



# Drug Utilization Review Board

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

Wednesday  
April 10, 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 – April 10, 2013

DATE: April 4, 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 April meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

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

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Juvisync<sup>®</sup>, Bydureon<sup>®</sup>, Jentadueto<sup>®</sup>, Janumet XR<sup>®</sup>, Nesina<sup>®</sup>, Kazano<sup>®</sup>, and Oseni<sup>®</sup> – See Appendix C.

Action Item – Vote to Prior Authorize Eliquis<sup>®</sup> and to Update Xarelto<sup>®</sup> Prior Authorization Criteria – See Appendix D.

Action Item – Vote to Prior Authorize Kuvan<sup>®</sup> – See Appendix E.

Action Item – Vote to Prior Authorize Gattex<sup>®</sup> – See Appendix F.

Action Item – Vote to Prior Authorize Kynamro<sup>™</sup> and to Update Juxtapid<sup>™</sup> Authorization Criteria – See Appendix G.

Action Item – Intervention Strategies for Reduction of Narcotic Overprescribing – See Appendix H.

Fiscal Year 2012 Annual Review – See Appendix I.

FDA and DEA Updates – See Appendix J.

Future Business

Adjournment



**Oklahoma Health Care Authority**  
**Drug Utilization Review Board**  
(DUR Board)  
**Meeting –April 10, 2013 @ 6:00 p.m.**

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

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**AGENDA**

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.**
  - A. March 13, 2013 DUR Minutes – Vote
  - B. March 14, 2013 DUR Recommendation Memorandum
  - C. Correspondence

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

4. **Update on DUR / Medication Coverage Authorization Unit – See Appendix B.**
  - A. Medication Coverage Activity for March 2013
  - B. Pharmacy Help Desk Activity for March 2013
  - C. Retrospective Drug Evaluation: Focusing on Safety

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

5. **Action Item - Vote to Prior Authorize Juvisync<sup>®</sup>, Bydureon<sup>®</sup>, Jentadueto<sup>®</sup>, Janumet XR<sup>®</sup>, Nesina<sup>®</sup>, Kazano<sup>®</sup>, and Oseni<sup>®</sup> – See Appendix C.**
  - A. COP Recommendations

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

6. **Action Item – Vote to Prior Authorize Eliquis<sup>®</sup> and to Update Xarelto<sup>®</sup> Prior Authorization Criteria– See Appendix D.**
  - A. COP Recommendations

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

7. **Action Item – Vote to Prior Authorize Kuvan<sup>®</sup> – See Appendix E.**  
A. COP Recommendations

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

8. **Action Item – Vote to Prior Authorize Gattex<sup>®</sup> – See Appendix F.**  
A. COP Recommendations

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

9. **Action Item - Vote to Prior Authorize Kynamro<sup>™</sup> and to Update Juxtapid<sup>™</sup> Prior Authorization Criteria – See Appendix G.**  
A. Background  
B. Product Summaries  
C. Cost Comparison  
D. Product Details

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

10. **Action Item – Intervention Strategies for Reduction of Narcotic Overprescribing – See Appendix H.**  
A. Prescriber Survey  
B. Narcotic Prescriber Profiling  
C. Quantity Limit Reduction  
D. COP Recommendations

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

11. **Fiscal Year 2012 Annual Review – See Appendix I.**  
A. Top 100 Drugs by Reimbursement  
B. Top 50 Drugs by Total Number of Claims  
C. Expenditures by Therapeutic Class

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

12. **FDA and DEA Updates – See Appendix J.**

13. **Future Business**  
A. May 2013 Meeting Cancelled  
B. New Product Reviews  
C. Annual Reviews

14. **Adjournment**



# Appendix A





OKLAHOMA HEALTH CARE AUTHORITY  
 DRUG UTILIZATION REVIEW BOARD MEETING  
 MINUTES of MEETING OF FEBRUARY 13, 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	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Shellie Keast, Pharm.D, M.S.; Clinical Assistant Professor	X	
Bethany Holderread, Pharm. D.; Clinical Pharmacist	X	
Chris Le, Pharm.D.; Assisant Director	X	
Mark Livesay, Operations Manager	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	
Jo'Nel Weber, Pharm.D.; Clinical Pharmacist		X
Graduate Students: Amany Hussein, Manish Mittal	X	
Visiting Pharmacy Student(s): Khiem Bui; Michael Schraad	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	
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	
Alison Martinez, Ph.D., Geneticist	X	
Jennie Melendez, Public Affairs-Information Representative	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	
Stacey Hale, Pharmacy Research Analyst	X	

OTHERS PRESENT:		
Roger Grotzinger, BMS	Janie Huff, Takeda	Brian Maves, Pfizer
Jim Fowler, AstraZeneca	Ron Schnare, Shire	Warren Tayes, Merck
Anne Hartshorn, AstraZeneca	Randy McGinley, Bayer	Patrick Moty, Supernus
Nancy Bursch-Smith, Johnson & Johnson	Steve Brammer, BMS	Steve Curry, Med
Tyler Hunter, Gilead	Kathy Phillips, Novo Nordisk	Don Kempin, Novo Nordisk
Mai Duong, Novartis	Clint Degner, Novartis	Jim Chapman, Abbott
Christopher Desimone, Aegerion	Jon Maguire, GSK	Audrey Rattan, Otsuka
John Bilber, Boehringer Ingelheim	Holly Turner, Merck	Roger Enix, Merck
Charlene Kaiser, Amgen		

PRESENT FOR PUBLIC COMMENT:	
Dr. Carl Rubenstein	Oklahoma Heart Hospital Physicians
Brandon Black	Merck & Company
Paul Cockrum	Bristol Meyers Squibb
Andrea Johnson	AstraZeneca
Marc Weitzel	Oklahoma Heart Hospital Mercy

**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: Juxtapid<

Speaker: Dr. Rubenstein

Agenda Item: No 7

Speaker: Brandon Black

Agenda Item: No 7

Speaker: Paul Cockrum

Agenda Item: No 8

Speaker: Andrea Johnson

Agenda Item: No 8

Speaker: Marc Weitzel

Dr. Muchmore recommends bringing back Juxtapid™ in April.

ACTION: NONE REQUIRED

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

3A: February 14, 2013 DUR Minutes

3B: February 14, 2013 DUR Recommendation Memorandum

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

ACTION: MOTION CARRIED

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

4A: Medication Coverage Activity: February 2013

4B: Pharmacy Help Desk Activity: February 2013

4C: SoonerCare Atypical Program Update

Materials included in agenda packet; presented by Dr. Keast

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
MEDICATIONS

5A: COP Recommendations

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE SELECT ORAL CORTICOSTEROID MEDICATIONS

6A: COP Recommendations

6B: Utilization Details

Materials included in agenda packet; presented by Dr. Moore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF DIABETES MEDICATIONS AND 30 DAY NOTICE TO PRIOR  
AUTHORIZE JUVISYNC®, BYDUREON®, JENTADUETO®, JANUMET XR®, NESINA®, KAZANO®, AND OSENI®

7A: Current Authorization Criteria

7B: Utilization Review

7C: Prior Authorization Review

7D: Market News and Update

7E: Cost Comparisons

7F: COP Recommendations

7G: Utilization Details

7H: Product Detail

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF ANTICOAGULANT MEDICATIONS AND 30 DAY NOTICE TO PRIOR  
AUTHORIZE ELIQUIS®

8A: Current Authorization Criteria

8B: Utilization Review

8C: Prior Authorization Review

8D: Market News and Update

8E: COP Recommendations

8F: Product Details

Materials included in agenda packet; presented Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: 30 DAY NOTICE TO PRIOR AUTHORIZE KUVAN®

9A: Introduction and Product Summary

9B: COP Recommendations

9C: Product Detail

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: 30 DAY NOTICE TO PRIOR AUTHORIZE GATTEX®

10A: Introduction and Product Summary

10B: Cost Comparison

10C: COP Recommendations

10D: Product Details

Materials included in agenda packet; presented by Dr. Le & Dr. Moore.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: FDA AND DEA UPDATES

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: FUTURE BUSINESS

Materials included in agenda packet; submitted by Dr. Cothran

12A: Fiscal Year 2012 Review

12B: New Product Reviews

12C: Annual Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: ADJOURNMENT

The meeting was adjourned at 7:22pm



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

## Memorandum

Date: March 14, 2013

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

From: Chris Le, Pharm.D.  
Assistant Director  
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of March 13, 2013

Recommendation 1: Vote to Prior Authorize Chronic Obstructive Pulmonary Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends establishing a Product Based Prior Authorization category for long acting bronchodilator medications to ensure appropriate and cost-effective utilization in accordance with current treatment guidelines. The following Tier 1 drug list has been determined to be acceptable for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board based on cost and clinical effectiveness for approval before referral to the Oklahoma Health Care Authority.

Tier 1	Tier 2
Long Acting Beta <sub>2</sub> Agonists*	
Serevent® (Salmeterol inhalation powder) Foradil® (formoterol aerosolized powder)	Perforomist® (formoterol nebulizer solution) Brovana® (arformoterol nebulizer solution) Arcapta® (indacaterol inhalation powder)
Long Acting Anticholinergics	
Spiriva® (tiotropium inhalation powder)	Tudorza® (aclidinium inhalation powder)

\*Combination agents qualify as Tier 1 agents

Tier 2 Approval Criteria:

1. The member must be age 18 or older, and
2. Have a diagnosis of COPD, chronic bronchitis, or emphysema, and
3. A 4 week trial of at least one LABA and a four week trial of one LAMA within the past 90 days, or
4. A documented adverse effect, drug interaction, or contraindication to all available Tier 1 products.
5. A clinical exception will be made for members who are unable to effectively use hand-actuated devices, such as Spiriva Handihaler® or those who are stable on nebulized therapy.

Recommendation 2: Vote to Prior Authorize Select Oral Corticosteroid Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of the following products:

- i Orapred ODT® (prednisolone sodium phosphate, orally disintegrating tabs)
- i Prednisolone sodium phosphate oral solution: 5 mg/5 ml, 20 mg/5 ml (Veripred™), and 25 mg/5ml

Approval Criteria:

1. Approval requires a patient specific, clinically significant reason why the member cannot use a tablet or an alternative strength liquid formulation.
2. Orapred ODT® will have a quantity limit of 10 tabs per month available without prior authorization for members 10 years or younger.

Recommendation 3: Annual Review of Diabetes Product Based Prior Authorization Category and 30 Day Notice to Prior Authorize New Anti-Diabetes Medications

NO ACTION

Recommendation 4: Fiscal Year 2012 Annual Review of Anticoagulant Medications and 30 Day Notice to Prior Authorize Eliquis® (Apixaban)

NO ACTION

**Gregg S. Govett, M.D., P.C.**  
1205 S. Air Depot Blvd., PMB 103  
Midwest City, OK 73110  
405-732-3755  
FAX: 405-733-1784

January 29, 2013

Oklahoma Health Care Authority  
ATTN: Drug Utilization Board  
2401 NW 23rd, Ste. 1A  
Oklahoma City, OK 73107

Re: Ciprodex

To Whom It May Concern:

As the current president of the Oklahoma Academy of Otolaryngology, Inc., I am writing this letter to request the inclusion of Ciprodex on the Oklahoma Medicaid Formulary. Ciprodex is the only otic drop available to physicians that includes a quinolone antibiotic with a steroid. It is indicated for ear infections in the presence of a tympanostomy tube or perforated tympanic membrane. The antibiotic treats the bacteria in the infection and the steroid suppresses the inflammation around the tympanostomy tube or in the middle ear. This combination of medications allows for faster healing and the medication is only used twice a day to improve parenteral or patient compliance. Quinolone antibiotics have not been shown to damage the cochlea which makes them safer for the treatment of middle ear infections as there is no risk of neural hearing loss secondary to the medication. This makes Ciprodex the preferred medication for the treatment of middle ear infections with granulation tissue in the middle ear. Thank you.

Sincerely,



Gregg S. Govett, M.D.

# Petition to Review Ciprodex Otic Suspension for Tier 1 Coverage on OK Medicaid

**Petition summary and background**  
 This petition is to show full support from Oklahoma Otolaryngologists/Otologists for using Ciprodex first line, in necessary cases, including Medicaid patients. In short, all physicians signing this petition agree with the attached letter, written by Dr. Gregg Govett.

**Action petitioned for**  
 We, the undersigned, are concerned physicians who urge the Drug Utilization Review Board to act now to MOVE CIPODEX TO TIER 1 ON OKLAHOMA STATE MEDICAID

Printed Name	Signature	Clinic Address	Comment	Date
Ahul Vaidys		Tulsa, OK		2/11/13
Steve Bramblee		Tulsa, OK		2/11/13
<del>Chad Stora</del>	<del></del>	<del>Tulsa, OK</del>		<del>2/11/13</del>
Bruce Hawkins		Tulsa, OK		2/11/13
John Moseley		Tulsa, OK		2-11-13
Chloe Fulkin				2-11-13
Thomas C. Seddon MD	Thomas A. Dodson MD	6802 S. Olympia, #200 Tulsa, OK 74132		2-11-13
Edward Piggus		Okeech, OK		2/13/13
Steve Richards		4700 W. Memorial #606 OKC OK 75120		2/13/13
JONATHAN PILLON		Edmond, OK		2/15/13
J. Mark Gilchrist		Edmond, OK		2/13/13
Spencer Voth		Tulsa, OK		2/14/13







Printed Name	Signature	Clinic Address	Comment	Date
Edward L. Barnard		Enid, OK 73703 3201 N. Ch. Bacon Sub 500 PHS Pharmacy II, I	This needs to be OK - PHS Pharmacy II, I	2/25/13
J. M. Dillinger		Enid, OK 73703 3201 N. Van Buren Street	Need a steroid curtain, imm. isotopic drug!	2/25/2013
William Howard		496 Fairview Ave Ponca City, OK		2/25/13
DAVID HARL		5020 E. 68th Tulsa, OK 74136	Need as a first-line therapy for selected patients	2/26/13
Chris Siemens		5020 E 68th Tulsa, OK 74136	Needs to be 1st line to reduce tx related	2-26-13
Thomas Munn		8803 S. 101st E Ave #165	need to	2/26/13
David W. Linkin		5020 E 68th Tulsa, OK 74136	Excellent point - we are getting treatment should be considered	2/26/13
Rick Vicon		4140 W Memorial OKC 3320 NW 56th St OKC OK 73112	<b>Must Get Approved</b>	2/27/13
Jason Sigman		5020 E. 68th St	Must have fill benefits for our patient	2/28/13
Gary Moon		5020 E. 68th St		3/4/13
Don Crankly		8095 WALNUT ST WIC	only med available to solve center prob	3/11/13
Charles H. Hollingsworth		205 SE Howard Ave	need 1st Tier access!	3/4/13
Mark Robertson		205 SE Howard Ave		3/7/13
Richard Wright		4	only stand 1/2b drug // worth	3/7/13
Scott Cordray		2448 E. 81st St.	This is a Must!!	3/13/13
A.E. Lortz		5020 E 68th	OK	3/14/13

# Petition to Review Ciprodex Otic Suspension for Tier 1 Coverage on OK Medicaid

**Petition summary and background** This petition is to show full support from Oklahoma Otolaryngologists/Otologists for using Ciprodex first line, in necessary cases, including Medicaid patients. In short, all physicians signing this petition agree with the attached letter, written by Dr. Gregg Govett.

**Action petitioned for** We, the undersigned, are concerned physicians who urge the Drug Utilization Review Board to act now to MOVE CIPRODEX TO TIER 1 ON OKLAHOMA STATE MEDICAID

Printed Name	Signature	Clinic Address	Comment	Date
Troy Miller		3350 NW 4th Suite 300 OKC OK 73102		
Ken Stern		535 NW 9th St Suite 200 OKC, OK 73102		
KATH CLAYTON		"		
Brent Smith		"		
ALBERT GIBSON		"		
Ken Dyer		3400 NW 54th OKC, OK 73112		
Michael McGee		"		
R. Stanley Baker		3400 NW 56th OKC	C-DEX is THE STANDARD OF CARE FOR A NUMBER OF MEDICALLY COMPLEX MONTHLY IT'S WAY TOO DIFFICULT TO PRESCRIBE WITH THE CURRENT DESIGN WITH THIS DRUG IS IMPROVED.	
Mark Wood				
Wayne Bynghall		3650 W. Brookcreek Rd Norman OK 73072		
Jeff Frederick		"		
DANNY CAMPBELL				

Printed Name	Signature	Clinic Address	Comment	Date
Sneil				
DANNY C. THOMAS	Danny Thomas SR			
Lauren King				
Josh Corley	Josh Corley			
Nicole Elkins				
DAN KEEN				



3/8/2013



**Mark Sumeray, MD, FRCS**  
Aegerion Pharmaceuticals, Inc  
Cambridge, MA

**Terry Cothran, RPH**  
Oklahoma University College of Pharmacy  
Director, Pharmacy Management Consultants  
University of Oklahoma Health Sciences Center

**Dear Mr. Cothran,**

We read with interest the recently published prior authorization policy issued by the Oklahoma Health Authority for coverage of Juxtapid (lomitapide) capsules. The policy outlines the requirement for an FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed via genetic testing ([Link to Lomitapide Policy](#)).

We were surprised to see a requirement for genetic testing in the policy. DNA sequencing for genotypic confirmation of HoFH is not routinely used in clinical practice for several reasons including the following: inadequate sensitivity to avoid false negatives, lack of relevance in the determination of appropriate treatment, and difficulty in access due to cost and limited availability. Moreover, genetic confirmation of diagnosis would result in failure to identify a significant number of patients with HoFH. In clinical practice, diagnosis of HoFH is typically made based on phenotypic criteria including LDL cholesterol level, presence of xanthomas in childhood, a history of Heterozygous Familial

Hypercholesterolemia (HeFH) in both parents, and lack of responsiveness to lipid lowering treatment (Raal and Santos. 2012 Atherosclerosis; [Link to Article](#)).

Due to the large number of genetic mutations (>1600), interpretation of genetic results is complex with autosomal co-dominant mutations of the LDL-R, apo B, PCSK9 and autosomal recessive LDLRAP1 genes yielding true homozygotes, compound heterozygotes, double heterozygotes and autosomal recessive hypercholesterolemia (ARH) combinations of the 2 mutated alleles affecting LDL receptor function. Given this, sequencing of a given patient's mutations may turn out to be challenging, time-consuming and expensive. This will be especially true if a mutation has not been previously described in a patient's family and if the patient is not a member of a group with a known founder mutation. Genetic testing can also have a wide-ranging sensitivity for FH diagnosis and commercial laboratories that offer genetic testing are not widely available. Importantly, patients with alleles for these genes are not identified correctly in ~15 to 20% of cases due to unrecognized mutations in alleles for one or more of these genes (Hopkins et al., 2011 J Clin Lipidol; [Link to Article](#)).

Guidelines from the National Lipid Association state that genetic testing is superfluous for diagnosis if clinical signs (e.g., extremely high LDL-C/TC level and xanthomas or family history) are present (Goldberg et al., 2011 J Clin Lipidol; [Link to Article](#)). This situation is particularly true of HoFH, where untreated LDL-C levels are typically >400 mg/dL, and xanthomas and CVD may be present from childhood. Furthermore, the positive or negative outcome of a genetic test has not historically influenced patient management, as medical interventions have been guided by clinical phenotype rather than genotype.

Currently marketed genetic tests can cost between \$1,000 - \$3,000 per test. The total cost of testing is dependent on the variability and complexity of the genetic mutations that gives

rise to a patient's HoFH. For example, testing may be relatively straightforward in a patient from a family with a known, common mutation. However, for a patient without a known or common mutation, genetic testing may be more time-consuming and expensive and involve sequencing the entire LDLR, apo B, PCSK9, or low density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes (<http://www.ncbi.nlm.nih.gov/gtr/conditions/C0020445/>). Given the various caveats described above, genetic screening is not typically used in routine clinical practice for diagnosis or clinical management of HoFH patients.

Finally, the requirement for genetic testing is not consistent with the FDA's review of lomitapide as reflected by the agency's comments on the REMS program contained in the briefing materials for the Endocrinologic and Metabolic Drugs Advisory Committee meeting on October 17<sup>th</sup> 2012. [Lomitapide FDA Briefing Document](#)

The relevant text from the review conducted by the Office of Surveillance and Epidemiology (Division of Risk Management) is detailed below:

**“Requiring a diagnosis of HoFH that relies on genetic testing or a family history in order to receive lomitapide is problematic for the following reasons:**

- **Genetic testing may not be available to all patients**
- **Not all of the genetic mutations that define HoFH are known**
- **Adopted individuals are likely unaware of their family history”**

Consequently, the FDA does not require physicians to perform genetic testing as part of the ETASU REMS program. Instead prescribers must affirm that their patient has a clinical or laboratory diagnosis consistent with HoFH when completing the prescription authorization form.

For all the reason stated above, we are respectfully requesting that the Drug Utilization Review Board reconsider implementing a policy requiring genetic confirmation of diagnosis of HoFH for coverage of patients. We would appreciate your support on this because, by requiring genetic testing, the policy may result in restricting lomitapide therapy from HoFH patients for whom it is medically appropriate.

Thank you in advance for your consideration in this matter.

Sincerely,

A handwritten signature in blue ink that reads "Mark Sumeray". The signature is written in a cursive style with a small flourish at the end.

Mark Sumeray, MD, FRCS

Chief Medical Officer

Aegerion Pharmaceuticals, Inc

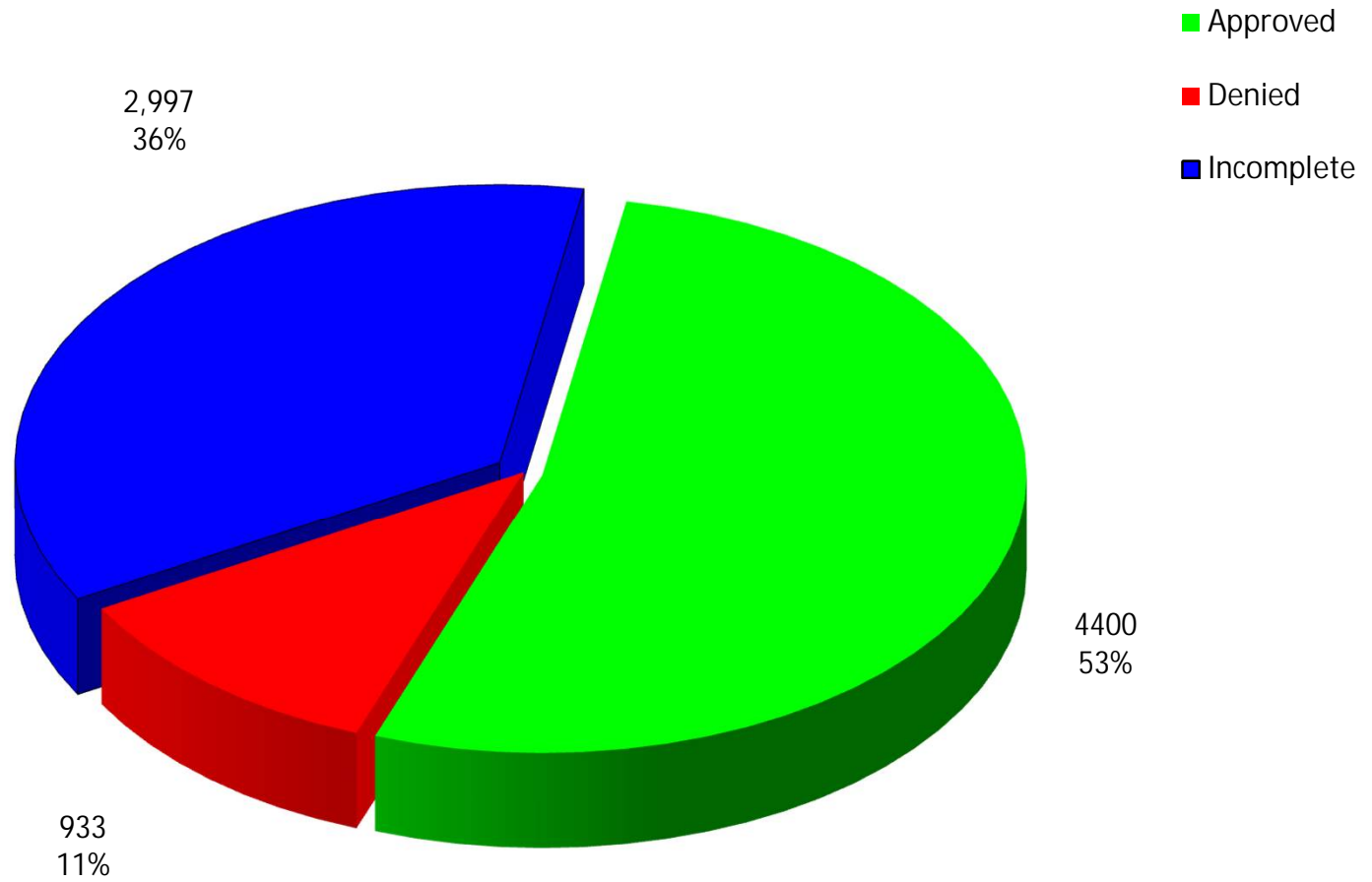




# Appendix B

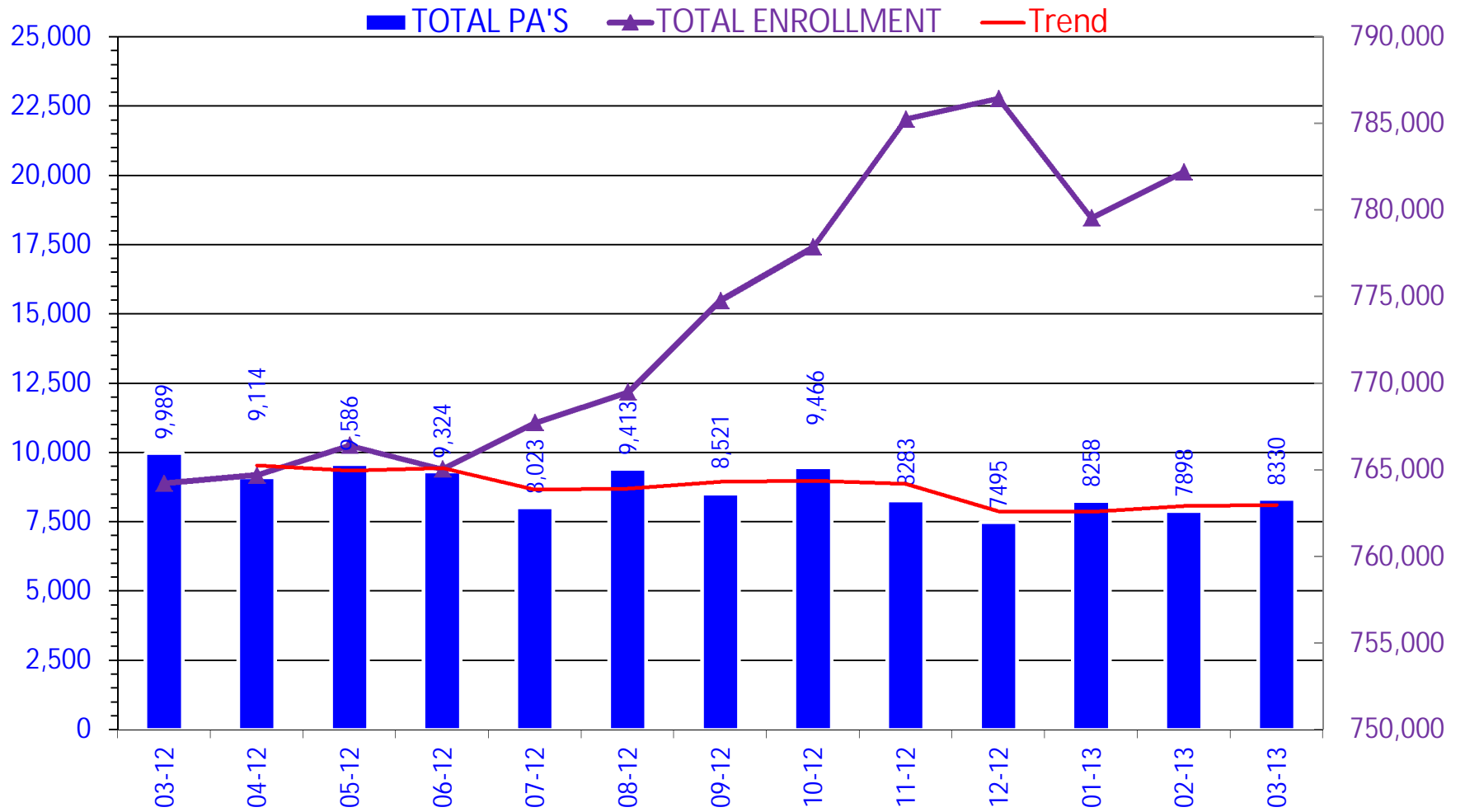


# PRIOR AUTHORIZATION ACTIVITY REPORT: March 2013



PA totals include approved/denied/incomplete/overrides

# PRIOR AUTHORIZATION REPORT: March 2012- March 2013



PA totals include approved/denied/incomplete/overrides

## Prior Authorization Activity 3/1/2013 Through 3/31/2013

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	385	180	17	188	355
Analgesic, Narcotic	412	212	27	173	243
Angiotensin Receptor Antagonist	45	12	3	30	360
Antiasthma	1,118	587	66	465	223
Antibiotic	22	2	4	16	7
Anticoagulant	67	44	3	20	321
Anticonvulsant	91	44	9	38	324
Antidepressant	211	57	34	120	342
Antidiabetic	155	79	18	58	358
Antihistamine	177	138	12	27	353
Antihyperlipidemic	18	2	2	14	361
Antimigraine	68	28	14	26	323
Antiplatelet	26	16	1	9	360
Antiulcers	331	106	84	141	176
Anxiolytic	108	80	5	23	248
Atypical Antipsychotics	468	292	16	160	341
Biologics	45	32	2	11	335
Bladder Control	63	6	17	40	359
Cardiovascular	32	17	3	12	263
Dermatological	129	31	47	51	90
Endocrine & Metabolic Drugs	127	61	12	54	238
Erythropoietin Stimulating Agents	28	19	0	9	104
Fibromyalgia	163	43	42	78	346
Gastrointestinal Agents	85	28	19	38	177
Glaucoma	10	3	0	7	360
Growth Hormones	68	53	2	13	147
HFA Rescue Inhalers	88	25	12	51	331
Insomnia	82	21	17	44	203
Multiple Sclerosis	16	10	0	6	251
Muscle Relaxant	129	37	54	38	71
Nasal Allergy	143	15	57	71	139
Neurological Agents	63	53	1	9	346
Nsaids	143	36	31	76	302
Ocular Allergy	58	13	18	27	210
Ophthalmic	46	11	5	30	11
Osteoporosis	23	9	4	10	360
Other*	171	33	32	106	187
Otic Antibiotic	27	10	1	16	13
Pediculicide	91	33	11	47	15
Prenatal Vitamins	11	0	1	10	0
Statins	229	177	13	39	361
Stimulant	497	296	18	183	309
Suboxone/Subutex	153	115	6	32	77
Synagis	63	45	5	13	38
Topical Antibiotic	11	1	0	10	7
Topical Antifungal	107	1	56	50	31
Topical Corticosteroids	42	1	21	20	7

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Vitamin	41	18	19	4	340
Pharmacotherapy	99	70	2	27	90
Emergency PAs	3	3	0	0	
<b>Total</b>	<b>6,788</b>	<b>3,205</b>	<b>843</b>	<b>2,740</b>	

<b>Overrides</b>					
Brand	56	32	3	21	280
Dosage Change	416	391	2	23	5
High Dose	1	0	1	0	0
Ingredient Duplication	17	13	1	3	3
Lost/Broken Rx	77	74	3	0	4
NDC vs Age	4	4	0	0	97
Nursing Home Issue	122	110	0	12	4
Other	37	37	0	0	5
Quantity vs. Days Supply	729	488	62	179	279
Quantity vs. Days SupplyQ	1	1	0	0	360
Stolen	3	3	0	0	5
Temporary Unlock	22	13	2	7	22
Third Brand Request	58	30	16	12	47
<b>Overrides Total</b>	<b>1,542</b>	<b>1,195</b>	<b>90</b>	<b>257</b>	

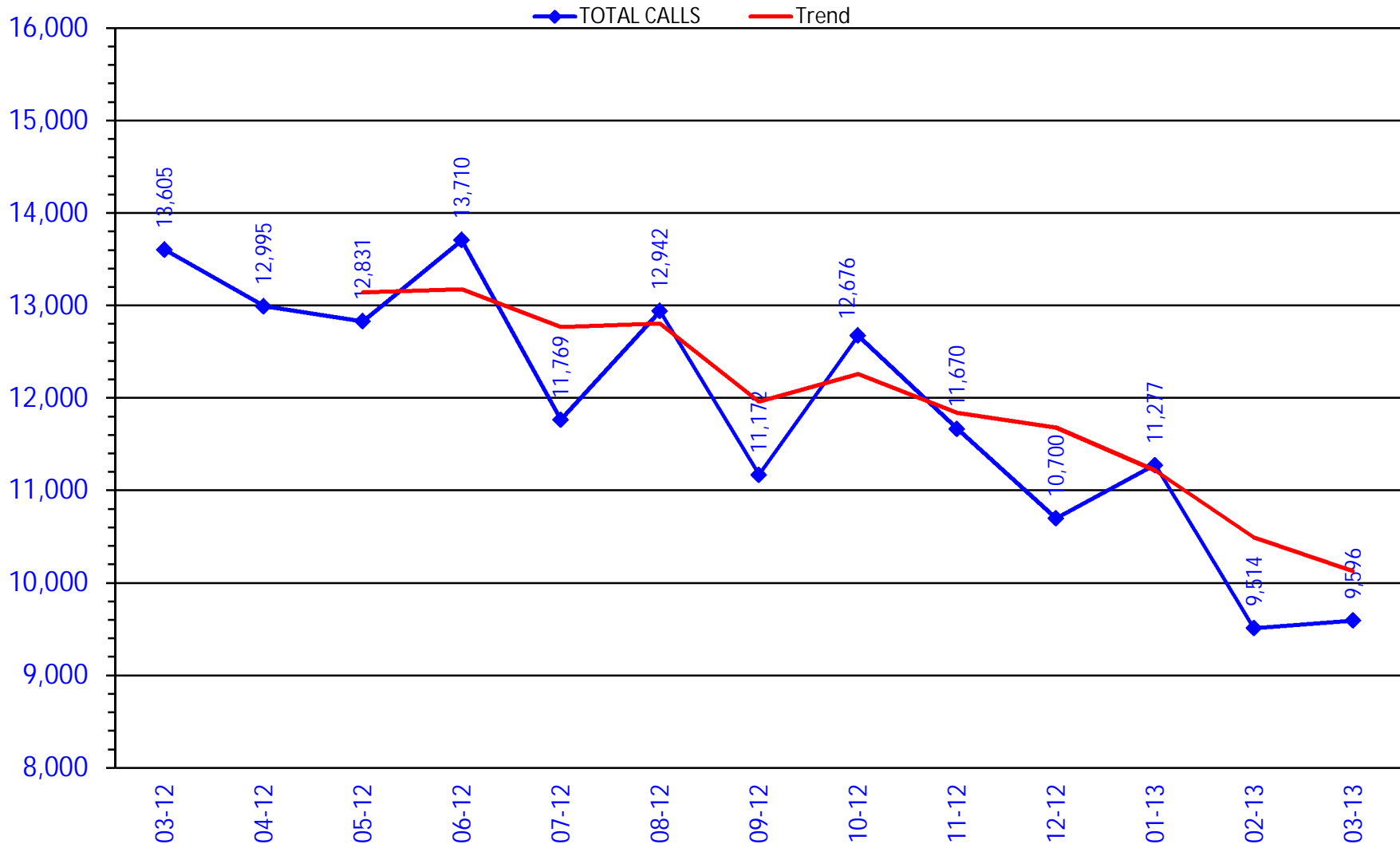
<b>Total Regular PAs + Overrides</b>	<b>8,330</b>	<b>4,400</b>	<b>933</b>	<b>2,997</b>	
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<b>Denial Reasons</b>	
Unable to verify required trials.	2,154
Does not meet established criteria.	934
Lack required information to process request.	809
Drug Not Deemed Medically Necessary	1

<b>Other PA Activity</b>	
Duplicate Requests	515
Letters	2,016
No Process	232
Changes to existing PAs	552
Partials	874

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

# CALL VOLUME MONTHLY REPORT: March 2012- March 2013







# Retrospective Drug Evaluation: Focusing on Safety



- 1. Zolpidem Utilization in Female Members**
- 2. Overview of FDA Safety Alerts**

# Zolpidem Utilization in Female Members

Oklahoma Health Care Authority  
April 2013

## Background<sup>1</sup>

On January 10, 2013, the FDA issued a Drug Safety Communication recommending that the bedtime dose of zolpidem be lowered because new data shows that blood levels in some patients may continue to be high the morning after taking the medication, particularly the extended release formulation. This can impair activities, including driving, that require mental alertness, even when the patient feels fully awake. Women appear to be more susceptible to this impairment because they do not eliminate the drug as quickly as men.

The FDA is requiring the manufacturers of all zolpidem-containing products, Ambien®, Ambien CR®, Edluar®, Zolpimist®, and generics to lower the recommended dose by 50% for women. Prescribers are advised to consider the lower doses for their male patients as well. No changes were recommended for Intermezzo®, sublingual zolpidem tabs, because of the already low dosing.

## Zolpidem® Utilization in the Female SoonerCare Population – CY 2012

Age Group	Zolpidem 5 mg			Zolpidem 10 mg		
	Members	Claims	Total Paid	Members	Claims	Total Paid
00-09	1	9	\$55.17	0	0	0
10-19	50	84	\$485.90	114	236	\$1,367.17
20-34	590	1,107	\$5,805.89	2,564	8,149	\$42,675.72
35-49	355	837	\$4,103.43	2,356	10,088	\$49,876.88
50-64	395	1,359	\$6,965.76	1,720	8,646	\$41,604.88
65-79	51	184	\$1,023.85	101	490	\$2,505.17
80-94	8	34	\$122.99	9	26	\$138.30
<b>Totals</b>	<b>1,450</b>	<b>3,614</b>	<b>\$18,562.99</b>	<b>6,864</b>	<b>27,635</b>	<b>\$138,168.12</b>

Age Group	Zolpidem CR 6.25 mg			Zolpidem CR 12.5 mg		
	Members	Claims	Total Paid	Members	Claims	Total Paid
00-09	0	0	0	0	0	0
10-19	0	0	0	2	4	\$389.46
20-34	4	7	\$753.30	81	321	\$32,307.86
35-49	12	27	\$3,035.59	101	488	\$50,600.37
50-64	7	18	\$1,918.94	95	535	\$55,665.49
65-79	0	0	0	4	23	\$2,431.20
80-94	0	0	0	0	0	0
<b>Totals</b>	<b>23</b>	<b>52</b>	<b>\$5,707.83</b>	<b>283</b>	<b>1,371</b>	<b>\$141,394.38</b>

## **Discussion and Recommendations**

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Currently immediate-release zolpidem is in Tier 1 of the hypnotics Product Based Prior Authorization category; extended-release zolpidem is in Tier 2. A quantity limit of 30 units for a 30 day supply is in place. Pediatric members 18 years of age or younger require a prior authorization.

The College of Pharmacy recommends that educational information be sent to all SoonerCare prescribers and pharmacies, followed by a letter to current prescribers of doses over the new recommended maximum.

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# Overview of FDA Safety Alerts

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Oklahoma Health Care Authority  
April 2013

## Introduction<sup>2,3</sup>

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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
12/12/2012	Varenicline(Chantix®)	Risk of cardiovascular adverse events
<p><b>Issue Details:</b> Meta-analysis performed by the manufacturer (Pfizer) shows a higher, but not statistically significant, occurrence of major adverse cardiovascular events (cardiovascular-related death, nonfatal heart attack, and nonfatal stroke) in patients receiving Chantix® compared to placebo.</p> <p><b>FDA Recommendations:</b> The FDA recommends that prescribers weigh risks of Chantix® against its benefits. Patients who experience new or worsening cardiovascular symptoms such as chest pain, shortness of breath, calf pain when walking, or sudden onset of weakness, numbness, or difficulty speaking, should contact their healthcare professional.</p>		

Date	Drug	Issue
2/12/2013	Clonidine extended release (Kapvay®)	Risk of cardiac conduction abnormalities
<p><b>Issue Details:</b> Clonidine, a sympatholytic drug, may worsen sinus node dysfunction and atrioventricular block, especially in patients also taking other sympatholytic drugs. Post-marketing surveillance reveals episodes of severe bradycardia requiring intervention with IV atropine, IV isoproterenol, and temporary cardiac pacing in patients with conduction abnormalities and/or who were currently on other sympatholytic drugs who were also taking clonidine.</p> <p><b>FDA Recommendations:</b> Warning added to product label with the following recommendation: Kapvay® should be titrated slowly and the patient's vital signs should be carefully monitored if patient has a history of cardiac conduction abnormalities or is on another sympatholytic medication; (alpha-adrenergic blockers – doxazosin, phentolamine, prazosin, terazosin; mixed alpha-and beta-adrenergic blockers – carvedilol, labetalol; central-acting sympathetic nervous system inhibitors – clonidine, methyldopa). Kapvay® is currently only FDA approved for children.</p>		

Date	Drug	Issue
2/15/2013	Denosumab (Xgeva®)	Risk of potentially fatal hypocalcemia
<p><b>Issue Details:</b> Xgeva® can cause severe symptomatic, even fatal, hypocalcemia.</p> <p><b>FDA Recommendations:</b> The product label has been updated to include the warning regarding this effect. The FDA recommends that pre-existing hypocalcemia be corrected prior to treatment and calcium levels be closely monitored during treatment. Supplementation with calcium, magnesium, and Vitamin D should be included as needed. Patients should be advised to report symptoms of hypocalcemia, including muscle spasms and twitching, cardiac arrhythmias, pins-and-needles sensations, irritability, lethargy, and seizures.</p>		

Date	Drug	Issue
3/12/2013	Azithromycin (Zithromax®, Zmax®)	Risk of potentially fatal heart rhythms
<p><b>Issue Details:</b> FDA issued a Drug Safety Communications after study results from medical researchers and the manufacturer showed potential abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. At particular risk are patients with existing QT interval prolongation, history of torsades de pointes, low blood levels of potassium or magnesium, bradycardia, or who use certain drugs to treat arrhythmias.</p> <p><b>FDA Recommendations:</b> Health care professionals should consider the risk of torsades de pointes and fatal heart rhythms when considering antibiotic treatment for patient who are already at risk for cardiovascular events. Other macrolide and non-macrolides such as fluoroquinolones also have the potential for QT prolongation and other significant side effects which must also be considered.</p>		

Date	Drug	Issue
3/14/2013	Incretin mimetic drugs -exenatide (Byetta®, Bydureon®), liraglutide (Victoza®), sitagliptin (Januvia®, Janumet®, Janumet XR®, Juvisync®), saxagliptin (Onglyza®, Kombiglyze XR®), alogliptin (Nesina®, Kazano®, Oseni®), and linagliptin (Tradjenta®, Jentadueto®).	Risk of pancreatitis and pre-cancerous findings of the pancreas
<p><b>Issue Details:</b> Academic researchers report possible increased risk of pancreatitis and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes who are being treated with incretin mimetics.</p> <p><b>FDA Recommendations:</b> The FDA has issued an early communication to inform the public and health care providers that this issue is being evaluated. Findings will be reported when review has been completed. Patients should continue to take medications as prescribed.</p>		

References:

<sup>1</sup> <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm>

<sup>2</sup> <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm342027.htm>

<sup>3</sup> <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm343805.htm>





# Appendix C





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**Vote to Prior Authorize Juvisync® (sitagliptin/simvastatin), Bydureon® (exenatide ER), Jentadueto® (linagliptin/metformin), Janumet XR® (sitagliptin/metformin ER), Nesina® (alogliptin), Kazano® (alogliptin/metformin), and Oseni® (alogliptin/pioglitazone)**

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**Oklahoma Health Care Authority  
April 2013**

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**Recommendations**

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The College of Pharmacy recommends moving all pioglitazone products into Tier 3 from the Special PA Category and placement of Jentadueto® (linagliptin/metformin), Janumet XR® (sitagliptin/metformin ER), Juvisync® (sitagliptin/simvastatin), Nesina® (alogliptin), Kazano® (alogliptin/metformin), Oseni® (alogliptin/pioglitazone), and Bydureon® (exenatide ER) into Tier 3 of the Diabetes Medication PBPA category with the following criteria:

1. To qualify for a Tier 2 medication, the member must have a trial of a Tier 1 medication (must include a trial of metformin titrated up to maximum dose), or a clinical reason why a Tier 1 medication is not appropriate.
2. For initiation with dual or triple therapy, additional Tier 2 medications can be approved based on current AACE or ADA guidelines.
3. To qualify for a Tier 3 medication, the member must have tried a Tier 2 medication in the same category and have a documented clinical reason why the Tier 2 medication is not appropriate.
4. To qualify for a Special Prior Authorized medication, the member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier 2 or Tier 3 medications, or have a documented clinical reason why the requested product is necessary for the member.
5. For members with steatohepatitis, pioglitazone can be approved after a trial of a Tier 1 medication (must include a trial of metformin titrated up to maximum dose), or a clinical reason why a Tier 1 medication is not appropriate.

\*Note that Tier 3 products can be moved to Tier 2 status based on supplemental rebate status or generic pricing and availability.

Tier 1	Tier 2*	Tier 3	Special PA
<p><b><u>Biaguanides</u></b>  Metformin (Glucophage®)  Metformin SR (Glucophage XR®)  Metformin-Glyburide (Glucovance®)  Metformin-Glipizide (Metaglip®)</p> <p><b><u>Sulfonylureas</u></b>  Glyburide (Diabeta®)  Glyburide Micronized (Micronase®)  Glipizide (Glucotrol®)  Glipizide SR (Glucotrol XL®)  Glimepiride (Amaryl®)</p> <p><b><u>Miscellaneous</u></b>  Chlorpropamide  Tolbutamide</p>	<p><b><u>DPP-4 Inhibitors</u></b>  Linagliptin (Tradjenta®)  Saxagliptin (Onglyza®)  Saxagliptin-Metformin (Kombiglyze®)  Sitagliptin (Januvia®)  Sitagliptin-Metformin (Janumet®)</p> <p><b><u>Glinides</u></b>  Repaglinide-Metformin (Prandimet®)  Repaglinide (Prandin®)  Nateglinide (Starlix®)</p> <p><b><u>GLP-1 Agonists</u></b>  Liraglutide (Victoza®)</p> <p><b><u>Alpha-Glucosidase Inhibitors</u></b>  Acarbose (Precose®)</p>	<p><b><u>DPP-4 Inhibitors</u></b>  <b>Sitagliptin-Met ER (Janumet XR®)</b>  <b>Sitagliptin-Simvastatin (Juvisync®)</b>  <b>Linagliptin-Metformin (Jentadueto™)</b>  <b>Alogliptin (Nesina®)</b>  <b>Alogliptin-Metformin (Kazano®)</b>  <b>Alogliptin- Pioglitazone (Oseni®)</b></p> <p><b><u>Thiazolidinediones</u></b>  <b>Pioglitazone (Actos®)</b>  <b>Pioglitazone-Metformin (Actoplus Met®, Actoplus Met XR®)</b>  <b>Pioglitazone-Glimepiride (Duetact®)</b></p> <p><b><u>GLP-1 Agonists</u></b>  Exenatide (Byetta®)  <b>Exenatide Qweek (Bydureon®)</b></p> <p><b><u>Alpha-Glucosidase Inhibitors</u></b>  Miglitol (Glyset®)</p>	<p><b><u>Biaguanides</u></b>  Metformin solution (Riomet®)  Metformin Long-Acting (Fortamet®, Glumetza®)</p> <p><b><u>Thiazolidinediones</u></b>  Rosiglitazone (Avandia®)  Rosiglitazone-Metformin (Avandamet®)  Rosiglitazone-Glimepiride (Avandaryl®)</p> <p><b><u>Amylinomimetic</u></b>  Pramlintide (Symlin®)</p>

\*Supplemental rebate for Tier 3 products or similarly priced generic products only.



# Appendix D



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## **Vote to Prior Authorize Eliquis® (Apixaban) and Update Xarelto® (Rivaroxaban) Prior Authorization Criteria**

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Oklahoma Health Care Authority  
April 2013

### **Recommendations:**

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The College of Pharmacy recommends the following:

Prior Authorization of Eliquis® (apixaban) with the following Criteria:

1. FDA approved diagnosis of nonvalvular atrial fibrillation.

Updating the Prior Authorization Criteria for Xarelto® (rivaroxaban):

1. FDA approved diagnosis of one of the following: non valvular atrial fibrillation, **deep vein thrombosis (DVT), pulmonary embolism (PE), or to reduce the risk of recurrent DVT and PE.**
2. 10 mg: the first 35 days will not require prior authorization to allow for use for postsurgical DVT prophylaxis only.
3. 15 mg and 20 mg: a diagnosis of nonvalvular atrial fibrillation, **deep vein thrombosis (DVT), pulmonary embolism (PE), or prophylaxis of recurrent DVT or PE** will be required.





# Appendix E





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# **Vote to Prior Authorize Kuvan® (Sapropterin)**

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**Oklahoma Health Care Authority**  
**April 2013**

## **Recommendations**

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The College of Pharmacy recommends prior authorization of Kuvan® (sapropterin) with the following criteria:

Kuvan® Approval Criteria:

1. FDA approved diagnosis of phenylketonuria.
2. Active management with phenylalanine restricted diet.
3. Initial approval will be for 30 days in duration. After which time, prescriber must verify that the member responded to treatment as defined by laboratory documentation of  $\geq 30\%$  decrease in blood phenylalanine levels.
4. Subsequent approvals will be for the duration of a year.





# Appendix F



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# **Vote to Prior Authorize Gattex® (Teduglutide)**

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**Oklahoma Health Care Authority**  
**April 2013**

## **Recommendations**

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The College of Pharmacy recommends prior authorization of Gattex® (teduglutide) with the following criteria:

### **Criteria for Approval for Gattex® (Teduglutide):**

1. Member must have diagnosis of severe Short Bowel Syndrome, and
2. Require parenteral nutrition at least 3 times per week, every week, for the past 12 months, with
3. Documentation of all of the following:
  - a. Prior use of supportive therapies such anti-motility agents, proton pump inhibitors, bile acid sequestrants, and octreotide.
  - b. Colonoscopy within the previous 6 months, with removal of polyps if present.
  - c. Gastro-intestinal malignancy has been ruled out.
4. Approval will be for the duration of 3 months, after which time, prescriber must verify benefit of medication by documented reduction of at least 20% in parenteral support.
5. Subsequent approvals will be for the duration of a year.





# Appendix G





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## 30 Day Notice to Prior Authorize Kynamro™ (Mipomersen) and Vote to Change Juxtapid™ (Lomitapide) Prior Authorization Criteria

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Oklahoma Health Care Authority  
April 2013

### Background

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The prior authorization criteria for Juxtapid™ (lopitapide) were previously approved at the meeting of February 2013. At the Drug Utilization Review Board's request, it is being brought back to evaluate the need for genetic testing as a means to confirm the diagnosis of homozygous familial hypercholesterolemia (HoFH).

Familial hypercholesterolemia is an autosomal dominant disorder usually caused by mutations in the low-density lipoprotein (LDL) receptor gene or other genes that lead to defective or absent LDL receptor function, which results in reduced uptake and clearance of circulating LDL cholesterol (LDL-C) by the liver. True homozygotes inherit defective genes from both the mother and father. The odds of two unrelated heterozygotes marrying are one in 250,000 and the chance of them having a child who is homozygous is one in four, meaning that the theoretical incidence of homozygous familial hypercholesterolemia is one in 1 million. Homozygotes may develop angina in childhood due to aortic stenosis and coronary atheroma. Myocardial infarction has been recorded as early as 2 years of age, and life expectancy does not generally extend beyond the early 20s.<sup>1</sup>

Clinical expert opinion suggests the requirement for genetic testing be removed from the Juxtapid™ (lopitapide) prior authorization criteria. It is also the opinion of the OHCA staff geneticist to allow treatment for those that meet clinical criteria, even in the absence of genetic confirmation. This is due to the fact that only 50% of the patients clinically diagnosed with "severe" familial hypercholesterolemia are shown to be true homozygotes for the low density lipid (LDL)-receptor mutation. Mutations in other genes (or a combination of mutations in LDL-receptor and another gene) can lead to the same clinical presentation. Clinical presentation includes the features listed below.<sup>2</sup>

1. Fatty skin deposits called xanthomas over parts of the hands, elbows, knees, ankles, and around the cornea of the eye (corneal arcus), which may already be present at birth or occur by early childhood.
2. Cholesterol deposits in the eyelids (xanthelasma).
3. Angina or other signs of coronary artery disease, which may be present at a young age.
4. A strong family history of familial hypercholesterolemia or early heart attacks.
5. High levels of LDL in either or both parents.
6. Blood tests show:
  - a. High levels of total cholesterol
    - i. Greater than 300 mg/dL in adults
    - ii. Greater than 250 mg/dL in children
  - b. High LDL levels

- i. Greater than 170-200 mg/dL in children
- ii. Greater than 220 mg/dL in adults
- c. Normal triglyceride levels.

### **Kynamro™ (Mipomersen) Medication Summary<sup>3</sup>**

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Kynamro™ (mipomersen) injection was approved January of 2013 and is currently available. Kynamro™ is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce LDL-cholesterol and apolipoprotein B (apo B), total cholesterol, and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia. It is administered as a once weekly subcutaneous injection of 200mg, injected into the abdomen, thigh region, or outer area of the upper arm.

Kynamro™ is contraindicated in patients with moderate to severe hepatic impairment, or active liver disease, including unexplained persistent elevations of serum transaminases or patients with known sensitivity to product components. Injection site reactions occur in 84% of patients and typically consist of one or more of the following: erythema, pain, tenderness, pruritus and local swelling. Flu-like symptoms occur in 30% of patients, typically within 2 days after an injection.

The most commonly reported adverse reactions (incidence  $\geq$  10% and greater than placebo) are injection site reactions, flu-like symptoms, nausea, headache and elevations in serum transaminases, specifically ALT. Severe adverse effects include elevations in transaminases and increased risk of hepatic steatosis with or without concomitant increases in transaminases. Kynamro™ is a Pregnancy Category B medication. However, it should be discontinued in nursing mothers, or nursing should be discontinued while patient is on Kynamro™, and the safety and effectiveness of this drug has not been established in pediatric patients.

### **Clinical Effectiveness of Kynamro™ and Juxtapid®**

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The safety and effectiveness of Kynamro™ as an adjunct to lipid-lowering medications in individuals with HoFH were evaluated in a multinational, placebo-controlled, 26-week trial in 51 patients with HoFH (34 patients on Kynamro™ and 17 on placebo). A diagnosis of functional HoFH was defined by the presence of at least one of the following clinical or laboratory criteria:

1. History of genetic testing confirming 2 mutated alleles at the LDL-R gene locus, or
2. Documented history of untreated LDL-C  $>$  500 mg/dL and at least one of the criteria:
  - a. Tendinous and/or cutaneous xanthoma prior to age 10 years or
  - b. Documentation of elevated LDL-C  $>$  190 mg/dL prior to lipid-lowering therapy consistent with heterozygous familial hyperlipidemia (HeFH) in both parents. In case a parent was not available, a history of coronary artery disease in a first degree male relative of the parent younger than 55 years or first degree female relative of the parent younger than 60 years was acceptable.

The primary efficacy endpoint was percent change in LDL-cholesterol from baseline to week 28 and the results are shown below.

## Response to Addition of Kynamro™ to Maximally Tolerated Lipid Lowering Medication in Patients with HoFH

	Kynamro™ (n=34)	Placebo (n=17)
<b>Mean Baseline LDL-C</b>	439 mg/dL (190-704 mg/dL range)	400 mg/dL (172-639 mg/dL range)
<b>Parameters</b>	<b>Percent Change from Baseline to End of Treatment*</b> (Mean or Median as Noted)	
<b>LDL - C†</b>	-25	-3
<b>Apo B†</b>	-27	-3
<b>TC†</b>	-21	-2
<b>Non-HDL-C†</b>	-25	-3
<b>TG<sup>a</sup></b>	-18	1
<b>HDL-C<sup>a,b</sup></b>	15	4

\*End of treatment represents two weeks following final dose of Kynamro™; last observation carried forward (LOCF).

† Denotes statistically significant difference between treatment groups based on the pre-specified gatekeeping method for controlling Type I error among the primary and secondary endpoints.

<sup>a</sup> Medians are presented due to non-normal distribution. <sup>b</sup> The treatment effect was not consistent across the Phase 3 trials.

The effectiveness of Juxtapid™ as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, were evaluated in a multinational, single-arm, open-label, 26-week trial involving 29 adults with HoFH. The diagnosis of HoFH was defined by the presence of at least one of the following clinical criteria:

1. Documented functional mutation(s) in both LDL receptor alleles, or alleles known to affect LDL receptor functionality.
2. Skin fibroblast LDL receptor activity <20% normal.
3. Untreated total cholesterol >500 mg/dL and triglycerides <300 mg/dL *and* both parents with documented untreated total cholesterol >250 mg/dL.

The primary efficacy endpoint was percent change in LDL-C from baseline to week 26, and the results are as shown below.

### Juxtapid™ Clinical Trial Results

Parameter	Baseline	Week 26 or LOCF (N=29)	
	Mean (SD)	Mean (SD)	Mean % Change
<b>LDL-C, direct (mg/dL)</b>	336 (114)	190 (104)	-40*
<b>TC (mg/dL)</b>	430 (135)	258 (118)	-36*
<b>Apo B (mg/dL)</b>	259 (80)	148 (74)	-39*
<b>Non-HDL-C (mg/dL)</b>	386 (132)	217 (113)	-40
<b>VLDL-C (mg/dL)</b>	21 (10)	13 (9)	-29
<b>TG (mg/dL)<sup>a</sup></b>	92 [72, 128]	57 [36, 78]	-45*
<b>HDL-C (mg/dL)</b>	44 (11)	41 (13)	-7

23 of 29 patients completed the study. LOCF = last observation carried forward.

\*Denotes statistical significance compared to baseline.

<sup>a</sup> Median values with interquartile range and median % change presented for TG.

## Cost Comparison

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The following is a cost comparison of current available pharmacologic treatment for HoFH.

Medications	Cost/Dose	Cost / Month	Cost / Year
HMG-CoA reductase inhibitors (statins)*	\$0.34 - \$5.68	\$10 - \$170	\$122 - \$2,044
Zetia® (Ezetimibe) 10mg oral tablets	\$5.48	\$164	\$1,972
Gemfibrozil 600mg oral tablets	\$0.20	\$12	\$144
Juxtapid™ (lomitapide) oral tablets †	\$679 - \$853	\$25,590 - \$76,770	\$307,080 - \$921,240 <sup>β</sup>
Kynamro™ (mipomersen) injection ‡	\$3,579	\$14,316	\$186,108

\* Price of atorvastatin 80mg and Crestor 40mg

† Price of 5mg and 20mg tablets (recommended dose is 20mg per day, up to 60mg per day)

‡ Price of four injections per month and 52 injections per year

<sup>β</sup> Manufacturer will cap price at \$295,000 per person per year.

## Recommendations:

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The College of pharmacy recommends prior authorization of Kynamro™ (mipomersen) with similar prior authorization criteria as Juxtapid™ (lomitapide). The College of Pharmacy also recommends the following changes to the prior authorization criteria:

### Prior Authorization Criteria for Juxtapid™ (lomitapide) and Kynamro™ (mipomersen):

1. FDA approved diagnosis of homozygous familial hypercholesterolemia defined by the presence of at least one of the following criteria:
  - a. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing, OR
  - b. Untreated total cholesterol >500 mg/dL and triglycerides <300 mg/dL *and*
    - i. both parents with documented untreated total cholesterol >250 mg/dL  
or
    - ii. presence of tendinous /cutaneous xanthoma prior to age 10 years.
1. Documented failure of high dose statin therapy (LDL reduction capability equivalent to atorvastatin 80mg or higher), and
2. Prescriber must be certified with Juxtapid™ or Kynamro™ REMS program.

## PRODUCT DETAILS OF KYNAMRO™ (MIPOMERSEN SODIUM)

**INDICATIONS:** Kynamro™ is indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). Limitations of use:

1. The safety and effectiveness of Kynamro™ have not been established in patients with hypercholesterolemia who do not have HoFH.
2. The effect of Kynamro™ on cardiovascular morbidity and mortality has not been determined.
3. The use of Kynamro™ as an adjunct to LDL apheresis is not recommended.

**DOSAGE FORMS:** Kynamro™ is available as a single-use vial containing 1 mL of a 200 mg/mL solution and single-use pre-filled syringe containing 1 mL of a 200 mg/mL solution.

### ADMINISTRATION:

- 200 mg once weekly as a subcutaneous injection
- Before treatment, measure ALT, AST, alkaline phosphatase, and total bilirubin

### CONTRAINDICATIONS:

- Moderate or severe hepatic impairment, or active liver disease, including unexplained persistent elevations of serum transaminases.
- Known sensitivity to product components.

### PREGNANCY CATEGORY B

### SPECIAL POPULATIONS:

- **Nursing mothers:** Discontinue drug or nursing.
- **Pediatric Patients:** Safety and effectiveness not established.

### WARNINGS AND PRECAUTIONS:

- Black Box Warning:

Kynamro™ can cause elevations in transaminases. In the Kynamro™ clinical trial in patients with HoFH, 4 (12%) of the 34 patients treated with Kynamro™ compared with 0% of the 17 patients treated with placebo had at least one elevation in alanine aminotransferase (ALT)  $\geq 3$ x upper limit of normal (ULN). There were no concomitant clinically meaningful elevations of total bilirubin, international normalized ratio (INR) or partial thromboplastin time (PTT).

Kynamro™ also increases hepatic fat, with or without concomitant increases in transaminases. In the trials in patients with heterozygous familial hypercholesterolemia (HeFH) and hyperlipidemia, the median absolute increase in hepatic fat was 10% after 26 weeks of treatment, from 0% at baseline, measured by magnetic resonance imaging (MRI). Hepatic steatosis is a risk factor for advanced liver disease; including steatohepatitis and cirrhosis.

Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment and then ALT, AST regularly as recommended. During treatment, withhold the dose of KYNAMRO if the ALT or AST are  $\geq 3$  x ULN. Discontinue Kynamro™ for clinically significant liver.

Because of the risk of hepatotoxicity, Kynamro™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Kynamro™ REMS.

- **Elevation of Transaminases:** In the clinical trial, 4 (12%) of the 34 subjects with HoFH treated with Kynamro™ compared to 0% of the 17 subjects treated with placebo had an elevation in ALT  $\geq 3x$  ULN, and 3 (9%) of those treated with Kynamro™ compared to 0% treated with placebo had at least one elevation in ALT  $\geq 5x$  ULN. **Full Liver Panel** (ALT, AST, total bilirubin, and alkaline phosphatase) before initiation of Kynamro™ and monthly thereafter during the first year of treatment. After the first year, conduct these tests at least every 3 months. Discontinue Kynamro™ for persistent or clinically significant elevations.
- **Hepatic Steatosis:** During the clinical trials in patients with heterozygous familial hypercholesterolemia (HeFH) and hyperlipidemia, the median absolute increase in hepatic fat was 10% after 26 weeks of treatment, from 0% at baseline, measured by magnetic resonance imaging (MRI).
- **Injection site reactions** occur in 84% of patients and typically consist of one or more of the following: erythema, pain, tenderness, pruritus and local swelling.
- **Flu-like symptoms**, which typically occur within 2 days after an injection, occur in 30% of patients and include one or more of the following: influenza-like illness, pyrexia, chills, myalgia, arthralgia, malaise or fatigue.
- The safety and efficacy of Kynamro™ treatment in patients with known renal impairment or in patients undergoing renal dialysis have not been established. Due to the lack of clinical data and Kynamro™ renal safety profile, Kynamro™ is not recommended in patients with severe renal impairment, clinically significant proteinuria, or on renal dialysis.

**ADVERSE REACTIONS:** common adverse reactions (incidence  $\geq 10\%$  and greater than placebo)

- injection site reactions
- flu-like symptoms
- nausea
- headache
- elevations in serum transaminases, specifically ALT

**DRUG INTERACTIONS:**

- Alcohol may increase levels of hepatic fat and induce or exacerbate liver injury. It is recommended that patients taking Kynamro™ should consume no more than one alcoholic drink per day.
- Caution should be exercised when Kynamro™ is used with other medications known to have potential for hepatotoxicity, for example isotretinoin, amiodarone, acetaminophen ( $>4$  g/day for  $\geq 3$  days/week), methotrexate, tetracyclines, and tamoxifen. The effect of concomitant administration of Kynamro™ with other hepatotoxic medications is unknown. More frequent monitoring of liver-related tests may be warranted.
- No clinically relevant pharmacokinetic interactions were reported between Kynamro™ and warfarin, or between Kynamro™ and simvastatin or ezetimibe.
- Coadministration of Kynamro™ with warfarin did not result in a pharmacodynamic interaction as determined by INR, aPTT and PT.

<sup>1</sup> Paul Durrington. **Dyslipidemia.** The Lancet. Volume 362, Issue 9385, 30 August 2003, Pages 717–731. Available online at: <http://www.sciencedirect.com/science/article/pii/S0140673603142341>

<sup>2</sup> **Familial hypercholesterolemia.** Medline Plus. Accessed online at: <http://www.nlm.nih.gov/medlineplus/ency/article/000392.htm>. Last accessed on 3/18/2013.

<sup>3</sup> **Kynamro™ Product Information.** Genzyme Corporation, a Sanofi Company. Available online at: <http://www.kynamro.com/families.aspx>. Last accessed 3/20/2013.



# Appendix H





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# Intervention Strategies for Reduction of Narcotic Overprescribing

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Oklahoma Health Care Authority  
April 2013

## Prescriber Survey

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Several platforms have been evaluated as a means for surveying prescribers. It appears an online method with a back-up mail option may be the most convenient method for access and tabulation of results. The following are sample questions, which the DUR Board may add to, delete, or modify.

1. What do you classify as chronic pain? Pain lasting for
  - a. > 1 month
  - b. > 3 months
  - c. > 6 months
  - d. > 1 year
2. For patients with chronic pain, when do you think it's appropriate to initiate long acting medications?
  - a. After 1 month or less
  - b. After 3 months
  - c. After 6 months
  - d. After 1 year or more
3. How often, in your clinical practice, is it appropriate for patients with chronic pain to be managed with immediate release narcotic analgesics instead of long acting narcotic analgesics?
  - a. Never
  - b. Rarely
  - c. About 50% of the time
  - d. Most of the time
  - e. All of the time
4. For your patients with chronic pain already managed with long acting narcotic analgesic, what do you think is an appropriate frequency of rescue medication per day?
  - a. Once a day
  - b. Twice a day
  - c. Three times a day
  - d. Four times a day or more if necessary
5. From your clinical practice experience what quantity of short acting narcotic analgesics is usually required for chronic pain patients maintained on long acting narcotic analgesics?
  - a. #30 or less per 30 days
  - b. #60 per 30 days
  - c. #90 per 30 days
  - d. #120 per 30 days
  - e. > than #120 per 30 days
6. Which do you think is more likely to be abused?
  - a. Short acting narcotic analgesics
  - b. Long acting narcotic analgesics

7. Do you utilize random urine drug screening for your patients who are on narcotic analgesics?
  - a. Yes
  - b. No
8. Do you feel that overprescribing of narcotic medications is a problem in Oklahoma?
  - a. Yes
  - b. No
  - c. Maybe

## Narcotic Prescriber Profiling

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Prescribers of all immediate release oral solid dosage forms of narcotic analgesics over a 6 month timeframe (October 2012 – February 2013) were analyzed to yield the following lists:

**Prescribers by Narcotic Prescriptions**

Rank	Prescriber	Narcotic Rxs	Total Rxs
1	RR	2,679	11,380
2	X	2,154	3,637
3	EE	1,443	4,868
4	DD	1,397	5,069
5	BBB	1,323	5,305
6	JJJ	1,267	7,345
7	JJ	1,257	2,708
8	V	1,209	5,142
9	B	1,209	2,497
10	W	1,125	5,038
11	CC	1,051	1,636
12	KKK	1,019	3,936
13	E	1,010	1,753
14	NNN	975	1,491
15	C	913	1,249
16	U	814	1,453
17	III	813	1,225
18	KK	806	1,336
19	EEE	739	2,301
20	XX	727	2,080
21	M	691	1,256
22	Y	685	1,007
23	LL	675	3,114
24	J	674	1,169
25	MMM	669	4,331

**Prescribers by Percent Narcotic Prescription**

Rank	Prescriber	% Narcotic Rxs	Narcotic Rxs	Total Rxs
1	C	73.10	913	1,249
2	Y	68.02	685	1,007
3	III	66.37	813	1,225
4	NNN	65.39	975	1,491
5	CC	64.24	1,051	1,636
6	H	60.96	651	1,068
7	KK	60.33	806	1,336
8	X	59.22	2,154	3,637
9	J	57.66	674	1,169
10	E	57.62	1,010	1,753
11	U	56.02	814	1,453
12	M	55.02	691	1,256
13	B	48.42	1,209	2,497
14	JJ	46.42	1,257	2,708
15	FF	36.67	396	1,080
16	Z	35.36	501	1,417
17	XX	34.95	727	2,080
18	MM	34.75	605	1,741
19	L	33.27	570	1,713
20	HHH	32.47	401	1,235
21	EEE	32.12	739	2,301
22	DDD	31.61	606	1,917
23	WW	31.51	554	1,758
24	TT	31.48	470	1,493
25	FFF	31.28	386	1,234

Fifteen prescribers (in red) appear in both listing.

## Strategy for Quantity Limit Reduction

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In a given month, approximately 95% of the claims for narcotic analgesics are for immediate release formulations. Claims for immediate release oral solid dosage forms with quantities greater than #120/claim, for the past 3 months, were analyzed to gain a better perspective. The following chart shows the number of prescriptions and quantities.

### Number of Claims with Quantities Greater than #120

Month	121-159 units/claim	160-179 units/claim	180-199 units/claim	200-239 units/claim	240 units or greater/claim	Total Claims
December 2012	811	134	1,374	94	315	2,728
January 2013	859	147	1,330	104	469	2,909
February 2013	826	137	1,264	90	428	2,745

Prescriptions written by prescribers listed in the top 25 lists account for 16% - 23% of all prescriptions with quantities greater than #120 per claim (16% during December and 23% during January and February).

## Recommendations

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The College of Pharmacy recommends implementation of quantity limit reductions after performance of prescriber surveys and general educational initiative regarding prescribing of immediate release narcotic analgesics. The educational information disseminated would also include the new quantity limit restrictions of less than #120 units per month (4 units per day). This educational initiative is expected to pre-emptively reduce the number of prescriptions for high volume immediate release narcotics. Following the educational initiative, quantity edits can be turned on to deny claims with quantities of #240 or greater in the first month, then tightened down to deny claims with quantities of #180 or greater in the following month, and so on, until the restriction is reduced to a maximum of #120 per 30 days (4 units per day). A manual prior authorization will be required for dosing in excess of the quantity limit.

During this same time, prescriber profiling will continue to be a priority as the DUR Board analyze data and recommend specific intervention(s).

### Principles for All Chronic Non-Cancer Pain Patients

1. **Self-care is the foundation for effective chronic non-cancer pain care** - Patient efforts to remain active and sustain rewarding life activities usually matter more than treatments prescribed for chronic pain.
2. **Your relationship with the patient supports effective self-care** - Listening, empathy, and encouraging patients to remain active and sustain rewarding life activities characterizes excellent care for patients with chronic pain.
3. **Guide care by progress toward resuming activities** - To track outcomes, have patients rate their ability to participate in rewarding life activities that pain makes difficult on a 0-10 scale (where 0 is “no difficulty” and 10 is “extreme difficulty”). Monitor return to work. For sedentary patients, consider tracking gradual increases in walking. Guiding care by changes in pain intensity should not be the primary indicator of successful care.
4. **Prioritize long-term effectiveness over short-term pain relief** - Differentiate treatments offered for short-term pain relief from steps patients take to resume activities. Short-term pain relief can be helpful, but long-term benefits of medications for chronic non-cancer pain are often modest, and risks may outweigh potential benefits.

### Principles When Considering Long-term Use of Opioids

1. **Put patient safety first** - Find common ground with patients by emphasizing their safety. Risks of long-term opioid use are significant, while benefits are typically modest. Possible adverse effects include addiction, overdose, dependence, depression, cognitive impairment, chronic constipation, motor vehicle accidents, and serious fractures due to falls, among others.
2. **Think twice before prescribing long-term opioids for axial low back pain, headache and fibromyalgia** - The long-term benefits of opioids for these conditions are unproven, while risks of addiction, overdose and other serious adverse effects are significant.
3. **Systematically evaluate risks** - Do not consider a therapeutic trial of opioids for chronic non-cancer pain before assessing risks of opioid misuse and abuse by taking a thorough history, reviewing the medical record, and checking Prescription Drug Monitoring Program data. Ask about past or current alcohol, tobacco and drug abuse, and mental health problems. Do not overestimate your ability to identify high risk patients. Risks of long-term opioid use are substantial, so be cautious when considering chronic opioid therapy, especially for higher risk patients.
4. **Consider intermittent opioid use** - Continuous use of long acting opioids has not been proven more effective or safer than intermittent use of short-acting opioids. Time-scheduled opioid prescribing has not been proven to reduce risks of opioid misuse or addiction. Higher doses with around-the-clock use may increase risks. Consider PRN prescriptions of short acting opioids to minimize risks of tolerance, dependence and dose-related medical risks of opioids. When opioids are prescribed for short-term pain management, set clear expectations for duration of use. Prescribe no more than needed for acute pain management--often a few days to a one week supply.
5. **Do not sustain opioid use long-term without decisive benefits** – Initial evaluation of long-term opioid use should be based on a therapeutic trial lasting no more than 90 days, preferably less. Long-term use of opioids should only be continued if decisive benefits are observed during the trial. Opioids should not be continued if improved function is not sustained. Involve the patient in determining functional goals for therapy. Continually monitor the benefit-to-harm ratio as benefits may decrease while harms accrue over time.
6. **Keep opioid doses as low as possible** - Reaching doses of 50 to 100 milligrams morphine equivalents or higher should trigger re-evaluation of the therapy. Risks increase with dose, but benefits of higher doses have not been established. Discontinuation is substantially more difficult at high dose.

\* These principles are not intended for palliative care of chronic pain at end of life.

### Principles for Patients Using Opioids Long-term

1. **Clearly communicate standardized expectations to reduce risks** - *Opioids have important hazards for patients, for family members, and for the community. Set clear expectations for use to reduce patient risks and for protecting others from unintentional or intentional diversion. Expectations should be standardized across all clinicians in your practice setting and communicated to patients verbally and with simple written materials.*
2. **Adhere to recommended precautions** - *Close and sustained monitoring of chronic opioid therapy is the standard for care. This includes asking about potential opioid misuse and about adverse behavioral, psychological and medical effects of opioids. Check urine drug screening results and Prescription Drug Monitoring data periodically. These precautions should increase in frequency and stringency for patients on regimens of 50 to 100 milligrams morphine equivalent dose or greater, and for patients with risk factors for opioid misuse. These safety precautions do not guarantee patient safety, so vigilance and caution are essential.*
3. **Avoid prescribing opioids and sedatives concurrently** - *Concurrent use of opioids and other CNS depressants increases risks of overdose and other adverse effects. Prescribing opioids and sedatives concurrently is not recommended.*
4. **Revisit discontinuing opioids or lowering dose** - *Regularly reassess whether doses can be reduced or opioids discontinued entirely. Many patients using opioids long-term are ambivalent about opioid use. Patients may be open to a trial of a slow taper. Opioids should be tapered when problems arise or if decisive benefits for function are not sustained. If a patient is diverting or engaging in high risk opioid misuse, discontinuation is mandatory. Non-fatal overdose should prompt immediate reduction of opioid dose or tapering off completely.*
5. **Identify and treat prescription opioid misuse disorders** – *When identified, patients with prescription opioid abuse or addiction should be treated rather than discharged from care. Know locally available referral options for addiction treatment including buprenorphine/naloxone treatment, methadone maintenance and counseling. Detoxification is not the standard of care, and is not supported by evidence, as the primary option for prescription opioid addiction.*

Prepared by the faculty of the National Summit for Opioid Safety (in alphabetical order): Jane Ballantyne, MD, MPH; Randi Beck, MD; Andrew Bertagnolli, PhD; Marie Boudreaux, MD; Hannah Burdge, DO; Mary Catlin, BSN, MPH; Roger Chou, MD; Gary Franklin, MD, MPH; Rivka Klaff, PharmD; Andrew Kolodny, MD; Erin Krebs, MD, MPH; Tony Mariano, PhD; Deborah Nelson, MA; Roger Rosenblatt, MD, MPH, MFR; Grant Scull, MD; Michelle Seelig, MD; Mark Stephens; Mark Sullivan, MD, PhD; David Tauben, MD; Claire Trescott, MD; and Michael Von Korff, ScD.

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\* These principles are not intended for palliative care of chronic pain at end of life.





# Appendix I





Top 100 Reimbursed Drugs by Fiscal Year		2012		2011	
Generic Name	Brand Name*	Rank	Amount Paid	Rank	Amount Paid
aripiprazole	Abilify	1	\$20,068,089.04	1	\$19,198,434.68
montelukast	Singulair	2	\$13,452,636.81	4	\$12,532,654.32
quetiapine	Seroquel	3	\$13,346,127.44	2	\$14,409,775.32
methylphenidate	Multiple Products	4	\$12,988,213.58	3	\$12,933,816.49
albuterol	Multiple Products	5	\$10,388,721.22	5	\$9,883,864.92
amphetamine-dextroamphetamine	Multiple Products	6	\$7,173,714.77	13	\$4,991,776.65
olanzapine	Zyprexa	7	\$6,836,513.91	6	\$8,396,685.78
budesonide inhalation	Pulmicort	8	\$6,240,760.33	8	\$6,549,143.69
lisdexamfetamine	Vyvanse	9	\$6,151,491.44	7	\$6,720,449.76
palivizumab	Synagis	10	\$5,995,348.89	11	\$5,172,392.11
dexamethylphenidate	Focalin	11	\$5,706,628.50	16	\$4,479,331.56
oxycodone	Multiple Products	12	\$5,659,354.95	9	\$5,881,683.41
antihemophilic factor (recombinant)	Multiple Products	13	\$5,134,983.60	14	\$4,845,018.11
fluticasone	Flovent	14	\$5,009,565.03	15	\$4,603,362.42
fluticasone-salmeterol	Advair	15	\$4,838,771.34	10	\$5,300,810.81
insulin glargine	Lantus	16	\$4,425,426.05	21	\$3,517,552.94
somatropin	Multiple Products	17	\$4,299,430.01	18	\$3,863,741.44
hydrocodone-acetaminophen	Multiple Products	18	\$4,232,744.91	20	\$3,650,412.54
atomoxetine	Strattera	19	\$4,110,414.13	26	\$2,782,840.08
paliperidone	Invega Inj	20	\$3,984,066.35	63	\$1,300,233.78
antihemophilic factor rAHF-PFM	Advate	21	\$3,921,808.72	25	\$2,809,236.33
telaprevir	Incivek	22	\$3,617,297.87	**	****
ziprasidone	Geodon	23	\$3,515,189.23	17	\$3,978,112.18
antiinhibitor coagulant complex	Feiba VH	24	\$3,483,793.05	12	\$5,069,283.24
insulin aspart	Novolog	25	\$3,332,611.60	27	\$2,711,559.78
duloxetine	Cymbalta	26	\$3,290,669.71	45	\$1,819,129.87
enoxaparin	Lovenox	27	\$3,019,341.19	24	\$2,813,904.24
azithromycin	Zithromax	28	\$3,008,226.61	19	\$3,786,289.64
efavirenz-emtricitabine-tenofovir	Atripla	29	\$2,880,942.65	32	\$2,342,125.70
adalimumab	Humira	30	\$2,794,494.70	33	\$2,289,102.31
cefixime	Suprax	31	\$2,717,284.81	44	\$1,909,318.60
clopidogrel	Plavix	32	\$2,584,671.30	29	\$2,481,618.05
paliperidone	Invega	33	\$2,582,594.85	23	\$2,877,150.52
etanercept	Enbrel	34	\$2,520,418.71	28	\$2,489,617.64
dornase	Pulmozyme	35	\$2,502,717.32	38	\$2,192,600.51
tobramycin	Tobi	36	\$2,485,310.58	42	\$1,959,860.65
peginterferon alfa-2a	Pegasys	37	\$2,462,534.18	40	\$2,136,207.10
quanfacine	Intuniv	38	\$2,416,586.67	**	****
tiotropium	Spiriva	39	\$2,260,522.64	47	\$1,724,811.54
pregabalin	Lyrica	40	\$2,193,967.59	37	\$2,219,688.74
clozapine	Multiple Products	41	\$2,180,312.29	43	\$1,918,735.11
glatiramer	Copaxone	42	\$2,169,545.26	49	\$1,715,711.26
c1 inhibitor (human)	Cinryze	43	\$2,137,463.15	22	\$3,186,787.24
amoxicillin	Amoxil	44	\$2,054,532.21	35	\$2,230,858.29
fluticasone	Flonase	45	\$2,038,082.52	31	\$2,359,782.02
ipratropium-albuterol	Multiple Products	46	\$1,992,601.95	53	\$1,508,352.08
buprenorphine-naloxone	Suboxone	47	\$1,910,814.56	71	\$1,197,886.02
cefdirin	Omnicef	48	\$1,904,459.16	36	\$2,224,990.94
levalbuterol	Xopenex	49	\$1,877,959.55	41	\$2,087,475.73
coagulation factor VIIa (recombinant)	Novoseven	50	\$1,872,184.42	65	\$1,277,638.24
amoxicillin-k clavulanate	Augmentin	51	\$1,842,074.22	30	\$2,401,114.45
insulin lispro (human)	Humalog	52	\$1,814,605.89	54	\$1,500,812.05
insulin detemir	Levemir	53	\$1,771,070.43	60	\$1,324,046.60
interferon beta-1a	Rebif	54	\$1,755,601.26	57	\$1,378,584.95
escitalopram	Lexapro	55	\$1,638,116.83	51	\$1,585,149.20
levetiracetam	Keppra	56	\$1,591,043.16	48	\$1,716,658.17
etonogestrel-ethinyl estradiol ring	Nuvaring	57	\$1,537,487.59	86	\$920,217.97
pioglitazone	Actos	58	\$1,527,362.09	39	\$2,156,525.25
gabapentin	Neurontin	59	\$1,524,866.01	91	\$859,809.82
oxcarbazepine	Trileptal	60	\$1,504,353.47	59	\$1,336,583.27
deferasirox	Exjade	61	\$1,501,451.73	66	\$1,273,964.69
fentanyl	Duragesic	62	\$1,458,484.95	62	\$1,310,595.21
risperidone	Risperdal Inj	63	\$1,454,159.46	50	\$1,601,282.26
imatinib	Gleevec	64	\$1,450,400.90	82	\$967,972.29
pancrelipase	Multiple Products	65	\$1,439,912.05	61	\$1,317,096.85
emtricitabine-tenofovir	Truvada	66	\$1,436,000.22	70	\$1,213,359.90
sitagliptin	Januvia	67	\$1,389,989.60	84	\$961,679.27
epinephrine inj	Multiple Products	68	\$1,384,465.73	98	\$765,991.76
oseltamivir	Tamiflu	69	\$1,361,108.86	34	\$2,246,369.21
cetirizine	Zyrtec	70	\$1,326,722.82	56	\$1,427,018.50

<b>Top 100 Drugs by Fiscal Year</b>		<b>2012</b>		<b>2011</b>	
<b>Generic Name</b>	<b>Brand Name*</b>	<b>Rank</b>	<b>Amount Paid</b>	<b>Rank</b>	<b>Amount Paid</b>
risperidone	Resperidal	71	\$1,309,364.43	67	\$1,253,905.07
omeprazole	Prilosec	72	\$1,305,803.77	58	\$1,346,508.49
alprazolam	Xanax	73	\$1,302,280.26	85	\$950,655.72
coagulation factor IX (recombinant)	Benefix	74	\$1,273,060.94	46	\$1,809,179.41
lamotrigine	Lamotrigine	75	\$1,229,551.64	64	\$1,290,697.38
divalproex	Depakote	76	\$1,217,700.07	55	\$1,434,834.80
oxycodone-acetaminophen	Multiple Products	77	\$1,180,078.58	78	\$1,039,369.02
norgestimate-eth estradiol	Multiple Products	78	\$1,164,436.76	76	\$1,075,651.79
memantine	Namenda	79	\$1,150,390.71	99	\$763,105.42
diazepam rectal gel	Diastat	80	\$1,146,524.83	75	\$1,082,964.06
oxymorphone	Opana	81	\$1,137,772.39	83	\$965,050.25
spacer/aerosol-holding chamber	Multiple Products	82	\$1,134,839.64	73	\$1,105,081.48
prednisolone	Multiple Products	83	\$1,133,060.25	72	\$1,153,926.87
sapropterin	Kuvan	84	\$1,106,731.09	93	\$843,041.38
atorvastatin	Lipitor	85	\$1,087,681.74	68	\$1,252,773.76
lacosamide	Vimpat	86	\$1,024,410.63	**	****
idursulfase	Elaprase	87	\$945,131.14	**	****
iloperidone	Fanapt	88	\$943,571.75	**	****
linezolid	Zyvox	89	\$938,158.93	96	\$779,545.90
morphine	Multiple Products	90	\$912,446.22	94	\$834,888.45
peginterferon alfa-2b	Peg-Intron	91	\$910,262.93	**	****
desmopressin	Stimate	92	\$895,392.04	90	\$868,098.59
norelgestromin-ethinyl estradiol	Ortho Evra	93	\$875,981.62	1	****
budesonide-formoterol	Symbicort	94	\$862,242.02	88	\$888,101.13
loratadine	Claritin	95	\$861,057.82	79	\$998,024.19
mometasone	Asmanex	96	\$860,387.76	81	\$970,839.33
permethrin	Multiple Products	97	\$827,425.34	**	****
varenicline	Chantix	98	\$811,334.58	**	****
capecitabine	Xeloda	99	\$808,675.31	**	****
pegademase	Adagen	100	\$792,741.72	**	****

\*Includes brand and generic where applicable.

# Top 50 Medications by Total Number of Claims

RANK	CLAIMS	Generic Name*	Claims	Units	Days	Members	Cost	Units/Day	Claims/Day	Cost/Day	Percentage Cost
1	343,706	hydrocodone-acetaminophen	343,706	22,851,730	5,175,679	110,771	\$4,232,744.91	4.42	3.10	\$0.82	3.50%
2	240,622	albuterol	240,622	13,649,307	5,148,987	104,474	\$10,388,721.22	2.65	2.30	\$2.02	8.59%
3	217,995	amoxicillin	217,995	23,399,500	2,098,940	157,932	\$2,054,532.21	11.15	1.38	\$0.98	1.70%
4	166,370	azithromycin	166,370	2,523,646	829,134	121,334	\$3,008,226.61	3.04	1.37	\$3.63	2.49%
5	161,463	cetirizine	161,463	17,563,551	4,709,990	72,545	\$1,326,722.82	3.73	2.23	\$0.28	1.10%
6	142,081	alprazolam	142,081	9,450,768	3,990,803	23,744	\$1,302,280.26	2.37	5.98	\$0.33	1.08%
7	97,487	omeprazole	97,487	4,067,961	3,231,240	28,409	\$1,305,803.77	1.26	3.43	\$0.40	1.08%
8	96,004	ibuprofen	96,004	6,416,495	1,500,145	68,719	\$748,924.98	4.28	1.40	\$0.50	0.62%
9	91,085	methylphenidate	91,085	3,453,000	2,707,861	15,229	\$12,988,213.58	1.28	5.98	\$4.80	10.74%
10	90,525	loratadine	90,525	6,807,986	2,752,295	42,103	\$861,057.82	2.47	2.15	\$0.31	0.71%
11	85,773	montelukast	85,773	2,569,143	2,571,063	19,552	\$13,452,636.81	1.00	4.39	\$5.23	11.13%
12	80,644	fluticasone	80,644	1,290,160	2,692,282	45,452	\$2,038,082.52	0.48	1.77	\$0.76	1.69%
13	79,223	sulfamethoxazole-trimethoprim	79,223	6,703,896	858,275	61,535	\$702,073.18	7.81	1.29	\$0.82	0.58%
14	78,017	clonazepam	78,017	4,707,233	2,246,322	14,524	\$640,407.28	2.10	5.37	\$0.29	0.53%
15	74,920	risperidone	74,920	3,333,968	2,300,775	15,239	\$1,309,364.43	1.45	4.92	\$0.57	1.08%
16	74,030	clonidine	74,030	3,370,147	2,296,541	13,803	\$607,087.15	1.47	5.36	\$0.26	0.50%
17	72,206	tramadol	72,206	5,417,699	1,275,113	28,027	\$629,830.46	4.25	2.58	\$0.49	0.52%
18	70,213	citalopram	70,213	2,495,533	2,345,012	19,954	\$539,602.06	1.06	3.52	\$0.23	0.45%
19	63,906	lisinopril	63,906	2,788,990	2,543,736	15,995	\$427,420.19	1.10	4.00	\$0.17	0.35%
20	60,400	amoxicillin	60,400	5,158,362	603,544	49,649	\$1,842,074.22	8.55	1.22	\$3.05	1.52%
21	60,067	amphetamine-dextroamphetamine	60,067	2,245,351	1,783,904	10,476	\$7,173,714.77	1.26	5.73	\$4.02	5.93%
22	59,420	sertraline	59,420	2,286,365	1,931,845	15,503	\$519,307.56	1.18	3.83	\$0.27	0.43%
23	57,578	cyclobenzaprine	57,578	2,898,513	1,205,893	27,761	\$453,347.75	2.40	2.07	\$0.38	0.37%
24	57,547	trazodone	57,547	2,333,237	1,824,467	14,955	\$513,358.30	1.28	3.85	\$0.28	0.42%
25	56,778	gabapentin	56,778	5,360,286	1,747,418	13,813	\$1,524,866.01	3.07	4.11	\$0.87	1.26%
26	56,437	oxycodone	56,437	3,278,115	715,814	29,966	\$1,180,078.58	4.58	1.88	\$1.65	0.98%
27	55,463	promethazine	55,463	2,066,917	399,681	35,673	\$623,696.21	5.17	1.55	\$1.56	0.52%
28	55,405	prednisolone	55,405	2,076,172	319,307	40,588	\$1,133,060.25	6.50	1.37	\$3.55	0.94%
29	54,449	cephalexin	54,449	4,268,560	493,107	46,425	\$620,838.99	8.66	1.17	\$1.26	0.51%
30	53,063	levothyroxine	53,063	2,123,406	2,110,787	10,747	\$617,890.87	1.01	4.94	\$0.29	0.51%
31	50,709	cefdinir	50,709	3,470,762	506,141	39,857	\$1,904,459.16	6.86	1.27	\$3.76	1.58%
32	49,680	fluoxetine	49,680	2,117,620	1,634,889	12,950	\$496,407.98	1.30	3.84	\$0.30	0.41%
33	47,490	diazepam	47,490	2,948,132	1,268,682	10,526	\$337,615.65	2.32	4.51	\$0.27	0.28%
34	47,370	prednisone	47,370	1,001,728	477,685	34,664	\$232,954.32	2.10	1.37	\$0.49	0.19%
35	46,635	metformin	46,635	3,140,491	1,507,481	10,952	\$434,366.07	2.08	4.26	\$0.29	0.36%
36	44,681	lorazepam	44,681	2,500,544	1,152,572	10,726	\$334,895.02	2.17	4.17	\$0.29	0.28%
37	43,148	zolpidem	43,148	1,241,729	1,249,935	10,648	\$418,250.47	0.99	4.05	\$0.33	0.35%
38	41,035	ranitidine	41,035	3,530,292	1,237,488	17,203	\$352,724.49	2.85	2.39	\$0.29	0.29%
39	40,853	dexmethylphenidate	40,853	1,301,774	1,211,707	6,761	\$5,706,628.50	1.07	6.04	\$4.71	4.72%
40	39,751	codeine-acetaminophen	39,751	2,798,447	268,277	31,471	\$364,761.09	10.43	1.26	\$1.36	0.30%

## Top 50 Medications by Total Number of Claims

RANK CLAIMS	Generic Name*	Claims	Units	Days	Members	Cost	Units/Day	Claims/Day	Cost/Day	Percentage cost
41	lisdexamfetamine	38,715	1,158,669	1,154,135	5,716	\$6,151,491.44	1.00	6.77	\$5.33	5.09%
42	triamcinolone	37,782	3,085,642	553,999	27,597	\$517,124.21	5.57	1.37	\$0.93	0.43%
43	simvastatin	37,542	1,552,637	1,557,678	9,018	\$368,658.79	1.00	4.16	\$0.24	0.30%
44	mupirocin	36,376	854,394	404,363	30,451	\$550,309.22	2.11	1.19	\$1.36	0.46%
45	fluticasone	35,900	410,970	1,120,865	16,039	\$5,009,565.03	0.37	2.24	\$4.47	4.14%
46	ondansetron	34,563	326,866	861,683	27,678	\$270,655.40	0.38	1.25	\$0.31	0.22%
47	meloxicam	34,182	1,322,083	1,150,650	15,923	\$239,777.60	1.15	2.15	\$0.21	0.20%
48	divalproex	33,639	2,716,675	1,010,593	5,541	\$1,217,700.07	2.69	6.07	\$1.20	1.01%
49	norgestimate-eth estradial	32,882	1,155,822	1,156,736	8,674	\$1,164,436.76	1.00	3.79	\$1.01	0.96%
50	aripiprazole	32,449	1,008,636	1,016,942	6,034	\$20,068,089.04	0.99	5.38	\$19.73	16.60%
		<b>3,758,259</b>	<b>214,599,910</b>	<b>84,912,461</b>		<b>\$120,906,836.08</b>	<b>2.53</b>	<b>8.48</b>	<b>\$1.42</b>	

\*Includes brand and generic products where applicable.

## Therapeutic Class by Fiscal Year

Penicillins	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Natural	18,802	\$184,620.96	17,580	\$169,994.85
Ampicillins	248,906	\$2,251,134.24	219,262	\$2,070,641.10
Penicillinase-Resistant	498	\$66,329.96	478	\$64,422.80
Extended Spectrum	0	\$0.00	0	\$0.00
Amidinopenicillins	0	\$0.00	0	\$0.00
Penicillin Combinations	69,615	\$2,460,222.08	60,529	\$1,901,808.21
<b>Total:</b>	<b>337,821</b>	<b>\$4,962,307.24</b>	<b>297,849</b>	<b>\$4,206,866.96</b>

Cephalosporins	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Cephalosporins - 1st Generation	60,698	\$835,103.31	56,524	\$687,410.09
Cephalosporins - 2nd Generation	18,731	\$633,376.48	15,372	\$665,177.52
Cephalosporins - 3rd Generation	67,439	\$4,339,957.85	65,155	\$5,001,709.57
Cephalosporins - 4th Generation	92	\$12,710.72	85	\$13,920.14
Cephalosporins Other	0	\$0.00	9	\$9,535.62
Cephalosporin Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>146,960</b>	<b>\$5,821,148.36</b>	<b>137,145</b>	<b>\$6,377,752.94</b>

Macrolide Antibiotics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Erythromycins	3,687	\$73,773.02	2,638	\$145,807.85
Troleandomycin	0	\$0.00	0	\$0.00
Not Classified	0	\$0.00	0	\$0.00
Azithromycin	189,133	\$3,786,289.64	166,370	\$3,008,226.61
Clarithromycin	3,353	\$104,755.02	2,924	\$231,568.28
Dirithromycin	0	\$0.00	0	\$0.00
Miocamycin	0	\$0.00	0	\$0.00
Roxithromycin	0	\$0.00	0	\$0.00
Spiramycin	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>196,173</b>	<b>\$3,964,817.68</b>	<b>171,932</b>	<b>\$3,385,602.74</b>

Tetracyclines	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Tetracyclines	28,121	\$327,217.62	28,094	\$283,567.37
Tetracycline Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>28,121</b>	<b>\$327,217.62</b>	<b>28,094</b>	<b>\$283,567.37</b>

Fluoroquinolones	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Fluoroquinolones	28,008	\$1,628,775.45	29,782	\$449,372.11
Fluoroquinolone Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>28,008</b>	<b>\$1,628,775.45</b>	<b>29,782</b>	<b>\$449,372.11</b>

Aminoglycosides	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Aminoglycosides	939	\$1,980,101.37	959	\$2,511,148.75
<b>Total:</b>	<b>939</b>	<b>\$1,980,101.37</b>	<b>959</b>	<b>\$2,511,148.75</b>

Sulfonamides	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Sulfonamides	2	\$844.09	2	\$593.79
Sulfa Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>2</b>	<b>\$844.09</b>	<b>2</b>	<b>\$593.79</b>

Antimycobacterial Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antimycobacterial Agents	646	\$42,094.06	652	\$37,201.91
Anti TB Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>646</b>	<b>\$42,094.06</b>	<b>652</b>	<b>\$37,201.91</b>

Antifungals	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antifungals	6,316	\$584,350.78	6,312	\$339,541.16
Imidazole-Related Antifungals	22,800	\$664,912.02	24,601	\$582,278.76
Antifungal - Glucan Synthesis Inhibitors	18	\$77,020.09	34	\$55,190.08
<b>Total:</b>	<b>29,134</b>	<b>\$1,326,282.89</b>	<b>30,947</b>	<b>\$977,010.00</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Antiviral</b>				
Antiretrovirals	8,235	\$7,472,238.95	9,006	\$8,843,363.16
CMV Agents	192	\$355,574.77	167	\$347,945.52
Hepatitis Agents	2,262	\$3,209,564.88	2,842	\$7,972,983.94
Herpes Agents	14,537	\$1,085,635.62	15,079	\$661,378.68
Influenza Agents	27,000	\$2,254,065.59	10,071	\$1,362,624.64
Respiratory Syncytial Virus	0	\$0.00	0	\$0.00
Misc. Antivirals	0	\$0.00	0	\$0.00
Antiviral Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>52,226</b>	<b>\$14,377,079.81</b>	<b>37,165</b>	<b>\$19,188,295.94</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Antimalarial</b>				
Antimalarial	2,465	\$36,021.56	3,058	\$38,984.86
Antimalarial Combinations	45	\$8,519.64	29	\$4,942.16
<b>Total:</b>	<b>2510</b>	<b>\$44,541.20</b>	<b>3087</b>	<b>\$43,927.02</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Amebicides</b>				
Amebicides	0	\$0.00	0	\$0.00
Amebicide Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>0</b>	<b>\$0.00</b>	<b>0</b>	<b>\$0.00</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Anthelmintic</b>				
Anthelmintic	4,532	\$69,787.68	4,265	\$80,959.97
Anthelmintic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>4,532</b>	<b>\$69,787.68</b>	<b>4,265</b>	<b>\$80,959.97</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Misc. Anti-Infectives</b>				
Misc. Anti-Infectives	22,079	\$1,276,528.96	25,356	\$1,767,582.23
Polymyxins	2	\$82.60	0	\$0.00
Carbapenems	505	\$310,385.04	354	\$171,805.97
Chloramphenicols	0	\$0.00	0	\$0.00
Ketolides	0	\$0.00	0	\$0.00
Lincosamides	15,771	\$566,887.71	17,696	\$577,291.99
Oxazolidinones	404	\$779,545.90	468	\$938,158.93
Streptogramins	0	\$0.00	1	\$4,641.05
Cyclic Lipopeptides	95	\$199,667.93	112	\$221,748.57
Glycylcyclines	26	\$19,574.05	12	\$23,354.11
Leprostatics	234	\$7,176.81	240	\$7,020.93
Antiprotozoal Agents	98	\$39,621.85	64	\$39,339.55
Anti-Infective Adjuvants	0	\$0.00	0	\$0.00
Sepsis Syndrome Agents	0	\$0.00	0	\$0.00
Misc. Anti-Infective Combinations	87,201	\$904,658.54	79,560	\$714,559.58
<b>Total:</b>	<b>126,415</b>	<b>\$4,104,129.39</b>	<b>123,863</b>	<b>\$4,465,502.91</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Vaccines</b>				
Viral Vaccines	3,444	\$58,867.22	4,165	\$83,443.80
Bacterial Vaccines	186	\$9,264.54	235	\$13,493.07
Mixed Vaccine Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>3,630</b>	<b>\$68,131.76</b>	<b>4,400</b>	<b>\$96,936.87</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Toxoids</b>				
Toxoids	8	\$305.93	24	\$1,065.38
Toxoid Combinations	37	\$1,435.17	10	\$384.73
<b>Total:</b>	<b>45</b>	<b>\$1,741.10</b>	<b>34</b>	<b>\$1,450.11</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Passive Immunizing Agents</b>				
Misc. Anti-Infectives	22,079	\$1,276,528.96	25,356	\$1,767,582.23
Polymyxins	2	\$82.60	0	\$0.00
Carbapenems	505	\$310,385.04	354	\$171,805.97
Chloramphenicols	0	\$0.00	0	\$0.00
Passive Immunizing Agents - Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>3,676</b>	<b>\$5,749,988.58</b>	<b>3,823</b>	<b>\$7,058,931.04</b>

Biologicals Misc	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Biologicals Misc	24	\$712,415.52	26	\$792,741.72
Allergenic Extracts	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>24</b>	<b>\$712,415.52</b>	<b>26</b>	<b>\$792,741.72</b>

Antineoplastics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Alkylating Agents	221	\$459,183.41	249	\$600,369.84
Antineoplastic Antibiotics	0	\$0.00	31	\$7,386.64
Antineoplastic Enzymes	0	\$0.00	18	\$107,188.10
Antimetabolites	4,532	\$709,650.91	4,756	\$892,948.64
Antineoplastic - Angiogenesis Inhibitors	5	\$47,846.76	23	\$116,199.53
Antineoplastic - Antibodies	2	\$11,886.07	5	\$26,333.27
Antineoplastic - Hormonal Agents	6,697	\$1,053,588.22	6,291	\$845,179.12
Antineoplastic - Immunomodulators	0	\$0.00	0	\$0.00
Mitotic Inhibitors	35	\$19,219.57	416	\$19,970.08
Antineoplastic Enzyme Inhibitors	478	\$2,833,718.56	679	\$4,499,980.93
Topoisomerase I Inhibitors	21	\$74,951.54	25	\$17,352.57
Antineoplastic Radiopharmaceuticals	0	\$0.00	0	\$0.00
Antineoplastics Misc.	357	\$233,664.16	469	\$296,144.45
Chemotherapy Rescue/Antidote Agents	78	\$12,572.49	73	\$7,634.14
Chemotherapy Adjuvants	0	\$0.00	6	\$23,758.36
Investigational - Antineoplastics	0	\$0.00	0	\$0.00
Antineoplastic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>12,426</b>	<b>\$5,456,281.69</b>	<b>13,041</b>	<b>\$7,460,445.67</b>

Corticosteroids	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Glucocorticosteroids	151,369	\$1,945,669.41	152,468	\$2,353,249.74
Mineralocorticoids	875	\$22,154.72	1005	\$22,405.17
<b>Total:</b>	<b>152,244</b>	<b>\$1,967,824.13</b>	<b>153473</b>	<b>\$2,375,654.91</b>

Androgen-Anabolic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Androgens	1,365	\$272,815.27	1,052	\$224,023.36
Anabolic Steroids	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>1,365</b>	<b>\$272,815.27</b>	<b>1052</b>	<b>\$224,023.36</b>

Estrogens	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Estrogens	14,250	\$688,132.67	15,173	\$805,092.53
Estrogen Combinations	1,913	\$155,804.97	1,958	\$176,676.93
<b>Total:</b>	<b>16,163</b>	<b>\$843,937.64</b>	<b>17,131</b>	<b>\$981,769.46</b>

Contraceptives	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Progestin Contraceptives - Oral	5,591	\$189,564.85	8,537	\$273,457.46
Progestin Contraceptives - Injectable	9,655	\$396,030.07	10,480	\$458,594.11
Progestin IUD	140	\$99,138.09	0	\$0.00
Progestin Implants	277	\$183,599.00	523	\$364,456.95
Emergency Contraceptives	840	\$31,256.74	1,217	\$42,961.66
Combination Contraceptives - Transdermal	5,360	\$503,918.46	8,496	\$875,981.62
Combination Contraceptives - Vaginal	9,737	\$920,217.97	14,239	\$1,537,487.59
Combination Contraceptives - Injectable	0	\$0.00	0	\$0.00
Combination Contraceptives - Oral	91,153	\$4,612,320.30	121,072	\$5,358,445.37
<b>Total:</b>	<b>122,753</b>	<b>\$6,936,045.48</b>	<b>164,564</b>	<b>\$8,911,384.76</b>

Progestins	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Progestins	4,438	\$300,495.63	5,320	\$350,382.54
<b>Total:</b>	<b>4,438</b>	<b>\$300,495.63</b>	<b>5320</b>	<b>\$350,382.54</b>

Antidiabetic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Insulin	54,339	\$10,990,099.62	58,513	\$13,628,494.12
Amylin Analogs	40	\$21,896.53	40	\$29,000.56
Incretin Mimetic Agents	1,170	\$395,836.32	1,512	\$561,536.04
Sulfonylureas	20,850	\$275,406.16	21,393	\$273,846.31
Amino Acid Derivatives	0	\$0.00	0	\$0.00
Biguanides	41,990	\$354,517.03	46,635	\$434,366.07
Meglitinide Analogues	297	\$43,570.06	279	\$36,552.82
Diabetic Other	1,825	\$391,685.99	1,761	\$421,289.70
Aldose Reductase Inhibitors	0	\$0.00	0	\$0.00
Alpha-Glucosidase Inhibitors	254	\$16,497.21	213	\$13,542.80
Dipeptidyl Peptidase-4	4,019	\$1,088,479.78	5,790	\$1,633,717.45
Dopamine Receptor Agonists - Antidiabetic	0	\$0.00	0	\$0.00
Insulin Sensitizing Agents	8,481	\$2,380,634.40	4,902	\$1,556,956.01
Antidiabetic Combinations	5,824	\$852,198.79	5,799	\$903,141.63
<b>Total:</b>	<b>139,089</b>	<b>\$16,810,821.89</b>	<b>146,837</b>	<b>\$19,492,443.51</b>

Thyroid	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Thyroid Hormones	48,736	\$562,038.99	54,630	\$650,794.35
Antithyroid Agents	937	\$20,155.91	1,176	\$23,994.28
<b>Total:</b>	<b>49,673</b>	<b>\$582,194.90</b>	<b>55,806</b>	<b>\$674,788.63</b>

Oxytocics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Oxytocics	759	\$11,105.51	682	\$9,027.70
Abortifacients/Agents For Cervical Ripening	0	\$0.00	0	\$0.00
Oxytocic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>759</b>	<b>\$11,105.51</b>	<b>682</b>	<b>\$9,027.70</b>

Misc. Endocrine	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Adrenal Steroid Inhibitors	0	\$0.00	0	\$0.00
Calcium Regulators	7,471	\$344,843.65	6,523	\$296,844.69
Hormone Receptor Modulators	455	\$73,975.67	446	\$82,185.54
Fertility Regulators	7	\$837.81	4	\$3,438.06
Luteinizing Hormone Releasing-Hormone	0	\$0.00	0	\$0.00
Lhrh/Gnrh Agonist Analog Pituitary Suppressants	344	\$503,505.62	263	\$534,654.69
Gnrh/Lhrh Antagonists	0	\$0.00	0	\$0.00
Growth Hormone	1,599	\$3,939,311.53	1,830	\$4,352,936.14
Growth Hormone Releasing Hormone	0	\$0.00	0	\$0.00
Growth Hormone	0	\$0.00	0	\$0.00
Somatostatic Agents	46	\$5,101.10	106	\$15,057.75
Growth Hormone Receptor Antagonist	0	\$0.00	0	\$0.00
Posterior Pituitary	12,553	\$1,017,020.84	12,767	\$1,087,352.97
Corticotropin	9	\$561,574.61	12	\$623,325.93
Prolactin Inhibitors	80	\$10,789.86	104	\$15,244.35
Vasopressin Receptor Antagonists	3	\$24,481.36	16	\$135,514.00
Progesterone Receptor Antagonists	0	\$0.00	0	\$0.00
Menopausal Symptoms Suppressants	0	\$0.00	0	\$0.00
Uterine Relaxants	0	\$0.00	0	\$0.00
Metabolic Modifiers	2,232	\$1,986,652.06	2,410	\$2,938,900.33
Endocrine And Metabolic Agents Misc. - Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>24,799</b>	<b>\$8,468,094.11</b>	<b>24,481</b>	<b>\$10,085,454.45</b>

Cardiotonics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Phosphodiesterase Inhibitors	2	\$12,511.55	20	\$44,183.29
Cardiac Glycosides	5,050	\$67,755.47	4,688	\$59,193.02
Calcium Sensitizers	0	\$0.00	0	\$0.00
Cardioprotectants	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>5,052</b>	<b>\$80,267.02</b>	<b>4,708</b>	<b>\$103,376.31</b>



Antianginal Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Nitrates	7,558	\$164,871.92	7,877	\$171,009.27
Potassium-Channel Activators	0	\$0.00	0	\$0.00
Antianginals-Other	1,047	\$263,955.83	1,255	\$346,315.34
Antianginal Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>8,605</b>	<b>\$428,827.75</b>	<b>9,132</b>	<b>\$517,324.61</b>

Beta Blockers	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Beta Blockers Non-Selective	12,470	\$178,712.34	14,074	\$208,656.46
Beta Blockers Cardio-Selective	51,489	\$1,012,299.00	55,652	\$1,165,848.77
Alpha-Beta Blockers	15,818	\$258,270.48	17,815	\$284,715.70
Beta Blocker Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>79,777</b>	<b>\$1,449,281.82</b>	<b>87,541</b>	<b>\$1,659,220.93</b>

Calcium Blockers	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Calcium Blockers	38,988	\$716,383.20	41,962	\$768,120.88
Calcium Channel Blocker Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>38,988</b>	<b>\$716,383.20</b>	<b>41,962</b>	<b>\$768,120.88</b>

Antiarrhythmic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiarrhythmic	0	\$0.00	0	\$0.00
Antiarrhythmics Type I - Nonspecific	0	\$0.00	0	\$0.00
Antiarrhythmics Type I-A	17	\$542.16	5	\$142.84
Antiarrhythmics Type I-B	38	\$683.21	30	\$540.18
Antiarrhythmics Type I-C	343	\$13,855.09	411	\$16,564.05
Antiarrhythmics Type Iii	1,651	\$55,184.57	1,900	\$75,383.68
Misc. Antiarrhythmic	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>2,049</b>	<b>\$70,265.03</b>	<b>2,346</b>	<b>\$92,630.75</b>

Antihypertensive	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
ACE Inhibitors	74,140	\$524,984.23	79,763	\$553,378.11
Angiotensin II Receptor Antagonists	6,542	\$617,157.94	9,341	\$589,257.42
Direct Renin Inhibitors	169	\$24,885.76	158	\$23,329.59
Antiadrenergic Antihypertensives	86,030	\$931,053.42	97,536	\$853,779.56
Selective Aldosterone Receptor Antagonists	53	\$5,316.01	55	\$4,271.13
Agents For Pheochromocytoma	1	\$79.72	0	\$0.00
Vasodilators	2,254	\$53,610.59	2,789	\$62,624.97
Antihypertensives - Monoamine Oxidase Inhibitors	0	\$0.00	0	\$0.00
Misc. Antihypertensives	0	\$0.00	0	\$0.00
Antihypertensive Combinations	28,133	\$938,426.79	30,379	\$872,676.32
<b>Total:</b>	<b>197,322</b>	<b>\$3,095,514.46</b>	<b>220,021</b>	<b>\$2,959,317.10</b>

Diuretics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Carbonic Anhydrase Inhibitors	609	\$46,483.82	639	\$51,427.14
Loop Diuretics	27,695	\$217,621.41	27,842	\$210,920.31
Mercurial Diuretics	0	\$0.00	0	\$0.00
Osmotic Diuretics	0	\$0.00	0	\$0.00
Potassium Sparing Diuretics	6,597	\$115,709.67	7,181	\$118,979.02
Thiazides And Thiazide-Like Diuretics	26,805	\$193,779.40	28,511	\$199,385.33
Miscellaneous Diuretics	0	\$0.00	0	\$0.00
Combination Diuretics	3,914	\$38,002.22	3,483	\$31,521.43
<b>Total:</b>	<b>65,620</b>	<b>\$611,596.52</b>	<b>67,656</b>	<b>\$612,233.23</b>

Vasopressors	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Vasopressors	340	\$16,818.62	359	\$18,116.81
Anaphylaxis Therapy Agents	5,849	\$765,991.76	7,486	\$1,384,465.73
Vasopressor Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>6,189</b>	<b>\$782,810.38</b>	<b>7,845</b>	<b>\$1,402,582.54</b>

Antihyperlipidemic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Bile Sequestrants	2,184	\$120,928.88	2,485	\$144,033.12
Fibric Acid Derivatives	10,662	\$996,677.90	12,968	\$1,251,247.36
Intestinal Cholesterol Absorption Inhibitors	582	\$95,674.38	509	\$97,726.87
Hmg Coa Reductase Inhibitors	63,066	\$2,066,949.52	69,087	\$2,173,069.72
Nicotinic Acid Derivatives	1,981	\$248,489.20	1,826	\$262,118.60
Misc. Antihyperlipidemics	1,596	\$229,326.24	1,269	\$197,946.26
Antihyperlipidemic Combinations	991	\$170,537.98	681	\$134,936.93
<b>Total:</b>	<b>81,062</b>	<b>\$3,928,584.10</b>	<b>88,825</b>	<b>\$4,261,078.86</b>

Misc. Cardiovascular	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Peripheral Vasodilators	2	\$17.30	2	\$17.95
Pulmonary Hypertension - Phosphodiesterase Inhibitors	559	\$476,736.64	649	\$662,134.06
Microvasodilators	0	\$0.00	0	\$0.00
Pulmonary Hypertension - Endothelin Receptor Antagonists	175	\$773,536.77	160	\$566,195.75
Prostaglandin Vasodilators	45	\$636,795.03	42	\$407,638.84
Vasoactive Natriuretic Peptides	0	\$0.00	0	\$0.00
Cardioplegic Soln	0	\$0.00	0	\$0.00
Vasoconstrictor Inhibitors	0	\$0.00	0	\$0.00
Impotence Agents	25	\$6,504.65	48	\$14,457.27
Vasoprotectants	0	\$0.00	0	\$0.00
Misc. Cardiovascular Combinations	986	\$235,802.92	631	\$163,977.20
<b>Total:</b>	<b>1,792</b>	<b>\$2,129,393.31</b>	<b>1,532</b>	<b>\$1,814,421.07</b>

Antihistamines	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Alkylamines	1	\$18.21	4	\$158.16
Ethanolamines	907	\$9,346.29	1,542	\$18,286.27
Ethylenediamines	0	\$0.00	0	\$0.00
Phenothiazines	58,759	\$585,244.86	55,463	\$623,696.21
Piperidines	4,700	\$72,504.22	4,902	\$79,277.80
Non-Sedating	257,388	\$2,615,923.97	253,469	\$2,253,574.45
Miscellaneous	0	\$0.00	0	\$0.00
Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>321,755</b>	<b>\$3,283,037.55</b>	<b>315,380</b>	<b>\$2,974,992.89</b>

Systemic And Topical Nasal Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Sympathomimetic Decongestants	904	\$5,571.05	1,042	\$6,144.91
Nasal Steroids	85,042	\$2,758,469.81	85,143	\$2,375,806.74
Nasal Anti-Infectives	12	\$1,588.42	5	\$545.10
Nasal Anticholinergics	762	\$11,528.48	873	\$12,026.86
Nasal Antiallergy	406	\$41,723.25	149	\$18,354.93
Nasal Mucolytics	0	\$0.00	0	\$0.00
Misc. Nasal Preparations	0	\$0.00	0	\$0.00
Nasal Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>87,126</b>	<b>\$2,818,881.01</b>	<b>87,212</b>	<b>\$2,412,878.54</b>

Cough/Cold/Allergy	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antitussives	98	\$647.94	119	\$965.56
Expectorants	7	\$56.93	112	\$993.33
Mucolytics	849	\$75,132.19	567	\$70,202.84
Misc. Respiratory Inhalants	1,167	\$30,950.62	1,033	\$32,682.37
Cough/Cold/Allergy Combinations	221	\$5,685.02	238	\$3,762.75
<b>Total:</b>	<b>2,342</b>	<b>\$112,472.70</b>	<b>2,069</b>	<b>\$108,606.85</b>

Antiasthmatic And Bronchodilator Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiasthmatics - Anticholinergics	12,217	\$1,924,399.62	12,793	\$2,505,124.95
Anti-Inflammatory Agents	12	\$641.12	9	\$552.85
Sympathomimetics	303,459	\$20,093,302.95	288,161	\$20,368,916.77
Xanthines	1,363	\$38,122.01	1,308	\$33,520.16
Steroid Inhalants	77,565	\$12,958,184.95	74,372	\$13,332,982.46
Leukotriene Modulators	95,090	\$12,601,832.09	86,330	\$13,521,827.70
Antiasthmatic - Monoclonal Antibodies	84	\$174,286.14	92	\$188,815.06
Asthma Combinations	131	\$1,299.29	9	\$95.90
<b>Total:</b>	<b>489,921</b>	<b>\$47,792,068.17</b>	<b>463,074</b>	<b>\$49,951,835.85</b>

Misc. Respiratory	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Peripheral Vasodilators	2	\$17.30	2	\$17.95
Pulmonary Hypertension - Phosphodiesterase Inhibitors	559	\$476,736.64	649	\$662,134.06
Cystic Fibrosis Agents	1,025	\$2,192,600.51	1,075	\$2,502,717.32
Pleural Sclerosing Agents	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>1,059</b>	<b>\$2,437,066.52</b>	<b>1,109</b>	<b>\$2,756,092.96</b>

Laxatives	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Saline Laxatives	185	\$15,347.38	185	\$16,202.74
Stimulant Laxatives	0	\$0.00	0	\$0.00
Bulk Laxatives	0	\$0.00	0	\$0.00
Lubricant Laxatives	0	\$0.00	1	\$150.25
Surfactant Laxatives	0	\$0.00	0	\$0.00
Miscellaneous Laxatives	26,569	\$643,661.95	31,157	\$743,666.27
Laxative Combinations	3,434	\$83,829.39	3,805	\$97,360.39
<b>Total:</b>	<b>30,188</b>	<b>\$742,838.72</b>	<b>35,148</b>	<b>\$857,379.65</b>

Antidiarrheals	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiperistaltic Agents	3,587	\$36,191.95	3,552	\$40,918.79
GI Adsorbents	0	\$0.00	0	\$0.00
Misc. Antidiarrheal Agents	2	\$13.64	5	\$29.83
Antidiarrheal Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>3,589</b>	<b>\$36,205.59</b>	<b>3,557</b>	<b>\$40,948.62</b>

Antacids	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Aluminum Salts	0	\$0.00	0	\$0.00
Bicarbonate	1	\$36.08	32	\$517.98
Calcium Salts	3	\$23.84	5	\$49.01
Magnesium Salts	0	\$0.00	0	\$0.00
Sodium Citrate	0	\$0.00	0	\$0.00
Antacid Combinations	265	\$2,086.33	451	\$4,739.25
<b>Total:</b>	<b>269</b>	<b>\$2,146.25</b>	<b>488</b>	<b>\$5,306.24</b>

Ulcer Drugs	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antispasmodics	19,453	\$438,254.79	20,029	\$451,951.59
H-2 Antagonists	51,856	\$749,003.97	53,924	\$623,769.60
Ulcer Drugs - Prostaglandins	404	\$5,259.00	553	\$7,081.58
Proton Pump Inhibitors	117,645	\$4,346,016.67	128,865	\$3,127,365.31
Misc. Anti-Ulcer	5,361	\$245,354.58	5,958	\$291,263.93
Ulcer Therapy Combinations	490	\$192,701.03	139	\$74,319.63
<b>Total:</b>	<b>195,209</b>	<b>\$5,976,590.04</b>	<b>209,468</b>	<b>\$4,575,751.64</b>

Antiemetics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiemetics - Antidopaminergic	0	\$0.00	0	\$0.00
Antiemetics - Anticholinergic	3,678	\$158,955.34	3,696	\$163,081.80
5-Ht3 Receptor Antagonists	42,475	\$517,181.86	51,972	\$559,304.89
Substance P/Neurokinin 1	136	\$56,515.80	223	\$102,921.75
Antiemetics Miscellaneous	146	\$76,029.30	182	\$84,369.48
<b>Total:</b>	<b>46,435</b>	<b>\$808,682.30</b>	<b>56,073</b>	<b>\$909,677.92</b>

Digestive Aids	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Choleretics	0	\$0.00	0	\$0.00
Digestive Enzymes	1,551	\$1,317,096.85	1,631	\$1,439,912.05
Gastric Acidifiers	0	\$0.00	0	\$0.00
Hydrocholeretics	0	\$0.00	0	\$0.00
Digestive Aids - Mixtures	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>1,551</b>	<b>\$1,317,096.85</b>	<b>1,631</b>	<b>\$1,439,912.05</b>

Misc. Gastrointestinal	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Gallstone Solubilizing Agents	872	\$66,178.70	889	\$54,816.27
Gastrointestinal Antiallergy Agents	24	\$10,689.03	50	\$26,818.92
Antiflatulents	0	\$0.00	0	\$0.00
Gastrointestinal Stimulants	9,692	\$98,030.88	8,500	\$80,730.10
Intestinal Acidifiers	2,883	\$55,708.43	2,938	\$59,290.29
Gastrointestinal Chloride Channel Activators	238	\$50,945.97	272	\$59,461.50
Inflammatory Bowel Agents	2,540	\$983,475.20	2,682	\$1,146,237.97
Irritable Bowel Syndrome	4	\$3,679.37	5	\$4,978.40
Peripheral Opioid Receptor Antagonists	33	\$17,556.60	62	\$53,192.41
Hepatotropics	0	\$0.00	0	\$0.00
Phosphate Binder Agents	1,205	\$482,676.39	1,365	\$578,190.09
<b>Total:</b>	<b>17,491</b>	<b>\$1,768,940.57</b>	<b>16,763</b>	<b>\$2,063,715.95</b>

Urinary Anti-Infectives	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Urinary Anti-Infectives	19,376	\$860,591.51	20,403	\$1,180,610.60
Combination Urinary Anti-Infectives	224	\$18,013.89	154	\$16,800.85
<b>Total:</b>	<b>19,600</b>	<b>\$878,605.40</b>	<b>20,557</b>	<b>\$1,197,411.45</b>

Urinary Antispasmodics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Urinary Antispasmodics	12,139	\$899,423.50	13,138	\$995,817.83
Urinary Antispasmodic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>12,139</b>	<b>\$899,423.50</b>	<b>13,138</b>	<b>\$995,817.83</b>

Vaginal Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Vaginal Anti-Infectives	5,678	\$149,414.35	5,906	\$165,128.03
Vaginal Anti-Inflammatory Agents	0	\$0.00	0	\$0.00
Douche Products	0	\$0.00	0	\$0.00
Spermicides	0	\$0.00	0	\$0.00
Vaginal Estrogens	1,699	\$206,552.11	1,882	\$268,600.27
Vaginal Progestins	2	\$417.24	16	\$4,191.71
Miscellaneous Vaginal Products	10	\$251.37	1	\$18.33
<b>Total:</b>	<b>7,389</b>	<b>\$356,635.07</b>	<b>7,805</b>	<b>\$437,938.34</b>

Miscellaneous Genitourinary Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Acidifiers	16	\$389.96	17	\$395.67
Alkalinizers	916	\$29,447.97	951	\$46,317.18
Urinary Analgesics	5,122	\$26,518.72	6,127	\$33,295.12
Cystinosis Agents	0	\$0.00	0	\$0.00
Interstitial Cystitis Agents	302	\$106,333.53	393	\$154,204.08
Urinary Stone Agents	11	\$1,910.55	19	\$3,710.56
G U Irrigants	926	\$9,765.94	487	\$8,052.76
Prostatic Hypertrophy Agents	6,082	\$231,061.87	6,631	\$153,708.68
<b>Total:</b>	<b>13,375</b>	<b>\$405,428.54</b>	<b>14,625</b>	<b>\$399,684.05</b>

Antianxiety Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Benzodiazepines	183,189	\$1,518,884.64	239,336	\$2,057,644.22
Misc. Antianxiety Agents	65,626	\$849,277.93	72,950	\$927,748.14
Antianxiety Agent Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>248,815</b>	<b>\$2,368,162.57</b>	<b>312,286</b>	<b>\$2,985,392.36</b>

Antidepressants	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Alpha-2 Receptor Antagonists	15,080	\$176,894.03	16,671	\$179,677.81
MAO Inhibitors	26	\$10,145.46	23	\$9,380.77
Modified Cyclics	53,683	\$455,206.54	57,816	\$538,537.17
Selective Serotonin Reuptake Inhibitors	200,536	\$3,394,955.95	214,079	\$3,669,911.69
Serotonin-Norepinephrine Reuptake Inhibitors	25,586	\$3,531,506.34	35,076	\$4,053,655.21
Tricyclic Agents	29,217	\$370,692.17	32,049	\$395,345.36
Misc. Antidepressants	23,456	\$730,784.79	25,847	\$738,168.01
Antidepressant Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>347,584</b>	<b>\$8,670,185.28</b>	<b>381,561</b>	<b>\$9,584,676.02</b>

Antipsychotics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Benzamides	0	\$0.00	0	\$0.00
Benzisoxazoles	76,042	\$7,681,543.57	85,502	\$10,273,756.84
Butyrophenones	5,561	\$257,770.90	6,098	\$290,016.79
Dibenzapines	53,176	\$24,955,954.58	52,132	\$22,836,182.75
Dihydroindolones	0	\$0.00	0	\$0.00
Diphenylbutylpiperidines	0	\$0.00	0	\$0.00
Phenothiazines	7,111	\$141,876.56	7,524	\$285,194.62
Quinolinone Derivatives	35,008	\$19,198,434.68	32,449	\$20,068,089.04
Thioxanthenes	431	\$8,537.07	321	\$6,297.61
Misc. Antipsychotics	9,639	\$4,083,234.64	9,655	\$4,171,968.83
Antimanic Agents	6,978	\$99,735.60	7,487	\$111,479.67
<b>Total:</b>	<b>193,946</b>	<b>\$56,427,087.60</b>	<b>201,168</b>	<b>\$58,042,986.15</b>

Hypnotics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Barbiturate Hypnotics	8,747	\$102,443.79	10,109	\$140,472.98
Non-Barbiturate Hypnotics	67,009	\$967,706.38	81,030	\$945,398.69
Selective Melatonin Receptor Agonists	337	\$45,164.41	212	\$31,381.66
Antihistamine Hypnotics	0	\$0.00	0	\$0.00
Hypnotics - Tricyclic Agents	12	\$1,868.91	4	\$680.14
Hypnotic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>76,105</b>	<b>\$1,117,183.49</b>	<b>91,355</b>	<b>\$1,117,933.47</b>

ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Amphetamines	100,549	\$11,775,209.23	99,375	\$13,403,028.01
Anorexiants Non-Amphetamine	0	\$0.00	0	\$0.00
Anti-Obesity Agents	0	\$0.00	0	\$0.00
Analeptics	180	\$155,819.18	124	\$155,402.97
Attention-Deficit/Hyperactivity Disorder	20,885	\$3,537,217.84	36,542	\$6,716,488.52
Misc. Stimulants	130,789	\$18,184,708.82	133,894	\$19,356,854.45
<b>Total:</b>	<b>252,403</b>	<b>\$33,652,955.07</b>	<b>269,935</b>	<b>\$39,631,773.95</b>

Misc Psychotherapeutic And Neurological Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Misc Psychotherapeutic And Neurological Agents	166	\$14,311.64	196	\$19,332.99
Antidementia	6,731	\$1,271,362.70	8,061	\$1,221,997.28
Smoking Deterrents	8,618	\$918,776.89	9,137	\$1,071,228.82
Premenstrual Dysphoric Disorder	25	\$192.56	14	\$114.40
Movement Disorder Drug Therapy	88	\$331,153.15	94	\$428,124.06
Multiple Sclerosis Agents	1,196	\$3,699,681.29	1,382	\$4,966,695.06
Anti-Cataleptic Agents	24	\$55,366.12	22	\$67,940.94
Fibromyalgia Agents	450	\$51,188.74	570	\$69,994.19
Pseudobulbar Affect	1	\$516.90	261	\$129,136.65
Agents For Chemical Dependency	481	\$67,389.20	537	\$71,684.85
Combination Psychotherapeutics	536	\$165,811.55	523	\$155,418.10
<b>Total:</b>	<b>18,316</b>	<b>\$6,575,750.74</b>	<b>20,797</b>	<b>\$8,201,667.34</b>

Analgesics - Nonnarcotic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Salicylates	290	\$9,382.73	248	\$9,272.31
Analgesics-Petide Channel Blockers	0	\$0.00	0	\$0.00
Analgesics Other	18,858	\$133,264.51	13,421	\$95,629.51
Analgesic Combinations	17,489	\$197,897.61	21,844	\$269,987.63
<b>Total:</b>	<b>36,637</b>	<b>\$340,544.85</b>	<b>35,513</b>	<b>\$374,889.45</b>

Analgesics - Narcotic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Narcotic Agonists	116,247	\$10,013,254.95	136,199	\$10,383,013.87
Narcotic Partial Agonists	6,003	\$1,626,952.29	7,482	\$2,192,531.55
Not Classified	0	\$0.00	0	\$0.00
Cannabinoid Agonists	0	\$0.00	0	\$0.00
Narcotic Combinations	424,419	\$5,378,831.23	449,871	\$6,058,712.73
<b>Total:</b>	<b>546,669</b>	<b>\$17,019,038.47</b>	<b>593,552</b>	<b>\$18,634,258.15</b>

Analgesics - Anti-Inflammatory	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
NSAID	176,624	\$1,883,729.61	187,872	\$2,071,061.19
Gold Compounds	5	\$1,915.90	2	\$677.13
Antirheumatic Antimetabolite	2	\$238.58	0	\$0.00
Interleukin-1 Receptor Antagonist	40	\$74,344.93	56	\$95,335.87
Anti-Tnf-Alpha - Monoclonal Antibodies	1,086	\$2,405,004.19	1,263	\$2,976,674.46
Pyrimidine Synthesis Inhibitors	381	\$10,015.38	415	\$12,463.10
Soluble Tumor Necrosis Factor Receptor Agents	1,276	\$2,489,617.64	1,202	\$2,520,418.71
Antirheumatics - Misc.	0	\$0.00	0	\$0.00
Selective Costimulation Modulators	0	\$0.00	47	\$91,512.49
Interleukin-1 Blockers	0	\$0.00	0	\$0.00
Interleukin-1Beta Blockers	0	\$0.00	6	\$100,344.18
Interleukin-6 Receptor Inhibitors	4	\$11,214.54	0	\$0.00
Analgesics - Anti-Inflammatory Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>179,418</b>	<b>\$6,876,080.77</b>	<b>190,863</b>	<b>\$7,868,487.13</b>

Migraine Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Migraine Products	62	\$33,160.44	61	\$43,491.54
Carboxylic Acid Derivatives	0	\$0.00	0	\$0.00
Serotonin Agonists	9,266	\$520,604.23	10,998	\$540,122.55
Migraine Combinations	311	\$42,917.55	195	\$30,960.15
<b>Total:</b>	<b>9,639</b>	<b>\$596,682.22</b>	<b>11,254</b>	<b>\$614,574.24</b>

Gout Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Gout Agents	4,142	\$95,794.44	4,723	\$159,320.14
Uricosurics	76	\$1,844.66	70	\$1,817.26
Gout Agent Combinations	19	\$635.44	31	\$1,050.46
<b>Total:</b>	<b>4,237</b>	<b>\$98,274.54</b>	<b>4,824</b>	<b>\$162,187.86</b>

Local Anesthetics-Parenteral	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Local Anesthetics - Amides	467	\$3,123.34	378	\$2,883.84
Local Anesthetics - Esters	626	\$2,754.05	738	\$3,429.26
Local Anesthetic Combinations	1	\$8.53	0	\$0.00
<b>Total:</b>	<b>1,094</b>	<b>\$5,885.92</b>	<b>1,116</b>	<b>\$6,313.10</b>

General Anesthetics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
General Anesthetics	0	\$0.00	0	\$0.00
Anesthetic Gasses	0	\$0.00	0	\$0.00
Barbiturate Anesthetics	0	\$0.00	0	\$0.00
Volatile Anesthetics	0	\$0.00	0	\$0.00
Misc. Anesthetics	3	\$156.32	80	\$1,715.20
<b>Total:</b>	<b>3</b>	<b>\$156.32</b>	<b>80</b>	<b>\$1,715.20</b>

Anticonvulsant	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Anticonvulsant - Benzodiazepines	63,310	\$1,598,780.21	80,529	\$1,929,882.78
Carbamates	589	\$299,025.35	603	\$362,091.99
Gaba Modulators	378	\$312,632.62	351	\$655,359.53
Hydantoins	12,771	\$452,184.20	12,244	\$422,156.34
Oxazolinediones	0	\$0.00	0	\$0.00
Succinimides	1,150	\$71,558.64	1,366	\$83,153.79
Valproic Acid	37,742	\$1,557,089.21	38,133	\$1,347,579.63
Misc. Anticonvulsants	166,184	\$10,062,269.79	188,425	\$10,819,733.31
Anticonvulsant Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>282,124</b>	<b>\$14,353,540.02</b>	<b>321,651</b>	<b>\$15,619,957.37</b>

Antiparkinsonian	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiparkinsonian Anticholinergic	12,481	\$116,398.69	13,902	\$128,281.73
Antiparkinsonian COMT Inhibitors	66	\$19,534.85	59	\$18,532.04
Antiparkinsonian Dopaminergic	10,914	\$326,958.57	11,786	\$270,946.57
Antiparkinsonian Monoamine Oxidase Inhibitor	29	\$7,691.79	43	\$15,014.36
Antiparkinsonian Adjuvants	21	\$1,469.38	42	\$3,382.18
<b>Total:</b>	<b>23,511</b>	<b>\$472,053.28</b>	<b>25,832</b>	<b>\$436,156.88</b>

Neuromuscular Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Depolarizing Muscle Relaxants	0	\$0.00	0	\$0.00
Nondepolarizing Muscle Relaxants	0	\$0.00	0	\$0.00
Neuromuscular Blocking Agent - Neurotoxins	57	\$94,365.32	0	\$0.00
Als Agents	8	\$7,485.79	8	\$8,556.25
<b>Total:</b>	<b>65</b>	<b>\$101,851.11</b>	<b>8</b>	<b>\$8,556.25</b>

Musculoskeletal Therapy Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Central Muscle Relaxants	101,796	\$1,045,986.50	116,320	\$1,279,396.74
Direct Muscle Relaxants	347	\$32,858.41	310	\$25,203.36
Misc. Muscle Relaxants	0	\$0.00	0	\$0.00
Viscosupplements	0	\$0.00	0	\$0.00
Articular Cartilage Repair Therapy	0	\$0.00	0	\$0.00
Muscle Relaxant Combinations	146	\$12,369.25	66	\$4,278.29
<b>Total:</b>	<b>102,289</b>	<b>\$1,091,214.16</b>	<b>116,696</b>	<b>\$1,308,878.39</b>

Antimyasthenic Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antimyasthenic Agents	195	\$11,736.13	221	\$14,881.12
Antimyasthenic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>195</b>	<b>\$11,736.13</b>	<b>221</b>	<b>\$14,881.12</b>

Vitamins	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Water Soluble Vitamins	14	\$193.33	70	\$2,332.45
Oil Soluble Vitamins	2,819	\$86,434.32	772	\$76,007.62
Misc. Nutritional Factors	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>2,833</b>	<b>\$86,627.65</b>	<b>842</b>	<b>\$78,340.07</b>

Multivitamins	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Vitamin Mixtures	0	\$0.00	0	\$0.00
B-Complex Vitamins	0	\$0.00	0	\$0.00
B-Complex W/ C	0	\$0.00	0	\$0.00
B-Complex W/ Folic Acid	0	\$0.00	0	\$0.00
B-Complex W/ Iron	0	\$0.00	0	\$0.00
B-Complex W/ Minerals	0	\$0.00	0	\$0.00
Bioflavonoid Products	0	\$0.00	0	\$0.00
Biotin W/ Vitamin C	0	\$0.00	0	\$0.00
Multivitamins	0	\$0.00	0	\$0.00
Multiple Vitamins W/ Iron	0	\$0.00	0	\$0.00
Multiple Vitamins W/ Minerals	54	\$1,866.33	347	\$11,686.03
Multiple Vitamins W/ Fluoride	0	\$0.00	0	\$0.00
Multiple Vitamins W/ Calcium	0	\$0.00	0	\$0.00
Multiple Vitamins W/ Minerals & Calcium-Folic Acid	4	\$45.99	11	\$65.79
Multiple Vitamins W/ Minerals & Fluoride-Folic Acid	0	\$0.00	0	\$0.00
Pediatric Vitamins	0	\$0.00	0	\$0.00
Pediatric Multiple Vitamins	0	\$0.00	0	\$0.00
Ped Multiple Vitamins W/ Minerals	58	\$1,505.14	103	\$2,687.27
Ped Multiple Vitamin W/ Iron	0	\$0.00	0	\$0.00
Ped Multiple Vitamin W/ Fluoride	1,685	\$22,072.34	1,733	\$23,264.38
Ped Multiple Vitamin W/ FI & Fe	239	\$2,467.39	181	\$2,422.55
Specialty Vitamins Products	0	\$0.00	0	\$0.00
Prenatal Vitamins	55,092	\$2,844,357.97	54,714	\$2,503,772.70
Vitamins W/ Lipotropics	0	\$0.00	0	\$0.00
Vitamins W/ Hormones	0	\$0.00	0	\$0.00
Hematinic-Vitamin Products	0	\$0.00	0	\$0.00
Iron W/ Vitamins	0	\$0.00	0	\$0.00
B-12 W/ Vitamins	0	\$0.00	0	\$0.00
Iron & B12 W/ Vitamins	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>57,132</b>	<b>\$2,872,315.16</b>	<b>57,089</b>	<b>\$2,543,898.72</b>

Minerals & Electrolytes	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Bicarbonates	1,066	\$15,834.86	1,360	\$29,896.61
Calcium	15	\$114.29	19	\$359.44
Chloride	0	\$0.00	0	\$0.00
Fluoride	1,894	\$13,131.36	1,725	\$12,965.41
Iodine Products	0	\$0.00	0	\$0.00
Magnesium	49	\$668.22	9	\$732.41
Manganese	0	\$0.00	0	\$0.00
Phosphate	223	\$4,295.31	186	\$3,904.63
Potassium	24,882	\$519,002.09	27,768	\$684,785.40
Sodium	2,288	\$42,635.73	2,269	\$276,015.80
Zinc	0	\$0.00	0	\$0.00
Mineral Combinations	0	\$0.00	0	\$0.00
Trace Minerals	0	\$0.00	0	\$0.00
Electrolyte Mixtures	191	\$2,519.32	302	\$5,003.60
<b>Total:</b>	<b>30,608</b>	<b>\$598,201.18</b>	<b>33,638</b>	<b>\$1,013,663.30</b>

Nutrients	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Carbohydrate	350	\$17,492.86	226	\$27,880.68
Lipids	7	\$209.27	3	\$122.17
Protein	1	\$67.98	68	\$4,654.48
Lipotropics	0	\$0.00	0	\$0.00
Misc. Nutritional Substances	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>358</b>	<b>\$17,770.11</b>	<b>297</b>	<b>\$32,657.33</b>

Dietary Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Infant Foods	0	\$0.00	4	\$32.77
Nutritional Supplements	111	\$38,545.95	114	\$40,059.00
Dietary Management Products	0	\$0.00	0	\$0.00
Tube Feedings	0	\$0.00	0	\$0.00
Nutritional Substitutes	0	\$0.00	3	\$211.38
Nutritional Modifiers	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>111</b>	<b>\$38,545.95</b>	<b>121</b>	<b>\$40,303.15</b>

Hematopoietic Agents	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Cobalamins	22	\$172.59	62	\$458.78
Intrinsic Factor	0	\$0.00	0	\$0.00
Folic Acid/Folates	10,868	\$63,086.99	16,702	\$96,045.40
Iron	1	\$4.77	0	\$0.00
Hematopoietic Growth Factors	598	\$1,007,606.87	701	\$1,181,228.15
Stem Cell Mobilizers	0	\$0.00	0	\$0.00
Agents For Gaucher Disease	46	\$507,546.04	46	\$763,365.86
Agents For Sickle Cell Anemia	0	\$0.00	19	\$754.42
Hematopoietic Mixtures	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>11,535</b>	<b>\$1,578,417.26</b>	<b>17,530</b>	<b>\$2,041,852.61</b>

Anticoagulants	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Heparins And Heparinoid-Like Agents	2,829	\$2,985,218.18	3,171	\$3,321,482.88
Coumarin Anticoagulants	10,134	\$102,745.06	11,062	\$112,192.93
Indanedione Anticoagulants	0	\$0.00	0	\$0.00
Thrombin Inhibitors	215	\$45,556.64	543	\$125,463.43
Anticoagulants - Misc.	0	\$0.00	0	\$0.00
Direct Factor Xa Inhibitors	0	\$0.00	183	\$34,824.20
In Vitro Anticoagulants	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>13,178</b>	<b>\$3,133,519.88</b>	<b>14,959</b>	<b>\$3,593,963.44</b>

Hemostatics	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Hemostatics - Systemic	86	\$26,594.43	191	\$36,796.85
Hemostatics - Topical	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>86</b>	<b>\$26,594.43</b>	<b>191</b>	<b>\$36,796.85</b>



Misc. Hematological	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antihemophilic Products	829	\$17,069,517.42	875	\$17,003,737.42
Platelet Aggregation Inhibitors	13,976	\$2,808,364.56	14,456	\$3,054,503.43
Hematorheological	555	\$7,962.90	558	\$10,300.36
Hemin	0	\$0.00	0	\$0.00
In Vitro Hematologic Agents	0	\$0.00	0	\$0.00
Plasma Expanders	0	\$0.00	0	\$0.00
Plasma Proteins	21	\$3,252.13	4	\$586.32
Protamine	0	\$0.00	0	\$0.00
Human Protein C	0	\$0.00	0	\$0.00
Thrombolytic Enzymes	46	\$6,507.76	26	\$14,017.50
Hematologic Oxygen Transporters	0	\$0.00	0	\$0.00
Complement Inhibitors	72	\$3,186,787.24	51	\$2,137,463.15
Plasma Kallikrein Inhibitors	4	\$67,177.68	2	\$35,278.44
<b>Total:</b>	<b>15,503</b>	<b>\$23,149,569.69</b>	<b>15,972</b>	<b>\$22,255,886.62</b>

Ophthalmic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Ophthalmic Anti-Infectives	49,739	\$748,481.94	46,884	\$804,997.34
Artificial Tears And Lubricants	134	\$4,230.54	151	\$4,631.13
Beta-Blockers - Ophthalmic	1,423	\$71,984.85	1,483	\$65,928.82
Ophthalmic Steroids	4,942	\$203,836.02	6,262	\$304,852.44
Prostaglandins - Ophthalmic	2,932	\$306,500.81	3,160	\$280,549.20
Cycloplegics	832	\$17,064.11	869	\$21,384.82
Ophthalmic Decongestants	66	\$572.92	50	\$703.64
Miotics	25	\$800.86	25	\$881.96
Adrenergic Agents	743	\$48,864.90	688	\$50,129.34
Ophthalmic - Angiogenesis Inhibitors	0	\$0.00	0	\$0.00
Ophthalmic Photodynamic Therapy Agents	0	\$0.00	0	\$0.00
Ophthalmic Immunomodulators	518	\$110,606.59	621	\$150,291.34
Ophthalmic Local Anesthetics	22	\$226.51	22	\$389.30
Ophthalmic Surgical Aids	0	\$0.00	0	\$0.00
Misc. Ophthalmics	7,616	\$583,976.49	6,154	\$216,520.39
Contact Lens Solutions	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>68,992</b>	<b>\$2,097,146.54</b>	<b>66,369</b>	<b>\$1,901,259.72</b>

Otic	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Otic Anti-Infectives	22,859	\$333,093.18	20,957	\$322,974.57
Otic Analgesics	5	\$121.05	0	\$0.00
Otic Steroids	71	\$2,285.79	78	\$2,278.06
Otic Miscellaneous	310	\$10,362.32	275	\$7,947.84
Otic Agents - For External Ear	0	\$0.00	0	\$0.00
Otic Combinations	34,521	\$707,255.96	29,522	\$547,573.06
<b>Total:</b>	<b>57,766</b>	<b>\$1,053,118.30</b>	<b>50,832</b>	<b>\$880,773.53</b>

Mouth & Throat	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Anti-Infectives - Throat	12,612	\$162,573.36	12,885	\$270,899.27
Antiseptics - Mouth/Throat	6,355	\$51,185.03	7,111	\$53,864.34
Lozenges	0	\$0.00	0	\$0.00
Steroids - Mouth	527	\$29,351.61	567	\$30,240.42
Antiallergy Agents	0	\$0.00	0	\$0.00
Mouthwashes	0	\$0.00	0	\$0.00
Anesthetics Topical Oral	3,561	\$30,054.18	3,589	\$32,512.95
Dental Products	4,290	\$47,485.38	3,235	\$35,157.30
Periodontal Products	0	\$0.00	0	\$0.00
Misc. Throat Products	163	\$21,114.18	195	\$27,732.58
<b>Total:</b>	<b>27,508</b>	<b>\$341,763.74</b>	<b>27,582</b>	<b>\$450,406.86</b>

Anorectal	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Rectal Steroids	901	\$9,652.25	1,020	\$10,164.50
Intrarectal Steroids	14	\$4,438.52	23	\$4,287.92
Rectal Local Anesthetics	0	\$0.00	0	\$0.00
Misc. Rectal Products	0	\$0.00	0	\$0.00
Rectal Protectants-Emollients	0	\$0.00	0	\$0.00
Rectal Combinations	656	\$46,517.69	674	\$51,434.32
<b>Total:</b>	<b>1,571</b>	<b>\$60,608.46</b>	<b>1,717</b>	<b>\$65,886.74</b>

Dermatological	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Acne Products	9,318	\$584,450.39	8,874	\$551,034.18
Rosacea Agents	198	\$23,523.58	165	\$18,504.11
Analgesics	0	\$0.00	0	\$0.00
Antibiotics - Topical	37,240	\$548,214.50	36,982	\$575,473.98
Antifungals - Topical	49,134	\$653,038.53	49,536	\$1,327,477.85
Antihistamines-Topical	0	\$0.00	2	\$9.71
Anti-Inflammatory Agents - Topical	120	\$11,665.97	115	\$13,442.81
Antipruritics	12	\$1,449.98	11	\$1,495.18
Antipsoriatics	2,209	\$693,060.47	2,180	\$774,892.38
Antiseborrheic Products	962	\$14,014.75	908	\$19,512.77
Antiviral - Topical	2,948	\$470,479.35	2,560	\$687,190.64
Antineoplastic Or Premalignant Lesions - Topical	199	\$43,615.05	153	\$39,795.77
Bath Products	0	\$0.00	0	\$0.00
Burn Products	4,789	\$52,629.80	4,741	\$53,215.15
Cauterizing Agents	1	\$23.42	0	\$0.00
Tar Products	0	\$0.00	1	\$5.27
Corticosteroids - Topical	68,063	\$2,193,061.07	65,364	\$1,673,819.59
Diaper Rash Products	0	\$0.00	0	\$0.00
Emollients	832	\$14,301.70	1,177	\$17,998.18
Emollient/Keratolytic	273	\$8,150.52	235	\$8,113.30
Enzymes - Topical	977	\$103,239.92	1,073	\$137,425.51
Hair Growth Agents	0	\$0.00	0	\$0.00
Hair Reduction Agents	0	\$0.00	0	\$0.00
Keratolytics/Antimitotics	356	\$38,849.87	333	\$41,540.32
Agents For External Genital And Perianal Warts	4	\$2,062.22	8	\$2,242.86
Immunomodulating Agents - Topical	1,272	\$514,213.77	950	\$348,815.12
Immunosuppressive Agents - Topical	3,179	\$539,831.61	2,574	\$596,891.78
Liniments	0	\$0.00	0	\$0.00
Local Anesthetics - Topical	2,425	\$72,143.58	2,419	\$94,884.26
Pigmenting-Depigmenting Agents	0	\$0.00	2	\$42.87
Agents For Facial Wrinkles	0	\$0.00	0	\$0.00
Glabellar Lines	0	\$0.00	0	\$0.00
Scabicides & Pediculicides	26,838	\$468,177.00	26,593	\$975,029.99
Sunscreens	0	\$0.00	0	\$0.00
Scar Treatment Products	0	\$0.00	0	\$0.00
Wound Care Products	137	\$14,511.39	57	\$5,425.09
Poison Ivy Products	0	\$0.00	0	\$0.00
Topical Vasoprotectants	0	\$0.00	0	\$0.00
Misc. Topical	508	\$5,394.50	631	\$6,755.06
Podiatric Products	0	\$0.00	0	\$0.00
Misc. Dermatological Products	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>211,994</b>	<b>\$7,070,102.94</b>	<b>207,644</b>	<b>\$7,971,033.73</b>

Antiseptics & Disinfectants	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antiseptics & Disinfectants	5	\$129.79	12	\$381.19
Chlorine Antiseptics	239	\$6,599.34	175	\$5,175.45
Iodine Antiseptics	0	\$0.00	1	\$4.11
Mercury Antiseptics	0	\$0.00	0	\$0.00
Silver Antiseptics	0	\$0.00	0	\$0.00
Water Purifiers	0	\$0.00	0	\$0.00
Disinfectants	0	\$0.00	0	\$0.00
Antiseptic Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>244</b>	<b>\$6,729.13</b>	<b>188</b>	<b>\$5,560.75</b>

Antidotes	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Antidotes	90	\$32,731.46	81	\$35,639.24
Antidotes - Chelating Agents	231	\$1,275,199.85	244	\$1,503,836.87
Benzodiazepine Antagonists	0	\$0.00	0	\$0.00
Narcotic Antagonists	906	\$44,576.04	1,081	\$66,449.57
Topical Antidotes	0	\$0.00	0	\$0.00
Antidote Kits	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>1,227</b>	<b>\$1,352,507.35</b>	<b>1,406</b>	<b>\$1,605,925.68</b>

Diagnostic Products	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Diagnostic Reagents	0	\$0.00	0	\$0.00
Diagnostic Drugs	7	\$10,547.72	7	\$13,490.00
Diagnostic Biologicals	7	\$207.40	36	\$515.56
Diagnostic Radiopharmaceuticals	0	\$0.00	0	\$0.00
Radiographic Contrast Media	0	\$0.00	0	\$0.00
Non-Radiographic Contrast Media	0	\$0.00	0	\$0.00
Diagnostic Products, Misc.	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>14</b>	<b>\$10,755.12</b>	<b>43</b>	<b>\$14,005.56</b>

Alternative Medicines	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Alternative Medicine - A'S	0	\$0.00	0	\$0.00
Alternative Medicine - B'S	0	\$0.00	0	\$0.00
Alternative Medicine - C'S	0	\$0.00	0	\$0.00
Alternative Medicine - D'S	0	\$0.00	0	\$0.00
Alternative Medicine - E'S	0	\$0.00	0	\$0.00
Alternative Medicine - F'S	0	\$0.00	0	\$0.00
Alternative Medicine - G'S	0	\$0.00	0	\$0.00
Alternative Medicine - H'S	0	\$0.00	0	\$0.00
Alternative Medicine - I'S	0	\$0.00	0	\$0.00
Alternative Medicine - J'S	0	\$0.00	0	\$0.00
Alternative Medicine - K'S	0	\$0.00	0	\$0.00
Alternative Medicine - L'S	0	\$0.00	0	\$0.00
Alternative Medicine - M'S	0	\$0.00	0	\$0.00
Alternative Medicine - N'S	0	\$0.00	0	\$0.00
Alternative Medicine - O'S	0	\$0.00	0	\$0.00
Alternative Medicine - P'S	0	\$0.00	0	\$0.00
Alternative Medicine - R'S	0	\$0.00	0	\$0.00
Alternative Medicine - S'S	0	\$0.00	0	\$0.00
Alternative Medicine - T'S	0	\$0.00	0	\$0.00
Alternative Medicine - U'S	0	\$0.00	0	\$0.00
Alternative Medicine - V'S	0	\$0.00	0	\$0.00
Alternative Medicine - W'S	0	\$0.00	0	\$0.00
Alternative Medicine - Y'S	0	\$0.00	0	\$0.00
Alternative Medicine Combinations	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>0</b>	<b>\$0.00</b>	<b>0</b>	<b>\$0.00</b>

Chemicals	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Acids, Bases, & Buffers	1	\$5.86	9	\$183.80
Liquids	155	\$2,378.57	176	\$3,158.67
Solids	295	\$2,552.68	351	\$2,864.14
Semi-Solids	4	\$79.08	6	\$78.88
Bulk Chemicals - A'S	4	\$65.57	7	\$142.00
Bulk Chemicals - B'S	1	\$9.19	0	\$0.00
Bulk Chemicals - C'S	1,821	\$7,765.32	753	\$5,213.35
Bulk Chemicals - D'S	10	\$43.10	35	\$210.30
Bulk Chemicals - E'S	48	\$255.00	55	\$319.86
Bulk Chemicals - F'S	1	\$8.30	1	\$5.71
Bulk Chemicals - G'S	0	\$0.00	7	\$479.62
Bulk Chemicals - H'S	21	\$531.08	12	\$190.48
Bulk Chemicals - I'S	3	\$19.55	0	\$0.00
Bulk Chemicals - J'S	0	\$0.00	0	\$0.00
Bulk Chemicals - K'S	16	\$2,114.14	11	\$738.09
Bulk Chemicals - L'S	256	\$1,323.32	196	\$1,186.56

Chemicals, Cont.	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Bulk Chemicals - M'S	4	\$24.18	1	\$7.28
Bulk Chemicals - N'S	0	\$0.00	0	\$0.00
Bulk Chemicals - O'S	75	\$463.39	56	\$434.92
Bulk Chemicals - P'S	12,061	\$56,235.45	8,298	\$39,497.52
Bulk Chemicals - Q'S	0	\$0.00	0	\$0.00
Bulk Chemicals - R'S	0	\$0.00	0	\$0.00
Bulk Chemicals - S'S	3	\$1,242.85	165	\$1,381.17
Bulk Chemicals - T'S	14	\$91.99	41	\$514.58
Bulk Chemicals - U'S	2	\$29.65	9	\$120.89
Bulk Chemicals - V'S	0	\$0.00	0	\$0.00
Bulk Chemicals - W'S	0	\$0.00	0	\$0.00
Bulk Chemicals - X'S	0	\$0.00	0	\$0.00
Bulk Chemicals - Y'S	0	\$0.00	0	\$0.00
Bulk Chemicals - Z'S	0	\$0.00	1	\$3.89
Bulk Chemicals	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>14,795</b>	<b>\$75,238.27</b>	<b>10,190</b>	<b>\$56,731.71</b>

Medical Devices	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Parenteral Therapy Supplies	0	\$0.00	0	\$0.00
Cardiology Supplies	0	\$0.00	0	\$0.00
Respiratory Therapy Supplies	22,046	\$1,105,437.18	21,870	\$1,135,395.52
Respiratory Aids	0	\$0.00	0	\$0.00
Medical Gases	0	\$0.00	0	\$0.00
GI-GU Ostomy & Irrigation Supplies	0	\$0.00	0	\$0.00
Hemodialytics & Hemofiltrates	0	\$0.00	0	\$0.00
Peritoneal Dialysis	0	\$0.00	0	\$0.00
Diabetic Supplies	0	\$0.00	0	\$0.00
Blood Monitoring Supplies	0	\$0.00	0	\$0.00
Enteral Nutrition Supplies	0	\$0.00	0	\$0.00
Bandages-Dressings-Tape	0	\$0.00	0	\$0.00
Fixed	0	\$0.00	0	\$0.00
Elastic Bandages & Supports	0	\$0.00	0	\$0.00
Surgical Supplies	0	\$0.00	0	\$0.00
Heating/Cooling Aids	0	\$0.00	0	\$0.00
Back Plasters	0	\$0.00	0	\$0.00
Contraceptives	81	\$1,380.54	69	\$1,776.37
Fertility Monitoring Test Supplies	0	\$0.00	0	\$0.00
Female Personal Care Products	0	\$0.00	0	\$0.00
Impotence Aids	0	\$0.00	0	\$0.00
Oral Hygiene Products	0	\$0.00	0	\$0.00
Infant Care Products	0	\$0.00	0	\$0.00
Auditory Supplies	0	\$0.00	0	\$0.00
Optical Supplies	0	\$0.00	0	\$0.00
Durable Medical Equipment	0	\$0.00	0	\$0.00
Misc. Devices	1	\$5.46	81	\$489.14
Blood Pressure Devices	0	\$0.00	0	\$0.00
Foot Care Products	0	\$0.00	0	\$0.00
First Aid Kits	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>22,128</b>	<b>\$1,106,823.18</b>	<b>22,020</b>	<b>\$1,137,661.03</b>

Pharmaceutical Adjuvants	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Alkalizing Agents	0	\$0.00	0	\$0.00
Antimicrobial Agents	0	\$0.00	28	\$192.58
Antioxidants	0	\$0.00	0	\$0.00
Antioxidants	0	\$0.00	0	\$0.00
Coloring Agents	0	\$0.00	5	\$49.34
Flavoring Agents	0	\$0.00	50	\$2,254.84
Pharmaceutical Excipients	148	\$1,045.59	1,548	\$14,698.29
Internal Vehicle Ingredients/Agents	0	\$0.00	0	\$0.00
Surfactants	0	\$0.00	0	\$0.00
Liquid Vehicle	5,196	\$320,574.29	3,091	\$238,085.24
Semi Solid Vehicle	91	\$457.30	3,245	\$19,820.68

Pharmaceutical Adjuvants, Cont.	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Delivery Devices	0	\$0.00	0	\$0.00
Gelatin Capsules	6	\$92.68	17	\$196.00
Non Gelatin Capsules	0	\$0.00	0	\$0.00
Placebos	0	\$0.00	3	\$12.99
Pharmaceutical Adjuvants Miscellaneous	0	\$0.00	0	\$0.00
<b>Total:</b>	<b>5,441</b>	<b>\$322,169.86</b>	<b>7,987</b>	<b>\$275,309.96</b>

Assorted Classes	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
Cardioplegic Solution	0	\$0.00		\$0.00
Chelating Agents	9	\$2,613.80		\$3.00
Collagen Implants	0	\$0.00		\$0.00
Cytoprotective Agents	0	\$0.00		\$0.00
Enzymes	1	\$3,432.52		\$0.00
Immunomodulators	69	\$453,057.19		\$75.00
Immunosuppressive Agents	4,659	\$1,394,730.83		\$5,108.00
K Removing Resin	112	\$5,964.30		\$137.00
Lymphatic Agents	0	\$0.00		\$0.00
Prostaglandins	0	\$0.00		\$0.00
Sclerosing Agents	0	\$0.00		\$0.00
Peritoneal Dialysis Solutions	0	\$0.00		\$0.00
Continuous Renal Replacement Therapy	0	\$0.00		\$0.00
Irrigation Solutions	62	\$891.27		\$160.00
Organ Preservation Solution	0	\$0.00		\$0.00
Misc Natural Products	0	\$0.00		\$0.00
Homeopathic Products	0	\$0.00		\$0.00
Not Classified	0	\$0.00		\$0.00
<b>Total:</b>	<b>4,912</b>	<b>\$1,860,689.91</b>	<b>5,483</b>	<b>\$2,041,842.39</b>

	2011		2012	
	Total Claims	Total Paid	Total Claims	Total Paid
<b>Grand Total:</b>	<b>6,091,451</b>	<b>\$366,397,659.07</b>	<b>6,356,889</b>	<b>\$398,500,538.43</b>





# Appendix J





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

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## FDA NEWS RELEASE

For Immediate Release: March 29, 2013

FDA approves Invokana to treat type 2 diabetes

First in a new class of diabetes drugs

The U.S. Food and Drug Administration today approved Invokana (canagliflozin) tablets, used with diet and exercise, to improve glycemic control in adults with type 2 diabetes.

Type 2 diabetes is the most common form of the disease, affecting about 24 million people and accounting for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney damage. Invokana works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels. Its safety and effectiveness were evaluated in nine clinical trials involving over 10,285 patients with type 2 diabetes. The trials showed improvement in hemoglobin A1c levels (a measure of blood sugar control) and fasting plasma glucose (blood sugar) levels.

Invokana has been studied as a stand-alone therapy and in combination with other type 2 diabetes therapies including metformin, sulfonylurea, pioglitazone, and insulin. Invokana should not be used to treat people with type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis.

The FDA is requiring five postmarketing studies for Invokana: a cardiovascular outcomes trial; an enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamic study and a safety and efficacy study.

The most common side effects of Invokana are vaginal yeast infection (vulvovaginal candidiasis) and urinary tract infection. Because Invokana is associated with a diuretic effect, it can cause a reduction in intravascular volume leading to orthostatic or postural hypotension (a sudden fall in blood pressure when standing up). This may result in symptoms such as dizziness or fainting, and is most common in the first three months of therapy. Invokana is manufactured for Janssen Pharmaceuticals, Inc., Titusville, N.J.

## FDA NEWS RELEASE

For Immediate Release: March 20, 2013

FDA approves Dotarem, a new magnetic resonance imaging agent

The U.S. Food and Drug Administration today approved Dotarem (gadoterate meglumine) for use in magnetic resonance imaging (MRI) of the brain, spine and associated tissues of patients ages 2 years and older.

Dotarem is a gadolinium-based contrast agent (GBCA) that helps radiologists see abnormalities on images of the central nervous system (CNS), the part of the body that contains the brain and spine, and surrounding tissues.

Dotarem's safety and effectiveness were established in a clinical trial of 245 adult and 38 pediatric patients ages 2 years and older with suspected CNS abnormalities. Each patient received a baseline MRI without Dotarem, and then the MRI was repeated following Dotarem administration.

Results showed that, in comparison to the baseline images, Dotarem MRI helped radiologists better see CNS lesions. Dotarem also helped the radiologists identify lesion borders and other lesion features. Similar results were obtained in a clinical trial conducted among patients who were known to have CNS abnormalities. All GBCAs, including Dotarem, carry a boxed warning about the risk of nephrogenic systemic fibrosis (NSF), a rare but serious condition associated with the use of GBCAs in certain patients with kidney disease. NSF is characterized by pain and thickening of the skin, and can cause fibrosis of internal organs. There is no known treatment for NSF, and all approved, professional GBCA labeling describes ways to minimize the NSF risk. Side effects to Dotarem were uncommon in clinical trials. However, the most commonly reported side effects were nausea, headache, pain or coldness at the injection site, and burning sensation. Dotarem is the seventh GBCA approved by the FDA for use in patients undergoing CNS MRI. Other FDA-approved GBCAs with a CNS MRI indication include Magnevist (1988), Prohance (1992), Omniscan (1993), Optimark (1999), Multihance (2004) and Gadavist (2011). Dotarem is marketed by Bloomington, Ind.-based Guerbet LLC.

## Safety Announcements

FDA Drug Safety Communication: Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms

**[3-12-2013]** The U.S. Food and Drug Administration (FDA) is warning the public that azithromycin (Zithromax or Zmax) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. This communication is a result of our review of a study by medical researchers as well as another study by a manufacturer of the drug that assessed the potential for azithromycin to cause abnormal changes in the electrical activity of the heart.

The azithromycin drug labels<sup>3</sup> have been updated to strengthen the *Warnings and Precautions* section with information related to the risk of QT interval prolongation and torsades de pointes, a specific, rare heart rhythm abnormality. Information has also been added regarding the results of a clinical QT study which showed that azithromycin can prolong the QTc interval. (see Data Summary)

**Health care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events (see Additional Information for Health Care Professionals below). FDA notes that the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.**

FDA released a statement on May 17, 2012<sup>4</sup>, about a **New England Journal of Medicine (NEJM)** study that compared the risks of cardiovascular death in patients treated with the antibacterial drugs azithromycin, amoxicillin, ciprofloxacin (Cipro), and levofloxacin (Levaquin), or no antibacterial drug.<sup>1</sup> The study reported an increase in cardiovascular deaths, and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (Zithromax) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. The risks of cardiovascular death associated with levofloxacin treatment were similar to those associated with azithromycin treatment.

FDA will update health care professionals and the public with any relevant information that becomes available about azithromycin and the risk of abnormal heart rhythms.

Additional Information for Health Care Professionals

- i Health care professionals should consider the risk of torsades de pointes and fatal arrhythmia when considering treatment options with azithromycin or alternative antibacterial drugs. Groups at higher risk include:
  - o Patients with known prolongation of the QT interval, a history of torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure
  - o Patients on drugs known to prolong the QT interval
  - o Patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents.
- i Elderly patients and patients with cardiac disease may be more susceptible to the effects of arrhythmogenic drugs on the QT interval.
- i The potential risk of QT prolongation should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide or fluoroquinolone drug classes also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.
- i Report adverse events involving azithromycin to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of the page.

## Safety Announcements

FDA Drug Safety Communication: FDA investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes

[3-14-2013] The U.S. Food and Drug Administration (FDA) is evaluating unpublished new findings by a group of academic researchers that suggest an increased risk of pancreatitis, or inflammation of the pancreas, and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with a class of drugs called incretin mimetics. These findings were based on examination of a small number of pancreatic tissue specimens taken from patients after they died from unspecified causes. FDA has asked the researchers to provide the methodology used to collect and study these specimens and to provide the tissue samples so the Agency can further investigate potential pancreatic toxicity associated with the incretin mimetics.

Drugs in the incretin mimetic class include exenatide (Byetta, Bydureon), liraglutide (Victoza), sitagliptin (Januvia, Janumet, Janumet XR, Juvisync), saxagliptin (Onglyza, Kombiglyze XR), alogliptin (Nesina, Kazano, Oseni), and linagliptin (Tadjenta, Jentadueto). These drugs work by mimicking the incretin hormones that the body usually produces naturally to stimulate the release of insulin in response to a meal. They are used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

FDA has not reached any new conclusions about safety risks with incretin mimetic drugs. This early communication is intended only to inform the public and health care professionals that the Agency intends to obtain and evaluate this new information. FDA will communicate its final conclusions and recommendations when its review is complete or when the Agency has additional information to report.

FDA previously warned the public about postmarketing reports of acute pancreatitis, including fatal and serious nonfatal cases, associated with the use of the incretin mimetic drugs exenatide and sitagliptin. A recently published study that examined insurance records also found the use of exenatide or sitagliptin could double the risk of developing acute pancreatitis. The Warnings and Precautions section of the drug labels and the patient Medication Guides for incretin mimetics contain warnings about the risk of acute pancreatitis. FDA has not previously communicated about the potential risk of pre-cancerous findings of the pancreas with incretin mimetics. Further, FDA has not concluded these drugs may cause or contribute to the development of pancreatic cancer.

At this time, patients should continue to take their medicine as directed until they talk to their health care professional, and health care professionals should continue to follow the prescribing recommendations in the drug labels.

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

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

### [Acetylcysteine Inhalation Solution](#)

[Acyclovir Sodium Injection](#) (initial posting 11/13/2012)

[Alfentanil \(Alfenta\) Injection](#) (initial posting 1/23/2012)

[Alteplase \(Cathflo Activase\)](#) (initial posting 1/27/2012) **UPDATED** 3/25/2013

### [Amikacin Injection](#)

[Amino Acid Products](#) (initial posting 2/14/2012) **UPDATED** 4/2/2013

[Aminocaproic Acid Injection](#) (initial posting 3/8/2013) **UPDATED** 3/26/2013

[Aminophylline](#) (initial posting 12/10/2012) **UPDATED** 3/26/2013

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

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

[Argatroban Injection](#) (initial posting date 2/11/2013)

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

[Atropine Sulfate Injection](#) **UPDATED** 3/29/2013

[Bacteriostatic 0.9% Sodium Chloride](#) (initial posting 9/10/2012)

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

[Bismuth subsalicylate/tetracycline hydrochloride/metronidazole \(Helidac\) Therapy](#) (initial posting 3/8/2012)

[Bumetanide Injection](#) (initial posting 6/21/2012) **UPDATED** 3/26/2013

[Bupivacaine Hydrochloride \(Marcaine, Sensorcaine\) Injection](#) **UPDATED** 3/26/2013

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

[Caffeine, anhydrous \(125 mg/mL\) and Sodium benzoate \(125 mg/mL\)](#) **UPDATED** 3/26/2013

[Caffeine and Ergotamine Tartrate Tablet](#) (initial posting 3/8/2012)

[Calcium Chloride Injection](#) (initial posting 12/11/2012) **UPDATED** 3/29/2013

[Calcium Gluconate Injection](#) (initial posting 1/10/2013) **UPDATED** 3/28/2013

[Cetorelix Acetate for Injection \(Cetrotide\)](#) (initial posting 9/20/2012)

[Chromic Chloride Injection](#)

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

[Citric Acid; Gluconolactone; Magnesium Carbonate Solution \(Renacidin\); Irrigation](#) (initial posting 6/30/2012)

[Cyanocobalamin Injection](#) **UPDATED** 3/26/2013

[Daunorubicin Hydrochloride Solution for Injection](#)

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

[Desmopressin Injection \(DDAVP\)](#)

[Dexamethasone Sodium Phosphate Injection](#) (initial posting 1/15/2013)

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

[Dextrose Injection](#) (initial posting 5/23/2012) **UPDATED** 3/29/2013

[Diazepam Injection](#) **UPDATED** 3/29/2013

[Dipyridamole Injection](#) (initial posting 7/24/2012)

[Doxorubicin \(adriamycin\) lyophilized powder](#) (initial posting 12/2/2011)

[Doxorubicin Liposomal Injection](#) **UPDATED** 3/19/2013

[Doxycycline Hyclate](#) (initial posting 1/18/2013) **UPDATED** 3/22/2013

[Edetate Calcium Disodium \(Calcium Disodium Versenate\) Injection](#) (initial posting 10/12/2012)

[Epinephrine Injection](#) (initial posting 4/27/2012) **UPDATED** 3/29/2013

[Epinephrine 1mg/mL \(Preservative Free\)](#) (initial posting 6/21/2012) **UPDATED** 3/26/2013

[Ethiodol \(ETHIODIZED OIL\) ampules](#)

[Etomidate \(Amidate\) Injection](#) (initial posting 2/9/2012) **UPDATED** 3/28/2013

[Fentanyl Citrate \(Sublimaze\) Injection](#) **UPDATED** 3/29/2013

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

[Fosphenytoin Sodium \(Cerebyx\) Injection](#) (initial posting 3/30/2012)

[Fospropofol disodium \(Lusedra\) Injection](#) (initial posting 6/18/2012)

[Furosemide Injection](#) (initial posting 6/20/2012) **UPDATED** 3/29/2013

[Gallium Nitrate Injection \(Ganite\)](#) (initial posting 4/4/2012)

[Heparin Sodium Premixes](#) (initial posting 7/5/2012)

[Hydromorphone Hydrochloride \(Dilaudid\) Injection](#) (initial posting 3/7/2012) **UPDATED** 3/26/2013

[Hydromorphone Hydrochloride Tablets](#) (initial posting 2/19/2013)

[Ibandronate sodium \(Boniva\) injection](#) (initial posting 6/6/2012) **UPDATED** 3/19/2013

[Intravenous Fat Emulsion](#)

[Isoniazid Tablets](#)

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

[Ketorolac Tromethamine Injection](#) **UPDATED** 3/28/2013

[Leucovorin Calcium Lyophilized Powder for Injection](#) **UPDATED** 4/2/2013

[Leuprolide Acetate Injection](#)

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

[Lidocaine HCL, 4% Topical Solution](#) (initial posting date - 2/12/2013)

[Lidocaine \(Xylocaine\) Hydrochloride Injection](#) (initial posting date - 2/22/2012) **UPDATED** 3/29/2013

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

[Lorazepam \(Ativan\) Injection](#) **UPDATED** 3/26/2013

[Magnesium Sulfate Injection](#) **UPDATED** 3/29/2013

[Mannitol Injection \(Osmitrol, Resectisol\) Injection](#) (initial posting date - 12/21/2011)

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

[Methoxsalen \(Oxsoalene\) 1% topical lotion](#)

[Methyldopate HCL Injection](#)

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

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

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

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

[Midazolam HCL \(Versed\) Injection](#) **UPDATED** 3/26/2013

[Morphine Sulfate Injection](#) **UPDATED** 3/26/2013

[Morphine Sulfate \(Astramorph PF, Duramorph, Infumorph\) Injection \(Preservative Free\)](#) **UPDATED** 3/26/2013

[Multi-Vitamin Infusion \(Adult and pediatric\)](#)

[Nalbuphine HCL \(Nubain\) Injection](#) (initial posting 5/15/2012) **UPDATED** 3/26/2013

[Naloxone \(Narcan\) Injection](#) (initial posting 2/22/2012) **UPDATED** 3/29/2013

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

[Nitroglycerin Ointment USP, 2% \(Nitro-Bid\)](#) (Initial posting 10/23/2012) **UPDATED** 3/28/2013

[Norethindrone and Ethinyl Estradiol Tablets, USP \(Ovcon 50 Tablets\)](#) (initial posting 4/16/2012)

[Ondansetron \(Zofran\) Injection 2 mg/mL](#) **UPDATED** 3/26/2013

[Ondansetron Injection 32 mg/50 mL premixed bags](#)

[Oseltamivir Phosphate \(Tamiflu\) for Oral Suspension \(6mg/mL 60 mL\)](#) (Initial posting 1/10/2013)

[Pancuronium Bromide Injection](#) **UPDATED** 3/26/2013

[Papaverine Hydrochloride Injection](#) (initial posting 12/17/2012)

[Peginterferon Alfa-2a \(Pegasys\) Injection-Prefilled Syringes](#) (initial posting 3/26/2012)

[Pentamidine isethionate inhalant \(NebuPent\)](#) (initial posting 8/27/2012)

[Pentamidine isethionate for injection \(Pentam 300\)](#) (initial posting 8/27/2012)

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

[Potassium Acetate Injection, USP 2 mEq/mL](#) **UPDATED** 3/29/2013

[Potassium Chloride Injection 2 mEq/mL](#) (initial posting 5/15/2012) **UPDATED** 3/26/2013

[Potassium Phosphate Injection](#) **UPDATED** 3/26/2013

[Procainamide HCL Injection](#) **UPDATED** 3/26/2013

[Prochlorperazine Injection](#) (initial posting 1/30/2012) **UPDATED** 4/2/2013

[Promethazine Injection](#) (initial posting 2/10/2012)

[Propofol \(Diprivan\) Injection](#) (initial posting 4/5/2012) **UPDATED** 3/29/2013

[Pyridostigmine Bromide \(Regnol\) Injection](#)

[Rifampin for Injection](#) (initial posting 3/22/2013) **UPDATED** 4/2/2013

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

[Selenium Injection](#) **UPDATED** 3/26/2013

[Sodium Acetate Injection](#) (initial posting 3/20/2012) **UPDATED** 3/26/2013

[Sodium benzoate and Sodium phenylacetate \(Ammonul\) Injection](#)

[Sodium Bicarbonate Injection](#) (initial posting 4/4/2012)

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

[Sodium Chloride 23.4%](#) **UPDATED**

[Sodium Phosphate Injection](#) **UPDATED** 3/26/2013

[Succinylcholine \(Anectine, Quelicin\) Injection](#) (initial posting 8/17/2012)

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

[Sulfamethoxazole 80mg/trimethoprim 160mg/ml injection \(SMX/TMP\) Bactrim](#)

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

[Technetium Tc99m Sestamibi Kit for Injection](#) (initial posting 2/14/2012)

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

[Tetracycline Capsules](#)

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

[Ticarcillin disodium/Clavulanic Potassium Injection \(Timentin\)](#) (initial posting 8/16/12)

[Ticlopidine \(Ticlid\) Tablets](#)

[Tobramycin Solution for Injection](#)

[Trace Elements](#) (initial posting 1/24/2013)

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

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

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

[Vitamin K Injection](#)(initial posting 2/12/2013)

[Zinc Injection](#) (initial posting 2/15/2012) **UPDATED** 3/29/2013