Drug Utilization Review Board

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

Wednesday
January 13, 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 – January 13, 2010**

DATE: January 7, 2010

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

Enclosed are the following items related to the January 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 Antipsychotics – See Appendix C.

30 Day Notice to Prior Authorize Ribavirin Capsules, Solution, and Dose Packs – See Appendix D.

Action Item – Annual Review of NSAIDs and 30 Day notice to Prior Authorize Zipsor™ and Cambia™ – See Appendix E.

Action Item – Annual Review of Topical Antifungals – See Appendix F.

FDA and DEA Updates – See Appendix G.

Future Business

Adjournment

ORI-4403 • P.O. BOX 26901 • OKLAHOMA CITY, OKLAHOMA 73126-0901 • (405) 271-9039 • FAX: (405) 271-2615

Drug Utilization Review Board

(DUR Board)

Meeting – January 13, 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. December 9, 2009 DUR Minutes – Vote
B. December 10, 2009 DUR Recommendation Memorandum
C. Correspondence

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

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

A. Medication Coverage Activity Audit for December 2009
B. Help Desk Activity Audit for December 2009

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

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

A. COP Recommendations

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

6. 30 Day Notice to Prior Authorize Ribavirin Capsules, Solution, and Dose Packs – See Appendix D.

A. Product Summary
B. Cost Comparison
C. COP Recommendations

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

7. Action Item – Annual Review of NSAIDs and 30 Day Notice to Prior Authorize Zipsor™ and Cambia™ – See Appendix E.

A. Current PA Criteria
B. Utilization Review
C. Market News & Updates
D. COP Recommendations
E. Utilization Details

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

8. Action Item – Annual Review of Topical Antifungals – See Appendix F.

A. Current PA Criteria
B. Utilization Review
C. Market News & Updates
D. COP Recommendations
E. Utilization Details

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. New Product Reviews

11. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of DECEMBER 9, 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, 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	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Leslie Robinson, D.Ph.; PA Coordinator	X	
Visiting Pharmacy Student(s): *none*		

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:

Frances Bauman, Novo Nordisk	Lon Lowrey, Novartis	Paul Davis, MHAT
Jim Fowler, Astra Zeneca	Kelly Rogers, Taro	John Seidenberger, Boehringer-Ingelheim
Donna Erwin, Bristol-Myers Squibb	Holly Turner, Merck	Sam Smothers, MedImmune
John Harris, Abbott	Albert Appiah, Pfizer	Charlene Kaiser, Amgen
Mallery Mayo	Craig Turner, Merck	Ryan Roberts, Xanodyne
Michael Hathaway, Otsuka	Kim Greenberg, Amylin	M. Patty Laster, Genentech
William Dozier, Gilead	Jim Dunlap, Lilly USA	Mario Munoz, Lilly USA
Cheri Ritchie, BMS	Becky Alderson, BMS	Lisa Bua, Pfizer

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 9	Mallery Mayo, Merck Medical Affairs
Agenda Item No. 9	Paul Davis, MHAT/Mental Health Association, Tulsa

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. 9 Mallery Mayo, Merck Medical Affairs

Agenda Item No. 9 Paul Davis, MHAT/Mental Health Association, Tulsa

ACTION: NONE REQUIRED

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

3A: November 12 2009 DUR Minutes

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

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review Response: August 2009

4B: Medication Coverage Activity Audit: November 2009

4C: Help Desk Activity Audit: November 2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE ON 2010 MEETING DATES**

Presented by Dr. Keast:

January 13, 2010	February 10, 2010	March 10, 2010	April 14, 2010
May 12, 2010	June 9, 2010	July 14, 2010	August 11, 2010
September 8, 2010	October 13, 2010	November 10, 2010	December 8, 2010

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE INTUNIV™**

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE VALTURNA™**

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

Dr. Winegardener moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE ANTIEMETICS**

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **60-DAY NOTICE TO PRIOR AUTHORIZE ATYPICAL ANTIPSYCHOTICS**

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

For Public Comment: Mallery Mayo, Merck Medical Affairs: Good evening Mr. Chairman. My name is Mallery Mayo. I'm a neuroscientist by training. I work for Merck in the medical affairs department and I'm just here today, we have a product that's just recently come to market known as Saphris. I'm just here today to act as a resource, let you know I'm here if you have any questions about Saphris. Thanks.

Dr. Winegardner: What is Saphris?

Ms. Mayo: It's also known as asenapine, a second generation antipsychotic.

Dr. Winegardner: And it's, I don't know anything about it. I've never heard anything about it.

Ms. Mayo: It was released …… stop me when you want me to tell you more or less.

Dr. Winegardner: No, I want to hear about the drug.

Ms. Mayo: Okay, it has an indicated for bipolar disorder, bipolar I disorder of mixed or manic episodes with and without psychotic features in adults. There's also an indication for acute treatment of schizophrenia in adults as well. This product is, the efficacy has been established in a number of clinical trials. For schizophrenia, there were three trials. In two of these, it demonstrated statistically significant to placebo. On the PANSS, which is the Positive and Negative Symptom Scale, it's a standard disease measure, for bipolar disorder there were two similarly designed trials with active comparator control arms and those studies, those are 3-week studies which is also typical of bipolar disorder in terms of clinical trials, and it was, Saphris was statistically significantly superior to placebo again in that study as well, in those two studies as well on the YMRS, the Young Mania Rating Scale. Saphris is dosed sublingually and it dissolves in saliva within seconds. We instruct patients, or the company instructs patients to not eat or drink for ten minutes following administration for the absorption. At that point, that product can be used in people irrespective of age, gender, age, sex, racial background, or renal impairment. Patients with severe hepatic impairment should not take it. In terms of safety and tolerability, are you OK with me?

Dr. Winegardner: Yeah.

Ms. Mayo: Okay, in terms of safety and tolerability, just like with all the other antipsychotics there's a boxed warning for patients that have severe, patients who have Alzheimer's or have dementia related psychosis. It shouldn't be used in those patients. The most widely reported side effects are greater than or equal to 5% and twice that of placebo for schizophrenia were somnolence, oral hypoesthesia, which is a slight numbing of the tongue, and akathisia, and then for bipolar disorder, it was somnolence, dizziness and extrapyramidal symptoms other than akathisia and weight increase. And as I mention weight increase, we also looked at 52-week data in patients with schizophrenia and schizoaffective disorder, and the weight gain, mean weight gain, mean change in baseline was around 0.9 kg, so around two pounds in a year.

Dr. Winegardner: In a year?

Ms. Mayo: In a year. Other metabolic parameters, for example, fasting glucose was around 1. …. an increase 1.4 after a year. Triglycerides, fasting triglycerides were a decrease, around 9.8 and also total cholesterol decreased around 6 mg/dL. ALT, which is a measure of liver function, increased about 1.7 U/L a year. So that's sort of some of its metabolic profile. As with the other atypicals, there are warnings against neuroleptic malignant syndrome, tardive dyskinesia orthostatic hypotension and syncope, suicide, dysphasia.

Dr. Winegardner: So why is it better than the other products out on the market?

Ms. Mayo: It represents a different option for one. The dosing is different. If someone is cheeking their meds, a sublingual tablet will dissolve immediately and avoid the problem of cheeking would be one instance. The actual formulation itself, though, that requires sublingual dosing. In terms of the metabolic profile, I think at least from our 52-week data; it shows to have a non-clinically significant difference in most cases across patients. Efficacy is again the exception of the non-inferiority study we have to olanzapine. Most of the data is with placebo, so that's kind of my package insert in a nutshell.

Dr. Muchmore: Well, there's a lot of subtle differences among these drugs and that emphasizes something that I think is very important and that is that it's individualized. The data from a group of people isn't necessarily going to apply to your one patient. Okay, our next speaker is Paul Davis from Mental Health Associates, Tulsa.

For Public Comment, Paul Davis: I actually came just bearing a letter, but I'm really willing to read it to you. It's just our statement of position, there are copies too. *"After reviewing the recommendation of the College of Pharmacy to add the Atypical Antipsychotic class to the P.B.P.A. program we wanted to commend the thorough analysis and consideration that this decision is getting. We all recognize the weight and impact that this proposal can have not just on the lives of Oklahomans relying upon these medications for their recovery, but also the cost to the taxpayers for this costly class of medications. It is the position of the Mental Health Association in Tulsa that open access should be allowed for psychotropic medications, and we will continue to encourage the Health Care Authority to implement this policy until a time when it is appropriate to restrict access. Our recommendation in response to the proposal of the College of Pharmacy would be to incorporate open access by allowing members with an FDA approved diagnosis to have access to the medications in this class without prior authorization. At this time the adverse effects of medications and the varying response to the medications from each person necessitate allowing physicians to continue to choose the best medication on a member by member basis. The increase in off label use of Atypical Antipsychotics, especially in children, is a point of concern, and we encourage the Health Care Authority to implement appropriate clinical and cost controls."*

Dr. Muchmore: Any questions? Thank you for coming.

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

ACTION: NONE REQUIRED

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.

A: Anxiolytic Criteria Review

B: Annual Review of Smoking Cessation Products

C: Annual Review of NSAIDs

D: New Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ADJOURNMENT**

The meeting was adjourned at 8:00 p.m.

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

Memorandum

Date: December 10, 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 December 9, 2009

Recommendation 1: Vote to Approve 2010 Meeting Dates

MOTION CARRIED by unanimous approval.

Meetings are held the second Wednesday of each month.

JANUARY 13, 2010
FEBRUARY 10, 2010
MARCH 10, 2010
APRIL 14, 2010
MAY 12, 2010
JUNE 9, 2010
JULY 14, 2010
AUGUST 11, 2010
SEPTEMBER 8, 2010
OCTOBER 13, 2010
NOVEMBER 10, 2010
DECEMBER 8, 2010

Recommendation 2: Vote to Prior Authorize Intuniv™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends placement of Intuniv™ in Tier 2 of the ADHD Product Based Prior Authorization Category. The existing criteria for this category will apply.

Tier-1*	Tier-2	Tier 3
amphetamine salt combo **(Adderall®)** dexmethylphenidate **(Focalin®)** methylphenidate IR **(Ritalin®, Methylin®)** methylphenidate SR **(Ritalin SR®)** methylphenidate ER **(Concerta®)** dexmethylphenidate **(Focalin XR®)** lisdexamfetamine **(Vyvanse®)**	atomoxetine **(Strattera®)** methylphenidate ER **(Metadate® CD)** methylphenidate ER **(Metadate® ER)** methylphenidate ER **(Ritalin® LA)** amphetamine salt combo **(Adderall XR®)** guanfacine **(Intuniv™)**	armodafinil **(Nuvigil®)** methamphetamine **(Desoxyn®)** methylphenidate patch **(Daytrana™)** modafinil **(Provigil®)** dextroamphetamine **(Dexedrine®, Dexedrine Spansules®)**

Recommendation 3: Vote to Prior Authorize Valturna™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends placement of Valturna™ in Tier 3 of the Direct Renin Inhibitors Product Based Prior Authorization Category. The existing criteria for this category will apply.

Approval Criteria

- FDA approved indication
- Recent trial, within the previous 6 months and at least 4 weeks in duration, of an ACE Inhibitor (or an ARB if previous trial of an ACEI) and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control.
- Clinical exceptions will be granted for members already currently on aliskiren and valsartan at the available doses of Valturna™.

Direct Renin inhibitors (Tekturna® and Tekturna HCT®)		
Tier-1	**Tier-2**	**Tier-3**
Tier-1 ACE Inhibitor + Diuretic	ARB + Diuretic	Aliskiren **(Tekturna™)** Aliskiren/HCTZ **(Tekturna HCT™)** Aliskiren/Valsartan **(Valturna™)**

Quantity limit of #30 per 30 apply for all medications in this category.

Recommendation 4: Vote to Prior Authorize Anti-Emetics

MOTION CARRIED by unanimous approval.

The College recommends prior authorization of granisetron, dolasetron, aprepitant, and cannabinoids. The following are the proposed approval criteria.

Approval Criteria for granisetron (Kytril® and Sancuso®), dolasetron (Anzemet®), and aprepitant (Emend®):

- Approved Diagnosis
- A recent (within the past 6 months) trial of ondansetron used for at least 3 days or one cycle that resulted in inadequate response.
- Approval length based on duration of need.
- Existing quantity limits apply.

Approval Criteria for cannabinoids (Marinol® and Cesamet®):

- For the diagnosis of HIV related loss of appetite: approve for 6 months
- For chemotherapy induced nausea and vomiting: A recent (within the past 6 months) trial of ondansetron used for at least 3 days or one cycle that resulted in inadequate response.
- Approval length based on duration of need.
- A quantity limit of 60 per 30 days also applies.

Building Lives

John Muchmore, M.D., Ph.D., Chair
Drug Utilization Review Board
Oklahoma Health Care Authority
4545 North Lincoln Boulevard, Suite 124
Oklahoma City, Oklahoma 73105

9 December 2009

RE: 60 Day Notice to Prior Authorize Atypical Antipsychotics

Dear Dr. Muchmore:

After reviewing the recommendation of the College of Pharmacy to add the Atypical Antipsychotic class to the P.B.P.A. program we wanted to commend the thorough analysis and consideration that this decision is getting. We all recognize the weight and impact that this proposal can have not just on the lives of Oklahomans relying upon these medications for their recovery, but also the cost to the taxpayers for this costly class of medications.

It is the position of the Mental Health Association in Tulsa that open access should be allowed for psychotropic medications, and we will continue to encourage the Health Care Authority to implement this policy until a time when it is appropriate to restrict access.

Our recommendation in response to the proposal of the College of Pharmacy would be to incorporate open access by allowing members with an FDA approved diagnosis to have access to the medications in this class without prior authorization. At this time the adverse effects of medications and the varying response to the medications from each person necessitate allowing physicians to continue to choose the best medication on a member by member basis.

The increase in off label use of Atypical Antipsychotics, especially in children, is a point of concern, and we encourage the Health Care Authority to implement appropriate clinical and cost controls.

Thank you for your consideration,

Michael W. Brose
Executive Director

Paul G. Davis
Director of Public Policy

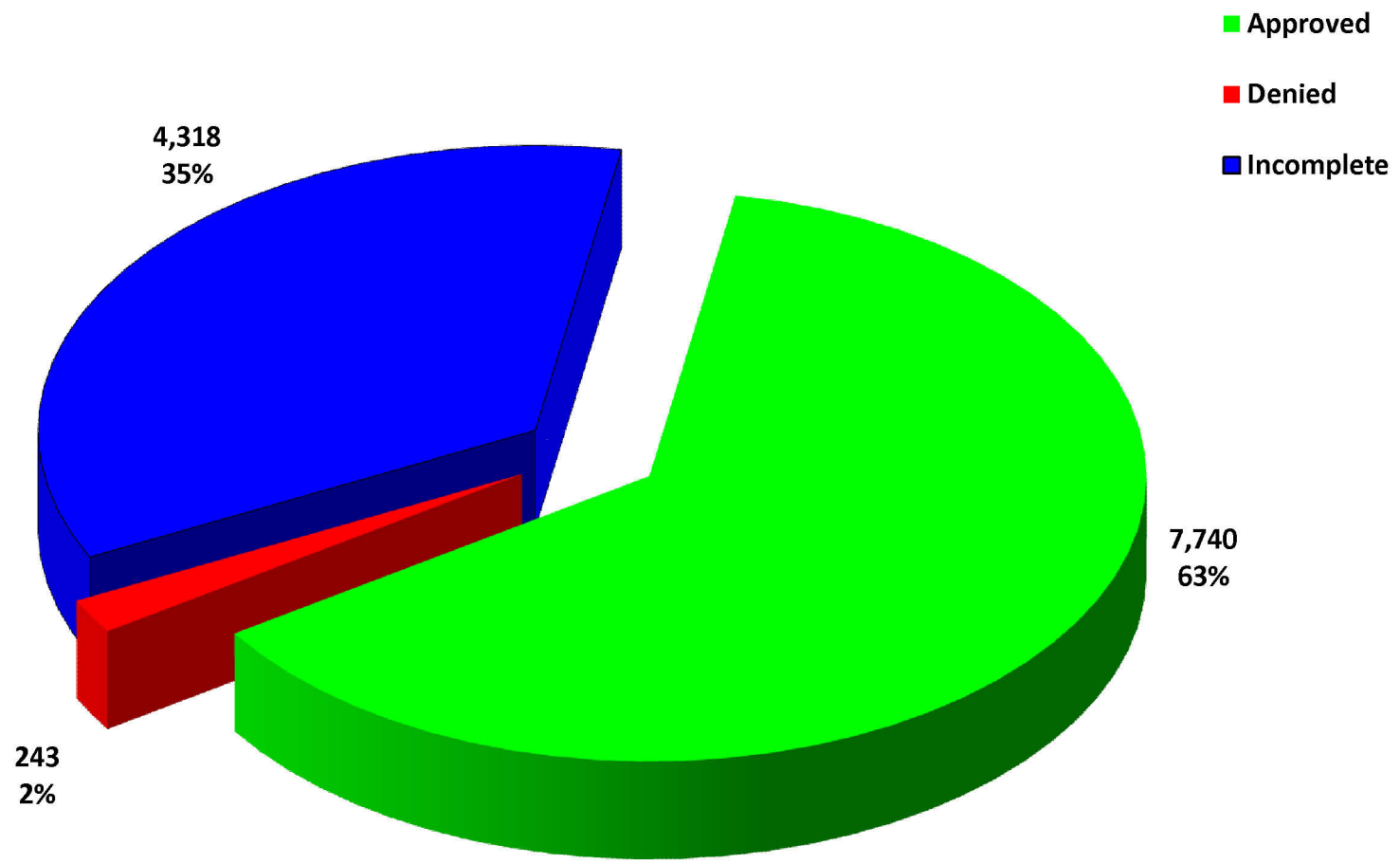
1870 South Boulder, Tulsa, Oklahoma 74119
Telephone (918) 585-1213 • Fax (918) 585-1263
www.mhat.org

MENTAL HEALTH ASSOCIATION IN TULSA

United Way

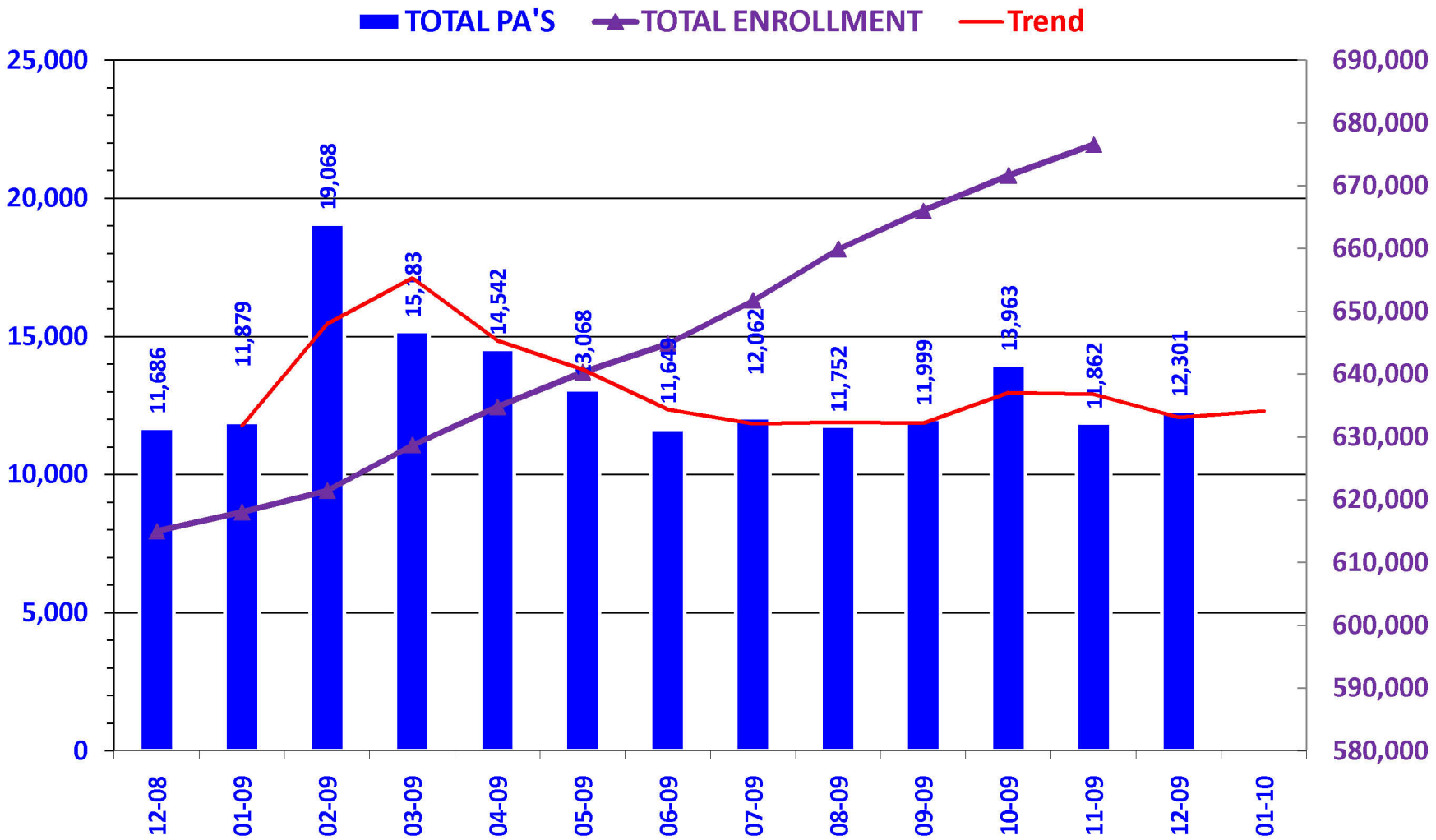
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: December 2009



PA totals include overrides

PRIOR AUTHORIZATION REPORT: December 2008 – December 2009



PA totals include overrides

Prior Authorization Activity

December 2009

	Average Length of Approvals in Days	Approved	Denied	Incomplete	Total
Advair/Symbicort	357	276	2	390	668
Amitiza	141	5	1	21	27
Antidepressant	335	157	7	424	588
Antihistamine	288	178	3	165	346
Antihypertensives	344	62	0	92	154
Antimigraine	59	2	0	1	3
Benzodiazepines	92	3,720	9	740	4,469
Bladder Control	268	5	0	20	25
Brovana (Arformoterol)	0	0	0	2	2
Byetta	268	2	0	5	7
Elidel/Protopic	102	18	1	37	56
ESA	59	141	0	35	176
Fibric Acid Derivatives	90	1	0	1	2
Fibromyalgia	342	30	0	29	59
Forteo	360	1	0	3	4
Glaucoma	272	8	0	12	20
Growth Hormones	172	31	0	2	33
HFA Rescue Inhalers	214	64	0	42	106
Insomnia	122	39	3	109	151
Misc Analgesics	176	6	30	30	66
Muscle Relaxant	41	64	76	72	212
Nasal Allergy	225	2	30	97	129
NSAIDS	325	37	3	76	116
Nucynta	48	3	0	2	5
Ocular Allergy	207	3	0	7	10
Ocular Antibiotics	17	4	0	9	13
Opioid Analgesic	164	75	4	115	194
Other	146	167	11	302	480
Otic Antibiotic	22	2	1	1	4
Pediculicides	16	16	4	32	52
Plavix	327	10	1	14	25
Proton Pump Inhibitors	111	83	2	283	368
Qualaquin (Quinine)	0	0	3	1	4
Singulair	256	474	4	412	890
Smoking Cessation	60	18	1	54	73
Statins	347	14	1	42	57
Stimulant	231	645	3	315	963
Symlin	222	2	0	1	3
Synagis	100	139	27	35	201
Topical Antibiotics	49	2	0	25	27
Topical Antifungals	72	7	0	37	44
Ultram ER and ODT	145	4	0	6	10
Xolair	195	2	1	5	8
Xopenex Nebs	232	33	0	22	55
Zetia (Ezetimibe)	361	10	0	10	20
Emergency PAs		3	0	0	3
Total		**6,565**	**228**	**4,135**	**10,928**

Overrides					
Brand	106	77	2	16	95
Dosage Change	21	452	4	25	481
High Dose	266	18	0	5	23
IHS - Brand	95	40	0	4	44
Ingredient Duplication	52	9	1	2	12
Lost/Broken Rx	28	89	2	4	95
Nursing Home Issue	9	98	1	11	110
Other	56	27	0	6	33
Quantity vs. Days Supply	240	380	7	151	538
Stolen	12	8	0	0	8
Overrides Total		**1,198**	**17**	**224**	**1,439**
Total Regular PAs + Overrides		**7,763**	**245**	**4,359**	**12,367**

Denial Reasons

Lack required information to process request.	2,149
Unable to verify required trials.	1,695
Does not meet established criteria.	196
Not an FDA approved indication/diagnosis.	181
Considered duplicate therapy. Member has a prior authorization for similar medication.	121
Member has active PA for requested medication.	101
Requested dose exceeds maximum recommended FDA dose.	95
Medication not covered as pharmacy benefit.	25
Drug Not Deemed Medically Necessary	4

Duplicate Requests: 870

Changes to existing PAs: 827

CALL VOLUME MONTHLY REPORT:
December 2008 – December 2009

Appendix C

30 DAY NOTICE TO PRIOR AUTHORIZE

ATYPICAL ANTIPSYCHOTICS

OKLAHOMA HEALTH CARE AUTHORITY
JANUARY 2010

RECOMMENDATIONS

The College of Pharmacy recommends the addition of the Atypical Antipsychotics class to the Product Based Prior Authorization program. The following Tier-1 drug list has 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 a 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.
- 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

Approval Criteria for Tier 2 Medication:

1. FDA-approved diagnosis.
2. 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.
3. 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 grandfathered.
4. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated and for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.

Approval Criteria for Tier 3 Medication:

1. FDA-approved diagnosis.
2. 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.
3. 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.
4. 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 grandfathered.
5. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated and for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
6. 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)	No Pediatric Indications	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	Tabs, Extended Release Tablets	No Pediatric Indications	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	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

30 DAY NOTICE TO PRIOR AUTHORIZE RIBAVIRIN CAPSULES, SOLUTION AND DOSE PACKS

OKLAHOMA HEALTHCARE AUTHORITY

JANUARY 2010

PRODUCT SUMMARY

Approximately 2.7 million people have ongoing hepatitis C virus (HCV) infection and it is the leading cause of death from liver disease in the United States. An estimated 240,000 children in the United States have antibodies to hepatitis C and present with fewer symptoms compared to adults. The primary source of HCV transmission is HCV-infected blood or blood products. A high risk of HCV infection is associated with blood transfusions, illicit intravenous drug use, perinatal transmission and multiple sexual partners. [1] Ribavirin is an anti-viral drug classified as a nucleoside antimetobolite. The oral formulations are indicated for hepatitis C infection in conjunction with peginterferon alfa-2b or peginterferon alfa-2a. It is currently available in capsules, tablets, solution and dose packs. There is currently a SMAC on the tablet formulation which offers a significant savings over the other formulations and packaging.

PRODUCT COST COMPARISON (ORAL DOSAGE FORMULATIONS)

Product	EAC / Unit	SMAC / Unit	Monthly Cost:
Ribavirin 200mg Capsules	$8.74	$1.63	$293.40*
Copegus® 200mg tablet	$11.63	$0.82	$147.60*
Rebetol® 200mg capsule	$9.32	$1.63	$293.40*
Ribasphere 200mg capsule	$8.74	$1.63	$293.40*
Ribasphere 200mg tablet	$7.30	$0.82	$147.60*
Ribasphere 400mg tablet	$14.60		$1,314.00*
Ribasphere 600mg	$21.90		$1,314.00*
Ribapak 400-400 (56)	$16.84		$943.04**
Ribapak 600-400 (56)	$21.12		$1,182.72**
Ribapak 600-600 (56)	$25.35		$1,419.60**
Rebetrol 40mg/ML	$2.05		$922.50***

*1200 mg/day
**800mg/day - Ribapak 400/400; 1000mg/day - Ribapak 600/400; 1200mg/day - Ribapak 600/600
***600 mg/day

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).

ECONOMIC IMPACT

The resulting savings from this prior authorization based on an increase from the current 22% use of the 200 mg tablet to 60% use would be approximately $300,000 annually. Less than 200 members would be affected by this prior authorization.

REFERENCES

1. Treatment Guidelines: AASLD Practice Guidelin: Diagnosis, Management, and Treatment of Hepatitis C. Hepatology, April 2004. Available at: http://74.125.95.132/search?q=cache:8KdTLI5UNpwJ:www.aasld.org/practiceguidelines/Practice%2520Guideline%2520Archive/Diagnosis,%2520Management%2520and%2520Treatment%2520of%2520Hepatitis%2520C.pdf+treatment+guidelines+hepatitis+c&cd=1&hl=en&ct=clnk&gl=us. Accessed December 2009.
2. Ribavirin(Oral Route). Mayo Clinic Drug Information 2009. Available at http://www.mayoclinic.com/health/drug-information/DR602577/DSECTION=before-using. Accessed December 26, 2009.
3. Clinical Trial: Ribavirin 200mg tablets under non-fasting conditions. U.S. National Institutes of Health September 2009. Available at: http://clinicaltrials.gov/ct2/show/NCT00835536. Accessed December 26, 2009.
4. Product Information Ribavirin tablets. Mallinckrodt Package Insert.
5. Product Information Ribapak®(Ribavirin) Package Insert.
6. Product Information Copegus®(Ribavirin) Package Insert.
7. Product Information Ribasphere®(Ribavirin) Package Insert.
8. Product Information Rebetol®(Ribavirin) Package Insert.

RIBAVIRIN PRODUCT DETAILS

PHARMACOKINETICS (ORAL)

- Significantly prolonged concentration in the erythrocyte (16-40days) and does not undergo protein binding.
- Undergoes hepatic metabolism which may be necessary for drug activation
- Oral dosage forms result in 64% bioavailability.
- Half-life elimination in plasma:
    1. Capsule (Rebetol®, Ribasphere®): Children 6.5-11 hours. Adults 24 hours in healthy adults, 44 hours in adults with chronic hepatitis C infection which may increase to 298 hours at steady state.
    2. Tablet (Copegus®): 120-170 hours.
- Time to peak: Capsule 3 hours; Tablet 2 hours
- Excretion: 61% in urine and 12% in feces
- Bioavailability of oral dosage form is increased with high-fat meal.
- Ribavirin does not inhibit CYP450 enzymes.

Optimal HCV Treatment: Guidelines

The current standard of care which results in highest overall sustained virologic response is combination of injections with long-acting peginterferon alfa and oral ribavirin.

Clinical Trials: Generic Tablets

Randomized, Open Label, Crossover Trial in healthy adults comparing Copegus tablets and ribavirin tablets yielded similar bioavailability.[3]

ADMINISTRATION AND PATIENT MONITORING INFORMATION

- Administer concurrently with interferon alfa injection.
- Capsule should not be opened, crushed, chewed, or broken. Capsules are not for use in children <5 years of age. Use oral solution for children 3-5 years, those ≤25 kg, or those who cannot swallow capsules.
- Capsule, in combination with interferon alfa-2b: may be administered with or without food, but consistently with regard to food intake.
- Capsule, in combination with peginterferon alfa-2b: administer with food.
- Solution, in combination with interferon alfa-2b: may be administered with or without food, but consistently with regard to food intake.
- Tablet: should be administered with food.

- Oral high-fat meals increase AUC and Cmax.
- Drink plenty of water to reduce side effects.
- Before beginning Ribavirin therapy, standard hematological and biochemical laboratory tests must be conducted for all patients. Pregnancy screening for women of childbearing potential must be done and monthly for 6 months post discontinuing therapy.
- After initiation of therapy, hematological tests should be performed at 2 weeks and 4 weeks and biochemical tests should be performed at 4 weeks.

Ribavirin Oral Dosing[7,8,9,10]

Product	Indication	Adult Dosage(s)	Other Dosing
Copegus® 200mg tablets Ribasphere 200mg tablets Ribapak™ 400, 600mg tablets 14,7 pack	Chronic Hepatitis C monoinfection, genotype 1,4 (in combination with peginterferon alfa-2a) Chronic Hepatitis C monoinfection, genotype 2,3 Coinfection with HIV	<75 kg: 1000 mg/day, in 2 divided doses for 48 weeks ≥75 kg: 1200 mg/day, in 2 divided doses for 48 weeks 800 mg/day, in 2 divided doses for 24 weeks 800 mg/day in 2 divided doses for 48 weeks (regardless of genotype)	**Renal impairment** Clcr <50 mL/minute: Oral route is not recommended. **Liver impairment** Hepatic decompensation (Child-Pugh class B and C): Use of ribavirin tablets is contraindicated. **Toxicity** *Patient without cardiac history:* Hemoglobin <10 g/dL: Children decrease dose to 7.5 mg/kg/day. Adults decrease dose to 600 mg/day Hemoglobin <8.5 g/dL: Discontinue *Patient with cardiac history:* Hemoglobin ≥2 g/dL during any 4-week period of treatment (same as above for Hemoglobin <10 g/dL) Hemoglobin <12 g/dL after 4 weeks of reduced dose: Discontinue
Rebetol® Ribasphere® capsules	Chronic Hepatitis C (in combination with interferon alfa-2b) Chronic Hepatitis C (in combination with peginterferon alfa-2b)	≤75 kg: 400 mg in the morning, then 600 mg in the evening >75 kg: 600 mg in the morning, then 600 mg in the evening 400 mg twice daily	
		Pediatric Dosage(s)	
Rebetol® capsule or Oral solution 40 mg/mL (100 mL)	Chronic Hepatitis C (in combination with interferon alfa-2b) Ages: 3-5 Wt: ≤25kg Genotype 1: 48 weeks; genotypes 2,3: 24 weeks	Children ≥3 years: 15 mg/kg/day in 2 divided doses. 25-36 kg: 400 mg/day (200 mg morning and evening) 37-49 kg: 600 mg/day (200 mg in the morning and 400 mg in the evening) 50-61 kg: 800 mg/day (400 mg in the morning and evening) >61 kg: Refer to adult dosing.	

Appendix E

Annual Review of Non-Steroidal Anti-Inflammatory Drugs - Fiscal Year 2009

30 Day Notice to PA Zipsor™ and Cambia™

Oklahoma HealthCare Authority

January 2010

Current Prior Authorization Criteria

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

1. Two consecutive trials with Tier 1 products with inadequate results within the last 120 days, or
2. Documented FDA-approved indication for which Tier 1 medications are not indicated
3. Other clinical exceptions may apply. The clinical exceptions for the non-steroidal, anti-inflammatory drugs in Tier 2 are demonstrated by the following conditions:
    a. history of upper GI bleeding; or
    b. history of NSAID-induced ulcer; or
    c. active peptic ulcer disease; or
    d. concurrent use of warfarin; or
    e. concurrent chronic use of oral corticosteroids; or
    f. chronic NSAID therapy in elderly or debilitated patients; or
    g. diagnosis of gout (indomethacin only)

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)	
Tier 1 (no PA required)	**Tier 2 (requires PA)**
diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®)
diclofenac potassium (Cataflam®)	diclofenac epolamine (Flector®)
diclofenac sodium (Voltaren®)	diclofenac sodium / misoprostol (Arthrotec®)
etodolac (Lodine®)	diclofenac sodium (Voltaren Gel®*)
etodolac ER (Lodine® XL)	indomethacin (Indocin®)
fenoprofen (Nalfon®)	naproxen sodium (Naprelan®)
flurbiprofen (Ansaid®)	piroxicam (Feldene®)
ibuprofen (Motrin®)	
ketoprofen (Orudis®)	
ketoprofen ER (Oruvail®)	
meclofenamate (Meclomen®)	
mefanamic acid (Ponstel®)	
meloxicam (Mobic®)	
nabumetone (Relafen®)	
naproxen (Naprosyn®)	
naproxen sodium (Anaprox®)	
naproxen EC (Naprosyn® EC)	
oxaprozin (Daypro®)	
sulindac (Clinoril®)	
tolmetin (Tolectin®)	

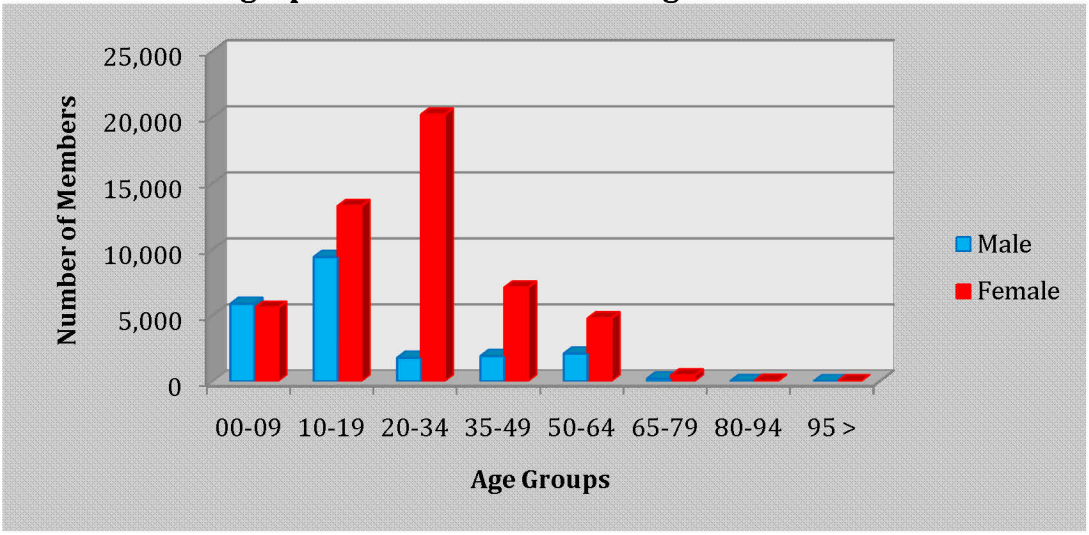
*Participated in Supplemental Rebate Program during CY2009.

Utilization of NSAIDs

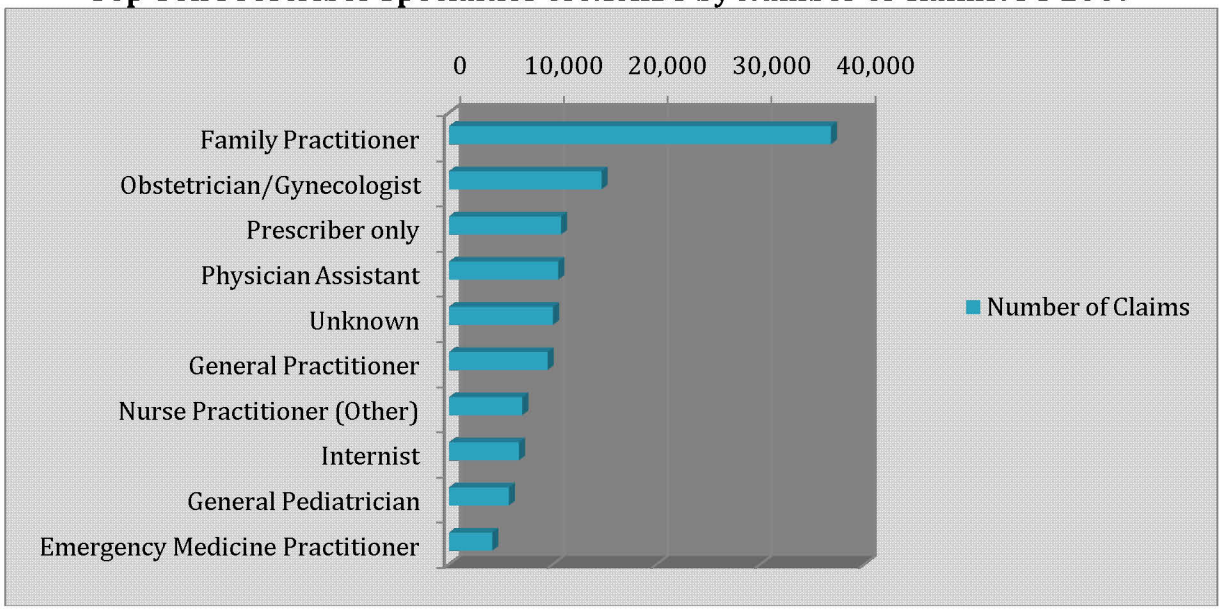
Comparison of Fiscal Years

Fiscal Year	Members	Claims	Cost	Cost/Claim	Per diem	Units	Days
2008	75,474	139,531	$1,819,238.52	$13.04	$0.68	9,166,173	2,692,915
2009	72,723	132,908	$1,798,364.55	$13.53	$0.67	8,159,469	2,692,622
Percent Change	-3.60%	-4.70%	-1.10%	3.80%	-1.50%	-11.00%	0.00%
Change	-2,751	-6,623	($20,873.97)	$0.49	($0.01)	1,006,704	-293

Demographics of Members Utilizing NSAIDs: FY 2009

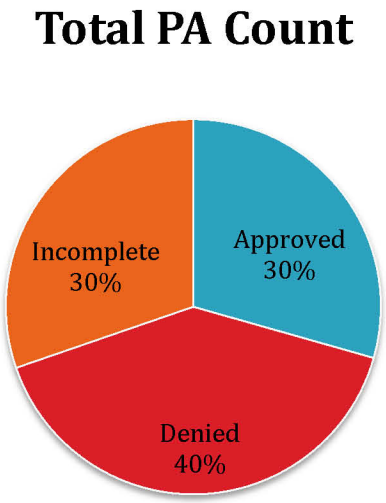


Top Ten Prescriber Specialties of NSAIDs by Number of Claims: FY 2009



Prior Authorization of NSAIDs

There were a total of 1,476 petitions submitted for this PBPA category during fiscal year 2009. Step edits are in place for point-of-sale claims when tier trials have been met. The following chart shows the status of the submitted petitions.



Market News and Updates

New products:

Zipsor™ (diclofenac potassium) is a new formulation of a benzenacetic acid derivative NSAID approved June 2009 for the relief of mild to moderate acute pain in adults age 18 and older. It is available as a 25mg liquid capsule for oral administration, and the recommended dose is 25mg four times daily. This is so far the lowest available dose of all oral diclofenac products. The most common adverse reactions reported in clinical trials were gastrointestinal effects including abdominal pain, constipation, diarrhea, dyspepsia, nausea, and vomiting. Other common adverse effects included dizziness, headache, somnolence, pruritus, and increased sweating. The unique property of this medication is that it is designed for rapid and constant absorption, with a new ProSorb® dispersion technology. Zipsor™ entered the market on September 18, 2009, and the current wholesale acquisition price of this medication is $219.00 for a 100-count bottle.

Cambia™ (diclofenac potassium) is a new formulation of a benzenacetic acid derivative NSAID approved June 2009 for the acute treatment of migraine attacks with or without aura in adults age 18 and older. It is available as a 50mg powder packet which is mixed with 1 to 2 ounces of water for oral administration. The unique property of this medication is that it is designed with a patented Dynamic Buffering Technology (DBT) which during clinical trials showed onset of pain relief within 15 to 30 minutes. This product has not yet been introduced to the market so no cost information is available at this time.

Market news:

Dear Healthcare Professional letter issued 12/04/09
Voltaren gel (diclofenac sodium topical gel) is an NSAID indicated for the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on joints of the spine, hip, or shoulder. Changes have been made to the Warnings and Precautions section of this medication's prescribing information regarding serious hepatic effects. Post marketing surveillance has detected cases of drug-induced hepatoxicity in the first month, and in some cases, the first 2 months of therapy, but can occur at any time during treatment. These cases include severe hepatic reactions such as liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The optimum times for making the first and subsequent transaminase measurement are not known. Based on clinical trial data and post marketing experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with diclofenac.

Recommendations

The College of Pharmacy recommends the addition of Zipsor™ and Cambia™ to the Non-Steroidal Anti-Inflammatory Product Based Prior Authorization category as Tier 2 products. The existing prior authorization criteria for this category will apply. Also, petitioners should supply documentation supporting the need for special formulations of diclofenac. Additionally, it is recommended that Ponstel (mefanamic acid) move to the category of Tier 2 due to its increased price and lack of available generic.

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)	
Tier 1 (no PA required)	**Tier 2 (requires PA)**
diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®)
diclofenac potassium (Cataflam®)	diclofenac epolamine (Flector®)
diclofenac sodium (Voltaren®)	**diclofenac potassium (Zipsor®, Cambia®)**
etodolac (Lodine®)	diclofenac sodium (Voltaren Gel®)
etodolac ER (Lodine® XL)	diclofenac sodium / misoprostol (Arthrotec®)
fenoprofen (Nalfon®)	indomethacin (Indocin®)
flurbiprofen (Ansaid®)	**mefanamic acid (Ponstel®)**
ibuprofen (Motrin®)	naproxen sodium (Naprelan®)
ketoprofen (Orudis®)	piroxicam (Feldene®)
ketoprofen ER (Oruvail®)	
meclofenamate (Meclomen®)	
meloxicam (Mobic®)	
nabumetone (Relafen®)	
naproxen (Naprosyn®)	
naproxen sodium (Anaprox®)	
naproxen EC (Naprosyn® EC)	
oxaprozin (Daypro®)	
sulindac (Clinoril®)	
tolmetin (Tolectin®)	

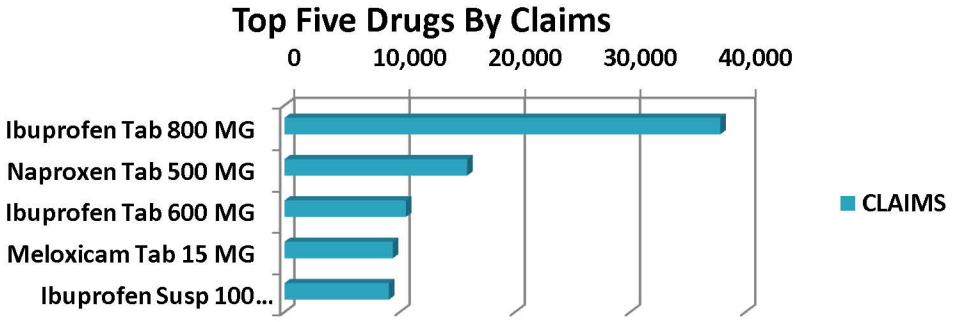
Utilization Details of Medication or Class: Fiscal Year 2009

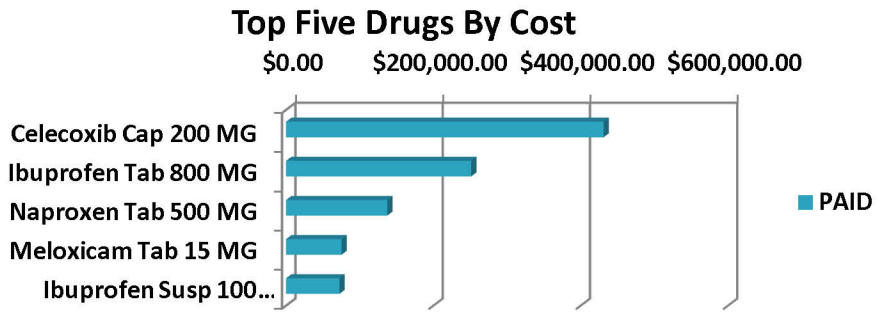
GENERIC NAME	CLAIMS	UNITS	DAYS	MEMBERS	PAID	UNITS/ DAY	CLAIMS/ MEMBER	PER DIEM
Celecoxib Cap 100 MG	179	9,826	6,159	54	$21,807.78	1.6	3.31	$3.54
Celecoxib Cap 200 MG	2,439	115,269	88,151	550	$431,146.57	1.31	4.43	$4.89
Celecoxib Cap 400 MG	4	360	360	1	$2,010.57	1	4	$5.58
Celecoxib Cap 50 MG	3	180	90	2	$210.81	2	1.5	$2.34
Diclofenac Potassium Tab 50 MG	769	38,984	15,225	541	$9,840.33	2.56	1.42	$0.65
Diclofenac Sodium Gel 1%	766	209,928	18,200	520	$53,974.55	11.53	1.47	$2.97
Diclofenac Sodium Tab Delayed Release 25 MG	23	1,140	524	13	$645.88	2.18	1.77	$1.23
Diclofenac Sodium Tab Delayed Release 50 MG	421	23,358	10,581	265	$7,996.11	2.21	1.59	$0.76
Diclofenac Sodium Tab Delayed Release 50 MG	409	23,480	10,367	274	$8,816.37	2.26	1.49	$0.85
Diclofenac Sodium Tab Delayed Release 75 MG	2,742	155,624	78,061	1,411	$57,584.52	1.99	1.94	$0.74
Diclofenac Sodium Tab Delayed Release 75 MG	126	7,319	3,667	64	$3,513.78	2	1.97	$0.96
Diclofenac Sodium Tab SR 24HR 100 MG	285	12,353	9,970	120	$6,474.05	1.24	2.38	$0.65
Diclofenac Sodium Tab SR 24HR 100 MG	74	3,584	2,594	31	$1,550.45	1.38	2.39	$0.60
Diclofenac w/ Misoprostol Tab 50-0.2 MG	61	4,408	1,794	19	$9,357.52	2.46	3.21	$5.22
Diclofenac w/ Misoprostol Tab 75-0.2 MG	131	7,788	4,068	28	$19,191.23	1.91	4.68	$4.72
Etodolac Cap 200 MG	159	8,068	3,118	103	$2,718.95	2.59	1.54	$0.87
Etodolac Cap 300 MG	377	24,759	10,289	214	$6,556.64	2.41	1.76	$0.64
Etodolac Tab 400 MG	2,225	121,708	58,788	1,156	$32,120.78	2.07	1.92	$0.55
Etodolac Tab 500 MG	593	32,904	16,736	300	$11,230.73	1.97	1.98	$0.67
Etodolac Tab SR 24HR 400 MG	357	20,120	11,270	135	$14,908.92	1.79	2.64	$1.32
Etodolac Tab SR 24HR 500 MG	189	9,348	5,089	91	$7,407.73	1.84	2.08	$1.46
Etodolac Tab SR 24HR 600 MG	143	5,055	4,350	72	$7,438.54	1.16	1.99	$1.71
Fenoprofen Calcium Tab 600 MG	10	320	130	2	$171.48	2.46	5	$1.32
FLECTOR DIS 1.3%	82	2,397	1,382	46	$12,287.88	1.73	1.78	$8.89
Flurbiprofen Tab 100 MG	60	3,296	1,697	26	$801.41	1.94	2.31	$0.47
Flurbiprofen Tab 50 MG	4	180	80	3	$42.56	2.25	1.33	$0.53
Ibuprofen Powder	7	253	80	5	$91.60	3.16	1.4	$1.15
Ibuprofen Susp 100 MG/5ML	9,060	1,091,268	104,126	7,025	$72,396.24	10.48	1.29	$0.70
Ibuprofen Susp 100 MG/5ML	4,982	1,034,576	49,204	3,829	$60,563.93	21.03	1.3	$1.23
Ibuprofen Susp 100 MG/5ML	1,601	191,748	20,760	1,306	$10,013.64	9.24	1.23	$0.48
Ibuprofen Susp 100 MG/5ML	463	55,258	6,668	393	$3,973.70	8.29	1.18	$0.60
Ibuprofen Susp 100 MG/5ML	45	5,500	557	36	$376.02	9.87	1.25	$0.68
Ibuprofen Susp 40 MG/ML	740	13,065	8,207	683	$6,177.28	1.59	1.08	$0.75

GENERIC NAME	CLAIMS	UNITS	DAYS	MEMBERS	PAID	UNITS/ DAY	CLAIMS/ MEMBER	PER DIEM
Ibuprofen Susp 40 MG/ML	260	4,395	3,109	231	$1,609.02	1.41	1.13	$0.52
Ibuprofen Susp 40 MG/ML	193	5,940	2,333	176	$1,780.91	2.55	1.1	$0.76
Ibuprofen Susp 40 MG/ML	185	2,805	1,318	172	$1,556.63	2.13	1.08	$1.18
Ibuprofen Susp 40 MG/ML	36	1,065	447	35	$379.44	2.38	1.03	$0.85
Ibuprofen Susp 40 MG/ML	34	525	265	33	$261.80	1.98	1.03	$0.99
Ibuprofen Susp 40 MG/ML	16	424	120	16	$182.30	3.53	1	$1.52
Ibuprofen Tab 400 MG	5,460	260,874	78,659	3,749	$31,755.24	3.32	1.46	$0.40
Ibuprofen Tab 400 MG	50	2,667	748	36	$315.09	3.57	1.39	$0.42
Ibuprofen Tab 600 MG	10,542	475,902	143,766	7,988	$60,553.55	3.31	1.32	$0.42
Ibuprofen Tab 600 MG	40	1,780	591	34	$250.84	3.01	1.18	$0.42
Ibuprofen Tab 800 MG	37,825	1,940,928	646,122	25,224	$251,352.93	3	1.5	$0.39
Ibuprofen Tab 800 MG	493	29,019	9,799	370	$3,568.20	2.96	1.33	$0.36
Indomethacin Cap 25 MG	110	7,772	2,832	53	$1,799.53	2.74	2.08	$0.64
Indomethacin Cap 50 MG	137	7,816	3,030	65	$2,407.19	2.58	2.11	$0.79
Indomethacin Cap CR 75 MG	101	4,993	2,956	28	$9,082.33	1.69	3.61	$3.07
Indomethacin Susp 25 MG/5ML	16	2,990	411	3	$784.75	7.27	5.33	$1.91
Ketoprofen Cap 50 MG	466	20,422	6,582	360	$4,871.93	3.1	1.29	$0.74
Ketoprofen Cap 75 MG	1,680	56,813	21,655	1,344	$14,840.26	2.62	1.25	$0.69
Ketoprofen Cap SR 24HR 200 MG	234	35,292	8,396	115	$21,177.58	4.2	2.03	$2.52
Ketoprofen Powder	25	5,765	438	11	$784.59	13.16	2.27	$1.79
Ketorolac Tromethamine IM Inj 30 MG/ML	37	355	429	23	$432.10	0.83	1.61	$1.01
Ketorolac Tromethamine IM Inj 30 MG/ML	3	24	90	1	$75.45	0.27	3	$0.84
Ketorolac Tromethamine Inj 15 MG/ML	2	38	8	1	$66.82	4.75	2	$8.35
Ketorolac Tromethamine Inj 30 MG/ML	36	203	145	30	$490.89	1.4	1.2	$3.39
Ketorolac Tromethamine Tab 10 MG	1,865	30,617	12,525	1,574	$14,715.78	2.44	1.18	$1.17
Meclofenamate Sodium Cap 100 MG	11	488	162	10	$398.04	3.01	1.1	$2.46
Meclofenamate Sodium Cap 50 MG	5	270	57	5	$131.95	4.74	1	$2.31
Mefenamic Acid Cap 250 MG	136	4,934	1,306	96	$35,764.34	3.78	1.42	$27.38
Mefenamic Acid Cap 250 MG	25	983	239	17	$6,251.82	4.11	1.47	$26.16
Meloxicam Susp 7.5 MG/5ML	6	650	140	4	$396.16	4.64	1.5	$2.83
Meloxicam Tab 15 MG	9,403	332,485	326,138	4,514	$75,281.52	1.02	2.08	$0.23
Meloxicam Tab 7.5 MG	6,238	261,169	195,819	3,162	$46,803.73	1.33	1.97	$0.24
Nabumetone Tab 500 MG	1,626	95,727	47,151	732	$36,421.18	2.03	2.22	$0.77
Nabumetone Tab 750 MG	1,907	112,409	56,962	792	$46,699.40	1.97	2.41	$0.82
Naproxen Sodium Tab 275 MG	133	4,241	1,463	111	$1,331.60	2.9	1.2	$0.91
Naproxen Sodium Tab 550 MG	2,763	92,013	44,349	2,119	$31,152.58	2.07	1.3	$0.70

GENERIC NAME	CLAIMS	UNITS	DAYS	MEMBERS	PAID	UNITS/ DAY	CLAIMS/ MEMBER	PER DIEM
Naproxen Sodium Tab SR 24HR 375 MG (Base Equiv)	39	2,280	1,170	9	$6,591.52	1.95	4.33	$5.63
Naproxen Sodium Tab SR 24HR 500 MG (Base Equiv)	1	60	20	1	$215.84	3	1	$10.79
Naproxen Sodium Tab SR 24HR 500 MG (Base Equiv)	1	60	30	1	$66.06	2	1	$2.20
Naproxen Susp 125 MG/5ML	315	82,542	5,249	194	$7,126.45	15.73	1.62	$1.36
Naproxen Tab 250 MG	1,105	56,920	23,017	748	$10,095.85	2.47	1.48	$0.44
Naproxen Tab 375 MG	2,227	101,863	50,538	1,465	$18,838.83	2.02	1.52	$0.37
Naproxen Tab 500 MG	15,851	779,231	387,438	9,770	$137,389.92	2.01	1.62	$0.35
Naproxen Tab EC 375 MG	137	6,752	3,410	84	$1,919.13	1.98	1.63	$0.56
Naproxen Tab EC 500 MG	669	36,997	18,546	412	$10,598.79	1.99	1.62	$0.57
Oxaprozin Tab 600 MG	326	17,845	9,798	150	$4,303.70	1.82	2.17	$0.44
Piroxicam Cap 10 MG	12	630	360	7	$95.96	1.75	1.71	$0.27
Piroxicam Cap 20 MG	100	3,742	3,612	42	$649.85	1.04	2.38	$0.18
Sulindac Tab 150 MG	140	8,403	4,433	64	$2,151.58	1.9	2.19	$0.49
Sulindac Tab 200 MG	413	26,510	13,271	210	$8,507.25	2	1.97	$0.64
Tolmetin Sodium Cap 400 MG	16	1,440	470	3	$1,123.61	3.06	5.33	$2.39
Tolmetin Sodium Tab 200 MG	3	180	90	1	$126.10	2	3	$1.40
Tolmetin Sodium Tab 600 MG	2	120	60	1	$132.68	2	2	$2.21
TOTALS	**132,908**	**72,723***	**8,159,469**	**2,692,622**	**$1,798,364.55**	**3.03**	**1.83**	**$0.67**

*Total number of unduplicated members





Appendix F

Annual Review of Topical Antifungals - Fiscal Year 2009

Oklahoma HealthCare Authority
January 2010

Current Prior Authorization Criteria

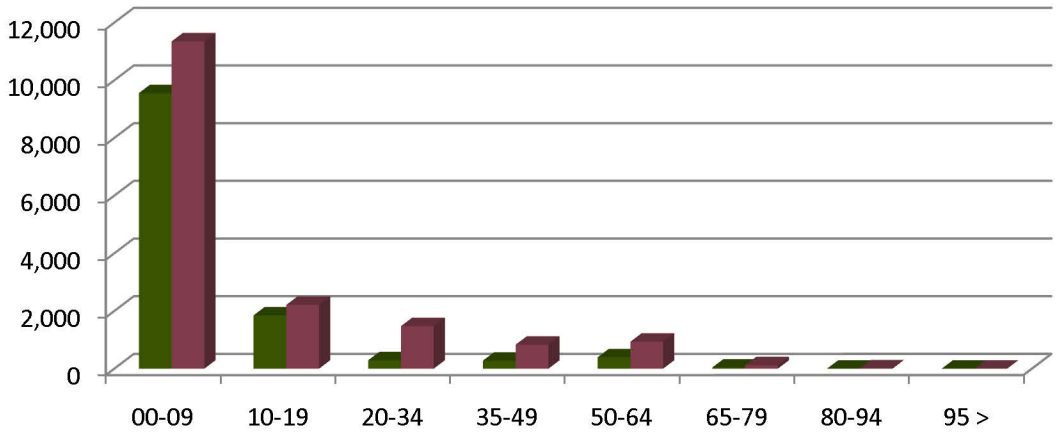
Topical Antifungal Medications	
Tier 1 products are covered with no authorization necessary.	
Tier 2 authorization requires: • Documented trials of at least two Tier 1 topical antifungal products within the last 30 days. • For treatments of Onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required in order for approval of Penlac®.	
Tier 1 (no PA required)	**Tier 2 (requires PA)**
Ciclopirox-0.77% Cream	Ciclopirox solution, shampoo, & gel (Penlac® and Loprox®), includes 0.77% Suspension
Clotrimazole-cream, solution	miconazole/zinc oxide/white petrolatum (Vusion®)
clotrimazole/betamethasone-1% and 0.05% crm, lot	oxiconazole (Oxistat®)
Econazole- 1% cream	sertaconazole nitrate (Ertaczo®)
Ketoconazole-2% cream, shampoo	butenafine (Mentax®)
Nystatin- cream, ointment	ketoconazole gel (Xolegel™)
nystatin/triamcinolone- cream, ointment	~~ketoconazole gel + 1% pyrithione zinc shampoo (Xolegel™ DUO)~~
Terbinafine 1% cream	naftifine (Naftin®)
Tolnaftate 1% cream, powder, solution	sulconazole (Exelderm®)
	Terbinafine (Lamisil® Spray)
	clotrimazole (Lotrimin® Lotion 1%)
	ketoconazole foam 2% (Extina®)
	Benzoic acid/Salicylic Acid (Bensal HP)

Utilization of Topical Antifungals

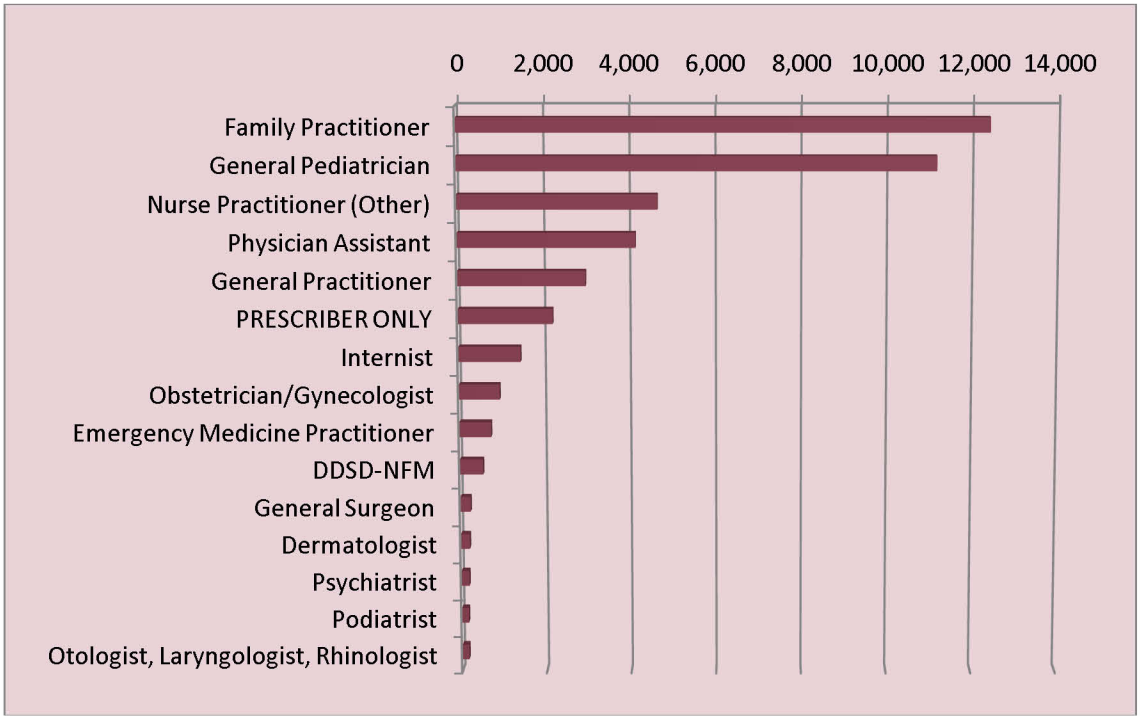
Comparison of Fiscal Years

Fiscal Year	Total Members	Total Claims	Total Paid	Paid per Claim	Per-Diem Paid	Total Units	Total Days
2008	29,039	44,220	$715,329.31	$16.18	$1.36	1,705,491	525,958
2009	29,367	43,212	$573,888.67	$13.28	$1.13	1,634,439	507,329
Percent Change	**1.13%**	**-2.28%**	**-19.77%**	**-17.92%**	**-16.90%**	**-4.17%**	**-3.54%**
	328	**-1,008**	**-$141,440.64**	**-$2.9**	**-$0.23**	**-71,052**	**-18,629**

Demographics of Members Utilizing Topical Antifungals: FY 2009



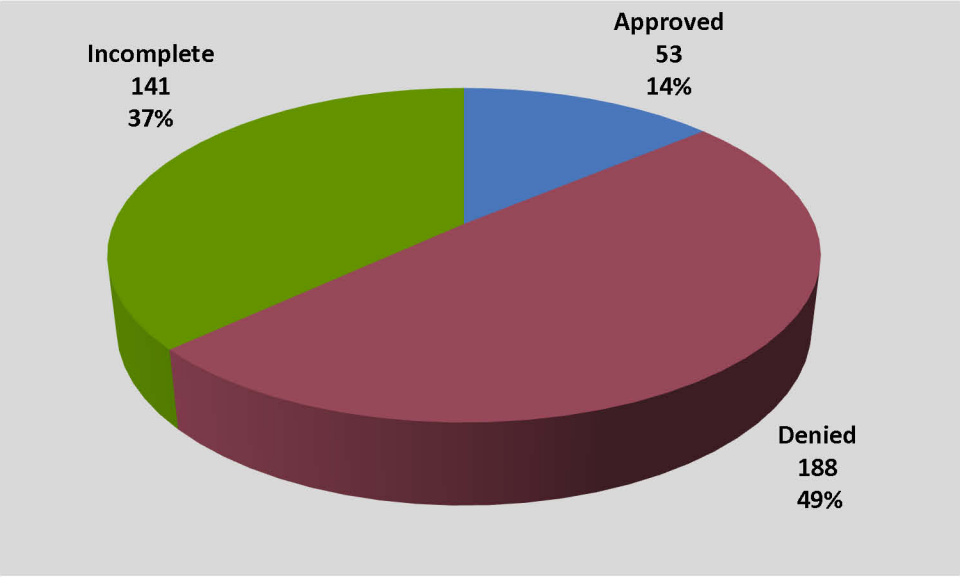
Top Prescriber Specialties of Topical Antifungals by Number of Claims: FY 2009



Prior Authorization of Topical Antifungals

There were a total of 382 petitions submitted for this PBPA category during fiscal year 2009. Step edits are in place for point-of-sale claims when tier trials have been met. The following chart shows the status of the submitted petitions.

Status of Petitions for Topical Antifungal Medications: FY 2009



Market News and Update

- **Vusion (miconazole/zinc oxide/white petrolatum)** - Patent expired on 3/27/2009. No generic products available.
- **Mentax (butenafine) cream** - Patent expires on 10/18/2010.
- **Xolegel DUO (ketoconazole gel + pyrithrione zinc shampoo)** – Product was transferred to DESI status in 9/2008.

Conclusions and Recommendations

The College of Pharmacy recommends no changes to this category at this time.

Utilization Details of Topical Antifungals: Fiscal Year 2009

Medication	Claims	Members	Units	Days	Paid	Units/ Day	Claims/ Member	% Paid
Nystatin Cream 100000 Unit/GM	11,961	9,180	384,073	124,649	$75,619.58	3.08	1.3	13.18%
Clotrimazole w/ Betamethasone Cream 1-0.05%	7,748	5,904	294,226	94,916	$106,352.06	3.1	1.31	18.53%
Nystatin-Triamcinolone Cream 100000-0.1 Unit/GM-%	5,002	4,026	179,366	58,154	$35,135.50	3.08	1.24	6.12%
Clotrimazole Cream 1%	3,811	3,063	130,248	46,554	$92,533.78	2.8	1.24	16.12%
Nystatin Oint 100000 Unit/GM	3,740	2,910	133,575	39,814	$26,041.22	3.35	1.29	4.54%
Ketoconazole Cream 2%	3,106	2,516	111,527	41,329	$54,160.00	2.7	1.23	9.44%
Nystatin Topical Powder	2,579	74,692	25,552	1,572	$52,150.05	3	2	9.09%
Ketoconazole Shampoo 2%	1,450	926	182,507	26,171	$34,645.60	6.97	1.57	6.04%
Econazole Nitrate Cream 1%	1,300	1,036	53.052	17,203	$24,836.26	3.08	1.25	4.33%
Ciclopirox Olamine Cream 0.77% (Base Equiv)	967	756	37,743	12,437	$28,633.47	3.03	1.28	4.99%
Nystatin-Triamcinolone Oint 100000-0.1 Unit/GM-%	838	668	27,617	9,598	$5,864.38	2.88	1.25	1.02%
Clotrimazole w/ Betamethasone Lotion 1-0.05%	313	257	10,965	3,997	$8,017.43	2.74	1.22	1.40%
Clotrimazole Solution 1%	165	102	4,448	1,906	$2,493.41	2.33	1.62	0.43%
Ciclopirox Solution 8%	91	65	608	2,351	$1,750.82	0.26	1.4	0.31%
Extina Aerosol 2%	70	39	6,150	1,669	$18,216.54	3.68	1.79	3.17%
Vusion® Ointment	19	5	1,000	187	$4,418.46	5.35	3.8	0.77%
Clotrimazole Powder	11	7	806	165	$63.87	4.89	1.57	0.01%
Mentax Cream 1%	8	5	195	140	$596.01	1.39	1.6	0.10%
Ertaczo Cream 2%	8	5	240	119	$583.64	2.02	1.6	0.10%
Oxistat Cream 1%	7	6	240	134	$512.99	1.79	1.17	0.09%
Loprox Shampoo 1%	6	2	720	165	$709.44	4.36	3	0.12%
Ciclopirox Olamine Susp 0.77%	3	2	150	50	$118.99	3	1.5	0.02%
Ciclopirox Gel 0.77%	2	2	130	29	$260.81	4.48	1	0.05%
Naftin Cream 1%	1	1	30	15	$65.33	2	1	0.01%
Fungizone Lotion 3%	1	1	30	5	$43.63	6	1	0.01%
Nystatin (Bulk) Powder	1	1	26	10	$41.33	2.64	1	0.01%
Nystatin (Bulk) Powder	1	1	75	10	$15.53	7.48	1	0.00%
TOTALS	**43,212**	**29,367***	**1,634,439**	**507,329**	**$573,888.67**	**3.22**	**1.47**	**100%**

*Total number of unduplicated members

Appendix G

Safety

Voltaren Gel (diclofenac sodium topical gel) 1% - Hepatic Effects Labeling Changes

Audience: Rheumatological healthcare professionals, pharmacists

[Posted 12/04/2009] Endo, Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the prescribing information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

In postmarketing reports, cases of drug-induced hepatotoxicity have been reported in the first month but can occur at any time during treatment with diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation.

Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The optimum times for making the first and subsequent transaminase measurement are not known. Based on clinical trial data and postmarketing experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with diclofenac.

[12/04/2009 - Dear Healthcare Professional Letter - Endo, Novartis]
[Sept 2009 - Prescribing Information - Endo]

Safety

Valproate Sodium and related products (valproic acid and divalproex sodium): Risk of Birth Defects

Audience: Neuropsychiatric and Obstetrical healthcare professionals

[Posted 12/03/2009] The FDA notified health care professionals and patients about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. Healthcare practitioners should inform women of childbearing potential about these risks, and consider alternative therapies, especially if using valproate to treat migraines or other conditions not usually considered life-threatening.

Women of childbearing potential should only use valproate if it is essential to manage their medical condition. Those who are not actively planning a pregnancy should use effective contraception, as birth defect risks are particularly high during the first trimester, before many women know they are pregnant. A valproate Medication Guide, provided with each outpatient prescription, will explain the benefits and risks of valproate and encourage patients to discuss options with their healthcare professional.

Pregnant women using valproate or other AEDs should be encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry (1-888-233-2334; www.aedpregnancyregistry.org).

[12/03/2009 - Information for Healthcare Professionals - FDA]

Safety

Norpramin (desipramine hydrochloride) - Dear Healthcare Professional Letter

Audience: Psychiatric healthcare professionals

[Posted 12/02/2009] Sanofi-Aventis and FDA notified healthcare professionals of changes to the Warnings and Overdosage sections of the Prescribing Information for Norpramin (desipramine hydrochloride), indicated for the treatment of depression. The new safety information states that extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients.

[December 2009 - Dear Healthcare Professional Letter - Sanofi-Aventis]

Safety

Nzu, Traditional Remedy for Morning Sickness

Audience: Consumers, Obstetrical healthcare professionals

[Posted 12/31/2009] The Texas Department of State Health Services and FDA notified healthcare professionals and consumers, especially pregnant or breastfeeding women, to avoid consuming a product called "Nzu", taken as a traditional remedy for morning sickness,because of the potential health risks from high levels of lead and arsenic, noted on laboratory analysis by Texas DSHS. Exposure to lead can result in a number of harmful effects, and a developing child is particularly at risk of effects on the brain and nervous system. Arsenic is a carcinogen, and excessive long-term exposure to it has been associated with a range of adverse health effects, including cancers of the urinary bladder, lung and skin. Nzu, which is sold at African specialty stores is also called Calabash clay, Calabar stone, Mabele, Argile and La Craie. It generally resembles balls of clay or mud and is usually sold in small plastic bags with a handwritten label identifying it as "Nzu" or "Salted Nzu." Anyone who has been ingesting the product should contact their health care provider.

Any adverse events that may be related to use should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program online [at www.fda.gov/MedWatch/report.htm], by phone 1-800-332-1088, or by returning the postage-paid FDA form 3500 [which may be downloaded from the MedWatch "Download Forms" page] by mail [to address on the pre-addressed form] or fax [1-800-FDA-0178].

[December 23, 2009 - Press Release - Texas Department of State Health Services]