Oklahoma Health Care Authority

# Drug Utilization Review Board

## Wednesday,
## June 11, 2014
## 4 p.m.

Oklahoma Health Care Authority
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

# *The University of Oklahoma*

*Health Sciences Center*

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS


MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Bethany Holderread, Pharm.D.

SUBJECT: Packet Contents for Board Meeting – June 11, 2014

DATE: June 2, 2014

NOTE: The DUR Board will meet at 4:00 p.m. The meeting will be held at 4345 N Lincoln Blvd.

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

**Call to Order**

**Public Comment Forum**

**Introduction of New Board Member**

**Acknowledgment of Speakers for Public Comment**

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

**Update of Medication Coverage Authorization Unit/FDA Safety Alerts – See Appendix B**

**Utilization Breakdown of Hydrocodone Containing Medications – See Appendix C**

**Action Item – Vote to Prior Authorize Sovaldi™ (Sofosbuvir), Olysio™ (Simeprevir), Victrelis® (Boceprevir), and Incivek® (Telaprevir) – See Appendix D**

**Action Item – Vote to Prior Authorize Trokendi XR™ (Topiramate ER), Aptiom® (Eslicarbazepine Acetate), Qudexy™ XR (Topiramate ER), and Generic Divalproex ER – See Appendix E**

**Annual Review of Triptan Anti-Migraine Medications and 30-Day Notice to Prior Authorize Zecuity® (Sumatriptan Iontophoretic Transdermal System) – See Appendix F**

**Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Esomeprazole Strontium and Aciphex® Sprinkle™ (Rabeprazole) – See Appendix G**

**Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Liptruzet™ (Ezetimibe/Atorvastatin) and Omtryg™ (Omega-3-Acid Ethyl Esters A) – See Appendix H**

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

**Future Business**

**Adjournment**

# Oklahoma Health Care Authority

## Drug Utilization Review Board

**(DUR Board)**

**Meeting – June 11, 2014 @ 4:00 p.m.**

Oklahoma Health Care Authority
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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## 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. Cothran, Dr. Muchmore, Chairman:

2. **Introduction of New Board Member**

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

4. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. May 14, 2014 DUR Minutes – Vote
   B. May 14, 2014 DUR Recommendation Memorandum

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

5. **Update of Medication Coverage Authorization Unit/ FDA Safety Alerts – See Appendix B**
   A. Medication Coverage Activity for May 2014
   B. Pharmacy Help Desk Activity for May 2014
   C. FDA Safety Alerts

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

6. **Utilization Breakdown of Hydrocodone Containing Medications – See Appendix C**
   A. Utilization of Hydrocodone
   B. Utilization Details

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

7. **Action Item – Vote to Prior Authorize Sovaldi™ (Sofosbuvir), Olysio™ (Simeprevir), Victrelis® (Boceprevir), and Incivek® (Telaprevir) – See Appendix D**
   A. COP Recommendations

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

8. **Action Item – Vote to Prior Authorize Trokendi XR™ (Topiramate ER), Aptiom® (Eslicarbazepine Acetate), Qudexy™ XR (Topiramate ER), and Generic Divalproex ER – See Appendix E**
   A. COP Recommendations

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

**9. Annual Review of Triptan Anti-Migraine Medications and 30-Day Notice to Prior Authorize Zecuity® (Sumatriptan Iontophoretic Transdermal System) – See Appendix F**

A. Current Authorization Criteria
B. Utilization of Triptan Anti-Migraine Medications
C. Prior Authorization
D. Market News and Updates
E. Summary
F. COP Recommendations

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

**10. Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Esomeprazole Strontium and Aciphex® Sprinkle™ (Rabeprazole) – See Appendix G**

A. Current Authorization Criteria
B. Utilization of Anti-Ulcer Medications
C. Prior Authorization
D. Market News and Updates
E. Summary
F. COP Recommendations

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

**11. Annual review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Liptruzet™ (Ezetimibe/Atorvastatin) and Omtryg™ (Omega-3-Acid Ethyl Esters A) – See Appendix H**

A. Current Authorization Criteria
B. Utilization of Antihyperlipidemic Medications
C. Prior Authorization
D. Market News and Updates
E. Summary
F. Discussion
G. COP Recommendations

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

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

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

**13. Future Business**

A. Annual Reviews
B. New Product Reviews

Items to be presented by Dr. Muchmore, Chairman:

**14. Adjournment**

# Appendix A

**OKLAHOMA HEALTH CARE AUTHORITY**
**DRUG UTILIZATION REVIEW BOARD MEETING**
**MINUTES OF MEETING OF MAY 14, 2014**

| BOARD MEMBERS: | PRESENT | ABSENT |
|---|---|---|
| Mark Feightner, Pharm.D. | | x |
| Anetta Harrell, Pharm.D. | x | |
| John Muchmore, M.D., Ph.D.; Chairman | x | |
| Paul Louis Preslar, D.O., MBA | x | |
| James Rhymer, D.Ph. | x | |
| Bruna Varalli-Claypool, MHS, PA-C | x | |
| Eric Winegardener, D.Ph. | x | |

| COLLEGE OF PHARMACY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Terry Cothran, D.Ph.; Pharmacy Director | x | |
| Michyla Adams, Pharm.D.; Clinical Pharmacist | x | |
| Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison | x | |
| Bethany Holderread, Pharm. D.; Clinical Coordinator | x | |
| Shellie Keast, Ph.D.; Assistant Professor | x | |
| Carol Moore, Pharm.D.; Clinical Pharmacist | | x |
| Brandy Nawaz, Pharm.D.; Clinical Pharmacist | x | |
| Leslie Robinson, D.Ph.; PA Coordinator | | x |
| Jennifer Sipols, Pharm.D.; Clinical Pharmacist | | x |
| Ashley Teel, Pharm.D.; Clinical Pharmacist | x | |
| Graduate Students: Tim Pham | x | |
| Visiting Pharmacy Student(s): N/A | | |

| | PRESENT | ABSENT |
|---|---|---|
| Marlene Asmussen, R.N.; Population Care Management Director | x | |
| Nico Gomez, Chief Executive Officer | x | |
| Sylvia Lopez, M.D., FAAP; Chief Medical Officer | x | |
| Ed Long, Chief Communications Officer | | x |
| Kelli Brodersen, Marketing Coordinator | x | |
| Nancy Nesser, Pharm.D., J.D.; Pharmacy Director | x | |
| Rebecca Pasternik-Ikard, Deputy State Medicaid Director | | x |
| Lynn Rambo-Jones, J.D.; Deputy General Counsel III | x | |
| Jill Ratterman, D.Ph.; Pharmacy Specialist | x | |
| Garth Splinter, M.D., M.B.A.; Medicaid Director | x | |
| Kerri Wade, Pharmacy Operations Manager | x | |

| OTHERS PRESENT: | | |
|---|---|---|
| Richard Ponder, J & J | Jim Chapman, Abbvie | David Williams, Forest |
| Melvin Nwamadi, Abbott | Joe Summers, UCB | Sharon Jackson, GSK |
| Ron Schnare, Shire | Russ Wilson, Johnson & Johnson | Jeff Frye, Astra Zeneca |
| Mark DeClerk, Lilly | Richard Uhles, Forest | Audrey Rattan, Otsuka |
| Warren Tayes, Merck | Charlene Kaiser, Amgen | Crystal Henderson, Otsuka |
| Brian Maves, Pfizer | Minesh Jariwala, Pfizer | Jim Fowler, Astra Zeneca |
| Rogers Grotzinger, BMS | Kim Greenberg, USL | Clint Degner, Novartis |

| PRESENT FOR PUBLIC COMMENT: | |
|---|---|
| Dr. Carla Schad | Sunovion Pharm |

**AGENDA ITEM NO. 1:** **CALL TO ORDER**

**1A: ROLL CALL**

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

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 2:** **PUBLIC COMMENT FORUM**

**DR. CARLA SCHAD** **AGENDA ITEM NO. 11**

**ACTION: NONE REQUIRED**

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

**3A: APRIL 9, 2014 DUR MINUTES-VOTE**

**3B: APRIL 9, 2014 DUR RECOMMENDATION MEMORANDUM**

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 4:** **VOTE TO CHANGE MEETING TIME AND LOCATION**

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 5:** **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SOONERPSYCH PROGRAM UPDATE**

**5A: MEDICATION COVERAGE ACTIVITY FOR APRIL 2014**

**5B: PHARMACY HELP DESK ACTIVITY FOR APRIL 2014**

**5C: SOONERPSYCH PROGRAM UPDATE**

Materials included in agenda packet; presented by Dr. Holderread

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 6:** **VOTE TO PRIOR AUTHORIZE OPHTHALMIC ANTI-INFLAMMATORIES**

**6A: INTRODUCTION**

**6B: COP RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. Holderread

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 7:** **VOTE TO PRIOR AUTHORIZE LORZONE™ (CHLORZOXAZONE)**

**7A: COP RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. Holderread

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 8:** **VOTE TO PRIOR AUTHORIZE FARXIGA™ (DAPAGLIFLOZIN) AND INVOKANA™ (CANAGLIFLOZIN)**

**8A: COP RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. Teel

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 9:** **VOTE TO PRIOR AUTHORIZE LUZU® (LULICONAZOLE)**

**9A: COP RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. Nawaz

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 10:** **VOTE TO PRIOR AUTHORIZE ZORVOLEX™ (DICLOFENAC) AND TIVORBEX™ (INDOMETHACIN)**

**10A: COP RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. Adams

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

**ACTION: MOTION CARRIED**

**AGENDA ITEM NO. 11:** **ANNUAL REVIEW OF ANTICONVULSANT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TROKENDI XR™ (TOPIRAMATE ER), APTIOM® (ESLICARBAZEPINE ACETATE), AND QUDEXY™ XR (TOPIRAMATE ER)**

**11A: CURRENT PRIOR AUTHORIZATION CRITERIA**

**11B: UTILIZATION OF ANTICONVULSANT MEDICATIONS**

**11C: PRIOR AUTHORIZATION OF ANTICONVULSANT MEDICATIONS**

**11D: MARKET NEWS AND UPDATES**

**11E: COP RECOMMENDATIONS**

**11F: UTILIZATION DETAILS**

**11G: PRODUCT DETAILS**

SPEAKER: Dr. Carla Schad

Materials included in agenda packet; presented by Dr. Adams

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 12:** **30-DAY NOTICE TO PRIOR AUTHORIZE SOVALDI™ (SOFOSBUVIR), OLYSIO™ (SIMEPREVIR), VICTRELIS® (BOCEPREVIR), AND INCIVEK® (TELAPREVIR)**

**12A: INTRODUCTION**
**12B: UTILIZATION OF SOVALDI™ AND OLYSIO™**
**12C: MARKET NEWS AND UPDATES**
**12D: MEDICATION SUMMARIES**
**12E: COP RECOMMENDATIONS**
**12F: UTILIZATION DETAILS**
**12G: PRODUCT DETAILS**

Materials included in agenda packet; presented by Dr. Holderread

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 13:** **FDA AND DEA UPDATES**

Materials included in agenda packet; presented by Dr. Cothran

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 14:** **FUTURE BUSINESS**

**14A: ANNUAL REVIEWS**
**14B: NEW PRODUCT REVIEWS**

Materials included in agenda packet; submitted by Dr. Cothran

**ACTION: NONE REQUIRED**

**AGENDA ITEM NO. 15:** **ADJOURNMENT**

The meeting was adjourned at 5:18 pm.

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

# Memorandum

**Date:** May 15, 2014

**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 May 14, 2014

**Recommendation 1: Vote to Prior Authorize Ophthalmic Anti-Inflammatory Medications**

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends establishing a Product Based Prior Authorization category for ophthalmic NSAIDs and ophthalmic corticosteroids to ensure appropriate cost-effective utilization in accordance with current treatment guidelines. The College of Pharmacy recommends the following tier list and criteria to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Health Care Authority.

In addition the College of Pharmacy will implement an educational initiative consisting of a targeted mailing to all prescribers of ophthalmic anti-inflammatory medications in the SoonerCare population in the previous 12 months. The mailing may include information regarding approval criteria of ophthalmic anti-inflammatory medications and a link to the OHCA web page which will contain the updated tier chart.

**Ophthalmic Non-Steroidal Anti-Inflammatory Drug (NSAIDs) Tier-2 Approval Criteria:**

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication to all lower tiered medications; or
3. A unique indication for which the Tier-1 anti-inflammatories lack.

| Ophthalmic NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) | |
|---|---|
| **Tier-1** | **Tier-2** |
| Voltaren® (diclofenac) Solution 0.1% | Nevanac™ (nepafenac) 0.1% Suspension |
| Acular® (ketorolac) Solution 0.5% | Acuvail® (ketorolac) Solution 0.45% |
| Acular LS ® (ketorolac) Solution 0.4% | Ilevro™ (nepafenac) 0.3 % Suspension |
| Ocufen® (flurbiprofen) Solution 0.03% | Prolensa™ (bromfenac) 0.07% Solution |
| | Bromfenac 0.09% Solution |

**Ophthalmic Corticosteroid Tier-2 Approval Criteria:**

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication to all lower tiered medications; or
3. A unique indication for which the Tier-1 anti-inflammatories lack.

| Ophthalmic Corticosteroids | |
|---|---|
| **Tier-1** | **Tier-2** |
| Dexamethasone Sodium Phosphate Solution 0.1% | Lotemax® (loteprednol) Gel 0.5% |
| Maxidex™ (dexamethasone) Suspension 0.1% | Lotemax® (loteprednol) Ointment 0.5% |
| FML Liquifilm® (fluorometholone) Suspension 0.1% | Pred Forte® (prednisolone Acetate) Suspension 1% |
| Flarex® (fluorometholone) Suspension 0.1% | FML Forte® (fluorometholone) Suspension 0.25% |
| Lotemax® (loteprednol) Suspension 0.5% | FML S.O.P® (fluorometholone) Ointment 0.1% |
| Omnipred® (prednisolone Acetate) Suspension 1% | |
| Durezol® (difluprednate) Emulsion 0.05% | |
| Pred Mild® (prednisolone Acetate) Suspension 0.12% | |
| Prednisolone Sodium Phosphate Solution 1% | |
| Vexol® (rimexolone) Suspension 1% | |

**Recommendation 2: Vote to Prior Authorize Lorzone™ (Chlorzoxazone)**

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Lorzone™ (chlorzoxazone) to the special PA category of the Skeletal Muscle Relaxants Product Based Prior Authorization category. The following criteria will apply:

**Lorzone ™ (Chlorzoxazone) Approval Criteria:**

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone™; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. The following quantity limits apply:
    a. Lorzone™ 375mg tablets: 120 tablets for 30 days
    b. Lorzone™ 750mg tablets: 120 tablets for 30 days

| Skeletal Muscle Relaxants | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Special PA** |
| Cyclobenzaprine (Flexeril®) | Metaxalone (Skelaxin®) | Carisoprodol (Soma®) 350mg |
| Baclofen (Lioresal®) | | Carisoprodol w Aspirin |
| Tizanidine (Zanaflex®) | | Carisoprodol, ASA, Codeine |
| Methocarbamol (Robaxin®) | | Carisoprodol (Soma®) 250mg |
| Chlorzoxazone (Parafon Forte®) | | Tizanidine Capsules (Zanaflex®) |
| Orphenadrine (Norflex®) | | Cyclobenzaprine ER (Amrix®) |
| | | Cyclobenzaprine 7.5mg (Fexmid®) |
| | | Chlorzoxazone (Lorzone™) |

**Recommendation 3: Vote to Prior Authorize Farxiga™ (Dapagliflozin) and Invokana™ (Canagliflozin)**

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Invokana™ and Farxiga™ to Tier-3 of the Anti-Diabetic Product Based Prior Authorization category. The existing criteria for this category will apply. In addition, the College of Pharmacy recommends moving Avandia®, Avandamet®, and Avandaryl® to Tier-3 and Precose® to Tier-1 of the Anti-Diabetic Product Based Prior Authorization category.

| Anti-Diabetic Medications | | | |
|---|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** | **Special PA** |
| **Biaguanides**<br>Metformin (Glucophage®)<br>Metformin SR (Glucophage XR®)<br>Metformin-Glyburide (Glucovance®)<br>Metformin-Glipizide (Metaglip®)<br><br>**Sulfonylureas**<br>Glyburide (Diabeta®)<br>Glyburide Micronized (Micronase®)<br>Glipizide (Glucotrol®)<br>Glipizide SR (Glucotrol XL®)<br>Glimepiride (Amaryl®)<br><br>**Miscellaneous**<br>Chlorpropamide<br>Tolbutamide<br><br>**Alpha-Glucosidase Inhibitors**<br>Acarbose (Precose®) | **DPP-4 Inhibitors**<br>Linagliptin (Tradjenta®)<br>Saxagliptin (Onglyza®)<br>Saxagliptin-Metformin (Kombiglyze®)<br>Sitagliptin (Januvia®)<br>Sitagliptin-Metformin (Janumet®)<br>Sitagliptin-Met ER (Janumet XR®)<br>Sitagliptin-Simvastatin (Juvisync®)<br>Alogliptin-Metformin (Kazano®)<br>Alogliptin (Nesina®)<br>Alogliptin-Pioglitazone (Oseni®)<br><br>**Glinides**<br>Repaglinide-Metformin (Prandimet®)<br>Repaglinide (Prandin®)<br>Nateglinide (Starlix®)<br><br>**GLP-1 Agonists**<br>Liraglutide (Victoza®)<br>Exenatide (Byetta®)<br>Exenatide Qweek (Bydureon®)<br><br>**Thiazolidinediones**<br>Pioglitazone (Actos®) | **DPP-4 Inhibitors**<br>Linagliptin-Metformin (Jentadueto™)<br><br>**Thiazolidinediones**<br>Pioglitazone-Metformin (Actoplus Met®, Actoplus Met XR®)<br>Pioglitazone-Glimepiride (Duetact®)<br><br>**Alpha-Glucosidase Inhibitors**<br>Miglitol (Glyset®)<br><br>**SGLT 2 Inhibitor**<br>Canagliflozin (Invokana™)<br>Dapagliflozin (Farxiga™)<br><br>**Thiazolidinediones**<br>Rosiglitazone (Avandia®)<br>Rosiglitazone-Metformin (Avandamet®)<br>Rosiglitazone-Glimepiride (Avandaryl®) | **Biaguanides**<br>Metformin solution (Riomet®)<br>Metformin Long-Acting (Fortamet®, Glumetza®)<br><br>**Amylinomimetic**<br>Pramlintide (Symlin®) |

**Recommendation 4: Vote to Prior Authorize Luzu® (Luliconazole)**

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of Luzu® (luliconazole) into Tier-2 of the Topical Antifungal Medications PBPA category. The existing criteria for this category will apply.

**Topical Antifungal Tier-2 Approval Criteria:**

1. Documented trials of at least two Tier-1 topical antifungal products within the last 30 days.
2. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

| Topical Antifungal Medications | |
|---|---|
| **Tier-1** | **Tier-2** |
| ciclopirox 0.77% cream | ciclopirox solution, shampoo, & gel (Penlac® and Loprox®), and 0.77% Suspension |
| clotrimazole 1% Rx cream, solution | miconazole/zinc oxide/white petrolatum (Vusion®) |
| econazole 1% cream | oxiconazole (Oxistat®) |
| ketoconazole 2% cream, shampoo | sertaconazole nitrate (Ertaczo®) |
| nystatin cream, ointment | butenafine (Mentax®) |
| clotrimazole 1% cream (OTC)* | ketoconazole gel (Xolegel™) |
| terbinafine 1% cream (OTC)* | Naftifine 1% and 2% cream, 1% and 2% gel (Naftin®) |
| tolnaftate 1% cream (OTC)* | sulconazole (Exelderm®) |
| | ketoconazole foam 2% (Extina®) |
| | nystatin/triamcinolone cream, ointment |
| | clotrimazole/betamethasone 1% and 0.05% cream, lotion |
| | Luliconazole cream 1% (Luzu®) |

*Over the counter antifungal products are covered for pediatric members 0-20 years of age without prior authorization.

**Recommendation 5: Vote to Prior Authorize Zorvolex™ (Diclofenac) and Tivorbex™ (Indomethacin)**

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Tivorbex™, based on the placement of other available indomethacin products, and Zorvolex™ to the Special PA category of the NSAIDs Product Based Prior Authorization category. The existing criteria for this category will apply.

| Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Special PA** |
| Diclofenac potassium (Cataflam®)<br>Diclofenac sodium (Voltaren®)<br>Diclofenac sodium ER (Voltaren® XR)<br>Etodolac (Lodine®)<br>Etodolac ER (Lodine® XL)<br>Flurbiprofen (Ansaid®)<br>Ibuprofen (Motrin®)<br>Ketoprofen (Orudis®)<br>Meclofenamate (Meclomen®)<br>Meloxicam (Mobic®)<br>Nabumetone (Relafen®)<br>Naproxen (Naprosyn®)<br>Naproxen EC (EC-Naprosyn®)<br>Naproxen sodium (Anaprox®)<br>Oxaprozin (Daypro®)<br>Sulindac (Clinoril®)<br>Tolmetin (Tolectin®) | Celecoxib (Celebrex®)<br>Diclofenac /Misoprostol (Arthrotec®)<br>Fenoprofen (Nalfon®) | Diclofenac (Zorvolex™)<br>Diclofenac epolamine patches (Flector®)<br>Diclofenac potassium (Zipsor®)<br>Diclofenac potassium powder packets for oral soln (Cambia®)<br>Diclofenac sodium topical gel (Voltaren® Gel)<br>Diclofenac sodium topical solution (Pennsaid®)<br>Ibuprofen/Famotidine (Duexis®)<br>Indomethacin (Indocin®)<br>Indomethacin (Tivorbex™)<br>Ketoprofen ER (Oruvail®)<br>Mefenamic acid (Ponstel®)<br>Naproxen Sodium (Naprelan®)<br>Naproxen/Esomeprazole (Vimovo®)<br>Piroxicam (Feldene®) |

**Tier-2 Approval Criteria:**

1. Previous use of at least two Tier-1 NSAID products (from different product lines) plus a PPI (proton pump inhibitor) within the last 120 days; or
2. For those with prior GI bleed who must have an NSAID, a Tier-2 product may be approved (Celebrex® should be taken with a PPI).

**Special Prior Authorization Criteria:**

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate, such as the diagnosis of gout for indomethacin; or
2. Previous use of at least two Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product.
4. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why member cannot use other available generic indomethacin products.

**Recommendation 6: Annual Review of Anticonvulsant Medications and 30-Day Notice to Prior Authorize Trokendi XR™ (Topiramate ER), Aptiom® (Eslicarbazepine Acetate), and Qudexy™ XR (Topiramate ER)**

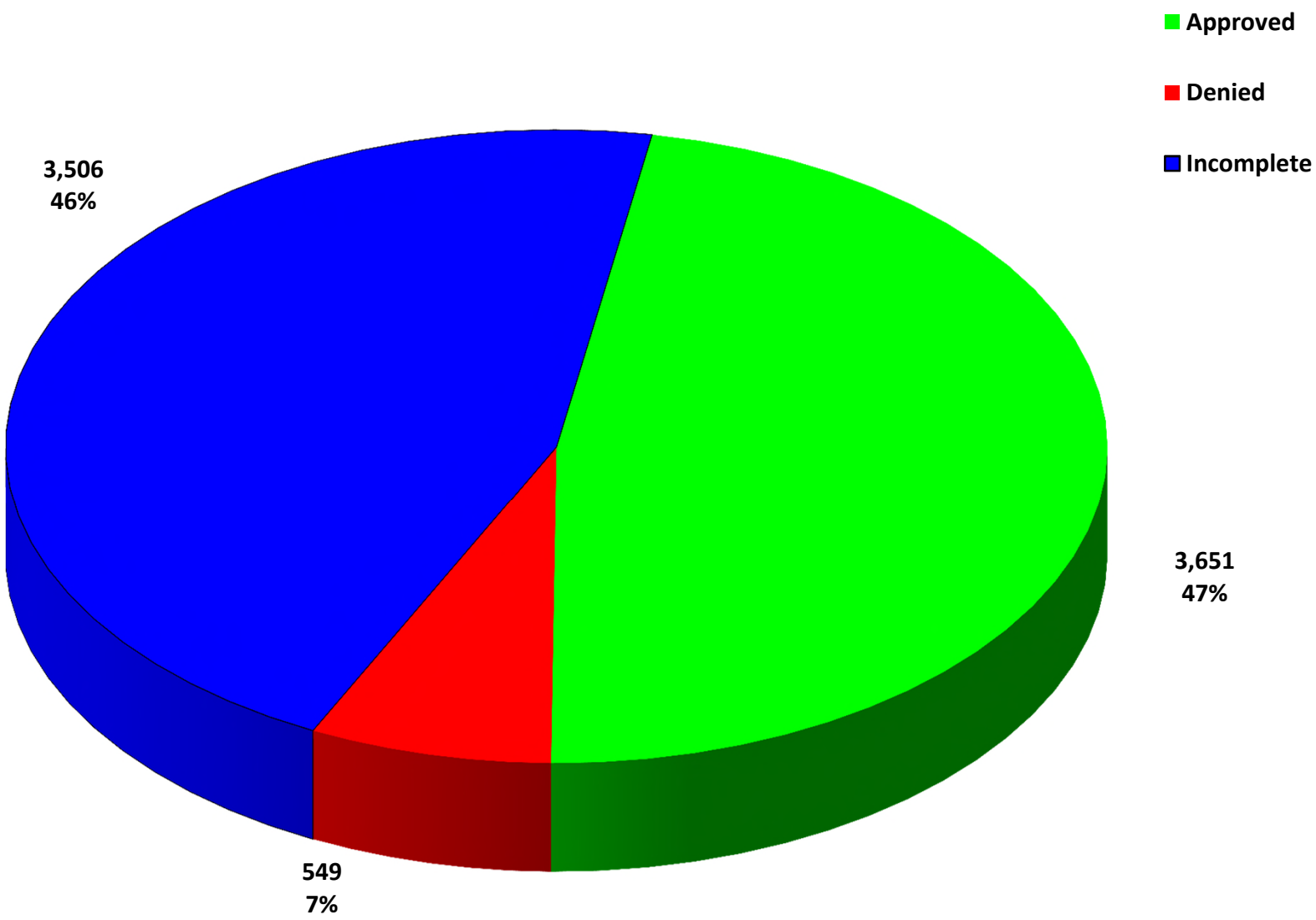
NO ACTION REQUIRED.

**Recommendation 7: 30-Day Notice to Prior Authorize Sovaldi™ (Sofosbuvir), Olysio™ (Simeprevir), Victrelis® (Boceprevir), and Incivek® (Telaprevir)**

NO ACTION REQUIRED.

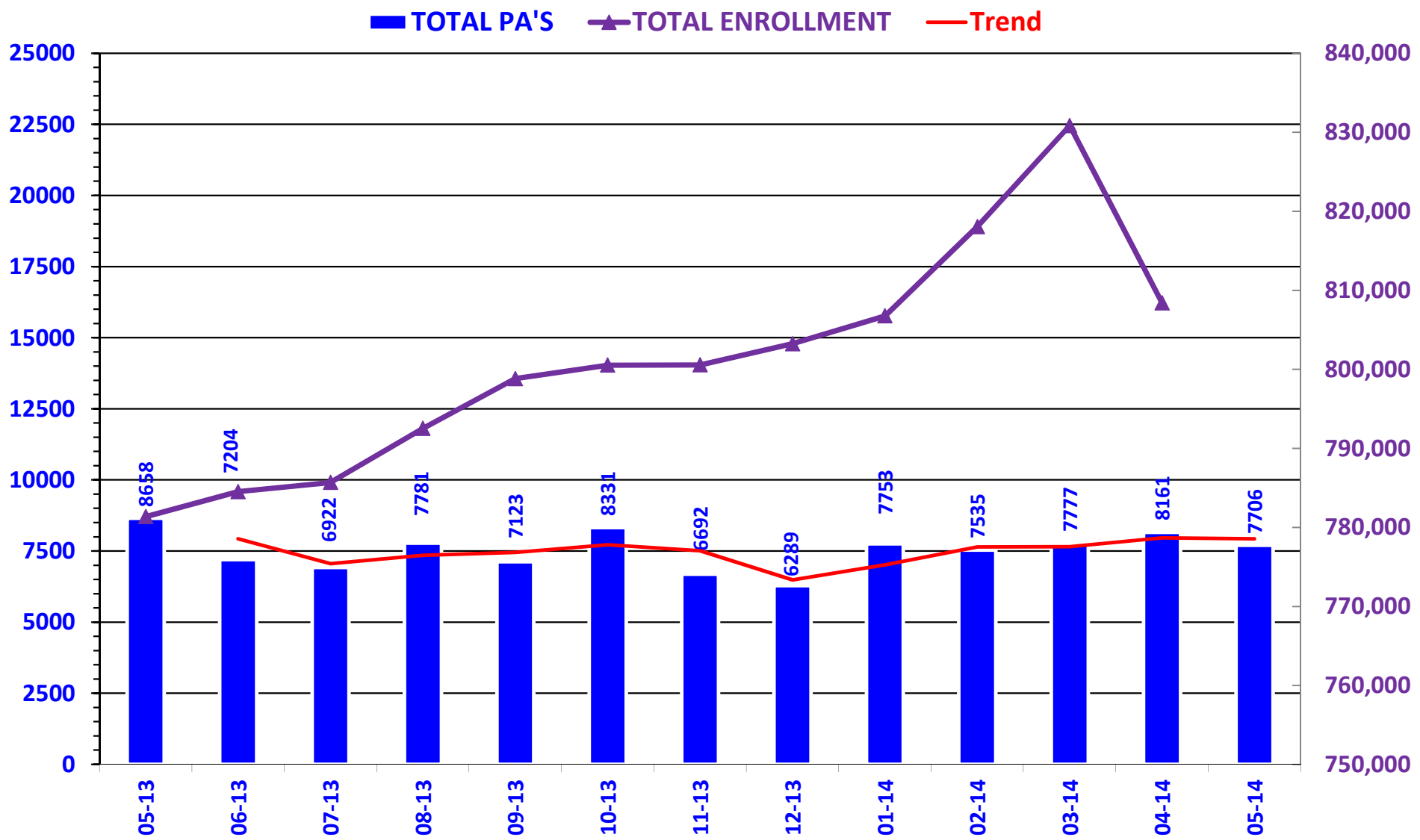
# Appendix B

# PRIOR AUTHORIZATION ACTIVITY REPORT:  MAY



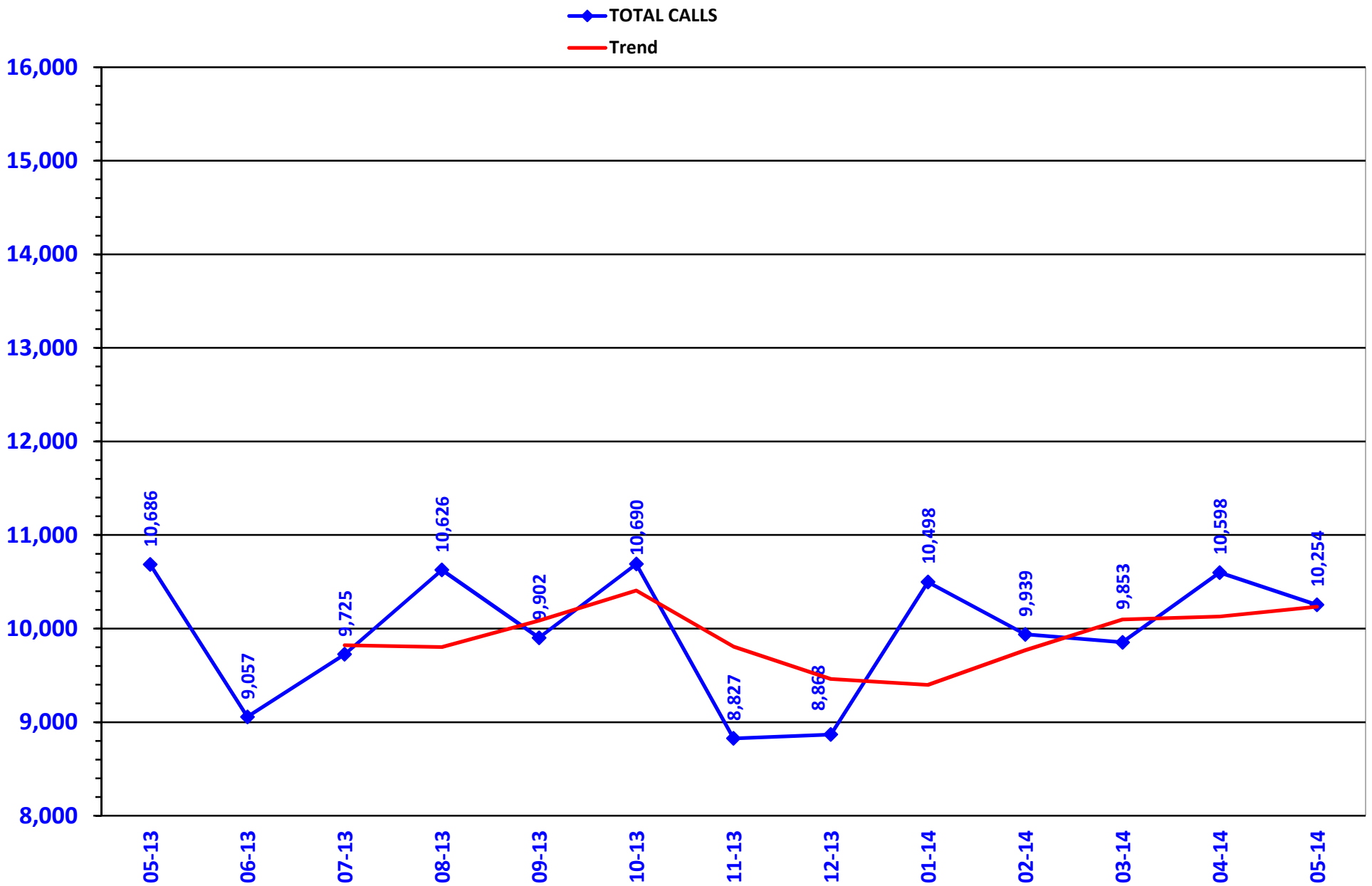

*PA totals include approved/denied/incomplete/overrides*

# PRIOR AUTHORIZATION REPORT: MAY 2013- MAY 2014




*PA totals include approved/denied/incomplete/overrides*

# CALL VOLUME MONTHLY REPORT:
# MAY 2013 – MAY 2014



# Prior Authorization Activity
## 5/1/2014 Through 5/31/2014

| | Total | Approved | Denied | Incomplete | Average Length of Approvals in Days |
|---|---|---|---|---|---|
| Advair/Symbicort/Dulera | 353 | 177 | 3 | 173 | 355 |
| Analgesic - NonNarcotic | 27 | 0 | 1 | 26 | 0 |
| Analgesic, Narcotic | 431 | 201 | 25 | 205 | 238 |
| Angiotensin Receptor Antagonist | 24 | 3 | 6 | 15 | 359 |
| Antiasthma | 193 | 77 | 10 | 106 | 336 |
| Antibiotic | 45 | 10 | 3 | 32 | 152 |
| Anticoagulant | 90 | 59 | 1 | 30 | 341 |
| Anticonvulsant | 89 | 36 | 5 | 48 | 277 |
| Antidepressant | 237 | 60 | 13 | 164 | 346 |
| Antidiabetic | 117 | 68 | 0 | 49 | 358 |
| Antigout | 12 | 6 | 0 | 6 | 359 |
| Antihistamine | 152 | 112 | 6 | 34 | 352 |
| Antihyperlipidemic | 21 | 3 | 5 | 13 | 359 |
| Antimigraine | 73 | 21 | 7 | 45 | 293 |
| Antiplatelet | 22 | 14 | 0 | 8 | 311 |
| Antiulcers | 239 | 54 | 47 | 138 | 209 |
| Antiviral | 11 | 8 | 0 | 3 | 78 |
| Anxiolytic | 79 | 57 | 2 | 20 | 228 |
| Atypical Antipsychotics | 428 | 204 | 12 | 212 | 340 |
| Benign Prostatic Hypertrophy | 13 | 0 | 2 | 11 | 0 |
| Biologics | 68 | 37 | 4 | 27 | 349 |
| Bladder Control | 59 | 4 | 6 | 49 | 359 |
| Botox | 31 | 16 | 2 | 13 | 315 |
| Cardiovascular | 30 | 18 | 2 | 10 | 295 |
| Chronic Obstructive Pulmonary Disease | 18 | 9 | 2 | 7 | 359 |
| Dermatological | 107 | 23 | 37 | 47 | 132 |
| Endocrine & Metabolic Drugs | 61 | 37 | 9 | 15 | 129 |
| Erythropoietin Stimulating Agents | 29 | 15 | 0 | 14 | 93 |
| Fibromyalgia | 172 | 41 | 21 | 110 | 334 |
| Gastrointestinal Agents | 138 | 24 | 15 | 99 | 111 |
| Glaucoma | 12 | 1 | 0 | 11 | 360 |
| Growth Hormones | 53 | 42 | 1 | 10 | 163 |
| HFA Rescue Inhalers | 63 | 22 | 3 | 38 | 343 |
| Insomnia | 62 | 16 | 6 | 40 | 215 |
| Multiple Sclerosis | 56 | 25 | 2 | 29 | 261 |
| Muscle Relaxant | 82 | 23 | 22 | 37 | 34 |
| Nasal Allergy | 95 | 7 | 25 | 63 | 177 |
| Neurological Agents | 73 | 63 | 1 | 9 | 321 |
| Nsaids | 195 | 23 | 23 | 149 | 308 |
| Ocular Allergy | 83 | 20 | 2 | 61 | 227 |
| Ophthalmic Anti-infectives | 17 | 1 | 0 | 16 | 175 |
| Osteoporosis | 27 | 6 | 1 | 20 | 359 |
| Other* | 142 | 15 | 22 | 105 | 265 |
| Otic Antibiotic | 29 | 5 | 1 | 23 | 12 |
| Pediculicide | 89 | 39 | 6 | 44 | 16 |
| Prenatal Vitamins | 17 | 0 | 1 | 16 | 0 |
| Respiratory Agents | 13 | 7 | 2 | 4 | 310 |
| Smoking Cess. | 10 | 1 | 1 | 8 | 87 |
| Statins | 59 | 29 | 4 | 26 | 359 |
| Stimulant | 924 | 396 | 24 | 504 | 330 |
| Suboxone/Subutex | 179 | 133 | 6 | 40 | 77 |
| Testosterone | 67 | 21 | 7 | 39 | 319 |
| Topical Antifungal | 57 | 1 | 10 | 46 | 23 |
| Topical Corticosteroids | 112 | 2 | 17 | 93 | 359 |
| Vitamin | 66 | 20 | 33 | 13 | 350 |
| Pharmacotherapy | 103 | 85 | 0 | 18 | 165 |
| Emergency PAs | 2 | 2 | 0 | 0 | |
| **Total** | **6,056** | **2,399** | **466** | **3,191** | |

* 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 | 43 | 3 | 11 | 215 |
| Cumulative Early Refill | 9 | 9 | 0 | 0 | 169 |
| Dosage Change | 434 | 397 | 1 | 36 | 6 |
| High Dose | 3 | 2 | 0 | 1 | 360 |
| Ingredient Duplication | 76 | 49 | 3 | 24 | 6 |
| Lost/Broken Rx | 97 | 89 | 1 | 7 | 4 |
| NDC vs Age | 7 | 7 | 0 | 0 | 281 |
| Nursing Home Issue | 214 | 167 | 25 | 22 | 7 |
| Other* | 26 | 21 | 0 | 5 | 4 |
| Quantity vs. Days Supply | 659 | 425 | 37 | 197 | 249 |
| STBS/STBSM | 16 | 16 | 0 | 0 | 73 |
| Stolen | 10 | 6 | 2 | 2 | 3 |
| Temporary Unlock | 23 | 18 | 4 | 1 | 20 |
| Third Brand Request | 28 | 12 | 7 | 9 | 20 |
| **Overrides Total** | **1,650** | **1,252** | **83** | **315** | |
| | | | | | |
| **Total Regular PAs + Overrides** | **7,706** | **3,651** | **549** | **3,506** | |

| | |
|---|---|
| **Denial Reasons** | |
| Unable to verify required trials. | 2,885 |
| Lack required information to process request. | 624 |
| Does not meet established criteria. | 531 |
| **Other PA Activity** | |
| Duplicate Requests | 506 |
| Letters | 3,046 |
| No Process | 6 |
| Changes to existing PAs | 445 |
| Helpdesk Initiated Prior Authorizations | 885 |
| PAs Missing Information | 48 |

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

# Retrospective Drug Evaluation: Focusing on Safety

***Overview of FDA Safety Alerts***

# Overview of FDA Safety Alerts

**Oklahoma Health Care Authority**
**June 2014**

## Introduction[1,2,3,4,5,6,7]

The following are recent FDA safety alerts included for the Drug Utilization Review Board's consideration. SoonerCare specific data may be presented where applicable.

| Date | Drug | Issue |
|---|---|---|
| **01/29/2014** | **Topiramate (Topamax®) tablets and sprinkle caps** | **Visual field defects** |
| **Issue Details:** Reports have been issued of patients experiencing visual field defects, independent of elevated intraocular pressure. Effects were reversible upon discontinuation of topiramate.<br>**FDA Recommendations:** The label has been updated to include a warning regarding the risk of visual field defects.<br>**Evaluation:** Generic topiramate immediate-release tablets and capsules were utilized by 7,894 members for a total of 35,983 claims during fiscal year 2013. | | |

| Date | Drug | Issue |
|---|---|---|
| **02/07/2014** | **Boceprevir (Victrelis®)** | **Pancytopenia** |
| **Issue Details:** Post marketing reports in patients who were receiving boceprevir in combination with peginterferon alfa and ribavirin revealed serious cases of pancytopenia including agranulocytosis and thrombocytopenia.<br>**FDA Recommendations:** Complete blood counts should be obtained prior to treatment, and then repeated on weeks 2, 4, 8, and 12, then monitored as deemed appropriate. The Warnings and Precautions section of the package insert has been updated to reflect these changes.<br>**Evaluation:** Review of claims data in calendar year 2013 revealed 44 SoonerCare members with paid fills of Victrelis®. All members were concomitantly receiving peginterferon alfa and ribavirin. Of these 44 members, 4 had a diagnosis of thrombocytopenia, 14 had a diagnosis of anemia, 11 had both thrombocytopenia and anemia, and 15 had no pancytopenia related issues. All diagnoses included in the review occurred either during or after the member received Victrelis® therapy. | | |

| Date | Drug | Issue |
|---|---|---|
| **02/10/2014** | **Eltrombopag (Promacta®)** | **Increased risk of hepatic decompensation in patients with chronic hepatitis C** |

**Issue Details:** An FDA Safety Announcement was issued regarding the use of Promacta® (eltrombopag) in combination with interferon and ribavirin in patients with chronic hepatitis C. Patients on this combination of therapy with chronic hepatitis C are at an increased risk of hepatic decompensation.
**FDA Recommendations:** The Warning and Precautions section of the label has been updated to include the risk of decompensation.
**Evaluation:** A review of pharmacy claims in 2014 revealed 7 SoonerCare members utilizing Promacta®. Claims history did not indicate any of those members to have been hospitalized with decompensation issues.

| Date | Drug | Issue |
|---|---|---|
| **03/06/2014** | **Doripenem (Doribax®)** | **Increased risk of death & lower clinical cure rates** |

**Issue Details:** An FDA Safety Announcement was issued regarding Doribax® (doripenem), a carbepenam antibiotic. The FDA warned when Doribax® was used to treat patients who developed pneumonia while on a ventilator, Doribax® carried an increased risk of death and lower clinical cure rates compared to use of imipenem and cilastatin. This safety information is based on an FDA analysis of data from a three-year clinical trial that was prematurely stopped in 2011 due to these safety concerns.
**FDA Recommendations:** The Warning and Precautions section of the label includes a new warning regarding this unapproved use. Doribax® has not been approved to treat any type of pneumonia.
**Evaluation:** A review of pharmacy claims revealed two SoonerCare members in 2012 who were administered Doribax®. One member did receive Doribax® for a diagnosis of pneumonia; it is unknown if this member was utilizing a ventilator. In 2013, one member was treated with Doribax® for a non-pneumonia related diagnosis.

| Date | Drug | Issue |
|---|---|---|
| **3/31/2014** | **Sildenafil (Revatio®)** | **Pediatric use for pulmonary arterial hypertension (PAH)** |

**Issue Details:** The FDA clarified its previous recommendation related to prescribing Revatio® (sildenafil) for children with pulmonary arterial hypertension (PAH). Sildenafil is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient.
**FDA Recommendations:** The evidence behind the FDA initial recommendation has not changed. The communication was intended to clarify the strength of the warning in the Revatio® drug label.
**Evaluation:** In calendar year 2013, there were 82 SoonerCare members (45 males and 37 females) under the age of 21 who had paid claims for sildenafil. Prescribers listed on these claims for sildenafil were cardiologists, pediatricians, and pulmonologists.

| Date | Drug | Issue |
|---|---|---|
| **04/13/2014** | **Opioid Analgesics** | **Increase in number of prescriptions for pregnant women** |

**Issue Details:** A recent article in the *New York Times* discussed the increasing number of prescriptions being written for pregnant women. The article cited a study published in the *Journal of Obstetrics & Gynecology* in March that reported an increase in prescriptions written for women enrolled in Medicaid. The prescriptions were said to have increased from 18.5% in 2000 to nearly 23% in 2007; Medicaid covers approximately 45% of births in the United States. An additional study of privately insured women published in *Anesthesia* in February found that 14% used opioid analgesics at least once during pregnancy. The article cited increasing evidence that opioid analgesic use in the first trimester may be associated with neural tube defects. Additionally, there are concerns that use of opioid analgesics at the end of pregnancy can lead to addiction in infants, or "neonatal abstinence syndrome". The article described discomfort associated with pregnancy often being the reason for the opioid prescription, even though other alternatives such as acetaminophen or physical therapy may be more appropriate.
**Evaluation:** A review of available claims data from January 1, 2014 to April 23, 2014 revealed 14.8% of pregnant SoonerCare members received a prescription for an opioid analgesic, and opioid analgesic claims accounted for 32.6% of the prescriptions filled by pregnant women.

| Date | Drug | Issue |
|---|---|---|
| **05/01/2014** | **Rilpivirine (Edurant®)** | **Reduced plasma concentrations** |

**Issue Details:** Rifampin and rifapentine have been found to significantly decrease Edurant® (rilpivirine) plasma levels. Edurant® is an antiretroviral medication used for the treatment of HIV.
**FDA Recommendations:** The Edurant® label has been updated to include a contraindication for co-administration with rifampin or rifapentine. The dose of Edurant® should be increased from 25mg/day to 50mg/day when Edurant® is co-administered with rifabutin.
**Evaluation:** Review of pharmacy claims history only revealed one SoonerCare member on Edurant® since its approval in 2011. There was no concurrent use of any of the drugs in question with Edurant®.

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[1] FDA Drug Safety Communication (topiramate) available online at: - http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm195797.htm Last revised: 2/11/2014. Last accessed: 5/7/2014.
[2] Drug Safety Communication (boceprevir) available online at http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm303600.htm Last revised: 3/19/2014. Last accessed: 5/7/2014.
[3] FDA Drug Safety Communication (eltrombopag) available online at http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm207394.htm Last revised: 3/27/2014. Last accessed: 5/7/2014.
[4] FDA Drug Safety Communication (doripenem) available online at: http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm388328.htm Last revised: 3/6/2014. Last accessed: 5/7/2014.
[5] FDA Drug Safety Communication (sildenafil) available online at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm391152.htm Last revised: 3/31/2014. Last accessed: 5/7/2014.
[6] Saint Louis, Catherine. "Surge in Narcotic Prescriptions for Pregnant Women." *New York Times* April 2013. Web. May 7 2014.
[7] Label revision (rilpivirine) available online at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist Last revised: 5/1/2014. Last accessed: 5/5/2014.

# Appendix C

# Utilization Breakdown of Hydrocodone Containing Medications

**Oklahoma Health Care Authority**
**June 2014**

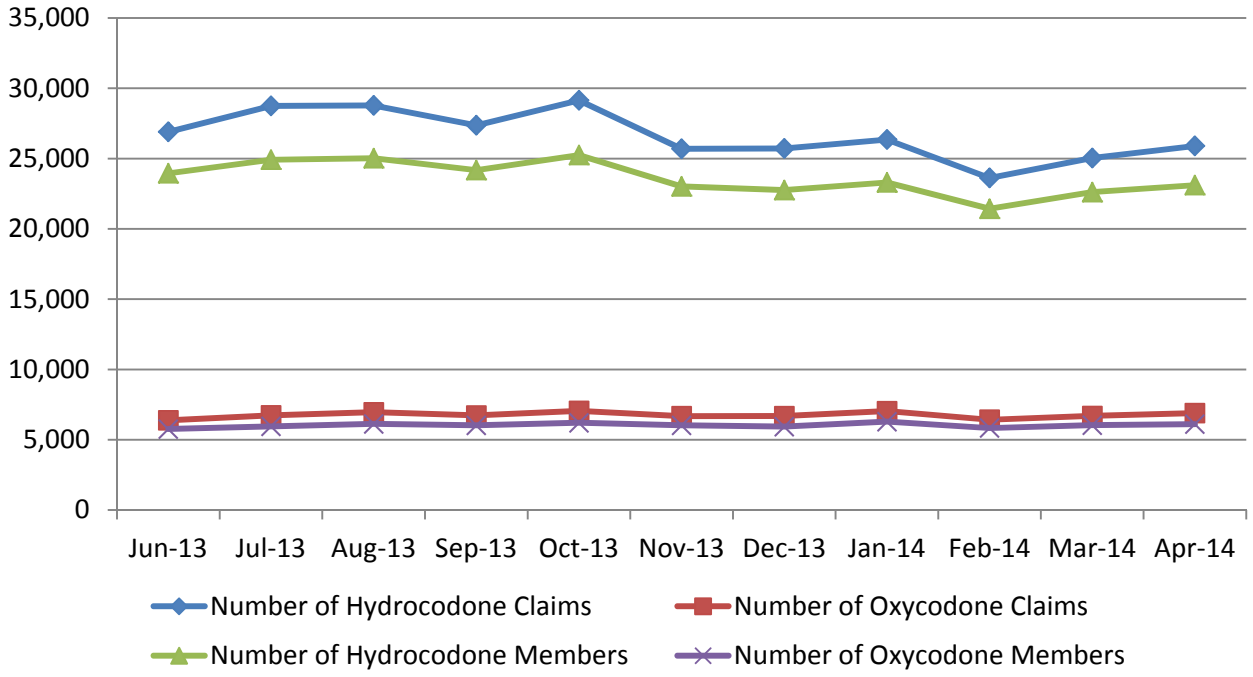
## Utilization of Hydrocodone Containing Medications

### Comparison of Calendar Years

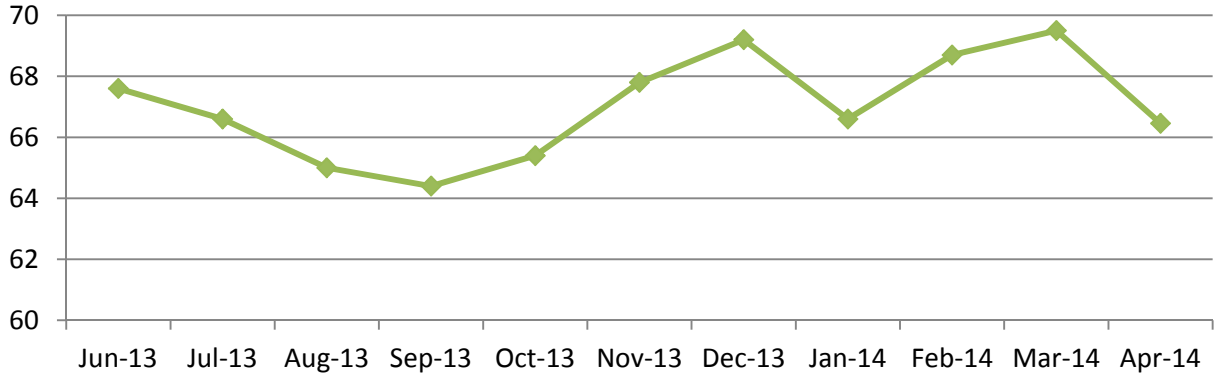
| Calendar Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days | Units/ Claim |
|---|---|---|---|---|---|---|---|---|
| **2012** | 112,874 | 344,881 | $4,642,126.58 | $13.46 | $0.88 | 22,959,947 | 5,265,633 | 66.57 |
| **2013** | 108,442 | 331,620 | $4,643,673.28 | $14.00 | $0.89 | 22,269,394 | 5,216,475 | 67.15 |
| **% Change** | **-3.90%** | **-3.80%** | **0.00%** | **4.00%** | **1.10%** | **-3.00%** | **-0.90%** | **0.87%** |
| **Change** | **-4,432** | **-13,261** | **$1,546.70** | **$0.54** | **$0.01** | **-690,553** | **-49,158** | **0.58** |

*Total number of unduplicated members

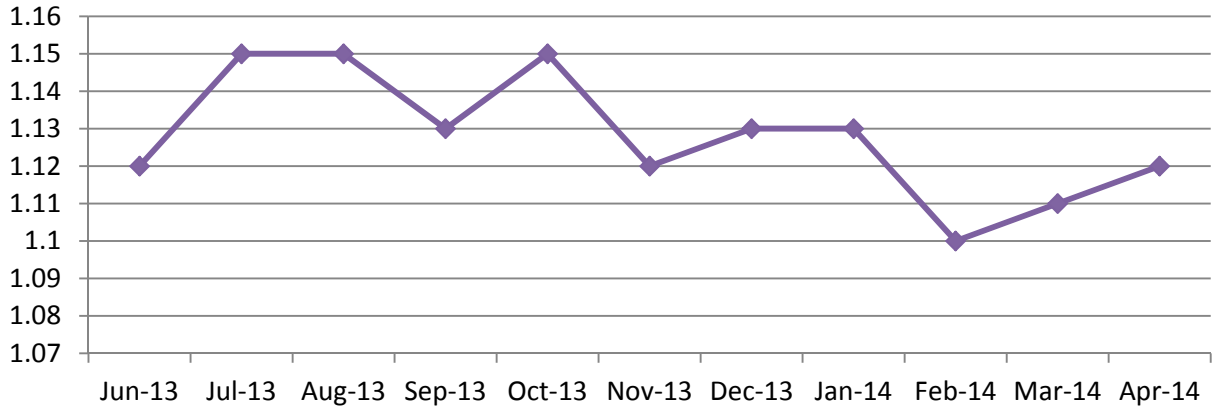
### Number of Claims Per Month: June 2013-April 2014



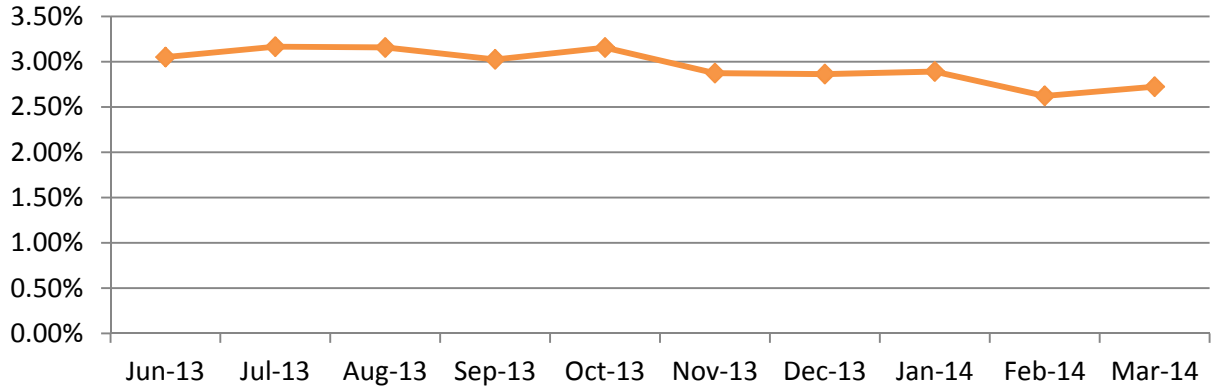
**Number of Units Per Claim: June 2013-April 2014**



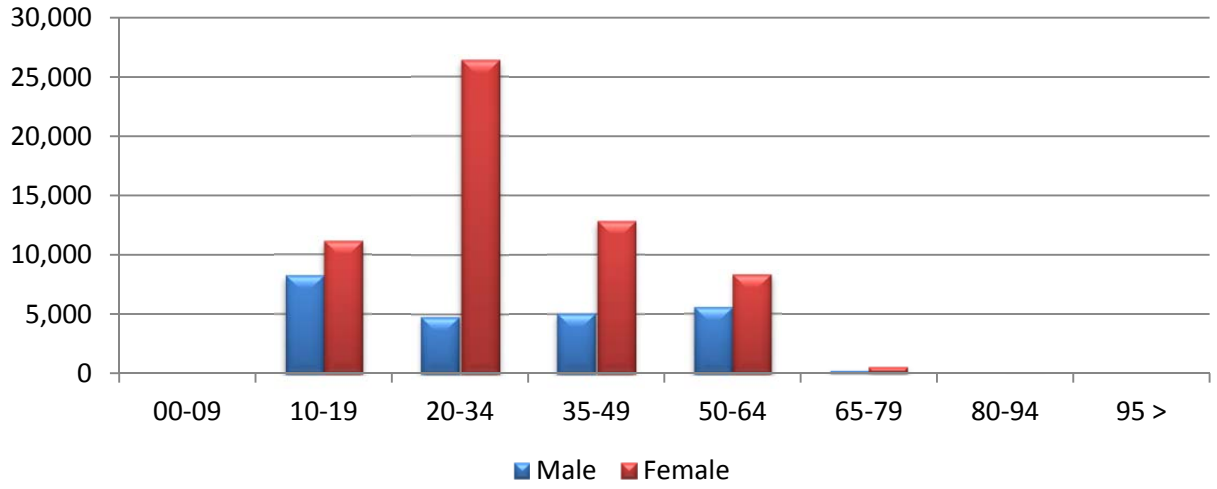

**Number of Claims Per Member: June 2013-April 2014**



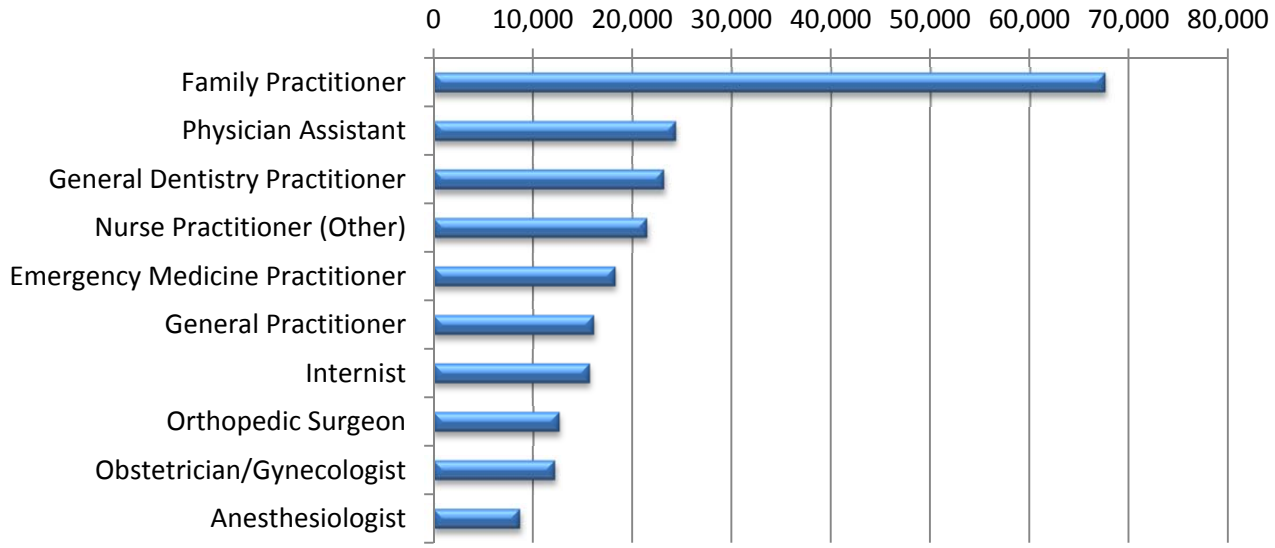

**Percent of Total Members: June 2013-March 2014**



**Demographics of Members Utilizing Solid Dosage Forms of Hydrocodone Containing Products**




**Top Prescriber Specialties of Hydrocodone Containing Products by Number of Claims**



## Utilization Details of Hydrocodone Containing Medications: June 2013 - April 2014

| Product Utilized | Total Claims | Total Members | Total Cost | Claims/ Member | Units/ Day | Hydrocodone MG/Day |
|---|---|---|---|---|---|---|
| **Hydrocodone/Acetaminophen Tablets** | | | | | | |
| HYDROCO/APAP TAB 10-325MG | 74,540 | 19,756 | $1,366,348.65 | 3.77 | 3.92 | 39.20 MG |
| HYDROCO/APAP TAB 7.5-325MG | 65,370 | 32,782 | $809,816.24 | 1.99 | 3.60 | 27.00 MG |
| HYDROCO/APAP TAB 5-325MG | 45,997 | 31,322 | $431,128.74 | 1.47 | 4.01 | 20.05 MG |
| HYDROCO/APAP TAB 7.5-500MG | 35,854 | 19,478 | $280,359.12 | 1.84 | 3.35 | 25.12 MG |
| HYDROCO/APAP TAB 10-500MG | 35,485 | 10,209 | $690,218.06 | 3.48 | 3.65 | 36.50 MG |
| HYDROCO/APAP TAB 5-500MG | 18,197 | 13,341 | $96,922.31 | 1.36 | 3.51 | 17.55 MG |
| HYDROCO/APAP TAB 10-650MG | 1,115 | 367 | $13,509.74 | 3.04 | 3.51 | 35.10 MG |
| HYDROCO/APAP TAB 7.5-650MG | 771 | 428 | $4,559.48 | 1.80 | 3.18 | 23.85 MG |
| HYDROCO/APAP TAB 2.5-500MG | 269 | 149 | $3,641.45 | 1.81 | 2.92 | 7.30 MG |
| HYDROCO/APAP TAB 7.5-750MG | 160 | 99 | $1,134.50 | 1.62 | 3.14 | 23.55 MG |
| HYDROCO/APAP TAB 5-300MG | 13 | 9 | $1,226.99 | 1.44 | 3.05 | 15.25 MG |
| VICODIN TAB 5-300MG | 6 | 4 | $811.72 | 1.50 | 4.88 | 24.40 MG |
| HYDROCO/APAP TAB 7.5-300 MG | 7 | 7 | $299.22 | 1.00 | 4.53 | 33.98 MG |
| HYDROCO/APAP TAB 10-660MG | 6 | 2 | $98.03 | 3.00 | 2.18 | 21.80 MG |
| HYDROCO/APAP TAB 10-300MG | 4 | 4 | $886.15 | 1.00 | 3.75 | 37.50 MG |
| VICODIN HP TAB 10-300MG | 3 | 1 | $730.71 | 3.00 | 6.00 | 60.00 MG |
| HYDROCO/APAP TAB 10-750MG | 1 | 1 | $34.84 | 1.00 | 2.00 | 20.00 MG |
| **Subtotal** | **277,798** | **88,287** | **$3,701,725.95** | **3.15** | **3.74** | **NA** |
| **Hydrocodone/Acetaminophen Liquids** | | | | | | |
| HYDROCO/APAP SOL 7.5-500MG | 6,984 | 5,986 | $60,845.80 | 1.17 | 30.52 | 15.26 MG |
| HYDROCO/APAP SOL 7.5-325MG | 5,063 | 4,570 | $231,540.09 | 1.11 | 29.61 | 14.81 MG |
| LORTAB ELX 7.5-500MG | 18 | 17 | $798.47 | 1.06 | 40.37 | 20.19 MG |
| LORTAB ELX 10-300MG | 8 | 7 | $511.05 | 1.14 | 13.19 | 8.79 MG |
| HYDROCO/APAP SOL 7.5-500MG | 1 | 1 | $4.90 | 1 | 62.00 | 31.00 MG |
| **Subtotal** | **12,074** | **10,317** | **$293,700.31** | **1.17** | **30.12** | **NA** |
| **Hydrocodone/Ibuprofen Tablets** | | | | | | |
| HYDROCOD/IBU TAB 7.5-200MG | 3,016 | 1,561 | $51,343.54 | 1.93 | 3.29 | 24.68 MG |
| IBUDONE TAB 10-200MG | 194 | 43 | $18,969.01 | 4.51 | 3.63 | 36.30 MG |
| HYDROCOD/IBU TAB 10-200MG | 81 | 31 | $6,911.23 | 2.61 | 3.55 | 35.50 MG |
| IBUDONE TAB 5-200MG | 65 | 41 | $2,784.69 | 1.59 | 3.08 | 15.40 MG |
| HYDROCOD/IBU TAB 5-200MG | 59 | 43 | $6,620.16 | 1.37 | 3.35 | 16.75 MG |
| HYDROCOD/IBU TAB 2.5-200MG | 25 | 17 | $2,690.16 | 1.47 | 2.46 | 6.15 MG |
| REPREXAIN TAB 10-200MG | 5 | 2 | $521.46 | 2.50 | 3.60 | 36.00 MG |
| **Subtotal** | **3,445** | **1,695** | **$89,840.25** | **2.03** | **3.32** | **NA** |
| **Total** | **293,317** | **98,834*** | **$4,085,266.51** | **2.97** | **4.17** | **NA** |

*Total number of unduplicated members.

# Appendix D

# Vote to Prior Authorize Sovaldi™ (Sofosbuvir), Olysio™ (Simeprevir), Victrelis® (Boceprevir), and Incivek® (Telaprevir)

**Oklahoma Health Care Authority**
**June 2014**

## Recommendations

The coverage of hepatitis C treatments will be updated as new medications and clinical guidelines become available.

The College of Pharmacy recommends the prior authorization of Sovaldi™ (sofosbuvir), Olysio™ (simeprevir), Victrelis® (boceprevir), and Incivek® (telaprevir) with the following criteria:

**Sovaldi™ (Sofosbuvir) Approval Criteria:**

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) with a METAVIR fibrosis score of F2 or greater; and
3. Sovaldi™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
4. Sovaldi™ must be used as a component of a combination regimen; and
5. Member must be eligible for ribavirin (RBV) therapy. Approvals will not be granted for regimens without RBV; and
6. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
7. The following regimens and requirements based on genotype will apply:
    a. Genotype 1:
        i. Triple therapy: Sovaldi™ + Pegylated Interferon (PEG-IFN) + RBV x 12 weeks
        ii. Members who are PEG-IFN ineligible may be approved for total treatment duration of 24 weeks with a patient-specific, clinically significant reason why member cannot use PEG-IFN.
    b. Genotype 2:
        i. Dual therapy: Sovaldi™ + RBV x 12 weeks
    c. Genotype 3:
        i. Dual therapy: Sovaldi™ + RBV x 24 weeks
    d. Genotype 4:
        i. Triple therapy: Sovaldi™ + PEG-IFN + RBV x 12 weeks
    e. Hepatocellular Carcinoma:
        i. Dual therapy: Sovaldi™ + RBV x 48 weeks or until time of liver transplant (whichever occurs first)
        ii. Approvals will only be granted for HCV infected members (regardless of genotype) with hepatocellular carcinoma meeting the MILAN criteria (MILAN

criteria defined as presence of a tumor 5cm or less in diameter in patients with single hepatocellular carcinomas and not more than three tumor nodules, each 3cm or less in diameter in patients with multiple tumors and no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor).

8. Member must sign consent/intent to treat contract; and
9. Member must have no illicit IV drug use or alcohol abuse in the last 6 months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
10. Must have documentation of immunization with the hepatitis A and B vaccines; and
11. Member must not have decompensated hepatic disease (Child Turcotte Pugh (CTP) class B or C); and
12. Female members must have a pregnancy test immediately prior to therapy initiation. Female partners of male patients should also be checked for pregnancy for informational purposes. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy and for 6 months after therapy completion; and
13. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine or St. John's wort; and
14. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease.
15. Members must be adherent for continued approval. Treatment gaps of therapy longer than 7 days/month will result in denial of subsequent requests for continued therapy.

**Olysio™ (Simeprevir) Approval Criteria:**

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic Hepatitis C (genotype 1) with a METAVIR fibrosis score of F2 or greater; and
3. HCV genotype testing must be confirmed and indicated on prior authorization request; and
4. Members with genotype 1a must be screened for the NS3 Q80K polymorphism prior to initiation of therapy. Approvals will not be granted for members with this polymorphism; and
5. Olysio™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
6. Olysio™ must be used as a component of a combination regimen.
    a. Olysio™ will be approved for combination therapy only.
    b. Triple therapy: Olysio™ + RBV + PEG-IFN x 12 weeks
    c. After completion of Olysio™ therapy member must continue on RBV and PEG-IFN therapy for
        i. an additional 12 weeks for treatment naïve patients

ii. an additional 36 weeks for previously treated, now relapsed members, including those with cirrhosis

7. Member must not have previously failed treatment with a hepatitis C protease inhibitor (non-responder or relapsed); and
8. Member must not have decompensated hepatic disease (CTP class B or C); and
9. Member must sign consent/intent to treat contract; and
10. Member must have no illicit IV drug use or alcohol abuse in the last 6 months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
11. Must have documentation of immunization with the hepatitis A and B vaccines; and
12. Female members must have a pregnancy test immediately prior to therapy initiation. Female partners of male patients should also be checked for pregnancy for informational purposes. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy and for 6 months after therapy completion; and
13. Member must not be taking the following medications: efavirenz, delavirdine, etravirine, nevirapine, ritanovir and any HIV protease inhibitor (boosted or not by ritanovir), rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, didanosine, milk thistle, or St. John's wort; and
14. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity weight management, severe concurrent medical diseases such as but not limited to retinal disease or autoimmune thyroid disease.
15. Members must be adherent for continued approval. Treatment gaps of therapy longer than 7 days/month will result in denial of subsequent requests for continued therapy.

**Victrelis® (Boceprevir) and Incivek® (Telaprevir) Approval Criteria:**

1. Use of Victrelis® or Incivek® requires a patient-specific, clinically significant reason why the member cannot use Olysio™ (simeprevir).

# Appendix E

# Vote to Prior Authorize Trokendi XR™ (Topiramate ER), Aptiom® (Eslicarbazepine Acetate), Qudexy™ XR (Topiramate ER), and Generic Divalproex ER

**Oklahoma Health Care Authority**
**June 2014**

## Recommendations

The College of Pharmacy recommends the prior authorization of Trokendi XR™ (topiramate extended-release), Aptiom® (eslicarbazepine acetate), Qudexy™ XR (topiramate extended-release), and generic divalproex extended-release with the following criteria:

1. **Trokendi XR™ (Topiramate Extended-Release) Approval Criteria:**
    a. An FDA approved diagnosis of partial onset or primary generalized tonic-clonic seizures or as adjunctive therapy in seizures associated with Lennox-Gastaut syndrome; and
    b. A patient specific, clinically significant reason why member cannot use the short-acting formulation, Topamax® (topiramate).
    c. A quantity limit of 30 per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 per 30 days on the higher strength capsules (200mg).
2. **Aptiom® (Eslicarbazepine Acetate) Approval Criteria:**
    a. An FDA approved diagnosis of partial-onset seizures as adjunctive therapy; and
    b. Member must be on current antiepileptic drug therapy (Aptiom® is only indicated for adjunctive treatment); and
    c. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
    d. A patient specific, clinically significant reason why member cannot use oxcarbazepine.
    e. A quantity limit of 30 per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 per 30 days on the higher strength tablets (600mg and 800mg).
3. **Qudexy™ XR (Topiramate Extended-Release) Approval Criteria:**
    a. An FDA approved diagnosis of partial onset or primary generalized tonic-clonic seizures or as adjunctive therapy in seizures associated with Lennox-Gastaut syndrome; and
    b. A patient specific, clinically significant reason why member cannot use the short-acting formulation, Topamax® (topiramate).
    c. A quantity limit of 30 per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 per 30 days on the higher strength capsules (150mg and 200mg).
4. **Divalproex Extended-Release Approval Criteria:**
    a. Generic divalproex ER will require a patient-specific, clinically significant reason why member cannot use brand name Depakote® ER.
    b. Brand name Depakote® ER will be the preferred product and will not require prior authorization.

# Appendix F

# Fiscal Year 2013 Annual Review of Triptan Anti-Migraine Medications and 30-Day Notice to Prior Authorize Zecuity® (Sumatriptan Iontophoretic Transdermal System)

**Oklahoma Health Care Authority**
**June 2014**

## Current Prior Authorization Criteria

| Triptan Anti-Migraine Medications | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** |
| Sumatriptan (Imitrex®) | Naratriptan (Amerge®) | Almotriptan (Axert®)<br>Eletriptan (Relpax®)<br>Frovatriptan (Frova®)<br>Rizatriptan (Maxalt®, Maxalt MLT®)<br>Sumatriptan (Sumavel® DosePro®)*<br>Sumatriptan/Naproxen (Treximet®)<br>Zolmitriptan (Zomig®, Zomig-ZMT®) |

*Requires a clinically significant reason why member cannot use all other available formulations of sumatriptan.

**Triptan Anti-Migraine Medication Tier-2 Approval Criteria:**

1. A trial of all available Tier-1 products with inadequate response; or
2. Documented adverse effect to all available Tier-1 products; or
3. Previous success with a Tier-2 product within the last 60 days.

**Triptan Anti-Migraine Medication Tier-3 Approval Criteria:**

1. A trial of all available Tier-2 products with inadequate response; or
2. Documented adverse effect to all available Tier-2 products; or
3. Previous success with a Tier-3 product within the last 60 days.

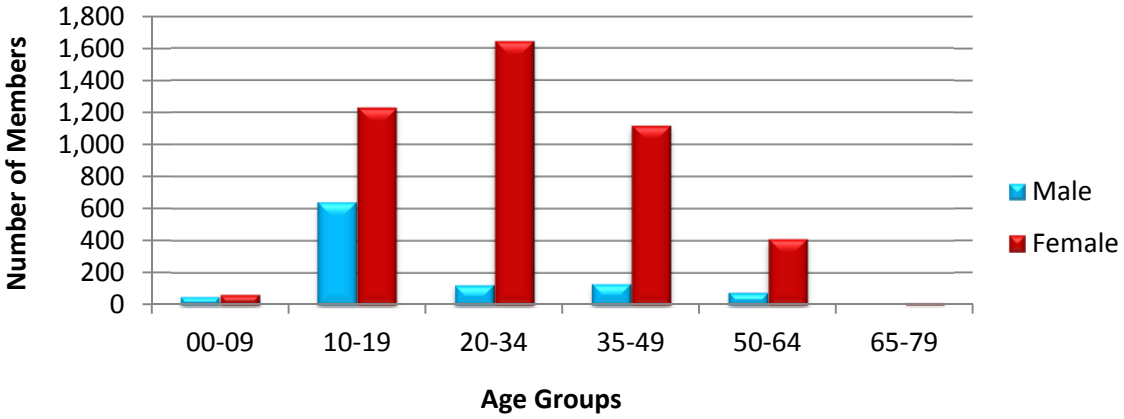
## Utilization of Triptan Anti-Migraine Medications

### Comparison of Fiscal Years

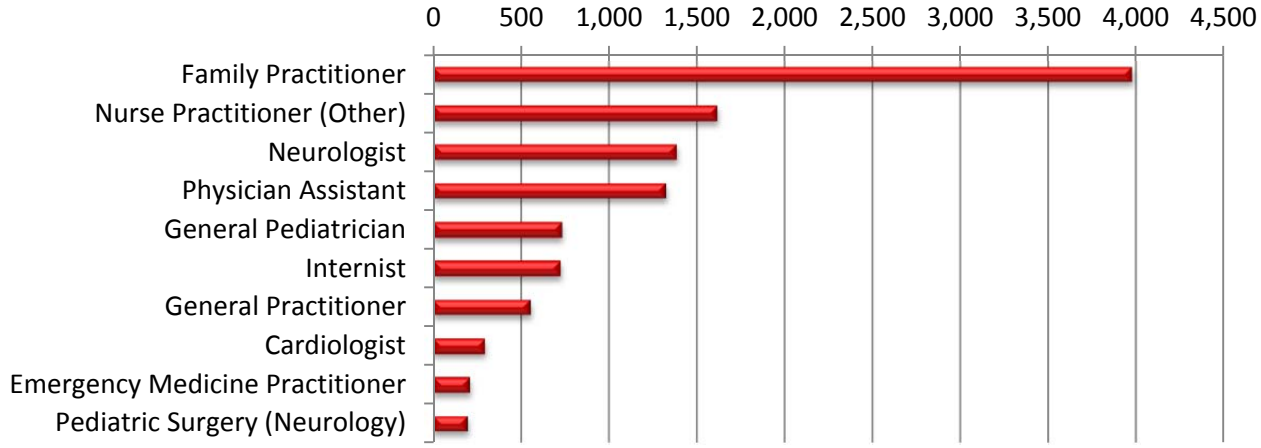
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2012** | 5,149 | 11,059 | $562,113.72 | $50.83 | $3.03 | 111,129 | 185,650 |
| **2013** | 5,548 | 11,705 | $540,635.91 | $46.19 | $2.85 | 117,293 | 189,524 |
| **% Change** | **7.70%** | **5.80%** | **-3.80%** | **-9.10%** | **-5.90%** | **5.50%** | **2.10%** |
| **Change** | **399** | **646** | **-$21,477.81** | **-$4.64** | **-$0.18** | **6,164** | **3,874** |

*Total number of unduplicated members.

**Demographics of Members Utilizing Triptan Anti-Migraine Medications**



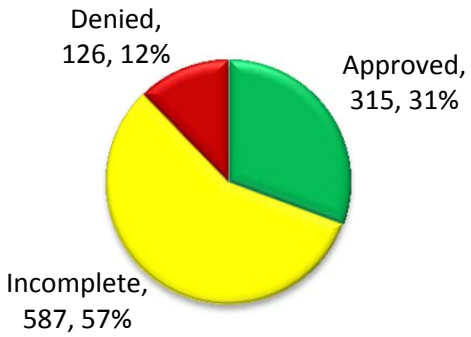

**Top Prescriber Specialties of Triptan Anti-Migraine Medications By Number of Claims**




## Prior Authorization of Triptan Anti-Migraine Medications

There was a total of 1,028 petitions submitted for the triptan anti-migraine medication category during fiscal year 2013. Computer edits are in place to detect Tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

**Status of Petitions**



## Market News and Updates[1, 2,3,4,5, 6]

**Anticipated Patent Expirations:**

- Axert® (almotriptan tablets)- 11/2015
- Frova® (frovatriptan tablets)- 11/2015
- Relpax® (eletriptan tablets)- 8/2017
- Treximet® (sumatriptan/naproxen tablets)- 10/2025
- Sumavel® DosePro® (sumatriptan needle-free injection)- 11/2026

**New Medications, Strengths, and Indications:**
In February 2013, Maxalt® tablets and Maxalt MLT® orally disintegrating tablets (ODTs) became available as generic products. State maximum allowable cost (SMAC) pricing was applied to generic rizatriptan tablets and ODTs in October 2013.

In September 2013, a new strength of Zomig® nasal spray, 2.5mg per actuation, was approved by the FDA and became available on the market in November 2013. This is in addition to the 5mg per actuation nasal spray and the 2.5mg and 5mg tablets and ODTs. Generic zolmitriptan is currently available in the tablet and ODT formulations.

In March 2014, the FDA approved Topamax® (topiramate) for the prevention of migraine headaches in adolescents ages 12 to 17 years. This is the first FDA approval of a medication for migraine prevention in this age group. Topiramate is recommended to be taken on a daily basis to reduce the frequency of migraine headaches. Topamax® was first approved by the FDA in 1996 to prevent seizures, and was approved for migraine prevention in adults in 2004.

In January 2013 NuPathe Inc. received FDA approval for Zecuity® which supplies sumatriptan in a novel delivery system. Zecuity® (sumatriptan iontophoretic transdermal system) is a single-use, battery-powered patch that is applied to the upper arm or thigh during a migraine and actively delivers 6.5mg of sumatriptan through the skin over a four-hour dosing period. Zecuity® uses an electric current to pull ionized drug particles through the skin while monitoring the skin's resistance to the transfer of sumatriptan during the four-hour dosing period. In late 2013, NuPathe Inc. delayed the launch of Zecuity® as it continued to seek a marketing partner. This extended NuPathe's previous goal of launch into the market by the end of 2013, to a hopeful launch by early 2014. Teva Pharmaceutical Industries Ltd. entered into a definitive agreement in January 2014 to acquire NuPathe Inc., including Zecuity®. Zecuity® is not yet available on the market.

## Zecuity® (Sumatriptan Iontophoretic Transdermal System)[7,8,9,10,11]

**Indications:** Zecuity® (sumatriptan) is indicated for the acute treatment of migraine with or without aura in adults. Zecuity® is indicated for use only after a clear diagnosis of migraine has been established, and is not indicated in the prevention of migraine attacks.

**Dosing:** Zecuity® is available as an iontophoretic transdermal system (TDS) that delivers 6.5mg of sumatriptan over 4 hours. The recommended dosage for the acute treatment of migraine is a single Zecuity® TDS applied to dry, intact, non-irritated skin of the upper arm or thigh. No more than two Zecuity® TDS should be used in any 24 hour period. The second Zecuity® TDS should be used no sooner than 2 hours after activation of the first transdermal system. Zecuity® should not be applied to a previous application site until that site remains erythema free for at least 3 days. The safety of using more than four Zecuity® TDS in one month has not been established.

**Mechanism of Action:** Zecuity® (sumatriptan) is a serotonin 5-$HT_{1B/1D}$ receptor agonist (triptan). Current theories proposed to explain the etiology of migraine headache suggest that symptoms are due to local cranial vasodilatation or to the release of sensory neuropeptides (including substance P and calcitonin gene-related peptide) through nerve endings in the trigeminal system. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine headache by binding to 5-$HT_{1B/1D}$ receptors located on intracranial blood vessels and sensory nerves of the trigeminal system; the agonist effects result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

**Efficacy:** The efficacy of Zecuity® in the acute treatment of migraine headaches with or without aura was demonstrated in a randomized, double-blind, controlled study. Patients were instructed to treat a migraine headache of moderate to severe pain with a single Zecuity® TDS or matching TDS with no sumatriptan in the drug reservoir. Additional medications were allowed as rescue therapy beginning 2 hours after the initial treatment. The primary efficacy endpoint was the proportion of patients who had no headache pain at 2 hours after TDS activation. Absence of nausea, photophobia, and phonophobia at 2 hours after TDS activation were assessed as secondary endpoints. Headache pain relief, defined as a reduction in migraine-related headache pain severity from moderate or severe pain to mild or no pain, was also assessed. A significantly greater proportion of patients had no headache pain, had headache pain relief, no nausea, no photophobia, or no phonophobia at two hours after TDS activation in the Zecuity® treatment group than in the control group.

**Cost:** The estimated acquisition cost of Zecuity® is not yet available.

## Recommendations

The College of Pharmacy recommends the addition of Zecuity® to Tier-3 of the Triptan Anti-Migraine Medications Product Based Prior Authorization category. The existing criteria for this category will apply. Additionally, use of Zecuity® will require a patient-specific, clinically significant reason why member cannot use sumatriptan tablets. A quantity limit of four Zecuity® TDS per month will apply, based on the prescribing information and recommended dosing. Furthermore, the College of Pharmacy recommends the following changes to the Triptan Anti-Migraine Medications Product Based Prior Authorization category:

1. Move rizatriptan to Tier-1, based on generic availability, State Maximum Allowable Cost (SMAC) pricing, and pediatric indication.

2. Change the quantity limit on zolmitriptan 2.5mg tablets and ODTs to 6 tablets per 30 days to be consistent with the other existing quantity limits. Then, move zolmitriptan tablets and ODTs to Tier-2, based on generic availability and State Maximum Allowable Cost (SMAC) pricing. Zomig® (zolmitriptan) nasal spray would remain in Tier-3, and will also require a patient-specific, clinically significant reason why member cannot use zolmitriptan tablets or ODTs.

3. Move sumatriptan injections and nasal sprays to Tier-3, based on State Maximum Allowable Cost (SMAC) pricing. Additionally, use of sumatriptan nasal spray or injection will require a patient-specific, clinically significant reason why member cannot use sumatriptan tablets.

| Triptan Anti-Migraine Medications | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** |
| Sumatriptan tablets (Imitrex®)<br>Rizatriptan (Maxalt®, Maxalt MLT®) | Naratriptan (Amerge®)<br>Zolmitriptan tabs & ODTs (Zomig®, Zomig-ZMT®) | Almotriptan (Axert®)<br>Eletriptan (Relpax®)<br>Frovatriptan (Frova®)<br>Sumatriptan injection (Imitrex®)<br>Sumatriptan nasal spray (Imitrex®)<br>Sumatriptan (Sumavel® DosePro®)<br>Sumatriptan (Zecuity® TDS)<br>Sumatriptan/Naproxen (Treximet®)<br>Zolmitriptan nasal spray (Zomig®) |

**Triptan Anti-Migraine Medication Tier-2 Approval Criteria:**

1. A trial of all available Tier-1 products with inadequate response; or
2. Documented adverse effect to all available Tier-1 products; or
3. Previous success with a Tier-2 product within the last 60 days.

**Triptan Anti-Migraine Medication Tier-3 Approval Criteria:**

1. A trial of all available Tier-2 products with inadequate response; or
2. Documented adverse effect to all available Tier-2 products; or
3. Previous success with a Tier-3 product within the last 60 days.
4. Use of any non-oral formulation will require a patient-specific, clinically significant reason why member cannot use the oral tablet formulation.

## Utilization Details of Triptan Anti-Migraine Medications

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | PERCENT COST |
|---|---|---|---|---|---|---|
| **SUMATRIPTAN PRODUCTS** | | | | | | |
| SUMATRIPTAN TAB 100MG | 3,930 | 1,875 | $70,770.98 | $18.01 | 2.1 | 13.09% |
| SUMATRIPTAN TAB 50MG | 3,915 | 2,138 | $70,101.29 | $17.91 | 1.8 | 12.97% |
| SUMATRIPTAN TAB 25MG | 2,187 | 1,266 | $40,645.21 | $18.58 | 1.7 | 7.52% |
| SUMATRIPTAN NASAL SPR 5MG/ACT | 184 | 114 | $40,606.33 | $220.69 | 1.6 | 7.51% |
| SUMATRIPTAN NASAL SPR 20MG/ACT | 184 | 94 | $43,637.74 | $237.16 | 2.0 | 8.07% |
| SUMATRIPTAN AUTO-INJ 6MG/0.5ML | 100 | 51 | $31,341.42 | $313.41 | 2.0 | 5.80% |
| SUMATRIPTAN INJ 6MG/0.5ML | 84 | 43 | $22,014.75 | $262.08 | 2.0 | 4.07% |
| SUMATRIPTAN INJ CART 6MG/0.5ML | 29 | 13 | $10,346.49 | $356.78 | 2.2 | 1.91% |
| SUMATRIPTAN AUTO-INJ 4MG/0.5ML | 7 | 5 | $2,337.22 | $333.89 | 1.4 | 0.43% |
| SUMATRIPTAN INJ CART 4MG/0.5ML | 3 | 3 | $1,382.41 | $460.80 | 1.0 | 0.26% |
| IMITREX NASAL SPR 20MG/ACT | 2 | 2 | $539.24 | $269.62 | 1.0 | 0.10% |
| SUMATRIPTAN INJ 4MG/0.5ML | 1 | 1 | $145.93 | $145.93 | 1.0 | 0.03% |
| SUMATRIPTAN INJ SYR 6MG/0.5ML | 1 | 1 | $85.40 | $85.40 | 1.0 | 0.02% |
| **SUBTOTAL** | **10,627** | **5,312*** | **$333,954.41** | **$31.43** | **2.0** | **61.77%** |
| **TIER-1 SUBTOTAL** | **10,627** | **5,312*** | **$333,954.41** | **$31.43** | **2.0** | **61.77%** |
| **NARATRIPTAN PRODUCTS** | | | | | | |
| NARATRIPTAN TAB 2.5MG | 370 | 183 | $18,861.16 | $50.98 | 2.0 | 3.49% |
| NARATRIPTAN TAB 1MG | 56 | 41 | $2,863.03 | $51.13 | 1.4 | 0.53% |
| **SUBTOTAL** | **426** | **222*** | **$21,724.19** | **$51.00** | **1.9** | **4.02%** |
| **TIER-2 SUBTOTAL** | **426** | **222*** | **$21,724.19** | **$51.00** | **1.9** | **4.02%** |
| **ELETRIPTAN PRODUCTS** | | | | | | |
| RELPAX TAB 40MG | 109 | 30 | $29,549.98 | $271.10 | 3.6 | 5.47% |
| RELPAX TAB 20MG | 15 | 6 | $5,025.58 | $335.04 | 2.5 | 0.93% |
| **SUBTOTAL** | **124** | **35*** | **$34,575.56** | **$278.84** | **3.5** | **6.40%** |
| **RIZATRIPTAN PRODUCTS** | | | | | | |
| MAXALT TAB 10MG | 92 | 31 | $36,386.83 | $395.51 | 3.0 | 6.73% |
| MAXALT-MLT TAB 10MG | 90 | 35 | $27,278.96 | $303.10 | 2.6 | 5.05% |
| RIZATRIPTAN TAB 10MG | 47 | 23 | $5,653.41 | $120.29 | 2.0 | 1.05% |
| MAXALT-MLT TAB 5MG | 36 | 17 | $7,483.46 | $207.87 | 2.1 | 1.38% |
| RIZATRIPTAN TAB 10MG ODT | 35 | 16 | $11,402.72 | $325.79 | 2.2 | 2.11% |
| RIZATRIPTAN TAB 5MG ODT | 11 | 10 | $2,308.20 | $209.84 | 1.1 | 0.43% |
| RIZATRIPTAN TAB 5MG | 9 | 6 | $339.46 | $37.72 | 1.5 | 0.06% |
| MAXALT TAB 5MG | 6 | 5 | $2,495.18 | $415.86 | 1.2 | 0.46% |
| **SUBTOTAL** | **326** | **118*** | **$93,348.22** | **$286.34** | **2.8** | **17.27%** |
| **SUMATRIPTAN/NAPROXEN PRODUCTS** | | | | | | |
| TREXIMET TAB 85-500MG | 57 | 11 | $13,043.09 | $228.83 | 5.2 | 2.41% |
| **SUBTOTAL** | **57** | **11*** | **$13,043.09** | **$228.83** | **5.2** | **2.41%** |
| **FROVATRIPTAN PRODUCTS** | | | | | | |
| FROVA TAB 2.5MG | 41 | 6 | $12,363.96 | $301.56 | 6.8 | 2.29% |
| **SUBTOTAL** | **41** | **6*** | **$12,363.96** | **$301.56** | **6.8** | **2.29%** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **ZOLMITRIPTAN PRODUCTS** | | | | | | |
| ZOMIG TAB 5MG | 34 | 10 | $7,798.00 | $229.35 | 3.4 | 1.44% |
| ZOMIG ZMT TAB 5MG | 13 | 3 | $2,991.28 | $230.10 | 4.3 | 0.55% |
| ZOMIG TAB 2.5MG | 10 | 2 | $4,376.72 | $437.67 | 5.0 | 0.81% |
| ZOMIG NASAL SPR 5MG/ACT | 7 | 3 | $1,869.28 | $267.04 | 2.3 | 0.35% |
| ZOLMITRIPTAN TAB 5MG | 1 | 1 | $53.21 | $53.21 | 1.0 | 0.01% |
| **SUBTOTAL** | **65** | **16*** | **$17,088.49** | **$262.90** | **4.1** | **3.16%** |
| **ALMOTRIPTAN PRODUCTS** | | | | | | |
| AXERT TAB 12.5MG | 21 | 6 | $6,910.28 | $329.06 | 3.5 | 1.28% |
| AXERT TAB 6.25MG | 9 | 5 | $2,290.71 | $254.52 | 1.8 | 0.42% |
| **SUBTOTAL** | **30** | **10*** | **$9,200.99** | **$306.70** | **3.0** | **1.70%** |
| **SUMATRIPTAN PRODUCTS** | | | | | | |
| SUMAVEL DOSEPRO INJ 6MG/0.5 | 9 | 3 | $5,337.00 | $593.00 | 3.0 | 0.99% |
| **SUBTOTAL** | **9** | **3*** | **$5,337.00** | **$593.00** | **3.0** | **0.99%** |
| **TIER-3 SUBTOTAL** | **652** | **193*** | **$184,957.31** | **$283.68** | **3.4** | **34.21%** |
| **TOTAL** | **11,705** | **5,548*** | **$540,635.91** | **$46.19** | **2.1** | **100.00%** |

*Total number of unduplicated members.

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[2] Drugs@FDA: FDA Approved Drug Products. Available online at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. Last revised 4/16/14. Last accessed 4/17/14.

[3] NuPathe Press Release: NuPathe's Zecuity Approved by the FDA for Acute Treatment of Migraine. Available online at: http://ir.nupathe.com/press-releases/nupathe-s-zecuity-approved-by-the-fda-for-the-acut-nasdaq-path-975802. Last revised 1/17/14. Last accessed 4/17/14.

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[6] FDA News Release: FDA Approves Topamax for migraine prevention in adolescents. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391026.htm. Last revised 3/28/14. Last accessed 4/17/14.

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[8] MedGadget: Zecuity® Electronic Drug Patch for Acute Migraines Approved in U.S. Available online at: http://www.medgadget.com/2013/01/zecuity-electronic-drug-patch-for-acute-migraines-approved-in-u-s.html. Last revised 1/18/13. Last accessed 4/17/14.

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[10] Drugs@FDA: Zecuity® Prescribing Information. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202278s000lbl.pdf. Last revised 1/2013. Last accessed 4/17/14.

[11] Zecuity® Package Insert, Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/zecuity-1/. Last revised 8/31/13. Last accessed 4/17/14.

# Appendix G

# Fiscal Year 2013 Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Esomeprazole Strontium and Aciphex® Sprinkle™ (Rabeprazole)

**Oklahoma Health Care Authority**
**June 2014**

| Anti-Ulcer Medications | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** |
| omeprazole (Prilosec®) | dexlansoprazole (Dexilant®) | esomeprazole magnesium (Nexium® Capsules, Packets, and I.V.) |
| pantoprazole (Protonix® Tablets) | lansoprazole (Prevacid® and ODT) | omeprazole (Prilosec® Suspension and Powder) |
| | rabeprazole sodium (Aciphex® Tablets) | pantoprazole (Protonix® Suspension & I.V.) |

## Current Prior Authorization Criteria

**Anti-Ulcer Medication Tier-2 Approval Criteria:**

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

**Anti-Ulcer Medication Tier-3 Approval Criteria:**

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications.
4. Special formulations including Orally Disentigrating Tablets (ODTs), Granules, Suspension, and Solution for I.V. require special reason for use.

**Proton-Pump Inhibitors for Pediatric Members Approval Criteria:**

1. A recent 14-day trial of an $H_2$ receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. GI bleed
    b. Zollinger-Ellison or similar disease

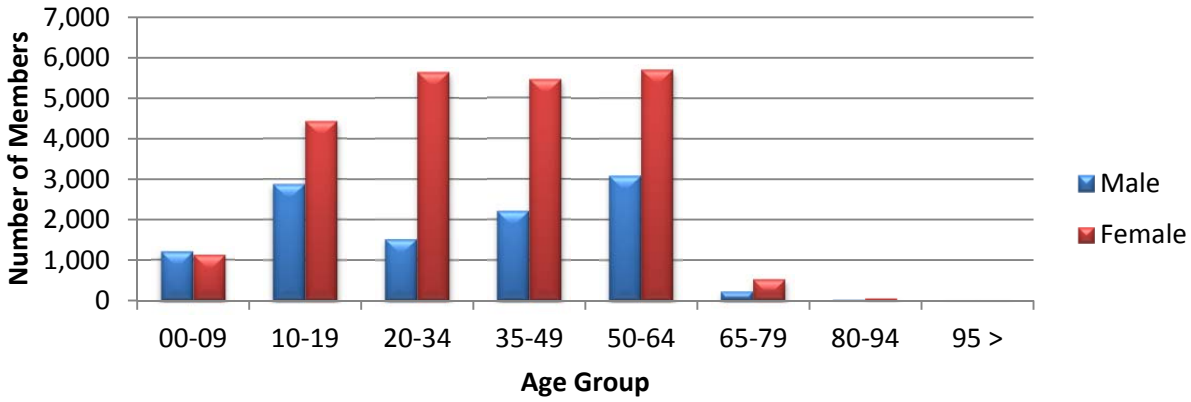
## Utilization of Anti-Ulcer Medications

### Comparison of Fiscal Years

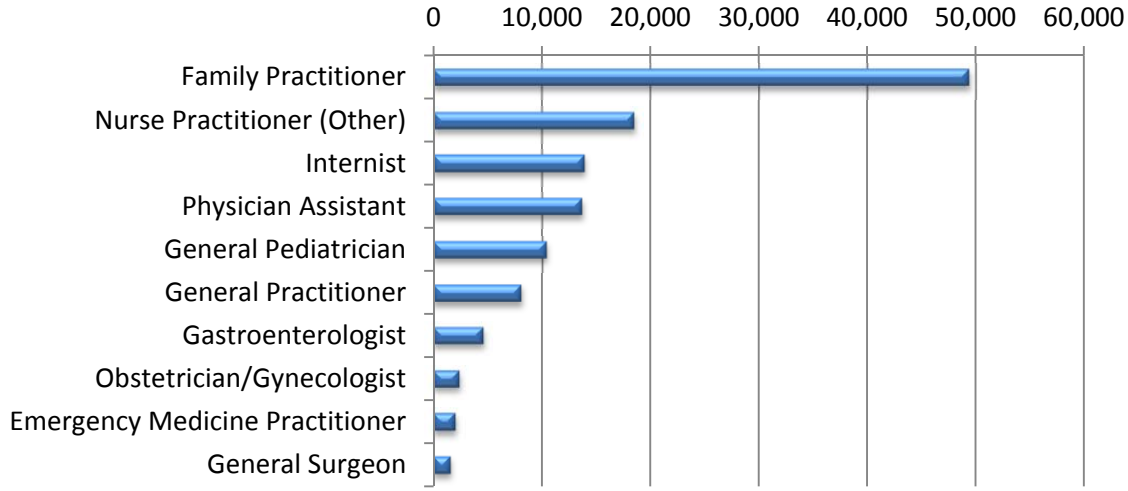
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost per Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2012** | 32,964 | 128,296 | $3,118,358.71 | $24.31 | $0.75 | 5,054,275 | 4,149,707 |
| **2013** | 34,261 | 134,499 | $2,959,086.05 | $22.00 | $0.68 | 5,359,434 | 4,373,823 |
| **% Change** | **3.90%** | **4.80%** | **-5.10%** | **-9.50%** | **-9.30%** | **6.00%** | **5.40%** |
| **Change** | **1,297** | **6,203** | **-$159,272.66** | **-$2.31** | **-$0.07** | **305,159** | **224,116** |

*Total number of unduplicated members.

### Demographics of Members Utilizing Anti-Ulcer Medications



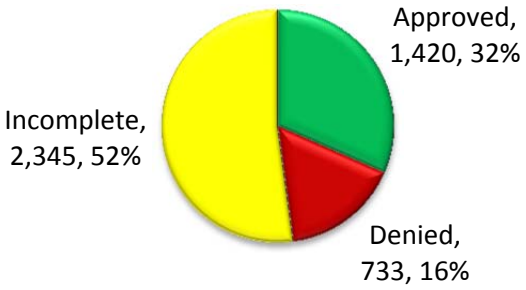

### Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



## Prior Authorization of Anti-Ulcer Medications

There was a total of 4,498 petitions submitted for anti-ulcer medications during fiscal year 2013. Computer edits are in place to detect Tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

**Status of Petitions**




## Market News and Updates[1, 2, 3]

**Anticipated Patent Expirations**

- Nexium® (esomeprazole magnesium)- 11/2014
- Dexilant® (dexlansaprazole)- 6/2020

**March 2014:** The FDA approved a New Drug Application allowing Nexium® 24-Hour 20mg to be over-the-counter (OTC). The OTC product is expected to be available in 1, 2, and 3 fourteen day course packs.

**March 2014:** The FDA released safety labeling changes for Nexium® products due to interactions with diagnostic investigations for neuroendocrine tumors. Nexium® products should be temporarily stopped at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial tests are performed, the same commercial lab should be used, as reference ranges between tests can vary.

## Esomeprazole Strontium Medication Summary[4]

- **FDA Approved:** January 2014
- **Indication:** Esomeprazole strontium is a proton pump inhibitor indicated for adults for the following indications:
  - Treatment of gastroesophageal reflux disease (GERD)
  - Risk reduction of non-steroidal anti-inflammatory drug (NSAID)-associated gastric ulcer
  - *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence
  - Treatment of pathological hypersecretory conditions including Zollinger-Ellsion Syndrome

- **Dosing:**
  - **GERD-** 24.6mg or 49.3mg by mouth each day for 6 to 8 weeks
  - **NSAID-associated gastric ulcer-** 24.6mg or 49.3mg by mouth each day for up to 6 months
  - ***H.pylori* (triple therapy)-** 49.3mg by mouth each day for 10 days
  - **Hypersecretory conditions-** 49.3mg by mouth twice daily

- **Mechanism of Action:** Esomeprazole strontium is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of H+/K+-ATPase in the gastric parietal cell.

- **Efficacy:** The safety and efficacy of esomeprazole strontium has been established based on adult studies of esomeprazole magnesium in the healing and maintenance of erosive esophagitis, symptomatic GERD, risk reduction of NSAID-associated gastric ulcer, *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence, and pathological hypersecretory conditions including Zollinger-Ellison Syndrome.
  - **GERD:** Two multicenter, randomized, double-blind, placebo-controlled studies were conducted in a total of 717 patients comparing four weeks of treatment with 22.3mg or 44.6mg of esomeprazole magnesium once daily versus placebo for resolution of GERD symptoms. The percentage of patients that were symptom-free of heartburn was significantly higher in the esomeprazole magnesium groups compared to placebo at all follow-up visits (Weeks 1, 2, and 4). No additional clinical benefit was seen with esomeprazole magnesium 44.6mg over esomeprazole magnesium 22.3mg.
  - **Hypersecretory:** In a multicenter, open-label, dose-escalation study of 21 patients with pathological hypersecretory conditions, esomeprazole magnesium significantly inhibited gastric acid secretion. Initial dose was 44.6mg of esomeprazole magnesium twice daily in 19/21 patients and 89.2mg of esomeprazole magnesium twice daily in 2/21 patients. Total daily esomeprazole magnesium doses ranging from 89.2mg to 267.6mg for 12 months maintained gastric acid output below the target levels of 10 mEq/hr in patients without prior gastric acid-reducing surgery and below 5 mEq/hr in patients with prior gastric acid-reducing surgery. At the month 12 final visit, 18/20 (90%) patients had Basal Acid Output (BAO) under satisfactory control (median BAO = 0.17 mmol/hr). Of the 18 patients, 13 (72%) had their BAO controlled with the original dosing regimen at the final visit.

- **Utilization/Cost:** There has been no utilization of esomeprazole strontium since its approval in January 2014.

| Medication | EAC Per Tablet or Capsule | EAC Per Day | EAC for 30 days of Therapy |
|---|---|---|---|
| Esomeprazole Strontium 49.3mg | $7.07 | $7.07-$14.14 | $212.10-$424.20 |
| Nexium® (esomeprazole magnesium) 40mg | $8.33 | $8.33-$16.66 | $249.90-$499.80 |
| Omeprazole Capsule 20mg | $0.08+ | $0.08-$0.16 | $2.40-$4.80 |

EAC= estimated acquisition cost
+ State maximum allowable cost (SMAC) pricing

## Aciphex® Sprinkle™ (Rabeprazole) Medication Summary[5]

- **FDA Approved:** March 2013
- **Indication:** Aciphex® Sprinkle™ is indicated for the following**:**
  - Healing and maintenance of erosive or ulcerative GERD
  - Healing of duodenal ulcers
  - *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence
  - Treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome
- **Dosing:**
  - **NSAID-associated gastric ulcer-** 20mg by mouth each day
  - ***H.pylori* (triple therapy)-** 20mg by mouth twice daily for 7 days
  - **Hypersecretory conditions-** 60mg by mouth each day
  - **GERD in ≥ 12 years-** 20mg by mouth each day
  - **GERD in 1-11 years old-**
    - <15 kg: 5mg by mouth once daily
    - >15 kg: 10mg by mouth once daily
- **Mechanism of Action:** Aciphex® Sprinkle™ suppresses gastric acid secretion by inhibiting gastric H+/ K+-ATPase at the secretory surface of the gastric parietal cell.
- **Efficacy:** The efficacy of Aciphex® Sprinkle™ in pediatric patients 1 to 11 years of age was evaluated by a multicenter, randomized, double-blind, parallel, 2 dose arm clinical trial in 127 pediatric patients with endoscopic and histologic evidence of GERD. Patients were randomized to one of two Aciphex® Sprinkle™ dose levels based on body weight. Patients weighing 6.0 to 14.9 kg received either 5mg or 10mg of Aciphex® Sprinkle™, and those with body weight ≥ 15 kg received either 10mg or 20mg of Aciphex® Sprinkle™. Healing rates for erosive endoscopic classification with the 5mg dose in patients <15kg was 88%, the 10mg dose in patients <15kg was 83%, and the 10mg dose in patients >15kg was 71%. Non-erosive healing rate was 78% with the 5mg dose and 100% with the 10mg dose for those <15 kg, and 81% with the 10mg dose in those weighing >15 kg.
- **Utilization/Cost:** There has been no utilization of Aciphex® Sprinkle™ since its approval in March 2013.

| Medication | EAC Per Tablet or Capsule | EAC Per Day | EAC for 30 days of Therapy |
|---|---|---|---|
| Aciphex® Sprinkle™ Capsule 5 or 10mg | $12.31 | $12.31-$24.62 | $369.30-$738.60 |
| Aciphex® Tablet 20mg | $0.94[+] | $0.94-$1.88 | $28.20-$56.40 |
| Omeprazole Capsule 20 mg | $0.08[+] | $0.08-$0.16 | $2.40-$4.80 |

EAC= estimated acquisition cost
+State maximum allowable cost (SMAC) pricing

## Recommendations

The College of Pharmacy recommends the addition of Aciphex® Sprinkle™ and Esomeprazole Strontium to Tier-3 of the Anti-Ulcer Product Based Prior Authorization category. The existing criteria for this category will apply.

| Anti-Ulcer Medications | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** |
| omeprazole (Prilosec®) | dexlansoprazole (Dexilant®) | esomeprazole magnesium (Nexium® Capsules, Packets, and I.V.) |
| pantoprazole (Protonix® Tablets) | lansoprazole (Prevacid® and ODT) | esomeprazole strontium |
| | rabeprazole sodium (Aciphex® Tablets) | omeprazole (Prilosec® Suspension and Powder) |
| | | pantoprazole (Protonix® Suspension & I.V.) |
| | | rabeprazole sodium (Aciphex® Sprinkle™) |

**Tier-2 Approval Criteria:**

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

**Tier-3 Approval Criteria:**

1. A 14-day of trial all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications.
4. Special formulations including ODTs, Sprinkle Capsules, Granules, Suspension, and Solution for I.V. require special reason for use.

**Proton-Pump Inhibitors for Pediatric Members Approval Criteria:**

1. A recent 14-day trial of an $H_2$ receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. GI bleed
    b. Zollinger-Ellison Syndrome or similar disease

## Utilization Details of Anti-Ulcer Medications

### Proton Pump Inhibitors

| Product Utilized | Total Claims | Total Members | Total Cost | Claims/ Member | Cost/ Day | % Cost | Cost/ Claim |
|---|---|---|---|---|---|---|---|
| **PANTOPRAZOLE PRODUCTS** | | | | | | | |
| PANTOPRAZOLE TAB 40MG | 18,643 | 5,249 | $151,936.67 | 3.55 | $0.27 | 5.13% | $8.15 |
| PROTONIX TAB 40MG | 37 | 27 | $676.79 | 1.37 | $0.63 | 0.02% | $18.29 |
| PANTOPRAZOLE TAB 20MG | 1,737 | 581 | $15,442.61 | 2.99 | $0.30 | 0.52% | $8.89 |
| **Subtotal** | **20,417** | **5,715** | **$168,056.07** | **3.57** | **$0.27** | **5.67%** | **$8.23** |
| **OMEPRAZOLE PRODUCTS** | | | | | | | |
| OMEPRAZOLE CAP 40MG | 28,247 | 8,005 | $389,624.44 | 3.53 | $0.45 | 13.17% | $13.79 |
| OMEPRAZOLE CAP 20MG | 69,980 | 21,442 | $863,703.18 | 3.26 | $0.35 | 29.19% | $12.34 |
| OMEPRAZOLE CAP 10MG | 2,456 | 1,008 | $36,686.12 | 2.44 | $0.50 | 1.24% | $14.94 |
| **Subtotal** | **100,683** | **28,793** | **$1,290,013.74** | **3.08** | **$0.38** | **43.60%** | **$12.81** |
| **Tier-1 Total** | **121,100** | **33,007** | **$1,458,070.35** | **3.66** | **$0.37** | **49.27%** | **$12.04** |
| **LANSOPRAZOLE PRODUCTS** | | | | | | | |
| PREVACID TAB 30MG STB | 478 | 83 | $95,657.06 | 5.76 | $6.79 | 3.23% | $200.12 |
| LANSOPRA TAB 30MG ODT | 6 | 4 | $904.22 | 1.5 | $5.02 | 0.03% | $150.70 |
| PREVACID TAB 15MG STB | 785 | 176 | $159,674.74 | 4.46 | $6.87 | 5.40% | $203.41 |
| LANSOPRA TAB 15MG ODT | 6 | 5 | $772.12 | 1.2 | $3.96 | 0.03% | $128.69 |
| LANSOPRA CAP 30MG DR | 6,043 | 850 | $252,065.99 | 7.11 | $1.41 | 8.52% | $41.71 |
| PREVACID CAP 30MG DR | 9 | 2 | $216.80 | 4.5 | $0.84 | 0.01% | $24.09 |
| LANSOPRA CAP 15MG DR | 780 | 148 | $36,286.06 | 5.27 | $1.56 | 1.23% | $46.52 |
| **Subtotal** | **8,107** | **1,211** | **$545,576.99** | **6.69** | **$2.27** | **18.45%** | **$67.30** |
| **DEXLANSOPRAZOLE PRODUCTS** | | | | | | | |
| DEXILANT CAP 60MG DR | 2,570 | 477 | $386,295.64 | 5.39 | $5.03 | 13.05% | $150.31 |
| DEXILANT CAP 30MG DR | 372 | 83 | $54,624.99 | 4.48 | $4.91 | 1.85% | $146.84 |
| **Subtotal** | **2,942** | **546** | **$440,920.63** | **4.94** | **$4.97** | **14.90%** | **$149.87** |
| **RABEPRAZOLE PRODUCTS** | | | | | | | |
| ACIPHEX TAB 20MG | 322 | 42 | $96,523.89 | 7.67 | $9.93 | 3.26% | $299.76 |
| **Subtotal** | **322** | **42** | **$96,523.89** | **7.67** | **$9.93** | **3.26%** | **$299.76** |
| **Tier-2 Total** | **11,371** | **1,732** | **$1,083,021.51** | **6.57** | **$3.20** | **36.61%** | **$95.24** |
| **ESOMEPRAZOLE PRODUCTS** | | | | | | | |
| NEXIUM CAP 40MG | 1,754 | 227 | $363,270.86 | 7.73 | $6.91 | 12.28% | $207.11 |
| NEXIUM CAP 20MG | 74 | 12 | $16,099.54 | 6.17 | $7.27 | 0.54% | $217.56 |
| NEXIUM GRA 40MG DR | 7 | 3 | $1,258.12 | 2.33 | $5.99 | 0.04% | $179.73 |
| NEXIUM GRA 20MG DR | 21 | 3 | $5,490.76 | 7 | $9.09 | 0.19% | $261.46 |
| NEXIUM GRA 10MG DR | 26 | 10 | $4,686.48 | 2.6 | $5.04 | 0.16% | $180.25 |
| NEXIUM GRA 5MG DR | 3 | 2 | $643.80 | 1.5 | $5.36 | 0.02% | $214.60 |

| Product Utilized | Total Claims | Total Members | Total Cost | Claims/ Member | Cost/ Day | % Cost | Cost/ Claim |
|---|---|---|---|---|---|---|---|
| NEXIUM GRA 2.5MG DR | 6 | 3 | $1,273.22 | 2 | $7.07 | 0.04% | $212.20 |
| **Subtotal** | **1,891** | **253** | **$392,722.78** | **7.47** | **$6.91** | **13.27%** | **$207.68** |
| **OMEPRAZOLE POWDER PRODUCTS** | | | | | | | |
| PRILOSEC POW 10MG | 53 | 25 | $6,928.67 | 2.12 | $4.43 | 0.23% | $130.73 |
| PRILOSEC POW 2.5MG | 41 | 19 | $10,945.56 | 2.16 | $8.90 | 0.37% | $266.96 |
| **Subtotal** | **94** | **44** | **$17,874.23** | **2.14** | **$6.67** | **0.60%** | **$190.15** |
| **OMEPRAZOLE SUSPENSION PRODUCTS** | | | | | | | |
| FIRST-OMEP SUS 2MG/ML | 1 | 1 | $31.57 | 1 | $1.05 | 0.00% | $31.57 |
| **Subtotal** | **1** | **1** | **$31.57** | **1** | **$1.05** | **0.00%** | **$31.57** |
| **OMEPRAZOLE/SODIUM BICARBONATE PRODUCTS** | | | | | | | |
| ZEGERID POW 20-1680MG | 1 | 1 | $6.74 | 1 | $0.22 | 0.00% | $6.74 |
| **Subtotal** | **1** | **1** | **$6.74** | **1** | **$0.22** | **0.00%** | **$6.74** |
| **PANTOPRAZOLE PACKAGED PRODUCTS** | | | | | | | |
| PROTONIX PAK | 41 | 8 | $7,359.41 | 5.13 | $6.10 | 0.25% | $179.50 |
| **Subtotal** | **41** | **8** | **$7,359.41** | **5.13** | **$6.10** | **0.25%** | **$179.50** |
| **Tier-3 Total** | **2,028** | **314** | **$417,994.73** | **6.45** | **$4.19** | **14.12%** | **$206.11** |
| **Total** | **134,499** | **34,261*** | **$2,959,086.05** | **3.93** | **$0.68** | **100%** | **$22.00** |

*Total number of unduplicated members.

## H2 Antagonists

| Product Utilized | Total Claims | Total Members | Total Cost | Claims/ Member | Cost/ Day | % Cost | Cost/ Claim |
|---|---|---|---|---|---|---|---|
| **CIMETIDINE PRODUCTS** | | | | | | | |
| CIMETIDINE TAB 200MG | 60 | 38 | $673.75 | 1.58 | $0.33 | 0.18% | $11.23 |
| **Subtotal** | **60** | **38** | **$673.75** | **1.58** | **$0.33** | **0.18%** | **$11.23** |
| **RANITIDINE PRODUCTS** | | | | | | | |
| RANITIDINE CAP 150MG | 2 | 1 | $42.18 | 2 | $0.70 | 0.01% | $21.09 |
| RANITIDINE TAB 150MG | 22,957 | 8,877 | $149,844.84 | 2.59 | $0.21 | 39.14% | $6.53 |
| RANITIDINE TAB 300MG | 2,595 | 987 | $20,589.71 | 2.63 | $0.21 | 5.38% | $7.93 |
| RANITID SYP 15MG/ML | 9,087 | 4,837 | $117,204.06 | 1.88 | $0.46 | 30.61% | $12.90 |
| RANITID SYP 75MG/5ML | 7,085 | 4,045 | $80,609.97 | 1.75 | $0.40 | 21.05% | $11.38 |
| RANITID SYP 150/10ML | 1 | 1 | $8.04 | 1 | $0.27 | 0.00% | $8.04 |
| ZANTAC INJ 25MG/ML | 2 | 1 | $219.24 | 2 | $5.62 | 0.06% | $109.62 |
| ZANTAC INJ 25MG/ML | 62 | 3 | $700.36 | 20.67 | $1.63 | 0.18% | $11.30 |
| RANITIDINE INJ 150/6ML | 2 | 1 | $23.10 | 2 | $1.65 | 0.01% | $11.55 |
| **Subtotal** | **41,793** | **17,711** | **$369,241.50** | **2.35** | **$0.29** | **96.44%** | **$19.69** |
| **FAMOTIDINE PRODUCTS** | | | | | | | |
| FAMOT SUS 40MG/5ML | 112 | 21 | $8,528.61 | 5.33 | $2.86 | 2.23% | $76.15 |
| **Subtotal** | **112** | **21** | **$8,528.61** | **5.33** | **$2.86** | **2.23%** | **$76.15** |

| NIZATIDINE PRODUCTS | | | | | | | |
|---|---|---|---|---|---|---|---|
| NIZATIDINE CAP 150MG | 176 | 36 | $4,413.31 | 4.89 | $0.81 | 1.15% | $25.08 |
| NIZATIDINE CAP 300MG | 1 | 1 | $28.61 | 1 | $0.95 | 0.01% | $28.61 |
| **Subtotal** | **177** | **37** | **$4,441.92** | **2.95** | **$0.88** | **1.16%** | **$25.10** |
| **Total** | **42,142** | **17,791*** | **$382,885.78** | **2.37** | **$0.30** | **100%** | **$9.09** |

*Total number of unduplicated members.

## Sucralfate

| Product Utilized | Total Claims | Total Members | Total Cost | Claims/ Member | Cost/ Day | % Cost | Cost/ Claim |
|---|---|---|---|---|---|---|---|
| SUCRALFATE PRODUCTS | | | | | | | |
| CARAFATE SUS 1GM/10ML | 1,600 | 875 | $195,083.65 | 1.83 | $6.55 | 58.07% | $121.93 |
| SUCRALFATE SUS 1GM/10ML | 28 | 12 | $11,141.10 | 2.33 | $17.04 | 3.32% | $397.90 |
| SUCRALFATE TAB 1GM | 4,693 | 2,306 | $129,637.01 | 2.04 | $1.06 | 38.59% | $27.62 |
| CARAFATE TAB 1GM | 2 | 2 | $82.14 | 1 | $1.37 | 0.02% | $41.07 |
| **Total** | **6,323** | **3,195*** | **$335,943.90** | **2.02** | **$2.20** | **100%** | **$53.13** |

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalent Evaluations. Available online at: http://orange-book.findthebest.com/. Last revised: 4/15/14. Last assessed: 4/18/14.
[2] NDA Approval Letter. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/204655Orig1s000ltr.pdf. Last revised: 3/28/14 Last assessed: 4/22/14.
[3] FDA MedWatch and Safety. Available online at http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm392718.htm. Last revised: 4/11/14. Last assessed: 4/22/14.
[4] Esomeprazole strontium Product Information. Amneal Pharmaceuticals, LLC. Available online at: http://amneal.com/Docs/EsomeprazoleStrontiumFull_PI_Rev_08-2013.pdf. Last revised: 3/31/14 Last assessed: 4/22/14.
[5] Aciphex Sprinkle Product Information. Eisai Inc. Available online at: http://www.aciphex.com/PDF/aciphexpi.pdf. Last revised: 10/31/13 Last assessed: 4/22/14.

# Appendix H

# Calendar Year 2013 Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Liptruzet™ (Ezetimibe/Atorvastatin) and Omtryg™ (Omega-3-Acid Ethyl Esters A)

**Oklahoma Health Care Authority**
**June 2014**

## Current Prior Authorization Criteria

**Statin Medications and Zetia® (Ezetimibe) Tier-2 Approval Criteria:**

1. A trial with atorvastatin, consisting of at least 8 weeks of continuous therapy, titrated to 40mg, 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 (20mg rosuvastatin or higher); or
2. Documented adverse effect or contraindication to all available lower tiered products; or
3. A clinical exception will apply for rosuvastatin 40mg for high risk members hospitalized for recent acute myocardial infarction or acute coronary syndrome.

**Statin Medications and Zetia® (Ezetimibe) Special PA Approval Criteria:**

1. A clinically significant reason why lower tiered medications with similar or higher LDL reduction cannot be used; and
    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 include the following:
    i. Documented active liver disease, or
    ii. Documented unexplained, persistent elevations of serum transaminases, or
    iii. Documented statin related myopathy.

| Statin Medications and Zetia® (Ezetimibe) | | |
|---|---|---|
| **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) |

*Crestor® 5 mg and Crestor® 10 mg require special reason for use.

**Lovaza® (Omega-3-Fatty Acid) and Vascepa™ (Icosapent Ethyl) Approval 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.

**Juxtapid™ (Lomitapide) and Kynamro® (Mipomersen) Approval Criteria:**

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia defined by the presence of at least one of the following criteria:
    a. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
    b. Untreated total cholesterol >500 mg/dL and triglycerides <300 mg/dL and
        i. Both parents with documented untreated total cholesterol >250 mg/dL; or
        ii. Presence of tendinous/cutaneous xanthoma prior to age 10 years.
2. Documented failure of high dose statin therapy (LDL reduction capability equivalent to atorvastatin 80mg or higher); and
3. Prescriber must be certified with appropriate (Juxtapid™ or Kynamro®) REMS program.

## Utilization of Antihyperlipidemic Medications

### Comparison of Calendar Years

### Statins, Zetia®, Lovaza®, and Vascepa™

| Calendar Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2012** | 17,080 | 73,902 | $2,190,760.76 | $29.64 | $0.70 | 3,211,644 | 3,111,580 |
| **2013** | 17,613 | 74,858 | $1,808,024.71 | $24.15 | $0.56 | 3,291,967 | 3,226,401 |
| **% Change** | **3.10%** | **1.30%** | **-17.50%** | **-18.50%** | **-20.00%** | **2.50%** | **3.70%** |
| **Change** | **533** | **956** | **-$382,736.05** | **-$5.49** | **-$0.14** | **80,323** | **114,821** |

*Total number of unduplicated members.

### Juxtapid™ and Kynamro®

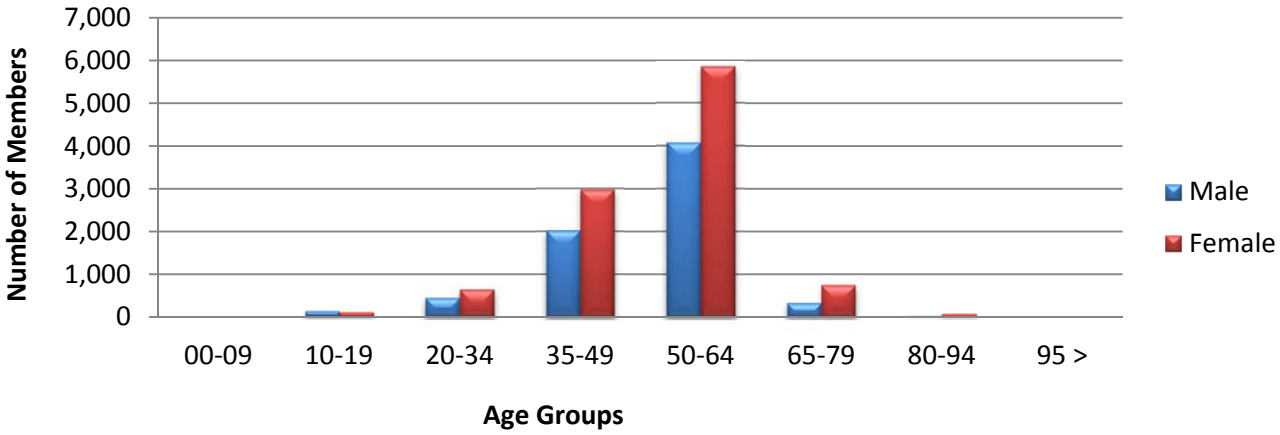
| Calendar Year[+] | *Total Members | [++]Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2013** | 1 | 6 | $153,649.50 | $25,608.25 | $853.61 | 180 | 180 |

[+]Juxtapid™ was FDA approved 12/26/2012 and Kynamro® was FDA approved 01/29/2013 therefore there was no utilization in Calendar Year 2012.

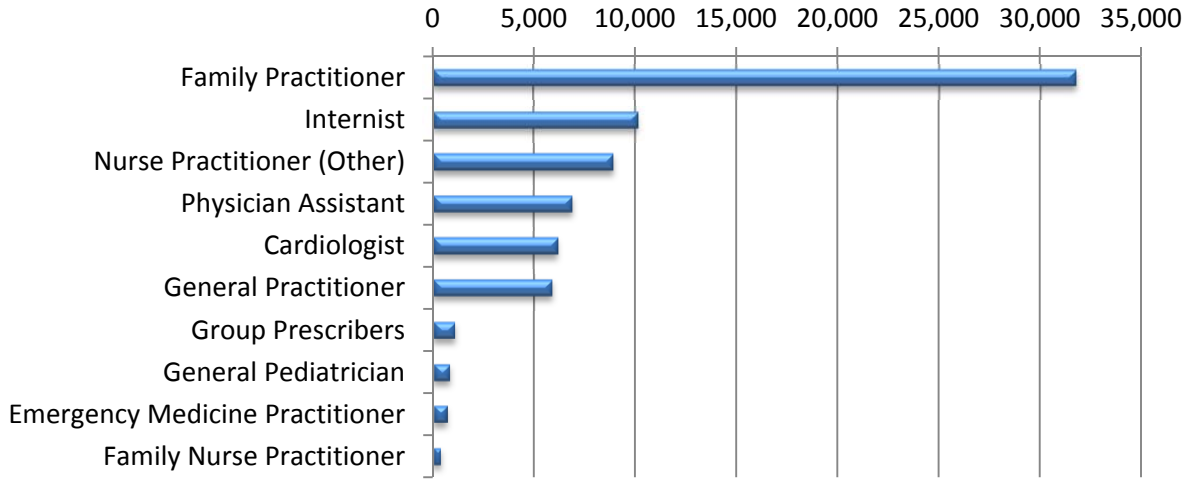
*Total number of unduplicated members.

[++]Kynamro® had no utilization in calendar year 2013.

**Demographics of Members Utilizing Statins, Zetia®, Lovaza®, and Vascepa™**



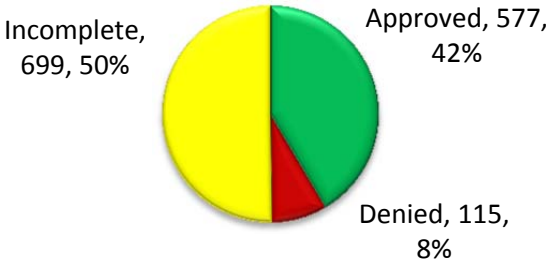

**Top Prescriber Specialties of Statins, Zetia®, Lovaza®, and Vascepa™ by Number of Claims**




## Prior Authorization of Antihyperlipidemic Medications

There was a total of 1,391 petitions submitted for antihyperlipidemic medications during calendar year 2013. There were 1,389 petitions submitted for statin medications, Zetia®, Lovaza®, and Vascepa™ combined. Two petitions were submitted for Juxtapid™, one was approved. There were no petitions submitted for Kynamro®. The following charts show the status of the submitted petitions.

## Status of Petitions of Statins, Zetia®, Lovaza®, Vascepa™, and Juxatpid®




## Market News and Updates

**Patent Expirations**

- Lovaza® (omega-3-fatty-acid)- generic formulation FDA approved April 2014
- Vytorin® (simvastatin/ezetimibe)- April 2017
- Crestor® (rosuvastatin)- June 2022
- Livalo® (pitavastatin)- February 2024
- Zetia® (ezetimibe)- October 2025
- Vascepa™ (icosapent ethyl) - April 2030

## Liptruzet™ (Ezetimibe/Atorvastatin) Summary[1]

- **FDA Approved:** May 2013

- **Indication:** Liptruzet™ is indicated as adjunctive therapy to diet for the following:
  - Reduction of elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia.
  - Reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments.
  - **Limitations of Use:** No incremental benefit of Liptruzet™ on cardiovascular morbidity and mortality over and above that demonstrated for atorvastatin has been established. Liptruzet™ has not been studied in Fredrickson Type I, III, IV and V dyslipidemias.

- **Dosing**: Liptruzet™ is an oral tablet available in 10/10mg, 10/20mg, 10/40mg, and 10/80mg.
  - The recommended dosage range is 10/10mg per day through 10/80mg per day.
  - The recommended starting dose is 10/10mg per day or 10/20mg per day.
  - The recommended starting dose for patients requiring a >55% reduction in LDL-C is 10/40mg per day.
  - Dosing of Liptruzet™ should occur either $\geq$2 hours before or $\geq$4 hours after administration of a bile acid sequestrant.

- **Mechanism of Action:** Liptruzet™ contains two lipid-lowering compounds with complementary mechanisms of action, a cholesterol inhibitor and an HMG-CoA reductase inhibitor.
  - Ezetimibe reduces blood cholesterol by inhibiting the absorption of cholesterol by the small intestine. Ezetimibe does not inhibit cholesterol synthesis in the liver or increase bile acid excretion. Ezetimibe localizes at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood; this distinct mechanism is complementary to that of statins.
  - Atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase (3-hydroxy-3-methylglutaryl-coenzyme A reductase) and cholesterol synthesis in the liver by increasing the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL; atorvastatin also reduces LDL production and number of LDL particles.

- **Contraindications:**
  - Active liver disease or unexplained persistent elevations of hepatic transaminase levels
  - Hypersensitivity to any component of Liptruzet™
  - Women who are pregnant or may become pregnant
  - Nursing mothers

- **Efficacy:**
  - **Primary Hyperlipidemia:** Liptruzet™ for the treatment of primary hyperlipidemia was evaluated in a multicenter, double-blind, placebo-controlled, clinical study. 628 patients with a diagnosis of hyperlipidemia were treated for up to 12 weeks and 246 patients were treated up to an additional 48 weeks. In the 12 week study, patients were randomized to receive: ezetimibe 10mg, atorvastatin 10mg, 20mg, 40mg, 80mg, or Liptruzet™ 10/10mg, 10/20mg, 10/40mg, or 10/ 80mg. After completing the 12 week study, patients who agreed to participate in the 48 week extension study were assigned to receive Liptruzet™ 10/10mg, 10/20mg, 10/40mg, 10/80mg, or atorvastatin 10mg, 20mg, 40mg, or 80mg. Patients receiving all doses of Liptruzet™ were compared to those receiving all doses of atorvastatin. At 12 weeks, Liptruzet™ lowered total-C, LDL-C, Apo-B, TG and non-HDL-C, and increased HDL-C significantly more than atorvastatin alone. The changes in lipid endpoints after an additional 48 weeks of treatment with Liptruzet™ (all doses) or with atorvastatin (all doses) were generally consistent with the 12-week data.
  - **Homozygous Familial Hypercholesterolemia**: Liptruzet™ for the treatment of homozygous familial hypercholesterolemia was evaluated in a double-blind, randomized 12-week study in patients with a clinical or genotypic diagnosis of HoFH. Data was analyzed from a subgroup of 36 patients receiving atorvastatin 40mg at baseline. Increasing the dose of atorvastatin from 40mg to 80mg produced a reduction of LDL-C of 2% from baseline. In patients administered Liptruzet™ (10/40mg and 10/80mg pooled), a reduction of LDL-C of 19% from baseline was observed. An extension study

showed at the end of 24 months, Liptruzet™ (10/40mg and 10/80mg pooled) produced a reduction of LDL-C that was consistent with that seen in the 12-week study.

- **Cost:**

| Medication | EAC Per Tablet or Capsule | EAC for 30 days of Therapy |
|---|---|---|
| Liptruzet™ (atorvastatin/ezetimibe) Tablets | $5.80 | $174.30 |
| Atorvastatin Tablets | $0.19-$0.27[+] | $5.70-$8.10 |
| Zetia® (ezetimibe) Tablets | $6.50 | $195.00 |

EAC=Estimated Acquisition Cost
[+] State Maximum Allowable Cost

## Omtryg™ (Omega-3-Acid Ethyl Esters A)[2]

- **FDA Approved:** April 2014

- **Indication:** Omtryg™ is indicated as adjunctive therapy to diet for the following:
  - Reduction of triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
  - **Limitations of Use:** The effect of Omtryg™ on risk of pancreatitis has not been determined. The effect of Omtryg™ on cardiovascular mortality and morbidity has not been determined.

- **Dosing**: Omtryg™ is available as 1.2gram oral capsules.
  - The daily dose of Omtryg™ is 4 capsules per day taken as a single dose or as 2 capsules given twice daily. Omtryg™ should be taken with meals.
  - Patients should be advised to swallow Omtryg™ capsules whole. Do not break open, crush, dissolve, or chew Omtryg™.

- **Mechanism of Action:** Omtryg™ is a combination of ethyl esters of omega-3 fatty acids, primarily eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).
  - The mechanism of action of Omtryg™ is not completely understood. Potential mechanisms of action include:
    - Inhibition of acyl-CoA: 1,2-diacylglycerol acyltransferase
    - Increased mitochondrial and peroxisomal ß-oxidation in the liver
    - Decreased lipogenesis in the liver
    - Increased plasma lipoprotein lipase activity
  - Omega-3-acid ethyl esters may reduce the synthesis of triglycerides in the liver because EPA and DHA are poor substrates for the enzymes responsible for TG synthesis, and EPA and DHA inhibit esterification of other fatty acids.

- **Contraindications:** Patients with known hypersensitivity (e.g. anaphylactic reaction) to omega-3-acid ethyl esters or any component of Omtryg™.

- **Efficacy:**
  - **Severe Hypertriglyceridemia:** The efficacy of Omtryg™ was evaluated in a randomized, double-blind, placebo-controlled, clinical study in patients with severe hypertriglyceridemia (500-1500 mg/dL). 254 patients entered a 6-week washout/dietary lead-in period and were then randomized to 12-week treatment with Omtryg ™, Omega-3-acid ethyl esters, or Placebo. Each treatment group was administered 4 capsules once daily. Each capsule of both Omtryg™ and omega-3-acid ethyl esters contained, among other components, at least 900mg of ethyl esters from omega-3 fatty acids sourced from fish oils. The primary efficacy endpoint was percent change in serum TG from baseline to Week 12. Omtryg™ statistically significantly reduced TG at Week 12 compared to placebo (p-value <0.05).

| | **Omtryg™ N= 104** | | **Omega-3-Acid Ethyl Esters N=103** | | **Placebo N=43** | | **Median difference from Placebo** | |
|---|---|---|---|---|---|---|---|---|
| **Parameter** | **BL** | **% Change** | **BL** | **% Change** | **BL** | **% Change** | **Omtryg™ vs. Placebo** | **Omega-3-Acid EE vs. Placebo** |
| TG | 702 | -24.7 | 655 | -26.8 | 624 | -17.4 | -12.2* | -14.0* |
| Non-HDL-C | 237 | -9.2 | 210 | -3.6 | 222 | -0.8 | -8.5 | -3.5 |
| TC | 270 | -8.1 | 244 | -1.0 | 250 | -0.8 | -6.9 | -1.9 |
| VLDL-C | 153 | -21.2 | 117 | -18.0 | 114 | +5.6 | -28.7** | -23.7* |
| HDL-C | 28 | 0.0 | 30 | 0.0 | 30 | 0.0 | +3.9 | +5.2 |
| LDL-C | 78 | +20.3 | 85 | +12.8 | 94 | -5.9 | +24.7** | +18.9* |

BL= Baseline (mg/dL) Median; % Change= Median Percent Change from Baseline;
Median Difference from Placebo = Hodges Lehmann median of all pairwise differences from placebo
*p<0.05, **p<0.01, statistically significant difference between treatment groups based on pre-specified Hommel method for controlling Type 1 error among secondary endpoints.

- **Cost:** The estimated acquisition cost of Omtryg™ is currently unavailable.

## Discussion

The antihyperlipidemic category was last reviewed January 2013; therefore, utilization data was analyzed by calendar year to view the complete annual changes to this category. While there was an increase in members and claims utilizing this category in calendar year 2013, the total cost decreased by 17.5%. This may be a result of generically available atorvastatin being moved to Tier-1 after a state maximum allowed cost (SMAC) was applied in May 2012. Also, Livalo®, Lescol®, and Lescol® XL were moved from Tier-2 to Special PA category in January 2013 resulting in more cost effective treatment being utilized. Prior authorizations submitted decreased by approximately 50% and resulted in decreased administrative costs for this category. The decrease may be due to the availability of Tier-1 medications that have high LDL% reduction capabilities that do not require prior authorization.

## Recommendations

The College of Pharmacy recommends the placement of Liptruzet™ (ezetimibe/atorvastatin) into the Special PA category of the Statin and Zetia® PBPA category. The existing criteria for this category will apply.

| Statin Medications and Zetia® (Ezetimibe) | | |
|---|---|---|
| **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) |
| | | ezetimibe/atorvastatin (Liptruzet™) |

*Crestor® 5 mg and Crestor® 10 mg require special reason for use.

Additionally the College of Pharmacy recommends the prior authorization of Omtryg™ (omega-3-acid ethyl esters A) 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.

| *% LDL Reduction* | *Lovastatin (Mevacor®)* | *Pravastatin (Pravachol®)* | *Simvastatin (Zocor®)* | *Atorvastatin (Lipitor®)* | *Rosuvastatin (Crestor®)* | *Pitavastatin (Livalo®)* | *Fluvastatin (Lescol®)* |
|---|---|---|---|---|---|---|---|
| 25-32 % | 20mg | 20mg | 10mg | | | 1 mg | 40mg |
| 31-39 % | 40mg | 40mg | 20mg | 10mg | | 2 mg | 80mg* |
| 37-45 % | | 80mg | 40mg | 20mg | 5mg | 4 mg | |
| 48-52 % | | | 80mg | 40mg | 10mg | | |
| 55-60 % | | | | 80mg | 20mg | | |
| 60-63 % | | | | | 40mg | | |

*Lescol® 40 mg bid and Lescol® XL 80 mg both fall into 31-39% LDL Reduction category.

## Utilization Details for Statin Medications and Zetia®

| MEDICATION NAME | CLAIMS | MEMBERS | COST | COST/ CLAIM | COST/ DAY | % COST |
|---|---|---|---|---|---|---|
| **Atorvastatin Products** | | | | | | |
| ATORVASTATIN TAB 40MG | 6,573 | 1,820 | $103,269.85 | $15.71 | $0.37 | 5.71% |
| ATORVASTATIN TAB 20MG | 5,381 | 1,626 | $80,793.94 | $15.01 | $0.38 | 4.47% |
| ATORVASTATIN TAB 10MG | 3,617 | 1,013 | $42,949.68 | $11.87 | $0.32 | 2.38% |
| ATORVASTATIN TAB 80MG | 2,876 | 768 | $49,443.93 | $17.19 | $0.39 | 2.73% |
| LIPITOR TAB 80MG | 5 | 3 | $73.85 | $14.77 | $0.49 | 0.00% |
| LIPITOR TAB 40MG | 3 | 3 | $56.02 | $18.67 | $0.62 | 0.00% |
| LIPITOR TAB 20MG | 2 | 2 | $26.11 | $13.06 | $0.44 | 0.00% |
| **SUBTOTAL** | **18,457** | **5,235** | **$276,613.38** | **$15.18** | **$0.43** | **15.29%** |
| **Lovastatin Products** | | | | | | |
| LOVASTATIN TAB 20MG | 2,134 | 547 | $20,135.19 | $9.44 | $0.21 | 1.11% |
| LOVASTATIN TAB 40MG | 1,537 | 356 | $19,404.50 | $12.62 | $0.28 | 1.07% |
| LOVASTATIN TAB 10MG | 455 | 131 | $3,961.39 | $8.71 | $0.19 | 0.22% |
| **SUBTOTAL** | **4,126** | **1034** | **$43,501.08** | **$10.26** | **$0.23** | **2.40%** |
| **Pravastatin Products** | | | | | | |
| PRAVASTATIN TAB 40MG | 9,658 | 2,783 | $161,981.02 | $16.77 | $0.37 | 8.96% |
| PRAVASTATIN TAB 20MG | 6,257 | 1,959 | $81,810.90 | $13.08 | $0.29 | 4.52% |
| PRAVASTATIN TAB 80MG | 1,626 | 448 | $35,011.65 | $21.53 | $0.48 | 1.94% |
| PRAVASTATIN TAB 10MG | 1,216 | 372 | $14,553.01 | $11.97 | $0.28 | 0.80% |
| **SUBTOTAL** | **18,757** | **5,562** | **$293,356.58** | **$15.84** | **$0.36** | **16.22%** |
| **Simvastatin Products** | | | | | | |
| SIMVASTATIN TAB 20MG | 13,797 | 3,379 | $120,119.08 | $8.71 | $0.21 | 6.64% |
| SIMVASTATIN TAB 40MG | 10,507 | 2,725 | $102,003.58 | $9.71 | $0.21 | 5.64% |
| SIMVASTATIN TAB 10MG | 3,567 | 961 | $28,525.25 | $8.00 | $0.20 | 1.58% |
| SIMVASTATIN TAB 80MG | 1,438 | 406 | $13,903.41 | $9.67 | $0.21 | 0.77% |
| SIMVASTATIN TAB 5MG | 183 | 39 | $1,303.90 | $7.13 | $0.21 | 0.07% |
| **SUBTOTAL** | **29,492** | **7,510** | **$265,855.22** | **$8.64** | **$0.21** | **14.70%** |
| **Tier-1 SUBTOTAL** | **70,832** | **19,341** | **$879,326.26** | **$12.82** | **$0.31** | **48.61%** |
| **Rosuvastatin Products** | | | | | | |
| CRESTOR TAB 20MG | 1,092 | 234 | $267,926.42 | $245.35 | $5.69 | 14.82% |
| CRESTOR TAB 40MG | 635 | 151 | $162,940.00 | $256.60 | $5.68 | 9.01% |
| CRESTOR TAB 10MG | 331 | 74 | $75,417.22 | $227.85 | $5.74 | 4.17% |
| CRESTOR TAB 5MG | 56 | 14 | $11,895.95 | $212.43 | $5.36 | 0.66% |
| **SUBTOTAL** | **2,114** | **473** | **$518,179.59** | **$235.56** | **$5.62** | **28.66%** |
| **Tier-2 SUBTOTAL** | **2,114** | **473** | **$518,179.59** | **$235.56** | **$5.62** | **28.66%** |
| **Niacin/Lovastatin Products** | | | | | | |
| ADVICOR TAB 500-20MG | 6 | 1 | $915.80 | $152.63 | $5.09 | 0.05% |
| ADVICOR TAB 1000-20 | 4 | 1 | $3,528.25 | $882.06 | $11.76 | 0.20% |
| ADVICOR TAB 1000-40 | 3 | 1 | $590.56 | $196.85 | $6.56 | 0.03% |
| **SUBTOTAL** | **13** | **3** | **$5,034.61** | **$410.52** | **$7.80** | **0.28%** |

| MEDICATION NAME | CLAIMS | MEMBERS | COST | COST/ CLAIM | COST/ DAY | % COST |
|---|---|---|---|---|---|---|
| **Fluvastatin Products** | | | | | | |
| LESCOL XL TAB 80MG | 40 | 13 | $8,201.80 | $205.05 | $5.80 | 0.45% |
| FLUVASTATIN CAP 40MG | 5 | 2 | $656.50 | $131.30 | $2.98 | 0.04% |
| FLUVASTATIN CAP 20MG | 2 | 2 | $362.30 | $181.15 | $3.02 | 0.02% |
| **SUBTOTAL** | **47** | **17** | **$9,220.60** | **$172.50** | **$3.93** | **0.51%** |
| **Pitavastatin Products** | | | | | | |
| LIVALO TAB 2MG | 32 | 10 | $7,008.11 | $219.00 | $5.19 | 0.39% |
| LIVALO TAB 4MG | 23 | 3 | $3,800.78 | $165.25 | $4.69 | 0.21% |
| LIVALO TAB 1MG | 7 | 3 | $1,051.80 | $150.26 | $4.08 | 0.06% |
| **SUBTOTAL** | **62** | **16** | **$11,860.69** | **$178.17** | **$4.65** | **0.66%** |
| **Simvastatin/Niacin Products** | | | | | | |
| SIMCOR TAB 1000-40 | 20 | 2 | $3,832.61 | $191.63 | $6.39 | 0.21% |
| SIMCOR TAB 500-40MG | 19 | 3 | $1,906.25 | $100.33 | $3.34 | 0.11% |
| SIMCOR TAB 1000-20 | 3 | 1 | $541.64 | $180.55 | $6.02 | 0.03% |
| **SUBTOTAL** | **42** | **6** | **$6,280.50** | **$157.50** | **$5.25** | **0.35%** |
| **Simvastatin/Ezetimibe Products** | | | | | | |
| VYTORIN TAB 10-40MG | 277 | 45 | $64,778.17 | $233.86 | $5.46 | 3.58% |
| VYTORIN TAB 10-20MG | 90 | 21 | $26,050.93 | $289.45 | $5.22 | 1.44% |
| VYTORIN TAB 10-80MG | 88 | 15 | $24,286.70 | $275.99 | $5.78 | 1.34% |
| VYTORIN TAB 10-10MG | 9 | 2 | $1,830.86 | $203.43 | $5.55 | 0.10% |
| **SUBTOTAL** | **464** | **83** | **$116,946.66** | **$250.68** | **$5.50** | **6.46%** |
| **Ezetimibe** | | | | | | |
| ZETIA TAB 10MG | 488 | 107 | $116,292.34 | $238.30 | $5.44 | 6.43% |
| **SUBTOTAL** | **488** | **107** | **$116,292.34** | **$238.30** | **$5.44** | **6.43%** |
| **Tier-3 SUBTOTAL** | **1,116** | **232** | **$265,635.40** | **$234.61** | **$5.43** | **14.69%** |
| **TOTAL:** | **74,062** | **17,613*** | **$1,633,141.25** | **$153.92** | **$3.58** | **100%** |

*Total number of unduplicated members.

## Utilization Details for Lovaza® and Vascepa™

| MEDICATION NAME | CLAIMS | MEMBERS | COST | COST/ CLAIM | COST/ DAY | % COST |
|---|---|---|---|---|---|---|
| LOVAZA CAP 1GM | 796 | 123 | $144,883.46 | $182.01 | $6.12 | 100% |
| **TOTAL** | **796** | **123*** | **$144,883.46** | **$182.01** | **$6.12** | **100%** |

*Total number of unduplicated members.

## Utilization Details for Juxtapid™ and Kynamro®

| MEDICATION NAME | CLAIMS | MEMBERS | COST | COST/ CLAIM | COST/ DAY | % COST |
|---|---|---|---|---|---|---|
| JUXTAPID 5MG CAPS | 6 | 1 | $153,649.50 | $25,608.25 | $853.61 | 100% |
| **TOTAL** | **6** | **1** | **$153,649.50** | **$25,608.25** | **$853.61** | **100%** |

*Total number of unduplicated members.

## PRODUCT DETAILS OF OMTRYG™ (OMEGA-3-ACID ETHYL ESTERS A ORAL CAPSULE)[2]

**INDICATIONS AND USE:**

- Omtryg™ is indicated as adjunctive therapy to diet for the following:
    - Reduction of TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
    - **Limitations of Use:** The effect of Omtryg™ on risk of pancreatitis has not been determined. The effect of Omtryg™ on cardiovascular mortality and morbidity has not been determined.

**DOSAGE FORMS:**

- Omtryg™ is available as 1.2gram oral capsules.

**ADMINSTRATION:**

- The daily dose of Omtryg™ is 4 capsules per day taken as a single dose or as 2 capsules given twice daily.
- Omtryg™ should be taken with meals.
- Patients should be advised to swallow Omtryg™ capsules whole.
- Do not break open, crush, dissolve, or chew Omtryg™.

**CONTRAINDICATIONS:** Patients with known hypersensitivity (e.g. anaphylactic reaction) to omega-3-acid ethyl esters or any component of Omtryg™.

**WARNINGS AND PRECAUTIONS:**

- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Omtryg™ may increase levels of LDL. Monitor LDL levels periodically during therapy.
- Use with caution in patients with known hypersensitivity to fish or shellfish.
- There is a possible association between omega-3-acid ethyl esters and more frequent recurrences of symptomatic atrial fibrillation or flutter in patients with paroxysmal or persistent atrial fibrillation, particularly within the first months of initiating therapy.

**SPECIAL POPULATIONS:**

- **Pregnancy**: Category C. There are no adequate and well-controlled studies in pregnant women. It is unknown whether Omtryg™ can cause fetal harm when administered to a pregnant woman. Omtryg™ should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.
- **Nursing Mothers**: Studies with omega-3-acid ethyl esters have demonstrated excretion in human milk. The effect of this excretion on the infant of a nursing mother is unknown; caution should be exercised when Omtryg™ is administered to a nursing mother.
- **Pediatric Use**: The safety and effectiveness of Omtryg™ have not been established in pediatric patients.

- **Geriatric Use**: A limited number of patients older than 65 years were enrolled in the clinical studies of omega-3-acid ethyl esters. Safety and efficacy findings in subjects older than 60 years did not appear to differ from those of subjects younger than 60 years.
- **Drug Abuse and Dependence**: Omtryg™ does not have any known drug abuse or withdrawal effects.

**ADVERSE REACTIONS:**

- Clinical Trials (Incidence >3% and greater than placebo)
  - Eructation (4%)
  - Dyspepsia (3%)
  - Taste perversion (4%)

**DRUG INTERACTIONS** Omtryg™ may prolong bleeding time. Patients taking Omtryg™ and an anticoagulant or other drug affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

**PATIENT COUNSELING INFORMTION:**

1. Use Omtryg™ with caution in patients with known sensitivity or allergy to fish or shellfish.
2. Advise patients that use of lipid-regulating agents does not reduce the importance of adhering to diet.
3. Advise patients to take Omtryg™ as prescribed. If a dose is missed, patients should take it as soon as they remember. However, if they miss one day of Omtryg™, they should not double the dose.
4. Advise patients to swallow Omtryg™ capsules whole. Do not break, open, crush, dissolve, or chew Omtryg™.

[1]Liptruzet™ Product Information. Merck & Co. Available online at: http://www.merck.com/product/usa/pi_circulars/l/liptruzet/liptruzet_pi.pdf. Last revised 05/2013. Last accessed 04/17/2014.

[2]Omtryg™ Product Information. Trygg Pharma. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204977s000lbl.pdf. Last revised 04/2014. Last accessed 04/30/2014.

# Appendix I

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

## FDA NEWS RELEASE

**For Immediate Release**: May 23, 2014

**FDA approves Dalvance to treat skin infections**

The U.S. Food and Drug Administration approved Dalvance (dalbavancin), a new antibacterial drug used to treat adults with skin infections.

Dalvance is intended to treat acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria like Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains) and Streptococcus pyogenes. The treatment is administered intravenously.

Dalvance is the first drug designated as a Qualified Infectious Disease Product (QIDP) to receive FDA approval. Under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act, Dalvance was granted QIDP designation because it is an antibacterial or antifungal human drug intended to treat serious or life-threatening infections.

As part of its QIDP designation, Dalvance was given priority review, which provides an expedited review of the drug's application. Dalvance's QIDP designation also qualifies it for an additional five years of marketing exclusivity to be added to certain exclusivity periods already provided by the Food, Drug and Cosmetic Act.

Dalvance's safety and efficacy were evaluated in two clinical trials with a total of 1,289 adults with ABSSSI. Participants were randomly assigned to receive Dalvance or vancomycin, another antibacterial drug. Results showed Dalvance was as effective as vancomycin for the treatment of ABSSSI.

The most common side effects identified in the clinical trials were nausea, headache and diarrhea. In the trials, more participants in the Dalvance group had elevations in one of their liver enzyme tests. The Dalvance drug label provides recommendations on dosage adjustment in patients with renal impairment.

Dalvance is marketed by Chicago-based Durata Therapeutics.

## FDA NEWS RELEASE

**For Immediate Release**: May 20, 2014

**FDA approves Entyvio to treat ulcerative colitis and Crohn's disease**

The U.S. Food and Drug Administration today approved Entyvio (vedolizumab) injection to treat adult patients with moderate to severe ulcerative colitis and adult patients with moderate to severe Crohn's disease.

Entyvio is approved to treat those conditions when one or more standard therapies (corticosteroids, immunomodulators, or tumor necrosis factor blocker medications) have not resulted in an adequate response.

Ulcerative colitis is a chronic disease that affects about 620,000 Americans. It causes inflammation and ulcers in the inner lining of the large intestine and is one of two main forms of chronic inflammatory bowel disease. The inflammation can lead to abdominal discomfort, gastrointestinal bleeding, and diarrhea.

Crohn's disease is a chronic inflammatory condition that causes inflammation, or swelling, and irritation of any part of the digestive tract—also called the gastrointestinal (GI) tract. More than a half million Americans have been diagnosed with Crohn's disease.

The safety and effectiveness of Entyvio for ulcerative colitis were established in two clinical trials involving approximately 900 patients who had not responded adequately to corticosteroids, immunomodulators, or tumor necrosis factor blocker medications. Evaluations of patients included measures of stool frequency, rectal bleeding, endoscopic findings and a physician's overall assessment.

Results showed that a greater percentage of participants treated with Entyvio compared to a placebo achieved and maintained clinical response, achieved and maintained clinical remission, achieved corticosteroid-free clinical remission, and as seen during endoscopy, had improved appearance of the colon.

The safety and effectiveness of Entyvio for Crohn's disease were established in three clinical trials involving approximately 1,500 patients who had not responded adequately to corticosteroids, immunomodulators, or tumor necrosis factor blocker medications. Results showed that a greater percentage of participants treated

with Entyvio compared to a placebo achieved clinical response, achieved clinical remission, and achieved corticosteroid-free clinical remission.
Entyvio is an integrin receptor antagonist. Integrin receptors are proteins expressed on the surface of certain cells. Integrin receptors function as bridges for cell-cell interactions. Entyvio blocks the interaction of a specific integrin receptor (expressed on circulating inflammatory cells) with a specific protein (expressed on cells in the interior wall of blood vessels), and thereby blocks the migration of those circulating inflammatory cells across those blood vessels and into areas of inflammation in the gastrointestinal tract.
The most common side effects in patients treated with Entyvio include headache, joint pain, nausea, and fever. The most serious risks associated with Entyvio include serious infections, hypersensitivity and infusion-related reactions; and hepatotoxicity.
Another type of integrin receptor antagonist has been associated with progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system. PML is caused by a virus and typically only occurs in patients whose immune systems are compromised. There were no cases of PML identified among Entyvio clinical trial participants.
In Entyvio clinical trials, participants were actively monitored for PML with frequent and regular screenings, and evaluations of any new, unexplained neurological symptoms, as necessary. Because clinical trials are conducted under tightly controlled conditions, adverse reaction rates observed in the clinical trials of a drug may not reflect the rates that might be observed in practice. Therefore, while there were no cases of PML seen among patients participating in Entyvio clinical trials, there remains uncertainty regarding the risk of PML in patients taking Entyvio.
Health care professionals should monitor patients on Entyvio for any new onset, or worsening, of neurological signs and symptoms. The FDA will continue to work with the sponsor to further investigate the risk of PML through a required post-marketing study and enhanced, expedited adverse event reporting.
Consumers and health care professionals are encouraged to report adverse reactions from the use of Entyvio to the FDA‘s MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch or by calling 1-800-FDA-1088.
Entyvio is marketed by Deerfield, Ill.-based Takeda Pharmaceuticals America, Inc.

## Safety Announcements

### FDA Drug Safety Communication: FDA warns of next-day impairment with sleep aid Lunesta (eszopiclone) and lowers recommended dose

**[5-15-2014]** The U.S. Food and Drug Administration (FDA) is warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. As a result, we have decreased the recommended starting dose of Lunesta to 1 mg at bedtime. Health care professionals should follow the new dosing recommendations when starting patients on Lunesta. Patients should continue taking their prescribed dose of Lunesta and contact their health care professionals to ask about the most appropriate dose for them.
A study of Lunesta found that the previously recommended dose of 3 mg can cause impairment to driving skills, memory, and coordination that can last more than 11 hours after receiving an evening dose. Despite these driving and other problems, patients were often unaware they were impaired. The new lower recommended starting dose of 1 mg at bedtime will result in less drug in the blood the next day.
Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. The 1 mg dose can be increased to 2 mg or 3 mg if needed, but the higher doses are more likely to result in next-day impairment of driving and other activities that require full alertness. We caution patients taking a 3 mg dose against driving or engaging in other activities that require complete mental alertness the day after use.
We have approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes.
We are continuing to evaluate the risk of impaired mental alertness with the entire class of sleep aid drugs, including over-the-counter drugs available without a prescription, and will update the public as new information becomes available.

## Safety Announcements

### FDA Drug Safety Communication: FDA study of Medicare patients finds risks lower for stroke and death but higher for gastrointestinal bleeding with Pradaxa (dabigatran) compared to warfarin

**[05-13-2014]** In its ongoing review of the blood thinner Pradaxa (dabigatran), the U.S. Food and Drug Administration (FDA) recently completed a new study in Medicare patients comparing Pradaxa to the blood thinner warfarin (Coumadin, Jantoven, and generics), for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. Pradaxa and warfarin are used to reduce the risk of stroke and blood clots in patients with a common type of abnormal heart rhythm called non-valvular atrial fibrillation (AF).

The new study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs, Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death, than warfarin. The study also found an increased risk of major gastrointestinal bleeding with use of Pradaxa as compared to warfarin. The MI risk was similar for the two drugs.

Importantly, the new study is based on a much larger and older patient population than those used in FDA's earlier review of post-market data, and employed a more sophisticated analytical method to capture and analyze the events of concern. This study's findings, except with regard to MI, are consistent with the clinical trial results that provided the basis for Pradaxa's approval.

As a result of our latest findings, we still consider Pradaxa to have a favorable benefit to risk profile and have made no changes to the current label or recommendations for use. Patients should not stop taking Pradaxa (or warfarin) without first talking with their health care professionals. Stopping the use of blood-thinning medications such as Pradaxa and warfarin can increase the risk of stroke and lead to permanent disability and death. Health care professionals who prescribe Pradaxa should continue to follow the dosing recommendations in the drug label.

We urge both health care professionals and patients to report side effects involving Pradaxa or warfarin to the FDA MedWatch program.

## Current Drug Shortages Index (as of June 3, 2014):

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

Amikacin Injection
Ammonium Chloride Injection (initial posting date 3/8/2013)
Atropine Sulfate Injection
Barium Sulfate for Suspension (initial posting date 10/12/2012)
Bumetanide Injection (initial posting date 6/21/2012) UPDATED 5/28/2014
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection
Calcium Gluconate Injection (initial posting date 1/10/2013)
Cefazolin Injection (initial posting date 3/31/2014)
Chloramphenicol Sodium Succinate Injection (initial posting date 1/7/2014)
Chromic Chloride Injection
Cidofovir Injection (initial posting date 2/15/2013)
Clindamycin phosphate (Cleocin) Injection (initial posting date 10/2/2013) UPDATED 5/28/2014
Copper Injection (initial posting date 4/25/2013)
Cyanocobalamin (Vitamin B12) Injection (initial posting date 1/25/2013)
Daunorubicin Hydrochloride Solution for Injection
Dexamethasone Sodium Phosphate Injection (initial posting date 1/15/2013) UPDATED 5/27/2014
Dexmethylphenidate Hydrochloride (Focalin) (initial posting date 2/13/2014)
Dextrose Injection Bags, 5% New!!
Disopyramide Phosphate (Norpace) CR (initial posting date 4/18/2014)

Doxorubicin (Adriamycin) Lyophilized Powder (initial posting date 12/2/2011) UPDATED 5/27/2014
Ephedrine Sulfate Injection (initial posting date 4/3/2014) UPDATED 5/28/2014
Epinephrine Injection (initial posting date 4/27/2012)
Epinephrine 1mg/mL (Preservative Free) (initial posting date 6/21/2012)
Erythrocin Lactobionate Lyophilized Powder for Injection (initial posting date 4/21/2014)
Ethiodol (Ethiodized Oil) Ampules
Fentanyl Citrate (Sublimaze) Injection UPDATED 5/28/2014
Haloperidol Lactate Injection (initial posting date 5/29/2014) New!!
Heparin Sodium Injection (initial posting date 7/5/2012) UPDATED 5/28/2014
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection UPDATED 5/27/2014
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) Injection (initial posting date - 2/22/2012) UPDATED 5/28/2014
Liotrix (Thyrolar) Tablets
Lorazepam (Ativan) Injection UPDATED 5/28/2014
Magnesium Sulfate Injection
Mannitol (Osmitrol, Resectisol) Injection (initial posting date - 12/21/2011)
Mecasermin [rDNA origin] (Increlex) Injection (initial posting date - 4/26/2013)
Methyldopate Hydrochloride Injection
Methylin Chewable Tablets (initial posting date 2/19/2013)
Methylphenidate Hydrochloride ER Tablets (initial posting date 2/19/2013) UPDATED 5/28/2014
Methylphenidate Hydrochloride Tablets (initial posting date 2/19/2013) UPDATED 5/28/2014
Methylprednisolone Sodium Succinate Injection (initial posting date 2/14/2014)
Morphine Sulfate (Astramorph PF, Duramorph, Infumorph) Injection (Preservative Free) UPDATED 5/28/2014
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine Hydrochloride (Nubain) Injection (initial posting date 5/15/2012)
Neostigmine Methylsulfate Injection (initial posting date 1/14/2013)
Nitroglycerin in 5% Dextrose Injection (initial posting date 12/20/2013)
Nitroglycerin (Nitronal) Injection (initial posting date 5/5/2014)
Ondansetron (Zofran) Injection
Pancuronium Bromide Injection
Papaverine Hydrochloride Injection (initial posting date 12/17/2012)
Phosphate (Glycophos) Injection (initial posting date 5/29/2013)
Piperacillin and Tazobactam (Zosyn) Injection (Initial Posting Date - 4/2/2014)
Potassium Acetate Injection, USP 2mEq/mL
Potassium Chloride Injection (initial posting date 5/15/2012)
Potassium Phosphate Injection
Procainamide HCL Injection
Prochlorperazine Injection (initial posting date 1/30/2012)
Reserpine Tablets (initial posting date 4/17/2013)
Rifampin for Injection (initial posting date 3/22/2013)
Secretin Synthetic Human (ChiRhoStim) Injection (ChiRhoStim) (initial posting date 6/15/2012)
Selenium Injection
Sincalide (Kinevac) Lyophilized Powder for Injection (initial posting date 6/21/2013)
Sodium Chloride 0.9% Injection Bags (initial posting date 1/15/2014)
Sodium Chloride 23.4%
Sodium Phosphate Injection
Succinylcholine (Anectine, Quelicin) Injection (initial posting date 8/17/2012)
Sufentanil Citrate (Sufenta) Injection
Tesamorelin (Egrifta) Injection Kit (initial posting date 3/26/2014)
Thiotepa (Thioplex) for Injection

Tiopronin (Thiola) (initial posting date 10/31/2013)
Tobramycin Solution for Injection
Trace Elements (initial posting date 1/24/2013)
Verapamil Hydrochloride Injection, USP (initial posting date 4/17/2013)
Vitamin A Palmitate (Aquasol A)
Zinc Injection (initial posting date 2/15/2012)