Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

October 12, 2005 @ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Gorman, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – October 12, 2005**

DATE: October 6, 2005

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

Enclosed are the following items related to the October 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 Rozerem™ – **See Appendix C.**

Action Item – Vote to Prior Authorize Ambien CR™ – **See Appendix D.**

Analysis of Non-Dual Claim Utilization – **See Appendix E**

Review and Discuss Asthma Utilization – **See Appendix F**

Action Item – Annual Review of Non-Sedating Antihistamines– **See Appendix G**

Review and Discuss Nasal Anti-Allergy Products – **See Appendix H.**

New Product Reviews and Notices – **See Appendix I.**
30 Day Notice to Prior Authorize Xopenex HFA™, Darvocet A500™ and Balacet 325™

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – October 12, 2005 @ 6:00p.m.

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

AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

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

A. September 14, 2005 DUR Minutes – Vote
B. Memorandum of September 14, 2005 DUR Recommendations
C. Provider Correspondence

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

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

A. Medication Coverage Activity Audit for September 2005
B. Help Desk Activity Audit for September 2005

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

5. Action Item – Vote to Prior Authorize Rozerem™ – See Appendix C.

A. Product Summary
B. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Ambien CR™ – See Appendix D.

A. Product Summary
B. COP Recommendations

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

7. Analysis of Non-Dual Claim Utilization – See Appendix E.

A. Background
B. Utilization Review
C. Discussion

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

8. Review and Discuss Asthma Utilization – See Appendix F.

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

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

9. Action Item – Annual Review of Non-Sedating Antihistamines – See Appendix G.

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

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

10. Review and Discuss Nasal Anti-Allergy Products – See Appendix H.

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

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

11. New Product Reviews and Notices – See Appendix I.

A. **30 Day Notice to Prior Authorize Xopenex HFA™**
B. **30 Day Notice to Prior Authorize Darvocet A500™ and Balacet 325™**
C. New Product Summaries

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Antipsychotic Utilization Review
B. Anticonvulsant Review
C. Muscle Relaxant Review
D. Osteoporosis Review
E. Contraceptive Utilization Review
F. Antidiabetic Utilization Review
G. Antiinfectives Utilization Review
H. Annual Reviews
I. New Product Reviews
- Flexeril® 5 mg

14. Adjournment

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of SEPTEMBER 14, 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
Carol Moore, Pharm.D. Clinical Pharmacist		X
Neeraj Patel, Pharm.D., Clinical Pharmacist	X	
Visiting Pharmacy Students: Eric Tisdale	X	

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

OTHERS PRESENT:

Miranda Porter, Ph.D., BMS	Rachelle McCoy, Amylin	Kay Kaut, Amylin
Joni Beck, Pharm.D., OUHSC	Jim Dunlap, Lobbyist, Lilly	Dale Roof, Takeda
Jim Delatte, Takeda	Alan Weiss, Astellas	Dave Case, Astellas
Erika Stafford, Astellas	Joe McIntosh, Novartis	Christi Davis O'Brien, Amylin
Jorge Nassar, BMS	Monte Summers, Amylin	Lance Burleson, MedImmune
Pat Evans, BMS	Curtis Krause, MedImmune	Vivian Fox, MedImmune
Mark DeClerk, Eli Lilly	Justin Springfield, Sepracor	Mary Anne McCaffree, OUHSC
Evie Knisely, Novartis	Holly Jacques, Merck	Jim Fowler, AstraZeneca

PRESENT FOR PUBLIC COMMENT:

Jim Davis, MD	Agenda Item No. 5
Rosalind Faburni, Ph.D., Amylin Phar.	Agenda Item No. 5
Dr. Ray Cornelison, OU College of Dermatology	Agenda Item No. 6
Dr. Daniel E. Garcia, Takeda Pharma	Agenda Item No. 10

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

1A: Roll Call

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

ACTION: NONE REQUIRED.

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

2A: Acknowledgement of Speakers and Agenda Item

Dr. Whitsett acknowledged speakers for Public Comment.

ACTION: NONE REQUIRED.

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

3A: August 10, 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 June 2005

4B: Medication Coverage Activity Report: August 2005

4C: Help Desk Activity Report: August 2005

4D: Prospective Drug Utilization Review: Annual Report FFY04

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

ACTION: NONE REQUIRED.

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

For Public Comment, Jim Davis, M.D.: *Byetta is a new drug that has just been released. It's the first in it's class of (unintelligible) increases (unintelligible) is a gastrointestinal hormone (unintelligible). It can be used with, I'm not supposed to say that, but any drug with diabetes. The ones that are approved are the sulfonylureas and the diguanides. It, for me it was a very amazing drug. I'm very much in favor of the medicine. I would use the medicine. I thank God that it can't happen to me, but if I was a gestational diabetic I would use the medicine. By gestational I mean a woman who may be requires insulin during her pregnancy and then became normal, I would use it. I think it's very interesting to consider the medication for a brand new Type I and I think for a lot of Type II's . . . for almost all Type II's, certainly someone who is new onset too or been diagnosed new onset. Medication would be very, very beneficial. It's disadvantage is that it has to be given by injection. It's advantage is it is the only diabetes medicine that has been shown to have weight loss associated with it. Glucophage or metformin may cause weight loss but it doesn't have to. But with Byetta you will lose weight. That's the big problem that we have with some of our diabetics especially Type II's. All diabetics who are poorly controlled gain weight. Type II's notoriously will gain weight and have a very hard time losing weight. I've had a few patients come and want Byetta who are not diabetics. They want it for weight loss. It's indicated. I didn't do it but this is amazing medicine. It's the first really new medicine we have had out since glucophage and glucophage wasn't really that new. If you go back, metformin was certainly same class drugs and glucophage has been on the European market for years. This is the first brand new diabetic drug. I think there is a great potential, great potential that will prevent long term complication of diabetes, possibly, and this is my opinion as a private practitioner, that it will, it has the potential of preventing diabetes. Taking diabetes which is a relenting disorder and stopping it and perhaps even reversing it. (unintelligible) I should say one other thing, too. I realize this is for the Medicaid. I think I am the only endocrinologist in this State, but certainly in Oklahoma City, that sees Medicaid patients other than the University. I'm the only one in private practice. I could be wrong, but I know that there are six that do not, I don't know about two. That's about it. This is a medicine I really like to use on these patients, really do like to use.*

Dr. Whitsett.: *The weight loss . . . I assume that's a healthy form of weight loss? Some forms of weight loss are not so healthy.*

Dr. Davis: *This is not a great weight loss. You're not going to say that somebody's losing thirty pounds and everything. They don't lose it immediately. It seems to be a progressive weight loss. In other words they will lose weight and they continue to lose weight. The studies that I've seen have gone well over a year and they've continued to lose weight and most of them are talking around ten pounds.*

Dr. Whitsett.: *Without treating a malabsorption or interfering with vitamin absorption...does it effect satiety or how does it seem to be doing that?*

Dr. Davis: *I don't know that that's fully known but it impairs gastric emptying and people feel, they eat less and they feel full. If they eat what they normally do they will often become nauseated as we all will when we overeat. And so they eat less and they lose weight. That's probably how it works. A number of doctors have recommended that it be used before eating so that the patient, and the patient eats slower so they get that feeling. They don't get overly full quick.*

Dr. Whitsett: *Is there an issue with patients who have gastroparesis since you mentioned gastric emptying?*

Dr. Davis: *That I'm not aware of. I do not know. I'm not, I wouldn't (unintelligible) into that. (unintelligible)*

Dr. Whitsett: *Patients who are thin that are diabetic, do they lose weight also, or not necessarily?*

Dr. Davis: *They will, not necessarily will they lose weight. They can, but not necessarily. Most, as I said, every diabetic, Type I, the very thin people gain weight if they have control. This allows less insulin, less sulfonylurea and that is the one thing that if a patient is well controlled and Byetta is started, you must cut the sulfonylurea out at least 50%, some people say 60%, 70% came back. You must cut back insulin. You do not have to cut back glitazone. You do not have to cut back metformin. If they are like most of my patients, poorly controlled, I don't know that it matters because (unintelligible) and my limited experience with Byetta, it's been amazing. I've had some patients come back within a month, they're getting much better control than they've ever gotten before.*

Dr. Whitsett: *Is an issue often in inpatients, diabetics come in and they're out of control and they're sick in two or three other ways, and one wants to optimize control is it the onset of action substative would be efficacious in that setting or is it something that needs to be given for an extended period of time to accrue a benefit?*

Dr. Davis: *Weight loss? Extended period of time. But for diabetic control it could be very quickly. However I will tell you, I wouldn't necessarily use Byetta if, for somebody who was acutely ill I would use insulin. I would slowly get them controlled and then when they go out, Byetta, I'll tell you, when you tell anybody, it's a very hard sell. To get somebody to use insulin. You tell them that they'll lose weight, that puts it right up there (unintelligible) but if you tell them they can get better control and there is a potential of using less medicines they get much more excited. And maybe I haven't had the problem because I'm so excited about the medication. I really am very excited.*

Dr. Hollen: *Dr. Davis, one quick question. Can you comment on the College of Pharmacy recommendations?*

Dr. Davis: *Well since I don't know . . . oh, these? I was just handed these when I was walking up, so I don't know. I would have to . . .*

Dr. Whitsett: *You may want to study those for a minute and then we'll give you a chance to make any comment on that after a bit.*

For Public Comment, Dr. Rosalind Faburni: *Good evening. My name is Rosalind Faburni. I'm here representing Amylin Pharmaceuticals. The next couple of minutes, I would like to highlight the current therapies for Type II diabetes, while helpful still are unable to get patients to agreed upon target goal, and talk about Byetta just as Dr. Davis had previously mentioned which is a first, is a unique first in class therapy approved for the treatment of Type II diabetes. It's effective. It has a favorable safety profile. It's easy to use and doesn't require intensive medical resources such as specialists. As you know, the complications of diabetes can be fatal, resulting in stroke, heart attacks or severely debilitating consequences requiring dialysis or leading to blindness or limb loss. All of these outcomes result in costs far and away the cost of therapy. To date, therapies for Type II diabetes have focused on utilizing insulin, insulin analogs or insulin secretagogues, such as sulfonylureas and agglutinates. By focusing on glucose uptake by peripheral tissues (unintelligible) insulin resistance like TZDs or hepatic glucose output, like metfomrin. As the disease progresses, more of these agents are required and thus more clinical expertise and resources are needed to manage these patients. On the patient side, increased therapies usually result in seemingly uncontrollable weight gain. This weight gain combined with the confusion of polypharmacy result in non-compliance and thus even more loss of control. Byetta as I mentioned earlier, is a new treatment alternative for patients with Type II diabetes. It's indicated for those who have failed metformin, sulfonylureas or a combination of both. It's the first entry into this new class of diabetes therapies the incretin mimetcs. It has similar glucoregulatory effects to the naturally occurring incretin hormone, GLP-1, which is in known diabetics, GLP-1 can help to restore balance between insulin supply and insulin amount. Byetta like GLP-1 the incretin hormone causes glucose to dependent insulin secretion, suppresses the inappropriate mealtime glucogan, slows gastric emptying and reduces caloric intake. These multiple effects of Byetta offer a unique treatment option by healthcare providers managing patients with Type II diabetes. The results of the Phase 3 30-week double blinded placebo clinical trials in 1400 patients failing metformin, sulfonylureas or a combination of both showed that in these patients treated with exenatide of highest dose experienced an average HBA1C drop of 1% and a weight loss. Just to get to some of the questions answered earlier of at least 3.5 pounds in 30 weeks. And 40% of patients received an HBA1C of 7% which as you know is a recommended goal for ADA. In the open label extension trial, the patients were able to attain the reduction in HBA1C up to a 1.2% and they continued to lose weight. Again, addressing some of the questions earlier on. With an average weight loss of 10-12 pounds. And they also demonstrated an improvement by 82 weeks in the cardiovascular risk profile with reductions in triglyerides, blood pressure, as well as increased HDL, the good cholesterol. Byetta comes in a fixed dose pen. It's injected twice a day before meals. Doesn't require any weight or meal dose adjustments. And diabetes expertise is not necessarily required to manage the use of (unintelligible). We would like the Board to consider open availability of Byetta for Medicaid for providers and patients. Thank you very much.*

Dr. Nesser: *Have you looked at our recommendations? They basically follow your package insert. They do require previous treatment with sulfonylurea or metformin for Type II who have not achieved control. We do think this is a very important new drug but we also want it to be used appropriately. Do you have any concerns with a program, a step-therapy program that would allow clients who have been on these two drugs as indicated by the FDA, as approved by the FDA, to move on to Byetta?*

Dr. Faburni: *As I can answer this question, we do not have any concerns. I think Dr. Davis wants to address this (unintelligible).*

Dr. Davis: *There are a number of things. I've looked at the recommendations. Try to answer your question, I really feel Byetta could be a first line drug and I think it can be combined and I would, depending on what I'm dealing with in a given patient, start it right away. Prior authorization of Byetta I don't think is necessary and considering that the majority of the diabetics are seen by non-endocrinologists, matter of fact they're seeing a very small number of diabetic population. I really think that would impair the ability to use the drug. I have some real problems with your patients have Type II diabetes and metformin have not achieved glycemic control. If the hemoglobin A was greater than 7 I agree with that. However some people say 6-5. The American, the American College of Clinical Endocrinology, the European Diabetes Association, all make it 6-5. And I think that you should talk with any, any endocrinologist who does with, deals with diabetes will tell you we'd like to get as low as we can. If we can get it to 6, then we get it to 6. If the patient will tolerate the medication. I'm not sure what you mean by this "clients who have not been on sulfonylurea or metformin for 90 days". I don't understand that at all.*

Dr. Nesser: *Well that, we're just trying to make sure that because of the way that the FDA has approved the drug which is how Medicaid is instructed to cover drugs, is in accordance with FDA or with studies. If you haven't taken metformin, how can you*

say that you failed metformin? And if you haven't taken it for at least 90 days, you can't see a significant change in A1C in less than 90 days. You can't see a meaningful change in the A1C.

Dr. Davis: *Well you can. It depends on what the AIC is and how they respond to the medication, but I agree. (unintelligible)*

Dr. Nesser: *Right. So, I mean while you, while you may feel like you could use it first line, in accordance with the directions we have under Federal law, that is outside the guidance. However, as an endocrinologist, we would give you that exception. The, the clients who are treated by family practitioners or non-specialists who have been on a sulfonylurea or metformin or both, they don't have to go to an endocrinologist to get the Byetta. Their other practioner can write it. That's not, I mean the endocrinologist is a separate exception. So I just want to make sure all that's clear.*

Dr. Davis: *And again, I'm getting my (unintelligible) but the control of diabetes in this State stinks. Since the majority of patients are being seen by primary, I don't wish to get myself into trouble but I'm seeing once a day insulin all the time. I'm seeing people all the time that have their blood sugars over 200 which is acceptable. And unhappily I also see the patients at the end stage of their diabetes and I am getting on my high horse. I've heard the AIDS advocates get oh this terrible disease. You watch somebody die from problems of diabetes and I'll take anything . . .*

Dr. Nesser: *We agree that we need . . .*

Dr. Davis: *I want, I want good control. I think Byetta would do it. And with less medication. With potential. And that's the thing that hurts me so much. The potential is really unbelievable.*

Dr. Whitsett: *I agree. How long has it been out? Okay. And roughly what is the cost I don't know if anyone has talked about that.*

Dr. Nesser: *It's a little higher than like say Actos or Avandia, but it's in the neighborhood. A little less than $200 a month.*

Dr. Whitsett: *And it comes in two different sizes . . . a 5 mcg, a 10 . . . are those comparable costs or . . .?*

Dr. Nesser: *I think it's a flat price. Yeah, it's for either strength, same price.*

Dr. Meece: *So if they've been on metformin for 90 days, there's no . . .*

Dr. Nesser: *For at least yeah, for at least 3 months.*

Dr. Meece: *So there's no PA.*

Dr. Nesser: *There's no PA. It would be in the step-therapy.*

Dr. Davis: *Please don't restrict yourself to (unintelligible). That's what ideally everybody should be doing (unintelligible).*

Dr. Joni Beck spoke and responded to Board members' questions regarding use, dose and other issues of Byetta.

Dr. Davis: *Could I just add one thing (unintelligible) remember that diabetes is a progressive disease. All diabetics if they live long enough, you know, it's every single one it's been shown by the great study done in Great Britain over 20 years which they show hemoglobin A1C and their beta-cell was continually declining over all that period of time, and I think, I really believe, I'm very passionate on this and since I don't have to worry about the FDA and all that kind of stuff (unintelligible) this is one thing I think is going to be a whole (unintelligible) taking a shot. Believe me at least in my hands I don't have any problems getting a patient to take a shot. And if anybody's ever taken a shot which I have, those needles are so small you don't feel them. Most diabetics are going to have to stick themselves two or three times a day and here at least a medicine that has the potential of reversing the problem in a medicine that has the potential, well not the potential, it won't make them go hyperglycemic. So I again . . .*

Dr. Faburni: *Just one quick point of clarification about the monotherapy. It's just to clarify that the FDA did give Amylin a approvable letter(unintelligible) to the on-going studies that we're doing (unintelligible).*

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

Motion made by Dr. McNeill to approve COP recommendations (HbA1C $\geq$ 6.5); second by Dr. Meece.

ACTION: MOTION CARRIED.

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

For Public Comment, Dr. Ray Cornelison: *Dr. Whitsett, I really don't have any prepared remarks. I think we have agreement between College of Pharmacy and when we met with them and I'm fully supportive of their recommendations. I'd be glad to answer any questions.*

Dr. McNeill: *In looking at the prior authorization criteria – do you have a copy of it? – there's a distinction between 30 grams on use of the face, neck and groin, and 100 grams on all other areas. I don't understand how we're going to make that distinction. So is there a workable solution between the pharmacy end and . . .*

Dr. Nesser: *I think that would just be after a PA is requested. Like, in other words, the first 90 days, whatever, whatever the quantity is, the quantity is. But after that, when, if the PA needs to be requested then we would find out where it is and that would be the amount.*

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

Dr. Meece moved to approve COP recommendations as submitted; seconded by Dr. Hrdlicka.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE REVATIO®

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

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE FENOFIBRATES**
Materials included in agenda packet; presented by Dr. Le.
Dr. McNeill moved to approve COP recommendations as submitted; seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE FOCALIN XR™**
Materials included in agenda packet; presented by Dr. Gorman.
Dr. Meece moved to approve COP recommendations as submitted; seconded by Dr. McNeill.
ACTION: MOTION CARRIED.

********** BREAK IN TAPE **********

AGENDA ITEM NO. 10: **NEW PRODUCT REVIEWS AND NOTICES**
10A: 30-Day Notice to Prior Authorize Rozerem®
For Public Comment, Dr. Daniel E. Garcia: (transcription begins after tape is restarted) *Rozerem has a unique mechanism of action citing the underlying pathophysiology of the sleep/wake cycle. Rozerem is not a benzodiazepine receptor agonist and as such does not suppress the central nervous system. Slide 2. Instead Rozerem works as a neurotonin MT-1 and MT-2 receptor agonists. The MT-1 receptor is believed to be responsible for the feeling of sleepiness, while the MT-2 receptor is believed to be responsible for the body adjusting to day and night, so the Circadian rhythm. Rozerem has negligible effect on other neurotransmitters. Rozerem differs from melatonin in its' chemical structure, selectivity, metabolism, affinity and its' proven efficacy and safety profile. Melatonin cannot make these claims. Matter of fact, if you look at the NIH consensus report, they said melatonin is not efficacious in producing sleep. Rozerem has been shown to be considerably consistently safe and efficacious in reduction of sleep latency and to increase total sleep time across both adult and elderly patients in both transient and chronic insomnia populations. The efficacy of Rozerem is supported by five Phase III randomized, double-blind, placebo controlled, multicentered clinical trials in over 2,400 subjects with transient or chronic insomnia.Rozerem has been evaluated for abuse liability and potential for dependence. You'll look at slide 3, 4 and 5, you will see Dr. Roland Griffith's studies at the Johns Hopkins University. He uses doses that are extremely high and with Rozerem he used 20 times the recommended dose, or a 160 mg. And what he showed was Rozerem had no abuse potential, no effect on cognitive performance and no effect on behavioral performance. In addition, there is no clinically meaningful difference versus placebo on standard measures of next day residual effects including psychomotor impairment, memory impairment, change in mood, or ability to concentrate, and memory and word recall tests. There have been no evidence of rebound or withdrawal symptoms upon discontinuation of Rozerem. Results of these studies led the FDA to classify Rozerem as the only non-scheduled treatment for insomnia and Rozerem is approved for longterm use. Safety assessment was based on exposure to Rozerem in 4,251 subjects including an open label trial in which nearly 600 subjects were exposed for six months or longer and more than 470 subjects received Rozerem for a year. The cytochrome 1A2 is a major isoenzyme that's involved in metabolism of Rozerem. If you'll look at slide 6 and 7, you'll see the drug interactions. Drug interactions because it's a 1A2 were studied with fluvoxamine, a known very strong 1A2 inhibitor. It did increase Rozerem levels, although there was no clinical correlate. Rozerem should not be used in combination with fluvoxamine. There is no appreciable interaction with fluoxetine or Prozac, so it's not a class effect.*
Dr. Whitsett: *And the reason it should not be coadministered is . . .*
Dr. Garcia: *Because you get increased levels of. . .*
Dr. Whitsett: *But you said your doses that were many times higher . . . didn't make any difference.*
Dr. Garcia: *Well we had to say that because that's what the FDA has in the package insert. So Rozerem should be used with caution in patients taking strong . . . or less strong 1A2 inhibitors. There's no dosage adjustment is necessary based on age, renal impairment including hemodialysis, mild to moderate COPD, or sleep apnea and mild hepatic impairment. Rozerem should be used with caution in patients with moderate panic impairment as measured by the Child-Pugh scoring system, which measures cirrhosis. Rozerem has a clean adverse event profile with no significant difference to placebo. You will see that in slide 8, the adverse event profile. The most common side effect reported with Rozerem includes headache, dizziness, somnolence and fatigue. Please refer to the package insert for additional dosing and safety information. My last slide – in conclusion Rozerem has a unique mechanism of action based on normal sleep physiology, but does not suppress the central nervous system. It is not a controlled substance and therefore abuse liability is minimal if not at all. It has minimal side effects and long term use is allowed. Thank you for considering Rozerem for inclusion in the Oklahoma State Medicaid program.*
Dr. Whitsett: *I don't think you mentioned about sleep onset, latency and what happens with REM sleep and slow wave sleep.*
Dr. Garcia: *There is no change in sleep architecture.*
Dr. Rhymer: *Are the patients like groggy the next morning, are they having trouble waking up?*
Dr. Garcia: *They do not. That was shown time after time. Digital substitution tests were done, word recall where you're given a list of words and then there is a time period where you wait and then you try to recall them. Balance tests, all those were negative with Rozerem.*
Dr. Whitsett: *How long has it been out?*
Dr. Garcia: *It was approved in July 22nd of this year. We've seen some prescriptions written for it . . . very few because it really has not been promoted at this time.*
Dr. Whitsett: *Has it been out in other countries?*

Dr. Garcia: *No it has not. The United States is the first country to have approval for Ramelteon.*
Dr. Whitsett: *And it is not just for short term?*
Dr. Garcia: *It is allowed for long term use. There is no restriction on its use and that's the way all hypnotics . . . the first hypnotics of the non-benzos had a specific restriction. Some of the newer ones don't have that restriction. We don't have that restriction.*
Dr. Whitsett: *And the dosage you said . . .*
Dr. Garcia: *Eight milligrams for everyone.*
Dr. Whitsett: *Everyone. What a deal. Okay. Any other questions?*
Dr. Garcia: *I have a question. On the recommendations for this product, it says "should not be approved in conjunction with QID benzodiazepines.. I really don't understand this.*
Dr. McNeill: *Same question I have, so . . .*
Dr. Garcia: *Okay, well maybe pharmacy can answer. Does anyone else have any questions? Okay, thank you.*
Materials included in agenda packet; presented by Dr. Browning.

10B: 30-Day Notice to Prior Authorize Ambien CR™
Materials included in agenda packet; presented by Dr. Gorman.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: ANNUAL REVIEW OF HMG-CoA REDUCTASE INHIBITORS
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: REVIEW AND DISCUSS TREATMENT OF HEAD LICE
Materials included in agenda packet; presented by Dr. Patel.
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: Neurontin® Review
14C: Asthma Utilization Review
14D: Muscle Relaxant Review
14E: Osteoporosis Review
14F: Annual Reviews
14G: New Product Reviews
- **Xopenex HFA™**
- **Balacet 325™**
- **Darvocet A500™**
- **Flexeril® 5 mg**

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: September 22, 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 September 14, 2005.

Recommendation 1: Vote to Prior Authorize Byetta®

MOTION CARRIED by majority approval.

- 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 ≥ ~~7.0~~ 6.5)
- 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

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

MOTION CARRIED by unanimous approval.

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 (regardless of age);
  - prescription by allergist or dermatologist regardless of age.

Recommendation 3: Vote on to Prior Authorize Revatio®

MOTION CARRIED by unanimous approval.

- **Diagnosis:**
  - Diagnosis and medical supervision by a pulmonary specialist and/or cardiologist.
  - Pulmonary Arterial Hypertension (early stage; NYHA Class II)

- **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.)

Recommendation 4: Annual Review of Fenofibrates

MOTION CARRIED by unanimous 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 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® 67mg Caps	Tricor® 48mg Tabs
Lofibra® 134mg Caps	Tricor® 145mg Tabs
Lofibra® 200mg Caps	Antara® 43mg Caps
Gefibrozil 600mg Tabs	Antara® 87mg Caps
Clofibrate 500mg Caps	Antara® 130mg Caps
	Triglide® 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.

Recommendation 5: Vote to Prior Authorize of Focalin™ XR

MOTION CARRIED by majority approval.

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.

Recommendation 6: Annual Review of HMG-CoA Reductase Inhibitors

No action required.

Laureate
Psychiatric Clinic and Hospital

6655 South Yale Avenue
Tulsa, OK 74136-3329
918.481.4000
918.481.4063 fax

www.laureate.com

Saint Francis Health System
Founded by The William K. Warren Foundation

Sept. 28, 2005

COPY

Nancy Nesser, D. Ph.., J.D.
Director, Pharmacy Services
Oklahoma Health Care Authority
4545 N. Lincoln Blvd., Ste. 124
Oklahoma City, OK 73105

Dear Dr. Nesser:

The purpose of this correspondence is to express my concerns over new quantity limitations on Medicaid patient medications. Patients are being unduly and unfairly penalized for needing higher doses of psychotropic medications. A large percentage of my adult population have treatment resistant depression requiring higher doses of medications and sometimes multiple medications. For example: requiring patients to use two (2) "punches" for Effexor XR 225 mg., you are unduly penalizing them for their chronic mental illness. Most of these patients require other medications and there are times where they have to make a decision to get their medications for their medical condition vs medications for their psychiatric condition. The doses of these medications are not outside the guidelines of the FDA; however, there are times that it requires more than one pill to reach the appropriate dose. I can think of no reason why this patient population should be held to a standard that is not congruent with appropriate medical practice and feel that this is a violation of their rights under the "American Disabilities Act".

If I can be of further help or respond to any specific questions, please do not hesitate to contact me at 918-491-3700.

Sincerely,

Jimmie D. McAdams, D.O.
Psychiatrist

JDM/acg

Laureate
Psychiatric Clinic and Hospital

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Sincerely,

Peter A. Rao, M.D.
Psychiatrist

PAR/acg

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Sincerely,

Stephanie Forbes D.O.

Stephanie Forbes, D.O.
Psychiatrist

SF/aeg

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Sincerely,

Tammie Saffa, PA-C

TS/acg

PARKSIDE

Behavioral Health Services & Hospital

October 3, 2005

Ronald Graham, D. Ph.
Clinical Assistant Professor
Pharmacy Director
Pharmacy Management Consultants
University of Oklahoma, College of Pharmacy

Dear Dr. Graham:

The contents of this letter is requested to be addressed at the October 12th DUR meeting.

The purpose of this correspondence is to express my concerns over new quantity limitations on Medicaid patient medications. Patients are being unduly and unfairly penalized for needing higher doses of psychotropic medications. A large percentage of my adult population have treatment resistant depression requiring higher doses of medications and sometimes multiple medications. For example, to require patients to use two (2) "punches" for Effexor XR 225mg you are unduly penalizing them for their chronic mental illness. Most of these patients require other medications and there are times where they have to make a decision to get their medications for their medical condition vs. medications for their psychiatric condition. The doses of these medications are not outside the guidelines of the FDA; however, there are times that it requires more than one pill to reach the appropriate dose. I can think of no reason why this patient population should be held to a standard that is not congruent with appropriate medical practice and feel that this is a violation of their rights under the "American Disabilities Act."

If I can be of further help or respond to any specific questions, please do not hesitate to contact me at 918-582-2131.

Sincerely,

Joe Piccione
Physician Assistant
Parkside Psychiatric Hospital and Facility

PARKSIDE

Behavioral Health Services & Hospital

October 3, 2005

Ronald Graham, D. Ph.
Clinical Assistant Professor
Pharmacy Director
Pharmacy Management Consultants
University of Oklahoma, College of Pharmacy

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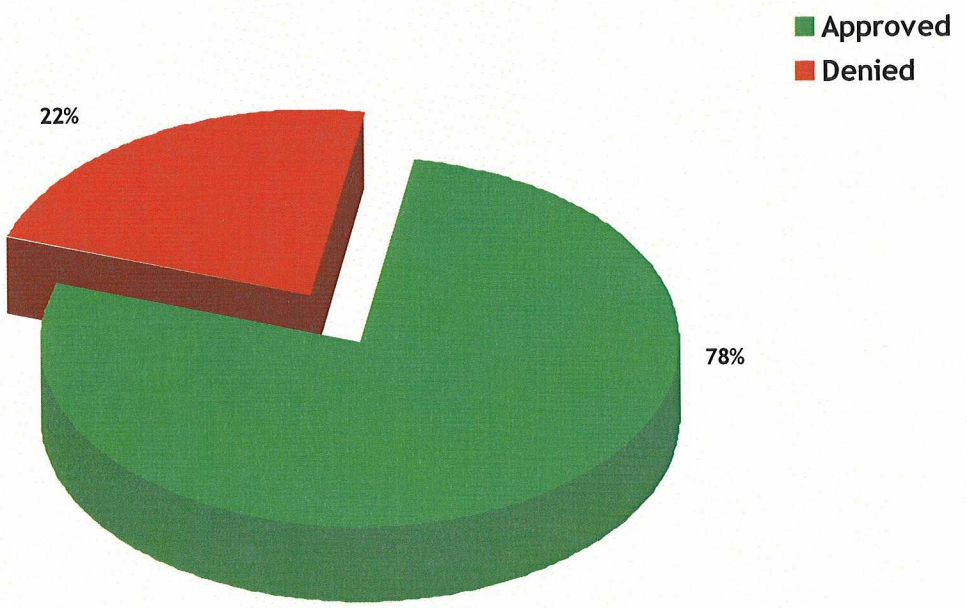
Sincerely,

John White, MD
Psychiatrist
Parkside Psychiatric Hospital and Facility

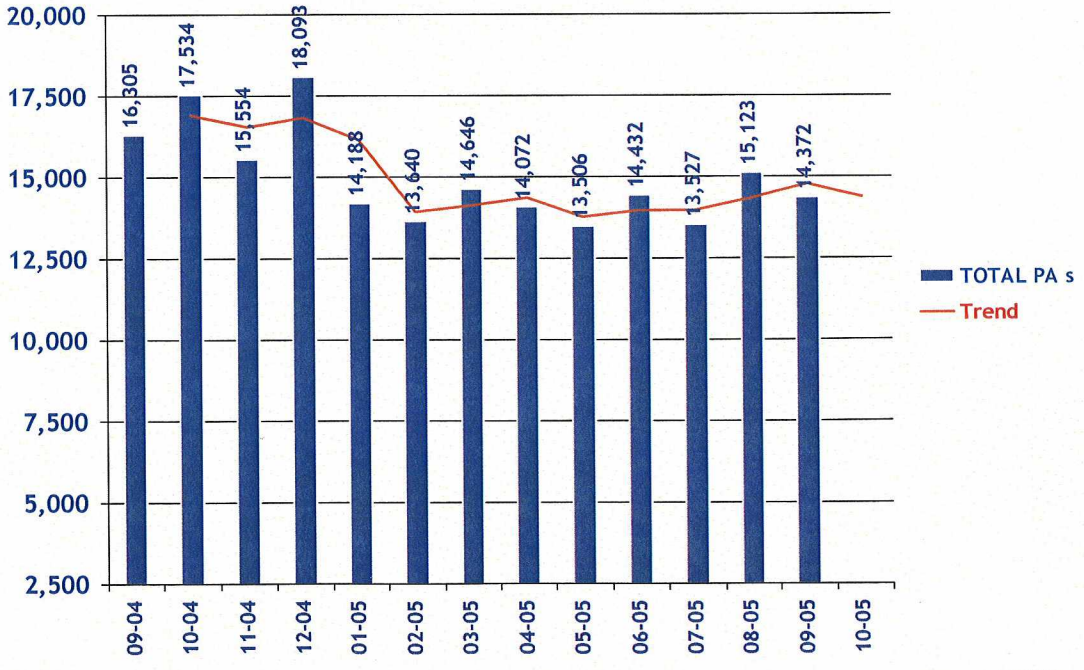
APPENDIX B

PRIOR AUTHORIZATION ACTIVITY REPORT
September 2005



PHARMACY Management consultants

PRIOR AUTHORIZATION REPORT
September 2004 - September 2005



PHARMACY Management consultants

Activity Audit for

September 01 2005 Through September 30 2005

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
App.	16		2986		1226		22		1137		168		47		10		91		628		40		361		
Den.		5		298		531		1		309		204		38		0		169		63		14		187	
Average Length of Approvals in Days	12		107		105		170		224		248		94		102		250		342		159		166		

Changes to existing PA's	1014
Total (Previous Year)	16305

*** Denial Codes**

762 = Lack of clinical information	7.14%
763 = Medication not eligible	5.92%
764 = Existing PA	3.51%
772 = Not qualified for requested Tier	7.38%
773 = Requested override not approved	18.67%

SUPER PA's

Admitted to Nursing Home	156
Early Refill Attempts	48761
Dosing Change	618
High Dose	63
Lost/Broken Rx	154
Stolen	19
Other	83
Wrong D.S. on Previous Rx	23
Quantity vs. Days Supply	2330
Brand	262
-- Approved	85
-- Denied	67

Monthly Totals

	Number	Percent of Total
Approved	8739	60.81%
Additional PA's	36	0.25%
Emergency PA's	8	0.06%
Duplicates	792	5.51%
Incompletes	2263	15.75%
Denied *	2534	17.63%
Total	14372	100.00%

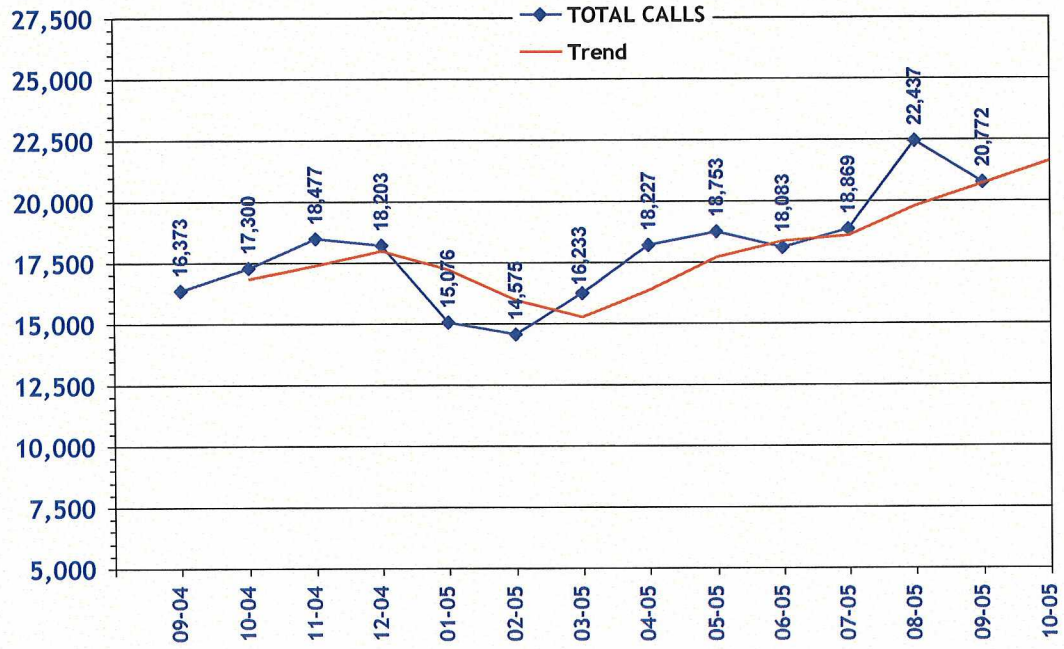
Daily Average of 684.38 for 21 Days

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
September 2004 - September 2005



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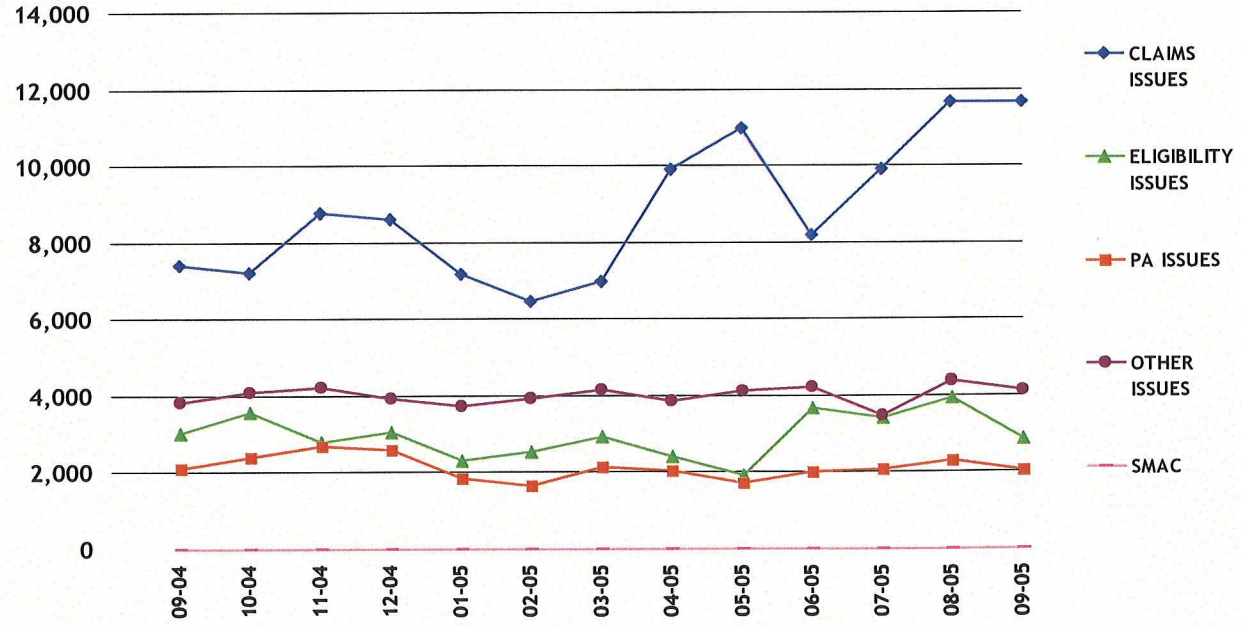
CALL VOLUME ISSUES
September 2004 - September 2005



PHARMACY Management Consultants

APPENDIX C

Vote to Prior Authorize Rozerem™ (ramelteon)

Oklahoma Medicaid
October 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

The College of Pharmacy has the following recommendation:

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

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.

APPENDIX D

Vote to Prior Authorize Ambien CR™ (zolpidem tartrate extended release)

Oklahoma Medicaid
October 2005

Manufacturer	Sanofi-Aventis
Classification	Nonbenzodiazepine Hypnotic 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. Currently, both strengths of the new formulation are flat priced at the same rate as the original 10 mg tablet.

Recommendation

The College of Pharmacy has the following recommendation:

- Require prior authorization for Ambien CR™ from first date of use. Must have documented reason for use of this product over the immediate release zopidem.
- 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.

APPENDIX E

Claim Utilization for Non-Dual Clients for Calendar Year 2004

Oklahoma Medicaid
October 2005

Background

On January 1, 2006 the new Medicare Part D Prescription Drug Program will begin. All Oklahoma Medicaid eligible clients who are also eligible for Medicare will no longer receive their primary pharmacy benefit through Oklahoma Medicaid. Estimates show that the percent of clients during calendar year 2004 who were considered Dual Eligibles (eligible for both Medicaid and Medicare) was 13.1 % of the Oklahoma Medicaid population. This 13.1 % of the population accounted for approximately 48.9 % of the costs to the Oklahoma Medicaid Pharmacy Program.

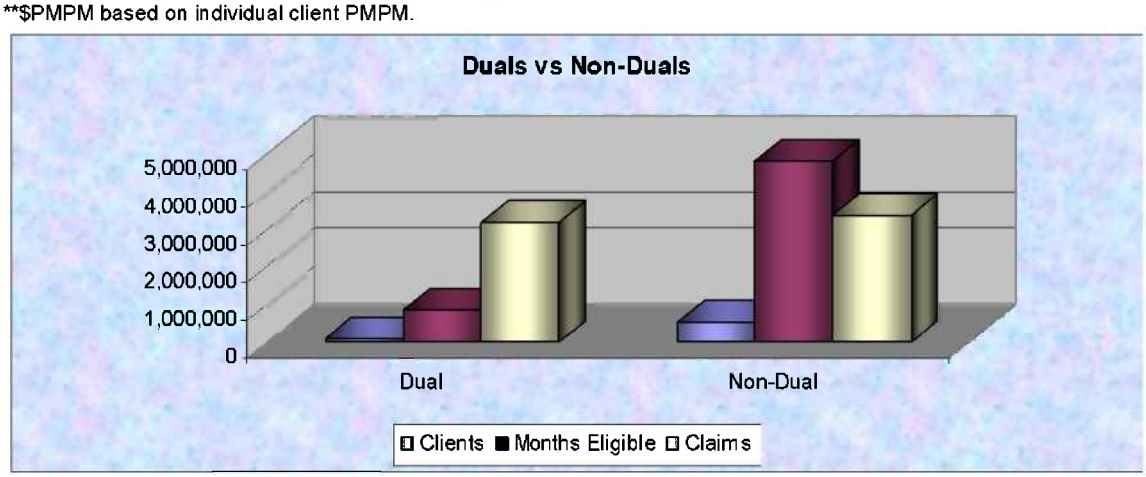
The purpose of this report is to review the utilization patterns of the remaining 86.9 % of the Oklahoma Medicaid population to assist in determining the future direction of the pharmacy program. Oklahoma Health Care Authority eligibility files were reviewed for Calendar Year 2004 to determine clients who were eligible for Medicaid pharmacy benefits. Clients who were not listed as eligible during the selected months or were eligible under a unique benefit plan were not included.

Utilization Overview

January 2004 through December 2004

Category	Clients	Months Eligible	Months/ Client	Claims	Total Paid*	$ PMPM**
Dual	80,979	854,422	10.55	3,186,968	$ 210,758,709	$ 244.95
Non-Dual	536,954	4,787,123	8.92	3,344,030	$ 220,306,969	$ 42.21
Total	**617,933**	**5,641,545**	**9.13**	**6,530,998**	**$ 431,065,678**	**$ 76.41**

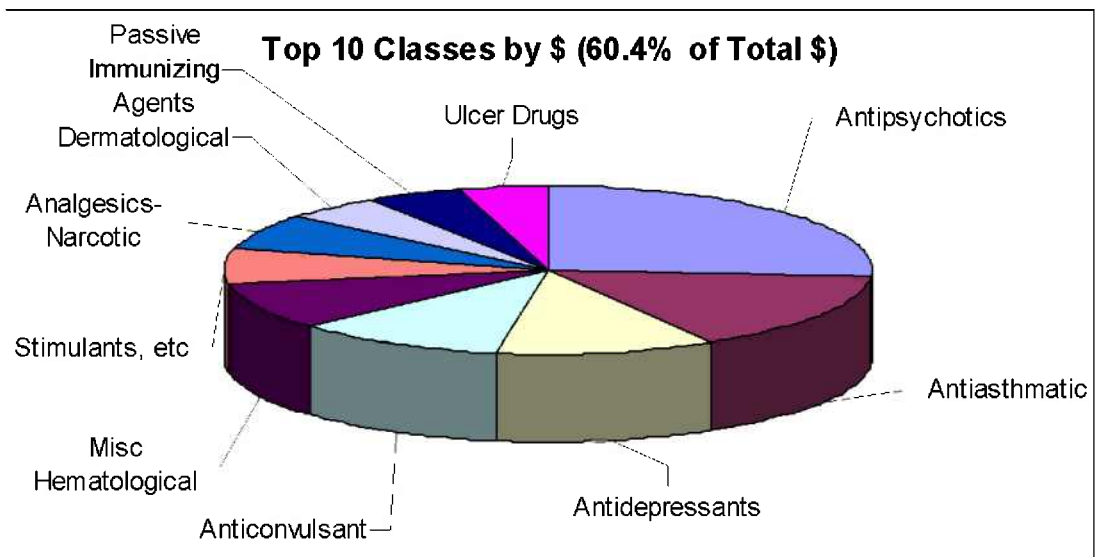
*Total Paid for all claims CY2004 was $435,577,476.09.
**$PMPM based on individual client PMPM.

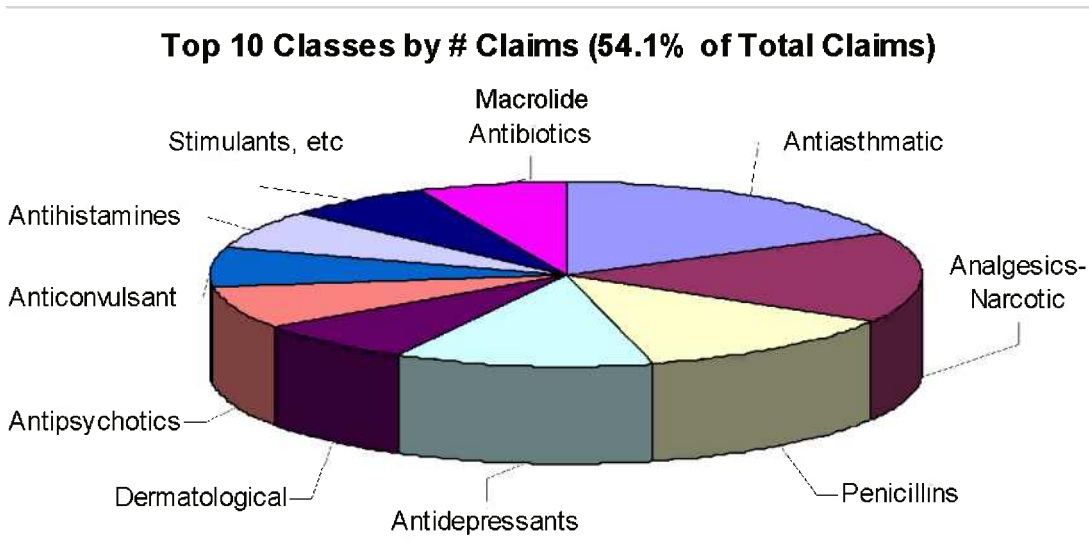


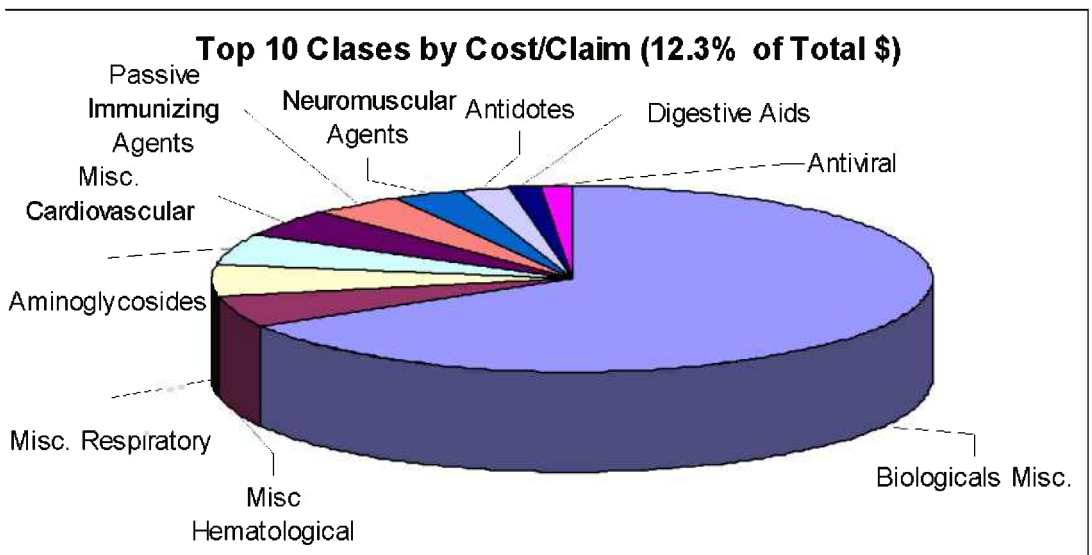
Non-Dual Clients by Age and Gender

Age	Gender	# Clients	PMPM $ Median	PMPM $ Mean	Months	Claims	Dollars	Age Group PMPM $
0-18	**Male**	212,303	$ 2.04	$ 30.89	1,950,359	874,418	$ 65,905,120	
	Female	204,481	$ 2.18	$ 20.74	1,873,225	771,141	$ 41,178,900	$ 28.01
19-20	**Male**	4,021	$ 0.59	$ 60.24	28,975	22,902	$ 2,317,315	
	Female	12,116	$ 11.66	$ 35.38	83,896	74,379	$ 3,311,291	$ 49.87
21-24	**Male**	1,839	$ 8.94	$ 142.04	17,826	23,029	$ 2,793,435	
	Female	21,612	$ 11.76	$ 33.93	151,803	136,912	$ 5,656,259	$ 49.81
25-34	**Male**	3,848	$ 12.01	$ 150.02	34,485	262,897	$ 5,946,374	
	Female	31,077	$ 12.66	$ 51.76	226,181	51,033	$ 13,209,699	$ 73.49
35-49	**Male**	6,543	$ 43.79	$ 195.52	60,751	130,330	$ 12,460,841	
	Female	20,097	$ 38.61	$ 132.86	170,749	373,738	$ 25,735,944	$ 165.00
50-64	**Male**	6,163	$ 96.30	$ 207.53	62,439	177,101	$ 13,175,780	
	Female	9,809	$ 146.02	$ 230.95	100,044	355,227	$ 23,896,842	$ 228.16
65-79	**Male**	671	$ 43.60	$ 141.14	6,025	14,772	$ 864,575	
	Female	1,210	$ 85.52	$ 172.40	11,209	35,442	$ 1,954,563	$ 163.58
80&>	**Male**	276	$ 119.45	$ 191.83	2,120	8,387	$ 420,825	
	Female	888	$ 156.65	$ 207.38	7,036	32,322	$ 1,479,207	$ 207.52
Overall		**536,954**			**4,787,123**	**3,344,030**	**$220,306,969**	**$ 46.02**

Review of Non-Dual Utilization Patterns







Therapeutic Classes in Multiple Lists

The following eight therapeutic classes were found in two of the previous top ten lists and account for 54.8 % of the total cost and 40.3 % of the total claims. (Note: by combining all anti-infectives into one class, the total paid was $24,839,375 which would rank it second by total paid.)

Class	Total Paid	Total Claims	Cost/Claim
Antipsychotics	$ 35,034,796	131,192	$ 267.05
Antiasthmatic	$ 20,285,216	314,086	$ 64.59
Antidepressants	$ 14,469,117	209,042	$ 69.22
Anticonvulsant	$ 13,867,098	126,801	$ 109.36
Misc Hematological	$ 12,218,806	7,842	$ 1,558.12
Stimulants, etc.	$ 9,194,176	118,592	$ 77.53
Analgesics-Narcotic	$ 9,013,719	284,653	$ 31.67
Dermatological	$ 6,559,438	135,656	$ 48.35

Therapy Management Issues for Non-Dual Category

A large portion of the established Therapy Management clients will transition to Medicare Part D. Since Therapy Management has been available only to clients in the Home and Community Based Waiver programs, it is important to know that there will be approximately 4,600 waiver clients in the non-dual population after December 31, 2005. This compares to about 15,000 currently. While many of these clients will still require therapy management services, this provides an opportunity for the program to focus on a new set of clients. Defining this new population set is still in development. Due to structural reorganization at OHCA, the pharmacy department will now be responsible for the Pharmacy Lock-In program. This group of about 500 clients will be transferred to Therapy Management in order to better monitor their drug utilization along with assuring access to care. Other ideas include focusing on those clients that are high utilizers of medical and pharmacy claims, those clients with disease states that respond well to disease state management and fit well with the pharmacy benefit, and perhaps clients that providers feel would benefit from a medication review.

Discussion

Medicaid is the safety net of the US Healthcare System, filling in the gaps for all plans both public and private. Even under tight and often outdated federal controls, Oklahoma Medicaid has managed to accomplish this task with great flexibility for both providers and clients. The national debate over changes to the Medicaid system continues, but there are only three few avenues for dealing with the rising costs to the system: cutting funding to providers, limiting eligibility, and reducing available benefits.

Ideally, changes to the Oklahoma Medicaid system would include an interdisciplinary team approach between areas of the healthcare system. Currently there is little incentive for the patients to be involved with the financial aspect of their healthcare once they become Medicaid eligible. Patients are free to use their benefit whenever they want, however they want. This pattern of health resource utilization often leads to suboptimal care for the patient. However, without changes to the overall program that include some aspect of patient responsibility, the focus for the future must continue to look towards traditional avenues of utilization management and cost containment.

The focus of the information provided here is on total dollars spent and number of clients. Issues of therapeutic misuse were not addressed but should certainly be part of the overall plan for the upcoming year. Further review of the data provided will be performed to determine potential problems or areas where containment measures might best be initiated.

Appendix

Table 1. *All Therapeutic Classes with Over $1 Million Paid for All Non-Duals*

Class	Total Paid	Total Claims	Cost/Claim
Antipsychotics	$ 35,034,796	131,192	$ 267.05
Antiasthmatic	$ 20,285,216	314,086	$ 64.59
Antidepressants	$ 14,469,117	209,042	$ 69.22
Anticonvulsant	$ 13,867,098	126,801	$ 109.36
Misc Hematological	$ 12,218,806	7,842	$ 1,558.12
Stimulants, etc.	$ 9,194,176	118,592	$ 77.53
Analgesics-Narcotic	$ 9,013,719	284,653	$ 31.67
Dermatological	$ 6,559,438	135,656	$ 48.35
Passive Immunizing Agents	$ 6,546,299	5,398	$ 1,212.73
Ulcer Drugs	$ 5,752,084	100,269	$ 57.37
Misc. Endocrine	$ 5,687,192	17,461	$ 325.71
Antidiabetic	$ 5,676,005	75,613	$ 75.07
Penicillins	$ 5,175,179	222,023	$ 23.31
Antiviral	$ 4,937,930	13,240	$ 372.96
Macrolide Antibiotics	$ 4,873,384	118,122	$ 41.26
Cephalosporins	$ 3,983,305	103,766	$ 38.39
Antihyperlipidemic	$ 3,879,746	30,237	$ 128.31
Analgesics- Anti-Inflammatory	$ 3,376,154	86,450	$ 39.05
Systemic and Topical Nasal Products	$ 3,122,766	46,268	$ 67.49
Contraceptives	$ 2,864,674	63,404	$ 45.18
Antihistamines	$ 2,720,569	122,495	$ 22.21
Antihypertensive	$ 2,212,189	87,866	$ 25.18
Misc Psychotherapeutic and Neurological Agents	$ 2,147,860	7,461	$ 287.88
Antineoplastics	$ 1,954,859	6,484	$ 301.49
Migraine Products	$ 1,844,347	12,228	$ 150.83
Ophthalmic	$ 1,585,660	45,578	$ 34.79
Antiemetics	$ 1,554,535	6,378	$ 243.73
Hematopoietic Agents	$ 1,531,163	4,993	$ 306.66
Misc. Anti-infectives	$ 1,527,081	54,071	$ 28.24
Musculoskeletal Therapy Agents	$ 1,480,420	59,425	$ 24.91
Unknown	$ 1,451,713	31,250	$ 46.46
Antifungals	$ 1,431,446	15,451	$ 92.64
Fluoroquinolones	$ 1,324,180	17,556	$ 75.43
Otic	$ 1,305,618	37,600	$ 34.72
Assorted Classes	$ 1,283,036	8,165	$ 157.14
Calcium Blockers	$ 1,229,342	21,301	$ 57.71
Anticoagulants	$ 1,199,059	9,680	$ 123.87
Aminoglycosides	$ 1,155,299	780	$ 1,481.15
Antianxiety Agents	$ 1,081,743	83,666	$ 12.93
Beta Blockers	$ 1,029,481	38,465	$ 26.76

APPENDIX F

Asthma Utilization (including inhaled corticosteroids)

July 2004 to June 2005

Oklahoma Medicaid
October 2005

NAEPP Asthma Guidelines

The guidelines were revised in July 2002. This revision made inhaled corticosteroids the preferred treatment for long-term control of all types of asthma, except for mild intermittent asthma. Bronchodilators, theophylline, and leukotriene agents are either adjunctive or alternate choices.

Utilization – July 2004 to June 2005

For the period of July 2004 to June 2005 a total of 104,627 clients received asthma medications through the Medicaid fee-for-service program. The chart below is a summary of the utilization. A detailed chart is at the end of this report.

Product	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Anticholinergics	17,483	1,516,780	472,704	$ 1,299,529.26	2.75
Anti-inflammatory Agents	1,574	161,878	42,621	$ 76,970.33	1.81
Sympathomimetics	298,569	21,177,946	6,972,471	$ 16,422,688.17	2.36
Xanthines	9,881	774,139	340,585	$ 224,376.59	0.66
Steroid Inhalants	43,848	1,717,376	1,249,309	$ 5,462,354.17	4.37
Leukotriene Modulators	109,560	3,359,602	3,313,389	$ 9,855,740.35	2.97
Asthma Combinations	251	51,532	2,702	$ 6,446.71	2.39
All Products	**481,166**	**28,759,253**	**12,393,781**	**$ 33,348,105.58**	**2.69**

	Fiscal Year 2004	*Fiscal Year 2005*	*Percent Change*	
Total Cost	$ 22,477,408.00	$ 33,348,105.58	Increased	48.6%
Total Claims	334,893	481,166	Increased	43.7%
Total Clients	81,690	104,627	Increased	28.0%
Per Diem	$ 2.64	$ 2.69	Increased	1.9%

Fiscal Year 2005

	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	19,109	120,651	7,552,502	3,248,441	$ 9,055,329.99	2.21
Non-Duals	85,518	360,515	21,206,751	9,145,340	$ 24,272,775.59	2.66

Claims were reviewed to determine the age of the clients.

All Clients		
Age	Female	Male
0 to 9	20,398	27,763
10 to 19	10,233	10,064
20 to 34	6,650	953
35 to 49	5,470	1,938
50 to 64	6,142	2,822
65 to 79	5,321	2,378
80 to 94	3,244	917
95 and over	290	44
Totals	**57,748**	**46,879**

Non-Dual Clients		
Age	Female	Male
0 to 9	20,395	27,762
10 to 19	10,229	10,058
20 to 34	6,214	626
35 to 49	3,982	955
50 to 64	3,216	1,513
65 to 79	217	118
80 to 94	150	62
95 and over	17	4
Totals	**44,420**	**41,098**

Non-Dual Cost Drivers and Possible Ways to Contain Cost

Singulair® – $7,935,562.39 or 32.7% of Market Share

At the May 2003 DUR Board Meeting, the Board voted on and approved a motion to require a prior authorization for Singulair® use in allergic rhinitis. Implementation of this PA was delayed due to the required steps needed for a rule change. The PA was slated to start 7/1/04 but the manufacturer signed a supplemental rebate.

Advair® – $4,978,527.30 or 20.5% of Market Share

	Flovent® HFA Cost/Inhal	Flovent® Diskus Cost/Inhal	Serevent® Diskus Cost/Inhal	Advair® Diskus Cost/Inhal
Fluticasone/Salmeterol 100-50 mcg	1 x 110mcg $0.06278	$0.98985	$1.64413	$2.04248
Fluticasone/Salmeterol 250/50 mcg	1 x 220mcg $0.09752	$1.37690	$1.64413	$2.58573
Fluticasone/Salmeterol 500/50 mcg	2 x 220mcg $0.19504	2 x 250mcg $2.75380	$1.64413	$3.57118

The use of the combination product, Advair®, is more cost effective than using the Flovent® and Serevent® Diskus together. However, the combination of Flovent® HFA and Serevent® Diskus is less expensive per inhalation than Advair® with a cost difference from approximately $0.34 to $1.73 per inhalation.

Requiring the use of Flovent® HFA/Serevent® Diskus instead of Advair® is one possible way to contain cost. Another possibility would be creating a PDL if future inhaled steroid/long-acting beta agonist products come to market.

Xopenex® (levalbuterol) - $1,939,144.94 or 8% of Market Share

Xopenex® nebs currently have a quantity limit of 288units/30 days supply in place. Last year prior authorization criteria for Xopenex® nebs was approved by the board requiring PA for those clients utilizing over 90 days of therapy in a floating 365 day period. Currently a metered dose HFA version of Xopenex® is planned for release around the first of the year. A quantity limit and possible PA will need to be evaluated for this formulation.

Disease Management

An additional cost strategy to optimize care would be to study the population group utilizing these medications and refer some of these clients into a disease or therapy management program. These clients could be screened for different variables such as high utilization of medical services (inpatient, emergency department, and physician visits) as well as over and under utilization of medications and physician specialty.

Recommendations

Asthma medications are a category that is often underutilized. While money spent in the pharmacy side of the cost equation may result in savings on the medical side, this should not preclude the exploration of measures to assist in containing both pharmacy and medical costs. The College of Pharmacy recommends that some or all of the suggested measures contained in this report be explored by the Board for future implementation.

Detailed Utilization for FY'05 for All Clients

	Total Claims	Total Units	Total Days	Clients	Total Paid
Anticholinergic					
Ipratropium Neb	6,925	1,218,527	147,167	2,486	$172,277.63
Ipratropium Powder	28	3,418	831	10	$17,769.53
Ipratropium MDI	4,103	76,539	114,612	1,265	$322,570.16
Spiriva Cap	6,427	218,296	210,094	2,259	$786,911.94
Anti-inflammatory Agents					
Cromolyn Nebs	927	153,028	24,590	453	$20,880.22
Intal MDI	601	7,894	16,886	290	$51,830.63
Tilade MDI	46	956	1,145	10	$4,259.48
Sympathomimetics					
Albuterol MDI	121,759	2,486,182	2,867,472	51,481	$1,298,674.24
Albuterol MDI Refill	8	187	238	5	$89.35
Albuterol Tab 2mg	558	43,725	15,042	183	$5,474.23
Albuterol Tab 4mg	992	78,159	30,214	258	$12,544.73
Albuterol Tab ER 4mg	1,426	95,752	47,023	316	$93,979.58
Albuterol Tab ER 8mg	317	24,168	11,743	51	$46,606.62
Albuterol Syrup 2mg/5ml	12,885	1,674,433	175,070	10,013	$86,199.47
Albuterol Neb 0.083%	38,472	7,015,888	643,862	19,415	$582,268.71
Albuterol Neb 0.5%	5,804	175,209	121,470	3,146	$53,856.89
Albuterol Neb 0.63mg/3ml	2,350	339,401	36,636	1,593	$179,921.26
Albuterol Neb 1.25mg/3ml	2,467	369,974	39,313	1,659	$194,454.91
Albuterol Powder	150	35,580	4,500	67	$14,247.80
Albuterol Aer HFA	2,937	28,488	70,357	1,407	$147,764.50
Formoterol Aer Cap	2,193	131,634	66,843	622	$194,761.54
Levalbuterol Neb 0.31mg	2,793	464,773	61,746	1,615	$395,270.13
Levalbuterol Neb 0.63mg	8,911	1,350,730	171,826	4,485	$1,137,701.01
Levalbuterol Neb 1.25mg	5,208	841,374	104,422	2,607	$700,606.38
Levalbuterol Conc Neb 1.25mg/0.5ml	6	384	125	6	$955.91
Metaproterenol Tab 10mg	22	3,069	671	2	$1,002.76
Metaproterenol Syrup 10mg/5ml	318	46,007	3,871	236	$2,464.54
Metaproterenol Neb 0.4%	16	3,088	288	7	$207.20
Metaproterenol Neb 0.6%	12	1,591	238	8	$200.50
Metaproterenol MDI	317	5,234	7,846	134	$12,526.24
Pirbuterol MDI	1,494	21,164	47,584	691	$129,874.67
Salmeterol MDI	32	614	953	21	$3,928.45
Salmeterol Diskus	3,082	190,802	88,091	898	$293,099.79
Terbutaline Tab 2.5mg	1,032	56,690	20,094	685	$25,074.18
Terbutaline Tab 5mg	831	46,034	17,710	523	$27,877.47
Terbutaline Inj 1mg/ml	27	1,670	517	7	$47,837.27
Terbutaline Powder	9	1,944	270	1	$5,032.44
Epinephrine Inj mg/ml	18	166	280	16	$146.85
Albuterol/Ipratropium Nebs	9,136	2,138,727	180,485	3,400	$1,358,562.11
Albuterol/Ipratropium MDI	21,947	446,911	593,595	6,313	$2,031,825.09
Fluticasone/Salmeterol Diskus 100-50	21,431	1,283,244	648,216	7,799	$2,551,935.73

Fluticasone/Salmeterol Diskus 250-50	23,167	1,388,610	699,408	7,590	$3,467,078.08
Fluticasone/Salmeterol Diskus 500-50	6,442	386,340	194,452	1,864	$1,317,643.54
Xanthine Bronchodilators					
Aminophylline Tab 100mg	3	150	74	1	$16.62
Aminophylline Tab 200mg	56	5,772	1,557	7	$429.73
Theophylline Cap CR 100mg	35	2,647	1,139	7	$1,220.21
Theophylline Cap CR 200mg	169	10,081	5,910	37	$6,731.43
Theophylline Cap CR 300mg	272	16,775	10,943	66	$13,541.55
Theophylline Cap ER 125mg	41	4,486	1,204	15	$1,384.41
Theophylline Cap ER 200mg	399	29,873	13,304	96	$10,730.94
Theophylline Cap ER 300mg	873	64,007	28,944	187	$25,527.84
Theophylline Cap ER 400mg	216	13,688	9,591	47	$14,903.34
Theophylline Elixir 80/15ml	49	35,988	720	19	$6,142.16
Theophylline Soln 80/15ml	1	225	20	1	$9.37
Theophylline Tab 125mg	7	510	150	2	$255.18
Theophylline Tab 250mg	1	90	90	1	$64.92
Theophylline Tab CR 100mg	68	6,792	2,053	21	$1,087.19
Theophylline Tab CR 200mg	1,444	110,704	47,445	343	$20,414.01
Theophylline Tab CR 300mg	2,599	197,628	89,637	527	$42,079.91
Theophylline Tab CR 400mg	203	11,252	7,535	49	$12,245.61
Theophylline Tab CR 600mg	75	4,346	3,756	22	$6,386.37
Theophylline Tab ER 100mg	81	6,216	2,608	23	$1,072.20
Theophylline Tab ER 200mg	1,056	82,314	34,601	244	$14,886.96
Theophylline Tab ER 300mg	1,963	151,560	68,728	423	$32,642.45
Theophylline Tab ER 400mg	108	7,275	4,625	36	$6,972.09
Theophylline Tab ER 450mg	80	6,470	3,351	16	$3,127.65
Theophylline Tab ER 600mg	34	1,170	1,080	13	$1,636.36
Theophylline Tab SR 300mg	2	200	100	1	$124.20
Theophylline Tab TD 200mg	35	2,780	1,090	5	$507.70
Theophylline Tab TD 300mg	11	1,140	330	2	$237.01
Steroid Inhalants					
Beclomethasone MDI 40mcg	1,022	7,736	25,216	502	$57,396.27
Beclomethasone MDI 42mcg	3	50	77	3	$125.10
Beclomethasone MDI 80mcg	633	5,090	16,155	252	$46,545.93
Beclomethasone MDI 84mcg	1	16	15	1	$51.08
Budesonide Neb 0.25mg/2ml	8,573	706,828	226,302	5,240	$1,596,404.83
Budesonide Neb 0.5mg/2ml	7,405	626,622	187,509	3,903	$1,468,835.42
Budesonide Inhaler	881	1,111	34,300	518	$132,948.18
Flunisolide MDI	986	8,819	25,247	379	$92,563.96
Flunisolide-M MDI	489	4,117	14,515	215	$41,537.11
Fluticasone MDI 44mcg	8,145	109,382	244,819	3,912	$544,119.62
Fluticasone MDI 110mcg	7,434	101,494	222,972	3,160	$659,284.13
Fluticasone MDI 220mcg	1,696	24,817	51,028	644	$241,959.29
Fluticasone Rotadisks 50mcg	153	9,301	4,280	68	$7,179.55
Fluticasone Rotadisks 100mcg	36	2,520	1,080	17	$2,627.78
Fluticasone Rotadisks 250mcg	3	300	90	2	$389.76
Fluticasone HFA 44mcg	1,689	18,810	49,112	1,294	$121,312.97

Fluticasone HFA 110mcg	1,236	15,028	36,707	955	$109,633.13
Fluticasone HFA 220mcg	240	3,108	7,057	174	$35,582.39
Triamcinolone MDI	3,213	72,227	102,828	1,335	$303,857.67
Leukotriene Modulators					
Montelukast Gran 4mg	2,772	83,474	85,827	1,442	$250,780.68
Montelukast Chew 4mg	23,327	699,147	702,798	7,886	$2,105,419.18
Montelukast Chew 5mg	34,232	1,035,711	1,033,434	10,313	$3,116,750.44
Montelukast Tab 10mg	47,141	1,421,883	1,427,650	12,333	$4,230,965.57
Zafirlukast Tab 10mg	64	3,420	1,875	14	$4,390.36
Zafirlukast Tab 20mg	2,024	115,967	61,805	319	$147,434.12
Asthma Combinations					
Guaifenesin/Dyphylline Cap 200-200	4	630	108	4	$350.18
Guaifenesin/Dyphylline Tab 200-200	44	3,816	1,179	20	$1,598.48
Guaifenesin/Dyphylline Tab 400-200	2	130	35	2	$70.45
Guaifenesin/Dyphylline Liq 300-300	25	4,650	181	24	$517.53
Guaifenesin/Dyphylline Elx 100-100	5	1,140	44	5	$49.22
Guaifenesin/Dyphylline Syr 50-100	165	34,950	1,055	129	$3,623.51
Theophylline/Guaifenesin Cap 150-90	1	60	30	1	$38.83
Theophylline/Guaifenesin Elx 150-90	5	6,156	70	1	$199.01

APPENDIX G

Prior Authorization Annual Review - Fiscal Year 2005

Non-Sedating Antihistamines (NSA)

Oklahoma Medicaid
October 2005

Current Definition of NSA Prior Authorization Category

- Legend non-sedating antihistamine only products are covered after a previous trial with an over-the-counter antihistamine. A 14 day trial of over-the-counter loratadine is required prior to coverage of a legend only product for all age groups.
    - Trial should have been in the last month and be of adequate dose and duration,
    - Over-the-counter loratadine is a covered benefit for clients under the age of 21 years without prior authorization, and
    - For clients 21 years of age or greater, loratadine is available with prior authorization AFTER documented over-the-counter failure of a non-loratadine product.
- For clients six months to two years of age, cetirizine syrup is available without prior authorization.
- Diagnosis must be for a chronic allergic condition.
- Clinical exceptions include asthma and COPD.
    - For diphenhydramine, exceptions are made for EPS and insomnia.
- Prior authorization is approved up to 90 days for non-chronic conditions, and may be approved for over 90 days for conditions which require continuous coverage throughout the year. (ie: asthma).

Utilization

For the period of July 2004 through June 2005, a total of 46,929 clients received non-sedating antihistamines products through the Medicaid fee-for-service program.

Product*		# of Claims	Total Units	Total Days	Units/Day	Total Cost	Per Diem
Rx	*Solid*	14,064	515,296	459,239	1.12	$ 991,175.59	2.16
	Liquid	14,859	1,841,631	418,357	4.40	$ 505,400.28	1.21
OTC	*Solid*	48,377	1,569,142	1,559,172	1.01	$ 854,254.86	0.55
	Liquid	31,164	4,200,779	812,765	5.17	$ 382,179.28	0.47
All Products		**108,464**	**8,126,848**	**3,249,533**		**$ 2,733,010.01**	**0.84**

*Does not include Singulair®.

Total Cost FY '05	**$ 2,733,010.01**
Total Cost FY '04	*$ 1,374,928.68*
Total Claims FY '05	**108,464**
Total Claims FY '04	*42,452*
Per Diem FY '05	**$ 0.84**
Per Diem FY '04	*$ 1.05*

Market share for select products.

Brand Name	Total Days/ Brand FY '05	% Share/ Brand FY '05	Total Days/ Brand FY '04	% Share/ Brand FY '04
Allegra	134,220	4.13%	90,962	6.97%
Clarinex	16,933	0.52%	9,914	0.75%
Zyrtec	726,443	22.36%	455,235	34.87%
Claritin (OTC)	2,371,937	72.99%	749,528	57.41%

Total petitions submitted for this category during FY05: 20,544.

Approved	*11,811*
Denied	6,734
Incomplete	1,999

*4,784 denied or incomplete petitions were subsequently approved

Age/Gender FY05

Age	Female	Male	Totals
0 to 10	14,716	16,863	31,579
11 to 20	7,286	6,822	14,108
21 to 34	302	77	379
35 to 49	159	67	226
50 to 64	196	63	259
65 to 79	174	57	231
80 to 94	122	15	137
≥95	9	1	10
Totals	**22,964**	**23,965**	**46,929**

	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
*Duals**	430	1,883	121,125	97,387	$ 161,395.58	1.66
*OTC loratadine***	297	754	92,532	71,231	$ 12,126.90	0.46
Non-Duals	46,249	105,827	8,005,724	3,152,146	$ 2,559,487.53	0.81

*Total of 680 unduplicated clients. **Coverage of OTC loratadine only will continue for Dual clients.

Changes to the NSA Prior Authorization Category

Fexofenadine has recently been approved and a SMAC will be applied when appropriate.

Desloratadine syrup has been approved for use in children 6 months of age and over.

Recommendations

The College of Pharmacy recommends adding desloratadine syrup to Tier 1 consistent with cetirizine criteria and the following changes once SMAC pricing has been applied to fexofenadine:

Non-Sedating Antihistamines

PA Criteria:

- Tier 2 non-sedating antihistamine only products are covered after a previous trial failure with an over-the-counter antihistamine and fexofenadine. A 14 day trial of over-the-counter loratadine and fexofenadine is required prior to coverage of a tier 2 product for all age groups.
  - Trials should have been in the last month and be of adequate dose and duration,
  - Over-the-counter loratadine and fexofenadine is a covered benefit for clients under the age of 21 years without prior authorization, and
  - For clients 21 years of age or greater, loratadine and fexofenadine is available with prior authorization AFTER documented over-the-counter failure of a non-loratadine product.
- For clients six months to two years of age, cetirizine syrup and desloratadine syrup are available without prior authorization.
- Diagnosis must be for a chronic allergic condition.
- Clinical exceptions include asthma and COPD.
  - For diphenhydramine, exceptions are made for EPS and insomnia.
- Prior authorization is approved up to 90 days for non-chronic conditions, and may be approved for over 90 days for conditions which require continuous coverage throughout the year.

Tier 1	Tier 2
• Over-the-counter loratadine • Fexofenadine • Cetirizine and desloratadine syrup for clients 6 months to 2 years of age	• Cetirizine • Desloratadine • Singulair (monotherapy only)

APPENDIX H

Review of Nasal Anti-Allergic Products

Oklahoma Medicaid
October 2005

Introduction

Allergic rhinitis is the most common form of rhinitis and affects up to 40% of children. Diagnosis is based primarily on history, but can be difficult based on overlapping conditions. Allergy testing may be performed to aid diagnosis, but is not always necessary and can result in false negatives if done improperly. There are two main forms of allergic rhinitis: seasonal and perennial.

Treatment options include allergen avoidance, pharmacotherapy, and immunotherapy. Pharmacotherapy consists of several classes of drugs: nasal corticosteroids, oral and nasal antihistamines, decongestants, nasal cromolyn, anticholinergics, ocular medications, and nasal saline.

Reviewed Nasal Products

Anticholinergics: This category is most effective for treatment of severe vasomotor symptoms. Ipratropium bromide 0.03% is approved for symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children 6 years of age and over, while the 0.06% is approved for symptomatic relief of rhinorrhea associated with the common cold for adults and children 12 years of age and over (and its safety for greater than 4 days has not been established). The most frequently reported adverse events are epistaxis and nasal dryness.

Antihistamines: Azelastine is approved for treatment of the symptoms of seasonal allergic rhinitis in children 5 years of age and over and for treatment of the symptoms of vasomotor rhinitis in adults and children 12 years of age and over. The primary adverse effects were altered taste and nasal burning.

Corticosteroids: These agents are the most effective agents for treating allergic rhinitis. Regular use is required for maximum benefit. These products are generally well tolerated. The most common side effects include sneezing, stinging, and local irritation. The aqueous formulations may be preferred as they are less irritating.

* Approved for children 3 years of age and over: Mometasone furoate (Nasonex).
* Approved for children 4 years of age and over: Fluticasone (Flonase).
* Approved for children 6 years of age and over. Beclomethasone (Beconase, Vancenase), Flunisolide (Nasalide), Budesonide (Rhinocort), and Triamcinolone (Nasacort).

Utilization Review

	Fiscal Year 2004	Fiscal Year 2005	Percent Change	
Total Claims	**46,972**	**69,854**	**Increased**	**48.7 %**
Anticholinergic	673	805	Increased	19.6 %
Antihistamine	1,482	2,727	Increased	84.0 %
Corticosteroids	44,817	66,322	Increased	48.0 %
Total Cost	**$ 3,157,892.14**	**$ 4,760,943.78**	**Increased**	**50.8 %**
Anticholinergic	$ 29,450.20	$ 23,519.58	Decreased	20.1 %
Antihistamine	$ 87,351.19	$ 69,117.68	Decreased	20.9 %
Corticosteroids	$ 3,041,090.75	$ 4,760,943.78	Increased	56.6 %
Cost per Claim	**$ 67.23**	**$ 68.16**	**Increased**	**1.4 %**
Anticholinergic	$ 43.76	$ 29.22	Decreased	33.2 %
Antihistamine	$ 58.94	$ 62.04	Increased	5.3 %
Corticosteroids	$ 67.86	$ 68.88	Increased	1.5 %

Fiscal Year 2005

	# of Clients	# of Claims	Total Units	Total Days	Total Cost	Per Diem
Duals	5,450	15,152	452,923	452,923	$ 999,287.83	2.21
Non-Duals	27,686	54,702	901,220	1,777,013	$ 3,761,655.95	2.12

Fiscal Year 2005 Non-Duals

Product	# of Claims	Total Units	Total Days	Total Cost	Per Diem	Cost/ Claim
Beconase	1	17	30	$ 54.40	$ 1.81	$ 54.40
Beconase AQ	284	7,184	7,952	$ 21,096.86	$ 2.65	$ 74.28
Rhinocort AQ	5,579	48,081	184,215	$ 407,237.38	$ 2.21	$ 72.99
Flunisolide 0.025%	1,399	35,125	40,469	$ 54,903.82	$ 1.36	$ 39.25
Nasalide 0.025%	33	825	925	$ 1,162.33	$ 1.26	$ 35.22
Nasarel 0.025%	201	5,034	5,515	$ 10,710.74	$ 1.94	$ 53.29
Flonase	24,806	396,976	812,535	$ 1,687,918.96	$ 2.08	$ 68.04
Nasonex	12,919	219,456	431,706	$ 932,840.82	$ 2.16	$ 72.21
Nasacort AQ	7,115	118,653	220,818	$ 510,239.01	$ 2.31	$ 71.71
Nasacort	3	30	85	$ 170.46	$ 2.01	$ 56.82
Atrovent 0.03%	7	210	210	$ 267.83	$ 1.28	$ 38.26
Ipratropium 0.03%	175	5,233	5,393	$ 5,974.63	$ 1 11	$ 34.14
Ipratropium 0.06%	188	2,940	4,763	$ 4,281.40	$ 0.90	$ 22.77
Astelin	1,992	61,456	62,397	$ 124,797.31	$ 2.00	$ 62.65
Total	**54,702**	**901,220**	**1,777,013**	**$ 3,761,655.95**	**$ 2.12**	**$ 68.77**

Recommendation

The College of Pharmacy recommends further review of these products for establishment of a Product Based Prior Authorization category.

APPENDIX I

30 Day Notice to Prior Authorize Xopenex HFA™ (levalbuterol)

Oklahoma Medicaid
October 2005

Manufacturer Sepracor
Classification Short-acting inhaled bronchodilator
Status: prescription only

Summary

Levalbuterol tartrate, (R)-albuterol tartrate, is currently available as an inhalant solution and has been approved by the FDA to be marketed as an HFA inhalation aerosol. The metered-dose inhaler is approved for the treatment or prevention of bronchospasm in adults, adolescents and children 4 years of age and older with reversible obstructive airway disease. The product is expected to be available by the end of 2005. Each actuation will deliver 59 mcg of levalbuterol tartrate (equivalent to 45 mcg of levalbuterol free base). The 15 g canister will provide 200 actuations per unit. Dosing for adults and children is 2 inhalations every 4 to 6 hours (1 inhalation every 4 hours may be sufficient).

Recommendation

The College of Pharmacy recommends Xopenex HFA™ be included with Xopenex® Inhalation Solution to require prior authorization for chronic use.

- Use of this product in excess of 90 days of therapy in a 360 day period will require prior authorization.
  - In the prior authorization request, the prescriber should explain why the client is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the NAEPP guidelines. Also the need for use of this product over an albuterol MDI should be stated.
  - Clinical exceptions will be made for clients with COPD.
- A quantity limit of 30 g (2 units) every 30 days will also apply.

References

1. Prescribing Information: Xopenex HFA™ (levalbuterol tartrate); Sepracor Inc., Marlborough, MA; March 2005.

30 Day Notice to Prior Authorize:
Darvocet A500™ (Propoxyphene napsylate/acetaminophen)
Balacet 325™ (Propoxyphene napsylate/acetaminophen)
Oklahoma Medicaid
October 2005

Manufacturer Darvocet 500™ - aaiPharma Inc.
Balacet 325™ - Cornerstone BioPharma, Inc.

Classification FDA classification: Narcotic, mixed
Status: prescription only
DEA status: Schedule IV

Summary
Propoxyphene /acetaminophen combine a peripherally acting analgesic (acetaminophen) and a centrally acting opioid agonist (propoxyphene) in a fixed dose.

Therapeutic Indications
Mild to moderate pain with or without fever. The combination produces greater analgesia than that produced by either agent administered alone.

Dosage Forms

Drug	Propoxyphene	Acetaminophen	Reimbursement
Darvocet N-100®	100 mg	650 mg	$0.52
Propoxyphene/ acetaminophen	100 mg	650 mg	$0.06 (SMAC)
Darvocet N-50®	50 mg	325 mg	$0.58
Propoxyphene/ acetaminophen	50 mg	325 mg	$0.11 (FMAC)
Darvocet A500™	100 mg	500 mg	$1.10
Balacet 325™	100 mg	325 mg	$1.04
Darvon-N®	100 mg	n/a	$0.89

Dosing[1]

- *Adults*: Usual dose of acetaminophen/propoxyphene napsylate is 650/100 every four hours as needed. Maximum recommended daily dose of propoxyphene napsylate is 600 mg. Oral dosing of acetaminophen is 650 to 1000 mg every 4 to 6 hours as needed, to a maximum of 4 g/24 hours
- *Pediatrics:* Safety and efficacy data on acetaminophen/propoxyphene in children are not available (Prod Info Darvocet-N(R) 50 and Darvocet-N(R) 100, 2000). Safety of propoxyphene has not been established in children under the age of 18. Pediatric oral dosing of acetaminophen is 10 to 15 mg/kg/dose every 4 to 6 hours to a maximum of 50 to 75 mg/kg/24 hours.

Warnings

- Chronic administration of propoxyphene may produce psychic and physical drug dependence.
- Acetaminophen, in doses over 4 g, may cause hepatotoxicity.

Manufacturers' Marketing Point

- Balacet 325™ (Cornerstone BioPharma, Inc) – Balacet 325™ attacks mild to moderate pain while helping to reduce the risk of acetaminophen toxicity[2].
- Darvocet A500™ (aaiPharma Inc) – "Darvocet A500™ will provide an important alternative for health care providers concerned about high acetaminophen intake in patients suffering from mild to moderate pain"[3]

Recommendations

Prior authorize Darvocet A500™ and Balacet 325™.

Criteria: Documented need to restrict acetaminophen use
Concurrent use of acetaminophen-containing products
Documented renal insufficiency

References

1. MICROMEDEX(R) Healthcare Series Vol. 125 expires 9/2005
2. www.prnewswire.com, June 20, 2005
3. www.docguide.com/news September 11, 2003

New Product Summaries

Oklahoma Medicaid
October 2005

Drug	Manufacturer	Indications	Dosage	Adverse Effects	Contraindications	New Molecular Entity	AWP/ unit
Actoplus Met (pioglitazone/metformin) tablets	Takeda	Type 2 diabetes mellitus	one 15mg pioglitazone/500mg metformin or one 15mg pioglitazone/850mg metformin tablets daily or multiple times daily	Fluid retention, jaundice, lactic acidosis (rare but fatal when it occurs)	CHF, impaired hepatic or renal function, alcohol use	No	$ 2.88/ tablet
Nevanac (nepafenac) ophthalmic suspension	Alcon	Treatment of pain and inflammation associated with eye procedures	one drop in affected eyes beginning one day prior to treatment; then continue during the day of treatment; and finally continue two weeks post operative	Opacity, sticky sensation, increased intraocular pressure	NSAID hypersens-itivity or allergy to any other component	Yes	$78.75 per 3mL bottle

APPENDIX J

Public Health Advisory
Suicidal Thinking in Children and Adolescents Being Treated With Strattera (Atomoxetine)

Today the Food and Drug Administration (FDA) directed Eli Lilly and Company (Lilly), the manufacturer of Strattera (atomoxetine), to revise the labeling for this product to include a boxed warning and additional warning statements that alert health care providers to an increased risk of suicidal thinking in children and adolescents being treated with this drug. FDA also informed Lilly that it has determined that a Patient Medication Guide (MedGuide), which will advise patients of the risks associated with Strattera and precautions that can be taken, should be distributed to patients when Strattera is dispensed.

Strattera is approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric and adult patients.

The increased risk of suicidal thinking for this drug was identified in a combined analysis of 12 short-term (6-18 weeks) placebo-controlled trials (11 in ADHD and 1 in enuresis [bedwetting]). These 12 trials involved a total of over 2200 patients, including 1357 receiving Strattera and 851 receiving placebo. The analysis showed a greater risk of suicidal thinking during the first few months of treatment in those receiving Strattera. The average risk of suicidal thinking was about 4 per thousand patients treated with Strattera compared to no events in placebo-treated patients. There was 1 suicide attempt among these approximately 2200 patients, occurring in a patient treated with Strattera. Based on these data, FDA has determined that the following points are appropriate for inclusion in the boxed warning:

- Strattera increases the risk of suicidal thinking in children and adolescents with ADHD.
- Anyone considering the use of Strattera in a child or adolescent for ADHD must balance the increased risk of suicidal thinking with the clinical need for the drug.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidal thinking or behaviors, or unusual changes in behavior.
- Families and caregivers should be advised to closely observe the patient and to communicate changes or concerning behaviors with the prescriber.

Pediatric patients being treated with Strattera should be closely observed for clinical worsening, as well as agitation, irritability, suicidal thinking or behaviors, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. This monitoring should include daily observation by families and caregivers and frequent contact with the physician.

In addition a MedGuide is being prepared for Strattera to provide directly to patients and their

families and caregivers information about the increased risk of suicidal thinking in children and adolescents prescribed Strattera. The MedGuide is intended to be distributed by the pharmacist with each prescription or refill of a medication.

A similar analysis in adult patients treated with Strattera for either ADHD or major depressive disorder (MDD) found no increased risk of suicidal ideation or behavior with use of Strattera.

FDA plans to work closely with Lilly to optimize the safe use of this drug and implement the proposed labeling changes and other safety communications in a timely manner.

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Date created: September 29, 2005

Mix-ups Involving Lindane

FDA Patient Safety News: Show #44, October 2005

In 2003, FDA issued an advisory on the potential neurologic toxicity of lindane, a topical second-line treatment for scabies and lice. The advisory noted the importance of limiting the use of lindane to just one application and specified that lindane must be dispensed only in single-use containers of one or two ounces. This was intended to reduce the possibility that patients would apply an excess amount of the product, or that they'd re-apply it.

A recent article in MMWR cautions about a different problem related to lindane. The article reported on 870 cases of illness from 1998 to 2003 that were caused by the unintentional ingestion of lindane. In a number of these cases, lindane was mistaken for a liquid oral medication, such as cough syrup.

The article notes that before the changes in 2003, bottles of bulk lindane were sometimes repackaged by pharmacies into smaller bottles that looked like those used for oral medications such as cough syrup, and that could have contributed to many unintentional ingestions. And because bottles of bulk lindane already in use weren't recalled from pharmacies after the 2003 advisory, some repackaging might still be occurring, even today. Also, some consumers might still have repackaged lindane in their homes. So, although the use of lindane appears to be declining, cases of accidental ingestion are continuing to occur.

The article points out several important reminders about the appropriate use and packaging of the product. First, lindane is a second-line therapy for scabies and lice, and should be used only if other treatments have failed or are intolerable. It shouldn't be used in children and small adults who weigh less than 110 pounds. Because of the risk of toxicity, lindane treatment should not be repeated.

Pharmacists should not transfer lindane to other containers. And they should dispense lindane only in the 1- or 2-ounce single use containers provided by the manufacturer.

Additional Information:

CDC. Morbidity and Mortality Weekly Report. June 3, 2005 / 54(21);533-535. Unintentional Topical Lindane Ingestions --- United States, 1998--2003.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5421a2.htm

FDA Patient Safety News is available at www.fda.gov/psn