Drug Utilization Review Board

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

Wednesday
September 11, 2013
6:00 p.m.

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

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Chris Le, Pharm.D.

SUBJECT: **Packet Contents for Board Meeting – September 11, 2013**

DATE: September 3, 2013

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

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

Call to Order

Public Comment Forum

Approval of DUR Board Meeting Minutes – See Appendix A.

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

Action Item – Vote to Prior Authorize Tysabri® (Natalizumab) – See Appendix C.

Action Item – Vote to Prior Authorize Diclegis® (Doxylamine/Pyridoxine) – See Appendix D.

Action Item – Vote to Prior Authorize Quillivant XR™ and Update the ADHD Product Based Prior Authorization Category – See Appendix E.

Action Item – Vote to Update the Atypical Antipsychotics Product Based Prior Authorization Category – See Appendix F.

FDA and DEA Updates – See Appendix G.

Future Business

Adjournment

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Oklahoma Health Care Authority
Drug Utilization Review Board

(DUR Board)

Meeting – September 11, 2013 @ 6:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.**
   A. August 14, 2013 DUR Minutes – Vote
   B. August 14, 2013 DUR Recommendation Memorandum

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

4. **Update on DUR / Medication Coverage Authorization Unit – See Appendix B.**
   A. Medication Coverage Activity for August 2013
   B. Pharmacy Help Desk Activity for August 2013

Items to be presented by Kori Hamman, Dr. Muchmore, Chairman

5. **Action Item – Vote to Prior Authorize Tysabri® (Natalizumab) – See Appendix C.**
   A. COP Recommendations

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

6. **Action Item – Vote to Prior Authorize Diclegis® (Doxylamine/Pyridoxine) – See Appendix D.**
   A. COP Recommendations

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

7. **Action Item – Vote to Prior Authorize Quillivant XR™ and Update the ADHD Product Based Prior Authorization Category – See Appendix E.**
   A. COP Recommendations

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

8. **Action Item – Vote to Update the Atypical Antipsychotics Product Based Prior Authorization Category – Appendix F.**
   A. COP Recommendations

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

9. FDA and DEA Updates – See Appendix G.

10. Future Business

A. Annual Reviews
B. New Product Reviews

11. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING OF AUGUST 14, 2013

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

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Shellie Keast, Ph.D.; Clinical Assistant Professor	x	
Michyla Adams, Pharm. D.; Clinical Pharmacist	x	
Bethany Holderread, Pharm. D.; Clinical Pharmacist	x	
Chris Le, Pharm.D.; Assisant Director	x	
Carol Moore, Pharm.D.; Clinical Pharmacist	x	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		x
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research		x
Leslie Robinson, D.Ph.; PA Coordinator	x	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	x	
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Jo'Nel Weber, Pharm.D.; Clinical Pharmacist		x
Graduate Students: Tim Pham	x	
Visiting Pharmacy Student(s): William Purcell , Geraint Harris, Kori Hamman	x	

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

OTHERS PRESENT:		
Deitra Maley , PDI	Carol Peek , OUHSC Ped Heme/Onc	Brad Clay, Amgen
Crystal Henderson, Otsuka	Sharon Tonseth, AstraZeneca	David Williams, Forest
Andrey Rattan, Otsuka	John Pittman, Putnam Family Physician	Mark DeClerk, Lilly
Charlene Kaiser, Amgen	Eric Gardner, Novartis	Sharon Jackson, GSK
Hilary Carter, Otsuka	Gregg Rasmussen	Gayle Reinhart, GSK
Mark Kaiser, Otsuka	Don Kempin, Novo Nordisk	Chad Kane, Merck
Jim Fowler, AstraZeneca	Russ Wilson, Johnson & Johnson	Tone Jones, Sunovion
Roger Grotzinger, BMS	Kathleen Karnik, Janssen	Greg Dougherty, DSI
Clint Degner, Novartis	Paul Davis, Mental Health Assoc.	Cherie Ritchie, Otsuka
Timmy Ford, Sunovion	Mike Brose, Mental Health Assoc.	Jon Maguire-Gsk

PRESENT FOR PUBLIC COMMENT:	
David Crawford	OU HSC Pediatric Hem-Oncology
John Pittman	Putnam City Physicians, Family Medical Center
Bill Clark	Sunovion Pharmaceuticals
Brieana Buckley	Biogen Idec
Kim Laubmeier	Otsuka America Pharmaceuticals
Jann Johnson	Astra Zeneca Medical Affairs
Patrick Horn	Hope Clinic/ Psychiatrist
Brian Maves	Pfizer Medical
Paul Davis	Mental Health Associates

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: Not an Agenda Item Speaker: David Crawford
Agenda Item: No 7 Speaker: John Pittman
Agenda Item: No 7 Speaker: Brian Maves
Agenda Item: No 8 Speaker: Bill Clark
Agenda Item: No 8 Speaker: Kim Laubmeier
Agenda Item: No 8 Speaker: Jann Johnson
Agenda Item: No 8 Speaker: Patrick Horn
Agenda Item: No 8 Speaker: Paul Davis
Agenda Item: No 9 Speaker: Brieana Buckley

ACTION: NONE REQUIRED

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

3A: JULY 10, 2013 DUR MINUTES

3B: JULY 10 2013 DUR RECOMMENDATION MEMORANDUM

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

ACTION: MOTION CARRIED

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

4A: MEDICATION COVERAGE ACTIVITY: JULY 2013

4B: PHARMACY HELP DESK ACTIVITY: JULY 2013

4C: SOONERCARE ATYPICAL RX PROGRAM UPDATE

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE FULYZAQ™ (CROFELEMER)

5A: COP RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread

Dr. Kuhls recommends *"the addition of Cryptosporidium and /or Giardia."*

Dr. Kuhls moved to approve with changes added; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE VECAMYL™ (MECAMYLAMINE)

6A: COP RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: FISCAL YEAR 2013 ANNUAL REVIEW OF ADHD MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE QUILLIVANT XR™ (METHYLPHENIDATE EXTENDED RELEASE) ORAL SUSPENSION

7A: CURRENT AUTHORIZATION CRITERIA

7B: UTILIZATION REVIEW

7C: PRIOR AUTHORIZATION REVIEW

7D: MARKET NEWS AND UPDATES

7E: PRODUCT SUMMARY

7F: COP RECOMMENDATIONS

7G: UTILIZATION DETAILS

7H: PRODUCT DETAILS

Materials included in agenda packet; presented by Dr. Adams

Dr. Kuhls recommends *"that the Tier structure needs to be reworked, and to consult with him."* Dr. Muchmore states that *"we table the agenda item and bring it up in the next meeting."*

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: FISCAL YEAR 2013 ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTICS

8A: CURRENT AUTHORIZATION CRITERIA

8B: UTILIZATION REVIEW

8C: PRIOR AUTHORIZATION REVIEW

8D: MARKET NEWS AND UPDATES

8E: UTILIZATION DETAILS

8F: COP RECOMMENDATIONS

8G: UTILIZATION DETAILS

Materials included in agenda packet; presented Dr. Le

Dr. Bell recommends *"that we postpone Atypical Antipsychotics until next meeting."*

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **30 DAY NOTICE TO PRIOR AUTHORIZE TYSABRI® (NATALIZUMAB)**

9A: SUMMARY

9B: UTILIZATION OF TYSABRI®

9C: COP RECOMMENDATIONS

9D: PRODUCT DETAILS

Materials included in agenda packet; presented by Kori Hamman, Pharmacy Intern.
Dr. Kuhls recommends *"a letter be sent out at 2 and 4 years."*

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: **30 DAY NOTICE TO PRIOR AUTHORIZE DICLEGIS® (DOXYLAMINE/PYRIDOXINE)**

10A: SUMMARY

10B: COP RECOMMENDATIONS

10C: PRODUCT DETAILS

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **FISCAL YEAR 2013 ANNUAL REVIEW OF SYNAGIS® (PALIVIZUMAB)**

11A: CURRENT AUTHORIZATION CRITERIA

11B: UTILIZATION OF SYNAGIS

11C: PRIOR AUTHORIZATION REVIEW

11D: COP RECOMMENDATIONS

Materials included in agenda packet; Questions were answered by Dr. Le

ACTION: NONE REQUIRED

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

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

ACTION: NONE REQUIRED

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

Materials included in agenda packet; submitted by Dr. Cothran

12A: ANNUAL REVIEWS

12B: NEW PRODUCT REVIEWS

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ADJOURNMENT**

The meeting was adjourned at 8:19 pm

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

Memorandum

Date: August 15, 2013

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

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

Subject: DUR Board Recommendations from Meeting of August 14, 2013

Recommendation 1: Vote to Prior Authorize Fulyzaq™ (Crofelemer)

MOTION CARRIED by unanimous approval.

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

1. FDA approved diagnosis of non-infectious diarrhea in adult patients with HIV/AIDS currently on anti-retroviral therapy.
2. Duration of diarrhea has been ≥4 weeks.
3. Dietary modifications have failed.
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
    a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
    b. Member does not have fever; and
    c. Stool studies for pathogens are negative including:
        i. Bacterial cultures
        ii. Ova, Parasite, Cryptosporidium and/or Giardia

iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive followed by a confirmatory test OR nucleic acid amplification test in patients with documented diarrhea. A toxin enzyme immunoassay should not be used as a stand-alone test.)

5. If stool study results are negative and the patient has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the doctor's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV) infection, microsporidium, or mycobacterium avium complex (MAC).
6. A quantity limit of 60 tablets per 30 days will apply.
7. Initial approval will be for 4 weeks of therapy. An additional 6 month approval may be granted if physician documents member is responding well to treatment.

Recommendation 2: Vote to Prior Authorize Vecamyl™ (Mecamylamine)

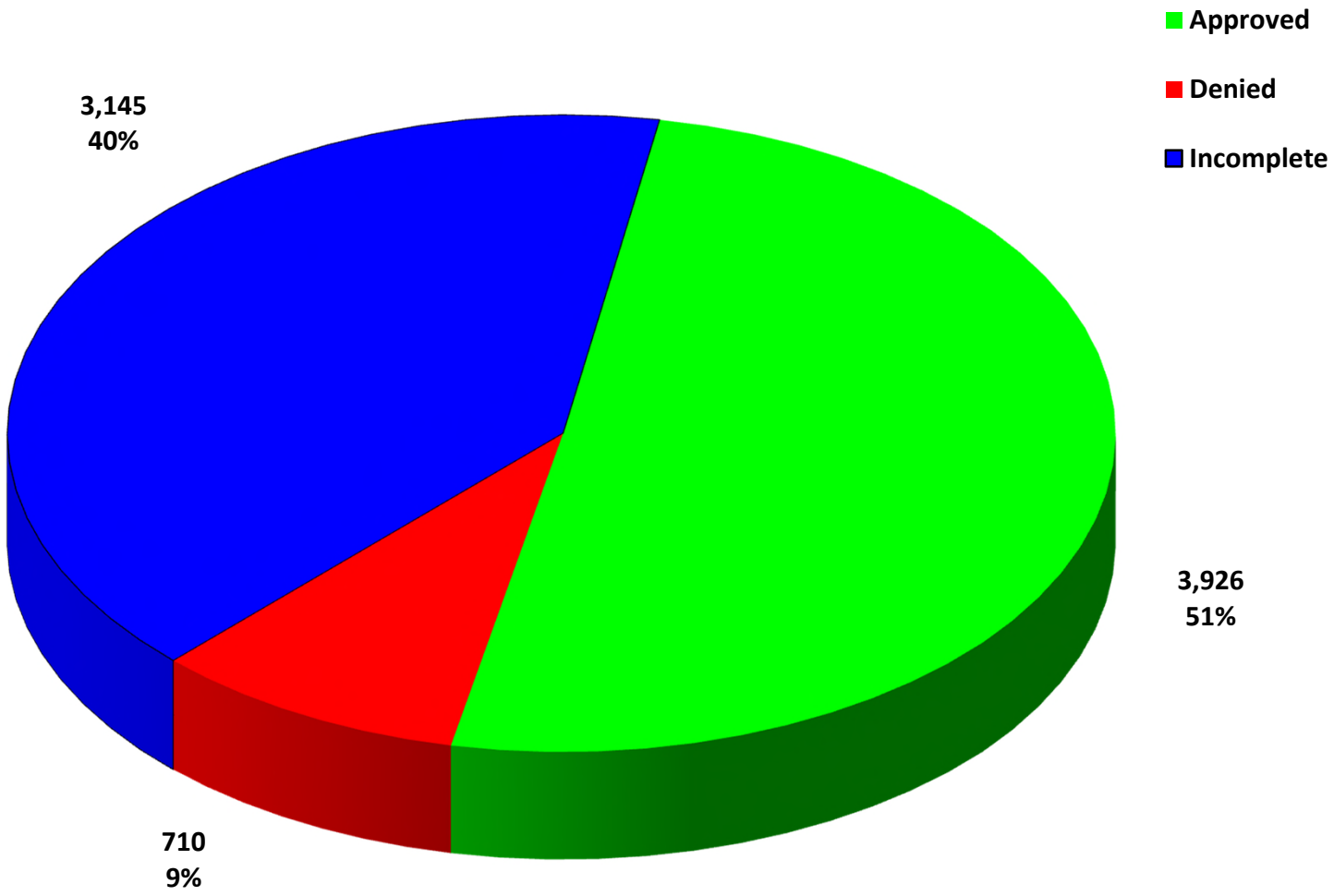
MOTION CARRIED by unanimous approval.

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

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

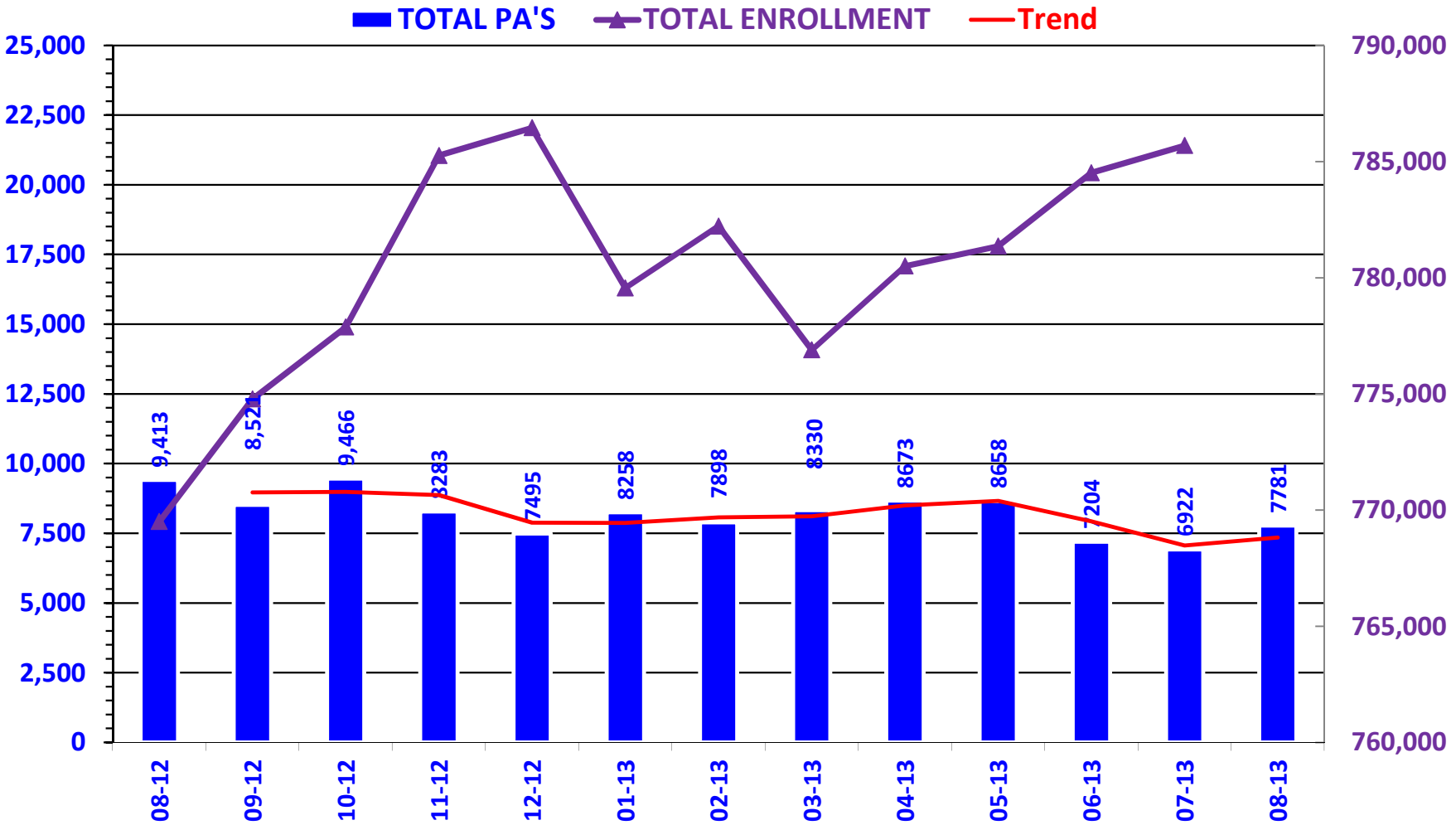
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: AUGUST 2013



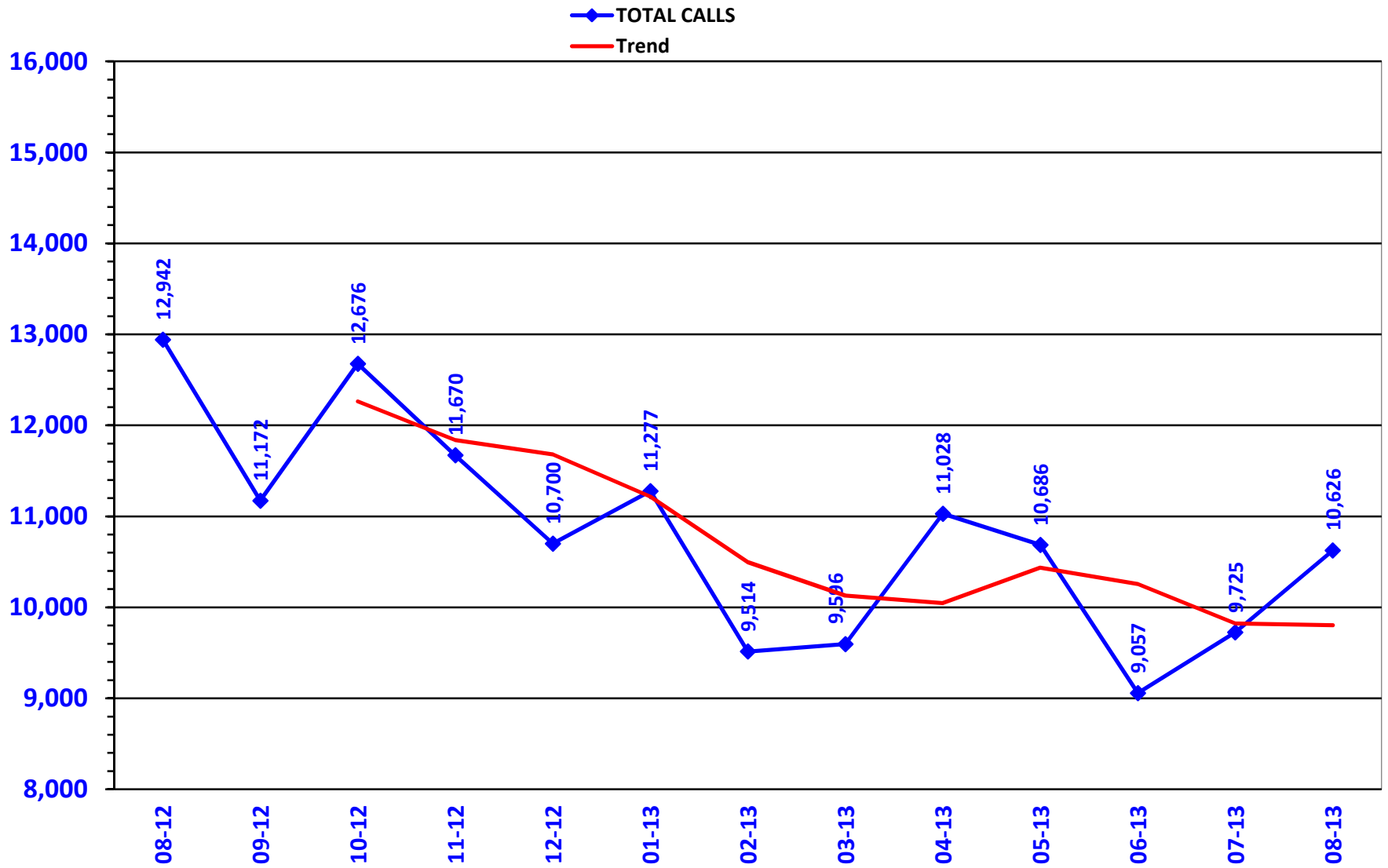
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: AUGUST 2012- AUGUST 2013



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
AUGUST 2012- AUGUST 2013



Prior Authorization Activity

8/1/2013 Through 8/31/2013

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	390	180	5	205	354
Analgesic, Narcotic	392	200	33	159	216
Angiotensin Receptor Antagonist	50	12	14	24	359
Antiasthma	267	131	8	128	288
Antibiotic	31	3	0	28	6
Anticoagulant	78	46	4	28	289
Anticonvulsant	75	34	1	40	322
Antidepressant	279	79	25	175	330
Antidiabetic	131	58	5	68	352
Antigout	10	4	0	6	309
Antihistamine	195	158	5	32	347
Antihyperlipidemic	22	7	3	12	334
Antimigraine	74	33	13	28	353
Antiplatelet	13	13	0	0	305
Antiulcers	271	76	80	115	125
Anxiolytic	106	74	4	28	258
Atypical Antipsychotics	467	298	7	162	337
Biologics	49	23	3	23	321
Bladder Control	68	8	17	43	325
Botox	36	19	11	6	361
Cardiovascular	42	23	3	16	269
Dermatological	146	29	67	50	94
Endocrine & Metabolic Drugs	149	64	11	74	230
Erythropoietin Stimulating Agents	29	19	0	10	100
Fibromyalgia	194	41	22	131	346
Gastrointestinal Agents	128	45	15	68	135
Genitourinary Agents	16	2	1	13	9
Growth Hormones	81	66	2	13	164
HFA Rescue Inhalers	80	29	7	44	315
Insomnia	90	16	15	59	179
Multiple Sclerosis	27	14	0	13	190
Muscle Relaxant	110	36	36	38	52
Nasal Allergy	120	9	42	69	150
Neurological Agents	69	40	10	19	348
Nsaids	189	32	24	133	279
Ocular Allergy	48	18	5	25	142
Ophthalmic	31	9	0	22	49
Osteoporosis	16	3	1	12	297
Other*	151	25	18	108	191
Otic Antibiotic	63	12	6	45	13
Pediculicide	142	53	24	65	16
Prenatal Vitamins	14	0	0	14	0
Smoking Cess.	13	6	0	7	71
Statins	68	19	12	37	359
Stimulant	565	347	18	200	320
Suboxone/Subutex	186	149	4	33	68
Topical Antibiotic	17	2	0	15	91
Topical Antifungal	70	3	23	44	61
Topical Corticosteroids	88	5	18	65	194
Vitamin	36	7	17	12	325
Pharmacotherapy	216	140	6	70	115
Emergency PAs	2	2	0	0	
Total	**6,200**	**2,721**	**645**	**2,834**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	57	31	4	22	281
Cumulative Early Refill	34	34	0	0	29
Dosage Change	415	387	1	27	9
High Dose	1	0	0	1	0
Ingredient Duplication	18	13	0	5	4
Lost/Broken Rx	89	76	3	10	5
NDC vs Age	16	15	0	1	110
Nursing Home Issue	108	97	0	11	10
Other	24	21	0	3	8
Quantity vs. Days Supply	748	490	46	212	260
Stolen	14	13	0	1	3
Temporary Unlock	44	33	5	6	26
Third Brand Request	45	27	6	12	27
Wrong D.S. on Previous Rx	2	2	0	0	6
Overrides Total	**1,581**	**1,205**	**65**	**311**	
Total Regular PAs + Overrides	**7,781**	**3,926**	**710**	**3,145**	

Denial Reasons	
Unable to verify required trials.	2,431
Does not meet established criteria.	717
Lack required information to process request.	694

Other PA Activity	
Duplicate Requests	505
Letters	3,054
No Process	49
Changes to existing PAs	485
Partials	882

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

Appendix C

Vote to Prior Authorize Tysabri® (Natalizumab)

Oklahoma Health Care Authority
September 2013

Recommendations

The College of Pharmacy recommends medical and pharmacy prior authorization of Tysabri® (natalizumab) with the following criteria:

Tysabri® (Natalizumab) Prior Authorization Criteria:

1. FDA approved diagnosis of multiple sclerosis or Crohn's disease; and
2. Treatment with at least two different first line therapeutic categories for multiple sclerosis or Crohn's disease that have failed to yield an adequate clinical response, or a patient specific, clinically significant reason why the member cannot use all available first and second line alternatives; and
3. Prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program.

Appendix D

Vote to Prior Authorize Diclegis® (Doxylamine/Pyridoxine)

Oklahoma Health Care Authority
September 2013

Recommendations[1]

The College of Pharmacy recommends prior authorization of Diclegis® (doxylamine/pyridoxine) with the following criteria:

Diclegis® (doxylamine/pyridoxine) Prior Authorization Criteria:

1. Nausea and vomiting associated with pregnancy; and
2. Trials with at least two non-pharmacologic therapies that have failed to relieve nausea and vomiting; and
3. Trials with at least three prescription medications that have failed to relieve nausea and vomiting (must include a trial of ondansetron); and
4. A patient-specific, clinically significant reason why member cannot use OTC doxylamine and OTC Vitamin B-6 (pyridoxine).

[1] *ACOG Practice Bulletin*: Nausea and Vomiting in Pregnancy; April 2004; Number 52. Available online at: http://www.molinahealthcare.com/medicaid/providers/mo/pdf/acog%20nausea%20%20vomiting%20pregnancy.pdf?E=true. Last accessed 7/30/13.

Appendix E

Vote to Prior Authorize Quillivant XR™ (Methylphenidate) Extended Release Oral Suspension and Update the ADHD Prior Authorization Category

Oklahoma Health Care Authority
September 2013

Recommendations

The College of Pharmacy recommends the addition of Quillivant XR™ to the ADHD Product Based Prior Authorization Category, as well as the following changes to the current criteria and tier structure.

TIER 1	TIER 2	TIER 3	SPECIAL PA
AMPHETAMINE			Desoxyn® tablets Dexedrine® tablets Dexedrine Spansules® caps ProCentra™ solution Methylin® Chewable Tablets Methylin® Solution Provigil® (modafinil tablets) Nuvigil® (armodafinil tablets) Xyrem® (sodium oxybate soln)
Short-Acting Adderall® tablets			
Long-Acting **Lowest Net Cost Long-Acting Product*	***Long-Acting*** *Intermediate Net Cost Range Product(s)*	***Long-Acting*** Adderall XR® capsules Vyvanse® capsules	
METHYLPHENIDATE			
Short-Acting Ritalin® tablets Focalin® tablets Methylin® tablets			
Long-Acting Methylin ER® tablets Ritalin SR® tablets Metadate ER® tablets **Lowest Net Cost Long-Acting Product*	***Long-Acting*** *Intermediate Net Cost Range Product(s)*	***Long-Acting*** Concerta® tablets Focalin XR® capsules Metadate CD® capsules Ritalin LA® capsules Daytrana™ patches Quillivant XR™ suspension	
NON-STIMULANTS∞			
	Lowest Net Cost Product	Kapvay® (clonidine ER tablets) Intuniv® (guanfacine ER tablets) Strattera® (atomoxetine caps)	

*Final Tier 1 category must contain a long-acting capsule.
∞ May rebate to Tier-2 status only.

Tier 2 Prior Authorization Approval Criteria:

1. FDA approved diagnosis; and
2. Trials with at least one long-acting Tier one drug from each category (one amphetamine and one methylphenidate):
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.

Tier 3 Prior Authorization Approval Criteria:

1. FDA approved diagnosis; and
2. Trials with at least one long-acting Tier one drug from each category (one amphetamine and one methylphenidate); and
3. Trials with at least two Tier 2 medications that did not yield adequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why member cannot use the available long acting capsule formulation.

Special Prior Authorization Approval Criteria:

1. **Desoxyn®, Dexedrine®, Dexedrine Spansules®, and ProCentra™ Solution** Criteria:
    a. Covered diagnosis; and
    b. A patient-specific, clinically significant reason why member cannot use all other available stimulant medications.
2. **Methylin® Chewable Tablets & Solution Criteria:**
    a. FDA approved diagnosis; and
    b. A patient-specific, clinically significant reason why member cannot use all other available formulations of long acting stimulant medications that can be used for members who cannot swallow capsules/tablets.
3. **Provigil®, Nuvigil®, and Xyrem® Criteria:**
    a. FDA approved diagnosis.
    b. Use of Provigil®, Nuvigil®, or Xyrem® requires a patient-specific, clinically significant reason why member cannot use stimulant medications to improve wakefulness during the daytime.
    c. Use of Xyrem® requires recent trials with Tier 1 and Tier 2 stimulants from different chemical categories, and trials with both Provigil® and Nuvigil® within the past 6 months, unless contraindicated, that did not yield adequate results.

d. The diagnosis of obstructive sleep apnea requires concurrent treatment for the obstructive sleep apnea.
e. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the petition.

Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum are not covered.
2. Prior Authorization is required for all tiers for members greater than 20 years of age and for members 0-4 years of age. All prior authorization requests for members under the age of 5 years must be reviewed by an OHCA contracted psychiatrist.
3. Please note, members currently stabilized on ADHD medications in the previous 30 days will be grandfathered.

Appendix F

Vote to Update the Atypical Antipsychotics Product Based Prior Authorization Category

Oklahoma Health Care Authority
September 2013

Recommendations

Based on the recommendations of the DUR Board the Atypical Antipsychotics Product Based Prior Authorization Category has been re-evaluated. New information as well as momentous market changes that have occurred in the preceding fiscal year have also been taken into consideration. The College of Pharmacy recommends the following changes to the Atypical Antipsychotics Product Based Prior Authorization Category as shown below. The final tier status of each branded product will apply across all available formulations of the product line.

Atypical Antipsychotics*

Tier 1	Tier 2	Tier 3†
risperidone **(Risperdal®, Risperdal Consta®)** olanzapine **(Zyprexa®)** quetiapine **(Seroquel®)** ziprasidone **(Geodon®)** clozapine **(Clozaril®)**¥	Supplemental Rebated Products	aripiprazole **(Abilify®, Abilify Maintena™)** asenapine **(Saphris®)** clozapine **(Fazaclo®)** iloperidone **(Fanapt™)** lurasidone **(Latuda®)** olanzapine/fluoxetine **(Symbyax®)** paliperidone **(Invega®, Invega Sustenna®)** quetiapine ER **(Seroquel XR®)**

* **Mandatory Generic Plan Applies**
† **May be rebated to Tier 2 status only**
¥ **Does not count toward a tier-1 trial**

Approval Criteria for Tier 2 Medication:

1. Trials of **two** Tier 1 products (not including clozapine), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Tier 3 Medication:

1. Trials of **two** Tier 1 products (not including clozapine), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and

2. Trials of **two** Tier 2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment for Depression:

1. For Abilify® (aripiprazole), Seroquel XR® (quetiapine extended release), or Symbyax® (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 applies.

Clinical Exceptions:

1. Members currently stabilized on a higher tiered medication defined by paid claim(s) for the higher tiered medication in the past 90 days will be approved.
2. Members being released from a hospital and stabilized on a higher tiered medication will be approved.
3. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
4. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
5. Lurasidone (Latuda®) may be approved for pregnant women with appropriate diagnosis.

Second Opinion Process for Children 0 - 4 Years of Age

Children less than 5 years of age will require a "second opinion" prior authorization to be reviewed by an OHCA-contracted child psychiatrist.

Educational Initiative for Inpatient Behavioral Health Providers

Due to the cost of inpatient psychiatric stays, the College of Pharmacy does not recommend removing the inpatient stabilization approval criteria at this time. However, COP and OHCA plan to work closely with the OHCA Inpatient Behavioral Health providers' group, which meets regularly at the agency, to educate them about the potential benefits of adopting the OHCA preferred drugs as their formulary products.

Appendix G

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

FDA NEWS RELEASE

For Immediate Release: Aug. 12, 2013
FDA approves new drug to treat HIV infection

The U.S. Food and Drug Administration today approved Tivicay (dolutegravir), a new drug to treat HIV-1 infection.
Tivicay is an integrase strand transfer inhibitor that interferes with one of the enzymes necessary for HIV to multiply. It is a pill taken daily in combination with other antiretroviral drugs.
Tivicay is approved for use in a broad population of HIV-infected patients. It can be used to treat HIV-infected adults who have never taken HIV therapy (treatment-naïve) and HIV-infected adults who have previously taken HIV therapy (treatment-experienced), including those who have been treated with other integrase strand transfer inhibitors. Tivicay is also approved for children ages 12 years and older weighing at least 40 kilograms (kg) who are treatment-naïve or treatment-experienced but have not previously taken other integrase strand transfer inhibitors.
About 50,000 Americans become infected with HIV each year and about 15,500 died from the disease in 2010, according to the Centers for Disease Control and Prevention.
Tivicay's safety and efficacy in adults was evaluated in 2,539 participants enrolled in four clinical trials. Depending on the trial, participants were randomly assigned to receive Tivicay or Isentress (raltegravir), each in combination with other antiretroviral drugs, or Atripla, a fixed-dose combination of efavirenz, emtricitabine and tenofovir. Results showed Tivicay-containing regimens were effective in reducing viral loads.
A fifth trial established the pharmacokinetics, safety and activity of Tivicay as part of treatment regimens for HIV-infected children ages 12 years and older weighing at least 40 kg who have not previously taken integrase strand transfer inhibitors.
Common side effects observed during clinical studies include difficulty sleeping (insomnia) and headache. Serious side effects include hypersensitivity reactions and abnormal liver function in participants co-infected with hepatitis B and/or C. The Tivicay label gives advice on how to monitor patients for the serious side effects.
Tivicay is marketed by ViiV Healthcare and manufactured by GlaxoSmithKline, both based in Research Triangle Park, N.C. Isentress is marketed by Whitehouse Station, N.J.-based Merck, and Atripla is marketed by San Francisco, Calif.-based Gilead.

Safety Announcements

FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection

[8-15-2013] The U.S. Food and Drug Administration (FDA) has required the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs be updated to better describe the serious side effect of peripheral neuropathy. This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent.
The risk of peripheral neuropathy occurs only with fluoroquinolones that are taken by mouth or by injection. Approved fluoroquinolone drugs include levofloxacin (Levaquin), ciprofloxacin (Cipro), moxifloxacin (Avelox), norfloxacin (Noroxin), ofloxacin (Floxin), and gemifloxacin (Factive). The topical formulations of fluoroquinolones, applied to the ears or eyes, are not known to be associated with this risk.
If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolone antibacterial drug, unless the benefit of

continued treatment with a fluoroquinolone outweighs the risk. Peripheral neuropathy is a nerve disorder occurring in the arms or legs. Symptoms include pain, burning, tingling, numbness, weakness, or a change in sensation to light touch, pain or temperature, or the sense of body position. It can occur at any time during treatment with fluoroquinolones and can last for months to years after the drug is stopped or be permanent. Patients using fluoroquinolones who develop any symptoms of peripheral neuropathy should tell their health care professionals right away.
FDA will continue to evaluate the safety of drugs in the fluoroquinolone class and will communicate with the public again if additional information becomes available.

Safety Announcements

FDA Drug Safety Communication: FDA investigating rare brain infection in patient taking Gilenya (fingolimod)

[8/29/2013] The U.S. Food and Drug Administration (FDA) is alerting the public that a patient in Europe diagnosed with possible multiple sclerosis (MS) has developed a rare and serious brain infection after taking the drug Gilenya (fingolimod). This is the first case of this disease, called progressive multifocal leukoencephalopathy or PML, reported following the administration of Gilenya to a patient who had not previously received Tysabri (natalizumab), an MS drug associated with a higher risk of PML.
Patients should not stop taking Gilenya without first discussing any questions or concerns with their health care professionals. We are providing this alert while we continue to investigate the PML case, and we are working with Gilenya's manufacturer, Novartis, to obtain and review all available information about this occurrence. We will communicate our final conclusions and recommendations after our evaluation is complete.
PML is a rare and serious brain infection caused by the John Cunningham (JC) virus that damages the fatty covering of the brain called myelin. Myelin is essential for the proper functioning of nerves in the white matter of the brain. PML usually causes death or severe disability. The JC virus is a common virus that is harmless in most people but can cause PML in people who have weakened immune systems. Some medications, including Gilenya, can weaken the immune system.
Gilenya is used to treat relapsing forms of MS, a nervous system disease that affects the brain and spinal cord. MS is thought to affect more than 2 million people worldwide. The drug was approved for use in the United States in September 2010. Novartis reports that approximately 71,000 patients worldwide have been treated with Gilenya.
The patient who developed PML received nearly eight months of Gilenya treatment before being diagnosed with PML. The patient had been treated with interferon beta-1a and azathioprine for one month before initiating Gilenya treatment; those medications were stopped when Gilenya was started. The patient also received multiple courses of intravenous corticosteroids for several months before and during Gilenya treatment. The diagnosis was made based on clinical symptoms and the detection of JC viral DNA in the cerebrospinal fluid. Gilenya treatment was stopped.
We urge health care professionals and patients to report side effects involving Gilenya to the FDA MedWatch program.

Safety Announcements

FDA Drug Safety Communication: FDA warns of rare but serious skin reactions with the pain reliever/fever reducer acetaminophen

[8-1-2013] The U.S. Food and Drug Administration (FDA) is informing the public that acetaminophen has been associated with a risk of rare but serious skin reactions. These skin reactions, known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can

be fatal. Acetaminophen is a common active ingredient to treat pain and reduce fever; it is included in many prescription and over-the-counter (OTC) products.
Reddening of the skin, rash, blisters, and detachment of the upper surface of the skin can occur with the use of drug products that contain acetaminophen. These reactions can occur with first-time use of acetaminophen or at any time while it is being taken. Other drugs used to treat fever and pain/body aches (e.g., non-steroidal anti-inflammatory drugs, or NSAIDS, such as ibuprofen and naproxen) also carry the risk of causing serious skin reactions, which is already described in the warnings section of their drug labels.
Anyone who develops a skin rash or reaction while using acetaminophen or any other pain reliever/fever reducer should **stop the drug** and seek medical attention right away. Anyone who has experienced a serious skin reaction with acetaminophen should not take the drug again and should contact their health care professional to discuss alternative pain relievers/fever reducers.
Health care professionals should be aware of this rare risk and consider acetaminophen, along with other drugs already known to have such an association, when assessing patients with potentially drug-induced skin reactions.
This new information resulted from the Agency's review of the FDA Adverse Event Reporting System (FAERS) database and the medical literature to evaluate cases of serious skin reactions associated with acetaminophen. It is difficult to determine how frequently serious skin reactions occur with acetaminophen, due to the widespread use of the drug, differences in usage among individuals (e.g., occasional vs. long-term use), and the long period of time that the drug has been on the market; however it is likely that these events (i.e., SJS, TEN, and AGEP) occur rarely.
FDA will require that a warning be added to the labels of prescription drug products containing acetaminophen to address the risk of serious skin reactions. FDA will also request that manufacturers add a warning about serious skin reactions to the product labels of OTC acetaminophen drug products marketed under a new drug application and will encourage manufacturers of drug products marketed under the OTC monograph do the same.

Current Drug Shortages Index (as of August 29th, 2013):

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

Acetylcysteine Inhalation Solution UPDATED 8/30/2013
Acyclovir Sodium Injection (initial posting 11/13/2012) UPDATED 8/30/2013
Alteplase (Cathflo Activase) (initial posting 1/27/2012)
Amikacin Injection
Aminocaproic Acid Injection (initial posting 3/8/2013) UPDATED 8/26/2013
Aminophylline (initial posting 12/10/2012)
Ammonium Chloride Injection (initial posting 3/8/2013) UPDATED 8/26/2013
Amytal Sodium Injection (initial posting date 1/31/2013)
Atracurium Besylate (initial posting 2/27/2012)
Atropine Sulfate Injection UPDATED 8/26/2013
Barium Sulfate for Suspension (initial posting 10/12/2012)
Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride (Helidac) (initial posting 3/8/2012)
Bumetanide Injection (initial posting 6/21/2012) UPDATED 8/26/2013
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection UPDATED 8/27/2013
Buprenorphine Hydrochloride (Buprenex) Injection
Caffeine and Ergotamine Tartrate (Cafergot) Tablets (initial posting 3/8/2012)
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection
Calcium Chloride Injection (initial posting 12/13/2012) UPDATED 8/26/2013
Calcium Gluconate Injection (initial posting 1/10/2013) UPDATED 8/30/2013
Chromic Chloride Injection UPDATED 8/26/2013

Cidofovir Injection (initial posting 2/15/2013)
Citric Acid; Gluconolactone; Magnesium Carbonate (Renacidin) Solution for Irrigation (initial posting 6/30/2012)
Copper (Cupric Chloride) Injection (initial posting 4/25/2013)
Cyanocobalamin Injection (initial posting 1/25/2013) UPDATED 8/30/2013
Daunorubicin Hydrochloride Solution for Injection
Denileukin Diftitox (Ontak) (initial posting 9/22/2012)
Desmopressin Acetate (DDAVP) Injection (initial posting 5/7/2013) UPDATED 8/28/2013
Dexamethasone Sodium Phosphate Injection (initial posting 1/15/2013) UPDATED 8/28/2013
Dexrazoxane (Zinecard) Injection UPDATED 8/30/2013
Dextrose Injection (initial posting 5/23/2012) UPDATED 8/26/2013
Dipyridamole Injection (initial posting 7/24/2012)
Dobutamine Hydrochloride Injection (initial posting 4/26/2013) UPDATED 8/26/2013
Doxorubicin (Adriamycin) Lyophilized Powder (initial posting 12/2/2011) UPDATED 8/28/2013
Doxycycline Hyclate (initial posting 1/18/2013)
Epinephrine Injection (initial posting 4/27/2012) UPDATED 8/26/2013
Epinephrine 1mg/mL (Preservative Free) (initial posting 6/21/2012)
Ethiodol (Ethiodized Oil) Ampules UPDATED 8/22/2013
Etomidate (Amidate) Injection (initial posting 2/9/2012) UPDATED 8/26/2013
Fentanyl Citrate (Sublimaze) Injection UPDATED 8/26/2013
Fluphenazine Decanoate Injection 4/25/2013 UPDATED 8/30/2013
Fluphenazine Hydrochloride Injection
Fluticasone Propionate and Salmeterol (Advair HFA) Inhalation Aerosol (initial posting date) - 10/17/2012)
Fosphenytoin Sodium (Cerebyx) Injection (initial posting 3/30/2012)
Furosemide Injection (initial posting 6/20/2012) UPDATED 8/26/2013
Gallium Nitrate (Ganite) Injection (initial posting 4/4/2012)
Heparin Sodium Injection (initial posting 7/5/2012) UPDATED 8/26/2013
Hydromorphone Hydrochloride (Dilaudid) Injection (initial posting 3/7/2012) UPDATED 8/26/2013
Hydromorphone Hydrochloride Tablets (initial posting 2/19/2013)
Ibandronate Sodium (Boniva) Injection (initial posting 6/6/2012)
Intravenous Fat Emulsion UPDATED 8/23/2013
Isoniazid; Rifampin (Rifamate) Capsules 3/15/2013 UPDATED 8/28/2013
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection UPDATED 8/28/2013
Leuprolide Acetate Injection
Levothyroxine Sodium (Levoxyl) Tablets (initial posting date - 3/15/2013)
Lidocaine Hydrochloride (Xylocaine) Injection (initial posting date - 2/22/2012) UPDATED 8/26/2013
Liotrix (Thyrolar) Tablets
Lomustine Capsules (initial posting date - 5/9/2013)
Lorazepam (Ativan) Injection UPDATED 8/26/2013
Magnesium Sulfate Injection UPDATED 8/26/2013
Mannitol (Osmitrol, Resectisol) Injection (initial posting date - 12/21/2011) UPDATED 8/26/2013
Mecasermin [rDNA origin] (Increlex) Injection (initial posting date - 4/26/2013)
Methazolamide (Glauctabs, Neptazane) Tablets
Methyldopate Hydrochloride Injection
Methylin Chewable Tablets (initial posting date - 2 /19/2013)
Methylphenidate Hydrochloride ER Tablets (initial posting date - 2/19/2013) UPDATED 8/21/2013
Methylphenidate Hydrochloride Tablets (initial posting date - 2/19/2013)
Metoclopramide (Reglan) Injection

Midazolam Hydrochloride (Versed) Injection
Morphine Sulfate Injection UPDATED 8/26/2013
Morphine Sulfate (Astramorph PF, Duramorph, Infumorph) Injection (Preservative Free) UPDATED 8/26/2013
Multi-Vitamin Infusion (Adult and Pediatric) UPDATED 8/23/2013
Nalbuphine Hydrochloride (Nubain) Injection (initial posting 5/15/2012) UPDATED 8/26/2013
Neostigmine Methylsulfate Injection (initial posting 1/14/2013)
Nitroglycerin Ointment USP, 2% (Nitro-Bid) (Initial posting 10/23/2012)
Ondansetron (Zofran) 2mg/mL Injection UPDATED 8/29/2013
Oseltamivir Phosphate (Tamiflu) Powder for Oral Suspension (Initial posting 1/10/2013)
Pancuronium Bromide Injection
Papaverine Hydrochloride Injection (initial posting 12/17/2012)
Pentamidine Isethionate (NebuPent) Inhalant (initial posting 8/27/2012)
Pentamidine Isethionate (Pentam 300) Injection (initial posting 8/27/2012)
Phosphate (Glycophos) Injection (initial posting 5/29/2013)
Pilocarpine HCL Opthalmic Gel 4% (Pilopine HS) (initial posting 6/1/2012)
Potassium Acetate Injection, USP 2mEq/mL
Potassium Chloride Injection (initial posting 5/15/2012) UPDATED 8/26/2013
Potassium Phosphate Injection UPDATED 8/26/2013
Procainamide HCL Injection UPDATED 8/26/2013
Prochlorperazine Injection (initial posting 1/30/2012)
Promethazine Injection (initial posting 2/10/2012) UPDATED 8/29/2013
Reserpine Tablets (initial posting 4/17/2013)
Rifampin for Injection (initial posting 3/22/2013) UPDATED 8/28/2013
Secretin Synthetic Human (ChiRhoStim) Injection (ChiRhoStim) (initial posting 6/15/2012)
Selenium Injection
Sincalide (Kinevac) Lyophilized Powder for Injection (initial posting 6/21/2013) UPDATED 8/27/2013
Sodium Acetate Injection (initial posting 1/31/2012)
Sodium Chloride 0.9% (5.8mL and 20mL) (initial posting 5/4/2012)
Sodium Chloride 23.4% UPDATED 8/30/2013
Sodium Phosphate Injection
Succinylcholine (Anectine, Quelicin) Injection (initial posting 8/17/2012)
Sufentanil Citrate (Sufenta) Injection UPDATED 8/29/2013
Sulfamethoxazole 80mg/ml;Trimethoprim 16mg/ml (SMX/TMP) (Bactrim) Injection
Technetium Tc99m Bicisate for Injection (Neurolite) (initial posting 5/4/2012)
Technetium Tc99m Sestamibi Kit for Injection (Cardiolite) (initial posting 5/4/2012)
Telavancin (Vibativ) Injection UPDATED 8/19/2013
Tetracycline Capsules
Thiotepa (Thioplex) for Injection
Ticarcillin Disodium/Clavulanic Potassium (Timentin) Injection (initial posting 8/16/12)
Tobramycin Solution for Injection UPDATED 8/30/2013
Trace Elements (initial posting 1/24/2013)
Tromethamine (Tham) Injection (initial posting 5/2/2012)
Verapamil Hydrochloride Injection, USP (initial posting 4/17/2013) UPDATED 8/26/2013
Vinblastine Sulfate Injection (initial posting 1/31/2012) UPDATED 8/30/2013
Vitamin A Palmitate (Aquasol A)
Zinc Injection (initial posting 2/15/2012) UPDATED 8/26/2013