THE UNIVERSITY OF OKLAHOMA

# MEMORANDUM

**TO:** Drug Utilization Review Board Members

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

**SUBJECT:** **Packet Contents for Board Meeting – July 13, 2004**

**DATE:** July 7, 2004

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

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

Call to Order

Public Comment Forum

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

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

**Action Item** – Discuss and Vote on Prior Authorization of Synagis™- **See Appendix C.**

**Action Item** – Discuss and Vote on Prior Authorization of "SSRIs"– **See Appendix D.**

**Action Item** – Discuss and Vote on Prior Authorization of "ARBs"- **See Appendix E.**

**Action Item** – Discuss and Vote on Maintenance Drug List - **See Appendix F.**

Review and Discuss Antibiotic Utilization – **See Appendix G.**

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

Future Business

Adjournment

# Drug Utilization Review Board

(DUR Board)

**Meeting – July 13, 2004 @ 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. Corrected May 11, 2004 DUR Minutes
   B. June 8, 2004 DUR Minutes - Vote
   C. Memorandum of June 8, 2004
   D. Provider Correspondence

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

4. **Update on DUR/MCAU Program - See Appendix B.**
   A. Prospective DUR Report – Annual Report
   B. Retrospective DUR Report for March / April 2004
   C. Medication Coverage Activity Audit for June 2004
   D. Help Desk Activity Audit for June 2004

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

5. **Action Item – Discuss and Vote on Prior Authorization of Synagis™- See Appendix C.**
   A. AAP Guidelines
   B. COP Recommendations

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

6. **Action Item – Discuss and Vote on Prior Authorization of SSRIs – See Appendix D.**
   A. Economic Review
   B. COP Recommendations

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

7. **Action Item – Discuss and Vote on Prior Authorization of ARBs – See Appendix E.**
   A. Economic Review
   B. COP Recommendations

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

8. **Action Item – Discuss and Vote on Maintenance Drug List – See Appendix F.**
   A. List of Drugs
   B. COP Recommendations

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

9. **Review and Discuss Antibiotic Utilization – See Appendix G.**
   A. Utilization Review
   B. COP Recommendations

10. **FDA and DEA Updates – See Appendix H.**

12. **Future Business**
   A. Hepatitis C Agents Review
   B. Epogen™ / Procrit™ Review
   C. Benzo/Ambien™ Follow-up Review
   E. Narcotics Review
   F. Xopenex Follow-up Review
   G. Vote on Fuzeon™ Prior Authorization

13. **Adjournment**

# APPENDIX A

# OKLAHOMA HEALTH CARE AUTHORITY
## DRUG UTILIZATION REVIEW BOARD MEETING
## MINUTES of MEETING of MAY 11, 2004

| BOARD MEMBERS: | PRESENT | ABSENT |
|---|---|---|
| Rick G. Crenshaw, D.O. | | X |
| Dorothy Gourley, D.Ph. | X | |
| Cathy Hollen, D.Ph. | X | |
| Dan McNeill, Ph.D., PA-C | X | |
| Cliff Meece, D.Ph. | X | |
| Dick Robinson, D.Ph., Vice-Chair | X | |
| James M. Swaim, D.Ph. | X | |
| Thomas Whitsett, M.D., Chair | X | |
| (VACANT) | | |
| (VACANT) | | |

| COLLEGE of PHARMACY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Leslie Browning, D.Ph./Clinical Pharmacist | X | |
| Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison | X | |
| Kelly Flannigan, D.Ph./Clinical Pharmacist | X | |
| Shellie Gorman, Pharm.D./Clinical Pharmacist | X | |
| Ronald Graham, D.Ph., Manager, Operations/DUR | X | |
| Chris Kim Le, Pharm.D.; Clinical Pharmacist | X | |
| Ann McIlvain, Pharm.D.; Clinical Pharmacist | X | |
| Carol Moore, Pharm.D.; Clinical Pharmacist | X | |
| Raj Patel, Pharm.D.; Clinical Pharmacist | X | |
| Carol Peek, Pharm.D.; Clinical Pharmacist | X | |
| Visiting Pharmacy Student: n/a | | |

| OKLAHOMA HEALTH CARE AUTHORITY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Kristall Bright; Pharmacy Financial Analyst | X | |
| Alex Easton, M.B.A.; Pharmacy Operations Manager | X | |
| Mike Fogarty, C.E.O | | X |
| Lynn Mitchell, M.D., M.P.H, Medical Director | | X |
| Nancy Nesser, D.Ph., J.D.; Pharmacy Director | X | |
| Howard Pallotta, J.D. | X | |
| Lynn Rambo-Jones, J.D. | | X |
| Rodney Ramsey; Pharmacy Claims Specialist | X | |

**OTHERS PRESENT:**

| | | |
|---|---|---|
| Steve Goodson, Pfizer | Jorge Nassar, BMS | JoAnne Hargraves, Schering |
| Woodie Zachry, Lilly | David Montgomery, Lilly | Brad Rice, Takeda |
| Aleza Tomlinson, Janssen | Angela Menchaca, Amgen | Phil Woodward, OPhA |
| Carter McBride, BMS | Michael Hunt, D.O. | Becky Alderson, BMS |
| Diana Morasch, AstraZeneca | Holly Jacques, Merck | Christi Davis O'Brien, AstraZeneca |
| Richard Ponder, Johnson & Johnson | Loren James | Patrick Evans, BMS |
| Toby Thompson, Pfizer | Jonathan Klock, Glaxo | Tim Myers, Schering |
| Lance Stewart, Merck | Mark DeClerk, Lilly | Tracy Copeland, Forest |
| David Dude, BMS | Holli Hill, Sankyo | Rebecca Waldrop, Sanofi |
| Ricky Conley, Boehringer Ingelheim | Kay Kaut, Amylin | Margaret Lapsley, NeighborCare |

**PRESENT FOR PUBLIC COMMENT:**

| | |
|---|---|
| Connie Lindsay, AstraZeneca | Thomas Henebry, OU/Pfizer |
| Robert Calder, Merck | Jerome L. Anderson, Cardiologist |

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 Connie Lindsay, Dr. Thomas Henebry, Dr. Robert Calder and Dr. Jerome Anderson; public comment for Agenda Item No. 9.

**ACTION:** NONE REQUIRED.

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

**3A: April 13, 2004 DUR Minutes**

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

**ACTION:** MOTION CARRIED.

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

**4A: Medication Coverage Activity Report: April 2004**

The April 2004 activity audit noted total number of petitions submitted was 15,644 including super-PA's and special circumstance PA's. Approval/denial/duplicate percentages were indicated on the reports included in the agenda packet for this meeting. Monthly reports included in agenda packet; presented by Dr. Browning.

**4B: Help Desk Activity Report: April 2004**

Total calls for April 2004 numbered 17,660 (75.4% pharmacies, 9.7% clients, 6.9% physicians, 8.0% other). Monthly reports included in agenda packet; presented by Dr. Browning. Dr. Swaim asked about the DME help desk and for questions concerning SoonerCare Choice PCP's Prescriber ID's provided by OHCA/EDS. It is a requirement now to have the correct PCP with the client submitted with the on-line claims processing.

**ACTION:** NONE REQUIRED.

AGENDA ITEM NO. 5: LONG TERM CARE CONSULTANT PHARMACIST PRESENTATION

Material included in agenda packet; handouts distributed at DUR Board Meeting; presented by Drs. Phil Woodward and Margaret Lapsley. Dr. Whitsett asked who benefits from the consultant pharmacist reducing costs in the nursing home? Margaret explained that it benefited the nursing home when they have to pay for some of the medications and also her employer can show that they do help reduce costs for their customers and overall medical expenses are reduced. Safety issues can actually save money too. Dr. Whitsett asked if the Board could be comforted in knowing that most consultant pharmacists are fairly conscientious in their duties. Margaret stated that pharmacists make recommendations to physicians and then the physicians decide if they want to make appropriate changes or leave it as prescribed. Dr. Whitsett asked about the Off-Label use of antipyschotics in the nursing home population. Dr. Lapsley reminded the Board that there are no current antipsychotics available with indications for Dementia and behavioral problems in the elderly. She stated that is the number one reason they are used in the nursing home population. One problem that consultant pharmacists have is getting the proper diagnosis for these patients. Sometimes there are not any documented symptoms which are common with these types of diagnoses. Symptoms such as hallucinations and delusions may be apparent but are not documented in the charts. Dr. Whitsett asked about the safety and efficacy of these products and questions have been raised for this class of medications for those Off-Label conditions. Dr. Whitsett said there is evidence of mortality and other issues associated with these medications. Dr. Lapsley stated that this is of concern for the pharmacist also and they have started looking at other indicators such as sugar levels and diabetes and look for history of stroke and check to see what kind of antipsychotic the patient is taking. The consultant pharmacist will then make a recommendation of possibly another medication or ask the physician to consider the risks against the benefits. Dr. Whitsett asked if the pharmacist

recommends dosage reduction? Dr. Lapsley stated that every 4 months it is required by law that dosage be evaluated for antipsychotics. Patients that come into the nursing home on high doses for antipsychotics are evaluated and recommendations are given to the physician to lower it to at least the highest recommended level for the elderly that the FDA approves. Dr. Whitsett asked what the percentage of nursing home clients that is taking antipsychotics? Dr Lapsley said she thought it was around 23% nationally. Dr. Whitsett asked if there are any trends developing in nursing homes as far as medications are concerned? Dr. Lapsley said she thought that the anti-epileptics are on the increase for uses similar to the antipsychotics and the reason she stated was because of no regulations on that particular class of medications. Dr. Graham asked if she felt that there is an overuse of benzo's in the nursing home? Dr. Lapsley indicated that this region of the U.S. has a higher usage than other regions. Dr. Lapsley stated that she thought that a lot of this higher use was due to staffing shortages within the nursing facility. She thinks it is probably easier to relax a patient than to re-direct them. Dr. Lapsley said they make recommendations to the physicians to get patients off of benzo's at least every 2 months because of regulations requiring it. Routine dosing is usually recommended being changed to as needed dosing. Dr. McNeill asked how many nursing homes does her company service at this time and if calculations of savings to medicaid have been done. Dr. Lapsley said they have 25 nursing facilities currently and are in the process of calculating savings at this time. Dr. McNeill asked if there has been any resistance from the providers (PCP's)? Dr. Lapsley said that usually they don't really look at that but sometimes the physician may agree to a recommendation but the provider won't pay for it.



**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 6:** **REVIEW OF OKLAHOMA STATE LAW & AGENCY POLICY FOR ADDING CATEGORIES TO THE PRODUCT BASED PRIOR AUTHORIZATION PROGRAM**

Materials included in agenda packet; presented by Dr. Nesser. Dr. Hollen requested a copy of slides presented at tonight's meeting. Dr. Nesser agreed to furnish these.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM No. 7:** **ANNUAL REVIEW OF ANTIHYPERTENSIVES – VOTE TO PRIOR AUTHORIZE CADUET™**

Materials included in agenda packet; presented by Dr. Moore.
Dr. Hollen wanted to know administrative costs for PBPA of antihypertensives.
Dr. Gourley moved to approve; motion seconded by Dr. Robinson.

**ACTION:** MOTION CARRIED.

Utilization Data for the Angiotensin II Receptor Blockers (ARB's) and Combination products was provided to the Board. Dr. Whitsett asked if there was any utilization information available on how Oklahoma Medicaid patients such as the diabetic population and heart failure population are doing with ARB's? What percentage of these clients are taking advantage of this class of drugs. Dr. Moore stated that the COP will be bringing that information to the Board in the future.

**AGENDA ITEM NO. 8:** **REVIEW & DISCUSS SSRI's**

Materials included in agenda packet; presented by Dr. Gorman.
Dr. Whitsett wanted to know percentage of usage for LTC facilities. Dr. Gorman said that would be looked at and brought back to the Board for review. Dr. Whitsett reminded the Board members of some of the recent emergence of adverse effects in the elderly population with this category.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 9: THIRTY (30) DAY NOTICE OF INTENT TO PRIOR AUTHORIZE/ PREFERRED DRUG LIST HMG-CoA INHIBITORS (STATINS)**

For Public Comment; Connie Lindsay: *Connie Lindsay with Astra Zeneca. I'll see how fast I can talk. I'll be speaking about Crestor® in the treatment of dyslipidemia. I want to touch briefly about efficacy. Crestor® does offer the greatest efficacy in the statin class with a 52% reduction in LDL at below 2 mg dose. There's an added benefit with Crestor® in that you do see an actual increase in HDL at every dose. The increase is generally between 8 and 14%. This is important when you consider that a one point reduction in LDL offers a one point decrease in cardiovascular risk. A one point increase in HDL offers a 3% reduction in cardiovascular risk. There is a 1:3 ratio. Physicians are very frustrated with trying to get patients to their LDL goal and there's an attenuation with HDL that will not happen with Crestor® . I'd like to talk briefly about compliance, particularly with this patient population. Compliance is not always easy and follow-up is not always easy. Eight out of ten patients will get to goal regardless of their risk category, whether they're diabetic, CHD risk equivalent, eight out of ten patients at just below 10 mg dose. So what that means is when a patient is diagnosed, a prescription is written for Crestor® , then that patient eight out of ten times, they're going to be at goal whether they really do follow up with you as a physician. We've recently heard information out of the ACC in New Orleans that confirmed again that lower is better. Not our trials but through the trials presented as well as reversal showing and demonstrating that we probably will see updates in the incept guidelines again, telling us that 100 mg LDL is not good enough for patients that are at risk. Crestor® will meet that need with the efficacy of a 52% reduction at the 2 mg dose. At the last meeting, I know there was some questions about safety, simply because our product is fairly new. I want you to know now that we've been in the market now for, in the U.S., 9½ months. We have a million prescriptions, or a million patients, two million prescriptions. Crestor® is now approved in 52 countries. We submit, on a weekly basis, adverse events to the FDA. We're required to do that by law. The FDA does quarterly intense in-depth scrutiny of our product. They just completed the last one in March and everything looked good. Everything looked, post clinical trials compared to pre side effects, everything looked pretty much in line. There were no changes or additions to our product labeling. Also just a reminder that our landmark trial which was the Stellar Trial, was the largest comparative trial that the FDA had ever seen before a product was approved, with over 10,000 patients, and that trial demonstrated all of the efficacy data that I just told you. I also want to let you know that, let's see, I don't want to forget anything . . . There was also a recent article published in Cardiology of April by Dr. Vidt that looked at over 10,000 patients on Crestor® for an average of 3.8 years and it did demonstrate a regression in renal disease which has also been demonstrated by the other statins. So that's really about it. Do you have any questions for me?*

Dr. Hollen: *In addition to HDL do you have any information with effect on like triglycerides, ~~lipoprotein relay~~ lipoprotein little a some of the other independent risk factors for heart disease?*

Ms. Lindsay: *Yes. All of those, and everything is positive. We have a good reduction on triglycerides that is similar to the other statins as well as the CRP's and little a and little b.*

Dr. Hollen: *OK. So you actually have CRP?*

Ms. Lindsay: *Yes. You can request . . . I can have that information sent to you personally or to the Board. I don't know really how that works.*

For Public Comment; Thomas Henebry: *I'm Tom Henebry, an interventional cardiologist at OU and also speaking on behalf of Pfizer. I want to talk very briefly, it's hard to be as eloquent as the previous speaker about the clinical efficaciousness of atorvastatin. I think as a cardiologist, we always look for outcome days and that's what I'm trying to present briefly. In primary prevention, the ASCOT trial, 10,000 patients, 36% reduction in days per cardiovascular events. In secondary prevention, 43% reduction in days, just days alone, number needed to treat less than 50 in the REGRESS Trial. The REGRESS trial and the MIRACLE trial combined four-and-a-half thousand patients, 50% reduction in stroke, which was a pleasant side effect. Recent study in the American Journal of Kidney Disease, diabetics on ACE and ARB for at least a year atorvastatin added a protein urea previous 2 grams reduced to 1 gram per day. Two major recent trials, our prior speaker mentioned, both changed the guidelines, I think that's one thing we all probably can agree on. Reversal trial, looking at atherosclerosis with intracardial ultrasound progression was stopped by atorvastatin, 4% progression with pravastatin. PROVE-IT trial was more important, it was funded by, not by Pfizer and is a clinical enterprise, and in that trial, atorvastatin was proven more efficacious than pravastatin, and I think we all can see the guideline going to somewhere LDL 75 to 80 mg percent. Safety data's important to those of us who remember Baycol™. We are in a similar situation before and more than 12,000 people randomized for good safety data. In the FDA pink sheet for various statins, we see the dose reduction and the incidence of 1 to 2+ protein urea. Most of the statins do what is expected and otherwise there was little need to, there was no Warfarin interaction with atorvastatin of clinical significance and no need to bother basic metabolic panels. I think to summarize I think we should from a clinical outcomes perspective we should let atorvastatin continue and view it as preferred drug.*

For Public Comment; Dr. Robert Calder: "Tape ended" . . . *Florida. Before that, I was right down the road in Ft. Sill for a couple of years as a preventive medicine officer, so, and this is my first trip back to Oklahoma in 20 years, so. I was surprised that Zocor® was not on the PDL, your proposed PDL and I'd like to offer a few comments in that regard. With respect to Zocor® 's outcomes efficacy and safety. We've heard a lot about outcomes and Zocor® has outcomes proven and in the labeling for the product. In 1994, the 4S trial, which was the first large outcome trial with a statin was published and that with over 4,000 patients, showed a 42% reduction of coronary mortality and a 30% reduction of total mortality. Following that up in 2002, we had the heart protection study with Zocor® at 40 mg which was over 20,000 patients, the largest outcomes trial ever done with a statin and that trial showed a 27% reduction in coronary events, 13% reduction in total mortality and an 18% reduction in coronary mortality. That was driven by a 38% reduction in coronary events, and not a fatal one. And so, as a result of these trials, Zocor® has outcomes in its' labeling, in our labeling, that the other statins don't have. With respect to efficacy, the 40 mg starting dose of Zocor® which is the recommended usual starting dose for Zocor® for people who are at high risk of an event, as it provides a mean LDL reduction of 41%. One study of typical CHD patients, the GOALS trial which was in patients who had CHD with LDL's of 150 to 180, 87% got to goal on Zocor® 20 to 80 mg, mean dosage 25 mg. Also Zocor® is also indicated to reduce triglycerides and to raise HDL. And it's also important when you're comparing the statins to compare the statins in the same head-to-head trial, and the same patient population because as an epidemiologist, I can tell you there's a lot of variation with all of the statins in any given patient population. The mean reduction might be 40% for example, but the 95% confidence interval on the standard deviation, not the, not the, not the standard or the mean, but the standard deviation, is plus or minus 24%, so when you're comparing two statins, even in the same patient population, the means really tell you partly they certainly are important statistically meaningful, but you have to at the patient level, remember that there's a wide range in effect. I used to say that you can drown crossing a creek with a mean depth of six inches. The mean can hide a lot of information particularly appropriate here. With respect to safety, the safety of Zocor®, there've been over a 160 million prescriptions for Zocor® written in the United States alone in the twelve years it's been on the market. And we take safety of course very seriously and like all of the statins, there have been reports of myopathy and rhabdomyalysis, rare reports with Zocor®. We don't recommend using Zocor® with potent CYP3A4 inhibitors and there are six of those listed in our labeling. We have relaxed our restrictions somewhat on . . . well we have relaxed it on niacin and fibrates other than gemfibrozil, and but again we don't recommend using more than ten of Zocor® with cyclosporine or gemfibrozil. In summary again outcomes efficacy and safety I think is what you should consider. And in addition to that, it's important to remember that Zocor® goes off patent June 23rd, 2006 and I understand that's an important factor obviously in your, in your calculations for how much money you'll save with various statins. And where you don't need a crystal ball to know whether or not Merck will fight the patent expiration because we won't. When it goes off patent June 23rd, that's it . . . it goes off patent. We extend the patents only through legitimate scientific studies and there are none of those in the offing for that. So, thank you very much and I welcome questions.*

For Public Comment; Jerome L. Anderson: *Thank you. I'm a cardiologist at Integris and Deaconess hospitals. I'm director of cardiac research at Southwest Integris and was involved in a PROVE-IT study that was mentioned earlier published here in April. So I wasn't paid to be here although I'm going to have to acknowledge Mr. Dude from Bristol Myers did alert me to the meeting. Currently I use all the statins and currently I speak for all the companies whether it's Zocor®, Pravachol®, or Lipitor®, Crestor®, and currently prescribe all those drugs and I think there's some market share information in this handout here. That probably is typical for a lot of practices in Oklahoma . . . where Lipitor® and Zocor® and Pravachol® are the big three, and Crestor® currently climbing in market share. At Baptist Hospital with the acute coronary syndrome, we're currently getting a report card, all cardiologists. You get admitted with chest pain, you're supposed to get a lipid profile and get one of these agents started in the hospital. If you don't do that, unstable angina, then you get your report card is lowered, compared to your compatriots there. At discharge, same way after bypass surgery or after a stent or after unstable angina's been diagnosed and treated, discharge on a statin is also part of your report card. It's not a, don't get fined or get physical beating, but you get compared to your colleagues, but that's part of the utilization we use at Baptist Hospital . . . drawing the lipids and treating the lipids on date of admission and discharge. So part of the argument here I think is not necessarily which statin is better as far as utilization of all the statins more often and there is the study from a recent meeting in New Orleans, one of our speakers talked about and less than 30% are on adequate Pravachol® doses or less than 40% are on adequate Zocor® doses of people admitted to the hospital, and 1% are on 80 mg of Lipitor®, so when you try to look at the PROVE-IT data and I was involved in that data at the, our local hospital, they're comparing 40 of pravastatin with 80 of the atorvastatin and, involved those patients and I think that study has some good points. It did not show reduced mortality, it did show reduced combined endpoints in hospitalization and recurrent angina where those, some of those endpoints. The mortality wasn't reduced so the endpoint data with 4S and the endpoint data with CARE and LIPID and West of Scotland, all those data points are very important. Mortality data and even the MIRACLE trial which was rehospitalization, primarily, and acute*

*coronary syndromes. I think all those data are important, I don't . . . Lescol® is a drug I don't use as often as I should perhaps, and Lipitor® is not a drug I use as often as I should. I tend to use the top four products in general, and part of that reason is for certain patients Zocor® has been around a lot and a lot of my patients are still on that and stable after their heart surgery twelve years ago. Pravastatins are used in our HIV patients. I take care of Dr. Brown's HIV patients, she sends them to me and a lot of them have lipid abnormalities and pravastatin is used primarily there and the same with the transplant patients, renal and cardiac and liver transplants with their lipid . . . liver function as being a concern and so I probably use all three agents similarly to your information here and I don't think there's one study that says one drug's better than another. You know, it's a cost analysis and those of us who are doctors still have a big duty to get to goal and none of the drugs do it in a perfect manner. It's more of titrating your dose and adding other statin adjutants like niacin and fibrates and stuff like that, so it's a continuing process trying to get them to goal or raise their HDL. So I am probably asking for access to all the drugs because that's how I did in my clinical practice and I don't ask them if they're on Medicaid and I don't ask my patients if they're on Medicare, if they're private pay, it's not the way I was taught at OU by Dr. Haffner and so I treat them, all the patients the same way so I think if I have a diverse patient population, diverse set of drugs with all other indications, my preference as a practitioner would be to have all drugs available. Thanks for your time.*

Dr. Gourley: *Do you have therapeutic substitution in your hospital or on the statins . . .?*

Dr. Anderson: *. . . therapeutic substitution, do you mean can you use whatever you want to? Yeah. I think they do their pricing. I have a preferred product in price but we have all the agents available for inpatients.*

Dr. Graham: *Dr. Anderson, if you were designing a preferred product list, for example, and you wanted . . . what I would ask is that you would, would you agree that you would want to not upset the marketplace any more than you have to, I mean as far as, in other words, if you have . . .*

Dr. Anderson: *Well, if any of the cardiologists go along, if primary care doctors go along, if the endocrinologists go along, I mean, if I do a third of Pravachol® and a third Zocor® and a third Lipitor® currently, and 10% Crestor® and 1% generics, I might be typical of a lot of doctors and so, whether they're Medicare or Medicaid patients, I try to treat them the same, in-patients or out-patients, so I'm not using generic Mevacor® in the hospital if they're a Medicare patient or if they're 92 years old, I'm using a brand name, so I think in answering your question, we try to use drugs to their efficacious and try to get to goal, and I'm not sure Lipitor® is better than pravastatin. There's a PROVE-ITstudy, they got to 60-something with 80 of the atorvastatin but the Alliance Study was just done at the VA, they got to 95 with atorvastatin, so you got one Lipitor® study saying they're getting to 95, you've got another one saying they're getting to 67, you've got the Prove-IT trial, they got to 95, so if you're using the same doses of drugs in two different studies done at the same time, you get different lipid levels, so I'm not sure if the VA men are different than the PROVE-IT patients. Those numbers, you have to interpret them differently. I can get to goal with any of those products.*

Dr. Whitsett: *The individuals, I think you mentioned a couple that where you would start with the pravastatin, the HIV patients, because of the number of possible interactions that's going to be out there and the transplant patients, are those the two major categories in which you would first think of pravastatin?*

Dr. Anderson: *Yeah, and again being involved in the study, I might use drugs more often if I have been involved in the PROVE-IT trial or the, just like the MERIT trial, I use more metoprolol than I use carbatolol because of being involved in the MERIT trial, and so you do have a little bit of exposure through your drug studies personally, but you know Zocor® led the field for many years and Pravachol® was second in line and so as a physician for 17 years, I have that certain habit of Zocor®, Pravachol®, Lipitor®, Crestor® because of my own personal experience, but there are certain categories where you might use each drug specifically. The 4S Trial, the Heart Protection Study, you know diabetic patients treated in a hypertension study, you might if you're going to have evidence based medicine, or if I'm going to talk to a lawyer who's my patient, I get a lot of fat diabetic lawyers, but I might put him on Zocor®, because it's evidence based, and the acute care ACS syndrome with PROVE-IT and MIRACLE, those are subgroup populations. So mortality data is important and Lipitor® doesn't have as much mortality data as Zocor® does. But they're all good products. I'm not here to talk about all of them at dinner meetings they're all good products.*

Dr. Hollen: *Do you have any insight when Pravachol®'s going to go generic?*

Dr. Anderson: *'96 also.*

Dr. Hollen: *2006?*

Dr. Anderson: *2006.*

Materials included in agenda packet; presented by Drs. Gorman and Kim. Dr. Whitsett asked about the cost difference when pravastatin is combined with aspirin such as Pravigard™. He concluded by adding aspirin that product went up significantly in price. Dr. Whitsett wanted to know what percentage of our adult population is using a statin? Dr. Hollen wanted to know why were we just looking at LDL reduction with costs associated rather than other variables. Dr. Kim explained there was some comparative data at the previous meeting and that most statins are compared across the board in this manner and the other variables haven't been studied as extensively as

LDL. LDL has been positively linked with the reduction in risks. Dr. Whitsett stated that efficacy has been demonstrated without outcome data. Dr. Whitsett said that he didn't think that the DUR Board was locking out any medication by trying to propose a rational approach to try and save money if we can with an additional secondary rebate. Dr. Hollen wants ~~to add triglyceride levels to PA criteria,~~ additional review of the statins and their effect on triglycerides.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 10:** **REVIEW & DISCUSS ANTIASTHMATICS (EXCLUDING INHALED CORTICOSTEROIDS)**

Materials included in agenda packet; presented by Dr. Flannigan. NAEPP Asthma guidelines were included in packet for quick reference. Medicare (CMS) reimburses for Xopenex™ at the same rate as for albuterol due to it having "no clinical advantage over albuterol" (direct quote). Recommendation was made to bring back levalbuterol and leukotriene agents for possible PA.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 11:** **FDA & DEA UPDATES**

Materials included in agenda packet; submitted by Dr. Graham. Dr. Whitsett asked if there is a policy for tablet splitting or requiring tablet splitting for clients? Dr. Nesser said there is not a stated policy in favor or against tablet splitting. Dr. Whitsett stated that he thought sometimes physicians prescribed a month's supply that they intend for the client to cut in half, and stretches it out over a two month's supply. Dr. Whitsett thinks that there could be some real savings if a policy like this didn't violate any rules or laws. Dr. Hollen asked if we could include any handouts from the previous month in the next packet?

**ACTION:** NONE REQUIRED.

**AGENDA ITEM No. 12:** **FUTURE BUSINESS**

**12A: Hepatitis C Agents Review**
**12B: Maintenance Drug List – Quantity Limits**
**12C: Epogen™/Procrit™ Review**
**12D: Antibiotic Review**
**12E: Benzo/Ambien™ Follow-Up Review**
**12F: Vote to PA Provigil™, Synagis™ and Fuzeon™**
**12G: Narcotics Review**
**12H: ARB Follow-Up Review**

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

**ACTION:** NONE REQUIRED.

**AGENDA ITEM No. 13:** **ADJOURNMENT**

The meeting was declared adjourned.

# OKLAHOMA HEALTH CARE AUTHORITY
## DRUG UTILIZATION REVIEW BOARD MEETING
## MINUTES of MEETING of JUNE 8, 2004

| BOARD MEMBERS: | PRESENT | ABSENT |
|---|---|---|
| Rick G. Crenshaw, D.O. | X | |
| Dorothy Gourley, D.Ph. | X | |
| Cathy Hollen, D.Ph. | X | |
| Dan McNeill, Ph.D., PA-C | X | |
| Cliff Meece, D.Ph. | X | |
| Dick Robinson, D.Ph., Vice-Chair | X | |
| James M. Swaim, D.Ph. | | X |
| Thomas Whitsett, M.D., Chair | | X |
| (VACANT) | | |
| (VACANT) | | |

| COLLEGE of PHARMACY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Leslie Browning, D.Ph./Clinical Pharmacist | X | |
| Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison | X | |
| Kelly Flannigan, Pharm.D../Clinical Pharmacist | X | |
| Shellie Gorman, Pharm.D./Clinical Pharmacist | X | |
| Ronald Graham, D.Ph., Manager, Operations/DUR | X | |
| Chris Kim Le, Pharm.D.; Clinical Pharmacist | X | |
| Ann McIlvain, Pharm.D.; Clinical Pharmacist | X | |
| Carol Moore, Pharm.D.; Clinical Pharmacist | X | |
| Neeraj Patel, Pharm.D.; Clinical Pharmacist | X | |
| Visiting Pharmacy Student: Laurie Terrell | X | |

| OKLAHOMA HEALTH CARE AUTHORITY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Kristall Bright; Pharmacy Financial Analyst | | X |
| Alex Easton, M.B.A.; Pharmacy Operations Manager | | X |
| Mike Fogarty, C.E.O | | X |
| Lynn Mitchell, M.D., M.P.H, Medical Director | | X |
| Nancy Nesser, D.Ph., J.D.; Pharmacy Director | X | |
| Howard Pallotta, J.D. | | X |
| Lynn Rambo-Jones, J.D. | X | |
| Rodney Ramsey; Pharmacy Claims Specialist | X | |

**OTHERS PRESENT:**

Jonathan Klock, Glaxo
Carter McBride, BMS
Lance Stewart, Merck
Ed Riordan; Astra Zeneca
Darryl Davis; Pfizer
Mark DeFreese; Takeda
Barbara Boner; Novartis
Connie Lindsay; Astra Zeneca
Linda Greeson; Pfizer
JoAnne Hargraves; Schering
Tim Clark; Amgen
Steve Goodson; Pfizer
Greg Navarro; Sepracor
Scott Mullins; Sanofi
Jorge Nassar, BMS
Christi Davis O'Brien, AstraZeneca
Patrick Evans, BMS
Robert Calder; Merck
Elizabeth Daily; BMS
Tim Sefcik; Takeda
Terrie Livingston; Novartis
Holly Jacques; Merck
Roger Enix; Merck
Robb Host; Cephelon
Kaye Rote; OMHCC
Geoff Holt; Pfizer
Andy Rubb
Mumkamhat Kamar; Astra Zeneca
Fred Rogers; Glaxo
Mark DeClerk, Lilly
Patti Kommire; BMS
Don Chesler; St. Anthony Hospital
Aliza Tomlinson; Janssen
Jim Wilson; GSK
Tim Myers; Schering-Plough
Jeff Tallent; NAMI
Holli Hill; Sankyo
Angela Menchaca; Amgen
Dave West; Organon
Tyrus Barker; Merck
Janie *"Illegible"*

PRESENT FOR PUBLIC COMMENT:

Terrie Livingston, Pharm.D.; Novartis
Jim Wilson, Pharm.D.; GlaxoSmithKline
Ron Painton, M.D.; Bristol-Myers Squibb
Mohammed Yasin, M.D.; Astra-Zeneca
Don Chesler, M.D.; St. Anthony Hospital
Clyde Cooper, Pharm.D.; Reliant
Timothy Birner, Pharm.D.; Sanofi-Synthelabo
Robert Calder, M.D.; Merck & Co.
Robert Herb; Astra Zeneca
Michael Hunt, M.D. ; Chickasha Clinic, Pediatrics

**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 Public Comment speakers as stated above.

**ACTION:** NONE REQUIRED.

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

**3A: May 11, 2004 DUR Minutes**

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

Corrections requested by Cathy Hollen; (Agenda Item 9, Dr. Hollen's first comment) should be lipoprotein little a; and (Agenda Item 9, last sentence) correct Dr. Hollen's final statement to read Dr. Hollen wants additional review of the statins and their effect on triglycerides .

**ACTION:** MOTION CARRIED.

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

**4A: Retrospective DUR Report: January/February 2004**

Total Drug Interactions (female) were selected for retrospective review for January 2004. Pharmacy and physician responses not received at date of this DUR Board Meeting. Total Drug Interactions (male) were selected for retrospective review for February 2004. Pharmacy and physician responses not received at date of this DUR Board Meeting. Materials included in agenda packet; presented by Dr. Flannigan.

**4B: Medication Coverage Activity Report: May 2004**

The May 2004 activity audit noted total number of petitions submitted was 13,960 including super-PA's and special circumstance PA's. Approval/denial/duplicate percentages were indicated on the reports included in the agenda packet for this meeting. Monthly reports included in agenda packet; presented by Dr. Browning.

**4C: Help Desk Activity Report: May 2004**

Total calls for May 2004 numbered 15,828 (86.5% pharmacies, 7.7% clients, 2.3% physicians, 3.5% other). Monthly reports included in agenda packet; presented by Dr. Browning.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 5:** DISCUSS & VOTE ON PRIOR AUTHORIZATION OF PROVIGIL™

Material included in agenda packet; presented by Dr. McIlvain.

Dr. McNeill moved to prior authorize Provigil™; motion seconded by Dr. Meece.

**ACTION:** MOTION CARRIED.

Speaking at request of Board Member: Don Chesler; St. Anthony Hospital: *Provigil is a little different mechanism than the stimulants and it is a useful augmentation for depression. Normally we would use lithium as a first augmentation and may use an atypical antipsychotic, but Provigil is a good choice. I have fairly limited experience, but I haven't seen as much tendency towards abuse as with the Class II stimulants, so it is a very good option for*

*resistant depressions. Sometimes it's for, you've got someone on SSRI maximum dose, add lithium, no response, maybe add cytomel, no response. Provigil then, if you can get them through the episode, so maybe carry it six months, take them off. There's not a very good guideline for how long to persist with augmentations. You try and get them better. I think the tendency would be if they get better, don't mess with it.*

Dr. Crenshaw moved to approve prior authorization recommendations as follows:

1. FDA approved indications
   a. Narcolepsy
   b. Obstructive sleep apnea/hypopnea syndrome
   c. Shift work sleep disorder
2. Off-Label uses:
   a. Depression
   b. Fatigue associated with multiple sclerosis and/or fibromyalgia
   c. Daytime sleepiness in patients with myotonic dystrophy
   d. Alcoholic organic brain syndrome during the early phase of abstinence
   e. Drug-induced somnolence only for patients with a diagnosis of cancer
3. Maximum approved dosing 200 mg daily, quantity limit of 30 tablets for 30 days.

Motion seconded by Dr. McNeill.

**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 6:** **DISCUSS & VOTE ON PRIOR AUTHORIZATION / PDL FOR "STATINS"**

For Public Comment, Clyde Cooper, Pharm.D.: *Thank you for giving me this opportunity. I am here this evening to talk to you about Lescol XL 80. My name's Dr. Clyde Cooper. I'm with the Medical Affairs department of Reliant Pharmaceuticals. Just first off, to start out, Lescol XL, also Fluvastatin, is approved for primary and secondary prevention of coronary events. I'll just walk through these slides that I've provided for you. Lescol XL 80 is really, should be considered almost like a new drug. It's not the IR. The IR was much weaker and less potency and with the encasing of the active ingredient in a polymer gel matrix, it avoids immediate release, avoids hepatic saturation, avoids plasma concentration in a peak plasma concentrations, increases the pharmacodynamic effects. These changes make it a very effective drug. According to the Valentine Study in Clinical Therapeutics in 2001, the LDL was lowered a median decreas of 38% of four weeks and a mean reduction of 36%, and 40% of the respondents in this study achieved a decrease of 40%. HDL has acheived more recognition and importance recently in some discussions and Lescol XL 80 has a median increase of 11% with a range of three to twenty. This range is dependent upon the total tryglycerides and the range of the tryglycerides themselves. The tryglycerides are decreased a median of 19% and up to 25%. With the level of effectiveness, with a 38% lowering and a LDL of 190 can be lowered to 118. This exceeds the NCPHB3 guidelines with two-plus risk factors. It should be noted that 95% of all U.S. adults have less than 190 mg LDL. Lescol XL is effective with a 38% lowering and an LDL of 160 would be lowered to 99. This is definitely in the range of those with coronary heart disease. With a 38% lowering, an LDL of 135 would be lowered to 84. If you went to some of the LDL levels when some of the PROVE-IT trials netted to 115, that would be in the same ballpark showing Lescol is effective. The XL 80 is comparable in effectiveness for 40% LDL lowering to the other products, 10 mg Lipitor; Lovostatin 40, 80; pravastatin 40 80; rosuvastatin 5 and simvastatin 20. The big advantage to Lescol is it's known in history of safety as well as efficacy. It is not metabolized by the cytochrome P450 isoenzyme, and so it's not . . . it's safer with cyclosporin, gemfibrozil, niacins, antifungals and some of the calcium channel blockers like Norvasc or amylodipine. According to the Medical Letter of 2001, there was no change in the statin concentration with again, fibrates, protease inhibitors, cyclosporin, erythromycin and some of the other drugs. So interactions are more common with statins and common drug metabolized by the cytochrome P450. Recent labeling changes indicate that the use of simvastatin in doses greater than 20 should be avoided and also for amiodorone and verapamil and avoid the doses greater than 10 for combinations with fibrates and niacin. There is a labeling warning with rosuvastatin with cyclosporin. According to Mengazzi and the American Journal of Cardiology in 2002 when the CPK for Lescol and placebo were compared, the CPK elevations were greater with a placebo than they were with Lescol 80. Lipids, in the LIPS study, there was absence of notable CPK and liver enzyme elevations. There were no differences in overall adverse events between the groups. There was no rhabdomyolsis reported with fluvastatin, and the reported cases of fatal rhabdomyolsis for all statins marketed in the U.S. Now according to the drug effectiveness review project, it kind of says that this is, because this is based on a volunteer reporting system, reported to the FDA, the adverse event reporting, and but this still has relevant merit, I believe, and the fact that there were no cases of rhabdomyolsis reported in the United States with fluvastatin. There's minimal risk for rhabdo and myopathy according to the drug effectiveness review project again, a review of*

*statins using fluvastatin up to 80 mg in organ transplant patients receiving cyclosporin identified no cases of rhabdo. Increased concentrations of simvastatin, lovastatin, or atorvastatin when used in combinations with the protease inhibitors may result in an increased risk for myopathy and rhabdo. Rhabdomyolsis and myopathies, a systematic review. This is again based on the effectiveness review. Well basically, it's a very safe product. I would want to mention that the V.A. has replaced Pravachol with Lescol and has adopted the criteria. Since simvastatin, lovastatin, and atorvastatin are metabolized by P3450 system that fluvastatin be used in combination therapy to avoid myalgias and any patient with myalgia with or without documented CPK elevation, and I will just jump then at my time to the end and simply say, if effectiveness is equal among the statins for patients who require LDL reductions up to 40% to meet their goal, and that's based on the statement from the drug effectiveness review project, then safety becomes the major concern. If you need a statin that has few drug interactions, minimal instances of myalgia and myopathy and rhabdo. A drug that can be used safely with fibrates and niacin, cyclosporin, protease inhibitors, etc. that can routinely be used for LDLs of 190 or less, and you need a statin for high end reduction for those patients who need, are greater than 190. Thank you.*

For Public Comment, Robert Calder: *I'm a physician. I've been with Merck for fourteen years. Prior to that was state epidemiologist in Florida and before that I was right down the road as a preventive medicine officer at Ft. Sill. The most important thing to remember about Zocor is that as a result of two landmark trials, it's indicated to reduce the risk of total mortality by reducing CHD events to reduce non-fatal MIs and also to reduce coronary and non-coronary revascularization procedures. So it's indicated to do what you want to accomplish in patients who are at high risk of coronary events regardless of LDL level, so that's a mouthful but that's what it's indicated . . . it's indicated to do what you want a statin to do. With respect again to diabetic patients in the heart protection study with Zocor 40 which my colleagues just handed out, there was also a sub-study published June 14th of last year in diabetic patients. There were almost 6,000 diabetic patients in the heart protection study with Zocor 40, that's four times more than all other statin trials prior to that time, all other statin outcome trials, four times. So we have terrific data in diabetic patients and I know that's very important to you here in Oklahoma. Next point, LDL is a surrogate for what you really want and that's the outcomes that I just mentioned. You're lowering LDL in hopes that you're achieving the outcomes that Zocor is indicated to do. And Zocor, one final point that I'm sure is important, economically speaking, and that is that Zocor will go off patent almost exactly two years from now, 10-23-2006, and so I'm sure that that affects the economic calculations. And in summary, we request that you add Zocor to Tier One without prior authorization. With the remaining five minutes, I'd be happy to answer any questions.*

Dr. Graham: *I'd like to ask you a question, doctor. What's your feelings on the recent decision to go over the counter in England?*

Dr. Calder: *I think the decision for over the counter statin products is, has certainly some public health benefits. I think as long as you're staying at doses that have been shown to have basically no adverse effects on CPK, no adverse effects on liver function tests, you know, I think that there is a public health advantage to giving, you know, very low doses like 10 of Lovastatin, low doses of Pravachol, etc. to people. I think again, as a public health professional, I'm an epidemiologist, public health preventive medicine board, and I see that as a positive. I think that the more we can do to use proven products, the better. Other questions? Thank you.*

For Public Comment: Dr. Yasin: *I'm Dr. Mohammed Yasin and I'm a clinician and also a researcher. I've done a reasonable amount of research on statins, including participating in a couple of landmark studies which was decreasing atherosclerotic plaque in the coronary arteries which was published in JAMA last year, and I have considerable experience using statins as well. Statins are all effective drugs but latest studies which were published including REVERSAL trial and PROVE-IT trial proved that lower the LDL is, better it is in coronary artery disease at least. And so in PROVE-IT trial the LDL was brought down to 60's so we needed a stronger drugs to lower the LDL level to be, to make a difference in these people. And the two drugs which are very, very effective in doing so is atorvastatin, which is Lipitor and rosuvastatin which is Crestor. And the advantage I think of Crestor over Lipitor in just one regard that it increases HDL a little more than Lipitor does. So that the ratio of LDL and HDL is better with Crestor. And I've used Crestor quite a bit in my own practice, and it's a fairly well tolerated drug. I haven't really have problems with the patients I have it used on, and I have gotten very good results with basically 10 mg, most are 10, I have only a couple of patients on 50 mg and actually the recommendation from the company is also to use 10 mg to start off. If you really want to make a difference and really bring the LDL low . . . I don't know what the low is . . . how low is low? Because we have no idea how low is low. We only that up to 60 makes a difference. Is below 60 very good? Maybe it is. Maybe it's not. We don't know.But the lower the levels are, the better it is and I think these drugs are very effective in doing so, and from the public heath standpoint, I think we should have these drugs on the formulary. If you have any questions, I'd be more than glad to answer your questions.*

For Public Comment: Robert Herb: *Hi. My name is Robert Herb. I'm with medical affairs with Astra Zeneca and I am going to be talking on two items, number six and number nine, so I'm getting clarification from the Chair as to whether I have . . . just stay with six? Well, as Dr. Yasin mentioned, rosuvastatin or Crestor is the new statin to market. We currently have four million prescriptions and over 1.6 million patients currently on Crestor. As he also*

*mentioned, recent data suggests clearly the notion that reducing LDL levels is a cornerstone of dyslipidemic management, cardiovascular risk reduction. However, most clinical trials that you see being discussed, including REVERSAL and PROVE-IT look at doses that are at the high end of that statin profile, i.e., the 80 mg doses of atorvastatin or 40 of Pravachol. What's interesting is that the observation is that clinicians in the U.S. particularly do not use high dose statins and usually are more likely to use lower dose statins. They only up-titrate if necessary. Given that fact and the dose response relationship associated with side effects rosuvastatin provides an opportunity for you to achieve a significant, at least 50% reduction in LDL at a 10 mg dose. Now what that equates to in terms of reaching ATB3 goals is that you're going to expect 80+% of patients to reach their ATB3 goal independent of their risk of spectrum in terms of Framingham at that 10 mg dose. There also is some interesting information that was recently published in Europe at the European Atherosclerotic Society meeting in which Crestor was compared to atorvastatin with regards to diabetic populations specifically and across the dose ranges, LDL lowering was more greater or more significantly accomplished than when compared to atorvastatin. Finally, there was some questions in the literature about CRP levels and clearly we now know that there is now published work on rosuvastatin showing a 30-40% reduction in CRP at the 10 and 20 mg doses. I would be remiss if I did not emphasize not only the efficacy of rosuvastatin but also the safety profile and I want you to be clear that Astra Zeneca's committed to a safe and effective product and that the safety of patients is our utmost concern. We following post-market surveillance over the time that the drug's been on the market, since September in the U.S., we have been exhaustive in our approach of evaluating that data and submit quarterly reports to the FDA. We are no more than two days away from any adverse event in the U.S. and six days away from any adverse event in the world and I am happy to say that the safety profile of Crestor is consistent with the class and is consistent with the U.S. labeling as we now find it. I would be happy to answer any questions relating to this or any other topics surrounding rosuvastatin and I would ask the Committee to consider rosuvastatin as a therapeutic option for those patients needing significant LDL lowering without prior authorization.*

Materials included in agenda packet; presented by Drs. Le and Gorman.

Dr. McNeill moved to accept the College of Pharmacy's recommendations of Tier-1 drugs; second by Dr. Gourley.

1. Lescol™ and Lescol XL™
2. Lovastatin (generic only)
3. Lipitor™

**ACTION:** MOTION CARRIED.

Dr. McNeill moved to accept the College of Pharmacy's recommendations of criteria with stated language change (remove "to high" from Criteria 1); second by Dr. Gourley.

1. Previous failure to achieve desired LDL or Triglyceride reduction with an initial statin – defined by at least 6 weeks of continuous therapy at standard dose.
2. Previous stabilization on non-preferred medication. (grandfathering)
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.

**ACTION:** MOTION CARRIED.

**AGENDA ITEM No. 7:** **THIRTY DAY NOTICE OF INTENT TO PRIOR AUTHORIZE FUZEON™**

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

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 8:** **THIRTY DAY NOTICE OF INTENT TO PRIOR AUTHORIZE / PDL "SSRI's"**

For Public Comment, Jim Wilson, Pharm.D.: *Good evening. I'm Jim Wilson. I'm a regional medical scientist with GlaxoSmithKline. I'm an employee of GSK. Prior to that, I was 27 years teaching College of Medicine pharmacy and nursing at the University of Nebraska. I'm still at clinic one day a month and keep in touch with what's going on. In front of you is a set of slides. There's about 20 in there. I want to pay particular attention just to seven of them and I'll go by the number on the slide number, not the page number. On slide number 3, the most important part of treating our psychiatric patients with antidepressants is improving their tolerability and their compliance or adherence to taking that medication. On slide 4 you see that according to EH Lin at about 4-month period of time*

*we lose about 50% of compliance or adherence to taking their medications. On slide number 6, Paxil CR is a formulation developed by GSK and is not a patent extension. Patent runs out exactly the same time as the old IR formulation on December 29th, 2006. And it is a special formulation that gives a sustained release after slipping into the small intestine to reduce the serotonin surge that occurs when you have a reuptake blockade occur with an SSRI. That has resulted in several good possibilities of tolerability with this particular preparation. On slide number 9, you'll see the bottom line, the take home at the end of the day. What happens when you take Paxil CR. There are four depression trials. We have a 7% dropout rate versus 6. With our panic disorder trials, we had 11% dropout rate versus 6. At our social anxiety disorder trials we had a 3% dropout versus 2 with placebo. On slide number 11, we've used a national managed care database which includes 36 million patients, 61 managed care organizations. Looking at data in a six-month period of time where the index date was the first day that a patient began an SSRI. On slide number 13, during that particular time, you'll see the changes between the other SSRI's and Paxil CR in tolerability over that period of time of six months. But I want to draw your attention to the first part of that chart which really got our attention up in Nebraska, and that's that 30-day first dropout period of 30%. We lose 30% compliance right out of the chute where they're not coming back for their refills and they're ending up costing us money in other places in the mental care area. Very, very concerned about that. Our clinic is trying to deal with this in different ways. On the bottom of slide 14, you'll see Paxil CR in significantly better, about 10% better tolerated, about 10% better compliance, than the other SSRI's in this comparative trial. Effexor was also looked at this trial but was not included in this data because it is not considered a true SSRI because it is a dual mechanism item. On page, excuse me, slide number 14B . . . I got a little carried away. I forgot about 15 and 16, so I just went A and B on 14, so please forgive me. It was about 2:00 in the morning. But time to discontinuation D Sheehan reported these results at the recent APA three weeks ago where Paxil CR versus Paxil IR is compared and a significantly different tolerability occuring with an increase in compliance with CR. Then my last item, the end of the day money, the economic results of that on slide 17, the top part of that is a monthly medical charge, a monthly antidepressant charges, and the difference for any indication. In other words, these clients came into a clinic and they were given an SSRI or given Paxil CR and Paxil IR for just about anything, whatever, they didn't code it with any particular situation; and you see a cost savings there of $59 per month. Now when they were coded with either major depression, social anxiety disorder, or panic, the cost savings rose to $109 per month on total costs of that patient in that particular care organization. So that's kind of the bottom line on slide 19. The formulation makes a difference. We have excellent placebo controlled clinical trials with this particular product. Our adherence, our compliance is about 28% versus the other SSRI's at 35% with CR versus old Paxil IR, and the cost savings is $59 per month difference on non-indication and $109 a month difference on indication specific information provided by the health care organization. Attached to this handout is an executive summary of more specific data and also our newest package insert with CR prescribed extra warnings dictated by the FDA. I'd be glad to answer any questions at this time.*

17

For Public Comment, Don Chesler: *Thank you. I'm Don Chesler. I'm an M.D. at St. Anthony Hospital, Chairman of the Department of Psychiatry. Well, first of all, I want to thank you for adding me on and I know that I was a late addition. And thank you for the hard work that you do and I know you have a lot of eyeballs on you. I was thinking last time I was here that Paxil and Prozac were the bad boys, now they're the good boys, and so that's one of those changes . . . I think it was two years ago that I was here. Just general comments, maybe it gets to be an old horse to beat, but open formulary is something we all hope for and realize that maybe it's not a reality in this world, but I know that, well when it comes down to failures, medication failures, we do measure it as far as Hamilton deep points, but also we measure it in terms of admissions which may cost some extra money. Other outcomes, impulsivity, what Dr. Wilson said, very true that people drop off of these medications due to problems with being able to tolerate them. That's the main reason that we're always asking for more options on these. So that's maybe the emotional argument. Now the scientific argument, or the evidence based argument is that there are some significant differences with regard to enzyme, P450 enzyme systems. Paxil, Prozac, Lexapro at higher doses have two of these six inhibitions, so you do get into some drug interactions at 2D6 which includes some of the antipsychotics which, which many of these people may be on with comorbid conditions. And then the other thing is that, you know the focus goes beyond just depression. We're talking about anxiety disorders and then that gets into the indication issue, and Paxil, Paxil CR, Zoloft have been the ones that have done the clinical trials to get indications for the anxiety disorders, so the, the breadth of anxiety disorders including panic disorder, obsessive compulsive disorder, generalized anxiety disorder, PTSD . . . we've got a lot of PTSD in Oklahoma, that tends to slice those two options in Paxil in its' forms, and also Zoloft in its' forms. I know another one that separates Zoloft is that they've done more trials on child and adolescent, so they have a unique indication down to six as far as OCD goes, so there's a lot more attention on us there, so . . . again just in general a call for open formulary and also the, to keep the option of Zoloft, Paxil, Paxil CR as available choices.*

Materials included in agenda packet; presented by Drs. Le and Gorman.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 9:** **THIRTY (30) DAY NOTICE OF INTENT TO PRIOR AUTHORIZE "ARB's"**

For Public Comment; Ronald Painton: *It's nice to be here, thanks. I'm Ron Painton and I'm an endocrinologist out northwest seeing patients. I just wanted to make a, say a few words, I'll make it short, on the ongoing thinking about kidney protection in treatment of high blood pressure and people with diabetes. I numbered these little piece of paper you have, and I'm not going to go through these in detail, but the current thinking probably is summarized on the first, and that is that if I can use terms like ACE and ARBs, I'm sure most of you know what I mean by that. The ACEs have been shown to delay progression of nephropathy in Type I's and Type II's, both ACEs and ARBs, the angiotensin converting enzyme inhibitors and the receptor blockers have been shown to decrease progression from microalbuminuria into macro, in other words, overt kidney disease in Type II's, whereas the data are more strong with ARBs in Type II's with hypertension, particularly when they already have renal insufficiency, and as you know, Type II diabetics, about 80% of excess mortality relates to macrovascular disease . . . strokes, heart attacks and certainly kidney disease. The next two really just summarize some things I won't bore you with. You know the diabetics have a high incidence of hypertension, many times not treated well. They progress to kidney disease very rapidly if untreated and many times, by the time we see Type II diabetics diagnosed, as many of you already know, they've actually been diabetic for years and we didn't know it. And they were undiagnosed until they finally become hyperglycemic and that's why so many times by the time we see them initially, they already have heart disease and kidney disease and the like, and then we have to make decisions on treatment. On three you know that, of course, diabetes is a major cause of renal disease, and four really just has to do with the use of irbesartan or Avapro™ brand name relates to the JNC seven guidelines concerning hypertension treatment. Pay attention particularly to number five. One of the reasons that I've found Avapro™ or irbesartan so effective in hypertension, particularly in my patients, being an endocrinologist in Type II diabetes, notice how it compares to the other ARBs, inserting the half life biovailability degree of AT1 blockade and then the, very importantly I think, the inhibition of, or at least blockade at the end of the 24 hours, and that's why, for example, irbesartan is so effective as a single dose. Now the last is really just comparing irbesartan to losartan, one of the other ARBs that we use and you can see it has a nice effect on blood pressure comparably. The discussion is on-going concerning which you use. I would urge you to consider that physicians should have a choice of both, and as a matter of fact, the ABA within the last couple of years has come out stating that ARBs should probably be considered the first line of therapy for kidney protection and high blood pressure control in Type II diabetics. And if I didn't say it before, I'll say it one more time, that about 90% of type of diabetes is Type II. I personally use a lot of combination therapy, ACEs and ARBs together, for blood pressure control. In patients who even respond to an ACE, sometimes they develop a cough as you know, perhaps 10% or so, sometimes you have to make a change at that point, so from my standpoint, I would certainly like to see both an ACE and an ARB as considered at the top tier. I hope that makes some sense. Thanks.*

For Public Comment; Terrie Livingston, Pharm.D.: *Hi, I'm Dr. Terrie Livingston. I'm one of the regional account scientific directors with Novartis Pharmaceuticals. What I wanted to do today was give you a brief overview of Diovan™. Diovan™ is an angiotensin receptor blocker that I'd like the Committee to consider. Keep in mind that the new JNC7 guidelines recommend ARBs now as first line therapy for hypertension. What differentiates Diovan™ from the rest of the other ARBs is the depth and breadth of the clinical data that supports the use of valsartan across the cardiovascular continuum. First, beginning with hypertension in which there are multiple studies that have demonstrated valsartan's efficacy in comparison to other antihypertensives and has shown and demonstrated either equal or superior efficacy. There is also data to support the use of valsartan in special populations, meaning difficult to treat or high risk patients. And so the ARB studies that have supported its' use in systolic hypertension isolated systolic hypertension as well as in the African-American population. Diovan™ has superior tolerability with a side effect profile that's been comparable to placebo. There was a study done by Wilgan and colleagues that looked at enhanced rates comparing amlodipine, lisinopril and valsartan. Valsartan was shown to be superior to amlodipine and lisinopril in terms of patient persistence and compliance. Valsartan is the only ARB indicated for heart failure, and this is based on the Val-HeFT study. It did demonstrate an overall reduction of heart failure morbidity of 13% and there was, the biggest benefit with valsartan was in the group that was not on an ACE inhibitor, and in this particular group there was a 41% reduction in all cause mortality, a 49% reduction in heart failure morbidity, and a 57% reduction in heart failure hospitalizations with valsartan. Dean Smith's group at the University of Michigan also did an economic impact of valsartan in particular to the Val-Heft results and they found that valsartan did provide a net cost savings strategy for the treatment of heart failure, so they not only increased survival but also decreased the overall costs associated with heart failure treatment. Based on the MARVAL study, this study was a study in Type II diabetics with or without hypertension and then compared valsartan to amlodipine in patients with microalbuminuria. And in this particular study, there was a 44% reduction in microalbuminuria*

*with valsartan compared to amlodipine, which only had an 8% reduction. In addition, 30% of the patients returned to normal albuminuria as compared to only 14.5% of the patients treated with amlodipine. And finally, I'd just like to address VALIANT which the results were released at the American Heart meeting this past November, and this was a study in post M.I. patients, and in this particular study, they demonstrated that valsartan was as effective as captopril in prolonging survival in patients post M.I., as well as preventing recurring M.I.'s and heart failure hospitalizations. So I'd just like to end with asking the Committee to consider the use of ARBs as first line therapy for the treatment of hypertension based on efficacy and safety, as well as the JNC7 guidelines. And specific to Diovan™ to consider evidence based medicine in which Novartis has demonstrated its' commitment across the cardiovascular continuum with over 45,000 patients participating in large outcome trials, beginning with Val-HeFT in heart failure patients, VALIANT for post-M.I., VALUE in high risk hypertensive patients which we actually will have the results very soon, and then the NAVIGATOR trial which is our large prevention trial. Thank you.*

For Public Comment, Timothy Birner, Pharm.D.: *Good evening. My name is Tim Birner and I'm a national medical manager with Sanofi-Synthelabo and I'm here to speak to, about irbesartan. We also already had a speaker, obviously on irbesartan so I'll only take a few minutes. I guess in some ways I disagree with the previous speaker where she is encouraging the use of ARBs as first line treatment for the treatment of hypertension. I think I actually where the opportunity for a drug like irbesartan is, specifically in patients with Type II diabetes. In your handout on page 54, there's a comment to that. There's no evidence to establish that ARBs should be used as initial therapy over ACEs or any other hypertensives. And because of that, your recommendation is to only in prior auth ARBs when a patient cannot tolerate an ACE, and I hope I can explain to you why we at Sanofi don't think that's a good idea. In the 2004 ADA guidelines, A level evidence, they recommend the patients with diabetes mellitus be treated to a diastolic of less than 80. JNC7 also recommends that diabetics be treated to less than 130/80. Oftentimes as you know, patients with Type II diabetes and hypertension are very difficult to treat and so that's a very aggressive goal and requires often two to three or four different therapeutic categories of medication. They do say that initial drug therapy may be with ACEs, ARBs or beta-blockers. Hypertensive Type II diabetic patients with microalbuminuria or clinical albuminuria, the ADA guidelines say that ACEs or ARBs have been shown to provide benefit. Because of, specifically, the IRMA 2 study with irbesartan, that's why they included ARBs in that recommendation. There was a 70% risk reduction in the progression from microalbuminuria to avert diabetic nephropathy in our IRMA 2 study. IDNT though, is the reason for this, the ADA guideline on diabetic nephropathy, and it's already been mentioned, but in those patients with Type II diabetes, hypertension and macroalbuminuria or diabetic nephropathy, the ADA recommends that an ARB be strongly considered, and that is based on the IDNT study that was published, a Dr. Lewis in the New England Journal of Medicine, which demonstrated that irbesartan reduced the composite risk of progression of renal disease and total mortality, independent of its' blood pressure lowering effect. Avapro™ is only one of two ARBs that are approved for the treatment of diabetic nephropathy, and the other agent is Cozaar™, so I would ask you to consider either one of those agents actually, because if you require that a patient fail on an ACE inhibitor, you're not giving the clinician the opportunity to use one of the two drugs that are approved for the treatment of diabetic nephropathy, and that's about 15% of Type II diabetics that have diabetic nephropathy. Avapro™ is FDA approved at 300 mg. It's the only FDA approved medication with a target dose. Overall, Avapro™ has numerous studies that have produced evidence that it has comparable efficacy to enalapril and amlodipine and atenolol, and it has several head-to-head studies that shows greater blood pressure reduction compared to losartan or Cozaar™. The renal protective benefits of patients with hypertension, Type II diabetes, and diabetic nephropathy has been demonstrated in the IDNT study and also in the losartan study called RENAAL, so again, I would hope that you would reconsider prior authorizing all the ARBs and at least consider having our data pro available for those patients with Type II diabetes and diabetic nephropathy. Do you have any questions? Thank you for your consideration.*

For Public Comment; Robert Calder: *Thank you once again. Cozaar™ has three indications. The first is of course, hypertension alone or in combination with other agents. The second is in the treatment of diabetic nephropathy as we just heard very nicely stated. And the third, to reduce the risk of stroke in patients with hypertension and LBHN. Surprisingly, that wasn't listed in Appendix G, page 52 of your material that I got on your website. What I'd like to do very briefly while my colleague is handing out a reprint is to discuss the two studies that support, the study that supports a diabetic nephropathy indication which is, was mentioned, the RENAAL trial, and the study that supports our stroke indication, which is the LIFE trial. And so those two trials are now in your hands and I will very briefly and well within my five minutes, discuss the highlights in each of those. The RENAAL trial, which stands for Reduction of Endpoints in NIDDM with the Angiotensin II Receptor Antagonist Losartan . . . you can tell why we call it RENAAL . . . was a randomized placebo controlled trial in 1,513 patients with Type II diabetes with nephropathy. The trial was randomizing people initially to Cozaar™ 50 or placebo on a background of conventional therapy. And the dosing was raised to 100 of Cozaar™ if the blood pressure goal of 140/90 wasn't met. And the mean duration was 3.4 years of follow-up. The primary endpoint was a composite endpoint of doubling of serum creatinine, end stage renal disease, or death. And there was a 16% significant reduction in the primary*

*endpoint. With respect to the components of that primary endpoint, there was a 25% reduction in the sustained doubling of serum creatinine, between 9% reduction in end stage renal disease, and a . . . however there was no effect in overall mortality. Secondary endpoints were a decrease in proteinuria by 34% and a decrease in the rate of GFR decline by 13%. I think the, that a very important result of the RENAAL trial is that the economic analyses of it are very simple. And they're simple because it's . . . this works simply in that delaying the onset of end stage renal disease saved a lot of money and that's why the economic analysis we have of this is quite simple. Turning to the LIFE trial, which stands for Losartan Intervention For Endpoint reduction . . . that was also a randomized double blind trial comparing Cozaar™ with atenolol in over 9,000 hypertensive patients with LDH. Again, started with Cozaar™ 50 or atenolol 50, and if the blood pressure goal of 140/90 wasn't met, then hydrochlorothiazide was added and ultimately the dose of either atenolol or Cozaar™ was increased up to 100. And the average dose at the end of the study was 80 mg for both atenolol and Cozaar™, by the way. 54% of the patients in the study were female, 6% were Black, 13% were diabetic, 14% had isolated systolic hypertension. The mean duration was 4.8 years, primary endpoint. There was a 13 . . . the primary endpoint was a composite of CV death, non-fatal stroke and non-fatal M.I. There was a 13% reduction in that primary endpoint, but that was driven mainly by a 25% reduction in stroke. However, there is no evidence of benefit in Black patients for stroke. There are two sub-studies that were pre-specified for the LIFE trial, and one was in diabetic patients . . . there were almost 1,200 diabetic patients, and that sub-study showed a 37% decrease in death due to cardiovascular causes amongst diabetic patients. And a 39% decrease in all caused mortality in diabetic patients. And in the patients who had isolated systolic hypertension, there were 1,326 of those patients . . . a 46% reduction in death due to cardiovascular causes and a 28% reduction in all caused mortality. So some very good data, I'm sure you'd agree, in both the LIFE and RENAAL trials, and on the basis of these trials and the evidence presented, we request that Cozaar™ and Hyzaar™ not be prior authorized, especially for diabetic patients. I'd be happy to address any questions.*

For Public Comment; Robert Herb: *Again, I'm Robert Herb from Astra-Zeneca medical affairs, now talking about Atacand™ or candesartan and being handed out is the PIs as well as some new data in heart failure. I'd like to focus my comments, and I'll make sure I don't take more than five minutes, on three specific areas regarding Atacand™. One is PK differences, pharmacokinetic differences, one is its' effects on hypertension, and finally, and probably most importantly, new mortality data in heart failure, specifically the CHARM trial. As you know, ARBs are not all created equal, although they're similar. Their blood pressure effects are not exact. In fact, we have a superiority claim in our label in comparison to losartan with regard to hypertension. Atacand™ also does not have interactions with the CYP-450 pathway, particularly the 3A4 cytochrome which provides again, additional advantage over losartan. We have true QD dosing which provides a true 24-hour blood pressure control and we also have no food interaction, which I think is something that is relevant to the Committee to consider. Again I want to reinforce the hypertension superiority claim within our label when comparing candesartan to losartan, specifically the claim studies. And finally, I'd like to point out to you that Atacand™ as an ARB is the first positive trial to demonstrate truly positive clinical trial in patient populations with heart failure. I've noted in your, in some of your web documents that you have over 13,000 patients which are heart failure patients and that CHARM data was broken down to people ACE tolerant and intolerant as well as those with normal and abnormal left ventricular functions, and CHARM data and our pending label change with regard to heart failure differentiated from both valsartan and the Val-HeFT trial as well as losartan and the ELITE I and II trials, and again, that change in our label is pending with the FDA. I'd be happy to answer your questions about that.*

Materials included in agenda packet; presented by Drs. Gorman and Moore.

**ACTION:** NONE REQUIRED.

For Public Comment; Michael Hunt: *Good evening. My name is Michael Hunt. I'm a pediatrician in Chickasha and I'm here not for any agenda item, but to sort of talk about pediatric issues in general and my trials and tribulations in Grady County. My practice is about 50% Medicaid, and in that fact, about 10% of my patients every month are new because of inability to follow the rules of Medicaid, so because I have contracted with Medicaid to have at least 500 patients minimum, every month up to 50 or 100 patients can be brand new, which means I might have never seen them. I might have seen them two, three, four months ago. So I've come here because of two big issues with prior approvals. And those prior approvals really are in the mental health attention deficit issues, and with asthma that I heard at the last meeting. Right now, I have a lot of kids who are having issues at school, school performance, and on attention deficit medications . . . Concerta™, Metadate™, Adderall™ and unfortunately, because of the way Oklahoma Medicaid and the Health Care Authority is allowed for those medications, we like to use generic drugs. Generic drugs, in my opinion, have been very harmful. It's taken me a lot of time to overcome generic drugs and it's taken a lot of time to get the medications that some of these kids come to me with to be approved of, and that takes a lot of staff time, a lot of office time, and a lot of clinic time. Each of these kids comes to*

*me on a fixed . . . you know, we're all now on Medicaid, and we all get the same amount of money per child per month. We're all capitated and so here are my issues. Number one is I have children who come brand new who have been on medication before. I don't have any medical records and I have to get them prior approval for the medications that they were on in order to get Concerta™, Metadate™, Strattera™, whatever have you approved, because they're non-generics. My second problem is with generics, you know, if you look at the . . . there's a classic trial for generic Tegretol™ that showed that there was a variance of 25% in the blood levels of generic Tegretol™ versus brand Tegretol™. Same thing goes with Adderall™, or with any of the stimulants for attention deficit. So one month, depending on which generic drug they get, they may have a 25% variance. So month they do very well, the next month my patients are doing worse and we're seeing them several times in the office. So that's been why I'm here today is number one to say, please, please, please let's re-think the generic versus stimulant class of medications for attention deficit because I have found that it takes me a lot longer from a clinical point of view to get kids stabilized on generic drugs than it does on some of the name brands. The other thing that I kind of understood from the last meeting that I attended last month was for asthma, Xopenex™ might need prior approval and there was a statement that said there was no efficacy or betterment of using Xopenex™ versus albuterol solution. And I can tell you there's a lot of studies, I didn't bring them with me, that says that Xopenex™ is by far better in pediatric cases at least, that shows that we get kids out of the hospital a lot quicker. The side effects of asthma treatment is a lot better when they don't have any tachycardia, when they don't have the jitteriness, they respond a lot better with Xopenex™, and for me to have a prior approval for Xopenex™ in all my kids, but again add yet another stage to my staffs' getting a prior approval. The third thing that I noticed is that you wanted to make prior approval for SSRIs. Again I come back to my kids with attention deficit. You know, if you look at the literature, 20 to 30 to 40% of kids who in attention deficit have a comorbidity, I'm in Chickasha, I'm not putting Chickasha down, I love Chickasha, but I can tell you more than 60% of my kids who have attention deficit have another comorbidity. They have depression, conduct disorders. If I have to yet do another level of paperwork to get an SSRI approved for their depression, oppositional defiance, etc., we're creating . . . a lot harder. The third thing I'd like to say is you have to look at my patient population. My patient population, if you go, they go, I give them a prescription. They go to the pharmacy. The pharmacy says it's not approved. Some of these people are so unwilling to fight for themselves that they will just go home. And in fact I've had two cases . . . one child actually burnt his room down because of his unability or inability of getting that prior author . . . approval completed. They never called me. They went home. Child went and did his thing because he didn't get his medications and now I have a child who's back to square one. These things are important to me, I'm here because prior approvals are a headache for me. I know there's a necessary need for them in some instances, but I just need to let you know what my patients and what I are experiencing in the field because of all the prior approvals that are facing us. Thanks for letting me speak. Have a good day.*

Dr. McNeill: *Could I ask a question? The . . . in our practice, we have about 60% or greater Medicaid, as well, and I haven't really addressed this, but if a new patient . . . and we do have a lot of new patients every month, new ones come on, a lot of other ones we never see again, so I share your pain there. But new patients coming into a practice, if they've been on something that's a Tier-2, and I refill it, when it gets to the pharmacy, you have documentation that they've been on, say Concerta™. . .*

Dr. Nesser: *If they were on Medicaid.*

Dr. McNeill: *. . . regardless of who writes it.*

Dr. Nesser: *Right. If they were a Medicaid patient who was just changing physicians, yes.*

Dr. McNeill: *And that would qualify as continuation of therapy, regardless of the PCP.*

Dr. Nesser: *Uh-huh.*

Dr. Hunt: *That is what I've heard in . . . from them, but in practice I can tell you that, after that 30 days is up, I've been told that without being put them back on generics, they've denied. I mean, I've spent two or three months trying to get kids who were once on Concerta™ back off of . . . onto Concerta™ after that 30 day, after I had gotten them, because I was supposed to do something with them. And I have . . . I won't change them. I mean I'll get them, I'll keep them on it and I have had to fight that battle of saying, here are the records . . . they've been on it. They say well, you know . . . they have to have a trial of . . .*

Dr. Nesser: *That was on Concerta™ or that was on a combination of Strattera™ and a stimulant, because that's different.*

Dr. Hunt: *They were on Concerta™.*

Dr. Nesser: *Yeah, and I know also that you personally have taken a lot of clients who were on an HMO who had different coverage and now are on fee-for-service.*

Dr. Hunt: *Right, and so maybe . . . the other thing is, is . . . what I think is also an issue is using more than one, you know, one product. I'll use a lot . . some stimulant, some Strattera™, you would use the stimulant and the SSRI, I mean there's, you know, the pediatrics is involved to the point where we're trying to do more with what we have and*

*that has been another issue is having Strattera™ and Concerta™ for a stimulant, and that has been an on-going issue where there's a lot of issues that says that from the pharmacy side, the Strattera™ hasn't been . . .*

Dr. Nesser: *There's no medical evidence.*

Dr. Hunt: *. . . evidence.*

Dr. Nesser: *Right.*

Dr. Hunt: *Well, but they have proven in the literature I've read, is that Strattera™ is just as efficacious as for certain populations of kids with attention deficit as a stimulant is, and so you know from, in your practice, when you see them, I mean, there's a place for that non-stimulant to work versus the stimulant, and using them both at the same time has also been a problem.*

Dr. Nesser: *Right. And you, the criteria for Strattera™ is the same as for Concerta™. It's when you get to using them both together . . .*

Dr. Hunt: *Both at the same time.*

Dr. Nesser: *. . . there's absolutely no evidence.*

Dr. Hunt: *Well, there's not going to be evidence for a good long time. There is a study that I think that is out, that is coming out by Lilly that will show that has looked at that but I don't think it was looked at for positive reasons. I think they were trying to show themselves as separate. I think the mechanism of action is so unique to Strattera™ versus the stimulants that I think that there is a huge place in those kids that are . . . that are not quite as hyperactive as their counterparts that are pure stimulants but don't get . . . who don't need . . . there are, there are two different types. The attention deficit with hyperactivity and attention deficit without hyperactivity. Strattera™ in my opinion has been very helpful with those kids without hyperactivity, however there is a point where you get, where you're having to give kids a large dose of a stimulant such as Concerta™ or Metadate™. And I've had to push over 100 mg. Parents get scared, doctors get scared, pharmacies get scared, and so you tend to drop that dose down and start a second medication to try to get them through. And I've also found that's where the Strattera™ really works nicely so you don't have to go to the over 100 mg dosages for a stimulant and you can keep it down to the ranges that are required. For instance, you know, Concerta™ has been the, the PI says that it has been mostly effective after 54 mg, there's a lot of data that shows it, up into the 100's, but hasn't been published as frequently. If you can't get it approved at over . . . at 75 or you know, doing a 54 in an 18, do a 54 and you do a 25 of Strattera™, those kids do very nicely in school, but that's clinical practice.*

Dr. Graham: *I just have one question. You refer to generics being sub-standard, I guess, less valuable, compared to the brands. Do you consider that in all categories or do you consider it only in the category . . .*

Dr. Hunt: *Well, I think it's really hard to . . . to do that because the antibiotics that we use, we use once . . . five daily dosing of Zithromax™. We tend to want to use once-a-day dosing in that area but we only want to . . . but we use three times a day dosing for the mental health for attention deficit. I think there is a huge body of literature that will show that there is a difference in generic medications. And since they are not as Tegretol™ has been, you know, generic Tegretol™ has been shown in the literature that it can have up to 25% difference in blood level. One month one maker is making X pill for, God knows what's in it, the next month they get a different brand, you know the kid that's one month completely stable on the generic stimulant and then the next month they're coming to you and telling you that either they're too sleepy or they're not concentrating enough. And so then you have to up the dose. And the generics that I take care of now, you will, we will see them almost every month because of the changes in manufacturer, and I think that's what has to, is the only thing I can come up with, because of the dosages will only change only because you have to do something to keep them in school.*

Dr. Gourley: *Do you ever report this to the pharmacist that dispensed it or to the FDA that there's a problem, or . .*

Dr. Hunt: *You can report it, but because they're allowed, it's not a reportable problem. Indeed, they'll tell you it's, well, we used this brand this month and that was the cheapest.*

Dr. Crenshaw: *I've seen that and thank God, we don't use it much anymore, but theophylline patients, I mean you can have them on a set dose and draw a level and they might change it to a generic, a different brand, and that level will drop, or it'll increase significantly and then they have side effects with it. And that's clinical experience, but I've experienced that myself.*

Dr. Hunt: *I have less problems with people or on named brands, because if you use a Concerta™ or a Metadate™, they're required by FDA to have exactly 10 mg in the pill, whereas the generics aren't required to have exactly . .*

(several people): *Yes they are, yes they are, yes they are, yes.*

Dr. Gourley: *The variation is there because the brand names could not qualify batch to batch any better than the generics can, so the variation is there.*

Dr. Hunt: *Then why, how do you, how do you address the fact that in Tegretol™ for instance, their blood levels can be 25% variant?*

Dr. Nesser: *Tegretol™ is a different drug. It is often considered as a narrow therapeutic index drug, so . . .*

Dr. Hollen: *But didn't we require a generic on that one just recently?*

Dr. Graham: *That's because the FDA didn't find any difference in it, and so that's what I was asking. Are you disagreeing with the FDA?*
Dr. Hunt: *. . . it doesn't mean that in clinical practice that you will always follow it because there is going to be variance in actual clinical practice.*
Dr. McNeill: *Concerning his asthma question . . . is that coming up as future business . . .*
Dr. Nesser: *It's future, yeah.*
Dr. Gourley: *What I meant by different drug is that other things can influence it. I didn't mean it was different from generic to brand name. Let me clarify that. I still don't believe that there's a difference in it.*
Dr. Robinson: *Like there's a variance in same drug, same person.*
Dr. Gourley: *Right, right. But the variance is due to outside factors and metabolism and type of . . . it's predicted that it's going to vary. That's why you do blood levels a lot of times.*

**AGENDA ITEM NO. 10:** **REVIEW & DISCUSS MAINTENANCE MEDICATION LIST / QUANTITY LIMITS**

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

**AGENDA ITEM NO. 11:** **FDA & DEA UPDATES**

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

**AGENDA ITEM No. 12:** **FUTURE BUSINESS**

**12A: Hepatitis C Agents Review**
**12B: Epogen™/Procrit™ Review**
**12C: Antibiotic Review**
**12D: Benzo/Ambien™ Follow-Up Review**
**12E: Vote to PA Synagis™, SSRI's, ARB's, Fuzeon™**
**12F: Narcotics Review**
**12G: Xopenex Follow-Up Review**

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

**AGENDA ITEM No. 13:** **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:** July 2, 2004

**To:** Nancy Nesser, DPh, JD
Pharmacy Director
Oklahoma Health Care Authority

**From:** Ron Graham, DPh
Operations Coordinator / DUR Manager
Pharmacy Management Consultants

**Subject:** DUR Board Recommendations from Meeting of June 8, 2004.

**Recommendation 1: Discuss and Vote on Prior Authorization of Provigil™.**

The DUR Board voted to approve prior authorization with the following criteria:

1. FDA approved indications
   a. Narcolepsy
   b. Obstructive sleep apnea/hypopnea syndrome
   c. Shift work sleep disorder
2. Off-Label uses:
   a. Depression
   b. Fatigue associated with multiple sclerosis and/or fibromyalgia
   c. Daytime sleepiness in patients with myotonic dystrophy
   d. Alcoholic organic brain syndrome during the early phase of abstinence
   e. Drug-induced somnolence only for patients with a diagnosis of cancer
3. Maximum approved dosing 200 mg daily, quantity limit of 30 tablets for 30 days.

MOTION CARRIED.

**Recommendation 2: Discuss and Vote on Prior Authorization / PDL for "Statins".**

The DUR Board voted to approve the following list of preferred drugs as Tier 1:

1. Lescol™ and Lescol XL™
2. Lovastatin (generic only)
3. Lipitor™

The DUR Board voted to approve the following criteria for moving from a Tier 1 statin to a Tier 2:

1. Previous failure to achieve desired LDL or Triglyceride reduction with an initial statin – defined by at least 6 weeks of continuous therapy at standard dose.
2. Previous stabilization on non-preferred medication. (grandfathering)
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.

MOTION CARRIED.

Santiago Reyes, M.D.

Respiratory Diseases of
Children and Adolescents

Suite 330 Baptist Medical Plaza Bldg. D
3366 N.W. Expressway
Oklahoma City, Oklahoma 73112
Telephone (405) 945-4495
Fax (405) 945-4376

June 9, 2004

Lynn Mitchell, M.D.
Medical Director of Oklahoma Medicaid Program
4545 N. Lincoln
Oklahoma City, OK 73105

Dear Dr. Mitchell,

The next DUR board meeting which will take place in July of the present year, I am aware of the proposed period for prior authorizations for synagis and I have some concerns.

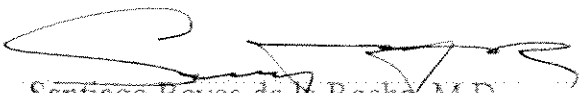
I feel that there are other important risk factors to be considered so patients may become eligible to receive this very cost effective medication. I don't think that the limit of five doses should be imposed as many times the epidemic season may not follow the October to April time frame.

I do believe there are some other important criteria to consider a patient as a candidate to receive synagis such as exposure to tobacco smoke, multiple household members, especially other school age siblings and of course low birth weight. I should also mention that low birth weight infants are not the only group of children at risk of developing serious complications and/or long term sequelae from RSV infections. Because effectiveness of using this medication in high risk populations has been demonstrated many times. I personally believe that infants from families with a strong history of reactive airway disease, who genetically may be predisposed to develop this condition, may also be considered as candidates to receive RSV prophylaxis knowing the long term sequelae of this infection in airways.

Lynn Mitchell
page 2

Thank you very much for your consideration to this very important matter.

Sincerely yours,



Santiago Reyes de la Rocha, M.D.

SR/lzs

cc: Nancy Nesser, D. Ph., J.D.
Medicaid Pharmacy Director
4545 N. Lincoln.
Oklahoma City, OK 73105

Paula Root
Medical Director Blue Lincs
Blue Cross and Blue Shield of Oklahoma
3401 N.W. 63rd.
Oklahoma City, OK 73116

June 21, 2004

# North Rock
MEDICATION CLINIC

Ron Graham, D.Ph.
Clinical Assistant Professor, DUR/Operations Manager
Pharmacy Management Consultants
College of Pharmacy, Department of Pharmacy: Clinical & Administrative Sciences
ORI – W4403, 1122 N.E. 13th
Oklahoma City, OK 73117

To all P&T Committee members:

Please add Paxil CR to your Medicaid formulary for the following reasons:

Paxil CR will aid us in effectively treating the anxiety patient. Its unique controlled release formula helps eliminate the high peak to trough ratios that may significantly impair the ability of patients to tolerate therapy. Undesirable side effects are often associated with the rapid rise and fall of the peak plasma drug concentrations. This more even distribution of drug throughout the day, achieved by use of the controlled release formulation, allows patients to tolerate the medication significantly better than the patient may be able to do with an immediate release product. When we can present an anxiety patient with a product that they can tolerate, we improve compliance, and enhance the opportunity for patients to continue therapy and respond to treatment.

Because of the more even distribution of Paxil CR into the bloodstream, it appears that serum concentrations are higher and we may be able to treat the patient with fewer dosing escalations, which is generally associated with fewer side effects. Patients are responding well to Paxil CR, and we are confident that the benefit of increased patient satisfaction will result in more favorable outcomes.

We urge the committee to continue to consider such products that aid us in treating anxiety with a favorable tolerability profile that enables patients to experience the benefits of effective therapy.

Thank you for your consideration:

Jahangir Ghaznavi, M.D. Medical Director of North Rock Clinic, Clinical Asstt. Professor OU – college of medi.

Adonis Al-Botros, M.D. Staff Psychiatrist

Rajeswararaju Bhupathiraju, M.D. Staff Psychiatrist

Sergio Sanchez, M.D. Staff Psychiatrist

Veronique Sebastian, M.D. Staff Psychiatrist

Surinder Randhawa, M.D. Staff Psychiatrist

Yolanda Padua, M.D. Staff Psychiatrist

SOUTHWESTERN PEDIATRICS & ALLERGY CLINIC, INC.
REX R. MATTHEWS, M.D.
ALLERGY AND PEDIATRICS
8220 S. PENNSYLVANIA
OKLAHOMA CITY, OKLAHOMA 73159

TELEPHONE
682-1443



To The Oklahoma DUR Board: 6/23/2004

I respectfully ask that your consideration be given to three areas when deciding on guidelines for Synagis approval in the coming months.

Low birth weight (less than 2500 g.) is an additional risk factor that I understand was not specifically identified before the AAP published their guidelines. But LBW has since been clinically proven to pose severe risk to this delicate population.

Smoking in the household is also a problem, especially in Oklahoma, that should be included to protect babies of smoking caregivers and parents.

Finally, please look at the data regarding the length of the RSV season for our area when deciding the number of injections given. Typically our season runs October through late April or early May. Synagis should be given during the entire season. This is in accordance with AAP guidelines.

Sincerely yours,

Rex Matthews, M.D.

# Oklahoma Academy of Family Physicians



Fifty Penn Place
Suite 501
Oklahoma City OK
73118-1803

405.842.0484
Fax 405.840.0138
800.678.6237
E-mail: sam-blackstock
@coxinet.net
Web Site: www.okafp.org



June 24, 2004

Drug Utilization Review Board
4545 N. Lincoln, Suite 124
Oklahoma City, OK. 73105

Dear Board Members,

**In response to your consideration to require a prior authorization for SSRI's. On be have of the members of the Oklahoma Academy of Family Physicians, I'd like to respectfully object and ask you to maintain open access for Medicaid patients and providers for the following reasons:**

1. In my clinical experience, not all SSRI's are the same. They differ in their selectivity, potency, and metabolism.

2. The prior authorization process takes a minimum of 24 hours to obtain approval. Medicaid patients may not return to the pharmacy 24 to 48 hours later for their medication, which means patients will go untreated. This could allow for relapse and/or possible hospitalizations, which would add an increased financial burden to the Medicaid system.

3. Many patients are currently well controlled on their SSRI. Grandfathering patients in the past has had some significant obstacles. Medicaid patients tend to change providers and pharmacies often. When this occurs, Medicaid patients have been denied their grandfathered medication.

Based on the negative impact prior authorization of SSRI's would have on Medicaid patients, the increased cost burden to the overall Medicaid system, and additional barrier this would create for Family Physicians to provide the treatment we deem appropriate for our patients, we implore you to continue open access for this class of medications.

Sincerely,

Sam Blackstock, CAE
Executive Vice President

Norman Regional
Family Medicine Associates

*Cynthia L. Taylor, M.D.*
*L. Diane Butler, A.R.N.P.*
*Susan M. Thompson, A.R.N.P.*

31

June 25, 2004

To The Oklahoma DUR Board:

It has come to my attention that the DUR Board will be meeting on July 13, 2004. I will be unable to attend this meeting, but I wanted to share my thoughts on Synagis protocol for the 2004-05 season.

As determined in the Holman Paper, low birth weight is one of the most important risk factors in determining which infants will receive Synagis prophylaxis. With this in mind, I would like to see the inclusion of low birth weight as a risk factor for Synagis prophylaxis.

In addition, it is well documented that smoking cessation programs are often unsuccessful. In light of the risk to the child, parents are unable or unwilling to quit smoking even though it puts their child at significant risk. Therefore, smoking should also be strongly considered as a potential risk factor for Synagis candidates.

Finally, I would like to see the number of injections per child be determined by the local virology lab at Children's Hospital. Last year the virology data showed RSV to be epidemic well into April. It would not be cost effective to provide prophylaxis through March only to have a child hospitalized in April due to inadequate Synagis antibody levels.

Thank you for your consideration in this matter.

Sincerely,

Cynthia Taylor

Cynthia Taylor, M.D.

CLT/tdh

*1237 E. Alameda • Norman, OK 73071 • 405.321.4511*

HELTON RURAL HEALTH CLINIC
108 West Ohio • P. O. Box 345
COALGATE, OK 74538
Fax: 580-927-9941
Phone: 580-927-2334



June 29, 2004

Dear Nancy Nesser,

It is my understanding that the Drug Utilization Review Board will be meeting in July to discuss Arbs formulary classification with Medicare. As a high Medicare prescriber and user of the Arb class, I am strongly requesting that the Arbs be left a separate class in a tier one position on Medicare formulary.

If you need additional information, please do not hesitate to contact me.

Sincerely,

R.J.Helton, D.O.

Wazir S. Ahmad, M.D., FAAP

PEDIATRICS
ADOLESCENT MEDICINE

600 PHYSICIANS AND SURGEONS BLDG.
1211 N. SHARTEL
OKLA. CITY, 235-9955

June 29, 2004

To The DUR Board:

I have been made aware that the DUR Board will be meeting on July 13, 2004. I am going to be unable to attend this meeting, but I would like to voice my concerns on Synagis protocol for next season.

As determined in the Holman Paper, low birth weight is one of the most important risk factors in determining which infants will receive Synagis prophylaxis. I would like to see the inclusion of low birth weight as a risk factor for prophylaxing babies with Synagis.

Also, it is well documented that smoking cessation programs are often unsuccessful. In light of the risk to the child, parents are unable or unwilling to quit smoking even though it puts their child at significant risk. Therefore, smoking should be considered as a potential risk factor for Synagis prophlaxis.

Lastly, I would like to see the number of injections per child to be determined by local virology data. Last year the virology data from Children's Hospital confirmed RSV to be prevalent well into the month of April. If we were to limit the number of injections to five, we may be putting babies at risk for RSV infection. Please consider these issues when determining your protocol for the next Synagis season.

Sincerely,

Wazir S. Ahmad, M.D. FAAP

# PRIME CARE FAMILY PRACTICE

S. Swami, M.D.
Internal Medicine
Board Certified

I. Kumar, M.D.
Pediatrics
Board Certified

N. Govinda, M.D.
Board Certified
Focusing on
Women's Health
Issues

Lori Stewart, ARNP
Nurse Practitioner

Wendy Robinson, PAC

July 1, 2004

Dr. Nancy Nesser
Medicaid Pharmacy Director of Oklahoma Program
Oklahoma Medicaid DUR Board
4545 N. Lincoln Blvd
Oklahoma City, OK 73105

RE: Synagis coverage for Medicaid eligible infants

Dear Madam:

I am writing to voice my thoughts regarding the Synagis protocol for the upcoming season.

It has been well documented and included in the AAP guidelines for Synagis that:

1. Infants born at 32-35 weeks would greatly benefit from RSV prophylaxis if
   a. There is environmental exposure to smoke in the household.
   b. Low birth weight < 2500 gms
   c. Presence of school age siblings in the family
   d. Multiple birth
   e. Crowded living conditions

Also it is very clearly stated in the guidelines from the AAP the RSV prophylaxis should be throughout the season and not limited to 5 or 6 doses during the season (though most often the 6 doses do cover the season).

It would be most welcome if these facts are strongly considered during the DUR Board meeting for the upcoming RSV season.

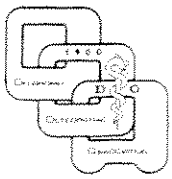
I thank you in advance for your time and consideration.

Sincerely,

Iresh Kumar, MD

CC:Dr. Lynn Mitchell
Dr. Thomas Witzen
Dr. Paula Root

*Lynette C. McLain*
*Executive Director*



*Oklahoma Osteopathic Association*
*4848 North Lincoln Boulevard*
*Oklahoma City, OK 73105-3335*
*(405) 528-4848 or (800)522-8379*
*fax (405) 528-6102*
*ooa@okosteo.org*



July 2, 2004

Thomas L. Whitsett, MD, Chair
Oklahoma Health Care Authority Drug Utilization Review Board
825 NE 19th Street
Oklahoma City, OK 73104-5417

RE: OHCA Efforts to Restrict Access to Mental Health Medicines

Dear Dr. Whitsett:

I am writing you on behalf of the 1,200 osteopathic physicians in Oklahoma to express opposition to the restrictions under consideration by the Drug Utilization Review Board, relative to the SSRI category of medicines, which are used to treat patients with depression.

As written, the new rules would establish a 2-tiered formulary for this category of products. Tier 1 would consist of only generically available products; while Tier 2 would contain the newer, more effective agents used to treat depression. Once the tiers are determined, manufacturers would then be given the "opportunity" to pay the Health Care Authority for the right to have a Tier 2 product moved to Tier 1 status. A formulary that is cost-driven is not designed to optimize patient care; and places the agency's fiscal concerns above those of the patients who rely on it for care.

Similar attempts to restrict physician-patient access to the full array of available prescription drug therapies has already been tried by the Health Care Authority in several other therapeutic categories, including anti-hypertensives, anti-arthritics, and anti-ulcer medicines; all in the name of cost containment. If passed as written, the SSRI rules will place Oklahoma's mental health community at the mercy of a fiscal grid.

Implementation of these new rules would restrict access to the choices physicians have available to treat Medicaid patients that are newly diagnosed with clinical depression, by requiring a "fail-first" treatment algorithm. This not only violates the fundamental medical practice of "first do no harm", but also places the state and taxpayers in the position of having to pay for multiple office visits, diagnoses and prescriptions.

This type of bureaucratic mandate limits a physician's ability to select the best medicine to treat a patient with depression at the point of initial diagnosis, and places this medically fragile population at increased risk.

Better and more patient-focused alternatives, including disease management and coordinated care are tried and proven methods of creating a balance between medical care and fiscal limitations. Cost-based prior authorization programs such as the one being considered for the SSRIs do restrict spending, but are not in the best medical interests of those who have to live within its confines.

For these reasons, the OOA respectfully requests that the Oklahoma Health Care Authority Drug Utilization Review Board reject the proposed rules as written.

Sincerely,

Lynette C McLain

Lynette C. McLain
Executive Director

/lm

c: Steven D. Hinshaw, DO, President
Rick Crenshaw, DO, Member, OHCA DUR Board
Senator Angela Monson
Representative Al Lindley
Mike Fogarty, Executive Director, OHCA
Lynn Mitchell, MD, Medical Director, OHCA

THE HEART AND MEDICAL CENTER
VIVEK KHETPAL, M.D.
*BOARD CERTIFIED IN INTERNAL MEDICINE,*
*CARDIOVASCULAR DISEASES, AND NUCLEAR CARDIOLOGY*
1400 BRYAN DR., SUITE 208 • DURANT, OKLAHOMA 74701
(580) 931-0500 • FAX (580) 920-8027



Nancy Nesser, PharmD, JD
Pharmacy Director
Oklahoma Health Care Authority
4545 N. Lincoln Street, Suite 124
Oklahoma City, OK 73105-9901

July 6, 2004

**Public Record**

Dear Nancy Nesser;

As a Cardiologist who treats a high percentage of Oklahoma State Medicaid hypertension patients, I understand that on July 13th the Drug Utilization Review board will be deciding whether or not to keep the Arb class in a Tier 1 category. In my practice, I use the arb class on a my patients because of their efficacy, tolerability and cardiovascular benefits. I ask that the Arb class be kept in the present classification as available without prior authorizations or step edits.

Sincerely,

Dr. Vivek Khetpal, M.D.

38

The University of Oklahoma
Health Sciences Center
COLLEGE OF MEDICINE

July 6, 2004

Nancy Nesser, Pharm DJD
Pharmacy Director
Oklahoma Health Care Authority
4545 N. Lincoln, Suite 124
Oklahoma City, OK 73105

**RE: Diovan/valsartan**

Dear Dr. Nesser:

I am writing to support the addition of Diovan to the formulary. As you may know, a soon to be published trial was done with the acronym VALUE. In this Diovan was found to be an effective antihypertensive but had a surprising corollary benefit. There was a 23% reduction in new onset diabetes when compared to the calcium channel blocker Amlodipine. I think we all continue to think of ace inhibitors as a first tier drug for diabetic patients to delay the onset of renal insufficiency and proteinuria. There seems to be a growing case for ARBs being used as a first line agent as well. Given its better tolerability in patients, specifically related to cough and angioedema, I think Diovan is an excellent choice for the conscientious physician to use as a first line antihypertensive, particularly in patients at risk for the development of diabetes mellitus type 2.

Thank you very much for your attention. I appreciate the care with which the Health Care Authority chooses medications for its formulary. It's your attention to detail and value that allows so many Oklahomans to be served.

Sincerely,

Stephen W. Cobb, M.D.
Assistant Professor

SWC/db

Department of Family and Preventive Medicine, Post Office Box 26901, 900 Northeast 10th Street, Oklahoma City, Oklahoma 73190
PHONE: (405) 271-4224 FAX:(405) 271-4125

# APPENDIX B

The following modules were activated as outlined below:

| | |
|---|---|
| April 23, 2003 | **Ingredient Duplication** |
| April 23, 2003 | **Low Dose Alert** |
| May 7, 2003 | **Therapeutic Duplication** |
| May 28, 2003 | **Drug-Drug Interaction** (SL1) – module was deactivated due to technical difficulty. |
| May 30, 2003 | **Drug-Disease Interaction** (SL1 & SL2) |
| June 03, 2003 | **Drug-Age Precautions** (Geriatric SL1) |
| June 10, 2003 | **Drug-Age Precautions** (Pediatric SL1 & SL2) |
| October 21, 2003 | **Drug-Pregnancy Precautions** (SL1 & SL2) |
| October 23, 2003 | **Underuse Precaution** |

# Prospective Drug Utilization Review

## October 01, 2002 through September 30, 2003

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| DD | NITROFURAN DERIVATIVES | 3 | 3 | 0 | 28,199 | 0.01% | 0.00% |
| | FURAZOLIDONE | 3 | 3 | 0 | 3 | 100.00% | 0.00% |
| ID | ANTI-ANXIETY DRUGS | 6 | 6 | 0 | 160,185 | 0.00% | 0.00% |
| | ALPRAZOLAM | 4 | 4 | 0 | 56,316 | 0.01% | 0.00% |
| | LORAZEPAM | 2 | 2 | 0 | 44,796 | 0.00% | 0.00% |
| ID | BARBITURATES | 1 | 1 | 0 | 22,805 | 0.00% | 0.00% |
| | PHENOBARBITAL | 1 | 1 | 0 | 22,781 | 0.00% | 0.00% |
| ID | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 3 | 3 | 0 | 221,480 | 0.00% | 0.00% |
| | NABUMETONE | 1 | 1 | 0 | 10,961 | 0.01% | 0.00% |
| | ROFECOXIB | 1 | 1 | 0 | 20,820 | 0.00% | 0.00% |
| | VALDECOXIB | 1 | 1 | 0 | 5,363 | 0.02% | 0.00% |
| ID | SEDATIVE-HYPNOTICS,NON-BARBITURATE | 2 | 2 | 0 | 61,248 | 0.00% | 0.00% |
| | FLURAZEPAM HCL | 1 | 1 | 0 | 637 | 0.16% | 0.00% |
| | TEMAZEPAM | 1 | 1 | 0 | 18,957 | 0.01% | 0.00% |
| ID | SKELETAL MUSCLE RELAXANTS | 1 | 1 | 0 | 113,436 | 0.00% | 0.00% |
| | CARISOPRODOL | 1 | 1 | 0 | 29,274 | 0.00% | 0.00% |

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| LD | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 1 | 1 | 0 | 22,057 | 0.00% | 0.00% |
| | CARVEDILOL | 1 | 1 | 0 | 16,173 | 0.01% | 0.00% |
| LD | HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE | 1 | 1 | 0 | 110,940 | 0.00% | 0.00% |
| | NATEGLINIDE | 1 | 1 | 0 | 2,800 | 0.04% | 0.00% |
| LD | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 2 | 2 | 0 | 51,247 | 0.00% | 0.00% |
| | ROSIGLITAZONE MALEATE | 2 | 2 | 0 | 30,763 | 0.01% | 0.00% |
| LR | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 3 | 3 | 0 | 22,057 | 0.01% | 0.00% |
| | CARVEDILOL | 3 | 3 | 0 | 16,173 | 0.02% | 0.00% |
| LR | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 9 | 9 | 0 | 51,247 | 0.02% | 0.00% |
| | ROSIGLITAZONE MALEATE | 9 | 9 | 0 | 30,763 | 0.03% | 0.00% |
| LR | HYPOTENSIVES, ACE INHIBITORS | 2 | 2 | 0 | 220,898 | 0.00% | 0.00% |
| | ENALAPRIL MALEATE | 1 | 1 | 0 | 42,865 | 0.00% | 0.00% |
| | LISINOPRIL | 1 | 1 | 0 | 100,858 | 0.00% | 0.00% |
| LR | ORAL ANTICOAGULANTS,COUMARIN TYPE | 2 | 2 | 0 | 64,259 | 0.00% | 0.00% |
| | WARFARIN SODIUM | 2 | 2 | 0 | 64,259 | 0.00% | 0.00% |
| MC | ALPHA/BETA-ADRENERGIC BLOCKING AGENTS | 13 | 13 | 0 | 22,057 | 0.06% | 0.00% |
| | CARVEDILOL | 13 | 13 | 0 | 16,173 | 0.08% | 0.00% |
| MC | AMMONIA INHIBITORS | 28 | 28 | 0 | 20,376 | 0.14% | 0.00% |
| | LACTULOSE | 28 | 28 | 0 | 20,344 | 0.14% | 0.00% |
| MC | ANALGESIC/ANTIPYRETICS,NON-SALICYLATE | 6 | 5 | 0 | 9,681 | 0.06% | 0.00% |
| | ACETAMINOPHEN/CAFFEINE/BUTALB | 6 | 5 | 0 | 9,139 | 0.07% | 0.00% |
| MC | ANTI-ANXIETY DRUGS | 9 | 9 | 0 | 160,185 | 0.01% | 0.00% |
| | LORAZEPAM | 5 | 5 | 0 | 44,796 | 0.01% | 0.00% |
| | ALPRAZOLAM | 4 | 4 | 0 | 56,316 | 0.01% | 0.00% |
| MC | ANTICONVULSANTS | 16 | 16 | 0 | 363,281 | 0.00% | 0.00% |
| | PHENYTOIN SODIUM EXTENDED | 9 | 9 | 0 | 50,556 | 0.02% | 0.00% |

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| MC | CONTRACEPTIVES,ORAL | 24 | 23 | 1 | 47,360 | 0.05% | 0.00% |
| | NORGESTIMATE-ETHINYL ESTRADIOL | 12 | 12 | 0 | 17,863 | 0.07% | 0.00% |
| | LEVONORGESTREL-ETH ESTRA | 5 | 4 | 1 | 8,741 | 0.06% | 0.01% |
| | NORETHINDRONE | 5 | 5 | 0 | 2,820 | 0.18% | 0.00% |
| MC | CONTRACEPTIVES,TRANSDERMAL | 6 | 6 | 0 | 11,152 | 0.05% | 0.00% |
| | ETHINYL ESTRADIOL/NORELGEST | 6 | 6 | 0 | 11,152 | 0.05% | 0.00% |
| MC | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 72 | 68 | 4 | 51,247 | 0.14% | 0.01% |
| | ROSIGLITAZONE MALEATE | 72 | 68 | 4 | 30,763 | 0.23% | 0.01% |
| MC | HYPOTENSIVES, ACE INHIBITORS | 11 | 11 | 0 | 220,898 | 0.00% | 0.00% |
| | LISINOPRIL | 5 | 5 | 0 | 100,858 | 0.00% | 0.00% |
| | ENALAPRIL MALEATE | 4 | 4 | 0 | 42,865 | 0.01% | 0.00% |
| MC | INTESTINAL MOTILITY STIMULANTS | 51 | 50 | 1 | 43,602 | 0.12% | 0.00% |
| | METOCLOPRAMIDE HCL | 51 | 50 | 1 | 43,602 | 0.12% | 0.00% |
| MC | LAXATIVES AND CATHARTICS | 23 | 23 | 0 | 44,221 | 0.05% | 0.00% |
| | LACTULOSE | 23 | 23 | 0 | 14,387 | 0.16% | 0.00% |
| MC | NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIB (NDRIS) | 11 | 11 | 0 | 26,915 | 0.04% | 0.00% |
| | BUPROPION HCL | 11 | 11 | 0 | 26,915 | 0.04% | 0.00% |
| MC | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 25 | 25 | 0 | 221,480 | 0.01% | 0.00% |
| | IBUPROFEN | 19 | 19 | 0 | 63,761 | 0.03% | 0.00% |
| MC | ORAL ANTICOAGULANTS,COUMARIN TYPE | 4 | 4 | 0 | 64,259 | 0.01% | 0.00% |
| | WARFARIN SODIUM | 4 | 4 | 0 | 64,259 | 0.01% | 0.00% |
| MC | PITUITARY SUPPRESSIVE AGENTS | 4 | 4 | 0 | 1,479 | 0.27% | 0.00% |
| | BROMOCRIPTINE MESYLATE | 4 | 4 | 0 | 1,159 | 0.35% | 0.00% |
| MC | STEROID ANTINEOPLASTICS | 3 | 3 | 0 | 25,790 | 0.01% | 0.00% |
| | MEGESTROL ACETATE | 3 | 3 | 0 | 25,768 | 0.01% | 0.00% |
| PA | ANTICONVULSANTS | 3 | 3 | 0 | 363,281 | 0.00% | 0.00% |
| | CLONAZEPAM | 3 | 3 | 0 | 39,353 | 0.01% | 0.00% |

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| PA | ANTIHISTAMINES | 1 | 1 | 0 | 196,010 | 0.00% | 0.00% |
| | LORATADINE | 1 | 1 | 0 | 70,774 | 0.00% | 0.00% |
| PA | ANTIMIGRAINE PREPARATIONS | 3 | 3 | 0 | 10,817 | 0.03% | 0.00% |
| | NARATRIPTAN HCL | 3 | 3 | 0 | 243 | 1.23% | 0.00% |
| PA | CONTRACEPTIVES,ORAL | 1 | 1 | 0 | 47,360 | 0.00% | 0.00% |
| | ETHINYL ESTRADIOL/DROSPIRENONE | 1 | 1 | 0 | 2,350 | 0.04% | 0.00% |
| PA | ESTROGENIC AGENTS | 3 | 3 | 0 | 77,772 | 0.00% | 0.00% |
| | ESTRADIOL | 3 | 3 | 0 | 8,918 | 0.03% | 0.00% |
| PA | NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIB (NDRIS) | 2 | 2 | 0 | 26,915 | 0.01% | 0.00% |
| | BUPROPION HCL | 2 | 2 | 0 | 26,915 | 0.01% | 0.00% |
| PA | OPHTHALMIC ANTIBIOTICS | 1 | 1 | 0 | 40,644 | 0.00% | 0.00% |
| | MOXIFLOXACIN HCL | 1 | 1 | 0 | 1,418 | 0.07% | 0.00% |
| PA | QUINOLONES | 3 | 3 | 0 | 71,611 | 0.00% | 0.00% |
| | LEVOFLOXACIN | 3 | 3 | 0 | 31,467 | 0.01% | 0.00% |
| PA | THYROID HORMONES | 3 | 3 | 0 | 134,780 | 0.00% | 0.00% |
| | LEVOTHYROXINE SODIUM | 3 | 3 | 0 | 131,292 | 0.00% | 0.00% |
| PA | TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY | 1 | 1 | 0 | 51,140 | 0.00% | 0.00% |
| | METHYLPHENIDATE HCL | 1 | 1 | 0 | 48,720 | 0.00% | 0.00% |
| PG | ABSORBABLE SULFONAMIDES | 4 | 4 | 0 | 50,642 | 0.01% | 0.00% |
| | SULFAMETHOXAZOLE/TRIMETHOPRIM | 4 | 4 | 0 | 48,704 | 0.01% | 0.00% |
| PG | ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL AGENTS | 8 | 5 | 3 | 12,177 | 0.07% | 0.02% |
| | METRONIDAZOLE | 8 | 5 | 3 | 12,151 | 0.07% | 0.02% |
| PG | ANALGESIC/ANTIPYRETICS,NON-SALICYLATE | 7 | 6 | 1 | 9,681 | 0.07% | 0.01% |
| | ACETAMINOPHEN/CAFFEINE/BUTALB | 7 | 6 | 1 | 9,139 | 0.08% | 0.01% |

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| PG | ANTI-ANXIETY DRUGS | 11 | 11 | 0 | 160,185 | 0.01% | 0.00% |
| | ALPRAZOLAM | 5 | 5 | 0 | 56,316 | 0.01% | 0.00% |
| | DIAZEPAM | 4 | 4 | 0 | 24,443 | 0.02% | 0.00% |
| PG | ANTICONVULSANTS | 13 | 13 | 0 | 363,281 | 0.00% | 0.00% |
| | PHENYTOIN SODIUM EXTENDED | 5 | 5 | 0 | 50,556 | 0.01% | 0.00% |
| | DIVALPROEX SODIUM | 4 | 4 | 0 | 65,109 | 0.01% | 0.00% |
| PG | CONTRACEPTIVES,INJECTABLE | 5 | 5 | 0 | 7,118 | 0.07% | 0.00% |
| | MEDROXYPROGESTERONE ACET | 5 | 5 | 0 | 7,116 | 0.07% | 0.00% |
| PG | CONTRACEPTIVES,ORAL | 41 | 30 | 11 | 47,360 | 0.09% | 0.02% |
| | NORGESTIMATE-ETHINYL ESTRADIOL | 24 | 13 | 11 | 17,863 | 0.13% | 0.06% |
| | LEVONORGESTREL-ETH ESTRA | 6 | 6 | 0 | 8,741 | 0.07% | 0.00% |
| | DESOGESTREL-ETHINYL ESTRADIOL | 3 | 3 | 0 | 1,479 | 0.20% | 0.00% |
| PG | CONTRACEPTIVES,TRANSDERMAL | 14 | 12 | 2 | 11,152 | 0.13% | 0.02% |
| | ETHINYL ESTRADIOL/NORELGEST | 14 | 12 | 2 | 11,152 | 0.13% | 0.02% |
| PG | EAR PREPARATIONS, MISC. ANTI-INFECTIVES | 4 | 4 | 0 | 6,033 | 0.07% | 0.00% |
| | HC/PRAMOXINE HCL/CHLOROXYLENOL | 4 | 4 | 0 | 4,399 | 0.09% | 0.00% |
| PG | ESTROGENIC AGENTS | 7 | 7 | 0 | 77,772 | 0.01% | 0.00% |
| | ESTRADIOL | 3 | 3 | 0 | 8,918 | 0.03% | 0.00% |
| | ESTROGENS,CONJUGATED | 3 | 3 | 0 | 50,982 | 0.01% | 0.00% |
| PG | HYPOTENSIVES, ACE INHIBITORS | 6 | 6 | 0 | 220,898 | 0.00% | 0.00% |
| | ENALAPRIL MALEATE | 3 | 3 | 0 | 42,865 | 0.01% | 0.00% |
| PG | HYPOTENSIVES,ANGIOTENSIN RECEPTOR ANTAGONIST | 3 | 3 | 0 | 73,219 | 0.00% | 0.00% |
| | TELMISARTAN/HCTZ | 3 | 3 | 0 | 1,145 | 0.26% | 0.00% |
| PG | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE | 16 | 16 | 0 | 221,480 | 0.01% | 0.00% |
| | IBUPROFEN | 12 | 12 | 0 | 63,761 | 0.02% | 0.00% |
| PG | SKELETAL MUSCLE RELAXANTS | 3 | 3 | 0 | 113,436 | 0.00% | 0.00% |
| | CARISOPRODOL | 3 | 3 | 0 | 29,274 | 0.01% | 0.00% |

| DUR Screen | Therapeutic Category/ Drug(s) (Hierarchical Ingredient) | # Alerts | # Overrides | # Cancellations & Non-Responses | # Claims Screened | % Alerts/ Total RX | % Cancels/ Total RX |
|---|---|---|---|---|---|---|---|
| PG | TETRACYCLINES | 4 | 4 | 0 | 26,583 | 0.02% | 0.00% |
| | DOXYCYCLINE HYCLATE | 3 | 3 | 0 | 16,875 | 0.02% | 0.00% |
| TD | HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S) | 1 | 1 | 0 | 51,247 | 0.00% | 0.00% |
| | ROSIGLITAZONE MALEATE | 1 | 1 | 0 | 30,763 | 0.00% | 0.00% |

| DUR Screen | Prescriber % Overrides | Consulted (MO) % Cancellations | Patient % Overrides | Consulted (PO) % Cancellations | Pharmacist % Overrides | Consulted (RO) % Cancellations | No Interface % Overrides | Consulted (00) % Cancellations |
|---|---|---|---|---|---|---|---|---|
| DD | 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ID | 15.4 | 0 | 69.2 | 0 | 15.4 | 0 | 0 | 0 |
| LD | 50 | 0 | 50 | 0 | 0 | 0 | 0 | 0 |
| LR | 25 | 0 | 68.8 | 0 | 6.3 | 0 | 0 | 0 |
| MC | 25.2 | 0.3 | 63.6 | 0.9 | 8.5 | 1.2 | 0 | 0 |
| PA | 90.5 | 0 | 9.5 | 0 | 0 | 0 | 0 | 0 |
| PG | 8.4 | 0 | 61.4 | 9 | 19.3 | 1.8 | 0 | 0 |
| TD | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 |

Early Refill Edits and Overrides

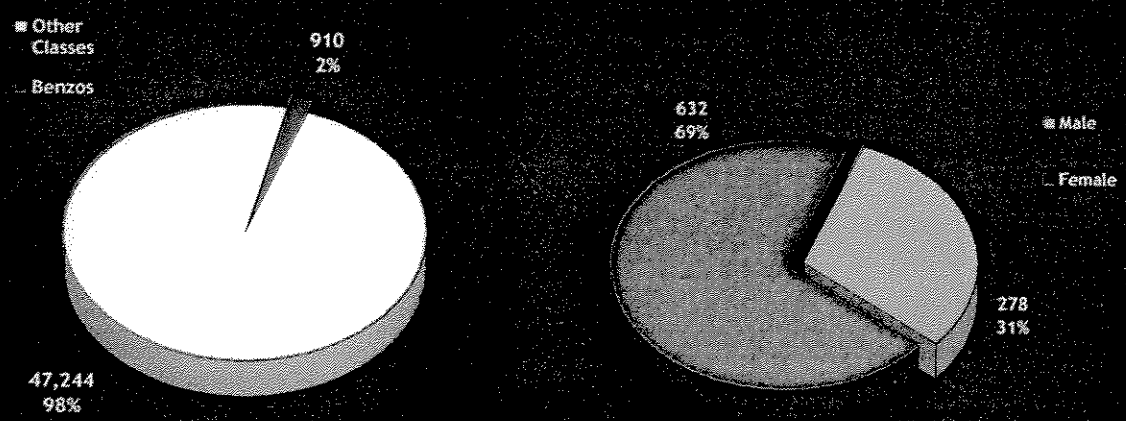
| | Oct-02 | Nov-02 | Dec-02 | Jan-03 | Feb-03 | Mar-03 | Apr-03 | May-03 | Jun-03 | Jul-03 | Aug-03 | Sep-03 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total ER edits | 21,200 | 17,163 | 22,964 | 39,570 | 35,882 | 29,255 | 65,228 | 44,072 | 41,445 | 35,860 | 45,987 | 47,434 |
| Total Super PA overrides (% total edits) | 246 (1.16%) | 231 (1.35%) | 163 (0.71%) | 239 (0.60%) | 267 (0.74%) | 300 (1.03%) | 302 (0.46%) | 265 (0.60%) | 330 (0.80%) | 305 (0.85%) | 336 (0.73%) | 359 (0.76%) |
| Override reason: | | | | | | | | | | | | |
| Dosage change | 177 | 115 | 163 | 186 | 195 | 224 | 232 | 184 | 213 | 212 | 252 | 245 |
| Wrong D.S. on previous Rx | 20 | 25 | 0 | 20 | 34 | 28 | 19 | 30 | 37 | 28 | 23 | 28 |
| Lost/Stolen/Broken Rx | 20 | 50 | 0 | 27 | 27 | 31 | 27 | 26 | 49 | 28 | 30 | 44 |
| Other | 29 | 41 | 0 | 6 | 11 | 17 | 24 | 25 | 31 | 37 | 31 | 42 |

# Response Follow-up for January 2004 and February 2004

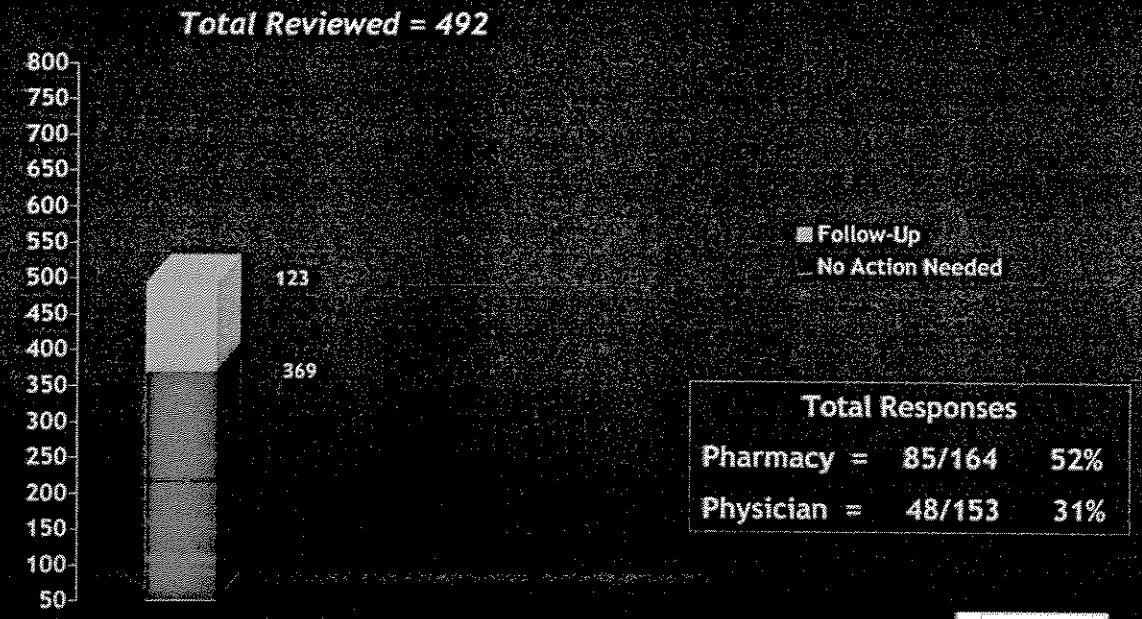
| January Responses | | |
|---|---|---|
| Pharmacy = | 62/109 | 57% |
| Physician = | 75/123 | 61% |

| February Responses | | |
|---|---|---|
| Pharmacy = | 14/26 | 54% |
| Physician = | 11/36 | 31% |

# Oklahoma Medicaid RetroDUR Activity Report - Reviewed March 2004 (Female)

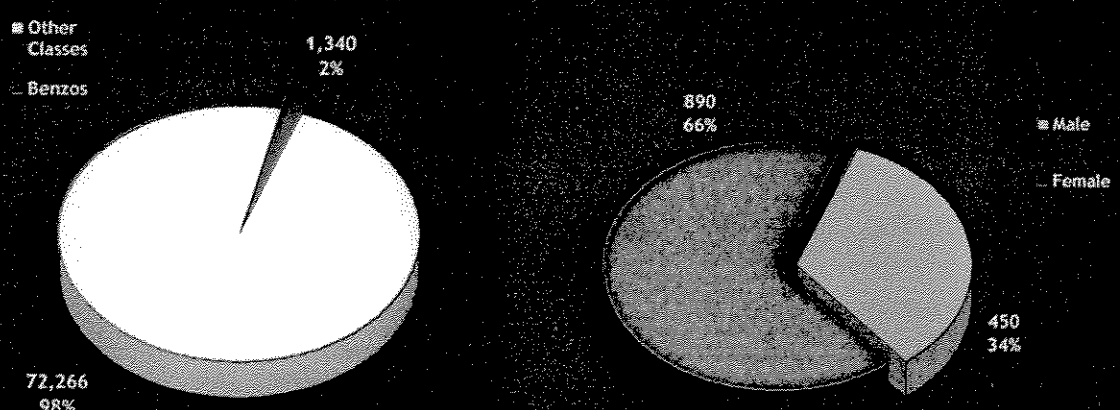


# Oklahoma Medicaid RetroDUR Activity Report
## Follow Up
## March 2004 (Female)



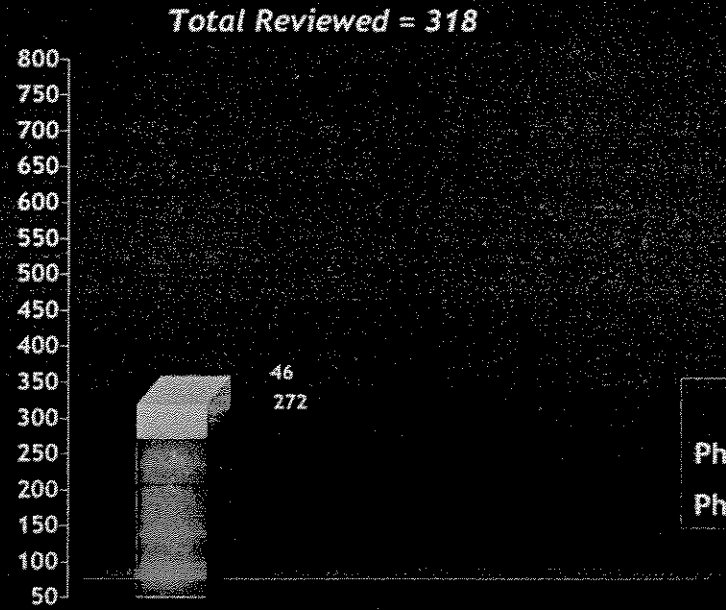

PHARMACY Management Consultants

# Oklahoma Medicaid RetroDUR Activity Report - Reviewed
## April 2004 (Male)




PHARMACY Management Consultants

# Oklahoma Medicaid RetroDUR Activity Report
## Follow Up
## April 2004 (Male)




| Total Responses | | | |
|---|---|---|---|
| Pharmacy | = | 12/28 | 43% |
| Physician | = | 4/57 | 7% |

PHARMACY Management Consultants

# Activity Audit for

June 01 2004 Through June 30 2004



| Date | Antiulcers | | Anxiolytic/ Hypnotics | | Antihistamine | | Growth Hormones | | Stimulant | | Smoking Cess. | | Nsaids | | ACE Inhibitors | | HTN Combos | | Calcium Channel Blockers | | Plavix | | NPA | | Misc | | Daily Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | app. | den. | |
| 1 | 4 | 22 | 144 | 27 | 20 | 13 | 0 | 0 | 31 | 6 | 0 | 0 | 10 | 16 | 1 | 6 | 1 | 2 | 0 | 7 | 25 | 3 | 7 | 3 | 0 | 2 | 350 |
| 2 | 8 | 40 | 255 | 28 | 38 | 47 | 0 | 1 | 44 | 15 | 0 | 0 | 15 | 35 | 3 | 7 | 0 | 3 | 4 | 15 | 28 | 4 | 5 | 6 | 0 | 3 | 604 |
| 3 | 8 | 42 | 223 | 33 | 34 | 33 | 0 | 1 | 53 | 16 | 0 | 0 | 18 | 37 | 4 | 7 | 1 | 1 | 5 | 22 | 39 | 10 | 12 | 2 | 0 | 3 | 604 |
| 4 | 8 | 44 | 209 | 46 | 34 | 29 | 3 | 0 | 54 | 20 | 0 | 0 | 10 | 29 | 2 | 13 | 5 | 6 | 8 | 14 | 22 | 8 | 8 | 1 | 0 | 3 | 576 |
| 5 | 2 | 11 | 73 | 5 | 15 | 5 | 0 | 0 | 15 | 9 | 0 | 0 | 5 | 8 | 2 | 1 | 1 | 1 | 1 | 7 | 7 | 1 | 0 | 0 | 0 | 1 | 170 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 7 | 22 | 176 | 12 | 32 | 22 | 0 | 0 | 45 | 21 | 0 | 0 | 7 | 23 | 2 | 6 | 1 | 1 | 4 | 17 | 25 | 3 | 9 | 2 | 0 | 0 | 437 |
| 8 | 11 | 44 | 181 | 40 | 45 | 29 | 2 | 0 | 50 | 12 | 0 | 0 | 18 | 35 | 3 | 5 | 3 | 4 | 5 | 8 | 34 | 9 | 40 | 7 | 0 | 1 | 586 |
| 9 | 16 | 90 | 174 | 35 | 28 | 41 | 2 | 0 | 52 | 18 | 0 | 0 | 15 | 26 | 4 | 20 | 2 | 2 | 5 | 19 | 18 | 5 | 15 | 14 | 0 | 3 | 604 |
| 10 | 19 | 94 | 143 | 21 | 37 | 17 | 7 | 0 | 61 | 21 | 0 | 0 | 17 | 30 | 1 | 10 | 1 | 1 | 6 | 13 | 25 | 6 | 17 | 10 | 0 | 3 | 560 |
| 11 | 25 | 143 | 150 | 25 | 39 | 25 | 3 | 0 | 46 | 18 | 0 | 0 | 15 | 50 | 8 | 10 | 2 | 2 | 11 | 12 | 25 | 2 | 31 | 14 | 0 | 5 | 661 |
| 12 | 8 | 22 | 42 | 9 | 8 | 12 | 0 | 0 | 15 | 6 | 0 | 0 | 1 | 4 | 2 | 4 | 1 | 0 | 1 | 6 | 6 | 3 | 2 | 1 | 0 | 2 | 155 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 16 | 100 | 119 | 13 | 21 | 18 | 0 | 0 | 30 | 13 | 0 | 0 | 6 | 23 | 2 | 7 | 3 | 1 | 1 | 10 | 18 | 11 | 7 | 6 | 0 | 1 | 426 |
| 15 | 38 | 189 | 166 | 41 | 38 | 35 | 2 | 0 | 43 | 19 | 1 | 1 | 13 | 35 | 1 | 14 | 2 | 1 | 2 | 17 | 23 | 11 | 17 | 22 | 0 | 4 | 735 |
| 16 | 25 | 144 | 157 | 26 | 27 | 29 | 3 | 0 | 47 | 19 | 0 | 0 | 10 | 30 | 1 | 4 | 3 | 3 | 6 | 22 | 15 | 8 | 27 | 13 | 0 | 2 | 621 |
| 17 | 37 | 143 | 141 | 27 | 26 | 24 | 1 | 0 | 51 | 17 | 0 | 0 | 15 | 28 | 4 | 1 | 3 | 3 | 1 | 13 | 25 | 5 | 12 | 15 | 0 | 5 | 597 |
| 18 | 28 | 106 | 127 | 20 | 30 | 24 | 6 | 0 | 60 | 20 | 0 | 0 | 11 | 17 | 2 | 7 | 0 | 5 | 2 | 5 | 22 | 4 | 7 | 12 | 0 | 1 | 516 |
| 19 | 4 | 31 | 34 | 7 | 12 | 8 | 1 | 0 | 12 | 5 | 0 | 0 | 5 | 7 | 1 | 2 | 0 | 1 | 2 | 3 | 8 | 0 | 7 | 6 | 0 | 0 | 156 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 12 | 119 | 155 | 25 | 24 | 25 | 1 | 0 | 42 | 15 | 0 | 0 | 5 | 15 | 2 | 5 | 2 | 2 | 4 | 11 | 16 | 5 | 15 | 9 | 0 | 1 | 510 |
| 22 | 29 | 147 | 170 | 31 | 33 | 30 | 0 | 0 | 54 | 13 | 0 | 0 | 8 | 25 | 0 | 5 | 0 | 5 | 9 | 6 | 31 | 2 | 26 | 25 | 0 | 1 | 650 |
| 23 | 22 | 138 | 170 | 20 | 38 | 30 | 3 | 0 | 48 | 13 | 0 | 0 | 13 | 28 | 0 | 13 | 1 | 3 | 5 | 17 | 18 | 6 | 30 | 10 | 0 | 1 | 627 |
| 24 | 28 | 86 | 111 | 18 | 34 | 22 | 1 | 0 | 57 | 24 | 0 | 0 | 12 | 21 | 0 | 7 | 1 | 2 | 6 | 10 | 17 | 2 | 24 | 12 | 0 | 1 | 496 |
| 25 | 99 | 54 | 148 | 27 | 33 | 19 | 1 | 0 | 61 | 16 | 0 | 0 | 15 | 23 | 4 | 7 | 1 | 2 | 2 | 11 | 21 | 6 | 34 | 10 | 1 | 1 | 596 |
| 26 | 17 | 17 | 36 | 11 | 13 | 4 | 0 | 0 | 20 | 3 | 0 | 0 | 3 | 4 | 1 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 1 | 134 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 85 | 47 | 139 | 17 | 24 | 16 | 0 | 0 | 41 | 9 | 1 | 0 | 5 | 11 | 1 | 2 | 1 | 2 | 3 | 14 | 13 | 3 | 18 | 3 | 0 | 1 | 456 |
| 29 | 145 | 90 | 170 | 32 | 42 | 58 | 1 | 0 | 47 | 18 | 0 | 0 | 12 | 32 | 0 | 10 | 1 | 3 | 8 | 20 | 29 | 11 | 42 | 14 | 0 | 1 | 786 |
| 30 | 110 | 31 | 160 | 24 | 27 | 24 | 1 | 0 | 58 | 21 | 0 | 0 | 18 | 16 | 1 | 3 | 2 | 3 | 2 | 14 | 19 | 0 | 21 | 5 | 0 | 3 | 563 |

# Activity Audit for

June 01 2004 Through June 30 2004

| 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. | Smoking Cess. app. | Smoking Cess. 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. | NPA app. | NPA den. | Misc app. | Misc den. | Daily Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| App. | 811 | | 3773 | | 752 | | 38 | | 1137 | | 2 | | 282 | | 52 | | 38 | | 103 | | 533 | | 433 | | 1 | | |
| Den. | | 2016 | | 620 | | 639 | | 2 | | 387 | | 1 | | 608 | | 176 | | 59 | | 313 | | 128 | | 222 | | 50 | |
| Average Length of Approvals in Days | 92 | | 93 | | 95 | | 181 | | 267 | | 92 | | 351 | | 357 | | 348 | | 349 | | 285 | | 175 | | 92 | | |

| | | |
|---|---|---|
| Smoking Cessation | 0 PA's for Zyban | 2 Total PA's Approved |
| | 2 PA's for Nicotine Patch | 2 Unique RID's |

| | |
|---|---|
| Changes to existing PA's | 919 |
| Total (Previous Year) | 8565 |

**Monthly Totals**

| | Number | Percent of Total |
|---|---|---|
| Approved | 8025 | 48.77% |
| Additional PA's | 9 | 0.05% |
| SUPER PA's | 942 | 5.73% |
| Emergency PA's | 4 | 0.02% |
| Duplicates | 921 | 5.60% |
| Incompletes | 1238 | 7.52% |
| Denied * | 5315 | 32.30% |
| Total | 16454 | 100.00% |

Daily Average of 632.85 for 26 Days

*** Denial Codes**

| | |
|---|---|
| 762 = Lack of clinical information | 66.08% |
| 763 = Medication not eligible | 3.82% |
| 764 = Existing PA | 12.06% |
| 772 = Not qualified for requested Tier | 5.61% |

**SUPER PA's**

| | |
|---|---|
| Early Refill Attempts | 68376 |
| Dosing Change | 560 |
| lost/stolen/broke | 149 |
| Other | 128 |
| wrong DS | 81 |
| Quantity vs. Days Supply | 24 |

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

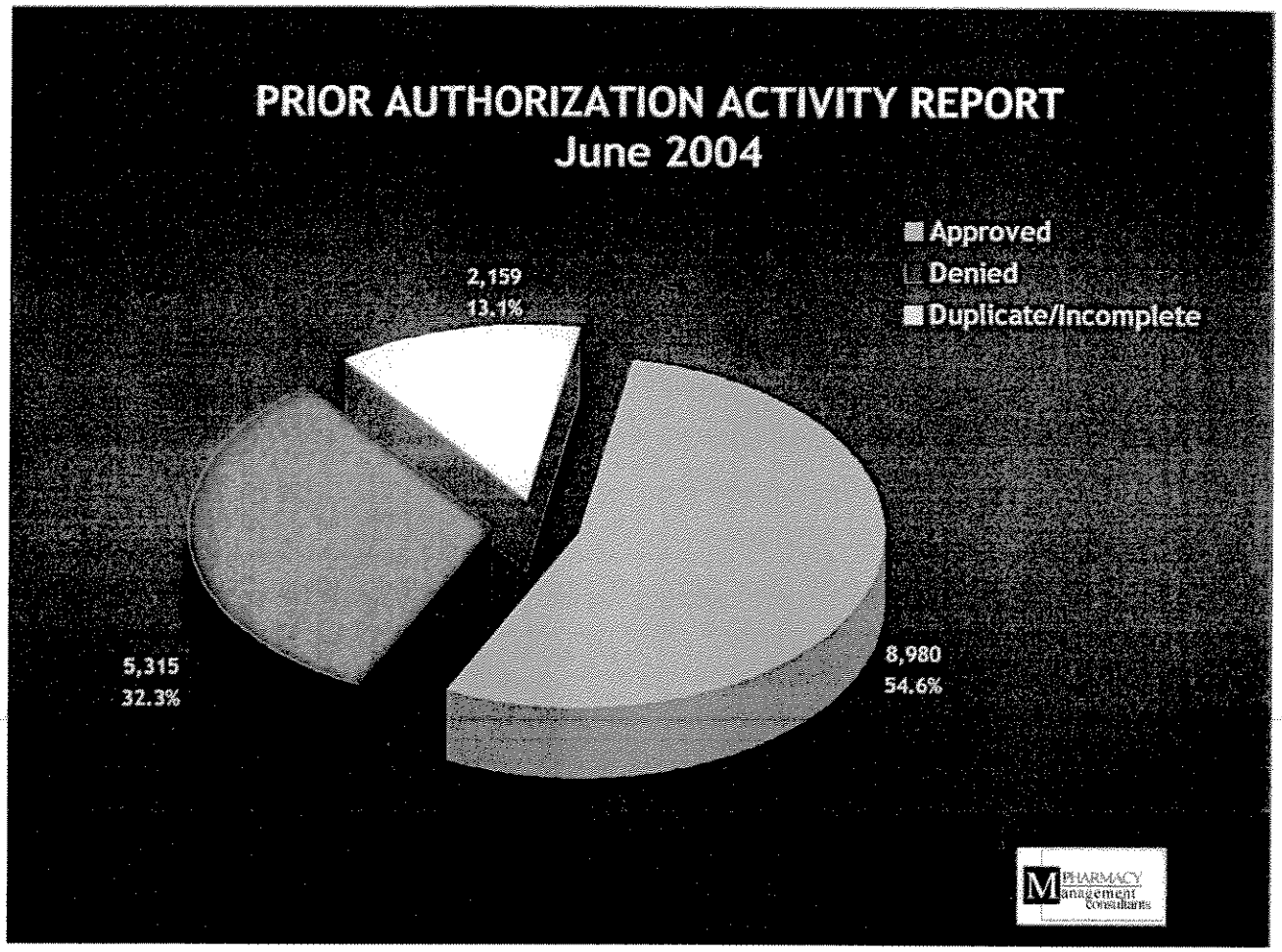
*Additional PA's: Done by the help desk (doctor letter responses, PA ran for the wrong person)*

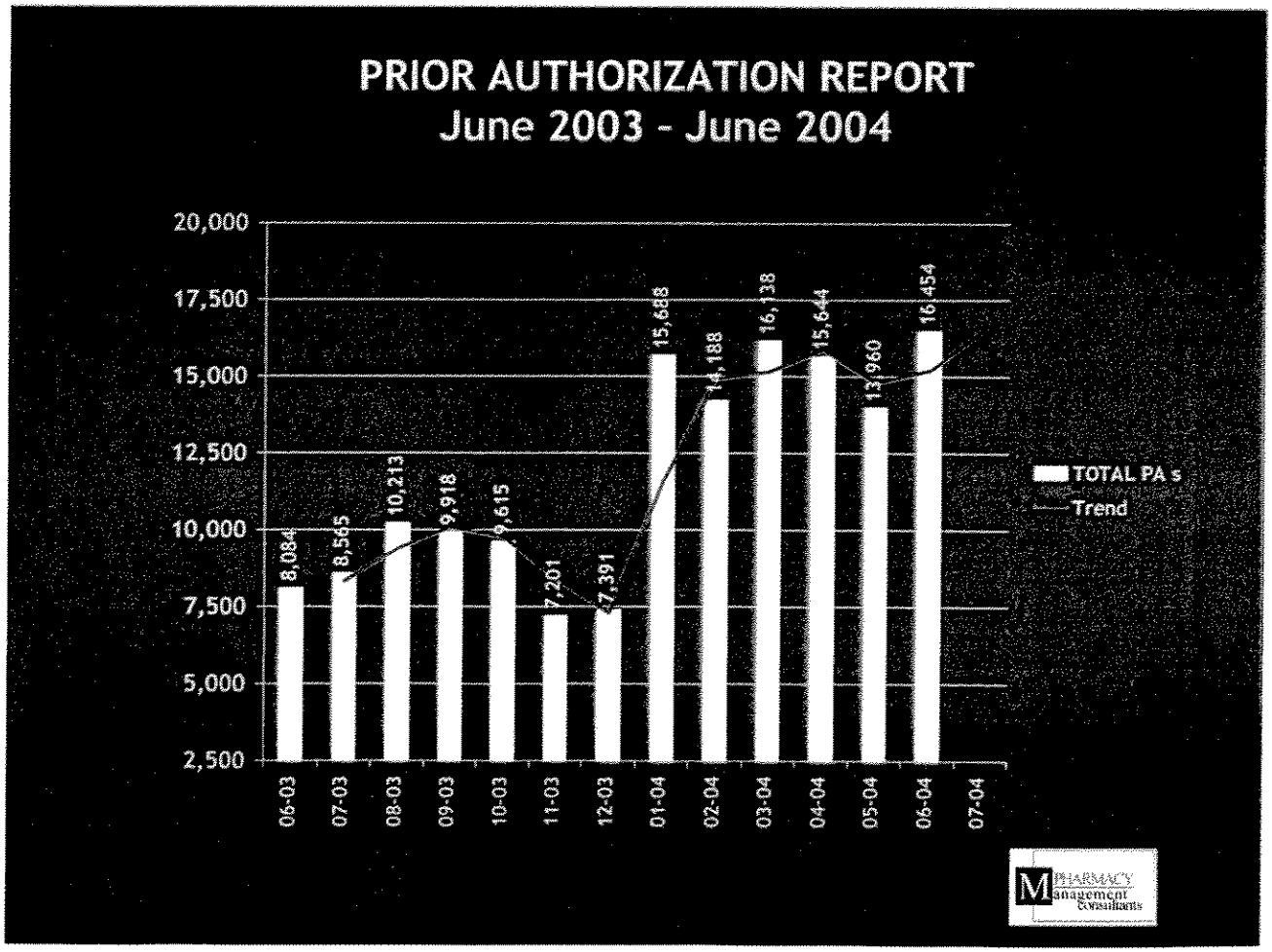
*Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)*

# PRIOR AUTHORIZATION ACTIVITY AUDIT

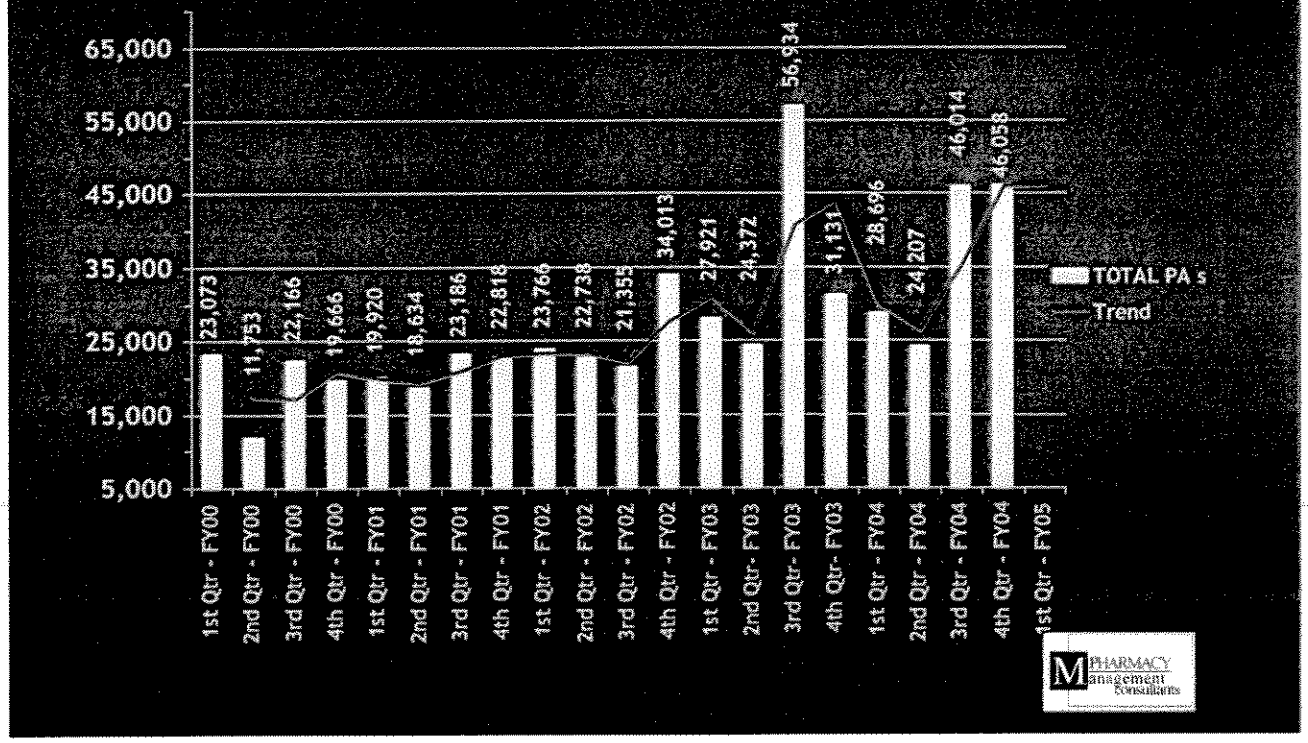
## Monthly Totals

| MONTH | 1999 Total *(approved/ duplicates/ denied)* | 2000 Total *(approved/ duplicates/ denied)* | 2001 Total *(approved/ duplicates/ denied)* | 2002 Total *(approved/ duplicates/ denied)* | 2003 Total *(approved/ duplicates/ denied)* | 2004 Total *(approved/ duplicates/ denied)* |
|---|---|---|---|---|---|---|
| January | 4,124 | 8,669 | 9,296 | 8,427 | 7,797 | 15,688 |
| February | 3,542 | 8,077 | 7,194 | 6,095 | 11,272 | 14,188 |
| March | 3,856 | 7,588 | 7,748 | 6,833 | 10,358 | 16,138 |
| April | 3,867 | 6,390 | 7,676 | 13,381 | 8,953 | 15,644 |
| May | 3,959 | 6,711 | 7,980 | 12,082 | 8,589 | 13,960 |
| June | 3,884 | 6,565 | 7,249 | 8,550 | 8,084 | 16,454 |
| July | 3,523 | 6,181 | 8,133 | 8,775 | 8,565 | |
| August | 10,676 | 7,183 | 8,195 | 9,353 | 10,213 | |
| September | 8,387 | 6,585 | 7,438 | 9,793 | 9,918 | |
| October | 3,863 | 6,140 | 7,956 | 11,584 | 9,615 | |
| November | 3,919 | 6,961 | 7,949 | 7,921 | 7,201 | |
| December | 3,953 | 6,206 | 6,385 | 4,867 | 7,391 | |
| **Calendar Year Total** | **57,553** | **83,256** | **93,199** | **107,661** | **107,956** | **92,072** |


PRIOR AUTHORIZATION ACTIVITY REPORT
June 2004
Approved
Denied
Duplicate/Incomplete
2,159
13.1%
5,315
32.3%
8,980
54.6%
PHARMACY Management Consultants

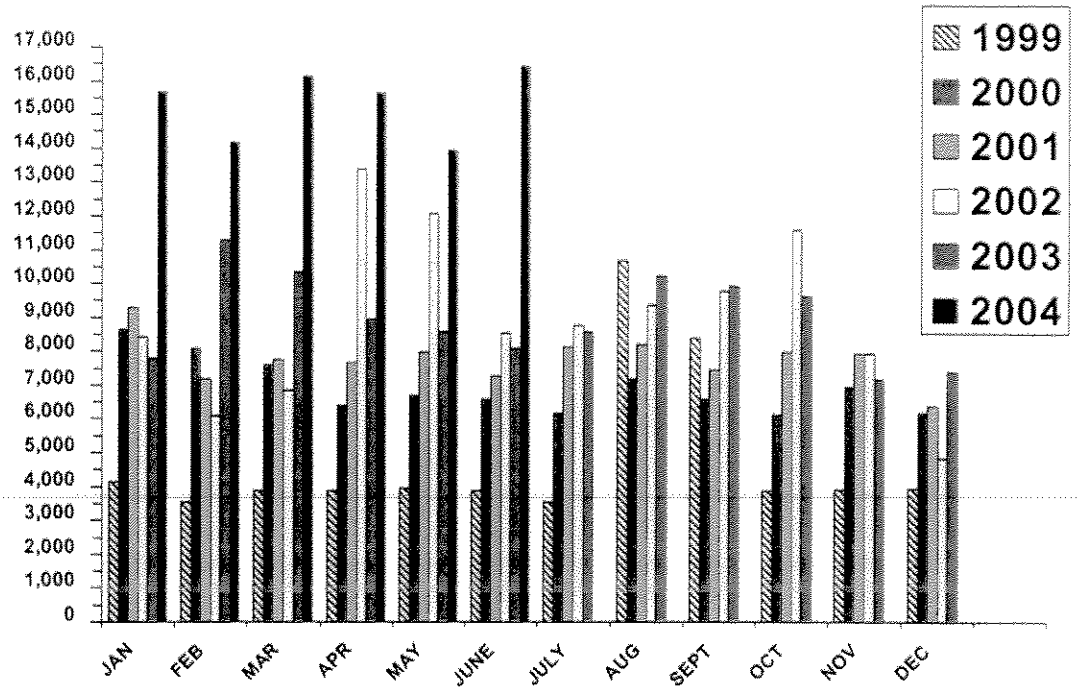

PRIOR AUTHORIZATION REPORT
June 2003 - June 2004
20,000
17,500
15,000
12,500
10,000
7,500
5,000
2,500
8,084
8,565
10,213
9,918
9,615
7,201
7,391
15,688
14,188
16,138
15,644
13,960
16,454
06-03
07-03
08-03
09-03
10-03
11-03
12-03
01-04
02-04
03-04
04-04
05-04
06-04
07-04
TOTAL PA s
Trend
PHARMACY Management Consultants

# PRIOR AUTHORIZATION QUARTERLY REPORT
## FY00 through FY04
### (July 1999 - June 2004)



## Monthly PA Activity

## Calendar Years 2000-2004




## Monthly PA Activity

## Calendar Years 2000-2004

# CALL VOLUME -JUNE 2004

| JUNE 04 | CALLER | | | | | ISSUE | | | | | TYPE OF CALL | | | | | RESOLUTION | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | | Resolved | | | | | | | |
| | Call Volume | Physician | Pharmacies | Clients | Other | Eligibility | Claims | PA Issue | SMAC | Other | Regular | Callback | Proactive | ProDUR | Other | Helpdesk Resolved | Transferred Pharmacist | Transferred Supervisor | OHCA | Reversals/ Adjustments | EDS | Customer Service | Provider Contracts |
| 1 | 798 | 18 | 671 | 87 | 22 | 148 | 297 | 98 | 1 | 254 | 750 | 11 | 2 | 29 | 6 | 781 | 5 | 4 | 0 | 0 | 0 | 8 | 0 |
| 2 | 676 | 19 | 586 | 26 | 45 | 120 | 232 | 89 | 0 | 235 | 633 | 14 | 2 | 20 | 7 | 661 | 6 | 1 | 0 | 0 | 0 | 8 | 0 |
| 3 | 738 | 18 | 626 | 55 | 39 | 116 | 303 | 73 | 0 | 246 | 693 | 21 | 4 | 9 | 11 | 730 | 1 | 1 | 0 | 0 | 0 | 6 | 0 |
| 4 | 688 | 17 | 607 | 40 | 24 | 107 | 281 | 90 | 1 | 209 | 619 | 16 | 0 | 42 | 11 | 674 | 5 | 1 | 0 | 0 | 0 | 8 | 0 |
| 5 | 148 | 0 | 143 | 3 | 2 | 12 | 101 | 7 | 0 | 28 | 143 | 2 | 0 | 3 | 0 | 148 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 54 | 0 | 53 | 0 | 1 | 7 | 43 | 0 | 0 | 4 | 53 | 1 | 0 | 0 | 0 | 54 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 763 | 21 | 655 | 57 | 30 | 105 | 275 | 113 | 1 | 269 | 702 | 20 | 3 | 30 | 8 | 751 | 2 | 0 | 2 | 1 | 0 | 7 | 0 |
| 8 | 774 | 19 | 661 | 71 | 23 | 120 | 264 | 114 | 0 | 276 | 745 | 13 | 2 | 8 | 6 | 760 | 0 | 0 | 3 | 2 | 0 | 9 | 0 |
| 9 | 773 | 15 | 612 | 70 | 76 | 128 | 238 | 141 | 0 | 266 | 641 | 79 | 5 | 42 | 6 | 754 | 6 | 0 | 0 | 2 | 0 | 10 | 1 |
| 10 | 725 | 13 | 624 | 56 | 32 | 103 | 304 | 125 | 0 | 193 | 670 | 22 | 3 | 24 | 6 | 712 | 3 | 0 | 1 | 2 | 0 | 6 | 1 |
| 11 | 534 | 15 | 485 | 19 | 15 | 78 | 199 | 95 | 3 | 159 | 491 | 3 | 1 | 29 | 10 | 525 | 5 | 0 | 0 | 1 | 0 | 3 | 0 |
| 12 | 141 | 0 | 135 | 4 | 2 | 33 | 54 | 16 | 0 | 38 | 134 | 0 | 1 | 5 | 1 | 140 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| 13 | 59 | 0 | 59 | 0 | 0 | 12 | 33 | 3 | 0 | 11 | 59 | 0 | 0 | 0 | 0 | 59 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 747 | 17 | 644 | 71 | 15 | 98 | 277 | 133 | 1 | 238 | 732 | 6 | 0 | 2 | 7 | 733 | 2 | 2 | 1 | 1 | 0 | 8 | 0 |
| 15 | 695 | 21 | 578 | 64 | 32 | 106 | 250 | 130 | 1 | 208 | 643 | 21 | 2 | 23 | 6 | 683 | 3 | 0 | 1 | 1 | 0 | 7 | 0 |
| 16 | 776 | 21 | 635 | 81 | 39 | 122 | 326 | 115 | 0 | 213 | 724 | 18 | 7 | 19 | 8 | 766 | 2 | 1 | 2 | 0 | 0 | 5 | 0 |
| 17 | 720 | 16 | 642 | 48 | 14 | 110 | 287 | 91 | 1 | 231 | 698 | 4 | 1 | 10 | 7 | 707 | 2 | 0 | 0 | 4 | 0 | 7 | 0 |
| 18 | 751 | 18 | 658 | 50 | 25 | 97 | 289 | 131 | 0 | 234 | 711 | 20 | 3 | 12 | 5 | 736 | 5 | 2 | 0 | 1 | 0 | 7 | 0 |
| 19 | 142 | 0 | 132 | 5 | 5 | 15 | 82 | 10 | 0 | 35 | 131 | 3 | 0 | 6 | 2 | 141 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 20 | 46 | 0 | 35 | 3 | 8 | 6 | 16 | 2 | 0 | 22 | 38 | 2 | 0 | 0 | 6 | 45 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| 21 | 731 | 11 | 629 | 62 | 29 | 130 | 313 | 93 | 0 | 195 | 685 | 16 | 3 | 17 | 10 | 721 | 3 | 1 | 0 | 0 | 0 | 6 | 0 |
| 22 | 701 | 27 | 575 | 69 | 30 | 100 | 261 | 117 | 0 | 223 | 660 | 13 | 0 | 24 | 4 | 672 | 11 | 4 | 1 | 6 | 0 | 7 | 0 |
| 23 | 680 | 26 | 566 | 64 | 24 | 87 | 257 | 114 | 0 | 222 | 636 | 9 | 1 | 24 | 10 | 671 | 4 | 0 | 0 | 0 | 0 | 5 | 0 |
| 24 | 730 | 19 | 626 | 57 | 28 | 104 | 350 | 96 | 1 | 178 | 697 | 12 | 2 | 8 | 11 | 717 | 7 | 0 | 0 | 0 | 0 | 6 | 0 |
| 25 | 668 | 16 | 575 | 57 | 20 | 92 | 278 | 100 | 0 | 198 | 640 | 7 | 0 | 9 | 12 | 660 | 0 | 1 | 1 | 1 | 0 | 4 | 0 |
| 26 | 139 | 1 | 129 | 5 | 4 | 30 | 71 | 9 | 0 | 29 | 135 | 1 | 0 | 2 | 1 | 139 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 45 | 0 | 45 | 0 | 0 | 14 | 19 | 1 | 0 | 11 | 45 | 0 | 0 | 0 | 0 | 45 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 714 | 11 | 620 | 55 | 28 | 98 | 314 | 83 | 0 | 219 | 679 | 4 | 0 | 15 | 16 | 699 | 6 | 2 | 0 | 0 | 0 | 6 | 0 |
| 29 | 739 | 16 | 621 | 68 | 34 | 108 | 286 | 112 | 0 | 232 | 689 | 19 | 1 | 25 | 5 | 732 | 0 | 0 | 0 | 0 | 0 | 7 | 0 |
| 30 | 739 | 20 | 623 | 64 | 32 | 105 | 318 | 100 | 0 | 212 | 704 | 13 | 7 | 10 | 5 | 727 | 4 | 2 | 1 | 0 | 0 | 4 | 0 |
| **Total** | **16,634** | **395** | **14,250** | **1,311** | **678** | **2,511** | **6,618** | **2,401** | **10** | **5,088** | **15,580** | **370** | **50** | **447** | **187** | **16,343** | **82** | **23** | **13** | **22** | **0** | **146** | **2** |
| **Percentage** | **100.00%** | **2.37%** | **85.67%** | **7.88%** | **4.08%** | **15.10%** | **39.79%** | **14.43%** | **0.06%** | **30.59%** | **93.66%** | **2.22%** | **0.30%** | **2.69%** | **1.12%** | **98.25%** | **0.49%** | **0.14%** | **0.08%** | **0.13%** | **0.00%** | **0.88%** | **0.01%** |

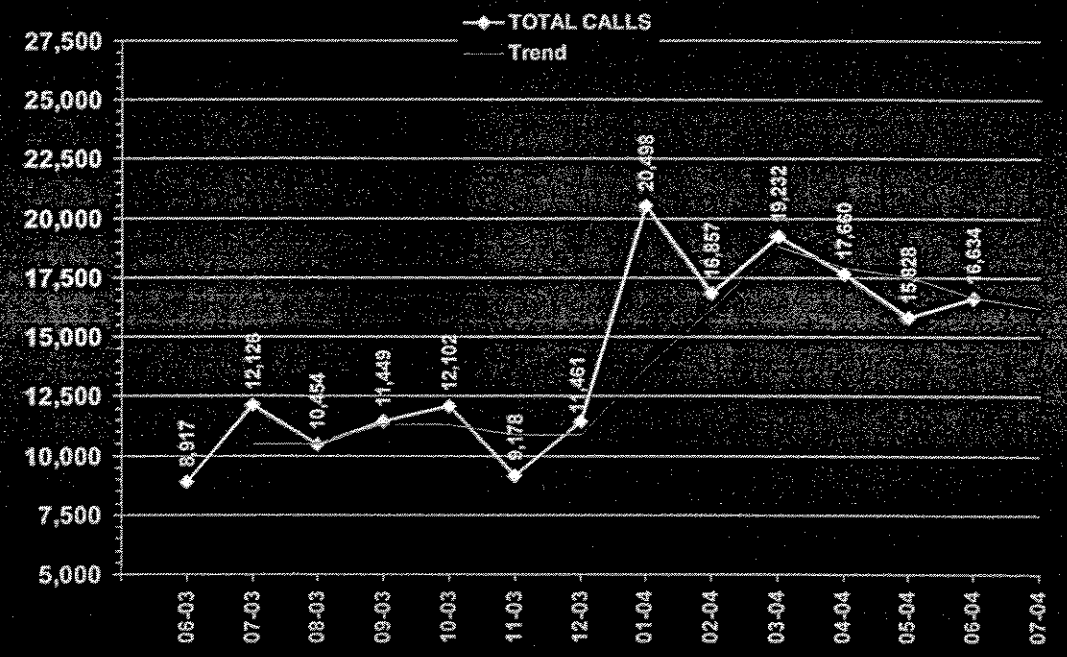
# CALL VOLUME

## Monthly Totals

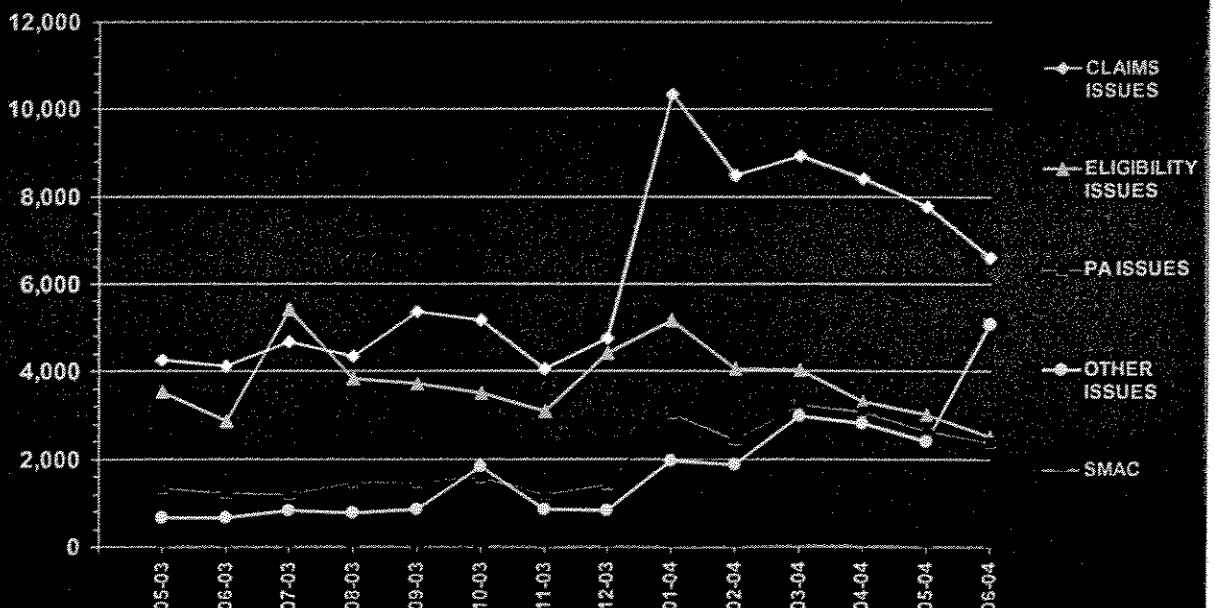
| MONTH | 1999 Total | 2000 Total | 2001 Total | 2002 Total | 2003 Total | 2004 Total |
|---|---|---|---|---|---|---|
| January | * 0 | 3,697 | 4,905 | 6,295 | 23,499 | 20,498 |
| February | * 0 | 3,335 | 4,393 | 5,049 | 17,354 | 16,857 |
| March | * 0 | 4,157 | 4,668 | 5,858 | 16,081 | 19,232 |
| April | * 0 | 3,337 | 4,556 | 8,047 | 12,378 | 17,660 |
| May | * 0 | 3,804 | 5,540 | 7,586 | 9,836 | 15,828 |
| June | * 0 | 2,820 | 4,982 | 6,368 | 8,917 | 16,634 |
| July | * 0 | 3,242 | 5,465 | 7,651 | 12,126 | |
| August | 3,883 | 4,333 | 6,881 | 7,629 | 10,454 | |
| September | 2,360 | 4,015 | 5,145 | 8,664 | 11,449 | |
| October | 1,963 | 4,398 | 5,912 | 9,608 | 12,102 | |
| November | 1,721 | 4,216 | 6,011 | 6,627 | 9,178 | |
| December | 2,475 | 3,804 | 5,314 | 11,710 | 11,461 | |
| **Calendar Year Total** | **12,402** | **45,158** | **63,772** | **91,092** | **154,835** | **106,709** |

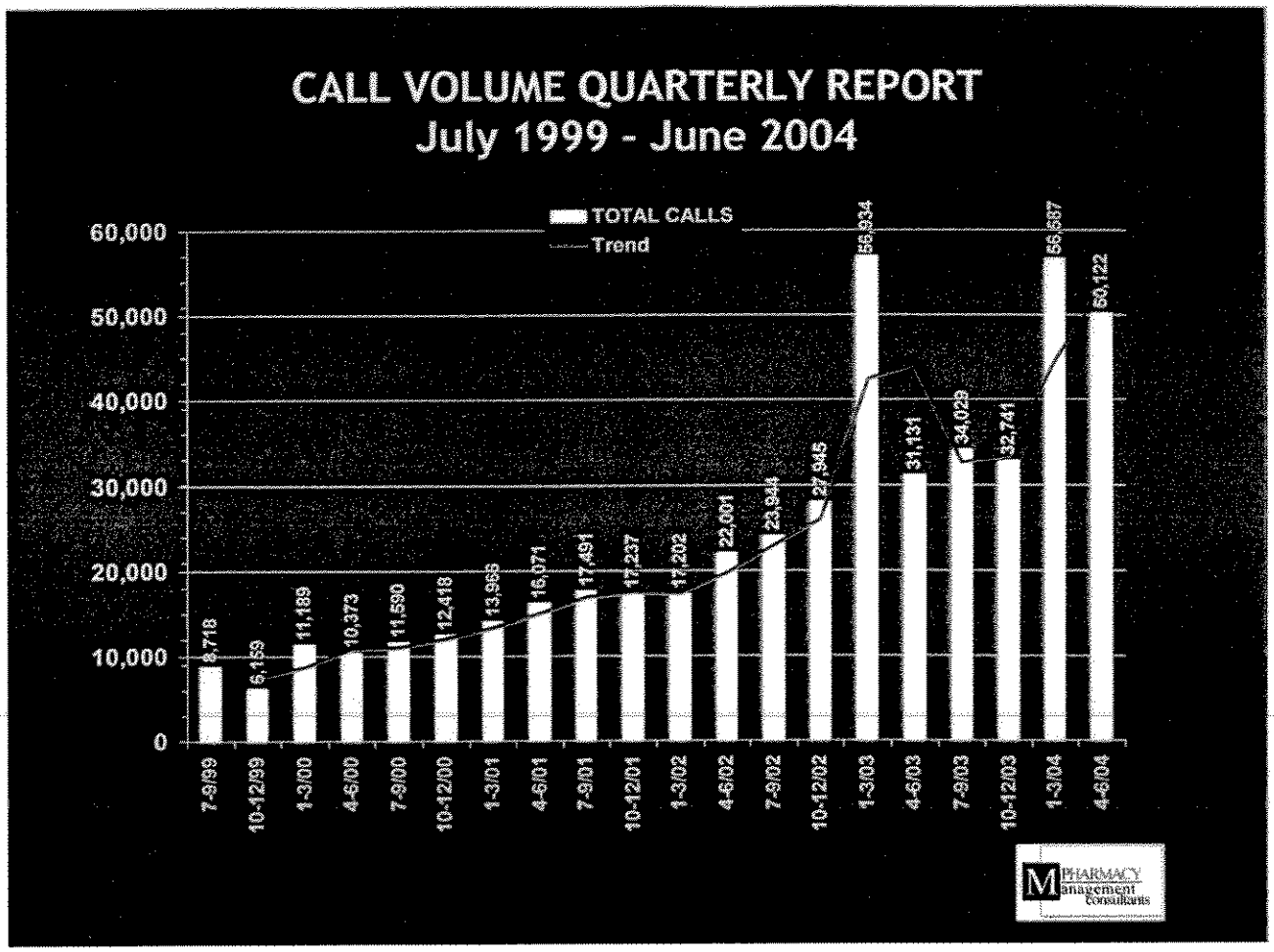
* Help Desk Call Center implemented in August 1999.

# CALL VOLUME MONTHLY REPORT
## June 2003 - June 2004



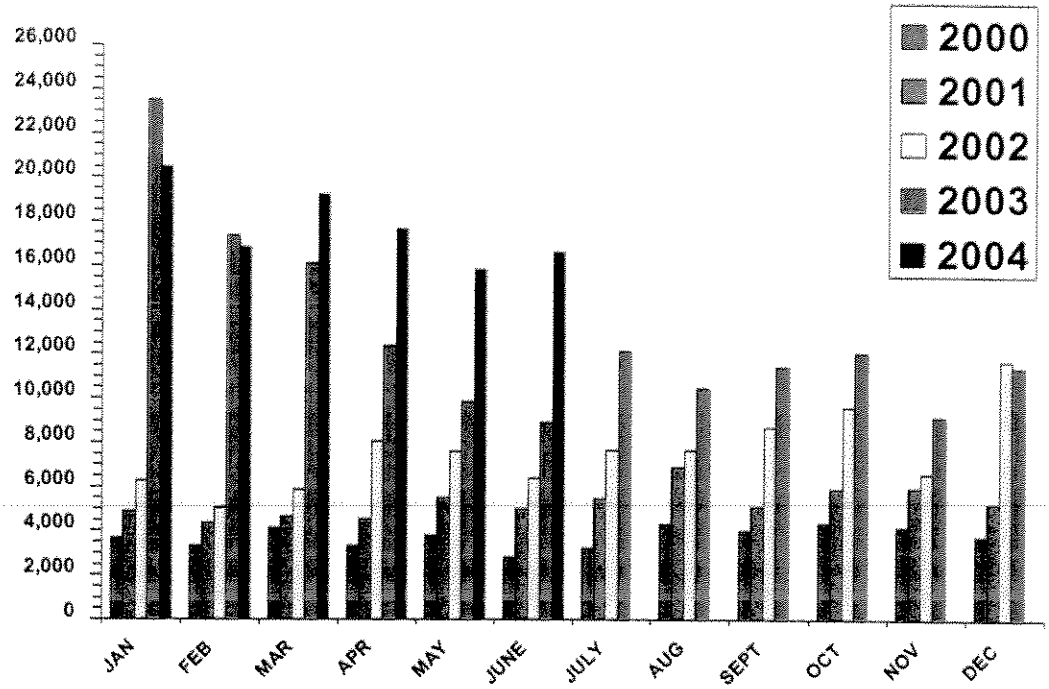

# CALL VOLUME ISSUES
## June 2003 - June 2004




CALL VOLUME QUARTERLY REPORT
July 1999 - June 2004
TOTAL CALLS
Trend
60,000
50,000
40,000
30,000
20,000
10,000
0
8,718
6,159
11,189
10,373
11,590
12,418
13,965
16,071
17,491
17,237
17,202
22,001
23,944
27,945
56,934
31,131
34,029
32,741
56,557
50,122
7-9/99
10-12/99
1-3/00
4-6/00
7-9/00
10-12/00
1-3/01
4-6/01
7-9/01
10-12/01
1-3/02
4-6/02
7-9/02
10-12/02
1-3/03
4-6/03
7-9/03
10-12/03
1-3/04
4-6/04
PHARMACY Management Consultants

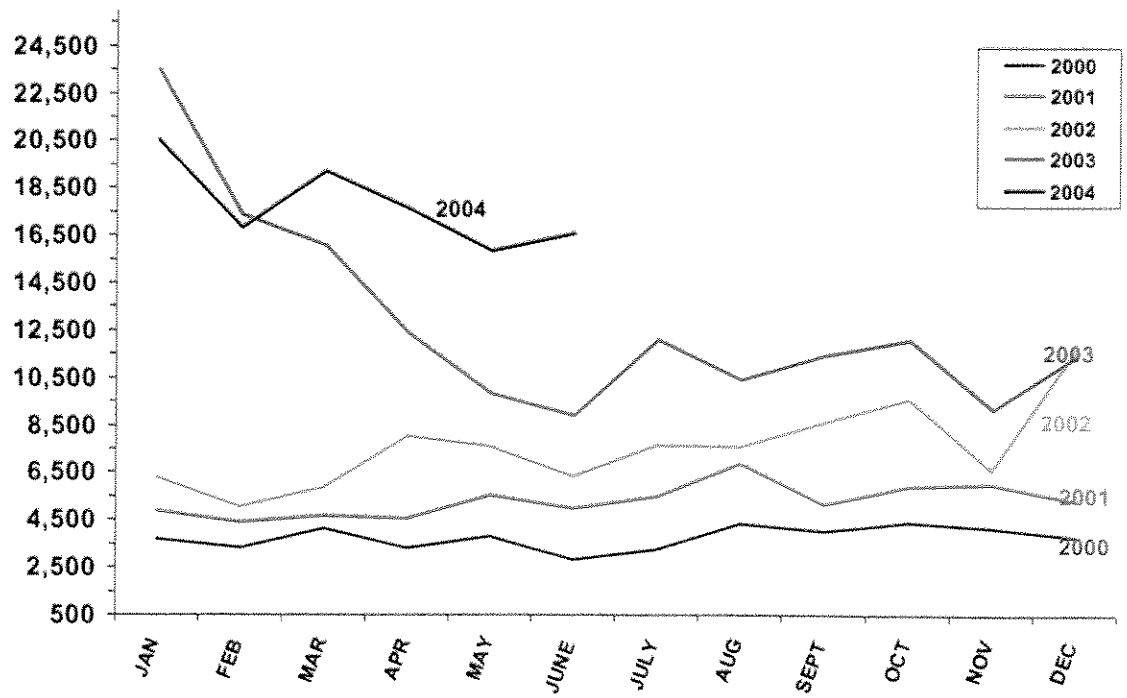
## Monthly Call Volume

## Calendar Years 2000-2004




## Monthly Call Volume

## Calendar Years 2000-2004



are, Idaho,
achusetts,
souri,
rth Carolina,
Dakota, Texas,

5), Indiana,
Nebraska (3/31),

ia (10/15-4/30)
Indiana (6),

outh Carolina

iospital, or

# APPENDIX C

# SYNAGIS™ (palivizumab)

Oklahoma Medicaid

July, 2004

## Vote to Prior Authorize Synagis™

Recommended Criteria for Prior Authorization of Synagis:

A. Client Selection. Client must be included in one of the following age groups at the beginning of the RSV season:*:

1) Infants and children less than 24 months old with Chronic Lung Disease (CLD) who have required medical treatment ($O_2$, bronchodilator, diuretic, or corticosteroid therapy) for CLD in the 6 months prior to RSV season.
2) Infants less than 12 months of age, born at 28 weeks gestation or earlier
3) Infants less than 6 months of age, born at 29-32 weeks gestation.
4) Infants, up to 6 months old at the start of RSV season, born at 32-36 weeks gestation, who have 2 or more of the following risk factors:
    a. Child care attendance
    b. School-aged siblings
    c. Exposure to environmental air pollutants (Tobacco smoke exposure can be controlled by the family, so is not a risk factor for Synagis prophylaxis)
    d. Congenital abnormalities of the airway
    e. Severe neuromuscular disease
5) Children up to 24 months old with hemodynamically significant cyanotic and acyanotic congenital heart disease.
6) Infants up to 12 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.

* Treatment should continue through the entire RSV season.

B. Length of treatment. Synagis will be approved for use only during RSV season, as determined by Oklahoma State Department of Health, which is generally October 1 through April 30.

C. Units authorized. The number of units authorized is to be calculated as the closest number of full vials necessary to provide the dose based on 15mg/kg per month.

D. Dose-pooling. To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

**Prior Authorization requirements in other states**

| Criteria | State |
|---|---|
| AAP Guidelines used | Alabama, Arkansas, Colorado, Delaware, Idaho, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, North Dakota, South Carolina, South Dakota, Texas, West Virginia |
| Date Restriction | Alabama (3/31), Delaware (10/15-4/15), Indiana, (10/15-4/30), Maryland (10/15-4/15), Nebraska (3/31), New York (11/1), North Dakota (10/1-4/30), West Virginia (10/15-4/30) |
| Number of Doses | Alabama (6), Delaware (6), Idaho (5), Indiana (6), Maine (6), Maryland (5), New Jersey (6), North Carolina (5), South Carolina (7), West Virginia (6) |
| Number of units by weight | Arkansas, Maryland |
| Single season (except w/ CLD) | Idaho, Michigan |
| Provider restriction | South Carolina, Indiana – physician, hospital, or infusion center only |
| Age (other than per AAP guidelines) | Washington – (1 yr) |

1. Palivizumab should be considered for infants and children younger than 2 years with CLD who have required medical therapy (supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy) for CLD within 6 months before the anticipated start of the RSV season
    - Patients with more severe CLD may benefit from prophylaxis during a second RSV season if they continue to require medical therapy for pulmonary or cardiac dysfunction.
2. Infants born at 32 weeks' gestation or earlier may benefit from RSV prophylaxis even if they do not have CLD. For these infants, major risk factors to consider include their gestational age and chronologic age at the start of the RSV season. (Evidence grade I.)
    - Infants born at 28 weeks' gestation or earlier may benefit from prophylaxis during their first RSV season whenever that occurs during the first 12 months of life. Infants born at 29 to 32 weeks' gestation may benefit most from prophylaxis up to 6 months of age. Once a child qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and not stop at the point an infant reaches either 6 or 12 months of age.
3. Although palivizumab and RSV-IGIV have been shown to decrease the likelihood of hospitalization for infants born between 32 and 35 weeks of gestation (Evidence grade I), the cost of administering prophylaxis to this large group of infants must be considered carefully.
    - Most experts recommend that prophylaxis be reserved for infants in this group who are at greatest risk of severe infection and who are younger than 6 months at the start of the RSV season. Epidemiologic data suggest that RSV infection is more likely to lead to hospitalization for these infants when the following risk factors are present: child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease. However, no single risk factor causes a very large increase in the rate of hospitalization, and the risk is additive as the number of risk factors for an individual infant increases. Therefore, prophylaxis should be considered for infants between 32 and 35 weeks' gestation only if 2 or more of these risk factors are present.
    - Exposure to tobacco smoke is a risk factor that can be controlled by the family of an infant at increased risk of RSV disease, and tobacco smoke control measures will be far less costly than palivizumab prophylaxis. High-risk infants never should be exposed to tobacco smoke. High-risk infants should be kept away from crowds and from situations where exposure to infected individuals cannot be controlled.
    - Participation in child care should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene.
    - All high-risk infants and their contacts should be immunized against influenza beginning at 6 months of age.
4. Prophylaxis against RSV should be initiated just before the onset of the RSV season and terminated at the end of the RSV season. In most seasons and in most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the beginning of November, and the last dose should be administered at the beginning of March, which will provide protection into April.[5] (Evidence grade III.)
    - To understand the epidemiology of RSV in their area, physicians should consult with local health departments or diagnostic virology laboratories or the Centers for Disease Control and Prevention if such information is not available locally. Decisions about the specific duration of prophylaxis should be individualized according to the duration of the RSV season. Pediatricians may wish to use RSV hospitalization data from their own region to assist in the decision-making process.
5. Children who are 24 months or younger with hemodynamically significant cyanotic and acyanotic CHD will benefit from 5 monthly intramuscular injections of palivizumab (15 mg/kg). (Evidence grade I.)
    - Decisions regarding prophylaxis with palivizumab in children with CHD should be made on the basis of the degree of physiologic cardiovascular compromise. Infants younger than 12 months with CHD who are most likely to benefit from immunoprophylaxis include:
        - i. infants who are receiving medication to control congestive heart failure;
        - ii. infants with moderate to severe pulmonary hypertension; and
        - iii. infants with cyanotic heart disease.
    - Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of palivizumab (15 mg/kg) should be considered as soon as the patient is medically stable.

The following groups of infants are not at increased risk from RSV and generally should not receive immunoprophylaxis:

- infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta and patent ductus arteriosus)
- infants with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure
- infants with mild cardiomyopathy who are not receiving medical therapy

Palivizumab or RSV-IGIV prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, children with severe immunodeficiencies (eg, severe combined immunodeficiency or severe acquired immunodeficiency syndrome) may benefit from prophylaxis. (Evidence grade III.)

6. Because palivizumab is not effective in the treatment of RSV disease, it is not licensed for this indication. (Evidence grade I.)
7. Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. However, there are insufficient data to determine the effectiveness of palivizumab use in these patients.
8. If an infant or child who is receiving immunoprophylaxis experiences a breakthrough RSV infection, prophylaxis should continue through the RSV season. (Evidence grade III.)
    - This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often cocirculates in a community.
9. Physicians should arrange for drug administration within 6 hours after opening a vial, because this product does not contain a preservative.
10. Recommendations cannot be made regarding the use of palivizumab as a means of prevention of nosocomial RSV disease.
    - RSV is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. In high-risk hospitalized infants, the major means to prevent RSV disease is strict observance of infection control practices including the use of rapid means to identify and isolate RSV-infected infants. If an RSV outbreak is documented in a high-risk unit (eg, pediatric intensive care unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene.
11. Palivizumab does not interfere with the response to vaccines.

A critical aspect of RSV prevention in high-risk infants is the education of parents and other caregivers about the importance of decreasing infants' exposure to and acquisition of RSV. Preventive measures include eliminating exposure to cigarette smoke and settings where RSV or other respiratory viruses may be transmitted (eg, child care centers). Emphasis on hand hygiene also is important in all settings including the home, especially during periods when contacts of high-risk children have respiratory tract infections or when infants are at risk of exposure to respiratory infections from siblings who are in child care or who attend school.

Palivizumab is administered once per month (eg, every 30 days) beginning just before the onset of the RSV season, which typically occurs in November but may vary by region. In general, 4 subsequent monthly doses (for a total of 5 doses) are sufficient to provide protection during the entire RSV season. Hospitalized infants determined to be at risk of severe RSV disease should receive RSV-IGIV or palivizumab 48 to 72 hours before discharge home from the hospital during the respiratory virus season and then every 30 days until the end of the season.

Factors other than degree of prematurity, CHD, and CLD that may influence the decision regarding prophylaxis include presence of other underlying conditions that predispose to respiratory complications (eg, neurologic disease in very low birth weight infants), number of young siblings, child care center attendance, anticipation of cardiac surgery, and distance to and availability of hospital care for severe respiratory illness. For many infants who qualify for the approved indications, risk of hospitalization for serious respiratory illness will be low, and the cost and logistic difficulties associated with prophylaxis may outweigh potential benefits.

# APPENDIX D

# Vote to Prior Authorize SSRIs

Oklahoma Medicaid
July 2004



## Currently Available SSRIs and Cost Comparison

| Generic Name | Brand Name | Dosage Forms Available | Dosage Range (mg/day) | Indications | 2003 Market Share | Cost Ratio CY03[1] | Avg Unit SMAC FY05[2] |
|---|---|---|---|---|---|---|---|
| Citalopram | Celexa® | 10, 20, & 40 mg tabs | 20 - 60 | 1 | 15.26% | 2.75 | |
| | Celexa® Solution | 10 mg/10 ml | | | 0.06% | 6.45 | |
| Escitalopram | Lexapro® | 5, 10 & 20 mg tabs | 10 -20 | 1 & 8 | 10.49% | 2.76 | |
| | Lexapro® Solution | 5 mg/5 ml | | | 0.02% | 5.25 | |
| Fluoxetine | Prozac® | 10 mg tab; 10,20 & 40 mg cap; | 20 - 80 | 1-3 & 7 | 0.40% | 4.27 | |
| | Fluoxetine | 10 & 20 mg tab[3]; 10,20 & 40[3] mg cap | | | 15.03% | 1.71 | $ 0.05 |
| | Prozac® Solution | 20 mg/5 ml | | | 0.02% | 2.42 | |
| | Fluoxetine Solution | | | | 0.18% | 6.28 | $ 0.15 |
| | Prozac Weekly® | 90 mg delayed-release cap[4] | | | 0.94% | 3.73 | |
| | Sarafem® | 10 & 20 mg cap | | 5 | 0.05% | 1.00 | |
| Fluvoxamine | Luvox® | 25, 50, & 100 mg tab | 50 - 300 | 2 | 0.02% | 1.45 | |
| | Fluvoxamine | | | | 1.71% | 2.43 | $ 0.55 |
| Paroxetine | Paxil® | 10, 20, 30, 40 mg tab | 10 - 50 | 1-4 & 8 | 17.02% | 3.31 | |
| | Paroxetine | | | | 2.89% | 2.91 | $ 1.73[5] |
| | Paxil® Suspension | 10 mg/5 ml | | | 0.09% | 7.01 | |
| | Paxil CR® | 12.5, 25 & 37.5 mg tab | | 1, 3, 5 & 6 | 6.54% | 3.72 | |
| Paroxetine Mesylate | Pexeva®[6] | 10, 20, 30 & 40 mg tab | 40 - 60 | 1 - 3 | N/A | N/A | |
| Sertraline | Zoloft® | 25, 50 & 100 mg tab | 50 - 200 | 1 - 6 | 29.22% | 3.51 | |
| | Zoloft® Concentrate | 20 mg/ml | | | 0.07% | 2.73 | |

[1] Cost ratio does not reflect any actual dollar amounts.
[2] Average SMAC is based on current SMAC pricing as of 2/04 (6/04 for paroxetine) and does not include any rebates.
[3] Fluoxetine 10 & 20 mg tabs and 40 mg cap currently have a prior authorization in place.
[4] Prozac Weekly currently has a prior authorization in place.
[5] New initial SMAC pricing as of 6/04.
[6] New product as of January 2004.

1. Major depressive disorder (MDD).
2. Obsessive-compulsive disorder (OCD).
3. Panic disorder, with or without agoraphobia.
4. Posttraumatic Stress Disorder (PTSD).
5. Premenstrual Dysphoric Disorder (PMDD).
6. Social anxiety disorder (social phobia).
7. Bulimia nervosa.
8. Generalized anxiety disorder.

## Savings Calculations

Based on a future projected use of the recommended tier-1 products a net cost savings and administrative cost has been calculated.

| | |
|---|---|
| Projected percent shift in market share to tier-1 products: | 24.2% |
| Projected maximum number of annual petitions: | 21,225 |
| Estimated Annual Savings (minus rebate and dispensing fees): | $ 2,186,359.43 |
| Potential Annual Administrative Cost*: | 267,010.50 |
| **Total Net Plan Savings:** | **$1,919,348.93** |

* The average cost for processing petitions is calculated at $6.50 per petition with the maximum cost at $12.58 per petition. The maximum cost was used in the estimation of administrative costs.

## Recommendations

The following tier-1 drug list 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.

1. Fluoxetine (generic only)
2. Fluvoxamine (generic only)
3. Paroxetine (generic only)

The current restrictions on fluoxetine will remain in effect regarding the use of the 10 & 20 mg tablets and 40 mg capsules. All brand name medications will be subject to Prior Authorization requirements beginning July 1, 2004 when a State MAC price is applied to that product.

The following criteria are recommended for approval of a tier-2 product:

1. Documented adverse effect, drug interaction, or contraindication to the tier-1 products.
2. Failure with a tier one medication defined as no beneficial or minimally beneficial response after at least 4 weeks of continuous use during which time the drug has been titrated up to the maximum recommended dose.
3. Unique indication not covered by a tier-1 product.
4. Clients who have been on a tier-2 product within the last 90 days would be allowed to continue current therapy without interruption.

Currently paroxetine requires a prior authorization for clients less than 18 years of age. The following paragraphs are excerpts from the FDA Public Health Advisory, March 22, 2004.

"Today the Food and Drug Administration (FDA) asked manufacturers of the following antidepressant drugs to include in their labeling a Warning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality. The drugs that are the focus of this new Warning are: Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine).

Among antidepressants, only Prozac (fluoxetine) is approved for the treatment of pediatric major depressive disorder. Prozac (fluoxetine), Zoloft (sertraline), and Luvox (fluvoxamine) are approved for pediatric obsessive compulsive disorder. None of these drugs is approved as monotherapy for use in treating bipolar depression, either in adults or children."

The current recommendations include fluoxetine and fluvoxamine as tier one for all ages. Paroxetine would continue to require prior authorization for clients under 18 years of age. Any further recommendations from the DUR Board regarding this age group would also be incorporated.

# APPENDIX E

**Mechanism of action:** The final active messenger of the renin-angiotensin pathway is angiotensin II. Angiotensin II binds to AT1 receptors to cause vasoconstriction and fluid retention, both of which lead to an increase in blood pressure. The angiotensin II receptor blockers (ARBs) lower blood pressure by blocking the AT1 receptors. Therefore they have similar effects to angiotensin converting enzyme (ACE) inhibitors, which inhibit the synthesis of angiotensin II by ACE. However, non-ACE pathways can produce some angiotensin II. ACE inhibitors also decrease bradykinin breakdown and this action could be involved in some of the beneficial and adverse effects of that class of drugs. Therefore, a potential for differential clinical effects exists for these two classes of drugs. (Therapeutics Letter, issue 28, January/February/March 1999)

## Product information[1]

**Angiotensin II Receptor Blockers:**

| *Drug* | *How Supplied* | *Dosing Schedule* | *Max Dose/Day* | *FDA Approved Indication(s)* |
|---|---|---|---|---|
| Candesartan - **Atacand** | 4, 8, 16, & 32 mg tablets | QD-BID | 32 mg | Hypertension |
| Eprosartan - **Teveten** | 400 & 800 mg tablets | QD-BID | 800mg | Hypertension |
| Irbesartan – **Avapro** | 75, 150, & 300 mg tablets | QD | 300 mg | Hypertension, Diabetic II Nephropathy |
| Losartan - **Cozaar** | 25, 50, & 100 mg tablets | QD-BID | 100 mg | Hypertension, Diabetic II nephropathy, Stroke reduction (HTN with LVH) |
| Olmesartan – **Benicar** | 5, 20, & 40 mg tablets | QD | 80 mg | Hypertension |
| Telmisartan - **Micardis** | 20, 40, & 80 mg tablets | QD | 80 mg | Hypertension |
| Valsartan – **Diovan** | 40, 80, 160, & 320 mg tablets | QD-BID* | 320 mg | Hypertension, Congestive Heart failure |

*BID dosing for CHF

**ARB Inhibitor/HCTZ Combinations:**

| *Drug* | *How Supplied* | *Dosing Schedule* | *Max Dose/Day* | *FDA Approved Indication(s)* |
|---|---|---|---|---|
| Candesartan/HCTZ – **Atacand HCT** | 16/12.5 & 32/12.5mg tablets | QD | 32/25 mg | Hypertension (not for initial therapy) |

| *Drug* | *How Supplied* | *Dosing Schedule* | *Max Dose/Day* | *FDA Approved Indication(s)* |
|---|---|---|---|---|
| Eprosartan/HCTZ – **Teveten HCT** | 600/12.5 & 600/25 mg tablets | QD | 600/25 mg | Hypertension (not for initial therapy) |
| Irbesartan/HCTZ – **Avalide** | 150/12.5 & 300/12.5 mg tablets | QD | 300/25 mg | Hypertension (not for initial therapy) |
| Losartan/HCTZ – **Hyzaar** | 50/12.5 & 100/25 mg tablets | QD-BID | 100/25 mg | Hypertension (not for initial therapy) |
| Olmesartan/HCTZ -**Benicar HCT** | 20/12.5, 40/12.5, & 40/25 mg tablets | QD | 40/25 mg | Hypertension (not for initial therapy) |
| Telmisartan/HCTZ – **Micardis HCT** | 40/12.5 & 80/12.5 mg tablets | QD | 160/25 mg | Hypertension (not for initial therapy) |
| Valsartan/HCTZ – **Diovan HCT** | 80/12.5, 160/12.5, & 160/25 mg tablets | QD | 160/25 mg | Hypertension (not for initial therapy) |

1. MICROMEDEX(R) Healthcare Series Vol. 120 expires 6/2004.

## Pharmacokinetic comparison[1, 2]

| | Candesartan | Eprosartan | Irbesartan | Losartan | Olmesartan | Telmisartan | Valsartan |
|---|---|---|---|---|---|---|---|
| **Oral Bioavailability** | 15% | 13% | 60-80% | 33% | 26% | 42-58% | 10-35% |
| **Food Effect** | no | Delayed absorption | no | 10% decrease bioavailability | no | 6-20% decrease in bioavailability | ~50% decrease in AUC |
| **Protein binding** | 99% | 98% | 90% | 95% | 99% | 99.5% | 94-95% |
| **Elimination half-life (hr)** | 3.5-4 (parent) 3-11 (metabolite) | 5-9 | 11-15 | 2 (parent) 6-9 (metabolite) | 12-18 (parent) 8-13 (metabolite) | 24 | 6 |
| **Active Metabolite** | Yes | No | No | Yes | Yes | No | No |
| **Metabolism** | O-demethylation | Glucoronide conjugation | CYP-2C9 | CYP-2C9 & 3A4 | De-esterification | Conjugation | Unknown |
| **Drug interactions** | None | None | None | Rifampin, fluconazole | None | Digoxin | None |
| **Dose in Hepatic impairment** | No change | No change | No change | Reduce initial dose | No change | Use w/ caution | No change |
| **Dose in Renal impairment** | No change | No change | No change | No change | No change | No change | No change |

1. MICROMEDEX(R) Healthcare Series Vol. 120 expires 6/2004.
2 Norwood, D, Branch E, Smith, B, Honewell,M. Olmesartan Medosomil for Hypertension: A Clinical Review. P&T 2002; 12:611-8.

## Savings Calculations

Based on a future projected use of the recommended tier-1 products a net cost savings and administrative cost has been calculated.

| | |
|---|---|
| Projected percent shift in market share to tier-1 products: | 30.5% |
| Projected maximum number of annual petitions: | 5,770 |
| Estimated Annual Savings (minus rebate and dispensing fees): | $ 615,304.25 |
| Potential Annual Administrative Cost*: | 72,586.60 |
| **Total Net Plan Savings:** | **$ 542,719.03** |

*The average cost for processing petitions is calculated at $6.50 per petition with the maximum cost at $12.58 per petition. The maximum cost was used in the estimation of administrative costs.

## Cost Comparisons of ARBS and Tier-1 ACEIs for CY03

| | Cost Ratio Compared to ARBs | CY03 Market Share | Cost Ratio Compared to Tier-1 ACEIs |
|---|---|---|---|
| Atacand® | 1.85 | 9.46% | 2.62 |
| Teveten® | 1.71 | 1.01% | 2.42 |
| Avapro® | 1.48 | 17.57% | 2.09 |
| Cozaar® | 1.64 | 32.00% | 2.32 |
| Benicar® | 1.00 | 6.29% | 1.41 |
| Micardis® | 1.10 | 5.36% | 1.56 |
| Diovan® | 1.70 | 28.31% | 2.40 |
| T1 ACEI* | 0.71 | | 1.00 |
| | | | |
| Atacand HCT® | 1.77 | 4.78% | 1.68 |
| Teveten HCT® | 2.76 | 0.35% | 2.61 |
| Avalide® | 1.16 | 12.15% | 1.10 |
| Hyzaar® | 1.40 | 48.40% | 1.33 |
| Benicar HCT® | 1.22 | 0.54% | 1.16 |
| Micardis HCT® | 1.00 | 3.69% | 0.95 |
| Diovan HCT® | 1.40 | 30.08% | 1.33 |
| T1 ACEI-HCT* | 1.05 | | 1.00 |

*ACEI calculations are based on the products which were tier-1 during CY03 and do NOT include deductions for rebates.

**Comments**

There is no published evidence to date suggesting or establishing the use of an ARB as initial therapy for hypertension. There are now six Tier 1 ACE Inhibitors which do not require prior authorization and are approved for the treatment of hypertension. Three of the six ACE Inhibitors are dosed once daily, making them as convenient for the client as an ARB.

Tier 1 ACE Inhibitors are indicated for hypertension, heart failure, left ventricular dysfunction (LVD) post-MI, diabetic nephropathy, and acute MI. They have proven to be safe, efficacious, and tolerable for most patients.

**Recommendations**

The college of pharmacy recommends moving the ARBs into the current Anti-Hypertensive Medications Product Based Prior Authorization category.

The following criteria are recommended for approval of a tier-2 ARB:

1. Documented trial of a tier-1 ACE Inhibitor.
2. Documented adverse effect or contraindication to a tier-1 product.
3. A unique indication for the tier-2 drug which the tier-1 drugs lack
4. Current users will be grandfathered unless there is a 90 day break in therapy

## Comparison of Sample Studies

| Study | Agents | Protocol | Results |
|---|---|---|---|
| Williams, PA 2001 | Olmesartan vs Captopril | Olm 5mg QD/Capt 25mg BID x 12 wks, May dbl after 4 wk & 8 wk to reponse | Sitting BP Olm -9.9 +/- 0.6 mmHg<br>Capt -6.8 +/- 0.6 mmHg<br>Mean BP Olm -14.7+/- 1.1mmHg<br>Capt -7.1 +/- 1.1mmHg± |
| Ball, K 2001 | Olmesartan vs Losartan | Olm 10mg QD/Los 50mg QD x 12 wks, May dbl after 4 wk. Could add HCTZ after 12 wks and dbl it after 16 wk if necessary | Trough seated Olm -10.6 +/- 0.5 mmHg<br>Losartan -8.5 +/- 0.6 mmHg<br>Mean BP Olm -14.9+/- 1.0mmHg<br>Los -11.6 +/- 1.0 mmHg |
| Oprail et al 2001 | Olmesartan vs Losartan vs Valsartan vs Irbesartan | Olm 20 mg QD, Los 50 mg QD, Val 80 mg QD, or Irb 150 mg QD x 8 wks | Seated Olmesartan -11mmHg<br>Losartan-8.2 mmHg<br>Valsartan-7.9 mmHg<br>Irbesartan-9.9 mmHg |
| CLAIM<br>Bakris et al. 2001 | Candesartan vs Losartan | Cand 16 mg QD or Los 50 mg QD, forced titration (dbl'd) after 2 wks x 6 wks | Trough Cand -13.3/10/.9 mmHg decrease<br>Los -9.8/8.7 mmHg decrease<br>Peak Cand -15.2 to 11.6 mmHg<br>Los -12.6 to 10.1 mmHg |
| ELITE II (CHF)<br>Pitt et al. 2001 | Losartan vs Captopril | Los 50 mg QD or Capt 150 mg/d | No diff in all-cause mortality, sudden death or resuscitation arrests, but discontinuation lower with losartan than captopril |
| ValHeFT (CHF)<br>Cohn et al. 2001 | Valsartan plus standard tx | Standard tx = ACEI, Digoxin, Diuretic, beta-Blockers | Val - 13.2% reduction in combined end point mortality/morbidity (Card arrest w/ resuscitation, hosp for CHF, or inotrope or vasodilator tx) |
| ELITE (CHF)<br>Pitt et al. 1997 | Losartan vs Captopril | Los 50 mg QD or Capt 50 mg tid x 48 wks | Losartan - lower mortality. No diff in increased serum creatinine levels or hospitalization for CHF, but fewer hospitalizations for any reason with losartan. And losartan better tolerated with less discontinuation |
| VALIANT<br>Pfeffer et al 2003 | Valsartan vs Captopril vs combination | Capt 50 mg tid, Val 160 mg bid, or capt 50 mg tid + Val 80 mg bid | No difference in overall mortality. Pts on Captopril alone or in comb had more discontinuation |
| IDNT<br>Lewis et al 2001 | Irbesartan vs Amlodipine vs placebo | Irbesartan 300 mg, Amlodipine 10 mg, or placebo | Irbesartan: 23% reduced risk of progression of advanced nephropathy in Type 2 diabetics compared to amlodipine, and 20%, compared to placebo |
| RENAAL<br>Brenner et al 2001 | Losartan vs placebo | Losartan 50 to 100 mg, or placebo | Losartan: 28% reduction in risk of ESRD, 25% reduction of risk of doubling of baseline serum creatinine concentration, in Type 2 diabetics with nephropathy (>300 mg/g albumin/creatinine ratio) |

# APPENDIX F

# Maintenance Drug List

Oklahoma Medicaid
July 2004



The Oklahoma Health Care Authority has selected drugs from certain disease states that are considered maintenance medications because they are taken on a regular schedule to treat chronic conditions. These products, or maintenance drugs, may be dispensed for up to 100 units.

**Anticoagulation:**

- cilostazol
- clopidogrel
- pentoxifylline
- ticlopidine
- warfarin

**Asthma:**

- albuterol
- albuterol extended release
- albuterol/ipratropium
- beclomethasone
- budesonide
- flunisolide
- fluticasone
- ipratropium
- triamcinolone
- salmeterol

**Diabetic:**

- acarbose
- acetohexamide
- chlorpropamide
- glimepiride
- glipizide
- glyburide
- insulin
- metformin
- metformin/glyburide
- nateglinide
- pioglitazone
- repaglinide
- rosiglitazone
- tolbutamide

**Hormone:**

- conjugated estrogens
- estradiol
- estropipate
- medroxyprogesterone acetate
- tamoxifen

**Cardiovascular (includes combinations where appropriate):**

- acebutolol
- amiloride
- amiodarone
- amlodipine
- atenolol
- atorvastatin
- benazepril
- betaxolol
- bisoprolol
- bumetanide
- candesartan
- captopril
- carvedilol
- chlorothiazide
- chlorthalidone
- clonidine
- diltiazem
- digoxin
- disopyramide
- doxazosin
- enalapril
- eprosartan
- ethacrynic acid
- felodipine
- flecainide
- fluvastatin
- fosinopril
- furosemide
- guanadrel
- guanethidine

- guanfacine
- hydralazine
- hydrochlorothiazide
- indapamide
- irbesartan
- isosorbide mononitrate
- isosorbide dinitrate
- isradipine
- labetalol
- lisinopril
- losartan
- lovastatin
- methyldopa
- metolazone
- metoprolol
- mexiletine
- minoxidil
- moexipril
- moricizine
- nadolol
- nicardipine
- nifedipine
- nisoldipine
- nitroglycerin (all oral forms)
- olmesartan
- perindopril
- pravastatin
- prazosin
- procainamide
- propranolol
- quinapril
- quinidine
- ramipril
- reserpine
- rosuvastatin
- simvastatin
- sotalol
- spironolactone
- telmisartan
- terazosin
- timolol
- torsemide
- triamterene
- trandolapril
- valsartan
- verapamil

**Thyroid:**

- levothyroxine
- liotrix
- liothyronine
- methimazole
- propylthiouracil
- thyroid

**Other:**

- allopurinol
- carbamazepine
- colchicine
- isoniazid
- phenobarbital
- phenytoin
- potassium
- prednisone
- prenatal vitamins
- primidone
- rifampin
- valproic acid

# APPENDIX G

# Drug Utilization Review of Antibiotics
# Calendar Year 2003

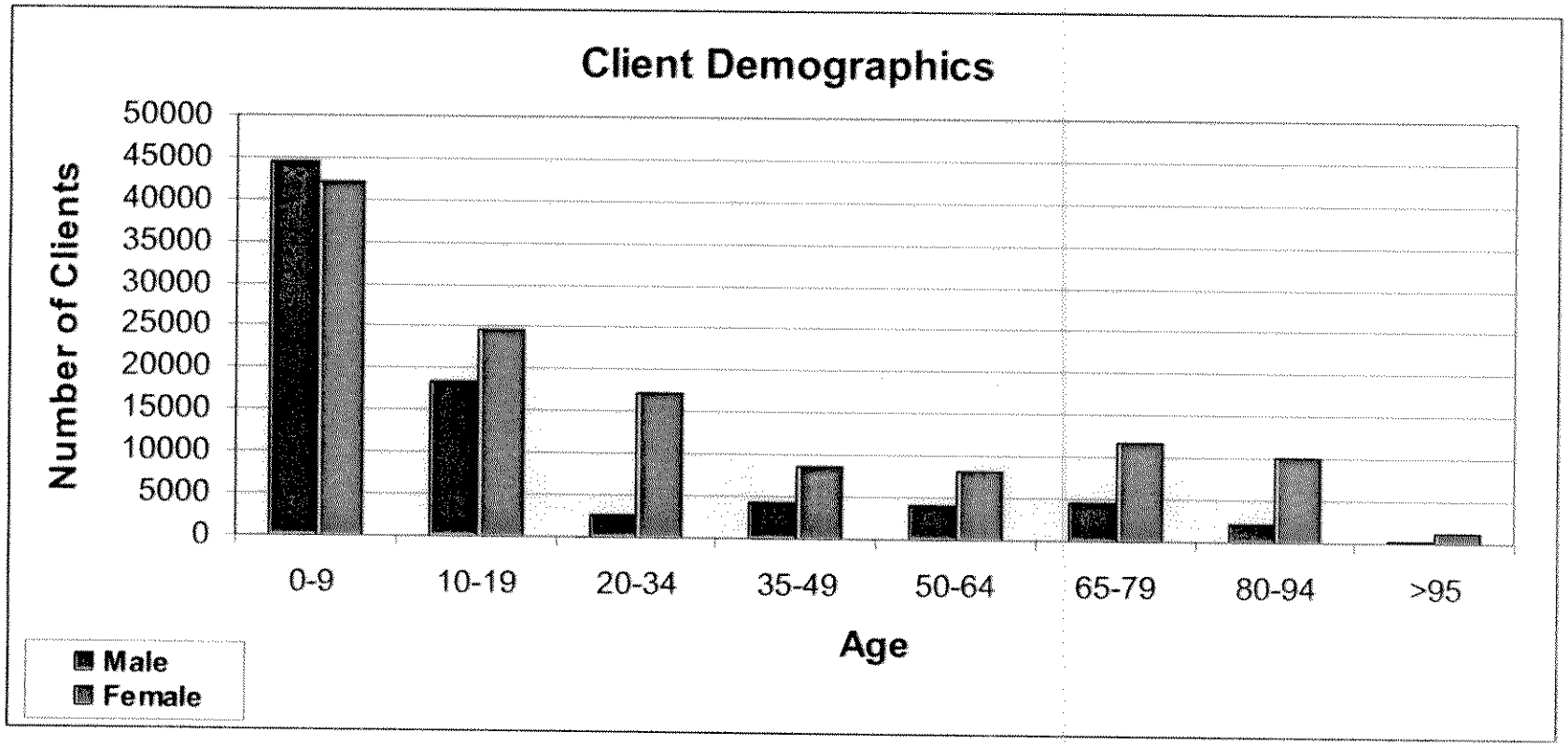
For the period of January 2003 through December 2003, a total of 204,081 clients received antibiotics through the Medicaid fee-for-service program.

| Therapeutic Class | Claims | Total Cost | % Cost | % Claims | Cost/Claim | Adjusted Cost/Claim | Claim/Client |
|---|---|---|---|---|---|---|---|
| 1. Penicillins | 10,144 | $ 117,879.69 | 0.45 | 2.01 | $ 111.43 | $ 40.18 | 1.21 |
| 2. Ampicillins | 108,593 | $ 934,561.91 | 3.54 | 21.47 | $ 13.99 | $ 13.31 | 1.38 |
| 3. Pen Resistant | 769 | $ 30,903.60 | 0.12 | 0.15 | $ 78.02 | $ 55.89 | 1.49 |
| 4. Extended Spectrum | 58 | $ 6,588.91 | 0.02 | 0.01 | $ 132.27 | $ 132.27 | 1.60 |
| 5. Pen Combos | 44,352 | $ 3,007,955.22 | 11.38 | 8.77 | $ 120.65 | $ 105.82 | 1.54 |
| 6. 1st Gen Cephs | 50,963 | $ 1,026,744.69 | 3.89 | 10.08 | $ 52.25 | $ 49.98 | 1.49 |
| 7. 2nd Gen Cephs | 25,200 | $ 1,466,729.87 | 5.55 | 4.98 | $ 149.12 | $ 78.86 | 1.36 |
| 8. 3rd Gen Cephs | 15,222 | $ 1,350,111.85 | 5.11 | 3.01 | $ 253.47 | $ 219.33 | 1.43 |
| 9. 4th Gen Cephs | 66 | $ 27,556.57 | 0.10 | 0.01 | $ 436.67 | $ 436.67 | 2.26 |
| 10. Erythromycins | 7,898 | $ 99,656.36 | 0.38 | 1.56 | $ 17.71 | $ 16.09 | 1.20 |
| 11. Macrolides-Other | 93,061 | $ 4,012,446.61 | 15.18 | 18.40 | $ 69.07 | $ 9.12 | 1.21 |
| 12. Tetracyclines | 15,109 | $ 295,221.86 | 1.12 | 2.99 | $ 98.59 | $ 81.46 | 1.92 |
| 13. Flouroquinolones | 39,889 | $ 3,323,412.42 | 12.58 | 7.89 | $ 111.67 | $ 103.09 | 1.40 |
| 14. Aminoglycosides | 1,062 | $ 984,674.06 | 3.73 | 0.21 | $ 340.14 | $ 140.60 | 2.25 |
| 15. Antimycobacterials | 586 | $ 42,357.06 | 0.16 | 0.12 | $ 95.92 | $ 87.06 | 3.07 |
| 16. Antifungals | 15,727 | $ 1,636,116.55 | 6.19 | 3.11 | $ 325.49 | $ 274.62 | 2.40 |
| 17. Antiretrovirals | 7,526 | $ 3,370,086.50 | 12.75 | 1.49 | $ 374.17 | $ 351.15 | 4.98 |
| 18. Antivirals | 13,566 | $ 2,836,355.01 | 10.73 | 2.68 | $ 626.01 | $ 598.81 | 2.26 |
| 19. Antimalarials | 9,514 | $ 278,791.57 | 1.06 | 1.88 | $ 63.60 | $ 50.40 | 2.73 |
| 20. Anthelmintics | 1,913 | $ 34,330.56 | 0.13 | 0.38 | $ 33.71 | $ 30.80 | 1.08 |
| 21. Miscellaneous | 12,668 | $ 1,073,834.61 | 4.06 | 2.50 | $ 472.19 | $ 290.65 | 1.91 |
| 22. Misc-Combos | 29,629 | $ 397,412.92 | 1.50 | 5.86 | $ 92.12 | $ 58.86 | 1.42 |
| 23. Vaccines | 2,217 | $ 70,029.09 | 0.27 | 0.44 | $ 108.11 | $ 79.17 | 1.11 |
| **Totals** | **505,732** | **$ 26,423,757.49** | **100.00** | **100.00** | **$ 181.58** | **$ 143.66** | **1.86** |

# Trends in CY 2002 and 2003

| | Calendar Year 02 | Calendar Year 03 | %Change | |
|---|---|---|---|---|
| Total Cost | $ 23,314,086.01 | $ 26,423,757.49 | Increased | 13.33 % |
| Total Claims | 495,477 | 505,732 | Increased | 2.06 % |
| Cost/Claim | $ 47.05 | $ 52.25 | Increased | 11.05 % |

| Therapeutic Class | Calendar Year 2002 | | Calendar Year 2003 | | Change in % Cost | Calendar Year 2002 | | Calendar Year 2003 | | Change in % Claims |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total Cost | % Cost | Total Cost | % Cost | | # of Claims | %Claims | # of Claims | %Claims | |
| 1. Penicillins | $ 62,879.41 | 0.27 | $ 117,879.69 | 0.45 | 0.18 | 9,939 | 2.01 | 10,144 | 2.01 | 0.00 |
| 2. Ampicillins | $ 803,701.16 | 3.45 | $ 934,561.91 | 3.54 | 0.09 | 105,126 | 21.22 | 108,593 | 21.47 | 0.26 |
| 3. Pen Resistant | $ 40,124.89 | 0.17 | $ 30,903.60 | 0.12 | 0.06 | 867 | 0.17 | 769 | 0.15 | 0.02 |
| 4. Extend. Spectrum | $ 13,339.47 | 0.06 | $ 6,588.91 | 0.02 | 0.03 | 104 | 0.02 | 58 | 0.01 | 0.01 |
| 5. Pen Combos | $ 2,912,453.56 | 12.49 | $ 3,007,955.22 | 11.38 | 1.11 | 44,558 | 8.99 | 44,352 | 8.77 | 0.22 |
| 6. 1st Gen Cephs | $ 994,496.77 | 4.27 | $ 1,026,744.69 | 3.89 | 0.38 | 52,130 | 10.52 | 50,963 | 10.08 | 0.44 |
| 7. 2nd Gen Cephs | $ 1,252,139.07 | 5.37 | $ 1,466,729.87 | 5.55 | 0.18 | 24,627 | 4.97 | 25,200 | 4.98 | 0.01 |
| 8. 3rd Gen Cephs | $ 1,282,068.80 | 5.50 | $ 1,350,111.85 | 5.11 | 0.39 | 15,668 | 3.16 | 15,222 | 3.01 | 0.15 |
| 9. 4th Gen Cephs | $ 17,545.82 | 0.08 | $ 27,556.57 | 0.10 | 0.03 | 44 | 0.01 | 66 | 0.01 | 0.00 |
| 10. Erythromycins | $ 105,438.81 | 0.45 | $ 99,656.36 | 0.38 | 0.08 | 8,666 | 1.75 | 7,898 | 1.56 | 0.19 |
| 11. Macrolides Other | $ 3,262,732.67 | 13.99 | $ 4,012,446.61 | 15.18 | 1.19 | 83,582 | 16.87 | 93,061 | 18.40 | 1.53 |
| 12. Tetracyclines | $ 271,085.78 | 1.16 | $ 295,221.86 | 1.12 | 0.05 | 15,543 | 3.14 | 15,109 | 2.99 | 0.15 |
| 13. Flouroquinolones | $ 3,162,938.72 | 13.57 | $ 3,323,412.42 | 12.58 | 0.99 | 43,137 | 8.71 | 39,889 | 7.89 | 0.82 |
| 14. Aminoglycosides | $ 945,719.28 | 4.06 | $ 984,674.06 | 3.73 | 0.33 | 1,390 | 0.28 | 1,062 | 0.21 | 0.07 |
| 15.Antimycobacterials | $ 66,294.97 | 0.28 | $ 42,357.06 | 0.16 | 0.12 | 921 | 0.19 | 586 | 0.12 | 0.07 |
| 16. Antifungals | $ 1,698,226.60 | 7.28 | $ 1,636,116.55 | 6.19 | 1.09 | 17,753 | 3.58 | 15,727 | 3.11 | 0.47 |
| 17. Antiretrovirals | $ 3,138,153.43 | 13.46 | $ 3,370,086.50 | 12.75 | 0.71 | 8,058 | 1.63 | 7,526 | 1.49 | 0.14 |
| 18. Antivirals | $ 1,860,441.89 | 7.98 | $ 2,836,355.01 | 10.73 | 2.75 | 7,809 | 1.58 | 13,566 | 2.68 | 1.11 |
| 19. Antimalarials | $ 172,965.65 | 0.74 | $ 278,791.57 | 1.06 | 0.31 | 10,815 | 2.18 | 9,514 | 1.88 | 0.30 |
| 20. Anthelmintics | $ 32,178.61 | 0.14 | $ 34,330.56 | 0.13 | 1.01 | 1,908 | 0.39 | 1,913 | 0.38 | 0.01 |
| 21. Miscellaneous | $ 885,498.63 | 3.80 | $ 1,073,834.61 | 4.06 | 0.27 | 10,775 | 2.17 | 12,668 | 2.50 | 0.33 |
| 22. Misc-Combos | $ 309,586.33 | 1.33 | $ 397,412.92 | 1.50 | 0.18 | 31,413 | 6.34 | 29,629 | 5.86 | 0.48 |
| 23. Vaccines | $ 24,075.69 | 0.10 | $ 70,029.09 | 0.27 | 0.16 | 644 | 0.13 | 2,217 | 0.44 | 0.31 |
| **Totals** | **$ 23,314,086.01** | **100.00** | **$ 26,423,757.49** | **100.00** | | **495,477** | **100.00** | **505,732** | **100.00** | |




| Age Group | 0-9 | 10-19 | 20-34 | 35-49 | 50-64 | 65-79 | 80-94 | >95 |
|---|---|---|---|---|---|---|---|---|
| Dollars Spent (Millions) | 7.234 $ | 3.863 $ | 2.580 $ | 5.582 $ | 2.715 $ | 2.315 $ | 1.890 $ | 0.220 $ |
| Class Incurred Greatest Cost | Ampicillins | Ampicillins | Ampicillins | Anti-retrovirals | Flouro-quinolones | Flouro-quinolones | Flouro-quinolones | Flouro-quinolones |

# APPENDIX H

## FDA Clears Medicinal Leeches for Marketing



ROCKVILLE, MD -- June 28, 2004 -- The Food and Drug Administration (FDA) has for the first time cleared the commercial marketing of leeches for medicinal purposes.

Leeches can help heal skin grafts by removing blood pooled under the graft and restore blood circulation in blocked veins by removing pooled blood.

Leeches have been used as an alternative treatment to blood-letting and amputation for several thousand years. They reached their height of medicinal use in the mid- 1800's. Today they are used in medicine throughout the world as tools in skin grafts and reattachment surgery.

Medicinal leeches (Hirudo medicinalis) are bloodsucking aquatic animals that live in fresh water.

Ricarimpex SAS, a French firm, is the first company to request and receive FDA clearance to market leeches as medical devices. The firm has been breeding leeches for 150 years. They are handled in a certified facility that tracks each lot.

In considering the firm's application, FDA reviewed the published literature on the use of leeches in medicine and evaluated safety data provided by the firm. FDA also reviewed information on how the leeches are fed, their environment, and the personnel who handle them.

FDA determined that leeches are medical devices because they meet the definition of a medical device under the Food Drug and Cosmetic Act. Under the law, a medical device is an article intended to diagnose, cure, treat, prevent, or mitigate a disease or condition, or to affect a function or structure of the body, that does not achieve its primary effect through a chemical action, and is not metabolized.

Source: The Food and Drug Administration

86



# FDA Public Health Advisory for Crestor (rosuvastatin)

Astra-Zeneca Pharmaceuticals today released a revised package insert for Crestor (rosuvastatin) for use in the 22 member states of the European Union (EU). The changes to the European labeling are in response to postmarketing spontaneous adverse event reports in patients receiving Crestor and highlight certain patient populations who may be at an increased risk for serious muscle toxicity (myopathy) associated with Crestor use, especially at the highest approved dose of 40 mg. These risk factors and many of the recommendations for how to minimize the risk of myopathy are already captured in the FDA approved labeling for Crestor in the U.S. FDA is alerting physicians to the need to carefully read the Crestor product label and follow the recommendations for starting doses, dose adjustments, and maximum daily doses to minimize the risk of myopathy in individual patients.

Crestor, a member of a class of cholesterol-lowering drugs commonly referred to as "statins", was approved in the U.S. in August 2003, based on review of an extensive clinical database involving approximately 12,000 patients. At that time, the FDA identified in the WARNINGS section of the product label those patients whose increased baseline risk for myopathy warranted more careful monitoring when prescribed Crestor. The U.S. approved labeling included a specific section titled, "Myopathy/Rhabdomyolysis", which states that patients who are of advanced age (≥ 65 years), have hypothyroidism, and/or renal insufficiency should be considered to have a greater risk for developing myopathy while receiving a statin. Physicians are warned to prescribe Crestor with caution in these patients, particularly at higher doses, as the risk of myopathy increases with higher drug levels.

In addition, the U.S. approved labeling for Crestor states that increased rosuvastatin drug levels were observed in certain sub-populations of patients (e.g., subgroups of Asians, patients concomitantly using cyclosporine and gemfibrozil), conferring increased risk of myopathy. Because of these findings, the FDA required Astra-Zeneca to make available in the U.S. a 5-mg dose that could be used in patients requiring less aggressive cholesterol-lowering or who were taking concurrent cyclosporine. The maximum recommended dose in the FDA-approved label is limited to 10 mg daily in patients with severe renal impairment or who are also taking gemfibrozil.

FDA has received reports of rhabdomyolysis in association with Crestor, as it has with other drugs in the statin class. In ongoing fashion, we are evaluating these reports of adverse muscle effects with regard to clinical severity and apparent relationship to the drug. FDA is comparing the frequency of reporting of muscle injury with Crestor to that with other statins, given differences in prescribing rates for the different drugs. Pending the evaluation of the recent Crestor safety experience, FDA is not proposing to change the US labeling for Crestor, but does

want to re-emphasize to physicians to the importance of carefully following the recommendations in the current product label. Analysis of accumulating safety data in the U.S. and worldwide will be considered in any future labeling changes for Crestor, and to make recommendations on risk management plans for Crestor.

Healthcare professionals prescribing Crestor are reminded of the following key safety messages from the Crestor label: start doses and maintenance doses of drug should be based on individual cholesterol goals and apparent risks for side-effects; all patients should be informed that statins can cause muscle injury, which in rare, severe cases, can cause kidney damage and other organ failure that are potentially life-threatening; and patients should be told to promptly report to their physician signs or symptoms of muscle pain and weakness, malaise, fever, dark urine, nausea, or vomiting.

The current FDA-approved label can be obtained at
http://www.fda.gov/cder/foi/label/2003/21366_crestor_lbl.pdf

Requires Adobe Acrobat Reader.

Back to Top Back to Drug Information

Date created: June 9, 2004

# Tablet Splitting: Evaluating Appropriateness for Patients

## Tool for Pharmacists From the 2003-2004 APhA Strategic Directions Committee

J Am Pharm Assoc 44(3):324-325, 2004. 
Posted 06/10/2004

The idea of splitting tablets has centered on patients using a device to halve their drug costs. Health insurers are increasingly urging patients to buy higherstrength tablets and take half at a time. In fact, some are offering free tablet splitters to anyone who agrees to do this voluntarily. But for some patients tablet splitting is not easy or voluntary. Cutting dosage forms into even doses can be tricky, particularly for those who are elderly. Further, promoting half tablets could tempt some patients to split other drugs that should always be taken whole.

The American Medical Association and APhA formally oppose mandatory tablet splitting. Done correctly, splitting prescription tablets can save money. Done incorrectly, the practice can endanger patient health.

The Strategic Directions Committee (SDC) reviewed the available literature and input from practitioners regarding the impact of the splitting of tablets on patient care. The SDC developed questions for pharmacists and decision makers to consider when evaluating the appropriateness of tablet splitting for individual patients and products. The guidelines appear in Figures 1 and 2.

The Committee also recommends that the Food and Drug Administration and the United States Pharmacopeia study the splitting of tablets to provide data on the appropriateness of tablet splitting from a scientific basis.

APhA welcomes feedback on these policies. Comments or suggestions should be forwarded to APhA Staff Counsel and Vice President for Policy and Communications Susan C. Winckler, JD, at swinckler@aphanet.org.

Editor's note: The 2003-2004 Strategic Directions Committee of the American Pharmacists Association (APhA) discussed a number of patient safety issues facing pharmacists, including the increasing prevalence of tablet splitting. This is an excerpt of its report to the APhA Board of Trustees.

### Acknowledgements

Members of APhA's 2003-2004 Strategic Directions Committee were Daniel A. Herbert, Chair; Loyd Allen, Bruce R. Canaday, Melinda C. Joyce, Bill Letendre, Karen L. Reed, Rod D. Shafer, Theodore G. Tong, and Andrew P. Traynor; Mitchel C. Rothholz and Susan C. Winckler, staff liaisons.

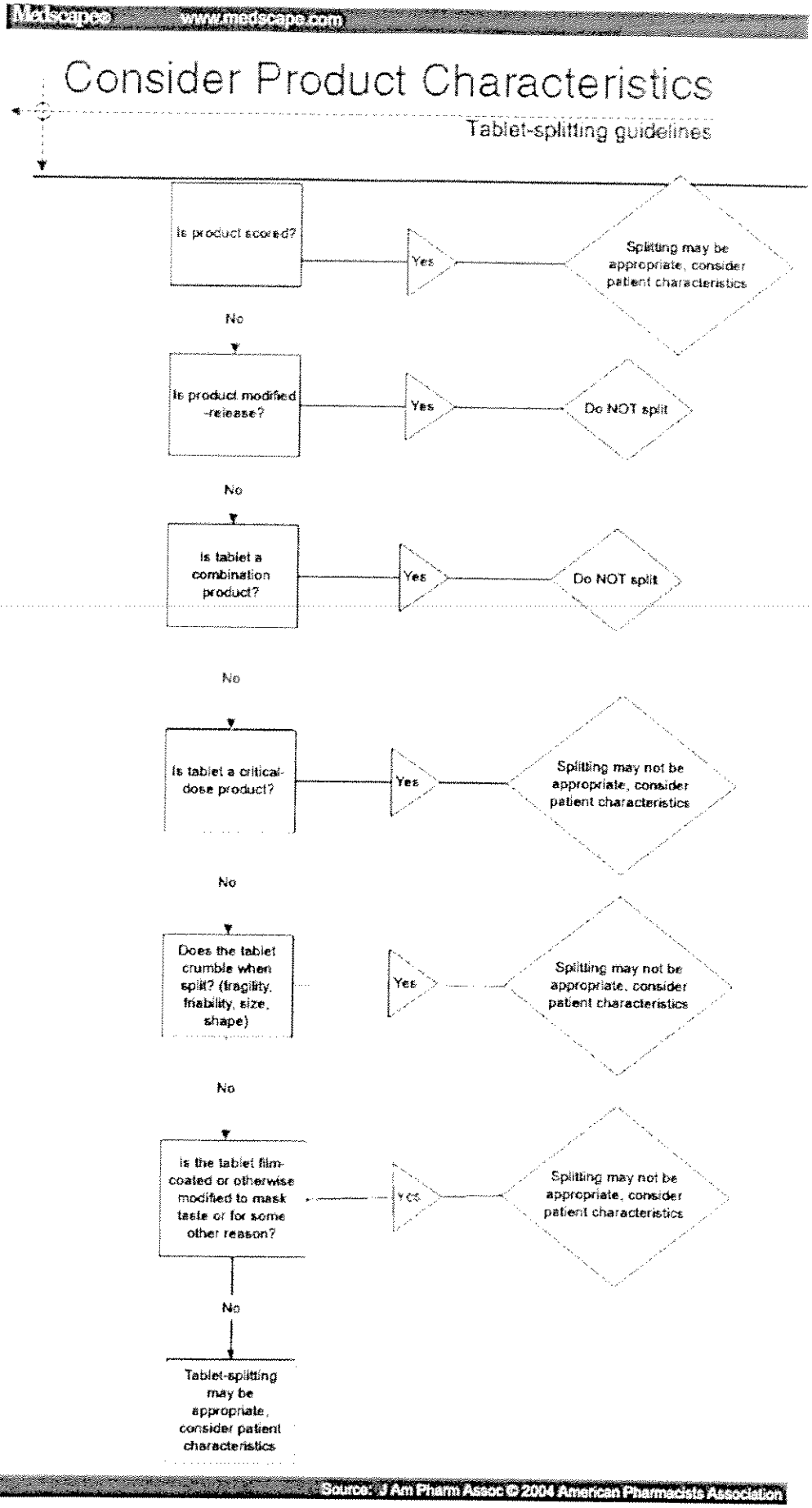



**Figure 1.** APhA Resource: Practice. Tool for Pharmacist Evaluation of Appropriateness of Tablet Splitting: Product Considerations

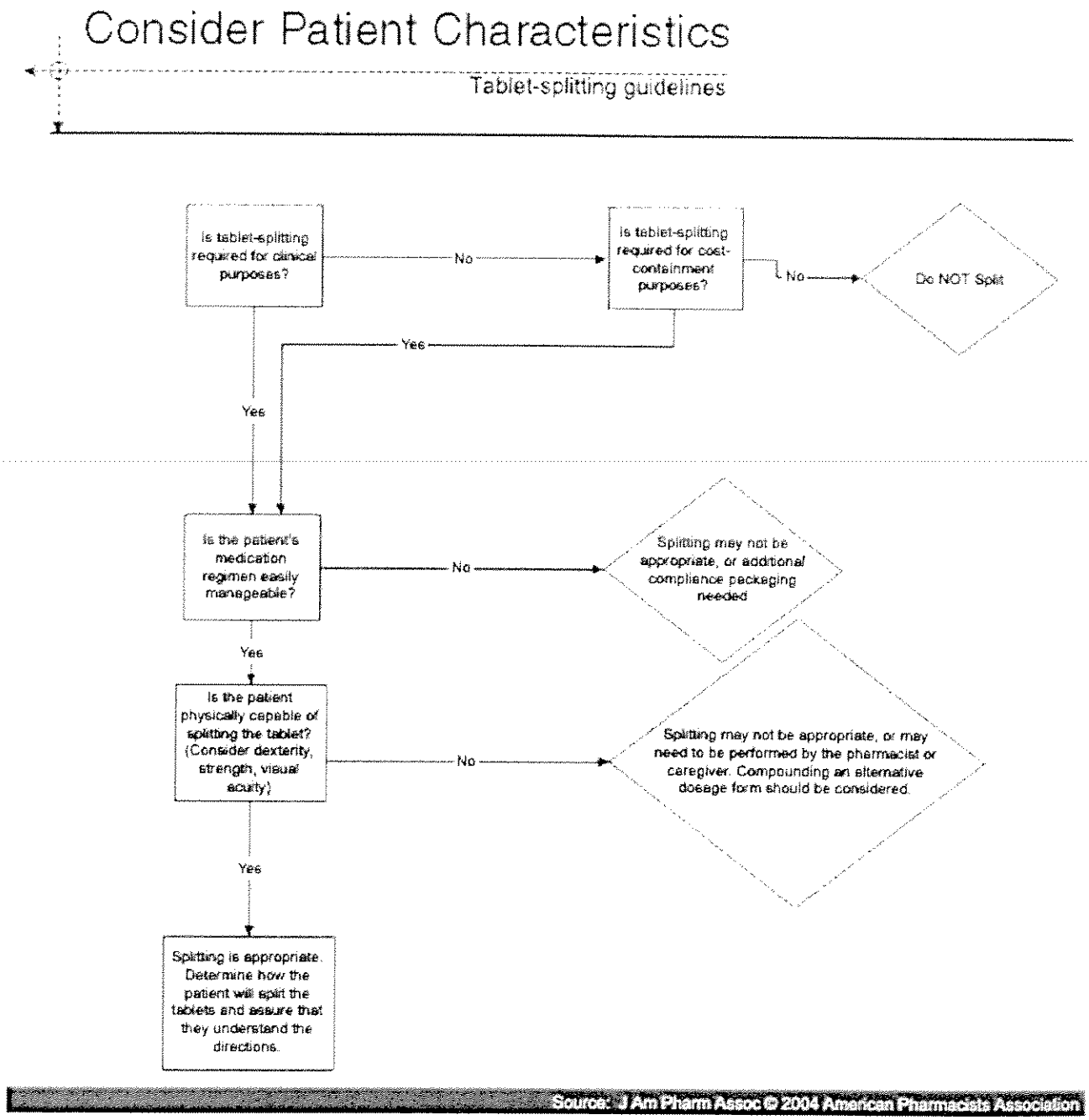



**Figure 2.** APhA Resource: Practice. Tool for Pharmacist Evaluation of Appropriateness of Tablet Splitting: Patient Considerations

# FDA Talk Paper

T04-21
July 2, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

## FDA Supports Broader Access to Lower Priced Drugs

The Food and Drug Administration (FDA) today issued responses to three Citizen Petitions. These agency decisions protect more rapid access to lower-priced prescription drugs.

In one action, FDA denied petitions submitted by Mylan Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. seeking to prohibit the marketing and distribution of reduced-price "authorized generic" versions of brand name products during "180-day exclusivity" periods, which enable the first generic applicants that challenge patents potentially blocking their products to market these products six months earlier than other generic applicants.

Marketing of authorized generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market.

The agency also denied a petition submitted by Pfizer, Inc., seeking to prevent generic applicants' waiver of 180-day exclusivity. Allowing eligible generic applicants to waive the exclusivity promotes competition by enabling other generic applicants to market their products sooner.

FDA's mission is protection and promotion of public health and does not generally call for review of the business dealings of drug manufacturers. FDA sees no reason to interfere with the marketing of authorized generics and waiving 180-day exclusivity, two long-standing, pro-competitive business practices.

Today's actions promise to advance broader, more rapid access to safe and effective prescription drugs for American consumers.

###