Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday,
April 8, 2015
4 p.m.

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

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Bethany Holderread, Pharm.D.

SUBJECT: Packet Contents for Board Meeting – April 8, 2015

DATE: April 1, 2015

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

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

Call to Order

Public Comment Forum

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

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

Fiscal Year 2014 Annual Review of SoonerCare Pharmacy Benefit – Appendix C

Action Item – Vote to Prior Authorize Sylvant™ (Siltuximab) – Appendix D

Action Item – Vote to Prior Authorize Ecoza™ (Econazole Nitrate), Jublia® (Efinaconazole), and Kerydin™ (Tavaborole) – Appendix E

Action Item – Vote to Prior Authorize Izba® (Travoprost Ophthalmic Solution) – Appendix F

Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Hemangeol™ (Propranolol Oral Solution), Sotylize™ (Sotalol Oral Solution), and Prestalia® (Perindopril/Amlodipine) – Appendix G

Annual Review of Hereditary Angioedema Medications and 30-Day Notice to Prior Authorize Ruconest® (C1 Esterase Inhibitor) – Appendix H

Annual Review of Diabetes Medications and 30-Day Notice to Prior Authorize Tanzeum™ (Albiglutide), Trulicity™ (Dulaglutide), Cycloset® (Bromocriptine), Jardiance® (Empagliflozin), Invokamet™ (Canagliflozin/Metformin), Xigduo™ XR (Dapagliflozin/Metformin Extended-Release), Glyxambi® (Empagliflozin/Linagliptin), Afrezza® (Insulin Human Inhalation Powder), and Toujeo® (Insulin Glargine) – Appendix I

Annual Review of Pediculicides – Appendix J

FDA and DEA Updates – Appendix K

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – April 8, 2015 @ 4:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. March 11, 2015 DUR Minutes – Vote
   B. March 11, 2015 DUR Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Oral Viscous Lidocaine Claims Analysis Update – See Appendix B**
   A. Medication Coverage Activity for March 2015
   B. Pharmacy Help Desk Activity for March 2015
   C. Oral Viscous Lidocaine Claims Analysis Update

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

5. **Fiscal Year 2014 Annual Review of SoonerCare Pharmacy Benefit – See Appendix C**
   A. Introduction
   B. Total Enrollment
   C. Traditional Versus Specialty Pharmacy Products
   D. Top 10 Therapeutic Classes by Reimbursement
   E. Hepatitis C Drug Spending
   F. Generic Medication Price Increases
   G. Conclusion
   H. Top 100 Reimbursed Drugs by Fiscal Year
   I. Top 50 Medications by Total Number of Claims
   J. Top Traditional Therapeutic Classes by Fiscal Year
   K. Top Specialty Therapeutic Classes by Fiscal Year

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

6. **Action Item – Vote to Prior Authorize Sylvant™ (Siltuximab) – See Appendix D**
   A. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Ecoza™ (Econazole Nitrate), Jublia® (Efinaconazole), and Kerydin™ (Tavaborole) – See Appendix E**
   A. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Izba® (Travoprost Ophthalmic Solution) – See Appendix F**
   A. College of Pharmacy Recommendations

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

9. **Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Hemangeol™ (Propranolol Oral Solution), Sotylize™ (Sotalol Oral Solution), and Prestalia® (Perindopril/Amlodipine) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Antihypertensive Medications
   C. Prior Authorization of Antihypertensive Medications
   D. Market News and Updates
   E. Product Summaries
   F. College of Pharmacy Recommendations
   G. Utilization Details of Antihypertensive Medications

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

10. **Annual Review of Hereditary Angioedema Medications and 30-Day Notice to Prior Authorize Ruconest® (C1 Esterase Inhibitor) – See Appendix H**
    A. Current Prior Authorization Criteria
    B. Utilization of Hereditary Angioedema Medications
    C. Prior Authorization of Hereditary Angioedema Medications
    D. Market News and Updates
    E. Ruconest® (C1 Esterase Inhibitor) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Hereditary Angioedema Medications

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

11. **Annual Review of Diabetes Medications and 30-Day Notice to Prior Authorize Tanzeum™ (Albiglutide), Trulicity™ (Dulaglutide), Cycloset® (Bromocriptine), Jardiance® (Empagliflozin), Invokamet™ (Canagliflozin/Metformin), Xigduo™ XR (Dapagliflozin/Metformin Extended-Release), Glyxambi® (Empagliflozin/Linagliptin), Afrezza® (Insulin Human Inhalation Powder), and Toujeo® (Insulin Glargine)**
    – See Appendix I
    A. Current Prior Authorization Criteria
    B. Utilization of Diabetes Medications
    C. Prior Authorization of Diabetes Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Diabetic Medications

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

12. Annual Review of Pediculicides – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Pediculicides
C. Prior Authorization of Pediculicides
D. Market News and Updates
E. Summary of Pediculicide Mailing
F. College of Pharmacy Recommendations
G. Utilization Details of Pediculicides

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

13. FDA and DEA Updates – See Appendix K

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

14. Future Business

A. Annual Reviews
B. New Product Reviews

Items to be presented by Dr. Muchmore, Chairman:

15. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF MARCH 11, 2015

BOARD MEMBERS:	PRESENT	ABSENT
Theresa Garton, M.D.	x	
Carla Hardzog-Britt, M.D.		x
Anetta Harrell, 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
Melissa Anderson, Pharm.D.; Clinical Pharmacist	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		x
Bethany Holderread, Pharm.D.; Clinical Coordinator	x	
Shellie Keast, Ph.D.; Assistant Professor	x	
Carol Moore, Pharm.D.; Clinical Pharmacist		x
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Leslie Robinson, D.Ph.; PA Coordinator		x
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Graduate Students: David George, Pharm.D.		x
Tammy Lambert, Pharm.D.	x	
Timothy Pham, Pharm.D.	x	
Visiting Pharmacy Student(s): Irene Macharia Ruigu	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:		
Doug Wood, ViiV	James McAdams, Orexo	Michael Mason, Alcon
Clint Degner, Novartis	Don Mask, Novartis	Mark DeClerk, Lilly
Janie Huff, Takeda	Melvin Nwamadi, Abbott	Bruce Christian, Lilly
Patrick Mumme, Alexion	M. Patty Laster, Astellas	Don Kempin, Novo Nordisk
John Harris, Mission	Rick Ulasewich, DSI	Evie Knisely, Novartis
Chris DeSimone, Aegerion	Jim Fowler, AstraZeneca	John Omigh, Lundbeck

PRESENT FOR PUBLIC COMMENT:	
Karen Ward	Aegerion
Andrea Sestak	OUHSC- Pediatrics
Jeff Knappen	Allergan
Mai Duong	Novartis

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA NO. 8 SPEAKER: KAREN WARD

2B: AGENDA NO. 9 SPEAKER: DR. ANDREA SESTAK

2C: AGENDA NO. 9 SPEAKER: MAI DUONG

2D: AGENDA NO. 14 SPEAKER: JEFF KNAPPEN

ACTION: NONE REQUIRED

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

3A: FEBRUARY 11, 2015 DUR MINUTES – VOTE

3B: FEBRUARY 11, 2015 DUR RECOMMENDATIONS MEMORANDUM

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: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/FDA SAFETY ALERTS**

4A: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2015

4B: PHARMACY HELP DESK ACTIVITY FOR FEBRUARY 2015

4C: FDA SAFETY ALERTS

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NO ACTION REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE LEMTRADA™ (ALEMTUZUMAB) AND PLEGRIDY™ (PEGINTERFERON BETA-1A)**

5A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE BRISDELLE® (PAROXETINE MESYLATE)

6A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Teel
Dr. Preslar moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ORENITRAM™ (TREPROSTINIL) AND REVATIO® (SILDENAFIL SUSPENSION)

7A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz
Dr. Harrell moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE MYALEPT™ (METRELEPTIN)

8A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Anderson
Ms. Varalli-Claypool moved to approve; seconded by Dr. Winegardner
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF ILARIS® (CANAKINUMAB)

9A: INTRODUCTION
9B: CURRENT PRIOR AUTHORIZATION CRITERIA
9C: UTILIZATION OF ILARIS® (CANAKINUMAB)
9D: PRIOR AUTHORIZATION OF ILARIS® (CANAKINUMAB)
9E: MARKET NEWS AND UPDATES
9F: COLLEGE OF PHARMACY RECOMMENDATIONS
9G: UTILIZATION DETAILS OF ILARIS® (CANAKINUMAB)

Materials included in agenda packet; presented by Dr. Anderson
Dr. Winegardner moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: 30-DAY NOTICE TO PRIOR AUTHORIZE SYLVANT™ (SILTUXIMAB)

10A: INTRODUCTION
10B: SYLVANT™ (SILTUXIMAB) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF TOPICAL ANTIFUNGAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ECOZA™ (ECONAZOLE NITRATE), JUBLIA® (EFINACONAZOLE), AND KERYDIN™ (TAVABOROLE)

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF TOPICAL ANTIFUNGAL MEDICATIONS
11C: PRIOR AUTHORIZATION OF TOPICAL ANTIFUNGAL MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF TOPICAL ANTIFUNGAL MEDICATIONS

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF GLAUCOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IZBA® (TRAVOPROST OPHTHALMIC SOLUTION)

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF GLAUCOMA MEDICATIONS
12C: PRIOR AUTHORIZATION OF GLAUCOMA MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: IZBA® (TRAVOPROST OPHTHALMIC SOLUTION) PRODUCT SUMMARY
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF GLAUCOMA MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF SOLIRIS® (ECULIZUMAB)

13A: INDICATION
13B: CURRENT PRIOR AUTHORIZATION CRITERIA
13C: UTILIZATION OF SOLIRIS® (ECULIZUMAB)
13D: PRIOR AUTHORIZATION OF SOLIRIS® (ECULIZUMAB)
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF SOLIRIS® (ECULIZUMAB)

Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF BOTULINUM TOXINS

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF BOTULINUM TOXINS
14C: PRIOR AUTHORIZATION OF BOTULINUM TOXINS
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF BOTULINUM TOXINS

Materials included in agenda packet; presented by Dr. Anderson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF SINGULAIR® (MONTELUKAST) AND ZYFLO CR® (ZILEUTON EXTENDED-RELEASE)

15A: INTRODUCTION
15B: CURRENT PRIOR AUTHORIZATION CRITERIA
15C: UTILIZATION OF SINGULAIR® AND ZYFLO CR®
15D: PRIOR AUTHORIZATION OF SINGULAIR® AND ZYFLO CR®
15E: MARKET NEWS AND UPDATES
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF SINGULAIR® AND ZYFLO CR®

Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FDA AND DEA UPDATES

Materials included in agenda packet; presented by Dr. Cothran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: **FUTURE BUSINESS**

17A: ANNUAL REVIEWS

17B: NEW PRODUCT REVIEWS

Materials included in agenda packet; submitted by Dr. Cothran

ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: **ADJOURNMENT**

The meeting was adjourned at 4:58pm

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

Memorandum

Date: March 12, 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 March 11, 2015

Recommendation 1: Vote to Prior Authorize Lemtrada™ (Alemtuzumab) and Plegridy™ (Peginterferon β-1a)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Lemtrada™ (alemtuzumab) with the following criteria:

Lemtrada™ (Alemtuzumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of Multiple Sclerosis; and
2. Member must have had an inadequate response to two or more drugs indicated for the treatment of Multiple Sclerosis; and
3. Lemtrada™ must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for two hours after each infusion; and
4. The prescriber must agree to monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine counts at periodic intervals for 48 months after the last dose of Lemtrada™; and
5. The prescriber must agree that baseline and yearly skin examinations will be performed while the member is utilizing Lemtrada™ therapy; and
6. Member, prescriber, pharmacy, and healthcare facility must all enroll in the Lemtrada™ REMS Program and maintain enrollment throughout therapy.

Additionally, the College of Pharmacy recommends placement of Plegridy™ (peginterferon β-1a) into Tier-2 of the Multiple Sclerosis Interferon Prior Authorization category. Current criteria for this category will apply.

Multiple Sclerosis Interferon Approval Criteria:

1. An FDA approved diagnosis of relapsing remitting Multiple Sclerosis; and
2. Authorization of Tier-2 medications requires previous failure of the preferred Tier-1 product defined as:
   a. Occurrence of an exacerbation after six months; or
   b. Significant increase in MRI lesions after six months; or
   c. Adverse reactions or intolerable side effects; and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. Compliance will be checked for continued approval every six months.

Multiple Sclerosis Interferon Medications*	
Tier-1	**Tier-2**
interferon β – 1a (Avonex®)	interferon β – 1a (Rebif®)
interferon β – 1b (Betaseron®)	interferon β – 1b (Extavia®)
	peginterferon β – 1a (Plegridy™)

*Tier structure based on supplemental rebate participation.

Recommendation 2: Vote to Prior Authorize Brisdelle® (Paroxetine Mesylate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Brisdelle® (paroxetine mesylate) with the following criteria:

Brisdelle® (Paroxetine Mesylate) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Member must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reasoning why a SSRI or SNRI is not appropriate for the member; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 3: Vote to Prior Authorize Orenitram™ (Treprostinil) and Revatio® (Sildenafil Oral Suspension)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Orenitram™ (treprostinil) and Revatio® (sildenafil) suspension with the following criteria:

Orenitram™ (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Previous failed trials of at least one of each of the following categories:
    a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist and/or cardiologist; and
4. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist and/or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for ages six years and younger. Members seven years and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation.
4. A quantity limit of 224mL per 30 days (two bottles) will apply.

Additionally, the College of Pharmacy recommends updating the current criteria for Adcirca® (tadalafil) with the following criteria:

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist and/or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets; and
4. A quantity limit of 60 tablets per 30 days will apply.

Recommendation 4: Vote to Prior Authorize Myalept™ (Metreleptin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Myalept™ (metreleptin) with the following criteria:

Myalept™ (Metreleptin) Approval Criteria:

1. An FDA approved diagnosis of leptin deficiency in patients with congenital or acquired generalized lipodystrophy; and
2. Approvals will not be granted for the following diagnoses:
    a. Metabolic disease without current evidence of generalized lipodystrophy

   b. HIV-related lipodystrophy
   c. General obesity not associated with congenital leptin deficiency
3. Myalept™ must be prescribed by an endocrinologist; and
4. Prescriber must agree to test for neutralizing antibodies in patients who experience severe infections or if they suspect Myalept™ is no longer effective.
   a. Baseline HbA1c, fasting glucose, and fasting triglycerides must be stated on prior authorization request
   b. Re-approvals will require recent lab values (HbA1c, fasting glucose, and fasting triglycerides) to ensure neutralizing antibodies have not developed; and
5. Prescriber and pharmacy must be enrolled in the Myalept™ REMS program; and
6. Approvals will be for the duration of three months to evaluate compliance and ensure the prescriber is assessing continued efficacy; and
7. A quantity limit of one vial per day will apply.

Recommendation 5: Annual Review of Ilaris® (Canakinumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Ilaris® (canakinumab) to Tier-3 of the Targeted Immunomodulator Agents Product Based Prior Authorization category for the diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA) with the following criteria:

Ilaris® (Canakinumab) Approval Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):

1. An FDA approved indication of Systemic Juvenile Idiopathic Arthritis; and
2. Ilaris® will not be approved for concurrent use with a tumor necrosis factor blocking agent (e.g. adalimumab, etanercept, or infliximab) or anakinra; and
3. Ilaris® should not be initiated in patients with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once every four weeks.
   a. Two years of age and older and body weight greater than 7.5kg: 4mg/kg every four weeks; max dose 300mg/dose; and
5. Recent trials of one Tier-1 product and all appropriate Tier-2 products that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
6. Prior stabilization on Ilaris® documented within the last 100 days.
7. Approvals will be for the duration of one year.

Targeted Immunomodulator Agents		
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3+**
methotrexate	adalimumab (Humira®)	abatacept (Orencia®)
hydroxychloroquine	certolizumab pegol (Cimzia®)	alefacept (Amevive®)
sulfasalazine	etanercept (Enbrel®)	anakinra (Kineret®)
minocycline		apremilast (Otezla®)
oral corticosteroids		**canakinumab (Ilaris®)**
leflunomide		golimumab (Simponi®)
mesalamine		golimumab (Simponi® Aria™)
6-mercaptopurine		infliximab (Remicade®)
azathioprine		rituximab (Rituxan®)
NSAIDs		tocilizumab (Actemra®)
		tofacitinib (Xeljanz®)
		ustekinumab (Stelara®)
		vedolizumab (Entyvio™)

Tier structure based on supplemental rebate participation.
DMARDs= Disease Modifying Anti-Rheumatic Drugs
*Supplemental rebated products
+ May be rebated to Tier-2 status only

Recommendation 6: 30-Day Notice to Prior Authorize Sylvant™ (Siltuximab)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of Topical Antifungal Medications and 30-Day Notice to Prior Authorize Ecoza™ (Econazole Nitrate), Jublia® (Efinaconazole), and Kerydin™ (Tavaborole)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Izba® (Travoprost Ophthalmic Solution)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Soliris® (Eculizumab)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Botulinum Toxins

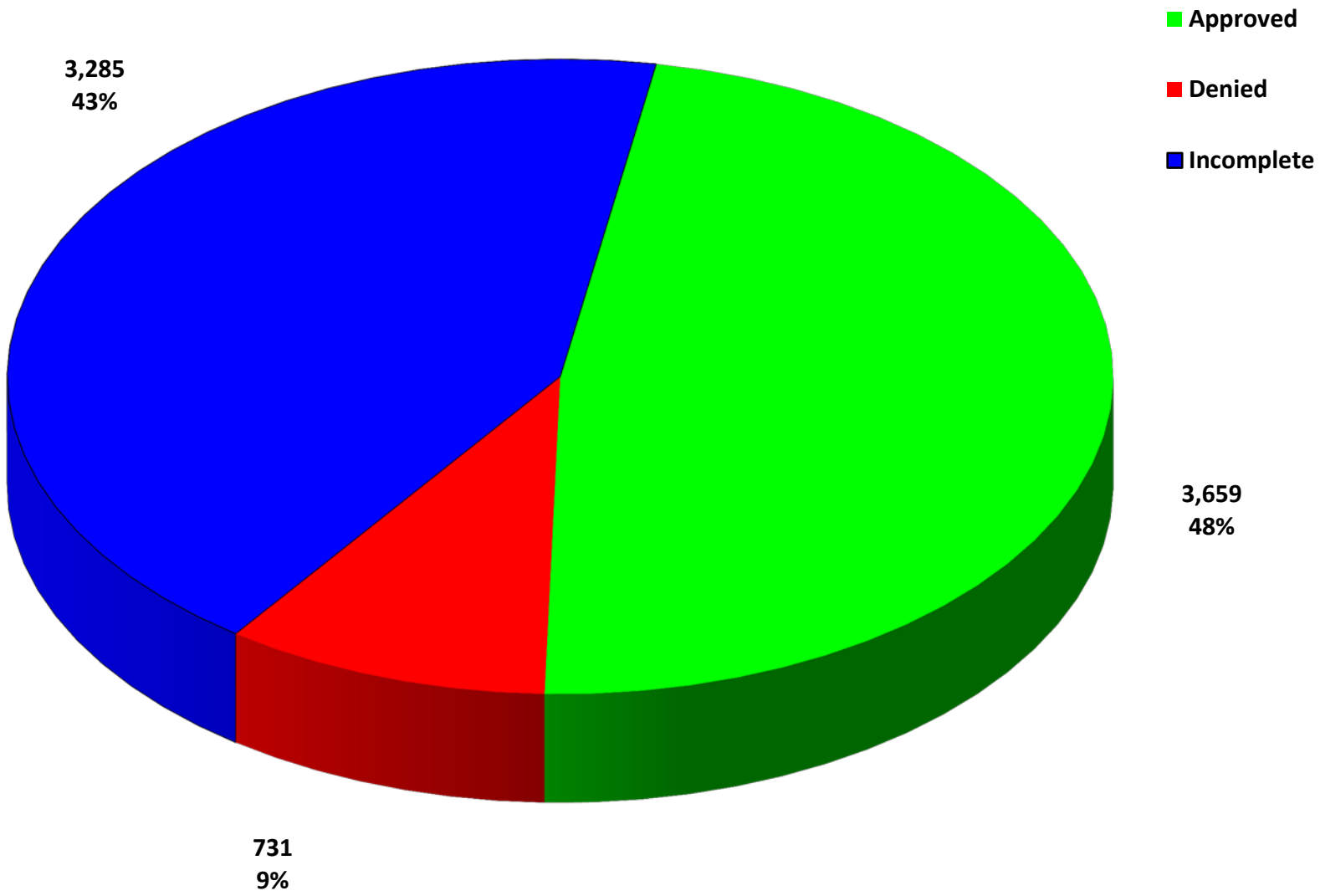
NO ACTION REQUIRED.

Recommendation 11: Annual Review of Singulair® (Montelukast) and Zyflo CR® (Zileuton Extended-Release)

NO ACTION REQUIRED.

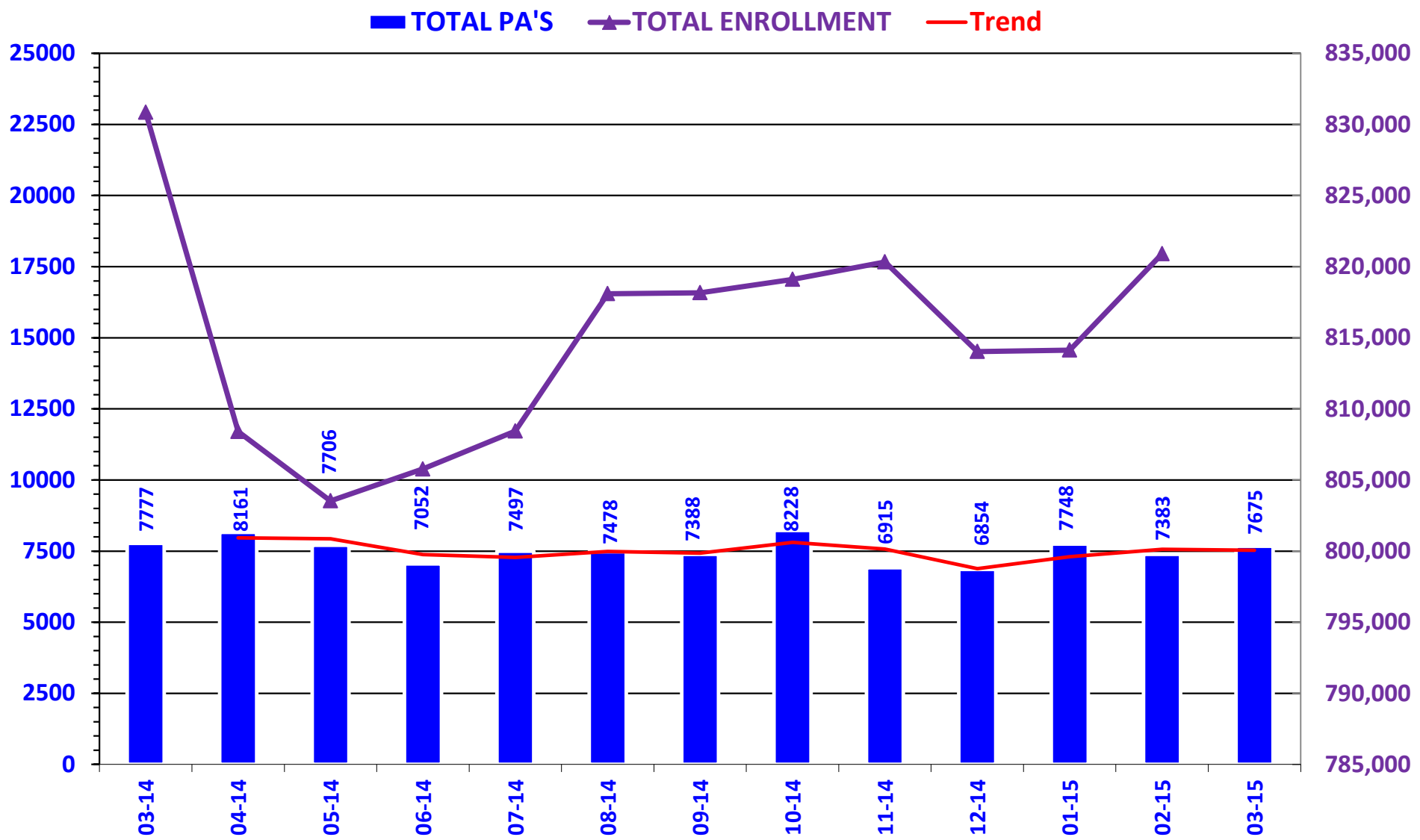
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: MARCH 2015



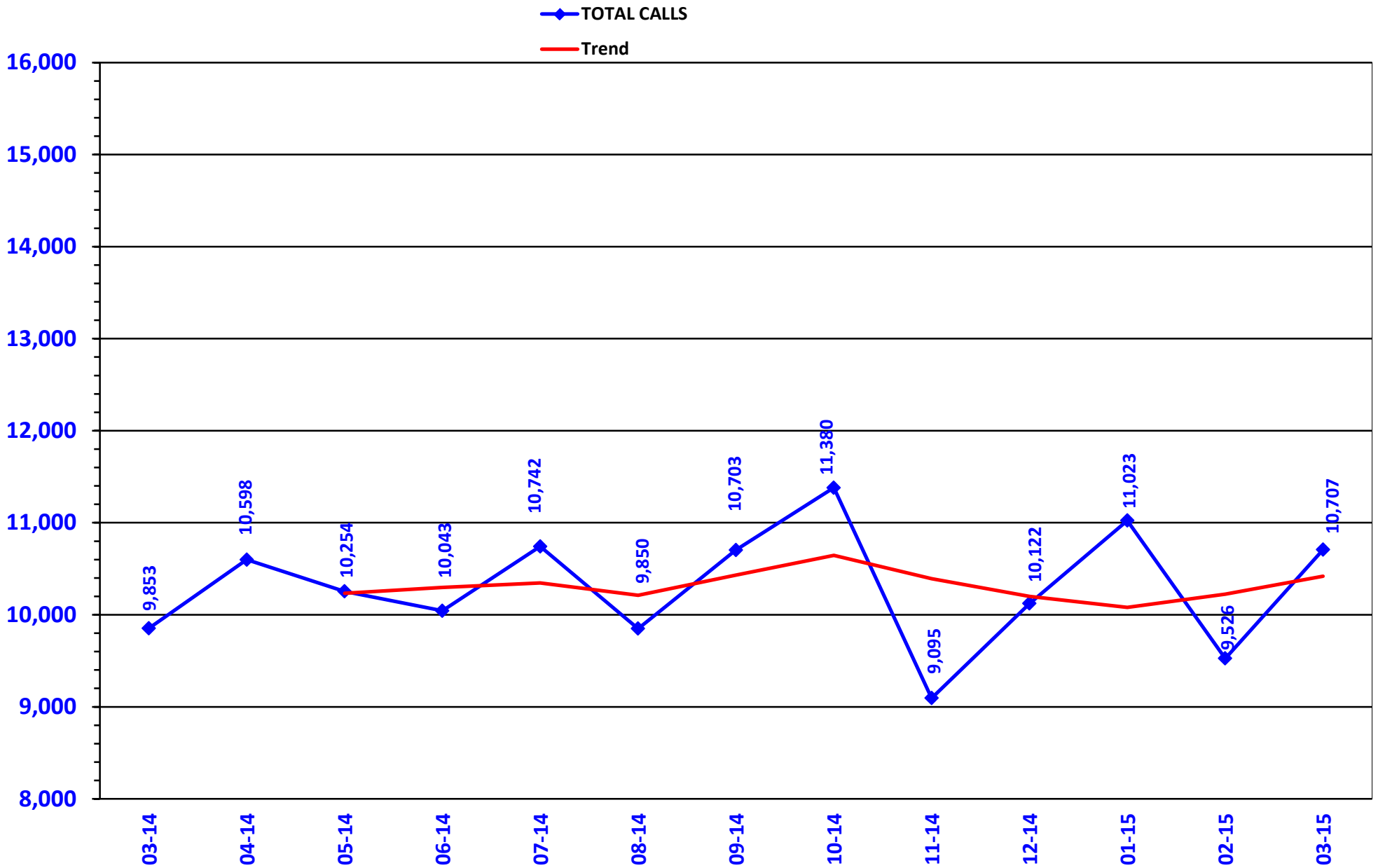
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: MARCH 2014 – MARCH 2015



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MARCH 2014 – MARCH 2015



Prior Authorization Activity

3/1/2015 Through 3/31/2015

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	376	161	10	205	356
Analgesic - NonNarcotic	22	0	1	21	0
Analgesic, Narcotic	466	254	25	187	157
Angiotensin Receptor Antagonist	50	5	19	26	359
Antiasthma	199	88	21	90	342
Antibiotic	26	6	2	18	208
Anticonvulsant	65	26	3	36	329
Antidepressant	88	13	7	68	337
Antidiabetic	224	96	17	111	352
Antihistamine	192	146	2	44	358
Antimigraine	38	7	7	24	311
Antiulcers	257	54	51	152	165
Anxiolytic	77	49	5	23	261
Atypical Antipsychotics	453	253	17	183	348
Biologics	72	40	3	29	333
Bladder Control	57	22	6	29	360
Blood Thinners	134	100	7	27	313
Botox	24	15	2	7	359
Calcium Channel Blockers	11	2	1	8	207
Cardiovascular	43	20	4	19	308
Cephalosporins	14	3	0	11	3
Chronic Obstructive Pulmonary Disease	14	3	0	11	358
Contraceptive	14	6	1	7	360
Dermatological	99	11	46	42	107
Endocrine & Metabolic Drugs	71	54	3	14	140
Erythropoietin Stimulating Agents	28	14	2	12	94
Fibromyalgia	138	30	23	85	344
Fish Oils	16	2	2	12	360
Gastrointestinal Agents	56	11	15	30	103
Growth Hormones	66	45	4	17	151
Hematopoietic Agents	18	9	1	8	105
Hepatitis C	132	72	14	46	8
HFA Rescue Inhalers	52	23	3	26	346
Insomnia	52	5	12	35	143
Linzess, Amitiza, and Relistor	76	17	9	50	187
Multiple Sclerosis	39	22	3	14	191
Muscle Relaxant	84	15	36	33	92
Nasal Allergy	105	2	26	77	55
Neurological Agents	51	26	5	20	347
NSAIDs	150	17	27	106	323
Ocular Allergy	47	7	11	29	121
Ophthalmic Anti-infectives	45	9	3	33	13
Ophthalmic Corticosteroid	10	0	2	8	0
Ophthalmic NSAIDs	13	0	3	10	0
Osteoporosis	21	7	4	10	274
Other*	222	33	49	140	249
Passive Immunizing Agents	11	4	1	6	99
Pediculicide	82	39	13	30	17
Prenatal Vitamins	25	1	5	19	242
Statins	83	31	8	44	359
Stimulant	938	406	41	491	342
Suboxone/Subutex	171	118	8	45	77
Synagis	89	59	2	28	50

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Testosterone	72	15	13	44	327
Topical Antifungal	41	2	6	33	38
Topical Corticosteroids	69	4	14	51	115
Vitamin	57	15	21	21	354
Pharmacotherapy	81	58	1	22	253
Emergency PAs	1	1	0	0	
Total	**6,227**	**2,553**	**647**	**3,027**	
Overrides					
Brand	40	33	1	6	345
Cumulative Early Refill	5	4	1	0	180
Dosage Change	357	325	5	27	9
High Dose	3	2	0	1	143
Ingredient Duplication	38	34	1	3	7
Lost/Broken Rx	98	88	3	7	5
NDC vs Age	45	45	0	0	262
Nursing Home Issue	75	61	0	14	7
Opioid Quantity	13	13	0	0	176
Other*	37	28	3	6	20
Quantity vs. Days Supply	691	450	60	181	278
STBS/STBSM	19	15	3	1	66
Stolen	12	9	0	3	4
Temporary Unlock	5	3	2	0	10
Third Brand Request	26	11	6	9	5
Wrong D.S. on Previous Rx	2	2	0	0	8
Overrides Total	**1,448**	**1,106**	**84**	**258**	
Total Regular PAs + Overrides	**7,675**	**3,659**	**731**	**3,285**	

Denial Reasons	
Unable to verify required trials.	2,733
Does not meet established criteria.	718
Lack required information to process request.	541

Other PA Activity	
Duplicate Requests	454
Letters	4,290
No Process	4
Changes to existing PAs	526
Helpdesk Initiated Prior Authorizations	897
PAs Missing Information	30

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

Oral Viscous Lidocaine Claims Analysis Update

Oklahoma Health Care Authority
April 2015

Background[1]

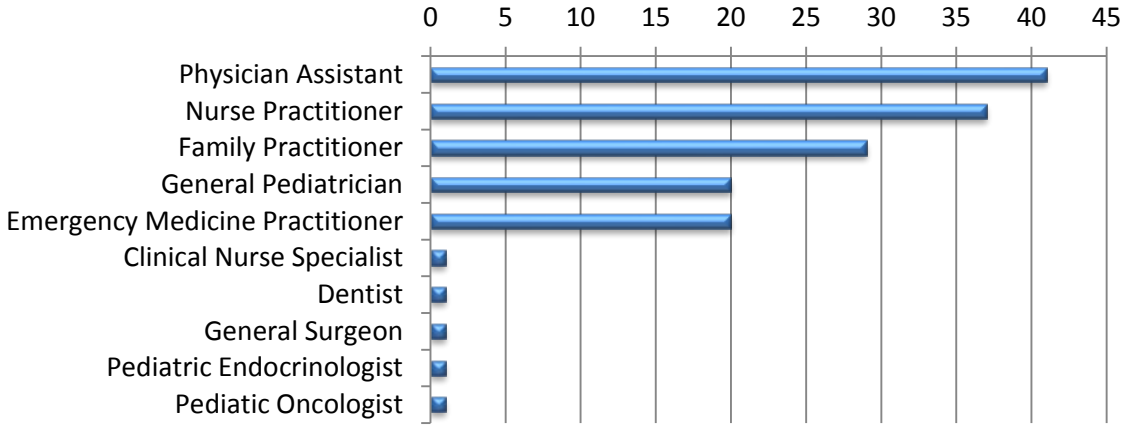
On June 26, 2014, the FDA issued a Drug Safety Communication regarding the use of oral, viscous lidocaine 2% solution for teething pain in infants and children. Serious adverse events, including seizure, severe brain injury, heart problems and death have occurred due to overdose, and accidental swallowing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

Mailing Summary

Despite FDA recommendations to restrict use of oral, viscous lidocaine in children, utilization in this population remained elevated. Based on these findings the College of Pharmacy and the Oklahoma Health Care Authority sent an educational mailing to recent prescribers of oral, viscous lidocaine in children five years of age and younger. The initiative outlined the FDA recommendations and provided prescribers with the number of claims they had written for viscous lidocaine for SoonerCare members under five years of age. The mailing also included an optional provider response page.

The report date included claims from August 01, 2014 to December 24, 2014. Prescribers were eligible for inclusion in the mailing if they were listed on two or more paid pharmacy claims for an oral viscous lidocaine product in children five years of age and younger, or one or more pharmacy claim(s) for an oral viscous lidocaine product in children two years of age and younger. A total of 152 prescribers were included in the mailing accounting for 297 lidocaine claims in children five years of age and younger.

Top Prescriber Specialties Included in the Mailing



Provider Response Summary

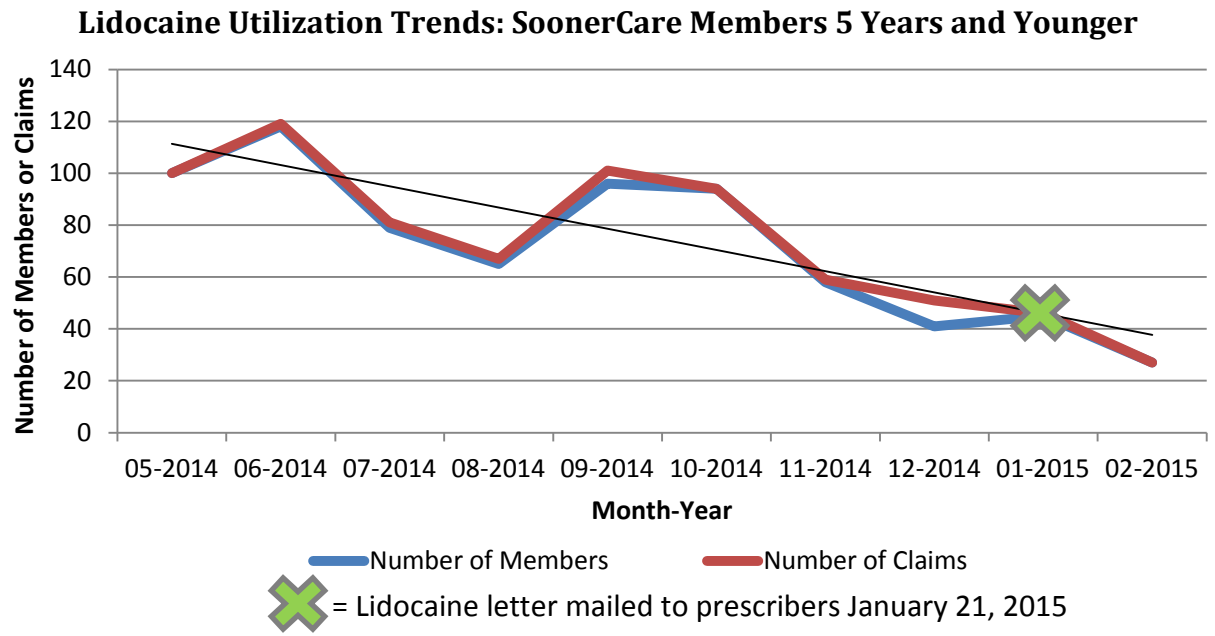
Provider Response Summary		
Q#	**Response**	**Total***
1	I will *continue* to prescribe viscous lidocaine to treat patient's teething pain despite the boxed warning.	0
2	I will modify my practice and will not use or prescribe viscous lidocaine for my patient's teething pain.	16
3	I will *continue* to prescribe viscous lidocaine but modify the amount and quantity on the prescription for teething pain.	2
4	I do not use or prescribe viscous lidocaine in my practice.	9
5	Other, comments.	24

*Responses can be included in multiple categories.

Summary of Additional Comments Provided	
Comment Category	**Total**
I do not prescribe viscous lidocaine for a teething diagnosis.	16
Other diagnoses provided for lidocaine use.	14
I only prescribe lidocaine to patients with painful mouth sores like herpangina, gingivostomatitis, hand-foot-mouth disease, or chemotherapy-induced oral mucositis to prevent dehydration.	13
I will modify my practice for children 5 years of age and younger.	5
I will prescribe less or recommend a different application technique.	2
Other	1

*Responses can be included in multiple categories, not all responses listed.

SoonerCare Claims Analysis



A review of SoonerCare pharmacy claims outlined in the chart found a steady decline in claims for oral, viscous lidocaine use in members five years of age and younger. In addition to the number of claims for oral viscous lidocaine in the pediatric population, the number of members utilizing these products also declined.

Recommendations

The FDA recommendations and the educational mailing have been effective in reducing prescribing of oral, viscous lidocaine in the SoonerCare pediatric population. Based on the downward trend in claims in the pediatric population as well as feedback from the prescribers regarding potential appropriate, emergency use of oral viscous lidocaine, the College of Pharmacy does not recommend any changes to the current criteria. Utilization of oral viscous lidocaine will be reassessed periodically to ensure prescribing of this product remains appropriate.

[1] FDA Drug Safety Communication (viscous lidocaine) available online at http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm Last revised 6/26/2014. Last accessed 10/29/2014

Appendix C

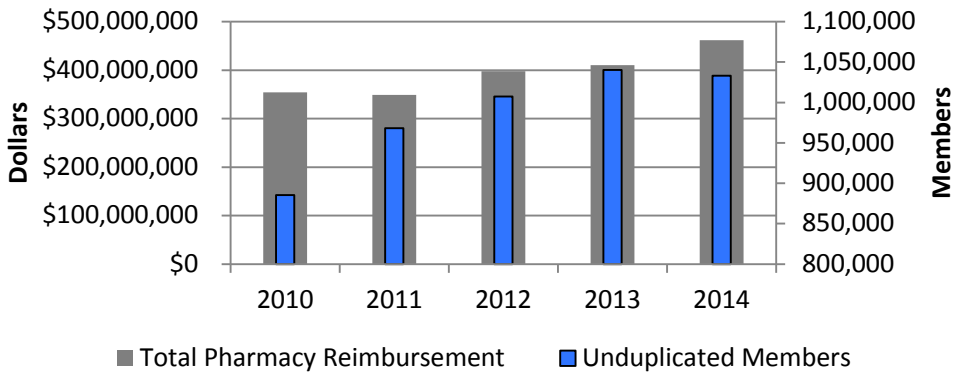
Fiscal Year 2014 Annual Review of SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
April 2015

Introduction

Although the pharmacy benefit is an optional program for Medicaid, all fifty states and the District of Columbia have chosen to include pharmacy coverage for their members. During State Fiscal Year (SFY) 2014, prescription drugs accounted for $462 million of the over $5 billion spent in the SoonerCare program. Over the past five fiscal years, the SoonerCare Pharmacy program has been relatively stable in terms of costs. For the years 2010 and 2011, the rate of change for pharmacy reimbursement was relatively flat. SFY 2012 saw an increase in reimbursement along with an increase in the cost per claim. This occurred after a two year trend in decreasing cost per claim. Several policies were put into place in early 2010 which had an effect on the cost per claim, including a product based prior authorization program for atypical antipsychotic medications, a two brand-name monthly prescription limit, higher member copay amounts, a reduced pharmacy dispensing fee, and lower physician administered and injectable drug reimbursement due to a maximum allowable cost initiative. Additionally, several highly utilized brand name products lost patent protection and became available generically between 2010 and 2014. However, SFY 2014 saw an increase in total pharmacy reimbursement and cost per claim most likely due to some very costly new medications including hepatitis C therapies and general price inflation, especially in the generic market. It is interesting to note that even with a decrease in the number of members and utilizers in 2014, the cost per day while increased from 2013, it is only now greater than the value for SFY 2010.

Fiscal Year	Unduplicated Members	Total Utilizers	Total Claims	Total Pharmacy Reimbursement	Total Days	Cost per Claim	Cost per day
2010	885,238	515,776	5,324,013	$354,475,694.77	124,209,520	$66.58	$2.85
2011	968,296	553,603	5,786,113	$349,233,642.43	137,528,391	$60.36	$2.54
2012	1,007,356	580,438	6,339,194	$397,941,931.61	154,075,711	$62.77	$2.58
2013	1,040,332	601,671	6,485,121	$410,705,535.37	158,399,466	$63.33	$2.59
2014	1,033,114	575,170	6,393,938	$462,429,007.75	157,599,570	$72.32	$2.93



Total Enrollment

Enrollment saw a slight decrease from last year likely due to the Federal Poverty Level (FPL) eligibility limit decrease for the SoonerPlan (Family Planning) and for full scope pregnancy benefits, effective January 1, 2014. Nevertheless, enrollment has increased by approximately 150,000 members over the past five years. Typically Medicaid enrollment is counter-cyclical with the economy. When the economy is good, Medicaid enrollment goes down but as the economy worsens, Medicaid enrollment goes up. A new online enrollment process has streamlined the ability to apply for SoonerCare services by providing access to the eligibility portal 24 hours a day. If an individual is found to be eligible they are given an identification number and can print a card for immediate access to medical and pharmacy services.

Fiscal year	2010	2011	2012	2013	2014
Total Number of Members*	885,238	968,296	1,007,356	1,040,332	1,033,114

*Excludes Insure Oklahoma membership

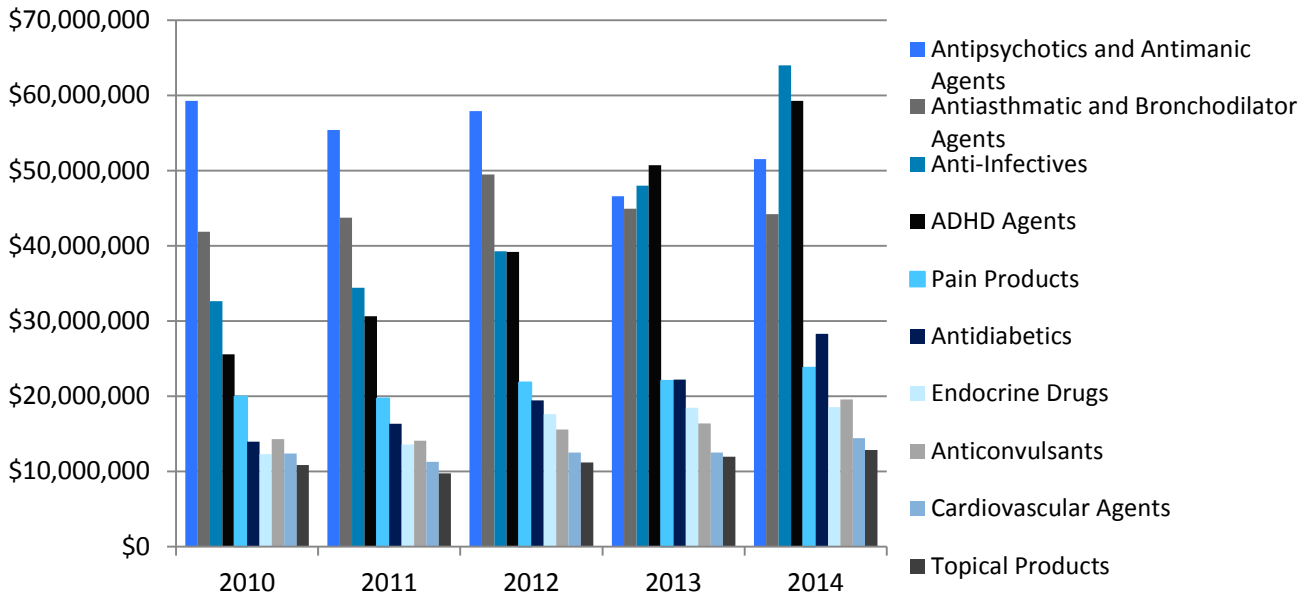
Traditional Versus Specialty Pharmacy Products

Traditional pharmaceuticals include products which are typically non-injectable and do not require special transportation, storage, or administration. These products treat many common chronic diseases such as diabetes or hypertension. In fiscal year 2014, the traditional pharmaceutical products comprised 88% of the total pharmacy reimbursement costs and accounted for 99.8% of utilizers. Specialty products, in contrast, are typically injectable and require special handling such as refrigerated transport and special administration techniques. These products include treatments for hemophilia, rheumatoid arthritis, and genetic deficiencies, for example. The specialty pharmaceutical products consisted of only 12% and 0.2% of total pharmacy reimbursement costs and member utilization, respectively.

Top 10 Therapeutic Classes by Reimbursement

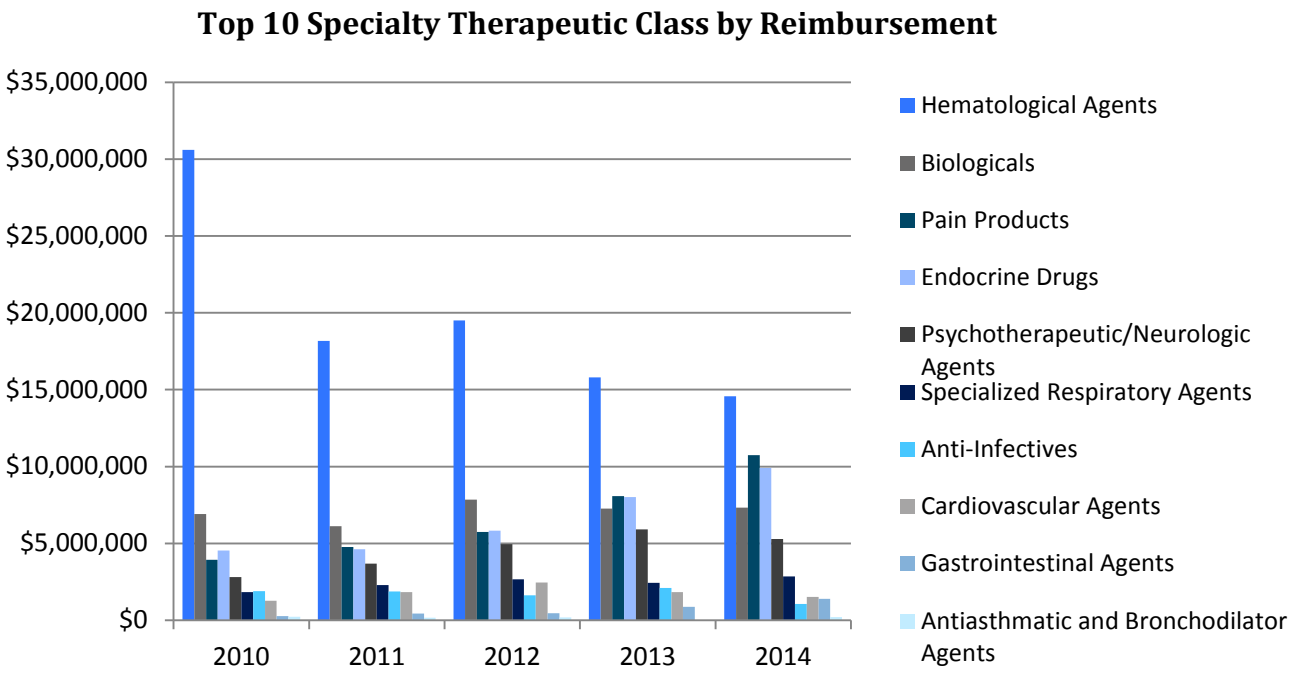
Top Traditional Classes by Reimbursement					
	2010	2011	2012	2013	2014
Antipsychotics and Antimanic Agents	$59,270,504	$55,406,483	$57,892,043	$46,571,763	$51,522,433
Antiasthmatic and Bronchodilator Agents	$41,875,966	$43,733,635	$49,470,990	$44,929,978	$44,204,091
Anti-Infectives	$32,614,756	$34,410,879	$39,273,314	$48,000,862	$63,983,980
ADHD Agents	$25,592,789	$30,618749	$39,194,353	$50,712,098	$59,266,414
Pain Products	$19,964,065	$19,720,044	$21,823,996	$22,056,504	$23,804,161
Antidiabetics	$13,951,748	$16,355,696	$19,461,697	$22,228,384	$28,286,842
Endocrine Drugs	$12,314,858	$13,587,130	$17,610,213	$18,466,244	$18,557,093
Anticonvulsants	$14,293,687	$14,081,405	$15,586,326	$16,392,364	$19,562,913
Cardiovascular Agents	$12,387,003	$11,268,901	$12,522,296	$12,495,320	$14,419,588
Topical Products	$10,867,698	$9,739,699	$11,185,310	$11,973,453	$12,855,442

Top 10 Traditional Therapeutic Class by Reimbursement



In the traditional category of drugs, antipsychotic medications are typically one of the highest cost categories in the SoonerCare Pharmacy program and continue to be for 2014. However, implementation of a step-therapy Product Based Prior Authorization program and the influx of generically available products have reduced the costs for this category. The cost of the ADHD class has more than doubled since 2010, driven by increased member enrollment, total claims, and the cost per claim, which is a reflection of the manufacturers' price increases, new products on the market, and increased use of multiple agents concurrently. The trend for anti-infective drugs has also been a steady increase due to higher costs for antiviral medications, anthelmintic medications, and cephalosporin, aminoglycoside, and tetracycline antibiotics. Furthermore, an increase in the cost per claim for the anti-diabetic medications can also be attributed to price inflation, new products, and the use of multiple agents concurrently for this disease state.

Top Specialty Classes by Reimbursement					
	2010	**2011**	**2012**	**2013**	**2014**
Hematological Agents	$30,608,254	$18,172,498	$19,506,014	$15,802,451	$14,581,053
Biologics	$6,905,563	$6,127,857	$7,853,008	$7,266,480	$7,335,778
Pain Products	$3,932,963	$4,762,275	$5,743,446	$8,087,585	$10,745,333
Endocrine Agents	$4,530,978	$4,616,747	$5,825,198	$8,006,778	$9,910,271
Psychotherapeutic/ Neurologic Agents	$2,815,508	$3,695,513	$4,964,755	$5,924,046	$5,285,387
Specialized Respiratory	$1,838,891	$2,282,523	$2,670,374	$2,438,662	$2,854,727
Anti-Infectives	$1,892,236	$1,880,002	$1,621,252	$2,112,958	$1,062,122
Cardiovascular Agents	$1,268,114	$1,827,973	$2,454,321	$1,829,626	$1,517,920
Gastrointestinal Agents	$265,321	$438,726	$462,307	$886,903	$1,390,862
Antiasthmatic and Bronchodilator Agents	$226,237	$163,195	$188,815	$14,808	$203,305



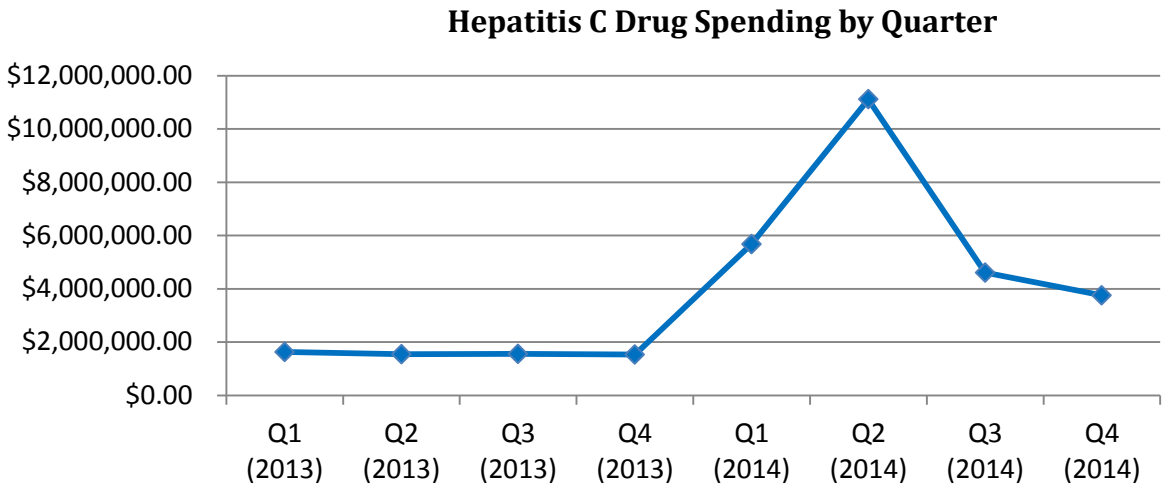
On the specialty side, hematological agents remain the highest cost category in 2014. However, costs for this class have dropped significantly since 2010 due to lower cost per claim for miscellaneous hematologicals, which includes a wide range of drugs such as anti-hemophilic factor, streptokinase, albumin, and dextran. The other hematological classes, anticoagulants and hematopoietic agents, showed relatively stable costs. Pain products which included anti-rheumatic agents had increased total members and costs per claim. Cardiovascular agents decreased slightly due to a decrease in the number of claims. There has also been a steady increase in the cost and utilization of certolizumab, which is included in the gastrointestinal agents as the criteria for use has been broadened since 2010.

Hepatitis C Drug Spending

The FDA approval of several new oral hepatitis C medications has increased drug spending in the antiviral class dramatically. Sofosbuvir and simeprevir, both FDA approved in the fourth quarter of 2013, were a restricted class by the State of Oklahoma preventing prior authorization management. The state removed restrictions in May of 2014 allowing for prior authorization implementation of the hepatitis C medications effective July 1, 2014.

	Fiscal Year 2013	Fiscal Year 2014
Total Hepatitis C Drug Spending	$6,931,306.72	$19,873,167.82

The state fiscal year 2014 date range includes 07/01/2013 to 06/30/2014; therefore prior authorization management of the hepatitis C medications would not be reflected in state fiscal year 2014 data. Claims analysis of the third and fourth quarter of 2014 revealed a downward trend in hepatitis C spending indicating prior authorization implementation and cost-effective management measures were successful.



Generic Medication Price Increases

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. Generic medication cost increases are particularly difficult to manage because they are often still more cost effective than their brand counterpart making non preferred drug status a less appropriate option.

Fiscal Year	Percent of Rx Spending on Generic Medications	Cost per Generic Claim	Cost per Brand Claim
2010	21%	$18.64	$204.89
2011	24%	$18.36	$213.30
2012	25%	$19.36	$236.18
2013	26%	$20.12	$253.66
2014	24%	$21.38	$310.61

The enlargement in the cost per brand claim in fiscal year 2014 is related to the increase in cost per claim of the hepatitis C medications, which averaged over $5,000 per claim. This increase may have shown a false reduction in the growth of percent of spending on generic medications, which has been steadily on the rise. The actual cost per generic claim continued to increase.

Generic Price Increase Examples			
Medication	**2012 Price***	**2015 Price***	**Percent Increase**
divalproex ER 500mg	$0.28	$1.68	500%
doxycycline hyclate 100mg	$0.19	$1.82	858%
levothyroxine 100mg	$0.18	$0.43	139%
prednisolone acetate 1% ophthalmic	$2.55	$8.93	250%
tetracycline 500mg	$0.11	$8.33	7,473%

*State maximum allowable cost per unit.

Conclusion

Over the past five years, reimbursement to pharmacies by SoonerCare increased annually after SFY2011. This is expected as price inflation and new products came to market after the corrections made in SFY2010 in response to the economic recession. Even though costs have risen, they have not risen in direct proportion to the increase in membership, indicating cost-effective management measures were successful. The goal of the SoonerCare program is to provide members with the most appropriate healthcare in a fiscally responsible manner. For the pharmacy benefit this is accomplished by the use of a robust prior authorization program, limiting the number of total prescriptions and the number of brand name prescriptions allowed each month for non-institutionalized adults, continuous product pricing maintenance, and prescriber outreach and education. Constant market review and response to changes such as the introduction of new hepatitis C treatments, growth of the specialty market, and introduction of biosimilars is necessary. SoonerCare will continue to strive to bring value-based pharmacy services to the members it serves.

Top 100 Reimbursed Drugs by Fiscal Year

Top 100 Reimbursed Drugs By Fiscal Year		2014		2013	
Generic Name	**Brand Name***	**Rank**	**Amount Paid**	**Rank**	**Amount Paid**
Aripiprazole	Abilify	1	$24,856,447.30	1	$21,606,922.64
Sofosbuvir	Sovaldi	2	$14,483,538.83	--	----------
Albuterol Sulfate	Multiple Products	3	$13,410,556.90	3	$12,741,925.12
Methylphenidate	Multiple Products	4	$12,558,955.79	2	$13,779,645.59
Lisdexamfetamine Dimesylate	Vyvanse	5	$11,028,853.01	8	$6,625,859.60
Guanfacine	Intuniv*	6	$10,300,325.84	6	$6,782,994.94
Amphetamine-Dextroamphetamine	Multiple Products	7	$9,450,848.80	4	$10,007,623.78
Insulin Glargine	Lantus	8	$7,763,599.20	11	$5,704,473.09
Dexmethylphenidate	Focalin*	9	$7,653,440.72	5	$7,049,905.48
Paliperidone Palmitate Injection	Invega Sustenna	10	$7,588,415.36	9	$6,484,523.61
Fluticasone Inhalation	Flovent	11	$6,819,068.16	10	$6,091,767.34
Atomoxetine	Strattera	12	$6,658,739.64	14	$5,153,572.24
Budesonide Inhalation	Pulmicort*	13	$6,006,560.44	7	$6,650,836.58
Adalimumab Injection	Humira	14	$5,923,690.86	21	$4,107,666.59
Oxycodone	Multiple Products	15	$5,922,762.44	12	$5,288,460.06
Somatropin Injection	Genotropin	16	$5,696,158.79	15	$4,990,611.57
Palivizumab Injection	Synagis	17	$5,339,769.34	13	$5,233,032.24
Insulin Aspart	Novolog	18	$5,114,169.18	24	$4,039,957.66
Antihemophilic Factor (Recombinant)	Multiple Products	19	$5,113,963.57	20	$4,194,450.42
Fluticasone-Salmeterol	Advair	20	$4,815,276.31	16	$4,966,660.29
Cefixime	Suprax	21	$4,765,193.67	23	$4,054,050.34
Duloxetine	Cymbalta*	22	$4,439,596.15	19	$4,512,521.52
Hydrocodone-Acetaminophen	Multiple Products	23	$4,341,052.61	18	$4,607,593.01
Quetiapine	Seroquel*	24	$4,260,475.05	17	$4,851,789.34
Oseltamivir	Tamiflu	25	$4,083,621.42	22	$4,072,405.70

Top 100 Reimbursed Drugs By Fiscal Year		2014		2013	
Generic Name	**Brand Name***	**Rank**	**Amount Paid**	**Rank**	**Amount Paid**
Insulin Detemir	Levemir	26	$3,841,971.39	38	$2,417,595.02
Antiinhibitor Coagulant Complex	Feiba	27	$3,638,809.35	25	$3,784,799.02
Etanercept	Enbrel	28	$3,590,856.27	28	$3,115,173.09
Antihemophilic Factor rAHF-PFM	Advate	29	$3,469,929.30	39	$2,329,323.87
Epinephrine	Multiple Products	30	$3,442,468.68	49	$1,992,397.52
Lurasidone	Latuda	31	$3,414,514.25	66	$1,369,237.15
Pregabalin	Lyrica	32	$3,229,506.16	37	$2,444,680.23
Cefdinir	Omnicef*	33	$2,973,000.65	27	$3,238,698.78
Tiotropium	Spiriva	34	$2,967,595.81	33	$2,637,266.67
Hydroxyprogesterone Caproate	Makena	35	$2,864,118.32	69	$1,316,576.42
Insulin Lispro	Humalog	36	$2,742,478.74	45	$2,097,785.17
Dornase Alfa Inhalation	Pulmozyme	37	$2,708,635.48	41	$2,254,993.26
Azithromycin	Zithromax*	38	$2,617,655.70	32	$2,751,493.94
Buprenorphine-Naloxone	Multiple Products	39	$2,601,714.48	34	$2,576,798.80
Paliperidone	Invega	40	$2,566,405.80	36	$2,487,073.16
Efavirenz-Emtricitabine-Tenofovir	Atripla	41	$2,509,366.78	29	$3,047,213.16
Glatiramer Acetate	Copaxone	42	$2,481,847.06	35	$2,504,753.02
Tobramycin Inhalation	Multiple Products	43	$2,469,670.45	42	$2,207,347.12
Divalproex Sodium	Depakote*	44	$2,409,128.55	81	$1,035,556.62
Oxycodone-Acetaminophen	Multiple Products	45	$2,251,328.96	74	$1,260,229.62
Lacosamide	Vimpat	46	$2,239,185.00	60	$1,479,775.15
Amoxicillin	Amoxil*	47	$2,213,813.38	40	$2,324,716.29
Prednisolone Sodium Phosphate	Multiple Products	48	$2,187,135.03	59	$1,480,919.56
Ipratropium-Albuterol	Multiple Products	49	$1,994,050.03	48	$2,035,324.80
Clozapine	Multiple Products	50	$1,928,803.81	47	$2,058,516.68
Montelukast	Singulair*	51	$1,835,358.95	26	$3,489,158.83
Amoxicillin-K-Clavulanate	Augmentin*	52	$1,829,584.58	44	$2,124,138.99
Emtricitabine-Tenofovir Disoproxil	Truvada	53	$1,748,623.54	52	$1,791,736.87
Cetirizine	Multiple Products	54	$1,655,819.46	54	$1,599,446.53
Interferon Beta-1a	Multiple Products	55	$1,654,427.22	50	$1,972,276.02
Sitagliptin	Januvia	56	$1,643,390.24	53	$1,626,689.17
Peginterferon Alfa-2a	Pegasys	57	$1,619,480.42	43	$2,158,632.19
Coagulation Factor VIIa	Novoseven	58	$1,619,384.48	70	$1,312,823.64
Pancrelipase	Multiple Products	59	$1,613,763.36	63	$1,384,481.70
Enoxaparin	Lovenox*	60	$1,605,963.26	31	$2,801,476.41
Eculizumab	Soliris	61	$1,580,192.48	145	$565,172.86
Memantine	Namenda	62	$1,534,550.10	61	$1,456,558.38
Gabapentin	Neurontin*	63	$1,526,822.71	55	$1,590,891.98
Fluticasone Propionate Nasal	Flonase*	64	$1,514,769.93	46	$2,060,193.26
Oxcarbazepine	Trileptal*	65	$1,512,866.08	56	$1,554,114.37
Iloperidone	Fanapt	66	$1,498,186.38	65	$1,371,038.63
Fentanyl	Multiple Products	67	$1,470,209.35	57	$1,541,371.33

Top 100 Reimbursed Drugs By Fiscal Year		2014		2013	
Generic Name	**Brand Name***	**Rank**	**Amount Paid**	**Rank**	**Amount Paid**
Telaprevir	Incivek	68	$1,395,039.15	30	$2,928,956.99
Etonogestrel-Ethinyl Estradiol Vaginal	Nuvaring	69	$1,381,170.40	58	$1,520,817.52
Morphine Sulfate	Multiple Products	70	$1,370,396.51	97	$839,551.08
Imatinib	Gleevec	71	$1,348,594.71	64	$1,378,669.74
Permethrin	Multiple Products	72	$1,343,626.75	87	$953,029.12
Deferasirox	Exjade	73	$1,329,658.46	62	$1,450,036.99
Beclomethasone Inhalation	Qvar	74	$1,302,396.99	79	$1,053,425.98
Spacer/Aerosol-Holding Chambers	Multiple Products	75	$1,263,140.65	73	$1,267,500.98
Clobazam	Onfi	76	$1,253,278.76	111	$750,329.18
Levalbuterol	Xopenex*	77	$1,249,238.49	51	$1,799,255.38
Levetiracetam	Keppra*	78	$1,242,167.95	68	$1,324,112.84
Doxycycline Hyclate	Vibramycin*	79	$1,201,926.41	141	$571,339.80
Norgestimate-Ethinyl Estradiol	Multiple Products	80	$1,190,776.05	75	$1,248,641.07
Budesonide-Formoterol Fumarate	Symbicort	81	$1,182,948.34	89	$947,880.77
Risperidone Injection	Risperdal Consta	82	$1,165,842.54	72	$1,269,069.30
Linezolid	Zyvox	83	$1,154,253.98	78	$1,106,170.61
Immune Globulin (Human)	Gamunex-C	84	$1,143,619.98	86	$990,753.38
Dimethyl Fumarate	Tecfidera	85	$1,105,730.34	--	----------
Lamotrigine	Lamictal*	86	$1,098,239.07	77	$1,214,235.29
Liraglutide	Victoza	87	$1,072,096.80	127	$649,967.25
C1 Esterase Inhibitor (Human)	Multiple Products	88	$1,066,966.55	91	$935,786.03
Darunavir Ethanolate	Prezista	89	$1,047,336.85	94	$869,070.62
Norelgestromin-Ethinyl Estradiol	Multiple Products	90	$1,043,554.10	83	$1,025,790.25
Rifaximin	Xifaxan	91	$1,018,410.04	128	$647,028.13
Acyclovir Topical	Zovirax*	92	$1,015,659.24	96	$853,949.94
Ceftibuten	Cedax*	93	$1,013,268.54	112	$748,259.17
Fingolimod	Gilenya	94	$996,679.56	113	$737,357.33
Omeprazole	Prilosec*	95	$955,759.75	71	$1,291,217.71
Risperidone Oral	Risperdal*	96	$944,717.38	76	$1,245,619.44
Sapropterin Dihydrochloride	Kuvan	97	$929,867.12	85	$1,004,126.88
Levothyroxine	Multiple Products	98	$927,159.86	120	$680,133.80
Asenapine	Saphris	99	$913,249.20	82	$1,032,657.81
Simeprevir	Olysio	100	$911,006.36	--	----------

*Includes brand and generic where applicable

Top 50 Medications by Total Number of Claims

Top 50 Medications by Total Number of Claims										
Rank	Generic Name	Brand Name	Claims	Members	Cost	Units/ Day	Cost/ Claim	Claims/ Client	Cost/ Day	% Cost
1	Hydrocodone-Acetaminophen	Multiple	315,235	103,538	$4,341,052.61	4.16	$13.77	3.04	$0.85	3.67%
2	Albuterol	Multiple	260,996	112,457	$13,410,556.90	2.54	$51.38	2.32	$2.36	11.34%
3	Amoxicillin	Amoxil*	221,796	161,151	$2,213,813.38	11.48	$9.98	1.38	$1.04	1.87%
4	Cetirizine	Multiple	197,696	87,597	$1,655,819.46	2.97	$8.38	2.26	$0.28	1.40%
5	Azithromycin	Zithromax*	152,324	113,539	$2,617,655.70	3.02	$17.18	1.34	$3.44	2.21%
6	Montelukast	Singulair	103,176	28,122	$1,835,358.95	1	$17.79	3.67	$0.59	1.55%
7	Omeprazole	Prilosec*	99,326	28,590	$955,759.75	1.25	$9.62	3.47	$0.29	0.81%
8	Ibuprofen	Multiple	95,316	66,338	$716,763.06	4.04	$7.52	1.44	$0.47	0.61%
9	Fluticasone Propionate Nasal	Flonase*	90,162	51,252	$1,514,769.93	0.48	$16.80	1.76	$0.50	1.28%
10	Methylphenidate	Multiple	86,839	13,870	$12,558,955.79	1.3	$144.62	6.26	$4.85	10.62%
11	Loratadine	Multiple	83,484	38,338	$804,357.80	2.5	$9.63	2.18	$0.31	0.68%
12	Clonidine	Catapres*	80,185	14,565	$616,053.26	1.46	$7.68	5.51	$0.25	0.52%
13	Alprazolam	Xanax*	79,442	13,743	$696,449.09	2.35	$8.77	5.78	$0.31	0.59%
14	Gabapentin	Neurontin*	74,519	17,569	$1,526,822.71	3.07	$20.49	4.24	$0.66	1.29%
15	Trimethoprim-Sulfamethoxazole	Multiple	70,643	56,078	$671,327.77	7.59	$9.50	1.26	$0.89	0.57%
16	Sertraline	Zoloft*	68,779	17,256	$615,717.99	1.18	$8.95	3.99	$0.28	0.52%
17	Risperidone	Risperdal*	67,921	12,917	$944,717.38	1.48	$13.91	5.26	$0.45	0.80%
18	Lisinopril	Multiple	67,705	17,533	$458,745.10	1.1	$6.78	3.86	$0.16	0.39%
19	Amphetamine-Dextroamphetamine	Multiple	65,848	10,322	$9,450,848.80	1.27	$143.53	6.38	$4.83	7.99%
20	Amoxicillin-K-Clavulanate	Augmentin*	63,241	52,284	$1,829,584.58	8.44	$28.93	1.21	$2.90	1.55%
21	Trazodone	Desyrel*	62,628	15,723	$571,094.87	1.24	$9.12	3.98	$0.29	0.48%
22	Prednisolone Sodium Phosphate	Multiple	60,024	43,593	$2,187,135.03	6.96	$36.44	1.38	$6.66	1.85%
23	Fluoxetine	Prozac*	58,943	14,775	$522,157.73	1.27	$8.86	3.99	$0.27	0.44%
24	Oxycodone-Acetaminophen	Multiple	58,153	29,241	$2,251,328.96	4.41	$38.71	1.99	$2.70	1.90%
25	Ondansetron	Zofran*	57,814	44,857	$663,765.02	0.98	$11.48	1.29	$0.96	0.56%
26	Citalopram	Celexa*	57,315	15,667	$382,268.28	1.01	$6.67	3.66	$0.19	0.32%
27	Tramadol	Ultram*	57,013	22,114	$445,518.18	3.9	$7.81	2.58	$0.42	0.38%
28	Levothyroxine	Multiple	56,886	11,879	$927,159.86	1	$16.30	4.79	$0.40	0.78%
29	Cyclobenzaprine	Multiple	56,673	26,557	$462,455.61	2.39	$8.16	2.13	$0.37	0.39%
30	Lisdexamfetamine Dimesylate	Vyvanse	55,604	10,989	$11,028,853.01	1	$198.35	5.06	$6.68	9.33%
31	Prednisone	Multiple	54,571	39,809	$314,460.39	2.06	$5.76	1.37	$0.60	0.27%

Top 50 Medications by Total Number of Claims										
Rank	Generic Name	Brand Name	Claims	Members	Cost	Units/ Day	Cost/ Claim	Claims/ Client	Cost/ Day	% Cost
32	Cephalexin	Keflex*	53,275	45,587	$666,950.12	9	$12.52	1.17	$1.37	0.56%
33	Cefdinir	Omnicef*	51,711	41,072	$2,973,000.65	6.92	$57.49	1.26	$5.78	2.51%
34	Triamcinolone Acetonide Topical	Multiple	50,341	35,635	$805,375.77	4.63	$16.00	1.41	$1.07	0.68%
35	Metformin	Multiple	48,780	11,575	$386,923.30	2.06	$7.93	4.21	$0.25	0.33%
36	Promethazine	Phenergan*	47,413	30,398	$500,318.85	5.03	$10.55	1.56	$1.32	0.42%
37	Clonazepam	Klonopin*	46,337	9,765	$401,940.64	2.11	$8.67	4.75	$0.30	0.34%
38	Dexmethylphenidate	Focalin*	45,740	6,558	$7,653,440.72	1.08	$167.32	6.97	$5.64	6.47%
39	Ranitidine	Zantac*	42,898	18,005	$369,677.05	3.04	$8.62	2.38	$0.29	0.31%
40	Guanfacine Extended-Release	Intuniv*	42,455	6,516	$10,300,325.84	1	$242.62	6.52	$8.21	8.71%
41	Fluticasone Propionate Inhalation	Flovent	39,472	17,154	$6,819,068.16	0.36	$172.76	2.3	$5.42	5.77%
42	Quetiapine	Seroquel*	38,666	7,242	$4,260,475.05	1.44	$110.19	5.34	$3.55	3.60%
43	Mupirocin	Bactroban*	37,613	31,727	$497,847.43	2.1	$13.24	1.19	$1.20	0.42%
44	Zolpidem	Ambien*	37,417	8,661	$327,913.04	0.99	$8.76	4.32	$0.30	0.28%
45	Meloxicam	Mobic*	37,247	16,706	$222,789.45	1.12	$5.98	2.23	$0.18	0.19%
46	Hydroxyzine HCl	Atarax*	31,732	17,103	$421,719.08	5.05	$13.29	1.86	$0.67	0.36%
47	Acetaminophen-Codeine	Multiple	31,250	24,825	$255,455.76	9.72	$8.17	1.26	$1.15	0.22%
48	Lamotrigine	Lamictal*	30,952	5,459	$1,098,239.07	1.92	$35.48	5.67	$1.16	0.93%
49	Hydroxyzine Pamoate	Vistaril*	30,659	11,965	$353,811.51	2.7	$11.54	2.56	$0.45	0.30%
50	Polyethylene Glycol 3350	Multiple	30,635	15,618	$733,258.46	16.89	$23.94	1.96	$0.86	0.62%
Total			**3,754,850**	**509,432[+]**	**$118,239,856.90**	**2.62**	**$31.49**	**7.37**	**$1.38**	**100%**

*Includes brand and generic where applicable.

[+] Total number of unduplicated members.

Top Traditional Therapeutic Classes by Fiscal Year

Anti-Infective Agents	2014		2013	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiviral	54,355	$35,524,845.84	59,858	$22,722,605.83
Cephalosporins	138,078	$10,187,405.38	142,975	$9,463,798.24
Anti-Infectives	117,304	$5,641,618.71	119,352	$5,011,050.46
Penicillins	300,956	$4,355,463.90	310,589	$4,806,995.97
Macrolide Antibiotics	157,198	$3,142,444.29	181,951	$3,259,654.28
Aminoglycosides	742	$1,485,363.85	505	$158,590.59
Tetracyclines	24,067	$1,396,799.23	27,206	$723,555.78
Antifungals	30,605	$1,208,252.32	30,938	$1,089,456.40
Anthelmintic	2,668	$566,501.20	2,780	$238,185.19
Fluoroquinolones	28,882	$383,130.48	29,529	$434,644.95
Antimalarial	3,892	$61,689.56	3,622	$57,150.72
Antimycobacterial Agents	506	$28,707.69	614	$31,101.58
Sulfonamides	5	$1,757.75	6	$4,072.11
Amebicides	0	$0.00	0	$0.00
Total:	**859,258**	**$63,983,980.20**	**909,925**	**$48,000,862.10**

ADHD Agents	2014		2013	
	Total Claims	Total Paid	Total Claims	Total Paid
ADHD/Anti-Narcolepsy	328,655	$59,266,414.82	308,437	$50,712,098.51
Total:	**328,655**	**$59,266,414.82**	**308,437**	**$50,712,098.51**

Antipsychotics and Antimanic Agents	2014		2013	
	Total Claims	Total Paid	Total Claims	Total Paid
Antipsychotics	205,226	$51,522,433.48	205,114	$46,571,763.70
Total:	**205,226**	**$51,522,433.48**	**205,114**	**$46,571,763.70**

Antiasthmatic and Bronchodilator Agents	2014		2013	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiasthmatic and Bronchodilator Agents	499,248	$44,204,091.00	494,882	$44,929,978.86
Total:	**499,248**	**$44,204,091.00**	**494,882**	**$44,929,978.86**

Anti-Diabetic Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Anti-Diabetic Agents		149,484	$28,286,842.86	148,671	$22,228,384.22
	Total:	**149,484**	**$28,286,842.86**	**148,671**	**$22,228,384.22**
Pain Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Analgesics - Narcotic		545,826	$20,403,181.73	576,899	$18,674,058.06
Analgesics - Anti-Inflammatory		195,522	$2,381,135.90	189,268	$2,233,851.55
Migraine Agents		12,394	$562,694.99	11,914	$670,187.95
Analgesics - Non-Narcotic		25,750	$334,618.56	29,716	$367,966.23
Gout		5,309	$110,845.35	4,955	$98,821.11
Local Anesthetics - Parenteral		1,288	$7,291.76	1,021	$7,555.71
General Anesthetics		205	$4,393.64	189	$4,063.63
	Total:	**786,294**	**$23,804,161.93**	**813,962**	**$22,056,504.24**
Endocrine Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Contraceptives		138,440	$8,703,449.81	151,066	$9,162,755.44
Corticosteroids		175,595	$3,628,930.10	170,954	$2,907,790.62
Other Endocrine		21,598	$3,546,659.65	21,906	$3,918,141.82
Estrogens		14,978	$1,062,898.63	16,664	$1,087,159.65
Thyroid		60,001	$997,711.86	57,633	$746,555.61
Progestins		5,894	$313,160.92	5,650	$347,327.05
Androgen - Anabolic		878	$249,963.41	1,049	$280,411.59
Oxytocics		538	$54,319.20	639	$16,102.89
	Total:	**417,922**	**$18,557,093.58**	**425,561**	**$18,466,244.67**
Anticonvulsant Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Anticonvulsant Agents		319,908	$19,562,913.56	320,619	$16,392,364.00
	Total:	**319,908**	**$19,562,913.56**	**320,619**	**$16,392,364.00**
Cardiovascular Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Antihyperlipidemics		91,073	$3,595,644.05	91,516	$3,472,601.91

Vasopressors		11,308	$3,477,392.40	8,539	$2,016,023.15
Antihypertensives		232,610	$2,808,204.35	225,925	$2,831,318.13
Beta Blockers		91,365	$1,954,390.71	89,831	$1,842,794.10
Antianginal Agents		9,510	$725,083.91	9,372	$637,691.53
Calcium Channel Blockers		43,270	$668,973.81	43,457	$775,759.27
Diuretics		65,883	$637,580.42	66,773	$616,533.57
Cardiovascular Agents		503	$278,657.84	484	$115,824.32
Cardiotonics		4,539	$173,091.51	4,742	$87,304.39
Antiarrhythmic Agents		2,299	$100,569.68	2,475	$99,469.92
	Total:	**552,360**	**$14,419,588.68**	**543,114**	**$12,495,320.29**
Topical Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Dermatological Agents		214,832	$9,294,566.11	205,463	$8,605,343.83
Ophthalmic Agents		62,695	$2,044,930.81	66,774	$1,975,284.69
Otic Agents		48,925	$1,026,666.90	51,066	$857,382.08
Mouth/Throat/Dental Agents		28,255	$424,813.73	28,712	$464,969.87
Anorectal Agents		1,619	$64,465.25	1,743	$70,473.34
	Total:	**356,326**	**$12,855,442.80**	**353,758**	**$11,973,453.81**
Gastrointestinal Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Ulcer Agents		217,512	$4,188,749.81	216,231	$4,473,799.37
Gastrointestinal Agents		15,860	$2,048,886.91	16,213	$1,786,024.87
Digestive Aids		1,634	$1,613,763.36	1,583	$1,384,481.70
Antiemetics		90,532	$1,443,626.52	77,055	$1,212,376.49
Laxatives		40,300	$1,019,647.19	37,815	$1,030,719.96
Antidiarrheals		3,520	$40,340.43	3,894	$47,814.64
Antacids		469	$2,978.04	378	$2,572.83
	Total:	**369,827**	**$10,357,992.26**	**353,169**	**$9,937,789.86**
Antidepressants		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Antidepressants		413,109	$9,638,875.40	398,134	$9,720,290.00
	Total:	**413,109**	**$9,638,875.40**	**398,134**	**$9,720,290.00**

Antineoplastic Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Antineoplastics		13,724	$8,637,222.95	13,914	$8,244,548.87
	Total:	**13,724**	**$8,637,222.95**	**13,914**	**$8,244,548.87**
Hematological Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Hematological Agents		15,573	$5,921,471.81	15,931	$2,109,312.00
Anticoagulants		14,622	$2,577,202.12	14,995	$3,482,880.58
Hematopoietic Agents		17,333	$409,939.73	17,690	$249,037.36
Hemostatics		220	$46,273.73	284	$51,968.29
	Total:	**47,748**	**$8,954,887.39**	**48,900**	**$5,893,198.23**
Non-Therapeutic Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Assorted Classes		6,124	$2,134,123.93	5,896	$2,207,651.99
Antidotes		1,485	$1,414,042.72	1,364	$1,595,163.21
Medical Devices		23,176	$1,264,320.29	23,902	$1,269,209.02
Chemicals		14,896	$487,209.06	15,546	$121,512.63
Pharmaceutical Adjuvants		1,506	$46,067.48	7,084	$510,037.75
Diagnostic Agents		30	$4,919.21	53	$7,328.31
Antiseptics & Disinfectants		62	$2,469.53	218	$7,174.38
Alternative Medicines		0	$0.00	0	$0.00
	Total:	**47,279**	**$5,353,152.22**	**54,063**	**$5,718,077.29**
Allergy Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Antihistamines		336,491	$3,155,608.08	335,565	$3,291,850.37
Systemic & Topical Nasal Agents		98,196	$1,964,345.53	93,232	$2,495,636.15
Cough/Cold/Allergy		2,009	$55,673.70	1,953	$69,994.80
	Total:	**436,696**	**$5,175,627.31**	**430,750**	**$5,857,481.32**
Psychotherapeutic/Neurologic Agents		**2014**		**2013**	
		Total Claims	**Total Paid**	**Total Claims**	**Total Paid**
Psychotherapeutic & Neurological Agents		17,585	$5,484,176.34	19,204	$3,752,200.76
	Total:	**17,585**	**$5,484,176.34**	**19,204**	**$3,752,200.76**

Genitourinary Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Urinary Anti-Infectives		19,463	$1,024,146.88	19,912	$1,111,085.12
Urinary Antispasmodics		13,605	$926,582.89	13,193	$815,459.86
Vaginal Agents		7,123	$580,889.71	7,721	$491,379.90
Genitourinary Agents		14,872	$473,198.98	14,870	$487,928.43
	Total:	**55,063**	**$3,004,818.46**	**55,696**	**$2,905,853.31**

Antianxiety Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Antianxiety Agents		208,586	$2,118,783.94	262,688	$2,650,066.04
	Total:	**208,586**	**$2,118,783.94**	**262,688**	**$2,650,066.04**

Neuromuscular Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Musculoskeletal Therapy Agents		123,162	$1,839,539.22	119,614	$1,490,553.01
Antiparkinsonian Agents		25,821	$690,730.51	26,296	$589,577.84
Antimyasthenic Agents		146	$19,156.76	209	$17,879.25
Neuromuscular Agents		14	$2,817.05	17	$23,860.69
	Total:	**78,764**	**$2,149,999.85**	**79,942**	**$2,200,925.16**

Nutritional Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Multivitamins		56,748	$2,527,760.50	46,807	$1,211,089.79
Minerals & Electrolytes		33,627	$1,023,369.88	31,890	$830,364.56
Vitamins		796	$76,697.71	646	$92,804.05
Dietary Products		123	$40,662.44	116	$34,927.34
Nutrients		298	$32,647.45	333	$28,119.61
	Total:	**91,592**	**$3,701,137.98**	**79,792**	**$2,197,305.35**

Hypnotics		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Hypnotics		57,404	$825,213.64	75,883	$970,464.32
	Total:	**57,404**	**$825,213.64**	**75,883**	**$970,464.32**

Biological Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Vaccines		5,713	$179,831.06	4,872	$140,857.31
Passive Immunizing Agents		8	$23,965.46	7	$43,092.48
Toxoids		282	$11,524.96	11	$415.70
	Total:	**6,003**	**$215,321.48**	**4,890**	**$184,365.49**

Top Specialty Therapeutic Classes by Fiscal Year

Hematological Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Hematological Agents		648	$12,769,709.03	623	$13,797,773.78
Hematopoietic Agents		584	$1,811,344.62	674	$2,004,677.54
	Total:	**1,232**	**$14,581,053.65**	**1,297**	**$15,802,451.32**

Pain Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Analgesics - Anti-Inflammatory		3,563	$10,742,967.57	3,131	$8,085,652.83
Local Anesthetics - Parenteral		125	$2,365.14	168	$1,932.98
	Total:	**3,688**	**$10,745,332.71**	**3,299**	**$8,087,585.81**

Endocrine Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Endocrine Agents		2,427	$7,046,152.41	2,565	$6,690,201.12
Progestins		788	$2,864,118.32	364	$1,316,576.42
	Total:	**3,215**	**$9,910,270.73**	**2,929**	**$8,006,777.54**

Biological Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Passive Immunizing Agents		3,367	$6,873,362.97	3,396	$6,696,949.85
Biological Agents		14	$462,414.99	18	$569,530.32
	Total:	**3,381**	**$7,335,777.96**	**3,414**	**$7,266,480.17**

Psychotherapeutic/Neurologic Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Psychotherapeutic & Neurological Agents		1,178	$5,285,387.02	1,428	$5,924,046.31
	Total:	**1,178**	**$5,285,387.02**	**1,428**	**$5,924,046.31**

Specialized Respiratory Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Specialized Respiratory Agents		984	$2,854,726.52	899	$2,438,661.82
	Total:	**984**	**$2,854,726.52**	**899**	**$2,438,661.82**

Cardiovascular Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Cardiovascular Agents		733	$1,517,920.23	945	$1,829,626.21
	Total:	**733**	**$1,517,920.23**	**945**	**$1,829,626.21**

Anti-Infective Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Aminoglycosides		161	$1,013,968.67	363	$2,086,794.18
Antivirals		16	$48,153.26	9	$26,163.41
	Total:	**177**	**$1,062,121.93**	**372**	**$2,112,957.59**

Gastrointestinal Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Gastrointestinal Agents		339	$1,390,862.30	254	$886,903.27
	Total:	**339**	**$1,390,862.30**	**254**	**$886,903.27**

Antiasthmatic and Bronchodilator Agents		2014		2013	
		Total Claims	Total Paid	Total Claims	Total Paid
Antiasthmatic and Bronchodilator Agents		72	$203,305.20	65	$148,808.37
	Total:	**72**	**$203,305.20**	**65**	**$148,808.37**

Total	2014		2013	
	Total Claims	Total Paid	Total Claims	Total Paid
Both Top Traditional and Specialty Therapeutic Classes	**6,390,611**	**$455,818,035.94**	**6,482,314**	**$406,488,404.25**

Appendix D

Vote to Prior Authorize Sylvant™ (Siltuximab)

Oklahoma Health Care Authority
April 2015

Recommendations

The College of Pharmacy recommends the prior authorization of Sylvant™ (siltuximab) with the following criteria:

Sylvant™ (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of Multicentric Castleman's Disease (also known as giant lymph node hyperplasia); and
2. Member must be Human Immunodeficiency Virus (HIV) and Human Herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
    a. 11 mg/kg via intravenous (IV) infusion every three weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status); and
5. Sylvant™ must be administered in a clinical setting able to provide resuscitation equipment, medications, and trained personnel; and
6. The prescriber must verify that a complete blood count (CBC) will be done prior to each dose for the first 12 months and for an additional three doses thereafter; and
7. Approvals will be for the duration of six months.

Appendix E

Vote to Prior Authorize Ecoza™ (Econazole Nitrate), Julia® (Efinaconazole), and Kerydin™ (Tavaborole)

Oklahoma Health Care Authority
April 2015

Recommendations

The College of Pharmacy recommends the addition of Julia® (efinaconazole) and Kerydin™ (tavaborole) to the Special Prior Authorization tier of the Topical Antifungal Product Based Prior Authorization category with the following criteria:

Julia® (Efinaconazole) and Kerydin™ (Tavaborole) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes;* and
2. A trial of oral antifungals (12 weeks for toenails); and
3. A patient-specific, clinically significant reason why member cannot use Penlac® (ciclopirox solution); and
4. A clinically significant reason the member requires treatment for onychomycosis (cosmetic reasons will not be approved).

Additionally, the College of Pharmacy recommends the addition of Ecoza™ (econazole nitrate) to Tier-2 of the Topical Antifungal Product Based Prior Authorization category. Current criteria for this category will apply.

Topical Antifungal Tier-2 Approval Criteria:

1. Documented, recent trials of at least two Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-2 (foams, shampoos, sprays, kits, etc.).
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/betamethasone requires a patient-specific, clinically significant reason why the member cannot use the individual components separately.
4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

Topical Antifungal Medications		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream	butenafine (Mentax®)	**efinaconazole (Jublia®)**
clotrimazole (Rx) cream, solution	ciclopirox solution, shampoo, gel, suspension (Penlac® and Loprox®)	**tavaborole (Kerydin™)**
clotrimazole (OTC)* cream	clotrimazole/betamethasone cream, lotion	
econazole cream	**econazole nitrate (Ecoza™)**	
ketoconazole cream, shampoo	ketoconazole foam (Extina®)	
nystatin cream, ointment, powder	ketoconazole gel (Xolegel™)	
terbinafine (OTC)* cream	luliconazole cream (Luzu™)	
tolnaftate (OTC)*cream	miconazole/zinc oxide/white petrolatum (Vusion®)	
	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

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

Appendix F

Vote to Prior Authorize
Izba® (Travoprost Ophthalmic Solution)

Oklahoma Health Care Authority
April 2015

Recommendations

The College of Pharmacy recommends the placement of Izba® (travoprost) into Tier-2 of the Glaucoma Medications Product Based Prior Authorization (PBPA) category. The existing criteria for this category will apply.

Glaucoma Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. The member must attempt at least three Tier-1 trials of a minimum of four weeks duration each within the last 120 days. Tier-1 trials may be from any pharmacologic class; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 products; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 products.
5. The member must have had a comprehensive, dilated eye exam within the last 365 day period as recommended by the National Institute of Health; and
6. Approvals will be for the duration of one year.

Glaucoma Medications*	
Tier-1	**Tier-2**
Beta-Blockers	
betaxolol (Betoptic® 0.5%)	betaxolol (Betoptic-S®)
carteolol (Ocupress® 1%)	brimonidine/timolol (Combigan®)
dorzolamide/timolol (Cosopt®)	timolol maleate (Timoptic Ocudose®)
levobunolol (Betagan®)	
metipranolol (OptiPranolol®)	
timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic-XE®)	
Prostaglandin Analogs	
travoprost 0.004% (Travatan-Z®)	bimatoprost (Lumigan®)
latanoprost (Xalatan®)	tafluprost (Zioptan™)
	travoprost 0.004% (Travatan®)
	unoprostone (Rescula®)
	travoprost 0.003% (Izba®)
Adrenergic Agonists	
dipivefrin (Propine®)	
Alpha-2 Adrenergic Agonists	
brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%)
brinzolamide/brimonidine (Simbrinza™)	apraclonidine (Iopidine®)
	brimonidine/timolol (Combigan®)
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®)	
dorzolamide (Trusopt®)	
brinzolamide (Azopt®)	
brinzolamide/brimonidine (Simbrinza™)	
acetazolamide (Diamox®)$^{+}$	
methazolamide (Neptazane®)$^{+}$	
($^{+}$Indicates Available Oral Products)	
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto® Carpine®, Pilopine HS®)	carbachol (Isopto®, Miostat® 1.5%, 3%)
	echothiophate iodide (Phospholine Iodide®)

*Tier structure based on supplemental rebate participation.

Appendix G

Fiscal Year 2014 Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Hemangeol™ (Propranolol Oral Solution), Sotylize™ (Sotalol Oral Solution), and Prestalia® (Perindopril/Amlodipine)

Oklahoma Health Care Authority
April 2015

Current Prior Authorization Criteria

There are 7 major subcategories of antihypertensive medications divided by drug class currently included in the Antihypertensive Product Based Prior Authorization category:

1. Calcium Channel Blockers (CCBs)
2. Angiotensin I Converting Enzyme Inhibitors (ACEIs)
3. ACEI/CCB Combination Products
4. ACEI/Hydrochlorothiazide (HCTZ) Combination Products
5. Angiotensin II Receptor Blockers (ARBs)
6. ARB Combination Products
7. Direct Renin Inhibitors (DRIs) and DRI Combination Products

Antihypertensive Tier-2 Approval Criteria:
(or Tier-3 medication when no Tier-2 medications exist)

1. A documented inadequate response to two Tier-1 medications (trials must include medication from all available classes where applicable); or
2. An adverse drug reaction to all Tier-1 classes of medications; or
3. Previous stabilization on the Tier-2 medication; or
4. A unique indication for which the Tier-1 antihypertensive medications lack.

Antihypertensive Tier-3 Approval Criteria:

1. A documented inadequate response to two Tier-1 medications and documented inadequate response to all available Tier-2 medications; or
2. An adverse drug reaction to all Tier-1 and Tier-2 classes of medications; or
3. Previous stabilization on the Tier-3 medication; or
4. A unique indication for which the lower tiered antihypertensive medications lack.

Direct Renin Inhibitors Approval Criteria:

1. An FDA approved indication; and
2. A recent trial, within the previous six months and at least four weeks in duration, of an ACEI (or an ARB if previous trial of an ACEI) and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control.
3. May be used in either monotherapy or combination therapy.

The following restrictions also apply for each individual product based on FDA approval information, special formulations, or individualized Drug Utilization Review Board criteria:

Catapres TTS® Patch (Clonidine Transdermal Patch) Approval Criteria:

1. An FDA-approved indication of hypertension in adults; and
2. A patient-specific, clinically significant reason why the member cannot take oral clonidine immediate-release tablets.

Epaned™ (Enalapril Powder for Oral Solution) Approval Criteria:

1. An age restriction for members age 7 years or older will apply with the following criteria:
    a. Consideration for approval requires a patient-specific, clinically significant reason why the member cannot swallow the oral tablet formulation even when crushed.

Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:

1. Authorization requires a patient-specific, clinically significant reason why the member cannot use the individual components.

Cardizem® CD (Diltiazem CD 360mg Capsules Only) Approval Criteria:

1. Authorization requires a patient-specific, clinically significant reason why the member cannot use two 180mg Cardizem CD® (diltiazem CD) capsules.

Vecamyl™ (Mecamylamine) Prior Authorization Criteria:

1. An FDA approved diagnosis of moderately severe to severe essential hypertension or uncomplicated malignant hypertension; and
2. Use of at least six classes of medications, in the past 12 months, that did not yield adequate blood pressure control. Treatment must have included combination therapy with a diuretic and therapy with at least a four-drug regimen. Medications can be from, but not limited to, the following classes: angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, diuretics, etc; and
3. Prescriber must verify member does not have any of the following contraindications:
    a. Coronary insufficiency
    b. Recent myocardial infarction
    c. Rising or elevated BUN, or known renal insufficiency
    d. Uremia
    e. Glaucoma
    f. Organic pyloric stenosis
    g. Currently receiving sulfonamides or antibiotics
    h. Known sensitivity to Vecamyl™ (mecamylamine)

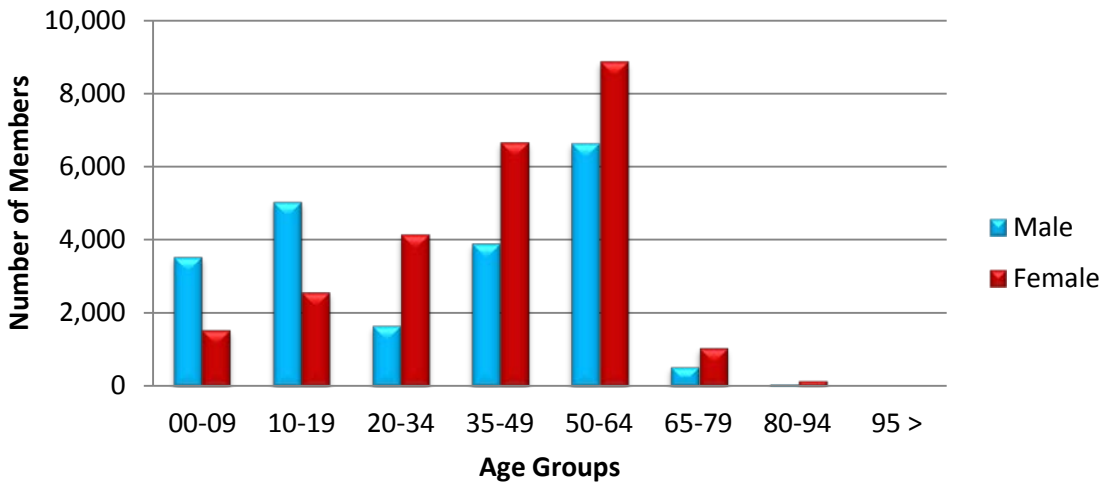
Utilization of Antihypertensive Medications: Fiscal Year 2014

Comparison of Fiscal Years

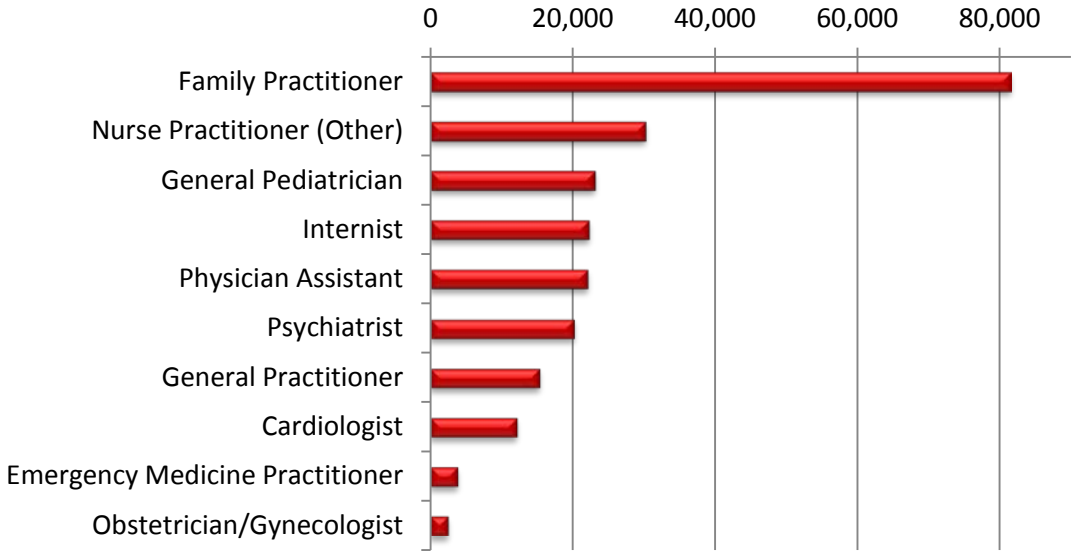
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	45,149	243,651	$3,382,559.50	$13.88	$0.37	11,224,660	9,065,814
2014	46,461	245,839	$3,170,896.38	$12.90	$0.34	11,347,648	9,240,353
% Change	**2.90%**	**0.90%**	**-6.30%**	**-7.10%**	**-8.10%**	**1.10%**	**1.90%**
Change	**1,312**	**2,188**	**-$211,663.12**	**-$0.98**	**-$0.03**	**122,988**	**174,539**

*Total number of unduplicated members.

Demographics of Members Utilizing Antihypertensive Medications

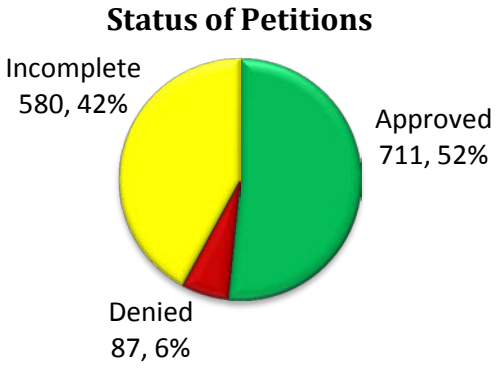


Top Prescriber Specialties of Antihypertensive Medications by Number of Claims



Prior Authorization of Antihypertensive Medications

There were 1,378 petitions submitted for antihypertensive medications during fiscal year 2014. Computer edits are in place to detect Tier-1 medications in members' recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



Market News and Updates[1]

Anticipated Patent Expirations:

- Benicar® (olmesartan), Benicar HCT® (olmesartan/HCTZ), Azor® (amlodipine/olmesartan), Tribenzor® (amlodipine/HCTZ/olmesartan): April 2016
- Tekturna® (aliskiren) and Tekturna HCT® (aliskiren/HCTZ): July 2018
- Edarbi® (azilsartan) and Edarbyclor® (azilsartan/chlorthalidone): January 2025

New FDA Approvals:

- Hemangeol™ (propranolol hydrochloride oral solution): March 2014
- Sotylize™ (sotalol hydrochloride oral solution): October 2014
- Prestalia® (perindopril arginine/amlodipine): January 2015

Hemangeol™ (Propranolol Hydrochloride Oral Solution)[2,3]

Indications: Hemangeol™ (propranolol oral solution) is a beta-adrenergic blocker indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.

Dosing:

- Propranolol oral solution is available as a 4.28mg/mL oral solution in one package size consisting of 120mL bottle.
- Treatment should be initiated between ages five weeks to five months old.
- The recommended starting dose is 0.15mL/kg (0.6mg/kg) twice daily. After two weeks, the dose can be increased to a maintenance dose of 0.4mL/kg (1.7mg/kg) twice daily.
- Doses should be administered at least nine hours apart during or after feeding.
- The dose should be readjusted for changes in the child's weight.
- Heart rate and blood pressure should be monitored for two hours after the first dose or after increasing the dose.

Mechanism of Action:

- The mechanism of propranolol oral solution on infantile hemangiomas is not well understood.

Contraindications:

- Premature infants with corrected age less than five weeks old
- Infants weighing less than 2kg
- Known hypersensitivity to propranolol or excipients
- Asthma or history of bronchospasm
- Bradycardia (less than 80 beats per minute), greater than first degree heart block, or decompensated heart failure
- Blood pressure less than 50/30mmHg
- Pheochromocytoma

Warnings and Precautions:

- Hypoglycemia: Propranolol oral solution should be administered during or after feeding. It should not be used in patients who are not able to feed or who are vomiting.
- Bradycardia and hypotension
- Bronchospasm: Propranolol oral solution use should be avoided in patients with asthma or lower respiratory infection.
- Increased risk of stroke in PHACE (posterior fossa malformations-hemangiomas-arterial anomalies-cardiac defects-eye abnormalities-sternal cleft-and supraumbilical raphe syndrome)

Adverse Reactions: The most common adverse reactions to propranolol oral solution (occurring ≥ 10% of patients) were:

- Sleep disorders
- Aggravated respiratory tract infections
- Diarrhea
- Vomiting

Clinical Studies: The safety and efficacy of propranolol oral solution was evaluated in two clinical studies of infants with infantile hemangioma (IH) treated with propranolol oral solution or placebo. Efficacy was evaluated by counting complete or nearly complete resolution of the target hemangioma.

- A greater proportion of patients treated with propranolol oral solution (61 of 101 patients) had complete or nearly complete resolution of their hemangioma at week 24.
- In a second study of 23 patients with proliferating IH including function-threatening IH that may leave permanent scars or deformity, large facial IH, smaller IH in exposed areas, severe ulcerated IH, or pedunculated IH, target lesions resolved in 36% of patients by three months.

Cost Comparison:

Drug Name	Strength	Cost/mL*	Cost/ Month+	Cost/ Year+
Hemangeol™ (propranolol oral solution)	4.28mg/mL	$3.30/mL	$534.79	$6,417.42
Propranolol oral solution	40mg/5mL	$0.13/mL	$11.27	$135.25
Propranolol oral solution	20mg/5mL	$0.09/mL	$15.61	$187.27

*Estimated acquisition cost

+Based on 6.8kg (15lbs) at a maintenance dose of 1.7mg/kg twice daily.

Sotylize™ (Sotalol Hydrochloride Oral Solution)[4]

Indications: Sotylize™ (sotalol oral solution) is an antiarrhythmic indicated for the treatment of life-threatening ventricular arrhythmias and the maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter (AFIB/AFL).

Dosing:

- Sotalol oral solution is available as a 5mg/mL oral solution in two package sizes consisting of a 250mL bottle and a 480mL bottle.
- Ventricular Arrhythmia: Therapy should be initiated at 80mg. The dose should be increased as needed in increments of 80mg, every three days to a maximum 320mg.
- Symptomatic AFIB/AFL: Therapy should be initiated at 80mg. The dose should be increased as needed in increments of 40mg, every three days to a maximum 160mg.
- Pediatrics: Dosage depends on age.
- If creatinine clearance is between 60 and 40mL/min, sotalol oral solution should be administered once daily, if less than 40 mL/min, sotalol is not recommended.

Mechanism of Action:

- Sotalol has both beta-adrenoreceptor blocking (Vaughan Williams Class II) and cardiac action potential duration prolongation (Vaughan Williams Class III) antiarrhythmic properties. Sotalol hydrochloride is a racemic mixture of two isomers, both of which have similar Class III antiarrhythmic effects, while the L-isomer is responsible for virtually all of the beta-blocking activity. The beta-blocking effect of sotalol is non-cardioselective, half maximal at an oral dose of about 80mg/day and maximal at doses between 320 and 640mg/day. Sotalol does not have partial agonist or membrane stabilizing activity. Although significant beta-blockade occurs at oral doses as low as 25mg, significant Class III effects are seen only at daily doses of 160mg and above. In children, a Class III electrophysiological effect can be seen at daily doses of 210mg/m^2 body surface area (BSA). A reduction of the resting heart rate due to the beta-blocking effect of sotalol is observed at daily doses of greater than or equal to 90mg/m^2 in children.

Contraindications:

- Sinus bradycardia (less than 50 beats per minute), sick sinus syndrome or 2nd or 3rd degree atrioventricular (AV) block unless a functioning pacemaker is present
- Congenital or acquired long QT syndromes, QT interval greater than 450ms
- Cardiogenic shock, uncontrolled heart failure
- Creatinine clearance less than 40mL/min
- Serum potassium less than 4mEq/L
- Bronchial asthma or related bronchospastic conditions
- Hypersensitivity to sotalol

Warnings and Precautions:

- QT prolongation, bradycardia, AV block, hypotension, worsening heart failure: Reduce the dose of sotalol oral solution as needed.
- Acute exacerbation of coronary artery disease upon cessation of therapy: Sotalol oral solution should note be abruptly discontinued.

- Electrolyte Disturbances: Sotalol oral solution should not be used in patients with hypokalemia or hypomagnesemia prior to correction of imbalance, as these conditions increase the potential for Torsade de Pointes.
- Hypoglycemia: Sotalol oral solution may mask symptoms of hypoglycemia or worsen hyperglycemia in diabetic patients; patients should be monitored appropriately.

Adverse Reactions: Most common adverse reactions (>10%) seen with oral sotalol (dose related) are:

- Fatigue
- Bradycardia
- Dizziness
- Headache

Clinical Studies: The safety and efficacy of sotalol oral solution is based on randomized clinical trials of oral sotalol tablets.

Cost Comparison:

Drug Name	Strength	Cost/mL or Tablet	Cost/ Month+	Cost/ Year+
Sotylize™ (sotalol oral solution)	5mg/mL	$1.52*	$2,918.40	$35,020.80
Sotalol oral tablets	160mg	$0.25∞	$15.00	$180.00

*Estimated acquisition cost
∞State maximum allowable cost
+Cost based on maximum dose of 320mg.

Prestalia® (Perindopril/Amlodipine Oral Tablet)[5,6]

Indications: Prestalia® (perindopril/amlodipine) is a combination of perindopril, an angiotensin converting enzyme inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension to lower blood pressure in patients not adequately controlled with monotherapy or as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

Dosing:

- Perindopril/amlodipine is available as an oral tablet in the following strengths:
  - 3.5mg/2.5mg
  - 7mg/5mg
  - 14mg/10mg
- Treatment should be initiated at 3.5mg/2.5mg, once daily.
- The dose should be adjusted according to blood pressure goals waiting one to two weeks between titration steps.
- The maximum recommended dose is 14mg/10mg once daily.

Mechanism of Action:

- Perindopril, a pro-drug, is hydrolyzed to perindoprilat, which inhibits ACE in humans and in animals. ACE catalyzes the conversion of the inactive decapeptide, angiotensin I, to the vasoconstrictor substance angiotensin II. Angiotensin II is a potent peripheral vasoconstrictor, which stimulates aldosterone secretion by the adrenal cortex, and provides negative feedback on renin secretion. Inhibition of ACE results in decreased

plasma angiotensin II, leading to decreased vasoconstriction, increased plasma renin activity and decreased aldosterone secretion.

- Amlodipine is a dihydropyridine calcium antagonist that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Contraindications:

- History of angioedema, or hypersensitivity to any ACEI or amlodipine
- Aliskiren, in combination with perindopril/amlodipine, should not be used in patients with diabetes.

Warnings and Precautions:

- Anaphylactoid Reactions: Anaphylactoid reactions including angioedema (head, neck, or intestinal)
- Myocardial infarction: Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of perindopril/amlodipine particularly in patients with severe obstructive coronary artery disease.
- Hypotension and Hyperkalemia: Hypotension and hyperkalemia can occur while on perindopril/amlodipine therapy
- Renal function should be monitored while on perindopril/amlodipine therapy

Adverse Reactions: The most common adverse reactions were:

- Edema (7.2%)
- Cough (3.2%)
- Headache (2.5%)
- Dizziness (2.5%)

Clinical Studies: The safety and efficacy of perindopril/amlodipine were evaluated in two clinical studies.

- The highest strength of perindopril/amlodipine was studied in 837 patients randomized to perindopril/amlodipine 14mg/10mg, perindopril erbumine 16mg, or amlodipine 10mg once daily for six weeks. At week six, perindopril/amlodipine 14mg/10mg produced statistically significantly greater reductions in blood pressure than each of the monotherapies.
- The lowest strength of perindopril/amlodipine was studied in 1,581 patients randomized to perindopril/amlodipine 3.5mg/2.5mg, perindopril arginine 3.5mg, perindopril arginine 5mg, amlodipine 2.5mg, amlodipine 5mg, or placebo. At week eight, perindopril/amlodipine 3.5mg/2.5mg produced statistically significantly greater reductions in blood pressure than perindopril arginine 3.5mg and amlodipine 2.5mg.

Cost Comparison:

- Perindopril/amlodipine cost and launch date information are unavailable at this time. The two individual components, perindopril and amlodipine, are available generically and both have a state maximum allowable cost.

Recommendations

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

Hemangeol™ (Propranolol Hydrochloride Oral Solution) Approval Criteria:

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

Sotylize™ (Sotalol Oral Solution) Approval Criteria:

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

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

Prestalia® (Perindopril/Amlodipine) Approval Criteria:

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

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

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

The following tables contain the current Antihypertensive Medication Tier structures. Most classes are based on supplemental rebate participation. Tier-2 criterion applies for Tier-3 medications when there are no Tier-2 medications available. Special dosage form criterion applies where applicable.

Angiotensin Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	perindopril erbumine (Aceon®)	enalapril powder (Epaned®)
captopril (Capoten®)		
enalapril (Vasotec®)		
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
quinapril (Accupril®)		
trandolapril (Mavik®)		
ramipril (Altace®)		

Angiotensin Converting Enzyme Inhibitors (ACEIs)/ Hydrochlorothiazide (HCTZ)Combinations		
Tier-1	**Tier-2**	**Tier-3**
benazepril/HCTZ (Lotensin® HCT)		fosinopril/HCTZ (Monopril-HCT®)
captopril/HCTZ (Capozide®)		
enalapril/HCTZ (Vasoretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		

ARBs (Angiotensin Receptor Blockers) and ARB Combination Products		
Tier-1	**Tier-2**	**Tier-3**
ACE Inhibitor:	amlodipine/valsartan (Exforge®)	amlodipine/olmesartan (Azor™)
benazepril (Lotensin®)	amlodipine/valsartan/HCTZ (Exforge® HCT)	azilsartan (Edarbi®)
captopril (Capoten®)	valsartan (Diovan®)	azilsartan/chlorthalidone (Edarbyclor®)
enalapril (Vasotec®)		candesartan (Atacand®)
enalaprilat (Vasotec® IV)		candesartan/HCTZ (Atacand® HCT)
fosinopril (Monopril®)		eprosartan (Teveten®)
lisinopril (Prinivil®, Zestril®)		eprosartan/HCTZ (Teveten® HCT)
moexipril (Univasc®)		olmesartan (Benicar®)
quinapril (Accupril®)		olmesartan/HCTZ (Benicar HCT®)
trandolapril (Mavik®)		olmesartan/ amlodipine/HCTZ (Tribenzor®)
ramipril (Altace®)		telmisartan (Micardis®)
ARB:		telmisartan/HCTZ (Micardis® HCT)
irbesartan (Avapro®)		telmisartan/amlodipine (Twynsta®)
irbesartan/HCTZ (Avalide®)		
losartan (Cozaar®)		
losartan/HCTZ (Hyzaar®)		
valsartan/HCTZ (Diovan HCT®)		

Calcium Channel Blockers (CCB)		
Tier-1	**Tier-2**	**Tier-3**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	diltiazem CD 360mg (Cardizem® CD)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	nimodipine solution (Nymalize®)
diltiazem (Tiazac®, Taztia XT®)	isradipine (Dynacirc®, Dynacirc CR®)	
*diltiazem CD (Cardizem® CD)	nicardipine (Cardene® SR)	
diltiazem ER (Cartia XT®, Diltia XT®)	nisoldipine (Sular®)	
diltiazem SR (Cardizem® SR)	verapamil (Covera-HS®)	
diltiazem XR (Dilacor® XR)	verapamil ER (Verelan® PM)	
felodipine (Plendil®)		
nicardipine (Cardene®)		
nifedipine (Adalat®, Procardia®)		
nifedipine CC (Adalat® CC)		
nifedipine ER		
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®, Verelan®)		
verapamil SR (Calan® SR, Isoptin® SR)		

*All strengths other than the 360mg.

Direct Renin inhibitors		
Tier-1	**Tier-2**	**Tier-3**
Tier-1 ACE Inhibitor + Diuretic	ARB + Diuretic	Aliskiren (Tekturna®)
		Aliskiren/HCTZ (Tekturna HCT®)
		Aliskiren/valsartan (Valturna®)
		Aliskiren/amlodipine (Tekamlo®)

Utilization Details of Antihypertensive Medications: Fiscal Year 2014

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
CALCIUM CHANNEL BLOCKERS						
TIER-1 UTILIZATION						
AMLODIPINE TAB 10MG	16,003	4,045	$122,120.45	$0.18	$7.63	3.85%
AMLODIPINE TAB 5MG	11,153	3,356	$69,301.48	$0.15	$6.21	2.19%
AMLODIPINE TAB 2.5MG	1,461	483	$10,844.01	$0.19	$7.42	0.34%
NIFEDIPINE CAP 10MG	1,157	912	$61,030.95	$2.97	$52.75	1.92%
VERAPAMIL TAB 240MG ER	1,027	229	$14,760.12	$0.36	$14.37	0.47%
NIFEDIPINE TAB 30MG ER	717	299	$15,612.50	$0.60	$21.77	0.49%
NIFEDICAL XL TAB 30MG	698	293	$14,874.07	$0.63	$21.31	0.47%
NIFEDICAL XL TAB 60MG	634	185	$19,408.08	$0.84	$30.61	0.61%
NIFEDIPINE TAB 90MG ER	595	161	$24,475.86	$0.93	$41.14	0.77%
NIFEDIPINE TAB 60MG ER	584	206	$18,756.60	$0.86	$32.12	0.59%
DILTIAZEM CAP 240MG CD	477	117	$14,037.43	$0.72	$29.43	0.44%
VERAPAMIL TAB 120MG ER	463	139	$6,920.99	$0.41	$14.95	0.22%
VERAPAMIL TAB 80MG	453	117	$4,018.32	$0.27	$8.87	0.13%
VERAPAMIL TAB 120MG	401	98	$3,594.61	$0.27	$8.96	0.11%
VERAPAMIL TAB 180MG ER	363	106	$5,699.32	$0.37	$15.70	0.18%
DILTIAZEM CAP 180MG CD	343	94	$8,468.92	$0.69	$24.69	0.27%
DILTIAZEM TAB 120MG	341	88	$4,742.95	$0.42	$13.91	0.15%
DILTIAZEM CAP 240MG ER	323	81	$9,907.72	$0.74	$30.67	0.31%
NIFEDIPINE TAB 30MG ER	317	113	$7,204.19	$0.62	$22.73	0.23%
DILTIAZEM TAB 60MG	292	89	$2,862.85	$0.31	$9.80	0.09%
DILTIAZEM CAP 240MG ER	281	86	$8,955.30	$0.72	$31.87	0.28%
NIFEDIPINE TAB 60MG ER	277	80	$11,476.80	$1.04	$41.43	0.36%
DILTIAZEM CAP 180MG ER	273	85	$6,915.86	$0.59	$25.33	0.22%
DILTIAZEM CAP 120MG CD	270	98	$5,777.21	$0.49	$21.40	0.18%
DILTIAZEM CAP 120MG ER	256	80	$5,919.70	$0.54	$23.12	0.19%
NIFEDIPINE CAP 20MG	245	184	$28,564.50	$6.37	$116.59	0.90%
DILTIAZEM TAB 30MG	196	81	$1,900.98	$0.31	$9.70	0.06%
DILTIAZEM TAB 90MG	193	47	$3,042.87	$0.52	$15.77	0.10%
AFEDITAB TAB 30MG CR	185	48	$4,490.84	$0.65	$24.27	0.14%
DILTIAZEM CAP 180MG ER	183	49	$5,522.05	$0.84	$30.18	0.17%
VERAPAMIL CAP 240MG ER	167	60	$5,079.69	$0.67	$30.42	0.16%
TAZTIA XT CAP 360MG/24	160	38	$7,256.11	$1.00	$45.35	0.23%
CARTIA XT CAP 120/24HR	150	46	$2,697.20	$0.53	$17.98	0.09%
DILTIAZEM CAP 120MG ER	149	44	$3,875.48	$0.68	$26.01	0.12%
DILTIAZEM CAP 120MG/24	140	35	$3,730.80	$0.91	$26.65	0.12%
VERAPAMIL CAP 120MG ER	129	49	$3,316.14	$0.62	$25.71	0.10%
CARTIA XT CAP 240/24HR	128	39	$3,500.18	$0.71	$27.35	0.11%
DILTIAZEM CAP 180MG/24	128	34	$4,522.93	$1.09	$35.34	0.14%
VERAPAMIL TAB 40MG	107	45	$1,898.43	$0.56	$17.74	0.06%
CARTIA XT CAP 180/24HR	105	36	$2,963.90	$0.58	$28.23	0.09%
FELODIPINE TAB 10MG ER	100	21	$3,851.04	$0.79	$38.51	0.12%
NIFEDIPINE TAB 90MG ER	100	31	$8,987.63	$1.98	$89.88	0.28%
DILTIAZEM CAP 360MG/24	88	29	$3,938.83	$1.04	$44.76	0.12%
VERAPAMIL CAP 180MG ER	88	28	$2,437.09	$0.69	$27.69	0.08%
VERAPAMIL CAP 360MG SR	87	21	$5,549.11	$1.50	$63.78	0.18%
AFEDITAB TAB 60MG CR	84	17	$2,944.80	$1.10	$35.06	0.09%
DILTIAZEM CAP 240MG/24	76	16	$2,928.72	$1.22	$38.54	0.09%
TAZTIA XT CAP 240MG/24	76	20	$3,155.10	$0.96	$41.51	0.10%
DILTIAZEM CAP 300MG CD	60	15	$1,948.94	$0.88	$32.48	0.06%
DILTIAZEM CAP 60MG ER	54	15	$2,906.65	$1.72	$53.83	0.09%
DILTIAZEM CAP 120MG ER	53	17	$3,294.49	$1.92	$62.16	0.10%
VERAPAMIL CAP 240MG SR	52	23	$1,899.37	$0.72	$36.53	0.06%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
DILTIAZEM CAP 300MG ER	50	13	$2,268.59	$0.83	$45.37	0.07%
TAZTIA XT CAP 180MG/24	47	17	$1,214.93	$0.74	$25.85	0.04%
TAZTIA XT CAP 120MG/24	45	10	$1,396.72	$0.88	$31.04	0.04%
DILTIAZEM CAP 360MG ER	44	17	$16,072.13	$8.36	$365.28	0.51%
DILT-XR CAP 240MG	44	14	$1,273.67	$0.71	$28.95	0.04%
DILTIAZEM CAP 420MG/24	38	8	$1,670.25	$1.04	$43.95	0.05%
DILT-XR CAP 180MG	38	10	$1,486.95	$0.92	$39.13	0.05%
FELODIPINE TAB 5MG ER	38	16	$1,302.44	$0.68	$34.27	0.04%
DILTIAZEM CAP 90MG ER	33	10	$2,280.06	$1.57	$69.09	0.07%
VERAPAMIL CAP 180MG SR	31	13	$901.25	$0.76	$29.07	0.03%
DILT-XR CAP 120MG	30	12	$1,006.04	$0.56	$33.53	0.03%
VERAPAMIL CAP 100MG ER	30	8	$2,119.66	$1.90	$70.66	0.07%
VERAPAMIL CAP 120MG SR	30	10	$681.21	$0.75	$22.71	0.02%
NIFEDIAC CC TAB 90MG ER	29	10	$2,616.78	$1.86	$90.23	0.08%
TAZTIA XT CAP 300MG/24	20	6	$1,220.93	$0.97	$61.05	0.04%
CARTIA XT CAP 300/24HR	16	4	$1,021.07	$0.81	$63.82	0.03%
NICARDIPINE CAP 30MG	14	4	$861.67	$1.46	$61.55	0.03%
PROCARDIA CAP 10MG	14	5	$597.30	$1.42	$42.66	0.02%
ADALAT CC TAB 90MG ER	13	2	$859.28	$2.20	$66.10	0.03%
NICARDIPINE CAP 20MG	13	2	$398.39	$1.08	$30.65	0.01%
NIFEDIPINE POWDER	11	10	$166.31	$0.55	$15.12	0.01%
VERAPAMIL POWDER	11	1	$105.49	$0.33	$9.59	0.00%
FELODIPINE TAB 2.5MG ER	7	3	$201.45	$0.61	$28.78	0.01%
CARDIZEM CD CAP 180MG/24	7	6	$150.75	$0.72	$21.54	0.00%
DILTIAZEM CAP 300MG/24	6	4	$426.54	$0.95	$71.09	0.01%
CARDIZEM CD CAP 120MG/24	5	1	$79.88	$0.53	$15.98	0.00%
CARDIZEM CD CAP 240MG/24	5	3	$95.55	$0.64	$19.11	0.00%
NORVASC TAB 5MG	2	1	$374.94	$3.12	$187.47	0.01%
NIFEDIAC CC TAB 30MG ER	1	1	$18.63	$0.62	$18.63	0.00%
TIER-1 SUBTOTAL	**43,114**	**12,949**	**$646,759.02**	**$1.04**	**$40.03**	**20.36%**
TIER-2 UTILIZATION						
AMLOD/ATORVA TAB 10-20MG	74	17	$22,603.47	$5.31	$305.45	0.71%
AMLOD/ATORVA TAB 10-40MG	61	13	$15,413.15	$5.69	$252.67	0.49%
MATZIM LA TAB 180MG/24	27	6	$2,461.07	$2.49	$91.15	0.08%
AMLOD/ATORVA TAB 5-40MG	27	7	$8,094.69	$6.26	$299.80	0.26%
MATZIM LA TAB 240MG/24	24	8	$3,179.54	$2.94	$132.48	0.10%
AMLOD/ATORVA TAB 10-10MG	24	8	$6,261.75	$4.17	$260.91	0.20%
AMLOD/ATORVA TAB 5-20MG	22	5	$6,707.50	$5.32	$304.89	0.21%
ISRADIPINE CAP 2.5MG	19	3	$1,396.16	$2.45	$73.48	0.04%
AMLOD/ATORVA TAB 10-80MG	16	3	$4,345.63	$5.57	$271.60	0.14%
MATZIM LA TAB 360MG/24	14	5	$2,563.16	$3.88	$183.08	0.08%
VERAPAMIL CAP 200MG ER	14	3	$845.36	$1.51	$60.38	0.03%
VERAPAMIL CAP 300MG ER	12	1	$745.71	$2.07	$62.14	0.02%
CARDIZEM LA TAB 120MG	8	4	$1,534.15	$3.65	$191.77	0.05%
AMLOD/ATORVA TAB 5-10MG	7	2	$1,740.40	$5.27	$248.63	0.05%
ISRADIPINE CAP 5MG	6	1	$1,057.98	$5.88	$176.33	0.03%
MATZIM LA TAB 300MG/24	5	1	$544.99	$3.63	$109.00	0.02%
MATZIM LA TAB 420MG/24	4	1	$1,518.93	$4.22	$379.73	0.05%
AMLOD/ATORVA TAB 5-80MG	4	1	$1,184.10	$4.93	$296.03	0.04%
TIER-2 SUBTOTAL	**368**	**89**	**$82,197.74**	**$4.18**	**$205.53**	**2.60%**
SPECIAL PRIOR AUTORIZATION UTILIZATION						
NIMODIPINE CAP 30MG	14	4	$4,402.54	$12.37	$314.47	0.14%
DILTIAZEM CAP 360MG CD	9	3	$1,965.20	$5.04	$218.36	0.06%
SPECIAL PA SUBTOTAL	**23**	**7**	**$6,367.74**	**$8.71**	**$266.42**	**0.20%**
TOTAL	**43,505**	**13,045**	**$735,324.50**	**$4.64**	**$170.66**	**23.16%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
ANGIOTENSIN RECEPTOR BLOCKERS (ARB) AND COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
LOSARTAN POT TAB 50MG	4,266	1,140	$35,536.95	$0.21	$8.33	1.12%
LOSARTAN POT TAB 100MG	3,065	876	$30,213.41	$0.23	$9.86	0.95%
LOSARTAN POT TAB 25MG	1,545	509	$12,892.23	$0.20	$8.34	0.41%
LOSARTAN/HCT TAB 100-25	1,429	393	$14,796.74	$0.23	$10.35	0.47%
LOSARTAN/HCT TAB 50-12.5	1,145	299	$10,087.40	$0.22	$8.81	0.32%
LOSARTAN/HCT TAB 100-12.5	579	153	$6,367.99	$0.26	$11.00	0.20%
VALSART/HCTZ TAB 160-12.5	359	83	$10,184.69	$0.69	$28.37	0.32%
VALSART/HCTZ TAB 160-25MG	234	56	$9,599.10	$0.88	$41.02	0.30%
VALSART/HCTZ TAB 320-25MG	212	46	$8,404.53	$0.95	$39.64	0.27%
IRBESARTAN TAB 150MG	194	47	$3,685.32	$0.41	$19.00	0.12%
IRBESARTAN TAB 300MG	192	53	$3,569.63	$0.43	$18.59	0.11%
VALSART/HCTZ TAB 80-12.5	178	37	$4,736.28	$0.64	$26.61	0.15%
IRBESAR/HCTZ TAB 150-12.5	58	14	$1,656.49	$0.61	$28.56	0.05%
VALSART/HCTZ TAB 320-12.5	53	20	$3,535.18	$1.24	$66.70	0.11%
IRBESARTAN TAB 75MG	39	9	$447.60	$0.29	$11.48	0.01%
IRBESAR/HCTZ TAB 300-12.5	34	10	$1,079.43	$0.68	$31.75	0.03%
COZAAR TAB 25MG	2	1	$135.54	$2.26	$67.77	0.00%
COZAAR TAB 50MG	2	1	$179.48	$2.99	$89.74	0.01%
HYZAAR TAB 100-25	2	1	$785.57	$4.36	$392.79	0.02%
AVAPRO TAB 150MG	2	2	$23.74	$0.40	$11.87	0.00%
TIER-1 SUBTOTAL	**13,590**	**3,750**	**$157,917.30**	**$0.91**	**$46.53**	**4.97%**
TIER-2 UTILIZATION						
DIOVAN TAB 160MG	386	85	$73,186.71	$5.04	$189.60	2.31%
DIOVAN TAB 80MG	373	66	$71,012.49	$4.85	$190.38	2.24%
DIOVAN TAB 320MG	330	67	$82,504.83	$5.70	$250.01	2.60%
EXFORGE TAB 10-320MG	195	29	$39,358.53	$6.73	$201.84	1.24%
EXFORGEH/10- TAB 320-25	99	14	$20,018.70	$6.75	$202.21	0.63%
EXFORGE TAB 5-160MG	92	15	$13,295.74	$4.82	$144.52	0.42%
EXFORGEH/5- TAB 160-12.5	60	9	$8,479.57	$4.71	$141.33	0.27%
DIOVAN TAB 40MG	77	16	$10,945.75	$3.80	$142.15	0.35%
EXFORGE TAB 5-320MG	38	8	$6,569.19	$5.76	$172.87	0.21%
EXFORGE TAB 10-160MG	23	5	$3,578.87	$5.38	$155.60	0.11%
EXFORGEH/5- TAB 160-25	13	2	$1,770.98	$4.54	$136.23	0.06%
EXFORGEH/10- TAB 160-12.5	12	3	$1,843.04	$5.12	$153.59	0.06%
EXFORGEH/10- TAB 160-25	11	3	$1,813.39	$5.50	$164.85	0.06%
TIER-2 SUBTOTAL	**1,709**	**322**	**$334,377.79**	**$5.28**	**$172.71**	**10.56%**
TIER-3 UTILIZATION						
BENICAR TAB 20MG	323	67	$49,794.94	$3.72	$154.16	1.57%
BENICAR TAB 40MG	198	50	$50,584.70	$5.12	$255.48	1.60%
BENICAR HCT TAB 40-25MG	188	38	$41,055.47	$5.09	$218.38	1.29%
BENICAR HCT TAB 20-12.5	141	25	$23,957.20	$3.84	$169.91	0.76%
MICARDIS TAB 80MG	97	22	$19,116.81	$5.54	$197.08	0.60%
BENICAR HCT TAB 40-12.5	96	21	$23,243.94	$5.02	$242.12	0.73%
MICARDIS TAB 40MG	85	22	$16,135.18	$4.76	$189.83	0.51%
TELMISARTAN TAB 40MG	64	20	$10,978.65	$3.98	$171.54	0.35%
TELMISARTAN TAB 80MG	64	14	$9,289.62	$4.55	$145.15	0.29%
EDARBYCLOR TAB 40-12.5	60	10	$7,394.89	$3.59	$123.25	0.23%
AZOR TAB 10-40MG	56	10	$10,922.94	$5.87	$195.05	0.34%
MICARDIS HCT TAB 80/12.5	54	12	$16,139.66	$5.60	$298.88	0.51%
CANDESARTAN TAB 32MG	45	9	$9,119.76	$4.09	$202.66	0.29%
MICARDIS HCT TAB 40/12.5	44	8	$6,932.46	$4.81	$157.56	0.22%
AZOR TAB 5-40MG	40	11	$9,968.64	$5.93	$249.22	0.31%
MICARDIS HCT TAB 80-25MG	35	9	$7,690.58	$4.84	$219.73	0.24%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
CANDESA/HCTZ TAB 32-12.5	32	5	$3,013.83	$2.58	$94.18	0.10%
MICARDIS TAB 20MG	30	6	$4,629.82	$4.68	$154.33	0.15%
EDARBI TAB 80MG	27	9	$3,341.93	$3.38	$123.78	0.11%
BENICAR TAB 5MG	19	6	$2,282.92	$2.45	$120.15	0.07%
TRIBENZOR40- TAB 10-25MG	18	6	$6,037.08	$7.19	$335.39	0.19%
CANDESARTAN TAB 8MG	17	2	$1,415.64	$1.90	$83.27	0.04%
TELMISA/HCTZ TAB 80-12.5	17	8	$4,605.44	$5.29	$270.91	0.15%
TRIBENZOR40- TAB 5-12.5MG	14	4	$3,613.57	$6.02	$258.11	0.11%
CANDESARTAN TAB 16MG	13	2	$2,044.55	$3.17	$157.27	0.06%
CANDESA/HCTZ TAB 16-12.5	11	1	$863.33	$2.62	$78.48	0.03%
TELMISARTAN TAB 20MG	11	3	$1,290.72	$3.98	$117.34	0.04%
AZOR TAB 5-20MG	10	2	$2,521.55	$4.67	$252.16	0.08%
TEVETEN HCT TAB 600-12.5	10	1	$1,357.70	$4.53	$135.77	0.04%
EDARBI TAB 40MG	9	1	$946.26	$3.50	$105.14	0.03%
EDARBYCLOR TAB 40-25MG	8	3	$771.44	$3.21	$96.43	0.02%
ATACAND TAB 32MG	7	4	$1,648.86	$5.00	$235.55	0.05%
CANDESARTAN TAB 4MG	7	2	$1,010.10	$4.81	$144.30	0.03%
EPROSART MES TAB 600MG	7	2	$1,823.43	$2.89	$260.49	0.06%
TRIBENZOR40- TAB 5-25MG	7	5	$3,331.12	$5.84	$475.87	0.11%
TELMISA/HCTZ TAB 40-12.5	6	4	$1,271.86	$4.24	$211.98	0.04%
TELMISA/HCTZ TAB 80-25MG	5	4	$1,684.59	$4.32	$336.92	0.05%
ATACAND HCT TAB 16-12.5	2	1	$757.10	$4.21	$378.55	0.02%
ATACAND HCT TAB 32-12.5	2	2	$258.08	$4.30	$129.04	0.01%
TRIBENZOR20- TAB 5-12.5MG	2	2	$536.12	$4.47	$268.06	0.02%
TEVETEN TAB 600MG	1	1	$404.63	$4.50	$404.63	0.01%
TIER-3 SUBTOTAL	**1,882**	**434**	**$363,787.11**	**$4.39**	**$205.32**	**11.46%**
TOTAL	**17,181**	**4,506**	**$856,082.20**	**$3.53**	**$141.52**	**26.99%**
ANGIOTENSIN CONVERTING ENZYME INHIBITORS (ACEIs) AND COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
LISINOPRIL TAB 20MG	22,719	6,629	$154,507.35	$0.17	$6.80	4.87%
LISINOPRIL TAB 10MG	21,023	6,443	$125,440.83	$0.15	$5.97	3.96%
LISINOPRIL TAB 40MG	10,654	2,778	$104,050.21	$0.23	$9.77	3.28%
LISINOPRIL TAB 5MG	8,701	2,706	$46,489.95	$0.13	$5.34	1.47%
LISINOP/HCTZ TAB 20-25MG	7,848	2,261	$62,297.61	$0.17	$7.94	1.96%
LISINOP/HCTZ TAB 20-12.5	7,503	2,155	$57,169.18	$0.18	$7.62	1.80%
LISINOP/HCTZ TAB 10-12.5	3,907	1,259	$28,821.85	$0.17	$7.38	0.91%
LISINOPRIL TAB 2.5MG	3,275	981	$16,446.36	$0.12	$5.02	0.52%
ENALAPRIL TAB 20MG	2,591	589	$31,648.33	$0.32	$12.21	1.00%
ENALAPRIL TAB 10MG	2,542	601	$24,487.78	$0.26	$9.63	0.77%
ENALAPRIL TAB 5MG	2,158	495	$16,730.78	$0.22	$7.75	0.53%
LISINOPRIL TAB 30MG	1,333	323	$11,810.40	$0.24	$8.86	0.37%
ENALAPRIL TAB 2.5MG	1,069	222	$8,027.69	$0.23	$7.51	0.25%
BENAZEPRIL TAB 20MG	845	224	$7,559.17	$0.20	$8.95	0.24%
BENAZEPRIL TAB 40MG	614	159	$6,001.46	$0.21	$9.77	0.19%
FOSINOPRIL TAB 40MG	519	91	$6,819.00	$0.41	$13.14	0.22%
RAMIPRIL CAP 10MG	388	80	$5,073.81	$0.28	$13.08	0.16%
BENAZEPRIL TAB 10MG	372	118	$3,456.04	$0.21	$9.29	0.11%
QUINAPRIL TAB 40MG	320	62	$4,100.56	$0.30	$12.81	0.13%
FOSINOPRIL TAB 20MG	308	69	$3,536.45	$0.29	$11.48	0.11%
QUINAPRIL TAB 20MG	299	67	$4,056.52	$0.33	$13.57	0.13%
ENALAPR/HCTZ TAB 10-25MG	295	68	$3,344.92	$0.25	$11.34	0.11%
CAPTOPRIL TAB 25MG	294	62	$7,642.11	$0.87	$25.99	0.24%
CAPTOPRIL TAB 12.5MG	209	41	$4,714.19	$0.67	$22.56	0.15%
CAPTOPRIL TAB 50MG	202	48	$8,528.61	$1.29	$42.22	0.27%
RAMIPRIL CAP 5MG	181	57	$2,538.84	$0.28	$14.03	0.08%
RAMIPRIL CAP 2.5MG	163	52	$2,168.72	$0.25	$13.31	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
FOSINOPRIL TAB 10MG	153	35	$1,988.00	$0.31	$12.99	0.06%
BENAZEP/HCTZ TAB 20-12.5	129	32	$4,465.01	$0.80	$34.61	0.14%
BENAZEPRIL TAB 5MG	120	28	$1,202.74	$0.23	$10.02	0.04%
BENAZEP/HCTZ TAB 20-25MG	101	26	$5,012.15	$0.99	$49.63	0.16%
ENALAPR/HCTZ TAB 5-12.5MG	90	25	$1,009.84	$0.27	$11.22	0.03%
QUINAPRIL TAB 10MG	74	24	$909.96	$0.22	$12.30	0.03%
RAMIPRIL CAP 1.25MG	71	15	$927.15	$0.34	$13.06	0.03%
BENAZEP/HCTZ TAB 10-12.5	69	19	$3,497.10	$1.15	$50.68	0.11%
CAPTOPR/HCTZ TAB 50-25MG	67	7	$1,997.94	$0.91	$29.82	0.06%
QNAPRIL/HCTZ TAB 20-25MG	41	9	$1,425.62	$0.75	$34.77	0.04%
QUINAPRIL TAB 5MG	31	6	$314.75	$0.28	$10.15	0.01%
CAPTOPR/HCTZ TAB 25-15MG	29	8	$681.85	$0.55	$23.51	0.02%
MOEXIPRIL TAB 15MG	26	5	$339.35	$0.38	$13.05	0.01%
QNAPRIL/HCTZ TAB 20-12.5	24	5	$687.68	$0.72	$28.65	0.02%
TRANDOLAPRIL TAB 4MG	24	6	$476.43	$0.47	$19.85	0.02%
MOEXIPR/HCTZ TAB 15-25MG	18	5	$595.34	$0.89	$33.07	0.02%
CAPTOPR/HCTZ TAB 25-25MG	17	4	$347.62	$0.35	$20.45	0.01%
CAPTOPRIL TAB 100MG	17	7	$239.25	$0.47	$14.07	0.01%
TRANDOLAPRIL TAB 1MG	17	3	$333.27	$0.44	$19.60	0.01%
FOSINOP/HCTZ TAB 20/12.5	14	3	$572.09	$1.27	$40.86	0.02%
MOEXIPRIL TAB 7.5MG	13	2	$153.47	$0.31	$11.81	0.00%
TRANDOLAPRIL TAB 2MG	13	2	$226.86	$0.44	$17.45	0.01%
QNAPRIL/HCTZ TAB 10-12.5	10	2	$226.92	$0.76	$22.69	0.01%
MOEXIPR/HCTZ TAB 7.5-12.5	5	2	$171.71	$0.52	$34.34	0.01%
BENAZEP/HCTZ TAB 5-6.25	4	1	$250.31	$0.83	$62.58	0.01%
MOEXIPR/HCTZ TAB 15-12.5	4	3	$83.10	$0.69	$20.78	0.00%
TIER-1 SUBTOTAL	**101,513**	**28,924**	**$785,604.23**	**$0.45**	**$18.40**	**24.79%**
TIER-2 UTILIZATION						
PERINDOPRIL TAB 4MG	12	1	$245.62	$0.68	$20.47	0.01%
TIER-2 SUBTOTAL	**12**	**1**	**$245.62**	**$0.68**	**$20.47**	**0.01%**
SPECIAL PRIOR AUTHORIZATION UTILIZATION						
EPANED SOL 1MG/ML	231	85	$68,638.22	$9.10	$297.14	2.16%
FOSINOP/HCTZ TAB 10/12.5	6	1	$432.94	$2.19	$72.16	0.01%
SPECIAL PA SUBTOTAL	**237**	**86**	**$69,071.16**	**$5.65**	**$184.65**	**2.17%**
TOTAL	**101,762**	**29,011**	**$854,921.01**	**$2.26**	**$74.51**	**26.97%**
ACE INHIBITOR/CALCIUM CHANNEL BLOCKER COMBINATIONS						
TIER-2 UTILIZATION						
AMLOD/BENAZP CAP 10-20MG	269	51	$8,191.57	$0.68	$30.45	0.26%
AMLOD/BENAZP CAP 10-40MG	256	44	$9,550.04	$0.84	$37.30	0.30%
AMLOD/BENAZP CAP 5-20MG	235	38	$5,657.00	$0.67	$24.07	0.18%
AMLOD/BENAZP CAP 5-10MG	112	25	$3,141.18	$0.72	$28.05	0.10%
AMLOD/BENAZP CAP 5-40MG	28	8	$1,043.93	$0.70	$37.28	0.03%
TARKA TAB 4-240 CR	17	5	$6,578.48	$5.72	$386.97	0.21%
TARKA TAB 2-240 CR	13	2	$1,671.78	$4.29	$128.60	0.05%
AMLOD/BENAZP CAP 2.5-10MG	1	1	$52.73	$0.59	$52.73	0.00%
TARKA TAB 2-180 CR	1	1	$367.95	$4.09	$367.95	0.01%
TIER-2 SUBTOTAL	**932**	**175**	**$36,254.66**	**$2.03**	**$121.49**	**1.14%**
TOTAL	**932**	**175**	**$36,254.66**	**$2.03**	**$121.49**	**1.14%**
DIRECT RENIN INHIBITORS (ALISKIREN)						
TIER-3 UTILIZATION						
TEKTURNA TAB 150MG	28	4	$5,915.86	$4.29	$211.28	0.19%
TEKTURNA TAB 300MG	12	4	$3,574.14	$4.58	$297.85	0.11%
AMTURNIDE 300 TAB -5-12.5	11	1	$1,390.02	$4.21	$126.37	0.04%
TEKTURNA HCT TAB 150-12.5	6	2	$816.30	$3.40	$136.05	0.03%
TEKTURNA HCT TAB 300-25MG	2	1	$873.18	$4.85	$436.59	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
TIER-3 SUBTOTAL	**59**	**12**	**$12,569.50**	**$4.27**	**$241.63**	**0.40%**
TOTAL	**59**	**12**	**$12,569.50**	**$4.27**	**$241.63**	**0.40%**
CLONIDINE PRODUCTS						
NO PRIOR AUTHORIZATION REQUIRED						
CLONIDINE TAB 0.1MG	55,048	11,630	$384,254.30	$0.23	$6.98	12.12%
CLONIDINE TAB 0.2MG	20,501	3,838	$155,510.42	$0.24	$7.59	4.90%
CLONIDINE TAB 0.3MG	4,291	718	$37,287.63	$0.28	$8.69	1.18%
CLONIDINE POWDER	39	11	$509.17	$0.37	$13.06	0.02%
CLORPRES TAB 0.1-15MG	4	3	$425.92	$3.55	$106.48	0.01%
SUBTOTAL:	**79,883**	**16,200**	**$577,987.44**	**$0.93**	**$28.56**	**18.23%**
SPECIAL PRIOR AUTHORIZATION (CLONIDINE TRANSDERMAL PATCH)						
CLONIDINE DIS 0.2/24HR	116	28	$15,395.14	$4.95	$132.72	0.49%
CLONIDINE DIS 0.1/24HR	101	26	$7,303.17	$2.67	$72.31	0.23%
CLONIDINE DIS 0.3/24HR	89	19	$15,793.43	$6.39	$177.45	0.50%
SPECIAL PA SUBTOTAL	**306**	**73**	**$38,491.74**	**$4.67**	**$127.49**	**1.22%**
TOTAL	**80,189**	**16,273**	**$616,479.18**	**$2.80**	**$78.03**	**19.45%**
SOTALOL PRODUCTS						
NO PRIOR AUTHORIZATION REQUIRED						
SOTALOL HCL TAB 80MG	299	56	$4,182.71	$0.42	$13.99	0.13%
SOTALOL HCL TAB 120MG	82	19	$1,397.83	$0.57	$17.05	0.04%
SOTALOL HCL TAB 160MG	33	6	$575.52	$0.56	$17.44	0.02%
SOTALOL AF TAB 80MG	14	4	$183.29	$0.44	$13.09	0.01%
SOTALOL HCL TAB 240MG	6	1	$142.92	$0.79	$23.82	0.00%
SOTALOL AF TAB 160MG	4	1	$59.18	$0.49	$14.80	0.00%
SOTALOL AF TAB 120MG	3	1	$40.95	$0.46	$13.65	0.00%
TOTAL	**441**	**88**	**$6,582.40**	**$0.53**	**$16.26**	**0.20%**
MISCELLANEOUS COMBINATION PRODUCTS						
NO PRIOR AUTHORIZATION REQUIRED						
BISOPRL/HCTZ TAB 5-6.25MG	390	88	$3,522.50	$0.21	$9.03	0.11%
ATENOL/CHLOR TAB 50-25MG	371	114	$2,985.46	$0.17	$8.05	0.09%
ATENOL/CHLOR TAB 100-25MG	284	70	$3,251.62	$0.25	$11.45	0.10%
BISOPRL/HCTZ TAB 10/6.25	164	46	$1,626.12	$0.21	$9.92	0.05%
METOPRL/HCTZ TAB 50-25MG	143	36	$6,884.86	$1.08	$48.15	0.22%
METOPRL/HCTZ TAB 100-25MG	117	30	$7,031.33	$1.48	$60.10	0.22%
BISOPRL/HCTZ TAB 2.5/6.25	111	30	$1,205.68	$0.21	$10.86	0.04%
BIDIL TAB	92	25	$22,705.88	$7.58	$246.80	0.72%
DUTOPROL TAB 50-12.5	30	5	$691.29	$0.72	$23.04	0.02%
PROPRAN/HCTZ TAB 80/25	19	3	$621.64	$0.83	$32.72	0.02%
METOPR/HCTZ TAB 100-50MG	15	2	$1,028.71	$1.49	$68.58	0.03%
PROPRANOLOL/HCTZ TAB 40/25	15	3	$536.23	$0.94	$35.75	0.02%
DUTOPROL TAB 25-12.5	11	6	$422.31	$0.76	$38.39	0.01%
DUTOPROL TAB 100-12.5	7	2	$137.27	$0.65	$19.61	0.00%
METHYLDOP/HCTZ TAB 250/15	1	1	$32.03	$1.07	$32.03	0.00%
TOTAL	**1770**	**461**	**$52,682.93**	**$1.18**	**$43.63**	**1.65%**
GRAND TOTAL	**245,839**	**46,461***	**$3,170,896.38**	**$0.34**	**$87.38**	**100%**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2015. Last accessed 03/2015.

[2] Hemangeol™ Product Information. Pierre Fabre Pharmaceuticals, Inc. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205410s000lbl.pdf. Last revised 03/2014. Last accessed 03/2015.

[3] Hemangeol™ (propranolol hydrochloride) – New Orphan Drug Approval. Optum RX. https://www.optumrx.com/RxsolHcpWeb/cmsContent.do?pageUrl=/HCP/RxNews/DrugApprovals/2014&pageName=DrugApprovalHemangeol03242014&disclaimer=RxNewsDisclaimer. Last accessed 3/2015.

[4] Sotylize™ Product Information. Arbor Pharmaceuticals, LLC. Available online at: http://arborpharma.com/docs/sotylize-pi.pdf. Last revised 10/2014. Last accessed 03/2015.
[5] Prestalia® Product Information. Symplmed Pharmaceuticals, LLC. Available online at: http://www.symplmed.com/pdf/Prestalia-PI.pdf. Last revised 01/2015. Last accessed 03/2015.
[6] Prestalia® (perindopril arginine and amlodipine besylate tablet) – New Drug Approval. Optum RX. https://www.optumrx.com/vgnlive/HCP/Assets/RxNews/Drug_Approvals_Prestalia_2015-0127.pdf. Last accessed 3/2015.

Appendix H

Fiscal Year 2014 Annual Review of Hereditary Angioedema Medications and 30-Day Notice to Prior Authorize Ruconest® (C1 Esterase Inhibitor)

Oklahoma Health Care Authority
April 2015

Current Prior Authorization Criteria

Cinryze® (C1 Esterase Inhibitor) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Cinryze® must be used for *prophylaxis* of hereditary angioedema; and
3. History of at least one or more abdominal or respiratory HAE attack(s) per month, or history of laryngeal attacks, or three or more emergency medical treatments per year; and
4. Member must not be currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
5. Documented intolerance, insufficient response, or contraindication to:
    a. Attenuated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone); and
    b. Antifibrinolytic agents (e.g. ε – aminocaproic acid, tranexamic acid); or
    c. Recent hospitalization for severe episode of angioedema.
6. Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every three to four days, approximately two times per week, to be infused at a rate of 1 mL/min.
    b. Initial doses should be administered in an outpatient setting by a healthcare provider. Patients can be taught by their healthcare provider to self-administer Cinryze® intravenously.
    c. A quantity limit of 8,000 units per month will apply (i.e. two treatments per week or eight treatments per month).

Berinert® (C1 Esterase Inhibitor), Kalbitor® (Ecallantide), and Firazyr® (Icatibant) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Berinert®, Kalbitor®, or Firazyr® must be used for *treatment* of acute attacks of hereditary angioedema.

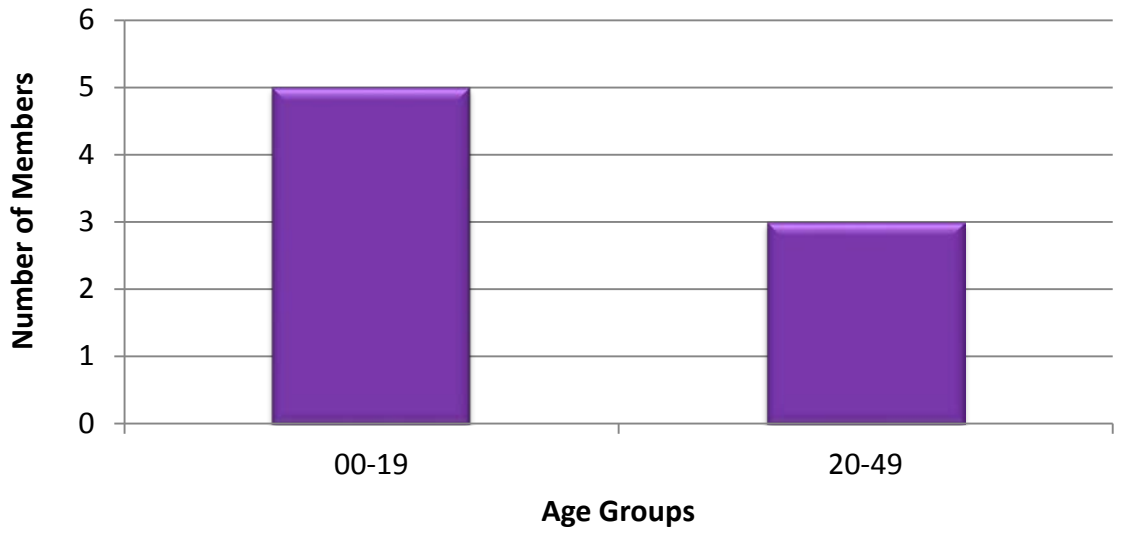
Utilization of Hereditary Angioedema Medications: Fiscal Year 2014

Comparison of Fiscal Years

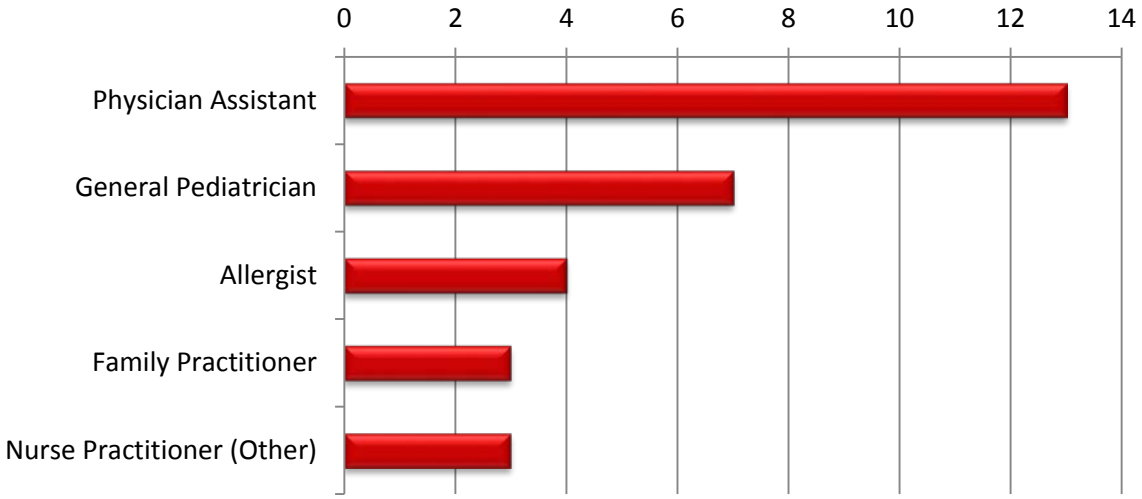
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	6	26	$978,868.87	$37,648.80	$1,527.10	419	641
2014	8	30	$1,275,801.77	$42,526.73	$1,814.80	510	703
% Change	**33.30%**	**15.40%**	**30.30%**	**13.00%**	**18.80%**	**21.70%**	**9.70%**
Change	**2**	**4**	**$296,932.90**	**$4,877.93**	**$287.70**	**91**	**62**

*Total number of unduplicated members.

Demographics of Members Utilizing Hereditary Angioedema Medications



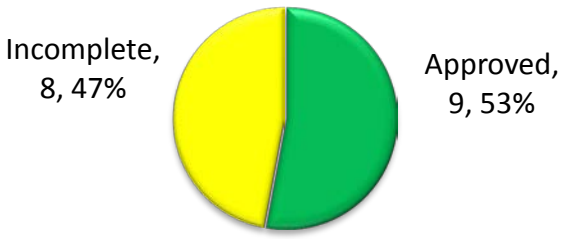
Top Prescriber Specialties of Hereditary Angioedema Medications by Number of Claims



Prior Authorization of Hereditary Angioedema Medications

There were 17 petitions submitted for the hereditary angioedema medications during fiscal year 2014. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[1]

New FDA Approvals:

- Ruconest® (C1 esterase inhibitor): July 2014

Ruconest® (C1 Esterase Inhibitor)[2,3]

Indications: Ruconest® is a C1 esterase inhibitor [recombinant] indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.

Dosing:

- Ruconest® is available as a 2,100 IU lyophilized powder for reconstitution and injection in a single-use vial.
- For intravenous use only.
- Each vial should be reconstituted by adding 14 mL sterile water for injection per vial to obtain a solution of 150 IU per mL.
- The reconstituted solution should be administered at room temperature as a slow intravenous injection over approximately five minutes.
- Appropriately trained patients may self-administer upon recognition of an HAE attack.
- The following table includes the recommended dose for an acute attack:

Body Weight	Ruconest® Dose for IV injection	Volume (mL) of reconstituted solution (150 IU/mL) to be administered
<84kg	50 IU per kg	Body weight in kg divided by three
≥84kg	4200 IU (2 vials)	28 mL

- If the attack symptoms persist, an additional (second) dose can be administered at the recommended dose level. Doses should not exceed 4,200 IU per dose. No more than two doses should be administered within a 24 hour period.

Mechanism of Action:

- C1 esterase inhibitor (C1INH) is a normal constituent of human blood and is one of the serine protease inhibitors (serpins). The primary function of C1INH is to regulate the activation of the complement and contact system pathways. C1INH exerts its inhibitory effect by irreversibly binding several proteases of the contact and complement systems. HAE patients have low levels of endogenous or functional C1INH. Although the events that induce attacks of angioedema in HAE patients are not well defined, it is thought that contact system activation, and resulting increased vascular permeability lead to the clinical manifestation of HAE attacks. Administration of Ruconest® increases plasma levels of functional C1INH activity.

Contraindications:

- Known or suspected allergy to rabbits and rabbit-derived products.
- History of immediate hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations.

Warnings and Precautions:

- Hypersensitivity reactions, including anaphylaxis may occur.
- Serious arterial and venous thromboembolic (TE) events have been reported at the recommended dose of plasma derived C1 esterase inhibitor products in patients with risk factors.

Adverse Reactions:

- The most common adverse reactions (≥ 2%) reported in clinical trials were headache, nausea, and diarrhea.

Clinical Studies: The safety and efficacy of Ruconest® were based on a randomized, placebo-controlled trial involving 75 patients with HAE. The primary endpoint was the time to beginning of relief of HAE symptoms, using patient-reported responses from a questionnaire.

- The median time to beginning of relief of symptoms was significantly shorter in patients treated with Ruconest® versus placebo (90 minutes versus 152 minutes).
- Further support was provided in two additional trials, demonstrating statistically significantly shorter times to beginning of relief of symptoms with Ruconest® versus placebo.

Cost Comparison:

Drug Name	Strength	Cost/ Vial	Cost/ HAE Attack+
Ruconest® (C1 esterase inhibitor, recombinant)	2,100 IU vial	$5,016.00*	$10,032.00-$20,064.00
Berinert® (C1 esterase inhibitor, human)	500 IU vial	$2,129.58∞	$8,518.32

∞State maximum allowable cost

*Estimated acquisition cost

+Based on maximum dose for 100kg adult.

Recommendations

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

Ruconest® (C1 Esterase Inhibitor) Approval Criteria:

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

Utilization Details of Hereditary Angioedema Medications: Fiscal Year 2014

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
CINRYZE SOL 500 UNIT	15	3	$1,005,846.71	$2,255.26	$67,056.45	78.84%
FIRAZYR 30MG/3ML	7	5	$173,567.34	$1,735.67	$24,795.33	13.60%
BERINERT INJ 500UNIT	6	3	$61,119.84	$485.08	$10,186.64	4.79%
KALBITOR 10MG/ML	2	1	$35,267.88	$1,137.67	$17,633.94	2.76%
TOTAL	**30**	**8***	**$1,275,801.77**	**$1,814.80**	**$29,918.09**	**100.00%**

*Total number of unduplicated members.

[1] "FDA Approves New Product to Treat Rare Genetic Disease." FDA News Release. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm405526.htm. Last revised: 07/17/2014. Last accessed: 03/2015.

[2] Ruconest® Product Information. Salix Pharmaceuticals, Inc. Available online at: https://81b77e9a9bc9711e90b1-f416dd7f832b6e1ad8c969a90667ca99.ssl.cf1.rackcdn.com/shared/pi/ruconest-pi.pdf. Last revised 02/2015. Last accessed 3/2015.

[3] Ruconest® (C1 esterase inhibitor [recombinant]). New Orphan Drug Approval. Optum RX. https://www.optumrx.com/vgnlive/HCP/Assets/RxNews/Drug%20Approval%202014-0717%20Ruconest.pdf. Last accessed 3/2015.

Appendix I

Fiscal Year 2014 Annual Review of Diabetes Medications and 30-Day Notice to Prior Authorize Tanzeum™ (Albiglutide), Trulicity™ (Dulaglutide), Cycloset® (Bromocriptine), Jardiance® (Empagliflozin), Invokamet™ (Canagliflozin/Metformin), Xigduo™ XR (Dapagliflozin/Metformin Extended-Release), Glyxambi (Empagliflozin/Linagliptin), Afrezza® (Insulin Human Inhalation Powder), and Toujeo® (Insulin Glargine)

Oklahoma Health Care Authority
April 2015

Current Prior Authorization Criteria

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

Diabetes Medications Tier-2 Approval Criteria:

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

Diabetes Medications Tier-3 Approval Criteria:

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

Diabetes Medications Special Prior Authorization Approval Criteria:

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

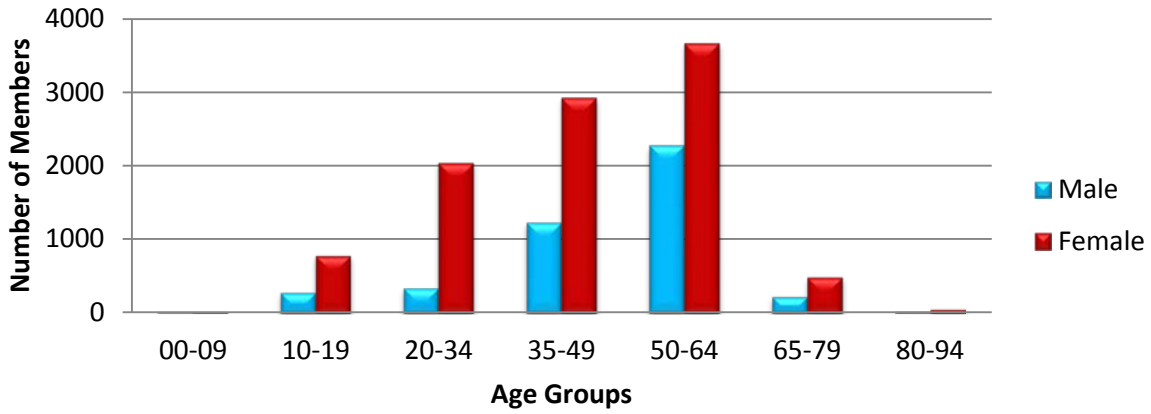
Utilization of Diabetes Medications: Fiscal Year 2014

Comparison of Fiscal Years

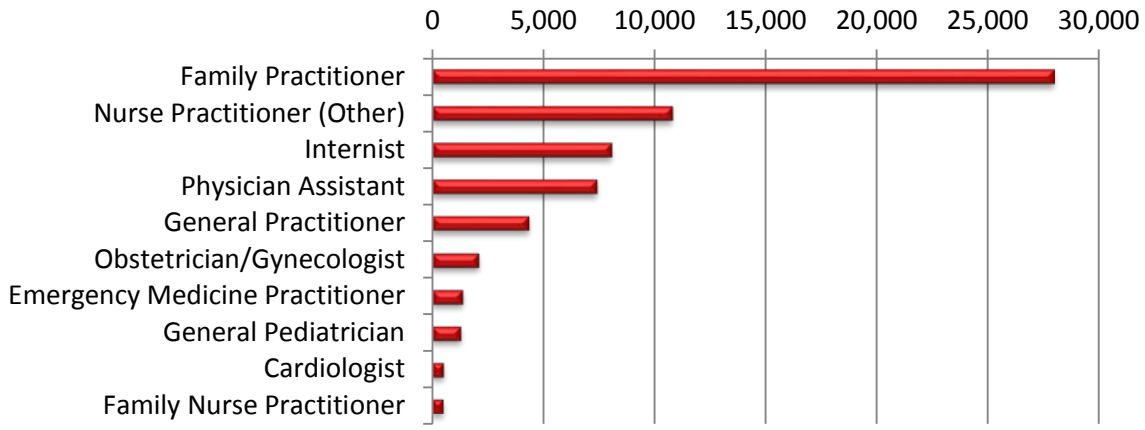
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	14,364	86,542	$4,838,936.86	$55.91	$1.67	5,354,337	2,891,085
2014	14,644	84,849	$5,057,624.99	$59.61	$1.77	5,153,907	2,850,222
% Change	**1.90%**	**-2.00%**	**4.50%**	**6.60%**	**6.00%**	**-3.70%**	**-1.40%**
Change	**280**	**-1,693**	**$218,688.13**	**$3.70**	**$0.10**	**-200,430**	**-40,863**

*Total number of unduplicated members.

Demographics of Members Utilizing Diabetes Medications



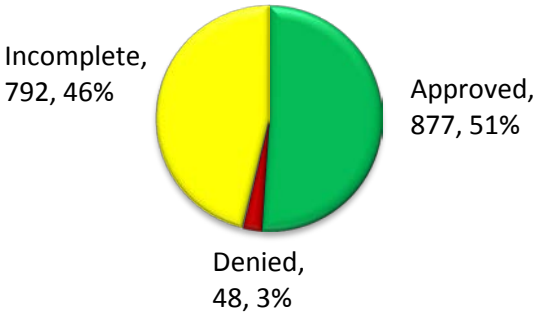
Top Prescriber Specialties of Diabetes Medications by Number of Claims



Prior Authorization of Diabetes Medications

There were 1,717 petitions submitted for the diabetes medications category during fiscal year 2014. Computer edits are in place to detect Tier-1 medications in members' recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates[1-10]

Anticipated Patent Expirations:

- Byetta® (exenatide): January 2020
- Victoza® (liraglutide): August 2025
- Januvia® (sitagliptin): April 2026
- Invokana™ (canagliflozin): February 2029
- Farxiga™ (dapagliflozin): May 2030
- Tradjenta® (linagliptin): March 2031

New FDA Approvals:

- Tanzeum™ (albiglutide): April 2014
- Cycloset® (bromocriptine): May 2014
- Afrezza® (insulin human inhalation powder): June 2014

- Jardiance® (empagliflozin): August 2014
- Invokamet™ (canagliflozin/metformin): August 2014
- Trulicity™ (dulaglutide): September 2014
- Xigduo™ XR (dapagliflozin/metformin ER): October 2014
- Glyxambi® (empagliflozin/linagliptin): January 2015
- Toujeo® (insulin glargine): February 2015

Tanzeum™ (Albiglutide)[2]

Indications: Tanzeum™ (albiglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosing: Albiglutide is available as a 30mg/0.5mL single-dose pen and a 50mg/0.5mL single-dose pen.

- Albiglutide should be administered subcutaneously once weekly at any time of day, without regard to meals.
- Therapy should be initiated at 30mg subcutaneously once weekly. The dose can be increased to 50mg once weekly in patients requiring additional glycemic control.

Mechanism of Action: Albiglutide is an agonist of the GLP-1 receptor and augments glucose-dependent insulin secretion. Albiglutide also slows gastric emptying.

Boxed Warnings:

- Carcinogenicity of albiglutide could not be assessed in rodents, but other GLP-1 receptor agonists have caused thyroid C-cell tumors in rodents at clinically relevant exposures. Human relevance of GLP-1 receptor agonist induced C-cell tumors in rodents has not been determined. It is unknown if albiglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans.
- Albiglutide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Contraindications:

- Albiglutide is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2.
- Albiglutide is contraindicated in patients with a prior serious hypersensitivity to albiglutide or any of the product components.

Warnings and Precautions:

- Thyroid C-cell Tumors: See Boxed Warnings
- Pancreatitis: Albiglutide should be discontinued if pancreatitis is suspected. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
- Hypoglycemia: Hypoglycemia can occur when albiglutide is used in combination with insulin secretagogues (e.g. sulfonylureas) or insulin. Consideration should be given to lowering the sulfonylurea or insulin dosage when starting albiglutide.
- Hypersensitivity Reactions: Albiglutide should be discontinued if a hypersensitivity reaction is suspected.

- Renal Impairment: Renal function should be monitored in patients with renal impairment and patients should report severe adverse gastrointestinal reactions.
- Macrovascular Outcomes: There have been no clinical trials establishing conclusive evidence of macrovascular risk reduction with albiglutide or any other antidiabetic drug.

Adverse Reactions: The most common adverse reactions reported (≥10%) with albiglutide were upper respiratory tract infection, diarrhea, nausea, and injection site reaction.

Use in Special Populations:
- Pregnancy: Albiglutide may cause fetal harm; albiglutide should only be used if the potential benefit justifies the potential risk to fetus.
- Nursing Mothers: Discontinue nursing or discontinue albiglutide.
- Renal Impairment: No dosage adjustment is recommended. Renal function should be monitored in patients with renal impairment and patients should report severe adverse gastrointestinal reactions.

Efficacy: Albiglutide has been studied as monotherapy and in combination with metformin, metformin and a sulfonylurea, a thiazolidinedione (with or without metformin), and insulin glargine (with or without oral anti-diabetic drugs). The efficacy was compared with placebo, glimepiride, pioglitazone, liraglutide, sitagliptin, insulin lispro, and insulin glargine.
- The mean HbA1c reduction for monotherapy albiglutide 50mg was -0.9% from baseline at Week 52.
- The mean HbA1c reduction for albiglutide in combination with metformin was -0.6%, compared to -0.3% for sitagliptin and metformin and -0.4% for glimepiride and metformin at Week 104.
- The mean HbA1c reduction for albiglutide in combination with pioglitazone with or without metformin was -0.8%, compared to -0.1% for placebo and pioglitazone with or without metformin at Week 52.
- The mean HbA1c reduction for albiglutide in combination with metformin and glimepiride was -0.6%, compared to -0.8% for pioglitazone, metformin and glimepiride at Week 52.
- The mean HbA1c reduction for albiglutide was -0.8%, compared to -1.0% for liraglutide at Week 32.
- The mean HbA1c reduction for albiglutide was -0.7% with metformin with or without sulfonylurea, compared to -0.8% for insulin glargine and metformin with or without sulfonylurea at Week 52.
- The mean HbA1c reduction for albiglutide was -0.8% with insulin glargine, compared to -0.7% for insulin lispro and insulin glargine at Week 26.

Trulicity™ (Dulaglutide)[3]

Indications: Trulicity™ (dulaglutide) is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosing: Dulaglutide is available in two strengths, 0.75mg/0.5mL and 1.5mg/0.5mL, in a single-dose pen and in a single-dose prefilled syringe.
- Dulaglutide should be administered subcutaneously once weekly at any time of day.

- The dose should be initiated at 0.75mg subcutaneously once weekly and the dose can be increased to 1.5mg once weekly in patients requiring additional glycemic control.

Mechanism of Action: Dulaglutide is a GLP-1 receptor agonist which stimulates insulin release. Dulaglutide also reduces glucagon secretion and delays gastric emptying.

Boxed Warnings:

- Dulaglutide causes thyroid C-cell tumors in rats. It is unknown whether dulaglutide causes thyroid C-cell tumors, including MTC, in humans as the human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Dulaglutide is contraindicated in patients with a personal or family history of MTC and in patients with MEN 2. Patients should be counseled regarding the potential risk of MTC and symptoms of thyroid tumors.

Contraindications:

- Dulaglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with MEN 2.
- Dulaglutide is contraindicated in patients with a prior serious hypersensitivity reaction to dulaglutide or any of the product components.

Warnings/Precautions:

- Thyroid C-cell Tumors: See Boxed Warnings
- Pancreatitis: Pancreatitis has been reported in clinical trials. Dulaglutide should be discontinued promptly if pancreatitis is suspected. Dulaglutide should not be restarted if pancreatitis is confirmed. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
- Hypoglycemia: When dulaglutide is used with an insulin secretagogue (e.g. sulfonylurea) or insulin, consideration should be given to lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia.
- Hypersensitivity Reactions: Dulaglutide should be discontinued if hypersensitivity reaction is suspected.
- Renal Impairments: Renal function should be monitored in patients with renal impairment reporting severe adverse gastrointestinal reactions.
- Macrovascular Outcomes: There have been no studies establishing conclusive evidence of macrovascular risk reduction with dulaglutide or any other diabetic drug.

Adverse reactions: The most common adverse reactions reported ($\geq$5%) are nausea, diarrhea, vomiting, abdominal pain, and decreased appetite.

Use in Special Populations:

- Pregnancy: Dulaglutide may cause fetal harm and should only be used if the potential benefit justifies the potential risk to fetus.
- Nursing Mothers: Discontinue nursing or discontinue dulaglutide.
- Renal Impairment: No dosage adjustment recommended. Renal function should be monitored in patients with renal impairment reporting severe adverse gastrointestinal reactions.

Efficacy: Dulaglutide has been studied as monotherapy and in combination with metformin, metformin and sulfonylurea, metformin and thiazolidinedione, and prandial insulin with or without metformin.

- The mean HbA1c reduction for monotherapy dulaglutide 1.5mg was -0.8% from baseline at Week 26.
- The mean HbA1c reduction for dulaglutide 1.5mg in addition to metformin was -1.1%, compared to -0.4% for sitagliptin 100mg and metformin at Week 52.
- The mean HbA1c reduction for dulaglutide 1.5mg in combination with metformin and thiazolidinedione was -1.5%, compared to -1.0% for exenatide, metformin, and thiazolidinedione at Week 26.
- The mean HbA1c reduction for dulaglutide 1.5mg in combination with metformin and sulfonylurea was -1.1%, compared to -0.6% for insulin glargine, metformin, and sulfonylurea at Week 52.
- The mean HbA1c reduction for dulaglutide 1.5mg in combination with prandial insulin with or without metformin was -1.6%, compared to -1.4% for insulin glargine and prandial insulin with or without metformin.

Cycloset® (Bromocriptine)[4]

Indications: Cycloset® (bromocriptine) is a dopamine receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosing: Bromocriptine is available as a 0.8mg oral tablet.

- Bromocriptine should be taken once daily within two hours after waking in the morning with food.
- The initial dose is one tablet (0.8mg) daily increased weekly by one tablet until maximal tolerated daily dose of 1.6mg to 4.8mg is achieved.

Mechanism of Action: The mechanism by which bromocriptine improves glycemic control is unknown.

Contraindications:

- Bromocriptine should not be used in patients with hypersensitivity to ergot-related drugs, bromocriptine, or to any of the excipients in Cycloset®.
- Bromocriptine should not be used in patients with syncopal migraines. Bromocriptine may precipitate hypotension.
- Bromocriptine should not be used in nursing women. Bromocriptine may inhibit lactation.

Warnings/Precautions:

- Hypotension: Bromocriptine can cause orthostatic hypotension and syncope, particularly upon initiation or dose escalation. Caution should be used in patients taking anti-hypertensive medications. Orthostatic vital signs should be assessed prior to initiation of bromocriptine and periodically thereafter. Patients should be advised during early treatment to avoid situations that could lead to injury if syncope was to occur.

- Psychosis: Bromocriptine may exacerbate psychotic disorders or reduce the effectiveness of drugs that treat psychosis. Bromocriptine use in patients with severe psychotic disorders is not recommended.
- Somnolence: Bromocriptine may cause somnolence. Patients should be advised not to operate heavy machinery if symptoms of somnolence occur.
- Interaction with Dopamine Antagonists: Concomitant use of bromocriptine with dopamine antagonists such as neuroleptic agents may diminish the effectiveness of both drugs. Concomitant use is not recommended.
- Other Dopamine Receptor Agonists: The effectiveness and safety of bromocriptine are unknown in patients already taking dopamine receptor agonists for other indications. Concomitant use is not recommended.
- Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with bromocriptine or any other antidiabetic drug. Bromocriptine does not increase the risk of macrovascular events.

Adverse reactions: The most common adverse reactions reported (≥5%) are nausea, fatigue, vomiting, and headache.

Efficacy: The mean HbA1c reduction is -0.1% for bromocriptine compared to placebo at Week 24 and -0.5% for bromocriptine, metformin, and sulfonylurea combination at Week 24.

Jardiance® (Empagliflozin)[5]

Indications: Jardiance® (empagliflozin) is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosing: Empagliflozin is available in two different strengths as a 10mg and 25mg tablet.

- The recommended dose is 10mg orally once daily, taken in the morning, with or without food.
- The dose of empagliflozin may be increased to 25mg once daily.
- Renal function should be assessed before starting empagliflozin. Empagliflozin should not be started if eGFR is below 45mL/min/1.73m^2. Empagliflozin should be discontinued if eGFR persistently falls below 45mL/min/1.73m^2.

Mechanism of Action: Sodium-glucose co-transporter 2 (SGLT2) is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Empagliflozin is an inhibitor of SGLT2, which reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Contraindications:

- History of serious hypersensitivity reaction to empagliflozin.
- Severe renal impairment, end-stage renal disease (ESRD), or dialysis.

Warnings/Precautions:

- Hypotension: Before initiating empagliflozin volume status should be assessed and corrected in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics.
- Renal Impairment: Renal function should be monitored during therapy. More frequent monitoring is recommended in patients with eGFR below 60mL/min/1.73m^2.
- Hypoglycemia: Consideration should be given to lowering the dose of insulin secretagogues or insulin to reduce the risk of hypoglycemia when initiating empagliflozin.
- Genital Mycotic Infections: Genital mycotic infections should be monitored for and treated as appropriate.
- Urinary Tract Infections: Urinary tract infections should be monitored for and treated as appropriate.
- Increased LDL-C: Increased LDL-C should be monitored for and treated as appropriate.
- Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with empagliflozin.

Adverse reactions: The most common adverse reactions reported (≥5%) were urinary tract infections and female genital mycotic infections.

Use in Special Populations:

- Pregnancy: There are no adequate and well-controlled studies in pregnant women. Empagliflozin should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Discontinue empagliflozin or discontinue nursing.
- Geriatric patients: Geriatric patients have a higher incidence of adverse reactions related to volume depletion and reduced renal function.
- Renal Impairment: Patients with renal impairment have a higher incidence of adverse reactions related to reduced renal function.

Efficacy: Empagliflozin was studied as monotherapy and in combination with metformin, sulfonylurea, pioglitazone, and insulin.

- The mean HbA1c reduction for monotherapy empagliflozin 25mg was -0.8% at Week 24.
- The mean HbA1c reduction for empagliflozin 25mg in combination with metformin was -0.7%, compared to -0.7% for metformin and glimepiride at Week 52.
- The mean HbA1c reduction for empagliflozin 25mg in combination with pioglitazone with or without metformin was -0.7%, compared to -0.1% for placebo and pioglitazone with or without metformin at Week 24.

Invokamet™ (Canagliflozin/Metformin)[6]

Indications: Invokamet™ (canagliflozin/metformin) is a SGLT2 inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin.

Dosing: Canagliflozin/metformin is available in four different strengths as a 50mg/500mg, 50mg/1000mg, 150mg/500mg, and 150mg/1000mg film-coated tablet.

- Canagliflozin/metformin is taken orally twice daily with meals, with gradual dose escalation to reduce the gastrointestinal side effects due to metformin.
- The daily dose should not exceed 300mg of canagliflozin and 2000mg of metformin.
- The daily dose should not exceed 50mg twice daily of canagliflozin in patients with an eGFR of 45 to 60mL/min/1.73m^2.
- Renal function should be assessed before starting canagliflozin/metformin. Canagliflozin/metformin should not be initiated or continued if creatinine levels are greater than or equal to 1.5mg/dL for males or 1.4mg/dL for females, or if eGFR is persistently below 45mL/min/1.73m^2.

Mechanism of Action: Canagliflozin is a SGLT2 inhibitor, which reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Metformin is a biguanide, which lowers both basal and postprandial glucose levels. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Boxed Warnings:

- Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.
- Symptoms of lactic acidosis include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.
- If acidosis is suspected, canagliflozin/metformin should be discontinued and the patient should be hospitalized immediately.

Contraindications:

- Renal impairment, ESRD, or dialysis
- Metabolic acidosis, including diabetic ketoacidosis
- History of serious hypersensitivity reaction to canagliflozin or metformin

Warnings/Precautions:

- <u>Lactic Acidosis:</u> Patients should be warned against excessive alcohol use. Canagliflozin/metformin is not recommended in hepatic impairment or hypoxic states. Normal renal function should be ensured before initiating canagliflozin/metformin and at least annually thereafter.
- <u>Hypotension:</u> Before starting canagliflozin/metformin, volume status should be assessed and hypovolemia should be corrected in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or on diuretics, ACE inhibitor, or ARB.
- <u>Renal Impairment:</u> Renal function should be monitored during therapy.
- <u>Radiological Studies and Surgical Procedures:</u> Canagliflozin/metformin should be temporarily discontinued for radiologic studies with intravascular administration of

iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids.

- Hyperkalemia: Potassium levels should be monitored in patients with impaired renal function and in patients predisposed to hyperkalemia.
- Hypoglycemia: Consideration should be given to a lower dose of insulin or the insulin secretagogue to reduce risk of hypoglycemia when used in combination with canagliflozin/metformin.
- Genital Mycotic Infections: Genital mycotic infections should be monitored for and treated as appropriate.
- Hypersensitivity Reactions: Canagliflozin/metformin should be discontinued if a hypersensitivity reaction occurs and the patient should be monitored until signs and symptoms resolve.
- Vitamin B_{12} Deficiency: Metformin may lower vitamin B_{12} levels. Hematologic parameters should be monitored annually.
- Increased LDL-C: Increased LDL-C should be monitored for and treated as appropriate.

Adverse reactions: The most common adverse reactions reported (≥5%) associated with canagliflozin were female genital mycotic infections, urinary tract infections, and increased urination. The most common adverse reactions (≥5%) reported associated with metformin were diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.

Use in Special Populations:

- Pregnancy: Canagliflozin/metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Canagliflozin/metformin should be discontinued or nursing should be discontinued.
- Geriatrics: Geriatric patients have a higher incidence of adverse reactions related to volume depletion.
- Renal Impairment: Patients with renal impairment have a higher incidence of adverse reactions related to reduced intravascular volume and renal function.

Efficacy: There have been no clinical efficacy studies conducted with canagliflozin/metformin combination tablets. However, coadministration of canagliflozin and metformin reduced HbA1c by -0.94%, compared to -0.17% to placebo and metformin at Week 26.

Xigduo™ XR (Dapagliflozin/Metformin Extended-Release)[7]

Indications: Xigduo™ XR (dapagliflozin/metformin extended-release) is a combination product of dapagliflozin a SGLT2 inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

Dosing: Dapagliflozin/metformin extended-release is available in four different strengths as a 5mg/500mg, 5mg/1000mg, 10mg/500mg, and 10mg/1000mg tablet.

- Dapagliflozin/metformin extended-release should be administered orally once daily in the morning with food.

- Tablets should be swallowed whole, not crushed, cut, or chewed.
- The daily dose should not exceed 10mg of dapagliflozin and 2000mg of metformin.
- No dose adjustment is required in patients with mild renal impairment.
- Dapagliflozin/metformin should not be used in patients with moderate to severe renal impairment. (Defined as eGFR <60mL/min/1.73m^2)

Mechanism of Action: Dapagliflozin is a SGLT2 inhibitor, which reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Metformin is a biguanide, which lowers both basal and postprandial glucose levels. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Boxed Warnings:
- Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.
- Symptoms of lactic acidosis include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.
- If acidosis is suspected, dapagliflozin/metformin should be discontinued and the patient should be hospitalized immediately.

Contraindications:
- Moderate to severe renal impairment
- Metabolic acidosis, including diabetic ketoacidosis
- History of serious hypersensitivity reaction to dapagliflozin or metformin

Warnings/Precautions:
- Lactic Acidosis: Patients should be warned against excessive alcohol use. Dapagliflozin/metformin is not recommended in hepatic impairment or hypoxic states. Normal renal function should be ensured before initiating therapy and at least annually thereafter.
- Hypotension: Before starting dapagliflozin/metformin, volume status should be assessed and hypovolemia should be corrected in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or on diuretics, ACE inhibitor, or ARB.
- Hypoglycemia: Consideration should be given to a lower dose of insulin or the insulin secretagogue to reduce risk of hypoglycemia when used in combination with dapagliflozin/metformin.
- Genital Mycotic Infections: Genital mycotic infections should be monitored for and treated as appropriate.
- Hypersensitivity Reactions: If hypersensitivity reactions occur dapagliflozin/metformin should be discontinued and the patient should be monitored until signs and symptoms resolve.
- Vitamin B_{12} Deficiency: Metformin may lower vitamin B_{12} levels. Hematologic parameters should be monitored annually.
- Increased LDL-C: Increased LDL-C should be monitored for and treated as appropriate.

- Bladder Cancer: An imbalance in bladder cancers was observed in clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer.
- Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with dapagliflozin/metformin.

Adverse reactions: The most common adverse reactions (≥5%) reported were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache.

Use in Special Populations:
- Pregnancy: Dapagliflozin/metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Dapagliflozin/metformin should be discontinued or nursing should be discontinued.
- Geriatrics: Geriatric patients have a higher incidence of adverse reactions related to reduced intravascular volume.
- Renal impairment: Patients with renal impairment have a higher incidence of adverse reactions related to reduced intravascular volume and renal function.

Efficacy: There have been no clinical efficacy studies conducted with dapagliflozin/metformin combination tablets. However, coadministration of dapagliflozin and metformin extended-release reduced HbA1c by -2.0%, compared to -1.4% for metformin extended-release alone.

Glyxambi® (Empagliflozin/Linagliptin)[8]

Indications: Glyxambi® (empagliflozin/linagliptin) is a SGLT2 inhibitor and a dipeptidyl peptidase-4 (DPP-4) inhibitor combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate.

Dosing: Empagliflozin/linagliptin is available in two strengths as a 10mg/5mg and 25mg/5mg tablet.
- The recommended dose is 10mg/5mg orally once daily, taken in the morning, with or without food.
- The dose may be increased to 25mg/5mg once daily.
- Renal function should be assessed before initiating empagliflozin/linagliptin. Empagliflozin/linagliptin should not be initiated if eGFR is below 45mL/min/1.73m^2, and should be discontinued if eGFR persistently falls below 45mL/min/1.73m^2.

Mechanism of Action: Empagliflozin is an inhibitor of SGLT2, which reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Linagliptin is a DPP-4 inhibitor which increases levels of incretin hormones, which stimulates insulin release and reduces glucagon secretion.

Contraindications:
- Severe renal impairment, ESRD, or dialysis

- History of hypersensitivity reaction to linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticarial, or bronchial hyperreactivity
- History of serious hypersensitivity reaction to empagliflozin

Warnings/Precautions:

- Pancreatitis: There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, empagliflozin/linagliptin should be promptly discontinued.
- Hypotension: Before initiating empagliflozin/linagliptin volume status should be assessed and corrected in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics.
- Renal Impairment: Renal function should be monitored during therapy. More frequent monitoring is recommended in patients with eGFR below 60mL/min/1.73m^2.
- Hypoglycemia: Consideration should be given to lowering the dose of insulin secretagogues or insulin to reduce the risk of hypoglycemia when initiating empagliflozin/linagliptin.
- Genital Mycotic Infections: Genital mycotic infections should be monitored for and treated as appropriate.
- Urinary Tract Infections: Urinary tract infections should be monitored for and treated as appropriate.
- Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with linagliptin including anaphylaxis, angioedema, and exfoliative skin conditions. Empagliflozin/linagliptin should be promptly discontinued in such cases.
- Increased LDL-C: Increased LDL-C should be monitored for and treated as appropriate.
- Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with empagliflozin/linagliptin.

Adverse reactions: The most common adverse reactions ($\geq$5%) associated with empagliflozin/linagliptin were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.

Use in Special Populations:

- Pregnancy: There are no adequate and well-controlled studies in pregnant women. Empagliflozin/linagliptin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Empagliflozin/linagliptin should be discontinued or nursing should be discontinued.
- Pediatrics: Safety and effectiveness of empagliflozin/linagliptin in pediatric patients has not been established.
- Geriatrics: Geriatric patients have a higher incidence of adverse reactions related volume depletion and reduced renal function.
- Renal impairment: Patients with renal impairment have a higher incidence of adverse reactions related to reduced renal function.

Efficacy: The mean HbA1c reduction with empagliflozin/linagliptin was -1.2%, compared to -0.7% with empagliflozin or linagliptin alone.

Afrezza® (Insulin Human Inhalation Powder)[9]

Indications: Afrezza® (insulin human) is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

Dosing: Insulin human inhalation powder is available as a single-use cartridge of 4 units or 8 units.

- Dosing of insulin human inhalation powder is individualized
- Insulin human inhalation powder should be administered using a single inhalation per cartridge
- Insulin human inhalation powder should be administered at the beginning of a meal
- Before initiating insulin human inhalation powder the following should be performed: detailed medical history, physical examination, and spirometry (FEV_1) in all patients to identify potential lung disease

Mechanism of Action: Insulin lowers blood glucose levels by stimulating peripheral glucose uptake by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis in adipocytes, inhibits proteolysis, and enhances protein synthesis.

Boxed Warnings:

- Risk of acute bronchospasm in patients with chronic lung disease. Acute bronchospasm has been observed in patients with asthma and COPD using insulin human inhalation powder.

Contraindications:

- During episodes of hypoglycemia
- Chronic lung disease, such as asthma or COPD

Warnings/Precautions:

- Acute Bronchospasms: Acute bronchospasms have been observed in patients with asthma and COPD. Prior to initiating, spirometry (FEV_1) should be performed in all patients. Insulin human inhalation powder should not be used in patients with chronic lung disease.
- Change in Insulin Regimen: Changes in the insulin regimen should be carried out under close medical supervision and with increased frequency of blood glucose monitoring.
- Hypoglycemia: Hypoglycemia could be life-threatening. Frequency of glucose monitoring should be increased with changes to: insulin dosage, coadministered glucose lowering medications, meal pattern, and physical activity; and in patients with renal or hepatic impairment and hypoglycemia unawareness.
- Decline in Pulmonary Function: Pulmonary function should be assessed before initiating, after six months of therapy, and annually, even in the absence of pulmonary symptoms.
- Lung Cancer: Insulin human inhalation powder should not be used in patients with active lung cancer. In patients with history of lung cancer or at risk for lung cancer, the benefit should outweigh the potential risk.
- Diabetic Ketoacidosis: More patients using insulin human inhalation powder experienced diabetic ketoacidosis (DKA) in clinical trials. Patients at risk for DKA should be monitored and changed to an alternate route of insulin delivery, if indicated.

- Hypersensitivity Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including insulin human inhalation powder.
- Hypokalemia: Hypokalemia could be life-threatening. Potassium levels should be monitored in patients at risk of hypokalemia and treated if indicated.
- Fluid Retention and Heart Failure with Concomitant use of Thiazolidinediones (TZDs): Patients should be observed for signs and symptoms of heart failure; consideration should be given to a dosage reduction or discontinuation if heart failure occurs.

Adverse reactions: The most common adverse reactions associated with insulin human inhalation powder (≥2%) were hypoglycemia, cough, and throat pain or irritation.

Efficacy: Insulin human inhalation powder was studied in adults with type 1 diabetes in combination with basal insulin. The efficacy was compared to insulin aspart. Insulin human inhalation powder was also studied in adults with type 2 diabetes in combination with oral antidiabetic medications. The efficacy was compared to placebo inhalation.

- The mean reduction for insulin human inhalation powder and basal insulin was -0.21%, compared to -0.40% with insulin aspart and basal insulin at Week 24.
- The mean reduction for insulin human inhalation powder and oral antidiabetic agents was -0.82%, compared to -0.42% with placebo and oral antidiabetic agents at Week 24.

Toujeo® (Insulin Glargine)[10]

Indications: Toujeo® (insulin glargine) is a long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.

Dosing: Insulin glargine is available as 300unit/mL in a 1.5mL SoloStar® disposable prefilled pen.

- Dosing is individualized
- Insulin glargine should be administered once daily at the same time every day

Mechanism of Action: Insulin lowers blood glucose levels by stimulating peripheral glucose uptake by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis in adipocytes, inhibits proteolysis, and enhances protein synthesis.

Contraindications:

- Use of insulin glargine during episodes of hypoglycemia
- Hypersensitivity to insulin glargine or its excipients

Warnings/Precautions:

- Disposable prefilled pens should not be shared between patients, even if the needle is changed.
- Change in Insulin Regimen: Changes in insulin regimens should be carried out under close medical supervision.
- Hypoglycemia: Hypoglycemia could be life-threatening. The frequency of glucose monitoring should be increased with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, and physical activity; and in patients with renal or hepatic impairment and hypoglycemia unawareness.

- Medication Errors: Accidental mix-ups between insulin products can occur. Patients should be instructed to check insulin labels before injection.
- Hypersensitivity Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products.
- Hypokalemia: Hypokalemia could be life-threatening. Potassium levels should be monitored in patients at risk of hypokalemia and treated if indicated.
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Patients should be observed for signs and symptoms of heart failure; consideration should be given to a dosage reduction or to discontinuation if heart failure occurs.

Adverse reactions: The most common adverse reactions associated with insulin glargine (≥5%) were hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema and weight gain.

Efficacy: The efficacy of Toujeo® given once daily was compared to that of Lantus® given once daily in open-label, randomized, active-control, parallel studies of up to 26 weeks in patients with type 1 and type 2 diabetes mellitus. The reduction in HbA1c and fasting plasma glucose with Toujeo® titrated to goal was similar to that of Lantus® titrated to goal.

Recommendations

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

Diabetes Medications Tier-2 Approval Criteria:

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

Diabetes Medications Tier-3 Approval Criteria:

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

Diabetes Medications Special Prior Authorization Approval Criteria:

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

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

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

Afrezza® (Insulin Human) Inhalation Powder Approval Criteria:

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

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

Toujeo® (Insulin Glargine) Approval Criteria:

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

Utilization Details of Diabetic Medications: Fiscal Year 2014

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
TIER-1 PRODUCTS						
METFORMIN PRODUCTS						
METFORMIN TAB 500MG	23,250	6,486	$163,723.68	$0.22	$7.04	3.24%
METFORMIN TAB 850MG	1,954	450	$14,824.82	$0.24	$7.59	0.29%
METFORMIN TAB 1000MG	19,153	4,434	$154,057.69	$0.25	$8.04	3.05%
METFORMIN TAB 500MG ER	3,965	1,253	$36,382.02	$0.27	$9.18	0.72%
METFORMIN TAB 750MG ER	414	136	$5,568.30	$0.35	$13.45	0.11%
SUBTOTAL	**48,736**	**12,759**	**$374,556.51**	**$0.24**	**$7.69**	**7.41%**
CHLORPROPAMIDE PRODUCTS						
CHLORPROPAM TAB 100MG	3	1	$78.06	$0.37	$26.02	0.00%
SUBTOTAL	**3**	**1**	**$78.06**	**$0.37**	**$26.02**	**0.00%**
GLIMEPIRIDE PRODUCTS						
GLIMEPIRIDE TAB 1MG	372	123	$2,606.65	$0.17	$7.01	0.05%
GLIMEPIRIDE TAB 2MG	1,121	305	$9,407.16	$0.22	$8.39	0.19%
GLIMEPIRIDE TAB 4MG	2,161	491	$18,630.47	$0.24	$8.62	0.37%
SUBTOTAL	**3,654**	**919**	**$30,644.28**	**$0.22**	**$8.39**	**0.61%**
GLIPIZIDE PRODUCTS						
GLIPIZIDE TAB 5MG	3,179	862	$20,300.53	$0.18	$6.39	0.40%
GLIPIZIDE TAB 10MG	3,091	737	$21,751.97	$0.20	$7.04	0.43%
GLIPIZIDE XL TAB 2.5MG	474	144	$7,175.49	$0.38	$15.14	0.14%
GLIPIZIDE XL TAB 5MG	1,127	339	$16,346.70	$0.37	$14.50	0.33%
GLIPIZIDE XL TAB 10MG	1,878	517	$42,934.08	$0.61	$45.72	0.84%
SUBTOTAL	**9,749**	**2,599**	**$108,508.77**	**$0.31**	**$11.13**	**2.14%**
GLYBURIDE PRODUCTS						
GLYBURIDE TAB 1.25MG	116	47	$1,237.45	$0.29	$10.67	0.02%
GLYBURID MCR TAB 1.5MG	8	3	$35.21	$0.12	$4.40	0.00%
GLYBURIDE TAB 2.5MG	1,382	631	$14,856.07	$0.31	$10.75	0.29%
GLYBURID MCR TAB 3MG	86	20	$772.01	$0.24	$8.98	0.02%
GLYBURIDE TAB 5MG	5,204	1,297	$85,754.20	$0.50	$16.48	1.70%
GLYBURID MCR TAB 6MG	70	15	$827.93	$0.34	$11.83	0.02%
SUBTOTAL	**6,866**	**2,013**	**$103,482.87**	**$0.45**	**$15.07**	**2.05%**
TOLBUTAMIDE PRODUCTS						
TOLBUTAMIDE TAB 500MG	10	1	$1,200.30	$4.00	$120.03	0.02%
SUBTOTAL	**10**	**1**	**$1,200.30**	**$4.00**	**$120.03**	**0.02%**
GLIPIZIDE/METFORMIN PRODUCTS						
GLIP/METFORM TAB 2.5-250M	9	4	$297.87	$0.66	$33.10	0.01%
GLIP/METFORM TAB 2.5-500M	58	20	$2,295.08	$1.20	$39.57	0.05%
GLIP/METFORM TAB 5-500MG	143	30	$6,811.07	$1.51	$47.63	0.13%
SUBTOTAL	**210**	**54**	**$9,404.02**	**$1.37**	**$44.78**	**0.19%**
GLYBURIDE/METFORMIN PRODUCTS						
GLYB/METFORM TAB 1.25-250	16	2	$232.52	$0.48	$14.53	0.00%
GLYB/METFORM TAB 2.5-500	299	64	$3,986.21	$0.40	$13.33	0.08%
GLYB/METFORM TAB 5-500MG	871	168	$12,482.92	$0.46	$14.33	0.25%
SUBTOTAL	**1,186**	**234**	**$16,701.65**	**$0.33**	**$14.08**	**0.33%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
ACARBOSE PRODUCTS						
ACARBOSE TAB 25MG	52	16	$2,072.77	$1.29	$39.83	0.04%
ACARBOSE TAB 50MG	53	13	$2,276.95	$1.42	$42.18	0.04%
ACARBOSE TAB 100MG	7	3	$230.71	$0.56	$32.96	0.00%
SUBTOTAL	**112**	**32**	**$4,580.43**	**$1.26**	**$40.89**	**0.08%**
NATEGLINIDE PRODUCTS						
NATEGLINIDE TAB 60MG	12	8	$771.38	$2.11	$64.28	0.02%
NATEGLINIDE TAB 120MG	81	21	$5,761.33	$2.15	$71.13	0.11%
SUBTOTAL	**93**	**29**	**$6,532.71**	**$2.15**	**$70.24**	**0.13%**
TIER-1 SUBTOTAL	**70,619**	**18,640**	**$655,689.60**	**$0.28**	**$9.41**	**12.96%**
TIER-2 PRODUCTS						
SAXAGLIPTIN PRODUCTS						
ONGLYZA TAB 2.5MG	67	23	$20,682.16	$9.30	$308.69	0.41%
ONGLYZA TAB 5MG	624	149	$203,057.36	$9.38	$325.41	4.01%
SUBTOTAL	**691**	**172**	**$223,739.52**	**$9.38**	**$323.79**	**4.42%**
SITAGLIPTIN PRODUCTS						
JANUVIA TAB 25MG	81	22	$32,237.50	$9.70	$397.99	0.64%
JANUVIA TAB 50MG	850	191	$344,677.02	$10.95	$405.50	6.81%
JANUVIA TAB 100MG	3,339	704	$1,266,475.72	$9.54	$379.30	25.04%
SUBTOTAL	**4,270**	**917**	**$1,643,390.24**	**$9.80**	**$384.87**	**32.49%**
SAXAGLIPTIN/METFORMIN PRODUCTS						
KOMBIGLYZE TAB 5-500MG	20	8	$9,509.54	$8.34	$475.48	0.19%
KOMBIGLYZE TAB 2.5-1000	86	17	$22,827.00	$7.93	$265.43	0.45%
KOMBIGLYZE TAB 5-1000MG	81	19	$33,917.27	$9.58	$418.73	0.67%
SUBTOTAL	**187**	**44**	**$66,253.81**	**$8.76**	**$354.30**	**1.31%**
SITAGLIPTIN/METFORMIN PRODUCTS						
JANUMET TAB 50-500MG	369	76	$115,181.32	$9.31	$312.14	2.28%
JANUMET TAB 50-1000	1,534	298	$429,992.07	$9.00	$280.31	8.50%
JANUMET XR TAB 50-500MG	8	2	$1,158.59	$4.83	$144.82	0.02%
JANUMET XR TAB 50-1000	161	44	$41,865.95	$8.61	$260.04	0.83%
JANUMET XR TAB 100-1000	231	43	$64,898.68	$9.41	$280.95	1.28%
SUBTOTAL	**2,303**	**463**	**$653,096.61**	**$9.05**	**$283.59**	**12.91%**
REPAGLINIDE PRODUCTS						
REPAGLINIDE TAB 0.5MG	14	7	$3,266.78	$8.23	$233.34	0.07%
REPAGLINIDE TAB 1MG	33	11	$7,859.60	$7.94	$238.17	0.16%
REPAGLINIDE TAB 2MG	32	11	$11,817.11	$12.44	$369.28	0.23%
SUBTOTAL	**79**	**29**	**$22,943.49**	**$9.82**	**$290.42**	**0.46%**
EXENATIDE PRODUCTS						
BYETTA INJ 5MCG	39	13	$15,222.45	$13.01	$390.32	0.30%
BYETTA INJ 10MCG	101	23	$49,993.87	$12.70	$494.99	0.99%
BYDUREON INJ	74	26	$30,807.01	$14.48	$416.31	0.61%
SUBTOTAL	**214**	**62**	**$96,023.33**	**$13.27**	**$448.71**	**1.90%**
LIRAGLUTIDE PRODUCTS						
VICTOZA INJ 18MG/3ML	2,225	513	$1,072,096.80	$15.30	$481.84	21.20%
SUBTOTAL	**2,225**	**513**	**$1,072,096.80**	**$15.30**	**$481.84**	**21.20%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
PIOGLITAZONE PRODUCTS						
PIOGLITAZONE TAB 15MG	569	161	$7,214.04	$0.29	$12.68	0.14%
PIOGLITAZONE TAB 30MG	1,007	221	$14,330.35	$0.35	$14.23	0.28%
PIOGLITAZONE TAB 45MG	533	129	$7,743.41	$0.33	$14.53	0.15%
SUBTOTAL	**2,109**	**511**	**$29,287.80**	**$0.33**	**$13.89**	**0.57%**
TIER-2 SUBTOTAL	**12,078**	**2,711**	**$3,806,831.60**	**$8.67**	**$315.19**	**75.26%**
TIER-3 PRODUCTS						
ALOGLIPTIN PRODUCTS						
NESINA TAB 25MG	14	6	$4,679.95	$9.75	$334.28	0.09%
SUBTOTAL	**14**	**6**	**$4,679.95**	**$9.75**	**$334.28**	**0.09%**
ALOGLIPTIN/PIOGLITAZONE PRODUCTS						
OSENI TAB 25-15MG	8	3	$2,322.83	$10.06	$290.35	0.05%
OSENI TAB 25-30MG	7	4	$2,654.49	$9.83	$379.21	0.05%
SUBTOTAL	**15**	**7**	**$4,977.32**	**$9.93**	**$331.82**	**0.10%**
LINAGLIPTIN PRODUCTS						
TRADJENTA TAB 5MG	1,447	276	$394,977.98	$9.29	$272.96	7.81%
SUBTOTAL	**1,447**	**276**	**$394,977.98**	**$9.29**	**$272.96**	**7.81%**
LINAGLIPTIN/METFORMIN PRODUCTS						
JENTADUETO TAB 2.5-500	18	5	$5,188.40	$9.61	$288.24	0.10%
JENTADUETO TAB 2.5-850	12	1	$3,387.26	$9.41	$282.27	0.07%
JENTADUETO TAB 2.5-1000	201	53	$62,002.78	$9.42	$308.47	1.23%
SUBTOTAL	**231**	**59**	**$70,578.44**	**$9.43**	**$305.53**	**1.40%**
PIOGLITAZONE/METFORMIN PRODUCTS						
PIOGLITA/MET TAB 15-500MG	117	14	$19,555.73	$5.17	$167.14	0.39%
PIOGLITA/MET TAB 15-850MG	79	13	$15,465.17	$5.07	$195.76	0.31%
ACTOPLUS MET XR 15-1000	12	2	$5,022.54	$13.95	$418.55	0.10%
ACTOPLUS MET XR 30-1000	4	1	$5,083.02	$14.12	$1,270.76	0.10%
SUBTOTAL	**212**	**30**	**$45,126.46**	**$5.97**	**$212.86**	**0.90%**
CANAGLIFLOZIN PRODUCTS						
INVOKANA TAB 100MG	99	30	$28,450.97	$9.68	$287.38	0.56%
INVOKANA TAB 300MG	74	24	$21,705.90	$9.78	$293.32	0.43%
SUBTOTAL	**173**	**54**	**$50,156.87**	**$9.72**	**$289.92**	**0.99%**
DAPAGLIFLOZIN PRODUCTS						
FARXIGA TAB 5MG	6	5	$1,822.02	$10.12	$303.67	0.04%
FARXIGA TAB 10MG	1	1	$305.92	$10.20	$305.92	0.01%
SUBTOTAL	**7**	**6**	**$2,127.94**	**$10.13**	**$303.99**	**0.05%**
TIER-3 SUBTOTAL	**2,099**	**438**	**$572,624.96**	**$8.96**	**$272.81**	**11.34%**
SPECIAL PA PRODUCTS						
PRAMLINTIDE PRODUCTS						
SYMLINPEN 60 INJ 1000MCG	4	1	$1,855.08	$16.27	$463.77	0.04%
SYMLNPEN 120 INJ 1000MCG	7	1	$8,269.58	$39.38	$1,181.37	0.16%
SUBTOTAL	**11**	**2**	**$10,124.66**	**$31.25**	**$920.42**	**0.20%**
METFORMIN PRODUCTS						
METFORMIN SOL 500MG/5ML	15	6	$1,891.08	$4.20	$126.07	0.04%
METFORMIN ER TAB 1000MG	24	7	$8,730.38	$9.09	$363.77	0.17%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	PERCENT COST
GLUMETZA TAB 1000MG	3	1	$1,732.71	$19.25	$577.57	0.03%
SUBTOTAL	**42**	**14**	**$12,354.17**	**$7.77**	**$294.15**	**0.24%**
SPECIAL PA SUBTOTAL	**53**	**16**	**$22,478.83**	**$12.32**	**$424.13**	**0.44%**
TOTAL	**84,849**	**14,644***	**$5,057,624.99**	**$1.77**	**$59.61**	**100%**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 3/20/15. Last accessed 3/20/15.
[2] Tanzeum™ Prescribing Information. Available online at: https://www.gsksource.com/gskprm/htdocs/documents/TANZEUM-PI-MG-IFU-COMBINED.PDF. Last revised 3/2015. Last accessed 3/20/15.
[3] Trulicity™ Prescribing Information. Available online at: http://pi.lilly.com/us/trulicity-uspi.pdf. Last revised 3/2015. Last accessed 3/20/15.
[4] Cycloset® Prescribing Information. Available online at: http://cdn.salix.com/shared/pi/cycloset-pi.pdf?id=767627. Last revised 9/2010. Last accessed 3/20/15
[5] Jardiance® Prescribing Information. Available online at: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Jardiance/jardiance.pdf. Last revised 8/2014. Last accessed 3/20/15.
[6] Invokamet™ Prescribing Information. Available online at: http://www.invokanahcp.com/invokamet/prescribing-information.pdf. Last revised 3/2015. Last accessed 3/20/15.
[7] Xigduo™ XR Prescribing Information. Available online at: http://www.azpicentral.com/xigduo/pi_xigduoxr.pdf#page=1. Last revised 10/2014. Last accessed 3/20/15.
[8] Glyxambi® Prescribing Information. Available online at: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Glyxambi/Glyxambi.pdf. Last revised 1/2015. Last accessed 3/20/15.
[9] Afrezza® Prescribing Information. Available online at: http://products.sanofi.us/afrezza/afrezza.pdf. Last revised 10/2014. Last accessed 3/20/15.
[10] Toujeo® Prescribing Information. Available online at: http://products.sanofi.us/toujeo/toujeo.pdf. Last revised 2/2015. Last accessed 3/20/15.

Appendix J

Fiscal Year 2014 Annual Review of Pediculicides

Oklahoma Health Care Authority
April 2015

Current Prior Authorization Criteria

Over-the-counter (OTC) treatments for lice are a covered benefit for all members. A prescription is required for coverage, and fills are limited to one individual package size for a seven day supply.

Pediculicides Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial with one Tier-1 medication with inadequate response or adverse effect; and
3. Requested medication must be age-appropriate.
4. A clinical exception to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

Pediculicides Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial with one Tier-1 medication with inadequate response or adverse effect; and
3. Trials with all available Tier-2 medication(s) with inadequate response or adverse effect; and
4. Requested medication must be age-appropriate.
5. A clinical exception to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

Pediculicides*		
Tier-1	**Tier-2**	**Tier-3**
Covered OTC Lice Products	benzyl alcohol (Ulesfia®) lotion	lindane lotion & shampoo
Generics with SMAC Pricing	spinosad (Natroba™) suspension	malathion (Ovide®) lotion
	ivermectin (Sklice®) lotion	

*Tier structure based on supplemental rebate participation.

The following restrictions also apply for each individual product based on FDA approval information:

1. **Benzyl Alcohol (Ulesfia®) Lotion:**
   a. Member must be at least six months old; and
   b. Due to mechanism of action, requires retreatment after seven days; and
   c. Hair length is required in order to approve the appropriate number of bottles if requesting more than two bottles per treatment (four bottles for both treatments).
2. **Crotamiton (Eurax®) Cream & Lotion:**
   a. Diagnosis of scabies; and
   b. Member must be at least 18 years of age; and

c. Member must have used permethrin 5% cream in the past seven to fourteen days with inadequate results; and
d. A quantity limit of 60 grams per 30 days will apply.

3. **Ivermectin (Sklice®) Lotion:**
   a. Member must be at least six months of age; and
   b. A quantity limit of 117mL per seven days will apply.
4. **Lindane Lotion & Shampoo:**
   a. Member must be at least 13 years old or weigh at least 110 pounds; and
   b. A quantity limit of 60mL per seven days will apply; and
   c. One seven day supply per 30 days maximum.
5. **Malathion (Ovide®) lotion:**
   a. Member must be at least six years of age; and
   b. A quantity limit of 60mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.
6. **Spinosad (Natroba™) Suspension:**
   a. Member must be at least six months of age; and
   b. A quantity limit of 120mL per seven days will apply; may be repeated once if needed for current infestation after seven days from original fill date.

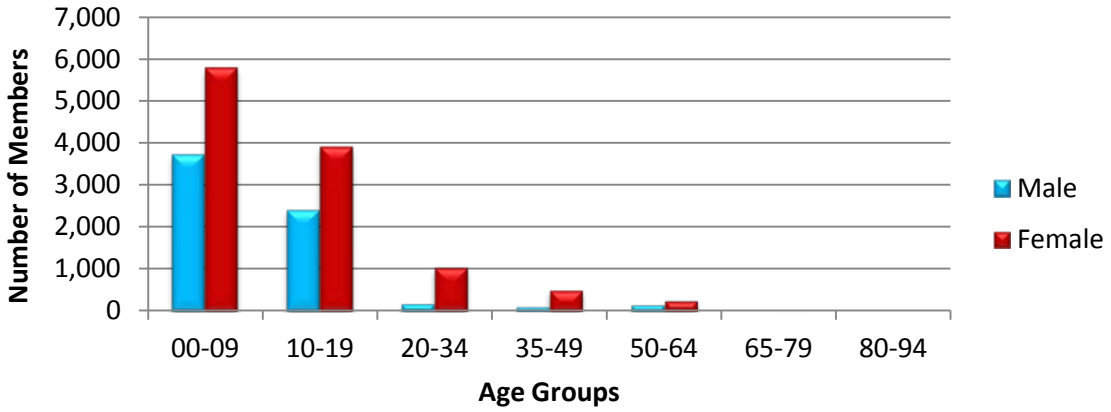
Utilization of Pediculicides: Fiscal Year 2014

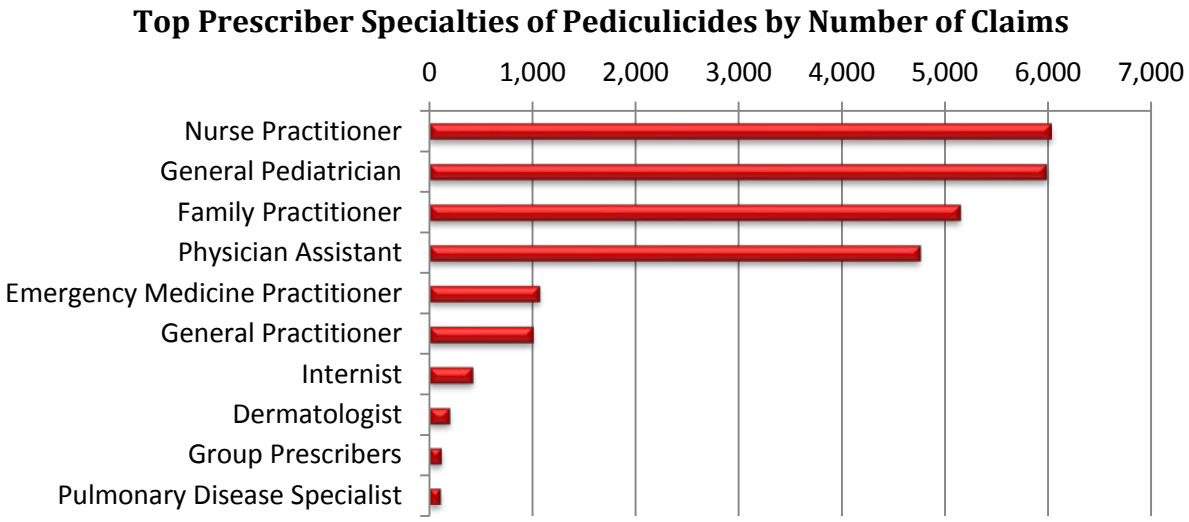
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2013	17,558	24,983	$1,071,009.93	$42.87	$4.04	1,784,634	264,984
2014	18,135	25,381	$1,502,697.45	$59.21	$5.75	1,877,707	261,367
% Change	**3.30%**	**1.60%**	**40.30%**	**38.10%**	**42.30%**	**5.20%**	**-1.40%**
Change	**577**	**398**	**$431,687.52**	**$16.34**	**$1.71**	**93,073**	**-3,617**

*Total number of unduplicated members.

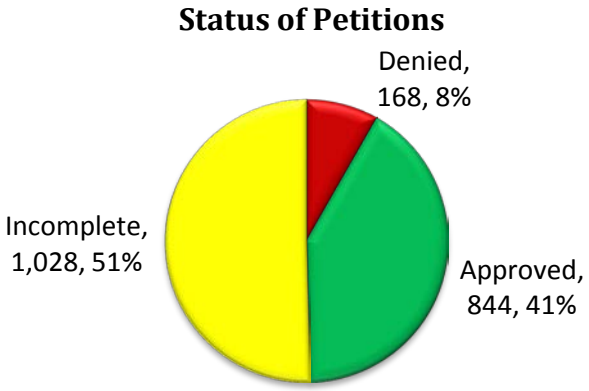
Demographics of Members Utilizing Pediculicides





Prior Authorization of Pediculicides

There were 2,040 petitions submitted for pediculicides during fiscal year 2014. The following chart shows the status of the submitted petitions. Computer edits are in place to detect Tier-1 medications in members' recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.



Market News and Updates[1,2,3]

Anticipated Patent Expirations:

- Ulesfia® (benzyl alcohol): May 2024
- Sklice® (ivermectin): October 2027

FDA Updates:

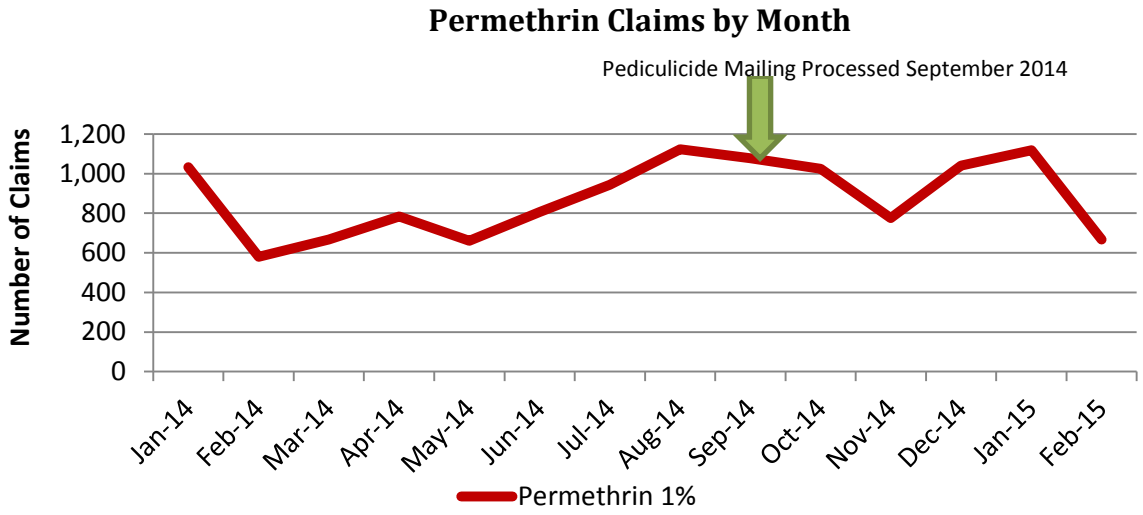
- ParaPRO announced that the FDA has approved an expanded age range for Natroba™ (spinosad) suspension, to include children age six months of age or older who have head lice. Natroba™ was initially approved in 2011 for use in patients four years of age or older.

Clinical Studies:

- An article published in the 2014 *Journal of Medical Entomology* examined permethrin resistant lice in North America. Genotyping found the frequency of permethrin resistant lice in the United States to be 84.4% from 1999 to 2009 and increased to 99.6% from 2007 to 2009. Current treatment guidelines from the American Academy of Pediatrics were last updated in 2010 and continue to recommend permethrin 1% as first-line treatment for lice infestations.

Summary of Pediculicide Mailing

- **September 2014 Pediculicide Mailing:**
  - An educational fax blast was sent to pharmacies to increase appropriate and cost-effective use of over-the-counter (OTC) lice treatments for SoonerCare members. A similar letter was also sent to SoonerCare prescribers of lice products; prescribers were eligible for inclusion in the mailing if they had prescribed at least one lice treatment for a SoonerCare member within the six months prior to the report date.
  - The letter informed prescribers and pharmacies that OTC treatments for lice are a covered benefit for all SoonerCare members. A prescription is required for coverage, and fills are limited to a quantity of four ounces for a seven day supply.
  - A list of the covered OTC treatments for lice was also included in the letter. The covered OTC products include generic Nix® products (permethrin 1%), and all products include a nit comb, which should be used, along with supplemental measures (washing bedding and clothing in hot water, etc.) to help ensure the initial treatment of lice is effective and to avoid re-infestation[3,4].
  - The chart below shows the number of permethrin claims by month from January 2014 to February 2015. The chart provides claims data for all covered OTC permethrin products.
  - Claims analysis following the mailing did not reveal an increase in OTC permethrin utilization in the SoonerCare population.



Recommendations

The College of Pharmacy does not recommend any changes at this time. The Oklahoma Health Care Authority is evaluating alternative supplemental rebate options for the Pediculicide Product Based Prior Authorization category.

Utilization Details of Pediculicides: Fiscal Year 2014

Product Utilized	Total Claims	Total Members	Total Cost	Cost/ Day	Cost/ Claim
OTC Permethrin Products					
PERMETHRIN LOTION 1%	8,411	5,957	$101,306.29	$1.25	$12.04
LICE LOTION TREATMENT 1%	942	669	$14,235.79	$1.35	$15.11
LICE LOTION TREATMENT 1%	271	179	$2,787.10	$1.29	$10.28
LICE LIQUID TREATMENT 1%	46	26	$608.06	$1.14	$13.22
Subtotal	**9,670**	**6,738**	**$118,937.24**	**$1.26**	**$12.30**
Prescription Permethrin Products					
PERMETHRIN CREAM 5%	14,923	11,711	$1,224,689.51	$7.98	$82.07
Tier-1 Subtotal	**24,593**	**17,864**	**$1,343,626.75**	**$5.42**	**$54.63**
Benzyl Alcohol Products					
ULESFIA LOTION 5%	487	416	$100,492.15	$9.90	$206.35
Spinosad Products					
SPINOSAD SUSPENSION 0.9%	206	157	$38,968.11	$17.27	$189.17
NATROBA SUSPENSION 0.9%	63	54	$15,023.84	$25.08	$238.47
Subtotal	**269**	**205**	**$53,991.95**	**$18.91**	**$200.71**
Ivermectin Products					
SKLICE LOTION 0.5%	1	1	$276.34	$39.40	$276.34
Tier-2 Subtotal	**757**	**610**	**$154,760.44**	**$11.90**	**$204.44**
Malathion Products					
MALATION LOTION 0.5%	13	10	$2,050.88	$16.67	$157.76
OVIDE LOTION 0.5%	3	3	$487.53	$23.22	$162.51
Subtotal	**16**	**13**	**$2,538.41**	**$17.63**	**$158.65**
Lindane Products					
LINDANE LOTION 1%	1	1	$87.99	$8.80	$87.99
Tier-3 Subtotal	**17**	**14**	**$2,626.40**	**$17.05**	**$154.49**
Crotamiton Products					
EURAX CREAM 10%	13	13	$1,629.88	$4.18	$125.38
EURAX LOTION 10%	1	1	$53.98	$1.80	$53.98
Subtotal	**14**	**14**	**$1,683.86**	**$4.01**	**$120.28**
Total	**25,381**	**18,135***	**$1,502,697.45**	**$5.75**	**$59.21**

*Total number of unduplicated members.

[1] FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 01/21/2015. Last accessed 03/20/2015.

[2] Yoon KS, Previte DJ, Hodgeon HE, et al. Knockdown Resistance Allele Frequencies in North American Head Louse (Anoplura:Pediculicide) Populations. *J. Med. Entomol.* 2014; 51(2): 450-457.

[3] Frankowski BL, Bocchini Jr JA, Council on School Health and Committee on Infectious Diseases. Head Lice. *Pediatrics: Official Journal of the American Academy of Pediatrics (AAP).* 2010; 126: 392-403.

[4] Parasites – Head Lice: Treatment, General Guidelines. Centers for Disease Control and Prevention (CDC). Available online at: http://www.cdc.gov/parasites/lice/head/treatment.html. Last revised 9/24/13.

Appendix K

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

FDA NEWS RELEASE

For Immediate Release: March 25th, 2015

FDA approves new treatment for diabetic retinopathy in patients with diabetic macular edema

The U.S. Food and Drug Administration expanded the approved use for Eylea (aflibercept) injection to treat diabetic retinopathy in patients with diabetic macular edema.

Diabetic retinopathy (DR) is the most common diabetic eye disease and is a leading cause of blindness in adults in the United States. According to the Centers for Disease Control and Prevention, diabetes (type 1 and type 2) affects more than 29 million people in the United States and is the leading cause of new blindness among people ages 20 to 74 years. In 2008, 33 percent of adults with diabetes aged 40 years or older had some form of DR. In some cases of DR with diabetic macular edema (DME), abnormal new blood vessels grow on the surface of the retina. Severe vision loss or blindness can occur if the new blood vessels break.

In February, the FDA approved Lucentis (ranibizumab injection) 0.3 mg to treat DR in patients with DME. Eylea is administered by a physician as an injection into the eye once a month for the first five injections and then once every two months. It is intended to be used along with appropriate interventions to control blood sugar, blood pressure and cholesterol.

The safety and efficacy of Eylea to treat DR in patients with DME were evaluated in 679 participants in two clinical studies where participants were randomly assigned to receive Eylea or macular laser photocoagulation, a laser-based treatment used to burn small areas of the retina. At week 100, participants being treated with Eylea showed significant improvement in the severity of their DR, compared to patients who did not receive Eylea.

The most common side effects associated with Eylea include bleeding of the conjunctiva (the tissue that lines the inside of the eyelids and covers the white part of the eye); eye pain; cataracts; floaters; increased pressure inside the eye (increased intraocular pressure); and separation of the interior jelly of the eye from the retina (vitreous detachment). Serious adverse reactions include infection within the eye (endophthalmitis) and retinal detachments.

The FDA granted breakthrough therapy designation to Eylea for the treatment of DR with DME. The FDA can designate a drug a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients with serious or life-threatening conditions. The FDA also reviewed the new use for Eylea under the agency's priority review program, which provides for an expedited review of drugs that demonstrate the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition.

The FDA previously approved Eylea to treat wet (neovascular) age-related macular degeneration, a condition in which abnormal blood vessels grow and leak fluid into the macula. Eylea is also approved to treat DME and macular edema secondary to retinal vein occlusions, both of which cause fluid to leak into the macula resulting in blurred vision.

Eylea is marketed by Tarrytown, N.Y.-based Regeneron Pharmaceuticals Inc. Lucentis is marketed by South San Francisco, California-based Genentech, a subsidiary of Roche Pharmaceuticals.

FDA NEWS RELEASE

For Immediate Release: March 10th, 2015

FDA approves first therapy for high-risk neuroblastoma

The U.S. Food and Drug Administration approved Unituxin (dinutuximab) as part of first-line therapy for pediatric patients with high-risk neuroblastoma, a type of cancer that most often occurs in young children. Neuroblastoma is a rare cancer that forms from immature nerve cells. It usually begins in the adrenal glands but may also develop in the abdomen, chest or in nerve tissue near the spine. Neuroblastoma typically occurs in children younger than five years of age. According to the National Cancer Institute, neuroblastoma occurs in approximately one out of 100,000 children and is slightly more common in boys. There are an

estimated 650 new cases of neuroblastoma diagnosed in the United States each year. Patients with high-risk neuroblastoma have a 40 to 50 percent chance of long term survival despite aggressive therapy.
Unituxin is an antibody that binds to the surface of neuroblastoma cells. Unituxin is being approved for use as part of a multimodality regimen, including surgery, chemotherapy and radiation therapy for patients who achieved at least a partial response to prior first-line multiagent, multimodality therapy.
The FDA granted Unituxin priority review and orphan product designation. Priority review shortens the timeframe for review of drug applications by four months, compared to standard reviews, and is granted to drugs that, if approved, will provide a significant improvement in safety or effectiveness in the treatment of a serious condition. Orphan product designation is given to drugs intended to treat rare diseases. With this approval, the FDA also issued a rare pediatric disease priority review voucher to United Therapeutics, which confers priority review to a subsequent drug application that would not otherwise qualify for priority review. This is the second rare pediatric disease priority review voucher granted by the FDA since inception of the rare pediatric disease review voucher program, which is designed to encourage development of new therapies for prevention and treatment of certain rare pediatric diseases.
The safety and efficacy of Unituxin were evaluated in a clinical trial of 226 pediatric participants with high-risk neuroblastoma whose tumors shrunk or disappeared after treatment with multiple-drug chemotherapy and surgery followed by additional intensive chemotherapy and who subsequently received bone marrow transplantation support and radiation therapy. Participants were randomly assigned to receive either an oral retinoid drug, isotretinoin (RA), or Unituxin in combination with interleukin-2 and granulocyte-macrophage colony-stimulating factor, which are thought to enhance the activity of Unituxin by stimulating the immune system, and RA.
Three years after treatment assignment, 63 percent of participants receiving the Unituxin combination were alive and free of tumor growth or recurrence, compared to 46 percent of participants treated with RA alone. In an updated analysis of survival, 73 percent of participants who received the Unituxin combination were alive compared with 58 percent of those receiving RA alone.
Unituxin carries a Boxed Warning alerting patients and health care professionals that Unituxin irritates nerve cells, causing severe pain that requires treatment with intravenous narcotics and can also cause nerve damage and life-threatening infusion reactions, including upper airway swelling, difficulty breathing, and low blood pressure, during or shortly following completion of the infusion. Unituxin may also cause other serious side effects including infections, eye problems, electrolyte abnormalities and bone marrow suppression.
The most common side effects of Unituxin were severe pain, fever, low platelet counts, infusion reactions, low blood pressure, low levels of salt in the blood, elevated liver enzymes, anemia, vomiting, diarrhea, low potassium levels in the blood, capillary leak syndrome (which is characterized by a massive leakage of plasma and other blood components from blood vessels into neighboring body cavities and muscles), low numbers of infection-fighting white blood cells (neutropenia and lymphopenia), hives, and low blood calcium levels.
Unituxin is marketed by Silver Spring, Maryland-based United Therapeutics.

FDA NEWS RELEASE

For Immediate Release: March 6th, 2015

FDA approves Farydak for treatment of multiple myeloma

The U.S. Food and Drug Administration approved Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States.
Biological products are generally derived from a living organism. They can come from many sources, including humans, animals, microorganisms or yeast.
A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
Sandoz, Inc.'s Zarxio is biosimilar to Amgen Inc.'s Neupogen (filgrastim), which was originally licensed in 1991. Zarxio is approved for the same indications as Neupogen, and can be prescribed by a health care professional for:

- patients with cancer receiving myelosuppressive chemotherapy;
- patients with acute myeloid leukemia receiving induction or consolidation chemotherapy;
- patients with cancer undergoing bone marrow transplantation;
- patients undergoing autologous peripheral blood progenitor cell collection and therapy; and

- patients with severe chronic neutropenia.

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was passed as part of the Affordable Care Act that President Obama signed into law in March 2010. The BPCI Act created an abbreviated licensure pathway for biological products shown to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product, called the "reference product." This abbreviated licensure pathway under section 351(k) of the Public Health Service Act permits reliance on certain existing scientific knowledge about the safety and effectiveness of the reference product, and enables a biosimilar biological product to be licensed based on less than a full complement of product-specific preclinical and clinical data.

A biosimilar product can only be approved by the FDA if it has the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product, and only for the indication(s) and condition(s) of use that have been approved for the reference product. The facilities where biosimilars are manufactured must also meet the FDA's standards.

The FDA's approval of Zarxio is based on review of evidence that included structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates Zarxio is biosimilar to Neupogen. Zarxio has been approved as biosimilar, not as an interchangeable product. **Under the BPCI Act, a biological product that that has been approved as an "interchangeable" may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.**

The most common expected side effects of Zarxio are aching in the bones or muscles and redness, swelling or itching at injection site. Serious side effects may include spleen rupture; serious allergic reactions that may cause rash, shortness of breath, wheezing and/or swelling around the mouth and eyes; fast pulse and sweating; and acute respiratory distress syndrome, a lung disease that can cause shortness of breath, difficulty breathing or increase the rate of breathing.

For this approval, the FDA has designated a placeholder nonproprietary name for this product as "filgrastim-sndz." The provision of a placeholder nonproprietary name for this product should not be viewed as reflective of the agency's decision on a comprehensive naming policy for biosimilar and other biological products. While the FDA has not yet issued draft guidance on how current and future biological products marketed in the United States should be named, the agency intends to do so in the near future.

Sandoz, a Novartis company, is based in Princeton, New Jersey. Neupogen is marketed by Amgen, based in Thousand Oaks, California.

FDA NEWS RELEASE

For Immediate Release: March 6th, 2015

FDA approves new antifungal drug Cresemba

The U.S. Food and Drug Administration approved Cresemba (isavuconazonium sulfate), a new antifungal drug product used to treat adults with invasive aspergillosis and invasive mucormycosis, rare but serious infections.

Aspergillosis is a fungal infection caused by Aspergillus species, and mucormycosis is caused by the Mucorales fungi. These infections occur most often in people with weakened immune systems.

Cresemba belongs to a class of drugs called azole antifungal agents, which target the cell membrane of a fungus. Cresemba is available in oral and intravenous formulations.

Cresemba is the sixth approved antibacterial or antifungal drug product designated as a Qualified Infectious Disease Product (QIDP). This designation is given to antibacterial or antifungal drug products that treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

As part of its QIDP designation, Cresemba was given priority review, which provides an expedited review of the drug's application. The QIDP designation also qualifies Cresemba for an additional five years of marketing exclusivity to be added to certain exclusivity periods already provided by the Food, Drug, and Cosmetic Act. As these types of fungal infections are rare, the FDA also granted Cresemba orphan drug designations for invasive aspergillosis and invasive mucormycosis.

The approval of Cresemba to treat invasive aspergillosis was based on a clinical trial involving 516 participants randomly assigned to receive either Cresemba or voriconazole, another drug approved to treat invasive aspergillosis. Cresemba's approval to treat invasive mucormycosis was based on a single-arm clinical trial involving 37 participants treated with Cresemba and compared with the natural disease

progression associated with untreated mucormycosis. Both studies showed Cresemba was safe and effective in treating these serious fungal infections.
The most common side effects associated with Cresemba include nausea, vomiting, diarrhea, headache, abnormal liver blood tests, (hypokalemia), constipation, shortness of breath, coughing and tissue swelling. Cresemba may also cause serious side effects including liver problems, infusion reactions and severe allergic and skin reactions.
Cresemba is marketed by Astellas Pharma US, Inc., based in Northbrook, Illinois.

FDA NEWS RELEASE

For Immediate Release: March 4th, 2015
FDA expands approved use of Opdivo to treat lung cancer

The U.S. Food and Drug Administration to expanded the approved use of Opdivo (nivolumab) to treat patients with advanced (metastatic) squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.
Lung cancer is the leading cause of cancer death in the United States, with an estimated 224,210 new diagnoses and 159,260 deaths in 2014. The most common type of lung cancer, NSCLC affects seven out of eight lung cancer patients, occurring when cancer forms in the cells of the lung.
Opdivo works by inhibiting the cellular pathway known as PD-1 protein on cells that blocks the body's immune system from attacking cancerous cells. Opdivo is intended for patients who have previously been treated with platinum-based chemotherapy.
Opdivo's efficacy to treat squamous NSCLC was established in a randomized trial of 272 participants, of whom 135 received Opdivo and 137 received docetaxel. The trial was designed to measure the amount of time participants lived after starting treatment (overall survival). On average, participants who received Opdivo lived 3.2 months longer than those participants who received docetaxel.
The safety and efficacy of Opdivo to treat squamous NSCLC was supported by a single-arm trial of 117 participants who had progressed after receiving a platinum-based therapy and at least one additional systemic regimen. The study was designed to measure objective response rate (ORR), or the percentage of participants who experienced partial shrinkage or complete disappearance of the tumor. Results showed 15 percent of participants experienced ORR, of whom 59 percent had response durations of six months or longer.
The most common side effects of Opdivo are fatigue, shortness of breath, musculoskeletal pain, decreased appetite, cough, nausea and constipation. The most serious side effects are severe immune-mediated side effects involving healthy organs, including the lung, colon, liver, kidneys and hormone-producing glands.
Opdivo for squamous NSCLC was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness in the treatment of a serious condition. Opdivo is being approved more than three months ahead of the prescription drug user fee goal date of June 22, 2015, the date when the agency was scheduled to complete its review of the application.
The FDA previously approved Opdivo to treat patients with unresectable or metastatic melanoma who no longer respond to other drugs.
Opdivo is marketed by Princeton, New Jersey-based Bristol-Myers Squibb.

Safety Announcements

FDA Drug Safety Communication: FDA review of study sheds light on two deaths associated with the injectable schizophrenia drug Zyprexa Relprevv (olanzapine pamoate)

[March 23rd, 2015] The U.S. Food and Drug Administration (FDA) has concluded a review of a study undertaken to determine the cause of elevated levels of the injectable schizophrenia drug Zyprexa Relprevv (olanzapine pamoate) in two patients who died. The study results were inconclusive. We are unable to exclude the possibility that the deaths were caused by rapid, but delayed, entry of the drug into the bloodstream following intramuscular injection. The study suggested that much of the drug level increase could have occurred after death, a finding that could explain the extremely high blood levels found in the two patients who died 3 to 4 days after receiving injections of appropriate doses of Zyprexa Relprevv. On the basis of all of the information reviewed, we are not recommending any changes to the current prescribing or use of Zyprexa Relprevv injection at this time. Patients should not stop receiving treatment without first talking to their health care professionals.

Treatment with Zyprexa Relprevv may help improve the symptoms of schizophrenia, which include hearing voices, seeing things that are not there, and being suspicious or withdrawn. The labeling for Zyprexa Relprevv carries a boxed warning, FDA's most serious type of warning, for post-injection delirium sedation (PDSS). PDSS is a serious condition with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma), delirium, or both. In clinical trials, cases of PDSS were observed within 3 hours after giving an intramuscular injection of Zyprexa Relprevv, although no deaths were reported. To reduce the risk of PDSS, there is also a Risk Evaluation and Mitigation Strategy (REMS) for Zyprexa Relprevv to ensure that patients are observed by health care professionals at a certified facility following injection.

Following the deaths of the two patients who received appropriate doses of Zyprexa Relprevv, FDA requested the drug's manufacturer, Eli Lilly and Company, to conduct an animal study to test whether movement of olanzapine into blood after death could lead to higher-than-expected blood levels of the drug. The study showed that some animals had increases in drug levels in the blood after death, which could account for the higher-than-expected blood levels found in the two patients who died.

Health care professionals should continue to follow the Zyprexa Relprevv Patient Care Program REMS requirements and current label recommendations. Notable requirements of the REMS include:

- For a patient to receive treatment, the prescriber, health care facility, patient, and pharmacy must all be enrolled in the Zyprexa Relprevv Patient Care Program.
- Zyprexa Relprevv injections must be administered at a REMS-certified health care facility with ready access to emergency response services.
- Patients must be continuously monitored at the REMS-certified health care facility for at least 3 hours following an intramuscular injection.
- Patients receiving Zyprexa Relprevv must be accompanied to their destination from the health care facility.

Patients should read the Medication Guide that comes with the Zyprexa Relprevv prescription each time before they get an intramuscular injection, as there may be new information. Patients receiving Zyprexa Relprevv or their caregivers should immediately report symptoms of PDSS to a health care professional. Symptoms of PDSS can include:

- feeling more sleepy than usual
- feeling dizzy
- feeling confused or disoriented
- trouble talking or walking
- feeling weak
- feeling nervous or anxious
- higher blood pressure
- seizures (convulsions)
- passing out (become unconscious or coma)

Safety Announcements

FDA Drug Safety Communication: FDA updates label for stop smoking drug Chantix (varenicline) to include potential alcohol interaction, rare risk of seizures, and studies of side effects on mood, behavior, or thinking

[March 9th, 2015] The U.S. Food and Drug Administration (FDA) is warning that the prescription smoking cessation medicine Chantix (varenicline) can change the way people react to alcohol. In addition, rare accounts of seizures in patients treated with Chantix have been reported. We have approved changes to the Chantix label to warn about these risks. Until patients know how Chantix affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink. Patients who have a seizure while taking Chantix should stop the medicine and seek medical attention immediately.

Millions of Americans have serious health problems caused by smoking, which can be reduced by quitting. Chantix is a prescription medicine that is FDA-approved to help adults quit smoking. In clinical trials, Chantix increased the likelihood of quitting smoking and "staying quit" for as long as 1 year compared to treatment with a placebo.

We reviewed the case series submitted by Pfizer, the manufacturer of Chantix, as well as the cases in the FDA Adverse Event Reporting System (FAERS) database describing patients who drank alcohol during treatment with Chantix and experienced adverse reactions. Some patients experienced decreased tolerance

to alcohol, including increased drunkenness, unusual or aggressive behavior, or they had no memory of things that happened.
We also reviewed FAERS and the medical literature for cases of seizures with Chantix and identified cases in which the patients who had seizures while taking Chantix either had no history of seizures or had a seizure disorder that had been well-controlled. In most of these cases, the seizures occurred within the first month of starting Chantix. Information about these risks has been added to the *Warnings and Precautions* section of the drug label and to the patient Medication Guide.
We also updated the *Warnings and Precautions* section of the label to include information about several studies that investigated the risk of neuropsychiatric side effects on mood, behavior, or thinking occurring with Chantix. These included observational studies, as well as analyses that Pfizer conducted of randomized controlled clinical trial data. These studies did not show an increased risk of neuropsychiatric side effects with Chantix; however, they did not examine all types of neuropsychiatric side effects, and they had limitations that prevented us from drawing reliable conclusions.
We previously communicated about possible serious neuropsychiatric side effects with Chantix in 2009 and 2011, and these recent studies were discussed at an FDA Advisory Committee meeting in October 2014. Pfizer is conducting a large clinical safety trial of Chantix to investigate this risk and results from this study are expected in late 2015. We will update the public as appropriate when this new information becomes available.

Safety Announcements

FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir Harvoni or Sovaldi in combination with another Direct Acting Antiviral drug

[3-24-2015] The U.S. Food and Drug Administration (FDA) is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. We are adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. We are recommending that health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct acting antiviral, such as the investigational drug daclatasvir or Olysio (simeprevir), with amiodarone. Patients should not stop taking any of their medicines without first talking to their health care professionals.
Harvoni and Sovaldi are used to treat chronic hepatitis C, a viral infection that can last a lifetime and lead to serious liver problems, including cirrhosis or liver cancer. These drugs reduce the amount of hepatitis C virus in the body by preventing the virus from multiplying within the body.
Our review of submitted postmarketing adverse event reports found that patients can develop a serious and life-threatening symptomatic bradycardia when either Harvoni or Sovaldi combined with another direct-acting antiviral is taken together with amiodarone. The reports included the death of one patient due to cardiac arrest and three patients requiring placement of a pacemaker to regulate their heart rhythms. The other patients recovered after discontinuing either the hepatitis C drugs or amiodarone, or both. The cause of these events could not be determined. Information about this serious risk of bradycardia has been added to the Warnings and Precautions, Drug Interactions, and Postmarketing Experience sections of the drug labels for Harvoni and Sovaldi. We will continue to monitor Harvoni and Sovaldi for risks of serious symptomatic bradycardia and further investigate the reason why the use of amiodarone with these hepatitis C drugs led to the heart-related events.
Health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone. However, in cases where alternative treatment options are unavailable, we recommend heart monitoring in an inpatient hospital setting for the first 48 hours. Subsequently, monitoring in a doctor's office or self-monitoring of the heart rate should be done every day through at least the first 2 weeks of treatment.
Patients taking either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone should seek medical attention right away if they experience signs or symptoms of symptomatic bradycardia such as:

- Near-fainting or fainting
- Dizziness or light-headedness
- Malaise

- Weakness
- Excessive tiredness
- Shortness of breath
- Chest pains
- Confusion or memory problems

Safety Announcements

FDA Drug Safety Communication: FDA strengthens warnings and changes prescribing instructions to decrease the risk of serious allergic reactions with anemia drug Feraheme (ferumoxytol)

[3-30-2015] The U.S. Food and Drug Administration (FDA) is strengthening an existing warning that serious, potentially fatal allergic reactions can occur with the anemia drug Feraheme (ferumoxytol). We have changed the prescribing instructions and approved a Boxed Warning, FDA's strongest type of warning, regarding these serious risks. Also added is a new Contraindication, a strong recommendation against use of Feraheme in patients who have had an allergic reaction to any intravenous (IV) iron replacement product. Health care professionals should follow the new recommendations in the drug label. Patients should immediately alert their health care professional or seek emergency care if they develop breathing problems, low blood pressure, lightheadedness, dizziness, swelling, a rash, or itching during or after Feraheme administration.

Feraheme is in a class of medicines called IV iron replacement products. It is used to treat iron-deficiency anemia—a condition in which there is a lower than normal number of oxygen-carrying red blood cells because of too little iron. People with anemia may feel tired or weak, and if left untreated, anemia can damage the heart, brain, and other organs. Feraheme is specifically approved for use only in adults with iron deficiency anemia in patients with chronic kidney disease. It is given as an IV infusion by health care professionals in a hospital, outpatient clinic, or medical office. Like other IV iron products, Feraheme may only be given where emergency personnel and equipment are immediately available to treat the potentially life-threatening allergic reactions that can occur with treatment.
All IV iron products carry a risk of potentially life-threatening allergic reactions. At the time of Feraheme's approval in 2009, this risk was described in the Warnings and Precautions section of the drug label. Since then, serious reactions, including deaths, have occurred despite the proper use of therapies to treat these reactions and emergency resuscitation measures. We have evaluated this risk further and have identified ways to reduce the risk of serious allergic reactions with Feraheme.
Based on our evaluation, the prescribing instructions and other label information were updated, adding a Boxed Warning that describes these serious risks and recommending that health care professionals:

- Only administer IV iron products to patients who require IV iron therapy.
- Do not administer Feraheme to patients with a history of allergic reaction to Feraheme or other IV iron products.
- Only administer diluted Feraheme as an IV infusion over a minimum of 15 minutes. Feraheme should not be given as an undiluted IV injection.
- Closely monitor patients for signs and symptoms of serious allergic reactions, including monitoring blood pressure and pulse during Feraheme administration and for at least 30 minutes following each infusion.
- Carefully consider the potential risks and benefits of Feraheme administration in elderly patients with multiple or serious medical conditions, as these patients may experience more severe reactions.
- Carefully consider the potential risks and benefits of Feraheme administration in patients with a history of multiple drug allergies. Patients with multiple drug allergies may also be at higher risk.

Current Drug Shortages Index (as of March 30th, 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***
Atropine Sulfate Injection	***Currently in Shortage***
Azathioprine Tablet	***Currently in Shortage***
Barium Sulfate for Suspension	***Currently in Shortage***
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection	***Currently in Shortage***
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection[12]	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefotaxime Sodium (Claforan) Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dextrose 5% Injection Bags	***Currently in Shortage***
Dextrose Injection USP, 70%	***Currently in Shortage***
Dimercaprol (Bal-in-Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Doxorubicin (Adriamycin) Injection	***Currently in Shortage***
Ephedrine Sulfate Injection	***Currently in Shortage***
Epinephrine 1mg/mL (Preservative Free)[13]	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fluorescein Sodium Injection	***Currently in Shortage***
Fluoxymesterone (Androxy) Tablets, USP	***Currently in Shortage***
Fomepizole Injection	***Currently in Shortage***
Haloperidol Lactate Injection	***Currently in Shortage***
Indigo Carmine Injection	***Currently in Shortage***
Irrigation Solutions	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
L-Cysteine Hydrochloride Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Liotrix (Thyrolar) Tablets	***Currently in Shortage***
Magnesium Sulfate Injection	***Currently in Shortage***
Mecasermin [rDNA origin] (Increlex) Injection	***Currently in Shortage***
Memantine Hydrochloride (Namenda) XR Capsules	***Currently in Shortage***
Methyldopate Hydrochloride Injection	***Currently in Shortage***
Methylene Blue Injection	***Currently in Shortage***
Methylin Chewable Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride ER Capsules/Tablets[14]	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nalbuphine Hydrochloride (Nubain) Injection	***Currently in Shortage***
Nebivolol (BYSTOLIC) Tablets	***Currently in Shortage***
Pancuronium Bromide Injection	***Currently in Shortage***
Papaverine Hydrochloride Injection	***Currently in Shortage***
Peritoneal Dialysis Solutions	***Currently in Shortage***
Phentolamine Mesylate Injection	***Currently in Shortage***
Phosphate (Glycophos) Injection	***Currently in Shortage***
Piperacillin and Tazobactam (Zosyn) Injection	***Currently in Shortage***

Potassium Chloride Injection	***Currently in Shortage***
Quazepam (Doral) Tablets	***Currently in Shortage***
Radium RA-223 Dichloride (Xofigo) Injection	***Currently in Shortage***
Reserpine Tablets	***Currently in Shortage***
Secretin Synthetic Human (ChiRhoStim) Injection	***Currently in Shortage***
Selenium Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Phosphate Injection	***Currently in Shortage***
Sterile Water for Injection Solutions	***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***
Trypan Blue (Membraneblue)	***Currently in Shortage***
Vancomycin Hydrochloride for Injection, USP	***Currently in Shortage***