



Drug Utilization Review Board

**Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1A
Oklahoma City, Oklahoma 73107
Ponca Room**

**Wednesday
November 13, 2013
6:00 p.m.**





The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members
FROM: Chris Le, Pharm.D.
SUBJECT: **Packet Contents for Board Meeting – November 13, 2013**
DATE: November 6, 2013

NOTE: The DUR Board will meet at 6:00 p.m. The meeting will be held in the Ponca Room at the Oklahoma Health Care Authority Offices in Shepherd Mall. (North Entrance)

Enclosed are the following items related to the November 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

Action Item – Vote on 2014 Meeting Dates – See Appendix B

Action Item – Update on DUR / Medication Coverage Authorization Unit / Safety Alerts and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets – See Appendix C

Action Item – Annual Review of Botulinum Toxins – See Appendix D

Action Item – Annual Review of Prenatal Vitamins – See Appendix E

Action Item – Annual Review of Antihypertensive Medications and 30 Day Notice to Prior Authorize Epaned™ – See Appendix F

Action Item – Annual Review of Nasal Allergy Medications and 30 Day Notice to Prior Authorize Zetonna® – See Appendix G

Action Item – Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Simbrinza™ and Rescula® – See Appendix H

Action Item – Annual Review of Pediculicides and 30 Day Notice to Prior Authorize Sklice® – See Appendix I

FDA and DEA Updates – See Appendix J

Future Business

Adjournment

**Oklahoma Health Care Authority
Drug Utilization Review Board**

(DUR Board)

Meeting – November 13, 2013 @ 6:00 p.m.

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1-A
Oklahoma City, Oklahoma 73107
Ponca Room (North Entrance)

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. September 11, 2013 DUR Minutes – Vote
- B. September 11, 2013 DUR Recommendation Memorandum
- C. October 9, 2013 DUR Recommendation Memorandum

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

4. Action Item – Vote on 2014 Meeting Dates – See Appendix B

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

5. Action Item – Update on DUR / Medication Coverage Authorization Unit / Safety Alerts and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets – See Appendix C

- A. Medication Coverage Activity for October 2013
- B. Pharmacy Help Desk Activity for October 2013
- C. Valproate Product Update
- D. Ketoconazole Safety Communication and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets
- E. Update on Safety Alerts

Items to be presented by Dr. Le, Dr. Muchmore, Chairman

6. Annual Review of Botulinum Toxins – See Appendix D

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. Market News and Updates
- E. COP Recommendations

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

7. Annual Review of Prenatal Vitamins – See Appendix E

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. COP Recommendations
- E. Utilization Details

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

8. Annual Review of Antihypertensive Medications and 30 Day Notice to Prior Authorize Epaned™ – See Appendix F

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. Market News and Updates
- E. Product Summary
- F. COP Recommendations
- G. Utilization Details
- H. Product Details

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

9. Annual Review of Nasal Allergy Medications and 30 Day Notice to Prior Authorize Zetonna® – See Appendix G

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. Market News and Updates
- E. COP Recommendation
- F. Utilization
- G. Product Details

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

10. Annual Review of Glaucoma Medications and 30 Day Notice to Prior Authorize Simbrinza™ and Rescula® – See Appendix H

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. Market News and Updates
- E. COP Recommendation
- F. Utilization Details
- G. Product Details

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

11. Annual Review of Pediculicides and 30 Day Notice to Prior Authorize Sklice® – See Appendix I

- A. Current Prior Authorization Criteria
- B. Utilization Review
- C. Prior Authorization Review
- D. Market News and Updates
- E. COP Recommendations

- F. Utilization Details
- G. Product Details

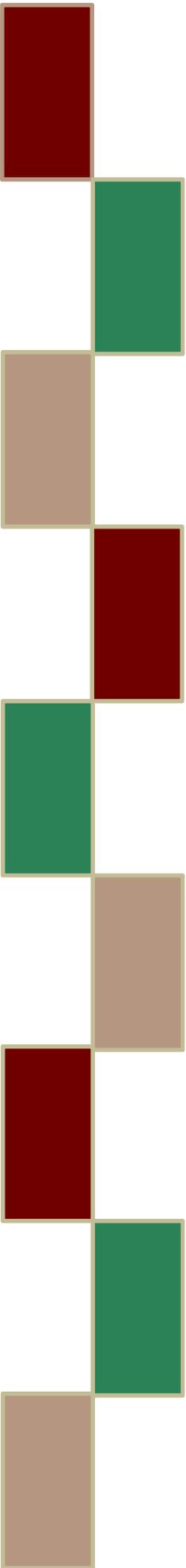
Items to be presented by Dr. Cothran, Dr. Muchmore, Chairman

12. FDA and DEA Updates – See Appendix J

13. Future Business

14. Adjournment

Appendix A



**OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING OF SEPTEMBER 11, 2013**

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.	X	
Anetta Harrell, Pharm.D.	X	
Evie Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.	X	
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.		X
Bruna Varalli-Claypool, MHS, PA-C	X	
Eric Winegardener, D.Ph.	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	X	
Michyla Adams, PharmD.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Shellie Keast, Ph.D.; Clinical Assistant Professor	X	
Bethany Holderread, Pharm. D.; Clinical Coordinator	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator	X	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist	X	
Jo'Nel Weber, Pharm.D.; Clinical Pharmacist		X
Graduate Students: Tim Pham	X	
Visiting Pharmacy Student(s): Nicholas Nelson and John Hallren	X	

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

OTHERS PRESENT:		
John Brunson, Impax	Paul Davis, Mental Health Association	Ron Cain, Pfizer
Don Kempin, Novo Nordisk	Patrick Moty, Supernus	Bob Atkins, Biogen
Kathleen Karnik, Janssen	Audrey Rattan, Otsuka	Mike Spence, Novartis
Brian Mayes, Pzifer	Hilary Carter, Otsuka	John Omick, Lundbeck
Jim Fowler, Astra Zeneca	Tamara Wilson, Novartis	Janie Huff, Takeda
Mark Kaiser, Otsuka	Jim Dunley, Phrma	Richard Ponder, J&J
Deitra Macy, PDI	Brieana Buckley, Biogen	Toné Jones, Sunovion
Kelly Zatorski, PDI	Hunter Hogan, Precision Rx	Ron Schnare, Shire
Mark Fueling, IT PMC	Aaron Zimmeran, Teva	
Cheri Ritchie, Otsuka	Toby Thompson, Pfizer	

PRESENT FOR PUBLIC COMMENT:	
Brian Maves	Pfizer Medical
Leland Dennis	Private Physician
Hunter Hogan	Pharmacist
Kathleen Karnik	Janssen
Willis Holloway	Private Physician
Paul Davis	Mental Health Assoc.
Brieana Buckley	Biogen Idec
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

- | | |
|-------------------|----------------------------|
| Agenda Item: No 8 | Speaker: Brian Maves |
| Agenda Item: No 8 | Speaker: Dr. Leland Dennis |
| Agenda Item: No 8 | Speaker: Dr. Hunter Hogan |
| Agenda Item: No 8 | Speaker: Kathleen Karnik |
| Agenda Item: No 8 | Speaker: Paul Davis |
| Agenda Item: No 5 | Speaker: Brieana Buckley |
| Agenda Item: No 8 | Speaker: Mai Duong |

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: AUGUST 14, 2013 DUR MINUTES

3B: AUGUST 14, 2013 DUR RECOMMENDATION MEMORANDUM

Dr. Winegardner moved to approve with corrections; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

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

4A: MEDICATION COVERAGE ACTIVITY: AUGUST 2013

4B: PHARMACY HELP DESK ACTIVITY: AUGUST 2013

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE TYSABRI® (NATALIZUMAB)

Materials included in agenda packet; presented by Dr. Holderread

Dr. Preslar moved to approve with changes added; seconded by Dr. Harrell.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE DICLEGIS® (DOXYLAMINE/PYRIDOXINE)

6A: COP RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE QUILLIVANT XR™ AND UPDATE THE ADHD PRODUCT BASED PRIOR AUTHORIZATION CATEGORY

7A: COP RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams

Dr. Kuhls recommends *"add generic methylphenidate XR to tier 3"*

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO UPDATE THE ATYPICAL ANTIPSYCHOTICS PRODUCT BASED PRIOR AUTHORIZATION CATEGORY

8A: COP RECOMMENDATIONS

Materials included in agenda packet; presented Dr. Le

Dr. Bell moved to approve with recommended changes; second by Dr. Harrell.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: FDA AND DEA UPDATES

Materials included in agenda packet; presented by Dr. Cothran.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: FUTURE BUSINESS

Materials included in agenda packet; submitted by Dr. Cothran

12A: ANNUAL REVIEWS

12B: NEW PRODUCT REVIEWS

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ADJOURNMENT

The meeting was adjourned at 7:34 pm



The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: September 11, 2013

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

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

Subject: DUR Board Recommendations from Meeting of September 11, 2013

Recommendation 1: Vote to Prior Authorize Tysabri® (Natalizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends medical and pharmacy prior authorization of Tysabri® (natalizumab).

Consideration for approval will be based on all of the following criteria:

1. An FDA approved diagnosis of multiple sclerosis or Crohn's disease; **AND**
2. Treatment with at least **two** different first line therapeutic categories for multiple sclerosis or Crohn's disease that have failed to yield an adequate clinical response, or a patient specific, clinically significant reason why the member cannot use all available first and second line alternatives; **AND**
3. Prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program.

Recommendation 2: Vote to Prior Authorize Diclegis® (Doxylamine/Pyridoxine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of Diclegis® (doxylamine/pyridoxine).

Consideration for approval will be based on **all** of the following criteria:

1. An FDA approved diagnosis of nausea and vomiting associated with pregnancy; **AND**
2. Trials with at least **two** non-pharmacologic therapies that have failed to relieve nausea and vomiting; **AND**
3. Trials with at least **three** prescription medications that have failed to relieve nausea and vomiting (must include a trial of ondansetron); **AND**
4. A patient-specific, clinically significant reason why member cannot use OTC doxylamine and OTC Vitamin B-6 (pyridoxine).

Recommendation 3: Vote to Prior Authorize Quillivant XR™ (Methylphenidate Extended Release) Oral Suspension and Update the ADHD Prior Authorization Category

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Quillivant XR™ to the ADHD Product Based Prior Authorization Category, as well as the following changes to the current criteria and tier structure.

TIER 1	TIER 2	TIER 3	SPECIAL PA
AMPHETAMINE			Desoxy® tablets Dexedrine® tablets Dextroamphetamine tablets <i>(generic Dexedrine®)</i> Dexedrine Spansules® caps Dextroamphetamine ER capsules <i>(generic Dexedrine Spansules®)</i> ProCentra™ solution Methylin® Chewable Tablets Methylin® Solution Methylphenidate Solution <i>(generic Methylin®)</i> Provigil® (modafinil tablets) Modafinil tablets <i>(generic Provigil®)</i> Nuvigil® (armodafinil tablets) Xyrem® (sodium oxybate soln)
Short-Acting Adderall® tablets Amphetamine/ Dextroamphetamine tablets <i>(generic Adderall®)</i>			
Long-Acting *Lowest Net Cost Long-Acting Product	Long-Acting Intermediate Net Cost Range Product(s)	Long-Acting Adderall XR® capsules Amphetamine/Dextroamphetamine ER capsules <i>(generic Adderall XR®)</i> Vyvanse® capsules	
METHYLPHENIDATE			
Short-Acting Ritalin® tablets Methylphenidate tablets <i>(generic Ritalin®)</i> Focalin® tablets Dexmethylphenidate tablets <i>(generic Focalin®)</i> Methylin® tablets Methylphenidate tablets <i>(generic Methylin®)</i>			
Long-Acting Methylin ER® tablets Methylphenidate ER tablets <i>(generic Methylin ER®)</i> Ritalin SR® tablets Methylphenidate SR tablets <i>(generic Ritalin SR®)</i> Metadate ER® tablets Methylphenidate ER tablets <i>(generic Metadate ER®)</i> *Lowest Net Cost Long-Acting Product	Long-Acting Intermediate Net Cost Range Product(s)	Long-Acting Concerta® tablets Methylphenidate ER tablets <i>(generic Concerta®)</i> Focalin XR® capsules Metadate CD® capsules Methylphenidate CD capsules <i>(generic Metadate CD®)</i> Ritalin LA® capsules Methylphenidate LA capsules <i>(generic Ritalin LA®)</i> Daytrana™ patches Quillivant XR™ suspension	
NON-STIMULANTS[∞]			
	Lowest Net Cost Product	Kapvay® (clonidine ER tablets) Intuniv® (guanfacine ER tablets) Strattera® (atomoxetine caps)	

*Final Tier 1 category must contain a long-acting capsule.

∞ May Rebate to Tier-2 Status only.

Tier 2 Prior Authorization Approval Criteria:

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

Tier 3 Prior Authorization Approval Criteria:

1. FDA approved diagnosis; and
2. Trials with at least one long-acting Tier one drug from each category (one amphetamine and one methylphenidate); and
3. Trials with at least two Tier 2 medications that did not yield adequate response:
 - a. Trials should have been within the last 365 days; and
 - b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
 - c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why member cannot use the available long acting capsule formulation.

Special Prior Authorization Approval Criteria:

1. **Desoxyn[®], Dexedrine[®], Dexedrine Spansules[®], and ProCentra[™] Solution**
Criteria:
 - a. Covered diagnosis; and
 - b. A patient-specific, clinically significant reason why member cannot use all other available stimulant medications.
2. **Methylin[®] Chewable Tablets & Solution Criteria:**
 - a. FDA approved diagnosis; and
 - b. A patient-specific, clinically significant reason why member cannot use all other available formulations of long acting stimulant medications that can be used for members who cannot swallow capsules/tablets.
3. **Provigil[®], Nuvigil[®], and Xyrem[®] Criteria:**
 - a. FDA approved diagnosis.
 - b. Use of Provigil[®], Nuvigil[®], or Xyrem[®] requires a patient-specific, clinically significant reason why member cannot use stimulant medications to improve wakefulness during the daytime.

- c. Use of Xyrem® requires recent trials with Tier 1 and Tier 2 stimulants from different chemical categories, and trials with both Provigil® and Nuvigil® within the past 6 months, unless contraindicated, that did not yield adequate results.
- d. The diagnosis of obstructive sleep apnea requires concurrent treatment for the obstructive sleep apnea.
- e. The diagnosis of shift work sleep disorder requires the member’s work schedule to be included with the petition.

Additional Criteria:

- 1. Doses exceeding 1.5 times the FDA maximum are not covered.
- 2. Prior Authorization is required for all tiers for members greater than 20 years of age and for members 0-4 years of age. All prior authorization requests for members under the age of 5 years must be reviewed by an OHCA contracted psychiatrist.
- 3. Please note, members currently stabilized on ADHD medications in the previous 30 days will be grandfathered.

Recommendation 4: Vote to Update the Atypical Antipsychotics Product Based Prior Authorization Criteria

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Atypical Antipsychotics Product Based Prior Authorization Category as shown below. The final tier status of each branded product will apply across all available formulations of the product line.

Atypical Antipsychotics*		
Tier 1	Tier 2	Tier 3[†]
risperidone (Risperdal® , Risperdal Consta®) olanzapine (Zyprexa®) quetiapine (Seroquel®) ziprasidone (Geodon®) clozapine (Clozaril®) [‡]	Supplemental Rebated Products	aripiprazole (Abilify® , Abilify Maintena™) asenapine (Saphris®) clozapine (Fazaclor®) iloperidone (Fanapt™) lurasidone (Latuda®) olanzapine/fluoxetine (Symbyax®) paliperidone (Invega® , Invega Sustenna®) quetiapine ER (Seroquel XR®)

* Mandatory Generic Plan Applies

† May be rebated to Tier 2 status only

‡ Does not count toward a tier-1 trial

Approval Criteria for Tier 2 Medication:

1. Trials of **two** Tier 1 products (not including clozapine), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.

Approval Criteria for Tier 3 Medication:

1. Trials of **two** Tier 1 products (not including clozapine), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
2. Trials of **two** Tier 2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects.
3. A manual prior authorization may be submitted for consideration of a Tier-3 product when the member has had at least 4 trials of Tier-1 and Tier-2 products (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment for Depression:

1. For Abilify® (aripiprazole), Seroquel XR® (quetiapine extended release), or Symbyax® (olanzapine/fluoxetine): a diagnosis of depression requires current use of an antidepressant, and previous trials with at least two other antidepressants from both categories (an SSRI and a dual acting antidepressant) that did not yield adequate response. Tier structure applies.

Clinical Exceptions:

1. Members currently stabilized on a higher tiered medication defined by paid claim(s) for the higher tiered medication in the past 90 days will be approved.
2. Members being released from a hospital and stabilized on a higher tiered medication will be approved.
3. Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
4. Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
5. Lurasidone (Latuda®) may be approved for pregnant women with appropriate diagnosis.

Second Opinion Process for Children 0 - 4 Years of Age

Children less than 5 years of age will require a “second opinion” prior authorization to be reviewed by an OHCA-contracted child psychiatrist.

Educational Initiative for Inpatient Behavioral Health Providers

Due to the cost of inpatient psychiatric stays, the College of Pharmacy does not recommend removing the inpatient stabilization approval criteria at this time. However, COP and OHCA plan to work closely with the OHCA Inpatient Behavioral Health providers' group, which meets regularly at the agency, to educate them about the potential benefits of adopting the OHCA preferred drugs as their formulary products.



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COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: October 10, 2013

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

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

Subject: DUR Board Recommendations from October 2013 Packet

No meeting was held October 9, 2013. The following annual reviews were included in a packet sent to the DUR board members. No changes were recommended by the College of Pharmacy to the current prior authorization criteria of the categories listed below.

Annual Review of Kalydeco™ (Ivacaftor)

NO ACTION REQUIRED

Annual Review of Makena® (17-Hydroxyprogesterone Caproate)

NO ACTION REQUIRED

Annual Review of Cinryze® and Berinert® (C1 Esterase Inhibitors), Kalbitor® (Ecallentide), and Firazyr® (Icatibant)

NO ACTION REQUIRED

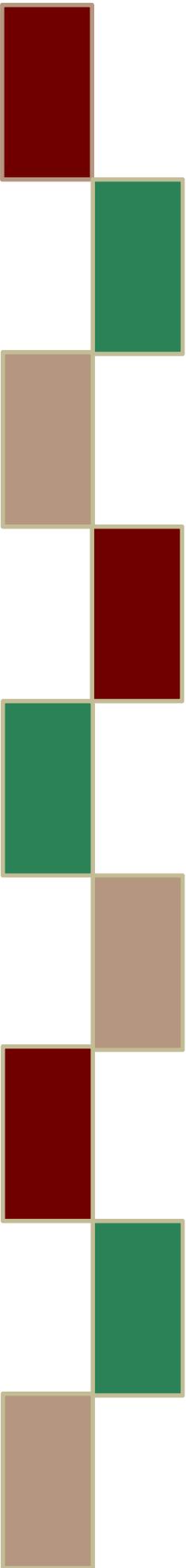
Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

NO ACTION REQUIRED

Annual Review of Xgeva® (Denosumab)

NO ACTION REQUIRED

Appendix B



2014 Drug Utilization Review Board Meeting Dates

Oklahoma Health Care Authority
November 2013

Meetings are Held the Second Wednesday of Every Month

January 8, 2014

February 12, 2014

March 12, 2014

April 9, 2014

May 14, 2014

June 11, 2014

July 9, 2014

August 13, 2014

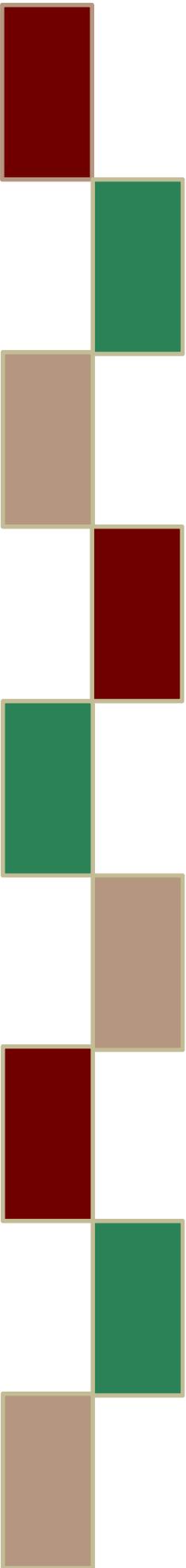
September 10, 2014

October 8, 2014

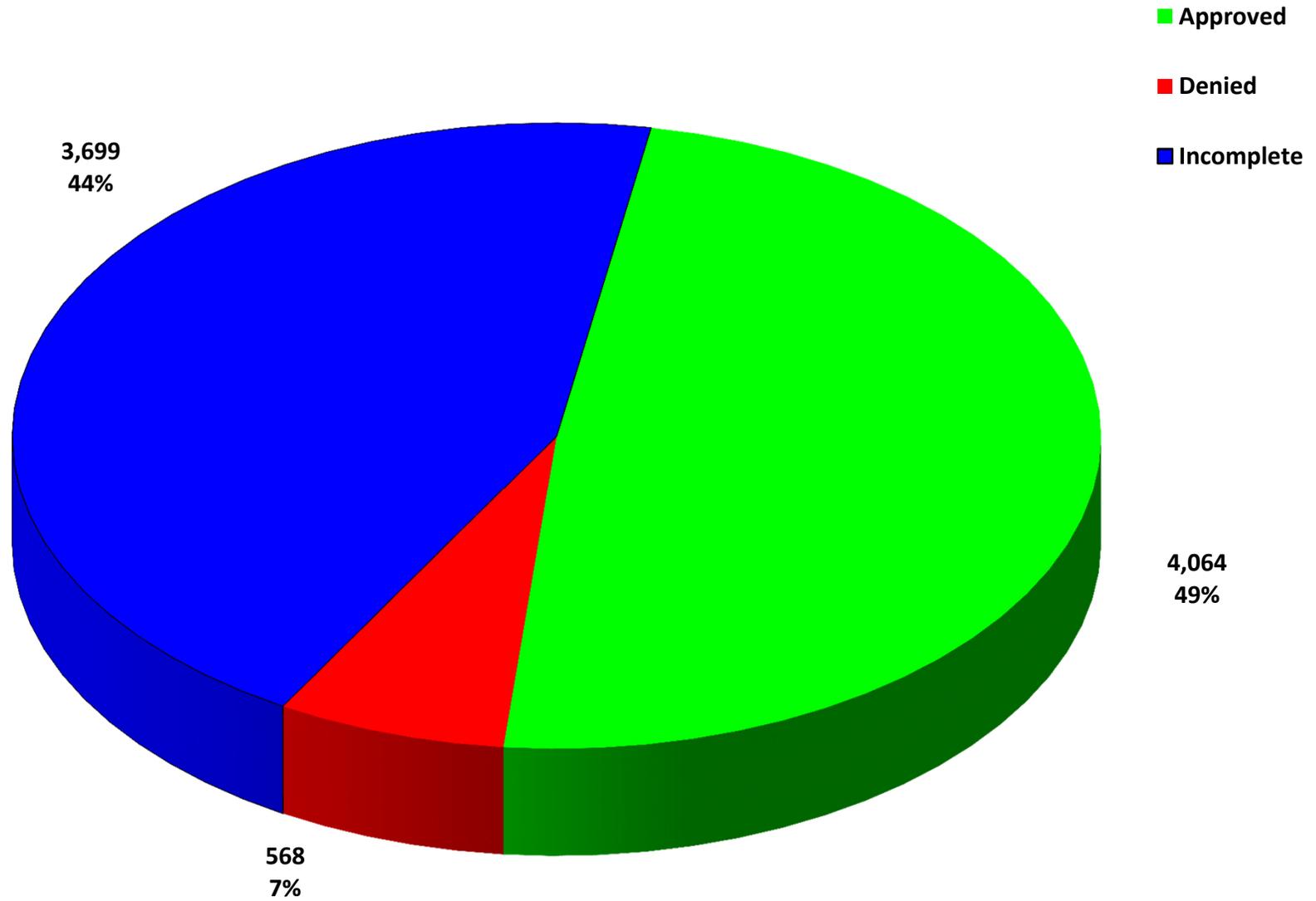
November 12, 2014

December 10, 2014

Appendix C

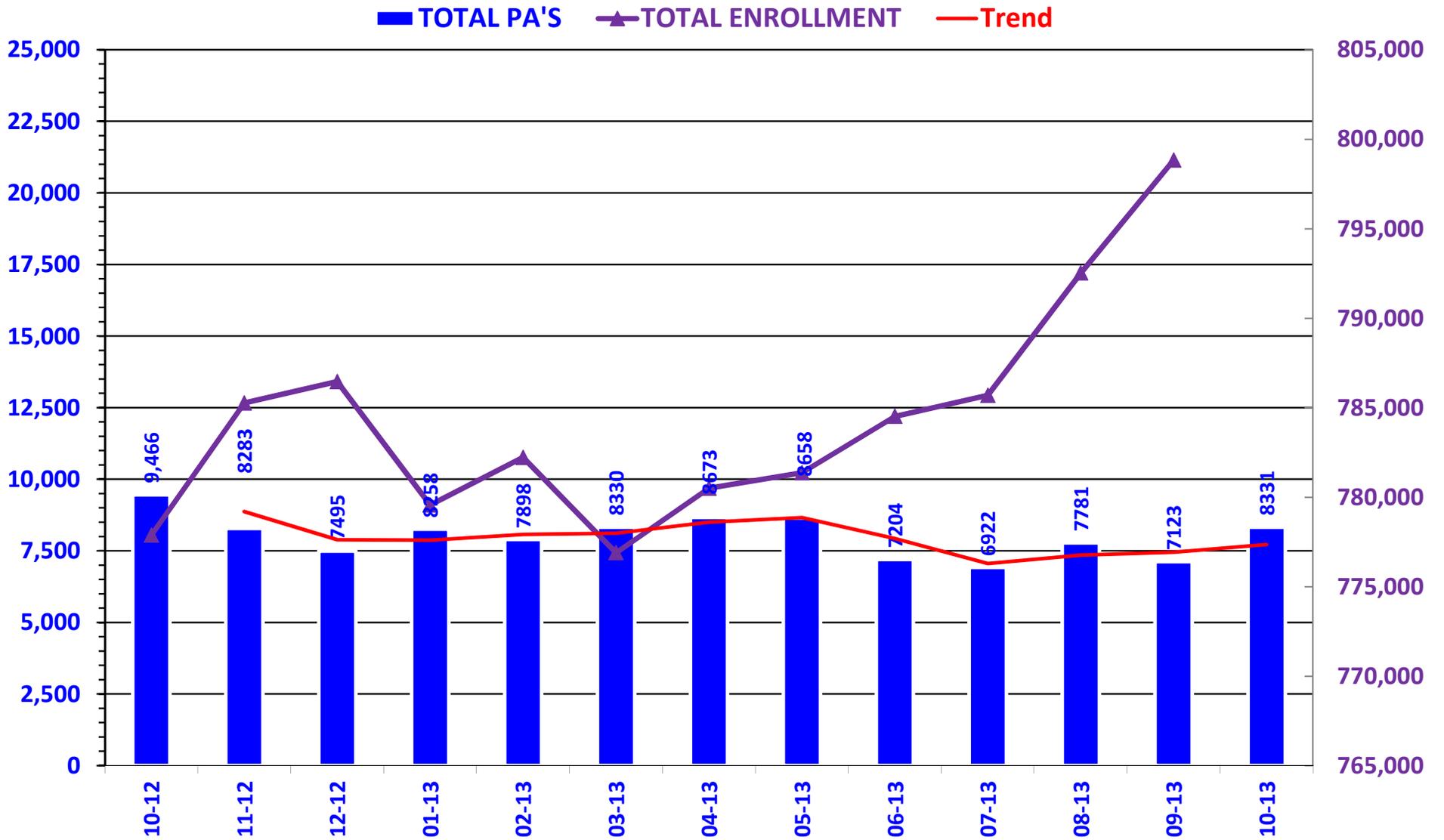


PRIOR AUTHORIZATION ACTIVITY REPORT: OCTOBER



PA totals include approved/denied/incomplete/overrides

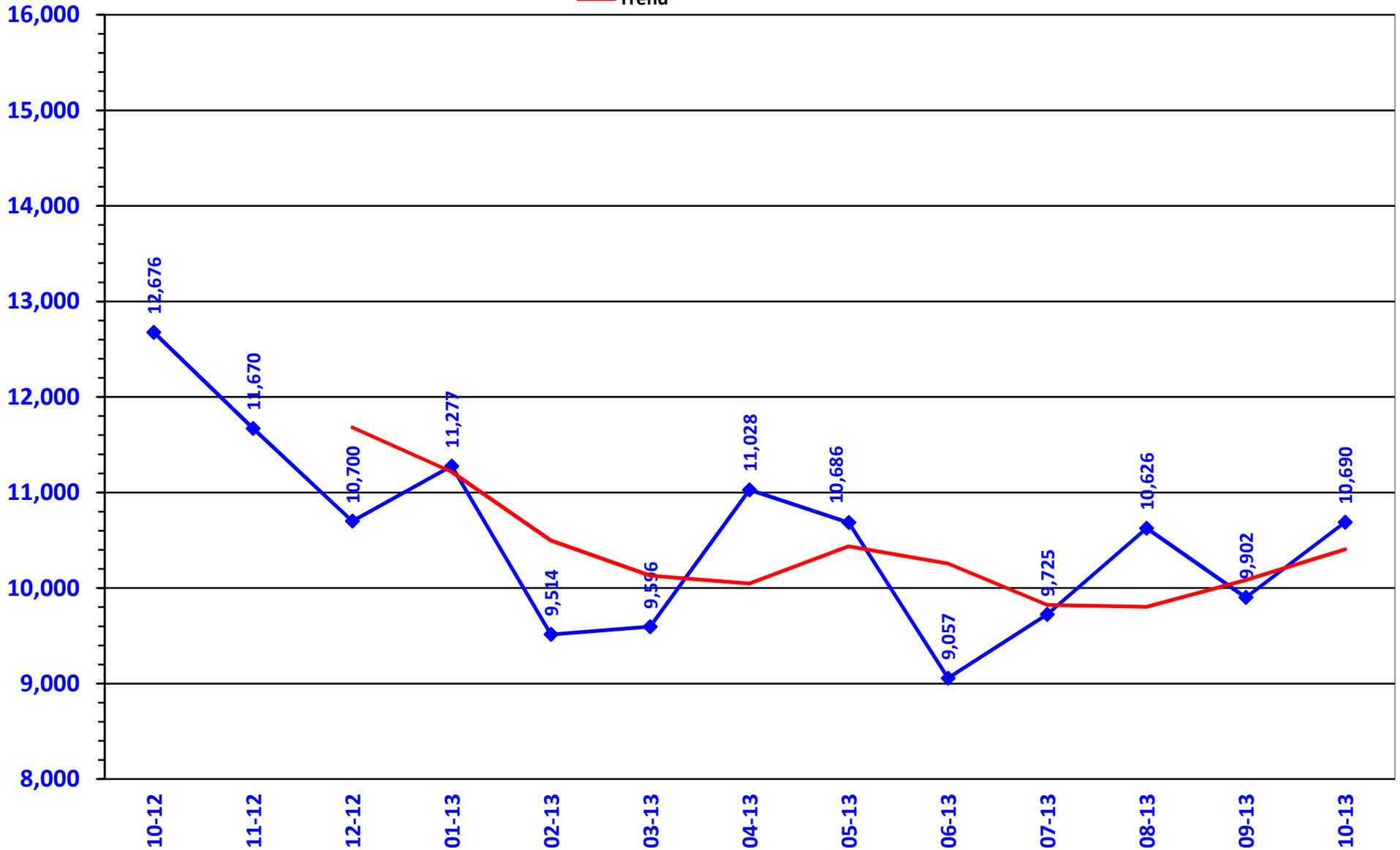
PRIOR AUTHORIZATION REPORT: OCTOBER 2012-OCTOBER 2013



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2012 - OCTOBER 2013

◆ TOTAL CALLS
— Trend



Prior Authorization Activity
10/1/2013 Through 10/31/2013

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	402	178	1	223	357
Analgesic, Narcotic	486	214	29	243	248
Angiotensin Receptor Antagonist	40	11	3	26	359
Antiasthma	268	147	6	115	303
Antibiotic	38	4	7	27	14
Anticoagulant	63	45	0	18	324
Anticonvulsant	95	51	1	43	345
Antidepressant	195	55	12	128	347
Antidiabetic	111	55	3	53	351
Antihistamine	184	132	2	50	347
Antihyperlipidemic	31	7	1	23	360
Antimigraine	64	17	6	41	348
Antiplatelet	19	10	0	9	351
Antiulcers	300	68	58	174	150
Anxiolytic	113	67	7	39	242
Atypical Antipsychotics	483	314	3	166	347
Biologics	52	25	1	26	331
Bladder Control	69	7	10	52	359
Botox	29	16	4	9	360
Cardiovascular	27	10	2	15	217
Chronic Obstructive Pulmonary Disease	17	2	2	13	359
Dermatological	121	21	39	61	99
Endocrine & Metabolic Drugs	63	40	6	17	137
Erythropoietin Stimulating Agents	26	17	0	9	100
Fibromyalgia	166	30	16	120	358
Gastrointestinal Agents	120	37	4	79	199
Glaucoma	18	2	1	15	359
Growth Hormones	60	52	2	6	151
HFA Rescue Inhalers	74	23	1	50	327
Insomnia	65	12	12	41	183
Multiple Sclerosis	51	24	1	26	225
Muscle Relaxant	105	26	26	53	41
Nasal Allergy	101	10	30	61	129
Neurological Agents	57	36	2	19	347
Nsaids	197	27	11	159	269
Ocular Allergy	55	14	7	34	116
Ophthalmic Anti-infectives	29	8	0	21	6
Osteoporosis	24	9	0	15	358
Other*	162	27	18	117	165
Otic Antibiotic	34	8	0	26	8
Pediculicide	110	36	18	56	19
Prenatal Vitamins	11	0	1	10	0
Smoking Cess.	14	2	0	12	86
Statins	87	29	4	54	359
Stimulant	601	357	23	221	323
Suboxone/Subutex	178	137	3	38	80
Synagis	559	240	92	227	141
Testosterone	92	27	0	65	333
Topical Antibiotic	13	1	0	12	92
Topical Antifungal	48	2	9	37	95
Topical Corticosteroids	180	13	12	155	215
Vitamin	51	15	19	17	336
Pharmacotherapy	182	123	1	58	131
Total	6,741	2,841	516	3,384	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Brand	51	45	0	6	351
Cumulative Early Fill	1	0	0	1	0
Cumulative Early Refill	23	22	1	0	180
Dosage Change	400	376	1	23	8
High Dose	7	7	0	0	257
Ingredient Duplication	17	10	0	7	11
Lost/Broken Rx	104	94	6	4	4
NDC vs Age	5	5	0	0	250
Nursing Home Issue	123	115	0	8	4
Other	37	31	2	4	30
Quantity vs. Days Supply	766	491	31	244	257
Stolen	11	9	2	0	5
Temporary Unlock	23	20	3	0	20
Third Brand Request	45	19	7	19	45
Wrong D.S. on Previous Rx	1	1	0	0	7
Overrides Total	1,590	1,223	52	315	
Total Regular PAs + Overrides	8,331	4,064	568	3,699	

Denial Reasons

Unable to verify required trials.	3,068
Lack required information to process request.	597
Does not meet established criteria.	581

Other PA Activity

Duplicate Requests	482
Letters	3,360
No Process	22
Changes to existing PAs	532
Partials	931

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

Retrospective Drug Evaluation: Focusing on Safety



- 1. Valproate Products Safety Intervention Results**
- 2. Ketoconazole Drug Safety Communication and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets**
- 3. Overview of FDA Safety Alerts**

1. Valproate Products Safety Intervention Results

Oklahoma Health Care Authority
November 2013

Background

On May 6, 2013, the FDA issued a Drug Safety Communication recommending that pregnant women should not take valproate sodium and related products, valproic acid and divalproex sodium, for prevention of migraine because of increased risk of lower IQ scores of the children born to these women. This contraindication will be added to the label and the drug's pregnancy category designation will be changed from "D" to "X" for this indication. Pregnant women with epilepsy or bipolar disorder should only be prescribed these products if other medications are not effective or are otherwise unacceptable. The pregnancy category will remain "D" for these indications.

Previous warnings have been issued regarding the use of valproate in pregnancy and an increased risk of autism, developmental delay, and congenital malformations. Therefore, the FDA reiterates its recommendations that women of childbearing age who are pregnant should not take these medications for any diagnosis unless they are essential to the management of the woman's condition. Non-pregnant women who are prescribed valproate products should use effective contraception. Women who become pregnant while on a valproate product should remain on it to avoid serious medical problems.

Intervention and Results

The College of Pharmacy retrieved data for the prescribers of valproate products for women of childbearing age for any indication. An informational letter (see next page) was sent to the 1,235 prescribers who had written prescriptions for a valproate product.

Recommendations

The College of Pharmacy recommends no further action at this time.



SoonerCare

Pharmacy Services

Dear Prescriber,

A review of SoonerCare pharmacy claims indicates that you prescribe valproate products for your patients. On May 6, 2013, the FDA issued a Drug Safety Communication recommending that pregnant women should not take valproate sodium and related products, valproic acid and divalproex sodium, for prevention of migraine because of increased risk of lower IQ scores of the children born to these women. The contraindication for use for migraine prophylaxis has been added to the product label and the pregnancy category for this diagnosis has been increased to "X". For the indications epilepsy and bipolar disorder the designation will remain pregnancy category D.

Valproate sodium and related products are antiepileptic agents whose activity is thought to be related to the elevated concentrations of gamma-aminobutyric acid (GABA) in the brain. FDA approved indications include:

- Absence seizure, Simple and complex
- Complex partial epileptic seizure
- Manic bipolar I disorder
- Migraine; Prophylaxis
- Seizure, Multiple seizure types; Adjunct (valproic acid)

Previous warnings have been issued regarding the use of valproate in pregnancy and an increased risk of autism, developmental delay, and congenital malformations. **Listed below are the recommendations from the FDA:**

- Women of childbearing age who are not pregnant should not take these medications for any diagnosis unless they are essential to the management of the woman's condition.
- Non-pregnant women who are prescribed valproate products should use effective contraception.
- Women who become pregnant while on a valproate product should remain on it to avoid serious medical problems
- It is not known whether the risk of neural tube defects or decreased IQ in the offspring of women receiving valproate is reduced by folic acid supplementation. Dietary folic acid supplementation both prior to conception and during pregnancy should be routinely recommended for patients using valproate
- To view more of the *FDA safety alert* go to:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm360487.htm>

Please remember that you are receiving this letter based upon the information available in the SoonerCare claims database at the time of review. Recent changes to therapy may not be reflected.

Sincerely,

Oklahoma Health Care Authority

2. Ketoconazole Drug Safety Communication and 30 Day Notice to Prior Authorize Ketoconazole Oral Tablets

Oklahoma Health Care Authority
November 2013

Background^{1,2}

On July 26, 2013, the FDA issued a Drug Safety Communication regarding potentially fatal liver injury, risks of drug interactions, and adrenal gland problems associated with the use of ketoconazole oral tablets. Topical formulations, including creams, shampoos, foams, and gels, were not included in this safety alert. The FDA has taken several steps to limit the use of ketoconazole, stressing the importance of using it only when other antifungal drugs are not available or tolerated by the patient. Actions include the following:

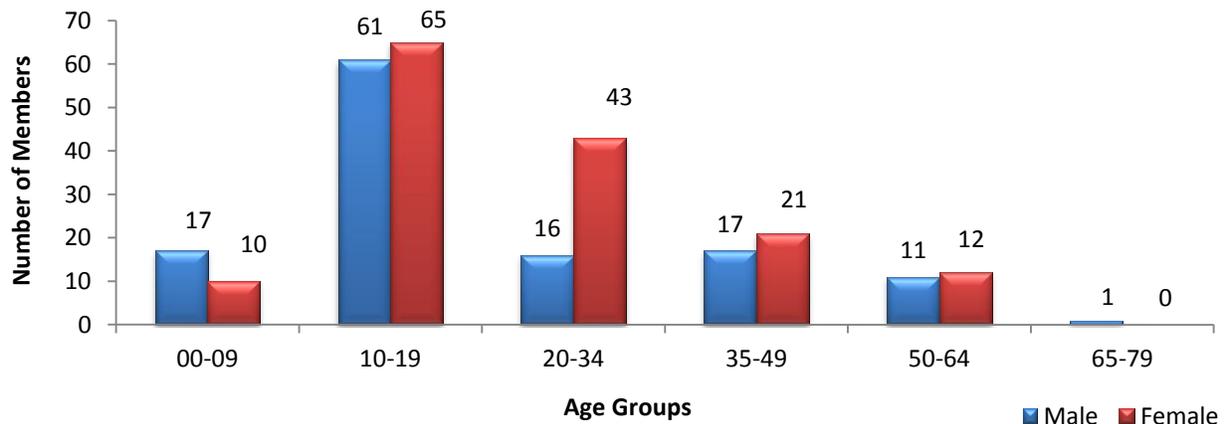
- Strengthening the boxed warnings regarding hepatotoxicity, adrenal insufficiency, and additional drug interactions.
- Adding acute and chronic liver disease as a contraindication.
- Adding a new Medication Guide to address these safety issues.
- Removing several indications for use, including *Candida* and dermatophyte infections, fungal infections of skin and nails.
- Limiting the use to blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis.

On October 16, the FDA further recommended that ketoconazole should not be used by researchers and pharmaceutical companies when evaluating drug interactions.

Evaluation of Ketoconazole Utilization - 1/1/2013-7/31/2013

Drug	Claims	Members	Cost	Units/Day	Claims/Member	Cost/Day
Ketoconazole Tab 200 mg	341	274	\$3,160.94	1.05	1.24	\$0.50

Demographics of Members Utilizing Ketoconazole 200mg Tabs



Doses and Approximate Costs of Ketoconazole and Alternative Agents

Diagnosis	Fluconazole	Itraconazole	Voriconazole	Ketoconazole
Blastomycosis	400-800 mg qd*	200 mg qd-bid	200-400 mg po bid*	200-400 mg qd
<i>Cost per month</i>	\$191-\$378	\$382-\$760	\$1,819-\$3,634	\$16-\$28
Coccidioidomycosis	200-400 mg qd*	200 mg qd-bid*		200-400 mg qd
<i>Cost per month</i>	\$97-\$191	\$382-\$760		\$16-\$28
Histoplasmosis	400-800 mg qd*	200 mg qd-bid		200-400 mg qd
<i>Cost per month</i>	\$191-\$378	\$382-\$760		\$16-\$28
Chromomycosis		200-400 mg qd*		200-400 mg qd
<i>Cost per month</i>		\$382-\$760		\$16-\$28
Paracoccidioidomycosis		100-200 mg qd*		200-400 mg qd
<i>Cost per month</i>		\$193-\$382		\$16-\$28

*Unlabeled use. All products have SMAC (State Maximum Allowable Cost) applied.

Discussion

A random sampling of the members with paid fills of ketoconazole in the selected time frame showed that the majority of the prescriptions were written for dermatological conditions, primarily dermatophytosis and pityriasis versicolor. Most of the claims were single fills for short durations.

Recommendations

The College of Pharmacy recommends prior authorization of ketoconazole oral tablets with the following criteria:

1. FDA approved indication of systemic fungal infections with one of the following;
 - a. blastomycosis
 - b. coccidioidomycosis
 - c. histoplasmosis
 - d. chromomycosis
 - e. paracoccidioidomycosis; and
2. Member is 3 years old or older, and
3. Member does not have underlying hepatic disease, and
4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; and
5. Other effective oral antifungal therapies are not tolerated and potential benefits outweigh the potential risks.
6. Hepatic function tests must be done at baseline and weekly during treatment.

3. Overview of Safety Alerts

Oklahoma Health Care Authority
November 2013

Introduction^{3,4,5,6}

The following are recent FDA safety alerts included for the DUR Board's consideration. SoonerCare specific data may be presented where applicable. The College will make recommendations as well as take recommendations from the DUR Board.

Date	Drug	Issue
8/1/2013	Acetaminophen	Risk of rare but serious skin reactions
<p>Issue Details: Incidence of Stevens-Johnsons Syndrome, toxic epidermal necrosis (TEN), and acute generalized exanthematous pustulosis (AGEP) has been associated with the use of acetaminophen and acetaminophen-containing prescription and over-the-counter products.</p> <p>FDA Recommendations: Label change for prescription medications to include warning. FDA will work with manufacturers of OTC products to address this issue on their labels as well. Major television networks as well as local channels have run stories on the danger to help get the information to the public.</p>		

Date	Drug	Issue
7/29/2013	Mefloquine	Risk of serious psychiatric and neurological side effects.
<p>Issue Details: Incidence of hallucinations and feelings of anxiety, mistrust, depression, as well as dizziness, loss of balance, or ringing in the ears have been associated with this antimalarial drug.</p> <p>FDA Recommendations: Boxed warning added to product information and the Medication Guide. The wallet card has been updated.</p> <p>Evaluation: Review of claims data revealed 33 SoonerCare members with pharmacy claims for mefloquine from 1/1/2013 to 7/31/2013.</p>		

Date	Drug	Issue
7/3/2013	Olmesartan and olmesartan-containing products (Benicar®, Benicar HCT®, Azor™, Tribenzor™)	Sprue-like enteropathy
<p>Issue Details: Post marketing surveillance has revealed the incidence of severe, chronic diarrhea with substantial weight loss in patients taking olmesartan and olmesartan-containing products months to years after initiation of treatment. Intestinal biopsies have demonstrated villous atrophy.</p> <p>FDA Recommendations: Warning added to the product label. Prescribers should consider discontinuation of this product if no other etiology is found.</p> <p>Evaluation: From 1/1/13 to 7/31/13, 743 claims have been submitted for 202 SoonerCare members, written by 198 different prescribers.</p>		

Date	Drug	Issue
8/15/2013	Fluoroquinolones, systemic: Levofloxacin (Levaquin), ciprofloxacin (Cipro), moxifloxacin (Avelox), norfloxacin (Noroxin), ofloxacin (Floxin), and gemifloxacin (Factive).	Peripheral neuropathy
<p>Issue Details: Incidence of possibly permanent peripheral neuropathy is associated with the use of oral or intravenous fluoroquinolones. Otic and ophthalmic formulations are not known to cause this adverse effect.</p> <p>FDA Recommendations: Warning added to product label and Medication Guides for all of the above listed fluoroquinolones. If symptoms occur, the fluoroquinolone should be discontinued and a non-fluoroquinolone antibiotic should be initiated, unless benefit of continuing the fluoroquinolone outweighs the risk.</p>		

References:

¹ FDA Drug Safety Communication (ketoconazole) available online at:

<http://www.fda.gov/Drugs/DrugSafety/ucm362415.htm> Last revised: 10/16/2013. Last accessed: 10/30/2013

² Acetaminophen: Drug Safety Communication available online at

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm363519.htm> Last revised: 8/10/2013. Last accessed: 10/30/2013

³ FDA Drug Safety Podcast (mefloquine) available online at:

<http://www.fda.gov/drugs/drugsafety/drugsafetypodcasts/ucm362919.htm> Last revised: 7/29/2013. Last accessed: 10/30/2013

⁴ FDA Drug Safety Communication (olmesartan) available online at

<http://www.fda.gov/Drugs/DrugSafety/ucm359477.htm> Last revised: 7/11/2013. Last accessed: 10/30/2013

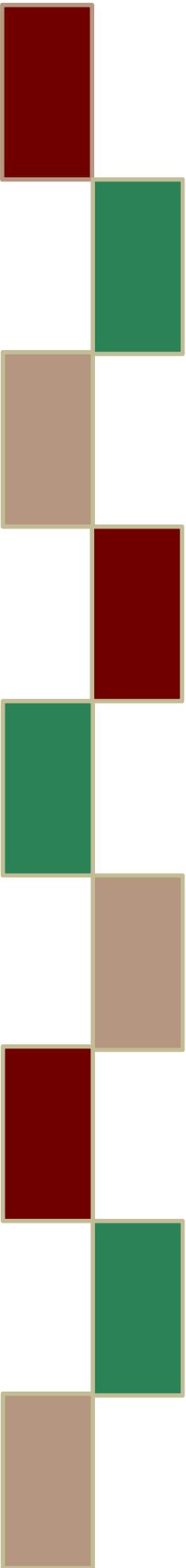
⁵ FDA Drug Safety Communication (olmesartan) available online at

<http://www.fda.gov/Drugs/DrugSafety/ucm359477.htm> Last revised: 7/11/2013. Last accessed: 10/30/2013

⁶ FDA Drug Safety Communication (fluoroquinolones) available online at

<http://www.fda.gov/Drugs/DrugSafety/ucm365050.htm> Last revised: 8/22/2013. Last accessed: 10/30/2013.

Appendix D



Fiscal Year 2013 Annual Review of Botulinum Toxins

Oklahoma Health Care Authority
November 2013

Prior authorization of Botulinum Toxins

The following are the current criteria for the prior authorization of botulinum toxin products:

1. Cosmetic indications will not be covered.
2. A diagnosis of chronic migraine will require manual review (tension headaches are not a covered diagnosis).
3. The following indications listed below have been determined to be appropriate and are covered.

Covered Indications
<ul style="list-style-type: none"> ▪ Spasticity associated with: <ul style="list-style-type: none"> ○ Cerebral Palsy ○ Paralysis ○ Generalized weakness/incomplete paralysis ○ Larynx ○ Anal fissure ○ Esophagus (achalasia and cardiospasm) ○ Eye and Eye movement disorders ▪ Cervical Dystonia

All botulinum toxin products are generally accepted as effective for the treatment of all of the indications on the list above. The following table includes all botulinum toxin products currently available, including FDA approved indications and off-labeled uses.

Brand Name	Chemical Name	FDA Approved Indications	Off-Label Uses
Botox [®] Cosmetic	OnabotulinumtoxinA	*Glabellar and canthal lines	
Botox [®]	OnabotulinumtoxinA	Axillary hyperhidrosis, cervical dystonia, chronic migraine, strabismus and blepharospasm associated with dystonia, upper limb spasticity, overactive bladder	Achalasia, acquired nystagmus, cosmetic use (lines/ wrinkles), gustatory sweating (Frey Syndrome), hand dystonia, headache (tension type), hyperhidrosis (palmar), sialorrhea (drooling in adults), Tourette's syndrome, spasticity associated with cerebral palsy, lower limb spasticity, laryngeal spasticity/dysfunction
Dysport [®]	AbobotulinumtoxinA	Cervical dystonia, *Glabellar lines	Same as above
Xeomin [®]	IncobotuliumtoxinA	Blepharospasm, Cervical dystonia	Same as above
Myobloc [®]	RimabotulinumtoxinB	Cervical dystonia	Sialorrhea (drooling)

*Cosmetic indications are not covered.

Botulinum toxins are billed through the medical claims system. They are denied if submitted through the pharmacy point of sale system. There are four covered products in this class: Botox[®], Dysport[®], Xeomin[®], and Myobloc[®]. Claims billed for Dysport[®], Xeomin[®], or Myobloc[®] are set to detect an appropriate diagnosis from the covered indications list and pay the claim at the point of billing, without further manual intervention. If an appropriate diagnosis is not detected, the claim is denied.

During fiscal year 2013, there was an increase in the number of prior authorizations received for the diagnosis of migraine for Botox[®]. As a result, the review process by the OHCA physician was enhanced. Specific criteria were developed and dispersed to the prior authorization department at the College of Pharmacy. Prior authorization requests were first reviewed by a clinical pharmacist and if necessary, the prior authorization request was sent to OHCA for a “second opinion” from the OHCA physician. At the same time, the prior authorization of Botox[®] for any covered diagnosis was changed to require a manual prior authorization to ensure appropriate reimbursement for the billing provider.

Chronic Migraine Criteria Development

The Botox[®] approval criteria for the prevention of chronic migraine headaches were initially developed internally at OHCA. Medical staff at OHCA then reached out to two SoonerCare contracted neurologists to review the criteria. After consultation, the criteria were altered to incorporate the changes suggested by the neurologists. The following information contributed to the prior authorization criteria development.

Botox[®] Use in Chronic Migraine Headache

Migraines are attacks with throbbing or pulsing pain usually on one side of the head. Patients often have an increased sensitivity to light, odors, and noise; and nausea and vomiting.

Migraines affect women three times more often than men. There are sometimes specific factors that can cause a migraine; these are called triggers and can vary from patient to patient.

A few of the common triggers include sudden changes in weather, too much or a lack of sleep, tobacco, alcohol, skipped meals, medication overuse, caffeine, aged cheeses, and hormones.¹

Migraine is a common and sometimes a debilitating disorder. There are two major subtypes of migraines: episodic and chronic. These are mainly defined by their frequency. Episodic migraines occur fewer than 15 days per month; while chronic migraine headaches are defined as ≥ 15 days per month. The prevalence of chronic migraine in the US is nearly 1%.²

Treatment for migraines aims to alleviate symptoms and prevent additional attacks. Acute or abortive treatments are used as early as possible to relieve pain and get the patient back to the task at hand. Acute treatments include the triptans, ergot derivatives, NSAIDs, narcotics, combination analgesics such as acetaminophen plus caffeine and/or a narcotic, OTC analgesics such as ibuprofen, acetaminophen, or aspirin, and medication for nausea if needed. Taking abortive medications frequently may lead to medication overuse headaches, formerly known as rebound headaches.

Lifestyle changes may reduce or prevent migraines. Some recommended lifestyle changes are consistent sleep schedules, regularly scheduled meals, stopping certain medications known to cause headaches, avoiding foods or beverages known to trigger migraines¹, and stop using tobacco. For patients taking acute relief medications more than three times a week, a preventative therapy is recommended. There are several categories of medications used in the prevention of migraine headaches recommended by the National Institute of Neurological Disorders and Stroke¹ and the American Academy of Neurology.³

- Anticonvulsants, including divalproex sodium, valproate sodium, carbamazepine, and topiramate
- Antihypertensives, including metoprolol, propranolol, timolol, atenolol, nadolol, nebivolol, pindolol, lisinopril, candesartan, clonidine, and guanfacine
- Antidepressants, including amitriptyline and venlafaxine
- Triptans, (menstrual related migraine prevention only) including frovatriptan, naratriptan, and zolmitriptan
- Nutraceuticals, including riboflavin, magnesium, coenzyme Q10, butterbur, feverfew

In October 2010 the FDA approved the use of Botox[®] injection (onabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine.⁴

Efficacy of Botox[®] in Chronic Migraine

The effectiveness of onabotulinumtoxinA (Botox[®]) has been evaluated in several studies. PREEMPT 1 was a double-blind, parallel-group, placebo-controlled trial lasting 24 weeks. The trial enrolled a total of 679 patients with a 1:1 onabotulinumtoxinA or placebo given every 12 weeks. No pharmacological prophylaxis medications were allowed. The patients in the onabotulinumtoxinA group were given 155U-195 units. The primary endpoint was mean change from baseline in frequency of headache episodes for the 28 day period ending with week 24. The primary endpoint was not met when comparing the two groups, onabotulinumtoxinA vs placebo (-5.2 vs -5.3; P = 0.344).

PREEMPT 2 (n=705) was identical in trial design to PREEMPT 1, but the primary endpoint in PREEMPT 2 was the mean change from baseline in frequency of headache days for the 28 day period ending week 24. The primary endpoint was met when comparing the two groups, onabotulinumtoxinA vs placebo (-9.0 vs -6.7; P < 0.001). In a pooled analysis of PREEMPT 1 and 2 there was a mean decrease from baseline in frequency of headache days, with statistically significant difference between the onabotulinumtoxinA vs placebo (-8.4 vs -6.6; P<0.001).⁵ The mean decrease in frequency of headache episodes between the two treatment groups was also statistically significant in the pooled analysis (P=0.009).⁶

The therapeutic gain of onabotulinumtoxinA over placebo is modest when looking at the PREEMPT trials. There was a statistically significant difference between the two study arms, but the absolute difference between the two groups was small (1.8 days).⁷

Adverse Effects: Botox® for Chronic Migraine Prevention

The following table shows the adverse reactions reported by >2% of Botox® treated patients and more frequent than in placebo-treated patients in the two chronic migraine double-blind, placebo-controlled clinical trials.

Adverse Reactions by Organ System Class	BOTOX® 155 Units-195 Units (N=687)	Placebo (N=692)
<u>Nervous system disorders</u>		
Headache	32 (5%)	22 (3%)
Migraine	26 (4%)	18 (3%)
Facial paresis	15 (2%)	0 (0%)
<u>Eye disorders</u>		
Eyelid ptosis	2 (<1%)	2 (<1%)
<u>Musculoskeletal and connective tissue disorders</u>		
Neck pain	25 (4%)	6 (1%)
Musculoskeletal stiffness	24 (4%)	2 (<1%)
Muscular weakness	21 (3%)	6 (1%)
Myalgia	18 (3%)	10 (1%)
Musculoskeletal pain	13 (2%)	6 (1%)
Muscle spasms		
<u>General disorders and administration site conditions</u>		
Injection site pain	23 (3%)	14 (2%)
<u>Vascular Disorders</u>		
Hypertension	11 (2%)	7 (1%)

Other adverse reactions that occurred more frequently in the Botox® group compared to the placebo group at a frequency less than 1% and potentially Botox® related include: vertigo, dry eye, eyelid edema, dysphagia, eye infection, and jaw pain. Severe worsening of migraine requiring hospitalization occurred in approximately 1% of Botox® treated patients in Study 1 and Study 2, usually within the first week after treatment, compared to 0.3% of placebo-treated patients.⁸

Cost Comparison

Medication	Cost (Based on 3 Months of Therapy)
amitriptyline 25-150 mg/day	\$22.97 - \$29.42*
venlafaxine 75-150 mg/day	\$33.07 - \$38.44*
propranolol 80-240 mg/day	\$74.12 - \$231.95*
topiramate 50-200mg/day	\$23.67 - \$33.46*
Botox® 155 units	\$970.35**

*Includes monthly dispensing fee. **One dose of Botox® for chronic migraine cost \$844.75 (155U), and the administration fee is \$125. If the procedure is done in a facility, then there may be additional associated costs

Place in Therapy

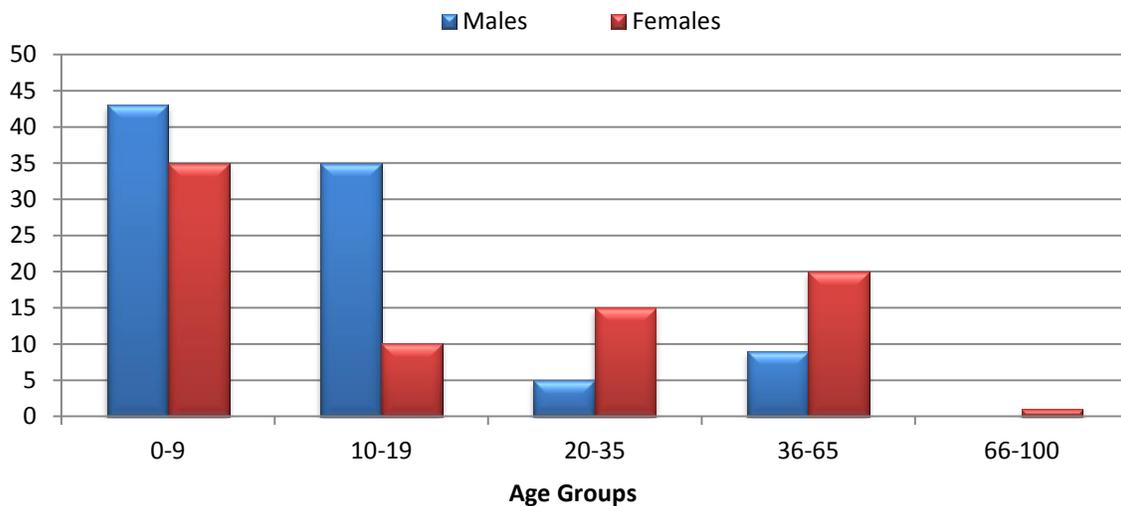
Due to the modest effect, high cost, and potential for severe adverse reactions, Botox® should be reserved for the patient who has failed all available recommended therapies.

Utilization of Botulinum Toxins

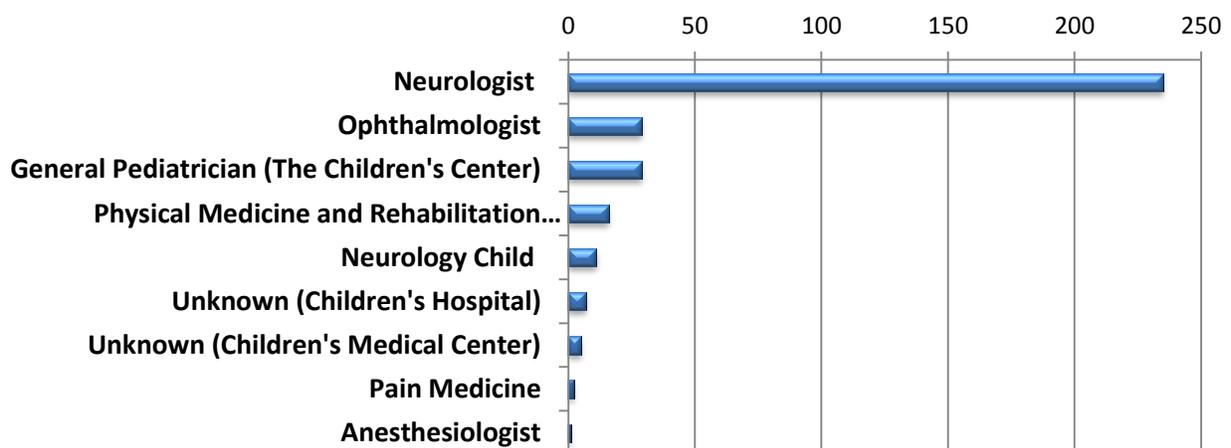
Utilization Comparison

Timeframe	Members	Claims	Cost	Cost/Claim
Oct 2011 – Sep 2012	199	345	\$400,690.95	\$1,161.42
Oct 2012 – Sep 2013	173	310	\$361,220.89	\$1,165.23
% Change	-13.1%	-10.1%	-9.9%	0.33%
Change	-26	-35	-\$39,470.06	\$3.81

Demographics of Members (Oct 2012 – Sep 2013)

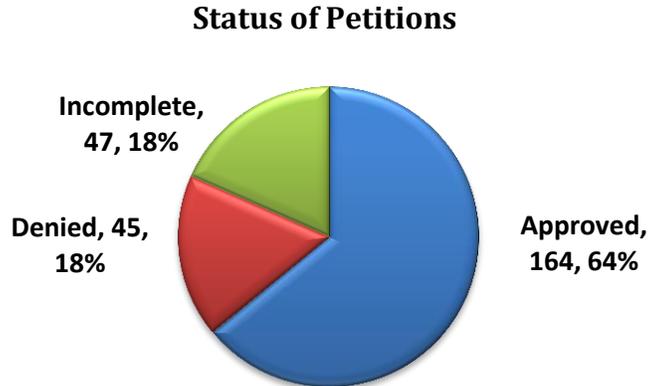


Top Prescriber Specialties by Claims (Oct 2012 – Sep 2013)



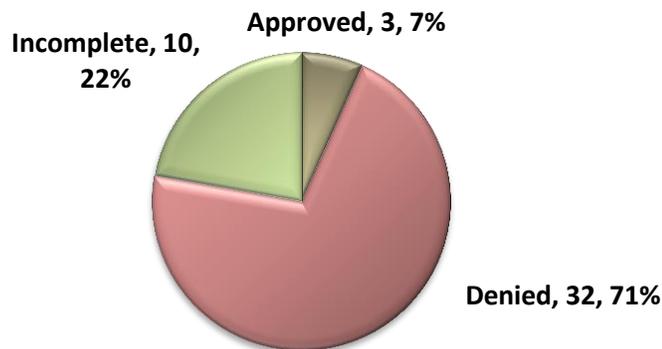
Prior Authorization of Botulinum Toxins

Beginning in April 2013, claims for Botox® required a manual prior authorization. There were a total of 256 petitions received from April 2013 through September 30, 2013. The following chart shows the status of the submitted petitions.



In addition, there were 122 approvals issued pre-emptively for members who had a diagnosis code in the covered diagnoses table before the manual prior authorization process was implemented. Of the 256 manual petitions received, 36 were for the diagnosis of migraine and 9 were for an overactive bladder diagnosis. The following chart shows the status of those petitions.

Status of Petitions: Migraine or Overactive Bladder (Neurogenic and Non-Neurogenic)



Market News and Update

- In September of 2013, Botox Cosmetic® received FDA approval for use to improve the appearance of moderate to severe canthal lines, also known as crow's feet, in adults.⁹ This indication is cosmetic in nature and is not covered by SoonerCare.
- In January of 2013, Botox® received FDA approval for use in the treatment of overactive bladder in patients who cannot use or do not respond adequately to anticholinergic medications.¹⁰ The following section provides details regarding the use of Botox® for this new indication.

Botox® Use in Overactive Bladder

Overactive bladder is a condition that results in urinary incontinence and may be idiopathic or neurogenic in nature. In population-based studies, overactive bladder (non-neurogenic) has a prevalence rate between 7-27% in males, and 9-43% in females.¹¹ The diagnosis of non-neurogenic overactive bladder consists of a combination of two or more of the following components: urgency, frequency, nocturia, and urgency incontinence, in the absence of other UTI or other obvious pathology. Neurogenic bladder dysfunction is caused by disorders of the central nervous system such as injury, tumor, or birth defects affecting the spinal cord, stroke recovery, cerebral palsy, Parkinson's disease, multiple sclerosis, etc. which results in urinary incontinence or retention. Although the patients' symptoms are good indicators of the predominant underlying disorder, in the complex patient additional procedures and measures may be necessary to determine the pathology of the diagnosis, which will further guide the course of treatment.

Treatment of Overactive Bladder (Non-Neurogenic)

The American Urologic Association states that it's important to recognize that overactive bladder is a complex of symptoms that may compromise quality of life, but generally is not life-threatening, and no treatment is an acceptable choice made by some patients and caregivers. As such, in pursuing a treatment plan, both the patient and the clinician should weigh the potential benefits and risks, including the severity and reversibility of the adverse events associated with the treatment. The following are the available treatment options for non-neurogenic overactive bladder:

- **First-Line Treatments:** Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as first line therapy to all patients with OAB – may be combined with anti-muscarinics.
- **Second-Line Treatments:**
 - Clinicians should offer oral anti-muscarinics, unless contraindicated, such as darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium as second-line therapy – including IR, ER, and topical formulations.
 - If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one anti-muscarinic medication, then a dose modification or a different anti-muscarinic medication may be tried.
 - Clinicians should manage constipation and dry mouth before abandoning effective anti-muscarinic therapy. Management may include bowel management, fluid management, dose modification or alternative anti-muscarinics.
 - Patients who are refractory to behavioral and medical therapy should be evaluated by an appropriate specialist if they desire additional therapy.
- **Third-line Treatments:** Clinicians may offer sacral neuromodulation (SNS), peripheral tibial nerve stimulation (PTNS), or intradetrusor Botox® as third-line options in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line OAB treatments.

Treatment of Neurogenic Overactive Bladder

The treatment of neurogenic bladder is aimed at preserving the upper tract physiology and functionality of the kidneys, minimization of lower tract complications, and should be compatible with the patient's lifestyle. Patients with neurogenic overactive bladder often have severe concomitant disease that significantly affects quality of life and more often than not they will require a full-time or part-time care-giver. Patients that may have upper urinary tract involvement should be managed by a urologist and closely followed to minimize the chance of irreversible kidney damage. The management of neurogenic bladder is complex and is significantly dependent on the patient's willingness, cognitive, and physical capabilities, or that of the caregiver. The following are the available treatment options for neurogenic overactive bladder:¹²

- **Non-Invasive Treatment Options**
 - **Assisted bladder emptying** such as the Valsalva technique, triggered reflex voiding, behavior modification techniques, or pelvic floor exercises.
 - **Lower urinary tract rehabilitation using electrical stimulation** such as intravesical electrostimulation, chronic peripheral pudendal stimulation, etc.
 - **Medication treatment** such as antimuscarinic agents, Phosphodiesterase inhibitors (PDE5i), adjunctive desmopressin if applicable. Long-term efficacy and safety of antimuscarinic therapy for neurogenic detrusor overactivity is well documented and outcomes may be maximized by using a combination of antimuscarinic agents. Alpha-blockers may help to decrease bladder outlet resistance and may be a preventive measure in spinal cord injury to prevent autonomic dysreflexia.
 - **External appliances** such as condom catheters or incontinence pads may be an option. Careful attention is required to minimize risk for urinary tract infection.
- **Minimally Invasive Treatment Options**
 - **Catheterization options** - Intermittent self- or third-party catheterization may be used to empty the bladder to avoid over-distention of the bladder. This method of bladder emptying may be coupled with use of anticholinergics or Botox injections if member also has problems with uninhibited contractions that cause leakage in between catheterizations. Aseptic intermittent catheterization is the method of choice and the frequency of catheterization should be 4-6 times per day. Indwelling transurethral and suprapubic catheterization are options, however close monitoring is necessary and the catheter should be changed frequently to minimize risks for UTI and other complications.
 - **Intravesical drug treatment or electrostimulation** may be an option for certain patients, depending on the pathology of the detrusor dysfunction.
 - **Botulinum toxin** injections directly into the detrusor muscle wall causes long-lasting but reversible chemical denervation of the detrusor, which reduces detrusor overactivity.
- **Surgical Treatment Options**
 - Bladder augmentation or bladder myectomy.

Efficacy of Botox® in Overactive Bladder (Non-Neurogenic)¹³

The efficacy of Botox was demonstrated in two double-blind, placebo-controlled, randomized; multi-center, 24-week clinical studies in patients with symptoms of urge urinary incontinence, urgency, and frequency. The primary efficacy endpoint was the average reduction in daily episodes of urinary incontinence. The two trials consisted of a total of 557 patients who received 100 units of Botox and 548 patients who received placebo injections into the detrusor muscle. Statistically significant improvement was observed in the primary and secondary endpoints as shown below:

Results of Study 1	Botox® 100 Units (278 Patients)	Placebo (272 Patients)	Treatment Difference	P-value
Daily Frequency of Urinary Incontinence Episodes (primary efficacy endpoint)				
Mean Baseline	5.5	5.1		
Mean Change at Week 2	-2.6	-1.0	-1.6	
Mean Change at Week 6	-2.8	-1.0	-1.8	
Mean Change at Week 12	-2.5	-0.9	-1.6 (-2.1, -1.2)	<0.001
Daily Frequency of Micturition Episodes (secondary efficacy endpoint)				
Mean Baseline	12.0	11.2		
Mean Change at Week 12	-1.9	-0.9	-1.0 (-1.5, -0.6)	<0.001
Volume Voided per Micturition (mL) (secondary efficacy endpoint)				
Mean Baseline	156	161		
Mean Change at Week 12	38	8	30 (17,43)	<0.001

Results of Study 2	Botox® 100 Units (275 Patients)	Placebo (269 Patients)	Treatment Difference	P-value
Daily Frequency of Urinary Incontinence Episodes (primary efficacy endpoint)				
Mean Baseline	5.5	5.7		
Mean Change at Week 2	-2.7	-1.1	-1.6	
Mean Change at Week 6	-3.1	-1.3	-1.8	
Mean Change at Week 12	-3.0	-1.1	-1.9 (-2.5, -1.4)	<0.001
Daily Frequency of Micturition Episodes (secondary efficacy endpoint)				
Mean Baseline	12.0	11.8		
Mean Change at Week 12	-2.3	-0.6	-1.7 (-2.2, -1.3)	<0.001
Volume Voided per Micturition (mL) (secondary efficacy endpoint)				
Mean Baseline	144	153		
Mean Change at Week 12	40	10	31 (20,41)	<0.001

The median duration of response in Study 1 and 2, based on patient qualification for re-treatment, was 19-24 weeks for the Botox® 100 Unit dose group compared to 13 weeks for placebo. To qualify for re-treatment, at least 12 weeks must have passed since the prior treatment, post-void residual urine volume must have been less than 200 mL and patients must have reported at least 2 urinary incontinence episodes over 3 days.

Efficacy of Botox® in Overactive Neurogenic Bladder

The efficacy of Botox® was demonstrated in two double-blind, placebo-controlled, randomized, multi-center clinical studies in patients with urinary incontinence due to detrusor overactivity associated with a neurologic condition who were either spontaneously voiding or using catheterization. A total of 691 spinal cord injury (T1 or below) or multiple sclerosis patients, who had an inadequate response to or were intolerant of at least one anticholinergic medication, were enrolled. These patients were randomized to receive either 200 or 300 Units of Botox® or placebo. Statistically significant improvement was observed in the primary endpoint as shown below. No additional benefit of Botox® 300 Units over 200 Units was demonstrated.

Results of Study 1	Botox® 200 Units	Placebo	Treatment Difference	P-value
Weekly Frequency of Urinary Incontinence Episodes (primary efficacy endpoint)				
Number of Patients	134	146		
Mean Baseline	32.3	28.3		
Mean Change at Week 2	-15.3	-10.0	-5.3	-
Mean Change at Week 6*	-19.9	-10.6	-9.2	<0.001
Mean Change at Week 12	-19.8	-8.8	-11.0	-
Max Cystometric Capacity (mL) (secondary endpoint)				
Number of Patients	123	129		
Mean Baseline	253.8	259.1		
Mean Change at Week 6*	135.9	12.1	123.9 (89.1, 158.7)	<0.001

*Primary efficacy timepoint

Results of Study 2	Botox® 200 Units	Placebo	Treatment Difference	P-value
Weekly Frequency of Urinary Incontinence Episodes (primary efficacy endpoint)				
Number of Patients	91	91		
Mean Baseline	32.7	36.8		
Mean Change at Week 2	-18.0	-7.9	-10.1	-
Mean Change at Week 6*	-19.6	-10.8	-8.8 (-14.5, -3.0)	0.003
Mean Change at Week 12	-19.6	-10.7	-8.9	-
Max Cystometric Capacity (mL) (secondary endpoint)				
Number of Patients	88	85		
Mean Baseline	239.6	253.8		
Mean Change at Week 6*	150.8	2.8	148 (101.8, 194.2)	<0.001

*Primary efficacy timepoint

The median duration of response in study 1 and 2, based on patient qualification for re-treatment was 295-337 days (42-48 weeks) for the 200 Units dose group compared to 96-127 days (13-18 weeks) for placebo. Re-treatment was based on loss of effect on incontinence episode frequency.

Adverse Effects of Botox® in Overactive Bladder Clinical Trials

The following are adverse reactions specific to the trials in patients with overactive bladder and do not include a comprehensive listing of all Botox® adverse side effects.

Non-Neurogenic Overactive Bladder Clinical Trials (within the first 12 weeks)	Botox® 100 Units (N=552)	Placebo (N=542)
Urinary tract infection*	99 (18%)	30 (6%)
Dysuria	50 (9%)	36 (7%)
Urinary retention	31 (6%)	2 (0%)
Bacteriuria	24 (4%)	11 (2%)
Residual urine volume*	17 (3%)	1 (0%)

*higher incidence in diabetic patients and those with max post-void residual volume \geq 200mls

Neurogenic Overactive Bladder Clinical Trials (within the first 12 weeks)	Botox® 200 Units (N=262)	Placebo (N=272)
Urinary tract infection	64 (24%)	47 (17%)
Urinary retention	45 (17%)	8 (3%)
Hematuria	10 (4%)	8 (3%)

The following adverse reactions with Botox® 200 units were reported at any time following initial injection and prior to re-injection or study exit (median duration of 44 weeks of exposure):

- Urinary tract infections (49%)
- Urinary retention (17%)
- Constipation (4%)
- Muscular weakness (4%)
- Dysuria (4%)
- Fall (3%)
- Gait disturbance (3%)
- Muscle spasm (2%)

Other post-marketing reported adverse effects include:

- Serious adverse events including fatal outcomes have been reported in patients who had received Botox® injected directly into salivary glands, the oro-lingual-pharyngeal region, esophagus and stomach.
- Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea.
- Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from therapeutic doses of Botox®.
- Treatment with Botox® and other botulinum toxin products can result in swallowing or breathing difficulties. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin.

- Patients with compromised respiratory status treated with Botox® for upper limb spasticity should be monitored closely for reduced lung function and increased risk for respiratory tract infections.
- Reduced blinking from Botox® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect, and corneal ulceration, especially in patients with VII nerve disorders.
- During the administration of Botox® for the treatment of strabismus, retrobulbar hemorrhages sufficient to compromise retinal circulation have occurred.
- Autonomic dysreflexia associated with intradetrusor injections of Botox® could occur in patients treated for detrusor overactivity associated with a neurologic condition and may require prompt medical therapy.
- Due to the risk of urinary retention, treat only patients who are willing and able to initiate catheterization post-treatment, if required, for urinary retention.

Cost Comparison

- **Anticholinergic Medications** – the average cost per day ranges from \$0.43 for Tier 1 medications up to \$5.65 for Tier 3 medications (\$12.90 to \$169.50 per month)
- **Botox®** - Costs range from \$529 to \$1,094 (100 to 200 units). The average re-injection time is 19-24 weeks for the 100 unit dose, and 42-48 weeks. An average of 6 months is selected for price comparison purposes (\$88-\$182.33 per month), not including hospital costs and physician administration fees.
- **Neurostimulation Devices** – not a covered SoonerCare benefit
- **Surgical Intervention** – costs range between \$30,000 - \$50,000 for the procedure, not including hospital costs.

Recommendations

- A. The College of Pharmacy recommends placement of Dysport®, Xeomin®, and Myobloc® under the manual prior authorization process to make the authorization requirements for all botulinum toxin products uniformed.
- B. The College of Pharmacy also recommends the following prior authorization criteria for making coverage determinations for the prevention of chronic migraine, or to improve symptoms associated with overactive bladder (non-neurogenic and neurogenic).
 1. **Approval Criteria for Botox® for Prevention of Migraine Headaches (other botulinum toxins will not be approved for this use):**
 - a. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes but is not limited to:
 - i. Increased intracranial pressure (e.g. tumor, pseudotumor cerebri, central venous thrombosis, etc.)

- ii. Decreased intracranial pressure (e.g. post-lumbar puncture headache, dural tear after trauma, etc.)
- b. Migraine headache exacerbation secondary to other medical conditions or therapies have been ruled out and/or treated. This includes but is not limited to:
 - i. Hormone replacement therapy or hormone-based contraceptives
 - ii. Chronic insomnia
 - iii. Obstructive sleep apnea
- c. Member has no contraindications to Botox injections
- d. FDA indications are met:
 - i. Member is 18 or older
 - ii. Member has a documented chronic migraine headaches
 - Frequency of 15 or more days per month; and
 - Duration of 4 hours per day or longer.
- e. The member has failed medical migraine preventive therapy including at least 3 agents in 3 or more categories, but not limited to:
 - i. Select antihypertensive therapy such as beta-blocker therapy
 - ii. Select anticonvulsant therapy
 - iii. Select antidepressant therapy (e.g. TCA or SNRI)
- f. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headache) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes but is not limited to:
 - i. Decongestants (alone or in combination product)
 - ii. Combination analgesics containing caffeine and/or butalbital (>5 day/mo)
 - iii. Narcotics
 - iv. Analgesic medications including acetaminophen and most NSAIDS
 - v. Ergotamine-containing medications (>8 day/mo)
 - vi. Triptans (>8 day/mo)
- g. Member is not taking any medications that are likely to be the cause of the headaches.
- h. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox recommended as treatment. (Not necessarily prescribed or administered by neurologists.)
- i. Members who smoke or use tobacco products will not be approved.

2. Approval Criteria for Botox® for Non-Neurogenic Overactive Bladder (other botulinum toxins will not be approved for this use):

- a. Member must have severe disease (> 6 urinary incontinence episode per day) and specific pathology determined via urodynamic studies.
- b. Member must have participated in behavioral therapy for at least 12 weeks that did not yield adequate clinical results.
- c. Member must have had compliant use of at least 3 antimuscarinic medication(s) for at least 12 weeks each, alone or in combination with behavioral therapy, that

did not yield adequate clinical results. One of those trials must have been an extended release formulation.

- d. Member must be 18 years of age or older, and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary.
- e. Only Urologists will be approved for administration of this procedure.

3. Approval Criteria for Botox® for Neurogenic Overactive Bladder (other botulinum toxins will not be approved for this use):

- a. Diagnosis of neurogenic bladder including underlying pathological dysfunction subtype confirmed by:
 - i. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
 - ii. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences.
- b. Must have a clinically significant reason why anticholinergic medications are no longer an option for the member.
- c. Member must be 18 years of age or older, and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary.
- d. Only Urologists will be approved for administration of this procedure.

¹ National Institute of Neurological Disorders and Stroke: Headache; Hope Through Research. Published online at: http://www.ninds.nih.gov/disorders/headache/detail_headache.htm Last accessed 11/4/2013.

² Dawn C. Buse, PhD, Aubrey N. Manack, PhD, Kristina M. Fanning, PhD, Daniel Serrano, PhD, Michael L. Reed, PhD, Catherine C. Turkel, PhD, PharmD, Richard B. Lipton, MD, Chronic Migraine Prevalence, Disability, and Sociodemographic Factors; Headache 2012; 52 (10):1456-1470. Published online at: <http://www.medscape.com/viewarticle/775862> Last accessed 11/4/2013.

³ S.D. Silberstein, S. Holland, F. Freitag, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society; Neurology 2012;78;1337-1345, Published online at <http://www.neurology.org/content/78/17/1337.full.pdf+html>. Last accessed 11/4/2013.

⁴ FDA approves Botox to treat chronic migraine; FDA News Release, Published at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229782.htm> . Last accessed 11/4/2013.

⁵ Robertson, Carrie and Garza, Ivan: Critical analysis of the use of onabotulinumtoxinA (botulinum toxin type A) in migraine. Neuropsychiatric Disease and Treatment 2012; 8: 35-48 Published online at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3261651/> . Last accessed 11/5/2013.

⁶ Dodick, David W., MD; Turkel, Catherine C., MD; et al OnabotulinumA for Treatment of Chronic Migraine: Pooled Results From the Double-Blind, Randomized, Placebo-Controlled Phases of the PREEMPT Clinical Program; Headache 2010; 50(6):921-36

⁷ Robertson, Carrie and Garza, Ivan: Critical analysis of the use of onabotulinumtoxinA (botulinum toxin type A) in migraine. Neuropsychiatric Disease and Treatment 2012; 8: 35-48 Published online at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3261651/> . Last accessed 11/5/2013.

⁸ Botox® full prescribing information. Published at http://www.allergan.com/assets/pdf/botox_pi.pdf Last accessed 11/5/2013.

⁹ FDA approves Botox Cosmetic to improve the appearance of crow's feet lines. FDA News Release. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367662.htm>. Last revised 9/11/2013. Last accessed 10/10/2013.

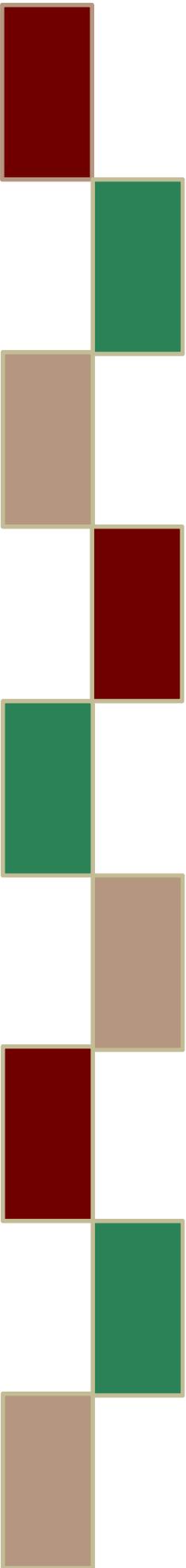
¹⁰ FDA approves Botox to treat overactive bladder. FDA News Release. Available online at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm336101.htm>. Last revised 1/22/2013. Last accessed 10/10/2013.

¹¹ Gormley, Ann E. Lightner, Deborah J. Burgio, Kathryn L., et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFA Guideline. Copyright 2012 American Urologic Association Education and Research. Published Online at <http://www.auanet.org/education/guidelines/overactive-bladder.cfm>. Last accessed 10/11/2013.

¹² Pannek, J. Stohrer, M. Blok, B., et al. Guidelines on Neurogenic Lower Urinary Tract Dysfunction. Copyright 2011 European Association of Urology. Published online at: http://www.uroweb.org/gls/pdf/17_Neurogenic%20LUTS.pdf. Last accessed 10/11/2013.

¹³ Botox Product Label. Allergan, Inc. available online at: http://www.allergan.com/assets/pdf/botox_pi.pdf. Last revised 1/2013. Last accessed 10/24/2013.

Appendix E



Fiscal Year 2013 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
November 2013

Current Prior Authorization Criteria

The prior authorization of select prenatal vitamins was implemented in February 2012. An educational outreach was implemented prior to the prior authorization of the prenatal vitamins that included an article in the provider newsletter, along with a targeted mailing initiative to all prescribers of prenatal vitamins in the SoonerCare population. The following criteria apply:

1. Prenatal vitamins with a cost per day greater than \$0.75 require prior authorization with the following criteria for approval:
 - a. A clinically significant reason why the member cannot use any available non-prior authorized products.
2. Prior authorization requirements may be removed when the product's price is at or below the designated pricing cutoff.

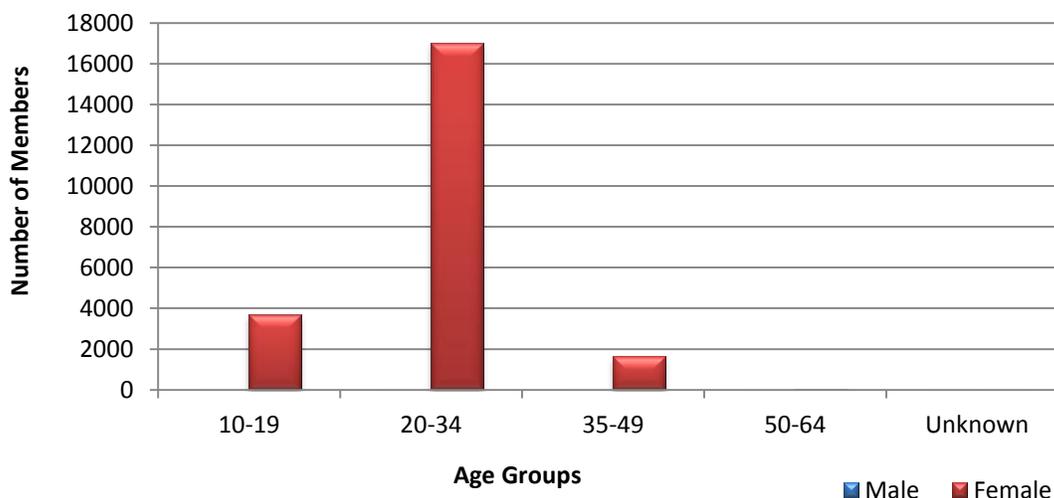
Utilization of Prenatal Vitamins

Comparison of Fiscal Years for Prenatal Vitamins

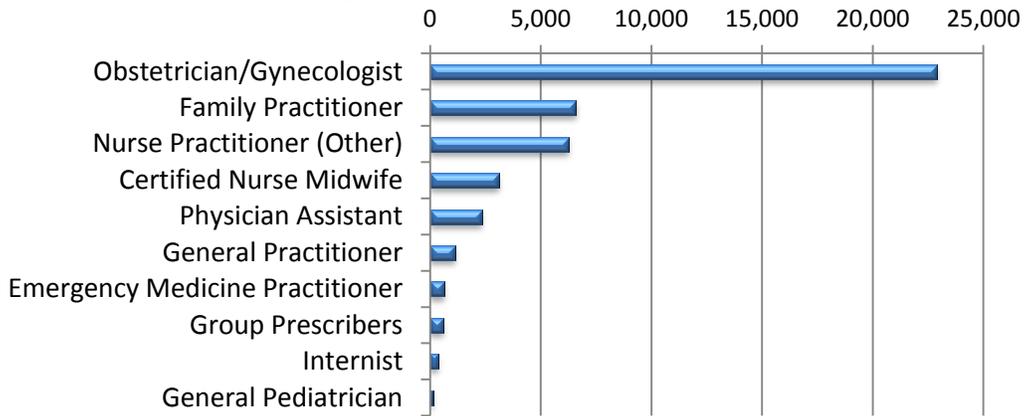
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2012	25,604	54,155	\$2,477,107.35	\$45.74	\$0.99	2,685,417	2,514,288
2013	22,304	44,361	\$1,165,116.12	\$26.26	\$0.56	2,126,059	2,087,966
% Change	-12.90%	-18.10%	-53.00%	-42.60%	-43.40%	-20.80%	-17.00%
Change	-3,300	-9,794	-\$1,311,991.23	-\$19.48	-\$0.43	-559,358	-426,322

*Total number of unduplicated members.

Demographics of Members Utilizing Prenatal Vitamins

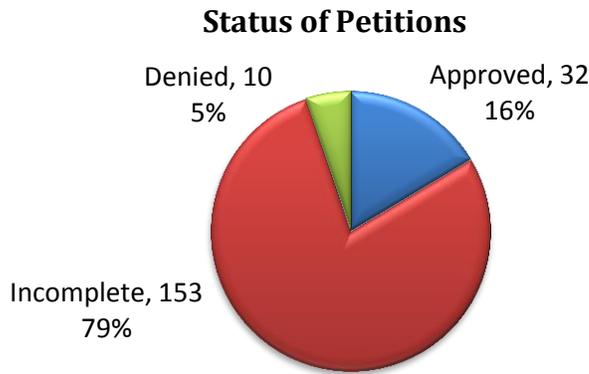


Top Prescriber Specialties of Prenatal Vitamins by Claims



Prior Authorization of Prenatal Vitamins

There were a total of 195 petitions submitted for prenatal vitamins during fiscal year 2013. The following chart shows the status of the submitted petitions.



Market News and Updates¹

- **01/14/13** Citranatal® 90 DHA became available in generic as Natalvirt™ 90 DHA, and Citranatal® Assure became available in generic as Natalvirt™ CA.
- **03/01/13** Prefera® OB became available in generic as VP-Heme One.
- **05/17/13** Select OB® + DHA became available in generic as Choice-OB + DHA.
- **09/20/13** Vitafol® Ultra was release as a new product.

Recommendations

The College of Pharmacy recommends a second educational initiative consisting of a targeted mailing to all prescribers of prenatal vitamins in the SoonerCare population in the last 12 months. The mailing may include information regarding coverage of prenatal vitamins, a sample prescription form, and a link to the OHCA web page which contains the updated list of covered products. An article will also be included in the SoonerCare member newsletter, with a link to the list of covered products. The list of preferred prenatal vitamin products will also be faxed to all SoonerCare contracted pharmacies.

Preferred Prenatal Vitamins

NDC Code	Description	Description Detail
00813-0202-01	O-CAL PRENATAL	PRENATAL VIT/IRON FUMARATE/FA ORAL 15-1MG TABLET
00813-9316-01	O-CAL FA	PRENATAL VIT/IRON FUMARATE/FA ORAL 66-1MG TABLET
00904-5339-60	PRENATAL PLUS	PNV WITH CA,NO.72/IRON/FA ORAL 27 MG-1 MG TABLET
10267-2069-01	PRENATAL LOW IRON	PNV WITH CA,NO.74/IRON/FA ORAL 27 MG-1 MG TABLET
10267-2069-05	PRENATAL LOW IRON	PNV WITH CA,NO.74/IRON/FA ORAL 27 MG-1 MG TABLET
13811-0007-10	TRINATAL RX 1	PRENATAL VIT27&CALCIUM/IRON/FA ORAL 60 MG-1 MG TABLET
13811-0014-90	COMPLETENATE	PNV #14/FERROUS FUM/FOLIC ACID ORAL 29 MG-1 MG TAB CHEW
13811-0010-30	COMPLETE NATAL DHA	PNV2/IRON B-G SUC-P/FA/OMEGA-3 ORAL 29-1-250MG COMBO.
13811-0514-10	VOL-NATE	PRENATAL VIT NO.73/IRON/FA ORAL 28 MG-1 MG TABLET
13811-0516-90	VOL-TAB RX	PRENATAL VIT #76/IRON,CARB/FA ORAL 29 MG-1 MG TABLET
13811-0519-10	VOL-PLUS	PNV WITH CA,NO.71/IRON/FA ORAL 27 MG-1 MG TABLET
13811-0519-50	VOL-PLUS	PNV WITH CA,NO.71/IRON/FA ORAL 27 MG-1 MG TABLET
13811-0529-90	TRIADVANCE	PRENATAL VIT 15/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
13811-0535-30	FOLIVANE-OB	PNV NO.15/IRON FUM & PS CMP/FA ORAL 85 MG-1 MG CAPSULE
13811-0536-30	TARON-C DHA	PNV#16/IRON FUM & PS/FA/OM-3 ORAL 35-1-200MG CAPSULE
13811-0563-01	TRIVEEN-U	PNV W-O CA NO5/FE FUMARATE/FA ORAL 106.5-1MG CAPSULE
13811-0614-90	TRINATAL GT	PRENATAL VIT 16/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
13811-0615-10	TRINATAL ULTRA	PRENATAL VIT 18/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
13925-0116-01	SE-NATAL 19	PRENATAL VIT/FE FUM/DOSS/FA ORAL 29 MG-1 MG TABLET
13925-0117-01	SE-NATAL 19	PRENATAL VIT/FE FUMARATE/FA ORAL 29 MG-1 MG TAB CHEW
13925-0119-90	SE-TAN DHA	PNV NO10/IRON FUM&P/FA/OMEGA-3 ORAL 30-1-310.1 CAPSULE
42192-0318-30	MULTINATAL PLUS	PV W-O VIT A/FE FUMARATE/FA ORAL 40-1MG TAB CHEW
44946-1046-00	PNV FOLIC ACID +	PRENATAL VIT COMBO NO.60/FERROUS FUMARATE/FOLIC ACID
44946-1046-02	PNV FOLIC ACID +	PRENATAL VIT COMBO NO.60/FERROUS FUMARATE/FOLIC ACID
44946-1046-04	PNV FOLIC ACID +	PRENATAL VIT COMBO NO.60/FERROUS FUMARATE/FOLIC ACID
51991-0159-91	VINATE GT	PRENATAL VIT 16/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
51991-0178-01	VINATE II	PRENATAL VITAMINS/FE BISGLY/FA ORAL 29 MG-1 MG TABLET
52747-0620-30	CONCEPT OB	PNV NO.15/IRON FUM & PS CMP/FA ORAL 85 MG-1 MG CAPSULE
52747-0621-30	CONCEPT DHA	PNV#16/IRON FUM & PS/FA/OM-3 ORAL 35-1-200MG CAPSULE
63044-0153-01	INATAL ADVANCE	PRENATAL VIT 15/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
63044-0153-64	INATAL ADVANCE	PRENATAL VIT 15/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
63044-0154-01	INATAL ULTRA	PRENATAL VIT 18/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
63044-0154-63	INATAL ULTRA	PRENATAL VIT 18/IRON CB/FA/DSS ORAL 90-1-50 MG TABLET
64376-0816-01	PRENATAL PLUS	PNV WITH CA,NO.72/IRON/FA ORAL 27 MG-1 MG TABLET
64376-0816-05	PRENATAL PLUS	PNV WITH CA,NO.72/IRON/FA ORAL 27 MG-1 MG TABLET
64376-0818-01	PRENATE PLUS	PNV WITH CA,NO.71/IRON/FA ORAL 27 MG-1 MG TABLET
65162-0668-10	PRENATAL PLUS	PNV WITH CA,NO.72/IRON/FA ORAL 27 MG-1 MG TABLET
65162-0668-50	PRENATAL PLUS	PNV WITH CA,NO.72/IRON/FA ORAL 27 MG-1 MG TABLET

Revised 09/26/2013

Utilization Details of Prenatal Vitamins: Fiscal Year 2013

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
CURRENT PREFERRED PRENATAL VITAMINS						
Prenat w/ Fe Fumarate-FA 27-1MG	PRENATAL TAB PLUS	13,174	7,270	\$123,360.67	\$0.20	10.59%
Prenat w/ Fe Fumarate-FA 27-1MG	PRENATAL VIT TAB PLUS	1,252	895	\$16,772.04	\$0.22	1.44%
Prenat w/o A w/Fe Fum-Fe Poly-FA 130-92.4-1MG	FOLIVANE-OB CAP	1,212	740	\$32,903.55	\$0.62	2.82%
Prenat w/ Fe Fumarate-FA 27-1MG	PRENAPLUS TAB	997	907	\$12,854.54	\$0.23	1.10%
Prenat w/ Fe Fumarate-FA 27-1MG	VOL-PLUS TAB	924	526	\$9,613.29	\$0.27	0.83%
Prenat w/ Iron Carbonyl-FA 29-1MG	PRENATAL TAB PLUS FE	894	578	\$6,806.59	\$0.16	0.58%
Prenat w/ DSS-Fe Fumarate-FA 29-1MG	SE-NATAL 19 TAB	609	385	\$9,649.45	\$0.34	0.83%
Prenat w/o A w/Fe Fum-Fe Poly-FA 130-92.4-1MG	CONCEPT OB CAP	428	282	\$13,124.84	\$0.61	1.13%
Prenat w/ Iron Carbonyl-FA 29-1MG	VOL-TAB RX TAB	316	195	\$3,557.78	\$0.25	0.31%
Prenat w/ DSS-Iron Carbonyl-FA 90-1MG	VINATE GT TAB	277	180	\$4,748.29	\$0.29	0.41%
Prenat w/ Fe Fumarate-FA 29-1MG	COMPLETENATE CHW	211	152	\$7,616.76	\$0.61	0.65%
Prenat w/ Fe Fumarate-FA 29-1MG	SE-NATAL 19 CHW	82	56	\$1,375.95	\$0.36	0.12%
Prenat w/ DSS-Fe Fumarate-FA 29-1MG	PRENATAL 19 TAB	45	44	\$715.15	\$0.31	0.06%
Prenat w/ DSS-FE Carbonyl-FA 90-1MG	TRIADVANCE TAB	24	11	\$291.23	\$0.30	0.02%
Prenat w/ Fe Bisglycinate Chelate-FA 29-1MG	VINATE II TAB	3	1	\$39.96	\$0.44	0.00%
Prenat w/o A w/ Fe Fum-FA 106.5-1MG	TRIVEEN-U CAP	2	1	\$23.22	\$0.39	0.00%
Prenat w/ Fe Fumarate-FA 15-1MG	O-CAL TAB PRENATAL	1	1	\$16.25	\$0.18	0.00%
Prenat w/ Fe Fumarate-FA 28-1 MG	VOL-NATE TAB	1	1	\$8.44	\$0.28	0.00%
Prenat w/ Fe Fumarate-FA 27-1MG	PRENATAL TAB LOW FE	1	1	\$4.84	\$0.16	0.00%
CURRENT PREFERRED PRENATAL VITAMINS WITH DHA						
Prenat w/Fe Fum-Fe Poly -FA-Omega 3 53.5-38-1MG	TARON-C DHA CAP	8,884	5,557	\$328,737.36	\$0.74	28.21%
Prenat w/Fe Fum-Fe Poly -FA-Omega 3 53.5-38-1MG	CONCEPT DHA CAP	6,557	3,366	\$224,282.03	\$0.75	19.25%
Prenat w/Fe Fum-Fe Poly -FA-Omega 3 15-15-1MG	SE-TAN DHA CAP	3,496	1,566	\$108,724.47	\$0.73	9.33%
Prenat-Fe Bis-Fe Prot Succ-FA-Ca & Omega 3 Cap 250	COMPLETE NAT PAK DHA	43	22	\$1,019.33	\$0.74	0.09%
CURRENT PRIOR AUTHORIZED PRENATAL VITAMINS						
Prenat w/ Fe Fumarate-FA 65-1MG	VITAFOL-OB TAB 65-1MG	1,146	506	\$43,955.09	\$0.87	3.77%
Prenat w/ Fe Polysac Cmplx-FA-DHA 29-1-200MG	VITAFOL-ONE CAP	619	299	\$47,752.65	\$2.02	4.10%
Prenat w/ Fe Fumarate-FA 60-1MG	VINATE ONE TAB	358	226	\$5,593.27	\$0.25	0.48%
Prenat w/ Iron Carbonyl-FA 29-1MG	PRENATABS RX TAB	176	148	\$2,055.80	\$0.25	0.18%
Prenat w/o A w/ Fe Fum-FA 40-1MG	VINATE CARE CHW	161	80	\$4,359.60	\$0.71	0.37%
Prenat w/o A w/FeCbn-FeGl-DSS-FA & DHA 300MG	CITRANATAL PAK ASSURE	155	83	\$10,627.45	\$2.26	0.91%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 27-1.25-300MG	PRENEXA CAP	149	71	\$21,743.97	\$3.25	1.87%
Prenat w/o A w/ Fe Cbnl-FA 20-1MG & B6	TARON-BC MIS	127	64	\$3,877.00	\$0.75	0.33%
Prenat w/ DSS-Iron Carbonyl-FA 90-1MG	VINATE ULTRA TAB	125	107	\$1,216.37	\$0.25	0.10%
Prenat w/ Sel-Fe Fumarate-FA 27-1MG	VINATE M TAB	124	82	\$1,565.38	\$0.22	0.13%
Prenat w/o A w/FeCbn-Fe Asp Glyc-FA-Fish 50-1-476MG	OB COMPLETE CAP ONE	117	67	\$19,202.17	\$3.08	1.65%
Prenat w/o A w/ Fe Fum-Methylfol-FA-DHA 27-0.6-0.4MG	PNV-DHA CAP	100	73	\$8,944.10	\$1.81	0.77%
Prenat w/o A w/ Fe Carbonyl-Fe Gluc-DSS-FA 27-1MG	VINACAL TAB	100	62	\$2,390.09	\$0.41	0.21%

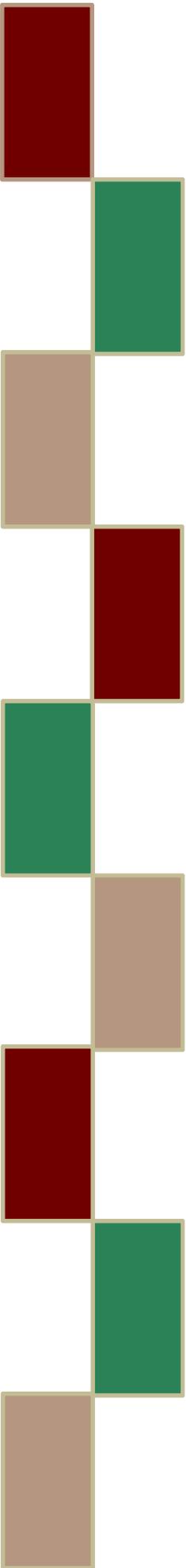
GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Prenat w/Fe Fum-FA 65-1 MG & DHA 250MG	VITAFOL-OB PAK +DHA	97	37	\$6,085.01	\$2.06	0.52%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 27-1.25-300MG	FOLCAL DHA CAP	90	46	\$5,558.79	\$1.32	0.48%
Prenat w/Fe Poly-FA 29-1MG & DHA 250MG	SELECT-OB+ PAK DHA	88	34	\$5,986.43	\$2.09	0.51%
Prenat w/ Fe Fumarate-FA 29-1MG	PRENATAL 19 CHW TAB	86	86	\$2,109.88	\$0.32	0.18%
Prenat w/o A w/FeCbn-FeGlu-FA 20-1MG & B6	CITRANATAL MIS B-CALM	84	51	\$4,501.76	\$1.39	0.39%
Prenat w/ Fe Fumarate-FA 60-1MG	TRINATAL RX TAB 1	72	36	\$1,079.96	\$0.27	0.09%
Prenat w/o A w/ Fe Cbn-DSS-FA-DHA 30-1-260MG	CITRANATAL CAP HARMONY	63	28	\$4,613.73	\$2.18	0.40%
Prenat-Fe Poly Cmplx-Fe Heme Poly-FA & Omega 3	PREFERA OB MIS + DHA	63	32	\$3,669.07	\$1.88	0.31%
Prenat w/o A w/ Fe Cbnyl-FA 20-1MG & B6	CITRANATAL MIS B-CALM	63	40	\$3,038.22	\$1.43	0.26%
Prenat w/o A w/ Fe Fum-Methylfol-FA-DHA 27-0.6-0.4MG	VIRT-PN DHA CAP	62	33	\$5,052.58	\$1.67	0.43%
Prenat w/ Fe Fum-Methylfolate-FA 27-0.6-0.4MG	PNV-SELECT TAB	57	33	\$3,225.08	\$1.29	0.28%
Prenat w/o A w/ Fe Fum-Methylfol-FA-DHA 27-0.6-0.4MG	ZATEAN-PN CAP DHA	54	33	\$3,321.94	\$1.49	0.29%
Prenat w/o A w/FeCbn-FeGI-DSS-FA 90 &DHA 300MG	CITRANATAL MIS 90 DHA	52	21	\$3,378.20	\$2.05	0.29%
Prenat w/ Fe Fumarate-FA 29-1MG	PRENATABS FA TAB	36	36	\$368.01	\$0.21	0.03%
Prenat -Fe Poly Cmplx-Fe Heme Poly-FA 28-6-1MG	PREFERA OB TAB	36	21	\$4,119.62	\$2.44	0.35%
Prenat w/ Fe Cbn-Fe Asp Glyc-FA-Omega (3) 27-1MG	ULTIMATECARE CAP ONE	35	25	\$2,576.36	\$1.03	0.22%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 30-1.2-265MG	TARON-PREX CAP	31	14	\$1,158.83	\$1.04	0.10%
Prenat w/o A w/FeCbn-FeGI-DSS-FA & DHA 250MG	PNV OB+DHA PAK	27	12	\$1,348.35	\$1.66	0.12%
Prenat w/o A w/FeCbn-FeGI-DSS-FA & DHA 250MG	CITRANATAL PAK DHA	27	13	\$1,733.70	\$2.14	0.15%
Prenat-Fe Poly Cmplx-Fe Heme Poly-FA-DHA 22-6-1-200MG	PREFERAOB CAP ONE	27	15	\$2,194.40	\$2.52	0.19%
Prenat w/o A w/Fe Cbn-DSS-FA-DHA 28-1-250MG	CITRANATAL CAP HARMONY	24	11	\$1,575.21	\$2.02	0.14%
Prenat w/o A w/ Fe Fum-Methylfolate-FA-Omega 3	ZATEAN-PN CAP PLUS	24	16	\$1,283.90	\$1.31	0.11%
Prenat w/o A w/FeCbn-Fe Asp Glyc-FA-Fish 40-10-1MG	OB COMPLETE CAP 400	24	10	\$2,542.46	\$3.03	0.22%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 29-1.25-325MG	TL-SELECT CAP	22	16	\$1,996.58	\$2.19	0.17%
Prenat w/o A w/ Fe Fum-Doc-FA-DHA 29-1.25-350MG	NEXA PLUS CAP	17	6	\$1,697.89	\$3.33	0.15%
Prenat w/o A w/Fe Fum-Fe Poly-FA 162.115.2-1MG	VINATE IC CAP	16	13	\$498.61	\$0.46	0.04%
Prenat w/ Fe Bisglycinate Chelate-FA 27-1MG	VINATE AZ TAB	16	11	\$369.72	\$0.56	0.03%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 27-1.25-300MG	VEMAVITE- CAP PRX 2	15	8	\$871.74	\$1.38	0.07%
Prenat w/Fe Fum-FA DR 27-1 MG & DHA 250MG	GESTICARE PAK DHA	12	6	\$759.18	\$2.11	0.07%
Prenat w/o A w/FeCbn-FeGI-DSS-FA & DHA 300MG	NATALVIRT CA PAK	12	6	\$698.16	\$1.94	0.06%
Prenat w/o A w/Fe Cbn-DSS-FA-DHA 27-1-250MG	ZATEAN-CH CAP	12	7	\$438.72	\$1.22	0.04%
Prenat w/o A w/Fe Fum-DSS-FA-DHA 30-1.24-265MG	FOLIVANE-PRX CAP DHA NF	11	3	\$382.56	\$1.16	0.03%
Prenat w/o A w/ Fe Fum-FA-Omega 3 28-1-250MG	NATELLE ONE CAP	11	5	\$1,295.28	\$3.93	0.11%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Prenatal w/ Sod Feredetate-FA 30-1 & Omega 3 DR	CAVAN-EC SOD MIS DHA	10	6	\$328.50	\$1.09	0.03%
Prenat w/ Ca Carb-B6-B12-FA 1MG	FOLBECAL TAB	10	7	\$257.84	\$0.72	0.02%
Prenat w/Fe Fum-L Methylfolate-FA-DHA Cap 27-1.13-0.4 MG	ROVIN-NV DHA CAP	8	7	\$446.41	\$1.62	0.04%
Prenat w/ Fe Fum-Methylfolate-FA 27-0.6-0.4 MG	ZATEAN-PN TAB	7	5	\$518.74	\$1.33	0.04%
Prenat w/ Fe Fum-Methylfolate-FA 27-0.6-0.4 MG	VIRT-PN TAB	6	3	\$480.21	\$1.33	0.04%
Prenat w/o A w/ Fe Fum-FA 28-1 MG	VIVA CT CHW 28-1MG	6	4	\$430.74	\$2.39	0.04%
Prenat-Fe Bis-Fe Prot Succ-FA-Ca & Omega DR 430	SETON ET-EC PAK	6	4	\$188.46	\$1.05	0.02%
Prenat-Fe Bis-Fe Prot Succ-FA-Ca & Omega (3) 400	PR NATAL 400 PAK	5	4	\$166.80	\$1.11	0.01%
Prenat w/o A w/ Fe Fum-DSS-FA-DHA 29-1.25-337.5MG	NEXA SELECT CAP	5	3	\$984.40	\$3.65	0.08%
Prenat w/o A w/ Fe Carbonyl-Docusate-FA 90-1MG	COMPLETE-RF TAB PRENATAL	4	4	\$85.58	\$0.36	0.01%
Prenat w/FE Cbn-Fe Gluc-FA 27-1MG	VINATE CAL TAB	3	1	\$31.47	\$0.35	0.00%
Prenat w/Fe Cbn-FA-DHA 15-0.5-50MG	TRIVEEN-TEN TAB	2	2	\$50.78	\$0.85	0.00%
Prenat w/Fe Poly-Na Fered-FA 27-1 & Omega DR 430MG	DUET DHA MIS BALANCED	2	2	\$194.05	\$3.23	0.02%
Prenat w/ FE Cbn -FA 50-1.25MG	ELITE-OB TAB	2	2	\$78.83	\$0.61	0.01%
Prenat w/o A w/ Fe Bisglycinate-FA 32-1MG	NESTABS TAB	2	1	\$77.36	\$1.29	0.01%
Prenat-Fe Bis-Fe Prot Succ-FA-Ca Tab & Omega 3 Cap 430 Pk	PR NATAL 430 PAK	2	1	\$58.26	\$0.97	0.01%
Prenat w/Fe Fum-FA 65-1MG & DHA 250MG	PNV-OB/DHA PAK	2	2	\$129.26	\$1.44	0.01%
Prenat w/o A w/ Fe Cbn-DSS-FA-DHA 30-1-260MG	PRENAISSANCE CAP BALANCE	2	2	\$128.08	\$2.13	0.01%
Prenat w/o A w/ Fe Bisglyc-FA 32-1MG & Omega	NESTABS DHA PAK	2	2	\$120.29	\$2.00	0.01%
Prenat w/o A w/FeCbn-FeGI-DSS-FA 90 &DHA 300MG	NATALVIRT MIS 90 DHA	2	2	\$113.20	\$1.89	0.01%
Prenat w/ Fe Cbn-Fe Bisglyc-FA-Fish Oil 35-5-1.2MG	ELITE-OB 400 CAP	2	2	\$110.66	\$1.84	0.01%
Prenat w/ Ca- B6-FA-Ginger 1.2MG	VP-GGR-B6 TAB	2	1	\$103.80	\$1.73	0.01%
Prenat w/ FE Cbn-Fe Asp Glyc-FA-Omega 30-10-1-200MG	OB COMPLETE/ CAP DHA	2	2	\$259.68	\$2.16	0.02%
Prenat w/Fe Poly-Na Fered-FA 27-1 & Omega DR 380MG	PRENAISSANCE MIS HARMONY	1	1	\$101.05	\$3.37	0.01%
Prenat w/ Ca- B6-FA-Ginger 1.22MG	B-NEXA TAB	1	1	\$53.70	\$1.79	0.00%
Prenat w/o A w/Fe Cbn-DSS-FA-DHA 29-1-265MG	CITRANATAL CAP HARMONY	1	1	\$237.22	\$2.37	0.02%
Prenat w/o A w/ Fe Fum-Doc-FA-DHA 29-1.25-350MG	EXTRA-VIRT CAP PLUS DHA	1	1	\$71.56	\$2.39	0.01%
Prenat w/o A w/ Fe Cbn-DSS-FA-DHA 30-1-260MG	VP-CH-PNV CAP	1	1	\$63.41	\$2.11	0.01%
Prenat w/ Fe Poly Cmplx-Fe Asp-Fe Gly-FA & DHA	PAIRE OB MIS	1	1	\$43.62	\$1.45	0.00%
Prenat-Fe Poly Cmplx-Fe Heme Poly-FA & Omega 3	HEMENATAL OB MIS + DHA	1	1	\$41.53	\$1.38	0.00%
Prenat-Fe Bis-Fe Prot Succ-FA-Ca & Omega DR 430	PR NATAL 430 PAK EC	1	1	\$35.56	\$1.19	0.00%
Prenat w/ Fe Fum-FA-Omega 3 28-1.25-200MG	ELITE OB CAP W/DHA	1	1	\$35.24	\$1.17	0.00%
Prenat w/o A w/ Fe Fum-FA 40-1MG	BP MULTINATL CHW +	1	1	\$23.13	\$0.77	0.00%
Prenat w/ Fe Fumarate-FA 29-1MG	VENATAL-FA TAB	1	1	\$7.80	\$0.26	0.00%
Total		44,361	22,304*	\$1,165,116.12	\$0.56	100%

*Total number of unduplicated members

¹ “Citranatal® 90 DHA,” “Citranatal® Assure,” “Prefera® OB,” “Select OB® + DHA,” “Vitafofol® Ultra.” Drug Information Online. Available online at: www.drugs.com. Last revised 10/2013. Last accessed 10/24/2013.

Appendix F



Fiscal Year 2013 Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Epaned™ (Enalapril Powder for Oral Solution)

Oklahoma Health Care Authority
November 2013

Current Prior Authorization Criteria

There are 7 categories of antihypertensive medications currently included in the Antihypertensives Product Based Prior Authorization program, as well as two special formulation products:

1. Calcium Channel Blockers (CCBs)
2. Angiotensin I Converting Enzyme Inhibitors (ACEIs)
3. ACEIs/CCBs Combination Products
4. ACEIs and Hydrochlorothiazide Combination Products
5. Angiotensin II Receptor Blockers (ARBs)
6. ARB Combination Products
7. Direct Renin Inhibitors (DRIs) and DRI Combination Products
8. Clonidine Extended Release Products (Nexiclon® XR) and Clonidine Transdermal Patches (Catapres TTS®)

To qualify for a Tier 2 antihypertensive medication (or Tier 3 medication when no Tier 2 medications exist) there must be

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 class of medications; OR
3. Previous stabilization on the Tier 2 medication; OR
4. A unique indication for which the Tier 1 antihypertensive medications lack

To qualify for a Tier 3 antihypertensive medication there must be

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 or 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

Criteria for DRIs Authorization

1. FDA approved indication; AND
2. Recent trial, within the previous 6 months and at least 4 weeks in duration, of an ACE inhibitor (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

Criteria for Authorization of Clonidine Special Formulation Products: Nexiclon XR® (Clonidine Extended Release) and Catapres TTS® Patch (Clonidine Transdermal Patch)

1. FDA-approved indication of hypertension in adults
2. Must provide a clinically significant reason why the member cannot take clonidine immediate release tablets

Calcium Channel Blockers (CCB medications)		
Tier-1	Tier-2	Tier-3
amlodipine (Norvasc®)	diltiazem (Cardizem® LA)	
diltiazem (Cardizem®)	nicardipine (Cardene® SR)	
diltiazem (Tiazac®, Taztia XT®)	verapamil (Covera-HS®)	
diltiazem CD (Cardizem® CD)	nisoldipine (Sular®)	
diltiazem ER (Cartia XT®, Diltia XT®)	amlodipine/atorvastatin (Caduet®)	
diltiazem SR (Cardizem® SR)	Diltiazem ER (Matzim LA®)	
diltiazem XR (Dilacor® XR)		
felodipine (Plendil®)		
isradipine (Dynacirc®, Dynacirc CR®)		
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)		
Verapamil ER (Verelan® PM)		

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

Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)		
Tier-1	Tier-2	Tier-3
benazepril (Lotensin®)		perindopril erbumine (Aceon®)
captopril (Capoten®)		
enalapril (Vasotec®)		
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
quinapril (Accupril®)		
trandolapril (Mavik®)		
ramipril (Altace®)		

ACE Inhibitor / Calcium Channel Blocker Combinations		
Tier-1	Tier-2	Tier-3
Tier-1 ACE + Tier 1 CCB	trandolapril / verapamil (Tarka®)	
	benazepril / amlodipine (Lotrel®)	
	enalapril / felodipine (Lexxel®)	

ACE Inhibitor / HCTZ Combinations		
Tier-1	Tier-2	Tier-3
benazepril/HCTZ (Lotensin® HCT)		
captopril/HCTZ (Capozide®)		
enalapril/HCTZ (Vasoretic®)		
fosinopril/HCTZ (Monopril-HCT®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		

Direct Renin inhibitors (Tekturna®)		
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®)

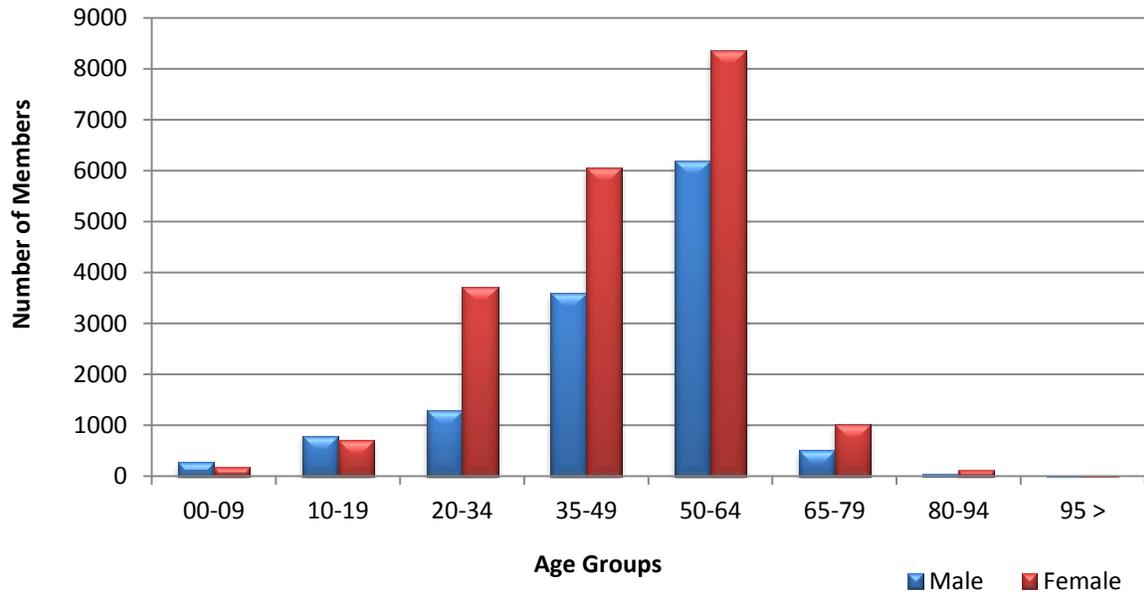
Utilization of Antihypertensive Medications

Comparison of Fiscal Years for Antihypertensive Medications

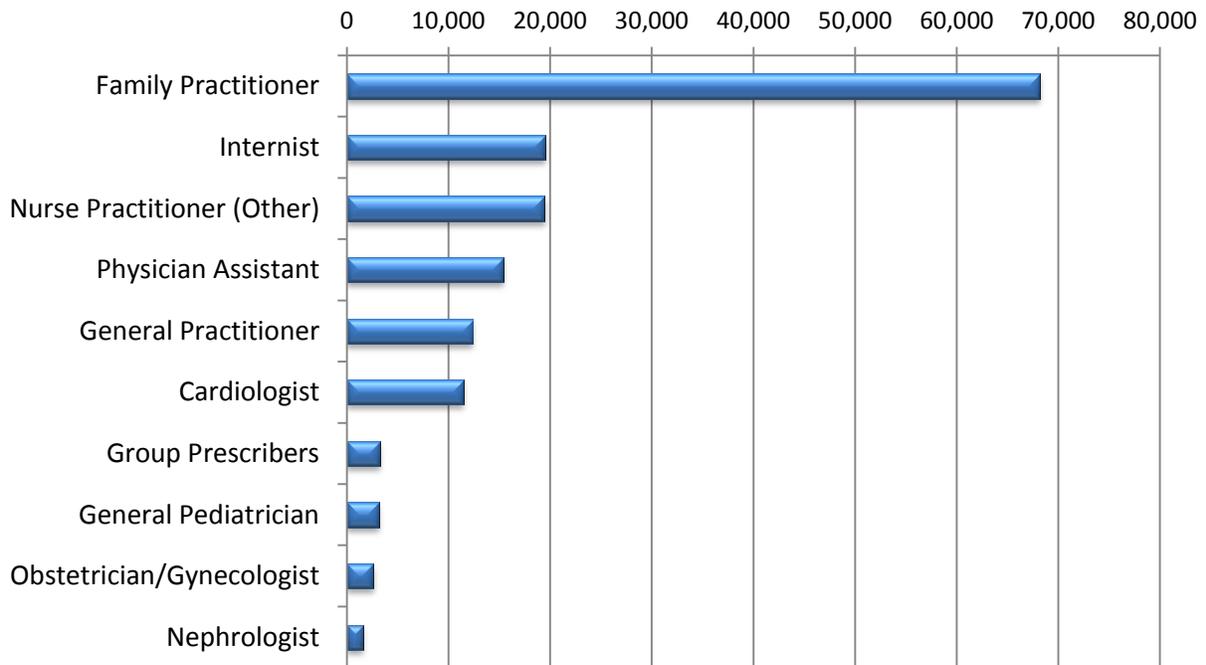
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2012	31,742	160,030	\$2,964,250.83	\$18.52	\$0.47	7,213,778	6,301,341
2013	32,883	164,473	\$2,747,773.86	\$16.71	\$0.42	7,577,116	6,582,982
% Change	3.60%	2.80%	-7.30%	-9.80%	-10.60%	5.00%	4.50%
Change	1,141	4,443	-\$216,476.97	-\$1.81	-\$0.05	363,338	281,641

*Total number of unduplicated members.

Demographics of Members Utilizing Antihypertensive Medications

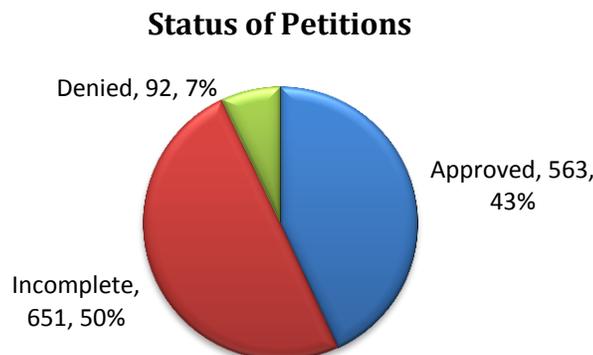


Top Prescriber Specialties of Antihypertensive Medications by Claims



Prior Authorization of Antihypertensive Medications

There were a total of 1,306 petitions submitted for this category during fiscal year 2013. 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

- **Anticipated Patent Expirations:**¹
 - **Diovan**[®] (Valsartan) – Patent expired September 2012; however there is currently no generic available for valsartan alone. The combination valsartan/HCTZ is available in generic.
 - **Micardis**[®] (Telmisartan), **Micardis HCT**[®] (Telmisartan/HCTZ), **Twynsta**[®] (Telmisartan/Amlodipine)- January 2014
 - **Tarka**[®] (Trandolapril/Verapamil HCl)- February 2015
 - **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 Products/Indications:**
 - **05/14/13** FDA approves Nymalize™ (nimodipine oral solution) to treat subarachnoid hemorrhage. Nimodipine previously was available only as a liquid-filled gel capsule.²
 - **08/13/13** FDA approves Epaned™, a liquid form of enalapril for children and adults.³
- **FDA Updates:**
 - **06/15/2012** FDA announces Pfizer is discontinuing Covera-HS[®] (verapamil HCL 180mg and 240mg extended release tablets) due to business reasons.⁴
 - **05/31/2013** FDA warns patients: do not discontinue ARB therapy without talking to your healthcare provider. Concerns were raised after a meta-analysis reported a statistically significant increase in risk of cancer in patients taking an ARB.⁵
 - **07/05/2013** FDA announces GlaxoSmithKline discontinued Dynacirc CR[®] tablets.⁴
- **Updated Package Labelling :**
 - **07/02/2013** FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to Benicar[®] (olmesartan).⁶

Nymalize™ (Nimodipine Oral Solution) Summary^{2, 7, 8}

- **Indications:** Nymalize™ is indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades I-V).

Dosing: Nymalize™ is available as an oral solution (60mg/20mL) supplied in a 16 ounce (473mL) bottle. Nymalize™ should be administered via enteral route only. The recommended oral dosage is 20mL (60mg) every four hours for 21 consecutive days. Nymalize™ administration should begin within 96 hours of the onset of SAH. Administer Nymalize™ one hour before a meal or two hours after a meal.

The FDA has warned against serious medication errors from intravenous administration of nimodipine oral capsules. The FDA has received reports of the oral product used intravenously, with serious, sometimes fatal, consequences. In 2006, the FDA added a Boxed Warning against IV use of nimodipine oral capsules. The prescribing information provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration.⁸

- **Efficacy:** The safety and efficacy of Nymalize™ in the treatment of patients with SAH is based on studies of nimodipine oral capsules. Nimodipine has been shown in 4 randomized double-blind, placebo-controlled trials to reduce the severity of neurological deficits resulting from vasospasm in patients who have had a recent SAH. The trials used doses ranging from 20-90mg every 4 hours, with drug given for 21 days in 3 studies, and for at least 18 days in the other.

Study 3 was a 554-patient trial that included SAH patients with all grades of severity (89% were in Hunt and Hess Grades I-III). Patients were treated with placebo or 60mg of nimodipine every 4 hours. There was a significant reduction in the overall rate of brain infarction and severely disabling neurological outcome at 3 months (Nimodipine 12 vs. Placebo 31 $p=0.001$). Study 4 enrolled much sicker patients, (Hunt and Hess Grades III-V), who had a high rate of death and disability, and used a dose of 90mg every 4 hours. Analysis of delayed ischemic deficits, showed a significant reduction in spasm-related deficits (Nimodipine 8(11%) vs. Placebo 25 (31%) $p=0.001$). When data were combined for Study 3 and Study 4, the treatment difference on success rate on the Glasgow Outcome Scale was 25.3% (nimodipine) versus 10.9% (placebo) for Hunt and Hess Grades IV or V ($p=0.045$).

- **Cost Comparison**

Nymalize™ or Nimodipine Dosage Form	Cost per mL or Capsule	Cost per Day	Cost for 21 days of Therapy
Nymalize™ Oral Solution 60mg/20mL	\$3.17*	\$380.40*	\$7,988.40*
Nimodipine Oral Capsule 30mg	\$4.96 ^α	\$59.52 ^α	\$1,249.92 ^α

*EAC = Estimated acquisition cost for brand medications.

^αSMAC = state maximum allowable cost for generic medications.

Epaned™ (Enalapril Powder for Oral Solution) Summary⁹

- **Indications:** Epaned™ is indicated for the treatment of hypertension in adults and children older than one month. Epaned™ is the first FDA approved oral solution for pediatric hypertension.
- **Dosing:** Epaned™ is supplied as a kit containing one bottle 150mg Powder for oral solution and one bottle 150mL Ora-Sweet®. (Each 150mg bottle is reconstituted with 150mL of Ora-Sweet® resulting in a 1mg/1mL oral solution).

The initial recommended adult dose of Epaned™ is 5mg by mouth once daily. The dose can be titrated upward to a maximum of 40mg daily. The dose may be divided and administered twice daily. The initial recommended pediatric dose of Epaned™ is 0.08mg/kg once daily. Doses above 0.58mg/kg (or in excess of 40mg) have not been studied in pediatric patients.

An initial dose of 2.5 mg daily is recommended in patients who are on concomitant diuretic therapy or who have moderate to severe renal impairment (creatinine-clearance ≤30mL/min). The solution may be taken without regard to food.

- **Efficacy:** Enalapril was evaluated in a clinical study involving 110 hypertensive pediatric patients 6 to 16 years of age. Patients weighing <50 kg received either 0.625mg, 2.5mg, or 20mg of enalapril daily, and patients weighing ≥50 kg received either 1.25mg, 5mg, or 40 mg of enalapril daily. Once daily administration lowered trough blood pressure in a dose-dependent manner. The dose-dependent antihypertensive efficacy of enalapril was consistent across all subgroups. The lowest doses studied, 0.625mg and 1.25mg, corresponding to an average of 0.02mg/kg once daily, did not offer consistent antihypertensive efficacy. Enalapril maleate was generally well tolerated.

Enalapril has been evaluated for safety in more than 10,000 patients, including over 1,000 patients treated for one year or more. A pharmacokinetic study was conducted in 40 hypertensive pediatric patients aged 2 months to ≤16 years following daily oral administration of 0.07 to 0.14mg/kg enalapril maleate. At steady state, the mean effective half-life for the accumulation of enalaprilat was 14 hours and the mean urinary recovery of total enalapril and enalaprilat in 24 hours was 68% of the administered dose. Conversion of enalapril to enalaprilat was in the range of 63-76%. The overall results of this study indicated that the pharmacokinetics of enalapril in hypertensive children are consistent across the studied age groups and consistent with pharmacokinetic historic data in healthy adults.

- **Cost Comparison**

Epaned™ or Enalapril Dosage Form	Cost Per mL or Tablet	Cost Per Day	Cost per Month
Epaned™ Powder for Solution 150mg/150mL	\$2.01*	\$10.05*	\$301.50*
Enalapril Tablet 5mg	\$0.13 ^α	\$0.13 ^α	\$13.00 ^α

*EAC= estimated acquisition cost

^αSMAC = state maximum allowable cost for generic medications. Monthly cost includes vehicle solution for compound.

Conclusions and Recommendations

The College of Pharmacy recommends the following:

1. Move Verelan[®] PM (verapamil ER) into Tier-2 of the CCB category.
2. Move Dynacirc[®] (isradipine) into Tier-2 of the CCB category.
3. Move Avapro[®] (irbesartan) and Avalide[®] (irbesartan/HCTZ) into Tier-1 of the ARB category.
4. Move Aceon[®] (perindopril erbumine) into Tier-2 of the ACEI category.
5. The prior authorization of Monopril-HCT[®] (fosinopril/HCTZ)
 - a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot use the individual components.
6. The prior authorization of Cardizem[®] CD (diltiazem CD) 360mg capsules
 - a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot use two 180mg Cardizem CD (diltiazem CD) capsules.
7. Place duration and quantity limits on the use of nimodipine oral capsules and Nymalize[™] (nimodipine oral solution) as follows:
 - a. A quantity limit of 252 capsules for 21 days will apply for Nimodipine oral capsules.
 - b. A quantity limit of 2,838 mL for 21 days will apply for Nymalize[™] oral solution.
8. Place an age restriction on Epaned[™] (enalapril powder for oral solution) for members aged 7 years or older with the following criteria:
 - a. Consideration for approval requires a patient specific, clinically significant reason why the member cannot swallow the oral tablet formulation.

Calcium Channel Blockers (CCB medications)		
Tier-1	Tier-2	Special PA Criteria
amlodipine (Norvasc [®])	amlodipine/atorvastatin (Caduet [®])	diltiazem CD (Cardizem [®] CD) 360mg
diltiazem (Cardizem [®])	diltiazem (Cardizem [®] LA)	
diltiazem (Tiazac [®] , Taztia XT [®])	diltiazem ER (Matzim LA [®])	
diltiazem CD (Cardizem [®] CD) (All strengths except 360mg)	isradipine (Dynacirc [®] , Dynacirc-ER[®])	
diltiazem ER (Cartia XT [®] , Diltia XT [®])	nicardipine (Cardene [®] SR)	
diltiazem SR (Cardizem [®] SR)	nisoldipine (Sular [®])	
diltiazem XR (Dilacor [®] XR)	verapamil ER (Verelan [®] PM)	
felodipine (Plendil [®])	verapamil (Covera-HS[®])	
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)		

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

Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)		
Tier-1	Tier-2	Tier-3
benazepril (Lotensin®)	perindopril erbumine (Aceon®)	Reserved for New Products
captopril (Capoten®)		
enalapril (Vasotec®)		
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
quinapril (Accupril®)		
trandolapril (Mavik®)		
ramipril (Altace®)		

ACE Inhibitor / HCTZ Combinations		
Tier-1	Tier-2	Special PA Category
benazepril/HCTZ (Lotensin® HCT)		fosinopril/HCTZ (Monopril-HCT®)
captopril/HCTZ (Capozide®)		
enalapril/HCTZ (Vasoretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		

Direct Renin inhibitors (Tekturna®)		
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 Calcium Channel Blocker Medications

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Amlodipine Besylate	AMLODIPINE TAB 10MG	15,380	3,752	\$127,350.47	\$0.21	16.47%
Amlodipine Besylate	AMLODIPINE TAB 5MG	10,931	3,155	\$85,255.79	\$0.20	11.03%
Amlodipine Besylate	AMLODIPINE TAB 2.5MG	1,502	457	\$11,799.29	\$0.22	1.53%
Amlodipine Besylate	NORVASC TAB 5MG	3	1	\$663.12	\$2.76	0.09%
Amlodipine Besylate	NORVASC TAB 10MG	1	1	\$314.78	\$3.50	0.04%
SUBTOTAL		27,817	7,366	\$225,383.45	\$0.20	29.16%
Diltiazem HCl	DILTIAZEM CAP 240MG CD	567	150	\$21,097.28	\$0.91	2.73%
Diltiazem HCl	DILTIAZEM CAP 180MG CD	425	112	\$13,871.86	\$0.86	1.79%
Diltiazem HCl	DILTIAZEM CAP 120MG CD	326	108	\$7,323.94	\$0.54	0.95%
Diltiazem HCl	DILTIAZEM CAP 300MG CD	101	28	\$4,979.23	\$1.12	0.64%
Diltiazem HCl	DILTIAZEM CAP 360MG CD	4	3	\$1,370.34	\$7.61	0.18%
Diltiazem HCl	CARDIZEM CD CAP 180MG/24	4	3	\$119.19	\$0.99	0.02%
Diltiazem HCl	DILTIAZEM TAB 120MG	340	92	\$3,322.68	\$0.27	0.43%
Diltiazem HCl	DILTIAZEM TAB 60MG	304	86	\$2,270.83	\$0.23	0.29%
Diltiazem HCl	DILTIAZEM TAB 30MG	213	79	\$1,431.23	\$0.22	0.19%
Diltiazem HCl	DILTIAZEM TAB 90MG	181	42	\$1,774.73	\$0.32	0.23%
Diltiazem HCl	DILTIAZEM CAP 240MG ER	362	95	\$11,501.14	\$0.75	1.49%
Diltiazem HCl	DILTIAZEM CAP 180MG ER	263	77	\$8,206.61	\$0.77	1.06%
Diltiazem HCl	DILTIAZEM CAP 120MG ER	243	69	\$5,511.97	\$0.53	0.71%
Diltiazem HCl	DILTIAZEM CAP 180MG ER	240	75	\$8,137.16	\$0.86	1.05%
Diltiazem HCl	DILTIAZEM CAP 120MG ER	216	71	\$4,943.72	\$0.60	0.64%
Diltiazem HCl	DILTIAZEM CAP 240MG ER	215	73	\$9,432.50	\$0.91	1.22%
Diltiazem HCl	DILTIAZEM CAP 360MG ER	108	26	\$37,805.43	\$8.23	4.89%
Diltiazem HCl	DILTIAZEM CAP 120MG ER	68	19	\$4,442.43	\$1.61	0.57%
Diltiazem HCl	DILTIAZEM CAP 60MG ER	46	17	\$2,294.42	\$1.65	0.30%
Diltiazem HCl	DILTIAZEM CAP 300MG ER	36	9	\$2,187.41	\$1.12	0.28%
Diltiazem HCl	DILTIAZEM CAP 90MG ER	30	9	\$1,721.08	\$1.58	0.22%
Diltiazem HCl	TAZTIA XT CAP 360MG/24	149	34	\$7,612.63	\$1.12	0.98%
Diltiazem HCl	TAZTIA XT CAP 180MG/24	48	14	\$1,063.01	\$0.62	0.14%
Diltiazem HCl	TAZTIA XT CAP 300MG/24	45	13	\$2,766.27	\$1.23	0.36%
Diltiazem HCl	TAZTIA XT CAP 240MG/24	37	15	\$1,871.90	\$0.97	0.24%
Diltiazem HCl	TAZTIA XT CAP 120MG/24	21	7	\$786.14	\$0.71	0.10%
Diltiazem HCl	CARTIA XT CAP 120/24HR	138	40	\$2,485.15	\$0.53	0.32%
Diltiazem HCl	CARTIA XT CAP 240/24HR	121	37	\$4,122.66	\$0.88	0.53%
Diltiazem HCl	CARTIA XT CAP 180/24HR	110	40	\$3,889.59	\$0.76	0.50%
Diltiazem HCl	CARTIA XT CAP 300/24HR	12	6	\$997.62	\$1.11	0.13%
Diltiazem HCl	DILTIAZEM CAP 360MG/24	106	31	\$5,165.70	\$1.16	0.67%
Diltiazem HCl	DILTIAZEM CAP 240MG/24	94	25	\$3,474.43	\$1.20	0.45%
Diltiazem HCl	DILTIAZEM CAP 120MG/24	89	25	\$2,262.85	\$0.83	0.29%
Diltiazem HCl	DILTIAZEM CAP 180MG/24	71	20	\$1,746.08	\$0.79	0.23%
Diltiazem HCl	DILTIAZEM CAP 420MG/24	24	5	\$1,704.76	\$1.31	0.22%
Diltiazem HCl	DILTIAZEM CAP 300MG/24	5	4	\$477.11	\$1.22	0.06%
Diltiazem HCl	MATZIM LA TAB 180MG/24	29	10	\$2,135.65	\$2.30	0.28%
Diltiazem HCl	MATZIM LA TAB 360MG/24	26	6	\$3,449.38	\$3.59	0.45%
Diltiazem HCl	MATZIM LA TAB 240MG/24	17	7	\$3,385.11	\$3.22	0.44%
Diltiazem HCl	MATZIM LA TAB 300MG/24	16	2	\$1,634.84	\$3.41	0.21%
Diltiazem HCl	MATZIM LA TAB 420MG/24	4	1	\$1,514.47	\$4.21	0.20%
Diltiazem HCl	CARDIZEM LA TAB 120MG	19	6	\$2,882.01	\$3.41	0.37%
Diltiazem HCl	DILT-XR CAP 240MG	20	11	\$593.42	\$0.76	0.08%
Diltiazem HCl	DILT-XR CAP 180MG	19	9	\$641.12	\$0.67	0.08%
Diltiazem HCl	DILT-XR CAP 120MG	12	8	\$452.32	\$0.54	0.06%
SUBTOTAL		5,529	1,619	\$210,859.40	\$0.97	27.27%
Felodipine	FELODIPINE TAB 10MG ER	162	28	\$7,399.83	\$1.05	0.96%
Felodipine	FELODIPINE TAB 5MG ER	65	14	\$2,144.84	\$0.70	0.28%
Felodipine	FELODIPINE TAB 2.5MG ER	3	3	\$106.17	\$0.71	0.01%
SUBTOTAL		230	45	\$9,650.84	\$0.94	1.25%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Isradipine	ISRADIPINE CAP 5MG	14	3	\$2,246.22	\$5.35	0.29%
Isradipine	ISRADIPINE CAP 2.5MG	14	2	\$1,101.66	\$2.62	0.14%
SUBTOTAL		28	5	\$3,347.88	\$3.99	0.43%
Nicardipine HCl	NICARDIPINE CAP 20MG	13	2	\$323.70	\$0.80	0.04%
Nicardipine HCl	NICARDIPINE CAP 30MG	4	2	\$134.49	\$0.75	0.02%
SUBTOTAL		17	4	\$458.19	\$0.78	0.06%
Nifedipine	NIFEDIPINE CAP 10MG	1,266	992	\$68,774.61	\$3.03	8.90%
Nifedipine	NIFEDIPINE CAP 20MG	300	222	\$31,018.86	\$6.15	4.01%
Nifedipine	PROCARDIA CAP 10MG	23	13	\$1,353.99	\$2.27	0.18%
Nifedipine	NIFEDIPINE TAB 30MG ER	801	308	\$18,932.87	\$0.67	2.45%
Nifedipine	NIFEDIPINE TAB 60MG ER	660	207	\$24,465.75	\$1.03	3.16%
Nifedipine	NIFEDIPINE TAB 90MG ER	643	158	\$32,642.87	\$1.17	4.22%
Nifedipine	NIFEDIPINE TAB 60MG ER	266	89	\$10,606.67	\$1.04	1.37%
Nifedipine	NIFEDIPINE TAB 30MG ER	247	103	\$6,117.60	\$0.61	0.79%
Nifedipine	NIFEDIPINE TAB 90MG ER	54	17	\$4,823.61	\$2.05	0.62%
Nifedipine	NIFEDICAL XL TAB 30MG	552	279	\$13,303.58	\$0.70	1.72%
Nifedipine	NIFEDICAL XL TAB 60MG	534	166	\$20,857.55	\$0.98	2.70%
Nifedipine	AFEDITAB TAB 30MG CR	99	36	\$2,612.73	\$0.71	0.34%
Nifedipine	AFEDITAB TAB 60MG CR	68	20	\$2,309.57	\$1.10	0.30%
Nifedipine	NIFEDIAC CC TAB 30MG ER	121	50	\$3,011.72	\$0.65	0.39%
Nifedipine	NIFEDIAC CC TAB 60MG ER	105	33	\$3,761.14	\$0.99	0.49%
Nifedipine	NIFEDIAC CC TAB 90MG ER	79	20	\$6,223.52	\$1.97	0.81%
Nifedipine	ADALAT CC TAB 90MG ER	59	11	\$3,937.47	\$2.15	0.51%
Nifedipine	ADALAT CC TAB 30MG ER	3	3	\$54.30	\$0.60	0.01%
Nifedipine	ADALAT CC TAB 60MG ER	1	1	\$26.27	\$0.88	0.00%
Nifedipine	NIFEDIPINE POW	7	6	\$100.23	\$0.60	0.01%
Nifedipine	NIFEDIPINE POW USP	3	2	\$73.61	\$0.82	0.01%
SUBTOTAL		5,891	2,736	\$255,008.52	\$1.34	32.99%
Nimodipine	NIMODIPINE CAP 30MG	9	4	\$3,223.92	\$18.32	0.42%
SUBTOTAL		9	4	\$3,223.92	\$18.32	0.42%
Verapamil HCl	VERAPAMIL TAB 40MG	81	32	\$1,503.91	\$0.61	0.19%
Verapamil HCl	VERAPAMIL TAB 80MG	405	103	\$3,352.59	\$0.24	0.43%
Verapamil HCl	VERAPAMIL TAB 120MG	344	93	\$2,909.70	\$0.25	0.38%
Verapamil HCl	VERAPAMIL TAB 240MG ER	1,208	255	\$17,365.45	\$0.37	2.25%
Verapamil HCl	VERAPAMIL TAB 120MG ER	496	135	\$8,040.06	\$0.43	1.04%
Verapamil HCl	VERAPAMIL TAB 180MG ER	450	117	\$7,468.39	\$0.42	0.97%
Verapamil HCl	VERAPAMIL CAP 120MG ER	155	49	\$3,428.90	\$0.56	0.44%
Verapamil HCl	VERAPAMIL CAP 180MG ER	104	38	\$2,253.57	\$0.52	0.29%
Verapamil HCl	VERAPAMIL CAP 240MG ER	237	67	\$5,398.28	\$0.55	0.70%
Verapamil HCl	VERAPAMIL CAP 120MG SR	21	6	\$508.98	\$0.74	0.07%
Verapamil HCl	VERAPAMIL CAP 360MG SR	128	31	\$7,695.74	\$1.46	1.00%
Verapamil HCl	VERAPAMIL CAP 180MG SR	14	6	\$387.51	\$0.56	0.05%
Verapamil HCl	VERAPAMIL CAP 240MG SR	22	13	\$650.44	\$0.51	0.08%
Verapamil HCl	VERAPAMIL CAP 100MG ER	22	8	\$1,326.03	\$2.01	0.17%
Verapamil HCl	VERAPAMIL CAP 200MG ER	14	4	\$996.36	\$1.44	0.13%
Verapamil HCl	VERAPAMIL CAP 300MG ER	22	5	\$1,750.22	\$2.08	0.23%
Verapamil HCl	VERAPAMIL POW	12	1	\$60.93	\$0.17	0.01%
SUBTOTAL		3,735	963	\$65,097.06	\$0.46	8.43%
TOTAL		43,251	12,504*	\$773,029.26	\$0.46	100%

*Total number of unduplicated members

Calcium Channel Blocker/Statin Combination Products

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Amlodipine -Atorvastatin	Caduet TAB 10-20MG	118	26	\$28,657.84	\$4.59	37.01%
Amlodipine -Atorvastatin	Caduet TAB 10-40MG	66	16	\$14,737.30	\$4.76	19.03%
Amlodipine -Atorvastatin	Caduet 10-10MG	39	6	\$6,468.49	\$3.65	8.35%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Amlodipine -Atorvastatin	Caduet TAB 5-40MG	31	6	\$7,164.52	\$5.03	9.25%
Amlodipine -Atorvastatin	Caduet TAB 5-10MG	29	6	\$5,858.77	\$4.34	7.57%
Amlodipine -Atorvastatin	Caduet TAB 5-20MG	27	7	\$7,995.38	\$4.84	10.33%
Amlodipine -Atorvastatin	Caduet TAB 10-80MG	15	3	\$3,925.50	\$4.85	5.07%
Amlodipine -Atorvastatin	Caduet TAB 5-80MG	6	1	\$873.72	\$4.85	1.13%
Amlodipine -Atorvastatin	Caduet TAB 2.5-40MG	4	1	\$1,743.28	\$4.84	2.25%
TOTAL		335	72*	\$77,424.80	\$4.59	100%

*Total number of unduplicated members

Utilization Details of Angiotensin Receptor Blocker Medications

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Azilsartan	EDARBI TAB 80MG	31	10	\$3,672.95	\$2.99	0.36%
Azilsartan	EDARBI TAB 40MG	2	1	\$189.04	\$3.15	0.02%
Azilsartan -Chlorthalidone	EDARBYCLOR TAB 40-25MG	20	5	\$2,062.44	\$2.86	0.20%
Azilsartan -Chlorthalidone	EDARBYCLOR TAB 40-12.5	47	10	\$4,857.95	\$3.06	0.47%
SUBTOTAL		100	26	\$10,782.38	\$3.00	1.05%
Candesartan	ATACAND TAB 32MG	51	10	\$10,548.81	\$4.33	1.02%
Candesartan	ATACAND TAB 16MG	24	8	\$3,316.26	\$3.07	0.32%
Candesartan	ATACAND TAB 4MG	11	1	\$1,984.03	\$6.01	0.19%
Candesartan	ATACAND TAB 8MG	7	2	\$1,891.70	\$3.50	0.18%
Candesartan	CANDESARTAN TAB 16MG	1	1	\$74.98	\$2.50	0.01%
Candesartan	CANDESARTAN TAB 32MG	1	1	\$301.44	\$3.35	0.03%
Candesartan -HCTZ	ATACAND HCT TAB 32-12.5	31	5	\$4,509.83	\$4.06	0.44%
Candesartan -HCTZ	CANDESA/HCTZ TAB 32-12.5	11	3	\$1,397.48	\$3.11	0.14%
Candesartan -HCTZ	ATACAND HCT TAB 16-12.5	9	2	\$1,571.89	\$4.03	0.15%
Candesartan -HCTZ	CANDESA/HCTZ TAB 16-12.5	5	1	\$261.80	\$1.75	0.03%
SUBTOTAL		151	34	\$25,858.22	\$3.91	2.51%
Eprosartan	EPROSART MES TAB 600MG	7	2	\$1,820.93	\$2.89	0.18%
Eprosartan-HCTZ	TEVETEN HCT TAB 600-12.5	7	1	\$1,328.34	\$4.03	0.13%
SUBTOTAL		14	3	\$3,149.27	\$3.28	0.31%
Irbesartan	IRBESARTAN TAB 150MG	189	32	\$10,107.76	\$1.09	0.98%
Irbesartan	IRBESARTAN TAB 300MG	185	34	\$11,079.23	\$1.27	1.07%
Irbesartan	IRBESARTAN TAB 75MG	27	3	\$968.95	\$0.87	0.09%
Irbesartan	AVAPRO TAB 150MG	3	1	\$271.83	\$3.02	0.03%
Irbesartan-HCTZ	IRBESAR/HCTZ TAB 150-12.5	59	14	\$4,001.70	\$1.33	0.39%
Irbesartan-HCTZ	IRBESAR/HCTZ TAB 300-12.5	42	9	\$2,669.71	\$1.44	0.26%
SUBTOTAL		505	93	\$29,099.18	\$1.21	2.82%
Losartan	LOSARTAN POT TAB 50MG	3,331	976	\$35,218.03	\$0.27	3.41%
Losartan	LOSARTAN POT TAB 100MG	2,421	636	\$26,812.56	\$0.26	2.60%
Losartan	LOSARTAN POT TAB 25MG	1,375	416	\$12,838.95	\$0.24	1.24%
Losartan	COZAAR TAB 25MG	15	6	\$204.06	\$0.45	0.02%
Losartan	COZAAR TAB 50MG	3	3	\$105.83	\$1.18	0.01%
Losartan	COZAAR TAB 100MG	1	1	\$10.23	\$0.34	0.00%
Losartan & HCTZ	LOSARTAN/HCT TAB 100-25	1,411	363	\$15,471.25	\$0.25	1.50%
Losartan & HCTZ	LOSARTAN/HCT TAB 50-12.5	1,057	282	\$10,682.26	\$0.26	1.04%
Losartan & HCTZ	LOSARTAN/HCT TAB 100-12.5	505	141	\$5,438.09	\$0.26	0.53%
Losartan & HCTZ	HYZAAR TAB 100-25	19	5	\$1,600.22	\$1.98	0.16%
SUBTOTAL		10,138	2,829	\$108,381.48	\$0.26	10.51%
Olmesartan	BENICAR TAB 20MG	348	78	\$49,008.85	\$3.29	4.75%
Olmesartan	BENICAR TAB 40MG	253	54	\$48,210.86	\$4.63	4.67%
Olmesartan	BENICAR TAB 5MG	33	8	\$3,402.11	\$2.41	0.33%
Amlodipine -Olmesartan	AZOR TAB 10-40MG	69	12	\$12,631.88	\$5.33	1.22%
Amlodipine -Olmesartan	AZOR TAB 5-40MG	50	9	\$11,244.67	\$5.33	1.09%
Amlodipine -Olmesartan	AZOR TAB 5-20MG	9	3	\$2,389.08	\$4.19	0.23%
Amlodipine -Olmesartan	AZOR TAB 10-20MG	3	1	\$893.82	\$4.26	0.09%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Olmesartan -HCTZ	BENICAR HCT TAB 40-25MG	242	49	\$51,661.11	\$4.64	5.01%
Olmesartan -HCTZ	BENICAR HCT TAB 20-12.5	180	34	\$24,008.99	\$3.52	2.33%
Olmesartan -HCTZ	BENICAR HCT TAB 40-12.5	94	23	\$19,068.04	\$4.59	1.85%
Olmesartan-Amlodipine-HCTZ	TRIBENZOR40- TAB 10-25MG	16	5	\$5,482.17	\$5.71	0.53%
Olmesartan-Amlodipine-HCTZ	TRIBENZOR40- TAB 5-25MG	15	3	\$4,001.79	\$5.34	0.39%
Olmesartan-Amlodipine-HCTZ	TRIBENZOR20- TAB 5-12.5MG	10	4	\$1,751.73	\$4.17	0.17%
Olmesartan-Amlodipine-HCTZ	TRIBENZOR40- TAB 5-12.5MG	3	1	\$1,468.98	\$5.44	0.14%
SUBTOTAL		1,325	284	\$235,224.08	\$4.16	22.80%
Telmisartan	MICARDIS TAB 40MG	208	31	\$35,491.49	\$4.46	3.44%
Telmisartan	MICARDIS TAB 80MG	208	30	\$38,941.50	\$5.15	3.78%
Telmisartan	MICARDIS TAB 20MG	33	7	\$5,047.72	\$4.15	0.49%
Telmisartan-HCTZ	MICARDIS HCT TAB 80-25MG	69	11	\$13,056.77	\$4.44	1.27%
Telmisartan-HCTZ	MICARDIS HCT TAB 40/12.5	64	10	\$10,320.91	\$4.41	1.00%
Telmisartan-HCTZ	MICARDIS HCT TAB 80/12.5	64	12	\$16,278.40	\$5.43	1.58%
SUBTOTAL		646	101	\$119,136.79	\$4.76	11.56%
Valsartan	DIOVAN TAB 160MG	569	122	\$91,568.79	\$4.41	8.88%
Valsartan	DIOVAN TAB 80MG	414	80	\$68,009.58	\$4.16	6.59%
Valsartan	DIOVAN TAB 320MG	321	77	\$72,673.41	\$4.80	7.05%
Valsartan	DIOVAN TAB 40MG	86	18	\$11,429.62	\$3.42	1.11%
Valsartan-HCTZ	VALSART/HCTZ TAB 160-12.5	245	59	\$30,352.04	\$2.79	2.94%
Valsartan-HCTZ	VALSART/HCTZ TAB 160-25MG	174	43	\$21,561.49	\$3.05	2.09%
Valsartan-HCTZ	VALSART/HCTZ TAB 320-25MG	170	41	\$29,863.11	\$3.77	2.90%
Valsartan-HCTZ	VALSART/HCTZ TAB 80-12.5	117	28	\$11,844.10	\$2.65	1.15%
Valsartan-HCTZ	DIOVAN HCT TAB 160-12.5	85	43	\$14,791.39	\$3.98	1.43%
Valsartan-HCTZ	DIOVAN HCT TAB 160-25MG	72	33	\$12,465.14	\$4.26	1.21%
Valsartan-HCTZ	DIOVAN HCT TAB 320-25MG	71	37	\$19,185.82	\$5.66	1.86%
Valsartan-HCTZ	VALSART/HCTZ TAB 320-12.5	61	18	\$10,008.34	\$3.09	0.97%
Valsartan-HCTZ	DIOVAN HCT TAB 80/12.5	52	23	\$6,989.87	\$3.53	0.68%
Valsartan-HCTZ	DIOVAN HCT TAB 320-12.5	30	19	\$8,272.90	\$4.90	0.80%
Amlodipine -Valsartan	EXFORGE TAB 10-320MG	225	32	\$38,926.75	\$5.77	3.77%
Amlodipine -Valsartan	EXFORGE TAB 5-160MG	84	15	\$10,564.20	\$4.19	1.02%
Amlodipine -Valsartan	EXFORGE TAB 5-320MG	56	11	\$8,533.93	\$5.08	0.83%
Amlodipine -Valsartan	EXFORGE TAB 10-160MG	53	10	\$7,035.39	\$4.54	0.68%
Amlodipine-Valsartan-HCTZ	EXFORGEH/10- TAB 320-25	93	14	\$16,252.50	\$5.83	1.58%
Amlodipine-Valsartan-HCTZ	EXFORGEH/5- TAB 160-12.5	43	5	\$5,243.33	\$4.06	0.51%
Amlodipine-Valsartan-HCTZ	EXFORGEH/10- TAB 160-12.5	13	2	\$1,723.92	\$4.42	0.17%
Amlodipine-Valsartan-HCTZ	EXFORGEH/5- TAB 160-25	12	2	\$1,461.66	\$4.06	0.14%
Amlodipine-Valsartan-HCTZ	EXFORGEH/10- TAB 160-25	8	2	\$1,097.60	\$4.57	0.11%
SUBTOTAL		3,054	734	\$499,854.88	\$4.15	48.47%
TOTAL		15,933	3,965*	\$1,031,486.28	\$1.59	100%

*Total number of unduplicated members

Utilization Details of Angiotensin Converting Enzyme Inhibitor Medications

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Benazepril HCl	BENAZEPRIL TAB 20MG	1,021	248	\$9,592.87	\$0.22	1.70%
Benazepril HCl	BENAZEPRIL TAB 40MG	777	188	\$7,443.70	\$0.22	1.32%
Benazepril HCl	BENAZEPRIL TAB 10MG	496	149	\$5,076.34	\$0.22	0.90%
Benazepril HCl	BENAZEPRIL TAB 5MG	148	33	\$1,387.46	\$0.24	0.25%
SUBTOTAL		2,442	618	\$23,500.37	\$0.22	4.17%
Captopril	CAPTOPRIL TAB 12.5MG	285	54	\$1,594.07	\$0.16	0.28%
Captopril	CAPTOPRIL TAB 25MG	278	61	\$1,543.94	\$0.17	0.27%
Captopril	CAPTOPRIL TAB 50MG	224	46	\$1,512.01	\$0.20	0.27%
Captopril	CAPTOPRIL TAB 100MG	29	5	\$260.52	\$0.30	0.05%
SUBTOTAL		816	166	\$4,910.54	\$0.18	0.87%
Enalapril Maleate	ENALAPRIL TAB 10MG	2,802	654	\$19,203.26	\$0.19	3.39%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Enalapril Maleate	ENALAPRIL TAB 20MG	2,712	602	\$21,495.98	\$0.21	3.80%
Enalapril Maleate	ENALAPRIL TAB 5MG	2,310	553	\$14,708.26	\$0.18	2.60%
Enalapril Maleate	ENALAPRIL TAB 2.5MG	1,009	218	\$6,107.45	\$0.18	1.08%
SUBTOTAL		8,833	2,027	\$61,514.95	\$0.19	10.87%
Fosinopril Sodium	FOSINOPRIL TAB 40MG	540	103	\$7,370.41	\$0.42	1.30%
Fosinopril Sodium	FOSINOPRIL TAB 20MG	428	90	\$4,912.85	\$0.32	0.87%
Fosinopril Sodium	FOSINOPRIL TAB 10MG	189	43	\$2,619.74	\$0.32	0.46%
SUBTOTAL		1,157	236	\$14,903.00	\$0.36	2.63%
Lisinopril	LISINOPRIL TAB 20MG	22,881	6,485	\$148,209.00	\$0.16	26.19%
Lisinopril	LISINOPRIL TAB 10MG	20,600	6,212	\$116,017.56	\$0.14	20.50%
Lisinopril	LISINOPRIL TAB 40MG	10,984	2,721	\$104,028.93	\$0.23	18.38%
Lisinopril	LISINOPRIL TAB 5MG	8,643	2,547	\$43,668.35	\$0.13	7.72%
Lisinopril	LISINOPRIL TAB 2.5MG	2,870	843	\$13,614.31	\$0.12	2.41%
Lisinopril	LISINOPRIL TAB 30MG	1,267	304	\$11,002.05	\$0.23	1.94%
SUBTOTAL		67,245	19,112	\$436,540.20	\$0.16	77.14%
Moexipril HCl	MOEXIPRIL TAB 15MG	33	7	\$566.91	\$0.44	0.10%
Moexipril HCl	MOEXIPRIL TAB 7.5MG	20	3	\$242.49	\$0.40	0.04%
SUBTOTAL		53	10	\$809.40	\$0.43	0.14%
Perindopril Erbumine	PERINDOPRIL TAB 4MG	15	2	\$349.62	\$0.53	0.06%
SUBTOTAL		15	2	\$349.62	\$0.53	0.06%
Quinapril HCl	QUINAPRIL TAB 40MG	362	74	\$4,412.61	\$0.28	0.78%
Quinapril HCl	QUINAPRIL TAB 20MG	322	69	\$4,137.11	\$0.32	0.73%
Quinapril HCl	QUINAPRIL TAB 10MG	87	24	\$1,061.76	\$0.24	0.19%
Quinapril HCl	QUINAPRIL TAB 5MG	30	6	\$402.96	\$0.32	0.07%
SUBTOTAL		801	173	\$10,014.44	\$0.29	1.77%
Ramipril	RAMIPRIL CAP 10MG	401	93	\$5,629.20	\$0.29	0.99%
Ramipril	RAMIPRIL CAP 5MG	197	55	\$3,162.75	\$0.34	0.56%
Ramipril	RAMIPRIL CAP 2.5MG	175	59	\$2,818.52	\$0.31	0.50%
Ramipril	RAMIPRIL CAP 1.25MG	29	8	\$429.49	\$0.37	0.08%
SUBTOTAL		802	215	\$12,039.96	\$0.31	2.13%
Trandolapril	TRANDOLAPRIL TAB 4MG	39	5	\$603.90	\$0.39	0.11%
Trandolapril	TRANDOLAPRIL TAB 2MG	23	3	\$401.81	\$0.43	0.07%
Trandolapril	TRANDOLAPRIL TAB 1MG	13	3	\$315.31	\$0.46	0.06%
SUBTOTAL		75	11	\$1,321.02	\$0.42	0.24%
TOTAL		82,239	22,570*	\$565,903.50	\$0.17	100%

*Total number of unduplicated members

ACEI/HCTZ Combination Products

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Benazepril & HCTZ	BENAZEP/HCTZ TAB 20-12.5	182	45	\$3,460.04	\$0.45	1.91%
Benazepril & HCTZ	BENAZEP/HCTZ TAB 20-25MG	178	37	\$2,556.11	\$0.35	1.41%
Benazepril & HCTZ	BENAZEP/HCTZ TAB 10-12.5	84	23	\$1,349.62	\$0.43	0.75%
Benazepril & HCTZ	BENAZEP/HCTZ TAB 5-6.25	12	2	\$142.20	\$0.41	0.08%
SUBTOTAL		456	107	\$7,507.97	\$0.41	4.15%
Captopril & HCTZ	CAPTOPR/HCTZ TAB 50-25MG	77	11	\$1,560.74	\$0.58	0.86%
Captopril & HCTZ	CAPTOPR/HCTZ TAB 25-15MG	27	4	\$529.40	\$0.49	0.29%
Captopril & HCTZ	CAPTOPR/HCTZ TAB 25-25MG	21	3	\$293.55	\$0.47	0.16%
Captopril & HCTZ	CAPTOPR/HCTZ TAB 50-15MG	2	2	\$26.07	\$0.43	0.01%
SUBTOTAL		127	20	\$2,409.76	\$0.54	1.32%
Enalapril & HCTZ	ENALAPR/HCTZ TAB 10-25MG	290	72	\$4,078.94	\$0.28	2.25%
Enalapril & HCTZ	ENALAPR/HCTZ TAB 5-12.5MG	129	33	\$1,420.13	\$0.26	0.78%
SUBTOTAL		419	105	\$5,499.07	\$0.25	3.03%
Fosinopril & HCTZ	FOSINOP/HCTZ TAB 20/12.5	29	5	\$986.62	\$1.06	0.55%
Fosinopril & HCTZ	FOSINOP/HCTZ TAB 10/12.5	19	3	\$1,362.09	\$2.26	0.75%
SUBTOTAL		48	8	\$2,348.71	\$1.53	1.30%
Lisinopril & HCTZ	LISINOP/HCTZ TAB 20-25MG	8,180	2,310	\$66,645.33	\$0.18	36.84%

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Lisinopril & HCTZ	LISINOP/HCTZ TAB 20-12.5	7,574	2,094	\$65,243.66	\$0.21	36.06%
Lisinopril & HCTZ	LISINOP/HCTZ TAB 10-12.5	3,971	1,211	\$27,927.01	\$0.16	15.44%
SUBTOTAL		19,725	5,615	\$159,816.00	\$0.19	88.34%
Moexipril & HCTZ	MOEXIPR/HCTZ TAB 15-25MG	23	4	\$473.14	\$0.63	0.26%
Moexipril & HCTZ	MOEXIPR/HCTZ TAB 15-12.5	7	3	\$235.17	\$0.46	0.13%
Moexipril & HCTZ	MOEXIPR/HCTZ TAB 7.5-12.5	5	2	\$179.78	\$0.46	0.10%
SUBTOTAL		35	9	\$888.09	\$0.54	0.49%
Quinapril & HCTZ	QUINAPRIL/HCTZ TAB 20-12.5	35	9	\$936.46	\$0.70	0.52%
Quinapril & HCTZ	QUINAPRIL/HCTZ TAB 20-25MG	34	7	\$1,095.46	\$0.76	0.61%
Quinapril & HCTZ	QUINAPRIL/HCTZ TAB 10-12.5	17	4	\$417.57	\$0.82	0.23%
SUBTOTAL		86	20	\$2,449.49	\$0.74	1.36%
TOTAL		20,896	5,884*	\$180,919.09	\$0.20	100%

*Total number of unduplicated members

ACEI/Calcium Channel Blocker Combination Products

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Amlodipine -Benazepril	AMLOD/BENAZP CAP 10-20MG	302	59	\$12,364.19	\$0.90	23.45%
Amlodipine -Benazepril	AMLOD/BENAZP CAP 10-40MG	262	47	\$12,138.75	\$1.09	23.02%
Amlodipine -Benazepril	AMLOD/BENAZP CAP 5-20MG	247	48	\$9,407.43	\$0.96	17.84%
Amlodipine -Benazepril	AMLOD/BENAZP CAP 5-10MG	135	25	\$3,832.10	\$0.76	7.27%
Amlodipine -Benazepril	AMLOD/BENAZP CAP 5-40MG	43	10	\$2,139.99	\$1.00	4.06%
Amlodipine -Benazepril	LOTREL CAP 5-20MG	9	1	\$1,589.30	\$4.82	3.01%
Amlodipine -Benazepril	AMLOD/BENAZP CAP 2.5-10MG	3	1	\$47.64	\$0.53	0.09%
SUBTOTAL		1,001	191	\$41,519.40	\$0.98	78.74%
Trandolapril-Verapamil	TARKA TAB 4-240 CR	31	5	\$7,814.47	\$4.62	14.82%
Trandolapril-Verapamil	TARKA TAB 2-240 CR	12	1	\$1,387.76	\$3.85	2.63%
Trandolapril-Verapamil	TARKA TAB 2-180 CR	5	1	\$1,517.59	\$3.89	2.88%
Trandolapril-Verapamil	TRANDO/VERAP TAB 4-240 CR	4	2	\$496.41	\$2.76	0.94%
SUBTOTAL		52	9	\$11,216.23	\$4.28	21.27%
TOTAL		1,053	199*	\$52,735.63	\$1.17	100%

*Total number of unduplicated members

Utilization Details of Direct Renin Inhibitor Medications

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Aliskiren	TEKURNA TAB 150MG	42	8	\$6,685.67	\$3.48	56.76%
Aliskiren	TEKURNA TAB 300MG	26	8	\$4,982.73	\$4.15	42.31%
SUBTOTAL		68	16	\$11,777.96	\$3.74	99.07%
Aliskiren-Valsartan	VALTURNA TAB 300-320	1	1	\$109.56	\$3.65	0.93%
TOTAL		69	17*	\$11,777.96	\$3.74	100%

*Total number of unduplicated members

Utilization Details of Clonidine Extended Release Medications

GENERIC NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Clonidine TD Patch Weekly 0.2 MG/24HR	CLONIDINE DIS 0.2/24HR	133	27	\$18,103.00	\$4.94	35.66%
Clonidine TD Patch Weekly 0.1 MG/24HR	CLONIDINE DIS 0.1/24HR	126	23	\$9,519.17	\$2.73	18.75%
Clonidine TD Patch Weekly 0.3 MG/24HR	CLONIDINE DIS 0.3/24HR	97	19	\$19,199.40	\$7.06	37.82%
Clonidine TD Patch Weekly 0.3 MG/24HR	CATAPRES-TTS DIS 0.3/24HR	10	1	\$3,815.18	\$13.63	7.52%
SUBTOTAL		366	70	\$50,636.75	\$4.99	99.75%
Clonidine ER Susp 0.09 MG/ML -Base Equiv	NEXICLON XR SUS 0.09/ML	3	1	\$128.04	\$1.42	0.25%
TOTAL		369	71*	\$50,764.79	\$4.96	100.00%

*Total number of unduplicated members

PRODUCT DETAILS OF EPANED™ (ENALAPRIL POWDER FOR ORAL SOLUTION)⁹

INDICATIONS AND USE: Epaned™ (enalapril for oral solution) is an antihypertensive indicated for the treatment of hypertension in adults and children older than one month.

DOSAGE FORMS: Epaned™ is supplied as a kit containing one bottle of 150mg Powder for oral solution and one bottle of 150mL Ora-Sweet®. (Each 150mg bottle is reconstituted with 150mL of Ora-Sweet® resulting in a 1mg/1mL oral solution). The solution should be discarded 60 days after reconstitution.

ADMINISTRATION: The initial recommended adult dose of Epaned™ is 5mg by mouth once daily. The dose can be titrated upward to a maximum of 40mg daily. The dose may be divided and administered twice daily if the antihypertensive effect diminishes at the end of the dosing interval. The initial recommended pediatric dose of Epaned™ is 0.08mg/kg once daily. Doses above 0.58mg/kg (or in excess of 40mg) have not been studied in pediatric patients.

CONTRAINDICATIONS:

- Hypersensitivity related to previous treatment with an (ACEI).
- Hereditary or idiopathic angioedema
- Should not be co-administered with aliskiren in diabetic patients.

SPECIAL POPULATIONS:

- Epaned™ is classified as pregnancy category D. Use of drugs that act on the renin angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. When pregnancy is detected, discontinue Epaned™ as soon as possible.
- Epaned™ has been detected in human breast milk.
- Epaned™ is not recommended in neonates and pediatric patients with a glomerular filtration rate $<30\text{mL}/\text{min}/1.73\text{m}^2$.

WARNINGS AND PRECAUTIONS:

- Angioedema of the face, intestines, extremities, lips, tongue, glottis and/or larynx including some fatal reactions have occurred in patients treated with ACEI including Epaned™.
- Sudden anaphylactoid reactions have occurred in some patients dialyzed with high-flux membranes and treated concomitantly with an ACEI.
- Epaned™ can cause symptomatic hypotension. Patients at increased risk of excessive hypotension include the following conditions: heart failure with systolic blood pressure below 100mmHg, ischemic heart disease, cerebrovascular disease, and high dose diuretic therapy.
- Rarely, ACEI have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis.
- Monitor renal function in patients treated with Epaned™. Changes in renal function including acute renal failure can be caused by drugs that inhibit the renin-angiotensin system.
- Serum potassium should be monitored in patients receiving Epaned™. Drugs that inhibit the renin-angiotensin system can cause hyperkalemia.

ADVERSE REACTIONS: The most commonly reported adverse reactions during clinical trials (occurring in at least 1% of patients treated with Epaned™ and greater incidence than placebo) were fatigue, orthostatic effects, asthenia, cough, and rash.

DRUG INTERACTIONS:

- Coadministration of Epaned™ and NSAIDs in patients who are elderly or with compromised renal function may result in deterioration of renal function and possible acute renal failure. Additionally NSAIDs may diminish the antihypertensive effect of Epaned™.
- Dual blockade of the renin-angiotensin system with ACEI or Aliskiren is associated with increased risk of hypotension, hyperkalemia, and changes in renal function.
- Epaned™ attenuates potassium loss caused by thiazide diuretics. Concomitant use with potassium-sparing diuretics may lead to significant increases in serum potassium.
- Lithium toxicity has been reported in patients receiving enalapril and lithium concomitantly.

PATIENT COUNSELING INFORMATION:

1. Epaned™ is for high blood pressure.
2. Epaned™ should be taken as an oral solution by mouth once daily.
3. Epaned™ can be taken with or without food.
4. Epaned™ should not be used during pregnancy. Report pregnancies to your physician as soon as possible.
5. Epaned™ can lower your blood pressure and cause lightheadedness. Use caution when beginning therapy until you know how the medication will affect you.
6. Avoid using salt substitutes containing potassium while on Epaned™ therapy.

PRODUCT DETAILS OF NYMALIZE™ (NIMODIPINE ORAL SOLUTION)⁷

INDICATIONS AND USE: Nymalize™ (nimodipine oral solution) is a dihydropyridine calcium channel blocker indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e. Hunt and Hess Grades I-V).

DOSAGE FORMS: Nymalize™ is supplied as an oral solution containing 60mg per 20mL.

ADMINISTRATION:

- The recommended adult dose of Nymalize™ is 60mg enterally every four hours for 21 consecutive days.
- Nymalize™ should be administered only enterally (e.g., oral, nasogastric tube or gastric tube route). Nymalize™ should not be administered intravenously or by other parenteral routes.
- Nymalize™ should be given one hour before a meal or two hours after a meal.
- Dosing of Nymalize™ should be started within 96 hours of the SAH.

CONTRAINDICATIONS: None listed.

SPECIAL POPULATIONS:

- Nymalize™ is classified as pregnancy category C. There are no adequate and well controlled studies in pregnant women to directly assess the effect on human fetuses. Nymalize™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- It is not known if Nymalize™ is excreted in human breast milk.
- The safety and effectiveness of Nymalize™ in pediatric patients has not been established.
- Clinical studies of Nymalize™ did not include sufficient numbers of subjects aged 65 and older to determine if they respond differently than younger patients.
- Plasma levels of Nymalize™ are increased in patients with cirrhosis. In addition to a lower dose in these patients blood pressure and pulse rate should be monitored closely.

WARNINGS AND PRECAUTIONS: Blood pressure should be carefully monitored during treatment with Nymalize™ due to the risk of hypotension.

ADVERSE REACTIONS: The most commonly reported adverse reactions during clinical trials (occurring in at least 1% of patients treated with Nymalize™ at recommended dosing and greater incidence than placebo) were decreased blood pressure, headache, nausea, and bradycardia.

DRUG INTERACTIONS:

- Coadministration of Nymalize™ and other anti-hypertensives may increase the blood pressure lowering effect. Blood pressure should be monitored carefully, and dose adjustments of the blood pressure lowering drugs may be necessary.
- Strong CYP3A4 inhibitors (e.g. macrolide antibiotics, HIV protease inhibitors, Azole antimycotics) can increase the plasma concentration of Nymalize™ possibly causing an increased blood pressure lowering effect. Coadministration of Nymalize™ and strong CYP3A4 inhibitors should generally be avoided.
- Nymalize™ plasma concentration and efficacy may be reduced when concomitantly administered with strong CYP 3A4 inducers (e.g. carbamazepine, phenobarbital, phenytoin,

rifampin, St. John's Wort). Coadministration of Nymalize™ and strong CYP3A4 inducers should generally be avoided.

PATIENT COUNSELING INFORMATION:

1. Nymalize™ is used to help reduce the negative effects of a certain type of stroke.
2. Nymalize™ should be taken as an oral solution by every four hours for three weeks.
3. Nymalize™ should be taken one hour before or two hours after eating.
4. Nymalize™ can lower your blood pressure and cause lightheadedness. Use caution when beginning therapy until you know how the medication will affect you.
5. Avoid ingesting grapefruit or grapefruit juice while on Nymalize™ therapy. Ingesting grapefruit while on Nymalize™ can increase your risk of a drop in blood pressure.

¹ "Cardene SR," "Diovan," "Benicar," "Benicar HCT," "Azor," Tribenzor," "Edarbi," "Edarbyclor," Micardis," Micardis HCT," "Twynsta," "Tarka," "Tekturna," "Tekturna HCT." U.S. Food and Drug Administration: Orange Book. Retrieved October 8, 2013. orange-book.findthedata.org

² Walsh, Sandy (2013, May 14). *FDA approves Nymalize—first nimodipine oral solution for use in certain brain hemorrhage patients*. Retrieved October 7, 2013, from U.S. Food and Drug Administration: www.fda.gov/newsevents/newsroom/pressannouncements/ucm352280.htm

³ *FDA Approves Epaned, a Liquid form of Enalapril for Children and Adults*. Retrieved October 14, 2013, from Silvergate Pharmaceuticals Inc.: www.silvergatepharma.com/fda-approves-epaned-a-liquid-form-of-enalapril-for-children-and-adults

⁴ *Drugs to be discontinued*. Retrieved October 7, 2013, from U.S. Food and Drug Administration: www.fda.gov/drugs/drugsafety/drugshortages/ucm050794.htm

⁵ *FDA to patients: Do not stop taking your angiotensin receptor blocker blood pressure medication without talking to a healthcare professional*. Retrieved October 9, 2013, from U.S. Food and Drug Administration: www.fda.gov/drugs/drugsafety/ucm354856.htm

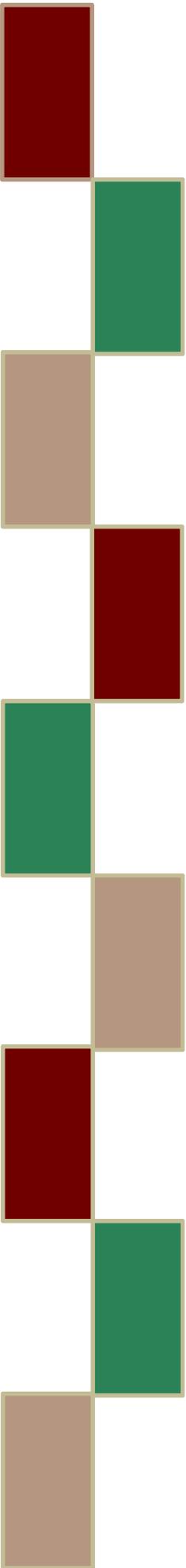
⁶ *FDA Drug Safety Communication: FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to blood pressure medicine olmesartan medoxomil*. Retrieved October 8, 2013, from U.S. Food and Drug Administration: www.fda.gov/drugs/drugsafety/ucm359477.htm

⁷ Nymalize™ [Package insert]. Atlanta, Georgia: Arbor Pharmaceuticals, Inc; 2013. Available online at: www.aborpharma.com Accessed October 28, 2013.

⁸ *FDA Drug Safety Communication: Serious medication errors from intravenous administration of nimodipine oral capsules*. Retrieved October 8, 2013, from U.S. Food and Drug Administration: www.fda.gov/drugs/drugsafety/informationforpatientsandproviders/ucm220386.htm

⁹ Epaned™ [Package insert]. Greenwood Village, Colorado: Silvergate Pharmaceuticals, Inc; 2013. Available online at: www.epaned.com Accessed October 4, 2013.

Appendix G



Fiscal Year 2013 Annual Review of Nasal Allergy Medications And 30-Day Notice to Prior Authorize Zetonna® (Ciclesonide)

Oklahoma Health Care Authority
November 2013

Current Prior Authorization Criteria

1. The following criteria are required for approval of a Tier 2 product:
 - a. Documented adverse effect or contraindication to the preferred products.
 - b. Failure with all Tier 1 medications defined as no beneficial response after at least three weeks of use at the maximum recommended dose.
2. The following criteria are required for approval of a Tier 3 product:
 - a. All Tier 2 criteria must be met.
 - b. Failure with all available Tier 2 products defined as no beneficial response after at least three weeks of use at the maximum recommended dose.
3. No grandfathering of Tier 2 or Tier 3 products will be allowed for this category.
4. For 2 to 4 year olds, the age appropriate lower-tiered generic products must be used prior to the use of higher tiered products.
5. Approvals will be for the duration of three months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

Nasal Allergy Products		
<i>Tier 1</i>	<i>Tier 2</i>	<i>Tier 3</i>
fluticasone (Flonase®)	beclomethasone (Beconase® AQ)	ciclesonide (Omnaris®)
flunisolide (Nasalide®, Nasarel™)	olopatadine (Patanase®)	budesonide (Rhinocort® AQ)
triamcinolone (Nasacort® AQ)		fluticasone (Veramyst™)
		mometasone (Nasonex®)
		azelastine (Astepro®)
		azelastine (Astelin®)
		beclomethasone (QNasl®)
		azelastine/fluticasone (Dymista™)

Tier structure based on supplemental rebate participation.

Utilization of Nasal Allergy Medications

Comparison of Fiscal Years for Nasal Allergy Medications

Fiscal Year	Members*	Claims	Cost	Cost/Claim
2012	46,565	84,196	\$2,363,846.07	\$28.08
2013	50,490	90,614	\$2,463,122.33	\$27.18
% Change	8.40%	7.60%	4.20%	-3.20%
Change	3,925	6,418	\$99,276.26	-\$0.90

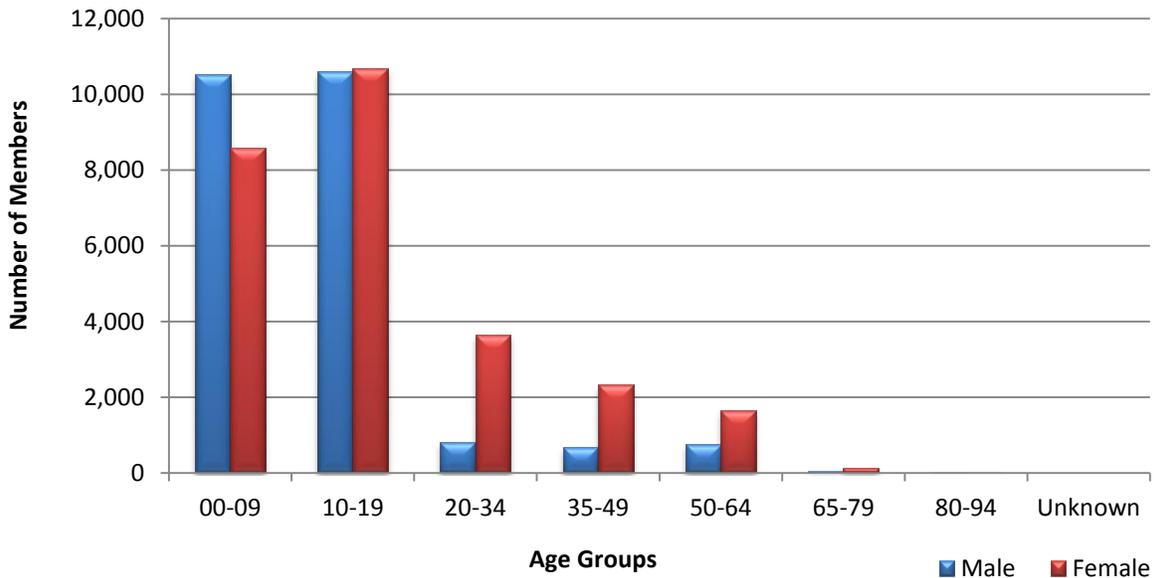
*Total number of unduplicated members.

Utilization Details of Nasal Allergy Medications

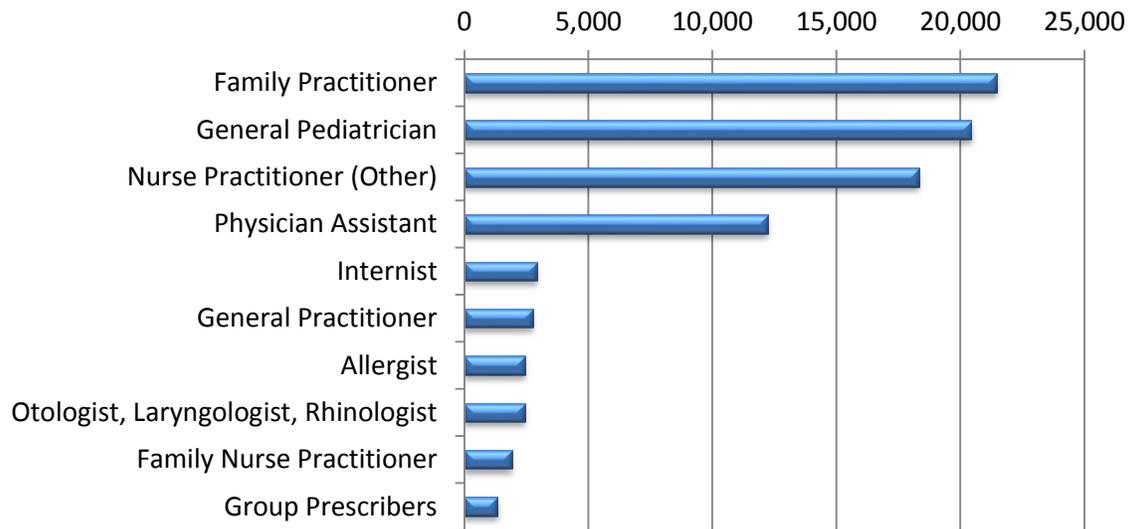
CHEMICAL NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/ DAY	% COST
Fluticasone	FLUTICASONE	85,444	48,428	\$2,053,520.09	\$0.74	83.37%
Fluticasone	VERAMYST	320	50	\$35,372.34	\$3.52	1.44%
Fluticasone	FLONASE	1	1	\$85.36	\$2.85	0.00%
Triamcinolone	TRIAMCINOLONE	2,454	1,370	\$201,828.68	\$2.48	8.19%
Triamcinolone	NASACORT AQ	5	1	\$619.85	\$4.13	0.03%
Flunisolide	FLUNISOLIDE SPR 0.25%	1,978	1,247	\$117,916.60	\$1.99	4.79%
Flunisolide	FLUNISOLIDE SPR 29 MCG	7	7	\$182.33	\$0.87	0.01%
Mometasone	NASONEX	197	61	\$25,696.74	\$3.58	1.04%
Beclomethasone	BECONASE AQ	36	18	\$5,710.67	\$5.51	0.23%
Beclomethasone	QNASL	8	2	\$972.52	\$4.05	0.04%
Budesonide	RHINOCORT	24	15	\$2,849.60	\$3.52	0.12%
Ciclesonide	OMNARIS	5	1	\$604.75	\$4.03	0.02%
Ciclesonide	ZETONNA	2	2	\$248.90	\$4.15	0.01%
TOPICAL CORTICOSTEROID SUBTOTAL		90,481		2,445,608.43	\$0.83	99.29%
Olopatadine	PATANASE	79	29	\$12,590.74	\$4.82	0.51%
Azelastine HCl	AZELASTINE	33	12	\$2,128.95	\$2.12	0.09%
Azelastine HCl	ASTEPRO	13	3	\$1,602.27	\$4.11	0.07%
Azelastine	DYMISTA	8	3	\$1,192.40	\$4.97	0.05%
TOPICAL ANTIHISTAMINE SUBTOTAL		133		\$17,514.36	\$4.13	0.72%
TOTAL		90,614	50,490*	\$2,463,122.33	\$0.83	100 %

*Total number of unduplicated members.

Demographics of Members Utilizing Nasal Allergy Medications

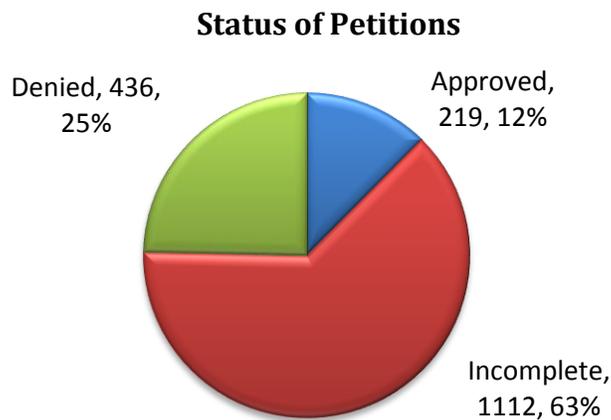


Top Prescriber Specialties of Nasal Allergy Medications by Claims



Prior Authorization of Nasal Allergy Medications

There were a total of 1,767 petitions submitted for the Nasal Allergy Product Based Prior Authorization category during fiscal year 2013. 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

- **Anticipated Patent Expirations:** ¹
 - Nasonex® (mometasone)- January 2014
 - Omnaris® (ciclesonide)- October 2017
 - Zetonna® (ciclesonide)- October 2017
 - Patanase® (olopatadine)- August 2020
 - Dymista™ (azelastine/fluticasone)- August 2023

- **1/2012** The U.S. Food and Drug Administration approved Zetonna® (ciclesonide) nasal aerosol for the treatment of symptoms associated with seasonal and perennial allergic rhinitis. The details of Zetonna® are below.
- **10/2013** The U.S. Food and Drug Administration approved Nasacort® Allergy 24HR (triamcinolone acetonide), an over-the-counter (OTC) nasal spray product for treatment of nasal allergy symptoms (nasal congestion, runny nose, sneezing, and itchy nose). Nasacort® Allergy 24HR is labeled for use in children 2 years of age and older, adolescents, and adults.²

Zetonna® (ciclesonide) Summary³

- **Indications:** Zetonna® (ciclesonide) is a nasal corticosteroid indicated for treatment of symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.
- **Dosing:** Zetonna® (ciclesonide) is available as a nasal aerosol. One canister consists of 60 actuations containing 37 mcg of ciclesonide per actuation. The recommended dose is 1 actuation per nostril once daily.
- **Efficacy:** One randomized, double-blind, parallel-group, multicenter, placebo-controlled dose-ranging trial and 3 confirmatory trials were conducted to assess efficacy. All of these studies showed statistically significant decreases in nasal symptoms (runny nose, nasal itching, sneezing, and nasal congestion) when compared to placebo.
- **Cost:** The estimated acquisition cost of Zetonna® (ciclesonide) is approximately \$140 per canister. The Tier 1 product fluticasone costs approximately \$24 per canister.

Conclusions and Recommendations:

The College of Pharmacy recommends the addition of Zetonna® (ciclesonide) to Tier 3 of the Nasal Allergy Product Based Prior Authorization. The existing criteria for this category will apply.

Nasal Allergy Products		
<i>Tier 1</i>	<i>Tier 2</i>	<i>Tier 3</i>
fluticasone (Flonase®)	beclomethasone (Beconase® AQ)	ciclesonide (Omnaris®)
flunisolide (Nasalide®, Nasarel™)	olapatadine (Patanase®)	budesonide (Rhinocort® AQ)
triamcinolone (Nasacort® AQ)		fluticasone (Veramyst™)
		mometasone (Nasonex®)
		beclomethasone (QNasl®)
		azelastine (Astepro®)
		azelastine (Astelin®)
		azelastine/fluticasone (Dymista™)
		Ciclesonide (Zetonna®)

Tier structure based on supplemental rebate participation.

PRODUCT DETAILS OF ZETONNA® (CICLESONIDE)³

INDICATIONS: Zetonna® (ciclesonide) is a nasal corticosteroid indicated for treatment of symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.

DOSAGE FORMS: Zetonna® is available as a nasal aerosol. Each actuation contains 37 mcg of ciclesonide with 60 actuations per canister.

ADMINISTRATION: The recommended dose is one actuation per nostril once daily.

CONTRAINDICATIONS: Known hypersensitivity to Zetonna® (ciclesonide).

SPECIAL POPULATIONS:

- **Pregnancy:** There are no adequate and well-controlled studies with Zetonna® in pregnant women. Zetonna® should be used during pregnancy only if the potential benefit justifies the potential risk (pregnancy category C).
- **Nursing Mothers:** It is not known whether Zetonna® is excreted in human milk. However, other corticosteroids are excreted in human milk. Caution should be used when Zetonna® is administered to nursing women.
- **Pediatrics:** The safety and effectiveness in pediatric patients under the age of 12 years has not been established.
- **Geriatrics:** Clinical trials of Zetonna® did not include sufficient numbers of patients 65 and over to determine whether they responded differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- **Hepatic Impairment:** No dose adjustment is required in patients with hepatic impairment.
- **Renal Impairment:** Trials in renal-impaired patients were not conducted since renal excretion of the active metabolite, des-ciclesonide, is a minor route of elimination.

WARNINGS AND PRECAUTIONS:

- Local nasal effects such as epistaxis, ulceration, and nasal perforations can occur.
- *Candida albicans* infection and impaired wound healing can occur with corticosteroids.
- Development of cataracts or glaucoma can occur with use of corticosteroids.
- Potential worsening of tuberculosis; fungal, bacterial, viral, or parasitic; or ocular herpes simplex. More serious or even fatal course of chicken pox or measles in susceptible individuals.
- Hypercorticism and adrenal suppression with very high dosages or at the regular dosage may occur in susceptible individuals.
- Potential reduction of growth velocity in children

ADVERSE REACTIONS: Most common serious adverse reactions reported were nasal discomfort, headaches, and epistaxis.

DRUG INTERACTIONS:

- In vitro studies and clinical pharmacology studies suggested that des-ciclesonide has no potential for metabolic drug interactions or protein binding-based drug interactions.

PATIENT COUNSELING INFORMATION:

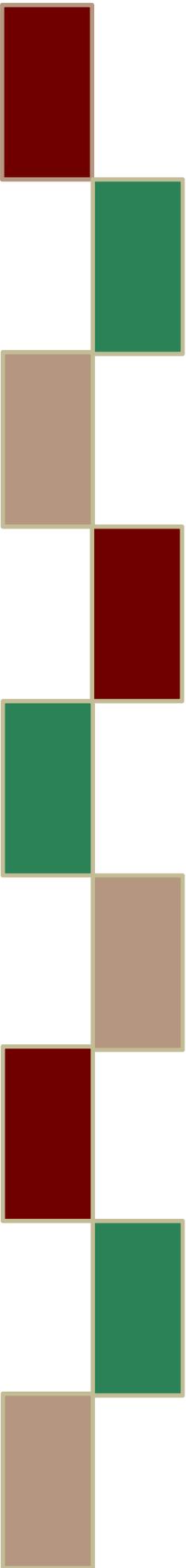
- Use Zetonna[®] daily, since its effectiveness depends on regular use.
- Local nasal effects can occur which may include nasal septal perforation, epistaxis, and nasal ulceration.
- Do not spray Zetonna[®] directly onto the nasal septum or into eyes.
- Glaucoma and cataracts are associated with nasal and inhaled corticosteroid use.

¹ "Zetonna" "Omnaris", "Patanase", "Nasonex", "Dymista" U.S Food and Drug Administration: Orange Book. Available online at: <http://orange-book.findthedata.org>. Last revised 10/2013. Last accessed 10/25/2013.

² FDA approves over-the-counter Nasacort Allergy 24HR to treat hay fever and nasal allergies. U.S. Food and Drug Administration. Available online at: <http://www.fda.gov/Drugs/NewsEvents/ucm370973.htm>. Last revised 10/2013. Last accessed 10/21/2013.

³ Zetonna[®] Product Information. Sunovion Pharmaceuticals, Inc. Available online at: <http://www.zetonna.com/downloads/ZETONNA-Prescribing-Information.pdf>. Last revised 03/2013. Last accessed 10/17/2013.

Appendix H



Fiscal Year 2013 Annual Review of Glaucoma Medications And 30-Day Notice to Prior Authorize Simbrinza™ (Brinzolamide/Brimonidine) and Rescula® (Unoprostone)

Oklahoma Health Care Authority
November 2013

Prior Authorization Criteria

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

Tier 2 Authorization Criteria:

1. FDA approved diagnosis; and
2. Recent trials (within the last 120 days) of at least three Tier 1 medications for a minimum of 4 weeks in duration each that did not provide adequate response or resulted in intolerable adverse effects. Tier 1 trials may be from any pharmacological class.
3. Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier 1 medications.
4. Approval may be granted if there is a unique FDA approved indication not covered by Tier 1 medications.
5. Member must have had a comprehensive dilated eye exam within the last 365 days as recommended by the National Institute of Health.
6. Approval duration will be for 1 year.

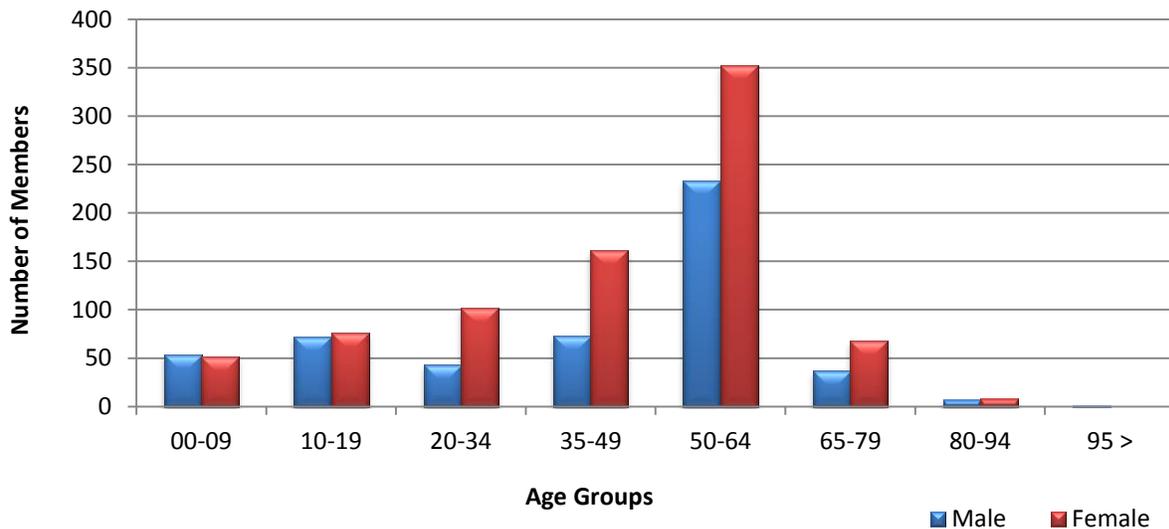
Utilization of Glaucoma Medications

Comparison of Fiscal Years

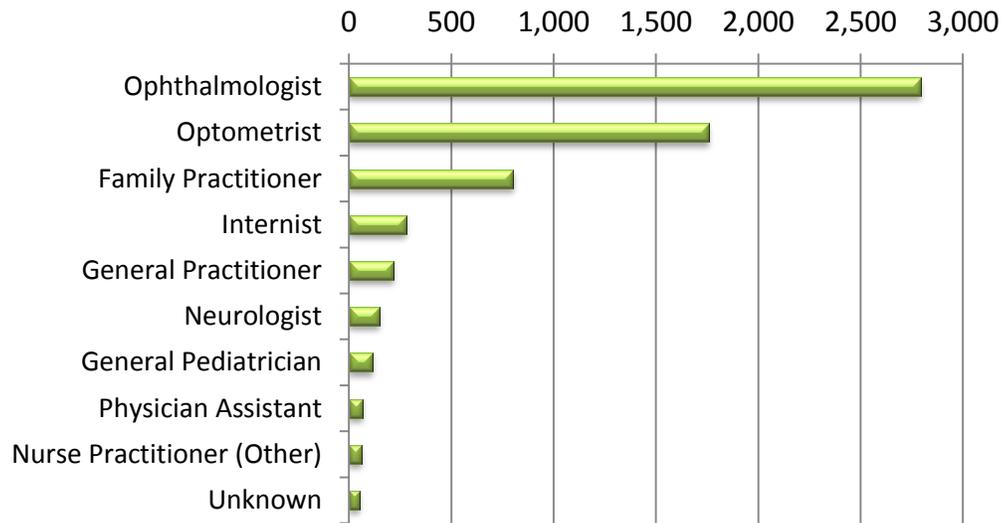
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2012	1,271	6,251	\$468,994.34	\$75.03	\$2.47	78,461	189,539
2013	1,339	6,601	\$492,656.91	\$74.63	\$2.37	87,229	208,156
% Change	5.40%	5.60%	5.00%	-0.50%	-4.00%	11.20%	9.80%
Change	68	350	\$23,662.57	-\$0.40	-\$0.10	8,768	18,617

*Total number of unduplicated members.

Demographics of Members



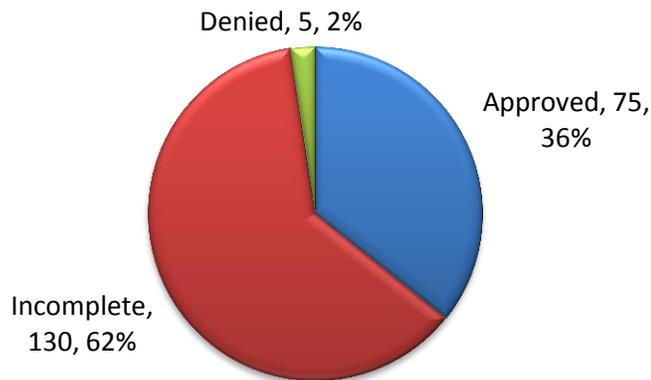
Top Prescriber Specialties of Glaucoma Medications by Number of Claims



Prior Authorization of Glaucoma Medications

There were a total of 210 petitions submitted for this category during fiscal year 2013. Computer edits are in place to detect tier-1 medications in member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expirations

- Cosopt PF® (dorzolamide/timolol)- 2/2015
- Zioptan™ (tafluprost)- 12/2017
- Rescula® (unoprostone)- 12/2017
- Istalol® (timolol)- 11/2018
- Simbrinza™ (brinzolamide/brimonidine)- 12/2019
- Combigan® (brimonidine/timolol)- 4/2022

Rescula® (0.15% unoprostone) ophthalmic solution is a synthetic docosanoid that was developed from a prostaglandin metabolite. It was first approved by the FDA in 2000 as a treatment option for patients who were intolerant to other intraocular pressure (IOP) lowering medications or insufficiently responded to other IOP medications. Manufacturing of Rescula® ceased in the mid-2000's, but now has been re-released with a labeling revision approved by the FDA in December 2012 to remove the previous limitations to its indication. Rescula® is indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

Simbrinza™ (1% brinzolamide/0.2% brimonidine) ophthalmic suspension was approved by the FDA in April 2013. Simbrinza™ is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

Rescula® (Unoprostone) Ophthalmic Solution^{1,2,3,4}

Rescula® is a 0.15% unoprostone ophthalmic solution available in a 5 milliliter bottle. The recommended dose of Rescula® is one drop in the affected eye(s) twice daily. Rescula® may be used concomitantly with other topical ophthalmic medications to lower IOP. If more than one topical ophthalmic medication is being used, the medications should be administered at least five minutes apart.

Rescula® is contraindicated in patients with hypersensitivity to unoprostone or any other ingredient in the product. Rescula® may gradually increase the pigmentation of the iris, as well as the periorbital pigmented tissues and eyelashes. The long term effects of increased pigmentation are not known. Iris color changes may not be noticeable for several months to years. The pigmentation of the periorbital pigmented tissues and eyelashes is expected to increase as long as Rescula® is administered, but has been reported to be reversible upon discontinuation of Rescula® in most patients. Treatment with Rescula® can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula® should be informed of the possibility of increased pigmentation.

The efficacy of Rescula® was evaluated in randomized controlled clinical trials of 6 months duration in patients with a mean baseline IOP of 23 mmHg. Rescula® lowered IOP by approximately 3-4 mmHg throughout the day, and it appeared to lower IOP without affecting cardiovascular or pulmonary function.

The cost per 5 milliliter bottle of Rescula® ophthalmic solution is \$104.54. Comparatively, a 2.5 milliliter bottle of latanoprost ophthalmic solution is \$11.31.

Simbrinza™ (Brinzolamide/Brimonidine) Ophthalmic Suspension^{5,6,7}

Simbrinza™ is a 1% brinzolamide/0.2% brimonidine ophthalmic suspension available in an 8 milliliter bottle. The recommended dose of Simbrinza™ is one drop in the affected eye(s) three times daily. Simbrinza™ suspension needs to be shaken well before each use. Simbrinza™ may be used concomitantly with other topical ophthalmic medications to lower IOP. If more than one topical ophthalmic medication is being used, the medications should be administered at least five minutes apart.

Simbrinza™ is contraindicated in children under the age of 2 years, and in patients with hypersensitivity to any component of the product. Simbrinza™ contains brinzolamide, which is a sulfonamide, and although administered topically, is absorbed systemically. Severe reactions to sulfonamides, including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias may occur with topical administration of Simbrinza™.

The efficacy of Simbrinza™ was evaluated in two clinical trials of 3 months duration in patients with open-angle glaucoma or ocular hypertension. The IOP-lowering effect was compared of Simbrinza™ dosed three times daily to individually administered 1% brinzolamide three times daily or 0.2% brimonidine three times daily. The IOP-lowering effect of Simbrinza™ was 1 to 3 mmHg greater than monotherapy with either 1% brinzolamide or 0.2% brimonidine throughout the duration of the trials.

The cost per 8 milliliter bottle of Simbrinza™ ophthalmic suspension is \$92.56. Comparatively, a 10 milliliter bottle of dorzolamide/timolol ophthalmic solution costs \$18.54.

Recommendations^{8,9,10}

The College of Pharmacy recommends the addition of Simbrinza™ and Rescula® to Tier 2 of the Glaucoma Medications Product Based Prior Authorization. The existing criteria for this category will apply.

Tier 2 Authorization Criteria:

1. FDA approved diagnosis; and
2. Recent trials (within the last 120 days) of at least three Tier 1 medications for a minimum of 4 weeks in duration each that did not provide adequate response or resulted in intolerable adverse effects. Tier 1 trials may be from any pharmacological class.
3. Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier 1 medications.
4. Approval may be granted if there is a unique FDA approved indication not covered by Tier 1 medications.
5. Member must have had a comprehensive dilated eye exam within the last 365 days as recommended by the National Institute of Health.
6. Approval duration will be for 1 year.

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

Utilization Details of Glaucoma Medications: Fiscal Year 2013

CHEMICAL NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/DAY	% COST
Travoprost	Travatan Z® 0.004% soln	1,566	426	\$207,353.87	\$4.28	42.09%
Latanoprost	Latanoprost 0.005% soln	1,366	340	\$23,003.62	\$0.56	4.67%
Dorzolamide/timolol	Dorzolamide/timolol 2/0.5% soln	517	158	\$14,236.43	\$0.77	2.89%
Timolol	Timolol 0.5% soln	468	193	\$4,198.14	\$0.24	0.85%
Brimonidine/timolol	Combigan® 0.2/0.5% soln	339	65	\$40,120.30	\$4.21	8.14%
Brimonidine	Brimonidine 0.2% soln	330	117	\$5,606.26	\$0.56	1.14%
Brimonidine	Brimonidine 0.15% soln	200	48	\$24,914.60	\$4.25	5.06%
Dorzolamide	Dorzolamide 2% soln	161	62	\$5,373.49	\$1.02	1.09%
Bimatoprost	Lumigan® 0.01% soln	160	54	\$24,789.57	\$4.88	5.03%
Brimonidine	Alphagan P® 0.1% soln	151	36	\$20,994.45	\$4.38	4.26%
Brinzolamide	Azopt® 1% susp	143	46	\$18,515.19	\$3.63	3.76%
Bimatoprost	Lumigan® 0.03% soln	143	39	\$23,112.54	\$4.74	4.69%
Timolol	Timolol 0.5% gel forming soln	85	30	\$3,733.08	\$1.42	0.76%
Timolol	Timolol 0.25% soln	80	29	\$605.83	\$0.22	0.12%
Brimonidine	Alphagan P® 0.15% soln	28	6	\$3,923.74	\$5.03	0.80%
Levobunolol	Levobunolol 0.5% soln	28	7	\$361.48	\$0.41	0.07%
Betaxolol	Betoptic-S® 0.25% susp	27	12	\$5,547.80	\$5.80	1.13%
Timolol	Betimol® 0.5% soln	12	4	\$1,021.08	\$4.25	0.21%
Dorzolamide/timolol	Cosopt PF® 2/0.5% PF soln	10	4	\$862.82	\$2.88	0.18%
Pilocarpine	Pilocarpine 1% soln	9	7	\$260.34	\$0.70	0.05%
Pilocarpine	Pilocarpine 4% soln	8	1	\$260.06	\$1.08	0.05%
Betaxolol	Betaxolol 0.5% soln	8	3	\$103.76	\$0.28	0.02%
Tafluprost	Zioptan™ 0.0015% soln	5	3	\$532.59	\$3.55	0.11%
Timolol	Timoptic Ocudose® 0.25% PF soln	5	1	\$1,377.90	\$9.19	0.28%
Levobunolol	Levobunolol 0.25% soln	4	1	\$34.04	\$0.71	0.01%
Echothiophate Iodide	Phospholine Iodide® 0.125% soln	2	2	\$170.88	\$3.42	0.03%
Pilocarpine	Pilocarpine 2% soln	2	2	\$45.90	\$0.38	0.01%
Timolol	Timolol 0.25% gel forming soln	1	1	\$101.59	\$3.39	0.02%
Timolol	Betimol® 0.25% soln	1	1	\$56.59	\$1.49	0.01%
Timolol	Istalol® 0.5% soln	1	1	\$196.51	\$6.55	0.04%
Dorzolamide/timolol	Cosopt® 2/0.5% soln	1	1	\$270.98	\$4.52	0.06%
Acetazolamide	Acetazolamide 250mg tablets	420	122	\$18,288.39	\$1.47	3.71%
Acetazolamide	Acetazolamide 500mg ER capsules	218	81	\$32,362.78	\$4.98	6.57%
Acetazolamide	Acetazolamide 125mg tablets	43	12	\$1,317.03	\$1.05	0.27%
Methazolamide	Methazolamide 50mg tablets	42	5	\$8,839.84	\$7.28	1.79%
Methazolamide	Methazolamide 25mg tablets	17	5	\$163.44	\$0.46	0.03%
TOTAL		6,601	1,339*	\$492,656.91	\$2.37	100.00%

*Total number of unduplicated members

PRODUCT DETAILS OF RESCULA® (UNOPROSTONE)

INDICATIONS AND USE: Rescula® (0.15% unoprostone) is a synthetic docosanoid that was developed from a prostaglandin metabolite indicated for the reduction of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension.

DOSAGE FORMS: 0.15% unoprostone ophthalmic solution (5 mL bottle)

ADMINISTRATION:

- The recommended dose is one drop of Rescula® in the affected eye(s) twice daily.
- Rescula® may be used concomitantly with other topical ophthalmic medications to lower IOP. If more than one topical ophthalmic medication is being used, the medications should be administered at least five minutes apart.

CONTRAINDICATIONS:

- Hypersensitivity to unoprostone or any component of Rescula®.

SPECIAL POPULATIONS:

- **Pregnancy:** There are no adequate or well-controlled studies with Rescula® in pregnant women. Animal studies showed an increase in incidence of miscarriages, resorptions, and premature delivery, a decrease in live birth index, and a decrease in weight at birth with subcutaneous administration of unoprostone. Because animal studies are not always predictive of human response, Rescula® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (Category C)
- **Nursing Mothers:** It is not known whether Rescula® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Rescula® is administered to a nursing woman.
- **Pediatrics:** The safety and effectiveness of Rescula® in pediatric patients have not been established.
- **Geriatrics:** No overall differences in safety or effectiveness have been observed between elderly and adult patients.
- **Renal Impairment:** No studies have been conducted in patients with renal impairment.
- **Hepatic Impairment:** No studies have been conducted in patients with hepatic impairment.

WARNINGS AND PRECAUTIONS:

- **Iris Pigmentation:** Rescula® may gradually increase the pigmentation of the iris. The pigmentation change is believed to be due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. The long term effects of increased pigmentation are not known. Iris color changes seen with the administration of Rescula® may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become browner in color. Neither nevi nor freckles of the iris appear to be affected by treatment. Treatment with Rescula® can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula® should be informed of the possibility of increased pigmentation.
- **Lid Pigmentation:** Rescula® has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long

as Rescula® is administered, but has been reported to be reversible upon discontinuation of Rescula® in most patients.

- **Intraocular Inflammation:** Rescula® should be used with caution in patients with active intraocular inflammation (e.g. uveitis) because the inflammation may be exacerbated.
- **Macular Edema:** Macular edema, including cystoid macular edema, has been reported. Rescula® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.
- **Contamination of Tip and Solution:** To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.
- **Use with Contact Lenses:** Rescula® contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS:

- Ocular adverse reactions reported in clinical trials in patients treated with Rescula® include the following:
 - Occurring in approximately 10-25% of patients: burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes, and injection.
 - Occurring in approximately 5-10% of patients: abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder.
 - Occurring in approximately 1-5% of patients: blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.
- Non-ocular adverse reactions reported in clinical trials in patients treated with Rescula® include the following:
 - Occurring in approximately 6% of patients: flu-like symptoms.
 - Occurring in approximately 1-5% of patients: accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis.

DRUG INTERACTIONS:

- Rescula® has no listed drug interactions.

PATIENT COUNSELING INFORMATION:

- Rescula® is an eye drop that is indicated to treat open-angle glaucoma or ocular hypertension in adults. Rescula® is not indicated for use in children.
- Before using Rescula®, talk to your doctor or healthcare provider if you are pregnant or plan to become pregnant, or are breastfeeding. It is not known if Rescula® can harm your unborn baby, and it is not known if it passes into your breast milk.
- Talk to your doctor or healthcare provider if you are allergic to unoprostone or any components of Rescula®.
- There is a chance of increased brown iris pigmentation with Rescula®, which is likely to be permanent. There is also a chance of eyelid skin darkening, which may be reversible after stopping use of Rescula®.
- Use Rescula® exactly as prescribed by your doctor.

- Eye drops can become contaminated by common bacteria known to cause eye infections if handled improperly or if the tip of the dispensing container touches the eye or surrounding surfaces. Serious damage to the eye and subsequent loss of vision may result from using contaminated drops. Always wash your hands before use. Do not touch the tip of the dispensing container to your eye or other surfaces. Always replace the cap after using. Do not use the eye drops if the solution changes color or looks different. Do not use the eye drops after the expiration date marked on the bottle.
- If you are using more than one eye medication, the medications should be dosed at least five minutes apart.
- The preservative in Rescula® may be absorbed by soft contact lenses. Remove contact lenses during dosing of Rescula®. Contact lenses may be reinserted 15 minutes after dosing of Rescula®.
- Common side effects include eye burning/stinging after dosing Rescula®, dry eyes, itching, increased length of eyelashes, and red eyes.
- Contact your doctor or healthcare provider if you have any questions about the use of Rescula®.

PRODUCT DETAILS OF SIMBRINZA™ (BRINZOLAMIDE/BRIMONIDINE)

INDICATIONS AND USE: Simbrinza™ (1% brinzolamide/0.2% brimonidine) is a fixed combination of a carbonic anhydrase inhibitor (brinzolamide) and an alpha 2 adrenergic receptor agonist (brimonidine) indicated for the reduction of elevated intraocular pressure (IOP) in patients 2 years of age and older with open-angle glaucoma or ocular hypertension.

DOSAGE FORMS: 1% brinzolamide/0.2% brimonidine ophthalmic suspension (8 mL bottle)

ADMINISTRATION:

- The recommended dose is one drop of Simbrinza™ in the affected eye(s) three times daily.
- Shake well before each use of Simbrinza™.
- Simbrinza™ may be used concomitantly with other topical ophthalmic medications to lower IOP. If more than one topical ophthalmic medication is being used, the medications should be administered at least five minutes apart.

CONTRAINDICATIONS:

- Children under the age of 2 years.
- Hypersensitivity to any component of Simbrinza™.

SPECIAL POPULATIONS:

- **Pregnancy:** There are no adequate or well-controlled studies with Simbrinza™ in pregnant women. Simbrinza™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (Category C)
- **Nursing Mothers:** It is not known whether brinzolamide or brimonidine are excreted in human milk following topical ocular administration. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Simbrinza™, a decision should be made whether to discontinue nursing or to discontinue the medication, taking into account the importance of the medication to the mother.
- **Pediatrics:** The individual component, brinzolamide, has been studied in pediatric glaucoma patients 4 weeks to 5 years of age. The individual component, brimonidine, has been studied in pediatric patients 2 to 7 years of age. Somnolence (50-83%) and decreased alertness was seen in patients 2 to 6 years old. Simbrinza™ is contraindicated in children under the age of 2 years.
- **Geriatrics:** No overall differences in safety or effectiveness have been observed between elderly and adult patients.
- **Renal Impairment:** Simbrinza™ has not been specifically studied in patients with severe renal impairment (CrCl < 30 mL/min). Since brinzolamide and its metabolite are excreted predominantly by the kidney, Simbrinza™ is not recommended in patients with severe renal impairment.
- **Hepatic Impairment:** Brimonidine, a component of Simbrinza™, has not been studied in patients with hepatic impairment. Caution should be exercised in patients with hepatic impairment.

WARNINGS AND PRECAUTIONS:

- **Sulfonamide Hypersensitivity Reactions:** Simbrinza™ contains brinzolamide, which is a sulfonamide, and although administered topically, is absorbed systemically. Severe reactions to sulfonamides, including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias may occur with

topical administration of Simbrinza™. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration. If signs of serious reaction or hypersensitivity occur, discontinue the use of Simbrinza™.

- **Corneal Endothelium:** Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing Simbrinza™ to patients with low endothelial cell counts.
- **Acute Angle-Closure Glaucoma:** The management of acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. Simbrinza™ has not been studied in patients with acute angle-closure glaucoma.
- **Contact Lens Wear:** The preservative in Simbrinza™, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of Simbrinza™ but may be reinserted 15 minutes after instillation.
- **Severe Cardiovascular Disease:** Brimonidine, a component of Simbrinza™, has a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies. Caution should be used when treating patients with severe cardiovascular patients.
- **Potential of Vascular Insufficiency:** Brimonidine, a component of Simbrinza™, may potentiate syndromes associated with vascular insufficiency. Simbrinza™ should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.
- **Contamination of Topical Ophthalmic Products After Use:** There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface. Patients should be counseled on proper use of multiple-dose containers of topical ophthalmic products.

ADVERSE REACTIONS:

- Adverse reactions reported in clinical trials in patients treated with Simbrinza™, occurring in approximately 3 to 5% of patients, in descending order of incidence include:
 - Blurred vision, eye irritation, dysgeusia, dry mouth, and eye allergy.
- Rates of adverse reactions reported with the individual components were comparable. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of Simbrinza™ patients.
- Other adverse reactions that have been reported with the individual components during clinical trials include:
 - For 1% brinzolamide:
 - Occurring in 5 to 10% of patients: blurred vision and bitter, sour or unusual taste.
 - Occurring in 1 to 5% of patients: blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus, and rhinitis.
 - For 0.2% brimonidine:
 - Occurring in 10 to 30% of patients: oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.
 - Occurring in 3 to 9% of patients: corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular

irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision, and muscle pain.

DRUG INTERACTIONS:

- **Oral Carbonic Anhydrase Inhibitors:** There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor (e.g. acetazolamide, methazolamide) and brinzolamide 1% ophthalmic suspension, a component of Simbrinza™. The concomitant administration of Simbrinza™ and oral carbonic anhydrase inhibitors is not recommended.
- **High-Dose Salicylate Therapy:** Carbonic anhydrase inhibitors may produce acid-base and electrolyte alterations. These alterations were not reported in clinical trials with brinzolamide 1% ophthalmic suspension. However, in patients treated with oral carbonic anhydrase inhibitors, rare instances of acid-base alterations have occurred with high-dose salicylate therapy. Therefore, the potential for such drug interactions should be considered in patients receiving Simbrinza™.
- **CNS Depressants:** Although specific drug interaction studies have not been conducted with Simbrinza™, the possibility of an additive or potentiating effect with CNS depressants (alcohol, opiates, barbiturates, sedatives, or anesthetics) should be considered.
- **Antihypertensives/Cardiac Glycosides:** Because brimonidine, a component of Simbrinza™, may reduce blood pressure, caution in using antihypertensive and/or cardiac glycoside medications with Simbrinza™ is advised.
- **Tricyclic Antidepressants:** Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with Simbrinza™ in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.
- **Monoamine Oxidase Inhibitors:** Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine and potentially result in an increased systemic side effect, such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

PATIENT COUNSELING INFORMATION:

- Simbrinza™ is an eye drop that is indicated to treat open-angle glaucoma or ocular hypertension in patients 2 years of age and older.
- Before using Simbrinza™, talk to your doctor or healthcare provider if you are pregnant or plan to become pregnant, or are breastfeeding. It is not known if Simbrinza™ can harm your unborn baby, and it is not known if it passes into your breast milk.
- Talk to your doctor or healthcare provider if you are allergic or have had a severe hypersensitivity reaction to sulfonamides. If you experience severe or unusual ocular or systemic reactions, or if signs of hypersensitivity occur, stop using Simbrinza™ and consult your doctor or healthcare provider.
- Talk to your doctor or healthcare provider about other medications you are currently taking (including oral medications). There are potential drug interactions with Simbrinza™. Talk to your doctor or healthcare provider for more information regarding these drug interactions.
- Use Simbrinza™ exactly as prescribed by your doctor. Shake the bottle well before each use.
- Eye drops can become contaminated by common bacteria known to cause eye infections if handled improperly or if the tip of the dispensing container touches the eye or surrounding surfaces. Serious damage to the eye and subsequent loss of vision may result from using

contaminated drops. Always wash your hands before use. Do not touch the tip of the dispensing container to your eye or other surfaces. Always replace the cap after using. Do not use the eye drops if the solution changes color or looks different. Do not use the eye drops after the expiration date marked on the bottle.

- Vision may be temporarily blurred following dosing with Simbrinza™. Use caution when operating machinery or driving a motor vehicle following dosing with Simbrinza™.
- Simbrinza™ may cause fatigue and/or drowsiness in some patients. Use caution when engaging in hazardous activities, operating machinery, or driving a motor vehicle while using Simbrinza™ due to the potential for a decrease in mental alertness.
- If you have eye surgery or develop an eye infection or have trauma to your eye, talk to your doctor or healthcare provider to see if you should continue using Simbrinza™.
- If you are using more than one eye medication, the medications should be dosed at least five minutes apart.
- The preservative in Simbrinza™ may be absorbed by soft contact lenses. Remove contact lenses during dosing of Simbrinza™. Contact lenses may be reinserted 15 minutes after dosing of Simbrinza™.
- Common side effects include blurred vision, eye irritation, bad or unusual taste, dry mouth, and eye allergy.
- Contact your doctor or healthcare provider if you have any questions about the use of Simbrinza™.

¹ Rescula® Drug Information. Micromedex 2.0. Available online at: <http://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch>. Last revised 2/7/13. Last accessed 10/23/13.

² Rescula® Package Insert. Med Library.org. Available online at: <http://medlibrary.org/lib/rx/meds/rescula/>. Last revised 1/4/13. Last accessed 10/23/13.

³ Rescula® Full Prescribing Information. Sucampo Pharma Americas, LLC. Available online at: <http://www.rescula.com/sites/default/files/2012.12.07%20RESCULA%20Product%20Label.pdf>. Last revised 11/2012. Last accessed 10/23/13.

⁴ Rescula® FDA Approval History. Drugs@FDA. Available online at: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.LabelApprovalHistory#apphist>. Last revised 10/22/13. Last accessed 10/23/13.

⁵ Simbrinza™ Drug Information. Micromedex 2.0. Available online at: <http://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch>. Last revised 8/14/13. Last accessed 10/17/13.

⁶ Simbrinza™ Package Insert. Med Library.org. Available online at: <http://medlibrary.org/lib/rx/meds/simbrinza/>. Last revised 4/19/13. Last accessed 10/17/13.

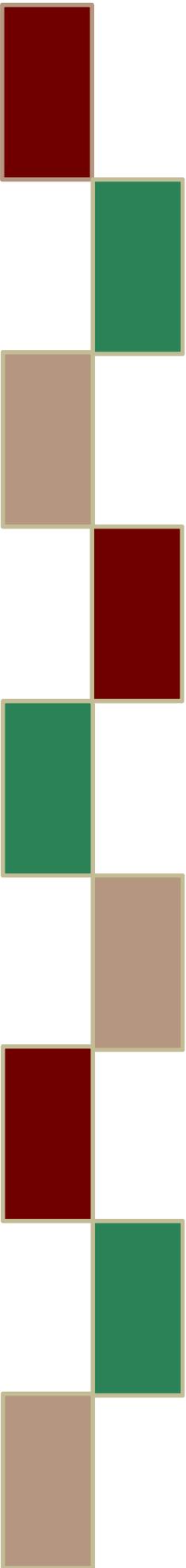
⁷ Simbrinza™ Full Prescribing Information. Alcon Laboratories, Inc. Available online at: http://ecatalog.alcon.com/pi/Simbrinza_us_en.pdf. Last revised 4/2013. Last accessed 10/17/13.

⁸ 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 9/2013. Last accessed 10/17/13.

⁹ American Optometric Association: Care of the Patient with Open Angle Glaucoma. Available online at: <http://www.aoa.org/optometrists/tools-and-resources/clinical-care-publications/clinical-practice-guidelines>. Last revised 2010. Last accessed 10/17/13.

¹⁰ Glaucoma Research Foundation: Care and Treatment of Glaucoma. Available online at: <http://www.glaucoma.org/treatment/>. Last revised 9/2013. Last accessed 10/17/13.

Appendix I



Fiscal Year 2013 Annual Review of Pediculicides and 30-Day Notice to Prior Authorize Sklice® (Ivermectin)

Oklahoma Health Care Authority
November 2013

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. Currently, the following OTC products are covered:

NDC CODE	NDC DESCRIPTION	PACKAGE SIZE	DRUG FORM	DESCRIPTION
00472-5242-67	PERMETHRIN	59	ML	PERMETHRIN TOPICAL 1% LIQUID
00472-5242-69	PERMETHRIN	118	ML	PERMETHRIN TOPICAL 1% LIQUID
46122-0108-46	LICE TREATMENT	59	ML	PERMETHRIN TOPICAL 1% LIQUID
49348-0460-30	LICE TREATMENT	60	ML	PERMETHRIN TOPICAL 1% LIQUID
49348-0460-34	LICE TREATMENT	60	ML	PERMETHRIN TOPICAL 1% LIQUID
62011-0112-01	LICE TREATMENT	59	ML	PERMETHRIN TOPICAL 1% LIQUID

Approval Criteria:

1. **Approval of a Tier 2 medication** requires a trial with one Tier 1 medication with inadequate response or adverse effect.
2. **Approval of a Tier 3 medication** requires trials with all available Tier 2 medication(s) with inadequate response or adverse effect.
3. **Clinical exception** applies if there is known resistance to OTC permethrin and pyrethrin.

TIER 1	TIER 2	TIER 3
Covered OTC Lice Products Generics with SMAC Pricing	Benzyl Alcohol (Ulesfia™) lotion Spinosad (Natroba™) suspension	Lindane lotion & shampoo Malathion (Ovide®) lotion

Tier structure based on supplemental rebate participation

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

Crotamiton (Eurax®) cream and lotion:

- Diagnosis of scabies; and
- Member must be at least 18 years of age; and
- Member must have used permethrin 5% cream in the past 7-14 days with inadequate results; and
- Quantity limit of 60 grams or milliliters for a 30 day supply.

Malathion (Ovide®) lotion:

- Member must be at least 6 years old; and
- Quantity limit of 60 milliliters for a 7 day supply; may be repeated once if needed for current infestation after 7 days from original fill date.

Lindane lotion & shampoo:

- Member must be at least 13 years old or weigh at least 110 pounds; and
- Quantity limit of 60 milliliters for a 7 day supply; and
- One 7 day supply per 30 days maximum.

Benzyl alcohol (Ulesfia™) lotion:

- Member must be at least 6 months old; and
- Due to mechanism of action, requires retreatment after 7 days; and
- Hair length would be required in order to approve the appropriate number of bottles if requesting more than 2 bottles per treatment (4 bottles for both treatments).

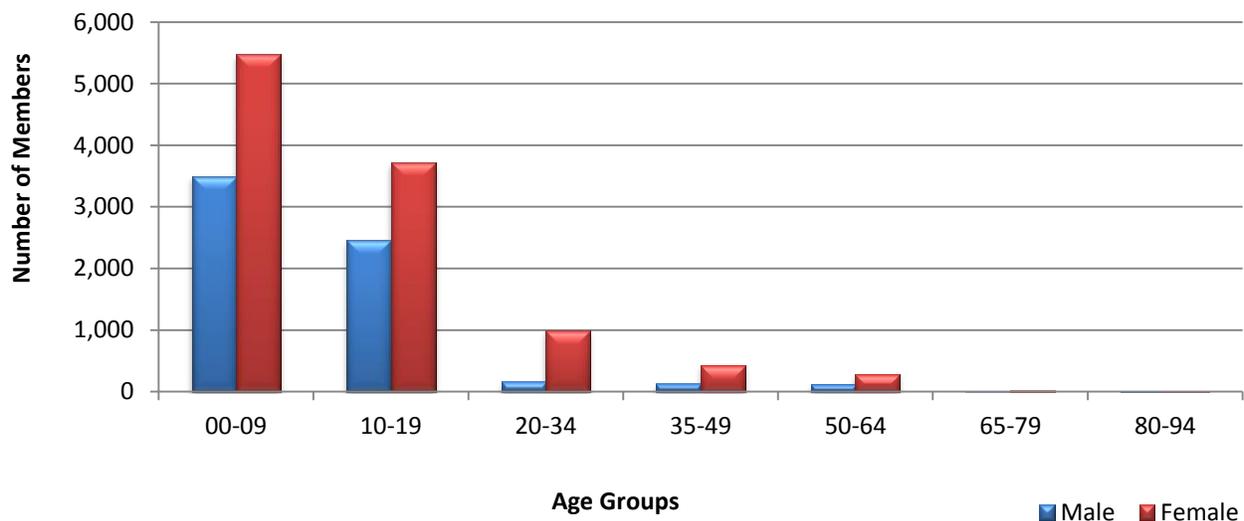
Utilization of Pediculicides

Comparison of Fiscal Years

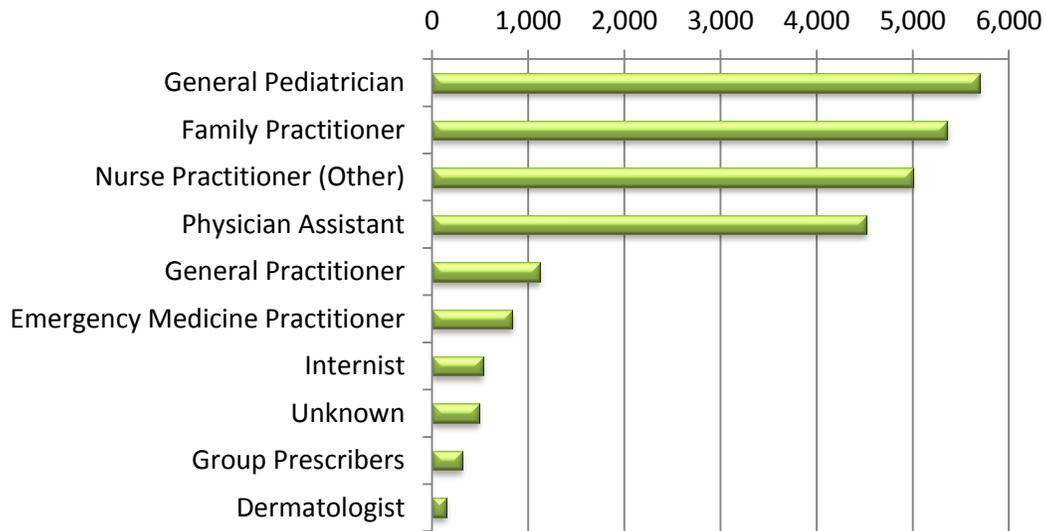
Fiscal Year	Members*	Claims	Cost	Cost/Claim	Perdiem	Units	Days
2012	18,416	26,165	\$962,647.74	\$36.79	\$3.41	1,824,643	282,019
2013	17,467	24,868	\$1,064,880.12	\$42.82	\$4.04	1,777,250	263,838
% Change	-5.20%	-5.00%	10.60%	16.40%	18.50%	-2.60%	-6.40%
Change	-949	-1,297	\$102,232.38	\$6.03	\$0.63	-47,393	-18,181

*Total number of unduplicated members.

Demographics of Members

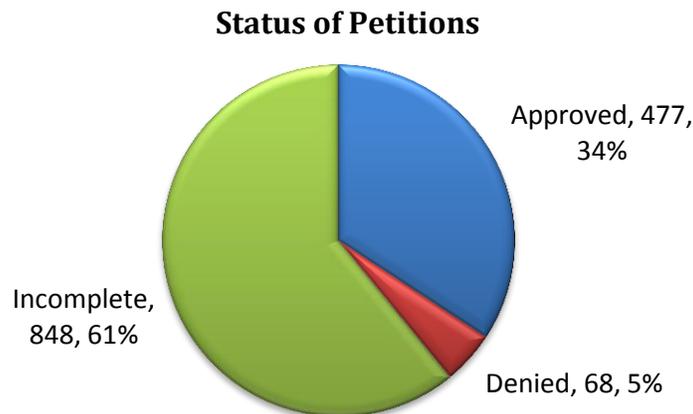


Top Prescriber Specialties of Pediculicides by Number of Claims



Prior Authorization of Pediculicides

There were a total of 1,393 petitions submitted for this category during fiscal year 2013. 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

Anticipated Patent Expirations

- Ulesfia™ (benzyl alcohol)- 8/2017
- Sklice® (ivermectin)- 5/2018

Sklice® (ivermectin) 0.5% lotion was approved by the FDA in February 2012.

Sklice® (Ivermectin) 0.5% Lotion^{1,2,3}

Sklice® is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older. Sklice® is available in a 4 ounce (117 gram) tube for single use. Sklice® lotion is for topical use only.

The recommended dosing is to apply Sklice® lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. Sklice® lotion should be left on the hair and scalp for 10 minutes, and then rinsed off with water. Sklice® lotion should be used in the context of an overall lice management program, which includes adjunctive measures such as washing all bedding and recently worn clothing in hot water and washing personal care items, such as combs, brushes, and hair clips in hot water. A fine tooth comb or special nit comb may be used to remove dead lice and nits.

Sklice® lotion has no known contraindications, but to prevent accidental ingestion in pediatric patients, it should be only used in pediatrics under the direct supervision of an adult. The most common adverse effects include conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation (all occurring < 1%).

The efficacy of Sklice® lotion was evaluated in two identical multi-center, randomized, double-blind, vehicle-controlled studies in patients 6 months of age and older with head lice infestation. All subjects received a single application of either Sklice® lotion or vehicle control with instructions not to use a nit comb. The primary efficacy was assessed as the proportion of patients who were free of live lice at day 2 and through day 8 to the final evaluation 14 (+2) days following a single application. Patients with live lice present at any time up to the final evaluation were considered treatment failures. In study 1, 76.1% of patients treated with Sklice® were free of live lice, as compared to 16.2% of patients treated with placebo. In study 2, 71.4% of patients treated with Sklice® were free of live lice, as compared to 18.9% of patients treated with placebo.

The cost per 4 ounce tube of Sklice® lotion is \$272.32. Comparatively, a 4 ounce bottle of permethrin costs \$11.03.

Recommendations^{4,5}

The College of Pharmacy recommends the addition of Sklice® to Tier 3 of the Pediculicides Product Based Prior Authorization category. The existing criteria for this category will apply, and a quantity limit of 117 grams (4 ounces) per 30 days will also apply.

TIER 1	TIER 2	TIER 3
Covered OTC Lice Products Generics with SMAC Pricing	Benzyl Alcohol (Ulesfia™) lotion Spinosad (Natroba™) suspension	Lindane lotion & shampoo Malathion (Ovide®) lotion Ivermectin (Sklice®) lotion

Tier structure based on supplemental rebate participation

Utilization Details of Pediculicides: Fiscal Year 2013

CHEMICAL NAME	BRAND NAME	CLAIMS	MEMBERS	COST	COST/DAY	% COST
Permethrin	Permethrin cream 5%	14,160	11,131	\$824,902.18	\$5.51	77.46%
Permethrin	Permethrin liquid 1%	9,906	6,775	\$122,595.78	\$1.20	11.51%
Benzyl Alcohol	Ulesfia™ lotion 5%	388	326	\$45,958.54	\$6.18	4.32%
Malathion	Ovide® lotion 0.5%	154	130	\$24,918.04	\$15.89	2.34%
Malathion	Malathion lotion 0.5%	121	104	\$19,131.67	\$15.01	1.80%
Spinosad	Natroba™ suspension 0.9%	88	76	\$20,689.71	\$21.03	1.94%
Spinosad	Spinosad suspension 0.9%	24	24	\$3,906.24	\$17.21	0.37%
Crotamiton	Eurax® cream 10%	16	15	\$1,524.82	\$3.18	0.14%
Lindane	Lindane lotion 1%	5	5	\$565.15	\$14.87	0.05%
Crotamiton	Eurax® lotion 10%	4	2	\$381.98	\$3.18	0.04%
Ivermectin	Sklice® lotion 0.5%	1	1	\$276.34	\$39.48	0.03%
Permethrin	Acticin® cream 5%	1	1	\$29.67	\$0.99	0.00%
TOTAL		24,868	17,467*	\$1,064,880.12	\$4.04	100.00%

*Total number of unduplicated members.

PRODUCT DETAILS OF SKLICE® (IVERMECTIN)

INDICATIONS AND USE: Sklice® (ivermectin) 0.5% lotion is indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

DOSAGE FORMS: Sklice® is available as a 0.5% topical lotion (4 ounce tube); each gram of lotion contains 5mg of ivermectin.

ADMINISTRATION:

- Apply Sklice® lotion to dry hair in an amount sufficient (up to 1 tube or 4 ounces) to thoroughly coat the hair and scalp. Leave Sklice® lotion on the hair and scalp for 10 minutes, and then rinse off with water.
- Sklice® lotion should be used in the context of an overall lice management program, which includes adjunctive measures such as washing all bedding and recently worn clothing in hot water and washing personal care items, such as combs, brushes, and hair clips in hot water. A fine tooth comb or special nit comb may be used to remove dead lice and nits.
- For topical use only. Sklice® lotion is not for oral, ophthalmic, or intravaginal use. Avoid contact with eyes.

CONTRAINDICATIONS: Sklice® lotion has no listed contraindications.

SPECIAL POPULATIONS:

- **Pregnancy:** There are no adequate or well-controlled studies with Sklice® in pregnant women. Sklice® lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (Category C)
- **Nursing Mothers:** Following oral administration, ivermectin is excreted in human milk in low concentrations. This has not been evaluated following topical administration. Caution should be exercised when Sklice® lotion is administered to a nursing woman.
- **Pediatrics:** The safety of Sklice® lotion has not been established in pediatric patients below the age of 6 months, and is not recommended in pediatric patients under the age of 6 months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.
- **Geriatrics:** Clinical studies of Sklice® lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.
- **Renal Impairment:** Sklice® lotion has not been studied in patients with renal insufficiency.
- **Hepatic Impairment:** Sklice® lotion has not been studied in patients with hepatic insufficiency.

WARNINGS AND PRECAUTIONS:

- **Ingestion in Pediatric Patients:** In order to prevent accidental ingestion, Sklice® lotion should only be administered to pediatric patients under the direct supervision of an adult.

ADVERSE REACTIONS:

- Adverse reactions reported in clinical trials in < 1% of subjects treated with Sklice® lotion include:
 - Conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and burning sensation of the skin

DRUG INTERACTIONS:

- Sklice® lotion has no listed drug interactions.

PATIENT COUNSELING INFORMATION:

- Sklice® lotion is used to treat head lice in people 6 months of age and older. It is not known if Sklice® is safe and effective for children under 6 months of age.
- Before using Sklice® lotion, tell your doctor if you or your child has any skin conditions or sensitivities, has any medical conditions, is pregnant or plans to become pregnant, or is breastfeeding or plans to breastfeed. It is not known if Sklice® lotion can harm your unborn baby, and it is not known if it passes into your breast milk.
- Keep Sklice® lotion and all medications out of the reach of children. Children will need an adult to apply Sklice® lotion for them.
- Apply Sklice® lotion directly to dry hair and scalp, covering the scalp and hair closest to the scalp first, and then applying outwards towards the ends of hair.
- Rub Sklice® lotion throughout hair. It is important to cover the entire head so that all lice and eggs are exposed to the lotion. Be sure that each hair is coated from the scalp to the tip. Use up to 1 entire tube (4 ounces) to completely cover scalp and hair.
- Allow Sklice® lotion to stay on hair and scalp for 10 minutes after it has been applied. Start timing after hair and scalp are completely covered with Sklice® lotion.
- After 10 minutes, completely rinse Sklice® lotion from hair and scalp using only water. You or anyone who helps you apply Sklice® lotion should wash their hands after application.
- Do not use Sklice® lotion again without talking to your health care provider first. The tube is intended for single use; discard any unused portion.
- Sklice® lotion should be used in the context of an overall lice management program, which includes adjunctive measures such as washing all bedding and recently worn clothing in hot water and washing personal care items, such as combs, brushes, and hair clips in hot water. A fine tooth comb or special nit comb may be used to remove dead lice and nits.
- Sklice® lotion is for topical use only. Do not swallow. Sklice® lotion is not for oral, ophthalmic, or intravaginal use. Avoid contact with eyes.
- Common side effects include eye redness or soreness, eye irritation, dandruff, dry skin, and burning sensation of the skin.

¹ Sklice® Drug Information. Micromedex 2.0. Available online at: http://www.micromedexsolutions.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/5606A0/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/934D89/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=924223&contentSetId=100&title=Ivermectin&servicesTitle=Ivermectin&brandName=Sklice. Last revised 8/26/13. Last accessed 10/15/13.

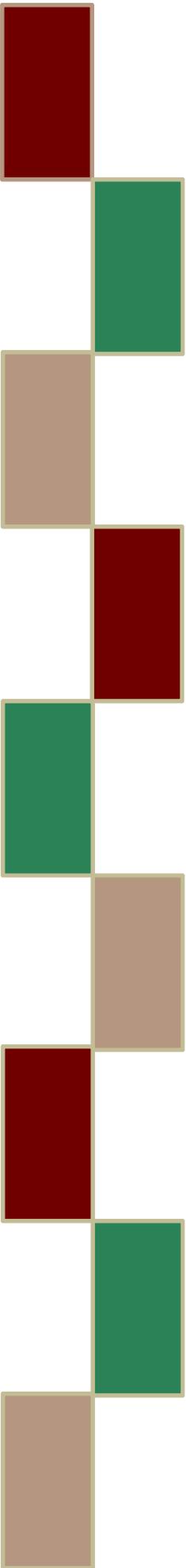
² Sklice® Package Insert. Med Library.org. Available online at: <http://medlibrary.org/lib/rx/meds/sklice/>. Last revised 2/2012. Last accessed 10/15/13.

³ Sklice® Full Prescribing Information. Sanofi Pasteur Inc. Available online at: <http://products.sanofi.us/Sklice/Sklice.pdf#page=1>. Last revised 2/2012. Last accessed 10/15/13.

⁴ CDC: Head Lice Treatment. Available online at: <http://www.cdc.gov/parasites/lice/head/treatment.html>. Last revised 9/24/13. Last accessed 10/15/13.

⁵ FDA: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Last revised 9/30/13. Last accessed 10/15/13.

Appendix J



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

FDA NEWS RELEASE

For Immediate Release: Oct. 23, 2013

FDA to complete phase-out of chlorofluorocarbon inhalers

The U.S. Food and Drug Administration will complete its phase-out of all inhaler medical products containing chlorofluorocarbons (CFCs) by Dec. 31, 2013. This effort is to comply with an international treaty to protect the ozone layer by phasing out the worldwide production of numerous substances, including CFCs, which contribute to ozone depletion.

While most inhaler products containing CFCs have already been phased out by the FDA, **two products currently remain on the market: Combivent Inhalation Aerosol and Maxair Autohaler.** However, these products will no longer be available after the end of this year. People with asthma or chronic obstructive pulmonary disease (COPD) who use these inhalers should talk to their health care professional about a prescription for an alternative treatment.

Inhalers are critical products for those persons suffering from asthma or COPD. In the United States, more than 25 million people suffer from asthma, a disease that affects the airways in the lungs and can cause coughing, trouble breathing, wheezing and tightness or pain in the chest. Additionally, 15 million people have been diagnosed with COPD, a serious lung disease that worsens over time. Symptoms can include chest tightness, chronic cough and excessive phlegm.

Most inhalers that used CFCs have already been phased out by the FDA. The inhaler that was most widely used—albuterol CFC inhaler—was phased out in 2008 and replaced with inhalers that use propellants called hydrofluoroalkanes (HFAs). There are many safe and effective inhalers available to treat asthma and COPD symptoms. All of these inhalers require a prescription, which must come from a licensed health care professional (a physician, physician's assistant or nurse practitioner).

CFCs damage the ozone layer, a thin, outer layer in the stratosphere that acts as earth's shield against the sun's radiation. The United States and most other countries signed an agreement in 1987 called the Montreal Protocol on Substances that Deplete the Ozone Layer to phase out the worldwide production and use of CFCs. In the United States, CFCs have been removed from such products as hairsprays, deodorants and air conditioning.

FDA NEWS RELEASE

For Immediate Release: Oct. 25, 2013

FDA approves extended-release, single-entity hydrocodone product

First to have updated labeling now required for all ER/LA opioid analgesics

The U.S. Food and Drug Administration today approved Zohydro ER (hydrocodone bitartrate extended-release capsules) for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate.

Zohydro ER, a Schedule II controlled substance under the Controlled Substances Act, is the first FDA-approved single-entity (not combined with an analgesic such as acetaminophen) and extended-release hydrocodone product.

Zohydro ER will offer prescribers an additional therapeutic option to treat pain, which is important because individual patients may respond differently to different opioids.

Zohydro ER is in the class of extended-release/long-acting (ER/LA) opioid analgesics. Due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with ER/LA opioid formulations, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Zohydro ER is not approved for as-needed pain relief.

The approved labeling for Zohydro ER conforms to updated labeling requirements for all ER/LA opioid analgesics announced by the FDA on Sept. 10, 2013.

The new class labeling and stronger warnings will more clearly describe the risks and safety concerns associated with ER/LA opioid analgesics, along with the appropriate use of these medications. These warnings are expected to improve the safety of all such medicines by encouraging more appropriate prescribing, patient monitoring, and patient counseling practices. Zohydro ER is the first opioid to be labeled in this manner. Schedule II drugs can only be dispensed through a physician's written prescription and no refills are allowed. There are also stringent recordkeeping, reporting, and physical security requirements for Schedule II controlled substances.

The FDA is requiring postmarketing studies of Zohydro ER to assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death associated with long term use beyond 12 weeks. These studies will also be required for other ER/LA opioid analgesics.

The safety of Zohydro ER is based on clinical studies of more than 1,100 people living with chronic pain. The efficacy of Zohydro ER is based on a clinical study that enrolled over 500 patients with chronic low back pain and showed significant improvement in chronic pain compared to placebo.

Zohydro ER will be part of the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS). Originally approved in 2012, the ER/LA Opioid Analgesics REMS requires companies to make available to health care professionals educational programs on how to safely prescribe ER/LA opioid analgesics and to provide Medication Guides and patient counseling documents containing information on the safe use, storage, and disposal of ER/ LA opioids.

The most common side effects of Zohydro ER are constipation, nausea, drowsiness (somnolence), fatigue, headache, dizziness, dry mouth, vomiting and itching (pruritus).

Zohydro ER is manufactured by San Diego-based Zogenix, Inc.

FDA NEWS RELEASE

For Immediate Release: Nov. 4, 2013

FDA: Janssen Pharmaceuticals, Inc. to plead guilty and pay over \$1.6 billion to resolve allegations of misbranding and filing false claims for its schizophrenia drug Risperdal

On behalf of the U.S. Food and Drug Administration, the U.S. Department of Justice today announced a guilty plea agreement with Janssen Pharmaceuticals, Inc., (JPI) of Titusville, N.J., and a \$400 million criminal fine for introducing a misbranded drug, Risperdal (risperidone), into interstate commerce. A Johnson & Johnson Company, JPI must also pay \$1.25 billion under a separate civil settlement concerning the same drug. The combined criminal plea and civil settlement agreement related to Risperdal totals more than \$1.67 billion. The FDA approved Risperdal in 2002 for the treatment of schizophrenia and in 2003 for the short-term treatment of acute mania and for mixed episodes associated with Bipolar 1 Disorder. But JPI began in March 2002 to market the drug for the treatment of agitation associated with dementia in the elderly, representing that Risperdal was safe and effective for this unapproved indication and subpopulation.

The FDA maintains that physicians may, within the practice of medicine, use a drug to treat patients for symptoms or diseases even when the drug is not FDA-approved for such uses. However, if a pharmaceutical manufacturer intends its drug to be used for a new use, not approved by the FDA, and introduces the drug

into interstate commerce for that use, the drug is misbranded, and introduction of that misbranded drug into interstate commerce is a violation of the law.

The U.S. Department of Justice action also alleges that JPI and Johnson & Johnson were aware that Risperdal posed serious health risks for the elderly, including increased risk of stroke, but that the companies downplayed those risks by combining negative data with other studies in order to support a perception of decreased risk from using the drug.

JPI had received repeated warnings from the FDA regarding its misleading marketing messages targeted to physicians. After a whistle blower complaint was filed, the FDA Office of Criminal Investigations initiated a criminal investigation into JPI's conduct.

JPI and Johnson & Johnson will submit to stringent requirements under a corporate integrity agreement with the U.S. Department of Health and Human Services' Office of the Inspector General. The agreement is designed to increase accountability and transparency and prevent future fraud and abuse.

FDA NEWS RELEASE

For Immediate Release: Nov. 1, 2013

FDA approves Gazyva for chronic lymphocytic leukemia

Drug is first with breakthrough therapy designation to receive FDA approval

The U.S. Food and Drug Administration today approved Gazyva (obinutuzumab) for use in combination with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia (CLL).

CLL is a blood and bone marrow disease that usually gets worse slowly. According to the National Cancer Institute, 15,680 Americans will be diagnosed and 4,580 will die from the disease this year.

Gazyva works by helping certain cells in the immune system attack cancer cells. Gazyva is intended to be used with chlorambucil, another drug used to treat patients with CLL.

Gazyva is the first drug with breakthrough therapy designation to receive FDA approval. This designation was requested by the sponsor and granted soon after the biologic license application to support marketing approval was submitted to the FDA. The FDA can designate a drug a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases.

The FDA also granted Gazyva priority review because the drug demonstrated the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. And the FDA granted Gazyva orphan product designation because it is intended to treat a rare disease.

Gazyva's approval for CLL is based on a study of 356 participants in a randomized open-label multicenter trial comparing Gazyva in combination with chlorambucil to chlorambucil alone in participants with previously untreated CLL. Participants receiving Gazyva in combination with chlorambucil demonstrated a significant improvement in progression free survival: an average of 23 months compared with 11.1 months with chlorambucil alone.

The most common side effects observed in participants receiving Gazyva in combination with chlorambucil were infusion-related reactions, a decrease in infection-fighting white blood cells (neutropenia), a low level of platelets in the blood (thrombocytopenia), low red blood cells (anemia), pain in the muscles and bones (musculoskeletal pain), and fever (pyrexia).

Gazyva is being approved with a boxed warning regarding Hepatitis B virus reactivation and a rare disorder that damages the material that covers and protects nerves in the white matter of the brain (progressive multifocal leukoencephalopathy). These are known risks with other monoclonal antibodies in this class and rare cases were identified in participants on other trials of Gazyva. Patients should be advised of these risks and assessed for Hepatitis B virus and reactivation risk.

Gazyva is marketed by Genentech, a member of the Roche Group, based in South San Francisco, Calif.

FDA NEWS RELEASE

For Immediate Release: Oct. 18, 2013

FDA approves Opsumit to treat pulmonary arterial hypertension

The U.S. Food and Drug Administration today approved Opsumit (macitentan), a new drug to treat adults with pulmonary arterial hypertension (PAH), a chronic, progressive and debilitating disease that can lead to death or the need for lung transplantation.

PAH is high blood pressure that occurs in the arteries that connect the heart to the lungs. It causes the right side of the heart to work harder than normal, which can lead to limitations on exercise ability and shortness of breath. Opsumit belongs to a class of drugs called endothelin receptor blockers, which act to relax the pulmonary arteries, decreasing blood pressure in the lungs.

Opsumit's safety and effectiveness were established in a long-term clinical trial where 742 participants were randomly assigned to take Opsumit or placebo. The average treatment duration was about two years. In the study, Opsumit was effective in delaying disease progression, a finding that included a decline in exercise ability, worsening symptoms of PAH or need for additional PAH medication.

Similar to other members of its drug class, Opsumit carries a Boxed Warning alerting patients and health care professionals that the drug should not be used in pregnant women because it can harm the developing fetus. Female patients can receive the drug only through the Opsumit Risk Evaluation and Mitigation Strategy (REMS) Program. This restricted-distribution program requires prescribers to be certified by enrolling in the program; all female patients to be enrolled in the program and comply with applicable pregnancy testing and contraception requirements before initiating treatment; and pharmacies to be certified and to dispense Opsumit only to patients who are authorized to receive it.

Common side effects observed in those treated with Opsumit include low red blood cell count (anemia), common cold-like symptoms (nasopharyngitis), sore throat, bronchitis, headache, flu and urinary tract infection.

Opsumit is marketed by San Francisco-based Actelion Pharmaceuticals US, Inc

FDA NEWS RELEASE

For Immediate Release: Oct. 25, 2013

FDA approves second brain imaging drug to help evaluate patients for Alzheimer's disease, dementia

The U.S. Food and Drug Administration today approved Vizamyil (flutemetamol F 18 injection), a radioactive diagnostic drug for use with positron emission tomography (PET) imaging of the brain in adults being evaluated for Alzheimer's disease (AD) and dementia.

Dementia is associated with diminishing brain functions such as memory, judgment, language and complex motor skills. The dementia caused by AD is associated with the accumulation in the brain of an abnormal protein called beta amyloid and damage or death of brain cells. However, beta amyloid can also be found in the brain of patients with other dementias and in elderly people without neurologic disease.

Vizamyil works by attaching to beta amyloid and producing a PET image of the brain that is used to evaluate the presence of beta amyloid. A negative Vizamyil scan means that there is little or no beta amyloid accumulation in the brain and the cause of the dementia is probably not due to AD. A positive scan means that there is probably a moderate or greater amount of amyloid in the brain, but it does not establish a diagnosis of AD or other dementia. Vizamyil does not replace other diagnostic tests used in the evaluation of AD and dementia.

Vizamyl is the second diagnostic drug available for visualizing beta amyloid on a PET scan of the brain. In 2012, FDA approved Amyvid (Florbetapir F 18 injection) to help evaluate adults for AD and other causes of cognitive decline.

Vizamyl's effectiveness was established in two clinical studies comprised of 384 participants with a range of cognitive function. All participants were injected with Vizamyl and were scanned. The images were interpreted by five independent readers masked to all clinical information. A portion of scan results were also confirmed by autopsy.

The study results demonstrate that Vizamyl correctly detects beta amyloid in the brain. The results also confirm that the scans are reproducible and trained readers can accurately interpret the scans. Vizamyl's safety was established in a total of 761 participants.

Vizamyl is not indicated to predict the development of AD or to check how patients respond to treatment for AD. Vizamyl PET images should be interpreted only by health care professionals who successfully complete training in an image interpretation program. The Vizamyl drug labeling includes information about image interpretation.

Safety risks associated with Vizamyl include hypersensitivity reactions and the risks associated with image misinterpretation and radiation exposure. Common side effects associated with Vizamyl include flushing, headache, increased blood pressure, nausea and dizziness.

Vizamyl is manufactured for GE Healthcare by Medi-Physics, Inc., based in Arlington Heights, Ill.

Safety Announcements

FDA Drug Safety Communication: FDA asks manufacturer of the leukemia drug Iclusig (ponatinib) to suspend marketing and sales

This update is in follow-up to the [FDA Drug Safety Communication: FDA investigating leukemia drug Iclusig \(ponatinib\) after increased reports of serious blood clots in arteries and veins](#) issued on October 11, 2013.

[10-31-2013] The U.S. Food and Drug Administration (FDA) has asked the manufacturer of the leukemia chemotherapy drug Iclusig (ponatinib) to suspend marketing and sales of Iclusig because of the risk of life-threatening blood clots and severe narrowing of blood vessels. We will continue to evaluate the drug to further understand its risks and potential patient populations in which the benefits of the drug may outweigh the risks. Patients currently receiving Iclusig should discuss with their health care professionals the risks and benefits of continuing treatment with the drug.

The drug manufacturer, Ariad Pharmaceuticals, has agreed to FDA's request to suspend marketing and sales of Iclusig while we continue to evaluate the safety of the drug. At this time, patients and health care professionals should follow FDA's new recommendations for the drug:

- Patients currently taking Iclusig who are not responding to the drug should immediately discontinue treatment and discuss alternative treatment options with their health care professionals.
- Patients who are currently taking Iclusig and responding to the drug and whose health care professionals determine that the potential benefits outweigh the risks should be treated under a single-patient Investigational New Drug (IND) application or expanded access registry program while FDA's safety investigation continues. FDA will work with the manufacturer on a plan to quickly transition these patients to a program that will allow access under an IND or expanded access registry program. Patients: For more information on access to treatment under an IND, please refer to the following website: [Access to Investigational Drugs Outside of a Clinical Trial \(Expanded Access\)](#)².
- Health care professionals should not start treating new patients with Iclusig unless no other treatment options are available and all other available therapies have failed. Upon the determination of their health care professional, these patients can be considered for treatment under an IND or expanded access registry program. Health care professionals: For more information on obtaining access to

treatment for your patient under an IND, please refer to the following website: [Physician Request for an Individual Patient IND under Expanded Access for Non-emergency or Emergency Use](#)

FDA's recent investigation of Iclusig revealed an increased frequency of blood clots and narrowing of blood vessels since the drug was approved in December 2012. Currently, approximately 24 percent of patients (nearly 1 out of 4) in the Phase 2 clinical trial (median treatment duration 1.3 years) and approximately 48 percent of patients in the Phase 1 clinical trial (median treatment duration 2.7 years) have experienced serious adverse vascular events, including fatal and life-threatening heart attack, stroke, loss of blood flow to the extremities resulting in tissue death, and severe narrowing of blood vessels in the extremities, heart, and brain requiring urgent surgical procedures to restore blood flow. In some patients, fatal and serious adverse events have occurred as early as 2 weeks after starting Iclusig therapy. The Phase 1 and 2 clinical trials did not include a control group so it is not possible to determine the relationship of these adverse events to Iclusig, however the increasing rate and pattern of the events strongly suggests that many are drug-related. At this time, FDA cannot identify a dose level or exposure duration that is safe.

In the Phase 2 clinical trial, adverse events affecting the blood vessels that supply the heart, brain, and extremities were observed in 12 percent, 6 percent, and 8 percent of patients, respectively. Patients with and without cardiovascular risk factors, including patients in their 20s, have experienced these events. Serious adverse reactions involving the eyes, which led to blindness or blurred vision, occurred in Iclusig-treated patients. High blood pressure occurred in 67 percent of patients treated with Iclusig in the clinical trials. Heart failure, including fatalities, occurred in 8 percent of patients treated with the drug.

We will continue to notify health care professionals and patients in a timely manner as more information becomes available.

Safety Announcements

FDA Drug Safety Communication: FDA approves label changes for anti-seizure drug Potiga (ezogabine) describing risk of retinal abnormalities, potential vision loss, and skin discoloration

This is an update to the [FDA Drug Safety Communication: Anti-seizure drug Potiga \(ezogabine\) linked to retinal abnormalities and blue skin discoloration](#) issued on 4/26/2013.

[10-31-2013] The U.S. Food and Drug Administration (FDA) has approved changes to the drug label of the anti-seizure drug Potiga (ezogabine), underscoring risks of abnormalities to the retina in the eye, potential vision loss, and skin discoloration, all of which may become permanent. The revised label includes a new boxed warning, the most serious type of warning FDA gives, because of the risk of abnormalities to the retina, a part of the eye that is needed for vision. We advise that Potiga use be limited to patients who have not responded adequately to several alternative therapies to decrease the frequency of seizures, or epilepsy, and for whom the benefits of treatment outweigh the risks.

These risks were previously described in a [Drug Safety Communication](#) in April 2013.

FDA recommends that patients have eye exams by an ophthalmic professional before starting Potiga and every six months during treatment. These exams should include visual acuity and dilated fundus photography, with additional vision testing as necessary. Patients whose vision cannot be monitored should generally not take Potiga. It is not known which individual patients are at risk for retinal abnormalities to develop, how long it takes for any sign of abnormality to be detected, their rate of progression, or their reversibility after stopping Potiga.

If retinal pigmentary abnormalities or vision changes are detected, Potiga should be stopped unless no other suitable seizure treatment options are available and the benefits of treatment outweigh the potential risk of vision loss. In addition, health care professionals should stop Potiga treatment in patients who do not show substantial clinical benefit after adequate dose titration. Seizures, which are due to unusual electrical activity

in the brain, are serious, and patients should not stop taking the drug without first discussing their treatment with their health care professionals.

Also included in the updated label are warnings regarding the risk for discoloration of the skin, nail, mucous membrane, and white-of-the-eye. The updated Potiga drug label states that if a patient develops skin discoloration, an alternate medication should be considered. These recommendations have been added to the Warnings and Precautions section of the drug label and to the patient Medication Guide, which should be included with every Potiga prescription filled.

FDA is working on modifying the current Risk Evaluation and Mitigation Strategy (REMS) for Potiga to address the risk of retinal pigmentary abnormalities, potential vision loss, and skin discoloration.

Current Drug Shortages Index (as of November 1, 2013):

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

[Acetylcysteine Inhalation Solution](#) **UPDATED** 11/1/2013

[Amikacin Injection](#)

[Aminocaproic Acid Injection](#) (initial posting 3/8/2013) **UPDATED** 11/1/2013

[Aminophylline](#) (initial posting 12/10/2012) **UPDATED** 11/1/2013

[Ammonium Chloride Injection](#) (initial posting 3/8/2013)

[Amytal Sodium Injection](#) (initial posting date 1/31/2013)

[Atracurium Besylate](#) (initial posting 2/27/2012)

[Atropine Sulfate Injection](#) **UPDATED** 11/1/2013

[Barium Sulfate for Suspension](#) (initial posting 10/12/2012)

[Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride \(Helidac\)](#) (initial posting 3/8/2012)

[Bumetanide Injection](#) (initial posting 6/21/2012) **UPDATED** 10/29/2013

[Bupivacaine Hydrochloride \(Marcaine, Sensorcaine\) Injection](#) **UPDATED** 11/1/2013

[Buprenorphine Hydrochloride \(Buprenex\) Injection](#)

[Caffeine and Ergotamine Tartrate \(Cafergot\) Tablets](#) (initial posting 3/8/2012)

[Caffeine Anhydrous \(125mg/mL\); Sodium Benzoate \(125mg/mL\) Injection](#)

[Calcium Chloride Injection](#) (initial posting 12/13/2012) **UPDATED** 11/1/2013

[Calcium Gluconate Injection](#) (initial posting 1/10/2013) **UPDATED** 10/29/2013

[Chromic Chloride Injection](#) **UPDATED** 11/1/2013

[Cidofovir Injection](#) (initial posting 2/15/2013)

[Citric Acid; Gluconolactone; Magnesium Carbonate \(Renacidin\) Solution for Irrigation](#) (initial posting 6/30/2012) **UPDATED** 11/1/2013

[Clindamycin phosphate \(Cleocin\)](#) (initial posting 10/2/2013) **UPDATED** 11/1/2013

[Copper Injection](#) (initial posting 4/25/2013)

[Cyanocobalamin Injection](#) (initial posting 1/25/2013) **UPDATED** 10/29/2013

[Daunorubicin Hydrochloride Solution for Injection](#)

[Denileukin Diftitox \(Ontak\)](#) (initial posting 9/22/2012)

[Desmopressin Acetate \(DDAVP\) Injection](#) (initial posting 5/7/2013)

[Dexamethasone Sodium Phosphate Injection](#) (initial posting 1/15/2013) **UPDATED** 10/29/2013

[Dexrazoxane \(Zinecard\) Injection](#)

[Dextrose Injection](#) (initial posting 5/23/2012) **UPDATED** 11/1/2013

[Dipyridamole Injection](#) (initial posting 7/24/2012) **UPDATED** 10/29/2013

[Dobutamine Hydrochloride Injection](#) (initial posting 4/26/2013) **UPDATED** 10/31/2013

[Doxorubicin \(Adriamycin\) Lyophilized Powder](#) (initial posting 12/2/2011)

[Epinephrine Injection](#) (initial posting 4/27/2012) **UPDATED** 11/1/2013

[Epinephrine 1mg/mL \(Preservative Free\)](#) (initial posting 6/21/2012) **UPDATED** 10/29/2013

[Ethiodol \(Ethiodized Oil\) Ampules](#)

[Etomidate \(Amidate\) Injection](#) (initial posting 2/9/2012) **UPDATED** 11/1/2013

[Fentanyl Citrate \(Sublimaze\) Injection](#) **UPDATED** 11/1/2013

[Fluphenazine Decanoate Injection](#) 4/25/2013

[Fluphenazine Hydrochloride Injection](#)

[Fluticasone Propionate and Salmeterol \(Advair HFA\) Inhalation Aerosol](#) (initial posting date) - 10/17/2012)

[Fosphenytoin Sodium \(Cerebyx\) Injection](#) (initial posting 3/30/2012) **UPDATED** 11/1/2013

[Furosemide Injection](#) (initial posting 6/20/2012)

[Heparin Sodium Injection](#) (initial posting 7/5/2012) **UPDATED** 11/1/2013

[Hydromorphone Hydrochloride \(Dilaudid\) Injection](#) (initial posting 3/7/2012) (**UPDATED** 11/1/2013)

[Hydromorphone Hydrochloride Tablets](#) (initial posting 2/19/2013) **UPDATED** 10/29/2013

[Intravenous Fat Emulsion](#) **UPDATED** 10/31/2013

[Isoniazid; Rifampin \(Rifamate\) Capsules](#) 3/15/2013

[Ketorolac Tromethamine Injection](#) **UPDATED** 11/1/2013

[Leucovorin Calcium Lyophilized Powder for Injection](#) **UPDATED** 10/31/2013

[Leuprolide Acetate Injection](#)

[Levothyroxine Sodium \(Levoxyl\) Tablets](#) (initial posting date - 3/15/2013)

[Lidocaine Hydrochloride \(Xylocaine\) Injection](#) (initial posting date - 2/22/2012) **UPDATED** 10/29/2013

[Liotrix \(Thyrolar\) Tablets](#)

[Lomustine Capsules](#) (initial posting date - 5/9/2013)

[Lorazepam \(Ativan\) Injection](#)

[Magnesium Sulfate Injection](#) **UPDATED** 11/4/2013

[Mannitol \(Osmitrol, Resectisol\) Injection](#) (initial posting date - 12/21/2011) **UPDATED** 11/4/2013

[Mecasermin \[rDNA origin\] \(Increlex\) Injection](#) (initial posting date - 4/26/2013)

[Methazolamide \(Glauctabs, Neptazane\) Tablets](#)

[Methyldopate Hydrochloride Injection](#)

[Methylin Chewable Tablets](#) (initial posting date - 2/19/2013)

[Methylphenidate Hydrochloride ER Tablets](#) (initial posting date - 2/19/2013) **UPDATED** 10/25/2013

[Methylphenidate Hydrochloride Tablets](#) (initial posting date - 2/19/2013) **UPDATED** 10/25/2013

[Metoclopramide \(Reglan\) Injection](#)

[Morphine Sulfate Injection](#) **UPDATED** 11/1/2013

[Morphine Sulfate \(Astramorph PF, Duramorph, Infumorph\) Injection \(Preservative Free\)](#) **UPDATED** 10/31/2013

[Multi-Vitamin Infusion \(Adult and Pediatric\)](#) **UPDATED** 10/31/2013

[Nalbuphine Hydrochloride \(Nubain\) Injection](#) (initial posting 5/15/2012)

[Neostigmine Methylsulfate Injection](#) (initial posting 1/14/2013) **UPDATED** 11/1/2013

[Nitroglycerin Ointment USP, 2% \(Nitro-Bid\)](#) (initial posting 10/23/2012)

[Ondansetron \(Zofran\) 2mg/mL Injection](#) **UPDATED** 11/1/2013

[Pancuronium Bromide Injection](#)

[Papaverine Hydrochloride Injection](#) (initial posting 12/17/2012) **UPDATED** 10/29/2013

[Pegvisomant \(Somavert\) Injection](#) (initial posting 10/21/2013)

[Phosphate \(Glycophos\) Injection](#) (initial posting 5/29/2013)

[Pilocarpine HCL Ophthalmic Gel 4% \(Pilopine HS\)](#) (initial posting 6/1/2012)

[Potassium Acetate Injection, USP 2mEq/mL](#)

[Potassium Chloride Injection](#) (initial posting 5/15/2012)

[Potassium Phosphate Injection](#)

[Procainamide HCL Injection](#)

[Prochlorperazine Injection](#) (initial posting 1/30/2012)

[Promethazine Injection](#) (initial posting 2/10/2012) **UPDATED** 11/1/2013

[Reserpine Tablets](#) (initial posting 4/17/2013)

[Rifampin for Injection](#) (initial posting 3/22/2013)

[Secretin Synthetic Human \(ChiRhoStim\) Injection \(ChiRhoStim\)](#) (initial posting 6/15/2012)

[Selenium Injection](#)

[Sincalide \(Kinevac\) Lyophilized Powder for Injection](#) (initial posting 6/21/2013)

[Sodium Acetate Injection](#) (initial posting 1/31/2012)

[Sodium Chloride 0.9% \(5.8mL and 20mL\)](#) (initial posting 5/4/2012)

[Sodium Chloride 23.4%](#) **UPDATED** 10/29/2013

[Sodium Phosphate Injection](#)

[Succinylcholine \(Anectine, Quelicin\) Injection](#) (initial posting 8/17/2012) **UPDATED** 10/25/2013

[Sufentanil Citrate \(Sufenta\) Injection](#)

[Sulfamethoxazole 80mg/ml;Trimethoprim 16mg/ml \(SMX/TMP\) \(Bactrim\) Injection](#)

[Technetium Tc99m Bicisate for Injection \(Neurolite\)](#) (initial posting 5/4/2012)

[Technetium Tc99m Sestamibi Kit for Injection \(Cardiolite\)](#) (initial posting 5/4/2012)

[Telavancin \(Vibativ\) Injection](#)

[Tetracycline Capsules](#)

[Thiotepa \(Thioplex\) for Injection](#)

[Ticarcillin Disodium/Clavulanic Potassium \(Timentin\) Injection](#) (initial posting 8/16/2012)

[Tiopronin \(Thiola\)](#) **New!!**

[Tobramycin Solution for Injection](#) **UPDATED** 10/29/2013

[Trace Elements](#) (initial posting 1/24/2013) **UPDATED** 10/29/2013

[Tromethamine \(Tham\) Injection](#) (initial posting 5/2/2012)

[Verapamil Hydrochloride Injection, USP](#) (initial posting 4/17/2013)

[Vinblastine Sulfate Injection](#) (initial posting 1/31/2012)

[Vitamin A Palmitate \(Aquasol A\)](#)

[Zinc Injection](#) (initial posting 2/15/2012) **UPDATED** 10/31/2013