Drug Utilization Review Board

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

Wednesday
March 14, 2012
6:00 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

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

SUBJECT: Packet Contents for Board Meeting – March 14, 2012

DATE: March 8, 2012

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 March meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Abstral®, Lazanda®, Nucynta® ER, and Oxecta® – See Appendix C.

Action Item – Vote to Prior Authorize Xgeva® – See Appendix D.

Action Item – Vote to Prior Authorize Hydroxyprogesterone Caproate – See Appendix E.

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

Action Item – Annual Review of Ampyra® – See Appendix G.

Action Item – Annual Review of Qutenza® – See Appendix H.

FDA and DEA Updates – See Appendix I.

Future Business

Adjournment

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Oklahoma Health Care Authority
Drug Utilization Review Board

(DUR Board)

Meeting – March 14, 2012 @ 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. February 8, 2012 DUR Minutes – Vote
B. February 9, 2012 DUR Recommendation Memorandum

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

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

A. Retrospective Drug Utilization Review for November 2011
B. Retrospective Drug Utilization Review Response for September 2011
C. Medication Coverage Activity for February 2012
D. Pharmacy Help Desk Activity for February 2012

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

5. Action Item – Vote to Prior Authorize Abstral®, Lazanda®, Nucynta® ER, and Oxecta® – See Appendix C.

A. Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) Speaker, Melton Edminsten, Chief Agent of Diversion
B. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Xgeva® – See Appendix D.

A. COP Recommendations

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

7. Action Item – Vote to Prior Authorize Hydroxyprogesterone Caproate – See Appendix E.

A. Product Summary
B. SoonerCare Birth Statistics
C. COP Recommendations

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

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

A. Cystic Fibrosis Overview
B. Product Summary
C. COP Recommendations

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

9. Action Item – Questions Regarding Annual Review of Ampyra® – See Appendix G.

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

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

10. Action Item – Questions Regarding Annual Review of Qutenza® – See Appendix H.

A. Current Authorization Criteria
B. Trends in Utilization
C. COP Recommendations

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

11. FDA and DEA Updates – See Appendix I.

12. Future Business

A. Annual Review Requip XL®
B. Annual Review Metasolv®
C. Fiscal Year 2011 Annual Review
D. New Product Reviews
E. Medical Product Reviews

13. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of FEBRUARY 8, 2012

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

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Shellie Keast, Pharm.D, M.S.; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Coordinator	X	
Mark Livesay, Operations Manager	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator	X	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Graduate Students: Amany Hussein, Manish Mittal	X	
Visiting Pharmacy Student(s): Susan Hernandez, Jo Nel Weber	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer	X	
Garth Splinter, M.D., M.B.A.; Director of Medicaid/Medical Services	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
Carter Kimble, MPH/Public Affairs- Information Rep.	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	
Stacey Hale, Pharmacy Research Analyst	X	

OTHERS PRESENT:		
Eric Gardner, Vertex Pharma	Warren Tayes, Merck	Bill White, Lundbeck
Laura Walker, Lundbeck	Charlene Kaiser, Amgen	Toby Thompson, Pfizer
Kay Walker, Pfizer	Tone Jones, Suyovion	Evan Rushing, Covidien
Holly Turner, Merck	Renee Parks, J&J	Russ Wilson, J&J
Donna Erwin, BMS	Sandra Manning, BMS	Jim Fowler, AstraZeneca
Shannon Pfieffer, Reckitt Benckiser	Janie Huff, Takeda	Laura Mitchell, Purdue

PRESENT FOR PUBLIC COMMENT:	
Agenda Item No. 6	Randy Clifton, Alexion
Agenda Item Nos. 8, 10, 12	Brad Clay, Amgen

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

Dr. Muchmore acknowledged the speakers for public comment:

Agenda Item No. 6 Randy Clifton, Alexion

Agenda Item Nos. 8, 10, 12 Brad Clay, Amgen

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: January 11, 2012 DUR Minutes

Dr. Preslar 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: Retrospective Drug Utilization Review: October 2011

4B: Medication Coverage Activity Audit: January 2012

4C: Pharmacy Help Desk Activity Audit: January 2012

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE SELECT PRENATAL VITAMINS

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE SOLIRIS®

For Public Comment; Randy Clifton:

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

Noted changes: Change age restriction to age 18 years; under 18 years requires a special request and documentation to approve for atypicals.

Dr. Bell moved to approve with noted changes; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ONFI™

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

Noted change: After one year, documentation of efficacy must be stated to continue approval.

Dr. Bell moved to approve with noted change; seconded by Dr. Kuhls.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF ERYTHROPOIETIN STIMULATING AGENTS

For Public Comment: Brad Clay:

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

Noted change: For eight weeks of therapy for oncology (cancer/chemotherapy) to twelve weeks for CKD (chronic kidney disease).

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF NARCOTIC ANALGESICS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ABSTRAL®, LAZANDA®, NUCYNTA ER®, AND OXECTA®

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

AGENDA ITEM NO. 10: 30-DAY NOTICE TO PRIOR AUTHORIZE XGEVA®
For Public Comment: Brad Clay:
Materials included in agenda packet; presented by Dr. Sipols.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: 30-DAY NOTICE TO PRIOR AUTHORIZE MAKENA™
Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: QUESTIONS REGARDING ANNUAL REVIEW OF MOZOBIL®, NPLATE®, ARCALYST®, AND ILARIS®
For Public Comment: Brad Clay:
Materials included in agenda packet; presented by Dr. Sipols.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: FDA & DEA UPDATES
Materials included in agenda packet; presented by Dr. Cothran.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: FUTURE BUSINESS
Materials included in agenda packet; submitted by Dr. Cothran.
A: Annual Review of Qutenza®
B: Annual Review of Miscellaneous Special Formulation Anti-Infectives
C: New Product Reviews
D: Medical Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ADJOURNMENT
The meeting was adjourned at 7:30 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: February 9, 2012

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

From: Shellie Keast, Pharm.D., M.S.
Drug Utilization Review Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of February 8, 2012

Recommendation 1: Vote to Prior Authorize Select Prenatal Vitamins

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends placing a prior authorization on any prenatal vitamin with a cost per day of greater than $0.75. All preferred products will contain 1 mg of Folic Acid and at least two products will contain DHA/Omega-3 (based on the two lowest priced products available). Products with a cost greater than $0.75 per day will require prior authorization with the following criteria for approval: clinically significant reason why the member cannot use any available non-prior authorized product.

Due to the transient nature of the use of prenatal vitamins during pregnancy, current members will be allowed to stay on their product for the duration of their pregnancy as long as they remain compliant.

Prior authorization requirements may be removed when the product's price is at or below the designated pricing cutoff.

Recommendation 2: Vote to Prior Authorize Soliris® (eculizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends medical prior authorization of Soliris® (eculizumab) with the following approval criteria:

1. Established diagnosis of paroxysmal nocturnal hemoglobinuria or atypical hemolytic uremic syndrome via ICD-9 coding in member's medical claims.
2. An age restriction of ~~19~~ 18 years and older will apply.
3. For members under 18 years of age, approval can be granted with a documented diagnosis of atypical hemolytic uremic syndrome.

Recommendation 3: Vote to Prior Authorize Onfi™ (clobazam)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Onfi™ (clobazam) with the following approval criteria:

1. Diagnosis of generalized tonic, atonic or myoclonic seizures; and
2. Previous failure of at least two non-benzodiazepine anticonvulsants; and
3. Previous failure of clonazepam.
4. For continuation prescriber must include information regarding improved response/effectiveness of this medication.

Recommendation 4: Annual Review of Erythropoietin Stimulating Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the ESA prior authorization criteria:

Continuation Criteria:

a. Continue dose if Hb is ≤ 11.0 g/dL.
b. If Hb is increasing and approaching 11.0 g/dL then reduce dose.
c. If more than 1 g/dL increase (but Hb not greater than upper limits listed below) has occurred in a 2 week period reduce dose by 25 to 50 %.

Discontinuation Criteria:

d. ESRD – Discontinue treatment if Hb is at or above 11.0 g/dL.
e. All others – Discontinue treatment if Hb is at or above 11.0 g/dL.

f. If a minimum increase of 1 g/dL has not been achieved after initial 8 weeks of therapy for anemia associated with chemotherapy and 12 weeks of therapy for ESRD.

Recommendation 5: Annual Review of Narcotic Analgesics

NO ACTION REQUIRED.

The College of Pharmacy recommends continuation of the Narcotic Analgesic Product Based Prior Authorization category.

Recommendation 6: Annual Review of Mozobil® (plerixafor), Nplate® (romiplostim), Arcalyst® (rilonacept), and Ilaris® (canakinumab)

NO ACTION REQUIRED.

The College of Pharmacy recommends continuation of the current criteria for these products.

Appendix B

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT
November 2011

MODULE	DRUG INTERACTION	DUPLICATION OF THERAPY	DRUG-DISEASE PRECAUTIONS	DOSING & DURATION
Total # of messages	56,729	71,348	1,001,598	34,418
Limits applied	Established, Major, Males and Females, Age 61-150	Duplication of Atypical Antipsychotics, Males and Females, Age 14-16	Contraindicated, Males and Females, Drug Dependence, Ages 0-150	High Dose, Duration, Proton Pump Inhibitors, Males & Females age 13-14
Total # of messages after limits were applied	64	233	81	54
Total # of members reviewed	64	188	67	54

LETTERS

Category	Prescribers	Pharmacies	Total Letters
Drug Interaction	0	0	0
Duplication of Therapy	81	0	81
Drug-Disease Precautions	16	0	16
Dosing & Duration	12	0	12
Total Letters Sent	109	0	109

Retrospective Drug Utilization Review Report

Claims Reviewed for September 2011

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 36-50	Duplication of Atypical Antipsychotics, Males and Females, Age 0-10	Contraindicated, Pregnancy, Females, Age 22-45	High Dose, Proton Pump Inhibitors, Males and Females, Age 0-10

Response Summary (Prescriber)
Letters Sent: 65
Response Forms Returned: 38

The response forms returned yielded the following results:

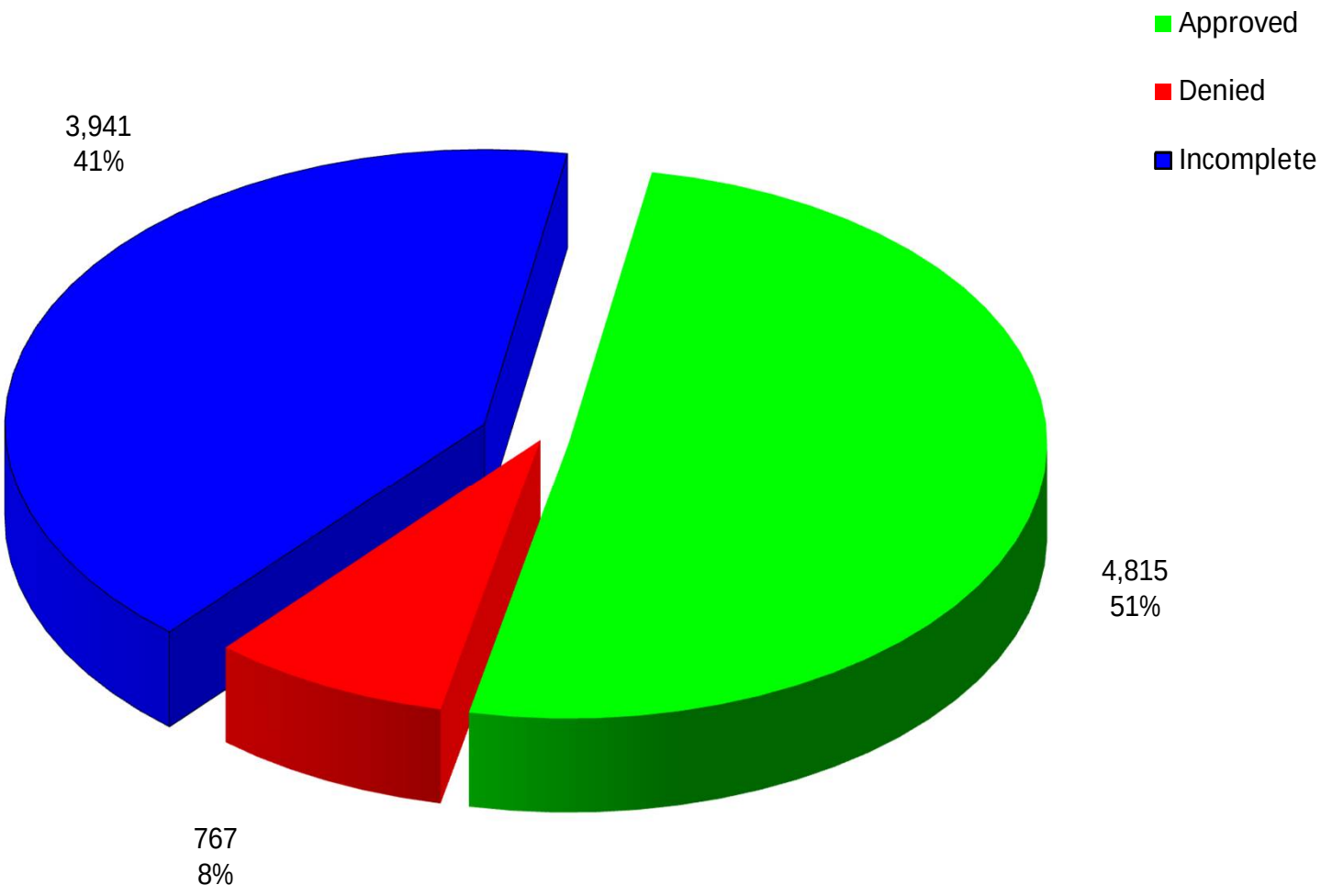
0 (0%)	*Record Error—Not my patient.*
2 (5%)	*No longer my patient.*
3 (8%)	*Medication has been changed prior to date of review letter.*
6 (15%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
25 (66%)	*I am aware of this situation and will plan to continue monitoring therapy.*
2 (5%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 2
Response Forms Returned: 1

The response forms returned yielded the following results:

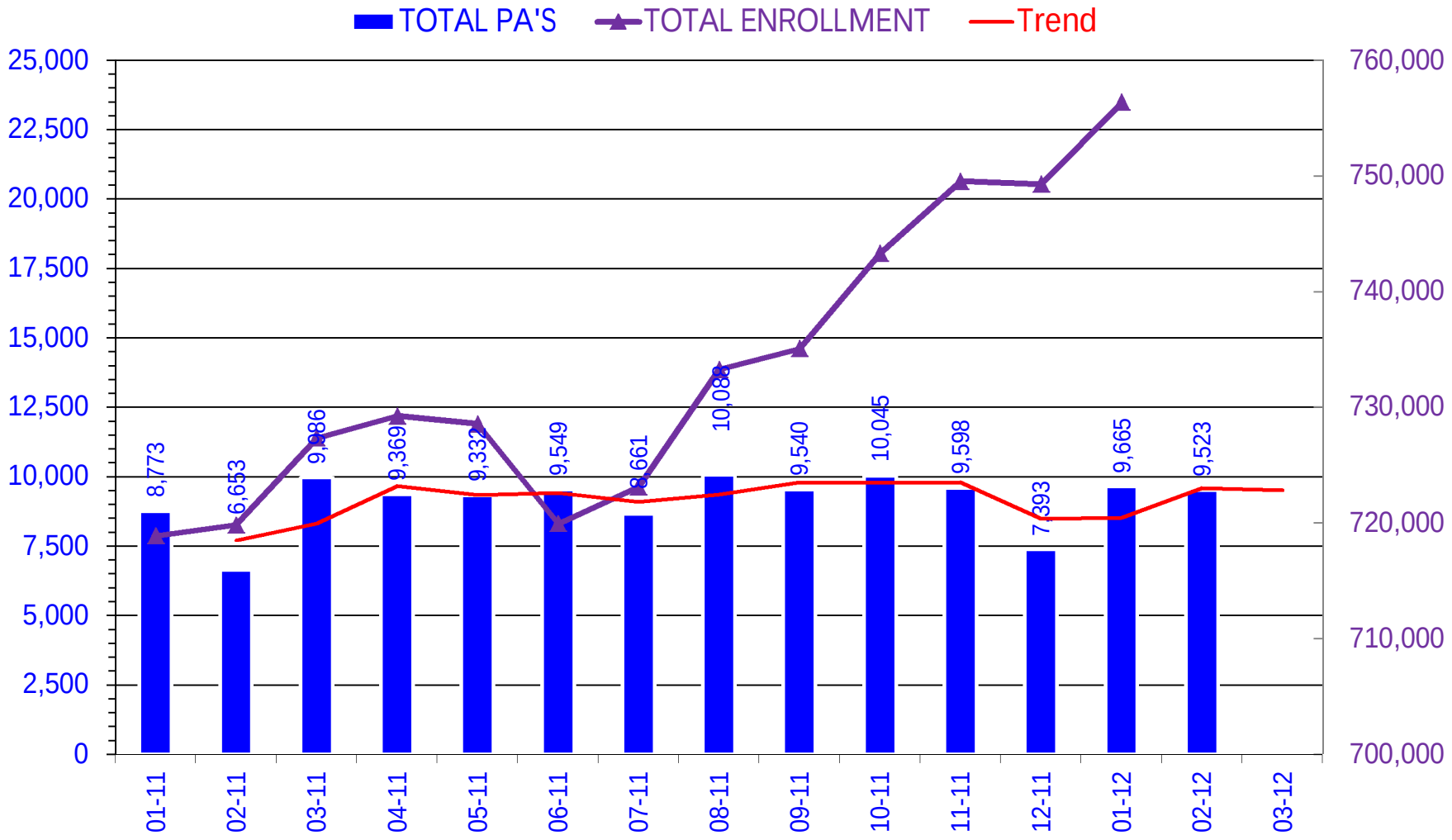
0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
0 (0%)	*Medication has been changed prior to date of review letter.*
1 (100%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
0 (0%)	*I am aware of this situation and will plan to continue monitoring therapy.*
0 (0%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: February 2012



PA totals include overrides

PRIOR AUTHORIZATION REPORT: February 2011 – February 2012



PA totals include overrides

Prior Authorization Activity

2/1/2012 Through 2/29/2012

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	353	158	22	173	358
Amitiza	30	7	6	17	283
Anti-Ulcer	419	127	59	233	100
Antidepressant	315	116	17	182	350
Antihistamine	206	149	4	53	351
Antihypertensives	65	14	4	47	304
Antimigraine	124	31	18	75	325
Atypical Antipsychotics	741	370	40	331	356
Benign Prostatic Hypertrophy	8	1	0	7	365
Benzodiazepines	64	38	3	23	252
Biologics	46	22	4	20	363
Bladder Control	60	11	12	37	337
Brovana (Arformoterol)	4	2	0	2	365
Byetta	14	6	0	8	363
Elidel/Protopic	30	15	7	8	94
ESA	108	74	7	27	113
Fibric Acid Derivatives	7	2	1	4	227
Fibromyalgia	140	41	29	70	354
Fortamet/Glumetza	3	2	0	1	361
Forteo	1	1	0	0	365
Glaucoma	18	5	1	12	294
Growth Hormones	51	37	3	11	175
HFA Rescue Inhalers	186	39	16	131	265
Insomnia	114	27	9	78	184
Insulin	8	6	0	2	197
Misc Analgesics	27	2	18	7	55
Multiple Sclerosis	12	6	1	5	225
Muscle Relaxant	124	55	32	37	56
Nasal Allergy	198	33	37	128	105
NSAIDS	140	24	13	103	278
Ocular Allergy	50	10	3	37	140
Ocular Antibiotics	51	11	3	37	14
Opioid Analgesic	368	187	15	166	277
Other	1,097	477	120	500	295
Otic Antibiotic	40	11	2	27	13
Pediculicides	118	42	15	61	14
Plavix	166	128	1	37	316
Singulair	798	406	26	366	254
Smoking Cessation	63	25	3	35	32
Statins	141	83	10	48	353
Stimulant	896	429	64	403	300
Suboxone/Subutex	113	91	4	18	77
Synagis	137	101	18	18	45
Topical Antibiotics	10	6	0	4	54
Topical Antifungals	8	2	1	5	27
Topical Corticosteroids	69	1	16	52	116
Ultram ER and ODT	6	2	0	4	178
Xolair	6	2	1	3	254
Xopenex Nebs	18	9	3	6	311
Zetia (Ezetimibe)	19	11	1	7	362
Emergency PAs	15	15	0	0	
Total	**7,805**	**3,470**	**669**	**3,666**	

Overrides					
Brand	58	26	8	24	280
Dosage Change	589	556	1	32	10
High Dose	5	5	0	0	101
Ingredient Duplication	10	7	1	2	7
Lost/Broken Rx	111	107	0	4	9
NDC vs Age	7	7	0	0	271
Nursing Home Issue	80	78	0	2	17
Other	27	25	0	2	9
Quantity vs. Days Supply	819	523	88	208	267
Stolen	8	8	0	0	6
Third Brand Request	2	2	0	0	13
Wrong D.S. on Previous Rx	2	1	0	1	6
Overrides Total	**1,718**	**1,345**	**98**	**275**	
Total Regular PAs + Overrides	**9,523**	**4,815**	**767**	**3,941**	

Denial Reasons	
Unable to verify required trials.	3,298
Does not meet established criteria.	717
Lack required information to process request.	662
Drug Not Deemed Medically Necessary	1

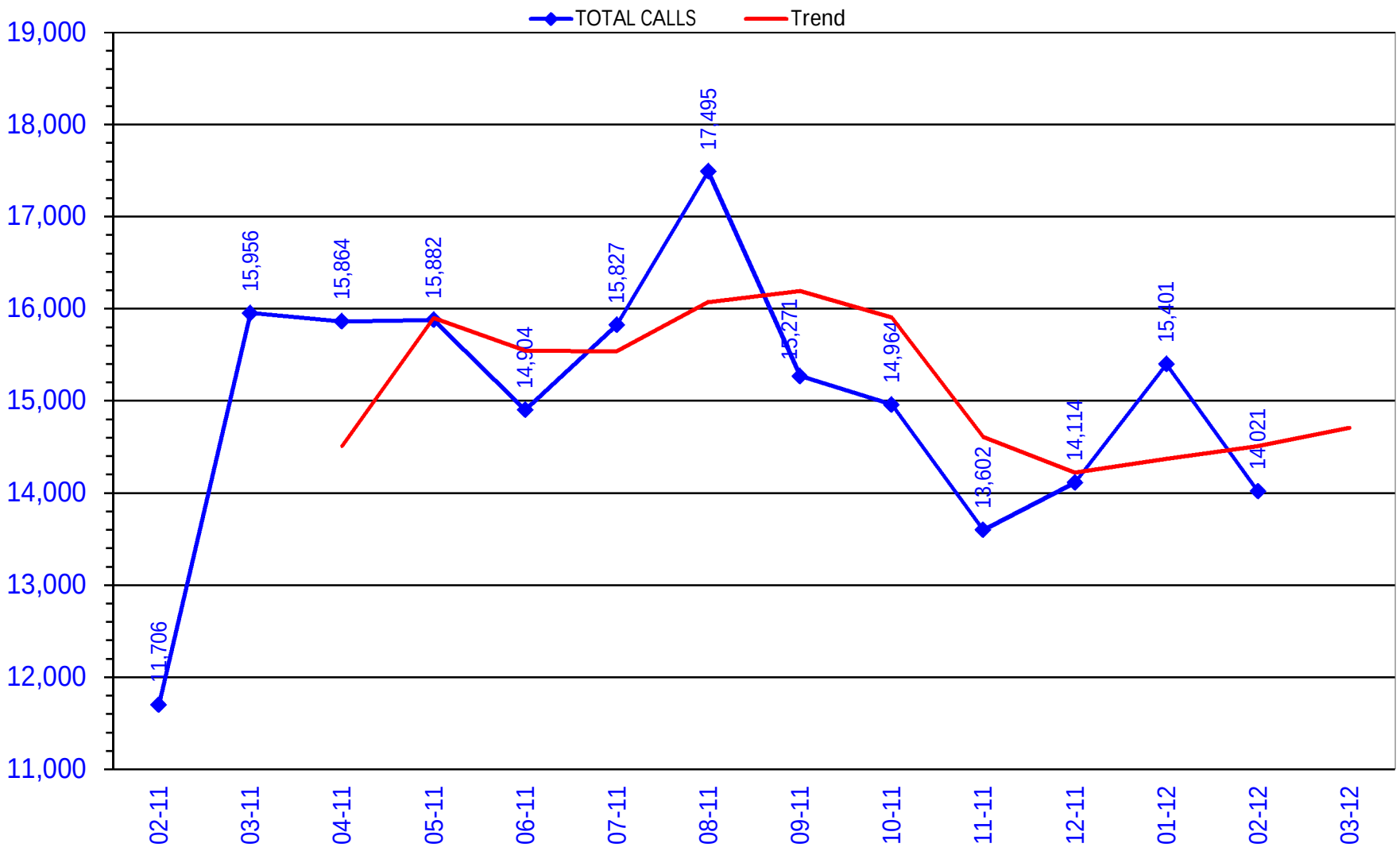
Duplicate Requests: 628

Letters: 1,816

No Process: 368

Changes to existing PAs: 520

CALL VOLUME MONTHLY REPORT:
February 2011 – February 2012



Appendix C

VOTE TO PRIOR AUTHORIZE ABSTRAL® (FENTANYL) SUBLINGUAL TABLETS, LAZANDA® (FENTANYL) NASAL SPRAY, NUCYNTA® ER (TAPENTADOL), AND OXECTA® (OXYCONDONE)

OKLAHOMA HEALTH CARE AUTHORITY

MARCH 2012

RECOMENDATIONS

The College of Pharmacy recommends placement of the following products in the Narcotic PBPA Tier structure:

Abstral® (fentanyl): to be placed in the Oncology Only Tier with an age restriction of at least 18 years of age and a quantity limit of four tablets daily. Additionally, a reason why other forms of fentanyl breakthrough pain therapy cannot be used must be provided.

Lazanda® (fentanyl): to be placed in the Oncology Only Tier (once a federal rebate is in place) with an age restriction of at least 18 years of age and a quantity limit of 5 mL per month. Additionally, a reason why other forms of fentanyl breakthrough pain therapy cannot be used must be provided.

Nucynta® ER (tapentadol): to be placed in Tier 3 of the Long-Acting Products with an age restriction of at least 18 years of age and a quantity limit of two tablets daily.

Oxecta® (oxycodone): to be placed in Tier 3 of the Short-Acting products with a quantity limit of 8 per day.

Narcotic Analgesics			
Tier-1 products are covered with no prior authorization necessary.			
Tier-2 authorization requires: ▪ documented 30 day trial/titration period with at least two Tier-1 medications within the last 90 days, or ▪ clinically appropriate pain therapy requiring time-released medication Tier-3 authorization requires: ▪ documented 30 day trial with at least two Tier-2 medications within the last 90 days, or ▪ documented allergy or contraindication to all Tier-2 medications			
▪ Members with an oncology-related diagnosis are exempt from the prior authorization process, although quantity and dosage limits still apply. Actiq®, Fentora®, and Onsolis® are approved only for oncology-related diagnoses.			
▪ Only one long-acting and one short-acting agent can be used concurrently			
Tier-1	**Tier-2**	**Tier-3**	**Oncology Only**
All immediate release narcotics not listed in a higher tier	**Long Acting**		
	fentanyl patch (Duragesic®)	oxymorphone (Opana® ER)	
	morphine ER	morphine sulfate (Kadian®)	
		morphine sulfate (Avinza®)	
		oxycodone (OxyContin®)	
		tramadol ER (Ultram ER®, Ryzolt®)	
		morphine and naltrexone (Embeda™)	
		hydromorphone ER (Exalgo®)	
		buprenorphine patch (Butrans®)	
		Tapentadol ER (Nucynta® ER)	
	Short Acting		
	oxymorphone (Opana®)	Hydrocodone/APAP (Xodol®, Zamicet®, Hycet®, Zolvit®, Liquicet)	fentanyl (Actiq®, Onsolis®, Fentora®, Abstral®, Lazanda®)
	Tapentadol (Nucynta®)	oxycodone/APAP (Primlev™, Xolox®)	
		Oxycodone (Oxecta®)	
		tramadol ODT (Rybix®)	

Appendix D

Vote to Prior Authorize Xgeva® (denosumab)

Oklahoma Health Care Authority, March 2012

Recommendations

The College of Pharmacy recommends medical prior authorization of Xgeva® with the following criteria:

1. FDA approved indication of prevention of skeletal-related events in patients with bone metastases from solid tumors.

Appendix E

Vote to Prior Authorize Hydroxyprogesterone Caproate

Oklahoma Health Care Authority, March 2012

Under Oklahoma state law, the OHCA DUR Board must review and make recommendations for any drug subject to prior authorization, whether covered under the pharmacy benefit, the medical benefit, or both. Accordingly, physician administered drugs are brought through the same DUR process as those dispensed by pharmacies.

Hydroxyprogesterone caproate is an intramuscular injectable indicated to reduce the risk of preterm delivery before 37 weeks gestation for women with a history of one spontaneous preterm delivery. It is to be administered by a healthcare provider, dosed once weekly starting between 16 and 21 weeks gestation and continuing until 37 weeks gestation or delivery, whichever is first.

SoonerCare Birth Statistics

- Calendar year 2010 (2011 data not yet available)
    - 51,798 births in Oklahoma[1]
    - 33,125 SoonerCare deliveries[1]
    - Oklahoma's premature birth rate for 2010 - 13.4%[2]
        - Approximately 4,439 SoonerCare premature births.
        - 803 SoonerCare members with medical or outpatient claims with the diagnosis code V243.1 - Supervision of high-risk pregnancy w/ history of pre-term labor.

Recommendations

The College of Pharmacy recommends medical prior authorization of this medication.

Criteria for Approval for Hydroxyprogesterone Caproate

1) Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and
2) Current singleton pregnancy; and
3) Gestational age between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
4) Authorizations will be for once a week administration in an office setting through 36 weeks, 6 days of gestation.

REFERENCES

[1]SoonerCare Delivery Fast Facts Available online at: www.okhca.org/research.aspx?id=87

[2]March of Dimes 2010 Premature Birth Report Card. Available online at: http://media.dssimon.com/mod10

Appendix F

30 Day Notice to Prior Authorize Kalydeco™ (Ivacaftor)

Oklahoma Health Care Authority
March 2012

Manufacturer	Vertex Pharmaceuticals, Inc.
Classification	Cystic Fibrosis Transmembrane Conductance Protein Potentiator
Status	Prescription Only

Cystic Fibrosis

Cystic fibrosis is caused by defects in the cystic fibrosis gene, which codes for a protein transmembrane conductance regulator (*CFTR*) that functions as a chloride channel and is regulated by cyclic adenosine monophosphate (cAMP). Mutations in the *CFTR* gene result in abnormalities of cAMP-regulated chloride transport across epithelial cells on mucosal surfaces.[1] The results range from life threatening to mild symptoms[2] in different individuals:

Symptoms in newborns may include:

- Delayed growth
- Failure to gain weight normally during childhood
- No bowel movements in first 24 to 48 hours of life
- Salty-tasting skin

Symptoms related to bowel function may include:

- Belly pain from severe constipation
- Increased gas, bloating, or a belly that appears swollen (distended)
- Nausea and loss of appetite
- Stools that are pale or clay colored, foul smelling, have mucus, or that float
- Weight loss

Symptoms related to the lungs and sinuses may include:

- Coughing or increased mucus in the sinuses or lungs
- Fatigue
- Nasal congestion caused by nasal polyps
- Recurrent episodes of pneumonia

Symptoms that may be noticed later in life:

- Infertility (in men)
- Repeated inflammation of the pancreas (pancreatitis)
- Respiratory symptoms

Kalydeco™ (ivacaftor) Summary

Kalydeco™ (ivacaftor) is indicated for the treatment of cystic fibrosis in patients age 6 years and older who have a *G551D* mutation in the cystic fibrosis transmembrane conductance regulator gene (CFTR). Although cystic fibrosis affects approximately 30,000 people in the United States, the G551D mutation is present in only about 4% of those affected.[3] If the patient's genotype is unknown, a CF mutation test should be used to detect the presence of the *G551D* mutation. Kalydeco™ (ivacaftor) is not effective in patients with CF who are homozygous for the *F508del* mutation in the *CFTR* gene and has not been studied in other populations of patients with CF.

Kalydeco™ (ivacaftor) is available as 150mg tablets, and should be taken orally every 12 hours with fat-containing food. The dose should be reduced in patients with moderate and severe hepatic impairment or when co-administered with drugs that are moderate or strong CYP3A inhibitors.

Efficacy

The efficacy of Kalydeco™ (ivacaftor) in patients with CF who have a *G551D* mutation in the *CFTR* gene was evaluated in two randomized, double-blind, placebo-controlled clinical trials.

- Trial 1 evaluated 161 patients with CF who were 12 years of age or older (mean age 26 years) with baseline FEV1 between 40-90% predicted [mean FEV_1 64% predicted (range: 32% to 98%)].
- Trial 2 evaluated 52 patients who were 6 to 11 years of age (mean age 9 years) with baseline FEV_1 between 40-105% predicted [mean FEV_1 84% predicted (range: 44% to 134%)].
- Patients in both trials were randomized 1:1 to receive either 150 mg of Kalydeco™ or placebo every 12 hours with food containing fat for 48 weeks in addition to their prescribed CF therapy.
- The primary efficacy endpoint in both studies was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV_1 through 24 weeks of treatment.
- In both studies, treatment with Kalydeco™ resulted in a significant improvement in FEV_1. The treatment difference between Kalydeco™ and placebo for the mean absolute change in percent predicted FEV_1 from baseline through Week 24 was 10.6 percentage points ($P < 0.0001$) in Trial 1 and 12.5 percentage points ($P < 0.0001$) in Trial 2 (Figure 3). These changes persisted through 48 weeks. Improvements in percent predicted FEV_1 were observed regardless of age, disease severity, sex, and geographic region.

Cost

Kalydeco™ (ivacaftor) 150mg tablets cost $431 per tab. Based on the cost per tablet at BID dosing, treatment with Kalydeco™ (ivacaftor) will be approximately $25,860 per month per member.

Recommendations

The College of Pharmacy recommends prior authorization of Kalydeco™ (ivacaftor) with the following criteria:

1. FDA approved indication of Cystic Fibrosis with a G551D mutation in the CFTR gene detected by genetic testing.
2. Age of 6 years or older.
3. Quantity limit of two tablets per day, #60 per 30 days will apply.
4. Initial approval will be for 6 months, after which time, compliance and information regarding efficacy, such as improvement in FEV_1, will be required for continued approval.

PRODUCT DETAILS OF KALYDECO™ (IVACAFTOR)[4]

FDA APPROVED: 2012

INDICATIONS: Kalydeco™ is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a *G551D* mutation in the *CFTR* gene.

DOSAGE FORM: 150mg Tablets.

ADMINISTRATION:

- Adults and pediatric patients age 6 years and older: one 150 mg tablet taken orally every 12 hours with fat-containing food.
- Reduce dose in patients with moderate and severe hepatic impairment.
- Reduce dose when co-administered with drugs that are moderate or strong CYP3A inhibitors.

CONTRAINDICATIONS: None listed.

SPECIAL POPULATIONS:

- **Pregnancy Category B.** Excretion into human milk is probable, although there are no human studies that have investigated the effects of ivacaftor on breast-fed infants.
- **Pediatric Use:** Safety and effectiveness in patients <6 years of age have not been established.
- **Geriatric Use:** CF is largely a disease of children and young adults. Clinical trials of KALYDECO did not include sufficient numbers of patients 65 years of age and over to determine whether they respond differently from younger patients.
- **Hepatic Impairment:** No dose adjustment is necessary for patients with mild hepatic impairment (Child-Pugh Class A). A reduced dose of 150 mg once daily is recommended in patients with moderate hepatic impairment (Child-Pugh Class B). Studies have not been conducted in patients with severe hepatic impairment (Child-Pugh Class C) but exposure is expected to be higher than in patients with moderate hepatic impairment. Therefore, use with caution at a dose of 150 mg once daily or less frequently in patients with severe hepatic impairment after weighing the risks and benefit of treatment.
- **Renal Impairment:** Kalydeco™ has not been studied in patients with mild, moderate, or severe renal impairment or in patients with end stage renal disease. No dose adjustment is necessary for patients with mild to moderate renal impairment; however, caution is recommended while using Kalydeco™ in patients with severe renal impairment (creatinine clearance less than or equal to 30 mL/min) or end stage renal disease.
- **Patients with CF who are Homozygous for the *F508del* Mutation in the *CFTR* Gene:** Efficacy results from a double-blind, placebo-controlled trial in patients with CF who are homozygous for the *F508del* mutation in the *CFTR* gene showed no statistically significant difference in forced expiratory volume exhaled in one second (FEV_1) over 16 weeks of Kalydeco™ treatment compared to placebo. Therefore, Kalydeco™ should not be used in patients homozygous for the *F508del* mutation in the *CFTR* gene.

WARNINGS & PRECAUTIONS:

- **Elevated transaminases (ALT or AST):** Transaminases (ALT and AST) should be assessed prior to initiating Kalydeco™, every 3 months during the first year of treatment, and annually thereafter. Patients who develop increased transaminase levels should be closely monitored until the abnormalities resolve. Dosing should be interrupted in patients with ALT or AST of greater than 5 times the upper limit of normal (ULN). Following resolution of transaminase elevations, consider the benefits and risks of resuming Kalydeco™ dosing.
- **Use with CYP3A inducers:** Concomitant use with strong CYP3A inducers (e.g., rifampin, St. John's Wort) substantially decreases exposure of ivacaftor which may diminish effectiveness. Therefore, coadministration is not recommended.

ADVERSE REACTIONS: (occurring ≥8% of patients with CF who have a *G551D* mutation in the *CFTR* gene)

- headache,
- oropharyngeal pain,
- upper respiratory tract infection,
- nasal congestion,
- abdominal pain,
- nasopharyngitis,
- diarrhea,
- rash,
- nausea,
- dizziness

DRUG INTERACTIONS:

CYP3A inhibitors: Reduce Kalydeco™ dose to 150 mg twice-a-week when co-administered with strong CYP3A inhibitors (e.g., ketoconazole). Reduce the Kalydeco™ dose to 150 mg once daily when co-administered with moderate CYP3A inhibitors (e.g., fluconazole). Avoid food containing grapefruit or Seville oranges.

PATIENT INFORMATION:

1. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements as the dose of Kalydeco™ may need to be adjusted when taken with certain medications. Especially tell your doctor if you take:
    a. antifungal medications such as ketoconazole (e.g., Nizoral®), itraconazole (e.g., Sporanox®), posaconazole (e.g., Noxafil®), voriconazole (e.g., Vfend®), or fluconazole (e.g., Diflucan®)
    b. antibiotics such as telithromycin (e.g., Ketek®), clarithromycin (e.g., Biaxin®), or erythromycin (e.g., Ery-Tab®)
2. Kalydeco™ can cause dizziness in some people who take it. Do not drive a car, use machinery or do anything that needs you to be alert until you know how Kalydeco™ affects you.
3. You should avoid food containing grapefruit or Seville oranges while you are taking Kalydeco™.
4. Call your doctor right away if you have any of the following symptoms of liver problems:
    a. pain or discomfort in the upper right stomach (abdominal) area
    b. yellowing of your skin or the white part of your eyes
    c. loss of appetite
    d. nausea or vomiting
    e. dark, amber-colored urine

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[1] http://emedicine.medscape.com/article/1001602-overview#a0104
[2] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001167/
[3] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289633.htm
[4] Kalydeco™ Product Information. Vertex Pharmaceuticals, Inc. Accessed online at: http://pi.vrtx.com/files/uspi_ivacaftor.pdf Last revised January 2012.

Appendix G

Annual Review of Ampyra® (dalfampridine) - Fiscal Year 2011

Oklahoma HealthCare Authority
March 2012

Current Prior Authorization Criteria (FDA approved in January 2010)

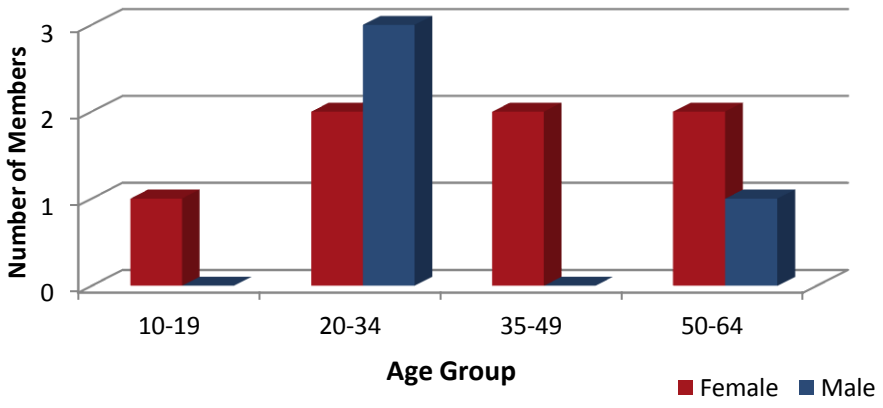
1. Member must have a diagnosis of Multiple Sclerosis
2. Kurtzke Expanded Disability Status Scale (EDSS) score between 4 and 7.5
3. A 90 day trial will be approved. If member has responded well to treatment and physician states that the member has shown improvement or the drug was effective, member may receive authorization for one year
4. Quantity limit of 60 for 30 days

Utilization of Ampyra® (Available on the market 3/1/10)

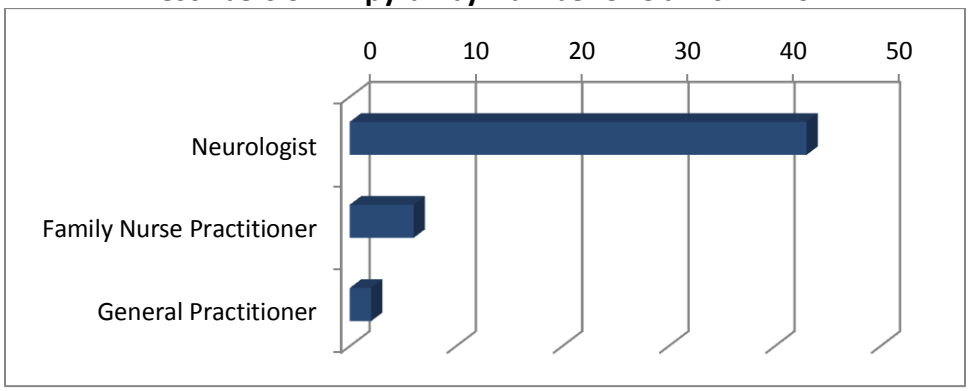
Comparison of Fiscal Years

Fiscal Year	Members	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2010	3	7	$6,707.94	$958.28	$31.94	360	120
2011	11	51	$ 55,642.02	$1,091.02	$36.37	2,940	1,530
Percent Change	**266.7%**	**628.6%**	**729.5%**	**13.9%**	**13.9%**	**716.7%**	**628.6%**
Change	**8**	**44**	**$48,934.08**	**$132.74**	**$4.43**	**2,580**	**1,320**

Demographics of Members Utilizing Ampyra®: FY 2011



Prescribers of Ampyra® by Number of Claims: FY 2011



Prior Authorization of Medication or Class

There were a total of 40 petitions submitted for this PBPA category during fiscal year 2011 since prior authorization was implemented in November 2010. The following chart shows the status of the submitted petitions.

Status	Total PA Count
Approved	13
Incomplete	27

Market News and Update

- Minor editorial revisions to the REMS communication plan, Dear Healthcare Professional and Dear Pharmacist Letters, and to the Medication Guide were submitted to the FDA and approved in November, 2011

Conclusion and Recommendations

The College of Pharmacy recommends no changes to the current prior authorization criteria.

Appendix H

Fiscal Year 2011 Annual Review of Qutenza® (capsaicin) 8% Patch

Oklahoma Health Care Authority, March 2012

Current Prior Authorization Criteria

1. FDA approved diagnosis (Postherpetic Neuralgia).
2. Provide documented treatment attempts at recommended dosing or contraindication to at least one agent from each of the following drug classes:
    a. Tricyclic antidepressants
    b. Anticonvulsants
    c. Topical lidocaine
3. Quantity limit of no more than 4 patches per treatment every 90 days.
4. Product must be administered by a healthcare provider.

Trends in Utilization

There has not been any pharmacy or medical utilization of this product. There was one pharmacy request for prior authorization during FY11 which was not approved. The specific J code (J7735) was not granted until January 1, 2011, any usage prior to that date in medical claims cannot be verified.

Recommendations

The College of Pharmacy does not recommend any changes to the current Prior Authorization for Qutenza® (capsaicin) 8% patch at this time.

Appendix I

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

FDA Drug Safety Communication: Interactions between certain HIV or hepatitis C drugs and cholesterol-lowering statin drugs can increase the risk of muscle injury

[3-01-2012] The U.S. Food and Drug Administration (FDA) is issuing updated recommendations concerning drug-drug interactions between drugs for human immunodeficiency virus (HIV) or hepatitis C virus (HCV) known as protease inhibitors and certain cholesterol-lowering drugs known as statins. Protease inhibitors and statins taken together may raise the blood levels of statins and increase the risk for muscle injury (myopathy). The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure, which can be fatal.

The labels for both the HIV protease inhibitors and the affected statins have been updated to contain consistent information about the drug-drug interactions. These labels also have been updated to include dosing recommendations for those statins that may safely be co-administered with HIV or HCV protease inhibitors.

Healthcare professionals should refer to the current drug labels for protease inhibitors and statins for the latest recommendations on prescribing these drugs.

Patients should contact their healthcare professional if they have any questions or concerns about taking protease inhibitors and statins.

Facts about statins and protease inhibitors

- Statins are a class of prescription drugs used together with diet and exercise to reduce blood levels of low-density lipoprotein (LDL) cholesterol ("bad cholesterol").
- HIV protease inhibitors are a class of prescription anti-viral drugs used to treat HIV.
- HCV protease inhibitors are a class of prescription anti-viral drugs used to treat hepatitis C infection.
- A side effect of taking HIV protease inhibitors is increased cholesterol and triglyceride (fat) levels. Therefore, some patients taking HIV protease inhibitors may need to take cholesterol-lowering medicines such as statins.

Additional Information for Healthcare Professionals

- Co-administration of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) protease inhibitors with certain statins can increase the risk of myopathy/rhabdomyolysis.
- Healthcare professionals should follow the recommendations in the drug labels when prescribing HIV or HCV protease inhibitors with statins.
- Healthcare professionals should report adverse events involving HIV or HCV protease inhibitors and/or statins to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

FDA announces safety changes in labeling for some cholesterol-lowering drugs

Important safety changes to the labeling for some widely used cholesterol-lowering drugs known as statins are being announced today by the U.S. Food and Drug Administration.

These products, when used with diet and exercise, help to lower a person's "bad" cholesterol (low-density lipoprotein cholesterol). The products include: Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin), Altoprev (lovastatin extended-release), Livalo (pitavastatin), Pravachol (pravastatin), Crestor (rosuvastatin), and Zocor (simvastatin). Combination products include: Advicor (lovastatin/niacin extended-release), Simcor (simvastatin/niacin extended-release), and Vytorin (simvastatin/ezetimibe).

The changes to the statin labels are:

- The drug labels have been revised to remove the need for routine periodic monitoring of liver enzymes in patients taking statins. FDA now recommends that liver enzyme tests should be performed before starting statin therapy, and as clinically indicated thereafter. FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing this rare side effect. Patients should notify their health care professional immediately if they have the following symptoms of liver problems: unusual fatigue or weakness; loss of appetite; upper belly pain; dark-colored urine; yellowing of the skin or the whites of the eyes.
- Certain cognitive (brain-related) effects have been reported with statin use. Statin labels will now include information about some patients experiencing memory loss and confusion. These reports generally have not been serious and the patients' symptoms were reversed by stopping the statin. However, patients should still alert their health care professional if these symptoms occur.
- Increases in blood sugar levels (hyperglycemia) have been reported with statin use. The FDA is also aware of studies showing that patients being treated with statins may have a small increased risk of increased blood sugar levels and of being diagnosed with type 2 diabetes mellitus. The labels will now warn healthcare professionals and patients of this potential risk.
- Health care professionals should take note of the new recommendations in the lovastatin label. Some medicines may interact with lovastatin, increasing the risk for muscle injury (myopathy/rhabdomyolysis). For example, certain medicines should never be taken (are contraindicated) with Mevacor (lovastatin) including drugs used to treat HIV (protease inhibitors) and drugs used to treat certain bacterial and fungal infections.

New generic to the market:

The first equivalent to Lexapro® (escitalopram oxalate) is now available in 5mg, 10mg, and 20mg.

Please note: All tablets are white to off-white in color and round.