Drug Utilization Review Board

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

Wednesday
April 8, 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 – April 8, 2009**

DATE: April 2, 2009

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

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

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Zolpimist™ – See Appendix C.

30 Day Notice to Prior Authorize Ryzolt™ – See Appendix D.

30 Day Notice to Prior Authorize Aplenzin® – See Appendix E.

30 Day Notice to Prior Authorize New Proton Pump Inhibitor Products – See Appendix F.

60 Day Notice to Prior Authorize Anti-Migraine Products and 30 Day Notice to Prior Authorize Treximet® – See Appendix G.

FDA and DEA Updates – See Appendix H.

Future Business

Adjournment

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Drug Utilization Review Board

(DUR Board)

Meeting – April 8, 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. March 11, 2009 DUR Minutes – Vote
B. March 26, 2009 DUR Recommendation Memorandum
C. Results of 2009 Supplemental Rebate Agreements

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 January 2009
B. Retrospective Drug Utilization Review Response for November 2008
C. Medication Coverage Activity Audit for March 2009
D. Help Desk Activity Audit for March 2009

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

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

A. COP Recommendations
B. Current Hypnotics PA Criteria

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

6. 30 Day Notice to Prior Authorize Ryzolt™ – See Appendix D.

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

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

7. 30 Day Notice to Prior Authorize Aplenzin® – See Appendix E.

A. Product Summary
B. COP Recommendations
C. Product Details

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

8. 30 Day Notice to Prior Authorize New Proton Pump Inhibitor Products – See Appendix F.

A. Product Summaries
B. COP Recommendations
C. Product Details

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

9. 60 Day Notice to Prior Authorize Anti-Migraine Products and 30 Day Notice to Prior Authorize Treximet® – See Appendix G.

A. Utilization Review
B. COP Recommendations

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

10. FDA and DEA Updates – See Appendix H.

11. Future Business

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

12. Adjournment

Appendix A

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

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Mark Feightner, Pharm.D.		X
Dorothy Gourley, D.Ph.		X
Evelyn Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.	X	
Dan McNeill, Ph.D., PA-C; Chairman	X	
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 Students: Brooke Reavis	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:

Brad W Robertson, GSK	David Henderson, GSK	Doug Ethel, GSK
Toby Thompson, Pfizer	Susan Stone, Allergan	Mark DeClerk, Lilly
Jim Dunlap, Lilly	Sam Smothers, MedImmune	David Lynham, MedImmume
David Barton, Schering Plough	Jim Graham, Johnson & Johnson	Aaron Mays, Alcon Labs
Kristen Thomas, Astra Zeneca	Donna Erwin, Bristol Myers	Paul Davis, MHAT
Dennis Simoneaux, GSK	Lana Stewart, Merck	Holly Turner, Merck
Kathleen Sumpter, Merck	Don Frailey, GSK	Rob Baxter, MedImmune
Jim Chapman, Abbott		

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 5 Dr. Martha Tarpay; Allergy Clinic, Mercy

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

1A: Roll Call

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

ACTION: NONE REQUIRED

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

Dr. McNeill recognized the speaker for public comment.

ACTION: NONE REQUIRED

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

3A: February 11, 2009 DUR Minutes

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

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review Responses: October 2008

4B: Medication Coverage Activity Audit: February 2009

4C: Help Desk Activity Audit: February 2009

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ADVAIR® AND SYMBICORT®**

For Public Comment, Dr. Martha Tarpay: I'm Martha Tarpay, practicing allergist, and I was asked to talk about the need for pre-authorization in certain patients for the Advair or Symbicort for the asthma. I would like to base my comments on review the 2007 National Institute of Health asthma guidelines, review the literature and on my personal experience. The National Institute of Health guidelines specifies step 4 in young children and step 3 and 4 the use of combined therapy, inhaled steroid, and long acting beta-2 agonists. There has been lots of controversy about the use of long acting beta-2 agonists. And that's based on the study when the drug was used alone. In 2009, in January, Dr. Harold Nelson, an expert in asthma treatment, reviewed all the available data on the combination of inhaled steroids and long acting beta-2 agonists and found no evidence, any published data, that the combination treatment increases the death rate in asthma. Review the literature of the combination therapy versus inhaled steroids suggests that low dose inhaled steroid with long acting beta-2 agonists is superior to middle dose inhaled steroid. So basically it will not have any data suggesting that when the long acting beta-2 agonists combine with the inhaled steroid, we aren't doing any harm to our patients. My personal experience is that if I give separate which is what we recommend to some of our patients before we give authorization, we give short acting beta-2 agonists and an inhaled steroid. They often, this patient will end up using only a short acting beta-2 agonist which can lead to increased morbidity and mortality. And why? Because they do not perceive that the inhaled steroid is doing anything for them. While the beta-2 agonist relieves their symptoms. So this is why we feel that delaying giving authorization for Advair actually can lead to increased morbidity in some of these patients and possibly mortality. So this is why we are concerned that the delay of getting this before we authorize or we get authorization for our patient with asthma, and basically this would be patients who have more very or severe asthma.

Dr. Le clarified the PA criteria with Board members and Dr. Tarpay.

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

Dr. Muchmore moved to approve as submitted with no supplemental rebate offers; seconded by Dr. Meece.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE FENOGLIDE™, LIPOFEN®, AND TRILIPIX™**

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

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

ACTION: MOTION CARRIED

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

Materials included in agenda packet; presented by Dr. Robinson.
Dr. Muchmore moved to approve as submitted; seconded by Dr. Meece.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF INSOMNIA PBPA CATEGORY AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZOLPIMIST®**

Materials included in agenda packet; presented by Dr. Robinson.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF GLAUCOMA PBPA CATEGORY**

Materials included in agenda packet; presented by Dr. Chonlahan.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: **UTILIZATION REVIEW OF ANTI-MIGRAINE PRODUCTS**

Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **UTILIZATION REPORT FOR SECOND QUARTER FISCAL YEAR 2009**

Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **FDA & DEA UPDATES**

Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **FUTURE BUSINESS**

Materials included in agenda packet; submitted by Dr. Graham.
13A: Utilization Review of Fibromyalgia
13B: Utilization Review of Otic Antibiotics
13C: Utilization Review of Antiemetics
13D: New Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ADJOURNMENT**

The meeting was adjourned at 6:47 p.m.

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

Memorandum

Date: March 26, 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 March 11, 2009

Recommendation 1: Vote to Prior Authorize Advair® and Symbicort®

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommended the following criteria for approval of Advair® and Symbicort®:

- Diagnosis of COPD: Approve for one year (auto-approve if in medical claims history).

- Diagnosis of Asthma:
  (If diagnosis in medical claims history and ICS claim in pharmacy history for 30 day in last 100 days – auto-approve for one year.)

  1. Member must be 4 years of age or older, AND
  2. Have used inhaled corticosteroid for at least one month immediately prior, AND

3. Considered uncontrolled by provider (required rescue medication > 2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids), OR
4. Clinical situation warranting initiation with combination therapy due to severity of asthma.

Recommendation 2: Vote to Prior Authorize Fenoglide™, Lipofen® and Trilipix™

MOTION CARRIED by unanimous approval.

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

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

Recommendation 3: Vote to Prior Authorize Astepro™

MOTION CARRIED by unanimous approval.

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

Recommendation 4: Annual Review of Insomnia Product Based Prior Authorization Category

No Action Required

The College of Pharmacy does not recommend any changes at this time.

Recommendation 5: Annual Review of Glaucoma Product Based Prior Authorization Category

No Action Required

The College of Pharmacy does not recommend any changes at this time.

Results of 2009 Supplemental Rebate Agreements

All supplemental rebated products are in blue. Please note that changes made to categories after January 2009 will not be reflected.

<table>
<tr><th colspan="2">Antihypertensives</th></tr>
<tr><td colspan="2">PA Criteria: Tier 1 products are covered with no authorization necessary.

Tier 2 authorization requires:
documented inadequate response to two Tier 1 medications, or
adverse drug reaction to all the Tier 1 medications, or
previous stabilization on the Tier 2 medication, or
a unique indication for which the Tier 1 antihypertensives are not indicated
Tier 3 authorization requires:
documented inadequate response to two Tier 1 medications and documented inadequate response to all available Tier 2 medications, or
adverse drug reaction to all the Tier 1 or all Tier 2 medications, or
previous stabilization on the Tier 3 medication, or
a unique indication for which the lower tiered antihypertensives are not indicated</td></tr>
<tr><th colspan="2">CCB (Calcium Channel Blockers)</th></tr>
<tr><th>Tier 1</th><th>Tier 2</th></tr>
<tr><td>nifedipine ER
nifedipine (Adalat, Procardia)
nifedipine CC (Adalat CC)
amlodipine/atorvastatin (Caduet)
verapamil (Calan, Isoptin, Verelan)
verapamil SR (Calan SR, Isoptin SR, Verelan PM)
nicardipine (Cardene)
diltiazem (Cardizem)
diltiazem CD (Cardizem CD)
diltiazem SR (Cardizem SR)
diltiazem ER (Cartia XT, Diltia XT)
diltiazem XR (Dilacor XR)
isradipine (Dynacirc)
isradipine (Dynacirc CR)
nifedipine XL (Nifedical XL, Procardia XL)
nimodipine (Nimotop)
amlodipine (Norvasc)
felodipine (Plendil)
diltiazem (Tiazac, Taztia XT)</td><td>nicardipine (Cardene SR)
diltiazem (Cardizem LA)
verapamil (Covera HS)
nisoldipine (Sular)</td></tr>
</table>

ACE/CCB		
Tier 1	**Tier 2**	**Tier 3**
• Tier 1 ACE + Tier 1 CCB	• enalapril/felodipine (Lexxel) • benazepril/amlodipine (Lotrel) • trandolapril/verapamil (Tarka)	

ARBs (Angiotensin Receptor Blockers) Medication
PA Criteria: Tier 1 products are covered with no authorization necessary. Tier 2 authorization requires inadequate response to two Tier 1 medications or • adverse drug reaction to all Tier 1 class of medications or • previous stabilization on the Tier 2 medications, or • a unique indication for which the Tier 1 antihypertensives are not indicated Tier 3 authorization requires documented inadequate response to two Tier 1 medications and documented inadequate response to all available tier 2 medications, or • adverse drug reaction to all Tier 1 or Tier 2 classes of medications, or • previous stablilization on the Tier 3 medication, or • a unique indication for which the lower tiered antihypertensives are not indicated.
* Clinical exception applies to members who have diabetes.

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

HMG-CoA Reductase inhibitors (Statins)

PA Criteria:

The following are criteria for approval of a Tier-2 Product:

- Previous failure to achieve desired LDL reduction with a preferred statin - defined by at least 6-8 weeks of continuous therapy at standard to high dose.
- Previous stabilization on non-preferred medication.
- Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
- Documented adverse effect or contraindication to the preferred products

Tier 1	Tier 2
• lovastatin (generic) • fluvastatin (Lescol & Lescol XL) • atorvastatin (Lipitor) • pravastatin (Pravachol) • simvastatin (Zocor)	• lovastatin (Altoprev & Mevacor) • rosuvastatin (Crestor) • pravastatin (Pravigard) • ezetimibe/simvastatin (Vytorin)

Statin/Niacin CR Combination Products

Tier 1	Tier 2
• Tier 1 statin and/or niacin CR • Simvastatin/niacin CR (Simcor)	• Lovastatin/Niacin CR (Advicor)

Fibric Acid Derivatives

PA criteria:

- The approval criteria for a tier 2 medication is as follows:
- Laboratory documented failure with a tier one medication after 6 months trial with a Tier 1 medications.
- Documented adverse effect, drug interaction, or contraindication to Tier 1 products.

Tier 1	Tier 2
• clofibrate (Atromid - S) • fenofibrate (Fenoglide) • micronized fenofibrates (Lofibra) • gemfibrozil (Lopid) • micronized fenofibrates (Tricor) • fenofibrates (Trilipix)	• micronized fenofibrates (Lipofen) • fenofibrates (Triglide) • micronized fenofibrates (Antara)

HFA Rescue Inhalers

- Tier-1 products are available without prior authorization.
- Tier-2 authorization requires:

1) Approved or clinically accepted indication, and
2) Specific reason member cannot use all available tier-1 products

Tier 1	Tier 2
• ProAir HFA (albuterol HFA) • Proventil HFA (albuterol HFA) • Ventolin HFA (albuterol HFA)	Xopenex HFA (levalbuterol HFA)

Nasal Allergy

PA criteria:

Nasal allergy medications will be included in product-based prior authorization effective 4/28/08. Tier 1 products will be covered with no prior authorization necessary.

Tier 2 Authorization Requires

- Documented adverse effect or contraindication to the Tier 1 products , or

Documented trials with all available Tier 1 corticosteroids with no beneficial response with the drug having been titrated to the recommended dose. Each trial must be at least 2 weeks in duration.

Tier 1	Tier 2
Corticosteroids • beclomethasone (Beconase AQ) • fluticasone (Flonase) • triamcinolone (Nasacort AQ) • flunisolide (Nasalide/Nasarel) • fluticasone (Veramyst) Other • azelastine (Astelin) • azelastine (Astepro) • ipratropium bromide (Atrovent) • olopatadine HCL (Patanase)	• mometasone (Nasonex) • ciclesonide (Omnaris) • budesonide (Rhinocort AQ)

ADHD and Narcolepsy

PA Criteria:

- Dose not to exceed 1.5 times the FDA approved maximum.
- No concurrent use of multiple products from this category, ie, Strattera + Stimulant, Methylphenidate + Amphetamine
- Prior authorization is required for all stimulants for adults age 21 and older.

Tier 2 authorization requires:

- Documented trial of a longer-acting Tier 1 medication within the last 30 days with inadequate results, and
- Diagnosis of ADHD or Narcolepsy

Tier 3 authorization requires:

- Documented trial of one Tier 1 long-acting product and one Tier 2 medication or two trials with either a Tier 1 or a Tier 2 medication with inadequate results (both trials within the last 60 days), and
- Diagnosis of ADHD or Narcolepsy.

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

Antidepressants

PA Criteria:

The following are criteria for approval of a Tier 2 Product:

- 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.
- 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.
- A unique FDA-approved indication not covered by Tier 1 products or other products from a different therapeutic class.
- A petition may be submitted for consideration whenever a unique member specific situation exists.

Tier 3 Authorization Criteria

- 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.
- 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.
- A unique FDA-approved indication not covered by a lowered tiered product or other products from a different therapeutic class.
- A petition may be submitted for consideration whenever a unique member specific situation exists.

Dual Acting Antidepressants

Tier 1	Tier 2	Tier 3
Any Tier 1 SSRI or • trazodone (Desyrel) • venlafaxine (Effexor) • mirtazapine (Remeron, Remeron SolTab) • bupropion (Wellbutrin, Wellbutrin SR, Wellbutrin XL)	• venlafaxine extended release tablets	• duloxetine (Cymbalta) • venlafaxine (Effexor XR capsules) • desvenlafaxine (Pristiq) • nefazodone (Serzone)

Bladder Control Drugs

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

- Tier-1 drug failure (i.e. inadequate clinical response or adverse effect), or
- Contraindication to the tier 1 drugs, or
- Stabilization on the tier 2 drug, or
- A unique indication which the tier 1 drugs lack.

- Patients who are currently stabilized on a Tier 2 medication will be allowed to continue their current treatment without prior authorization.

Tier 1	Tier 2
• tolterodine (Detrol) • tolterodine extended release (Detrol LA) • oxybutynin (Ditropan) • darifenacin (Enablex) • flavoxate (Urispas) • solifenacin (VESIcare)	• oxybutinin extended release (Ditropan XL) • oxybutynin (Oxytrol) • trospium (Sanctura, Sanctura XR) • fesoderodine fumarate tablets (Toviaz)

Anti-Ulcer

- Prior Authorization required for:
- ranitidine (Zantac) capsules, effervescent forms and,
- lansoprazole (Prevacid) granules and solutabs forms.
- lansoprazole/naproxen (Prevacid NapraPac)
- esomeprazole IV (Nexium IV)

Tier 2 authorization requires:

- Documented 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

Tier 1	Tier 2
• omeprazole (Prilosec) 20mg capsules • lansoprazole (Prevacid) capsules *BID dosing requires PA	• rabeprazole sodium (Aciphex) • esomeprazole magnesium (Nexium) • omeprazole (Prilosec) 40mg capsules • prantoprazole sodium (Protonix) • omeprazole (Zegerid) packets & capsules

Narcotic Analgesics

PA Criteria:

Tier 1 products are covered with no prior authorization or step therapy required.

Tier 2 authorization requires:

- documented 30 day trial/titration period with at least two Tier 1 medications within the last 90 days, or
- clinically appropriate pain therapy requiring time-released medication

Tier 3 authorization requires:

- documented 30 day trial with at least two Tier 2 medications within the last 90 days, or
- documented allergy or contraindication to all Tier 2 medications
- Members with an oncology-related diagnosis are exempt from the prior authorization process, although quantity and dosage limits still apply. Actiq and Fentora are approved only for oncology-related diagnoses
- Only one long-acting and one short-acting agent can be used concurrently

Narcotic

Tier 1 All immediate release narcotics not listed in a higher tier.

Tier 2	Tier 3	Oncology Only
Long Acting		
• fentanyl patches (Duragesic) • oxymorphone (Opana ER) • morphine ER	• morphine sulfate (Avinza) • morphine sulfate (Kadian) • oxycodone (OxyContin)	
Short Acting		
• hydrocodone (Xodol)		• fentanyl (Actiq) • fentanyl (Fentora)

NSAIDs	

PA Criteria:
 	
• Two consecutive trials with Tier 1 products within the last 120 days that did not yield adequate results.
• Clinical exceptions for NSAIDs in Tier 2 are demonstrated by the following conditions:
  ○ History of upper GI bleeding, or
  ○ History of NSAID-induced ulcer, or
  ○ Active peptic ulcer disease, or
  ○ Concurrent chronic use of oral corticosteroids, or
  ○ Chronic NSAID therapy in elderly or debilitated patients, or
  ○ Indomethacin for management of gout.
  ○ These clinical conditions are demonstrated by documentation sent by the prescribing physician and pharmacist.	

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

Pediculicides

PA Criteria:

- Covered OTC products

Malathion lotion (Ovide): No prior authorization necessary

- Member must be at least 6 years old
- Quantity limit of 60ml for 7 day supply; may be repeated once if needed for current infestation after 7 days from original fill date

PA Criteria:

Lindane lotion & shampoo

- Available only after first-line treatment with an OTC product has failed
- Member must be at least 13 years old or weigh at least 110 pounds
- Quantity limit of 60ml for 7 day supply
- One 7 day supply per 30 days maximum

Crotamiton lotion & cream (Eurax)

- Available only after treatment with OTC product has failed
- quantity limit of 60 grams or milliliters for 30 day supply

Ophthalmic Anti-Infective

PA Criteria:

1. Approved indication/suspected infection by organism not known to be covered by any tier one antibiotics.
2. Known contraindication to all indicated tier one medication.
3. Prescription by optometrists/ophthalmologists or
4. When used for pre/post-operative prophylaxis.

Tier 1	Tier 2
• ciprofloxacin (Ciloxan) • levofloxacin (Quixin) • gentamincin (Gentak) • ofloxacin (Ocuflox) • tobramycin (AK-Tob) • sodium sulfacetamide (Bleph-10, Sodium Sulamyd) • trifluridine (Viroptic) • natamycin (Natacyn) • plymyxin B/trimethoprim (Polytrim) • neomycin/polymyxin B/gramicidin (AK-Spore) • moxifloxacin (Vigamox) • gatifloxacin (Zymar) • azithromycin (Azasite)	

Ocular Allergy

Criteria for Tier 2 Product:

- FDA approved diagnosis.
- A trial of at least one Tier 1 product of a similar type for a minimum of two weeks in the last 30 days.
- Documentation of clinical need for Tier 2 product over Tier 1 should be noted on the petition.
- Clinical exceptions granted for products with allergic reaction or contraindication.

Tier 1	Tier 2
• ketotifen fumarate (Alaway, Zaditor OTC) • epinastine (Elestat) • cromolyn sodium (Opticrom) • azelastine (Optivar) • olopatadine (Patanol)	• pemirolast potassium (Alamast) • nedocromil sodium (Alocril) • lodoxamide tromethamine (Alomide) • loteprednol etabonate (Alrex) • emadastine difumarate (Emadine) • olopatadine (Pataday)

Ophthalmic Glaucoma Medications	
Tier 1 products are covered with no authorization necessary	
Tier 2 authorization requires: • Comprehensive dilated eye exam within the last 365 day period, and • FDA-approved indication, and • Trial of a Tier 1 product for a minimum of 4 weeks with inadequate results within the last 90 days, or • Documented adverse effect, drug interaction, or contraindication to Tier 1 products, or • Unique FDA-approved indication for which Tier 1 medications are not indicated	
Prostaglandin Analogs	
Tier 1	**Tier 2**
• travoprost (Travatan, Travatan Z) • latanoprost (Xalatan)	bimatoprost (Lumigan)

Appendix B

Retrospective Drug Utilization Review Report

Claims Reviewed for January 2009

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Total # of messages returned by system when no limits were applied	45,679	67,188	1,181,749	33,635
Limits which were applied	Established, Major, Males and Females, Age 0-18	Males and Females, Narcotics, Age 10-17	Contraindicated, Asthma, Males and Females, Age 0-18	High Dose, Statins, Males and Females, Age 0-150
Total # of messages after limits were applied	16	123	482	29
Total # of members reviewed after limits were applied	16	117	406	29

LETTERS			
Prescribers		**Pharmacies**	
Sent	**Responded**	**Sent**	**Responded**
79		22	

Retrospective Drug Utilization Review Report

Claims Reviewed for November 2008

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 57-65	Antihistamines, Males and Females, Age 5-6	Contraindicated, Pregnancy, Females, Age 22-65	Dose and Duration, Nuvaring®, Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 52
Response Forms Returned: 15

The response forms returned yielded the following results:

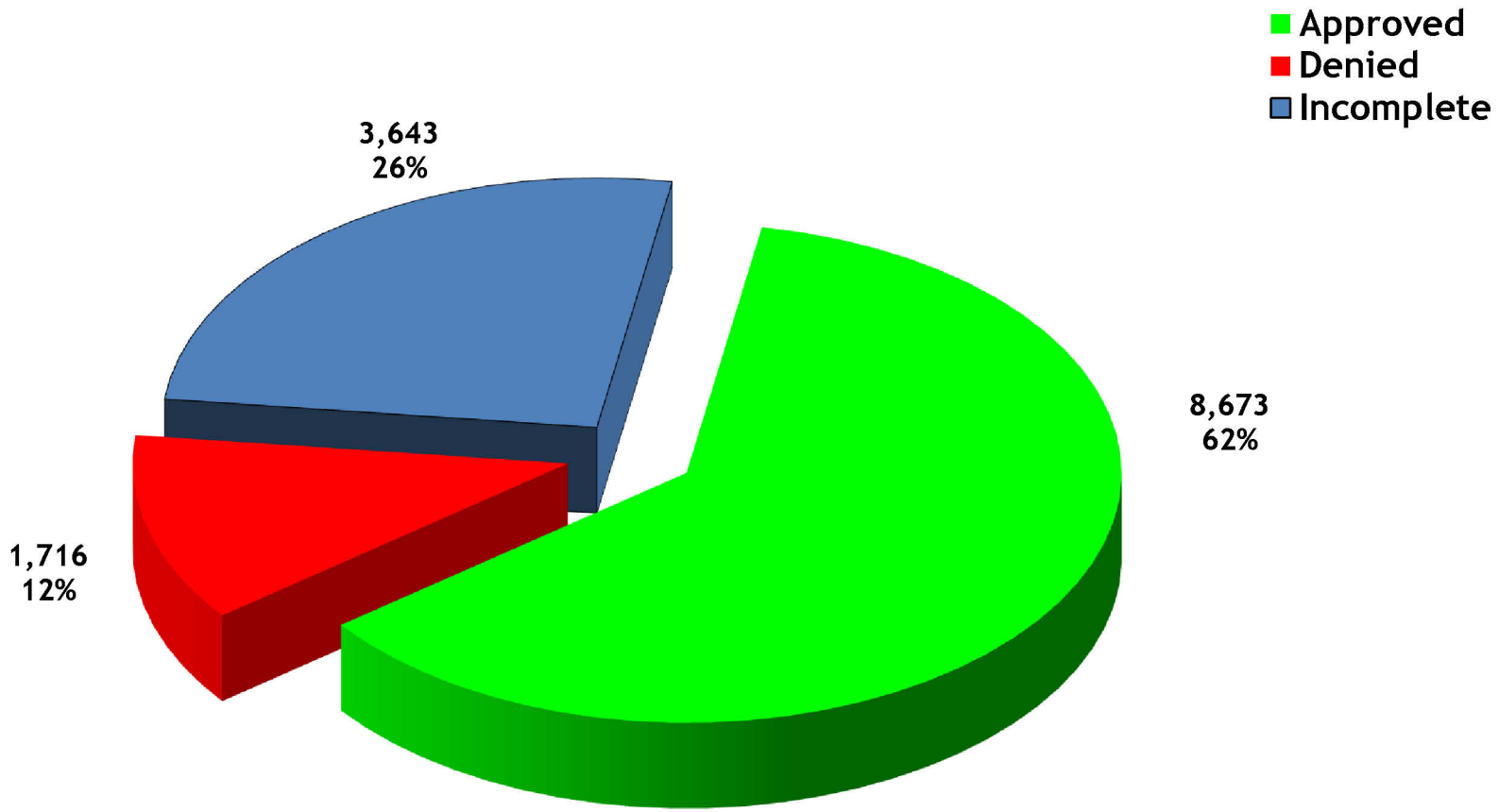
1 (7%)	*Record Error—Not my patient.*
3 (20%)	*No longer my patient.*
3 (20%)	*Medication has been changed prior to date of review letter.*
1 (7%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
6 (40%)	*I am aware of this situation and will plan to continue monitoring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

Response Summary (Pharmacy)
Letters Sent: 45
Response Forms Returned: 20

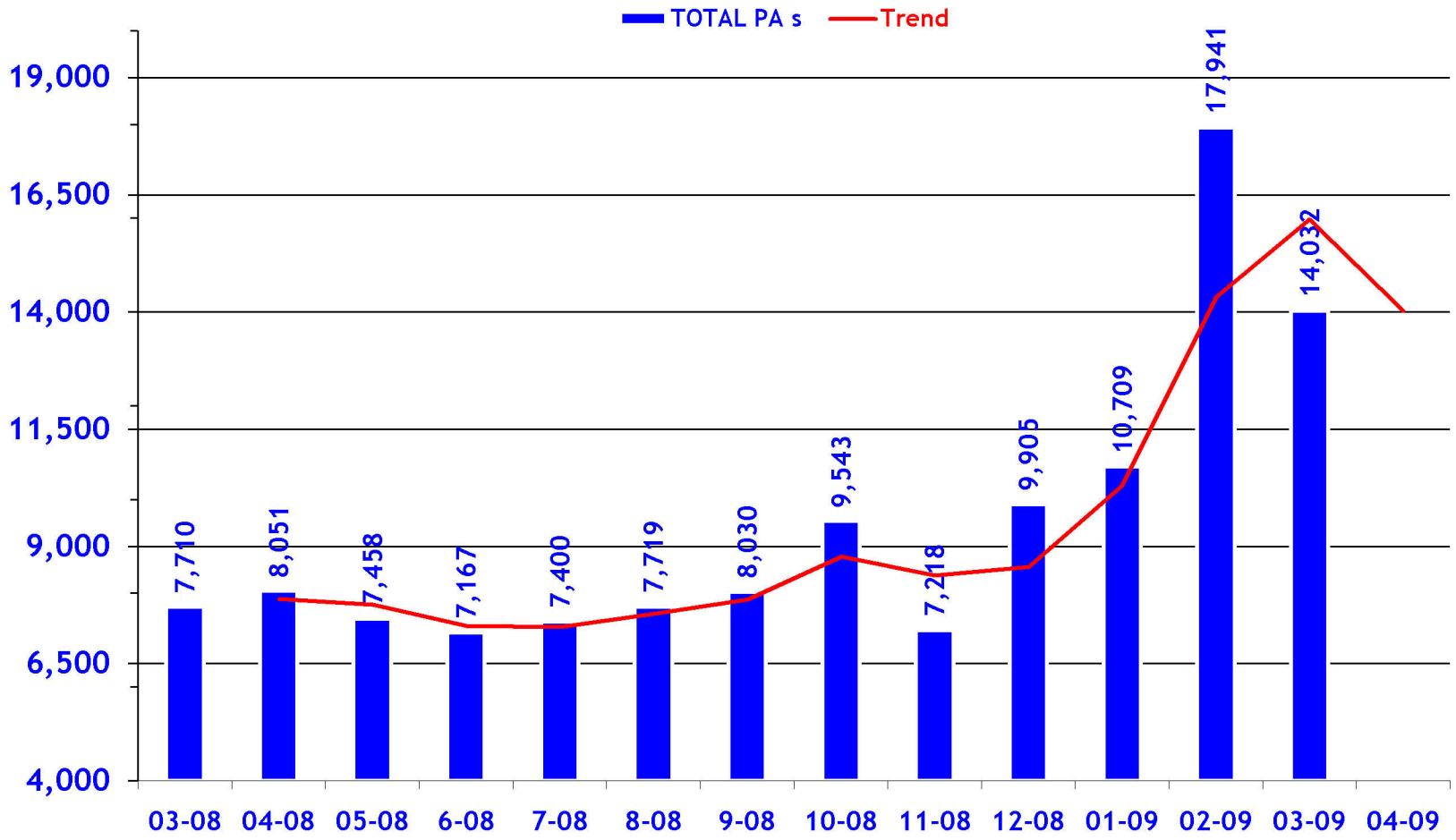
The response forms returned yielded the following results:

2 (10%)	*Record Error—Not my patient.*
1 (5%)	*No longer my patient.*
2 (10%)	*Medication has been changed prior to date of review letter.*
8 (40%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
5 (25%)	*I am aware of this situation and will plan to continue monitoring therapy.*
2 (10%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT
March 2009



PRIOR AUTHORIZATION REPORT
March 2008 – March 2009



Activity Audit for

3/1/2009 Through 3/31/2009

	Average Length of	Approved	Denied	Incomplete	Total
ACE Inhibitors	61	11	1	4	16
Angiotensin Receptor Antagonist	352	23	40	45	108
Antidepressant	277	247	134	309	690
Antihistamine	273	203	77	161	441
Antiulcers	11	10	3	4	17
Anxiolytic	91	3,295	173	475	3,943
Calcium Channel Blockers	184	6	1	2	9
Growth Hormones	172	42	6	5	53
HTN Combos	187	8	3	10	21
Insomnia	117	53	68	69	190
Nsaids	338	29	32	32	93
Plavix	357	105	6	51	162
Stimulant	219	688	174	310	1,172
Others	241	3,953	998	2,166	7,117
Emergency PAs		0	0	0	0
Total		**8,673**	**1,716**	**3,643**	**14,032**
Overrides					
Brand	169	43	5	13	61
Dosage Change	13	384	16	20	420
High Dose	271	3	1	1	5
IHS - Brand	74	90	2	1	93
Ingredient Duplication	9	7	0	1	8
Lost/Broken Rx	18	75	1	3	79
Nursing Home Issue	15	74	0	0	74
Other	90	29	0	3	32
Quantity vs. Days Supply	225	300	73	103	476
Stolen	21	3	2	0	5
Overrides Total		**910**	**98**	**143**	**1,151**

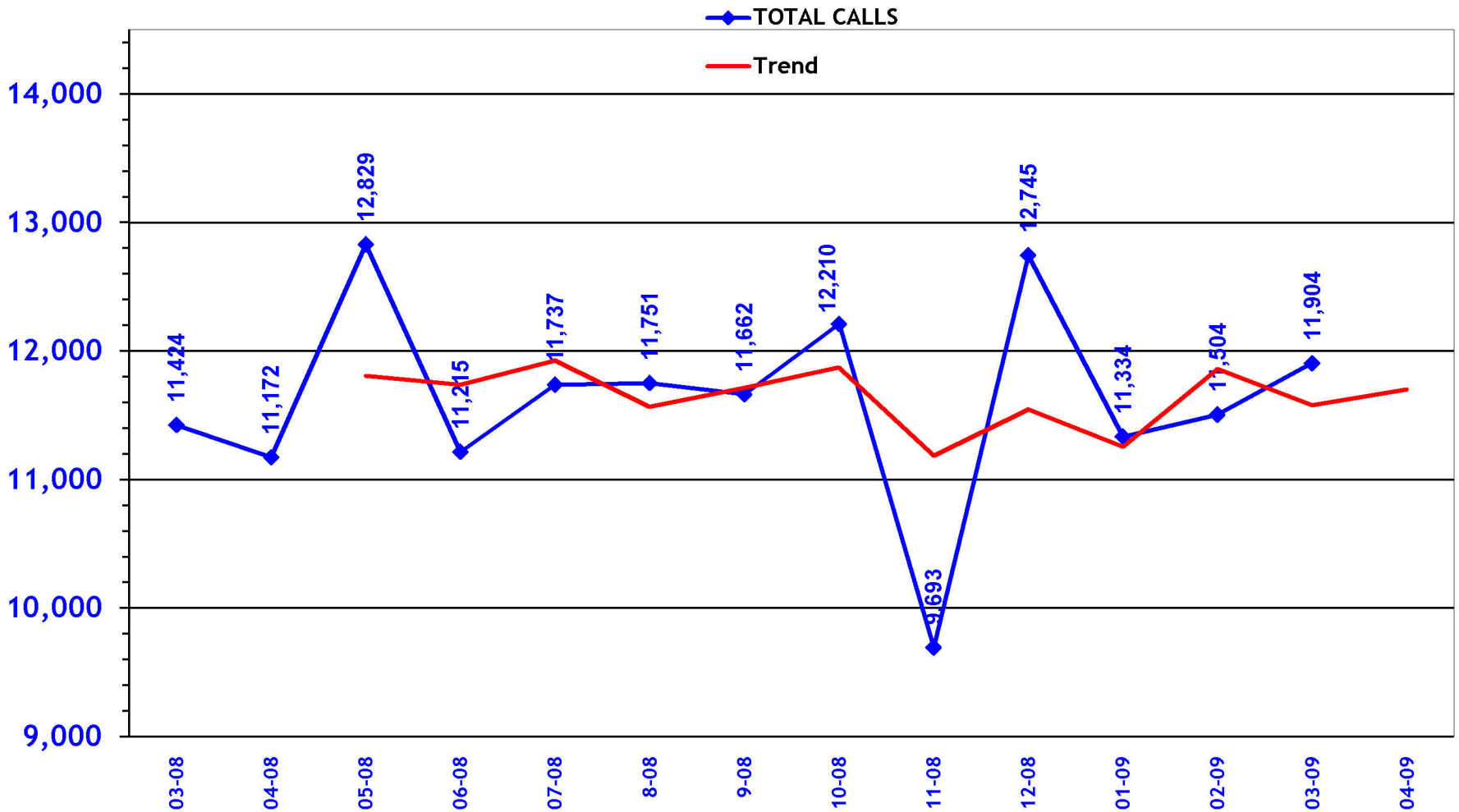
Denial Reasons

Lack required information to process request.	2,510
Unable to verify required trials.	1,982
Does not meet established criteria.	404
Not an FDA approved indication/diagnosis.	168
Requested dose exceeds maximum recommended FDA dose.	75
Member has active PA for requested medication.	67
Considered duplicate therapy. Member has a prior authorization for similar medication.	62
Medication not covered as pharmacy benefit.	26
Drug Not Deemed Medically Necessary	5

Duplicate Requests: 871

Changes to existing PAs: 907

CALL VOLUME MONTHLY REPORT
March 2008 – March 2009



Appendix C

Vote to Prior Authorize Zolpimist™ (Zolpidem Oral Spray)

Oklahoma Health Care Authority
April 2009

Recommendations

The College of Pharmacy recommends placement of Zolpimist™ in Tier 3 of the Hypnotics Category with a manual prior authorization. The existing prior authorization criteria for this category will apply. In addition, the petition should also include information regarding why member must have the oral spray formulation of zolpidem. A Quantity Limit similar to all other hypnotic medications will apply.

Current Prior Authorization of Hypnotic Medications

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

All pediatric members require a prior authorization for use.
Quantity limits also applies for all products based on maximum recommended dose.

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

Mandatory Generic Plan Applies.
***Requires reason for use.**

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

Appendix D

30 Day Notice to Prior Authorize Ryzolt™ (Tramadol HCL ER)

Oklahoma Health Care Authority
April 2009

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

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 μ-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.

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 ER Fentanyl **(Duragesic® Patches)** Oxymorphone **(Opana® ER)**	Morphine sulfate **(Kadian®)** Morphine sulfate **(Avinza®)** Oxycodone **(Oxycontin®)** Tramadol **(Ryzolt™, Ultram ER®)**	
	Short-Acting		
	Hydrocodone/APAP **(Xodol®)**		

Mandatory Generic Plan Applies

Blue Color Indicates Supplemental Rebate Participation

Ryzolt™ Product Details

Indication

Ryzolt™ is 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.

Dosage Forms

100mg, 200mg, and 300mg extended release tablets

Contraindications

Ryzolt™ is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma, and hypercapnia in unmonitored settings or the absence of resuscitative equipment. Ryzolt™ is also contraindicated in patients with known hypersensitivity to the drug or its ingredients.

Pregnancy Risk Factor C

Precautions

- **Seizures**-seizures have been reported in patients receiving tramadol HCl within the recommended dosage range and postmarketing reports indicate seizure risk is increased with doses above the recommended range. Concomitant use of tramadol HCl increases seizure risk in patients taking: SSRIs, TCAs, MAOIs, neuroleptics, or other drugs that reduces the seizure threshold.
- doses exceeding recommended range alone or in combination with CNS depressants; increased **risk of seizure** and overdose which has resulted in fatalities within one hour of administration
- **increased risk of suicide** in patients with suicidal ideation, suicidal, emotional disturbances
- **increased risk of suicide** in patients who are addiction prone
- **anaphylactoid reactions** including serious and rarely fatal reactions, have been reported, often following the first dose; increased risk in patients with a history of anaphylactoid reactions to codeine or other opioids
- **Physical dependence**, in which case, abrupt discontinuation may induce **withdrawal symptoms**: i.e., anxiety, sweating, nausea, diarrhea, tremors, insomnia
- **abuse, misuse and diversion**- potential for abuse and subject to criminal diversion. Also use with caution in patients with history of drug abuse.
- **Serotonin Syndrome**-the development of a potentially life-threatening serotonin syndrome may occur with the use of tramadol products within the recommended dosage range, particularly with concomitant use of: SSRIs, SNRIs, TCAs, MAOIs, and Triptans, with drugs which impair metabolism of serotonin, and with drugs which impair metabolism of tramadol (CYP2D6 and CYP3A4 inhibitors).
- **CNS depression**- increased risk when used with CNS depressants: alcohol, anesthetic agents, narcotics, phenothiazines, sedative hypnotics, tranquilizers, or other opioids.
- **abdominal conditions**-may complicate clinical assessment of patient with acute abdominal conditions
- **cirrhosis, advanced**- reduced drug metabolism

- **epilepsy, history of seizures, or other risk for seizures** (eg, head trauma, metabolic disorders, alcohol and drug withdrawal, CNS infections); increased risk of seizure
- **geriatric patients** age 75 years and older; higher risk of adverse effects
- **hepatic impairment**, severe; extended-release dose form should not be used due to lack of dosing flexibility. There are no dosing adjustments for patients with mild or moderate hepatic impairment. Ryzolt™ has not been studied in patients with severe hepatic impairment and therefore is not recommended for use in this patient population
- **renal impairment**, severe; extended-release dose form should not be used due to lack of dosing flexibility. There are no dosing adjustments for patients with mild or moderate renal insufficiency. Ryzolt™ has not been studied in patients with severe renal insufficiency and therefore is not recommended for use in this patient population.
- **increased intracranial pressure or head injury**; may result in exaggerated carbon dioxide retention, secondary elevation of cerebrospinal fluid pressure, and miosis obscuring intracranial pathology
- **respiratory depression** risk

Common Adverse Effect

☑ Nausea	☑ Dizziness	☑ Headache
☑ Constipation	☑ Somnolence	

Less Common Adverse effects

☑ Vomiting	☑ Dry mouth	☑ Anorexia	☑ Insomnia
☑ Pruritus	☑ Fatigue	☑ Vertigo	

Drug Interactions

Caution is advised when Ryzolt™ is coadministered with CYP2D6 and CYP3A4 inhibitors, serotonergic drugs, and triptans. Concomitant administration of CYP2D6 and/or CYP3A4 inhibitors, such as quinidine, fluoxetine, paroxetine, amitriptyline (CYP2D6 inhibitors), ketoconazole, and erythromycin (CYP3A4 inhibitors), may reduce metabolic clearance of tramadol, increasing the risk for serious adverse events. Use with carbamazepine is not recommended.

Patient Information

- Use caution in driving, operating machinery, or doing other dangerous activities until you know how Ryzolt™ affects you. Ryzolt™ may impair your mental and physical abilities to perform these tasks.
- Ryzolt™ should not be taken with alcohol-containing beverages.
- Ryzolt™ should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.
- Clinical experience suggests that signs and symptoms of withdrawal may be reduced by tapering medication when discontinuing tramadol therapy.

REFERENCE

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

Appendix E

30 Day Notice to Prior Authorize Aplenzin® (Buproprion Hydrobromide)

Oklahoma Health Care Authority
April 2009

Manufacturer	Biovail Corporation
Classification	Antidepressant
Status	Prescription only

Summary

Aplenzin® (bupropion hydrobromide) received FDA approval in April 2008 and has recently entered the market. Aplenzin® is an aminoketone antidepressant indicated for the treatment of major depressive disorder. This product also carries the black box warning regarding suicidalality associated with all antidepressants.

It is available as 174mg, 348mg, and 522mg film coated extended release tablets. Patients may see a ghost tablet in stools due to the formulation of this medication. The recommended starting dose is 174mg, and should be titrated to the usual target dose of 348mg per day. The 522mg tablets offer one dose for patients needing the maximum recommended dose for bupropion. However, as with other antidepressants, the full antidepressant effect may not be evident until at least 4 weeks of treatment. The 522mg dose should be considered for patients in whom no clinical improvement is shown after several weeks of treatment at 348mg/day.

When switching patients from Wellbutrin®, Wellbutrin SR® or Wellbutrin XL® tablets to Aplenzin®, give the equivalent total daily dose when possible:

- 522 mg bupropion HBr are equivalent to 450 mg bupropion HCl
- 348 mg bupropion HBr are equivalent to 300 mg bupropion HCl
- 174 mg bupropion HBr are equivalent to 150 mg bupropion HCl

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.

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.

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
Blue Color Indicates Supplemental Rebate Participation

Aplenzin® (bupropion hydrobromide) Product Detail

Indications

Treatment of major depressive disorder

Dosage Forms

- 174 mg Aplenzin® extended-release tablets
- 348 mg Aplenzin® extended-release tablets
- 522 mg Aplenzin® extended-release tablets

Pregnancy Risk Factor C

Contraindications

- Patients with seizure disorder
- Patients using other bupropion products, including Zyban®, Wellbutrin®, Wellbutrin® SR, & XL
- Current or prior diagnosis of bulimia or anorexia nervosa
- Abrupt discontinuation of alcohol, sedatives (including benzodiazepines)
- Use of MAO inhibitor; stop at least 2 weeks prior to bupropion use
- Patients allergic to bupropion or any of the ingredients that make up Aplenzin®

Precautions

- **Suicide risk:** Closely monitor high risk patients and all other patients
- Risk of activation of **psychosis and/or mixed/manic episodes**. Screen patients for bipolar disorder. Aplenzin® is not approved for bipolar depression
- **Seizure risk**: Can be minimized by limiting daily dose to 522 mg and slow dose increase. Extreme caution with high risk patients
- **Hepatic impairment**: Use with caution; reduce dose and/or frequency. Severe hepatic cirrhosis: Extreme caution; max. 174 mg/48 hours
- Potential for **hepatotoxicity**
- Risk of restlessness, agitation, anxiety, insomnia; risk of neuropsychiatric events, incl. delusions, hallucinations, psychosis, concentration disturbance, paranoia, confusion
- **Loss of appetite** should be considered if weight loss is a concern
- Risk of anaphylactictoid **reactions**; erythema multiforme, Stevens-Johnson syndrome; risk of arthralgia, myalgia, and fever with rash and other symptoms suggestive of delayed hypersensitivity
- Risk of **severe hypertension**; may require acute treatment. Caution in patients with recent history of MI or unstable heart disease

Common Adverse Effect

Common side effects reported in studies of major depressive disorder include weight loss, loss of appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often.

Less Common Adverse effects

- Leg cramps
- Gastric reflux
- Chills
- Photosensitivity
- Decreased libido
- Rash

Drug Interactions

- CYP2B6 substrates or inhibitors (e.g. cyclophosphamide, orphenadrine, thiotepa), efavirenz, fluvoxamine, norfluoxetine, nelfinavir, paroxetine, ritonavir sertraline: May increase bupropion activity
- Carbamazepine, phenobarbital, phenytoin: May induce bupropion metabolism
- Bupropion may be an inducer of drug metabolizing enzymes
- Drugs metabolized by CYP2D6, e.g. certain antidepressants (e.g., nortriptyline, imipramine, desipramine, paroxetine, fluoxetine, sertraline), antipsychotics (e.g., haloperidol, risperidone, thioridazine), beta-blockers (e.g., metoprolol), and Type 1C antiarrhythmics (e.g., propafenone, flecainide): Consider dose reduction when using with bupropion. Bupropion & hydroxybupropion inhibit CYP2D6
- MAO inhibitors: Increase bupropion toxicity. Contraindicated
- Levodopa, amantadine: Cautious bupropion dosing
- Drugs that lower seizure threshold: Cautious bupropion dosing
- Nicotine transdermal system: Monitor for severe hypertension
- Alcohol: Minimize consumption or avoid

Patient Information

- If you have nausea, take your medicine with food.
- If you have trouble sleeping, do not take your medicine too close to bedtime.
- Do not drink a lot of alcohol while taking Aplenzin®.
- The Aplenzin® tablet is covered by a shell that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet. This is normal. This is the empty shell passing from your body.
- Do not chew, cut, or crush Aplenzin®tablets.
- If you are taking Aplenzin® for the treatment of major depressive disorder, it may take several weeks for you to feel that Aplenzin® is working.

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

Appendix F

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

Oklahoma Health Care Authority
April 2009

Prilosec Suspension™ Summary

Manufacturer AstraZeneca Pharmaceuticals LP
Classification Proton Pump Inhibitor
Status Prescription Only

Prilosec Suspension™ (omeprazole magnesium) is a PPI that suppresses gastric acid secretion by specific inhibition of the (H^+,K^+)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, omeprazole magnesium blocks the final step of acid production. Prilosec Suspension™ is a prescription medicine indicated for the following:

- Treatment of duodenal ulcer in adults
  - 20mg once daily for 4-8 weeks
- Treatment of gastric ulcer in adults
  - 40mg once daily for 4-8 weeks
- Treatment of gastroesophogeal reflux disease (GERD) in pediatric patients and adults
  - 20mg daily for 4 weeks
- Maintenance of healing of erosive esophagitis in pediatric patients and adults
  - 20mg daily for 4-8 weeks
- Treatment of pathological hypersecretory conditions in adults
  - 60mg daily

Prilosec Suspension™ should be administered as follows:

1. Empty the contents of a 2.5 mg packet into a container containing 5 mL of water, or
2. Empty the contents of a 10 mg packet into a container containing 15 mL of water.
3. Stir and leave 2 to 3 minutes to thicken.
4. Drink within 30 minutes.
5. If any material remains after drinking, add more water, stir and drink immediately.

Kapidex™ Summary

Manufacturer Takeda Pharmaceuticals North America, Inc.
Classification Proton Pump Inhibitor
Status Prescription Only

Kapidex™ (dexlansoprazole) received FDA approval in January 2009. Kapidex™ is a prescription medicine indicated for the following:

- Healing for all grades of erosive esophagitis (EE) for up to 8 weeks
  - 60mg once daily
- Maintaining healing of EE for up to 6 months
  - 30mg once daily
- Treating heartburn associated with non-erosive gastroesophogeal reflux disease (GERD) for 4 weeks
  - 30mg once daily

The recommended starting doses are shown above along with the indication. Kapidex™ should be taken whole with or without food. The capsules can be opened and contents sprinkled on one tablespoon applesauce and swallowed immediately. Kapidex™ has not been studied in patients with severe hepatic impairment, but for patients with moderate hepatic impairment (Child-Pugh Class B), a maximum dose of 30mg daily should be considered. No adjustment is necessary for mild hepatic impairment or renal dysfunction.

Dexlansoprazole is a PPI that suppresses gastric acid secretion by specific inhibition of the (H^+,K^+)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, dexlansoprazole blocks the final step of acid production.

The dual delayed release formulation of Kapidex™ results in a dexlansoprazole plasma concentration-time profile with two distinct peaks; the first peak occurs 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours. Dexlansoprazole is extensively metabolized in the liver by oxidation, reduction, and subsequent formation of sulfate, glucuronide and glutathione conjugates to inactive metabolites.

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 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®) capsules	omeprazole/antacid **(Zegerid®)***
	esomeprazole **(Nexium®)***
	pantoprazole **(Protonix®)***
	rabeprazole **(Aciphex®)***

***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

Kapidex™ (dexlansoprazole) Product Detail[i]

Indications

- Healing for all grades of erosive esophagitis (EE) – 60mg once daily for up to 8 weeks
- Maintaining healing of EE – 30mg once daily for up to 6 months
- Treating heartburn associated with non-erosive gastroesophogeal reflux disease (GERD) – 30mg once daily for 4 weeks

Dosage Forms

30 and 60mg delayed release capsules

Pregnancy Risk Factor B

Contraindications

Kapidex™ is contraindicated in patients with known hypersensitivity to any component of the formulation.

Precautions

Symptomatic response with Kapidex™ does not preclude the presence of gastric malignancy.

Common Adverse Effect

- Diarrhea
- Abdominal Pain
- Nausa

Less Common Adverse effects

- Anemia
- Arrhythmias
- Swelling
- Infections
- Dizziness
- Headache

Drug Interactions

Kapidex™ causes inhibition of gastric acid secretion and therefore may interact with drugs that have pH-dependent absorption pharmacokinetics. Kapidex™ is likely to substantially decrease the systemic concentrations of the HIV protease inhibitor atazanavir, which is dependent upon the presence of gastric acid for absorption, and may result in a loss of therapeutic effect of atazanavir and the development of HIV resistance. Therefore, Kapidex™ should not be co-administered with atazanavir. It is theoretically possible that Kapidex™ may interfere with the absorption of other drugs where gastric pH is an important determinant of oral bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole).

There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors and warfarin concomitantly. Patients treated with Kapidex™ and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Patient Information

- Kapidex™may cause diarrhea, stomach pain, nausea, common cold, vomiting, and gas.
- Kapidex™ should be swallowed whole without regard to food. Alternatively, the capsules can be opened and sprinkled onto applesauce.
- If a dose is missed, take it as soon as you remember.

Prilosec Suspension™ (omeprazole) Product Detail[ii]

Indications

Prilosec Suspension™ is a prescription medicine indicated for the following:

- Treatment of duodenal ulcer in adults
  - 20mg once daily for 4-8 weeks
- Treatment of gastric ulcer in adults
  - 40mg once daily for 4-8 weeks
- Treatment of gastroesophogeal reflux disease (GERD) in pediatric patients and adults
  - 20mg daily for 4 weeks
- Maintenance of healing of erosive esophagitis in pediatric patients and adults
  - 20mg daily for 4-8 weeks
- Treatment of pathological hypersecretory conditions in adults
  - 60mg daily

After oral administration, the onset of the antisecretory effect of omeprazole occurs within one hour, with the maximum effect occurring within two hours**.** Based on a relative bioavailability study, the AUC and Cmax of Prilosec (omeprazole magnesium) for Delayed-Release Oral Suspension™ were 87% and 88% of those for Prilosec® Delayed-Release Capsules, respectively. Omeprazole is extensively metabolized by the cytochrome P450 (CYP) enzyme system.

Special Populations

The safety and effectiveness of Prilosec® for the treatment of GERD in patients <1 year of age have not been established. Consider dose reduction, particularly for maintenance of healing of erosive esophagitis in patients with hepatic impairment. No adjustment is necessary for renal dysfunction.

Dosage Forms

2.5 or 10mg unit dose packets

Pregnancy Risk Factor C

Contraindications

Prilosec Delayed-Release Suspension™ is contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticaria.

Precautions

- Symptomatic response with Prilosec Suspension™ does not preclude the presence of gastric malignancy.
- Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Common Adverse Effect

- Headache
- Abdominal Pain
- Nausa

- Diarrhea
- Vomiting
- Flatulance

Less Common Adverse effects

- Acid regurgitation
- Upper respiratory infections
- Constipation
- Rash
- Dizziness
- Asthenia
- Back pain
- Cough

Drug Interactions

Because of its profound and long lasting inhibition of gastric acid secretion, it is theoretically possible that omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters, and iron salts). In the clinical trials, antacids were used concomitantly with the administration of Prilosec®.

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including omeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin may need to be monitored for increases in INR and prothrombin time.

Although in normal subjects no interaction with theophylline or propranolol was found, there have been clinical reports of interaction with other drugs metabolized via the cytochrome P450 system (e.g., cyclosporine, disulfiram, benzodiazepines). Patients should be monitored to determine if it is necessary to adjust the dosage of these drugs when taken concomitantly with Prilosec®.

Patient Information

- Prilosec Suspension™ should be taken before eating.
- Before taking, the packets should be mixed according to the directions above.

REFERENCES

[i] **Kapidex(™)** Prescribing Information. Takeda Pharmaceuticals, Inc. Accessed at: http://www.kapidex.com/pi.aspx.

[ii] **Prilosec(™)** Prescribing Information. AstraZeneca Pharmaceuticals. Accessed at: http://www.fda.gov/cder/foi/label/2008/022056s001019810s087lbl.pdf

Appendix G

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

Oklahoma HealthCare Authority, April 2009

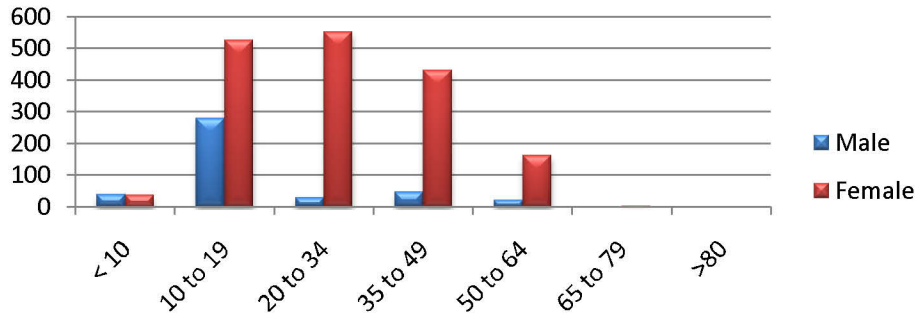
This category was introduced for possible inclusion in the Product Based Prior Authorization program in March 2009. See the March DUR packet for a more complete discussion of the category. This notice and statement of potential economic impact are presented to meet the statutory requirements of 63 O.S.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

Summary of Paid Claims – July 2008 through December 2008

RANK COST	GENERIC NAME	CLAIMS	UNITS	DAYS	MEMBERS	UNITS/ DAY	CLAIMS/ MEMBER
1	Sumatriptan **(Imitrex®)**	2,253	23,011	31,520	1,100	0.73	2.05
2	Rizatriptan **(Maxalt®, Maxalt MLT®)**	1,155	10,366	14,003	540	0.74	2.14
3	Eletriptan **(Relpax®)**	541	4,540	7,021	263	0.65	2.06
4	Zolmitriptan **(Zomig®, Zomig ZMT®)**	528	3,459	6,205	228	0.56	2.32
5	Sumatriptan-Naproxen **(Treximet®)**	335	3,322	4,821	180	0.69	1.86
6	Frovatriptan **(Frova®)**	209	1,629	2,703	111	0.6	1.88
7	Almotriptan **(Axert®)**	104	927	1,409	40	0.66	2.60
8	Naratriptan **(Amerge®)**	28	234	426	14	0.55	2.00
		5,153	**47,488**	**68,108**		**0.70**	**2.21**

Member Demographics

There were 2,191 members utilizing these medications during this time period. A total of 56 were categorized as Advantage Waiver and 41 were in nursing homes.

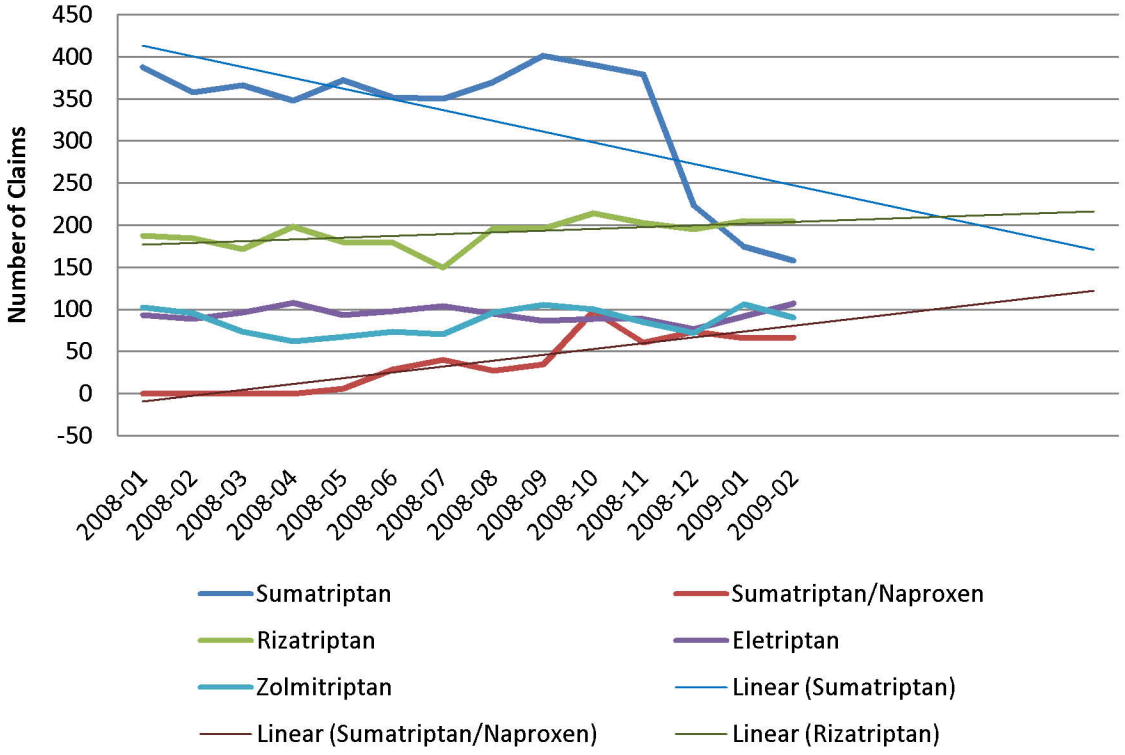


Market Analysis

Two manufacturers of sumatriptan generic were issued 180 day exclusivity rights on February 9, 2009. Rizatriptan has an anticipated product patent expiration date of June 2012. The following table shows the number of claims in February 2008 versus February 2009 and the percent change in market share.

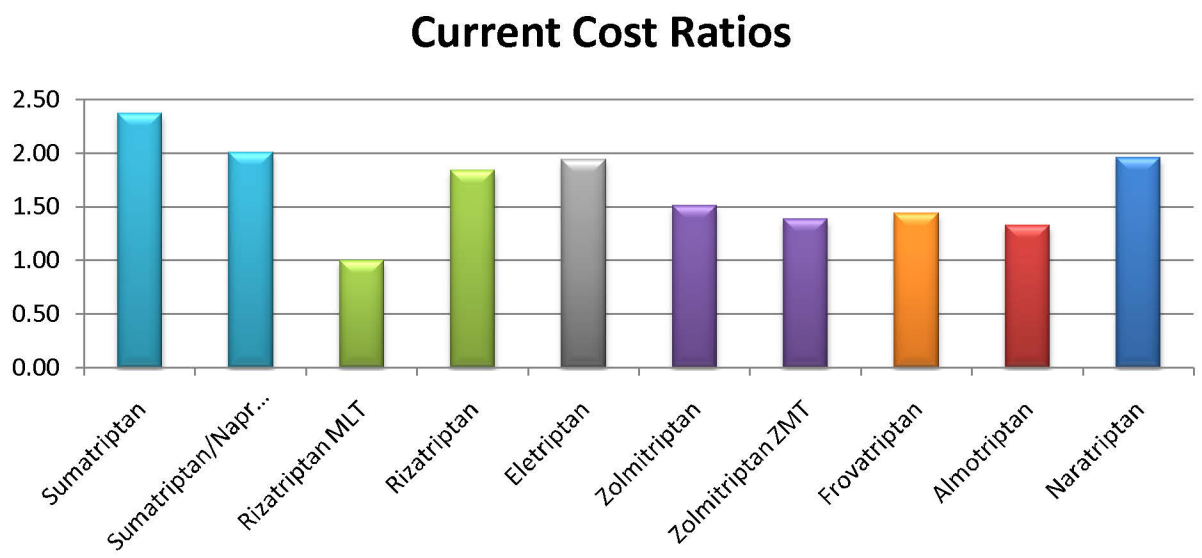
	Feb-08		Feb-09		Change
Product	**Claims**	**Percent**	**Claims**	**Percent**	**Percent**
Sumatriptan (Imitrex®)	372	47%	167	24%	↓49%
Sumatriptan/Naproxen (Treximet®)	0	0	67	10%	↑100%
Rizatriptan (Maxalt®, Maxalt MLT®)	170	22%	204	30%	↑36%
Zolmitriptan (Zomig®, Zomig ZMT®)	93	12%	90	13%	↑8%
Eletriptan (Relpax®)	87	11%	107	16%	↑5%
Frovatriptan (Frova®)	42	5%	35	5%	0
Almotriptan (Axert®)	17	2%	10	2%	0
Naratriptan (Amerge®)	5	1%	8	1%	0
Total	786	100%	688	100%	N/A

The trend in claims over the past fourteen months for the top four products (plus the new combination product) is shown below. There appears to have been a sharp decline in sumatriptan claims beginning in December 2008 with a rise in the number of sumatriptan/naproxen claims as well as an increase in rizatriptan and a small increase in zolmitriptan and eletriptan.

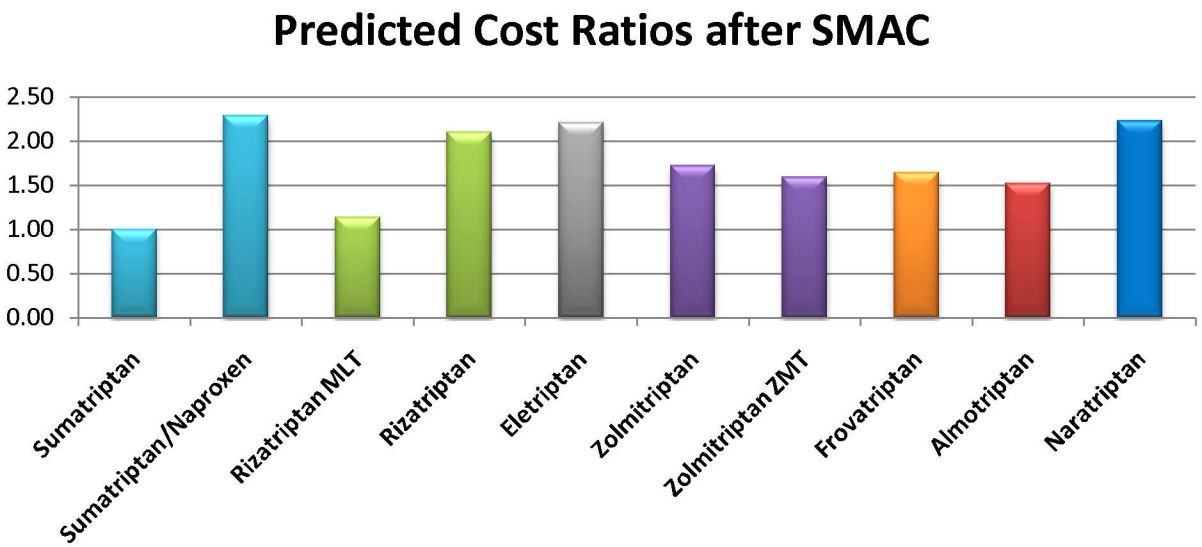


The following graphs show the ratios of the net unit costs (reimbursement – federal rebate). The lowest net unit cost is a 1:1 ratio and is reflected as a 1.00 on the graph. The other bars indicate the ratio of each product's net unit cost to the product with the lowest net unit cost. The ratios do not reflect actual dollar amounts but provide a visual comparison of the net unit cost of each product to the lowest net unit cost.

The first graph is a ratio of the current net unit costs. At this time, all sumatriptan products have higher net unit costs than all other products which are available.



Since only two manufacturers have approved sumatriptan generic products at this time, with market exclusivity periods of 180 days, the net unit cost of generic sumatriptan is high. However, the cost is expected to decrease rapidly at the end of the exclusivity period. According to the FDA website, there are at least four other manufacturers with tentative approval. It is expected that the cost of the generic will be approximately 25% of the current AWP of branded sumatriptan within one year. The graph below predicts the cost ratio one year from now, after the SMAC has been applied.



Recommendations:

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.

Additionally, 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

Potential Secondary Costs

Overall efficacy is considered to be equal across this class, but drug selection requires individual patient history which includes, but is not limited to: other illnesses, disease risk factors, and current symptoms.

Potential Administrative Costs

Based on a potential shift of proposed Tier 3 products to a Tier 1 product of 60%, it is estimated that approximately 1200 petitions would be required. The proposed tier changes would affect approximately 50% of the total population for this PBPA category.

Previously, it has been theorized that total cost per petition to the *healthcare system* (includes cost to physicians, pharmacists, and program) is between $7.63 and $14.82. Total cost for prior authorization to the *healthcare system* is estimated to be between $9,156 and $17,784 annually. Anticipated actual administrative cost to the program is projected to be less than $3,000.

Potential Program Savings

Potential net ingredient savings to the program based on recommended tiers and a potential shift of 60% of market share from Tier 3 to Tier 1 is estimated to be 42 % of the 2008 total reimbursement to pharmacies for this category of drugs. This includes the projected SMAC for the new generic product.

Appendix H

Information for Healthcare Professionals
Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

The current instructions for use for all insulin pens already state that the pens are not to be shared among patients. The FDA reminds healthcare providers, healthcare facilities, and patients that each insulin pen (and each insulin pen cartridge) is designed for single-patient use only and is never to be shared among patients. Insulin pens are not designed, and are not safe, for one pen to be used for more than one patient, even if needles are changed between patients because any blood contamination of the pen reservoir could result in transmission of already existing blood-borne pathogens from the previous user. The FDA is working with the Centers for Disease Control and Prevention (CDC), professional societies and healthcare organizations to reinforce patient and healthcare provider education about proper and safe use of insulin pens.

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

To report any unexpected adverse or serious events associated with the use of insulin pens or insulin cartridges, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178,

by mail using the postage-paid address form provided online, or by telephone to 1-800-FDA-1088.

*Insulin pens are pen-shaped injector devices for insulin that are intended for use by a single patient. The pens have an insulin reservoir, or an insulin cartridge, that usually contains enough insulin for a patient to self-administer several doses (injections) of insulin before the reservoir or cartridge is empty. The patient changes the needle before each insulin injection. Insulin pens are designed to be safe for one patient to use one pen multiple times, with a new, fresh needle for each injection.

Recommendations and Information for Healthcare Professionals Regarding Insulin Pens and Insulin Cartridges, and other reusable injector devices:

- Insulin pens containing multiple doses of insulin are meant for use **by a single patient only,** and are not to be shared between patients.
- Identifying the insulin pen with the **name of the patient and other patient identifiers** provides a mechanism for verifying that the correct pen is used on the correct patient, and can help minimize medication errors. Ensure the identifying patient information does not obstruct the dosing window or other product information such as the product name and strength.
- Be aware that the likelihood of sharing insulin pens and cartridges is increased when the pens are not marked with the patient name or other patient identifiers.
- The disposable needle should be ejected from the insulin pen and properly discarded after each injection. A new needle should be attached to the insulin pen before each new injection.
- Although the incident leading to this FDA alert occurred with insulin pens, the same risk may exist with shared use of any reusable injection device.
- Hospitals and other healthcare facilities should review their policies and educate their staff regarding safe use of insulin pens.

Information for Healthcare Professionals to Provide When Counseling Patients:

- Patients should be instructed that insulin pens containing multiple doses are meant for use **by a single patient only.**
- Patients should be instructed to never share their insulin pen with another person.
- Patients should be advised that sharing of their insulin pens could result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

Background Information

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/), and in a smaller number of patients in at least one other hospital. At these hospitals, the same insulin pens may have been used for multiple patients, although the disposable needles were reportedly changed for each patient. Because each of these devices can result in blood contamination of the pen reservoir or cartridge, even if the needle is changed before each use, patients who were treated with insulin pens at

the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

The current instructions for use of insulin pens already state that the pens are not to be shared among patients. The FDA reminds healthcare providers and patients that insulin pens and insulin cartridges are never to be shared among patients. Pathogenic contaminants can enter the cartridge after injection while the needle is still attached to the pen. Thus, insulin pens are not safe for use in multiple patients because of the risk of cross-contamination. The FDA is working with the Centers for Disease Control and Prevention (CDC), professional societies and healthcare organizations to determine if further actions or communications are needed.

How to Report Side Effects and Medication Errors

The FDA urges both healthcare professionals and patients to report side effects and medication errors from the use of insulin, insulin pens and insulin cartridges to the FDA's MedWatch Adverse Event Reporting program available:

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

Reference

1. *ISMP Medication Safety Alert! Acute Care*, Institute for Safe Medication Practices (ISMP). February 12, 2009, Vol. 14, Issue 3.

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Date created: March 19, 2009

FDA Public Health Advisory
Risk of Burns during MRI Scans from Transdermal Drug Patches with Metallic Backings

The FDA has been made aware of information about certain transdermal patches (medicated patches applied to the skin) that contain aluminum or other metals in the backing of the patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch.

Transdermal patches slowly deliver medicines through the skin. Some patches contain metal in the layer of the patch that is not in contact with the skin (the backing). The metal in the backing of these patches may not be visible. The labeling for most of the medicated patches that contain metal in the backing provides a warning to patients about the risk of burns if the patch is not removed before an MRI scan. However, not all transdermal patches that contain metal have this warning for patients in the labeling.

FDA is in the process of reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning about the risk of burns to patients who wear the patches during an MRI scan.

Until this review is complete, FDA recommends that healthcare professionals referring patients to have an MRI scan identify those patients who are wearing a patch before the patients have the MRI scan. The healthcare professional should advise these patients about the procedures for removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan. MRI facilities should follow published safe practice recommendations concerning patients who are wearing patches.[1,2]

Until this safety issue is resolved, FDA recommends that patients who use medicated patches (including nicotine patches) do the following:

- Tell the doctor referring you for an MRI scan that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones)
- Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure.

- Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

The FDA urges health care professionals and patients to report possible cases of skin burns while wearing patches during an MRI to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at http://www.fda.gov/medwatch/index.html.

(1) Kanal, et. al, "ACR Guidance Document for Safe MR Practices: 2007," AJR 2007; 188:1–27.
(2) Guidelines for Screening Patients For MR Procedures and Individuals for the MR Environment, Institute for Magnetic Resonance Safety, Education, and Research, www.imrser.org, 2009.

Update: (03/9/2009) FDA has evaluated the composition of available patches to determine which of them contain metal components and to assure that this information is included in their labeling. Based on current information from this evaluation, FDA is working with the manufacturers of the following patches to update the labeling to include adequate warnings to patients about the risk of burns to the skin if the patch is worn during an MRI scan. It should be noted that some of the drugs listed may have a generic equivalent and more than one size and strength of patch. FDA will update this posting as information becomes available.

Proprietary Name	Generic/Established Name
Catapres TTS	Clonidine
Neupro	Rotigotine
Lidopel	Lidocaine HCl and epinephrine
Synera	Lidocaine/Tetracaine
Transderm-Scop	Scopolamine
Prostep	Nicotine transdermal system
Habitrol	Nicotine transdermal system
Nicotrol TD	Nicotine transdermal system
Androderm	Testosterone transdermal system
Fentanyl	Fentanyl
Salonpas Power Plus	Methyl Salicylate/Menthol

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PDF requires the free Adobe Acrobat Reader

Date created: March 5, 2009 Updated: March 10, 2009