Drug Utilization Review Board

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1A
Oklahoma City, Oklahoma 73107
Ponca Room

Wednesday
July 10, 2013
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: Chris Le, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – July 10, 2013**

DATE: July 10, 2013

NOTE: The DUR Board will meet at 6:00 p.m. The meeting will be held in the Ponca Room at the Oklahoma Health Care Authority Offices in Shepherd Mall. (North Entrance)

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.

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

Action Item – Vote to Prior Authorize Oxtellar XR™ and Sabril® – See Appendix C.

Action Item – Vote to Prior Authorize Aubagio® and Tecfidera™ – See Appendix D.

Action Item – Annual Review of Topical Corticosteroids – See Appendix E.

30 Day Notice to Prior Authorize Fulyzaq™ – See Appendix F.

30 Day Notice to Prior Authorize Vecamyl™ – See Appendix G.

Action Item – Opioid Prescribing Initiative for Appropriate Treatment & Education – See Appendix H.

Presentation of Singulair® PA in the SoonerCare Population- Slides Only

Action Item – Annual Review of Uloric® and Colcrys® – See Appendix I.

FDA and DEA Updates – See Appendix J.

Future Business

Adjournment

Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting – July 10, 2013 @ 6:00 p.m.

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1-A
Oklahoma City, Oklahoma 73107
Ponca Room (North Entrance)

AGENDA
Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call To Order**
   A. Roll Call – Dr. Cothran

Items to be presented by Dr. Muchmore, Chairman:

2. **Public Comment Forum**
   A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.**
   A. June 12, 2013 DUR Minutes – Vote
   B. June 13, 2013 DUR Recommendation Memorandum

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

4. **Update on DUR / Medication Coverage Authorization Unit – See Appendix B.**
   A. Medication Coverage Activity for June 2013
   B. Pharmacy Help Desk Activity for June 2013
   C. Retrospective Drug Evaluation: Focusing on Safety

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

5. **Action Item – Vote to Prior Authorize Oxtellar XR™ and Sabril® – See Appendix C.**
   A. COP Recommendations

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

6. **Action Item – Vote to Prior Authorize Aubagio® and Tecfidera™ – See Appendix D.**
   A. COP Recommendations

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

7. **Action Item – Annual Review of Topical Corticosteroids – See Appendix E.**
   A. Current Authorization Criteria
   B. Utilization Review
   C. Prior Authorization Review
   D. Market News and Updates
   E. COP Recommendations
   F. Utilization Details

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

8. 30 Day Notice to Prior Authorize Fulyzaq™ – See Appendix F.

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

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

9. 30 Day Notice to Prior Authorize Vecamyl™ – See Appendix G.

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

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

10. Action Item – Opioid Prescribing Initiative for Appropriate Treatment & Education – See Appendix H.

A. Survey Responses
B. COP Recommendations

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

11. Presentation of Singulair® PA in the SoonerCare Population – Slides Only

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

12. Action Item – Annual Review of Uloric® and Colcrys® – See Appendix I.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorization Review
D. Market News and Update
E. COP Recommendations

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

13. FDA and DEA Updates – See Appendix J.

14. Future Business

A. Annual Reviews
B. New Product Reviews

15. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING OF JUNE 12, 2013

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.		X
Anetta Harrell, Pharm.D.	X	
Evie Knisely, Pharm.D.		X
Thomas Kuhls, M.D.	X	
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.	X	
Bruna Varalli-Claypool, MHS, PA-C	X	
Eric Winegardener, D.Ph.		X

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison		X
Shellie Keast, Ph.D.; Clinical Assistant Professor		X
Bethany Holderread, Pharm. D.; Clinical Pharmacist	X	
Chris Le, Pharm.D.; Assisant Director	X	
Mark Livesay, Operations Manager	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator		X
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Jo'Nel Weber, Pharm.D.; Clinical Pharmacist		X
Graduate Students: Manish Mittal		X
Visiting Pharmacy Student(s): Roy Yarbrough, Clay Faison, Kori Hamman	X	

	PRESENT	ABSENT
Nico Gomez, Chief Executive Officer		X
Marlene Asmussen, R.N., Population Care Management Director	X	
Garth Splinter, M.D., M.B.A.; Medicaid Director	X	
Sylvia Lopez, M.D., FAAP, Chief Medical Officer	X	
Rebecca Pasternik-Ikard, Deputy State Medicaid Director	X	
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Lynn Rambo-Jones, J.D.; Deputy General Counsel III	X	
Alison Martinez, Ph.D., Geneticist		X
Jennie Melendez, Public Affairs-Information Representative	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	
Stacey Hale, Drug Rebate Manager	X	

OTHERS PRESENT:		
Bob Gustafson,Lundbeck	Dennis Jacobsen, Genzyme	Brian Maves, Pfizer
Jim Fowler, AstraZeneca	Mark DeClerk, Lilly	Phillip Kenner, Acc
Bob Atkins, Biogen Idec	Randy Huetsch, Aegerion	Deron Grothe, Teva
Janie Huff, Takeda	Sharon Jackson, GSK	Tone' Jones, Sunovion
Clint Degner, Novartis	Warren Tayes, Merck	Richard Ponder, J & J
Jon Maguire, GSK	Jim Chapman, AbbVie	Charlene Kaiser, Amgen
Ben Liniger, Alcon		

PRESENT FOR PUBLIC COMMENT:	
Maria Barr	Amgen
Heather Handl	Biogen
Brent Day	Biogen
Mai Duong	Novartis

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

1A: Roll Call

Dr. Muchmore called the meeting to order. Roll call by Dr. Cothran established the presence of a quorum.

ACTION: NONE REQUIRED

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

Agenda Item: No 7 — Maria Barr
Agenda Item: No 9 — Heather Handl
Agenda Item: No 9 — Brent Day
Agenda Item: No 9 — Mai Duong

ACTION: NONE REQUIRED

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

3A: April 10, 2013 DUR Minutes

3B: April 10, 2013 DUR Recommendation Memorandum

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

ACTION: MOTION CARRIED

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

4A: Medication Coverage Activity: April & May 2013

4B: Pharmacy Help Desk Activity: April & May 2013

4C: Retrospective Drug Evaluation: Duplication of Narcotic Therapy

Materials included in agenda packet; presented by Dr. Le

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE KYNAMRO™ (MIPOMERSEN)**

5A: COP Recommendations

Materials included in agenda packet; presented by Dr. Le

Dr. Harrell moved to approve; seconded by Dr. Bell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **FY2012 ANNUAL REVIEW OF ANTICONVULSANT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OXTELLAR XR™ (OXCARBAZEPINE ER) AND SABRIL® (VIGABATRIN)**

6A: CURRENT AUTHORIZATION CRITERIA

6B: UTILIZATION REVIEW

6C: PRIOR AUTHORIZATION REVIEW

6D: MARKET NEWS AND UPDATES
6E: OXTELLAR XR™, FYCOMPA™, AND SABRIL® PRODUCT SUMMARIES
6F: COP RECOMMENDATIONS
6G: UTILIZATION DETAILS
6H: OXTELLAR XR™, FYCOMPA™, SABRIL®, PRODUCT DETAILS
Materials included in agenda packet; presented by Dr. Holderread
Dr. Kuhls recommended that criteria should read as "prior authorization for all members, FDA approved diagnosis, and by a neurologist in the shared program"... "Quantity limits for the older ones not so sure for the pediatric patients."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: CALENDAR YEAR 2012 ANNUAL REVIEW OF BIOLOGIC PRODUCTS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS, CROHN'S DISEASE, PLAQUE PSORIASIS AND ANKYLOSING SPONDYLITIS
7A: CURRENT AUTHORIZATION CRITERIA
7B: UTILIZATION REVIEW
7C: PRIOR AUTHORIZATION REVIEW
7D: MARKET NEWS AND UPDATES
7E: COP RECOMMENDATIONS
7F: UTILIZATION DETAILS
Materials included in agenda packet; presented by Dr. Holderread
Dr. Muchmore recommends ... "You're going to get us some more information on the Tysabri."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: CALENDAR YEAR 2012 ANNUAL REVIEW OF TESTOSTERONE PRODUCTS
8A: CURRENT AUTHORIZATION CRITERIA
8B: UTILIZATION REVIEW
8C: PRIOR AUTHORIZATION REVIEW
8D: MARKET NEWS AND UPDATES
8E: COP RECOMMENDATIONS
8F: UTILIZATION DETAILS
Materials included in agenda packet; presented Dr. Adams
Dr. Kuhls moved to approve; second by Ms. Varralli-Claypool
Dr. Muchmore recommends that the word "or" be replaced by "and" & "gonadotropin's assays" and "morning testosterone" be added to the criteria.
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: CALENDAR YEAR 2012 ANNUAL REVIEW OF MULTIPLE SCLEROSIS MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE AUBAGIO® (TERIFLUNOMIDE) AND TECFIDERA™ (DIMETHYL FUMARATE)
9A: CURRENT AUTHORIZATION CRITERIA
9B: UTILIZATION REVIEW
9C: PRIOR AUTHORIZATION REVIEW
9D: MARKET NEWS AND UPDATES
9E: COP RECOMMENDATIONS
9F: TECIFIDERA™ PRODUCT DETAILS
Materials included in agenda packet; presented by Dr. Le.
Dr. Muchmore recommends that "verification of lab test with acceptable values and the person who is qualified to prescribe these items has found them acceptable." Dr. Kuhls recommends that the word "No" be removed from "no bone marrow suppression and no liver injury or failure."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: CALENDAR YEAR 2012 ANNUAL REVIEW OF LEUKOTRIENE MODIFIERS: SINGULAIR® (MONTELUKAST) AND ZYFLO CR® (ZILEUTON)
10A: CURRENT AUTHORIZATION CRITERIA
10B: UTILIZATION REVIEW
10C: PRIOR AUTHORIZATION REVIEW

10D: MARKET NEWS AND UPDATES
10E: COP RECOMMENDATIONS
10F: UTILIZATION DETAILS
Materials included in agenda packet; presented by Dr. Le
Dr. Kuhls recommends that "remove PA for adults with asthma."
Ms. Varalli-Claypool moved to approve; seconded by Dr. Preslar
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: CALENDAR YEAR 2012 ANNUAL REVIEW OF HORIZANT® AND GRALISE™ (GABAPENTIN EXTENDED RELEASE)
11A: CURRENT AUTHORIZATION CRITERIA
11B: UTILIZATION REVIEW
11C: PRIOR AUTHORIZATION REVIEW
11D: MARKET NEWS AND UPDATES
11E: COP RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Le
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: FDA AND DEA UPDATES
Materials included in agenda packet; presented by Dr. Cothran.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: FUTURE BUSINESS
Materials included in agenda packet; submitted by Dr. Cothran
12A: SAFETY REVIEWS
12B: NARCOTIC PRESCRIBER SURVEY RESULTS
12C: NEW PRODUCT REVIEWS
12D: ANNUAL REVIEWS
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ADJOURNMENT
The meeting was adjourned at 7:32pm

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

Memorandum

Date: June 13, 2013

To: Nancy Nesser, Pharm.D., J.D.
Pharmacy Director
Oklahoma Health Care Authority

From: Chris Le, Pharm.D.
Assistant Director
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of June 12, 2013

Recommendation 1: Vote to Prior Authorize Kynamro™ (Mipomersen)

MOTION CARRIED by unanimous approval.

The College of pharmacy recommends prior authorization of Kynamro™ (mipomersen) with the following criteria:

Prior Authorization Criteria for Kynamro™ (Mipomersen):

1. FDA approved diagnosis of homozygous familial hypercholesterolemia defined by the presence of at least one of the following criteria:
    a. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
    b. Untreated total cholesterol >500 mg/dL and triglycerides <300 mg/dL *and*
        i. both parents with documented untreated total cholesterol >250 mg/dL; or
        ii. presence of tendinous /cutaneous xanthoma prior to age 10 years.
1. Documented failure of high dose statin therapy (LDL reduction capability equivalent to atorvastatin 80mg or higher); and
2. Prescriber must be certified with Kynamro™ REMS program.

Recommendation 2: Annual Review of Anticonvulsant Medications and 30 Day Notice to Prior Authorize Oxtellar XR™ (Oxcarbazepine ER) and Sabril® (Vigabatrin)

NO ACTION REQUIRED.

Recommendation 3: Annual Review of Biologic Products for the Treatment of Rheumatoid Arthritis, Crohn's Disease, Plaque Psoriasis, and Ankylosing Spondylitis

NO ACTION REQUIRED.

Recommendation 4: Calendar Year 2012 Annual Review of Testosterone Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of the Testosterone class of medications to the Product Based Prior Authorization program. The following tier-1 drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Healthcare Authority. The following is the proposed tier list and approval criteria.

Testosterone Products

Tier-1	Tier-2	Special PA
Methyltestosterone powder	Testosterone patch (**Androderm®**)	Fluoxymesterone oral tablet (**Androxy®**)
Testosterone cypionate injection (**Depo-Testosterone®**)	Testosterone topical gel (**Androgel 1.62%, Fortesta®**)	Methyltestosterone oral tablet/capsule (**Android®, Methitest®, Testred®**)
Testosterone enanthate injection	Testosterone topical solution (**Axiron®**)	Testosterone buccal tablet (**Striant®**)
Testosterone topical gel (**Androgel® 1%, Testim®**)		

*Brand products are subject to the Brand Name Override where generics are available

All testosterone replacement products will require a prior authorization with the following approval criteria:

1. FDA approved diagnosis:
   a) Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, orchidectomy/orchiectomy; or
   b) Idiopathic gonadotropin or luteinizing-hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation ; or
   c) Delayed puberty; or
   d) Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal women with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and

2. Must include two labs showing pre-medication morning testosterone levels below 300ng/dL and one lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis

Tier-2 Prior Authorization Criteria:

1. A trial of at least two tier-1 products (must include at least one injectable and one topical formulation) at least 12 weeks in duration, or
2. A patient-specific, clinically significant reason why member cannot use all available tier-1 medications, or
3. Prior stabilization on a tier-2 medication (within the past 180 days)
4. Approval will be for one year

Special Prior Authorization Criteria:

1. Must provide a patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone
2. Approval will be for one year

Recommendation 5: Calendar Year 2012 Annual Review of Multiple Sclerosis Medications and 30 Day Notice to Prior Authorize Aubagio® (Teriflunomide) and Tecfidera™ (Dimethy Fumarate)

NO ACTION REQUIRED.

The DUR Board requested a review of Tysabri® (natalizumab)

Recommendation 6: Calendar Year 2012 Annual Review of Leukotriene Modifiers: Singulair® (Montelukast) and Zyflo CR® (Zileuton)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the removal of the prior authorization on all formulations of Singulair®, except the granules, for pediatric SoonerCare members aged 0-20. ~~The asthma prior authorization criteria will remain effective for adult members aged 21 and above.~~ The prior authorization will be removed for adult members with a diagnosis of asthma in claims history. The College of Pharmacy recommends the following changes to the allergic rhinitis criteria:

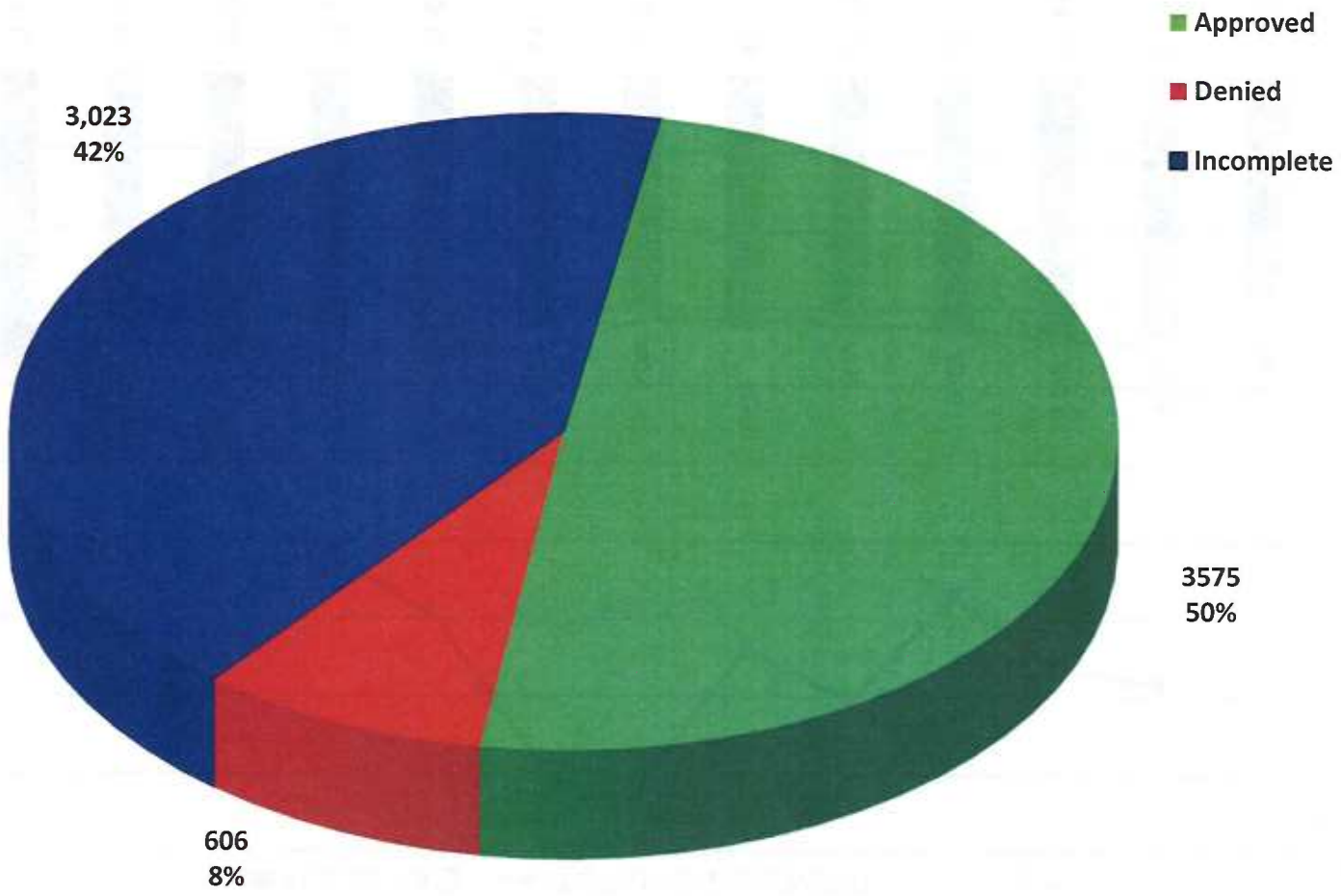
For members 21 years of age or older – Recent trial of an oral antihistamine, 14 days in duration, that has failed to relieve allergic rhinitis symptoms.

Recommendation 7: Calendar Year 2012 Annual Review of Horizant® and Gralise™ (Gabapentin Extended Release)

NO ACTION REQUIRED.

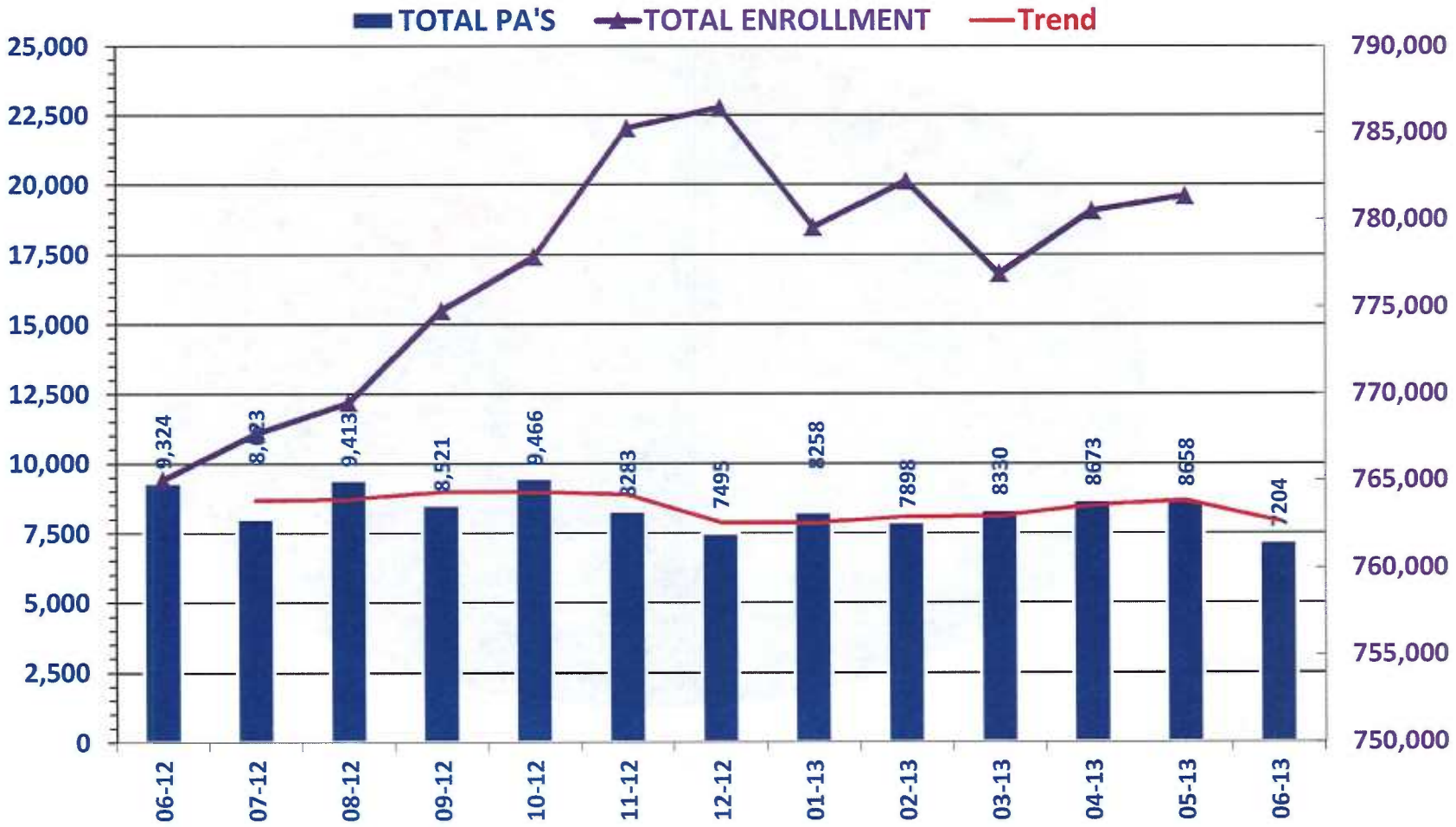
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2013



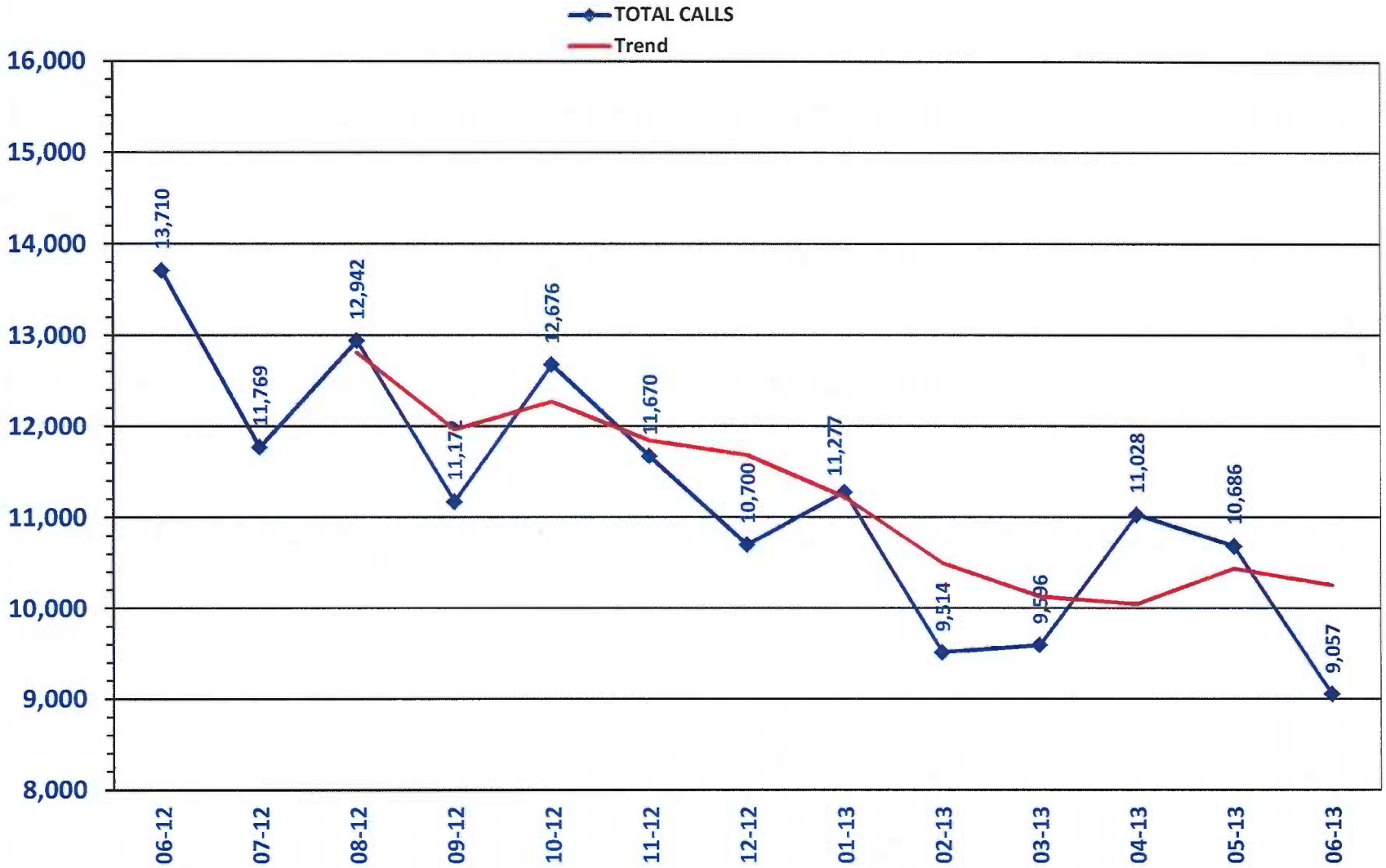
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2012- JUNE 2013



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JUNE 2012-JUNE 2013



Prior Authorization Activity
6/1/2013 Through 6/30/2013

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	350	153	10	187	352
Analgesic, Narcotic	365	163	27	175	244
Angiotensin Receptor Antagonist	51	5	4	42	359
Antiasthma	701	403	20	278	216
Antibiotic	34	7	1	26	20
Anticoagulant	53	33	2	18	290
Anticonvulsant	68	24	1	43	325
Antidepressant	242	73	18	151	334
Antidiabetic	119	47	7	65	342
Antihistamine	173	123	7	43	348
Antihyperlipidemic	37	10	5	22	359
Antimigraine	50	17	6	27	318
Antiplatelet	17	10	1	6	356
Antiulcers	243	63	53	127	173
Anxiolytic	84	62	1	21	212
Atypical Antipsychotics	374	232	7	135	339
Benign Prostatic Hypertrophy	19	1	9	9	360
Biologics	42	27	0	15	302
Bladder Control	61	8	7	46	358
Botox	41	29	6	6	382
Cardiovascular	32	19	2	11	337
Dermatological	142	26	54	62	98
Endocrine & Metabolic Drugs	160	81	8	71	249
Erythropoietin Stimulating Agents	43	21	1	21	114
Fibromyalgia	151	41	19	91	340
Gastrointestinal Agents	94	30	14	50	118
Genitourinary Agents	16	3	2	11	61
Glaucoma	11	5	0	6	256
Growth Hormones	68	55	4	9	155
HFA Rescue Inhalers	60	16	6	38	342
Insomnia	52	10	6	36	211
Multiple Sclerosis	34	17	0	17	241
Muscle Relaxant	101	24	33	44	59
Nasal Allergy	120	10	28	82	144
Neurological Agents	60	41	5	14	355
NSAIDS	138	15	26	97	286
Ocular Allergy	71	19	10	42	115
Ophthalmic	33	7	3	23	57
Osteoporosis	18	6	2	10	357
Other*	164	27	11	126	153
Otic Antibiotic	48	16	1	31	30
Pediculicide	117	45	7	65	15
Smoking Cess.	10	3	1	6	88
Statins	58	19	6	33	359
Stimulant	458	311	14	133	333
Suboxone/Subutex	172	125	4	43	73
Topical Antibiotic	22	2	1	19	47
Topical Antifungal	65	4	23	38	77
Topical Corticosteroids	57	2	14	41	192
Vitamin	59	16	36	7	359
Pharmacotherapy	221	143	4	74	160
Emergency PAs	4	4	0	0	
Total	**5,983**	**2,653**	**537**	**2,793**	

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	50	37	2	11	305
Dosage Change	305	286	4	15	6
High Dose	1	1	0	0	360
Ingredient Duplication	12	10	0	2	3
Lost/Broken Rx	115	103	7	5	5
NDC vs Age	6	6	0	0	135
Nursing Home Issue	49	49	0	0	12
Other	16	10	5	1	3
Quantity vs. Days Supply	599	390	37	172	255
Stolen	5	3	2	0	4
Temporary Unlock	24	14	6	4	19
Third Brand Request	39	13	6	20	40
Overrides Total	**1,221**	**922**	**69**	**230**	
Total Regular PAs + Overrides	**7,204**	**3,575**	**606**	**3,023**	

Denial Reasons	
Unable to verify required trials.	2,343
Lack required information to process request.	665
Does not meet established criteria.	619

Other PA Activity	
Duplicate Requests	400
Letters	2,881
No Process	214
Changes to existing PAs	462
Partials	782

* Includes any therapeutic category with less than 10 prior authorizations for the month.

Retrospective Drug Evaluations: Focusing on Safety

1. Valproate Utilization in Pregnant Female Members for Migraine
2. Overview of FDA Safety Alerts

Valproate Utilization in Pregnant Female Members for Migraine

Oklahoma Health Care Authority
July 2013

Background[i]

On May 6, 2013, the FDA issued a Drug Safety Communication recommending that pregnant women should not take valproate sodium and related products, valproic acid and divalproex sodium, for prevention of migraine because of increased risk of lower IQ scores of the children born to these women. This contraindication will be added to the label and the drug's pregnancy category designation will be changed from "D" to "X" for this indication. Pregnant women with epilepsy or bipolar disorder should only be prescribed these products if other medications are not effective or are otherwise unacceptable. The pregnancy category will remain "D" for these indications.

Previous warnings have been issued regarding the use of valproate during pregnancy resulting in an increased risk of autism, developmental delay, and congenital malformations. Therefore, the FDA reiterates its recommendations that women of childbearing age who are not pregnant should not take these mediations for any diagnosis unless they are essential to the management of the woman's condition. Non-pregnant women who are prescribed valproate products should use effective contraception. Women who become pregnant while on a valproate product should remain on it to avoid serious medical problems.

Valproate Utilization in the Female SoonerCare Population CY 2012

Evaluation of females with paid claims for valproate products and diagnosis codes for migraine headaches during CY2012 revealed 17 women with these indicators. Two members received divalproex during pregnancy. One of these members had the additional diagnosis of epilepsy. Both had the divalproex claims in the first trimester of their pregnancies, one had only one more fill after pregnancy was determined, the other did not receive prenatal care until the 3rd trimester.

	Members	Seizure disorder	Bipolar disorder	Both diagnoses
Valproate + dx of migraines + pregnant	2	1	0	0
Valproate + dx of migraines	17	9	7	5

Discussion and Recommendations

Based on the small number of women who were exposed to valproate during pregnancy and the short duration of that exposure, prescribers appear to be aware of the potential risks involved with the use of valproate in SoonerCare's female population. Therefore the College of Pharmacy recommends no action at this time.

Overview of FDA Safety Alerts

Oklahoma Health Care Authority
July 2013

Introduction[2, 3]

The following are recent FDA safety alerts included for the DUR Board's consideration. SoonerCare specific data may be presented where applicable. The College will make recommendations for additional action as well as take recommendations from the DUR Board.

Date	Drug	Issue
4/25/2013	**Dabigatran (Pradaxa®)**	**Increased risk of thrombotic event upon discontinuation**
Issue Details: As with other oral anticoagulants, the risk of stroke increases if dabigatran is discontinued without adequate alternative anticoagulant therapy in place **FDA Recommendations:** Boxed warning added to product information regarding the need to initiate an alternative anticoagulant if dabigatran is discontinued.		

Date	Drug	Issue
6/18/2013	**Olanzapine pamoate (Zyprexa Relprevv®)**	**Two deaths following injection**
Issue Details: FDA has issued a Drug Safety Communication regarding the unexplained deaths of two patients 3-4 days after receiving an intramuscular injection of olanzapine pamoate. Blood levels of olanzapine were found to be very high at postmortem evaluation. Olanzapine intramuscular administration requires monitoring for at least 3 hours post-injection, per the Risk Evaluation and Mitigation Strategy (REMS). **FDA Recommendations:** FDA recommends that health care professionals continue to follow the REMS requirements and drug label recommendations while the FDA investigates these deaths.		

References:

[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350868.htm
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350868.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm357601.htm

Appendix C

Vote to Prior Authorize
Oxtellar XR™ (Oxcarbazepine ER) and Sabril® (Vigabatrin)

Oklahoma Health Care Authority
July 2013

Conclusions and Recommendations:

The College of Pharmacy recommends the following:

1. Prior Authorization of Oxtellar XR™ (oxcarbazepine ER) with the following criteria:
    a. A patient specific, clinically significant reason why member cannot use the short-acting formulation.
    b. A quantity limit of 30 per 30 days will apply on the lower strength tablets (150mg and 300mg).
2. Prior Authorization of Sabril® (vigabatrin) with the following criteria:
    a. FDA approved diagnosis of refractory complex seizures in adults, OR infantile spasms in children ages 1 month to 2 years of age.
    b. Members with refractory complex seizures must have previous trials of at least three other antiepileptic medications.
    c. Members with infantile spasms must have had a previous trial with adrenocorticotropic hormone (ACTH) OR have a diagnosis of infantile spasms with tuberous sclerosis.
    d. Prescription must be written by a neurologist.
    e. Member, prescriber, and pharmacy must all register in the SHARE program and maintain enrollment throughout therapy.

Appendix D

Vote to Prior Authorize
Aubagio® (Teriflunomide) and Tecfidera™ (Dimethyl Fumarate)

Oklahoma Health Care Authority
July 2013

Recommendations[1,2]

The College of Pharmacy recommends the prior authorization of Aubagio® (teriflunomide) and Tecfidera™ (dimethyl fumarate) with the following criteria:

Aubagio® (Teriflunomide) Prior Authorization Criteria:

1. Documented diagnosis of relapsing forms of Multiple Sclerosis.
2. All of the following will be required for initiation of treatment:
    a. No concurrent use with other disease modifying therapies.
    b. Verification that female members are not pregnant and currently on a reliable contraceptive.
    c. Verification that member has no active infection(s).
    d. CBC counts and verification that levels are acceptable to the prescriber.
    e. Liver function tests and verification that levels are acceptable to the prescriber.
    f. Blood pressure measurement and verification that blood pressure is being monitored.
    g. Verification that members do not have tuberculosis, or completion of standard medical treatment for patients with tuberculosis.
3. Approval of Aubagio® will be initially for 6 months, after which time, all of the following will be required for further approval:
    a. Medication compliance.
    b. Repeat CBC counts and verification that counts are acceptable to the prescriber.
    c. Repeat liver function tests and verification that levels are acceptable to the prescriber.
    d. Verification that female members are not pregnant and still on reliable contraceptive.

e. Verification that blood pressure and symptoms of renal failure are being monitored.

4. Compliance will be checked every 6 months there-after for continuation of therapy.

5. Quantity limit of #30 tablets per 30 days applies.

Tecfidera™ (Dimethyl Fumarate) Prior Authorization Criteria:

1. Documented diagnosis of relapsing forms of Multiple Sclerosis.

2. All of the following will be required for initiation of treatment:

   a. No concurrent use with other disease modifying therapies

   b. Verification from the prescriber that member has no active infection(s).

   c. CBC counts and verification that levels are acceptable to the prescriber.

3. Compliance will be checked every 6 months there-after for continuation of therapy.

4. Quantity limit of #60 tablets per 30 days applies.

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[1] Aubagio® Prescribing Information. Pillar5 Pharma Inc. Available on line at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202992s000lbl.pdf. Last revised: September 2012; Last accessed 11/12/2012

[2] Tecfidera™ Prescribing Information. Biogen Idec, Inc. Available on line at: http://www.tecfidera.com/pdfs/full-prescribing-information.pdf Last revised: March 2013; Last accessed 5/17/2013.

Appendix E

Calendar Year 2012 Annual Review of Topical Corticosteroids

Oklahoma Health Care Authority
July 2013

Current Prior Authorization Criteria

Tier 2 Approval Criteria

1. Documented trials of ALL Tier 1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief.
    a. If Tier 1 trials are completed and do not yield adequate relief, the member must also provide a clinical reason for requesting a Tier 2 in the same potency instead of trying a higher potency.
2. When the same medication is available in Tier 1, a clinical reason must be provided for using a special dosage form of that medication in Tier 2 (foams, shampoos, kits, etc.).

Topical Corticosteroids	
Tier 1	Tier 2
Ultra high to high potency	
Augmented betamethasone dipropionate (Diprolene AF® G,C)	Amcinonide (C,O,L)
Betamethasone dipropionate (C,O,L)	Augmented betamethasone dipropionate (Diprolene® O, L)
Clobetasol propionate 0.05% (C,G,O,So)	Clobetasol propionate 0.05% (Clobex® L,Sh,Spr; Olux® F, Olux-E™ F)
Diflorasone diacetate 0.05% (ApexiCon E® C)	Desoximetasone 0.25% (Topicort® C,O,) 0.05% (G)
Fluocinonide 0.05% (G,C,O)	Fluocinonide 0.1% (Vanos® C)
Halobetasol propionate (Ultravate® C, O)	Halobetasol propionate (Halonate™, F)
	Halobetasol propionate/lactic acid (Ultravate® X C)
	Halcinonide (Halog® C,O)
Med/high to medium potency	
Betamethasone dipropionate (C,L)	Betamethasone dipropionate/calcipotriene (Taclonex® O, Sus, Spr)
Betamethasone valerate (C,O,L)	Betamethasone valerate 0.12% (Luxiq® Foam)
Fluocinolone acetonide 0.025% (Synalar® C,O)	Desoximetasone 0.05% (Topicort LP ® C)
Fluocinonide emollient (C)	Flurandrenolide tape (Cordran®)
Fluticasone propionate (Cutivate® C,O)	Fluticasone propionate (Cutivate® L)
Hydrocortisone valerate 0.2% (C)	Hydrocortisone butyrate 0.1% (So)
Mometasone furoate 0.1% (Elocon® C,O,L)	Hydrocortisone probutate (Pandel® C)
Triamcinolone acetonide (Pediaderm™, Trianex™ C,O,L)	Hydrocortisone valerate (Westcort® C,O)
	Prednicarbate (Dermatop® O,C)
	Triamcinolone acetonide (Kenalog® Spray)
Low potency	
Alclometasone dipropionate (Aclovate® C,O)	Coclortolone pivalate (Cloderm® C)
Desonide 0.05% (C,O,L)	Desonide 0.05% (Desonate® G, Verdeso® F)
Fluocinolone acetonide 0.01% (Synalar So, C; Derma-Smooth®; Derma-Smooth FS® oil)	Desonide/emollient (Desowen® kit C,O)
Hydrocortisone acetate 2.5% (C,O,L)	Fluocinolone acetonide 0.01% (Capex® Sh)
Hydrocortisone/urea (U-Cort® C)	Hydrocortisone/lidocaine (C)

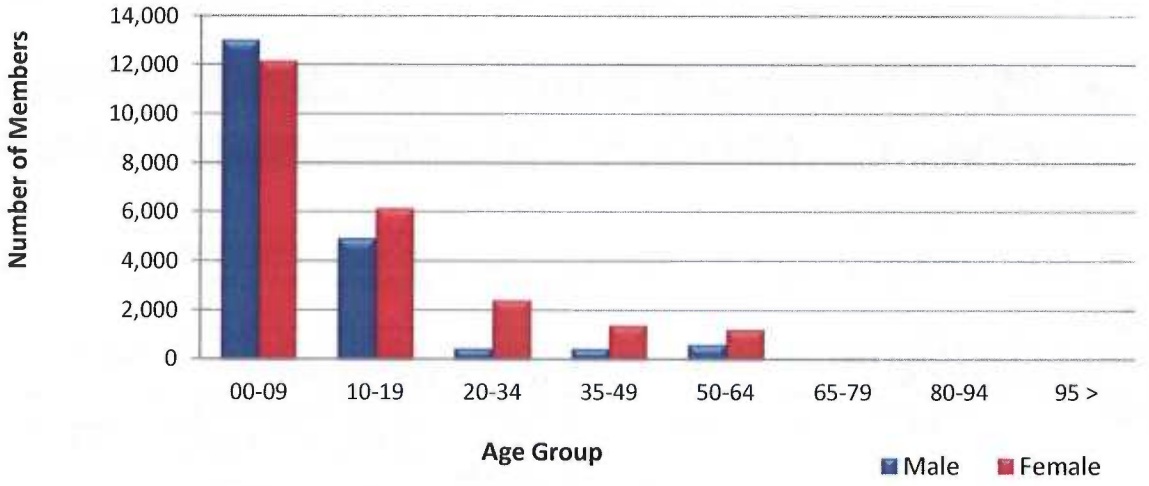
C= Cream, O = Ointment, L = Lotion, G = Gel, Sh = Shampoo, So – Solution, Spr = Spray, Sus = Suspension, F = Foam

Utilization of Topical Corticosteroids

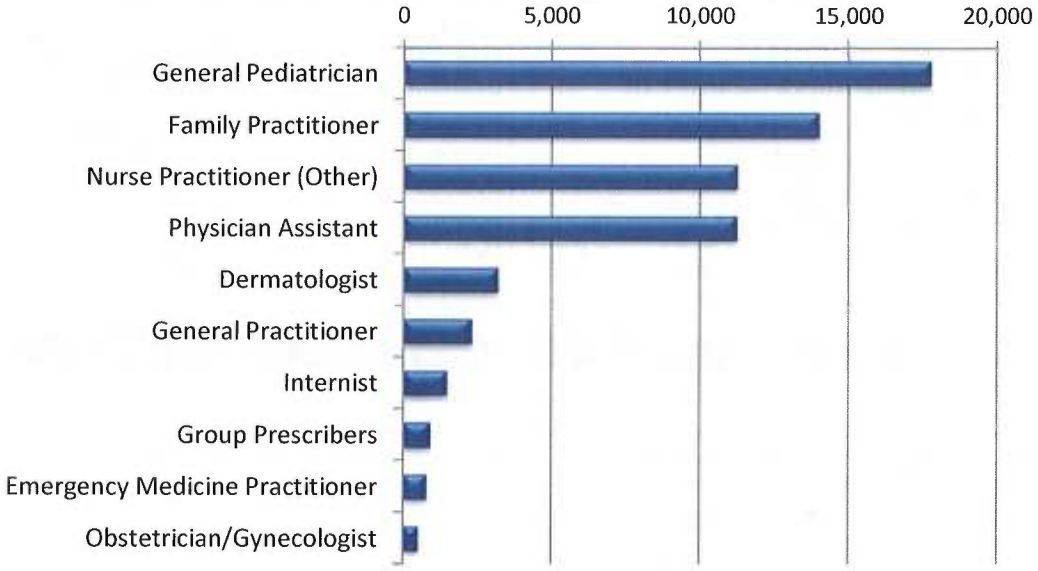
Comparison of Calendar Years (CY)

CY	Members	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
2011	39,603	60,861	$1,910,239.44	$31.39	$2.06	3,859,840	925,436
2012	43,113	65,997	$1,387,214.29	$21.02	$1.38	4,058,520	1,001,812
% Change	8.9%	8.4%	-27.4%	-33.0%	-33.0%	5.1%	8.3%
Change	3,510	5,136	-$523,025.15	-$10.37	-$0.68	198,680	76,376

Demographics of Members Utilizing Topical Corticosteroids: CY 2012



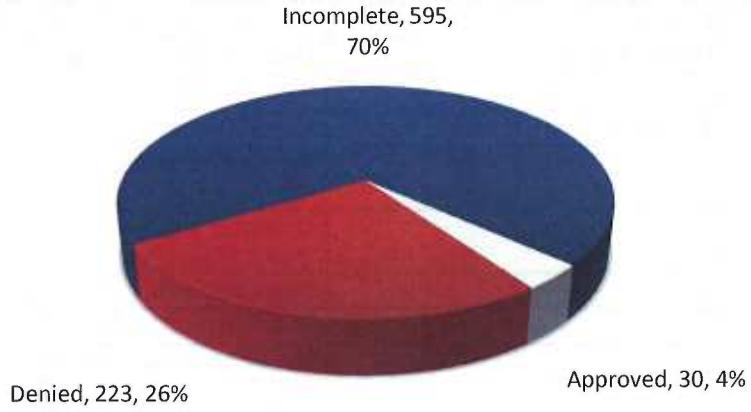
Top 10 Prescribers of Topical Corticosteroids by Number of Claims: CY 2012



Prior Authorization of Topical Corticosteroids

There were a total of 848 petitions submitted for this PBPA category during calendar year 2012. The following chart shows the status of the submitted petitions.

Status of Petitions for Topical Corticosteroids: CY 2012



Market News and Updates

- Olux-E® foam (clobetasol emollient) – generic approved August 2012
- Vanos® (fluocinonide 0.1% cream) - patent expiration December 2021
- Verdeso® (desonide) – patent expires September 2019
- Multiple products in this category experienced price increases since the implementation of this prior authorization category, most notably was desonide 0.05% lotion, which increased from $103.25 per 59 ml bottle to $202.96 per bottle.

Conclusion and Recommendations

The College of Pharmacy recommends moving selected products with significant price increases to Tier-2 as indicated in red on the Tier chart. Additionally, products may be moved throughout the year in response to price increases as necessary. The existing criteria will apply.

Tier 2 Approval Criteria

1. Documented trials of ALL Tier 1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief.
    a. If Tier 1 trials are completed and do not yield adequate relief, the member must also provide a clinical reason for requesting a Tier 2 in the same potency instead of trying a higher potency.
2. When the same medication is available in Tier 1, a clinical reason must be provided for using a special dosage form of that medication in Tier 2 (foams, shampoos, kits, etc.).

Topical Corticosteroids	
Tier 1	Tier 2
Ultra high to high potency	
Augmented betamethasone dipropionate (C)	Betamethasone dipropionate (C,O)
Clobetasol propionate 0.05% (C,G,O,So)	Fluocinonide 0.05% (G,So)
Fluocinonide 0.05% (C,O)	Diflorasone diacetate 0.05% (C, ApexiCon E® C, O)
Halobetasol propionate (Ultravate® C, O)	Amcinonide (C,O,L)
	Augmented betamethasone dipropionate (Diprolene® O,G,L)
	Clobetasol propionate 0.05% (Clobex® L,Sh,Spr; Olux® F, Olux-E™ F)
	Desoximetasone 0.25% (Topicort® C,O,) 0.05% (G)
	Fluocinonide 0.1% (Vanos® C)
	Halobetasol propionate (Halonate™, F)
	Halobetasol propionate/lactic acid (Ultravate® X C)
	Halcinonide (Halog® C,O)
Med/high to medium potency	
Betamethasone dipropionate (L)	Mometasone furoate 0.1% (O)
Betamethasone valerate 0.1% (C)	Betamethasone valerate 0.1% (O,L)
Fluocinonide emollient (C)	Fluocinolone acetonide 0.025% (Synalar® C,O)
Fluticasone propionate (Cutivate® C,O)	Hydrocortisone valerate 0.2% (O)
Mometasone furoate 0.1% (Elocon® C,L)	Betamethasone dipropionate/calcipotriene (Taclonex® O, Sus, Spr)
Triamcinolone acetonide (Pediaderm™, Trianex™ C,O,L)	Betamethasone valerate 0.12% (Luxiq® Foam)
Hydrocortisone valerate 0.2% (C)	Desoximetasone 0.05% (Topicort LP ® C)
	Flurandrenolide tape (Cordran®)
	Fluticasone propionate (Cutivate® L)
	Hydrocortisone butyrate 0.1% So
	Hydrocortisone probutate (Pandel® C)
	Hydrocortisone valerate (Westcort® C,O)
	Prednicarbate (Dermatop® O,C)
	Triamcinolone acetonide (Kenalog® Spray)
Low potency	
Alclometasone dipropionate (Aclovate® C,O)	Fluocinolone acetonide 0.01% (C, So, Synalar® So)
Desonide 0.05% (C,O)	Coclortolone pivalate (Cloderm® C)
Fluocinolone acetonide 0.01% (Synalar So, C; Derma-Smooth®; Derma-Smooth FS® oil)	Desonide 0.05% (Desonate® G, Verdeso® F, L)
Hydrocortisone acetate 2.5% (C,O,L)	Desonide/emollient (Desowen® kit C,O)
Hydrocortisone/urea (U-Cort® C)	Fluocinolone acetonide 0.01% (Capex® Sh)
	Hydrocortisone/lidocaine (C)

C= Cream, O = Ointment, L = Lotion, G = Gel, Sh = Shampoo, So – Solution, Spr = Spray, Sus = Suspension, F = Foam

Utilization Details of Topical Corticosteroids: Calendar Year 2012

BRAND NAME	CLAIMS	MEMBERS	COST	UNITS/ DAY	COST/ UNIT	2013 COST/UNIT	COST/ CLAIM	COST/ DAY	TIER
Triamcinolone cream 0.1%	21,778	16,642	$256,347.51	4.71	$0.17	$0.15	$11.77	$0.80	T1 medium
Triamcinolone ointment 0.1%	6,246	4,490	$93,129.64	6.15	$0.15	$0.15	$14.91	$0.93	T1 medium
Triamcinolone cream 0.025%	5,655	4,562	$55,818.38	4.08	$0.18	$0.18	$9.87	$0.73	T1 medium
Hydrocortisone cream 2.5%	3,752	3,056	$30,572.25	2.99	$0.21	$0.21	$8.15	$0.62	T1 low
Triamcinolone cream 0.5%	2,555	2,009	$40,218.81	2.45	$0.48	$0.50	$15.74	$1.18	T1 medium
Mometasone cream 0.1%	2,400	1,761	$43,111.24	2.46	$0.48	$0.39	$17.96	$1.19	T1 medium
Fluticasone cream 0.05%	2,325	1,666	$81,875.54	3.67	$0.64	$0.62	$35.22	$2.35	T1 medium
Desonide cream 0.05%	2,300	1,732	$65,564.91	2.67	$0.71	$0.74	$28.51	$1.89	T1 low
Clobetasol ointment 0.05%	1,445	792	$30,145.95	3.06	$0.38	$0.38	$20.86	$1.17	T1 high
Desonide lotion 0.05%	1,405	1,044	$238,430.35	5.31	$1.56	$2.57	$169.70	$8.27	T1 low
Hydrocortisone cream 1%	1,355	1,162	$13,477.99	3.24	$0.26	$0.27	$9.95	$0.84	T1 low
Triamcinolone ointment 0.025%	1,341	1,012	$18,751.45	4.49	$0.22	$0.23	$13.98	$1.00	T1 medium
Desonide ointment 0.05%	1,148	780	$24,285.90	3.22	$0.40	$0.41	$21.15	$1.30	T1 low
Betamethasone diprop cream 0.05%	1,000	726	$52,532.38	2.9	$1.21	$1.42	$52.53	$3.50	T1 medium
Hydrocortisone ointment 2.5%	950	729	$8,309.56	2.57	$0.23	$0.22	$8.75	$0.59	T1 low
Betamethasone valerate cream 0.1%	923	680	$23,407.02	2.38	$0.64	$0.64	$25.36	$1.52	T1 medium
Clobetasol cream 0.05%	888	625	$16,099.16	2.89	$0.38	$0.36	$18.13	$1.09	T1 high
Hydrocortisone valerate cream 0.2%	753	570	$20,012.51	3.02	$0.60	$0.77	$26.58	$1.80	T1 medium
Clobetasol solution 0.05%	669	341	$11,797.99	2.97	$0.31	$0.30	$17.64	$0.91	T1 high
Triamcinolone ointment 0.5%	647	475	$13,763.00	2.54	$0.67	$0.67	$21.27	$1.69	T1 medium
Betamethasone diprop ointment 0.05%	601	383	$48,773.00	2.92	$1.68	$1.87	$81.15	$4.90	T1 high
Triamcinolone lotion 0.1%	567	457	$21,254.12	3.74	$0.56	$0.60	$37.49	$2.09	T1 medium
Mometasone ointment 0.1%	529	376	$16,328.54	2.49	$0.79	$0.86	$30.87	$1.97	T1 medium
betamethasone cr (augmented) 0.05%	433	339	$13,731.82	2.51	$0.75	$0.74	$31.71	$1.89	T1 high
Fluocinonide cream 0.05%	384	274	$5,906.15	3.01	$0.32	$0.33	$15.38	$0.97	T1 high
Hydrocortisone lotion 2.5%	381	293	$9,019.98	4.7	$0.28	$0.25	$23.67	$1.30	T1 low
Fluocinolone oil for scalp 0.01%	289	202	$10,318.44	4.93	$0.30	$0.31	$35.70	$1.47	T1 low
Betamethasone valerate ointment 0.1%	275	210	$8,976.36	2.26	$0.80	$0.85	$32.64	$1.82	t1 medium
Triamcinolone lotion 0.025%	271	228	$9,946.49	3.73	$0.57	$0.57	$36.70	$2.14	T1 medium
Fluocinolone oil for body 0.01%	237	158	$8,658.27	5.41	$0.29	$0.30	$36.53	$1.59	T1 low
Fluocinonide solution 0.05%	217	149	$9,096.84	2.8	$0.70	$1.21	$41.92	$1.96	T1 high
Fluocinolone cream 0.025%	211	164	$8,072.60	2.12	$1.52	$1.83	$38.26	$3.23	T1 medium
Fluocinonide ointment 0.05%	192	128	$8,649.57	3.46	$0.67	$0.65	$45.05	$2.31	T1 high
Hydrocortisone ointment 1%	173	155	$1,061.26	2.56	$0.16	$0.17	$6.13	$0.41	T1 low
Fluticasone ointment 0.005%	155	111	$4,717.66	2.55	$0.66	$0.65	$30.44	$1.67	T1 medium
Derma-Smooth™ oil/FS Body	138	94	$5,376.18	5.41	$0.32	$0.31	$38.96	$1.73	T1 low
Mometasone solution 0.1%	125	94	$4,104.90	2.55	$0.64	$0.66	$32.84	$1.62	T1 medium
Fluocinonide gel 0.05%	109	85	$2,719.16	2.09	$0.85	$1.14	$24.95	$1.77	T1 high
Derma-Smooth™ oil/FS Scalp	101	68	$4,058.69	5.61	$0.33	$0.33	$40.19	$1.85	T1 low
Alclometasone cream 0.05%	93	82	$2,565.88	2.52	$0.74	$0.74	$27.59	$1.86	T1 low
Fluocinolone solution 0.01%	92	69	$6,734.21	2.59	$1.18	$2.66	$73.20	$3.05	T1 low
Betamethasone diprop lotion 0.05%	91	54	$3,561.12	3.39	$0.64	$0.62	$39.13	$2.17	T1 medium
Halobetasol cream 0.05%	88	60	$2,419.94	2.08	$0.79	$0.74	$27.50	$1.65	T1 high
Hydrocortisone micronized powder	86	44	$489.95	3.04	$0.06	$0.15	$5.70	$0.19	T1 low
Clobetasol emollient cream 0.05%	73	45	$1,297.03	3.6	$0.34	$0.37	$17.77	$1.23	T1 high
Fluocinolone ointment 0.025%	57	27	$4,099.32	4.95	$0.80	$1.43	$71.92	$3.98	T1 medium
Clobetasol gel 0.05%	53	42	$1,278.14	2.76	$0.48	$0.49	$24.12	$1.32	T1 high
Betamethasone valerate lotion 0.1%	51	31	$2,807.03	3.86	$0.85	$0.83	$55.04	$3.27	T1 medium
Triamcinolone powder	50	35	$482.43	10.05	$0.05	$0.06	$9.65	$0.51	T1 medium
Fluocinolone cream 0.01%	48	29	$4,309.94	2.64	$1.94	$1.96	$89.79	$5.12	T1 medium
Halobetasol ointment 0.05%	46	29	$1,278.84	2.29	$0.73	$0.78	$27.80	$1.67	T1 high
Fluocinonide emulsified cream 0.05%	25	22	$306.44	2.05	$0.27	$0.28	$12.26	$0.56	T1 medium
Triamcinolone ointment 0.05%	25	22	$338.13	8.72	$0.08	$0.11	$13.53	$0.68	T1 medium

BRAND NAME	CLAIMS	MEMBERS	COST	UNITS/ DAY	COST/ UNIT	2013 COST/UNIT	COST/ CLAIM	COST/ DAY	TIER
Hydrocortisone micronized powder	23	17	$242.24	3.06	$0.11	$0.15	$10.53	$0.35	T1 low
Fluocinonide emulsified cream 0.05%	20	16	$258.56	2.54	$0.25	$0.38	$12.93	$0.64	T1 medium
Diflorasone cream 0.05%	19	6	$6,125.31	6.67	$3.40	$3.80	$322.38	$22.69	T1 high
Alclometasone ointment 0.05%	17	12	$498.92	2.72	$0.69	$0.71	$29.35	$1.88	T1 low
Hydrocortisone acetate powder	17	13	$152.82	4.66	$0.06	$0.06	$8.99	$0.30	T1 low
Hydrocortisone butyrate solution 0.1%	12	10	$197.85	3.01	$0.32	$0.26	$16.49	$0.96	T2 medium
Trianex™ ointment 0.05%	11	10	$53.47	2.15	$0.18	0.06	$4.86	$0.38	T1 medium
Apexicon E cream 0.05%	10	2	$384.14	4.05	$1.28	3.91	$38.41	$5.19	T1 high
Augmented betamethasone gel 0.05%	9	6	$540.79	1.67	$1.37	3.17	$60.09	$2.28	T1 high
Hydrocortisone powder	8	6	$192.97	3.95	$0.26	$0.28	$24.12	$1.04	T1 low
Beta-val cream 0.1%	6	4	$39.49	3	$0.15	0.78	$6.58	$0.46	T1 medium
Clobex® shampoo 0.05%	6	1	$2,596.47	3.93	$3.67	2.54	$432.75	$14.42	T2 high
Clobetasol aerosol foam 0.05%	5	1	$826.79	3.75	$1.84	$1.89	$165.36	$6.89	T2 high
Clobetasol shampoo 0.05%	5	2	$1,390.99	5.46	$2.36	$2.58	$278.20	$12.88	T2 high
Hydrocortisone valerate ointment 0.2%	5	1	$293.69	2	$0.98	4.25	$58.74	$1.96	T1 medium
Fluocinolone powder	4	1	$17.38	1.5	$0.10	$0.11	$4.35	$0.14	T1 medium
Luxiq® aerosol foam 0.12%	3	1	$1,108.17	10	$3.69	4.63	$369.39	$36.94	T2 medium
Verdeso® aerosol foam 0.05%	2	1	$351.10	2	$3.51	$3.65	$175.55	$7.02	T2 low
Desoximetasone cream 0.25%	2	1	$53.09	2.05	$1.18	1.86	$26.55	$2.41	T2 high
Diflorasone ointment 0.05%	2	2	$82.95	1.2	$2.77	2.76	$41.48	$3.32	T1 high
Capex® shampoo 0.01%	2	2	$581.86	5.45	$2.42	2.91	$290.93	$13.22	T2 low
Prednicarbate cream 0.1%	2	1	$66.72	5	$0.89	1.16	$33.36	$4.45	T2 medium
Desoximetasone cream 0.05%	1	1	$148.70	6	$2.48	3.30	$148.70	$14.87	T2 medium
Cordran® tape 24x3 4mcg/cm^2	1	1	$233.10	0.75	$77.70	188.73	$233.10	$58.27	T2 medium
Fluticasone lotion 0.05%	1	1	$347.09	2	$5.78	5.72	$347.09	$11.57	T2 medium
Hydrocortisone cream 1%	1	1	$24.79	15.2	$0.16	0.06	$24.79	$2.48	T1 low
Hydrocortisone powder	1	1	$7.28	0.3	$0.08	0.07	$7.28	$0.02	T1 low
Elocon® cream 0.1%	1	1	$7.59	0.75	$0.51	0.43	$7.59	$0.38	T1 medium
Totals	65,997	43,113*	$1,387,214.29	4.05	$0.34		$21.02	$1.38	

*Total unduplicated number of members

Appendix F

30 Day Notice to Prior Authorize Fulyzaq™ (Crofelemer)

Oklahoma Health Care Authority
July 2013

Manufacturer	Patheon, Inc. for Salix Pharmaceuticals, Inc.
Classification	Anti-diarrheal
Status	Prescription Only

Introduction[1, 2, 3, 4]

The CDC estimates approximately 4,693 people are living with HIV/AIDS in Oklahoma. Treatment guidelines from the National Institute of Health recommend antiretroviral therapy (ART) in all HIV/AIDS patients to reduce the risk of disease progression. There were 642 SoonerCare members with a claim for ART in fiscal year 2012. Unpleasant side effects accompanied by ART lead to noncompliance, with diarrhea being one of the leading adverse events resulting in discontinuation of ART. Medication persistence and adherence have important implications for treatment efficacy and minimization of drug resistance. Avoiding food as a result of gastrointestinal symptoms can lead to reduced consumption of nutrients, consequently adding to the wasting and malnutrition associated with HIV/AIDS. The current recommended treatments from the National Institute of Health for ART-associated diarrhea are dietary modifications, use of calcium carbonate, bulk forming agents, or anti-motility agents.

Medication Summary [5, 6]

Fulyzaq™ (crofelemer) is an anti-diarrheal agent indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. Fulyzaq™ was FDA approved in December 2012 and is the first FDA approved medication for HIV/AIDS associated diarrhea. The recommended dose is 125mg by mouth twice daily.

Fulyzaq™ inhibits chloride ion channels that regulate chloride ion and fluid secretion by intestinal epithelial cells. Fulyzaq™ acts by blocking chloride ion secretion and the accompanying high volume water loss in diarrhea, normalizing the flow of chloride ion and water in the gastrointestinal tract.

The efficacy of Fulyzaq™ was evaluated in a randomized, double-blind, placebo-controlled (one month) and placebo-free (five month), multi-center study. The study enrolled HIV-positive patients on stable anti-retroviral therapy (ART) with a history of diarrhea for one month or more. The primary efficacy endpoint was the proportion of patients with a clinical response, defined as less than or equal to 2 watery bowel movements per week during at least 2 of the 4 weeks of the placebo-controlled phase. Patients received placebo for 10 days followed by randomization to Fulyzaq™ or placebo for 31 days of treatment. A five month placebo-free period followed the double-blind period. The most frequently used ARTs in each group were Truvada® (tenofovir/emtricitabine), Norvir® (ritonavir), and Kaletra® (lopinavir/ritonavir).

A significantly larger proportion of patients in the Fulyzaq™ group experienced clinical response compared with patients in the placebo group (17.6% vs. 8.0%, $p < 0.01$). Fulyzaq™ was found to be less effective in African-Americans. Of the 24 clinical responders to Fulyzaq™, 22 entered the placebo-free period; 16 were responding at the end of month 3, and 14 were responding at the end of month 5.

The most commonly reported adverse reactions during clinical trials (occurring in at least 3% of patients treated with Fulyzaq™ and greater incidence than placebo) were upper respiratory tract infections, bronchitis, cough, flatulence, and increased bilirubin.

Infectious etiologies of diarrhea must be ruled out prior to starting Fulyzaq™ therapy. There is a risk that patients with infectious etiologies will not receive the appropriate treatments, and their disease may worsen.

The estimated acquisition cost of Fulyzaq™ is approximately $9.50 per tablet or $570.24 for a 30 day supply. There has been no utilization of Fulyzaq™ in the SoonerCare population since its approval in December 2012.

Recommendations

The College of Pharmacy recommends the prior authorization of Fulyzaq™ with the following criteria:

Fulyzaq™ (Crofelemer) Prior Authorization Criteria:

1. FDA approved diagnosis of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy.
2. A quantity limit of 60 tablets per 30 days.

PRODUCT DETAILS OF FULYZAQ™ (CROFELEMER) [5, 6]

INDICATIONS AND USE:

- Fulyzaq™ (crofelemer) is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy.
- Fulyzaq™ is an inhibitor of both the cyclic adenosine monophosphate (cAMP)-stimulated cystic fibrosis transmembrane conductance regulator (CFTR) chloride ion channel, and the calcium-activated chloride ion channels (CaCC) at the luminal membrane of enterocytes. The CFTR chloride ion channel and CaCC regulate chloride ion and fluid secretion by intestinal epithelial cells. Fulyzaq™ acts by blocking chloride ion secretion and accompanying high volume water loss in diarrhea, normalizing the flow of chloride ion and water in the GI tract.

DOSAGE FORMS: 125mg delayed-release tablets

ADMISTRATION: The recommended dose of Fulyzaq™ is 125mg by mouth twice daily.

CONTRAINDICATIONS: None listed

SPECIAL POPULATIONS:

- Fulyzaq™ is classified as pregnancy category C. There are no adequate, well-controlled studies in pregnant women. Fulyzaq™ should be used during pregnancy only if clearly-needed.
- It is not known whether Fulyzaq™ is excreted in human milk.
- The safety and effectiveness of Fulyzaq™ have not been established in pediatric patients less than 18 years of age.
- Clinical studies with Fulyzaq™ did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently than younger patients.
- No dose modifications are recommended with respect to CD4 cell count and HIV viral load.

WARNINGS AND PRECAUTIONS: Infectious etiologies of diarrhea must be ruled out prior to starting Fulyzaq™ therapy. There is a risk that patients with infectious etiologies will not receive the appropriate treatments, and their disease may worsen. Fulyzaq™ is not indicated for the treatment of infectious diarrhea.

ADVERSE REACTIONS: The most commonly reported adverse reactions reported during clinical trials (occurring in at least 2% of patients treated with Fulyzaq™ and greater incidence than placebo) were upper respiratory tract infections, bronchitis, cough, flatulence, increased bilirubin, nausea, back pain, arthralgia, urinary tract infection, nasopharyngitis, musculoskeletal pain, hemorrhoids, giardiasis, anxiety, increased alanine aminotransferase, and abdominal distension.

DRUG INTERACTIONS:

- *In vitro* studies have shown that Fulyzaq™ has the potential to inhibit cytochrome P450 isoenzyme 3A and transporters MRP2 and OATP1A2 in the gut.
- Due to the minimal absorption of Fulyzaq™ it is unlikely to inhibit cytochrome P450 isoenzymes systemically.
- Fulyzaq™ did not have a clinically relevant interaction with Viracept (nelfinavir), Retrovir® (zidovudine), or Epivir® (lamivudine) in a drug-drug interaction trial.

PATIENT COUNSELING INFORMATION:

1. Fulyzaq™ is for diarrhea associated with some of the HIV/AIDS medications you are taking.
2. Fulyzaq™ should be taken by mouth twice daily.
3. Fulyzaq™ can be taken with or without food.
4. Fulyzaq™ tablets should be swallowed whole. Tablets should not be crushed or chewed.
5. Fulyzaq™ is not used for stomach virus or other types of infection. If you believe you have diarrhea due to an infection or virus, contact your prescriber.

References:

1. The Henry J Kaiser Family Foundation. People Living with HIV/AIDS. February 2012. Available at <kff.org/hivaids/state-indicator/people-living-with-hivaids/?state=ok> Accessed June 14, 2013.
2. Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection." Available at <aidsinfo.nih.gov> Accessed June 14, 2013. K-12 Table 17c.
3. Gupta R, Ordonez RM, Koenig S. Global Impact of Antiretroviral Therapy-Associated Diarrhea. *AIDS Patient Care and STDs.* November 2012; 26:1-3.
4. New Your State Department of Health AIDS Institute. Gastrointestinal Complications of HIV. Available at <www.hivguidelines.org> Accessed June 14, 2013. 1-5.
5. Fulyzaq™ [Package insert]. Raleigh, North Carolina: Salix Pharmaceuticals, Inc; 2012. Available online at: <www.fulyzaq.com> Accessed June 14, 2013.
6. Liscinsky, Morgan. "FDA approves first anti-diarrheal drug for HIV/AIDS patients." U.S. Food and Drug Administration. December 31, 2012. Web. June 14,2013. <www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701>

Appendix G

30 Day Notice to Prior Authorize Vecamyl™ (Mecamylamine)

Oklahoma Health Care Authority
July 2013

Manufacturer	Manchester Pharmaceuticals, Inc.
Classification	Antihypertensive
Status	Prescription Only

Summary[1,2,3]

Mecamylamine was previously available under the brand name Inversine®; however, it was discontinued by the manufacturer (Targacept, Inc.) in September 2009. Vecamyl™ was approved by the FDA in March 2013.

Vecamyl™ is a ganglionic blocker that inhibits acetylcholine at the autonomic ganglia, causing a decrease in blood pressure. Vecamyl™ is indicated for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension in adults.

Vecamyl™ is available as 2.5mg tablets. Therapy is usually initiated with one 2.5mg tablet by mouth twice daily after meals. This initial dosage should be modified by increments of one 2.5mg tablet at intervals of not less than 2 days until the desired blood pressure response occurs (the criterion being a dosage just under that which causes signs of mild orthostatic hypotension). The average total daily dosage of Vecamyl™ is 25mg, usually in three divided doses. However, as little as 2.5mg daily may be sufficient to control hypertension in some patients. In severe or urgent cases, larger increments at smaller intervals may be needed. Partial tolerance may develop in certain patients, requiring an increase in the daily dosage of Vecamyl™.

Vecamyl™ should not be used in mild, moderate, labile hypertension and may prove unsuitable in uncooperative patients. Vecamyl™ is a secondary amine that readily penetrates into the brain and may cause central nervous system effects such as tremor, chorea, impaired cognition, and seizures. When Vecamyl™ is withdrawn, this should be done gradually and other antihypertensive therapy usually must be substituted. When ganglionic blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. In some patients, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. Vecamyl™ is contraindicated in the following:

- Coronary insufficiency
- Recent myocardial infarction
- Rising or elevated BUN (blood urea nitrogen), or known renal insufficiency
- Uremia
- Glaucoma

- Organic pyloric stenosis
- Currently receiving sulfonamides or antibiotics
- Known sensitivity to Vecamyl™ (mecamylamine)

Mecamylamine has been shown to be effective in treating moderately severe to severe hypertension when it was first approved by the FDA in 1956. No new trials were performed to evaluate the efficacy of Vecamyl™ in the treatment of hypertension. Vecamyl™ was approved as a generic medication (mecamylamine) under an abbreviated new drug application (ANDA), but is being marketed under the brand name Vecamyl™. Mecamylamine is not listed among current references as an acceptable alternative agent to consider for supplemental use after first-line antihypertensive agents have failed to provide adequate response. More predictably effective agents with safer side effect profiles and proven effects on morbidity and mortality have replaced mecamylamine for use in both essential and malignant hypertension.

Cost: The cost per 2.5mg tablet is $52.80. Based on the average total daily dosage of 25mg (ten 2.5mg tablets), the average daily cost is $528.00 and the average monthly cost is $15,840.00.

Recommendations

The College of Pharmacy recommends prior authorization of Vecamyl™ with the following criteria:

Vecamyl™ (Mecamylamine) Prior Authorization Criteria:

1. FDA approved diagnosis of moderately severe to severe essential hypertension or uncomplicated malignant hypertension.
2. Use of at least 6 classes of medications, in the past 12 months, that did not yield adequate blood pressure control. Treatment must have included combination therapy with a diuretic. Medications can be from, but not limited to, the following classes: ACE inhibitors, ARBs, CCBs, DRIs, beta blockers, alpha blockers, alpha agonists, diuretics, etc.
3. Prescriber must verify member does not have any of the following contraindications:
    a. Coronary insufficiency
    b. Recent myocardial infarction
    c. Rising or elevated BUN, or known renal insufficiency
    d. Uremia
    e. Glaucoma
    f. Organic pyloric stenosis
    g. Currently receiving sulfonamides or antibiotics
    h. Known sensitivity to Vecamyl™ (mecamylamine)

PRODUCT DETAILS OF VECAMYL® (MECAMYLAMINE)

INDICATIONS AND USE: Vecamyl™ is indicated for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.

DOSAGE FORMS: 2.5mg tablets.

ADMINISTRATION:

- The recommended starting dose is one 2.5mg tablet by mouth twice daily after meals.
- The initial dosage should be modified by increments of 2.5mg at intervals of not less than 2 days until the desired blood pressure response occurs or signs of orthostatic hypotension appear.
- The average total daily dose of Vecamyl™ is 25mg, usually in three divided doses. However, as little as 2.5mg daily may be sufficient to control hypertension in some patients. In severe or urgent cases, larger increments at smaller intervals may be needed. Partial tolerance may develop in certain patients, requiring an increase in the daily dosage of Vecamyl™.
- The initial regulation of dosage should be determined by blood pressure readings in the erect position at the time of maximal effect of the drug, as well as by other signs and symptoms of orthostatic hypotension.
- The effective maintenance dose should be regulated by blood pressure reading in the erect position and by limitation of dose to that which causes slight faintness or dizziness in this position.
- Close supervision and education of the patient, as well as critical adjustment of dosage, are essential to successful therapy.
- Vecamyl™ should be taken after meals for a more gradual absorption and smoother control of excessively high blood pressure. The timing of doses in relation to meals should be consistent.
- The morning dose of Vecamyl™ should be small or completely omitted because the body excessively responds to antihypertensive agents at this time of day. The largest dose is best tolerated at noon or in the evening.

CONTRAINDICATIONS:

- Coronary insufficiency
- Recent myocardial infarction
- Rising or elevated BUN, or known renal insufficiency
- Uremia
- Glaucoma
- Organic pyloric stenosis
- Currently receiving sulfonamides or antibiotics
- Known sensitivity to Vecamyl™ (mecamylamine)

SPECIAL POPULATIONS:

- **Pregnancy:** Animal reproduction studies have not been conducted with Vecamyl™ and there are no adequate and well-controlled studies in pregnant women. It is not known whether Vecamyl™ can cause fetal harm when given to a pregnant woman or can affect reproductive capacity. Vecamyl™ should be given to a pregnant woman only if clearly needed, and only if the potential benefit outweighs the potential risk. (Category C)
- **Nursing Mothers:** Vecamyl™ may be excreted in human milk. Because of the potential for serious adverse effects in nursing infants from Vecamyl™, a decision should be made whether to

discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

- **Pediatrics:** Safety and effectiveness of Vecamyl™ in pediatric patients have not been established.
- **Geriatrics:** Geriatric patients may be more sensitive to the usual adult doses of Vecamyl™, especially if age-related decrements in renal function are also present. However, no specific dosing guidelines in geriatric patients are provided.
- **Renal Impairment:** Vecamyl™ should be administered with caution, if at all, in patients with renal insufficiency. Vecamyl™ is contraindicated in renal insufficiency, rising or elevated BUN, and uremia. No specific dosing recommendations have been reported.

WARNINGS AND PRECAUTIONS:

- Vecamyl™ is a secondary amine that readily penetrates into the brain and may cause central nervous system effects such as tremor, chorea, impaired cognition, and seizures. These effects occur rarely and have occurred most often when large doses of Vecamyl™ were used, especially in patients with cerebral or renal insufficiency.
- When Vecamyl™ is withdrawn, this should be done gradually and other antihypertensive therapy usually must be substituted. When ganglionic blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. In some patients, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure.
- The patient's condition should be evaluated carefully, particularly as to renal and cardiovascular function. When renal, cerebral, or coronary blood flow is deficient, any additional impairment, which might result from added hypotension, must be avoided. The use of Vecamyl™ in patients with marked cerebral and coronary arteriosclerosis or after a recent cerebral accident requires caution.
- The action of Vecamyl™ may be potentiated by excessive heat, fever, infection, hemorrhage, pregnancy, anesthesia, surgery, vigorous exercise, other antihypertensive drugs, alcohol, and salt depletion as a result of diminished intake or increased excretion due to diarrhea, vomiting, excessive sweating, or diuretics.
- Since urinary retention may occur in patient on Vecamyl™, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture.
- Frequent loose bowel movements with abdominal distention and decreased borborygmi may be the first signs of paralytic ileus. If these are present, Vecamyl™ should be discontinued immediately and remedial steps taken.

ADVERSE REACTIONS:

- **Cardiovascular:** orthostatic hypotension, syncope
- **Gastrointestinal:** constipation, glossitis, loss of appetite, nausea, paralytic ileus, vomiting, xerostomia
- **Neurologic:** asthenia, chorea, orthostatic dizziness, impaired cognition, paresthesia, sedation, seizure, tremor
- **Ophthalmic:** blurred vision, mydriasis
- **Psychiatric:** mental disorder, mental aberrations
- **Renal:** urinary retention
- **Reproductive:** impotence, reduced libido
- **Respiratory:** pulmonary edema, pulmonary fibrosis

- **Other:** drug tolerance, fatigue, withdrawal signs or symptoms (rebound hypertension, cerebrovascular accident, acute congestive heart failure)

DRUG INTERACTIONS:

- Patients receiving antibiotics and sulfonamides generally should not be treated with ganglionic blockers.
- The action of Vecamyl™ may be potentiated by anesthesia, other antihypertensive drugs, and alcohol.
- Coadministration of Vecamyl™ and bethanechol can result in severe hypotension.
- Coadministration of Vecamyl™ and sodium bicarbonate can result in hypotension.

PATIENT COUNSELING INFORMATION:

- You should not discontinue Vecamyl™ without talking to your physician first. Stopping Vecamyl™ suddenly increases your risk of rebound high blood pressure, stroke, and heart failure.
- Vecamyl™ may cause dizziness, lightheadedness, or fainting, especially when rising from a lying or sitting position. This effect may be increased by alcoholic beverages, exercise, or during hot weather. Getting up slowly may help lessen such a reaction.
- Vecamyl™ may cause paralytic ileus. Tell your physician right away if you have frequent loose bowel movements with abdominal bloating and decreased stomach rumbling, as these can be the first signs of paralytic ileus.
- Vecamyl™ may cause impaired cognition, tremor, abnormal involuntary movements, and seizures. Tell your physician if you experience any of these side effects.
- You may develop tolerance to Vecamyl™, and your dose may need to be increased. Talk to your physician if your blood pressure readings are higher than usual.
- The effect of taking Vecamyl™ in pregnancy is unknown, and Vecamyl™ may be excreted in human milk. Talk to your physician if you are pregnant or wish to become pregnant, or are breastfeeding.
- Take Vecamyl™ tablets by mouth after meals as directed by your physician. The timing of doses in relation to meals should be consistent.

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[1] "Mecamylamine" Drug Information. Micromedex 2.0. Available online at: http://www.micromedexsolutions.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/2B2ECF/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/AD6DC3/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=2507&contentSetId=31&title=MECAMYLAMINE&servicesTitle=MECAMYLAMINE. Last revised: April 2013; Last accessed 6/24/2013.

[2] Vecamyl™ Package Insert. Med Library.org. Available online at: http://medlibrary.org/lib/rx/meds/vecamyl/. Last revised: February 2012; Last accessed 6/24/2013.

[3] Vecamyl™ Prescribing Information. Manchester Pharmaceuticals, Inc. Available online at: http://manchesterpharma.com/assets/files/100ct%20Vecamyl%20(Mecamylamine%20HCl%20Tablets%20USP)%202%205%20mg%20Rev12b.pdf. Last revised: September 2012; Last accessed 6/24/2013.

Appendix H

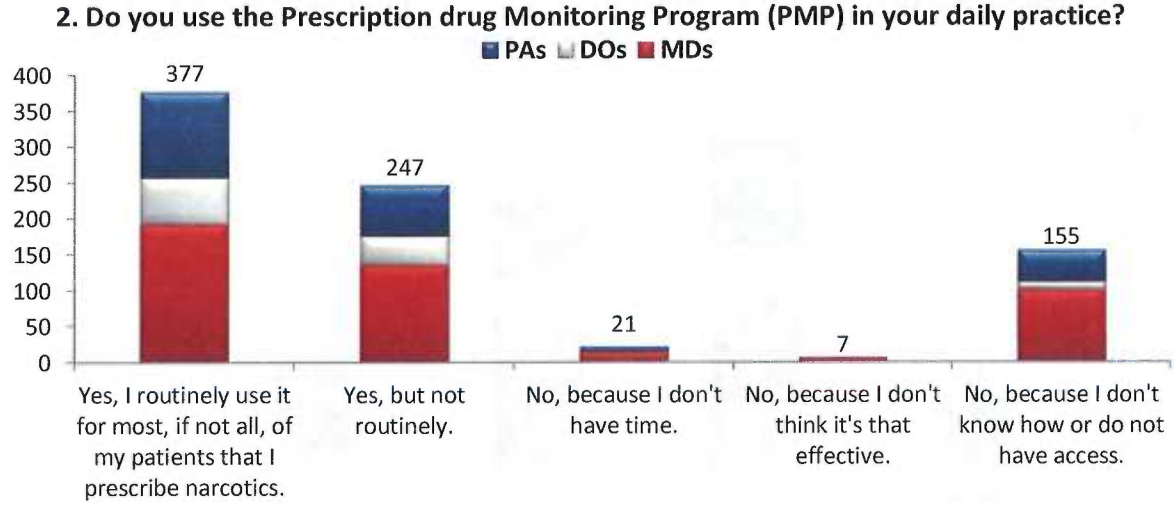
OPIATE - Opioid Prescribing Initiative for Appropriate Treatment & Education

Oklahoma Health Care Authority
July 2013

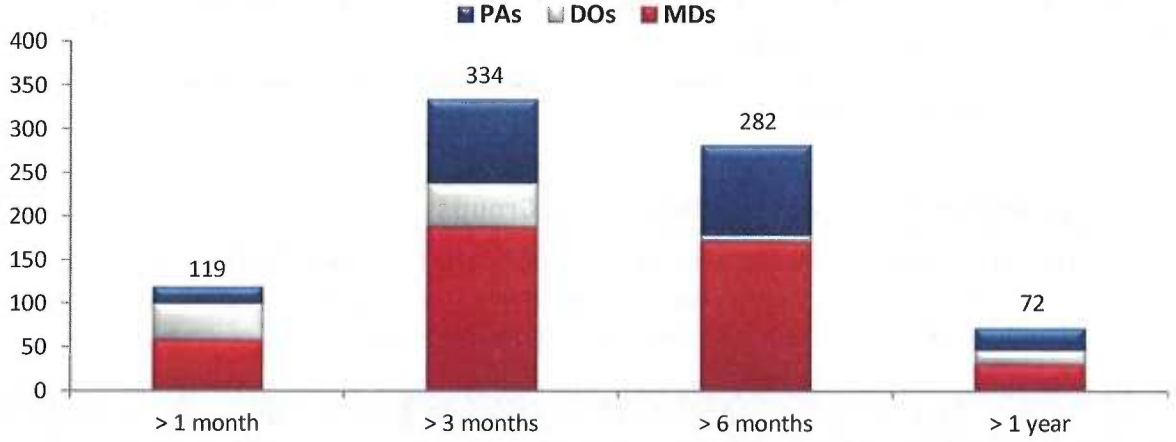
Survey Responses for Three Main Prescribing Groups

Three main prescriber groups were targeted: Medical Doctors, Doctors of Osteopathy, and Physician Assistants. Surveys were made available online starting April 29th, 2013. Data were collected on June 24th, 2013. The following tables show the results.

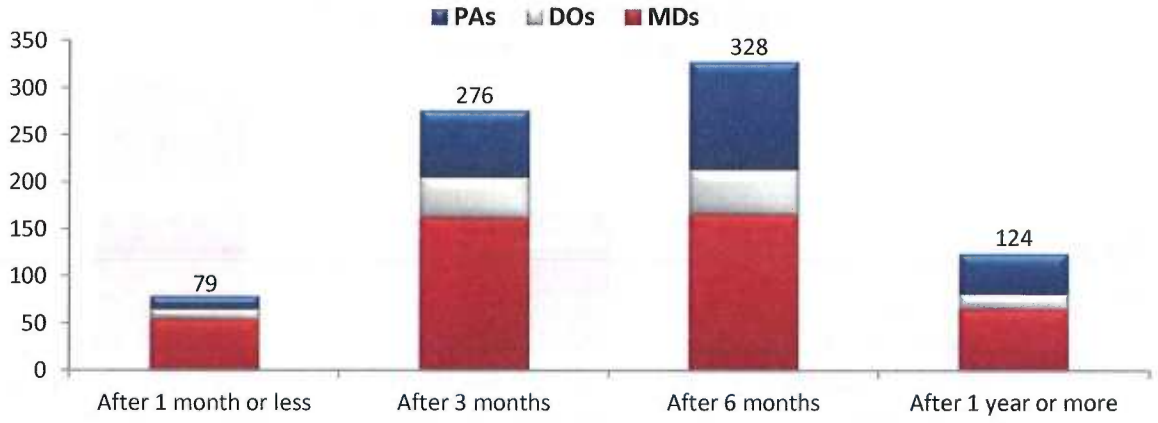
Distributing Board/Association	Surveys Sent	Responses Received
Oklahoma Medical Board	4,545 (3,388 MDs, 1,157 PAs)	690 (447 MDs, 243 PAs)
Oklahoma Osteopathic Association	1,200	117



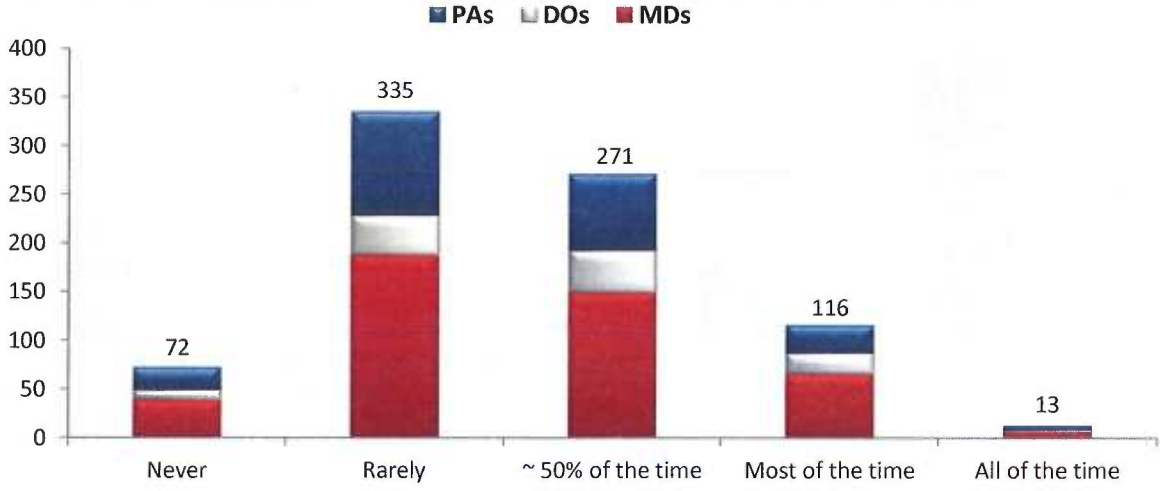
3. What do you classify as chronic pain? Pain lasting for:



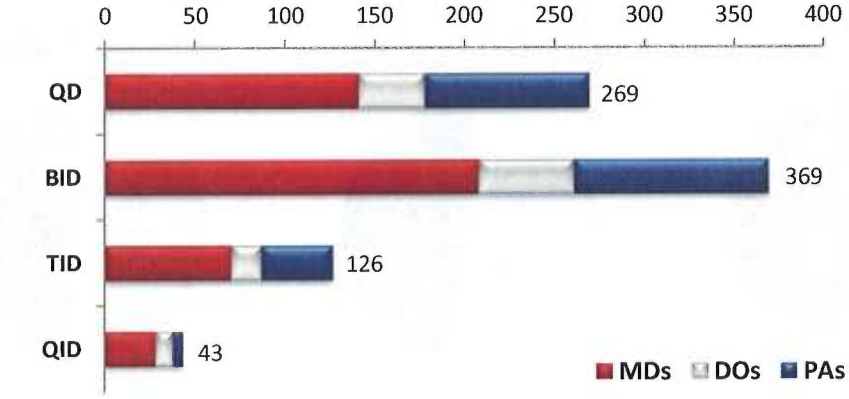
4. For patients with chronic pain, when do you think it's appropriate to initiate long acting medications?



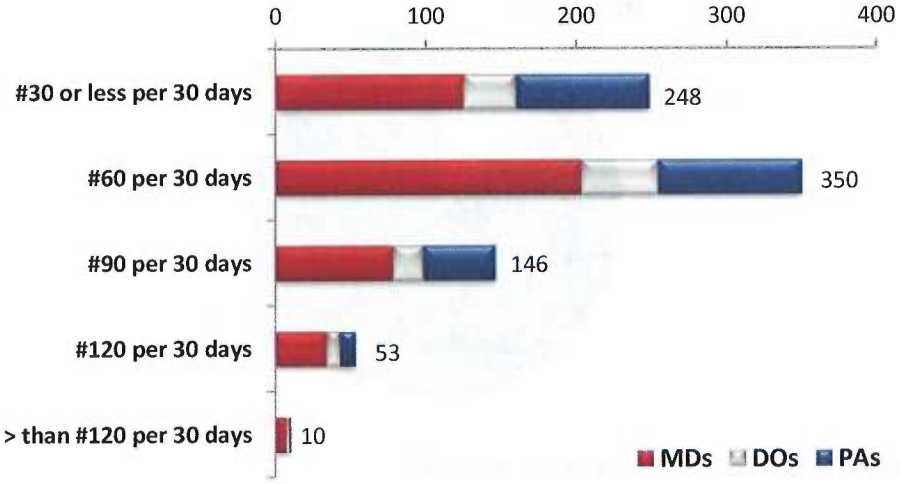
5. How often, in your clinical practice, is it appropriate for patients with chronic pain to be managed with immediate release instead of long acting narcotic analgesics?



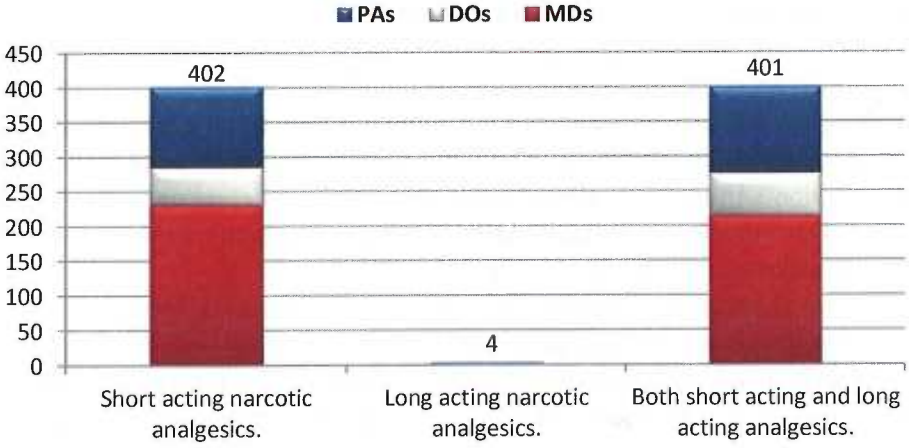
6. For your patients with chronic pain already managed with a long acting narcotic analgesic, what do you think is an appropriate frequency of rescue medication per day?



7. From clinical practice experience what quantity of short acting narcotic analgesics is usually required for chronic pain patients maintained on long acting narcotic analgesics?

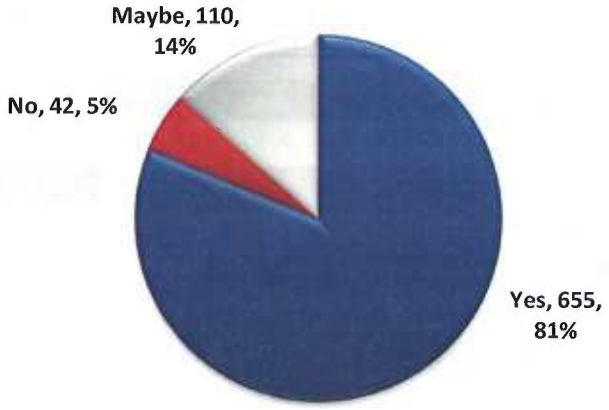


8. Which do you think is more likely to be abused?



9. Do you utilize random urine drug screening for your patients who are on narcotic analgesics?

10. Do you think that overprescribing of narcotic medications is a problem in Oklahoma?



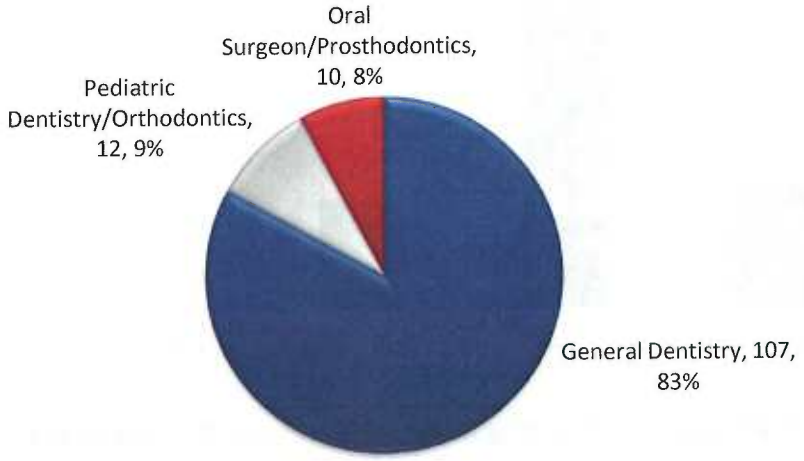
The survey responses yield the following observations:

1. The majority of prescribers prefer not to treat chronic pain diagnoses.
2. Most prescribers use the PMP; however, there are a number of prescribers who may not be familiar with the PMP or how to access it.
3. Most prescribers define chronic pain as pain lasting for more than 3-6 months, and also believe this is an appropriate timeframe to initiate long acting narcotic analgesics.
4. Approximately half of prescribers surveyed (400 of 807) think it is appropriate to treat chronic pain with immediate release narcotics for 50% of their patients or more.
5. Most prescribers think that patients maintained on long acting narcotic analgesics require QD to TID dosing of rescue medications per day, and no more than 90 tablets of short acting narcotic analgesics per month.
6. The majority of prescribers believe either short acting, or both short and long acting narcotic analgesics are likely to be abused.
7. Most prescribers agreed that narcotic overprescribing is a problem in Oklahoma; however, less than 50% of prescribers utilize random drug screening in their practice.

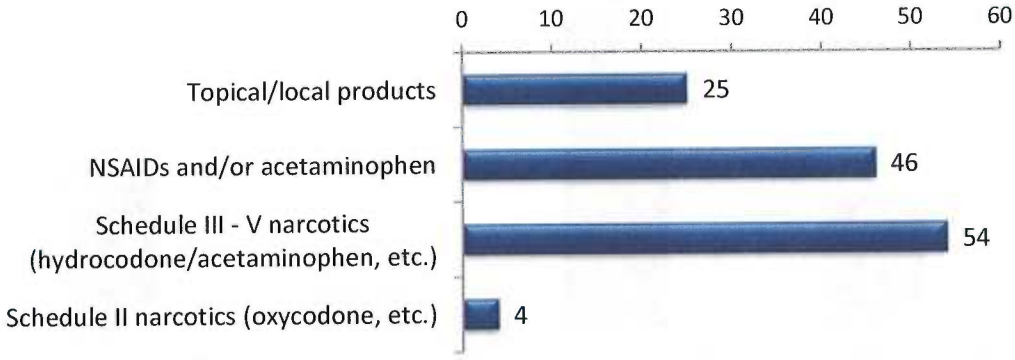
Survey Responses from Dentists

This survey was distributed via email by the Oklahoma Dental Association. Surveys were sent via email to 1,233 dentists by the Oklahoma Dental Association on May 13, 2013. Data were collected on June 24, 2013. A total of 129 surveys were completed.

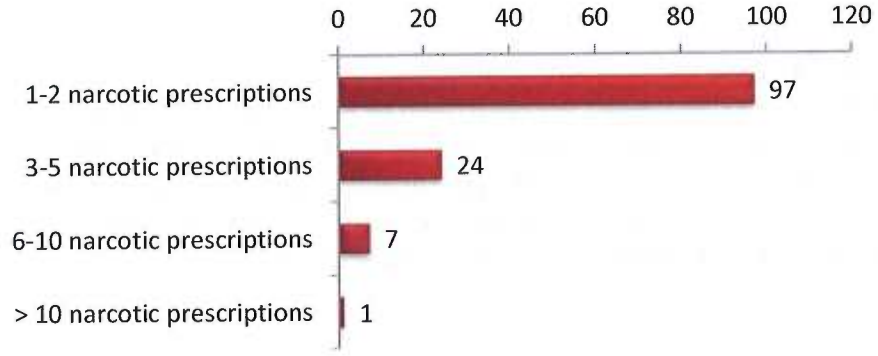
1. What best describes your dental practice?



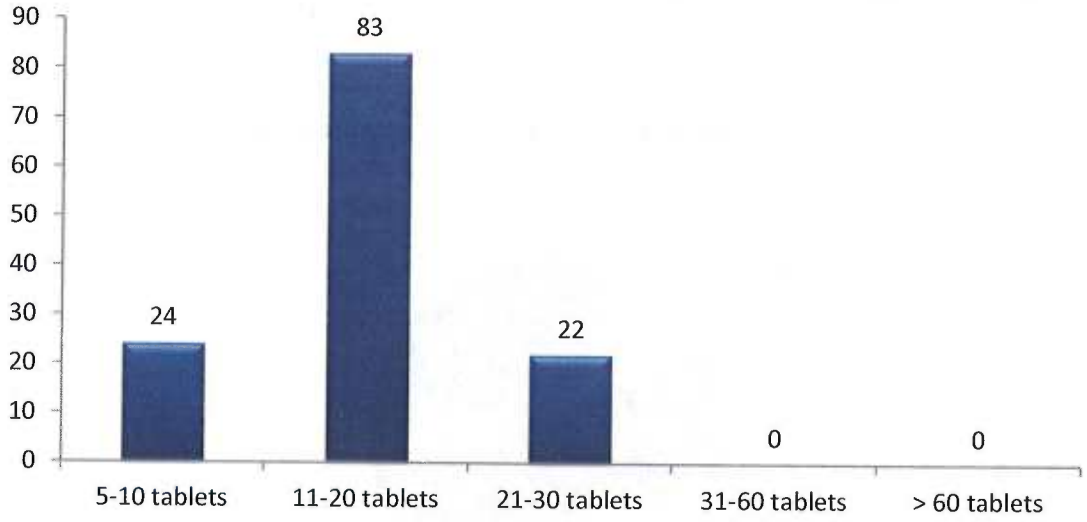
2. What types of analgesics do you use for the majority of your patients?



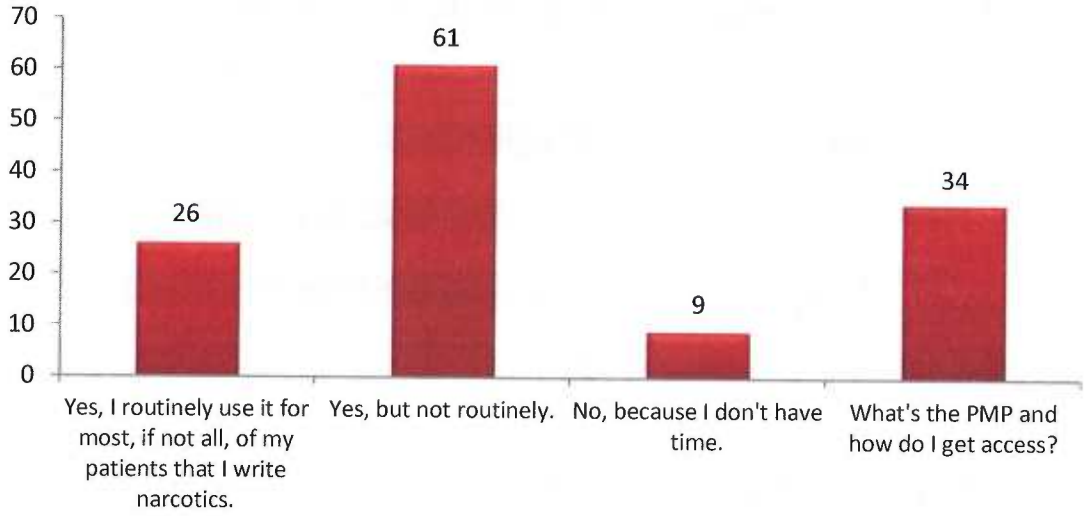
3. On an average day, how many narcotic prescriptions do you write?



4. What do you think is a sufficient quantity of narcotics for most of your patients?



5. Do you use the prescription drug monitoring program (PMP) in your daily practice?



The survey responses yield the following observations:

1. Schedule II narcotic analgesics are prescribed by few dental practitioners.
2. The majority of dental practitioners write 5 or less narcotic prescriptions per day, and when a narcotic prescription is written the quantity rarely exceeds 30 tablets.
3. Most prescribers use the PMP; however, there are a number of prescribers who may not be familiar with what the PMP is or how to access it.

Recommendations

The College of Pharmacy recommends the following:

1. Explore strategies to increase awareness/utility of the PMP by partnering with OBNDD, professional organizations, and/or educational institutions.
2. Implement a general educational initiative regarding appropriate prescribing of narcotic analgesics for all SoonerCare prescribers.
3. Targeted interventional initiative:
    a. Prescriber-specific comparison data and recommendations based prescriber profile will be sent to the top 50 prescribers.
    b. General information regarding appropriate narcotic prescribing will be sent to the top 25% narcotic prescribers.
4. Plan for sequential reduction of immediate release narcotic quantity per claim:
    a. All claims with quantities exceeding #240 units or greater in the first month will be rejected at the point of sale. The quantity limit will be reduced to #180 units in the following month, and so on reducing by 30 units per month, until the limit is reduced to a maximum of #120 per 30 days (4 units per day).
5. A manual prior authorization will be required for dosing in excess of the quantity limit.

Appendix I

Calendar Year 2012 Annual Review of Uloric® (Febuxostat) and Colcrys® (Colchicine)

Oklahoma Health Care Authority
July 2013

Current Prior Authorization Criteria

The prior authorization of Uloric® and Colcrys® was implemented in March 2012. The current approval criteria are as follows:

Uloric® (febuxostat) Prior Authorization Criteria:

1. Failure of allopurinol defined by persistent gouty attacks with serum urate levels below 6.5mg/dL.
2. Clinical reason why allopurinol is not a viable option for the member.
3. Quantity limit of #30 per 30 days will apply.

Colcrys® (colchicine) will have a free floating 2 days supply of 6 tablets per 365 days. Long term use of Colcrys® will require a petition and member must have:

1. Failure of allopurinol defined by persistent gouty attacks with serum urate levels below 6.5mg/dL.
2. Clinical reason why colchicine/probenecid would not be a viable option for the member.
3. Quantity limit of #60 per 30 days will apply for gout.
4. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Utilization of Uloric® and Colcrys®

Trends in Utilization: Uloric®

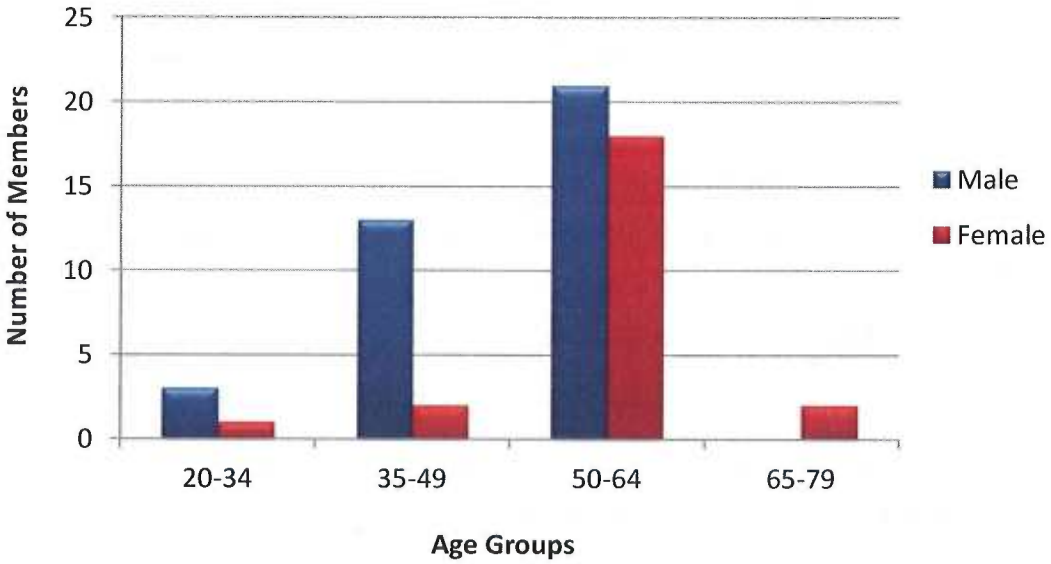
Calendar Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2011	65	283	$44,791.79	$158.27	$5.26	8,441	8,516
2012	60	233	$40,308.40	$173.00	$5.63	6,920	7,160
% Change	-7.70%	-17.70%	-10.00%	9.30%	7.00%	-18.00%	-15.90%
Total	-5	-50	-$4,483.39	$14.73	$0.37	-1,521	-1,356

Utilization Details of Uloric®: CY 2012

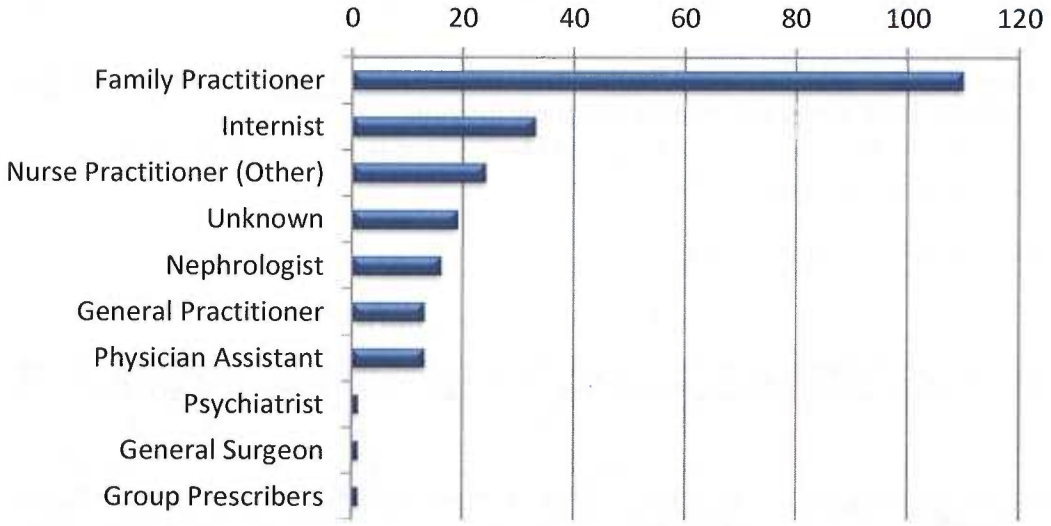
Medication Name	Claims	Members	Cost	Cost/Day	% Cost
Uloric® 40mg tablet	145	42	$25,100.95	$5.74	62.27%
Uloric® 80mg tablet	88	24	$15,207.45	$5.45	37.73%
TOTAL	233	60*	$40,308.40	$5.63	100.00%

*Total number of unduplicated members

Demographics of Members Utilizing Uloric®: CY 2012



Prescribers of Uloric® by Number of Claims: CY 2012



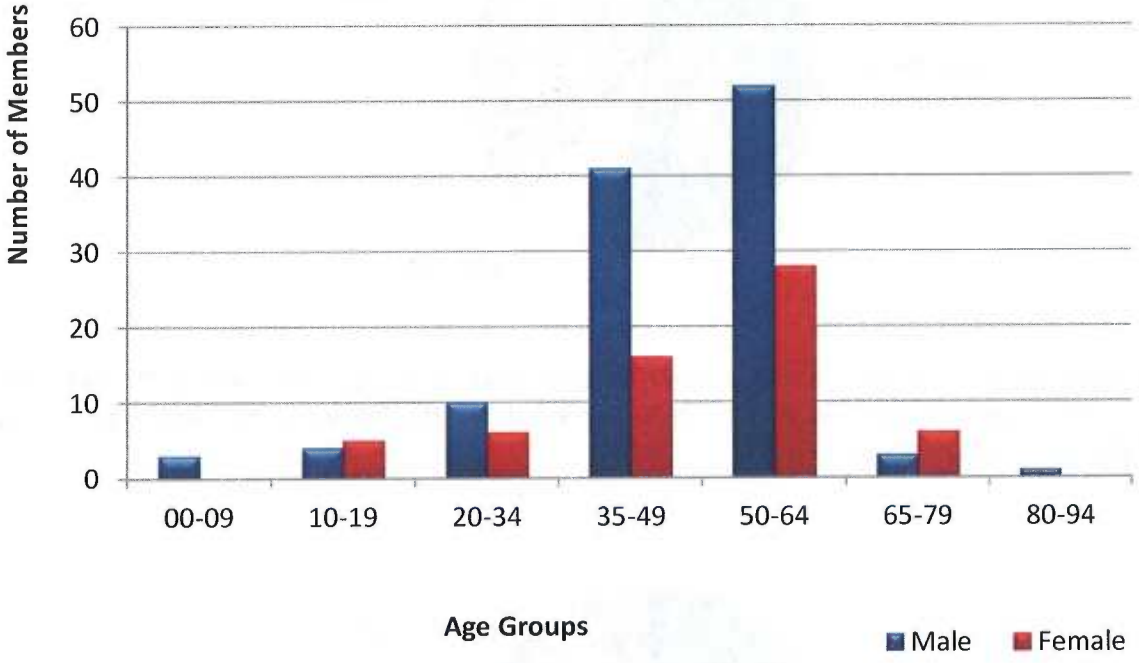
Trends in Utilization: Colcrys®

Calendar Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2011	181	395	$81,633.12	$206.67	$8.72	15,982	9,364
2012	175	412	$45,098.57	$109.46	$7.84	8,772	5,753
% Change	-3.30%	4.30%	-44.80%	-47.00%	-10.10%	-45.10%	-38.60%
Total	-6	17	-$36,534.55	-$97.21	-$0.88	-7,210	-3,611

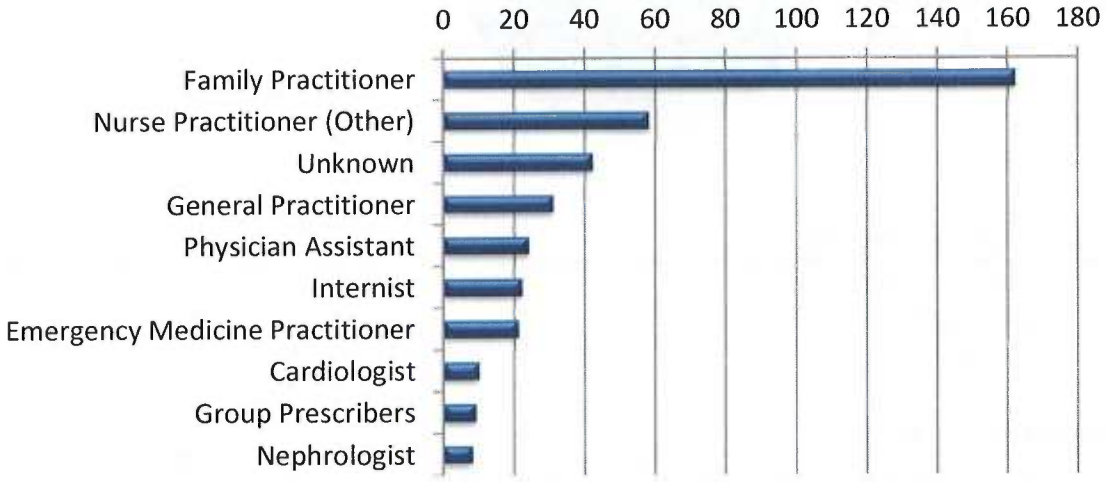
Utilization Details of Colcrys®: CY 2012

Medication Name	Claims	Members	Cost	Cost/Day	% Cost
Colcrys® 0.6mg tablet	412	175	$45,098.57	$7.84	100.00%

Demographics of Members Utilizing Colcrys®: CY 2012

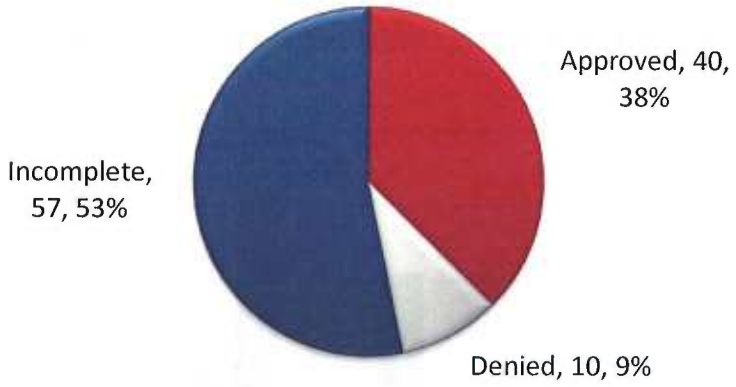


Prescribers of Colcrys® by Number of Claims: CY 2012

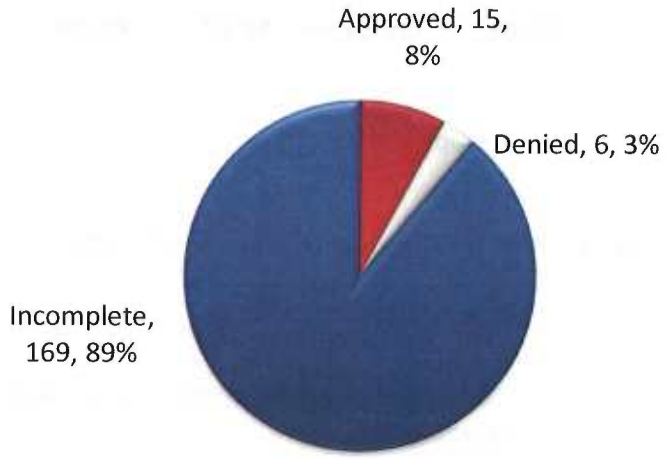


Prior Authorization of Uloric® and Colcrys®

There were a total of 107 petitions submitted for Uloric® during calendar year 2012. The following chart shows the status of the submitted petitions.



There were a total of 190 petitions submitted for Colcrys® during calendar year 2012. Colcrys® has a free floating 2 days supply of 6 tablets per 365 days. The following chart shows the status of the submitted petitions.



Market News and Update

Anticipated Patent Expirations:

- Uloric®- 2019
- Colcrys®- 2028

Recommendations

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

Appendix J

FDA & DEA Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA NEWS RELEASE

FDA takes action to protect consumers from dangerous medicines sold by illegal online pharmacies

International Operation Pangea VI combats online sale and distribution of unapproved prescription medicines

The U.S. Food and Drug Administration, in partnership with international regulatory and law enforcement agencies, took action this week against more than 9,600 websites that illegally sell potentially dangerous, unapproved prescription medicines to consumers. These actions include the issuance of regulatory warnings, and seizure of offending websites and $41,104,386 worth of illegal medicines worldwide.

The action occurred as part of the 6th annual International Internet Week of Action (IIWA), a global cooperative effort to combat the online sale and distribution of potentially counterfeit and illegal medical products. As part of this year's international effort – Operation Pangea VI – the FDA's Office of Criminal Investigations, in coordination with the United States Attorney's Office for the District of Colorado, seized and shut down 1,677 illegal pharmacy websites. The effort ran from June 18 to June 25, 2013.

Many of these websites appeared to be operating as a part of an organized criminal network that falsely purported its websites to be "Canadian Pharmacies." These websites displayed fake licenses and certifications to convince U.S. consumers to purchase drugs they advertised as "brand name" and "FDA approved." The drugs received as part of Operation Pangea were not from Canada, and were neither brand name nor FDA approved. These websites also used certain major U.S. pharmacy retailer names to trick U.S. consumers into believing an affiliation existed with these retailers.

The FDA's Office of Criminal Investigations Cybercrime Investigations Unit banner is now displayed on seized websites to help consumers identify them as illegal. Here are some examples:

- http://www.canadianhealthandcaremall.com/[2]
- http://www.walgreens-store.com[3]
- http://www.c-v-s-pharmacy.com[4]

During Operation Pangea VI, the largest Internet-based action of its kind, the FDA targeted websites selling unapproved and potentially dangerous prescription medicines that could pose significant public health risks. Products purchased from the websites targeted during Operation Pangea also bypassed existing safety controls required by the FDA, and the protections provided when used under a doctor's care. In general, prescription medicines, including those purchased online, should only be used with a valid prescription and under the supervision of a licensed health care provider.

The goal of Pangea VI, which involves law enforcement, customs, and regulatory authorities from 99 countries, was to identify the makers and distributors of illegal drug products and medical devices and remove these products from the supply chain.

Some of the medicines that were sold illegally by the websites[5] targeted during Operation Pangea VI included:

- Avandaryl: FDA-approved Avandaryl (glimepiride and rosiglitazone) is used to treat type 2 diabetes and to minimize potential associated risks, including edema caused by fluid retention, worsening the condition of the heart, or heart failure. Avandaryl must be prescribed by a certified healthcare provider and dispensed by a certified pharmacy with a medication guide explaining the potential risks.
- "Generic Celebrex": "Generic Celebrex" sold online is not an FDA-approved product. FDA-approved Celebrex (celecoxib) is a non-steroidal anti-inflammatory product used to treat the signs and symptoms of osteoarthritis and rheumatoid arthritis and to manage acute pain in adults. To minimize the potential

associated risks, including gastrointestinal bleeding, heart attack, or stroke, in some people with long term use, Celebrex must be dispensed with a medication guide explaining the potential risks.

- "Levitra Super Force" and "Viagra Super Force": While Levitra (vardenafil) and Viagra (sildenafil) are FDA-approved medicines used to treat erectile dysfunction (ED), Levitra Super Force and Viagra Super Force are not FDA-approved products and claim to contain dapoxetine. The FDA has not determined the safety or efficacy of dapoxetine. People with certain heart conditions should not take ED medicines containing vardenafil or sildenafil. There are also potentially dangerous drug interactions or serious adverse effects with these drugs, such as loss of hearing or vision.
- Clozapine: FDA-approved Clozaril (clozapine) is used to treat severe schizophrenia and is associated with potentially fatal agranulocytosis, a severely low (and dangerous) white blood cell count that can predispose patients to serious, life-threatening infections. To minimize potential risks, consumers who are prescribed FDA-approved Clozaril must be enrolled in a registry that ensures regular monitoring of their blood counts.

The FDA in collaboration with other federal agencies screened drug products received through selected International Mail Facilities during the IIWA. Preliminary findings show that certain drug products from abroad, such as antidepressants, hormone replacement therapies, sleep aids, and other drugs to treat erectile dysfunction, high cholesterol, and seizures were on the way to U.S. consumers.
In addition to health risks, these pharmacies pose non-health–related risks to consumers, including credit card fraud, identity theft, or computer viruses. The FDA encourages consumers to report suspected criminal activity at www.fda.gov/oci6.
The FDA provides consumers with information to identify an illegal pharmacy website and advice on how to find a safe online pharmacy through BeSafeRx: Know Your Online Pharmacy.

The IIWA is a collaborative effort between the FDA, INTERPOL, the World Customs Organization, the Permanent Forum of International Pharmaceutical Crime, Heads of Medicines Agencies Working Group of Enforcement Officers, the pharmaceutical industry, and national health and law enforcement agencies from 99 participating countries.

FDA NEWS RELEASE

For Immediate Release: June 28, 2013

FDA approves the first non-hormonal treatment for hot flashes associated with menopause

The U.S. Food and Drug Administration today approved Brisdelle (paroxetine)to treat moderate to severe hot flashes (vasomotor symptoms) associated with menopause. Brisdelle, which contains the selective serotonin reuptake inhibitor paroxetine mesylate, is currently the only non-hormonal treatment for hot flashes approved by the FDA.
There are a variety of FDA-approved treatments for hot flashes, but all contain either estrogen alone or estrogen plus a progestin.
Hot flashes associated with menopause occur in up to 75 percent of women and can persist for up to five years, or even longer in some women. Hot flashes are not life-threatening, but the symptoms can be very bothersome, causing discomfort, embarrassment and disruption of sleep.
The safety and effectiveness of Brisdelle were established in two randomized, double-blind, placebo-controlled studies in a total of 1,175 postmenopausal women with moderate to severe hot flashes (a minimum of seven to eight per day or 50-60 per week). The treatment period lasted 12 weeks in one study and 24 weeks in the other study. The results showed that Brisdelle reduced hot flashes compared to placebo. The mechanism by which Brisdelle reduces hot flashes is unknown.

The most common side effects in patients treated with Brisdelle were headache, fatigue, and nausea/vomiting.
Brisdelle contains 7.5 mg of paroxetine and is dosed once daily at bedtime. Other medications such as Paxil and Pexeva contain higher doses of paroxetine and are approved for treating conditions such as major depressive disorder, obsessive-compulsive disorder, panic disorder and generalized anxiety disorder. All medications that are approved for treating depression, including Paxil and Pexeva, have a Boxed Warning about an increased risk of suicide in children and young adults. Because Brisdelle contains the same active ingredient as Paxil and Pexeva, a Boxed Warning about suicidality is included in the Brisdelle label.
Additional labeled warnings include a possible reduction in the effectiveness of tamoxifen if both medications are used together, an increased risk of bleeding, and a risk of developing serotonin syndrome (signs and symptoms can include confusion, rapid heart rate, and high blood pressure). Brisdelle will be dispensed with a Medication Guide that informs patients of the most important information about the medication. The Medication Guide will be distributed to patients each time the prescription is refilled.
Consumers and health care professionals are encouraged to report adverse reactions from the use of Brisdelle to the FDA MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch2 or by calling 1-800-FDA-1088.
Brisdelle and Pexeva are marketed by Noven Therapeutics, LLC., based in Miami, Fla. Paxil is marketed by GlaxoSmithKline, based in Philadelphia, Pa.

FDA NEWS RELEASE

For Immediate Release: June 20, 2013

FDA approves Plan B One-Step emergency contraceptive for use without a prescription for all women of child-bearing potential

Today, the U.S. Food and Drug Administration announced it has approved the use of Plan B One-Step (levonorgestrel) as a nonprescription product for all women of child-bearing potential. This action complies with the April 5, 2013 order of the United States District Court in New York to make levonorgestrel-containing emergency contraceptives available as an over-the-counter (OTC) product without age or point-of-sale restrictions.
Plan B One-Step is an emergency contraceptive intended to reduce the chance of pregnancy following unprotected sexual intercourse or a known or suspected contraceptive failure (e.g., condom). Plan B One-Step is a single-dose pill (1.5 mg tablet) that is effective in decreasing the chance of pregnancy and should be taken as soon as possible within three days after unprotected sex.
On June 10, 2013, the agency notified a United States District Court judge in New York of its intent to comply with the court's April 5, 2013 order instructing the FDA to make levonorgestrel-containing emergency contraceptives available as an over-the-counter (OTC) product without age or point-of-sale restrictions. To comply, the FDA asked Teva Women's Health, the manufacturer of Plan B One-Step, to submit a supplemental application seeking approval of the one-pill product to be made available without any restrictions. The agency has fulfilled its commitment to the court by promptly completing its review and approval of the supplemental application.
Plan B One-Step was first approved in July 2009 for use without a prescription for women age 17 and older and as a prescription-only option for women younger than age 17. In April 2013, the product was approved for nonprescription use for women as young as 15. With this approval, the product is now available without a prescription for use by all women of reproductive potential.
The product contains higher levels of a hormone found in some types of daily use oral hormonal contraceptive pills and works in a similar way to these contraceptive pills by stopping ovulation and therefore preventing pregnancy.

Plan B One-Step will not stop a pregnancy when a woman is already pregnant and there is no medical evidence that the product will harm a developing fetus.
The product will not protect a woman from HIV/AIDS or other sexually transmitted diseases. It is important that young women who are sexually active see a health care provider for routine checkups. The health care provider should counsel the patient about, and test them for sexually transmitted diseases, discuss effective methods of routine birth control, and answer any other questions the patient may have.
Some women taking Plan B One-Step have reported experiencing the following side effects: nausea, vomiting, stomach pain, headache, dizziness and breast tenderness. These are similar to the side effects of regular prescription-only birth control pills.

FDA NEWS RELEASE

For Immediate Release: June 21, 2013

FDA approves Vibativ for hospitalized patients with bacterial pneumonia

The U.S. Food and Drug Administration today expanded the approved use of the antibiotic Vibativ (telavancin) to treat patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by Staphylococcus aureus. Vibativ should be used for the treatment of HABP/VABP only when alternative treatments are not suitable.
Bacterial pneumonia is a lung infection that can be caused by many different types of bacteria. Vibativ is approved only to treat S. aureus, not other bacteria that cause pneumonia. HABP/VABP, also known as nosocomial pneumonia, is a particularly serious lung infection because patients in the hospital and especially those on ventilators are often already very sick and usually cannot fight the infection.
Vibativ's safety and effectiveness to treat HABP/VABP were evaluated in 1,532 patients enrolled in two clinical trials. Patients were randomly assigned to receive Vibativ or vancomycin, another antibiotic approved by the FDA.
The trials measured the percentage of patients who died from any cause (all-cause mortality) 28 days after the initiation of treatment. Among patients presumed to test positive for S. aureus taken at baseline, mortality rates were comparable between the Vibativ and vancomycin treatment arms, except for patients who had pre-existing kidney problems.
During clinical trials, more patients with pre-existing kidney problems treated with Vibativ died compared to those treated with vancomycin. Vibativ can also cause new or worsening kidney problems in patients. This information has been added to Vibativ's Boxed Warning.
Diarrhea was the most common side effect identified in the clinical trials.
Vibativ was approved in 2009 to treat complicated skin and skin structure infections. It is marketed by Theravance, Inc., based in San Francisco, Calif.

Safety Announcements

FDA Drug Safety Communication: FDA is investigating two deaths following injection of long-acting antipsychotic Zyprexa Relprevv (olanzapine pamoate)

[6-18-2013] The U.S. Food and Drug Administration (FDA) is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa Relprevv (olanzapine pamoate). The patients died 3-4 days after receiving an appropriate dose of the drug, well after the 3-hour post-injection monitoring period required under the Zyprexa Relprevv Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death. High doses of olanzapine can cause delirium, cardiopulmonary arrest, cardiac arrhythmias, and reduced level of consciousness ranging from sedation to coma.

FDA is providing this information to health care professionals while it continues its investigation. If therapy with Zyprexa Relprevv is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations. Patients and caregivers should talk to their health care professional(s) about any questions or concerns.
Under the REMS, patients are required to receive the Zyprexa Relprevv injection at a REMS-certified health care facility, to be continuously monitored at the facility for at least 3 hours following an injection, and to be accompanied home from the facility. The Zyprexa Relprevv label contains warnings about the risk of post-injection delirium sedation syndrome (PDSS), a serious condition in which the drug enters the blood too fast following an intramuscular injection, causing greatly elevated blood levels with marked sedation (possibly including coma) and/or delirium. In the clinical trials supporting the approval of Zyprexa Relprevv, cases of PDSS were observed within 3 hours after administration of Zyprexa Relprevv, but there were no deaths due to PDSS. These two patients died 3-4 days after receiving an appropriate dose of the drug, and it is not clear whether they died from PDSS.
At this time, FDA is continuing to evaluate these deaths and will provide an update when more information is available.

Safety Announcements

Vecuronium Bromide For Injection by Sagent Pharmaceuticals, Inc.: Recall - Elevated Impurity Result Detected

[UPDATE 06/13/2013] Sagent Pharmaceuticals Expands a Nationwide Voluntary Recall to All Lots of Vecuronium Bromide for Injection, 10mg Single Use Vials Manufactured by Mustafa Nevzat (MN Pharmaceuticals).
[Posted 06/10/2013]
AUDIENCE: Pharmacy, Patient, Health Professional
ISSUE: Sagent Pharmaceuticals, Inc. announced the voluntary nationwide recall of three lots of Vecuronium Bromide for Injection 10mg (NDC number 25021-657-10) manufactured by Mustafa Nevzat Ilac Sanayii A.S. (MN Pharmaceuticals) and distributed by Sagent. Sagent has initiated this voluntary recall of Vecuronium Bromide for Injection to the user level due to the discovery of an elevated impurity result detected during routine quality testing of stability samples at the 18-month interval. The elevated impurity result has the potential to result in prolonged neuromuscular blockade for critically ill patients with renal failure.
BACKGROUND: Vecuronium Bromide for Injection is a neuromuscular blocking agent indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation and is supplied in a glass vial. The lot numbers being recalled are: 11I30481A, 11I30721A and 11I32581A, which were distributed to hospitals, wholesalers and distributors nationwide from January 2012 through May 2012. Sagent is not aware of any adverse patient events resulting from the use of this product and is continuing its diligent investigation of the situation.
RECOMMENDATION: Sagent's Distributor, DDN, is notifying Sagent's distributors and customers by fax, email and certified mail and is arranging for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return all recalled lots of the product. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[1]
- Download form[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Safety Announcements

Warfarin 2 mg Tablets by Zydus Pharmaceuticals USA Inc.: Recall - Due to Oversized Tablets

[Posted 06/12/2013]

AUDIENCE: Pharmacy, Patient, Health Professional

ISSUE: Zydus Pharmaceuticals USA Inc. is voluntarily recalling one lot of Warfarin 2 mg Tablets, Lot #MM5767, expiration date June 2014 to the retail level. Four tablets of Warfarin 2 mg Tablets, Lot MM5767, have been found to be oversized in one product complaint.

Ingestion of a greater than intended dose of Warfarin, could lead to an increased pharmacological effect of warfarin. As a result, patients would be more likely to develop bleeding as an adverse reaction and in some patients that bleeding into a critical organ (mostly the central nervous system) could be fatal. The risk of bleeding is increased if overdosing is repeated continuously on a daily basis.

BACKGROUND: The product is used as prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE), prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement and reduction in the risk of death, recurrent myocardial infarction (MI), and thromboembolic events such as stroke or systemic embolization after myocardial infarction. Product is packaged in HDPE Bottle of 1000's count, which may have been dispensed to patients in smaller bottles. The only lot affected of Warfarin 2 mg Tablets being recalled is Lot MM5767.

The product can be identified by its NDC #6838205310. The product was distributed nationwide in the United States to wholesalers/distributors, retailers and mail order providers, from November 2012 to December 2012.

RECOMMENDATION: Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this particular lot of Warfarin 2 mg Tablets. Anyone with an existing inventory of this particular Lot MM5767 of Warfarin 2 mg Tablets should stop use and distribution, quarantine the recalled lots immediately and call INMAR at 1-800-967-5952 between the hours of 7 a.m. to 4 p.m. CST, Monday through Friday, to arrange for their return. In case patients have tablets of this lot of product, make sure all the tablets are of same size and if unsure, patients should consult their dispensing pharmacy.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Current Drug Shortages Index (as of July 1, 2013):

The information provided in this section is provided voluntarily by manufacturers.

Acetylcysteine Inhalation Solution
Acyclovir Sodium Injection (initial posting 11/13/2012)
Alfentanil Hydrochloride (Alfenta) (initial posting 1/23/2012)
Alteplase (Cathflo Activase) (initial posting 1/27/2012) UPDATED 6/20/2013
Amikacin Injection
Amino Acid Products (initial posting 2/14/2012)
Aminocaproic Acid Injection (initial posting 3/8/2013)
Aminophylline (initial posting 12/10/2012)
Ammonium Chloride Injection (initial posting 3/8/2013)
Amytal Sodium Injection (initial posting date 1/31/2013)
Atracurium Besylate (initial posting 2/27/2012)
Atropine Sulfate Injection UPDATED 7/1/2013
Bacteriostatic 0.9% Sodium Chloride (initial posting 9/10/2012)
Barium Sulfate for Suspension (initial posting 10/12/2012) UPDATED 6/21/2013
Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride (Helidac) (initial posting 3/8/2012)
Bumetanide Injection (initial posting 6/21/2012)
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection
Buprenorphine Hydrochloride (Buprenex) Injection
Caffeine, anhydrous (125 mg/mL) and Sodium benzoate (125 mg/mL)
Caffeine and Ergotamine Tartrate Tablet (Cafergot) (initial posting 3/8/2012)
Calcium Chloride Injection (initial posting 12/13/2012) UPDATED 7/1/2013
Calcium Gluconate Injection (initial posting 1/10/2013) UPDATED 7/1/2013
Chromic Chloride Injection
Cidofovir Injection (initial posting 2/15/2013)
Citric Acid; Gluconolactone; Magnesium Carbonate Solution (RENACIDIN); Irrigation (initial posting 6/30/2012) UPDATED 6/26/2013
Copper Injection (Cupric Chloride) (initial posting 4/25/2013)
Cyanocobalamin Injection (initial posting 1/25/2013) UPDATED 7/1/2013
Daunorubicin Hydrochloride Solution for Injection
Denileukin diftitox (Ontak) (initial posting 9/22/2012)
Desmopressin Acetate (DDAVP) Injection (initial posting 5/7/2013)
Dexamethasone Sodium Phosphate Injection(initial posting 1/15/2013) UPDATED 6/26/2013
Dexrazoxane Injection (Zinecard)
Dextrose Injection (initial posting 5/23/2012)
Diazepam Injection
Dipyridamole Injection (initial posting 7/24/2012)
Dobutamine Hydrochloride Injection (initial posting 4/26/2013)
Doxorubicin (adriamycin) lyophilized powder (initial posting 12/2/2011)
Doxycycline Hyclate (initial posting 1/18/2013)
Edetate Calcium Disodium (Calcium Disodium Versenate) Injection (initial posting 10/12/2012)
Epinephrine Injection (initial posting 4/27/2012)
Epinephrine 1mg/mL (Preservative Free) (initial posting 6/21/2012)
Ethiodol (Ethiodized Oil) Ampules
Etomidate (Amidate) Injection (initial posting 2/9/2012)

Fentanyl Citrate (Sublimaze) Injection UPDATED 6/28/2013
Fluphenazine Decanoate Injection 4/25/2013
Fluphenazine Hydrochloride Injection 4/29/2013
Fluticasone Propionate and Salmeterol (Advair HFA) Inhalation Aerosol (initial posting date) - 10/17/2012)
Fosphenytoin Sodium (Cerebyx) Injection (initial posting 3/30/2012)
Furosemide Injection (initial posting 6/20/2012)
Gabapentin Enacarbil (Horizant) ER Tablet (initial posting 4/16/2013)
Gallium Nitrate (Ganite) Injection (initial posting 4/4/2012)
Heparin Sodium Premixes (initial posting 7/5/2012)
Hydromorphone Hydrochloride (Dilaudid) Injection (initial posting 3/7/2012) UPDATED 6/25/2013
Hydromorphone Hydrochloride Tablets (initial posting 2/19/2013)
Ibandronate Sodium (Boniva) Injection (initial posting 6/6/2012)
Intravenous Fat Emulsion
Isoniazid; Rifampin (Rifamate) Capsules 3/15/2013
Ketorolac Tromethamine Injection UPDATED 6/28/2013
Leucovorin Calcium Lyophilized Powder for Injection UPDATED 6/25/2013
Leuprolide Acetate Injection UPDATED 6/25/2013
Levothyroxine sodium (Levoxyl) Tablets (initial posting date - 3/15/2013)
Lidocaine Hydrochloride (Xylocaine) Injection (initial posting date - 2/22/2012) UPDATED 7/1/2013
Liotrix (Thyrolar) Tablets
Lomustine Capsules (initial posting date - 5/9/2013)
Lorazepam (Ativan) Injection
Magnesium Sulfate Injection
Mannitol (Osmitrol, Resectisol) Injection (initial posting date - 12/21/2011)
Mecasermin [rDNA origin] (Increlex) Injection (initial posting date - 4/26/2013)
Methazolamide (Glauctabs, Neptazane) Tablets
Methoxsalen 1% Topical Lotion (Oxsoralen)
Methyldopate Hydrochloride Injection
Methylin Chewable Tablets (initial posting date - 2 /19/2013)
Methylphenidate Hydrochloride ER Tablets (initial posting date - 2/19/2013)
Methylphenidate Hydrochloride Tablets (initial posting date - 2/19/2013)
Metoclopramide (Reglan) Injection
Midazolam Hydrochloride (Versed) Injection UPDATED 7/1/2013
Morphine Sulfate Injection UPDATED 6/25/2013
Morphine Sulfate (Astramorph PF, Duramorph, Infumorph) Injection (Preservative Free)
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine HCl (Nubain) Injection (initial posting 5/15/2012)
Naloxone (Narcan) Injection (initial posting 2/22/2012)
Neostigmine Methylsulfate Injection (initial posting 1/14/2013)
Nitroglycerin Ointment USP, 2% (Nitro-Bid) (Initial posting 10/23/2012)
Ondansetron (Zofran) Injection 2 mg/mL UPDATED 6/25/2013
Oseltamivir Phosphate (Tamiflu) for Oral Suspension (6mg/mL 60 mL) (Initial posting 1/10/2013)
Pancuronium Bromide Injection
Papaverine Hydrochloride Injection (initial posting 12/17/2012) UPDATED 7/1/2013
Peginterferon Alfa-2a (Pegasys) Injection - Prefilled Syringes (initial posting 3/26/2012)
Pentamidine Isethionate Inhalant (NebuPent) (initial posting 8/27/2012)
Pentamidine Isethionate for Injection (Pentam 300) (initial posting 8/27/2012)
Phosphate Injection (Glycophos) (initial posting 5/29/2013)

Pilocarpine HCL Opthalmic Gel 4% (Pilopine HS) (initial posting 6/1/2012)
Potassium Acetate Injection, USP 2 mEq/mL
Potassium Chloride Injection (initial posting 5/15/2012)
Potassium Phosphate Injection
Procainamide HCL Injection
Prochlorperazine Injection (initial posting 1/30/2012)
Promethazine Injection (initial posting 2/10/2012) UPDATED 6/25/2013
Reserpine Tablets (initial posting 4/17/2013)
Rifampin for Injection (initial posting 3/22/2013)
Secretin Synthetic Human (ChiRhoStim) Injection (ChiRhoStim) (initial posting 6/15/2012)
Selenium Injection
Sincalide (Kinevac) Injection (initial posting 6/21/2013) New!!
Sodium Acetate Injection (initial posting 1/31/2012)
Sodium Benzoate and Sodium Phenylacetate (Ammonul) Injection
Sodium Bicarbonate Injection (initial posting 3/20/2012)
Sodium Chloride 0.9% (5.8mL and 20mL) (initial posting 5/4/2012)
Sodium Chloride 23.4%
Sodium Phosphate Injection UPDATED 7/1/2013
Succinylcholine (Anectine, Quelicin) Injection (initial posting 8/17/2012)
Sufentanil Citrate (Sufenta) Injection
Sulfamethoxazole 80mg/Trimethoprim 160mg/ml Injection (SMX/TMP) (Bactrim)
Technetium Tc99m Bicisate for Injection (Neurolite) (initial posting 5/4/2012)
Technetium Tc99m Sestamibi Kit for Injection (Cardiolite) (initial posting 5/4/2012)
Telavancin (Vibativ) Injection
Tetracycline Capsules
Thiotepa (Thioplex) for Injection
Ticarcillin disodium/Clavulanic Potassium Injection (Timentin) (initial posting 8/16/12)
Ticlopidine (Ticlid) Tablets
Tobramycin Solution for Injection
Trace Elements (initial posting 1/24/2013)
Tromethamine (Tham) Injection (initial posting 5/2/2012)
Verapamil Hydrochloride Injection, USP (initial posting 4/17/2013)
Vinblastine Sulfate Injection (initial posting 1/31/2012)
Vitamin A Palmitate (Aquasol A)
Zinc Injection (initial posting 2/15/2012)