Drug Utilization Review Board

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

Wednesday
August 8, 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 – August 8, 2012

DATE: August 2, 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 August 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 Qnasl™ and Dymista™ – See Appendix C.

Action Item – Vote to Prior Authorize Subsys™ – See Appendix D.

Action Item – Vote to Prior Authorize Botulinum Toxin Products – See Appendix E.

Action Item – Atypical Antipsychotics Annual Review Follow-Up – See Appendix F.

Action Item – Annual Review of Synagis – See Appendix G.

30 Day Notice to Prior Authorize Select Gonadotropin-Releasing Hormone Analogs for Central Precocious Puberty – 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 – August 8, 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. July 11, 2012 DUR Minutes – Vote
B. July 12, 2012 DUR Recommendation Memorandum
C. Correspondence

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 April 2012
B. Retrospective Drug Utilization Review Response for February 2012
C. Medication Coverage Activity for July 2012
D. Pharmacy Help Desk Activity for July 2012

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

5. Action Item – Vote to Prior Authorize Qnasl™ and Dymista™ – See Appendix C.

A. COP Recommendations

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

6. Action Item – Vote to Prior Authorize Subsys™ – See Appendix D.

A. COP Recommendations

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

7. Action Item – Vote to Prior Authorize Botulinum Toxin Products – See Appendix E.

A. Cost Comparison
B. COP Recommendations

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

8. Atypical Antipsychotics Annual Review Follow-Up – See Appendix F.

A. Background
B. Efficacy of Abilify®
C. Utilization of Abilify®
D. Utilization from Inpatient Stabilization
E. Conclusions
F. COP Recommendations

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

9. Annual Review of Synagis® – See Appendix G.

A. Current Authorization Criteria
B. Utilization Review
C. New Recommendations from AAP
D. Referrals to Care Management Services
E. RSV Season Recap
F. COP Recommendations

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

10. 30 Day notice to Prior Authorize Select Gonadotropin-Releasing Hormone Analogs for Central Precocious Puberty – See Appendix H.

A. 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 of Pradaxa®
B. New Fiscal Year Annual Reviews
C. New Product Reviews
D. Medical Product Reviews

13. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of JULY 11, 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	
Brandy Nawaz, 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	
Jo 'Nel Weber, Pharm.D.; Clinical Pharmacist	X	
Graduate Students: Amany Hussein, Manish Mittal	X	
Visiting Pharmacy Student(s): Anh Huynh	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, M.Ph.; Public Affairs- Information Representative		X
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst		X
Stacey Hale, Pharmacy Research Analyst	X	

OTHERS PRESENT:		
John Davis, Ipsen	Deron Grothe, Teva Pharma	Jason Hooks, Teva Respirator
Audrey Rattan, Otsuka	Ben Liniger, Alcon	Glenda Owens, Endo
David Williams, Forest	Ken Stranigan, Ipsen	Charlotte Buswold, Endo
Toby Thompson, Pfizer	Jon Maguire, GSK	Andrew Thompson, Celgene
Warren Tyes, Merck	Jim Fowler, AZ	Scott Lasorsc, Genentech
Jeff Stockard, Walgreens	Charlene Kaiser, Amgen	Linda Cantu, BMS
Brian Maves, Pfizer	Jim Chapman, Abbott	

PRESENT FOR PUBLIC COMMENT:	
Agenda Item No. 8	Karen Campbell, Allergan
Agenda Item No. 9	Paul Polansky, Endo Pharmaceuticals
Agenda Item No. 10	John Mattson, Teva

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. 8 Karen Campbell, Allergan

Agenda Item No. 9 Paul Polansky, Endo

Agenda Item No. 10 John Mattson, Teva

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: May 9, 2012 DUR Minutes

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

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review: February & March 2012

4B: Retrospective Drug Utilization Review Response: December 2011; January 2012

4C: Medication Coverage Activity: May & June 2012

4D: Pharmacy Help Desk Activity: May & June 2012

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE ZIOPTAN®

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE KEFLEX® 750 MG

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DUEXIS®

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

Dr. Bell moved to approve with the addition of noting a reason in the Special PA category why unable to use Ibuprofen or famotidine separately; seconded by Dr. Rhymer.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: 30-DAY NOTICE TO PRIOR AUTHORIZE BOTULINUM TOXIN PRODUCTS

For Public Comment: Karen Campbell, Allergan

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: 60-DAY NOTICE TO PRIOR AUTHORIZE SELECT GONADOTROPIN-RELEASING HORMONE ANALOGS FOR CENTRAL PRECOCIOUS PUBERTY

For Public Comment: Paul Polansky, Endo

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: QUESTIONS REGARDING 30-DAY NOTICE TO PRIOR AUTHORIZE QNASL™

For Public Comment: John Mattson, Teva

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: QUESTIONS REGARDING 30-DAY NOTICE TO PRIOR AUTHORIZE SUYBSYS™

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: QUESTIONS REGARDING 30-DAY NOTICE TO PRIOR AUTHORIZE DYMISTA™

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

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 Synagis®

B: New Fiscal Year Annual Reviews

C: New Product Reviews

D: Medical Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ADJOURNMENT

The meeting was adjourned at 7:10 p.m.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: July 12, 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 July 11, 2012

Recommendation 1: Vote to Prior Authorize Zioptan® (tafluprost)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following:

1. Zioptan® (tafluprost) to be added to Tier 2.
2. Tier 2 criteria apply.
3. If requesting based on preservative free status, member must have documented allergy to all Tier 1 preservatives options to qualify for tafluprost.

Recommendation 2: Vote to Prior Authorize Keflex® (cephalexin) 750 mg

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Keflex® (cephalexin) 750 mg to the Miscellaneous Anti-Infectives category.

Recommendation 3: Vote to Prior Authorize Duexis® (ibuprofen/famotidine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Duexis® (ibuprofen/famotidine) to the Special Prior Authorization Tier of the NSAID Product Based Prior Authorization category.

The DUR Board recommends the following additional criteria for the use of Duexis® (ibuprofen/famotidine):

4. For Duexis® (ibuprofen/famotidine), a reason for use of the combined ibuprofen and famotidine product over the individual ingredients must be provided.

From: Andrew Carter
Sent: Tuesday, July 24, 2012 11:25 AM
To: Keast, Shellie L. (HSC)
Subject: Daytrana

Hello, my name is Andrew Carter. I am a physician assistant in Tulsa working under the supervision of Dr David Shadid.

We feel the Daytrana patch would be a beneficial tier 1 addition due to its unique delivery system.

If you have any questions fell free to call.

Andrew Carter, PA-C David L. Shadid, DO

918.747.5565

Appendix B

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT
April 2012

MODULE	DRUG INTERACTION	DUPLICATION OF THERAPY	DRUG-DISEASE PRECAUTIONS	DOSING & DURATION
Total # of messages	59,976	76,541	1,061,912	34,632
Limits applied	Established, Major, Males and Females, Age 51-60	Hypnotics, Males and Females, Age 60-150	Contraindicated, Females, Normal Pregnancy, Ages 30-34	High Dose, Duration, Proton Pump Inhibitors, Females, age 0-10
Total # of messages after limits were applied	110	38	229	108
Total # of members reviewed	110	36	218	108

LETTERS

Category	Prescribers	Pharmacies	Total Letters
Drug Interaction	2	4	6
Duplication of Therapy	9	0	9
Drug-Disease Precautions	0	0	0
Dosing & Duration	27	0	27
Total Letters Sent	38	4	42

Retrospective Drug Utilization Review Report

Claims Reviewed for February 2012

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 19-35	Duplication of Benzodiazepines, Males and Females, Age 25-34	Safety alert issued, Diabetes utilizing Aliskiren and ACE or ARB medications, Males and Females, Ages 0-150	High Dose, Duration, Non-sedating Antihistamines, Males and Females, Age 0-1

Response Summary (Prescriber)
Letters Sent: 117
Response Forms Returned: 34

The response forms returned yielded the following results:

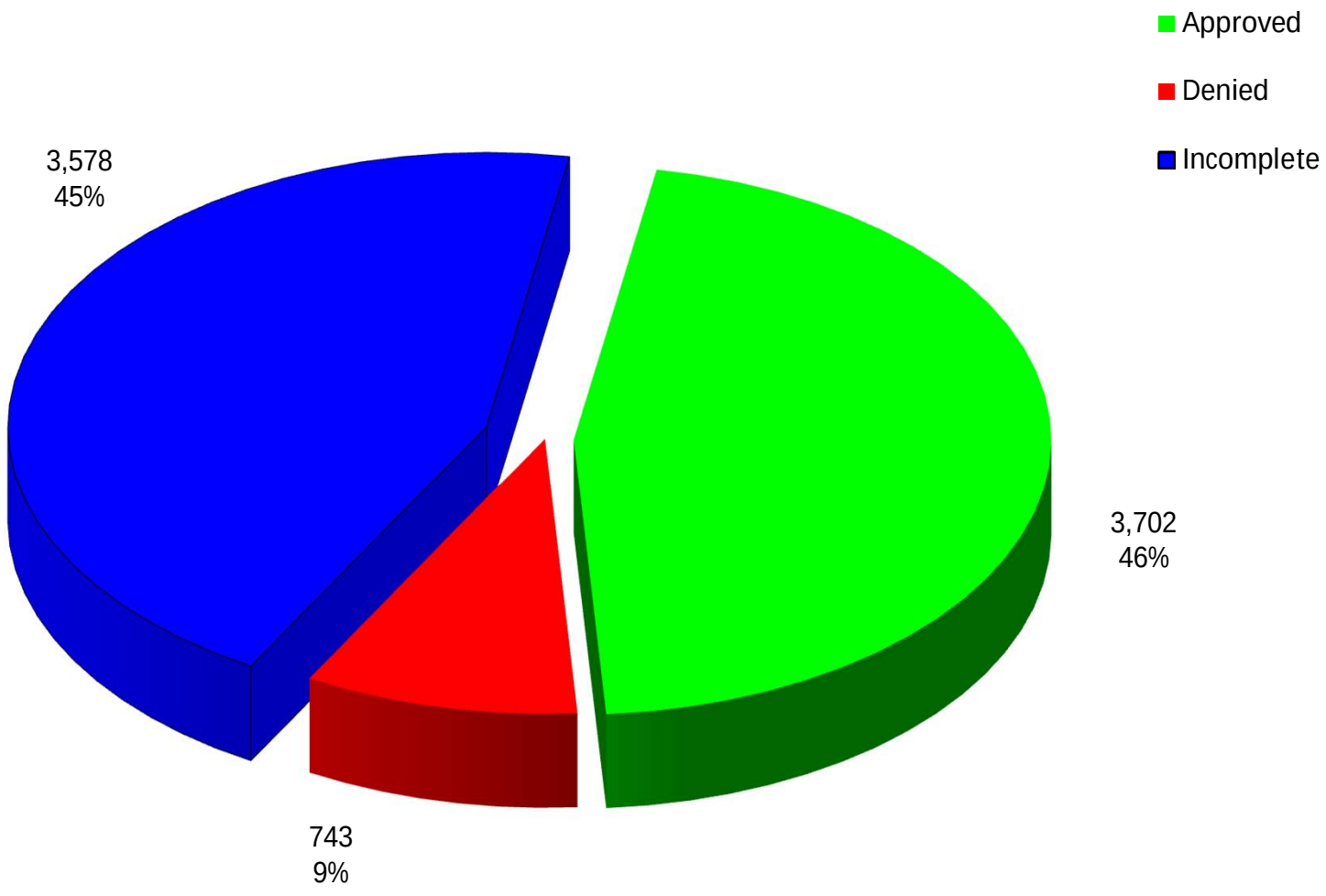
1 (3%)	*Record Error—Not my patient.*
4 (12%)	*No longer my patient.*
2 (6%)	*Medication has been changed prior to date of review letter.*
10 (29%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
9 (26%)	*I am aware of this situation and will plan to continue monitoring therapy.*
8 (24%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 58
Response Forms Returned: 51

The response forms returned yielded the following results:

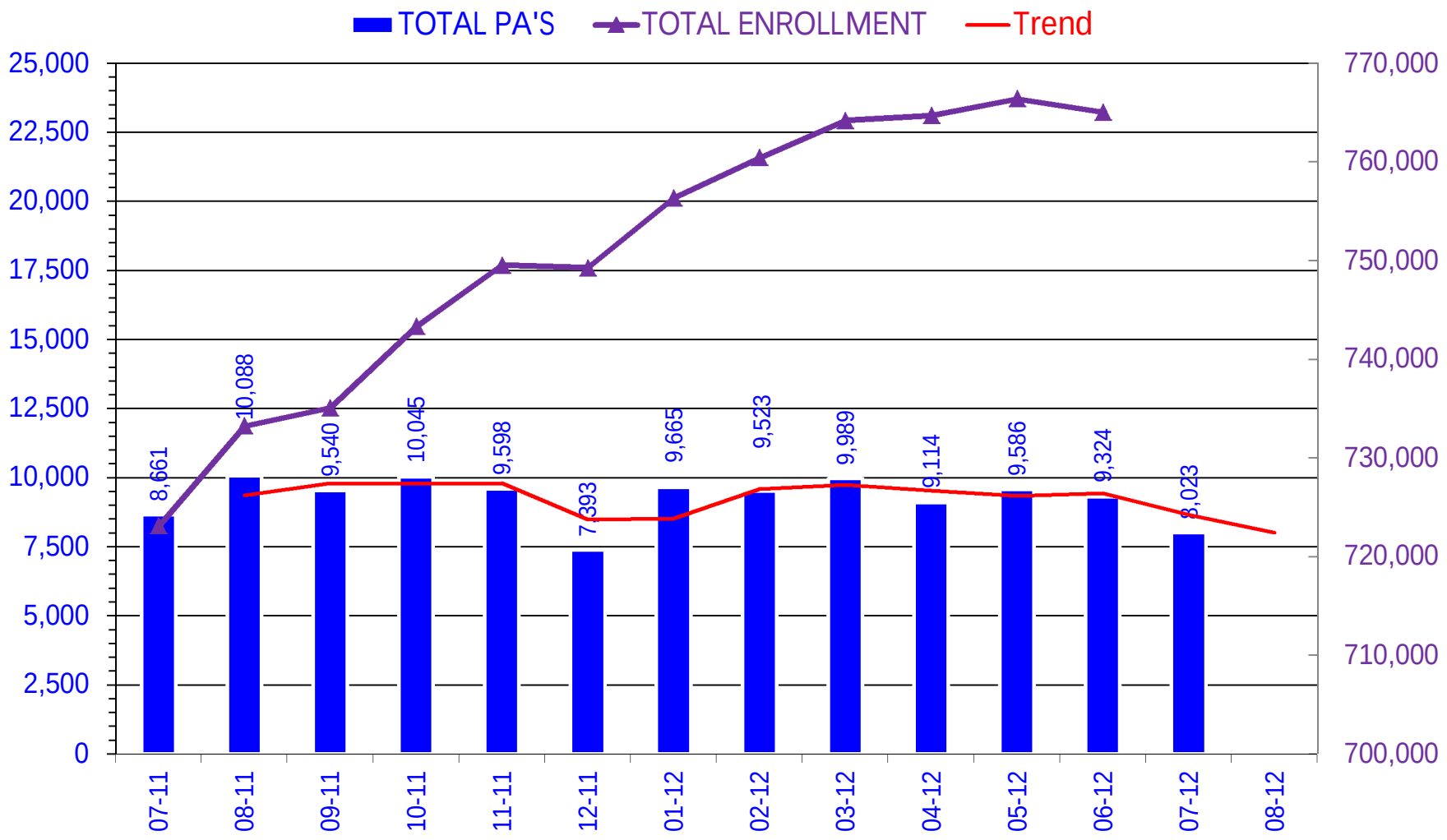
0 (0%)	*Record Error—Not my patient.*
1 (2%)	*No longer my patient.*
3 (6%)	*Medication has been changed prior to date of review letter.*
23 (45%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
16 (31%)	*I am aware of this situation and will plan to continue monitoring therapy.*
8 (16%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: July 2012



PA totals include overrides

PRIOR AUTHORIZATION REPORT: July 2011 – July 2012



PA totals include overrides

Prior Authorization Activity

7/1/2012 Through 7/31/2012

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	285	111	17	157	355
Amitiza	32	9	6	17	146
Anti-Ulcer	333	88	81	164	99
Antidepressant	324	95	19	210	342
Antihistamine	191	134	4	53	353
Antihypertensives	74	15	7	52	335
Antimigraine	74	24	11	39	302
Atypical Antipsychotics	488	237	23	228	331
Benign Prostatic Hypertrophy	4	0	0	4	0
Benzodiazepines	64	48	2	14	211
Biologics	40	17	3	20	328
Bladder Control	55	12	9	34	323
Byetta	38	17	3	18	358
Elidel/Protopic	44	15	2	27	85
ESA	46	24	4	18	68
Fibric Acid Derivatives	2	0	0	2	0
Fibromyalgia	133	27	24	82	333
Fortamet/Glumetza	2	0	0	2	0
Forteo	2	1	0	1	359
Glaucoma	17	1	0	16	360
Growth Hormones	75	49	4	22	155
HFA Rescue Inhalers	127	16	25	86	331
Insomnia	81	16	12	53	187
Insulin	6	2	0	4	184
Misc Analgesics	38	2	29	7	79
Multiple Sclerosis	15	10	1	4	190
Muscle Relaxant	118	39	52	27	50
Nasal Allergy	159	24	49	86	135
NSAIDS	161	19	30	112	308
Ocular Allergy	59	7	7	45	85
Ocular Antibiotics	47	14	4	29	34
Opioid Analgesic	379	192	19	168	288
Other	984	336	127	521	272
Otic Antibiotic	57	11	1	45	8
Pediculicides	137	39	3	95	14
Plavix	10	0	2	8	0
Prenatal Vitamins	21	0	0	21	0
Singulair	649	282	32	335	249
Smoking Cessation	67	17	4	46	34
Statins	62	37	1	24	352
Stimulant	646	366	18	262	334
Suboxone/Subutex	135	97	5	33	79
Topical Antibiotics	10	1	2	7	13
Topical Antifungals	12	4	5	3	10
Topical Corticosteroids	71	2	23	46	87
Ultram ER and ODT	10	2	2	6	355
Xolair	14	3	6	5	352
Xopenex Nebs	18	10	0	8	358
Zetia (Ezetimibe)	21	8	1	12	357
Emergency PAs	3	3	0	0	
Total	**6,440**	**2,483**	**679**	**3,278**	

8/2/2012 10:35:03 AM

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	60	41	1	18	311
Dosage Change	489	464	0	25	10
High Dose	10	7	0	3	238
Ingredient Duplication	12	10	0	2	5
Lost/Broken Rx	94	89	3	2	5
NDC vs Age	12	12	0	0	272
Nursing Home Issue	110	106	1	3	13
Other	27	26	0	1	22
Quantity vs. Days Supply	762	457	59	246	275
Stolen	5	5	0	0	4
Third Brand Request	2	2	0	0	3
Overrides Total	**1,583**	**1,219**	**64**	**300**	
Total Regular PAs + Overrides	**8,023**	**3,702**	**743**	**3,578**	

Denial Reasons	
Unable to verify required trials.	3,090
Does not meet established criteria.	697
Lack required information to process request.	508

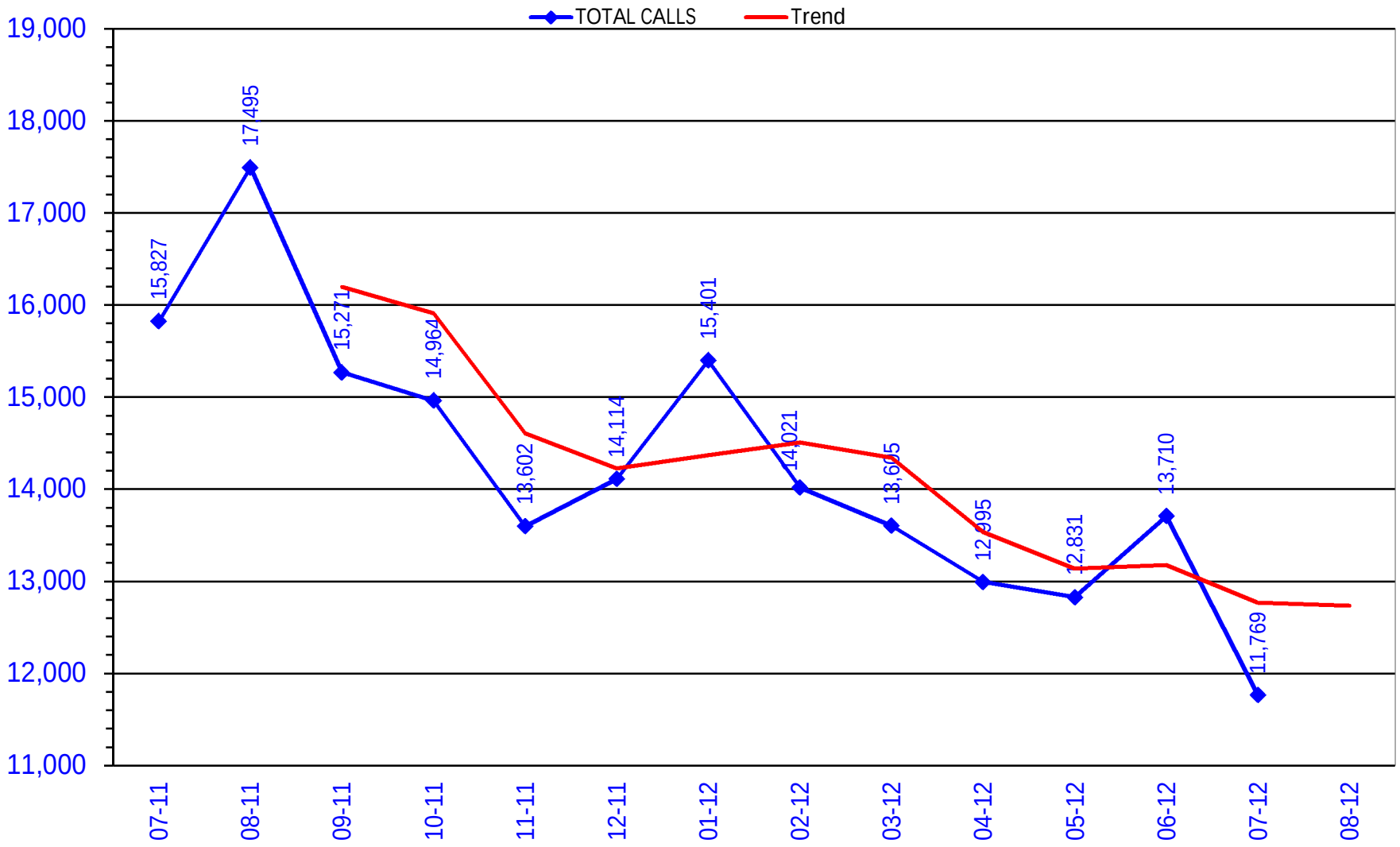
Duplicate Requests: 640

Letters: 2,454

No Process: 342

Changes to existing PAs: 422

CALL VOLUME MONTHLY REPORT:
July 2011 – July 2012



Appendix C

Vote to Prior Authorize Qnasl™ (beclomethasone dipropionate) and Dymista™ (azelastine/fluticasone)

Oklahoma Health Care Authority, August 2012

Recommendations

The College of Pharmacy recommends placement of Qnasl™ (beclomethasone dipropionate) and Dymista™ (azelastine/fluticasone) into Tier 3 of the Nasal Allergy Product Based Prior Authorization category.

Criteria for nasal allergy products are as follows:

1. The following criteria are required for approval of a Tier 2 product:
    a. Documented adverse effect or contraindication to the preferred products.
    b. Failure with all Tier 1 medications defined as no beneficial response after at least three weeks 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 use at the maximum recommended dose.
3. 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.
4. No grandfathering of Tier 2 or Tier 3 products will be allowed for this category.
5. For 2 to 4 year olds, the age appropriate lower-tiered generic products must be used prior to the use of higher tiered products.
6. Petitions for Dymista™ (azelastine/fluticasone) also require a patient specific, clinically significant reason why both products cannot be used separately.

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®)
		Azelastine (Astepro®)
		Azelastine (Astelin®)
		Azelastine/fluticasone (Dymista™)
		Beclomethasone (Qnasl™)

Appendix D

Vote to Prior Authorize Subsys™ (fentanyl sublingual spray)

Oklahoma Health Care Authority, August 2012

Recommendations

The College of Pharmacy recommends placement of Subsys™ (fentanyl sublingual spray) within the Oncology Only Tier of the Narcotic Analgesics PBPA category subject to the following criteria:

1. FDA approved indication of breakthrough cancer pain.
2. Age of 18 years or older.
3. Quantity limit of #120 sprays per 30 days (4 packs of #30 sprays).
4. Reason why other forms of fentanyl breakthrough pain therapy cannot be used.

Tier 1	Tier 2	Tier 3	Oncology Only
All immediate release narcotics not listed in a higher tier	**Long Acting**		
	fentanyl patches (Duragesic®)	morphine sulfate ER (Avinza®)	
	morphine ER	morphine sulfate ER (Kadian®)	
		morphine/naltrexone (Embeda®)	
		Oxycodone ER (OxyContin®)	
		oxymorphone (Opana® ER)	
		tramadol ER (Ultram ER®, Ryzolt®)	
		hydromorphone ER (Exalgo®)	
		buprenorphine patch (Butrans®)	
		Tapentadol ER (Nucynta® ER)	
	Short Acting		
	Tapentadol (Nucynta®)	hydrocodone/APAP (Xodol®, Zamicet®, Hycet®, Zolvit®, Liquicet®)	fentanyl (Actiq®)
	Oxymorphone (Opana® IR)	oxycodone/APAP (Primlev™, Xolox®)	fentanyl (Fentora®)
		tramadol ODT (Rybix®)	Fentanyl (Onsolis® buccal film)
		Oxycodone (Oxecta®)	Fentanyl (Abstral®, Lazanda®)
			Fentanyl (Subsys™) sublingual spray

Appendix E

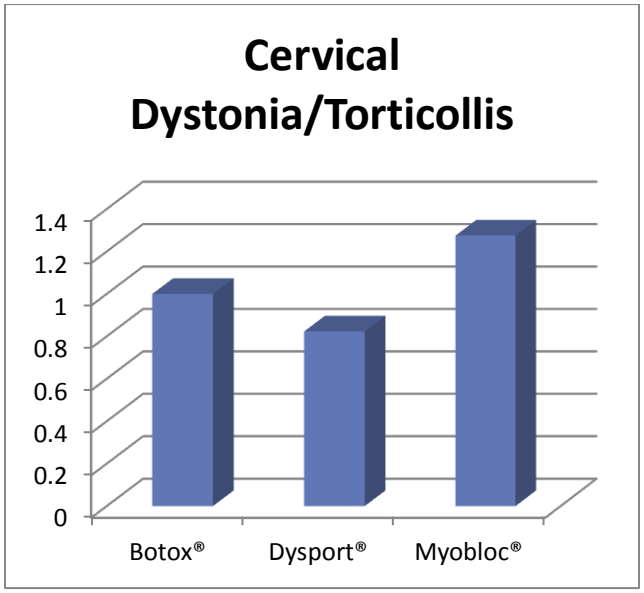
Vote to Prior Authorize Botulinum Toxin Products

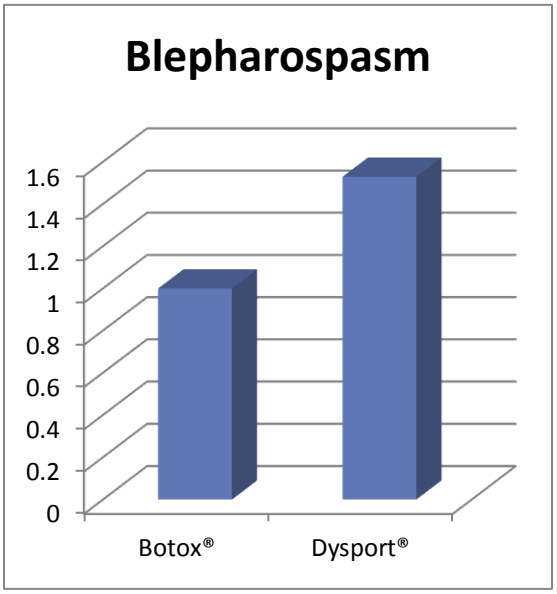
Oklahoma Health Care Authority, August 2012

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.

Cost Comparison

Currently the brand Botox® has the majority of the market share for Oklahoma SoonerCare. This product also has the widest range of FDA approved indications. The average cost for the two main FDA approved indications after federal rebates is represented below with the Botox® brand used as a baseline regardless of the product with the lowest average cost for the indication. The charts do not indicate actual dollar amounts but represent a ratio of the other products to Botox® for each indication. There were no claims for Myobloc® for the indication of blepharospasm in calendar year 2011.





Based on the relative similarity of costs between products and the current utilization, the College of Pharmacy does not recommend a Product Based Prior Authorization Category for these agents at this time.

Recommendations

In February 2011, payment through pharmacy claims was discontinued and these products are only payable through medical claims. The OHCA physicians who review medical prior authorizations have recommended a list of approved diagnoses codes. The College of Pharmacy recommends:

- Coverage of indications on the recommended list to ensure appropriate use of these medications.
- A diagnosis of chronic migraine will require manual review (tension headaches are not a covered diagnosis).
- Cosmetic indications will not be covered.

Diagnosis Code	Long Diagnosis Description
333.71	Athetoid cerebral palsy, double athetosis (syndrome) Vogt's disease, excludes infantile cerebral palsy (343.0-343.9)
333.81	Blepharospasm
333.82	Orofacial dyskinesia
333.83	Spasmodic torticollis
334.1	Hereditary spastic paraplegia
341.1	Schilder's disease
342.11	Spastic hemiplegia affecting dominant side
342.12	Spastic hemiplegia affecting nondominant side
343.0	Diplegic infantile cerebral palsy
343.1	Hemiplegic infantile cerebral palsy
343.2	Quadriplegic infantile cerebral palsy
343.3	Monoplegic infantile cerebral palsy
343.4	Infantile hemiplegia
343.8	Other specified infantile cerebral palsy
343.9	Unspecified infantile cerebral palsy
344.01	Quadriplegia and quadriparesis, C1-C4, complete
344.02	Quadriplegia and quadriparesis, C1-C4, incomplete
344.03	Quadriplegia and quadriparesis, C5-C7, complete
344.04	C5-C7, incomplete
344.1	Paraplegia
344.2	Diplegia of upper limbs
344.30	Monoplegia of lower limb affecting unspecified side
344.31	Monoplegia of lower limb affecting dominant side
344.32	Monoplegia of lower limb affecting nondominant side
344.40	Monoplegia of upper limb affecting unspecified side
344.41	Monoplegia of upper limb affecting dominant side
344.42	Monoplegia of upper limb affecting nondominant side
351.8	Other facial nerve disorders
374.03	Spastic entropion
374.13	Spastic ectropion
378.0	Esotropia
378.00	Unspecified esotropia
378.01	Monocular esotropia

378.02	Monocular esotropia with A pattern
378.03	Monocular esotropia with V pattern
378.04	Monocular esotropia with other noncomitancies
378.05	Alternating esotropia
378.06	Alternating esotropia with A pattern
378.07	Alternating esotropia with V pattern
378.08	Alternating esotropia with other noncomitancies
378.1	Exotropia
378.10	Unspecified exotropia
378.11	Monocular exotropia
378.12	Monocular exotropia with A pattern
378.13	Monocular exotropia with V pattern
378.14	Monocular exotropia with other noncomitancies
378.15	Alternating exotropia
378.16	Alternating exotropia with A pattern
378.17	Alternating exotropia with V pattern
378.18	Alternating exotropia with other noncomitancies
378.2	Intermittent heterotropia
378.20	Unspecified intermittent heterotropia
378.21	Intermittent esotropia, monocular
378.22	Intermittent esotropia, alternating
378.23	Intermittent exotropia, monocular
378.24	Intermittent exotropia, alternating
378.3	Other and unspecified heterotropia
378.30	Unspecified heterotropia
378.31	Hypertropia
378.32	Hypotropia
378.33	Cyclotropia
378.34	Monofixation syndrome
378.35	Accommodative component in esotropia
378.4	Heterophoria
378.40	Unspecified heterophoria
378.41	Esophoria
378.42	Exophoria
378.43	Vertical heterophoria
378.44	Cyclophoria
378.45	Alternating hyperphoria
378.5	Paralytic strabismus
378.50	Unspecified paralytic strabismus
378.51	Paralytic strabismus, third or oculomotor nerve palsy, partial
378.52	Paralytic strabismus, third or oculomotor nerve palsy, total
378.53	Paralytic strabismus, fourth or trochlear nerve palsy
378.54	Paralytic strabismus, sixth or abducens nerve palsy
378.55	Paralytic strabismus, external ophthalmoplegia
378.56	Paralytic strabismus, total ophthalmoplegia
378.6	Mechanical strabismus
378.60	Unspecified mechanical strabismus
378.61	Mechanical strabismus from Brown's (tendon) sheath syndrome

378.62	Mechanical strabismus from other musculofascial disorders
378..63	Mechanical strabismus from limited duction associated with other conditions
378.7	Other specified strabismus
378.71	Duane's syndrome
378.72	Progressive external ophthalmoplegia
378.73	Strabismus in other neuromuscular disorders
378.8	Other disorders of binocular eye movements
378.81	Palsy of conjugate gaze
378.82	Spasm of conjugate gaze
378.83	Convergence insufficiency or palsy in binocular eye movement
378.84	Convergence excess or spasm in binocular eye movement
378.85	Anomalies of divergence in binocular eye movement
378.86	Internuclear ophthalmoplegia
378.87	Other dissociated deviation of eye movements
378.9	Unspecified disorder of eye movements
478.75	Laryngeal spasm
530.0	Achalasia and cardiospasm
565.0	Anal fissure
754.1	Congenital musculoskeletal deformity of sternocleidomastoid muscle
784.49	Other voice and resonance disorders

Appendix F

ATYPICAL ANTIPSYCHOTICS ANNUAL REVIEW FOLLOW-UP

OKLAHOMA HEALTH CARE AUTHORITY
AUGUST 2012

BACKGROUND

At the annual review of atypical antipsychotic medications during the May DUR Board meeting, several questions were posed regarding the utilization of aripiprazole (Abilify®) in the SoonerCare population:

1. Is aripiprazole (Abilify®) superior compared to other atypical antipsychotics?
2. Is aripiprazole (Abilify®) superior compared to other atypical antipsychotics in the inpatient setting?
3. Why is there such high use of aripiprazole (Abilify®) compared with other atypical antipsychotics?
4. What percent of petitions for aripiprazole (Abilify®) were approved due to inpatient stabilization?
5. What percent of overall aripiprazole (Abilify®) utilization were due to initiation in inpatient facilities?

EFFICACY OF ABILIFY (ARIPIPRAZOLE)

Data regarding comparative efficacy of atypical antipsychotics have previously been presented. To date, the CATIE trial is the only non-manufacturer sponsored, prospective, randomized, clinical trial comparing efficacy and safety of atypical antipsychotics available at the time of the study. This trial, which included aripiprazole, showed that for the treatment of schizophrenia, there were no significant differences in effectiveness among the atypical antipsychotics, except olanzapine, which appeared to be slightly more effective than the other agents, but had a higher incidence of adverse effects[1].

More recently, the Center for Evidence-Based Policy conducted an update to their meta-analysis of Atypical Antipsychotics review[2]. The search included the major databases for clinical citations including: Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, MEDLINE, and PsycINFO. The researchers concluded that there were few differences in short term efficacy, however, clozapine and olanzapine have been found to result in lower rates of discontinuation over periods of up to 2 years. This meta-analysis evaluated available evidence for the use of antipsychotics in children and adolescents with pervasive developmental disorders or disruptive behavior disorders. The evaluation showed risperidone, aripiprazole, and olanzapine improved behavioral symptoms in children and adolescents with pervasive developmental disorders when compared to placebo, and risperidone and quetiapine showed efficacy in children and adolescents with disruptive behavior disorders. There were no head to head trials to evaluate comparative efficacy. A post hoc analysis of 5 pooled studies focusing on aripiprazole came to the conclusion that aripiprazole was no different than risperidone in parameters of the Positive and Negative Syndrome Scale.[3]

Due to the relatively low incidence of schizophrenia and bipolar disorders in the general population, it is suspected that atypical antipsychotics are often used for off-labeled indications. The Agency for Healthcare Research and Quality (AHRQ) released a report: Off-Label Use of Atypical Antipsychotics, Executive Summary No. 43, which showed the following results:

Adapted from Table A. Summary of strength of evidence of efficacy, by drug and condition[4]

Condition	Condition Subtype	Aripiprazole	Olanzapine	Quetiapine	Risperidone	Ziprasidone
Anxiety	general anxiety DO	O	-	++	-	-
	social phobia	O	+	-	O	O
ADHD	no co-occurring disorders	O	O	O	+	O
	bipolar children	-	O	O	O	O
	mentally retarded children	O	O	O	+	O
Dementia	overall	++	+	+	++	O
	psychosis	+	+-	+-	++	O
	agitation	+	++	+-	++	O
Depression	augmentation: SSRI/SNRI	++	+	++	++	+
	monotherapy	O	-	++	O	O
Eating Disorders		O	—	-	O	O
Insomnia		O	O	-	O	O
OCD	augmentation of SSRI	O	+	—	++	-
	augmentation: citalopram	O	O	+	+	O
Personality Disorder	borderline	+	+-	+	O	-
	schizotypal	O	O	O	+-	O
PTSD		O	+-	+	++	O
Substance Abuse	alcohol	—	-	-	O	O
	cocaine	O	-	O	-	O
	methamphetamine	-	O	O	O	O
	methadone clients	O	O	O	-	O
Tourette's Syndrome		O	O	O	+	-

++ moderate or high evidence of efficacy, + low or very low evidence of efficacy, +- mixed results, - low or very low evidence of inefficacy
— moderate or high evidence of inefficacy, O no trials, ☐ Approved by FDA for the indication
MDD = major depressive disorder; SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin-norepinephrine reuptake inhibitors
Note: Symbols denote strength of evidence, not size of potential effect. For example in dementia "++" indicates moderate-to-high strength of evidence that there is a beneficial effect, however the size of the effect is small.

In addition, several retrospective claims analyses compared time to hospitalization and cost of psychiatric hospitalizations between adults using select atypical antipsychotics in commercially insured adults[5] and Medicaid beneficiaries in 10 states[6]. In commercially insured adults, aripiprazole was associated with a lower risk of hospitalization when compared to ziprasidone, olanzapine and quetiapine, but not risperidone. Total healthcare costs were significantly lower when compared to quetiapine, but not risperidone and the others. In Medicaid beneficiaries, time to psychiatric hospitalization for members initiating on aripiprazole was significantly longer compared to olanzapine, quetiapine, and ziprasidone, but not risperidone. The costs of psychiatric hospitalization in beneficiaries initiating aripiprazole were significantly lower compared to those initiating quetiapine, but not for risperidone and the others. Retrospective claims analyses are subject to coding and classification errors. Both of these claims analyses were sponsored by the makers of aripiprazole.

Due to the variable response to atypical antipsychotics for individuals, medication side effect and safety profiles also play an important part in the choice of the agent used. The following shows the results of weight gain during first time use of select atypical antipsychotics in children and adolescents over 11 weeks[7].

Medication	Average Weight Gain
Aripiprazole (Abilify®)	10 lbs.
Risperidone (Risperdal®)	12 lbs.
Quetiapine (Seroquel®)	13 lbs.
Olanzapine (Zyprexa®)	19 lbs.
Untreated	0.42 lbs.

Other adverse effects associated with atypical antipsychotics use are shown in the following table:

Comparison of Atypical Antipsychotic Side Effect Profiles

	Clozapine[b] (Clozaril®)	Risperidone (Risperdal®)	Olanzapine (Zyprexa®)	Quetiapine[c] (Seroquel®)	Ziprasidone (Geodon®)	Aripiprazole[d] (Abilify®)
EPS/TD	0[a]	+	0[a]	0[a]	0[a]	0[a]
Increased Prolactin Level	0	+++	0	0	+	0
Glucose Abnormality	+++	++	+++	++	0	0
Lipid Abnormalities	+++	++	+++	++	0	0
QTc Prolongation	0	+	0	0	++	0
Weight Gain	+++	++	+++	++	0	0
Sedation	+++	+	+	++	0	+
Hypotension	+++	+	+	++	0	0
Anticholinergic	+++	0	++	0	0	0

Adapted from Table 3 of Treating Schizophrenia: A Quick Reference Guide.[8]

[a] Possible exception of akathisia, side effect may be dose dependent.

[b] May also cause agranulocytosis, seizures, and myocarditis.

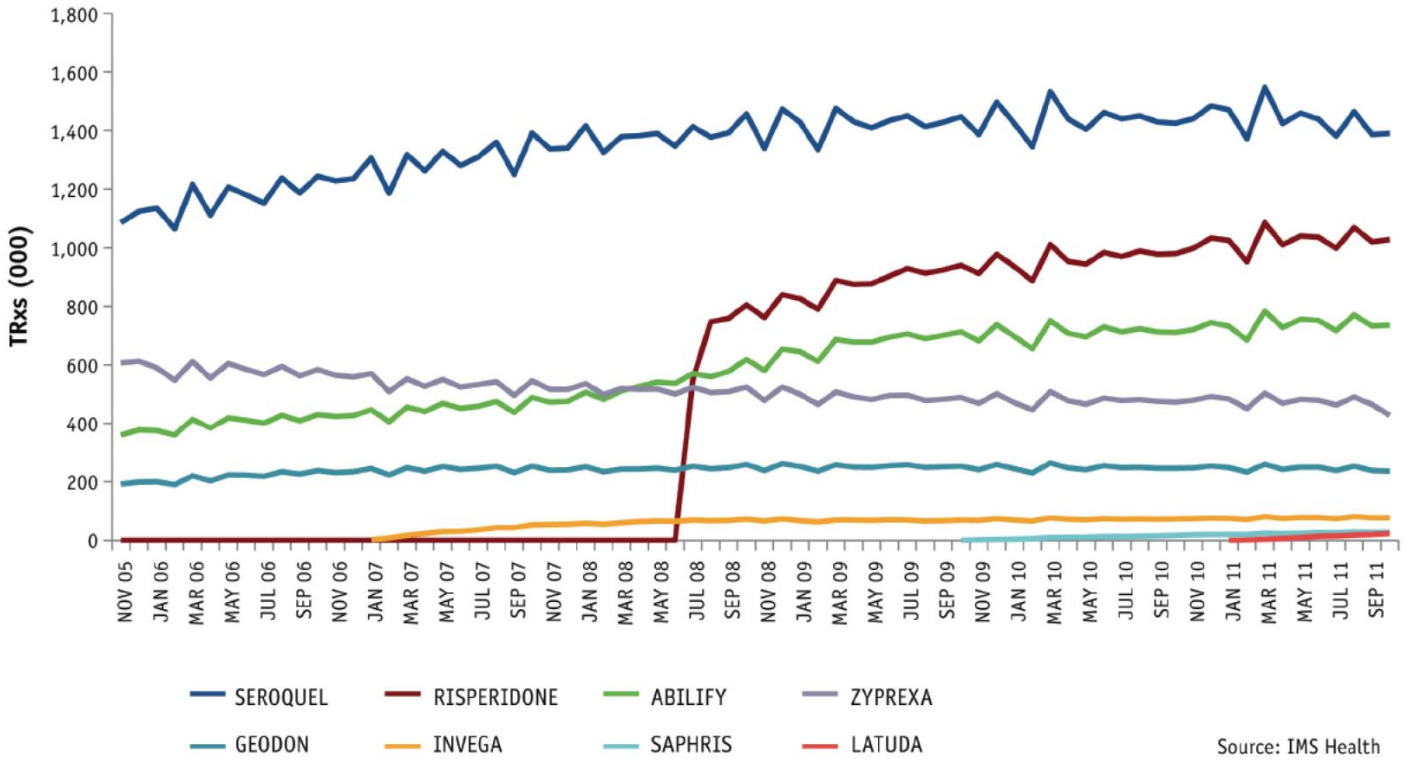
[c] Also carries warning about potential development of cataracts

[d] Also causes nausea and headache.

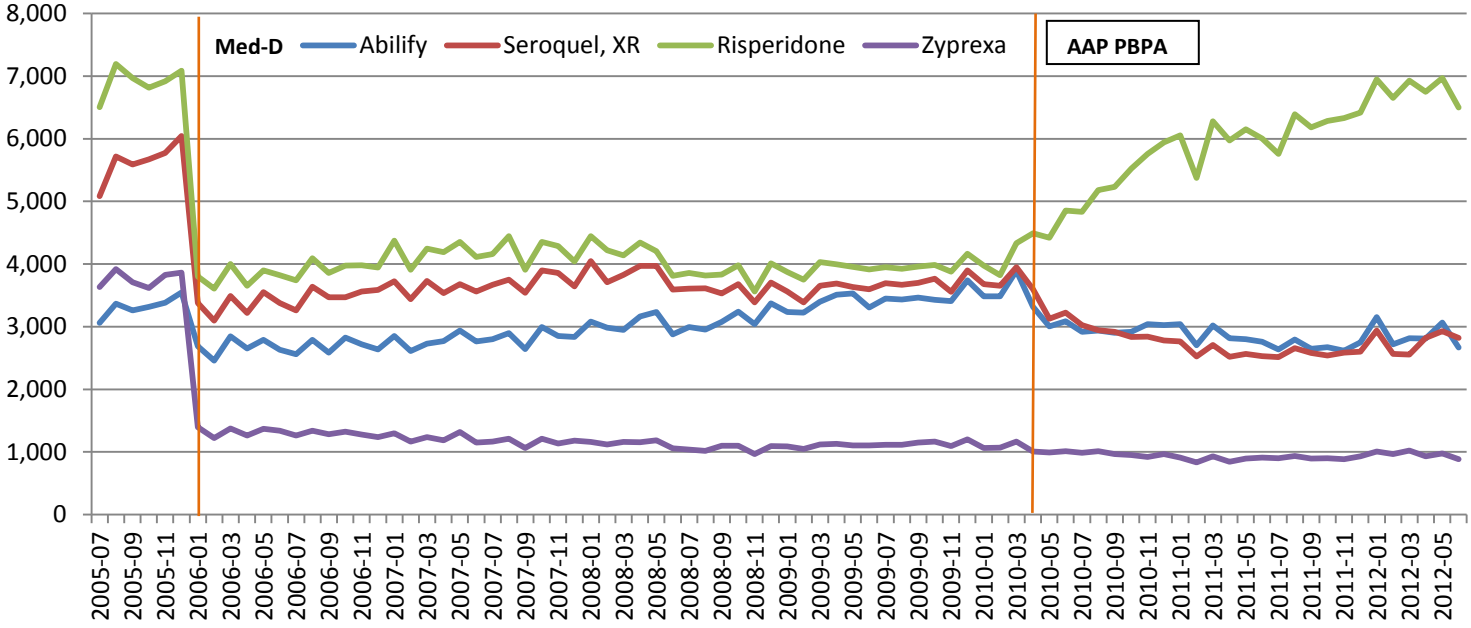
UTILIZATION OF ABILIFY® (ARIPIPRAZOLE)

National utilization trends of atypical antipsychotic medications are first evaluated to establish perspective of general utilization trends in the United States. Aripiprazole's utilization trend is then evaluated to detect fluctuations and possible outstanding differences from the general trend in the SoonerCare population and compared against the utilization trends of the most utilized products in this category.

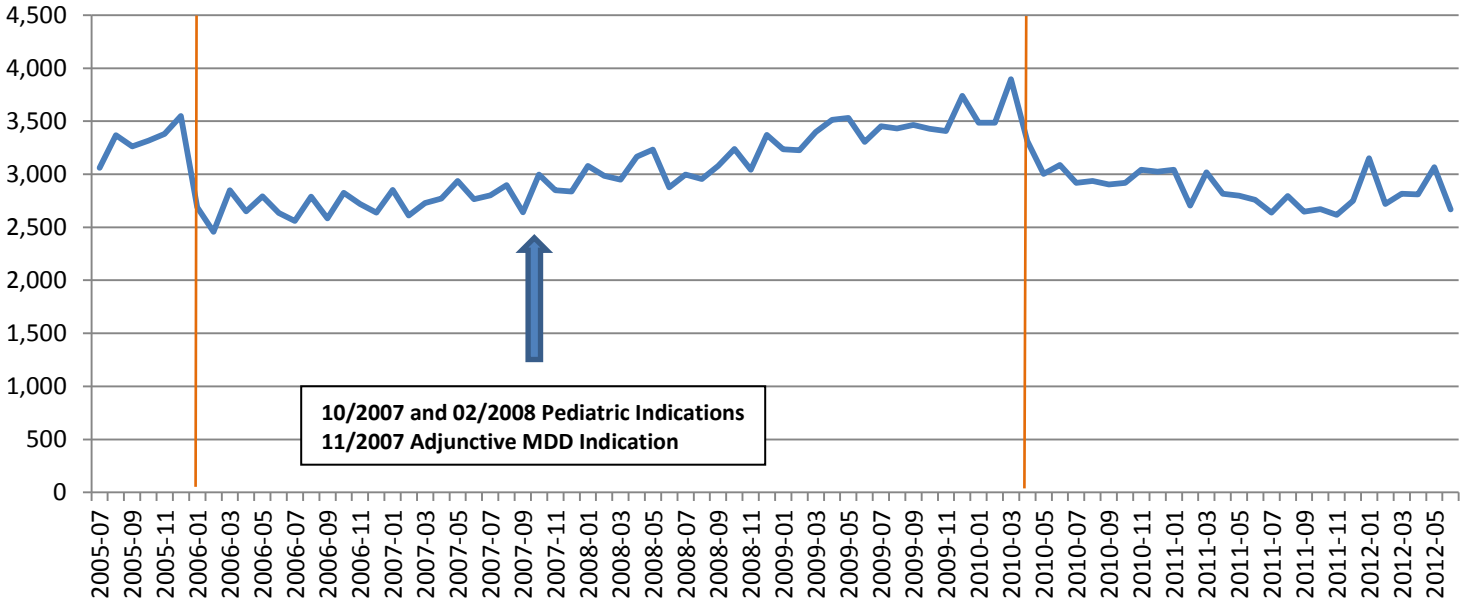
National Utilization Trends of Select Atypical Antipsychotics[9]



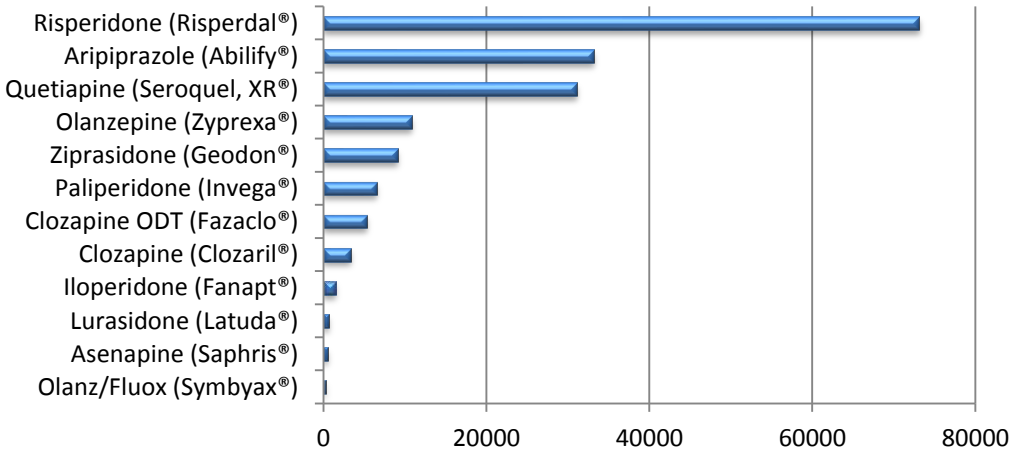
Utilization of Top Atypical Antipsychotics in the SoonerCare Population: FY 2006 – FY 2012



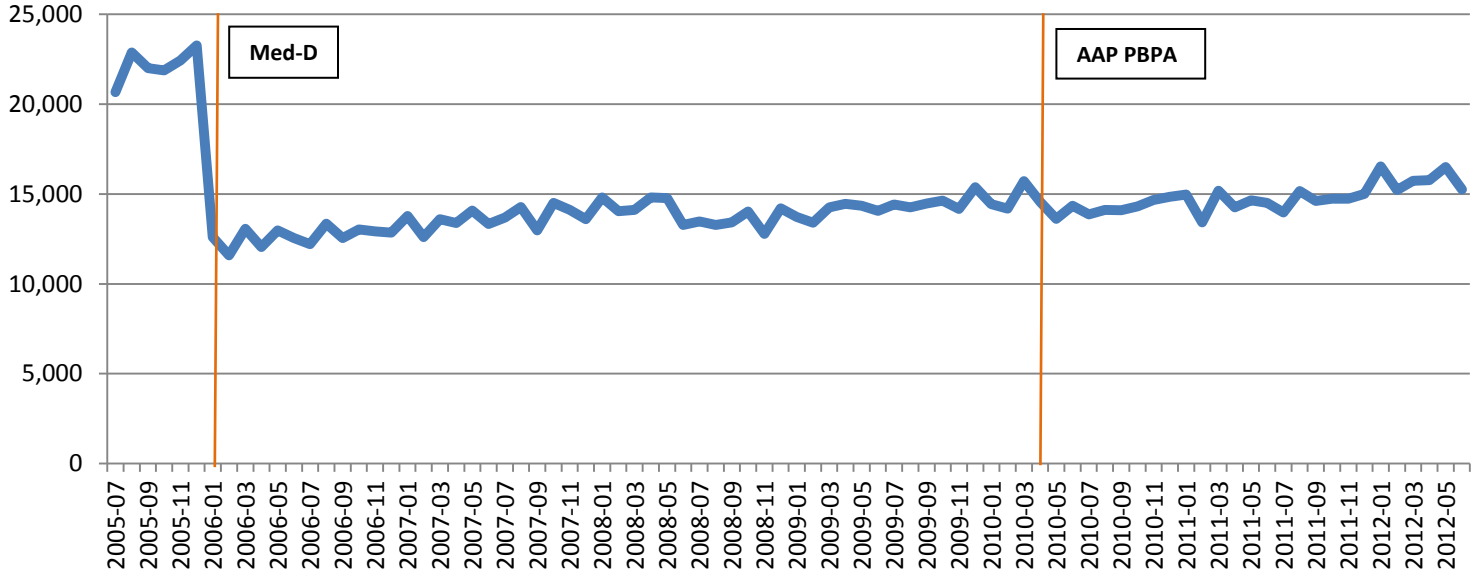
Utilization of Aripiprazole (Abilify®) in the SoonerCare Population: FY 2006 – FY 2012



Utilization Comparison by Total Claims : CY 2011



Utilization of Atypical Antipsychotics in the SoonerCare Population: FY 2006 – FY 2012



National utilization data shows aripiprazole to be one of the top 3 most utilized products among the atypical antipsychotics. The utilization trends for aripiprazole in the SoonerCare population increased significantly from 2008 to the early 2010 most likely due to the added pediatric indications and adjunctive treatment for MDD indications. However, there was a decline upon the implementation of the Atypical Antipsychotics PBPA category in April of 2010 across all branded antipsychotics. The use of these medications currently shows a trending increase, but not specific to aripiprazole.

UTILIZATION FROM INPATIENT STABILIZATION

Petitions for atypical antipsychotics were tracked from May 11, 2012 thru July 10, 2012 to determine the percentage of petitions that were approved due to stabilization of the medication in the inpatient setting. The following table shows the results:

Product	Total Members Utilizing Product	Petitions Approved due to Stabilization	Total Approved Petitions	% Approved due to Stabilization	Overall % of Total
Risperidone	7,198	1	39	3%	0.01%
Abilify®	3,168	82	247	33%	2.59%
Seroquel®	2,288	1	1	100%	0.04%
Olanzapine	799	23	48	48%	2.88%
Seroquel XR®	806	14	41	34%	1.74%
Ziprasidone	656	5	35	14%	0.76%
Clozaril®	227	0	0	0%	0.00%
Fazaclo®	194	1	1	100%	0.52%
Invega®	322	6	18	33%	1.86%
Fanapt®	183	4	10	40%	2.19%
Saphris®	179	0	20	0%	0.00%
Latuda®	151	11	24	46%	7.28%
Risperidone ODT	113	0	0	0%	0.00%
Zyprexa Zydis®	90	0	0	0%	0.00%
Symbyax®	20	0	0	0%	0.00%
Abilify® Soln	12	0	0	0%	0.00%
Abilify® Disc	4	0	0	0%	0.00%

CONCLUSIONS

In conclusion, the College of Pharmacy presents the following answers to the questions that were posed:

1. Is aripiprazole (Abilify®) superior compared to other atypical antipsychotics?
    a. Clinical data does not suggest superior efficacy, however, the adverse side effect profile of aripiprazole is more favorable compared to the other atypical antipsychotics.
2. Is aripiprazole (Abilify®) superior compared to other atypical antipsychotics in the inpatient setting?
    a. No data was detected to evaluate the comparable efficacy of aripiprazole in the inpatient setting. Retrospective claims analyses show positive outcomes for aripiprazole in time to hospitalization and healthcare costs when compared to the most utilized atypical antipsychotics, except risperidone; however, retrospective claims analyses have their limitations.
3. Why is there such high use of aripiprazole (Abilify®) compared with other atypical antipsychotics?
    a. Nationally, aripiprazole is one of the top utilized medications in this category. When compared with other branded products in this category, the utilization trend does not appear to be significantly higher in the SoonerCare population. The overall utilization trend showed a noticeable increase after aripiprazole received the expanded indications.
4. What percent of petitions for aripiprazole (Abilify®) were approved due to inpatient stabilization?
    a. 33 %
5. What percent of overall aripiprazole (Abilify®) utilization were due to initiation in inpatient facilities?
    a. 2.6 %

RECOMMENDATION

The College of Pharmacy recommends an addition to the atypical antipsychotic's antidepressant criteria:

Approval Criteria for Use as Adjunctive Treatment for Depression:

1. For **aripiprazole, quetiapine extended release, or olanzapine/fluoxetine**: a diagnosis of depression requires current use of an antidepressant and previous trials with at least two other antidepressants from both categories (an SSRI and a dual acting antidepressant) that did not yield adequate response. Tier structure still applies.

In addition, the College of Pharmacy also recommends investigation of an academic detailing program to positively influence the prescribing practices of atypical antipsychotics by SoonerCare providers in the state of Oklahoma.

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[1] Lieberman JA, Stroup TS, et al. **Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia.** ***NEJM*****.** 353(12);1209-1223: September 2005.

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[4] Maglione M, Ruelaz Maher A, Hu J, Wang Z, Shanman R, Shekelle PG, Roth B, Hilton L, Suttorp MJ, Ewing BA, Motala A, Perry T. **Off-Label Use of Atypical Antipsychotics: An Update. Comparative Effectiveness Review No. 43**. (Prepared by the Southern California/RAND Evidence-based Practice Center under Contract No. HHSA290-2007-10062-1.) AHRQ Publication No. 11-EHC087-EF. Rockville, MD: Agency for Healthcare Research and Quality. September 2011. www.effectivehealthcare.ahrq.gov/reports/final.cfm**.**

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[6] Yonghua Jing[a], Stephen S. Johnston[b], Robert Fowler[b], John A. Bates[a], Robert A. Forbes[c], Tony Hebden[a]. **Comparison of second-generation antipsychotic treatment on psychiatric hospitalization in Medicaid beneficiaries with bipolar disorder.** JME. Vol. 14, No. 6, 2011. Pages 777-786.

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[8] American Psychiatric Association: **Practice Guidelines for the Treatment of Patients with Schizophrenia. 2nd Ed.** February 2004.Available online at www.phsyc.org

[9] Adapted from Table 2 of PM360, The Essential Resource for Pharma Marketers, January 2012.

Appendix G

Annual Review of Synagis® (palivizumab) - Fiscal Year 2012

Oklahoma Health Care Authority
August 2012

Prior Authorization of Synagis® during FY '12

Prior authorization is required for all members who receive Synagis® in an outpatient setting. Synagis® is approved for members who meet the established criteria based on a modified version of the American Academy of Pediatrics (AAP) guidelines.

Current Criteria for Prior Authorization of Synagis®

A. Member Selection. Members must be included in one of the following age groups at the beginning of the RSV season:*

1) Infants and children less than 24 months old with Chronic Lung Disease (CLD) (formerly bronchopulmonary dysplasia) who have required medical treatment (O2, bronchodilator, corticosteroid, or diuretic therapy) for CLD in the 6 months prior to RSV season.
2) Infants up to 24 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.
3) Infants less than 12 months of age, born at 28 weeks gestation or earlier.
4) Infants less than 6 months of age, born at 29-31 weeks gestation.
5) Infants less than 12 months of age, born before 35 weeks gestation, with congenital abnormalities of the airway.
6) Infants less than 12 months of age, born before 35 weeks gestation, with severe neuromuscular disease.
7) Infants, up to 3 months old at the start of RSV season, born at 32-34 weeks gestation, who have one of the following risk factors: (up to three doses only)
    a. Child care attendance
    b. Siblings younger than 5 years of age

* Treatment is authorized for the entire RSV season (as indicated) except for members meeting criteria #7, in which case, a maximum of 3 doses will be authorized. Prescribers may request special consideration for additional doses (up to the end of the RSV season as indicated) on an individual patient basis for members meeting criteria #7.

B. Length of treatment. Synagis® is approved for use only during RSV season. Approval dates were from November 1 through March 31.

C. Units authorized. The maximum duration of therapy is five (5) doses, with a dose to be administered no more often than every 30 days. Infants born at 32-34 weeks gestation will receive a maximum of three doses. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as one of the approved total.

D. Dose-pooling. To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization

For the period of November 1, 2011 through March 31, 2012, a total of 737 SoonerCare members received Synagis® from a pharmacy provider. There were no claims submitted by physicians.

RSV Season	Members	Claims	Cost	Cost/dose	Doses	Units	Days
2010 - 11	750	2,874	$5,135,430.37	$2,174.27	2,739	2,492	86,048
2011- 12	737	2,897	$5,941,589.03	$2,577.16	2,295	2,641	86,896
Percent Change	**-1.70%**	**0.80%**	**15.70%**	**18.53%**	**-16.2%**	**6.00%**	**0.98%**
Change	**-13**	**23**	**$806,158.66**	**$402.89**	**-444**	**150**	**848**

Claim Type	Cost per Vial
Synagis® 50 mg/0.5 ml vial	$1,203.79
Synagis® 100 mg/ml vial	$2,273.12

Pharmacy Claims

Product	# of Claims	Total Units	Total Days	Total Cost	Total Members
Synagis® 50 mg/0.5 ml vial	924	542	27,718	$1,260,243.42	490
Synagis® 100 mg/ml vial	1,973	2,099	59,178	$4,681,345.61	663
Total	**2,897**	**2,641**	**86,896**	**$5,941,589.03**	**737***

*Total unduplicated members for 11-12

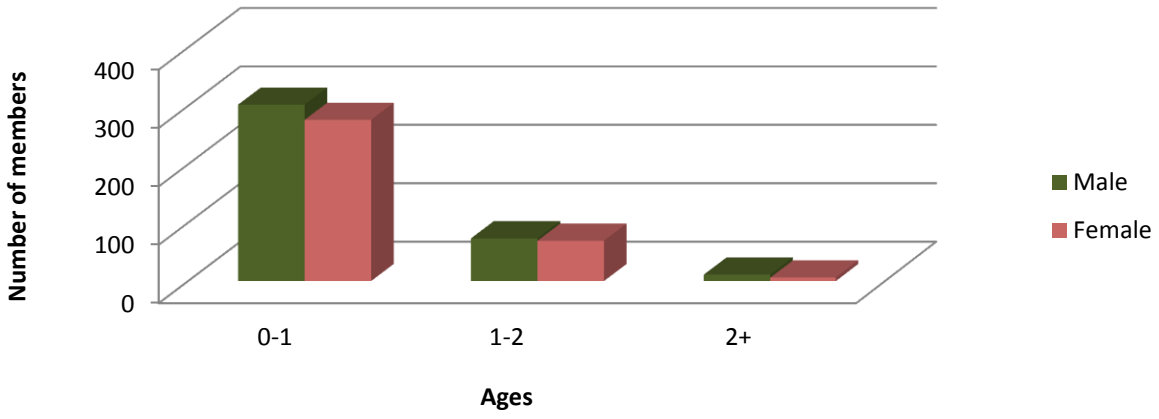
PA Activity

Total petitions - RSV Season 11-12
A total of 1,745 petitions were submitted for consideration of Synagis®.

Approved 860
Denied 387
Incomplete 498
Subsequently approved.....148

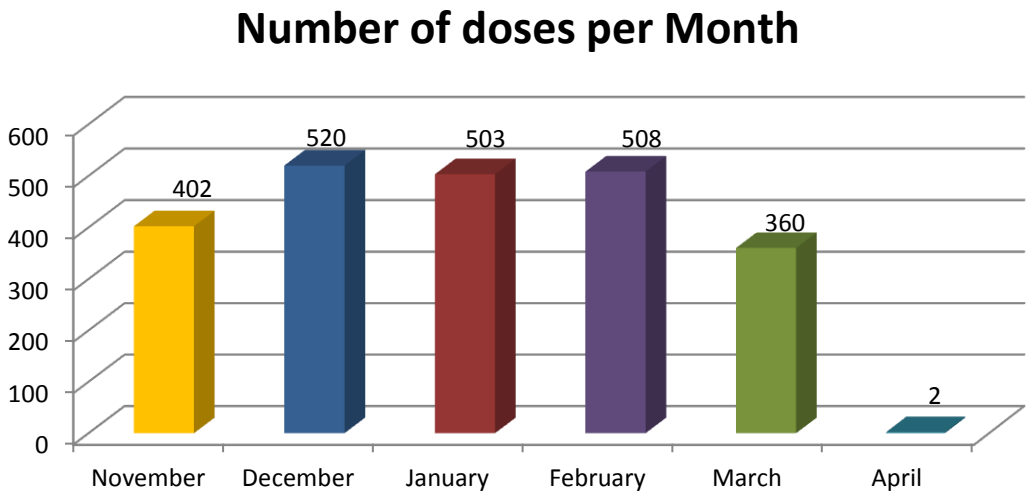
Demographics

Claims were reviewed to determine the age/gender of the members. The 2-year olds were under 24 months at the time of approval.



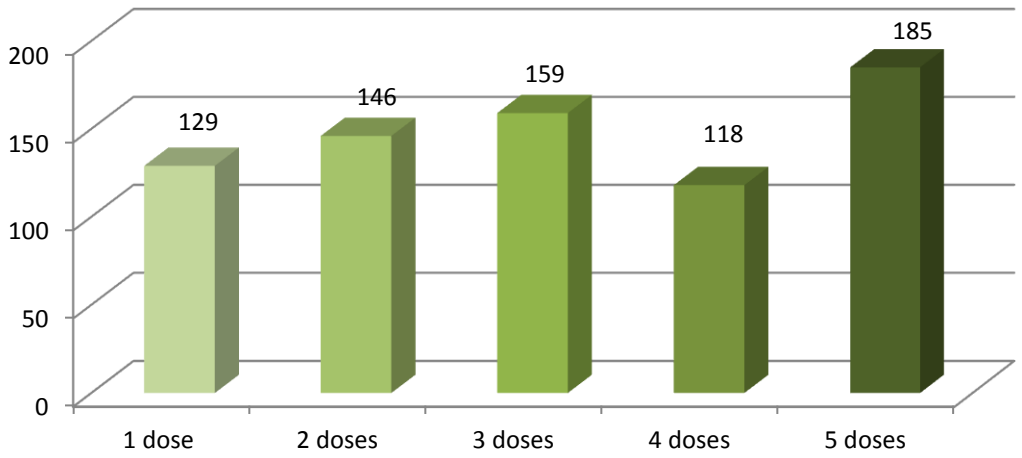
Dose Data

A total of **2,295 doses** were given through the season. The average cost per dose was **$2,577.16**. Synagis® was limited to 5 doses for the season. Members born at 32-34 weeks gestation received a maximum of 3 doses. Two doses were given in April after review and approval by the OHCA neonatologist.



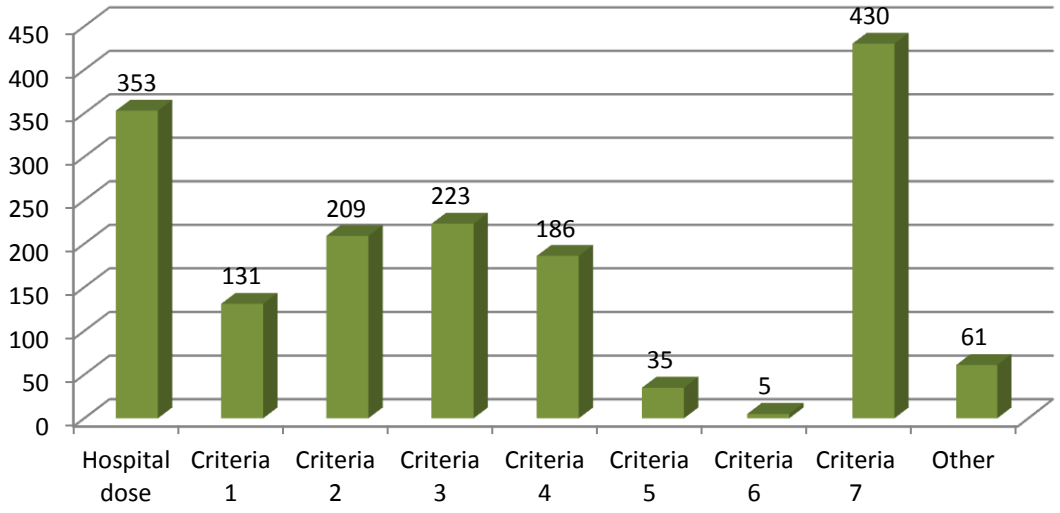
Dosing

The following chart shows the number of members and the doses received.

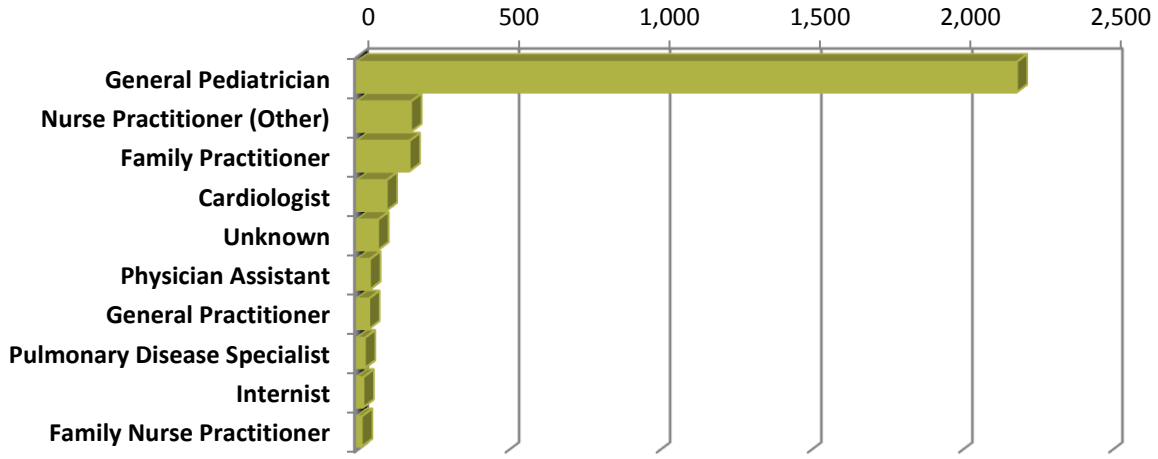


Criteria Totals

The criteria that were met for the approved petitions were tracked and totaled, along with the doses of palivizumab administered in the hospital prior to discharge. Members meeting more than one criterion were counted in each category.



Prescriber Specialty by Number of Claims



Discussion

New Recommendations from AAP

The American Academy of Pediatrics Committee on Infectious Diseases recently met and evaluated the recommendations published in the 2009 Red Book. Modifications to the current guidelines include clarifications to the following SoonerCare criteria:

5) Infants less than 12 months of age, born before 35 weeks gestation, with congenital abnormalities of the airway
6) Infants less than 12 months of age, born before 35 weeks gestation, with severe neuromuscular disease

Infants with either of these risk factors will be considered for prophylaxis at any gestational age, and should receive a maximum of 5 doses of palivizumab during the first year of life.

Referrals to Care Management Services

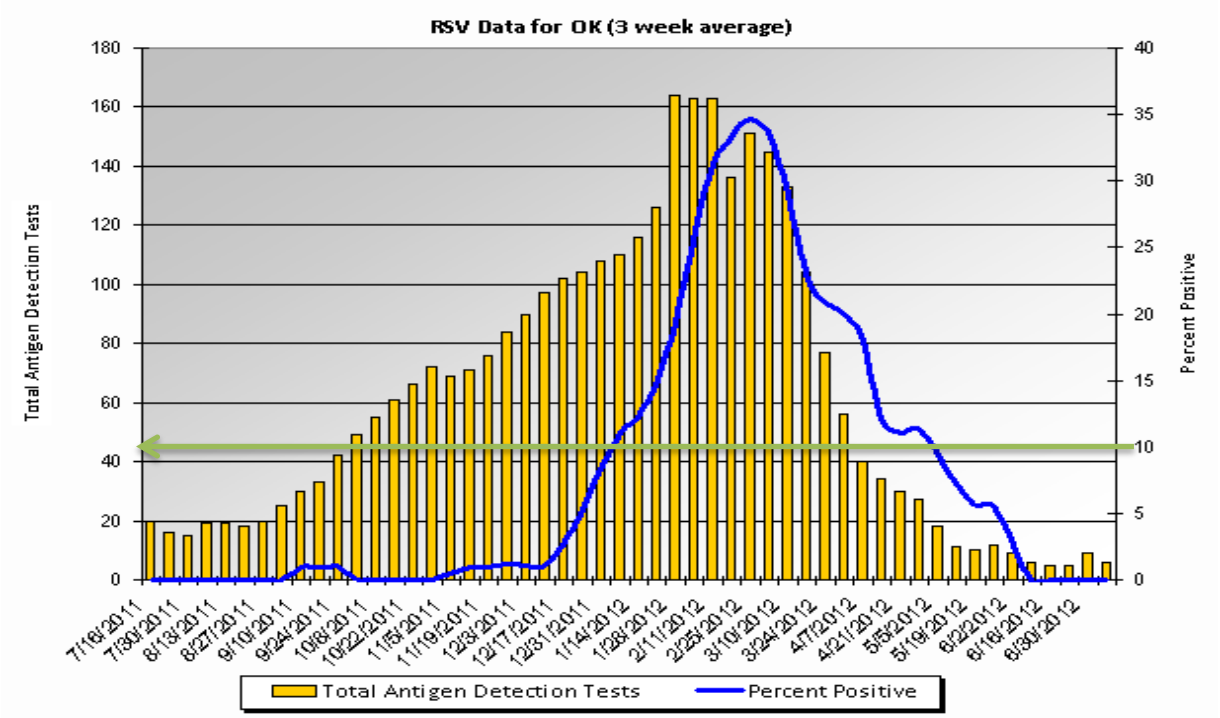
To maximize appropriate referrals, continuity of care, and compliance, OHCA Care Management Services are available to assist with infants felt to be at increased risk of noncompliance. Nurse managers contact the parents to discuss and educate them about the importance of getting Synagis® each month, as well as other safety issues. The following message is sent back to the prescriber and the pharmacy with each approved petition:

- *For patients at risk of non-compliance, OHCA Care Management Services are available to assist. Please contact them at 877-252-6002.*

For the 2011-12 RSV season, **42 children** were referred to the Care Management Services.

RSV Season Recap

In one of the mildest winters on record, the 2011-12 RSV season did not reach the epidemic threshold until January. Increased rainfall and higher-than-normal temperatures in February, March, and April may have contributed to the incidence of RSV during those months. The peak level was similar to previous years. By the end of April, the number of cases had decreased to almost the 10% threshold.



From the National Respiratory and Enteric Virus Surveillance System (NREVSS) at the Centers for Disease Control website: http://www.cdc.gov/surveillance/nrevss/rsv/state.html

Recommendations

The College of Pharmacy recommends updating the existing palivizumab prior authorization criteria in accordance with the AAP guidelines as follows:

5) Infants less than 12 months of age, ~~born before 35 weeks gestation,~~ with congenital abnormalities of the airway
6) Infants less than 12 months of age, ~~born before 35 weeks gestation,~~ with severe neuromuscular disease

Appendix H

30 Day Notice to Prior Authorize Select Gonadotropin-Releasing Hormone Analogs for Central Precocious Puberty

Oklahoma Health Care Authority, August 2012

This category was introduced for possible inclusion in the Product Based Prior Authorization program in May 2012. See the May and July DUR packet for a more complete discussion of the category. This notice is presented to meet the statutory requirements of 63 O.S. Sec. 5030.5.

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.

Recommendations

The College of Pharmacy recommends medical and pharmacy prior authorization of select gonadotropin-releasing hormone analogs for central precocious puberty.

Criteria for Approval

1. FDA approved indication – central precocious puberty (ICD-9 –CM Diagnosis Code 259.1) confirmed by submitting:
    - Documentation of onset of symptoms at ages less than 8 years of age in females and 9 years of age in males.
    - Documentation that bone age is advanced 1 year beyond the chronological age.
    - Lab assessment:
        - Documentation of abnormal basal gonadotropin levels, OR
        - Documentation of pubertal response to a gonadotropin releasing hormone analog stimulation test.

2. Documentation of a failed trial of lower tiered products or FDA approved indication not covered by a lowered tiered product.

Tier 1	Tier 2	Tier 3
Leuprolide (Lupron® Depot, Lupron Depot-Ped)	Histrelin (Supprelin LA®)	Nafarelin (Synarel®)

Appendix I

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

FDA NEWS RELEASE

For Immediate Release: July 23, 2012
FDA approves Tudorza Pressair to treat chronic obstructive pulmonary disease

The U.S. Food and Drug Administration today approved Tudorza Pressair (aclidinium bromide) for the long-term maintenance treatment of bronchospasm (narrowing of the airways in the lung) associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
COPD is the fourth leading cause of death in the United States.
Tudorza Pressair, a dry powder inhaler used twice daily, is a long-acting antimuscarinic agent that helps muscles around the large airways of the lungs stay relaxed to improve airflow.
The safety and efficacy of Tudorza Pressair were demonstrated in three randomized, placebo-controlled confirmatory clinical trials that included 1,276 patients ages 40 and older with a clinical diagnosis of COPD. Those treated had a smoking history of at least one pack a day for 10 years.
Tudorza Pressair may cause serious side effects, including paradoxical bronchospasm, new or worsened increased pressure in the eyes (acute narrow-angle glaucoma), or new or worsened urinary retention. Tudorza Pressair should not be used as a rescue therapy to treat sudden breathing problems (acute bronchospasm) and is not recommended for people younger than 18 years. The most common side effects reported by patients using Tudorza Pressair include headache, inflammation of the nasal passage (nasopharyngitis), and cough.
Tudorza Pressair is distributed by St. Louis-based Forest Pharmaceuticals, a subsidiary of Forest Laboratories.

FDA NEWS RELEASE

For Immediate Release: July 20, 2012
FDA approves Afinitor for advanced breast cancer

The U.S. Food and Drug Administration today approved Afinitor (everolimus) for use in combination with Aromasin (exemestane) to treat certain postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer.
The drug combination is intended for use in women with recurrence or progression of their cancer after treatment with Femara (letrozole) or Arimidex (anastrozole).
Breast cancer is the second leading cause of cancer-related death among women. This year an estimated 226,870 women will be diagnosed with breast cancer, and 39,510 will die from the disease.
"This is the first approval from the class of drugs known as mTOR inhibitors for the treatment of postmenopausal women with advanced hormone-receptor positive breast cancer," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research.
The safety and effectiveness of Afinitor was evaluated in a clinical study of 724 patients with advanced breast cancer. All patients had experienced menopause, had estrogen receptor-positive, HER2-negative breast cancer that had spread, and had previously received treatment with Femara or Arimidex. Patients were selected to receive either Afinitor in combination with Aromasin or Aromasin with a placebo. Patients received treatment until their cancers progressed or side effects became unacceptable.

The study was designed to measure the length of time a patient lived without the cancer progressing, or progression-free survival (PFS). Patients who were assigned to receive Afinitor plus Aromasin combination had a 4.6 month improvement in the median time to disease progression or death compared to patients receiving the placebo plus Aromasin.
The most common side effects observed in patients receiving Afinitor for breast cancer were mouth ulcers, infections, rash, fatigue, diarrhea and decreased appetite. Patients aged 65 years and older should be monitored closely as these patients experience a higher rate of serious side effects than younger patients receiving the treatment.
The FDA has previously approved Afinitor to treat patients with advanced renal cell carcinoma that has progressed after treatment with other cancer therapies, in adult patients with progressive advanced neuroendocrine tumors of pancreatic origin, for patients with renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, and for adults and children with subependymal giant cell astrocytoma associated with TSC who require treatment but are not candidates for curative surgery.
Afinitor is marketed by East Hanover, N.J.-based Novartis Pharmaceuticals Corporation.

FDA NEWS RELEASE

For Immediate Release: July 16, 2012
FDA approves first drug for reducing the risk of sexually acquired HIV infection

Today, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir disoproxil fumarate), the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners. Truvada, taken daily, is to be used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at high risk.
The FDA previously approved Truvada to be used in combination with other antiretroviral agents for the treatment of HIV-infected adults and children 12 years or older.
As part of PrEP, HIV-uninfected individuals who are at high risk will take Truvada daily to lower their chances of becoming infected with HIV should they be exposed to the virus. A PrEP indication means Truvada is approved for use as part of a comprehensive HIV prevention strategy that includes other prevention methods, such as safe sex practices, risk reduction counseling, and regular HIV testing.
As a part of this action, the FDA is strengthening Truvada's Boxed Warning to alert health care professionals and uninfected individuals that Truvada for PrEP must only be used by individuals who are confirmed to be HIV-negative prior to prescribing the drug and at least every three months during use. The drug is contraindicated for PrEP in individuals with unknown or positive HIV status. The FDA strongly recommends against such use.
Truvada for PrEP is being approved with a Risk Evaluation and Mitigation Strategy (REMS) to minimize the risk to uninfected individuals of acquiring HIV infection and to reduce the risk of development of resistant HIV-1 variants. The central component of this REMS is a training and education program to assist prescribers in counseling individuals who are taking or considering Truvada for PrEP. The training and education program will not restrict distribution of Truvada but will provide information about the importance of adhering to the recommended dosing regimen and understanding the serious risks of becoming infected with HIV while taking Truvada for the PrEP indication.
Truvada's safety and efficacy for PrEP were demonstrated in two large, randomized, double-blind, placebo-controlled clinical trials. The iPrEx trial evaluated Truvada in 2,499 HIV-negative men or transgender women who have sex with men and with evidence of high risk behavior for HIV infection, such as inconsistent or no condom use during sex with a partner of positive or unknown HIV status, a high number of sex partners, and exchange of sex for commodities. Results showed Truvada was effective in reducing the risk of HIV infection

by 42 percent compared with placebo in this population. Efficacy was strongly correlated with drug adherence in this trial.
The Partners PrEP trial was conducted in 4,758 heterosexual couples where one partner was HIV-infected and the other was not (serodiscordant couples). The trial evaluated the efficacy and safety of Truvada and tenofovir versus placebo in preventing HIV infection in the uninfected male or female partner. Results showed Truvada reduced the risk of becoming infected by 75 percent compared with placebo.
No new side effects were identified in the clinical trials evaluating Truvada for the PrEP indication. The most common side effects reported with Truvada included diarrhea, nausea, abdominal pain, headache, and weight loss. Serious adverse events in general, as well as those specifically related to kidney or bone toxicity, were uncommon.
As a condition of approval, Truvada's manufacturer, Gilead Sciences, Inc., is required to collect viral isolates from individuals who acquire HIV while taking Truvada and to evaluate these isolates for the presence of resistance. Additionally, the company is required to collect data on pregnancy outcomes for women who become pregnant while taking Truvada for PrEP and to conduct a trial to evaluate drug adherence and its relationship to adverse events, risk of seroconversion, and resistance development in seroconverters. Gilead has committed to provide national drug utilization data in order to better characterize individuals who utilize Truvada for a PrEP indication and to develop an adherence questionnaire that will assist prescribers in identifying individuals at risk for low compliance.
Gilead Sciences, Inc. is based in Foster City, Calif.

FDA NEWS RELEASE

For Immediate Release: July 17, 2012
FDA approves weight-management drug Qsymia

The U.S. Food and Drug Administration today approved Qsymia (phentermine and topiramate extended-release) as an addition to a reduced-calorie diet and exercise for chronic weight management.
The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese) or adults with a BMI of 27 or greater (overweight) who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia).
Qsymia is a combination of two FDA-approved drugs, phentermine and topiramate, in an extended-release formulation. Phentermine is indicated for short-term weight loss in overweight or obese adults who are exercising and eating a reduced calorie diet. Topiramate is indicated to treat certain types of seizures in people who have epilepsy and to prevent migraine headaches.
Qsymia must not be used during pregnancy because it can cause harm to a fetus. Data show that a fetus exposed to topiramate, a component of Qsymia, in the first trimester of pregnancy has an increased risk of oral clefts (cleft lip with or without cleft palate). Females of reproductive potential must not be pregnant when starting Qsymia therapy or become pregnant while taking Qsymia. Females of reproductive potential should have a negative pregnancy test before starting Qsymia and every month while using the drug and should use effective contraception consistently while taking Qsymia.
The safety and efficacy of Qsymia were evaluated in two randomized, placebo-controlled trials that included approximately 3,700 obese and overweight patients with and without significant weight-related conditions treated for one year. All patients received lifestyle modification that consisted of a reduced calorie diet and regular physical activity.
The recommended daily dose of Qsymia contains 7.5 milligrams of phentermine and 46 mg of topiramate extended-release. Qsymia is also available at a higher dose (15 mg phentermine and 92 mg of topiramate extended-release) for select patients.

Results from the two trials show that after one year of treatment with the recommended and highest daily dose of Qsymia, patients had an average weight loss of 6.7 percent and 8.9 percent, respectively, over treatment with placebo. Approximately 62 percent and 69 percent of patients lost at least five percent of their body weight with the recommended dose and highest dose of Qsymia, respectively, compared with about 20 percent of patients treated with placebo.
Patients who did not lose at least three percent of their body weight by week 12 of treatment with Qsymia were unlikely to achieve and sustain weight loss with continued treatment at this dose. Therefore, response to therapy with the recommended daily dose of Qsymia should be evaluated by 12 weeks to determine, based on the amount of weight loss, whether to discontinue Qsymia or increase to the higher dose. If after 12 weeks on the higher dose of Qsymia, a patient does not lose at least five percent of body weight, then Qsymia should be discontinued, as these patients are unlikely to achieve clinically meaningful weight loss with continued treatment.
Qsymia must not be used in patients with glaucoma or hyperthyroidism. Qsymia can increase heart rate; this drug's effect on heart rate in patients at high risk for heart attack or stroke is not known. Therefore, the use of Qsymia in patients with recent (within the last six months) or unstable heart disease or stroke is not recommended. Regular monitoring of heart rate is recommended for all patients taking Qsymia, especially when starting Qsymia or increasing the dose.
The FDA approved Qsymia with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a Medication Guide advising patients about important safety information and elements to assure safe use that include prescriber training and pharmacy certification. The purpose of the REMS is to educate prescribers and their patients about the increased risk of birth defects associated with first trimester exposure to Qsymia, the need for pregnancy prevention, and the need to discontinue therapy if pregnancy occurs. Qsymia will only be dispensed through specially certified pharmacies.
Vivus Inc. will be required to conduct 10 postmarketing requirements, including a long-term cardiovascular outcomes trial to assess the effect of Qsymia on the risk for major adverse cardiac events such as heart attack and stroke.
The most common side effects of Qsymia are tingling of hands and feet (paresthesia), dizziness, altered taste sensation, insomnia, constipation, and dry mouth.
Qsymia is marketed by Vivus Inc. in Mountain View, Calif.

Safety Announcements

FDA Drug Safety Communication: Seizure risk for multiple sclerosis patients who take Ampyra (dalfampridine)

[7-23-2012] The U.S. Food and Drug Administration (FDA) is updating health care professionals and the public about the risk of seizures in patients with multiple sclerosis (MS) who are starting Ampyra (dalfampridine). Using information received from post-market adverse event reports, FDA recently evaluated seizure risk in MS patients taking Ampyra (dalfampridine). The majority of seizures happened within days to weeks after starting the recommended dose and occurred in patients having no history of seizures (see Data Summary).
In addition, FDA is updating the Ampyra drug label to clarify recommendations that kidney function should be checked in patients before starting Ampyra and monitored at least annually while Ampyra treatment continues. Additionally, patients who miss a dose should not take extra doses– an extra dose of Ampyra can increase seizure risk.
Seizures are a known side effect of Ampyra, and seizure risk increases with higher blood levels of the drug. Ampyra is eliminated from the body through the kidneys, and patients with kidney impairment may develop higher blood levels of the drug, thereby increasing their seizure risk. Ampyra should not be used in patients

with a history of seizures or who have moderate to severe renal (kidney) impairment (measured as creatinine clearance [CrCl] less than or equal to 50 mL/min).
In patients with mild renal impairment (CrCl 51-80 mL/min), the blood levels of Ampyra may reach levels associated with increased seizure risk. Therefore for patients with mild renal impairment, the use of Ampyra requires careful consideration of the potential benefits of treatment as well as the potential risk of seizure.
FDA reminds health care professionals that there are age-related decreases in renal function, and mild renal impairment is common after age 50, even when serum creatinine is normal. Renal function should be assessed by estimating creatinine clearance (see Data Summary).

Additional Information for Patients

- Ampyra can cause seizures, even if you have never had a seizure before.
- Stop taking Ampyra and call your doctor right away if you have a seizure.
- The chance of having a seizure is higher if you take too much Ampyra or if your kidneys have decreased function. Loss of some kidney function is common after age 50.
- Tell your health care professional if you have kidney problems.
- Your health care professional should order blood tests periodically to evaluate your kidney function.
- Do not take Ampyra if you have ever had a seizure.
- Read the Medication Guide that comes with your Ampyra prescription.
- Ampyra tablets should be taken whole and not divided, crushed, chewed, or dissolved.
- Do not take double or extra doses of Ampyra if a dose is missed. Side effects, including seizures, are more frequent at higher doses.
- Discuss any questions you have about Ampyra with your health care professional.
- Report any side effects you experience to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of the page.

Additional Information for Health Care Professionals

- Ampyra is contraindicated in patients with a history of seizures or with moderate to severe renal impairment (CrCl $\leq$ 50 mL/min).
- Mild renal impairment is common after age 50.
- The potential benefits of Ampyra treatment should be carefully considered against the risk of seizures before using Ampyra in patients with mild renal impairment (CrCl 51-80 mL/min).
- Most of the seizures reported with Ampyra treatment occurred in patients without a history of seizures.
- A patient's CrCl (calculated using the Cockroft-Gault equation) should be known before initiating Ampyra treatment and monitored at least annually while Ampyra treatment continues, even when serum creatinine levels appear to be normal.
- The maximum recommended dose of Ampyra is 10 mg twice daily (taken 12 hours apart). Ampyra tablets should be taken whole and not divided, crushed, chewed, or dissolved.
- Tell patients they should not take double or extra doses of Ampyra if a dose is missed. Adverse effects, including seizures, are more frequent at higher doses.
- Ampyra should be discontinued permanently if a seizure occurs.
- Report adverse events involving Ampyra to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

Seizures are a known side effect of Ampyra, and seizure risk increases with higher blood levels of the drug. Using information from FDA's Adverse Event Reporting System (AERS), FDA further evaluated the risk of seizures in MS patients taking Ampyra (dalfampridine). FDA's analysis identified postmarketing case reports of seizures associated with Ampyra at the labeled recommended dose, with many cases of seizures occurring within the first week of starting Ampyra. The vast majority of seizures occurred in patients without a prior history of seizures. Some patients had been taking other drugs that could have increased the risk of seizures or

lowered the seizure threshold. Potentially, age-related renal dysfunction and resultant increases in Ampyra plasma concentrations contributed to the risk of seizure.

Mild renal impairment is common after age 50, even when serum creatinine levels are in the normal range. FDA noted that most patients who experienced a seizure were at least 50 years old and were at risk for mild age-related renal impairment. In patients with mild renal impairment (CrCl 51-80 mL/min), the blood levels of Ampyra may reach levels that have been associated with an increased risk of seizures. The potential benefits of Ampyra treatment must therefore be carefully considered against the potential risk of seizures before using Ampyra in patients with mild renal impairment.

Before starting treatment with Ampyra, renal function should be assessed; if CrCl is unknown, it can be estimated using the Cockcroft-Gault equation (multiplied by 0.85 for women):

$$CrCl = \frac{(140 - age) \times weight(kg)}{SerumCr(mg/dl) \times 72}$$

Patients with a creatinine clearance between 51-80 mL/min are considered to have mild renal impairment and are at a greater risk of seizure when taking Ampyra. Use of Ampyra remains contraindicated in patients with a creatinine clearance ≤ 50 mL/min.

Reference

1. Acorda Therapeutics, Response to FDA's Information Request dated July 11, 2012, Submitted on July 11, 2012.

Current Drug Shortages (as of July 27, 2012):

- Drug Shortages: Current Drug Shortages: Hydromorphone Hydrochloride Injection[9] (updated)
- Drug Shortages: Current Drug Shortages: Levofloxacin Injection[10] (updated)
- Drug Shortages: Resolved Drug Shortages: Neupro (rotigotine transdermal system)[11]
- Drug Shortages: Current Drug Shortages: Dextrose Injection[14] (updated)
- Drug Shortages: Current Drug Shortages: Dipyridamole Injection[15]
- Drug Shortages: Current Drug Shortages: Lidocaine HCL, 4% Topical Solution[16] (updated)
- Drug Shortages: Current Drug Shortages: Amino Acid Products[26] (updated)
- Drug Shortages: Current Drug Shortages: Asparaginase Injection[27] (updated)
- Drug Shortages: Current Drug Shortages: Bupivacaine Hydrochloride Injection[28] (updated)
- Drug Shortages: Current Drug Shortages: Calcium Chloride Injection[29] (updated)
- Drug Shortages: Current Drug Shortages: Diltiazem Injection[30] (updated)
- Drug Shortages: Current Drug Shortages: Epinephrine 1mg/mL (Preservative Free)[31] (updated)
- Drug Shortages: Current Drug Shortages: Fentanyl Citrate Injection[32] (updated)
- Drug Shortages: Current Drug Shortages: Nalbuphine HCl Injection[35] (updated)
- Drug Shortages: Current Drug Shortages: Phytonadione Injectable Emulsion (Vitamin K)[36] (updated)
- Drug Shortages: Current Drug Shortages: Potassium Chloride Injection 2 mEq/mL[37] (updated)
- Drug Shortages: Current Drug Shortages: Naloxone Injection[38] (updated)
- Drug Shortages: Current Drug Shortages: NeoProfen (ibuprofen lysine) Injection[39] (updated)
- Drug Shortages: Current Drug Shortages: Sodium Acetate Injection[40] (updated)
- Drug Shortages: Current Drug Shortages: Sodium Bicarbonate Injection[41] (updated)
- Drug Shortages: Current Drug Shortages: Vecuronium Injection[42] (updated)
- Drug Shortages: Current Drug Shortages: Zinc Injection[43] (updated)
- Drug Shortages: Current Drug Shortages: Amikacin Injection[60] (updated)
- Drug Shortages: Current Drug Shortages: Atropine Sulfate Injection[61] (updated)
- Drug Shortages: Current Drug Shortages: Etomidate Injection[63] (updated)
- Drug Shortages: Current Drug Shortages: Fluorouracil Injection[64] (updated)

- Drug Shortages: Current Drug Shortages: Furosemide Injection[65] (updated)
- Drug Shortages: Current Drug Shortages: Naltrexone Oral Tablets[67] (updated)
- Drug Shortages: Current Drug Shortages: Neupro (rotigotine transdermal system)[68] (updated)
- Drug Shortages: Current Drug Shortages: Oxymorphone Hydrochloride Oral Tablet[69] (updated)
- Drug Shortages: Current Drug Shortages: Selenium Injection[71] (updated)
- Drug Shortages: Current Drug Shortages: Sodium Thiosulfate Injection[72] (updated)
- Drug Shortages: Current Drug Shortages: Foscarnet Sodium Injection[94] (updated)
- Drug Shortages: Current Drug Shortages: Lidocaine HCL, 4% Topical Solution[95]
- Drug Shortages: Current Drug Shortages: Oxcarbazepine Oral Suspension[96]
- Drug Shortages: Current Drug Shortages: Boniva (ibandronate sodium) Injection[105] (updated)
- Drug Shortages: Current Drug Shortages: Calcium Chloride Injection[106] (updated)
- Drug Shortages: Current Drug Shortages: Chloroprocaine (Nesacaine) Injection[107] (updated)
- Drug Shortages: Current Drug Shortages: Dextrose Injection[108] (updated)
- Drug Shortages: Current Drug Shortages: Digoxin Injection[109] (updated)
- Drug Shortages: Current Drug Shortages: Diltiazem Injection [110](updated)
- Drug Shortages: Current Drug Shortages: Diphenhydramine Hydrochloride Injection[111] (updated)
- Drug Shortages: Current Drug Shortages: Diphenhydramine Hydrochloride Injection[112] (updated)
- Drug Shortages: Current Drug Shortages: Fospropofol disodium (Lusedra) Injection[115] (updated)
- Drug Shortages: Current Drug Shortages: Fosphenytoin Sodium Injection[116] (updated)
- Drug Shortages: Current Drug Shortages: Hydromorphone Hydrochloride Injection[117] (updated)
- Drug Shortages: Current Drug Shortages: Lorazepam Injection[119] (updated)
- Drug Shortages: Current Drug Shortages: Methylphenidate HCL[120] (updated)
- Drug Shortages: Current Drug Shortages: Midazolam Injection [121](updated)
- Drug Shortages: Current Drug Shortages: Morphine Sulfate Injection[122] (updated)
- Drug Shortages: Current Drug Shortages: Morphine Sulfate Injection (Preservative Free)[123] (updated)
- Drug Shortages: Current Drug Shortages: Ondansetron Injection[125] (updated)
- Drug Shortages: Current Drug Shortages: Phytonadione Injectable Emulsion, (Vitamin K)[126] (updated)
- Drug Shortages: Current Drug Shortages: Potassium Chloride Injection 2 mEq/mL[127] (updated)
- Drug Shortages: Current Drug Shortages: Propofol Injection [128](updated)
- Drug Shortages: Current Drug Shortages: Sufentanil Citrate Injection[131] (updated)
- Drug Shortages: Current Drug Shortages: Ticlopidine Tablets [132](updated)