Drug Utilization Review Board

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

Wednesday
September 9, 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 – September 10, 2009**

DATE: September 3, 2009

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

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

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

30 Day Notice to Prior Authorize Fibromyalgia Medications – See Appendix C.

30 Day Notice to Prior Authorize to Otic Anti-Infectives – See Appendix D.

Action Item – Annual Review of Anti-Ulcer Product Based Prior Authorization Category – See Appendix E.

Action Item – Annual Review of Narcotic Analgesic Product Based Prior Authorization Category and 30 Day Notice to Prior Authorize Onsolis™, Nucynta™, Zamicet™, and Embeda™ – See Appendix F.

Action Item – Annual Review of Synagis Prior Authorization – See Appendix G.

FDA and DEA Updates – See Appendix H.

Future Business

Adjournment

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Drug Utilization Review Board

(DUR Board)

Meeting – September 9, 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. Muchmore, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. Muchmore, Chairman:

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

A. August 12, 2009 DUR Minutes – Vote
B. August 13, 2009 DUR Recommendation Memorandum
C. Provider Correspondence

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

4. Update on DUR / Medication Coverage Authorization Unit – See Appendix B.

A. Retrospective Drug Utilization Review for May 2009
B. Retrospective Drug Utilization Review Response for April 2009
C. Medication Coverage Activity Audit for August 2009
D. Help Desk Activity Audit for August 2009

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

5. 30 Day Notice to Prior Authorize Fibromyalgia Medications – See Appendix C.

A. COP Recommendations
B. Fibromyalgia Treatment

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

6. 30 Day Notice to Prior Authorize Otic Anti-Infectives – See Appendix D.

A. COP Recommendations

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

7. Action Item – Annual Review of Anti-Ulcer Product Based Prior Authorization Category – See Appendix E.

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

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

8. Action Item – Annual Review of Narcotic Analgesic Product Based Prior Authorization Category and 30 Day Notice to Prior Authorize Onsolis™, Nucynta™, Zamicet™, and Embeda™ – See Appendix F.

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

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

9. Action Item – Annual Review of Synagis Prior Authorization – See Appendix G.

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

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

10. FDA and DEA Updates – See Appendix H.

11. Future Business

A. Pediculicides Annual Review
B. Anxiolytic Criteria Review
C. New Product Reviews
D. Annual Reviews

12. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of AUGUST 12, 2009

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.	X	
Anetta Harrell, Pharm.D.	X	
Evelyn Knisely, Pharm.D.		X
Thomas Kuhls, M.D.		X
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.	X	
Bruna Varalli-Claypool, PA-C, B.A.		X
Eric Winegardener, 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, M.S.; 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 Student(s): Blake Fitzpatrick, Khang Truong	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:

David Williams, Forest Pharm.	Sam Smothers, MedImmune	Patty Haywood, MedImmune
Jim Dunlap, Eli Lilly	Carlos Palasciano, Hawthorn	Mark DeClerk, Lilly
Jim Fowler, AstraZeneca	Darryl Davis, Pfizer	Richard Ponder, Johnson & Johnson
Mario Munoz, Lilly USA	Kelly Rogers, Taro	Lana Stewart, Merck
Brian Shank, Pfizer	Bryan Dillon, BMS	Jim Turner, Astellas
Mike Presley, Forest Pharm	Curt McAllister, Pfizer	

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 8	Elson Kim, Forest Labs Inc.
Agenda Item No. 8	Brian Maves, Pfizer

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

1A: Roll Call

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

ACTION: NONE REQUIRED

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

Dr. Muchmore recognized the speakers for public comment:

For Agenda Item No. 8; Elson Kim, Forest Labs Inc. and Brian Maves, Pfizer

ACTION: NONE REQUIRED

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

3A: July 8, 2009 DUR Minutes

Correction, page 1 of minutes: Dr. James Rhymer was present for the meeting of July 8, 2009.

Dr. Preslar moved to approve as corrected; seconded by Dr. Winegardener.

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review: April 2009

4B: Retrospective Drug Utilization Review Response: March 2009

4C: Medication Coverage Activity Audit: July 2009

4D: Help Desk Activity Audit: July 2009

4E: Medication Therapy Management Services Activity Audit: FY2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE GELNIQUE™ AND UPDATE BLADDER CONTROL PRODUCT BASED PRIOR AUTHORIZATION CATEGORY**

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO APPLY QUANTITY RESTRICTIONS TO HYDROCODONE PRODUCTS**

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

Dr. Winegardener moved to amend the recommendations submitted, deleting tablets per day quantity limit; seconded by Dr. Feightner.

ACTION: MOTION CARRIED

PRESENTED OUT OF ORDER:

AGENDA ITEM NO. 9: **SOONERCARE PROGRAM OVERVIEW**

Presented by Dr. Nesser.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **60-DAY NOTICE TO PRIOR AUTHORIZE OTIC ANTI-INFECTIVE PRODUCTS**

Materials included in agenda packet; presented by Drs. Keast and Chonlahan.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: **60-DAY NOTICE TO PRIOR AUTHORIZE FIBROMYALGIA PRODUCTS**

For Public Comment: Elson Kim: Good afternoon. My name is Elson Kim. I am a Doctor of Pharmacy representing Forest Laboratory and I thank you for the opportunity to speak with you today on fibromyalgia and Milnacipran, brand name Savella. Fibromyalgia affects 2 to 4% of the population with a prevalence higher in women and increasing with age. Roughly 3% of the population in the fourth decade have fibromyalgia, which increases to greater than 7% after the seventh decade. It drops off from there in a reverse j-curve. Ninety-eight percent of patients with fibromyalgia present with widespread pain and tender points and 75% or more will additionally have comorbid symptoms of fatigue, morning stiffness, and sleep disturbance as well as cognitive impairment, categories often overlooked in treatment criteria. Persistent or intense stimuli can lead to abnormal changes in the spinal cord and brain. This results in increased sensitivity and an exaggerated response to both non-painful and painful stimuli that are characteristics of abnormal central processing. This mechanism represents a pathological hallmark of fibromyalgia and many other chronic pain syndromes, including irritable bowel, temporomandibular disorder, migraine and low back pain. Chronic fatigue syndrome, irritable bowel and migraine tension headaches often overlap fibromyalgia symptoms as frequently as 80% of the time; whereas minority subgroups may have physiological and psychological disturbances 30 to 40% of the time. A peer reviewed publication and a recent metanalysis has shown that SSRI's and TCA's have limited clinical benefit in fibromyalgia. Newer, more specific SNRI's showed increased clinical efficacy and emerging animal evidence suggest that SNRI's with a preference for norepinephrine reuptake reaction play a more important role in chronic pain states. Milnacipran is reported to inhibit norepinephrine reuptake with an approximate threefold higher potency over serotonin. Milnacipran is less likely to have a drug-to-drug interaction pharmacokinetically, because it has low protein binding, negligible effect on P450 and is primarily excreted unchanged through the kidneys, an important issue, as fibromyalgia patients typically are on multiple medication. In two pivotal trials, Milnacipran demonstrated simultaneous and significant improvement in three key outcomes in fibromyalgia and have the tolerable side effect profile and appears to offer a number of additional unique treatment attributes in comparison to other FDA approved and non-FDA approved fibromyalgia medication. These two trials incorporated recommendations formulated to identify in red the chief symptoms using a composite responder approach. As such, to qualify as a composite responder in these studies, patients were required to achieve clinically meaningful improvements in pain, their own personal impression of change and improvements in physical function. These these three hurdles demanded simultaneous improvement within a single patient. Results show that both a 100 and 200 mg doses were statistically significantly superior to placebo with approximately one-third of all 1,400 Milnacipran patients meeting this rigorous composite responder criteria for up to six months. We have one year data as well. In regards to safety, Milnacipran is safe, well tolerated and weight neutal, an important factor to these already vulnerable patients who suffer from weight issues when a number of other medications commonly used to treat fibromyalgia and compound this problem. In both studies, roughly 25% of Milnacipran patients versus 12% on placebo prematurely discontinue due to adverse reactions. But the most common discontinuation reason is nausea, palpitations and headache. As usual, I'm here to answer any questions you may have. Thank you very much.

For Public Comment: Brian Maves: Good evening. I'm Brian Maves, clinical pharmacist from Pfizer Pharmaceutical. I'm going to paraphrase and kind of change the status. I know it's the preference of this Board to have a physician or a patient advocate present to you and to that end, we had hoped to have Dr. Kaplan here. Unfortunately he had to give a deposition and so he is unable to present his side. We also have a letter from Dr. Douglas, Dr. John Nelson, too, from Advanced Pain Management of Oklahoma. Dr. Kaplan is a neurologist from Oklahoma City here. Both individuals wanted to express their concern on this issue, not as far as drug selection, but as far as that they thought it was a dangerous precedent to have a physician or a provider go through a non-FDA approved medication to get to an FDA-approved medication; in this instance of fibromyalgia. And so in support of this, they expressed their concern and I also have supporting evidence from both the Oklahoma Pharmacists Association, Dr. Phil Woodward, and then our own State Attorney General, Drew Edmondson, in a memo dated the 17th of March 2009. Here he states "Just as it is inappropriate for pharmaceutical companies to market drugs for off-label uses, it is equally inappropriate for health insurance companies to refuse to reimburse for physician prescribed medications unless a patient first undergoes treatment with drugs that are off label." As a pharmacist myself, practicing for 29 years, 20 of that within the United States Army and then another nine years here with Pfizer, it is a precedence I think we really need to take a look at for this population as this doctor here explained is difficult to treat and requires access to the best and the latest FDA-approved medications available to treat this condition. With that, I do have these letters available. I can leave them with Mr. Graham if need be and I thank the Board for your time.

Dr. Winegardener: Do we have studies to show that the FDA-approved items are more effective than the non-FDA approved items?

Dr. Maves: That's a dilemma that I think a lot of physicians are looking at as far as where are the guidelines, the current guidelines to treat fibromyalgia. It's a difficult diagnosis and it's a, it requires both a behavioral, I think, component as well as a medical component, and the FDA though, did do a regular, those drugs that are currently approved, Cymbalta, Savella and Lyrica, did go through rigorous testing to prove, you know, pain control and treatment of fibromyalgia based upon tender points and some of the currently available guidelines. You're not going to, I think it's unfortunate that Amitriptyline, which is one of the drugs I know that you're looking at generically, is probably never going to go through, you know, that testing, to get approval for this; but it's our state, we just didn't feel as a company, that individuals should have to go through first a non-FDA approved drug to get to drugs that are currently FDA-approved for this indication. Did that answer your question?

Dr. Winegardener: Well, it did, but I might point out that when I go to the dentist and get a tooth pulled, many times I'll get a prescription for a non-FDA approved pain medication called Tylenol with Codeine No. 3 and we all know that that works. I guess I, I'm not trying to be argumentative. I just, I just want to know, I mean, we need to have enough data for us to see that these are truly going to be better options than the older options that are non-FDA approved. That's, I guess it's a statement rather than a question.

Dr. Maves: The data that I would submit, sir, the data that proves that is the data that actually brought those drugs before the Food and Drug Administration to earn that label to treat fibromyalgia. Up into herefore, you know a conglomerate of disease entities, pain, tender points, you know, different symptoms.
Materials included in agenda packet; presented by Drs. Keast and Patel.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **SOONERCARE PROGRAM OVERVIEW**
See above.

AGENDA ITEM NO. 10: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **FUTURE BUSINESS**
Materials included in agenda packet; submitted by Dr. Graham.
11A: Synagis Annual Review
11B: Anxiolytic Criteria Review
11C: New Product Reviews
11D: Annual Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ADJOURNMENT**
The meeting was adjourned at 7:55 p.m.

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

Memorandum

Date: August 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 August 12, 2009

Recommendation 1: Vote to Prior Authorize Gelnique™ and Update the Bladder Control PBPA Category

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends immediate placement of Gelnique™ into Tier 2 of the current Bladder Control PBPA Category. The College of Pharmacy also recommends a 3 tiered system for this category to be effective January of 2010. The College recommends product placement in Tier 1 and Tier 3 as shown below, in which Tier 3 products may rebate down to Tier 2. The following criteria will apply.

Tier 2 Authorization Criteria:

1. Trial of one Tier 1 medication that yielded inadequate clinical response or adverse effects, or
2. A unique indication which the Tier 1 drugs lack.

Tier 3 Authorization Criteria:

1. Trial of all Tier 2 medications that yielded inadequate clinical response or adverse effects, or

2. A unique indication which the Tier 2 drugs lack.

The College also recommends grandfathering of medications in this category.

Bladder Control Medications		
Tier 1	***Tier 2***	***Tier 3***
Flavoxate **(Urispas®)** Oxybutynin **(Ditropan®)** Tolterodine **(Detrol®)**	Supplemental Rebated Tier 3	Trospium **(Sanctura™, Sanctura XR™)** Oxybutynin ER Tabs **(Ditropan XL®)** Oxybutynin Patch **(Oxytrol®)** Oxybutynin Gel **(Gelnique™)** Tolterodine ER Tabs **(Detrol LA®)** Darifenacin **(Enablex®)** Solifenacin **(VESIcare®)** Fesoterodine **(Toviaz™)**

*Hyoscyamine can be used as adjuvant therapy only. By itself, it will not count as a Tier 1 trial.

Recommendation 2: Vote to Apply Quantity Restrictions to Hydrocodone Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following restrictions be applied to hydrocodone/APAP combination products.

1. Retain Ingredient Duplication Module.
2. Establish a new quantity limit for a maximum of ~~6 tablets per day or~~ 3,250 mg of APAP per day~~, whichever is less~~.
3. Establish an annual claim limit of 12 per 365 days.

Approval Criteria for Greater than 12 Claims:

1. Members may be approved for greater than 12 claims per year if the member has a pain contract with a single prescriber. A copy of the pain contract should be submitted with the prior authorization request. Requests outside of the plan outlined in the contract will not be approved.
2. Members with a current oncology related diagnosis may be approved for greater than 12 claims per year if the medication is being used as a break-through therapy and adjustments to dosing are required.
3. Medication will not be approved as the only therapy for chronic pain use. Members with chronic pain who require around-the-clock pain control should be on a long-acting pain medication. An additional claim may be approved to allow time for changes in therapy to be made.

Douglas W. Kaplan, MD
Neurology

Diagnosis & Treatment For Diseases Of The Brain, Spine & Peripheral Nerves
- *Electromyography*
- *Electroencephalography*

4120 West Memorial Road Suite 204
Oklahoma City, OK 73120
Tel (405) 749 - 4270
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August 10, 2009

Oklahoma State Medicaid Board Drug Utilization

Dear Sirs,

My name is Dr. Douglas W. Kaplan and I am a neurologist in private practice in Oklahoma City. I am writing this letter on behalf of my patients who have fibromyalgia. There are several drugs that are FDA approved for fibromyalgia and Lyrica is one of them. I have used this drug in my clinical practice with good results. Patients with fibromyalgia have had their pain symptoms improved with good long-term efficacy. They typically have fewer side-effects with Lyrica than other medications previously prescribed for this condition.

The fact that this drug is effective and FDA approved for fibromyalgia makes it my first choice for my patients.

I hope you take this into consideration on when deciding on drug utilization protocol.

Sincerely,

Douglas W. Kaplan, M.D.

DWK/ygf

Advanced Pain Management of Oklahoma, PC

Dr. John Nelson, M.D.

8/12/09

TO WHOM IT MAY CONCERN,

I HAD HOPED TO ATTEND TODAYS HEARING BUT MY SCHEDULE WOULD NOT ALLOW - THE ONLY TWO MEDICATIONS OFFICIALLY approved for the treatment of Fibromyalgia are Lyrica + Cymbalta - the use of Neurontin, Elavil, etc are OFF Label and have not Met the clinical trial Evidence of efficacy for Lyrica + Cymbalta. It makes No medical sense to have to use off-Label drugs with inferior effectiveness when proven - effective drugs that are FDA approved + specifically indicated are available.

Sincerely -

John W. Nelson

P.O. Box 271435 Oklahoma City, Oklahoma 73137

Phone (405) 702-8623 • Fax (405) 702-8628 • ADVANCEDPM@COXINET.NET

Link to AG Letter: http://www.oag.state.ok.us/oagweb.nsf/0/C39B3AE6DE7444DA8625757B00603FC8?OpenDocument

Link to APF Postition Statement: http://www.painfoundation.org/newsroom/position-statements/step-therapy-therapeutic-switching.html

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From: Orvie [mailto:oprewitt@ncfsfa.org]
Sent: Wednesday, August 12, 2009 4:54 PM
To: Nancy Nesser
Subject: Statement for Oklahoma Drug Utilization Review Board Meeting Tonight

Statement for the Oklahoma Drug Utilization Review (DUR) Board Meeting
August 12, 2009
Oklahoma Health Care Authority, Oklahoma City, OK

I deal daily with chronic pain and advocate for millions of others. In Oklahoma alone, 2% to 4% of the population, between 72,847 and 145,694 people deal daily with the chronic pain of fibromyalgia.

Oklahomans health and well-being will be compromised if a 60 day notice to prior authorize fibromyalgia products is utilized. Often this process, known as step therapy includes another component known as therapeutic-switching, both implemented by insurance companies.

Step therapies over-ride the treating physician's prescription authority. The physician, who knows the patient's health history and has examined the patient decides, along with the patient, the most appropriate treatment plan. Insurance companies, however, often refuse to pay for the physician's recommended medications/therapies. Instead, they routinely require alternate medications/therapies they decide upon, require patients to use those, and have documented failure, before they will even consider paying for the original medications/therapies the physician ordered. Months can pass utilizing step therapies. Insurance companies do this without ever examining the patient.

Therapeutic switching also over-rides the treating physician's prescription authority. This practice involves the insurance company switching medications that have been prescribed to an individual to a different medication which is a less-expensive substitute. This is done even if the patient has been stabilized for quite some time on the original medication. The switch is often done at the pharmacy level without the patient being alerted to the reason nor the physician giving permission. The problem lies in the switch because if the biologics/exact formulation are not the same, the patient could be put at risk. Problems could be adverse effects, different side effects, etc., and, in some cases, life threatening. Again, insurance companies do this without ever examining the patient.

These issues are not isolated in Oklahoma. In the words of Dr. Nabih Abdou, a treating physician in Missouri, who has been taking care of Rheumatic Disease and Fibromyalgia patients for over 20 years:

"The waiting time and hurdles caused by step therapy and therapeutic switching can cause needless suffering by patients and, in some cases endanger patients' health. We, as treating physicians who have a greater and more reliable insight to the patient's condition, need legislation to assure patient access to medical care and

appropriate medications. Patients need appropriate treatment to prevent them from being disabled and/or burdening their families who care for them, the society, and their professions. Insurance providers should not be functioning as doctors. We need to ensure Missouri citizens' medical decisions are made by them and their treating physician."

In response to Columbia Tribune's "Who's the Doctor? Insurers reject prescriptions to save money" (January 11, 2009), Will Rowe, CEO of the American Pain Foundation, Baltimore, MD, who represents 76.5 million Americans in pain, summed up the problems:

"Dear Editor –

People with "invisible" pain conditions such as fibromyalgia are suffering needlessly due to overly restrictive heath care plans. With step therapy, insurers make it next to impossible for patients to receive appropriate access to medically necessary care they need.
Requiring people in pain to "fail" on several medications before they are allowed to take medications that their doctors think is the best choice is not only inhumane, it is downright dangerous. Undertreated pain has serious physiological, psychological, social, and economic consequences. Ironically, undertreated pain drives up the cost of healthcare because it extends lengths of stay in hospitals, increases emergency room visits, and leads to unplanned clinic visits.

There are an estimated 76.5 million Americans in pain, all of whom have a right to timely and appropriate care. Insurance companies need to stop practicing medicine without a license and put an end to the needless suffering of their plan participants."

I am also attaching a "Position Statement on Step Therapy and Therapeutic Switching" from the American Pain Foundation, one of our collaborators.

Insurance companies have a history of refusing to pay for "off-label" medications and insisting on utilizing FDA approved treatments. However, in the case of fibromyalgia, they now want to "prior authorize" FDA approved treatments for fibromyalgia. Often, in the "prior authorize" period, they require "off-label" treatments with documented failure, before even considering the FDA approved medications. Whose interest is best served by such practices? It is obvious these practices are utilized by insurance companies for financial benefits. The best interest of the patient should be the deciding factor for treatment, not what is in the best financial interest of the insurance company.

To further support the above, in a March 2009 letter to the Centers for Medicare and Medicaid Services (CMS), copy attached, Oklahoma Attorney General W.A. Drew Edmondson and a coalition of attorneys general from 16 other jurisdictions are voicing support for a proposed CMS rule that will prevent health insurance companies from requiring that patients first try "off-label" prescription treatments before the companies will provide Medicare Part D coverage for certain prescription medications.

You have an opportunity to help Oklahomans. Insurance companies should not be acting as doctors nor should they be allowed to make final medical decisions for people they have never examined, let alone met. Healthcare is a hot topic and appropriate treatment is a large part of the issue. You can help by ensuring Oklahomans get the most appropriate and effective treatment for their conditions as deemed by their treating physicians and themselves. Your actions can show Oklahomans you truly care for their health by working to improve their healthcare. Patients should get "what the doctor ordered".

On behalf of the thousands of Oklahoma citizens we serve, we thank you in advance for your consideration of this request.

Orvie Prewitt, President
NATIONAL CHRONIC FATIGUE SYNDROME AND
FIBROMYALGIA ASSOC.
P.O. Box 18426
Kansas City, MO 64133
(816) 305-4009 (cell phone)
(816) 737-1343 (24 Hr. Info.Line)
Fax: (816) 524-6782
Website: www.ncfsfa.org
Attachments

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Santiago Reyes, M.D.

Respiratory Diseases of Children and Adolescents

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

Dear Ron Graham, D. Ph,

As you are well aware, the Committee on Infectious Disease has issued new recommendations surrounding RSV prophylaxis. I want to express my concern regarding these new recommendations and the potential for adverse outcomes in a vulnerable population. As a Pediatric Pulmonologist, I feel that the recommendations are not based on the compilation of clinical data outlined in the medical literature.

There are two areas of greatest concern based on my medical experience and research which I have outlined below.

- The first is the discontinuation of prophylaxis in the 32 weeks, 0 Days to 34 weeks 6 days infants once they reach 3 months of age. This recommendation is not supported by the FDA-approved label or the pharmacokinetics of Synagis. This will potentially leave infants unprotected during the peak of our RSV season in Oklahoma.
- The second concern is the non-inclusion of infants 32 weeks, 0 Days to 34 weeks 6 days who will be more than 3 months of age at the onset of the RSV season. Clinical evidence indicates that these infants who are 3-6 months of age are still at significant risk of hospitalization due to RSV.

It would be my recommendation that the State of Oklahoma payers maintain criteria that is based on the scientific evidence reported in peer-reviewed medical journals. At a minimum the plans should continue with the previously accepted 2006 COID recommendations.

Sincerely,

Santiago Reyes de la Rocha, M.D.

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for May 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	43,626	55,456	990,328	30,844
Limits which were applied	Established, Major, Males and Females, Age 66-150	Males and Females, Narcotics, Age 23-25	Contraindicated, Epilepsy, Males and Females, Age 0-18	High dose and Duration , Fibric Acid Derivatives, Males and Females, Age 0-150
Total # of messages after limits were applied	10	161	133	27
Total # of members reviewed after limits were applied	10	142	69	27

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
67		4	

Retrospective Drug Utilization Review Report

Claims Reviewed for April 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 52-65	Benzodiazepine Anticonvulsants, Males and Females, Age 51-150	Contraindicated, Asthma, Males and Females, Age 76-150	High Dose and Duration, Benzodiazepines, Males and Females, Age 26-150

Response Summary (Prescriber)
Letters Sent: 25
Response Forms Returned: 15

The response forms returned yielded the following results:

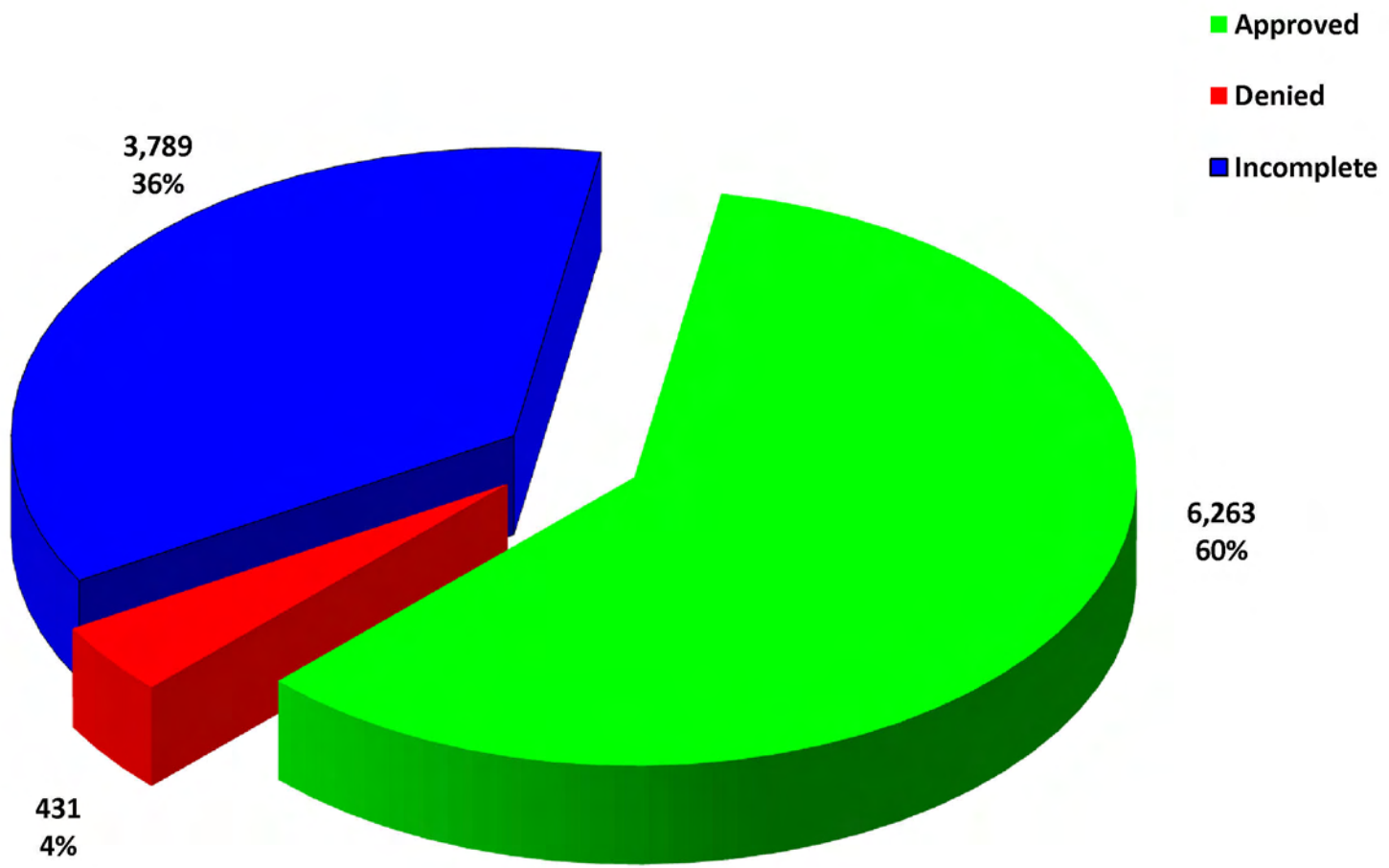
0 (0%)	*Record Error—Not my patient.*
1 (7%)	*No longer my patient.*
2 (13%)	*Medication has been changed prior to date of review letter.*
4 (27%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
5 (33%)	*I am aware of this situation and will plan to continue monitoring therapy.*
3 (20%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 3
Response Forms Returned: 3

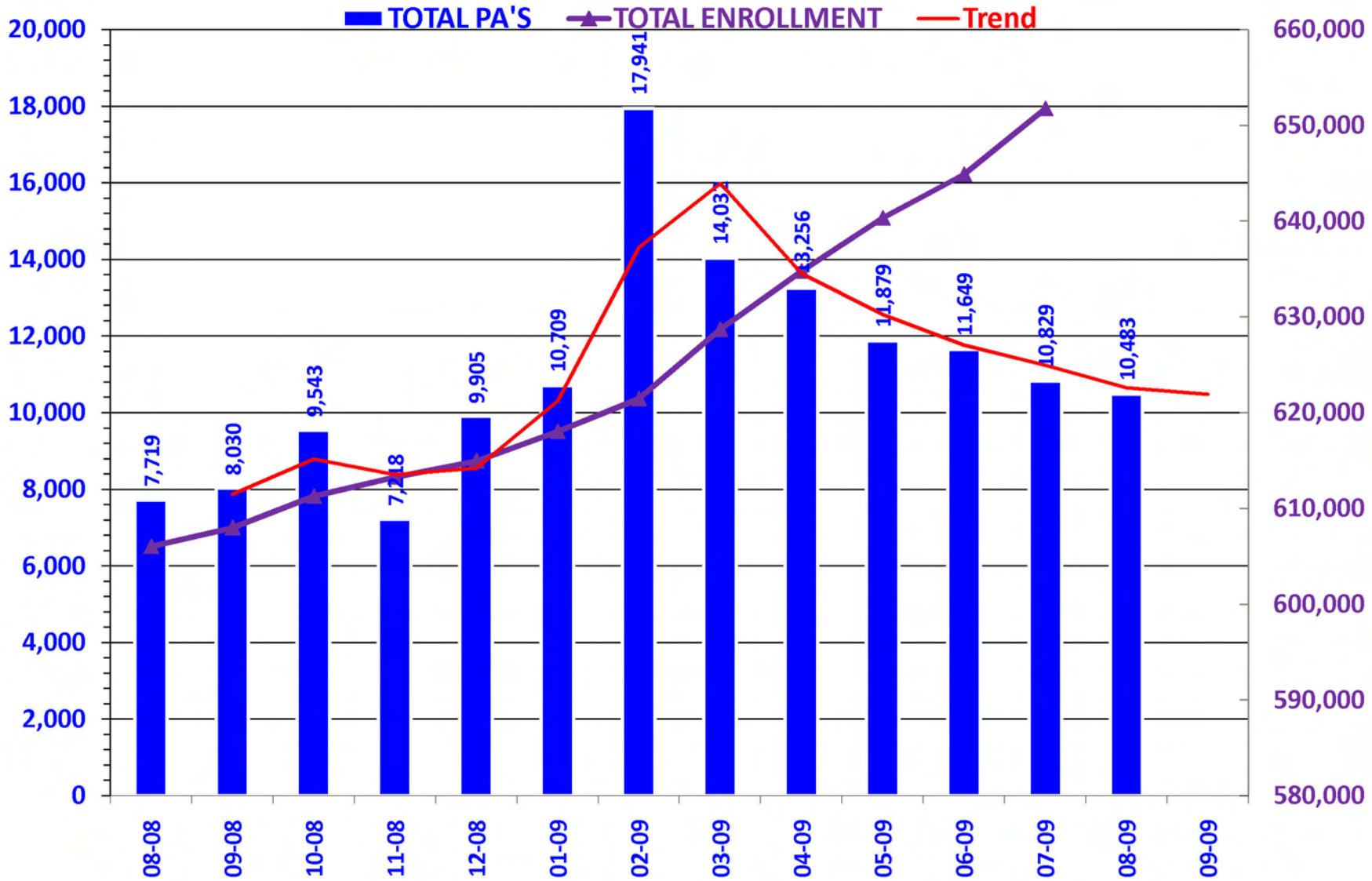
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
1 (33%)	*Medication has been changed prior to date of review letter.*
0 (0%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
2 (67%)	*I am aware of this situation and will plan to continue monitoring therapy.*
0 (0%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: August 2009



PRIOR AUTHORIZATION REPORT: August 2008 – August 2009



Activity Audit for

8/1/2009 Through 8/31/2009

	Average Length of	Approved	Denied	Incomplete	Total
Amitiza	183	8	0	24	32
Antidepressant	331	156	43	363	562
Antihistamine	322	178	14	178	370
Antihypertensives	332	48	10	91	149
Benzodiazepines	92	3,774	41	725	4,540
Bladder Control	324	7	2	7	16
Brovana (Arformoterol)	92	1	0	0	1
Byetta	363	2	0	2	4
Elidel/Protopic	88	24	1	26	51
ESA	62	78	6	30	114
Fibric Acid Derivatives	0	0	1	3	4
Forteo	363	4	0	5	9
Glaucoma	362	3	0	13	16
Growth Hormones	172	41	1	3	45
HFA Rescue Inhalers	229	65	0	66	131
Insomnia	128	36	12	115	163
Misc Analgesics	151	11	27	34	72
Muscle Relaxant	70	60	62	74	196
Nasal Allergy	121	6	60	133	199
NSAIDS	322	35	15	76	126
Ocular Allergy	107	5	1	27	33
Ocular Antibiotics	33	7	0	17	24
Opioid Analgesic	140	109	7	130	246
Other	126	139	22	237	398
Pediculicides	17	45	8	39	92
Plavix	360	105	2	59	166
Proton Pump Inhibitors	130	122	46	327	495
Qualaquin (Quinine)	0	0	0	1	1
Singulair	268	338	8	420	766
Smoking Cessation	71	27	5	71	103
Statins	361	27	5	30	62
Stimulant	235	735	25	359	1,119
Symlin	360	1	0	0	1
Synagis	89	1	1	1	3
Topical Antibiotics	13	6	4	34	44
Topical Antifungals	38	6	0	25	31
Ultram ER and ODT	0	0	1	4	5
Xolair	354	1	0	1	2
Xopenex Nebs	187	34	0	29	63
Zetia (Ezetimibe)	349	15	1	10	26
Emergency PAs		3	0	0	3
Total		**6,263**	**431**	**3,789**	**10,483**

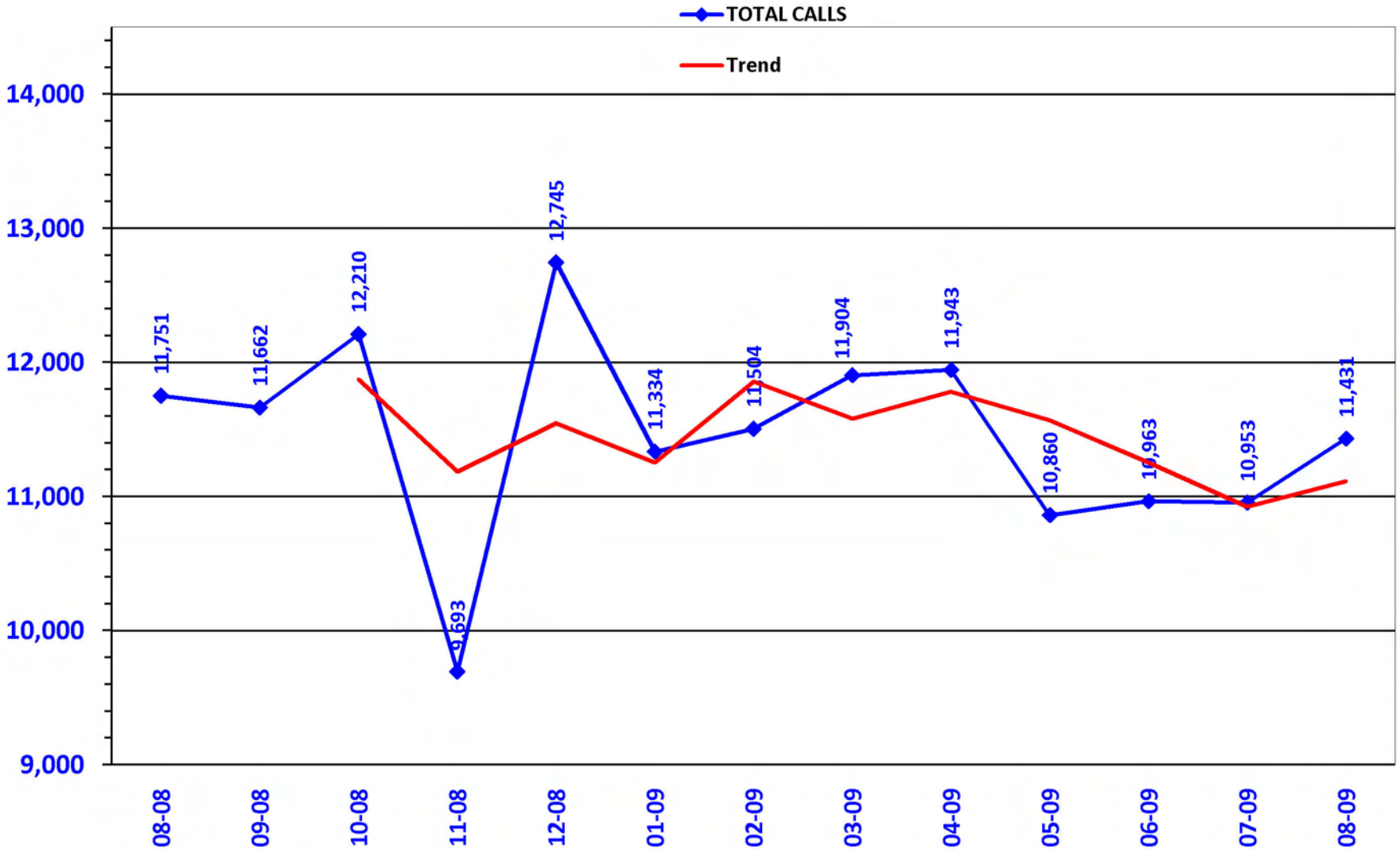
Overrides					
Brand	152	62	4	9	75
Dosage Change	20	448	5	26	479
High Dose	72	3	0	0	3
IHS - Brand	112	30	1	4	35
Ingredient Duplication	20	9	0	2	11
Lost/Broken Rx	17	84	2	2	88
Nursing Home Issue	12	72	0	1	73
Other	28	35	2	11	48
Quantity vs. Days Supply	214	313	26	116	455
Stolen	31	1	0	1	2
Wrong D.S. on Previous Rx	364	1	0	0	1
Overrides Total		**1,058**	**40**	**172**	**1,270**
Grand Total		**7,321**	**471**	**3,961**	**11,753**

Denial Reasons	
Lack required information to process request.	2,041
Unable to verify required trials.	1,638
Does not meet established criteria.	287
Not an FDA approved indication/diagnosis.	167
Considered duplicate therapy. Member has a prior authorization for similar medication.	88
Requested dose exceeds maximum recommended FDA dose.	81
Member has active PA for requested medication.	50
Medication not covered as pharmacy benefit.	30
Drug Not Deemed Medically Necessary	17

Duplicate Requests: 794

Changes to existing PAs: 1,048

CALL VOLUME MONTHLY REPORT: August 2008 – August 2009



Appendix C

30 Day Notice to Prior Authorize Fibromyalgia Medications

Oklahoma HealthCare Authority, September 2009

This category was introduced for possible inclusion in the Product Based Prior Authorization program in July 2009. See the July DUR and August DUR packets for a more complete discussion of the category. This notice and statement is presented to meet the statutory requirements of 63 O.S. Sec. 5030.5.

Recommendations:

The College of Pharmacy recommends placing Fibromyalgia products into the Product Based Prior Authorization Program. The following Tier 1 drug list has been reviewed and determined to be acceptable for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

Tier 1	Tier 2	Tier 3*
Amitriptyline Cyclobenzaprine Fluoxetine Tramadol	Supplemental Rebated Tier 3	Lyrica® (Pregabalin) Cymbalta® (Duloxetine HCl) Savella™ (Milnacipran)

*May be rebated to Tier 2 status only.

Approval Criteria:

1. Recent trials (within the last six months) of two Tier 1 medications and all available Tier 2 medications at least 3 weeks in duration that did not provide adequate response, or resulted in intolerable adverse effects, or
2. Contraindication(s) to all available lower tiered medications,
3. Current stabilization on Tier 2 or Tier 3 medications (samples will not be accepted if member has not had appropriate lower tiered trials).
4. Clinical Exceptions include:
    a. Diagnosis of seizures, diabetic neuropathy, or neuropathy for Lyrica®(Pregabalin)
    b. Diagnosis of diabetic neuropathy for Cymbalta® (Duloxetine HCl)

A Fibromyalgia information sheet will also be included with the prior authorization response to the pharmacies and physicians.

Appendix

1. Management of Fibromyalgia Syndrome. JAMA 2004[1]

Strong Evidence for Efficacy

Amitriptyline: often helps sleep and overall well-being; dose, 25-50 mg at bedtime
Cyclobenzaprine: similar response to amitriptyline and adverse effects; dose, 10-30mg at bedtime

Modest Evidence for Efficacy

Tramadol: administered with or without acetaminophen; dose, 200-300 mg/day

Serotonin reuptake inhibitors (SSRIs):

Fluoxetine (only one carefully evaluated at this time): dose, 20-80 mg; may be used with tricyclic given at bedtime; uncontrolled report of efficacy using sertraline

Dual-reuptake inhibitors (SNRIs):

Venlafaxine: 1 RCT ineffective but 2 case reports found higher dose effective
Milnacipran: effective in single Randomized Controlled Trial (RCT)
Duloxetine: effective in single RCT
Pregabalin: second-generation anticonvulsant; effective in single RCT

Weak Evidence for Efficacy

Growth hormone: modest improvement in subset of patients with FMS with low growth hormone levels at baseline
5-Hydroxytryptamine (serotonin): methodological problems
Tropisetron: not commercially available
S-adenosyl-methionine: mixed results

No Evidence for Efficacy

Opioids, corticosteroids, nonsteroidal anti-inflammatory drugs, benzodiazepene and non-benzodiazepene hypnotics, melatonin, calcitonin, thyroid hormone, guaifenesin, dehydroepiandrosterone, magnesium

2. EULAR Evidence-Based Recommendations for the Management of Fibromyalgia Syndrome. Ann Rheum Dis 2007[2]

Table 3 Effect size calculated using modified Cohen's d method for recommended treatments where data available

Intervention	Effect size (95% confidence interval)		NNH
	Pain	Function	
Pharmacological			
Amitriptyline	1.033 (−0.393, 2.458)[20–23]	0.51 (−12.847, 13.868)[22 24]	45.56 (−36.06, 127.17)
Dual re-uptake	0.341 (−0.644, 1.323)[25 26]	0.438 (−2.77, 3.647)[25 27]	9.91 (6.87, 12.96)
MAOI	0.822 (−0.024, 1.669)[22 23]	Cannot calculate	24.29 (2.93, 37.14)
SSRI	0.824 (−0.417, 2.064)[22 28 29]	0.536 (−7.323, 8.395)[22 28 29]	8.25 (5.8, 10.7)
Tramadol	0.657 (−0.276, 1.589)[30 31]	0.189 (−6.312, 6.689)[30 31]	35 (only one study)
Tropisetron	0.799 (−0.884, 2.482)[32]	Cannot calculate	27.47 (only one study)
Pramipexole	0.736 (−0.556, 2.028)[33]	0.606 (−7.073, 8.285)[33]	−21 (only one study)
Non-pharmacological			
Pool-based exercise	0.437 (−0.659, 1.532)[34 35]	0.495 (−1.68, 2.67)[34]	−8 (one study)
Balneotherapy	1.408 (0.684, 2.133)[36–38]	2.085 (−5.334, 9.979)[36 38]	Cannot calculate
Aerobic exercise	0.377 (−0.794, 1.549)[39–43]	0.062 (−5.174, 5.297)[39–42]	−13.5 (one study)
Strength training	2.225 (1.159, 3.292)[44 45]	1.031 (−29.197, 31.259)[44 46]	16.15 (one study)

MAOI, monoamine oxidase inhibitor; NNH, number needed to harm; SSRI, selective serotonin reuptake inhibitor.

Conclusions of the EULAR:

- Tramadol is recommended for the management of pain in Fibromyalgia. (Ib A)
- Simple analgesics such as Acetaminophen and other weak opioids can also be considered in the treatment of fibromyalgia. Corticosteroids and strong opioids are not recommended. (IV D)
- Antidepressants: amitriptyline, fluoxetine, duloxetine, and milnacipran reduce pain and often improve function, therefore they are recommended for the treatment of fibromyalgia. (Ib A)
- Pramipexole and pregabalin reduce pain and are recommended for the treatment of fibromyalgia. (Ib A)

3. Treatment of Fibromyalgia Syndrome with Antidepressants. JAMA 2009[3]

This is a meta-analysis of randomized controlled clinical trials to determine the efficacy of antidepressants in the treatment of FMS. The following table shows the results:

Results:

Table 1. Effect Sizes of the Different Classes of Antidepressants on Selected Outcome Variables

Outcome	No. of Studies	Patients Taking Antidepressants, No.	Statistical Method	Effect Size (95% CI)	Test for Overall Effect *P* Value
Tricyclic Antidepressants					
Pain	6	128	SMD (random)	–1.64 (–2.57 to –0.71)	<.001
Fatigue	4	95	SMD (random)	–1.12 (–1.87 to –0.38)	.003
Sleep	5	105	WMD (fixed)	–1.84 (–2.62 to –1.06)	<.001
Depressed mood	1	20	WMD (fixed)	–0.60 (–4.53 to 3.33)	.76
HRQOL	3	94	WMD (fixed)	–0.31 (–0.60 to –0.01)	.04
Selective Serotonin Reuptake Inhibitors					
Pain	6	132	SMD (random)	–0.39 (–0.77 to –0.01)	.04
Fatigue	5	94	WMD (fixed)	–0.17 (–0.47 to 0.12)	.25
Sleep	4	75	SMD (random)	–0.23 (–0.56 to 0.10)	.18
Depressed mood	5	94	WMD (fixed)	–0.37 (–0.66 to –0.07)	.02
HRQOL	3	62	WMD (fixed)	–0.41 (–0.78 to –0.05)	.03
Serotonin and Noradrenaline Reuptake Inhibitors					
Pain	3	804	SMD (random)	–0.36 (–0.46 to –0.25)	<.001
Fatigue	1	477	WMD (fixed)	–0.08 (–0.20 to 0.05)	.23
Sleep	2	327	SMD (random)	–0.31 (–0.47 to –0.14)	<.001
Depressed mood	2	309	SMD (random)	–0.26 (–0.42 to –0.10)	.001
HRQOL	2	703	SMD (random)	–0.31 (–0.44 to –0.17)	<.001
Monoamine Oxidase Inhibitors					
Pain	3	89	SMD (random)	–0.54 (–1.02 to –0.07)	.03
Fatigue	1	30	WMD (fixed)	0.30 (–1.04 to 1.64)	.66
Sleep	1	30	WMD (fixed)	1.00 (–0.49 to 2.49)	.19
Depressed mood	1	28	WMD (fixed)	0.18 (–2.16 to 2.52)	.88
HRQOL	NA	NA	NA	NA	NA

Abbreviations: CI, confidence interval; HRQOL, health-related quality of life; NA, not assessed; SMD, standardized mean difference; WMD, weighted mean difference.

Conclusions of the meta-analysis:

- Short-term usage of amitriptyline and duloxetine can be considered for the treatment of pain and sleep disturbances in FMS.
- Before treatment is initiated, concomitant diseases related to potential adverse effects of the drugs and patients' preferences should be considered.
- Goals of pharmacological therapy should be defined (no cure, but possible symptom reduction).
- Since evidence for a long-term effect of antidepressants in FMS is still lacking, their effects should be re-evaluated at regular intervals to determine whether benefits outweigh adverse effects.

References:

1. Goldenberg, DL, Burckhardt, C, Crofford, L. Management of fibromyalgia syndrome. JAMA 2004; 292:2388.
2. Carville, SF, Arendt-Neilson et al. EULAR evidence-based recommendations for the management of fibromyalgia syndrome. Ann Rhuem Dis 2008: 67: 536-541.
3. Winfried H, Kathrin, B et al. Treatment of Fibromyalgia Syndrome with Antidepressants. JAMA 2009; 301:198-209.

Appendix D

30 Day Notice to Prior Authorize Otic Anti-infectives

Oklahoma Health Care Authority
September 2009

This category was introduced for possible inclusion in the Product Based Prior Authorization program in July 2009. See the July DUR and August DUR packets for a more complete discussion of the category. This notice and statement is presented to meet the statutory requirements of 63 O.S. Sec. 5030.5.

Recommendation

The College of Pharmacy recommends establishing a PBPA category for otic antibiotics to ensure appropriate use in accordance with current treatment guidelines. The following Tier 1 drug list has been approved and determined to be acceptable for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Health Care Authority. No supplemental rebate will be offered for this category.

Prior Authorization Criteria

1. Member must have adequate 14-day trial of at least two Tier – 1 medications, or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 products or infection by organism not known to be covered by all Tier-1 agents.
3. A ciprofloxacin combination product may be approved when a steroid containing product is required for severe otitis externa and the tympanic membrane is not intact.

Otic Antibiotics		
Tier-1	**Tier-2**	**Special PA***
Ofloxacin **(Floxin Otic)**	Ofloxacin (**Floxin Otic**) **Droperette**	Acetic Acid, Antipyrine, Benzocaine, Glycerin **(Auralgan)**
Acetic acid **(Vosol, Acetasol)**	Ciprofloxacin, Dex or HC **(Ciprodex or Cipro HC)**	Acetic Acid, HC **(Acetasol HC, Vosol HC)**
Neomycin, Polymixin B, HC **(Cortisporin, Cortomycin, Pediotic)**	Neomycin,Polymixin B, HC, thonzonium **(Cortisporin TC)**	
Chloroxylenol/Pramoxine **(Chlorpram Z)**	Neomycin,Colistin, HC **(Coly-Mycin, and Coly Mycin-ES)**	
Pramoxine/Chloroxylenol/ Benzalkonium/HC **(Hydro)**	Chloroxylenol/Pramoxine/Zinc **(Zinotic, Zinotic ES)**	
	Chloroxylenol, benzocaine, and HC **(Trioxin)**	

***Special Prior Authorization criteria previously approved by DUR Board.**

An otic anti-infective information sheet will also be included with the prior authorization response to the pharmacies and prescribers.

Appendix E

Fiscal Year 2009 Annual Review of Anti-Ulcers and Vote to Include Pediatric Anti-ulcer Criteria

Oklahoma Health Care Authority
September 2009

Current Prior Authorization of Anti-Ulcer Medications

Anti-Ulcer Medications

The following products requires prior authorization with a special reason for use:

- ranitidine (Zantac) – effervescent tablets and capsules

Tier 1	Tier 2
omeprazole (Prilosec® 10mg & 20mg caps)	omeprazole (Prilosec® 40mg caps & Susp)*
lansoprazole (Prevacid®) capsules	omeprazole/antacid (Zegerid® Caps &Packets)*
dexlansoprazole (Kapidex®) capsules	lansoprazole (Prevacid®ODT and Granules)*
	esomeprazole (Nexium® Caps and I.V.)*
	pantoprazole sodium (Protonix® Tabs, Susp, & I.V.)*
	rabeprazole sodium (Aciphex® Tabs)

*Special Formulations including ODTs, Granules, Suspension, and Solution for I.V. require special reason for use.
Blue Color Indicates Supplemental Rebate Participation
Mandatory Generic Plan Applies

Approval Criteria

- Documented recent trial of a Tier 1 medication with inadequate results or adverse effect, or
- Documented contraindication to the Tier 1 medications, or
- Documented FDA-approved indication for which Tier 1 products are not indicated

Quantity Limits

- Omeprazole 10 mg: #60 for 30 days
- Omeprazole 20 mg: #120 for 30 days
- All other proton pump inhibitors: #30 for 30 days

Trends in Utilization of Anti-Ulcer Medications

Comparison of Fiscal Year Utilization

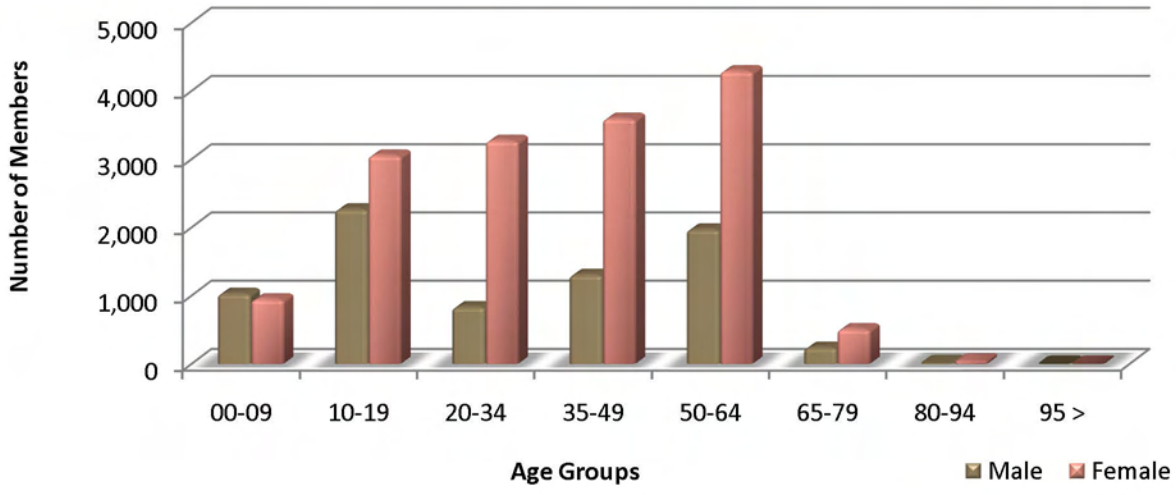
Fiscal Year	Members	Claims	Units	Days
2008	22,094	94,886	3,567,508	3,099,978
2009	23,438	100,795	3,804,316	3,186,666
Change	1,344	5,909	236,808	86,688
Percent Change	6.10%	6.20%	6.60%	2.80%

Utilization Anti-ulcer Medications during Fiscal Year 2008

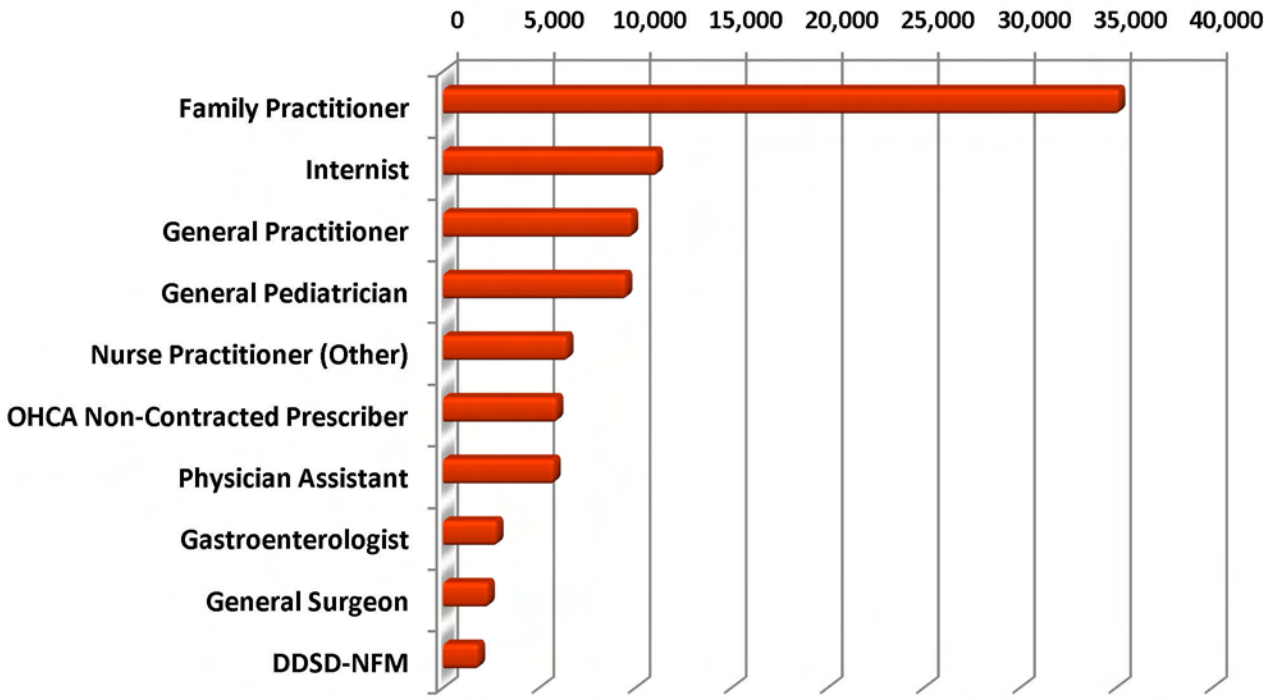
Medication	Claims	Members	Units	Days	Units/ Day	Claims/ Member	% Cost
OMEPRAZOLE CAP 20MG	44,585	13,069	2,064,982	1,516,629	1.36	3.41	8.71%
PREVACID CAP 30MG DR	27,996	6,968	865,010	829,790	1.04	4.02	48.65%
NEXIUM CAP 40MG	9,112	1,490	285,588	272,659	1.05	6.12	16.36%
PANTOPRAZOLE TAB 40MG	7,525	1,334	232,726	224,669	1.04	5.64	7.07%
PREVACID CAP 15MG DR	5,656	1,878	170,466	166,747	1.02	3.01	9.70%
ACIPHEX TAB 20MG	2,309	327	71,970	68,946	1.04	7.06	4.27%
PREVACID TAB 15MG STB	967	293	28,531	29,122	0.98	3.3	1.44%
OMEPRAZOLE CAP 40MG	775	492	25,930	23,004	1.13	1.58	1.57%
NEXIUM CAP 20MG	578	121	17,940	17,128	1.05	4.78	1.02%
OMEPRAZOLE CAP 10MG	577	239	18,742	17,029	1.1	2.41	0.12%
PREVACID TAB 30MG STB	349	82	10,970	10,291	1.07	4.26	0.57%
KAPIDEX CAP 60MG DR	131	107	3,930	3,930	1	1.22	0.17%
PANTOPRAZOLE TAB 20MG	103	36	3,078	3,078	1	2.86	0.11%
NEXIUM GRA 40MG DR	30	9	969	860	1.13	3.33	0.06%
PROTONIX TAB 40MG	22	6	780	660	1.18	3.67	0.03%
KAPIDEX CAP 30MG DR	19	17	630	603	1.04	1.12	0.03%
PREVACID GRA 15MG	14	8	375	351	1.07	1.75	0.02%
NEXIUM GRA 20MG DR	13	2	630	361	1.75	6.5	0.04%
PROTONIX PAK	12	3	360	360	1	4	0.02%
PRILOSEC CAP 40MG	10	6	330	300	1.1	1.67	0.03%
PRILOSEC POW 10MG	5	2	270	70	3.86	2.5	0.01%
PROTONIX INJ 40MG	5	4	19	19	1	1.25	0.00%
NEXIUM GRA 10MG DR	1	1	30	30	1	1	0.00%
PREVACID GRA 30MG	1	1	60	30	2	1	0.00%
TOTALS	100,795	23,438*	3,804,316	3,186,666	1.19	4.3	100%

*Total number of unduplicated members

Demographics of Members Utilizing Anti-ulcer Medications during Fiscal Year 2009



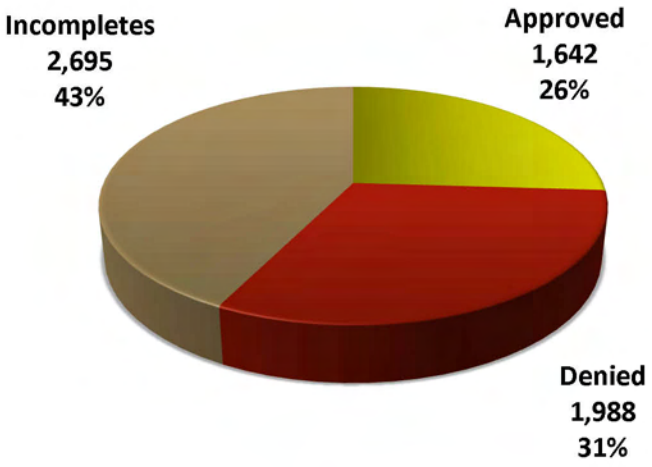
Prescribers of Anti-ulcer Medications by Number of Claims: FY 2009



Prior Authorizations of Anti-ulcer Medications: FY 2009

There were a total of 6,325 petitions submitted for this PBPA category during fiscal year 2009. The following chart includes step therapy petitions as well as Refill Too Soon and Quantity Limit Override petitions. Most prior authorizations for this category are processed through Point-of-Sale edits.

Status of Petitions for Anti-ulcer Medications: FY 2009



Patent Expirations

- **Prevacid® (lansoprazole)** – The patent for Lansoprazole is expected to expire in the Fall of 2009. Prevacid 15mg delayed release caps will be available over the counter around the same time the patent expires.
- **Aciphex® (rabeprazole)** – The patent for Aciphex is expected to expire in during 2009. The FDA has already approved a first-time generic 20-mg formulation for rabeprazole sodium delayed-release tablets (Teva Pharmaceutical Industries) in early 2007. However, there is yet to be a generic available on the market for this medication.
- **Nexium® (esomeprazole)** – The patent for esomeprazole is expected to expire in 2014.

Proton Pump Inhibitors and Plavix® Drug Interaction

Reports suggest that use of certain PPIs may make clopidogrel less effective[1,2] by inhibiting the enzyme that converts clopidogrel to the active form of the drug. However, other reports do not suggest this effect.[3,4] Currently, there is no evidence that other drugs that reduce stomach acid, such as H2 blockers or antacids interfere with the antiplatelet activity of Plavix®. The Food & Drug Administration (FDA) along with the manufacturer of Plavix® are in the process of conducting studies to obtain additional information regarding this drug interaction and will communicate its conclusions and any recommendations to the public when the data is available. For now, the FDA has the following recommendations[5]:

- Healthcare providers should continue to prescribe and patients should **continue to take clopidogrel as directed**, because clopidogrel has demonstrated benefits in preventing blood clots that could lead to a heart attack or stroke.
- Healthcare providers should **re-evaluate the need for starting or continuing treatment with a PPI**, including Prilosec OTC, in patients taking clopidogrel.
- Patients taking clopidogrel should **consult with their healthcare provider if they are currently taking or considering taking a PPI**, including Prilosec OTC.

Proton Pump Inhibitors and Increased Risk of Pneumonia

Results of a recently published study in the Journal of the American Medical Association (JAMA) showed that use of acid suppressive medications was associated with a 30% increased risk of **hospital acquired pneumonia**. [6] The risk was statistically significant for PPIs, but not for H_2 receptor antagonists. These results are consistent with recently published data in the outpatient setting showing an increased risk for **community acquired pneumonia** in current users of acid-suppressive medication (both proton-pump inhibitors and H_2 receptor antagonists).[7,8,9] Possible explanations include impairment of white blood cell function associated with proton-pump inhibitor therapy or introduction and colonization of bacteria in the stomach and airways resulting from the increased gastric pH.

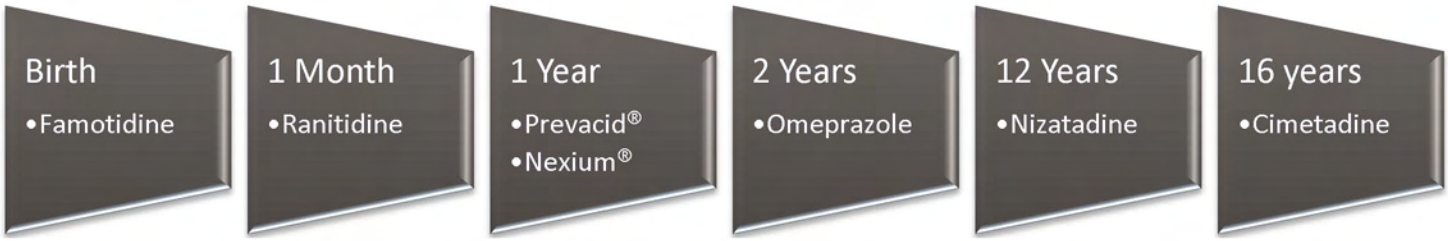
The theory that non–critically ill hospitalized patients would benefit from stress-ulcer prophylaxis has not been examined in a large, well-designed trial, and current guidelines do not support the use of these medications in nonventilated hospitalized patients. However, 40% to 70% of inpatients receive some form of acid-suppressive medication during their hospitalization, approximately 50% of which are initiations. This data, along with emerging data regarding PPIs and **increased risk of gastrointestinal neoplasia**[10], malabsorption of nutrients leading to **increase risk of hip fractures**[11], and **increased susceptibility of infections** in the lower gastrointestinal tract (notably due to *Salmonella*, *Campylobacter*, and *Clostridium difficile,*)[12] should prompt the prescriber in reconsidering casual use of acid suppressive agents, specifically PPIs, for uncomplicated reflux.

The latest clinical guidelines endorsed by the American Academy of Pediatrics, compiled and published by the The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)[13] suggests the following non-pharmacologic and pharmacologic treatments for pediatric GERD:

- Diet Changes in the Infant
- Position Changes in the Infant, Child, and Adolescent
- Lifestyle and Diet Changes in the Child and Adolescent
- Acid Suppressant Therapy – H_2 receptor antagonists or proton pump inhibitors for 2-4 weeks
- Prokinetic Therapy – generally not recommended due to adverse effects of Cisapride
- Surgical Therapy - potential risks, benefits and costs of successful prolonged medical therapy vs. fundoplication have not been well studied in infants or children.

Non-pharmacologic therapy is covered in depth in the recommendations because in the infant with non-complicated gastro-esophageal reflux, there is no evidence that pharmacological therapy affects the natural history of GER. Recurrent vomiting due to GER generally decreases in frequency over the first year of life and resolves by 12 months of age.[14] The guidelines did not recommend a first line agent or class of medication, however, the recommendations presented efficacy data in infants and children for the class of H_2 receptor antagonists. PPIs were mentioned as the stronger class of medications for reduction of gastric acidity, however, the guidelines did point out there was a lack of evidence regarding use of these agents in the pediatric population. Most likely due to the available evidence in the pediatric population, recommendations published in the Journal of Clinical Pediatrics[15] recommend the H_2 receptor antagonists as first-line therapy because of their overall safety profile and proven efficacy for uncomplicated GER.

In the SoonerCare population, according to fiscal year 2009 utilization data, approximately 30% of members utilizing the PPI category are 19 years old or younger, and 8% are under the age of 10. The following chart shows the ages for which the H_2 receptor antagnosists and PPIs with a pediatric indication are approved:

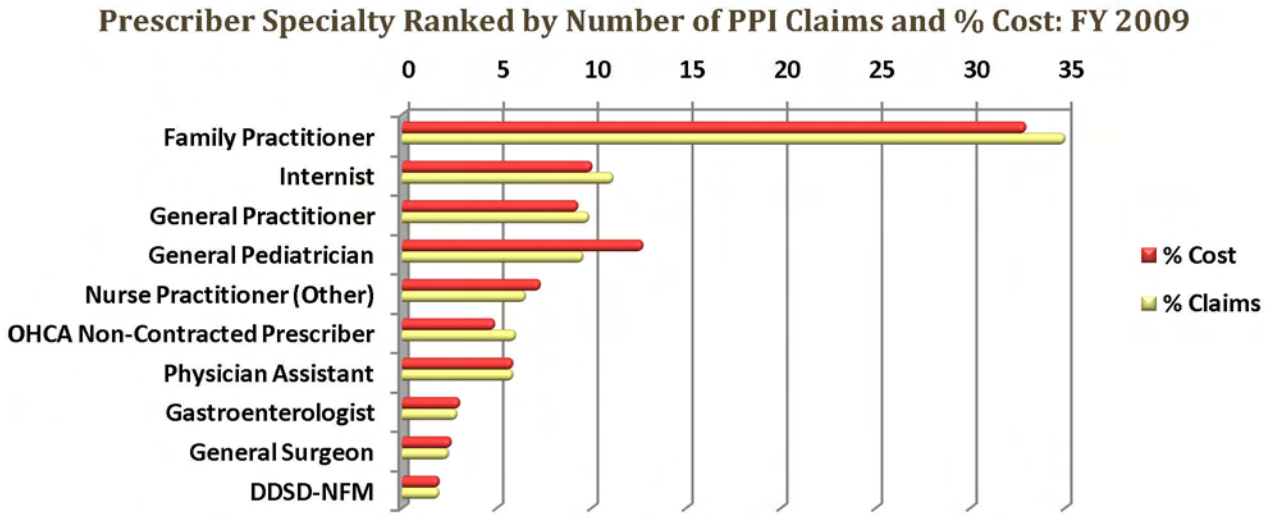


The following table shows a general comparison of medications approved in the pediatric population based on estimated acquisition costs of the special oral formulations.

Medication	Generic	Cost
Famotidine (Pepcid® Susp 40mg/5ml)	No	$3.60 per ml (50mls)
Ranitidine (Zantac® Syrup 15mg/ml)	Yes	$0.17 per ml (480mls)
Lansoprazole (Prevacid 15mg, 30mg ODT)	No	$4.35 per 15mg tab, $5.25 per 30mg tab
Esomeprazole (Nexium® 10mg, 20mg & 40mg Susp)	No	$5.67 per packet, same for all strengths
Omeprazole Caps (Prilosec® 20mg Caps)	Yes	$0.31 per cap
Nizatadine (Axid® 150mg/10ml Oral Sol)	No	$0.74 per ml (480mls)
Cimetadine 300mg/5mls Susp	Yes	$0.08 per ml (237mls and 473mls)

Among the pediatric population who are unable to swallow capsules and tablets, special formulations such as orally disintegrating tablets or suspensions are often used. However, in the PPI category, these special

formulations are more costly as most of these products have recently entered the market and generic formulations will not be available for some time. Patented products are also actively marketed by their respective manufacturers, as opposed to generic products, which are not marketed once the patent/ exclusivity is lost. Altogether, this may explain the higher % cost of scripts written by pediatricians as shown on the graph below :



Conclusion and Recommendations

With the patents of Aciphex® and Prevacid® anticipated to expire soon, the proton pump inhibitor category will have more available generic products than ever before. In addition, a review of the utilization of PPIs in the pediatric population demonstrates a need for additional criteria to ensure appropriate usage of these agents in this population. The College of Pharmacy has the following recommendations for this category:

- **Restructuring of the tiers** for the PPI Product Based Prior Authorization Category - the College recommends a 3 tier structure with tier one consisting of products available in the generic formulation with a reasonable SMAC applied. Tiers 2 and 3 and the suggested approval criteria are below.
- **Addition of Pediatric Specific Criteria** - for the majority of pediatric members with uncomplicated GER, the College recommends use of H2 antagonists as a first line agent.
- **Prior Authorization of Pepcid® Suspension** - due to the high cost of this product, the College recommends this product be reserved for members who are too young to use other products.

Anti-Ulcer Medications

Special Prior Authorizations of Miscellaneous Products

- **ranitidine (Zantac® Effervescent Tabs)** – must have reason why member cannot take other dosage forms.
- **famotidine (Pepcid® Suspension)** – reserved for members less than 1 month old.

Tier 1	Tier 2	Tier 3
omeprazole (Prilosec® 10mg & 20mg caps)	pantoprazole (Protonix® Tabs)	omeprazole (Prilosec ®40mg caps & Susp)*
	Supplemental Rebated Tier 3	omeprazole/antacid (Zegerid® Caps & Pkts)*
		esomeprazole (Nexium® Caps and I.V.)*
		lansoprazole (Prevacid® Caps and ODT)*
		dexlansoprazole (Kapidex® caps)
		pantoprazole (Protonix® Susp & I.V.)*
		rabeprazole sodium (Aciphex® Tabs)

Mandatory Generic Plan Applies
***Special Formulations including ODTs, Granules, Suspension, and Solution for I.V. require special reason for use.**

Criteria for Approval of a Tier-2 medication:

1. A 14-day trial of omeprazole dosed up to 40mg per day (two 20mg caps) that has resulted in inadequate relief of symptoms or intolerable adverse effects.
2. Contraindication to all available Tier 1 medications.
3. An indication not covered by lower tiered medications.

Criteria for Approval of a Tier-3 medication:

1. A 14-day trial all available Tier 2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects.
2. Contraindication to all available Tier 2 medications.
3. An indication not covered by lower tiered medications.

Criteria for Approval of Age Appropriate PPIs for Pediatric Members under the age of 19:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects.
2. Recurrent or severe disease such as:
    a. GI bleed
    b. Presence of concomitant gastrointestinal conditions
    c. Chronic use of corticosteroids

[1] Gilard M et al. **Influence of omeprazole on the antiplatelet action of clopidogrel associated with aspirin: the randomized, double-blind OCLA (Omeprazole Clopidogrel Aspirin) Study.** J Am Coll Cardiol 2008: 51:256-60.

[2] Gilard M et al. **Influence of omeprazole on the antiplatelet action of clopidogrel associated to aspirin.** J Thromb Haemost 2006; 4:2508-9.

[3] Small DS et al. **Effects of the proton pump inhibitor lansoprazole on the pharmacokinetics and pharmacodynamics of prasugrel and clopidogrel.** J Clin Pharmacol 2008; 48: 475-484.

[4] Siller-Matula JM et al. **Effects of pantoprazole and esomeprazole on platelet inhibition by clopidogrel.** Am Heart J 2009; 157:148e1-148.e5.

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[6] Herzig SJ, Howell MD, Ngo LH, Marcantonio ER. **Acid-Suppressive Medication Use and the Risk for Hospital-Acquired Pneumonia.** JAMA 2009; 301(20):2120-8.

[7] Gulmez SE, Holm A, Frederiksen H, Jensen TG, Pedersen C, Hallas J. **Use of proton pump inhibitors and the risk of community-acquired pneumonia: a population-based case-control study.** *Arch Intern Med.* 2007;167(9):950-955.

[8] Laheij RJ, Sturkenboom MC, Hassing RJ, Dieleman J, Stricker BH, Jansen JB. **Risk of community-acquired pneumonia and use of gastric acid-suppressive drugs.** *JAMA.* 2004;292(16):1955-1960.

[9] Sarkar M, Hennessy S, Yang YX. **Proton-pump inhibitor use and the risk for community-acquired pneumonia**. *Ann Intern Med.* 2008;149(6):391-398.

[10] A H Poulsen, S Christensen, J K McLaughlin, R W Thomsen, H T Sørensen, J H Olsen, S Friis. **Proton pump inhibitors and risk of gastric cancer: a population-based cohort study.** *British Journal of Cancer* (2009) **100**, 1503–1507.

[11] Yu-Xiao Yang, MD, MSCE; James D. Lewis, MD, MSCE; Solomon Epstein, MD; David C. Metz, MD. **Long-term Proton Pump Inhibitor Therapy and Risk of Hip Fracture.** *JAMA.* 2006;296:2947-2953.

[12] Gulmez SE, Holm A, Frederiksen H, Jensen TG, Pedersen C, Hallas J. **Use of Proton Pump Inhibitors and the Risk of Community-Acquired Pneumonia: a population-based case-control study.** *Arch Intern Med. 2007;167:950-955.*

[13] **Guidelines for Evaluation and Treatment of Gastroesophageal Reflux in Infants and Children.** Guidelines are available as a **PDF file** from The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Web site free-of-charge at: http://www.naspghan.org/user-assets/Documents/pdf/PositionPapers/GERD.pdf.

[14] Nelson SP, Chen EH, Syniar GM, et al. **One-year follow-up of symptoms of gastroesophageal reflux during infancy.** Pediatric Practice Research Group. *Pediatrics* 1998;102:E67.

[15] Sanjay Chawla, Divya Seth, Prashant Mahajan and Deepak Kamat. **Gastroesophageal Reflux Disorder: A Review for Primary Care Providers.** *Clin Pediatr (Phila)* 2006; 45; 7

Appendix F

Annual Review of Narcotic Analgesics – FY2009 and 30 Day Notice to PA Onsolis™, Nucynta™, Zamicet™, and Embeda™

OKLAHOMA HEALTH CARE AUTHORITY

AUGUST 2009

CURRENT PRIOR AUTHORIZATION CRITERIA

Narcotic Analgesics
Tier-1 products are covered with no prior authorization necessary.
Tier-2 authorization requires: ▪ documented 30 day trial/titration period with at least two Tier-1 medications within the last 90 days, or ▪ clinically appropriate pain therapy requiring time-released medication Tier-3 authorization requires: ▪ documented 30 day trial with at least two Tier-2 medications within the last 90 days, or ▪ documented allergy or contraindication to all Tier-2 medications
• Members with an oncology-related diagnosis are exempt from the prior authorization process, although quantity and dosage limits still apply. Actiq® and Fentora® are approved only for oncology-related diagnoses.
• Only one long-acting and one short-acting agent can be used concurrently

Tier-1	Tier-2	Tier-3	Oncology Only
All immediate release narcotics not listed in a higher tier	**Long Acting**		
	fentanyl patch (Duragesic®)	morphine sulfate (Avinza®)	
	morphine ER	morphine sulfate (Kadian®)	
	oxymorphone (Opana® ER)	oxycodone (OxyContin®)	
		tramadol ER (Ultram ER®, Ryzolt®)	
	Short Acting		
	hydrocodone (Xodol®)		fentanyl (Actiq®)
			fentanyl (Fentora®)

Blue Color indicates supplemental rebate participation

OTHER PRIOR AUTHORIZED ANALGESICS

Darvocet A500 (propoxyphene napsylate 100 mg / acetaminophen 500 mg)

Balacet 325 (propoxyphene napsylate 100 mg / acetaminophen 325 mg)

- Approved for members with documented need to restrict acetaminophen use or documented renal insufficiency or hepatic impairment.
- A quantity limit of 180/30 on each of the products also applies.

Ultram ODT

- Diagnosis indicating that the member has a condition that prevents them from swallowing tablets,
- A quantity limit of 240 units for 30 days for the ODT.

UTILIZATION FOR FISCAL YEAR 2009

TRENDS IN UTILIZATION

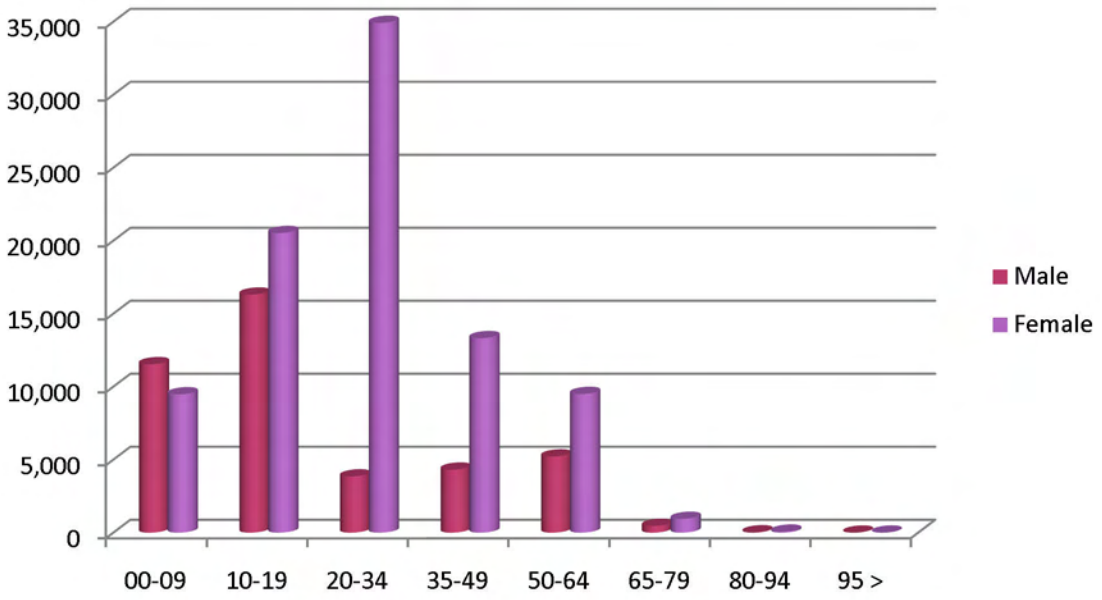
Fiscal Year	Members	Claims	Units	Days
2008	124,810	446,011	28,050,744	6,021,849
2009	130,764	469,620	30,325,004	6,591,183
Percent Change	**4.8%**	**5.3%**	**8.1%**	**7.1%**
	5,954	**23,609**	**2,274,260**	**436,334**

UTILIZATION DETAILS OF NARCOTIC ANALGESICS BY CLASS

GENERIC NAME	CLAIMS	MEMBERS	CLAIMS/ MEMBER	% COST
Hydrocodone Combinations	260,885	82,481	3.16	20.85%
Opioid Agonists	91,604	22,972	3.99	66.14%
Codeine Combinations	41,056	31,536	1.30	1.88%
Opioid Combinations	39,730	23,024	1.73	5.15%
Propoxyphene Combinations	29,400	16,073	1.83	1.66%
Opioid Partial Agonist	3,271	837	3.91	3.58%
Tramadol Combinations	2,790	1,491	1.87	0.49%
Dihydrocodeine Combinations	629	307	2.05	0.19%
Pentazocine Combinations	255	107	2.38	0.06%
	469,620	**130,764***	**2.63**	

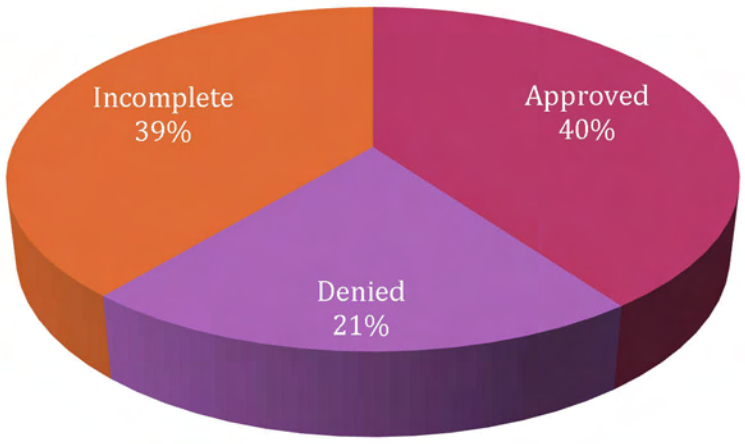
*Unduplicated Members

MEMBER DEMOGRAPHICS



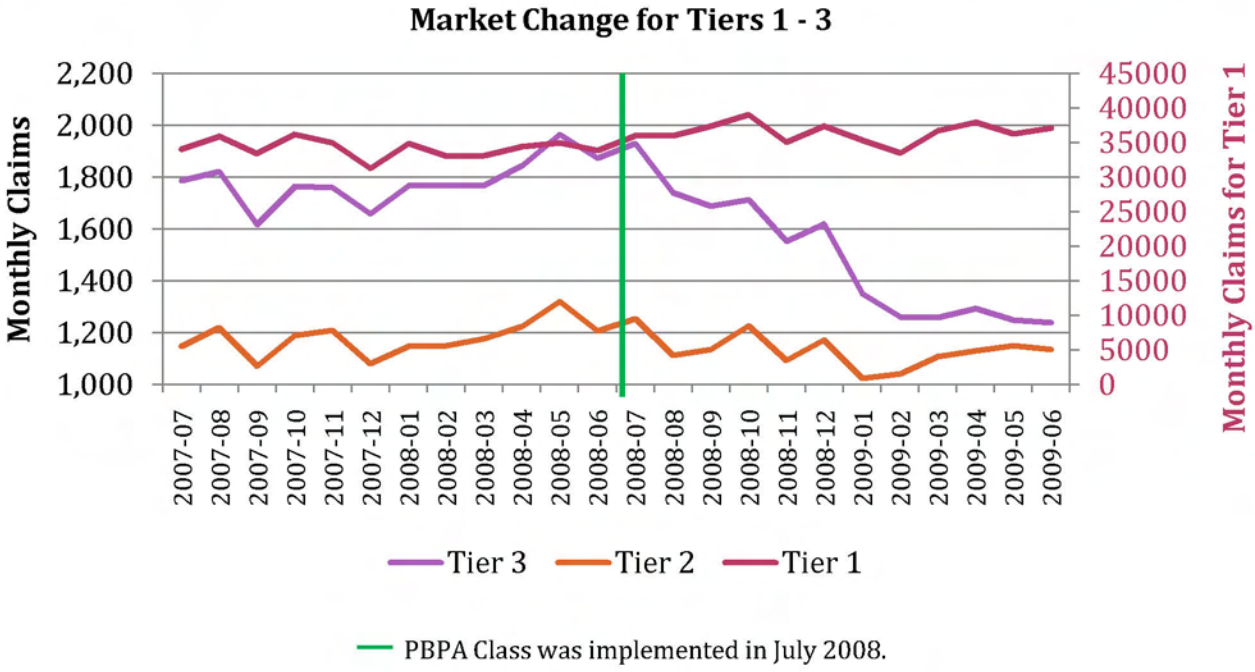
PRIOR AUTHORIZATION REQUESTS

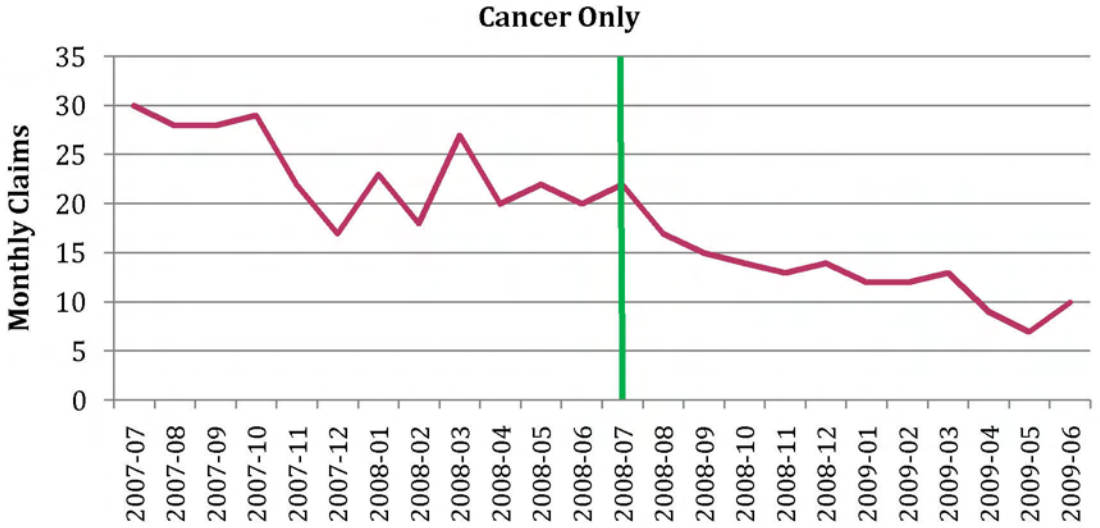
Most prior authorization requests for this category are handled through DUR Plus at Point of Sale. There were a total of 5,666 manual petitions submitted for Narcotic Analgesics during fiscal year 2009. The following chart shows the status of the submitted petitions.



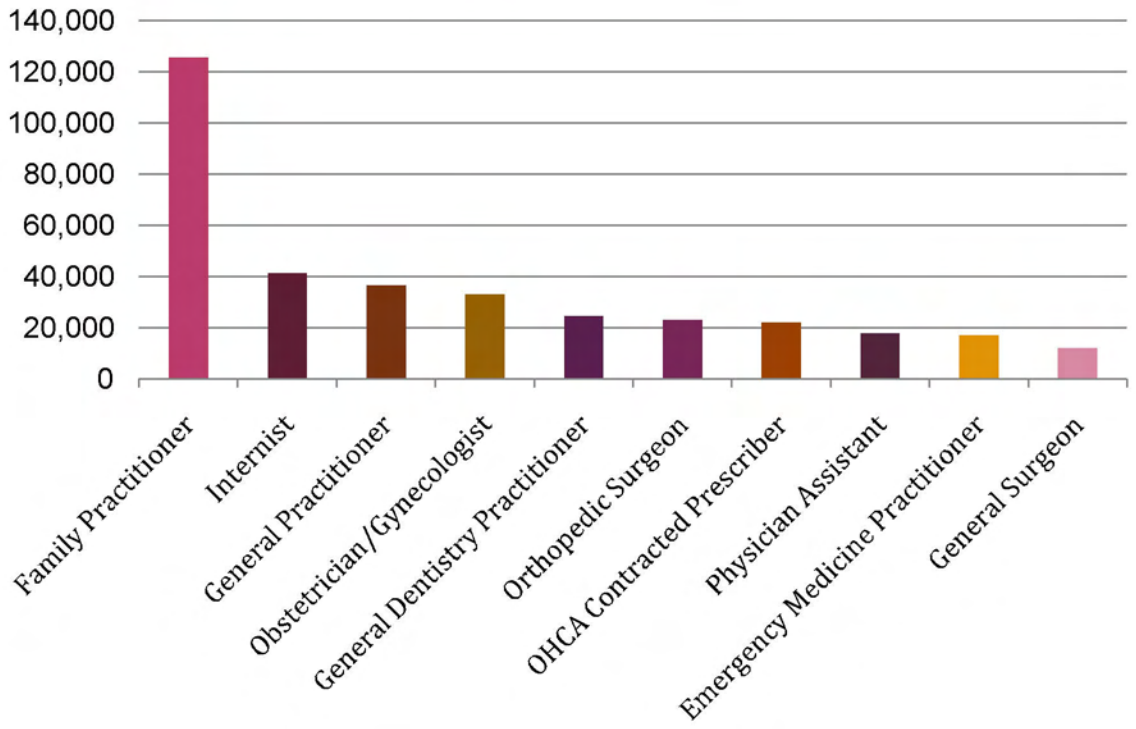
MARKET SHIFT

The table below shows the shift in the market for Tiers 1, 2 and 3. Due to the high number of Tier 1 claims, the axis for these claims is on the right. The greatest change in number of monthly claims occurred in the Tier 3 medications. There was a reduction in the average claims count of approximately 250 claims for this Tier level. Additionaly for the Cancer Only products the average monthly claims have been reduced by 50% (see table 2 below).





PRESCRIBERS OF NARCOTIC ANALGESICS



MARKET UPDATES

Ryzolt® (tramadol extended release) – Approved Dec 30, 2008

- Ryzolt® is extended release tramadol indicated for treatment of chronic pain. It is to be used around- the-clock, not as needed.
- This product was placed into Tier 3 in June 2009.

Zamicet™ (hydrocodone bitartrate and acetaminophen) – Approved September 2008

- Indicated for the relief of moderate to moderately severe pain.
- Oral solution with 10 mg hydrocodone and 325 mg acetaminophen per 15 mL.
- Dosing is every 4 to 6 hours. May be given to children as young as 2 years of age.

Nucynta™ (tapentadol) – Approved November 20, 2008, Available July 2009

- Indicated for the treatment of acute pain.
- Dosing should start with 50-100mg every 4 -6 hours as needed. An extra dose may be given on the first day 1 hour after initiation. Max of 700mg on day 1 and 600mg in following days.

Onsolis™ (fentanyl) – Approved July 16, 2009

- Onsolis™ is a new dosage form of fentanyl indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. It is a film placed on the cheek and absorbed through the oral mucosa.
- Patients will need to be enrolled in the FOCUS Program to receive Onsolis™. The patient will receive their prescription via a traceable courier (with proof of delivery and adult signature required). The patient will receive a counseling call at the time of the first prescription to verify that they are opioid tolerant and discuss how to use the drug.

Embeda™ (morphine and naltrexone) - Approved August 13, 2009

- Embeda™ is extended release morphine intended for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. It is not to be used as needed.
- The capsules may be sprinkled onto soft food like applesauce, but they cannot be crushed or chewed. Crushing will activate the naltrexone and render the morphine ineffective in treating pain.

RECOMENDATIONS

The College of Pharmacy recommends continuation of the Narcotic PBPA Category. In addition, the College of Pharmacy recommends placement of the following products in the current Tier structure:

Onsolis™: to be placed in the Oncology Only section with a quantity limit of 4 units per day.

Nucynta™: to be placed in Tier 2 of the short-acting products Tier structure, with a quantity limit of 6 tablets per day. One Tier 1 trial must be tramadol.

Embeda™: to be placed in Tier 3 of the long-acting products Tier structure, with a quantity limit of 2 capsules per day.

Zamicet™: to be placed in Tier 2 of the short-acting products with a quantity limit based on a maximum of 3,250 mg of APAP per day.

Narcotic Analgesics
Tier-1 products are covered with no prior authorization necessary.
Tier-2 authorization requires: ▪ documented 30 day trial/titration period with at least two Tier-1 medications within the last 90 days, or ▪ clinically appropriate pain therapy requiring time-released medication for long-acting products Tier-3 authorization requires: ▪ documented 30 day trial with at least two Tier-2 medications within the last 90 days, or ▪ documented allergy or contraindication to all Tier-2 medications
• Members with an oncology-related diagnosis are exempt from the prior authorization process, although quantity and dosage limits still apply. Actiq®, Fentora®, and Onsolis® are approved only for oncology-related diagnoses.
• Only one long-acting and one short-acting agent can be used concurrently

Tier-1	Tier-2	Tier-3	Oncology Only
All immediate release narcotics not listed in a higher tier	**Long Acting**		
	fentanyl patch (Duragesic®)	morphine sulfate (Avinza®)	
	morphine ER	morphine sulfate (Kadian®)	
	oxymorphone (Opana® ER)	oxycodone (OxyContin®)	
		tramadol ER (Ultram ER®, Ryzolt®)	
		morphine and naltrexone (Embeda™)	
	Short Acting		
	hydrocodone (Xodol®)		fentanyl (Actiq®)
	hydrocodone (Zamicet™)		fentanyl (Fentora®)
	Tapentadol (Nucynta™)		Fentanyl (Onsolis™)

Blue Color indicates supplemental rebate participation

APPENDIX

QUANTITY LIMITS ON ANALGESICS

Medication	Restriction
Butorphanol (**Stadol**) nasal spray	10mL per 30 days (four 2.5 mL bottles = 100 sprays total)
Fentanyl transdermal (**Duragesic**) 12.5, 25, 50, 75, & 100 mcg/hr patches	12.5, 25, 50, & 75 mcg- 10 patches per 30 days 100 mcg – no limit
Fentanyl oral transmucosal (**Actiq**) 200, 400, 600, 800, 1200, 1600 mcg lozenges	120 lozenges per 30 days
Hydromorphone (**Dilaudid**) 2, 4, & 8 mg immediate release tablets	2 or 4 mg – 180 tablets per 30 days 8 mg – 120 tablets per 30 days
Meperidine (**Demerol**) 50 & 100 mg tablets	60 tablets per 30 days
Methadone (**Dolophine**) 5, 10, & 40 mg tablets	240 tablets per 30 days
Morphine sulfate (**Avinza**) 30, 60, 90, & 120 mg extended release caps	30 capsules per 30 days
Morphine sulfate (**Kadian**) 20, 30, 50, 60, 80, 100 & 200 mg sustained release capsules	60 capsules per 30 days
Oxycodone / ibuprofen (**Combunox**) 5 / 400 mg tablets	28 tablets per 30 days
Oxycodone (**Oxy IR**) 5, 15, & 30 mg immediate release tabs & caps	240 tablets/capsules per 30 days
Oxycodone (**OxyContin**) 10, 20, 40, & 80 mg controlled release tabs	10, 20, 40 mg – 60 tabs per 30 days 80 mg – no limit
Tramadol (**Ultram**) 50 mg tablets	240 tablets per 30 days
Fentanyl buccal (**Fentora**) 100, 200, 400, 600, 800 mcg buccal tablets	120 tablets per 30 days
Oxymorphone (**Opana IR**) 5 & 10 mg tablets	5 mg – 120 per 30 days 10 mg – 240 per 30 days
Oxymorphone (**Opana ER**) 5, 10, 20, & 40 mg tablets	5, 10 & 20 mg – 60 per 30 days 40 mg – 120 per 30 days
Pentazocine (**Talwin Cpd, Talwin NX, Talacen**) tablets	12.5 mg / Aspirin 325 mg – 240 tablets per 30 days 50 mg / Naloxone 0.5 mg – 360 tablets per 30 days 25 mg / APAP 650 mg – 180 tablets per 30 days
All product combinations containing acetaminophen (**Lortab, Percocet, Tylenol w/Codeine, Darvocet**, etc)	Maximum of 4 gms of APAP per day for 30 days (or as product labeling indicates) Hydrocodone products limited to 3,250 gm of APAP per day.
All product combinations containing aspirin (**Percodan, Fiorinal**, etc)	Maximum of 4 gms of ASA per day for 30 days (or as product labeling indicates)
All product combinations containing ibuprofen (**Vicoprofen, Reprexain**)	150 tablets per 30 days

RECENTLY ADDED CHANGES TO HYDROCODONE COMBINATION PRODUCTS

1. Use of the Point of Sale Ingredient Duplication Module set to deny claims for concurrent use of hydrocodone products.
2. Quantity limit for a maximum of 3,250 mg of APAP per day.
3. Annual claim limit of 12 per 365 days.

Approval Criteria for Greater than 12 Claims:

1. Members may be approved for greater than 12 claims per year if the member has a pain contract with a single prescriber. A copy of the pain contract should be submitted with the prior authorization request. Requests outside of the plan outlined in the contract will not be approved.
2. Members with a current oncology related diagnosis may be approved for greater than 12 claims per year if the medication is being used as break-through therapy and adjustments to dosing are required.
3. Medication will not be approved as the only therapy for chronic pain use. Members with chronic pain who require around-the-clock pain control should be on a long-acting pain medication. An additional claim may be approved to allow time for changes in therapy to be made.

NUCYNTA™ PRODUCT DETAILS*

INDICATION

Nucynta™ is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

DOSAGE FORMS

50 mg, 75 mg, 100 mg tablets

CONTRAINDICATIONS

Nucynta™ is contraindicated in patients with impaired pulmonary function (significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment). Nucynta ™ is also contraindicated in patients with paralytic ileus and with concomitant use or use within 14 days of monoamine oxidase inhibitors (MAOIs).

PRECAUTIONS

- **Respiratory depression**- Nucynta™ should be administered with caution to patients with conditions accompanied by hypoxia, hypercapnia or decreased respiratory reserve such as: asthma, chronic obstructive pulmonary disease or cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, central nervous system (CNS) depression or coma. In such patients, even usual therapeutic doses of Nucynta™ may increase airway resistance and decrease respiratory drive to the point of apnea.
- **CNS Depression-** Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with Nucynta™ may exhibit additive CNS depression.
- **Head Injury and Increased Intracranial Pressure-** Opioid analgesics can raise cerebrospinal fluid pressure as a result of respiratory depression with carbon dioxide retention. Therefore, Nucynta™ should not be used in patients who may be susceptible to the effects of raised cerebrospinal fluid pressure such as those with evidence of head injury and increased intracranial pressure.
- **Misuse and Abuse-** Nucynta™ can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Nucynta™ in situations where the physician or pharmacist is concerned about an increased risk of misuse and abuse. Nucynta™ may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death.
- **Driving and Operating Machinery-** Patients should be cautioned that Nucynta™ may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery.

- **Interactions with Alcohol and Drugs of Abuse-** Due to its mu-opioid agonist activity, Nucynta™ may be expected to have additive effects when used in conjunction with alcohol, opioids, or illicit drugs that cause central nervous system depression, respiratory depression, hypotension, and profound sedation, coma or death.
- **Seizures-** Nucynta™ has not been systematically evaluated in patients with a seizure disorder and such patients were excluded from clinical studies. Nucynta™ should be prescribed with care in patients with a history of a seizure disorder or any condition that would put the patient at risk of seizures.
- **Serotonin Syndrome Risk-** The development of a potentially life-threatening serotonin syndrome may occur with use of Serotonin and Norepinephrine Reuptake Inhibitor (SNRI) products, including Nucynta™, particularly with concomitant use of serotonergic drugs such as Selective Serotonin Reuptake Inhibitors (SSRIs), SNRIs, tricyclic antidepressants (TCAs), MAOIs and triptans, and with drugs that impair metabolism of serotonin (including MAOIs).
- **Withdrawal-** Withdrawal symptoms may occur if Nucynta™ is discontinued abruptly. Withdrawal symptoms may be reduced by tapering Nucynta™.
- **Hepatic Impairment-** A study of Nucynta™ in subjects with hepatic impairment showed higher serum concentrations than in those with normal hepatic function. Nucynta™ should be used with caution in patients with moderate hepatic impairment.
- **Use in Pancreatic/Biliary Tract Disease-** Like other drugs with mu-opioid agonist activity, Nucynta™ may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis.

COMMON ADVERSE EFFECT

- ☑ Nausea
- ☑ Constipation
- ☑ Vomiting
- ☑ Dizziness
- ☑ Somnolence

LESS COMMON ADVERSE EFFECTS

- ☑ Pruritus
- ☑ Dry mouth
- ☑ Fatigue
- ☑ Anxiety
- ☑ Hyperhidrosis
- ☑ Insomnia
- ☑ Decreased Appetite
- ☑ Dyspepsia

PREGNANCY RISK CATEGORY C

DRUG INTERACTIONS

Nucynta™ is mainly metabolized by glucuronidation. The following substances have been included in a set of interaction studies without any clinically significant finding: acetaminophen, acetylsalicylic acid, naproxen and probenecid. The pharmacokinetics of tapentadol were not affected when gastric pH or gastrointestinal motility were increased by omeprazole and metoclopramide, respectively.

Patients receiving other opioid agonist analgesics, general anesthetics, phenothiazines, antiemetics, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with Nucynta™ may exhibit an additive CNS depression. Nucynta™ is contraindicated in patients who are receiving monoamine oxidase (MAO) inhibitors or who have taken them within the last 14 days due to potential additive effects on norepinephrine levels which may result in adverse cardiovascular events.

PATIENT INFORMATION

Use caution in driving, operating machinery, or doing other dangerous activities until you know how Nucynta™ affects you. Nucynta™ may impair your mental and physical abilities to perform these tasks.

Nucynta™ should not be taken with alcohol-containing beverages.

Clinical experience suggests that signs and symptoms of withdrawal may be reduced by tapering medication when discontinuing tapentadol therapy.

REFERENCE

*Adapted from: Nucynta(TM) (tapentadol) Product Information. PriCara. September 1, 2009.

ZAMICET™ PRODUCT DETAILS*

INDICATION

Zamicet™ is indicated for the relief of moderate to moderately severe pain.

DOSAGE FORMS

Solution containing 10mg of hydrocodone and 325mg of acetaminophen per 15mL

CONTRAINDICATIONS

Zamicet™ is also contraindicated in patients with known hypersensitivity to the drug or its ingredients. Cross-sensitivity may occur in patients known to be hypersensitive to other opioids.

WARNINGS

- **Respiratory Depression**: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Infants may have increased sensitivity to the respiratory depressant effects of opioids.
- **Head Injury and Increased Intracranial Pressure**: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure.
- **Acute Abdominal Conditions**: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
- **Misuse, Abuse and Diversion of Opioids**: Hydrocodone bitartrate oral solution contains hydrocodone, an opioid agonist, and is a Schedule III controlled substance. Opioid agonists have the potential for being abused and are sought by abusers and people with addiction disorders, and are subject to diversion.

PRECAUTIONS

- **Special Risk Patients**: As with any narcotic analgesic agent, hydrocodone bitartrate and acetaminophen oral solution should be used with caution in elderly or debilitated patients, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.
- **Pediatric Use**: Safety and effectiveness in the pediatric population below the age of two years have not been established.
- **Geriatric Use**: Clinical studies of hydrocodone bitartrate and acetaminophen oral solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

- **Cough Reflex**: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when hydrocodone bitartrate and acetaminophen oral solution is used postoperatively and in patients with pulmonary disease.

PREGNANCY RISK FACTOR C

- **Teratogenic Effects**: There are no adequate and well controlled studies in pregnant women. Hydrocodone bitartrate and acetaminophen oral solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nonteratogenic Effects**: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent.
- **Nursing Mothers**: Acetaminophen is excreted in breast milk in small amounts, but the significance of its effects on nursing infants is not known.

COMMON ADVERSE EFFECT

- ☑ Abdominal Pain
- ☑ Constipation
- ☑ Somnolence
- ☑ Nausea
- ☑ Dizziness
- ☑ Vomiting

LESS COMMON ADVERSE EFFECTS

- ☑ Anxiety
- ☑ Fatigue
- ☑ Dyspnea
- ☑ Hypotension
- ☑ Fear

DRUG INTERACTIONS

- Patients receiving narcotics, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with hydrocodone bitartrate and acetaminophen oral solution may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.
- The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

PATIENT INFORMATION

- To avoid a possible overdose, it is important that you do not take more than a single dosage at one time, or that you don't take doses at intervals less than 4 hours apart.
- Do not take this drug if you have allergies or unusual reactions to narcotic pain relievers or acetaminophen.

- Since a household teaspoon is not accurate and can be mixed-up with a tablespoon (which can cause overdosage), it is strongly recommended that you obtain and use a proper measuring device.

REFERENCE

*Adapted from: Zamicet(TM) (hydrocodone and acetaminophen) Product Information. Hawthorne Pharmaceuticals, Inc. September 1, 2009.

EMBEDA™ PRODUCT DETAILS*

INDICATION

Embeda™ is used in the management of moderate to severe pain when continuous pain management is needed for an extended amount of time.

DOSAGE FORMS

Capsules containing pellets of morphine sulfate with a sequestered core of naltrexone HCl: 20mg/0.8mg, 30mg/1.2 mg, 50mg/2mg, 60mg/2.4mg, 80mg/3.2mg, 100mg/4mg (morphine sulfate/naltrexone HCl)

CONTRAINDICATIONS

Embeda™ is contraindicated in patients with respiratory depression, acute or severe asthma, hypercarbia, or paralytic ileus. Embeda™ is also contraindicated in patients with known sensitivity to the drugs or its components.

PREGNANCY RISK FACTOR C

PRECAUTIONS

- **Respiratory distress** - Respiratory depression is the primary concern of opiates. Respiratory depression/distress is more likely to occur in patients with underlying respiratory disorders, and elderly or debilitated patients, usually following large initial doses in opioid non-tolerant patients, or when opioids are given in conjunction with other opiates or drugs that depress respiration.
- **CNS depression** – increased risk when used with other CNS depressants such as alcohol, narcotics, phenothiazines, sedative hypnotics, tranquilizers, and other opioids. Embeda™ may impair the ability to operate machinery or perform certain tasks such as driving.
- **Hypoventilation** – patients with preexisting medical conditions including COPD or other pulmonary disease. These patients are at increased risk of hypoventilation.
- **Intracranial CO2 retention** – Embeda™ should be used with extreme caution in patients who have evidence of increased intracranial pressure or impaired consciousness. Opioids may obscure the clinical course of a patient with a head injury and should be used only if clinically warranted.
- **Hypotension –** Embeda™ can cause severe hypotension and should be used with caution in patients in circulatory shock.
- **Hepatic** – half-life of Embeda™ was increased in patients with alcoholic cirrhosis.

- **Renal impairment** – AUC is increased and clearance is decreased in patients with renal insufficiency.
- **Physical dependence** - abrupt discontinuation may induce withdrawal symptoms: i.e., anxiety, sweating, nausea, diarrhea, tremors, insomnia, myalgia, and rhinorrhea.
- **Abuse, misuse and diversion** - Embeda™ is a C-II and may be subject to misuse, abuse, addiction, and criminal diversion. Embeda™ should be used with caution in patients with a history of drug abuse. Embeda™ is intended for use as an oral agent. Crushing or chewing pellets will result in uncontrolled release of both morphine and naltrexone. The presence of talc as an excipient will cause tissue necrosis when Embeda™ is used as an injection.
- **Abdominal conditions** - Embeda™ may cause constipation and nausea. Patients with paralytic ileus may experience bolus release when motility is restored. Diarrhea may cause decreased absorption. Embeda™ should be used with caution in patients with pancreatic/biliary tract disease.
- **Geriatric patients** - exercise caution when used in elderly patients.
- **Pediatric patients** – use has not been studied in patients under age of 18.

COMMON ADVERSE EFFECT

- ☑ Nausea
- ☑ Constipation
- ☑ Somnolence
- ☑ Dyspnea
- ☑ Vomiting
- ☑ Fatigue
- ☑ Dizziness
- ☑ Pruritis

LESS COMMON ADVERSE EFFECTS

- ☑ Dry mouth
- ☑ Anorexia
- ☑ Headache
- ☑ Flushing

DRUG INTERACTIONS

Use with other CNS may increase depressant effects including hypoventilation, hypotension, and profound sedation. Embeda™ may enhance the activity of skeletal muscle relaxants and result in increased respiratory depression. Use with MAOIs is not recommended. Patients who were previously taking MAOIs must undergo a 14-day washout before beginning Embeda™ to prevent severe and unpredictable reactions. There was an isolated incident of Cimetidine causing confusion and respiratory depression in a dialysis patient also taking Embeda™. Morphine can reduce the efficacy of diuretics. Use of Embeda™ with anti-cholinergics may lead to increased constipation which may result in paralytic ileus (see above).

PATIENT INFORMATION

- Patients should use caution in driving, operating machinery, or doing other dangerous activities until they know how Embeda™ affects them. Embeda™ may impair their mental and physical abilities to perform these tasks.
- Embeda™ should not be taken with alcohol-containing beverages.
- Embeda™ should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.
- Patients should tell their doctor if they have any trouble breathing while taking Embeda™.
- Embeda™ pellets should be swallowed whole. They should not be crushed or chewed. The capsules can be opened to sprinkle the pellets on applesauce.
- Patients should tell their doctor if they are experiencing breakthrough pain while taking Embeda™.
- Patients should not abruptly discontinue taking Embeda™.
- Patients should begin taking a stool softener and/or laxative while taking Embeda™.

REFERENCE

*Adapted from: Embeda™ (morphine sulfate/naltrexone HCl) Product Information. King Pharmaceuticals. September 1, 2009.

ONSOLIS™ PRODUCT DETAILS*

INDICATION

Onsolis™ (fentanyl) is an opioid indicated for the management of breakthrough pain in cancer patients over the age of 18.

DOSAGE FORMS

200 mcg, 400 mcg, 600 mcg, 800 mcg, and 1200 mcg buccal soluble film

CONTRAINDICATIONS

Onsolis™ is contraindicated in patients who are opioid naïve, who are experiencing pain due to acute or post-operative episodes, who are experiencing pain due to headache/migraine, or who have dental pain. Onsolis™ is also contraindicated in patients with known sensitivity to the drug or its components.

PREGNANCY RISK FACTOR C

PRECAUTIONS

- **Respiratory Depression** - Respiratory depression is the primary concern of opiates. Respiratory depression/distress is more likely to occur in patients with underlying respiratory disorders, and elderly or debilitated patients, usually following large initial doses in opioid non-tolerant patients, or when opioids are given in conjunction with other opiates or drugs that depress respiration.
- **Children** – Onsolis™ films can be fatal to children. Proper storage and disposal is crucial to preventing accidental ingestion by children.
- **CNS depression** – increased risk when used with other CNS depressants such as alcohol, narcotics, phenothiazines, sedative hypnotics, tranquilizers, and other opioids. Onsolis™ may impair the ability to operate machinery or perform certain tasks such as driving.
- **Hypoventilation** – patients with preexisting medical conditions including COPD or other pulmonary disease. These patients are at increased risk of hypoventilation.
- **Intracranial CO2 retention** – Onsolis™ should be used with extreme caution in patients who have evidence of increased intracranial pressure or impaired consciousness. Opioids may obscure the clinical course of a patient with a head injury and should be used only if clinically warranted.
- **Cardiac disease** – increased risk of bradycardia.
- **Hepatic & renal impairment** - Insufficient information exists to make recommendations regarding the use of Onsolis™ in patients with impaired renal or hepatic function. Fentanyl is

metabolized primarily via the CYP3A4 isoenzyme system and the inactive metabolite is mostly eliminated in urine. If the drug is used in these patients, it should be used with caution because of the hepatic metabolism and renal excretion of fentanyl.

- **Physical dependence -** Physical dependence is not ordinarily a concern when treating a patient with chronic cancer pain, and fear of tolerance and physical dependence should not deter using doses that adequately relieve the pain.
- **Abuse, misuse and diversion -** Onsolis™ is a C-II and may be subject to misuse, abuse and addiction.
- **Abdominal conditions -** Onsolis™ may cause constipation.
- **Geriatric patients** - exercise caution when individually titrating in elderly patients.

COMMON ADVERSE EFFECT

☑ Nausea
☑ Constipation
☑ Dizziness
☑ Somnolence
☑ Headache
☑ Vomiting
☑ Dehydration
☑ Dyspnea

LESS COMMON ADVERSE EFFECTS

☑ Dry mouth
☑ Fatigue
☑ Anorexia
☑ Insomnia
☑ Diarrhea
☑ Confusion
☑ Depression

DRUG INTERACTIONS

- Use with other CNS depressants or CYP3A4 inhibitors (e.g., indinavir, nelfinavir, ritonavir, clarithromycin, itraconazole, ketoconazole, nefazodone, saquinavir, telithromycin, aprepitant, diltiazem, erythromycin, fluconazole, grapefruit juice, verapamil, or cimetidine) may increase depressant effects including hypoventilation, hypotension, and profound sedation.
- CYP3A4 inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's wort, or troglitazone) may result in a decrease in fentanyl plasma concentrations.
- Use with MAOIs is not recommended. Patients who were previously taking MAOIs must undergo a 14-day washout before beginning Onsolis™ to prevent severe and unpredictable reactions.

PATIENT INFORMATION

- Use caution in driving, operating machinery, or doing other dangerous activit**ies until you know how Onsolis™** affects you. Onsolis™ may impair your mental and physical abilities to perform these tasks.
- Onsolis™ should not be taken with alcohol-containing beverages.
- Onsolis™ should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.
- Tell your doctor if you have any trouble breathing while taking Onsolis™.
- You will be enrolled in the FOCUS program and receive Onsolis™ from a special pharmacy

REFERENCE

*Adapted from: Onsolis™ (fentanyl buccal soluble film) Product Information. Aveva Drug Delivery Systems. September 1, 2009.

Appendix G

Prior Authorization Annual Review - Fiscal Year 2009
Synagis®

Oklahoma Health Care Authority

Definition of Prior Authorization Category for FY '09

Prior authorization is required for all members who receive Synagis® in an outpatient setting. Synagis® is approved for members who meet the established criteria based on the current American Academy of Pediatrics (AAP) guidelines.

Current Criteria for Prior Authorization of Synagis

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

1) Infants and children less than 24 months old with Chronic Lung Disease (CLD) (formerly bronchopulmonary dysplasia) who have required medical treatment (O_2, bronchodilator, corticosteroid, or diuretic therapy) for CLD in the 6 months prior to RSV season.
2) Infants less than 12 months of age, born at 28 weeks gestation or earlier
3) Infants less than 6 months of age, born at 29-31 weeks gestation.
4) Infants, up to 6 months old at the start of RSV season, born at 32-35 weeks gestation, who have 2 or more of the following risk factors:
    a. Child care attendance
    b. School-aged siblings
    c. Exposure to environmental air pollutants (Tobacco smoke exposure can be controlled by the family, therefore not a risk factor for Synagis prophylaxis)
    d. Congenital abnormalities of the airway
    e. Severe neuromuscular disease
5) Children up to 24 months old with hemodynamically significant cyanotic and acyanotic congenital heart disease.
6) Infants up to 12 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.

* Treatment should continue through the entire RSV season.

B. Length of treatment. Synagis® is approved for use only during RSV season, which is generally November 1 through April 30, as determined by Oklahoma State Dept. of Health. Approval dates will be October 15, 2008 through March 31, 2009

C. Units authorized. The maximum duration of therapy is six (6) doses, with a dose to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as one of the six.

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

Utilization

For the period of October 15, 2008 through March 31, 2009, a total of 942 SoonerCare members received Synagis® from a pharmacy provider or a physician's office.

RSV Season	Members	Claims	Cost	Total Doses	Cost/Dose	Units	Days
2007 - 08	718	3,395	$4,703,554.70	2,462	$1,899.70	2,940	101,858
2008 - 09	942*	4,838	$7,490,168.46	3,530	$2,121.86	4,243	142,367
Percent Change	**31.38%**	**42.96%**	**60.06%**	**43.38%**	**11.69%**	**44.32%**	**39.77%**
Change	**224**	**1,443**	**$2,786,613.76**	**1,068**	**$222.16**	**1,303**	**40,509**

*One member had pharmacy and outpatient claims

Claim type	EAC per vial/increment
Synagis® 50 mg/0.5 ml vial	$933.35
Synagis® 100 mg/ml vial	$1,762.43
Synagis® 50 mg increments - 90378	$881.21

EAC = Estimated Acquisition Cost

Pharmacy Claims

Product	# of Claims	Total Units	Total Days	Total Cost	Total Members
Synagis® 50 mg/0.5 ml vial	1,524	764	44,704	$1,420,133.28	653
Synagis® 100 mg/ml vial	3,298	3,452	97,183	$6,046,242.51	863
Total	**4,822**	**4,216**	**141,887**	**$7,466,375.79**	**936****

**Total unduplicated members for 08-09

Physician Office Claims – CPT code 90378

Product	# of Claims	Total Units	Total Days	Total Cost	Total Members
Synagis® 50 mg increments	16	27†	480	$23,792.67	7

† One unit = 0.5 mls

PA Activity

Total petitions - RSV Season 08-09

A total of 1,960 petitions were submitted for consideration of Synagis®.

Approved	1,051
Denied	402
Incomplete	507

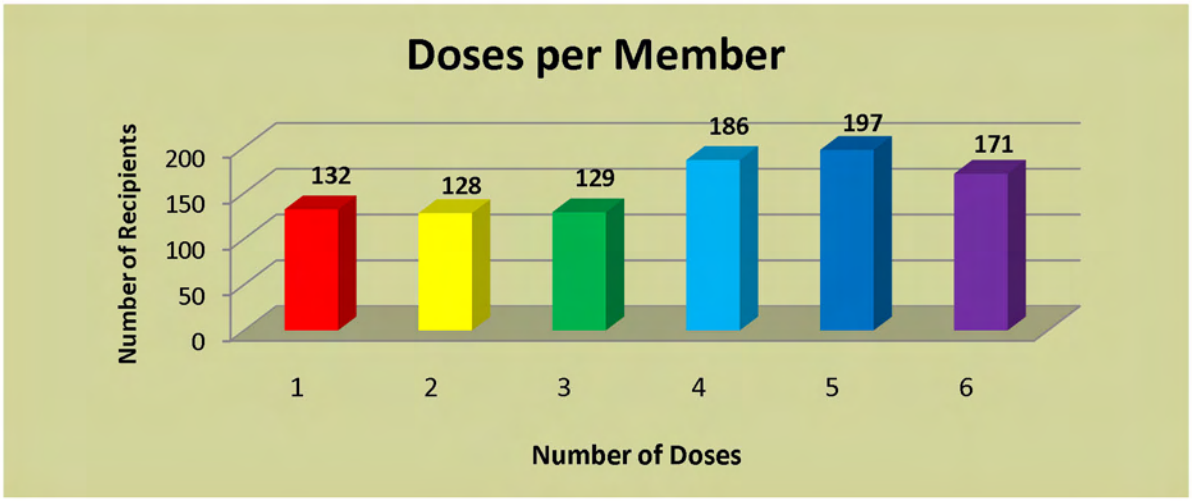
Demographics

Claims were reviewed to determine the age/gender of the members. The 2-year olds were under 24 months at the time of approval.

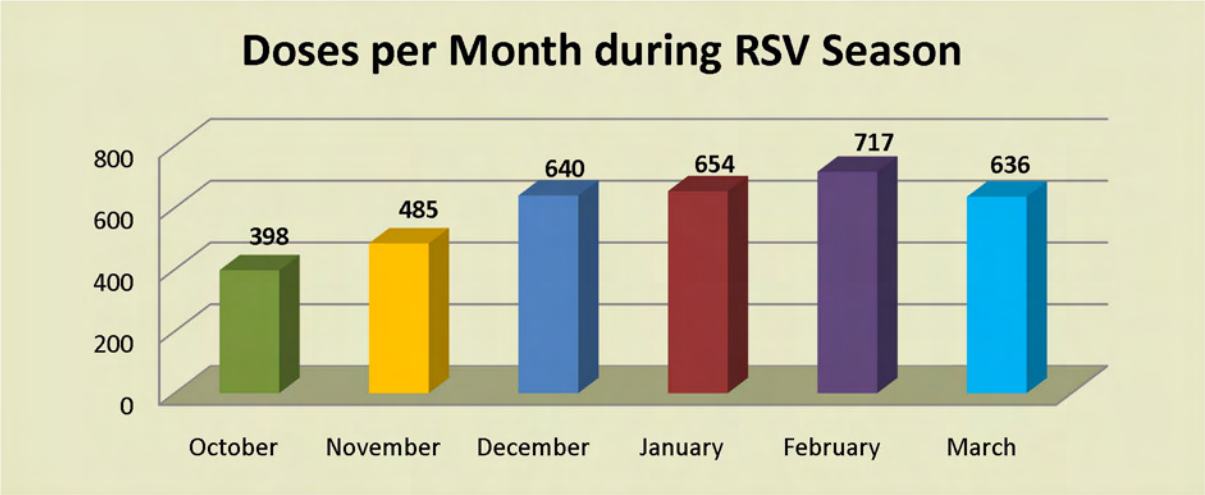
Age	Female	Male	Totals
0	392	445	837
1	53	46	99
2	4	2	6
Totals	**449**	**493**	**942**

Dose Data

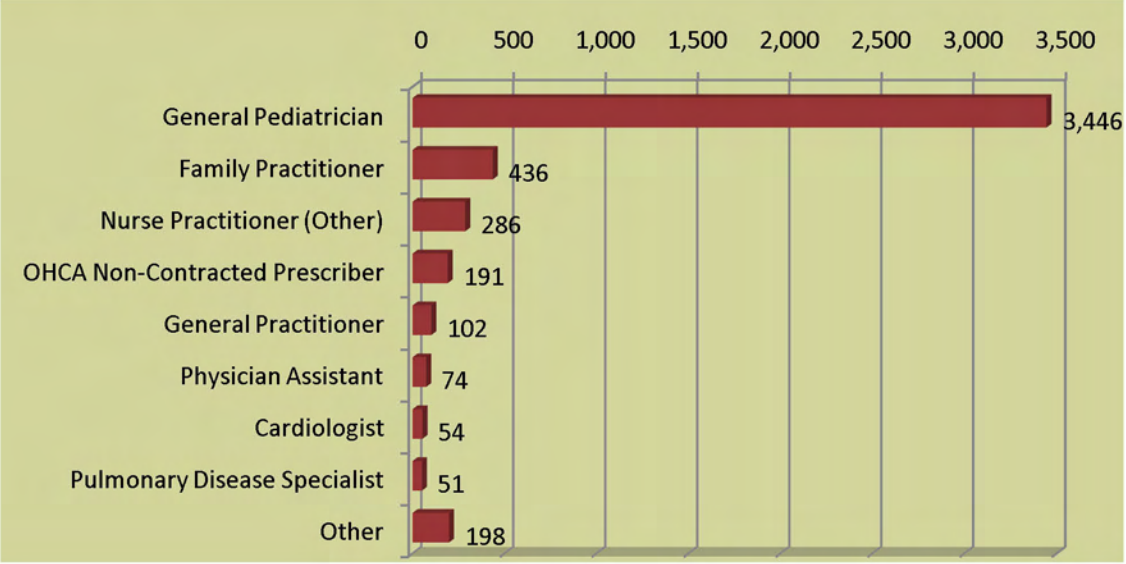
A total of **3,530 doses** were given through the season. The average cost per dose was **$2,121.86**. Synagis was limited to 6 doses for the season. None of the members had more than the six approved doses.



Dosing

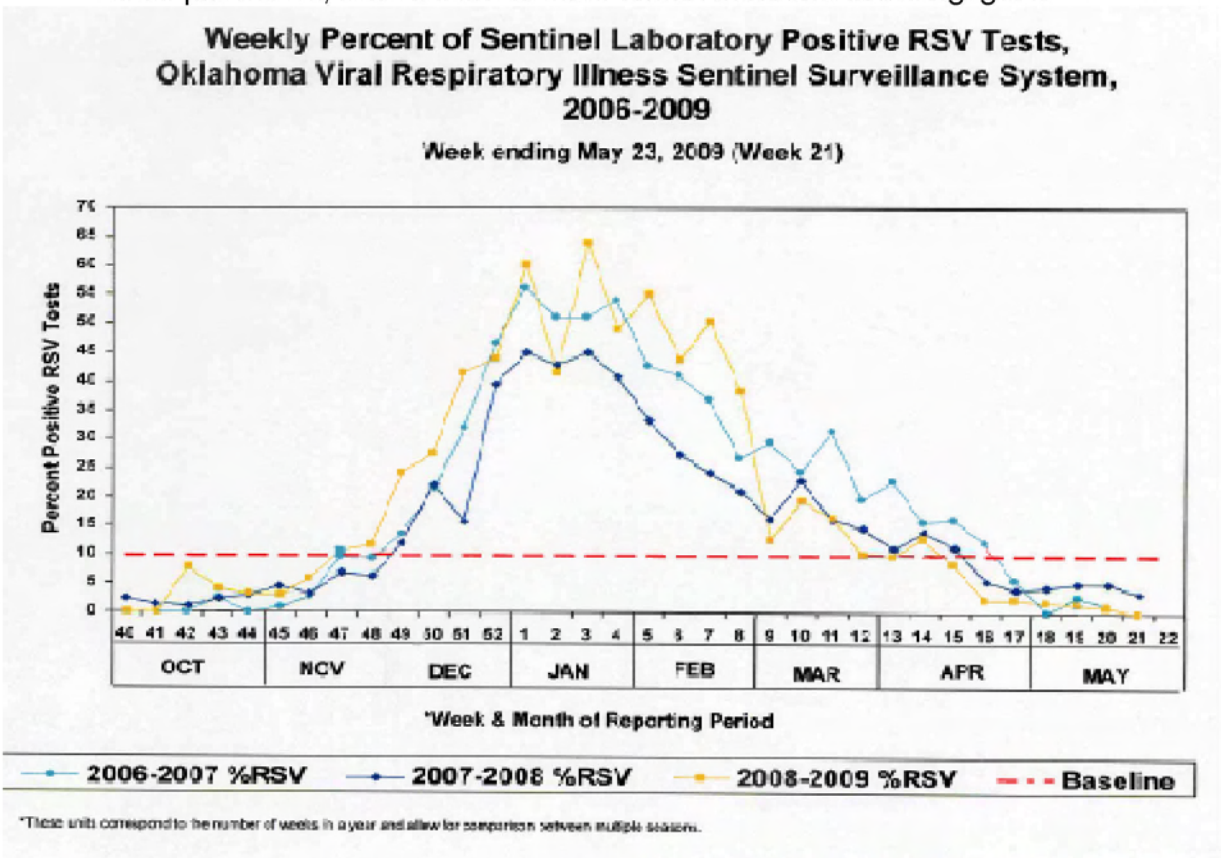


Prescriber Specialty



Discussion

- The 2008-09 RSV season (yellow line in graph below) did not reach the epidemic threshold until the end of November. After the peak in January, there was a gradual decline in cases into February, and then a rapid drop off of cases by the first of March. By the end of March the number of reported cases had decreased to the 10% threshold. After a slight increase in the first week of April, which corresponded to a cold snap, the incidence of RSV quickly dropped to near zero. Considering the increase in lab tests in May due to the H1N1 pandemic, the number of RSV cases detected was negligible.



From the Oklahoma State Health Department website: http://www.health.state.ok.us/program/cdd/flu

- The AAP's Committee on Infectious Diseases has updated the guidelines for immunoprophylaxis with palivizumab. These new guidelines have been published in the 2009 Red Book.

Recommendations

The College of Pharmacy recommends modification of the existing palivizumab authorization criteria in keeping w/ the updated guidelines.

Recommended Criteria for Prior Authorization of Synagis®

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

1) Infants and children less than 24 months old with Chronic Lung Disease (CLD) (formerly bronchopulmonary dysplasia) who have required medical treatment (O_2, bronchodilator, corticosteroid, or diuretic therapy) for CLD in the 6 months prior to RSV season.
2) Infants up to 24 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.
3) Infants less than 12 months of age, born at 28 weeks gestation or earlier
4) Infants less than 6 months of age, born at 29-31 weeks gestation.
5) Infants less than 12 months of age, born before 35 weeks gestation, with congenital abnormalities of the airway
6) Infants less than 12 months of age, born before 35 weeks gestation, with severe neuromuscular disease
7) Infants, up to 3 months old at the start of RSV season, born at 32-34 weeks gestation, who have one of the following risk factors: (up to three doses only)
    a. Child care attendance
    b. Siblings younger than 5 years of age

* Treatment should continue through the entire RSV season as indicated, except #7 (only up to 3 months of age).

B. Length of treatment. Synagis® is approved for use only during RSV season, which is generally November 15 through April 30, as determined by Oklahoma State Dept. of Health. Approval dates will be November 1 through March 31, 2009

C. Units authorized. The maximum duration of therapy is five (5) doses, with a dose to be administered no more often than every 30 days. Infants born at 32-34 weeks gestation will receive a maximum of three doses; prophylaxis to be administered only up to 3 months of age. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as one of the approved total.

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

Appendix H

Safety

Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Enbrel, Humira, Cimzia, and Simponi) August 2009

Audience: Rheumatologists, gastroenterologists, oncologists, dermatologists

[UPDATED 08/31/2009] Supplemental Q&As added

[Posted 08/04/2009] FDA notified healthcare professionals that it has completed its analysis of tumor necrosis factor (TNF) blockers and has concluded that there is an increased risk of lymphoma and other cancers associated with the use of these drugs in children and adolescents. This new safety information is now being added to the Boxed Warning for these products. FDA has also identified new safety information related to the occurrence of leukemia and new-onset psoriasis in patients treated with TNF blockers. The current prescribing information for TNF blockers does contain a warning for malignancies, but does not specifically mention leukemia. FDA is also requiring updates to the current Medication Guide to help patients understand the risks associated with TNF blocker therapy.

TNF blockers are approved for the treatment of one or more of a number of immune system diseases including juvenile idiopathic arthritis (JIA), rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ankylosing spondylitis.

Safety

Leukotriene Inhibitors: Montelukast (marketed as Singulair), Zafirlukast (marketed as Accolate), and Zileuton (marketed as Zyflo and Zyflo CR)

Audience: Pulmonology healthcare professionals

[UPDATED 08/28/2009] The June 12, 2009 Healthcare Professional Sheet has been updated.

FDA provided healthcare professionals with updated information on the original March 2008 early communication and January 2009 follow-up communication about the ongoing safety review for the leukotriene inhibitors, montelukast, zafirlukast and zileuton. Neuropsychiatric events have been reported in some patients taking montelukast (Singulair), zafirlukast (Accolate), and zileuton (Zyflo and Zyflo CR). FDA has requested that manufacturers include a precaution in the drug prescribing information (drug labeling). The reported neuropsychiatric events include postmarket cases of agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking and behavior (including suicide), and tremor. FDA recommends that:

- Patients and healthcare professionals should be aware of the potential for neuropsychiatric events with these medications.
- Patients should talk with their healthcare providers if these events occur.
- Healthcare professionals should consider discontinuing these medications if patients develop neuropsychiatric symptoms.

Safety

Orlistat (marketed as Alli and Xenical): Early Communication about an Ongoing Safety Review

Audience: Endocrinological healthcare professionals, patients

FDA notified healthcare professionals and patients that it is reviewing new safety information regarding reports of liver-related adverse events in patients taking orlistat. Orlistat is marketed in the United States as a prescription product, Xenical, and as an over-the-counter (OTC) product, Alli. Between 1999 and October 2008, 32 reports of serious liver injury, including 6 cases of liver failure, in patients using orlistat were submitted to FDA's Adverse Event Reporting System. The most commonly reported adverse events described in the 32 reports of serious liver injury were jaundice, weakness, and abdominal pain. FDA is reviewing other data on suspected cases of liver injury submitted by the manufacturers of orlistat, analysis of these data is ongoing and no definite association between liver injury and orlistat has been established at this time. FDA is not advising healthcare professionals to change their prescribing practices with orlistat. Consumers currently taking Xenical should continue to take it as prescribed and those using over-the-counter Alli should continue to use the product as directed.

FDA urges both healthcare professionals and consumers to report side effects from the use of orlistat (Alli and Xenical) to FDA's MedWatch Adverse Event Reporting program.

Safety

CellCept (mycophenolate mofetil) August 2009

Audience: Renal, cardiac, and hepatic transplantation healthcare professionals

[Posted 08/14/2009] Roche notified healthcare professionals that cases of Pure Red Cell Aplasia (PRCA) have been reported in patients treated with CellCept. The WARNINGS and ADVERSE REACTIONS sections of the CellCept Prescribing Information have been revised to reflect this new safety information.

PRCA is a type of anemia in which there is a selective reduction of red blood cell precursors on bone marrow examination. Patients with PRCA may present with fatigue, lethargy, and/or abnormal paleness of the skin (pallor). In some cases, PRCA was found to be reversible with dose reduction or cessation of CellCept therapy. In transplant patients, however, reduced immunosuppression may place the graft at risk.

Oklahoma

2008

Statewide Offices
McAlester—918-426-5020
Oklahoma City—405-475-7500
Tulsa—918-459-9600

State Facts	2008 Federal Drug Seizures
Population:3,617,316	**Cocaine:** 51.6 kgs.
State Prison Population:24,245	**Heroin:** 6.7 kgs.
Probation Population:27,737	**Methamphetamine:** 21.0 kgs.
Violent Crime Rate	**Marijuana:** 321.9 kgs.
National Ranking: 14	**Hashish:** 0.0 kgs.
	MDMA: 0.0 kgs./736 du
	Meth Lab Incidents: 102 (DEA, state, and local)

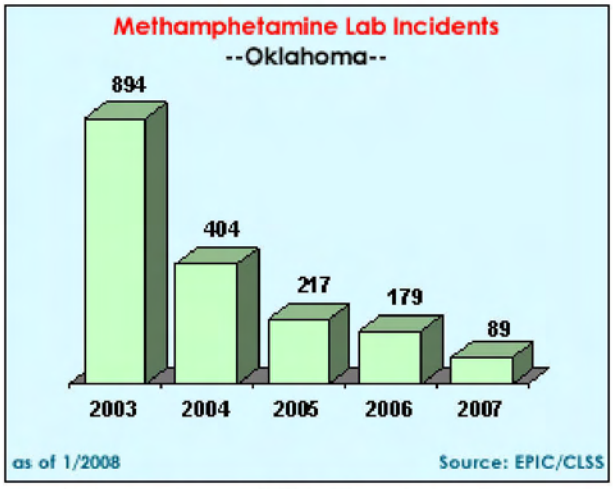
Sources

Drug Situation: Methamphetamine, particularly crystal methamphetamine, which is produced in Mexico and the Southwest United States, remains the principal drug of concern in the State of Oklahoma. Cocaine, particularly crack cocaine, is a significant problem in the urban areas of the state. Oklahoma also serves as a transshipment point for drugs being transported to the eastern United States via Interstates 40 and 44. Interstate 35 also provides a critical north-south transportation avenue for drug traffickers.

Cocaine: Cocaine continues to be readily available throughout Oklahoma. The cocaine is transported from Texas and Mexico via commercial airlines and motor vehicles. Mexican poly-drug traffickers dealing in marijuana and methamphetamine bring some of the cocaine into the state. Some of the cocaine HCl is converted into crack cocaine for sale at the retail level. The majority of the cocaine purchased in the Oklahoma City area is transported in by local suppliers who travel to south Texas and Mexico return to distribute the product.

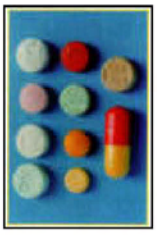
Heroin: Black Tar heroin is available in limited quantities near the metropolitan areas in Oklahoma. It is rare to encounter brown or Colombian white heroin. Demand for heroin has declined in recent years. The majority of heroin traffickers in Oklahoma receive their heroin from Mexico. Most of the heroin transported into Oklahoma is concealed in hidden compartments in passenger vehicles.

Methamphetamine: Methamphetamine from Mexico continues to be the primary drug of choice in Oklahoma, particularly the solid form (crystal) of methamphetamine has become more prevalent. Most of the methamphetamine in the state is brought in by Hispanic organizations via motor vehicles. An increase in the amount of crystal methamphetamine has been seen over the past two years.



The number of local small “mom and pop” laboratories has declined significantly over the last two years. This decline is due primarily to the passage of Pseudoephedrine Control Laws in mid-2004. Since these laws were passed, the number of labs seized has decreased by approximately 90% in the State of

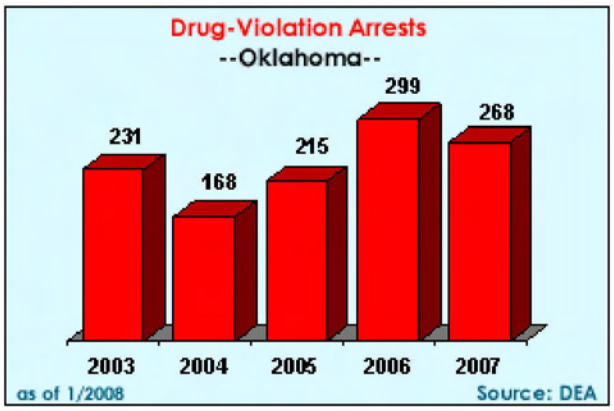
Oklahoma. Over 90% of the labs seized since 2004 are non-operational: either a dumpsite or glassware only.



Club Drugs: The majority of the MDMA seen in Oklahoma comes from the West Coast, Nevada, and Texas. A small number of seizures have involved MDMA originating in Canada.

Marijuana: Marijuana is readily available in all areas of Oklahoma. Marijuana imported from Mexico is prevalent and is usually imported in combination with other illegal drugs being transported to Oklahoma and other states north and east. The majority of the marijuana is imported from the southwest border via passenger vehicle and occasionally in freight vehicles. Mexican "Sensimilla", usually found in "pressed/brick" form, is the most common type of marijuana seen in Oklahoma, particularly in urban areas. Domestically produced marijuana is also available in Oklahoma, though not as readily in recent years.

Other Drugs: The most popular pharmaceutical substances abused /diverted in Oklahoma are hydrocodone products. Oxycodone products as well as alprazolam, and phentermine are also often abused/diverted. Methadone is a pharmaceutical drug of abuse on the rise in Oklahoma. Much of the diversion is through indiscriminate prescribing by physicians , unscrupulous pharmacists, the passing of fraudulent prescriptions, doctor shopping, pharmacy break-ins, and hospital thefts.



Pharmaceutical Diversion: Current investigations indicate that diversion of hydrocodone products continues to be the most common drug of abuse/diversion. As indicated above, the primary methods of diversion are indiscriminate prescribing (Physicians issuing prescriptions for controlled substances without a legitimate medical need), pharmacists diverting controlled substances from pharmacies, "doctor shopping" (going to multiple physicians to obtain prescriptions for a controlled pharmaceutical), forged /falsified prescriptions, and thefts. Methadone has recently been identified as a growing abuse problem in Oklahoma .

DEA Mobile Enforcement Teams: This cooperative program with state and local law enforcement counterparts was conceived in 1995 in response to the overwhelming problem of drug-related violent crime in towns and cities across the nation. Since the inception of the MET Program, 473 deployments have been completed nationwide, resulting in 19,643 arrests. There have been six MET deployments in the State of Oklahoma since the inception of the program. In March 2005, the METs prioritized investigations to target and dismantle methamphetamine trafficking organizations and clandestine laboratory operators. At least five of the MET deployments targeted methamphetamine trafficking organizations.

Other Enforcement Operations: The number of Operation Pipeline interdictions is increasing within the state of Oklahoma. California, Arizona, New Mexico, and Texas are most often reported as the domestic states of origin. Since the state of Oklahoma is traversed by numerous Interstate Highways, interdictions are common in all areas. Seizures of illicit drugs traveling through Oklahoma en route to their destinations north and east are routine, as well as seizures of large amounts of currency en route to the west and southwest border states.

DEA Regional Enforcement Teams: This program was designed to augment existing DEA division resources by targeting drug organizations operating in the United States where there is a

lack of sufficient local drug law enforcement. This program was conceived in 1999 in response to the threat posed by drug trafficking organizations that have established networks of cells to conduct drug trafficking operations in smaller, non-traditional trafficking locations in the United States. As of January 31, 2005, there have been 27 deployments nationwide, and one deployment in the U.S. Virgin Islands, resulting in 671 arrests. There has been one RET deployment in the State of Oklahoma since the inception of the program, in McAlester.

Drug Courts/Treatment Centers: There are currently Twenty-two drug courts operating in the state of Oklahoma with eleven more in the planning stages.

According to the Oklahoma Department of Mental Health and Substance Abuse Services, there are currently 148 drug and alcohol treatment centers operating in the state of Oklahoma.

Current Laws Regarding Criminal Sanctions and Precursor Chemicals: Over the past several years, the Oklahoma Legislature has passed numerous laws regarding methamphetamine and its precursor chemicals. These include additional penalties for manufacturing methamphetamine in the presence of minors; possessing or distributing methamphetamine in the vicinity of schools, public parks, public pools or on a marked school bus; and for tampering with anhydrous ammonia equipment. Any possession of anhydrous ammonia in unapproved containers is considered prima facie evidence of manufacture. Any possession of three (3) ingredients such as iodine, red phosphorous and ether is considered prima facie evidence of intent to manufacture methamphetamine. The average lab manufacturing sentence in the state is approximately 20 years. House Bill 2316 passed both the Oklahoma House and Senate in May 2002 and went in to effect on July 1, 2002. This new law puts a 24 gram limit on all cold medicines containing pseudoephedrine or ephedrine. The charge carries a five year maximum sentence. If a retailer knowingly distributes pseudoephedrine, ephedrine, or phenylpropanolamine with the knowledge that it will be used to manufacture methamphetamine, the sentence carries a maximum of ten years incarceration. House Bill 1326, effective July 1, 2003 requires state registration (mirroring Federal Law) for the handling/distribution of products containing Pseudoephedrine at both the wholesale and retail levels. Ephedrine has been a Schedule IV controlled substance in the State of Oklahoma since 1996.

House Bill 2176, signed into law in April 2004, made all hard tablet Pseudoephedrine a Schedule V controlled substance in Oklahoma. Products in the form of gel capsules, liquid capsules, and/or liquid preparations are exempt. Hard tablet form may be dispensed by a licensed Oklahoma pharmacist or technician without a prescription to a consumer provided that such dispensing does not exceed nine grams of pseudoephedrine in any 30 day period. Also, a signature in a record book and an identification card with photo is required of all persons who purchase, receive, or otherwise acquire pseudoephedrine tablets.

The "Combat Methamphetamine Epidemic Act of 2005" (CMEA) - The CMEA was signed into law on March 9, 2006 to regulate, among other things, retail over-the-counter sales of ephedrine, pseudoephedrine, and phenylpropanolamine products. Retail provisions of the CMEA include daily sales limits and 30-day purchase limits, placement of product out of direct customer access, sales logbooks, customer ID verification, employee training, and self-certification of regulated sellers.

New Legislation: The Oklahoma Taxpayer and Citizen Protection Act of 2007 [HB 1804 text, DOC] denies illegal immigrants state identification, and requires all state and local agencies to verify citizenship status of applicants before authorizing benefits. The law also requires public employers to enter job applicants into an electronic immigration database to verify legal status.

Among other things, it contains employment, labor law and civil rights provisions to protect citizens and legal immigrants who lose their jobs at companies that employ illegal immigrants to perform the same or similar work. The measure targets employers who knowingly hire illegal aliens in order to gain a competitive advantage. Key elements of the bill focus on determining worker eligibility, including technology called the Basic Pilot program, which screens Social Security numbers to make sure they are real and that they match up with the job applicant's name. Created by the federal government to verify the eligibility of government employees, use of

the program is mandated in Georgia, authorities said. It is free to employers who voluntarily sign up. Public agencies will be required to use the program beginning Nov. 1 and private companies by July 1, 2008. The measure would also limit state driver's licenses and identity cards to citizens and legal immigrants and would require state and local agencies to verify the citizenship and immigration status of applicants for state or local benefits. It also retains an in-state tuition program for children of illegal immigrants attending state colleges and universities. The measure now allows students to continue paying in-state tuition but new applicants must apply for citizenship within one year. The measure would not affect emergency medical and humanitarian services, such as visits to hospital emergency rooms and enrollment in public schools that are required by federal law.