South Dakota

Department of Social Services

Medicaid P&T Committee Meeting

March 13, 2009

DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES
700 Governors Drive
Pierre, South Dakota 57501-2291
(605) 773-3495
FAX (605) 773-5246

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

Friday, March 13, 2009
1:00 – 3:00 PM

DDN Locations:
Sioux Falls
University Center Room 282S
4801 Career Avenue

Pierre
Capitol Building Room B12
500 E Capitol

Rapid City
Rapid City Regional Hospital
353 Fairmont Blvd/Edu. Services

Call to Order

Approval of Minutes of Previous Meeting

Prior Authorization Update

Review of Top 15 Therapeutic Categories/Top 25 Drugs

Old Business
- **Duplicate Antipsychotic Therapy Update**
- **Antidepressant Mailing Update**
- **Quantity Limits Update**
- **Singulair® Update**
- **Xopenex® Update**

Drug Product and Utilization Review
- **Lyrica® Review**
- **Targeted Immunomodulator Review (Enbrel®, Kineret®, Orencia®, Humira®, Remicade®, Cimzia®, Raptiva® and Amevive®)**
- **Xolair® Review**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

Minutes of the December 12, 2008
Pharmacy & Therapeutics (P&T) Committee Meeting
SD Department of Social Services, Medical Services Division

Members present
Verdayne Brandenburg, M.D.; Dana Darger, R.Ph.; James Engelbrecht, M.D.; William Ladwig, R.Ph.; Dennis Hedge, PharmD.; Rick Holm, M.D.; Debra Farver, PharmD.; Timothy Soundy, M.D.

Members absent
Willis Sutliff, M.D.
Galen Goeden, R.Ph.

DSS staff present
Mike Jockheck, R.Ph.; Larry Iversen

HID staff present
Candace Rieth, Pharm.D.

Administrative Business
The P&T meeting was called to order by chair, D. Darger, at approximately 1pm. The minutes of the September 8, 2008 meeting were presented. B. Ladwig made a motion to approve as written, with a second by R. Holm. The motion was approved unanimously.

Prior Authorization Statistics
C. Rieth presented an overview of the prior authorization (PA) activity for September 2008. There were a total of 1,887 PAs processed in the month of September, with 99.63% of those requests responded to in less than 8 hours. There were 1,676 (89%) requests received electronically and 211 (11%) requests received by fax. In response to a request from the committee, C. Rieth presented the number of approvals and denials, by form type, for the faxed (manual) PA requests.

Analysis of the Top 15 Therapeutic Classes
C. Rieth reviewed the Top 15 Therapeutic Classes by total cost of claims from 04/01/2008 – 06/30/2008. The top five classes were antipsychotics, anticonvulsants, cerebral stimulants, proton-pump inhibitors, and antidepressants. The top 15 therapeutic classes make up 42.78% of total claims.

Duplicate Antipsychotic Therapy
Committee members asked for information regarding duplicate antipsychotic utilization. C. Rieth presented utilization information for the antipsychotics including patients with multiple antipsychotic scripts. T. Soundy made a motion to recommend that the State investigate duplicate antipsychotic therapy, further. T. Soundy suggested that this be done through an internal peer review process. R. Holm seconded the motion. D. Yocum spoke against prior authorization of antipsychotics. P. Arens, representing NAMI, spoke against prior authorization

of antipsychotics. R. Sang, a local practitioner spoke against prior authorization of antipsychotics. The motion was approved unanimously.

Invega Review
Invega review tabled.

Antidepressant Review
C. Rieth provided the committee with a draft provider letter regarding a two-tiered process for antidepressants. V. Brandenburg made a motion to send the letter to providers. B. Ladwig seconded the motion. A provider letter will be sent prior to the next meeting.

Quantity Limits
C. Rieth presented the committee with a list of quantity limit suggestions. B. Ladwig made a motion to implement the quantity limits listed. D. Farver seconded the motion. S. Schmitz, representing Glaxo, spoke regarding limits on Requip XL. The motion was approved unanimously.

Singulair Review
In response to a previous request from the committee, C. Rieth presented information regarding diagnoses codes submitted on patients utilizing Singulair. V. Brandenburg made a motion to place Singulair on prior authorization with an automatic approval on the first prescription received by a recipient. J. Engelbrecht seconded the motion. M. Stafford, representing Merck, requested that the committee members table the motion until he can provide additional data. V. Brandenburg made a motion to table. R. Holm seconded. The motion was tabled until the committee receives additional data.

Altabax Review
C. Rieth reviewed Altabax utilization with committee members. B. Ladwig made a motion to place a 5g quantity limit on Altabax with a prior authorization for larger tubes. T. Soundy seconded the motion. Motion passed unanimously.

Vusion Review
C. Rieth reviewed Vusion utilization with committee members. R. Holm made a motion to place Vusion on prior authorization. T. Soundy seconded the motion. Motion passed unanimously.

Xopenex Review
C. Rieth reviewed Xopenex utilization with committee members. V. Brandenburg made a motion to send educational letters stating the cost factor of Xopenex. R. Holm seconded the motion. S. Hylla, representing Sepracor, spoke against prior authorization of Xopenex. Motion passed unanimously.

Because of time restraints, it was requested that the meeting be adjourned. Lyrica will be tabled until the March meeting. The next meeting date is March 13, 2009. The location will be sent to members and interested parties as soon as possible. The SD Medicaid P&T meeting was adjourned at 3:00pm.

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
January 1, 2009 – January 31, 2009

PA Response Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
1,690	1,686	4	99.76%	0.24%

By Form Type

Form Type	Description	Approve	Deny
ANT	Antihistamines	12	48
ARB	ARBS	15	13
DAW	Dispense As Written	18	43
GRH	Growth Hormone	3	4
HLM	Head Lice Medication	3	0
MAX	Max Units Override	74	1,144
PPI	Proton Pump Inhibitors	84	228
ULT	Ultram ER	0	1
Totals		209	1,481

By Request Type

01/01/09 - 01/31/09	# of	Electronic Requests		Faxed Requests		Mailed Requests		Phone Requests	
	Requests	#	%	#	%	#	%	#	%
Prior Authorizations:									
Antihistamines	60	52	87%	8	13%	0	0%	0	0%
ARBS	28	22	79%	6	21%	0	0%	0	0%
Dispense As Written	61	37	61%	24	39%	0	0%	0	0%
Growth Hormone	7	4	57%	3	43%	0	0%	0	0%
Head Lice Medication	3	0	0%	3	100%	0	0%	0	0%
Max Units Override	1,218	1,139	94%	79	6%	0	0%	0	0%
Proton Pump Inhibitors	312	248	79%	64	21%	0	0%	0	0%
Ultram ER	1	0	0%	1	100%	0	0%	0	0%
Prior Authorization Totals	1,690	1,502	89%	188	11%	0	0%	0	0%

South Dakota Medicaid
Monthly PA Report
January 1, 2009 – January 31, 2009

Electronic PAs (unique)

01/01/09 - 01/31/09	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antihistamines	6	46	0	52	11.50%	52
ARBS	9	12	0	21	42.90%	22
Dispense As Written	0	37	0	37	0.00%	37
Growth Hormone	0	4	0	4	0.00%	4
Max Units Override	19	1,056	0	1,075	1.80%	1,139
Proton Pump Inhibitors	27	201	0	228	11.80%	248
Prior Authorization Totals:	61	1,356	0	1,417	4.3%	1,502

Manual Approvals and Denials

01/01/09 - 01/31/09	# Requests	# Approved	# Denied
Prior Authorizations:			
Antihistamines	8	6	2
ARBS	6	6	0
Dispense as Written	24	18	6
Growth Hormone	3	3	0
Head Lice	3	3	0
Max Units	79	55	24
Proton Pump Inhibitors	64	57	7
Ultram ER	1	0	1
Prior Authorization Totals:	188	148	40

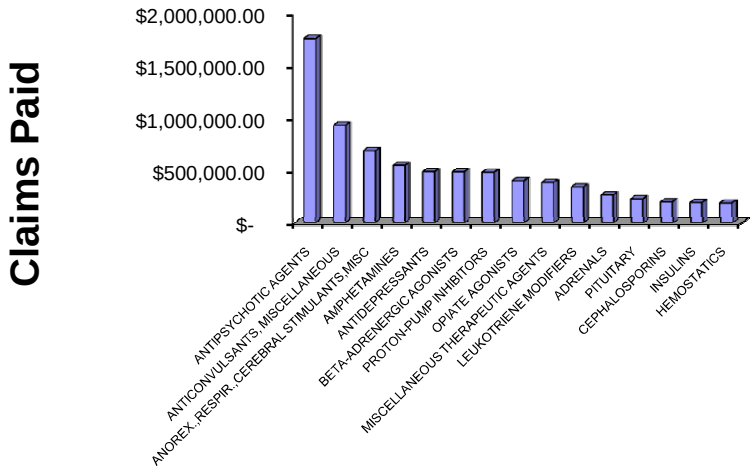
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 10/01/2008 - 12/31/2008

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	6,362	$ 1,751,948.61	$ 275.38	3.69%
ANTICONVULSANTS, MISCELLANEOUS	5,814	$ 928,059.27	$ 159.62	3.37%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	5,079	$ 687,035.86	$ 135.27	2.94%
AMPHETAMINES	3,850	$ 548,515.37	$ 142.47	2.23%
ANTIDEPRESSANTS	11,936	$ 489,324.53	$ 41.00	6.92%
BETA-ADRENERGIC AGONISTS	7,290	$ 487,659.57	$ 66.89	4.23%
PROTON-PUMP INHIBITORS	5,249	$ 482,447.37	$ 91.91	3.04%
OPIATE AGONISTS	11,409	$ 401,147.09	$ 35.16	6.61%
MISCELLANEOUS THERAPEUTIC AGENTS	1,281	$ 386,127.71	$ 301.43	0.74%
LEUKOTRIENE MODIFIERS	3,195	$ 341,372.86	$ 106.85	1.85%
ADRENALS	4,110	$ 267,248.45	$ 65.02	2.38%
PITUITARY	513	$ 229,905.50	$ 448.16	0.30%
CEPHALOSPORINS	5,396	$ 201,727.14	$ 37.38	3.13%
INSULINS	1,441	$ 196,142.73	$ 136.12	0.84%
HEMOSTATICS	12	$ 190,486.32	$ 15,873.86	0.01%
TOTAL TOP 15	72,937	$ 7,589,148.38	$ 104.05	42.28%

Total Rx Claims From 10/01/2008 - 12/31/2008	172,491

Top 15 Therapeutic Classes
Based on Total Cost of Claims

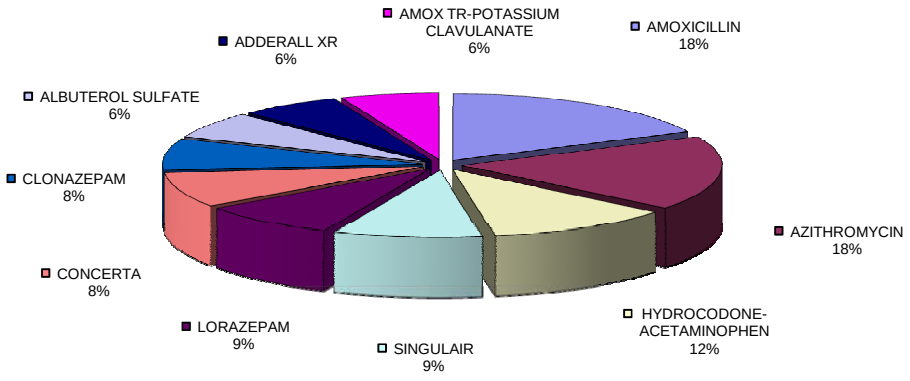


TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/2008 - 12/31/2008

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	6,164	$ 56,659.78	$ 9.19	3.57%
AZITHROMYCIN	MACROLIDES	6,114	$ 139,816.89	$ 22.87	3.54%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	3,986	$ 41,327.84	$ 10.37	2.31%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,177	$ 338,881.76	$ 106.67	1.84%
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,947	$ 25,966.32	$ 8.81	1.71%
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS(	2,856	$ 417,915.44	$ 146.33	1.66%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	2,594	$ 22,477.82	$ 8.67	1.50%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	2,214	$ 41,704.31	$ 18.84	1.28%
ADDERALL XR	AMPHETAMINES	2,180	$ 381,684.24	$ 175.08	1.26%
AMOX TR-POTASSIUM CLAVULANA	PENICILLINS	2,094	$ 59,885.01	$ 28.60	1.21%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,022	$ 42,370.61	$ 20.95	1.17%
FLUOXETINE HCL	ANTIDEPRESSANTS	1,998	$ 17,841.74	$ 8.93	1.16%
SERTRALINE HCL	ANTIDEPRESSANTS	1,857	$ 21,809.69	$ 11.74	1.08%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	1,779	$ 14,163.22	$ 7.96	1.03%
CEFDINIR	CEPHALOSPORINS	1,733	$ 97,891.46	$ 56.49	1.00%
LEVOTHYROXINE SODIUM	THYROID AGENTS	1,663	$ 15,353.77	$ 9.23	0.96%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	1,630	$ 52,074.94	$ 31.95	0.94%
PREVACID	PROTON-PUMP INHIBITORS	1,623	$ 253,675.11	$ 156.30	0.94%
CEPHALEXIN	CEPHALOSPORINS	1,614	$ 19,900.54	$ 12.33	0.94%
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,588	$ 367,483.75	$ 231.41	0.92%
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	1,547	$ 11,383.19	$ 7.36	0.90%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,530	$ 269,072.88	$ 175.86	0.89%
TRAZODONE HCL	ANTIDEPRESSANTS	1,466	$ 10,076.24	$ 6.87	0.85%
ACETAMINOPHEN-CODEINE	OPIATE AGONISTS	1,380	$ 11,664.02	$ 8.45	0.80%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,379	$ 10,240.57	$ 7.43	0.80%
TOTAL TOP 25		59,135	$ 2,741,321.14	$ 46.36	34.28%

Total Rx Claims From 10/01/2008 - 12/31/2008	172,491

Top 10 Drugs
Based on Number of Claims

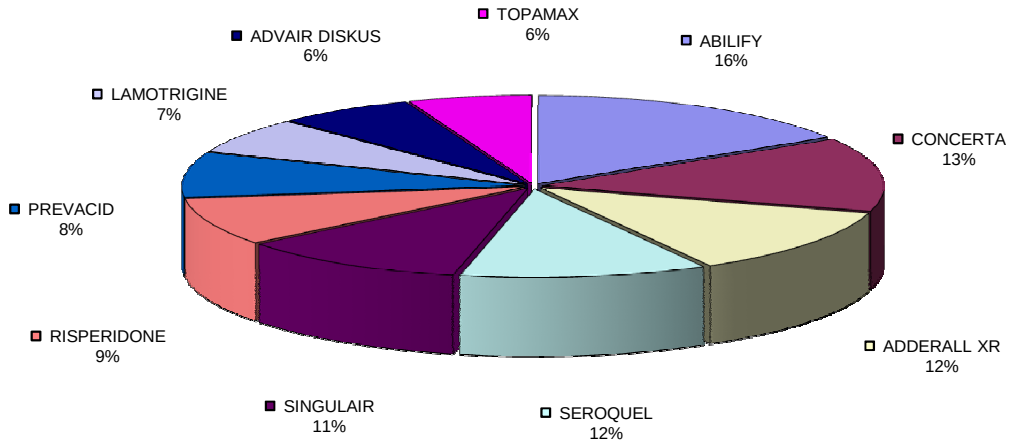


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/2008 - 12/31/2008

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,329	$ 505,183.94	$ 380.12	0.77%
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,856	$ 417,915.44	$ 146.33	1.66%
ADDERALL XR	AMPHETAMINES	2,180	$ 381,684.24	$ 175.08	1.26%
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,588	$ 367,483.75	$ 231.41	0.92%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,177	$ 338,881.76	$ 106.67	1.84%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,530	$ 269,072.88	$ 175.86	0.89%
PREVACID	PROTON-PUMP INHIBITORS	1,623	$ 253,675.11	$ 156.30	0.94%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	790	$ 205,554.57	$ 260.20	0.46%
ADVAIR DISKUS	BETA-ADRENERGIC AGONISTS	1,082	$ 201,927.85	$ 186.62	0.63%
TOPAMAX	ANTICONVULSANTS, MISCELLANEOUS	582	$ 182,871.90	$ 314.21	0.34%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,166	$ 175,910.45	$ 150.87	0.68%
ZYPREXA	ANTIPSYCHOTIC AGENTS	343	$ 170,789.63	$ 497.93	0.20%
VYVANSE	AMPHETAMINES	1,152	$ 152,648.88	$ 132.51	0.67%
OXYCONTIN	OPIATE AGONISTS	469	$ 152,284.45	$ 324.70	0.27%
AZITHROMYCIN	MACROLIDES	6,114	$ 139,816.89	$ 22.87	3.54%
FOCALIN XR	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	895	$ 122,669.92	$ 137.06	0.52%
RISPERDAL CONSTA	ANTIPSYCHOTIC AGENTS	153	$ 108,283.31	$ 707.73	0.09%
PULMICORT	ADRENALS	451	$ 104,865.26	$ 232.52	0.26%
NEXIUM	PROTON-PUMP INHIBITORS	560	$ 104,194.94	$ 186.06	0.32%
EFFEXOR XR	ANTIDEPRESSANTS	694	$ 102,656.20	$ 147.92	0.40%
CYMBALTA	ANTIDEPRESSANTS	710	$ 100,879.89	$ 142.08	0.41%
NUTROPIN AQ	PITUITARY	47	$ 100,841.23	$ 2,145.56	0.03%
CEFDINIR	CEPHALOSPORINS	1,733	$ 97,891.46	$ 56.49	1.00%
GEODON	ANTIPSYCHOTIC AGENTS	275	$ 96,802.66	$ 352.01	0.16%
KEPPRA	ANTICONVULSANTS, MISCELLANEOUS	345	$ 93,417.97	$ 270.78	0.20%
TOTAL TOP 25		31,844	$ 4,948,204.58	$ 155.39	18.46%

Total Rx Claims From 10/01/2008 - 12/31/2008	172,491

Top 10 Drugs
Based on Total Claims Cost



Singulair Utilization
01/01/2008 – 12/31/2008

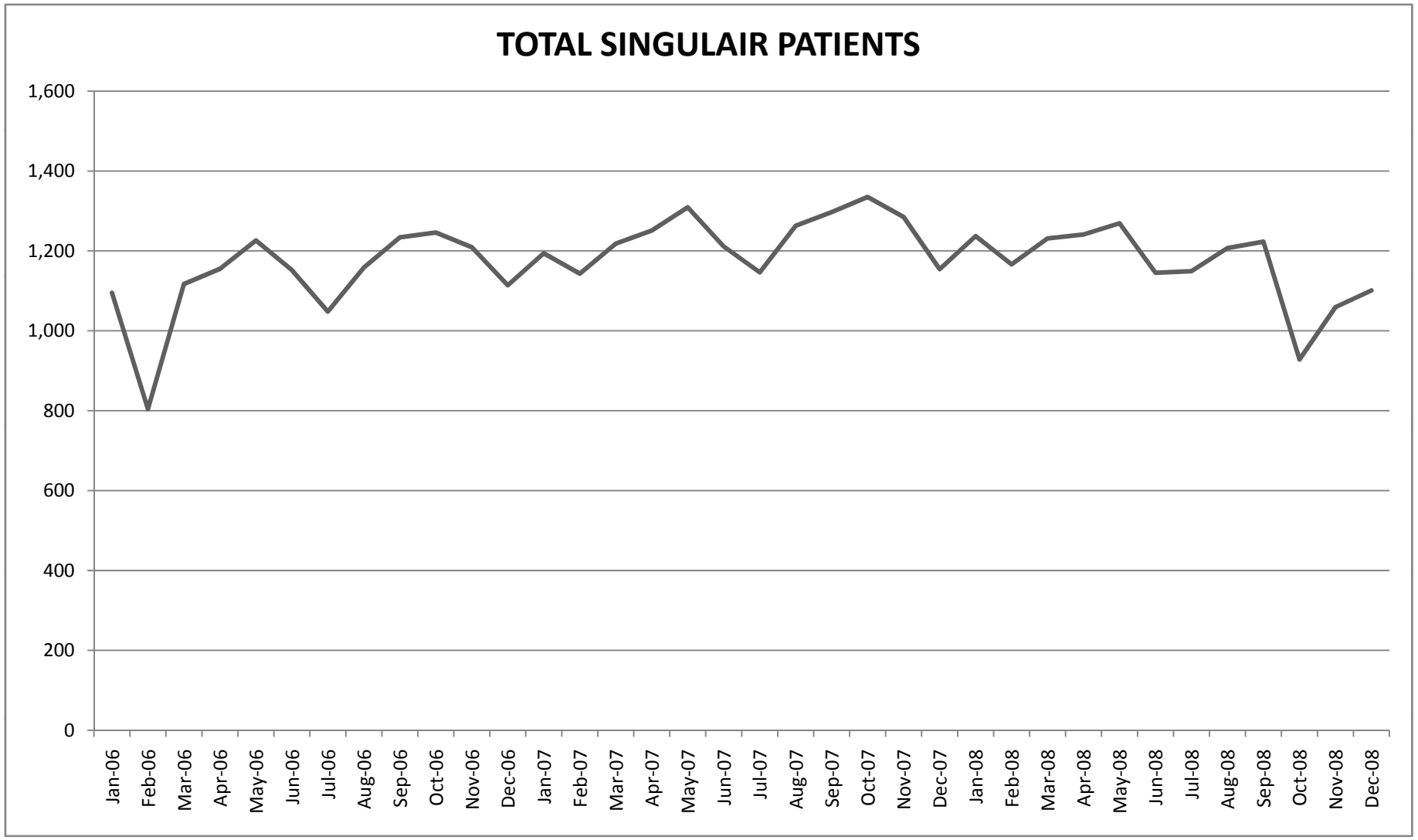
Label Name	Rx Num	Total Reimb Amt	Average cost per script
SINGULAIR 10 MG TABLET	4596	$485,394.16	$105.61
SINGULAIR 4 MG TABLET CHEW	4722	$496,106.30	$105.06
SINGULAIR 5 MG TABLET CHEW	5140	$532,479.12	$103.60
Totals	14458	$1,513,979.58	3,765 recipients

Summary by Age
01/01/2008 – 12/31/2008

Age	Recip Count	Rx Count
0	12	15
1	177	371
2	224	667
3	239	688
4	259	899
5	289	1077
6	264	1145
7	249	976
8	236	980
9	228	1037
10	201	806
11	168	682
12	162	606
13	141	543
14	100	361
15	95	404
16	91	284
17	92	344
18	70	322
19	41	157
20	13	54
21	9	23
22	6	12
23	12	51
24	12	53
25	14	45
26	14	39

Age	Recip Count	Rx Count
27	12	51
28	14	41
29	11	32
30	15	64
31	8	33
32	11	47
33	7	25
34	9	28
35	13	57
36	8	41
37	10	41
38	13	44
39	17	89
40	8	36
41	7	43
42	10	43
43	14	55
44	6	31
45	8	46
46	9	33
47	5	36
48	10	50
49	9	63
50	7	26
51	6	35
52	10	67
53	9	68

Age	Recip Count	Rx Count
54	3	24
55	8	53
56	5	22
57	10	62
58	3	17
59	16	109
60	6	43
61	9	72
62	3	31
63	9	88
64	3	33
65	3	25
66	1	1
67	1	11
89	1	1


TOTAL SINGULAIR PATIENTS
1,600
1,400
1,200
1,000
800
600
400
200
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
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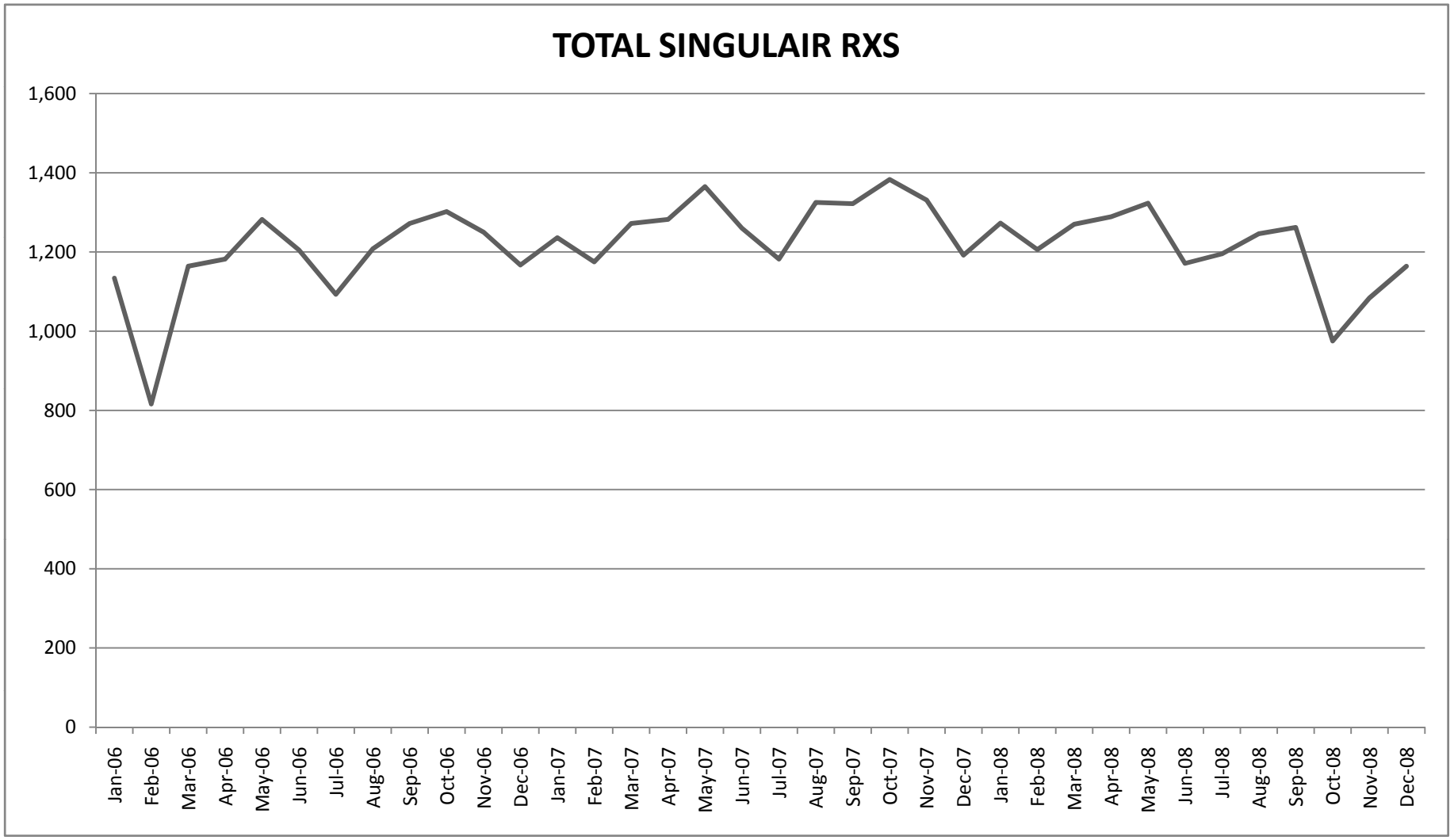
Nov-08
Dec-08


TOTAL SINGULAIR RXS
1,600
1,400
1,200
1,000
800
600
400
200
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
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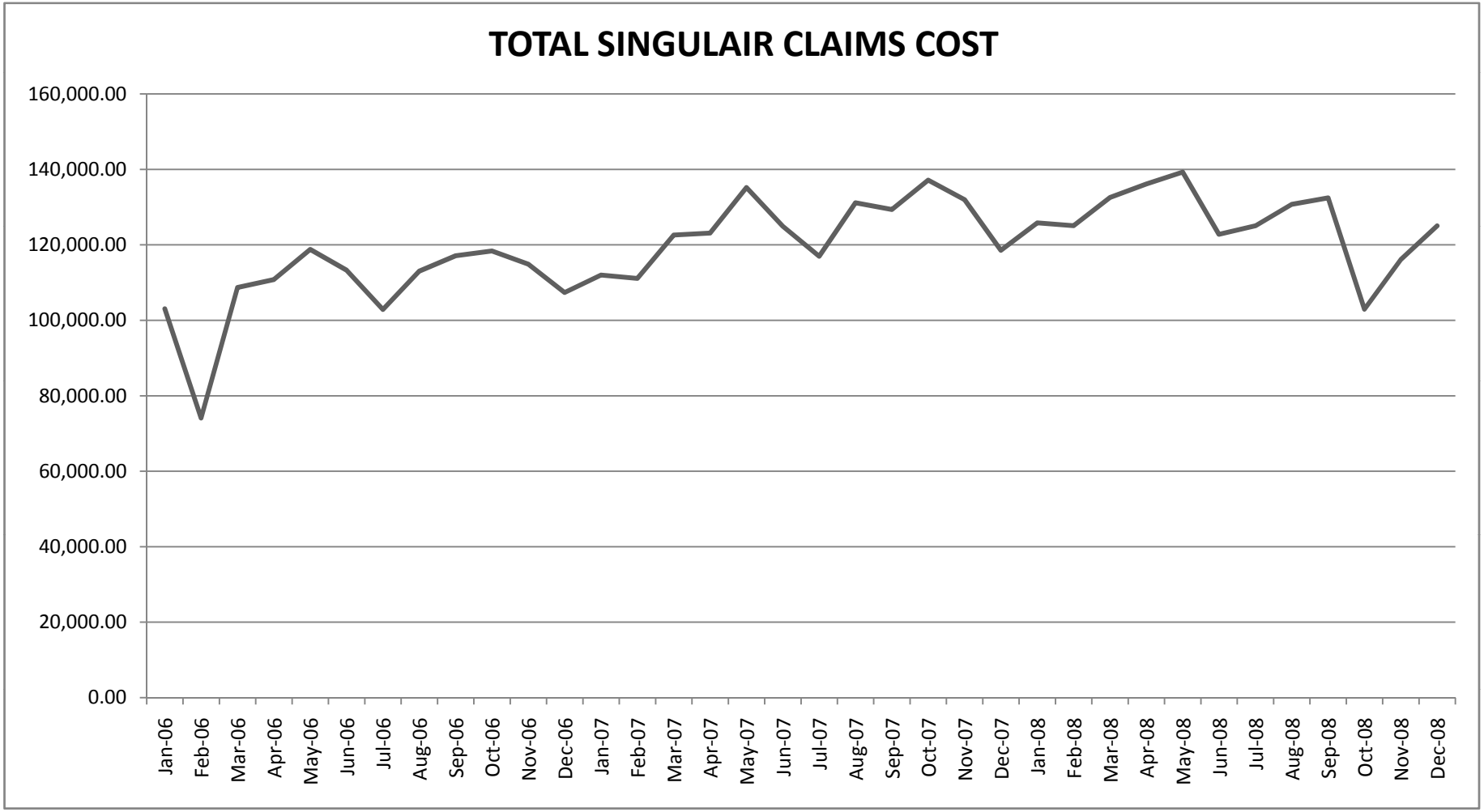
Dec-08


TOTAL SINGULAIR CLAIMS COST
160,000.00
140,000.00
120,000.00
100,000.00
80,000.00
60,000.00
40,000.00
20,000.00
0.00
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
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Jul-08
Aug-08
Sep-08
Oct-08
Nov-08
Dec-08

SINGULAIR PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a prescription for Singulair for the treatment of Seasonal Allergic Rhinitis or Perennial Allergic Rhinitis must use an oral or nasal antihistamine AND a nasal corticosteroid for a minimum of two months.

- **Singulair will be covered for the diagnosis of Asthma.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed two month trial of continuous oral or nasal antihistamine AND a nasal corticosteroid.	Was trial for at least 60 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication: (provide description below):	
Medical Justification for use of Singulair without trial of oral/nasal antihistamine AND nasal corticosteroid:	
Physician Signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
700 GOVERNORS DRIVE
PIERRE, SD 57501-2291
PHONE: 605-773-3495
FAX: 605-773-5246
WEB: dss.sd.gov

DSS
Strong Families - South Dakota's Foundation and Our Future

Dear Medicaid Provider:

The South Dakota Medicaid Pharmacy & Therapeutics (P&T) Committee works with the Department of Social Services (DSS) in developing guidelines to ensure recipients receive cost-effective and appropriate medication therapy. As a part of this process, the P&T Committee requested an educational mailing be sent regarding the average treatment costs of albuterol and levalbuterol. You are receiving this letter because Department records indicate a patient(s) in your care received a prescription for levalbuterol.

On December 12, 2008, the South Dakota Medicaid P&T Committee reviewed the utilization of short acting beta2 agonist. No evidence exists which shows levalbuterol is more effective or exhibits a better safety profile than albuterol.

With the recent FDA removal of inhalers containing chlorofluorocarbon (CFC) propellants, providers were required to transition their patients to an alternative propellant, hydrofluoroalkane (HFA). Available albuterol HFA Inhaler products and their corresponding average cost to DSS per prescription are Ventolin HFA ($36), ProAir HFA ($37), Proventil HFA ($43), and Xopenex HFA ($49).

Albuterol and levalbuterol are also available as nebulizer solutions. Currently, the average Medicaid reimbursement per prescription of levalbuterol solution is $118 versus $22 for albuterol. Studies comparing levalbuterol and albuterol in children have not demonstrated superiority of levalbuterol over albuterol. Therefore, the Department would ask that levalbuterol be reserved for only those patients who do not tolerate albuterol.

In presenting this information to you, the Department recognizes that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware. The Department is dedicated to improving the health and well being of our patients. We thank you for your participation in the South Dakota Medicaid Program and hope that you will assist us in making the most effective utilization of our resources as we continue to provide valuable pharmacy benefits to our patients. Please contact me with any questions you may have.

Sincerely,

Mike Jockheck, RPh
Pharmacy Consultant
DSS, Medical Services

South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Lyrica®

I. Overview

Lyrica® (pregabalin) is indicated for use in patients with fibromyalgia, neuropathic pain associated with diabetic peripheral neuropathy, adjunctive therapy for adult patients with partial-onset seizures, and postherpetic neuralgia. It was approved by the FDA in December 2004.

Treatment of neuropathic pain is one of pregabalin's leading uses. Neuropathic pain is chronic pain that arises from damage to sensory nerves and includes pain arising from trapped or compressed nerves, drug-induced nerve damage, diabetic neuropathy, post-herpetic pain, phantom limb syndrome following limb amputation, peripheral neuropathy and fibromyalgia.

II. Pharmacology

Although the mechanism of action of pregabalin is unknown, results with genetically modified mice and with compounds structurally related to pregabalin (such as gabapentin) suggest that binding to the alpha$_2$-delta subunit may be involved in pregabalin's antinociceptive and antiseizure effects in animal models. In vitro, pregabalin reduces the calcium-dependent release of several neurotransmitters, possibly by modulation of calcium channel function.

While pregabalin is a structural derivative of the inhibitory neurotransmitter GABA, it does not bind directly to $GABA_A$, $GABA_B$, or benzodiazepine receptors, does not augment $GABA_A$ responses in cultured neurons, does not alter rat brain GABA concentration, or have acute effects on GABA uptake or degradation. In cultured neurons, however, prolonged application of pregabalin increases the density of GABA transporter protein and increases the rate of functional GABA transport. Pregabalin does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake.

III. Pharmacokinetics

Drug	T_{max} hours	Metabolism	$T_{1/2}$ hours
Pregabalin	1.5	Not appreciably metabolized; approximately 90% excreted in urine unchanged.	6.3

IV. Drug Interactions

Precipitant drug	Object drug	Description
Pregabalin	Ethanol Lorazepam Oxycodone	Additive effects on cognitive and gross motor functioning were seen when pregabalin was coadministered with these drugs. No clinically important effects on respiration were seen.
Pregabalin	Thiazolidinediones	Because the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, take care when coadministering these agents.

V. Warnings and Precautions

- Angioedema (e.g., swelling of the throat, head, and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment.
- Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur.
- Increased seizure frequency may occur in patients with seizure disorders if pregabalin is rapidly discontinued. Withdraw pregabalin gradually over a minimum of one week.
- Pregabalin may cause peripheral edema. Exercise caution when co-administering pregabalin and thiazolidinedione antidiabetic agents.
- Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.

VI. Adverse Effects

In controlled trials of all patient populations combined, dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, and "thinking abnormally" (primarily difficulty with concentration/attention) were more commonly reported by subjects treated with pregabalin than by subjects treated with placebo (five percent or more and twice the rate of that seen in placebo).

There have been post marketing reports of angioedema in patients. Specific symptoms include swelling of the face, mouth, and neck. Some of these reported incidents were life-threatening with respiratory compromise requiring emergency treatment. Caution should be exercised when prescribing pregabalin in patients who have had previous episodes of angioedema or are currently taking other drugs associated with angioedema (e.g. angiotensin converting enzyme inhibitors).

There have been reports of hypersensitivity reactions after initiation of therapy, weight gain, ophthalmic effects, creatine kinase elevation, decreased platelet count, and prolonged PR intervals.

VII. Dosing and Administration

Drug	Adult Dosing	Pediatric Dosing	Availability
Pregabalin	*Neuropathic pain associated with diabetic peripheral neuropathy* – Start 50mg three times a day (150mg/day). Titrate to 300mg/day within one week based on efficacy and tolerability. Maximum recommended dose of pregabalin is 300mg/day in patients with creatinine clearance (CLcr) of at least 60mL/min. Dose should be adjusted for patients with reduced renal function. Doses of 600mg/day have not been shown to confer additional significant benefit and are less well tolerated. *Epilepsy* – Doses of 150 to 600mg/day have been shown to be effective as adjunctive therapy in the treatment of partial-onset seizures in adults.	The safety and efficacy of pregabalin in pediatric patients have not been established.	Capsules: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg.

Drug	Adult Dosing	Pediatric Dosing	Availability
	The total daily dose should be divided and given two or three times daily. The efficacy and adverse reaction profiles of pregabalin have been shown to be dose related. In general, it is recommended that patients be started on a total daily dose no greater than 150mg/day (75 mg two times a day, or 50mg three times a day). Based on individual patient response and tolerability, the dose may be increased to a maximum dose of 600mg/day. *Postherpetic neuralgia* – Recommended dose is150 to 300mg/day in patients with CLcr of at least 60mL/min. Start 75mg two times a day, or 50mg three times a day (150mg/day). Increase to 300mg/day within one week based on efficacy and tolerability. Because pregabalin is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function. Patients who do not experience sufficient pain relief following two to four weeks of treatment with 300mg/day and who are able to tolerate pregabalin may be treated with up to 300mg two times a day or 200mg three times a day (600mg/day). In view of the dose-dependent adverse effects and the higher rate of treatment discontinuation caused by adverse reactions, dosing above 300mg/day should be reserved only for those patients who have ongoing pain and are tolerating 300mg daily. *Fibromyalgia* – Recommended dose is 300 – 450mg/day (for patients with a CLcr greater than 60mL/min). Dosing should begin at 75mg BID (150mg/day) and may be increased to 150mg BID (300mg/day) within one week based on efficacy and		

Drug	Adult Dosing	Pediatric Dosing	Availability
	tolerability. Patients who do not experience sufficient benefit may increase to 225mg BID (450mg/day). There is no evidence that doses above 450mg/day confers additional benefit and is not recommended.		

VIII. Clinical Efficacy

Drug	Condition	Duration	Methods/Results/Conclusions
Pregabalin versus placebo	Fibromyalgia	8 weeks	529 patients with fibromyalgia were followed to primary endpoint of comparison of end point mean pain scores. Pregabalin at 450mg/day significantly reduced the average severity of pain compared with placebo. Significantly more patients in the pregabalin group had ≥ 50% improvement in pain at the end point. Pregabalin at 300 – 450mg/day was associated with significant improvements in sleep quality, fatigue, and global measures of change. Dizziness and somnolence were the most frequent adverse events.
Pregabalin versus placebo	Fibromyalgia	6 weeks (open label) 26 weeks (double blind)	633 patients (279 pregabalin and 287 placebo) were followed to determine the time to loss of therapeutic response (LTR). Time to LTR was significantly longer for patients treated with pregabalin. 61% of placebo patients (vs. 32% of pregabalin patients) had lost therapeutic response. Most adverse effects were mild or moderate in intensity.
Pregabalin versus placebo	Fibromyalgia	14 weeks	745 patients were randomized and had a baseline mean pain score=6.7. Differences from placebo in mean change from baseline to endpoint in pain score were: 300 mg/d, -0.71 (*P*=.0009); 450 mg/d, -0.98, 600 mg/d, -1.00 (each *P*<.0001). On the PGIC, 68% of 300-mg/d, 78% of 450-mg/d, and 66% of 600-mg/d patients reported at least minimal improvement *vs* 48% of placebo patients, representing a statistically significant superiority. Pregabalin 450 and 600 mg/d were associated with statistically significant improvements in total FIQ score: mean differences from placebo at endpoint were: 450 mg/d, -5.24 (*P*=.0041); 600 mg/d, -5.34 (*P*=.0034). Incidence of AEs increased with dosage.

Drug	Condition	Duration	Methods/Results/Conclusions
			The most common AEs were dizziness (pregabalin, 35.8%; placebo, 7.6%) and somnolence (pregabalin, 18.0%; placebo, 3.8%).

IX. Conclusion

Choosing therapy for neuropathic pain can be challenging because of the large number of medications available to treat this condition. Based on a review of evidence comparing pregabalin and gabapentin to placebo, both agents were consistently more effective than placebo for pain relief and/or improvement in function. Further head to head trials are needed to provide evidence supporting the use of pregabalin over gabapentin in the treatment of neuropathic pain.

HID recommendation: It is recommended that a prior authorization be placed on pregabalin based on the lack of clinical evidence comparing pregabalin to gabapentin for patients with neuropathic pain. It is further recommended that if a patient fails a course of gabapentin, the provider may request a prior authorization for pregabalin.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2008.
2. Lyrica® [package insert]. New York, NY; Pfizer Pharmaceuticals; 2007.
3. Crofford LJ, Rowbotham MC, et al. Pregabalin for the treatment of fibromyalgia syndrome: results of a randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2005 Apr;52(4):1264-73.
4. Crofford LJ, Simpson S, et al. A Six-month, Double-blind, Placebo-controlled, Durability of Effect Study of Pregabalin for Pain Associated With Fibromyalgia. Presentation Number L44, American College of Rheumatology Annual Scientific Meeting, November 10-15, 2006, Washington, DC.
5. Arnold LM, Russell IJ, et al. Pregabalin for Management of Fibromyalgia Syndrome (FMS): A 14-Week, Randomized, Double-Blind, Placebo-Controlled, Monotherapy Trial. [poster] Presented at the 59th Annual American Academy of Neurology, May 1-3, 2007; Boston, MA.

South Dakota Medicaid
Lyrica Utilization 05/01/07 to 04/30/08

Label Name	Rx Num	Total Reimb Amt	Average Cost per script
LYRICA 225 MG CAPSULE	1	$64.56	$64.56
LYRICA 300 MG CAPSULE	12	$1,454.46	$121.21
LYRICA 200 MG CAPSULE	24	$3,699.26	$154.14
LYRICA 25 MG CAPSULE	50	$6,192.01	$123.84
LYRICA 150 MG CAPSULE	139	$20,320.01	$146.19
LYRICA 100 MG CAPSULE	255	$39,212.22	$153.77
LYRICA 50 MG CAPSULE	463	$71,757.62	$154.98
LYRICA 75 MG CAPSULE	565	$78,069.49	$138.18
Total 394 Recipients	**1509**	**$220,769.63**	**$146.30**

Lyrica Utilization Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
14	1	3
15	2	12
17	2	2
18	2	13
19	4	17
20	2	15
21	1	5
22	4	14
23	2	17
24	3	12
25	7	18
26	6	20
27	9	39
28	6	18
29	8	22
30	8	33
31	6	12
32	8	17
33	9	16
34	10	22
35	7	23
36	9	33

Age	Recip Count	Rx Count
37	8	37
38	13	21
39	14	62
40	12	48
41	6	33
42	8	24
43	17	50
44	16	49
45	14	54
46	12	53
47	14	33
48	12	47
49	7	47
50	15	58
51	16	71
52	14	82
53	4	16
54	10	51
55	9	41
56	10	35
57	9	49
58	5	35

Age	Recip Count	Rx Count
59	7	21
60	7	29
61	6	24
62	1	9
63	7	31
64	4	10
65	1	6

South Dakota Medicaid
Gabapentin Utilization 05/01/07 to 04/30/08

Label Name	Rx Num	Total Reimb Amt	Average Cost per script
GABAPENTIN 100 MG CAPSULE	428	$7,271.70	$16.99
GABAPENTIN 300 MG CAPSULE	1202	$33,566.78	$27.93
GABAPENTIN 400 MG CAPSULE	162	$5,373.77	$33.17
GABAPENTIN 600 MG TABLET	460	$29,848.33	$64.89
GABAPENTIN 800 MG TABLET	171	$12,880.39	$75.32
NEURONTIN 100 MG CAPSULE	13	$1,078.53	$82.96
NEURONTIN 250 MG/5 ML SOLN	33	$3,762.07	$114.00
NEURONTIN 800 MG TABLET	10	$3,865.25	$386.53
Total 504 Recipients	2479	$97,646.82	$39.39

Gabapentin Utilization Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
1	1	1
3	3	25
4	1	4
6	1	1
7	2	12
8	2	15
10	2	6
11	2	10
13	2	12
14	3	7
15	2	2
16	5	18
17	9	33
18	5	17
19	7	65
20	4	21
21	3	9
22	10	55
23	6	33
24	4	4
25	8	35
26	11	61
27	3	17
28	8	30

Age	Recip Count	Rx Count
29	9	37
30	8	54
31	10	22
32	9	21
33	8	22
34	11	70
35	10	51
36	9	31
37	13	58
38	11	39
39	9	25
40	7	22
41	8	22
42	13	35
43	7	27
44	15	58
45	14	88
46	17	78
47	13	66
48	11	58
49	13	66
50	16	83
51	11	80
52	17	95

Age	Recip Count	Rx Count
53	13	65
54	9	81
55	15	88
56	7	36
57	14	79
58	10	65
59	10	51
60	11	62
61	14	76
62	9	49
63	8	44
64	6	49
65	3	25
69	1	2
76	1	6

Lyrica Recipient Count and Diagnosis
05/01/2007 - 04/30/2008

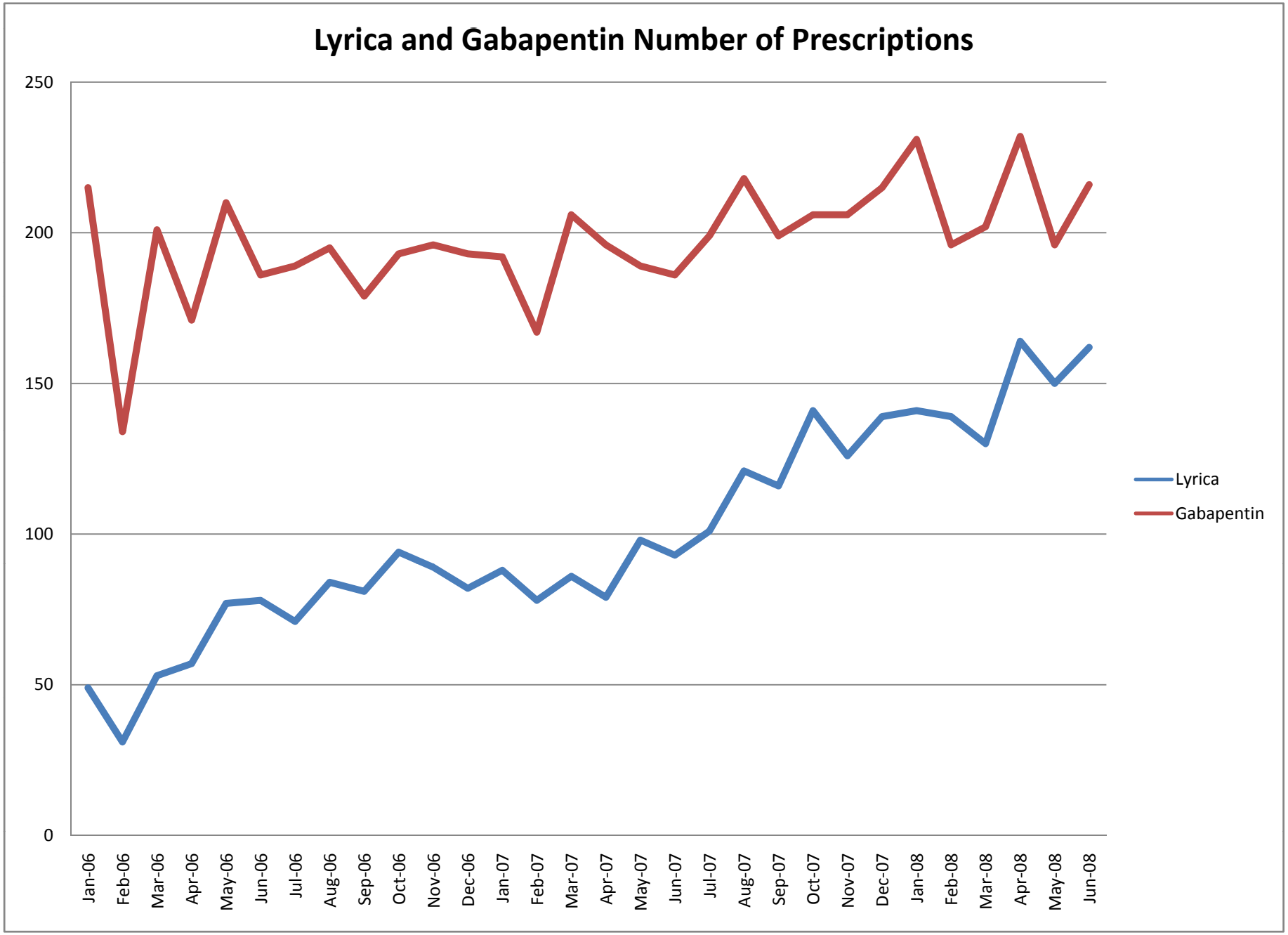
Recipient Count	Diagnosis
20	Seizure
10	Post-herpetic neuralgia
84	Neuropathic Pain
209	Myalgia/Myositis

Gabapentin Recipient Count and Diagnosis
05/01/2007 - 04/30/2008

Recipient Count	Diagnosis
57	Seizure
13	Post-herpetic neuralgia
104	Neuropathic Pain
159	Myalgia/Myositis

At the June P&T meeting, committee members asked how many patients had a prescription for gabapentin prior to using Lyrica.

05/01/07 - 04/30/08
Number of unique patients that took Lyrica: 394
Number of unique patients that took Lyrica 6 or more times during time period: 92
Number of unique patients taking gabapentin (up to 2 years) prior to taking Lyrica: 77


Lyrica and Gabapentin Number of Prescriptions
250
200
150
100
50
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
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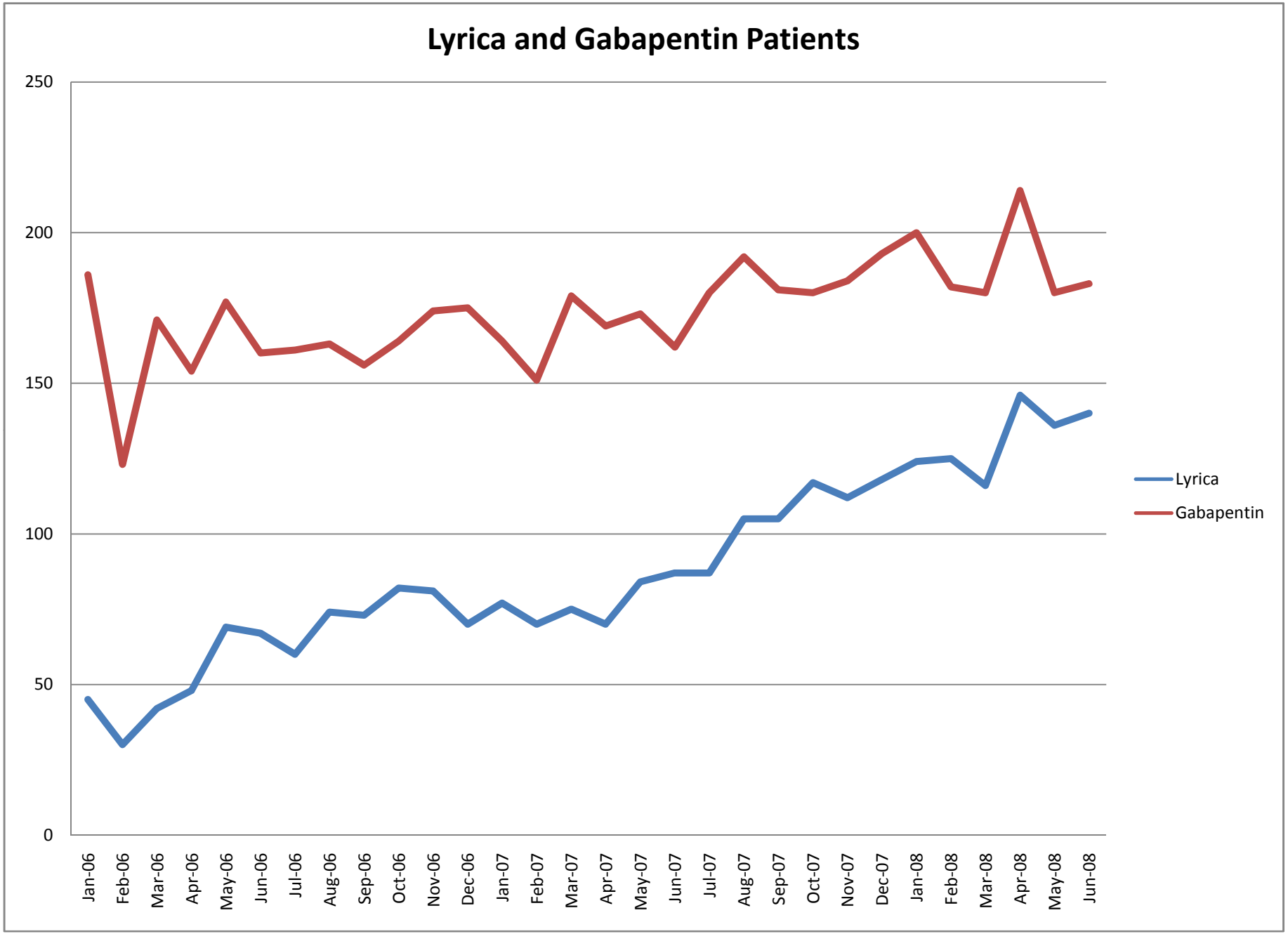
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin


Lyrica and Gabapentin Patients
250
200
150
100
50
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
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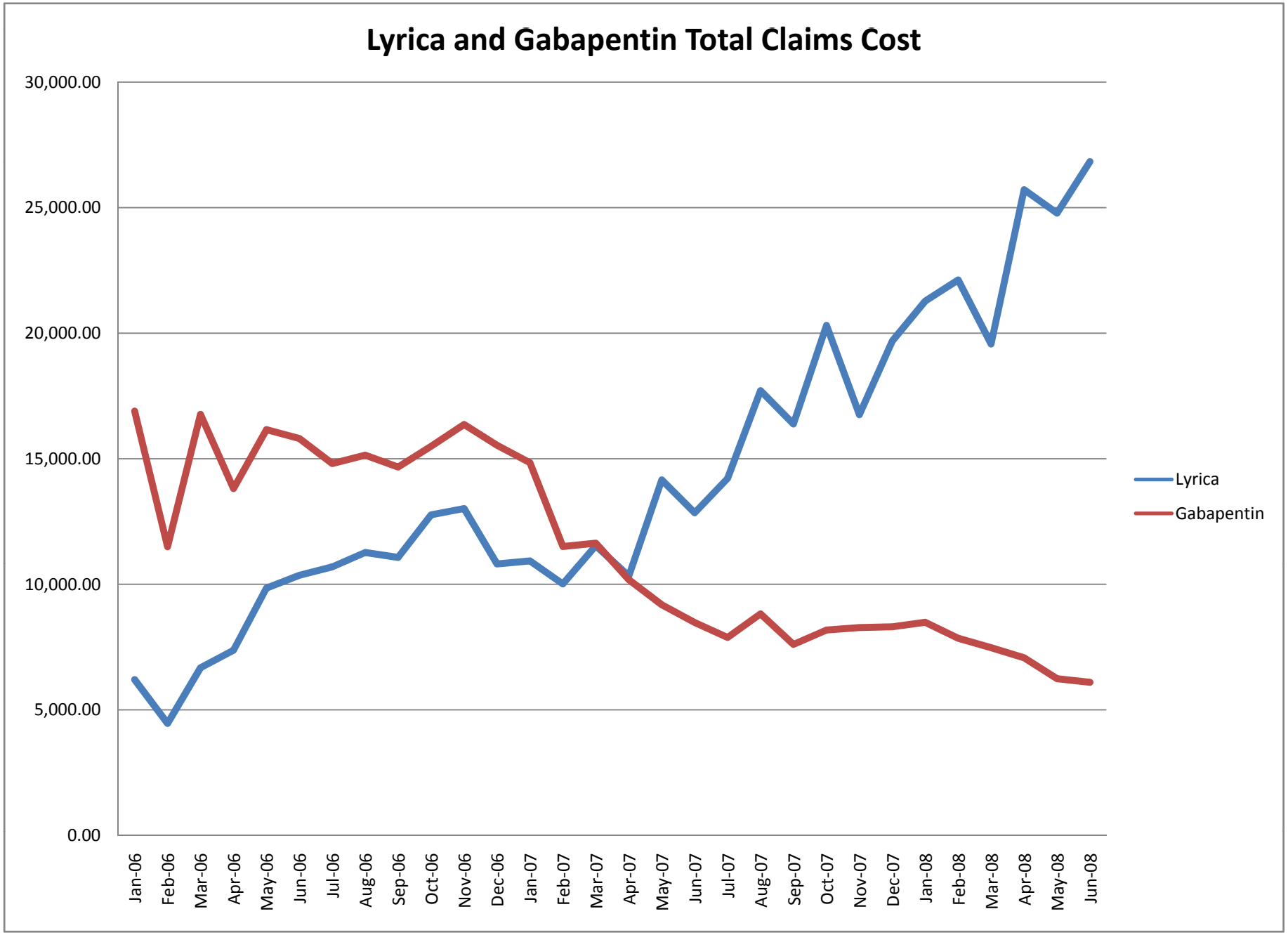
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin


Lyrica and Gabapentin Total Claims Cost
30,000.00
25,000.00
20,000.00
15,000.00
10,000.00
5,000.00
0.00
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
Sep-07
Oct-07
Nov-07
Dec-07
Jan-08
Feb-08
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin

LYRICA PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Lyrica (pregabalin) must first try Gabapentin.

- **Gabapentin does not require a prior authorization.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Dosage: (must be completed)

Diagnosis for this request:

Qualifications for coverage:

☐ Failed / intolerant to gabapentin

Adverse Reaction (attach FDA MedWatch form) or contraindication to gabapentin: (provide description below):

Medical Justification for use of pregabalin without trial of gabapentin:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Targeted Immune Modulators Review

I. Overview

Targeted immune modulators (TIMs) are used in the treatment of certain types of immunologic and inflammatory diseases, including ankylosing spondylitis (AS), Crohn's disease, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis (PsA), rheumatoid arthritis (RA), and ulcerative colitis (UC). The drugs work by selectively blocking steps in the inflammatory and immune cascades by either interfering with the activation of T cells, by targeting the inflammatory mediator TNF-α or by competitively blocking the Interleukin-1 (IL-1) receptor.

Table 1 summarizes the TIMs included in this review.

Table 1. Targeted Immune Modulators

Generic Name	Brand Name	Manufacturer
Abatacept	Orencia®	Bristol-Myers Squibb
Adalimumab	Humira®	Abbott
Alefacept	Amevive®	Astellas
Anakinra	Kineret®	Amgen
Certolizumab	Cimzia®	UCB
Efalizumab	Raptiva®	Genentech
Etanercept	Enbrel®	Immunex
Infliximab	Remicade®	Centocor

II. Pharmacology

TNF is a naturally occurring cytokine that is involved in normal anti-inflammatory and immune responses. Elevated levels of TNF are found in the synovial fluid of RA, including juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis patients and play an important role in the pathological inflammation and joint destruction that are hallmarks of these diseases. Increased levels of TNF are also found in psoriasis plaques.

TNF inhibitors block these specific proinflammatory mediators. Adalimumab, etanercept, certolizumab and infliximab target TNF-α. Adalimumab binds specifically to TNF-α, blocking its interaction with both the p55 and p75 cell surface TNF receptor. Etanercept binds circulating TNF-α and lymphotoxin-α preventing them from interacting with a cell surface receptor. Infliximab binds both circulating and transmembrane forms of TNF-α, thereby preventing binding with the receptor. Certolizumab binds to human TNF-α selectively neutralizing it.

IL-1, another naturally occurring cytokine, has both immune and pro-inflammatory actions. Anakinra competitively blocks the IL-1 receptor, thus blocking various inflammatory and immunological responses.

The immunosuppressant agents abatecept, alefacept and efalizumab produce their immune response by inhibiting T-cell activation. Abatecept suppresses inflammation, decreases anticollagen antibody production and reduces antigen-specific production of interferon-gamma. Treatment with alefacept results in a reduction in circulating total CD4+ and CD8+ T-lymphocyte counts. CD2 is also expressed at low levels on the surface of killer cells and certain bone marrow B lymphocytes. Efalizumab inhibits the binding of leukocyte function antigen-1 (LFA-1) to intercellular adhesion molecule-1 (ICAM-1), thereby inhibiting the adhesion of leukocytes to other cell types.

III. Indications

Table 2. FDA approved indications for the agents included in this review

Generic Name	FDA Approved Indications
Abatecept	• Moderately to severely active RA in adults. • Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 and older.
Adalimumab	• Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease. • Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older. • Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. • Reducing signs and symptoms in ankylosing spondylitis patients with active disease. • Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. • The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
Alefacept	• Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.
Anakinra	• Reducing signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).
Certolizumab	• Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
Efalizumab	• Treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Etanercept	• Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. • Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older. • Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. • Reducing signs and symptoms in patients with active ankylosing spondylitis. • Treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Infliximab	• In combination with methotrexate for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. • Reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. • Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease. • Reducing signs and symptoms in patients with active ankylosing spondylitis. • Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. • Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. • Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

IV. Dosing and Administration

Table 3. Dosing recommendations for the agents included in this review

Drug	Dosing and Administration	Availability
Abatacept	• <60 kg 500 mg • 60 – 100 kg 750 mg • >100 kg 1,000 mg • Pediatric patients weighing less than 75 kg receive 10 mg/kg. • Administer as a 30-minute intravenous infusion. • Following initial dose, give at 2 and 4 weeks, then every 4 weeks.	• 250 mg single-use vial
Adalimumab	• RA, PsA, AS – 40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week. • Juvenile idiopathic arthritis – 15 kg to < 30 kg: 20 mg every other week. ≥ 30 kg: 40 mg every other week. • Crohn's Disease – Initial dose is 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week. • Plaque psoriasis – 80 mg initial dose followed by 40 mg every other week starting one week after initial dose.	• 40 mg/0.8 ml in a single-use prefilled pen • 40 mg/0.8 ml in a single-dose prefilled glass syringe • 20 mg/0.4 ml in a single-dose prefilled glass syringe
Alefacept	• 7.5 mg given once weekly as an IV bolus or 15 mg given once weekly as an IM injection. • Recommended regimen is a course of 12 weekly injections. • Retreatment with an additional 12-week course may be initiated provided that CD4+ T lymphocyte counts are within the normal range, and a minimum of a 12-week interval has passed since the previous course of treatment.	• 7.5 mg single-use vial for IV administration • 15 mg single-use vial for IM administration
Anakinra	• Recommended dose for the treatment of patients with rheumatoid arthritis is 100mg/day administered by subcutaneous injection. Higher doses did not result in a higher response. • Dose should be administered at approximately the same time every day. • Consider a dose of 100mg every other day for RA patients who have severe renal insufficiency or end stage renal disease.	• Single-use preservative free, prefilled glass syringes containing 100mg of anakinra.
Certolizumab	• 400 mg subcutaneously initially and at weeks 2 and 4.	• Two single-use glass vials each containing 200 mg of lyophilized Cimzia for

Drug	Dosing and Administration	Availability
	• If response occurs, follow with 400 mg subcutaneously every four weeks.	reconstitution.
Efalizumab	• Single 0.7 mg/kg subcutaneously conditioning dose followed by weekly subcutaneous doses of 1 mg/kg not to exceed 200mg.	• Single-use vial designed to deliver 125 mg of efalizumab.
Etanercept	• A 50 mg dose should be given as one subcutaneous injection using either a 50 mg single-use prefilled syringe or a single-use prefilled SureClick autoinjector. • A 50 mg dose can also be given as two 25 mg subcutaneous injections using 25 mg single-use prefilled syringes or multiple-use vials. • Adult RA, AS, and PsA – 50 mg per week • Adult plaque psoriasis – 50 mg dose given twice weekly (administered 3 or 4 days apart) for 3 months followed by a reduction to a maintenance dose of 50 mg per week. • Juvenile idiopathic arthritis – pediatric patients ages 2 to 17 years is 0.8 mg/kg per week (max of 50 mg per week).	• 25 mg single-use prefilled syringe • 50 mg single-use prefilled syringe • 50 mg single-use prefilled SureClick autoinjector • 25 mg multiple-use vial
Infliximab	• RA - 3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. • Crohn's Disease (adults) – 5mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter. For adult patients who respond and then lose their response, consideration may be given to treatment with 10 mg/kg. Patients who do not respond by week 14 are unlikely to respond with continued dosing and consideration should be given to discontinuation. • Crohn's Disease (children) - The recommended dose is 5 mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks. • AS , PsA– 5mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 6 weeks thereafter. • UC – 5 mg/kg given as an induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter.	• 100mg single-use vials

V. Pharmacokinetics

Table 4. Pharmacokinetics of the agents included in this review

Drug	C_{max} (mcg/ml)	t ½	Onset of action	Systemic clearance	Volume of distribution
Abatacept	171 - 398	8 – 25 days	> 12 days	0.13 - 0.47 ml/h/kg	0.02 - 0.13 (L/kg)
Adalimumab	4.7 ± 1.6	10 – 20 days	1 – 14 days	12 ml/h	4.7 – 6 L
Alefacept	1.4	11 – 12 days	30 – 60 days	0.25 ml/h/kg	94 ml/kg
Anakinra	3.1 – 29	7 - 8 hours	7 – 21 days	137 ± 21 ml/min	3.6 – 15 L
Certolizumab	0.5 – 90	14 days	8 weeks	17 ml/h	6.4 L
Efalizumab	9 - 12	6.2 days	14 days	24 ± 18 ml/kg/day	58 ml/kg (10mg/kg dose)
Etanercept	4.7 ± 1.6	10 – 20 days	1 – 28 days	12 ml/hr	4.7 – 6.0 L
Infliximab	118	7.7 – 9.5 days	2 – 14 days	0.012 – 0.032 L/h	3 L

VI. Drug Interactions

Abatacept (Orencia)

- Concurrent administration of a TNF antagonist with Orencia has been associated with an increased risk of serious infections and no significant additional efficacy over use of the TNF antagonists alone.
- There is insufficient experience to assess the safety and efficacy of Orencia administered concurrently with other biologic RA therapy and therefore such use is not recommended.
- Parenteral drug products containing maltose can interfere with the readings of blood glucose monitors that use test strips with glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) resulting in falsely elevated blood glucose readings on the day of infusion. Patients should be advised to consider methods of glucose monitoring that do not react with maltose.

Adalimumab (Humira)

- Concurrent administration of anakinra (an interleukin-1 antagonist) and another TNF-blocking agent has been associated with a risk of serious infections, an increased risk of neutropenia and no additional benefit compared to these medicinal products alone.
- Live vaccines should not be given concurrently with Humira.
- Humira has been studied in RA patients taking concomitant methotrexate. Although methotrexate reduced the apparent Humira clearance, the data do not suggest the need for dose adjustment of either Humira or methotrexate.

Alefacept (Amevive) – no formal drug interaction studies have been performed.

Anakinra (Kineret)

- No drug-drug interaction studies in human subjects have been conducted.
- Toxicologic and toxicokinetic studies in rats did not demonstrate any alteration in the clearance or toxicologic profile of either methotrexate or Kineret when the two agents were administered together.

- In a study in which patients with active RA were treated for up to 24 weeks with concurrent Kineret and etanercept therapy, a 7% rate of serious infections was observed, which was higher than that observed with etanercept alone.
- Two percent of patients treated concurrently with Kineret and etanercept developed neutropenia.

Certolizumab (Cimzia)

- Concurrent administration of anakinra and another TNF blocker has shown an increased risk of serious infections, an increased risk of neutropenia, and no added benefit compared to these medicinal products alone.
- Do not give live (including attenuated) vaccines concurrently with Cimzia.
- Interference with certain coagulation assays has been detected in patients treated with Cimzia. Cimzia may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities. This effect has been observed with the PTT-LA test from Diagnostica Stago, and the HemosIL APTT-SP liquid and HemosIL lyophilized silica tests from Instrumentation Laboratories. Other aPTT assays may be affected as well. Interference with thrombin time (TT) and prothrombin time (PT) assays have not been observed. There is no evidence that Cimzia therapy has an effect on *in vivo* coagulation.

Efalizumab (Raptiva)

- No formal drug interaction studies have been performed with Raptiva. Raptiva should not be used with other immunosuppressive drugs.
- Live (including live-attenuated) vaccines should not be administered during Raptiva treatment.
- Increases in lymphocyte counts related to the pharmacologic mechanism of action are frequently observed during Raptiva treatment.

Etanercept (Enbrel)

- Specific drug interaction studies have not been conducted with Enbrel. However, it was observed that the pharmacokinetics of Enbrel were unaltered by concomitant methotrexate in rheumatoid arthritis patients.
- In a study in which patients with active RA were treated for up to 24 weeks with concurrent Enbrel and anakinra therapy, a 7% rate of serious infections was observed, which was higher than that observed with Enbrel alone.
- Two percent of patients treated with Enbrel and anakinra concurrently developed neutropenia.
- In a study of patients with Wegener's granulomatosis, the addition of Enbrel to standard therapy (including cyclophosphamide) was associated with a higher incidence of non-cutaneous solid malignancies. The use of Enbrel in patients receiving concurrent cyclophosphamide therapy is not recommended.
- Patients in a clinical study who were on established therapy with sulfasalazine, to which Enbrel was added, were noted to develop a mild decrease in mean neutrophils counts in comparison to groups treated with either Enbrel or sulfasalazine alone.

Infliximab (Remicade)

- Concurrent administration of etanercept (another TNFα-blocking agent) and anakinra (an interleukin-1 receptor antagonist) has been associated with an increased risk of serious infections and increased risk of neutropenia and no additional benefit compared to these medicinal products alone. Other TNFα-blocking agents (including Remicade) used in combination with anakinra may also result in similar toxicities.
- Specific drug interaction studies, including interactions with methotrexate, have not been conducted.

VII. Adverse Events

Table 5. Adverse Events > 2% for the agents included in this review

Adverse Event	Abatacept n=1,955 %	Adalimumab n=705 %	Alefacept n=1,869 %	Anakinra n=1,565 %	Certolizumab n=620 %	Efalizumab n=1,213 %	Etanercept n=349 %	Infliximab n=1,129 %
↓ CD4+ T lymphocyte counts below normal	-	-	48	-	-	-	-	-
↓ CD8+ T lymphocyte counts below normal	-	-	59	-	-	-	-	-
↓ Lymphocytes below normal	-	-	22	-	-	-	-	-
Abdominal pain	-	7	-	5	-	-	5	12
Accidental injury	-	10	-	-	-	-	-	-
Acne	-	-	-	-	-	4	-	-
Alkaline phosphatase ↑	-	5	-	-	-	-	-	-
Arthralgia	-	-	-	6	6	-	-	8
Asthenia	-	-	-	-	-	-	5	-
Back pain	7	6	-	-	-	4	-	8
Bronchitis	-	-	-	-	-	-	-	10
Chills	-	-	-	-	-	13	-	-
Cough	8	-	-	-	-	-	6	12
Diarrhea	-	-	-	7	-	-	-	12
Dizziness	9	-	-	-	-	-	7	-
Dyspepsia	6	-	-	-	-	-	4	10
Fatigue	-	-	-	-	-	-	-	9
Fever	-	-	-	-	-	7	-	7
Flu syndrome	-	7	-	6	-	7	-	-
Headache	18	12	-	12	-	32	17	18
Hematuria	-	5	-	-	-	-	-	-
Hyper-cholesterolemia	-	6	-	-	-	-	-	-
Hyperlipidemia	-	7	-	-	-	-	-	-
Hypertension	7	5	-	-	-	-	-	7
Injection site pain	-	12	-	-	-	-	37	-

Adverse Event	Abatacept n=1,955 %	Adalimumab n=705 %	Alefacept n=1,869 %	Anakinra n=1,565 %	Certolizumab n=620 %	Efalizumab n=1,213 %	Etanercept n=349 %	Infliximab n=1,129 %
Injection site reaction	-	8	16	71	-	-	-	-
Lab test abnormal	-	8	-	-	-	-	-	-
Low-titer antibodies	-	-	3	-	4	-	-	-
Moniliasis	-	-	-	-	-	-	-	5
Mouth Ulcer	-	-	-	-	-	-	2	-
Myalgia	-	-	-	-	-	8	-	-
Nasopharyngitis	12	-	-	-	-	-	-	-
Nausea	-	9	-	8	-	11	9	21
Pain	3	-	-	-	-	10	-	8
Pharyngitis	-	-	-	-	-	-	7	12
Pruritus	-	-	-	-	-	-	-	7
Rash	4	12	-	-	-	-	5	10
Respiratory disorder	-	-	-	-	-	-	5	-
Rhinitis	-	-	-	-	-	-	12	8
Serious infection (bacterial, viral, pneumonia, and pyelonephritis)	-	-	-	-	3	29	35	-
Sinusitis	-	11	-	7	-	-	3	14
URI	-	17	-	14	20	-	29	32
UTI	6	8	-	-	7	-	-	8
Vomiting	-	-	-	-	-	-	3	-
Worsening of RA	-	-	-	19	-	-	-	-

VIII. Black Box Warnings

Adalimumab (Humira)

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infection due to other opportunistic pathogens.
- Humira should be discontinued if a patient develops a serious infection or sepsis during treatment.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Humira.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

Certolizumab (Cimzia)

- Tuberculosis, invasive fungal, and other opportunistic infections, some fatal, have occurred. Perform test for latent TB; if positive, start treatment for TB prior to starting Cimzia. Monitor all patients for active TB during Cimzia treatment, even if initial tuberculin skin test is negative.

Efalizumab (Raptiva)

- Infections, including serious infections leading to hospitalizations or death, have been observed in patients treated with Raptiva. These infections have included bacterial sepsis, viral meningitis, invasive fungal disease and other opportunistic infections. Patients should be educated about the symptoms of infection and be closely monitored for signs and symptoms of infection during and after treatment with Raptiva. If a patient develops a serious infection, Raptiva should be discontinued and appropriate therapy instituted.
- Progressive Multifocal Leukoencephalopathy (PML) resulting from JC virus infection has occurred during therapy with Raptiva.

Etanercept (Enbrel)

- Patients treated with Enbrel are at increased risk for developing serious infections that may lead to hospitalization or death.
- Most patients who developed these infections were taking concomitant immunosuppresants such as methotrexate or corticosteroids.
- Enbrel should be discontinued if a patient develops a serious infection or sepsis.
- Reported infections include: active TB, including reactivation of latent TB; invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis; bacterial, viral and other infections due to opportunistic pathogens.

Infliximab (Remicade)

- Patients treated with Remicade are at increased risk for developing serious infections that may lead to hospitalization or death.
- Most patients who developed these infections were taking concomitant immunosuppresants such as methotrexate or corticosteroids.
- Remicade should be discontinued if a patient develops a serious infection or sepsis.
- Reported infections include: active TB, including reactivation of latent TB; invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis; bacterial, viral and other infections due to opportunistic pathogens.
- Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported in adolescent and young adult patients with Crohn's disease treated with Remicade. This rare type of T-cell lymphoma has a very aggressive disease course and is usually fatal. All of these hepatosplenic T-cell lymphomas with Remicade have occurred in patients on concomitant treatment with azathioprine or 6-mercaptopurine.

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FDA News

FOR IMMEDIATE RELEASE
Feb. 19, 2009

Media Inquiries:
Rita Chappelle, 301-796-4672
Consumer Inquiries:
888-INFO-FDA

FDA Advises Public of Serious Adverse Event with Psoriasis Drug Raptiva

The U.S. Food and Drug Administration today issued a public health advisory concerning three confirmed, and one possible report of progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug Raptiva (efalizumab). Three of those patients have died. All four patients were treated with the drug for more than three years. None of the patients were receiving other treatments that suppress the immune system.

The FDA is reviewing this latest information. The agency will take appropriate steps to:

- ensure that the risks of Raptiva do not outweigh its benefits;
- that patients prescribed Raptiva are clearly informed of the signs and symptoms of PML; and
- that health care professionals carefully monitor patients for the possible development of PML.

PML is caused by a virus that affects the central nervous system. PML usually occurs in people whose immune systems have been severely weakened. It leads to an irreversible decline in neurologic function and death. Symptoms may include unusual weakness, loss of coordination, changes in vision, difficulty speaking and personality changes. There is no known effective prevention or treatment.

Psoriasis is a chronic disease, for which a number of effective therapeutic options are available, including four other approved biologic agents, ultraviolent light therapy, and the drugs cyclosporine, acitretin, and methotrexate. Generally, treatment for psoriasis patients involves a rotation of therapies.

In October 2008, the product labeling for Raptiva was revised to highlight in a boxed warning the risks of life-threatening infections, including PML. At that time, the FDA directed Genentech, the manufacturer, to develop a risk evaluation and mitigation strategy (REMS) to include a medication guide to educate patients about the drug's risks.

The FDA strongly recommends that health care professionals carefully monitor patients on Raptiva, as well as those who have discontinued the drug, for any signs or symptoms of neurologic disease, and that they periodically reassess the benefits of continued treatment. Patients should be aware of the symptoms of PML and contact their health care professionals immediately if they experience any such symptoms.

Raptiva is a once-weekly injection approved for adults with moderate to severe plaque psoriasis who are candidates for systemic (whole body) therapy or phototherapy. The drug works by suppressing T-cells (blood cells that help fight infection) in the immune system. These cells, when activated, migrate to the skin and cause inflammation which results in the red, inflamed and scaly patches of skin, which is associated with psoriasis. By suppressing T-cells, Raptiva decreases the function of the immune system which increases a patient's susceptibility to infections.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

--Online: www.fda.gov/MedWatch/report.htm
--Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
--Fax: (800) FDA-0178
--Phone: (800) FDA-1088

Read the FDA's 2009 Public Health Advisory

#

RSS Feed for FDA News Releases [what is RSS?]

Targeted Immune Modulators Utilization
01/01/2008 – 12/31/2008

Label Name	Rx Num	Total Reimb Amt	Average cost per script
ENBREL 25 MG KIT	38	$53,223.13	$1,400.61
ENBREL 50 MG/ML SYR	32	$52,808.93	$1,650.28
ENBREL 50 MG/ML SURECLICK SYR	66	$111,242.81	$1,685.50
HUMIRA 40 MG/0.8 ML PEN	121	$191,509.58	$1,582.72
HUMIRA CROHN'S STARTER PACK	1	$4,877.67	$4,877.67
KINERET 100 MG/0.67 ML SYR	10	$14,141.30	$1,414.13
RAPTIVA 125 MG KIT	3	$5,323.68	$1,774.56
TOTAL	271	$433,127.10	54 Recipients

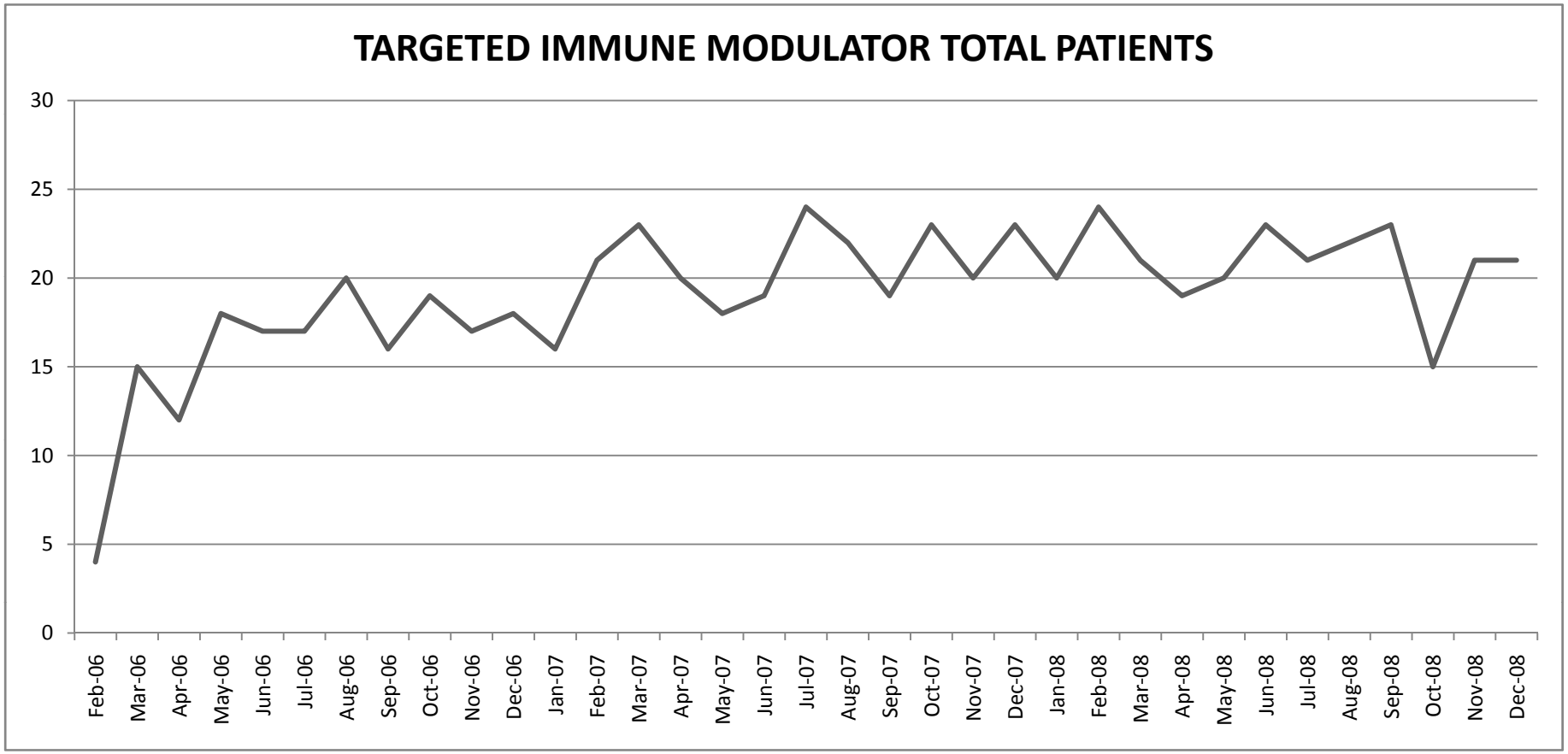
Market Share 2008

Label Name	Percentage
ENBREL	50.18%
HUMIRA	45.02%
KINERET	3.69%
RAPTIVA	1.11%

Summary by Age
01/01/2008 – 12/31/2008

Age	Recip Count	Rx Count
11	1	5
16	2	4
19	2	10
20	2	8
22	1	9
26	1	8
28	2	4
29	2	3
30	1	3
31	1	7
32	1	1
33	2	6
34	2	19
35	1	10
38	2	6
39	2	13

Age	Recip Count	Rx Count
40	1	2
41	2	9
43	4	12
45	3	20
46	3	12
47	1	13
48	1	4
49	2	10
50	2	4
53	1	4
55	2	15
57	1	5
58	3	22
59	2	18
62	1	5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15
10
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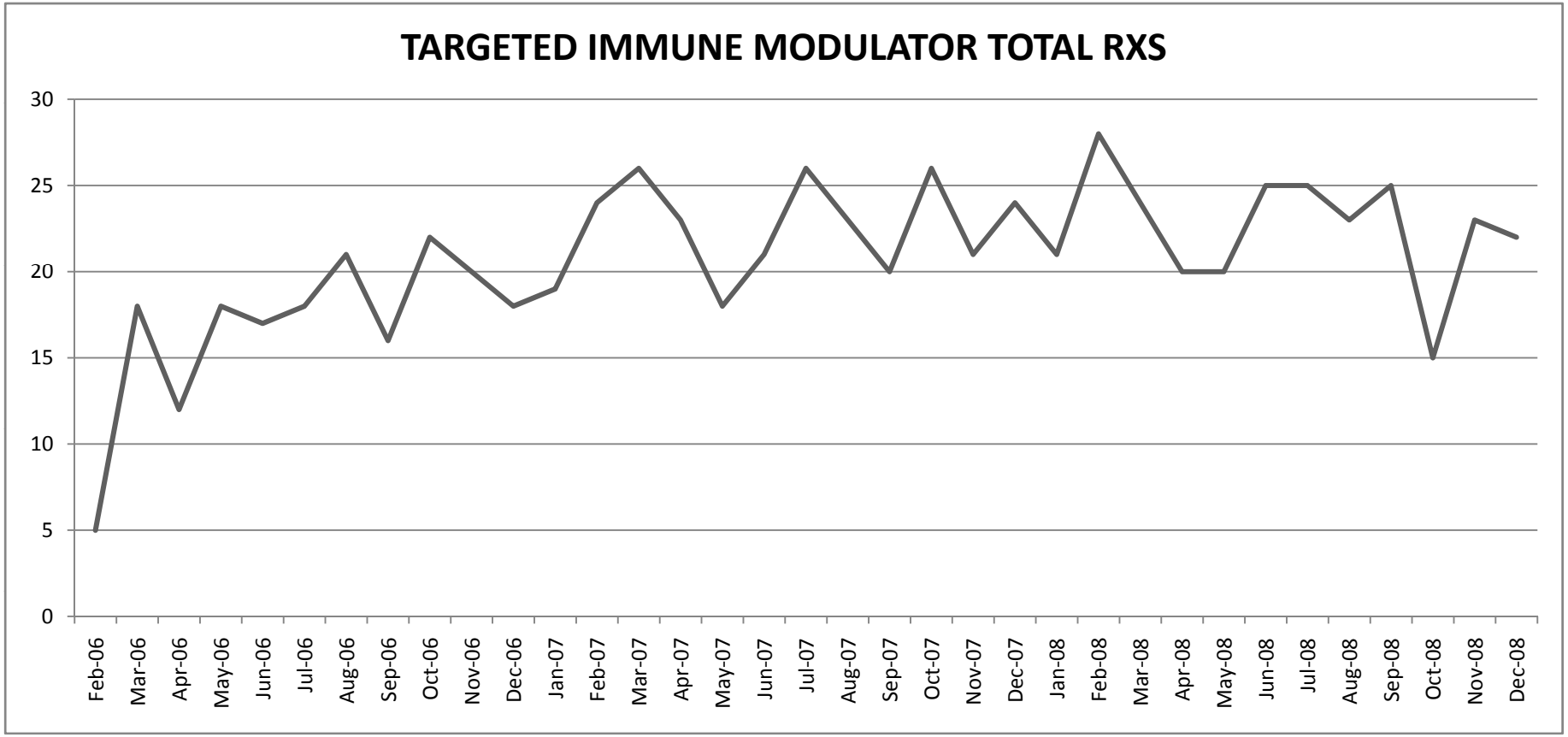
TARGETED IMMUNE MODULATOR TOTAL RXS
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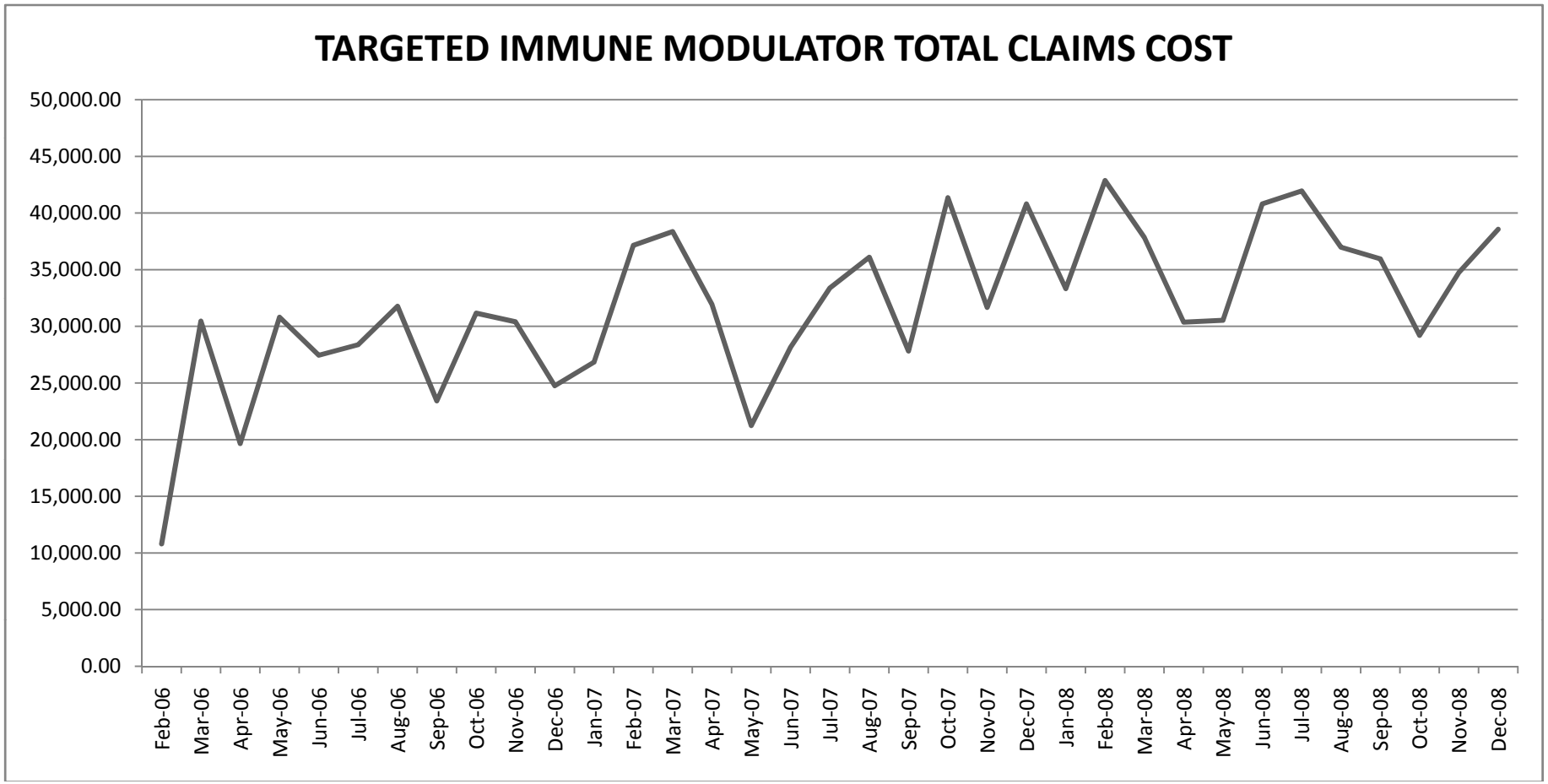
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South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Xolair® Review
March 13, 2009

I. Overview

Allergic asthma is a chronic disorder in which exposure to allergens such as dust, mold, and pollen triggers airway inflammation and obstruction. Allergic asthma is the most common form of asthma, affecting over 50% of the 20 million asthma sufferers. Over 2.5 million children under the age of 18 suffer from allergic asthma. Although many of the symptoms of allergic asthma and non-allergic asthma are the same (coughing, wheezing, shortness of breath or rapid breathing) allergic asthma is triggered by inhaled allergens. Common inhaled allergens include dust mites, pet dander, pollen, and mold.

Bronchodilators (e.g., anti-cholinergic agents and inhaled beta2-agonists) are generally used for patients with acute exacerbations of asthma. The preferred therapy for patients with moderate persistent asthma is regular treatment with a combination of inhaled corticosteroids and a long-acting inhaled beta2-agonsist. For patients with severe persistent asthma, the primary therapy includes inhaled corticosteroid at higher doses plus a long-acting beta2-agonist.

Xolair is the first monoclonal antibody treatment for allergy related asthma. It is indicated for adults and adolescents (12 years of age and older) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

II. Pharmacology

Xolair inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcεRI receptors on basophils in atopic patients.

III. Pharmacokinetics

Drug	Absolute Bioavailability	Peak Serum Concentrations	Serum Elimination t 1/2
Xolair	62%	7-8 days	26 days

IV. Black Box Warning

Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, patients should be closely observed for an appropriate period of time after Xolair administration, and health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur.

V. Warnings/Precautions

- Anaphylaxis (see Black Box Warning)
- Malignancy – malignant neoplasms were observed in 20 of 4127 (0.5%) Xolair-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of asthma and other allergic disorders. The observed malignancies in Xolair-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each.
- Xolair has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus.

VI. Drug Interactions

No formal drug interaction studies have been performed with Xolair. The concomitant use of Xolair and allergen immunotherapy has not been evaluated.

VII. Adverse Events ≥ 1% More Frequent in Xolair-Treated Patients

Adverse Event	Xolair n=738 %	Placebo n=717 %
Pain	7	5
Fatigue	3	2
Arthralgia	8	6
Fracture	2	1
Leg pain	4	2
Arm pain	2	1
Dizziness	3	2
Pruritus	2	1
Dermatitis	2	1
Earache	2	1
Injection site reactions	45	43
Severe injection site reactions	12	9

VIII. Dosage and Administration

Xolair 150 to 375 mg is administered SC every 2 or 4 weeks. Because the solution is slightly viscous, the injection may take 5-10 seconds to administer. Doses and dosing frequency are determined by serum IgE level and body weight. Doses more than 150 mg are divided among more than one injection site. Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during treatment cannot be used as a guide for dose determination. Dose determination should be based on serum IgE levels obtained at the initial dose determination

IX. Treatment Guidelines

National Heart Lung and Blood Institute

Stepwise Approach for Managing Asthma in Youths ≥ 12 years of age and adults

- **Intermittent Asthma**
  Step 1 – Preferred: Inhaled short-acting beta2-agonist (SABA) PRN

- **Persistent Asthma: Daily Medication (consult with asthma specialist if step 4 care or higher is required). Consider consultation at step 3.**
  Step 2 – Preferred: Low-dose inhaled corticosteroid (ICS)
  Alternative: Cromolyn, leukotriene receptor antagonist (LTRA), Nedocromil, or Theophylline

  Step 3 – Preferred: Low-dose ICS + long-acting inhaled beta2-agonist (LABA) OR medium-dose ICS
  Alternative: Low-dose ICS+ either LTRA, Theophylline, or Zileuton

  Step 4 – Preferred: Medium-dose ICS + LABA
  Alternative: Medium-dose ICS + either LTRA, Theophylline, or Zileuton

  Step 5 – Preferred: High-dose ICS+LABA AND consider Omalizumab for patients who have allergies

  Step 6 – Preferred: High-dose ICS+LABA+oral corticosteroid AND consider Omalizumab for patients who have allergies
- Each step: Patient education, environmental control and management of comorbidities.
- Quick relief medication for all patients. (SABA as needed for symptoms)
- Short course of oral systemic corticosteroids may be needed.
- Use of SABA > 2 days a week for symptom relief generally indicates inadequate control and the need to step up treatment.

Global Initiative for Asthma (2008)

Role in therapy – Anti-IgE (omalizumab) is a treatment option limited to patients with elevated serum levels of IgE. Its current indication is for patients with severe allergic asthma who are uncontrolled on inhaled glucocorticosteroids, although the dose of concurrent treatment has varied in different studies. Improved asthma control is reflected by fewer symptoms, less need for reliever medications, and fewer exacerbations. Further investigations will likely provide additional clarification of the role of anti-IgE in other clinical settings.

X. Conclusion

Xolair is a subcutaneously administered monoclonal anti-IgE antibody that reduces free IgE concentrations and promotes down regulation of IgE receptors on basophils. Xolair can be useful as adjunctive therapy with inhaled corticosteroids in patients with step 5 or 6 persistent asthma. Continued studies are required to determine which patients may most benefit from Xolair.

References

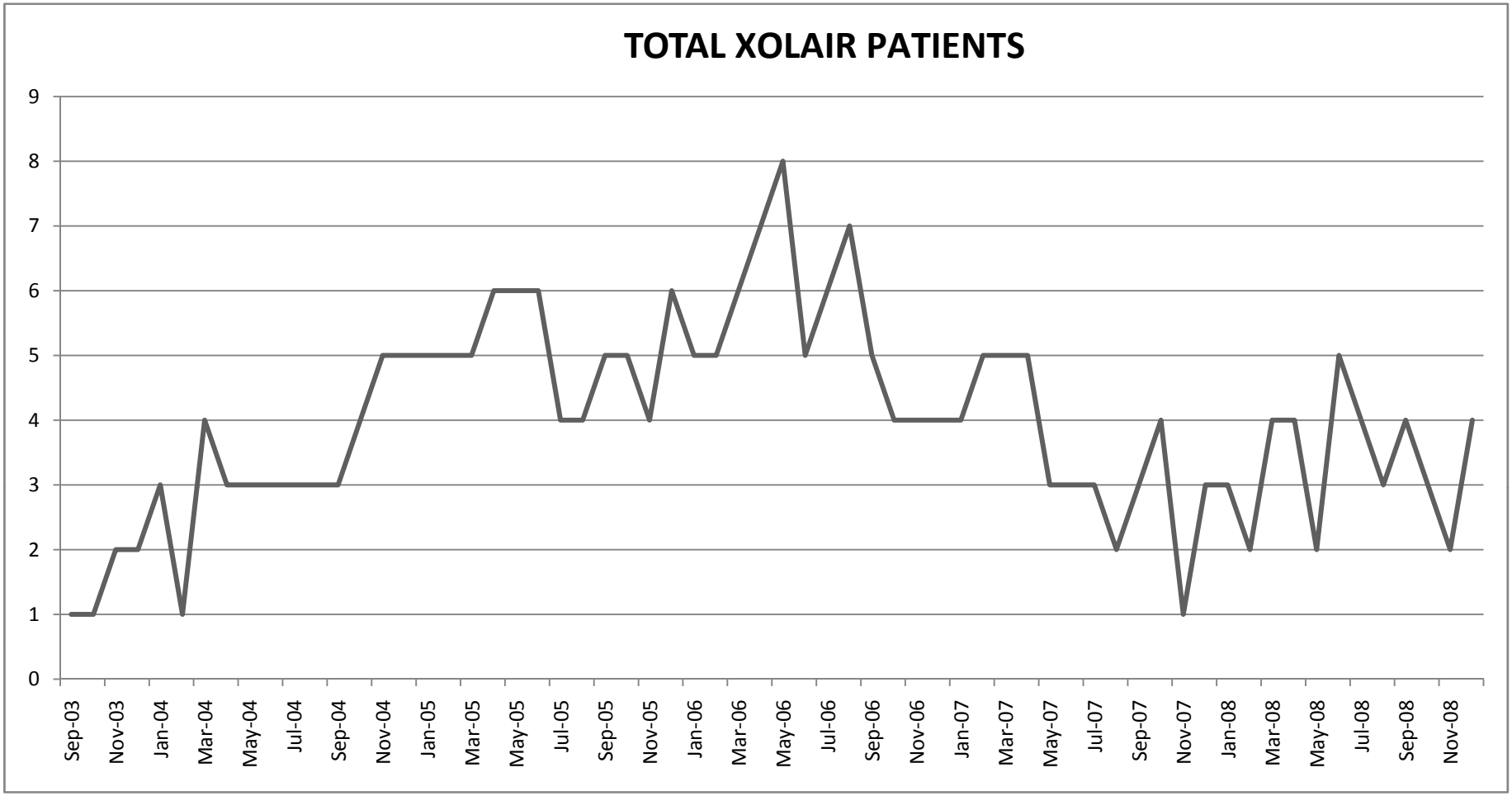
1. Wolters Kluwer Health, Inc, ed. Drug Facts and Comparisons. St Louis, MO. 2008.
2. Xolair® Prescribing Information, July 2008, Genentech, Inc.
3. National Heart Lung and Blood Institute. U.S. Department of Health and Human Services. NIH Publication 08-5846, Oct. 2007.
4. Asthma and Allergy Foundation of America. Accessed online at www.aafa.org Feb. 2009.
5. Global Strategy for Asthma Management and Prevention 2008 (update) Accessed online at www.ginasthma.org. Feb. 2009.

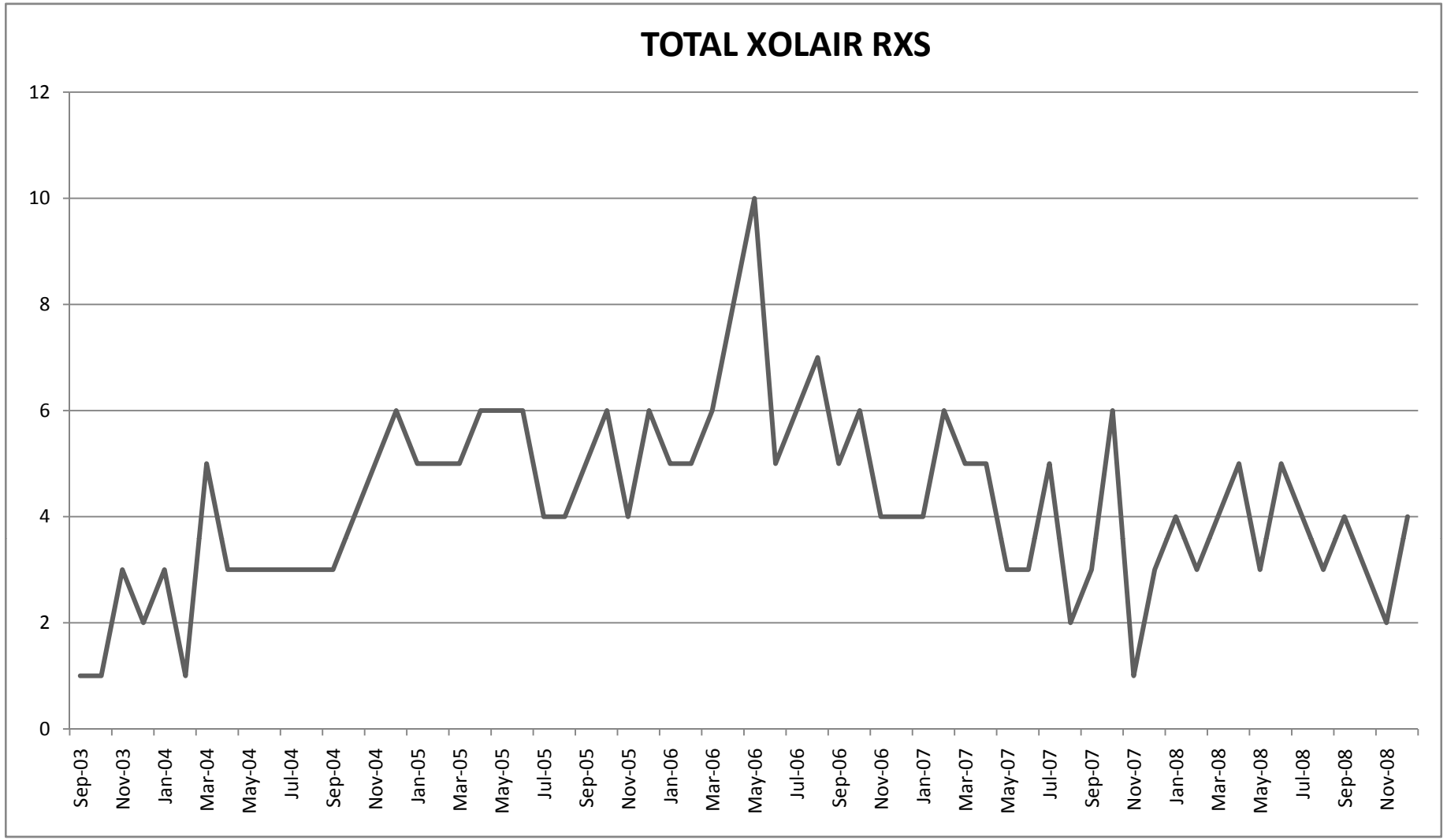
Xolair Utilization
01/01/2008 – 12/31/2008

Label Name	Rx Num	Total Reimb Amt	Average cost per script
XOLAIR 150 MG VIAL	44	$70,207.27	$1,595.62
TOTAL	44	$70,207.27	8 recipients

Summary by Age
01/01/2008 – 12/31/2008

Age	Recip Count	Rx Count
13	2	4
14	1	10
15	1	3
52	1	6
54	1	5
60	1	5
62	1	11


TOTAL XOLAIR PATIENTS
9
8
7
6
5
4
3
2
1
0
Sep-03
Nov-03
Jan-04
Mar-04
May-04
Jul-04
Sep-04
Nov-04
Jan-05
Mar-05
May-05
Jul-05
Sep-05
Nov-05
Jan-06
Mar-06
May-06
Jul-06
Sep-06
Nov-06
Jan-07
Mar-07
May-07
Jul-07
Sep-07
Nov-07
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08


TOTAL XOLAIR RXS
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10
8
6
4
2
0
Sep-03
Nov-03
Jan-04
Mar-04
May-04
Jul-04
Sep-04
Nov-04
Jan-05
Mar-05
May-05
Jul-05
Sep-05
Nov-05
Jan-06
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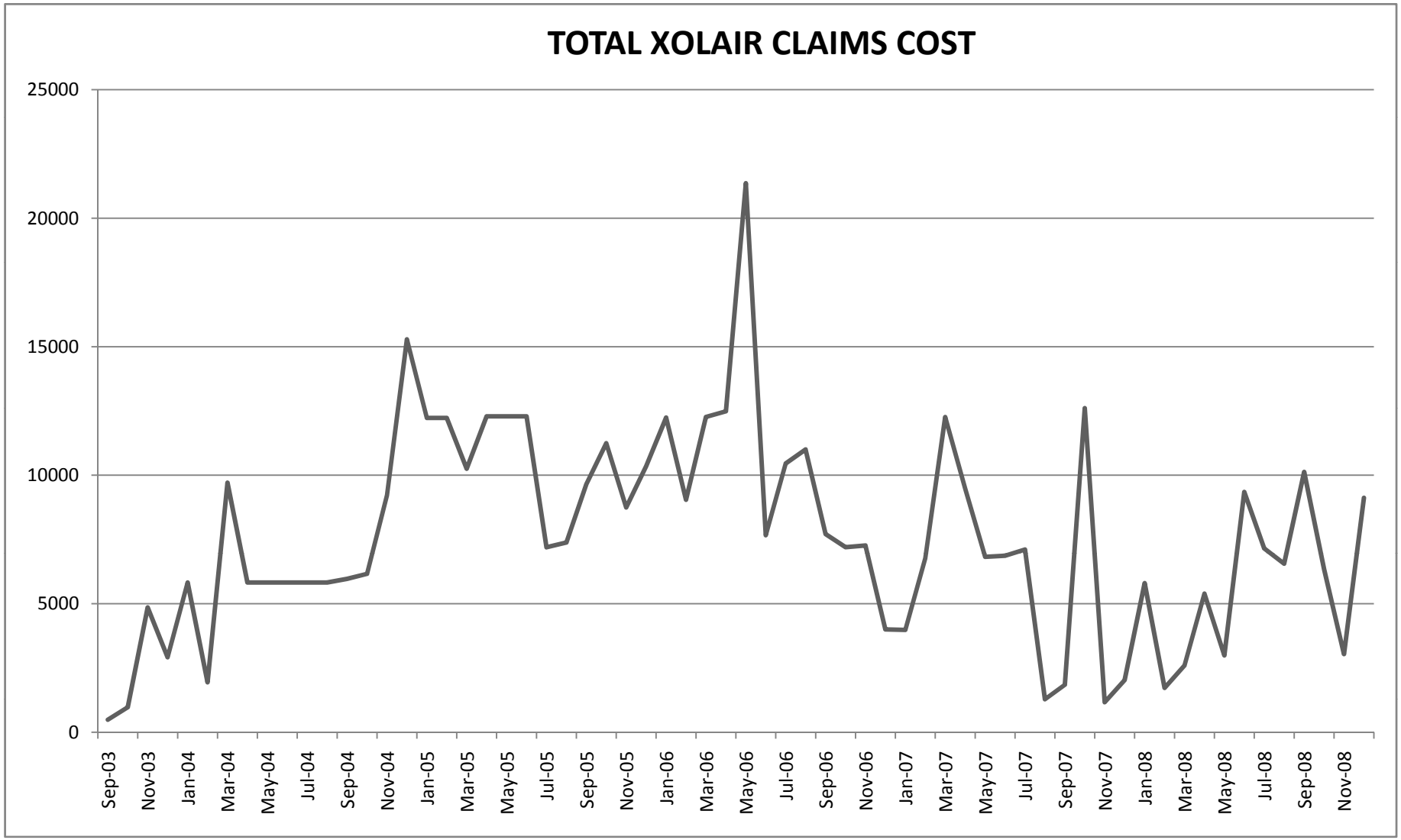
TOTAL XOLAIR CLAIMS COST
25000
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15000
10000
5000
0
Sep-03
Nov-03
Jan-04
Mar-04
May-04
Jul-04
Sep-04
Nov-04
Jan-05
Mar-05
May-05
Jul-05
Sep-05
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