Drug Utilization Review Board

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

Wednesday
June 10, 2009
6:00 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

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

SUBJECT: **Packet Contents for Board Meeting – June 10, 2009**

DATE: June 4, 2009

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

Enclosed are the following items related to the June 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 – 30 Day Notice to Prior Authorize Anti-Migraine Products and Vote to Prior Authorize Treximet® – See Appendix C.

Action Item – Vote to Prior Authorize New Proton Pump Inhibitors – See Appendix D.

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

Action Item – Vote to Prior Authorize Aplenzin® – See Appendix F.

Action Item – Vote to Prior Authorize Acetasol® HC – See Appendix G.

Action Item – Vote to Prior Authorize Exforge HCT® – See Appendix H.

Action Item – Election of Officers

FDA and DEA Updates – See Appendix I.

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 – June 10, 2009 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. McNeill, Chairman:

1. Call To Order

A. Roll Call – Dr. Graham

Items to be presented by Dr. McNeill, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. McNeill, Chairman:

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

A. April 8, 2009 DUR Minutes – Vote
B. April 9, 2009 DUR Recommendation Memorandum
C. Provider Correspondence

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

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

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

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

5. Action Item - 30 Day Notice to Prior Authorize Anti-Migraine Products and Vote to Prior Authorize Treximet® – See Appendix C.

A. COP Recommendations

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

6. Action Item – Vote to Prior Authorize New Proton Pump Inhibitors – See Appendix D.

A. COP Recommendations

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

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

A. COP Recommendations
B. Product Summary
C. Current PA Criteria for Ultram® ER

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

8. Action Item – Vote to Prior Authorize Aplenzin® – See Appendix F.

A. COP Recommendations

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

9. Action Item – Vote to Prior Authorize Acetasol® HC – See Appendix G.

A. Product Summary
B. COP Recommendations

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

10. Action Item – Vote to Prior Authorize Exforge HCT® – See Appendix H.

A. COP Recommendations

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

11. Action Item – Election of Officers

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

12. FDA and DEA Updates – See Appendix I.

13. Future Business

A. Hydrocodone Utilization Proposal
B. Utilization Review of Fibromyalgia Products
C. Utilization Review of Otic Antibiotics
D. New Product Reviews

14. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of APRIL 8, 2009

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

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

Mark DeClerk, Lilly	Kirsten Hua Mar, Lilly	David Williams, Forest Pharmaceuticals
Jim Dunlap, Lilly	Jeff Himmelberg, GlaxoSmithKline	M. Patty Laster, Genentech
Donna Erwin, Bristol-Myers Squibb	Jim Fowler, AstraZeneca	Kristen Thomas, AstraZeneca
David Barton, Schering-Plough	Janie Huff, Takeda	Susan Stone, Allergan
Lon Lowrey, Novartis	Pat Traham, Taro Pharmaceuticals	Richard Ponder, Johnson & Johnson
Lance Stewart, Merck	Tracy Copeland, Daiichi Sankyo	Russell Dyer, Allergan
William Dozier, Gilead		

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 9 Michael Jones, Pharm.D.; GlaxoSmithKline

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

1A: Roll Call

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

ACTION: NONE REQUIRED

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

Dr. McNeill recognized the speaker for public comment:

For Agenda Item No. 9; Michael Jones, Pharm.D.; GlaxoSmithKline

ACTION: NONE REQUIRED

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

3A: March 11, 2009 DUR Minutes

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

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review: January 2009

4B: Retrospective Drug Utilization Review Responses: November 2008

4C: Medication Coverage Activity Audit: March 2009

4D: Help Desk Activity Audit: March 2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ZOLPIMIST™**

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

Dr. Kuhls moved to approve; seconded by Dr. Muchmore.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **30-DAY NOTICE TO PRIOR AUTHORIZE RYZOLT™**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **30-DAY NOTICE TO PRIOR AUTHORIZE ALPLENZIN®**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: **30-DAY NOTICE TO PRIOR AUTHORIZE NEW PROTON PUMP INHIBITOR PRODUCTS**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **60-DAY NOTICE TO PRIOR AUTHORIZE ANTI-MIGRAINE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TREXIMET®**

For Public Comment: Michael Jones, Pharm.D: Thank you very much for allowing me to address the Board and I'll get right to some of the key succinct points of this product since this is the last item before you guys get to go home. What I'd really like to center on, this is a dual combination of an NSAID and the sumatriptan, which you're probably very familiar with. The key component of the kinetics, however, is I've got a chart, but I'm going to address this chart in words so you can get a picture. There's certain inflammatory markers and neural kinins and peptide markers that present themselves through this path of the migraine. We know this. Neurologists have been treating this for years. They have been giving separate scripts of NSAIDs and

triptans and things like that. I'm not going to take a lot of your time in saying that, one, patients are not compliant even if they get those scripts. We've tried to get them to be compliant. They take either the NSAID first thinking that it's going to stave off some of that cascade and save the expensive triptan for later, etc. The other point, though, is that when we use this particular formulation as almost I like to describe it as wicked together with the RT technology of the Imitrex and having the NSAID on board, the Naproxen on board, you get almost a delay of a peak of that NSAID that you wouldn't get if you took an NSAID by itself or in conjunction with a triptan unless it's in this particular formulation, delays that peak from a two to six hour window when now we know that that has been validated with most of the PGE and type inflammatory markers present. So by putting the package together if you will, in this particular molecule or combination, is almost a perfect validation clinically of what they've been doing for the last ten years. I do have it graphically presented. This is how I do it with all my doctors that I present it and I show it. I'll make this available. I realize I'm not allowed to pass it out, but that's basically what I just described, is the unique kinetics of this Treximet molecule working together in succinct order of the way these inflammatory markers actually present in the average migraine. And this is why we're getting a whole lot of success. A lot of triptan failures even on short acting triptans, are coming across almost 80% to this particular formulation. That's where I'll leave my discussion and entertain any questions.
Materials included in agenda packet; presented by Dr. Keast.
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.
11A: Utilization Review of Fibromyalgia
11B: Utilization Review of Otic Antibiotics
11C: Utilization Review of Antiemetics
11D: New Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ADJOURNMENT**
The meeting was adjourned at 6:43 p.m.

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

Memorandum

Date: April 9, 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 April 8, 2009

Recommendation 1: Vote to Prior Authorize Zolpimist™

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Zolpimist™ with a manual prior authorization. The petition should also include information regarding why member must have the oral spray formulation of zolpidem. A Quantity Limit similar to all other hypnotic medications will apply.

AHMED AMAYEM, M.D.
1145 S. W. 74th Street, Building I, Suite 100
Oklahoma City, OK 73139
Phone 405-632-1783
Fax 405-631-0508

April 24, 2009

Ron Graham, D.P.H.
OU Medical Center
By Fax 405-271-2615

Dear Ron,

I am a pain management physician and almost all of my patients are being treated for chronic pain. These patients need to be on long acting narcotics for their chronic pain.

We do not have any available long acting narcotics on Tier One. Please help me to facilitate treating this chronic pain problem. Short acting narcotics have a high potential for abuse and diversion and are not suitable for chronic pain patients.

If you have any questions, please call me at (405) 632-1783. Thank you for your assistance with this situation.

Sincerely,

Ahmed Amayem, M.D.

Mercy Medical Neurologists

J. Mike Banowetz, MD ■ W. Dean Shipley, MD ■ Michael A. Tribbey, MD ■ Wayne L. Wasemiller, MD

Shellie Gorman Keast, PharmD, MS
Drug Utilization Review Manager
Pharmacy Management Consultants
ORI-W4403, PO Box 26901
Oklahoma City, OK 73126-0901

Dear Dr. Gorman:

It is my understanding that the Drug Utilization Board will be voting on migraine medications for the Medicaid formulary in the near future. I would like to voice my support for Treximet being accessible to as many patients as possible for the treatment of migraine. I have had success in the use of Treximet in my practice. It is difficult to persuade patients to take both their triptan and NSAID at the same time. This treatment treats the many stages of migraine, both early and late stages. Please continue to keep Treximet available for all patients.

Sincerely,

Wayne L. Wasemiller, MD

4120 W. MEMORIAL ROAD ■ SUITE 218 ■ OKLAHOMA CITY, OK 73120 ■ **405-302-2661** phone ■ **405-302-2670** fax

Douglas W. Kaplan, MD
Neurology

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

4120 West Memorial Road Suite 204
Oklahoma City, OK 73120
Tel (405) 749 - 4270
Fax (405) 749 - 4277

May 1, 2009

Shellie Gorman Keast, PharmD, MS
Drug Utilization Review Manager
Pharmacy Management Consultants
ORI-W4403, PO Box 26901
Oklahoma City, OK 73126-0901

Dear Dr. Gorman and board members:

I am a board certified neurologist specializing in headache in Oklahoma City. I am writing in support of keeping Treximet on the State of Oklahoma formulary without prior authorization. Treximet has proven to be beneficial to my patients, even many who were satisfied with a single triptan. In my experience, patients often fail to follow directions of taking two medications simultaneously. This fact was referenced in a recent Headache journal article by Drs Ng-Mak, et al. Treximet treats patients in all stages of migraine, during both peripheral and central sensitization.

Please contact me if you have any questions.

Sincerely,

Douglas W. Kaplan, MD

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for February 2009

Module	**Drug Interaction**	**Duplication of Therapy**	**Drug-Disease Precautions**	**Dosing & Duration**
Total # of messages returned by system when no limits were applied	42,645	63,811	973,270	33,635
Limits which were applied	Established, Major, Males and Females, Age 19-30	Males and Females, Narcotics, Age 18-22	Contraindicated, Asthma, Males and Females, Age 19-50	Duration only, Influenza Agents, Males and Females, Age 0-150
Total # of messages after limits were applied	39	220	243	48
Total # of members reviewed after limits were applied	39	185	194	48

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
86		10	

Retrospective Drug Utilization Review Report

Claims Reviewed for January 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 0-18	Narcotics, Males and Females, Age 10-17	Contraindicated, Asthma, Male and Females, Age 0-18	High Dose, Statins, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 79
Response Forms Returned: 50

The response forms returned yielded the following results:

4 (8%)	*Record Error—Not my patient.*
1 (2%)	*No longer my patient.*
2 (4%)	*Medication has been changed prior to date of review letter.*
8 (16%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
21 (42%)	*I am aware of this situation and will plan to continue monitoring therapy.*
14 (28%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 22
Response Forms Returned: 15

The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
3 (20%)	*Medication has been changed prior to date of review letter.*
6 (40%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
5 (33%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (7%)	*Other*

Retrospective Drug Utilization Review Report

Claims Reviewed for February 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 19-30	Narcotics, Males and Females, Age 18-22	Contraindicated, Asthma, Males and Females, Age 19-50	Duration only, Influenza Agents, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 86
Response Forms Returned: 29

The response forms returned yielded the following results:

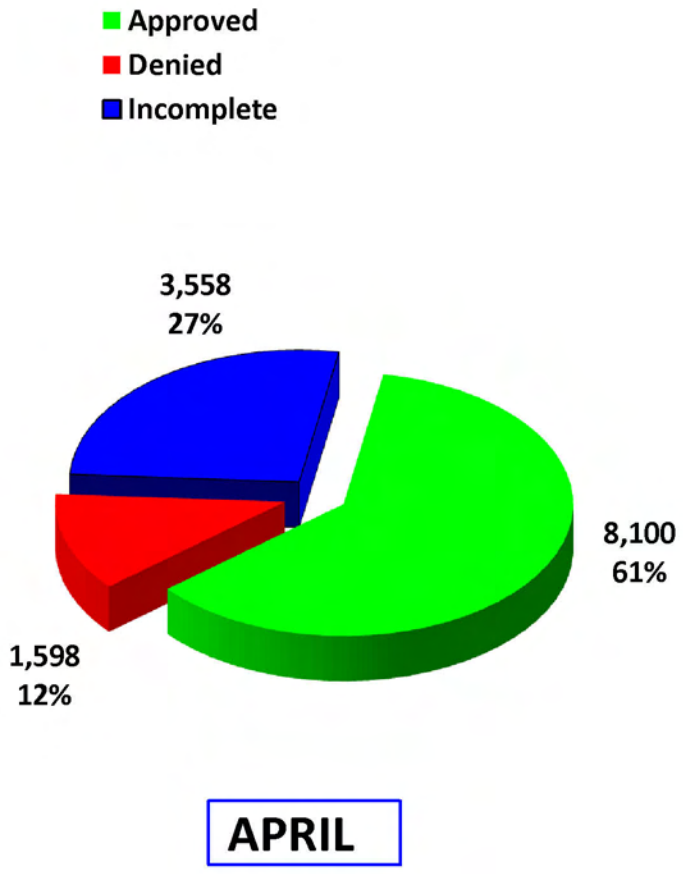
1 (3%)	*Record Error—Not my patient.*
3 (10%)	*No longer my patient.*
6 (21%)	*Medication has been changed prior to date of review letter.*
5 (17%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
9 (31%)	*I am aware of this situation and will plan to continue monitoring therapy.*
5 (17%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 10
Response Forms Returned: 4

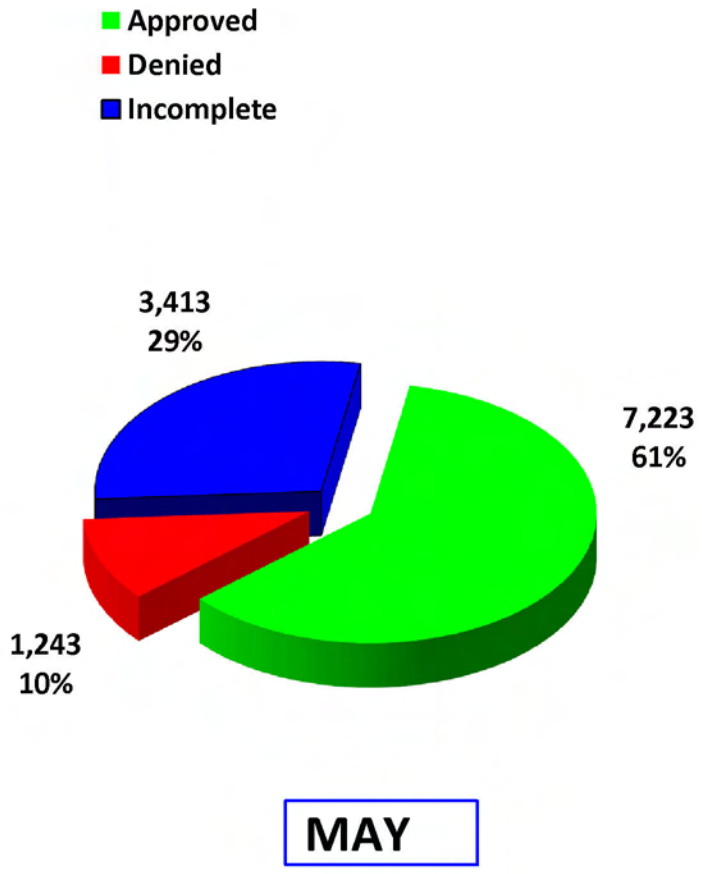
The response forms returned yielded the following results:

0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
0 (0%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
1 (25%)	*I am aware of this situation and will plan to continue monitoring therapy.*
3 (75%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: April – May 2009

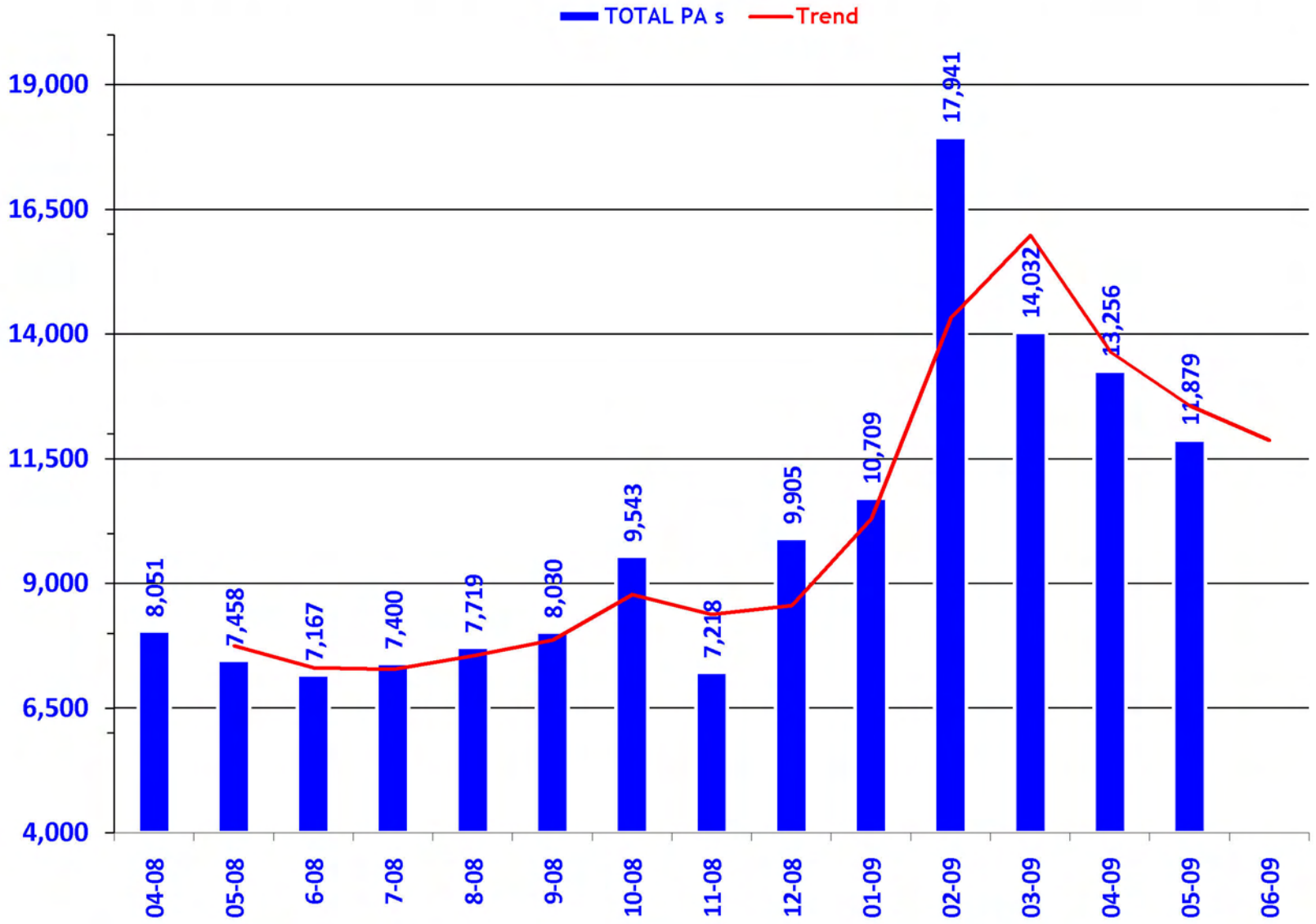


APRIL



MAY

PRIOR AUTHORIZATION REPORT: April 2008 – May 2009



Activity Audit for
4/1/2009 Through 4/30/2009

	Average Length of	Approved	Denied	Incomplete	Total
ACE Inhibitors	71	14	0	1	15
Angiotensin Receptor Antagonist	348	29	28	61	118
Antidepressant	262	221	137	285	643
Antihistamine	304	262	109	197	568
Antiulcers	27	18	1	5	24
Anxiolytic	91	3,981	180	524	4,685
Calcium Channel Blockers	109	5	1	3	9
Growth Hormones	180	43	1	7	51
HTN Combos	216	5	2	7	14
Insomnia	100	55	55	95	205
Nsaids	329	34	27	48	109
Plavix	352	128	4	69	201
Stimulant	222	632	146	316	1,094
Others	184	2,668	907	1,940	5,515
Emergency PAs		5	0	0	5
Total		**8,100**	**1,598**	**3,558**	**13,256**
Overrides					
Brand	121	108	4	23	135
Dosage Change	17	421	11	10	442
High Dose	30	1	0	0	1
IHS - Brand	46	81	0	7	88
Ingredient Duplication	13	15	3	2	20
Lost/Broken Rx	15	90	6	3	99
Nursing Home Issue	13	72	0	1	73
Other	13	43	4	5	52
Quantity vs. Days Supply	210	300	71	107	478
Stolen	19	5	1	0	6
Overrides Total		**1,040**	**97**	**149**	**1,286**

Denial Reasons

Lack required information to process request.	2,338
Unable to verify required trials.	1,974
Does not meet established criteria.	332
Not an FDA approved indication/diagnosis.	200
Considered duplicate therapy. Member has a prior authorization for similar medication.	84
Member has active PA for requested medication.	67
Medication not covered as pharmacy benefit.	49
Requested dose exceeds maximum recommended FDA dose.	48
Drug Not Deemed Medically Necessary	12

Duplicate Requests: 901

Changes to existing PAs: 962

Activity Audit for

5/1/2009 Through 5/31/2009

	Average Length of	Approved	Denied	Incomplete	Total
ACE Inhibitors	51	10	1	1	12
Angiotensin Receptor Antagonist	350	40	26	53	119
Antidepressant	275	228	119	299	646
Antihistamine	299	222	71	180	473
Antiulcers	6	10	0	2	12
Anxiolytic	91	3,647	152	528	4,327
Calcium Channel Blockers	55	8	1	3	12
Growth Hormones	177	43	2	5	50
HTN Combos	181	6	5	7	18
Insomnia	121	54	37	87	178
Nsaids	341	35	27	47	109
Plavix	354	117	10	65	192
Stimulant	216	559	98	283	940
Others	155	2,243	694	1,853	4,790
Emergency PAs		1	0	0	1
Total		**7,223**	**1,243**	**3,413**	**11,879**
Overrides					
Brand	135	86	10	11	107
Dosage Change	12	425	14	31	470
High Dose	127	5	0	1	6
IHS - Brand	51	85	2	6	93
Ingredient Duplication	14	3	1	1	5
Lost/Broken Rx	10	83	7	2	92
Nursing Home Issue	15	31	0	1	32
Other	11	22	2	3	27
Quantity vs. Days Supply	219	280	59	108	447
Stolen	15	7	0	0	7
Wrong D.S. on Previous Rx	0	0	0	1	1
Overrides Total		**939**	**92**	**158**	**1,189**

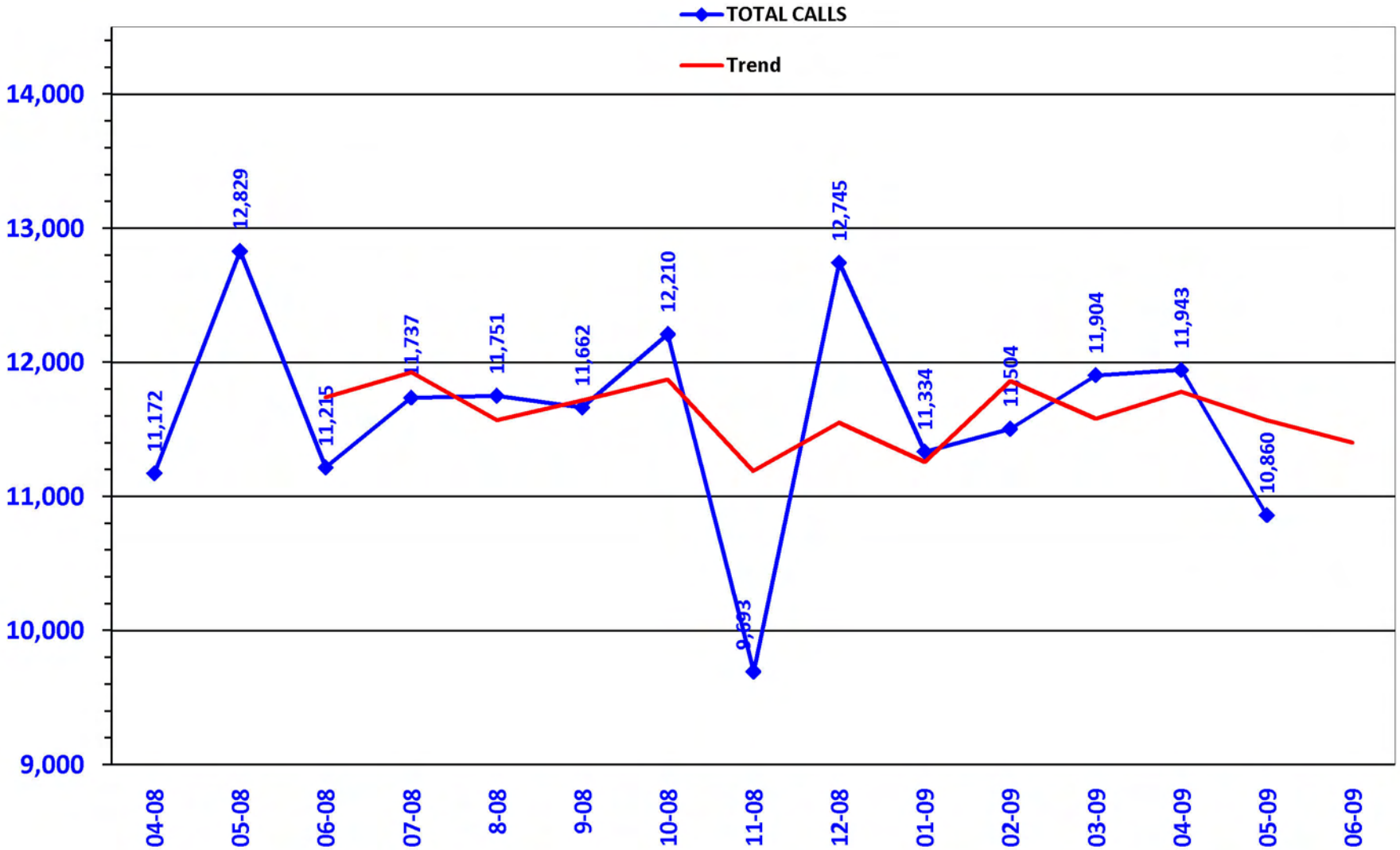
Denial Reasons

Lack required information to process request.	2,213
Unable to verify required trials.	1,635
Does not meet established criteria.	351
Not an FDA approved indication/diagnosis.	179
Considered duplicate therapy. Member has a prior authorization for similar medication.	83
Member has active PA for requested medication.	77
Requested dose exceeds maximum recommended FDA dose.	53
Medication not covered as pharmacy benefit.	24
Drug Not Deemed Medically Necessary	6

Duplicate Requests: 767

Changes to existing PAs: 906

CALL VOLUME MONTHLY REPORT: April 2008 – May 2009



Appendix C

30 Day Notice to Prior Authorize Anti-Migraine Medications and Vote to Prior Authorize Treximet®

Oklahoma HealthCare Authority, June 2009

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

Recommendations - Treximet®

The College of Pharmacy recommends immediate prior authorization of Treximet® with a quantity limit of 9 tabs per 30 days. Approval of this product would require a reason why the member cannot take separate generic products.

Recommendations – 30 Day Notice to PA Anti-Migraine Products

The College of Pharmacy recommends the addition of the Anti-Migraine class to the Product Based Prior Authorization program once a reasonable SMAC has been placed on the generic sumatriptan. The following Tier 1 drug list has been reviewed and determined to be acceptable for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority.

Approval Criteria

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

- Trial of all available Tier 1 products with inadequate response, or
- Documented adverse effect to all the Tier 1 products, or
- Previous success with a Tier 2 product within the last 60 days.

To qualify for a Tier 3 product the member must meet one of the following criteria:

- Trial of all available Tier 2 products with inadequate response, or
- Documented adverse effect to all available Tier 2 products, or
- Previous success with a Tier 3 medication within the last 60 days.

Approvals will be granted for one year.

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

*Mandatory generic plan

Appendix D

Vote to Prior Authorize New Proton Pump Inhibitor Products: Kapidex™ (dexlansoprazole) and Prilosec Suspension™ (omeprazole)

Oklahoma Health Care Authority
June 2009

Recommendations

The College of Pharmacy recommends placement of Kapidex™ and Prilosec Suspension™ in Tier 2 of the Anti-Ulcer PBPA Category. The existing prior authorization criteria will apply. The College also recommends that quantity limits of one dosage unit per day be applied, consistent with other products in this category.

Anti-Ulcer Medications

Tier 1	Tier 2
omeprazole **(Prilosec® 10 and 20mg caps)**	omeprazole **(Prilosec® 40mg Caps)***
lansoprazole (Prevacid®)	omeprazole/antacid **(Zegerid®)***
	esomeprazole **(Nexium®)***
	pantoprazole **(Protonix®)***
	rabeprazole **(Aciphex®)***
	dexlansoprazole **(Kapidex™)**

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

Approval Criteria

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

Quantity Limit

- Omeprazole 10 mg: #60 for 30 days
- Omeprazole 20 mg: #120 for 30 days
- All other PPI's: #30 for 30 days

Appendix E

Vote to Prior Authorize Ryzolt™ (Tramadol HCL ER)

Oklahoma Health Care Authority
June 2009

Manufacturer	Purdue Pharma, L.P.
Classification	Centrally Acting Synthetic Opioid Analgesic
Status	Prescription Only

Recommendations

The College of Pharmacy recommends placement of both Ryzolt™ and Ultram® ER into Tier 3 of the Narcotic Analgesic Category. The existing prior authorization criteria for this category will apply.

Prior Authorization Criteria:

1. Tier 2 agents will only be approved after:
   a. A minimum 30 day documented trial/titration period of at least two Tier 1 agents in the past 90 days or
   b. Clinically appropriate pain therapy requiring time-released medication.

   In either case, diagnosis should be for pain related to a chronic condition.
2. Tier 3 agents will only be approved after:
   a. A minimum 30 day documented trial period of at least two Tier 2 agents in different classes in the past 90 days or
   b. Documented allergy or contraindication to all Tier 2 agents.
3. Members with an oncology related diagnosis will be exempt from the prior authorization process, quantity and dosage limits would still apply.
4. Actiq® and Fentora® are only approved for oncology related diagnoses.
5. Only 1 long-acting and 1 short-acting agent can be used concurrently regardless of diagnosis.

Tier 1	Tier 2	Tier 3	Oncology Only
Immediate Release Narcotic Agents Not Listed in Higher Tier	**Long-Acting**		Fentanyl **(Actiq®)** Fentanyl **(Fentora®)**
	Morphine sulfate ER Fentanyl **(Duragesic® Patches)** Oxymorphone **(Opana® ER)**	Morphine sulfate ER **(Kadian®)** Morphine sulfate ER **(Avinza®)** Oxycodone ER **(Oxycontin®)** Tramadol ER **(Ryzolt™, Ultram ER®)**	
	Short-Acting		
	Hydrocodone/APAP **(Xodol®)**		

Mandatory Generic Plan Applies
Blue Color Indicates Supplemental Rebate Program Participation

Ryzolt™ Summary

Ryzolt™ (tramadol hydrochloride extended-release) received FDA approval in December 2008. Ryzolt™ is a prescription medicine indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.

Tramadol HCl ER is a centrally acting synthetic opioid analgesic. Its mechanism is not completely understood, but its activity is thought to be due to the following three mechanisms:

- Binding of parent compound to mu-opioid receptors
- Binding of M1 metabolite to μ-opioid receptors
- Weak inhibition of reuptake of norepinephrine and serotonin.

After oral administration, Ryzolt™ is rapidly and extensively hydrolyzed by *N*- and *O*-demethylation and glucuronidation or sulfation in the liver to its active metabolite M1. Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the *O*-demethylated medtabolite (M1) to μ-opioid receptors.

The recommended starting dose is 100mg once a day with a maximum of 300mg a day. Ryzolt™ should be taken whole with liquid and with or without food. Ryzolt has not been studied, and therefore should not be used, in the following populations:

- Patients with severe renal insufficiency (CL_{CR} <30 mL/min).
- Patients with severe hepatic impairment.

Current Prior Authorization of Ultram® ER:

Approval Criteria:

1. FDA approved diagnosis for the use of Ultram® ER,
2. Diagnosis indicating that the member has a condition that requires extended pain treatment with an around-the-clock dosing schedule,
3. The reason immediate release tramadol is inappropriate, and
4. The physician's signature

A quantity limit of #30 tabs per 30 days supply also applies. Maximum covered dose per day is 300mg due to lack of efficacy and increased risk for side effects and seizures with doses higher than 300mg per day.

REFERENCE

Ryzolt(TM) (tramadol HCl extended-release) Product Information. Purdue. January 16,2009.

Appendix F

Vote to Prior Authorize Aplenzin® (Buproprion Hydrobromide)

Oklahoma Health Care Authority
June 2009

Manufacturer Biovail Corporation
Classification Antidepressant
Status Prescription only

Recommendations

The College of Pharmacy recommends placement of Aplenzin® (bupropion hydrobromide) in Tier 3 of the Anti-Depressants PBPA Category with quantity limits of one tablet per day on each dosage strength. The existing prior authorization criteria will apply.

SSRIs (Selective Serotonin Reuptake Inhibitors)		
Tier-1	**Tier-2**	**Tier-3**
citalopram (Celexa®)	escitalopram (Lexapro®)	
fluoxetine (Prozac®, Sarafem®)	fluoxetine (Prozac® Weekly™)	
fluvoxamine (Luvox®)	fluoxetine (40mg capsules)	
paroxetine (Paxil®, Paxil CR®)	fluvoxamine CR (Luvox CR)	
sertraline (Zoloft®)	paroxetine (Pexeva®)	
Dual Acting Antidepressants		
Tier-1	**Tier-2**	**Tier-3**
bupropion (Wellbutrin®, Wellbutrin SR® & XL®)	Venlafaxine ER Tabs®	Bupropion (Aplenzin®)
mirtazapine (Remeron®, Remeron SolTab®)		duloxetine (Cymbalta®)
trazodone (Desyrel®)		desvenlafaxine (Pristiq®)
venlafaxine (Effexor®)		nefazodone (Serzone®)
		venlafaxine (Effexor XR®) Caps
Monoamine Oxidase Inhibitors		
Tier-1	**Tier-2**	**Tier-3**
		phenelzine (Nardil®)
		selegiline (Zelapar®)
		selegiline patch (Emsam®)
		tranylcypromine (Parnate®)

Mandatory Generic Plan Applies

Criteria for Approval of a Tier 2 Medication:

1. A documented, recent (within 6 months) trial of a Tier 1 medication at least 4 weeks in duration and titrated to recommended dosing, that did not provide an adequate response. Tier 1 selection can be from any classification.
2. Prior stabilization on the Tier 2 medication documented within the last 100 days. A past history of success on the Tier 2 medication will also be considered with adequate documentation.
3. A unique FDA-approved indication not covered by Tier 1 products or other products from a different therapeutic class.
4. A petition may be submitted for consideration whenever a unique member specific situation exists.

Criteria for Approval of a Tier 3 Medication:

1. A documented, recent (within 6 months) trial with a Tier 1 and a Tier 2 medication at least 4 weeks in duration and titrated to recommended dose, that did not provide an adequate response. Tier 1 and Tier 2 selection can be from any classification.
2. Prior stabilization on the Tier 3 medication documented within the last 100 days. A past history of success on the Tier 3 medication will also be considered with adequate documentation.
3. A unique FDA-approved indication not covered by a lowered tiered product or other products from a different therapeutic class.
4. A petition may be submitted for consideration whenever a unique member specific situation exists.

REFERENCE

Aplenzin® (bupropion hydrobromide). Prescribing Information. http://www.fda.gov/cder/foi/label/2008/022108lbl.pdf

Appendix G

Vote to Prior Authorize Acetasol® HC Otic Drops

Oklahoma Health Care Authority
June 2009

Manufacturer	Actavis Pharmaceuticals
Classification	Combination Anti-infective/Anti-inflammatory
Status	Prescription Only

Summary

Acetasol® HC Otic drops is a combination otic preparation consisting of acetic acid 2% and hydrocortisone 1%. Acetic acid lowers the pH of the ear canal and suppresses the growth of both bacterial and fungal organisms. The hydrocortisone reduces inflammation and irriation associated with infection. Acetasol® HC is instilled topically in the ear three to four times a day for typically 5-7 days.

Acetasol® HC is a very commonly used treatment of acute otitis externa and has been available in both the brand and generic formulation for over a decade. Recently the number of manufacturers of this product has dwindled. As of April 2009, the estimated acquisition price of this product rose from approximately $14.00 to around $200.00 per 10mL bottle.

Recommendations

The College of Pharmacy recommends prior authorization of Acetasol® HC. The approval criteria is as follows:

1. Diagnosis of acute otitis externa
2. Recent (within 6 months) trials with all other commonly used topical otic anti-infectives that has failed to resolve infection.

Common Otic Topical Antibiotic Preparation and Estimated Price

Acetic Acid 2% (**Acetasol®**) Generic Otic Solution - $27
Neomycin/PolymyxinB/hydrocortisone (**Cortisporin® HC**) Generic Otic Solution and Suspension - $12
Ofloxacin 3% (**Floxin® Otic**) Generic Drops - $12 to $24, Brand dropperette $80
Ciprofloxacin 0.2%/hydrocortisone 1% (**Cipro® HC**) Brand Otic Suspension - $106
Ciproflaxacin 0.3%/dexamethasone 0.1% (**Ciprodex®**) Brand Otic Suspension - $106

REFERENCE

Acetasol HC Otic Drops Product Information. Micromedex Healthcare Series by Thomson Healthcare, Inc. Copyright 2009.

Appendix H

Vote to Prior Authorize Exforge HCT®

Oklahoma Health Care Authority
June 2009

Manufacturer	Novartis Pharmaceuticals Corp.
Classification	Combination Antihypertensive
Status	Prescription Only

Recommendations

The College of Pharmacy recommends placement of Exforge HCT® in Tier-3 of the ARB Combination Anti-hypertensives PBPA Category. The following existing prior authorization criteria for this category will apply:

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

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

To qualify for a Tier 3 Antihypertensive medication there must be

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

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

Blue Color indicates Supplemental Rebate Participation.

REFERENCE

Exforge HCT® Product Information. Novartis Pharmaceuticals. April 2009.

Appendix I

Drugs

Propylthiouracil (PTU)-Induced Liver Failure

FDA ALERT [06/03/2009]:

FDA is notifying healthcare professionals of the risk of serious liver injury, including liver failure and death, with the use of propylthiouracil (PTU) in adult and pediatric patients.

Reports to FDA's Adverse Event Reporting System (AERS) suggest there is an increased risk of hepatotoxicity with PTU when compared to methimazole (MMI). Although both PTU and MMI are indicated for the treatment of hyperthyroidism due to Graves' disease, healthcare professionals should carefully consider which drug to initiate in a patient recently diagnosed with Graves' disease. Physicians should closely monitor patients on PTU therapy for symptoms and signs of liver injury, especially during the first six months after initiation of therapy. PTU and MMI were approved in 1947 and 1950, respectively.

FDA has identified 32 AERS cases (22 adult and 10 pediatric) of serious liver injury associated with PTU use. Of the adult cases, 12 deaths and 5 liver transplants occurred. Among the pediatric patients, 1 case resulted in death and 6 in liver transplants.

In contrast, for MMI 5 AERS cases of serious liver injury were identified. All five cases were in adult patients and 3 resulted in death.

In general, PTU is considered second-line drug therapy except in patients who are allergic to or intolerant of methimazole. Rare cases of embryopathy, including aplasia cutis, have been reported with use of MMI during pregnancy, while no such cases have been reported with PTU use. Thus, PTU may be more appropriate for patients with Graves' disease who are in their first trimester of pregnancy.

On April 18, 2009, FDA held a public workshop with the American Thyroid Association (ATA) to discuss PTU-related hepatotoxicity. FDA is continuing to monitor these serious reported adverse events and working to make changes to the PTU prescribing information, particularly for use in pediatric patients. Also, the ATA plans to update its treatment guidelines

for Graves' disease in the upcoming months.

This information reflects FDA's current analysis of data available to FDA concerning propylthiouracil (PTU)). Posting this information does not mean that FDA has concluded there is a causal relationship between the drug product and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing the product. FDA intends to update this document when additional information or analyses become available.

Adverse reactions or quality problems experienced with the use of this Product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, using the contact information at the bottom of this sheet.

Recommendations and Information for Healthcare Professionals:

Reserve PTU use for patients who are in their first trimester of pregnancy, or who are allergic to or intolerant of methimazole.

- Closely monitor patients on PTU therapy for signs and symptoms of liver injury, especially during the first six months after initiation of therapy.
- If liver injury is suspected, promptly discontinue PTU therapy and evaluate the patient for evidence of liver injury and provide supportive care.
- PTU should not be used in pediatric patients unless the patient is allergic to or intolerant of MMI, and there are no other treatment options available.
- Rare cases of embryopathy, including aplasia cutis, have been reported with use of MMI during pregnancy. No such cases have been reported with PTU use during pregnancy. Therefore, PTU may be more appropriate for patients with Graves' disease who are in their first trimester of pregnancy.
- Counsel patients to promptly advise you if they note any of the following signs or symptoms: fatigue, weakness, vague abdominal pain, loss of appetite, itching, easy bruising or yellowing of the eyes or skin.

References

Rivkees SA. The treatment of Graves' disease in children. J Pediatr Endocrinol Metab 2006 Sep;19(9):1095-111.

The Food and Drug Administration and American Thyroid Association.

Propylthiouracil (PTU)-Related Liver Toxicity: Public Workshop, April 19, 2009, Washington, D.C.

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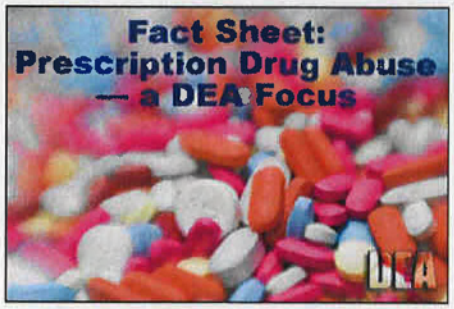

Useful Links

- Nearly 7 million Americans are abusing prescription drugs*—more than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined. That 7 million was just 3.8 million in 2000, an 80 percent increase in just 6 years.
- Prescription pain relievers are new drug users' drug of choice, vs. marijuana or cocaine.
- Opioid painkillers now cause more drug overdose deaths than cocaine and heroin combined.
- Nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers. A shocking 40 percent of teens and an almost equal number of their parents think abusing prescription painkillers is safer than abusing "street" drugs.
- Misuse of painkillers represents three-fourths of the overall problem of prescription drug abuse; hydrocodone is the most commonly diverted and abused controlled pharmaceutical in the U.S.
- Twenty-five percent of drug-related emergency department visits are associated with abuse of prescription drugs.
- Methods of acquiring prescription drugs for abuse include "doctor-shopping," traditional drug-dealing, theft from pharmacies or homes, illicitly acquiring prescription drugs via the Internet, and from friends or relatives.
- DEA works closely with the medical community to help them recognize drug abuse and signs of diversion and relies on their input and due diligence to combat diversion. Doctor involvement in illegal drug activity is rare—less than one tenth of one percent of more than 750,000 doctors are the subject of DEA investigations each year—but egregious drug violations by practitioners unfortunately do sometimes occur. DEA pursues criminal action against such practitioners.
- DEA Internet drug trafficking initiatives over the past 3 years have identified and dismantled organizations based both in the U.S. and overseas, and arrested dozens of conspirators. As a result of major investigations such as Operations Web Tryp, PharmNet, Cyber Rx, Cyber Chase, and Click 4 Drugs, Bay Watch, and Lightning Strike, tens of millions of dosage units of prescription drugs and tens of millions of dollars in assets have been seized.

* Prescription drugs refers to abuseable pharmaceuticals controlled under federal law enforced by the DEA.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

AS Medications Solution LLC. Announces a Nationwide Recall of All Lots of Digoxin Tablets 0.25mg Due to Size Variability

Contact:
Bill Norkus
(847) 680-3515

FOR IMMEDIATE RELEASE -- Libertyville, IL, May 11, 2009 – A S Medication Solutions, LLC, a drug repackage company, announced today that all tablets of Caraco brand Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of August, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. Caraco Pharmaceutical Laboratories, Ltd manufactured the recalled tablets. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Digoxin is a drug product used to treat heart failure and abnormal heart rhythms. It has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and slow heart rate. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of heart failure and abnormal heart rhythms.. Consequently, as a precautionary measure, A S Medication Solutions, LLC is recalling these tablets to the consumer level to minimize any potential risk to patients.

Consumers with the products with the following NDC codes that are within expiration should return these products to the place of purchase.

Product Identification

Caraco Digoxin
A-S Medication Solutions, Digoxin 0.25 mg is a scored round biconvex white tablet imprinted with "441"

NDC Numbers:
Digoxin Tablets, USP, 0.25 mg
54569-5758-0 (30-count)

Patients using A-S Medication Solutions, Digoxin tablets, USP, 0.25 mg, who have medical questions should contact their healthcare provider for additional instructions or guidance.

Healthcare providers who have this product should return the product to their place of purchase. Healthcare providers can call A-S Medication Solutions Recall Coordinator at (847) 680-3515, Monday through Friday, 8:00 a.m. – 4:00 p.m. CST, for instructions on how to return the affected product or for any other inquiries related to this action.

Any adverse reactions experienced with the use of all affected product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at Med Watch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

#

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
May 7, 2009

Media Inquiries:
Rita Chappelle,
301-796-4672
Consumer Inquiries:
888-INFO-FDA

Testosterone Gel Safety Concerns Prompt FDA to Require Label Changes, Medication Guide

The U.S. Food and Drug Administration today announced that it is requiring manufacturers of two prescription topical testosterone gel products, AndroGel 1% and Testim 1%, to include a boxed warning on the products' labels. The agency is requiring this action after receiving reports of adverse effects in children who were inadvertently exposed to testosterone through contact with another person being treated with these products (secondary exposure).

The gels are approved for use in men who either no longer produce testosterone or produce it in very low amounts. Both products are applied once daily, to the shoulders or upper arms. Only AndroGel 1% is approved for application to the abdomen. Precautions in the current labels instruct users to wash their hands after using the product and to cover the treated skin with clothing.

"These drugs are approved for an important medical need, but can have serious, unintended side effects if not used properly," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We must ensure that the adults using them are well-informed about the precautions needed to protect children from secondary exposure."

In 2007, 1.4 million prescriptions for AndroGel—the most commonly dispensed gel form of testosterone—were dispensed by U.S. retail pharmacies. Approximately 25,000 of those were dispensed for off-label use in women. During the same period, some 370,000 prescriptions were dispensed for Testim, according to data from SDI: Vector One National.

Despite the currently labeled precautions, as of Dec. 1, 2008, the FDA has received reports of eight cases of secondary exposure to testosterone in children ranging in age from nine months to five years. Since that time, additional reports of secondary

exposure have been received by the agency and are presently under review.

Of the fully reviewed cases, adverse events reported in these children included inappropriate enlargement of the genitalia (penis or clitoris), premature development of pubic hair, advanced bone age, increased libido, and aggressive behavior.

In most cases, the signs and symptoms regressed when the child no longer was exposed to the product. However, in a few cases, enlarged genitalia did not fully return to age-appropriate size and bone age remained modestly greater than the child's chronological age.

In some cases, children had to undergo invasive diagnostic procedures and, in at least one case, a child was hospitalized and underwent surgery due to a delay in recognizing the underlying cause of the signs and symptoms.

Signs of inappropriate virilization (development of male secondary sexual characteristics) in children and the possibility of secondary testosterone exposure should be brought to a health care provider's attention.

In most of the cases, users of these products failed to follow appropriate use instructions, resulting in direct contact between treated skin and the child.
The required label changes will provide additional information about the risk of secondary exposure and the steps that should be taken to reduce this risk. The FDA also is requiring that the manufacturers of these products develop a Medication Guide as part of a Risk Evaluation and Mitigation Strategy to ensure that the benefits of these products continue to outweigh their potential risks.

The FDA recommends the following precautions be taken to minimize the potential for secondary exposure:

- Adults who use testosterone gels should wash their hands with soap and warm water after every application;
- Adults should cover the application site with clothing once the gel has dried;
- Adults should wash the application site thoroughly with soap and warm water prior to any situation where skin-to-skin contact with another person is anticipated;
- Children and women should avoid contact with testosterone application sites on the skin of men who use these products; and
- Adults should note that use of any similar, but unapproved, products from the marketplace — including the Internet — that can result in the same serious adverse effects should be avoided.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of these gels to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

- Online
- Regular Mail: use postage-paid FDA form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: (800) FDA-0178

- Phone: (800) FDA-1088

AndroGel 1% is manufactured by Marietta, Ga.-based Solvay Pharmaceuticals. Testim 1% is made by Auxilium Pharmaceuticals, Malvern, Pa.

For more information:

- Information on FDA's Drug Safety Initiative
- Information on FDA-approved drugs