action Item – Vote to Prior Authorize Focalin XR™ – See Appendix G.**

A. Product Summary
B. COP Recommendations
C. Prior Authorization Criteria and Tier Structure

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

**10. New Product Reviews and Notices – See Appendix H.**

A. **30 Day Notice to Prior Authorize Rozerem®**
B. **30 Day Notice to Prior Authorize Ambien CR™**
C. New Product Summaries

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

**11. Action Item – Annual Review of HMG-CoA Reductase Inhibitors – See Appendix I.**

A. Current Prior authorization Criteria
B. Utilization Review
C. Anticipated Market Changes to Class
D. COP Recommendations

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

**12. Review and Discuss Treatment of Head Lice – See Appendix J.**

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

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

**14. Future Business**

A. Antipsychotic Utilization Review
B. Neurontin® Review
C. Asthma Utilization Review
D. Muscle Relaxant Review
E. Osteoporosis Review
F. Annual Reviews
G. New Product Reviews
   - Xopenex® HFA
   - Balacet®
   - Darvocet-A-500®
   - Flexeril® 5 mg

**15. Adjournment**

# APPENDIX A

# OKLAHOMA HEALTH CARE AUTHORITY
# DRUG UTILIZATION REVIEW BOARD MEETING
# MINUTES of MEETING of AUGUST 10, 2005

| BOARD MEMBERS: | PRESENT | ABSENT |
|---|---|---|
| Brent Bell, D.O., D.Ph. | X | |
| Dorothy Gourley, D.Ph. | X | |
| Cathy Hollen, D.Ph. | X | |
| Kyle Hrdlicka, D.O. | X | |
| Dan McNeill, Ph.D., PA-C | X | |
| Clif Meece, D.Ph. | X | |
| James Rhymer, D.Ph | | X |
| Dick Robinson, D.Ph., Vice-Chair | X | |
| Thomas Whitsett, M.D., Chair | | X |

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

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

**OTHERS PRESENT:**

| | | |
|---|---|---|
| Jon Nickerson, AstraZeneca | Jim Fowler, AstraZeneca | Aliza Tomlinson, NAPCoE/OMcN |
| Jonathan Klock, GlaxoSmithKline | Jason Heiderscheidt, P&G Pharma | Erika Stafford, Astellas Pharma |
| Dale Roof, Takeda | Teresa Peden, NAMI Oklahoma | Richard Ponder, Johnson & Johnson |
| Sandy Ruble, KEI | Jim Dunlap, Lilly | Holly Jacques, Merck |
| Brian Leugs, PhRMA | Michelle Martinoe, Santarus | S. Randhawa, Red Rock |
| Michelle Gau, Pfizer | Susan Wellmon, Lilly | JoAnne Hargraves, Schering-Plough |
| Roger Enix, Merck | Jim Landrum, Novartis | Randy Huetsch, Eyetech Pharmaceuticals |
| Joe McIntosh, Novartis | Evie Knisely, Novartis | Mary Beth Webb, Boehringer-Ingelheim |
| David Case, Astellas Pharma | Nash Halem, Takeda | Anne Hartshorn, AstraZeneca |
| Pamela S. Allen, MD, OU Dermatology | Ron Schnare, Abbott | Cheryl McIntosh, Novartis |

**PRESENT FOR PUBLIC COMMENT:**

| | |
|---|---|
| J. Ghaznavi, MD, Red Rock | Quantity limits |
| Bhupathi Raju, MD, Red Rock | Quantity limits |
| Jeff Seaman, MD, OU | Quantity limits |
| Dennis Jacobsen, Schering-Plough | Agenda Item No. 5 |
| Evie Knisely, PharmD, Novartis | Agenda Item No. 6 |
| Pamela S. Allen, MD, OU Dermatology | Agenda Item No. 6 |
| Raymond Cornelison, OU Dermatology | Agenda Item No. 6 |

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

**1A:** **Roll Call**

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

**ACTION:** NONE REQUIRED.

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

**2A:** **Acknowledgement of Speakers and Agenda Item**

Dr. Robinson acknowledged speakers for Public Comment.

**ACTION:** NONE REQUIRED.

**For Public Comment, J. Ghaznavi:** *Good afternoon ladies and gentlemen, honorable Board members of the Oklahoma DUR, Oklahoma Health Care Authority. I'm Dr. J.H. Ghaznavi and I'm the Medical Director as I mentioned of the North Rock clinic at Red Rock Behavioral Health Services in Oklahoma City, and we see most chronically mentally ill patients and we see more than about a thousand patients a week. And we have about six to seven psychiatrists plus two residents. Incidentally, I've been a clinical faculty for about a decade. Now the concern that I have is those chronically ill patients, particularly those who are schizophrenic and those are schizoaffective and bipolar patients, my question and my concern is those patients who are stable, if this new limitation about these punches and FDA approval dosage, that could have a negative impact on our patients' best well being. What, as for example, some patients are not, a lot of the patients are not on FDA approved dosing. A lot of them are well above the FDA approved dosing. Just for example, give Seroquel® or say for example, Zyprexa®. A lot of all patient, they're so severely sick that . . . go to the FDA approved dosage, says for example, Seroquel® 600 to 800 mg. Still they are having psychotic symptoms or bipolar symptoms. Then you have two options. Either push their doses farther and see if they have any side effects or add another medication. Some of those patients are so (unintelligible), they have already used a lot of other different medications. So we try to go up on those patients on the max possible doses where their side effects are minimum or no side effects but their symptoms are controlled. So a lot of those patients are controlled so that they can function, particularly the newer antipsychotic medication, antidepressant medication, these medications already evidence states that they keep patients much better, functioning better and they're productive citizens, a lot of those patients. My question is, if those patients, if we cut down their dosage, I'm almost certain a lot of them will decompensate and they're already a lot of them are complaining, and then they'll end up in a hurry in the hospital. Because our goal is to keep all patients stable, productive and do as much as possible, the best interests to our patients is keep them out of the hospital, because the most costly part is hospitalization. If the patient goes to the hospital we all know twice in a year, ten days, that will eat up all the benefit that we see up front by cutting down. So my concern is I would like to request for flexibility on those dosage, particularly the chronically mentally ill patients and also I'd like to request like the punch because, two punches, because most of the patients that we see, they have more than four, five or six different issues. Particularly there are a lot of medical issues that we have to also address. So I'd like to make it short right now, a lot of other people here to express their concern. I would like to see, because if we use two punches, say as for example, Seroquel®, if we give 300 mg pill, two units a day, and if we use another 200 mg, that uses two punches, but they're already on some high blood pressure medication, maybe some diabetes medication, maybe some asthma medication, maybe some bladder control medication. So it is very hard for them to accommodate giving two punches. So I would like you, to request that be flexible on those and also those patients who are stable, I would like to see, as long as they're not having a severe side effects or drug-drug interaction, like to keep the patient on the higher dosage if possible.*

**Dr. Robinson:** *Now I must make just a little confession. I've been out of the loop; I've been away for two or three months. I wonder if somebody could explain these quantity limits.*

**Dr. Gorman:** *Let me sort of explain the policy and that might help. Some of the other speakers may not have as many concerns to address. Requirements were voted on in 2003 and we waited until now to implement them just trying to not have to implement them. The policy for the College on approving these, we've set things pretty much at the FDA max to give a kind of starting place, because you can't tighten something up without having someplace to start. Our policy is, if they're stable on it, if there's no other efficient way to get to this dosing by fewer number of pills, then we're approving them. If dosing is really extremely high, then we're asking just for some supporting information for the dose for the patient, like you know, how long they took to get up to it, if they're having side effects, that type of thing. The issue with the number of scripts, most of the things we're asking for are things that can get 100 days' supply. If it takes two pills to get a 100 days' supply, say it's going to be two pills and they'll each be once a day, then that's three months' worth for two prescriptions, and gives them an extra brand name prescription every three months. Does everybody understand that?*

**Dr. Hollen:** *So it's a 30-day supply or 100 units, whichever's greatest?*

**Dr. Gorman:** *Right. So if they're taking 90 pills a month, but they could take that in two dosage forms, if they can be . . . now some patients I know the doctors don't want to give them a whole three months, and that's another thing that we'll give the approval for, but if it's something they could take, let's go with Effexor XR® 150, if they're on a dose of 225 and they were taking three 75's, if they get 100 of the 150's, 100 of the 75's, they've only paid two copays for the three months' supply and only used two brand name punches. That leaves them a whole other maintenance med that they could get 100 units of possibly. So, at first we'll need a little bit of staggering to get it worked out, but it's definitely more efficient for the patient and for the Health Care Authority. And anything, if the patient's just incredibly unstable, we just need doctors to write this patient's stable, we're afraid they're going to decompensate, please leave this dose. We're just mostly trying to catch the ones... just an example of Seroquel®,*

*they had sixteen 25 mg tablets being dosed just 200 mg bid instead of using a 200 mg tablet twice a day. So these are the things we're really looking for and hope that maybe helps with some of your questions and concerns.*

**Dr. Hrdlicka:** *Is it not his issue though that these patients are far exceeding doses than FDA approval, so instead of 200 bid, these patients are getting 400-600 mg bid in some cases, so therefore, they're needing maybe 240 pills, you know. I'll give an example. Is that what you're saying?*

**Dr. Ghaznavi:** *Well if some patients, say, they're on 1000 mg, so we can give 300 mg Seroquel®, 300 mg pills, we can give them three pills at night and a 100 mg one pill in the daytime, some of them. Because I do not believe in giving like 100 mg two or three times a day because it is a twice a day dose. A lot, most of the time we do the highest number because of the sedation at night. So you're right because our patients, a lot of them, are much higher than FDA approved 800 mg dosing. And also, they're on much more than six prescriptions, like three generic and three name brand. So the biggest concern is that you know, those patients, even if you change the color of the pill, honestly, because they have been seeing day in and day out, if you change the color of the pill, in a hurry there in the hospital and not in the emergency room. So I guess, for example I have one patient that's been in the hospital more than 40 times. Since she have put on a higher dose antipsychotic and a newer generation antidepressant, she had only one episode in two years, had been to hospital two days. So in the long run, it is cutting down the cost up front maybe giving maybe 200 mg extra. But we are watching very carefully for any bad adverse reaction, drug-drug reaction or side effects. And of course if you look at some of the empirical data and some of the case study, you can see that there are certain patients they are already trying on 1600 and they do better on 1600. So I'd recommend at least be flexible on certain cases.*

**Dr. Gorman:** *And we are, if the doctor writes, you know, they decompensate easily, I've finally got them settled, we're approving them. Really we're just looking for the most efficient dosing that we can get out of this. Not so much exactly what their dose is, but there has to be some place to start catching the ones that could be changed, unfortunately.*

**Dr. Ghaznavi:** *Well, a few of, we have received some back, reply back that well, we approved for one month for titration purpose. So we are having a little confusion about that, like OK, this patient is on Zyprexa® 30 mg or 40 mg, we'll give you two months to titrate them down. So that's another big concern I have.*

**Dr. Gorman:** *Yes. The main reason they came out right at the beginning when everyone was trying to adjust, but I think now you'll see it'll be a lot ... (unintelligible)*

**Dr. Ghaznavi:** *Yeah, (unintelligible) yeah, because in one month it's very hard to titrate or two months.*

**Dr. Gorman:** *We really want to work with all the providers, you know it's just, anything we can do to just sort of level it off a little bit is what we're after. We're really trying to be flexible and if you have any one particular patient there is a problem with, give us a call, give me a call, I'll be happy to look it up, check it out, see what we can do for you.*

**Dr. Ghaznavi:** *Thank you, I appreciate it. Thank you.*

**For Public Comment, Dr. Raju:** *I'm sure that most of the needs are already told by Dr. Ghaznavi, so his material is the same thing I wanted to say. I work in a different mental health centers, just like the same kind of where he works. And the problems with this is the same thing like especially with the Seroquel® if they are on the higher doses and you would suddenly have to decrease their dose and they can get to relapse. Sometimes, even in spite of all our instructions, the patient themselves will take, drops out of that, and as usual, the dose what they were taking before. Our kind of thing is we have to add another antipsychotic it's not good to give two antipsychotics rather than giving the maximum dose which is FDA approved for these patients Seroquel® is FDA approved for bipolar at 800 mg so there's (unintelligible) and some patients who are already on higher doses than that for more than a year or so are stable with those medication, hard to decrease the dose when they're stable. So this is what I wanted to bring to your attention. Thank you very much.*

**For Public Comment, Dr. Seaman:** *I'm a resident training doctor, OU Psychiatry, so charged with training the next generation of psychiatrists for Oklahoma, at least a portion of them and you've told me everything I needed to hear, and I'll reassure them that the Board is really going to be flexible, understand our needs and all we've got to do is communicate and you understand that we'll get things adjusted as necessary on an individual basis. So I really don't have any concern at this point. You said exactly what I needed to hear. Thank you.*

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

**3A: June 14, 2005 DUR Minutes**

Dr. McNeill moved to approve minutes as submitted; seconded by Dr. Meece.

**ACTION:** MOTION CARRIED.

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

**4A: Retrospective Drug Utilization Review Report for April 2005**

**4B: Medication Coverage Activity Report: June, July 2005**

**4C: Help Desk Activity Report: June, July 2005**

**4D: Pharmacotherapy Management Program Annual Report FY05**

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

**ACTION:** NONE REQUIRED.

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

**For Public Comment, Dennis Jacobsen:** *Good evening. I'll try to be brief. This is a little bit difficult for me since sixteen months ago, I was at the University of Kansas on faculty there and we had hours to talk to students, so the Board meeting just went on and on and on because we had nothing else to do. Anyway, I'm a medical science specialist with Schering-Plough in the global medical affairs department. I'd like to thank you for the opportunity to address you tonight. I'd like to briefly discuss four items related to patient care with Zetia®. The prevalence of use for Zetia® with monotherapy, efficacy and safety of Zetia® monotherapy, efficacy and safety of adding Zetia® to a statin compared to up-titrating the statin and finally some outcomes data with Zetia® which I've heard is a concern of the committee here. First of all, through discussions with the sales force in the State of Oklahoma, it is our understanding that a significant of Medicaid patients are on Zetia® monotherapy in the State of Oklahoma, likely because of statin intolerance. Next the monotherapy efficacy and safety of Zetia®. Zetia® is the first and only compound in a new class of lipid lowering agents called cholesterol absorption inhibitors. Zetia® has been available in the US a little over two years and is now widely accepted as a primary or secondary lipid lowering agent. There's quite a bit of use in the field. It's got a novel mechanism of action which actually the MOA was recently published in a paper in Science, actually at the time that it was approved the mechanism of action was not known. But I won't bore you with all those details. Importantly, Zetia® has no side effect on absorption of other dietary fat soluble acids or fat soluble vitamins. It's not metabolized by cytochrome P450 enzymes and therefore is unlikely to affect the dispostition of other drugs metabolized by the cytochrome P450 enzymes. Zetia® and its' active metabolite are eliminated primary by fecal means, to a small extent by renal excretion. Safety analysis of all well controlled randomized trials with Zetia® has resulted and has demonstrated that Zetia® is generally well tolerated. In fact the side effect profile is similar to placebo in all the trials that have been published to-date. In addition, the need to discontinue Zetia® due to recurrence of any specific side effects has been similar to placebo. Importantly, no continuous monitoring of liver enzymes is necessary with Zetia® which of course is something that is required for most, if not all, statins. There are three indications currently for Zetia®, three distinctive hyperlipidemic patient types. First is for primary Hypercholesterolemia, second is use in combination with a statin for homozygous familial hypercholesterolemia, and lastly it's uniquely indicated for the adjunctive therapy of patients with sitosterolemia. Zetia® 10 mg given daily as monotherapy, produces a significant 18-20% reduction in LDL-C. Favorable changes in HDL-C and triglycerides are also seen. If you take this into context, using epidemiological data, this might suggest that a 20-25% reduction in cardiovascular events may be observed. It is important to recognize however, that this assumes that the primary determinant of CP outcomes results is because of LDL-C reduction and not because of something else that has not been measured at this point. Thirdly, I'd like to talk to you briefly about the Zetia® in titration. Zetia® versus titration of a statin. In a series of well controlled studies, patients that were not at LDL-C goal had Zetia® added to their treatment regime, and 72% of the patients who had not attained their LDL-C target when Zetia® was added, were at the LDL-C target. And this is greater than if the same patients would have been titrated according to a statin alone. A unique study in the American Heart Journal in 2004 compared doubling of atorvastatin, the most widely used statin at the present time, from 10 mg to 20 mg versus adding 10 mg of Zetia® to 10 mg of atorvastatin. The titration group only decreased LDL-C by 8.6% whereas the group that had Zetia® added to it reduced LDL-C by 23%, almost a threefold decrease in LDL-C by adding 10 mg of Zetia® versus titrating, doubling the atorvastatin dose. In terms of a safety profile when adding Zetia® to a statin, it's, Zetia® again is similar to placebo. Up titrating statins also has the concern that the higher the statin dose, the more side effects are usually seen with the statins. Finally on outcome studies, there are no currently planned or ongoing studies with Zetia® monotherapy. There are four on-going studies with Zetia® in combination with simvastatin, for outcome events. They probably to this committee's concern, the most important of those studies would be the Approva trial which hopes to start enrolling patients this month and thus, after a two and a half year outcome we should have the results of that trial in three years. Thank you for your time and attention.*

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

Motion made by Dr. Gourley to accept COP recommendations; second by Dr. Meece.

**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 6:** **VOTE TO PRIOR AUTHORIZE ELIDEL® AND PROTOPIC®**

**For Public Comment, Dr. Raymond Cornelison:** *Thank you for allowing me a little bit of time to address this issue. I'm Chairman of the Department of Dermatology at the University of Oklahoma College of Medicine. The disclaimer is I don't speak for the College of Medicine in this presentation, nor do I speak for OU Physicians which is the physician group I belong to. Briefly, what I would like to discuss is the recommendations from the College of Pharmacy. As far as I'm aware and Dr. Allen, Pam Allen, one of our practice members is also here to speak on this issue, I don't think we were consulted or had any type of input into this as dermatologists. Pam, I don't think you knew it. The problem with these authorizations, these prior authorization criteria, is that there's no evidence to support that these are based in my opinion, science and studies available in the literature. The problem with these drugs, both pimecrolimus and tacrolimus is that they're misused, in my opinion. And the way they're misused is that they are probably overused in some areas of the body and skin and underused in other areas. These are very, as you know, these are very large molecules and so it's very difficult for these molecules to penetrate, and in fact in all the studies the blood levels of these drugs has been almost imperceptible, so they have a very safe window, very wide window of safety, and they are used . . . because of that, they may be used with some impunity, but the main point is these are not equivalent drugs to topical steroids and they have very different indications and they have very different uses and very different places that they're affected. I'll give you an example. It's probably not a good idea to use a steroid, a topical steroid for very long, at least, around the eye, because of problems with possible cataract formation, increased intraocular pressure. On the other hand, these*

*drugs are excellent drugs for eyelid dermatitis in most patients. They're also excellent drugs for children with more thin skin, they're excellent drugs where you have thinner skin, like intertriginous areas. They work well there. They work well sometimes on the buttocks. Unfortunately, they get also used on palm dermatitis and sole dermatitis, and the skin is so thick there, even though part of the barrier is broken, that they're not effective drugs there, in my opinion. And so I don't think we should have this prior authorization criteria because it really doesn't address the problem with the use of these drugs vis-a-vis topical steroids. And certainly to require some physicians to use topical steroids first and have a failure could lead to excessive use of topical steroids, so I would say that those are things that concern me about this proposed policy. I really believe and believed from day one that the problem with the use of these drugs and the use of topical steroids is like a lot of things in medicine, that's education of the physician about how to use the drug, and there hasn't been enough of that done. Part of that may lie at the feet of the dermatologists, I don't know, but certainly these drugs are not used at all by dermatologists the way they're used by a lot of physicians in primary care. And we see lots of failures coming to us as a result of that. Well the problem with a failure is if you've given it to a patient with bad hand dermatitis and the Elidel® and the Protopic® hasn't helped; you're not going to get that mother to use it on the face where it ought to be used for the child with atopic dermatitis. They just say it doesn't work, it doesn't, well I'm not going to use it . . . Dr. X gave that to me. . . problem that we're into with these drugs. To require prior authorization, I think, is an unnecessary burden that we can get around, and what I'm here to propose is that the Department of Dermatology and our physicians there would be more than happy to work with the College of Pharmacy and come forward with a set of recommendations regarding prior authorization or anything else, limits on these drugs, that I think would be more livable for the practitioner out there and something that this Board might feel comfortable with, because working with the College of Pharmacy, I think we can come up with some very good recommendations and a much more rational use of these drugs, and not penalize the practitioner with prior authorization necessarily. Thank you.*

**Dr. McNeill:** *Could I ask a question? Maybe I didn't follow everything you said, but I hear you arguing on both sides of the fence here.*

**Dr. Cornelison:** *You're right.*

**Dr. McNeill:** *What types of, do you have any ideas about what the dermatologists, Department of Dermatology might come up with?*

**Dr. Cornelison:** *Yes. I think, number one, we might want to address in a more detailed fashion, the location and the use of the drug in different locations. That's very important, number one. Number two, we would want to address the ability of any physician to prescribe these drugs without prior authorization provided that they're meeting criteria that they can justify in the medical record, so that if I'm a pediatrician and I have a child with facial atopic dermatitis, I would, it would be, and I can document that in my medical record, then I would say that pediatrician ought to be allowed to use the drug without prior authorization, provided they can document to the Authority that they're doing that, and if the Authority wanted to check on that physician, OK? On the other hand, if we, if we aren't careful, we'll continue to have these drugs . . . this is no way, these prior authorization criteria, in no way address the real problem which is the use of the drug appropriately. These are very valuable and good drugs and very safe drugs, but they are used, maybe underused in some areas and overused in other areas of the body.*

**Dr. Hrdlicka:** *Can I ask a question? And this is really a question more maybe for you or for the Board, when you say prior authorization, these patients are taking these prescriptions to the pharmacy, correct? And the pharmacy's filling them and submitting a claim to the, to the Health Care Authority, alright, and then how is it that they get "prior authorization" if, I mean if they walk in, I mean, how do you go about getting that?*

**Dr. Nesser:** *There's a form that the pharmacist can fill out, and can either send it to the doctor for some information or just get the information from the physician and then they fax it to the College of Pharmacy, and then . . .*

**Dr. Hrdlicka:** *You review that and you see that they meet the criteria and you approve it or disapprove it? How long does that process take?*

**Dr. Gorman:** *From our side, it's 24 hours that we have, but usually two or three hours.*

**Dr. Hrdlicka:** *And then is it at that time that the pharmacy will go ahead and fill the prescription, after you have gotten prior authorization? How often do those claims get denied because of the bureaucracy? And the only reason, I've been on that side, I've been on the pharmacist side where they submit and they've got $10,000 worth of stuff and they get a check for $4,200, you know, and then they've got all these, litany, and maybe it's better now than it was when I was counting, but you know what I'm saying?*

**Dr. Gorman:** *I don't quite get what you're saying.*

**Dr. Graham:** *Well, they're usually not filled before the prior authorization is approved. That's what you were asking I guess.*

**Dr. Hrdlicka:** *And it's all done electronically now, correct?*

**Dr. Graham:** *Yes.*

**Dr. Hrdlicka:** *So that when that, when the pharmacy submits the claim electronically and they get it back and it says approved for so many dollars or whatever . . . they know and once it's approved then rarely does it get denied later to them? Because most of the time when I, it's been a few years, a lot of it was done by hand . . .*

**Dr. Graham:** *Yeah, it's usually approved for a quantity limit or a time period.*

**Dr. Nesser:** *Right, and they know, they know when they send that claim it comes back and says we're going to pay you fifty bucks and . . .*

**Dr. Hrdlicka:** *They don't get denied later on . . . now my next question is, if we took his recommendation and it sounds to me like his main recommendation is that he wants to change maybe a little bit of the way the indications are used and so that they would, so that you don't have, is it possible that you would have, that you could . . .*

**Dr. Gorman:** *I'm not sure how to do what he suggested without PA'ing it, because otherwise how would you document . . .*

**Dr. Robinson:** *I don't know that hashing that tonight would be too productive. What I heard, actually what I kind of heard him say, I think, was that he would like to see us perhaps table this for a month and the College of Dermatology and Pharmacy get together and review it. I don't know whether that's what the Board wants to do or not, but at least that, is that pretty much . . .*

**Dr. Cornelison:** *Yes sir. I do think we could come back with a much more workable recommendation.*

**Dr. Robinson:** *Whether what you've discussed tonight is feasible or not could be discussed around the table.*

**Dr. Hrdlicka:** *Am I understanding though, that you would like to see a set of workable recommendations that would not require prior authorization for the meds . . . is that . . .*

**Dr. Cornelison:** *I think that would be our goal in order to decrease, just decrease the paperwork factor for the physician. On the other hand, there might be, I wouldn't want to preclude that at this point until I have a chance to sit down with the College of Pharmacy and really look at where they came up with their recommendations.*

**Dr. Gourley:** *I think the whole thing is this was prompted by an FDA action that came out about the safety of the drug, and that's what prompted us to put in these prior authorization recommendations, was that we reviewed claims and we found that it was being used outside the package insert indication which was on pediatric patients that were less than two years of age. So that's what prompted us to do this.*

**Dr. McNeill:** *. . . our patient population . . . if you keep that in mind, I would imagine 99% of the dermatological conditions treated by this population are going to be through primary care, would you agree with that . . . in the high 90's?*

**Dr. Cornelison:** *I don't know. I would think it would be less than that, but I don't have any figures to . . .*

**Dr. McNeill:** *Well, if there is, if we do decide to table this until the next meeting, I hope that's kept in mind that outside of Oklahoma City and Tulsa, Ardmore, you're not going to find a dermatologist without having to drive, so I think these medications should be available and used appropriately and let's keep that in mind.*

**Dr. Cornelison:** *I certainly agree with that and I think the primary care physicians do a great job of taking care of the majority of these people. Where we do see the breakdown it was in the area selecting what area of the skin you're going to treat because this can vary, these drugs can be extremely effective or they can just be a waste of money and so that's what we really need to address.*

**Dr. Hollen:** *Have we tried doing an education effort with this as far as sending out a newsletter or including it in one of the newsletters?*

**Dr. Hrdlicka:** *I mean I think I'd recommend that these two entities get together and come up with a, come up with a plan and then take that plan and send it out to the people that use it.*

**Dr. Robinson:** *Well let's see in the meantime what Pam Allen wants to say.*

**For Public Comment, Pam Allen:** *Hello. I'm Pamela Allen, one of the associate professors at OU Department of Dermatology and also one of the attendings who regularly supervise residents, medical students as well as PA's in our department and many of the Medicaid patient population, and so, yes, Elidel® has been a revolutionizing treatment in our care of atopic dermatitis which you may know is a very chronic recurring type of skin disease and that we have found that even in very limited or short term use of topical steroids, side effects can occur. Even on a systemic level, we've seen reports as well as clinical cases within three to four weeks, you can have a systemic side effects of cushionoid type of changes, skin atrophy, telangiectasias, all of these things due to the absorption of topical steroids, all of which or none of which Elidel® has, and you must keep in mind that, although the concern of the FDA has been raised, there is no black box warning as of today, and this has been going on for over eight months or coming up to a year now. So usually if it's of that much of a concern, something would have been in place by now within you know, a month of the concern, so keep that in mind. On the authorization criteria that's been proposed, one thing that kind of concerns me is the length of time topical application of corticosteroid is used as a trial. Six weeks, even though it may control or maintain the dermatitis, remember that this is a recurring disease. This is lifelong and there is no cure. So inevitably it's going to return, so chronic use of these topical, these corticosteroids that may work still have, you know, longterm side effects. So what are you going to do with a patient that has chronic disease? What are you going to maintain them on? And so Elidel® is a wonderful medication that can maintain patients when they initially flare. The very first signs and symptoms of itching, pruritus, and erythema, don't have to reach for that topical steroid which continues the possibilities of the skin atrophy, the bruising, and systemic side effects of topical steroids. So that I think would be a question mark in my mind. Also, the areas that Dr. Cornelison has reviewed, it's been shown, especially on the face and neck that Elidel® works best, not on thick hyperkeratotic skin, and so yes, palms and soles are not the areas really that you want to treat anyway. Also, the groin in the clinical exceptions was not added in there. That is a definite area of mucosal absorption that you would not want to put topical steroids in. So definitely I would think we would need to table this discussion and maybe come up with some new or proposed options and guidelines in treating atopic patients.*

**Dr. Graham:** *Dr. Allen, could I ask you . . . do you ever use it on children under two years of age?*

**Dr. Allen:** *Under two years of age? I would say that for those where they do have atopic dermatitis on, you know, they're starting out early. I mean we're seeing them in infancy. You don't want to use topical steroids for long periods of time. We do see those side effects and I would say yes. That has been something I think as a clinical determination, I have used it in those patients and it's helped.*

**Dr. Graham:** *Would it be unusual, or would it be pretty common, would you say?*

**Dr. Allen:** *I would say not on a regular basis. If a person . . . depends on what stage of their atopic dermatitis that they have. If they have moderate to severe, I'm not going to put Elidel® in any region. It stings, it burns on very irritated excoriated skin, and so that I see a lot of times in our primary care doctors . . . putting it on when it's extremely flared and they don't get their response that they're wanting, and then they refer them on to dermatology. So I think education and the appropriate uses of it, it's clinically approved for mild to moderate eczema, so it needs to be used in the initial first signs and symptoms. It doesn't do a bit of good for when it's already flared out. And so it really is an education problem and I agree with Dr. Cornelison and his recommendations as well.*

**Dr. Graham:** *I believe we had over 3,000 children under two years of age with this use last year.*
**Dr. Allen:** *And were they primary care doctors or dermatologists?*
**Dr. Graham:** *The majority of them were primary care.*
**Dr. Allen:** *Were there any issues regarding the safety of it in any of those patients?*
**Dr. Graham:** *Well, it's against the FDA recommendations, so you know, I'm not sure . . . it's such a new drug that anyone can quote safety records on that.*
**Dr. Allen:** *Interestingly enough, there are two large long term studies being used now on, in Novartis, patients on Elidel®, patients less than two years of age, and they're on-going right now. So if there were any issues at that point and even now, they would have pulled the studies). So they're either looking at indications for less than two years of age at this point, so we're probably a little ahead of the game right now.*
**Dr. Gourley:** *It appears that the main objection to this criteria is the steroid use prior to using the products.*
**Evie Knisely:** *We have some other physicians that have also addressed this issue. I'll give these to you with the others, but if you're thinking about putting together some type of committee some of these people might be people that you might want to involve as well.*
Materials included in agenda packet; presented by Dr. Chonlahan.
Dr. McNeill moved to table until the next DUR Board meeting; seconded by Dr. Bell.
**ACTION:** MOTION CARRIED, ITEM TABLED TO 9-14-05.

**AGENDA ITEM NO. 7:** **VOTE ON PLACEMENT OF ADHD PBPA CATEGORY IN SUPPLEMENTAL REBATE PROGRAM AND 30-DAY NOTICE TO PRIOR AUTHORIZE FOCALIN™ XR**

Materials included in agenda packet; presented by Dr. Gorman.
Dr. Meece moved to approve COP recommendations; seconded by Dr. McNeill.
**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 8:** **ANNUAL REVIEW OF SYNAGIS®**

Materials included in agenda packet; presented by Dr. Moore.
Dr. McNeill moved to approve recommendations; seconded by Dr. Gourley.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 9:** **REVIEW & DISCUSS PULMONARY HYPERTENSION MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE REVATIO®**

**Dr. Hrdlicka:** What kind of input do you get from specialists that actually prescribe these drugs such as pulmonologists?
**Jill Ratterman:** *I'm Jill Ratterman. I'm a clinical pharmacist here and I work for the Health Care Authority. I used to work for five years for one of the primary companies that dispense Flolan, Tracleer, Remodulin and now probably Revatio, so I kind of was the background person for it so if you have any questions about the disease or anything along those lines. As you can tell from the numbers in the packet, there are very few patients in the state that have this disease and that are being treated for it. There are pulmonologists that generally use it and cardiologists are very knowledgeable and use drugs appropriately. We're trying to prevent with this prior authorization patients learning that there's a Sildenafil out there and going, oh I can get this covered by Medicaid if I use it under this brand name so that's the point of trying to get this prior authorization. It's not going to be a huge burden on these physicians. I expect five, maybe ten patients a year requiring this kind of therapy, and that's really pushing it considering (unintelligible), so it's not going to be a huge burden on those physicians. They already have to go through a lot of paperwork to get Flolan approved or anything like that. There's a ton of paperwork for these patients anyway. Any questions?*
**Dr. McNeill:** *I'll ask the most obvious question. Do five of these tablets equal one therapeutic Viagra. Do you get the same side effect?*
**Dr. Ratterman:** *I first heard about this about three or four years ago and that's been my questions from the get-go and I've never received a response to that question, from doctors, from the drug company . . .*
**Dr. Meece:** *. . .they're the same thing.*
**Dr. Ratterman:** *It's the same thing.*
Materials included in agenda packet; presented by Dr. Chonlahan.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 10:** **30-DAY NOTICE TO PRIOR AUTHORIZE FENOFIBRATES**

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

**AGENDA ITEM NO. 11:** **30-DAY NOTICE TO PRIOR AUTHORIZE BYETTA®**

Dr. Hrdlicka wanted to know if an endocrinologist or diabetes specialist had been consulted regarding the recommendations.
Materials included in agenda packet; presented by Dr. Patel.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 12:** **REVIEW AND DISCUSS ESTROGEN PRODUCTS**

Dr. Hollen wondered how many women we had in the Medicaid population who are unprotected for osteoporosis due to the fear created by the Women's Health Initiative. A possible prospective DUR or educational effort might be attempted for this population.
Materials included in agenda packet; presented by Dr. Moore.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 13:** **FDA & DEA UPDATES**

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

**AGENDA ITEM NO. 14:** **FUTURE BUSINESS**

**14A:** **Antipsychotic Utilization Review**
**14B:** **Pediculides Review**
**14C:** **Neurontin® Follow-Up Review**
**14D:** **Renal Product Review**
**14E:** **Antifungal Review**
**14F:** **Annual Reviews**
**14G:** **New Product Reviews**

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

**AGENDA ITEM NO. 15:** **ADJOURNMENT**

The meeting was declared adjourned.

# The University of Oklahoma College of Pharmacy

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


# Memorandum

**Date:** August 16, 2005

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

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

**Subject:** DUR Board Recommendations from Meeting of August 10, 2005.

**Recommendation 1: Vote to Prior Authorize Zetia**

MOTION CARRIED by unanimous approval.

The approval criterion is as follows:

1. Diagnosis:
   - Hypercholesterolemia, primary
   - Hypercholesterolemia, homozygous familial
   - Sitosterolemia, homozygous

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

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

## Recommendation 2: Vote to Prior Authorize Elidel®/Protopic®

MOTION TABLED UNTIL 9/14/2005 by unanimous approval.

## Recommendation 3: Vote on Placement of ADHD PBPA Category in Supplemental Rebate Program

MOTION CARRIED by majority approval.

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

Approval Criteria for Tier-2 and Tier-3

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

| Tier 2 |
| --- |
| • amphetamine salt combo (Adderall XR®)<br>• methylphenidate ER (Concerta®)<br>• dexmethylphenidate (Focalin, Focalin XR®)<br>• methylphenidate ER (Metadate CD®, Ritalin LA®)<br>• atomoxetine (Strattera®) |

## Recommendation 4: Annual Review of Synagis®

No action was required.

August 3, 2005

Nancy Nesser, J.D., D.Ph.
Planning Director
Oklahoma Health Care Authority
4545 North Lincoln Blvd., Suite 124
Oklahoma City, Oklahoma 73105

To Whom It May Concern:

The current quantity limitations placed on certain new generation medications is an understandable way to cut costs. However, a patient who requires Seroquel (Quetiapine) may require an FDA approved daily dose of 800 mg. Under the quantity limitations a patient would have to use two (2) punches per month to achieve this dose.

To suggest that a doctor change the dose for financial purposes is egregious. It is our opinion that reaching the proper therapeutic dose will enable the patient to continue with the freedom of attending an Out Patient Clinic. Further, the cost involved in maintaining the patient's medical therapy will far outweigh the cost of inpatient services, which is often necessitated by medication decompensation.

We truly hope that your decision will be reconsidered.

Sincerely,

Richard Zielinski

Richard Zielinski, MD

**MIDWEST HEALTH ASSOCIATES**
EVERETT E. BAYNE, MD PAUL M. EMRICH, LMFT/LPC

July 21, 2005

Nancy Nesser, J.D., D.Ph.
Planning Director
Oklahoma Health Care Authority
4545 North Lincoln Blvd., Suite 124
Oklahoma City, Oklahoma 73105

Dear Ms. Nesser:

As a medical physician who provides health care to patients within the Medicaic population, this new policy on "quantity limits" is one of the more damaging I have seen Psychiatry is a science, but quantity limits are strictly about the numbers. It is disturbing to think that a physician, who is ultimately charged with the responsibility and care of the patient does not have the final decision in the treatment of the patient, as a result of yet another Oklahoma Health Care Authority Policy. I have had to make medication changes to patients, who prior to this policy were improving and are now experiencing problems, because the prescription I am writing does not fit in the new "quantity limit policy".

I have had the opportunity to discuss this new policy with several colleagues and there is consensus that changes should be made.

This policy may look good for the bottom line, but falls short with real people, who are now changing medications, doses, and experiencing relapses because of the additional red tape involved in filling a prescription. This is a "side effect" of your new policy as it requires more time and energy from all parties, delays prescriptions from being filled in a timely manner and ultimately impairs the treatment of the patient when access to medications are denied due to red tape. Ultimately our responsibility is to the patient and this policy does not reflect our responsibility very well

Sincerely Yours,

Everett E. Bayne, M.D.
Psychiatrist

LINDEN AND ASSOCIATES

5801 N. Broadway Suite 410
Oklahoma City, OK 73118

August 3, 2005

Nancy Nesser, J.D., D.Ph.
Planning Director
Oklahoma Health Care Authority
4545 North Lincoln Blvd., Suite 124
Oklahoma City, Oklahoma 73105

Dear Nancy:

On behalf of Linden and Associates and Linden Pharmacy we wish to address, the quantity limit guidelines and impact upon the providers and patients. As you are aware, not all patients will respond to medication that falls within FDA guidelines and will also be used for other disease states than what is currently approved by the FDA. A good percentage of our patients don't show the desired results with conventional prescribing methods. You are asking us to reduce the medications received by our patients to FDA approved guidelines, which did not control their symptoms.

For example: the limit on Seroquel only allows 600 mg without a quantity limit override. Although the therapeutic dose allowed by the FDA is up to 800 mg per day. An 800 mg dose would result in a patient using two of their three name brand punches allowed per month. Currently the override process is taking about three hours from the time a pharmacy calls in to the help desk and the time they receive the fax to send the doctor. Faxes sent to doctors can take from one day up to a week depending on the backlog. Then the help desk has twenty-four hours to return the fax. One example of an antidepressant override is as follows. Effexor XR 150 mg the patient is on 300 mg the first rejection wanted information from a journal or clinical trial the maximum FDA dose is 225 mg. Our response was in the package insert one study of the development program for the product responded to a mean dose of 350mg/day ( range of 150 to 375 mg / day ). The return fax asks for the physician to produce a study for this dosage and safety. Next the doctor's office contacts the drug manufacture for the study and it take a day to receive. After the information is received it is faxed to the help desk and is still pending they have twenty-four hours to respond. Currently we received one override after going thru all of these steps. If documentation is not provided for a high dose medication the response is approved for one or more months for the Doctor to reduce the dose to FDA guidelines. While this process is pending sometimes for a week or more some patients go without medication. All patients will have to make two or more trips for their medication, and they tell us they can't afford the gas.

We fully understand the need for everyone to control cost, but when you have children who are suspended from school for aggression, and other patients will require emergency room visits or hospital admission. We ask that the total cost and impact to patients, society and providers be considered.

August 3, 2005

Quantity Limit Overrides

Sincerely,

Linden and associates

Dr. David E. Linden M.D.

Dr. Adonis Al-Botros M.D.

Gil Torres P.A.

Amy Renolds P.A.C.

Wayne Lemon D.Ph.

# APPENDIX B

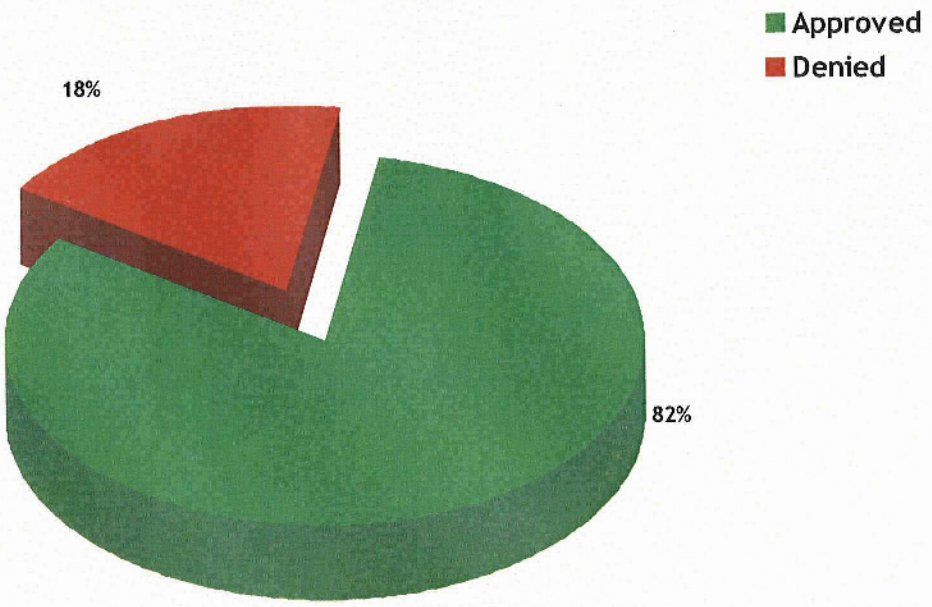
# Retrospective Drug Utilization Review Report

***Claims Reviewed for June 2005***

| Module | Drug Interaction | Duplication of Therapy | Drug-Disease Precautions | Dosing & Duration |
|---|---|---|---|---|
| **Total # of messages returned by system when no limits were applied** | 107,932 | 105,889 | 939,752 | 49,338 |
| **Limits which were applied** | Established, major, females 21 - 50 yrs old | Migraine Products | Contraindicated, Chronic Liver Disease, females | High dose, Starlix & Prandin |
| **Total # of messages after limits were applied** | 101 | 115 | 283 | 50 |
| **Total # of clients reviewed after limits were applied** | 101 | 111 | 227 | 50 |

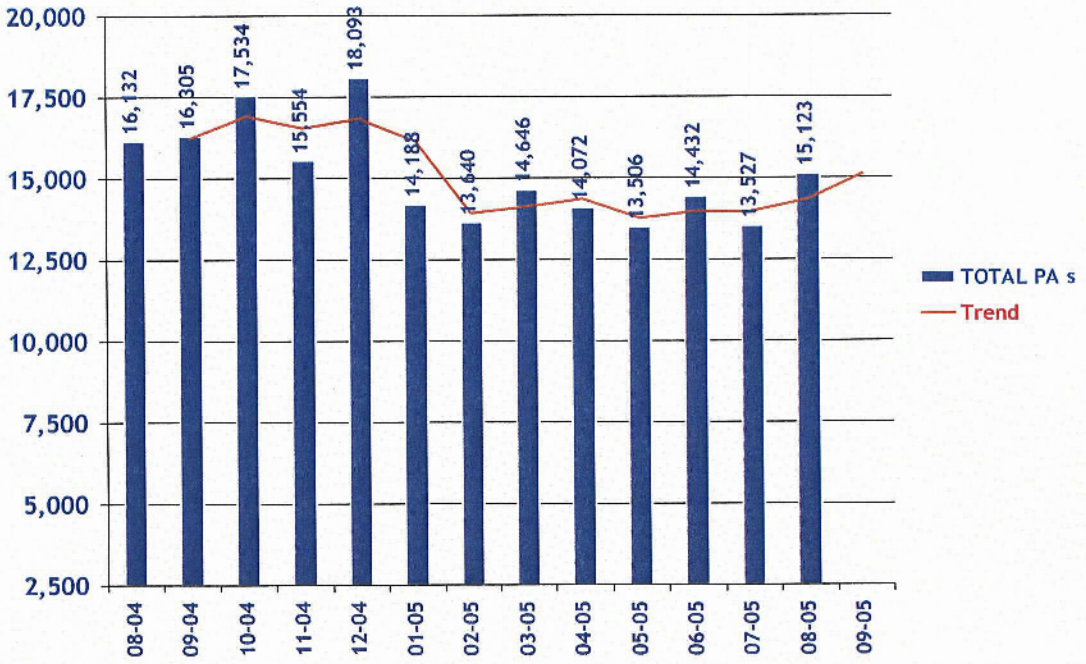
| LETTERS | | | |
|---|---|---|---|
| **Prescribers** | | **Pharmacies** | |
| **Sent** | **Responded** | **Sent** | **Responded** |
| 74 | 15 | 8 | 1 |

# PRIOR AUTHORIZATION ACTIVITY REPORT
## August 2005




PHARMACY Management Consultants

# PRIOR AUTHORIZATION REPORT
## August 2004 - August 2005




PHARMACY Management

# Activity Audit for

August 01 2005 Through August 31 2005

| Date | Antiulcers app. | Antiulcers den. | Anxiolytic/ Hypnotics app. | Anxiolytic/ Hypnotics den. | Antihistamine app. | Antihistamine den. | Growth Hormones app. | Growth Hormones den. | Stimulant app. | Stimulant den. | Nsaids app. | Nsaids den. | ACE Inhibitors app. | ACE Inhibitors den. | HTN Combos app. | HTN Combos den. | Calcium Channel Blockers app. | Calcium Channel Blockers den. | Plavix app. | Plavix den. | ARB app. | ARB den. | Anti-depressants app. | Anti-depressants den. | Daily Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| App. | 6 | | 2867 | | 1230 | | 39 | | 1185 | | 195 | | 38 | | 7 | | 84 | | 659 | | 28 | | 845 | | |
| Den. | | 8 | | 281 | | 419 | | 2 | | 257 | | 217 | | 44 | | 6 | | 158 | | 95 | | 10 | | 154 | |
| Average Length of Approvals in Days | 32 | | 98 | | 99 | | 163 | | 226 | | 328 | | 236 | | 106 | | 280 | | 355 | | 160 | | 178 | | |

| | |
|---|---|
| Changes to existing PA's | 999 |
| Total (Previous Year) | 16132 |

| * Denial Codes | |
|---|---|
| 762 = Lack of clinical information | 8.35% |
| 763 = Medication not eligible | 1.59% |
| 764 = Existing PA | 4.38% |
| 772 = Not qualified for requested Tier | 9.42% |
| 773 = Requested override not approved | 16.74% |

| SUPER PA's | |
|---|---|
| Admitted to Nursing Home | 98 |
| Early Refill Attempts | 45493 |
| Dosing Change | 592 |
| Lost/Broken Rx | 119 |
| Stolen | 30 |
| Other | 57 |
| Wrong D.S. on Previous Rx | 11 |
| Quantity vs. Days Supply | 4556 |
| Brand | 189 |
| -- Approved | 65 |
| -- Denied | 32 |

**Monthly Totals**

| | Number | Percent of Total |
|---|---|---|
| Approved | 9603 | 63.50% |
| Additional PA's | 20 | 0.13% |
| Emergency PA's | 15 | 0.10% |
| Duplicates | 787 | 5.20% |
| Incompletes | 2554 | 16.89% |
| Denied * | 2144 | 14.18% |
| Total | 15123 | 100.00% |

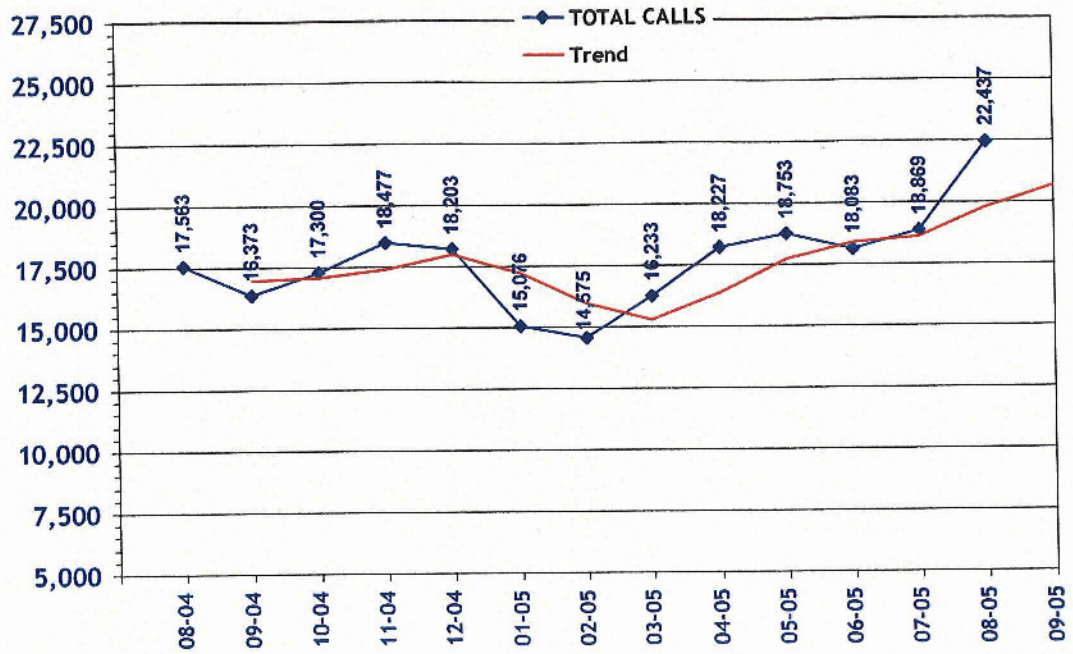
Daily Average of 560.11 for 27 Days

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

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

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

# CALL VOLUME MONTHLY REPORT
## August 2004 - August 2005

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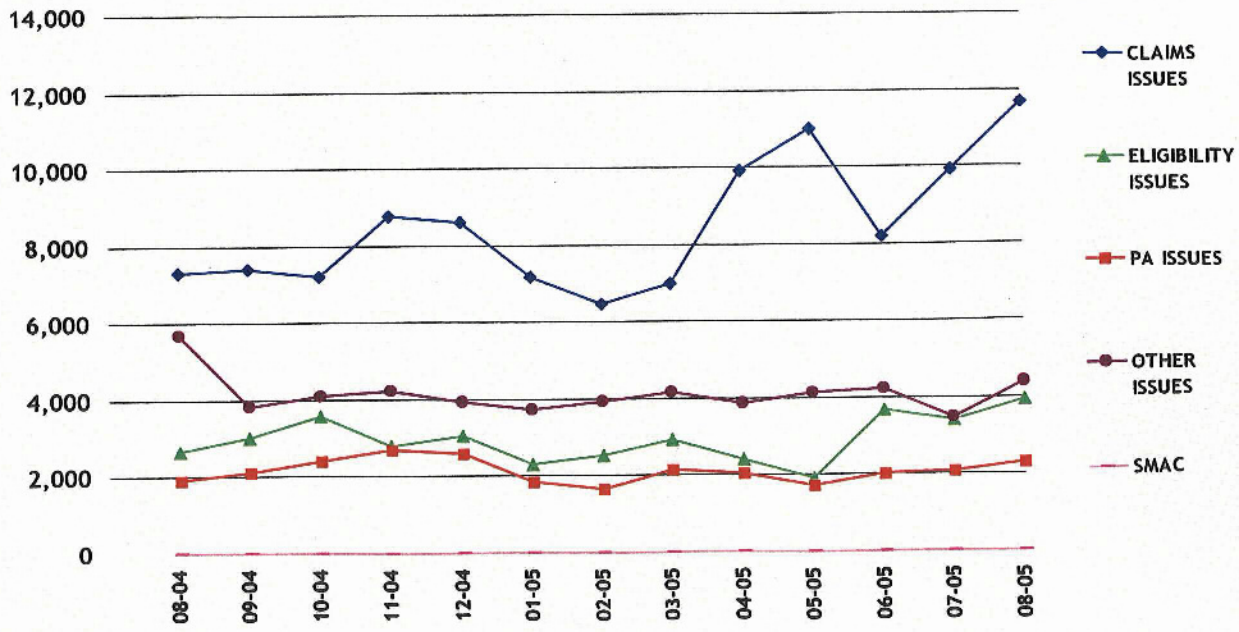
# CALL VOLUME ISSUES
## August 2004 - August 2005




PHARMACY Management Consultants

# Prospective Drug Utilization Review

October 01, 2003 through September 30, 2004

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non_Responses | # Claims Screened | % Alerts/ Total RX | % Can-cels /Total RX |
|---|---|---|---|---|---|---|---|
| ID | ANTI-ANXIETY DRUGS | 6 | 6 | 0 | 4,367 | 0.14% | 0.00% |
| | BARBITURATES | 1 | 1 | 0 | 748 | 0.13% | 0.00% |
| | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 4 | 4 | 0 | 35,456 | 0.01% | 0.00% |
| | SEDATIVE-HYPNOTICS,NON-BARBITURATE | 3 | 3 | 0 | 10,042 | 0.03% | 0.00% |
| | SKELETAL MUSCLE RELAXANTS | 1 | 1 | 0 | 2,804 | 0.04% | 0.00% |
| LD | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 1 | 1 | 0 | 689 | 0.15% | 0.00% |
| | BETA-ADRENERGIC BLOCKING AGENTS | 1 | 1 | 0 | 19,386 | 0.01% | 0.00% |
| | HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE | 2 | 2 | 0 | 16,074 | 0.01% | 0.00% |
| | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 2 | 2 | 0 | 1,315 | 0.15% | 0.00% |
| LR | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 2 | 2 | 0 | 689 | 0.29% | 0.00% |
| | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 10 | 10 | 0 | 7,803 | 0.13% | 0.00% |
| | HYPOTENSIVES, ACE INHIBITORS | 2 | 2 | 0 | 16,654 | 0.01% | 0.00% |
| | ORAL ANTICOAGULANTS,COUMARIN TYPE | 2 | 2 | 0 | 1,795 | 0.11% | 0.00% |
| MC | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 13 | 13 | 0 | 3,515 | 0.37% | 0.00% |

| | | | | | | |
|---|---|---|---|---|---|---|
| AMMONIA INHIBITORS | 17 | 17 | 0 | 2,158 | 0.79% | 0.00% |
| ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL AGENTS | 5 | 3 | 2 | 864 | 0.58% | 0.23% |
| ANALGESIC/ANTIPYRETICS,NON-SALICYLATE | 6 | 5 | 0 | 242 | 2.48% | 0.00% |
| ANALGESICS, NARCOTICS | 1 | 1 | 0 | 16,263 | 0.01% | 0.00% |
| ANTI-ANXIETY DRUGS | 10 | 10 | 0 | 20,451 | 0.05% | 0.00% |
| ANTICONVULSANTS | 16 | 16 | 0 | 29,345 | 0.05% | 0.00% |
| ANTIMETABOLITES | 1 | 1 | 0 | 172 | 0.58% | 0.00% |
| ANTIMIGRAINE PREPARATIONS | 1 | 1 | 0 | 166 | 0.60% | 0.00% |
| ANTIPSYCHOTICS,DOPAMINE AN-TAGONISTS,BUTYROPHENONES | 2 | 2 | 0 | 512 | 0.39% | 0.00% |
| BARBITURATES | 3 | 3 | 0 | 1,863 | 0.16% | 0.00% |
| BETA-ADRENERGIC BLOCKING AGENTS | 2 | 1 | 1 | 4,246 | 0.05% | 0.02% |
| CALCIUM CHANNEL BLOCKING AGENTS | 1 | 1 | 0 | 4,128 | 0.02% | 0.00% |
| CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC | 1 | 1 | 0 | 23 | 4.35% | 0.00% |
| CONTRACEPTIVES, INJECTABLE | 2 | 2 | 0 | 167 | 1.20% | 0.00% |
| CONTRACEPTIVES, INJECTABLE | 22 | 21 | 1 | 1,564 | 1.41% | 0.06% |
| CONTRACEPTIVES, ORAL | 28 | 17 | 11 | 1,495 | 1.87% | 0.74% |
| CONTRACEPTIVES, TRANSDERMAL | 6 | 6 | 0 | 417 | 1.44% | 0.00% |
| ESTROGENIC AGENTS | 1 | 1 | 0 | 1,656 | 0.06% | 0.00% |
| HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE | 5 | 4 | 1 | 28,906 | 0.02% | 0.00% |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 85 | 81 | 4 | 14,267 | 0.60% | 0.03% |
| | HYPOTENSIVES, ACE INHIBITORS | 11 | 11 | 0 | 5,937 | 0.19% | 0.00% |
| | INTESTINAL MOTILITY STIMULANTS | 72 | 71 | 1 | 6,892 | 1.04% | 0.01% |
| | LAXATIVES AND CATHARTICS | 23 | 23 | 0 | 7,725 | 0.30% | 0.00% |
| | LHRH(GNRH) AGONIST ANALOG PITUITARY SUPPRESSANTS | 1 | 1 | 0 | 6 | 16.67% | 0.00% |
| | LIPOTROPICS | 4 | 4 | 0 | 4,138 | 0.10% | 0.00% |
| | NOREPINEPHRINE AND DOPAMINE RE-UPTAKE INHIB (NDRIS) | 12 | 12 | 0 | 4,957 | 0.24% | 0.00% |
| | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 26 | 26 | 0 | 46,104 | 0.06% | 0.00% |
| | ORAL ANTICOAGULANTS,COUMARIN TYPE | 4 | 4 | 0 | 1,795 | 0.22% | 0.00% |
| | PITUITARY SUPPRESSIVE AGENTS | 1 | 1 | 0 | 42 | 2.38% | 0.00% |
| | PROGESTATIONAL AGENTS | 3 | 3 | 0 | 144 | 2.08% | 0.00% |
| | RECTAL PREPARATIONS | 2 | 2 | 0 | 64 | 3.13% | 0.00% |
| | SEDATIVE-HYPNOTICS,NON-BARBITURATE | 6 | 6 | 0 | 13160 | 0.05% | 0.00% |
| | STEROID ANTINEOPLASTICS | 4 | 4 | 0 | 3296 | 0.12% | 0.00% |
| | VAGINAL ANTIBIOTICS | 1 | 1 | 0 | 60 | 1.67% | 0.00% |
| PA | ADRENERGICS, AROMATIC, NON-CATECHOLAMINE | 1 | 1 | 0 | 9,562 | 0.01% | 0.00% |
| | ANTICONVULSANTS | 1 | 1 | 0 | 13,888 | 0.01% | 0.00% |
| | ANTIHISTAMINES | 1 | 1 | 0 | 7,140 | 0.01% | 0.00% |
| | CONTRACEPTIVES, ORAL | 1 | 1 | 0 | 1,495 | 0.07% | 0.00% |
| | LOOP DIURETICS | 1 | 1 | 0 | 28,456 | 0.00% | 0.00% |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | NOREPINEPHRINE AND DOPAMINE RE-UPTAKE INHIB (NDRIS) | 2 | 2 | 0 | 777 | 0.26% | 0.00% |
| | OPHTHALMIC ANTIBIOTICS | 1 | 1 | 0 | 2,064 | 0.05% | 0.00% |
| PG | ABSORBABLE SUFONAMIDES | 4 | 4 | 0 | 5,834 | 0.07% | 0.00% |
| | ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL AGENTS | 8 | 5 | 3 | 1,289 | 0.62% | 0.23% |
| | ANALGESIC/ANTIPYRETICS,NON-SALICYLATE | 8 | 7 | 1 | 2,789 | 0.29% | 0.04% |
| | ANALGESICS,NARCOTICS | 2 | 2 | 0 | 46,436 | 0.00% | 0.00% |
| | ANTI-ANXIETY DRUGS | 12 | 12 | 0 | 37,317 | 0.03% | 0.00% |
| | ANTI-MANIA DRUGS | 2 | 2 | 0 | 1,002 | 0.20% | 0.00% |
| | ANTICONVULSANTS | 15 | 15 | 0 | 29,345 | 0.05% | 0.00% |
| | ANTIPARKINSONISM DRUGS,ANTICHOLINERGIC | 1 | 1 | 0 | 810 | 0.12% | 0.00% |
| | BARBITURATES | 1 | 1 | 0 | 1,115 | 0.09% | 0.00% |
| | BETA-ADRENERGIC AGENTS | 1 | 1 | 0 | 30080 | 0.00% | 0.00% |
| | BETA-ADRENERGICS AND GLUCOCOR-TICOIDS COMBINATION | 2 | 2 | 0 | 13522 | 0.01% | 0.00% |
| | BETA-ADRENERGIC BLOCKING AGENTS | 1 | 1 | 0 | 19,386 | 0.01% | 0.00% |
| | BONE RESORPTION INHIBITORS | 1 | 1 | 0 | 2,252 | 0.04% | 0.00% |
| | CONTRACEPTIVES, INJECTABLE | 5 | 5 | 0 | 736 | 0.68% | 0.00% |
| | CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC | 1 | 1 | 0 | 23 | 4.35% | 0.00% |
| | CONTRACEPTIVES,ORAL | 41 | 30 | 11 | 5,428 | 0.76% | 0.20% |
| | CONTRACEPTIVES, TRANSDERMAL | 14 | 12 | 2 | 1,536 | 0.91% | 0.13% |
| | EAR PREPARATIONS, MISC. ANTI-INFECTIVES | 4 | 4 | 0 | 148 | 2.70% | 0.00% |

| | | | | | | |
|---|---|---|---|---|---|---|
| EAR PREPARATIONS,ANTIBIOTICS | 1 | 1 | 0 | 624 | 0.16% | 0.00% |
| ESTROGENIC AGENTS | 7 | 7 | 0 | 7,816 | 0.09% | 0.00% |
| GLUCOCORTICOIDS | 1 | 0 | 1 | 7,735 | 0.01% | 0.01% |
| HYPOTENSIVES, ACE INHIBITORS | 6 | 6 | 0 | 24,932 | 0.02% | 0.00% |
| HYPOTENSIVES,ANGIOTENSIN RECEPTOR ANTAGONIST | 4 | 4 | 0 | 14,233 | 0.03% | 0.00% |
| LHRH(GNRH) AGONIST ANALOG PITUITARY SUPPRESSANTS | 1 | 1 | 0 | 6 | 16.67% | 0.00% |
| LIPOTROPICS | 3 | 3 | 0 | 10,418 | 0.03% | 0.00% |
| NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 13 | 13 | 0 | 16,720 | 0.08% | 0.00% |
| PROGESTATIONAL AGENTS | 1 | 1 | 0 | 168 | 0.60% | 0.00% |
| RECTAL PREPARATIONS | 1 | 1 | 0 | 64 | 1.56% | 0.00% |
| SEDATIVE-HYPNOTICS,NON-BARBITURATE | 2 | 2 | 0 | 4,788 | 0.04% | 0.00% |
| SKELETAL MUSCLE RELAXANTS | 3 | 3 | 0 | 8,432 | 0.04% | 0.00% |
| TETRACYCLINES | 4 | 4 | 0 | 2,331 | 0.17% | 0.00% |
| TOPICAL ANTIPARASITICS | 2 | 2 | 0 | 17,889 | 0.01% | 0.00% |

| | DUR Screen | Prescriber % Overrides | Consulted (MO) % Cancellations | Patient % Overrides | Consulted (P0) % Cancellations | Other Source % Overrides | Consulted (R0) % Cancellations |
|---|---|---|---|---|---|---|---|
| 10-03 | MC | 22.3 | 0 | 0 | 0 | 0 | 0 |
| | PA | 100 | 0 | 0 | 0 | 0 | 0 |
| | PG | 27 | 0 | 0 | 0 | 0 | 0 |
| 11-03 | LR | 0 | 0 | 0 | 0 | 0 | 0 |
| | MC | 22.3 | 0 | 0 | 0 | 0 | 0 |
| | PA | 100 | 0 | 0 | 0 | 0 | 0 |
| | PG | 10.9 | 0 | 0 | 0 | 0 | 0 |
| 12-03 | ID | 15.4 | 0 | 0 | 0 | 0 | 0 |
| | LD | 50 | 0 | 0 | 0 | 0 | 0 |
| | LR | 28.6 | 0 | 0 | 0 | 0 | 0 |
| | MC | 25.1 | 0 | 0 | 0 | 0 | 0 |
| | PA | 0 | 0 | 0 | 0 | 0 | 0 |
| | PG | 2.2 | 0 | 0 | 0 | 0 | 0 |
| | TD | 0 | 0 | 0 | 0 | 0 | 0 |
| 1-04 | LR | 100 | 0 | 0 | 0 | 0 | 0 |
| | MC | 100 | 0 | 0 | 0 | 0 | 0 |
| 2-04 | ID | 50 | 0 | 0 | 0 | 0 | 0 |
| | LD | 0 | 0 | 0 | 0 | 0 | 0 |
| | LR | 100 | 0 | 0 | 0 | 0 | 0 |
| | MC | 84.8 | 0 | 0 | 0 | 0 | 0 |
| | PG | 0 | 0 | 0 | 0 | 0 | 0 |
| 3-04 | LD | 0 | 0 | 0 | 0 | 0 | 0 |
| | MC | 0 | 0 | 0 | 0 | 0 | 0 |
| | PA | 100 | 0 | 0 | 0 | 0 | 0 |
| 4-04 | HD | 0 | 0 | 0 | 0 | 0 | 0 |
| | PA | 100 | 0 | 0 | 0 | 0 | 0 |
| 5-04 | NONE | | | | | | |
| 6-04 | MC | 0 | 0 | 0 | 0 | 0 | 0 |
| 7-04 | NONE | | | | | | |
| 8-04 | PG | 100 | 0 | 0 | 0 | 0 | 0 |
| 9-04 | PG | 100 | 0 | 0 | 0 | 0 | 0 |

| | Oct-03 | Nov-03 | Dec-03 | Jan-04 | Feb-04 | Mar-04 | Apr-04 | May-04 | Jun-04 | Jul-04 | Aug-04 | Sep-04 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total ER edits | 26,997 | 36,072 | 36,972 | 48,765 | 64,055 | 72,054 | 70,203 | 62,233 | 68,376 | 79,715 | 59,511 | 59,688 |
| Total Super PA over-rides (% total edits) | 369 (1.37%) | 279 (0.77%) | 193 (0.52%) | 720 (1.48%) | 744 (1.16%) | 940 (1.30%) | 804 (1.15%) | 724 (1.16%) | 942 (1.38%) | 1,332 (1.67%) | 1,605 (2.70%) | 1,366 (2.29%) |
| | | | | | | | | | | | | |
| Override reason: | | | | | | | | | | | | |
| Dosage change | 259 | 205 | 135 | 431 | 507 | 656 | 573 | 473 | 560 | 683 | 666 | 583 |
| Wrong D.S. on previous Rx | 14 | 21 | 10 | 74 | 63 | 81 | 65 | 61 | 81 | 66 | 77 | 88 |
| Lost/Stolen/ Broken Rx | 35 | 20 | 15 | 69 | 84 | 101 | 66 | 81 | 149 | 141 | 149 | 138 |
| Other | 61 | 33 | 33 | 146 | 90 | 102 | 100 | 108 | 128 | 130 | 136 | 114 |
| Quantity vs. Day Supply | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | 24 | 312 | 577 | 443 |

# APPENDIX C

# Vote to Prior Authorize Byetta® (Exenatide)

**Oklahoma Medicaid**
**September 2006**

| | |
|---|---|
| **Manufacturer** | Amylin Pharmaceuticals |
| **Marketed by** | Amylin Pharmaceuticals and Eli Lilly and Company |
| **Classification** | FDA classification: Incretin mimetic<br>Status: prescription only |


## Summary

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


## Recommendations

The College of Pharmacy recommends:

- Prior authorization of Byetta®
- Patients must have Type 2 diabetes and currently taking metformin, a sulfonylurea, or a combination and have not achieved adequate glycemic control (HbA1C $\geq 7.0$[1])
- Clients that have been on a sulfonylurea or metformin for 90 of the past 180 days will NOT require prior authorization
- Clinical exception will be allowed if Byetta® is prescribed by an endocrinologist

**Byetta® (Exenatide)**[2]

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

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

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

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

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

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[1] *Diabetes Care* 28:S4-S36, 2005.
[2] Byetta® package insert.

# APPENDIX D

# Elidel® (Pimecrolimus) and Protopic® (Tacrolimus)

**Oklahoma Medicaid**

**September 2005**

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

- **Clinical Diagnosis:**

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

- **Adherence to Age Restrictions:**

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

- **Prior Authorization Criteria:**

  - The first 90 days of a 12 month period will be covered without a prior authorization.
  - After the initial period, authorization will be granted with documentation of one trial of a tier-1 topical corticosteroid of six weeks duration within the past 90 days.
  - Therapy will be approved only once each 90 day period to ensure appropriate short-term and intermittent utilization as advised by the FDA.
  - Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas.
  - Authorizations will be restricted to those patients who are not immunocompromised.

- **Clinical exceptions include a documented:**
  - adverse effect, drug interaction or contraindication to tier-1 products;
  - atopic dermatitis on the face or groin where physician does not want to use topical corticosteroids,
  - prescription by allergist or dermatologist regardless of age.

**Utilization in Oklahoma Medicaid**

**FY '04**

| Drugname | Total Claims | Total Units | Total Days | Clients | Total Paid |
|---|---|---|---|---|---|
| Elidel Cream 1% | 10,758 | 531,825 | 149,280 | 6,327 | $ 899,322.83 |
| Protopic Ointment 0.03% | 582 | 26,050 | 8,315 | 350 | $ 50,174.27 |
| Protopic Ointment 0.1% | 823 | 48,780 | 11,941 | 390 | $ 98,622.48 |
| **TOTAL** | **12,163** | **606,655** | **169,536** | **6,888*** | **$ 1,048,119.58** |

**FY '05**

| Drugname | Total Claims | Total Units | Total Days | Clients | Total Paid |
|---|---|---|---|---|---|
| Elidel Cream 1% | 16,619 | 938,889 | 253,531 | 9,264 | $ 1,656,777.46 |
| Protopic Ointment 0.03% | 693 | 35,596 | 11,828 | 356 | $ 71,676.93 |
| Protopic Ointment 0.1% | 1,193 | 74,360 | 19,009 | 517 | $ 154,452.58 |
| **TOTAL** | **18,505** | **1,048,845** | **284,368** | **9,877*** | **$ 1,882,906.97** |

**(FY '04 vs FY '05 ~ 44 % increase cost and 30 % increase clients)**

**Claims per Age ≤ 2 years of Age**

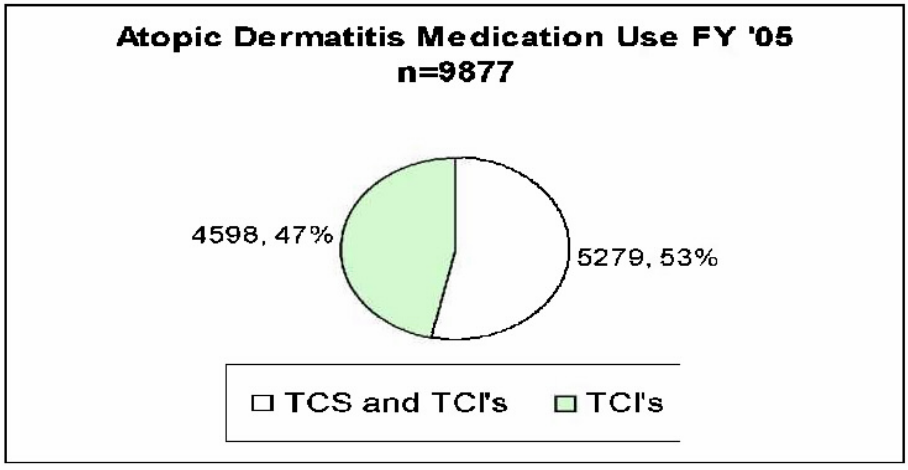
**FY '04 (Total Clients=6,888)**

| | <1 yr | 1 yr | 2 yr | % < 2 yr |
|---|---|---|---|---|
| Female | 488 | 420 | 338 | |
| Male | 687 | 581 | 369 | |
| **Total** | **1175** | **1001** | **707** | **~ 32 %** |

**FY '05 (Total Clients=9,877)**

| | <1 yr | 1 yr | 2 yr | % < 2 yr |
|---|---|---|---|---|
| Female | 658 | 652 | 493 | |
| Male | 1,023 | 733 | 541 | |
| **Total** | **1,681** | **1,385** | **1,034** | **~ 31 %** |

**Clients with both TCI's and TCS claims FY '05**



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

# APPENDIX E

# Vote to Prior Authorize Revatio® (Sildenafil)

**Oklahoma Medicaid**
**September 2005**

## Recommendations

- The College of Pharmacy also recommends a prior authorization be placed on Revatio®. The approval criterion is as follows:
  - **Diagnosis:**
    - Diagnosis and medical supervision by a pulmonary specialist and/or cardiologist.
    - Pulmonary Arterial Hypertension (early stage; NYHA ClassII)
  - **Gender:**
    - Prior authorization required only for male clients.
  - **Quantity Limitation:**
    - 90 tablets per 30 days

      (FDA-approved daily dosage is 20mg tablet T.I.D.)

## Pulmonary Arterial Hypertension (PAH)

- A rare and fatal lung disease involving the pulmonary arteries (untreated median survival < 3years)
- Predominantly women between 20-40 y.o.a.,
- ~ 500 to 1,000 new cases per year in the U.S.
- Vague symptoms: dyspnea, fatigue, chest pain, palpitations, syncope (children)
- Diagnosis "Gold Standard" : Right Heart Cardiac Catherization (mean Pulmonary Arterial Pressure)
- NYHA Class I-IV and WHO Group I Classification
- Idiopathic (IPAH) or familial (FPAH)

## Cost comparison for Pulmonary Arterial Hypertensive Drugs

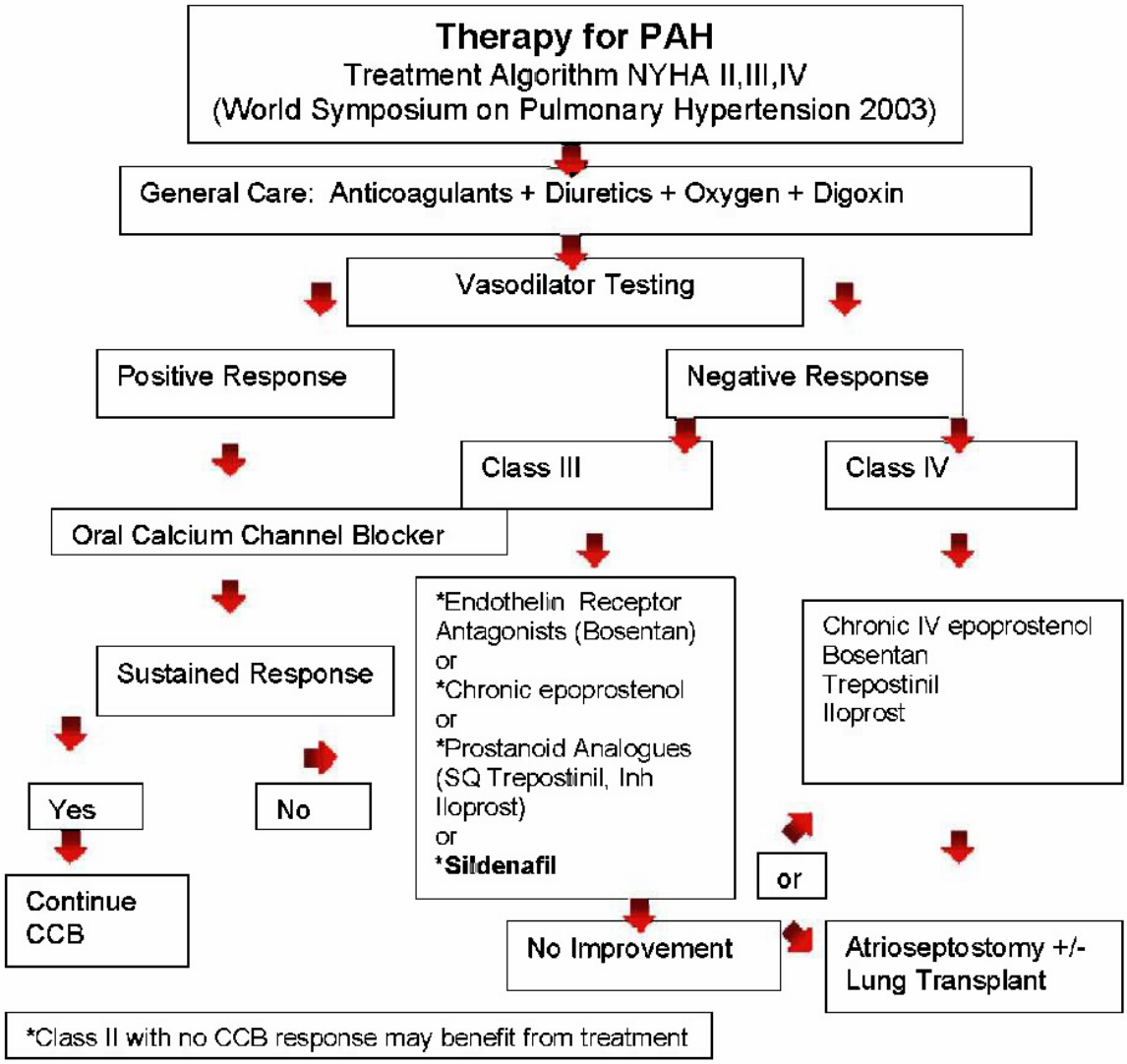
| Product | Route of administration | Dosage | Approximate annual cost |
|---|---|---|---|
| Nifedipine | Oral | 10mg tid | $259** |
| Hydralazine | Oral | 100mg bid | $450 |
| Bosentan (Tracleer®) (Actelion) | Oral | 62.5 mg bid X4 weeks, then 125 mg bid | $36,000 |
| Epoprostenol (Flolan®) (GlaxoSmithKline)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

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

## Age and Gender FY '05

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

## Treatment Algorithm



# APPENDIX F

# Vote on Product Based Prior Authorization of Fenofibrates

**Oklahoma Medicaid**
**September 2005**

## Recommendations

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

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

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

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

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

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

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

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

## Fibric Acid Derivatives

- Increases lipoprotein lipase activity, which is the enzyme that catalyzes lipolysis of the triglyceride core of the chylomicron and catabolism of VLDL, thus lowering TG levels.
- Recommended in patients with very high TG to reduce the risk for acute pancreatitis or in patients with elevated TG.
- May be used as an adjunctive treatment with statins for patients with both elevated LDL and atherogenic dyslipidemia.
- The most common adverse effects of fibric acid derivatives are gastrointestinal distress, skin reactions, myopathy, and cholesterol gallstones. Take with food.
- There are currently four fibric acid derivatives. However, bezafibrate is not available in the United States, and clofibrate is available but rarely used.
- TriCor® has recently received FDA approval for a new formulation that utilizes nanoparticle technology to allow the drug to dissolve faster and more completely in the gastrointestinal tract. This allows the medication to be taken with or without food. The Lofibra and Antara are also micronized fenofibrate formulations. Although all the products result in the same degree of lipid lowering outcome, they are not interchangeable as each holds a patent for its own micronization process.

| Drug | Brand Name | Usual Adult Dose | Available Dosage Forms | FDA Indications |
|---|---|---|---|---|
| Clofibrate | Atromid-S® | 500 mg QID | Capsule: 500 mg | Hypercholesterolemia<br>Central Diabetes Insipidus |
| Fenofibrate | TriCor®<br>Lofibra®<br>Antara® | 54-160 mg QD<br>67-200 mg QD<br>43-130 mg QD | Tablet: 54, 160 mg<br>Capsule: 67, 134, 200 mg<br>Capsule: 43, 87, 130 mg | Hypercholesterolemia,<br>Hypertriglyceridemia |
| Gemfibrozil | Lopid® | 600 mg BID | Tablet: 600 mg | Hypercholesterolemia,<br>Reduction of CHD risk |

## Utilization Summary

| | *Fiscal Year 2003* | *Fiscal Year 2004* | *Percent Change* |
|---|---|---|---|
| Total Claims | 7,532 | 9,120 | Increased 21.1 % |
| Total Cost | $ 371,829.67 | $ 543,999.52 | Increased 46.3 % |
| Cost Per-Diem | $ 1.29 | $ 1.49 | Increased 15.5 % |

Table 2a. Market Share and Cost

| Product | Total Claims | Total Days | Total Reimbursement | % Market Share | % Cost |
|---|---|---|---|---|---|
| *Tricor® Tabs** | 1,410 | 66,982 | $185,988.31 | 49.19 | 80.64 |
| *Lofibra® Caps* | 20 | 842 | $1,478.05 | 0.62 | 0.64 |
| *Gemfibrozil Tabs* | 2,004 | 68,339 | $43,172.34 | 50.19 | 18.72 |

*Includes all forms of Tricor® still available, but no longer being manufactured.

# APPENDIX G

# Vote to Prior Authorize Focalin™ XR (dexmethylphenidate hydrochloride)

**Oklahoma Medicaid**
**September 2005**

| | |
|---|---|
| **Manufacturer** | Novartis Pharmaceuticals Corporation |
| **Classification** | Central Nervous System Stimulant<br>Status: prescription only (schedule II) |


## Summary*

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


## Recommendation

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

---

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

| ADHD and Narcolepsy | | |
|---|---|---|
| **PA Criteria:**<br>First step of immediate release stimulants prior to once-daily extended release formulations.<br>• Dose not to exceed 1.5 times the FDA approved maximum.<br>• No concurrent use of multiple products from this category, ie, Strattera + Stimulant, Methylphenidate + Amphetamine<br>• Desoxyn & Cylert require two Tier-1 trials and are not available for supplemental rebate.<br>• Prior authorization is required for all products for adults age 21 and older. | | |
| Tier 1 | Tier 2 | Tier 3 |
| • amphetamine salt combo (Adderall)<br>• dextroamphetamine (Dexedrine, Dextrostat)<br>• methylphenidate ER (Metadate ER)<br>• methylphenidate (Ritalin)<br>• methylphenidate SR (RitalinSR) | • amphetamine salt combo (Adderall XR)<br>• methylphenidate ER (Concerta)<br>• dexmethylphenidate (Focalin, Focalin XR)<br>• methylphenidate ER (Metadate CD, Ritalin LA)<br>• atomoxetine (Strattera) | • pemoline (Cylert)<br>• methamphetamine (Desoxyn) |

# APPENDIX H

# 30 Day Notice to Prior Authorize Rozerem™ (ramelteon)

**Oklahoma Medicaid**
**September 2005**

**Manufacturer** Takeda Pharmaceuticals
**Classification** FDA classification: melatonin receptor agonist
Status: prescription only

**Summary** Ramelteon is a melatonin receptor agonist that is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

**Recommendations**

- Rozerem™ should be included in the sedative/hypnotic category for which a 90 day period of availability is followed by a requirement for prior authorization.
- Quantity limit of #90 tablets per 90 days, when so requested by physician, otherwise #30 tablets per 30 days.
- Should not be approved in conjunction with QID benzodiazepines.

**Cost comparison**

| | Average Wholesaler Price (AWP) | Daily Dose | Monthly Dose (30 day supply) |
|---|---|---|---|
| Ambien | $313.38/100 | 5mg | $94.01 |
| Ambien | $353.63/100 | 10mg | $106.09 |
| Sonata | $273.83/100 | 5mg | $82.15 |
| Sonata | $336.79/100 | 10mg | $101.04 |
| Lunesta | $370.47/100 | 1, 2, 3 mg | $111.00 |
| Rozerem | $84.38/30 | 8mg | $84.38 |

# Rozerem™ (ramelteon)

## Pharmacological data

Ramelteon is a melatonin receptor agonist that exhibits high affinity to both the $MT_1$ and $MT_2$ receptors, and shows selectivity over the $MT_3$ receptor. The activity of ramelteon at the $MT_1$ and $MT_2$ receptors is believed to contribute to its sleep-promoting properties. This is because these receptors are thought to be involved in the maintainance of the circadian rhythm underlying the normal sleep-wake cycle, when acted on by endogenous melatonin.

## Therapeutic indications

- Ramelteon is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

## Bioavailability/pharmacokinetics

*Absorption*

- Ramelton is rapidly absorbed with the median peak concentration at 0.75 hours after fasted oral administration
- Ramelteon undergoes extensive first-pass metabolism limiting the absolute bioavailability to only 1.8%

*Distribution*

- Ramelteon undergoes protein binding in approximately 82% of human serum, independent of concentration
- Binding to albumin accounts for most of that binding
- Ramelteon is not distributed selectively to red blood cells.
- Ramelteon has a mean volume of distribution of 73.6L after IV administration.

*Metabolism*

- Ramelteon is metabolized primarily by oxidation to hydroxyl and carbonyl derivatives, with secondary metabolism producing glucuronide conjugates.
- The rank order of the principal metabolites by prevalence in human serum is M-II, M-IV, M-I, and M-III.
- The metabolites are formed rapidly and exhibit a monophasic decline and rapid elimination.

*Elimination*

- Approximately 84% of the metabolites are excreted in urine and approximately 4% in the feces.
- Less than 0.1% of the dose excreted is the parent compound.
- Elimination is essentially complete at 96 hours after the dose was given.
- The half-life of M-II is 2 to 5 hours, independent of dose.

**Dosage forms**

Oral

- Rozerem™ is supplied as a round, pale orange-yellow, flim-coated, 8mg tablet
- Available in bottles of #30, 100, or 500 tablets

**Dosage range**

- 8mg taken 30 minutes prior to bedtime
- Should not be taken with or immediately following a high-fat meal

**Known adverse effects/toxicities**

- Whole Body System
  *Influenza*
- Digestive System
  *Nausea*
- Musculoskeletal System
  *Myalgia, arthralgia*
- Nervous System
  *Headache, somnolence, fatigue, dizziness, insomnia exacerbated, depression, taste dysfunction*
- Respiratory System
  *Upper respiratory tract infection*

**Special precautions**

- Ramelteon should be used with caution in patients with moderate hepatic impairment. It has not been evaluated in patients with severe hepatic impairment.
- No adjustments of ramelteon dosage is required in patients with any type of renal impairment
- Ramelteon does not exacerbate mild to moderate obstructive sleep apnea.
- Ramelteon has not been studied in subjects with severe sleep apnea or severe COPD and should not be used in these populations.
- Ramelteon is pregnancy category C

**Contraindications**

- Ramelteon is contradindicated in patients with a hypersensitivity to ramelteon or any components in the Rozerem™ formulation.

**Drug interactions**

- Ramelteon has a highly variable inter-subject pharmacokinetic profile.
- CYP1A2 is the major isoenzyme involved in the metabolism of ramelteon
- Many drugs that are inhibitors of the CYP450 enzyme system will cause an increase in levels of ramelteon; some of these include fluvoxamine, ketoconazole, fluconazole

- Drugs that are inducers of the CYP450 system can cause a decrease in the level of ramelteon; i.e., rifampin
- Although the consumption of alcohol in conjunction with ramelteon did not cause any clinically meaningful effects on peak or total exposure to ramelteon, patients should be cautioned not to consume Rozerem™ with alcohol

**Patient monitoring guidelines**

- No standard monitoring required

**Patient information**

- Ramelteon should be taken within 30 minutes prior to bed
- Patients should be advised to avoid hazardous activities after taking ramelteon
- Ramelteon should not be taken with or immediately following a high fat meal
- Patients should be advised to contact their health care provider if they experience worsening insomnia or behavioral disturbances

**REFERENCES**

1. Rozerem™ package insert.

# 30 Day Notice to Prior Authorize Ambien CR™ (zolpidem tartrate extended release)

**Oklahoma Medicaid**
**September 2005**

| | |
|---|---|
| **Manufacturer** | Sanofi-Aventis |
| **Classification** | Nonbenzodiazepine Hypnotic<br>Status: prescription only (schedule IV) |


## Summary

Zolpidem tartrate is indicated for the short-term treatment of insomnia. The currently available product is scheduled to lose its patent protection in October 2006 or in 2007 dependent on patent extensions. On September 6, 2005, Sanofi-Aventis received approval to sell Ambien CR™, a new extended release version of zolpidem tartrate in the United States. The extended release version will be available in a 12.5 mg dose for adults and a 6.25 mg for elderly patients.


## Recommendation

At present, the College of Pharmacy has the following recommendation:

- Include Ambien CR™ in the prior authorization category with anxiolytics and hypnotics.
- Place a quantity limit on Ambien CR™: 30 units for a 30 day supply.

The College of Pharmacy also recommends further review of the hypnotic category once a generic product is available in the nonbenzodiazepine hypnotic category.

# New Product Summaries

**Oklahoma Medicaid**
**September 2005**

| Drug | Manufacturer | Indications | Dosage | Adverse Effects | Contraindications | New Molecular Entity | AWP/ unit |
|---|---|---|---|---|---|---|---|
| **Proquin-XR** (ciprofloxacin hydrochloride) extended release tablet | DEPOMED INC. | Treatment of uncomplicated UTI caused by E. coli and Klebsiella | 500mg daily with food for 3 days | headache, micturition urgency, nasopharyngitis | -hypersensitivity to quinolone class of antimicrobials agents | NO | N/A |
| **Glumetza** (metformin hydrochloride) extended release tablet | BIOVAIL | Adjunct to diet and exercise to improve glycemic control in adult patients (18 years and older) with Type 2 diabetes | 1000mg daily with food | nausea, vomiting, diarrhea | -patients with renal disease or renal dysfunction | NO | N/A |
| **Cardura XL** (doxazosin mesylate extended release tablets) | PFIZER | Treatment of the signs and symptoms of benign prostatic hyperplasia | 4 mg given once daily, should be administered with breakfast. | Abdominal pain, asthenia, headache, hypotension, dizziness, nausea | -hypersensitivity to other quinazolines, doxazosin, or any of the inert ingredients. | NO | N/A |
| **Megace ES** (megestrol acetate) oral suspension 125mg/ml | PAR PHARM | Treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of AIDS. | 625mg/day (5 mL/day or one teaspoon daily) | Abdominal pain, cardiomyopathy, constipation, dry mouth, increased salivation, leucopenia | History of hypersensitivity to megestrol acetate or any component of the formulation. Known or suspected pregnancy. | NO | $3.25 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Halflytely and Bisacodyl** tablets bowel prep kit | BRAINTREE INC. | HalfLytely and Bisacodyl Tablets Bowel Prep Kit is indicated for bowel cleansing prior to colonoscopy. | Take 4 bisacodyl tablets by mouth. Wait for a bowel movement, then drink the solution at a rate of 1 (8oz.) glass every 10 min. Drink all of the solution. | Nausea, cramping, fullness, vomiting, overall discomfort | -patients known to be hypersensitive to any of the components. -patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon | NO | $48.75 |
| **Zmax** (azithromycin extended release) for oral suspension | PFIZER | treatment of patients with mild to moderate infections caused by susceptible strains of microorganisms in Community-acquired pneumonia and Acute bacterial sinusitis | single 2.0 g (60ml) dose on empty stomach | diarrhea, nausea, abdominal pain, headache, vomiting | Zmax is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide or ketolide antibiotic. | NO | $51.89 |
| **BiDil (isosorbide dinitrate and hydralazine hydrochloride)** | **NITROMED** | **BiDil is indicated for the treatment of heartfailure as an adjunct to standard therapy** | **One tablet three times a day** | **headache, dizziness, chest pain, asthenia, nausea, bronchitis, hypotension** | **BiDil is contraindicated in patients who are allergic to organic nitrates.** | **NO** | **$2.25** |

# APPENDIX I

# Annual Review of HMG-CoA Reductase Inhibitors

**Oklahoma Medicaid**
**September 2005**

## Current Prior Authorization Criteria of HMG-CoA Reductase Inhibitors

The class of HMG-CoA Reductase Inhibitors (Statins) was included in the Product Based Prior Authorization program during fiscal year 2004.

| HMG-CoA Reductase Inhibitors (Statins) | |
|---|---|
| *Tier One* | *Tier Two* |
| *As approved by DUR Board:*<br>Lovastatin (Mevacor® Altoprev®)<br>Fluvastatin (Lescol® and Lescol XL®)<br>Atorvastatin (Lipitor®)<br>*By supplemental rebate participation:*<br>Rosuvastatin (Crestor®)<br>Pravastatin (Pravachol®)<br>Simvastatin (Zocor®)<br>Lovastatin/Niacin (Advicor®) | Pravastatin/Aspirin (Pravaguard®) |

### Criteria for Authorization

To qualify for a tier-2 medication, there must be:

1. Previous failure to achieve desired LDL reduction with a preferred statin - defined by at least 6-8 weeks of continuous therapy at standard to high dose.
2. Previous stabilization on non-preferred medication.
3. Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
4. Documented adverse effect or contraindication to the preferred products.

## Utilization of Statins

**Trends in Utilization of Statins**

| | *Fiscal Year 2004* | *Fiscal Year 2005* | *Percent Change* | |
|---|---|---|---|---|
| **Total Cost** | $12,549,409.71 | $16,859,495.49 | Increased | 34.3 % |
| **Total Claims** | 87,811 | 118,055 | Increased | 34.4 % |
| **Total Clients** | 20,364 | 25,354 | Increased | 24.5 % |
| **Total Days** | 4,011,338 | 5,265,562 | Increased | 31.3 % |
| **Per-Diem** | $3.13 | $3.20 | Increased | 2.23 % |

## Utilizing of Statins by 25,354 Clients during Fiscal Year 2005

| Name of Drug | Total Claims | Total Units | Total Days | Total Costs | Units/Day | PerDiem |
|---|---|---|---|---|---|---|
| Atorvastatin (Lipitor®) | 61,752 | 2,745,361 | 2,743,163 | $8,085,601.77 | 1.00 | $2.95 |
| Simvastatin Simvastatin (Zocor®) | 33,740 | 1,472,414 | 1,516,566 | $6,008,551.54 | 0.97 | $3.96 |
| Pravastatin (Pravachol®) | 8,314 | 384,590 | 378,926 | $1,447,386.35 | 1.01 | $3.82 |
| Rosuvastatin (Crestor®) | 6,465 | 315,941 | 287,319 | $750,117.48 | 1.10 | $2.61 |
| Lovastatin (Mevacor® Altoprev®) | 4,395 | 200,256 | 188,181 | $226,977.00 | 1.06 | $1.21 |
| Fluvastatin (Lescol® and Lescol XL®) | 2,867 | 133,420 | 129,808 | $281,910.04 | 1.03 | $2.17 |
| Lovastatin/Niacin (Advicor®) | 499 | 23,840 | 20,349 | $53,865.54 | 1.17 | $2.65 |
| Pravastatin/Aspirin (Pravaguard®) | 23 | 1,240 | 1,250 | $5,085.77 | 0.99 | $4.07 |
| **TOTALS** | **118,055** | **5,277,062** | **5,265,562** | **$16,859,495.49** | **1.00** | **$3.20** |

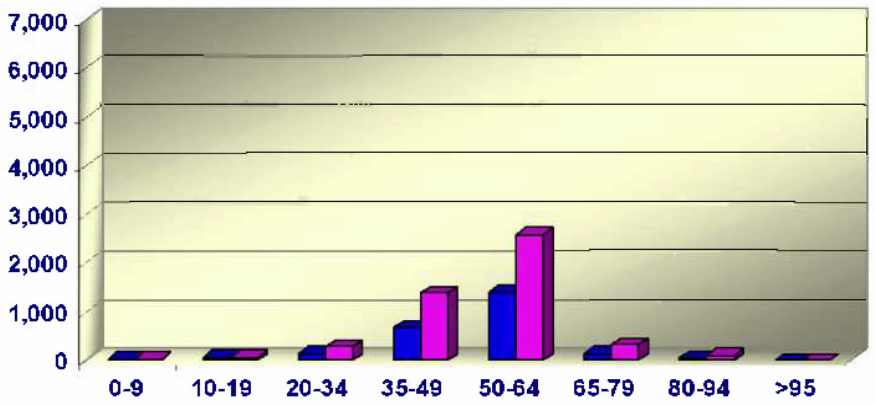
## Utilization of Statins by 7,180 Non-Dual Eligible Clients

| Name of Drug | Total Claims | Total Units | Total Days | Total Costs | Units/Day | PerDiem |
|---|---|---|---|---|---|---|
| Atorvastatin (Lipitor®) | 16,964 | 763,456 | 761,759 | $2,261,435.76 | 1.00 | $2.97 |
| Simvastatin Simvastatin (Zocor®) | 7,635 | 323,763 | 337,753 | $1,329,636.47 | 0.96 | $3.94 |
| Rosuvastatin (Crestor®) | 1,692 | 105,223 | 75,633 | $197,138.61 | 1.39 | $2.61 |
| Pravastatin (Pravachol®) | 1,577 | 70,771 | 69,290 | $272,001.98 | 1.02 | $3.93 |
| Lovastatin (Mevacor® Altoprev®) | 880 | 39,818 | 38,132 | $43,833.18 | 1.04 | $1.15 |
| Fluvastatin (Lescol® and Lescol XL®) | 386 | 17,882 | 17,008 | $38,043.37 | 1.05 | $2.24 |
| Lovastatin/Niacin (Advicor®) | 130 | 6,614 | 5,884 | $15,041.50 | 1.12 | $2.56 |
| Pravastatin/Aspirin (Pravaguard®) | 5 | 460 | 460 | $2,011.81 | 1.00 | $4.37 |
| **TOTALS** | **29,269** | **1,327,987** | **1,305,919** | **$4,159,142.68** | **1.02** | **$3.18** |

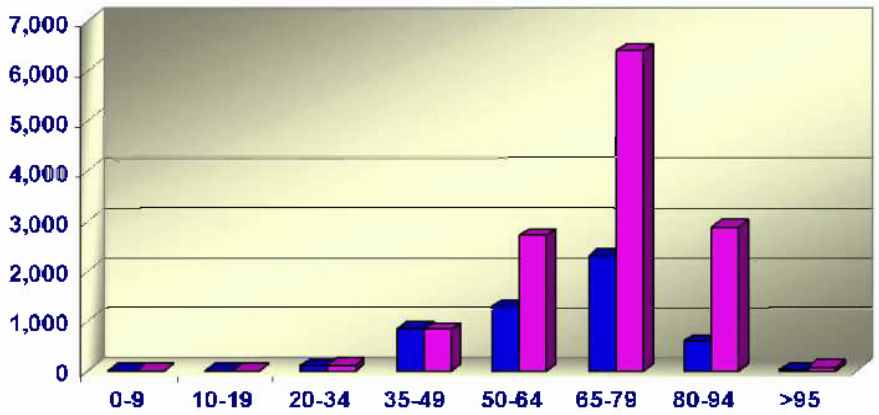
## Utilization of Statins by 18,174 Dual Eligible Clients

| Name of Drug | Total Claims | Total Units | Total Days | Total Costs | Units/Day | PerDiem |
|---|---|---|---|---|---|---|
| Atorvastatin (Lipitor®) | 44,788 | 1,981,905 | 1,981,404 | $5,824,166.01 | 1.00 | $2.94 |
| Simvastatin Simvastatin (Zocor®) | 26,105 | 1,148,650 | 1,178,813 | $4,678,915.07 | 0.97 | $3.97 |
| Pravastatin (Pravachol®) | 6,737 | 313,819 | 309,636 | $1,175,384.37 | 1.01 | $3.80 |
| Rosuvastatin (Crestor®) | 4,773 | 210,718 | 211,686 | $552,978.87 | 1.00 | $2.61 |
| Lovastatin (Mevacor® Altoprev®) | 3,515 | 160,438 | 150,049 | $183,143.82 | 1.07 | $1.22 |
| Fluvastatin (Lescol® and Lescol XL®) | 2,481 | 115,538 | 112,800 | $243,866.67 | 1.02 | $2.16 |
| Lovastatin/Niacin (Advicor®) | 369 | 17,226 | 14,465 | $38,824.04 | 1.19 | $2.68 |
| Pravastatin/Aspirin (Pravaguard®) | 18 | 780 | 790 | $3,073.96 | 0.99 | $3.89 |
| **TOTALS** | **88,786** | **3,949,074** | **3,959,643** | **$12,700,352.81** | **1.00** | **$3.21** |

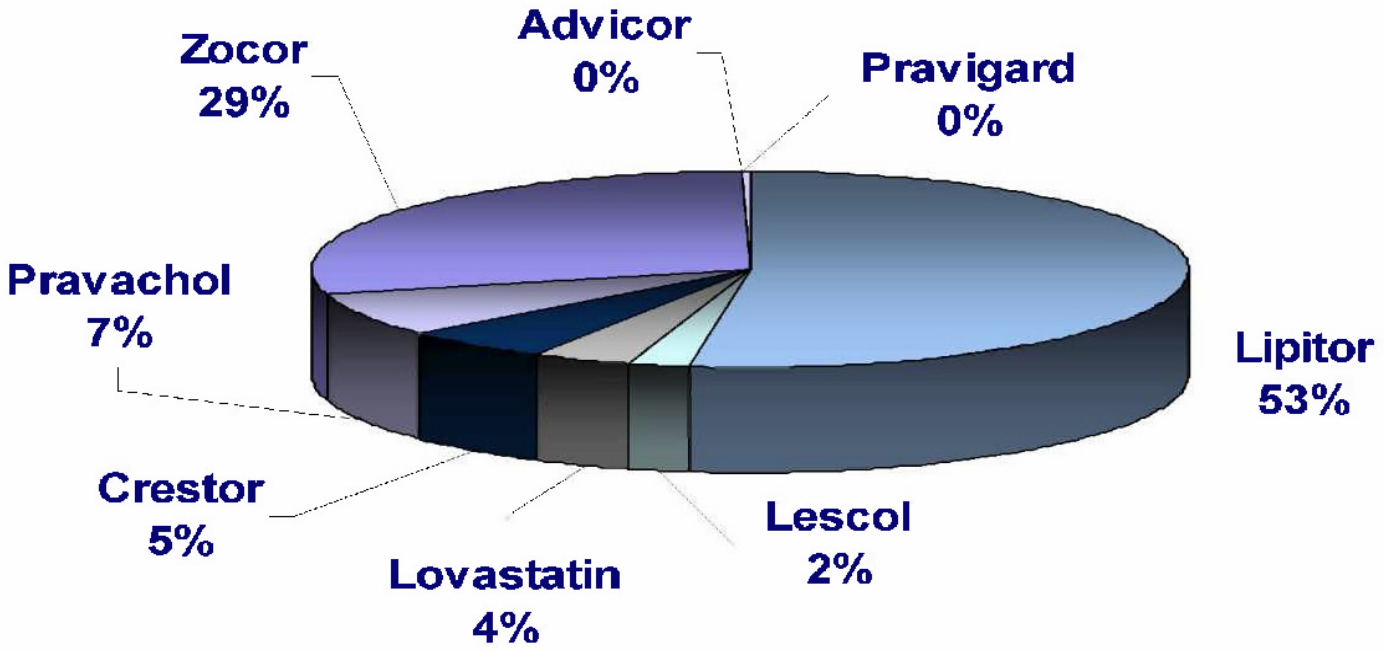
NON-DUAL ELIGIBLE CLIENTS UTILIZING STATINS




DUAL ELIGIBLE CLIENTS UTILIZING STATINS




## Market Share by Therapy Days



## Anticipated Changes in the Class of Cholesterol Lowering Medications

### HDL Elevator[1]

Clinical trials have shown that even modest increases in HDL cholesterol concentrations can significantly reduce CHD risks. Inhibition of the cholesteryl ester transfer protein (**CETP**) results in increases of high-density lipoprotein (HDL) cholesterol levels. Human trials are well under way and the late stage research and development of torcetrapib/Lipitor®, a combination CETP inhibitor/statin, are near completion.

### Omacor®[2]

Omacor® is scheduled to enter the market and made available to physicians, pharmacists and patients in the Fall of 2005. Omacor®, a purified form of omega-3 acid extracted from marine fish, is available by prescription only. It has been approved by the FDA as an adjunct along with diet and exercise for the treatment of extremely elevated TG (>500 mg/dL.) The mechanism of action is not completely understood; however, it is believed that Omacor® exerts its TG lowering properties by inhibiting substrates that are responsible for TG synthesis, specifically acyl CoA:1,2-diacylglycerol acyltransferase.

Omacor® is supplied as 1-gram transparent soft-gelatin capsules filled with light-yellow oil. The daily dose of Omacor is 4 g per day. The daily dose may be taken as a single 4-g dose (4 capsules) or as two 2-g doses (2 capsules given twice daily.)

Omacor® treatment to reduce very high TG levels may result in elevations in LDL-C and non-HDL-C in some individuals. Patients should be monitored to ensure that the LDL-C level does not increase excessively. The effects of Omacor® on cardiovascular outcomes, such as mortality and morbidity, have not been determined.

### Zocor® Patent

The patent for Zocor® is scheduled to expire in December 2005. Generic simvastatin is anticipated to be available in the first part of 2006.

## Conclusion and Recommendation

The College of Pharmacy recommends no changes at this time, with further evaluation of this class after several months of experience without the dual eligible clients in order to assess changes in utilization, emerging medical data on safety, clinical outcomes and efficacy, and potential cost minimization strategies to ensure appropriate use in conjunction with best practice guidelines.

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[1] Brousseau ME. Diffenderfer MR, et al. **Effects of cholesteryl ester transfer protein inhibition on high-density lipoprotein subspecies, apolipoprotein A-I metabolism, and fecal sterol excretion.** [Journal Article] *Arteriosclerosis, Thrombosis & Vascular Biology. 25(5):1057-64, 2005 May.*

[2] Reliant Pharmaceuticals, Inc. Product Literature Omacor®. April 2005. Available online at: http://www.omacorrx.com/OMACOR_Prescribing_Information.pdf.

# APPENDIX J

# Treatment of Head Lice

**Oklahoma Medicaid**
**September 2005**

## Introduction

Head lice occur commonly in all age groups, but especially in elementary school children during the winter months. Pediculosis capitis is an infestation of lice on the scalp. This is the most common type of pediculosis in the world, infecting about 6-12 million people annually in the United States alone.[1] Head lice are parasitic insects found on the heads of people. Itching is the primary symptom which is a result of an allergic reaction to louse saliva and takes two or more weeks to develop.[2] These insects do not hop, jump, or fly. Rather they are transmitted by person to person contact.[3]

## Diagnosis

Head lice infestations are diagnosed by lice or viable eggs (nits) on examination. Lice can be difficult to detect. A bright light, magnifying glass and separating the hair may aid inspection. However, combing through the hair with a louse comb and examining the teeth of the comb for living lice detects more cases than direct visualization alone.[4]

## Pharmacologic Treatment

Most topical and systemic treatments are toxic to the nervous system of the louse. Because some developing embryos survive initial treatment, a second course treatment, seven to ten days after the first course is recommended to kill newly hatched nymphs.[5] No product currently available kills all eggs.

## Pyrethrums (composite of pyrethrins)

| Product Name | Form | Active Ingredients |
|---|---|---|
| A-200 Lice Treatment Kit | Shampoo | Pyrethrins 0.33%/<br>Piperonyl butoxide 4% |
| | Aerosol spray | 0.5% resmethrin |
| Bio-Sentry Lice Killing | Shampoo | Pyrethrum extract 0.33%/<br>Piperonyl butoxide 4% |
| Bio-Sentry Lice Treatment | Cream rinse | Pyrethrum extract 0.33%/<br>Piperonyl butoxide 4% |
| End-Lice | Liquid | Pyrethrins 0.33%/<br>Piperonyl butoxide 4% |
| Innogel Plus | Gel | Pyrethrins 0.33%/<br>Piperonyl butoxide 4% |
| Licetrol | Shampoo | Pyrethrins 0.33%/<br>Piperonyl butoxide technical 4% |
| Pronto Lice Killing | Shampoo | Piperonyl butoxide 4%,<br>Pyrethrum extract 0.33% |
| | Aerosol spray | 0.4% 3-phenoxybenzyl-(1R,3S; 1RS)-2,2-dimethyl-3(2-methylprop-1-enyl) cyclopropanecarboxylate |

| | | |
|---|---|---|
| R&C Shampoo/Conditioner | Shampoo | Pyrethrins 0.33%/<br>Piperonyl butoxide 3% |
| R&C spray | Spray | Phenothrin 0.4% |
| RID Lice Elimination Kit | Shampoo | Pyrethrins 0.33%/<br>Piperonyl butoxide 4% |
| | Aerosol spray | 0.5%permethrin |

## Pyrethroids (synthetic insecticide)

| Product Name | Form | Active Ingredients |
|---|---|---|
| Nix | Cream rinse | Permethrin 1% |

## Lindane (an organochlorine)

| Product Name | Form | Active Ingredients |
|---|---|---|
| Lindane 1% | Shampoo and lotion | Gamma benzene hexachloride 1% |

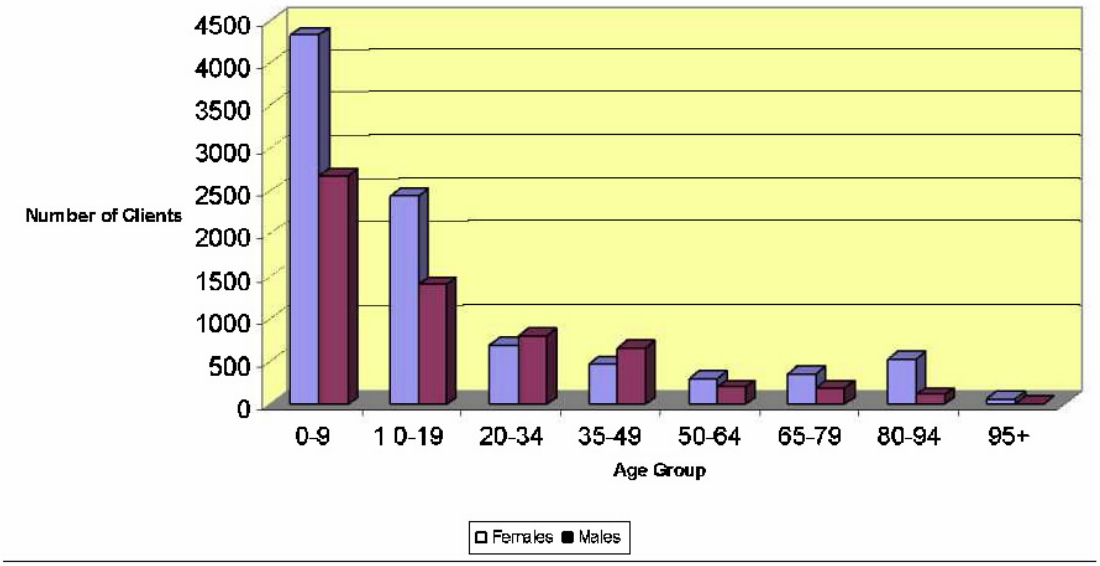
## Malathion (an organophosphate)

| Product Name | Form | Active Ingredients |
|---|---|---|
| Ovide | Lotion | 0.005g of malathion per mL (+/-)-[dimethoxyphosphinothioyl0-thio] butanedioic acid diethyl ester |

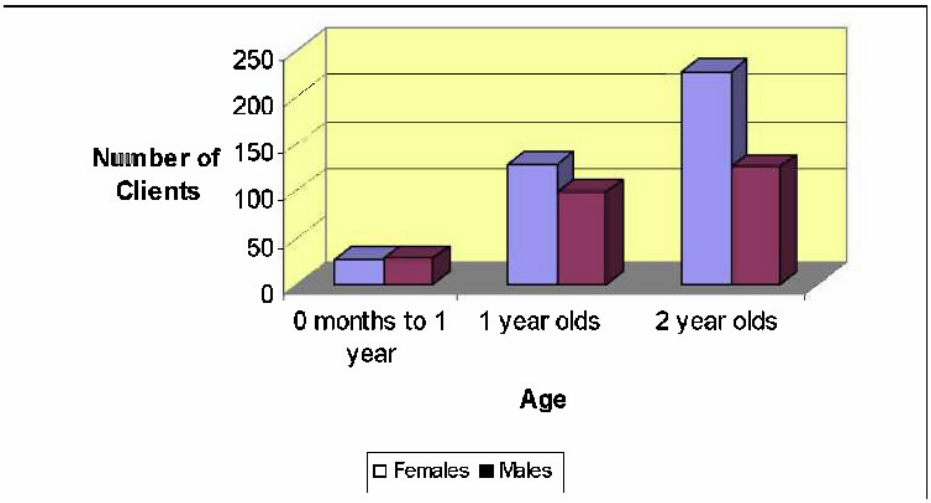
## Total Cost and Percent Changes for Prescription Treatments

| | *Fiscal Year 2004* | *Fiscal Year 2005* | *Percent Change* |
|---|---|---|---|
| **Total Cost** | **$ 885,124.48** | **$ 1,617,242.42** | **45%** |
| Lindane lotion 1% | $ 130,514.17 | $ 226,937.18 | 43% |
| Lindane shampoo 1% | $ 558,551.32 | $ 967,083.73 | 42% |
| Ovide lotion 0.5% | $ 196,058.99 | $ 423,221.51 | 54% |

## Age and Gender Distribution




## Age and Gender Distribution for Clients Less than 2 Years Old



## Cost Per treatment of OTC and RX Treatments Available

| OTC* | Cost per treatment |
|---|---|
| Walgreens Stop Lice Complete Lice Tx Kit | $14.99 |
| RID Complete Lice Elimination Kit | $20.99 |
| Pronto Lice Killing Shampoo Kit | $10.99 |
| Pronto Plus Complete Lice Removal System, 3-Step Elimination Kit | $17.99 |
| Nix Lice Treatment | $12.99 |
| CVS Lice Killing Shampoo | $8.99 |
| CVS Permethrin Lotion 1% Lice Treatment | $9.19 |
| **Prescription** | |
| Lindane lotion 1% (SMAC) | $123.82 |
| Lindane shampoo 1% (SMAC) | $110.82 |
| Ovide lotion 0.5% (EAC) | $110.65 |

*- Prices from Walgreens and CVS website

## Discussion

**PYRETHRINS** - Available OTC. They are effective against lice and cosmetically acceptable. Pyrethrins are unstable in heat and light, do not kill all unhatched eggs, and have no residual activity. Therefore, require a second treatment 1 week after the first. Treatment failures with pyrethrins are common.

**PERMETHRIN –** Also available OTC. A synthetic compound based on the insecticidal components of natural pyrethrins, permethrin is heat and light stable and does have residual activity for 2 weeks or more. Resistance appears to occur even at higher concentrations.

**LINDANE –** Was once the most common treatment for head lice. In October 2003, the FDA issued a public health advisory concerning the use of topical formulations of Lindane lotion and shampoo. The boxed warning emphasizes that it is a second-line treatment and is not recommended for use in infants and should be used with caution in children and adults weighing <50kg.

**MALATHION (OVIDE®) –** An irreversible cholinesterase inhibitor, probably the fastest killing and most ovicidal pediculocide for treatment of head lice. However, it usually is not prescribed due to its objectionable odor, fear of flammability of its alcohol vehicle and its prolonged (8-12 hours) application time. Malathion has been effective against lice that were resistant to permethrin. Malathion is contraindicated in neonates and infants.

## Recommendations

The College of Pharmacy recommends the following:

1. Research the option of covering OTC products for step therapy protocol.
2. If OTC coverage is possible, recommend step therapy approach:
    - Step one – OTC treatment
    - Step two – Rx as appropriate for the patient

Reference:

[1] Huyn TH, Norman RA. Scabies and pediculosis: Dermatologic Clinics 2004;22;7-11.
[2,3,4,5] Flinders DC, Schweinitz PD. Pediculosis and Scabies: American Family Physician 2004;69;2.

# APPENDIX K

## FDA News

**FOR IMMEDIATE RELEASE**
P05-56
August 31, 2005

**Media Inquiries:**
Lenore Gelb, 301-827-6242
**Consumer Inquiries:**
888-INFO-FDA

# FDA Approves New Influenza Vaccine for Upcoming Flu Season

The Food and Drug Administration (FDA) today approved Fluarix, an influenza vaccine for adults that contains inactivated virus. Fluarix is approved to immunize adults 18 years of age and older against influenza virus types A and B contained in the vaccine. Influenza is also commonly called the flu.

"FDA"s approval of Fluarix is a big step toward providing an adequate supply of flu vaccine for the American public," said Mike Leavitt, Secretary of Health and Human Services (HHS). "Having more manufacturers of influenza vaccine licensed in the U.S., and having more vaccine dosages, is critical to public health and I applaud FDA for taking such quick action to obtain and evaluate the data needed to license Fluarix in time for this year"s influenza season."

The approval of Fluarix breaks new ground in that it is the first vaccine approved using FDA"s accelerated approval process. Accelerated approval allows products that treat serious or life-threatening illnesses to be approved based on successfully achieving an endpoint that is reasonably likely to predict ultimate clinical benefit, usually one that can be studied more rapidly than showing protection against disease. In this case, the manufacturer demonstrated that after vaccination with Fluarix adults made levels of protective antibodies in the blood that FDA believes are likely to be effective in preventing flu. GlaxoSmithKline, the manufacturer of Fluarix, will do further clinical studies as part of the accelerated approval process to verify the clinical benefit of the vaccine.

"Previous shortages highlighted the need for additional influenza vaccine manufacturers for the U.S. market," said FDA Commissioner Lester Crawford. "Accelerated approval has allowed us to evaluate and approve Fluarix in record time so that we can make available additional safe and effective flu vaccines. I commend our Center for Biologics for taking extraordinary steps to help us be better prepared for both the upcoming and future flu seasons."

This success required close cooperation among the FDA, the National Institutes of Health, and the product manufacturer," said Dr. Jesse Goodman, Director of FDA"s Center for Biologics Evaluation and Research. "The dedicated staff of this Center is doing everything possible to prepare for the upcoming flu season."

FDA based the accelerated approval of Fluarix on thorough evaluation of safety and effectiveness data from four clinical studies involving approximately 1,200 adults. Other data from post-marketing reports in other countries where Fluarix is already approved were also reviewed as part of FDA"s safety assessment.

In the United States it is estimated that more than 200,000 people are hospitalized from flu complications, and about 36,000 people die from flu each year. Although no vaccine is 100% effective against preventing disease, vaccination is the best protection against influenza and can prevent many illnesses and deaths.

Fluarix is manufactured in Dresden, Germany by Sächsisches Serumwerk (SSW), a subsidiary of GlaxoSmithKline Biologicals, of Rixensart, Belgium. It will be distributed by GSK in Research Triangle Park, NC.

# FDA Statement

**FOR IMMEDIATE RELEASE**
Statement
August 26, 2005

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

## FDA Takes Action on Plan B
## Statement by FDA Commissioner Lester M. Crawford

Thank you for coming today.

We are announcing the action we took today of sending a letter to Barr Labs concerning their application to allow Plan B to be sold over-the-counter.

I want to start by making sure everyone is clear on what this drug is. Also, it's important that we define what the FDA has been asked by Barr Labs to address with respect to this drug.

Plan B has been referred to as emergency contraception. It contains one of the same active ingredients used in ordinary prescription birth control pills -- only in the case of Plan B – each pill contains a much higher dose and is taken in a different way.

Like ordinary birth control pills, Plan B is currently available to all women as a prescription drug. There is a second drug called Preven that is similar to Plan B. That drug is also sold with a prescription. Preven was first introduced on the market before Plan B.

The question we have been asked to address is whether Plan B should be available without a prescription on a pharmacy shelf, similar to the way other over-the-counter medicines like some cough syrups and allergy pills are sold, for women age 16 and older, and remain prescription-only for those under the age of 16.

The issues that we were asked to resolve, and the proposal that was put forward by Barr Labs, presented us with many difficult and novel policy and regulatory issues.

In some cases, the questions we were asked to answer were unprecedented for this agency. In particular:

Can age be used as a criterion on which we decide whether a drug should be prescription or over-the-counter, as has been proposed in this case?

Can the prescription and over-the-counter version of the same drug be marketed in a single package?

In addition, if we do use age as the only criterion on which we decide whether a drug is sold as a prescription product, or an over-the-counter product, how, as a practical matter, would such a limitation be enforced?

These are profound regulatory decisions that cut to the heart of our work. The answers to these questions can establish very broad and far-reaching policies that could have a significant effect on the way FDA regulates many different drugs.

In fact, the answers to these questions could establish pathways that could make many more products available as over-the-counter drugs.

That could be a positive public health step, and one that I would support as the agency's Commissioner if it means we could safely make many more effective medicines more easily available.

We believe these novel regulatory issues should be considered in an open, public process.

Rather than answering these questions in the context of a decision on a single drug, we need to have an open process to solicit public comment.

These regulatory and policy questions are too profound and cut across too many different products to be made behind closed doors.

And so today we are also announcing that we are taking the action of publishing an advance notice of proposed rulemaking to initiate an open public process to consider these important regulatory and policy questions.

This notice will speak only to the regulatory and policy issues raised by this application.

The resubmitted supplemental new drug application that the FDA was asked to review provides for a switch from prescription only status to Over the Counter status only for women ages sixteen years and older.

Plan B would remain prescription only for women under sixteen years of age.

The FDA's drug center, the Center for Drug Evaluation and Research or CDER, completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but only for women who are 17 years of age and older.

What we are saying today is that the Agency is unable at this time to reach a decision on the approvability of the application because of these unresolved regulatory and policy issues that relate to the application we were asked to evaluate.

We need to resolve these policy and regulatory questions before we can reach a final decision on the underlying science that was presented to us.

FDA is both a scientific and a regulatory agency. And what we are saying today is that there are unique regulatory issues that need to be addressed before we can take a final action on the application.

We are beginning a process that will address the regulatory questions today, but we believe we can only decide these issues in an open, public process.

Through this process, all interested parties can weigh in on the questions of whether a drug may be both prescription and over the counter based on uses by different subpopulations and whether the prescription and over the counter versions of the drug may be marketed in a single package.

There is precedent for this kind of careful, public policy making inside FDA and inside many federal agencies. This action ensures that the rules that an Agency like ours sets are done so in an open fashion. These rules have lots of implications that aren't always easy to anticipate at first blush.

Today I am making the commitment that we will work with our stakeholders to make sure that this process is expeditious and thorough.

Before I close, I want to step back and give you a little more detail on the regulatory pathway that led us to our current action.

And I want to help explain why the question of whether a drug can be sold simultaneously both over the counter and as a prescription product, in the same dosage, for the same indication, and in the same package, and with age as the only deciding criteria, is so profound.

FDA used to prohibit products from being both over the counter and prescription at the same time. They had to be one or the other. The idea was that if an active ingredient was safe and effective without a practitioner's supervision it had to be over-the-counter. If it needed a prescription for one group of people, then it needed a prescription for all people.

That was FDA's practice for a very long time.

In the late 1970s, FDA formed a task force to undertake a formal process to consider changing that policy, to determine whether a drug could be sold prescription and over-thecounter in different settings, for example, for different medical indications.

But ultimately, this task force rejected changing the policy, and so the policy continued. And from the 1950s until the 1980s, drugs were either only prescription or only over-thecounter.

There was no molecule that existed on the market as both a prescription drug and an over-the-counter product.

Then in the 1980s, the agency was challenged on an application. FDA decided to allow the molecule to be sold as a prescription product for one use and an over-the-counter product for another.

Since then, there have been only a small number of ingredients approved as both prescription and over-thecounter and in these cases there was a meaningful difference in the way the two products are used.

In the Plan B application, we are grappling not with the same question but with a different question: whether we can have the same molecule exist as both a prescription and over-thecounter product for the SAME indication?

And if FDA were to attempt to limit sale of an over-thecounter product to a particular sub population, would FDA be able to enforce such a limitation as matter of law, and could it do so as practical matter and then how?

Moreover, we are being asked to determine whether a product can be labeled for over-the-counter and prescription us and be sold in the same package.

I am committed to expediting this rule-making process, and in order to do so, I have ordered a 60-day comment period instead of the usual 90 to 120 day comment period. FDA will process and post the comments as they come in to us and finalization of this regulatory and policymaking process will be a personal priority of mine.

The action FDA took today underscores the Agency's commitment to public health and safety.

As an agency and as its Commissioner personally, I want to say that FDA remains committed to making safe and effective contraceptive products available to women and men who choose to use them.

####

FDA Letter to Sponsor
Federal Register Document [PDF 17KB]
Online Comment Form

# Isotretinoin (marketed as Accutane) Capsule Information

**FDA ALERT [08/2005]: PREGNANCY: Strengthened Risk Management Program. FDA has approved a strengthened risk management plan for Accutane and generic isotretinoin to make sure females do not become pregnant while taking this medicine. Isotretinoin causes birth defects. This new plan is called iPLEDGE. Starting December 31, 2005 all:**

- **wholesalers who distribute isotretinoin**
- **doctors who prescribe isotretinoin**
- **pharmacies that dispense isotretinoin**
- **patients that take isotretinoin must register and agree to carry out the iPLEDGE program.**

**[07/2005]: SUICIDAL THOUGHTS OR ACTIONS: In addition to the strengthened risk management program for pregnancy, FDA continues to assess reports of suicide or suicide attempts associated with the use of isotretinoin. All patients treated with isotretinoin should be observed closely for symptoms of depression or suicidal thoughts, such as sad mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating, or for mood disturbance, psychosis, or aggression. Patients should stop isotretinoin and they or their caregiver should contact their healthcare professional right away if the patient has any of the previously mentioned symptoms. Discontinuation of treatment may be insufficient and further evaluation may be necessary. [Action taken 08/12//05: Labeling revision]**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

- **Patient Information Sheet** [PDF] or [HTML] (updated 8/12/2005)
- **Healthcare Professional Information**
  - Healthcare Professional Sheet [PDF] or [HTML] (updated 8/12/2005)
  - Prescribing Information (Accutane Label)

## Other Information

- Public Health Advisory (8/12/2005)
- FDA News (8/12/2005)
- Questions and Answers [HTML] [PDF] (8/12/2005)
- Approval Letter (8/12/2005)

- Medication Guide (8/12/2005)
- Isotretinoin is marketed under these names:
  - Accutane
  - Amnesteem
  - Claravis
  - Sotret
- Regulatory History of Isotretinoin from Drugs@FDA

**Historical Information**

**Do Not Buy Accutane (isotretinoin) Over the Internet**

- You should not buy Accutane over the Internet because you will bypass important safeguards designed to protect your health (and the health of others).
- Accutane has special safety restrictions on how it is distributed to the public. Also, drugs purchased from foreign Internet sources are not the FDA-approved versions of the drugs, and they are not subject to FDA-regulated manufacturing controls or FDA inspection of manufacturing facilities.

To learn more about buying drugs safely, please see

- Buying Prescription Medicines Online: A Consumer Safety Guide
- FDA strengthens controls, issues consumer alert on importing certain prescription drugs
- FDA Import Alert

**Report Adverse Events to MedWatch**

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Date created: May, 2005, updated August 17, 2005