Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday,
July 8, 2015
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 – July 8, 2015

DATE: July 1, 2015

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 July meeting.
Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on Medication Coverage Authorization Unit/SoonerPsych Program Update – Appendix B

Action Item – Vote to Prior Authorize Avycaz™ (Ceftazidime/Avibactam) and Zerbaxa™ (Ceftolozane/Tazobactam) – Appendix C

Action Item – Vote to Prior Authorize Copaxone® (Glatiramer Acetate) 40mg/mL – Appendix D

Action Item – Vote to Prior Authorize Invega Trinza™ (3-Month Paliperidone Palmitate Injection) – Appendix E

Action Item – Vote to Prior Authorize Cholbam™ (Cholic Acid) – Appendix F

Action Item – Vote to Prior Authorize Natpara® (Parathyroid Hormone Injection) – Appendix G

Action Item – Vote to Prior Authorize Zenzedi® (Dextroamphetamine), Evekeo™ (Amphetamine), and Aptensio XR™ (Methylphenidate Extended-Release) – Appendix H

Action Item – Vote to Prior Authorize Xtoro™ (Finafloxacin) and Ofloxacin Otic – Appendix I

Action Item – Vote to Prior Authorize Hetlioz® (Tasimelteon) and Belsomra® (Suvorexant) – Appendix J

Annual Review of Antidepressant Medications and 30-Day Notice to Prior Authorize Irenka™ (Duloxetine) – Appendix K

Annual Review of Alzheimer's Medications and 30-Day Notice to Prior Authorize Namzaric™ (Memantine Extended-Release/Donepezil) – Appendix L

30-Day Notice to Prior Authorize Corlanor® (Ivabradine) – Appendix M

Annual Review of Opioid Analgesics & Buprenorphine Products and 30-Day Notice to Prior Authorize Hysingla® ER (Hydrocodone Bitartrate Extended-Release) – Appendix N

30-Day Notice to Prior Authorize Various Special Formulations: Sitavig® (Acyclovir Buccal Tablets), Rasuvo® (Methotrexate Injection), Otrexup™ (Methotrexate Injection), Onmel™ (Itraconazole Oral Tablets), & Purixan® (Mercaptopurine Oral Suspension) – Appendix O

Annual Review of Growth Hormone – Appendix P

FDA and DEA Updates – Appendix Q

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 08, 2015 @ 4:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. June 10, 2015 DUR Minutes – Vote
   B. June 10, 2015 DUR Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/SoonerPsych Program Update – See Appendix B**
   A. Medication Coverage Activity for June 2015
   B. Pharmacy Help Desk Activity for June 2015
   C. SoonerPsych Program Update

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

5. **Action Item – Vote to Prior Authorize Avycaz™ (Ceftazidime/Avibactam) and Zerbaxa™ (Ceftolozane/Tazobactam) – See Appendix C**
   A. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize to Prior Authorize Copaxone® (Glatiramer Acetate) 40mg/mL – See Appendix D**
   A. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Invega Trinza™ (3-Month Paliperidone Palmitate Injection) – See Appendix E**
   A. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Cholbam™ (Cholic Acid) – See Appendix F**
   A. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Natpara® (Parathyroid Hormone Injection) – See Appendix G**
   A. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Zenzedi® (Dextroamphetamine), Evekeo™ (Amphetamine), and Aptensio XR™ (Methylphenidate Extended-Release) – See Appendix H**
    A. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Xtoro™ (Finafloxacin) and Ofloxacin Otic – See Appendix I**
    A. Ofloxacin Otic Solution Update
    B. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Hetlioz® (Tasimelteon) and Belsomra® (Suvorexant) – See Appendix J**
    A. College of Pharmacy Recommendations

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

13. **Annual Review of Antidepressant Medications and 30-Day Notice to Prior Authorize Irenka™ (Duloxetine) – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of Antidepressants
    C. Prior Authorization of Antidepressants
    D. Market News and Updates
    E. Irenka™ (Duloxetine) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Antidepressants

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

14. **Annual Review of Alzheimer's Medications and 30-Day Notice to Prior Authorize Namzaric™ (Memantine Extended-Release/Donepezil) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Alzheimer's Medications
    C. Prior Authorization of Alzheimer's Medications
    D. Market News and Updates
    E. Namzaric™ (Memantine Extended-Release/Donepezil) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Alzheimer's Medications

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

15. **30-Day Notice to Prior Authorize Corlanor® (Ivabradine) – See Appendix M**
    A. Introduction
    B. Corlanor® (Ivabradine) Product Summary
    C. College of Pharmacy Recommendations

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

16. **Annual Review of Opioid Analgesics & Buprenorphine Products and 30-Day Notice to Prior Authorize Hysingla® ER (Hydrocodone Bitartrate Extended-Release) – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of Opioid Analgesics & Buprenorphine Products
    C. Prior Authorization of Opioid Analgesics & Buprenorphine Products
    D. Opioid Analgesic Utilization Trends

E. Market News and Updates
F. Hysingla® ER (Hydrocodone Bitartrate Extended-Release) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Opioid Analgesics and Buprenorphine Products

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

17. 30-Day Notice to Prior Authorize Various Special Formulations: Sitavig® (Acyclovir Buccal Tablets), Rasuvo® (Methotrexate Injection), Otrexup™ (Methotrexate Injection), Onmel™ (Itraconazole Oral Tablets), & Purixan® (Mercaptopurine Oral Suspension) – See Appendix O
A. Introduction
B. Product Summaries
C. College of Pharmacy Recommendations

Non-Presentation, Questions Only:

18. Annual Review of Growth Hormone – See Appendix P
A. Current Prior Authorization Criteria
B. Utilization of Growth Hormone
C. Prior Authorization of Growth Hormone
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Growth Hormone

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

19. FDA and DEA Updates – See Appendix Q

Items to be presented by Dr. Muchmore, Chairman:

20. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF JUNE 10, 2015

BOARD MEMBERS:	PRESENT	ABSENT
Theresa Garton, M.D.	x	
Carla Hardzog-Britt, M.D.	x	
Anetta Harrell, Pharm.D.	x	
Ashley Huddleston, Pharm. D.	x	
James Osborne, Pharm.D.		x
Paul Louis Preslar, D.O., MBA	x	
James Rhymer, D.Ph.	x	
Bruna Varalli-Claypool, MHS, PA-C		x
Eric Winegardner, D.Ph.	x	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	x	
Michyla Adams, Pharm.D.; Clinical Pharmacist	x	
Krystin Lorg, Pharm.D.; Clinical Pharmacist	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		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
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Graduate Students: Christina Bulkley, Pharm.D.	x	
David George, Pharm.D.		x
Tammy Lambert, Pharm.D.	x	
Timothy Pham, Pharm.D.	x	
Visiting Pharmacy Student(s): Chase Krueger, Rebekah Panak	x	

	PRESENT	ABSENT
Marlene Asmussen, R.N.; Population Care Management Director		x
Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm	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
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Garth Splinter, M.D.; M.B.A.; Medicaid Director	x	
Joseph Young, Deputy General Counsel IV	x	
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:		
Mark DeClerk, Lilly	Tim Hambacher, Otsuka	Jim Fowler, AstraZeneca
Doug Wood, ViiV Healthcare	Don Kempin, Novo Nordisk	Jim Chapman, AbbVie
Melvin Nwamadi, Abbott	Hope Berry, USL	Larry Goolsby, J&J
Richard Ponder, J&J	Aaron Shaw, Boehringer	Brian Maves, Pfizer
Aaron Zimmerman, Teva Pharm	Erica Brumleve, GSK	Deron Grothe, Teva
Mike Moran, Alkermes	Clint Degner, Novartis	Ryan Huddleston, Pharm.D.
Crystal Henderson, Otsuka	Jon MaGuire, GSK	Glenn Belenjian, Merck
Audrey Rattan, Alkermes	Phillip Church, Teva	Brent Hildebrand, Gilead
Roger Grotzinger, BMS	Jeff Knappen, Allergan	Rick Uhles, Actavis
Ron Schnare, Shire	David Tritsat, J&J	

PRESENT FOR PUBLIC COMMENT:	
Ron Kaufman	Upsher-Smith
Steve Vogel	Teva
Peter Dorson	J&J
Courtney Walker	Novo Nordisk

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**

2A: NON AGENDA ITEM SPEAKER: RON KAUFMAN
2B: AGENDA NO. 15 SPEAKER: STEVE VOGEL
2C: AGENDA NO. 8 SPEAKER: PETER DORSON
2D: AGENDA NO. 5 SPEAKER: COURTNEY WALKER

ACTION: NONE REQUIRED

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

3A: APRIL 8, 2015 DUR MINUTES – VOTE
3B: APRIL 8, 2015 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Harrell moved to approve; seconded by Dr. Hardzog-Britt

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/CHRONIC MEDICATION ADHERENCE PROGRAM UPDATE**

4A: MEDICATION COVERAGE ACTIVITY FOR APRIL 2015
4B: PHARMACY HELP DESK ACTIVITY FOR APRIL 2015
4C: MEDICATION COVERAGE ACTIVITY FOR MAY 2015
4D: PHARMACY HELP DESK ACTIVITY FOR MAY 2015
4E: CHRONIC MEDICATION ADHERENCE PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NO ACTION REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE TANZEUM™ (ALBIGLUTIDE), TRULICITY™ (DULAGLUTIDE), CYCLOSET® (BROMOCRIPTINE), JARDIANCE® (EMPAGLIFLOZIN), INVOKAMET™ CANAGLIFLOZIN/METFORMIN), XIGDUO™ XR (DAPAGLIFLOZIN/METFORMIN EXTENDED-RELEASE), GLYXAMBI® (EMPAGLIFLOZIN/LINAGLIPTIN), AFREZZA® (INSULIN HUMAN INHALATION POWDER), AND TOUJEO® (INSULIN GLARGINE)**

5A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread
Dr. Harrell moved to approve; seconded by Dr. Rhymer

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE RUCONEST® (C1 ESTERASE INHIBITOR)**

6A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Nawaz
Dr. Winegardner moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE HEMANGEOL™ (PROPRANOLOL ORAL SOLUTION), SOTYLIZE™ (SOTALOL ORAL SOLUTION), AND PRESTALIA® (PERINDOPRIL/AMLODIPINE)**

7A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz
Dr. Rhymer moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE INVEGA TRINZA™ (3-MONTH PALIPERIDONE PALMITATE INJECTION)**

8A: CURRENT PRIOR AUTHORIZATION CRITERIA
8B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
8C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
8D: MARKET NEWS AND UPDATES
8E: INVEGA TRINZA™ (3-MONTH PALIPERIDONE PALMITATE INJECTION) PRODUCT SUMMARY
8F: COLLEGE OF PHARMACY RECOMMENDATIONS
8G: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **30-DAY NOTICE TO PRIOR AUTHORIZE CHOLBAM™ (CHOLIC ACID)**

9A: INTRODUCTION
9B: CHOLBAM™ (CHOLIC ACID) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE NATPARA® (PARATHYROID HORMONE)**

10A: INTRODUCTION
10B: NATPARA® (PARATHYROID HORMONE) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **ANNUAL REVIEW OF ADHD & NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZENZEDI® (DEXTROAMPHETAMINE), EVEKEO™ (AMPHETAMINE), AND APTENSIO XR™ (METHYLPHENIDATE EXTENDED-RELEASE)**

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF ADHD & NARCOLEPSY MEDICATIONS
11C: PRIOR AUTHORIZATION OF ADHD & NARCOLEPSY MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: BINGE EATING DISORDER (BED) SUMMARY
11G: COLLEGE OF PHARMACY RECOMMENDATIONS
11H: UTILIZATION DETAILS OF ADHD & NARCOLEPSY MEDICATIONS

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF OTIC ANTI-INFECTIVES AND 30-DAY NOTICE TO PRIOR AUTHORIZE XTORO™ (FINAFLOXACIN)**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF OTIC ANTI-INFECTIVES
12C: PRIOR AUTHORIZATION OF OTIC ANTI-INFECTIVES
12D: MARKET NEWS AND UPDATES
12E: XTORO™ (FINAFLOXACIN) PRODUCT SUMMARY
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF OTIC ANTI-INFECTIVES

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **ANNUAL REVIEW OF INSOMNIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HETLIOZ® (TASIMELTEON) AND BELSOMRA® (SUVOREXANT)**

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF INSOMNIA MEDICATIONS
13C: PRIOR AUTHORIZATION OF INSOMNIA MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF INSOMNIA MEDICATIONS

Materials included in agenda packet; presented by Dr. Lorg

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF CEPHALOSPORIN ANTIBIOTICS & SYSTEMIC ANTIBIOTIC SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AVYCAZ™ CEFTAZIDIME/AVIBACTAM) AND ZERBAXA™ (CEFTOLOZANE/TAZOBACTAM)**

14A: INTRODUCTION
14B: CURRENT PRIOR AUTHORIZATION CRITERIA
14C: UTILIZATION OF CEPHALOSPORIN ANTIBIOTICS & SYSTEMIC ANTIBIOTIC SPECIAL FORMULATIONS
14D: PRIOR AUTHORIZATION OF CEPHALOSPORIN ANTIBIOTICS & SYSTEMIC ANTIBIOTIC SPECIAL FORMULATIONS
14E: CEPHALOSPORIN UTILIZATION EVALUATION
14F: MARKET NEWS AND UPDATES

14G: PRODUCT SUMMARIES
14H: COLLEGE OF PHARMACY RECOMMENDATIONS
14I: UTILIZATION DETAILS OF CEPHALOSPORIN ANTIBIOTICS
14J: UTILIZATION DETAILS OF SYSTEMIC ANTIBIOTIC SPECIAL FORMULATIONS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: 30-DAY NOTICE TO PRIOR AUTHORIZE COPAXONE® (GLATIRAMER ACETATE) 40MG/ML
15A: INTRODUCTION
15B: CURRENT PRIOR AUTHORIZATION CRITERIA
15C: COPAXONE® (GLATIRAMER ACETATE) UTILIZATION
15D: MARKET NEWS AND UPDATES
15E: DISCUSSION
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF COPAXONE® (GLATIRAMER ACETATE)
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FDA AND DEA UPDATES
Materials included in agenda packet; presented by Dr. Cothran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: ADJOURNMENT
The meeting was adjourned at 5:24 pm

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

Memorandum

Date: June 11, 2015

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

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

Subject: DUR Board Recommendations From Meeting of June 10, 2015

Recommendation 1: Vote to Prior Authorize Tanzeum™ (Albiglutide), Trulicity™ (Dulaglutide), Cycloset® (Bromocriptine), Jardiance® (Empagliflozin), Invokamet™ (Canagliflozin/Metformin), Xigduo™ XR (Dapagliflozin/Metformin Extended-Release), Glyxambi (Empagliflozin/Linagliptin), Afrezza® (Insulin Human Inhalation Powder), and Toujeo® (Insulin Glargine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends moving Actos® (pioglitazone) and Prandin® (repaglinide) to Tier-1 based on generic availability and state maximum allowable cost. Additionally, the College of Pharmacy recommends the placement of Tanzeum™ (albiglutide), Trulicity™ (dulaglutide), Cycloset® (bromocriptine), Jardiance® (empagliflozin), Invokamet™ (canagliflozin/metformin), Xigduo™ XR (dapagliflozin/metformin extended-release), and Glyxambi® (empagliflozin/linagliptin) into Tier-3 of the Diabetes Medications Product Based Prior Authorization category. Current criteria for this category will apply.

Diabetes Medications*			
Tier-1	**Tier-2+**	**Tier-3**	**Special PA**
Biguanides metformin (Glucophage®) metformin SR (Glucophage XR®) metformin/glipizide (Metaglip®) metformin/glyburide (Glucovance®) **Sulfonylureas** chlorpropamide glimepiride (Amaryl®) glipizide (Glucotrol®) glipizide SR (Glucotrol XL®) glyburide (Diabeta®) glyburide micronized (Micronase®) tolbutamide **Alpha-Glucosidase Inhibitors** acarbose (Precose®) **Glinides** nateglinide (Starlix®) **repaglinide (Prandin®)** **Thiazolidinedione** **pioglitazone (Actos®)**	**DPP-4 Inhibitors** saxagliptin (Onglyza®) saxagliptin/metformin (Kombiglyze®) sitagliptin (Januvia®) sitagliptin/metformin (Janumet®) sitagliptin/metformin ER (Janumet XR®) **Glinides** repaglinide/metformin (Prandimet®) **GLP-1 Agonists** exenatide (Byetta®) exenatide (Bydureon®) liraglutide (Victoza®)	**DPP-4 Inhibitors** alogliptin (Nesina®) alogliptin/metformin (Kazano®) alogliptin/pioglitazone (Oseni®) linagliptin (Tradjenta®) linagliptin/metformin (Jentadueto™) **Thiazolidinediones** pioglitazone/glimepiride (Duetact®) pioglitazone/metformin (Actoplus Met®, Actoplus Met XR®) rosiglitazone (Avandia®) rosiglitazone/glimepiride (Avandaryl®) rosiglitazone/metformin (Avandamet®) **Alpha-Glucosidase Inhibitors** miglitol (Glyset®) **SGLT 2 Inhibitor** canagliflozin (Invokana™) **canagliflozin/metformin (Invokamet™)** dapagliflozin (Farxiga™) **dapagliflozin/metformin (Xigduo™ XR)** **empagliflozin (Jardiance®)** **Dopamine Agonist** **bromocriptine (Cycloset®)** **SGLT-2/DPP-4 Inhibitor** **empagliflozin/linagliptin (Glyxambi®)** **GLP-1 Agonists** **albiglutide (Tanzeum™)** **dulaglutide (Trulicity™)**	**Biguanides** metformin ER (Fortamet®, Glumetza®) metformin solution (Riomet®) **Amylinomimetic** pramlintide (Symlin®)

*Tier structure based on supplemental rebate participation.
+Rebated Products

Diabetes Medications Tier-2 Approval Criteria:

1. A trial of a Tier-1 medication (must include a trial of metformin titrated up to maximum dose), or a patient-specific, clinically significant reason why a Tier-1 medication is not appropriate.
2. For initiation with dual or triple therapy, additional Tier-2 medications can be approved based on current AACE or ADA guidelines.

Diabetes Medications Tier-3 Approval Criteria:

1. Member must have tried a Tier-2 medication in the same category and have a documented clinical reason why the Tier-2 medication is not appropriate. (For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used.)

Diabetes Medications Special Prior Authorization Approval Criteria:

1. Member must be currently stabilized on the requested medication or have attempted at least three other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member.

Furthermore, the College of Pharmacy recommends the prior authorization of Afrezza® (insulin human inhalation powder) with the following criteria:

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate; and
4. For the diagnosis of type 1 diabetes, the member must use Afrezza® with a long-acting insulin; and
5. The member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Lastly, the College of Pharmacy recommends the prior authorization of Toujeo® (insulin glargine) with the following criteria:

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine), and the member must be using a minimum of 100 units of Lantus® (insulin glargine) per injection.

Recommendation 2: Vote to Prior Authorize Ruconest® (C1 Esterase Inhibitor)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Ruconest® (C1 esterase inhibitor) with the following criteria:

Ruconest® (C1 Esterase Inhibitor) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema; and
2. Ruconest® must be used for *treatment* of acute attacks of hereditary angioedema; and
3. A patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor, human).

Recommendation 3: Vote to Prior Authorize Hemangeol™ (Propranolol Oral Solution), Sotylize™ (Sotalol Oral Solution) and Prestalia® (Perindopril/Amlodipine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Hemangeol™ (propranolol oral solution) and Sotylize™ (sotalol oral solution) with the following criteria:

Hemangeol™ (Propranolol Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of treatment of proliferating infantile hemangioma requiring systemic therapy; and
2. A patient-specific, clinically significant reason why the member cannot use the generic propranolol solutions (20mg/5mL and 40mg/5mL) which are available without prior authorization.

Sotylize™ (Sotalol Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of life-threatening ventricular arrhythmias or for the maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter; and
2. A patient-specific, clinically significant reason why the member cannot use sotalol oral tablets in place of the oral solution formulation; and
3. A quantity limit of 64mL per day or 1,920mL per 30 days will apply.

Additionally, the College of Pharmacy recommends the addition of Prestalia® (perindopril/amlodipine) to Tier-3 of the ACE Inhibitor/Calcium Channel Blocker category with the following criteria:

Prestalia® (Perindopril/Amlodipine) Approval Criteria:

1. An FDA approved diagnosis; and
2. Documented trials of inadequate response to two Tier-1 angiotensin converting enzyme inhibitors (ACEIs) in combination with amlodipine; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components separately; and
4. A quantity limit of 30 tablets per 30 days will apply.

Angiotensin Converting Enzyme Inhibitor (ACEI)/ Calcium Channel Blocker (CCB) Combinations*		
Tier-1	**Tier-2**	**Tier-3**
Tier-1 ACE + Tier-1 CCB		benazepril/amlodipine (Lotrel®)
		enalapril/felodipine (Lexxel®)
		perindopril/amlodipine (Prestalia®)
		trandolapril/verapamil (Tarka®)

*Tier-2 criterion applies for Tier-3 medications when there are no Tier-2 medications available.

Recommendation 4: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Invega Trinza™ (3-Month Paliperidone Palmitate Injection)

NO ACTION REQUIRED.

Recommendation 5: 30-Day Notice to Prior Authorize Cholbam™ (Cholic Acid)

NO ACTION REQUIRED.

Recommendation 6: 30-Day Notice to Prior Authorize Natpara® (Parathyroid Hormone Injection)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of ADHD & Narcolepsy Medications and 30-Day Notice to Prior Authorize Zenzedi® (Dextroamphetamine), Evekeo™ (Amphetamine), and Aptensio XR™ (Methylphenidate Extended-Release)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Otic Anti-Infectives and 30-Day Notice to Prior Authorize Xtoro™ (Finafloxacin)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Hetlioz® (Tasimelteon) and Belsomra® (Suvorexant)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Cephalosporin Antibiotics & Systemic Antibiotic Special Formulations and 30-Day Notice to Prior Authorize Avycaz™ (Ceftazidime/Avibactam) and Zerbaxa™ (Ceftolozane/Tazobactam)

NO ACTION REQUIRED.

Recommendation 11: 30-Day Notice to Prior Authorize Copaxone® (Glatiramer Acetate) 40mg/mL

NO ACTION REQUIRED.

INTEGRIS

NEUROLOGY

I am writing on behalf of my medical practice and my patients to keep Copaxone 40mg three times a week as the preferred agent on Oklahoma Medicaid. It would be a disservice to allow Copaxone 40mg to be replaced with a possible generic version in the future that may or may not protect the patient from further disability, despite the fact that the FDA has deemed them equivalent, and I would not endorse the use of generic glatiramer acetate.

Copaxone is a random copolymer chain of amino acids that are represented in myelin basic protein and has a very unique mode of action affecting the central nervous system. Copaxone is also backed by thousands of scientific and clinical studies. The generic version only has a short term study looking at the inflammatory side of the disease and not the neurodegenerative side or any of the physiochemical properties. Copaxone is extremely difficult to develop and Teva's proprietary process to manufacture this product has ensured consistency in every batch. There was a study published in January 2014 comparing Copaxone with a generic version and that data demonstrated significant differences in the biological and immunological effects between the branded drug and the generic. Even though this study was not done with the generic version approved by the FDA, this data shows the possible significant ramifications of changes in physiochemical properties between Copaxone and a generic on the immune system of patients, with possible implications on efficacy and safety in RRMS patients.

A generic glatiramer acetate would also mean 208 more injections/year for patients and not include the nursing support available 24/7 at no extra cost for patients. This also includes injection trainings, tips and education given to ensure their experience is a favorable one for entire duration of their treatment.

Because of this information, I would not endorse the use of generic glatiramer acetate. At the very least, I ask that you allow patients already on Copaxone 40mg three times a week to remain on that option and under no circumstances, allow them to be changed to a generic option.

Thank you,

Arlene Jaquez LPN

Arlene Jaquez LPN

3433 NW 56th Street, Suite 710 · Oklahoma City, OK 73112 · 405.713.9930 · F: 405.713.9931 · integrisok.com

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Thank you,

Catherine E Porter MD

Catherine Porter M.D.

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Thank you,

Ursula Ready LPN

Ursula Ready LPN

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Thank you,

Farhat Husain M.D.

Farhat Husain M.D.

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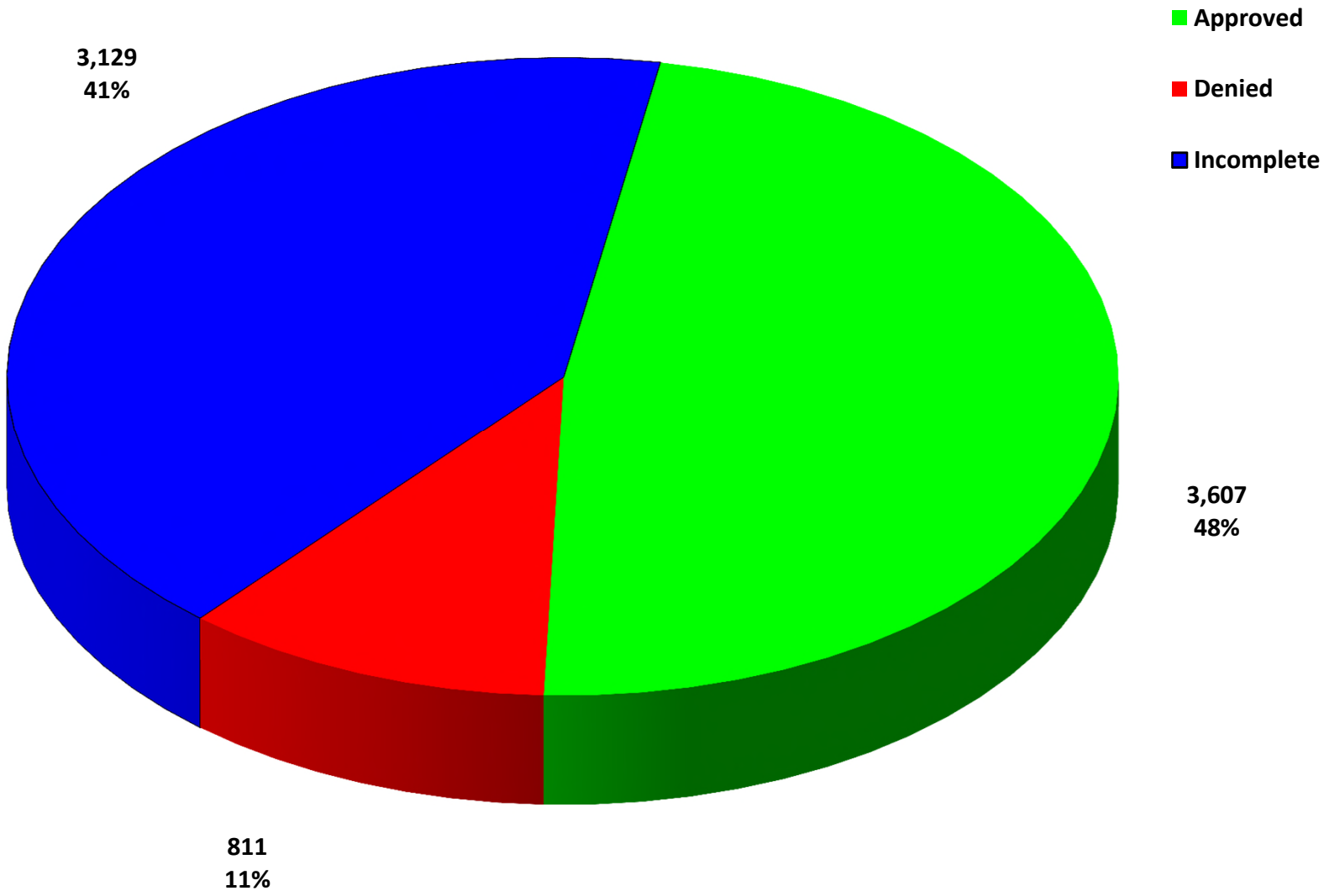
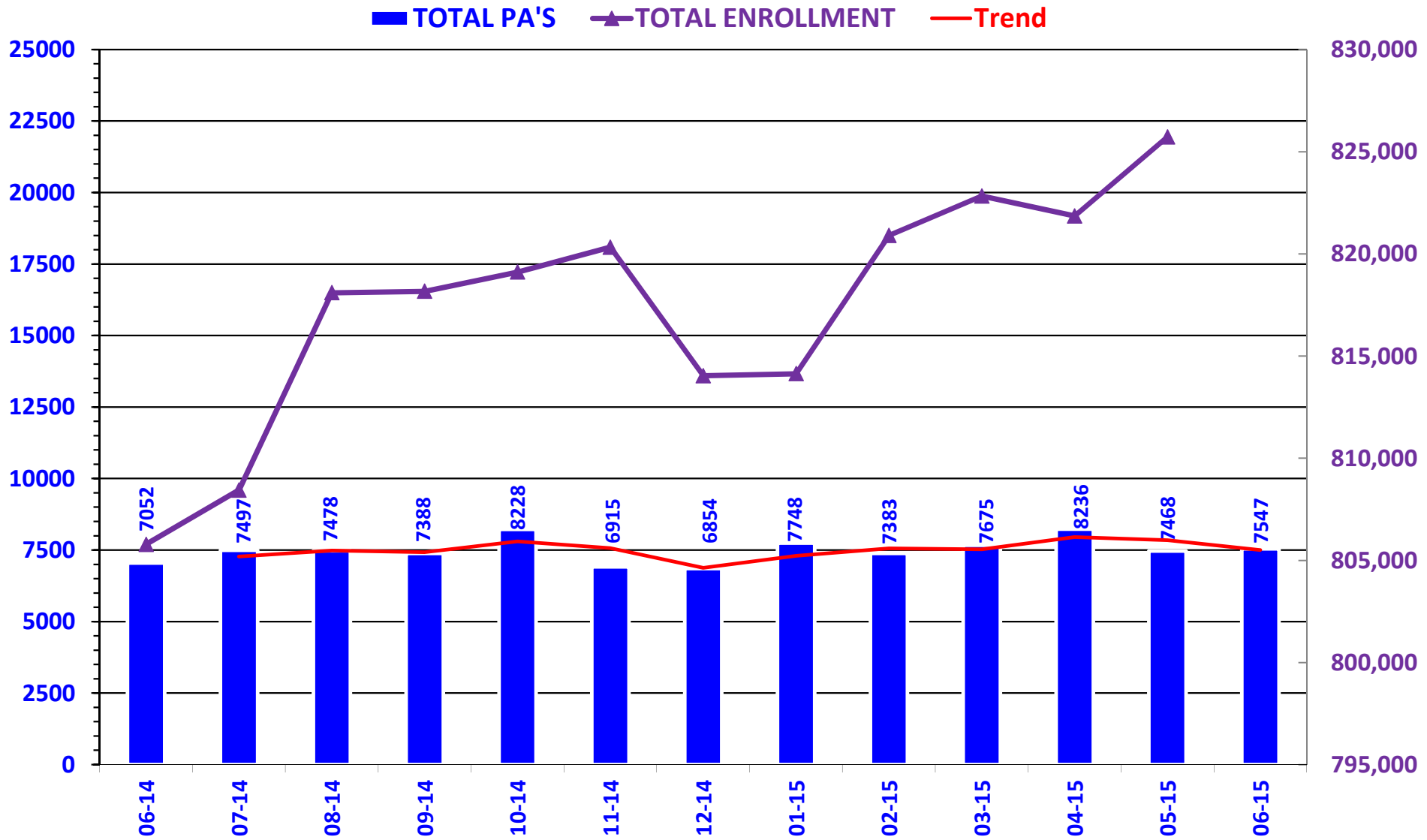
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2015



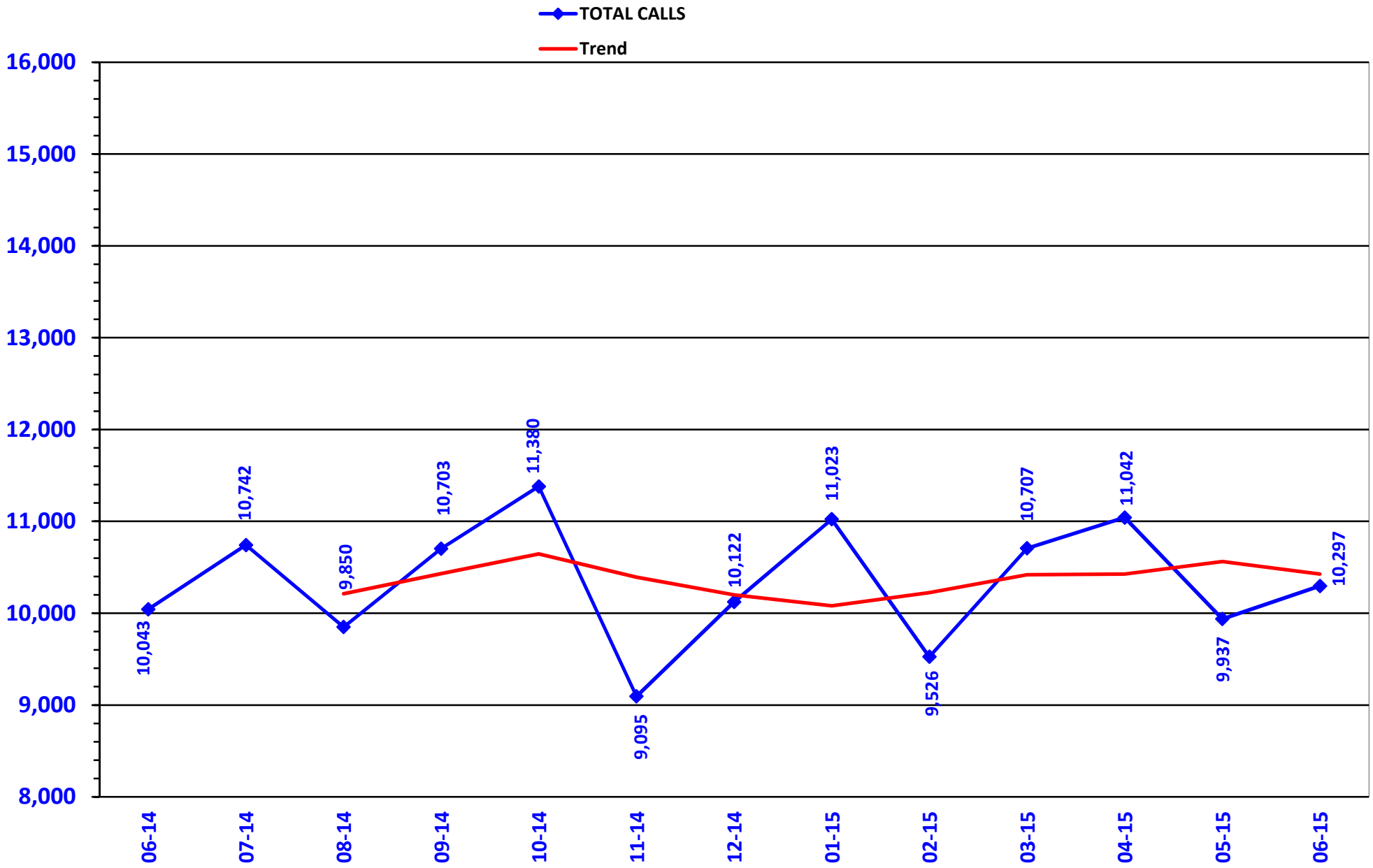
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2014 – JUNE 2015



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JUNE 2014 – JUNE 2015



Prior Authorization Activity

6/1/2015 Through 6/30/2015

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	340	150	17	173	358
Analgesic - NonNarcotic	22	1	2	19	361
Analgesic, Narcotic	420	227	24	169	166
Angiotensin Receptor Antagonist	18	4	7	7	358
Antiasthma	199	72	18	109	320
Antibiotic	34	10	2	22	152
Anticonvulsant	77	23	13	41	330
Antidepressant	95	19	21	55	344
Antidiabetic	193	86	19	88	359
Antifungal	16	2	6	8	48
Antigout	10	7	0	3	360
Antihistamine	134	102	5	27	354
Antimigraine	48	4	8	36	275
Antiulcers	196	53	43	100	160
Anxiolytic	65	45	3	17	261
Atypical Antipsychotics	566	287	17	262	343
Benign Prostatic Hypertrophy	14	2	6	6	361
Biologics	87	44	12	31	330
Bladder Control	39	10	6	23	359
Blood Thinners	143	87	6	50	319
Botox	29	21	5	3	348
Calcium Channel Blockers	12	5	1	6	132
Cardiovascular	55	21	6	28	311
Chronic Obstructive Pulmonary Disease	24	6	5	13	359
Dermatological	111	15	56	40	105
Diabetic Supplies	475	227	21	227	262
Endocrine & Metabolic Drugs	76	46	9	21	135
Erythropoietin Stimulating Agents	36	19	5	12	99
Fibromyalgia	127	33	27	67	344
Fish Oils	14	2	2	10	361
Gastrointestinal Agents	72	16	19	37	65
Growth Hormones	53	37	5	11	169
Hematopoietic Agents	10	5	1	4	141
Hepatitis C	170	80	43	47	8
HFA Rescue Inhalers	49	23	6	20	328
Insomnia	64	13	12	39	180
Insulin	24	15	3	6	337
Linzess, Amitiza, and Relistor	73	9	18	46	268
Multiple Sclerosis	38	24	3	11	247
Muscle Relaxant	93	14	33	46	95
Nasal Allergy	83	12	18	53	235
Neurological Agents	49	23	11	15	360
NSAIDs	159	21	26	112	273
Ocular Allergy	52	11	10	31	236
Ophthalmic Anti-infectives	22	5	1	16	17
Osteoporosis	23	7	4	12	358
Other*	206	51	34	121	207
Otic Antibiotic	15	1	1	13	26
Pediculicide	122	52	16	54	17
Prenatal Vitamins	24	0	7	17	0
Statins	63	17	4	42	361
Stimulant	822	392	40	390	329
Suboxone/Subutex	205	144	9	52	79

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Testosterone	48	15	8	25	342
Topical Antifungal	40	2	12	26	284
Topical Corticosteroids	64	0	20	44	0
Vitamin	78	20	39	19	254
Pharmacotherapy	77	61	0	16	289
Emergency PAs	0	0	0	0	
Total	**6,473**	**2,700**	**775**	**2,998**	

Overrides					
Brand	38	27	0	11	265
Cumulative Early Refill	4	4	0	0	180
Diabetic Supplies	110	83	0	27	242
Dosage Change	303	287	8	8	6
High Dose	1	1	0	0	118
Ingredient Duplication	52	47	3	2	19
Lost/Broken Rx	63	59	1	3	4
NDC	1	1	0	0	26
NDC vs Age	20	20	0	0	300
Nursing Home Issue	52	47	0	5	5
Opioid Quantity	10	9	1	0	164
Other*	24	22	0	2	16
Quantity vs. Days Supply	465	357	20	88	277
STBS/STBSM	11	9	0	2	61
Stolen	15	13	0	2	4
Temporary Unlock	2	2	0	0	26
Third Brand Request	27	15	4	8	33
Wrong D.S. on Previous Rx	1	1	0	0	3
Overrides Total	**1,074**	**907**	**36**	**131**	
Total Regular PAs + Overrides	**7,547**	**3,607**	**811**	**3,129**	

Denial Reasons	
Unable to verify required trials.	2,854
Does not meet established criteria.	813
Lack required information to process request.	473

Other PA Activity	
Duplicate Requests	552
Letters	4,625
No Process	58
Helpdesk Initiated Prior Authorizations	767
PAs Missing Information	36

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

SoonerPsych Program Update

Oklahoma Health Care Authority
July 2015

Prescriber Mailing Summaries

The SoonerPsych program is an educational quarterly mailing to prescribers with members on atypical antipsychotic medications. Each mailing includes a gauge showing prescribers how their prescribing compares to other prescribers of atypical antipsychotics regarding potential differences from generally accepted evidence-based prescribing practices. Each mailing also includes an informational page with evidence-based material related to the mailing topic

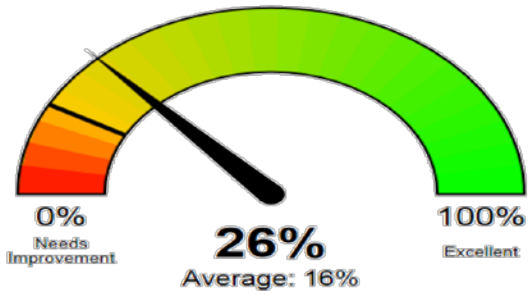
The SoonerPsych program updated to the "report card" format in April of 2014. The following list includes details of previous SoonerPsych mailings processed in the new "report card" format.

- **Diagnosis: April 2014**
  - Inclusion Criteria: Prescribers were eligible if they had prescribed atypical antipsychotics for members whose recent twelve month medical claims history lacked a diagnosis with a strong indication for prescribing an antipsychotic medication.
  - Number of Prescribers and Patients Flagged: A total of 1,665 prescribers were flagged for having at least one patient without a target diagnosis. These prescribers had 11,865 flagged patients without a target diagnosis.
  - Number of Prescribers and Members Included in the Mailing: A total of 200 prescribers were included in the mailing which included 8,069 flagged patients without a target diagnosis.
- **Polypharmacy: July 2014**
  - Inclusion Criteria: Prescribers were eligible if they had prescribed atypical antipsychotics for members whose pharmacy claims history indicated concurrent use of two or more atypical antipsychotic medications for more than 90 days.
  - Number of Prescribers and Patients Flagged: A total of 1,364 prescribers were flagged for having at least one patient with polypharmacy. These prescribers had 10,423 patients flagged for polypharmacy.
  - Number of Prescribers and Members Included in the Mailing: A total of 141 prescribers were included in the mailing which included 924 patients flagged for polypharmacy.
- **Adherence: October 2014**
  - Inclusion Criteria: Prescribers were eligible if they had prescribed atypical antipsychotics for members whose proportion of days covered (PDC) or adherence was calculated as less than 80%.
  - Number of Prescribers and Patients Flagged: A total of 1,534 prescribers were flagged for having at least one member using an atypical antipsychotic considered non-

adherent. These prescribers accounted for 10,108 flagged patients considered non-adherent.
    - Number of Prescribers and Members Included in the Mailing: A total of 199 prescribers were included in the mailing which included 1,368 patients flagged for non-adherence.
- **Metabolic Monitoring: January 2015**
    - Inclusion Criteria: Prescribers were eligible if they had prescribed atypical antipsychotics for members whose recent twelve month medical claims history lacked glucose testing. Prescribers were also eligible for inclusion if they had prescribed atypical antipsychotics for members with a diagnosis of hyperlipedmia whose recent twelve month medical claims history lacked lipid testing.
    - Number of Prescribers and Patients Flagged: A total of 1,222 prescribers were flagged for having at least one member with missing metabolic monitoring while on atypical antipsychotic medications. These prescribers accounted for 8,238 flagged patients for missing metabolic monitoring.
    - Number of Prescribers and Members Included in the Mailing: A total of 200 prescribers were included in the mailing which included 1,308 patients flagged for missing metabolic monitoring.
- **Diagnosis: April 2015**
    - Inclusion Criteria: Prescribers were eligible if they had prescribed atypical antipsychotics for members whose recent twelve month medical claims history lacked a diagnosis with a strong indication for prescribing an antipsychotic medication.
    - Number of Prescribers and Patients Flagged: A total of 1,691 prescribers were flagged for having at least one patient without a target diagnosis. These prescribers had 16,416 flagged patients without a target diagnosis.
    - Number of Prescribers and Members Included in the Mailing: A total of 200 prescribers were included in the mailing which included 1,962 flagged patients without a target diagnosis.

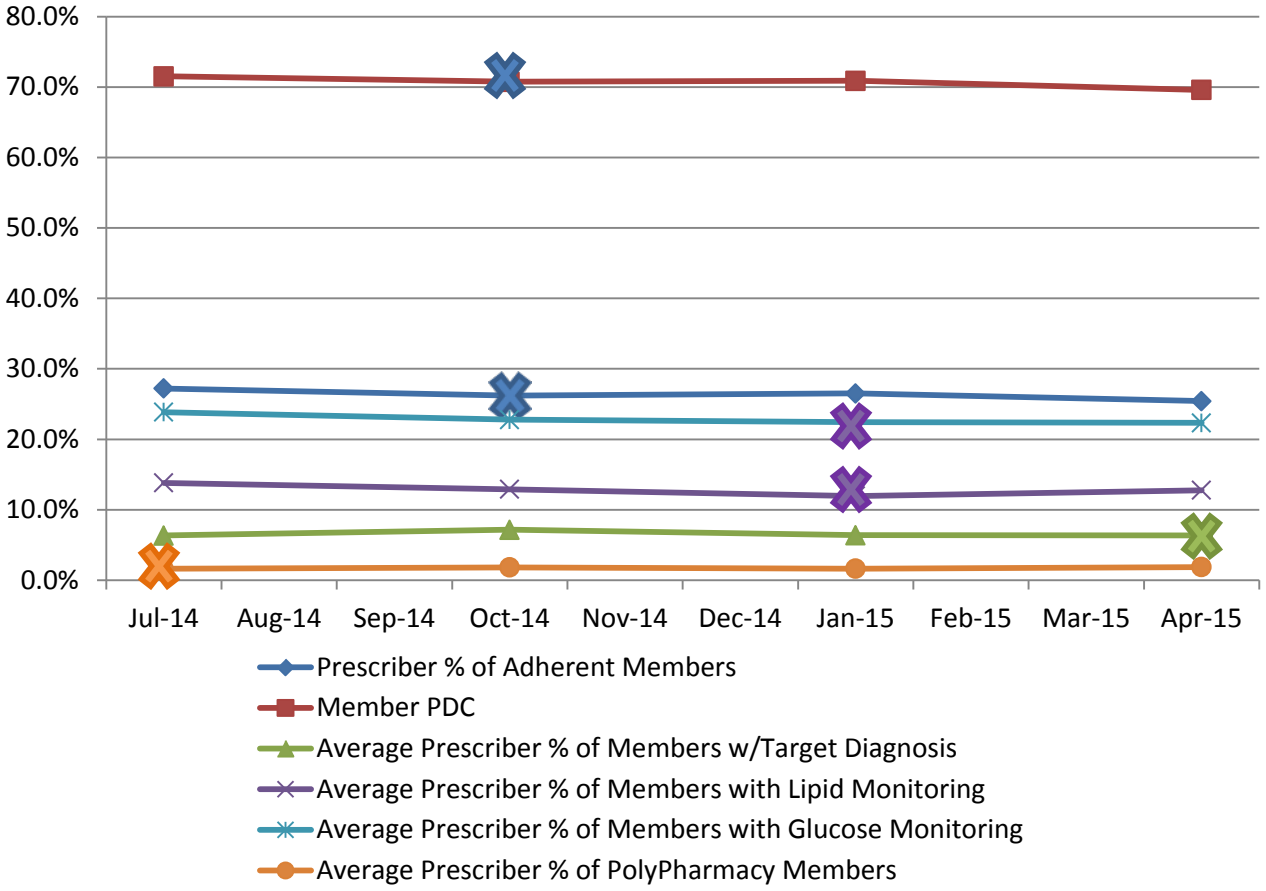
Example Gauge

Each gauge includes the individual prescriber's performance in relation to the specific mailing topic as well as the average of other prescribers for comparison.



SoonerPsych Trends

Each time a mailing is processed, all modules or topics are tracked. The line graph below shows prescriber trends for each topic. Markers indicate when a mailing was processed. The line graph below depicts the percentage for all atypical antipsychotic SoonerCare prescribers and does not differentiate those prescribers who received a mailing and did not receive a mailing.



The prescriber percent of adherent members and the member PDC experience a slight increase after the adherence mailing was processed in October 2014.

The diagnosis mailing was first processed in April 2014 and again in April 2015. The average prescriber percent of members with a target diagnosis increased slightly in October 2014, but has since declined.

The metabolic mailing was processed in January 2015. An increase was seen in the average prescriber percentage of members with lipid monitoring, however no increase was seen in the average prescriber percentage of members with glucose monitoring.

The polypharmacy mailing was processed in July 2014. The average prescriber percent of members with polypharmacy increased slightly in October 2014.

Conclusions

Most mailings appear to be effective in improving evidence-based care in the quarter immediately following the mailing, but then the effect of the intervention appears to decline over time. The College of Pharmacy would like to investigate the percentages for the prescribers included in the mailings alone to see if there is a greater impact in the intervened population versus the entire atypical antipsychotic prescriber population. The College of Pharmacy will continue to work with the Oklahoma Health Care Authority to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing atypical antipsychotic medications.

Appendix C

Vote to Prior Authorize
Avycaz™ (Ceftazidime/Avibactam) and Zerbaxa™ (Ceftolozane/Tazobactam)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the prior authorization of Avycaz™ (ceftazidime/avibactam) and Zerbaxa™ (ceftolozane/tazobactam) with the following criteria:

Avycaz™ (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of one of the following infections caused by designated susceptible microorganisms:
    a. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole; or
    b. Complicated urinary tract infections (cUTI), including Pyelonephritis; and
2. Member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Avycaz™ must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin-beta lactamase inhibitor combination (e.g. piperacillin-tazobactam), a carbapenam (e.g. ertapenem, meropenem, imipenem-cilastatin), a cephalosporin (e.g. ceftriaxone, ceftazidime) in combination with metronidazole, or other cost effective therapeutic equivalent medication(s).
5. A quantity limit of 42 vials per 14 days will apply.

Zerbaxa™ (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of one of the following infections caused by designated susceptible microorganisms:
    a. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole; or
    b. Complicated urinary tract infections (cUTI), including Pyelonephritis; and
2. Member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa™ must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin-beta lactamase inhibitor combination (e.g. piperacillin-tazobactam), a carbapenam (e.g. ertapenem, meropenem, imipenem-cilastatin), a cephalosporin (e.g. ceftriaxone, ceftazidime) in combination with metronidazole, or other cost effective therapeutic equivalent medication(s).
5. A quantity limit of 42 vials per 14 days will apply.

Appendix D

Vote to Prior Authorize
Copaxone® (Glatiramer Acetate) 40mg/mL

Oklahoma Health Care Authority
July 2015

Recommendations

Recommendations regarding the generic formulation of Copaxone® (glatiramer acetate) 20mg will not be made by the College of Pharmacy at this time. Further information from the FDA regarding equivalency to the branded formulation is required.

Based on federal rebate pricing and net cost, the College of Pharmacy recommends the prior authorization of Copaxone® (glatiramer acetate) 40mg with the criteria presented below. A pre-emptive educational initiative will be sent to prescriber and pharmacy providers before these prior authorizations become effective.

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing, remitting Multiple Sclerosis; and
2. Approvals will not be granted for concurrent use with other disease modifying therapies; and
3. Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and
4. Compliance will be checked for continued approval every six months.

Appendix E

Vote to Prior Authorize
Invega Trinza™ (3-Month Paliperidone Palmitate Injection)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Product Based Prior Authorization (PBPA) category:

1. Moving aripiprazole tablets to Tier-1 when the state maximum allowable cost is comparable to other Tier-1 generic medications.
2. After moving aripiprazole tablets to Tier-1, the College of Pharmacy recommends requiring a trial of aripiprazole as one of the Tier-1 trials for authorization of a Tier-2 medication.
    a. If an aripiprazole tablets trial is inappropriate for the member, a patient-specific, clinically significant reason would need to be provided; or
    b. An FDA approved diagnosis not covered by aripiprazole.
3. Additionally, after moving aripiprazole tablets to Tier-1, the College of Pharmacy recommends adding a required trial of aripiprazole to the approval criteria for atypical antipsychotics as adjunctive treatment for major depressive disorder.
4. Lastly, the College of Pharmacy recommends placing Invega Trinza™ into Tier-3. Current criteria for this category will apply.

Atypical Antipsychotic Tier-2 Approval Criteria:

1. Trials of two Tier-1 medications at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
    a. One of the Tier-1 trials must include a trial with aripiprazole unless member has a patient-specific, clinically significant reason why aripiprazole is not appropriate or an FDA approved diagnosis not covered by aripiprazole.
    b. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Tier-3 Approval Criteria:

1. Trials of two Tier-1 medications at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
    a. One of the Tier-1 trials must include a trial with aripiprazole unless member has a patient-specific, clinically significant reason why aripiprazole is not appropriate or an FDA approved diagnosis not covered by aripiprazole.
    b. Clozapine does not count towards a Tier-1 trial.

2. Trials of two Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least four trials of Tier-1 and Tier-2 medications (two trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects.
4. Use of Versacloz™ (clozapine oral suspension) and Fazaclo® (clozapine orally disintegrating tablet) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment for Major Depression Disorder:
Authorization of Seroquel XR® (quetiapine extended-release) or Symbyax® (olanzapine/fluoxetine) for a diagnosis of major depressive disorder requires current use of an antidepressant, and previous trials with at least two other antidepressants from both categories (an SSRI and duloxetine) and a trial of aripiprazole tablets that did not yield adequate response. Tier structure applies.

Atypical Antipsychotics*		
Tier-1	**Tier-2**	**Tier-3+**
aripiprazole (Abilify®)	aripiprazole (Abilify Maintena®)	clozapine (Fazaclo®)
clozapine (Clozaril®)¥	asenapine (Saphris®)	clozapine oral suspension (Versacoz™)
olanzapine (Zyprexa®)	iloperidone (Fanapt™)	olanzapine/fluoxetine (Symbyax®)
quetiapine (Seroquel®)	lurasidone (Latuda®)	**paliperidone (Invega Trinza™)∞**
risperidone (Risperdal®)	paliperidone (Invega®)	
risperidone (Risperdal Consta®)	paliperidone (Invega® Sustenna®)	
ziprasidone (Geodon®)	quetiapine ER (Seroquel XR®)	

*Tier structure based on supplemental rebate participation.
+ May be rebated to Tier-2 status only.
¥ Does not count toward a Tier-1 trial.
∞ In addition to tier trials, use of Invega Trinza™ requires members to have been adequately treated with the 1-month paliperidone extended-release injection (Invega® Sustenna®) for at least four months.
ER = extended-release

Appendix F

Vote to Prior Authorize
Cholbam™ (Cholic Acid)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the prior authorization of Cholbam™ (cholic acid) with the following criteria:

Cholbam™ (Cholic Acid) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
    a. Treatment of bile acid disorders due to single enzyme defects (SEDs); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
2. Treatment with Cholbam™ should be initiated and monitored by a hepatologist or pediatric gastroenterologist; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin and INR will be monitored every month for the first three months, every three months for the next nine months, every six months during the next three years and annually thereafter; and
4. Cholbam™ should be discontinued if liver function does not improve within three months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of three months to monitor for compliance and liver function tests.
6. Continuation approvals will be granted for the duration of one year.
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

Appendix G

Vote to Prior Authorize
Natpara® (Parathyroid Hormone Injection)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the prior authorization of Natpara® (parathyroid hormone injection) with the following criteria:

Natpara® (Parathyroid Hormone Injection) Approval Criteria:

1. An FDA approved diagnosis as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism; and
    a. Natpara® is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations.
    b. Natpara® is not FDA approved for hypoparathyroidism due to acute post-surgery.
2. Magnesium deficiency must be ruled out; and
3. Member must have pretreatment serum calcium above 7.5mg/dL before starting Natpara®; and
4. Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and
5. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and
6. Health care provider and dispensing pharmacy must be certified through the Natpara® Risk Evaluation and Mitigation Strategies (REMS) Program; and
7. A quantity limit of two cartridges (each package contains two 14-day cartridges) per 28 days will apply. The maximum covered dose will be 100mcg per day.

Appendix H

Vote to Prior Authorize Zenzedi® (Dextroamphetamine), Evekeo™ (Amphetamine), and Aptensio XR™ (Methylphenidate Extended-Release)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the following changes to the ADHD & Narcolepsy Medications Product Based Prior Authorization (PBPA) category:

1. Place Zenzedi® (dextroamphetamine) into the Special Prior Authorization (PA) category.
    a. The existing criteria for other dextroamphetamine products in the Special PA category will apply.
2. Place Evekeo™ (amphetamine) into the Special PA category based on estimated acquisition cost and FDA approved indications.
    a. Evekeo™ (amphetamine) will require a covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications.
    c. A quantity limit of 90 tablets per 30 days will apply.
3. Place Aptensio XR™ (methylphenidate ER) into Tier-3 based on estimated acquisition cost.
    a. The existing criteria for this category will apply.
    b. A quantity limit of 30 capsules per 30 days will apply.
4. Add specific criteria for the new indication of binge eating disorder (BED) for Vyvanse® (lisdexamfetamine).

ADHD & Narcolepsy Medications Tier-2 Approval Criteria:

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

ADHD & Narcolepsy Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A trial with at least one long-acting Tier-1 stimulant; and
3. A trial with at least one long-acting Tier-2 stimulant that did not yield adequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in the member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the prescriber.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why the member cannot use the available long-acting capsule formulation.
5. Use of Kapvay® (clonidine extended-release tablets) requires:
    a. An FDA approved diagnosis; and
    b. Recent trials with a long-acting Tier-1 stimulant and a long-acting Tier-2 stimulant, and a trial of Intuniv® and Strattera® within the past six months, unless contraindicated, that did not yield adequate results; and
    c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate release tablets.

ADHD & Narcolepsy Medications Special Prior Authorization (PA) Approval Criteria:

1. Desoxyn®, Dexedrine®, Dexedrine Spansules®, Evekeo®, ProCentra® Solution, and Zenzedi® Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why member cannot use all other available stimulant medications.
2. Daytrana®, Quillivant XR®, and Methylin® Chewable Tablets and Solution Criteria:
    a. An FDA approved diagnosis; and
    b. A patient-specific, clinically significant reason why member cannot use all other available formulations of long-acting stimulant medications that can be used for members who cannot swallow capsules or tablets.
3. Provigil®, Nuvigil®, and Xyrem® Criteria:
    a. An FDA approved diagnosis; and
    b. Use of Provigil® or Nuvigil® requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime.
    c. Use of Xyrem® requires recent trials with Tier-1 and Tier-2 stimulants from different chemical categories, and trials with both Provigil® and Nuvigil® within the past six months, unless contraindicated, that did not yield adequate results.
    d. The diagnosis of obstructive sleep apnea requires concurrent treatment for the obstructive sleep apnea.
    e. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

ADHD & Narcolepsy Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum are not covered.
2. Prior Authorization is required for all tiers for members greater than 20 years of age and for members 0-4 years of age. All prior authorization requests for members under the age of 5 years must be reviewed by an OHCA contracted psychiatrist.
3. Vyvanse® (Lisdexamfetamine) Approval Criteria: Binge Eating Disorder (BED)
    a. An FDA approved diagnosis of moderate-to-severe binge eating disorder; and
    b. Member must be 18 years or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
    e. A quantity limit of 30 capsules per 30 days will apply; and
    f. Initial approvals will be for the duration of three months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

ADHD & Narcolepsy Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			Daytrana™ (methylphenidate ER) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) **Evekeo™ (amphetamine sulfate)** Methylin® (methylphenidate soln & chew tabs) Nuvigil® (armodafinil) ProCentra™ (dextroamphetamine) Provigil® (modafinil) Quillivant XR® (methylphenidate ER) Xyrem® (sodium oxybate) **Zenzedi® (dextroamphetamine)**
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Vyvanse® (lisdexamfetamine)+	Adderall XR® brand name only (amphetamine/ dextroamphetamine ER)	amphetamine/ dextroamphetamine ER (generic Adderall XR®)	
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate) Ritalin® (methylphenidate)			
Long-Acting			
Metadate CD® brand name only (methylphenidate ER) Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) Ritalin SR® (methylphenidate ER)	Focalin XR® (dexmethylphenidate ER) Ritalin LA® brand name only (methylphenidate ER)	**Aptensio XR™ (methylphenidate ER)** Concerta® (methylphenidate ER) methylphenidate ER (generic Metadate CD®) methylphenidate ER (generic Ritalin LA®)	
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)		Kapvay® (clonidine ER)	

*Tier structure based on State Maximum Allowable Cost (SMAC) and/or supplemental rebate participation.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ER = Extended-Release
SR = Sustained-Release
Soln = Solution

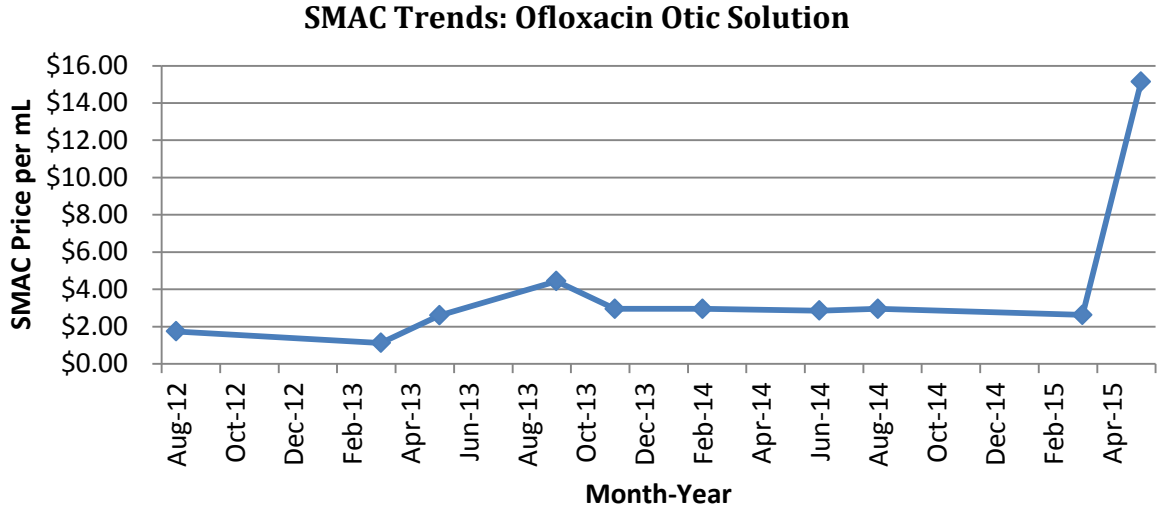
Appendix I

Vote to Prior Authorize Xtoro™ (Finafloxacin) and Ofloxacin Otic

Oklahoma Health Care Authority
July 2015

Ofloxacin Otic Solution Update

Ofloxacin otic solution has increased in price by more than 400% since November 2013. The increase in price is a result of fewer manufacturers producing the product, and does not appear to be transient. The graph below outlines the state maximum allowable cost (SMAC) price increase trend for ofloxacin otic solution since August 2012.



The most recent SMAC price updated in May 2015 is $15.15 per mL, resulting in a 10mL bottle costing around $151.50. This price is significantly greater than the $29.50 cost per bottle in November of 2013. In quarter one of 2015 a total of 4,019 members utilized ofloxacin otic solution for a total of 4,406 claims. Based on these utilization estimates, the ofloxacin price increase could result in an annual total increase in spending of approximately $2,150,128.00.

It is important to note that all Tier-1 otic anti-infectives have similar spectrum coverage including *Pseudomonas aeruginosa* and *Staphylococcus aureus*, and that all pathogens covered by ofloxacin otic solution are covered by at least one Tier-1 alternative. Tier-1 alternatives that could be used in place of ofloxacin otic solution include the following treatment options:

- Ciprodex® (ciprofloxacin/dexamethasone) otic suspension is available without a prior authorization for those who need a fluoroquinolone otic antibiotic.
- Other Tier-1 options available without prior authorization include: acetic acid (Vosol®, Acetasol®) and neomycin/polymyxin B/hydrocortisone (Cortisporin®, Pediotic®).
- Ofloxacin ophthalmic solution is also available without prior authorization if the prescriber chooses for the member to use the ophthalmic solution in the ear.

Recommendations

The College of Pharmacy recommends the following changes to the Otic Anti-Infectives Product Based Prior Authorization (PBPA) category:

1. Place Xtoro™ (finafloxacin) into Tier-2. The existing criteria for this category will apply.
2. Move ofloxacin otic solution to Tier-2 based on an increased state maximum allowable cost (SMAC).
    a. The existing criteria for this category will apply.
    b. Initiate an educational mailing regarding these tier changes, which will include the option of utilizing ofloxacin ophthalmic solution for otic conditions as well other Tier-1 otic anti-infectives.

Otic Anti-Infectives		
Tier-1	**Tier-2**	**Special PA**
acetic acid (VoSol®, Acetasol®)	chloroxylenol/benzocaine/HC (Trioxin®)	acetic acid/HC (Acetasol® HC, VoSol® HC)
ciprofloxacin/dexamethasone (Ciprodex®)	chloroxylenol/pramoxine/zinc/ glycerin (Zinotic®, Zinotic® ES)	antipyrine/benzocaine/ glycerin/zinc (Neotic®)
neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	ciprofloxacin (Cetraxal®)	
	ciprofloxacin/HC (Cipro® HC)	
	finafloxacin (Xtoro™)	
	neomycin/colistin/HC/ thonzonium (Cortisporin® TC, Coly-Mycin® S)	
	ofloxacin (Floxin® Otic)	

Tier structure based on supplemental rebate participation and/or state maximum allowable cost (SMAC).
HC = hydrocortisone

Otic Anti-Infectives Tier-2 Approval Criteria:

1. Member must have an adequate 14-day trial of at least two Tier-1 medications; or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 medications or infection by an organism not known to be covered by any of the Tier-1 medications.

Otic Anti-Infectives Special Prior Authorization (PA) Approval Criteria:

1. Diagnosis of acute otitis externa; and
2. Recent (within 6 months) trials with all other commonly used topical otic anti-infectives that have failed to resolve infection; or
3. Allergy to all available products and failure of acetic acid alone.

Appendix J

Vote to Prior Authorize Hetlioz® (Tasimelteon) and Belsomra® (Suvorexant)

Oklahoma Health Care Authority
July 2015

Recommendations

The College of Pharmacy recommends the following changes to the Insomnia Medications Product Based Prior Authorization (PBPA) category:

1. The addition of Belsomra® (suvorexant) to Tier-3 based on estimated acquisition cost. The current criteria for this category will apply.
2. Moving Lunesta® (eszopiclone) to Tier-1 based on generic availability and state maximum allowable cost.
3. The creation of a Special Prior Authorization (PA) category for unique dosage formulations and medications with limited indications. Authorization for unique dosage formulations would require a patient-specific, clinically significant reason for use in place of the lower tiered formulations.
4. The prior authorization of Hetlioz® (tasimelteon) with the criteria listed below.

Hetlioz® (Tasimelteon) Approval Criteria:

1. An FDA approved diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24); and
2. Member must be 18 years of age or older; and
3. Member must be totally blind; and
4. A failed trial of appropriately timed doses of melatonin.
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.
6. A quantity limit of 30 capsules for 30 days will apply.

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	ramelteon (Rozerem®)	doxepin (Silenor®)
eszopiclone (Lunesta®)		**suvorexant (Belsomra®)**	**tasimelteon (Hetlioz®)+**
flurazepam (Dalmane®)			temazepam (Restoril®) 7.5mg and 22.5mg
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Edluar®)
triazolam (Halcion®)			zolpidem SL tablets (Intermezzo®)
zaleplon (Sonata®)			zolpidem oral spray (Zolpimist®)
zolpidem (Ambien®)			

*Unique dosage formulations require a special reason for use in place of Tier-1 formulations.
+ Individual criteria specific to tasimelteon.

Appendix K

Calendar Year 2014 Annual Review of Antidepressant Medications and 30-Day Notice to Prior Authorize Irenka™ (Duloxetine)

Oklahoma Health Care Authority
July 2015

Current Prior Authorization Criteria

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			fluoxetine 60mg tablets
escitalopram (Lexapro®)			fluoxetine DR (Prozac® Weekly™)
fluoxetine (Prozac®, Sarafem®)			fluvoxamine CR (Luvox CR®)
fluvoxamine (Luvox®)			paroxetine CR (Paxil CR®)
paroxetine (Paxil®)			paroxetine (Pexeva®)
sertraline (Zoloft®)			
Dual Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®)	vilazodone (Viibryd®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		desvenlafaxine (Pristiq®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron® SolTab™)		levomilnacipran (Fetzima®)	trazodone ER (Oleptro®)
trazodone (Desyrel®)		nefazodone (Serzone®)	venlafaxine ER tablets (Effexor XR® tablets)
venlafaxine (Effexor®, Effexor XR® capsules)			
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
	vortioxetine (Brintellix®)		

*Tier structure based on supplemental rebate participation and/or state maximum allowable cost (SMAC).
CR = Controlled-Release
DR = Delayed-Release
ER = Extended-Release

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within six months) trial of two Tier-1 medications at least four weeks in duration and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least one medication from the SSRI category and one trial with duloxetine; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within six months) trial with two Tier-1 medications (one medication from the SSRI category and one trial with duloxetine) and a trial of a Tier-2 medication at least four weeks in duration and titrated to recommended dosing, that did not provide an adequate response; or
2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Special Prior Authorization (PA) Approval Criteria:

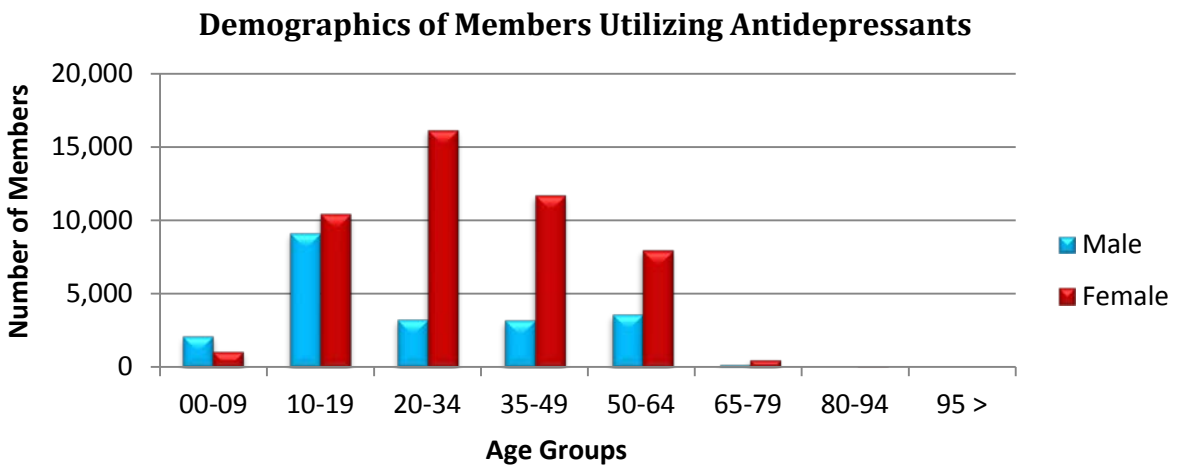
1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists.
3. Tier structure rules still apply.

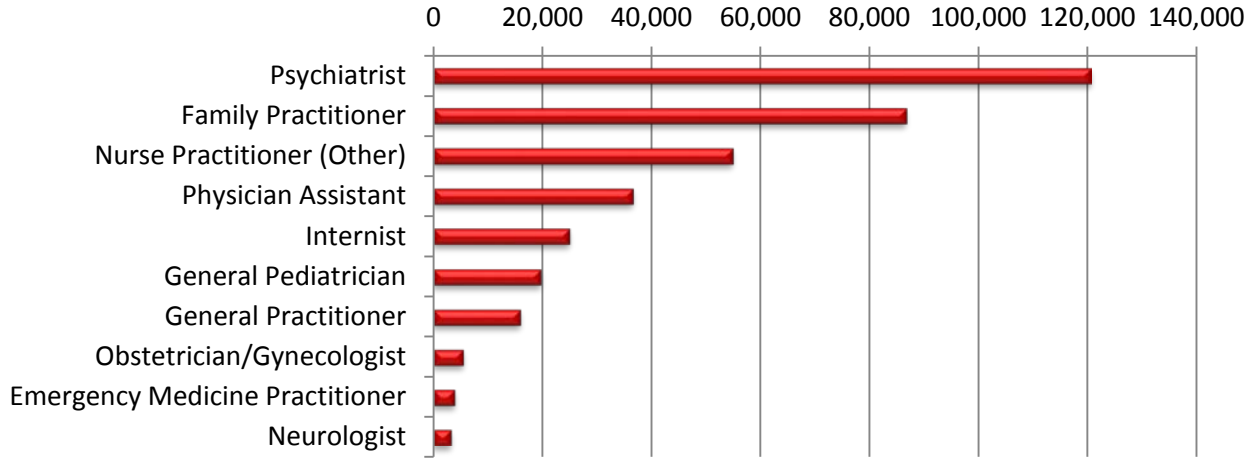
Utilization of Antidepressants: Calendar Year 2014

Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	69,028	372,218	$9,466,877.96	$25.43	$0.78	14,342,054	12,215,115
2014	69,580	387,434	$7,135,523.99	$18.42	$0.56	14,899,878	12,725,456
% Change	**0.80%**	**4.10%**	**-24.60%**	**-27.60%**	**-28.20%**	**3.90%**	**4.20%**
Change	**552**	**15,216**	**-$2,331,353.97**	**-$7.01**	**-$0.22**	**557,824**	**510,341**

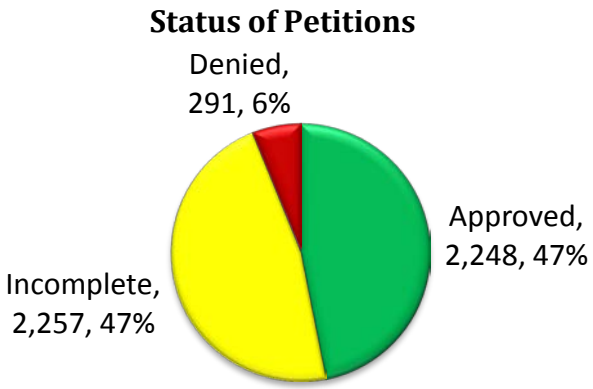
*Total number of unduplicated members.





Prior Authorization of Antidepressants

There were 4,796 petitions submitted for the antidepressant medication category during calendar year 2014. Computer edits are in place to detect Tier-1 medications in the member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



Market News and Updates[1]

Anticipated Patent Expirations:

- Emsam® (selegiline ER transdermal patches): June 2018
- Viibryd® (vilazodone hydrochloride oral tablets): June 2022
- Pexeva® (paroxetine mesylate oral tablets): February 2023
- Aplenzin® (bupropion hydrobromide ER oral tablets): June 2026
- Pristiq® (desvenlafaxine succinate ER oral tablets): July 2027
- Oleptro® (trazodone hydrochloride ER oral tablets): March 2029
- Brintellix® (vortioxetine hydrobromide oral tablets): June 2031
- Fetzima® (levomilnacipran hydrochloride ER oral capsules): May 2032

Irenka™ (Duloxetine 40mg Delayed-Release Capsules) Product Summary[2,3,4,5,6]

In December 2013, the FDA approved a branded generic product, Irenka™; however, this product just recently became available on the market. Irenka™ is available as duloxetine 40mg delayed-release capsules. This strength is in addition to the currently available 20mg, 30mg, and 60mg duloxetine delayed-release capsules (generic Cymbalta®). Irenka™ was approved through an Abbreviated New Drug Application (ANDA) based on previous duloxetine clinical trials, and is indicated for the treatment of major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathy, and chronic musculoskeletal pain. Irenka™ is not indicated for the treatment of fibromyalgia. The recommended dosing of Irenka™ matches the recommended dosing of Cymbalta®, and a cost comparison between Irenka™ and Cymbalta®, based on a dose of 40mg per day, is shown below.

Cost Comparison:

Medication Name	Strength	Cost/Unit	Cost/Month
Irenka™ (duloxetine)	40mg	$7.68+	$230.40
Cymbalta® (duloxetine)	20mg	$1.14*	$68.40

+Estimated Acquisition Cost (EAC)
*State Maximum Allowable Cost (SMAC)
Cost/month is based on a dose of 40mg/day.

Recommendations

The College of Pharmacy recommends placing Irenka™ (duloxetine 40mg delayed-release capsules) into the Special Prior Authorization (PA) category of the Antidepressants Product Based Prior Authorization (PBPA) category. The existing criteria for this category will apply. Additionally, use of Irenka™ for the diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain will require a patient-specific, clinically significant reason why the member cannot use two duloxetine 20mg capsules in place of Irenka™ 40mg capsules.

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			fluoxetine 60mg tablets
escitalopram (Lexapro®)			fluoxetine DR (Prozac® Weekly™)
fluoxetine (Prozac®, Sarafem®)			fluvoxamine CR (Luvox CR®)
fluvoxamine (Luvox®)			paroxetine CR (Paxil CR®)
paroxetine (Paxil®)			paroxetine (Pexeva®)
sertraline (Zoloft®)			
Dual Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®)	vilazodone (Viibryd®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		desvenlafaxine (Pristiq®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron® SolTab™)		levomilnacipran (Fetzima®)	**duloxetine 40mg (Irenka™)**
trazodone (Desyrel®)		nefazodone (Serzone®)	trazodone ER (Oleptro®)
venlafaxine (Effexor®, Effexor XR® capsules)			venlafaxine ER tablets (Effexor XR® tablets)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
	vortioxetine (Brintellix®)		

*Tier structure based on supplemental rebate participation and/or state maximum allowable cost (SMAC).
CR = Controlled-Release
DR = Delayed-Release
ER = Extended-Release

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within six months) trial of two Tier-1 medications at least four weeks in duration and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least one medication from the SSRI category and one trial with duloxetine; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within six months) trial with two Tier-1 medications (one medication from the SSRI category and one trial with duloxetine) and a trial of a Tier-2 medication at least four weeks in duration and titrated to recommended dosing, that did not provide an adequate response; or
2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists.
3. Tier structure rules still apply.
4. When Irenka™ (Duloxetine 40mg) is being requested for non-depression related diagnoses, the criteria below will apply:
    a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
    b. A patient-specific, clinically significant reason why the member cannot use two duloxetine 20mg capsules in place of Irenka™ 40mg capsules; and
    c. A quantity limit of 30 capsules per 30 days will apply.

Utilization Details of Antidepressants: Calendar Year 2014

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
SERTRALINE PRODUCTS						
SERTRALINE TAB 100MG	31,456	7,125	$257,026.30	$0.25	$8.17	3.60%
SERTRALINE TAB 50MG	27,756	9,680	$200,949.85	$0.22	$7.24	2.82%
SERTRALINE TAB 25MG	11,672	4,179	$82,456.75	$0.23	$7.06	1.16%
SERTRALINE CON 20MG/ML	426	121	$29,484.98	$2.14	$69.21	0.41%
SERTRALINE TAB 50MG	148	42	$1,026.13	$0.22	$6.93	0.01%
ZOLOFT TAB 100MG	35	13	$5,556.23	$4.31	$158.75	0.08%
SERTRALINE TAB 100MG	17	7	$122.68	$0.24	$7.22	0.00%
SUBTOTAL	**71,510**	**21,167**	**$576,622.92**	**$0.25**	**$8.06**	**8.08%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	30,769	9,434	$194,796.40	$0.19	$6.33	2.73%
FLUOXETINE CAP 40MG	13,801	3,692	$149,806.21	$0.32	$10.85	2.10%
FLUOXETINE CAP 10MG	10,934	3,792	$66,971.18	$0.20	$6.13	0.94%
FLUOXETINE TAB 10MG	3,319	1,166	$24,966.01	$0.25	$7.52	0.35%
FLUOXETINE TAB 20MG	1,238	527	$38,294.84	$1.00	$30.93	0.54%
FLUOXETINE SOL 20MG/5ML	1,149	258	$8,696.24	$0.26	$7.57	0.12%
PROZAC CAP 20MG	34	12	$12,602.83	$12.42	$370.67	0.18%
PROZAC CAP 40MG	11	1	$8,575.57	$16.81	$779.60	0.12%
SUBTOTAL	**61,255**	**18,882**	**$504,709.28**	**$0.25**	**$8.24**	**7.07%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	28,298	8,447	$168,552.70	$0.19	$5.96	2.36%
TRAZODONE TAB 100MG	21,811	6,047	$159,450.83	$0.23	$7.31	2.23%
TRAZODONE TAB 150MG	13,162	3,506	$107,441.65	$0.25	$8.16	1.51%
TRAZODONE TAB 300MG	767	198	$89,685.24	$3.27	$116.93	1.26%
SUBTOTAL	**64,038**	**18,198**	**$525,130.42**	**$0.26**	**$8.20**	**7.36%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	26,674	9,022	$142,611.09	$0.16	$5.35	2.00%
CITALOPRAM TAB 40MG	17,692	4,633	$99,354.15	$0.16	$5.62	1.39%
CITALOPRAM TAB 10MG	9,039	3,011	$50,585.32	$0.17	$5.60	0.71%
CITALOPRAM SOL 10MG/5ML	191	46	$7,781.18	$1.47	$40.74	0.11%
CELEXA TAB 20MG	70	30	$454.63	$0.22	$6.49	0.01%
CELEXA TAB 40MG	21	5	$2,147.29	$3.41	$102.25	0.03%
SUBTOTAL	**53,687**	**16,747**	**$302,933.66**	**$0.16**	**$5.64**	**4.25%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 20MG	13,339	3,230	$133,971.95	$0.30	$10.04	1.88%
ESCITALOPRAM TAB 10MG	12,451	4,487	$106,365.37	$0.26	$8.54	1.49%
ESCITALOPRAM TAB 5MG	818	338	$6,951.06	$0.27	$8.50	0.10%
ESCITALOPRAM SOL	142	39	$21,982.98	$5.34	$154.81	0.31%
LEXAPRO TAB 20MG	47	9	$11,573.67	$6.23	$246.25	0.16%
LEXAPRO TAB 10MG	29	5	$4,271.30	$4.91	$147.29	0.06%
LEXAPRO TAB 5MG	2	2	$19.77	$0.33	$9.89	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
SUBTOTAL	**26,828**	**8,110**	**$285,136.10**	**$0.32**	**$10.63**	**4.00%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	11,861	2,503	$1,903,108.39	$4.58	$160.45	26.67%
DULOXETINE CAP 30MG	3,987	1,272	$643,893.96	$4.97	$161.50	9.02%
DULOXETINE CAP 20MG	440	146	$64,413.42	$4.71	$146.39	0.90%
CYMBALTA CAP 60MG	437	221	$101,164.27	$7.51	$231.50	1.42%
CYMBALTA CAP 30MG	123	72	$26,688.02	$6.87	$216.98	0.37%
CYMBALTA CAP 20MG	7	5	$1,597.26	$6.94	$228.18	0.02%
SUBTOTAL	**16,855**	**4,219**	**$2,740,865.32**	**$4.76**	**$162.61**	**38.41%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	9,860	2,984	$88,689.17	$0.29	$8.99	1.24%
MIRTAZAPINE TAB 30MG	7,065	2,068	$66,636.93	$0.30	$9.43	0.93%
MIRTAZAPINE TAB 45MG	2,735	621	$35,532.34	$0.38	$12.99	0.50%
MIRTAZAPINE TAB 15MG ODT	248	92	$8,125.87	$1.10	$32.77	0.11%
MIRTAZAPINE TAB 7.5MG	222	72	$7,580.69	$1.18	$34.15	0.11%
MIRTAZAPINE TAB 30MG ODT	151	50	$5,287.49	$1.07	$35.02	0.07%
MIRTAZAPINE TAB 45MG ODT	47	9	$1,497.98	$0.98	$31.87	0.02%
SUBTOTAL	**20,328**	**5,896**	**$213,350.47**	**$0.33**	**$10.50**	**2.99%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE CAP 150MG ER	9,273	2,304	$114,954.88	$0.36	$12.40	1.61%
VENLAFAXINE CAP 75MG ER	6,727	2,639	$71,881.85	$0.31	$10.69	1.01%
VENLAFAXINE TAB 75MG	2,948	896	$58,965.83	$0.63	$20.00	0.83%
VENLAFAXINE CAP 37.5 ER	1,881	1,051	$17,762.79	$0.30	$9.44	0.25%
VENLAFAXINE TAB 37.5MG	1,150	530	$21,660.98	$0.62	$18.84	0.30%
VENLAFAXINE TAB 100MG	523	127	$16,239.42	$1.01	$31.05	0.23%
VENLAFAXINE TAB 50MG	267	91	$6,975.53	$0.84	$26.13	0.10%
VENLAFAXINE TAB 25MG	150	60	$3,553.05	$0.72	$23.69	0.05%
EFFEXOR XR CAP 37.5MG	39	16	$395.44	$0.36	$10.14	0.01%
EFFEXOR XR CAP 75MG	25	6	$12,176.01	$15.03	$487.04	0.17%
EFFEXOR XR CAP 150MG	20	6	$9,215.58	$10.97	$460.78	0.13%
SUBTOTAL	**23,003**	**7,726**	**$333,781.36**	**$0.44**	**$14.51**	**4.68%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG SR	8,052	2,600	$138,443.11	$0.55	$17.19	1.94%
BUPROPN HCL TAB 150MG XL	6,126	2,240	$173,748.91	$0.86	$28.36	2.43%
BUPROPN HCL TAB 300MG XL	5,888	1,442	$165,822.27	$0.80	$28.16	2.32%
BUPROPION TAB 100MG SR	1,953	724	$32,140.90	$0.54	$16.46	0.45%
BUPROPION TAB 100MG	1,744	643	$75,225.06	$1.38	$43.13	1.05%
BUPROPION TAB 75MG	1,714	669	$49,983.52	$0.97	$29.16	0.70%
BUPROPION TAB 200MG SR	1,111	282	$28,658.92	$0.83	$25.80	0.40%
WELLBUTRIN TAB XL 150MG	95	29	$23,763.19	$8.29	$250.14	0.33%
BUPROPION TAB 150MG ER	32	18	$507.43	$0.45	$15.86	0.01%
BUPROPION TAB 100MG ER	28	10	$391.88	$0.47	$14.00	0.01%
BUPROPION TAB 200MG ER	25	16	$551.61	$0.67	$22.06	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
BUDEPRION TAB 150MG SR	24	15	$537.05	$0.60	$22.38	0.01%
WELLBUTRIN TAB 150MG SR	11	4	$904.27	$2.74	$82.21	0.01%
WELLBUTRIN TAB XL 300MG	9	1	$5,343.39	$19.79	$593.71	0.07%
BUDEPRION TAB 100MG SR	6	4	$102.99	$0.62	$17.17	0.00%
BUDEPRION XL TAB 300MG	2	2	$48.16	$0.80	$24.08	0.00%
WELLBUTRIN TAB 200MG SR	1	1	$32.99	$1.10	$32.99	0.00%
SUBTOTAL	**26,821**	**8,700**	**$696,205.65**	**$0.80**	**$25.96**	**9.76%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	6,829	2,582	$44,990.83	$0.19	$6.59	0.63%
PAROXETINE TAB 40MG	4,845	1,214	$50,929.89	$0.29	$10.51	0.71%
PAROXETINE TAB 10MG	2,509	1,020	$16,640.90	$0.20	$6.63	0.23%
PAROXETINE TAB 30MG	1,737	470	$15,327.14	$0.25	$8.82	0.21%
PAXIL SUS 10MG/5ML	82	18	$13,371.02	$5.61	$163.06	0.19%
PAXIL TAB 40MG	5	1	$2,419.84	$5.38	$483.97	0.03%
SUBTOTAL	**16,007**	**5,305**	**$143,679.62**	**$0.26**	**$8.98**	**2.01%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	1,475	274	$27,988.16	$0.61	$18.98	0.39%
FLUVOXAMINE TAB 50MG	1,130	345	$16,998.28	$0.49	$15.04	0.24%
FLUVOXAMINE TAB 25MG	351	99	$4,667.06	$0.43	$13.30	0.07%
SUBTOTAL	**2,956**	**718**	**$49,653.50**	**$0.54**	**$16.80**	**0.70%**
TIER-1 SUBTOTAL	**383,288**	**69,288***	**$6,372,068.30**	**$0.51**	**$16.62**	**89.30%**
VILAZODONE PRODUCTS						
VIIBRYD TAB 40MG	426	87	$73,412.66	$5.80	$172.33	1.03%
VIIBRYD TAB 20MG	67	18	$13,384.70	$6.16	$199.77	0.19%
VIIBRYD TAB 10MG	18	8	$6,258.03	$11.59	$347.67	0.09%
VIIBRYD KIT	5	5	$863.35	$5.76	$172.67	0.01%
SUBTOTAL	**516**	**118**	**$93,918.74**	**$6.05**	**$182.01**	**1.32%**
VORTIOXETINE PRODUCTS						
BRINTELLIX TAB 10MG	29	15	$7,227.34	$8.31	$249.22	0.10%
BRINTELLIX TAB 20MG	18	9	$4,403.43	$8.15	$244.64	0.06%
BRINTELLIX TAB 5MG	1	1	$256.82	$8.56	$256.82	0.00%
SUBTOTAL	**48**	**25**	**$11,887.59**	**$8.26**	**$247.66**	**0.17%**
TIER-2 SUBTOTAL	**564**	**131***	**$105,806.33**	**$6.24**	**$187.60**	**1.48%**
DESVENLAFAXINE PRODUCTS						
PRISTIQ TAB 100MG	483	90	$120,150.00	$7.22	$248.76	1.68%
PRISTIQ TAB 50MG	398	100	$103,566.68	$7.12	$260.22	1.45%
DESVENLAFAX TAB 50MG ER	22	2	$2,135.31	$5.08	$97.06	0.03%
DESVENLAFAX TAB 100MG ER	4	2	$1,176.03	$4.90	$294.01	0.02%
SUBTOTAL	**907**	**194**	**$227,028.02**	**$7.13**	**$250.31**	**3.18%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 40MG	73	27	$15,202.82	$7.45	$208.26	0.21%
FETZIMA CAP 80MG	58	17	$12,977.59	$7.46	$223.75	0.18%
FETZIMA CAP 120MG	13	5	$3,018.18	$7.74	$232.17	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
FETZIMA CAP 20MG	5	2	$1,124.82	$7.50	$224.96	0.02%
SUBTOTAL	**149**	**51**	**$32,323.41**	**$7.48**	**$216.94**	**0.45%**
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 100MG	18	3	$539.18	$1.00	$29.95	0.01%
NEFAZODONE TAB 200MG	16	2	$756.58	$0.97	$47.29	0.01%
NEFAZODONE TAB 250MG	12	1	$484.60	$1.35	$40.38	0.01%
NEFAZODONE TAB 150MG	5	2	$193.24	$1.29	$38.65	0.00%
NEFAZODONE TAB 50MG	2	1	$36.18	$0.60	$18.09	0.00%
SUBTOTAL	**53**	**9**	**$2,009.78**	**$1.06**	**$37.92**	**0.03%**
SELEGILINE PRODUCTS						
EMSAM DIS 12MG/24H	4	1	$4,606.01	$38.38	$1,151.50	0.06%
EMSAM DIS 6MG/24HR	3	1	$3,681.90	$40.91	$1,227.30	0.05%
SUBTOTAL	**7**	**2**	**$8,287.91**	**$39.47**	**$1,183.99**	**0.12%**
TIER-3 SUBTOTAL	**1,116**	**212***	**$269,649.12**	**$7.04**	**$241.62**	**3.78%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE TAB 225MG ER	657	172	$138,764.74	$5.73	$211.21	1.94%
VENLAFAXINE TAB 150MG ER	266	94	$24,467.50	$2.67	$91.98	0.34%
VENLAFAXINE TAB 75MG ER	163	59	$11,819.25	$2.36	$72.51	0.17%
VENLAFAXINE TAB 37.5 ER	77	28	$6,644.72	$2.83	$86.30	0.09%
SUBTOTAL	**1,163**	**353**	**$181,696.21**	**$4.46**	**$156.23**	**2.55%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 25MG ER	521	143	$51,740.24	$2.94	$99.31	0.73%
PAROXETIN ER TAB 37.5MG	259	53	$27,258.17	$3.04	$105.24	0.38%
PAROXETIN ER TAB 12.5MG	190	68	$21,268.20	$3.18	$111.94	0.30%
PEXEVA TAB 20MG	6	2	$2,905.99	$8.12	$484.33	0.04%
PAXIL CR TAB 37.5MG	6	1	$932.22	$5.18	$155.37	0.01%
PEXEVA TAB 40MG	1	1	$261.83	$8.73	$261.83	0.00%
SUBTOTAL	**983**	**268**	**$104,366.65**	**$3.08**	**$106.17**	**1.46%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE CAP 100MG ER	115	29	$41,366.11	$11.79	$359.71	0.58%
FLUVOXAMINE CAP 150MG ER	95	16	$36,646.26	$12.98	$385.75	0.51%
LUVOX CR CAP 150MG	10	1	$8,943.15	$28.39	$894.32	0.13%
LUVOX CR CAP 100MG	2	1	$2,456.98	$39.63	$1,228.49	0.03%
SUBTOTAL	**222**	**47**	**$89,412.50**	**$13.33**	**$402.76**	**1.25%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 90MG DR	60	6	$8,252.73	$4.90	$137.55	0.12%
FLUOXETINE TAB 60MG	37	6	$4,171.06	$3.76	$112.73	0.06%
SUBTOTAL	**97**	**12**	**$12,423.79**	**$4.45**	**$128.08**	**0.17%**
TRAZODONE PRODUCTS						
OLEPTRO TAB 24HR150	1	1	$101.09	$3.37	$101.09	0.00%
SUBTOTAL	**1**	**1**	**$101.09**	**$3.37**	**$101.09**	**0.00%**
SPECIAL PA SUBTOTAL	**2,466**	**619***	**$388,000.24**	**$4.61**	**$157.34**	**5.44%**
TOTAL	**387,434**	**69,574***	**$7,135,523.99**	**$0.56**	**$18.42**	**100.00%**

*Total number of unduplicated members

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 6/11/15. Last accessed 6/10/15.
[2] Irenka™ Prescribing Information. Lupin Pharmaceuticals, Inc. Available online at: http://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5e288ace-c350-4e14-8552-e2c2c563e6fe&type=display. Last revised 6/2015. Last accessed 6/16/15.
[3] Micromedex 2.0: Irenka™ Drug Information. Available online at: http://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch. Last revised 6/8/15. Last accessed 6/16/15.
[4] Irenka™ Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/irenka/. Last revised 6/1/15. Last accessed 6/16/15.
[5] Cymbalta® Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/cymbalta-1/. Last revised 7/14/17. Last accessed 6/16/15.
[6] Drugs@FDA: Drug Details: Duloxetine. Available online at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. Last updated 6/15/15. Last accessed 6/16/15.

Appendix L

Calendar Year 2014 Annual Review of Alzheimer's Medications and 30-Day Notice to Prior Authorize Namzaric™ (Memantine Extended-Release/Donepezil)

Oklahoma Health Care Authority
July 2015

Current Prior Authorization Criteria

Alzheimer's Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the regular formulation.
2. An age restriction for ages 0-50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive regular formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient specific, clinically significant information supporting the use of the medication.

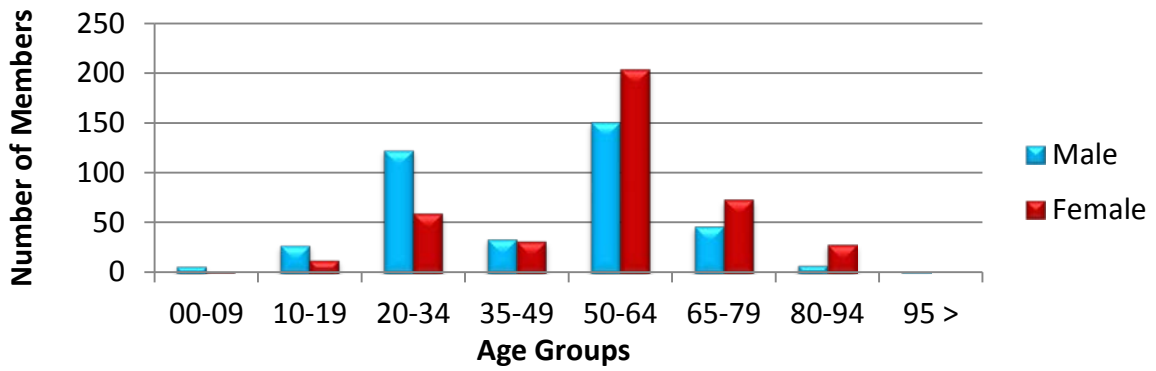
Utilization of Alzheimer's Medications: Calendar Year 2014

Comparison of Calendar Years

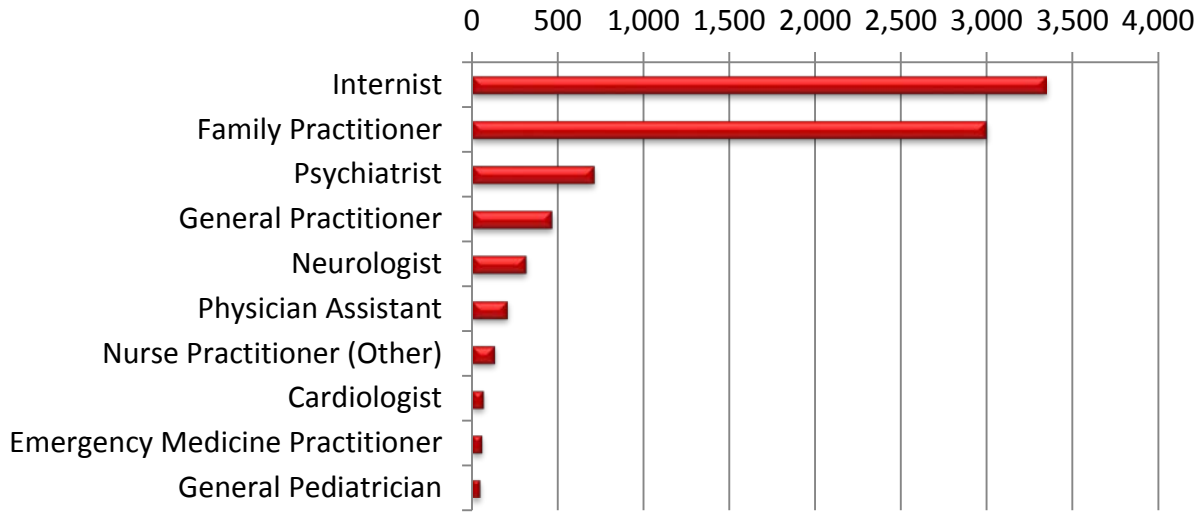
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	898	8,773	$1,586,112.15	$180.79	$6.32	418,686	251,053
2014	812	8,507	$1,684,391.24	$198.00	$7.23	367,192	232,937
% Change	**-9.60%**	**-3.00%**	**6.20%**	**9.50%**	**14.40%**	**-12.30%**	**-7.20%**
Change	**-86**	**-266**	**$98,279.09**	**$17.21**	**$0.91**	**-51,494**	**-18,116**

*Total number of unduplicated members.

Demographics of Members Utilizing Alzheimer's Medications



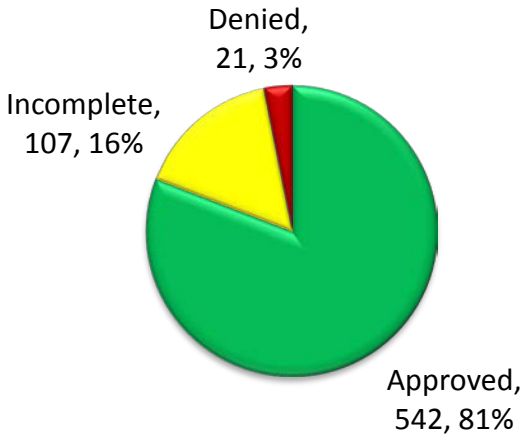
Top Prescriber Specialties of Alzheimer's Medications by Number of Claims



Prior Authorization of Alzheimer's Medications

There were 670 petitions submitted for the Alzheimer's medications category during calendar year 2014. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expirations:

- Namenda® (memantine tablets and oral solution): October 2015
- Exelon® (rivastigmine transdermal patches): January 2019
- Namenda XR® (memantine ER capsules): September 2029

New FDA Approvals:

- In December 2014, the FDA approved Namzaric™, a fixed-dose combination of memantine extended-release and donepezil. Namzaric™ combines Namenda XR® (memantine ER) and Aricept® (donepezil) in a single, once-daily capsule. Namzaric™ became available on the market in May 2015.

Namzaric™ (Memantine ER/Donepezil Capsules) Product Summary[2,3,4]

Indications: Namzaric™ (memantine ER/donepezil) is indicated for the treatment of moderate-to-severe dementia of the Alzheimer's type in patients stabilized on memantine and donepezil.

Dosing:

- Namzaric™ is available as a fixed-dose combination of 14mg memantine ER and 10mg donepezil capsules (Namzaric™ 14mg/10mg), and as 28mg memantine ER and 10mg donepezil capsules (Namzaric™ 28mg/10mg).
- Memantine ER/donepezil should be taken once daily in the evening with or without food, and capsules may be taken whole or the capsule may be opened, the entire contents sprinkled on applesauce, and swallowed without chewing.
- Patients stabilized on memantine (10mg twice daily or 28mg ER once daily) and donepezil 10mg may be switched to memantine ER/donepezil 28mg/10mg.
- Patients with severe renal impairment stabilized on memantine (5mg twice daily or 14mg ER once daily) and donepezil 10mg may be switched to memantine ER/donepezil 14mg/10mg.

Mechanism of Action: Memantine is an N-methyl-D-aspartate (NMDA) antagonist that prevents glutamate from activating the NMDA receptors of the central nervous system. Donepezil is a reversible acetylcholinesterase (AChE) inhibitor that enhances cholinergic function and improves cognition. The combination of memantine and donepezil acts to improve the symptoms of Alzheimer's disease but does not prevent or slow the neurodegeneration of the disease.

Contraindications:

- Known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation

Safety:

- Because of their pharmacological action, cholinesterase inhibitors, including donepezil, may have vagotonic effects on the sinoatrial and atrioventricular nodes. This effect may manifest as bradycardia or heart block in patients both with and without known underlying cardiac conduction abnormalities. Syncopal episodes have been reported in association with the use of donepezil.
- Cholinomimetics, including donepezil, are believed to have some potential to cause generalized convulsions. However, seizure activity also may be a manifestation of Alzheimer's disease.
- Donepezil, as a cholinesterase inhibitor, is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia.
- Through their primary action, cholinesterase inhibitors, including donepezil, may be expected to increase gastric acid secretion due to increased cholinergic activity. Patients treated with memantine ER/donepezil should be monitored closely for symptoms of active or occult gastrointestinal bleeding, especially those at increased risk for developing ulcers.

- Upon initiation of treatment, as a predictable consequence of its pharmacological properties, donepezil has been shown to produce diarrhea, nausea, and vomiting. Although in most cases, these effects have been mild and transient, sometimes lasting one to three weeks, and have resolved during continued use of donepezil, patients should be observed closely at the initiation of treatment.
- Because of their cholinomimetic actions, cholinesterase inhibitors should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease.
- Alterations of urine pH towards the alkaline condition may lead to a reduced clearance of memantine, resulting in an accumulation of the drug with a possible increase in adverse reactions. Urine pH is altered by diet, drugs (e.g., carbonic anhydrase inhibitors, sodium bicarbonate), and the clinical state of the patient (e.g., renal tubular acidosis or severe infections of the urinary tract); therefore, memantine should be used with caution under these conditions.

Adverse Reactions: Common adverse reactions to memantine ER/donepezil include diarrhea, nausea, vomiting, loss of appetite, ecchymosis, infectious disease, dizziness, headache, syncope, and insomnia.

Efficacy:

- The effectiveness of memantine ER/donepezil as a treatment for patients with moderate--to-severe Alzheimer's disease was established by demonstrating the bioequivalence of memantine ER/donepezil with co-administered memantine ER and donepezil.

Cost Comparison:

Medication Name	Cost/Unit*	Cost/Month	Cost/Year
Aricept® (donepezil) 10mg	$0.14[+]	$4.20	$50.40
Namenda® (memantine) 10mg	$5.97[∞]	$358.20	$4,298.40
Namenda XR® (memantine ER) 28mg	$11.34[∞]	$340.20	$4,082.40
Namzaric™ (memantine ER/donepezil) 28mg/10mg	$11.34[∞]	$340.20	$4,082.40

*Costs listed in the table above do not reflect net costs.

[+]Cost/unit based on state maximum allowable cost (SMAC).

[∞]Cost/unit based on estimated acquisition cost (EAC).

Recommendations

The College of Pharmacy recommends the prior authorization of Namzaric™ (memantine ER/donepezil) with the following criteria:

Alzheimer's Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the regular formulation.
2. An age restriction for ages 0-50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive regular formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient specific, clinically significant information supporting the use of the medication.
3. Namzaric™ (Memantine ER/Donepezil) Approval Criteria:
    a. Member must have a patient-specific, clinically significant reason why the separate products cannot be used over this combination product; and
    b. A quantity limit of 30 capsules per 30 days will apply.

Utilization Details of Alzheimer's Medications: Calendar Year 2014

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
MEMANTINE PRODUCTS						
NAMENDA TAB 10MG	4,632	513	$1,233,779.14	$10.23	$266.36	73.25%
NAMENDA XR CAP 28MG	959	169	$250,179.43	$10.25	$260.88	14.85%
NAMENDA TAB 5MG	471	89	$112,004.21	$9.39	$237.80	6.65%
NAMENDA XR CAP 14MG	42	15	$10,280.26	$10.27	$244.77	0.61%
NAMENDA XR CAP 7MG	28	8	$3,867.89	$10.45	$138.14	0.23%
NAMENDA SOL	12	3	$4,744.21	$13.79	$395.35	0.28%
NAMENDA XR CAP 21MG	6	3	$1,585.75	$10.50	$264.29	0.09%
NAMENDA XR CAP	1	1	$270.20	$9.01	$270.20	0.02%
NAMENDA TAB 5-10MG	1	1	$269.15	$8.97	$269.15	0.02%
SUBTOTAL	**6,152**	**802**	**$1,616,980.24**	**$10.18**	**$262.84**	**96.00%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,682	254	$12,615.90	$0.23	$7.50	0.75%
DONEPEZIL TAB 5MG	427	114	$2,565.09	$0.19	$6.01	0.15%
DONEPEZIL TAB HCL 23MG	19	3	$4,854.74	$8.94	$255.51	0.29%
SUBTOTAL	**2,128**	**371**	**$20,035.73**	**$0.30**	**$9.42**	**1.19%**
RIVASTIGMINE PRODUCTS						
EXELON DIS 9.5MG/24	65	10	$22,718.03	$12.14	$349.51	1.35%
RIVASTIGMINE CAP 6MG	41	6	$4,990.54	$4.45	$121.72	0.30%
RIVASTIGMINE CAP 3MG	40	6	$4,797.89	$4.00	$119.95	0.28%
RIVASTIGMINE CAP 1.5MG	26	4	$2,946.06	$3.97	$113.31	0.17%
EXELON DIS 13.3/24	17	3	$6,070.09	$11.90	$357.06	0.36%
EXELON DIS 4.6MG/24	13	3	$4,611.82	$11.83	$354.76	0.27%
SUBTOTAL	**202**	**32**	**$46,134.43**	**$7.91**	**$228.39**	**2.74%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	13	2	$612.38	$1.57	$47.11	0.04%
GALANTAMINE TAB 8MG	12	2	$628.46	$1.75	$52.37	0.04%
SUBTOTAL	**25**	**4**	**$1,240.84**	**$1.65**	**$49.63**	**0.07%**
TOTAL	**8,507**	**812***	**$1,684,391.24**	**$7.23**	**$198.00**	**100.00%**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 6/16/15. Last accessed 6/17/15.
[2] Namzaric™ Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/namzaric/. Last revised 12/23/14. Last accessed 6/18/15.
[3] Namzaric™ Prescribing Information. Actavis, Inc. Available online at: http://pi.actavis.com/data_stream.asp?product_group=1941&p=pi&language=E. Last revised 12/2014. Last accessed 6/18/15.
[4] Micromedex 2.0: Drug Information. Available online at: http://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch. Last revised 6/16/15. Last accessed 6/18/15.

Appendix M

30-Day Notice to Prior Authorize Corlanor® (Ivabradine)

Oklahoma Health Care Authority
July 2015

Introduction[1,2]

Chronic heart failure is a debilitating progressive condition in which the heart is unable to pump enough blood throughout the body. There are different types of heart failure which include the following: left-sided (systolic or diastolic failure), right-sided, and congestive heart failure (CHF). The severity of heart failure is classified using the New York Heart Association (NYHA) functional classification system. This system classifies the severity of heart failure based on patient symptoms. In each type, increased heart rate has been linked to increased morbidity and mortality.

Heart failure affects roughly 5.1 million people in the United States; approximately 50% of which die within five years of diagnosis. In 2009, heart failure contributed to 1 out of 9 deaths in the United States. The 2010 estimated annual cost of heart failure in the United States was $32 billion or approximately 2% of the total annual United States health-care budget; approximately 60% of these expenses were from hospital care.

Risk factors for heart failure include high blood pressure, coronary artery disease, heart attack, diabetes, and smoking among other things. General standards of medication management of chronic heart failure include the use of angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, aldosterone blockers, diuretics, digoxin, warfarin, and isosorbide dinitrate/hydralazine. Corlanor® (ivabradine) is a heart rate lowering medication approved by the FDA in April 2015 for stable, chronic heart failure to reduce the risk of hospitalization.

Corlanor® (Ivabradine) Product Summary[3,4,5,6]

Indications: Corlanor® (ivabradine) is indicated in patients with stable, symptomatic chronic heart failure to reduce the risk of hospitalization for worsening heart failure. It should only be used in patients with an ejection fraction of 35% or less who are in sinus rhythm, have a resting heart rate of at least 70 beats per minute (bpm), and are receiving the maximally tolerated beta-blocker dose (or have a contraindication to beta-blocker use).

Dosing:

- Ivabradine is available as 5mg and 7.5mg oral tablets.
- The initial recommended dose is 5mg orally twice daily.
- The maximum recommended dose is 7.5mg twice daily.
- Ivabradine should be taken with meals.
- After two weeks of initial dosing, the dose can be titrated based on resting heart rate or comorbid conditions as specified in the following table:

Titration and Dose Adjustment	
Resting Heart Rate	**Dose Adjustment**
> 60 bpm	Increase dose by 2.5mg (given twice daily), up to a maximum dose of 7.5mg twice daily
50 – 60 bpm	Maintain current dose
< 50 bpm or signs and symptoms of bradycardia	Decrease dose by 2.5mg (given twice daily); if current dose is 2.5mg twice daily, discontinue therapy
Comorbidities	**Dose Adjustment**
Renal Failure	1) CrCl > 15 mL/min: No adjustment 2) No data available for use with CrCl ≤ 15 mL/min
Hepatic Insufficiency	1) Mild-to-moderate hepatic impairment (Child-Pugh A and B): No adjustment 2) Severe hepatic impairment (Child-Pugh C): Use is contraindicated
History of conduction defects or bradycardia that could lead to hemodynamic compromise	Initiate at 2.5mg orally twice daily; titrate based on resting heart rate as specified above

Mechanism of Action: Ivabradine reduces spontaneous pacemaker activity at the cardiac sinus node by blocking the hyperpolarization-activated cyclic nucleotide-gated (HCN) channel to selectively inhibit I_f current, thus reducing the heart rate. Ventricular repolarization and myocardial contractility are not affected by ivabradine.

Contraindications:

- Acute decompensated heart failure
- Concomitant use with strong CYP3A4 inhibitors
- Pacemaker dependent (heart rate maintained exclusively by the pacemaker)
- Resting heart rate < 60 beats per minute before treatment
- Severe hepatic impairment
- Severe hypotension (< 90/50 mmHg)
- Sick sinus syndrome, sinoatrial block, or third-degree atrioventricular block, except in presence of functioning demand pacemaker

Special Populations:

- Pregnancy: Ivabradine may cause fetal toxicity when administered to a pregnant woman based on embryo-fetal toxicity and cardiac teratogenic effects observed in animal studies.
- Lactation: There is no information regarding the presence of ivabradine in human milk, the effects of ivabradine on the breastfed infant, or the effects of the drug on milk production. Animal studies have shown, however, that ivabradine is present in rat milk. Because of the potential risk to breastfed infants from exposure to ivabradine breastfeeding is not recommended while taking ivabradine.

- Pediatric Use: The safety and effectiveness of ivabradine in pediatric patients have not been established.
- Geriatric Use: No pharmacokinetic differences have been observed in elderly (≥ 65 years) or very elderly (≥ 75 years) patients compared to the overall population.

Safety:

- Atrial Fibrillation: Ivabradine increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with ivabradine compared to placebo was 5% vs. 3.9% per patient-year, respectively. Cardiac rhythm should be regularly monitored and ivabradine should be discontinued if atrial fibrillation develops.
- Bradycardia and Conduction Disturbances: Bradycardia, sinus arrest and heart block have occurred with ivabradine. Risk factors for bradycardia include sinus node dysfunction, conduction defects, ventricular dyssynchrony, and use of other negative chronotropes. Concurrent use of verapamil or diltiazem also increases ivabradine exposure which can contribute to heart rate lowering and should be avoided. Use of ivabradine in patients with second degree atrioventricular block should be avoided unless a functioning demand pacemaker is present.
- Drug Interactions: Ivabradine is primarily metabolized by CYP3A4. Concomitant use of CYP3A4 inhibitors increases ivabradine plasma concentrations, and use of CYP3A4 inducers decreases ivabradine plasma concentrations. Increased plasma concentrations may exacerbate bradycardia and conduction disturbances.

Adverse Drug Reactions: (≥ 1% with ivabradine versus placebo and occurring in > 1% with ivabradine in clinical trials)

Adverse Reaction	Corlanor® N = 3,260	Placebo N = 3,278
Bradycardia	10%	2.2%
Hypertension, blood pressure increased	8.9%	7.8%
Atrial fibrillation	8.3%	6.6%
Phosphenes, visual brightness	2.8%	0.5%

Efficacy:

- In a randomized study (N = 6,505) of patients with stable NYHA class II to IV heart failure, ivabradine in addition to standard care reduced the composite outcome of cardiovascular (CV) death or hospitalization due to worsening heart failure by a significant 18% compared with placebo plus standard care. The effect was due to a reduced rate of hospitalization for worsening heart failure in ivabradine-treated patients (15.6% vs 20.2%). There was no difference in CV mortality between groups.
- Ivabradine also significantly reduced the risk of total, second, and third hospitalizations for worsening heart failure, as well as hospitalizations for any cause and for CV causes.
- In patients with stable coronary artery disease and a left ventricular ejection fraction of less than 40% (N=10,917), the addition of ivabradine to standard therapy did not improve the composite outcome of CV death and hospitalization due to acute

myocardial infarction (MI) or heart failure. In a subpopulation of patients who had a heart rate of 70 bmp or greater (N = 5,392; ivabradine-treated, N = 2,699), ivabradine significantly reduced the incidence of hospitalization due to fatal and nonfatal MI, unstable angina, and coronary revascularization, after a median of 19 months. However, in patients who had stable coronary artery disease without clinical heart failure (N=19,102) and with a heart rate of 70 bpm or greater, the addition of ivabradine to standard therapy did not reduce the risk of death from CV causes or non-fatal MI after a median of 27.8 months.

Utilization: Ivabradine has been utilized by one member in the SoonerCare population since its approval on April 15, 2015.

Cost Comparison:

Corlanor® (ivabradine) vs. Recommended Maximum Beta-Blocker Doses for Chronic Heart Failure				
Medication Name	**Strength**	**Cost Per Unit*,◊**	**Cost Per Month+**	**Cost Per Year**
Corlanor® (ivabradine)	**5mg, 7.5mg**	**$6.60***	**$396.00**	**$4,752**
bisoprolol	10mg	$0.51◊	$15.30	$183.60
carvedilol	25mg	0.06◊	$7.20	$86.40
Coreg CR® (carvedilol CR)	80mg	7.03*	$210.90	$2,530.80
metoprolol succinate	200mg	1.20◊	$36.00	$432.00

* Cost based on Estimated Acquisition Cost (EAC).

◊ Cost based on state maximum allowable cost (SMAC).

+ Cost based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Corlanor® (ivabradine) with the following criteria:

Corlanor® (Ivabradine) Approval Criteria:

1. An FDA approved diagnosis of symptomatic stable, chronic worsening heart failure; and
2. The prescriber must verify that the member has left ventricular ejection fraction ≤ 35%; and
3. The prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute; and
4. The member must be on maximal/maximally tolerated doses of beta-blockers or have a contraindication to beta-blockers; and
5. A quantity limit of 60 tablets per 30 days will apply.

[1] "About Heart Failure." American Heart Association. Available online at: http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/About-Heart-Failure_UCM_002044_Article.jsp. Last revised 04/2015. Last accessed 06/2015.

[2] "Heart Failure Fact Sheet." Centers for Disease Control and Prevention. Available online at: http://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_heart_failure.htm. Last revised 12/2013. Last accessed 06/2015.

[3] Borer JS , Bohm M , Ford I , et al. Effect of ivabradine on recurrent hospitalization for worsening heart failure in patients with chronic systolic heart failure: the SHIFT Study. *Eur Heart J* 2012; 33(22):2813-2820.

[4] Fox K , Ford I , Steg PG , et al. Ivabradine for patients with stable coronary artery disease and left-ventricular systolic dysfunction (BEAUTIFUL): a randomized, double-blind, placebo-controlled trial. *Lancet* 2008; 372(9641):807-816.

[5] Fox K , Ford I , Steg PG , et al. Ivabradine in stable coronary artery disease without clinical heart failure. *N Engl J Med* 2014; 371(12):1091-1099.

[6] Nawarskas, James J., Brandi N. Bowman, and Joe R. Anderson. "Ivabradine." *Cardiology in Review* 23.4 (2015): 207+210. *PubMed*. Web.

Appendix N

Calendar Year 2014 Annual Review of Opioid Analgesics & Buprenorphine Products and 30-Day Notice to Prior Authorize Hysingla® ER (Hydrocodone Bitartrate Extended-Release)

Oklahoma Health Care Authority
July 2015

Current Prior Authorization Criteria

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caffeine/codeine (Fiorinal with Codeine®) codeine codeine/APAP hydromorphone (Dilaudid®) hydrocodone/APAP (Norco®) hydrocodone/IBU (Vicoprofen®, Ibudone®, Reprexain™) hydromorphone (Dilaudid®) methadone (Dolophine®) morphine IR (MSIR®) oxycodone/APAP (Percocet®) oxycodone/ASA (Percodan®) oxycodone ER 10mg, 15mg, 20mg only (Oxycontin®) oxycodone IR (Oxy IR®) oxycodone/ibuprofen (Combunox™) tramadol/APAP (Ultracet®) tramadol (Ultram®)	**Long-Acting:** buprenorphine (Butrans®) fentanyl patches (Duragesic®) morphine ER tablets (MS Contin®) oxycodone ER (Oxycontin®) **Short-Acting:** oxymorphone IR (Opana®) tapentadol IR (Nucynta®)	**Long-Acting:** hydromorphone ER (Exalgo®) morphine sulfate ER (Avinza®) morphine sulfate ER (Kadian®) morphine/naltrexone (Embeda®) oxymorphone ER (Opana® ER)+ tapentadol ER (Nucynta® ER) tramadol ER (Ultram ER®, Ryzolt®) **Short-Acting:** hydrocodone/APAP (Xodol®, Zamicet®, Liquicet®) hydrocodone/APAP/caffeine (Trezix™) oxycodone/APAP (Primlev™, Xolox®) oxycodone (Oxecta®)	**Short-Acting:** Unique strengths of hydrocodone/APAP **Long-Acting:** hydrocodone bitartrate ER (Zohydro™ ER) oxycodone/APAP ER (Xartemis™ XR) **Oncology Only:** fentanyl (Actiq®) fentanyl (Fentora®) fentanyl (Onsolis® buccal film) fentanyl (Abstral®, Lazanda®) fentanyl (Subsys™ SL spray)

APAP: Acetaminophen, ASA: Aspirin, IBU: Ibuprofen, IR: Immediate-Release, ER: Extended-Release, SL: Sublingual
*Tier Structure based on supplemental rebate participation. Tier-2 medications subject to move to Tier-3.
+Brand name Opana® ER preferred. Generic oxymorphone extended-release tablets require special authorization. The generic formulation is not abuse-deterrent.

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process, and do not require pain contracts.
- Only one long-acting and one-short acting agent can be used concurrently.
- Short-acting, solid dosage formulation products are limited to a quantity of four units per day or a quantity of 120 units per 30 days.
- An age restriction applies on oral liquid narcotic analgesic products for all members older than 12 years of age and oral solid dosage forms for all members younger than 10 years of age.

Opioid Analgesics Tier-2 Approval Criteria:

1. A documented 30-day trial/titration period with at least one Tier-1 medication within the last 90 days is required for a Tier-2 long-acting medication; or
2. A documented 30-day trial with at least two Tier-1 short-acting medications within the last 90 days is required for a Tier-2 short-acting medication; or
3. Authorization of a long-acting medication requires a chronic pain condition requiring daily, around-the-clock, long-term opioid treatment.

Opioid Analgesics Tier-3 Approval Criteria:

1. A documented 30-day trial with at least two Tier-2 long-acting medications within the last 90 days is required for approval of a long-acting Tier-3 medication; or
2. A documented 30-day trial with at least two Tier-2 short-acting medications within the last 90 days is required for approval of a Tier-3 short-acting medication; or
3. A documented allergy or contraindication to all Tier-2 medications.

Opioid Analgesics Special PA Approval Criteria:

1. Actiq®, Fentora®, Onsolis®, Abstral®, Lanzanda® and Subsys™ are approved for oncology-related diagnoses only.
2. Authorization of unique strengths of hydrocodone/acetaminophen require a patient-specific, clinically significant reason the member cannot use generic Norco® (hydrocodone/APAP 5-325mg, 7.5-325mg, or 10-325mg).

Zohydro™ ER (Hydrocodone Bitartrate) Extended-Release Capsules Approval Criteria:

1. A chronic pain condition requiring daily, around-the-clock, long-term opioid treatment; and
2. A patient-specific, clinically significant reason why the member cannot use all other available long-acting Tier-2 and Tier-3 medications.
3. Tier structure rules still apply.

Xartemis™ XR (Oxycodone/APAP) Extended-Release Tablets Approval Criteria:

1. An acute pain condition requiring around-the-clock opioid treatment; and
2. A patient-specific, clinically significant reason for the following:
    a. Why the member cannot use any other opioid medication for treatment of acute pain; and
    b. Why the member requires a long-acting medication for an acute pain condition; and
    c. Why the member cannot use Oxycontin® (oxycodone ER) and OTC acetaminophen individual products in place of this combination product.
3. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and
4. The member must not exceed 3,250mg of acetaminophen per day from all sources.
5. Tier structure rules still apply.

Approval Criteria for Greater than 12 Claims of Hydrocodone Products:

1. Members may be approved for greater than 12 claims per year if the member has a pain contract with a single prescriber. A copy of the pain contract should be submitted

with the prior authorization request. Requests outside of the plan outlined in the contract will not be approved.

2. Members with a current oncology-related diagnosis or hemophilia diagnosis do not require a pain contract for additional approvals.
3. Immediate-release hydrocodone products will not be approved as the only therapy for chronic pain use. Members with chronic pain who require around-the-clock pain control should be on a long-acting pain medication. An additional claim may be approved to allow time for changes in therapy to be made.

Suboxone® (Buprenorphine/Naloxone Tablets and Film), Subutex® (Buprenorphine Sublingual Tablets), Zubsolv® (Buprenorphine/Naloxone Sublingual Tablets) and Bunavail™ (Buprenorphine/Naloxone Buccal Films) Approval Criteria:

1. Suboxone® is the preferred product. Bunavail™ and Zubsolv® authorization requires a patient-specific, clinically significant reason why Suboxone® is not appropriate.
2. Oral buprenorphine products must be prescribed by a licensed physician who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a DEA (X) number; and
3. Member must have an FDA approved diagnosis of opiate abuse/dependence; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
6. The following limitations will apply:
    a. **Suboxone®** 2mg/0.5mg and 8mg/2mg tablets and film: A quantity limit of 90 units per 30 days will apply.
    b. **Suboxone®** 12mg/3mg film: A quantity limit of 60 films per 30 days will apply.
    c. **Subutex®** 2mg and 8mg tablets will only be approved if the member is pregnant (product may be used for the duration of the pregnancy only), or has a documented serious allergy or adverse reaction to naloxone.
    d. **Zubsolv®** sublingual tablets: A quantity limit of 90 tablets per 30 days will apply.
    e. **Bunavail™** 2.1mg/0.3mg and 4.2mg/0.7mg buccal films: A quantity limit of 90 films per 30 days will apply.
    f. **Bunavail™** 6.3mg/1mg buccal films: A quantity limit of 60 films per 30 days will apply.

High Dose Buprenorphine Products Approval Criteria:

1. Each request for greater than 24mg bioequivalent buprenorphine per day should be evaluated on a case-by-case basis.
2. A taper schedule or dates of an attempted taper with reason for failure should be documented on the petition or a patient-specific, clinically significant reason a taper schedule or attempt is not appropriate for the member should be documented/provided; and
3. Opioid urine drug screens should be submitted with high-dose requests that plan to continue high-dose treatment longer than the duration of one month.
    a. Urine drug screens must show the absence of opioid medications other than buprenorphine products for continued approval; or

b. Prescriber must document a patient-specific reason the member should continue therapy, reason for opioid use, and document a plan for member to discontinue opioid use; and

4. Symptoms associated with withdrawal at lower doses or symptoms requiring high doses should be listed on petition; and
5. Each approval will be for the duration of one month. If urine drug screen and other documentation are submitted indicating high-dose therapy is necessary an approval can be granted for the duration of three months.
6. Continued high-dose authorization after the three month approval will require a new (recent) urine drug screen.

Utilization of Opioid Analgesics & Buprenorphine Products: Calendar Year 2014

Comparison of Calendar Years: Opioid Analgesics

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	153,841	554,875	$16,221,644.55	$29.23	$1.76	38,315,636	9,219,592
2014	140,231	523,823	$18,607,078.76	$35.52	$2.00	37,107,158	9,291,706
% Change	**-8.80%**	**-5.60%**	**14.70%**	**21.50%**	**13.60%**	**-3.20%**	**0.80%**
Change	**-13,610**	**-31,052**	**$2,385,434.21**	**$6.29**	**$0.24**	**-1,208,478**	**72,114**

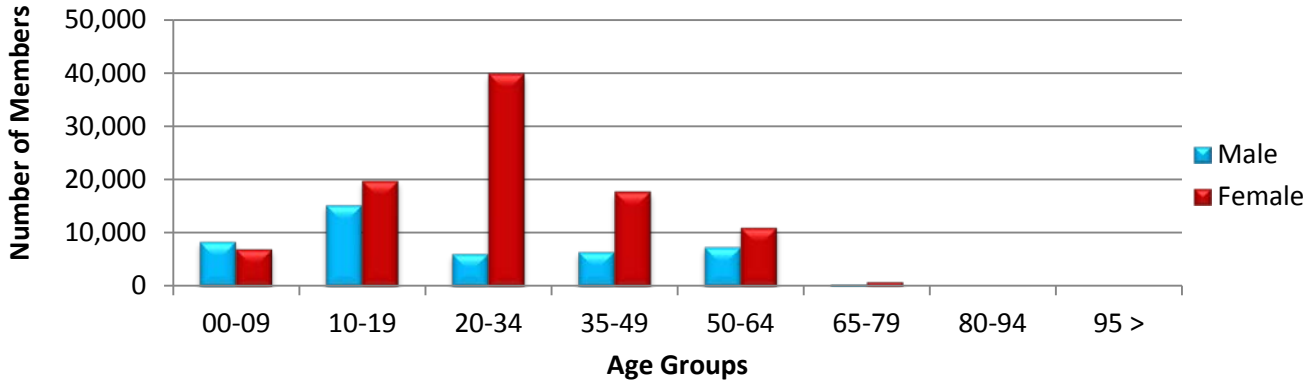
*Total number of unduplicated members.

Comparison of Calendar Years: Buprenorphine Products

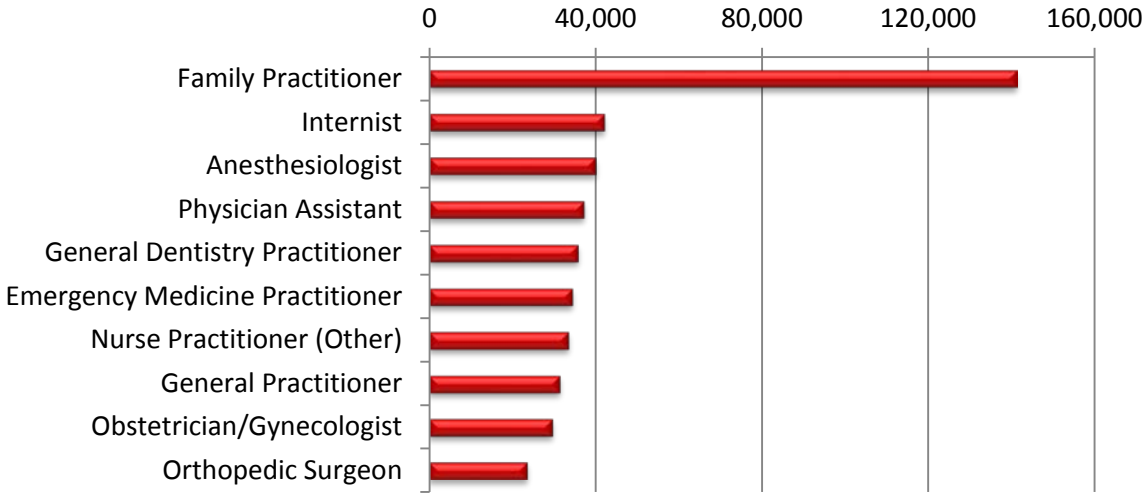
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	872	6,560	$2,692,821.20	$410.49	$15.76	381,125	170,898
2014	992	7,526	$2,772,856.40	$368.44	$14.39	422,102	192,636
% Change	**13.80%**	**14.70%**	**3.00%**	**-10.20%**	**-8.70%**	**10.80%**	**12.70%**
Change	**120**	**966**	**$80,035.20**	**-$42.05**	**-$1.37**	**40,977**	**21,738**

*Total number of unduplicated members.

Demographics of Members Utilizing Opioid Analgesics & Buprenorphine Products



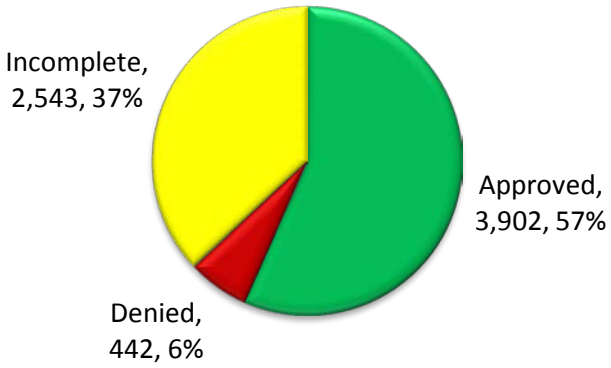
Top Prescriber Specialties of Opioid Analgesics & Buprenorphine Products By Number of Claims



Prior Authorization of Opioid Analgesics & Buprenorphine Products

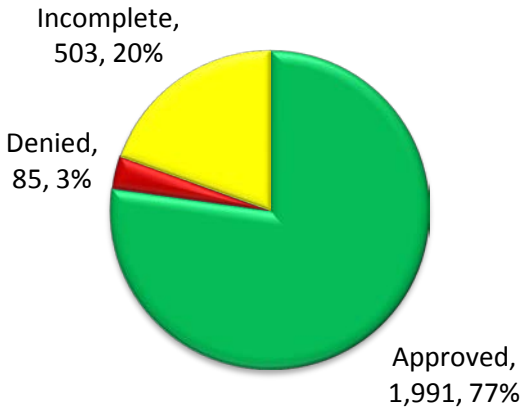
There were 6,887 prior authorization requests submitted for the opioid analgesics category during calendar year 2014. Computer edits are in place to detect Tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions: Opioid Analgesics



There were 2,579 prior authorization requests submitted for the buprenorphine products category during calendar year 2014. Computer edits are in place to detect diagnosis, concomitant opioid claims, and quantities/day supply and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions: Buprenorphine Products



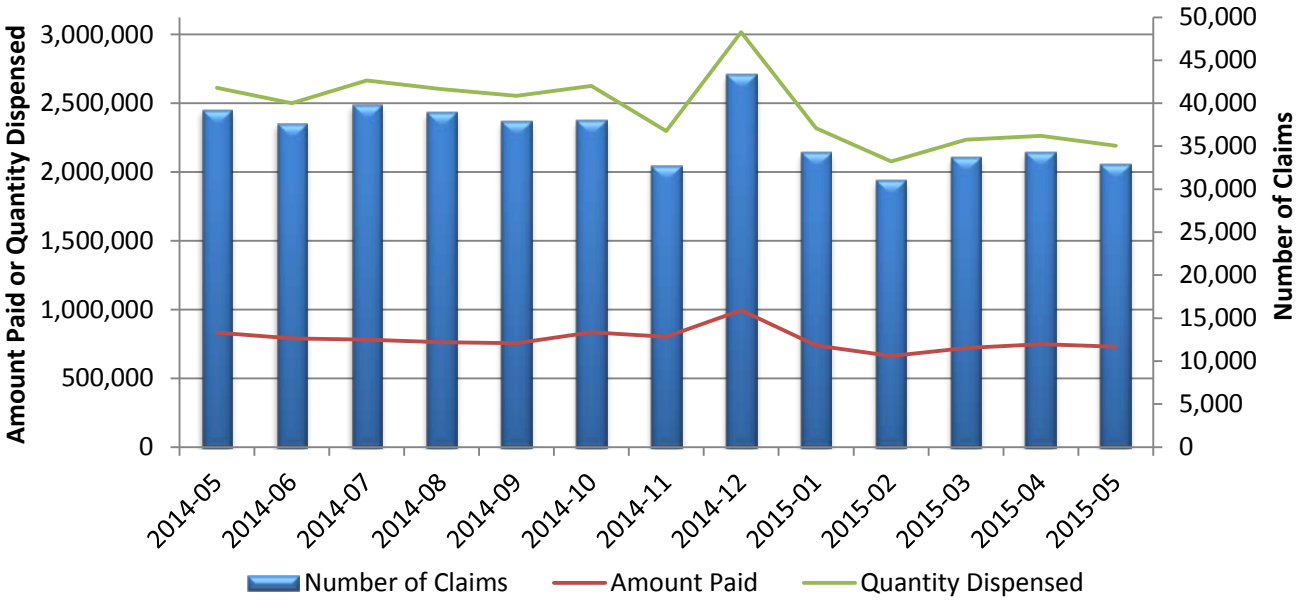
Opioid Analgesic Utilization Trends

In July of 2013, the Drug Utilization Review board voted to reduce the number of immediate-release narcotic units per claim resulting in a maximum quantity of 120 units per 30 day supply. In November of 2014, the College of Pharmacy and the Oklahoma Health Care Authority began implementation of a quantity reduction on all immediate-release, solid dosage form opioid analgesics. The quantity limit was phased in over a three month period and was fully implemented by the end of January 2015.

The phases and medications affected are outlined in the list below (*Of note, hydrocodone became a Schedule II medication 10/06/14*).

- Phase-1 implemented 11/10/14:
  - Drugs included: hydromorphone, morphine IR, codeine, codeine combination products, and oxymorphone
- Phase-2 implemented 12/08/14:
  - Drugs included: oxycodone and oxycodone combination products
- Phase-3 implemented 01/21/15:
  - Drugs included: hydrocodone combination products

Short-Acting Opioid Analgesic Trends: May 2014 - May 2015
Number of Claims, Amount Paid, Quantity Dispensed



Six Year Trend in Utilization of Opioid Analgesics

Calendar Year	Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2009	137,177	472,313	$15,445,073.26	$32.70	$2.32	30,626,889	6,661,796
2010	149,744	518,200	$15,301,884.16	$29.53	$1.97	34,389,996	7,771,934
2011	155,907	561,800	$16,043,606.57	$28.56	$1.83	38,278,004	8,760,325
2012	161,981	585,868	$16,414,461.71	$28.02	$1.75	40,194,163	9,391,441
2013	153,841	554,875	$16,221,644.55	$29.23	$1.76	38,315,636	9,219,592
2014	140,231	523,823	$18,607,078.76	$35.52	$2.00	37,107,158	9,291,706

Top 10 Products by Claims: Calendar Year 2014

Medication	Claims	Members	Cost	Cost/ Day	Units/ Day
Hydrocodone/APAP Tab 10-325MG	117,302	23,726	$1,855,807.11	$0.64	3.81
Hydrocodone/APAP Tab 7.5-325MG	97,918	43,499	$1,131,718.14	$0.82	3.53
Hydrocodone/APAP Tab 5-325MG	62,999	39,727	$534,616.34	$1.07	3.86
Tramadol Tab 50MG	57,378	21,906	$380,773.92	$0.35	3.84
Oxycodone/APAP Tab 5-325MG	23,344	18,349	$247,345.56	$1.61	5.32
Oxycodone/APAP Tab 10-325MG	21,436	6,136	$1,998,253.13	$4.06	4.16
Codeine/APAP Tab 30-300MG	19,427	13,675	$146,121.69	$0.87	3.72
Codeine/APAP Soln 12-120MG/5ML	12,618	11,010	$77,504.58	$1.10	20.49
Oxycodone Tab 30MG	10,688	1,525	$1,274,438.52	$4.19	4.46
Hydrocodone/APAP Soln 7.5-325MG/15ML	10,626	9,231	$445,467.80	$6.16	30.4
SUBTOTAL	**433,736**		**$8,092,046.79**		
CATEGORY TOTAL	**523,823**		**$18,607,078.76**		
PERCENT OF TOTAL	**82.80%**		**43.49%**		

Top 10 Products by Cost: Calendar Year 2014

Medication	Claims	Members	Cost	Cost/ Day	Units/ Day
OxyContin Tab 80MG CR	1,823	202	$2,266,417.90	$42.08	2.76
Oxycodone/APAP Tab 10-325MG	21,436	6,136	$1,998,253.13	$4.06	4.16
Hydrocodone/APAP Tab 10-325MG	117,302	23,726	$1,855,807.11	$0.64	3.81
Oxycodone Tab 30MG	10,688	1,525	$1,274,438.52	$4.19	4.46
Hydrocodone/APAP Tab 7.5-325MG	97,918	43,499	$1,131,718.14	$0.82	3.53
OxyContin Tab 60MG CR	1,010	147	$710,846.63	$23.79	2.05
OxyContin Tab 40MG CR	1,216	213	$570,737.47	$16.07	2.04
Hydrocodone/APAP Tab 5-325MG	62,999	39,727	$534,616.34	$1.07	3.86
Oxycodone/APAP Tab 7.5-325MG	10,302	5,340	$492,758.37	$3.10	3.92
Hydrocodone/APAP Soln 7.5-325MG/15ML	10,626	9,231	$445,467.80	$6.16	30.4
SUBTOTAL	**335,320**		**$11,281,061.41**		
CATEGORY TOTAL	**523,823**		**$18,607,078.76**		
PERCENT OF TOTAL	**64.01%**		**60.63%**		

Market News and Updates[1,2,3,4]

Anticipated Patent Expirations:

- Exalgo® (hydromorphone ER tablets): July 2014
- Butrans® (buprenorphine patches): September 2017
- Zohydro™ ER (hydrocodone bitartrate ER capsules): November 2019
- Nucynta® (tapentadol tablets) and Nucynta® ER (tapentadol ER tablets): June 2025
- Embeda® (morphine/naltrexone ER capsules): June 2027
- Xartemis™ XR (oxycodone/APAP ER tablets): May 2032

FDA Update:

- **04/2015:** The FDA issued final guidance to assist industry in developing opioid drug products with abuse-deterrent properties. To combat opioid misuse and abuse, the FDA is encouraging manufacturers to develop abuse-deterrent drugs that work correctly when taken as prescribed, but may be formulated to deter misuse and abuse.

FDA Approvals:

- **11/2014:** The FDA approved Hysingla™ ER (hydrocodone bitartrate extended-release tablets), an extended-release (ER) opioid analgesic to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Hysingla™ ER has approved labeling describing the product's abuse-deterrent properties including that the tablet is difficult to crush, break, or dissolve. It also forms a viscous hydrogel and cannot be easily prepared for injection.
- **01/2015:** Zogenix, Inc. announced the FDA approval of a new formulation of Zohydro™ ER (hydrocodone bitartrate ER capsules) with BeadTek™. BeadTek™ is a formulation of technology designed to provide abuse-deterrent properties without changing the release properties of hydrocodone when Zohydro™ ER is used as intended. BeadTek™ incorporates excipients that form a viscous gel when crushed and dissolved in liquids.

Hysingla™ ER (Hydrocodone Bitartrate Extended-Release Tablets)[5]

Indications: Hysingla™ ER (hydrocodone bitartrate extended-release tablets) is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

- **Limitations of use:**
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, Hysingla™ ER should be reserved for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
  - Hysingla™ ER is not indicated as an as-needed analgesic.

Dosing:

- Hysingla™ ER is available as 20mg, 30mg, 40mg, 60mg, 80mg and 120mg extended-release tablets.
- Hysingla™ ER should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.
- The dosing regimen for each patient should be initiated individually, taking into account the patient's prior analgesic treatment experience and risk factors for addiction, abuse, and misuse.
- Hysingla™ ER is administered orally once daily (every 24 hours).
- The starting dose for patients who are not opioid tolerant is 20mg by mouth every 24 hours. Daily doses of Hysingla™ ER greater than or equal to 80mg are only for use in opioid tolerant patients.
- Treatment should be individualized; doses should be titrated to an effective and tolerable dose.
- Tablets must be swallowed whole and are not to be chewed, crushed, or dissolved.

Conversion Factors to Hysingla™ ER		
Opioid	**Oral Dose (mg)**	**Approximate Oral Conversion Factor**
codeine	133	0.15
hydromorphone	5	4
methadone	13.3	1.5
morphine	40	0.5
oxycodone	20	1
oxymorphone	10	2
tramadol	200	0.1

The conversion factors in this table are only for the conversion from one of the listed oral opioid analgesics to Hysingla™ ER. It is extremely important to monitor all patients closely when converting from methadone to other opioid agonists. The ratio between methadone and other opioid agonists may vary widely as a function of previous dose exposure. Methadone has a long half-life and tends to accumulate in the plasma.

- To calculate the estimated daily Hysingla™ ER dose using the above table:
  - For patients on a single opioid, sum the current total daily dose of the opioid and then multiply the total daily dose by the approximate oral conversion factor to calculate the approximate oral hydrocodone daily dose.

- For patients on a regimen of more than one opioid, calculate the approximate oral hydrocodone dose for each opioid and sum the totals to obtain the approximate oral hydrocodone daily dose.
- Reduce the calculated daily oral hydrocodone dose by 25%.

Contraindications: Hysingla™ ER is contraindicated in patients with any of the following:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus and gastrointestinal obstruction
- Hypersensitivity to any component of Hysingla™ ER

Warnings and Precautions:

- Addiction, Abuse, Misuse: Hysingla™ ER contains hydrocodone, a Schedule II substance. As an opioid Hysingla™ ER exposes users to the risks of addiction, abuse, and misuse.
- Life-Threatening Respiratory Depression: Serious, life-threatening, or fatal respiratory depression has been reported with the use of modified-release opioids, even when used as recommended.
- Neonatal Opioid Withdrawal Syndrome: Prolonged use of Hysingla™ ER during pregnancy can result in withdrawal signs in the neonate.
- Interactions with Central Nervous System (CNS) Depressants: Hypotension, profound sedation, coma, respiratory depression, and death may result if Hysingla™ ER is used concomitantly with alcohol or other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids).
- Use in Elderly, Cachectic, and Debilitated Patients: Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients.
- Use in Patients with Chronic Pulmonary Disease: Patients with significant chronic obstructive pulmonary disease and patients having a decreased respiratory reserve should be monitored closely as Hysingla™ ER may decrease respiratory drive to the point of apnea.
- Use in Patients with Head Injury and Increased Intracranial Pressure: In the presence of head injury or a preexisting increase in intracranial pressure, the possible respiratory depressant effects of opioid analgesics and their potential to elevate cerebrospinal fluid pressure (resulting from vasodilation following CO_2 retention) may be markedly exaggerated.
- Hypotensive Effect: Hysingla™ ER may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients.
- Decreased Bowel Motility: Opioids diminish propulsive peristaltic waves in the gastrointestinal tract and decrease bowel motility.
- Driving and Operating Heavy Machinery: Hysingla™ ER may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.

- Interaction with Mixed Agonist/Antagonist Opioid Analgesics: Avoid the use of mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) in patients who are receiving, a course of therapy with a full opioid agonist analgesic. In these patients, mixed agonist/antagonist analgesics may reduce the analgesic effect and may precipitate withdrawal symptoms.
- QTc Interval Prolongation: QTc prolongation has been observed with Hysingla™ ER following daily doses of 160mg. This observation should be considered in making clinical decisions regarding patient monitoring when prescribing Hysingla™ ER in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QTc interval.

Adverse Reactions: The most common adverse reactions (≥5%) reported by patients during clinical trials include the following:

- Nausea
- Constipation
- Vomiting
- Dizziness
- Headache
- Somnolence
- Fatigue
- Upper Respiratory Tract Infection

Use in Special Populations:

- Pregnancy: Hysingla™ ER is pregnancy category B. There are no adequate and well-controlled studies of Hysingla™ ER use during pregnancy. Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome.
- Labor and Delivery: Opioids cross the placenta and may produce respiratory depression in neonates. Hysingla™ ER is not recommended for use in women immediately prior to and during labor, when use of shorter acting analgesics or other analgesic techniques are more appropriate.
- Nursing Mothers: Hydrocodone is present in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue Hysingla™ ER, taking into account the importance of the drug to the mother.
- Pediatric Use: The safety and effectiveness of Hysingla™ ER in pediatric patients has not been established.
- Geriatric Use: Of the 1,827 subjects exposed to Hysingla™ ER in the pooled chronic pain studies, 13% were age 65 years and older, while 2% were age 75 years and older. In clinical trials with appropriate initiation of therapy and dose titration, no untoward or unexpected adverse reactions were seen in the elderly patients who received Hysingla™ ER.
- Hepatic Impairment: No adjustment in starting dose with Hysingla™ ER is required in patients with mild or moderate hepatic impairment. Therapy should be initiated with one-half the initial dose of Hysingla™ ER in patients with severe hepatic impairment.
- Renal Impairment: Patients with moderate or severe renal impairment or end stage renal disease have higher plasma concentrations than those with normal renal function. Therapy should be initiated with one-half the initial dose of Hysingla™ ER in these patients.

Efficacy: The efficacy and safety of Hysingla™ ER was evaluated in a randomized, double-blind, placebo-controlled, 12-week clinical trial in both opioid-experienced and opioid-naïve patients with moderate-to-severe chronic low back pain. A total of 905 chronic low back pain patients entered an open-label conversion and dose-titration period for up to 45 days with Hysingla™ ER. Patients were dosed once daily with Hysingla™ ER (20mg to 120mg). Patients stopped their previous opioid analgesics and nonopioid analgesics prior to starting Hysingla™ ER treatment. Following the dose titration period, 588 patients (65%) were randomized at a ratio of 1:1 into a 12-week double-blind treatment period with their fixed stabilized dose of Hysingla™ ER (or matching placebo). Patients were allowed to use rescue medication (immediate-release oxycodone 5mg) up to six doses per day. Hysingla™ ER provided greater analgesia compared with placebo. There was a statistically significant difference in the weekly average pain scores at week 12 between the two groups. Treatment with Hysingla™ ER resulted in a higher proportion of responders, defined as patients with at least a 30% and 50% improvement, as compared with placebo.

Clinical Abuse Potential Studies: Two randomized, double-blind, placebo and active-controlled clinical studies in non-dependent recreational opioid users were conducted to characterize the abuse potential of Hysingla™ ER following physical manipulation and administration via the intranasal and oral routes.

- Intranasal Abuse Potential Study: Twenty-five subjects completed the study. Treatments studied included tampered intranasally administered Hysingla™ ER 60mg tablets, powdered hydrocodone 60mg, and placebo. Incomplete dosing due to granules falling from the subjects' nostrils occurred in 82% of subjects receiving tampered Hysingla™ ER compared to no subjects with powdered hydrocodone or placebo. The intranasal administration of tampered Hysingla™ ER was associated with statistically significantly lower mean and median scores on scales that measure drug liking and desire to take the drug again ($p<0.001$ for both), compared with powdered hydrocodone.
- Oral Abuse Potential Study: Thirty-five subjects completed the study. Treatments studied included oral administrations of chewed Hysingla™ ER 60mg tablets, intact Hysingla™ ER 60mg tablets, 60mg aqueous hydrocodone solution, and placebo. The oral administration of chewed and intact Hysingla™ ER was associated with statistically lower mean and median scores on scales that measure drug liking and desire to take drug again ($p<0.001$), compared to hydrocodone solution.

Cost Comparison:

Medication	EAC Per Tablet or Capsule	EAC Per Day	EAC for 30 Days of Therapy
Hysingla™ ER Tablets	$6.94-$35.91	$6.94-$35.91	$208.20-$1,077.30
Zohydro™ ER Capsules	$6.48-$7.93	$12.96-$15.86	$388.80-$475.80
Morphine ER Tablets	$0.61-$5.10[+]	$1.22-$10.20	$36.60-$306.00

Costs do not reflect supplemental rebated prices or net costs.
EAC= estimated acquisition cost
[+]State maximum allowable cost (SMAC) pricing.
Dosing shown above for Hysingla™ ER and Zohydro™ ER is based on maximum strength available. Hysingla™ ER largest strength available is 120mg per day versus 100mg (50mg twice daily) for Zohydro ER.
Morphine dosed twice daily with maximum dose of 400mg per day shown.

Recommendations

The College of Pharmacy recommends the following changes to the Opioid Analgesics Product Based Prior Authorization (PBPA) category.

1. The addition of Hysingla™ ER (hydrocodone bitartrate extended-release tablets) to Tier-3. Current criteria for this category will apply.
    a. Hysingla™ ER is currently rebated to Tier-2, but will be placed in Tier-3 if the manufacturer chooses not to participate in supplemental rebates.
2. Moving Zohydro™ ER (hydrocodone bitartrate extended-release capsules) from the Special Prior Authorization (PA) category to Tier-3 based on reformulation with abuse-deterrent properties and to encourage supplemental rebate participation.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caffeine/codeine (Fiorinal with Codeine®) codeine codeine/APAP hydromorphone (Dilaudid®) hydrocodone/APAP (Norco®) hydrocodone/IBU (Vicoprofen®, Ibudone®, Reprexain™) hydromorphone (Dilaudid®) methadone (Dolophine®) morphine IR (MSIR®) oxycodone/APAP (Percocet®) oxycodone/ASA (Percodan®) oxycodone ER 10mg, 15mg, 20mg only (Oxycontin®) oxycodone IR (Oxy IR®) oxycodone/ibuprofen (Combunox™) tramadol/APAP (Ultracet®) tramadol (Ultram®)	**Long-Acting:** buprenorphine (Butrans®) fentanyl patches (Duragesic®) **hydrocodone bitartrate ER (Hysingla™ ER)** morphine ER tablets (MS Contin®) oxycodone ER (Oxycontin®) **Short-Acting:** oxymorphone IR (Opana®) tapentadol IR (Nucynta®)	**Long-Acting:** **hydrocodone bitartrate ER (Zohydro™ ER)** hydromorphone ER (Exalgo®) morphine sulfate ER (Avinza®) morphine sulfate ER (Kadian®) morphine/naltrexone (Embeda®) oxymorphone ER (Opana® ER)+ tapentadol ER (Nucynta® ER) tramadol ER (Ultram ER®, Ryzolt®) **Short-Acting:** hydrocodone/APAP (Xodol®, Zamicet®, Liquicet®) hydrocodone/APAP/caffeine (Trezix™) oxycodone/APAP (Primlev™, Xolox®) oxycodone (Oxecta®)	**Short-Acting:** Unique strengths of hydrocodone/APAP **Long-Acting:** oxycodone/APAP ER (Xartemis™ XR) **Oncology Only:** fentanyl (Actiq®) fentanyl (Fentora®) fentanyl (Onsolis® buccal film) fentanyl (Abstral®,Lazanda®) fentanyl (Subsys™ SL spray)

APAP: Acetaminophen, ASA: Aspirin, IBU: Ibuprofen, IR: Immediate-Release, ER: Extended-Release, SL: Sublingual
*Tier Structure based on supplemental rebate participation. Tier-2 medications subject to move to Tier-3.
+Brand name Opana® ER preferred. Generic oxymorphone extended-release tablets require special authorization. The generic formulation is not abuse-deterrent.

Utilization Details of Opioid Analgesics and Buprenorphine Products: Calendar Year 2014

Short-Acting Opioid Analgesics

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
HYDROCODONE SHORT-ACTING PRODUCTS						
HYDROCO/APAP TAB 10-	117,302	23,726	$1,855,807.11	3.81	4.94	$15.82
HYDROCO/APAP TAB 7.5-325	97,918	43,499	$1,131,718.14	3.53	2.25	$11.56
HYDROCO/APAP TAB 5-325MG	62,999	39,727	$534,616.34	3.86	1.59	$8.49
HYDROCO/APAP SOL 7.5-325	10,626	9,231	$445,467.80	30.4	1.15	$41.92
HYDROCOD/IBU TAB 7.5-200	2,711	1,314	$43,594.65	3.24	2.06	$16.08
HYDROCO/APAP TAB 10-	894	672	$21,103.83	3.53	1.33	$23.61
HYDROCO/APAP TAB 7.5-500	847	699	$7,315.39	3.3	1.21	$8.64
HYDROCO/APAP TAB 5-500MG	633	556	$3,514.33	3.33	1.14	$5.55
HYDROCO/APAP SOL 7.5-500	241	224	$2,551.61	28.95	1.08	$10.59
HYDROCOD/IBU TAB 10-	136	43	$25,142.90	3.5	3.16	$184.87
IBUDONE TAB 10-200MG	90	31	$9,004.23	3.65	2.9	$100.05
HYDROCOD/IBU TAB 5-200MG	54	28	$7,012.54	3.24	1.93	$129.86
HYDROCO/APAP TAB 10-	49	32	$621.76	3.38	1.53	$12.69
HYDROCO/APAP TAB 7.5-650	37	34	$181.05	3.35	1.09	$4.89
LORTAB ELX 7.5-500	20	16	$309.47	38.82	1.25	$15.47
HYDROCO/APAP TAB 2.5-500	20	16	$258.51	3.06	1.25	$12.93
LORTAB ELX 10-300MG	13	12	$798.50	15.32	1.08	$61.42
HYDROCO/APAP TAB 7.5-750	12	10	$85.37	3.25	1.2	$7.11
HYDROCO/APAP TAB 7.5-300	11	7	$999.78	4.06	1.57	$90.89
VICODIN HP TAB 10-300MG	11	1	$2,593.82	6	11	$235.80
HYDROCOD/IBU TAB 2.5-200	9	5	$1,118.53	2.46	1.8	$124.28
HYDROCO/APAP TAB 5-300MG	9	4	$664.45	1.99	2.25	$73.83
HYDROCO/APAP TAB 10-	7	5	$1,244.16	4.19	1.4	$177.74
IBUDONE TAB 5-200MG	7	7	$186.67	2.4	1	$26.67
VICODIN TAB 5-300MG	4	3	$230.94	3.3	1.33	$57.74
SUBTOTAL	**294,660**	**96,180**	**$4,096,141.88**	**4.12**	**3.06**	**$13.90**
OXYCODONE SHORT-ACTING PRODUCTS						
OXYCOD/APAP TAB 5-325MG	23,344	18,349	$247,345.56	5.32	1.27	$10.60
OXYCOD/APAP TAB 10-325MG	21,436	6,136	$1,998,253.13	4.16	3.49	$93.22
OXYCODONE TAB 30MG	10,688	1,525	$1,274,438.52	4.46	7.01	$119.24
OXYCOD/APAP TAB 7.5-325	10,302	5,340	$492,758.37	3.92	1.93	$47.83
OXYCODONE TAB 15MG	7,976	1,608	$389,318.63	4.32	4.96	$48.81
OXYCODONE TAB 10MG	3,772	1,203	$104,624.87	3.96	3.14	$27.74
ENDOCET TAB 10-325MG	3,452	1,271	$373,344.79	4.21	2.72	$108.15
OXYCODONE TAB 5MG	2,272	1,052	$44,662.64	4.26	2.16	$19.66
OXYCODONE TAB 20MG	1,770	434	$124,361.11	4.05	4.08	$70.26
ENDOCET TAB 5-325MG	417	366	$3,734.56	5.32	1.14	$8.96
ENDOCET TAB 7.5-325	320	215	$17,467.35	3.83	1.49	$54.59

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
OXYCODONE CAP 5MG	138	93	$14,285.40	5.01	1.48	$103.52
OXYCOD/ASA TAB	107	69	$3,575.11	3.51	1.55	$33.41
OXYCOD/APAP TAB 7.5-500	72	53	$1,700.34	3.69	1.36	$23.62
OXYCODONE CON 100/5ML	71	27	$33,748.15	3.38	2.63	$475.33
OXYCOD/APAP TAB 10-650MG	66	44	$1,632.07	3.62	1.5	$24.73
OXYCODONE SOL 5MG/5ML	66	40	$2,146.66	18.94	1.65	$32.53
OXYCOD/APAP CAP 5-500MG	29	24	$413.78	4.19	1.21	$14.27
ROXICET SOL 5-325/5	14	12	$280.48	34.57	1.17	$20.03
OXYCOD/APAP TAB 2.5-325	7	7	$231.65	2.96	1	$33.09
ENDOCET TAB 10-650MG	3	3	$135.03	3.52	1	$45.01
OXYCODONE POW HCL	2	2	$74.28	0.91	1	$37.14
ENDOCET TAB 7.5-500M	2	2	$34.03	3.4	1	$17.02
OXYCODONE POW HCL	1	1	$75.00	0.03	1	$75.00
SUBTOTAL	**86,327**	**31,512**	**$5,128,641.51**	**4.32**	**2.74**	**$59.41**
TRAMADOL SHORT-ACTING PRODUCTS						
TRAMADOL HCL TAB 50MG	57,378	21,906	$380,773.92	3.84	2.62	$6.64
TRAMADL/APAP TAB 37.5-325	1,083	675	$12,751.44	3.45	1.6	$11.77
ULTRACET TAB 37.5-325	3	3	$37.70	1.56	1	$12.57
SUBTOTAL	**58,464**	**22,414**	**$393,563.06**	**3.83**	**2.61**	**$6.73**
CODEINE PRODUCTS						
APAP/CODEINE TAB 300-30MG	19,427	13,675	$146,121.69	3.72	1.42	$7.52
APAP/CODEINE SOL 120-12/5	12,618	11,010	$77,504.58	20.49	1.15	$6.14
APAP/CODEINE TAB 300-60MG	2,205	1,123	$35,995.16	3.47	1.96	$16.32
BUT/APAP/CAF CAP CODEINE	931	374	$38,404.35	3.7	2.49	$41.25
ASCOMP/COD CAP 30MG	287	114	$32,235.03	4.16	2.52	$112.32
BUT/ASA/CAF/ CAP COD 30MG	211	83	$17,527.38	3.21	2.54	$83.07
APAP/CODEINE TAB 300-15MG	90	71	$741.10	3.43	1.27	$8.23
CODEINE SULF TAB 30MG	68	26	$2,079.14	3.17	2.62	$30.58
SYNALGOS-DC CAP	10	5	$644.58	1.76	2	$64.46
APAP/CAFF/DI TAB HYDROCOD	6	5	$252.24	3.98	1.2	$42.04
CODEINE SULF TAB 15MG	4	3	$64.44	2.16	1.33	$16.11
CAPITAL/COD SUS 120-12/5	3	1	$1,122.87	20	3	$374.29
FIORICET/COD CAP	1	1	$14.30	3	1	$14.30
CODEINE SULF TAB 60MG	1	1	$12.24	6	1	$12.24
SUBTOTAL	**35,862**	**25,984**	**$352,719.10**	**7.53**	**1.38**	**$9.84**
MORPHINE SHORT-ACTING PRODUCTS						
MORPHINE SUL TAB 15MG	3,249	828	$36,656.65	3.67	3.92	$11.28
MORPHINE SUL TAB 30MG	1,767	314	$39,507.31	4.06	5.63	$22.36
MORPHINE SUL SOL 20MG/ML	131	69	$5,873.22	5.48	1.9	$44.83
MORPHINE SUL SOL	64	34	$1,049.96	19.71	1.88	$16.41
MORPHINE SUL SOL	41	13	$1,380.38	22.77	3.15	$33.67
MORPHINE SUL INJ 10MG/ML	18	12	$228.94	9.71	1.5	$12.72
MORPHINE SUL SOL 100/5ML	15	10	$282.52	2.54	1.5	$18.83
MORPHINE SUL INJ 2MG/ML	10	8	$266.61	5.57	1.25	$26.66

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
MORPHINE SUL INJ 5MG/ML	5	5	$24.42	1	1	$4.88
MORPHINE SUL INJ 4MG/ML	5	3	$292.57	7.42	1.67	$58.51
MORPHINE SUL INJ 8MG/ML	3	3	$15.60	1	1	$5.20
MORPHINE SUL INJ 50MG/ML	2	2	$22.62	17.31	1	$11.31
MORPHINE POW SULFATE	1	1	$12.29	0.02	1	$12.29
SUBTOTAL	**5,311**	**1,202**	**$85,613.09**	**4.06**	**4.42**	**$16.12**
HYDROMORPHONE SHORT-ACTING PRODUCTS						
HYDROMORPHON TAB 4MG	1,516	446	$23,279.42	4.09	3.4	$15.36
HYDROMORPHON TAB 2MG	771	479	$7,496.40	4.15	1.61	$9.72
HYDROMORPHON TAB 8MG	640	112	$35,042.85	3.87	5.71	$54.75
DILAUDID TAB 4MG	9	1	$3,909.64	11.25	9	$434.40
HYDROMORPHON LIQ 1MG/ML	9	4	$1,456.34	29.73	2.25	$161.82
HYDROMORPHON INJ	3	1	$323.74	6.3	3	$107.91
HYDROMORPHON POW HCL	3	1	$258.80	0.84	3	$86.27
SUBTOTAL	**2,951**	**948**	**$71,767.19**	**4.12**	**3.11**	**$24.32**
MEPERIDINE PRODUCTS						
MEPERIDINE SOL 50MG/5ML	781	521	$4,525.22	9.83	1.5	$5.79
MEPERIDINE TAB 50MG	449	343	$5,332.42	3.45	1.31	$11.88
MEPERITAB TAB 50MG	372	299	$3,828.01	4.22	1.24	$10.29
MEPERIDINE TAB 100MG	65	20	$1,223.97	2.59	3.25	$18.83
MEPERITAB TAB 100MG	26	11	$1,228.92	2.84	2.36	$47.27
DEMEROL INJ 50MG/ML	15	13	$82.74	0.97	1.15	$5.52
DEMEROL INJ 100MG/ML	12	5	$97.25	1.67	2.4	$8.10
MEPERIDINE INJ 100MG/ML	4	1	$76.76	4.42	4	$19.19
SUBTOTAL	**1,724**	**1,184**	**$16,395.29**	**4.4**	**1.46**	**$9.51**
OXYMORPHONE SHORT-ACTING PRODUCTS						
OXYMORPHONE TAB HCL	469	97	$197,146.75	3.9	4.84	$420.36
OXYMORPHONE TAB HCL 5MG	123	38	$24,261.14	3.16	3.24	$197.25
SUBTOTAL	**592**	**126**	**$221,407.89**	**3.75**	**4.7**	**$374.00**
TAPENTADOL SHORT-ACTING PRODUCTS						
NUCYNTA TAB 100MG	94	17	$42,723.52	3.68	5.53	$454.51
NUCYNTA TAB 50MG	54	21	$10,967.53	3	2.57	$203.10
NUCYNTA TAB 75MG	41	20	$8,623.25	2.84	2.05	$210.32
SUBTOTAL	**189**	**51**	**$62,314.30**	**3.34**	**3.71**	**$329.71**
PENTAZOCINE PRODUCTS						
PENTAZ/NALOX TAB 50-0.5MG	1,103	551	$108,097.41	3.65	2	$98.00
PENTA/APAP TAB 25-650MG	1	1	$32.15	5	1	$32.15
SUBTOTAL	**1,104**	**552**	**$108,129.56**	**3.65**	**2**	**$97.94**
FENTANYL SHORT-ACTING PRODUCTS						
FENTANYL CIT INJ 0.05MG/1	33	13	$146.44	2.09	2.54	$4.44
FENTORA TAB 200MCG	20	5	$43,131.49	2.46	4	$2,156.57
FENTANYL OT LOZ 800MCG	13	1	$21,375.12	3.92	13	$1,644.24
FENTORA TAB 400MCG	9	2	$62,147.39	3.79	4.5	$6,905.27
SUBSYS SPR 800MCG	5	3	$63,354.94	4.4	1.67	$12,670.99

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
SUBSYS SPR 400MCG	3	1	$32,408.31	6	3	$10,802.77
SUBSYS SPR 600MCG	2	1	$23,377.71	5	2	$11,688.86
FENTANYL OT LOZ 200MCG	2	2	$266.38	1.41	1	$133.19
FENTORA TAB 600MCG	1	1	$8,908.94	4	1	$8,908.94
SUBSYS SPR 200MCG	1	1	$4,961.61	4	1	$4,961.61
SUBSYS SPR 100MCG	1	1	$298.87	3.33	1	$298.87
SUBTOTAL	**90**	**25**	**$260,377.20**	**3.63**	**3.6**	**$2,893.08**
TOTAL	**487,724**	**139,912***	**$10,797,070.07**	**4.25**	**3.48**	**$22.16**

*Total number of unduplicated members.

Long-Acting Opioid Analgesics

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
MORPHINE LONG-ACTING PRODUCTS						
MORPHINE SUL TAB 30MG ER	5,614	1,088	$363,023.36	2.28	5.16	$64.66
MORPHINE SUL TAB 15MG ER	5,339	1,343	$174,984.25	2.21	3.98	$32.77
MORPHINE SUL TAB 60MG ER	2,939	467	$364,400.91	2.35	6.29	$123.99
MORPHINE SUL TAB 100MG ER	1,016	133	$224,871.71	2.69	7.64	$221.33
MORPHINE SUL TAB 200MG ER	180	28	$58,793.66	2.46	6.43	$326.63
MORPHINE SUL CAP 80MG ER	86	13	$46,434.27	1.87	6.62	$539.93
MORPHINE SUL CAP 30MG ER	86	18	$18,747.29	1.73	4.78	$217.99
MORPHINE SUL CAP 100MG ER	47	8	$72,903.59	3.87	5.88	$1,551.14
MORPHINE SUL CAP 20MG ER	38	14	$8,100.47	1.91	2.71	$213.17
MORPHINE SUL CAP 50MG ER	37	6	$11,533.78	1.46	6.17	$311.72
MORPHINE SUL CAP 60MG ER	35	10	$16,546.65	1.97	3.5	$472.76
AVINZA CAP 90MG	21	4	$10,298.13	1	5.25	$490.39
MORPHINE SUL CAP 10MG ER	21	11	$3,381.04	1.87	1.91	$161.00
KADIAN CAP 200MG CR	17	2	$48,583.29	2	8.5	$2,857.84
AVINZA CAP 120MG	14	2	$7,965.36	1	7	$568.95
MORPHINE SUL CAP 90MG ER	14	3	$5,937.16	1	4.67	$424.08
KADIAN CAP 50MG CR	12	1	$6,896.07	2	12	$574.67
MS CONTIN TAB 60MG CR	12	1	$38,093.71	12	12	$3,174.48
KADIAN CAP 150MG CR	10	1	$21,137.39	2	10	$2,113.74
KADIAN CAP 200MG ER	5	2	$17,548.61	2.4	2.5	$3,509.72
AVINZA CAP 60MG	4	1	$1,147.50	1	4	$286.88
MORPHINE SUL CAP 120MG ER	3	1	$3,002.19	2	3	$1,000.73
KADIAN CAP 50MG ER	2	1	$1,238.11	2	2	$619.06
MORPHINE SUL CAP 45MG ER	2	2	$865.47	2	1	$432.74
MORPHINE SUL CAP 60MG ER	2	1	$572.00	1	2	$286.00
MORPHINE SUL CAP 30MG ER	1	1	$149.23	1	1	$149.23
SUBTOTAL	**15,557**	**2,554**	**$1,527,155.20**	**2.3**	**6.09**	**$98.17**
METHADONE PRODUCTS						
METHADONE TAB 10MG	3,224	448	$61,771.83	4.9	7.2	$19.16
METHADONE TAB 5MG	401	113	$3,030.39	3.02	3.55	$7.56

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
METHADONE SOL 5MG/5ML	227	96	$2,527.94	5.59	2.36	$11.14
METHADONE CON 10MG/ML	11	6	$776.05	3.97	1.83	$70.55
METHADONE SOL 10MG/5ML	7	5	$44.29	1.68	1.4	$6.33
METHADOSE CON 10MG/ML	2	2	$41.80	6.88	1	$20.90
METHADONE POW	1	1	$4.04	0.37	1	$4.04
SUBTOTAL	**3,873**	**635**	**$68,196.34**	**4.72**	**6.1**	**$17.61**
FENTANYL LONG-ACTING PRODUCTS						
FENTANYL DIS 25MCG/HR	2,415	799	$120,849.39	0.34	3.02	$50.04
FENTANYL DIS 50MCG/HR	2,347	593	$190,686.66	0.34	3.96	$81.25
FENTANYL DIS 100MCG/H	1,785	263	$386,047.10	0.41	6.79	$216.27
FENTANYL DIS 75MCG/HR	1,624	309	$216,697.21	0.35	5.26	$133.43
FENTANYL DIS 12MCG/HR	675	276	$96,795.28	0.34	2.45	$143.40
DURAGESIC DIS 100MCG/H	20	6	$28,917.74	0.42	3.33	$1,445.89
DURAGESIC DIS 75MCG/HR	17	2	$19,408.57	0.43	8.5	$1,141.68
DURAGESIC DIS 50MCG/HR	8	1	$4,656.77	0.33	8	$582.10
SUBTOTAL	**8,891**	**1,614**	**$1,064,058.72**	**0.35**	**5.51**	**$119.68**
OXYCODONE LONG-ACTING PRODUCTS						
OXYCONTIN TAB 80MG CR	1,823	202	$2,266,417.90	2.76	9.02	$1,243.24
OXYCONTIN TAB 40MG CR	1,216	213	$570,737.47	2.04	5.71	$469.36
OXYCONTIN TAB 20MG CR	1,103	230	$297,433.95	2.01	4.8	$269.66
OXYCONTIN TAB 60MG CR	1,010	147	$710,846.63	2.05	6.87	$703.81
OXYCONTIN TAB 30MG CR	886	185	$343,962.20	2.05	4.79	$388.22
OXYCONTIN TAB 10MG CR	391	146	$52,518.78	1.98	2.68	$134.32
OXYCONTIN TAB 15MG CR	264	74	$56,321.71	2.05	3.57	$213.34
OXYCONTIN TAB 60MG CR	8	1	$4,515.37	2	8	$564.42
OXYCODONE TAB 20MG ER	7	4	$1,383.05	2	1.75	$197.58
OXYCODONE TAB 80MG ER	4	3	$4,060.29	2.75	1.33	$1,015.07
OXYCODONE TAB 40MG ER	3	3	$1,377.70	2.33	1	$459.23
OXYCODONE TAB 10MG ER	3	3	$257.66	2	1	$85.89
SUBTOTAL	**6,718**	**854**	**$4,309,832.71**	**2.23**	**7.87**	**$641.54**
OXYMORPHONE LONG-ACTING PRODUCTS						
OPANA ER TAB 20MG	228	52	$102,384.03	2.01	4.38	$449.05
OPANA ER TAB 40MG	221	35	$192,249.23	2.18	6.31	$869.91
OPANA ER TAB 30MG	208	30	$143,422.64	2.12	6.93	$689.53
OPANA ER TAB 10MG	157	40	$39,207.66	1.98	3.93	$249.73
OPANA ER TAB 15MG	85	20	$30,160.24	2	4.25	$354.83
OXYMORPHONE TAB 20MG ER	38	8	$10,743.09	2	4.75	$282.71
OXYMORPHONE TAB 30MG ER	26	6	$11,722.98	2	4.33	$450.88
OPANA ER TAB 5MG	15	12	$2,030.19	2	1.25	$135.35
OXYMORPHONE TAB 40MG ER	11	3	$9,019.66	3.02	3.67	$819.97
OXYMORPHONE TAB 10MG ER	9	3	$1,592.55	2	3	$176.95
OXYMORPHONE TAB 15MG ER	8	3	$1,648.71	2	2.67	$206.09
OPANA ER TAB 40MG	2	1	$1,921.05	2.5	2	$960.53
OPANA ER TAB 30MG	2	2	$1,172.30	2	1	$586.15

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
OPANA ER TAB 7.5MG	2	2	$402.94	2	1	$201.47
OPANA ER TAB 10MG	1	1	$233.43	2	1	$233.43
SUBTOTAL	**1,013**	**148**	**$547,910.70**	**2.07**	**6.84**	**$540.88**
HYDROMORPHONE LONG-ACTING PRODUCTS						
EXALGO TAB 16MG	63	12	$51,503.56	1.08	5.25	$817.52
EXALGO TAB 12MG	39	8	$22,760.97	1	4.88	$583.61
HYDROMORPHON TAB 16MG ER	27	7	$18,582.81	1	3.86	$688.25
EXALGO TAB 32MG	23	5	$64,198.32	1.81	4.6	$2,791.23
HYDROMORPHON TAB 12MG ER	17	7	$9,932.88	1.12	2.43	$584.29
HYDROMORPHON TAB 32MG ER	6	1	$25,178.68	3	6	$4,196.45
HYDROMORPHON TAB 8MG ER	5	3	$1,528.68	1	1.67	$305.74
EXALGO TAB 8MG	1	1	$167.87	1	1	$167.87
SUBTOTAL	**181**	**31**	**$193,853.77**	**1.21**	**5.84**	**$1,071.02**
BUPRENORPHINE TRANSDERMAL PRODUCTS						
BUTRANS DIS 10MCG/HR	88	38	$22,657.42	0.14	2.32	$257.47
BUTRANS DIS 15MCG/HR	37	16	$14,331.89	0.14	2.31	$387.35
BUTRANS DIS 20MCG/HR	33	11	$14,490.81	0.14	3	$439.12
BUTRANS DIS 5MCG/HR	29	10	$4,786.59	0.14	2.9	$165.05
SUBTOTAL	**187**	**51**	**$56,266.71**	**0.14**	**3.67**	**$300.89**
TAPENTADOL LONG-ACTING PRODUCTS						
NUCYNTA ER TAB 100MG	39	16	$12,795.67	2	2.44	$328.09
NUCYNTA ER TAB 150MG	23	5	$9,826.59	2	4.6	$427.24
NUCYNTA ER TAB 250MG	21	2	$11,384.86	2	10.5	$542.14
NUCYNTA ER TAB 200MG	10	3	$4,938.80	2	3.33	$493.88
NUCYNTA ER TAB 50MG	3	3	$549.36	2	1	$183.12
SUBTOTAL	**96**	**25**	**$39,495.28**	**2**	**3.84**	**$411.41**
TRAMADOL LONG-ACTING PRODUCTS						
TRAMADOL HCL TAB 100MG ER	21	6	$1,651.02	1	3.5	$78.62
TRAMADOL HCL TAB 200MG ER	11	2	$1,183.55	1	5.5	$107.60
SUBTOTAL	**32**	**7**	**$2,834.57**	**1**	**4.57**	**$88.58**
TOTAL	**36,548**	**5,050***	**$7,809,604.00**	**2.04**	**7.24**	**$213.68**

*Total number of unduplicated members.

Oral Buprenorphine Products

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
SUBOXONE MIS 8-2MG	4,759	705	$1,921,953.95	2.12	6.75	$403.86
BUPREN/NALOX SUB 8-2MG	1,582	275	$625,192.65	2.29	5.75	$395.19
BUPRENORPHIN SUB 8MG	776	131	$110,307.21	2.58	5.92	$142.15
SUBOXONE MIS 2-0.5MG	147	54	$26,431.76	1.85	2.72	$179.81
SUBOXONE MIS 4-1MG	80	26	$27,110.81	1.94	3.08	$338.89
SUBOXONE MIS 12-3MG	56	18	$33,470.13	1.5	3.11	$597.68
BUPREN/NALOX SUB 2-0.5MG	46	17	$5,828.75	1.53	2.71	$126.71
ZUBSOLV SUB 5.7-1.4	42	11	$18,129.32	2.41	3.82	$431.65
BUPRENORPHIN SUB 2MG	36	19	$3,540.92	3.73	1.89	$98.36
BUNAVAIL MIS 6.3-1MG	2	2	$890.90	2	1	$445.45
TOTAL	**7,526**	**992***	**$2,772,856.40**	**2.19**	**7.59**	**$368.44**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 06/17/15. Last accessed 06/18/2015.

[2] FDA: News Release: FDA Issues Final Guidance on the Evaluation and Labeling of Abuse-Deterrent Opioids. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm. Last revised 04/2015. Last accessed 06/2015.

[3] FDA: News Release: FDA Approves Extended-Release, Single-Entity Hydrocodone Product With Abuse-Deterrent Properties. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm423977.htm. Last revised 11/2014. Last accessed 06/2015.

[4] Zogenix: News Release: Zogenix Receives FDA Approval of New Formulation of Zohydro ER. Available online at: http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle_print&ID=2012326. Last revised 01/2015. Last accessed 06/2015.

[5] Hysingla™ ER Product Information. Purdue Pharma L.P. Available online at: http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h . Last revised 02/2015. Last accessed 06/2015.

Appendix O

30-Day Notice to Prior Authorize Various Special Formulations: Sitavig® (Acyclovir Buccal Tablets), Rasuvo® (Methotrexate Injection), Otrexup™ (Methotrexate Injection), Onmel™ (Itraconazole Oral Tablets), & Purixan® (Mercaptopurine Oral Suspension)

Oklahoma Health Care Authority
July 2015

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies created to provide a more efficient treatment response. Some of the new formulations incur greater costs for production resulting in greater costs for the payer and consumer. Clinical review of each product and its comparative cost to other formulations are provided below for reference.

Sitavig® (Acyclovir Buccal Tablet) Product Summary [1,2,3]

Indication: Sitavig® (acyclovir buccal tablet) is indicated for treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

Dosing and Administration:

- Sitavig® is available as a 50mg buccal tablet.
- The tablet should be applied as a single dose to the upper gum region within one hour of onset of prodromal symptoms and before the appearance of any signs of herpes labialis.
- Once applied, Sitavig® stays in position and gradually dissolves during the day.
- Food and drink can be taken normally when Sitavig® is in place.
- If Sitavig® does not adhere or falls off within the first six hours, the same tablet should be repositioned immediately. If the tablet cannot be repositioned, a new tablet should be placed.

Other Antiviral Formulations Available:

- Acyclovir:
  - Acyclovir is available in a generic 200mg oral capsule, a 400mg and 800mg oral tablet formulation, and a 200mg/5mL oral suspension.
  - Acyclovir oral tablets are not FDA approved for use in the diagnosis of recurrent herpes labialis (cold sores), but are commonly used.
- Valacyclovir:
  - Valacyclovir is a similar antiviral with the herpes labialis indication. Valacyclovir is available as a generic oral tablet in two strengths (500mg and 1 gram).

Antiviral Formulation Cost Comparison:

Antiviral Product	Cost Per Tablet	Cold Sore Dosing	Cost for Cold Sore Treatment
Sitavig® 50mg Buccal Tablets	$84.48[+]	50mg-100mg for one day	$168.96
Acyclovir 400mg Oral Tablets	$0.16*	400mg TID for 5-10 days[Δ]	$4.80
Valacyclovir 1 gram Oral Tablets	$0.99*	2 grams every 12 hours for 1 day	$3.96

*State maximum allowable cost (SMAC)
[+]Estimated acquisition cost (EAC)
[Δ]Acyclovir 400mg oral tablets are not FDA approved for use in cold sores. Dosing in table above is from Micromedex® Solutions, a drug information source.
TID: three times daily

Antiviral Calendar Year 2014 Utilization: There was no utilization of Sitavig® during calendar year 2014. A total of 8,108 members utilized acyclovir or valacyclovir during calendar year 2014 accounting for 14,797 claims. As these products have multiple indications, not all claims are for the diagnosis of herpes labialis (cold sores).

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ACYCLOVIR PRODUCTS						
ACYCLOVIR TAB 400MG	4,334	2,340	$45,569.65	2.34	1.85	$10.51
ACYCLOVIR TAB 800MG	1,963	1,354	$23,358.70	2.73	1.45	$11.90
ACYCLOVIR SUS 200/5ML	1,593	1,249	$118,435.51	18.39	1.28	$74.35
ACYCLOVIR CAP 200MG	1,094	642	$9,640.68	3.29	1.7	$8.81
ZOVIRAX SUS 200/5ML	2	1	$137.69	15	2	$68.85
SUBTOTAL	**8,986**	**5,385**	**$197,142.23**	**4.22**	**1.67**	**$21.94**
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 500MG	3,253	1,525	$96,722.06	1.36	2.13	$29.73
VALACYCLOVIR TAB 1GM	2,558	1,583	$82,644.94	1.45	1.62	$32.31
SUBTOTAL	**5,811**	**2,980**	**$179,367.00**	**1.39**	**1.95**	**$30.87**
TOTAL	**14,797**	**8,108***	**$376,509.23**	**2.86**	**1.82**	**$25.44**

*Total number of unduplicated members.

Otrexup™ (Methotrexate Injection) Product Summary [4]

Indication: Otrexup™ (methotrexate injection) is a folate analog metabolic inhibitor indicated for the following:

- Management of patients with severe, active rheumatoid arthritis (RA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).
- Management of patients with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose NSAIDs.
- Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not responsive to other forms of therapy, but only when the diagnosis has been established,

as by biopsy or dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses.

Limitation of Use: Otrexup™ is not indicated for the treatment of neoplastic diseases.

Dosing and Administration:

- Otrexup™ is available as a single-dose auto-injector containing preservative-free, unbuffered, sterile methotrexate solution in the following strengths: 7.5mg/0.4mL, 10mg/0.4mL, 15mg/0.4mL, 20mg/0.4mL, and 25mg/0.4mL.
- Otrexup™ is for once-weekly subcutaneous use only to be administered in the abdomen or thigh.
- The following recommended doses apply (doses should be adjusted gradually to achieve an optimal response):
    - RA: Starting dose of 7.5mg once weekly
        - Limited experience shows a significant increase in the incidence and severity of toxic reactions at doses greater than 20mg/week in adults.
    - pJIA: Starting dose of 10mg/m^2 once weekly
        - Data is too limited to assess how doses over 20mg/m^2/week might affect the risk of toxicity in children.
    - Psoriasis: 10mg to 25mg once weekly
        - Doses of 30mg/week should not ordinarily be exceeded.
        - Once optimal clinical response has been achieved, the dosage should be reduced to the lowest possible amount of drug and to the longest possible rest period.
        - The use of Otrexup™ may permit the return to conventional topical therapy, which should be encouraged.
- Another formulation of methotrexate should be used for alternative dosing in patients who require doses less than 7.5mg per week, doses more than 25mg per week, high-dose regimens, or dose adjustments between the available doses.

Other Methotrexate Formulations Available, Methotrexate Cost Comparison, and Methotrexate Utilization are listed after the Rasuvo® (Methotrexate Injection) Product Summary.

Rasuvo® (Methotrexate Injection) Product Summary [5,6,7,8,9,10]

Indication: Rasuvo® (methotrexate injection) is a folate analog metabolic inhibitor indicated for the following:

- Management of selected adults with severe, active RA who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose NSAIDs.
- Children with active pJIA who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose NSAIDs.
- Symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established,

as by biopsy or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses.

Limitation of Use: Rasuvo® is not indicated for the treatment of neoplastic diseases.

Dosing and Administration:

- Rasuvo® is available as a single-dose auto-injector containing preservative-free methotrexate solution in the following strengths: 7.5mg/0.15mL, 10 mg/0.20mL, 12.5mg/0.25mL, 15mg/0.30mL, 17.5mg/0.35mL, 20mg/0.40mL, 22.5mg/0.45mL, 25mg/0.50mL, 27.5mg/0.55mL, and 30mg/0.60mL.
- Rasuvo® is for once-weekly subcutaneous use only to be administered in the abdomen or thigh.
- The following recommended doses apply (doses should be adjusted gradually to achieve an optimal response):
    - RA: Starting dose of 7.5mg once weekly
        - Limited experience shows a significant increase in the incidence and severity of toxic reactions at doses greater than 20mg/week in adults.
    - pJIA: Starting dose of 10mg/m^2 once weekly
        - Data is too limited to assess how doses over 20mg/m^2/week might affect the risk of toxicity in children.
    - Psoriasis: 10mg to 25mg once weekly
        - Doses of 30mg/week should not ordinarily be exceeded.
        - Once optimal clinical response has been achieved, the dosage should be reduced to the lowest possible amount of drug and to the longest possible rest period.
        - The use of Rasuvo® may permit the return to conventional topical therapy, which should be encouraged.
- Another formulation of methotrexate should be used for alternative dosing in patients who require doses less than 7.5mg per week, doses more than 30mg per week, high-dose regimens, or dose adjustments of less than 2.5mg increments.

Other Methotrexate Formulations Available:

- Methotrexate is available generically as a 2.5mg oral tablet and in a brand formulation, Trexall®, which comes in 5mg, 7.5mg, 10mg, and 15mg strengths. Both oral formulations have multiple indications including RA, pJIA, psoriasis, and neoplastic diseases.
    - Otrexup™ clinical findings submitted to the FDA demonstrated increased bioavailability of subcutaneous methotrexate compared to oral methotrexate at every dose. These findings highlighted the saturable limitations of oral methotrexate at doses of 15mg and above.
- Methotrexate is also available generically for injection in a single-use vial containing preservative free methotrexate solution in the following strengths: 50mg/2mL, 100mg/4mL, 250mg/10mL, and 1 gram/40mL.
    - The injection may be given by the intramuscular, intravenous, intra-arterial, or intrathecal route.

- Patients are typically started on oral therapy, and later placed on the injectable therapy to avoid gastrointestinal toxicities associated with high doses (≥15mg once weekly) of the oral therapy.

Methotrexate Formulation Cost Comparison:

Methotrexate Product	Cost Per Tablet or mL	RA Dosing	Cost per 28 Days of Treatment
Otrexup™ Syringe	$361.68[+]	7.5mg/0.4mL once weekly	$578.68
Rasuvo® Syringe	$788.48[+]	7.5mg/0.15mL once weekly	$473.08
Methotrexate 2.5mg Oral Tablets	$1.57*	7.5mg once weekly	$18.84
Trexall® 7.5mg Oral Tablets	$18.51[+]	7.5mg once weekly	$74.04
Methotrexate 25mg/mL Inj.[Δ]	$2.32[+]	7.5mg once weekly	$18.56

*State maximum allowable cost (SMAC)
[+]Estimated acquisition cost (EAC)
[Δ] Single use vial; smallest package size 2mL.

Methotrexate Calendar Year 2014 Utilization: There was no utilization of Otrexup™ or Rasuvo® during calendar year 2014. A total of 1,047 members utilized the methotrexate oral tablet or injectable formulations during calendar year 2014 accounting for 4,995 claims. As these products have multiple indications, not all claims are for the diagnoses of RA, pJIA, or psoriasis.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	PERCENT COST	CLAIMS/ MEMBER	COST/ CLAIM
ORAL METHOTREXATE PRODUCTS						
METHOTREXATE TAB 2.5MG	3,995	864	$262,234.58	93.14%	4.62	$65.64
TREXALL TAB 7.5MG	29	8	$3,980.83	1.41%	3.63	$137.27
TREXALL TAB 10MG	5	2	$460.86	0.16%	2.5	$92.17
TREXALL TAB 15MG	1	1	$138.97	0.05%	1	$138.97
SUBTOTAL	**4,030**	**872**	**$266,815.24**	**94.76%**	**4.62**	**$66.21**
INJECTABLE METHOTREXATE PRODUCTS						
METHOTREXATE INJ 25MG/ML	495	166	$9,333.20	3.31%	2.98	$18.85
METHOTREXATE INJ 50MG/2ML	356	95	$4,063.31	1.44%	3.75	$11.41
METHOTREXATE INJ 25MG/ML	58	19	$635.21	0.23%	3.05	$10.95
METHOTREXATE INJ 250/10ML	48	26	$624.06	0.22%	1.85	$13.00
METHOTREXATE INJ 100/4ML	7	2	$63.25	0.02%	3.5	$9.04
METHOTREXATE INJ 200/8ML	1	1	$13.00	0.00%	1	$13.00
SUBTOTAL	**965**	**257**	**$14,732.03**	**5.22%**	**3.75**	**$15.27**
TOTAL	**4,995**	**1,047***	**$281,547.27**	**100%**	**4.77**	**$25.44**

*Total number of unduplicated members.

Onmel™ (Itraconazole Oral Tablet) Product Summary [11,12]

Indication: Onmel™ (itraconazole tablet) is an azole antifungal indicated for treatment of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes*.

Dosing and Administration:

- Onmel™ is available as a 200mg oral tablet.
- The recommended dose of Omnel™ is 200mg by mouth once daily for 12 consecutive weeks.
- Onmel™ should be taken with a full meal at the same time each day.

Other Itraconazole Formulations Available:

- Itraconazole is available generically in a 100mg oral capsule formulation. The oral capsule formulation is indicated for the diagnosis of onychomycosis with similar dosing to Onmel™.

Itraconazole Formulation Cost Comparison:

Itraconazole Product	Cost Per Tablet or Capsule	Onychomycosis Dosing	Cost per 12 Weeks of Treatment
Onmel™ 200mg Oral Tablets	$33.29[+]	200mg QD for 12 weeks	$2,796.36
Itraconazole 100mg Oral Capsules	$4.76*	200mg QD for 12 weeks	$799.68

[+]Estimated acquisition cost (EAC)
*State maximum allowable cost (SMAC)

Itraconazole Calendar Year 2014 Utilization: There was no utilization of Onmel™ during calendar year 2014. A total of 128 members utilized the itraconazole oral capsule formulation during calendar year 2014 accounting for 271 claims. As generic itraconazole has multiple indications, not all claims are for the diagnoses of onychomycosis.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ITRACONAZOLE PRODUCTS						
ITRACONAZOLE CAP 100MG	271	128	$93,336.60	2.28	2.12	$344.42
TOTAL	**271**	**128***	**$93,336.60**	**2.28**	**2.12**	**$344.42**

*Total number of unduplicated members.

Purixan® (Mercaptopurine Oral Suspension) Product Summary [13,14,15,16]

Indication: Purixan® (mercaptopurine oral suspension) is a nucleoside metabolic inhibitor indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) as a component of a combination maintenance therapy regimen.

Dosing and Administration:

- Purixan® is available as a 20mg/mL oral suspension.
- The starting dose of Purixan® in multi-agent combination chemotherapy regimens is 1.5 to 2.5mg/kg (50 to 75mg/m^2) as a single daily dose.

- After initiating Purixan®, continuation of appropriate dosing requires periodic monitoring of absolute neutrophil count (ANC) and platelet count to assure sufficient drug exposure (that is to maintain ANC at a desirable level) and to adjust for excessive hematological toxicity.
- Patients with inherited little or no thiopurine S-methyltransferase (TPMT) activity are at increased risk for severe mercaptopurine toxicity from conventional doses of mercaptopurine and generally require dose reduction. Testing for TPMT gene polymorphism should be considered in patients who experience severe bone marrow toxicities.
- Prior to initiation of Purixan®, patients or caregivers should be trained on proper handling, storage, administration, disposal and clean-up of accidental spillage of the medication.
- Prior to administration, the bottle should be shaken vigorously for at least 30 seconds to ensure the oral suspension is well mixed.
- Once opened, Purixan® should be used within six weeks.
- A press-in bottle adapter and two oral dispensing syringes (one 1mL and one 5mL) are provided. The oral dispensing syringes are intended for multiple uses.

Other Mercaptopurine Formulations Available:

- Mercaptopurine is available generically as a 50mg oral tablet.
    - The bioavailability of Purixan® is equivalent to that of the tablet formulation of mercaptopurine, as measured by the AUC (area under the concentration curve). Purixan® reduced the variability in the absorption of mercaptopurine, proving to be a reliable alternative to the tablet.
    - The oral suspension may allow for more accurate dosing in children.

Mercaptopurine Formulation Cost Comparison:

Mercaptopurine Product	Cost Per Tablet or mL	ALL Dosing	Cost per 30 Days of Treatment
Purixan® 20mg/mL Suspension	$11.09[+]	1.5mg to 2.5mg/kg/day	$1,330.80
Mercaptopurine 50mg Tablets	$2.16*	1.5mg to 2.5mg/kg/day	$129.60

[+]Estimated acquisition cost (EAC)
*State maximum allowable cost (SMAC)
Dosing based on 32kg individual (average weight for a 10 year old male).

Mercaptopurine Calendar Year 2014 Utilization: Purixan® was utilized by three members for a total of six claims during calendar year 2014. A total of 116 members utilized the mercaptopurine tablet formulation during calendar year 2014 accounting for 589 claims.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	UNITS/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
MERCAPTOPURINE PRODUCTS						
MERCAPTOPUR TAB 50MG	589	116	$28,807.95	1.62	5.08	$48.91
PURIXAN SUS 20MG/ML	6	3	$6,675.06	2.78	2	$1,112.51
TOTAL	**595**	**118***	**$35,483.01**	**1.64**	**5.04**	**$59.64**

*Total number of unduplicated members.

Recommendations

The College of Pharmacy recommends the prior authorization of Sitavig® (acyclovir buccal tablets), Otrexup™ (methotrexate injection), Rasuvo® (methotrexate injection), Onmel™ (itraconazole oral tablets), & Purixan® (mercaptopurine oral suspension) with the following criteria:

1. **Sitavig® (Acyclovir Buccal Tablets) Approval Criteria:**
    a. An FDA approved diagnosis of recurrent herpes labialis (cold sores); and
    b. A patient-specific, clinically significant reason why the member cannot use oral acyclovir or valacyclovir oral tablets.

2. **Rasuvo® (Methotrexate Injection) and Otrexup™ (Methotrexate Injection) Approval Criteria:**
    a. An FDA approved diagnosis of one of the following:
        i. Adults with severe, active rheumatoid arthritis (RA); or
        ii. Children with active polyarticular juvenile idiopathic arthritis (pJIA); or
        iii. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
    b. Members with a diagnosis of RA or pJIA must have had an adequate trial of full dose NSAIDs; and
    c. A patient-specific, clinically significant reason why the oral tablets cannot be used.

3. **Onmel™ (Itraconazole Oral Tablets) Approval Criteria:**
    a. An FDA approved diagnosis of onychomychosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes;* and
    b. A patient-specific, clinically significant reason why the itraconazole 100mg oral capsules cannot be used in place of the Onmel™ 200mg tablets.

4. **Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:**
    a. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
    b. An age restriction on members older than 10 years of age will apply. Members younger than 10 years of age would not require prior authorization for Purixan™ therapy; and
    c. Members older than 10 years of age would require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

[1] Sitavig® Product Information. Innocutis Holdings, LLC. Available online at: http://sitavig.com/wp-content/uploads/2015/06/sitavig-prescribing-information-2014-11.pdf. Last revised 04/2013. Last accessed 06/2015.
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Appendix P

Calendar Year 2014 Annual Review of Growth Hormone

Oklahoma Health Care Authority
July 2015

Current Prior Authorization Criteria

Covered Indications *(prior to epiphyseal closure)*:

1. Classic human growth hormone (hGH) deficiency as determined by childhood hGH stimulation tests
2. Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly, and one of the following:
    a. Deficiency of three or more pituitary hormones and IGF-1 greater than or equal to 2.5 standard deviation (SD) below the mean for the member's age; or
    b. No deficiency or deficiency in less than three pituitary hormones and IGF-1 less than 50th percentile and failure of a growth hormone stimulation test
3. Panhypopituitarism in children with height less than 2.25 SD below the mean for age and MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot"
4. Short stature associated with Prader-Willi Syndrome
5. Short stature associated with chronic renal insufficiency (pre-transplantation)
6. History of intrauterine growth restriction who have not reached a normal height (greater than 2.25 SD below mean for age and gender) by age two years
7. Idiopathic short stature (ISS) who are greater than or equal to 2.25 SD below mean for height and are unlikely to catch up in height
8. Turner syndrome or 45X, 46XY mosaicism
9. Hypoglycemia with evidence for hGH deficiency
10. Short-stature homeobox-containing gene (SHOX) deficiency with genetic evidence for SHOX deficiency
11. Other evidence for hGH deficiency submitted for panel review and decision

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (Eli Lilly) - Vials, Cartridge Kits
	Norditropin® (NovoNordisk) - NordiPen Cartridges, NordiFlex® Pens, FlexPro® Pens
	Nutropin® and Nutropin AQ® (Genentech) - Vials, Pen Cartridge
	Omnitrope® (Sandoz) - Vials, Cartridge
	Saizen® (EMD Serono) - Vials, Cartridges for Easypod, Cool.click, Click.easy
	Serostim® (EMD Serono) - Vials
	Zorbtive® (EMD Serono) - Vials

*Supplemental rebated product
(All products contain the identical 191 amino acid sequence found in pituitary-derived hGH.)

Growth Hormone Tier-2 Approval Criteria:

1. Documented allergic reaction to non-active components of all available Tier-1 medications; or
2. A clinical exception applies to members with a diagnosis of AIDS wasting syndrome, in which case Serostim® can be used, regardless of its current Tier status.

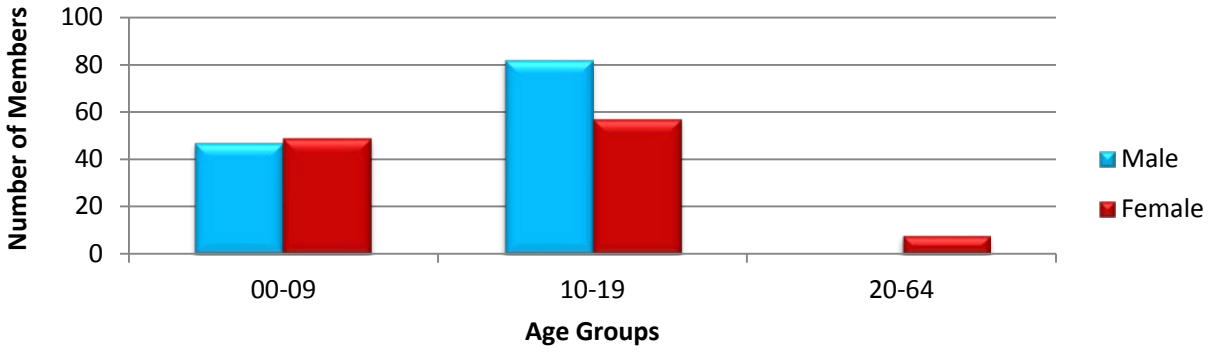
Utilization of Growth Hormone: Calendar Year 2014

Comparison of Calendar Years

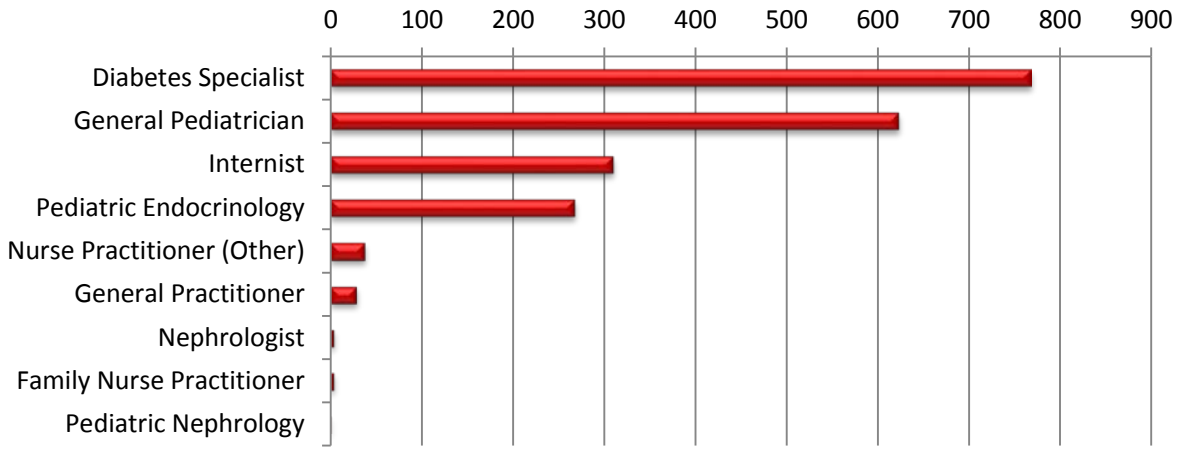
Calendar Year	*Total Members	Total Claims	Total Cost	Cost per Claim	Cost per Day	Total Units	Total Days
2013	236	1,971	$5,535,173.09	$2,808.31	$97.72	19,358	56,643
2014	286	2,045	$5,909,511.38	$2,889.74	$101.40	22,529	58,279
% Change	**21.19%**	**3.75%**	**6.76%**	**2.90%**	**3.77%**	**16.38%**	**2.89%**
Change	**50**	**74**	**$374,338.29**	**$81.43**	**$3.68**	**3,171**	**1,636**

*Total number of unduplicated members

Demographics of Members Utilizing Growth Hormone

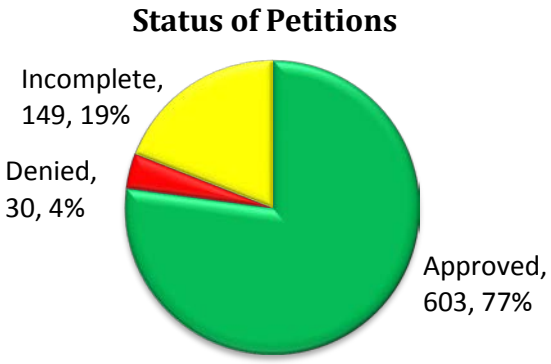


Top Prescriber Specialties of Growth Hormone by Number of Claims



Prior Authorization of Growth Hormone

There were 782 prior authorization requests submitted for growth hormone during calendar year 2014. The following chart shows the status of the submitted petitions.



Market News and Updates[1,2]

Anticipated Patent Expirations:

- Norditropin®: December 2015
- Saizen®: April 2016
- Serostim®: April 2016
- Zorbtive®: April 2016
- Genotropin®: November 2018

Safety Update:

- **08/2014:** A research article published by French scientists in *Neurology* suggests that use of growth hormone is associated with an increased risk of hemorrhagic stroke particularly subarachnoid hemorrhage. Growth hormone is known to have mitogenic and proliferative properties, and a preliminary study found increased cardiac and cerebrovascular mortality in growth hormone-treated children. Further investigation revealed a high incidence of stroke in the study population, occurring at an average age of 24.2 years. Studied growth hormone treatment was started at a mean age of 11 years and continued for an average of 3.9 years. Researchers felt that this is a "strong relationship" and that patients using growth hormone not only for growth hormone deficiency, but also for performance enhancement should be informed of the risk. The FDA has not acted on this information yet. Further study is recommended.

Recommendations

The College of Pharmacy does not recommend any changes at this time.

Utilization Details of Growth Hormone: Calendar Year 2014

Product Utilized	Total Claims	Total Members	Total Cost	Units/ Day	Cost/ Day	Cost/ Claim	Percent Cost
Genotropin Products							
GENOTROPIN INJ 5MG	1,009	126	$2,266,040.95	0.17	$77.37	$2,245.83	38.35%
GENOTROPIN INJ 12MG	391	52	$2,052,365.02	0.16	$179.28	$5,249.02	34.73%
GENOTROPIN INJ 1MG	110	19	$314,501.20	1	$101.19	$2,859.10	5.32%
GENOTROPIN INJ 0.6MG	106	14	$143,765.91	1	$60.56	$1,356.28	2.43%
GENOTROPIN INJ 1.2MG	86	15	$293,176.94	1	$121.75	$3,409.03	4.96%
GENOTROPIN INJ 0.4MG	78	10	$77,544.38	1	$35.51	$994.16	1.31%
GENOTROPIN INJ 0.8MG	68	11	$154,702.87	0.99	$80.57	$2,275.04	2.62%
GENOTROPIN INJ 1.6MG	40	8	$181,673.09	0.99	$160.49	$4,541.83	3.07%
GENOTROPIN INJ 1.8MG	25	3	$127,790.34	1	$182.56	$5,111.61	2.16%
GENOTROPIN INJ 0.2MG	22	7	$12,525.31	1	$20.33	$569.33	0.21%
GENOTROPIN INJ 2MG	21	3	$118,991.00	1	$202.37	$5,666.24	2.01%
GENOTROPIN INJ 1.4MG	19	5	$75,552.94	1	$142.02	$3,976.47	1.28%
Subtotal	**1,975**	**273**	**$5,818,629.95**	**0.40**	**$103.36**	**$2,946.14**	**98.45%**
Tier-1 Subtotal	**1,975**	**231**	**$5,818,629.95**	**0.40**	**$103.36**	**$2,946.14**	**98.45%**
Norditropin Products							
NORDITROPIN INJ 10/1.5ML	44	8	$69,476.16	0.14	$52.67	$1,579.00	1.18%
NORDITROPIN INJ 15/1.5ML	11	3	$4,049.01	0.19	$15.34	$368.09	0.07%
NORDITROPIN INJ 5/1.5ML	7	1	$3,296.50	0.06	$18.84	$470.93	0.06%
Subtotal	**62**	**12**	**$76,821.67**	**0.14**	**$86.85**	**$2,418.02**	**1.31%**
Omnitrope Products							
OMNITROPE INJ 10/1.5ML	8	1	$14,059.76	0.20	$62.77	$1,757.47	0.24%
Subtotal	**8**	**1**	**$14,059.76**	**0.2**	**$62.77**	**$1,757.47**	**0.24%**
Tier-2 Subtotal	**70**	**13**	**$90,881.43**	**0.15**	**$149.62**	**$1,298.31**	**1.55%**
Total	**2,045**	**244***	**$5,909,511.38**	**0.39**	**$101.40**	**$2,889.74**	**100%**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Updated: 5/31/15. Accessed 6/18/15.

[2] Joanna Lyford. "Use of Growth Hormone in Children Linked to Stroke in Adults." *The Pharmaceutical Journal*. Available online at: http://www.pharmaceutical-journal.com/news-and-analysis/news/use-of-growth-hormone-in-children-linked-to-stroke-in-adults/20066165.article. Last revised 08/14/2014. Last accessed 06/22/15.

Appendix Q

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

FDA NEWS RELEASE

For Immediate Release: June 22nd, 2015

FDA approves new antiplatelet drug used during heart procedure

The U.S. Food and Drug Administration approved Kengreal (cangrelor), an intravenous antiplatelet drug that prevents formation of harmful blood clots in the coronary arteries. It is approved for adult patients undergoing percutaneous coronary intervention (PCI), a procedure used to open a blocked or narrowed coronary artery to improve blood flow to the heart muscle.

According to the Centers for Disease Control and Prevention, PCI is performed on approximately 500,000 people in the United States each year. The coronary arteries are opened by inflating a balloon at the site of the narrowing, usually followed by placement of a small mesh tube, called a stent, to keep the artery open.

By preventing platelets from accumulating, Kengreal reduces the risk of serious clotting complications related to the procedure, including heart attack and clotting of the stent (stent thrombosis).

As with other FDA-approved anti-platelet drugs, bleeding, including life-threatening bleeding, is the most serious risk of Kengreal.

In a clinical trial that compared Kengreal to Plavix (clopidogrel) in more than 10,000 participants, Kengreal significantly reduced the occurrence of heart attack, the need for further procedures to open the artery and stent thrombosis. The overall occurrence of serious bleeding was low but more common with Kengreal than with clopidogrel. Approximately one in every 170 Kengreal patients had a serious bleed versus approximately one in every 275 clopidogrel patients.

Kengreal is manufactured by The Medicines Company based in Parsippany, New Jersey.

Safety Announcements

FDA Drug Safety Communication: FDA determines 2013 labeling adequate to manage risk of retinal abnormalities, potential vision loss, and skin discoloration with anti-seizure drug Potiga (ezogabine); requires additional study

[6-16-15] Based on reviews of additional safety reports from patients treated with the anti-seizure drug Potiga (ezogabine), the U.S. Food and Drug Administration (FDA) has determined that the potential risks of vision loss due to pigment changes in the retina and of skin discoloration can be adequately managed by following the current recommendations in the Potiga labeling. To further explore any potential long-term consequences of these pigment changes, we have required the Potiga manufacturer, GlaxoSmithKline, to conduct a long-term observational study.

Our review of additional safety reports does not indicate that the pigment changes in the retina observed in some patients affect vision. Skin discoloration associated with the use of Potiga appears to be a cosmetic effect and does not appear to be associated with more serious adverse effects. Therefore, we have determined that a modification of the Risk Evaluation and Mitigation Strategy (REMS) is not needed at this time to ensure that the benefits of Potiga outweigh the risks of retinal and skin pigment changes. We expect that the required long-term observational study will provide further information on whether pigment changes in the retina caused by Potiga can lead to vision loss or other long-term side effects. In addition, the study should provide more information on the relationship between pigment changes in the retina and skin discoloration.

Potiga is approved for use in combination with other anti-seizure drugs to treat partial-onset seizures in adult patients who have had an inadequate response to several alternative therapies and for whom the benefits of treatment outweigh the risks. Health care professionals should continue to follow the recommendations provided in the Boxed Warning, FDA's most serious type of warning, and the Warnings and Precautions and Indications and Usage sections of the labeling.

Safety Announcements

FDA alerts health care providers, researchers and patients not to use certain products from ScienceLab.com

[6-15-15] The U.S. Food and Drug Administration is alerting health care providers, researchers and patients not to purchase or use drugs labeled or marketed as sterile by ScienceLab.com due to the possibility of products being contaminated.

FDA is alerting health care providers to immediately check their inventory and quarantine any drug products labeled as sterile from ScienceLab.com, and not to administer them to patients. Administration of a non-sterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death. Patients who may have received any product produced by ScienceLab.com and who have concerns should contact their health care provider.
FDA investigators inspected the headquarters of ScienceLab.com in Houston, Texas and observed conditions that could result in a lack of sterility of purportedly sterile drug products, which puts patients at risk.
FDA is not aware of reports of illness associated with the use of these products at this time.
FDA asks health care providers to report to FDA if they have sterile product from ScienceLab.com in inventory by sending an email to: CDERDrugSupplyChainIntegrity@fda.hhs.gov.

In addition, FDA asks health care providers, researchers and patients to report adverse events or quality problems associated with the use of ScienceLab.com's products to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at MedWatch Online Voluntary Reporting Form; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178

Safety Announcements

FDA Drug Safety Communication: FDA reporting permanent skin color changes associated with use of Daytrana patch (methylphenidate transdermal system) for treating ADHD

[6-24-15] The U.S. Food and Drug Administration (FDA) is warning that permanent loss of skin color may occur with use of the Daytrana patch (methylphenidate transdermal system) for Attention Deficit Hyperactivity Disorder (ADHD). FDA added a new warning to the drug label to describe this skin condition, which is known as chemical leukoderma.
Patients or their caregivers should watch for new areas of lighter skin, especially under the drug patch, and immediately report these changes to their health care professionals. Patients should not stop using the Daytrana patch without first talking to their health care professionals. We are recommending that health care professionals consider alternative treatments for patients who experience these skin color changes.
The Daytrana patch treats ADHD by working to increase attention and decrease restlessness in children and adolescents who are overactive, cannot concentrate for very long, or are easily distracted and impulsive.
Chemical leukoderma is a skin condition that causes the skin to lose color due to repeated exposure to specific chemical compounds. The condition is not physically harmful, but it is disfiguring. The areas of skin color loss described with the Daytrana patch ranged up to 8 inches in diameter. This condition is not thought to be reversible, which may cause emotional distress.
We reviewed cases of chemical leukoderma associated with the Daytrana patch reported to the FDA Adverse Event Reporting System (FAERS) database and described in the medical literature. FAERS includes only reports submitted to FDA so there are likely additional cases about which we are unaware. FDA identified 51 FAERS cases from April 2006 to December 2014 and one published case that was not recorded in FAERS. The time to onset of leukoderma after starting Daytrana ranged from 2 months to 4 years. All of the patients described a decrease in or loss of skin color. In most cases, the loss of skin color was limited to the areas around where the patch was rotated. However, a small number of patients also reported skin color changes on parts of the body where the patch was never applied. In all cases, the decreased skin color was permanent.

Current Drug Shortages Index (as of June 30th, 2015):

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

Acetohydroxamic Acid (Lithostat) Tablets	***Currently in Shortage***
Aprepitant (Emend) Capsules	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azathioprine Tablet	***Currently in Shortage***
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection	***Currently in Shortage***
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection	***Currently in Shortage***

Calcium Chloride Injection, USP	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefotaxime Sodium (Claforan) Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Chloroquine Phosphate Tablets	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dextrose 5% Injection Bags	***Currently in Shortage***
Dextrose Injection USP, 70%	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Doxorubicin (Adriamycin) Injection	***Currently in Shortage***
Ephedrine Sulfate Injection	***Currently in Shortage***
Epinephrine 1mg/mL (Preservative Free)	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Ethiodized Oil (Lipiodol) Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fluoxymesterone (Androxy) Tablets, USP	***Currently in Shortage***
Fomepizole Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Haloperidol Lactate Injection	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
Indigo Carmine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
L-Cysteine Hydrochloride Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Liotrix (Thyrolar) Tablets	***Currently in Shortage***
Magnesium Sulfate Injection	***Currently in Shortage***
Mecasermin [rDNA origin] (Increlex) Injection	***Currently in Shortage***
Memantine Hydrochloride (Namenda) XR Capsules	***Currently in Shortage***
Methyldopate Hydrochloride Injection	***Currently in Shortage***
Methylin Chewable Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride ER Capsules/Tablets	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nebivolol (BYSTOLIC) Tablets	***Currently in Shortage***
Nimodipine (Nymalize) Oral Solution	***Currently in Shortage***
Pancuronium Bromide Injection	***Currently in Shortage***
Peritoneal Dialysis Solutions	***Currently in Shortage***
Phentolamine Mesylate Injection	***Currently in Shortage***
Phosphate (Glycophos) Injection	***Currently in Shortage***
Piperacillin and Tazobactam (Zosyn) Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Quazepam (Doral) Tablets	***Currently in Shortage***
Reserpine Tablets	***Currently in Shortage***
Secretin Synthetic Human (ChiRhoStim) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sufentanil Citrate (Sufenta) Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Thiotepa (Thioplex) for Injection	***Currently in Shortage***

Tiopronin (Thiola)	***Currently in Shortage***
Tobramycin Injection	***Currently in Shortage***
Trace Elements	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable Suspension (Aristospan)	***Currently in Shortage***
Trimipramine Maleate (SURMONTIL) Capsules	***Currently in Shortage***
Vancomycin Hydrochloride for Injection, USP	***Currently in Shortage***