Drug Utilization Review Board

Oklahoma Health Care Authority
4545 North Lincoln Boulevard, Suite 124
Oklahoma City, Oklahoma 73105
OHCA Board Room

Wednesday
March 11, 2009
6:00 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Keast, Pharm.D., M.S.

SUBJECT: **Packet Contents for Board Meeting – March 11, 2009**

DATE: March 5, 2009

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

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

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Advair® and Symbicort® – See Appendix C.

Action Item – Vote to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™ – See Appendix D.

Action Item – Vote to Prior Authorize Astepro® – See Appendix E.

Action Item – Annual Review of Insomnia PBPA Category and 30 Day Notice to Prior Authorize Zolpimist® – See Appendix F.

Action Item – Annual Review of Glaucoma PBPA Category – See Appendix G.

Utilization Review of Anti-Migraine Products – See Appendix H.

Utilization Report for Second Quarter Fiscal Year 2009 – See Appendix I.

FDA and DEA Updates – See Appendix J.

Future Business

Adjournment

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Drug Utilization Review Board

(DUR Board)

Meeting – March 11, 2009 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. McNeill, Chairman:

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

A. February 11, 2008 DUR Minutes – Vote
B. February 13, 2008 DUR Recommendation Memorandum
C. Provider Correspondence

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

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

A. Retrospective Drug Utilization Review Responses for October 2008
B. Medication Coverage Activity Audit for February 2009
C. Help Desk Activity Audit for February 2009

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

5. Action Item – Vote to Prior Authorize Advair® and Symbicort® – See Appendix C.

A. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™ – See Appendix D.

A. COP Recommendations

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

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

A. Product Summary
B. COP Recommendations

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

8. Action Item – Annual Review of Insomnia PBPA Category and 30 Day Notice to Prior Authorize Zolpimist® – See Appendix F.

A. Current PA Criteria
B. Utilization Review
C. COP Recommendations

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

9. Action Item – Annual Review of Glaucoma PBPA Category – See Appendix G.

A. Current PA Criteria
B. Utilization Review
C. COP Recommendations

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

10. Utilization Review of Anti-Migraine Products – See Appendix H.

A. Product Overview
B. Current Restrictions
C. Utilization Review
D. COP Recommendations

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

11. Utilization Report for Second Quarter Fiscal Year 2009 – See Appendix I.

A. Top 25 Sub-Therapeutic Classes by Total Reimbursement
B. Top 10 Sub-Therapeutic Classes with Top 5 Products by Total Reimbursement
C. Top 25 Drugs by Total Reimbursement

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

12. FDA and DEA Updates – See Appendix J.

13. Future Business

A. Utilization Review of Fibromyalgia
B. Utilization Review of Otic Antibiotics
C. Utilization Review of Antiemetics
D. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of FEBRUARY 11, 2009

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

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Metha Chonlahan, D.Ph.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Ronald Graham, D.Ph.; Pharmacy Director	X	
Shellie Keast, Pharm.D.; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Pharmacist/Coordinator	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research		X
Leslie Robinson, D.Ph.; PA Coordinator	X	
Visiting Pharmacy Students: Tram Dinh, Brian Wesley	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer	X	
Nico Gomez; Director of Gov't and Public Affairs		X
Lynn Mitchell, M.D., M.P.H,; Director of Medicaid/Medical Services		X
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.; Director of Legal Services		X
Lynn Rambo-Jones, J.D.; Deputy General Counsel III	X	
Rodney Ramsey; Drug Reference Coordinator	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	

OTHERS PRESENT:

Jeff Himmelberg, GlaxoSmithKline	John Harris, Abbott	Mark DeClerk, Lilly
Donna Erwin, BMS	Jim Graham, Johnson & Johnson	Sam Smothers, MedImmune
Patty Howard, MedImmune	Tracy Copeland, Daiichi Sankyo	Jim Fowler, Astra Zeneca
Mark Edwards, Astra Zeneca	M. Patty Laster, Genentech Inc	Karina Forrest, NAMI OK
Meg Propes, Astra Zeneca	Janie Huff, Takeda	Lance Stewart, Merck
Linda Canto, BMS	Michael McGuire, BMS	Jorge Nassar, BMS
David Henderson, GlaxoSmithKline	Jim Dunlap, Eli Lilly	Pat Trahan, Taro
Paul Davis, MHAT	Aaron Mays, Alcon Labs	David Williams, Forest Labs Inc
Matt Kytz, Forest Labs Inc	Brad Robertson, GlaxoSmithKline	

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 5	James Osborne, Pharm.D.; GlaxoSmithKline
Agenda Item No. 5	Jonathan Schwartz, M.D.
Agenda Item No. 6	Sherwanna Clarke, Pharm.D.; Abbott

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

1A: Roll Call

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

ACTION: NONE REQUIRED

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

Dr. McNeill recognized the speaker for public comment.

ACTION: NONE REQUIRED

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

3A: January 14, 2009 DUR Minutes

Dr. Preslar moved to approve as submitted; seconded by Dr. Bell.

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review: November 2008

4B: Retrospective Drug Utilization Review Responses: September 2008

4C: Medication Coverage Activity Audit: January 2009

4D: Help Desk Activity Audit: January 2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **30-DAY NOTICE TO PRIOR AUTHORIZE ADVAIR® AND SYMBICORT®**

For Public Comment; James Osborne, Pharm.D. Thank you. I'll introduce myself while Ron hands out that little handout. My name is James Osborne and I'm a regional medical scientist for GlaxoSmithKline and just disclose everything. We make Ventolin HFA, Flovent HFA as well as Advair Diskus and HFA. First I just want to start by thanking you guys for allowing me to make a few brief comments. I will just dive into it and discuss some differences and also some common ground with what has been recommended and our perspective at GlaxoSmithKline. First of all as you noticed as I disclosed all the products we make for respiratory, we have a preferred agent at every step of treatment, so whether it's step one, two, three, four, five or six, we manufacture a preferred agent. So we want our products to be used appropriately just like you guys want to be used appropriately and clearly, that doesn't mean everybody gets Advair or even everybody gets Flovent, but when you look at not only the Advair package insert for approved indications but the NIH treatment guidelines for asthma, there's really two appropriate uses for Advair when it comes to asthma patients. When we're talking about patients 12 years of age and older, the first, what you have outlined in your recommendation, which is patients who are uncontrolled on inhaled corticosteroid. The second half of not only our indication but the other positioning of Advair or combination products rather than the NIH treatment guidelines are for patients whose disease severity clearly warrants initiation with two controller drugs. And that is where this recommended prior authorization, kind of where we have the disconnect here. And if you look at that top figure on that handout, you'll see that this Figure 4.6 from the NIH treatment guidelines, patients 12 and older, assessing severity and initiating treatment, you'll see that they give guidance on how to classify the severity of the asthma, but at the bottom for each given severity, they make a treatment recommendation at what step of care. So you really use the term step treatment for step one, step two, they don't mean for every patient to start at the lowest step and work their way up. They mean for people who are untreated to have their severity assessed and treatment started at that appropriate level. And so when you look at the mild persistent patients, they recommend step two, which is a low dose of inhaled corticosteroid or a product we make like Flovent. However, when you look at patients who present with moderate persistent asthma, they give a definition of that, somebody who has daily symptoms, or daily albuterol use separate from what they use to, for pre-treatment of exercise with bronchospasm, patients with some limitation of their activity level, or people who have lung functions less than 80% of predicted. You'll see that they recommend initiating therapy at step three for those patients. So a little clearer description of what that patient is. Daily treatment. If they were to take two puffs a day of their albuterol, that albuterol canister would last 100 days on average. So that is not an uncommon patient to present. Untreated, yet not mild, just untreated. Step three treatment, we can see on the bottom of the page, preferred treatments are low dose inhaled corticosteroid or a medium dose of inhaled steroids. You can see that again, according to the package insert as well as the treatment guidelines for patients 12 and older, it would be appropriate use of the products, these combination of products, to initiate in patients who were not previously on inahled steroid, if they met the severity criteria. One of them, not all of them. And the difficulty with using pharmacy claims to determine that, is all you get is the frequency of their albuterol refill, which doesn't really tell you how often they're using it, but you also don't get some of the patient-specific information you would need to assess severity. Lung function assessment, if it was done. You don't know their activity level, you don't know their symptom frequency because

pharmacy claims data can't give you that. So I'll just leave, we would like you guys to reconsider instituting prior authorization for these combination products because appropriate utilization of Advair or any other combination product does oftentimes include patients who were not previously treated with an inhaled corticosteroid. So I'll leave my comments there and be happy to take any questions at this point from the Board.

Board Member Feightner: Have the recommendations changed with the long-acting beta agonists with that usage? I've seen where Serovent is no longer recommended for any asthma patient, I've seen that.

Board Member Knisely: You're talking about the FDA safety? That's not officially done yet. They're still in consideration.

Dr. Osborne: Yeah, I will say we certainly recommend it and the NIH guidelines currently do not recommend using Serovent or any long-acting beta agonist by itself in asthma always in combination with inhaled corticosteroid. This information, some of the safety information about the use of long-acting beta agonists in the asthma have been in our package insert since 2003, so these guidelines first came out 2007, do incorporate that information into how they place these medications. They do now give equal weighting to the medium dose inhaled corticosteroid option at step three. That is different from the 2003 treatment updates, so previously, the only preferred treatment at step three or for patients with moderate persistent asthma was low dose combination. Now they allow both options, equal weighting is preferred regimens, although they acknowledge that the combination is more effective and there is just a wealth of information to show that low dose combination outperforms a higher dose of an inhaled steroid alone.

Board Member Feightner: Okay, I was just caught by surprise by that and the fact that the same drug is in Advair, so that took me back a little bit that Salmeterol is in Advair as well and now we have a drug that's questioned by the FDA's safety guidelines, still being debated. That threw up a flag for me.

Dr. Osborne: Sure, and it should. And we aren't going to candy coat that or to not discuss that. But when you look at the clinical data that has come out, whether you look at meta-analyses or data of large insurance plans, these risks don't appear to be the same for patients using monotherapy versus those who are using concurrent inhaled corticosteroids, so it's very difficult to differentiate what is the effect of the beta agonist versus what is the effect of not treating the disease, which is usually an anti-inflammatory.

Board Member Feightner: I've seen those from like regulation of the beta receptors, is that like using the long acting beta-2's makes the short acting less effective, or what was the rationale behind that? Do they know?

Board Member Knisely: I don't think they know. I think it .....

Dr. Osborne: Again, I could speculate but we don't know the answer to that. I can tell you that we have plenty of data generated at Glaxo as well as non-Glaxo data to show that when patients are on long acting beta agonists, they still respond to the short acting beta agonist. If you inhale a therapeutic dose of Salmeterol, you're only occupying about 4% of the beta-2 receptor, so there are beta-2 receptors available for the short acting drug when it's required. So there is this question of when patients are treated with a beta agonist by itself without an anti-inflammatory are their symptoms masked? They feel OK, but the inflammation is not being addressed, are they more likely to get into trouble.

For Public Comment; Jonathan Schwartz, M.D.: Thank you for being so accommodating. My name is Jonathan Schwartz. I'm a pulmonary physician here in Oklahoma City. A couple of things and actually I want to make two points. One of them was just discussed as well, but in terms of the treatment of both asthma and chronic obstructive pulmonary disease, we do have step therapy as you know that are national and international therapy and United States National Heart, Lung and Blood Institute that you talked about also the GOLD criteria in COPD but I certainly do understand that cost is important and for those patients that we currently take care of that are already on this combination therapy, whether it be Advair, whether it be Symbicort, I think it's important that they be continued to, be allowed to continue on this medication. It is not just stopped and saying we have to follow this. I think that's important. Also it's hard to build exceptions for anything, but I think where exceptions are important are when we're dealing with for instance a patient who has, we use the term asthmatic bronchitis, and it's kind of a messy term. We have asthma, we have COPD, but there are patients who have some degree of fixed airways obstruction who also do have reversibility. We don't normalize them. This type of medication should be also considered in that type of patient as considered for a first line therapy because of the fact you have a long acting bronchodilator and an inhaled corticosteroid. There are other exceptions, too, although when someone has faced obstruction and COPD we tend to go with long acting bronchodilators first, as per the GOLD criteria. If someone has very severe asthma then combination therapy should be initiated as opposed to just starting inhaled corticosteroids in certain patients. So I realize that you do need (unintelligible) therapies but there are patient exceptions. Certainly there are patients who are already on these medications in my opinion, who should be continued on those medications if they're doing well and if they're stable. Part of our guidelines and certainly in asthma, do call for us as clinicians, to try and step down therapy, which we do over three to six months' time. I would hate to have that step down therapy occur immediately with, and unfortunately, patients not being able to continue with medication. The only other thing I wanted to mention too in regards, because treatment of rhinitis certainly interacts with treatment of asthma and COPD and the compound that you just talked about. In terms of step-wise therapy, and I do understand two weeks, three weeks, but one of the advantages of the nasal antihistamine sprays, and there are two of them out now as well, not just Astelin and Astepro, but also Patanase, is that these patients do see very quick improvement, sometimes they'll see some immediate improvement and then long-term improvement. The other advantage of those medications in terms of cost efficacy is they can be used on a PRN basis, so the patients don't have to refill it every month, so that does add to their utility. They're not only treating rhinitis and also when we treat the upper airway we treat the lower airway as well. I want to thank you for your time. If there are any questions I'll be happy to answer.

Board Member Knisely: The patient who is that you mentioned, the asthmatic, so if the obstructive component and the irreversibility component, are those patients officially classed, would they be diagnosed as being an asthma patient or a COPD or both?

Dr. Schwartz: It depends on who's seeing the patient, in all honesty. We do certainly, both guidelines call for the use of spirometry. In a specialist's office, spirometry is going to be done on every patient. It should be done in follow-up visits. We have failed miserably in a lot of cases, in non-specialty offices with the use of spirometry, yet one of the advantages of combination therapy, and I'm not saying it's a good advantage necessarily, but it treats both disorders. It treats asthma and COPD. That's not necessarily the right reason to start something unless we see evidence of severity and certainly we do want to see spirometry if possible. But there are times, particularly in rural areas where that may not be available. The physician may not have that available, so I think we have to be a little more malleable in terms of not expecting every physician to do spirometry because it just can't be done. It should be but we haven't reached that point. As far as asthmatic bronchitis, yes there are patients who smoke who we see have more of an asthmatic component, yet they still, we don't normalize them completely and that would be, in my opinion, that's we have used these medications, Advair and Symbicort with very good efficacy and use one agent alone as opposed to several, three or four agents.
Board Member Bell: Don't most asthma patients eventually develop some degree of COPD?
Dr. Schwartz: Many do, may can. We don't know. We do not have a predictor. One of the causes of fixed airways obstruction is prior asthma. There are some asthmatics though, who go through their whole life who can maintain normal function. Some can begin to develop evidence of fixed airway obstruction without reversibility in their childhood and we don't have a marker yet to identify that. But there are very elegant studies which have been done using bronchoscopy and biopsy etc. to actually show evidence of changes in the microscopic level, addressing to the fixed airways obstruction.
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF FIBRIC ACID DERIVATIVE PBPA CATEGORY AND 30-DAY NOTICE TO PRIOR AUTHORIZE FENOGLIDE™, LIPOFEN®, AND TRILIPIX™**

For Public Comment; Sherwanna Clark, Pharm.D.: Good evening. My name is. Dr. Sherwanna Clark. I'm a government regional clinical executive with Abbott Laboratories and I'm going to talk with you briefly about Trilipix which is fenofibric acid delayed release capsule. As Trilipix is the only fenofibric acid that is currently extensively studied and has the FDA approval for combination in use with statin drugs. When Trilipix was first brought to market what we did was do three randomized double blind 12-week multicentered Phase III clinical studies, and what we tried to do was design the study looking at Trilipix coadministered with one of three statins, the three most commonly used statins on the market. The first study was looking at rosuvastatin 10 and 20 mg, study looked at simvastatin 20 or 40 mg, and study 3 looked at atorvastatin 20 or 40 mg. And this was looked at in over 2,600 patients, the largest study to-date looking at statins in combination with the fenofibric acid. The primary efficacy influence for the statins were the mean percent changes from baseline, looking at HDL, triglycerides and LDL. For each statin dose, it was coadministered with Trilipix. There were three primary comparisons. All three primary comparisons were required to demonstrate superiority of the combination therapy over the aforementioned monotherapy. Statistically significant differences were observed for all three primary comparisons for Trilipix coadministered with both the low and moderate dose statins in all three studies, as well as in the pooled studies. I'm sure in your paperwork you will find the specifics around the studies and the outcomes that the primary analysis were very positive with this trial. After the 12-week study, over 1,800 patients that completed this double-blind study were allowed to go to a 52-week open label study which gave us 64 weeks' worth of data to include safety data. The study is actually still on-going to about two years' worth of safety data in combination with the statin. The safety of Trilipix in combination with low and moderate dose statins was evaluating in 2,201 patients who received at least one dose of Trilipix coadministered with a statin. The combination is generally well tolerated with a safety profile consistent with those of the individual monotherapy treatments. In clinical trials, which is very important as you remember the previous history of fibrates in combination with the statins, the major concern was rhabdomyolysis and in this particular 64-week study there were no cases of rhabdo that was observed in these trials. There were no unexpected safety signals that were reported as well in the study. When you look at the dosing of Trilipix, the recommended dose is 135 mg in adult patients with primary hyperlipidemia. The recommended dose range is from 45 to 135 mg per day for adults with severe tryglyceridemia and should be individualized based on patient response and adjusted if necessary, obviously, if the patient has renal dysfunction, then making adjustments for those patients. And with that, I will be more than happy to answer any questions that you may have.
Board Member Bell: You said there was no rhabdomyolysis. What was the N of the study?
Dr. Clark: The N is 2698.
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF NASAL ALLERGY PBPA CATEGORY AND 30-DAY NOTICE TO PRIOR AUTHORIZE ASTEPRO™**

Materials included in agenda packet; presented by Dr. Robinson.
Dr. Feightner moved to approve recommendations with change to "failure of Tier 1 after at least three weeks use"; seconded by Dr. Bell.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF OCULAR ALLERGY PBPA CATEGORY**
Materials included in agenda packet; presented by Drs. Chonlahan and Keast.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **UTILIZATION REVIEW OF ANTI-ULCER/GERD MEDICATION FOR CHILDREN**
Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: **HYDROCODONE PRODUCT EVALUATION**
Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED

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

AGENDA ITEM NO. 12: **FUTURE BUSINESS**
Materials included in agenda packet; submitted by Dr. Graham.
12A: Annual Reviews
12B: Utilization Review of Anti-Emetics
12C: Utilization Review of Anti-Migraine Products
12D: New Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **ADJOURNMENT**
The meeting was adjourned at 7:35 p.m.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: February 13, 2009

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

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

Subject: DUR Board Recommendations from Meeting of February 11, 2009

Recommendation 1: Annual Review of Fibric Acid Derivatives PBPA Category

No Action Required

Recommendation 2: Annual Review of Nasal Allergy PBPA Category

MOTION CARRIED by unanimous approval.

The DUR Board recommended the following changes to the PBPA Criteria:

1. The following criteria are required for approval of a Tier 2 product (or a Tier 3 product if no Tier 2 exists):

    a. Documented adverse effect or contraindication to the preferred products.
    b. Failure with ~~at least two~~ Tier 1 medications defined as no beneficial response after at least ~~two~~ three weeks use of each during which time the drug has been

titrated to the recommended dose. All available Tier 1 corticosteroids should be tried prior to approval of higher Tiered products).

2. The following criteria are required for approval of a Tier 3 product:

    a. All Tier 2 criteria must be met.
    b. Failure with all available Tier 2 products defined as no beneficial response after at least ~~two~~ three weeks use of each during which time the drug has been titrated to the recommended dose.

3. Approvals will be for the duration of three months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

Recommendation 3: Annual Review of Ocular Allergy PBPA Category

No Action Required

James S. Seebass, D.O.
4645 S. Wheeling Avenue
Tulsa, OK 74105

February 25, 2009

Shellie Gorman Keast, Pharm.D., M.S.
DUR Manager
Pharmacy Management Consultants
ORI-W4403 PO Box 26901
Oklahoma City, OK 73126-0901

Dear Board members,

I have recently been made aware of your Board's pending action on a "30-Day Notice of Prior Authorization of Advair and Symbicort." As a pulmonologist who has treated asthma for thirty-plus years, I am deeply concerned about this possible action.

The 2007 N.I.H. Guidelines on Asthma repeatedly stress CONTROL, which is the driving message of the document. Every study since the late 1990s has shown that combination treatment with low dose inhaled steroids (ICS) and long acting beta agonists (LABA) is more effective than using double the dose of ICS alone.

ICS alone are recommended for mild disease, but clinicians don't often see mild disease in their offices. Several years ago, an analysis of asthmatics showed that only 22.7% had mild disease. 62% of moderate asthmatics thought their disease was "totally" or "well" controlled. Mild intermittent asthma is attributed to "allergies" and mild persistent asthma doesn't interfere with daily life functions enough to bring the patient in for medical attention.

Also, we know that it may take 4 weeks, and in some cases up to 6 months, for the maximum anti-inflammatory effect of ICS to be realized. In spite of our efforts to educate asthmatic patients about this delay in action, they often revert to using a rescue medicine alone and don't return to the physician's office for follow-up. A recent article in the *European Respiratory Journal* reported that 92% of physician visits for asthma were for exacerbations, and only 8% were for routine follow-up.

Because the 2007 NIH guidelines repeatedly stress control, it seems counterintuitive, in the face of all the data and clinical experience, to take a step backward by insisting on treatment with ICS alone. It seems far more logical to get control of the asthma, then, if indicated, see if therapy with ICS alone will maintain that control.

Work on the 2007 NIH Guidelines was begun in 2004 by an 18-member group. It took 3 ½ years to finish and publish the 450-page document. Included in that time frame was the publication of the SMART STUDY and the "LABA scare." The concern about LABAs is reflected in the report.

However, since the publication of the guidelines, there have been a number of re-evaluations showing that LABAs with ICS are not associated with any increased risk of death. Most recently, in January of 2009, Hal Nelson, MD, of the National Jewish Hospital and an acknowledged international expert on asthma, authored an AAAI Joint Commission statement of the safety of the ICS/LABA combination in the treatment of asthma. This current information negates any concern about the safety of the combination treatment.

ICS have been available for use in asthma since the mid-1970s, but they were not widely used until the late 1990s when the ICS/LABA combination was introduced. A graph of the asthma death rate shows a distinct decline associated with the introduction

of combination therapy. To me, trying an ICS alone is not a rational treatment of choice. Like most practicing physicians, I simply would not have been able to persuade patients to pay for a medication that took weeks to work when Albuterol was inexpensive and gave them immediate results. The addition of a LABA gave the bronchodilation that afforded relief and allowed time for the steroids to take affect.

Thank you for your time and consideration of this important issue. I hope you will decide to allow the use of combination therapy early in the treatment of asthma so that control may be more effectively achieved.

Sincerely,

James S. Seebass, D.O.

James S. Seebass, D.O., F.A.C.I.O.
Past Chair, Department of Internal Medicine
OSU Health Science Center

Dear Ms. Gorman,
I am writing to support the idea of open access to combination of inhaled steroids and long acting bronchodilators (Advair and Symbicort). According to the NAEEP asthma guidelines we should start meds based on severity of asthma. We should not try inhaled steroids when we know that patient needs a combination therapy. There is a medicolegel aspect also. If we believe patient needs combination therapy and we start on inhaled steroids and fatal exacerbation happens then we will be held liable.
If you have any questions feel free to contact me.

Truly,
iftikhar

Iftikhar Hussain, MD
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Website: www.aaicenter.net

Via Email
Subject: 30 Day Notice to Prior Authorize Advair and Symbicort

February 10, 2009

Nancy Nesser, PhD
Director of Pharmacy Servfices
Oklahoma Health Care Authority
4545 North Lincoln Blvd
Oklahoma City, OK 73105

Dr Nesser:

After reviewing Appendix C for tomorrow's DUR Board meeting (see attachment) , I felt the necessity of making a few comments based on >30 years experience working with the OKC VAMC P&T committe while director of the Outpatient Chest Medicine Clinic. Having worked at OUHSC in the Pulmonary Disease and Critical Care Section since 1975, I recognize that the VA Pharmacy and the OHCA are similarly charged with providing excellent medication coverage for their clients (be they Veterans or Medicaid patients) while attempting to stay within very regulated budgets.

That being said, I would like to raise a few concerns with the attached "Automated and Non-Automated Prior Authorization Criteria":

1. Am I to understand that any patient who has diagnosis of COPD recorded at OHCA in the past year with automatically qualify for a combination ICS/LABA?

A. According to the GOLD/ATS guidelines for COPD therapy (revised 2007), such combination therapy should be restricted to patients with moderately severe to severe disease. Thus it would seem inappropriate, and an extra expense, to allow such treatment for mild and moderate patients.

B. If a patient has a diagnosis of COPD established more than 12 months ago and has PFTs documenting moderately severe to severe disease in the past, do you really expect to require "re-certification" of the existence of the "chronic, progressive disease" (GOLD/ATS Statement, 2007)? It seems a true waste of time to redocument the presence of this disease anymore than I hope you require the redocumentation of insulin requiring diabetes.

2. With respect to the astmatic patient with a diagnosis of asthma within the past 12 months, is there some way to document that severity of the disease.

A. If severity is mild then only rescue albuterol is indicated (NAEPP Guidelines, 2007). If the patient has more that mild disease, then twice daily low-dose inhaled corticosteroid is the drug of first choice. The addition of the LABA is only indicated if the disease is not well controlled (e.g., frequent rescue albuterol usage, multiple ER or hospital visits). Again, issuing combination therapy to mild persistant, even some moderate persistent asthma patients might be considered wasteful. On the other hand, I do not know how you can apply any 30 days/100 days rule on when the patient has taken enough ICS to say he/she has failed and now qualifies for combination therapy. I assume that you would fill an addition prescription for a separate LABA (salmeterol or formoterol), but in the end this would cost more than just moving up to one of the "combo" devises (Advair or Symbicort).

B. Once again, after a particular patient has "qualified" for combination therapy, it is likely a waste of both your time and the physician's to recheck whether the patient still has asthma. Such renewal authorizations should be "automatic".

3. I do not exactly understand the "Non-Automated PAC" for COPD. I can only assume that patients with a new diagnosis of COPD will now qualify for combination therapy, again without regard to the severity of the disease. This bothers me, as combination of ICS and LABA are only indicated in the later stage of COPD (GOLD/ATS guidelines, 2007). Treatment of mild disease is recommended as a rescue inhaler only (albuterol alone or albuterol/ipratropium combination). For moderate disease, most pulmonologists would choose the long acting anticholinergic tiotropium with albuterol for rescue. Severe disease might require the addition of a LABA, reserving the use of the combination of ICS and LABA for moderately severe to very severe disease.

4. With regard to the "Non-Automated PAC" for asthmatics to get combination ICS/LABA, I agree with all the statements but question whether statement #2 should include part of #3 (and his/her disease is still uncontrolled). Then statement #3 should allow the provider to state that this patient's asthma is at least moderately severe to severe at this time and would be best treated with combination therapy immediately.

5. As new director of the Fellows' Chest Medicine Clinic in Presbyterian Professional Building with a majority of our clients being Medicaid funded, my final thoughts for an easier transition to new guidelines are the following:

A. Continued assess (or 'grandfathering') of patients currently receiving combination therapy. The cost to OHCA in ER visits will certainly exceed any funds saved trying to wean these patients back to single drug ICS.
B. A provision to allow the provider to document level of severity (FEV1%predicted, # of ER visits, # cans of rescue albuterol used [that should be in your database]) and avoid delaying adequate treatment when everyone knows he/she is a severe asthmatic.
C. Providing automatic authorization Rxs from the state's board certified pumonologist and allergists, who are seeing patients on referral from their PCPs, who have likely already started some therapy but have requested consultation to improve the medical regimen. Further delaying appropriate therapy could be dangerous.
D. All providers should be made aware of the latest asthma (NAEPP 2007) and COPD (GOLD/ATS, 2007) guidelines to help select the approved therapies.
E. Finally, the OHCA board should be commended on their goal to contain costs in this current ecomonic crisis, but with respect to inhaled pulmonary medication they should remember that it has been shown many times that patient compliance and ultimately outcome has always been improved with combination therapy.

Thank you for listening. If you have any futher questions from me, feel free to respond to this e-mail, or call my cell (245-5305).

David C Levin, MD
Professor of Medicine
Pulmonary Disease and
Critical Care Section

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Founded 1925

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Sycamore Square
120 North Bryant, Suite A4
Edmond, Oklahoma

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March 2, 2009

Shellie Gorman Keast, Pharm.D.
DUR Board
1122 N.E. 13th Street
Oklahoma City, OK 73104

Dear Dr. Keast:

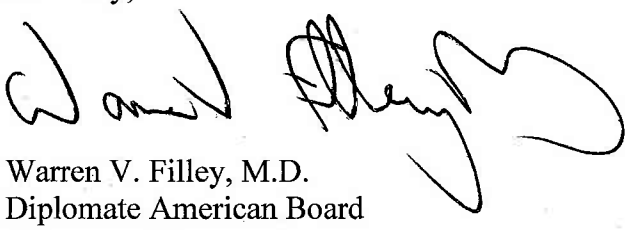
It has come to my attention that the Drug Utilization Review Board is considering elimination of combined inhaled corticosteroid/long acting bronchodilator products for use across the board without prior authorization. As a physician who sees a large number of asthmatics (both DHS and Medicare patients) I can assure that this will have a devastating effect on my practice and the patients I serve.

If you make this decision you will be going against the 2007 NHLIB/NAEPP Asthma Guidelines. This will have disastrous repercussions. There is no reason to use a drug combination in the lower step of care for the asthmatic patient, but as one reaches the upper tier of asthma problems a combination product is absolutely considered the preferred choice. Since using combination products I have seen a significant decrease in the symptoms of my patients as well as a decrease in their office and emergency room visits, not to mention a significant diminution in hospitalizations. These drugs in combination are absolutely critical for the well being of my patients. In addition, the FDA advisory panel which met in December 2008 recommended one of the components of these drugs (the long acting bronchodilator) should ***NEVER*** be given by itself to a patient for asthma. My experience in the past is that when 2 separate inhalers are given the steroid is often discontinued but the LABA is continued. From the time of the FDA board meeting forward I have refused to prescribe a single agent LABA MDI for my asthmatic patients. When they do use a combined product they cannot stop one without stopping the other and it significantly reduces their chances for side effects and problems as well as reducing their asthma symptoms.

Although the guidelines vary with age groups, combination products of inhaled corticosteroids and LABA's are considered the preferred treatment in Steps 3 and above for ages 12 to adult, Steps 4 and above for children ages 5-11, and Steps 5 and above for children 0-4. Please do not make it

harder for my patients to get this medication. It is only going to cause unnecessary exacerbations of asthma with the potential for hospitalizations and even death. I sincerely ask you to reconsider your recommendations and to follow the NHLIB/NAEPP 2007 Asthma Guidelines.

Sincerely,



Warren V. Filley, M.D.
Diplomate American Board
Allergy and Immunology
FAAAI, FACAAI
Clinical Professor of Medicine – OU Health Sciences
President – Oklahoma Allergy & Asthma Clinic

WVF:gt

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for October 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 51-56	Antihistamines, Males and Females, Age 3-4	Contraindicated, Pregnancy, Females, Age 0-21	High Dose and Duration, Zyvox®, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 25
Response Forms Returned: 17

The response forms returned yielded the following results:

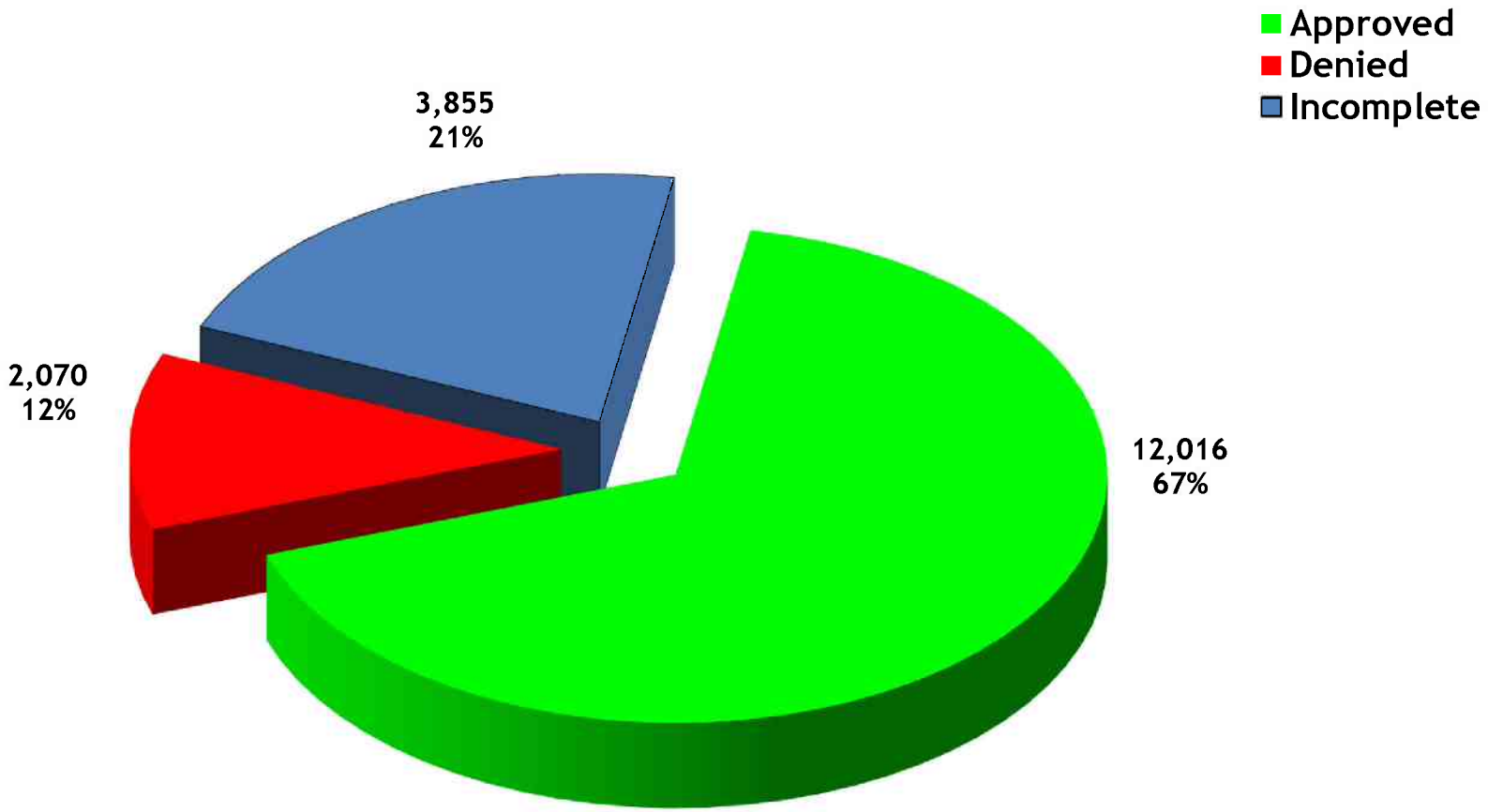
5 (29%)	*Record Error—Not my patient.*
1 (6%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
3 (18%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
7 (41%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (6%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 4
Response Forms Returned: 1

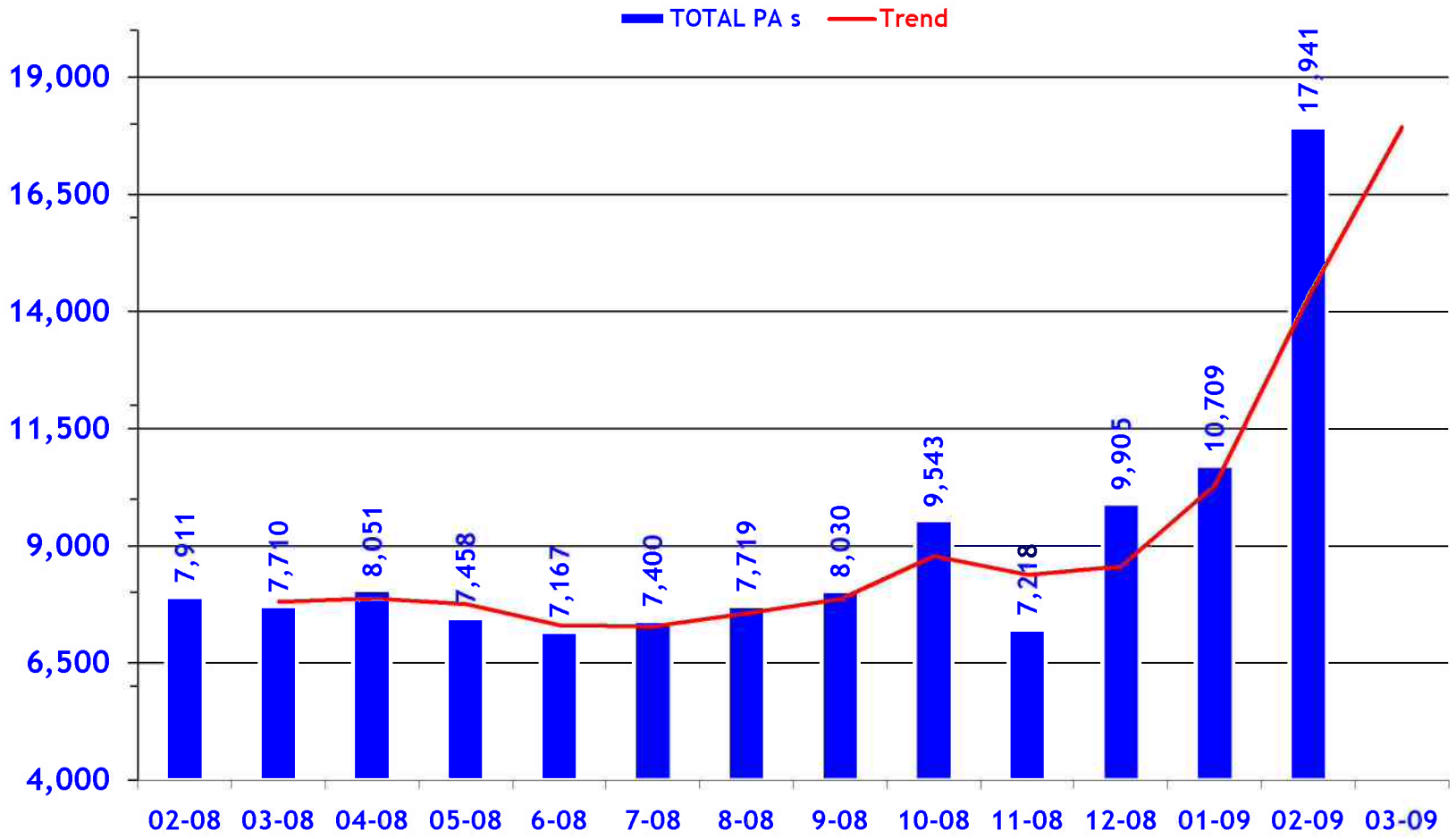
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
1 (100%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
0 (0%)	*I am aware of this situation and will plan to continue monitoring therapy.*
0 (0%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
February 2009



PRIOR AUTHORIZATION REPORT
February 2008 – February 2009



Activity Audit for

2/1/2009 Through 2/28/2009

	Average Length of Approvals in Days	Approved	Denied	Incomplete	Total
ACE Inhibitors	18	9	0	1	10
Angiotensin Receptor Antagonist	340	32	45	38	115
Antidepressant	281	231	152	241	624
Antihistamine	289	255	108	133	496
Antiulcers	52	13	1	5	19
Anxiolytic	90	3,205	160	442	3,807
Calcium Channel Blockers	62	8	3	2	13
Growth Hormones	172	35	0	6	41
HTN Combos	123	3	4	4	11
Insomnia	130	68	67	99	234
Nsaids	311	35	22	41	98
Plavix	354	110	4	52	166
Stimulant	219	600	144	249	993
Others	307	7,409	1,360	2,542	11,311
Emergency PAs		3	0	0	3
Total		**12,016**	**2,070**	**3,855**	**17,941**
Overrides					
Brand	294	24	3	5	32
Dosage Change	14	349	12	13	374
High Dose	88	3	0	0	3
Ingredient Duplication	12	9	0	1	10
Lost/Broken Rx	16	77	3	3	83
Nursing Home Issue	9	128	1	9	138
Other	30	30	3	5	38
Quantity vs. Days Supply	223	272	76	101	449
Stolen	5	9	0	1	10
Overrides Total		**892**	**98**	**137**	**1,127**

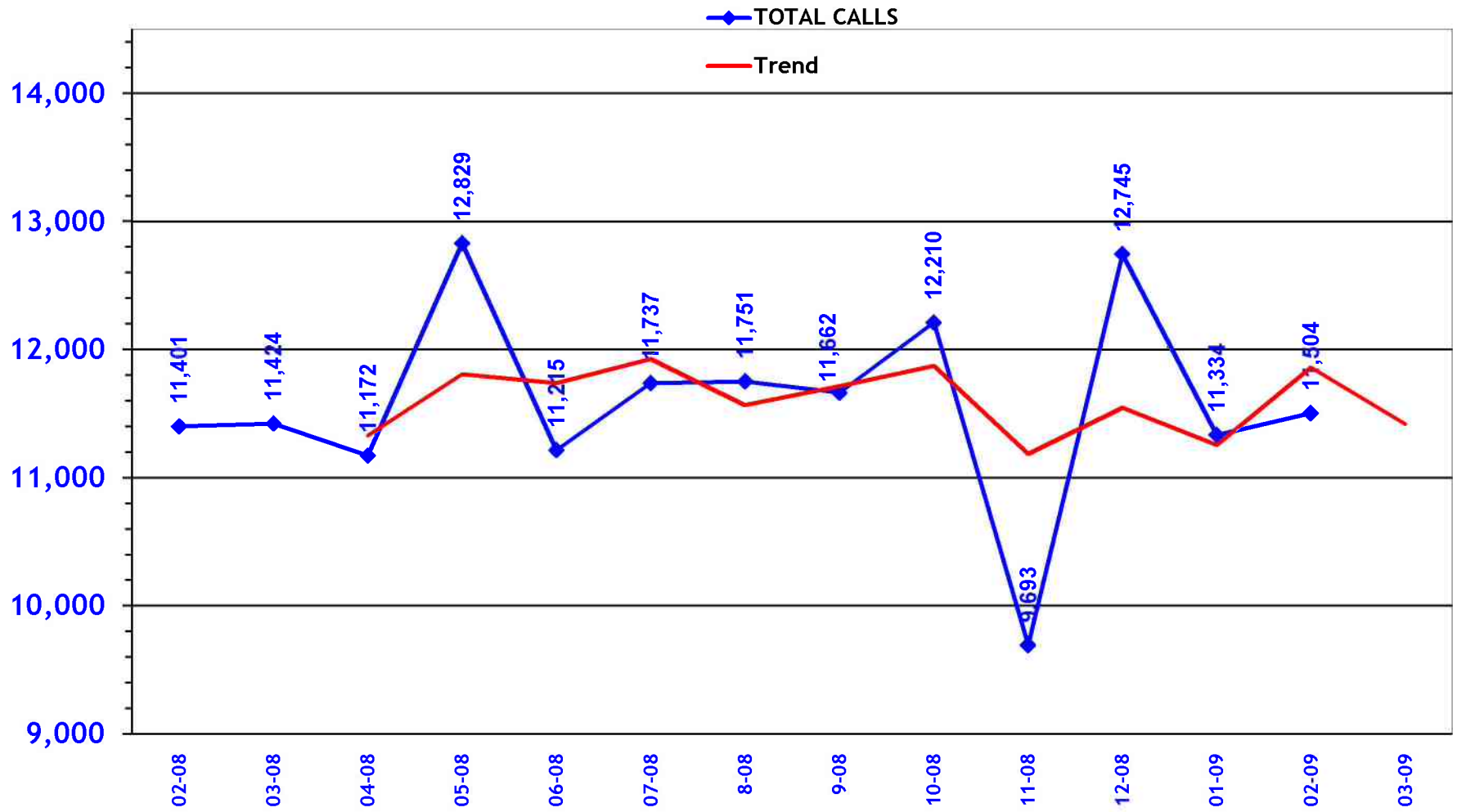
Denial Reasons

Lack required information to process request.	2,898
Unable to verify required trials.	2,139
Does not meet established criteria.	370
Not an FDA approved indication/diagnosis.	203
Considered duplicate therapy. Member has a prior authorization for similar medication.	83
Requested dose exceeds maximum recommended FDA dose.	62
Member has active PA for requested medication.	60
Medication not covered as pharmacy benefit.	31
Drug Not Deemed Medically Necessary	8
Member not approved for TB coverage and/or medication requested not associated with TB symptoms.	1

Duplicate Requests: 1,000

Changes to existing PAs: 638

CALL VOLUME MONTHLY REPORT
February 2008 – February 2009



Appendix C

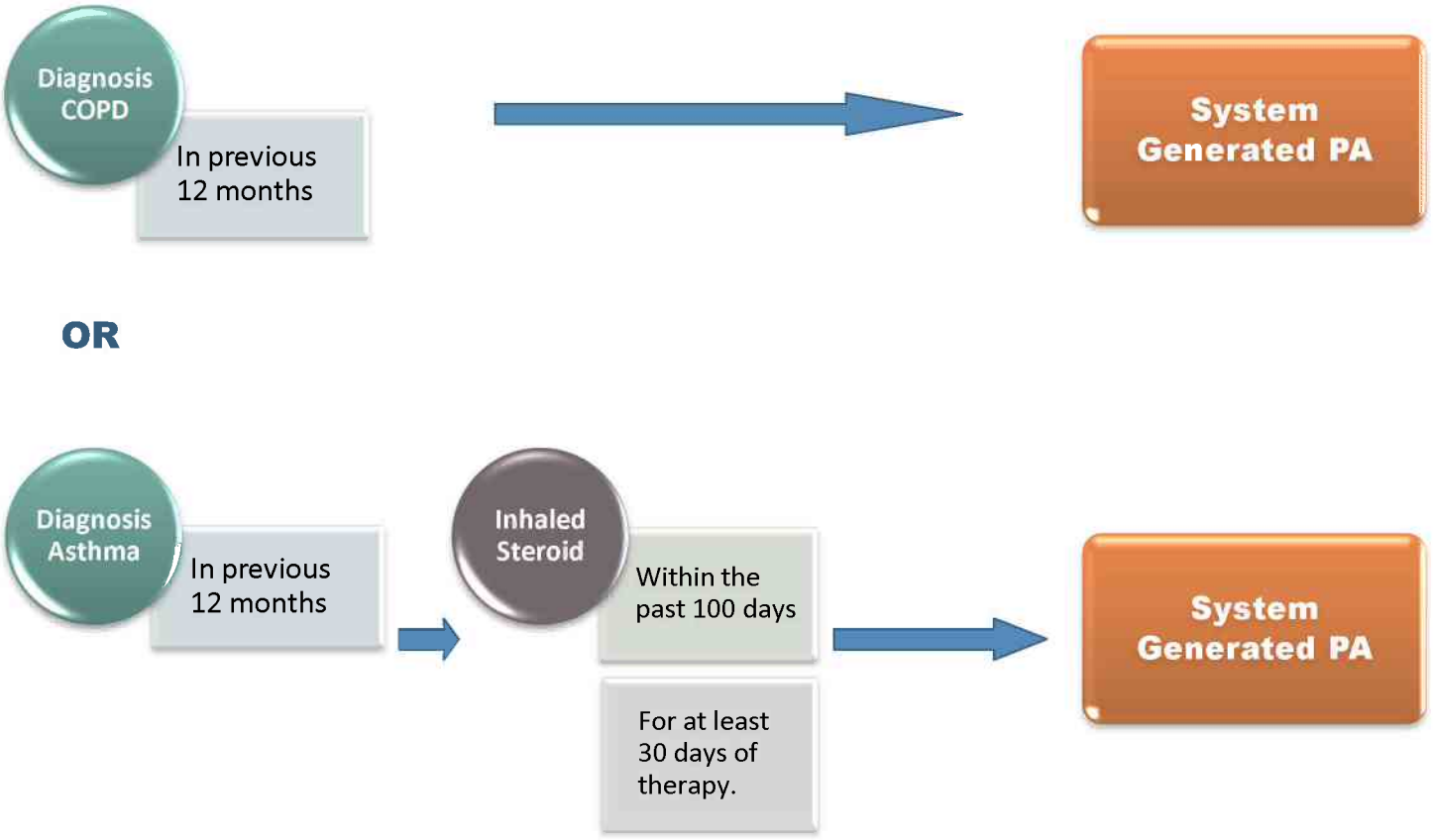
Vote to Prior Authorize Advair® and Symbicort®

Oklahoma Health Care Authority, March 2009

Recommendation

The College of Pharmacy recommends prior authorization of Advair® and Symbicort® with the following automated and non-automated criteria.

Automated Prior Authorization Criteria



Non-Automated Prior Authorization Criteria

For members who do not meet the automated criteria the following will apply when a petition is submitted:

- **Diagnosis of COPD: Approve for one year.**
- **Diagnosis of Asthma:**
  1. Member must be 4 years of age or older, AND
  2. Have used inhaled corticosteroid for at least one month immediately prior, AND
  3. Considered uncontrolled by provider (required rescue medication > 2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids), OR
  4. Clinical situation warranting initiation with combination therapy due to severity of asthma.

Appendix D

Vote to Prior Authorize Fenoglide™, Lipofen®, and Trilipix™

Oklahoma Healthcare Authority

March 2009

Recommendation

The College of Pharmacy recommends the addition of the following new products to Tier 2 of the Fibric Acid Derivative PBPA category:

- **Fenoglide™ Tabs –fenofibrate, available as 40mg and 120mg oral tablets.**
- **Lipofen® Caps – fenofibrate, available as 50mg and 150mg oral capsules.**
- **Trilipix™ Caps – fenofibrate, available as 45mg and 135mg oral capsules.**

Appendix E

Vote to Prior Authorize Astepro™ (azelastine hydrochloride)

Oklahoma Health Care Authority
March 2009

Summary

Astepro™ (azelastine hydrochloride) received FDA approval in October 15, 2008. Astepro™ is a prescription medicine used to treat symptoms of seasonal (not perennial) allergic rhinitis in patients 12 years of age and older. It helps prevent the release of histamine from mast cells and prevents it from binding to receptors if any is released. It is a reformulation of Astelin® with a less bitter taste and less nasal discomfort.

Dose

The recommended dose is one or two sprays in each nostril twice daily for a total dose of four to eight sprays per day. Each spray has a volume of 0.317 ml containing 137mcg of azelastine hydrochloride.

Recommendations

The College of Pharmacy recommends the addition of Astepro™ to the Nasal Allergy Product Based Prior Authorization category as a Tier 3 product. The existing prior authorization criteria for this category will apply.

Appendix F

Fiscal Year 2008 Annual Review of Hypnotic Medications and 30 Day Notice to Prior Authorize Zolpimist™ (Zolpidem Oral Spray)

Oklahoma Health Care Authority
March 2009

Current Prior Authorization of Hypnotic Medications

1. In order to receive a Tier 2 product (or a Tier 3 product if no Tier 2 products exists) a minimum trial of 30 days with at least two Tier 1 products (including zolpidem) should be attempted. Also, clinical documentation of attempts to correct any primary cause for insomnia should be provided.
2. In order to receive a Tier 3 product, all available Tier 2 products should be attempted for a minimum of 30 days each. All other Tier 2 criteria should also be met.
3. FDA approved diagnosis (Ambien CR® only covered for sleep maintenance insomnia).
4. No concurrent anxiolytic benzodiazepine therapy greater than TID dosing and no concurrent ADHD medications.
5. Approvals granted for 6 months.

There is currently an age restriction in place. All pediatric members require a prior authorization for use. Quantity limits also applies for all products based on maximum recommended dose.

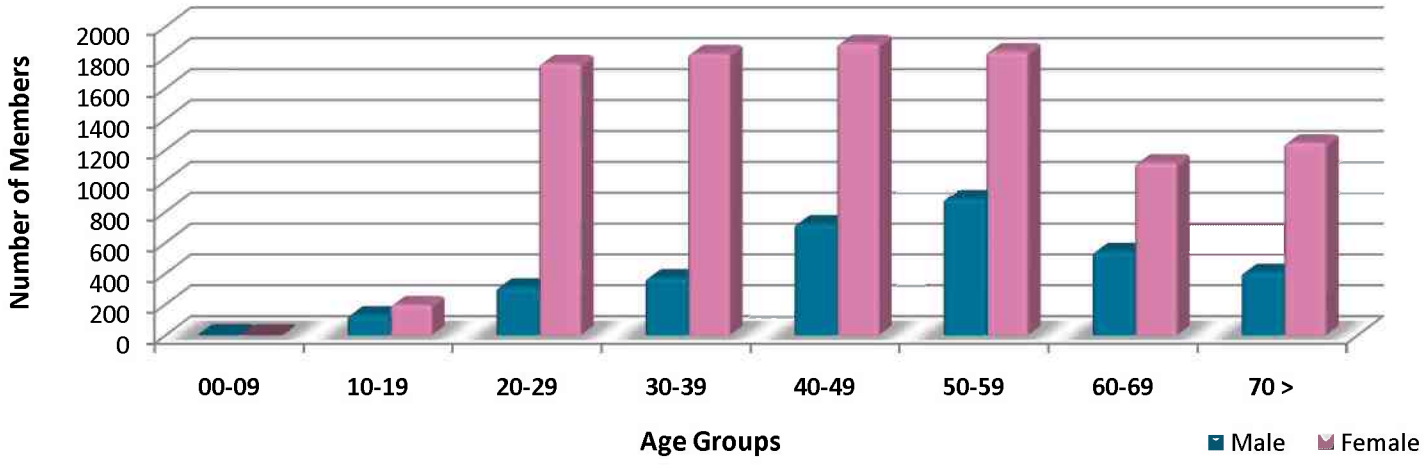
Tier 1	Tier 2	Tier 3
Estazolam **(ProSom®)** Temazepam **(Restoril®) 15 and 30mg** Flurazepam **(Dalmane®)** Triazolam **(Halcion®** Zolpidem* **(Ambien®)**		Eszopiclone **(Lunesta®)** Temazepam **(Restoril®) 7.5 and 22.5 mg** Ramelteon **(Rozerem®)** Zaleplon **(Sonata®)** Zolpidem **(Ambien CR®)**

***Mandatory Generic Plan Applies.**

Trends in Utilization

Fiscal Year	Members	Claims	Cost	Cost/ Claim	Per-Diem	Units	Days
2007	13,598	46,664	$2,528,048.87	$54.18	$1.92	1,361,038	1,317,523
2008	13,553	55,017	$1,820,455.26	$33.09	$1.13	1,611,789	1,604,429
% Change	-0.30%	17.90%	-28.00%	-38.90%	-41.10%	18.40%	21.80%
Change	-45	8,353	-$707,593.61	-$21.0	-$0.79	250,751	286,906

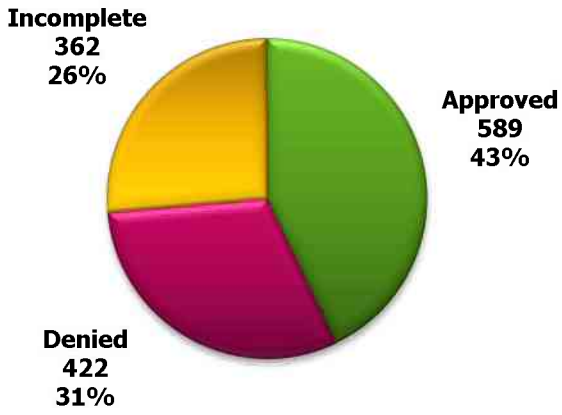
Member Demographics for Fiscal Year 2008



Prescribers of Hypnotic Medications: FY 2008

Specialty	Claims	Cost
Family Practitioner	19,147	$578,003.99
Psychiatrist	9,219	$400,792.00
Internist	7,463	$194,595.38
General Practitioner	6,041	$183,681.78
DDSD-NFM	2,551	$122,561.93
Unknown	1,631	$50,289.47
Obstetrician/Gynecologist	1,305	$31,318.79
General Surgeon	1,042	$29,049.44
General Pediatrician	926	$36,191.39
Physician Assistant	775	$30,452.20

Prior Authorization of Hypnotic Medications: FY 2008



Market Changes

- The patent for Sonata® has expired and a generic is currently available with a SMAC price applied.
- Zolpimist™ (zolpidem) has been developed by Novadel Pharma, Inc. using NovaMist™ technology to deliver zolpidem in an oral spray formulation. Zolpimist™ has been approved by the FDA for the short-term treatment of insomnia characterized by difficulties with sleep initiation. NovaDel is currently seeking a partner for its commercialization.

Recommendations

The College of Pharmacy has the following recommendations for the class of Hyptonic Medications:

- Move Sonata® to Tier 1 of the category.
- Placement of Zolpimist™ in Tier 3 of the Hypnotics Category with a hard prior authorization (Hard PA). The existing prior authorization criteria for this category will apply. In addition, the petition should also include information regarding why member must have the oral spray formulation of zolpidem. A Quantity Limit similar to all other hypnotic medications will apply.

Zolpimist™ Product Details

Manufacturer: NovaDel Pharma, Inc.
Classification: Nonbarbiturate Hypnotic
Status: Prescription only

Summary
Zolpimist™ (zolpidem tartrate) received FDA approval in December 19, 2008. Zolpimist™ is a prescription medicine used for short-term treatment of insomnia characterized by difficulties with sleep initiation. It binds to the BZ1 receptor preferentially with a high affinity ratio of the α1/α5 subunits.

The recommended dose in adults is two sprays into the mouth over the tongue. For elderly or debilitated patients, the recommended dose is one spray into the mouth over the tongue. Each spray contains 5 mg of zolpidem.

Pregnancy Risk Factor C

Contraindications

Known hypersensitivity to zolpidem tartrate.

Precautions

- Need to evaluate for co-morbid diagnoses
- Severe anaphylactic and anaphylactoid reactions
- Abnormal thinking and behavioral changes
- Withdrawal effects
- CNS-depressant effects
- Special populations

Common Adverse Effects from Short-Term Use (<10 nights)

- Drowsiness
- Dizziness
- Diarrhea

Common Adverse Effects from Long-Term Use (28-35 days)

- Dizziness
- Drugged feelings

Serious Side Effects

- Serious anaphylactic and anaphylactoid reactions
- Abnormal thinking, behavior changes, and complex behaviors
- Withdrawal effects
- CNS-depressant effects

Drug Interactions

- CNS depressants: Enhanced CNS-depressant effects with combination use. Use with alcohol causes additive psychomotor impairment.
- Imipramine: Decreased alertness observed with combination use.
- Chlorpromazine: Impaired alertness and psychomotor performance observed with combination use.
- Rifampin: Combination use decreases exposure to and effects of zolpidem.
- Ketoconazole: Combination use increases exposure to and effect of zolpidem.

Patient Information

- Drinking alcohol or using other medications that cause drowsiness while using Zolpimist™ may intensify the effect.
- Do not drive or do other dangerous activities after taking Zolpimist until you feel fully awake.
- After taking Zolpimist, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night.

REFERENCE

Zolpimist(TM) (zolpidem tartrate) Product Information. http://www.fda.gov/cder/foi/label/2008/022196lbl.pdf

Appendix G

Prior Authorization Annual Review - Fiscal Year 2008

Glaucoma Medications

Oklahoma Health Care Authority
March 2009

Prior Authorization Criteria (approved 07/2007, implemented 01/2008):

1. FDA approved diagnosis.
2. Member must attempt at least one Tier-1 trial of a minimum of 4 weeks duration within the last 90 days. Tier-1 trial may be from any pharmacologic class.
3. Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to Tier-1 products.
4. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 products.
5. Member must have had a comprehensive dilated eye exam within the last 365 day period as recommended by the National Institute of Health.
6. Approval duration will be for 1 year.

Update on Fiscal Year 2008

April 2008 – Placement of Combigan(™) (brimonidine tartrate and timolol maleate) 0.2%/0.5% into the Tier 2 products in the Anti-Glaucoma PBPA category. Information regarding need for use of combination product over single ingredient products must also be provided.

August 2008 – Wyeth notification of shortage of echothiophate iodide (Phospholine Iodide®) due to limited supply of raw materials

December 2008 – FDA approval of bimatoprost (Lumigan®) for treatment of hypotrichosis treatment of the eyelashes

Ophthalmic Glaucoma Medications	
Tier-1	**Tier-2**
Beta-Blockers	
betaxolol (Betoptic® 0.5%)	betaxolol (Betoptic-S®)
carteolol (Ocupress®)	brimonidine/timolol (Combigan®)
dorzolamide/timolol (Cosopt®)	timolol maleate (Timoptic® 0.5% dropperette)
levobunolol (Betagan®)	
metipranolol (OptiPranolol®)	
timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic Ocudose®, Timoptic-XE®)	
Prostaglandin Analogs	
latanoprost (Xalatan®)	bimatoprost (Lumigan®)
travoprost (Travatan®, Travatan-Z®)	
Adrenergic Agonists	
dipivefrin (Propine®)	
Alpha-2 Adrenergic Agonists	
brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%)
	apraclonidine (Iopidine® 1%)
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®)	brinzolamide (Azopt®)
acetazolamide (Diamox®)*	dorzolamide (Trusopt®)
dichlorphenamide (Daranide®)*	
methazolamide (Neptazane®)*	
* (Indicates Available Oral Products)	
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto® Carpine, Pilopine HS®, 0.5%, 1%, 2%, 4%, 6%)	carbachol (Isopto®, Miostat® 1.5%, 3%)
	*echothiophate iodide (Phospholine Iodide®)
Combination Products	
	*brimonidine tartrate 0.2%/timolol maleate 0.5% (Combigan™)

Tier 1 due to Supplemental Rebate Program Participation

Utilization

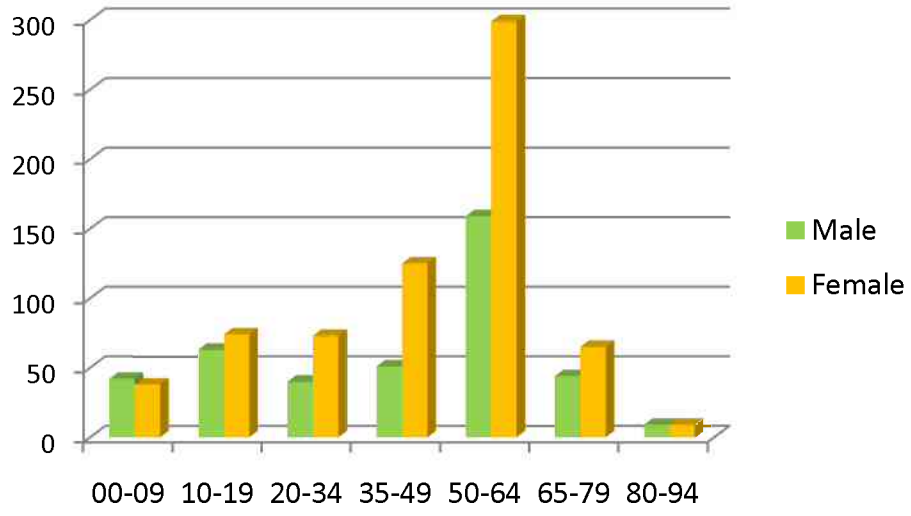
For the period of July 2007 through June 2008 a total of 1,091 members received glaucoma products through the SoonerCare program.

FY 2007 versus FY 2008			% Change
Cost FY '08		**$445,348.20**	**7.2** ↑
	Cost FY '07	*$415,442.69*	
Claims FY '08		**5,413**	**0.5** ↑
	Claims FY '07	*5,389*	
Cost/Claim FY '08		**$82.27**	**6.7** ↑
	Cost/claim FY '07	*$77.09*	
Members FY '08		**1,091**	**1.0** ↑
	Members FY '07	*1,081*	

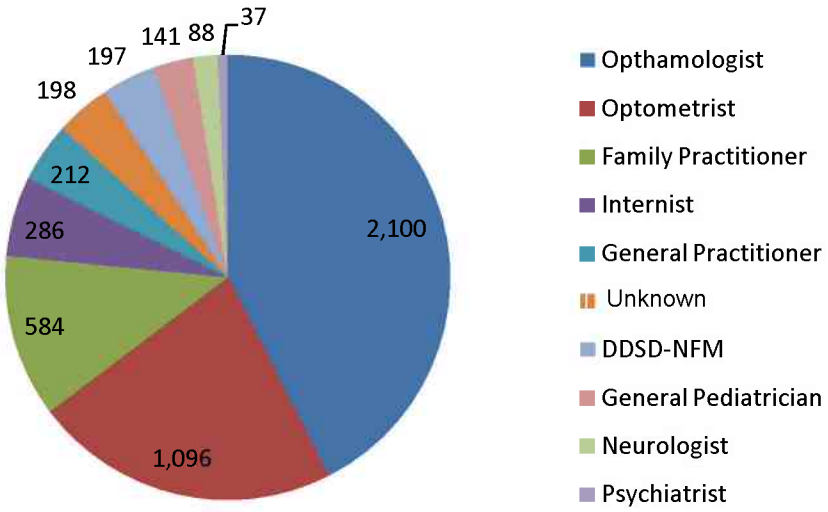
Total petitions submitted for this category during FY08: 114

Approved	*39*
Denied	*53*
Incomplete	22

Age and Gender FY08



Prescriber Specialty



Recommendations

The College of Pharmacy recommends continued monitoring and evaluation of the glaucoma medication category.

CHEMICAL NAME	BRAND NAME	CLAIMS	UNITS	DAYS	MEMBERS	COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
Latanoprost	XALATAN SOL 0.005%	1,063	3,220	31,616	277	$83,093.86	0.1	3.84	$2.63	18.66%
Bimatoprost	LUMIGAN SOL 0.03%	761	3,460	23,560	179	$95,070.07	0.15	4.25	$4.04	21.35%
Dorzolamide-Timolol	COSOPT SOL 2-0.5%OP	552	5,691	18,593	149	$64,752.32	0.31	3.70	$3.48	14.54%
Travoprost	TRAVATAN SOL 0.004%	485	1,522	12,042	136	$42,430.59	0.13	3.57	$3.52	9.53%
Brimonidine	ALPHAGAN P SOL 0.15%	430	4,478	10,966	110	$43,572.41	0.41	3.91	$3.97	9.78%
Acetazolamide	ACETAZOLAMID TAB 250MG	358	23,466	10,101	101	$7,203.84	2.32	3.54	$0.71	1.62%
Travoprost	TRAVATAN Z SOL 0.004%	278	1,095	7,116	95	$30,393.83	0.15	2.93	$4.27	6.82%
Timolol Maleate	TIMOLOL MAL SOL 0.5% OP	243	2,565	7,122	95	$2,022.41	0.36	2.56	$0.28	0.45%
Acetazolamide	DIAMOX CAP 500MG CR	169	8,648	4,619	58	$24,150.46	1.87	2.91	$5.23	5.42%
Timolol Maleate	TIMOLOL GEL SOL 0.5% OP	162	965	4,539	41	$5,486.29	0.21	3.95	$1.21	1.23%
Brimonidine	BRIMONIDINE SOL 0.2% OP	161	1,345	3,655	56	$3,388.11	0.37	2.88	$0.93	0.76%
Brimonidine	ALPHAGAN P SOL 0.1%	116	1,050	3,243	43	$10,179.74	0.32	2.70	$3.14	2.29%
Dorzolamide HCl	TRUSOPT SOL	107	1,080	2,508	32	$6,942.19	0.43	3.34	$2.77	1.56%
Brinzolamide	AZOPT SUS 1% OP	106	1,075	3,136	36	$8,480.64	0.34	2.94	$2.70	1.90%
Betaxolol HCl	BETOPTIC-S SUS 0.25% OP	91	932	2,066	22	$8,293.46	0.45	4.14	$4.01	1.86%
Echothiophate Iodide	PHOSPHOLINE SOL 0.125%OP	41	240	1,864	17	$3,441.25	0.13	2.41	$1.85	0.77%
Timolol Maleate	TIMOLOL MAL SOL 0.25% OP	39	438	1,025	15	$333.49	0.43	2.60	$0.33	0.07%
Brimonidine -Timolol	COMBIGAN SOL 0.2/0.5%	30	165	550	15	$2,139.44	0.3	2.00	$3.89	0.48%
Levobunolol HCl	LEVOBUNOLOL SOL 0.5% OP	29	265	794	6	$282.78	0.33	4.83	$0.36	0.06%
Pilocarpine HCl	PILOCARPINE SOL 4% OP	28	495	759	3	$300.10	0.65	9.33	$0.40	0.07%
Methazolamide	METHAZOLAMID TAB 25MG	27	676	674	7	$266.44	1	3.86	$0.40	0.06%
Methazolamide	METHAZOLAMID TAB 50MG	27	2,471	900	3	$604.90	2.75	9.00	$0.67	0.14%
Acetazolamide	ACETAZOLAMID TAB 125MG	26	2,470	1,225	7	$417.70	2.02	3.71	$0.34	0.09%
Timolol	BETIMOL SOL 0.5%	25	195	680	8	$1,084.50	0.29	3.13	$1.59	0.24%
Dipivefrin HCl	DIPIVEFRIN SOL 0.1% OP	23	180	583	5	$192.30	0.31	4.60	$0.33	0.04%
Pilocarpine HCl	PILOCARPINE SOL 2% OP	13	195	295	1	$117.45	0.66	13.00	$0.40	0.03%
Timolol	BETIMOL SOL 0.25%	6	35	30	1	$167.58	1.17	6.00	$5.59	0.04%
Levobunolol HCl	LEVOBUNOLOL SOL 0.25% OP	5	50	185	2	$60.96	0.27	2.50	$0.33	0.01%
Betaxolol HCl	BETAXOLOL SOL 0.5% OP	4	25	144	3	$116.85	0.17	1.33	$0.81	0.03%
Timolol	ISTALOL SOL 0.5% OP	4	20	120	1	$298.72	0.17	4.00	$2.49	0.07%
Timolol	TIMOLOL GEL SOL 0.25% OP	2	10	60	1	$48.30	0.17	2.00	$0.81	0.01%
Pilocarpine HCl	PILOCARPINE SOL 0.5% OP	1	15	20	1	$8.98	0.75	1.00	$0.45	0.00%
Pilocarpine HCl	PILOCARPINE SOL 1% OP	1	15	5	1	$6.24	3	1.00	$1.25	0.00%
	Totals	**5,413**	**68,552**	**154,795**	**1,091**	**$445,348.20**	**0.44**	**5.17**	**$2.88**	**100%**

Appendix H

Review of Anti-Migraine (Triptan) Utilization

Oklahoma Health Care Authority
March 2009

Introduction[1,2]

Migraine headache accounts for 10-20% of all headaches in adults. It is three times more prevalent in women (18%) than men (6%). The usual age of onset is 15-35 years of age, but prevalence is highest in the 35-45 age group and tends to decrease after age 45. An estimated 8.7 million females and 2.6 million males experience moderate to severe migraine-associated disability. Gender differences in migraine occurrence have been linked to menstruation, but even postmenopausal women have a higher incidence of migraines than males.

Migraine headaches are more common in lower socioeconomic groups; this may be related to diet, stress, increased use of OTC medications, and/or reduced access to health care. Lower income households are also more likely to use emergency care services to treat migraines than are other economic groups. Treatment is either abortive (symptomatic) or prophylactic (preventative).

Abortive Migraine Therapies
- Simple analgesics (ASA, APAP, butalbital)
- NSAIDs
- Ergots
- Triptans
- Miscellaneous (e.g.Butorphanol, Chlorpromazine, Midrin, Metoclopramide)

Prophylactic Therapies
- NSAIDs/Aspirin
- Beta Blockers
- Calcium Channel Blockers
- Antidepressants
- Anticonvulsants
- Miscellaneous (e.g. clonidine, cyproheptadine, ergonovine, methysergide)

Generic Name	Trade Name	FDA Indications	Dosage Forms Available	Dosing Range Day	Frequency of Dosing
Almotriptan	Axert®	- Migraine with or without aura	Tabs	6.25 mg – 12.5 mg (Max of 25 mg)	QD; May repeat 1x after 2h
Eletriptan	Relpax®	- Migraine with or without aura	Tabs	20 mg – 40 mg (Max of 80 mg)	QD; May repeat 1x after 2h
Frovatriptan	Frova®	- Migraine with or without aura	Tabs	2.5 mg – 5 mg (Max of 7.5 mg)	QD; May repeat 1x after 2h
Naratriptan	Amerge®	- Migraine with or without aura	Tabs	1 mg – 2.5 mg (Max of 5 mg)	QD; May repeat 1x after 4h
Rizatriptan	Maxalt® Maxalt-MLT®	- Migraine with or without aura	Tabs, ODT	5 mg – 10 mg (Max of 30 mg)	QD; May repeat 2x q2h
Sumatriptan	Imitrex® Imitrex Nasal®	- Migraine with or without aura -Cluster Headache	Tabs, Solution for Subcutaneous Injection, Intranasal Solution	Migraine: 25 mg – 100 mg po, 6 mg SQ 5 mg – 20 mg INH (Max of 200 mg Oral; 12 mg SQ; 40 mg INH) Cluster HA: 4 mg – 6 mg SQ (Max of 12 mg)	QD; May repeat 1x after 1h (Tabs); May repeat 1x after 2h (SQ/INH)
Sumatriptan w/ Naproxen	Treximet®	- Migraine with or without aura	Tabs	1 Tab (85/500) (Max of 2 Tabs)	QD; May repeat 1x after 2h
Zolmitriptan	Zomig® Zomig-ZMT® Zomig Nasal®	- Migraine with or without aura	Tabs, ODT, Intranasal Solution	1.25 mg – 2.5 mg 5mg INH 2.5 mg – 5 mg ODT (Max of 10mg)	QD; May repeat 1x after 2h

Current Restrictions

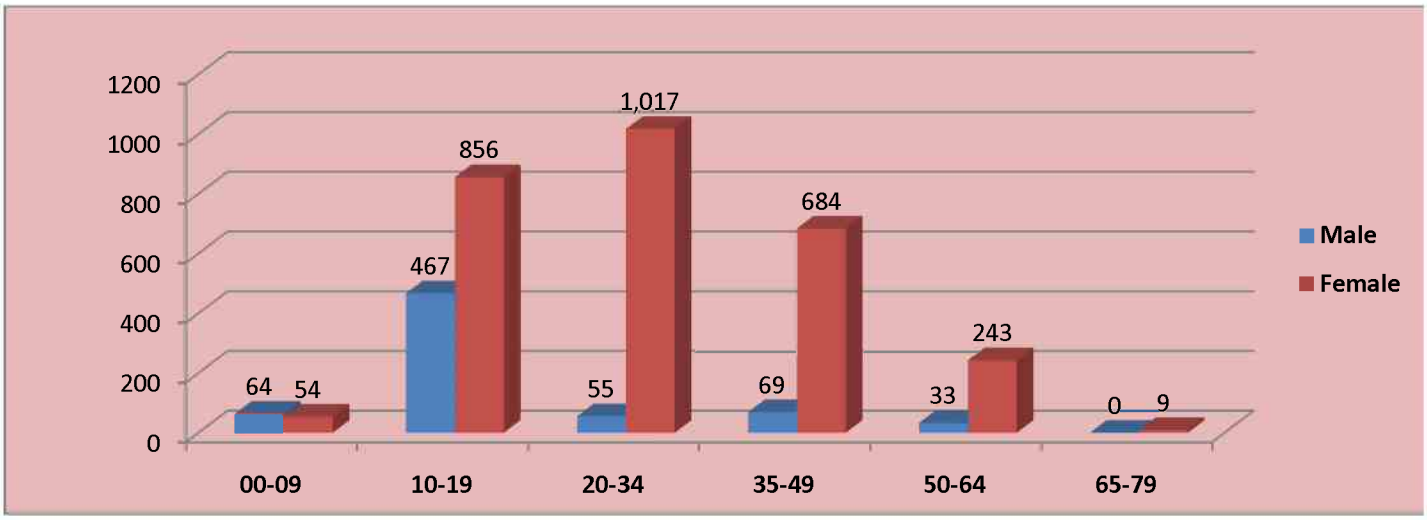
Quantity Limits are currently in place for all of the triptans.

Medication	Quantity Limit	Maximum daily dose
Almotriptan (**Axert**®) 6.25 and 12.5 mg tablets	12 tablets per 30 days	25mg
Eletriptan (**Relpax**®)	8 tablets per 30 days	80mg
Frovatriptan (**Frova**®) 2.5 mg tablets	12 tablets per 30 days	7.5mg
Naratriptan (**Amerge**®) 1 and 2.5 mg tablets	9 tablets per 30 days	5mg
Rizatriptan (**Maxalt**®; **Maxalt MLT**®) 5 and 10 mg tablets and orally disintegrating tablets	12 tablets per 30 days	30mg
Sumatriptan (**Imitrex**®) 25, 50 & 100 mg tablets	18 tablets per 30 days	200mg
Sumatriptan (**Imitrex**®) injection 6mg/0.5mL autoinjector (syringes)	4 kits per 30 days	12mg
Sumatriptan (**Imitrex**®) injection 6mg/0.5mL vials	8 vials per 30 days	12mg
Sumatriptan (**Imitrex**®) 5mg & 20 mg/100 µL nasal spray	12 nasal units per 30 days	40mg
Zolmitriptan (**Zomig**®; **Zomig-ZMT**®) tablets, orally disintegrating tablets, and nasal spray	2.5 mg - 12 tablets per 30 days 5 mg – 6 tablets per 30 days Nasal Spray – 6 units per 30 days	10mg for all three forms

Utilization of Triptans

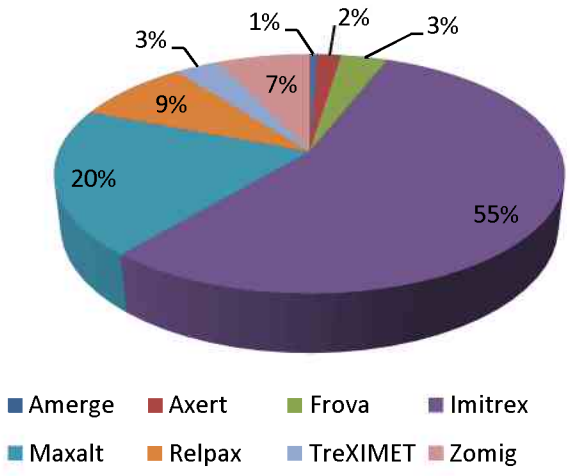
Calendar Year	Total Members	Total Claims	Total Cost	Cost / Claim	Cost/ Day	Total Units	Total Days
2007							
	3,539	9,641	$1,980,573.36	$205.43	$14.65	91,436	135,187
2008							
	3,646	9,956	$2,198,451.64	$220.82	$16.62	94,793	132,276
% Change	**3.00%**	**3.30%**	**11.00%**	**7.50%**	**13.40%**	**3.70%**	**-2.20%**
Change	**107**	**315**	**$217,878.28**	**$15.39**	**$1.97**	**3,357**	**-2,911**

Demographics

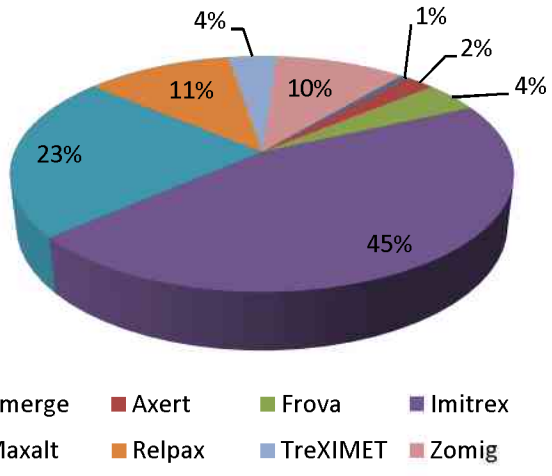


Market Share

Market share by cost



Market share by claims



Market Update

- April 2008 – Treximet® (sumatriptan/naproxen) approved by the FDA
- November 2008 – the first sumatriptan generic product was approved by the FDA.

Recommendations

The College of Pharmacy recommends the following:

- Put quantity limit of 9 tabs per 30 day supply on Treximet®
- Place this category of drugs into the PBPA system with the following criteria:

Approval Criteria

To qualify for a Tier 2 drug, member must meet one of the following criteria:

- Trial of a tier one medication with inadequate response
- Documented adverse effect to the Tier 1 medication, or
- Previous stabilization on the Tier 2 medication within the last 100 days.

To qualify for a Tier 3 drug, member must have:

- Trials of all available Tier 2 medications with inadequate response
- Documented adverse effect to all available Tier 2 medications, or
- Previous stabilization on the Tier 3 medication within the last 100 days.

Tier 1	Tier 2	Tier 3
Sumatriptan (**Imitrex®**)	(Supplemental rebated Tier 3)	Almotriptan **(Axert®)** Eletriptan **(Relpax®)** Frova®triptan **(Frova®)** Naratriptan **(Amerge®)** Rizatriptan **(Maxalt®; Maxalt MLT®)** Zolmitriptan **(Zomig®; Zomig-ZMT®)** Sumatriptan/Naproxen **(Treximet®)**

Utilization Details of Triptans

Drug	Claims	Units	Days	Members	Cost/ claim	Cost
AMERGE® TAB 1MG	5	34	37	4	$180.49	$902.44
AMERGE® TAB 2.5MG	51	446	921	16	$221.36	$11,289.44
AMERGE®	**56**	**480**	**958**	**20**	**$217.71**	**$12,191.88**
AXERT® TAB 12.5MG	202	1,907	2,566	63	$187.15	$37,805.24
AXERT® TAB 6.25MG	22	132	312	8	$121.18	$2,665.94
AXERT®	**224**	**2,039**	**2,878**	**71**	$180.67	**$40,471.18**
FROVA® TAB 2.5MG	418	3,720	5,263	188	$185.66	$77,604.96
FROVA®	**418**	**3,720**	**5,263**	**188**	$185.66	**$77,604.96**
IMITREX® INJ 6MG/0.5	21	91	365	10	$688.88	$14,466.53
IMITREX® KIT 4MG/0.5	19	27	158	7	$250.40	$4,757.53
IMITREX® KIT 6MG/0.5	153	342	2,158	56	$392.98	$60,125.67
IMITREX® KIT RF	102	292	1,283	26	$449.55	$45,853.98
IMITREX® KIT RF	2	2	15	2	$169.32	$338.64
IMITREX® SPR 20MG/ACT	182	1,429	3,506	78	$276.45	$50,314.39
IMITREX® SPR 5MG/ACT	88	560	1,597	46	$207.51	$18,260.66
IMITREX® TAB 100MG	1,732	18,571	24,738	702	$243.05	$420,962.73
IMITREX® TAB 25MG	832	10,300	11,632	399	$301.78	$251,083.53
IMITREX® TAB 50MG	1,390	15,178	17,944	639	$249.99	$347,489.23
IMITREX®	**4,521**	**46,792**	**63,396**	**1,965**	**$268.45**	**$1,213,652.89**
MAXALT ®TAB 10MG	810	7,990	10,210	330	$205.46	$166,423.80
MAXALT ®TAB 5MG	230	2,009	2,155	105	$183.15	$42,125.24
MAXALT-MLT ®TAB 10MG	970	8,880	12,906	395	$188.98	$183,309.84
MAXALT-MLT ®TAB 5MG	240	2,055	2,675	99	$174.73	$41,935.95
MAXALT®	**2,250**	**20,934**	**27,946**	**929**	**$192.80**	**$433,794.83**
RELPAX ®TAB 20MG	322	2,864	4,079	130	$171.16	$55,111.95
RELPAX® TAB 40MG	799	7,069	10,426	297	$170.97	$136,608.49
RELPAX®	**1,121**	**9,933**	**14,505**	**427**	**$171.03**	**$191,720.44**
TREXIMET® TAB 85-500MG	369	3,774	5,264	198	$206.62	$76,242.86
TreXIMET ®	**369**	**3,774**	**5,264**	**198**	**$206.62**	**$76,242.86**
ZOMIG® SPR 5MG	129	773	2,198	53	$175.21	$22,602.50
ZOMIG® TAB 2.5MG	365	3,170	4,095	162	$172.85	$63,090.90
ZOMIG® TAB 5MG	303	1,752	3,197	110	$126.94	$38,463.15
ZOMIG® ZMT TAB 2.5 MG	115	880	1,240	47	$145.85	$16,772.70
ZOMIG® ZMT TAB 5MG	85	546	1,336	34	$139.33	$11,843.35
ZOMIG®	**997**	**7,121**	**12,066**	**406**	**$153.23**	**$152,772.60**
TOTALS	**9,956**	**94,793**	**132,276**	**3,646***	**$220.82**	**$2,198,451.64**

*Unduplicated members

Appendix I

Top 25 Sub-Therapeutic Classes by Total Reimbursement
Second Quarter Fiscal Year 2009

Rank 2nd Qtr FY09	Rank 1st Qtr FY09	Sub-Therapeutic Class	Total Cost 2nd Qtr FY09	Total Cost 1st Qtr FY09	Total Claims	Total Members	Cost / Day	Change in Total Cost	Percent Generic	Current Restrictions
1	1	Misc. Hematological - Antihemophilic	$6,614,524	$6,746,498	190	51	$1,872.74	($131,974)	0%	None
2	2	Antipsychotics - Dibenzodiazepines	$6,242,754	$6,157,384	16,830	6,068	$12.20	$85,370	6%	Qty Limits
3	4	Antiasthmatics - Beta Adrenergics	$5,437,267	$4,612,060	75,502	40,182	$3.19	$825,206	35%	None
4	3	Anticonvulsants - Miscellaneous	$5,331,679	$5,431,635	34,128	12,875	$5.19	($99,956)	56%	None
5	6	Antipsychotics - Quinolinone Derivatives	$5,067,371	$4,438,661	10,599	4,773	$15.17	$628,711	0%	Qty Limits
6	7	Antiasthmatics - Leukotriene Modulators	$4,232,738	$3,869,520	38,139	22,104	$3.71	$363,218	0%	None
7	5	Antipsychotics - Benzisoxazoles	$3,427,939	$4,570,005	14,466	5,631	$7.68	($1,142,066)	75%	Qty Limits
8	N/A	Biologicals - Monoclonal Antibodies	$3,269,813	N/A	2,117	707	$53.66	N/A	0%	Prior Auth
9	8	Analgesics - Narcotic Agonists	$3,042,370	$2,997,700	23,979	9,850	$5.71	$44,671	83%	Step Therapy
10	11	ADHD - Amphetamines	$2,571,773	$2,096,920	23,197	9,307	$3.72	$474,852	22%	Step Therapy
11	12	Antiasthmatics - Steroid Inhalants	$2,467,501	$1,951,614	13,875	9,314	$6.25	$515,887	0%	None
12	9	Ulcer Drugs - Proton Pump Inhibitors	$2,437,994	$2,429,899	25,827	12,678	$3.00	$8,095	53%	Step Therapy
13	10	ADHD - Miscellaneous	$2,343,013	$2,210,569	22,118	8,729	$3.55	$132,444	25%	Step Therapy
14	13	Antidiabetic - Insulin	$1,943,160	$1,858,716	12,073	4,026	$5.47	$84,445	0%	Qty Limits
15	15	Analgesics - Narcotic Combinations	$1,267,246	$2,997,700	95,388	47,225	$1.11	($1,730,454)	99%	Step Therapy
16	16	Antidepressants - SNRIs	$1,167,097	$1,126,144	7,268	3,237	$4.73	$40,953	11%	Step Therapy
17	17	Antivirals - Antiretrovirals	$1,150,769	$1,080,861	1,491	284	$25.50	$69,907	5%	None
18	18	Antihyperlipidemic - HMG CoA Reductase	$1,054,777	$1,022,184	13,712	7,245	$1.92	$32,592	53%	Step Therapy
19	19	Antipsychotics - Miscellaneous	$1,050,270	$981,778	3,068	1,268	$11.09	$68,491	0%	Qty Limits
20	26	Anti-infectives - Azythromycin	$980,714	$701,709	41,259	35,630	$4.72	$279,006	99%	None
21	20	Systemic and Topical Nasal Products - Nasal	$978,532	$934,977	15781	11,855	$1.93	$43,555	38%	Step Therapy
22	21	Antivirals - Hepatitis C Agents	$952,239	$906,239	732	152	$44.98	$45,999	41%	None
23	14	Anticonvulsants - Valproic Acid	$941,450	$1,267,309	9745	3,740	$3.23	($325,859)	49%	None
24	23	Misc. Endocrine - Growth Hormone	$903,968	$867,265	384	154	$81.60	$36,703	0%	Prior Auth
25	22	Contraceptives - Combinations	$881,607	$878,573	17311	8,794	$1.43	$3,034	55%	None

Top 10 Sub-Therapeutic Classes with Top 5 Products by Total Reimbursement
Second Quarter Fiscal Year 2009

Rank 2nd Qtr FY09	Rank 1st Qtr FY09	Therapeutic Class	Total Cost 2nd Qtr FY09	Total Cost 1st Qtr FY09	Total Claims	Total Members	Generic %	Cost / Day	Change in Total Cost
1	1	**Misc. Hematological - Antihemophilic**	$6,614,524.47	$6,746,498.08	190	51	0%	$1,872.74	($131,973.61)
1	1	Novoseven®	$2,899,782.15	$2,419,764.05	20	5	0%	$6,249.53	$480,018.10
2	2	Antihemophilic Factor (Recombinant)	$1,550,009.47	$1,441,658.71	92	27	0%	$870.79	$108,350.76
3	3	Feiba®	$1,038,129.11	$1,471,149.90	17	3	0%	$2,916.09	($433,020.79)
4	4	Advate®	$687,882.80	$896,474.88	24	8	0%	$1,577.71	($208,592.08)
5	5	Alphanine®	$198,318.46	$184,987.60	13	5	0%	$1,095.68	$13,330.86
2	2	**Antipsychotics - Dibenzodiazepines**	$6,242,754.42	$6,157,384.45	16,830	6,068	6%	$12.20	$85,369.97
1	1	Seroquel®	$3,829,247.80	$3,835,082.09	11,677	4,552	0%	$10.45	($5,834.29)
2	2	Zyprexa®	$2,099,297.73	$2,057,699.98	3,482	1,356	0%	$18.53	$41,597.75
3	3	Clozapine	$304,543.48	$257,659.52	1,556	274	55%	$10.81	$46,883.96
4	4	Loxapine	$9,665.41	$6,942.86	115	40	100%	$2.69	$2,722.55
3	4	**Antiasthmatics - Beta Adrenergics**	$5,437,266.75	$4,612,060.35	75,502	40,182	35%	$3.19	$825,206.40
1	1	Advair®	$1,958,733.37	$1,823,784.09	10079	6272	0%	$6.41	$134,949.28
2	2	Albuterol HFA and Neb	$1,712,010.34	$1,210,070.13	46966	30533	38%	$1.78	$501,940.21
3	3	Xopenex®	$804,966.84	$561,034.73	4401	3243	0%	$10.42	$243,932.11
4	4	Ipratropium-Albuterol	$420,562.83	$432,091.33	3515	1945	43%	$4.59	($11,528.50)
5	5	Symbicort®	$191,505.01	$255,154.91	1084	730	0%	$6.00	($63,649.90)
4	3	**Anticonvulsants - Miscellaneous**	$5,331,678.91	$5,431,634.57	34,128	12,875	56%	$5.19	($99,955.66)
1	1	Topamax®	$1,462,478.57	$1,372,324.41	4,583	1,960	0%	$10.45	$90,154.16
2	2	Lamotrigine	$1,277,871.11	$1,371,400.95	5,191	2,036	79%	$7.99	($93,529.84)
3	3	Keppra®	$1,062,345.67	$1,045,416.85	3,688	1,436	4%	$9.97	$16,928.82
4	5	Lyrica®	$658,948.95	$631,961.78	4,290	2,063	0%	$5.10	$26,987.17
5	4	Oxcarbazepine	$519,321.67	$656,678.15	4,264	1,722	78%	$4.09	($137,356.48)
5	6	**Antipsychotics - Quinolinone Derivatives**	$5,067,371.47	$4,438,660.81	10,599	4,773	0%	$15.17	$628,710.66
1	1	Abilify®	$5,067,371.47	$4,438,660.81	10,599	4,773	0%	$15.17	$628,710.66

Rank 2nd Qtr FY09	Rank 1st Qtr FY09	Therapeutic Class	Total Cost 2nd Qtr FY09	Total Cost 1st Qtr FY09	Total Claims	Total Members	Generic %	Cost / Day	Change in Total Cost
6	7	**Antiasthmatics - Leukotriene Modulators**	$4,232,738.12	$3,869,520.04	38,139	22,093	0%	$3.71	$363,218.08
1	1	Singulair®	$4,217,462.81	$3,856,154.66	38,015	22,054	0%	$3.71	$361,308.15
2	2	Accolate®	$9,317.51	$10,660.07	102	48	0%	$3.02	($1,342.56)
3	3	Zyflo CR®	$5,957.80	$5,732.65	22	9	0%	$9.72	$225.15
7	5	**Antipsychotics - Benzisoxazoles**	$3,427,939.25	$4,570,005.29	14,466	5,631	75%	$7.68	($1,142,066.04)
1	1	Risperdone	$2,013,075.03	$3,152,864.29	11,699	4,653	93%	$5.51	($1,139,789.26)
2	2	Invega®	$887,017.86	$889,190.17	1,997	903	0%	$13.80	($2,172.31)
3	3	Risperdal® Injection	$527,846.36	$527,950.83	770	226	0%	$31.18	($104.47)
8	N/A	**Biologicals - Monoclonal Antibodies**	$3,269,812.67	N/A	2,117	707	0%	$53.66	N/A
1	N/A	Synagis®	$3,269,812.67	N/A	2,117	707	0%	$53.66	N/A
9	8	**Analgesics - Narcotic Agonists**	$3,042,370.06	$3,000,961.57	23,979	9,850	83%	$5.71	$41,408.49
1	1	Oxycodone	$2,070,022.38	$1,991,390.59	6,557	1,867	51%	$11.28	$78,631.79
2	2	Fentanyl	$342,610.91	$357,616.39	1,735	657	99%	$6.87	($15,005.48)
3	3	Morphone Sulfate	$211,048.28	$202,256.03	2,861	1,002	90%	$2.73	$8,792.25
4	4	Opana®	$126,668.69	$147,864.95	314	105	0%	$14.40	($21,196.26)
5	5	Tramadol	$108,553.45	$100,205.84	9,908	5,930	99%	$0.68	$8,347.61
10	11	**ADHD - Amphetamines**	$2,571,772.72	$2,097,185.44	23,197	9,307	22%	$3.72	$474,587.28
1	1	Amphetamine	$1,498,543.54	$1,288,529.47	14,254	5,722	32%	$3.53	$210,014.07
2	2	Vyvanse®	$1,059,551.94	$797,765.18	8,688	3,785	0%	$4.11	$261,786.76
3	3	Dextroamphetamine	$11,672.36	$9,095.40	250	98	99%	$1.52	$2,576.96
4	4	Desoxyn®	$2,004.88	$985.39	5	2	0%	$13.37	$1,019.49

Top 25 Drugs by Total Reimbursement

Second Quarter Fiscal Year 2009

Rank 2nd Qtr FY09	Rank 1st Qtr FY09	Product Name	Therapeutic Class	Total Cost 2nd Qtr FY09	Total Cost 1st Qtr FY09	Total Claims	Total Members	Cost / Day	Change in Total Cost
1	1	Abilify®	Antipsychotics - Quinolinone Derivatives	$5,067,371	$4,438,661	10,599	4,773	$15.17	$628,711
2	2	Singulair®	Antiasthmatics - Leukotriene Modulators	$4,217,463	$3,853,127	38,015	22,054	$3.71	$364,335
3	3	Seroquel®	Antipsychotics - Dibenzodiazepines	$3,829,248	$3,835,082	11,677	4,552	$10.45	($5,834)
4	N/A	Synagis®	Biologicals - Monoclonal Antibodies	$3,269,813	N/A	2,117	707	$53.66	N/A
5	5	Novoseven®	Misc. Hematological - Antihemophilic	$2,899,782	$2,419,764	20	5	$6,249.53	$480,018
6	6	Zyprexa®	Antipsychotics - Dibenzodiazepines	$2,099,298	$2,057,700	3,482	1,356	$18.53	$41,598
7	7	Oxycodone	Analgesics - Narcotic Agonists	$2,070,022	$1,988,871	6,557	1,867	$11.28	$81,151
8	4	Risperdone	Antipsychotics - Benzisoxazoles	$2,013,075	$3,152,864	11,699	4,653	$5.51	($1,139,789)
9	8	Advair®	Antiasthmatics - Beta Adrenergics	$1,958,733	$1,823,784	10,079	6,272	$6.41	$134,949
10	17	Albuterol Products	Antiasthmatics - Beta Adrenergics	$1,712,010	$1,210,070	46,966	30,533	$1.78	$501,940
11	18	Pulmicort®	Antiasthmatics - Steroid Inhalants	$1,643,741	$1,202,358	6,657	4,485	$9.22	$441,384
12	10	Antihemophilic Factor	Misc. Hematological - Antihemophilic	$1,550,009	$1,441,659	92	27	$870.79	$108,351
13	11	Methylphenidate	ADHD - Miscellaneous	$1,535,853	$1,414,092	15,257	6,305	$3.36	$121,761
14	15	Amphetamine	ADHD - Amphetamines	$1,498,544	$1,288,389	14,254	5,722	$3.53	$210,154
15	12	Prevacid®	Ulcer Drugs - Proton Pump Inhibitors	$1,467,416	$1,405,174	9,166	4,651	$5.42	$62,242
16	13	Topamax®	Anticonvulsants - Miscellaneous	$1,462,479	$1,372,324	4,583	1,960	$10.45	$90,154
17	14	Lamotrigine	Anticonvulsants - Miscellaneous	$1,277,871	$1,371,401	5,191	2,036	$7.99	($93,530)
18	19	Keppra®	Anticonvulsants - Miscellaneous	$1,062,346	$1,045,417	3,688	1,436	$9.97	$16,929
19	26	Vyvanse®	ADHD - Amphetamines	$1,059,552	$797,765	8,688	3,785	$4.11	$261,787
20	20	Geodon®	Antipsychotics - Miscellaneous	$1,039,246	$969,209	2,961	1,234	$11.25	$70,037
21	9	Feiba®	Misc. Hematological - Antihemophilic	$1,038,129	$1,471,150	17	3	$2,916.09	($433,021)
22	28	Azythromycin	Anti-infectives - Azythromycin	$980,714	$701,709	41,259	35,630	$4.72	$279,006
23	16	Divalproex	Anticonvulsants - Valproic Acid	$907,824	$1,230,632	8,538	3,292	$3.53	($322,808)
24	23	Lipitor®	Antihyperlipidemic - HMG CoA	$887,787	$863,470	5,762	3,124	$3.70	$24,316
25	22	Invega®	Antipsychotics - Benzisoxazoles	$887,018	$889,190	1,997	903	$13.80	($2,172)

Appendix J

Information for Healthcare Professionals
Zonisamide (marketed as Zonegran, and generics)

FDA ALERT [February 23, 2009]: Following a review of updated clinical data, the FDA has determined that treatment with zonisamide can cause metabolic acidosis in some patients. Zonisamide is indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy.

Metabolic acidosis is a disturbance in the body's acid-base balance that results in excessive acidity of the blood. Metabolic acidosis is diagnosed by laboratory tests measuring the serum bicarbonate level in the blood to determine the presence and severity of metabolic acidosis.

Metabolic acidosis can result in hyperventilation, and non-specific symptoms such as fatigue and anorexia, or more severe symptoms including cardiac arrhythmias or stupor. Chronic metabolic acidosis can have adverse effects on the kidneys and on bones, and can retard growth in children. Patients with predisposing conditions or therapies, including renal disease, severe respiratory disorders, diarrhea, surgery, ketogenic diet, or certain other drugs may be at greater risk for developing metabolic acidosis following treatment with zonisamide. The risk of zonisamide-induced metabolic acidosis appears to be more frequent and severe in younger patients.

The FDA recommends that healthcare professionals measure serum bicarbonate before starting treatment and periodically during treatment with zonisamide, even in the absence of symptoms. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing zonisamide (using dose tapering), and modifying the patient's antiepileptic treatment as appropriate. If the decision is made to continue patients with metabolic acidosis on zonisamide, then alkali treatment should be considered.

The FDA is working with the makers of zonisamide to revise the product labeling to reflect this new safety information.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug,

please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

Recommendations and Information for Healthcare Providers to consider when prescribing zonisamide (marketed as Zonegran) and generics:

- Zonisamide can cause metabolic acidosis, characterized by hyperchloremia and decreased serum bicarbonate. Metabolic acidosis is often asymptomatic.
- Generally, zonisamide-induced metabolic acidosis occurs early in treatment, but may occur at any time during treatment.
- The risk of development of zonisamide-induced metabolic acidosis appears to be greater at higher doses of zonisamide, but can occur with doses as low as 25 mg daily.
- Conditions or therapies that may predispose patients to acidosis include renal disease, severe respiratory disorders, diarrhea, surgery, ketogenic diet, or other drugs (e.g. acetazolamide)
- Younger patients may be at risk for zonisamide-induced metabolic acidosis. Data from one pediatric clinical trial shows a higher incidence of metabolic acidosis compared to data from trials of zonisamide in adults.
- Signs and symptoms of persistent metabolic acidosis may include hyperventilation, fatigue and anorexia. More severe symptoms may include cardiac arrhythmias and stupor.
- Chronic, untreated metabolic acidosis may increase the risk for kidney stones, nephrocalcinosis, and bone abnormalities (e.g., osteoporosis, osteomalacia, and rickets in pediatric patients) with an increased risk for fractures.
- Chronic metabolic acidosis in pediatric patients can reduce growth rates, resulting in a reduction in the maximal height achieved. The specific effects of zonisamide on growth and bone have not been investigated.
- Although the effects of metabolic acidosis from zonisamide on the fetus are not clearly known, metabolic acidosis in pregnancy (due to other causes) may affect fetal development (i.e., decreased fetal growth, decreased fetal oxygenation and fetal death) and the ability of the fetus to tolerate labor. In addition, significant amounts of zonisamide can appear in the breast milk of nursing women taking zonisamide, and the effects of this exposure on the infant from metabolic acidosis, or any other cause, are unknown.
- A pre-treatment (baseline) and periodic measurements of serum bicarbonate are recommended during zonisamide treatment. In addition, if signs or symptoms of metabolic acidosis are observed, serum bicarbonate should be measured.
- If metabolic acidosis develops and persists, consideration should be given to reducing the dose of zonisamide, or to discontinuing zonisamide using dose tapering and

modifying the patient's treatment as appropriate. If the decision is made to continue patients with persistent acidosis on zonisamide, then alkali treatment should be considered.

Information for Patients to consider if they are taking zonisamide (marketed as Zonegran) and generics:

Zonisamide may cause a condition known as metabolic acidosis. Metabolic acidosis is a decrease in serum bicarbonate, a blood chemical, to below the normal range. Serum bicarbonate is a chemical that helps the body keep acid and base in balance. Your doctor may order a blood test to measure serum bicarbonate levels in your blood.

- Generally, zonisamide-induced metabolic acidosis occurs early in treatment, but it can develop at any time during treatment.

- Some symptoms of metabolic acidosis are breathing fast (hyperventilation), fatigue, and loss of appetite. More severe symptoms include an irregular heart beat or unconsciousness.

- Chronic, untreated, metabolic acidosis may increase the risk of kidney stones and the risk of different types of bone diseases which may increase the risk for a bone fracture. Metabolic acidosis in pregnancy may negatively affect fetal development. In addition, zonisamide can appear in the breast milk of nursing women taking zonisamide, and the effects of this exposure on the infant are unknown.

- Talk to your doctor about any medical conditions you have or medicines you may be taking since these could make metabolic acidosis worse. These are conditions such as kidney disease, severe lung disorders, diarrhea, surgery, certain kinds of diets, or other drugs (e.g. acetazolamide). Tell you doctor if you are pregnant or nursing or if you are planning to become pregnant.

- Although not approved by the FDA, zonisamide is sometimes used in children. Metabolic acidosis increases the risk for slowed growth in children and could reduce the overall height that they achieve.

Data Summary

Zonisamide is an antiepileptic drug that is approved as adjunctive therapy for the treatment of partial seizures in adults with epilepsy.

Following a review of updated clinical data, the FDA has determined that treatment with zonisamide can cause metabolic acidosis in some patients.

The development of metabolic acidosis generally appears to be dose-dependent and can occur at doses as low as 25 mg daily. The zonisamide-related decreases in serum bicarbonate are usually mild to-moderate (average decrease of about 2 mEq/L) in adult patients treated with various doses of zonisamide. However, some adult patients have experienced severe serum bicarbonate decreases as much as 10 mEq/L below their baseline. Conditions or therapies that predispose patients to developing acidosis (such as renal disease, severe respiratory disorders, diarrhea, surgery, ketogenic diet, or other medications) may worsen the bicarbonate-lowering effects of zonisamide.

The pivotal, placebo-controlled trials supporting the approval of zonisamide as adjunctive epilepsy treatment in adults did not collect serum bicarbonate data.

Zonisamide is not approved for the treatment of epilepsy in pediatric patients, as monotherapy treatment of epilepsy in adults, or for migraine prophylaxis in adults. However, serum bicarbonate data have been collected in various clinical development programs for these off-label indications. These data show that zonisamide treatment can cause metabolic acidosis in these patients.

The pediatric program consisted primarily of a large open-label, uncontrolled, adjunctive treatment trial of patients aged 3-16 years with partial epilepsy. In that trial, the incidence of a persistent decrease in serum bicarbonate to levels less than 20 mEq/L was up to 90% and generally increased with higher doses. The incidence of a persistent markedly abnormally low serum bicarbonate value (less than 17 mEq/L and more than 5 mEq/L decrease from a pretreatment value of at least 20 mEq/L) was as high as 18% and appeared to increase with higher doses.

In placebo-controlled studies of zonisamide monotherapy in adults with epilepsy or as prophylaxis for migraine in adults, the incidence of a persistent treatment-emergent decrease in serum bicarbonate (to <20 mEq/L) ranged from 21% in patients treated with a 25 mg daily dose to 43% in patients treated with a 300 mg daily dose. The incidence of persistent abnormally low serum bicarbonate was 2% or less across all doses evaluated.

The relatively high frequencies of varying severities of metabolic acidosis observed in pediatric patients (compared to the frequency and severity of metabolic acidosis observed in adults) suggest that pediatric patients may be more at risk than adults to developing metabolic acidosis.

The FDA urges both healthcare professionals and patients to report side effects from the use of zonisamide (marketed as Zonegran) and its generics to the FDA's MedWatch Adverse Event Reporting program available:

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

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Date created: February 23, 2009

FDA Public Health Advisory
Updated Safety Information about Raptiva (efalizumab)

Since the approval of Raptiva (efalizumab) in October 2003, the FDA has received reports of three confirmed cases and one possible case of progressive multifocal leukoencephalopathy (PML) in patients who were 47 to 73 years of age who were using Raptiva for the treatment of moderate to severe plaque psoriasis. Two of the patients with confirmed PML and one patient with possible PML died. All four patients were treated with Raptiva continuously for more than three years. None of the patients were receiving other treatments that suppress the immune system while taking Raptiva.

PML is a rare, serious, progressive neurologic disease caused by a virus that affects the central nervous system. When PML occurs, it is usually in people whose immune systems have been severely weakened and often results in an irreversible decline in neurologic function and death. There is no known effective treatment for PML.

Raptiva works by affecting T-cells in the immune system. The effects of Raptiva also decrease the function of the immune system and increase susceptibility to infections.

Raptiva was approved for the treatment of moderate to severe plaque psoriasis in 2003. There were no cases of PML seen in the clinical trials that supported the approval of Raptiva. At the time of approval, a total of 2,764 patients had been treated with Raptiva. Of those 2,764 patients, 2400 had been treated for three months, 904 for six months, and 218 for one year or more.

In October 2008, the labeling for Raptiva was changed to highlight, in a Boxed Warning, the risks of life-threatening infections, including PML. In addition, FDA directed Genentech, the manufacturer of Raptiva, to develop a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that patients receive risk information about Raptiva.

The FDA is reviewing this latest information. The agency will take appropriate steps to ensure that the risks of Raptiva do not outweigh its benefits, that patients prescribed Raptiva are clearly informed of the signs and symptoms of PML, and that health care professionals carefully monitor patients for the possible development of PML.

Healthcare providers should, in the interim, be aware of the following information and advice:

- Raptiva increases the risk of PML. Longer, continuous use may further increase this risk.
- Inform patients using Raptiva of the potential risk of developing PML.
- There are no known screening tests that can reliably predict PML or medical interventions that can prevent or treat this disease.
- Monitor patients being treated with Raptiva for the onset of neurologic symptoms. Discontinue Raptiva if PML is suspected.
- Patients treated with Raptiva should be periodically re-evaluated to ensure that the benefit of treatment continues to outweigh the risks. Consideration should be given to use of other approved therapies to control the patients' psoriasis.
- The effects of periodic or intermittent use of Raptiva, or the concomitant use of other immunosuppressant drugs on the risk for PML is not known.

Patients using Raptiva should:

- Be aware that Raptiva increases the risk of developing PML. PML is a disease that is fatal or causes severe disability.
- Talk with their healthcare provider about the benefits and risks of treatment with Raptiva.
- Be aware of the symptoms of PML which may include unusual weakness, loss of coordination, changes in vision, difficulty speaking and sometimes personality changes.
- Contact their healthcare provider immediately if they experience these symptoms.
- Understand that there are no laboratory screening tests for PML or medical interventions that can prevent or treat PML

The FDA asks health care providers and patients to report possible cases of PML to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at http://www.fda.gov/medwatch/index.html.

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PDF requires the free Adobe Acrobat Reader

Date created: February 19, 2009

FDA to Meet with Drug Companies about REMS for Certain Opioid Drugs

On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. (Opioid REMS Meeting Invitation Template; Opioids Products Chart. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks.

Opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients. Opioid drugs have serious risks when used improperly. The FDA, drug manufacturers, and others have taken a number of steps in the past to prevent misuse, abuse and accidental overdose of these drugs, including providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients. Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade. The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access.

The FDA recognizes the need to achieve balance between appropriate access and risk mitigation, and believes an effective strategy would benefit from input from industry, patient advocacy groups, the pain and addiction treatment communities, the general public, and other stakeholders.

In the first of a series of meetings with stakeholders, the FDA has invited those companies that market the affected opioid drugs to a meeting with the agency on March 3 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. FDA is planning a public meeting in late spring or early summer to allow for broader public input and participation. Through this process, FDA hopes to gain valuable

information that will lead to practical and effective solutions for development of a REMS and for appropriate use of these opioid drug products. For information about REMS see: Public Law 110-85.

- Opioid REMS Meeting Invitation Template
- Opioids Products Chart

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PDF requires the free Adobe Acrobat Reader

Date created: February 9, 2009

News Release
FOR IMMEDIATE RELEASE
February 11, 2009
DEA Public Affairs
Number: 202-307-7977

DEA Launches New Educational Website for Parents

FEB 11 -- (WASHINGTON, DC) – Today the Drug Enforcement Administration (DEA) announced its new educational website for parents, www.GetSmartAboutDrugs.com. The website was developed to be a resource for parents and caregivers to help them identify drug abuse, prevent children from using drugs, and find resources for substance abuse prevention. The site is designed to speak to parents and caregivers of middle-school, high-school, and college-aged children in an informative and non-technical manner.

The website was introduced at the annual National Leadership Forum of one of the DEA's partner organizations, the Community Anti-Drugs Coalition of America (CADCA) in National Harbor, Maryland. Speaking to forum participants, "DEA wants to share our knowledge about drugs with parents, teachers, and all those who care about keeping our children safe," said Acting Administrator Michele M. Leonhart. "In this fight, information is power, and DEA's new website has current, accurate, and practical information about how to spot signs of abuse, identify drugs and paraphernalia , and how to talk to teens about drugs. With just a few clicks, parents will be confident and ready to help their kids resist drugs."

The parent website is a follow-up to DEA's highly popular site for teens, www.JustThinkTwice.com. Educated and involved parents are an important part of the solution to the problem of drug abuse in America. But the Partnership for a Drug-Free America's 2007 Partnership Attitude Tracking Survey found that a majority of parents of middle school children (51%) report they need more tools and information to help their kids deal with drugs and alcohol.

Having the facts about drug use by kids today is important, because:

- Today's kids are more likely to begin abusing drugs with prescription and over-the-counter drugs like Vicodin and Xanax than with marijuana. Users of www.GetSmartAboutDrugs.com will learn that parents and family members are the main source of these drugs for kids.
- Among children as young as 11, inhaling the fumes from common household products to get high is popular and can be fatal even for first time users. Parents can use a visual glossary to discover the hidden dangers in your home.
- Being caught in possession of illegal drugs can prohibit a young person from qualifying for federal college loans. Parents can find out about the legal, health, financial and social consequences of drug abuse.

DEA is the nation's authoritative source on current drug trends. Because of the investigations it conducts and the seizures it makes, DEA has real-time, localized information about what drugs can be found in America's neighborhoods. Because its regional laboratories regularly keep DEA apprised of what the labs receive, DEA can provide the public with accurate details about substances. This information is put to use in this website's visual glossary, which contains searchable drug and paraphernalia information, photos and descriptions. If a parent finds an unknown substance in a child's room or car, he or she can identify the substance by searching the glossary's entries for powders, leaves, liquids or other characteristics.

DEA's www.GetSmartAboutDrugs.com was designed and built and is hosted by Rock Creek Strategic Marketing (RCSM) of Chevy Chase, Maryland, who worked closely with the DEA to strategize, design and develop a site that was more than just a series of web pages but instead was an experience that was relevant, easy-to-use, accessible, and most importantly, engaging for the target audience. The overall look of the site was designed to communicate the

seriousness of the topic area while softening the overall visual experience to help communicate on a more personal level with parents and caregivers. Says Scott Johnson, Co-Founder and Principal of RCSM, "Important Government technology initiatives such as this must be carefully branded and deliver a superior user experience to be fully successful. It is the lack of these that often causes worthy government programs to be unrecognized and underutilized. As a parent, this site speaks to me, and effectively delivers the information, resources and encouragement that I need as I fight to keep my own kids free from drugs."

In support of the www.GetSmartAboutDrugs.com website, DEA has released a 47-page booklet, *Prescription for Disaster: How Teens Abuse Medicine*, which focuses on the dangers of prescription drugs. This reference tool includes, like the website, a photo glossy of many kinds of drugs, along with details about their forms, effects and sources. It also includes basic information about prescription and over-the-counter medicines and ideas for what parents can do to educate their children about the dangers of drugs.

Copies of the booklet can be downloaded from www.GetSmartAboutDrugs.com or obtained by contacting DEA's office of Demand Reduction.

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