Drug Utilization Review Board

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

Wednesday
February 10, 2010
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 – February 10, 2010**

DATE: February 4, 2010

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

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

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Antipsychotics – See Appendix C.

Action Item – Vote to Prior Authorize Zipsor™, Cambia™, and Update NSAID PBPA Criteria and 30 Day Notice to Prior Authorize Pennsaid® – See Appendix D.

Action Item – Vote to Prior Authorize Ribavirin Capsules, Solution, and Dose Packs – See Appendix E.

30 Day Notice to Prior Authorize Twynsta® – See Appendix F.

FDA and DEA Updates – See Appendix G.

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – February 10, 2010 @ 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. January 13, 2010 DUR Minutes – Vote

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 September 2009
B. Medication Coverage Activity Audit for January 2010
C. Help Desk Activity Audit for January 2010

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

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

A. COP Recommendations
B. Second Opinion Process
C. Continuous Use Questionnaire Process

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

6. Action Item – Vote to Prior Authorize Zipsor™, Cambia™, and to Update NSAID PBPA Criteria and 30 Day Notice to Prior Authorize Pennsaid® – See Appendix D.

A. COP Recommendations

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

7. Action Item – Vote to Prior Authorize Ribavirin Capsules, Solution, and Dose Packs – See Appendix E.

A. COP Recommendations

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

8. 30 Day Notice to Prior Authorize Twynsta® – See Appendix F.

A. Product Summary
B. COP Recommendations

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

9. FDA and DEA Updates – See Appendix G.

10. Future Business

A. Anxiolytic Criteria Review
B. Annual Review of Smoking Cessation Products
C. Annual Review of HFA Products
D. Annual Review of Growth Hormones
E. New Product Reviews

11. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JANUARY 13, 2010

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, MHS, PA-C	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	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Visiting Pharmacy Student(s): Cory Beck, Krystin Bruehl, Rachel Young	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:

Evan Leonard, AstraZeneca	Jim Graham, Ortho McNeill Janssen	Peter Dorson, OMJSA
Craig Turner, Merck	John Seidenberger, Boehringer Ingelheim	Lon Lowrey, Novartis
Linda Canto, BMS	Richard Ponder, J&J	Charlene Kaiser, Amgen
Paul Davis, MHAT	Steve Erby, Novartis	Ben Lehr, Alcon
Dennis & Karen Graham, NAMI/parents	Pat Trahan, Taro Pharmaceuticals	Tim Farley, Pfizer
Michael Hathaway, Otsuka	Donna Parker, Stepping Stones	Lisa Sherman, Strativa
Janie Huff, Takeda	John Omick, Novartis	Brian Marcum, NAMI/Tulsa
Jim Fowler, AstraZeneca	Toby Thompson, Pfizer	James Jansen, Pfizer
Monica Kuykendall, citizen	Aaron Mays, Alcon	Jim Turner, Astellas
Jim Dunlap, Lilly USA	Mario Munoz, Lilly USA	
Robert Vlk, Azur	David Williams, Forest	

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 5	Dann Huffman, AstraZeneca; Michael McGuire; Bristol-Myers Squibb; Valerie Pennington, Novartis; Jinneh Dyson, NAMI; Maria M. Kane, M.D., Psychiatrist; Cameo Hughes, Stepping Stones
Agenda Item No. 7	Gary Dickinson, Xanadyne

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.

Agenda Item No. 5: Dann Huffman, AstraZeneca; Michael McGuire; Bristol-Myers Squibb; Valerie Pennington, Novartis; Jinneh Dyson, NAMI; Maria M. Kane, M.D., Psychiatrist; Cameo Hughes, Stepping Stones

Agenda Item No. 7: Gary Dickinson, Xanadyne

ACTION: NONE REQUIRED

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

3A: December 9, 2009 DUR Minutes

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON DUR/MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: Medication Coverage Activity Audit: December 2009

4B: Help Desk Activity Audit: December 2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **30-DAY NOTICE TO PRIOR AUTHORIZE ANTIPSYCHOTICS**

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

Board members discussed criteria and PA approval issues.

For Public Comment: Dann Huffman, AstraZeneca: Thank you. I appreciate the opportunity to address this group and I need to make you aware that due to several of the recent developments within our industry, that the remarks that I'll provide for this organization board tonight, I hope are helpful, but they have been scripted and exquisitely looked at all the way up through legal, and so that may explain some of the rigidity at times of the information I'm presenting relative to what you may be interested in. So that, I realize I've got a few minutes here. I'm going to read some prepared remarks and then I'd welcome any questions that you might have relative to Seroquel and Seroquel extended release based on that. And with that, my name is Dann Huffman. I'm the regional scientific manager in the CNS area with AstraZeneca and I'd like to highlight some of the key points for Seroquel XR and Seroquel as you would make considerations that do involve that product, or those products. Seroquel extended release, or Seroquel XR is FDA approved as adjunctive treatment to antidepressants in adults with major depressive disorder, MDD if you will, based on two 6-week efficacy trials in adults with MDD who'd had an inadequate response to antidepressant treatment. For Seroquel XR, the formulation releases drug predominantly via an erosion control over a day with plasma levels peaking at approximately six hours. It offers once-a-day dosing for all approved indications. For MDD, dosing involves 50 mg once daily in the evening and then the dose can be increased to 150 mg by day three, and subsequently adjusted within the recommended dosing range for MDD of 150 to 300 mg daily. Seroquel XR is the only medication its' class that's approved by the FDA to treat both major depressive as adjunctive therapy and acute depressive episodes associated with bipolar disorder as monotherapy. Also Seroquel, the immediate release formulation, is now approved for the treatment of schizophrenia in adolescents age 13 to 17 years of age as monotherapy and for the acute treatment of manic episodes and bipolar I disorder in children and adolescents ages 10 to 17, both as monotherapy and as an adjunct to lithium or divalproex. Seroquel should be administered to children and adolescents twice daily, however, it can be administered up to three times daily where needed. The total daily dose for initial five days with Seroquel in this population is 50 mg day one, 100 mg day two, 200 mg day three, 300 day four, and 400 mg day five. Recommended daily therapeutic ranges in this population are 400 to 800 mg for schizophrenia and 400 to 600 mg for bipolar I disorder. And as I said, please bear with me. The prescribing information for Seroquel and Seroquel XR contained the following box warnings: "Elderly Patients With Dementia-Related Psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Seroquel and Seroquel XR are not approved for this treatment of these patients with dementia- related psychosis. Antidepressants have increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders Seroquel is not approved for use in patients under the age of 10 years of age. Seroquel XR is not approved for use in pediatric patients. The prescribing information for Seroquel and Seroquel XR includes warnings and precautions for neuroleptic malignant syndrome, hyperglycemia, diabetes mellitus, hyperlipidemia, weight gain, leukopenia, neutropenia, agranulocytosis. Warnings and precautions also include the risk of orthostatic hypotension, cataracts, seizures,

hyperprolactinemia and dysphasia. The prescribing information also includes a warning and precaution regarding increases in blood pressure in children and adolescents. The most commonly observed adverse reactions associated with the use of Seroquel XR and Seroquel in adults were somnolence, dry mouth, dizziness, constipation, increased appetite, dysthymia, abdominal pain, postural hypotension, dyspepsia, weight gain, fatigue, pharyngitis, lethargy, ALT increases, dysarthria and also nasal congestion. And most commonly observed adverse reactions associated with the use of Seroquel in children and adolescents are somnolence, dizziness, fatigue, increased appetite, nausea, vomiting, dry mouth, tachycardia and weight gain. Thank you. Those are the prepared remarks. Are there any questions relative to this data or other information you'd like to ask?
Dr. Muchmore: Are the children indications recent?
Mr. Huffman: The children indications, I believe, are December 4th. I say, I believe, the 3rd or the 4th from the FDA, based on data submitted several months previous to that, yes.
Dr. Muchmore: I wasn't aware of those.
Mr. Huffman: Yes. Any others?
Member of Audience: What is your monotherapy? I think what you used (unintelligible) what you said ……..
Mr. Huffman: I apologize … what's ……
Member of Audience: Mono ……. you said monotherapy, I think?
Mr. Huffman: There are uses of monotherapy for Seroquel XR as well as Seroquel and let me just ask the Board to be frank with you. Is it okay if I answer a question from the audience, or, I'm not sure of your point ma'am.
Dr. Muchmore: Sure, go ahead.
Mr. Huffman: So for example in the case of schizophrenia, montherapy with Seroquel or Seroquel XR. In the case of bipolar mania, monotherapy with Seroquel or Seroquel XR, but there's also adjunct, additional lithium or depakote studies that have been done with both of those indications.
Dr. Muchmore: What he means by monotherapy is the only drug, rather than a combination of drugs that also has to be used.
Mr. Huffman: Yes, I'm sorry if I didn't make that clear in my remarks, but exactly. So no other drug except that drug appropriate for those. With the side effect burden that's ……
Dr. Muchmore: Okay, we have a lot of speakers to get through. Are there any more questions for Mr. Huffman. Okay, thank you sir. The next one is Michael McGuire from Bristol-Myers Squibb.
For Public Comment: Michael McGuire; Bristol-Myers Squibb: Good evening. Thanks for the opportunity to speak to you tonight. Again, my name is Dr. Michael McGuire. I'm a senior medical science liason Bristol-Myers Squibb. Again, thanks for the opportunity to speak to you about Abilify. Abilify has fourteen FDA approved indications. The first is for treatment of schizophrenia in adults and adolescents ages 13 to 17; acute and maintenance treatment of bipolar disorder, manic episodes in adult and adolescents aged 10 to 17, as an adjunct antidepressant in major depressive disorder, patients who have had inadequate response to an antidepressant. It's also indicated for irritability and autistic disorder, and that's in children ages 6 to 17 years of age, and it has an intramuscular formulation for the treatment of agitation in patients with schizophrenia or bipolar, or one manic or mixed episodes. Now according to Surveillance Data Inc**.,** 75% of aripiprazole prescriptions are for FDA approved indications. So I wanted to expand upon the pediatric information. In adolescent schizophrenia, there were 302 adolescents in that trial, again ages 13 to 17. We evaluated 10 or 30 mg versus placebo and both doses were superior to placebo in the primary endpoint. The most common adverse events included extrapyramidal disorder, somnolence and tremor. In pediatric bipolar disorder, there was a 4-week trial with a total of 296 pediatric patients, ages 10 to 17. Again, 10 or 30 mg per day. Both doses were superior to placebo. The most common adverse events included somnolence, extrapyramidal disorder, fatigue, nausea, blurred vision, salivary hypersecretion and dizziness. And then most recently, irritability and autistic disorder. There were two trials for that indication. One was a flexibly dosed trial of 2 to 15 mg per day. That included 98 children. And the other trial was a fixed dose study of 5, 10 or 15 mg. That included 218 children, all again 6 to 17 years of age and both of those were positive on the primary endpoint. Most common adverse events, I'm going to read these; sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder and lethargy. So overall, in these trials, the aripiprazole was safe, the most tolerated. There were no clinically significant differences versus placebo on that body of parameters. There is a statement in the label that talks about special consideration in pediatric patients. It says that there needs to be a thorough diagnostic evaluation as well as just a consideration of the risk and benefits in that population and medication should be part of an overall treatment program that not only includes medication, but also psychological education on it and social interventions. Now there's a couple of pharmacoeconomic evaluations I wanted to share with you. One was a recent retrospective claims database analysis that looked at patients with bioplar disorder who are on a mood stabilizer as well as an atypical antipsychotic. It evaluated time to psychiatric rehospitalization and 90-day follow-up period. In that trial aripriprazole had a longer time to rehospitalization as well as lower psychiatric and overall total healthcare costs, relative to the other atypicals. Bettinger and collegues from the University of Texas conducted an independent analysis of five atypicals, risperidone, olanzapine, quetiapine, ziprasidone and aripiprazole, and the rated efficacy, cost, adverse events and adherence to generate a utility score, and in their model, in their analysis, aripiprazole had the highest utility score. Regarding its' mechanism of action, it is unique within the class, within the atypical antipsychotics. It's the first and only dopamine partial agonist. It's a partial agonist at dopamine type 2 and type 3 receptors, as well as partial agonist against serotonin 1-A receptors. It's an agonist against serotonin 2-A receptors. In fair balance, there's two boxed warnings, my colleague spoke to those. Those apply for aripiprazole as well. Increased mortality in elderly patients with dementia-related psychosis, aripiprazole is not indicated in that population, as well as suicidality in antidepressant drugs. It's indicated as an adjunct in that population. We know that antidepressants have a risk of suicidal thinking and behavior. Again, aripiprazole is not indicated in pediatric patients with depression. So I do have a couple of copies of the PI if anybody would like one and they're also available on abilify.com. So in closing, aripiprazole has the broadest range of indications across both adult and pediatric populations and it's one of only two with FDA approvals in youth. So I respectfully ask that aripiprazole

remain available as a first-line agent and that open access to all the atypicals be preserved in the State of Oklahoma. Any questions?
Dr. Muchmore: Do they give you a figure on the incidence of hyperprolactinemia with aripiprazole?
Dr. McGuire: Yeah, the incidence of hyperprolactinemia is actually very low because of the …….
Dr. Muchmore: I just wondered if you had a figure of what they're quoting.
Dr. McGuire: I don't know the exact number off the top of my head. It's low because it of the, because of the intrinsic activity of the drug and dopamine receptors. What we actually see is a reduction in proactin levels. So actually some of our trials have seen hypoprolactinemia. We do see that though and especially if someone is switched from something that's a dopamine antagonist, we see proactin levels actually trimmed down.
Dr. Muchmore: Any other questions for Dr. McGuire? We have question here.
Member of the Audience: Well I'm not sure if this is the appropriate time. I have a question for the Board and I didn't get an agenda, so, will you take a question?
Dr. Muchmore: Yeah, go ahead and ask your question.
Member of the Audience: If, you know, the idea of doing away with somebody's antipsychotic medications and using some of the older generation now is to save money, I don't understand why your Board doesn't go negotiated drug companies, sort of like the V.A. does, to get a cheaper price and you wouldn't have to approve them.
Dr. Muchmore: They're all given that opportunity to negotiate and some of them do.
Member of the Audience: I don't know that you get the kind of results that the V.A. does or if you imported from Canada, but I know that we can turn a huge savings, I promise. Take my word for it.
Dr. Muchmore: The next speaker is Valerie Pennington from Novartis. For the interest of those who have attended and asked questions, the purpose of the Board is to do our dead level best to see that everybody that needs particular medications gets them without totally busting the budget with casual use, sleeping use, non-indicated use of these expensive medications.
For Public Comment: Valerie Pennington, Novartis: Good evening. Thank you very much for allowing me to present to you this evening. I am a pharmacist with the neuroscience group for Novartis. And I'm here tonight to present you with information about iloperidone which is our new atypical antipsychotic that has recently been approved for the acute treatment of schizophrenia in adult patients only. Iloperidone is a dual antagonist, as most of the atypicals are at the dopamine$_2$ and the 5-HT$_{2A}$ receptors with a greater affinity for 5-HT$_{2A}$. It does have have some alpha adronergic effects as well, with no appreciable muscarinic effects. It is formulated as an oral tablet formulation and it's recommended to be started at a 1 mg BID dose, and then it can be titrated daily to a target range of 12 to 24 mg per day. It is metabolized by the hepatic P-450 system, enzyme groups 2D6 and 3A4, and it can be given without regard to meals. With regard to efficacy studies, it has now been studied in greater than 3,200 patients overall. There are two phase III clinical studies that appear in the product labeling. Both are short-term studies, one being a 6-week and one being a 4-week study in adult patients who met DSM criteria for schizophrenia. The primary endpoint for these studies was change from baseline in the BPRS total score or the the PANSS total score, and in both studies, there were iloperidone arms as well as active comparator and then placebo arms. In both studies, iloperidone was shown to be superior to placebo on the primary endpoint, pre-specified primary endpoint, so both studies didn't meet that primary endpoint, so with regard to efficacy, those are the two that appear in the labeling. With regard to adverse effects that occurred in greater than or equal to 5% or two times placebo, dizziness, dry mouth, somnolence, fatigue, orthostatic hypotension, tachycardia and weight gain were the primary things that were seen. And then in terms of other safety related things with iloperidone, iloperidone has been shown to prolong the QTC interval by approximately nine milliseconds; however, throughout the clinical development program, there were no episodes of torsades or other cardiac arrhythmias that were seen. With regard to metabolic effects, they were similar to placebo overall. The weight gain was modest at approximately an average of five pounds overall and we have data out to two years with regard to weight gain. With regard to laboratory abnormalities, they were very similar to placebo overall, with regard to chemistries including glucose and then hematologic and urinalysis. Additionally, there were no medically important changes seen in cholesterol, prolactin levels or triglyceride levels. So overall, that tells you what the safety profile looks like and the labeling includes similar warnings to the other atypical agents with regard to tardive dyskinesia, EPS, NMS, etc., I'm sorry, not EPS but neuromuscular malignant syndrome. So overall the agent has been shown to be efficacious in clinical studies against both the positive and negative symptoms of schizophrenia. It has a favorable safety profile with a low incidence of EPS and akathisia and metabolic profile as well. The weight gain is modest with this agent in comparison to other agents. The discontinuations in clinical studies were similar to placebo and so the adherence level is similar to placebo from what we've seen so far and basically it represents an additional treatment option for adult schizophrenic patients, a population that require individualized therapy and multiple options available to them so that they can be treated effectively. And so I will, with that, conclude and answer any questions that you might have.
Dr. Muchmore: Does anybody have any questions? Okay, thank you very much. Okay, the next speaker …….. I'm not sure I can read this …
For Public Comment: Jinneh Dyson, NAMI: Good evening and thank you for your time. My name's Jinneh Dyson, and I'm with NAMI Oklahoma, and I stand here to read a letter first from one of our family members who was unable to be here as well as a letter from NAMI Oklahoma's Board of Directors. The letter's from Ellen Harris and she's a Tulsa NAMI family member as well as a NAMI Oklahoma State Board Member. *"My son is a top student, a gentle and thoughtful family member and a hard worker. While attending OU, he suffered a psychotic break. He had an initial recovery but then after another break, he remained delusional and hallucinating for the better part of three years. Thanks to having a full spectrum of medications available and the ability to change those medications for optimal recovery, he is once again a gentle and thoughtful person; able to spend quality time with his family, has started to read again, and has hope for the future. Medication is the one thing that keeps my son from living in psychosis 24 hours a day, every day for the rest of his life. Some that he takes is very expensive and some is not. All are necessary to keep him in recovery. What would a fail-first policy have done to him? A fail-first policy could have kept him on*

medication that controlled the most dangerous symptoms, but left him trapped in a world of fear and isolation, essentially keeping him chemically warehoused within himself. A fail-first policy could have made the progress toward the proper accommodation of medications be even slower, progressing and worsening his illness, diminishing his chances of recovery and lengthening any possible recovery. Too much is at stake here. Rationing medication is a very dangerous option. Services for mentally ill people are already limited. Fewer hospital beds are available, community services are being cut and our jails are filled with the mentally ill. Dictating what medications and in what order or combinations physicians can prescribe, they may save a few dollars from the budget line, but the cost of time dollars will be enormous, both financially and in human loss. Thank you for your time. Ellen Harris" The second letter is the letter from the NAMI Oklahoma Board of Directors: *"NAMI, Oklahoma: We want to take this opportunity to express our gratitude to this Board for your comprehensive analysis of the atypical antipsychotic proposal recommended by the College of Pharmacy. While this proposal directly affects individuals and families who are cognizant of the social, psychological and economic impact that this positive implementation will have on all Oklahomans. It is the position of NAMI Oklahoma that open access be allowed and that a system is implemented that will allow individual members to have access to medications in this class without prior authorization. We recognize that this is a point of concern and we will continue to encourage the Health Care Authority to identify other avenues that would not impose restrictions on treatment. We will also continue to collaborate with the Health Care Authority on identifying appropriate clinical and cost controls that would not append additional barriers and hardships to Oklahomans in recovery."* Thank you for your time.

Dr. Muchmore: Any questions? Okay, thank you very much. Our next speaker is Dr. Maria Kane, psychiatry.

For Public Comment: Maria M. Kane, M.D., Psychiatrist: Good evening. My name is Dr. Maria Kane. I'm a psychiatrist in private practice here in Oklahoma City. I have learned about this whole agenda recently and I felt compelled to come here. I have been here before, before the Board when the discussion when the discussion with regards to the SSRIs or the antidepressants were being discussed and I guess I always feel compelled when situations like this arise because I have been an advocate of psychiatric treatment. I've been a psychiatrist and I've been practicing since 1977 when I got out of my residency training. So also I guess I have been affected personally with utilization review and I'm not saying utilization review in terms of medications, but I lost my husband thirteen years ago to suicide, so I've always been sensitive to utilization review, especially when it comes to limiting the number of days in the hospital or restricting access to medications. But having practiced for 32 years, I think I'm able to offer a unique perspective and having practiced only in Oklahoma all those 32 years, I'm able to, I guess offer some observations that I've had through those years that perhaps not many psychiatrists are able to do. So I'm here specifically for all my colleagues who are not able to come here today and obviously for myself and for my patients. And I'm not trying to be here to speak for any pharmaceutical company or any particular drugs. I believe that the medications that are out there in the market right now wouldn't be there if they don't work. I always believe that, I guess basically, they all work in the same manner and are all effective, and perhaps the only difference is in the side effect profile. So having worked with both the first generation antipsychotics like in the '70's when I was doing my residency, and having been introduced to the atypicals when they first came out in 1989 with the prototype Clozaril. I have to say that I would as much as we all know that they all work in the same way in terms of the mechanism of action that's involved, which is dopamine antagonism or dopamine blockade, but I think we all know that with introduction of atypicals, that there has been a lot of progress in terms of being able to implement the institutionalization which was quite a, kind of an impossible concept back when in the '80's when it was first being talked about and trying to get the patients out of the various State hospitals around the country. So having had the medications available to us since '89, I think we all know that has been the mean reason that patients have been able to get out into the community and not be warehoused or institutionalized all their lives. I think without atypicals we would still see psychiatric hospitals with patients in the thousands you know, that are not really able to enjoy a freer life out there in the community, so what I'm here tonight mainly to I guess make a case for open access to medications because although, like I said, we all know that the same mechanism of action applies to all of them, but there are so many subtle differences in terms of the various properties that each medication out there is able to offer in terms of movement disorder or extrapyramidal symptoms. I think we all know that some of the medications that are loosely bound to the receptor sites are somehow just preferred at times when the situation warrants it and so specific patients will not be able to tolerate those medications that are tightly bound to the receptor site, or some medications would be activating, others are more sedating, and so in terms of the metabolic issues involved at this point, I think we all know that some cause so much weight gain and the others are weight neutral, so my own opinion is that restricting access to the atypicals that we have really enjoyed using, and in fact I think when I first entered psychiatry back in the '70's without the atypicals at that point was really somewhat frustrating. So I guess the main message I'd like to convey is that monitoring with the use of second opinion or questionnaires in six months, I guess we could handle that, although we're all inundated with paperwork at this point. But I think limiting access should probably be reconsidered by the Board. Thank you.

Dr. Muchmore: Thank you. Are there any questions?

Dr. Kuhls: I have a question. Say you have a patient that you need to start on an atypical. How long do you leave that patient on that medication before you would say I need to switch to another medication. Is there ……..

Dr. Kane: Well I guess kind of rule of thumb that we follow would be to push the medication to the max or else even if it's not to the maximum, allow dosage if the patient starts to exhibit any side effects, then obviously, or is not able to tolerate because of adverse reaction or whatnot, then obviously we'd try to switch to a different medication. In most patients, typically, mental illness is genetic and also caused by a chemical imbalance. It's typical for us to usually put patients on medications that has been successfully used by other family members. So I think except for, it's very rare that, I think we tend to have a strong family history of mental illness and more than likely we will have a family member that has been on medications and so therefore, it really, we don't really have to choose or make that very expensive analysis or anything. But because they're more likely actually to respond to the medications that other family members have been successful on.

Dr. Muchmore: Any other questions? Okay, thank you Dr. Kane. The last one is Cameo Hughes from Stepping Stones.
For Public Comment: Cameo Hughes, Stepping Stones: Hi, I was diagnosed in I believe 2003, manic-depressive bipolar. I live at Stepping Stones. It's an assisted living center. I'm in the independent housing program. It's teaching us to get back out into the community. It took me a good five years or so to finally be on a medication combination that truly got me working really close to 100% again, because at one time I had held a job and rented and been a family member. And then I became too ill to do that. Well, here recently I had been on Geodon and that was part of the combination and they, my insurance, Medicaid, quit paying for the Geodon. So we had to try new things. And with trying new medication combinations, you can have bad effects or even some setbacks and have to rebuild back to a personal level of ability again. Of course I've had wonderful people to help me. The worst of it was when we have to find something that worked, as good as we could without the Geodon, is I wound up having some severe anxiety attacks where I thought I was dying, which of course you can't really die from an anxiety attack, and it took three visits to the emergency room to finally boil down that I was having anxiety attacks, for them to give me a piece of paper that said, hey she's having anxiety attacks and then show that to my psychiatrist and then he would try something new to help and finally we've gotten back to a combination that's much better. But I would like to go back to the Geodon. My new combination is really just like two more pills added on, minus the Geodon. And is there any way that the Medicaid would go back to paying for the Geodon?
Dr. Muchmore: Medicaid has never turned down Geodon up to this point in time, so I don't know where that information came from.
Ms. Hughes: Okay, well that's what I was told, that my Part D plan ….
(several): That's Medicare.
Dr. Muchmore: We have no influence over Medicare. But Medicaid has not turned it down and if somebody was on Geodon and well established, this process would not change it. They'd still stay on it if they're Medicaid. But Medicare, that's not our . .
Ms. Hughes: So, all I need to do, okay, so what I'm understanding is you can have Medicare and Medicaid and both plans are paying for certain medications.
Dr. Nesser: No, if you're on Medicare, your medications are paid for primarily by Medicare.
Ms. Hughes: Even if you have Medicaid.
Dr. Nesser: There's a few drugs that we can still cover, but we can't cover the antipsychotics once you're on a Part D plan.
Dr. Muchmore: And as I understand, and is this true, that different Part D carriers will approve different drugs.
Dr. Knisely: She may need to look for a different Part D plan.
Ms. Hughes: Well, thank you and I'll just kind of jot a note of it. Illness is a trial and a struggle and we always appreciate any help and as you all work out your difficulties, I'm sure less funding makes it very difficult. We have to work out our difficulties and …..
Dr. Muchmore: And I believe our system has some good points, and one of them is if you've been on Geodon and doing well and you're Medicaid, you'll continue on it.
Ms. Hughes: Well, thank you. I didn't know, apparently didn't ….
Dr. Muchmore: We're glad you're working hard to recover.
Ms. Hughes: Thank you.
Discussion among Board members regarding grandfathering of individuals stabilized on medications and supplemental rebate process which might affect costs from year to year.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **30-DAY NOTICE TO PRIOR AUTHORIZE RIBAVIRIN CAPSULES, SOLUTION & DOSE PACKS**
Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF NSAIDs AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZIPSOR™ AND CAMBIA™**
For Public comment: Gary Dickinson, Xanadyne: Thank you for letting me present to the Board tonight. My name's Gary Dickinson. I'm in family practice for over 27 years now and I have seen prescriptions for pain medications come and go over those 27 years. I've seen trends change in 27 years on the way narcotics have been prescribed and I don't think I have spent too much time telling the Board about the escalation in the use of controlled medications for pain management, and also the consequential results of problems with drug abuse, improper use of these medications that not only affect the patient but affect our society as well. So I'm here to discuss the medication from the Xanadyne Pharmaceutical company, known as Zipsor, which is a one and only liquid-filled capsule that's an NSAID, and this is the first of its' kind that has been approved by the FDA. It is the chemical diclofenac potassium. As I go ahead and discuss this further, I'd like to also speak and say that this medication last month was approved by the Texas State Medicaid to be used for management of acute mild to moderate pain in adults and it was approved without prior authorization. So in Texas they've seen the advantages of using this medication and they have adopted it for their Medicaid patients. The reason why Zipsor is so effective is based on its' bioavailability from what's called a prosorb dispersion technology. As the liquid-filled capsule enters the stomach, it disperses rapidly into the stomach. This creates a larger surface area for the medication to be absorbed. This provides also a more steady, more consistent and faster absorption of the medication for the patient; and in fact, the T_{max} is 28 minutes to reach the peak level of pain management.

With this, the technology has been able to surpass any other NSAID and particularly with the diclofenac molecule, there's no other molecule that's equivalent; the bioequivalent to Zipsor, because of this new technology. Zipsor is dosed as a 25 mg capsule, up to four times per day, for the management of acute, mild to moderate pain in adults. It is consistent with the guidelines that have been presented by the FDA in recommending that we use the lowest dose of NSAID and also an NSAID that reaches fast levels of absorption and reaches a peak level at a rapid rate so that it's in the body for a shorter period of time. Both of these properties will help to reduce the possible side effects and complications that we are aware of that NSAIDs may possess. The main advantages, as I alluded to in my opening statements, is that this medication is effective and it presents a viable alternative to physicians who are treating acute, moderate pain in adults. As a physician who's been on the front lines taking care of patients in this category, I have found that medication has been effective. I've used it now for the past five months, not only in my own practice, but also in urgent care evening setting, where we see patients who meet this criteria of needing treatment for acute pain, and I have found it to be very effective. I've also found it to be well received by the patients. In doing so, we've been able to reduce the use of our class, of our controlled medications such as codeine, hydrocodone, propoxyphene, and tramadol. The studies that were done for Zipsor were based on post-operative bunionectomy patients who had an average pain level of 7, post-operatively, and with the use of Zipsor 25 mg QID, within 48 hours, their pain levels reported at an average of 1. It is effective; it does reach the same potency levels of treatment and results based on the mild opiate narcotics. We have found it very useful for treating patients who present with acute pain from low back pain, musculoskeletal injuries, headache. This has been really a nice alternative to try to be able to be a tool that we can use to effectively treat acute pain in adults, but also to reduce and limit our use of narcotics. In summary, I'll re-emphasize that this is the first liquid-filled product of an NSAID in a capsule form that's been approved by the FDA and meets their guidelines to produce good pain management for mild to moderate pain in adults in a safe and effective manner. Also, I'll leave in summary that this has been approved, once again, like I said, in the State of Texas for Medicaid without prior authorization. When they saw the advantages of being able to use a medication like this as compared to having to use narcotic medications, and knowing that they're doing so with a medication that is effective and will help these patients. Thank you very much.

Dr. Muchmore: Anybody have any questions of Dr. Dickinson?

Dr. Nesser: I have one. Is that approved in Texas with or without a supplemental rebate?

Dr. Dickinson: That's approved without a supplemental rebate.

Dr. Nesser: That seems pretty out there, since this is going to be about $8 a day and you can get generic diclofenac potassium for 65¢ a day.

Dr. Dickinson: Right. Generic diclofenac potassium has to be prescribed as low as 50 and as high as 75 mg to reach the same bioequivalency as a 25 mg dose of Zipsor because of the different technology.

Dr. Nesser: Right, I'm talking about two 50 mg tablets a day, 65¢, compared to four of these 25's is going to be at least $2.00 a tablet ……. $8.00 a day.

Dr. Dickinson: Right. And I do understand that. My understanding is that when they did research on numbers of patients who are treated for drug dependency and the cost of treating those patients, also the cost to society of putting patients that we have to take care of, that they felt like there was a cost benefit ratio there that had them approve the medication without prior authorization and without a supplemental benefit.

Dr. Nesser: I still think it's a stretch to say this is going to keep people from getting narcotics.

Dr. Dickinson: Well, I …… no, I, no ……. patients are, I mean they can be pretty shifty you know. They can continue to pursue, but you know, this is something that if the patient knows that I've got a good medication for pain management, I'm going to treat them with something that I know is effective, you know, I think that we can limit on use of narcotics and you know, I think that if they don't get the results, if you know, if they're actually seeking medication that's a narcotic; sure, I think they're going to continue to go until they seek that and find that out. If a patient is legitimately there for pain management, I think this is a good product for them.

Dr. Nesser: So if they're legitimately there for pain management, what are the studies that indicate that this product is that much better than the generic diclofenac.

Dr. Dickinson: Well, generic diclofenac has not been studied with the same, in the same type of manner that this was studied.

Dr. Nesser: So in other words, you haven't, you don't have an active comparator study against the generic diclofenac for the Zipsor?

Dr. Dickinson: The bioavailability of the Zipsor is not bioequivalent to the generic diclofenac potassium, and the studies were done with opiates and in comparison with them.

Dr. Muchmore: Okay, any other questions of Dr. Dickinson?

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF TOPICAL ANTIFUNGALS

Topic tabled to next regularly scheduled Board meeting.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **FDA & DEA UPDATES**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: **FUTURE BUSINESS**

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

A: Anxiolytic Criteria Review
B: Annual Review of Smoking Cessation Products
C: Annual Review of HFA Products
D: New Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **ADJOURNMENT**

The meeting was adjourned at 7:40 p.m.

Appendix B

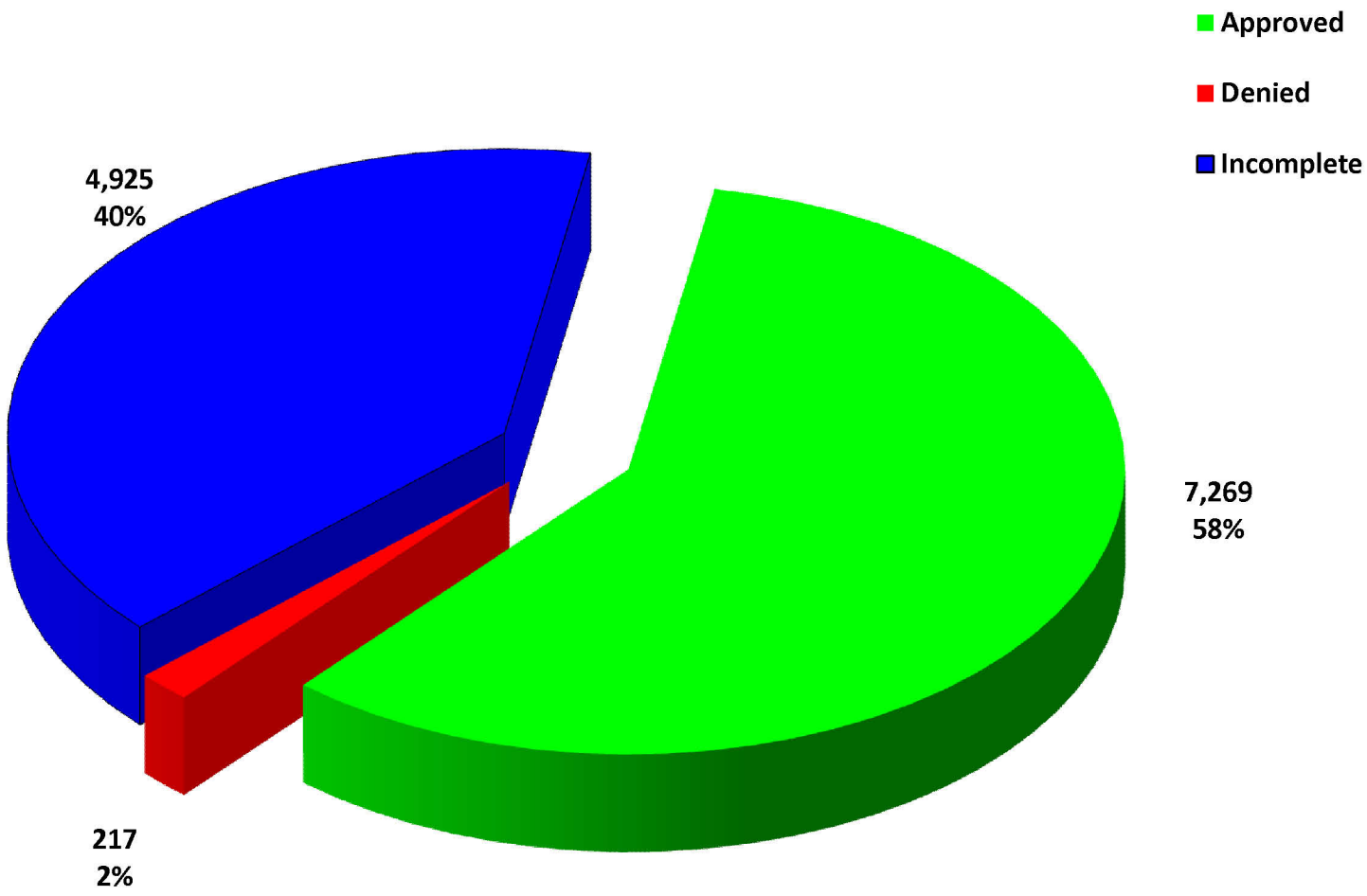
Retrospective Drug Utilization Review Report

Claims Reviewed for September 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	46,646	60,251	1,064,416	36,475
Limits which were applied	Established, Major, Males and Females, Age 36-50	Males and Females, Narcotics, Age 30-31	Contraindicated, Glaucoma, Males and Females, Age 0-150	High Dose Only, Benzodiazepines, Males and Females, Age 0-19
Total # of messages after limits were applied	94	201	81	12
Total # of members reviewed after limits were applied	94	162	0	12

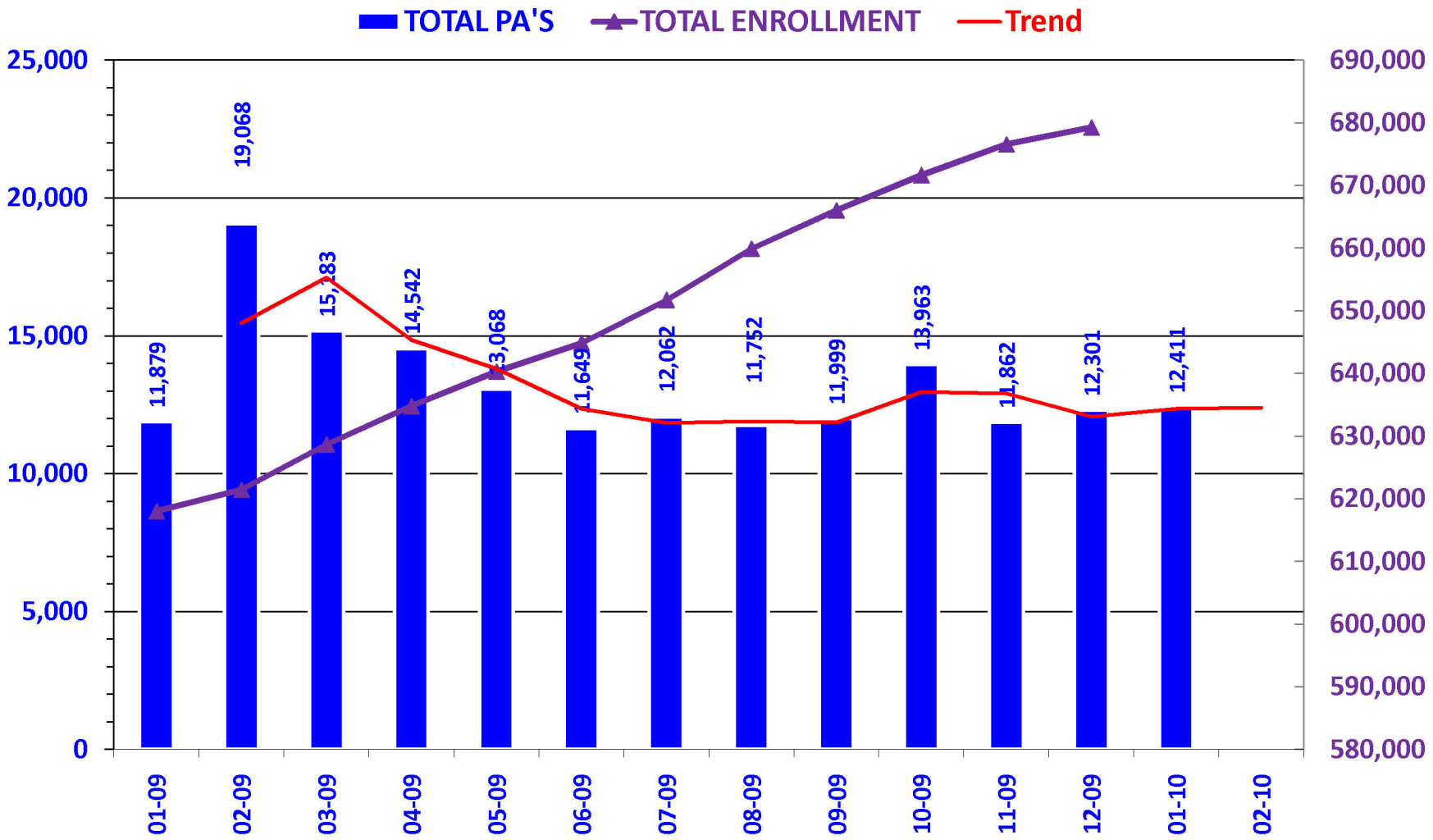
LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
215		39	

PRIOR AUTHORIZATION ACTIVITY REPORT: January 2010



PA totals include overrides

PRIOR AUTHORIZATION REPORT: January 2009 – January 2010



PA totals include overrides

Prior Authorization Activity

January 2010

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	529	237	0	292	355
Amitiza	8	2	0	6	218
Antidepressant	489	141	1	347	339
Antihistamine	330	166	0	164	270
Antihypertensives	135	51	0	84	337
Antimigraine	84	11	0	73	220
Benzodiazepines	4,214	3,556	7	651	91
Bladder Control	82	14	0	68	363
Brovana (Arformoterol)	4	0	0	4	0
Byetta	9	4	0	5	276
Elidel/Protopic	49	25	0	24	86
ESA	218	168	1	49	56
Fibric Acid Derivatives	4	0	1	3	0
Fibromyalgia	103	34	2	67	327
Forteo	3	1	0	2	364
Glaucoma	27	7	0	20	311
Growth Hormones	29	22	5	2	173
HFA Rescue Inhalers	84	49	0	35	230
Insomnia	119	34	1	84	117
Misc Analgesics	59	11	17	31	161
Muscle Relaxant	231	77	65	89	34
Nasal Allergy	493	49	12	432	190
NSAIDS	177	43	1	133	270
Nucynta	5	3	0	2	40
Ocular Allergy	13	1	0	12	85
Ocular Antibiotics	22	3	3	16	7
Opioid Analgesic	162	49	3	110	149
Other	419	121	30	268	138
Otic Antibiotic	52	12	0	40	12
Pediculicides	44	7	4	33	10
Plavix	9	6	0	3	359
Proton Pump Inhibitors	637	119	5	513	100
Singulair	697	382	1	314	264
Smoking Cessation	108	30	5	73	64
Statins	61	21	0	40	348
Stimulant	1,028	591	8	429	246
Synagis	160	109	9	42	71
Topical Antibiotics	22	5	0	17	10
Topical Antifungals	35	5	0	30	30
Ultram ER and ODT	8	3	0	5	160
Xolair	5	1	0	4	365
Xopenex Nebs	42	25	0	17	218
Zetia (Ezetimibe)	28	20	0	8	360
Emergency PAs	2	2	0	0	
Total	**11,039**	**6,217**	**181**	**4,641**	

Overrides					
Brand	102	69	4	29	126
Dosage Change	470	414	12	44	12
High Dose	15	10	0	5	256
IHS - Brand	78	68	0	10	84
Ingredient Duplication	8	6	0	2	9
Lost/Broken Rx	72	67	2	3	11
Nursing Home Issue	72	66	0	6	8
Other	24	16	0	8	26
Quantity vs. Days Supply	526	332	18	176	239
Stolen	4	3	0	1	20
Wrong D.S. on Previous Rx	1	1	0	0	58
Overrides Total	**1,372**	**1,052**	**36**	**284**	
Total Regular PAs + Overrides	**12,411**	**7,269**	**217**	**4,925**	

Denial Reasons

Lack required information to process request.	2,382
Unable to verify required trials.	1,918
Does not meet established criteria.	248
Not an FDA approved indication/diagnosis.	172
Member has active PA for requested medication.	156
Considered duplicate therapy. Member has a prior authorization for similar medication.	109
Requested dose exceeds maximum recommended FDA dose.	91
Medication not covered as pharmacy benefit.	33
Drug Not Deemed Medically Necessary	4
Drug Deemed Medically Necessary	1

Duplicate Requests: 883

Changes to existing PAs: 868

CALL VOLUME MONTHLY REPORT:
January 2009 – January 2010

Appendix C

VOTE TO PRIOR AUTHORIZE

ATYPICAL ANTIPSYCHOTICS

OKLAHOMA HEALTH CARE AUTHORITY
FEBRUARY 2010

RECOMMENDATIONS

The College of Pharmacy recommends the addition of the Atypical Antipsychotics class to the Product Based Prior Authorization program. The following Tier lists have been reviewed and determined to be an acceptable combination 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. The following are the recommendations for this category:

- Children less than 5 years of age will require a "second opinion" prior authorization to be reviewed by an OHCA-contracted child psychiatrist. Current users will be allowed to remain on current medication until the petition is submitted and reviewed. See Appendix 1 for second opinion process.
- For all members on atypical antipsychotics, after six months of use, a questionnaire will be sent to the prescriber to be filled out and returned for continuation of therapy. See Appendix 2 for suggested process for questionnaires.
- Requests for unusual dosing or indications will be referred to the OHCA-contracted psychiatrist for review.
- In addition, the College recommends the following tier structure and approval criteria:

Atypical Antipsychotics*		
Tier 1	**Tier 2**	**Tier 3†**
risperidone (Risperdal®)₸ **clozapine (Clozaril®)**	**Supplemental Rebated Tier-3 medications**	**olanzapine (Zyprexa®)** **quetiapine (Seroquel®)** **ziprasidone (Geodon®)** **aripiprazole (Abilify®)** **paliperidone (Invega®)** **quetiapine ER (Seroquel XR®)** **asenapine (Saphris®)** **clozapine (Fazaclo®)** **olanzapine/fluoxetine (Symbyax®)** **iloperidone (Fanapt™)**

***Mandatory Generic Plan Applies**
†May be rebated to Tier 2 status only
₸Includes Risperdal Consta

Approval Criteria for Tier 2 Medication:

1. Current users/inpatient discharge:
    a. Members currently stabilized on a higher tiered medication defined by paid claim(s) for the higher tiered medication in the past 90 days will be approved.
    b. Members being released from a hospital and stabilized on a higher tier medication will be approved.
2. Clinical conditions:
    a. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
    b. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
3. Step therapy:
    a. A trial of risperidone, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Tier 3 Medication:

1. Current users/inpatient discharge:
    a. Members currently stabilized on a higher tiered medication defined by paid claim(s) for the higher tiered medication in the past 90 days will be approved.
    b. Members being released from a hospital and stabilized on a higher tier medication will be approved.
2. Clinical conditions:
    a. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
    b. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
3. Step therapy:
    a. A trial of risperidone, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
    b. A trial of all available Tier 2 medications, at least 14 days in duration, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
    c. For aripiprazole and quetiapine: a diagnosis of depression requires current use of an antidepressant, and previous trials with at least two other antidepressants.

APPENDIX 1

SECOND OPINION PROCESS

1. Prior authorization for the requested medication is received by the prior authorization unit.
2. Clinical pharmacist contacts the on-call psychiatrist and provides information.
3. On-call psychiatrist contacts physician who submitted prior authorization request.
4. On-call psychiatrist contacts clinical pharmacists with results of review.
5. Clinical pharmacist issues appropriate response based on the results.

APPENDIX 2

CONTINUOUS USE QUESTIONNAIRE PROCESS

1. Claims will be reviewed and members with six months of continuous use of medications from this class will be input into a tracking system.
2. The questionnaire will be mailed to the last physician of record for the medication.
3. Returned questionnaires will be noted and the answers entered into the tracking system.
4. Each month the review process will be repeated.
5. After the first six months, response rates and the answers provided will be reviewed and reported to the DUR Board.
6. Further development of the tool will be made based on the initial review process.

APPENDIX 3

Generic Name	Trade Name	FDA Indications	Dosage Forms Available	Youngest Age Indicated	Frequency of Dosing
Clozapine	Clozaril® Fazaclo®	- Schizophrenia: treatment-resistant or suicidal behavior, recurrent-initial and maintenance - Schizoaffective DO: suicidal behavior, recurrent-initial and maintenance	Tabs, ODT	No Pediatric Indications	QD, 12.5mg – 900mg
Risperidone	Risperdal®	- Schizophrenia: initial and maintenance - Bipolar I DO: initial and maintenance as monotherapy or combo with Lithium or Valproate - Autistic DO: irritability in children-initial and maintenance	Tabs, ODT, Oral Solution, Powder for reconstitution (IM Inj)	5 years of age	1mg – 6mg QD-BID Q 2 wks (IM)
Olanzapine	Zyprexa®	- Schizophrenia - Bipolar I DO: maintenance or acute mixed or manic episodes - Agitation: Schizophrenia or Bipolar I DO	Tabs, ODT, Powder for reconstitution (IM Inj)	13 to 17 for Schizophrenia and Bipolar I	5mg – 20mg QD Q 2-4 hrs (IM)
Quetiapine	Seroquel® Seroquel XR®	- Schizophrenia: initial, maintenance, re-initiation - Bipolar DO: depressed phase or maintenance - Manic Bipolar I DO: initial, maintenance, or re-initiation - Major Depressive DO: adjunct to antidepressants – adults, XR only	Tabs, Extended Release Tablets	10 to 17 for Bipolar I 13 to 17 for Schizophrenia	25mg – 800mg QD-TID
Ziprasidone	Geodon®	- Schizophrenia: initial and maintenace - Bipolar I DO: acute manic or mixed episodes -Agitation, acute: Schizophrenia	Caps, Powder for reconstitution (IM Inj)	No Pediatric Indications	20mg – 160mg BID Q 2-4 hrs (IM)
Aripiprazole	Abilify®	- Schizophrenia: initial and maintenance - Bipolar I DO: adjunct to Lithium or Valproate; monotherapy, manic or mixed episodes - Major Depressive DO: adjunct to antidepressants - Psychomotor agitation: Schizophrenia and Bipolar DO -Irritability assoc with Autistic DO	Tabs, ODT, Oral Solution, Solution for IM injection	10` years of age	10mg – 30mg QD Q 2 hrs (IM)
Paliperidone	Invega®	- Schizophrenia - Schizoaffective DO	Extended Release Tablets, Solution for IM injection	No Pediatric Indications	6mg – 12mg QD
Asenapine	Saphris®	- Schizophrenia - Acute treatment - Bipolar I DO - Acute manic or mixed episodes	Sublingual Tablets (5mg and 10mg)	No Pediatric Indications	5mg-10mg SL BID
Olanzapine/ fluoxetine	Symbyax®	-Depressive episodes associated with Bipolar I Disorder -Treatment resistant depression	Capsules	No Pediatric Indications	6/25 mg – 12/50 mg QD
Iloperidone	Fanapt™	- Schizophrenia - Acute treatment	Tablets	No Pediatric Indications	12mg to 24mg daily (BID)

Appendix D

Vote to Prior Authorize Zipsor®, Cambia®, and Update the NSAID Product Based Prior Authorization Criteria Plus 30 Day Notice to Prior Authorize Pennsaid®

Oklahoma Health Care Authority, February 2010

Recommendations:

The College of Pharmacy recommends placing Zipsor and Cambia into the NSAID Product Based Prior Authorization Program. The College of Pharmacy also recommends the following changes to the Tier Lists and Criteria for the NSAID Category.

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)		
Tier 1	**Tier 2**	**Tier 3**
diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®)	diclofenac epolamine (Flector®)
diclofenac potassium (Cataflam®)	diclofenac sodium / misoprostol (Arthrotec®)	**diclofenac potassium (Zipsor®, Cambia®)**
diclofenac sodium (Voltaren®)		diclofenac sodium (Voltaren Gel®)
etodolac (Lodine®)		**diclofenac sodium (PENNSAID®)***
etodolac ER (Lodine® XL)		indomethacin (Indocin®)
fenoprofen (Nalfon®)		mefanamic acid (Ponstel®)
flurbiprofen (Ansaid®)		naproxen sodium (Naprelan®)
ibuprofen (Motrin®)		piroxicam (Feldene®)
ketoprofen (Orudis®)		
ketoprofen ER (Oruvail®)		
meclofenamate (Meclomen®)		
meloxicam (Mobic®)		
nabumetone (Relafen®)		
naproxen (Naprosyn®)		
naproxen sodium (Anaprox®)		
naproxen EC (Naprosyn® EC)		
oxaprozin (Daypro®)		
sulindac (Clinoril®)		
tolmetin (Tolectin®)		

*To be voted on at the March meeting.

Approval Criteria:

1. Criteria for approval of the non-steroidal, anti-inflammatory drugs in Tier 2 are demonstrated by the following conditions:
    a. Previous use of at least two Tier 1 NSAID (from different product lines) plus a PPI
    b. For those with prior GI bleed who must have an NSAID, then a Tier 2 product may be approved (Note: celecoxib should also be taken with a PPI).
2. Criteria for the non-steroidal, anti-inflammatory drugs in Tier 3 are demonstrated by the following conditions:
    a. Special indications, such as the diagnosis of gout for indomethacin, OR
    b. Previous use of at least two Tier 1 NSAIDs (from different product lines) AND
    c. Reason why a special formulation is needed over a Tier-1 product

30 Day Notice to Prior Authorize PENNSAID® (diclofenac sodium)

Oklahoma Health Care Authority, February 2010

Manufacturer	Mallinckrodt Brand Pharmaceuticals, Inc.
Classification	Non-Steroidal Anti-Inflammatory Drug
Status	Prescription Only

PENNSAID® Summary

PENNSAID® is a non-steroidal anti-inflammatory drug indicated for treatment of the symptoms associated with osteoarthritis of the knee(s) only for a treatment regimen of not more than three months duration, whether continuous or intermittent. PENNSAID® is a solution formulation of diclofenac sodium containing 45% dimethyl sulfoxide (DMSO), propylene glycol, glycerin and alcohol and is intended for external use only. PENNSAID® is not recommended for use with other NSAIDs because of the absence of any evidence demonstrating synergistic benefits and the potential for additive side effects.

The dose of PENNSAID® is 40 drops per knee, 4 times a day. The procedure is to dispense 10 drops into the hand or directly onto the knee and then spread evenly around the front, back and sides of the knee and repeat this procedure until the recommended dose has been applied and the knee is completely covered. The most common adverse reactions were related to the application site. In the open-label uncontrolled long-term safety study, the withdrawal rate for an application site event was 14%.

Recommendations

The College of Pharmacy recommends placing PENNSAID® into Tier 3 of the NSAID Product Based Prior Authorization Category.

Product Details

Indication- PENNSAID® is indicated for the drug indicated for the treatment of the symptoms associated with osteoarthritis of the knee(s) only for a treatment regimen of not more than three months duration, whether continuous or intermittent.

Dosage Forms- 1.5% w/w diclofenac sodium solution (16.05mg/mL) in a solution base consisting of dimethyl sulfoxide, propylene glycol, ethanol, and purified water. It is supplied in bottles of 15, 60, and 150 mL with a plastic dropper cap.

Contraindications-

- **Hypersensitivity to diclofenac sodium**.
- **Hypersensitivity to aspirin or other NSAIDs** -history of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.
- **Coronary artery bypass graft (CABG) surgery-** use in the perioperative period.

Pregnancy Risk Category: C (prior to 30 weeks gestation); **D** (starting at 30 weeks gestation)

Warnings and precautions-

- **Serious cardiovascular events-** such as potentially fatal thrombotic events, myocardial infarction, and stroke can occur with NSAID treatment. Use the lowest effective dose of PENNSAID® in patients with known CV disease or risk factors for DV disease.
- **Gastrointestinal adverse events-** including inflammation, bleeding, ulceration, and perforation can occur at any time in patients treated with NSAIDs.
- **Elevation of liver tests** may occur. Discontinue PENNSAID® immediately if abnormal liver tests persist or worsen.
- **Hypertension** can occur with NSAID treatment. Monitor blood pressure closely.
- **Fluid retention or heart failure** – use PENNSAID® with caution in patients with these conditions
- **Renal toxicity-** long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury. Use with caution in the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics and ACE inhibitors.
- **Dermatological-** NSAIDs can cause serious skin events such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal.
- **Not for use during pregnancy.**
- **Asthma-** do not administer to patients with aspirin sensitive asthma and use with caution in patients with preexisting asthma.
- **Avoid exposure of treated knees to natural or artificial sunlight.**
- **Avoid contact of PENNSAID® with eyes and mucosa.**
- **Avoid concurrent use of oral NSAIDs**

Common adverse reactions-

- **Application site reactions-** most common were dry skin (32%), contact dermatitis characterized by skin erythema and induration (9%), contact dermatitis with vesicles (2%), and pruritus (4%). In the open-label uncontrolled long-term safely study, the withdrawal rate for an application site event was 14%.
- **Gastrointestinal-** dyspepsia (8%), abdominal pain (6%), flatulence (4%), diarrhea (4%), nausea (4%), and constipation (3%).
- **Dermatological (non-application site) -** rash (3%), dry skin (2%), paresthesia (2%), pruritus (2%)
- **Other-** pharyngitis (4%), edema (3%), infection (3%), ecchymosis (2%), accidental injury (2%), sinusitis (1%), halitosis (1%).

Drug interactions-

- **Aspirin-** reduces protein binding of diclofenac.
- **Anticoagulants-** increases the risk of serious GI bleeding
- **ACE inhibitors-** decreases ACE inhibitor effect
- **Diuretics-** reduced natriuretic effect of furosemide and thiazides.
- **Lithium-** elevated plasma lithium levels and reduced lithium clearance
- **Oral Non-steroidal Anti-Inflammatory Drugs-** concomitant use of oral NSAIDs with PENNSAID® has been evaluated in one Phase 3 controlled trial and in combination with oral diclofenac, compared to oral diclofenac alone, resulted in a higher rate of rectal hemorrhage (3% vs. <1%), and more frequent abnormal creatinine (12% vs. 7%), urea (20% vs. 12%), and hemoglobin (13% vs. 9%).
- **Topical Treatments-** instruct patients that before applying sunscreen, insect repellant, lotion, moisturizer, cosmetics, or other topical medications to the same skin surface of the knee treated with PENNSAID®, they must wait until the treated area is completely dry.

Patient information-

- Apply PENNSAID® Topical Solution exactly as your doctor tells you. Do not apply anywhere on your body other than where your doctor tells you.
- Apply to clean, dry skin that does not have any cuts, infections, or rashes.
- Use 4 times each day on your knee(s).
- Do not get PENNSAID® in your eyes, nose, or mouth. Only use it on your skin. If you get PENNSAID® in your eyes, rinse right away with water or saline. Call your doctor if your eyes are irritated for more than one hour.
- Steps for use:
    - Wash your hands with soap and water before and after applying PENNSAID®
    - Your total dose for each knee is 40 drops. You will use 10 drops at a time. Put 10 drops either on your hand or directly on your knee.
    - Spread evenly on the front, back, and sides of your knee. Repeat this step 3 more times so that your knee is completely covered with a total of 40 drops of PENNSAID®.
- After you use PENNSAID®, do not:
    - Cover your knee with clothing until your knee is completely dry.
    - Put sunscreen, insect repellant, lotion, moisturizer, cosmetics, or other topical medications on your knee until it is completely dry.
    - Take a shower or bath for at least 30 minutes.
    - Use heating pads or apply bandages to the skin where you have applied PENNSAID®
    - Expose your skin to sunlight or artificial light (tanning booths) where you have put PENNSAID®

REFERENCE
PENNSAID® Topical Solution (diclofenac sodium) Product Information. Mallinckrodt Brand Pharmaceuticals, Inc. February 2009.
Diclofenac monograph. Lexi-Comp, Inc. (Lexi-Drugs) Lexi-Comp, Inc. Accessed February 2, 2010.

Appendix E

VOTE TO PRIOR AUTHORIZE RIBAVIRIN CAPSULES, SOLUTION AND DOSE PACKS

OKLAHOMA HEALTHCARE AUTHORITY

FEBRUARY 2010

RECOMMENDATIONS

The College of Pharmacy recommends placing a prior authorization on Ribavirin capsules, suspension and dose packs. Approval would be based on clinical supporting information regarding the inability of member to swallow, hypersensitivity to tablet formulation, medical reasons why member cannot take tablet formulation, or for use in children 3 to 17 years of age (capsules and suspension only).

Appendix F

30 Day Notice to Prior Authorize Twynsta™ (telmisartan and amlodipine)

Oklahoma Health Care Authority
February 2010

Manufacturer	Boehringer Ingelheim
Classification	Angiotensin II Receptor Blocker (ARB) and Calcium Channel Blocker (CCB)
Status	Prescription Only

Twynsta™ Summary

Twynsta™(telmisartan and amlodipine) is a combination of telmisartan, an angiotensin II receptor blocker, and amlodipine, a dihydropyridine calcium channel blocker, indicated for treatment of hypertension:

- Alone or with other antihypertensive medications.
- May be substituted for its individually titrated components
- May also be used as initial therapy in patients likely to require multiple agent to achieve their blood pressure goals

The following products are currently available:

Product	EAC – Estimated Acquisition Cost	SMAC – State Maximum Allowable Cost
Amlodipine		2.5 mg - $0.11 5 mg - $0.11 10 mg - $0.15
Micardis	20 mg – $ 2.64 60 mg – $2.65	
Micardis HCT	40/12.5mg – $2.64 40/25 mg - $2.64 80/12.5 mg – $2.64 80/25 mg – $2.64	
Twynsta™	40/5 mg – $3.70 40/10 mg – $3.70 80/5 mg – $3.70 80/10 mg – $3.70	

Recommendations

The College of Pharmacy recommends placement of Twynsta™ in Tier 3 of the ARBs (Angiotensin Receptor Blockers) and ARB Combination Products Product Based Prior Authorization Category. The existing criteria for this category will apply.

Tier-1	Tier-2	Tier 3
Any Tier-1 ACE Inhibitor:	amlodopine / valsartan (Exforge®)	amlodipine / olmesartan (Azor™)
benazepril (Lotensin®)	amlodopine / valsartan (Exforge® HCT)	candesartan (Atacand®)
captopril (Capoten®)	irbesartan (Avapro®)	candesartan / HCTZ (Atacand® HCT)
enalapril (Vasotec®)	irbesartan / HCTZ (Avalide®)	losartan (Cozaar®)
enalaprilat (Vasotec® IV)	telmisartan (Micardis®)	losartan / HCTZ (Hyzaar®)
fosinopril (Monopril®)	telmisartan / HCTZ (Micardis® HCT)	eprosartan (Teveten®)
lisinopril (Prinivil®, Zestril®)	valsartan (Diovan®)	eprosartan / HCTZ (Teveten® HCT)
moexipril (Univasc®)	valsartan / HCTZ (Diovan HCT®)	telmisartan/amlodipine (Twynsta™)
quinapril (Accupril®)	olmesartan (Benicar®)	
trandolapril (Mavik®)	olmesartan / HCTZ (Benicar HCT®)	

Mandatory Generic Plan applies.

To qualify for a Tier 2 antihypertensive medication (or Tier 3 medication when no Tier 2 medications exist) there must be

- documented inadequate response to two Tier 1 medications, or
- adverse drug reaction to all Tier 1 class of medications, or
- previous stabilization on the Tier 2 medication, or
- a unique indication for which the Tier 1 antihypertensives lack

To qualify for a Tier 3 antihypertensive medication there must be

- documented inadequate response to two Tier 1 medications and documented inadequate response to all available Tier 2 medications, or
- adverse drug reaction to all Tier 1 or Tier 2 classes of medications, or
- previous stabilization on the Tier 3 medication, or
- a unique indication for which the lower tiered antihypertensives lack

Medication Product Details[1]

Indication

Twynsta™(telmisartan and amlodipine) is a combination of telmisartan, an angiotensin II receptor blocker, and amlodipine, a dihydropyridine calcium channel blocker, indicated for treatment of hypertension:

- Alone or with other antihypertensive medications.
- May be substituted for its individually titrated components
- May also be used as initial therapy in patients likely to require multiple agent to achieve their blood pressure goals

Dosage Forms: Tablets: 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg

Contraindications: None

Pregnancy Risk Category: C (first trimester), D (second and third trimesters)

Precautions

Fetal/Neonatal Morbidity and Mortality – Drugs that act directly on the rennin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Twynsta™ should be discontinued if pregnancy is being considered or as soon as pregnancy is detected. Most toxicity occurred in the second and third trimesters and included hypotension, neonatal skull hypoplasia, anuria, reversible and irreversible renal failure, oligohydramnosis, and death

Hypotension and Hyperkalemia – The telmisartan component of Twynsta™ can cause symptomatic hypotension in volume or salt depleted patients (those on high doses of diuretics). The condition should be corrected prior to starting Twynsta™ or a reduced dose should be initiated and closely monitored. Elevated potassium levels can occur in patients taking ARBs, particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy, or on potassium supplements, potassium-sparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels. Serum electrolyte values should be periodically evaluated.

Impaired Hepatic Function – Since telmisartan is eliminated by biliary excretion and amlodipine is extensively metabolized by the liver, patients with impaired hepatic function should be started at lower doses, initiating the amlodipine individually using 2.5 mg before titrating the dose using the combination product.

Dual Blockade of the Renin-Angiotensin-Aldosteroine System – Combination therapy with an ACE-inhibitor (ramipril) and an angiotensin II receptor blocker (telmisartan) did not provide additional benefit compared to monotherapy, but did result in increased incidence of renal dysfunction. Therefore the concomitant use ramipril and telmisartan is not recommended.

Heart Failure – In clinical trials patients with NYHA Class III or IV heart failure reported increased incidence of pulmonary edema while taking amlodipine. Patients with heart failure should be closely monitored.

Risk of Myocardial Infarction or Increased Angina – Patients with severe obstructive coronary artery disease have developed increased frequency, duration, or severity of angina or acute myocardial infarction upon starting calcium channel blocker therapy or at the time of dosage increase.

Common Adverse Effect

- ☑ Peripheral Edema
- ☑ Dizziness
- ☑ Orthostatic hypotension
- ☑ Back pain
- ☑ Headache
- ☑ Fatigue
- ☑ Flushing
- ☑ Palpitations
- ☑ URI
- ☑ Diarrhea

Drug Interactions

Digoxin
Use caution when Twynsta™ is administered to patients taking digoxin, since telmisartan can cause elevation of digoxin peak and trough plasma concentrations. Digoxin levels should be monitored when initiating, adjusting, and discontinuing telmisartan.

Lithium
When patients are taking Twynsta™ concomitantly with lithium, the telmisartan component can cause elevation of serum lithium concentration. Monitoring of lithium levels is recommended.

Ramipril
Co-administration of telmisartan and ramipril can result in increased C_{max} and AUC concentrations of ramipril and decreased C_{max} and AUC concentrations of telmisartan. Therefore the combination of ramipril and telmisartan is not recommended.

Patient Information

- Take Twynsta™ exactly as your doctor tells you. Your doctor may change your dose. Do not change your dose of Twynsta™ without talking to your doctor
- Take Twynsta™ one time each day at the same time
- Twynsta™ should start working within 2 weeks
- Take Twynsta™ with or without food
- Tell your doctor immediately if you are pregnant or plan to become pregnant
- Tell your doctor if you are breast-feeding or are planning to breast-feed

REFERENCE
[1]Twynsta(TM) (telmisartan/amlodipine) Product Information. Boehringer Ingelheim Pharmaceuticals, Inc. October 2009.

Appendix G

Safety

Zyprexa (olanzapine): Use in Adolescents

Audience: Neuropsychiatric healthcare professionals

[Posted 01/29/2010] Lilly and FDA notified healthcare professionals of changes to the Prescribing Information for Zyprexa related to its indication for use in adolescents (ages 13-17) for treatment of schizophrenia and bipolar I disorder [manic or mixed episodes]. The revised labeling states that:

> Section 1, Indications and Usage: When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and hyperlipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.
>
> Section 17.14, Need for comprehensive Treatment Program in Pediatric Patients: Zyprexa is indicated as an integral part of a total treatment program for pediatric patients with schizophrenia and bipolar disorder that may include other measures (psychological, educational, social) for patients with the disorder. Effectiveness and safety of ZYPREXA have not been established in pediatric patients less than 13 years of age.

[01/04/2010 - Dear Healthcare Professional Letter - Lilly]
[12/2009 - Prescribing Information - Lilly]

Drugs

Follow-Up to the October 2008 Updated Early Communication about an Ongoing Safety Review of Tiotropium (marketed as Spiriva HandiHaler)

[01-14-2010] This is a Follow-Up to previous Early Communications issued in 2008 by the U.S. Food and Drug Administration (FDA) describing a potential increase in the risk of stroke, heart attack, or death from a cardiovascular cause related to the use of tiotropium, which is marketed as Spiriva HandiHaler. FDA has now completed its review and believes the available data do not support an association between the use of Spiriva HandiHaler and an increased risk for these serious adverse events.

FDA is advising healthcare professionals to continue to prescribe Spiriva HandiHaler as recommended in the drug label.

Spiriva HandiHaler is a long-acting respiratory medication used for the treatment of chronic obstructive pulmonary disease (COPD). Consumers currently using Spiriva HandiHaler should talk to their healthcare professional if they have any questions or concerns about the use of this medication.

The March 2008 Early Communication described data submitted by the manufacturer of Spiriva HandiHaler that suggested there may be a small excess risk of stroke in patients using tiotropium (the active ingredient in Spiriva HandiHaler) compared to placebo (2 cases of stroke per 1000 treated patients). The Updated Early Communication from October 2008 reported two additional publications that suggested an increased risk of death, heart attack or stroke in patients using tiotropium or drugs that work similarly to tiotropium.[1,2]

Since these initial communications, FDA has completed its analysis of the *Understanding the Potential Long-Term Impacts on Function with Tiotropium* (UPLIFT) trial. UPLIFT was a large, 4-year clinical trial that compared Spiriva HandiHaler to placebo in 5,992 patients with COPD.

In the UPLIFT trial, there was no significant increase in the risk of stroke [0.95 (95% CI 0.70, 1.29)], heart attack [0.73 (95% CI 0.53, 1.00)], or cardiovascular death [0.73 (95% CI 0.56, 0.96)] between Spiriva HandiHaler and placebo.

In November 2009, the FDA Pulmonary - Allergy Drugs Advisory Committee also reviewed data from the UPLIFT trial and voted that the UPLIFT findings adequately resolve the potential safety concerns for stroke, heart attack and cardiovascular death.

References:

1. Singh S, Loke YK, Furberg CD. Inhaled anticholinergics and risk of major adverse cardiovascular events in patients with chronic obstructive pulmonary disease. JAMA 2008; 300 (12): 1439-1450.

2. Lee TA, Pickard S, Au DH et al. Risk of Death Associated with Medications for Recently Diagnosed Chronic Obstructive Pulmonary Disease. Annals of Internal Medicine 2008; 149: 380-390.

Related Information

- Early Communication about an Ongoing Safety Review of Tiotropium (marketed as Spiriva HandiHaler)
  10/7/2008
- Tiotropium (marketed as Spiriva HandiHaler) Information

Contact Us

- **Report a Serious Problem**

- 1-800-332-1088
- 1-800-FDA-0178 Fax

MedWatch Online

Regular Mail: Use postage-paid FDA Form 3500

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20852-9787

News & Events

FDA NEWS RELEASE

For Immediate Release: Jan. 22, 2010
Contact: Sandy Walsh, 301-796-4669, sandy.walsh@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Approves Ampyra to Improve Walking in Adults with Multiple Sclerosis

The U.S. Food and Drug Administration today approved Ampyra (dalfampridine) extended release tablets to improve walking in patients with multiple sclerosis (MS). In clinical trials, patients treated with Ampyra had faster walking speeds than those treated with an inactive pill (placebo). This is the first drug approved for this use.

MS is a chronic, often disabling, disease that affects the central nervous system—the brain, spinal cord, and optic nerves. There are about 400,000 people in the United States and 2.5 million people world-wide with MS.

The progress, severity, and specific symptoms of MS are unpredictable and vary from one person to another. Symptoms can be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. About half of all people with MS experience cognitive impairments like difficulties in concentration, attention, memory, and judgment, although these symptoms are usually mild and are frequently overlooked. Depression also is common among MS patients.

"Trouble with walking is one of the most debilitating problems people with MS face," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research.

Ampyra, when given at doses greater than that recommended (10 milligrams twice a day), can cause seizures. The most common adverse reactions reported by patients taking Ampyra in clinical trials include urinary tract infection, insomnia, dizziness, headache, nausea, weakness, back pain, balance disorder, swelling in the nose or throat, constipation, diarrhea, indigestion, throat pain, and burning, tingling or itching of skin.

Ampyra should not be used in patients with moderate to severe kidney disease. In these patients, blood levels with the drug approach those associated with the occurrence of seizures.

Ampyra will be manufactured under licenses from Elan of Dublin, Ireland, and distributed by Acorda Therapeutics Inc. of Hawthorne, N.Y.

For information about FDA drug approvals:
http://www.fda.gov/Drugs/default.htm

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