South Dakota Department of Social Services

Medicaid P&T Committee Meeting

June 6, 2014

DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES
700 Governors Drive
Pierre, South Dakota 57501-2291
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SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

Friday, June 6, 2014
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

Review of Drug Spend

Patent Expirations

Old Business
- **Hepatitis C**
- **Luzu**
- **Hetlioz**

New Business
- **Advair Utilization**
- **Stimulant Use in Adults**
- **Oral Allergen Extracts (Ragwitek, Grastek, Oralair)**
- **Northera**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

Minutes of the March 21, 2014
Pharmacy & Therapeutics (P&T) Committee Meeting
South Dakota Department of Social Services, Division of Medical Services

Members Present

Richard Holm, MD; Michelle Baack, MD; Bill Ladwig, RPh; James Engelbrecht, MD; Kelly Oehlke, PharmD; Dana Darger, RPh

DSS staff present

Mike Jockheck, RPh; Kirby Stone, Director of Medical Services

Administrative Business

The P&T meeting was called to order by D. Darger at 1:00pm. The minutes of the December 6, 2013 meeting were presented. M. Baack made a motion to approve. J. Engelbrecht seconded the motion. The motion was approved unanimously.

Prior Authorization Update and Statistics

The committee reviewed the prior authorization (PA) activity for January 2014. There were a total of 2,907 PA's processed in the month of January, with 99.86% of those requests responded to in less than eight hours. There were 2,312 (80%) requests received electronically and 595 (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 10/1/2013 – 12/31/2013. 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 40.51% 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 10.61% of total claims. The committee requested that Advair utilization and stimulant usage in adults be added to the agenda for the June meeting.

Quantity Limit Review

The committee reviewed a list of quantity limit suggestions sorted by drug name. A motion was made by B. Ladwig to implement the quantity limits shown on the list. M. Baack seconded the motion. The motion was approved unanimously.

Brisdelle Second Review

The committee made a motion at the March meeting to place Brisdelle on prior authorization. The prior authorization form was provided for committee review. A motion was made by J. Engelbrecht to approve the form. M. Baack seconded the motion. There was no public comment. The motion was approved unanimously.

Sovaldi and Olysio Review
The committee reviewed Olysio and Sovaldi. The committee heard testimony from Michele Puyear (Gilead) and Kathleen Karnik (Janssen). A motion was made by B. Ladwig to place Sovaldi and Olysio on prior authorization using available guidelines. R. Holm seconded the motion. The motion was approved unanimously. Forms and criteria will be brought to the June meeting for committee review.

Luzu Review
The committee reviewed Luzu clinical information. There was no public comment. A motion was made by B. Ladwig to place Luzu on prior authorization. R. Holm seconded the motion. The motion was approved unanimously. A prior authorization form will be brought to the June meeting for committee review.

Hetlioz Review
The committee reviewed Hetlioz clinical information. There was no public comment. A motion was made by M. Baack to place Hetlioz on prior authorization. R. Holm seconded the motion. The motion was approved unanimously. A prior authorization form will be brought to the June meeting for committee review.

Prior Authorization Forms and Criteria Annual Review
The committee reviewed current prior authorization forms and criteria. Changes made include:

1. Antidepressant form – PA brand SSRIs only
2. Oracea/Solodyn form – remove tetracycline

J. Engelbrecht made a motion to make the listed changes to the prior authorization forms. R. Holm seconded the motion. The motion was approved unanimously.

The next meeting is scheduled for June 6, 2014. K. Oehlke made a motion to adjourn the P&T Committee meeting. J. Engelbrecht seconded the motion. The motion passed unanimously and the meeting was adjourned.

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2014 – April 30, 2014

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
2,982	2,973	9	99.70%	0.3%

By Form Type

Form Type	Description	Approve	Deny
ADP	Antidepressant	146	235
AFX	Amrix and Fexmid	0	3
ALT	Altabax	0	5
AMB	Ambien CR	4	21
ANF	Anti-Infectives(anti-biotic)	0	54
ANT	Antihistamines	11	54
APS	Antipsychotic	231	269
ARB	ARBS	5	8
COA	Oral Anticoagulants	10	15
DAW	Dispense As Written	13	21
GIA	Gastrointestinal Agents	0	1
GRH	Growth Hormone	4	4
GSM	Genitourinary SMR	2	21
HEP	Hepatitis Meds	0	8
HLM	Head Lice Medication	18	95
LID	Lidoderm	3	103
MAX	Max Units Override	74	915
MSA	Multiple Sclerosis Agents	1	0
NAR	Name Brand Narcotics	1	0
NUC	Opioids	2	19
ONF	Onfi	4	0
OPH	Ophthalmic Antihistamines	2	49
PPI	Proton Pump Inhibitors	35	92
STE	Nasal Steroids	31	79
STI	Stimulants	10	9
SUB	Suboxone/Subutex	3	3
TIM	Targeted Immune Modulators	8	14
TOP	Topical Acne Agents	18	144
TRP	Triptans	21	41
ULT	Ultram ER	3	0
XIF	Xifaxan	5	34
XOL	Xolair	1	0
Totals		666	2316

South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2014 – April 30, 2014

By Request Type

04/01/14 - 04/30/14	# of Requests	Electronic Requests		Faxed Requests	
		#	%	#	%
Prior Authorizations:					
Antidepressant	381	248	65%	133	35%
Amrix and Fexmid	3	2	67%	1	33%
Altabax	5	4	80%	1	20%
Ambien CR	25	22	88%	3	12%
Anti-Infectives	54	54	100%	0	0%
Antihistamines	65	55	85%	10	15%
Antipsychotic	500	290	58%	210	42%
ARBS	13	6	46%	7	54%
Oral Anticoagulants	25	17	68%	8	32%
Dispense As Written	34	19	56%	15	44%
Gastrointestinal Agents	1	1	100%	0	0%
Growth Hormone	8	3	38%	5	63%
Genitourinary SMR	23	18	78%	5	22%
Hepatitis Meds	8	8	100%	0	0%
Head Lice Medication	113	72	64%	41	36%
Lidoderm	106	77	73%	29	27%
Max Units Override	989	896	91%	93	9%
Multiple Sclerosis Agents	1	0	0%	1	100%
Name Brand Narcotics	1	0	0%	1	100%
Opioids	21	18	86%	3	14%
Onfi	4	0	0%	4	100%
Ophthalmic Antihistamines	51	47	92%	4	8%
Proton Pump Inhibitors	127	99	78%	28	22%
Nasal Steroids	110	95	86%	15	14%
Stimulants	19	15	79%	4	21%
Suboxone/Subutex	6	3	50%	3	50%
Targeted Immune Modulators	22	10	45%	12	55%
Topical Acne Agents	162	127	78%	35	22%
Triptans	62	50	81%	12	19%
Ultram ER	3	3	100%	0	0%
Xifaxan	39	28	72%	11	28%
Xolair	1	0	0%	1	100%
Prior Authorization Totals	2982	2287	77%	695	23%

South Dakota Medicaid
Monthly Prior Authorization Report
April 1, 2014 – April 30, 2014

Electronic PAs (unique)

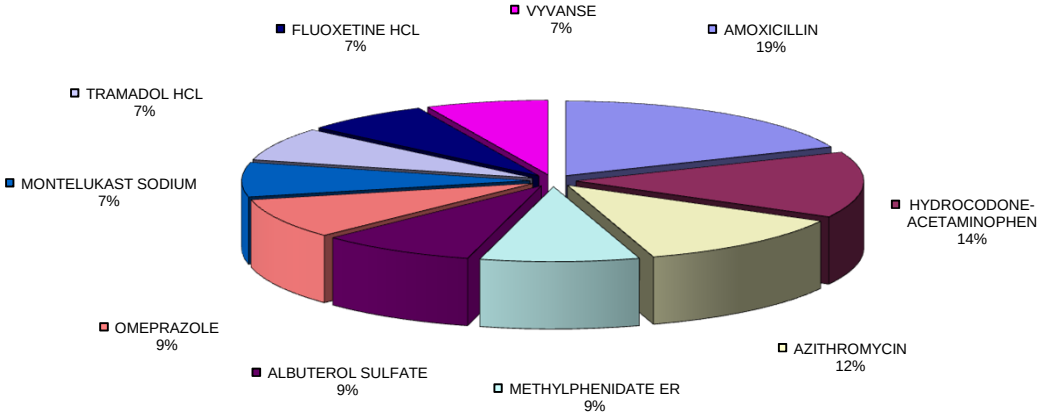
04/01/14 - 04/30/14	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antidepressant	66	175	0	241	27.40%	248
Amrix and Fexmid	0	2	0	2	0.00%	2
Altabax	0	4	0	4	0.00%	4
Ambien CR	3	12	0	15	20.00%	22
Anti-Infectives(anti-biotic)	0	54	0	54	0.00%	54
Antihistamines	9	44	0	53	17.00%	55
Antipsychotic	92	193	0	285	32.30%	290
ARBS	0	6	0	6	0.00%	6
Oral Anticoagulants	4	13	0	17	23.50%	17
Dispense As Written	0	18	0	18	0.00%	19
Gastrointestinal Agents	0	1	0	1	0.00%	1
Growth Hormone	0	3	0	3	0.00%	3
Genitourinary SMR	2	16	0	18	11.10%	18
Hepatitis Meds	0	8	0	8	0.00%	8
Head Lice Medication	0	70	0	70	0.00%	72
Lidoderm	0	75	0	75	0.00%	77
Max Units Override	26	804	0	830	3.10%	896
Opioids	1	17	0	18	5.60%	18
Ophthalmic Antihistamines	1	46	0	47	2.10%	47
Proton Pump Inhibitors	21	72	0	93	22.60%	99
Nasal Steroids	23	72	0	95	24.20%	95
Stimulants	7	5	0	12	58.30%	15
Suboxone/Subutex	0	3	0	3	0.00%	3
Targeted Immune Modulators	0	10	0	10	0.00%	10
Topical Acne Agents	8	117	0	125	6.40%	127
Triptans	14	32	0	46	30.40%	50
Ultram ER	3	0	0	3	100.00%	3
Xifaxan	0	28	0	28	0.00%	28
TOTALS	280	1900	0	2180	12.80%	2287

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 01/01/2014 - 03/31/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	8,180	$ 70,065.18	$ 8.57	3.93%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	6,240	$ 109,266.43	$ 17.51	3.00%
AZITHROMYCIN	MACROLIDES	5,353	$ 82,022.93	$ 15.32	2.57%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,897	$ 615,294.22	$ 157.89	1.87%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	3,817	$ 70,731.76	$ 18.53	1.83%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,785	$ 44,266.81	$ 11.70	1.82%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	3,253	$ 70,394.21	$ 21.64	1.56%
TRAMADOL HCL	OPIATE AGONISTS	3,165	$ 24,149.20	$ 7.63	1.52%
FLUOXETINE HCL	ANTIDEPRESSANTS	3,057	$ 24,109.20	$ 7.89	1.47%
VYVANSE	AMPHETAMINES	3,003	$ 576,775.20	$ 192.07	1.44%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	2,982	$ 22,861.72	$ 7.67	1.43%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,774	$ 24,459.37	$ 8.82	1.33%
SERTRALINE HCL	ANTIDEPRESSANTS	2,765	$ 21,226.04	$ 7.68	1.33%
DEXTROAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,250	$ 318,741.51	$ 141.66	1.08%
TRAZODONE HCL	ANTIDEPRESSANTS	2,207	$ 13,327.97	$ 6.04	1.06%
CEFDINIR	CEPHALOSPORINS	2,206	$ 108,024.50	$ 48.97	1.06%
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	2,107	$ 57,651.31	$ 27.36	1.01%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	2,088	$ 474,974.14	$ 227.48	1.00%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	2,052	$ 11,451.89	$ 5.58	0.99%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,048	$ 12,461.59	$ 6.08	0.98%
VENTOLIN HFA	BETA-ADRENERGIC AGONISTS	2,017	$ 95,785.55	$ 47.49	0.97%
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	1,917	$ 15,024.11	$ 7.84	0.92%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,908	$ 13,052.74	$ 6.84	0.92%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,793	$ 28,932.63	$ 16.14	0.86%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,691	$ 13,987.08	$ 8.27	0.81%
TOTAL TOP 25		76,555	$ 2,919,037.29	$ 38.13	36.80%

Total Rx Claims From 01/01/2014 - 03/31/2014	208,024

Top 10 Drugs
Based on Number of Claims

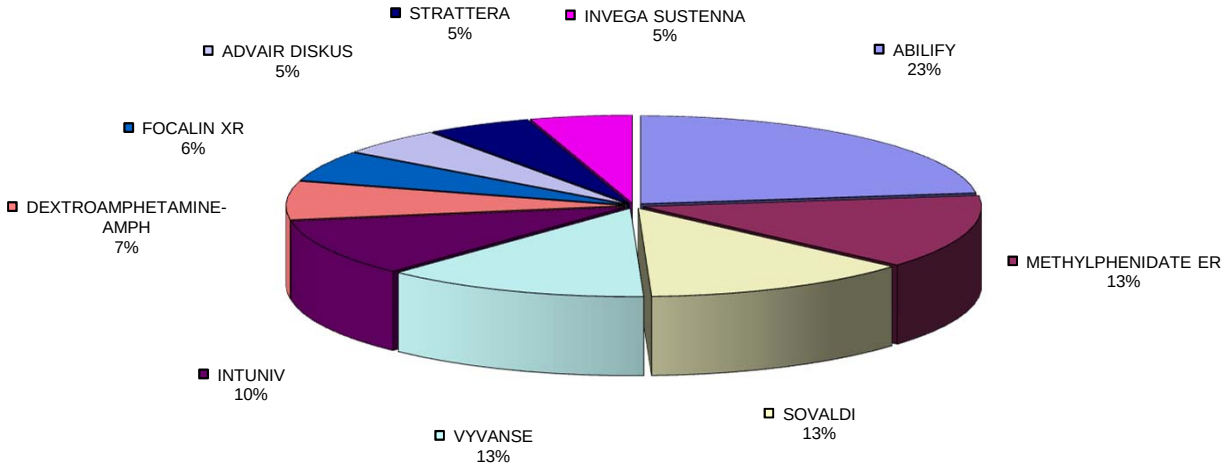


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 01/01/2014 - 03/31/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,475	$1,048,491.33	$ 710.84	0.71%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,897	$ 615,294.22	$ 157.89	1.87%
SOVALDI	NUCLEOSIDES AND NUCLEOTIDES	20	$ 585,840.79	$29,292.04	0.01%
VYVANSE	AMPHETAMINES	3,003	$ 576,775.20	$ 192.07	1.44%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	2,088	$ 474,974.14	$ 227.48	1.00%
DEXTROAMPHETAMINE-AMPH	AMPHETAMINES	2,250	$ 318,741.51	$ 141.66	1.08%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	1,135	$ 256,025.37	$ 225.57	0.55%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	792	$ 229,756.42	$ 290.10	0.38%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	986	$ 228,243.35	$ 231.48	0.47%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	151	$ 222,671.43	$ 1,474.65	0.07%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	664	$ 182,554.27	$ 274.93	0.32%
PULMOZYME	MUCOLYTIC AGENTS	56	$ 175,566.81	$ 3,135.12	0.03%
LATUDA	ANTIPSYCHOTIC AGENTS	259	$ 173,987.70	$ 671.77	0.12%
PREVACID	PROTON-PUMP INHIBITORS	610	$ 166,010.45	$ 272.15	0.29%
LANTUS SOLOSTAR	INSULINS	479	$ 162,962.76	$ 340.21	0.23%
DULOXETINE HCL	ANTIDEPRESSANTS	724	$ 147,479.92	$ 203.70	0.35%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	59	$ 145,730.57	$ 2,470.01	0.03%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	790	$ 137,446.30	$ 173.98	0.38%
COPAXONE	IMMUNOMODULATORY AGENTS	27	$ 134,511.89	$ 4,981.92	0.01%
BUDESONIDE	CORTICOSTEROIDS (RESPIRATORY TRACT)	454	$ 132,704.29	$ 292.30	0.22%
OXYCONTIN	OPIATE AGONISTS	447	$ 130,215.59	$ 291.31	0.21%
NEXIUM	PROTON-PUMP INHIBITORS	458	$ 123,754.62	$ 270.21	0.22%
NOVOLOG	INSULINS	402	$ 123,719.47	$ 307.76	0.19%
TAMIFLU	NEURAMINIDASE INHIBITORS	870	$ 123,461.03	$ 141.91	0.42%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	50	$ 123,375.81	$ 2,467.52	0.02%
TOTAL TOP 25		22,146	$6,740,295.24	$ 304.36	10.65%

Total Rx Claims From 01/01/2014 - 03/31/2014	208,024

Top 10 Drugs
Based on Total Claims Cost



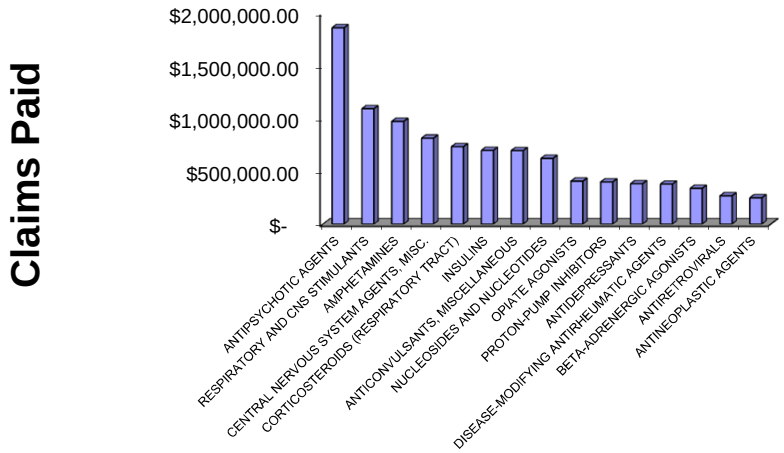
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 01/01/2014 - 03/31/2014

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	6,909	$ 1,858,889.22	$ 269.05	3.32%
RESPIRATORY AND CNS STIMULANTS	6,997	$ 1,094,337.57	$ 156.40	3.36%
AMPHETAMINES	6,264	$ 974,674.60	$ 155.60	3.01%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	3,158	$ 815,937.84	$ 258.37	1.52%
CORTICOSTEROIDS (RESPIRATORY TRACT)	3,020	$ 734,597.97	$ 243.24	1.45%
INSULINS	2,206	$ 699,105.68	$ 316.91	1.06%
ANTICONVULSANTS, MISCELLANEOUS	8,769	$ 696,893.75	$ 79.47	4.22%
NUCLEOSIDES AND NUCLEOTIDES	629	$ 623,845.55	$ 991.81	0.30%
OPIATE AGONISTS	13,911	$ 407,215.33	$ 29.27	6.69%
PROTON-PUMP INHIBITORS	6,151	$ 400,258.87	$ 65.07	2.96%
ANTIDEPRESSANTS	16,705	$ 383,541.55	$ 22.96	8.03%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	168	$ 379,302.53	$ 2,257.75	0.08%
BETA-ADRENERGIC AGONISTS	8,170	$ 339,553.60	$ 41.56	3.93%
ANTIRETROVIRALS	225	$ 268,212.09	$ 1,192.05	0.11%
ANTINEOPLASTIC AGENTS	416	$ 249,922.41	$ 600.78	0.20%
TOTAL TOP 15	83,698	$ 9,926,288.56	$ 118.60	40.23%

Total Rx Claims From 01/01/2014 - 03/31/2014	208,024

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	24,084	26,081	26,564	27,595	27,918	27,146	
Recip_Average_Rx_Cost	$163.65	$153.85	$201.79	$165.42	$161.82	$183.32	$177.78	$182.59	$164.79	$167.54	$170.38	$174.45	$172.51

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	$4,587,734.20	$4,954,424.54	$4,080,090.86	$4,746,275.35	$4,785,341.30	$4,365,074.23	$5,013,158.64	$4,581,863.02	$4,060,586.10	$54,143,988.39
Rx_Count	75,726	68,046	54,790	68,603	68,081	57,927	65,531	66,326	62,204	72,336	65,855	56,555	781,980
Average_Rx_Cost	$67.32	$64.48	$63.58	$66.87	$72.77	$70.44	$72.43	$72.15	$70.17	$69.30	$69.58	$71.80	$69.24
Recip_Count	27,719	25,992	22,293	24,675	24,016	21,411	22,579	23,562	23,753	25,747	24,481	21,790	
Recip_Average_Rx_Cost	$183.92	$168.80	$156.27	$185.93	$206.30	$190.56	$210.21	$203.10	$183.77	$194.71	$187.16	$186.35	$187.99

PHARMACIST'S LETTER

PL Detail-Document **#300150**
–This PL Detail-Document gives subscribers
additional insight related to the Recommendations published in–
PHARMACIST'S LETTER / PRESCRIBER'S LETTER
January 2014

PRESCRIBER'S LETTER

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]**
Aciphex (Eisai)	Rabeprazole delayed-release tablet	Kremers Urban, Lupin, Mylan, Teva, Torrent	Generic now available
Aricept (Eisai)	Donepezil 23 mg tablet	Dr. Reddy's, Par	Generic now available
Atacand (AstraZeneca)	Candesartan	Sandoz	Generic now available
Campral (Forest)	Acamprosate delayed-release tablet	Glenmark	Generic now available
Cymbalta (Lilly)	Duloxetine	Citron (Aurobindo), Lupin, Teva, Torrent	Generic now available
Dacogen (Eisai)	Decitabine for injection	Dr. Reddy's	Generic now available
Focalin XR (Novartis)	Dexmethylphenidate extended-release capsule	Mylan, Par, Teva	Generic now available
Hepsera (Gilead)	Adefovir	Sigmapharm	Generic now available
Kapvay (Concordia)	Clonidine extended-release tablet	Par	Generic now available
Lidoderm (Teikoku Pharma)	Lidocaine patch	Actavis	Generic now available
Micardis (Boehringer Ingelheim)	Telmisartan	Actavis	Generic now available
Myfortic (Novartis)	Mycophenolic acid delayed-release tablet	Mylan	Generic now available.

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Niaspan (Abbott)	Niacin extended-release tablet	Teva	Generic now available
Nitrolingual (Pohl-Boskamp)	Nitroglycerin sublingual spray	Perrigo	Generic now available
Prandin (Novo Nordisk)	Repaglinide	Caraco, Mylan	Generic now available
PrevPac (Takeda)	Amoxicillin/Clarithromycin/Lansoprazole	Teva	Generic now available
Rilutek (Covis)	Riluzole	Apotex, Glenmark, Impax (Global), Mylan, Sun (Caraco)	Generic now available
Soriatane (Stiefel)	Acitretin	Teva	Generic now available
Temodar (Merck)	Temozolomide	Teva, Sun	Generic now available
Tobi (Novartis)	Tobramycin inhalation solution	Teva	Generic now available
Trilipix (AbbVie)	Choline Fenofibrate delayed-release capsule	Anchen (Par), Lupin, Mylan	Generic now available
Vfend (Pfizer)	Voriconazole oral suspension	Mylan	Generic now available.
Zomig/Zomig-ZMT (AstraZeneca)	Zolmitriptan tablet and orally disintegrating tablet	Apotex, Glenmark, Mylan (tablet only), Zydus (orally disintegrating tablet only)	Generic now available
Zymaxid (Allergan)	Gatifloxacin 0.5% ophthalmic solution	Lupin	Generic now available
Lovaza (GlaxoSmithKline)	Omega-3-Acid Ethyl Esters	Apotex,[f,20] Par,[f,84] Teva[f,84]	Early 2014[84]
Loestrin 24 Fe (Warner Chilcott)	Ethinyl estradiol/Norethindrone acetate	Amneal	January 2014[15]
Micardis HCT (Boehringer Ingelheim)	Telmisartan	Actavis	January 2014

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Nexium IV (AstraZeneca)	Esomeprazole injection	Sun	January 2014[70,h]
Precedex (Hospira)	Dexmedetomidine	Akorn, Caraco, Mylan, Sandoz	January 2014
Rapamune (Pfizer)	Sirolimus	Zydus	January 2014
Twynsta (Boehringer Ingelheim)	Amlodipine/Telmisartan	Lupin	January 2014
Exelon (Novartis)	Rivastigmine oral solution	Ranbaxy	February 2014
Hectorol (Genzyme)	Doxercalciferol oral capsule and injection	Cobrek (injection), Hikma (injection), Roxane (capsule), Sandoz (injection)	February 2014[64]
Avelox (Bayer)	Moxifloxacin tablet	Apotex, Aurobindo, Dr. Reddy's, Teva, Torrent	March 2014[16]
Evista (Lilly)	Raloxifene	Teva, Invagen, Actavis	March 2014[17]
Renvela (Genzyme)	Sevelamer carbonate tablet	Impax[f,55]	March 2014[55,h]
Orapred ODT (Concordia)	Prednisolone sodium phosphate orally disintegrating tablet	Mylan	April 2014[45,h]
Pennsaid (Mallinckrodt)	Diclofenac 1.5% topical solution	Apotex,[f,93] Paddock	April 2014
Copaxone (Teva)	Glatiramer injection	Mylan,[f.,82] Sandoz[f,82]	May 2014
Exalgo (Mallinckrodt)	Hydromorphone extended-release tablet 32 mg	Actavis[f,3]	May 2014[3,h]
Lunesta (Sunovion)	Eszopiclone	Glenmark, Mylan, Orchid, Sun	May 2014[4,h]
Nexium (AstraZeneca)	Esomeprazole magnesium delayed-release capsule	Ranbaxy	May 2014[19,h]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Actonel (Warner Chilcott)	Risedronate	Aurobindo, Teva, Mylan	June 2014
Xeloda (Hoffmann La Roche)	Capecitabine	Teva	June 2014
Boniva (Roche)	Ibandronate injection	Sun, Teva Parenteral	September 2014
Renagel (Genzyme)	Sevelamer hydrochloride (oral suspension)	Impax[f,55]	September 2014[55,h]
Renvela (Genzyme)	Sevelamer Carbonate (oral suspension)	Impax[f,55]	September 2014[55,h]
Exforge (Novartis)	Amlodipine/Valsartan	Lupin, Matrix, Par	October 2014[37]
Intuniv (Shire)	Guanfacine extended-release tablet	Actavis, Sandoz, Teva, TWI	December 2014[75,h]
Namenda (Forest)	Memantine tablet	Amneal, Apotex, Lupin, Mylan, Upsher-Smith, Torrent, Unichem, Wockhardt	January 2015[21,h]
Sustiva (Bristol-Myers Squibb)	Efavirenz	Tablet: Aurobindo, Cipla, Emcure, Hetero, Macleods, Matrix, Micro Labs, Par, Strides Capsule: Aurobindo, Cipla, Micro Labs	March 2015
Welchol (Daiichi Sankyo)	Colesevelam tablet and oral suspension	Impax,[f,22] Actavis,[i,23,71] Glenmark[f,59]	March 2015[22,h]
Abilify (Otsuka)	Aripiprazole	Tablet: Alembic, Barr, Sun, Torrent Orally disintegrating tablet: Alembic, Barr, Zydus	April 2015[40]
Zyvox (Pfizer)	Linezolid tablet	Gate, Glenmark, Mylan, Teva	May 2015[36,h]
Zyvox (Pfizer)	Linezolid oral suspension	Roxane	May 2015[36,h]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Factive (Cornerstone)	Gemifloxacin tablet	Orchid	June 2015
Aggrenox (Boehringer Ingelheim)	Aspirin/Dipyridamole	Barr	July 2015[24,h]
Gleevec (Novartis)	Imatinib	Sun	July 2015
AndroGel 1% (AbbVie)	Testosterone	Actavis, Par	August 2015[25,h]
Baraclude (Bristol-Myers Squibb)	Entecavir	Teva	August 2015[95,d]
Valcyte (Roche)	Valganciclovir tablet	Ranbaxy	September 2015
Asacol HD (Warner Chilcott)	Mesalamine delayed-release tablet	Zydus[f,90]	November 2015[90]
Avodart (GlaxoSmithKline)	Dutasteride	Barr, Banner, Endo, Roxane, Sandoz	November 2015
Axert (Ortho-McNeil-Janssen)	Almotriptan	Teva	November 2015
Jalyn (GlaxoSmithKline)	Dutasteride/Tamsulosin	Impax,[i,13] Mylan,[i,13] Actavis[i,72]	November 2015[13,72,d]
Celebrex (Pfizer)	Celecoxib	Actavis, Mylan, Teva	December 2015
Patanol (Alcon)	Olopatadine	Apotex, Sandoz, Wockhardt	December 2015[32,h]
OxyContin (Purdue)	Oxycodone extended-release tablet (new formulation)	Impax, Mallinckodt, Teva	January 2016[12]
Glumetza (Santarus)	Metformin extended-release tablet	Lupin, Sun	February 2016[h]
Crestor (AstraZeneca)	Rosuvastatin	Aurobindo, Glenmark, Mylan, Par, Sandoz, Sun, Teva, Actavis	May 2016[26,h]
Nuvigil (Teva)	Armodafinil	Mylan, Lupin, Actavis	June 2016[31,h]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Zegerid/Zegerid OTC (Santarus)	Omeprazole/Sodium bicarbonate capsule and oral suspension	Dr. Reddy's,[i,10] Par, Perrigo, Zydus[i.10]	July 2016[10,d]
Enablex (Novartis)	Darifenacin	Anchen	August 2016
Oracea (Galderma)	Doxycycline	Lupin, Mylan	August 2016
Retin-A Micro (Valeant)	Tretinoin gel, microspheres	Spears	September 2016
Benicar/Benicar HCT (Daiichi Sankyo)	Olmesartan/Olmesartan HCTZ	Olmesartan: Mylan, Sandoz Olmesartan HCTZ: Mylan	October 2016
Seroquel XR (AstraZeneca)	Quetiapine extended-release tablet	Accord, Handa, Lupin,[f,43] Mylan,[f,53] Osmotica,[f,53] Torrent[f,53]	November 2016[74,h]
Kaletra (Abbott)	Lopinavir/Ritonavir	Aurobindo, Cipla, Hetero, Matrix, Mylan	December 2016[2,d]
Sensipar (Amgen)	Cinacalcet tablet	Barr, Teva	December 2016[51]
Zetia (Merck)	Ezetimibe	Glenmark, Mylan	December 2016[28,h]
Zyvox (Pfizer)	Linezolid injection	Teva	Late 2016[36,h]
Azilect (Teva)	Rasagiline mesylate tablet	Apotex, Mylan, Actavis	February 2017[30]
Vytorin (Merck)	Ezetimibe/Simvastatin	Mylan	April 2017[18]
Strattera (Lilly)	Atomoxetine	Actavis[f,29], Apotex, Aurobindo, Dr. Reddy's, Glenmark, Mylan, Sandoz, Sun, Teva[f,29]	May 2017[29]
Reyataz (Bristol-Myers Squibb)	Atazanavir	Emcure, Matrix, Teva	July 2017[52,h]
Relpax (Pfizer)	Eletriptan	Apotex, Teva	August 2017[62,d]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Adcirca (Lilly)	Tadalafil	Synthon	November 2017
Cubicin (Cubist)	Daptomycin	Hospira, Teva[f,69]	December 2017[69,h]
Exforge HCT (Novartis)	Amlodipine/Valsartan/ Hydrochlorothiazide	Lupin, Teva, Par, Torrent[i,38]	December 2017[38,d]
Viagra (Pfizer)	Sildenafil	Actavis, Amneal, Apotex, Dr. Reddy's, Hetero, Macleods, Mylan, Teva, Torrent	December 2017[91]
Viread (Gilead)	Tenofovir disoproxil fumarate	Aurobindo, Cipla, Matrix, Invagen, Strides Arcolab, Teva	December 2017[8,33,h]
Atripla (Gilead)	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate	Aurobindo, Cipla, Hetero, Matrix, Teva	August 2018[33,68,h]
Fentora (Cephalon)	Fentanyl buccal tablet	Barr,[f,56] Impax,[f,57] Actavis	October 2018[56,h]
Levitra (GlaxoSmithKline)	Vardenafil	Teva	October 2018[42]
Zemplar (AbbVie)	Paricalcitol	Dr.Reddy's[i,96]	October 2018[96,d]
Epzicom (GlaxoSmithKline)	Abacavir sulfate/Lamivudine	Tablet: Aurobindo, Cipla, Matrix, Mylan, Teva Tablet for Suspension: Cipla	November 2018
Fortesta (Endo)	Testosterone gel	Actavis[i,65]	November 2018[65,d]
Lyrica (Pfizer)	Pregabalin	Lupin, Mylan, Sandoz, Teva, Actavis, Wockhardt	December 2018[50]
Exelon (Novartis)	Rivastigmine transdermal patch	Actavis[i,66]	January 2019[66,d]
Ranexa (Gilead)	Ranolazine	Lupin	February 2019[81,h]
Emend (Merck)	Fosaprepitant injection	Accord,[i,35] Sandoz[i,35]	March 2019[35,d]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Prezista (Janssen)	Darunavir	Lupin,[79,i] Mylan, Teva	December 2019[79,d]
Silenor (Somaxon)	Doxepin	Actavis, Mylan,[f,39] Par, Zydus	January 2020[39,h]
Vigamox (Alcon)	Moxifloxacin ophthalmic	Akorn, Apotex, Lupin,[i,54] Teva, Actavis[i,6]	March 2020[6,47,54,d]
Safyral (Bayer)	Drospirenone/Ethinyl estradiol/Levomefolate calcium	Actavis[i,46]	April 2020[46,d]
Chantix (Pfizer)	Varenicline	Apotex, Mylan, Teva	May 2020[49,d]
Detrol LA (Pfizer)	Tolterodine extended-release capsule	Mylan	May 2020
Lialda (Shire)	Mesalamine delayed-release tablet	Actavis	June 2020[76,d]
Oleptro (Angelini)	Trazodone extended-release tablet	Actavis[i,11]	June 2020[11,d]
AndroGel 1.62% (AbbVie)	Testosterone	Perrigo,[i,58] Actavis[i,67]	August 2020[58,67,d]
Lescol XL (Novartis)	Fluvastatin extended-release	Mylan, Par	October 2020
Absorica (Ranbaxy)	Isotretinoin	Actavis[i,88]	September 2021
Bystolic (Forest)	Nebivolol	Glenmark[f,63]	September 2021[63]
Emtriva (Gilead)	Emtricitabine	Aurobindo, Cipla, Matrix	September 2021[7,d]
Truvada (Gilead)	Emtricitabine/ Tenofovir disoproxil fumarate	Aurobindo, Hetero, Matrix, Strides Arcolab, Teva	September 2021
Vimpat (UCB)	Lacosamide	Actavis,[i,77] Mylan,[i,78] Others[i,5]	March 2022[d]
Banzel (Eisai)	Rufinamide	Glenmark,[i,80] Hetero,[i,80] Lupin,[i,80] Mylan,[i.80] Roxane[i,80]	November 2022[80,d]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Xyrem (Jazz)	Sodium oxybate	Amneal[i,48]	December 2022[48,d]
Vimovo (AstraZeneca)	Naproxen/Esomeprazole magnesium delayed-release tablet	Dr. Reddy's	February 2023[27,d]
Aloxi (Eisai)	Palonosetron injection	Dr. Reddy's, Teva	January 2024
Gralise (Depomed)	Gabapentin	Actavis	February 2024
Pataday (Alcon)	Olopatadine	Apotex, Barr, Actavis[i,32]	May 2024[32,d]
Treximet (Pozen)	Sumatriptan/Naproxen	Dr. Reddy's, Mylan, Par	October 2025
Januvia (Merck)	Sitagliptin	Mylan, Sandoz, Sun	April 2026
Natazia (Bayer)	Dienogest/estradiol valerate	Lupin[i,61]	May 2026[61,d]
Aplenzin (Biovail)	Bupropion hydrobromide extended-release tablet	Paddock,[i,83] Actavis	June 2026[83,d]
Nuedexta (Avanir)	Dextromethorphan/Quinidine	Wockhardt[f,85]	July 2026[85]
Dexilant (Takeda)	Dexlansoprazole	Handa,[i,92] Impax,[i,92] Par	February 2027[92,d]
Axiron (Eli Lilly)	Testosterone transdermal solution	Actavis[i,9]	July 2027
Emend (Merck)	Aprepitant capsule	Sandoz	September 2027
Janumet (Merck)	Sitagliptin/Metformin	Sandoz	July 2028
Angiomax (Medicines Co)	Bivalirudin	Hospira	January 2029
Lo Loestrin Fe (Warner Chilcott)	Ethinyl estradiol/Norethindrone acetate/Ferrous fumarate	Actavis,[i,94] Barr	February 2029[d]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Acanya (Valeant)	Benzoyl peroxide/Clindamycin phosphate	Actavis[i,87]	August 2029
Savella (Cypress)	Milnacipran	Mylan[i,14]	September 2029
Suboxone (Reckitt Benckiser)	Buprenorphine/Naloxone sublingual film	Actavis[i,86]	March 2030[d]
Uloric (Takeda)	Febuxostat	Mylan[i,89]	September 2031[d]
Advicor (Abbott)	Lovastatin/Niacin	Barr	Uncertain
Alocril (Allergan)	Nedocromil ophthalmic	Akorn	Uncertain[g]
Avandamet (GlaxoSmithKline)	Rosiglitazone/Metformin	Teva	Uncertain
Avandaryl (GlaxoSmithKline)	Rosiglitazone/Glimepiride	Teva	Uncertain
Avandia (GlaxoSmithKline)	Rosiglitazone	Dr. Reddy's, Hikma, Mylan, Sandoz, Roxane, Teva, Actavis	Uncertain
Bromday (Bausch & Lomb)	Bromfenac	Coastal Pharms, Luitpold	Uncertain[g]
CellCept (Roche Palo)	Mycophenolate mofetil hydrochloride injection	Bedford Labs	Uncertain[g]
Dibenzyline (Wellspring)	Phenoxybenzamine	Roxane	Uncertain[g]
Diovan (Novartis)	Valsartan	Alembic, Aurobindo, Dr. Reddy's, Ivax, Lupin, Mylan, Ranbaxy, Actavis	Uncertain[34,g]
Exalgo (Mallinckrodt)	Hydromorphone extended-release tablet 8 mg, 12 mg, 16 mg	Actavis[f,44]	Uncertain[44]
Lamictal ODT (GlaxoSmithKline)	Lamotrigine orally disintegrating tablet	Actavis	Uncertain[60]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Vanos (Medicis)	Fluocinonide	Fougera, Glenmark, Perrigo, Taro	Uncertain[41,h]
Vivelle-Dot (Novartis)	Estradiol extended-release transdermal film	Mylan[f.,73]	Uncertain[73]

a. This list is not all-inclusive.
b. Current through December 2013. 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.
c. 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. Availability uncertain due to ongoing litigation. Because there are multiple patent expiration dates and/or little information concerning which patents are being challenged, we are unable to estimate a date of availability at this time. We will continue to follow and update when new information is available.
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 received approval or tentative approval from the FDA. Generic manufacturer has settled patent litigation with the brand manufacturer. Generic availability may be sooner than patent expiration date.
i. Generic manufacturer has not received approval or tentative approval from the FDA, but has filed patent challenge.

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PHARMACIST'S LETTER — *Evidence and Recommendations You Can Trust…* — PRESCRIBER'S LETTER

3120 West March Lane, Stockton, CA 95219 ~ TEL (209) 472-2240 ~ FAX (209) 472-2249

SOVALDI
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 Sovaldi must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C (genotypes 1, 2, 3, or 4) with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with ribavirin or in combination with pegylated interferon and ribavirin. **(must not be used as monotherapy)**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Absence of renal impairment (eGFR must be >30mL/min/1.73m^2) and absence of end stage renal disease (ESRD).
- Documentation showing that patient is drug and alcohol free for the past 12 months.

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

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH:

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

PHYSICIAN NAME:	PHYSICIAN DEA NUMBER:	SPECIALIST INVOLVED IN THERAPY:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

<table>
<tr><td rowspan="2">Requested Drug:

□ Sovaldi

Dosage:
_____</td><td rowspan="2">Documented liver fibrosis:</td><td>Diagnosis for this request:

Genotype:</td><td colspan="2">Patient is drug and alcohol free for past 12 months:

□ YES □ NO</td></tr>
<tr><td>Pegylated interferon dose:

Ribavirin dose:</td><td>Negative pregnancy test in the past 30 days:

□ YES □ NO</td><td>eGFR:</td></tr>
<tr><td colspan="5">PHYSICIAN SIGNATURE: DATE:</td></tr>
</table>

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)	

OLYSIO
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 Olysio must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C, genotype 1, with compensated liver disease.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with pegylated interferon and ribavirin. **(must not be used as monotherapy)**
- Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.

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

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

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

PHYSICIAN NAME:	PHYSICIAN DEA NUMBER:	SPECIALIST INVOLVED IN THERAPY:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug: □ **Olysio** Dosage: _____	Presence of Q80K polymorphism? □ YES □ NO	Diagnosis for this request: Pegylated interferon dose: Ribavirin dose:	Genotype: Negative pregnancy test in the past 30 days □ YES □ NO
PHYSICIAN SIGNATURE:			DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

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Denied: (Reasons)	

LUZU
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

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For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Luzu must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must be 18 years of age or older.
- Patient must have documented history of failure of two topical antifungal agents (clotrimazole, econazole) and two oral antifungal agents (terbinafine, fluconazole, itraconazole).

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

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

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

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

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: □ **Luzu**	Diagnosis for this request:
Failed therapy (Drug and Dose) 1. 2. 3. 4.	Start Date: End Date: 1. 2. 3. 4.
PHYSICIAN SIGNATURE: DATE:	

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

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

HETLIOZ
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

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

SD Medicaid requires that patients receiving a new prescription for Hetlioz must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must try and fail a generic sedative-hypnotic.

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

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

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

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

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: □ **Hetlioz**	Diagnosis for this request: Failed therapy (Drug and Dose) Start Date: End Date:
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)

Advair Utilization from 04/01/13 to 03/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ADVAIR HFA 45-21 MCG INHALER	30	$6,487.01	$216.23
ADVAIR HFA 230-21 MCG INHALER	171	$56,536.14	$330.62
ADVAIR HFA 115-21 MCG INHALER	632	$168,989.11	$267.39
ADVAIR 100-50 DISKUS	866	$189,618.11	$218.96
ADVAIR 500-50 DISKUS	579	$212,378.90	$366.80
ADVAIR 250-50 DISKUS	1793	$488,579.55	$272.49
1,109 recipients	**4071**	**$1,122,588.82**	

Summary by Age	
0-9	155
10-19	416
20-29	79
30-39	107
40-49	95
50-59	172
60+	85

325 recipients had 5 or more claims during the year

373 recipients had 1 claim during the year

Adult (21 and older) Stimulant Utilization from 04/01/13 to 03/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ADDERALL XR 20 MG CAPSULE	2	$363.91	$181.96
ADDERALL XR 25 MG CAPSULE	13	$5,472.17	$420.94
ADDERALL XR 30 MG CAPSULE	1	$133.17	$133.17
AMPHETAMINE SALTS 10 MG TABLET	330	$21,406.40	$64.87
AMPHETAMINE SALTS 15 MG TABLET	52	$2,112.38	$40.62
AMPHETAMINE SALTS 20 MG TABLET	564	$40,385.10	$71.60
AMPHETAMINE SALTS 30 MG TABLET	264	$15,397.05	$58.32
AMPHETAMINE SALTS 5 MG TABLET	56	$4,066.67	$72.62
AMPHETAMINE SALTS 7.5 MG TAB	2	$134.92	$67.46
D-AMPHETAMINE ER 10 MG CAPSULE	30	$7,725.10	$257.50
D-AMPHETAMINE ER 15 MG CAPSULE	84	$26,232.78	$312.30
DAYTRANA 20 MG/9 HOUR PATCH	11	$1,258.73	$114.43
DAYTRANA 30 MG/9 HOUR PATCH	5	$1,033.09	$206.62
DEXMETHYLPHENIDATE 10 MG TAB	4	$168.45	$42.11
DEXMETHYLPHENIDATE 5 MG TAB	9	$232.56	$25.84
DEXTROAMP-AMPHET ER 10 MG CAP	98	$13,120.21	$133.88
DEXTROAMP-AMPHET ER 15 MG CAP	58	$7,189.82	$123.96
DEXTROAMP-AMPHET ER 20 MG CAP	586	$105,322.16	$179.73
DEXTROAMP-AMPHET ER 25 MG CAP	104	$13,035.47	$125.34
DEXTROAMP-AMPHET ER 30 MG CAP	552	$87,326.41	$158.20
DEXTROAMP-AMPHET ER 5 MG CAP	13	$1,465.65	$112.74
DEXTROAMPHETAMINE 10 MG TAB	21	$3,038.05	$144.67
DEXTROAMPHETAMINE 10 MG TAB	66	$13,840.37	$209.70
DEXTROAMPHETAMINE 5 MG TAB	1	$127.06	$127.06
FOCALIN 10 MG TABLET	1	$65.53	$65.53
FOCALIN 5 MG TABLET	1	$19.36	$19.36
FOCALIN XR 10 MG CAPSULE	29	$6,112.54	$210.78
FOCALIN XR 15 MG CAPSULE	14	$1,750.38	$125.03
FOCALIN XR 20 MG CAPSULE	66	$15,231.40	$230.78
FOCALIN XR 25 MG CAPSULE	15	$3,404.24	$226.95
FOCALIN XR 30 MG CAPSULE	11	$2,288.47	$208.04
FOCALIN XR 40 MG CAPSULE	9	$2,086.32	$231.81
FOCALIN XR 5 MG CAPSULE	20	$4,102.19	$205.11
INTUNIV ER 1 MG TABLET	8	$1,968.93	$246.12
INTUNIV ER 2 MG TABLET	42	$6,816.88	$162.31
INTUNIV ER 3 MG TABLET	28	$6,505.39	$232.34
INTUNIV ER 4 MG TABLET	64	$11,887.75	$185.75
METADATE ER 20 MG TABLET	4	$565.22	$141.31
METHYLPHENIDATE 10 MG TABLET	222	$11,152.10	$50.23
METHYLPHENIDATE 20 MG TABLET	196	$11,760.80	$60.00
METHYLPHENIDATE 5 MG TABLET	51	$1,617.90	$31.72
METHYLPHENIDATE ER 10 MG TAB	3	$72.65	$24.22
METHYLPHENIDATE ER 18 MG TAB	67	$8,358.61	$124.76
METHYLPHENIDATE ER 20 MG TAB	24	$2,266.18	$94.42
METHYLPHENIDATE ER 27 MG TAB	64	$10,038.80	$156.86

Adult (21 and older) Stimulant Utilization from 04/01/13 to 03/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
METHYLPHENIDATE ER 36 MG TAB	211	$49,167.97	$233.02
METHYLPHENIDATE ER 54 MG TAB	177	$22,672.09	$128.09
METHYLPHENIDATE LA 20 MG CAP	10	$1,431.69	$143.17
METHYLPHENIDATE LA 30 MG CAP	14	$2,001.22	$142.94
METHYLPHENIDATE LA 40 MG CAP	45	$6,322.81	$140.51
METHYLPHENIDATE SR 20 MG TAB	12	$917.74	$76.48
MODAFINIL 100 MG TABLET	2	$2,054.50	$1,027.25
MODAFINIL 200 MG TABLET	37	$33,373.35	$901.98
RITALIN LA 10 MG CAPSULE	5	$901.81	$180.36
RITALIN LA 20 MG CAPSULE	1	$165.65	$165.65
RITALIN LA 40 MG CAPSULE	2	$348.14	$174.07
STRATTERA 10 MG CAPSULE	8	$2,741.90	$342.74
STRATTERA 100 MG CAPSULE	58	$12,560.12	$216.55
STRATTERA 25 MG CAPSULE	29	$6,192.28	$213.53
STRATTERA 40 MG CAPSULE	112	$29,602.15	$264.30
STRATTERA 60 MG CAPSULE	119	$25,125.90	$211.14
STRATTERA 80 MG CAPSULE	68	$17,053.63	$250.79
VYVANSE 20 MG CAPSULE	46	$8,939.84	$194.34
VYVANSE 30 MG CAPSULE	213	$36,344.78	$170.63
VYVANSE 40 MG CAPSULE	239	$43,998.16	$184.09
VYVANSE 50 MG CAPSULE	171	$29,765.52	$174.07
VYVANSE 60 MG CAPSULE	162	$27,431.47	$169.33
VYVANSE 70 MG CAPSULE	293	$52,667.17	$179.75
796 recipients	**5899**	**$890,439.21**	

Summary by Age	
21-30	386
31-40	251
41-50	91
51-60	59
61+	9

PRODUCT DETAILS OF RAGWITEK™ (SHORT RAGWEED POLLEN ALLERGEN EXTRACT)

INDICATIONS AND USE: Ragwitek (short ragweed pollen allergen extract) is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen.

DOSAGE FORMS: Ragwitek is available as 12 Amb a 1-Unit (Amb a 1-U) tablets.

ADMINISTRATION:

- One tablet daily.
- Initiate treatment at least 12 weeks before the expected onset of each ragweed pollen season and continue treatment throughout the season.
- Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute.
- Administer the first dose of Ragwitek under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose.

CONTRAINDICATIONS:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- A history of eosinophilic esophagitis.
- Hypersensitivity to any of the inactive ingredients contained in this product.

SPECIAL POPULATIONS:

- Ragwitek is classified as pregnancy category C. Because systemic and local adverse reactions with immunotherapy may be poorly tolerated during pregnancy, Ragwitek should be used during pregnancy only if clearly needed.
- Caution should be exercised when Ragwitek is administered to a nursing woman.
- Ragwitek is not approved for use in pediatric patients
- Ragwitek is not approved for use in patients over 65 years of age because safety and efficacy have not been established.

WARNINGS AND PRECAUTIONS:

Ragwitek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.
Do not administer Ragwitek to patients with severe, unstable or uncontrolled asthma.
Observe patients in the office for at least 30 minutes following the initial dose.
Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
Ragwitek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
Ragwitek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- Prescribe auto-injectable epinephrine to patients receiving Ragwitek
- Ragwitek can cause local reactions in the mouth or throat that could compromise the upper airway. Consider discontinuation of Ragwitek in patients who experience persistent and escalating adverse reactions in the mouth or throat.
- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue Ragwitek and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- Ragwitek has not been studied in subjects with moderate or severe asthma. Withhold immunotherapy with Ragwitek if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of Ragwitek.
- Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with Ragwitek to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers, or thrush) or oral wounds, such as those following oral surgery or dental extraction.

ADVERSE REACTIONS:

- Most common adverse reactions (≥5% of patients) were throat irritation, oral pruritus, ear pruritus, oral paraesthesia, mouth edema, and tongue pruritus.

PATIENT COUNSELING INFORMATION:

- Ragwitek is used to treat ragweed pollen induced allergic reactions.
- Carefully remove the tablet from the blister package with dry hands and put the tablet under your tongue. Do not swallow for at least 1 minute.

- Take the first tablet of Ragwitek in your doctor's office.
- Ragwitek may cause life-threatening allergic reactions. The signs and symptoms may include trouble breathing, throat tightness or swelling, trouble swallowing or speaking, dizziness or fainting, rapid or weak heartbeat, severe stomach cramps/vomiting/diarrhea, or severe flushing/itching of the skin.
- Keep an auto-injectable epinephrine with you at all times.

References:

1. Ragwitek® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2014.

PRODUCT DETAILS OF GRASTEK® (TIMOTHY GRASS POLLEN ALLERGEN EXTRACT)

INDICATIONS AND USE: Grastek (timothy grass pollen allergen extract) is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens.

DOSAGE FORMS: Grastek is available as 2800 Bioequivalent Allergy Units (BAUs) tablets.

ADMINISTRATION:

- One tablet daily.
- Initiate treatment at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, Grastek may be taken daily for three consecutive years.
- Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute.
- Administer the first dose of Grastek under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose.

CONTRAINDICATIONS:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- A history of eosinophilic esophagitis.
- Hypersensitivity to any of the inactive ingredients contained in this product.

SPECIAL POPULATIONS:

- Grastek is classified as pregnancy category B. There are no adequate and well-controlled studies of Grastek in pregnant women. Grastek should be used during pregnancy only if clearly needed.
- Caution should be exercised when Grastek is administered to a nursing woman.
- The safety and effectiveness in children and adolescents 5 through 17 years of age have been established. The safety and efficacy in pediatric patients below 5 years of age have not been established.
- There is no clinical trial experience with Grastek in patients over 65 years of age.

WARNINGS AND PRECAUTIONS:

Grastek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.
Do not administer Grastek to patients with severe, unstable or uncontrolled asthma.
Observe patients in the office for at least 30 minutes following the initial dose.
Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
Grastek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
Grastek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- In case of oral inflammation or wounds, stop treatment with Grastek to allow complete healing of the oral cavity.
- Prescribe auto-injectable epinephrine to patients receiving Grastek.
- Continue discontinuation of Grastek and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- Withhold immunotherapy with Grastek if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of Grastek.
- Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Grastek can cause local reactions in the mouth or throat that could compromise the upper airway. Consider discontinuation of Grastek in patients who experience persistent and escalating adverse reactions in the mouth or throat.

ADVERSE REACTIONS:

- Most common adverse reactions (≥5% of patients) were ear pruritus, oral pruritus, tongue pruritus, mouth edema, and throat irritation.

PATIENT COUNSELING INFORMATION:

- Grastek is used to treat grass pollen induced allergic reactions.
- Carefully remove the foil from the blister unit with dry hands and put the tablet under your tongue. Do not swallow for at least 1 minute.
- Grastek may cause life-threatening allergic reactions. The signs and symptoms may include trouble breathing, throat tightness or swelling, trouble swallowing or

speaking, dizziness or fainting, rapid or weak heartbeat, severe stomach cramps/vomiting/diarrhea, or severe flushing/itching of the skin.

- Keep an auto-injectable epinephrine with you at all times.
- The first dose must be administered in a doctor's office.
- If you have persistent reactions in the mouth or throat, discontinue Grastek and contact a healthcare professional.
- If you have asthma and experience difficulty breathing, stop Grastek and contact a healthcare professional.

References:

1. Grastek® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2014.

PRODUCT DETAILS OF ORALAIR® (SWEET VERNAL, ORCHARD, PERENNIAL RYE, TIMOTHY, and KENTUCKY BLUE GRASS MIXED POLLENS ALLERGEN EXTRACT)

INDICATIONS AND USE: Oralair is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. Oralair is approved for use in persons 10 through 65 years of age.

DOSAGE FORMS: Oralair is available as 100 IR (index of reactivity) and 300 IR tablets.

ADMINISTRATION:

- Administer the first dose of Oralair in a healthcare setting in which acute allergic reactions can be treated under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions. After receiving the first dose of Oralair, observe the patient for at least 30 minutes to monitor for signs and symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home.
- Administer Oralair to children under adult supervision.
- Remove the Oralair tablet from the blister just prior to dosing.
- Place the Oralair tablet immediately under the tongue until complete dissolution for at least 1 minute before swallowing.
- Wash hands after handling Oralair tablet.
- Do not take the Oralair tablet with food or beverage. To avoid swallowing allergen extract, food or beverage should not be taken for 5 minutes following dissolution of the tablet.
- Initiate treatment 4 months before the expected onset of each grass pollen season and maintain it throughout the season.

CONTRAINDICATIONS:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- Hypersensitivity to any of the inactive ingredients contained in this product.

SPECIAL POPULATIONS:

- Oralair is classified as pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Oralair should be used during pregnancy only if clearly needed.
- Caution should be exercised when Oralair is administered to a nursing woman.

- The safety and effectiveness in children and adolescents 10 through 17 years of age have been established. Oralair is not approved for use in children younger than 10 years of age.
- There is no clinical trial experience with Oralair in patients over 65 years of age.

WARNINGS AND PRECAUTIONS:

Oralair can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema.
Do not administer Oralair to patients with severe, unstable or uncontrolled asthma.
Observe patients in the office for at least 30 minutes following the initial dose.
Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
Oralair may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
Oralair may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- Prescribe auto-injectable epinephrine to patients receiving Oralair.
- Withhold immunotherapy with Oralair if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of Oralair.
- Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with Oralair to allow complete healing of the oral cavity in patients with oral inflammation or oral wounds, such as those following oral surgery or dental extraction.
- The risk of Oralair may be increased when treatment is initiated during the grass pollen season.

ADVERSE REACTIONS:

- Most common adverse reactions (≥5% of patients) were ear pruritus, oral pruritus, tongue pruritus, mouth edema, cough, oropharyngeal pain, and throat irritation.

PATIENT COUNSELING INFORMATION:

- Oralair is used for sublingual immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis and is not indicated for the immediate relief of allergy symptoms.

- Carefully remove the foil from the blister unit with dry hands and put the tablet under your tongue. Do not swallow for at least 1 minute.
- Do not take Oralair with food or beverage. Food or beverage should not be taken for the following 5 minutes.
- Wash hands after handling the tablet.
- Keep an auto-injectable epinephrine with you at all times.
- The first dose must be administered in a doctor's office.

References:

1. Oralair® [package insert]. Lenoir, NC: Greer Laboratories, Inc.; April 2014.

PRODUCT DETAILS OF NORTHERA™ (DROXIDOPA)

INDICATIONS AND USE: Northera (droxidopa) is indicated for the treatment of orthostatic dizziness, lightheadedness, or the 'feeling that you are about to black out' in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated.

DOSAGE FORMS: Northera is available as 100 mg, 200 mg, and 300 mg capsules.

ADMINISTRATION: The recommended starting dose of Northera is 100 mg three times during the day: upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep). Titrate by 100 mg three times daily, up to a maximum dose of 600 mg three times daily.

SPECIAL POPULATIONS:

- Northera is classified as pregnancy category C. There are no adequate and well-controlled studies of Northera in pregnant women.
- Choose nursing or Northera.
- The safety and effectiveness of Northera in pediatric patients have not been established.
- No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified difference in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
- Clinical experience with Northera in patients with severe renal function impairment (GFR less than 30 mL/min) is limited.

WARNINGS AND PRECAUTIONS:

- Northera can cause or exacerbate supine hypertension and may increase cardiovascular risk if supine hypertension is not well-managed.
- Postmarketing cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia, muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.
- Northera may exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure. Careful consideration should be given to this potential risk prior to initiating therapy in patients with these conditions.
- Northera contains FD+C Yellow No. 5 (tartrazine) which may cause allergic-type reactions in certain susceptible persons.

ADVERSE REACTIONS: Common adverse reactions (greater than 5%) are headache, dizziness, arrhythmias, and congestive heart failure.

DRUG INTERACTIONS:

- Use of dopa-decarboxylase inhibitors may require dose adjustments of Northera.
- Administering Northera in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension.

PATIENT COUNSELING INFORMATION:

- Northera is a prescription medicine used for lightheadedness or the feeling that you are going to 'black out'.
- Northera causes elevations in blood pressure and increases the risk of supine (lying face up) hypertension which could lead to strokes, heart attacks and death. Rest and sleep in an upper body elevated position and monitor blood pressure.
- Take the late afternoon dose at least three hours before bedtime to reduce the risk of supine hypertension.
- Consult a physician if you are pregnant or nursing.
- Take Northera the same way each time, either with food or without food.
- If a dose is missed, patients should take the next dose at the regularly scheduled time and should not double the dose.

References:

1. Northera® [package insert]. Charlotte, NC: Chelsea Therapeutics; February 2014.