

South Dakota Department of Social Services

Medicaid P&T Committee Meeting

December 6, 2013

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



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, December 6, 2013
1:00 – 3:00 PM**

**DDN Locations:
Sioux Falls
University Center
Room FADM253
4801 North Career Avenue**

**Pierre
Capitol Building
DDN Room B
500 E Capitol**

**Rapid City
University Center
Room UC113
4300 Cheyenne Blvd**

Call to Order

Approval of Minutes of Previous Meeting

Prior Authorization Update

Review of Top 15 Therapeutic Categories/Top 25 Drugs

Old Business

Review of Drug Spend

Quantity Limit Review

Tramadol Utilization

Hydrocodone Utilization

Epinephrine Auto-Injection Devices

New Business

Brisdelle

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

**Minutes of the September 20, 2013
Pharmacy & Therapeutics (P&T) Committee Meeting
South Dakota Department of Social Services, Division of Medical Services**

Members Present

Mikel Holland, MD; Lenny Petrik, PharmD; Richard Holm, MD; Debra Farver, PharmD; Dana Darger, RPh; Michelle Baack, MD; Kelly Oehlke, PharmD; Timothy Soundy, MD; Bill Ladwig, RPh; James Engelbrecht, MD

DSS staff present

Mike Jockheck, RPh

Administrative Business

The P&T meeting was called to order by D. Darger at 1:04 pm. The minutes of the June 28, 2013 meeting were presented. M. Baack made a motion to approve. D. Farver seconded the motion. The motion was approved unanimously.

Prior Authorization Update and Statistics

The Committee reviewed the prior authorization (PA) activity for July 2013. There were a total of 2,412 PA's processed in the month of July, with 99.92% of those requests responded to in less than eight hours. There were 1,875 (78%) requests received electronically and 537 (22%) requests received by fax.

Analysis of the Top 15 Therapeutic Classes

The Committee reviewed the top 15 therapeutic classes by total cost of claims from 4/1/2013 – 6/30/2013. The top five classes were antipsychotics, respiratory and CNS stimulants, amphetamines, central nervous system agents, misc., and corticosteroids (respiratory tract). The top 15 therapeutic classes make up 40.93% of total claims. The Committee also reviewed the top 25 drugs based on total claims cost and number of claims. The top 25 drugs by claims cost make up 10.99% of total claims. The Committee requested that tramadol utilization be presented at the December meeting.

Opiates Review

At the June 2013 meeting, the Committee reviewed opiate utilization. The topic was brought back with additional utilization reports. In June, the Committee suggested that a letter be sent to the top 25 prescribers of opiates. M. Jockheck reported that the letter was mailed in August 2013. The Committee heard a presentation regarding the South Dakota Prescription Drug Monitoring Program (PDMP). Members of the South Dakota Board of Pharmacy present to discuss the PDMP were Randy Jones and Kari Shanard-Koenders. Douglas Heilman represented the South Dakota Attorney General's office. The Committee requested more information regarding the utilization of hydrocodone/APAP combinations. The Committee also inquired if DSS could check with the Board of Pharmacy to determine how many of the prescribers who received a letter have registered to use the PDMP.

PPI Review

The Committee reviewed the proton pump inhibitor utilization data. The topic was tabled.

Diclegis Review

M. Baack made a motion to approve the PA form as presented. The motion was seconded by L. Petrik. The motion passed unanimously. There was no public comment.

Zolpidem Review

The Committee reviewed the zolpidem PA form. J. Englebrecht expressed concern with the recommended PA. D. Darger made a motion to implement a one per day quantity limit on zolpidem products. The motion was seconded by K. Oehlke. The motion passed unanimously. There was no public comment.

Diabetes Test Strip Review

The Committee reviewed diabetes test strip utilization data. The topic was tabled. The Committee heard testimony from Rashelle Mason (Roche Diagnostics), Alan Kaska (Abbott Diabetes Care), and Sharon D'Agostino (Johnson & Johnson).

Giazo Review

The Committee reviewed utilization data for Giazo. The topic was tabled. There was no public comment.

Delzicol Review

The Committee reviewed utilization data for Delzicol. The topic was tabled. There was no public comment.

Epinephrine Auto-Injection Devices Review

The Committee reviewed utilization data for epinephrine auto-injectors. The Committee requested more information pertaining to the products currently available in the market place and how those products compare. There was no public comment.

The next meeting is scheduled for December 6, 2013. M. Baack motioned to adjourn the P&T Committee meeting. B. Ladwig seconded the motion. The motion passed unanimously, and the meeting was adjourned.



**South Dakota Medicaid
Monthly Prior Authorization Report
October 1, 2013 – October 31, 2013**

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
3,554	3,542	12	99.66%	0.34%

By Form Type

Form Type	Description	Approve	Deny
ADP	Antidepressant	147	240
AFX	Amrix and Fexmid	0	2
ALT	Altabax	1	1
AMB	Ambien CR	6	13
ANF	Anti-Infectives	0	6
ANT	Antihistamines	6	63
APS	Antipsychotic	722	348
ARB	ARBS	13	30
COA	Oral Anticoagulants	5	11
DAW	Dispense As Written	8	21
GRH	Growth Hormone	9	13
GSM	Genitourinary SMR	8	78
HLM	Head Lice Medication	16	89
LID	Lidoderm	0	83
MAX	Max Units Override	67	915
MSA	Multiple Sclerosis Agents	0	2
NUC	Opioids	1	29
ONF	Onfi	6	3
OPH	Ophthalmic Antihistamines	1	28
PPI	Proton Pump Inhibitors	60	134
SMR	Skeletal Muscle Relaxants	1	5
STE	Nasal Steroids	10	71
STI	Stimulants	1	6
SUB	Suboxone/Subutex	1	4
TIM	Targeted Immune Modulators	8	6
TOP	Topical Acne Agents	24	147
TRP	Triptans	4	58
ULT	Ultram ER	0	9
VUS	Vusion	0	1
XIF	Xifaxan	1	11
XOL	Xolair	1	0
Totals		1127	2427

**South Dakota Medicaid
Monthly Prior Authorization Report
October 1, 2013 – October 31, 2013**

By Request Type

10/01/13 - 10/31/13	# of Requests	Electronic Requests		Faxed Requests	
		#	%	#	%
Prior Authorizations:					
Antidepressant	387	300	78%	87	22%
Amrix and Fexmid	2	2	100%	0	0%
Altabax	2	1	50%	1	50%
Ambien CR	19	17	89%	2	11%
Anti-Infectives	6	5	83%	1	17%
Antihistamines	69	52	75%	17	25%
Antipsychotic	1070	636	59%	434	41%
ARBS	43	35	81%	8	19%
Oral Anticoagulants	16	14	88%	2	13%
Dispense As Written	29	15	52%	14	48%
Growth Hormone	22	2	9%	20	91%
Genitourinary SMR	86	69	80%	17	20%
Head Lice Medication	105	64	61%	41	39%
Lidoderm	83	67	81%	16	19%
Max Units Override	982	901	92%	81	8%
Multiple Sclerosis Agents	2	0	0%	2	100%
Opioids	30	26	87%	4	13%
Onfi	9	2	22%	7	78%
Ophthalmic Antihistamines	29	26	90%	3	10%
Proton Pump Inhibitors	194	158	81%	36	19%
Skeletal Muscle Relaxants	6	5	83%	1	17%
Nasal Steroids	81	70	86%	11	14%
Stimulants	7	6	86%	1	14%
Suboxone/Subutex	5	3	60%	2	40%
Targeted Immune Modulators	14	6	43%	8	57%
Topical Acne Agents	171	131	77%	40	23%
Triptans	62	52	84%	10	16%
Ultram ER	9	6	67%	3	33%
Vusion	1	1	100%	0	0%
Xifaxan	12	7	58%	5	42%
Xolair	1	0	0%	1	100%
Prior Authorization Totals	3554	2679	75%	875	25%



**South Dakota Medicaid
Monthly Prior Authorization Report
October 1, 2013 – October 31, 2013**

Electronic PAs (unique)

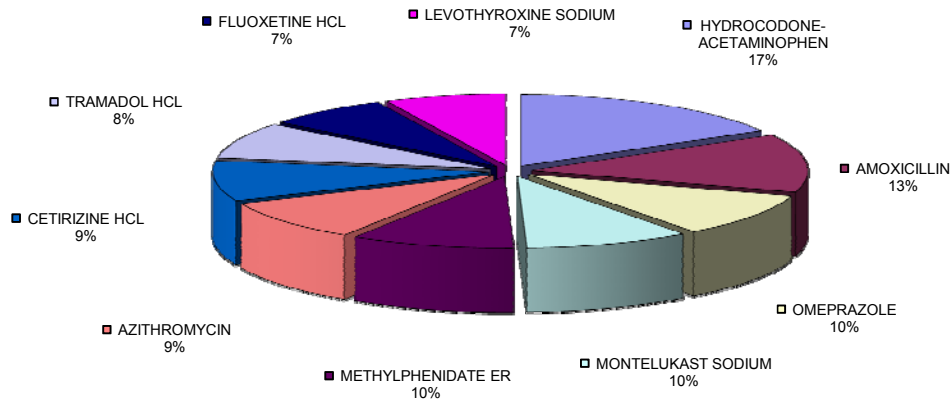
10/01/13 - 10/31/13	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antidepressant	98	181	0	279	35.10%	300
Amrix and Fexmid	0	2	0	2	0.00%	2
Altabax	0	1	0	1	0.00%	1
Ambien CR	5	6	0	11	45.50%	17
Anti-Infectives(anti-biotic)	0	5	0	5	0.00%	5
Antihistamines	5	46	0	51	9.80%	52
Antipsychotic	358	264	0	622	57.60%	636
ARBS	8	11	0	19	42.10%	35
Oral Anticoagulants	3	11	0	14	21.40%	14
Dispense As Written	0	15	0	15	0.00%	15
Growth Hormone	0	2	0	2	0.00%	2
Genitourinary SMR	5	63	0	68	7.40%	69
Head Lice Medication	0	61	0	61	0.00%	64
Lidoderm	0	64	0	64	0.00%	67
Max Units Override	21	825	0	846	2.50%	901
Opioids	0	24	0	24	0.00%	26
Onfi	0	2	0	2	0.00%	2
Ophthalmic Antihistamines	0	25	0	25	0.00%	26
Proton Pump Inhibitors	42	95	0	137	30.70%	158
Skeletal Muscle Relaxants	0	5	0	5	0.00%	5
Nasal Steroids	7	63	0	70	10.00%	70
Stimulants	1	5	0	6	16.70%	6
Suboxone/Subutex	0	3	0	3	0.00%	3
Targeted Immune Modulators	2	4	0	6	33.30%	6
Topical Acne Agents	9	119	0	128	7.00%	131
Triptans	2	47	0	49	4.10%	52
Ultram ER	0	6	0	6	0.00%	6
Vusion	0	1	0	1	0.00%	1
Xifaxan	0	7	0	7	0.00%	7
TOTALS	566	1963	0	2529	22.40%	2679

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 07/01/2013 - 09/30/2013

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	6,247	\$ 90,462.31	\$ 14.48	3.22%
AMOXICILLIN	PENICILLINS	4,904	\$ 40,839.51	\$ 8.33	2.53%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,686	\$ 43,033.34	\$ 11.67	1.90%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	3,612	\$ 75,688.33	\$ 20.95	1.86%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,578	\$ 602,476.60	\$ 168.38	1.85%
AZITHROMYCIN	MACROLIDES	3,462	\$ 51,908.76	\$ 14.99	1.79%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	3,391	\$ 27,577.81	\$ 8.13	1.75%
TRAMADOL HCL	OPIATE AGONISTS	3,065	\$ 24,403.65	\$ 7.96	1.58%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,691	\$ 22,031.92	\$ 8.19	1.39%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,650	\$ 21,823.46	\$ 8.24	1.37%
VYVANSE	AMPHETAMINES	2,606	\$ 456,688.73	\$ 175.25	1.35%
SERTRALINE HCL	ANTIDEPRESSANTS	2,525	\$ 19,877.68	\$ 7.87	1.30%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,308	\$ 14,158.12	\$ 6.13	1.19%
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	2,183	\$ 17,232.20	\$ 7.89	1.13%
TRAZODONE HCL	ANTIDEPRESSANTS	2,118	\$ 12,676.09	\$ 5.98	1.09%
DEXTRAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,088	\$ 297,306.19	\$ 142.39	1.08%
VENTOLIN HFA	BETA-ADRENERGIC AGONISTS	2,065	\$ 92,654.72	\$ 44.87	1.07%
LISINAPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,977	\$ 11,021.68	\$ 5.57	1.02%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,918	\$ 32,550.25	\$ 16.97	0.99%
CEPHALEXIN	CEPHALOSPORINS	1,898	\$ 20,638.90	\$ 10.87	0.98%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,892	\$ 399,568.67	\$ 211.19	0.98%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,867	\$ 29,680.11	\$ 15.90	0.96%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,777	\$ 14,319.49	\$ 8.06	0.92%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,750	\$ 12,164.44	\$ 6.95	0.90%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,630	\$ 40,244.52	\$ 24.69	0.84%
TOTAL TOP 25		67,888	\$ 2,471,027.48	\$ 36.40	35.05%

Total Rx Claims From 07/01/2013 - 09/30/2013	193,716
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**Top 10 Drugs
Based on Number of Claims**

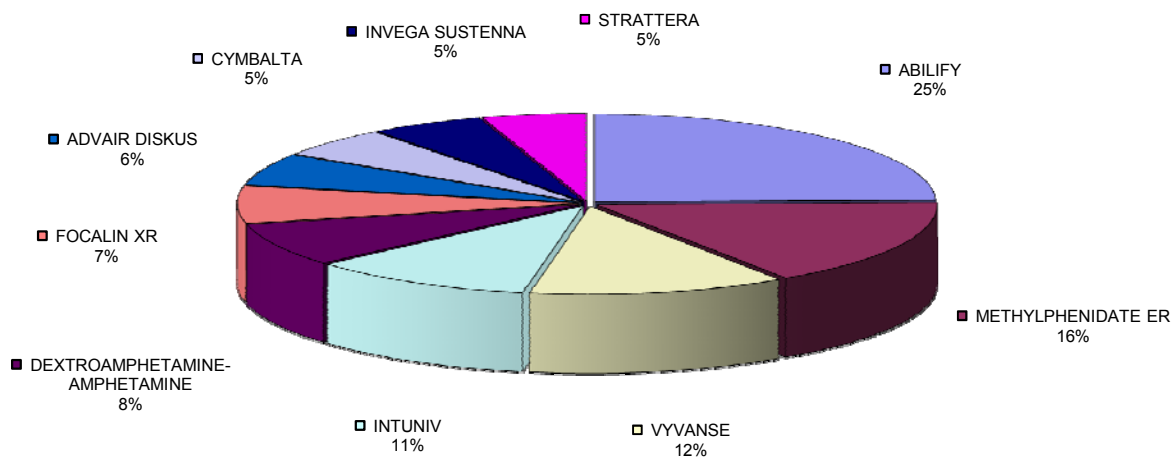


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 07/01/2013 - 09/30/2013

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,527	\$ 924,970.41	\$ 605.74	0.79%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,578	\$ 602,476.60	\$ 168.38	1.85%
VYVANSE	AMPHETAMINES	2,606	\$ 456,688.73	\$ 175.25	1.35%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,892	\$ 399,568.67	\$ 211.19	0.98%
DEXTROAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,088	\$ 297,306.19	\$ 142.39	1.08%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	1,182	\$ 257,247.94	\$ 217.64	0.61%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	821	\$ 221,796.94	\$ 270.15	0.42%
CYMBALTA	ANTIDEPRESSANTS	775	\$ 207,800.51	\$ 268.13	0.40%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	149	\$ 202,242.47	\$ 1,357.33	0.08%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	872	\$ 185,610.10	\$ 212.86	0.45%
PULMOZYME	MUCOLYTIC AGENTS	57	\$ 176,421.92	\$ 3,095.12	0.03%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	65	\$ 173,502.60	\$ 2,669.27	0.03%
PREVACID	PROTON-PUMP INHIBITORS	654	\$ 162,122.35	\$ 247.89	0.34%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	624	\$ 157,989.26	\$ 253.19	0.32%
OXYCONTIN	OPIATE AGONISTS	462	\$ 153,789.70	\$ 332.88	0.24%
COPAXONE	IMMUNOMODULATORY AGENTS	32	\$ 153,327.13	\$ 4,791.47	0.02%
KALYDECO	CYSTIC FIBROSIS (CFTR) POTENTIATORS	5	\$ 133,669.65	\$ 26,733.93	0.00%
LANTUS SOLOSTAR	INSULINS	433	\$ 130,119.26	\$ 300.51	0.22%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	801	\$ 124,481.01	\$ 155.41	0.41%
NEXIUM	PROTON-PUMP INHIBITORS	455	\$ 119,614.60	\$ 262.89	0.23%
LATUDA	ANTIPSYCHOTIC AGENTS	201	\$ 113,335.18	\$ 563.86	0.10%
NOVOLOG	INSULINS	425	\$ 107,738.77	\$ 253.50	0.22%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	45	\$ 102,052.56	\$ 2,267.83	0.02%
ONE TOUCH ULTRA TEST STRIPS	DIABETES MELLITUS	597	\$ 100,196.28	\$ 167.83	0.31%
HELIXATE FS	HEMOSTATICS	3	\$ 96,521.04	\$ 32,173.68	0.00%
TOTAL TOP 25		20,349	\$ 5,760,589.87	\$ 283.09	10.50%

Total Rx Claims From 07/01/2013 - 09/30/2013	193,716
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**Top 10 Drugs
Based on Total Claims Cost**



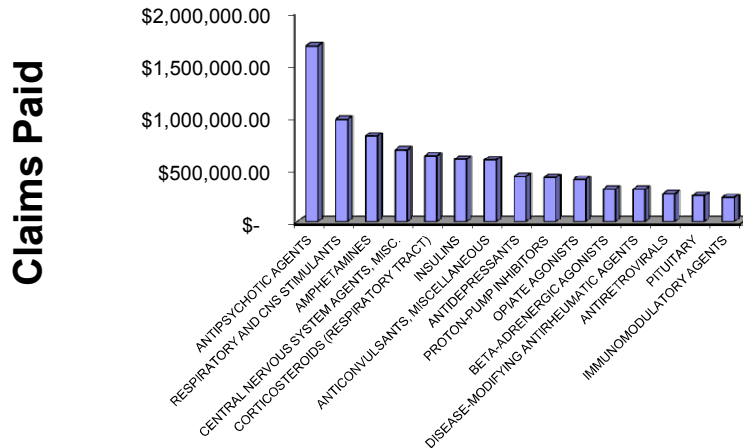
**SOUTH DAKOTA MEDICAID
Cost Management Analysis**

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 07/01/2013 - 09/30/2013

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	7,063	\$ 1,680,194.21	\$ 237.89	3.65%
RESPIRATORY AND CNS STIMULANTS	6,171	\$ 978,828.40	\$ 158.62	3.19%
AMPHETAMINES	5,536	\$ 820,423.65	\$ 148.20	2.86%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	2,827	\$ 686,271.73	\$ 242.76	1.46%
CORTICOSTEROIDS (RESPIRATORY TRACT)	2,785	\$ 629,119.22	\$ 225.90	1.44%
INSULINS	2,236	\$ 597,226.40	\$ 267.10	1.15%
ANTICONVULSANTS, MISCELLANEOUS	8,315	\$ 592,382.30	\$ 71.24	4.29%
ANTIDEPRESSANTS	15,449	\$ 432,106.24	\$ 27.97	7.98%
PROTON-PUMP INHIBITORS	5,994	\$ 423,110.75	\$ 70.59	3.09%
OPIATE AGONISTS	13,959	\$ 404,931.24	\$ 29.01	7.21%
BETA-ADRENERGIC AGONISTS	6,178	\$ 312,194.66	\$ 50.53	3.19%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	143	\$ 311,448.26	\$ 2,177.96	0.07%
ANTIRETROVIRALS	249	\$ 267,663.09	\$ 1,074.95	0.13%
PITUITARY	505	\$ 251,232.71	\$ 497.49	0.26%
IMMUNOMODULATORY AGENTS	49	\$ 232,155.94	\$ 4,737.88	0.03%
TOTAL TOP 15	77,459	\$ 8,619,288.80	\$ 111.28	39.99%

Total Rx Claims From 07/01/2013 - 09/30/2013	193,716
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**Top 15 Therapeutic Classes
Based on Total Cost of Claims**



**SD Medicaid Drug Spend
2011 - 2013**

Drug Spend 2011

Total	201101	201102	201103	201104	201105	201106	201107	201108	201109	201110	201111	201112	Row SubTotal
Rx_Dollars	\$4,586,829.96	\$4,464,243.15	\$6,407,099.31	\$4,704,204.28	\$3,672,867.07	\$4,498,920.94	\$4,281,621.96	\$4,762,037.68	\$4,377,384.75	\$4,623,177.89	\$4,756,651.74	\$4,735,578.24	\$55,870,616.97
Rx_Count	73,796	72,737	103,888	74,926	56,458	67,989	65,321	73,077	68,628	73,662	74,838	73,517	878,837
Average_Rx_Cost	\$62.16	\$61.38	\$61.67	\$62.78	\$65.05	\$66.17	\$65.55	\$65.16	\$63.78	\$62.76	\$63.56	\$64.41	\$63.57
Recip_Count	28,028	29,016	31,751	28,438	22,697	24,542	24,083	26,080	26,564	27,595	27,918	27,146	

Drug Spend 2012

Total	201201	201202	201203	201204	201205	201206	201207	201208	201209	201210	201211	201212	Row SubTotal
Rx_Dollars	\$4,849,391.09	\$4,996,964.58	\$5,257,480.62	\$4,879,456.62	\$4,919,227.18	\$4,913,110.35	\$3,845,410.10	\$4,863,924.43	\$4,014,311.03	\$4,823,060.40	\$4,576,570.48	\$4,442,910.36	\$56,381,817.24
Rx_Count	77,559	77,425	79,756	74,004	74,771	75,497	57,784	72,290	63,540	77,195	73,719	71,209	874,749
Average_Rx_Cost	\$62.53	\$64.54	\$65.92	\$65.94	\$65.79	\$65.08	\$66.55	\$67.28	\$63.18	\$62.48	\$62.08	\$62.39	\$64.45
Recip_Count	29,127	30,436	29,892	28,110	27,214	23,028	22,802	26,410	25,432	28,740	28,017	27,137	

Drug Spend 2013

Total	201301	201302	201303	201304	201305	201306	201307	201308	201309	201310	201311	201312	Row SubTotal
Rx_Dollars	\$5,098,186.25	\$4,387,497.68	\$3,483,800.54	\$4,587,735.29	\$4,954,661.74	\$4,077,464.64	\$4,713,002.58	\$4,779,998.67	\$4,355,061.73	\$3,669,651.21	0	0	\$44,107,060.33
Rx_Count	75,728	68,046	54,793	68,603	68,079	57,899	65,472	66,214	62,030	52,855	0	0	639,719
Average_Rx_Cost	\$67.32	\$64.48	\$63.58	\$66.87	\$72.78	\$70.42	\$71.99	\$72.19	\$70.21	\$69.43	0	0	\$68.95
Recip_Count	27,718	25,991	22,292	24,674	24,013	21,400	22,559	23,521	23,675	21,095	0	0	

Summary by Age 2013	
Age	Recip Count
0-9	29,090
10-19	17,254
20-29	7,162
30-39	4,677
40-49	2,570
50-59	2,337
60-69	1,031
70-79	312
80+	625

SD Medicaid Quantity Limit Suggestions					
NDC	Drug Name	Strength	Rx Count	Suggested Max Supply	Max Days
00591320201	HYDROCODONE-ACETAMINOPHEN	5MG-325MG	1671	408	34
00487950125	ALBUTEROL SULFATE	2.5 MG/3ML	1588	360	30
53746027205	SULFAMETHOXAZOLE-TRIMETHOPRIM	800-160 MG	1466	600	30
54092051502	INTUNIV	2 MG	1346	34	34
53746010905	HYDROCODONE-ACETAMINOPHEN	5MG-325MG	1317	408	34
00406035705	HYDROCODONE-ACETAMINOPHEN	5 MG-500MG	1229	136	34
65162066810	PRENATAL PLUS	27 MG-1 MG	1203	34	34
53746046605	IBUPROFEN	800 MG	1157	136	34
68180072320	CEFDINIR	250 MG/5ML	1071	600	30
45802011222	MUPIROCIN	2%	1042	22	30
50383082416	SULFAMETHOXAZOLE-TRIMETHOPRIM	200-40MG/5	1012	68	34
00781149668	AZITHROMYCIN	250 MG	973	36	30
00093314705	CEPHALEXIN	500 MG	961	272	34
00603107558	CHERATUSSIN AC	100-10MG/5	952	2040	34
54092051702	INTUNIV	3 MG	936	34	34
00781261305	AMOXICILLIN	500 MG	852	204	34
00603389028	HYDROCODONE-ACETAMINOPHEN	5MG-325MG	830	408	34
00088221905	LANTUS SOLOSTAR	100/ML (3)	816	300	150
00406051201	OXYCODONE-ACETAMINOPHEN	5MG-325MG	814	408	34
50111043302	TRAZODONE HCL	50 MG	814	272	34
00172541211	FLUCONAZOLE	150 MG	783	34	34
00093202623	AZITHROMYCIN	200 MG/5ML	758	180	30
00093714618	AZITHROMYCIN	250 MG	756	36	30
00591034905	HYDROCODONE-ACETAMINOPHEN	5 MG-500MG	736	136	34
00228300350	CLONAZEPAM	0.5 MG	706	272	34
54092051902	INTUNIV	4 MG	706	34	34
50111078766	AZITHROMYCIN	250 MG	701	36	30
00004082009	TAMIFLU	6 MG/ML	699	120	10
00487950103	ALBUTEROL SULFATE	2.5 MG/3ML	694	360	30
54092051302	INTUNIV	1 MG	669	34	34
00116200116	CHLORHEXIDINE GLUCONATE	0.12%	665	473	15
00781523864	ONDANSETRON ODT	4 MG	664	136	34
00603129558	HYDROCODONE-ACETAMINOPHEN	7.5-500/15	662	4080	34
00065853302	CIPRODEX	0.3 %-0.1%	651	15	10
50111056303	CYCLOBENZAPRINE HCL	10 MG	650	102	34
76204020025	ALBUTEROL SULFATE	2.5 MG/3ML	648	360	30
16714029904	AMOXICILLIN	500 MG	618	204	34
00603233832	ACETAMINOPHEN-CODEINE	300MG-30MG	617	340	34
59762312001	AZITHROMYCIN	200 MG/5ML	602	180	30
00603389021	HYDROCODONE-ACETAMINOPHEN	5MG-325MG	590	408	34
59746017710	CYCLOBENZAPRINE HCL	10 MG	586	102	34
00591074905	OXYCODONE-ACETAMINOPHEN	5MG-325MG	583	408	34
00406036505	HYDROCODONE-ACETAMINOPHEN	5MG-325MG	581	408	34
50111043303	TRAZODONE HCL	50 MG	581	272	34
50111043401	TRAZODONE HCL	100 MG	578	136	34

SD Medicaid Quantity Limit Suggestions					
NDC	Drug Name	Strength	Rx Count	Suggested Max Supply	Max Days
00093202723	AZITHROMYCIN	100 MG/5ML	570	180	30
65162066850	PRENATAL PLUS	27 MG-1 MG	565	34	34
53746011005	HYDROCODONE-ACETAMINOPHEN	10MG-325MG	557	408	34
00093714923	AZITHROMYCIN	200 MG/5ML	549	180	30
55111068405	IBUPROFEN	800 MG	547	136	34
45802026937	PERMETHRIN	0.05	539	60	5
00591569550	MINOCYCLINE HCL	100 MG	519	68	34
00093681673	BUDESONIDE	0.5 MG/2ML	507	120	30
00603295721	CLONIDINE HCL	0.1 MG	506	136	34
00487950160	ALBUTEROL SULFATE	2.5 MG/3ML	501	360	30
16714061305	SERTRALINE HCL	100 MG	499	68	34
00603385632	HYDROCHLOROTHIAZIDE	25 MG	485	136	34
00597007541	SPIRIVA	18 MCG	474	30	30
29300013510	CLONIDINE HCL	0.1 MG	474	136	34
00093015010	ACETAMINOPHEN-CODEINE	300MG-30MG	464	340	34
60258086016	CETIRIZINE HCL	1 MG/ML	462	340	34
53746019005	NAPROXEN	500 MG	461	102	34
59762491005	SERTRALINE HCL	100 MG	456	68	34
65862049647	SULFAMETHOXAZOLE-TRIMETHOPRIM	200-40MG/5	454	2000	34
00591024110	LORAZEPAM	1 MG	449	340	34
00093101042	MUPIROCIN	0.02	447	22	30
00093202694	AZITHROMYCIN	200 MG/5ML	439	180	34
00228300450	CLONAZEPAM	1 MG	438	136	34
65862039010	ONDANSETRON ODT	4 MG	436	136	34
00093310905	AMOXICILLIN	500 MG	431	204	34
68180040203	CEFPROZIL	250 MG/5ML	431	600	30
00603158558	PROMETHAZINE-CODEINE	6.25-10/5	426	1020	34
00406036705	HYDROCODONE-ACETAMINOPHEN	10MG-325MG	423	408	34
53746010205	GABAPENTIN	300 MG	422	204	34
50111043301	TRAZODONE HCL	50 MG	412	272	34
00591246501	DESMOPRESSIN ACETATE	0.2 MG	406	204	34
53746046505	IBUPROFEN	600 MG	404	136	34
00472024260	PERMETHRIN	0.05	403	60	5
00093202631	AZITHROMYCIN	200 MG/5ML	397	180	30
00555097202	AMPHETAMINE SALT COMBO	10 MG	397	136	34
59762311001	AZITHROMYCIN	100 MG/5ML	396	180	30
00406051205	OXYCODONE-ACETAMINOPHEN	5MG-325MG	389	408	34
00406055201	OXYCODONE HCL	5 MG	385	408	34
00781185220	AMOX TR-POTASSIUM CLAVULANATE	875-125 MG	375	68	34
45802062626	CETIRIZINE HCL	1 MG/ML	372	340	34
59762314001	AZITHROMYCIN	200 MG/5ML	372	180	30
00603616032	TRAZODONE HCL	50 MG	365	272	34
00472162716	PROMETHAZINE-CODEINE	6.25-10/5	360	1020	34
63304062510	FUROSEMIDE	40 MG	357	68	34
68180072220	CEFDINIR	125 MG/5ML	353	600	30

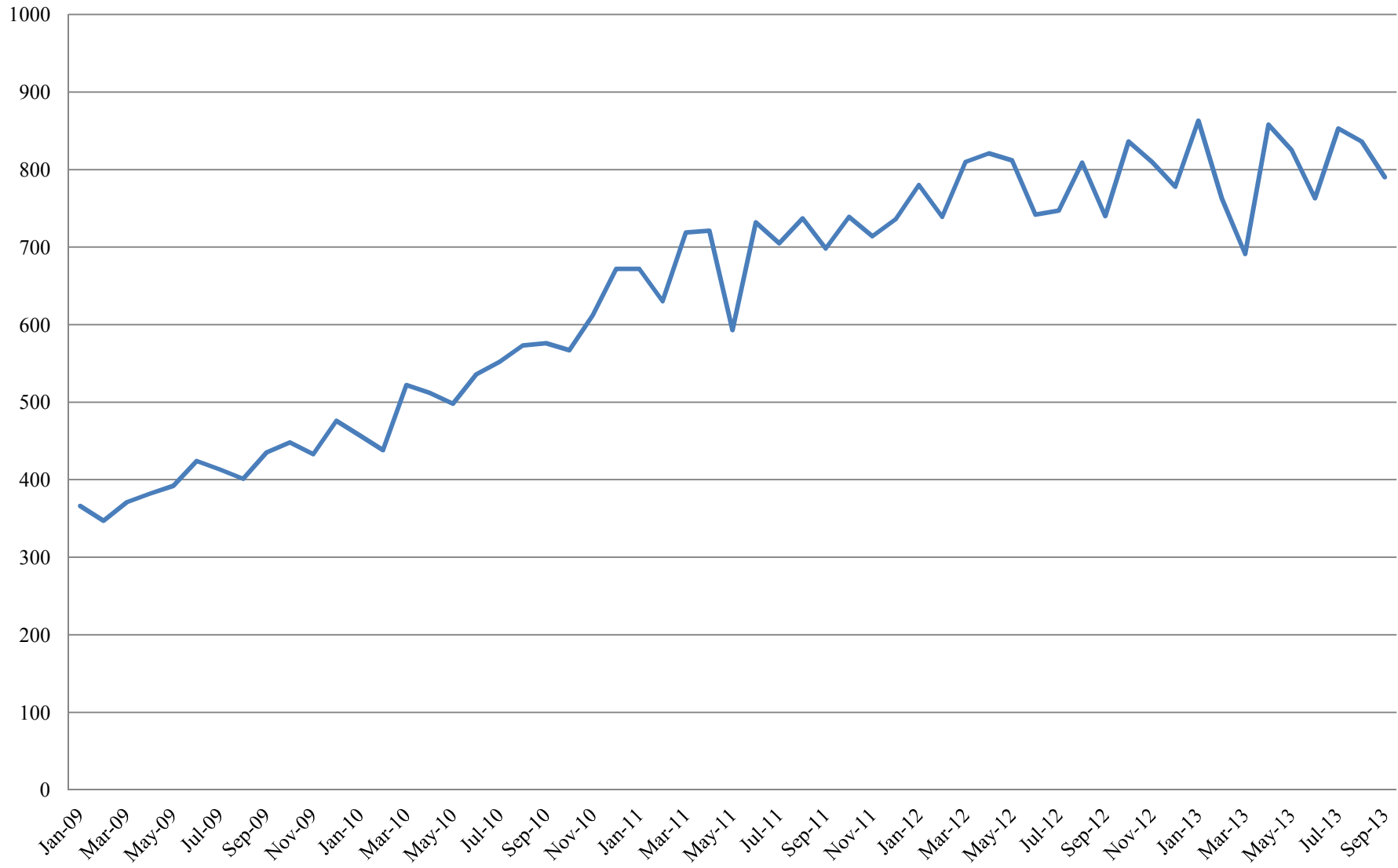
SD Medicaid Quantity Limit Suggestions					
NDC	Drug Name	Strength	Rx Count	Suggested Max Supply	Max Days
65862001305	SERTRALINE HCL	100 MG	350	68	34
00093681573	BUDESONIDE	0.25MG/2ML	339	120	30
47781030301	NITROFURANTOIN MONO-MACRO	100 MG	337	136	34
24208091055	ERYTHROMYCIN	5MG/G	336	4	1
24208031510	POLYMYXIN B SUL-TRIMETHOPRIM	10K/ML-0.1	335	10	1
00591252205	METRONIDAZOLE	500 MG	333	102	34
00093777205	CLOZAPINE	100 MG	332	306	34

SD Medicaid Tramadol Utilization			
January 2013 - June 2013			
Label Name	Rx Num	Total Reimb Amt	Average Cost per Script
TRAMADOL ER 100 MG TABLET	30	\$3,123.00	\$104.10
TRAMADOL ER 300 MG TABLET	30	\$5,666.74	\$188.89
TRAMADOL HCL 50 MG TABLET	5896	\$45,742.06	\$7.76
TRAMADOL HCL ER 200 MG TABLET	26	\$4,453.30	\$171.28
ULTRAM 50 MG TABLET	1	\$5.66	\$5.66
ULTRAM ER 200 MG TABLET	1	\$115.80	\$115.80
ULTRAM ER 300 MG TABLET	5	\$1,760.65	\$352.13
2088 recipients	5989	\$60,867.21	

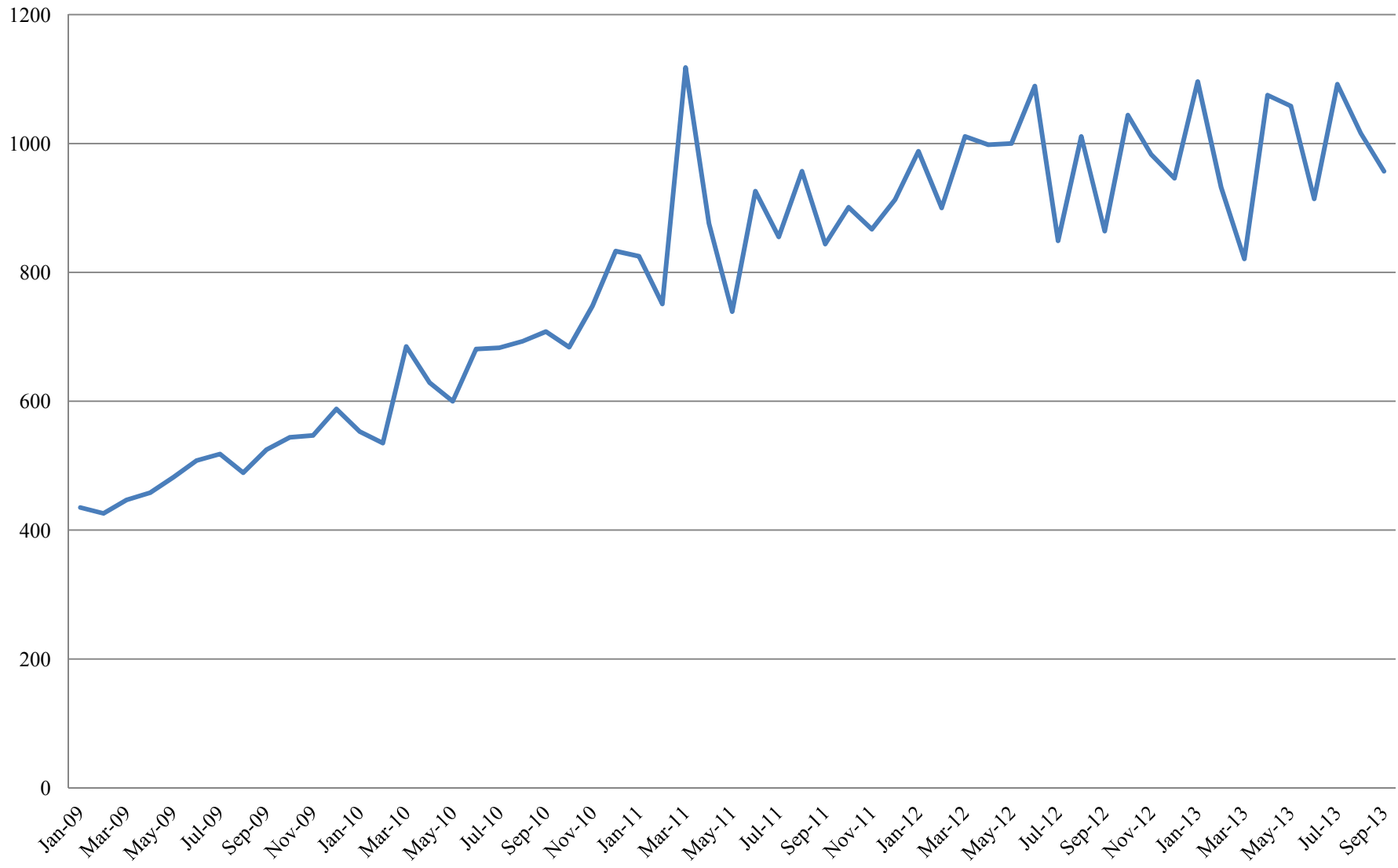
Summary by Age (decades)

Age (decades)	Recip Count	Rx Count
0-9	3	5
10-19	173	273
20-29	435	998
30-39	562	1587
40-49	394	1344
50-59	354	1231
60-69	158	535
70-79	3	3
80+	6	13

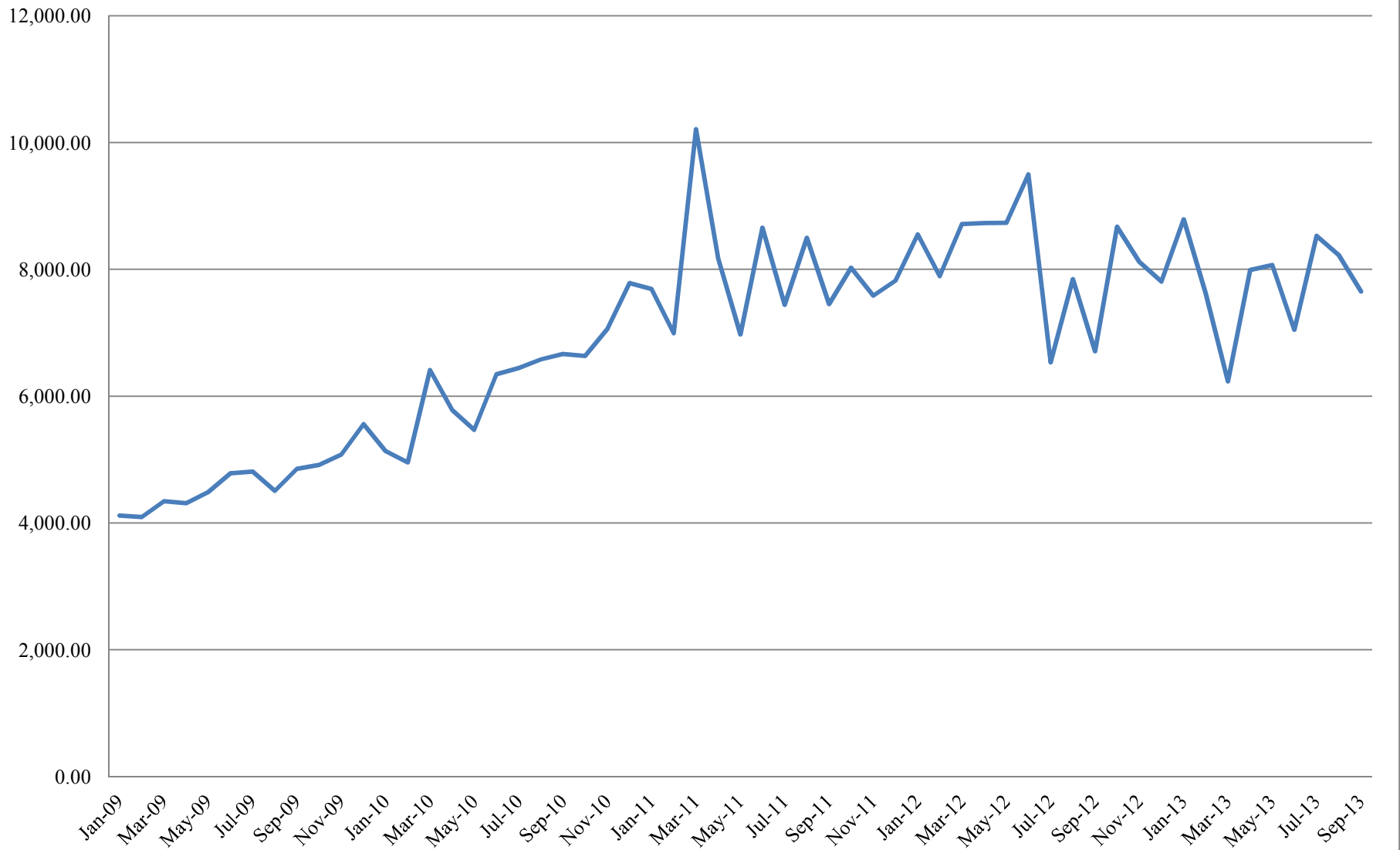
SD Medicaid Tramadol Patients January 2009 - September 2013



SD Medicaid Tramadol Script Count January 2009 - September 2013



SD Medicaid Tramadol Claims Cost January 2009 - September 2013



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Drugs

FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure

Safety Announcement

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Additional Information for Healthcare Professionals

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List of Marketed Acetaminophen-Containing Prescription Products

References

Safety Announcement

[1-13-2011] The U.S. Food and Drug Administration (FDA) is asking drug manufacturers to limit the strength of acetaminophen in prescription drug products, which are predominantly combinations of acetaminophen and opioids. This action will limit the amount of acetaminophen in these products to 325 mg per tablet, capsule, or other dosage unit, making these products safer for patients.

In addition, a *Boxed Warning* highlighting the potential for severe liver injury and a *Warning* highlighting the potential for allergic reactions (e.g., swelling of the face, mouth, and throat, difficulty breathing, itching, or rash) are being added to the label of all prescription drug products that contain acetaminophen.

These actions will help to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen.

Acetaminophen is widely and effectively used in both prescription and over-the-counter (OTC) products to reduce pain and fever. It is one of the most commonly-used drugs in the United States. Examples of prescription products that contain acetaminophen include hydrocodone with acetaminophen (Vicodin, Lortab), and oxycodone with acetaminophen (Tylox, Percocet).

OTC products containing acetaminophen (e.g., Tylenol) are not affected by this action. Information about the potential for liver injury is already required on the label for OTC products containing acetaminophen. FDA is continuing to evaluate ways to reduce the risk of acetaminophen related liver injury from OTC products. Additional safety measures relating to OTC acetaminophen products will be taken through separate action, such as a rulemaking as part of the ongoing OTC monograph proceeding for internal analgesic drug products.

Additional Information for Patients

- Acetaminophen-containing prescription products are safe and effective when used as directed, though all medications carry some risks.
- Do not stop taking your prescription pain medicine unless told to do so by your healthcare professional.
- Carefully read all labels for prescription and OTC medicines and ask the pharmacist if your prescription pain medicine contains acetaminophen.
- Do not take more than one product that contains acetaminophen at any given time.
- Do not take more of an acetaminophen-containing medicine than directed.
- Do not drink alcohol when taking medicines that contain acetaminophen.
- Stop taking your medication and seek medical help immediately if you:
 - Think you have taken more acetaminophen than directed or
 - Experience allergic reactions such as swelling of the face, mouth, and throat, difficulty breathing, itching, or rash.
- Report side effects to FDA's MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

The maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg. However, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. For example, for a product that previously contained 500 mg of acetaminophen with an opioid and was prescribed as 1-2 tablets every 4-6 hours, once reformulated to contain 325 mg of acetaminophen, the dosing instructions can remain unchanged.

- Advise patients not to exceed the acetaminophen maximum total daily dose (4 grams/day).
- Severe liver injury, including cases of acute liver failure resulting in liver transplant and death, has been reported with the use of acetaminophen.
- Educate patients about the importance of reading all prescription and OTC labels to ensure they are not taking multiple acetaminophen-containing products.
- Advise patients not to drink alcohol while taking acetaminophen-containing medications.
- Rare cases of anaphylaxis and other hypersensitivity reactions have occurred with the use of acetaminophen.
- Advise patients to seek medical help immediately if they have taken more acetaminophen than directed or experience swelling of the face, mouth, and throat, difficulty breathing, itching, and rash.
- Report adverse events to FDA's MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Data Summary and Discussion

A number of studies have tried to answer the question of how common liver injury is in relation to the use of acetaminophen. Although many questions remain about the full scope of the problem, the following examples indicate what is known about the extent of liver failure cases reported in the medical literature and clearly indicates a reason for concern:

- From 1998 to 2003, acetaminophen was the leading cause of acute liver failure in the United States, with 48% of acetaminophen-related cases (131 of 275) associated with accidental overdose.¹
- A 2007 Centers for Disease Control and Prevention (CDC) population-based report estimates that, nationally, there are 1600 cases of acute liver failure (ALF) each year (all causes). Acetaminophen-related ALF was the most common etiology.²
- Summarizing data from three different surveillance systems, there were an estimated 56,000 emergency room visits, 26,000 hospitalizations, and 458 deaths related to acetaminophen-associated overdoses per year during the 1990-1998 period.³
- In a study that combined data from 22 specialty medical centers in the United States, acetaminophen-related liver injury was the leading cause of ALF for the years 1998 through 2003.¹ This study also found that a high percentage of cases of liver injury due to acetaminophen were related to unintentional overdose, in which the patient mistakenly took too much acetaminophen. This finding was confirmed in a later study (2007).² Many other cases of acute liver injury are caused by intentional overdoses of acetaminophen (i.e., associated with self-harm).
- Across various studies, consumers were found to have taken more than the recommended dose when using an OTC product, a prescription product, or both. The Toxic Exposure Surveillance System (TESS), now named the National Poison Data System (NPDS), which captures data from calls to 61 poison control centers, provides additional data on acetaminophen overdose and serious injury. In 2005, TESS showed that calls about poisoning cases that resulted in major injury numbered 1,187 for OTC single-ingredient products, 653 for OTC combination products, and 1,470 for prescription-opioid combination products.⁴

The risk of liver injury associated with the use of acetaminophen was discussed at the Joint Meeting of the FDA Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and Anesthetic and Life Support Drugs Advisory Committee, held on June 29-30, 2009 (for [complete safety reviews and background information](#)¹ discussed at this meeting).

The Advisory Committee recommended a range of additional regulatory actions such as adding a boxed warning to prescription acetaminophen products, withdrawing prescription combination products from the market, or reducing the amount of acetaminophen in each dosage unit. FDA considered the Committee's advice for OTC products when deciding to limit the amount of acetaminophen per dosage unit in prescription products.

By limiting the maximum amount of acetaminophen in prescription products to 325 mg per dosage unit, patients will be less likely to overdose on acetaminophen if they mistakenly take too many doses of acetaminophen-containing products.

For more information on safety considerations for acetaminophen, visit the following link on the FDA web site: [Acetaminophen Information](#)²

List of Marketed Acetaminophen-Containing Prescription Products (products affected by the new dosage unit limits are in italics)

The label may not spell out the whole word or may have an abbreviation, such as "APAP, AC, Acetaminophn, Acetaminoph, Acetaminop, Acetamin or Acetam "

Brand Name	Generic Name	Dosage Form	Strength
No Current Brand Name	Acetaminophen; Aspirin; Codeine Phosphate	Capsule; Oral	150mg; 180mg; 30mg
<i>No Current Brand Name</i>	<i>Acetaminophen; Caffeine; Dihydrocodeine Bitartrate</i>	<i>Capsule; Oral</i>	<i>356.4mg; 30mg; 16mg</i>
<i>No Current Brand Name</i>	<i>Acetaminophen; Caffeine; Dihydrocodeine Bitartrate</i>	<i>Tablet; Oral</i>	<i>712.8mg; 60mg; 32mg</i>
No Current Brand Name	Acetaminophen; Codeine Phosphate	Solution; Oral	120mg/ 5mL; 12mg/ 5mL
No Current Brand Name	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 15mg
<i>No Current Brand Name</i>	<i>Acetaminophen; Codeine Phosphate</i>	<i>Tablet; Oral</i>	<i>650mg; 30mg</i>
<i>No Current Brand Name</i>	<i>Acetaminophen; Codeine Phosphate</i>	<i>Tablet; Oral</i>	<i>650mg; 60mg</i>
Capital and Codeine	Acetaminophen; Codeine Phosphate	Suspension; Oral	120mg/ 5mL; 12mg/ 5mL
Tylenol W/ Codeine No. 3	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 30mg
Tylenol W/ Codeine No. 4	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 60mg
<i>No Current Brand Name</i>	<i>Acetaminophen; Butalbital; Caffeine</i>	<i>Tablet; Oral</i>	<i>500mg; 50mg; 40mg</i>
<i>Esgic-Plus</i>	<i>Acetaminophen; Butalbital; Caffeine</i>	<i>Tablet; Oral</i>	<i>500mg; 50mg; 40mg</i>
<i>No Current Brand Name</i>	<i>Acetaminophen; Butalbital; Caffeine</i>	<i>Capsule; Oral</i>	<i>500mg; 50mg; 40mg</i>
<i>Esgic-Plus</i>	<i>Acetaminophen; Butalbital; Caffeine</i>	<i>Capsule; Oral</i>	<i>500mg; 50mg; 40mg</i>
No Current Brand Name	Acetaminophen; Butalbital; Caffeine	Tablet; Oral	325mg; 50mg; 40mg
Fioricet	Acetaminophen; Butalbital; Caffeine	Tablet; Oral	325mg; 50mg; 40mg
No Current Brand Name	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
Fioricet w/ codeine	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
Phrenilin with Caffeine and Codeine	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
<i>Anexsia</i>	<i>Acetaminophen; Hydrocodone Bitartrate</i>	<i>Tablet; Oral</i>	<i>500mg; 5mg</i>
<i>Anexsia</i>	<i>Acetaminophen; Hydrocodone Bitartrate</i>	<i>Tablet; Oral</i>	<i>750mg; 10mg</i>
<i>Anexsia</i>	<i>Acetaminophen; Hydrocodone Bitartrate</i>	<i>Tablet; Oral</i>	<i>325mg; 5mg</i>

¹ Prepared by Health Information Designs, LLC

Anexsia 7.5/ 325	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 7.5mg
Anexsia 7.5/ 650	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	650mg; 7.5mg
Co-Gesic	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Capsule; Oral	500mg; 5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	325mg/ 15mL; 10mg/ 15mL
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	325mg/ 15mL; 7.5mg/ 15mL
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	500mg/ 15mL; 10mg/ 15mL
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	500mg/ 15mL; 7.5mg/ 15mL
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 10mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 2.5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 7.5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 7.5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	650mg; 10mg
Lortab	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 10mg
Lortab	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 5mg
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 10mg
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 5mg
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 7.5mg
Vicodin	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	500mg; 5mg
Vicodin Es	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	750mg; 7.5mg
Vicodin Hp	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	660mg; 10mg
Zydone	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	400mg; 10mg
Zydone	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	400mg; 5mg
Zydone	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	400mg; 7.5mg
Oxycet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 10mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 2.5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 7.5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	400mg; 10mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	400mg; 2.5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	400mg; 5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	400mg; 7.5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	500mg; 10mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 10mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 2.5mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 7.5mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	500mg; 7.5mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	650mg; 10mg
Roxicet	Acetaminophen; Oxycodone Hydrochloride	Solution; Oral	325mg/ 5mL; 5mg/ 5mL
Roxicet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
Roxicet 5/ 500	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	500mg; 5mg
Roxilox	Acetaminophen; Oxycodone Hydrochloride	Capsule; Oral	500mg; 5mg
Tylox	Acetaminophen; Oxycodone Hydrochloride	Capsule; Oral	500mg; 5mg
Talacen	Acetaminophen; Pentazocine Hydrochloride	Tablet; Oral	650mg; EQ 25mg BASE
Ultracet	Acetaminophen; Tramadol Hydrochloride	Tablet; Oral	325mg; 37.5mg

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1. Larson AM, Polson J, Fontana RJ, Davern TJ, Lalani E, Hynan LS, et al. Acute Liver Failure Study Group (ALFSG). Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. *Hepatology*. 2005; 42:1364-72.
2. Bower WA, Johns M, Margolis HS, Williams IT, Bell BP. Population-based surveillance for acute liver failure. *Am J Gastroenterol*. 2007;102:2459-63.
3. Nourjah P, Ahmad SR, Karwoski C, Willy M. Estimates of acetaminophen (Paracetamol)-associated overdoses in the United States *Pharmacoepidemiol Drug Saf*. 2006;15:398-405.
4. Lai MW, Klein-Schwartz W, Rodgers GC, Abrams JY, Haber DA, Bronstein AC, Wruk KM. 2005 Annual Report of the American Association of Poison Control Centers' national poisoning and exposure database. *Clin Toxicol*. 2006;44:803-932.

Related Information

- [Acetaminophen Information](#)³
- [FDA limits acetaminophen in prescription combination products; requires liver toxicity warnings](#)⁴
Press Release - 1/13/2011

- [Questions and Answers about Oral Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit](#)⁵
1/13/2011
- [List of Marketed Acetaminophen-Containing Prescription Products](#)⁶
- [2009 Meeting Materials, Drug Safety and Risk Management Advisory Committee](#)⁷
- [FDA Drug Safety Podcast for Healthcare Professionals: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure](#)⁸ [ARCHIVED]

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1-800-FDA-0178 Fax
Report a Serious Problem
[MedWatch Online](#)⁹

Regular Mail: Use postage-paid [FDA Form 3500](#)¹⁰

Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857

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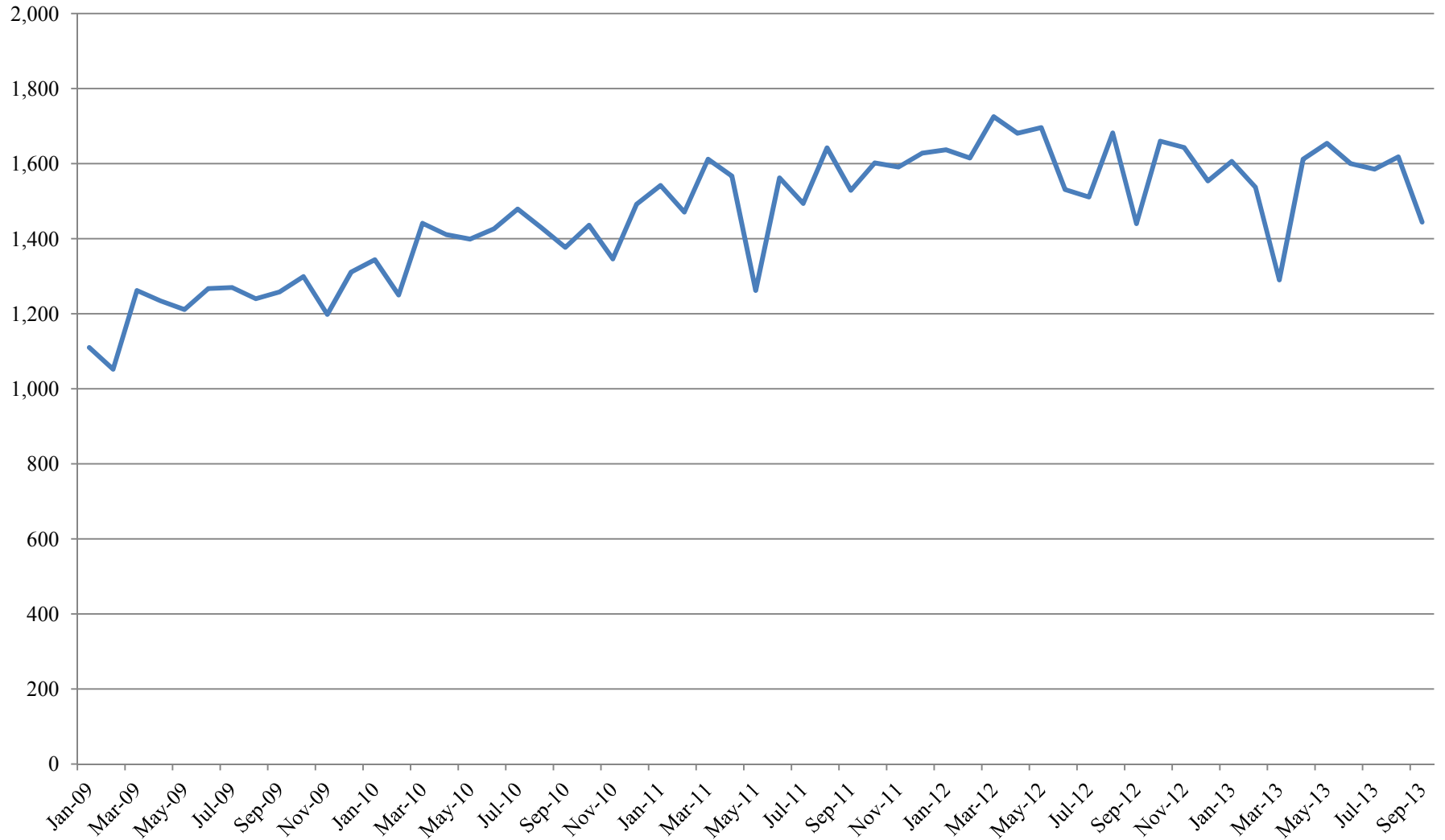
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9. <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
10. <http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>

SD Medicaid Hydrocodone/APAP Utilization			
10/24/12 - 10/23/13			
Label Name	Rx Num	Total Reimb Amt	Average Cost per Script
HYDROCODON-ACETAMIN 7.5-325/15	97	\$6,003.73	\$61.89
HYDROCODON-ACETAMIN 7.5-500/15	1365	\$12,775.76	\$9.36
HYDROCODON-ACETAMINOPH 2.5-500	6	\$76.40	\$12.73
HYDROCODON-ACETAMINOPH 7.5-300	6	\$184.60	\$30.77
HYDROCODON-ACETAMINOPH 7.5-325	1323	\$27,007.96	\$20.41
HYDROCODON-ACETAMINOPH 7.5-500	510	\$4,506.95	\$8.84
HYDROCODON-ACETAMINOPH 7.5-650	5	\$53.41	\$10.68
HYDROCODON-ACETAMINOPH 7.5-750	72	\$660.95	\$9.18
HYDROCODON-ACETAMINOPHEN 5-300	70	\$3,858.00	\$55.11
HYDROCODON-ACETAMINOPHEN 5-325	12282	\$166,944.41	\$13.59
HYDROCODON-ACETAMINOPHEN 5-500	4245	\$24,381.08	\$5.74
HYDROCODON-ACETAMINOPHN 10-300	3	\$478.70	\$159.57
HYDROCODON-ACETAMINOPHN 10-325	4304	\$84,757.77	\$19.69
HYDROCODON-ACETAMINOPHN 10-500	556	\$7,669.79	\$13.79
HYDROCODON-ACETAMINOPHN 10-650	541	\$4,839.84	\$8.95
HYDROCODON-ACETAMINOPHN 10-660	23	\$331.34	\$14.41
HYDROCODON-ACETAMINOPHN 10-750	1	\$8.10	\$8.10
VICODIN 5-300 MG TABLET	11	\$1,068.74	\$97.16
VICODIN ES 7.5-300 MG TABLET	2	\$56.40	\$28.20
ZAMICET 10-325 MG/15 ML SOLN	37	\$2,344.24	\$63.36
8751 recipients	25459	\$348,008.17	

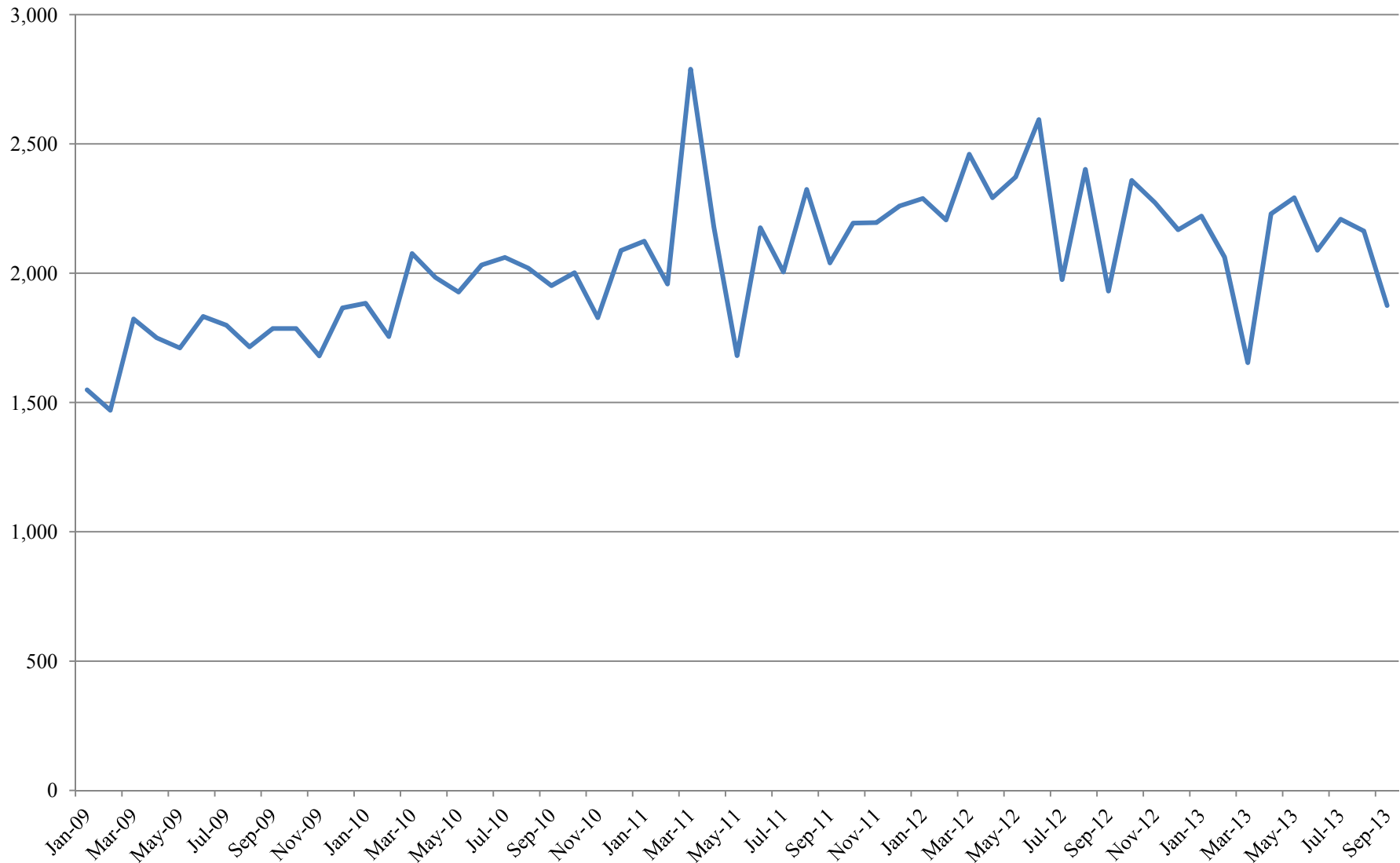
Summary by Age (decades)

Age (decades)	Recip Count	Rx Count
0-9	760	887
10-19	1894	2685
20-29	2297	5269
30-39	1727	6102
40-49	953	4288
50-59	825	4662
60-69	285	1545
70-79	7	11
80+	3	10

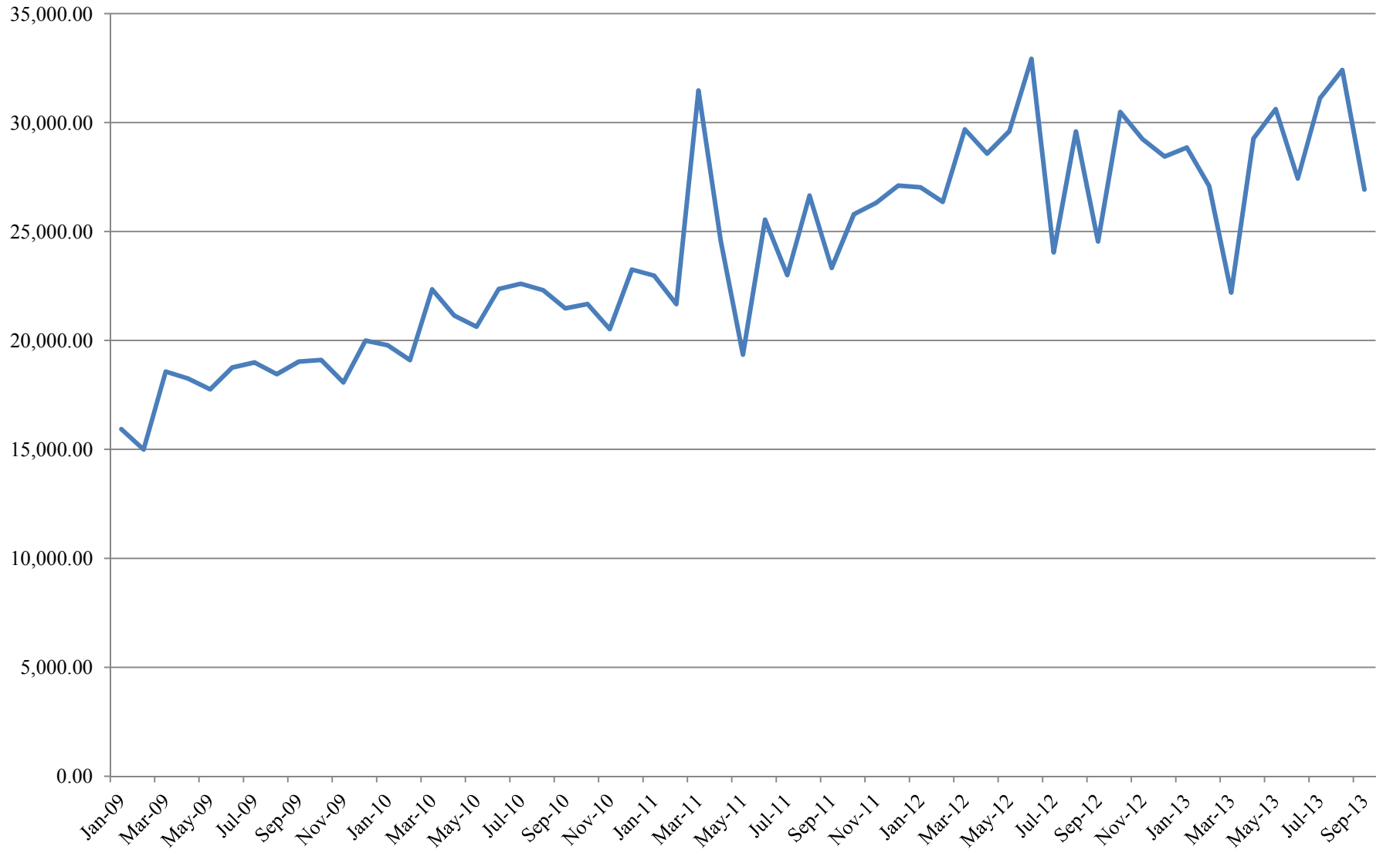
SD Medicaid Hydrocodone/APAP Patients January 2009 - September 2013



SD Medicaid Hydrocodone/APAP Script Count January 2009 - September 2013



SD Medicaid Hydrocodone/APAP Claims Cost January 2009 - September 2013



**South Dakota Medicaid
Pharmacotherapy Review
Epinephrine Auto-Injection Devices**

I. Indication

Epinephrine auto-injection is indicated in the emergency treatment of allergic reactions (Type 1) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Epinephrine auto-injection is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thread or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

II. Dosage and Administration

Patients greater than or equal to 30kg (66 lbs) inject 0.3mg. Patients 15 to 30 kg (33 lbs – 66 lbs) inject 0.15mg. Inject intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection.

III. Warnings and Precautions

- In conjunction with use, seek immediate medical or hospital care.
- Do not inject intravenously, into buttock, or into digits, hands or feet.
- The presence of a sulfite in this product should not deter use.
- Administer with caution in patients with heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.
- Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include the following: hyperthyroid persons, persons with cardiovascular disease, hypertension, or diabetes, elderly patients, pregnant women and pediatric patients.

IV. Adverse Reactions

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

V. Drug Interactions

- Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.
- The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines.

- The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs.
- The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs.
- Ergot alkaloids may reverse the pressor effects of epinephrine.

VI. Utilization

SD Medicaid Epinephrine Auto-Injector Utilization			
10/24/12 - 10/23/13			
Label Name	Rx Num	Total Reimb Amt	Avg Cost per Script
AUVI-Q 0.15 MG AUTO-INJECTOR	8	\$2,120.89	\$265.11
AUVI-Q 0.3 MG AUTO-INJECTOR	10	\$2,344.41	\$234.44
EPIPEN JR 0.15 MG AUTO-INJCT	1	\$176.54	\$176.54
EPIPEN 2-PAK 0.3 MG AUTO-INJCT	477	\$118,361.99	\$248.14
EPIPEN JR 2-PAK 0.15 MG INJCTR	405	\$108,184.81	\$267.12
731 recipients	901	\$231,188.64	

Reference

1. EpiPen[®] [prescribing information]. Basking Ridge, NJ. Mylan Specialty L.P.; August 2012.
2. Auvi-Q[®] [prescribing information]. Bridgewater, NJ. Sanofi-Aventis U.S. LLC; September 2012.

**South Dakota Medicaid
Pharmacotherapy Review
Brisdelle[®]**

I. Indication

Brisdelle (paroxetine) is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS). Brisdelle is not indicated for the treatment of any psychiatric condition.

II. Dosage and Administration

The recommended dosage of Brisdelle is 7.5mg once daily, at bedtime.

III. Contraindications

- Concurrent use with monoamine oxidase inhibitors (MAOI) or use within 14 days of MAOI use.
- Use with thioridazine.
- Use with pimozide.
- Pregnancy

IV. Warnings and Precautions

- Suicidality: Monitor for suicidality or unusual changes in behavior.
- Serotonin Syndrome: Serotonin syndrome, which is potentially life-threatening, has been reported with SSRIs. Discontinue Brisdelle and initiate supportive treatment.
- Tamoxifen: Efficacy of tamoxifen may be reduced when administered concomitantly with Brisdelle.
- Abnormal Bleeding: Caution patients about the risk of bleeding associated with the concomitant use of Brisdelle and non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation.
- Hyponatremia: Can occur in association with syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Bone Fracture: Epidemiological studies have reported an association between SSRI treatment and fractures.
- Activation of Mania/Hypomania: Screen for bipolar disorder and monitor for mania/hypomania.
- Seizures: Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.
- Akathisia: Can occur, most likely in the first few weeks of treatment.
- Acute Angle Closure Glaucoma: May cause acute angle closure in patients with narrow angle glaucoma.
- Cognitive and Motor Impairment: May cause impairment; patients should not operate machinery or motor vehicles until certain that Brisdelle does not affect them adversely.

V. Adverse Reactions

The most common adverse reactions ($\geq 2\%$) reported in clinical trials were headache, fatigue, and nausea/vomiting.

VI. Drug Interactions

Paroxetine is a strong CYP2D6 inhibitor. Co-administration of Brisdelle can alter concentrations of other drugs that are metabolized by CYP2D6. Consider potential drug interactions prior to and during therapy.

VII. Cost

Brisdelle costs approximately \$4.85 per capsule.

Reference

1. Brisdelle[®] [prescribing information]. Miami, FL. Noven Therapeutics, LLC; July 2013.