

South Dakota Department of Social Services

Medicaid P&T Committee Meeting

June 5, 2015





DEPARTMENT OF SOCIAL SERVICES

MEDICAL SERVICES

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**SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA**

Friday, June 5, 2015

1:00 – 3:00 PM

DDN Locations:

Sioux Falls

University Center

Room FADM253

4801 North Career Avenue

Pierre

Capitol Building

DDN Room A

500 E Capitol

Rapid City

SDSMT

Room CB109

501 E Joseph St.

Call to order

Approval of minutes of previous meeting

Prior authorization update

Review of top 15 therapeutic categories/top 25 drugs

Review of drug spend

Patent expirations

Old business

Agents used to treat idiopathic pulmonary fibrosis (Ofev, Esbriet) form

Xtoro form

Hemangeol form

New business

Review of Trokendi XR

Review of Oxtellar XR

Review of Akynzeo

Review of Nuessa

Review of Cholbam

Review of Copaxone 40

Oral presentations and comments by manufacturers' representatives

Next meeting date/adjournment

**Minutes of the March 20, 2015
Pharmacy & Therapeutics (P&T) Committee Meeting
South Dakota Department of Social Services, Division of Medical Services**

Members present

Bill Ladwig, RPh; Dana Darger, RPh; M. Holland; M. Baack; T. Soundy; R. Holm; Lenny Petrik; Deb Farver; Kelley Oehlke

DSS staff present

Mike Jockheck, RPh

Administrative business

The P&T meeting was called to order by D. Darger at 1:00 p.m. The minutes of the December 12, 2014 meeting were presented. B. Ladwig 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 January 2015. There were a total of 3,514 PAs processed in the month of January, with 99.91% of those requests responded to in less than eight hours. There were 2,799 (80%) requests received electronically and 715 (20%) 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 10/1/2014 – 12/31/2014. The top five classes were antipsychotics, respiratory and CNS stimulants, central nervous system agents, misc., amphetamines, and insulins. The top 15 therapeutic classes make up 37.33% 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 9.86% of total claims.

Stimulant use in adults

The committee reviewed stimulant use in adults at the December meeting. It was requested that a form be developed for the March meeting. After reviewing the form provided, the committee recommended changing the wording of the first line to "new prescription for a stimulant used for ADHD." The committee also added "treated" to the criteria question asking if the patient was diagnosed before age 16. A motion was made by B. Ladwig to make recommended changes to the ADHD for adults form. M. Baack seconded the motion. The motion was approved unanimously.

Otezla review

The committee reviewed the prior authorization form provided for Otezla. P. McDermott, representing Celgene, spoke regarding Otezla. B. Ladwig made a motion to approve the Otezla PA form. K. Oehlke seconded the motion. The motion was approved unanimously.

GLP-1 receptor agonists review

The committee reviewed the prior authorization form provided for GLP-1 receptor agonists. There was no public comment. The committee suggested removing “trial of metformin or a sulfonylurea.” J. Engelbrecht made a motion to approve the form. B. Ladwig seconded the motion. The motion was approved unanimously.

Topical therapies for onychomycosis review

The committee reviewed the prior authorization form provided for topical therapies for onychomycosis. There was no public comment. R. Holm made a motion to approve the form. B. Ladwig seconded the motion. The motion was approved unanimously.

Prior authorization forms and criteria annual review

The committee reviewed current prior authorization forms and criteria. Changes made include:

1. Brand-name narcotic form: add diagnosis to the form.
2. ARB form: must fail one ACE-I and a generic ARB.
3. Triptans: add rizatriptan and zolmitriptan to triptans that do not require PA
4. PPIs: add rabeprazole to PPIs that do not require PA
5. Nasal Steroids: remove Rhinocort
6. Oral Anticoagulants: add Savaysa to form

A motion was made by M. Holland to accept these changes. T. Soundy seconded the motion. The motion was approved unanimously.

Xtoro review

The committee reviewed Xtoro clinical information. There was no public comment. The committee requested that a form be developed and brought back to the June meeting.

Hemangeol review

The committee reviewed Hemangeol clinical information. There was no public comment. The committee requested that a form be developed and brought back to the June meeting.

Idiopathic pulmonary fibrosis review

The committee reviewed agents used to treat idiopathic pulmonary fibrosis. Mike Donze, representing Boehringer Ingelheim, spoke regarding Ofev. The committee requested that a form be developed and brought back to the June meeting.

The next meeting is scheduled for June 5, 2015. B. Ladwig made a motion to adjourn the P&T Committee meeting. R. Holm seconded the motion. The motion passed unanimously and the meeting was adjourned.



**South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2015 – April 30, 2015**

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
3,315	3,312	3	99.91%	0.09%

By Form Type

Form Type	Description	Approve	Deny
ADP	Antidepressant	168	279
AFX	Amrix and Fexmid	2	1
ALT	Altabax	1	2
AMB	Ambien CR	6	7
ANF	Anti-Infectives	0	77
ANT	Antihistamines	8	49
APS	Antipsychotic	236	548
ARB	ARBS	4	9
COA	Oral Anticoagulants	20	32
DAW	Dispense As Written	20	20
EME	Antiemetics	0	16
GRH	Growth Hormone	5	0
GSM	Genitourinary SMR	6	23
HEP	Hepatitis Meds	0	13
HLM	Head Lice Medication	5	62
LID	Lidoderm	0	53
MAX	Max Units Override	41	908
MSA	Multiple Sclerosis Agents	1	0
NAR	Name Brand Narcotics	3	4
NUC	Opioids	9	27
ONF	Onfi	6	7
OPH	Ophthalmic Antihistamines	0	32
PPI	Proton Pump Inhibitors	41	110
SMR	Skeletal Muscle Relaxants	5	15
STE	Nasal Steroids	21	78
STI	Stimulants	4	35
SUB	Suboxone/Subutex	6	4
TIM	Targeted Immune Modulators	9	7
TOP	Topical Acne Agents	19	131
TRP	Triptans	26	62
ULT	Ultram ER	5	3
XIF	Xifaxan	5	16
XOL	Xolair	1	2
Totals		683	2632

**South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2015 – April 30, 2015**

By Request Type

04/01/15 - 04/30/15	# of Requests	Electronic Requests		Faxed Requests	
		#	%	#	%
Prior Authorizations:					
Antidepressant	447	336	75%	111	25%
Amrix and Fexmid	3	2	67%	1	33%
Altabax	3	2	67%	1	33%
Ambien CR	13	12	92%	1	8%
Anti-Infectives(anti-biotic)	77	76	99%	1	1%
Antihistamines	57	50	88%	7	12%
Antipsychotic	784	523	67%	261	33%
ARBS	13	11	85%	2	15%
Oral Anticoagulants	52	31	60%	21	40%
Dispense As Written	40	13	33%	27	68%
Antiemetics	16	16	100%	0	0%
Growth Hormone	5	0	0%	5	100%
Genitourinary SMR	29	23	79%	6	21%
Hepatitis Meds	13	0	0%	13	100%
Head Lice Medication	67	51	76%	16	24%
Lidoderm	53	49	92%	4	8%
Max Units Override	949	854	90%	95	10%
Multiple Sclerosis Agents	1	0	0%	1	100%
Name Brand Narcotics	7	0	0%	7	100%
Opioids	36	30	83%	6	17%
Onfi	13	3	23%	10	77%
Ophthalmic Antihistamines	32	27	84%	5	16%
Proton Pump Inhibitors	151	120	79%	31	21%
Skeletal Muscle Relaxants	20	20	100%	0	0%
Nasal Steroids	99	83	84%	16	16%
Stimulants	39	34	87%	5	13%
Suboxone/Subutex	10	3	30%	7	70%
Targeted Immune Modulators	16	8	50%	8	50%
Topical Acne Agents	150	115	77%	35	23%
Triptans	88	68	77%	20	23%
Ultram ER	8	6	75%	2	25%
Xifaxan	21	15	71%	6	29%
Xolair	3	1	33%	2	67%
Prior Authorization Totals	3315	2582	78%	733	22%



**South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2015 – April 30, 2015**

Electronic PAs (Unique)

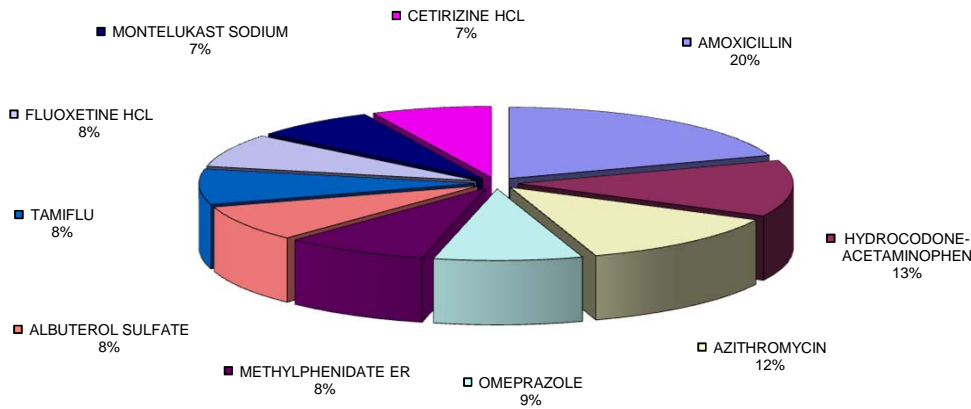
04/01/15 - 04/30/15	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antidepressant	109	219	1	329	33.10%	336
Amrix and Fexmid	1	1	0	2	50.00%	2
Altabax	0	2	0	2	0.00%	2
Ambien CR	6	5	0	11	54.50%	12
Anti-Infectives	0	75	0	75	0.00%	76
Antihistamines	5	42	0	47	10.60%	50
Antipsychotic	34	434	0	468	7.30%	523
ARBS	3	8	0	11	27.30%	11
Oral Anticoagulants	2	28	0	30	6.70%	31
Dispense As Written	0	13	0	13	0.00%	13
Antiemetics	0	12	0	12	0.00%	16
Genitourinary SMR	4	17	0	21	19.00%	23
Head Lice Medication	0	51	0	51	0.00%	51
Lidoderm	0	46	0	46	0.00%	49
Max Units Override	0	787	0	787	0.00%	854
Opioids	6	24	0	30	20.00%	30
Onfi	0	3	0	3	0.00%	3
Ophthalmic Antihistamines	0	27	0	27	0.00%	27
Proton Pump Inhibitors	24	80	0	104	23.10%	120
Skeletal Muscle Relaxants	5	12	0	17	29.40%	20
Nasal Steroids	17	65	0	82	20.70%	83
Stimulants	0	33	0	33	0.00%	34
Suboxone/Subutex	0	3	0	3	0.00%	3
Targeted Immune Modulators	2	6	0	8	25.00%	8
Topical Acne Agents	6	106	0	112	5.40%	115
Triptans	14	44	0	58	24.10%	68
Ultram ER	3	3	0	6	50.00%	6
Xifaxan	0	15	0	15	0.00%	15
Xolair	0	1	0	1	0.00%	1
TOTALS	241	2162	1	2404	10.00%	2582

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 01/01/2015 - 03/31/2015

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	9,230	\$ 80,673.48	\$ 8.74	4.15%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	5,977	\$ 158,733.98	\$ 26.56	2.68%
AZITHROMYCIN	MACROLIDES	5,835	\$ 91,386.99	\$ 15.66	2.62%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	4,073	\$ 48,058.65	\$ 11.80	1.83%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,943	\$ 704,623.03	\$ 178.70	1.77%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	3,793	\$ 69,943.74	\$ 18.44	1.70%
TAMIFLU	NEURAMINIDASE INHIBITORS	3,741	\$ 591,051.15	\$ 157.99	1.68%
FLUOXETINE HCL	ANTIDEPRESSANTS	3,529	\$ 33,725.47	\$ 9.56	1.59%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	3,342	\$ 67,615.41	\$ 20.23	1.50%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	3,302	\$ 24,425.54	\$ 7.40	1.48%
VYVANSE	AMPHETAMINES	3,228	\$ 654,919.50	\$ 202.89	1.45%
SERTRALINE HCL	ANTIDEPRESSANTS	3,096	\$ 23,365.60	\$ 7.55	1.39%
TRAMADOL HCL	OPIATE AGONISTS	3,063	\$ 27,242.94	\$ 8.89	1.38%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,965	\$ 41,867.87	\$ 14.12	1.33%
TRAZODONE HCL	ANTIDEPRESSANTS	2,687	\$ 16,106.29	\$ 5.99	1.21%
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	2,372	\$ 61,374.92	\$ 25.87	1.07%
DEXTROAMPHETAMINE-AMPHET ER	AMPHETAMINES	2,349	\$ 303,024.16	\$ 129.00	1.06%
LISINAPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	2,254	\$ 12,401.77	\$ 5.50	1.01%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,197	\$ 12,591.96	\$ 5.73	0.99%
CEFDINIR	CEPHALOSPORINS	2,164	\$ 106,938.11	\$ 49.42	0.97%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,115	\$ 50,191.80	\$ 23.73	0.95%
VENTOLIN HFA	BETA-ADRENERGIC AGONISTS	2,071	\$ 103,753.15	\$ 50.10	0.93%
FLUTICASON PROPRIONATE	CORTICOSTEROIDS (EENT)	1,956	\$ 27,240.47	\$ 13.93	0.88%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,936	\$ 13,066.19	\$ 6.75	0.87%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,868	\$ 15,315.69	\$ 8.20	0.84%
TOTAL TOP 25		83,086	\$ 3,339,637.86	\$ 40.19	37.32%

Total Rx Claims From 01/01/2015 - 03/31/2015	222,638
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**Top 10 Drugs
Based on Number of Claims**

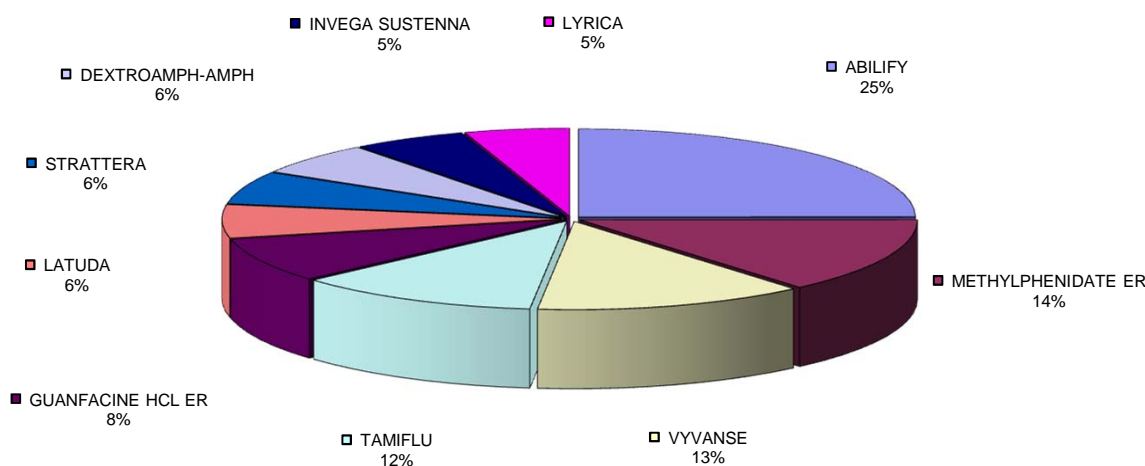


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 01/01/2015 - 03/31/2015

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,569	\$ 1,267,833.49	\$ 808.05	0.70%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,943	\$ 704,623.03	\$ 178.70	1.77%
VYVANSE	AMPHETAMINES	3,228	\$ 654,919.50	\$ 202.89	1.45%
TAMIFLU	NEURAMINIDASE INHIBITORS	3,741	\$ 591,051.15	\$ 157.99	1.68%
GUANFACINE HCL ER	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,743	\$ 413,615.51	\$ 237.30	0.78%
LATUDA	ANTIPSYCHOTIC AGENTS	409	\$ 308,917.62	\$ 755.30	0.18%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,014	\$ 305,459.08	\$ 301.24	0.46%
DEXTROAMPH-AMPH	AMPHETAMINES	2,349	\$ 303,024.16	\$ 129.00	1.06%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	180	\$ 274,968.00	\$ 1,527.60	0.08%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	749	\$ 254,780.16	\$ 340.16	0.34%
LANTUS SOLOSTAR	INSULINS	534	\$ 228,697.00	\$ 428.27	0.24%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	67	\$ 216,120.24	\$ 3,225.68	0.03%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	700	\$ 214,543.79	\$ 306.49	0.31%
PULMOZYME	MUCOLYTIC AGENTS	73	\$ 206,591.13	\$ 2,830.02	0.03%
HARVONI	HCV ANTIVIRALS	6	\$ 197,322.60	\$ 32,887.10	0.00%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	740	\$ 196,436.30	\$ 265.45	0.33%
PREVACID	PROTON-PUMP INHIBITORS	589	\$ 191,997.61	\$ 325.97	0.26%
NOVOLOG FLEXPEN	INSULINS	369	\$ 165,092.82	\$ 447.41	0.17%
HYDROCODONE-APAP	OPIATE AGONISTS	5,977	\$ 158,733.98	\$ 26.56	2.68%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	53	\$ 158,612.75	\$ 2,992.69	0.02%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	831	\$ 155,886.24	\$ 187.59	0.37%
NOVOLOG	INSULINS	410	\$ 148,711.72	\$ 362.71	0.18%
OXYCONTIN	OPIATE AGONISTS	379	\$ 139,524.91	\$ 368.14	0.17%
XENAZINE	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	15	\$ 134,748.29	\$ 8,983.22	0.01%
BUDESONIDE	CORTICOSTEROIDS (RESPIRATORY TRACT)	440	\$ 131,322.57	\$ 298.46	0.20%
TOTAL TOP 25		30,108	\$ 7,723,533.65	\$ 256.53	13.52%

Total Rx Claims	222,638
From 01/01/2015 - 03/31/2015	

**Top 10 Drugs
Based on Total Claims Cost**



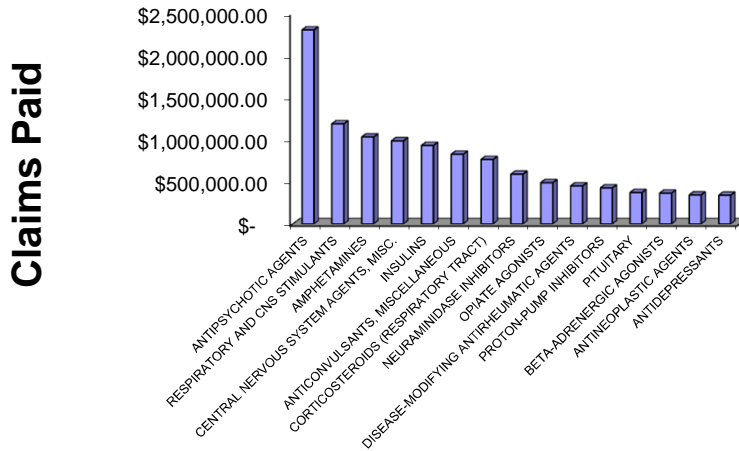
**SOUTH DAKOTA MEDICAID
Cost Management Analysis**

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 01/01/2015 - 03/31/2015

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	7,071	\$ 2,300,430.28	\$ 325.33	3.18%
RESPIRATORY AND CNS STIMULANTS	7,123	\$ 1,189,440.61	\$ 166.99	3.20%
AMPHETAMINES	6,561	\$ 1,032,907.93	\$ 157.43	2.95%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	3,232	\$ 988,013.70	\$ 305.70	1.45%
INSULINS	2,351	\$ 932,041.80	\$ 396.44	1.06%
ANTICONSULSANTS, MISCELLANEOUS	9,477	\$ 828,042.00	\$ 87.37	4.26%
CORTICOSTEROIDS (RESPIRATORY TRACT)	3,067	\$ 766,283.00	\$ 249.85	1.38%
NEURAMINIDASE INHIBITORS	3,741	\$ 591,051.15	\$ 157.99	1.68%
OPIATE AGONISTS	13,533	\$ 491,065.94	\$ 36.29	6.08%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	166	\$ 451,613.34	\$ 2,720.56	0.07%
PROTON-PUMP INHIBITORS	6,443	\$ 428,163.68	\$ 66.45	2.89%
PITUITARY	565	\$ 373,030.68	\$ 660.23	0.25%
BETA-ADRENERGIC AGONISTS	8,509	\$ 365,648.15	\$ 42.97	3.82%
ANTINEOPLASTIC AGENTS	510	\$ 343,937.69	\$ 674.39	0.23%
ANTIDEPRESSANTS	18,981	\$ 341,022.40	\$ 17.97	8.53%
TOTAL TOP 15	91,330	\$ 11,422,692.35	\$ 125.07	41.02%

Total Rx Claims From 01/01/2015 - 03/31/2015	222,638
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**Top 15 Therapeutic Classes
Based on Total Cost of Claims**



SD Medicaid Drug Spend 2012 - 2015

Drug Spend 2012

Total	201201	201202	201203	201204	201205	201206	201207	201208	201209	201210	201211	201212	Row SubTotal
Rx_Dollars	\$4,849,391.09	\$4,997,072.08	\$5,257,537.69	\$4,879,456.62	\$4,919,253.17	\$4,913,164.11	\$3,845,419.78	\$4,863,874.68	\$4,014,447.34	\$4,823,060.40	\$4,576,545.82	\$4,443,459.76	\$56,382,682.54
Rx_Count	77,559	77,426	79,761	74,004	74,773	75,503	57,785	72,290	63,542	77,195	73,717	71,219	874,774
Average_Rx_Cost	\$62.53	\$64.54	\$65.92	\$65.94	\$65.79	\$65.07	\$66.55	\$67.28	\$63.18	\$62.48	\$62.08	\$62.39	\$64.45
Recip_Count	29,127	30,437	29,893	28,110	27,215	23,029	22,803	26,411	25,434	28,741	28,017	27,141	
Recip_Average_Rx_Cost	\$166.49	\$164.18	\$175.88	\$173.58	\$180.76	\$213.35	\$168.64	\$184.16	\$157.84	\$167.81	\$163.35	\$163.72	\$172.76

Drug Spend 2013

Total	201301	201302	201303	201304	201305	201306	201307	201308	201309	201310	201311	201312	Row SubTotal
Rx_Dollars	\$5,098,169.75	\$4,387,497.68	\$3,483,772.72	\$4,587,727.94	\$4,954,424.54	\$4,080,139.76	\$4,746,330.61	\$4,785,381.28	\$4,365,123.88	\$5,013,735.15	\$4,581,524.61	\$4,062,575.21	\$54,146,403.13
Rx_Count	75,726	68,046	54,790	68,602	68,081	57,928	65,533	66,327	62,205	72,336	65,859	56,582	782,015
Average_Rx_Cost	\$67.32	\$64.48	\$63.58	\$66.87	\$72.77	\$70.43	\$72.43	\$72.15	\$70.17	\$69.31	\$69.57	\$71.80	\$69.24
Recip_Count	27,719	25,992	22,293	24,675	24,016	21,412	22,581	23,564	23,754	25,749	24,485	21,798	
Recip_Average_Rx_Cost	\$183.92	\$168.80	\$156.27	\$185.93	\$206.30	\$190.55	\$210.19	\$203.08	\$183.76	\$194.72	\$187.12	\$186.37	\$187.98

Drug Spend 2014

Total	201401	201402	201403	201404	201405	201406	201407	201408	201409	201410	201411	201412	Row SubTotal
Rx_Dollars	\$5,147,300.76	\$5,032,624.29	\$5,434,147.99	\$5,247,611.60	\$5,248,010.35	\$4,405,071.19	\$4,931,375.07	\$4,738,777.48	\$4,538,235.88	\$5,773,974.96	\$5,036,186.43	\$5,931,145.84	\$61,464,461.84
Rx_Count	68,519	68,225	71,659	71,966	67,552	54,782	61,854	61,147	54,408	73,097	63,572	72,538	789,319
Average_Rx_Cost	\$75.12	\$73.77	\$75.83	\$72.92	\$77.69	\$80.41	\$79.73	\$77.50	\$83.41	\$78.99	\$79.22	\$81.77	\$77.87
Recip_Count	25,131	25,541	26,527	25,767	24,324	20,669	22,363	22,719	21,996	25,738	23,583	25,398	
Recip_Average_Rx_Cost	\$204.82	\$197.04	\$204.85	\$203.66	\$215.75	\$213.12	\$220.51	\$208.58	\$206.32	\$224.34	\$213.55	\$233.53	\$212.12

Drug Spend 2015

Total	201501	201502	201503	201504	201505	201506	201507	201508	201509	201510	201511	201512	Row SubTotal
Rx_Dollars	\$6,059,744.91	\$5,577,837.15	\$6,214,562.53	\$5,636,761.54	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$23,488,906.13
Rx_Count	75,374	70,061	77,203	71,307	0	0	0	0	0	0	0	0	293,945
Average_Rx_Cost	\$80.40	\$79.61	\$80.50	\$79.05	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$79.91
Recip_Count	27,966	26,519	27,976	26,044	0	0	0	0	0	0	0	0	
Recip_Average_Rx_Cost	\$216.68	\$210.33	\$222.14	\$216.43	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$216.48

Anticipated Availability of First-Time Generics

—To help explain the benefits of generic drugs to your patients, the FDA has patient education materials available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm169209.htm>—

Brand^a (Manufacturer)	Generic Name	Generic Manufacturer(s)^{b,1}	Anticipated Availability^c
<i>AndroGel 1%</i> (AbbVie)	Testosterone	Perrigo	Generic now available
<i>Carac</i> (Valeant)	Fluorouracil cream 0.5%	Spear	Generic now available
<i>Celebrex</i> (Pfizer)	Celecoxib	Lupin, Mylan, Teva	Generic now available
<i>Epivir</i> (Glaxo)	Lamivudine oral solution	Silarx	Generic now available
<i>Exforge HCT</i> (Novartis)	Amlodipine/Valsartan/ Hydrochlorothiazide	Teva	Generic now available
<i>Femhrt</i> (Warner Chilcott)	Ethinyl estradiol/norethindrone	Glenmark	Generic now available
<i>Generess Fe</i> (Actavis)	Norethindrone, Ethinyl estradiol, Ferrous fumarate	Mylan	Generic now available
<i>Intuniv</i> (Shire)	Guanfacine extended-release tablet	Actavis	Generic now available
<i>Lamictal ODT</i> (GlaxoSmithKline)	Lamotrigine orally disintegrating tablet	Impax	Generic now available
<i>Lybrel</i> (Wyeth)	Levonorgestrel 0.09 mg/ethinyl estradiol 0.02 mg	Glenmark	Generic now available
<i>Kenalog</i> (Ranbaxy)	Triamcinolone topical spray	Perrigo	Generic now available
<i>Methylin</i> (Mallinckrodt)	Methylphenidate chewable tablet	Gavis (Novel)	Generic now available

More . . .

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>Neupogen</i> (Amgen)	Filgrastim	Sandoz	Biosimilar ¹ now available (filgrastim-sndz [<i>Zarxio</i>])
<i>Nexium</i> (AstraZeneca)	Esomeprazole magnesium delayed-release capsule	Teva (Ivax)	Generic now available
<i>Orapred ODT</i> (Concordia)	Prednisolone sodium phosphate orally disintegrating tablet	Mylan	Generic now available
<i>Patanase</i> (Alcon)	Olopatadine nasal spray	Apotex	Generic now available
<i>Robaxin</i> (Hikma)	Methocarbamol injection	Mylan	Generic now available
<i>Stromectol</i> (Merck)	Ivermectin	Edenbridge	Generic now available
<i>Taxotere</i> (Sanofi)	Docetaxel	Accord, Actavis, Dr. Reddy's	Generic now available
<i>Testim</i> (Auxilium)	Testosterone transdermal gel	Upsher Smith	Generic now available
<i>Valcyte</i> (Roche)	Valganciclovir tablet	Dr. Reddy's, Qualitest (Endo)	Generic now available
<i>Zemplar</i> (AbbVie)	Paricalcitol injection	Hospira	Generic now available
<i>Zyvox</i> (Pfizer)	Linezolid injection	Teva	Generic now available
<i>Mirapex ER</i> (Boehringer Ingelheim)	Pramipexole extended-release tablet	Anchen, Sandoz	2015 ¹¹³
<i>Abilify</i> (Otsuka)	Aripiprazole	<u>Tablet</u> : Alembic, Apotex, Hetero, Sun, Teva, Torrent <u>Orally disintegrating tablet</u> : Alembic, Teva, Zydus	Second quarter 2015 ¹¹³
<i>Oxytrol</i> (Actavis)	Oxybutynin transdermal patch	Teva	Second quarter 2015 ¹¹³
<i>Welchol</i> (Daiichi Sankyo)	Colesevelam tablet and oral suspension	Impax, ^{f,22} Actavis, ^{i,23,71} Glenmark ^{f,59}	Second quarter 2015 ¹¹³

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
Zyvox (Pfizer)	Linezolid	Tablet: Gate, Glenmark, Hetero, Mylan, Teva Oral suspension: Roxane	May 2015 ²⁴
Namenda (Forest)	Memantine	Tablet: Alembic, Amneal, Apotex, Aurobindo, Jubilant Life, Lupin, Macleods, Mylan, Upsher- Smith, Torrent, Unichem, Wockhardt, Zydus	July 2015
Targretin (Eisai)	Bexarotene	Mylan ^{f,47}	July 2015 ⁴⁷
Copaxone (Teva)	Glatiramer 20 mg/mL	Sandoz	September 2015 ¹¹⁶
Emend (Merck)	Aprepitant capsule	Sandoz	Fourth quarter 2015 ¹¹³
Namenda (Forest)	Memantine	Oral solution: Silarx	October 2015 ²⁴
Asacol HD (Warner Chilcott)	Mesalamine delayed-release tablet	Zydus ^{f,90}	November 2015 ⁹⁰
Avodart (GlaxoSmithKline)	Dutasteride	Actavis, Amneal, Apotex, Banner, Endo, Roxane, Sandoz, Teva	November 2015
Axert (Ortho-McNeil-Janssen)	Almotriptan	Teva	November 2015
Frova (Endo)	Frovatriptan	Mylan	November 2015 ^{e,37}
Jalyn (GlaxoSmithKline)	Dutasteride/Tamsulosin	Anchen, Impax, ^{h,13} Mylan, ^{h,13} Actavis ^{h,72}	November 2015 ^d
Patanol (Alcon)	Olopatadine 0.1% ophthalmic solution	Actavis, Apotex, Sandoz, Wockhardt	December 2015
Gleevec (Novartis)	Imatinib	Apotex, Sun	February 2016 ²⁴
Glumetza (Santarus)	Metformin extended-release tablet	Lupin, ^{f,17} Sun	February 2016 ¹⁷

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>Enablex</i> (Novartis)	Darifenacin	Anchen	March 2016 ⁹⁷
<i>Epzicom</i> (GlaxoSmithKline)	Abacavir sulfate/Lamivudine	<u>Tablet</u> : Aurobindo, Cipla, Hetero, Matrix, Mylan, Teva <u>Tablet for Suspension</u> : Cipla, Mylan	March 2016 ⁹⁷
<i>Crestor</i> (AstraZeneca)	Rosuvastatin calcium	Actavis, Apotex, Aurobindo, Glenmark, Mylan, Par, Sandoz, Sun, Teva, Torrent	May 2016 ²⁶
<i>Lantus</i> (Sanofi-Aventis)	Insulin glargine	Eli Lilly/Boehringer Ingelheim	Mid-2016 ¹⁰⁸ (This product will be a new brand of insulin glargine [<i>Basaglar</i>], not a generic.)
<i>Cubicin</i> (Cubist)	Daptomycin	Hospira, Teva ^{f,69}	June 2016 ¹⁹
<i>Nuvigil</i> (Teva)	Armodafinil	Actavis, Apotex, Breckenridge, Lupin, Mylan, Teva	June 2016 ³¹
<i>Zegerid/Zegerid OTC</i> (Santarus)	Omeprazole/Sodium bicarbonate capsule and oral suspension	Dr. Reddy's, ^{h,10} Par, Perrigo (capsule), Zydus ^{h,32}	July 2016 ²⁴
<i>Benicar/Benicar HCT</i> (Daiichi Sankyo)	Olmesartan/Olmesartan HCTZ	<u>Olmesartan</u> : Mylan, Sandoz, Teva <u>Olmesartan HCTZ</u> : Mylan, Teva	October 2016 ²⁴
<i>Seroquel XR</i> (AstraZeneca)	Quetiapine extended-release tablet	Accord, Handa, Lupin, ^{f,43} Mylan, Osmotica, ^{f,53} Torrent ^{f,53}	November 2016 ⁷⁴
<i>Kaletra</i> (Abbott)	Lopinavir/Ritonavir	<u>Tablet</u> : Aurobindo, Cipla, Hetero, Matrix, Mylan <u>Oral solution</u> : Cipla	December 2016 ^{9,36}
<i>ProAir HFA</i> (Teva)	Albuterol	Perrigo, ^{f,34} Catalent ^{f,34}	December 2016 ³⁴
<i>Relpax</i> (Pfizer)	Eletriptan	Apotex, Teva	December 2016 ⁹⁷
<i>Zetia</i> (Merck)	Ezetimibe	Glenmark, Mylan	December 2016 ²⁸

Brand^a (Manufacturer)	Generic Name	Generic Manufacturer(s)^{b,1}	Anticipated Availability^c
<i>Aggrenox</i> (Boehringer Ingelheim)	Aspirin/Dipyridamole	Barr	January 2017
<i>Revatio</i> (Pfizer)	Sildenafil injection	Aurobindo	January 2017
<i>Azilect</i> (Teva)	Rasagiline mesylate tablet	Apotex, Mylan, Orchid, ^{f,30} Sandoz ^{f,30}	February 2017
<i>Vytorin</i> (Merck)	Ezetimibe/Simvastatin	Mylan	April 2017
<i>Strattera</i> (Lilly)	Atomoxetine	Actavis, ^{h,29} Apotex, Aurobindo, Dr. Reddy's, Glenmark, Mylan, Sandoz, Sun, Teva ^{h,29}	May 2017
<i>Metozolv</i> (Salix)	Metoclopramide orally disintegrating tablet	Novel	July 2017
<i>Reyataz</i> (Bristol-Myers Squibb)	Atazanavir	Aurobindo, Emcure, Matrix, Teva	July 2017 ⁵²
<i>Treximet</i> (Pozen)	Sumatriptan/Naproxen	Alphapharm, ^{f,102} Dr. Reddy's, Mylan, Par, Teva ^{f,102}	August 2017 ¹⁰²
<i>Nasonex</i> (Merck)	Mometasone	Apotex, ^{h,95} Teva ^{h,95}	October 2017 ^d
<i>Viagra</i> (Pfizer)	Sildenafil	Actavis, Amneal, Apotex, Dr. Reddy's, Hetero, Macleods, Mylan, Teva	December 2017 ^{91,92}
<i>Viread</i> (Gilead)	Tenofovir disoproxil fumarate	Aurobindo, Cipla, InvaGen, Lupin, Macleods, Matrix, Strides Arcolab, Teva	December 2017 ⁸
<i>Sensipar</i> (Amgen)	Cinacalcet tablet	Teva	March 2018 ⁵¹
<i>Acanya</i> (Valeant)	Benzoyl peroxide/Clindamycin phosphate	Actavis ^{f,87}	July 2018 ⁸⁷
<i>Aloxi</i> (Eisai)	Palonosetron injection	Dr. Reddy's, Sandoz, ^{f,78} Teva	September 2018 ⁷⁸

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>Fentora</i> (Cephalon)	Fentanyl citrate buccal/sublingual tablet	Actavis, ^{h,56} Teva, ^{f,56} Impax ^{f,57}	October 2018 ^{d,56}
<i>Vesicare</i> (Astellas)	Solifenacin succinate	Teva	October 2018 ²⁰
<i>Fortesta</i> (Endo)	Testosterone gel	Actavis ⁶⁵	November 2018 ^d
<i>Lyrica</i> (Pfizer)	Pregabalin	<u>Capsule:</u> Actavis, Alembic, Apotex, Lupin, Mylan, Sandoz, Teva, Wockhardt <u>Oral solution:</u> Apotex, Lupin	December 2018 ⁵⁰
<i>Exelon</i> (Novartis)	Rivastigmine transdermal patch	Actavis, ^{h,66} Noven ^{h,64}	January 2019 ^d
<i>Ranexa</i> (Gilead)	Ranolazine	Lupin	February 2019 ⁸¹
<i>AzaSite</i> (InSite Vision)	Azithromycin 1% ophthalmic solution	Mylan, ^{h,16} Sandoz	March 2019 ^d
<i>Emend</i> (Merck)	Fosaprepitant injection	Accord, ^{h,35} Sandoz ^{h,35}	March 2019 ^d
<i>Angiomax</i> (Medicines Co)	Bivalirudin	Hospira, Sagent, Teva ^{f,105}	June 2019 ¹⁰⁵
<i>Factive</i> (Cornerstone)	Gemifloxacin tablet	Orchid	September 2019
<i>Sustiva</i> (Bristol-Myers Squibb)	Efavirenz	<u>Tablet:</u> Aurobindo, Cipla, Emcure, Hetero, Macleods, Matrix, Micro Labs, Par, Strides <u>Capsule:</u> Aurobindo, Cipla, Micro Labs	October 2019 ^{e,21}
<i>Ritalin LA</i> (Novartis)	Methylphenidate extended-release capsule	Actavis, Teva	November 2019 ^{e,38}
<i>Silenor</i> (Somaxon)	Doxepin	Actavis, Mylan, Par, Zydus	January 2020 ³⁹

Brand^a (Manufacturer)	Generic Name	Generic Manufacturer(s)^{b,1}	Anticipated Availability^c
<i>Vigamox</i> (Alcon)	Moxifloxacin ophthalmic	Actavis, Akorn, Apotex, Lupin, Teva	March 2020 ^{d,6}
<i>Safyral</i> (Bayer)	Drospirenone/Ethinyl estradiol/Levomefolate calcium	Actavis ^{h,46}	April 2020 ^d
<i>Lialda</i> (Shire)	Mesalamine delayed-release tablet	Zydus ^{h,76}	June 2020 ^d
<i>Lescol XL</i> (Novartis)	Fluvastatin extended-release	Mylan, Par, Teva	October 2020
<i>Adcirca</i> (Lilly)	Tadalafil	Synthon	November 2020 ^{d,18}
<i>Sutent</i> (Pfizer)	Sunitinib	Mylan	February 2021
<i>Tarceva</i> (OSI)	Erlotinib tablet	Mylan	May 2021 ^{e,73}
<i>Absorica</i> (Ranbaxy)	Isotretinoin	Actavis ^{h,88}	September 2021 ^d
<i>Atripla</i> (Gilead)	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate	Aurobindo, Cipla, Emcure, Hetero, Macleods, Matrix, Teva	September 2021 ^{e,68}
<i>Bystolic</i> (Forest)	Nebivolol	Actavis, ^{f,67} Alkem, ^{f,67} Amerigen, ^{f,67} Glenmark, ^{f,63} Hetero, ^{f,67} Indchemie, ^{f,67} Torrent ^{f,67}	September 2021 ⁶³
<i>Emtriva</i> (Gilead)	Emtricitabine	Aurobindo, Cipla, Matrix	September 2021 ^{d,4}
<i>Truvada</i> (Gilead)	Emtricitabine/Tenofovir disoproxil fumarate	Aurobindo, Cipla, Hetero, Matrix, Strides Arcolab, Teva	September 2021 ^{d,68}
<i>Vimpat</i> (UCB)	Lacosamide tablet	Aurobindo	March 2022
<i>Chantix</i> (Pfizer)	Varenicline	Apotex, Mylan, Teva	August 2022 ^{d,49}

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>HalfLytely</i> (Braintree)	Polyethylene glycol 3350, potassium chloride, sodium bicarbonate, sodium chloride, bisacodyl	Novel	October 2022
<i>Banzel</i> (Eisai)	Rufinamide	Glenmark, ^{h,80} Hetero, ^{h,80} Lupin, ^{h,80} Mylan, ^{h,80} Roxane	November 2022 ^d
<i>Selzentry</i> (Pfizer)	Maraviroc	Hetero, Sandoz	November 2022
<i>Vyvanse</i> (Shire)	Lisdexamfetamine	Actavis, ^{h,55} Amneal, Mylan, Roxane, Sandoz ^{h,55}	June 2023 ^d
<i>Gralise</i> (Depomed)	Gabapentin	Actavis, Incepta, ^{f,98} Zydus ^{f,98}	January 2024 ^{62,98}
<i>Pataday</i> (Alcon)	Olopatadine	Actavis, Apotex, Sandoz, Teva, Wockhardt	May 2024 ^{d,100,101}
<i>Xyrem</i> (Jazz)	Sodium oxybate	Amneal, ^{h,48} Roxane ^{f,7}	June 2024 ^d
<i>Januvia</i> (Merck)	Sitagliptin	Actavis, Apotex, Mylan, Sandoz, Sun, Teva	April 2026
<i>Natazia</i> (Bayer)	Dienogest/estradiol valerate	Lupin ^{h,61}	May 2026 ^d
<i>Aplenzin</i> (Biovail)	Bupropion hydrobromide extended-release tablet	Actavis, Paddock ^{h,83}	June 2026 ^d
<i>Nuedexta</i> (Avanir)	Dextromethorphan/Quinidine	Par, Sandoz, ^{f,103} Wockhardt ^{f,85}	July 2026 ^{85,103}
<i>AndroGel 1.62%</i> (AbbVie)	Testosterone	Perrigo ^{h,58}	October 2026 ^d
<i>Norvir</i> (Ritonavir)	Ritonavir 100 mg tablet	Roxane	March 2027 ^{d,25}
<i>Solodyn</i> (Medicis)	Minocycline extended-release tablet 65 mg, 80 mg, 105 mg, 115 mg	Mylan, Ranbaxy, Teva	March 2027
<i>Ampyra</i> (Acorda)	Dalfampridine	Accord, ^{h,75} Actavis, ^{h,75} Aurobindo, ^{h,75} Roxane, ^{h,75} Alkem, ^{h,75} Mylan ^{h,75}	May 2027

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>Lumigan</i> (Allergan)	Bimatoprost ophthalmic solution 0.01%	Apotex, Sandoz	June 2027
<i>Prezista</i> (Janssen)	Darunavir	Hetero, Lupin, Mylan, Teva	June 2027 ^{d,79}
<i>Toviaz</i> (Pfizer)	Fesoterodine extended-release tablet	Accord, ^{h,117} Alkem, ^{h,117} Amneal, ^{h,117} Amerigan, ^{h,117} Cadila, ^{h,117} Impax, ^{h,117} Lupin, ^{h,117} Sandoz, ^{h,117} Sun, Wockhardt, ^{h,118} Zydus ^{h,117}	June 2027 ^d
<i>Levitra</i> (GlaxoSmithKline)	Vardenafil	Teva	July 2027 ^{e,42}
<i>Pristiq</i> (Wyeth)	Desvenlafaxine succinate extended-release tablet	Roxane	July 2027 ^{d,33}
<i>Axiron</i> (Eli Lilly)	Testosterone transdermal solution	Actavis, ^{h,111} Perrigo ^{h,112}	September 2027 ^d
<i>Oracea</i> (Galderma)	Doxycycline	Lupin, Mylan	December 2027 ^{d,110}
<i>Janumet</i> (Merck)	Sitagliptin/Metformin	Apotex, Sandoz	July 2028
<i>Olepro</i> (Angelini)	Trazodone extended-release tablet	Actavis ^{h,11}	July 2028 ^{d,11}
<i>Onglyza</i> (Bristol-Myers Squibb)	Saxagliptin	Actavis ^{h,99}	November 2028 ^d
<i>Staxyn</i> (Bayer)	Vardenafil	Actavis, Par ^{h,40}	December 2028 ^d
<i>Lo Loestrin Fe</i> (Actavis)	Ethinyl estradiol/Norethindrone acetate/Ferrous fumarate	Amneal, ^{h,94} Lupin ^{h,94}	February 2029
<i>Isentress</i> (Merck)	Raltegravir tablet	Hetero	March 2029
<i>Remodulin</i> (United Therapeutics)	Treprostinil injection	Sandoz	March 2029
<i>Qsymia</i> (Vivus)	Phentermine/Topiramate extended-release capsule	Actavis ^{h,41}	June 2029 ^d

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>Savella</i> (Cypress)	Milnacipran	Mylan ^{h,14}	September 2029 ^d
<i>Zubsolv</i> (Orexo)	Buprenorphine/Naloxone sublingual tablet	Actavis ^{h,84}	October 2029 ^d
<i>Contrave</i> (Orexigen)	Bupropion/Naloxone sustained release tablet	Actavis ^{h,115}	February 2030 ^d
<i>Suboxone</i> (Reckitt Benckiser)	Buprenorphine/Naloxone sublingual film	Actavis ^{h,86}	March 2030 ^d
<i>Copaxone</i> (Teva)	Glatiramer 40 mg/mL	Dr. Reddy's ^{h,94} Mylan, ^{h,70} Momenta, ^{h,70} Sandoz ^{h,70}	August 2030 ¹⁰⁸
<i>Dexilant</i> (Takeda)	Dexlansoprazole	Dr. Reddy's, ^{h,104} Handa, ^{h,93} Impax, ^{h,92} Par	September 2030 ^d
<i>Uloric</i> (Takeda)	Febuxostat	Mylan, ^{h,89} Roxane ^{h,106}	September 2031 ^d
<i>Vimovo</i> (AstraZeneca)	Naproxen/Esomeprazole magnesium delayed-release tablet	Actavis, ^{h,77} Anchen, ^{h,77} Dr. Reddy's, Lupin, ^{h,77} Mylan ^{h,77}	May 2033 ^d
<i>Acova</i> (Pfizer)	Argatroban 100 mg/mL injection	Baxter, Hikma, Mylan, Par, Pliva	Uncertain ^g
<i>Advicor</i> (Abbott)	Lovastatin/Niacin	Teva ^{f,107}	Uncertain ⁹⁷
<i>Alocril</i> (Allergan)	Nedocromil ophthalmic	Akorn	Uncertain ^g
<i>Avandamet</i> (GlaxoSmithKline)	Rosiglitazone/Metformin	Teva	Uncertain ²⁷
<i>Avandaryl</i> (GlaxoSmithKline)	Rosiglitazone/Glimepiride	Teva	Uncertain ²⁷
<i>Avandia</i> (GlaxoSmithKline)	Rosiglitazone	Actavis, Dr. Reddy's, Mylan, Roxane, Sandoz, Teva, West- ward (Hikma)	Uncertain ²⁷
<i>CellCept</i> (Roche Palo)	Mycophenolate mofetil hydrochloride injection	Bedford Labs	Uncertain ^g

Brand ^a (Manufacturer)	Generic Name	Generic Manufacturer(s) ^{b,1}	Anticipated Availability ^c
<i>CellCept</i> (Roche Palo)	Mycophenolate mofetil oral suspension	Alkem	Uncertain ^g
<i>Dibenzyline</i> (Wellspring)	Phenoxybenzamine	Roxane	Uncertain ^g
<i>Exalgo</i> (Mallinckrodt)	Hydromorphone extended-release tablet 32 mg	Actavis ^{f,3}	Uncertain ^g
<i>Exelon</i> (Novartis)	Rivastigmine oral solution	Ranbaxy	Uncertain ^g
<i>Fusilev</i> (Spectrum)	Levoleucovorin calcium injection	Innopharma, Sandoz	Uncertain ¹¹⁴
<i>Glyset</i> (Pharmacia & Upjohn)	Miglitol tablets	Orient	Uncertain ^g
<i>Latisse</i> (Allergan)	Bimatoprost 0.03%	Apotex, Lupin, Sandoz	Uncertain ⁴⁵
<i>Megace ES</i> (Par)	Megestrol acetate oral suspension 125 mg/mL	TWi Pharmaceuticals	Uncertain ⁵⁴
<i>OxyContin</i> (Purdue)	Oxycodone extended-release tablet (new formulation)	Actavis, ^{h,97} Impax, ^{f,12} Par, ^{h,97} Sandoz, ^{h,97} Teva ^{h,82}	Uncertain, ^{17,97}
<i>Protopic</i> (Astellas)	Tacrolimus ointment	Fougera	Uncertain ^g
<i>Renagel</i> (Genzyme)	Sevelamer hydrochloride (oral suspension)	Impax ^{f,15}	Uncertain
<i>Renvela</i> (Genzyme)	Sevelamer carbonate (oral suspension)	Impax ^{f,15}	Uncertain
<i>Rezira</i> (Hawthorn)	Hydrocodone/pseudoephedrine oral solution	Tris Pharma, Paddock	Uncertain ^g
<i>Sarafem</i> (Warner Chilcott)	Fluoxetine tablet	Teva	Uncertain ^g

- This list is not all-inclusive.
- Current through April 2015. These are manufacturers with either approval or tentative approval to market the generic version of the drug unless otherwise noted. For drugs already available, manufacturers with tentative approval are not listed.
- Generic availability is subject to change as a result of litigations and patent exclusivities.

- d. Ongoing litigation; availability may be sooner than patent expiration date.
- e. Generic manufacturer has settled patent litigation with the brand manufacturer. Generic availability may be sooner than patent expiration date.
- f. Generic manufacturer has not received approval or tentative approval from the FDA, but has settled patent litigation with the brand manufacturer.
- g. Patents have expired; however, generics are not yet available.
- h. Generic manufacturer has not received approval or tentative approval from the FDA, but has filed patent challenge.
- i. A biosimilar is not a generic. Biosimilars and their reference product are complex biologic medicines that originate in living organisms. A biosimilar is not the exact duplicate of the reference biologic, but is very similar and is expected to have the same efficacy and safety for its approved indications.⁶⁰

Users of this PL Detail-Document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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Evidence and Recommendations You Can Trust...



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**XTORO
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 Xtoro must meet the following criteria:

- Patient must be 1 year of age or older.
- Patient must have a diagnosis of acute otitis externa (AOE).
- Ciprofloxacin, ciprofloxacin/dexamethasone, ofloxacin, neomycin/polymyxin B/hydrocortisone, and acetic acid solution do not require a prior authorization.

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

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH
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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 Drug:	Diagnosis for this Request:	History of Failure:
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)	

PRODUCT DETAILS OF TROKENDI (TOPIRAMATE)

INDICATIONS AND USE: Trokendi is an antiepileptic drug indicated for:

- Partial onset seizure and primary generalized tonic-clonic seizures – initial therapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures.
- Lennox-Gastaut Syndrome (LGS)-adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome.

DOSAGE FORMS: Extended-release capsules: 25mg, 50 mg, 100mg, and 200 mg.

ADMINISTRATION:

- Do not sprinkle on food, chew or crush the capsules.
- Monotherapy (partial onset or generalized tonic-clonic seizures) – The recommended initial dose for adults and patients 10 years and older is 50 mg once daily. Increase dose weekly by increments of 50 mg for first 4 weeks then 100 mg for weeks 5 and 6. Recommended dose is 400 mg once daily.
- Adjunctive therapy (adults with partial onset seizures or LGS) – The recommended initial dose is 25 mg to 50 mg once daily. Increase dose weekly by increments of 25 mg to 50 mg to achieve an effective dose. Recommended dose is 200 mg to 400 mg once daily.
- Adjunctive therapy (adults with primary generalized tonic-clonic seizures) – The recommended initial dose is 25 mg to 50 mg once daily. Increase dose weekly to an effective dose by increments of 25 mg to 50 mg. Recommended dose is 400 mg once daily.
- Adjunctive therapy (pediatric patients 6 years and older with partial onset seizures, primary generalized tonic-clonic seizures or LGS) – The recommended initial dose is 25 mg once at nighttime (based on a range of 1 mg/kg to 3 mg/kg once daily) for first week. Increase dosage at 1- or 2-week intervals by increments of 1 mg/kg to 3 mg/kg. Dose titration should be guided by clinical outcome. Recommended dose is 5 mg/kg to 9 mg/kg once daily.

CONTRAINDICATIONS:

- Do not use alcohol 6 hours prior to and 6 hours after topiramate.
- Do not use in patients with metabolic acidosis taking concomitant metformin.

WARNINGS AND PRECAUTIONS:

- Acute myopia and secondary angle closure glaucoma: Untreated elevated intraocular pressure can lead to permanent visual loss.
- Oligohydrosis and hyperthermia: Monitor decreased sweating and increased body temperature, especially in pediatric patients.
- Metabolic acidosis: Measure baseline and periodic measurement of serum bicarbonate. Consider dose reduction or discontinuation if clinically appropriate.

- Suicidal behavior and ideation: Antiepileptic drugs increase the risk of suicidal behavior or ideation.
- Cognitive/neuropsychiatric: Topiramate may cause cognitive dysfunction. Use caution when operating machinery including automobiles. Depression and mood problems may occur.
- Fetal toxicity: Topiramate use during pregnancy can cause cleft lip and/or palate.
- Withdrawal of AEDs: Withdrawal of topiramate should be done gradually.
- Hyperammonemia and encephalopathy: Patients with inborn errors of metabolism or reduced mitochondrial activity may have an increased risk of hyperammonemia. Measure ammonia if encephalopathic symptoms occur.
- Kidney stones: Avoid use with other carbonic anhydrase inhibitors, other drugs causing metabolic acidosis, or in patients on a ketogenic diet.
- Hypothermia: Reported with concomitant valproic acid use.

ADVERSE REACTIONS: The most common adverse reactions (greater than 5% more frequent than placebo or low-dose topiramate in monotherapy) were paresthesia, anorexia, weight decrease, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, difficulty with memory, difficulty with concentration/attention, cognitive problems, confusion, mood problems, fever, infection and flushing.

DRUG INTERACTIONS:

- Oral contraceptives: Decreased contraceptive efficacy and increased breakthrough bleeding, especially at doses greater than 200 mg per day.
- Phenytoin or carbamazepine: Concomitant administration with topiramate decreased plasma concentrations of topiramate.
- Other carbonic anhydrase inhibitors: Monitor for the appearance or worsening of metabolic acidosis.
- Lithium: Monitor lithium levels when co-administered with high-dose topiramate.

COST

- Trokendi XR 25 mg approximately \$7 per capsule.
- Trokendi XR 50 mg approximately \$9 per capsule.
- Trokendi XR 100 mg approximately \$17 per capsule.
- Trokendi XR 200 mg approximately \$23 per capsule.

References:

1. Trokendi XR [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; August 2013.

PRODUCT DETAILS OF OXTELLAR XR (OXCARBAZEPINE)

INDICATIONS AND USE: Oxtellar is an antiepileptic drug indicated for adjunctive therapy in the treatment of partial seizures in adults and children 6 to 17 years of age.

DOSAGE FORMS: Extended-release tablets: 150mg, 300mg and 600 mg.

ADMINISTRATION:

- Recommended daily dose is 1,200 mg to 2,400 mg once per day.
- Adults: Initiate with a dose of 600 mg once per day. Dose increases can be made at weekly intervals in 600 mg per day increments to achieve the recommended daily dose.
- Children: Target dose is based upon weight. Titrate to target dose over two to three weeks. Initiate with 8 mg/kg to 10 mg/kg once per day. Increase in weekly increments of 8 mg/kg to 10 mg/kg once daily, not to exceed 600mg, to achieve target daily dose.
- Patients with creatinine clearance less than 30 mL/minutes: Start at 300 mg per day and increase slowly.
- Geriatric patients: Start at lower dose (300 mg or 450 mg per day) and increase slowly.
- In conversion of oxcarbazepine immediate-release to Oxtellar XR, higher doses of Oxtellar XR may be necessary.

WARNINGS AND PRECAUTIONS:

- Hyponatremia: Monitor sodium as recommended.
- Anaphylactic reactions and angioedema: Discontinue if occurs.
- Patients with a past history of hypersensitivity reaction to carbamazepine: Only use based upon risk benefit.
- Serious dermatological reactions: Discontinue if observed.
- Suicidal behavior and ideation: Monitor for symptoms.
- Withdrawal of Oxtellar XR: Withdraw gradually.
- Multi-organ hypersensitivity: Discontinue if suspected.
- Hematologic reactions: Discontinue if suspected.

ADVERSE REACTIONS: The most commonly observed ($\geq 5\%$) and more frequent than placebo adverse reactions were dizziness, somnolence, headache, balance disorder, tremor, vomiting, diplopia, asthenia, and fatigue.

DRUG INTERACTIONS:

- Phenytoin, carbamazepine, and phenobarbital coadministration: Greater dose of Oxtellar XR may be required.
- Oral contraceptives: Advise patients that Oxtellar XR may decrease the effectiveness of hormonal contraceptives. Additional non-hormonal forms of contraception are recommended.

COST

- Oxtellar XR 150 mg approximately \$4 per tablet.
- Oxtellar XR 300 mg approximately \$6 per tablet.
- Oxtellar XR 600 mg approximately \$11 per tablet.

References:

1. Oxtellar XR [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; October 2012.

PRODUCT DETAILS OF AKYNZEO (NETUPITANT/PALONOSETRON)

INDICATIONS AND USE: Akynzeo is a fixed combination of netupitant, a substance P/neurokinin 1 (NK₁) receptor antagonist, and palonosetron, a serotonin-3 (5-HT₃) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

DOSAGE FORMS: Capsule: 300 mg netupitant/0.5 mg palonosetron.

ADMINISTRATION:

- One capsule administered approximately 1 hour prior to the start of chemotherapy.

WARNINGS AND PRECAUTIONS:

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron with or without known hypersensitivity to other 5-HT₃ receptor antagonists.
- Serotonin syndrome has been reported with 5-HT₃ receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

USE IN SPECIFIC POPULATIONS:

- Avoid use in patients with severe hepatic impairment.
- Avoid use in patients with severe renal impairment or end-stage renal disease.

ADVERSE REACTIONS: The most common adverse reactions (incidence $\geq 3\%$) are headache, asthenia, dyspepsia, fatigue, constipation, and erythema.

DRUG INTERACTIONS:

- Inhibition of CYP3A4 by netupitant can result in increased plasma concentrations of the concomitant drug that can last at least 4 days and may last longer after single dosage administration of Akynzeo; use with caution.
- Inducers of CYP3A4 decreased plasma concentrations of netupitant; avoid use.

PATIENT COUNSELING INFORMATION:

- Take with or without food approximately 1 hour prior to the start of chemotherapy.
- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron. Seek immediate medical attention if any signs or symptoms of hypersensitivity reaction occur.
- Seek immediate medical attention if the following symptoms occur: changes in mental status, autonomic instability, or neuromuscular symptoms.

COST

- Akynzeo costs approximately \$540 dollars per capsule.

References:

1. Akynzeo [package insert]. Woodcliff Lake, NJ: Eisai Inc.; October 2014.

PRODUCT DETAILS OF NUVESSA (METRONIDAZOLE VAGINAL GEL 1.3%)

INDICATIONS AND USE: Nuvessa is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in non-pregnant women.

DOSAGE FORMS: Vaginal gel – 65 mg of metronidazole in 6 grams of gel (1.3%) in a prefilled applicator.

ADMINISTRATION:

- A single-dose, pre-filled disposable applicator administered once intravaginally at bedtime.

WARNINGS AND PRECAUTIONS:

- Convulsive seizures and peripheral neuropathy have been reported in patients treated with oral or intravenous metronidazole. Discontinue promptly if abnormal neurologic signs develop.
- Metronidazole may interfere with certain serum chemistry lab values.

ADVERSE REACTIONS: The most common adverse reactions (incidence $\geq 1\%$) were vulvovaginal candidiasis, headache, vulvovaginal pruritus, nausea, diarrhea, and dysmenorrhea.

DRUG INTERACTIONS:

- Prolonged anticoagulant effects of warfarin and other coumarin anticoagulants have been reported with co-administration of oral metronidazole.
- Elevated plasma lithium concentrations have been reported with oral metronidazole.

PATIENT COUNSELING INFORMATION:

- Do not consume alcoholic beverages and preparations containing ethanol or propylene glycol during and for at least 24 hours after treatment.
- Do not use if disulfiram has been used within the last two weeks, and inform the healthcare provider if taking oral anticoagulants or lithium.
- Do not engage in vaginal intercourse or use other vaginal products following the single administration.
- Consider discontinuing milk feeding or pump and discard the milk during treatment and for 24 hours after treatment.
- Discontinue use and consult a healthcare provider if vaginal irritation occurs.

COST

- Nuvessa 1.3% costs approximately \$165 per treatment.

References:

1. Nuessa [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2015.

PRODUCT DETAILS OF CHOLBAM (CHOLIC ACID)

INDICATIONS AND USE: Cholbam is a bile acid indicated for treatment of bile acid synthesis disorders due to single enzyme defects as well as adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

DOSAGE FORMS: Capsules: 50 mg, 250 mg.

ADMINISTRATION:

- Take with food. Do not chew or crush the capsules.
- The recommended dosage is 10 to 15 mg/kg once daily or in two divided doses, in pediatric patients and adults.
- The recommended dosage in patients with concomitant familial hypertriglyceridemia is 11 to 17 mg/kg once daily or in two divided doses and is adjusted based on clinical response.
- Monitor AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter. Administer the lowest dose that effectively maintains liver function.
- Discontinue Cholbam if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; continue to monitor liver function and consider restarting a lower dose when parameters return to baseline.

WARNINGS AND PRECAUTIONS:

- Monitor liver function and discontinue if liver function worsens while on treatment.

ADVERSE REACTIONS: The most common adverse reactions, occurring in $\geq 1\%$, are diarrhea, reflux esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy.

DRUG INTERACTIONS:

- Bile salt efflux pump (BSEP) inhibitors (e.g., cyclosporine): Avoid concomitant use; if concomitant use is necessary, monitor serum transaminases and bilirubin.
- Bile acid resins and aluminum-based antacids: Take at least 1 hour before or 4 to 6 hours after a bile acid binding resin or aluminum-based antacids.

PATIENT COUNSELING INFORMATION:

- Undergo laboratory testing periodically while on treatment to assess liver function.
- Cholbam may worsen liver impairment; therefore, immediately report any symptoms associated with liver impairment (e.g., skin or whites of the eyes turn yellow, urine turns dark or brown, pain on the right side of stomach, bleeding or bruising occurring more easily than normal, or increased lethargy).

COST

- Cholbam 250 mg approximately \$890 per capsule.
- Cholbam 50 mg approximately \$300 per capsule.

References:

1. Cholbam [package insert]. San Diego, CA: Manchester Pharmaceuticals, Inc.; March 2015.

PRODUCT DETAILS OF COPAXONE 40 (GLATIRAMER ACETATE INJECTION)

INDICATIONS AND USE: Copaxone is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

DOSAGE FORMS:

- Injection – 40 mg/mL in a single-dose prefilled syringe.

ADMINISTRATION:

- For subcutaneous injections only.
- Copaxone 40 mg/mL three times per week.

WARNINGS AND PRECAUTIONS:

- Immediate post-injection reaction (flushing, chest pain, palpitations, anxiety, dyspnea, throat constriction, and/or urticarial), generally transient and self-limiting.
- Chest pain, usually transient.
- Lipoatrophy and skin necrosis may occur. Instruct patients in proper injection technique and to rotate injection sites.

ADVERSE REACTIONS: In a controlled study of Copaxone 40 mg/mL, most common adverse reactions ($\geq 10\%$ and ≥ 1.5 times higher than placebo) were injection site reactions.

COST:

- Copaxone 40 mg approximately \$450 per kit.

EXAMPLE CRITERIA FOR COVERAGE IN OTHER STATE MEDICAID PROGRAMS:

- 15 states polled: 14 have Copaxone on PA, 1 does not.
- Peer-reviewed literature documenting why the requested medication is the only appropriate choice.
- Documented treatment failure.
- Adverse drug reaction.
- Clinical documentation explaining why Copaxone 20mg cannot be utilized (i.e., severe lipoatrophy, post-injection syndrome, significant compliance issues).
- Written letter of medical necessity.

References:

1. Copaxone [package insert]. Overland Park, KS: Teva Neuroscience, Inc.; January 2014.