



Drug Utilization Review Board

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

Wednesday
February 13, 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 – February 13, 2013

DATE: February 7, 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 February meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

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

Action Item – Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Update Antihyperlipidemics Prior Authorization Criteria, and Prior Authorize Vascepa™ and Juxtapid™ – See Appendix C.

Action Item – Vote to Prior Authorize Binosto™ and Update Osteoporosis Medications Prior Authorization Criteria – See Appendix D.

Action Item – Vote to Prior Authorize Xeljanz® – See Appendix E.

Action Item – FY12 Annual Review of Narcotic Analgesics – See Appendix F.

30 Day Notice to Prior Authorize Chronic Obstructive Pulmonary Disease Medications – See Appendix G.

30 Day Notice to Prior Authorize Miscellaneous Corticosteroid Products – See Appendix H.

FDA and DEA Updates – See Appendix I.

Future Business

Adjournment

Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting –February 13, 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. January 9, 2013 DUR Minutes – Vote
 - B. January 10, 2013 DUR Recommendation Memorandum

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

4. **Action Item – Update on DUR / Medication Coverage Authorization Unit – See Appendix B.**
 - A. Medication Coverage Activity for January 2013
 - B. Pharmacy Help Desk Activity for January 2013
 - C. Retrospective Drug Evaluation: Duplication of Narcotic Therapy
 - D. Vote on Brimonidine Safety Recommendations

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

5. **Action Item – Vote to Update Antihyperlipidemics Prior Authorization Criteria, and Prior Authorize Vascepa™ and Juxtapid™ – See Appendix C.**
 - A. COP Recommendations

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

6. **Action Item - Vote to Prior Authorize Binosto™ and Update Osteoporosis Medications Prior Authorization Criteria – See Appendix D.**
 - A. COP Recommendations

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

7. **Action Item – Vote to Prior Authorize Xeljanz[®] – See Appendix E.**
 - A. COP Recommendations

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

8. **Action Item – FY12 Annual Review of Narcotic Analgesics – See Appendix F.**
 - A. Background and Statistics Update
 - B. Current Authorization Criteria and Tier Structure
 - C. Utilization Review
 - D. Prior Authorization Review
 - E. COP Recommendations

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

9. **30 Day Notice to Prior Authorize Chronic Obstructive Pulmonary Disease Medications – See Appendix G.**
 - A. COP Recommendations

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

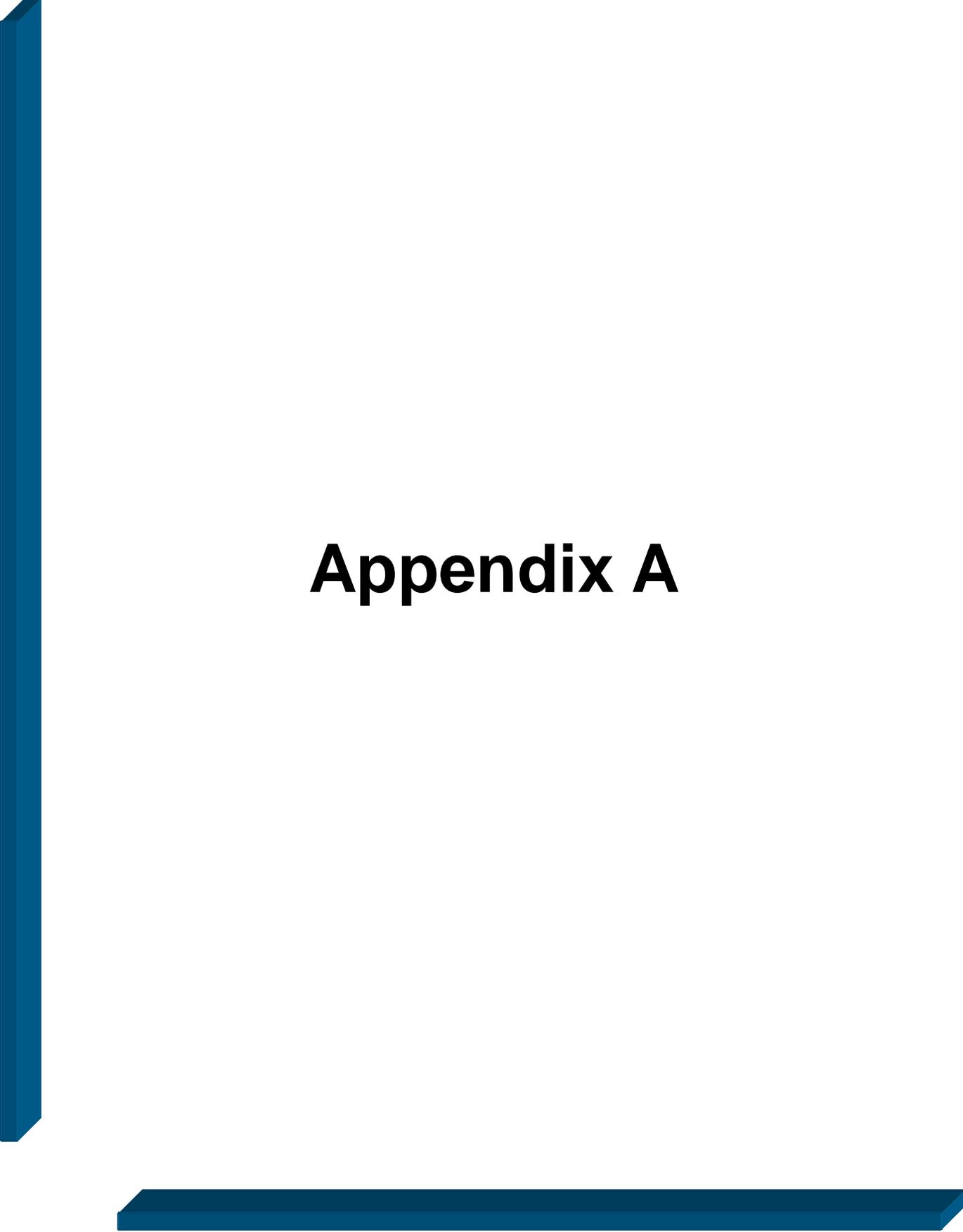
10. **30 Day Notice to Prior Authorize Miscellaneous Corticosteroid Products – See Appendix H.**
 - A. Summary
 - B. COP Recommendations

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

11. **FDA and DEA Updates – See Appendix I.**

12. **Future Business**
 - A. Annual Reviews
 - B. New Product Reviews

13. **Adjournment**



Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
 DRUG UTILIZATION REVIEW BOARD MEETING
 MINUTES of MEETING of December 12, 2012

| 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, Pharm.D, M.S.; Clinical Assistant Professor | X | |
| Chris Le, Pharm.D.; Assisant Director | X | |
| Mark Livesay, Operations Manager | X | |
| Carol Moore, Pharm.D.; Clinical Pharmacist | X | |
| Brandy Nawaz, Pharm.D.; Clinical Pharmacist | X | |
| Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research | X | |
| Leslie Robinson, D.Ph.; PA Coordinator | | X |
| Jennifer Sipols, Pharm.D.; Clinical Pharmacist | X | |
| Jo'Nel Weber, Pharm.D.; Clinical Pharmacist | X | |
| Bethany Holderread, Pharm. D., Clinical Pharmacist | X | |
| Graduate Students: Amany Hussein, Manish Mittal | X | |
| Visiting Pharmacy Student(s): n/a | | N/A |

| OKLAHOMA HEALTH CARE AUTHORITY STAFF: | PRESENT | ABSENT |
|--|---------|--------|
| Mike Fogarty, J.D., M.S.W.; Chief Executive Officer | | X |
| Sylvia Lopez, M.D., FAAP, Chief Medical Officer | X | |
| Garth Splinter, M.D., M.B.A.; Medicaid Director | 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 | |
| Jennie Melendez, 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: | | |
|---------------------------------|-------------------------|---------------------|
| Roger Grotzinger, BMS | Clint Degrier, Novartis | Mai Duong, Novartis |
| Janie Huff, Takeda | Jim Fowler, AstraZeneca | Warren Tayes, Merck |
| David Williams, Forest | Sam Smothers, Medimmune | Steve Curry, Meda |
| Mai Duong, Novartis | Charlene Kaiser, Amgen | Jim Chapman, Abbott |
| Russ Wilson Johnson and Johnson | | |

| PRESENT FOR PUBLIC COMMENT: | |
|-----------------------------|--------|
| Brian Maves | Pfizer |
| Brad Clay | Amgen |

AGENDA ITEM NO. 1: CALL TO ORDER

1A: Roll Call

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

Agenda Item NO 8:

Speaker: Brad Clay

Agenda Item NO 9:

Speaker: Brian Maves

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: December 12, 2012 DUR Minutes

3B: December 13, 2012 DUR Recommendation Memorandum

Ms. Varalli-Claypool 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: December 2012

4B: Pharmacy Help Desk Activity: December 2012

4C: Retrospective Drug Evaluation: Focusing on Safety

Dr. Kuhls moved to approve with the recommendation of taking out the "Clinical exception may apply for prescriptions written by ophthalmologists/optometrists criteria"; seconded by Dr. Preslar

Reports included in agenda packet; presented by Dr. Le

ACTION: MOTION CARRIED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE LINZESS™

5A: COP Recommendations

Materials included in agenda packet; presented by Dr. Le

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: 60 DAY NOTICE TO PRIOR AUTHORIZE CHRONIC OBSTRUCTIVE PULMONARY DISEASE

MEDICATIONS

6A: Utilization Review

6B: Cost Comparison

6C: Economic Impact

6D: Market Analysis
6E: COP Recommendations
Materials included in agenda packet; presented by Dr. Weber.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF ANTIHYPERLIPDEMIC AND 30 DAY NOTICE TO PRIOR AUTHORIZE VASCEPA™ AND JUXTAPID™
7A: Current Authorization Criteria
7B: Utilization Review
7C: Prior Authorization Review
7D: Market News and Update
7E: Vascepa™ and Juxtapid™ Product Summaries
7F: COP Recommendations
7G: Utilization Details
7H: Vascepa™ and Juxtapid™ Product details
Materials included in agenda packet; presented by Dr. Nawaz
Dr. Muchmore recommends that criteria should read as: "one 8 week trial of either simvastatin or atorvastatin." Dr. Muchmore recommends that Tier 2 Approval Criteria Item 1 should read "20mg or higher."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF OSTEOPOROSIS MEDICATIONS AND 30 DAY NOTICE TO PRIOR AUTHORIZE BINOSTO™
8A: Current Authorization Criteria
8B: Utilization Review
8C: Prior Authorization Review
8D: Market News and Update
8E: COP recommendations
8F: Utilization Details
8G: Binosto™ Product Details
For Public Comment: Brad Clay
Materials included in agenda packet; presented by Dr. Le
Dr. Muchmore recommends "having the diagnosis code for Paget's disease then a 60 day supply once a day will be approved."
Dr. Muchmore recommends that between B and C change the "and" to an "or" then add the criteria of "the non-healing fracture can qualify for 6 months of Teriparatide."
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: 30 DAY NOTICE TO PRIOR AUTHORIZE XELJANZ®
9A: Summary
9B: Mechanism of Action
9C: Efficacy
9D: Safety
9E: Cost
9F: COP Recommendations
G: Product Details
For Public Comment: Brian Maves
Materials included in agenda packet; presented by Dr. Le.
Dr. Muchmore and Dr. Kuhls recommend adding into the criteria... "two available disease specific tier 2 agents"... Dr. Kuhls and Dr. Muchmore recommend adding to the criteria "negative Tuberculosis test or successful treatment of active Tuberculosis, or close evaluation of latent TB".
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: FDA AND DEA UPDATES
Materials included in agenda packet; presented by Dr. Cothran.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: FUTURE BUSINESS
Materials included in agenda packet; submitted by Dr. Cothran
A: DUR of Oral Corticosteroids
B: Annual Reviews
C: New Product Reviews
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: ADJOURNMENT
The meeting was adjourned at 7:18



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

Memorandum

Date: January 10, 2013

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

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

Subject: DUR Board Recommendations from Meeting of January 9, 2013

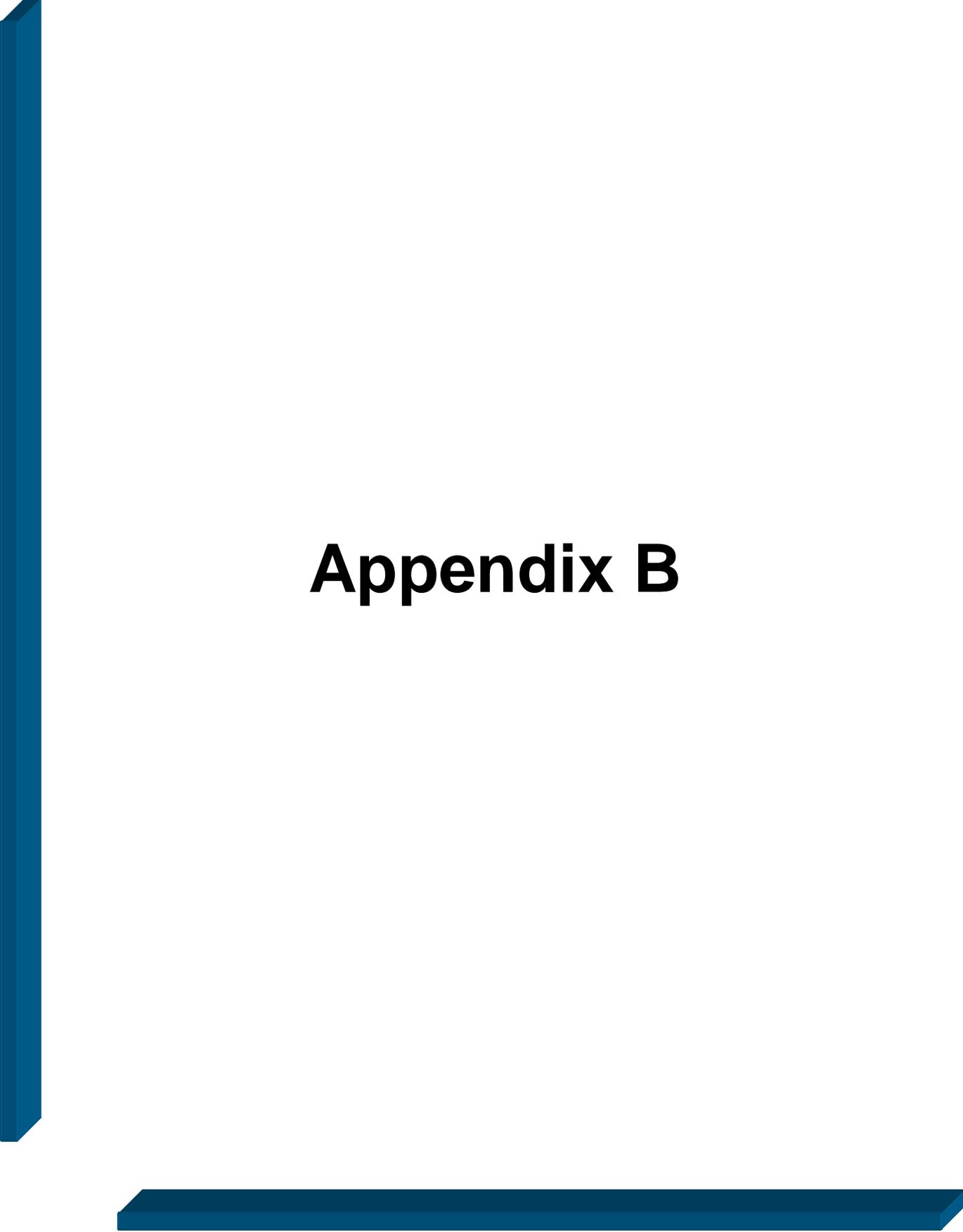
Recommendation 1: Vote to Prior Authorize Linzess™ and Update Amitiza® Criteria

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Linzess™ (linaclotide) with the following changes to the current criteria for Amitiza® (lubiprostone):

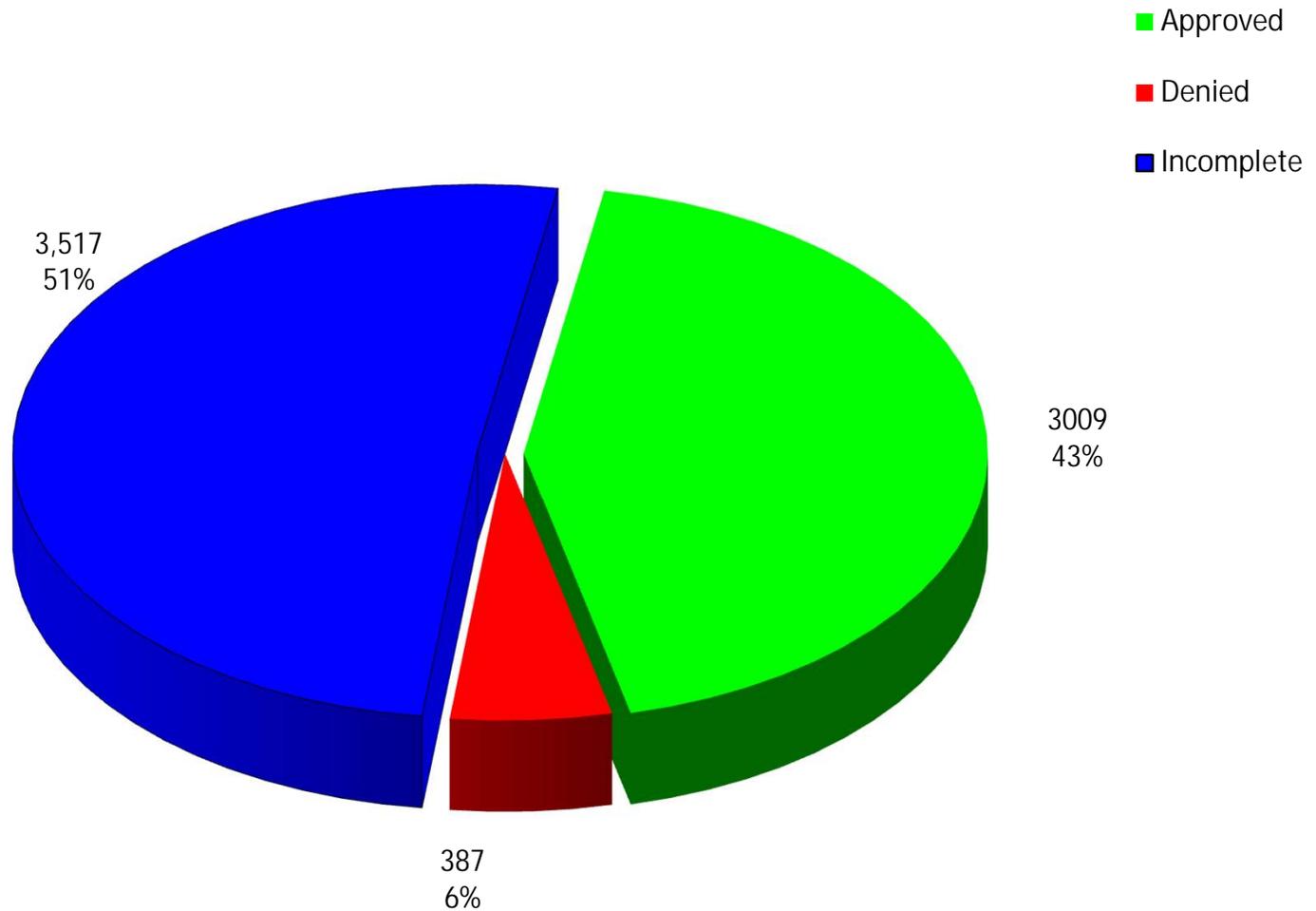
Amitiza® and Linzess™ Prior Authorization Criteria:

1. Members 18 years of age or older with an FDA approved diagnosis, and
 - a. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients).
 - b. Documented and updated Colon Screening for members >50 years of age.
2. Documented trials of at least three different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be OTC or prescription.
3. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment.
4. Quantity limits apply based on maximum recommended daily dose.



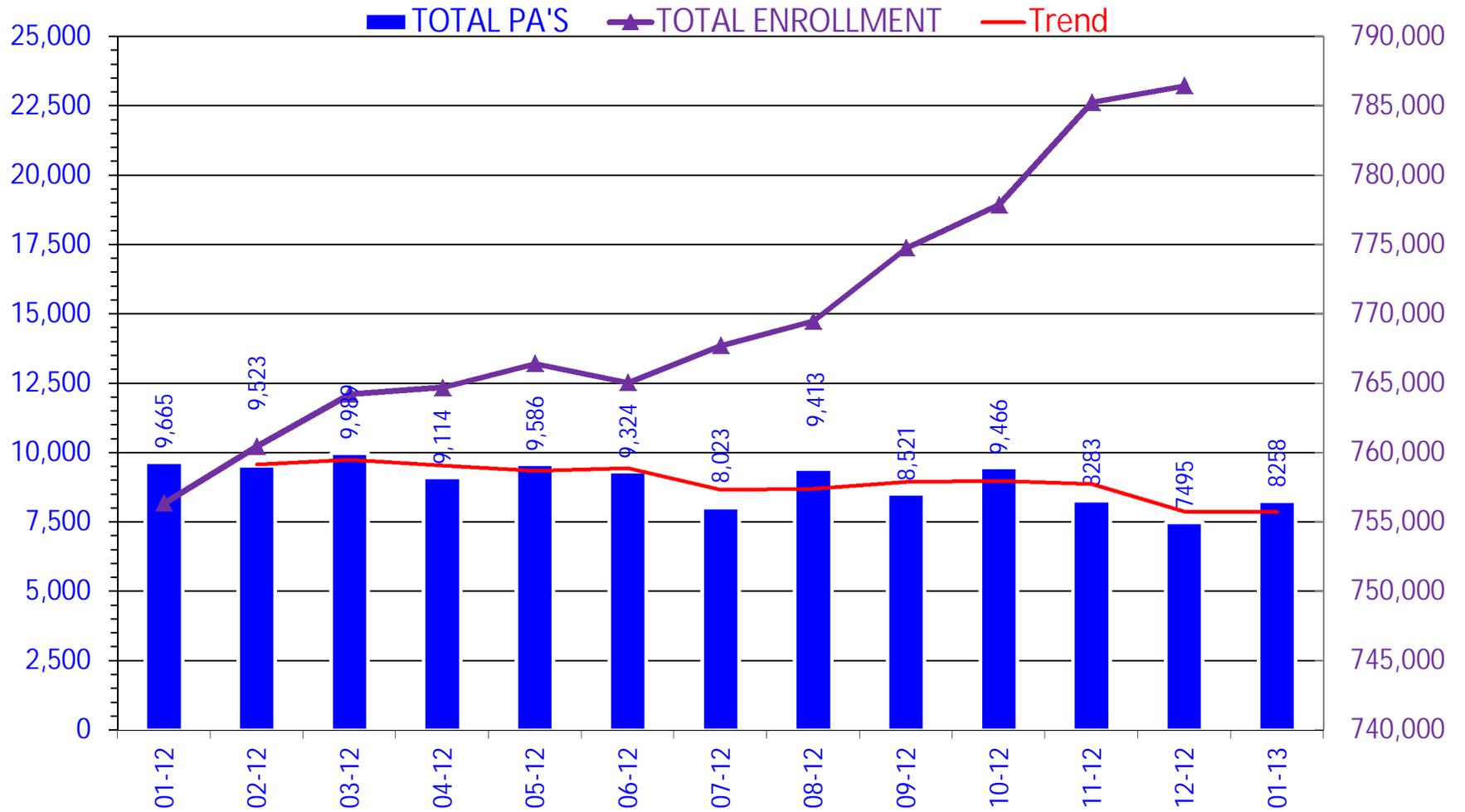
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: January 2013



PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: January 2012- January 2013



PA totals include approved/denied/incomplete/overrides

Prior Authorization Activity 1/1/2013 Through 1/31/2013

| | Total | Approved | Denied | Incomplete | Average Length of Approvals in Days |
|-----------------------------------|-------|----------|--------|------------|-------------------------------------|
| Advair/Symbicort/Dulera | 397 | 158 | 3 | 236 | 349 |
| Analgesic, Narcotic | 430 | 190 | 15 | 225 | 262 |
| Angiotensin Receptor Antagonist | 48 | 12 | 4 | 32 | 359 |
| Antiasthma | 1,101 | 572 | 11 | 518 | 247 |
| Antibiotic | 29 | 1 | 4 | 24 | 11 |
| Anticoagulant | 45 | 19 | 1 | 25 | 331 |
| Anticonvulsant | 79 | 28 | 0 | 51 | 324 |
| Antidepressant | 269 | 76 | 11 | 182 | 339 |
| Antidiabetic | 186 | 117 | 5 | 64 | 348 |
| Antifungal | 11 | 4 | 0 | 7 | 24 |
| Antihistamine | 165 | 125 | 5 | 35 | 350 |
| Antihyperlipidemic | 15 | 2 | 1 | 12 | 357 |
| Antimigraine | 71 | 24 | 7 | 40 | 293 |
| Antiplatelet | 18 | 14 | 0 | 4 | 345 |
| Antiulcers | 327 | 78 | 42 | 207 | 106 |
| Anxiolytic | 85 | 60 | 4 | 21 | 186 |
| Atypical Antipsychotics | 411 | 257 | 4 | 150 | 350 |
| Benign Prostatic Hypertrophy | 12 | 0 | 7 | 5 | 0 |
| Biologics | 41 | 18 | 3 | 20 | 344 |
| Bladder Control | 68 | 6 | 7 | 55 | 328 |
| Calcium Channel Blockers | 11 | 2 | 0 | 9 | 221 |
| Cardiovascular | 55 | 31 | 0 | 24 | 300 |
| Dermatological | 115 | 26 | 24 | 65 | 81 |
| Endocrine & Metabolic Drugs | 121 | 58 | 3 | 60 | 276 |
| Erythropoietin Stimulating Agents | 46 | 22 | 4 | 20 | 99 |
| Fibromyalgia | 164 | 38 | 13 | 113 | 345 |
| Gastrointestinal Agents | 77 | 30 | 8 | 39 | 165 |
| Glaucoma | 29 | 9 | 1 | 19 | 319 |
| Growth Hormones | 84 | 56 | 7 | 21 | 137 |
| HFA Rescue Inhalers | 84 | 18 | 3 | 63 | 331 |
| Insomnia | 62 | 9 | 6 | 47 | 146 |
| Multiple Sclerosis | 20 | 11 | 1 | 8 | 192 |
| Muscle Relaxant | 137 | 58 | 33 | 46 | 74 |
| Nasal Allergy | 117 | 7 | 29 | 81 | 163 |
| Neurological Agents | 44 | 33 | 2 | 9 | 350 |
| Nsaids | 137 | 20 | 6 | 111 | 306 |
| Ocular Allergy | 39 | 14 | 6 | 19 | 136 |
| Ophthalmic | 27 | 6 | 2 | 19 | 25 |
| Osteoporosis | 25 | 11 | 1 | 13 | 360 |
| Other* | 174 | 27 | 17 | 130 | 202 |
| Otic Antibiotic | 34 | 10 | 2 | 22 | 13 |
| Pediculicide | 126 | 44 | 4 | 78 | 19 |
| Prenatal Vitamins | 16 | 2 | 0 | 14 | 85 |
| Smoking Cess. | 52 | 18 | 2 | 32 | 39 |
| Statins | 65 | 27 | 3 | 35 | 357 |
| Stimulant | 568 | 334 | 7 | 227 | 319 |
| Suboxone/Subutex | 169 | 124 | 1 | 44 | 79 |
| Synagis | 150 | 106 | 13 | 31 | 72 |
| Topical Antibiotic | 15 | 2 | 0 | 13 | 9 |

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

| | Total | Approved | Denied | Incomplete | Average Length of Approvals in Days |
|--------------------------------------|--------------|--------------|------------|--------------|-------------------------------------|
| Topical Antifungal | 166 | 1 | 37 | 128 | 14 |
| Topical Corticosteroids | 30 | 1 | 1 | 28 | 14 |
| Vitamin | 46 | 22 | 17 | 7 | 359 |
| Pharmacotherapy | 95 | 66 | 0 | 29 | 130 |
| Emergency PAs | 5 | 5 | 0 | 0 | |
| Total | 6,913 | 3,009 | 387 | 3,517 | |
| Overrides | | | | | |
| Brand | 45 | 26 | 1 | 18 | 328 |
| Dosage Change | 366 | 330 | 3 | 33 | 8 |
| High Dose | 5 | 5 | 0 | 0 | 284 |
| Ingredient Duplication | 7 | 7 | 0 | 0 | 6 |
| Lost/Broken Rx | 88 | 80 | 6 | 2 | 4 |
| NDC vs Age | 6 | 6 | 0 | 0 | 326 |
| Nursing Home Issue | 105 | 100 | 0 | 5 | 3 |
| Other | 24 | 21 | 1 | 2 | 4 |
| Quantity vs. Days Supply | 639 | 446 | 24 | 169 | 264 |
| Stolen | 1 | 1 | 0 | 0 | 3 |
| Temporary Unlock | 2 | 2 | 0 | 0 | 4 |
| Third Brand Request | 56 | 28 | 8 | 20 | 40 |
| Wrong D.S. on Previous Rx | 3 | 3 | 0 | 0 | 10 |
| Overrides Total | 1,345 | 1,053 | 43 | 249 | |
| Total Regular PAs + Overrides | 8,258 | 4,062 | 430 | 3,766 | |

Denial Reasons

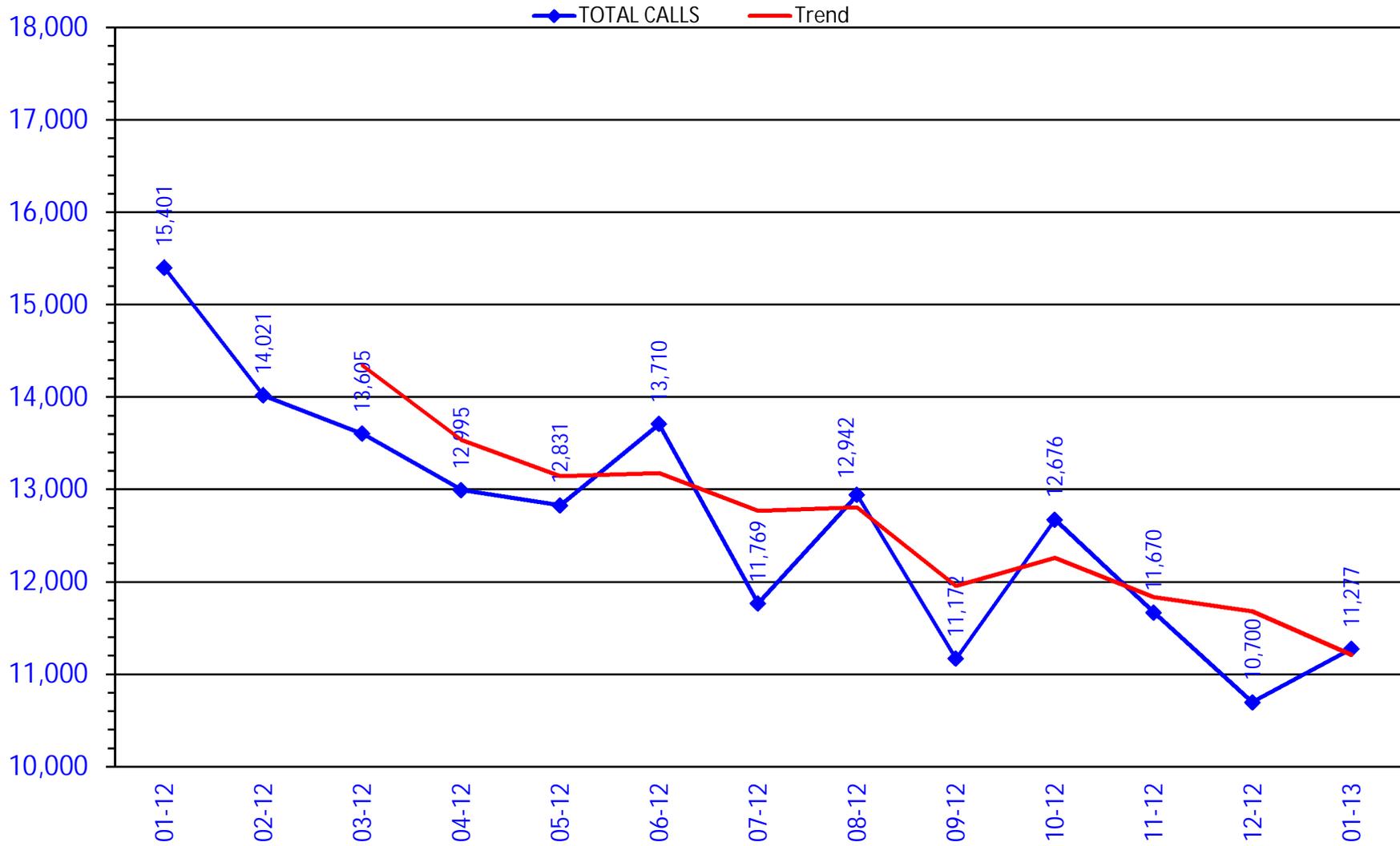
| | |
|---|-------|
| Unable to verify required trials. | 2,798 |
| Lack required information to process request. | 1,003 |
| Does not meet established criteria. | 446 |

Other PA Activity

| | |
|--------------------------|-------|
| Duplicate Requests: | 526 |
| Letters: | 2,694 |
| No Process: | 525 |
| Changes to existing PAs: | 535 |
| Partials: | 890 |

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

CALL VOLUME MONTHLY REPORT: January 2012- January 2013



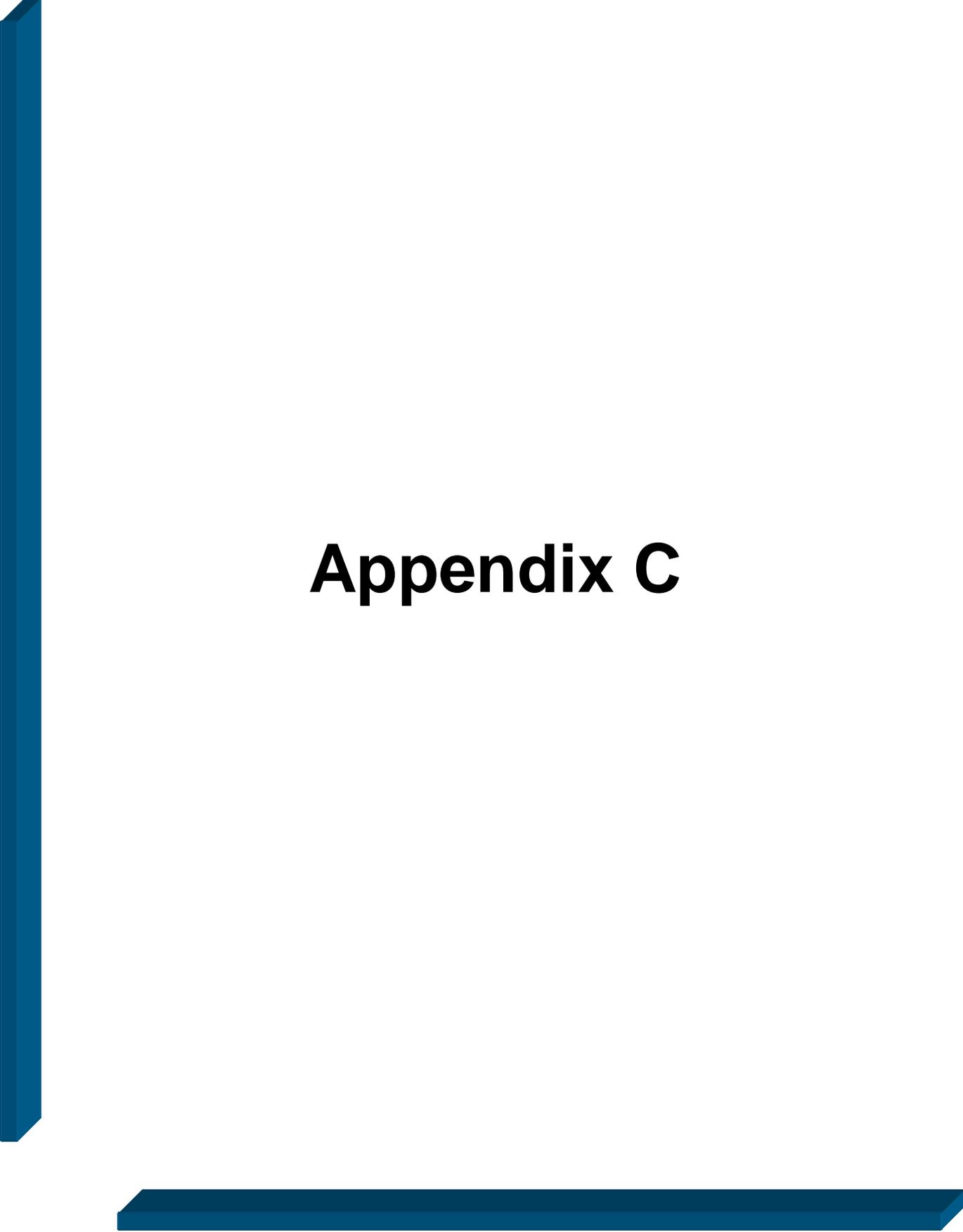
RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT

Duplication of Narcotic Therapy

September, October, and November 2012

| Parameters | Total Messages | Messages Reviewed | Members Reviewed | Members Intervened |
|--------------------------------|-----------------|--------------------|------------------|--------------------|
| Males and Females Age 32-48 | 32,624 | 2,436 | 2,338 | 283 |
| Letters | | | | |
| Prescribers: 506 | Pharmacies: 264 | Total Letters: 770 | | |

| Top 25 Narcotic Combination Messages Arranged by Total Messages Reviewed | | Messages Flagged | Messages Reviewed | Members Reviewed | Members Intervened |
|---|---|---------------------|----------------------|---------------------|-----------------------|
| 1 | Tramadol 50 MG and hydro/apap 7.5-750 MG | 7,930 | 553 | 538 | 76 |
| 2 | Oxyco/apap 7.5-500 MG and hydro/apap 7.5-500 MG | 5,724 | 222 | 214 | 41 |
| 3 | Morphine Sulfate ER 60 MG and hydro/apap 7.5-500 MG | 987 | 106 | 100 | 8 |
| 4 | Oxycodone 5 MG and hydro/apap 7.5-500 MG | 1,626 | 120 | 115 | 24 |
| 5 | Fentanyl Patch 75 MCG/HR and hydro/apap 7.5-500 MG | 748 | 87 | 82 | 3 |
| 6 | Hydro/apap 7.5-750 MG and hydro/apap 5-325 MG | 2,073 | 81 | 77 | 5 |
| 7 | Oxycodone ER 80 MG hydro/apap 7.5-750 MG | 575 | 61 | 54 | 4 |
| 8 | Oxycodone 5 MG and Oxycodone ER 80 | 561 | 72 | 69 | 0 |
| 9 | Morphine Sulfate 30 MG and Morphine ER 60 MG | 538 | 70 | 68 | 1 |
| 10 | Tramadol 50 MG and Oxycodone/apap 7.5-500 | 920 | 65 | 64 | 16 |
| 11 | Morphine Sulfate ER 60 MG and Oxyco/apap 7.5-500 | 402 | 56 | 53 | 2 |
| 12 | Morphine Sulfate ER 60 MG and Oxycodone 5 MG | 360 | 54 | 51 | 0 |
| 13 | Apap/codeine 300-60 hydro/apap 7.5-500 MG | 1,014 | 40 | 37 | 14 |
| 14 | Fentanyl Patch 75 MCG/HR and Oxyco/apap 7.5-500 MG | 338 | 47 | 41 | 0 |
| 15 | Fentanyl Patch 75 MCG/HR and Oxycodone 5 MG | 341 | 51 | 44 | 1 |
| 16 | Oxycodone ER 80 MG and Oxycodone/apap 7.5-325 | 314 | 41 | 37 | 0 |
| 17 | Methadone 5 MG and hydrocodone/apap 7.5-500 MG | 458 | 25 | 25 | 3 |
| 18 | Tramadol 50 MG and apap/codeine 300-60 MG | 426 | 22 | 22 | 1 |
| 19 | Oxycodone 5 MG and Oxycodone/apap 7.5-325 MG | 426 | 29 | 29 | 6 |
| 20 | Methadone 5 MG and Oxycodone 5 MG | 368 | 31 | 31 | 1 |
| 21 | Oxyco/apap 7.5-500 MG and Oxyco/apap 10-650 MG | 522 | 25 | 25 | 6 |
| 22 | Morphine Sulfate 30 MG and hydro/apap 7.5-500 MG | 320 | 20 | 19 | 4 |
| 23 | Hydromorphone 8 MG and hydro/apap 7.5-750 MG | 302 | 27 | 27 | 3 |
| 24 | Oxycodone 5 MG and Tramadol HCl 50 MG | 294 | 20 | 20 | 6 |
| 25 | Fentanyl Patch 75 MCG/HR and Fentanyl 100 MCG/HR | 298 | 17 | 17 | 0 |



Appendix C

Vote to Update Antihyperlipidemics Prior Authorization Criteria and Prior Authorize Vascepa™ (icosapent ethyl) and Juxtapid™ (lomitapide),

Oklahoma Health Care Authority
February 2013

Recommendations:

The College of Pharmacy recommends the following changes:

1. Prior Authorization of Vascepa™ (icosapent ethyl) with the following criteria:
 1. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides ≥ 500 mg/dL), and controlled diabetes (fasting glucose < 150 mg/dL at the time of triglycerides measurement and HgA_{1C} $< 7.5\%$), and
 2. Previous failure with both nicotinic acid and fibric acid medications.
 These criteria will also apply for Lovaza® (omega-3-fatty-acid).

2. Prior Authorization of Juxtapid™ (lomitapide) with the following criteria:
 1. FDA approved diagnosis of homozygous familial hypercholesterolemia confirmed via genetic testing, and
 2. Documented failure of high dose statin therapy (LDL reduction capability equivalent to atorvastatin 40mg or higher), and
 3. Prescriber must be certified with Juxtapid™ REMS program.

3. Changes to the Antihyperlipidemics Product Based Prior Authorization criteria and tiers as follows:

| Tier 1 | Tier 2 | Special PA |
|--------------------------|-------------------------|--|
| atorvastatin (Lipitor®) | rosuvastatin (Crestor®) | lovastatin (Altoprev®) |
| simvastatin (Zocor®) | | simvastatin/ezetimibe (Vytorin®) |
| lovastatin (Mevacor®) | | ezetimibe (Zetia®) |
| pravastatin (Pravachol®) | | simvastatin/niacin (Simcor®) |
| | | lovastatin/niacin (Advicor®) |
| | | pitavastatin (Livalo®) |
| | | fluvastatin (Lescol®, Lescol® XL) |

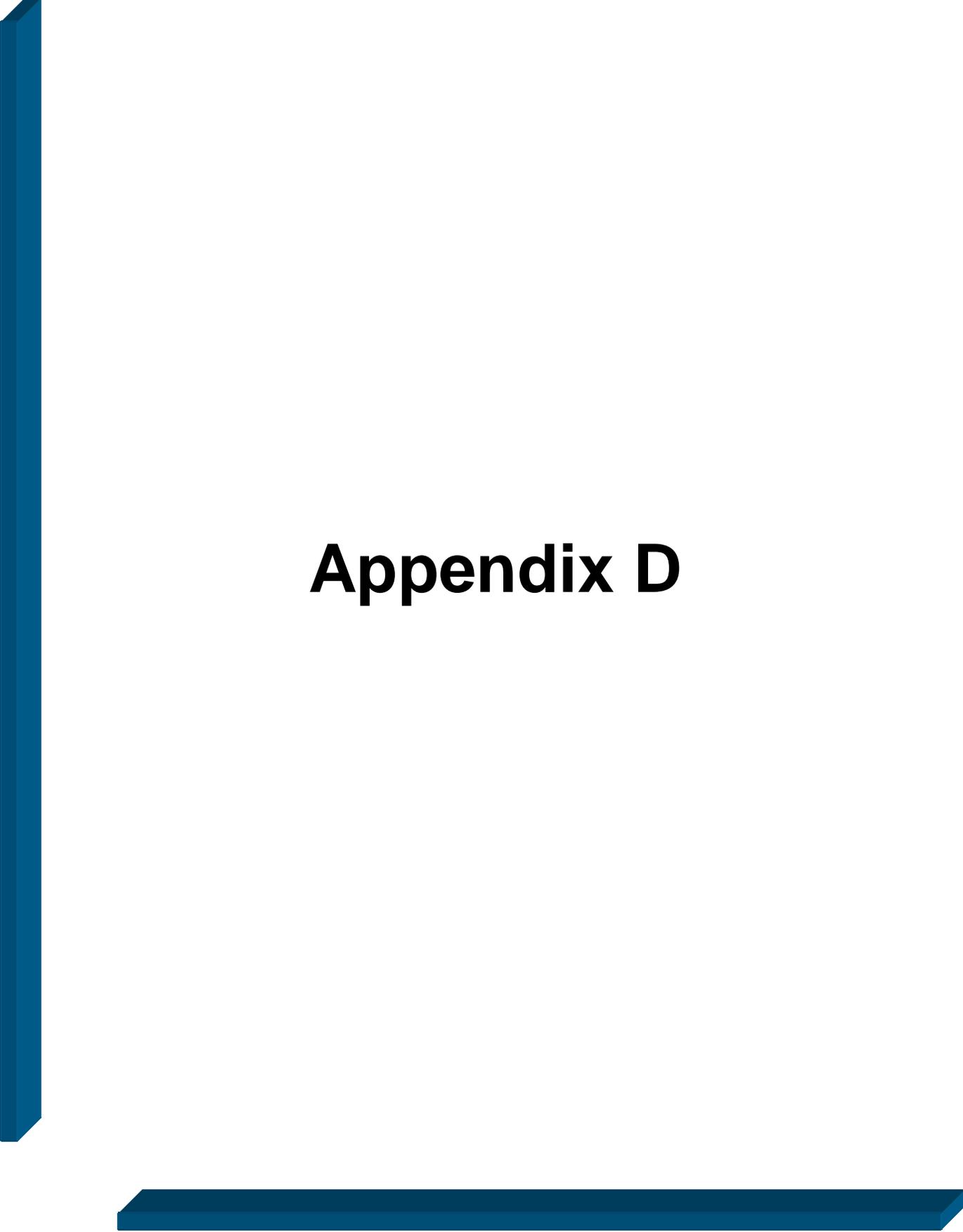
Tier 2 approval criteria:

1. A trial with atorvastatin, consisting of at least 8 weeks of continuous therapy, titrated to 40 mg, which did not yield adequate LDL reduction. The minimum starting dose of the Tier 2 medication may only be at the moderate to high LDL lowering doses (20 mg rosuvastatin or higher), or
2. Documented adverse effect or contraindication to all available lower tiered products, or

3. Clinical exception for high risk members hospitalized for recent acute myocardial infarction or acute coronary syndrome for rosuvastatin 40 mg.

To qualify for a Special PA medication, there must be:

1. A clinically significant reason why lower tiered medications with similar or higher LDL reduction cannot be used.
 - i. Simcor® (simvastatin/niacin) and Advicor® (lovastatin/niacin) will also require a clinically significant reason why the member cannot use the individual products separately.
2. Clinical exceptions for Ezetimibe:
 - i. Documented active liver disease, or
 - ii. Documented unexplained, persistent elevations of serum transaminases,
or
 - iii. Documented statin related myopathy.



Appendix D

Vote to Prior Authorize Binosto™ (Alendronate) and Update Osteoporosis Criteria

Oklahoma Health Care Authority
February 2013

Recommendations

The College of Pharmacy recommends the following :

- Establishment of a Tier for medications with special criteria.
- Placement of Binosto™ into the Special Criteria Tier.
- Placement of Boniva® IV and Actonel® 30mg tablets into the Special Criteria Tier.
- Changes to the Osteoporosis PBPA Category criteria:

| Tier 1* | Tier 2 | Special Criteria Apply |
|--|---|---|
| Alendronate (Fosamax®) Calcium + Vitamin D† | Alendronate + D (Fosamax®+D) Ibandronate (Boniva®) Risedronate (Actonel®) | Teriparatide (Forteo®) Denosumab (Prolia™) Zoledronic Acid (Reclast®) Ibandronate (Boniva® IV) Risedronate ER (Atelvia™) Alendronate (Binosto™) Risedronate 30mg Tabs (Actonel®) |

Mandatory Generic Plan Applies.

*Calcitonin and raloxifene are not included as Tier 1 trials.

†Must be used at recommended doses in conjunction with Tier 1 bisphosphonate for trial to be accepted unless member has a recent laboratory result showing adequate Vitamin D or member is unable to tolerate calcium. OTC Calcium and Vitamin D are only covered for members with osteoporosis.

Tier 2 Approval Criteria:

1. A trial of at least one Tier 1 medication, compliantly used for at least 6 months concomitantly with calcium + vitamin D, that failed to prevent fracture, or improve BMD scores, or
2. Hypersensitivity to or intolerable adverse effects with all Tier 1 products.

Special Prior Authorization Criteria

1. **Teriparatide (Forteo®)** requires
 - a. A Bone Mineral Density test (T-score at or below -2.5) within the last month, and
 - b. A minimum 12 month trial with a bisphosphonate plus adequate calcium and vitamin D, or
 - c. A 12 month trial of Prolia™ (Denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results.
 - d. The diagnosis of non-healing fracture may be approved for six months.
 - e. Approval will be for a maximum of 2 years of therapy.

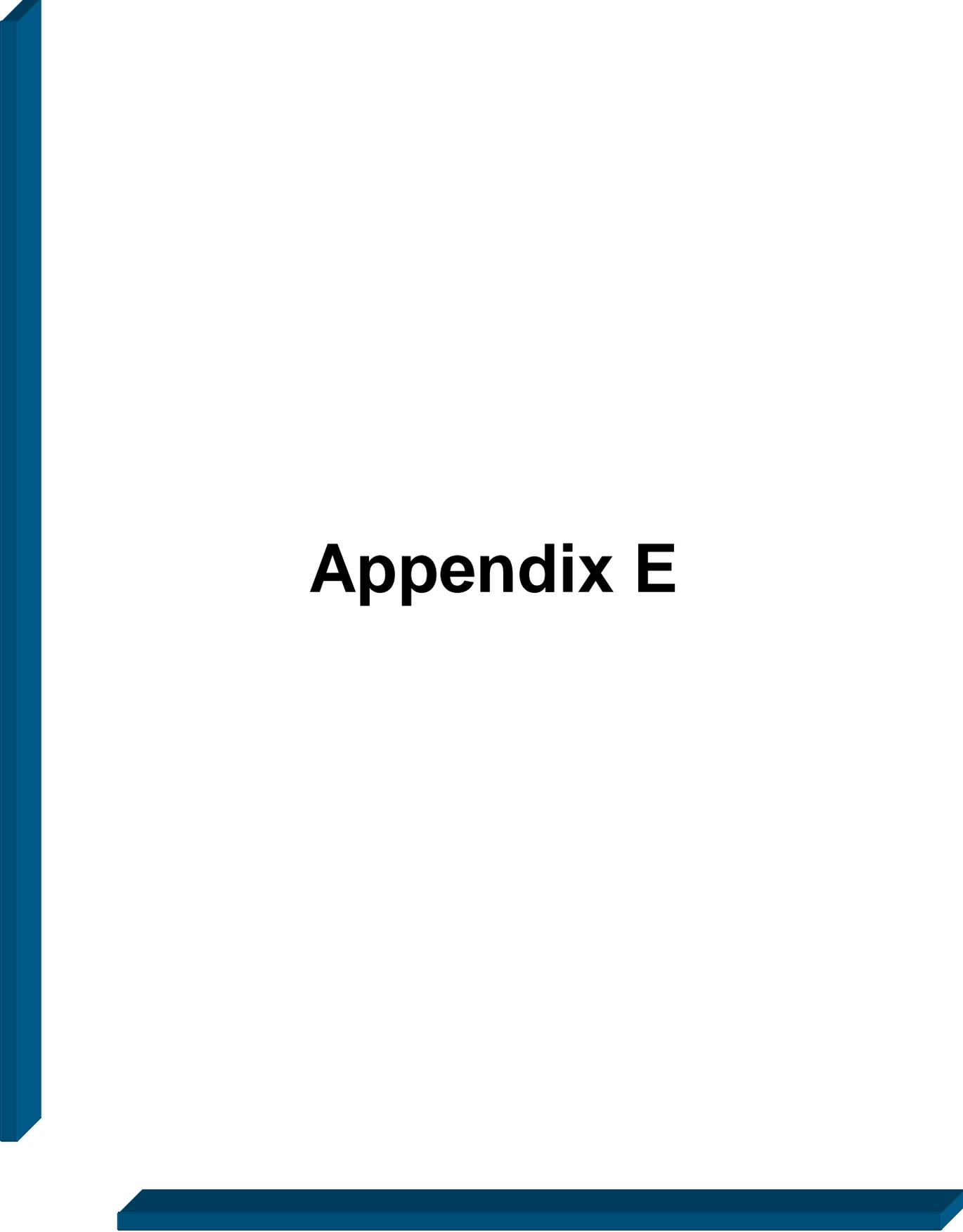
2. Prolia™, Reclast®, Boniva® IV requires:

- a. A minimum 12 month trial with a Tier 1 or Tier 2 bisphosphonate plus adequate calcium and vitamin D, or
- b. Contraindication to or intolerable adverse effects with Tier 1 and Tier 2 products.
- c. Clinical exceptions may apply for members with
 - i. Severe esophageal disease (e.g., ulcerations, strictures)
 - ii. Inability to take anything by mouth
 - iii. Inability to sit or stand for prolonged periods
 - iv. Inability to take bisphosphonates orally for other special medical circumstances that justify the method of administration

3. Atelvia™, Binosto™, and Actonel® 30mg Tabs

- a. Patient specific, clinically significant reason why member cannot use all other available Tier 1 and Tier 2 products.
- b. Members with diagnosis in history of Paget's disease will not require prior authorization.

Quantity Limits apply for all products based on FDA recommended maximum doses. No concomitant therapies will be approved.



Appendix E

Vote to Prior Authorize Xeljanz® (Tofacitinib)

Oklahoma Health Care Authority
February 2013

Recommendations:

The College of Pharmacy recommends placement of Xeljanz® (tofacitinib) into Tier 3 of the Biologic Products for the Treatment of Rheumatoid Arthritis, Crohn's Disease, Plaque Psoriasis, and Ankylosing Spondylitis Prior Authorization Category. The existing criteria for this category will apply. In addition, the College also recommends the following safety criteria be met before approval:

1. Negative tuberculosis test, successful treatment of active tuberculosis, or close evaluation and appropriate treatment of latent tuberculosis.
2. Severe hepatic impairment has been ruled out.
3. Approval will be for 12 weeks, after which time, prescriber must confirm performance of the following tests for further approval:
 - a. Lymphocytes
 - b. Neutrophils
 - c. Hemoglobin
 - d. Liver enzymes
 - e. Lipid panel
 - f. Updated tuberculosis test
4. Subsequent approvals will be for the duration of one year.

| Tier 1 | Tier 2 | Tier 3 |
|---------------------------------------|------------------------------|-------------------------------|
| DMARDs appropriate to disease: | Adalimumab (Humira®) | Abatacept (Orencia®) |
| Methotrexate | Certolizumab pegol (Cimzia®) | Alefacept (Amevive®) |
| Hydroxychloroquine | Etanercept (Enbrel®) | Anakinra (Kineret®) |
| Sulfasalazine | Golimumab (Simponi®) | Infliximab (Remicade®) |
| Minocycline | Ustekinumab (Stelara®) | Rituximab (Rituxan®) |
| Leflunomide | | Tocilizumab (Actemra®) |
| Mesalamine | | Tofacitinib (Xeljanz®) |
| 6-Mercaptopurine | | |
| Azathioprine | | |

Tier 2 authorization criteria:

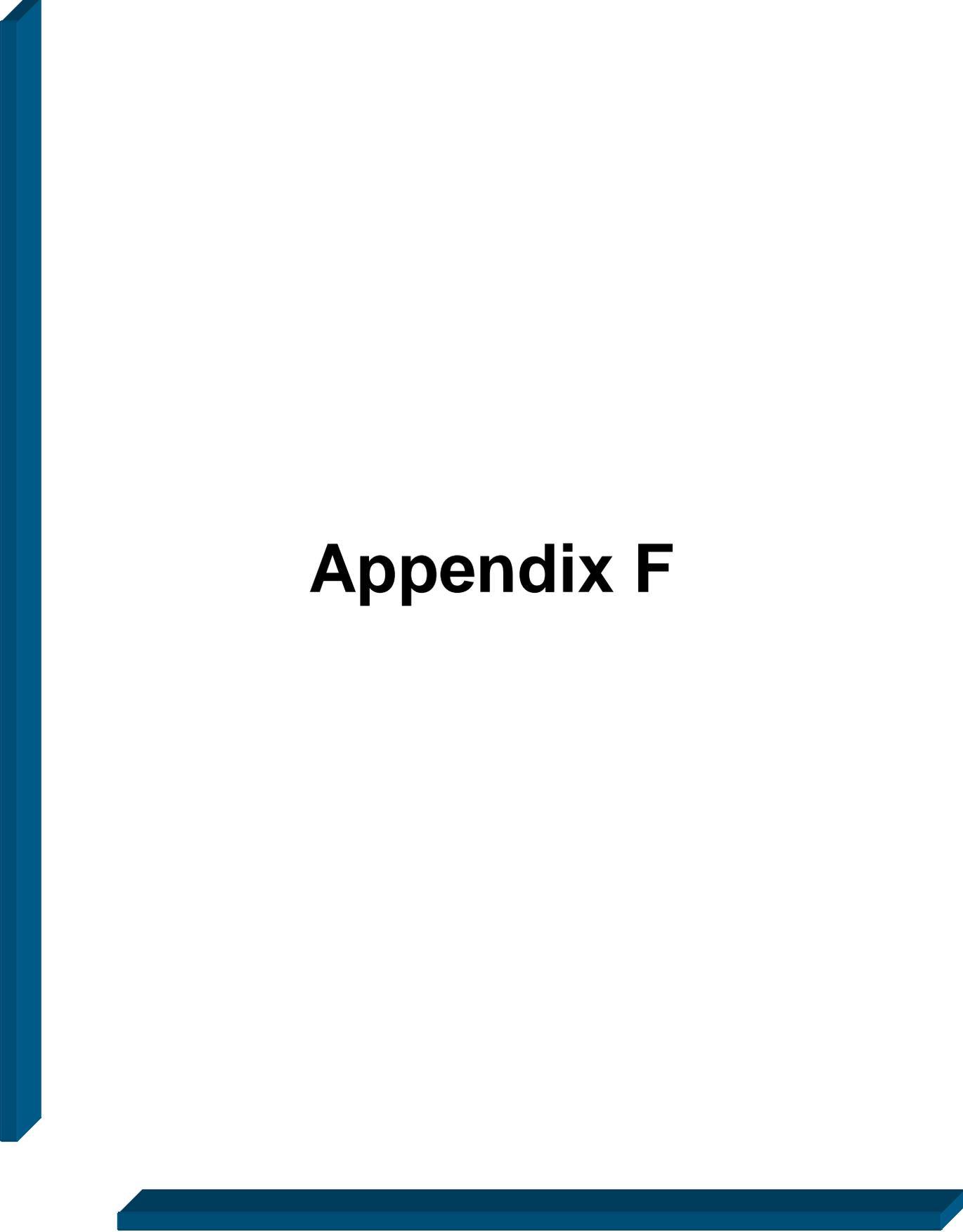
1. Medication-specific FDA approved diagnosis.
2. A trial of at least one Tier 1 product in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects.
3. Prior stabilization on the Tier 2 medication documented within the last 100 days.

Tier 3 authorization criteria:

1. Medication-specific FDA approved diagnosis.
2. Recent trials of one Tier 1 product and all available diagnosis-specific Tier 2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects.
3. Prior stabilization on the Tier 3 medication documented within the last 100 days.
4. A unique FDA-approved indication not covered by Tier 2 products.

Table 1: Additional Medication Information

| Drug name | Mechanism | Dose Form | FDA-approved indications | | | | |
|-------------------------------------|--|-----------|--------------------------|-----------------|------------------|------------------------|--|
| | | | Rheumatoid arthritis | Crohn's disease | Plaque psoriasis | Ankylosing spondylitis | Other Indications |
| Adelimumab (Humira®) | TNF (tumor necrosis factor) blocking | SC | X | X | X | X | Psoriatic arthritis, Juvenile Idiopathic Arthritis |
| Infliximab (Remicade®) | TNF blocking | IV | X | X | X | X | Psoriatic arthritis, Ulcerative colitis |
| Etanercept (Enbrel®) | TNF blocking | SC | X | | X | X | Psoriatic arthritis, Juvenile Idiopathic Arthritis |
| Certolizumab pegol (Cimzia®) | TNF blocking | SC | X | X | | | |
| Golimumab (Simponi®) | TNF blocking | SC | X | | | X | Psoriatic arthritis |
| Rituximab (Rituxan®) | Anti-B-cell | IV | X | | | | Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Wegener's Granulomatosis, Microscopic Polyangiitis |
| Anakinra (Kineret®) | IL-1 (Interleukin-1) receptor antagonist | SC | X | | | | |
| Abatacept (Orencia®) | Selective T-Cell Costimulation Modulator | IV | X | | | | Juvenile Idiopathic Arthritis |
| Tocilizumab (Actemra®) | IL-6 receptor antagonist | IV | X | | | | Juvenile Idiopathic Arthritis |
| Natalizumab (Tysabri®) | Selective adhesion molecule inhibitor | IV | | X | | | Multiple sclerosis |
| Alefacept (Amevive®) | CD2 receptor antagonist | IV | | | X | | |
| Ustekinumab (Stelara®) | IL-12,23 receptor antagonist | SC | | | X | | |
| Tofacitinib (Xeljanz®) | Janus kinase inhibitor | Oral | X | | | | |



Appendix F

Fiscal Year 2012 Annual Review of Narcotic Analgesics

Oklahoma Health Care Authority
February 2013

Background and Statistics Update

The narcotic analgesics product based prior authorization category was first implemented July 2008. The initial review was presented amidst concerns of increasing rates of prescription drug abuse juxtaposed with the need to provide adequate pain relief for SoonerCare members.

Narcotic prescription drug abuse has been on the rise over the past two decades, surpassing all other forms of illicit drugs of abuse except marijuana. National data collected from the National Survey on Drug Use and Health (NSDUH), sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA), indicate that during 2009-2010, approximately 4.6% of persons in the U.S. 12 years of age and older reported having used pain relievers for non-medical purposes in the past year. According to this survey, Oklahoma ranked the highest in the nation, with overall rates exceeding 7%, and rates as high as 15% in the 18-25 age group.

After the initiation of the narcotics analgesic product based prior authorization program, subsequent initiatives to reduce narcotic prescription drug abuse were gradually put into place over the years. In addition to the Pharmacy Lock-in program, the following table shows clinical edits currently in effect for this category:

| Date | Clinical Edits |
|--------------|---|
| July 2008 | Step therapy (3 Tiers and Oncology-Only tier) |
| August 2009 | Hydrocodone ingredient duplication ProDUR edit |
| October 2009 | Quantity limits applied to all narcotic/acetaminophen combination products* |
| August 2010 | Hydrocodone 13 script limit per 360 day period (counted from January 2010) |
| May 2011 | Suboxone (buprenorphine) prior authorization |

*Based on 3,250mg of acetaminophen per day.

The NSDUH recently released updated statistics shown in Table 1. Oklahoma now ranks 12th in the nation in percentage of persons 12 years and older who've used prescription drugs for non-medical purposes in the past year. National and state initiatives such as the Prescription Monitoring Program, as well as the steps taken by SoonerCare, have had a significantly positive impact in reducing prescription drug abuse in the state. The downward trend seen in prescription drug abuse in the state of Oklahoma over the recent years demonstrates our progress thus far, and serves as encouragement for continued efforts in this area of prescription drug management.

Table 1: Nonmedical Use of Prescription Pain Relievers in the Past Year among Persons Aged 12 or Older, by Age Group and State: 2009-2010 and 2010-2011¹

| 2009-2010 | 12 or Older | 12 - 17 | 18 - 25 | 26 or Older | 2010-2011 | 12 or Older | 12-17 | 18-25 | 26 or Older |
|--------------------------|-------------|-------------|--------------|-------------|--------------------------|-------------|-------------|--------------|-------------|
| 1 Oklahoma | 7.01 | 7.94 | 15.65 | 5.3 | 1 Oregon | 6.37 | 7.36 | 15 | 4.86 |
| 2 Oregon | 6.68 | 7.86 | 14.71 | 5.26 | 2 Colorado | 6 | 7.4 | 14.01 | 4.44 |
| 3 Arizona | 6.31 | 7.58 | 12.68 | 5.07 | 3 Washington | 5.75 | 7.44 | 13.4 | 4.28 |
| 4 Colorado | 6.23 | 7.23 | 13.51 | 4.86 | 4 Idaho | 5.73 | 7.15 | 11.98 | 4.37 |
| 5 Washington | 6.2 | 7.48 | 14.44 | 4.7 | 5 Indiana | 5.68 | 6.97 | 14.41 | 3.97 |
| 6 Idaho | 6.09 | 7.52 | 13.2 | 4.59 | 6 Arizona | 5.66 | 8.04 | 11.49 | 4.36 |
| 7 Nevada | 5.96 | 7.74 | 13.22 | 4.62 | 7 Nevada | 5.62 | 7.79 | 11.94 | 4.34 |
| 8 Rhode Island | 5.93 | 6.29 | 14.64 | 4.24 | 8 Delaware | 5.61 | 5.95 | 14.26 | 4.13 |
| 9 New Mexico | 5.78 | 8.29 | 11.17 | 4.47 | 9 Arkansas | 5.55 | 7.81 | 12.89 | 4.02 |
| 10 Indiana | 5.73 | 7.57 | 14.75 | 3.93 | 10 New Mexico | 5.45 | 8.6 | 11.22 | 4.02 |
| 11 Louisiana | 5.67 | 6.39 | 13.93 | 4 | 11 Alaska | 5.32 | 6.89 | 10.69 | 4.06 |
| 12 West Virginia | 5.61 | 7.25 | 14.39 | 4.11 | 12 Oklahoma | 5.19 | 7.04 | 11.11 | 3.86 |
| 13 Delaware | 5.56 | 6.19 | 13.7 | 4.14 | 13 Rhode Island | 5.18 | 5.33 | 12.3 | 3.8 |
| 14 Michigan | 5.53 | 6.4 | 13.41 | 4.06 | 14 Vermont | 5.13 | 6.47 | 13 | 3.59 |
| 15 Arkansas | 5.51 | 7.48 | 12.39 | 4.13 | 15 Michigan | 5.11 | 6.35 | 11.74 | 3.81 |
| 16 Ohio | 5.48 | 7.62 | 13.59 | 3.89 | 16 Tennessee | 5 | 6.94 | 13.07 | 3.46 |
| 17 Alaska | 5.41 | 6.71 | 11.36 | 4.05 | 17 Ohio | 5 | 7.12 | 11.84 | 3.61 |
| 18 N. Hampshire | 5.38 | 6.2 | 14.9 | 3.78 | 18 Louisiana | 4.87 | 6.46 | 11.6 | 3.4 |
| 19 Kentucky | 5.36 | 7.54 | 13.67 | 3.78 | 19 Montana | 4.84 | 7.62 | 10.68 | 3.51 |
| 20 Virginia | 5.13 | 6.97 | 12.48 | 3.62 | 20 Missouri | 4.83 | 6.77 | 11.74 | 3.41 |
| 21 Missouri | 5.13 | 6.77 | 13.22 | 3.57 | 21 West Virginia | 4.79 | 7.21 | 12.35 | 3.38 |
| 22 Mississippi | 5.1 | 8.52 | 11.06 | 3.51 | 22 Wyoming | 4.68 | 6.6 | 9.89 | 3.51 |
| 23 Massachusetts | 5.07 | 5.61 | 13.12 | 3.58 | 23 California | 4.68 | 6.06 | 9.35 | 3.62 |
| 24 Montana | 5.07 | 7.09 | 12.31 | 3.58 | 24 D. of Columbia | 4.68 | 4.23 | 8.35 | 3.88 |
| 25 South Carolina | 5.06 | 6.06 | 12.3 | 3.74 | 25 South Carolina | 4.62 | 5.94 | 10.67 | 3.44 |
| United States | 4.89 | 6.43 | 11.54 | 3.53 | United States | 4.57 | 6.09 | 10.43 | 3.37 |

Current Prior Authorization Criteria and Tier Structure

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process, although quantity and dosage limits still apply. All immediate release oral fentanyl products are approved only for oncology-related diagnoses.
- Only one long-acting and one short-acting agent can be used concurrently.

Tier 2 authorization requires:

1. Documented 30 day trial/titration period with at least two Tier 1 medications within the last 90 days, or
2. Clinically appropriate pain therapy requiring time-released medication.

Tier 3 authorization requires:

1. Documented 30 day trial with at least two Tier 2 medications within the last 90 days, or
2. Documented allergy or contraindication to all Tier 2 medications.

| Tier 1 | Tier 2 | Tier 3 | Oncology Only |
|---|--|---|---|
| All immediate release narcotics not listed in a higher tier | Long Acting | | |
| | morphine ER fentanyl patches (Duragesic®) | morphine sulfate ER (Avinza®) 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®) oxymorphone (Opana® IR) | hydrocodone/APAP (Xodol®, Zamiset®, Hycet®, Zolvit®, Liquicet®) hydrocodone/APAP/caffeine (Trezix™) oxycodone/APAP (Primlev™, Xolox®) tramadol ODT (Rybix®) oxycodone (Oxecta®) | fentanyl lozenges (Actiq®) fentanyl buc tabs(Fentora®) fentanyl buc film (Onsolis®) fentanyl SL tabs (Abstral®) fentanyl SL spray (Subsys™) fentanyl nasal spray (Lazanda®) |

Mandatory generic plan applies

Quantity limits apply based on recommended daily dosing. All acetaminophen combinations products have quantity limits based on a maximum of 3,250mg of acetaminophen per day.

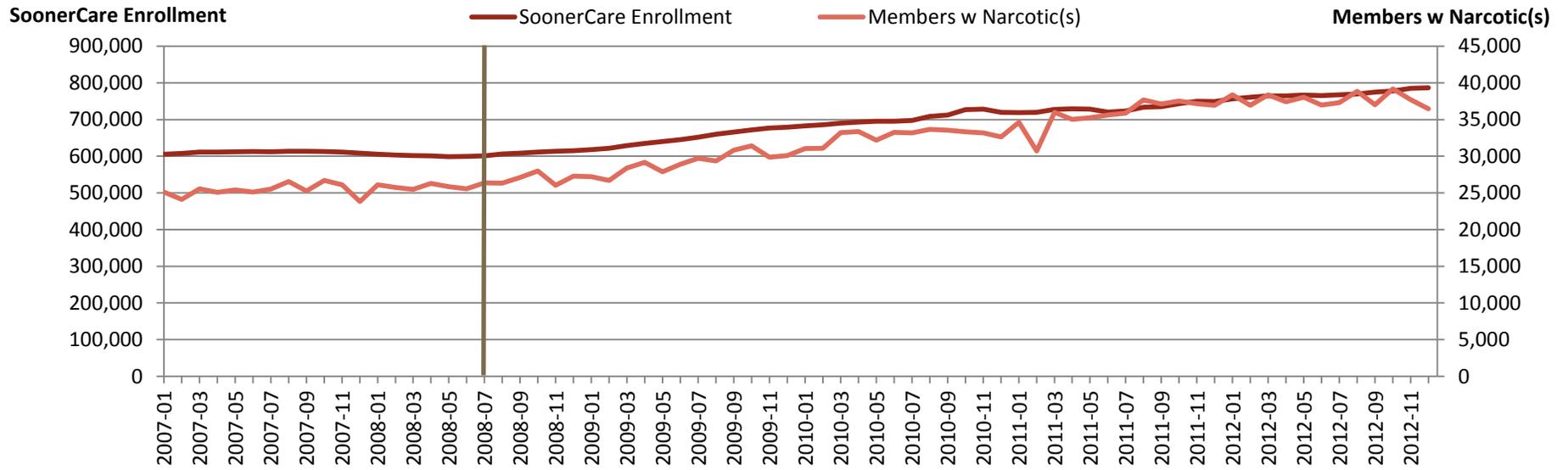
Utilization of Narcotic Analgesics

| Fiscal Year | Total Members | Total Claims | Total Cost | Cost/Claim | Cost/Day | Total Units | Total Days |
|-----------------|---------------|---------------|-----------------------|---------------|---------------|------------------|------------------|
| 2011 | 153,112 | 545,869 | \$16,992,835.77 | \$31.13 | \$2.05 | 36,719,828 | 8,279,028 |
| 2012 | 160,198 | 600,341 | \$18,948,444.51 | \$31.56 | \$1.97 | 40,985,461 | 9,598,932 |
| % Change | 4.60% | 10.00% | 11.50% | 1.40% | -3.90% | 11.60% | 15.90% |
| Change | 7,086 | 54,472 | \$1,955,608.74 | \$0.43 | -0.08 | 4,265,633 | 1,319,904 |

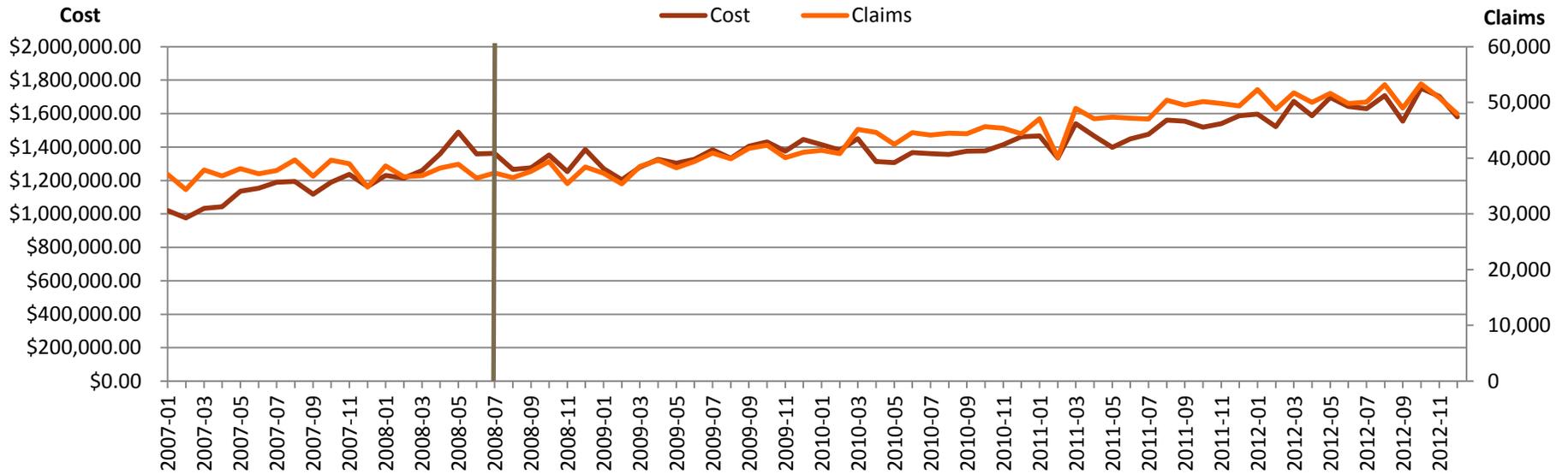
Six Year Trend in Utilization of Narcotic Analgesics

| Fiscal Year | Total Members | Total Claims | Total Cost | Cost / Claim | Cost/Day | Total Units | Total Days |
|-------------|---------------|--------------|-----------------|--------------|----------|-------------|------------|
| 2007 | 122,956 | 435,839 | \$12,084,572.55 | \$27.73 | \$2.13 | 27,061,297 | 5,673,589 |
| 2008 | 125,322 | 453,452 | \$15,005,652.21 | \$33.09 | \$2.41 | 28,497,389 | 6,228,888 |
| 2009 | 129,904 | 453,349 | \$15,603,745.37 | \$34.42 | \$2.47 | 29,171,979 | 6,306,745 |
| 2010 | 144,912 | 505,080 | \$16,603,239.13 | \$32.87 | \$2.25 | 32,978,283 | 7,369,357 |
| 2011 | 153,373 | 546,454 | \$17,002,232.58 | \$31.11 | \$2.05 | 36,772,088 | 8,282,692 |
| 2012 | 160,198 | 600,341 | \$18,948,444.51 | \$31.56 | \$1.97 | 40,985,461 | 9,598,932 |

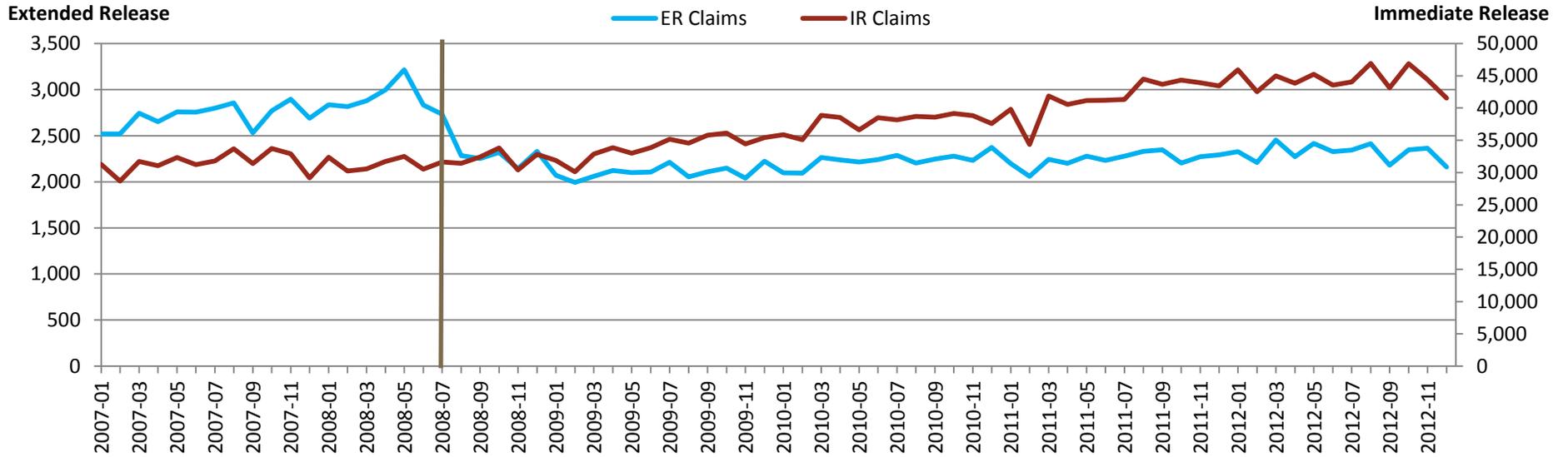
Trends of Members with Narcotic Claims vs. Total SoonerCare Enrollment



Trends of Cost vs. Claims

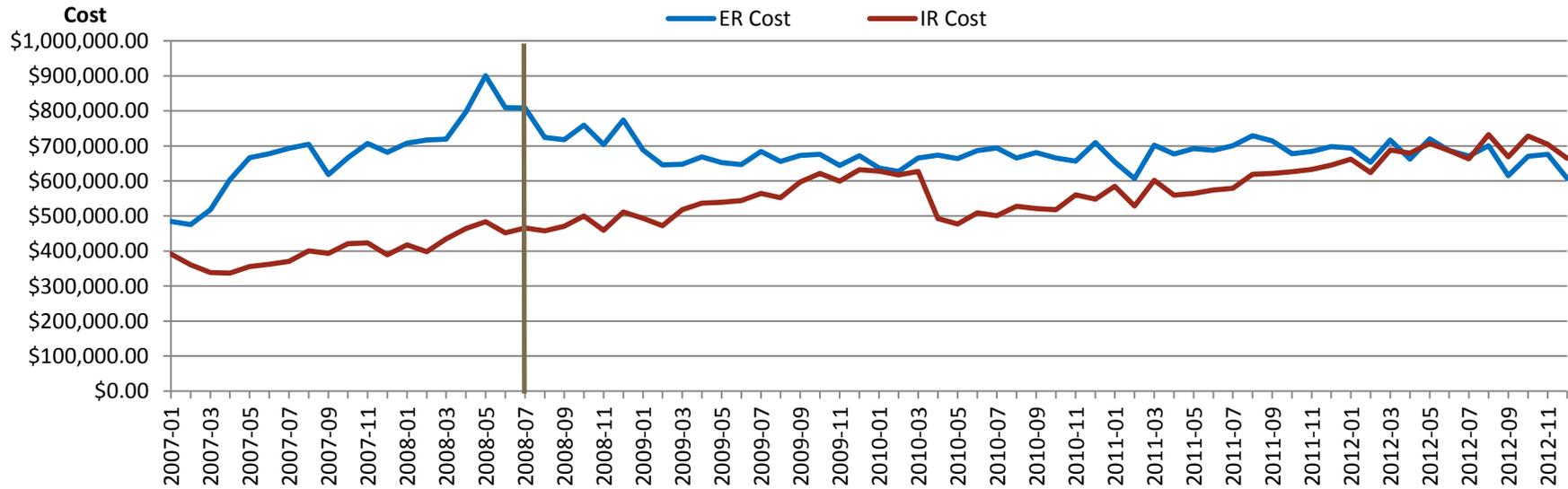


Trends in Utilization of Extended Release vs. Immediate Release Narcotic Analgesics by Total Claims*



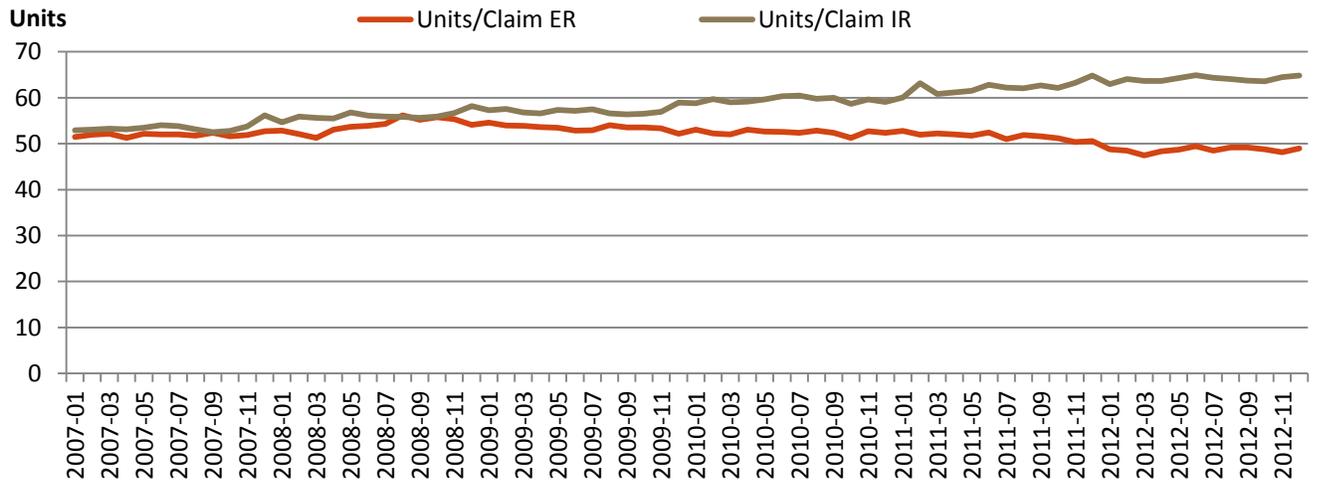
*Does not include liquid dosage forms and oncology-only medications

Trends in Cost of Extended Release vs. Immediate Release Narcotic Analgesics*



*Does not include liquid dosage forms and oncology-only medications

Trends in Units/Claim of Extended Release vs. Immediate Release Analgesics



*Does not include liquid dosage forms and oncology-only medications

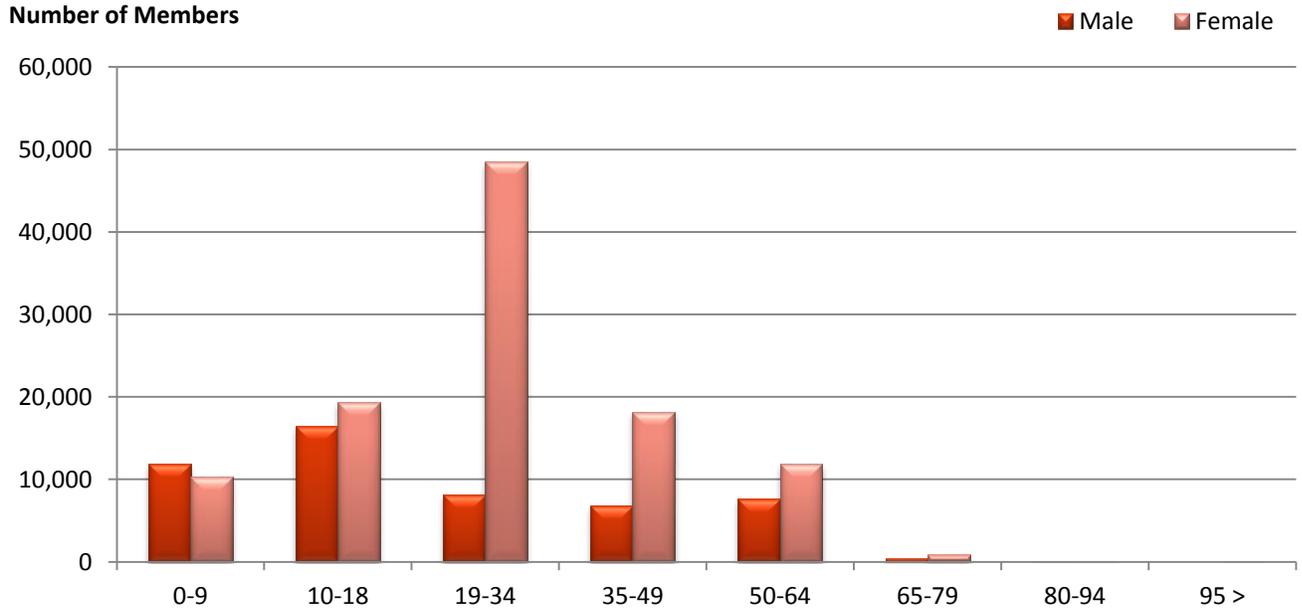
Top 10 Products by Claims: FY 2012

| MEDICATION | CLAIMS | MEMBERS | COST | COST/DAY | UNITS/DAY |
|-------------------------|----------------|---------|------------------------|----------|-----------|
| HYDRO/APAP TAB 7.5-500 | 96,709 | 43,690 | \$781,912.99 | \$0.63 | 3.49 |
| HYDRO/APAP TAB 10-500MG | 81,946 | 17,228 | \$1,384,987.37 | \$0.71 | 3.84 |
| TRAMADOL HCL TAB 50MG | 73,305 | 28,124 | \$633,543.63 | \$0.49 | 4.25 |
| HYDRO/APAP TAB 5-500MG | 51,397 | 33,353 | \$355,117.91 | \$0.88 | 3.65 |
| HYDRO/APAP TAB 10-325MG | 38,651 | 10,117 | \$796,171.74 | \$0.92 | 4.3 |
| HYDRO/APAP TAB 7.5-325 | 30,055 | 15,441 | \$416,955.70 | \$1.12 | 4.06 |
| HYDRO/APAP TAB 5-325MG | 23,583 | 16,118 | \$221,354.02 | \$1.19 | 4.27 |
| OXY/APAP TAB 5-325MG | 22,421 | 18,054 | \$164,698.11 | \$1.21 | 5.49 |
| APAP/CODTAB 300-30MG | 21,247 | 15,694 | \$174,107.10 | \$1.10 | 3.79 |
| APAP/COD SOL 120-12/5 | 17,780 | 15,483 | \$132,156.72 | \$1.35 | 21.55 |
| SUBTOTAL | 457,094 | | \$5,061,005.29 | | |
| CATEGORY TOTAL | 600,341 | | \$18,948,444.51 | | |
| PERCENT OF TOTAL | 76% | | 27% | | |

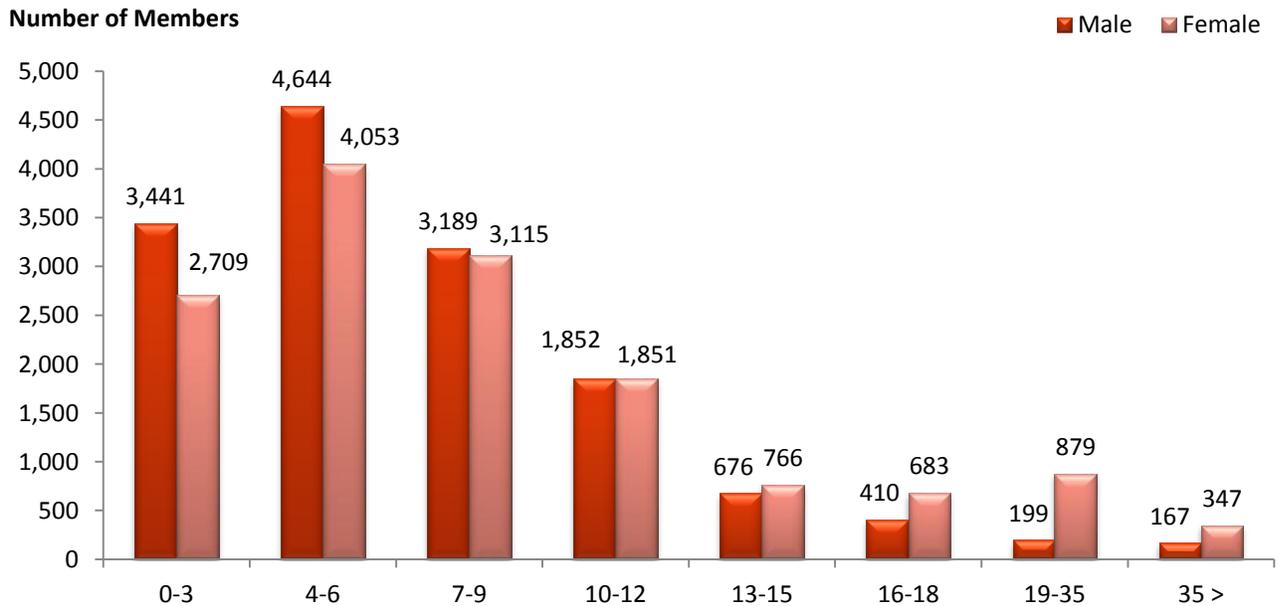
Top 10 Products by Cost: FY 2012

| MEDICATION | CLAIMS | MEMBERS | COST | COST/DAY | UNITS/DAY |
|-------------------------|----------------|---------|------------------------|----------|-----------|
| OXYCONTIN TAB 80MG CR | 2,667 | 319 | \$2,786,139.21 | \$35.46 | 2.72 |
| HYDRO/APAP TAB 10-500MG | 81,946 | 17,228 | \$1,384,987.37 | \$0.71 | 3.84 |
| SUBOXONE SUB 8-2MG | 2,948 | 525 | \$1,314,297.22 | \$16.73 | 2.23 |
| HYDRO/APAP TAB 10-325MG | 38,651 | 10,117 | \$796,171.74 | \$0.92 | 4.3 |
| HYDRO/APAP TAB 7.5-500 | 96,709 | 43,690 | \$781,912.99 | \$0.63 | 3.49 |
| OXYCONTIN TAB 40MG CR | 1,839 | 327 | \$752,008.42 | \$13.87 | 2.01 |
| OXYCONTIN TAB 60MG CR | 1,139 | 208 | \$748,905.00 | \$22.17 | 2.18 |
| TRAMADOL HCL TAB 50MG | 73,305 | 28,124 | \$633,543.63 | \$0.49 | 4.25 |
| FENTANYL DIS 100MCG/H | 1,863 | 344 | \$621,485.61 | \$11.33 | 0.41 |
| SUBOXONE MIS 8-2MG | 1,539 | 323 | \$583,293.76 | \$14.44 | 2.1 |
| SUBTOTAL | 302,606 | | \$10,402,744.95 | | |
| CATEGORY TOTAL | 600,341 | | \$18,948,444.51 | | |
| PERCENT OF TOTAL | 50% | | 55% | | |

Demographics of Members Utilizing Narcotic Analgesics: FY 2012

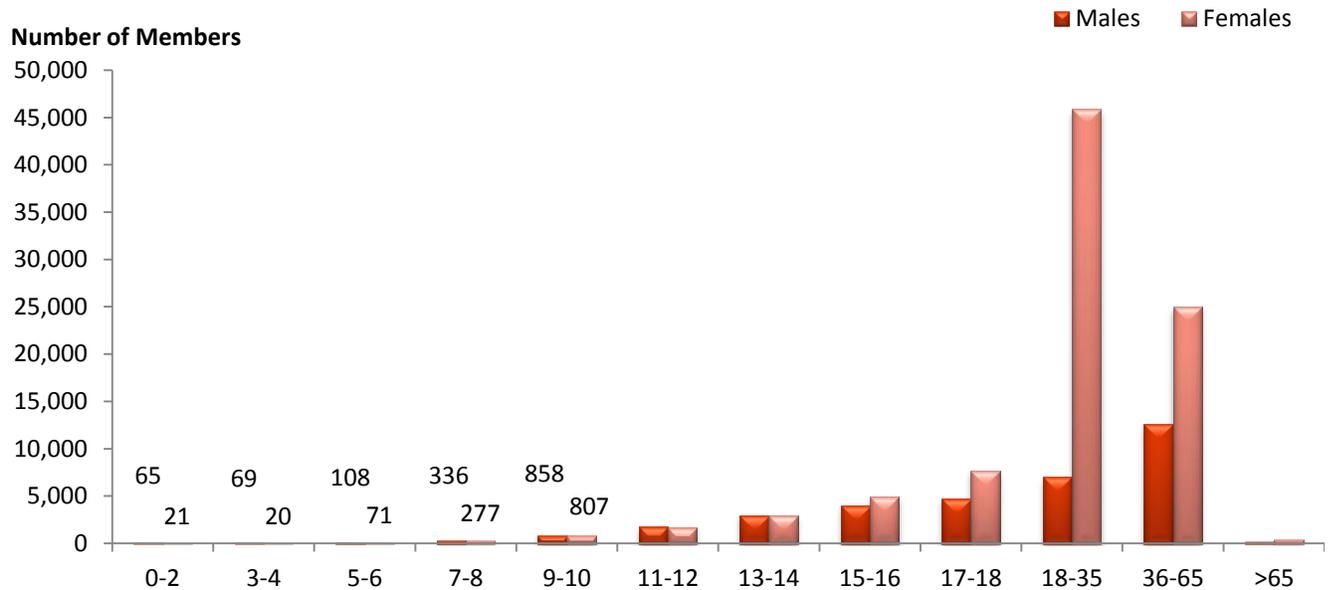


Demographics of Members on Oral Liquid Narcotic Analgesics: FY 2012



Of the 28,984 members who had a claim during fiscal year 2012 for an oral liquid form of a narcotic analgesic 21,151 members were 9 years of age or younger.

Demographics of Members on Short Acting Oral Solid Narcotic Analgesics: FY 2012



Of the 124,466 members who had a claim during fiscal year 2012 for a short acting oral solid formulation of narcotic analgesic 2,632 members were 10 years of age or younger.

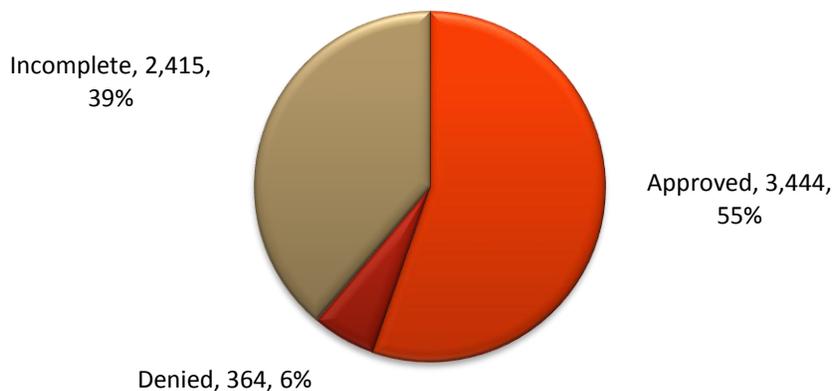
Top Prescriber Specialties of Narcotic Analgesics: FY 2012

| Specialty | Claims | Cost | Comparison By Number of Claims |
|-----------------------------|---------|----------------|--------------------------------|
| Family Practitioner | 179,300 | \$7,032,677.04 | |
| Internist | 45,593 | \$2,738,716.79 | |
| ER Practitioner | 44,304 | \$756,413.72 | |
| Physician Assistant | 42,807 | \$470,638.84 | |
| Gen. Dentistry Practitioner | 41,438 | \$266,956.32 | |
| Nurse Practitioner (Other) | 37,354 | \$494,498.31 | |
| Obstetrician/Gynecologist | 35,222 | \$355,527.11 | |
| General Practitioner | 26,133 | \$1,045,887.58 | |
| Orthopedic Surgeon | 26,103 | \$577,220.76 | |
| Anesthesiologist | 21,222 | \$1,773,541.57 | |
| General Surgeon | 13,178 | \$172,460.15 | |

Prior Authorization of Narcotic Analgesics

Most step therapy prior authorization requests for this category are handled through the DUR Plus point-of-sale (POS) prior authorization system. There were a total of 6,223 manual petitions submitted for Narcotic Analgesics during Fiscal Year 2012 for step therapy (that did not meet POS requirements) and quantity limit, ingredient duplication, and claim limit overrides. The following chart shows the status of the submitted petitions.

Status of Petitions Submitted: FY 2012



Market News and Update

Anticipated Patent Expirations:

- Oxycontin® (oxycodone, controlled release)- April 2013
- Exalgo® (hydromorphone, extended release)- July 2014
- Butrans® (buprenorphine patch)- September 2017
- Avinza® (morphine sulfate extended release)- November 2017
- Nucynta™ (tapentadol)- June 2018

A generic equivalent of oxymorphone hydrochloride extended release tablets (Opana® ER) was marketed in January of 2013. However, this generic formulation is not an abuse deterrent formulation similar to the brand name Opana® ER and may pose a safety risk.² This product also has a higher net cost when compared to the brand name product. As a result, a special prior authorization requirement was implemented on February 4, 2013 in which the prescriber must state the reason the member cannot use brand name Opana® ER.

On January 25, 2013 the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee voted 19 to 10 in favor of reclassifying hydrocodone-containing products from Schedule III drugs under the Controlled Substances Act to Schedule II. Among narcotic analgesics, hydrocodone is ranked as the most commonly abused medication, followed by Oxycontin®.³ Proponents of the change emphasize hydrocodone's potential for addiction and abuse, while those opposing raised the issue of restricted access for millions of legitimate pain patients.

Discussion

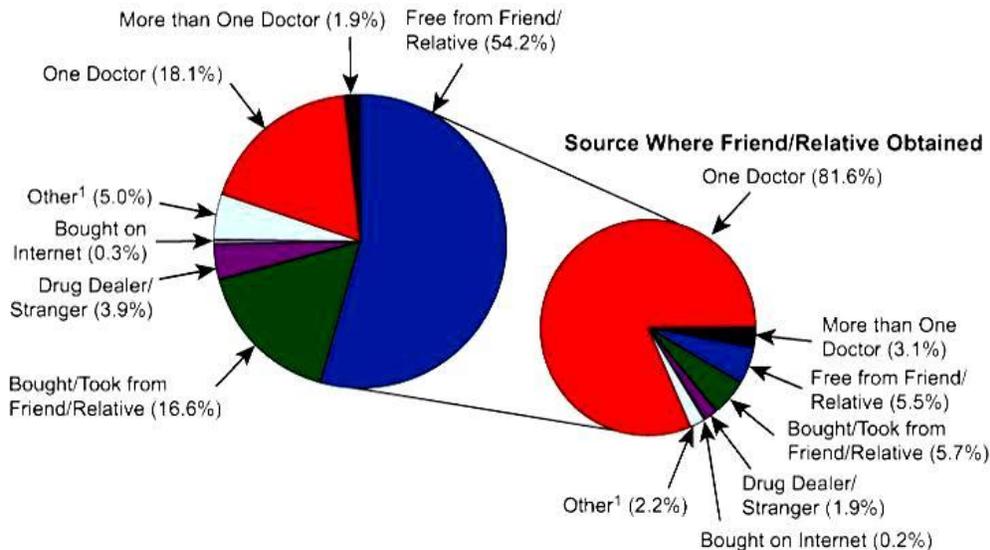
Data indicates a decline in prescription drug abuse rates in the state of Oklahoma over the past 3 years. National and state initiatives, including those implemented by SoonerCare have contributed to this decline. This shows the measures taken to decrease inappropriate use of these medications, when implemented strategically in well planned steps, minimally impacted the availability of these medications for members who need them to maintain adequate pain relief. This was a primary concern upon implementing edits for this category of medications.

In light of these positive outcomes, SoonerCare utilization data shows a disproportionate increase in utilization of narcotics compared to the increase in total enrollment which is concerning. The cost and utilization trends for the extended release narcotic analgesics remained stable after the implementation of the product based prior authorization category. However, utilization trends for the immediate release products show the following:

- Increases in costs
- Increases in claims
- Increases in units per claim

Although quantity limits are in place for all hydrocodone products containing acetaminophen, these quantities are fairly liberal, allowing up to 240 tablets for a 30 day supply on certain strengths. Medication supply is a major contributing factor for prescription drug abuse as statistics show that over 50% of abusers reported obtaining narcotic pain relievers free, from a friend or relative as shown on the Figure 1.

Figure 1: Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2010-2011



Note: The percentages do not add to 100 percent due to rounding. The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

The following is a list of management strategies used by other state Medicaid programs:

| State | Management Strategies |
|---------------|---|
| Arkansas | Cumulative quantity edit on all short-acting pain medications to 124 units per 31 days. The daily quantity edit is 6:1 so prescriber could treat “acute” pain situations. Maximum paid is 31 day supply per month, but after 21 days it will no longer be considered an acute situation and has to be moved to chronic which could be managed with long-acting agents. However, 1 short-acting and 1 long-acting agent is allowed for non-cancer patients. |
| West Virginia | Quantity limit of 4 units of short-acting opioid agents per day. Pharmacists are required to submit a form that they have the patient sign when paying cash and it is submitted to pharmacy department. |
| West Virginia | Send out letters and reports to the Top 50 Opioid Prescribers comparing them to other prescribers in the Medicaid Program. |
| West Virginia | Send out letters to the next 150 Top Opioid Prescribers and information regarding access to the Board of Pharmacy PMP, WV Board of Medicine Chronic Pain Treatment Guidelines, and templates for narcotic contracts and patient informed consent agreements. The letters are signed by the Medical Director and the DUR Board Chairman and seem to have some effect because of the signatures. |
| New York | Short-acting opioids have duration of therapy limit of 90 days total (for patients without a diagnosis of cancer or sickle-cell disease). |
| Pennsylvania | Limits member to only one short-acting opioid at a time. At point-of-sale the online claims adjudication system will verify if the recipient has a record of any other prescription for an analgesic, narcotic short acting within the last 60 days, may require medication is being prescribed by an appropriate specialist or in consultation with an appropriate specialist. |
| Texas | Clinical edit that detects opioid overutilization. If member has 8 or more opioid claims or 150 or more day supply of opiates in a defined time frame (TX it is 60 days), the claim will require prior authorization and go through a series of questions/criteria. This applies to all opioids cumulatively. |
| Delaware | Quantity limit for short-acting narcotic analgesics of 120 per 30 days with a total of 720 short-acting units only per year. Quantity limit for Oxycodone 15 mg of 240 units per 365 days and total quantity limit for Oxycodone 30 mg of 60 units per 365 days. For patients who have met the total quantity limit, long acting opioid therapy must be initiated. |
| Delaware | Prior Authorization is required when total narcotic analgesic dose exceeds 200 mg morphine or equivalent per 24 hours. If the diagnosis includes an inflammatory pain component, then the patient must have tried or be contraindicated to a NSAID drug. If the diagnosis is a form of neuropathic pain, then patient must first try or be contraindicated to two neuropathic pain medications. |
| Delaware | For all prior authorizations for high dose narcotics (long-acting and short-acting narcotics) requests must include: Member over the age of 12 years old, pain assessment charts must include an assessment filled out by the physician, physician-patient pain management contract must be provided, documentation must be included for random urine or blood tests twice a year, one pharmacy must be selected for ALL prescription services, patient must not have an active addiction to illicit substances or prescription drugs, patients should be tapered off if the patient has committed serious or repeated drug seeking behavior or patient makes no progress toward therapeutic goals. |

Recommendations

The College of Pharmacy recommends the following:

1. Apply an age restriction on oral liquid narcotic analgesic products for all members older than 12 years of age.
2. Apply an age restriction on oral solid dosage forms of narcotic analgesic products for all members younger than 10 years of age.

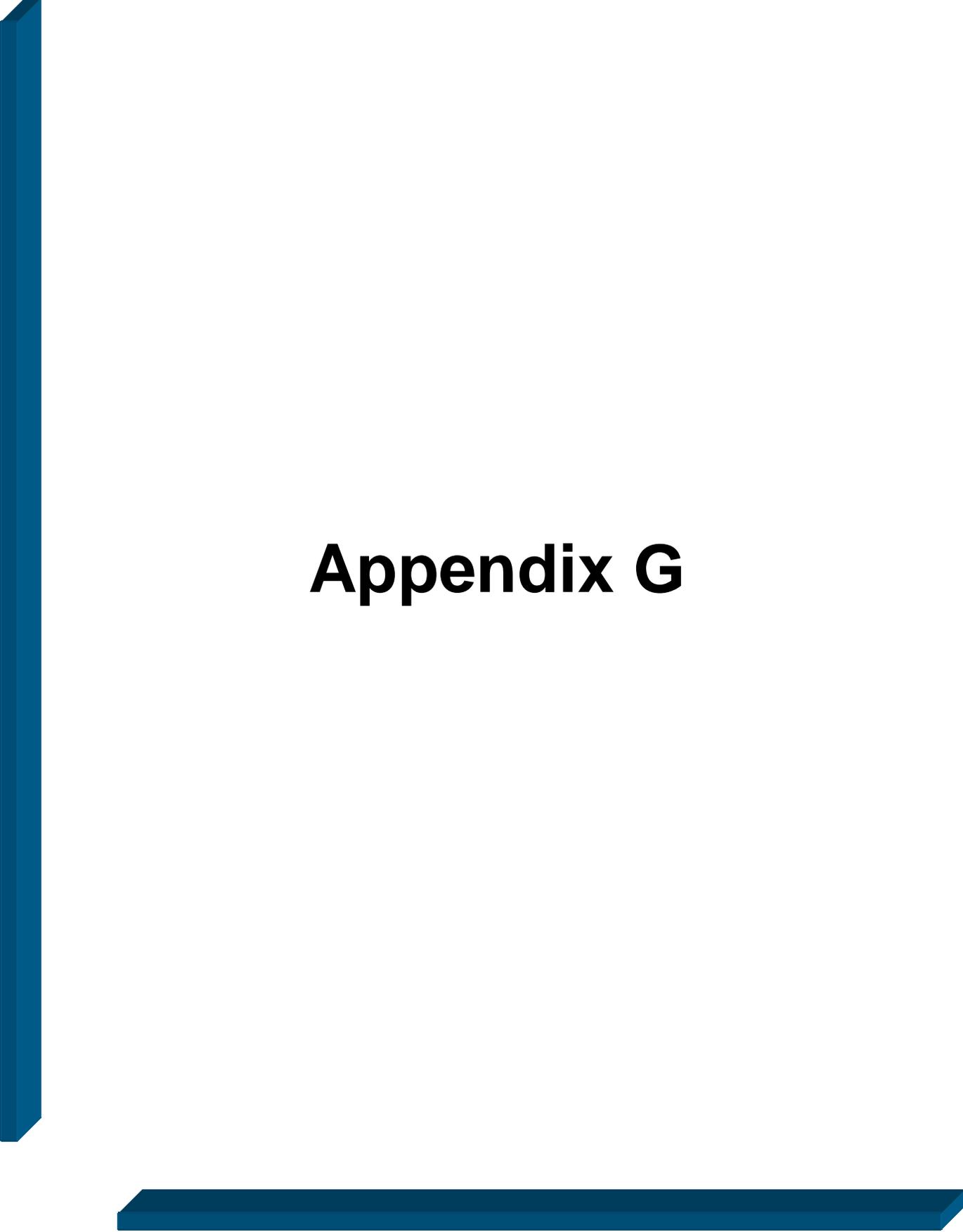
In addition, the College of Pharmacy recommends the consideration of other management strategies such as:

- Lower quantity limits on immediate release products
- General educational initiative detailing responsible opioid prescribing
- Prescriber profiling and targeted education
- Require use of the Oklahoma Prescription Monitoring Program (PMP) for all prescribers who prescribe narcotics

¹ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

² Jason Koebler. FDA Approves Painkiller Obama Administration Warned About in December. U.S. News. January 2013. Available online at: <http://www.usnews.com/news/articles/2013/01/11/fda-approves-painkiller-obama-administration-warned-about-in-december>.

³ National Institutes of Health. National Institute on Drug Abuse. Commonly Abused Prescription Drugs Chart. <http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart>.



Appendix G

30 Day Notice to Prior Authorize Chronic Obstructive Pulmonary Disease Medications

Oklahoma Health Care Authority
February 2013

This category was introduced for possible inclusion in the Product Based Prior Authorization program in December 2012. See the December 2012 and January 2013 DUR packet for a more complete discussion of the category. This notice and statement of potential economic impact are presented to meet the statutory requirements of 63 O.S. Sec. 5030.5.

Recommendations

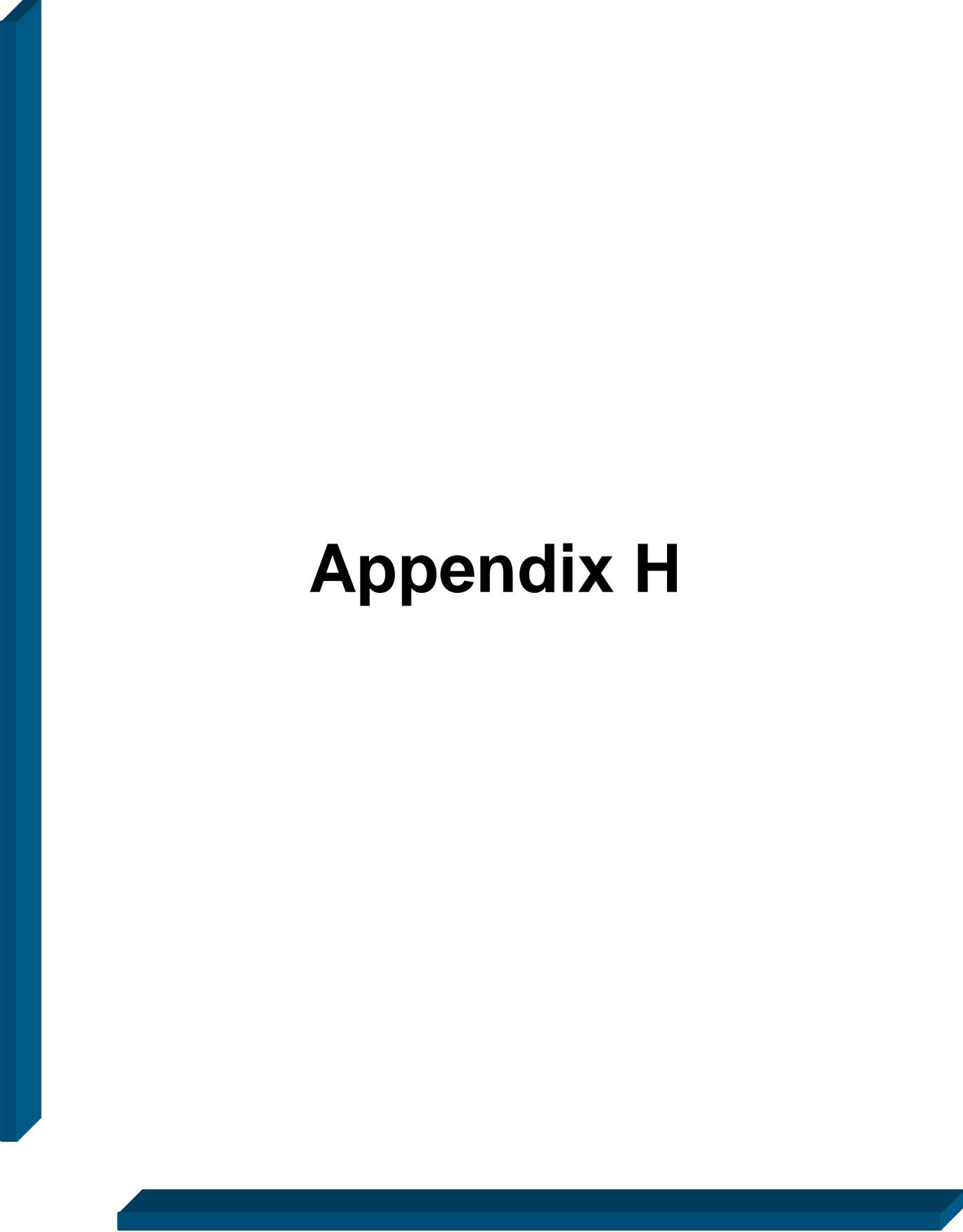
The College of Pharmacy recommends establishing a Product Based Prior Authorization category for long acting bronchodilator medications to ensure appropriate and cost-effective utilization in accordance with current treatment guidelines. The following Tier 1 drug list has been determined to be acceptable for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Health Care Authority.

| Tier 1 | Tier 2 |
|--|--|
| Long Acting Beta ₂ Agonists* | |
| Serevent® (Salmeterol inhalation powder) Foradil® (formoterol aerosolized powder) | Perforomist® (formoterol nebulizer solution) Brovana® (arformoterol nebulizer solution) Arcapta® (indacaterol inhalation powder) |
| Long Acting Anticholinergics | |
| Spiriva® (tiotropium inhalation powder) | Tudorza® (aclidinium inhalation powder) |

*Combination agents qualify as Tier 1 agents

Tier-2 Approval Criteria:

1. The member must be age 18 or older, and
2. Have a diagnosis of COPD, chronic bronchitis, or emphysema, and
3. A 4 week trial of at least one LABA and a four week trial of one LAMA within the past 90 days, or
4. A documented adverse effect, drug interaction, or contraindication to all available Tier 1 products.
5. A clinical exception will be made for members who are unable to effectively use hand-actuated devices, such as Spiriva Handihaler® or those who are stable on nebulized therapy.



Appendix H

30 Day Notice to Prior Authorize Miscellaneous Corticosteroid Products

Oklahoma Health Care Authority
February 2013

Summary ^{1, 2, 3}

Corticosteroids—sometimes referred to as glucocorticoids or steroids—are a synthetic form of cortisol, a hormone produced by the adrenal glands. They are used for many inflammatory and autoimmune conditions. They produce the anti-inflammatory and immunosuppressive response by interacting with steroid-specific receptors in the cells, inhibiting the movement of inflammatory cells into the area of inflammation, inhibiting neutrophil function, and inhibiting prostaglandin production.

Commonly used oral corticosteroids include dexamethasone, methylprednisolone, prednisone, prednisolone, and hydrocortisone. Less common are budesonide and cortisone. These drugs differ in their relative potency and available modes of administration. Dexamethasone is the most potent of the corticosteroids, whereas cortisone and hydrocortisone are the least potent. Prednisone is an intermediate-acting corticosteroid that is metabolized in the liver to the active metabolite, prednisolone.

| Drug | Trade Name* | Oral Dosage Strengths | Comparable Dose |
|--|--|--|-----------------|
| Short-Acting Glucocorticoids | | | |
| Cortisone acetate | Cortisone | 25 mg tabs | 25 mg |
| Hydrocortisone | Cortef® | 5, 10, 20 mg tabs | 20 mg |
| Intermediate-Acting Glucocorticoids | | | |
| Methylprednisolone | Medrol® | 2, 4, 8, 16, 32, mg tabs 4 mg tab dose-pack | 4 mg |
| Prednisolone | Orapred ODT® Millipred™ Orapred® Pediapred® Veripred™ Flo-Pred™ | 10, 15, 30 mg orally disintegrating tabs 5 mg tabs 5mg/5ml oral solution 10mg/5ml oral solution 15mg/5ml oral solution 20mg/5ml oral solution 25mg/5ml oral solution 15mg/5ml oral suspension | 5 mg |
| Prednisone | Prednisone Intensol™ Rayos® | 5mg/ml oral solution concentrate 1 mg/ml oral solution 1, 2.5, 5, 10, 20, 50 tabs 1, 2, 5 mg delayed release tabs | 5 mg |
| Long-Acting Glucocorticoids | | | |
| Betamethasone | Celestone® | 0.6mg/5ml oral solution | 0.75 mg |
| Dexamethasone | Baycadron™, Dexamethasone Intensol™ | 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs; 0.5mg/5ml oral elixir 0.5mg/5ml oral solution 1mg/ml oral solution concentrate | 0.75 mg |

Products under Consideration ^{4, 5}

- Orapred ODT[®] (prednisolone sodium phosphate, orally disintegrating tabs), approved in June 2006, is available in 10 mg, 15 mg, and 30 mg tablets.
- Prednisolone sodium phosphate oral solution, 25 mg/5 ml, was FDA approved in September 2010, but was not available on the market until September 2012.
- Veripred[™] (prednisolone sodium phosphate oral solution), 20 mg/5 ml solution, has been available since October 2008.

The initial daily dose ranges from 10 to 60 mg for prednisolone, 5 to 60 mg for prednisone, depending on the indication and its severity. Dosage is adjusted to achieve adequate response. Maintenance dose should be the lowest dose that will maintain an adequate clinical response. If satisfactory response is not achieved after a reasonable trial, the drug should be discontinued. Corticosteroids should be withdrawn gradually if discontinuing long-term or high-dose therapy.

Cost Comparison

| Drug | Strength | Cost/unit | Drug | Strength | Cost/unit |
|--|------------|--------------------------|--|------------|-------------------------|
| Orapred ODT [®] (prednisolone sodium phosphate, orally disintegrating tab) | 10 mg | \$6.89 | Millipred [™] (prednisolone) tab | 5 mg | \$0.50 |
| | 15 mg | \$10.37 | | | |
| | 30 mg | \$14.77 | | | |
| Prednisolone oral sol | 25 mg/5 ml | \$0.69/ml (\$3.45/25 mg) | Prednisolone oral sol | 15 mg/5 ml | \$0.08/ml (\$0.66/25mg) |
| Veripred [™] oral sol | 20 mg/5 ml | \$0.66/ml (\$4.13/25 mg) | | | |
| Prednisolone oral sol | 5 mg/5 ml | \$0.23/ml (\$5.75/25mg) | | | |

25 mg dose of prednisolone was randomly selected for comparison of cost.

Recommendations

The College of Pharmacy recommends the prior authorization of the following products:

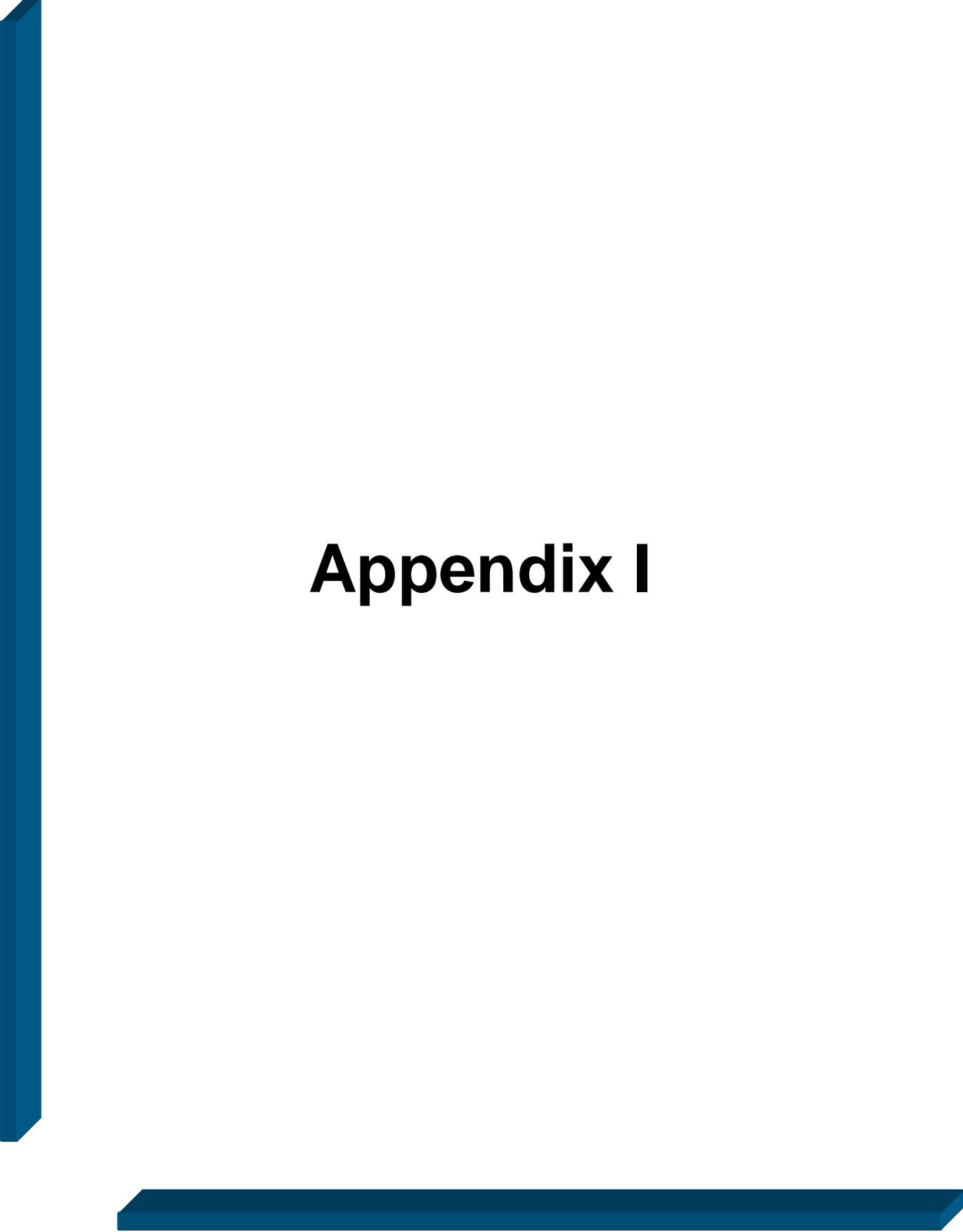
- Orapred ODT[®] (prednisolone sodium phosphate, orally disintegrating tabs)
- Prednisolone sodium phosphate oral solution, 5 mg/5 ml and 25 mg/5 ml
- Veripred[™] (prednisolone sodium phosphate) 20 mg/5 ml

Approval Criteria

Approval requires a patient specific, clinically significant reason why the member cannot use other available formulations of oral corticosteroids.

References

1. Donahue KE, Gartlehner G, Jonas DE, Lux LJ, Thieda P, Jonas B, Hansen RA, Morgan LC, Williams SC, Lohr KN. Comparative Effectiveness of Drug Therapy for Rheumatoid Arthritis and Psoriatic Arthritis in Adults. Comparative Effectiveness Review No. 11. (Prepared by RTI-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016.) Rockville, MD: Agency for Healthcare Research and Quality. November 2007. Available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.
2. Goslee J, Robinson, V. Oral Corticosteroids. (prepared for National Community Pharmacists Association on-line Continuing Education Program) Available online at: http://www.k9addisons.com/oral_corticosteroids.html
3. AHFS drug information 2004. McEvoy GK, ed. Corticosteroids general statement. Bethesda, MD: American Society of Health-System Pharmacists; 2004:2886-98.
4. Orapred ODT® Label Information. Shionogi Inc. Available online at: <http://orapredodt.com/whyodt.htm> Last revised 2011.
5. Prednisone Intensol™ Oral Solution (Concentrate) Label information. Roxane Laboratories. Available online at: https://www.rli-touchpoint.com/tpPortal/appmanager/touchpoint/rli?nfpb=true&windowLabel=rli_productcatalog_portlet&rli_productcatalog_portlet_actionOverride=%2Fportlets%2FProductCatalog%2FgetPage&rli_productcatalog_portletpag=22



Appendix I

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

FDA NEWS RELEASE

For Immediate Release: Feb. 4, 2013

FDA approval of generic version of cancer drug Doxil is expected to help resolve shortage

The U.S. Food and Drug Administration today approved the first generic version of the cancer drug Doxil (doxorubicin hydrochloride liposome injection).

Doxorubicin hydrochloride liposome injection is currently on the FDA's drug shortage list. For products on the shortage list, the FDA's Office of Generic Drugs is using a priority review system to expedite the review of generic applications to help alleviate shortages.

Generic drugs approved by the FDA have the same high quality and strength as brand-name drugs. The generic manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs.

The generic is made by Sun Pharma Global FZE (Sun). Doxorubicin hydrochloride liposome injection is administered intravenously by a health care professional. Sun's generic will be available in 20 milligram and 50 milligram vials.

In February 2012, to address the shortage of doxorubicin hydrochloride liposome injection, the FDA announced¹ it would exercise enforcement discretion for temporary controlled importation of Lipodox (doxorubicin hydrochloride liposome injection), an alternative to Doxil produced by Sun and its authorized distributor, Caraco Pharmaceutical Laboratories Ltd. that is not approved in the United States. Enforcement discretion was also used to release one lot of Janssen's Doxil made under an unapproved manufacturing process.

For the present time, FDA intends to continue exercising enforcement discretion for importation of Lipodox, and limited supplies of Doxil are available. Once supplies of Sun's generic doxorubicin hydrochloride liposome injection are sufficient to meet projected demand, FDA expects to stop exercising enforcement discretion for any unapproved doxorubicin HCl liposomal product.

FDA NEWS RELEASE

For Immediate Release: Jan. 29, 2013

FDA approves new orphan drug Kynamro to treat inherited cholesterol disorder

The U.S. Food and Drug Administration today approved Kynamro (mipomersen sodium) injection as an addition to lipid-lowering medications and diet to treat patients with a rare type of high cholesterol called homozygous familial hypercholesterolemia (HoFH). The addition of Kynamro helps to reduce low-density lipoprotein-cholesterol (LDL-C), apolipoprotein B, total cholesterol, and non-high density lipoprotein-cholesterol (non HDL-C).

HoFH, an inherited condition that affects about one out of every one million people in the United States, occurs when the body is unable to remove LDL-C, often called "bad" cholesterol, from the blood causing abnormally high levels of circulating LDL-C. For those with HoFH, heart attacks and death often occur before age 30. Kynamro is an orphan drug approval, meaning it was developed to treat a disorder affecting fewer than 200,000 people. In December 2012, the FDA approved Juxtapid (lomitapide) to reduce LDL-C, total cholesterol, apolipoprotein B, and non HDL-C in patients with HoFH.

The safety and effectiveness of Kynamro were evaluated in a clinical trial of 51 patients with HoFH. On average, levels of LDL-C fell by about 25 percent during the first 26 weeks in those receiving the drug. Kynamro carries a Boxed Warning on the serious risk of liver toxicity because it is associated with liver enzyme

abnormalities and accumulation of fat in the liver, which could lead to progressive liver disease with chronic use.

The FDA approved Kynamro with a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use, including prescriber and pharmacy certification, and documentation of safe-use conditions, which requires a prescription authorization form for each new prescription.

The most common adverse reactions in the clinical trial included injection site reactions, flu-like symptoms, nausea, headache and elevations in liver enzymes (serum transaminases).

The FDA is requiring four postmarketing studies for Kynamro: the development of a sensitive assay that binds double-stranded (ds) DNA; a study to assess for the presence of antibodies to ds-DNA in patients treated with Kynamro; a long-term registry of patients with HoFH to determine the long-term safety of Kynamro; and an enhanced pharmacovigilance program to monitor reports of malignancy, immune-mediated reactions, and hepatic abnormalities in patients treated with Kynamro.

Kynamro is manufactured by Cambridge, Mass.-based Genzyme Corp.

FDA NEWS RELEASE

For Immediate Release: Jan. 23, 2013

FDA approves Exjade to remove excess iron in patients with genetic blood disorder

First imaging companion diagnostic to detect liver iron concentration also cleared

The U.S. Food and Drug Administration today expanded the approved use of Exjade (deferasirox) to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT).

NTDT is a milder form of thalassemia that does not require individuals to get frequent red blood cell transfusions. However, over time, some patients with NTDT are still at risk for iron overload that can lead to damage to vital organs.

The FDA is also authorizing marketing of FerriScan as an imaging companion diagnostic for Exjade therapy in patients with NTDT. The agency previously cleared FerriScan for measuring liver iron concentration (LIC), but its use in Exjade clinical studies to select patients for therapy, and to manage therapy, defined its role as an imaging companion diagnostic necessary for Exjade's safe and effective use. FerriScan measures LIC non-invasively using magnetic resonance imaging.

An estimated 1,000 people in the United States have thalassemia, according to the National Heart, Lung, and Blood Institute. Thalassemia conditions can cause the body to make fewer healthy red blood cells and less hemoglobin, a protein that carries oxygen to all parts of the body and returns carbon dioxide to the lungs so it can be exhaled. Some patients with thalassemia require frequent transfusions of red blood cells to maintain an acceptable level of hemoglobin. Iron overload is common in these patients.

Exjade was previously approved for treatment of chronic iron overload due to blood transfusions in patients ages 2 years and older, and this approval extends its use to treat patients with NTDT who show iron overload. Exjade should be used in patients with NTDT who have an LIC of at least 5 milligrams of iron per gram of dry liver tissue weight.

Exjade's new indication is being approved under the FDA's accelerated approval program, which provides patients earlier access to promising new drugs intended to treat serious or life-threatening illnesses while the company conducts additional studies to confirm the drug's clinical benefit. Exjade was approved based on clinical data showing it can reduce LIC to less than 5 mg/g dry weight, a surrogate endpoint that is judged reasonably likely to predict a clinical benefit to patients.

The safety and effectiveness of Exjade to treat chronic iron overload in patients with NTDT were established in two clinical trials designed to measure the number of patients whose LIC was reduced to less than 5 mg/g dry weight after 52 weeks of treatment. In the first trial, 166 patients were randomly assigned to receive 5 mg/kg of Exjade, 10 mg/kg of Exjade, or a placebo daily. Results showed 15 percent and 27 percent of Exjade-treated

patients achieved the target LIC, respectively, compared with 4 percent in placebo-treated patients. The second trial contained 133 patients from the first study who received an additional year of Exjade treatment or switched from placebo to Exjade treatment. Thirty-five percent of the evaluable patients in this extension trial achieved the target LIC.

The FDA reviewed data for the FerriScan through the de novo classification process, a regulatory pathway for medical devices that are generally moderate-risk but are not comparable to an already legally marketed device. The FDA's granting of the de novo request for FerriScan was based largely on data from the Exjade clinical studies that used FerriScan LIC results as the primary outcome measure. Additionally, investigators conducted a 230-patient study that found FerriScan results were as accurate as liver biopsy for measuring LIC. "The FerriScan device is a non-invasive test that helps physicians to select appropriate patients for Exjade therapy as well as monitor their response to the drug, and discontinue therapy when LIC reaches safe levels," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

Exjade is marketed by East Hanover, N.J.-based Novartis. FerriScan is marketed by Resonance Health, based in Australia.

Safety Announcements

Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist)

[1-10-2013] The U.S. Food and Drug Administration (FDA) is notifying the public of new information about zolpidem, a widely prescribed insomnia drug. FDA recommends that the bedtime dose be lowered because new data show that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. Today's announcement focuses on zolpidem products approved for bedtime use, which are marketed as generics and under the brand names Ambien, Ambien CR, Edluar, and Zolpimist.

FDA is also reminding the public that all drugs taken for insomnia can impair driving and activities that require alertness the morning after use. Drowsiness is already listed as a common side effect in the drug labels of all insomnia drugs, along with warnings that patients may still feel drowsy the day after taking these products. Patients who take insomnia drugs can experience impairment of mental alertness the morning after use, even if they feel fully awake.

FDA urges health care professionals to caution all patients (men and women) who use these zolpidem products about the risks of next-morning impairment for activities that require complete mental alertness, including driving. For zolpidem products, data show the risk for next-morning impairment is highest for patients taking the extended-release forms of these drugs (Ambien CR and generics). Women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men (see Data Summary).

Because use of lower doses of zolpidem will result in lower blood levels in the morning, FDA is requiring the manufacturers of Ambien, Ambien CR, Edluar, and Zolpimist to lower the recommended dose. FDA has informed the manufacturers that the recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edluar, and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR). FDA also informed the manufacturers that, for men, the labeling should recommend that health care professionals consider prescribing the lower doses 5 mg for immediate-release products and 6.25 mg for extended-release products (see Dosing Recommendations).

The recommended doses of Intermezzo, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men.

FDA is continuing to evaluate the risk of impaired mental alertness with other insomnia drugs, including over-the-counter (OTC) drugs available without a prescription.

To decrease the potential risk of impairment with all insomnia drugs, health care professionals should prescribe, and patients should take, the lowest dose capable of treating the patient's insomnia. Patients who drive or whose activities require full alertness the morning after use of an insomnia drug should discuss the appropriateness of their medicine with their health care professional.

Safety Announcements

Public Notification: "MAXILOSS Weight Advanced" Contains Hidden Drug Ingredient

[1-8-2013] The Food and Drug Administration (FDA) is advising consumers not to purchase or use "MAXILOSS Weight Advanced," a product promoted and sold for weight loss on various websites, including www.dreamlifeweightloss.com¹, and in some retail stores.

FDA laboratory analysis confirmed that "MAXILOSS Weight Advanced" contains sibutramine. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. The product poses a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Consumers should stop using this product immediately and throw it away. Consumers who have experienced any negative side effects should consult a health care professional as soon as possible.

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

i Complete and submit the report Online: www.fda.gov/MedWatch/report.htm²

i Download form³ or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Note: This notification is to inform the public of a growing trend of dietary supplements or conventional foods with hidden drugs and chemicals. These products are typically promoted for sexual enhancement, weight loss, and body building and are often represented as being "all natural." FDA is unable to test and identify all products marketed as dietary supplements. Because these products may have potentially harmful hidden ingredients, consumers should exercise caution before purchasing any product in the above categories.

Current Drug Shortages Index (as of February 5, 2013):

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

[Acetylcysteine Inhalation Solution](#) **UPDATED** 2/4/2013

[Acyclovir Sodium Injection](#) (initial posting 11/13/2012)

[Alfentanil \(Alfenta\) Injection](#) (initial posting 1/23/2012)

[Amikacin Injection](#)

[Amino Acid Products](#) (initial posting 2/14/2012)

[Aminophylline](#) (initial posting 12/10/2012)

[Ammonium Chloride Injection](#)

[Amytal Sodium Injection](#) (initial posting date 1/31/2013) **New!!**

[Atracurium besylate](#) (initial posting 2/27/2012)

[Atropine Sulfate Injection](#) **UPDATED** 2/4/2013

[Bacteriostatic 0.9% Sodium Chloride](#) (initial posting 9/10/2012) **UPDATED** 1/28/2013

[Barium Sulfate for Suspension](#) (initial posting 10/12/2012)
[Bismuth subsalicylate/tetracycline hydrochloride/metronidazole \(Helidac\) Therapy](#) (initial posting 3/8/2012)
[Bumetanide Injection](#) (initial posting 6/21/2012) **UPDATED** 2/4/2013
[Bupivacaine Hydrochloride \(Marcaine, Sensorcaine\) Injection](#) **UPDATED** 2/4/2013
[Buprenorphine hydrochloride \(Buprenex\) Injection](#)
[Caffeine, anhydrous \(125 mg/mL\) and Sodium benzoate \(125 mg/mL\)](#)
[Caffeine and Ergotamine Tartrate Tablet](#) (initial posting 3/8/2012)
[Calcium Chloride Injection](#) (initial posting 12/11/2012) **UPDATED** 2/4/2013
[Calcium Gluconate Injection](#) (initial posting 1/10/2013) **UPDATED** 1/28/2013
[Cetorelix Acetate for Injection \(Cetrotide\)](#) (initial posting 9/20/2012)
[Chromic Chloride Injection](#)
[Citric Acid; Gluconolactone; Magnesium Carbonate Solution \(Renacidin\); Irrigation](#) (initial posting 6/30/2012)
[Corticotropin Ovine Triflutate](#)
[Cyanocobalamin Injection](#)
[Daunorubicin Hydrochloride Solution for Injection](#)
[Denileukin diftitox \(Ontak\) injection](#) (initial posting 9/22/2012)
[Desmopressin Injection \(DDAVP\)](#)
[Dexamethasone Sodium Phosphate Injection](#) (initial posting 1/15/2013) **UPDATED** 1/31/2013
[Dexrazoxane \(Zinecard\) Injection](#) **UPDATED** 2/5/2013
[Dextrose Injection](#) (initial posting 5/23/2012) **UPDATED** 2/4/2013
[Diazepam Injection](#)
[Dipyridamole Injection](#) (initial posting 7/24/2012)
[Doxorubicin \(adriamycin\) lyophilized powder](#) (initial posting 12/2/2011)
[Doxorubicin Liposomal \(Doxil\) Injection](#)
[Doxycycline Hyclate](#) (initial posting 1/18/2013)
[Edetate Calcium Disodium \(Calcium Disodium Versenate\) Injection](#) (initial posting 10/12/2012)
[Epinephrine Injection](#) (initial posting 4/27/2012) **UPDATED** 2/4/2013
[Epinephrine 1mg/mL \(Preservative Free\)](#) (initial posting 6/21/2012)
[Ethiodol \(ETHIODIZED OIL\) ampules](#)
[Etomidate \(Amidate\) Injection](#) (initial posting 2/9/2012) **UPDATED** 2/4/2013
[Fentanyl Citrate \(Sublimaze\) Injection](#) **UPDATED** 2/4/2013
[Fluticasone Propionate and Salmeterol \(Advair HFA\) Inhalation Powder](#) (initial posting date) - 10/17/2012)
[Fosphenytoin Sodium \(Cerebyx\) Injection](#) (initial posting 3/30/2012) **UPDATED** 1/28/2013
[Fospropofol disodium \(Lusedra\) Injection](#) (initial posting 6/18/2012)
[Furosemide Injection](#) (initial posting 6/20/2012) **UPDATED** 2/4/2013
[Gallium Nitrate Injection \(Ganite\)](#) (initial posting 4/4/2012)
[Heparin Sodium Premixes](#) (initial posting 7/5/2012) **UPDATED** 2/4/2013
[Hydromorphone Hydrochloride \(Dilaudid\) Injection](#) (initial posting 3/7/2012) **UPDATED** 2/4/2013
[Ibandronate sodium \(Boniva\) injection](#) (initial posting 6/6/2012)
[Intravenous Fat Emulsion](#) **UPDATED** 1/25/2013
[Isoniazid Tablets](#) **UPDATED** 2/5/2013
[Ketorolac Tromethamine Injection](#) **UPDATED** 2/4/2013
[Leucovorin Calcium Lyophilized Powder for Injection](#) **UPDATED** 1/28/2013
[Leuprolide Acetate Injection](#) **UPDATED** 2/1/2013
[Lidocaine \(Xylocaine\) Hydrochloride Injection](#) (initial posting date - 2/22/2012) **UPDATED** 1/4/2013
[Liotrix \(Thyrolar\) Tablets](#)
[Lorazepam \(Ativan\) Injection](#) **UPDATED** 2/4/2013
[Magnesium Sulfate Injection](#) **UPDATED** 2/4/2013

[Mannitol Injection \(Osmitrol, Resectisol\) Injection](#) (initial posting date - 12/21/2011) **UPDATED** 2/4/2013

[Methadone Injection](#) (initial posting - 11/13/2012)

[Methazolamide \(Glauctabs, Neptazane\) Tablets](#)

[Methoxsalen \(Oxsoralen\) 1% topical lotion](#)

[Methyldopate HCL Injection](#)

[Metoclopramide \(Reglan\) Injection](#) **UPDATED** 2/4/2013

[Midazolam HCL \(Versed\) Injection](#) **UPDATED** 2/4/2013

[Morphine Sulfate Injection](#) **UPDATED** 2/4/2013

[Morphine Sulfate \(Astramorph PF, Duramorph, Infumorph\) Injection \(Preservative Free\)](#) **UPDATED** 2/4/2013

[Multi-Vitamin Infusion \(Adult and pediatric\)](#)

[Nalbuphine HCl \(Nubain\) Injection](#) (initial posting 5/15/2012) **UPDATED** 2/4/2013

[Naloxone \(Narcan\) Injection](#) (initial posting 2/22/2012) **UPDATED** 2/4/2013

[Neostigmine Methylsulfate Injection](#) (initial posting 1/14/2013)

[Nitroglycerin Ointment USP, 2% \(Nitro-Bid\)](#) (Initial posting 10/23/2012)

[Norethindrone and Ethinyl Estradiol Tablets, USP \(Ovcon 50 Tablets\)](#) (initial posting 4/16/2012)

[Ondansetron \(Zofran\) Injection 2 mg/mL](#) **UPDATED** 2/4/2013

[Ondansetron Injection 32 mg/50 mL premixed bags](#)

[Oseltamivir Phosphate \(Tamiflu\) for Oral Suspension \(6mg/mL 60 mL\)](#) (Initial posting 1/10/2013)

[Pancuronium Bromide Injection](#) **UPDATED** 2/4/2013

[Papaverine Hydrochloride Injection](#) (initial posting 12/17/2012) **UPDATED** 1/29/2013

[Peginterferon Alfa-2a \(Pegasys\) Injection-Prefilled Syringes](#) (initial posting 3/26/2012)

[Pentamidine isethionate inhalant \(NebuPent\)](#) (initial posting 8/27/2012)

[Pentamidine isethionate for injection \(Pentam 300\)](#) (initial posting 8/27/2012)

[Perflutren Lipid Microsphere \(DEFINITY\) Injection](#) (initial posting 3/23/2012)

[Phentolamine Mesylate \(Regitine\) Injection](#)

[Pilocarpine HCL Ophthalmic Gel 4% \(Pilopine HS\)](#) (initial posting 6/1/2012)

[Potassium Acetate Injection, USP 2 mEq/mL](#) **UPDATED** 2/4/2013

[Potassium Chloride Injection 2 mEq/mL](#) (initial posting 5/15/2012) **UPDATED** 2/4/2013

[Potassium Phosphate Injection](#)

[Procainamide HCL Injection](#)

[Prochlorperazine Injection](#) (initial posting 1/30/2012)

[Promethazine Injection](#) (initial posting 2/10/2012)

[Propofol \(Diprivan\) Injection](#) (initial posting 4/5/2012) **UPDATED** 2/5/2013

[Secretin Synthetic Human \(ChiRhoStim\) Injection \(ChiRhoStim\)](#) (initial posting 6/15/2012)

[Selenium Injection](#)

[Sodium Acetate Injection](#) (initial posting 3/20/2012) **UPDATED** 2/4/2013

[Sodium benzoate and Sodium phenylacetate \(Ammonul\) Injection⁹⁶](#)

[Sodium Bicarbonate Injection](#) (initial posting 4/4/2012) **UPDATED** 2/4/2013

[Sodium Chloride 0.9% \(5.8mL and 20mL\)](#) (initial posting 5/4/2012)

[Sodium Chloride 23.4%](#) **UPDATED** 1/28/2013

[Sodium Phosphate Injection](#) **New!!**

[Succinylcholine \(Anectine, Quelicin\) Injection](#) (initial posting 8/17/2012) **UPDATED** 2/4/2013

[Sufentanil Citrate \(Sufenta\) Injection](#)

[Sulfamethoxazole 80mg/trimethoprim 160mg/ml injection \(SMX/TMP\) Bactrim\)](#)

[Technetium Tc99m Bicisate for Injection \(Neurolite\)](#) (initial posting 5/4/2012)

[Technetium Tc99m Sestamibi Kit for Injection](#) (initial posting 2/14/2012)

[Telavancin \(Vibativ\) Injection](#)

[Tetracycline Capsules](#)

[Thiotepa \(Thioplex\) for Injection](#)

[Thyrotropin alfa \(Thyrogen\) injection 1.1mg/vial](#)

[Ticarcillin disodium/Clavulanic Potassium Injection \(Timentin\)](#) (initial posting 8/16/12)

[Ticlopidine \(Ticlid\) Tablets](#)

[Tobramycin Solution for Injection](#) **UPDATED** 1/28/2013

[Trace Elements](#) (initial posting 1/24/2013) **New!!**

[Tromethamine \(Tham\) Injection](#) (initial posting 5/2/2012)

[Vinblastine Sulfate Injection](#) (initial posting 1/31/2012)

[Vitamin A Palmitate \(Aquasol A\) Injection](#)

[Zinc Injection](#) (initial posting 2/15/2012)