Oklahoma Health Care Authority

Drug Utilization Review Board

November 2015

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 November 2015

DATE: November 1, 2015

Enclosed are the following items related to the November DUR packet.
Material is arranged in order of the agenda.

DUR Board Meeting Minutes – Appendix A

Update on Medication Coverage Authorization Unit/Topical Antifungal Medication Post-Educational Mailing – Appendix B

30-Day Notice to Prior Authorize Ibrance® (Palbociclib) – Appendix C

30-Day Notice to Prior Authorize Keveyis™ (Dichlorphenamide) – Appendix D

Annual Review of Xgeva® (Denosumab) – Appendix E

Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Pramosone® (Hydrocortisone/Pramoxine Topical Cream and Lotion) and Enstilar® (Calcipotriene/Betamethasone Dipropionate Foam) – Appendix F

Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Omidria® (Phenylephrine/Ketorolac Injection) – Appendix G

Annual Review of Tetracycline and Fluoroquinolone Antibiotics and 30-Day Notice to Prior Authorize Tetracycline Capsules, Minocycline Tablets, Ofloxacin Tablets, & Moxifloxacin Tablets – Appendix H

Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum) – Appendix I

Fiscal Year 2015 Annual Review of Erythropoiesis-Stimulating Agents – Appendix J

FDA and DEA Updates – Appendix K

Future Business

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
November 2015

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4345 N. Lincoln Blvd.
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AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   - A. October 14, 2015 DUR Minutes
   - B. October 14, 2015 DUR Recommendations Memorandum
   - C. Correspondence

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

2. **Update on Medication Coverage Authorization Unit/Topical Antifungal Medication Post-Educational Mailing – See Appendix B**
   - A. Medication Coverage Activity for October 2015
   - B. Pharmacy Help Desk Activity for October 2015
   - C. Topical Antifungal Medication Post-Educational Mailing

Items to be presented by Dr. Schmidt, Dr. Borders, Dr. Medina, Dr. Muchmore, Chairman:

3. **30-Day Notice to Prior Authorize Ibrance® (Palbociclib) – See Appendix C**
   - A. Ibrance® (Palbociclib) Product Summary
   - B. Utilization Details of Ibrance® (Palbociclib)
   - C. Recommendations

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

4. **30-Day Notice to Prior Authorize Keveyis™ (Dichlorphenamide) – See Appendix D**
   - A. Hyperkalemic and Hypokalemic Periodic Paralysis Background Information
   - B. Keveyis™ (Dichlorphenamide) Product Summary
   - C. College of Pharmacy Recommendations

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

5. **Annual Review of Xgeva® (Denosumab) – See Appendix E**
   - A. Current Prior Authorization Criteria
   - B. Utilization of Xgeva® (Denosumab)
   - C. Prior Authorization of Xgeva® (Denosumab)
   - D. Market News and Updates
   - E. Hypercalcemia of Malignancy Summary
   - F. College of Pharmacy Recommendations

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

6. **Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Pramosone® (Hydrocortisone/Pramoxine Topical Cream and Lotion) and Enstilar® (Calcipotriene/Betamethasone Dipropionate Foam) – See Appendix F**
   - A. Current Prior Authorization Criteria
   - B. Utilization of Topical Corticosteroids
   - C. Prior Authorization of Topical Corticosteroids
   - D. Market News and Updates

E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Topical Corticosteroids

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

7. Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Omidria® (Phenylephrine/Ketorolac Injection) – See Appendix G

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Ophthalmic Anti-Inflammatories
D. Prior Authorization of Ophthalmic Anti-Inflammatories
E. Market News and Updates
F. Omidria® (Phenylephrine/Ketorolac Injection) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Ophthalmic NSAIDs
I. Utilization Details of Ophthalmic Corticosteroids

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

8. Annual Review of Tetracycline and Fluoroquinolone Antibiotics and 30-Day Notice to Prior Authorize Tetracycline Capsules, Minocycline Tablets, Ofloxacin Tablets, & Moxifloxacin Tablets – See Appendix H

A. Introduction
B. Current Prior Authorization Criteria
C. Tetracycline Antibiotic Utilization
D. Clinical Comparison: Oral, Immediate-Release Tetracycline Antibiotics
E. Fluoroquinolone Antibiotic Utilization
F. Clinical Comparison: Oral Fluoroquinolone Antibiotics
G. College of Pharmacy Recommendations
H. Utilization Details of Oral Tetracycline Antibiotics
I. Utilization Details of Oral Fluoroquinolone Antibiotics

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

9. Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Xiaflex® (Collagenase Clostridium Histolyticum)
C. Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)
D. Market News and Updates
E. Peyronie's Disease Summary
F. College of Pharmacy Recommendations

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

10. Annual Review of Erythropoiesis-Stimulating Agents – See Appendix J

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Erythropoiesis-Stimulating Agents (ESAs)
D. Prior Authorization of ESAs
E. Market News and Updates
F. College of Pharmacy Recommendations
G. Utilization Details of ESAs

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

11. FDA and DEA Updates – See Appendix K

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

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

The December DUR Meeting will be held on December 16, 2015 at 4:30 PM

A. Hepatitis C Medications/Technivie™ (Ombitasvir/Paritaprevir/Ritonavir) & Daklinza™ (Daclatasvir)
B. HFA Rescue Inhalers/ProAir® RespiClick (Albuterol Sulfate)
C. Fibromyalgia Medications
D. Maintenance Asthma & COPD Medications/Stiolto™ Respimat® (Tiotropium/Olodaterol), Arnuity™ Ellipta® (Fluticasone Furoate), & Utibron™ Neohaler® (Indacaterol/Glycopyrrolate)
E. Hematopoietic Growth Factors/Neulasta® (Pegfilgrastim), Granix® (Tbo-filgrastim), & Zarxio™ (Filgrastim-sndz)
F. Aggrenox® (Aspirin/Dipyridamole Extended-Release)
G. Oral Antifungal Medications/Noxafil® (Posaconazole) & Cresemba® (Isavuconazonium)
H. Cortisporin® (Neomycin/Polymyxin B/Hydrocortisone Otic Suspension)

***Future business subject to change.**

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF OCTOBER 14, 2015

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director		x
Michyla Adams, Pharm.D.; Clinical Pharmacist	x	
Wendi Chandler, 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	
Grace Hsu, Pharm.D.; Clinical Pharmacist	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.; Academic Detailing Pharmacist		x
Graduate Students: Christina Bulkley, Pharm.D.		x
David George, Pharm.D.		x
Timothy Pham, Pharm.D.	x	

	PRESENT	ABSENT
Marlene Asmussen, R.N.; Population Care Management Director		x
Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm	x	
Nico Gomez, Chief Executive Officer		x
Sylvia Lopez, M.D.; FAAP; Chief Medical Officer		x
Ed Long, Chief Communications Officer		x
Kelli Brodersen, Marketing Coordinator	x	
Nancy Nesser, Pharm.D.; J.D.; Pharmacy Director	x	
Rebecca Pasternik-Ikard, Deputy State Medicaid Director		x
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Garth Splinter, M.D.; M.B.A.; Medicaid Director	x	
Joseph Young, Deputy General Counsel IV	x	
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:		
Sean Seago, Merck	Fran Kaiser, Merck	Paul McDermott, Celegene
Jana Shardonofsky, Vertex	Quynh Doan, Abbvie	Lon Lowrey, Novartis
Rick Ulasewich, DSL	Phillip Lafferty, Celegene	Roger Grotzinger, BMS
Gay Thomas, BMS	Kaitlin Harrison, Student	Brooke Winegardner
Jim Chapman, AbbVie	Brian Maves, Pfizer	Bob Gustafson, Lundbeck
Michele Puyear, Gilead Science	Mevin Nwamadi, Abbott	Mark DeClerk, Lilly
Jim Fowler, AstraZeneca	Eric Gardner, Vertex	Jason Schwier, Amgen

PRESENT FOR PUBLIC COMMENT:	
Fran Kaiser	Merck
Paul McDermott	Celegene
Mai Duong	Novartis
Quynh Doan	AbbVie

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA NO. 9 & 12 SPEAKER: FRAN KAISER
2B: AGENDA NO. 14 SPEAKER: PAUL MCDERMOTT
2C: AGENDA NO. 14 SPEAKER: MAI DUONG
2D: AGENDA NO. 14 SPEAKER: QUYNH DOAN

ACTION: NONE REQUIRED

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

3A: SEPTEMBER 9, 2015 DUR MINUTES – VOTE
3B: SEPTEMBER 9, 2015 DUR RECOMMENDATIONS MEMORANDUM
3C: VERIPRED™ AND MILLIPRED™ PRIOR AUTHORIZATION MEMORANDUM
3D: CORRESPONDENCE

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **VOTE ON 2016 MEETING DATES**

4A: 2016 DUR BOARD MEETING DATES

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 5: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/BOWEL PREPARATION MEDICATION POST- EDUCATIONAL MAILING**

5A: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2015
5B: PHARMACY HELP DESK ACTIVITY FOR SEPTEMBER 2015
5C: BOWEL PREPARATION MEDICATION POST-EDUCATIONAL MAILING

Materials included in agenda packet; presented by Dr. Holderread

Dr. Harrell moved to approve; seconded by Ms. Varalli-Claypool
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE TYKERB® (LAPATINIB), HALAVEN® (ERIBULIN), IXEMPRA® (IXABEPILONE), KADCYLA® (ADO-TRASTUZUMAB), AFINITOR® (EVEROLIMUS), & PERJETA® (PERTUZUMAB)
6A: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented Dr. Schmidt, Dr. Borders, Dr. Medina
Dr. Harrell moved to approve; seconded by Dr. Huddleston
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ORKAMBI™ (LUMACAFTOR/IVACAFTOR)
7A: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Teel
Dr. Winegardner moved to approve; seconded by Dr. Rhymer
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE SAVAYSA® (EDOXABAN)
8A: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Hsu
Dr. Harrell moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE EPANOVA® (OMEGA-3-CARBOXYLIC ACIDS), PRALUENT® (ALIROCUMAB), & REPATHA™ (EVOLOCUMAB)
9A: COLLEGE OF PHARMACY RECOMMENDATIONS
9B: ATTACHMENT A: DIAGNOSIS OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH)
9C: ATTACHMENT B: FRAMINGHAM HEART STUDY AND FRAMINGHAM RISK SCORE
9D: DRAFT PCSK9 INHIBITOR PRIOR AUTHORIZATION FORM
Materials included in agenda packet; presented by Dr. Adams
Dr. Winegardner moved to approve; seconded by Dr. Rhymer
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF CONSTIPATION AND DIARRHEA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE MOVANTIK™ (NALOXEGOL), VIBERZI™ (ELUXADOLINE), & XIFAXAN® (RIFAXIMIN)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
10C: PRIOR AUTHORIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: PRODUCT SUMMARIES
10F: COLLEGE OF PHARMACY RECOMMENDATIONS
10G: UTILIZATION DETAILS OF CONSTIPATION AND DIARRHEA MEDICATIONS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **30-DAY NOTICE TO PRIOR AUTHORIZE DARAPRIM® (PYRIMETHAMINE)**

11A: TOXOPLASMOSIS BACKGROUND INFORMATION
11B: DARAPRIM® (PYRIMETHAMINE) PRODUCT SUMMARY
11C: DARAPRIM® (PYRIMETHAMINE) COST UPDATE
11D: UTILIZATION DETAILS OF DARAPRIM® (PYRIMETHAMINE)
11E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF ALLERGY IMMUNOTHERAPIES AND 30-DAY NOTICE TO PRIOR AUTHORIZE ORALAIR® (SWEET VERNAL, ORCHARD, PERENNIAL RYE, TIMOTHY, & KENTUCKY BLUE GRASS MIXED POLLENS ALLERGEN EXTRACT)**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: PRIOR AUTHORIZATION OF ALLERGY IMMUNOTHERAPIES
12C: ORALAIR® (ALLERGEN EXTRACT) PRODUCT SUMMARY
12D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Teel

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **ANNUAL REVIEW OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DYLOJECT™ (DICLOFENAC SODIUM)**

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)
13C: PRIOR AUTHORIZATION OF NSAIDS
13D: MARKET NEWS AND UPDATES
13E: DYLOJECT™ (DICLOFENAC SODIUM) PRODUCT SUMMARY
13F: NSAID PRICE TRENDS
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF NSAIDS

Materials included in agenda packet; presented by Dr. Hsu

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE COSENTYX® (SECUKINUMAB)**

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
14C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
14D: MARKET NEWS AND UPDATES
14E: COSENTYX® (SECUKINUMAB) PRODUCT SUMMARY
14F: HIDRADENITIS SUPPURATIVA SUMMARY
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: UTILIZATION DETAILS OF TARGETED IMMUNOMODULATOR AGENTS

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF INHALED TOBRAMYCIN PRODUCTS AND PULMOZYME® (DORNASE ALFA) AND 30-DAY NOTICE TO PRIOR AUTHORIZE CAYSTON® (AZTREONAM INHALATION) & KITABIS™ PAK (TOBRAMYCIN INHALATION)**

15A: INTRODUCTION
15B: CURRENT PRIOR AUTHORIZATION CRITERIA
15C: UTILIZATION OF INHALED TOBRAMYCIN PRODUCTS, DORNASE ALFA, & AZTREONAM INHALATION
15D: PRIOR AUTHORIZATION OF INHALED TOBRAMYCIN PRODUCTS AND DORNASE ALFA
15E: MARKET NEWS AND UPDATES
15F: PRODUCT SUMMARIES
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF INHALED TOBRAMYCIN PRODUCTS, DORNASE ALFA, & AZTREONAM INHALATION

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF XOLAIR® (OMALIZUMAB)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF XOLAIR® (OMALIZUMAB)
16C: PRIOR AUTHORIZATION OF XOLAIR® (OMALIZUMAB)
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; Questions only

ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: **FDA AND DEA UPDATES**

Materials included in agenda packet; presented by Dr. Keast

ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

18A: OPHTHALMIC ANTI-INFLAMMATORIES/OMIDRIA™ (PHENYLEPHRINE/KETOROLAC INJECTION)
18B: TOPICAL CORTICOSTEROIDS
18C: XIAFLEX® (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM)
188: XGEVA® (DENOSUMAB)
18E: ERYTHROPOIETIN STIMULATING AGENTS
18F: PRIALT® (ZICONOTIDE)
18G: TETRACYCLINE AND OFLOXACIN 400MG TABLETS
18H: KEVEYIS™ (DICHLOROPHENAMIDE)
18I: IBRANCE® (PALBOCICLIB)

***Future business subject to change.

AGENDA ITEM NO. 19: **ADJOURNMENT**

The meeting was adjourned at 5:24 pm

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

Memorandum

Date: October 15, 2015

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

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

Subject: DUR Board Recommendations From Meeting of October 14, 2015

Recommendation 1: Vote on 2016 Meeting Dates

MOTION CARRIED by unanimous approval.

Meetings are held the second Wednesday of every month at 4:00PM

January 13, 2016	May 11, 2016	September 14, 2016
February 10, 2016	June 8, 2016	October 12, 2016
March 9, 2016	July 13, 2016	November 9, 2016
April 13, 2016	August 10, 2016	December 14, 2016

Recommendation 2: Bowel Preparation Medication Post-Educational Mailing: Consideration of Implementation of a Product Based Prior Authorization Category

NO ACTION REQUIRED.

The College of Pharmacy recommends the following in regards to the bowel preparation medications:

1. Conduct a complete drug utilization review of the bowel preparation medication class to evaluate safety, efficacy, and cost of all products.

a. The drug utilization review should also include claims analysis for potential inappropriate use.
2. If appropriate, consider implementation of a PBPA category.
3. Alternatives to a PBPA category include additional targeted educational mailings to encourage appropriate, cost-effective utilization of the bowel preparation medications.

Recommendation 3: Vote to Prior Authorize Tykerb® (Lapatinib), Halaven® (Eribulin), Ixempra® (Ixabepilone), Kadcyla® (Ado-Trastuzumab), Afinitor® (Everolimus), & Perjeta® (Pertuzumab)

MOTION CARRIED by unanimous approval.

Tykerb® (Lapatinib) Approval Criteria:

1. An FDA approved diagnosis of metastatic or recurrent breast cancer; and
2. Positive expression of Human Epidermal Receptor Type 2 (HER2); and
3. Tykerb® must be used in combination with one of the following:
    a. Herceptin® (trastuzumab); or
    b. Xeloda® (capecitabine); or
    c. An aromatase inhibitor [e.g. Aromasin® (exemestane), Femara® (letrozole) or Arimidex® (anastrozole)] if also estrogen receptor positive (ER positive).

Halaven® (Eribulin) Approval Criteria:

1. Diagnosis of metastatic breast cancer; and
2. Previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

Ixempra® (Ixabepilone) Approval Criteria:

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Usage as either:
    a. In combination with capecitabine after failure of an anthracycline and a taxane; or
        i. May be used in combination in taxane only resistance if anthracyclines not indicated; or
    b. Monotherapy after failure of an anthracycline, a taxane, and capecitabine.

Kadcyla® (Ado-Trastuzumab) Approval Criteria:

1. Positive expression of Human Epidermal Receptor Type 2 (HER2); and
2. Diagnosis of metastatic breast cancer; and
3. Member has previously received trastuzumab and a taxane, separately or in combination; and
4. Members should also have either:
    a. Received prior therapy for metastatic disease; or
    b. Developed disease recurrence during or within six months of completing adjuvant therapy.

Perjeta® (Pertuzumab) Approval Criteria:

1. Positive expression of Human Epidermal Receptor Type 2 (HER2); and
2. Usage for either:
    a. Metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; or
    b. Neoadjuvant treatment of patients with locally advanced, inflammatory, or early stage breast cancer (either greater than 2cm in diameter or node positive); and
3. Used in combination with trastuzumab and docetaxel (neoadjuvant treatment may also contain other agents as well in addition to trastuzumab and docetaxel).

Afinitor® (Everolimus) Approval Criteria (Breast Cancer Diagnosis):

1. Diagnosis of advanced breast cancer; and
2. Negative expression of Human Epidermal Receptor Type 2 (HER2); and
3. Hormone receptor-positive (ER positive); and
4. Used in combination with exemestane; and
5. Member must have failed treatment with, have a contraindication to, or be intolerant to letrozole or anastrozole.

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors of Pancreatic Origin (PNET) Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic neuroendocrine tumors of pancreatic origin (PNET); and
2. Progressive disease from a previous treatment.

Afinitor® (Everolimus) Approval Criteria (Renal Cell Carcinoma Diagnosis):

1. Diagnosis of advanced renal cell carcinoma; and
2. Failure of treatment with sunitinib or sorafenib.

Afinitor® (Everolimus) Approval Criteria [Renal Angiomyolipoma and Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC); and
2. Not requiring immediate surgery; and
3. Used in pediatric and adult patients with age ≥ 1 year.

Afinitor® (Everolimus) Approval Criteria [Subependymal Giant Cell Astrocytoma (SEGA) with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC); and
2. Requires therapeutic intervention but cannot be curatively resected.

Recommendation 4: Vote to Prior Authorize Orkambi™ (Lumacaftor/Ivacaftor)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Orkambi™ (lumacaftor/ivacaftor) with the following criteria:

Orkambi™ (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in patients who are homozygous for the F508del mutation in the CFTR gene detected by genetic testing; and
2. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene; and
3. Orkambi™ will not be approved for patients with CF other than those homozygous for the F508del mutation; and
4. Member must be 12 years of age or older; and
5. Members using Orkambi™ must be supervised by a pulmonary specialist; and
6. The prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi™, every three months during the first year of treatment, and annually thereafter; and
7. Members must not be taking any of the following medications concomitantly with Orkambi™: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
8. A quantity limit of four tablets per day or 112 tablets per 28 days will apply.
9. Initial approval will be for the duration of three months, after which time, compliance will be required for continued approval. After six months of utilization, compliance and information regarding efficacy, such as improvement in FEV_1, will be required for continued approval.

Recommendation 5: Vote to Prior Authorize Savaysa® (Edoxaban)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Savaysa® (edoxaban) with the following criteria:

Savaysa® (Edoxaban) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
    a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation; or
    b. For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
3. Member must not have a creatinine clearance (CrCl) greater than 95mL/min because of increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and
4. A quantity limit of 30 tablets per 30 days will apply.

In September 2015, the FDA approved a 60mg strength tablet of Brilinta® (ticagrelor). The 60mg dose is labeled to be used twice daily after one year of therapy with the 90mg twice daily dosage. The College of Pharmacy recommends the following changes to the prior authorization criteria for Brilinta® (ticagrelor):

Brilinta® (Ticagrelor) Approval Criteria:

1. The first 90 days of therapy with the 90mg strength tablets does not require prior authorization; and
2. Approved diagnostic criteria: acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction) with or without percutaneous coronary intervention (PCI); and
3. Approvals of the 90mg twice daily dosage will be for the duration of one year after which time the member should switch to the 60mg twice daily dosage or provide patient-specific, clinically significant reasoning for continuing the 90mg twice daily dosage; and
4. The 60mg twice daily dosage may be approved after one year of therapy with the 90mg twice daily dosage.

Recommendation 6: Vote to Prior Authorize Epanova® (Omega-3-Carboxylic Acids), Praluent® (Alirocumab), & Repatha™ (Evolocumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Epanova® (omega-3-carboxylic acids) with the following criteria:

Lovaza® (Omega-3-Acid Ethyl Esters), Vascepa® (Icosapent Ethyl), and Epanova® (Omega-3-Carboxylic Acids) Approval Criteria:

1. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides ≥ 500mg/dL), and controlled diabetes (fasting glucose < 150mg/dL at the time of triglycerides measurement and HgA1C < 7.5%); and
2. Previous failure with both nicotinic acid and fibric acid medications; and
3. Use of Vascepa® or Epanova® requires a patient-specific, clinically significant reason why the member cannot use omega-3-acid ethyl esters (generic Lovaza®).

Additionally, the College of Pharmacy recommends the prior authorization of PCSK9 inhibitors, Praluent® (alirocumab) and Repatha™ (evolocumab), with the following criteria:

PCSK9 Inhibitors Approval Criteria:

1. An FDA approved diagnosis of heterozygous familial hypercholesterolemia (HeFH) defined by the presence of one of the following criteria:
    a. A documented functional mutation(s) in the LDL receptor (LDLR) gene or other HeFH-related genes via genetic testing; or
    b. Definite HeFH using either the Simon Broome Register criteria or the Dutch Lipid Network criteria; or
2. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least one of the following:
    a. A documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
    b. An untreated total cholesterol greater than 500mg/dL and at least one of the following:

        i. Documented evidence of definite HeFH in both parents; or
        ii. Presence of tendinous/cutaneous xanthoma prior to age 10 years; or
3. An FDA approved diagnosis of clinical atherosclerotic cardiovascular disease defined by the presence of one of the following criteria:
    a. High cardiovascular risk confirmed by Framingham risk score; and
        i. Supporting diagnoses/conditions signifying this risk level; or
    b. Documented history of Coronary Heart Disease (CHD); and
        i. Supporting diagnoses/conditions and dates of occurrence signifying history of CHD; and
4. Member must be 18 years of age or older for the diagnosis of HeFH or clinical atherosclerotic cardiovascular disease, or must be 13 years of age or older for the diagnosis of HoFH; and
5. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    b. LDL-cholesterol (LDL-C) levels should be included following at least 12 weeks of treatment with each statin medication; and
    c. For statin intolerance due to myalgia, creatine kinase (CK) labs verifying rhabdomyolysis must be provided; and
    d. Tier structure rules still apply; and
6. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
7. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
8. Repatha™ requests for the dosing regimen of 420mg once monthly require a diagnosis of HoFH or require a patient-specific, clinically significant reason why the member cannot use Repatha™ at the dosing regimen of 140mg every 2 weeks; and
9. A quantity limit of 2 syringes or pens per 28 days will apply for Praluent® and a quantity limit of 2 syringes or autoinjectors per 28 days will apply for Repatha™. Patients with the diagnosis of HoFH needing 3 Repatha™ syringes or autoinjectors per 30 days (for the dosing regimen of 420mg once monthly) will be approved for a quantity limit override upon meeting PCSK9 inhibitors approval criteria.
10. Initial approvals will be for the duration of three months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every six months thereafter for continued approval.

Recommendation 7: Annual Review of Constipation and Diarrhea Medications and 30-Day Notice to Prior Authorize Movantik™ (Naloxegol), Viberzi™ (Eluxadoline), & Xifaxan® (Rifaximin)

NO ACTION REQUIRED.

Recommendation 8: 30-Day Notice to Prior Authorize Daraprim® (Pyrimethamine)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Allergy Immunotherapies and 30-Day Notice to Prior Authorize Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, & Kentucky Blue Grass Mixed Pollens Allergen Extract)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Non-Steroidal Anti-Inflammatory Drugs and 30-Day Notice to Prior Authorize Dyloject™ (Diclofenac Sodium)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Cosentyx® (Secukinumab)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Inhaled Tobramycin Products & Pulmozyme® (Dornase Alfa) and 30-Day Notice to Prior Authorize Cayston® (Aztreonam Inhalation) & Kitabis™ Pak (Tobramycin Inhalation)

NO ACTION REQUIRED.

Recommendation 13: Annual Review of Xolair® (Omalizumab)

NO ACTION REQUIRED.

Oklahoma DUR Board
Attention: Nancy Nesser
4345 N. Lincoln Blvd
Oklahoma City, OK 73105

October 12, 2015

Oklahoma DUR Board:

As a medical doctor/dermatologist treating patients in Oklahoma, I am writing to express my concern regarding access to medical care in the Oklahoma Medicaid program for people with psoriasis. I routinely see Medicaid patients at my clinic in Oklahoma City.

The National Psoriasis Foundation recently identified aspects of Medicaid policies nationwide that are onerous and provide barriers to care for patients with psoriasis (and psoriatic arthritis). I am writing as a dermatologist who is concerned about access to treatment for patients in my practice and community. I have seen firsthand the pain and disability that can be experienced by patients who do not have a treatment that works for them, as well as significant improvements in mental and physical functioning in patient that receive appropriate medical treatment.

Psoriasis is a non-contagious, chronic, inflammatory, painful, disfiguring and disabling autoimmune disease for which there is no cure. It is the most prevalent autoimmune disease in the U.S. and is estimated to affect approximately 17.5 million Americans. About a quarter of these would be people with moderate to severe disease. People with severe psoriasis are significantly more likely to be considered "low-income" than those with mild disease, and to report that their psoriasis is the reason they are not working. Up to 30 percent of people with psoriasis also develop psoriatic arthritis. Additionally, psoriasis is connected with an increased risk for other serious, chronic and life-threatening conditions including cardiovascular disease, diabetes, hypertension, and stroke.

While recognizing the fiscal constraints experienced by state government, I ask that you consider that reasonable Medicaid policies may improve members' health status and ability to work. Access to appropriate and timely treatment is important to prevent much of the disability and psychosocial impacts of the disease. Psoriasis poses a severe hardship, both in terms of direct economic costs as well as substantial physical and psychological burden. Total direct and indirect health care costs of psoriasis for patients with insurance are calculated at $11.25 billion annually with work loss accounting for 40% of the cost burden. Approximately 60 percent of psoriasis patients missed an average of 26 days of work a year due to their disease. It is in the best interest of all concerned that psoriasis patients and their physicians have the resources to find the treatment that enables people to fully participate in society.

Given the above points, I have reviewed Medicaid policies related to treatment of psoriasis and have the following recommendations:

1.The addition of secukinumab (Cosentyx) to the Oklahoma Medicaid formulary in the Tier 2 position. Cosentyx is the first in its class of human IgG1 monoclonal antibody that selectively

binds to and neutralizes the proinflammatory cytokine interleukin 17A (IL-17A). IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses and plays a key role in the pathogenesis of psoriasis. It has been a welcome addition to my armamentarium for the treatment of plaque psoriasis in my practice as it is quick acting and proven to be well-tolerated and safe. The current Tier 2 biologic offerings on the Oklahoma Medicaid formulary for treatment of plaque psoriasis include etanercept (Enbrel), and adalimubab (Humira) – both of these agents have the same mechanism of action. Cosentyx works from an entirely different pathway so will allow excellent expansion of treatment options available to our Medicaid patients.

2. Elimination of the multi-step failure policy. Patients are required to try and fail a Tier 1 product, and both Humira and Enbrel before qualifying for Tier 3 products. The requirement to have a trial of two separate agents that have the same mechanism of action is redundant, and a costly requirement. While it is reasonable to expect patients to try a less expensive option first, if it is not contraindicated, the multi-step failure policy places excessive burden on the patient and is not appropriate in all cases. Many older systemic medications such as methotrexate cannot be taken chronically due to ultimate hepatic irritation. Insurers need to trust the physician that they have considered these in their decision to prescribe a biologic as "first-line" systemic treatment due to their proven safety over long treatment periods and efficacy.

Thank you for your consideration.

Sincerely,

Carlos Garcia, M.D.
Medical and Surgical Dermatologist,
Coordinator- Oklahoma City Dermatological Society

Tulsa Pediatric
After Hours Urgent Care

October 2, 2015

To Whom It May Concern:

I am writing in regards to the recent removal of millipred from tier 1. In our urgent care setting, we find the use of millipred very helpful. It has a much better taste which means higher patient compliance and less repeat visits due to medication concerns. My other concern with prednisolone being the medication currently available is its alcohol content. Granted it is in very low amounts, I would still prefer to give my patients medications that are alcohol free.

Thank you for your time. I love seeing our Medicaid population and want to continue to serve them in the best way possible.

Sincerely,

Erin J. Grimes, MD

Tulsa Pediatric Urgent Care

Physician Owner, Lab Director

Tulsa Pediatric
After Hours Urgent Care

Leah Baxter, DO
Katie Dalton, DO
Erin Grimes, MD
Liz Bader, DO

October 5, 2015

To Whom It May Concern:

I am writing in regards to the recent removal of Millipred from tier 1. In our urgent care setting, we find the use of Millipred very helpful. It has a much better taste which means higher patient compliance and less repeat visits due to medication concerns. I am also concerned with prednisolone being the medication currently available because of its high alcohol content. Granted it is in very low amounts, I would still prefer an option for my patients that is alcohol free.

We enjoy seeing our Medicaid patients and would like to continue giving the best possible care. Thanks for your time.

Sincerely,

Leah Baxter, DO
Tulsa Pediatric Urgent Care
Physician/Owner

7723 E. 91st St., Tulsa, OK 74133
Phone: 918.895.7808 Fax: 918.895.7807 www.tulsapediatricurgentcare.com

FAMILY
HEALTH CENTER

10-12-15

To: Director of Pharmacy

Dear Sir —

This letter is regarding your removal of Millypred from the Medicaid formulary. This drug is the only palatable steroid liquid available and I wish you would return the liquid to the formulary. I have been using it exclusively in pediatric patients for several years because of compliance. I realize there are cheaper alternatives but I also know what they taste like. I hope you will reconsider the decision to take Millypred off.

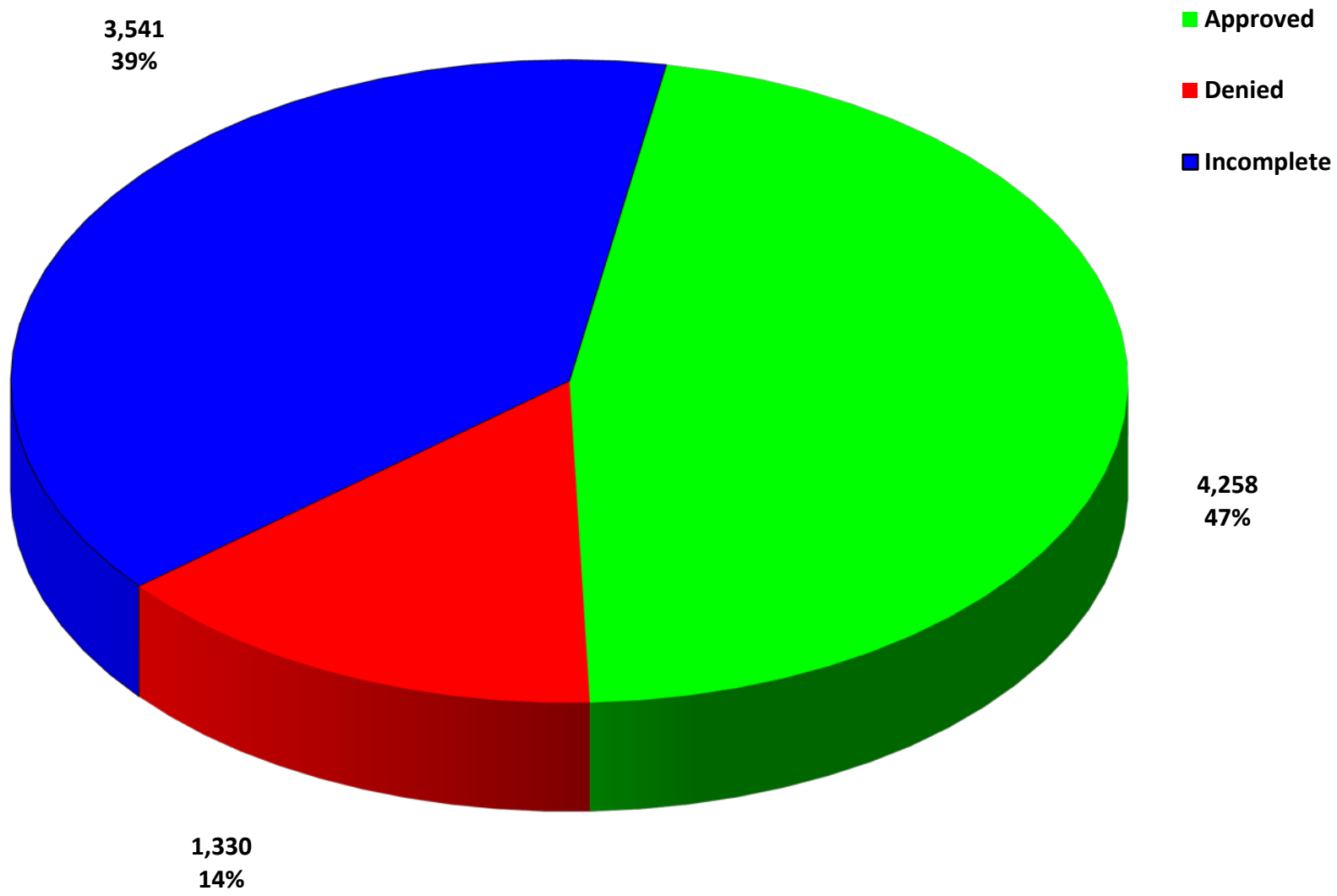
Thanks

Shaton Hoee APRN-CNP

1104 Walnut Drive • Ardmore, Oklahoma 73401 • Phone (580) 226-0543 • Fax (580) 226-2284

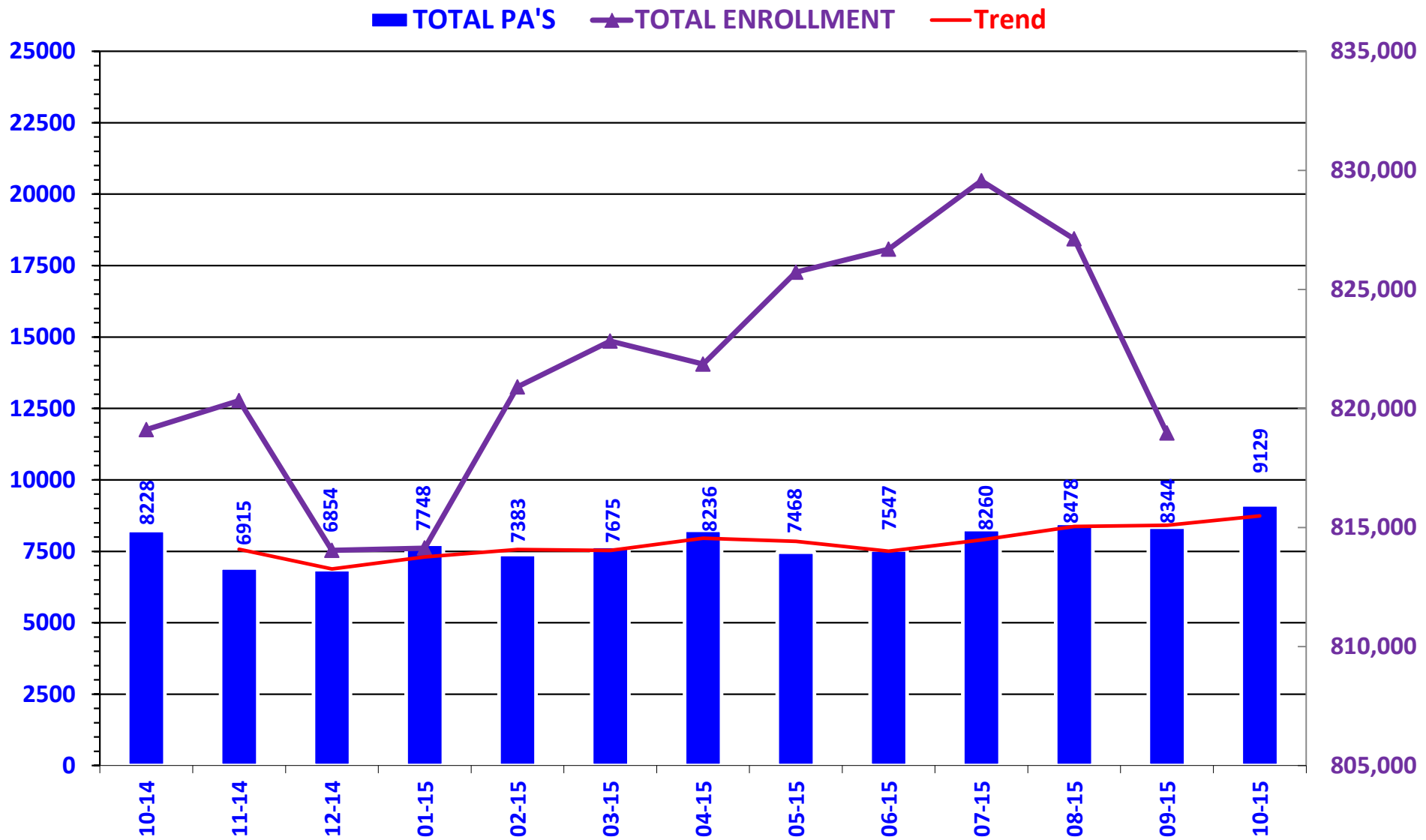
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: OCTOBER 2015



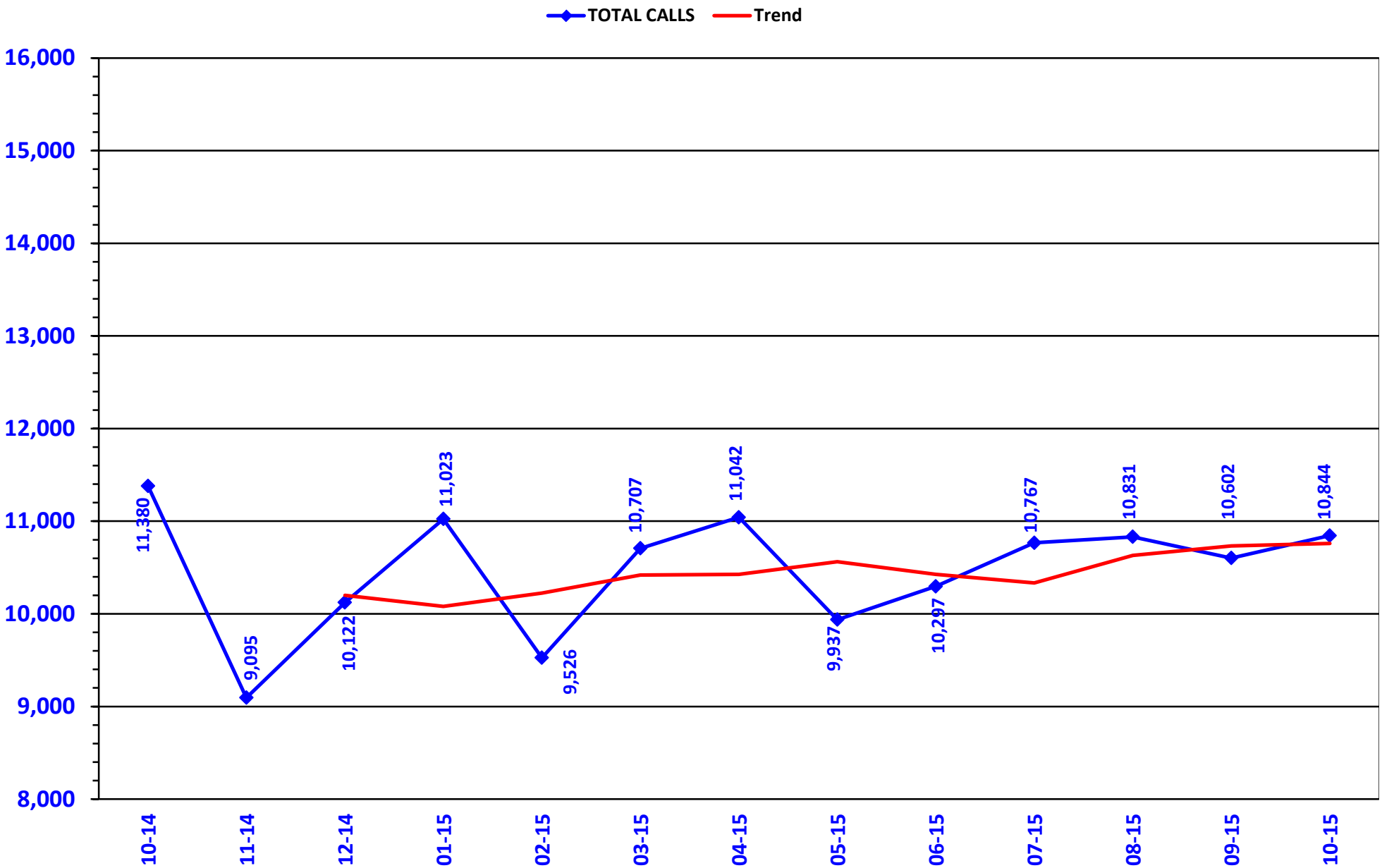
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: OCTOBER 2014 – OCTOBER 2015



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
OCTOBER 2014 – OCTOBER 2015



Prior Authorization Activity

10/1/2015 Through 10/31/2015

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	446	189	58	199	352
Analgesic - NonNarcotic	28	1	4	23	7
Analgesic, Narcotic	456	243	48	165	151
Angiotensin Receptor Antagonist	18	4	1	13	277
Antiasthma	179	74	25	80	338
Antibiotic	48	9	9	30	64
Anticoagulant	13	9	1	3	359
Anticonvulsant	86	37	14	35	349
Antidepressant	101	24	18	59	302
Antidiabetic	162	67	17	78	345
Antifungal	11	2	3	6	24
Antihistamine	234	183	18	33	357
Antimigraine	61	6	14	41	240
Antiulcers	206	54	53	99	134
Anxiolytic	74	52	4	18	247
Atypical Antipsychotics	532	245	56	231	334
Biologics	89	33	18	38	353
Bladder Control	58	17	11	30	324
Blood Thinners	130	84	8	38	323
Botox	26	18	4	4	343
Cardiovascular	86	33	6	47	277
Cephalosporins	11	3	1	7	5
Chronic Obstructive Pulmonary Disease	51	8	11	32	360
Contraceptive	13	7	3	3	263
Corticosteroid	14	1	3	10	28
Dermatological	108	23	49	36	88
Diabetic Supplies	498	255	27	216	230
Endocrine & Metabolic Drugs	63	40	8	15	129
Erythropoietin Stimulating Agents	18	9	5	4	94
Fibromyalgia	146	36	54	56	331
Fish Oils	18	3	4	11	360
Gastrointestinal Agents	108	32	27	49	107
Glaucoma	10	0	2	8	0
Growth Hormones	79	65	4	10	150
Hepatitis C	183	99	50	34	8
HFA Rescue Inhalers	68	19	9	40	353
Insomnia	47	5	11	31	213
Insulin	46	9	9	28	254
Linzess, Amitiza, and Relistor	75	12	23	40	228
Multiple Sclerosis	66	24	16	26	232
Muscle Relaxant	72	14	24	34	72
Nasal Allergy	110	22	28	60	270
Neurological Agents	44	29	4	11	336
NSAIDs	185	31	51	103	314
Ocular Allergy	44	6	8	30	177
Ophthalmic Anti-infectives	10	3	3	4	7
Ophthalmic Corticosteroid	10	3	1	6	9
Ophthalmic NSAIDs	12	2	1	9	23
Osteoporosis	19	9	4	6	318
Other*	242	37	64	141	201
Otic Antibiotic	19	0	3	16	0
Pediculicide	235	112	19	104	17
Prenatal Vitamins	17	0	0	17	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Statins	66	19	11	36	347
Stimulant	1,091	519	127	445	340
Suboxone/Subutex	229	174	6	49	85
Synagis	395	88	133	174	150
Testosterone	57	20	12	25	315
Topical Antibiotic	11	0	0	11	0
Topical Antifungal	37	0	4	33	0
Topical Corticosteroids	71	1	17	53	177
Vitamin	71	22	33	16	283
Pharmacotherapy	80	72	1	7	256
Emergency PAs	0	0	0	0	
Total	**7,793**	**3,217**	**1,260**	**3,316**	
Overrides					
Brand	58	32	6	20	288
Cumulative Early Refill	6	6	0	0	70
Diabetic Supplies	10	8	0	2	142
Dosage Change	352	321	1	30	8
High Dose	2	2	0	0	186
Ingredient Duplication	67	46	2	19	13
Lost/Broken Rx	84	74	6	4	6
NDC vs Age	30	30	0	0	286
Nursing Home Issue	31	27	1	3	5
Opioid Quantity	11	11	0	0	177
Other*	41	39	0	2	11
Prescriber Temp Unlock	1	1	0	0	13
Quantity vs. Days Supply	615	429	46	140	270
STBS/STBSM	15	15	0	0	77
Stolen	13	11	0	2	4
Temporary Unlock	2	1	1	0	27
Third Brand Request	26	14	7	5	22
Overrides Total	**1,336**	**1,041**	**70**	**225**	
Total Regular PAs + Overrides	**9,129**	**4,258**	**1,330**	**3,541**	

Denial Reasons	
Unable to verify required trials.	3,080
Does not meet established criteria.	1,277
Lack required information to process request.	522

Other PA Activity	
Duplicate Requests	601
Letters	6,979
No Process	15
Changes to existing PAs	388
Helpdesk Initiated Prior Authorizations	887
PAs Missing Information	36

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

Topical Antifungal Medication Post-Educational Mailing

Oklahoma Health Care Authority
November 2015

Topical Antifungal Medication Letter

The College of Pharmacy and the Oklahoma Health Care Authority are engaged in an effort to promote cost effective utilization of topical antifungal medications. In October 2014, an educational letter was sent to SoonerCare contracted pharmacies regarding appropriate and cost-effective use of topical, over the counter (OTC) antifungal products for SoonerCare members 20 years of age and younger with a medical need.

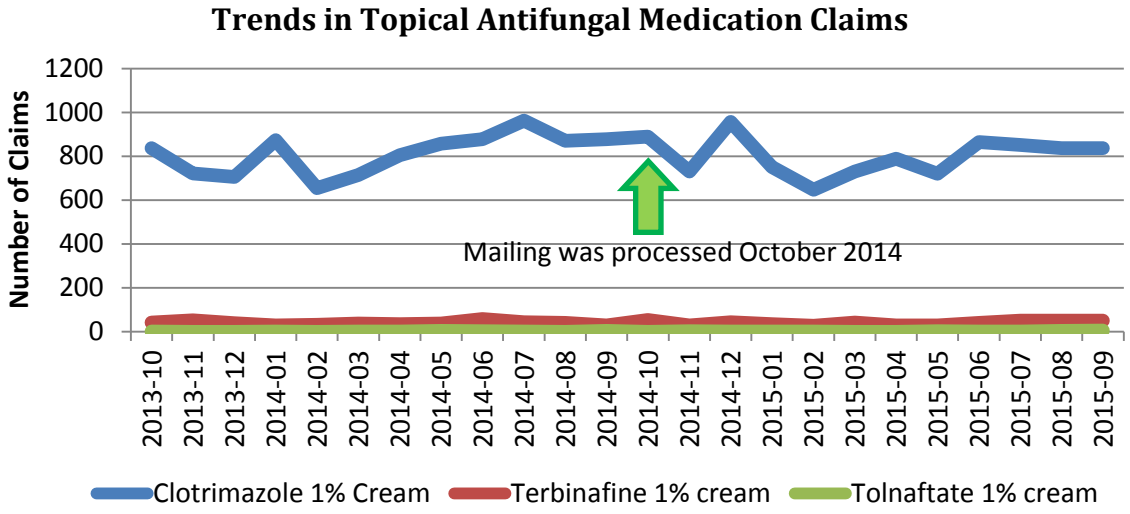
The letter encouraged the use of topical, OTC antifungal products that are covered without prior authorization for SoonerCare members who are 20 years of age or younger. These medications include the following:

- Clotrimazole 1% cream
- Terbinafine 1% cream
- Tolnaftate 1% cream

While a prior authorization is not required for the listed products, a prescription is required for coverage for pediatric members. For members age 21 years and older other Tier-1 products available without prior authorization include clotrimazole 1% cream (prescription only), econazole 1% cream, ketoconazole 2% cream, and nystatin cream or ointment.

Topical Antifungal Medication Trends

The chart below shows the trends in claims of each of the three topical, OTC antifungal products that are covered without prior authorization for SoonerCare members who are 20 years of age or younger. The mailing was processed in October of 2014 and is noted on the chart below.



Conclusions

Following the mailing, no real change was seen in utilization of the OTC topical antifungal products. It is possible the mailing intervention was ineffective since only pharmacies were included. Future mailings should include prescribers who have prescribed a topical antifungal product in the previous six months. The mailing should also include a “Preferred Topical Antifungal Medications Change Form” that may encourage prescribers to use generic, low-cost medications by simplifying the prescription writing process for preferred medications.

Appendix C

30-Day Notice to Prior Authorize Ibrance® (Palbociclib)

Oklahoma Health Care Authority
November 2015

Ibrance® (Palbociclib) Product Summary[1,2,3]

Palbociclib is a selective inhibitor of CDK 4/6 kinase activity, and was approved under accelerated approval based on progression-free survival (PFS). A phase 2, open-label study assessed the safety and efficacy of palbociclib in combination with letrozole versus letrozole alone as first-line treatment for postmenopausal women with advanced ER-positive, HER2-negative breast cancer. Median PFS reported was 20.2 months for the combination group vs. 10.2 months for the letrozole alone group (HR, 0.488; 95% CI, 0.319-0.748).

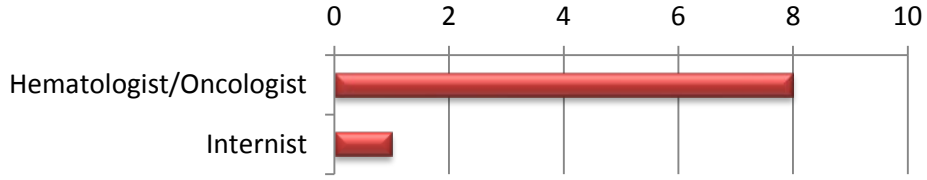
Utilization Details of Palbociclib: February 2015 to September 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	TOTAL UNITS	COST/ CLAIM
IBRANCE 75MG CAP	1	1	$10,405.31	21	$10,405.31
IBRANCE 100MG CAP	5	5	$52,012.05	105	$10,402.41
IBRANCE 125MG CAP	19	8	$197,642.39	399	$10,402.23
TOTAL	**25**	**9***	**$260,059.75**	**525**	**$10,402.39**

*Total number of unduplicated members.

Detailed demographic information could not be provided due to the small number of SoonerCare members utilizing palbociclib. All members utilizing palbociclib from February 2015 to September 2015 were female with a diagnosis of malignant neoplasm of the breast.

Top Prescriber Specialties of Palbociclib by Number of Members



Recommendations

Ibrance® (Palbociclib) Approval Criteria:

1. An FDA approved diagnosis of metastatic breast cancer for first line use only; and
2. Member must be estrogen receptor (ER)-positive; and
3. Member must have negative expression of Human Epidermal Receptor Type 2 (HER2); and
4. Ibrance® must be used in combination with letrozole (for postmenopausal women only).

[1] NCCN. NCCN Guidelines Version 3.2015 Breast Cancer. Retrieved October 19, 2015, http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

[2] Ibrance® [package insert]. NY, NY: Pfizer; 2015.

[3] Finn RS, Crown JP, Lang I, et al. The cycline-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18: a randomized phase 2 study. Lancet Oncol 2015;16:25-35

Appendix D

30-Day Notice to Prior Authorize Keveyis™ (Dichlorphenamide)

Oklahoma Health Care Authority
November 2015

Hyperkalemic and Hypokalemic Periodic Paralysis Background Information[1,2,3,4]

Periodic paralysis is a rare muscle disorder related to a defect in muscle ion channels characterized by episodes of painless muscle weakness. Periodic paralysis affects approximately 5,000 Americans and the two most common types of this disorder are classified as either hyperkalemic or hypokalemic. Hyperkalemic periodic paralysis occurs when episodes can be induced by elevated potassium and hypokalemic periodic paralysis episodes occur in association with low potassium blood levels.

Hyperkalemic periodic paralysis is rare with an estimated prevalence of 1 in 200,000 affecting women and men equally. Symptoms usually start within the first decade of life, but can affect individuals as early as the first year with generalized weakness. The attack of weakness can affect only one limb, but generalized weakness with hypotonia is more common. Triggers of hyperkalemic periodic paralysis attacks include anesthesia, cold exposure, rest after exercise, fasting, or the ingestion of small amounts of potassium. Acute attacks usually are brief and do not require treatment. Mild exercise or sugar intake can abort attacks for some patients. In severe symptomatic attacks accompanied by severe hyperkalemia, thiazide diuretics, inhaled beta adrenergic agonists, and intravenous calcium can be used. Dietary modifications can prevent attacks by avoiding foods rich in potassium and avoiding carbohydrate loading. Avoiding strenuous activity is recommended. In patients with disabling attacks that are not responsive to nonpharmacological measures, pharmacological preventative treatment includes thiazide diuretics (hydrochlorothiazide) and carbonic anhydrase inhibitors.

Hypokalemic periodic paralysis is the most common of the periodic paralyses, but is still quite rare, with an estimated prevalence of 1 in 100,000 and is three to four times more common in men than women. Attacks begin in late childhood or teenage years and vary in frequency and duration. Attacks usually last several hours, but range from minutes to days and may be triggered by rest after vigorous exercise, stress, or high-carbohydrate meals. These triggers are often associated with an increased release of epinephrine or insulin, both of which cause movement of potassium ions into cells and low potassium blood levels. Acute treatment involves oral administration of 60 to 120 mEq of potassium chloride given incrementally. Nonpharmacological interventions including low-carbohydrate diet and refraining from vigorous exercise are recommended for preventative treatment. If lifestyle changes are not sufficiently effective in preventing attacks, pharmacological treatment including symptomatic potassium supplementation, potassium-sparing diuretics (spironolactone or triamterene), and carbonic anhydrase inhibitors (acetazolamide or dichlorphenamide) may be effective.

The mechanism whereby carbonic anhydrase inhibitors are effective in hypokalemic periodic paralysis is not well understood. Animal model studies suggest that these agents trigger

calcium-activated potassium channels on skeletal muscle. These agents can cause side effects such as malaise and fatigue which limit tolerability in some patients. Kidney stones are also a potential complication of treatment with these agents. Keveyis™ (dichlorphenamide), a carbonic anhydrase inhibitor, is the first drug approved by the FDA to treat primary periodic paralysis. Dichlorphenamide was previously available under the brand name, Daranide®, for the treatment of elevated intraocular pressure, but in June of 2002 was withdrawn from the market by the manufacturer. In 2007, the Food and Drug Administration (FDA) determined that Daranide® was not withdrawn from sale for reasons of safety or effectiveness and could be approved under an abbreviated new drug application (ANDA).

Keveyis™ (Dichlorphenamide) Product Summary[5,6,7]

FDA Approved: August 2015

Indications: Keveyis™ (dichlorphenamide) is an oral carbonic anhydrase inhibitor indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

Dosing:

- Keveyis™ (dichlorphenamide) is available in a 50mg strength tablet.
- The initial dose is 50mg twice daily.
- The dose should be titrated based on individual response.
- The maximum recommended dose is 200mg daily.

Mechanism of Action: Dichlorphenamide is a carbonic anhydrase inhibitor. However, the precise mechanism by which dichlorphenamide exerts its therapeutic effects in patients with periodic paralysis is unknown.

Contraindications:

- Hepatic insufficiency: dichlorphenamide may aggravate hepatic encephalopathy.
- Severe pulmonary disease: Severe pulmonary disease can limit metabolic acidosis compensation. Dichlorphenamide can cause hyperchloremic non-anion gap metabolic acidosis.
- Hypersensitivity to dichlorphenamide or other sulfonamides
- Concomitant use with high dose aspirin: Anorexia, tachypnea, lethargy, and coma have been reported with concomitant use of dichlorphenamide and high-dose aspirin. The concomitant use of dichlorphenamide and high dose aspirin is contraindicated. Dichlorphenamide should be used with caution in patients receiving low dose aspirin.

Warnings and Precautions:

- Hypersensitivity/Anaphylaxis/Idiosyncratic Reactions: Dichlorphenamide should be discontinued at the first appearance of skin rash or any sign of immune-mediated or idiosyncratic adverse reaction.
- Hypokalemia: Baseline and periodic measurement of serum potassium are recommended; if hypokalemia develops or persists, consideration should be given to reducing the dose or discontinuing dichlorphenamide.

- Metabolic Acidosis: Baseline and periodic measurement of serum bicarbonate are recommended; if metabolic acidosis develops or persists, consideration should be given to reducing the dose or discontinuing dichlorphenamide.
- Falls: Consideration should be given to reducing the dose or discontinuing dichlorphenamide in patients who experience falls.

Adverse Reactions: The most common adverse reactions during clinical trials (≥10% and greater than placebo) include the following:

- Paresthesias
- Cognitive disorder
- Dysgeusia
- Confusional state

Use in Special Populations:

- Pregnancy: Dichlorphenamide is pregnancy category B. There are no adequate and well-controlled studies of dichlorphenamide in pregnant women. Dichlorphenamide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: It is not known whether dichlorphenamide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dichlorphenamide is administered to a nursing woman.
- Pediatric Use: The safety and effectiveness of dichlorphenamide in pediatric patients have not been established.
- Geriatric Use: The risk of falls and of metabolic acidosis in patients using dichlorphenamide are greater in elderly patients.
- Overdosage: Symptoms of overdosage or toxicity may include drowsiness, anorexia, nausea, vomiting, dizziness, paresthesias, ataxia, tremor, and tinnitus.

Efficacy: The efficacy and safety of dichlorphenamide was evaluated in two clinical studies, each examining hyperkalemic and hypokalemic periodic paralysis patients. In study 1, the primary endpoint was the average number of self-reported attacks of muscle weakness per week. In study 2, the endpoint in the hypokalemic substudy was the incidence of acute intolerable worsening. In the hyperkalemic substudy, the endpoint was similar to study 1. The inclusion criteria comprised regular episodes of weakness at least once a week and no more than three times a day.

- In study 1, dichlorphenamide-treated patients experienced fewer attacks per week compared to placebo (hypokalemic substudy: 2.2 fewer attacks per week, $p = 0.02$; hyperkalemic substudy: 3.9 fewer attacks per week, $p = 0.08$).
- In study 2, fewer patients with hypokalemic periodic paralysis experienced acute worsening compared to placebo (2 patients vs. 11 patients, respectively; $p = 0.02$). Dichlorphenamide-treated patients with hyperkalemic periodic paralysis had 2.3 fewer attacks per week versus placebo ($p = 0.006$).

Cost Comparison:

Medication	EAC Per Tablet	SMAC Per Tablet	EAC/SMAC for 28 Days of Therapy
Keveyis™ (dichlorphenamide) 50mg Tablets	**$144.14**	**N/A**	**$16,143.68***
Acetazolamide 250mg Tablets	N/A	$2.13	$119.28[+]

EAC = estimated acquisition cost
SMAC = state maximum allowable cost
*Based on maximum daily dose (200 mg per day).
[+]Based on recommended dosing of 250mg twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Keveyis™ (dichlorphenamide) with the following criteria:

Keveyis™ (Dichlorphenamide) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants; and
2. Prescriber documentation that all nonpharmacological treatments failed including the following:
    a. Hyperkalemic periodic paralysis:
        i. Acute attacks can be aborted with sugar or mild exercise
        ii. Avoiding foods rich in potassium
        iii. Avoiding fasting
        iv. High-carbohydrate diet
        v. Avoiding strenuous activity
        vi. Avoiding prolonged cold exposure
    b. Hypokalemic periodic paralysis:
        i. Low-carbohydrate diet (avoiding carbohydrate loading)
        ii. Avoiding vigorous exercise (some mild attacks can be aborted by low level exercise)
3. Prescriber documentation of frequent and severe attacks requiring pharmacological treatment (at least one attack per week but no more than three attacks per day); and
4. A four-week trial within the last 90 days of acetazolamide in combination with
    a. Spironolactone or triamterene in hypokalemic periodic paralysis; or
    b. Hydrochlorothiazide in hyperkalemic periodic paralysis
5. A quantity limit of four tablets per day will apply.

[1] UpToDate: Hyperkalemic periodic paralysis. Available online at: http://www.uptodate.com/contents/hyperkalemic-periodic-paralysis?source=search_result&search=hyperkalemic+periodic+paralysis&selectedTitle=1%7E12 . Last revised 09/2015. Last accessed 10/2015.

[2] UpToDate: Hypokalemic periodic paralysis. Available online at: http://www.uptodate.com/contents/hypokalemic-periodic-paralysis?source=search_result&search=hypokalemic+periodic+paralysis&selectedTitle=1%7E20 . Last revised 09/2015. Last accessed 10/2015.

[3] Keveyis™ (dichlorphenamide) New Orphan Drug Approval. Optum RX. https://www.optumrx.com/vgnlive/HCP/Assets/RxNews/Drug%20Approvals_Keveyis_2015-0812.pdf. Last accessed 10/2015.

[4] Food and Drug Administration. HHS: Determination That Daranide (Dichlorphenamide) Tablets, 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness. http://www.gpo.gov/fdsys/pkg/FR-2007-08-06/pdf/E7-15230.pdf. Last accessed 10/2015.

[5] Keveyis™ Prescribing Information. Taro Pharmaceutical Industries Ltd. Available online at: http://keveyis.com/FINAL%20Approved%20Keveyis%20PI_%208.7.15.pdf. Last revised 08/2015. Last accessed 10/2015.

[6] Keveyis™ (dichlorphenamide) New Orphan Drug Approval. Optum RX. https://www.optumrx.com/vgnlive/HCP/Assets/RxNews/Drug%20Approvals_Keveyis_2015-0812.pdf. Last accessed 10/2015.

[7] Phase III Randomized, Double-Blind, Placebo-Controlled Study of Dichlorphenamide for Periodic Paralyses and Associated Sodium Channel Disorders. Last updated: 10/28/2015. Last accessed: 10/2015. Available at: https://clinicaltrials.gov/ct2/show/NCT00004802.

Appendix E

Annual Review of Xgeva® (Denosumab)

Oklahoma Health Care Authority
November 2015

Current Prior Authorization Criteria

Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of one of the following:
    a. Prevention of skeletal-related events in patients with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity.

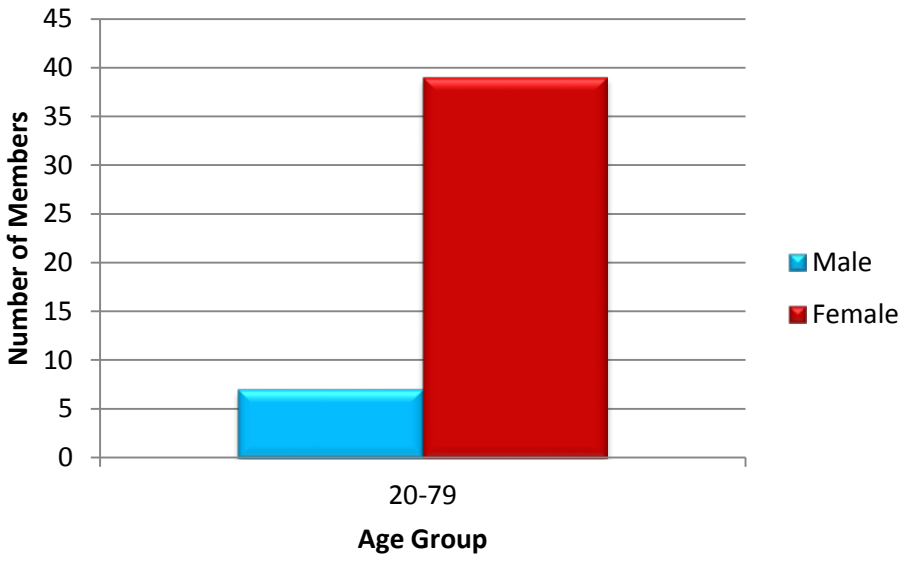
Utilization of Xgeva® (Denosumab): Fiscal Year 2015

Fiscal Year 2015 Utilization of Xgeva® (Denosumab): Medical Claims

*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
46	197	$347,648.40	$1,764.71	8,832.86

*Total number of unduplicated members.

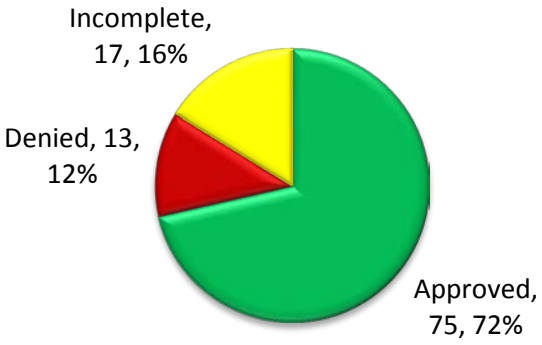
Demographics of Members Utilizing Xgeva® (Denosumab)



Prior Authorization of Xgeva® (Denosumab)

There were 105 prior authorization requests submitted for Xgeva® (denosumab) during fiscal year 2015. The following chart shows the status of the submitted petitions.

Status of Petitions



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

FDA Approvals and New Indications:

- **December 2014**: The FDA approved Xgeva® (denosumab) for the treatment of hypercalcemia of malignancy (HCM) refractory to bisphosphonate therapy. Xgeva® (denosumab) was first approved in November 2010 for the indication of preventing skeletal-related events in patients with bone metastases from solid tumors. In June 2013, the FDA approved another indication for Xgeva® (denosumab) for the treatment of giant cell tumor of bone.

Hypercalcemia of Malignancy Summary[3, 4, 5]

HCM is a serious complication in patients with advanced cancer and occurs most often in patients with myeloma, lymphoma, squamous cell cancer (e.g. lung, head, and neck cancer), kidney cancer, and breast cancer. If HCM is untreated, it can lead to progressive mental impairment, coma, renal failure, and death. About 2.7% of patients with cancer in the US developed HCM in 2012.

Denosumab Dosing for HCM:

- Xgeva® (denosumab) is available as a 120mg/1.7mL (70mg/mL) solution in a single-use vial for subcutaneous injection
- The recommended dose of Xgeva® (denosumab) for a diagnosis of HCM is 120mg administered every four weeks as a subcutaneous injection in the upper thigh, abdomen, or upper arm with additional 120mg doses on Days 8 and 15 of the first month of therapy.

Efficacy:

- The safety and efficacy of Xgeva® (denosumab) for the treatment of HCM was demonstrated in a single-arm, open-label trial that enrolled 33 patients with HCM (with or without bone metastases) refractory to treatment with intravenous bisphosphonate

therapy. Participants received Xgeva® (denosumab) subcutaneously every four weeks with additional 120mg doses on Days 8 and 15 of the first month of therapy.

Refractory HCM was defined as an albumin-corrected calcium of greater than 12.5 mg/dL (3.1 mmol/L) despite treatment with intravenous bisphosphonate therapy in 7-30 days prior to initiation of Xgeva® (denosumab) therapy. The primary outcome measure was the proportion of patients achieving a response, defined as corrected serum calcium (CSC) less than or equal to 11.5 mg/dL (2.9 mmol/L) within 10 days after Xgeva® (denosumab) administration. A total of 21 patients out of 33 [63.6% of patients (45.1, 79.6)] achieved a response. The median time to response (CSC ≤11.5 mg/dL) was 9 days (95% CI: 8, 19) and the median duration of response was 104 days (95% CI: 7, not estimable). The median time to complete response (CSC ≤10.8 mg/dL) was 23 days (95% CI: 9, 36) and the median duration of complete response was 34 days (95% CI: 1, 134).

Cost Comparison:

Medication Name	Cost Per Unit	Cost Per Dose
Xgeva® (denosumab) 120mg/1.7mL	**$1,170.92[+]**	**$1,990.56**
Zometa® (zoledronic acid) 4mg/5mL	$27.97[*]	$139.85

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

Recommendations

The College of Pharmacy recommends the addition of the criteria below for Xgeva® (denosumab) for the indication of hypercalcemia of malignancy.

Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of one of the following:
    a. Prevention of skeletal-related events in patients with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; or
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity.
    c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
        i. Member must have albumin-corrected calcium of greater than 12.5 mg/dL (3.1 mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy.

[1]Amgen Press Release: FDA approves Amgen's Xgeva™ (denosumab) for the prevention of skeletal-related events in patients with bone metastases from solid tumors. Available online at: http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-newsArticle&ID=1498709. Last revised 11/18/2010. Last accessed 10/22/2015.

[2]Amgen Press Release: FDA approves Amgen's Xgeva® (denosumab) for the treatment of giant cell tumor of bone. Available online at: http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-newsArticle&ID=1829715. Last revised 06/13/2013. Last accessed 10/22/2015.

[3]Amgen Press Release: FDA approves Amgen's Xgeva® (denosumab) for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Available online at: http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-newsArticle&ID=1995709. Last revised 12/08/2014. Last accessed 10/22/2015.

[4]Medscape Medical News: FDA approves new indication for denosumab (Xgeva). Available online at: http://www.medscape.com/viewarticle/836252. Last revised 12/09/2014. Last accessed 10/22/2015.

[5]Xgeva® Package Insert. Amgen, Inc. Available online at: http://medlibrary.org/lib/rx/meds/xgeva-1/. Last revised 06/22/2015. Last accessed 10/22/2015.

Appendix F

Fiscal Year 2015 Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Pramosone® (Hydrocortisone/Pramoxine Topical Cream and Lotion) and Enstilar® (Calcipotriene/Betamethasone Dipropionate Foam)

Oklahoma Health Care Authority
November 2015

Current Prior Authorization Criteria

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

Tier-2 Topical Corticosteroid Approval Criteria:

1. Documented trials of all Tier-1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief.
    a. If Tier-1 trials are completed and do not yield adequate relief, the member must also provide a clinical reason for requesting a Tier-2 in the same potency instead of trying a higher potency.
2. When the same medication is available in Tier-1, a clinical reason must be provided for using a special dosage form of that medication in Tier-2 (foams, shampoos, sprays, kits, etc.).
3. Topical steroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

The following page contains the current Topical Corticosteroid Tier Chart.

Topical Corticosteroids	
Tier-1	**Tier-2**
Ultra-High to High Potency	
augmented betamethasone dipropionate (**Diprolene AF®**) **C, G**	amcinonide **C,O,L**
clobetasol propionate 0.05% (**Temovate®**) **C,G,O,So**	augmented betamethasone dipropionate (**Diprolene®**) **O,G,L**
fluocinonide 0.05% **C,O**	betamethasone dipropionate (**Diprosone®**) **C,O**
halobetasol propionate (**Ultravate®**) **C,O**	clobetasol propionate 0.05% (**Clobex®**) **L,Sh,Spr**; (**Olux®**) **F**, (**Olux-E®**) **F**
diflorasone diacetate 0.05% (**Apexicon®**) **C**, (**Apexicon E®**) **C,O**	desoximetasone 0.25% (**Topicort®**) **C,O** (0.05%) **G**
	fluocinonide 0.05% **G,So**
	fluocinonide 0.1% (**Vanos®**) **C**
	halcinonide (**Halog®**) **C,O**
	halobetasol propionate/lactic acid (**Ultravate X®**) **C**
Medium/High to Medium Potency	
betamethasone dipropionate (**Betanate®**) **L**	betamethasone dipropionate/calcipotriene (**Taclonex®**) **O,Sus,Spr**
betamethasone valerate 0.1% (**Beta-Val®**) **C**	betamethasone valerate 0.1% (**Beta-Val®**) **O,L**
fluocinonide emollient (**Lidex E®**) **C**	betamethasone valerate 0.12% (**Luxiq®**) **F**
fluticasone propionate (**Cutivate®**) **C,O**	desoximetasone 0.05% (**Topicort LP®**) **C**
hydrocortisone butyrate 0.1% **So**	fluocinolone acetonide 0.025% (**Synalar®**) **C,O**
hydrocortisone valerate 0.2% **C**	flurandrenolide tape (**Cordran®**)
mometasone furoate (**Elocon®**) **C,L**	fluticasone propionate (**Cutivate®**) **L**
triamcinolone acetonide **C,O,L**	hydrocortisone butyrate 0.1% **C,O**
	hydrocortisone probutate (**Pandel®**) **C**
	hydrocortisone valerate 0.2% **O**
	hydrocortisone valerate (**Westcort®**) **C,O**
	mometasone furoate 0.1% **O**
	prednicarbate (**Dermatop®**) **O,C**
	triamcinolone acetonide (**Kenalog®**) **Spr**
Low Potency	
alclometasone dipropionate (**Aclovate®**) **C,O**	clocortolone pivalate (**Cloderm®**) **C**
fluocinolone acetonide 0.01% (**Synalar®**) **So, C** (**Derma-Smooth®**; **Derma-Smooth FS®**) **oil**	desonide 0.05% **C,O**
hydrocortisone acetate 2.5% **C,O,L**	desonide 0.05% (**Desonate®**) **G**
hydrocortisone/urea (**U-Cort®**) **C**	desonide 0.05% (**Verdeso®**) **F,L**
	desonide/emollient (**Desowyn® kit**) **C,O**
	fluocinolone acetonide 0.01% (**Capex®**) **Sh**
	hydrocortisone 2.5% (**Texacort®**) **So**

C= Cream; O = Ointment; L = Lotion; G = Gel, Sh = Shampoo; So = Solution; Spr = Spray; Sus = Suspension; F = Foam

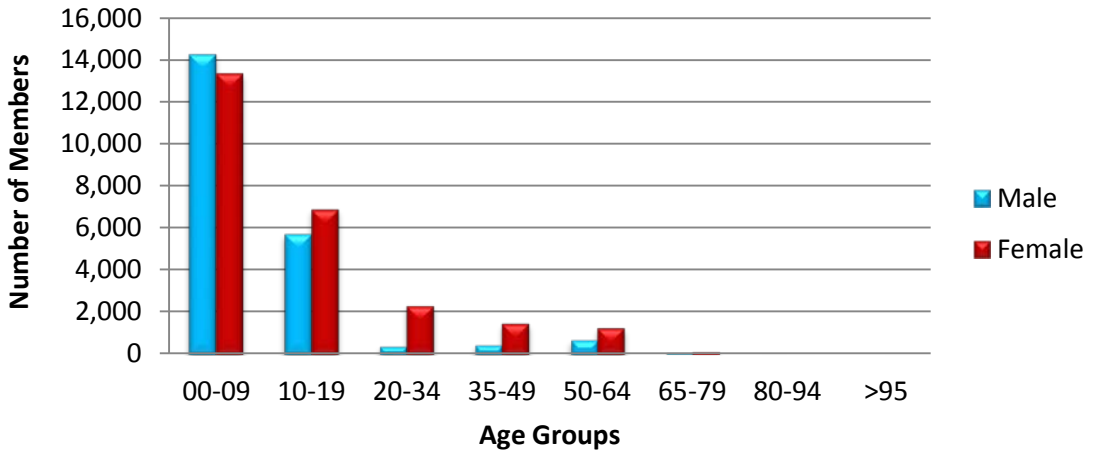
Utilization of Topical Corticosteroids: Fiscal Year 2015

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	48,699	74,648	$1,560,244.67	$20.90	$1.36	4,503,901	1,145,971
2015	47,095	74,007	$1,825,428.21	$24.67	$1.58	4,934,131	1,154,627
% Change	**-3.30%**	**-0.90%**	**17.00%**	**18.00%**	**16.20%**	**9.60%**	**0.80%**
Change	**-1,604**	**-641**	**$265,183.54**	**$3.77**	**$0.22**	**430,230**	**8,656**

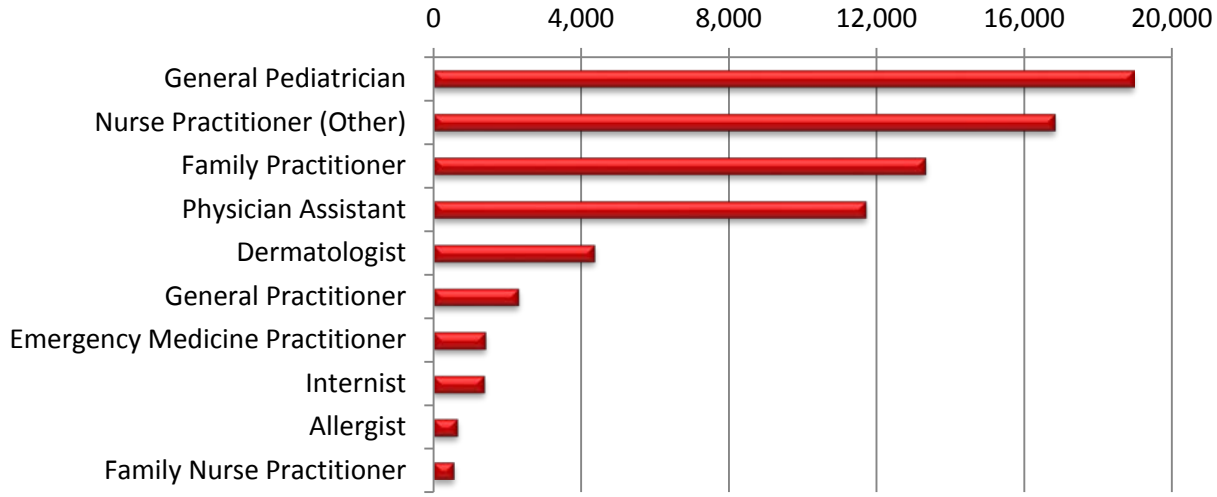
*Total number of unduplicated members.

Despite a decrease in utilization, there was an increase in total cost from fiscal year 2014 to fiscal year 2015. The increase in cost is likely due to the rising costs of generic, Tier-1 medications. Recommendations regarding moving the more costly generics to Tier-2 can be found at the end of this report.

Demographics of Members Utilizing Topical Corticosteroids



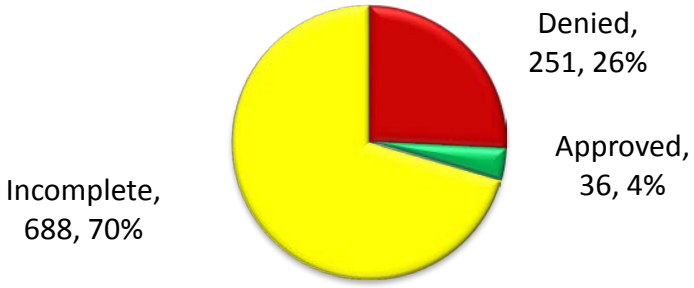
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims



Prior Authorization of Topical Corticosteroids

There were 975 prior authorizations submitted for the topical corticosteroid medication category during fiscal year 2015. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[1,2]

Patent Expirations:

- Desonate® (desonide 0.05% gel): August 2020
- Topicort® Spray (desoximetasone 0.25%): September 2028
- Verdeso® (desonide 0.05% foam): November 2028
- Capex® shampoo, Texacort® 2.5% topical solution, Halog®, Cordran®, Pandel®, and U-Cort® are not available generically, but have no unexpired patents or exclusivities.

New Drug Approvals:

- Enstilar® (calcipotriene and betamethasone 0.005%-0.064% foam) was approved on October 16, 2015 for treatment of plaque psoriasis in adults 18 years and older.

Pramosone® (Hydrocortisone Acetate/Pramoxine) Product Summary[3,4]

Indications: Topical corticosteroids are indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Dosing:

- Pramosone® cream 1% (hydrocortisone acetate 1%/pramoxine HCl 1% cream) is available in a 1 ounce tube and 2 ounce tube.
- Pramosone® lotion 2.5% (hydrocortisone acetate 2.5%/pramoxine HCl 1% lotion) is available in 2 fluid ounces and 4 fluid ounces.
- Topical corticosteroids are generally applied to the affected area as a thin film three to four times daily depending on the severity of the condition.
- Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.
- If an infection develops, the use of occlusive dressing should be discontinued and appropriate antimicrobial therapy instituted.

Mechanism of Action:

- The mechanism of action of anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy.
- Pramoxine hydrochloride is a topical anesthetic agent which provides temporary relief from itching and pain. It acts by stabilizing the neuronal membrane of nerve endings with which it comes into contact.

Contraindications: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Safety:

- HPA Axis Suppression: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Patients receiving a large dose of a potent topical steroid applied to a large surface area and under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using urinary free cortisol and adrenocorticotropic hormone (ACTH) stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery from HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.
- Irritation: If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.
- Infection: In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.
- Laboratory Monitoring: Urinary free cortisol and ACTH stimulation tests may be helpful in evaluating HPA axis suppression.
- Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Special Populations:

- Pregnancy: Hydrocortisone/pramoxine is pregnancy category C. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-

controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

- Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to nursing women.
- Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface to body weight ratio. HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

Adverse Reactions: The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- Burning
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypertrichosis
- Miliaria
- Acneiform eruptions
- Hypopigmentation
- Perioral dermatitis
- Allergic contact dermatitis
- Maceration of the skin
- Secondary infection
- Skin atrophy
- Striae

Cost Comparison:

Drug	Package Size	EACW[+]	SMAC*	Cost per package
Pramosone® 1%/1% Cream	28.4 grams	$5.75/gram	N/A	$163.30
Pramosone® 1%/1% Cream	57 grams	$3.40/gram	N/A	$193.80
Pramosone® 2.5%/1% Lotion	59 mL	$3.51/mL	N/A	$207.09
Pramosone® 2.5%/1% Lotion	118 mL	$2.28/mL	N/A	$269.04
Hydrocortisone 2.5% Cream	28.4 grams	N/A	$0.17/gram	$4.83
Hydrocortisone 2.5% Lotion	59 mL	N/A	$0.25/mL	$14.75
Hydrocortisone 2.5% Lotion	118 mL	N/A	$0.25/mL	$29.50

[+]EACW= estimated wholesaler acquisition cost

*SMAC= state maximum allowable cost

Enstilar® (Calcipotriene/Betamethasone Dipropionate Foam) Product Summary[5,6,7]

Indications: Enstilar® foam (calcipotriene/betamethasone dipropionate foam) is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

Dosing:

- Enstilar® foam (calcipotriene/betamethasone dipropionate) is available as 0.005%-0.064% alcohol-free foam in a pressurized spray.
- Each gram of calcipotriene/betamethasone dipropionate foam contains 52.2mcg calcipotriene hydrate (equivalent to 50mcg of calcipotriene) and 0.643mg of betamethasone dipropionate (equivalent to 0.5mg of betamethasone).
- Calcipotriene/betamethasone dipropionate foam should be shaken before use.
- Calcipotriene/betamethasone dipropionate foam should be applied to affected area(s) once daily for up to four weeks.
- Therapy should be discontinued when control is achieved.
- More than 60 grams every four days should not be used.
- Calcipotriene/betamethasone dipropionate foam should not be used with occlusive dressings unless directed by a physician.
- Calcipotriene/betamethasone dipropionate foam is not for oral, ophthalmic, or intravaginal use.
- Use should be avoided on the face, groin, or axillae, or if skin atrophy is present at the treatment site.

Mechanism of Action:

- Calcipotriene/betamethasone dipropionate foam combines the pharmacological effects of calcipotriene hydrate as a synthetic vitamin D3 analog and betamethasone dipropionate as a synthetic corticosteroid. While their pharmacologic and clinical effects are known, the exact mechanisms of their actions in plaque psoriasis are unknown.

Contraindications: None.

Safety:

- Flammability: The propellants in calcipotriene/betamethasone dipropionate foam are flammable. Patients should avoid fire, flame, and smoking during and immediately following application.
- Hypercalcemia and Hypercalciuria: Hypercalcemia and hypercalciuria have been observed with use of calcipotriene/betamethasone dipropionate foam. If hypercalcemia or hypercalciuria develop, treatment should be discontinued until parameters of calcium metabolism have normalized.
- Effects on Endocrine System: Topical corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Risk factors include the use of high-potency topical corticosteroids, use over a large surface area or

on areas under occlusion, prolonged use, altered skin barrier, liver failure, and use in pediatric patients. Use should be modified if HPA axis suppression develops.

- Risks of Ultraviolet Light Exposure: Patients who apply calcipotriene/betamethasone dipropionate foam to exposed skin should avoid excessive exposure to either natural or artificial sunlight, including tanning booths and sun lamps. Consideration should be given to avoiding or limiting use of phototherapy in patients who use calcipotriene/betamethasone dipropionate foam.

Special Populations:

- Pregnancy: Calcipotriene/betamethasone dipropionate foam is pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Pregnant women were excluded from the clinical studies conducted with calcipotriene/betamethasone dipropionate foam. It should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Calcipotriene has been shown to be fetotoxic and betamethasone dipropionate has been shown to be teratogenic in animals when given systemically.
- Nursing Mothers: Calcipotriene/betamethasone dipropionate foam should not be used on the breast when nursing. Systemically administered corticosteroids appear in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topically administered calcipotriene or corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when calcipotriene/betamethasone dipropionate foam is administered to nursing women.

Adverse Reactions: The following adverse reactions were reported in less than 1% of patients during clinical trials:

- Application site irritation
- Application site pruritus
- Folliculitis
- Skin hypopigmentation
- Hypercalcemia
- Urticaria
- Exacerbation of psoriasis

Efficacy: The efficacy of Enstilar® foam was evaluated in two multicenter, randomized, double-blind trials.

- In Trial One, 302 subjects were randomized to 1 of 3 treatment groups: Enstilar® foam, betamethasone dipropionate in the same vehicle, or calcipotriene hydrate in the same vehicle.
- In Trial Two, 426 subjects were randomized to 1 of 2 treatment groups: Ensitlar® foam or the vehicle alone.
- A total of 45% of the patients in Trial One and 53.3% of patients in Trial Two treated with Enstilar® foam were “clear” or “almost clear” by week four, as assessed by the Investigator Global Assessment score of disease severity.

Cost Comparison: Cost information for Enstilar® foam is not available at this time. Taclonex® (calcipotriene and betamethasone) 0.005%-0.064% topical suspension made by the same company, LEO Pharma Incorporated, is a Tier-2 medication and the following chart includes cost information for reference purposes.

Drug	Package Size	EACW+	SMAC*	Cost per package
Taclonex® 0.005%/0.064% Suspension	120 mL	$13.06/mL	N/A	$1,567.20
Taclonex® 0.005%/0.064% Suspension	60 mL	$13.06/mL	N/A	$783.60
Betamethasone Dipropionate 0.05% Cream	50 grams	N/A	$0.39/gram	$19.50

+EACW= estimated wholesaler acquisition cost
*SMAC= state maximum allowable cost

Recommendations

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

1. Placement of Pramosone® (hydrocortisone acetate/pramoxine HCL) cream and lotion into Tier-2 of the low-potency product-based prior authorization category; and
2. Placement of Enstilar® foam (calcipotriene/betamethasone dipropionate foam) into Tier-2 of the medium/high to medium potency category; and
3. Move fluocinonide 0.05% solution and betamethasone dipropionate 0.05% (Diprosone®) ointment from Tier-2 into Tier-1 of the ultra-high to high potency category; and
4. Move diflorasone diacetate 0.05% (Apexicon®, Apexicon E®) cream and ointment, halobetasol propionate (Ultravate®) ointment, and clobetasol propionate 0.05% (Temovate®) cream and ointment from Tier-1 into Tier-2 of the ultra-high to high potency category; and
5. Move hydrocortisone valerate 0.2% cream from Tier-1 into Tier-2 of the medium/high to high potency category; and
6. Move fluocinolone acetonide 0.01% (Synalar®, Derma-Smooth®, Derma-Smooth FS®) solution and oil from Tier-1 to Tier-2 of the low potency category.

Current Tier trial requirements specified at the beginning of this report would continue to apply.

Topical Corticosteroids	
Tier-1	**Tier-2**
Ultra-High to High Potency	
augmented betamethasone dipropionate (**Diprolene AF®**) **C, G**	amcinonide **C,O,L**
clobetasol propionate 0.05% (**Temovate®**) **G,So**	augmented betamethasone dipropionate (**Diprolene®**) **O,G,L**
fluocinonide 0.05% **C,O, So**	betamethasone dipropionate (**Diprosone®**) **C**
halobetasol propionate (**Ultravate®**) **C**	clobetasol propionate 0.05% (**Clobex®**) **L,Sh,Spr**; (**Olux®**) **F**, (**Olux-E®**) **F**
betamethasone dipropionate (**Diprosone®**) **O**	desoximetasone 0.25% (**Topicort®**) **C,O** (0.05%) **G**
	fluocinonide 0.05% **G**
	fluocinonide 0.1% (**Vanos®**) **C**
	halcinonide (**Halog®**) **C,O**
	halobetasol propionate/lactic acid (**Ultravate X®**) **C**
	diflorasone diacetate 0.05% (**Apexicon®**) **C,** (**Apexicon E®**) **C,O**
	halobetasol propionate (**Ultravate®**) **O**
	clobetasol propionate 0.05% (**Temovate®**) **C,O**
Medium/High to Medium Potency	
betamethasone dipropionate (**Betanate®**) **L**	betamethasone dipropionate/calcipotriene (**Taclonex®**) **O, Sus, Spr**
betamethasone valerate 0.1% (**Beta-Val®**) **C**	betamethasone valerate 0.1% (**Beta-Val®**) **O,L**
fluocinonide emollient (**Lidex E®**) **C**	betamethasone valerate 0.12% (**Luxiq®**) **F**
fluticasone propionate (**Cutivate®**) **C,O**	desoximetasone 0.05% (**Topicort LP®**) **C**
hydrocortisone butyrate 0.1% **So**	fluocinolone acetonide 0.025% (**Synalar®**) **C,O**
mometasone furoate (**Elocon®**) **C,L**	flurandrenolide tape (**Cordran®**)
triamcinolone acetonide **C,O,L**	fluticasone propionate (**Cutivate®**) **L**
	hydrocortisone butyrate 0.1% **C,O**
	hydrocortisone probutate (**Pandel®**) **C**
	hydrocortisone valerate 0.2% **O, C**
	hydrocortisone valerate (**Westcort®**) **C,O**
	mometasone furoate 0.1% **O**
	prednicarbate (**Dermatop®**) **O,C**
	triamcinolone acetonide (**Kenalog®**) **Spr**
	betamethasone dipropionate/calcipotriene (**Enstilar®**) **F**
Low potency	
alclometasone dipropionate (**Aclovate®**) **C,O**	clocortolone pivalate (**Cloderm®**) **C**
fluocinolone acetonide 0.01% (**Synalar®**) **C**	desonide 0.05% **C,O**
hydrocortisone acetate 2.5% **C,O,L**	desonide 0.05% (**Desonate®**) **G**
hydrocortisone/urea (**U-Cort®**) **C**	desonide 0.05% (**Verdeso®**) **F,L**
	desonide/emollient (**Desowyn®** kit) **C,O**
	fluocinolone acetonide 0.01% (**Capex®**) **Sh**
	hydrocortisone 2.5% (**Texacort®**) **So**

	hydrocortisone/pramoxine (**Pramosone®**) **C, L**
	fluocinolone acetonide 0.01% (**Synalar®**) **So,** (**Derma-Smooth®; Derma-Smooth FS®**) **Oil**

C= Cream; O = Ointment; L = Lotion; G = Gel, Sh = Shampoo; So = Solution; Spr = Spray; Sus = Suspension; F = Foam

Utilization Details of Topical Corticosteroids: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
TIER-1 MEDICATIONS						
LOW-POTENCY PRODUCTS						
HYDROCORT CREAM 2.5%	4,408	3,408	$29,634.70	$0.51	$6.72	1.62%
HYDROCORT OINT 2.5%	2,266	1,522	$17,169.55	$0.51	$7.58	0.94%
HYDROCORT CREAM 1%	2,171	1,859	$16,519.25	$0.60	$7.61	0.90%
HYDROCORT LOTION 2.5%	556	426	$13,151.65	$1.35	$23.65	0.72%
FLUOCIN ACET OIL BODY	428	278	$70,255.07	$6.17	$164.15	3.85%
ALCLOMETASON CREAM 0.05%	314	232	$21,486.38	$3.40	$68.43	1.17%
HYDROCORT OINT 1%	278	225	$2,057.81	$0.56	$7.40	0.11%
FLUOCIN ACET OIL SCALP	214	131	$34,489.24	$5.91	$161.16	1.89%
FLUOCIN ACET OIL 0.01% SC	200	146	$35,569.01	$6.77	$177.85	1.95%
ALCLOMETASON OINT 0.05%	125	78	$7,818.43	$3.11	$62.55	0.43%
FLUOCIN ACET SOL 0.01%	113	79	$18,234.43	$7.53	$161.37	1.00%
FLUOCIN ACET CREAM 0.01%	59	48	$4,996.05	$5.28	$84.68	0.27%
SUBTOTAL	**11,132**	**8,432**	**$271,381.57**	**$3.48**	**$77.76**	**14.85%**
MEDIUM/HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLON CREAM 0.1%	26,820	19,632	$302,620.96	$0.75	$11.28	16.58%
TRIAMCINOLON OINT 0.1%	8,746	6,291	$116,246.93	$0.81	$13.29	6.37%
TRIAMCINOLON CRE 0.025%	7,428	5,776	$64,928.24	$0.65	$8.74	3.56%
TRIAMCINOLON CREAM 0.5%	3,008	2,232	$46,406.33	$1.12	$15.43	2.54%
TRIAMCINOLON OINT 0.025%	2,181	1,673	$24,347.74	$0.81	$11.16	1.33%
MOMETASONE CREAM 0.1%	2,146	1,563	$44,173.17	$1.27	$20.58	2.42%
FLUTICASONE CREAM 0.05%	1,565	1,049	$41,057.79	$1.60	$26.24	2.25%
BETAMETH VAL CREAM 0.1%	1,391	887	$39,408.69	$1.52	$28.33	2.16%
TRIAMCINOLON LOTION 0.1%	1,205	975	$107,785.58	$4.12	$89.45	5.90%
TRIAMCINOLON OINT 0.5%	1,020	748	$18,396.56	$1.39	$18.04	1.01%
TRIAMCINOLON LOT 0.025%	737	548	$42,394.78	$2.30	$57.52	2.32%
HC VALERATE CREAM 0.2%	371	314	$45,668.63	$7.92	$123.10	2.50%
FLUTICASONE OINT 0.005%	363	271	$11,743.94	$1.57	$32.35	0.64%
BETAMETH DIP LOTION 0.05%	159	115	$6,502.05	$1.92	$40.89	0.36%
MOMETASONE SOL 0.1%	109	79	$2,155.85	$0.92	$19.78	0.12%
TRIANEX OINTMENT 0.05%	34	31	$464.48	$0.58	$13.66	0.03%
FLUOCINONIDE CRE -E 0.05%	24	22	$1,497.99	$3.10	$62.42	0.08%
HC BUTYRATE SOL 0.1%	18	15	$570.07	$1.49	$31.67	0.03%
SUBTOTAL	**57,325**	**42,221**	**$916,369.78**	**$1.88**	**$34.66**	**50.20%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
ULTRA HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL CREAM 0.05%	1,217	827	$199,825.23	$9.41	$164.19	10.95%
CLOBETASOL OINT 0.05%	1,132	675	$248,233.65	$11.61	$219.29	13.60%
AUG BETAMET CREAM 0.05%	955	659	$15,621.42	$0.98	$16.36	0.86%
CLOBETASOL SOL 0.05%	905	514	$86,153.14	$4.47	$95.20	4.72%
FLUOCINONIDE CREAM 0.05%	600	392	$23,773.47	$2.08	$39.62	1.30%
FLUOCINONIDE OINT 0.05%	382	224	$29,358.28	$3.75	$76.85	1.61%
CLOBETASOL E CREAM 0.05%	115	77	$9,284.86	$4.73	$80.74	0.51%
CLOBETASOL GEL 0.05%	69	43	$2,834.32	$2.25	$41.08	0.16%
HALOBETASOL CREAM 0.05%	66	33	$6,524.61	$5.55	$98.86	0.36%
HALOBETASOL OINT 0.05%	46	39	$6,776.92	$8.34	$147.32	0.37%
AUG BETAMET GEL 0.05%	5	5	$419.21	$5.82	$83.84	0.02%
APEXICON E CREAM 0.05%	1	1	$138.99	$19.86	$138.99	0.01%
SUBTOTAL	**5,493**	**3,489**	**$628,944.10**	**$6.57**	**$100.20**	**34.47%**
TIER-1 SUBTOTAL	**73,950**	**54,142**	**$1,816,695.45**	**$3.98**	**$70.87**	**99.52%**
TIER-2 MEDICATIONS						
LOW-POTENCY PRODUCTS						
DESONIDE CREAM 0.05%	19	7	$2,806.42	$5.66	$147.71	0.15%
DESONIDE OINTMENT 0.05%	18	6	$2,064.48	$6.90	$114.69	0.11%
DESONIDE LOTION 0.05%	10	4	$3,154.95	$19.36	$315.50	0.17%
SUBTOTAL	**47**	**17**	**$8,025.85**	**$10.64**	**$192.63**	**0.43%**
MEDIUM/HIGH TO MEDIUM POTENCY PRODUCTS						
HC VALERATE OINTMENT 0.2%	1	1	$171.30	$5.71	$171.30	0.01%
SUBTOTAL	**1**	**1**	**$171.30**	**$5.71**	**$171.30**	**0.01%**
ULTRA HIGH TO HIGH POTENCY PRODUCTS						
FLUOCINONIDE SOL 0.05%	7	1	$213.48	$3.05	$30.50	0.01%
BETAMETH DIP OINT 0.05%	1	1	$32.06	$4.58	$32.06	0.00%
CLOBETASOL SHAMPOO 0.05%	1	1	$290.07	$41.44	$290.07	0.02%
SUBTOTAL	**9**	**3**	**$535.61**	**$16.36**	**$117.54**	**0.03%**
TIER-2 SUBTOTAL	**57**	**21**	**$8,732.76**	**$10.90**	**$160.49**	**0.47%**
TOTAL	**74,007**	**47,095***	**$1,825,428.21**	**$1.58**	**$78.80**	**100%**

*Total number of unduplicated members.

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[6] PR Newswire: LEO Pharma Inc. Announces FDA Approval of Enstilar® (calcipotriene and betamethasone dipropionate) Foam, 0.005%/0.064% for Plaque Psoriasis. Available at: http://www.prnewswire.com/news-releases/leo-pharma-inc-announces-fda-approval-of-enstilarcalcipotriene-and-betamethasone-dipropionate-foam-00050064-for-plaque-psoriasis-534079501.html. Last accessed 10/2015.
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Appendix G

Fiscal Year 2015 Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Omidria® (Phenylephrine/Ketorolac) Injection

Oklahoma Health Care Authority
November 2015

Introduction

The ophthalmic non-steroidal anti-inflammatory drugs (NSAIDs) and ophthalmic corticosteroids were voted to be established as Product Based Prior Authorization (PBPA) categories by the drug utilization review (DUR) board in May 2014. After several educational interventions were executed, the PBPA categories were implemented August 15, 2014.

Current Prior Authorization Criteria

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

***Not a required Tier-1 trial. Does not have to be attempted to get a Tier-2 medication

Ophthalmic NSAIDs Tier-2 Approval Criteria:

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

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone sodium phosphate solution 0.1%	fluorometholone (FML Forte®) suspension 0.25%
dexamethasone (Maxidex™) suspension 0.1%	fluorometholone (FML S.O.P®) ointment 0.1%
difluprednate (Durezol®) emulsion 0.05%	loteprednol (Lotemax®) gel 0.5%
fluorometholone (FML Liquifilm®) suspension 0.1%	loteprednol (Lotemax®) ointment 0.5%
fluorometholone (Flarex®) suspension 0.1%	prednisolone acetate (Pred Forte®) suspension 1%
loteprednol (Lotemax®) suspension 0.5%	
prednisolone acetate (Omnipred®) suspension 1%	
prednisolone acetate (Pred Mild®) suspension 0.12%	
prednisolone sodium phosphate solution 1%	
rimexolone (Vexol®) suspension 1%	

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

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

Utilization of Ophthalmic Anti-Inflammatories: Fiscal Year 2015

Comparison of Fiscal Years: Ophthalmic NSAIDs

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	668	943	$75,279.90	$79.83	$3.92	4,319	19,204
2015	546	778	$18,865.03	$24.25	$1.19	3,914	15,807
% Change	**-18.3%**	**-17.5%**	**-74.9%**	**-69.6%**	**-69.6%**	**-5.4%**	**-17.7%**
Change	**-122**	**-165**	**-$56,414.87**	**-$55.58**	**-$2.73**	**-225**	**-3,397**

*Total number of unduplicated members.
Total costs do not reflect rebated prices or net costs.

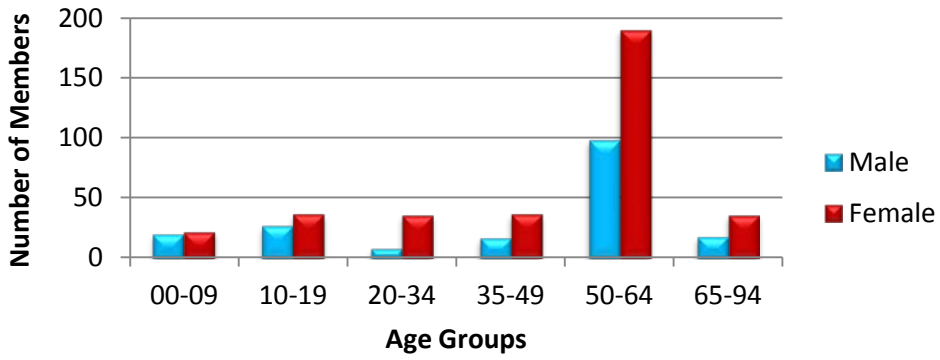
Comparison of Fiscal Years: Ophthalmic Corticosteroids

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	3,190	4,447	$254,801.07	$57.30	$3.11	29,556	81,932
2015	3,020	4,269	$319,463.26	$74.83	$3.72	28,346	85,831
% Change	**-5.3%**	**-4.0%**	**25.4%**	**30.6%**	**19.6%**	**-4.1%**	**4.8%**
Change	**-170**	**-178**	**$64,662.19**	**$17.53**	**$0.61**	**-1,210**	**3,899**

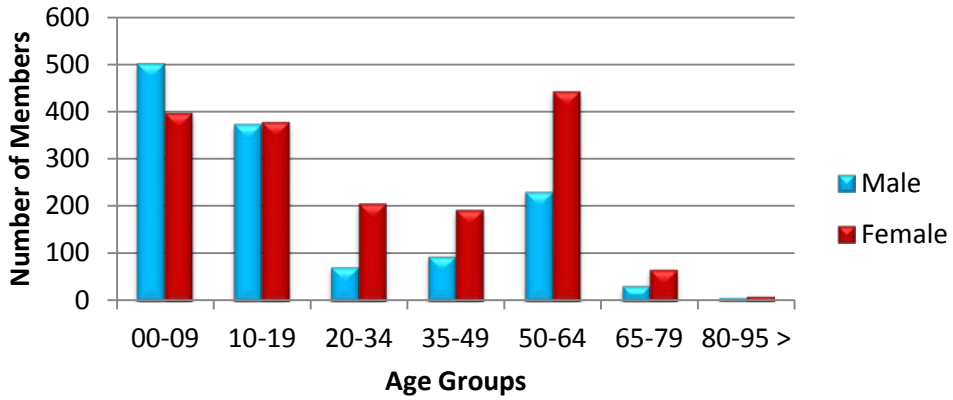
*Total number of unduplicated members.
Total costs do not reflect rebated prices or net costs.

Despite a decrease in utilization the total cost has increased. The increase in total cost is most likely due to price increases particularly, among generic formulations.

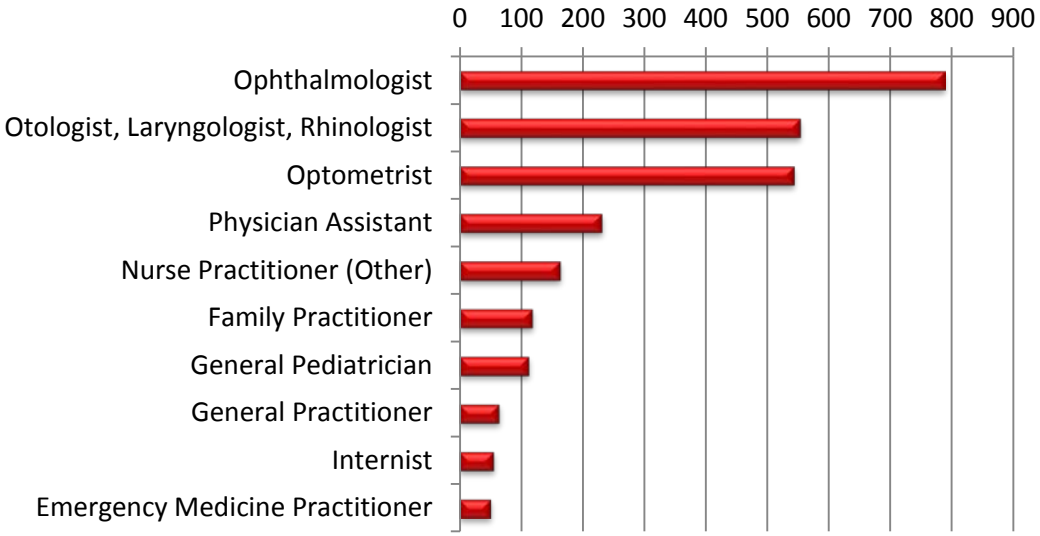
Demographics of Members Utilizing Ophthalmic NSAIDs



Demographics of Members Utilizing Ophthalmic Corticosteroids



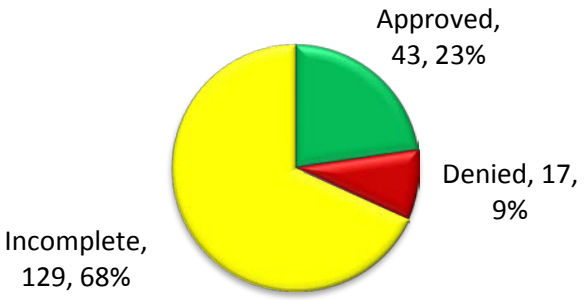
Top Prescriber Specialties of Ophthalmic Anti-Inflammatories by Number of Claims



Prior Authorization of Ophthalmic Anti-Inflammatories

There were 189 prior authorization requests submitted for ophthalmic anti-inflammatories during fiscal year 2015. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expirations:

- Lotemax® (loteprednol) gel: January 2017
- Durezol® (difluprednate) emulsion: November 2019
- Prolensa™ (bromfenac) solution: September 2025
- Nevanac™ (nepafenac) suspension: January 2027
- Acular LS® (ketorolac) solution: November 2027
- Acuvail® (ketorolac) solution: August 2029
- Ilevro™ (nepafenac) suspension: March 2032

FDA Approvals and New Indications:

- **June 2014**: The FDA approved Omidria®, the first and only product approved by the FDA to prevent intraoperative miosis and to reduce postoperative pain during intraocular lens procedures and cataract surgery.

Omidria® (Phenylephrine/Ketorolac) Product Summary[3]

Indications: Omidria® (phenylephrine/ketorolac) is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative pain. Phenylephrine/ketorolac is added to an irrigation solution used during cataract surgery or intraocular lens replacement.

Dosing:

- Omidria® is available as a single-patient-use vial and contains 10.16mg/mL (1% w/v) of phenylephrine and 2.88mg/mL (0.3% w/v) of ketorolac.
- A total of 4mL of phenylephrine/ketorolac is diluted in 500mL of ophthalmic irrigating solution prior to cataract surgery or intraocular lens replacement.

Mechanism of Action: Phenylephrine is an alpha 1-adrenergic receptor agonist and acts as a mydriatic agent by contracting the radial muscle of the iris. Ketorolac is a non-steroidal anti-inflammatory drug (NSAID) that inhibits both cyclooxygenase (COX-1 and COX-2) enzymes, which decreases prostaglandin concentrations. The decreased prostaglandin concentrations lead to reduced pain and prevention of miosis.

Contraindications: Phenylephrine/ketorolac is contraindicated in patients with a known hypersensitivity to any of its ingredients.

Warnings and Precautions:

- Elevations in blood pressure may occur from systemic exposure of phenylephrine.
- There is potential for cross-sensitivity to phenylacetic acid derivatives, acetylsalicylic acid, and other NSAIDs.

Adverse Reactions: The most common adverse reactions (2% to 24%) experienced during clinical trials were increased intraocular pressure, eye irritation, anterior chamber inflammation, and posterior capsule opacification.

Special Populations:

- Pregnancy: Phenylephrine/ketorolac is pregnancy category C. Phenylephrine/ketorolac should only be used in pregnant women if clearly needed.
- Nursing Mothers: Use caution when administering phenylephrine/ketorolac to nursing women.
- Pediatric Use: The safety and effectiveness of phenylephrine/ketorolac in pediatric patients younger than 18 years of age have not been established.
- Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and adult patients using phenylephrine/ketorolac.

Efficacy: The efficacy of phenylephrine/ketorolac was evaluated in two Phase 3, randomized, double-masked, multicenter, placebo-controlled clinical trials. The studies included 808 adult patients undergoing intraocular lens replacement or cataract surgery. The patients were randomized to either phenylephrine/ketorolac or placebo and were treated with preoperative topical mydriatic and anesthetic agents. Postoperative pain was evaluated by self-administered 0-100mm visual analog scales (VAS) and pupil diameter was measured throughout the surgical procedure. The placebo groups experienced progressive constriction and the phenylephrine/ketorolac groups maintained mydriasis. Approximately 23% of the placebo-treated patients and 4% of the phenylephrine/ketorolac-treated patients had a pupil diameter less than 6mm ($p < 0.01$). Pain during the initial 10-12 hours post operation was statistically significantly less in the phenylephrine/ketorolac-treated patients than in the placebo-treated patients. About 17% of the placebo-treated patients reported no pain and 26% of phenylephrine/ketorolac-treated patients reported no pain ($p < 0.01$).

Utilization: There has been no utilization of Omidria® since it was approved by the FDA in June 2014.

Cost Comparison:

Medication Name	Cost Per Unit	Package Size	Cost Per Package
Omidria® (phenylephrine/ketorolac) 1%/3% injection	**$122.76[+]**	**4mL**	**$491.04**

[+]EAC= estimated acquisition cost

Recommendations

The College of Pharmacy recommends the prior authorization of Omidria® (phenylephrine/ketorolac) with the following criteria:

Omidria® (Phenylephrine/Ketorolac) Approval Criteria:

1. An FDA approved diagnosis of preventing intraoperative miosis and reducing postoperative pain in patients undergoing cataract surgery or intraocular lens replacement; and
2. Prescriber must be an ophthalmologist.

Utilization Details of Ophthalmic NSAIDs: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION						
DICLOFENAC PRODUCTS						
DICLOFENAC SOL 0.1% OP	248	166	$2,501.83	$0.52	1.49	$10.09
SUBTOTAL	**248**	**166**	**$2,501.83**	**$0.52**	**1.49**	**$10.09**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN SOL 0.03% OP	2	2	$18.78	$0.57	1.00	$9.39
SUBTOTAL	**2**	**2**	**$18.78**	**$0.57**	**1.00**	**$9.39**
KETOROLAC PRODUCTS						
KETOROLAC SOL 0.5%	459	328	$5,987.13	$0.63	1.40	$13.04
SUBTOTAL	**459**	**328**	**$5,987.13**	**$0.63**	**1.40**	**$13.04**
TIER-1 SUBTOTAL	**709**	**492***	**$8,507.74**	**$0.59**	**1.44**	**$12.00**
TIER-2 UTILIZATION						
BROMFENAC PRODUCTS						
PROLENSA SOL 0.07%	13	12	$2,378.35	$7.08	1.08	$182.95
SUBTOTAL	**13**	**12**	**$2,378.35**	**$7.08**	**1.08**	**$182.95**
KETOROLAC PRODUCTS						
KETOROLAC SOL 0.4%	16	14	$195.08	$1.00	1.14	$12.19
SUBTOTAL	**16**	**14**	**$195.08**	**$1.00**	**1.14**	**$12.19**
NEPAFENAC PRODUCTS						
ILEVRO DRO 0.3% OP	20	18	$3,620.04	$6.58	1.11	$181.00
NEVANAC SUS 0.1%	20	17	$4,163.82	$11.63	1.18	$208.19
SUBTOTAL	**40**	**35**	**$7,783.86**	**$8.57**	**1.14**	**$194.60**
TIER-2 SUBTOTAL	**69**	**59***	**$10,357.29**	**$7.19**	**1.17**	**$150.11**
TOTAL	**778**	**546***	**$18,865.03**	**$1.19**	**1.42**	**$24.25**

*Total number of unduplicated members.

Utilization Details of Ophthalmic Corticosteroids: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION						
DEXAMETHSONE PRODUCTS						
DEXAMETH PHO SOL 0.1% OP	1,177	988	$26,830.72	$1.92	1.19	$22.80
MAXIDEX SUS 0.1% OP	31	30	$2,740.55	$7.94	1.03	$88.40
SUBTOTAL	**1,208**	**1,018**	**$29,571.27**	**$2.07**	**1.19**	**$24.48**
DIFLUPREDNATE PRODUCTS						
DUREZOL EMU 0.05%	480	293	$72,341.43	$6.71	1.64	$150.71
SUBTOTAL	**480**	**293**	**$72,341.43**	**$6.71**	**1.64**	**$150.71**
FLUOROMETHOLONE PRODUCTS						
FLAREX SUS 0.1% OP	8	7	$461.94	$5.13	1.14	$57.74
FLUOROMETHOL SUS 0.1% OP	293	221	$22,081.08	$3.94	1.33	$75.36
FML LIQUIFLM SUS 0.1% OP	10	8	$1,172.81	$5.69	1.25	$117.28
SUBTOTAL	**311**	**236**	**$23,715.83**	**$4.02**	**1.32**	**$76.26**
LOTEPREDNOL PRODUCTS						
LOTEMAX SUS 0.5%	192	137	$46,371.05	$9.70	1.40	$241.52
SUBTOTAL	**192**	**137**	**$46,371.05**	**$9.70**	**1.40**	**$241.52**
PREDNISOLONE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISOLONE SUS 1% OP	1,958	1,384	$132,292.38	$2.80	1.41	$67.57
PRED MILD SUS 0.12% OP	47	32	$5,938.71	$5.96	1.47	$126.36
PRED SOD PHO SOL 1% OP	7	7	$302.67	$2.16	1.00	$43.24
SUBTOTAL	**2,012**	**1,423**	**$138,533.76**	**$2.86**	**1.41**	**$68.85**
RIMEXOLONE PRODUCTS						
VEXOL SUS 1% OP	16	5	$1,265.38	$2.02	3.20	$79.09
SUBTOTAL	**16**	**5**	**$1,265.38**	**$2.02**	**3.20**	**$79.09**
TIER-1 SUBTOTAL	**4,219**	**2,984***	**$311,798.72**	**$3.68**	**1.41**	**$73.90**
TIER-2 UTILIZATION						
FLUOROMETHOLONE PRODUCTS						
FML FORTE SUS 0.25% OP	2	2	$303.47	$7.59	1.00	$151.74
FML OIN 0.1% OP	2	2	$212.68	$17.72	1.00	$106.34
SUBTOTAL	**4**	**4**	**$516.15**	**$9.93**	**1.00**	**$129.04**
LOTEPREDNOL PRODUCTS						
LOTEMAX GEL 0.5%	30	27	$4,158.64	$6.51	1.11	$138.62
LOTEMAX OIN 0.5%	4	4	$874.37	$9.40	1.00	$218.59
SUBTOTAL	**34**	**31**	**$5,033.01**	**$6.88**	**1.10**	**$148.03**
PREDNISOLONE PRODUCTS						
PRED FORTE SUS 1% OP	12	8	$2,115.38	$7.03	1.50	$176.28
SUBTOTAL	**12**	**8**	**$2,115.38**	**$7.03**	**1.50**	**$176.28**
TIER-2 SUBTOTAL	**50**	**34***	**$7,664.54**	**$7.06**	**1.47**	**$153.29**
TOTAL	**4,269**	**3,020***	**$319,463.26**	**$3.72**	**1.41**	**$74.83**

*Total number of unduplicated members.
Total 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 10/14/2015. Last accessed 10/22/2015.
[2]Omeros Corporation Press Release: Omeros receives FDA approval of Omidria for use in cataract and other intraocular lens replacement procedures. Available online at: http://investor.omeros.com/phoenix.zhtml?c=219263&p=irol-newsArticle_print&ID=1936166. Last revised 06/02/2014. Last accessed 10/22/2015.
[3]Omidria® Package Insert. Omeros Corporation. Available online at: http://medlibrary.org/lib/rx/meds/omidria/. Last revised 06/26/2015. Last accessed 10/20/2015.

Appendix H

Fiscal Year 2015 Annual Review of Tetracycline and Fluoroquinolone Antibiotics and 30-Day Notice to Prior Authorize Tetracycline Capsules, Minocycline Tablets, Ofloxacin Tablets, & Moxifloxacin Tablets

Oklahoma Health Care Authority
November 2015

Introduction

Since fiscal year 2011, the average cost per claim of generic medications has increased by 16.4%. The rising cost of both brand and generic medications have contributed to a total increase in prescription drug expenditures. Additional details related to the rising costs of generic medications were provided in the April Drug Utilization Review meeting which included the Fiscal Year 2014 SoonerCare Pharmacy Benefit Annual Review.

Of note, tetracycline HCl has increased significantly in price since 2012. The unit price increased 9,100% from $0.11 per unit to $10.12 per unit. This report evaluates utilization and includes recommendations by the College of Pharmacy.

Current Prior Authorization Criteria

Doxycycline Monohydrate Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the hyclate formulation cannot be used.

Doryx® (Doxycycline Delayed-Release 50mg, 75mg, 100mg, 150mg, & 200mg Tablets)

1. Member must have a patient-specific, clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

Oracea® (Doxycycline Delayed-Release 40mg Capsules):

1. Member must have a patient-specific, clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

Solodyn® (Minocycline Extended-Release Tablets)

1. Member must have a patient-specific, clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

The following tetracycline and fluoroquinolone oral formulations are available without prior authorization:

- Doxycycline hyclate (immediate-release) formulations: 20mg tablets, 50mg capsules, and 100mg tablets and capsules
- Tetracycline 250mg and 500mg capsules
- Minocycline immediate-release 50mg, 100mg, and 75mg capsules
- Ciprofloxacin and levofloxacin 250mg, 500mg, and 750mg tablets

Tetracycline Antibiotic Utilization: Fiscal Year 2015

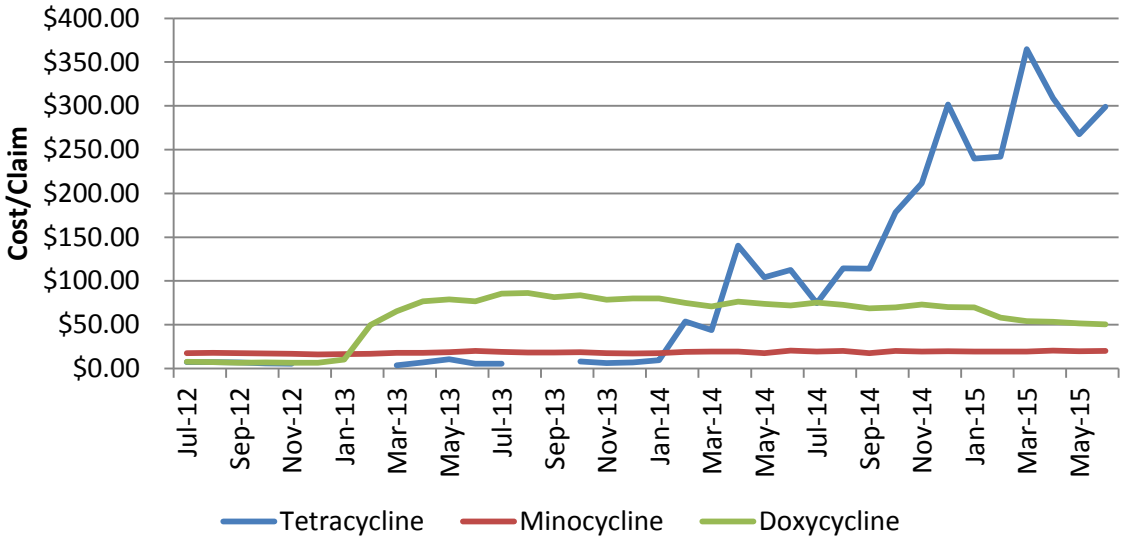
Comparison of Fiscal Years: Oral Tetracycline Antibiotics

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	14,774	24,045	$1,382,049.71	$57.48	$2.66	839,000	518,958
2015	14,068	23,378	$1,150,828.36	$49.23	$2.29	844,086	502,651
% Change	**-4.80%**	**-2.80%**	**-16.70%**	**-14.40%**	**-13.90%**	**0.60%**	**-3.10%**
Change	**-706**	**-667**	**-$231,221.35**	**-$8.25**	**-$0.37**	**5,086**	**-16,307**

*Total number of unduplicated members.
Chart includes tetracycline, doxycycline, and minocycline oral formulations.

- Despite a decrease in overall spending from fiscal year 2014 to fiscal year 2015 in the tetracycline antibiotic class, the cost per unit of tetracycline 250mg and 500mg capsules continued to climb.

Three Year Trend: Cost/Claim of Tetracycline Antibiotics

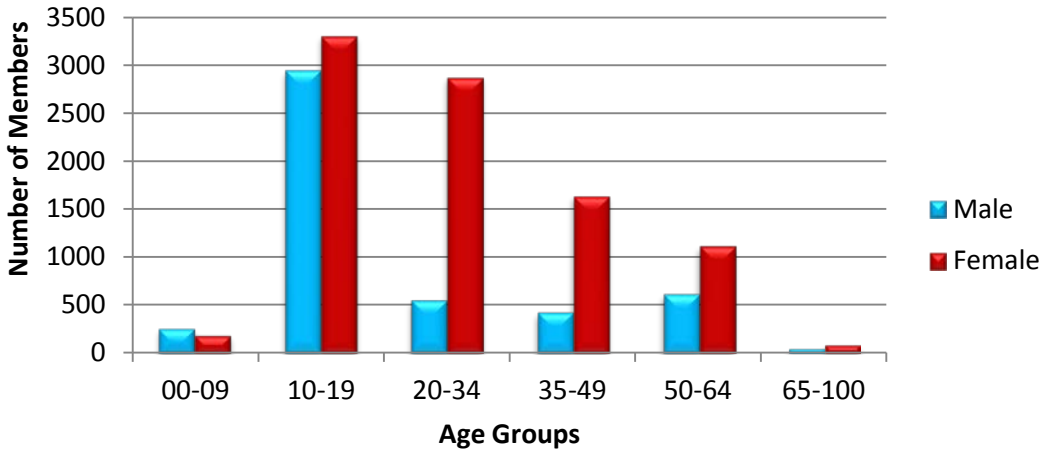


- The cost per claim of tetracycline has increased significantly since early 2014.
- The immediate-release doxycycline cost per claim spiked initially in early 2013, but appears to have leveled off. Both the hyclate and monohydrate formulations remain similar in price except for a few individual strengths which are much more costly

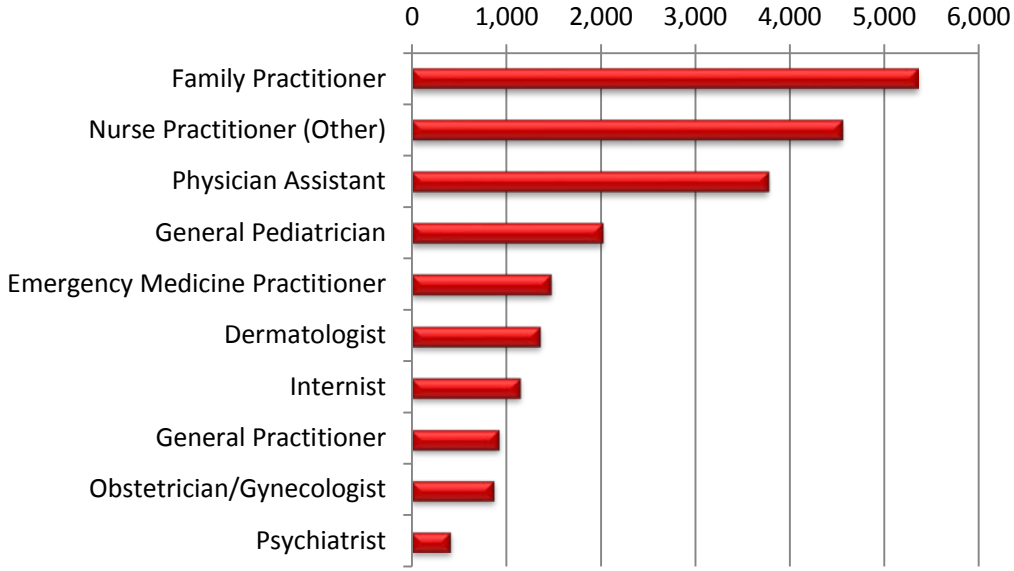
($15.04/capsule for monohydrate 150mg capsule and $14.29/capsule for monohydrate 75mg capsule).

- Overall costs of minocycline immediate-release have remained similar, however it is important to note that the cost of minocycline tablets is significantly greater than the cost of the minocycline capsule formulation despite availability in the same strengths (50mg, 75mg, and 100mg). The average cost per claim of the capsules is around $16.89 compared to the tablet formulation which has an average cost per claim of $99.03.

Demographics of Members Utilizing Tetracycline Antibiotics



Top Prescriber Specialties of Tetracycline Antibiotics by Number of Claims



Clinical Comparison: Oral, Immediate-Release Tetracycline Antibiotics[1,2,3]

Tetracycline	Doxycycline	Minocycline
How Supplied: 250mg, 500mg Cap **Dosing (most indications):** Adults: 1 to 2 grams/day divided in 2-4 doses Pediatrics: 25-50 mg/kg/day divided in 2-4 doses **Cost:** $228.91/claim* **Indications:** • Acne vulgaris • Actinomycotic infection • Amebic infection • Anthrax • Bartonellosis • Brucellosis • Chancroid • Chlamydia trachomatis infection • Cholera • Clostridial infection • Disease caused by rickettsiae • Gonorrhea • Granuloma inguinale • Helicobacter pylori GI tract infection • Inclusion conjunctivitis • Infection by Campylobacter • Infection of skin • Listeriosis • Lymphogranuloma venereum • Mycoplasma pneumonia • Nongonococcal urethritis due to Ureaplasma urealyticum • Periodontitis • Plague • Psittacosis • Relapsing fever • Respiratory tract infection • Shigellosis • Syphilis • Trachoma • Tularemia • Urinary tract infectious disease • Vincent's infection • Yaws	**How Supplied:** Monohydrate: 50mg, 75mg, 100mg, 150mg Cap/Tab, 25mg/5mL Susp Hyclate: 20mg, 50mg, 100mg Cap/Tab **Dosing (most indications):** Adults: 100mg every 12 hours Pediatrics: 2.2 to 4.4mg/kg/day in 1-2 divided doses **Cost:** $63.85/claim* **Indications:** • Acinetobacter infection • Acne vulgaris • Actinomycotic infection • Amebic infection • Anthrax • Bartonellosis • Brucellosis • Chancroid • Chlamydial infection • Cholera • Clostridial infection • E. coli Infection • Enterobacteriaceae Infection • Epididymitis • Gonorrhea • Granuloma inguinale • Inclusion conjunctivitis • Infection by Campylobacter • Listeriosis • Lymphogranuloma venereum • Malaria; Prophylaxis • Nongonococcal urethritis • Plague • Psittacosis • Q fever • Relapsing fever • Respiratory tract infection • Rocky Mountain spotted fever • Rosacea, inflammatory lesions • Shigellosis • Staphylococcal infection of skin • Syphilis • Tularemia • Typhus group rickettsial disease • Urinary tract infectious disease • Vincent's infection • Yaws	**How Supplied:** 50mg, 75mg, 100mg Cap/Tab **Dosing (most indications):** Adults: initial, 200mg followed by 100mg every 12 hours, or 100 to 200mg initially, followed by 50mg 4 times daily Pediatrics: 4mg/kg initially then 2mg/kg every 12 hours **Cost:** $19.61/claim* **Indications:** • Acne vulgaris • Allergy to penicillin - Bacterial infectious disease • Amebic dysentery • Anthrax • Bacterial infectious disease • Chlamydia trachomatis infection • Disease caused by rickettsiae • Inclusion conjunctivitis • Infection due to Mycobacterium marinum • Infection of skin • Meningococcal infectious disease, Asymptomatic carrier state • Periodontitis • Respiratory tract infection • Syphilis • Ureaplasma urealyticum infection • Urinary tract infectious disease

*Cost based on average cost/claim during fiscal year 2015.
Pediatric dosing only for older than 8 years of age.

Fluoroquinolone Utilization Evaluation: Fiscal Year 2015

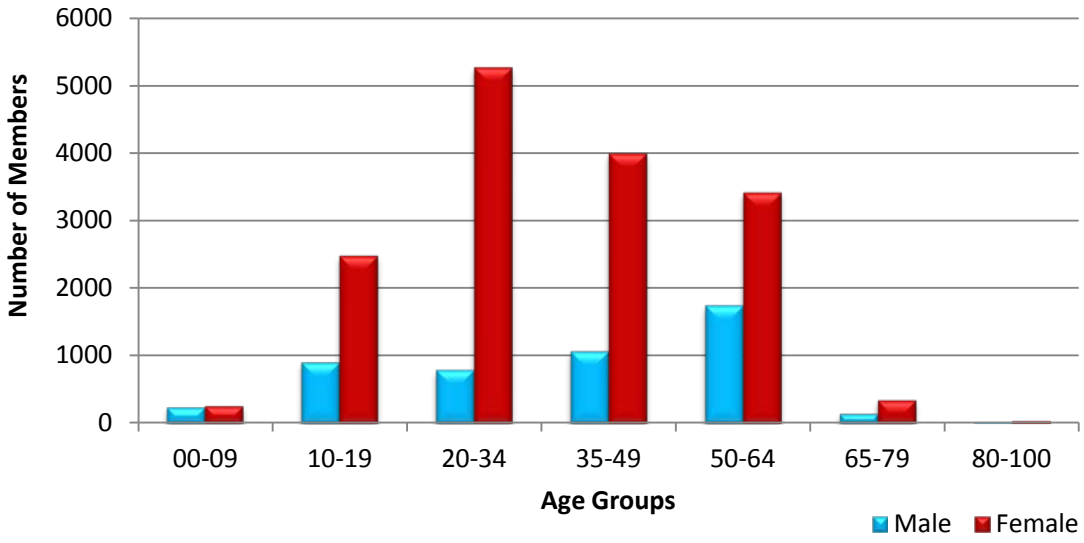
Comparison of Fiscal Years: Oral Fluoroquinolone Antibiotics

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	21,882	28,799	$371,822.06	$12.91	$1.50	470,992	248,063
2015	20,725	28,060	$260,927.17	$9.30	$1.09	452,239	239,690
% Change	**-5.30%**	**-2.60%**	**-29.80%**	**-28.00%**	**-27.30%**	**-4.00%**	**-3.40%**
Change	**-1,157**	**-739**	**-$110,894.89**	**-$3.61**	**-$0.41**	**-18,753**	**-8,373**

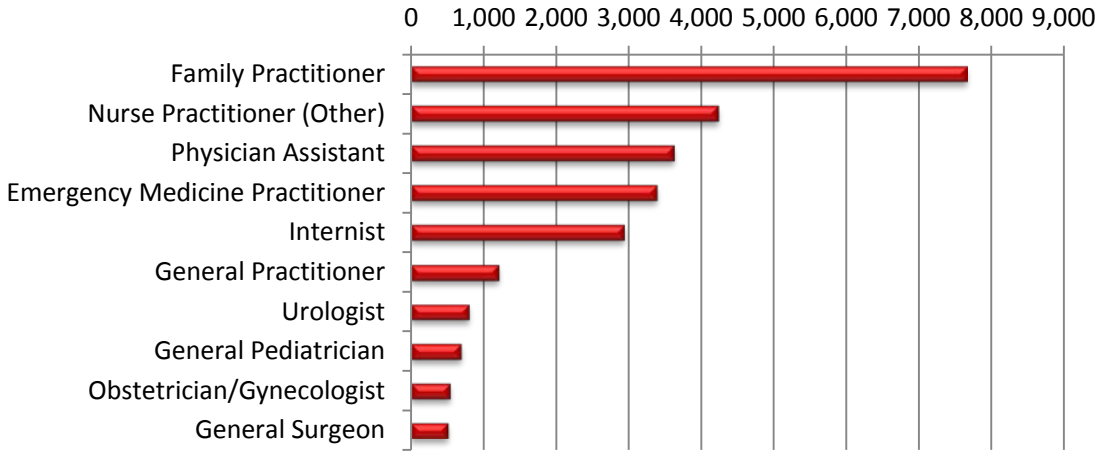
*Total number of unduplicated members.
Chart includes ciprofloxacin, levofloxacin, moxifloxacin, and ofloxacin oral formulations.

- Despite a decrease in overall spending and utilization from fiscal year 2014 to fiscal year 2015 in the fluoroquinolone class, the cost per claim varies among the different products and formulations.
- The average cost per claim for ciprofloxacin during fiscal year 2015 was $8.05/claim. The immediate-release ciprofloxacin products range in cost from $0.31 to $0.43 per tablet. The ciprofloxacin 100mg tablets and the extended-release formulations (500mg and 1000mg extended-release tablets) are more costly than the standard, immediate release strengths (100mg: $12.86/tablet, 500mg ER: $8.13/tablet, 1000mg ER $8.91/tablet).
- Claims for moxifloxacin and ofloxacin 400mg tablets are 16 times more expensive than the ciprofloxacin and levofloxacin products.

Demographics of Members Utilizing Fluoroquinolone Antibiotics



Top Prescriber Specialties of Fluoroquinolone Antibiotics by Number of Claims



Clinical Comparison: Oral Fluoroquinolone Antibiotics[4,5,6,7]

Ciprofloxacin	Levofloxacin	Moxifloxacin	Ofloxacin
How Supplied: 100mg, 250mg, 500mg, 750mg IR Tab, 500mg, 1000mg ER Tab, 250mg/5mL, 500mg/5mL Powder for Susp. **Dosing (most indications):** Adults: 500mg to 750mg every 12 hours Pediatrics: 10 to 20mg/kg every 12 hours **Cost:** $8.05/claim* **Indications:** • Bacterial prostatitis • Bronchitis, chronic, acute exacerbations • Gonorrhea • Infection of bone/joint • Infection of skin/ subcutaneous tissue • Infectious diarrhea • Infectious disease of abdomen • Inhalational anthrax • Lower RTI • Pyelonephritis • Sinusitis • Typhoid fever • Urinary tract infectious disease	**How Supplied:** 250mg, 500mg, 750mg IR Tab, 500mg/20mL soln, 250mg/10mL syrup **Dosing (most indications):** Adults: 500mg to 750mg daily Pediatrics: 16 to 20 mg/kg/day in 2 divided doses **Cost:** $7.39/claim* **Indications:** • Acute bacterial exacerbation of chronic bronchitis • Bacterial prostatitis • Bacterial sinusitis • Community acquired pneumonia • Infection of skin/ subcutaneous tissue • Inhalational anthrax • Nosocomial pneumonia • Plague • Pyelonephritis • Urinary tract infection	**How Supplied:** 400mg tab **Dosing (most indications):** Adults: 400mg once daily Pediatrics: Not indicated **Cost:** $132.27/claim* **Indications:** • Acute infective exacerbation of chronic obstructive pulmonary disease • Bacterial sinusitis • Community acquired pneumonia • Infection of skin/ subcutaneous tissue • Infectious disease of abdomen • Plague	**How Supplied:** 400mg tab **Dosing (most indications):** Adults: 400mg every 12 hours Pediatrics: Not indicated **Cost:** $146.44/claim+ **Indications:** • Acute bacterial exacerbation of chronic bronchitis • Chlamydial infection • Community acquired pneumonia • Cystitis • Gonorrhea • Infection due to Staphylococcus aureus • Infection of skin/ subcutaneous tissue • Nongonococcal urethritis • Pelvic inflammatory disease • Prostatitis • Urinary tract infectious disease

*Cost based on average cost/claim during fiscal year 2015.
+Based cost of 400mg tablets twice daily for 7 days.
RTI = Respiratory Tract Infection

Recommendations

The College of Pharmacy recommends the following changes to the tetracycline antibiotics category:

1. Remove the prior authorization on doxycycline monohydrate immediate-release capsules and tablets except on the 75mg capsules, 150mg capsules, and the 150mg tablets.
2. Prior authorize tetracycline 250mg and 500mg capsules with the following criteria:
   Tetracycline 250mg and 500mg Oral Capsules Approval Criteria:
   a. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline or minocycline capsules and/or other cost effective therapeutic equivalent medication(s).
3. Prior authorize minocycline immediate-release tablets with the following criteria:
   Minocycline Tablets Approval Criteria:
   a. Approval requires a patient-specific, clinically significant reason why the member requires the immediate-release tablet formulation and cannot use the immediate-release capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Additionally, the College of Pharmacy recommends the following changes to the fluoroquinolone antibiotics category:

1. Place an age restriction of six years and younger on levofloxacin 25mg/mL oral solution, ciprofloxacin 250mg/mL oral suspension, and ciprofloxacin 500mg/mL oral suspension. Members older than six years of age would require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.
2. Prior authorize ofloxacin 400mg and moxifloxacin 400mg tablets with the following criteria:
   Ofloxacin 400mg and Moxifloxacin 400mg Oral Tablets Approval Criteria:
   a. Approval requires a patient-specific, clinically significant reason why the member cannot use ciprofloxacin tablets, levofloxacin tablets, and/or other cost effective therapeutic equivalent medication(s).
3. Prior authorize ciprofloxacin 100mg tablets with the following criteria:
   Ciprofloxacin 100mg Oral Tablets Approval Criteria:
   a. Approval requires a patient-specific, clinically significant reason why the member cannot use alternative strengths of ciprofloxacin tablets or levofloxacin tablets and/or other cost effective therapeutic equivalent medication(s).
4. Prior authorize ciprofloxacin 500mg and 1000mg extended-release tablets with the following criteria:
   Ciprofloxacin 500mg and 1000mg Extended-Release Tablets Approval Criteria:
   a. Approval requires a patient-specific, clinically significant reason why the member cannot use the immediate-release formulation of ciprofloxacin tablets, levofloxacin tablets, and/or other cost effective therapeutic equivalent medication(s).

Utilization Details of Oral Tetracycline Antibiotics: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	% COST	COST/ CLAIM
DOXYCYCLINE PRODUCTS						
DOXYCYCL HYC CAP 100MG	9,257	7,092	$585,691.28	1.31	50.89%	$63.27
DOXYCYCL HYC TAB 100MG	4,346	3,328	$288,848.03	1.31	25.10%	$66.46
DOXYCYCL HYC CAP 50MG	716	403	$41,316.63	1.78	3.59%	$57.70
VIBRAMYCIN SYP 50MG/5ML	267	231	$20,595.33	1.16	1.79%	$77.14
DOXYCYCLINE SUS 25MG/5ML	130	115	$8,988.41	1.13	0.78%	$69.14
DOXYCYCLINE TAB 20MG	76	46	$1,877.23	1.65	0.16%	$24.70
DOXYCYC MONO CAP 100MG	54	46	$967.24	1.17	0.08%	$17.91
VIBRAMYCIN SUS 25MG/5ML	25	25	$1,995.17	1	0.17%	$79.81
DOXYCYC MONO TAB 50MG	12	1	$357.83	12	0.03%	$29.82
DOXYCYC MONO TAB 100MG	6	5	$148.17	1.2	0.01%	$24.70
MORGIDOX CAP 2X100MG	2	1	$117.88	2	0.01%	$58.94
DOXYCYC MONO CAP 50MG	1	1	$6.32	1	0.00%	$6.32
Subtotal	**14,892**	**10,887**	**$950,909.52**	**1.37**	**82.61%**	**$63.85**
MINOCYCLINE PRODUCTS						
MINOCYCLINE CAP 100MG	6,031	2,499	$118,739.83	2.41	10.32%	$19.69
MINOCYCLINE CAP 50MG	2,066	859	$28,617.50	2.41	2.49%	$13.85
MINOCYCLINE CAP 75MG	118	42	$2,022.35	2.81	0.18%	$17.14
MINOCYCLINE TAB 100MG	79	57	$11,004.44	1.39	0.96%	$139.30
MINOCYCLINE TAB 50MG	28	16	$2,623.37	1.75	0.23%	$93.69
MINOCYCLINE TAB 75MG	3	3	$192.34	1	0.02%	$64.11
MINOCYCLINE TAB 45MG ER	1	1	$93.49	1	0.01%	$93.49
Subtotal	**8,326**	**3,360**	**$163,293.32**	**2.48**	**14.21%**	**$19.61**
TETRACYCLINE PRODUCTS						
TETRACYCLINE CAP 500MG	91	71	$18,254.81	1.28	1.59%	$200.60
TETRACYCLINE CAP 250MG	69	43	$18,370.71	1.6	1.60%	$266.24
Subtotal	**160**	**114**	**$36,625.52**	**1.4**	**3.19%**	**$228.91**
TOTAL	**23,378**	**14,068***	**$1,150,828.36**	**1.66**	**100%**	**$49.23**

*Total number of unduplicated members.

Utilization Details of Oral Fluoroquinolone Antibiotics: Fiscal Year 2015

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	% COST	COST/ CLAIM
CIPROFLOXACIN PRODUCTS						
CIPROFLOXACN TAB 500MG	14,892	12,166	$69,349.21	1.22	26.58%	$4.66
CIPROFLOXACN TAB 250MG	1,869	1,630	$8,880.79	1.15	3.40%	$4.75
CIPROFLOXACN TAB 750MG	367	292	$3,976.16	1.26	1.52%	$10.83
CIPROFLOXACN SUS 250MG/5	159	130	$20,588.45	1.22	7.89%	$129.49
CIPROFLOXACN SUS 500MG/5	108	94	$14,605.01	1.15	5.60%	$135.23
CIPRO (10%) SUS 500MG/5	77	68	$11,812.87	1.13	4.53%	$153.41
CIPRO (5%) SUS 250MG/5	66	64	$10,891.41	1.03	4.17%	$165.02
CIPROFLOXACN TAB 500MG ER	15	14	$951.05	1.07	0.36%	$63.40
CIPROFLOXACN TAB 1000MG ER	3	1	$287.37	3	0.11%	$95.79
Subtotal	**17,556**	**14,062**	**$141,342.32**	**1.25**	**54.16%**	**$8.05**
LEVOFLOXACIN PRODUCTS						
LEVOFLOXACIN TAB 500MG	5,940	4,784	$27,128.25	1.24	10.40%	$4.57
LEVOFLOXACIN TAB 750MG	3,759	3,132	$24,915.59	1.2	9.55%	$6.63
LEVOFLOXACIN TAB 250MG	283	241	$1,325.38	1.17	0.51%	$4.68
LEVOFLOXACIN SOL 25MG/ML	184	144	$21,753.52	1.28	8.34%	$118.23
LEVAQUIN TAB 750MG	1	1	$10.35	1	0.00%	$10.35
Subtotal	**10,167**	**7,774**	**$75,133.09**	**1.31**	**28.80%**	**$7.39**
MOXIFLOXACIN PRODUCTS						
MOXIFLOXACIN TAB 400MG	319	269	$42,111.49	1.19	16.14%	$132.01
AVELOX ABC TAB 400MG	9	8	$957.64	1.13	0.37%	$106.40
AVELOX TAB 400MG	8	3	$1,372.92	2.67	0.53%	$171.62
Subtotal	**336**	**280**	**$44,442.05**	**1.20**	**17.04%**	**$132.27**
OFLOXACIN PRODUCTS						
OFLOXACIN TAB 400MG	1	1	$9.71	1	0.00%	$9.71
Subtotal	**1**	**1**	**$9.71**	**1**	**0.00%**	**$9.71**
TOTAL	**28,060**	**20,725 ***	**$260,927.17**	**1.35**	**100%**	**$9.30**

*Total number of unduplicated members.

[1] Tetracycline. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[2] Doxycycline. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[3] Minocycline. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[4] Ciprofloxacin. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[5] Levofloxacin. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[6] Moxifloxacin. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.
[7] Ofloxacin. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 30, 2015.

Appendix I

Fiscal Year 2015 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
November 2015

Current Prior Authorization Criteria

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria (Dupuytren's Contracture):

1. An FDA approved indication of Dupuytren's contracture with palpable cord, functional impairment, and fixed-flexion contractures of the metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint of 30 degrees or more; and
2. Member must be 18 years of age or older; and
3. The member must not be a candidate for needle aponeurotomy; and
4. The prescriber must be trained in the treatment of Dupuytren's contracture and injections of the hand; and
5. A quantity limit of 3 doses (one dose per 4 weeks) per cord will apply.

Utilization of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2015

Fiscal Year 2015 Utilization of Collagenase Clostridium Histolyticum: Medical Claims

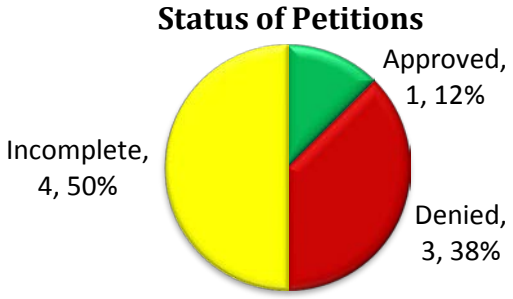
*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
1	1	$3,457.80	$3,457.80	90

*Total number of unduplicated members.

- There were no pharmacy claims for collagenase clostridium histolyticum during fiscal year 2015.
- Detailed demograhic information could not be provided due to the small number of members utizilizing collagenase clostridium histolyticum during fiscal year 2015.
- The only prescriber specialty listed on paid claims for collagenase clostridium histolyticum during fiscal year 2015 was urologist.

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 8 prior authorization requests submitted for collagenase clostridium histolyticum during fiscal year 2015. The following chart shows the status of the submitted prior authorization requests.



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

Anticipated Patent Expiration:

- Xiaflex® (collagenase clostridium histolyticum): July 2028

New FDA Approvals and Indications:

- **December 2013:** The FDA approved a new indication for Xiaflex® for the treatment of men with curvature of the penis, a condition known as Peyronie's disease. Xiaflex® is the first FDA-approved non-surgical treatment option for men with this condition, who have a plaque (lump) in the penis that results in a curvature deformity of at least 30 degrees upon erection.
- **October 2014:** Auzilium Pharmaceuticals announced the FDA approved a supplemental Biologics Application (sBLA) for Xiaflex® for the treatment of up to two Dupuytren's contracture (DC) joints in the same hand during a single treatment visit.

Pipeline Updates:

- **January 2013:** BioSpecifics Technologies Corporation announced progress for Xiaflex® to include the potential treatment of adult patients with edematous fibrosclerotic panniculopathy, commonly known as cellulite.
- **November 2014:** Imprimis Pharmaceuticals commenced a research study using Imprimis' patent-pending pentoxifylline formulation for the treatment of Peyronie's disease. The company expects to announce the findings for this initial research during 2015.

Peyronie's Disease Summary[2,5,6,7]

Peyronie's disease (PD) is the development of fibrous scar tissue inside the penis that causes curvature, and painful erections. PD is thought to be caused by microvascular trauma to the penile shaft in the erect state secondary to sexual activity. It is hypothesized that repetitive minor trauma to the penis initiates an inflammatory response leading to changes in the tunical collagen and scarring. Excessive deposition of collagen results in the formation of a plaque which may restrict tunica lengthening on the effected side during an erection and can lead to penile curvature, penile deformity, penile discomfort, penile pain, and erectile dysfunction (ED).

The estimated prevalence rates of PD vary among different studies. Dibenedetti (2011) used a population based methodology in a U.S. sample aged 18 years and older; the study reported a prevalence rate of 0.5% for men who had been formally diagnosed with PD. Alternatively Schwarzer (2001) conducted a community-based study among men in Cologne, Germany and reported a prevalence rate of 3.2% in men aged 31-78 years.

Symptoms of PD include a significant bend to the penis, erectile dysfunction, shortening of the penis, and penile pain with or without an erection. In a small percentage of cases, PD does not require treatment, and may spontaneously improve, but in many cases it will remain stable or worsen without treatment.

In late 2013, the FDA approved Xiaflex® (collagenase clostridium histolyticum) to treat men with PD. Xiaflex® was first approved by the FDA in 2010 for the treatment of Dupuytren's contracture, a progressive hand disease that can affect a person's ability to straighten and

properly use their fingers. Xiaflex® is the first FDA-approved non-surgical treatment option for men with this condition, who have a plaque (lump) in the penis that results in a curvature deformity of at least 30 degrees upon erection. Xiaflex® is believed to work in PD by breaking down the buildup of collagen that causes the curvature deformity.

Guidelines from the American Urological Association (AUA) state that clinicians may administer intralesional Xiaflex® in combination with modeling by the clinician and by the patient for the reduction of penile curvature in patients with stable PD, penile curvature greater than 30 degrees and less than 90 degrees, and intact erectile function (with or without the use of medications). The guidelines do not recommend Xiaflex® for patients whose primary concerns are pain or ED as Xiaflex® is a therapy for curvature and does not treat pain or ED.

A treatment course of Xiaflex® for PD consists of a maximum of four treatment cycles. Each treatment cycle consists of two Xiaflex® injection procedures (in which Xiaflex® is injected directly into the collagen-containing structure of the penis) and one penile modeling procedure performed by the health care professional. For each plaque causing the curvature deformity, up to four treatment cycles may be repeated at approximately six week intervals.

Xiaflex® has a boxed warning for corporal rupture (penile fracture) and because of this Xiaflex® is available only through a restricted program called the Xiaflex® REMS program. Additional warnings and precautions include risk of hypersensitivity reactions and abnormal coagulation if patients have used anticoagulant medications within seven days prior to the injection. Xiaflex® is contraindicated in PD plaques that involve the penile urethra.

The safety and effectiveness of Xiaflex® for the treatment of PD were established in two randomized double-blind, placebo-controlled studies in 832 men with PD and penile curvature deformity of at least 30 degrees. At baseline, penile pain was either not present or was mild in most patients. Participants were given up to four treatment cycles of Xiaflex® or placebo and were then followed 52 weeks. Xiaflex® treatment significantly reduced penile curvature deformity [treatment difference -17.2% (-26.2%, -7.6%)] and related bothersome effects compared with placebo [treatment difference -1.2 (-2.4, -0.03)].

Recommendations

The College of Pharmacy recommends the following criteria for Xiaflex® (collagenase clostridium histolyticum) for the diagnosis of Peyronie's Disease:

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria (Peyronie's Disease):

1. A diagnosis of stable Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy; and
2. Member must be 18 years or older; and
3. Member must have pain outside the circumstances of intercourse that is refractory to other available treatments; and
4. Peyronie's plaques must not involve the penile urethra; and
5. Member must have intact erectile function (with or without the use of medications); and
6. Prescriber must be certified to administer Xiaflex® through the Xiaflex® REMS program; and
7. A maximum of 8 injection procedures will be approved.

[1] PRNewswire: Auxilium Pharmaceuticals, Inc. Announces Issuance of Patent for Clostridial Collagenase Xiaflex® Expected to Have Patent Protection through 2028. Available online at: http://www.prnewswire.com/news-releases/auxilium-pharmaceuticals-inc-announces-issuance-of-patent-for-clostridial-collagenase-104769494.html. Last revised 10/12/2010. Last accessed 11/01/2015.

[2] FDA. FDA Approves First Drug Treatment for Peyronie's Disease. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm377849.htm. Last revised 12/06/2013. Last accessed 11/01/2015.

[3] PRNewswire: Auxilium Pharmaceuticals, Inc. Announces Xiaflex® Now Approved For The Concurrent Treatment Of Up To Two Affected Joints In The Same Hand In Dupuytren's Contracture Patients. Available online at: http://www.prnewswire.com/news-releases/auxilium-pharmaceuticals-inc-announces-xiaflex-now-approved-for-the-concurrent-treatment-of-up-to-two-affected-joints-in-the-same-hand-in-dupuytrens-contracture-patients-320363088.html. Last revised 10/20/2014. Last accessed 11/01/2015.

[4] PRNewswire: Biospecifics Technologies Corp. Announces Xiaflex® Progress in Two Pipeline Indications. Available online at: http://investors.biospecifics.com/2013-01-07-BioSpecifics-Technologies-Corp-Announces-XIAFLEX-Progress-in-Two-Pipeline-Indications. Last revised 01/07/2013. Last accessed 11/01/2015.

[5] Imprimis Pharmaceuticals. Pentoxifylline for Peyronie's Disease. Available online at: http://imprimispharma.com/our-business/urology/. Last accessed 11/01/2015.

[6] Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. American Urological Association Education and Research, Inc. Available online at: https://www.auanet.org/education/guidelines/peyronies-disease.cfm. Last revised 04/2015. Last accessed 11/01/2015.

[7] Xiaflex® Prescribing Information. Auxilium Pharmaceuticals, Inc. Available online at: http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.html. Last revised 07/2015. Last accessed 10/22/15.

Appendix J

Fiscal Year 2015 Annual Review of Erythropoiesis-Stimulating Agents

Oklahoma Health Care Authority
November 2015

Introduction

Hematopoietic growth factors are a group of glycoproteins that help promote blood cell growth and bone marrow proliferation. There are five classic hematopoietic growth factors, including erythropoietin, granulocyte colony-stimulating factor (G-CSF), granulocyte-macrophage colony-stimulating factor (GM-CSF), macrophage colony-stimulating factor (M-CSF), and interleukin-3 (IL-3). These glycoproteins are produced naturally in lymphocytes and monocytes, and have been demonstrated to stimulate progenitor cells of different hematopoietic cell lineages to form colonies of recognizable mature blood cells. The current prior authorization criteria for the recombinant human erythropoietin products, or erythropoiesis-stimulating agents (ESAs), is listed below.

Current Prior Authorization Criteria

Aranesp® (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved diagnosis of anemia due to chemotherapy in patients with non-myeloid malignancies; or
2. An FDA approved diagnosis of anemia associated with chronic renal failure; and
    a. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis (ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately); and
3. Recent hemoglobin levels must be provided; and
4. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if member's recent hemoglobin level is less than 11 g/dL.

Procrit® and Epogen® (Epoetin Alfa) Approval Criteria:

1. An FDA approved diagnosis of anemia due to chemotherapy in patients with non-myeloid malignancies; or
2. An FDA approved diagnosis of anemia in zidovudine-treated HIV-infected patients; or
3. An FDA approved indication for the reduction of allogeneic blood transfusion in surgery patients; or
4. An FDA approved diagnosis of anemia associated with chronic renal failure; and
    a. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis (ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately); and
5. Recent hemoglobin levels must be provided; and

6. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if member's recent hemoglobin level is less than 11 g/dL.

Utilization of ESAs: Fiscal Year 2015

Comparison of Fiscal Years for ESAs: Pharmacy Claims
Aranesp® (Darbepoetin Alfa), Procrit® (Epoetin Alfa), and Epogen® (Epoetin Alfa)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2014	50	288	$220,812.17	$766.71	$44.70	527	4,940
2015	52	299	$227,228.17	$759.96	$39.88	637	5,698
% Change	**4.00%**	**3.80%**	**2.90%**	**-0.90%**	**-10.80%**	**20.90%**	**15.30%**
Change	**2**	**11**	**$6,416.00**	**-$6.75**	**-$4.82**	**110**	**758**

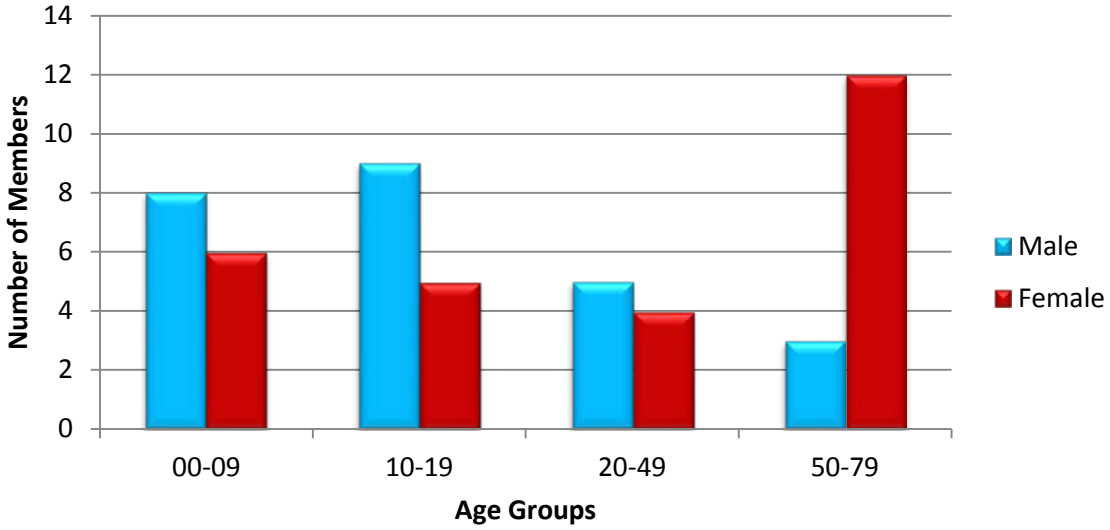
*Total number of unduplicated members.

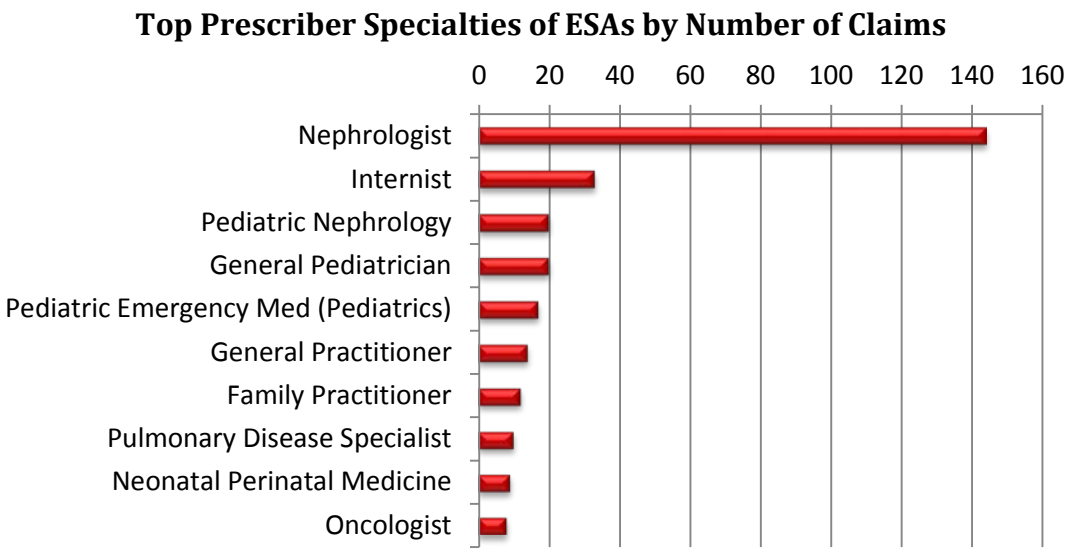
Fiscal Year 2015 Utilization of ESAs: Medical Claims
Aranesp® (Darbepoetin Alfa), Procrit® (Epoetin Alfa), and Epogen® (Epoetin Alfa)

*Total Members	Total Claims	Total Cost	Cost/Claim
58	301	$145,101.26	$482.06

*Total number of unduplicated members.
Totals exclude darbepoetin alfa and epoetin alfa claims for anemia in end stage renal disease for members on dialysis. ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately.

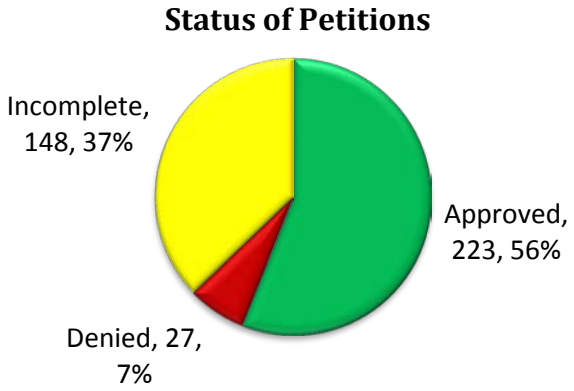
Demographics of Members Utilizing ESAs





Prior Authorization of ESAs

There were 398 prior authorization requests submitted for the ESAs during fiscal year 2015. The following chart shows the status of the submitted petitions.



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

Biosimilars: The Affordable Care Act amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. A *biosimilar* product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. An *interchangeable* biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

- **August 2015:** The FDA released guidance for the industry regarding nonproprietary naming of biological products. The draft guidance and proposed rule calls for biologics, including reference products and biosimilars, to bear a nonproprietary name with an FDA-designated suffix.

Pipeline Updates:

- **December 2014:** Hospira submitted a Biologics License Application (BLA) to the FDA for Retacrit™, a proposed biosimilar to Epogen® (epoetin alfa) and Procrit® (epoetin alfa). If approved, Retacrit™ would be the first biosimilar ESA approved by the FDA. Currently, Hospira has two hematopoietic growth factor biosimilars approved in Europe, including Retacrit™ (epoetin zeta) and Nivestim™ (filgrastim).

Recommendations

The College of Pharmacy does not recommend any changes to the Erythropoiesis-Stimulating Agents (ESAs) Product Based Prior Authorization (PBPA) category at this time. As new ESA biosimilar products become available, the ESA category will be reevaluated.

Utilization Details of ESAs: Fiscal Year 2015

ESAs: Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20000/ML	191	23	$99,480.84	$36.29	$520.84	43.78%
PROCRIT INJ 2000/ML	25	4	$3,636.83	$7.64	$145.47	1.60%
PROCRIT INJ 40000/ML	16	6	$61,287.96	$136.80	$3,830.50	26.97%
EPOGEN INJ 10000/ML	15	4	$9,237.27	$32.99	$615.82	4.07%
PROCRIT INJ 10000/ML	13	7	$11,609.21	$16.85	$893.02	5.11%
PROCRIT INJ 3000/ML	3	1	$5,898.05	$67.02	$1,966.02	2.60%
PROCRIT INJ 4000/ML	2	1	$784.88	$60.38	$392.44	0.35%
EPOGEN INJ 4000/ML	1	1	$1,094.83	$36.49	$1,094.83	0.48%
SUBTOTAL	**266**	**47**	**$193,029.87**	**$40.51**	**$725.68**	**84.95%**
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 100MCG	22	2	$15,772.46	$102.42	$716.93	6.94%
ARANESP INJ 60MCG	6	2	$10,540.87	$20.91	$1,756.81	4.64%
ARANESP INJ 25MCG	2	1	$1,433.92	$7.97	$716.96	0.63%
ARANESP INJ 40MCG	1	1	$1,145.03	$19.08	$1,145.03	0.50%
ARANESP INJ 500MCG	1	1	$3,505.00	$500.71	$3,505.00	1.54%
ARANESP INJ 60MCG	1	1	$1,801.02	$64.32	$1,801.02	0.79%
SUBTOTAL	**33**	**8**	**$34,198.30**	**$36.65**	**$1,036.31**	**15.05%**
TOTAL	**299**	**52***	**$227,228.17**	**$39.88**	**$759.96**	**100.00%**

*Total number of unduplicated members.

ESAs: Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
PROCRIT INJ J0885	202	43	$88,027.80	$435.78
ARANESP INJ J0881	86	14	$55,139.38	$641.16
EPOGEN INJ J0885	13	1	$1,934.08	$148.78
TOTAL	**301**	**58***	**$145,101.26**	**$482.06**

*Total number of unduplicated members.

Totals exclude darbepoetin alfa and epoetin alfa claims for anemia in end stage renal disease for members on dialysis. ESAs are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately.

[1] The U.S. Food and Drug Administration. Biosimilars. Available online at: http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm. Last revised 8/27/15. Last accessed 10/27/15.

[2] Academy of Managed Care Pharmacy. AMCP Is Disappointed in FDA's Draft Guidance and Proposed Rule Calling for Suffix on Nonproprietary Names of Biological Products. Available online at http://www.amcp.org/Newsletter.aspx?id=20115. Last revised 8/27/15. Last accessed 10/27/15.

[3] PR Newswire: Hospira Submits New Biologics License Application to U.S. FDA for Proposed Epoetin Alfa Biosimilar. Available online at: http://www.prnewswire.com/news-releases/hospira-submits-new-biologics-license-application-to-us-fda-for-proposed-epoetin-alfa-biosimilar-300018991.html. Last revised 1/12/15. Last accessed 10/27/15.

[4] Specialty Pharma Journal: Hospira Presents Data Demonstrating the Biosimilarity Between Amgen's Epogen and Hospira's Proposed Biosimilar. Available online at: http://www.spjnews.com/2015/03/hospira-presents-data-demonstrating-the-biosimilarity-between-amgens-epogen-and-hospiras-proposed-biosimilar/. Last revised 3/27/14. Last accessed 10/27/15.

[5] Biosimilar News: Apotex Biosimilar of Amgen's Neulasta Under Review by FDA. Available online at: http://www.biosimilarnews.com/apotex-biosimilar-of-amgens-neulasta-under-review-by-fda. Last revised 12/19/14. Last accessed 10/27/15.

[6] Biosimilar News: FDA Has Accepted Apotex Filgrastim Biosimilar Filing . Available online at: http://www.biosimilarnews.com/fda-has-accepted-apotex-filgrastim-biosimilar-filing. Last revised 2/20/15. Last accessed 10/27/15.

Appendix K

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

FDA NEWS RELEASE

For Immediate Release: October 16th, 2015

FDA approves Praxbind, the first reversal agent for the anticoagulant Pradaxa

Praxbind approved for specific emergency situations

The U.S. Food and Drug Administration granted accelerated approval to Praxbind (idarucizumab) for use in patients who are taking the anticoagulant Pradaxa (dabigatran) during emergency situations when there is a need to reverse Pradaxa's blood-thinning effects.

The FDA approved Pradaxa in 2010 to prevent stroke and systemic blood clots in patients with atrial fibrillation, as well as for the treatment and prevention of deep venous thrombosis and pulmonary embolism. Praxbind is the first reversal agent approved specifically for Pradaxa and works by binding to the drug compound to neutralize its effect. Praxbind solution is for intravenous injection.

The safety and effectiveness of Praxbind were studied in three trials involving a total of 283 healthy volunteers taking Pradaxa (i.e., people who did not require an anticoagulant). In the healthy volunteers who were given Praxbind, there was an immediate reduction in the amount of Pradaxa in participants' blood (measured as unbound dabigatran plasma concentration) that lasted for a period of at least 24 hours. In this study, the most common side effect from use of Praxbind was headache.

Another trial included 123 patients taking Pradaxa who received Praxbind due to uncontrolled bleeding or because they required emergency surgery. In this ongoing trial, based on laboratory testing, the anticoagulant effect of Pradaxa was fully reversed in 89 percent of patients within four hours of receiving Praxbind. In this patient trial, the most common side effects were low potassium (hypokalemia), confusion, constipation, fever and pneumonia.

Reversing the effect of Pradaxa exposes patients to the risk of blood clots and stroke from their underlying disease (such as atrial fibrillation). The Praxbind labeling recommends patients resume their anticoagulant therapy as soon as medically appropriate, as determined by their health care provider.

Praxbind is approved under the FDA's accelerated approval program, which allows the agency to approve drugs for serious conditions that fill an unmet medical need based on an effect on a surrogate or an intermediate clinical endpoint that is reasonably likely to predict a clinical benefit to patients. The program is designed to provide patients with earlier access to promising new drugs, but the company will be required to submit additional clinical information after approval to confirm the drug's clinical benefit.

Praxbind and Pradaxa are both marketed by Boehringer Ingelheim of Ridgefield, Connecticut.

FDA NEWS RELEASE

For Immediate Release: October 9th, 2015

FDA expands approved use of Opdivo in advanced lung cancer

Opdivo demonstrates survival benefit in squamous and non-squamous non-small cell lung cancer

The U.S. Food and Drug Administration approved Opdivo (nivolumab) to treat patients with advanced (metastatic) non-small cell lung cancer whose disease progressed during or after platinum-based chemotherapy.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new diagnoses and 158,040 deaths in 2015. The most common type of lung cancer, non-small cell lung cancer (NSCLC), is further divided into two main types named for the kinds of cells found in the cancer – squamous cell and non-squamous cell (which includes adenocarcinoma).Opdivo works by targeting the cellular pathway known as PD-1/PD-L1 (proteins found on the body's immune cells and some cancer cells). By blocking this pathway, Opdivo may help the body's immune system fight the cancer cells. Earlier this year, the FDA approved Opdivo to treat patients with advanced squamous NSCLC whose disease progressed during or after platinum-based chemotherapy. The approval expands the use of Opdivo to also treat patients with non-squamous NSCLC.

The safety and effectiveness of Opdivo for this use was demonstrated in an international, open-label, randomized study of 582 participants with advanced NSCLC whose disease progressed during or after treatment with platinum-based chemotherapy and appropriate biologic therapy. Participants were treated with Opdivo or docetaxel. The primary endpoint was overall survival, and the secondary endpoint was

objective response rate (the percentage of patients who experienced complete or partial shrinkage of their tumors). Those treated with Opdivo lived an average of 12.2 months compared to 9.4 months in those treated with docetaxel. Additionally, 19 percent of those treated with Opdivo experienced a complete or partial shrinkage of their tumors, an effect that lasted an average of 17 months, compared to 12 percent among those taking docetaxel, which lasted an average of six months.

While patients who received Opdivo lived longer than those who received docetaxel across the study, an evaluation of samples from a subgroup of patients' tumors suggests that the level of PD-L1 expression in NSCLC tumors may help identify patients who are more likely to live longer due to treatment with Opdivo. Therefore, the FDA also approved the PD-L1 IHC 28-8 pharmDx test to detect PD-L1 protein expression levels and help physicians determine which patients may benefit most from treatment with Opdivo.

The most common side effects of Opdivo are fatigue, musculoskeletal pain, decreased appetite, cough and constipation. Opdivo also has the potential to cause serious side effects that result from the immune system effect of Opdivo (known as "immune-mediated side effects"). These severe immune-mediated side effects involve healthy organs, including the lung, colon, liver, kidneys, hormone-producing glands and the brain.

The FDA granted Opdivo breakthrough therapy designation for this indication based on preliminary clinical evidence that suggested Opdivo may offer a substantial improvement over available therapies. It also received priority review status, which is granted to drugs that, at the time the application was submitted, have the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. The approval of Opdivo occurred approximately three months ahead of the prescription drug user fee goal date of January 2, 2016, the date when the agency was scheduled to complete its review of the application.

Another drug called Keytruda (pembrolizumab), manufactured by Merck, also targets the PD-1/PD-L1 pathway and was granted accelerated approval last week for treating NSCLC specifically for patients whose tumors expressed PD-L1.

Opdivo is marketed by Bristol-Myers Squibb based in Princeton, New Jersey. The PD-L1 IHC 28-8 pharmDx test is marketed by Dako North America Inc. in Carpinteria, California.

Safety Announcements

FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie

[10-22-2015] The U.S. Food and Drug Administration (FDA) is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, we are requiring the manufacturer to add new information about this safety risk to the drug labels.

Patients taking these medicines should contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of liver injury. Patients should not stop taking these medicines without first talking to their health care professionals. Stopping treatment early could result in drug resistance to other hepatitis C medicines. Health care professionals should closely monitor for signs and symptoms of worsening liver disease, such as ascites, hepatic encephalopathy, variceal hemorrhage, and/or increases in direct bilirubin in the blood.

Viekira Pak and Technivie are used to treat chronic hepatitis C, a viral infection that can last a lifetime and lead to serious liver and other health problems, including cirrhosis, liver cancer, and death. These medicines reduce the amount of hepatitis C virus in the body by preventing it from multiplying and may slow down the disease.

Our review of adverse events reported to the FDA Adverse Event Reporting System (FAERS) database and to the manufacturer of these medicines, AbbVie, identified cases of hepatic decompensation and liver failure in patients with underlying liver cirrhosis who were taking these medicines. Some of these events resulted in liver transplantation or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment with it.

Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to FAERS were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended. FAERS includes only reports submitted to FDA, so there are likely additional cases about which we are unaware.

We are requiring AbbVie to include information about serious liver injury adverse events to the Contraindications, Warnings and Precautions, Postmarketing Experience, and Hepatic Impairment sections of the Viekira Pak and Technivie drug labels.
We urge health care professionals and patients to report side effects involving Viekira Pak or Technivie to the FDA MedWatch program.

Safety Announcements

FDA Drug Safety Communication: FDA requires drug interaction studies with potassium-lowering drug Kayexalate (sodium polystyrene sulfonate)

[10-22-2015] The U.S. Food and Drug Administration (FDA) is requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth – drug interactions that could affect how well the other medications work.
Kayexalate (sodium polystyrene sulfonate) and generic brands Kionex and SPS are used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. They work by binding potassium in the large intestine so it can be removed from the body. Potassium is a mineral that helps the body function properly. When people have too much potassium in their blood it can cause problems with heart rhythm, which in rare cases can be fatal. Patients should not stop taking their potassium-lowering drugs without talking to their health care professional.
The approved labeling for Kayexalate describes its potential to decrease absorption of lithium and thyroxine; however, extensive drug-drug interaction studies with Kayexalate have not been performed. During FDA's review of another potassium-lowering drug, Veltassa (patiromer), we found that Veltassa bound to about half of the medications tested, some of which are commonly used in patients who require potassium-lowering drugs. Such binding could decrease the effects of these medications. The label for Veltassa contains a warning not to take other orally administered medications within 6 hours of taking Veltassa. Similar to Veltassa, Kayexalate may also bind to other medications administered by mouth. To reduce this potential risk, prescribers and patients should consider separating Kayexalate dosing from other medications taken by mouth by at least 6 hours. This includes both prescription medications, such as antibiotics, blood pressure lowering agents and blood thinners, and those purchased over-the-counter without a prescription, such as antacids and laxatives. Health care professionals should monitor blood levels or clinical response to the other medications when appropriate.
If the studies conducted by the Kayexalate manufacturer, Concordia Pharmaceuticals, confirm significant interactions with other medications, FDA will require all manufacturers of sodium polystyrene sulfonate products to update the drug labels to include information about these drug interactions.
We urge health care professionals and patients to report side effects involving Kayexalate or other sodium polystyrene sulfonate products to the FDA MedWatch program.

Safety Announcements

FDA Drug Safety Communication: FDA review found no increased cardiovascular risks with Parkinson's disease drug entacapone

[10-26-2015] A Food and Drug Administration (FDA) safety review has found no clear evidence of an increased risk of heart attacks, stroke, or other cardiovascular events associated with the use of entacapone for the treatment of Parkinson's disease. As a result, our recommendations for using Comtan (entacapone) and Stalevo (a combination of entacapone, carbidopa, and levodopa) will remain the same in the drug labels. Patients should discuss any questions they have with their health care professionals.
Entacapone-containing products, Comtan and Stalevo, have been shown to be effective in treating symptoms of Parkinson's disease, such as muscle stiffness, tremors, spasms, and poor muscle control. The combination of entacapone with carbidopa and levodopa in Stalevo has been shown to reduce end-of-dose "wearing-off" in patients with Parkinson's disease to a greater degree than with entacapone alone or with the two-drug combination of carbidopa and levodopa.
We alerted patients and health care professionals about a possible increased risk for cardiovascular events and death with Stalevo in an August 2010 Drug Safety Communication. This possible safety issue was observed in a clinical trial called the Stalevo Reduction in Dyskinesia Evaluation in Parkinson's Disease (STRIDE-PD) and in a meta-analysis that combined the cardiovascular-related findings from 15 clinical trials comparing Stalevo to carbidopa/levodopa. Carbidopa and levodopa have been used extensively and have not been shown to have an increased cardiovascular risk. We were concerned that the entacapone in

Stalevo was responsible for these cardiovascular risks because the comparison drugs do not contain this ingredient.
To better understand the significance of these findings, we required the Stalevo manufacturer, Novartis, to study the potential for cardiovascular risk with the entacapone component of the drug. We examined the results from this required study and from one additional study and concluded they do not show an increased risk of cardiovascular adverse events with entacapone. The results observed in the original meta-analysis were driven by results of a single study (STRIDE-PD), which was not designed to assess cardiovascular risks. We believe that the meta-analysis and STRIDE-PD results are chance findings and do not represent a true increase in risk due to entacapone.
Novartis's study assessed the potential for hearts attacks associated with entacapone in patients 18 to 64 years old with Parkinson's disease using data from an electronic commercial insurance database. The risk for myocardial infarction that did not result in death was not significantly increased in patients treated with entacapone compared to the control group that received other Parkinson's disease drugs. No one in either group died from a myocardial infarction. This study had limitations, including that few patients had a myocardial infarction making it difficult to assess an association with the drug.
The second study by Graham et al. assessed the risk of myocardial infarction, stroke, or death in Medicare patients at least 65 years old with Parkinson's disease treated with entacapone compared to those receiving other Parkinson's disease drugs. The study results did not support an association between entacapone use and increased cardiovascular risks.
In light of the results from these two additional studies, FDA finds no evidence of an increased risk of myocardial infarction, stroke, or other cardiovascular events associated with the use of entacapone, Comtan or Stalevo. As a result, the drug labels will remain unchanged.

Current Drug Shortages Index (as of November 3rd, 2015):

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

Acetohydroxamic Acid (Lithostat) Tablets	***Currently in Shortage***
Ammonium Chloride Injection	***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***
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 1mg/mL (Preservative Free)	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Ethiodized Oil (Lipiodol) Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fomepizole Injection	***Currently in Shortage***

Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Haloperidol Lactate Injection	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
Indigo Carmine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
L-Cysteine Hydrochloride Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Levetiracetam (Keppra) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Liotrix (Thyrolar) Tablets	***Currently in Shortage***
Magnesium Sulfate Injection	***Currently in Shortage***
Mecasermin [rDNA origin] (Increlex) Injection	***Currently in Shortage***
Memantine Hydrochloride (Namenda) XR Capsules	***Currently in Shortage***
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***
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***
Pancuronium Bromide Injection	***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***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sufentanil Citrate (Sufenta) Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Thiotepa (Thioplex) for Injection	***Currently in Shortage***
Tiopronin (Thiola)	***Currently in Shortage***
Tobramycin Injection	***Currently in Shortage***
Trace Elements	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable Suspension (Aristospan)	***Currently in Shortage***
Trimipramine Maleate (SURMONTIL) Capsules	***Currently in Shortage***
Vancomycin Hydrochloride for Injection, USP	***Currently in Shortage***