Drug Utilization Review Board

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

Wednesday
December 11, 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 – December 11, 2013**

DATE: December 2, 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 November 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

Announcement Regarding DUR Board Meeting Time and Location – See Appendix B

Action Item – Update on Medication Coverage Authorization Unit, RetroDUR, and Vote to Prior Authorize Ketoconazole Oral Tablets – See Appendix C

Action Item – Vote to Update the Antihypertensive Product Based Prior Authorization Category and Prior Authorize Epaned™ – See Appendix D

Action Item – Vote to Prior Authorize Zetonna® – See Appendix E

Action Item – Vote to Prior Authorize Rescula® and Simbrinza™ – See Appendix F

Action Item – Vote to Prior Authorize Sklice® – See Appendix G

Action Item – Fiscal Year 2013 Annual Review of Advair®, Symbicort®, Dulera®, and 30 Day Notice to Prior Authorize Breo™ Ellipta™ – See Appendix H

FDA and DEA Updates – See Appendix I

Future Business

Adjournment to Proposed Executive Session as Recommended by the General Counsel and Authorized by the Open Meetings Act, Okla. State. § 307 (8) (4), (7). The Executive Session will take place at Iron Starr, 3700 N. Shartel, Oklahoma City, OK 73118.

Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting – December 11, 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. November 13, 2013 DUR Minutes – Vote
   B. November 13, 2013 DUR Recommendation Memorandum

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

4. **Announcement Regarding DUR Board Meeting Time and Location - See Appendix B**

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

5. **Action Item – Update on Medication Coverage Authorization Unit, RetroDUR, and Vote to Prior Authorize Ketoconazole Oral Tablets – See Appendix C**
   A. Medication Coverage Activity Report for November 2013
   B. Pharmacy Help Desk Activity Report for November 2013
   C. Retrospective Drug Utilization Review Report for July, August, and September
   D. Vote to Prior Authorize Ketoconazole Oral Tablets

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

6. **Action Item – Vote to Update the Antihypertensive Product Based Prior Authorization Category and Prior Authorize Epaned™ – See Appendix D**
   A. COP Recommendations

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

7. **Action Item – Vote to Prior Authorize Zetonna® – See Appendix E**
   A. COP Recommendations

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

8. **Action Item - Vote to Prior Authorize Rescula® and Simbrinza™ – See Appendix F**
   A. COP Recommendations

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

9. Action Item - Vote to Prior Authorize Sklice® – See Appendix G

A. COP Recommendations

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

10. Fiscal Year 2013 Annual Review of Advair®, Symbicort®, Dulera®, and 30 Day Notice to Prior Authorize Breo™ Ellipta™ – See Appendix H

A. Current Prior Authorization Criteria
B. Prior Authorization Review
C. Market News and Updates
D. Product Summary
E. COP Recommendations
F. Utilization Details
G. Product Details

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

12. FDA and DEA Updates – See Appendix I

13. Future Business

14. Adjournment to Proposed Executive Session as Recommended by the General Counsel and Authorized by the Open Meetings Act, Okla. State. § 307 (8) (4), (7). The Executive Session will take place at Iron Starr, 3700 N. Shartel, Oklahoma City, OK 73118.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF NOVEMBER 13, 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	
Michyla Adams, Pharm.D.; Clinical Pharmacist	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Bethany Holderread, Pharm. D., Clinical Coordinator	x	
Shellie Keast, Ph.D.; Clinical Assistant Professor	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	
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Jo'Nel Weber, Pharm.D.; Clinical Pharmacist		x
Graduate Students: Tim Pham	x	
Visiting Pharmacy Student(s): Stefan Miranov, Daniel Vo	x	

	PRESENT	ABSENT
Marlene Asmussen, R.N., Population Care Management Director		x
Nico Gomez, Chief Executive Officer		x
Chris Le, Pharm.D.; Clinical Pharmacist Consultant	x	
Sylvia Lopez, M.D., FAAP, Chief Medical Officer		x
Ed Long, Chief Communications Officer		x
Jennie Melendez, Marketing Coordinator	x	
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	x	
Rebecca Pasternik-Ikard, Deputy State Medicaid Director		x
Jill Ratterman, D.Ph.; Pharmacy Specialist	x	
Garth Splinter, M.D., M.B.A.; Medicaid Director		x
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:		
Jon Maguire, GSK	Clint Degner, Novartis	Sharon Jackson, GSK
Don Kempin, Novo Nordisk	Michael Spence, Novartis	Rod Hudson, Takeda
Charlene Kaiser, Amgen	Audrey Rattan, Otsuka	Jim Chapman, Abbvie
Brian Maves, Pfizer	Joe Summers, UCB	Bob Gustafson, Lundbeck
Jim Fowler, Astra Zeneca	Deitra Macy, DDI	Tone Jones, Sunovion
Warren Tayes , Merck	Jesse Lewis , BMS	John Omick, Lundbeck
Patrick Harvey, Walgreens	Mai Duong, Novartis	
Thomas Fillers, Novartis	Janie Huff, Takeda	

PRESENT FOR PUBLIC COMMENT:	
Karen Campbell	Allergan

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 6 Karen Campbell

ACTION: NONE REQUIRED

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

3A: SEPTEMBER 11, 2013 DUR MINUTES

3B: SEPTEMBER 11, 2013 DUR RECOMMENDATION MEMORANDUM

3C: OCTOBER 9, 2013 DUR RECOMMENDATIONS MEMORANDUM

Dr. Kuhls moved to approve September DUR Minutes; seconded by Dr. Harrell

Dr. Bell moved to approve October DUR Minutes; seconded by Ms. Varalli-Claypool

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **VOTE ON 2014 MEETING DATES**

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 5: **UPDATE ON DUR/MEDICATION COVERAGE AUTHORIZATION UNIT/SAFETY ALERTS AND 30 DAY NOTICE TO PRIOR AUTHORIZE KETOCONAZOLE ORAL TABLETS**

5A: MEDICATION COVERAGE ACTIVITY: OCTOBER 2013

5B: PHARMACY HELP DESK ACTIVITY: OCTOBER 2013

5C: VALPORATE PRODUCT UPDATE

5D: KETOCONAZOLE SAFETY COMMUNICATION AND 30 DAY NOTICE TO PRIOR AUTHORIZE KETOCONAZOLE ORAL TABLETS

5E: UPDATE ON SAFETY ALERTS

Materials included in agenda packet; presented by Dr. Holderread

Dr. Muchmore states “off label use of treating Cushing’s disease when other modalities are not available.” Dr. Kuhls recommends “making sure those pediatric patients that really need Synagis get it.”

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF BOTULINUM TOXINS**

6A: CURRENT PRIOR AUTHORIZATION CRITERIA
6B: UTILIZATION REVIEW
6C: PRIOR AUTHORIZATION REVIEW
6D: MARKET NEWS AND UPDATES
6E: COP RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Le
Dr. Winegardener recommends "Change to five episodes on medications, use Botox before surgery."
Dr. Winegardener moved to approve with modifications; seconded by Kuhls
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF PRENATAL VITAMINS
7A: CURRENT PRIOR AUTHORIZATION CRITERIA
7B: UTILIZATION REVIEW
7C: PRIOR AUTHORIZATION REVIEW
7D: COP RECOMMENDATIONS
7E: UTILIZATION DETAILS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF ANTIHYPERTENSIVE MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE EPANED™
8A: CURRENT PRIOR AUTHORIZATION CRITERIA
8B: UTILIZATION REVIEW
8C: PRIOR AUTHORIZATION REVIEW
8D: MARKET NEWS AND UPDATES
8E: PRODUCT SUMMARY
8F: COP RECOMMENDATIONS
8G: UTILIZATION DETAILS
8H: PRODUCT DETAILS
Materials included in agenda packet; presented Dr. Holderread
Dr. Muchmore recommends "use of Epaned requires reason why crushed tablets cannot be used for 7 years and older."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF NASAL ALLERGY MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE ZETONNA®
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION REVIEW
9C: PRIOR AUTHORIZATION REVIEW
9D: MARKET NEWS AND UPDATES
9E: COP RECOMMENDATIONS
9F: UTILIZATION DETAILS
9G: PRODUCT DETAILS
Materials included in agenda packet; presented Dr. Teel
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF GLAUCOMA MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE SIMBRINZA™ AND RESCULA®
10A: CURRENT PRIOR AUTHORIZATION CRITERIA

10B: UTILIZATION REVIEW
10C: PRIOR AUTHORIZATION REVIEW
10D: MARKET NEWS AND UPDATES
10E: COP RECOMMENDATIONS
10F: UTILIZATION DETAILS
10G: PRODUCT DETAILS
Materials included in agenda packet; presented Dr. Adams
Dr. Kuhls recommends "check data on patients and an eye exam educational initiative."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF PEDICULICIDES AND 30 DAY NOTICE TO PRIOR AUTHORIZE SKLICE®
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION REVIEW
11C: PRIOR AUTHORIZATION REVIEW
11D: MARKET NEWS AND UPDATES
11E: COP RECOMMENDATIONS
11F: UTILIZATION DETAILS
11G: PRODUCT DETAILS
Materials included in agenda packet; presented Dr. Adams
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: ANNUAL REVIEWS
12B: NEW PRODUCT REVIEWS
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ADJOURNMENT
The meeting was adjourned at 7:30pm

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

Memorandum

Date: November 14, 2013

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

From: Bethany Holderread, Pharm.D.
Clinical Pharmacist
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of November 13, 2013

Recommendation 1: Vote on 2014 Meeting Dates

MOTION CARRIED by unanimous approval.

January 8, 2014
February 12, 2014
March 12, 2014
April 9, 2014
May 14, 2014
June 11, 2014
July 9, 2014
August 13, 2014
September 10, 2014
October 8, 2014
November 12, 2014
December 10, 2014

Recommendation 2: Retrospective Drug Evaluation: Focusing on Safety and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets

NO ACTION REQUIRED.

Recommendation 3: Annual Review of Botulinum Toxins

MOTION CARRIED by unanimous approval.

A. The College of Pharmacy recommends placement of Dysport®, Xeomin®, and Myobloc® under the manual prior authorization process to make the authorization requirements for all botulinum toxin products uniformed.

B. The College of Pharmacy also recommends the following prior authorization criteria for making coverage determinations for the prevention of chronic migraine, or to improve symptoms associated with overactive bladder (non-neurogenic and neurogenic).

1. **Approval Criteria for Botox® for Prevention of Migraine Headaches (other botulinum toxins will not be approved for this use):**
    a. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes but is not limited to:
        i. Increased intracranial pressure (e.g. tumor, pseudotumor cerebri, central venous thrombosis, etc.)
        ii. Decreased intracranial pressure (e.g. post-lumbar puncture headache, dural tear after trauma, etc.)
    b. Migraine headache exacerbation secondary to other medical conditions or therapies have been ruled out and/or treated. This includes but is not limited to:
        i. Hormone replacement therapy or hormone-based contraceptives
        ii. Chronic insomnia
        iii. Obstructive sleep apnea
    c. Member has no contraindications to Botox injections
    d. FDA indications are met:
        i. Member is 18 or older
        ii. Member has a documented chronic migraine headaches
            - Frequency of 15 or more days per month; and
            - Duration of 4 hours per day or longer.
    e. The member has failed medical migraine preventive therapy including at least 3 agents in 3 or more categories, but not limited to:
        i. Select antihypertensive therapy such as beta-blocker therapy
        ii. Select anticonvulsant therapy

iii. Select antidepressant therapy (e.g. TCA or SNRI)

f. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headache) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes but is not limited to:
   i. Decongestants (alone or in combination product)
   ii. Combination analgesics containing caffeine and/or butalbital (>5 day/mo)
   iii. Narcotics
   iv. Analgesic medications including acetaminophen and most NSAIDS
   v. Ergotamine-containing medications (>8 day/mo)
   vi. Triptans (>8 day/mo)
g. Member is not taking any medications that are likely to be the cause of the headaches.
h. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox recommended as treatment. (Not necessarily prescribed or administered by neurologists.)
i. Members who smoke or use tobacco products will not be approved.

2. **Approval Criteria for Botox® for Non-Neurogenic Overactive Bladder (other botulinum toxins will not be approved for this use):**
   a. Member must have severe disease (≥ 5 urinary incontinence episode per day on medication) and specific pathology determined via urodynamic studies.
   b. Member must have participated in behavioral therapy for at least 12 weeks that did not yield adequate clinical results.
   c. Member must have had compliant use of at least 3 antimuscarinic medication(s) for at least 12 weeks each, alone or in combination with behavioral therapy, that did not yield adequate clinical results. One of those trials must have been an extended release formulation.
   d. Member must be 18 years of age or older, and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary.
   e. Only Urologists will be approved for administration of this procedure.

3. **Approval Criteria for Botox® for Neurogenic Overactive Bladder (other botulinum toxins will not be approved for this use):**
   a. Diagnosis of neurogenic bladder including underlying pathological dysfunction subtype confirmed by:

i. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
ii. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences.

b. Must have a clinically significant reason why anticholinergic medications are no longer an option for the member.
c. Member must be 18 years of age or older, and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary.
d. Only Urologists will be approved for administration of this procedure.

Recommendation 4: Annual Review of Prenatal Vitamins

NO ACTION REQUIRED.

The College of Pharmacy recommends a second educational initiative consisting of a targeted mailing to all prescribers of prenatal vitamins in the SoonerCare population in the last 12 months. The mailing may include information regarding coverage of prenatal vitamins, a sample prescription form, and a link to the OHCA web page which contains the updated list of covered products. An article will also be included in the SoonerCare member newsletter, with a link to the list of covered products. The list of preferred prenatal vitamin products will also be faxed to all SoonerCare contracted pharmacies.

Recommendation 5: Annual Review of Antihypertensive Medications and 30 Day Notice to Prior Authorize Epaned™ (Enalapril Powder for Oral Solution)

NO ACTION REQUIRED.

Recommendation 6: Annual Review of Nasal Allergy Medications and 30 Day Notice to Prior Authorize Zetonna® (Ciclesonide)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Simbrinza™ (Brinzolamide/Brimonidine) and Rescula® (Unoprostone)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Pediculicides and 30 Day Notice to Prior Authorize Sklice® (Ivermectin)

NO ACTION REQUIRED.

Appendix B

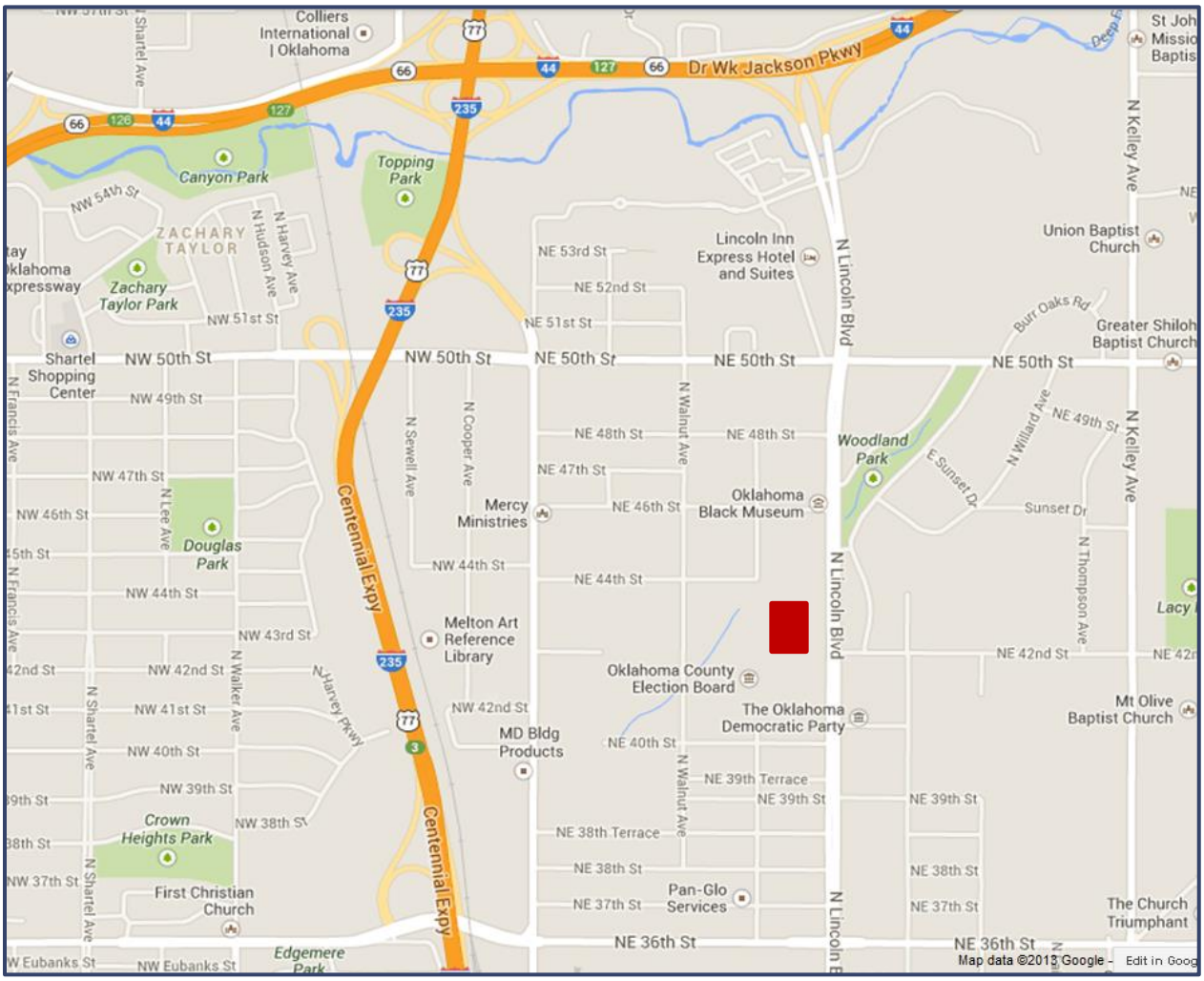
Drug Utilization Review Board Meetings

Oklahoma Health Care Authority
December 2013

Location and Time Change

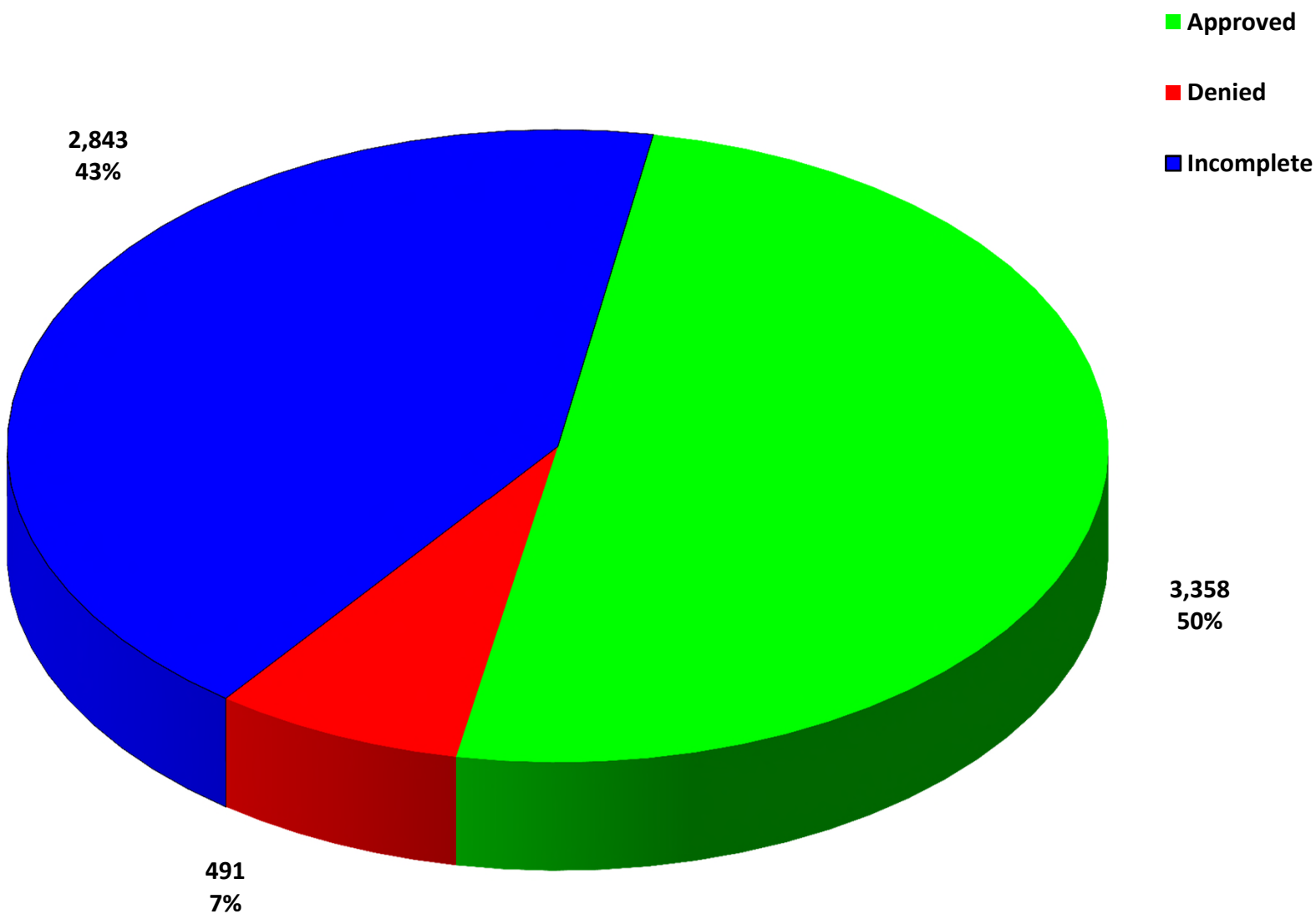
Beginning March 2014, the meetings of the Drug Utilization Review Board will be held at **4:00pm** on the second Wednesday of every month. The offices of the Oklahoma Health Care Authority are expected to move to their new location by the spring of 2014. Information regarding the new location is shown below. When relocation is finalized, the new address will be printed on your DUR packet. Thank you for your time and professional contribution to the DUR Board meetings.

The Lincoln Center
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105



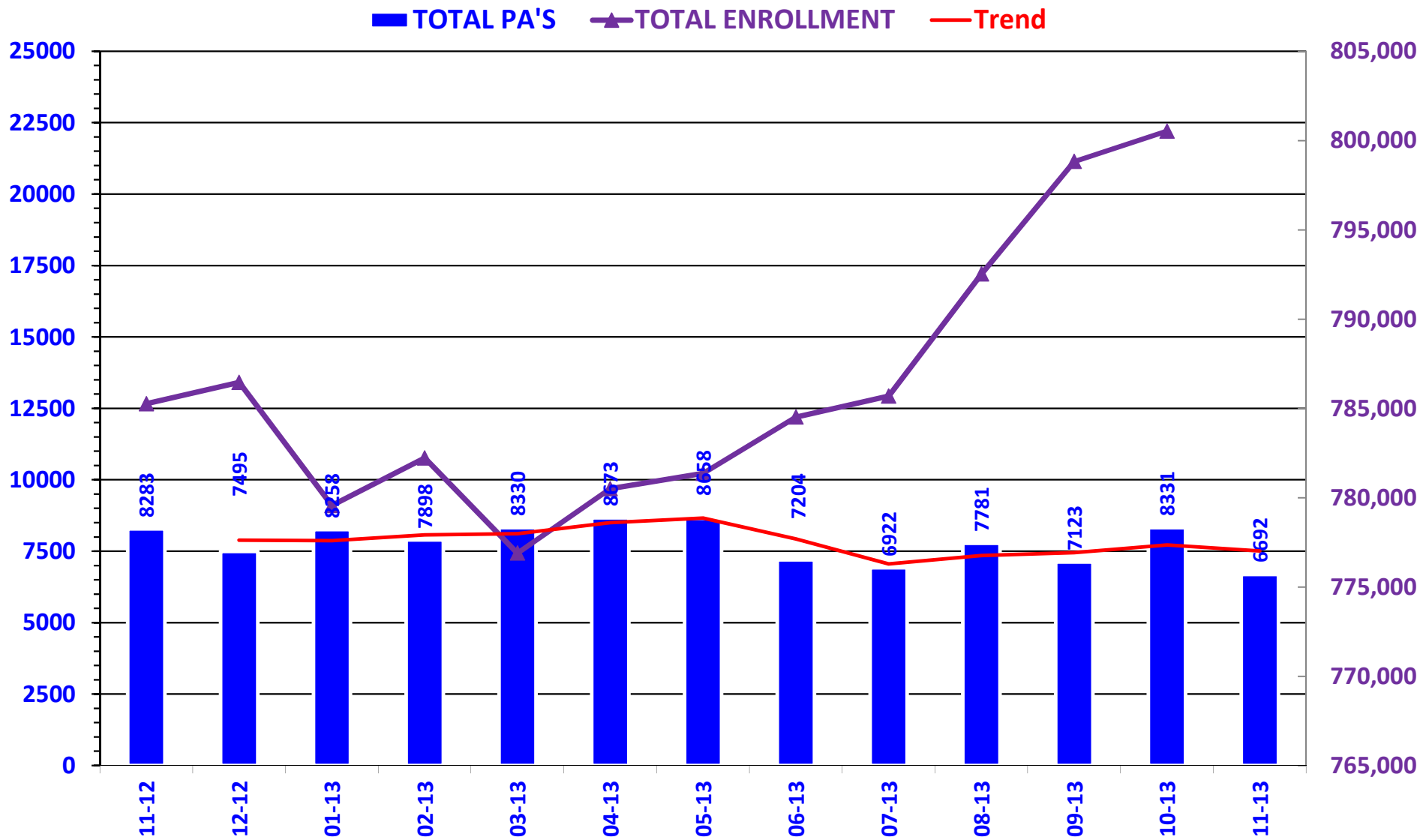
Appendix C

PRIOR AUTHORIZATION ACTIVITY REPORT: NOVEMBER



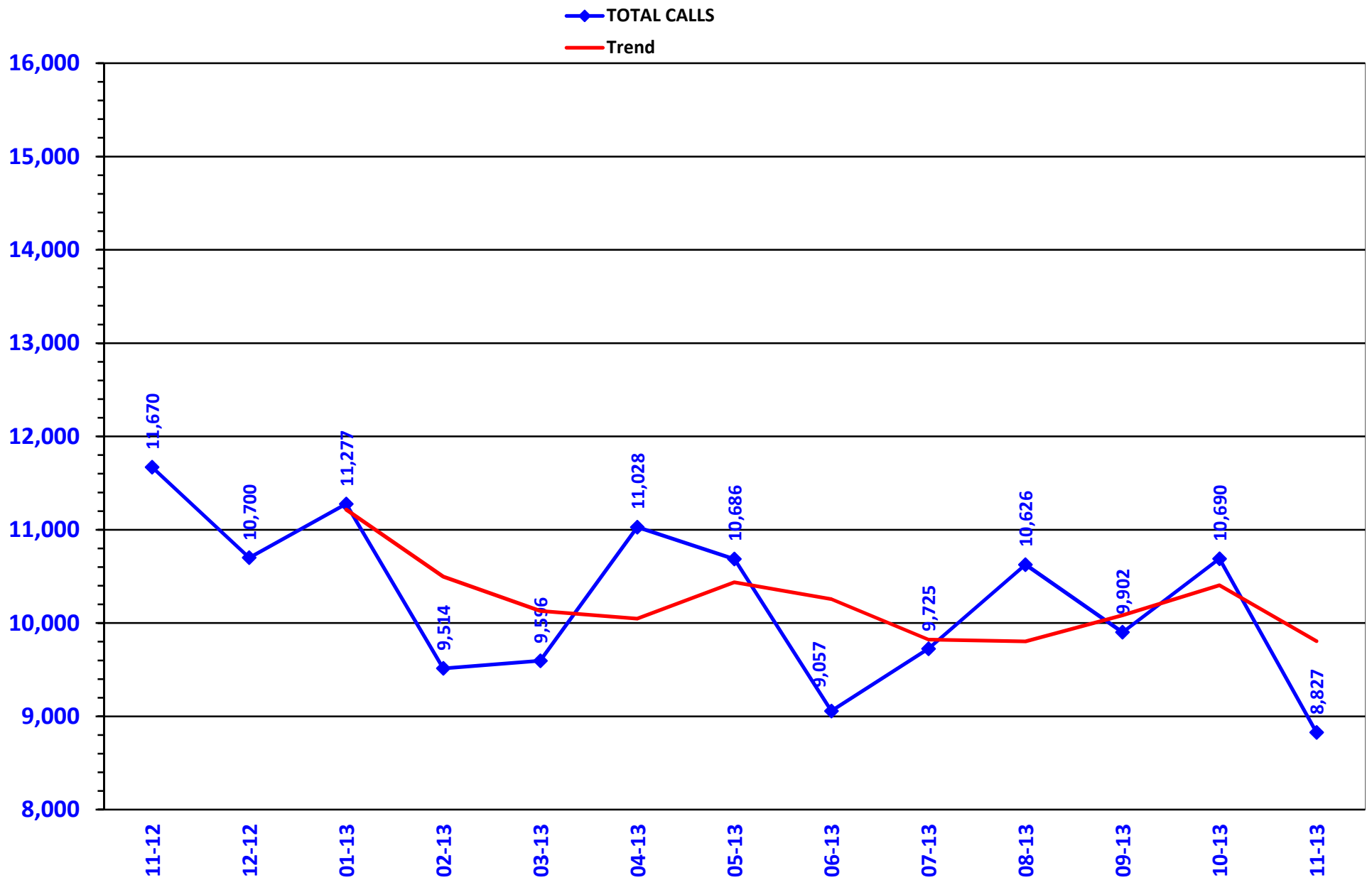
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: NOVEMBER 2012 – NOVEMBER 2013



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
NOVEMBER 2012 - NOVEMBER 2013



Prior Authorization Activity

11/1/2013 Through 11/30/2013

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	353	170	2	181	358
Analgesic, Narcotic	396	202	18	176	237
Angiotensin Receptor Antagonist	41	8	3	30	358
Antiasthma	234	129	6	99	293
Antibiotic	33	5	3	25	39
Anticoagulant	66	39	1	26	325
Anticonvulsant	103	64	2	37	335
Antidepressant	192	59	15	118	337
Antidiabetic	110	47	2	61	336
Antihistamine	107	81	1	25	331
Antihyperlipidemic	35	5	6	24	359
Antimigraine	64	22	1	41	304
Antiplatelet	20	13	0	7	359
Antiulcers	234	57	53	124	149
Antiviral	12	11	0	1	150
Anxiolytic	73	55	1	17	232
Atypical Antipsychotics	397	255	6	136	344
Biologics	48	29	1	18	313
Bladder Control	56	8	6	42	358
Botox	22	12	1	9	361
Cardiovascular	35	18	1	16	305
Chronic Obstructive Pulmonary Disease	17	1	1	15	361
Dermatological	99	18	42	39	89
Endocrine & Metabolic Drugs	46	28	3	15	117
Erythropoietin Stimulating Agents	37	18	1	18	114
Fibromyalgia	152	43	12	97	334
Gastrointestinal Agents	111	36	10	65	137
Glaucoma	21	3	1	17	359
Growth Hormones	46	32	3	11	136
HFA Rescue Inhalers	59	20	1	38	313
Insomnia	52	11	5	36	170
Multiple Sclerosis	25	12	0	13	201
Muscle Relaxant	86	26	26	34	63
Nasal Allergy	96	4	27	65	153
Neurological Agents	39	23	1	15	348
Nsaids	124	13	11	100	334
Ocular Allergy	30	3	2	25	87
Ophthalmic Anti-infectives	23	2	1	20	9
Osteoporosis	28	12	0	16	358
Other*	134	35	15	84	196
Otic Antibiotic	27	6	1	20	16
Pediculicide	118	53	6	59	13
Statins	53	16	3	34	359
Stimulant	501	327	15	159	325
Suboxone/Subutex	165	114	10	41	76
Synagis	349	195	68	86	118
Testosterone	63	20	3	40	349
Topical Antibiotic	14	3	1	10	95
Topical Antifungal	55	2	5	48	49
Topical Corticosteroids	132	1	21	110	5
Vitamin	45	11	23	11	328
Pharmacotherapy	76	62	2	12	79
Emergency PAs	4	4	0	0	
Total	**5,458**	**2,443**	**449**	**2,566**	

* 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	40	21	3	16	314
Cumulative Early Refill	8	8	0	0	179
Dosage Change	320	301	0	19	5
High Dose	4	3	0	1	242
Ingredient Duplication	22	15	0	7	3
Lost/Broken Rx	67	61	3	3	10
NDC vs Age	2	1	0	1	359
Nursing Home Issue	35	33	0	2	19
Other	32	29	0	3	15
Quantity vs. Days Supply	637	403	28	206	274
Stolen	13	9	0	4	3
Temporary Unlock	26	23	1	2	23
Third Brand Request	36	16	7	13	24
Overrides Total	**1,234**	**915**	**42**	**277**	
Total Regular PAs + Overrides	**6,692**	**3,358**	**491**	**2,843**	

Denial Reasons	
Unable to verify required trials.	2,466
Does not meet established criteria.	486
Lack required information to process request.	386

Other PA Activity	
Duplicate Requests	422
Letters	3,001
No Process	43
Changes to existing PAs	445
Partials	756

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

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT

Duplication of Narcotic Therapy

July, August, and September 2013

Pharmacy claims were reviewed over a three month period for duplication of immediate release opioid medications. Member profiles were flagged if the computer edit detected two or more claims for a narcotic analgesic with overlapping day supplies during that month. A total of 825 messages were reviewed for 794 members, and 565 letters were sent to providers. The details are below:

Parameters	Total Messages	Messages Reviewed	Members Reviewed	Members Intervened
Males and Females Age 0-35	18,811	825	794	133

Letters		
Prescribers: 310	Pharmacies: 255	Total Letters: 565

	Top 25 Narcotic Combination Messages Arranged by Total Messages Reviewed	Messages Flagged	Messages Reviewed	Members Reviewed	Members Intervened
1	Tramadol 50 MG and hydro/apap 7.5-750 MG	6408	286	279	30
2	Oxyco/apap 7.5-500 MG and hydro/apap 7.5-500 MG	4317	206	191	41
3	Oxycodone 5 MG and hydro/apap 7.5-650 MG	1470	39	38	14
4	Hydro/apap 7.5-750 MG and hydro/apap 5-325 MG	1383	52	50	4
5	Tramadol 50 MG and Oxycodone/apap 7.5-500	762	30	30	6
6	APAP/codeine 300/60 MG and Hydro/apap 7.5/500 MG	825	42	41	5
7	Oxycodone 5 MG and Oxycodone/apap 7.5/325 MG	436	19	16	7
8	Tramadol 50 MG and apap/codeine 300-60 MG	310	14	14	0
9	Morphine Sulfate 30 MG and hydro/apap 7.5-500 MG	302	8	8	1
10	Oxycodone/apap 7.5/500 MG and Oxy/apap 10/650 MG	435	24	24	6
11	Methadone 5 MG and hydrocodone/apap 7.5-500 MG	288	2	2	0
12	Oxycodone 5 MG and Tramadol HCl 50 MG	256	5	5	2
13	Hydromorphone 8 MG and hydro/apap 7.5-750 MG	204	7	7	0
14	But/APAP/Caff/Cod and hydro/apap 7.5-500 MG	183	7	7	0
15	Methadone 5 MG and Oxycodone 15 MG	112	2	2	1
16	Hydromorphone 8 MG and Oxycodone/apap 7.5/325 MG	104	4	4	0
17	Meperidine 50 MG and hydro/apap 7.5/500 MG	108	13	13	1
18	Methadone 5 MG and Oxycodone/apap 5/325 MG	82	2	2	0
19	Tramadol 50 MG and hydro/ibu 7.5/200 MG	76	5	5	1
20	Oxycodone 5 MG and Oxycodone 15 MG	74	2	2	2
21	Pentaz/nalox 50/0.5 MG and hydro/apap 7.5-500 MG	64	4	3	2
22	Morphine Sulfate 30 MG and Oxycodone 30 MG	62	3	3	2
23	Oxycodone/apap 5/500 MG and hydro/apap 7.5/500 MG	63	4	4	0
24	Hydromorphone 8 MG and Methadone 10 MG	42	3	3	1
25	But/ASA/Caff/Cod and hydro/apap 7.5-500 MG	60	3	3	0

Vote to Prior Authorize Ketoconazole Oral Tablets

Oklahoma Health Care Authority
December 2013

Recommendations

The College of Pharmacy recommends prior authorization of ketoconazole oral tablets with the following criteria:

1. FDA approved indication of systemic fungal infections with one of the following:
    a. blastomycosis
    b. coccidioidomycosis
    c. histoplasmosis
    d. chromomycosis
    e. paracoccidioidomycosis; and
2. Member is 3 years old or older; and
3. Member does not have underlying hepatic disease; and
4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; or
5. Other effective oral antifungal therapies are not tolerated or potential benefits outweigh the potential risks; and
6. Hepatic function tests must be done at baseline and weekly during treatment.
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Appendix D

Vote to Update the Antihypertensive Product Based Prior Authorization Category and Prior Authorize Epaned™ (Enalapril Powder for Oral Solution)

Oklahoma Health Care Authority
December 2013

Recommendations

The College of Pharmacy recommends the following:

1. Move Verelan® PM (verapamil ER) into Tier-2 of the CCB category.
2. Move Dynacirc® (isradipine) into Tier-2 of the CCB category.
3. Move Avapro® (irbesartan) and Avalide® (irbesartan/HCTZ) into Tier-1 of the ARB category.
4. Move Aceon® (perindopril erbumine) into Tier-2 of the ACEI category.
5. Prior authorize Monopril-HCT® (fosinopril/HCTZ) with the following criteria:
    a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot use the individual components.
6. Prior authorize Cardizem® CD (diltiazem CD) 360mg capsules with the following criteria:
    a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot use two 180mg Cardizem CD (diltiazem CD) capsules.
7. Place duration and quantity limits on the use of nimodipine oral capsules and Nymalize™ (nimodipine oral solution) as follows:
    a. A quantity limit of 252 capsules for 21 days will apply for Nimodipine oral capsules.
    b. A quantity limit of 2,838 mL for 21 days will apply for Nymalize™ oral solution.
8. Place an age restriction on Epaned™ (enalapril powder for oral solution) for members aged 7 years or older with the following criteria:
    a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot swallow the oral tablet formulation even when crushed.

Appendix E

Vote to Prior Authorize Zetonna® (Ciclesonide Nasal Aerosol)

Oklahoma Health Care Authority
December 2013

Recommendations

The College of Pharmacy recommends the addition of Zetonna® (ciclesonide) to Tier 3 of the Nasal Allergy Product Based Prior Authorization category. The existing criteria for this category will apply.

1. The following criteria are required for approval of a Tier 2 product:
    a. Documented adverse effect or contraindication to all preferred Tier 1 products.
    b. Failure with all Tier 1 medications defined as no beneficial response after at least three weeks of use at the maximum recommended dose.
2. The following criteria are required for approval of a Tier 3 product:
    a. All Tier 2 criteria must be met.
    b. Failure with all available Tier 2 products defined as no beneficial response after at least three weeks of use at the maximum recommended dose.
3. No grandfathering of Tier 2 or Tier 3 products will be allowed for this category.
4. For members 2 to 4 years of age, the age appropriate lower-tiered generic products must be used prior to the use of higher tiered products.
5. Approvals will be for the duration of three months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

Nasal Allergy Products		
Tier 1	***Tier 2***	***Tier 3***
fluticasone(Flonase®)	**beclomethasone** (Beconase® AQ)	**ciclesonide** (Omnaris®)
flunisolide (Nasalide®, Nasarel™)	**olapatadine** (Patanase®)	**budesonide** (Rhinocort® AQ)
triamcinolone (Nasacort® AQ)		**fluticasone** (Veramyst™)
		mometasone (Nasonex®)
		beclomethasone (QNasl®)
		azelastine (Astepro®)
		azelastine (Astelin®)
		azelastine/fluticasone (Dymista™)
		Ciclesonide (Zetonna®)

Tier structure based on supplemental rebate participation.

Appendix F

Vote to Prior Authorize Rescula® (Unoprostone) and Simbrinza™ (Brinzolamide/Brimonidine)

Oklahoma Health Care Authority
December 2013

Recommendations

The College of Pharmacy recommends the addition of Simbrinza™ and Rescula® to Tier 2 of the Glaucoma Medications Product Based Prior Authorization category. The existing criteria for this category will apply. As recommended by the DUR Board, the College of Pharmacy will implement an educational initiative consisting of a targeted mailing to prescribers of glaucoma medications and postcards to members with a diagnosis of glaucoma to increase the appropriate utilization of medications and annual eye exams in the Oklahoma SoonerCare population.

Tier 1	Tier 2
Beta-Blockers	
betaxolol (Betoptic® 0.5%) carteolol 1% soln (Ocupress®) dorzolamide/timolol (Cosopt®) levobunolol (Betagan®) metipranolol (OptiPranolol®) timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic-XE®)	betaxolol (Betoptic-S®) brimonidine/timolol (Combigan®) timolol maleate (Timoptic Ocudose®)
Prostaglandin Analogs	
travoprost (Travatan®, Travatan-Z®) latanoprost (Xalatan®)	bimatoprost (Lumigan®) tafluprost (Zioptan™) **unoprostone (Rescula®)**
Alpha-2 Adrenergic Agonists	
brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%) apraclonidine (Iopidine®) brimonidine/timolol (Combigan®) **brinzolamide/brimonidine (Simbrinza™)**
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®) dorzolamide (Trusopt®) acetazolamide (Diamox®)* methazolamide (Neptazane®)* **Indicates Oral Products Only*	brinzolamide (Azopt®) **brinzolamide/brimonidine (Simbrinza™)**
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto Carpine®, Pilopine HS®)	carbachol (Miostat®) echothiophate iodide (Phospholine Iodide®)

Tier structure based on supplemental rebate participation.

Appendix G

Vote to Prior Authorize Sklice® (Ivermectin)

Oklahoma Health Care Authority
December 2013

Recommendations

The College of Pharmacy recommends the addition of Sklice® to Tier 3 of the Pediculicides Product Based Prior Authorization category. The existing criteria for this category will apply, and a quantity limit of 117 grams (4 ounces) every 30 days will also apply. In addition, the College of Pharmacy recommends an educational initiative targeting prescribers to remind them that SoonerCare covers OTC products with a prescription. The educational mailing will include a letter, a sample prescription, and a list of covered OTC products.

Approval Criteria:

- **Approval of a Tier 2 medication** requires a trial with one Tier 1 medication with inadequate response or adverse effect.
- **Approval of a Tier 3 medication** requires trials with all available Tier 2 medication(s) with inadequate response or adverse effect.
- Clinical exception applies if there is known resistance to OTC permethrin and pyrethrin.

Tier 1	Tier 2	Tier 3
Covered OTC & Rx Permethrin Products	Benzyl Alcohol (Ulesfia™) lotion	Lindane lotion & shampoo
Prescription Generics with SMAC Pricing	Spinosad (Natroba™) suspension	Malathion (Ovide®) lotion
		Ivermectin (Sklice®) lotion

Tier structure based on supplemental rebate participation.

Utilization Details of Pediculicides: Fiscal Year 2013

CHEMICAL NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/CLAIM	% COST
Permethrin	Permethrin cream 5%	14,160	11,131	$824,902.18	$58.26	77.46%
Permethrin	Permethrin liquid 1%	9,906	6,775	$122,595.78	$12.38	11.51%
Benzyl Alcohol	Ulesfia™ lotion 5%	388	326	$45,958.54	$118.45	4.32%
Malathion	Ovide® lotion 0.5%	154	130	$24,918.04	$161.81	2.34%
Malathion	Malathion lotion 0.5%	121	104	$19,131.67	$158.11	1.80%
Spinosad	Natroba™ susp 0.9%	88	76	$20,689.71	$235.11	1.94%
Spinosad	Spinosad susp 0.9%	24	24	$3,906.24	$162.76	0.37%
Crotamiton	Eurax® cream 10%	20	17	$1,906.80	$95.34	0.18%
Lindane	Lindane lotion 1%	5	5	$565.15	$113.03	0.05%
Ivermectin	Sklice® lotion 0.5%	1	1	$276.34	$276.34	0.03%
Permethrin	Acticin® cream 5%	1	1	$29.67	$29.67	0.00%
	Totals	**24,868**	**17,467***	**$1,064,880.12**	**$42.82**	**100.00%**

*Total number of unduplicated members.

Appendix H

Fiscal Year 2013 Annual Review of Advair® (Fluticasone/Salmeterol), Symbicort® (Budesonide/Formoterol), Dulera® (Mometasone/ Formoterol), and 30 Day Notice to Prior Authorize Breo™ Ellipta™ (Fluticasone/Vilanterol Inhalation Powder)

Oklahoma Health Care Authority
December 2013

Current Prior Authorization Criteria

Approval Criteria:

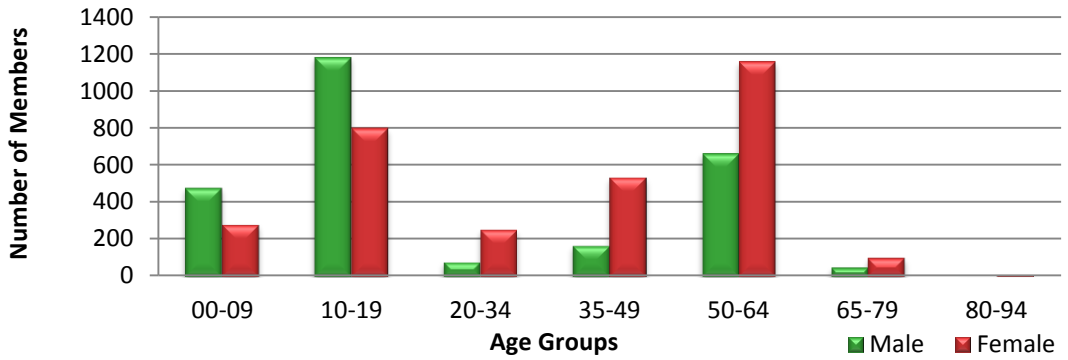
1. Diagnosis of COPD, or
2. Diagnosis of Asthma:
    a. Medication must be indicated for member's age; and
    b. Member must have used an inhaled corticosteroid (ICS) product for at least one month immediately prior to request for authorization; and
    c. Member's asthma considered uncontrolled by prescriber:
        i. Requires rescue inhaler more than 2 days per week for reasons other than prevention of exercise induced bronchospasms; or
        ii. Requires oral systemic corticosteroids; or
    d. Clinical situation warranting initiation with combination therapy due to severity of asthma.

Utilization of Advair®, Symbicort®, and Dulera®

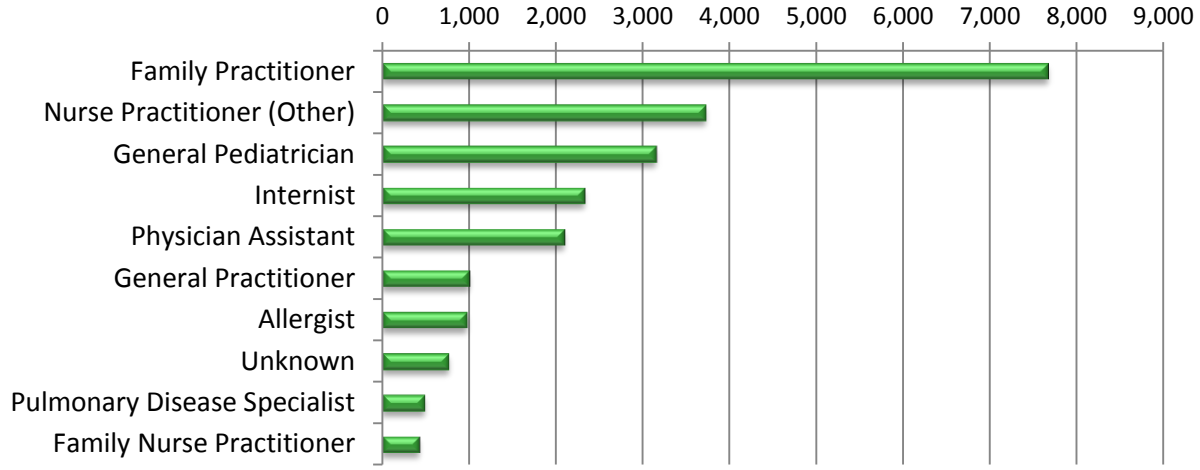
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Cost/Day	Units	Days
2012	5,989	24,923	$5,758,068.97	$231.03	$7.58	1,138,650	759,740
2013	5,761	23,914	$6,101,998.37	$255.16	$8.37	1,043,201	728,644
% Change	**-3.80%**	**-4.0%**	**6.00%**	**10.40%**	**10.40%**	**-8.40%**	**-4.10%**
Change	**-228**	**-1,009**	**$343,929.40**	**$24.13**	**$0.79**	**-95,449**	**-31,096**

*Total number of unduplicated members

Demographics of Members Utilizing Advair®, Symbicort®, and Dulera®



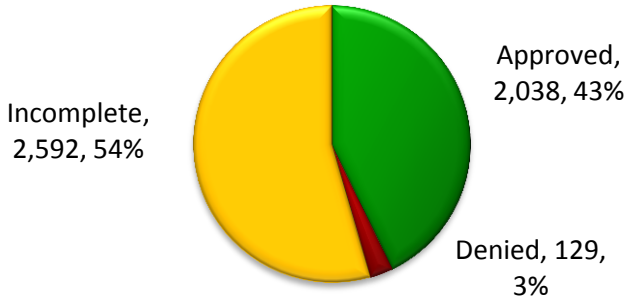
Prescribers of Advair®, Symbicort®, and Dulera® by Number of Claims



Prior Authorization of Advair®, Symbicort®, and Dulera®

There were a total of 4,759 petitions submitted for Advair®, Symbicort®, and Dulera® during fiscal year 2013. Computer edits are in place to detect an inhaled corticosteroid or a diagnosis of COPD in members' recent pharmacy/medical claims history, and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expirations

- Advair® (fluticasone propionate/salmeterol)-08/2016
- Dulera® (mometasone/formoterol)-05/2020
- Symbicort® (budesonide/formoterol)-04/2026

In May of 2013 GlaxoSmithKline received FDA approval for Breo™ Ellipta™. This product combines an inhaled corticosteroid (fluticasone) and a novel LAB_2A (vilanterol) in the Ellipta™ device which allows the two medications to be mixed prior to inhalation. Breo™ Ellipta™ is indicated to be dosed once daily which may be an advantage to existing therapies, which are indicated to be dosed twice daily. The following section contains details of this medication.

Breo™ Ellipta™ (Fluticasone Furoate and Vilanterol Inhalation Powder)[1]

Indication: Breo™ Ellipta™ is indicated for long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo™ Ellipta™ is also indicated to reduce exacerbations of COPD patients with a history of exacerbations.

Dosing: Breo™ Ellipta™ is available as an inhalation powder; each device contains two double-foil blister strips of powder for oral inhalation. One strip contains fluticasone furoate 100 mcg per blister and the other contains vilanterol 25 mcg per blister. The FDA approved dose and regimen of Breo™ Ellipta™ is one inhalation (100 mcg fluticasone furoate/25 mcg vilanterol) once daily.

Contraindications: Breo™ Ellipta™ is contraindicated in those with a severe hypersensitivity to milk proteins or any ingredients found in Breo™ Ellipta™.

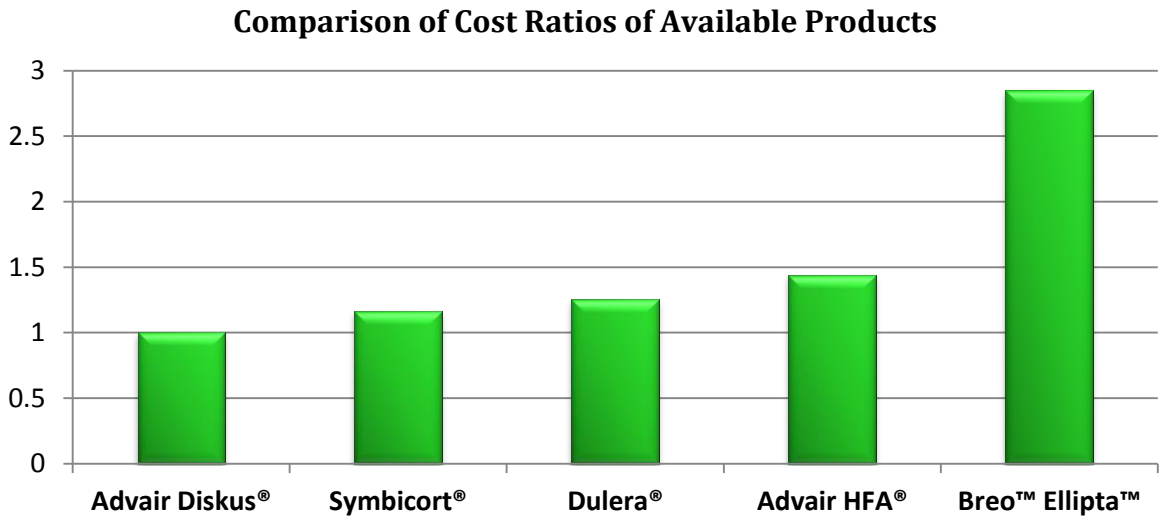
Efficacy: The safety and efficacy of Breo™ Ellipta™ was evaluated in 7,700 patients with COPD. The efficacy of Breo™ Ellipta™ is based primarily on the dose-ranging trials and 4 confirmatory trials.

The co-primary efficacy endpoints in Trial 1 and 2 of the confirmatory trials were weighted mean FEV_1 (0 to 4 hours) post dose on Day 169 and change from baseline in trough FEV_1 on Day 169 (the mean of the FEV_1 values obtained 23 and 24 hours after the final dose on Day 168). Breo™ Ellipta™ 100 mcg/25 mcg demonstrated a larger increase in the weighted mean FEV_1 (0 to 4 hours) relative to placebo and fluticasone furoate 100 mcg at Day 168. The second co-primary variable was the change from baseline in trough FEV_1 following the final treatment day. At Day 169, both Trials 1 and 2 demonstrated significant increases in trough FEV_1 for all strengths of fluticasone furoate/vilanterol compared to placebo, however, Breo™ Ellipta™ 100 mcg/25 mcg compared with vilanterol did not achieve statistical significance.

Trials 3 and 4 were designed to evaluate the effect of Breo™ Ellipta™ on the rate of moderate and severe COPD exacerbations. 3,255 subjects were treated with fluticasone/salmeterol 250 mcg/50 mcg (Advair®) twice daily during a 4-week run-in period prior to being randomly assigned to one of the following treatment groups:

1. fluticasone/vilanterol 100 mcg/25 mcg (Breo™ Ellipta™)
2. fluticasone/vilanterol 50 mcg/25 mcg
3. fluticasone/vilanterol 200 mcg/25 mcg
4. vilanterol 25 mcg

The primary efficacy variable was the annual rate of moderate/severe exacerbations in both trials. Patients treated with fluticasone/vilanterol 100 mcg/ 25 mcg (Breo™ Ellipta™) had a lower annual rate of moderate/severe COPD exacerbations compared with vilanterol in both trials. The lower dose and higher dose evaluated did not show an advantage over the Breo™ Ellipta™ dose.



Recommendations

The College of Pharmacy recommends prior authorization of Breo™ Ellipta™ (fluticasone/vilanterol) with the following criteria:

Breo™ Ellipta™ (fluticasone/vilanterol) authorization requires:

1. FDA approved diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD; and
2. Trials of Advair® and Symbicort® consisting of at least 30 days each within the last 90 days that did not adequately control COPD symptoms.

Utilization Details for Advair®, Symbicort®, and Dulera®: Fiscal Year 2013

MEDICATION NAME	CLAIMS	MEMBERS	COST	COST/ CLAIM	COST/ DAY	% COST
ADVAIR DISKU 250/50	9,538	2,404	$2,457,546.06	$257.66	$8.54	40.27%
ADVAIR DISKU 100/50	3,403	938	$704,126.36	$206.91	$6.84	11.54%
ADVAIR DISKU 500/50	2,971	707	$1,005,203.55	$338.34	$11.21	16.47%
ADVAIR HFA 115/21	1,989	610	$504,725.21	$253.76	$8.26	8.27%
ADVAIR HFA 230/21	587	193	$197,872.94	$337.09	$11.11	3.24%
ADVAIR HFA 45/21	317	159	$60,705.96	$191.50	$6.27	0.99%
SYMBICORT 160-4.5	3,234	875	$763,181.04	$235.99	$7.45	12.51%
SYMBICORT 80-4.5	870	259	$182,759.67	$210.07	$6.78	3.00%
DULERA 200-5MCG	525	178	$116,877.02	$222.62	$7.36	1.92%
DULERA 100-5MCG	480	188	$109,000.56	$227.08	$7.51	1.79%
TOTAL:	**23,914**	**5,761***	**$6,101,998.37**	**$248.10**	**$8.37**	**100%**

*Total number of unduplicated members.

PRODUCT DETAILS OF BREO™ ELLIPTA™ (FLUTICASONE FUROATE AND VILANTEROL INHALATION POWDER)

INDICATIONS AND USE:

- Breo™ Ellipta™ is a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo™ Ellipta™ is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

DOSAGE FORMS:

- Breo™ Ellipta™ is an inhalation powder. The inhaler is a disposable light grey and pale blue plastic inhaler that contains two double-foil blister strips, each with 30 blisters containing powder intended for oral inhalation only. One strip contains fluticasone furoate (100 mcg per blister, and the other strip contains vilanterol (25 mcg per blister)).

ADMINSTRATION:

- Breo™ Ellipta™ 100 mcg/25 mcg should be administered as one inhalation once daily by the orally inhaled route only. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis.
- Breo™ Ellipta™ should be taken at the same time every day.
- Do not use Breo™ Ellipta™ more than one time every 24 hours.
- No dosage adjustment is required for geriatric patients, patients with hepatic impairment, or renally impaired patients.

CONTRAINDICATIONS:

- Breo™ Ellipta™ is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

SPECIAL POPULATIONS:

- Hepatic Impairment: Fluticasone furoate exposure may increase in patients with moderate or severe impairment. Monitor for systemic corticosteroid effects.
- Pregnancy Category C.

WARNINGS AND PRECAUTIONS:

- LABA's can increase the risk of asthma-related death.
- Do not initiate Breo™ Ellipta™ in acutely deteriorating COPD or to treat acute symptoms.
- Do not use in combination with an additional medicine containing a LABA because of risk of overdose.
- *Candida albicans* infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth without swallowing after inhalation to help reduce the risk.
- There is an increased risk of pneumonia in patients with COPD taking Breo™ Ellipta™. Monitor patients for signs and symptoms of pneumonia.

- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- There is risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to Breo™ Ellipta™.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Breo™ Ellipta™ and institute alternative therapy.
- Use with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.
- Assess for decrease in bone mineral density initially and periodically thereafter.
- Close monitoring for glaucoma and cataracts is warranted.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS: (Incidence $\geq$3% and more common than placebo)

- Nasopharyngitis (9%)
- Upper respiratory tract infection (7%)
- Headache (7%)
- Oral candidiasis (5%)

DRUG INTERACTIONS:

- Strong cytochrome P450 3A4 inhibitors (e.g., ketoconazole): Use with caution. May cause systemic corticosteroid and cardiovascular effects.
- Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate the beta-adrenergic agonist effect of vilanterol on vascular system.
- Beta-blockers: Use with caution. May block bronchodilator effects of beta-agonists and produce bronchospasm.
- Diuretics: Use with caution. Electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

PATIENT COUNSELING INFORMTION:

- Patients should be informed that LABAs, such as vilanterol, one of the active ingredients in Breo™ Ellipta™, increase the risk of asthma-related death. Breo™ Ellipta™ is not indicated for the treatment of asthma.
- Breo™ Ellipta™ is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Acute symptoms should be treated with a rescue inhaler such as albuterol.
- When patients are prescribed Breo™ Ellipta™, other medicines containing LABAs should not be used.
- Patients should be advised that localized infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic antifungal therapy while still continuing therapy with Breo™ Ellipta™, but at times therapy with Breo™ Ellipta™ may need to be temporarily interrupted under close medical supervision. Rinsing the mouth without swallowing after inhalation is advised to help reduce the risk of thrush.

- Patients with COPD who have received Breo™ Ellipta™ have a higher risk of pneumonia and should be instructed to contact their healthcare providers if they develop symptoms of pneumonia (e.g., fever, chills, change in sputum color, increase in breathing problems).
- Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to consult their physicians without delay. Patients should be informed of potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex.
- Patients should be advised that Breo™ Ellipta™ may cause systemic corticosteroid effects of hypercorticism and adrenal suppression. Additionally, patients should be instructed that deaths due to adrenal insufficiency have occurred during and after transfer from systemic corticosteroids.
- Patients who are at an increased risk for decreased BMD (bone mineral density) should be advised that the use of corticosteroids may pose an additional risk.
- Long-term use of inhaled corticosteroids may increase the risk of some eye problems (cataracts or glaucoma); regular eye examinations should be considered.
- Patients should be informed of adverse effects associated with $beta_2$-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness.

Breo™ Ellipta™ Product Information. GlaxoSmithKline. Available online at: http://us.gsk.com/products/assets/us_breo_ellipta.pdf. Last revised 05/2013. Last accessed 11/19/2013.

Appendix I

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

FDA NEWS RELEASE

For Immediate Release: Nov. 22, 2013

FDA approves new treatment for hepatitis C virus

The U.S. Food and Drug Administration today approved Olysio (simeprevir), a new therapy to treat chronic hepatitis C virus infection.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with the hepatitis C virus have no symptoms of the disease until liver damage becomes apparent, which may take several years. Most of these people then go on to develop chronic hepatitis C. Some will also develop scarring and poor liver function (cirrhosis) over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections or liver cancer. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with the hepatitis C virus.

Olysio is a protease inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. It is to be used as a component of a combination antiviral treatment regimen. In clinical studies, Olysio was evaluated in combination with peginterferon-alfa and ribavirin, two drugs also used to treat hepatitis C virus infection. Olysio is intended for adults with compensated liver disease (a diseased liver that is still functioning), including cirrhosis, who have not received treatment for their infection (treatment naïve) or for whom previous treatment has not been effective (treatment experienced).

Olysio was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that, if approved, would provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to available therapies.

The safety and effectiveness of Olysio were evaluated in five clinical studies of 2,026 treatment-naive and treatment-experienced participants randomly assigned to receive Olysio plus peginterferon-alfa and ribavirin or placebo plus peginterferon-alfa and ribavirin. The studies were designed to measure whether a participant's hepatitis C virus was no longer detected in the blood at least 12 weeks after finishing treatment (sustained virologic response), suggesting a participant's infection had been cured.

Results showed 80 percent of treatment-naive participants given Olysio plus peginterferon-alfa and ribavirin achieved sustained virologic response, compared to 50 percent of participants receiving peginterferon-alfa and ribavirin alone. In one of the studies with treatment-experienced participants whose infection returned (prior relapsers), 79 percent receiving Olysio plus peginterferon-alfa and ribavirin achieved sustained virologic response compared to 37 percent of participants receiving peginterferon-alfa and ribavirin alone.

Another study examined Olysio's safety and effectiveness in treatment-experienced participants, including prior relapsers, those who partially responded to prior therapy (partial responders) and those who did not respond to prior therapy (null responders). Adding Olysio improved response rates in each of these subgroups compared to peginterferon-alfa and ribavirin alone.

A reduction in Olysio's effectiveness was observed in participants infected with the genotype 1a hepatitis C virus with an NS3 Q80K polymorphism, a strain of the hepatitis C virus commonly found in the United States. Olysio's drug label includes a recommendation to screen for the presence of the strain prior to beginning therapy and to consider alternative therapy if the strain is detected.

The most common side effects reported in clinical study participants treated with Olysio in combination with peginterferon-alfa and ribavirin were rash (including photosensitivity), itching (pruritis) and nausea. Serious photosensitivity reactions resulting in hospitalization were reported. Patients will be advised to limit sun

exposure and to use sun protective measures during treatment with Olysio in combination with peginterferon alfa and ribavirin. Olysio should not be used alone to treat chronic hepatitis C infection.
Olysio is marketed by Janssen Pharmaceuticals, based in Raritan, N.J. Victrelis is marketed by Whitehouse Station, N.J.-based Merck, and Incivek is marketed by Cambridge, Mass.-based Vertex Pharmaceuticals.

FDA NEWS RELEASE

FDA approves first generic versions of Aciphex delayed-release tablets to treat GERD
For Immediate Release: Nov. 8, 2013

The U.S. Food and Drug Administration today approved the first generic versions of Aciphex (rabeprazole sodium) delayed-release tablets, used to treat gastroesophageal reflux disease (GERD) in adults and adolescents (ages 12 and up).
GERD, also called acid reflux or acid regurgitation, is a common condition in which backward flow of acid from the stomach causes heartburn and possible injury to the esophagus (the tube that connects the throat and stomach).
Rabeprazole is in a class of medications called proton-pump inhibitors. The medication works by decreasing the amount of acid made in the stomach, treating the symptoms of GERD such as heartburn, regurgitation of acid, and nausea. The medication helps allow the esophagus to heal, and prevent further damage to the esophagus. Rabeprazole is also used to treat conditions in which the stomach produces too much acid, such as Zollinger-Ellison syndrome. In addition, rabeprazole is used to treat ulcers (sores in the lining of the stomach or intestine) and is used in combination with other medications to eliminate *H. pylori*, a type of bacteria that causes ulcers.
In the clinical trials for Aciphex in adults, the most common adverse reactions reported by those taking Aciphex were sore throat, flatulence, infection, and constipation. In studies of adolescents, the adverse reactions most frequently reported by those taking Aciphex were abdominal pain, diarrhea, and headache.
Generic prescription drugs approved by the FDA have the same high quality and strength as brand-name drugs. Generic prescription drug manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs.
Information about the availability of generic rabeprazole can be obtained from the manufacturers.

FDA NEWS RELEASE

For Immediate Release: Nov. 8, 2013
FDA approves Aptiom to treat seizures in adults

The U.S. Food and Drug Administration today approved Aptiom (eslicarbazepine acetate) as an add-on medication to treat seizures associated with epilepsy.
Epilepsy is a brain disorder caused by abnormal or excessive activity in the brain's nerve cells. Approximately 200,000 new cases of seizures and epilepsy occur in the United States each year.
Aptiom is approved for the treatment of partial seizures, the most common type of seizure seen in people with epilepsy. Seizures can cause a wide range of symptoms, including repetitive limb movements, unusual behavior and generalized convulsions with loss of consciousness. Seizures can have serious consequences, including injury and death.
Three clinical studies in which participants with partial epilepsy were randomly assigned to receive Aptiom or placebo demonstrated that Aptiom is effective in reducing the frequency of seizures.

The most common side effects reported by patients receiving Aptiom in clinical trials included dizziness, drowsiness, nausea, headache, double-vision, vomiting, fatigue and loss of coordination. These and other side effects and recommendations for monitoring are described in the drug label.
Like other antiepileptic drugs, Aptiom may cause suicidal thoughts or actions in a very small number of people. Patients should contact their health care professionals right away if they have thoughts about suicide or dying, new or worsened anxiety or depression, or other unusual changes in behavior or mood.
Aptiom is being approved with a Medication Guide that provides patients with important information about the medication that can help patients avoid serious adverse events. The guide will be distributed each time a patient fills their prescription.
Aptiom is marketed by Sunovion Pharmaceuticals Inc., based in Marlborough, Mass.

FDA NEWS RELEASE

For Immediate Release: Nov. 13, 2013
FDA approves Imbruvica for rare blood cancer

Second drug with breakthrough therapy designation to receive FDA approval
The U.S. Food and Drug Administration today approved Imbruvica (ibrutinib) to treat patients with mantle cell lymphoma (MCL), a rare and aggressive type of blood cancer.
MCL is a rare form of non-Hodgkin lymphoma and represents about 6 percent of all non-Hodgkin lymphoma cases in the United States. By the time MCL is diagnosed, it usually has already spread to the lymph nodes, bone marrow and other organs.
Imbruvica is intended for patients with MCL who have received at least one prior therapy. It works by inhibiting the enzyme needed by the cancer to multiply and spread. Imbruvica is the third drug approved to treat MCL. Velcade (2006) and Revlimid (2013) are also approved to treat the disease.
Imbruvica is the second drug with breakthrough therapy designation to receive FDA approval. The Food and Drug Administration Safety and Innovation Act, passed in July 2012, gave the FDA the ability to designate a drug a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases.
The FDA is approving Imbruvica under the agency's accelerated approval program, which allows the FDA to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. This program provides earlier patient access to promising new drugs while the company conducts confirmatory clinical trials. The FDA also granted Imbruvica priority review and orphan-product designation because the drug demonstrated the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition and is intended to treat a rare disease, respectively.
Imbruvica’s accelerated approval for MCL is based on a study where 111 participants were given Imbruvica daily until their disease progressed or side effects became intolerable. Results showed nearly 66 percent of participants had their cancer shrink or disappear after treatment (overall response rate). An improvement in survival or disease-related symptoms has not been established.
The most common side effects reported in participants receiving Imbruvica are low levels of platelets in the blood (thrombocytopenia), diarrhea, a decrease in infection-fighting white blood cells (neutropenia), anemia, fatigue, musculoskeletal pain, swelling (edema), upper respiratory infection, nausea, bruising, shortness of breath (dyspnea), constipation, rash, abdominal pain, vomiting, and decreased appetite. Other clinically significant side effects include bleeding, infections, kidney problems and the development of other types of cancers.

Imbruvica is co-marketed by Sunnyvale, Calif.-based Pharmacyclics and Raritan, N.J.-based Janssen Biotech, Inc. Velcade (bortezomib) is marketed by Millennium Pharmaceuticals, based in Cambridge, Mass. Revlimid (lenalidomide) is marketed by Summit, N.J.-based Celgene.

FDA NEWS RELEASE

For Immediate Release: Nov. 22, 2013

FDA approves Nexavar to treat type of thyroid cancer

The U.S. Food and Drug Administration today expanded the approved uses of Nexavar (sorafenib) to treat late-stage (metastatic) differentiated thyroid cancer.

Thyroid cancer is a cancerous growth of the thyroid gland, which is located in the neck. Differentiated thyroid cancer is the most common type of thyroid cancer. The National Cancer Institute estimates that 60,220 Americans will be diagnosed with thyroid cancer and 1,850 will die from the disease in 2013.

Nexavar works by inhibiting multiple proteins in cancer cells, limiting cancer cell growth and division. The drug's new use is intended for patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

The safety and effectiveness of Nexavar were established in a clinical study involving 417 participants with locally recurrent or metastatic, progressive differentiated thyroid cancer that does not respond to radioactive iodine treatment. Nexavar increased the length of time patients lived without the cancer progressing (progression-free survival) by 41 percent. Half of patients receiving Nexavar lived without cancer progression for at least 10.8 months compared to at least 5.8 months for participants receiving a placebo.

The most common side effects in patients treated with Nexavar were diarrhea, fatigue, infection, hair loss (alopecia), hand-foot skin reaction, rash, weight loss, decreased appetite, nausea, gastrointestinal and abdominal pains and high blood pressure (hypertension). Thyroid stimulating hormone, a potential promoter of thyroid cancer, is more likely to become elevated while on treatment with Nexavar, requiring adjustment of thyroid hormone replacement therapy.

The FDA completed its review of Nexavar's new indication under its priority review program. This program provides for an expedited, six-month review for drugs that may offer a significant improvement in safety or effectiveness of the treatment, prevention or diagnosis of a serious condition. Nexavar also received orphan-product designation by the FDA because it is intended to treat a rare disease or condition.

The FDA approved Nexavar to treat advanced kidney cancer in 2005. In 2007, the agency expanded the drug's label to treat liver cancer that cannot be surgically removed.

Nexavar is co-marketed by Bayer HealthCare Pharmaceuticals Inc., based in Wayne, N.J., and Onyx Pharmaceuticals, based in South San Francisco, Calif.

Safety Announcements

FDA Drug Safety Communication: FDA warns of serious skin reactions with the anti-seizure drug Onfi (clobazam) and has approved label changes

[12-3-2013] The U.S. Food and Drug Administration (FDA) is warning the public that the anti-seizure drug Onfi (clobazam) can cause rare but serious skin reactions that can result in permanent harm and death. We have approved changes to the Onfi drug label and the patient Medication Guide to describe the risk of these serious skin reactions. Patients taking Onfi should seek immediate medical treatment if they develop a rash, blistering or peeling of the skin, sores in the mouth, or hives. Health care professionals should discontinue use of Onfi and consider an alternate therapy at the first sign of rash, unless it is clearly not drug-related.

These rare but serious skin reactions, called Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur at any time during Onfi treatment. However, the likelihood of skin reactions is greater during the first 8 weeks of treatment or when Onfi is stopped and then re-started. All cases of SJS and TEN in the FDA case series have resulted in hospitalization, one case resulted in blindness, and one case resulted in death.
Onfi is a benzodiazepine medication used in combination with other medicines to treat seizures associated with a severe form of epilepsy called Lennox-Gastaut Syndrome. Serious skin reactions have not generally been associated with other benzodiazepines.
Patients should not stop taking Onfi without first talking to their health care professionals. Stopping Onfi suddenly can cause serious withdrawal problems, such as seizures that will not stop, hallucinations (hearing or seeing things that are not real), shaking, nervousness, and stomach or muscle cramps.
The Onfi drug label has been revised to add information about the risk for serious skin reactions to the *Warnings and Precautions* section and to the Medication Guide.

Safety Announcements

FDA Drug Safety Communication: FDA requires removal of some prescribing and dispensing restrictions for rosiglitazone-containing diabetes medicines.

[11-25-2013] The U.S. Food and Drug Administration (FDA) has determined that recent data for rosiglitazone-containing drugs, such as Avandia, Avandamet, Avandaryl, and generics, do not show an increased risk of heart attack compared to the standard type 2 diabetes medicines metformin and sulfonylurea. As a result, we are requiring removal of the prescribing and dispensing restrictions for rosiglitazone medicines that were put in place in 2010. This decision is based on our review of data from a large, long-term clinical trial and is supported by a comprehensive, outside, expert re-evaluation of the data conducted by the Duke Clinical Research Institute (DCRI).
Type 2 diabetes is a disease that can lead to serious complications and premature death. Rosiglitazone is a treatment option that can improve blood sugar control in some patients with the disease. Patients with type 2 diabetes should continue to work closely with their health care professionals to determine treatment options that are most appropriate.
FDA continues to evaluate the safety and effectiveness of drugs after they go on the market. In the case of rosiglitazone medicines, previous data from a large, combined analysis of mostly short-term, randomized clinical trials of rosiglitazone had suggested an elevated risk of heart attack, so we required a Risk Evaluation and Mitigation Strategy (REMS), called the Rosiglitazone REMS program. The Rosiglitazone REMS program restricted the use of rosiglitazone medicines to help ensure that their benefits outweighed the risks.
Although some scientific uncertainty about the cardiovascular safety of rosiglitazone medicines still remains, in light of the new re-evaluation of the **R**osiglitazone **E**valuated for **C**ardiovascular **O**utcomes and **R**egulation of Glycemia in **D**iabetes (RECORD) trial, our concern is substantially reduced and the rosiglitazone REMS program requirements will be modified. We are also requiring revisions to the rosiglitazone prescribing information and the patient Medication Guide to include this new information.
Under FDA's proposed modifications to the rosiglitazone REMS program:

- Distribution of the medicines will no longer be restricted. Rosiglitazone may be used along with diet and exercise to improve control of blood sugar in patients with type 2 diabetes mellitus.
- Health care professionals, pharmacies, and patients will no longer be required to enroll in the rosiglitazone REMS program to be able to prescribe, dispense, or receive rosiglitazone medicines.
- As part of the REMS, sponsors will ensure that health care professionals who are likely to prescribe rosiglitazone medicines are provided training based on the current state of knowledge concerning the cardiovascular risk of rosiglitazone medicines. Manufacturers will also send Dear Healthcare Provider and Dear Professional Society letters to educate prescribers about the new information.

Safety Announcements

FDA Drug Safety Communication: Updated recommendations to decrease risk of spinal column bleeding and paralysis in patients on low molecular weight heparins

[11-6-2013] The U.S. Food and Drug Administration (FDA) is recommending that health care professionals carefully consider the timing of spinal catheter placement and removal in patients taking anticoagulant drugs, such as enoxaparin, and delay dosing of anticoagulant medications for some time interval after catheter removal to decrease the risk of spinal column bleeding and subsequent paralysis after spinal injections, including epidural procedures and lumbar punctures. These new timing recommendations, which can decrease the risk of epidural or spinal hematoma, will be added to the labels of anticoagulant drugs known as low molecular weight heparins, including Lovenox and generic enoxaparin products and similar products. Health care professionals and institutions involved in performing spinal/epidural anesthesia or spinal punctures should determine, as part of a preprocedure checklist, whether a patient is receiving anticoagulants and identify the appropriate timing of enoxaparin dosing in relation to catheter placement or removal. To reduce the potential risk of bleeding, consider both the dose and the elimination half-life of the anticoagulant:

- For enoxaparin, placement or removal of a spinal catheter should be delayed for at least 12 hours after administration of prophylactic doses such as those used for prevention of deep vein thrombosis. Longer delays (24 hours) are appropriate to consider for patients receiving higher therapeutic doses of enoxaparin (1 mg/kg twice daily or 1.5 mg/kg once daily).
- A postprocedure dose of enoxaparin should usually be given no sooner than 4 hours after catheter removal.
- In all cases, a benefit-risk assessment should consider both the risk for thrombosis and the risk for bleeding in the context of the procedure and patient risk factors.

  Epidural or spinal hematomas are a known risk of enoxaparin in the setting of spinal procedures and are already described in the *Boxed Warning* and the *Warnings and Precautions* sections of the labels for Lovenox and generic enoxaparin products. However, these serious adverse events continue to occur. To address this safety concern, FDA worked with the manufacturer of Lovenox, Sanofi-Aventis, to further evaluate this risk and to update the *Warnings and Precautions* section of the Lovenox label with these additional timing recommendations. The labels for generic enoxaparin products will also be revised accordingly, as will those of other low molecular weight heparin-type products.

  Before undergoing an epidural or spinal procedure, patients should inform their health care professional if they are taking any anticoagulant drugs. When undergoing these types of procedures, patients should alert their health care professional immediately if they experience any symptoms such as numbness, tingling, leg weakness or paralysis, or loss of control over their bladder or bowels.

  It is important to note that all anticoagulants carry the risk of causing spinal bleeding when used in conjunction with epidural/spinal anesthesia or spinal puncture. We are continuing to evaluate the safety of other anticoagulants to determine if additional label changes are needed.

Current Drug Shortages Index (as of December 2, 2013):

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

Acetylcysteine Inhalation Solution
Amikacin Injection UPDATED 12/2/2013
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
Barium Sulfate for Suspension (initial posting 10/12/2012)
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 and Ergotamine Tartrate (Cafergot) Tablets (initial posting 3/8/2012)
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection
Calcium Chloride Injection (initial posting 12/13/2012)
Calcium Gluconate Injection (initial posting 1/10/2013)
Chromic Chloride Injection
Cidofovir Injection (initial posting 2/15/2013)
Citric Acid; Gluconolactone; Magnesium Carbonate (Renacidin) Solution for Irrigation (initial posting 6/30/2012)
Clindamycin phosphate (Cleocin) (initial posting 10/2/2013) UPDATED 11/25/2013
Copper Injection (initial posting 4/25/2013)
Cyanocobalamin Injection (initial posting 1/25/2013)
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)
Dextrose Injection (initial posting 5/23/2012)
Dipyridamole Injection (initial posting 7/24/2012)
Dobutamine Hydrochloride Injection (initial posting 4/26/2013)
Doxorubicin (Adriamycin) Lyophilized Powder (initial posting 12/2/2011)
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
Fluphenazine Decanoate Injection 4/25/2013
Fluphenazine Hydrochloride Injection
Furosemide Injection (initial posting 6/20/2012)
Heparin Sodium Injection (initial posting 7/5/2012)
Hydromorphone Hydrochloride (Dilaudid) Injection (initial posting 3/7/2012)
Hydromorphone Hydrochloride Tablets (initial posting 2/19/2013)
Intravenous Fat Emulsion
Isoniazid; Rifampin (Rifamate) Capsules 3/15/2013
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection UPDATED 11/26/2013
Levothyroxine Sodium (Levoxyl) Tablets (initial posting date - 3/15/2013)
Lidocaine Hydrochloride (Xylocaine) Injection (initial posting date - 2/22/2012)
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

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
Morphine Sulfate Injection
Morphine Sulfate (Astramorph PF, Duramorph, Infumorph) Injection (Preservative Free)
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine Hydrochloride (Nubain) Injection (initial posting 5/15/2012)
Neostigmine Methylsulfate Injection (initial posting 1/14/2013)
Ondansetron (Zofran) 2mg/mL Injection
Pancuronium Bromide Injection
Papaverine Hydrochloride Injection (initial posting 12/17/2012)
Pegvisomant (Somavert) Injection (initial posting 10/21/2013)
Phosphate (Glycophos) Injection (initial posting 5/29/2013)
Pilocarpine HCL Opthalmic Gel 4% (Pilopine HS) (initial posting 6/1/2012)
Potassium Acetate Injection, USP 2mEq/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)
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) Lyophilized Powder for Injection (initial posting 6/21/2013)
Sodium Chloride 0.9% (5.8mL and 20mL) (initial posting 5/4/2012)
Sodium Chloride 23.4%
Sodium Phosphate Injection
Succinylcholine (Anectine, Quelicin) Injection (initial posting 8/17/2012)
Sufentanil Citrate (Sufenta) Injection
Sulfamethoxazole 80mg/ml;Trimethoprim 16mg/ml (SMX/TMP) (Bactrim) Injection
Telavancin (Vibativ) Injection
Tetracycline Capsules
Thiotepa (Thioplex) for Injection
Ticarcillin Disodium/Clavulanic Potassium (Timentin) Injection (initial posting 8/16/2012)
Tiopronin (Thiola)
Tobramycin Solution for Injection UPDATED 11/26/2013
Trace Elements (initial posting 1/24/2013)
Tromethamine (Tham) Injection (initial posting 5/2/2012)
Verapamil Hydrochloride Injection, USP (initial posting 4/17/2013)
Vitamin A Palmitate (Aquasol A)
Zinc Injection (initial posting 2/15/2012)