Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday,
February 10, 2016
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 (DUR) Board Members

FROM: Bethany Holderread, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – February 10, 2016

DATE: February 1, 2016

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

Enclosed are the following items related to the February meeting.
Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on Medication Coverage Authorization Unit/Oral Viscous Lidocaine Claims Analysis Update – Appendix B

Action Item – Vote to Prior Authorize Duopa™ (Carbidopa/Levodopa Enteral Suspension) and Rytary™ (Carbidopa/Levodopa Extended-Release Capsules) – Appendix C

Action Item – Vote to Prior Authorize Cortisporin® and Pediotic® (Neomycin/Polymyxin B/Hydrocortisone Otic) – Appendix D

Action Item – Vote to Prior Authorize Migranal® (Dihydroergotamine Nasal Spray) – Appendix E

Action Item – Vote to Prior Authorize Strensiq™ (Asfotase Alfa) – Appendix F

Action Item – Vote to Prior Authorize Varubi™ (Rolapitant) – Appendix G

Action Item – Vote to Prior Authorize Xuriden™ (Uridine Triacetate) – Appendix H

Annual Review of Gout Medications and 30-Day Notice to Prior Authorize Mitigare™ (Colchicine Capsules) and Zurampic® (Lesinurad) – Appendix I

Annual Review of Seizure Medications and 30-Day Notice to Prior Authorize Spritam® (Levetiracetam) – Appendix J

30-Day Notice to Prior Authorize Solaraze® (Diclofenac Gel) – Appendix K

Annual Review of Ulcerative Colitis Medications and 30-Day Notice to Prior Authorize Uceris® (Budesonide Extended-Release Tablets), Uceris® (Budesonide Rectal Foam), and Miscellaneous Mesalamine Products – Appendix L

Annual Review of Ocular Allergy Medications and 30-Day Notice to Prior Authorize Pazeo® (Olopatadine Ophthalmic) – Appendix M

Annual Review of Gonadotropin Releasing Hormones – Appendix N

Annual Review of Northera™ (Droxidopa) – Appendix O

FDA and DEA Updates – Appendix P

Future Business (Upcoming Product and Class Reviews)

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – February 10, 2016 @ 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. January 13, 2016 DUR Minutes – Vote
- B. January 13, 2016 DUR Recommendations Memorandum

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

4. Update on Medication Coverage Authorization Unit/Oral Viscous Lidocaine Claims Analysis Update – See Appendix B
- A. Medication Coverage Activity for January 2016
- B. Pharmacy Help Desk Activity for January 2016
- C. Oral Viscous Lidocaine Claims Analysis Update

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

5. Action Item – Vote to Prior Authorize Duopa™ (Carbidopa/Levodopa Enteral Suspension) and Rytary™ (Carbidopa/Levodopa Extended-Release Capsules) – See Appendix C
- A. Introduction
- B. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Cortisporin® and Pediotic® (Neomycin/Polymyxin B/ Hydrocortisone Otic) – See Appendix D
- A. Introduction
- B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Migranal® (Dihydroergotamine Nasal Spray) – See Appendix E
- A. Indication(s)
- B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Strensiq™ (Asfotase Alfa) – See Appendix F
- A. Introduction
- B. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Varubi™ (Rolapitant) – See Appendix G

A. Introduction
B. College of Pharmacy Recommendations

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

10. Action Item – Vote to Prior Authorize Xuriden™ (Uridine Triacetate) – See Appendix H

A. Introduction
B. College of Pharmacy Recommendations

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

11. Annual Review of Gout Medications and 30-Day Notice to Prior Authorize Mitigare™ (Colchicine Capsules) and Zurampic® (Lesinurad) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Gout Medications
C. Prior Authorization of Gout Medications
D. Market News and Updates
E. Mitigare™ (Colchicine Capsules) Product Summary
F. Zurampic™ (Lesinurad) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Gout Medications

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

12. Annual Review of Seizure Medications and 30-Day Notice to Prior Authorize Spritam® (Levetiracetam) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Seizure Medications
C. Prior Authorization of Seizure Medications
D. Market News and Updates
E. Spritam® (Levetiracetam) Product Summary
F. Vimpat® (Lacosamide) Product Summary
G. Banzel® (Rufinamide) Product Summary
H. Fycompa® (Perampanel) Product Summary
I. College of Pharmacy Recommendations
J. Utilization Details of Seizure Medications

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

13. 30-Day Notice to Prior Authorize Solaraze® (Diclofenac Gel) – See Appendix K

A. Actinic Keratosis Background Information
B. Solaraze® (Diclofenac 3% Gel) Product Summary
C. College of Pharmacy Recommendations

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

14. Annual Review of Ulcerative Colitis Medications and 30-Day Notice to Prior Authorize Uceris® (Budesonide Extended-Release Tablets), Uceris® (Budesonide Rectal Foam), and Miscellaneous Mesalamine Products – See Appendix L

A. Ulcerative Colitis (UC) Background Information
B. Current Prior Authorization Criteria
C. Utilization of UC Medications
D. Prior Authorization of UC Medications
E. Market News and Updates
F. Uceris® (Budesonide) Extended-Release Tablets Product Summary
G. Uceris® (Budesonide) Rectal Foam Product Summary
H. Asacol® HD (Mesalamine) Delayed-Release Tablets Product Summary
I. Pentasa® (Mesalamine) Controlled-Release Capsules Product Summary
J. Rowasa® (Mesalamine) Rectal Suspension Enema Product Summary
K. Lialda® (Mesalamine) Delayed-Release Capsules Product Summary

L. Colazal® (Balsalazide) Capsules Product Summary
M. Dipentum® (Olsalazine) Capsules Product Summary
N. Canasa® (Mesalamine) Suppositories Product Summary
O. Apriso® (Mesalamine) Extended-Release Capsules Product Summary
P. Delzicol® (Mesalamine) Delayed-Release Capsules Product Summary
Q. Cost Comparison
R. College of Pharmacy Recommendations
S. Utilization Details of Ulcerative Colitis Medications

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

15. Annual Review of Ocular Allergy Medications and 30-Day Notice to Prior Authorize Pazeo® (Olopatadine Ophthalmic) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Ocular Allergy Medications
C. Prior Authorization of Ocular Allergy Medications
D. Market News and Updates
E. Pazeo® (Olopatadine Ophthalmic) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Ocular Allergy Medications

Non-Presentation, Questions Only:

16. Annual Review of Gonadotropin Releasing Hormones (GnRH) – See Appendix N

A. Introduction
B. FDA Approved GnRH Options for Treatment of Central Precocious Puberty or Endometriosis
C. Current Prior Authorization Criteria
D. Utilization of GnRH Medications
E. Prior Authorization of GnRH Medications
F. Market News and Updates
G. College of Pharmacy Recommendations
H. Utilization Details of GnRH Medications

Non-Presentation, Questions Only:

17. Annual Review of Northera™ (Droxidopa) – See Appendix O

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Northera™ (Droxidopa)
D. Prior Authorization of Northera™ (Droxidopa)
E. Market News and Updates
F. College of Pharmacy Recommendations

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

18. FDA and DEA Updates – See Appendix P

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

19. Future Business* (Upcoming Product and Class Reviews)

A. Makena® (Hydroxyprogesterone Caproate)
B. Multiple Sclerosis Medications
C. Growth Hormone
D. Vasomotor Symptom Medications
E. Idiopathic Pulmonary Fibrosis Medications
F. Botulinum Toxins
G. Pulmonary Arterial Hypertension Medications
H. Cerdelga™ (Eliglustat)
I. Hemophilia Medication Pharmacy Providers

***Future business subject to change.**

20. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF JANUARY 13, 2016

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	
John Muchmore, M.D., Ph.D.; Chairman	x	
James Osborne, Pharm.D.	x	
Paul Louis Preslar, D.O., MBA ; Vice Chairman	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	
Melissa Abbott, Pharm.D.; Clinical Pharmacist	x	
Michyla Adams, 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	
Tammy Lambert, Ph.D.; Postdoctoral Research Fellow	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	
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	x	
Graduate Students: Christina Bulkley, Pharm.D.		x
David George, Pharm.D.		x
Timothy Pham, Pharm.D.	x	
Visiting Pharmacy Student(s): Matthew Fogle	x	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Marlene Asmussen, R.N.; Population Care Management Director	x	
Burl Beasley, D.Ph., M.P.H., M.S. Pharm; Clinical Pharmacist	x	
Kelli Brodersen, Marketing Coordinator	x	
Nico Gomez, Chief Executive Officer		x
Ed Long, Chief Communications Officer	x	
Sylvia Lopez, M.D., FAAP; Chief Medical Officer	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:		
Patrick Mumme, Alexion	Bryan McGee, Alexion	Melvin Nwamedi, Abbott
Quynh Chau Doan, AbbVie	Jim Chapman, AbbVie	Richard Ponder, Johnson & Johnson
Erica Brumleve, GSK	Audrey Rattan, Alkermes	Gay Thomas, BMS
John Michael Thomas, BMS	Eric Leonard, Astellas	M. Patty Laster, Astellas
Jon MaGuire, GSK	Aaron Shaw, BI	Clint Degner, Novartis
Kirsten Mar, Astra Zeneca	Dave Hibbard, Teva	John Harris, Misson
Marc Parker, Sunovion	Brent Hildebrand, Gilead	Jim Fowler, Astra Zeneca
Sean Seago, Merck	Anthony DeLeon, BMS	Brian Maves, Pfizer

PRESENT FOR PUBLIC COMMENT:	
Bryan McGee	Alexion
Quynh Chau Doan	AbbVie
Dave Hibbard	Teva
John Michael Thomas	BMS

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: AGENDA NO. 12 SPEAKER: BRYAN MCGEE

2B: AGENDA NO. 5 & 15 SPEAKER: QUYNH CHAU DOAN

2C: AGENDA NO. 9 SPEAKER: DAVE HIBBARD

2D: AGENDA NO. 5 SPEAKER: JOHN MICHAEL THOMAS

ACTION: NONE REQUIRED

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

3A: DECEMBER 16, 2015 DUR MINUTES – VOTE

3B: DECEMBER 16, 2015 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Preslar moved to approve with correction; seconded by Dr. Harrell

ACTION: MOTION CARRIED

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

4A: MEDICATION COVERAGE ACTIVITY FOR DECEMBER 2015

4B: PHARMACY HELP DESK ACTIVITY FOR DECEMBER 2015

4C: SOONERPSYCH PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NO ACTION REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE DAKLINZA™ (DACLATASVIR) AND TECHNIVIE™ (OMBITASVIR/PARITAPREVIR/RITONAVIR)

5A: INDICATION(S)

5B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE NOXAFIL® (POSACONAZOLE) AND CRESEMBA® (ISAVUCONAZONIUM SULFATE)

6A: INDICATION(S)

6B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented Dr. Holderread

Dr. Rhymer moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE NEULASTA® (PEGFILGRASTIM), GRANIX® (TBO-FILGRASTIM), AND ZARXIO™ (FILGRASTIM-SNDZ)

7A: INTRODUCTION

7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE AGGRENOX® (ASPIRIN/DIPYRIDAMOLE EXTENDED-RELEASE)

8A: INTRODUCTION

8B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

Dr. Rhymer moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE PROAIR® RESPICLICK (ALBUTEROL SULFATE INHALATION POWDER)

9A: INDICATION(S)

9B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

Dr. Osborne recommends changing name of class to "short-acting $beta_2$ agonists."

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE STIOLTO™ RESPIMAT® (TIOTROPIUM BROMIDE/OLODATEROL), ARNUITY™ ELLIPTA® (FLUTICASONE FUROATE), UTIBRON™ NEOHALER® (INDACATEROL/GLYCOPYRROLATE), SEEBRI™ NEOHALER® (GLYCOPYRROLATE), & NUCALA® (MEPOLIZUMAB)

10A: INTRODUCTION

10B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF ANTI-MIGRAINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE MIGRANAL® (DIHYDROERGOTAMINE MESYLATE NASAL SPRAY)

11A: CURRENT PRIOR AUTHORIZATION CRITERIA

11B: UTILIZATION OF ANTI-MIGRAINE MEDICATIONS

11C: PRIOR AUTHORIZATION OF ANTI-MIGRAINE MEDICATIONS

11D: MARKET NEWS AND UPDATES

11E: MIGRANAL® (DIHYDROERGOTAMINE MESYLATE NASAL SPRAY) PRODUCT SUMMARY

11F: COLLEGE OF PHARMACY RECOMMENDATIONS

11G: UTILIZATION DETAILS OF ANTI-MIGRAINE MEDICATIONS

11H: UTILIZATION DETAILS OF DIHYDROERGOTAMINE PRODUCTS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: 30-DAY NOTICE TO PRIOR AUTHORIZE STRENSIQ™ (ASFOTASE ALFA)
12A: OVERVIEW
12B: STRENSIQ™ (ASFOTASE ALFA) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF ANTI-EMETIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VARUBI™ (ROLAPITANT)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ANTI-EMETIC MEDICATIONS
13C: PRIOR AUTHORIZATION OF ANTI-EMETIC MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: VARUBI™ (ROLAPITANT) PRODUCT SUMMARY
13F: COST COMPARISON
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF ANTI-EMETIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: 30-DAY NOTICE TO PRIOR AUTHORIZE CORTISPORIN® AND PEDIOTIC® (NEOMYCIN/POLYMYXIN B/HYDROCORTISONE OTIC)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF CORTISPORIN® AND PEDIOTIC® OTIC
14C: MARKET NEWS AND UPDATES
14D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF PARKINSON'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DUOPA™ (CARBIDOPA/LEVODOPA ENTERAL SUSPENSION) AND RYTARY™ (CARBIDOPA/LEVODOPA EXTENDED-RELEASE CAPSULES)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF PARKINSON'S DISEASE MEDICATIONS
15C: PRIOR AUTHORIZATION OF PARKINSON'S DISEASE MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: DUOPA™ (CARBIDOPA/LEVODOPA ENTERAL SUSPENSION) PRODUCT SUMMARY
15F: RYTARY™ (CARBIDOPA/LEVODOPA EXTENDED-RELEASE CAPSULES) PRODUCT SUMMARY
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF PARKINSON'S DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: 30-DAY NOTICE TO PRIOR AUTHORIZE XURIDEN™ (URIDINE TRIACETATE)
16A: OVERVIEW
16B: XURIDEN™ (URIDINE TRIACETATE) PRODUCT SUMMARY

16C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF TESTOSTERONE PRODUCTS
17C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: ELECTION OF THE DRUG UTILIZATION REVIEW BOARD 2016-2017 OFFICERS
Presented by Dr. Cothran
Chairman Election: Ms. Varalli-Claypool nominated Dr. Muchmore for chairman. Ms. Varalli-Claypool moved to approve; seconded by Dr. Preslar
Vice Chairman Election: Ms. Varalli-Claypool nominated Dr. Preslar for vice chairman. Ms. Varalli-Claypool moved to approve; seconded by Dr. Harrell
ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: FDA AND DEA UPDATES
Materials included in agenda packet; presented by Dr. Cothran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
20A: GROWTH HORMONE
20B: MAKENA® (HYDROXYPROGESTERONE CAPROATE)
20C: GOUT MEDICATIONS/MITIGARE™ (COLCHICINE CAPSULES)/ZURAMPIC® (LESINURAD)
20D: GONADOTROPIN RELEASING HORMONES
20E: MULTIPLE SCLEROSIS MEDICATIONS
20F: NORTHERA™ (DROXIDOPA)
20G: SEIZURE MEDICATIONS/SPRITAM® (LEVETIRACETAM)
20H: SOLARAZE® (DICLOFENAC GEL)
20I: ULCERATIVE COLITIS AND CROHN'S DISEASE ORAL MEDICATIONS
***Future business subject to change.**
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: ADJOURNMENT
The meeting was adjourned at 5:10 pm

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

Memorandum

Date: January 14, 2016

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 January 13, 2016

Recommendation 1: Vote to Prior Authorize Daklinza™ (Daclatasvir) and Technivie™ (Ombitasvir/Paritaprevir/Ritonavir)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Daklinza™ (daclatasvir) and Technivie™ (ombitasvir/paritaprevir/ritonavir) with criteria similar to the other prior authorized hepatitis C medications (see criteria noted in red). Additionally, the College of Pharmacy recommends the changes noted in red to the Hepatitis C medications prior authorization category.

Viekira Pak™ (ombitasvir/paritaprevir/ritonavir/dasabuvir), Harvoni® (sofosbuvir/ledipasvir), and Sovaldi® (sofosbuvir) are the preferred direct-acting antivirals for treatment of chronic hepatitis C genotype-1. Use of Sovaldi® (sofosbuvir) and Olysio® (simeprevir) in combination or Olysio® (simeprevir) alone for treatment of HCV genotype-1 requires patient-specific, clinically significant reasoning why Viekira Pak™, Harvoni®, or Sovaldi® with peginterferon and ribavirin is not appropriate for the member.

Daklinza™ (Daclatasvir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) **genotype-3**; and

3. Member must have a METAVIR fibrosis score of **F2** or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Daklinza™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on genotype and concomitant drug therapy will apply:
    a. **Genotype-3, treatment-naïve or treatment-experienced, without cirrhosis:**
        i. Daklinza™ 60mg with Sovaldi® for 12 weeks
    b. **Genotype-3, treatment-naïve or treatment-experienced, with cirrhosis:**
        i. Daklinza™ 60mg with Sovaldi® in combination with weight-based ribavirin for 12 weeks
    c. **Genotype-3, without cirrhosis, and concomitant use of moderate CYP3A inducer(s):**
        i. Daklinza™ 90mg with Sovaldi® 400mg for 12 weeks
        ii. Moderate Inducers: bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, and rifapentine
    d. **Genotype-3, without cirrhosis, and concomitant use of strong CYP3A inhibitors:**
        i. Daklinza™ 30mg with Sovaldi® for 12 weeks
        ii. Strong CYP3A inhibitors include the following: atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, and voriconazole
    e. New regimens will apply as approved by the FDA
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
11. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis; and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy and for six months after therapy completion; and
15. Member must not be taking the following medications: carbamazepine, phenytoin, phenobarbital, rifampin, amiodarone, and St. John's wort; and

16. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
17. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
18. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
19. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Technivie™ (Ombitasvir/Paritaprevir/Ritonavir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) **genotype-4**; and
3. Member must have a METAVIR fibrosis score of **F2** or **F3** (Technivie™ is not indicated in cirrhotic patients) or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Technivie™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on genotype, cirrhosis status, and prior treatment status will apply:
    a. **Genotype-4, treatment-naïve and experienced, non-cirrhotic:**
        i. Technivie™ in combination with weight-based ribavirin for 12 weeks
    b. New regimens will apply as approved by the FDA
8. Member must not have previously failed treatment with a hepatitis C protease inhibitor (non-responder or relapsed); and
9. Member must sign and submit the Hepatitis C Intent to Treat contract; and
10. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
11. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
12. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
13. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
14. Member must not have cirrhosis, decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and

15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin); and
16. The prescriber must verify that the member's ALT levels will be monitored during the first four weeks of starting treatment and as clinically indicated thereafter; and
17. Member must not be taking the following medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (combined oral contraceptives), St. John's wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil, triazolam, orally administered midazolam, atazanavir/ritonavir, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, salmeterol and voriconazole; and
18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Harvoni® (Ledipasvir/Sofosbuvir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) **genotype-1, genotype-4, genotype-5, or genotype-6**; and
3. Member must have a METAVIR fibrosis score of **F2** or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Harvoni® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:
    a. **Genotype-1:**
        i. **Treatment-naïve without cirrhosis who have a pre-treatment HCV-RNA less than 6 million IU/mL:**
            1. Harvoni® for 8 weeks
        ii. **Treatment-naïve with or without cirrhosis:**

1. Treatment-naïve patients who are cirrhotic or have a pre-treatment HCV-RNA greater than 6 million IU/mL
2. Harvoni® for 12 weeks

iii. Treatment-experienced without cirrhosis

1. Treatment-experienced patients who have failed previous treatment with either peginterferon alfa, ribavirin, or an HCV protease inhibitor
2. Harvoni® for 12 weeks

iv. Treatment-experienced with cirrhosis

1. Treatment-experienced patients who have failed previous treatment with either peginterferon alfa, ribavirin, or an HCV protease inhibitor
2. Harvoni® with weight-based ribavirin for 12 weeks

b. Genotype-4, Genotype-5, or Genotype-6:

i. Treatment-naïve and treatment-experienced, with or without cirrhosis:

1. Harvoni® for 12 weeks

c. New regimens will apply as approved by the FDA

8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
11. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis; and
14. Member must not have severe renal impairment (estimated Glomerular Filtration Rate [eGFR] <30mL/min/1.73m^2); and
15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for those on ribavirin); and
16. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, tipranavir/ritonavir, simeprevir, rosuvastatin, St. John's wort, or elvitegravir/cobicistat/emtricitabine in combination with tenofovir disoproxil fumarate; and
17. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease.
18. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
19. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.

20. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Viekira Pak™ (Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) **genotype-1**; and
3. Member must have a METAVIR fibrosis score of **F2** or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Viekira Pak™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
5. Hepatitis C Virus (HCV) genotype/subtype testing must be confirmed and indicated on prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on prior treatment experience, genotypic subtype, and cirrhosis will apply:
   a. **Genotype 1a, without cirrhosis:**
      i. Viekira Pak™ with weight-based ribavirin for 12 weeks
   b. **Genotype 1a, with cirrhosis:**
      i. Viekira Pak™ with weight-based ribavirin for 24 weeks
      ii. Viekira Pak™ with weight-based ribavirin for 12 weeks may be considered for some patients based on prior treatment history.
   c. **Genotype 1b, without cirrhosis:**
      i. Viekira Pak™ for 12 weeks
   d. **Genotype 1b, with cirrhosis:**
      i. Viekira Pak™ with weight-based ribavirin for 12 weeks
   e. New regimens will apply as approved by the FDA
8. Member must not have previously failed treatment with a hepatitis C protease inhibitor (non-responder or relapsed); and
9. Member must sign and submit the Hepatitis C Intent to Treat contract; and
10. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
11. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
12. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
13. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
14. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and

15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for those on ribavirin); and
16. The prescriber must verify that the member's ALT levels will be monitored during the first four weeks of starting treatment and as clinically indicated thereafter; and
17. Member must not be taking the following medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol, St. John's wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil, triazolam, oral midazolam; and
18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Sovaldi™ (Sofosbuvir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) **genotype-1, genotype-2, genotype-3, or genotype-4**; and
3. Member must have a METAVIR fibrosis score of **F2** or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Sovaldi™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
5. Sovaldi™ must be used as a component of a combination regimen; and
6. Member must be eligible for ribavirin (RBV) or daclatasvir therapy. Approvals will not be granted for regimens without RBV or daclatasvir; and
7. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
8. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
9. The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply:
    a. **Genotype 1:**
        i. **Treatment-naïve or experienced, non-cirrhotic or cirrhotic:**
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
    b. **Genotype 2:**
        i. **Treatment-naïve, non-cirrhotic:**

1. Sovaldi™ with weight-based ribavirin for 12 weeks

ii. Treatment-naïve, cirrhotic:

1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks

iii. Treatment-experienced, non-cirrhotic or cirrhotic:

1. Sovaldi® with weight-based ribavirin for 16 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks

c. Genotype 3:

i. Treatment-naïve, non-cirrhotic

1. Daklinza™ with Sovaldi® for 12 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
3. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)

ii. Treatment-naïve, cirrhotic

1. Daklinza™ with Sovaldi® and weight based ribavirin for 12 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
3. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)

iii. Treatment-experienced, non-cirrhotic

1. Daklinza™ with Sovaldi® for 12 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
3. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)

iv. Treatment-experienced, cirrhotic

1. Daklinza™ with Sovaldi® and weight based ribavirin for 12 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
3. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)

d. Genotype 4:

i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:

1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks

e. New regimens will apply as approved by the FDA. For regimens containing Olysio™ with Sovaldi® please refer to Olysio™ criteria.

10. Member must sign and submit the Hepatitis C Intent to Treat contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
13. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
15. Member must not have decompensated cirrhosis; and
16. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and
17. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine or St. John's wort; and

18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease.
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Olysio™ (Simeprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic Hepatitis C genotype 1; and
3. Member must have a METAVIR fibrosis score of **F2** or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request; and
4. Hepatitis C Virus (HCV) genotype/subtype testing must be confirmed and indicated on prior authorization request; and
5. Members with genotype 1a must be screened for the NS3 Q80K polymorphism prior to initiation of therapy. Approvals will not be granted for members with this polymorphism; and
6. Olysio™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
7. Olysio™ must be used as a component of a combination regimen. Olysio™ will be approved for combination therapy only.
8. The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply
    a. **Genotype 1a and 1b:**
        i. **Treatment-naïve, non-cirrhotic:**
            1. Olysio™ with Sovaldi™ +/- weight-based ribavirin for 12 weeks
        ii. **Treatment-naïve, cirrhotic:**
            1. Olysio™ with Sovaldi™ +/- weight-based ribavirin for 24 weeks
        iii. **Treatment-experienced, non-cirrhotic:**
            1. Olysio™ with Sovaldi™ +/- weight-based ribavirin for 12 weeks
        iv. **Treatment-experienced, cirrhotic:**
            1. Olysio™ with Sovaldi™ +/- weight-based ribavirin for 24 weeks
    b. New regimens will apply as approved by the FDA
9. Member must not have previously failed treatment with a hepatitis C protease inhibitor (non-responder or relapsed); and
10. Member must sign and submit the Hepatitis C Intent to Treat Contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
13. Member must have no illicit IV drug use or alcohol abuse in the last six months and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
15. Member must not have decompensated cirrhosis; and
16. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and
17. Member must not be taking the following medications: efavirenz, delavirdine, etravirine, nevirapine, ritanovir and any HIV protease inhibitor (boosted or not by ritanovir), rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, didanosine, milk thistle, or St. John's wort; and
18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity weight management, severe concurrent medical diseases such as but not limited to retinal disease or autoimmune thyroid disease.
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Recommendation 2: Vote to Prior Authorize Noxafil® (Posaconazole) and Cresemba® (Isavuconazonium Sulfate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Noxafil® (posaconazole) and Cresemba® (isavuconazonium sulfate) with the following criteria:

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
    a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy; or
    b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole; or
2. Treatment of invasive mucormycosis; or

3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization; and
4. For the diagnosis of OPC, only the oral suspension may be used.

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
    a. Invasive aspergillosis
    b. Invasive mucormycosis
2. For the treatment of invasive aspergillosis, a patient-specific, clinically significant reason why voriconazole cannot be used must be provided.

Recommendation 3: Vote to Prior Authorize Neulasta® (Pegfilgrastim), Granix® (Tbo-filgrastim), and Zarxio™ (Filgrastim-sndz)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Neulasta® (pegfilgrastim), Granix® (tbo-filgrastim), and Zarxio™ (filgrastim-sndz) with the following criteria:

Neulasta® (Pegfilgrastim), Granix® (Tbo-filgrastim), and Zarxio™ (Filgrastim-sndz) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Neupogen® (filgrastim).
3. Additional consideration for Neulasta® will be given for caregivers or members who cannot self-inject at home. The prescriber must provide specific documentation of the reason the caregiver or member cannot self-inject at home.

Recommendation 4: Vote to Prior Authorize Aggrenox® (Aspirin/Dipyridamole Extended-Release)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Aggrenox® (aspirin/dipyridamole ER) with the following criteria:

Aggrenox® (Aspirin/Dipyridamole ER) Approval Criteria:

1. An FDA approved indication for the prophylaxis of recurrent thromboembolic stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why member cannot use immediate-release dipyridamole and over-the-counter (OTC) aspirin in place of Aggrenox® must be provided.
4. A quantity limit of 60 capsules for a 30 day supply will apply.

Recommendation 5: Vote to Prior Authorize ProAir® RespiClick (Albuterol Sulfate Inhalation Powder)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of ProAir® RespiClick (albuterol sulfate inhalation powder) into Tier-2 of the Short-Acting Beta$_2$ Agonists Product Based Prior Authorization (PBPA) category. Current criteria for this category will apply.

Tier-1 products are covered with no prior authorization necessary.

Tier-2 Short-Acting Beta$_2$ Agonists Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications.

Short-Acting Beta$_2$ Agonists	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA)	albuterol HFA (Ventolin® HFA)
albuterol HFA (Proventil® HFA)	levalbuterol HFA (Xopenex® HFA)
	albuterol sulfate inhalation powder (ProAir® RespiClick)*

*FDA approved for ages 12 years and older.

Recommendation 6: Vote to Prior Authorize Arnuity™ Ellipta® (Fluticasone Furoate), Stiolto™ Respimat® (Tiotropium Bromide/Olodaterol), Utibron™ Neohaler® (Indacaterol/Glycopyrrolate), Seebri™ Neohaler® (Glycopyrrolate), & Nucala® (Mepolizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following criteria and updates to the maintenance asthma and COPD Product Based Prior Authorization (PBPA) category:

Arnuity™ Ellipta® (Fluticasone Furoate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not an option for the member.

Breo® Ellipta® (Fluticasone Furoate/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD; or
2. An FDA approved diagnosis of asthma in patients 18 years and older; and
3. Trials of Advair® and Symbicort®, consisting of at least 30 days each within the last 90 days that did not adequately control COPD or asthma symptoms.

Inhaled Corticosteroids		
Tier-1	**Tier-2**	**Special PA**
beclomethasone dipropionate (QVAR®)	budesonide/formoterol (Symbicort®)	fluticasone furoate (Arnuity™ Ellipta®)
budesonide (Pulmicort®)	fluticasone/salmeterol (Advair®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
ciclesonide (Alvesco®)	mometasone/formoterol (Dulera® HFA)	
fluticasone propionate (Flovent®)		
flunisolide (Aerospan®)		
mometasone furoate (Asmanex®)		

Spiriva® Respimat® (Tiotropium Bromide Soft Mist Inhaler) Approval Criteria for Asthma Diagnosis:

1. Member must have an FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. Member must have used a high-dose inhaled corticosteroid and long-acting beta$_2$ agonist (ICS/LABA) product for at least one month immediately prior to request for authorization; and
4. Member must have had a trial of a leukotriene receptor antagonist for at least one month in the last 90 days; and
5. Member must have a history of exacerbations despite required trials; and
6. Member must remain on an ICS or ICS/LABA while on tiotropium therapy; and
    a. Member's asthma must be considered uncontrolled by prescriber:
        i. Member requires rescue inhaler more than two days per week for reasons other than prevention of exercise induced bronchospasms; or
        ii. Member requires oral systemic corticosteroids; or
    b. Clinical situation warranting initiation of tiotropium therapy in addition to an ICS/LABA due to severity of asthma; and
7. A clinically significant reason the member is unable to use Spiriva® Handihaler® (tiotropium) which does not require prior authorization.

Stiolto™ Respimat® (Tiotropium/Olodaterol) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components.

Utibron™ Neohaler® (Indacaterol/Glycopyrrolate) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and

3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components.

Seebri™ Neohaler® (Glycopyrrolate) Approval Criteria:

1. The college of pharmacy recommends placement of Seebri™ Neohaler® (glycopyrrolate) into Tier-2 of the Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Anticholinergics (LAMA) product based prior authorization category. The current criteria for this category will apply.

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Anticholinergics (LAMA)		
Tier-1	**Tier-2**	**Special PA**
Long Acting Beta$_2$ Agonists* (LABA)		
Serevent® (salmeterol inhalation powder)	Perforomist® (formoterol nebulizer solution)	
Foradil® (formoterol aerosolized powder)	Brovana® (arformoterol nebulizer solution)	
	Arcapta® (indacaterol inhalation powder	
	Striverdi® Respimat® (olodaterol inhalation spray)	
Long Acting Anticholinergics (LAMA)		
Spiriva® (tiotropium inhalation powder)	Tudorza® (aclidinium inhalation powder)	
	Spiriva® Respimat® (tiotropium soft mist inhaler)*	
	Incruse™ Ellipta®(umeclidinium inhalation powder)	
	Seebri™ Neohaler® (glycopyrrolate)	
LABA/LAMA Combination Products		
		Stiolto™ Respimat® (tiotropium/olodaterol)
		Utibron™ Neohaler® (indacaterol/glycopyrrolate)

*See Spiriva® Respimat® (tiotropium soft mist inhaler) Approval Criteria for Asthma.

Nucala® (Mepolizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of patients with severe eosinophilic phenotype asthma; and
2. Member must be age 12 years or older; and
3. Member must have a baseline blood eosinophil count of 150 cell/mcL or greater within the last six weeks of initiation of dosing; and
4. Member must have had at least two asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of high-dose inhaled corticosteroid (ICS) plus at least one additional controller medication; and

5. Member must have failed a high-dose ICS (≥ 880 mcg/day fluticasone propionate or equivalent daily dose or ≥ 440 mcg/day in ages 12 to 17) used compliantly for at least the past 12 months (for ICS/LABA combination products, the highest approved dose meets this criteria); and
6. Member must have failed at least one other asthma controller medication used in addition to the high-dose ICS compliantly for at least the past three months; and
7. Nucala® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of six months after which time compliance will be evaluated for continued approval; and
9. A quantity limit of 1 vial per 28 days will apply.

Recommendation 7: Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Migranal® (Dihydroergotamine Mesylate Nasal Spray)

NO ACTION REQUIRED.

Recommendation 8: 30-Day Notice to Prior Authorize Strensiq™ (Asfotase Alfa)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Varubi™ (Rolapitant)

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Cortisporin® and Pediotic® (Neomycin/Polymyxin B/Hydrocortisone Otic)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Parkinson's Disease Medications and 30-Day Notice to Prior Authorize Duopa™ (Carbidopa/Levodopa Enteral Suspension) and Rytary™ (Carbidopa/Levodopa Extended-Release Capsules)

NO ACTION REQUIRED.

Recommendation 12: 30-Day Notice to Prior Authorize Xuriden™ (Uridine Triacetate)

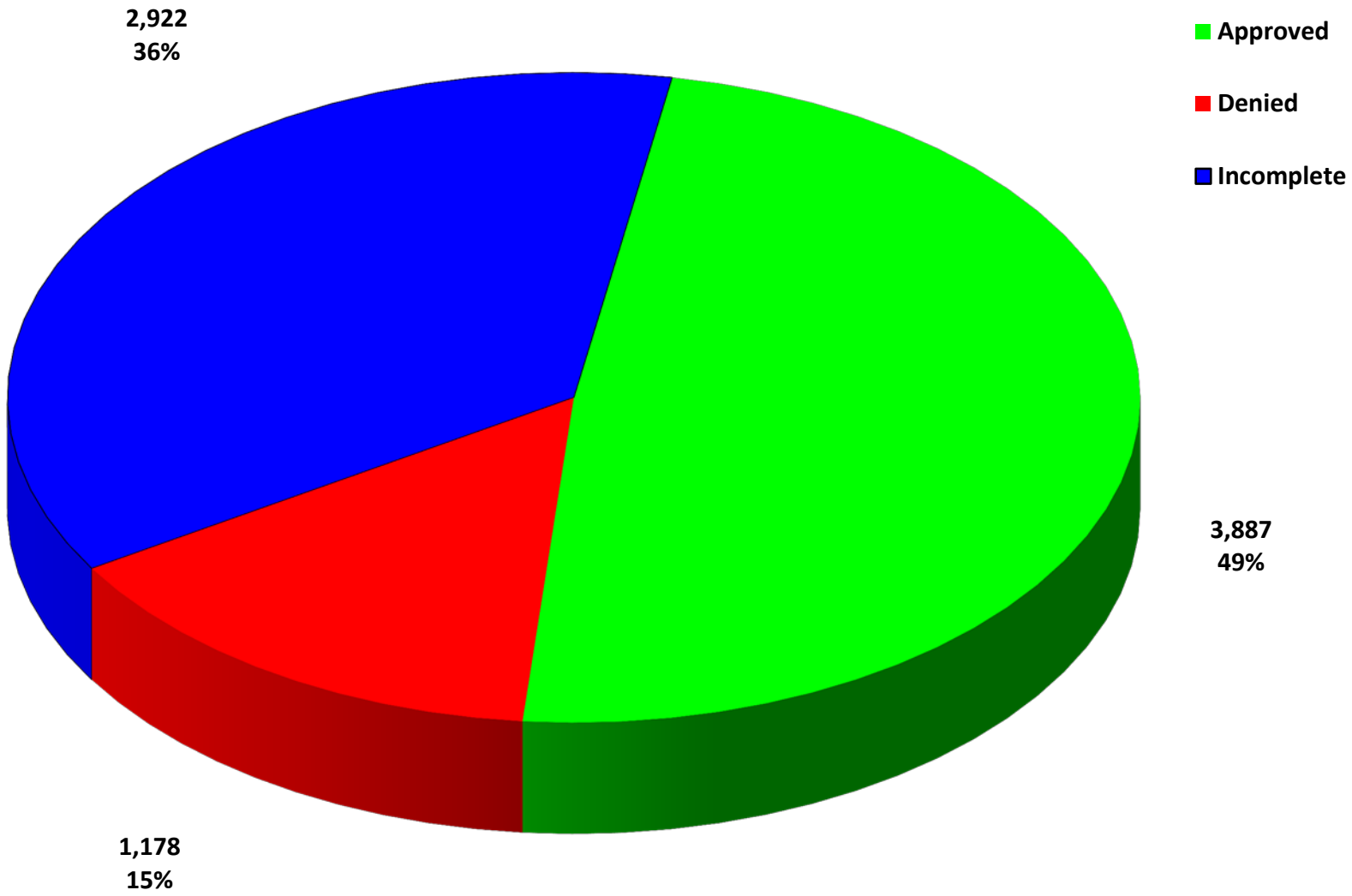
NO ACTION REQUIRED.

Recommendation 13: Annual Review of Testosterone Products

NO ACTION REQUIRED.

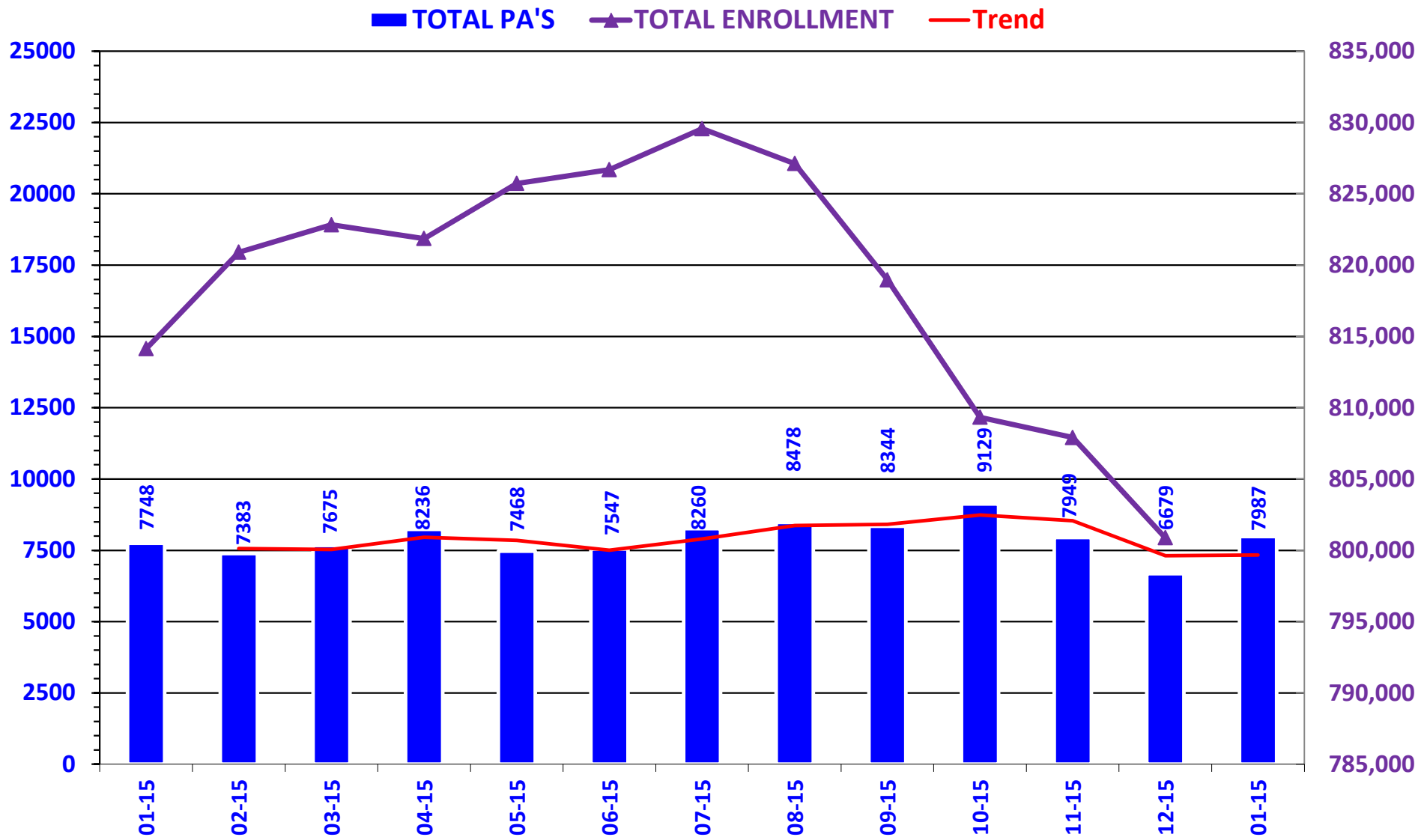
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JANUARY 2016



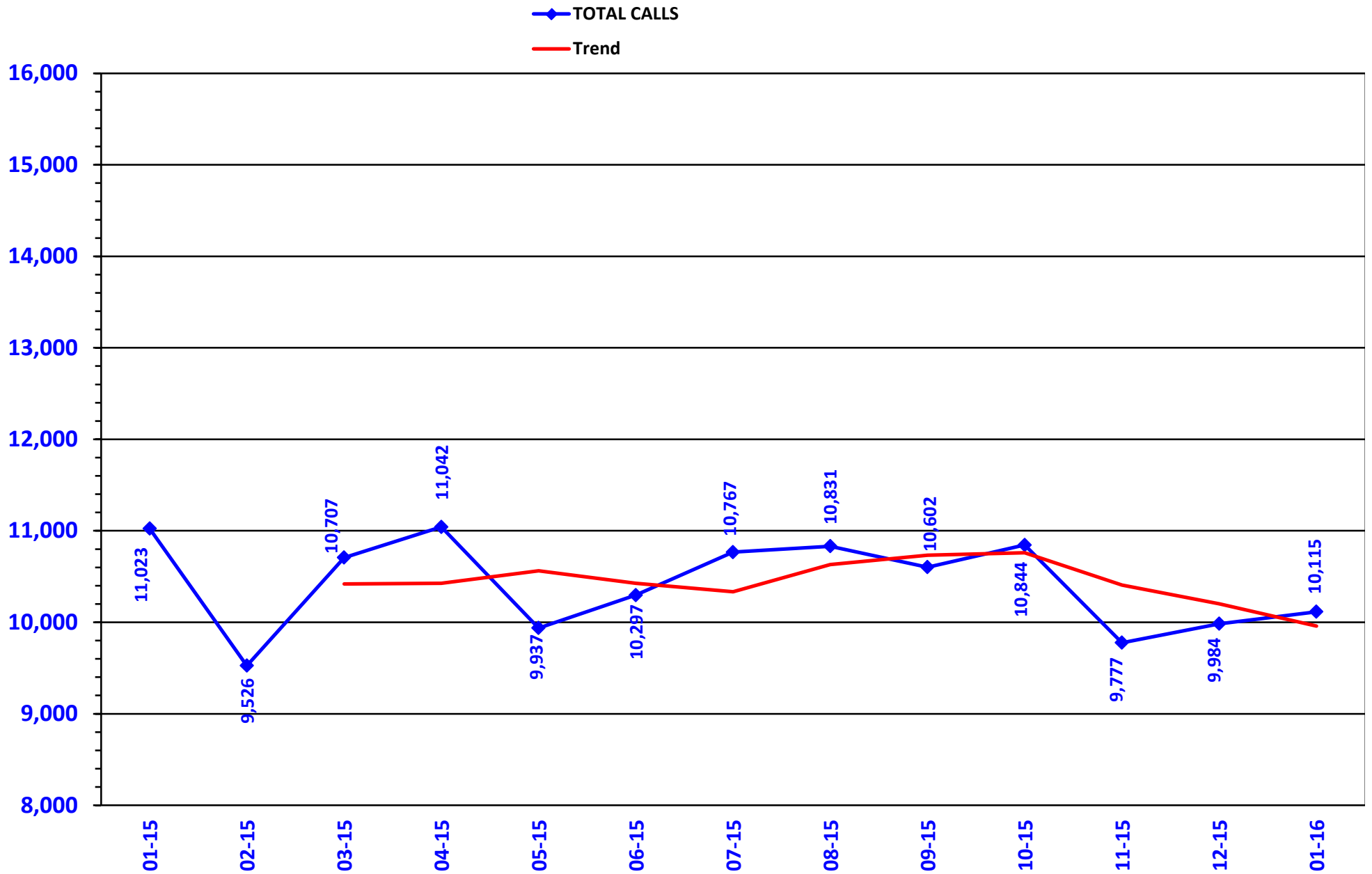
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JANUARY 2015 – JANUARY 2016



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JANUARY 2015 – JANUARY 2016



Prior Authorization Activity

1/1/2016 Through 1/31/2016

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	398	156	59	183	355
Analgesic - NonNarcotic	25	0	9	16	0
Analgesic, Narcotic	419	249	48	122	159
Angiotensin Receptor Antagonist	34	10	7	17	359
Antiasthma	103	33	20	50	331
Antibiotic	48	17	5	26	145
Anticonvulsant	70	35	9	26	320
Antidepressant	104	25	21	58	335
Antidiabetic	165	73	27	65	350
Antifungal	12	2	3	7	63
Antihistamine	159	127	10	22	350
Antimigraine	40	9	10	21	215
Antiulcers	226	56	70	100	131
Anxiolytic	62	33	6	23	243
Atypical Antipsychotics	528	245	46	237	352
Benign Prostatic Hypertrophy	12	0	6	6	0
Biologics	106	52	16	38	293
Bladder Control	45	17	11	17	359
Blood Thinners	137	79	11	47	309
Botox	45	30	7	8	360
Calcium Channel Blockers	10	4	1	5	111
Cardiovascular	51	30	6	15	291
Cephalosporins	14	9	0	5	15
Chronic Obstructive Pulmonary Disease	57	19	9	29	355
Contraceptive	20	18	1	1	266
Corticosteroid	14	3	1	10	24
Dermatological	102	16	57	29	85
Diabetic Supplies	505	286	18	201	205
Endocrine & Metabolic Drugs	90	58	10	22	129
Erythropoietin Stimulating Agents	17	13	2	2	123
Fibromyalgia	179	26	81	72	351
Fish Oils	23	0	11	12	0
Gastrointestinal Agents	90	30	22	38	127
Glaucoma	11	2	1	8	359
Growth Hormones	88	67	8	13	142
Hepatitis C	171	100	31	40	11
HFA Rescue Inhalers	89	24	11	54	330
Insomnia	40	6	16	18	211
Insulin	30	6	5	19	357
Linzess, Amitiza, and Relistor	116	15	42	59	158
Miscellaneous Antibiotics	10	0	1	9	0
Multiple Sclerosis	33	15	7	11	189
Muscle Relaxant	60	12	20	28	24
Nasal Allergy	94	25	17	52	283
Neurological Agents	60	39	8	13	344
NSAIDs	168	30	51	87	268
Ocular Allergy	26	3	7	16	267
Ophthalmic Anti-infectives	20	6	5	9	11
Osteoporosis	22	9	5	8	357
Other*	202	54	36	112	235
Otic Antibiotic	16	0	6	10	0
Passive Immunizing Agents	10	7	0	3	214
Pediculicide	46	17	5	24	14

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Statins	71	19	10	42	360
Stimulant	906	441	93	372	334
Suboxone/Subutex	232	179	7	46	76
Synagis	104	45	27	32	91
Testosterone	37	10	11	16	340
Topical Antifungal	35	0	6	29	0
Topical Corticosteroids	64	2	22	40	40
Vitamin	61	19	24	18	277
Pharmacotherapy	49	43	0	6	243
Emergency PAs	1	1	0	0	
Total	**6,782**	**2,956**	**1,102**	**2,724**	
Overrides					
Brand	48	25	13	10	292
Cumulative Early Refill	3	2	1	0	9
Diabetic Supplies	2	2	0	0	123
Dosage Change	331	305	1	25	12
High Dose	3	3	0	0	149
Ingredient Duplication	32	24	1	7	10
Lost/Broken Rx	79	77	2	0	11
NDC vs Age	29	29	0	0	300
Nursing Home Issue	26	26	0	0	8
Opioid Quantity	8	7	1	0	141
Other*	29	27	0	2	10
Quantity vs. Days Supply	576	379	53	144	261
STBS/STBSM	23	17	2	4	61
Stolen	7	3	2	2	10
Temporary Unlock	2	2	0	0	27
Third Brand Request	20	14	2	4	12
Overrides Total	**1,205**	**931**	**76**	**198**	
Total Regular PAs + Overrides	**7,987**	**3,887**	**1,178**	**2,922**	

Denial Reasons	
Unable to verify required trials.	2,604
Does not meet established criteria.	1,126
Lack required information to process request.	372

Other PA Activity	
Duplicate Requests	545
Letters	6,582
No Process	10
Changes to existing PAs	580
Helpdesk Initiated Prior Authorizations	736
PAs Missing Information	51

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

Oral Viscous Lidocaine Claims Analysis Update

Oklahoma Health Care Authority
February 2016

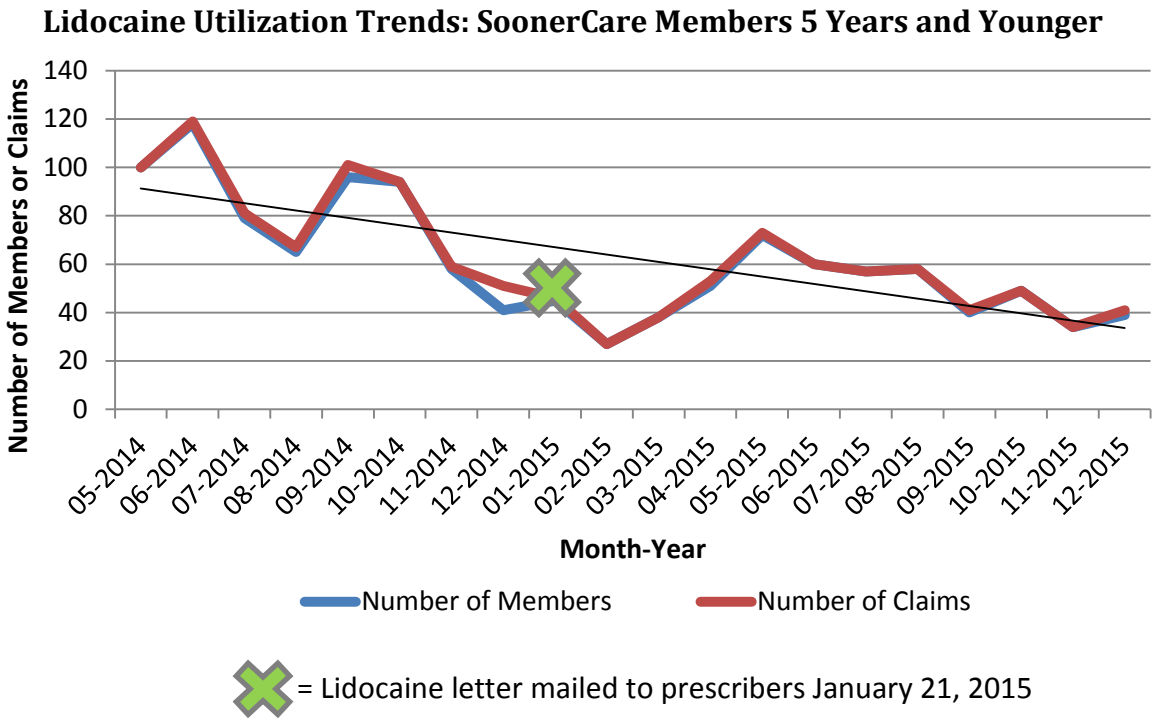
Background[1]

On June 26, 2014, the FDA issued a Drug Safety Communication regarding the use of oral viscous lidocaine 2% solution for teething pain in infants and children. Serious adverse events, including seizure, severe brain injury, heart problems and death have occurred due to overdose, and accidental swallowing of lidocaine. The FDA recommended the addition of a boxed warning to the product label. Parents and caregivers are encouraged not to use over-the-counter (OTC) topical medications for teething pain, but to follow the American Academy of Pediatrics' (AAP) recommendations to use a chilled teething ring or gentle rubbing of the gums with a finger.

In January 2015, the University of Oklahoma College of Pharmacy and the Oklahoma Health Care Authority sent an educational mailing to recent prescribers of oral viscous lidocaine in children five years of age and younger. The initiative outlined the FDA recommendations and provided prescribers with the number of claims they had written for viscous lidocaine for SoonerCare members under five years of age. The mailing also included an optional provider response page. A total of 152 prescribers were included in the mailing accounting for 297 lidocaine claims in children five years of age and younger.

A claims analysis to evaluate the efficacy of the mailing was conducted in March 2015. It appeared that the educational mailing was effective in reducing prescribing of oral viscous lidocaine in the SoonerCare pediatric population based on a downward trend in claims in the pediatric population as well as feedback from the prescribers indicating they planned to change their prescribing habits. Responses revealed 35.3% of prescribers indicated they would change their prescribing habits and no longer prescriber viscous lidocaine in the pediatric population or prescribe less frequently with smaller quantities. As a result, the College of Pharmacy did not recommend any changes to the lidocaine coverage criteria, but instead recommended reassessing utilization of oral viscous lidocaine periodically to ensure prescribing remains appropriate.

SoonerCare Claims Analysis



A review of SoonerCare pharmacy claims outlined in the chart found a decline in claims for oral viscous lidocaine use in members five years of age and younger from May 2014 to March 2015. After the intervention and initial decline in claims, claims gradually increased from March 2015 to June 2015 but have since declined and are now similar to the months immediately following the intervention. The overall trend in utilization has decreased significantly since May 2014.

Recommendations

Assessment of oral viscous lidocaine claims in the pediatric SoonerCare population did not reveal disproportionate prescribing. It is important to note that SoonerCare claims do not encompass OTC topical medications for teething pain. Caregivers may continue utilizing OTC topical medications for teething pain if they are uninformed of the potential risks. Based on this claims analysis and the inability to assess OTC lidocaine utilization, the College of Pharmacy recommends including an article in the member newsletter detailing the AAP recommendations to use a chilled teething ring or gentle rubbing of the gums with a finger for teething pain. Utilization of prescription oral viscous lidocaine claims will be reassessed periodically to ensure prescribing in the pediatric population remains appropriate.

[1] FDA Drug Safety Communication (viscous lidocaine) available online at http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm Last revised 01/16/2016. Last accessed 01/29/2016.

Appendix C

Vote to Prior Authorize Duopa™ (Carbidopa/Levodopa Enteral Suspension) and Rytary™ (Carbidopa/Levodopa Extended-Release Capsules)

Oklahoma Health Care Authority
February 2016

Introduction[1,2]

- **Duopa™ (carbidopa/levodopa)** is an enteral suspension for the treatment of motor fluctuations for people with advanced Parkinson's disease. Duopa™ is administered using a portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally-placed tube. Duopa™ was approved by the FDA as an orphan drug, a designation granted to products intended for the treatment of rare diseases or conditions affecting fewer than 200,000 patients in the United States.
- **Rytary™ (carbidopa/levodopa extended-release capsules)** is an extended-release capsule formulation of carbidopa/levodopa for the treatment of Parkinson's disease (PD), postencephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. Rytary™ contains immediate-release and extended-release beads, with a specific amount of carbidopa and levodopa in a 1:4 ratio, and provides both initial and extended levodopa plasma concentrations after a single dose.

Recommendations

The College of Pharmacy recommends the prior authorization of Duopa™ (carbidopa/levodopa enteral suspension) and Rytary™ (carbidopa/levodopa extended-release capsules) with the following criteria:

Duopa™ (Carbidopa/Levodopa Enteral Suspension) Approval Criteria:

1. An FDA approved diagnosis of advanced Parkinson's disease; and
2. For long-term administration, member or caregivers must be willing and able to administer Duopa® through a percutaneous endoscopic gastrostomy; and
3. Patients must be experiencing three hours or more of "off" time on their current Parkinson's disease drug treatment and they must have demonstrated a clear responsiveness to treatment with levodopa; and
4. Approvals will be for a quantity of one cassette per day.

Rytary™ (Carbidopa/Levodopa Extended-Release Capsules) Approval Criteria

1. An FDA approved diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism that may follow carbon monoxide intoxication or manganese intoxication; and
2. A patient-specific, clinically significant reason why the member cannot use other generic carbidopa/levodopa combinations including Sinemet® CR (carbidopa/levodopa extended-release tablets).

[1]AbbVie Inc. "Abbvie Announces U.S. Fda Approval of Duopa™ (Carbidopa and Levodopa) Enteral Suspension for the Treatment of Motor Fluctuations in Patients with Advanced Parkinson's Disease." Available online at: http://abbvie.mediaroom.com/2015-01-12-AbbVie-Announces-U-S-FDA-Approval-of-DUOPA-carbidopa-and-levodopa-Enteral-Suspension-for-the-Treatment-of-Motor-Fluctuations-in-Patients-with-Advanced-Parkinsons-Disease. Last revised 01/12/2015. Last accessed 12/29/2015.
[2]Brooks, Megan. Medscape. "FDA Okays Carbidopa/Levodopa ER (Rytary) in Parkinson's." Available online at: http://www.medscape.com/viewarticle/837773. Last revised 01/08/2015. Last accessed 12/29/2015.

Appendix D

Vote to Prior Authorize Cortisporin® and Pediotic® (Neomycin/Polymyxin B/Hydrocortisone Otic)

Oklahoma Health Care Authority
February 2016

Introduction[1,2]

- Cortisporin® and Pediotic® otic have increased in price by more than 450% since November 2012. The most recent state maximum allowable cost (SMAC) price updated in August 2015 is $8.46 per mililiter, resulting in a 10mL bottle costing around $84.60. This price is significantly greater than the $20.20 cost per bottle in November 2012.
- All Tier-1 otic anti-infectives have similar spectrum coverage including *Pseudomonas aeruginosa* and *Staphylococcus aureus*, and all pathogens covered by Cortisporin® otic are covered by at least one Tier-1 alternative.

Recommendations

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

1. Place neomycin/polymyxin B/hydrocortisone (Cortisporin®, Pediotic®) into Tier-2.
    a. The existing criteria for this category will apply.
2. Place neomycin/colistin/hydrocortisone/thonzonium (Cortisporin® TC, Coly-Mycin® S) into Tier-1.
    a. The existing criteria for this category will apply.
3. Initiate an educational mailing regarding these tier changes, which will include the option of utilizing neomycin/colistin/hydrocortisone/thonzonium (Cortisporin® TC, Coly-Mycin® S) 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/colistin/HC/ thonzonium (Cortisporin® TC, Coly-Mycin® S)	ciprofloxacin (Cetraxal®)	
	ciprofloxacin/HC (Cipro® HC)	
	finafloxacin (Xtoro™)	
	ofloxacin (Floxin® Otic)	
	neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	

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 six 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.

[1] Cortisporin. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; August 2015. Accessed December 18, 2015.

[2] Cortisporin-TC. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; November 2015. Accessed December 18, 2015.

Appendix E

Vote to Prior Authorize Migranal®
(Dihydroergotamine Mesylate Nasal Spray)

Oklahoma Health Care Authority
February 2016

Indication(s)[1]

Migranal® (dihydroergotamine mesylate nasal spray) is indicated for the acute treatment of migraine headaches with or without aura.

Recommendations

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

1. The addition of a special prior authorization (PA) category:
    a. Placement of sumatriptan (Sumavel® DosePro®), sumatriptan patch (Zecuity®), sumatriptan injection (Imitrex®), and sumatriptan nasal spray (Imitrex®) into the special PA category.
    b. Placement of sumatriptan/naproxen (Treximet®) into the special PA category and require a patient-specific, clinically significant reason why the member cannot use the individual components separately.
    c. Placement of dihydroergotamine nasal spray (Migranal®) and dihydroergotamine injection (D.H.E. 45®) in the special PA category with the criteria noted in red.

Tier-1 products are covered with no prior authorization necessary.

Anti-Migraine Medications Tier-2 Approval Criteria:

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

Anti-Migraine Medications Tier-3 Approval Criteria:

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

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.
2. Use of Zecuity® will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection).
3. Use of Treximet® (sumatriptan/naproxen) will require a patient-specific, clinically significant reason why the member cannot use the individual ingredients separately.
4. Use of dihydroergotamine injection (D.H.E. 45®) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan products.
5. Use of dihydroergotamine nasal spray (Migranal®) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan products and dihydroergotamine injection (D.H.E. 45®).

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
sumatriptan (Imitrex®) rizatriptan (Maxalt®, Maxalt MLT®)	naratriptan (Amerge®) zolmitriptan (Zomig®, Zomig-ZMT®)	almotriptan (Axert®) eletriptan (Relpax®) frovatriptan (Frova®) zolmitriptan nasal spray (Zomig®)	**dihydroergotamine injection (D.H.E. 45®)** **dihydroergotamine nasal spray (Migranal®)** sumatriptan injection (Imitrex®) sumatriptan nasal spray (Imitrex®) sumatriptan (Sumavel® DosePro®) sumatriptan (Zecuity®)* sumatriptan/Naproxen (Treximet®)

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

[1]Migranal® Prescribing Information, Valeant™ Pharmaceuticals North America. Available online at: http://valeant.com/Portals/25/Pdf/PI/Migranal-PI.pdf. Last revised 06/2007. Last accessed 12/2015.

Appendix F

Vote to Prior Authorize Strensiq™ (Asfotase Alfa)

Oklahoma Health Care Authority
February 2016

Introduction[1]

Strensiq™ (asfotase alfa) is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP). The estimated acquisition cost per month for Strensiq™ is $141,926.40 (dosing based on an 80kg patient injecting six times a week).

Recommendations

The College of Pharmacy recommends the prior authorization of Strensiq™ (asfotase alfa) with the following criteria:

Strensiq™ (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of patients with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by laboratory testing of:
    a. Low age-adjusted ALP activity; and
    b. Elevated pyridoxal 5'-phophate (PLP) levels; and
3. Member's weight (kg) must be provided and have been taken within the last four weeks to ensure accurate weight-based dosing; and
4. The 80mg/0.8mL vial should not be used in pediatric patients weighing less than 40kg.

[1]Strensiq™ Prescribing Information. Alexion Pharmaceutical, Inc. Available online at: http://www.strensiq.com/images/pi.pdf. Last revised: 10/2015. Last accessed 12/2015.

Appendix G

Vote to Prior Authorize Varubi™ (Rolapitant)

Oklahoma Health Care Authority
February 2016

Introduction[1,2,3,4]

- **Emend® (aprepitant)** is a substance P/neurokinin-1 (NK1) receptor antagonist. Aprepitant is indicated in combination with other anti-emetic medications for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) in patients 12 years of age and older and patients less than 12 years of age who weigh at least 30kg. Aprepitant is also indicated for prevention of postoperative nausea and vomiting in adult patients. Aprepitant is available as oral capsules and as an oral solution. Emend® is also available as fosaprepitant for intravenous (IV) administration.
- **Diclegis® (doxylamine/pyridoxine)** is an oral tablet containing 10mg doxylamine and 10mg pyridoxine, and is indicated for the treatment of nausea and vomiting of pregnancy that is not responsive to conservative management. The recommended dosage of Diclegis® is two tablets at bedtime, up to a maximum of four tablets per day (one tablet in the morning, one tablet midafternoon, and two tablets at bedtime) if symptoms persist at the dosage of two tablets per day. Over-the-counter (OTC) doxylamine is available as 25mg tablets, and OTC pyridoxine (vitamin B_6) is available in multiple strengths, with the lowest available strength being 25mg. In August 2015, the American College of Obstetricians and Gynecologists (ACOG) published an updated practice bulletin regarding the treatment of nausea and vomiting of pregnancy, and it recommends treatment with vitamin B_6 (pyridoxine) or vitamin B_6 (pyridoxine) plus doxylamine as first-line pharmacotherapy.
- **Akynzeo® (netupitant/palonosetron)** is a combination product containing a substance P/NK1 receptor antagonist and a 5-HT_3 receptor antagonist. Akynzeo® is indicated for prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with HEC (including cisplatin-based regimens) or anthracycline and cyclophosphamide-based regimens (including other regimens not highly emetogenic) in adult patients.
- **Varubi™ (rolapitant)** is a substance P/NK1 receptor antagonist. Rolapitant is indicated in combination with other anti-emetic medications for the prevention of delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cisplatin-based chemotherapy, MEC, or regimens containing an anthracycline and cyclophosphamide in adult patients.

Recommendations

The College of Pharmacy recommends the following:

1. Revising the existing criteria for Emend® (aprepitant) to differentiate trial requirements in members receiving moderately or highly emetogenic chemotherapy and to include specific criteria for the oral suspension formulation
2. Revising the existing criteria for Diclegis® (doxylamine/pyridoxine) in response to the updated 2015 ACOG practice guidelines for the treatment of nausea and vomiting of pregnancy
3. Revising the existing criteria for Akynzeo® (netupitant/palonosetron) to require a failed trial of aprepitant (Emend®) based on estimated net cost per chemotherapy cycle
4. The prior authorization of Varubi™ (rolapitant) with the criteria noted in red

New proposed criteria specific to each medication is as follows:

Kytril® and Sancuso® (Granisetron), Anzemet® (Dolasetron), and Emend® (Aprepitant) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past six months) used for at least three days or one cycle that resulted in inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and
3. No ondansetron trial is required for authorization of Emend® (aprepitant) in members receiving highly emetogenic chemotherapy; and
4. Approval length will be based on duration of need.
5. For Emend® (aprepitant) oral suspension, an age restriction of six years and younger will apply. Members older than six years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used.

Diclegis® (Doxylamine/Pyridoxine) Approval Criteria:

1. An FDA approved diagnosis of nausea and vomiting of pregnancy that is not responsive to conservative management; and
2. Trials with at least two non-pharmacological therapies that have failed to relieve nausea and vomiting; and
3. ~~Trials with at least two prescription medications that have failed to relieve nausea and vomiting; and~~
4. A patient-specific, clinically significant reason why member cannot use over-the-counter (OTC) doxylamine and OTC Vitamin B_6 (pyridoxine).

Akynzeo® (Netupitant/Palonosetron) Approval Criteria:

1. An FDA approved diagnosis for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. A previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. Approval length based on duration of need.
4. A quantity limit of one capsule per chemotherapy cycle will apply.

Varubi™ (Rolapitant) Approval Criteria:

1. An FDA approved indication for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; and
2. A previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. Approval length based on duration of need.
4. A quantity limit of two tablets per chemotherapy cycle will apply.

[1] Emend® (aprepitant) Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/emend-2/. Last revised 1/8/16. Last accessed 1/28/16.
[2] Diclegis® (doxylamine/pyridoxine) Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/diclegis/. Last revised 1/13/15. Last accessed 1/28/16.
[3] Akynzeo® (netupitant/palonosetron) Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/akynzeo-1/. Last revised 12/9/15. Last accessed 1/28/16.
[4] Varubi™ (rolapitant) Package Insert. Medlibrary.org. Available online at: http://medlibrary.org/lib/rx/meds/varubi/. Last revised 10/7/15. Last accessed 1/28/16.

Appendix H

Vote to Prior Authorize Xuriden™ (Uridine Triacetate)

Oklahoma Health Care Authority
February 2016

Introduction[1]

Xuriden™ (uridine triacetate) is a pyrimidine analog indicated for uridine replacement therapy in individuals with hereditary orotic aciduria. It is available in 2g single-use packets containing orange-flavored oral granules. Uridine triacetate was approved by the U.S. Food and Drug Administration (FDA) in September 2015 as an orphan drug. It is the first and only FDA-approved treatment for patients with hereditary orotic aciduria.

Recommendations

The College of Pharmacy recommends the prior authorization of Xuriden™ (uridine triacetate) with the following criteria:

Xuriden™ (Uridine Triacetate) Approval Criteria:

1. An FDA approved diagnosis of hereditary orotic aciduria defined by at least one of the following:
    a. Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patients erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone; or
    b. Evidence of megaloblastic anemia; or
        i. Shown not to improve with iron supplements
        ii. Normal serum folate and vitamin B12 levels and no evidence of Transcobalamine II deficiency
    c. Orotic acid crystals visualized in the urine via microscopy; and
2. Current weight of member must be provided on the prior authorization request; and
    a. Weights should be reassessed every six months to ensure proper dosing and effectiveness; or
    b. Prescriber can indicate urine orotic acid levels are within normal ranges and dosing remains appropriate; and
3. The prescriber must verify that the patient/caregiver is able to properly measure and administer medication; and
4. A quantity limit of four packets per day will apply.

[1] Xuriden™ Prescribing Information. Wellstat Therapeutics Corporation. Available online at: http://www.xuriden.com/FPI.pdf. Last revised 09/2015. Last accessed 12/2015.

Appendix I

Fiscal Year 2015 Annual Review of Gout Medications and 30-Day Notice to Prior Authorize Mitigare™ (Colchicine Capsules) and Zurampic™ (Lesinurad)

Oklahoma Health Care Authority
February 2016

Current Prior Authorization Criteria

Colcrys® (Colchicine) Approval Criteria:

1. Failure of allopurinol defined by persistent gouty attacks with serum urate levels greater than 6.5mg/dL; and
2. A patient-specific, clinically significant reason why colchicine/probenecid would not be a viable option for the member; and
3. Quantity limit of 60 tablets per 30 days will apply for gout.
4. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Uloric® (Febuxostat) Approval Criteria:

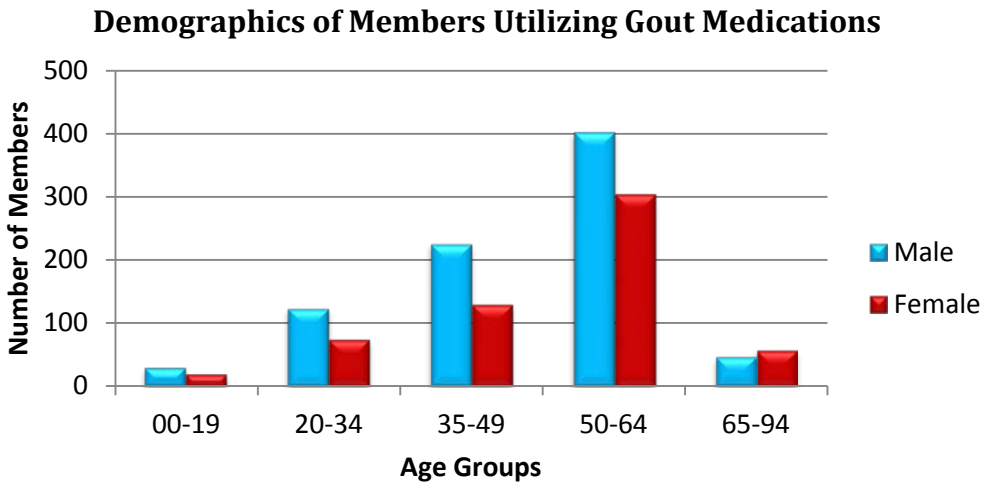
1. Failure of allopurinol defined by persistent gouty attacks with serum urate levels greater than 6.5mg/dL; and
2. A patient-specific, clinically significant reason why allopurinol would not be a viable option for the member; and
3. Quantity limit of 30 tablets per 30 days will apply.

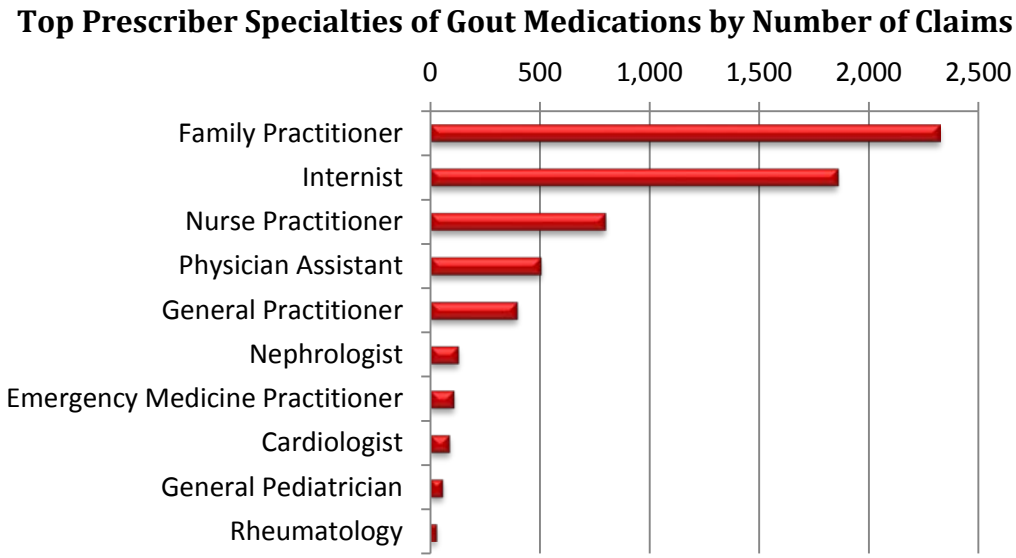
Utilization of Gout Medications: Fiscal Year 2015

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	1,401	5,237	$108,768.28	$20.77	$0.54	249,923	200,064
2015	1,419	6,502	$135,591.93	$20.85	$0.57	328,573	237,867
% Change	**1.30%**	**24.20%**	**24.70%**	**0.40%**	**5.60%**	**31.50%**	**18.90%**
Change	**18**	**1,265**	**$26,823.65**	**$0.08**	**$0.03**	**78,650**	**37,803**

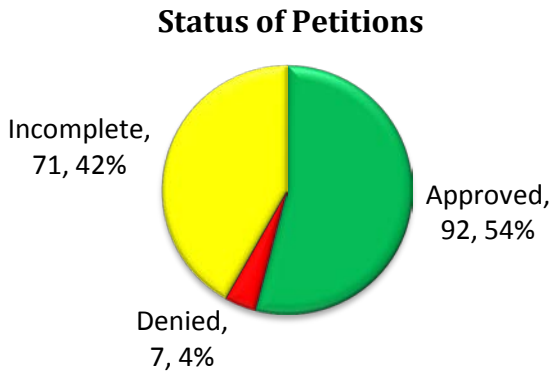
*Total number of unduplicated members.





Prior Authorization of Gout Medications

There were 170 prior authorization requests submitted for gout medications during fiscal year 2015. The following chart shows the status of the submitted petitions.



Market News and Updates[1,2,3]

Anticipated Patent Expirations:

- Colcrys® (colchicine): February 2029
- Uloric® (febuxostat): September 2031

New FDA Approvals:

- **September 2014/January 2015:** The U.S. Food and Drug Administration (FDA) approved Mitigare™ (colchicine capsules) in September 2014 while the authorized generic was approved January 2015. Mitigare™ capsules are indicated for prophylaxis of gout flares in adults.
- **December 2015:** The FDA approved Zurampic™ (lesinurad) tablets in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a XOI alone.

Mitigare™ (Colchicine Capsules) Product Summary[4]

Indications: Mitigare™ (colchicine capsules) is indicated for the prophylaxis of gout flares in adults. The safety and efficacy for treatment of acute gout flares has not been studied. Mitigare™ is not an analgesic and is not indicated to treat pain from other areas.

Dosing:

- Mitigare™ is available as a 0.6mg colchicine capsule.
- The recommended dosing is 0.6mg once or twice daily. The maximum dose is 1.2mg per day.
- Mitigare™ is administered orally without regard to meals.

Mechanism of Action: Mitigare™ is believed to be effective due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of β-tubulin into microtubules, thereby preventing the activation, degranulation, and migration of neutrophils to sites of inflammation. It also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1b (IL-1b) activation.

Contraindications: Mitigare™ is contraindicated in patients who have both renal and hepatic impairment. Additionally, it should not be used in patients with renal or hepatic impairment who are taking drugs that inhibit both P-glycoprotein (P-gp) and cytochrome (CYP) 3A4 inhibitors (e.g., clarithromycin, ketoconazole, amiodarone, verapamil). Combining these dual inhibitors with colchicine in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity.

Warnings and Precautions:

- Fatal Overdose: Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. Mitigare™ should be kept out of the reach of children.
- Blood Dyscrasias: Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia,

pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses.

- Interactions with CYP3A4 and P-gp Inhibitors: Because colchicine is a substrate for the CYP3A4 metabolizing enzyme and the P-gp efflux transporter, inhibition of either of these pathways may lead to colchicine-related toxicity. Inhibition of both CYP3A4 and P-gp by dual inhibitors such as clarithromycin has been reported to produce life-threatening or fatal colchicine toxicity due to significant increases in systemic colchicine levels. Therefore, concomitant use of Mitigare™ and inhibitors of CYP3A4 or P-glycoprotein should be avoided. If avoidance is not possible, reduced daily dose should be considered and the patient should be monitored closely for colchicine toxicity. Use of Mitigare™ in conjunction with drugs that inhibit both P-gp and CYP3A4 is contraindicated in patients with renal or hepatic impairment.
- Neuromuscular Toxicity: Neuromuscular toxicity and rhabdomyolysis have been reported from chronic treatment with colchicine in therapeutic doses, especially in combination with other drugs known to cause this effect. Patients with impaired renal function and elderly patients (even those with normal renal and hepatic function) are at increased risk. Once colchicine treatment is ceased, the symptoms generally resolve within one week to several months.

Adverse Reactions: The most common adverse reactions for Mitigare™ are as follows (these effects are generally reversible by stopping treatment or lowering the dose):

- Neurological: sensory motor neuropathy
- Dermatological: alopecia, maculopapular rash, purpura, rash
- Hematological: leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, aplastic anemia
- Hepatobiliary: elevated AST, elevated ALT
- Musculoskeletal: myopathy, elevated CPK, myotonia, muscle weakness, muscle pain, rhabdomyolysis
- Reproductive: azoospermia, oligospermia
- Digestive: abdominal cramping, abdominal pain, diarrhea, lactose intolerance, nausea, vomiting

Gastrointestinal disorders are the most common adverse reaction and are often the first signs of toxicity. Therapy may need to be reduced or stopped if diarrhea, nausea, vomiting and/or abdominal pain occur.

Use in Special Populations:

- Pregnancy: Mitigare™ is pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Colchicine crosses the human placenta. Developmental studies in animals were not conducted with Mitigare™, however published animal reproduction and development studies with colchicine demonstrated embryofetal toxicity, teratogenicity, and altered postnatal development at exposures within or above the clinical therapeutic range. Colchicine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The effect of colchicine on labor and delivery is unknown.

- Nursing Mothers: Colchicine is excreted into human milk. Limited information suggests that infants exclusively breastfed receive less than 10 percent of the maternal weight-adjusted dose. While there are no published reports of adverse effects in breast-feeding infants of mothers taking colchicine, colchicine can affect gastrointestinal cell renewal and permeability. Caution should be exercised and breastfeeding infants should be observed for adverse effects when Mitigare™ is administered to a nursing woman.
- Pediatric Use: Gout is rare in pediatric patients; the safety and effectiveness of Mitigare™ in pediatric patients has not been evaluated in controlled studies.
- Geriatric Use: Because of the increased incidence of decreased renal function in the elderly population, and the higher incidence of other co-morbid conditions in the elderly population requiring the use of other medications, reducing the dosage of colchicine when elderly patients are treated with colchicine should be carefully considered.
- Renal Impairment: No dedicated pharmacokinetic study has been conducted using Mitigare™ in patients with varying degrees of renal impairment. Colchicine is known to be excreted in urine in humans and the presence of severe renal impairment has been associated with colchicine toxicity. Urinary clearance of colchicine and its metabolites may be decreased in patients with impaired renal function. Dose reduction or alternatives should be considered for the prophylaxis of gout flares in patients with severe renal impairment. Colchicine is not effectively removed by hemodialysis. Patients who are undergoing hemodialysis should be monitored carefully for colchicine toxicity.
- Hepatic Impairment: No dedicated pharmacokinetic study using Mitigare™ has been conducted in patients with varying degrees of hepatic impairment. The presence of severe hepatic impairment has been associated with colchicine toxicity. Hepatic clearance of colchicine may be significantly reduced and plasma half-life prolonged in patients with chronic hepatic impairment. Dose reduction or alternatives should be considered for the prophylaxis of gout flares in patients with severe hepatic impairment.

Drug Interactions:

- CYP3A4: The concurrent use of Mitigare™ and CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, grapefruit juice, erythromycin, and verapamil) should be avoided due to the potential for serious and life-threatening toxicity. If co-administration is necessary, the dose of Mitigare™ should be adjusted by either reducing the daily dose or reducing the dose frequency, and the patient should be monitored carefully for colchicine toxicity
- P-glycoprotein: The concomitant use of Mitigare™ and inhibitors of P-gp (e.g., clarithromycin, ketoconazole, and cyclosporine) should be avoided due to the potential for serious and life-threatening toxicity.
- HMG-CoA Reductase Inhibitors and Fibrates: Use of these medications may increase the risk of myopathy when combined with Mitigare™. Patient complaints of muscle pain or weakness could be an indication to check serum creatinine kinase levels for signs of myopathy.
- Drug-Drug Interaction Studies: Four pharmacokinetic studies evaluated the effects of co-administration of voriconazole (200mg twice daily), fluconazole (200mg daily), cimetidine (800mg twice daily), and propafenone (225mg) on systemic levels of colchicine. Colchicine can be administered with these drugs at the tested doses without

a need for dose adjustment. However, these results should not be extrapolated to other co-administered drugs.

Efficacy: The evidence for the efficacy of colchicine in patients with chronic gout is derived from the published literature. Two randomized clinical trials assessed the efficacy of colchicine 0.6mg twice a day for the prophylaxis of gout flares in patients with gout initiating treatment with urate lowering therapy. In both trials, treatment with colchicine decreased the frequency of gout flares in a six month period from an average of 2.91 flares (placebo) to 0.51 flares (colchicine).

Cost Comparison:

Medication	Cost Per Capsule or Tablet*	Cost for 30 Days of Therapy
Mitigare™ (colchicine capsules) 0.6mg	**$6.04**	**$362.40**
Colcrys™ (colchicine tablets) 0.6mg	$6.95	$417.00
colchicine capsules 0.6mg	$5.20	$312.00
colchicine tablets 0.6mg	$5.93	$355.80
colchicine/probenecid 0.5mg/500mg	$0.75[+]	$90.00[¥]

Dosing based on maintenance and maximum recommended dosing according to package labeling.
Costs do not reflect supplemental rebated prices or net costs.
*EAC = Estimated Acquisition Cost
[+]SMAC = State Maximum Allowable Cost
[¥]Dosing based on maximum recommended dose of four tablets per day.

Zurampic™ (Lesinurad) Product Summary[5]

Indications: Zurampic™ (lesinurad) is an inhibitor of the urate transporter, URAT1, indicated in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a XOI alone. It is not recommended for the treatment of asymptomatic hyperuricemia and it is not recommended to be used as monotherapy.

Dosing:

- Zurampic™ is available as a 200mg oral tablet.
- The recommended dosage of lesinurad is 200mg once daily in combination with a xanthine oxidase inhibitor, including allopurinol or febuxostat.
- Failure to take lesinurad with a XOI may increase the risk of renal adverse reactions.
- The maximum daily dose of lesinurad is 200mg daily.
- Lesinurad tablets should be taken in the morning with food and water at the same time as the morning dose of XOI. Patients should be instructed to stay well hydrated when taking lesinurad.
- Lesinurad may be added to treatment when target serum uric acid levels are not achieved with the appropriate dose of XOI alone.
- It is not recommended to be taken in patients taking less than 300mg of allopurinol (or less than 200mg in patients with a creatinine clearance [CrCl] less than 60mL/min).
- If treatment with a XOI is interrupted, the lesinurad treatment should be interrupted as well.

- Renal function should be assessed before initiating treatment and should not be initiated if CrCl is below 45mL/min. Lesinurad should be discontinued if CrCl falls below 45mL/min.
- Gout flares may occur with initiation of lesinurad due to changing serum uric acid levels from the mobilization of urate from tissue deposits. The flare should be managed as appropriate for the patient, and lesinurad does not need to be discontinued.

Mechanism of Action: Lesinurad inhibits transporter proteins involved in uric acid absorption in the kidney. One of the transporters inhibited is a urate transporter, URAT1, which is responsible for the majority of the renal reabsorption of uric acid. By inhibiting URAT1, lesinurad increases uric acid excretion and thereby lowers serum uric acid (sUA). Lesinurad also inhibits organic anion transporter (OAT)-4, a uric acid transporter involved in diuretic-induced hyperuricemia.

Contraindications:

- Lesinurad is contraindicated in patients with the following conditions:
    - Severe renal impairment (CrCl less than 30mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
    - Tumor lysis syndrome of Lesch-Nyhan syndrome

Warnings and Precautions:

- Renal Events: Treatment with lesinurad in combination with a XOI was associated with an increased incidence of serum creatinine elevations, most of which were reversible. Adverse reactions related to renal function occurred after initiating lesinurad. A higher incidence of elevations of serum creatinine and renal-related adverse events, including serious adverse reactions of acute renal failure, was observed with lesinurad 400mg. The highest incidence in these adverse effects was with monotherapy. Renal function should be assessed before initiating treatment and should not be initiated if CrCl is below 45mL/min. Frequent monitoring of creatinine clearance should occur in patients with CrCl less than 60mL/min, or with serum creatinine elevations greater than 1.5 to 2 times the pretreatment value. Treatment should be interrupted in patients with elevations greater than two times the pretreatment value. In patients with complaints of flank pain, nausea or vomiting (indicating possible acute uric acid nephropathy), treatment should be interrupted and serum creatinine measured promptly. Treatment should not be restarted without another explanation for the serum creatinine abnormalities.
- Cardiovascular Events: In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, non-fatal myocardial infarctions, or non-fatal strokes) were observed with lesinurad. A causal relationship has not been established.

Adverse Reactions: The most common adverse reactions (≥5% and more frequently than placebo + XOI) reported during clinical trials of lesinurad include the following:

- Headache
- Influenza
- Blood creatinine increase in patients with creatinine clearance ≥ 30 to 60 mL/min

Use in Special Populations:

- Pregnancy: There are no available human data on the use of lesinurad during pregnancy. No teratogenicity or effects on fetal development were observed in embryo-fetal development studies with oral administration of lesinurad to pregnant rats and rabbits during organogenesis at doses that produced maternal exposures up to approximately 45 and 10 times the exposure at the maximum recommended human dose (MRHD). No adverse developmental effects were observed in a pre- and postnatal study with administration of lesinurad to pregnant rats from organogenesis through lactation at a dose approximately five times the MRHD.
- Nursing Mothers: Although lesinurad was observed in animal breast milk, it is not known if lesinurad is present in human breast milk. There is no information for determining infant risk when used during breastfeeding. The potential benefits of drug treatment should be considered along with the potential risks before prescribing this drug during breastfeeding.
- Pediatric Use: The safety and efficacy of lesinurad have not been established in pediatric patients younger than 18 years of age.
- Geriatric Use: No dose adjustment is necessary in elderly patients. No overall differences in safety and efficacy comparing lesinurad and placebo were observed between subjects 65 years and older and younger subjects. However, greater sensitivity of some older individuals cannot be ruled out.
- Renal Impairment: The safety and efficacy of lesinurad were evaluated in studies that included gout patients with mild-to-moderate renal impairment. There were no clear differences in patients with mild renal impairment compared to patients with normal renal function, and no dose adjustment is recommended. Patients with moderate renal impairment had a higher incidence of renal related adverse reactions compared to patients with mild impairment or normal function. No dose adjustment is recommended in patients with CrCl of 45mL/min to less than 60mL/min. Lesinurad should be discontinued when CrCl is persistently less than 45mL/min. The safety and efficacy of lesinurad have not been evaluated in gout patients with severe renal impairment, end-stage renal disease, or receiving dialysis. It is not expected to be effective in these patient populations.
- Hepatic Impairment: No dose adjustment is necessary in patients with mild or moderate hepatic impairment (Child-Pugh classes A and B). Lesinurad has not been studied in patients with severe hepatic impairment and therefore is not recommended.
- Secondary Hyperuricemia: No studies have been conducted in patients with secondary hyperuricemia (including organ transplant recipients). Lesinurad is contraindicated for use in tumor lysis syndrome or Lesch-Nyhan syndrome, where uric acid formation is greatly increased.

Drug Interactions:

- CYP2C9 Inhibitors, CYP2C9 Poor Metabolizers, and CYP2C9 Inducers: Lesinurad exposure is increased when it is co-administered with inhibitors of CYP2C9 and in CYP2C9 poor metabolizers. It should be used with caution in patients taking moderate inhibitors of CYP2C9 (e.g., fluconazole, amiodarone) and in CYP2C9 poor metabolizers. Lesinurad

exposure is decreased when it is co-administered with moderate inducers of CYP2C9 (e.g., rifampin, carbamazepine), which may decrease the therapeutic effect.

- CYP3A Substrates: In interaction studies lesinurad reduced the plasma concentrations of sildenafil and amlodipine. There was no clinically significant interaction with atorvastatin, but HMG-CoA reductase inhibitors are sensitive CYP3A substrates that may be affected. The possibility of reduced efficacy of concomitant CYP3A substrates should be considered and their efficacy (e.g., blood pressure and cholesterol levels) should be monitored.
- Epoxide Hydrolase Inhibitors: In vitro studies suggest that lesinurad is not an inhibitor of epoxide hydrolase, but inhibitors of epoxide hydrolase (e.g., valproic acid) may interfere with metabolism of lesinurad. It should not be administered with inhibitors of epoxide hydrolase.
- Hormonal Contraceptives: Oral, injectable, transdermal, and implantable forms of hormonal contraceptives may not be reliable when co-administered with lesinurad. Females should practice additional methods of contraception when taking lesinurad.
- Aspirin: At doses greater than 325mg per day, aspirin may decrease the efficacy of lesinurad in combination with allopurinol. Aspirin at doses less than 325mg per day do not affect the efficacy of lesinurad.

Efficacy:

- The efficacy of lesinurad 200mg and 400mg once daily was studied in three multicenter, randomized, double-blind, placebo-controlled clinical studies in adult patients with hyperuricemia and gout in combination with a XOI (allopurinol or febuxostat). All studies were of 12 months duration and patients received prophylaxis for gout flares with colchicine or non-steroidal anti-inflammatory drugs (NSAIDs) during the first five months of lesinurad treatment.
- Study 1 and Study 2 enrolled patients with gout who were on a stable dose of allopurinol of at least 300mg (or 200mg for moderate renal impairment) that had a serum uric acid >6.5 mg/dL and reported at least two gout flares in the prior 12 months. Mean years since gout diagnosis were 12 years. More than half of the patients (61%) had mild or moderate renal impairment and 19% of the patients had tophi. Patients continued their allopurinol dose and were randomized 1:1:1 to receive lesinurad 200mg, lesinurad 400mg, or placebo once daily. The average dose of allopurinol in the studies was 310mg (range: 200-900mg). Lesinurad 200mg in combination with allopurinol was superior to allopurinol alone in lowering serum uric acid to less than 6mg/dL at month six with 54% of the patients achieving their serum uric acid target. Additionally, reduction in serum uric acid levels to <6mg/dL was noted for lesinurad 200mg in combination with allopurinol at month one and was maintained throughout the 12-month study.
- Study 3 enrolled gout patients with measurable tophi. Patients received febuxostat 80mg once daily for three weeks and then were randomized 1:1:1 to once daily doses of lesinurad 200mg, lesinurad 400mg, or placebo in combination with febuxostat. A total of 66% of patients had mild or moderate renal impairment. Fifty percent of patients did not reach target serum uric acid <5.0 mg/dL at baseline after three weeks of febuxostat

treatment. There was no statistical evidence of a difference in the patients treated with lesinurad 200mg in combination with febuxostat achieving sUA <5mg/dL by month six (57%), compared with patients receiving febuxostat alone (47%).

- In each of the three studies of lesinurad in combination with a XOI, the rates of gout flare requiring treatment from the end of month six to the end of month twelve were not statistically different between lesinurad 200mg in combination with allopurinol or febuxostat compared with allopurinol or febuxostat alone. In Study 3, the proportion of patients who experienced a complete resolution of ≥1 target tophus was not statistically different between lesinurad 200mg in combination with febuxostat compared with febuxostat alone.
- The estimated differences between lesinurad and placebo in the proportions of patients achieving target sUA levels in the renal impairment subgroups were largely consistent with the results in the overall population in the three studies.

Cost Comparison: Cost information for Zurampic™ is not available.

Medication	Cost Per Capsule or Tablet	Cost for 30 Days of Therapy
allopurinol 100mg	$0.20[+]	$24.00
allopurinol 300mg	$0.39[+]	$23.40
Uloric® (febuxostat) 40mg, 80mg	$9.56*	$286.80

Dosing based on maintenance and maximum recommended dosing according to package labeling.
Costs do not reflect supplemental rebated prices or net costs.
*EAC = Estimated Acquisition Cost
[+]SMAC = State Maximum Allowable Cost

Recommendations

The College of Pharmacy recommends the prior authorization of Mitigare™ (colchicine capsules) and Zurampic™ (lesinurad) with the following criteria:

Mitigare™ (Colchicine Capsules) Approval Criteria:

1. Failure of allopurinol defined by persistent gouty attacks with serum urate levels greater than 6.5mg/dL; and
2. A patient-specific, clinically significant reason why colchicine/probenecid would not be a viable option for the member.
3. Quantity limit of 60 tablets per 30 days will apply for gout.
4. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Zurampic™ (Lesinurad) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of gout in patients who have not achieved target serum uric acid (sUA) levels with a xanthine oxidase inhibitor (XOI) alone; and
3. Failure of allopurinol and febuxostat alone defined by serum urate levels greater than 6.5mg/dL; and

4. Prescriber must verify that member has a creatinine clearance greater than 45mL/min prior to initiating treatment and for continued approval; and
5. Prescriber must verify that member will take Zurampic™ concomitantly with a XOI; and
6. Prescriber must document member is not taking more than 325mg of aspirin per day and member is not taking any epoxide hydrolase inhibitors; and
7. Prescriber must document member has no contraindications for use of Zurampic™ including any of the following**:** Tumor lysis syndrome or Lesch-Nyhan syndrome, severe renal impairment (CrCl less than 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis.
8. A quantity limit of one tablet daily will apply

Utilization Details of Gout Medications: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ALLOPURINOL PRODUCTS					
ALLOPURINOL TAB 100MG	2,267	591	$13,708.43	3.84	$6.05
ALLOPURINOL TAB 300MG	3,403	741	$33,450.76	4.59	$9.83
Subtotal	**5,670**	**1,332**	**$47,159.19**	**4.44**	**$8.32**
COLCHICINE/PROBENECID PRODUCTS					
COLCHICINE/PROBENECID 500/0.5mg	128	37	$5,510.01	3.46	$43.05
Subtotal	**128**	**37**	**$5,510.01**	**3.46**	**$43.05**
COLCHICINE PRODUCTS					
COLCHICINE CAP 0.6MG	2	2	$46.24	1	$23.12
COLCHICINE TAB 0.6MG	113	72	$5,772.39	1.57	$51.08
COLCRYS TAB 0.6MG	364	125	$22,936.66	2.91	$63.01
	479		**$28,755.29**	**2.72**	**$60.03**
FEBUXOSTAT PRODUCTS					
FEBUXOSTAT 40MG	149	26	$35,147.49	5.73	$235.89
FEBUXOSTAT 80MG	76	15	$19,019.95	5.07	$250.26
SUBTOTAL	**225**	**41**	**$54,167.44**	**5.77**	**$240.74**
TOTAL	**6,502**	**1,609***	**$135,591.93**	**4.58**	**$20.85**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Cost per claim may correspond to a member receiving several months of therapy in one claim.

[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 12/28/2015. Last accessed 12/29/2015.
[2] Mitigare™. Colchicine History. Hikma Americas, Inc/West-ward Pharmaceutical Corp. Available online at: http://www.mitigare.com/pharmacists/colchicine-history/. Last revised 10/22/15. Last accessed 1/28/15.
[3] Food and Drug Administration. FDA Approves Zurampic to Treat High Blood Uric Acid Levels Associated with Gout. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm478791.htm. Last revised 12/23/15. Last accessed 1/21/15.
[4] Mitigare™ Product Information. Hikma Americas, Inc/West-Ward Pharmaceutical Corp. Available online at: http://www.mitigare.com/wp-content/uploads/2015/10/pi.pdf. Last revised 09/2014. Last accessed 1/28/15.
[5] Zurampic™ Product Information. AstraZeneca. Available online at: http://www.azpicentral.com/zurampic/zurampic.pdf. Last revised 12/2015. Last accessed 1/21/15.

Appendix J

Fiscal Year 2015 Annual Review of Seizure Medications and 30-Day Notice to Prior Authorize Spritam® (Levetiracetam)

Oklahoma Health Care Authority
February 2016

Current Prior Authorization Criteria

1. Anticonvulsants are included in the mandatory generic plan.
    a. All brand-name anticonvulsants (with a generic equivalent) will require prior authorization.
        i. Brand-name medications (with a generic equivalent) will be approved for all members who are currently stable on these medications and have a seizure diagnosis.
2. Prior authorization will be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.
    a. Members 12 years and older must have a documented medical reason demonstrating the need for non-standard dosage forms.
    b. Criteria for approval of extended-release formulations:
        i. Previously stabilized on the short-acting formulation; and
        ii. Dosing is not more than once daily; and
        iii. Member must provide a reason why the short-acting formulation is not adequate; and
        iv. Dose packs will not be approved if standard dosage forms are available.
3. Quantity limit restrictions will be placed on lower strength tablets and capsules. The highest strengths will continue to have no quantity restrictions unless a maximum dose is specified for a particular medication.

Felbatol® (Felbamate) Approval Criteria:

1. Initial prescription must be written by a neurologist; and
2. Member must have failed therapy with at least three other medications commonly used for seizures.

Onfi® (Clobazam) Approval Criteria:

1. An FDA approved diagnosis of severe seizures or generalized tonic, atonic, or myoclonic seizures; and
2. Previous failure of at least two non-benzodiazepine anticonvulsants; and
3. Previous failure of clonazepam; and
4. Initial approvals will be for the duration of three months. For continuation the prescriber must include information regarding improved response/effectiveness of the medication.

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric patients 10 years or older, or infantile spasms in children ages 1 month to 2 years of age; and
2. Members with refractory complex seizures must have previous trials of at least three other antiepileptic medications; or
3. Members with infantile spasms must have had a previous trial with adrenocorticotropic hormone (ACTH) or have a diagnosis of infantile spasms with tuberous sclerosis; and
4. Prescription must be written by a neurologist; and
5. Member, prescriber, and pharmacy must all register in the SHARE program and maintain enrollment throughout therapy.

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures as adjunctive therapy; and
2. Member must be on current antiepileptic drug therapy (Aptiom® is only indicated for adjunctive treatment); and
3. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
4. A patient-specific, clinically significant reason why member cannot use oxcarbazepine.
5. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Oxtellar XR™ (Oxcarbazepine Extended-Release) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the short-acting formulation.
2. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (150mg and 300mg).

Trokendi XR™ (Topiramate Extended-Release) Approval Criteria:

1. An FDA approved diagnosis of partial onset or primary generalized tonic-clonic seizures or as adjunctive therapy in seizures associated with Lennox-Gastaut syndrome; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate).
3. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (200mg).

Qudexy™ XR (Topiramate Extended-Release) Approval Criteria:

1. An FDA approved diagnosis of partial onset or primary generalized tonic-clonic seizures or as adjunctive therapy in seizures associated with Lennox-Gastaut syndrome; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate).

3. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

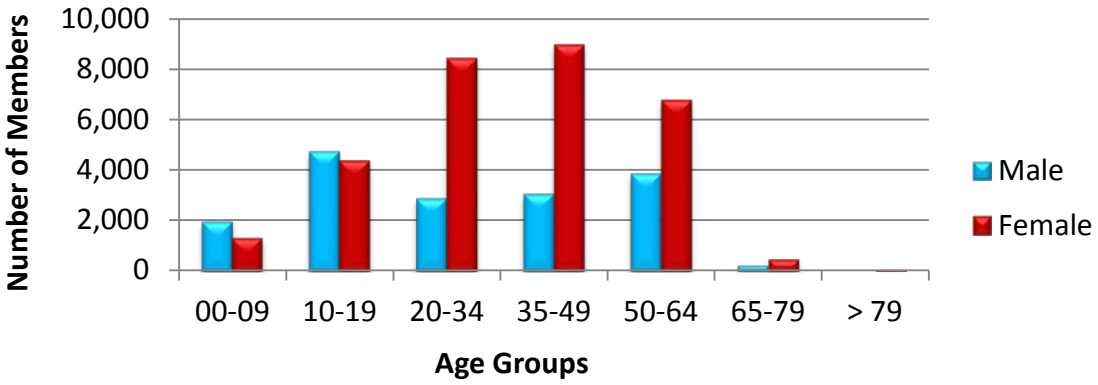
Utilization of Seizure Medications: Fiscal Year 2015

Comparison of Fiscal Years

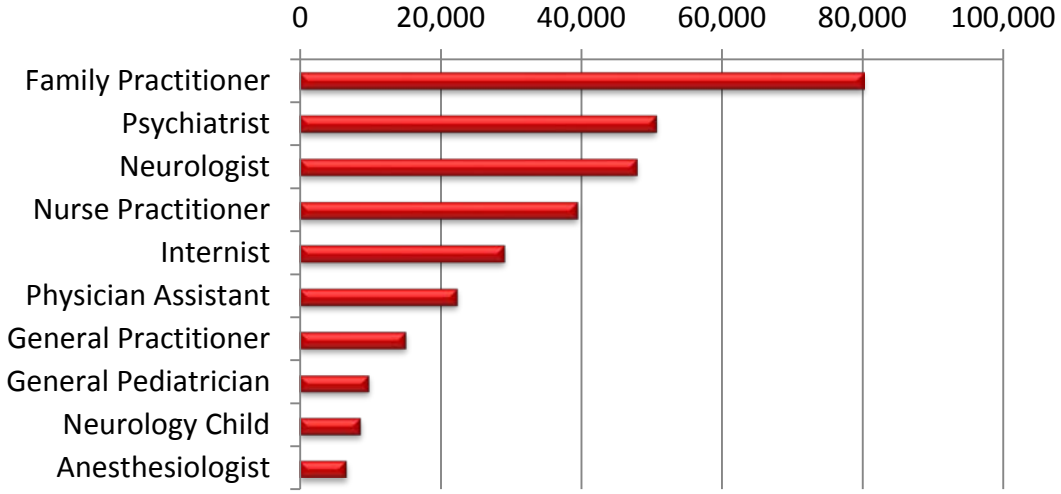
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	47,105	325,684	$19,808,051.80	$60.82	$2.03	30,605,622	9,771,326
2015	47,238	338,578	$22,656,510.72	$66.92	$2.23	31,724,935	10,178,024
% Change	**0.30%**	**4.00%**	**14.40%**	**10.00%**	**9.90%**	**3.70%**	**4.20%**
Change	**133**	**12,894**	**$2,848,458.92**	**$6.10**	**$0.20**	**1,119,313**	**406,698**

*Total number of unduplicated members.

Demographics of Members Utilizing Seizure Medications

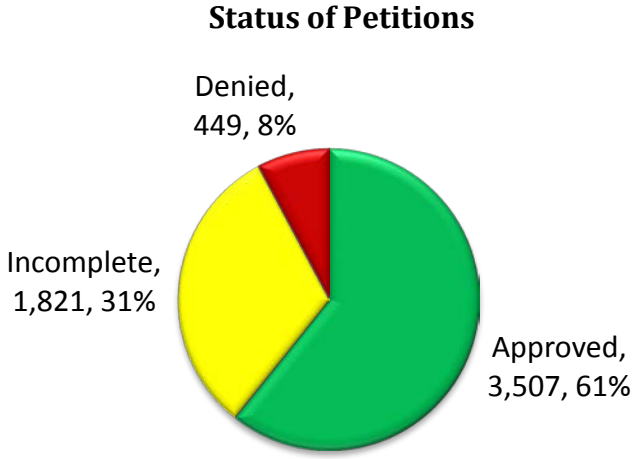


Top Prescriber Specialties of Seizure Medications by Number of Claims



Prior Authorization of Seizure Medications

There were 5,777 prior authorization requests submitted for seizure medications during fiscal year 2015. The following chart shows the status of the submitted petitions.



Market News and Updates[1,2,3,4,5,6,7]

Anticipated Patent Expirations:

- Onfi® (clobazam): October 2018
- Lyrica® (pregabalin): December 2018
- Vimpat® (lacosamide): March 2022
- Banzel® (rufinamide): May 2023
- Oxtellar XR™ (oxcarbazepine extended-release): April 2027
- Trokendi XR™ (topiramate extended-release): April 2028
- Aptiom® (eslicarbazepine): April 2030

New FDA Approvals and Indications:

- **September 2014:** The FDA approved a supplemental new drug application (sNDA) for Vimpat® (lacosamide) as monotherapy in the treatment of partial-onset seizures in patients with epilepsy 17 years of age and older. Vimpat® was first FDA approved in 2008 as an adjunctive treatment of partial-onset seizures in the same age group.
- **June 2015:** The FDA approved an sNDA for Fycompa® (perampanel) as an adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. Fycompa® was first FDA approved in 2012 as an adjunctive treatment of partial-onset seizures with or without secondary generalized seizures in the same age group.
- **July 2015:** The FDA approved Spritam® (levetiracetam) as an adjunctive treatment of partial-onset seizures, myoclonic seizures, and PGTC seizures in adults and children with epilepsy. Spritam® is the first FDA approved medication to use ZipDose® Technology, which uses three-dimensional printing (3DP) to produce a porous formulation that rapidly disintegrates with a sip of liquid.

- **August 2015:** The FDA approved an sNDA for Aptiom® (eslicarbazepine) as monotherapy in the treatment of partial-onset seizures. Aptiom® was first FDA approved in 2013 as an adjunctive treatment of partial-onset seizures.

Medications in the Pipeline:

- **Levetiracetam Product:** The FDA approved Elepsia XR™ (levetiracetam extended-release 1000mg and 1500mg tablets) in April 2015 as an adjunctive treatment of partial-onset seizures in patients with epilepsy 12 years of age and older. However, in September 2015, the FDA withdrew their approval of Elepsia XR™ due to regulatory issues at the manufacturing plant. The pharmaceutical company and manufacturer of Elepsia XR™ are currently working with the FDA to resolve the manufacturing issues.

Spritam® (Levetiracetam) Product Summary[8,9,10]

Indications: Spritam® (levetiracetam) is indicated for adjunctive therapy in the treatment of:

- Partial-onset seizures in patients with epilepsy 4 years of age and older weighing at least 20 kilograms (kg)
- Myoclonic seizures in patients with juvenile myoclonic epilepsy 12 years of age and older
- Primary generalized tonic-clonic (PGTC) seizures in patients with idiopathic generalized epilepsy 6 years of age and older

Dosing:

- Spritam® is available as 250mg, 500mg, 750mg, and 1,000mg oral, spearmint-flavored tablets.
- Spritam® tablets should be taken as whole tablets with a sip of liquid, and the tablet should be swallowed only after it disintegrates. Spritam® tablets should not be swallowed intact.
- Spritam® tablets disintegrate in a mean time of 11 seconds (ranging from 2 to 27 seconds) in the mouth, when taken with a sip of liquid, to produce small particles that may be swallowed.
- Spritam® is not recommended for use in pediatric patients who weigh less than 20kg.
- The recommended dosing of Spritam® is based on indication, age group (and weight, if applicable), and renal function, with the maximum recommended dose being 1500mg twice daily (*see following table for the recommended dosing regimens*).

Age	Weight	Recommended Dosing*
Partial-Onset Seizures		
≥ 4 years	> 40kg	500mg twice daily; increase as needed and tolerated by 500mg twice daily every 2 weeks; maximum recommended dose is 1500mg twice daily
≥ 4 years	20-40kg	250mg twice daily; increase by 250mg twice daily every 2 weeks; maximum recommended dose is 750mg twice daily
Myoclonic Seizures		

≥ 12 years	n/a[+]	500mg twice daily; increase by 500mg twice daily every 2 weeks; maximum recommended dose is 1500mg twice daily
Primary Generalized Tonic-Clonic Seizures		
≥ 6 years	> 40kg	500mg twice daily; increase as needed and tolerated by 500mg twice daily every 2 weeks; maximum recommended dose is 1500mg twice daily
≥ 6 years	20-40kg	250mg twice daily; increase by 250mg twice daily every 2 weeks; maximum recommended dose is 750mg twice daily

*Recommended dosing is based on the prescribing information for Spritam® (levetiracetam). Dose adjustments are recommended for patients with renal impairment based on creatinine clearance (see prescribing information).
[+]Weight not specified in the prescribing information for the diagnosis of myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.

Estimated Acquisition Cost: The estimated acquisition cost (EAC) of Spritam® is not yet available. Spritam® is anticipated to be released and available on the market in the first quarter of 2016.

Vimpat® (Lacosamide) Product Summary[11]

FDA Approval: 2008

Indications: Vimpat® (lacosamide) is indicated for monotherapy or adjunctive therapy in the treatment of partial-onset seizures in patients 17 years of age and older.

Dosing:

- Lacosamide is available as 50mg, 100mg, 150mg, and 200mg oral tablets, 10mg/mL oral solution, and 10mg/mL intravenous (IV) solution.
- The recommended dosing of lacosamide for monotherapy is 100mg twice daily, increasing the dose weekly by 50mg twice daily up to a recommended maintenance dose of 150mg to 200mg twice daily (300mg to 400mg per day).
- The recommended dosing of lacosamide for adjunctive therapy is 50mg twice daily, increasing the dose weekly based on patient response and tolerability by 50mg twice daily up to a recommended maintenance dose of 100mg to 200mg twice daily (200mg to 400mg per day).

Estimated Acquisition Cost: The EAC of Vimpat® 200mg tablets is $14.09, resulting in a monthly cost of $845.40 at the recommended maintenance dose of 200mg twice daily. The EAC of Vimpat® has been steadily increasing over the past few years.

Banzel® (Rufinamide) Product Summary[12]

FDA Approval: 2008

Indications: Banzel® (rufinamide) is indicated for adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut Syndrome in patients one year of age and older.

Dosing:

- Rufinamide is available as 200mg and 400mg oral tablets and as a 40mg/mL oral suspension.
- The recommended dosing of rufinamide in patients 17 years of age and older is 400mg to 800mg per day, administered in two equally divided doses, increasing the dose every other day by 400mg to 800mg up to a maximum daily dose of 3200mg, administered in two equally divided doses. It is not known whether doses lower than 3200mg per day are effective.
- The recommended dosing of rufinamide in pediatric patients 1 year of age to younger than 17 years of age is 10mg/kg/day in two equally divided doses, increasing the dose every other day by approximately 10mg/kg increments to a target dose of 45mg/kg/day, administered in two equally divided doses and not to exceed 3200mg per day. It is not known whether doses lower than the target doses are effective.

Estimated Acquisition Cost: The EAC of Banzel® 400mg tablets is $17.39, resulting in a monthly cost of $4,173.60 at the maximum recommended dose of 3200mg per day. The EAC of Banzel® has been steadily increasing over the past few years.

Fycompa® (Perampanel) Product Summary[13]

FDA Approval: 2012

Indications: Fycompa® (perampanel) is indicated for adjunctive therapy in patients with epilepsy 12 years of age and older in the treatment of:

- Partial-onset seizures with or without secondarily generalized seizures
- Primary generalized tonic-clonic (PGTC) seizures

Dosing:

- Perampanel is available as 2mg, 4mg, 6mg, 8mg, 10mg, and 12mg oral tablets.
- The recommended dosing of perampanel for partial-onset seizures in patients not receiving concomitant enzyme-inducing antiepileptic drugs (AEDs) is 2mg once daily at bedtime, increasing the dose by 2mg increments no more frequently than weekly intervals, to a recommended maintenance dose of 8mg to 12mg once daily.
    - A dose of 12mg once daily resulted in somewhat greater reductions in seizure rates than the dose of 8mg once daily, but with a substantial increase in adverse reactions. Individual dosing should be adjusted based on clinical response and tolerability.
- The recommended dosing of perampanel for PGTC seizures in patients not receiving concomitant enzyme-inducing AEDs is 2mg once daily at bedtime, increasing the dose by 2mg increments no more frequently than weekly intervals, to a recommended maintenance dose of 8mg once daily.
    - Patients who are tolerating perampanel well at 8mg once daily and require further control of seizures may benefit from a dose increase up to 12mg once daily if tolerated. Individual dosing should be adjusted based on clinical response and tolerability.

Estimated Acquisition Cost: The EAC of Fycompa® 12mg tablets is $23.78, resulting in a monthly cost of $713.40 at the maximum recommended dose of 12mg per day. The EAC of Fycompa® has been steadily increasing over the past few years.

Recommendations

The College of Pharmacy recommends the following:

1. Revising the existing criteria for Aptiom® (eslicarbazepine) to include its new indication for monotherapy
2. The prior authorization of Spritam® (levetiracetam) with the criteria noted in red
3. The prior authorization of Vimpat® (lacosamide) with the criteria noted in red
4. The prior authorization of Banzel® (rufinamide) with the criteria noted in red
5. The prior authorization of Fycompa® (perampanel) with the criteria noted in red

New proposed criteria specific to each medication is as follows:

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures ~~as adjunctive therapy~~; and
2. ~~Member must be on current antiepileptic drug therapy (Aptiom® is only indicated for adjunctive treatment); and~~
3. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
4. A patient-specific, clinically significant reason why member cannot use oxcarbazepine.
5. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Spritam® (Levetiracetam) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures, myoclonic seizures, or primary generalized tonic-clonic (PGTC) seizures; and
2. A patient-specific, clinically significant reason why the member cannot use generic formulations of levetiracetam.
3. A quantity limit of 60 tablets per 30 days will apply.

Vimpat® (Lacosamide) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least three other medications commonly used for seizures.
4. Members currently stable on Vimpat® and who have a seizure diagnosis will be grandfathered.

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut Syndrome; and
2. Initial prescription must be written by a neurologist; and

3. Member must have failed therapy with at least three other medications commonly used for seizures.
4. Members currently stable on Banzel® and who have a seizure diagnosis will be grandfathered.

Fycompa® (Perampanel) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of partial-onset seizures with or without secondarily generalized seizures or primary generalized tonic-clonic (PGTC) seizures; and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least three other medications commonly used for seizures.
4. Members currently stable on Fycompa® and who have a seizure diagnosis will be grandfathered.

Utilization Details of Seizure Medications: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	35,315	10,676	$323,783.74	$0.28	$9.17	1.43%
GABAPENTIN TAB 600MG	20,218	4,380	$740,626.45	$1.18	$36.63	3.27%
GABAPENTIN TAB 800MG	10,138	1,912	$332,398.23	$1.09	$32.79	1.47%
GABAPENTIN CAP 100MG	8,290	3,225	$53,131.43	$0.21	$6.41	0.23%
GABAPENTIN CAP 400MG	4,984	1,381	$50,931.20	$0.34	$10.22	0.22%
GABAPENTIN SOL 250/5ML	631	130	$47,984.23	$2.52	$76.04	0.21%
NEURONTIN CAP 300MG	30	14	$3,189.48	$3.16	$106.32	0.01%
NEURONTIN TAB 800MG	13	1	$8,304.83	$21.57	$638.83	0.04%
GRALISE TAB 300MG	7	1	$3,786.59	$14.02	$540.94	0.02%
NEURONTIN CAP 100MG	3	3	$23.15	$0.26	$7.72	0.00%
NEURONTIN TAB 600MG	1	1	$506.99	$16.90	$506.99	0.00%
SUBTOTAL	**79,630**	**21,724**	**$1,564,666.32**	**$0.63**	**$19.65**	**6.91%**
BENZODIAZEPINE PRODUCTS						
CLONAZEPAM TAB 1MG	23,465	4,983	$119,247.99	$0.17	$5.08	0.53%
CLONAZEPAM TAB 0.5MG	15,338	4,270	$63,942.49	$0.15	$4.17	0.28%
CLONAZEPAM TAB 2MG	6,501	1,279	$34,381.20	$0.18	$5.29	0.15%
DIAZEPAM GEL 10MG	1,283	714	$515,409.22	$67.53	$401.72	2.27%
ONFI TAB 10MG	908	120	$530,974.56	$19.67	$584.77	2.34%
ONFI TAB 20MG	754	97	$764,113.46	$33.84	$1,013.41	3.37%
CLONAZEP ODT TAB 0.25MG	634	205	$33,843.01	$2.18	$53.38	0.15%
ONFI SUS 2.5MG/ML	536	75	$507,765.95	$32.86	$947.32	2.24%
CLONAZEP ODT TAB 0.5MG	386	103	$16,464.64	$1.77	$42.65	0.07%
DIAZEPAM GEL 20MG	266	138	$131,939.56	$72.94	$496.01	0.58%
CLONAZEP ODT TAB 0.125MG	232	99	$14,112.72	$2.51	$60.83	0.06%
CLONAZEP ODT TAB 1MG	197	67	$7,617.26	$1.70	$38.67	0.03%
DIASTAT ACDL GEL 5-10MG	197	117	$96,457.49	$53.12	$489.63	0.43%
DIAZEPAM GEL 2.5MG	143	87	$46,246.63	$38.41	$323.40	0.20%
DIASTAT ACDL GEL 12.5-	102	49	$70,473.29	$70.26	$690.91	0.31%
CLONAZEP ODT TAB 2MG	57	20	$1,647.16	$1.88	$28.90	0.01%
DIASTAT PED GEL 2.5MG GEL	38	31	$13,135.57	$44.23	$345.67	0.06%
KLONOPIN TAB 2MG	8	1	$1,655.08	$6.90	$206.89	0.01%
KLONOPIN TAB 1MG	5	1	$1,023.95	$7.53	$204.79	0.00%
ONFI TAB 5MG	2	1	$241.58	$4.03	$120.79	0.00%
KLONOPIN TAB 0.5MG	1	1	$128.73	$5.85	$128.73	0.00%
SUBTOTAL	**51,053**	**12,458**	**$2,970,821.54**	**$2.09**	**$58.19**	**13.11%**
OXCARBAZEPINE PRODUCTS						
OXCARBAZEPIN TAB 300MG	10,841	2,505	$202,600.45	$0.62	$18.69	0.89%
OXCARBAZEPIN TAB 600MG	7,553	1,310	$262,366.13	$1.16	$34.74	1.16%
OXCARBAZEPIN TAB 150MG	7,384	2,074	$104,160.18	$0.47	$14.11	0.46%
OXCARBAZEPIN SUS	2,380	411	$495,668.77	$6.59	$208.26	2.19%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
TRILEPTAL SUS	524	87	$250,549.28	$16.15	$478.15	1.11%
OXTELLAR XR TAB 600MG	86	13	$52,535.15	$19.47	$610.87	0.23%
TRILEPTAL TAB 600MG	63	6	$63,646.93	$33.87	$1,010.27	0.28%
OXTELLAR XR TAB 300MG	28	5	$6,109.26	$7.27	$218.19	0.03%
TRILEPTAL TAB 300MG	18	2	$6,051.24	$11.21	$336.18	0.03%
OXTELLAR XR TAB 150MG	7	2	$890.53	$4.24	$127.22	0.00%
TRILEPTAL TAB 150MG	2	2	$282.78	$4.71	$141.39	0.00%
SUBTOTAL	**28,886**	**6,417**	**$1,444,860.70**	**$1.67**	**$50.02**	**6.38%**
LAMOTRIGINE PRODUCTS						
LAMOTRIGINE TAB 100MG	10,593	2,349	$80,268.51	$0.25	$7.58	0.35%
LAMOTRIGINE TAB 25MG	8,182	2,953	$76,821.99	$0.31	$9.39	0.34%
LAMOTRIGINE TAB 200MG	7,618	1,337	$69,377.69	$0.28	$9.11	0.31%
LAMOTRIGINE TAB 150MG	4,042	839	$31,384.15	$0.25	$7.76	0.14%
LAMOTRIGINE CHW 25MG	412	73	$14,455.81	$1.16	$35.09	0.06%
LAMICTAL TAB 200MG	175	19	$110,440.78	$21.38	$631.09	0.49%
LAMOTRIGINE CHW 5MG	141	52	$4,561.69	$1.08	$32.35	0.02%
LAMICTAL TAB 150MG	120	12	$84,676.07	$23.57	$705.63	0.37%
LAMICTAL TAB 100MG	94	16	$62,518.41	$22.42	$665.09	0.28%
LAMICTAL ODT TAB 100MG	91	12	$55,440.05	$20.70	$609.23	0.24%
LAMOTRIGINE TAB 200MG ER	84	16	$31,197.56	$12.45	$371.40	0.14%
LAMOTRIGINE TAB 300MG ER	76	16	$47,939.03	$20.10	$630.78	0.21%
LAMICTAL XR TAB 200MG	70	11	$49,985.06	$23.80	$714.07	0.22%
LAMOTRIGINE TAB 50MG ER	63	9	$16,351.09	$8.74	$259.54	0.07%
LAMOTRIGINE TAB 100MG ER	50	9	$26,028.33	$17.35	$520.57	0.11%
LAMOTRIGINE TAB 250MG ER	38	7	$37,665.98	$33.72	$991.21	0.17%
LAMICTAL ODT TAB 25MG	33	10	$17,650.53	$17.83	$534.86	0.08%
LAMICTAL TAB 25MG	28	6	$13,097.29	$18.66	$467.76	0.06%
LAMICTAL ODT TAB 50MG	27	9	$10,835.75	$14.49	$401.32	0.05%
LAMICTAL ODT TAB 200MG	25	4	$16,261.07	$21.68	$650.44	0.07%
LAMICTAL XR TAB 250MG	21	3	$27,253.60	$44.75	$1,297.79	0.12%
LAMICTAL XR TAB 300MG	13	3	$17,270.92	$44.28	$1,328.53	0.08%
LAMOTRIGINE TAB 100MG	11	4	$4,667.00	$16.09	$424.27	0.02%
LAMICTAL CHW 25MG	11	1	$41,061.43	$121.84	$3,732.86	0.18%
LAMOTRIGINE TAB 50MG	8	5	$2,549.55	$10.62	$318.69	0.01%
LAMICTAL XR TAB 50MG	7	2	$2,833.06	$15.15	$404.72	0.01%
LAMICTAL XR TAB 100MG	6	2	$5,065.66	$28.14	$844.28	0.02%
LAMOTRIGINE TAB 25MG	4	3	$1,431.96	$11.93	$357.99	0.01%
LAMOTRIGINE TAB 25MG ER	3	2	$515.97	$6.53	$171.99	0.00%
LAMOTRIGINE TAB 200MG	3	2	$1,724.31	$19.16	$574.77	0.01%
LAMICTAL STARTER KIT	1	1	$453.77	$16.21	$453.77	0.00%
LAMICTAL XR TAB 25MG	1	1	$242.27	$8.08	$242.27	0.00%
SUBTOTAL	**32,051**	**7,788**	**$962,026.34**	**$0.98**	**$30.02**	**4.25%**
LEVETIRACETAM PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
LEVETIRACETA SOL	10,135	1,488	$291,674.22	$0.96	$28.78	1.29%
LEVETIRACETA TAB 500MG	9,382	2,053	$135,907.64	$0.48	$14.49	0.60%
LEVETIRACETA TAB 1000MG	4,714	728	$154,975.90	$1.09	$32.88	0.68%
LEVETIRACETA TAB 750MG	3,530	645	$78,704.33	$0.74	$22.30	0.35%
LEVETIRACETA TAB 250MG	1,464	353	$16,231.68	$0.38	$11.09	0.07%
LEVETIRACETA TAB 500MG	577	104	$19,384.52	$1.11	$33.60	0.09%
LEVETIRACETA TAB 750MG	511	86	$29,120.70	$1.90	$56.99	0.13%
KEPPRA TAB 1000MG	104	11	$103,399.96	$34.13	$994.23	0.46%
KEPPRA SOL 100MG/ML	95	13	$50,082.25	$17.47	$527.18	0.22%
KEPPRA XR TAB 500MG	91	9	$67,663.27	$24.80	$743.55	0.30%
KEPPRA XR TAB 750MG	86	9	$79,384.23	$28.95	$923.07	0.35%
KEPPRA TAB 500MG	56	8	$29,914.65	$17.77	$534.19	0.13%
KEPPRA TAB 750MG	44	6	$38,769.17	$24.85	$881.12	0.17%
LEVETIRACETM INJ 500/5ML	37	3	$4,184.28	$15.67	$113.09	0.02%
KEPPRA TAB 250MG	13	3	$5,029.03	$12.89	$386.85	0.02%
KEPPRA INJ 500/5ML	1	1	$127.61	$18.23	$127.61	0.00%
SUBTOTAL	**30,840**	**5,520**	**$1,104,553.44**	**$1.20**	**$35.82**	**4.88%**
TOPIRAMATE PRODUCTS						
TOPIRAMATE TAB 50MG	9,372	2,891	$74,212.29	$0.26	$7.92	0.33%
TOPIRAMATE TAB 100MG	8,815	1,904	$76,369.03	$0.28	$8.66	0.34%
TOPIRAMATE TAB 25MG	7,936	3,208	$53,702.71	$0.22	$6.77	0.24%
TOPIRAMATE TAB 200MG	3,611	611	$48,325.59	$0.43	$13.38	0.21%
TOPIRAMATE CAP 25MG	469	97	$34,955.02	$2.50	$74.53	0.15%
TOPIRAMATE CAP 15MG	429	110	$20,196.99	$1.55	$47.08	0.09%
TOPAMAX TAB 100MG	60	6	$44,702.50	$24.83	$745.04	0.20%
TROKENDI XR CAP 100MG	28	5	$13,749.58	$16.37	$491.06	0.06%
TOPAMAX TAB 200MG	26	3	$22,825.22	$25.94	$877.89	0.10%
TOPAMAX SPR CAP 25MG	22	3	$33,314.35	$50.48	$1,514.29	0.15%
TROKENDI XR CAP 200MG	20	2	$14,248.77	$23.75	$712.44	0.06%
TOPAMAX TAB 25MG	19	3	$3,530.36	$6.19	$185.81	0.02%
TROKENDI XR CAP 50MG	15	5	$3,611.01	$8.02	$240.73	0.02%
TROKENDI XR CAP 25MG	12	2	$2,239.75	$6.22	$186.65	0.01%
TOPAMAX SPR CAP 15MG	3	1	$634.73	$7.05	$211.58	0.00%
TOPAMAX TAB 50MG	3	1	$1,667.34	$18.53	$555.78	0.01%
SUBTOTAL	**30,840**	**8,852**	**$448,285.24**	**$0.47**	**$14.54**	**1.98%**
DIVALPROEX, VALPROATE, & VALPROIC ACID PRODUCTS						
DIVALPROEX TAB 500MG DR	8,231	1,609	$242,609.61	$0.98	$29.48	1.07%
DIVALPROEX TAB 500MG ER	7,460	1,453	$1,107,319.21	$4.87	$148.43	4.89%
DIVALPROEX TAB 250MG DR	6,101	1,454	$61,070.18	$0.33	$10.01	0.27%
DIVALPROEX TAB 250MG ER	3,642	841	$329,694.65	$2.99	$90.53	1.46%
DIVALPROEX CAP 125MG	2,405	394	$312,816.67	$4.46	$130.07	1.38%
VALPROIC ACD SYP 250/5ML	2,206	308	$29,727.61	$0.46	$13.48	0.13%
DIVALPROEX TAB 125MG DR	1,743	427	$14,840.25	$0.28	$8.51	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
VALPROIC ACD CAP 250MG	1,475	283	$35,000.79	$0.80	$23.73	0.15%
DEPAKOTE SPR CAP 125MG	312	39	$82,584.89	$8.69	$264.70	0.36%
DEPAKOTE ER TAB 500MG	277	56	$87,851.72	$10.57	$317.15	0.39%
VALPROIC ACD SOL 250/5ML	134	65	$1,521.75	$0.37	$11.36	0.01%
DEPAKOTE TAB 500MG DR	124	16	$52,500.53	$14.77	$423.39	0.23%
DEPAKOTE TAB 250MG DR	82	14	$12,653.05	$5.14	$154.31	0.06%
DEPAKOTE ER TAB 250MG	78	8	$23,719.53	$10.40	$304.10	0.10%
VALPROATE INJ 500/5ML	40	1	$3,523.38	$20.48	$88.08	0.02%
DEPAKENE SYP 250/5ML	30	4	$529.96	$0.59	$17.67	0.00%
STAVZOR CAP 250MG	20	8	$4,522.63	$8.92	$226.13	0.02%
DEPAKOTE TAB 125MG DR	17	2	$1,387.80	$2.72	$81.64	0.01%
VALPROATE INJ 100MG/ML	10	1	$6,138.98	$20.46	$613.90	0.03%
STAVZOR CAP 125MG	4	1	$338.91	$2.82	$84.73	0.00%
STAVZOR CAP 500MG	1	1	$296.85	$9.90	$296.85	0.00%
SUBTOTAL	**34,392**	**6,985**	**$2,410,648.95**	**$2.34**	**$70.09**	**10.64%**
PHENYTOIN PRODUCTS						
PHENYTOIN EX CAP 100MG	6,899	1,086	$202,499.56	$0.99	$29.35	0.89%
DILANTIN CAP 100MG	1,044	136	$88,170.39	$2.78	$84.45	0.39%
PHENYTOIN SUS 125/5ML	309	47	$11,844.17	$1.37	$38.33	0.05%
PHENYTOIN CHW 50MG	306	48	$11,751.18	$1.24	$38.40	0.05%
DILANTIN CHW 50MG	177	26	$14,111.04	$2.72	$79.72	0.06%
DILANTIN CAP 30MG	93	13	$3,692.31	$1.32	$39.70	0.02%
PHENYTEK CAP 200MG	66	12	$7,139.87	$3.82	$108.18	0.03%
PHENYTEK CAP 300MG	58	12	$5,021.11	$2.49	$86.57	0.02%
DILANTIN-125 SUS 125/5ML	25	3	$2,377.62	$3.17	$95.10	0.01%
PHENYTOIN EX CAP 300MG	10	3	$336.75	$1.12	$33.68	0.00%
SUBTOTAL	**8,987**	**1,386**	**$346,944.00**	**$1.30**	**$38.61**	**1.53%**
CARBAMAZEPINE PRODUCTS						
CARBAMAZEPIN TAB 200MG	4,846	969	$284,587.92	$1.96	$58.73	1.26%
CARBAMAZEPIN CHW 100MG	981	207	$40,022.87	$1.36	$40.80	0.18%
EPITOL TAB 200MG	845	224	$21,504.59	$0.85	$25.45	0.09%
CARBAMAZEPIN TAB 200MG	708	149	$66,226.12	$3.03	$93.54	0.29%
CARBAMAZEPIN TAB 400MG	642	96	$86,685.12	$4.42	$135.02	0.38%
CARBAMAZEPIN CAP 300MG	557	80	$64,689.56	$3.84	$116.14	0.29%
CARBAMAZEPIN SUS 100/5ML	339	44	$46,014.83	$4.70	$135.74	0.20%
CARBAMAZEPIN CAP 200MG	331	49	$39,364.63	$3.85	$118.93	0.17%
TEGRETOL-XR TAB 100MG	264	53	$16,890.15	$2.06	$63.98	0.07%
CARBAMAZEPIN CAP 100MG	135	30	$12,815.77	$3.25	$94.93	0.06%
TEGRETOL TAB 200MG	122	11	$31,219.15	$8.58	$255.89	0.14%
TEGRETOL-XR TAB 400MG	111	13	$25,433.97	$7.17	$229.13	0.11%
TEGRETOL-XR TAB 200MG	98	14	$19,897.91	$6.25	$203.04	0.09%
TEGRETOL SUS 100/5ML	86	9	$22,330.59	$8.38	$259.66	0.10%
CARBATROL CAP 300MG	71	9	$11,364.72	$5.34	$160.07	0.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
CARBATROL CAP 200MG	65	6	$14,306.36	$6.91	$220.10	0.06%
CARBATROL CAP 100MG	5	1	$299.35	$2.00	$59.87	0.00%
SUBTOTAL	**10,206**	**1,964**	**$803,653.61**	**$2.61**	**$78.74**	**3.55%**
PREGABALIN PRODUCTS						
LYRICA CAP 150MG	3,882	701	$1,288,587.80	$11.26	$331.94	5.69%
LYRICA CAP 75MG	2,868	751	$892,437.60	$10.57	$311.17	3.94%
LYRICA CAP 100MG	2,414	544	$862,942.94	$12.12	$357.47	3.81%
LYRICA CAP 50MG	1,394	410	$472,376.14	$11.76	$338.86	2.08%
LYRICA CAP 300MG	1,206	179	$370,864.24	$10.28	$307.52	1.64%
LYRICA CAP 200MG	852	153	$248,158.83	$9.94	$291.27	1.10%
LYRICA CAP 225MG	380	68	$121,673.15	$10.73	$320.19	0.54%
LYRICA CAP 25MG	122	51	$34,336.92	$9.36	$281.45	0.15%
LYRICA SOL 20MG/ML	1	1	$584.24	$38.95	$584.24	0.00%
SUBTOTAL	**13,119**	**2,858**	**$4,291,961.86**	**$11.11**	**$327.16**	**18.94%**
ZONISAMIDE PRODUCTS						
ZONISAMIDE CAP 100MG	3,066	442	$59,621.30	$0.66	$19.45	0.26%
ZONISAMIDE CAP 50MG	793	148	$12,033.85	$0.51	$15.18	0.05%
ZONISAMIDE CAP 25MG	559	123	$7,683.67	$0.45	$13.75	0.03%
ZONEGRAN CAP 100MG	24	2	$17,441.20	$24.36	$726.72	0.08%
ZONEGRAN CAP 25MG	10	1	$2,591.26	$8.64	$259.13	0.01%
SUBTOTAL	**4,452**	**716**	**$99,371.28**	**$0.75**	**$22.32**	**0.44%**
LACOSAMIDE PRODUCTS						
VIMPAT TAB 200MG	1,582	198	$995,609.38	$21.54	$629.34	4.39%
VIMPAT TAB 100MG	1,352	224	$786,668.08	$20.19	$581.86	3.47%
VIMPAT TAB 50MG	661	137	$239,353.30	$12.64	$362.11	1.06%
VIMPAT TAB 150MG	596	116	$357,731.59	$20.25	$600.22	1.58%
VIMPAT SOL 10MG/ML	557	78	$318,932.40	$20.03	$572.59	1.41%
VIMPAT INJ 200MG/20ML	37	1	$16,477.57	$61.95	$445.34	0.07%
SUBTOTAL	**4,785**	**754**	**$2,714,772.32**	**$19.68**	**$567.35**	**11.98%**
PHENOBARBITAL PRODUCTS						
PHENOBARB TAB 64.8MG	1,010	128	$19,316.01	$0.62	$19.12	0.09%
PHENOBARB TAB 32.4MG	861	111	$20,330.68	$0.77	$23.61	0.09%
PHENOBARB ELX 20MG/5ML	736	127	$45,062.82	$2.24	$61.23	0.20%
PHENOBARB SOL 20MG/5ML	659	131	$37,772.85	$1.99	$57.32	0.17%
PHENOBARB TAB 97.2MG	426	51	$9,126.02	$0.70	$21.42	0.04%
PHENOBARB TAB 16.2MG	228	32	$4,096.13	$0.60	$17.97	0.02%
PHENOBARB TAB 30MG	99	17	$1,705.16	$0.57	$17.22	0.01%
PHENOBARB TAB 60MG	64	14	$796.49	$0.40	$12.45	0.00%
PHENOBARB TAB 15MG	60	10	$1,072.57	$0.62	$17.88	0.00%
PHENOBARB TAB 100MG	24	7	$308.78	$0.44	$12.87	0.00%
SUBTOTAL	**4,167**	**628**	**$139,587.51**	**$1.13**	**$33.50**	**0.62%**
ETHOSUXIMIDE PRODUCTS						
ETHOSUXIMIDE CAP 250MG	770	130	$104,339.84	$4.43	$135.51	0.46%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
ETHOSUXIMIDE SOL 250/5ML	554	97	$49,948.72	$3.06	$90.16	0.22%
ZARONTIN CAP 250MG	26	3	$5,643.57	$7.24	$217.06	0.02%
SUBTOTAL	**1,350**	**230**	**$159,932.13**	**$3.93**	**$118.47**	**0.71%**
RUFINAMIDE PRODUCTS						
BANZEL TAB 400MG	510	65	$811,810.82	$53.83	$1,591.79	3.58%
BANZEL SUS 40MG/ML	269	40	$217,806.66	$29.40	$809.69	0.96%
BANZEL TAB 200MG	116	24	$50,786.15	$14.76	$437.81	0.22%
SUBTOTAL	**895**	**129**	**$1,080,403.63**	**$41.67**	**$1,207.15**	**4.77%**
ACETAZOLAMIDE PRODUCTS						
ACETAZOLAMID TAB 250MG	497	138	$63,444.99	$4.26	$127.66	0.28%
ACETAZOLAMID CAP 500MG	164	72	$27,781.46	$5.57	$169.40	0.12%
ACETAZOLAMID TAB 125MG	61	13	$5,927.10	$3.47	$97.17	0.03%
SUBTOTAL	**722**	**223**	**$97,153.55**	**$4.50**	**$134.56**	**0.43%**
PRIMIDONE PRODUCTS						
PRIMIDONE TAB 50MG	491	104	$5,452.79	$0.33	$11.11	0.02%
PRIMIDONE TAB 250MG	347	43	$5,926.33	$0.55	$17.08	0.03%
MYSOLINE TAB 250MG	20	3	$53,416.25	$89.03	$2,670.81	0.24%
MYSOLINE TAB 50MG	2	1	$21.78	$0.36	$10.89	0.00%
SUBTOTAL	**860**	**151**	**$64,817.15**	**$2.32**	**$75.37**	**0.29%**
FELBAMATE PRODUCTS						
FELBAMATE TAB 600MG	257	27	$103,983.05	$13.86	$404.60	0.46%
FELBAMATE SUS 600/5ML	92	9	$77,098.98	$27.92	$838.03	0.34%
FELBATOL TAB 600MG	62	8	$58,104.61	$31.48	$937.17	0.26%
FELBAMATE TAB 400MG	60	8	$11,233.91	$6.14	$187.23	0.05%
FELBATOL TAB 400MG	53	5	$23,127.41	$14.62	$436.37	0.10%
FELBATOL SUS 600/5ML	12	2	$10,960.89	$30.45	$913.41	0.05%
SUBTOTAL	**536**	**59**	**$284,508.85**	**$17.91**	**$530.80**	**1.26%**
VIGABATRIN PRODUCTS						
SABRIL POW 500MG	146	18	$1,325,828.60	$302.70	$9,081.02	5.85%
SABRIL TAB 500MG	6	2	$60,275.46	$334.86	$10,045.91	0.27%
SUBTOTAL	**152**	**20**	**$1,386,104.06**	**$303.97**	**$9,119.11**	**6.12%**
PERAMPANEL PRODUCTS						
FYCOMPA TAB 6MG	127	33	$63,244.44	$16.87	$497.99	0.28%
FYCOMPA TAB 4MG	94	31	$46,714.90	$17.02	$496.97	0.21%
FYCOMPA TAB 2MG	62	27	$16,202.34	$9.17	$261.33	0.07%
FYCOMPA TAB 8MG	59	16	$30,753.22	$17.37	$521.24	0.14%
FYCOMPA TAB 10MG	5	3	$2,086.19	$13.91	$417.24	0.01%
FYCOMPA TAB 12MG	1	1	$631.73	$21.06	$631.73	0.00%
SUBTOTAL	**348**	**111**	**$159,632.82**	**$15.63**	**$458.72**	**0.70%**
TIAGABINE PRODUCTS						
TIAGABINE TAB 4MG	119	17	$54,392.75	$15.60	$457.08	0.24%
GABITRIL TAB 12MG	28	3	$10,651.44	$12.68	$380.41	0.05%
GABITRIL TAB 16MG	28	3	$15,512.61	$18.67	$554.02	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
TIAGABINE TAB 2MG	14	2	$4,762.19	$18.82	$340.16	0.02%
GABITRIL TAB 4MG	11	4	$6,122.58	$13.61	$556.60	0.03%
GABITRIL TAB 2MG	10	1	$4,226.37	$14.09	$422.64	0.02%
SUBTOTAL	**210**	**30**	**$95,667.94**	**$15.53**	**$455.56**	**0.42%**
METHSUXIMIDE PRODUCTS						
CELONTIN CAP 300MG	70	7	$10,911.69	$5.36	$155.88	0.05%
SUBTOTAL	**70**	**7**	**$10,911.69**	**$5.36**	**$155.88**	**0.05%**
ESLICARBAZEPINE PRODUCTS						
APTIOM TAB 800MG	21	4	$10,357.97	$16.36	$493.24	0.05%
APTIOM TAB 600MG	3	1	$3,808.92	$42.32	$1,269.64	0.02%
APTIOM TAB 400MG	1	1	$699.40	$38.86	$699.40	0.00%
SUBTOTAL	**25**	**6**	**$14,866.29**	**$20.06**	**$594.65**	**0.07%**
EZOGABINE PRODUCTS						
POTIGA TAB 50MG	2	1	$359.50	$5.99	$179.75	0.00%
SUBTOTAL	**2**	**1**	**$359.50**	**$5.99**	**$179.75**	**0.00%**
TOTAL	**338,578**	**47,248***	**$22,656,510.72**	**$2.23**	**$66.92**	**100.00%**

*Total number of unduplicated members.

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Appendix K

30-Day Notice to Prior Authorize Solaraze® (Diclofenac 3% Gel)

Oklahoma Health Care Authority
February 2016

Actinic Keratosis Background Information[1,2,3,4,5]

An actinic keratosis (AK), also called a solar keratosis or a sun spot, is a scaly, crusty lesion caused by damage from the sun's ultraviolet (UV) rays. AKs typically appear on sun-exposed areas such as the face, bald scalp, lips, ears, the back of the hands and forearms, shoulders, and neck, and are often elevated, rough in texture, and resemble warts. AKs typically are very small in the beginning and develop slowly. Patients will often have multiple AKs at the same time. AKs are considered a precursor of skin cancer, or a precancerous spot. If left untreated, up to ten percent of AKs develop into squamous cell carcinoma, the second most common form of skin cancer. In rarer instances, AKs may also develop into basal cell carcinoma, the most common form of skin cancer.

Treatment options for AKs include destructive therapies (e.g., surgery, cryotherapy, dermabrasion), topical medications (e.g., 5-fluorouracil [5-FU], imiquimod, ingenol mebutate, diclofenac), chemical peels (e.g., trichloroacetic acid), and photodynamic therapy (PDT). In general, lesion-directed treatments, such as cryotherapy and surgical procedures, are the primary approach for isolated lesions. Field-directed therapies, such as topical 5-FU, imiquimod, ingenol mebutate, and diclofenac, are particularly useful for treating areas with multiple AKs.

Solaraze® (Diclofenac 3% Gel) Product Summary[6]

FDA Approval: 2000

Indications: Solaraze® (diclofenac 3% gel) is indicated for the topical treatment of actinic keratosis (AK) in adult patients.

Dosing:

- Solaraze® is available as a 3% diclofenac sodium topical gel, and is available in 100g tubes. Each gram of gel contains 30mg of diclofenac sodium.
- The recommended dosage of Solaraze® is to apply to lesions twice daily. Solaraze® gel should be smoothed onto the affected skin gently.
- Solaraze® gel is applied to adequately cover each lesion. The amount of gel needed depends on the size of the lesion site. Normally 0.5g of gel is used on each 5cm x 5cm lesion site.
- Sun avoidance, including avoidance of exposure to sunlight and the use of sunlamps, is indicated during therapy.
- The recommended duration of therapy is from 60 days to 90 days.

- Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Cost: There is a generic product available for Solaraze®. The state maximum allowable cost (SMAC) of generic diclofenac 3% topical gel is $7.17 per gram, resulting in a cost of $717.00 per 100g tube.

Recommendations

The College of Pharmacy recommends the prior authorization of Solaraze® (diclofenac 3% gel) with the following criteria:

Solaraze® (Diclofenac 3% Gel) Approval Criteria:

1. An FDA approved diagnosis of actinic keratosis (AK); and
2. Patient-specific information must be documented on the prior authorization form, including all of the following:
    a. Number of AK lesions being treated; and
    b. Sizes of each lesion being treated; and
    c. Anticipated duration of treatment; and
3. Approval quantity and length will be based on patient-specific information provided, in accordance with Solaraze® prescribing information and FDA approved dosing regimen.

[1] Skin Cancer Foundation: Actinic Keratosis. Available online at: http://www.skincancer.org/skin-cancer-information/actinic-keratosis. Last revised 7/24/15. Last accessed 1/26/16.
[2] American Academy of Dermatology: Actinic Keratosis. Available online at: https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis. Last accessed 1/26/16.
[3] American Osteopathic College of Dermatology: Actinic Keratosis. Available online at: http://www.aocd.org/?ActinicKeratosis. Last accessed 1/26/16.
[4] National Cancer Institute at the National Institutes of Health: General Information About Skin Cancer. Available online at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0032519/#CDR0000258035__202. Last accessed 1/26/16.
[5] UpToDate®: Treatment of Actinic Keratosis. Available online at: http://www.uptodate.com/contents/treatment-of-actinic-keratosis. Last revised 1/4/16. Last accessed 1/26/16.
[6] Solaraze® Prescribing Information, Fougera Pharmaceuticals Inc. Available online at: http://www.solaraze.com/pdf/solaraze_pi.pdf. Last accessed 1/26/16.

Appendix L

Calendar Year 2015 Annual Review of Ulcerative Colitis Medications and 30-Day Notice to Prior Authorize Uceris® (Budesonide Extended-Release Tablets), Uceris® (Budesonide Rectal Foam), and Miscellaneous Mesalamine Products

Oklahoma Health Care Authority
February 2016

Ulcerative Colitis Background Information[1,2,3,4]

Ulcerative colitis (UC) is a chronic inflammatory disease characterized by relapsing and remitting episodes of mucosal inflammation in the colon and in 95% of cases, the rectum. The hallmark symptom patients present with is bloody diarrhea often accompanied by symptoms of abdominal pain, rectal urgency, and tenesmus. UC is estimated to affect 500,000 people in the United States with an incidence rate of 8 to 12 per 100,000 per year. Annually, UC accounts for a quarter million physician visits, 30,000 hospitalizations, over a million workdays lost, and direct medical costs exceeding four billion dollars.

UC and Crohn's Disease (CD) are both part of a group of conditions known as Inflammatory Bowel Disease but have several notable differences. UC affects only the colon while CD most commonly affects the ileum and the beginning of the colon but it can affect any part of the gastrointestinal tract, from the mouth to the anus. CD can affect the entire thickness of the bowel wall, while UC only involves the innermost lining of the colon. In CD, the inflammation can skip parts of bowel leaving normal areas in between patches of inflammation which does not occur in UC.

UC treatment goals include induction and maintenance of remission, reducing need for long-term corticosteroid use, minimizing cancer risks, and improved quality of life. Clinical management of UC is guided by severity of disease which can range from mild to fulminant based on frequency and severity of diarrhea, presence of systemic symptoms, and laboratory abnormalities. Pharmacological treatment includes aminosalicylates (sulfasalazine, mesalamine, olsalazine, and balsalazide), corticosteroids (oral and rectal), immunomodulators (methotrexate, azathioprine), and biologic therapies (infliximab, adalimumab, vedolizumab, and golimumab).

Ulcerative Colitis Practice Guidelines in Adults by the American College of Gastroenterology published in 2010 recommend first-line treatment for mild-to-moderate disease severity with topical mesalamine, oral aminosalicylates, or topical steroids. Topical mesalamine is superior to topical steroids or oral aminosalicylates if the patient is willing to use rectal therapy. The combination of topical and oral aminosalicylates is more effective than either used individually. Updated guidelines by The American College of Gastroenterology Committee are currently in progress.

Current Prior Authorization Criteria

Mesalamine Rectal Kits Approval Criteria:

1. The provider must document a medical reason the member cannot use a standard dosage form or the standard dosage form has been used and was ineffective. The prescriber must indicate reason for use of the non-standard dosage form.

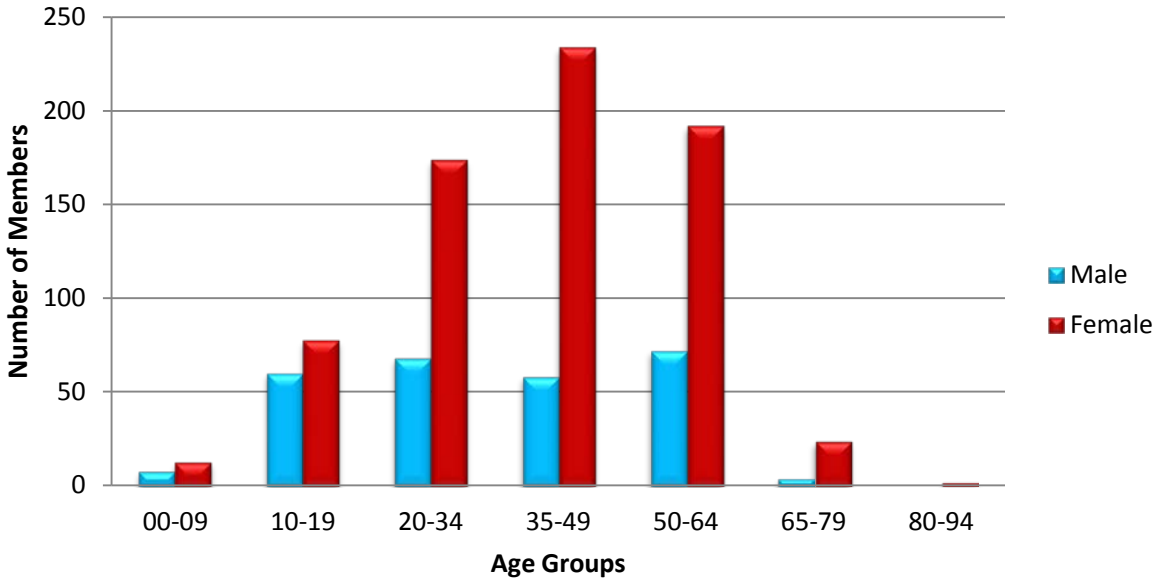
Utilization of UC Medications: Calendar Year 2015

Comparison of Calendar Years

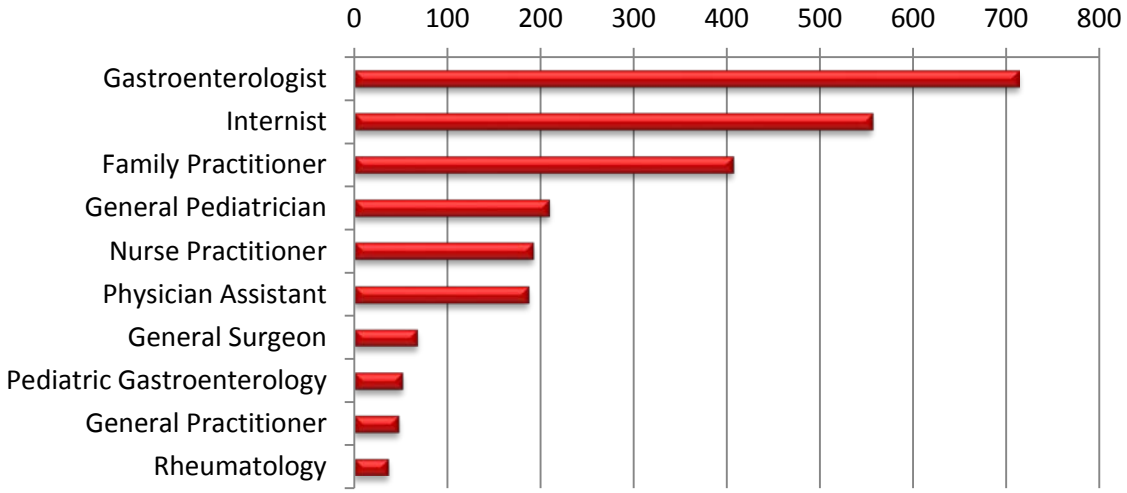
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	652	2,661	$933,054.62	$350.64	$12.12	374,070	77,009
2015	642	2,569	$1,042,801.08	$405.92	$13.75	383,894	75,867
% Change	**-1.50%**	**-3.50%**	**11.80%**	**15.80%**	**13.40%**	**2.60%**	**-1.50%**
Change	**-10**	**-92**	**$109,746.46**	**$55.28**	**$1.63**	**9,824**	**-1,142**

*Total number of unduplicated members.

Demographics of Members Utilizing UC Medications



Top Prescriber Specialties of Utilizing UC Medications by Number of Claims



Prior Authorization of UC Medications

There were 63 prior authorization requests submitted for UC medications during calendar year 2015. The following chart shows the status of the submitted petitions.

Status of Petitions

Market News and Updates[5,6,7]

Patent Expirations:

- Pentasa® (mesalamine controlled-release tablets), Dipentum® (olsalazine capsules), and Cortifoam® (10% hydrocortisone rectal aerosol foam): There are no unexpired patents; however, no generic formulations are available at this time.
- Delzicol® (mesalamine delayed-release tablets): April 2020
- Lialda® (mesalamine delayed-release tablets): June 2020
- Asacol® HD (mesalamine delayed-release tablets): November 2021
- Canasa® (mesalamine suppositories): June 2028
- Apriso® (mesalamine extended-release tablets): May 2030

Uceris® (Budesonide Extended-Release Tablets) Product Summary[8]

Indications: Uceris® (budesonide extended-release tablets) is a glucocorticosteroid indicated for the induction of remission in patients with active, mild-to-moderate ulcerative colitis.

Dosing:

- Uceris® (budesonide extended-release tablets) is available as 9mg extended-release tablets.
- The recommended dose for the induction of remission in adult patients with active, mild-to-moderate ulcerative colitis is one 9mg tablet to be taken once daily by mouth in the morning with or without food for up to eight weeks.

Mechanism of Action:

- Budesonide has high topical glucocorticosteroid (GCS) activity and substantial first-pass elimination. The formulation contains budesonide in an extended release tablet core. The tablet core is enteric coated to protect dissolution in gastric juice which delays budesonide release until exposure to a pH ≥ 7 in the small intestine. Upon disintegration of the coating, the core matrix provides extended-release of budesonide in a time dependent manner.

Contraindications: Known hypersensitivity to budesonide or any of the ingredients in Uceris®.

Safety:

- Hypercorticism and Adrenal Suppression: Since Uceris® is a glucocorticosteroid, general warnings concerning glucocorticoids should be followed.
- Transferring Patients from Systemic Glucocorticoids: There is risk of impaired adrenal function when transferring from glucocorticoid treatment with higher systemic effects to glucocorticoid treatment with lower systemic effects, such as Uceris®. Patients should be tapered slowly from systemic corticosteroids if transferring to Uceris®.
- Immunosuppression: There is risk for potential worsening of infections (e.g., existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex). Uceris® should be used with caution in patients with these infections. More serious or even fatal courses of chickenpox or measles can occur in susceptible patients.

Adverse Reactions: The most common adverse reactions experienced during clinical studies (incidence ≥ 2%) were headache, nausea, decreased blood cortisol, upper abdominal pain, fatigue, flatulence, abdominal distension, acne, urinary tract infection, arthralgia, and constipation.

Efficacy:

- Two similarly-designed, randomized, double-blind, placebo-controlled studies were conducted in a total of 970 adult patients with active, mild-to-moderate UC which was defined as an Ulcerative Colitis Disease Activity Index (UCDAI) of ≥ 4 and ≤ 10. UCDAI is a four-component scale (total score of 0 to 12) that encompasses the clinical assessments of stool frequency, rectal bleeding, mucosal appearance, and physician's

rating of disease activity (score of 0 to 3 for each of the components). The baseline median UCAI score in both studies was 7.

- Both studies compared Uceris® 9mg and 6mg with placebo and included an active reference arm (mesalamine 2.4 grams in Study 1; and budesonide 9mg not approved for UC in Study 2).
- The primary endpoint was induction of remission after eight weeks of treatment which was defined as a UCDAI score of ≤ 1, with subscores of 0 for rectal bleeding, stool frequency, and mucosal appearance and a ≥ 1 point reduction in an endoscopy-only score.
- In both studies, Uceris® 9mg extended-release tablets demonstrated superiority to placebo in inducing remission.

Treatment Group	Study 1 n/N (%)	Study 2 n/N (%)
Uceris® 9mg	22/123 (17.9)	19/109 (17.4)
Uceris® 6mg	16/121 (13.2)	9/109 (8.3)
mesalamine 2.4 grams	15/124 (12.1)	N/A
budesonide 9mg	N/A	13/103 (12.6)
Placebo	9/121 (7.4)	4/89 (4.5)
Treatment Differences between Uceris® 9mg and placebo (95% CI)	10.4% (2.2%, 18.7%)	12.9% (4.6%, 21.3%)

Cost Comparison:

Drug	Package Size	EAC	SMAC	Cost per Month
Uceris® 9mg (budesonide ER tablets)	**30 tablet bottle**	**$56.76/tablet**		**$1,702.80**
budesonide 3mg capsules	varies		$9.05/capsule	$271.50
prednisone 10mg tablet	varies		$0.17/tablet	$30.60*
sulfasalazine 500mg tablet	varies		$0.18/tablet	$21.60[+]
mesalamine rectal enema	60 mL		$0.22/mL	$396.00
hydrocortisone rectal enema	60 mL		$0.09/mL	$162.00

EAC = estimated acquisition cost
SMAC = state maximum allowed cost
*Based on maximum recommended dosing of 60mg/day
[+]Based on maintenance dose of 2 grams/day

Uceris® (Budesonide Rectal Foam) Product Summary[9,10]

Indications: Uceris® (budesonide rectal foam) is a glucocorticosteroid indicated for the induction of remission in patients with active, mild-to-moderate distal ulcerative colitis extending up to 40cm from the anal verge.

Dosing:

- Uceris® (budesonide rectal foam) is available as rectal foam that contains 2mg budesonide per metered dose.

- The recommended dose is one metered dose administered rectally twice daily for two weeks followed by one metered dose administered once daily for four weeks.
- Uceris® rectal foam is for rectal administration only.
- The canister should be warmed in the hands while shaking it vigorously for 10 to 15 seconds prior to use.

Mechanism of Action: Budesonide has glucocorticosteroid (GCS) activity.

Contraindications: Uceris® rectal foam is contraindicated in patients with a history of a known hypersensitivity to budesonide or any of the ingredients of Uceris® rectal foam. Reactions have included anaphylaxis.

Safety:

- Hypercorticism and Adrenal Suppression: General warnings concerning glucocorticosteroids should be followed.
- Impaired Adrenal Function in Patients Transferred from Other Glucocorticoids: Patients should be tapered slowly from glucocorticosteroids with high systemic effects, and monitored for withdrawal symptoms and unmasking of allergies (e.g., rhinitis, eczema).
- Increased Risk of Infection Including Serious and Fatal Chicken Pox and Measles: Patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex should be monitored due to the increased risk of infection.
- Flammable Contents: The contents of Uceris® rectal foam are flammable. Patients should be instructed to avoid fire, flame, and smoking during and immediately following administration.

Adverse Reactions: The most common adverse reactions experienced during clinical studies (incidence ≥ 2%) were decreased blood cortisol, adrenal insufficiency, and nausea.

Efficacy:

- The safety and efficacy of Uceris® rectal foam were based on two studies involving 546 adult patients with active, mild-to-moderate distal ulcerative colitis with disease extending at least 5cm but no further than 40cm from the anal verge (confirmed by endoscopy). The primary endpoint was the percentage of patients in remission after six weeks of treatment, defined as a decrease or no change in the stool frequency subscore from baseline, a rectal bleeding subscore of 0, and an endoscopy score of 0 or 1.
- Maintenance use of oral and rectal corticosteroids and rectal 5-aminosalicylic acid (5-ASA) products were prohibited during the course of the trials, but were allowed as rescue therapy.
- Oral 5-ASA products were allowed at doses ≤ 4.8 grams/day. Concomitant oral 5-ASA use at baseline was 59% and 51% in Studies 1 and 2, respectively.
- In both studies, the proportion of patients in remission at week six was greater with Uceris® rectal foam versus placebo (study 1: 38.3% vs. 25.8%, $p = 0.032$; study 2: 44% versus 22.4%, $p < 0.001$).

Cost Comparison:

Drug	Package Size	EAC	SMAC	Cost per Month
Uceris® rectal foam	**2 x (33.4 grams)[¥]**	**$8.09/gram**	**NA**	**$540.41**
Sulfasalazine 500mg tablet	varies	NA	$0.18/tablet	$21.60[+]
Mesalamine rectal enema	60 mL	NA	$0.23/mL	$414.00
Hydrocortisone rectal enema	60 mL	NA	$0.09/mL	$162.00

EAC = estimated acquisition cost
SMAC = state maximum allowed cost
[+]Based on maintenance dose of 2 grams/day
[¥] Uceris® rectal foam is supplied as a kit containing two aerosol canisters, each canister contains fourteen metered doses and is 33.4 grams each.

Asacol® HD (Mesalamine) Delayed-Release Tablets Product Summary[11]

Indications:

- Asacol® HD (mesalamine) delayed-release tablet is an aminosalicylate indicated for the treatment of moderately active ulcerative colitis in adults.
- Limitation of Use: Safety and effectiveness of Asacol® HD beyond six weeks have not been established.

Dosing:

- Asacol® HD (mesalamine) delayed-release tablets is available in an 800mg dose.
- The recommended dose is two 800mg tablets three times daily (4.8 grams/day) with or without food for six weeks.
- Tablets should be swallowed whole without cutting, breaking, or chewing.
- One Asacol® HD 800mg tablet cannot be substituted for two Asacol® (mesalamine) delayed-release 400mg tablets.

Pentasa® (Mesalamine) Controlled-Release Capsules Product Summary[12]

Indications: Pentasa® (mesalamine) controlled-release capsule is indicated for the induction of remission and for the treatment of patients with mildly to moderately active ulcerative colitis.

Dosing:

- Pentasa® (mesalamine) controlled-release capsules are available in 250mg and 500mg strengths.
- The recommended dosage for the induction of remission and the symptomatic treatment of mildly to moderately active ulcerative colitis is 1 gram (four Pentasa® 250mg capsules or two Pentasa® 500mg capsules) four times a day for a total daily dosage of 4 grams.
- Treatment duration in controlled trials was up to eight weeks.
- Pentasa® capsules may be swallowed whole, or alternatively, the capsule may be opened and the entire contents sprinkled onto applesauce or yogurt.
- The entire contents should be consumed immediately. The capsules and capsule contents must not be crushed or chewed.
- The safety and efficacy of Pentasa® in pediatric patients have not been established.

Rowasa® (Mesalamine) Rectal Suspension Enema Product Summary[13]

Indications: Rowasa® (mesalamine) rectal suspension enema is indicated for the treatment of active, mild-to-moderate distal ulcerative colitis, proctosigmoiditis, or proctitis.

Dosing:

- Rowasa® (mesalamine) rectal suspension enema is available as a 60mL aqueous suspension containing 4 grams mesalamine per bottle.
- The usual dosage of Rowasa® rectal suspension enema in 60mL units is one rectal instillation (4 grams) once a day, preferably at bedtime, and retained for approximately eight hours.
- While the effect of Rowasa® rectal suspension enema may be seen within 3 to 21 days, the usual course of therapy would be from three to six weeks depending on symptoms and sigmoidoscopic findings. Studies available to date have not assessed if Rowasa® rectal suspension enema will modify relapse rates after the six-week, short-term treatment.
- Rowasa® rectal suspension enema is for rectal use only.

Lialda® (Mesalamine) Delayed-Release Capsules Product Summary[14]

Indications: Lialda® (mesalamine) delayed-release capsule is a locally acting 5-aminosalicylic acid (5-ASA) indicated for the induction of remission in adults with active, mild-to-moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.

Dosing:

- Lialda® (mesalamine) delayed-release capsule is available as a 1.2 gram dose.
- For induction of remission of active, mild-to-moderate ulcerative colitis the recommended dosage is two to four 1.2 gram tablets taken once daily with food.
- For maintenance of remission of ulcerative colitis the recommended dosage is two 1.2 gram tablets taken once daily with food.

Colazal® (Balsalazide) Capsules Product Summary[15]

Indications: Colazal® (balsalazide) capsule is indicated for the treatment of mildly to moderately active ulcerative colitis in patients five years of age and older. Safety and effectiveness of Colazal® beyond eight weeks in children (ages 5-17 years) and twelve weeks in adults have not been established.

Dosing:

- Colazal® (balsalazide) capsule is available as a 750mg dose.
- The recommended adult dose is three 750mg Colazal® capsules three times a day (6.75 grams/day) with or without food for eight weeks. Some adult patients required treatment for up to twelve weeks.
- Pediatric dose is either:
    - Three 750mg Colazal® capsules three times a day (6.75 grams/day) with or without food for eight weeks; or

    - One 750mg Colazal® capsule three times a day (2.25 grams/day) with or without food for up to eight weeks.
- Capsules may be swallowed whole or may be opened and sprinkled on applesauce, then chewed or swallowed immediately.

Dipentum® (Olsalazine) Capsules Product Summary[16]

Indications: Dipentum® (olsalazine) capsule is indicated for the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.

Dosing:

- Dipentum® (olsalazine) capsule is available as a 250mg dose.
- The recommended dose in adults for maintenance of remission is 1 gram per day in two divided doses.

Canasa® (Mesalamine) Suppositories Product Summary[17]

Indications: Canasa® (mesalamine) suppositories are an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative proctitis. Safety and effectiveness of Canasa® beyond six weeks have not been established.

Dosing:

- Canasa® (mesalamine) is available as a 1000mg rectal suppository.
- The recommended dose is one 1000mg rectal suppository once daily at bedtime.

Apriso® (Mesalamine) Extended-Release Capsules Product Summary[18]

Indications: Apriso® (mesalamine) extended-release capsules are indicated for the maintenance of remission of ulcerative colitis in patients 18 years of age and older.

Dosing:

- Apriso® (mesalamine) extended-release capsules are available as a 0.375 gram dose.
- The recommended dose for maintenance of remission of ulcerative colitis in adult patients is 1.5 grams (four Apriso® capsules) by mouth once daily in the morning.
- Apriso® may be taken without regard to meals.
- Apriso® should not be co-administered with antacids.
- An evaluation of renal function is recommended before initiating therapy with Apriso®.

Delzicol® (Mesalamine) Delayed-Release Capsules Product Summary[19]

Indications: Delzicol® (mesalamine) delayed-release capsule is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis in patients 12 years of age and older, and maintenance of remission of ulcerative colitis in adults.

Dosing:

- Delzicol® (mesalamine) delayed-release capsule is available as a 400mg dose.

- The recommended dose for the treatment of mildly to moderately active ulcerative colitis:
  - Adults: 800mg three times daily (2.4 grams/day) for six weeks
  - Pediatric Patients 12 Years or Older: Total daily dose is weight-based up to a maximum of 2.4 grams/day for up to six weeks.
- For maintenance of remission of ulcerative colitis in adults: 1.6 grams daily in divided doses.
- Capules should be swallowed whole with water and not opened, crushed, broken, or chewed.
- Two Delzicol® 400mg capsules should not be substituted with one mesalamine delayed-release 800mg tablet.
- An evaluation of renal function is recommended before initiating therapy with Delzicol®.

Cost Comparison

Drug	Strength	EAC	Cost per Month*
Asacol® HD (mesalamine) delayed-release tablet	800mg	$7.59/tablet	$1,366.20
Pentasa® (mesalamine) controlled-release capsule	250mg	$2.47/capsule	$1,185.60
Pentasa® (mesalamine) controlled-release capsule	500mg	$4.95/capsule	$1,188.00
Rowasa® (mesalamine) rectal suspension enema	4grams (60 mL)	$0.23/mL[+]	$414.00
Lialda® (mesalamine) delayed-release capsule	1.2grams	$8.32/capsule	$998.40
Colazal® (balsalazide) capsule	750mg	$0.59/capsule[+]	$159.30
Dipentum® (olsalazine) capsule	250mg	$13.16/capsule	$1,579.20
Canasa® (mesalamine) suppository	1000mg	$31.29/suppository	$938.70
Apriso® (mesalamine) extended-release capsules	0.375grams	$3.67/capsule	$440.40
Delzicol® (mesalamine) delayed-release capsule	400mg	$3.13/capsule	$563.40
sulfasalazine tablet	500mg	$0.18/tablet[+]	$21.60[¥]

EAC = estimated acquisition cost

[+]SMAC = state maximum allowed cost

*Costs listed in the table above do not take into account federal or supplemental rebate participation; therefore, do not reflect net costs.

[¥]Based on maintenance dose of 2 grams/day

Recommendations

The College of Pharmacy recommends the prior authorization of Uceris® extended-release tablets, Uceris® rectal foam, and various mesalamine products with the following criteria:

Uceris® (Budesonide) Extended-Release Tablets Approval Criteria:

1. An FDA approved diagnosis of induction of remission in patients with active, mild-to-moderate ulcerative colitis; and
2. Previous failure of at least two of the following:
    a. Oral aminosalicylates; or
    b. Topical mesalamine; or
    c. Topical steroids; or
    d. A contraindication to all preferred medications; and
3. A patient-specific, clinically significant reason why the member cannot use other oral corticosteroids available without prior authorization; and
4. Approvals will be for the duration of eight weeks in accordance with manufacturer maximum recommended duration of therapy.
5. A quantity limit of 30 tablets per 30 days will apply.

Uceris® (Budesonide) Rectal Foam Approval Criteria:

1. An FDA approved diagnosis of induction of remission in patients with active, mild-to-moderate distal ulcerative colitis extending up to 40cm from the anal verge; and
2. A patient-specific, clinically significant reason why the member cannot use oral aminosalicylates, topical mesalamine, or other topical (rectally administered) corticosteroids available without prior authorization; and
3. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy.
4. A quantity limit of 133.6 grams per 42 days will apply.

Asacol® HD (Mesalamine) Delayed-Release Tablets Approval Criteria:

1. An FDA approved indication of the treatment of moderately active ulcerative colitis; and
2. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that do not require prior authorization; and
3. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 180 tablets per 30 days will apply.

Pentasa® (Mesalamine) 500mg Controlled-Release Capsules Approval Criteria:

1. An FDA approved indication for the induction of remission or for the treatment of patients with mildly to moderately active ulcerative colitis; and
2. A patient-specific, clinically significant reason the member cannot use Pentasa® 250mg controlled-release capsules or other available mesalamine products that do not require prior authorization; and
3. Approvals will be for the duration of eight weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 240 capsules per 30 days will apply

Rowasa® (Mesalamine) Rectal Suspension Enema Approval Criteria:

1. The first three weeks of treatment would not require prior authorization.
2. An FDA approved indication for the treatment of active, mild-to-moderate distal ulcerative colitis, proctosigmoiditis, or proctitis; and
3. A patient-specific, clinically significant reason the member cannot use Canasa® (mesalamine suppositories) which do not require prior authorization; and
4. Provider documentation member is still having active symptoms after three weeks of treatment; and
5. Approvals will be for the duration of six weeks in accordance with manufacturer recommended duration of therapy; and
6. A quantity limit of 30 enemas (1,800 mL) per 30 days will apply.

Lialda® (Mesalamine) Delayed-Release Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 60 capsules per 30 days will apply
2. For quantity limit requests for greater than two capsules per day:
    a. An FDA approved indication for the induction of remission in patients with active, mild-to-moderate ulcerative colitis; and
    b. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that are indicated to induce remission that do not require prior authorization; and
    c. Approvals will be for the duration of eight weeks in accordance with manufacturer recommended duration of therapy; and
    d. A maximum approval of 120 capsules per 30 days will apply.

Colazal® (Balsalazide) Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 270 capsules per 30 days will apply.
2. The first twelve weeks of treatment would not require prior authorization.
3. After twelve weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.
4. An age restriction of five years and older will apply.

Dipentum® (Olsalazine) Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply

Pentasa® (Mesalamine) 250mg Controlled-Release Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 480 capsules per 30 days will apply.
2. The first eight weeks of treatment would not require prior authorization.
3. After eight weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Canasa® (Mesalamine) Suppositories Quantity Limit Approval Criteria:

1. A quantity limit of 30 suppositories per 30 days will apply.
2. The first six weeks of treatment would not require prior authorization.
3. After six weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Apriso® (Mesalamine) Extended-Release Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Delzicol® (Mesalamine) Delayed-Release Capsules Quantity Limit Approval Criteria:

1. A quantity limit of 180 capsules per 30 days will apply.

Utilization Details of Ulcerative Colitis Medications: Calendar Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SULFASALAZINE MEDICATIONS						
SULFASALAZINE TAB 500MG	460	153	$9,219.84	$0.69	$20.04	0.88%
SULFASALAZINE TAB 500MG	214	79	$7,502.15	$1.17	$35.06	0.72%
SULFAZINE TAB 500MG	141	60	$2,385.57	$0.58	$16.92	0.23%
SULFAZINE EC TAB 500MG	46	23	$1,510.73	$1.09	$32.84	0.14%
SUBTOTAL	**861**	**315**	**$20,618.29**	**$0.88**	**$26.22**	**1.97%**
MESALAMINE MEDICATIONS						
LIALDA TAB 1.2GM	313	74	$204,510.16	$21.80	$653.39	19.63%
ASACOL HD TAB 800MG	311	79	$205,599.11	$22.27	$661.09	19.73%
PENTASA CAP 500MG CR	229	65	$162,995.39	$24.81	$711.77	15.64%
DELZICOL CAP 400MG	211	43	$88,981.84	$14.71	$421.71	8.54%
APRISO CAP 0.375GM	155	32	$61,685.00	$13.33	$397.97	5.92%
CANASA SUP 1000MG	95	45	$76,510.05	$26.09	$805.37	7.34%
MESALAMINE ENE 4GM	47	17	$16,785.77	$14.38	$357.14	1.61%
PENTASA CAP 250MG CR	27	8	$11,604.95	$15.03	$429.81	1.11%
ASACOL TAB 400MG DR	1	1	$133.43	$4.45	$133.43	0.01%
SUBTOTAL	**1,389**	**364**	**$828,805.70**	**$17.43**	**$507.96**	**79.53%**
BALASALAZIDE MEDICATIONS						
BALSALAZIDE CAP 750MG	49	11	$6,846.20	$4.66	$139.72	0.66%
SUBTOTAL	**49**	**11**	**$6,846.20**	**$4.66**	**$139.72**	**0.66%**
OLSALAZINE MEDICATIONS						
DIPENTUM CAP 250MG	10	2	$13,949.16	$46.50	$1,394.92	1.34%
SUBTOTAL	**10**	**2**	**$13,949.16**	**$46.50**	**$1,394.92**	**1.34%**
BUDESONIDE MEDICATIONS						
BUDESONIDE CAP	246	80	$162,573.68	$21.20	$660.87	15.60%
UCERIS TAB 9MG	6	3	$9,287.08	$51.59	$1,547.85	0.89%
SUBTOTAL	**252**	**83**	**$171,860.76**	**$36.40**	**$1,104.36**	**16.49%**
HYDROCORTISONE MEDICATIONS						
HYDROCORT ENE 100MG	8	7	$720.97	$5.42	$90.12	0.07%
SUBTOTAL	**8**	**7**	**$720.97**	**$5.42**	**$90.12**	**0.07%**
TOTAL	**2,569**	**642***	**$1,042,801.08**	**$13.75**	**$472.78**	**100.00%**

*Total number of unduplicated members.

Costs listed in the table above do not take into account federal or supplemental rebate participation; therefore, do not reflect net costs.

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Appendix M

Fiscal Year 2015 Annual Review of Ocular Allergy Medications and 30-Day Notice to Prior Authorize Pazeo® (Olopatadine Ophthalmic)

Oklahoma Health Care Authority
February 2016

Current Prior Authorization Criteria

Ocular Allergy Medications*		
Tier-1	**Tier-2**	**Tier-3**
cromolyn (Crolom®)	azelastine (Optivar®)	alcaftadine (Lastacaft™)
ketotifen (Alaway®, Zaditor® OTC)		bepotastine (Bepreve™)
		emedastine (Emadine®)
		epinastine (Elestat®)
		lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine (Pataday®, Patanol®)

*Tier structure based on supplemental rebate participation and/or state maximum allowable cost (SMAC). Tier-2 medications are subject to move to Tier-3.
OTC = Over-the-counter

Ocular Allergy Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial of one Tier-1 product for a minimum of two weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ocular Allergy Tier-3 Approval Criteria:

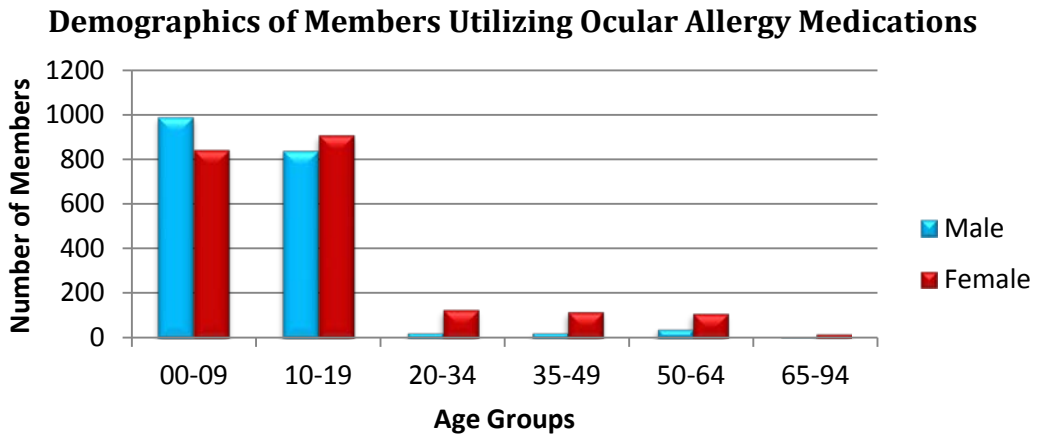
1. An FDA approved diagnosis; and
2. Recent trials of one Tier-1 product and all available Tier-2 medications for a minimum of two weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

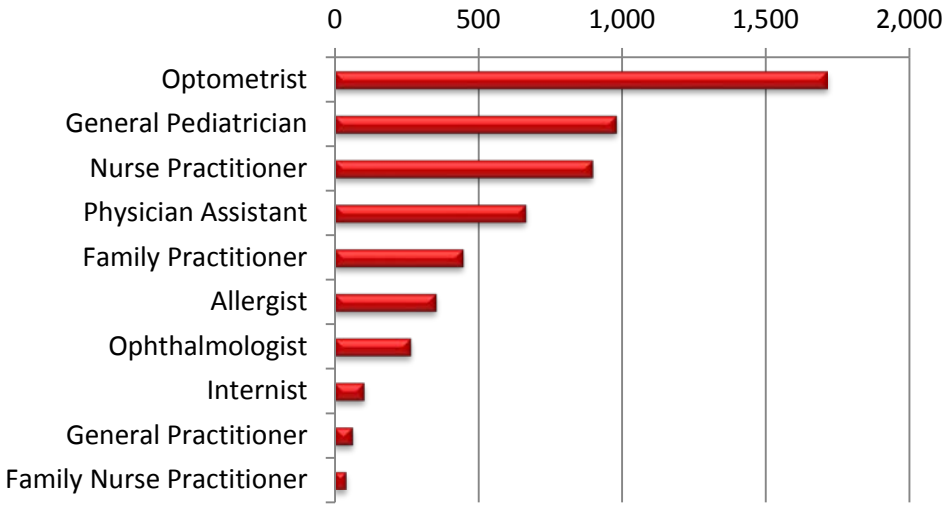
Utilization of Ocular Allergy Medications: Fiscal Year 2015

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	4,274	5,734	$123,024.76	$21.46	$0.69	38,610	177,901
2015	4,048	5,679	$131,875.22	$23.22	$0.74	37,150	178,290
% Change	**-5.30%**	**-1.00%**	**7.20%**	**8.20%**	**7.20%**	**-3.80%**	**0.20%**
Change	**-226**	**-55**	**$8,850.46**	**$1.76**	**$0.05**	**-1,460**	**389**

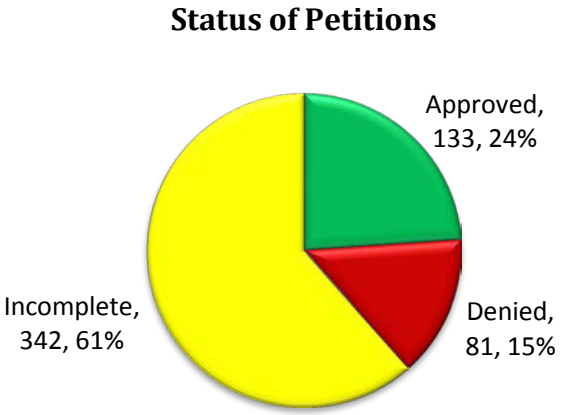
*Total number of unduplicated members.





Prior Authorization of Ocular Allergy Medications

There were 556 prior authorization requests submitted for the ocular allergy medications during fiscal year 2015. 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[1,2]

Patent Expirations:

- The patent for Patanol® (olopatadine) expired in December 2015. Multiple generic products have been approved by the U.S. Food and Drug Administration (FDA).
- Pataday® (olopatadine): May 2024
- Bepreve™ (bepotastine): September 2024
- Lastacaft® (alcaftadine): December 2027
- Pazeo® (olopatadine): May 2032

FDA Approvals:

- **February 2015:** Alcon, a division of Novartis, announced the FDA approval of Pazeo® (olopatadine hydrochloride ophthalmic solution). Pazeo® is indicated for the treatment of ocular itching associated with allergic conjunctivitis. Pazeo® solution is dosed once daily, and was approved with efficacy data at 24 hours, post dose.

Pazeo® (Olopatadine Ophthalmic) Product Summary[3]

Indications: Pazeo® (olopatadine ophthalmic) is a mast cell stabilizer indicated for the treatment of ocular itching associated with allergic conjunctivitis.

Dosing:

- Pazeo® is available as an ophthalmic solution containing 7.76mg of olopatadine hydrochloride per one milliliter of solution (0.7%). Pazeo® is supplied in a 4mL bottle that contains 2.5mL of olopatadine hydrochloride ophthalmic solution.
- The recommended dosage of Pazeo® is to instill one drop in each affected eye once daily.
- Care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to prevent contaminating the tip and solution.
- Patients who wear soft contact lenses should be instructed to wait at least five minutes after instilling Pazeo® before they insert their contact lenses.

Mechanism of Action: Olopatadine is a mast cell stabilizer and a histamine (H_1) antagonist. Decreased chemotaxis and inhibition of eosinophil activation has also been demonstrated.

Contraindications: None

Warning and Precautions:

- Contamination of Tip and Solution: Care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to prevent contaminating the tip and solution. The bottle should be kept tightly closed when not in use.
- Contact Lens Use: Patients should not wear a contact lens if their eye is red. The preservative in Pazeo® solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses should be instructed to wait at least five minutes after instilling Pazeo® before they insert their contact lenses.

Adverse Reactions: The most commonly reported adverse reactions in clinical trials (2-5% of patients) were blurred vision, dry eye, superficial punctate keratitis, dysgeusia, and abnormal sensation in eye.

Use in Special Populations:

- Pregnancy: There are no adequate or well-controlled studies with Pazeo® in pregnant women. Olopatadine caused maternal toxicity and embryo fetal toxicity in rats at levels 1,080 to 14,400 times the maximum recommended human ophthalmic dose (MRHOD). There was no toxicity in rat offspring at exposures estimated to be 45 to 150 times that at MRHOD. Pazeo® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical, ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Caution should be exercised when Pazeo® is administered to a nursing mother.
- Pediatric Use: The safety and effectiveness of Pazeo® have been established in pediatric patients two years of age and older.
- Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Efficacy: The efficacy of Pazeo® was established in two randomized, double-masked, placebo-controlled, conjunctival allergen challenge (CAC) clinical studies in patients with a history of allergic conjunctivitis (Studies 1 and 2).

- In Study 1, patients were randomized to receive Pazeo®, Pataday®, or vehicle.
- In Study 2, patients were randomized to receive Pazeo®, Pataday®, Patanol®, or vehicle.
- Patients were evaluated with an ocular itching severity score ranging from 0 (no itching) to 4 (incapacitating itch) at several time points after CAC administration. A one unit difference compared to vehicle was considered a clinically meaningful change in the ocular itching severity score.
- Pazeo® demonstrated statistically significantly improved relief of ocular itching compared to vehicle at 30-34 minutes, 16 hours, and 24 hours after study treatment.
- Pazeo® demonstrated statistically significantly improved relief of ocular itching compared to Pataday® at 24 hours after study treatment, but not at 30-34 minutes after study treatment.

Cost Comparison:

Medication	Cost/mL	Bottle Size	Cost/Bottle
Pazeo® (olopatadine)	$63.04*	2.5mL	$157.60
Pataday® (olopatadine)	$66.82*	2.5mL	$167.05
olopatadine (generic Patanol®)	$8.26	5mL	$41.30
ketotifen (generic Zaditor®)	$1.80	5mL	$9.00

*Cost/mL based on estimated acquisition cost (EAC). Costs listed in the table above do not take into account federal or supplemental rebate participation; therefore, do not reflect net costs.

Recommendations

The College of Pharmacy recommends the following changes to the Ocular Allergy Medication Product Based Prior Authorization (PBPA) category:

1. The addition of Pazeo® (olopatadine solution) to Tier-3. Current Tier-3 criteria for this category will apply.
    a. Pazeo® (olopatadine solution) is currently rebated to Tier-2, but will be placed in Tier-3 if the manufacturer chooses not to participate in supplemental rebates.
2. Move olopatadine (generic Patanol®) to Tier-2 based on state maximum allowable cost (SMAC). Current Tier-2 criteria for this category will apply.

Ocular Allergy Medications*		
Tier-1	**Tier-2**	**Tier-3**
cromolyn (Crolom®)	azelastine (Optivar®)	alcaftadine (Lastacaft™)
ketotifen (Alaway®, Zaditor® OTC)	**olopatadine (Pazeo®)**	bepotastine (Bepreve™)
	olopatadine (Patanol®)	emedastine (Emadine®)
		epinastine (Elestat®)
		lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine (Pataday®)

*Tier structure based on supplemental rebate participation and/or state maximum allowable cost (SMAC). Tier-2 medications are subject to move to Tier-3.
OTC = Over-the-counter

Ocular Allergy Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial of one Tier-1 product for a minimum of two weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ocular Allergy Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Recent trials of one Tier-1 product and all available Tier-2 medications for a minimum of two weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Utilization Details of Ocular Allergy Medications: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ DAY	COST/ CLAIM
TIER-1 MEDICATIONS						
KETOTIFEN PRODUCTS						
KETOTIF FUM DRO 0.025% OP	2,646	2,016	$34,876.70	1.31	$0.44	$13.18
ALAWAY DRO 0.025% OP	1,172	941	$14,459.68	1.25	$0.35	$12.34
ZADITOR DRO 0.025% OP	651	498	$10,662.60	1.31	$0.54	$16.38
EYE ITCH REL DRO 0.025% OP	142	94	$1,528.43	1.51	$0.35	$10.76
ITCHY EYE DRO 0.025% OP	10	6	$115.31	1.67	$0.38	$11.53
ALLERGY EYE DRO 0.025% OP	8	6	$88.31	1.33	$0.37	$11.04
ALAWAY CHILD DRO 0.025% OP	8	7	$84.48	1.14	$0.34	$10.56
SUBTOTAL	**4,637**	**3,472**	**$61,815.51**	**1.34**	**$0.42**	**$13.33**
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	664	512	$7,404.55	1.3	$0.35	$11.15
SUBTOTAL	**664**	**512**	**$7,404.55**	**1.3**	**$0.35**	**$11.15**
TIER-1 SUBTOTAL	**5,301**	**3,965**	**$69,220.06**	**1.34**	**$0.41**	**$13.06**
TIER-2 MEDICATIONS						
OLOPATADINE PRODUCTS[+]						
PATANOL SOL 0.1% OP	219	51	$43,114.23	4.29	$6.90	$196.87
PATADAY SOL 0.2% OP	112	40	$16,003.39	2.8	$4.61	$142.89
SUBTOTAL	**331**	**86**	**$59,117.62**	**3.85**	**$6.08**	**$178.60**
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05% OP	37	31	$1,697.21	1.19	$1.38	$45.87
SUBTOTAL	**37**	**31**	**$1,697.21**	**1.19**	**$1.38**	**$45.87**
TIER-2 SUBTOTAL	**368**	**110**	**$60,814.83**	**3.35**	**$5.55**	**$165.26**
TIER-3 MEDICATIONS						
BEPOTASTINE PRODUCTS						
BEPREVE DRO 1.5% OP	6	2	$1,216.07	3	$6.76	$202.68
SUBTOTAL	**6**	**2**	**$1,216.07**	**3**	**$6.76**	**$202.68**
ALCAFTADINE PRODUCTS						
ALREX SUS 0.2% OP	2	2	$351.36	1	$8.78	$175.68
SUBTOTAL	**2**	**2**	**$351.36**	**1**	**$8.78**	**$175.68**
LOTEPREDNOL PRODUCTS						
LASTACAFT SOL 0.25% OP	2	1	$272.90	2	$4.55	$136.45
SUBTOTAL	**2**	**1**	**$272.90**	**2**	**$4.55**	**$136.45**
TIER-3 SUBTOTAL	**10**	**5**	**$1,840.33**	**2**	**$6.57**	**$184.03**
TOTAL	**5,679**	**4,048***	**$131,875.22**	**1.4**	**$0.74**	**$23.22**

*Total number of unduplicated members.

[+]Effective January 1st 2015, Tier-2 products Pataday® and Patanol® were moved to Tier-3 based on withdrawal of supplemental rebate participation.

Costs do not reflect rebated prices or net costs.

[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 01/28/16. Last accessed 01/29/16.
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Appendix N

Fiscal Year 2015 Annual Review of Gonadotropin Releasing Hormone Medications

Oklahoma Health Care Authority
February 2016

Introduction[1,2,3,4]

Gonadotropin releasing hormone (GnRH) medications include analogs (e.g., leuprolide acetate and histrelin) and agonists (e.g., nafarelin). GnRH medications work by providing continuous stimulation to the pituitary gonadotrophs. Continuous stimulation leads to desensitization of the gonadotroph cells and suppression of gonadotropins resulting in decreased sex steroid production or pituitary-gonadal axis suppression. Approved indications for these drugs, depending on the specific agent, include advanced prostate cancer, endometriosis, and precocious puberty.

FDA Approved GnRH Options for Treatment of Central Precocious Puberty or Endometriosis

GnRH Agonist	Method of Administration and Frequency	Indication(s)
Goserelin (Zoladex®)	3.6mg subcutaneously every 28 days	Prostate cancer, Endometriosis, Dysfunctional uterine bleeding, Advanced breast cancer
histrelin (Supprelin® LA)	50mg subcutaneous implant every 12 months	Central precocious puberty
leuprolide (Lupron Depot®)	3.75mg monthly 11.25mg every 3 months	Anemia due to vaginal bleeding from fibroids, Endometriosis
leuprolide (Lupron Depot-Ped®)	7.5mg, 11.25mg, or 15mg monthly 11.25mg or 30mg every 3 months	Central precocious puberty
leuprolide/norethindrone (Lupaneta Pack®)	3.75mg intramuscularly monthly 11.25mg intramuscularly every 3 months (both with daily norethindrone 5mg)	Endometriosis
Nafarelin (Synarel®)	CPP: 1600-1800mcg (8-9 sprays) intranasally divided 2-3 times daily Endometriosis: 400mcg (2 sprays) divided twice daily	Endometriosis, Central precocious puberty

Products only indicated for the diagnosis of prostate cancer are not included in the table; this exclusion includes specific medication strengths that only have a prostate cancer diagnosis.

Current Prior Authorization Criteria

Gonadotropin Releasing Hormone (GnRH) Medications*		
Tier-1	**Tier-2**	**Tier-3**
leuprolide (Lupron® Depot)	histrelin (Supprelin® LA)	nafarelin (Synarel®)
leuprolide (Lupron Depot-Ped®)		
leuprolide depot/norethindrone tablets (Lupaneta Pack™)		

*Lupron® does not require prior authorization when submitted for a cancer diagnosis.

Lupron Depot® (Leuprolide), Supprelin® LA (Histrelin), and Synarel® (Nafarelin)
Approval Criteria:

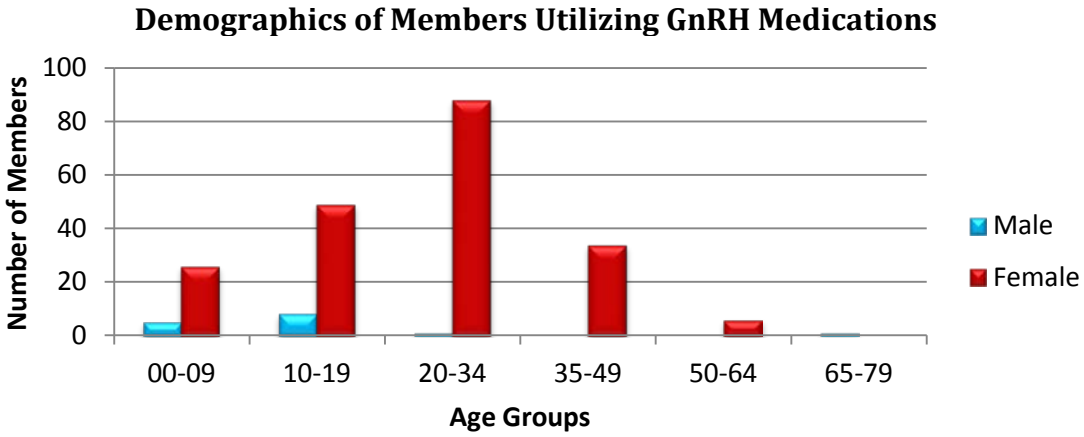
1. An FDA approved diagnosis of central precocious puberty confirmed by submitting the following:
    a. Documentation of onset of symptoms less than 8 years of age in females and 9 years of age in males; and
    b. Documentation that bone age is advanced 1 year beyond the chronological age; and
    c. Lab assessment:
        i. Documentation of abnormal basal gonadotropin levels; or
        ii. Documentation of pubertal response to a gonadotropin releasing hormone analog stimulation test
2. Approvals may be granted with documentation of failed trials of lower tiered products or an FDA approved indication not covered by a lowered tiered product.

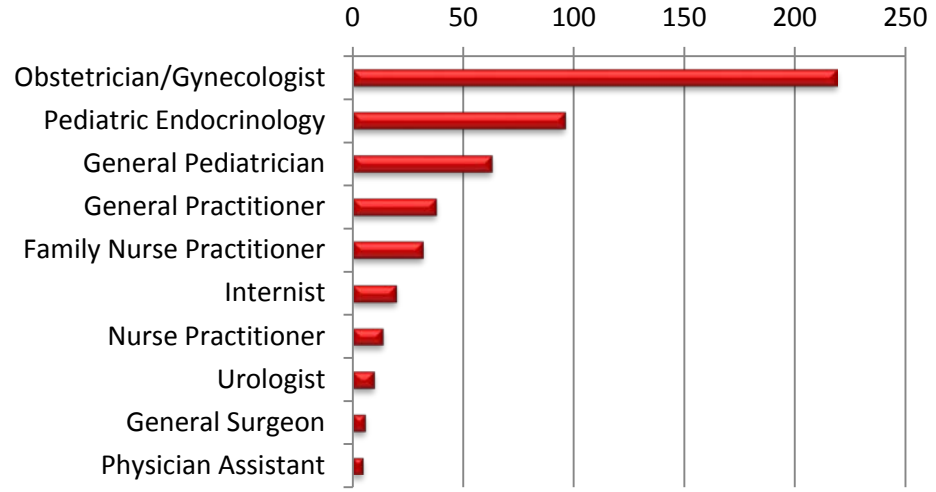
Utilization of GnRH Medications: Fiscal Year 2015

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	216	462	$1,177,784.23	$2,549.32	$47.42	464	24,838
2015	218	511	$1,571,155.07	$3,074.67	$53.08	518	29,598
% Change	**0.90%**	**10.60%**	**33.40%**	**20.60%**	**11.90%**	**11.60%**	**19.20%**
Change	**2**	**49**	**$393,370.84**	**$525.35**	**$5.66**	**54**	**4,760**

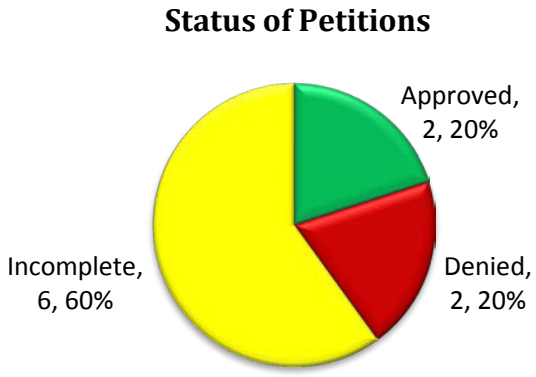
*Total number of unduplicated members





Prior Authorization of GnRH Medications

There were 10 prior authorization requests submitted for GnRH medications during fiscal year 2015. The following chart shows the status of the submitted petitions.



Market News and Updates[5,6,7]

Anticipated Patent Expirations:

- Lupron Depot® and Lupron Depot-Ped®: December 2016
- Lupaneta Pack®: December 2016
- Supprelin® LA: June 2026

Pipeline Updates:

- **January 2015:** AbbVie announced positive results from two Phase 3 clinical trials evaluating elagolix, an investigational drug that inhibits GnRH receptors in the pituitary gland ultimately reducing circulating sex hormones. The trials were designed to evaluate the safety and efficacy of elagolix in premenopausal women with endometriosis. Results from the trials show that after six months of treatment, elagolix reduced scores of non-menstrual pelvic pain and menstrual pain associated with endometriosis.

Guidance:

- **January 2016:** The American Academy of Pediatrics released a clinical report titled "Evaluation and Referral of Children with Signs of Early Puberty." The report is intended to serve as a guide for physicians to help distinguish which signs of early sexual maturation require only observation and which require referral to a pediatric endocrinology specialist. According to the authors of the report, signs of early sexual maturation can vary with a patient's ethnicity or obesity status.

Recommendations

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

Utilization Details of GnRH Medications: Fiscal Year 2015

Pharmacy Claims

Product Utilized	Total Claims	Total Members	Total Cost	Cost/ Day	Cost/ Claim
Leuprolide Depot Products					
LUPRON DEPOT INJ 11.25MG	147	108	$416,664.70	$37.79	$2,834.45
LUPRON DEPOT INJ 3.75MG	138	52	$129,613.91	$30.69	$939.23
LUPRON DEPOT INJ 7.5MG	22	3	$26,860.28	$38.15	$1,220.92
Subtotal	**307**	**160**	**$573,138.89**	**$35.93**	**$1,866.90**
Leuprolide Depot Pediatric Products					
LUPR DEP-PED INJ 30MG (3 MONTH)	96	32	$626,339.34	$77.44	$6,524.37
LUPR DEP-PED INJ 11.25MG (3 MONTH)	46	16	$271,251.77	$74.93	$5,896.78
LUPR DEP-PED INJ 15MG	32	6	$66,137.73	$73.16	$2,066.80
LUPR DEP-PED INJ 7.5MG	16	2	$17,443.41	$38.94	$1,090.21
LUPR DEP-PED INJ 11.25MG	12	8	$16,282.64	$29.99	$1,356.89
Subtotal	**202**	**59**	**$997,454.89**	**$73.33**	**$4,937.90**
Leuprolide Injection Products					
LEUPROLIDE INJ 1MG/0.2ML	2	2	$561.29	$13.36	$280.65
Subtotal	**2**	**2**	**$561.29**	**$13.36**	**$280.65**
Total	**511**	**218***	**$1,571,155.07**	**$53.08**	**$3,074.67**

*Total number of unduplicated members

Medical Claims

Product Utilized	Total Claims	Total Members	Total Cost	Cost/ Claim
Leuprolide Products (J9218)				
LEUPROLIDE PER 1MG (J9218)	37	35	$561.93	$15.19
Total	**37**	**35***	**$561.93**	**$15.19**

*Total number of unduplicated members

[1] Garner C. Uses of GnRH Agonists. *J Obstet Gynecol Neonatal Nurs.* September 1994; 23 (7):563-70.
[2] Carel JC, Eugster EA, Rogol A, et al. Consensus Statement of the Use of Gonadotropin-Releasing Hormone Analogs in Children. *Pediatrics* 2009;123:e752–e762.
[3] Wolters Kluwer: Up-to-Date. Treatment of Precocious Puberty. Available online at: http://www.uptodate.com/contents/treatment-of-precocious-puberty?source=search_result&search=gonadotropin+releasing+hormone+agonists&selectedTitle=7%7E150#H568107578. Last revised 12/09/2015. Last accessed 01/28/2016.
[4] Kaplowitz P: Medscape. Precocious Puberty Medication. Available online at: http://emedicine.medscape.com/article/924002-medication. Last revised 09/04/2015. Last accessed 01/29/2016.
[5] 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 01/28/2016. Last accessed 01/28/2016.
[6] AbbVie. AbbVie Announces Positive Top-Line Results From Phase 3 Study of Investigational Medicine Elagolix in Patients with Endometriosis. Available online at: http://abbvie.mediaroom.com/2015-01-08-AbbVie-Announces-Positive-Top-Line-Results-From-Phase-3-Study-of-Investigational-Medicine-Elagolix-in-Patients-with-Endometriosis. Last revised 01/08/2015. Last accessed 01/29/2016.
[7] American Academy of Pediatrics. AAP Report Says Signs of Early Sexual Maturation Don't Always Mean Puberty Has Started. Available online at: https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Report-Says-Sign-of-Early-Sexual-Maturation-Don't-Always-Mean-Puberty-Has-Started.aspx. Last revised 12/14/2015. Last accessed 01/29/2016.

Appendix O

Annual Review of Northera™ (Droxidopa)

Oklahoma Health Care Authority
February 2016

Introduction[1]

Northera™ (droxidopa) is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (OH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond two weeks of treatment has not been demonstrated. The continued effectiveness of Northera™ should be assessed periodically.

Current Prior Authorization Criteria

Northera™ (Droxidopa) Approval Criteria:

1. An FDA approved diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; and
2. Member must be 18 years of age or older; and
3. Member must have tried and failed two of the following medications at recommended dosing within the last 90 days:
    a. Midodrine; or
    b. Fludrocortisone; or
    c. Pyridostigmine; or
    d. Have a contraindication to all preferred medications.
4. Initial approval will be for the duration of two weeks of treatment only.
5. Continued approval will require the prescriber to provide information regarding improved member response/effectiveness of this medication to determine whether Northera™ is continuing to provide a benefit.
6. Continued approval will be for the duration of three months. Each approval will require prescriber documentation of member response/effectiveness to Northera™.

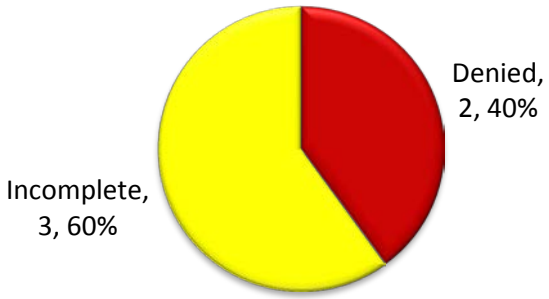
Utilization of Northera™ (Droxidopa): Fiscal Year 2015

There was no utilization of Northera™ (droxidopa) during fiscal year 2015.

Prior Authorization of Northera™ (Droxidopa)

There were 5 prior authorization requests submitted for Northera™ (droxidopa) during fiscal year 2015. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[2,3]

Patent Expirations:

- Northera™ (droxidopa): February 2021

Updates:

- The Michael J. Fox Foundation for Parkinson's Research is funding a Phase II clinical study on droxidopa investigating its potential to treat cognitive impairment in Parkinson's disease. The study is currently recruiting.

Recommendations

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

[1] Northera™ Prescribing Information. Lundbeck. Available online at: http://www.lundbeck.com/upload/us/files/pdf/Products/Northera_PI_US_EN.pdf . Last revised 08/2014. Last accessed 01/29/2016.
[2] 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 01/28/16. Last accessed 01/29/16.
[3] Study to Assess the Clinical Benefit and Safety of Droxidopa in Parkinson's disease. Available at: https://foxtrialfinder.michaeljfox.org/trial/3782/. Last accessed: 01/29/2016.

Appendix P

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

FDA NEWS RELEASE

For Immediate Release: January 28th, 2016

FDA approves first drug to show survival benefit in liposarcoma

The U.S. Food and Drug Administration approved Halaven (eribulin mesylate), a type of chemotherapy, for the treatment of liposarcoma (a specific type of soft tissue sarcoma) that cannot be removed by surgery (unresectable) or is advanced (metastatic). This treatment is approved for patients who received prior chemotherapy that contained an anthracycline drug.

Soft tissue sarcoma (STS) is a disease in which cancer cells form in the soft tissues of the body, including the muscles, tendons, fat, blood vessels, lymph vessels, nerves and tissues around joints. Liposarcoma is a specific type of STS that occurs in fat cells. STS can form almost anywhere in the body, but is most common in the head, neck, arms, legs, trunk and abdomen. In 2014, an estimated 12,000 cases of STS were diagnosed in the United States, according to the National Cancer Institute.

The efficacy and safety of Halaven were evaluated in 143 clinical trial participants with advanced liposarcoma that was unresectable or had spread to nearby lymph nodes (locally advanced) or other parts of the body (metastatic), and who had been treated with chemotherapy. Participants were treated with either Halaven or another chemotherapy drug called dacarbazine until their disease spread or until they were no longer able to tolerate the side effects of treatment. The study was designed to measure the length of time from the start of treatment until a patient's death. The median overall survival for patients with liposarcoma receiving Halaven was 15.6 months compared to 8.4 months for those who received dacarbazine.

The most common side effects among participants treated with Halaven were fatigue, nausea, hair loss, constipation, certain nerve damage causing weakness or numbness in the hands and feet (peripheral neuropathy), abdominal pain and fever. Halaven may also cause low levels of infection-fighting white blood cells or decreased levels of potassium or calcium.

Serious side effects from treatment with Halaven may include a decrease in white blood cell count, which can increase the risk of serious infections that could lead to death; numbness, tingling or burning in the hands and feet (neuropathy); harm to a developing fetus; as well as changes in heartbeat (QTc prolongation), that may also lead to death.

The FDA granted the Halaven application priority review status, intended to facilitate and expedite the development and review of certain drugs in light of their potential to benefit patients with serious or life-threatening conditions. Halaven also received orphan drug designation, which provides incentives such as tax credits, user fee waivers, and eligibility for exclusivity to assist and encourage the development of drugs for rare diseases.

Halaven is marketed by Eisai based in Woodcliff Lake, New Jersey.

FDA NEWS RELEASE

For Immediate Release: January 28th, 2016

FDA approves Zepatier for treatment of chronic hepatitis C genotypes 1 and 4

The U.S. Food and Drug Administration approved Zepatier (elbasvir and grazoprevir) with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients. Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take several years. Some people with chronic HCV infection develop cirrhosis over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections or liver cancer. According to the Centers for Disease Control and Prevention, approximately 3 million Americans are infected with HCV, of which genotype 1 is the most common and genotype 4 is one of the least common.

The safety and efficacy of Zepatier with or without ribavirin was evaluated in clinical trials of 1,373 participants with chronic HCV genotype 1 or 4 infections with and without cirrhosis. The participants received Zepatier with or without ribavirin once daily for 12 or 16 weeks. The studies were designed to measure whether a participant’s hepatitis C virus was no longer detected in the blood 12 weeks after

finishing treatment (sustained virologic response or SVR), suggesting a participant's infection had been cured.
The overall SVR rates ranged from 94-97 percent in genotype 1-infected subjects and from 97-100 percent in genotype 4-infected subjects across trials for the approved treatment regimens. In order to maximize SVR rates for patients, the product label provides recommendations regarding length of treatment with or without ribavirin specifically tailored to the characteristics of the patient and their virus. It is recommended that healthcare professionals screen genotype 1a-infected patients for certain viral genetic variations prior to starting treatment with Zepatier to determine dosage regimen and duration.
The most common side effects of Zepatier without ribavirin were fatigue, headache and nausea. The most common side effects of Zepatier with ribavirin were anemia and headache.
Zepatier carries a warning alerting patients and health care providers that elevations of liver enzymes to greater than five times the upper limit of normal occurred in approximately 1 percent of clinical trial participants, generally at or after treatment week eight. Liver-related blood tests should be performed prior to starting therapy and at certain times during treatment. Zepatier should not be given to patients with moderate or severe liver impairment.
Zepatier was granted breakthrough therapy designation for the treatment of chronic HCV genotype 1 infection in patients with end stage renal disease on hemodialysis and for the treatment of chronic HCV genotype 4 infection. Breakthrough therapy designation is a program designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.
Zepatier is marketed by Merck & Co. Inc. based in Whitehouse Station, New Jersey.

Current Drug Shortages Index (as of February 1st, 2016):

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

Acetohydroxamic Acid (Lithostat) Tablets	***Currently in Shortage***
Ammonium Chloride Injection	***Currently in Shortage***
Anagrelide Hydrochloride Capsules	***Currently in Shortage***
Aprepitant (Emend) Capsules	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azathioprine Tablet	***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***
Cefepime 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***
Desmopressin Acetate Injection	***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***
Epinephrine Injection	***Currently in Shortage***
Eptifibatide (Integrilin) Injection	***Currently in Shortage***
Ethiodized Oil (Lipiodol) Injection	***Currently in Shortage***

Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fomepizole Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
Indigotindisulfonate Sodium (Indigo Carmine) 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***
Levetiracetam (Keppra) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
LifeCare PCA™ Sterile Empty Vial and Injector	***Currently in Shortage***
Liotrix (Thyrolar) Tablets	***Currently in Shortage***
Mecasermin [rDNA origin] (Increlex) Injection	***Currently in Shortage***
Memantine Hydrochloride (Namenda) XR Capsules	***Currently in Shortage***
Meropenem for Injection, USP	***Currently in Shortage***
Methyldopate Hydrochloride Injection	***Currently in Shortage***
Methylin Chewable Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride ER Capsules/Tablets	***Currently in Shortage***
Metoprolol Injection	***Currently in Shortage***
Morphine Sulfate Injection, USP, CII, (Preservative-Free)(For PCA Use Only)	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Mupirocin Calcium Nasal Ointment	***Currently in Shortage***
Nebivolol (BYSTOLIC) Tablets	***Currently in Shortage***
Nimodipine (Nymalize) Oral Solution	***Currently in Shortage***
Peritoneal Dialysis Solutions	***Currently in Shortage***
Phentolamine Mesylate Injection	***Currently in Shortage***
Piperacillin and Tazobactam (Zosyn) Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Reserpine Tablets	***Currently in Shortage***
Sacrosidase (Sucraid) Oral Solution	***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***
Sumatriptan (Imitrex) Nasal Spray	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Tigecycline (Tygacil) Injection	***Currently in Shortage***
Tiopronin (Thiola)	***Currently in Shortage***
Tobramycin Injection	***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***