South Dakota Department of Social Services

Medicaid P&T Committee Meeting

September 26, 2014

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

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

Friday, September 26, 2014
1:00 – 3:00 PM

Ramada Sioux Falls Airport Hotel & Suites
1301 West Russell
Sioux Falls, SD

Call to order

Approval of minutes of previous meeting

Prior authorization update

Review of top 15 therapeutic categories/top 25 drugs

Old Business
- **Hepatitis C**
  - **Treatment once per lifetime**
  - **Criteria for combination use**
- **Stimulant use in adults**
- **Oral allergen extracts (Ragwitek, Grastek, Oralair)**

New Business
- **Intuniv**
- **Transdermal androgens**
- **Phosphate binders**
- **Zontivity**
- **Evzio**
- **Otezla**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

Minutes of the June 6, 2014
Pharmacy & Therapeutics (P&T) Committee Meeting
South Dakota Department of Social Services, Division of Medical Services

Members Present

Richard Holm, MD; Bill Ladwig, RPh; Kelly Oehlke, PharmD; Dana Darger, RPh; Debra Farver, PharmD; Mikel Holland, MD; James Engelbrecht, MD

DSS staff present

Mike Jockheck, RPh; Ann Schwartz, Dep. Director of Medical Services; 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 March 21, 2014 meeting were presented. B. Ladwig made a motion to approve. R. Holm seconded the motion. The motion was approved unanimously.

Prior Authorization Update and Statistics

The committee reviewed the prior authorization (PA) activity for April 2014. There were a total of 2,982 PA's processed in the month of April, with 99.70% of those requests responded to in less than eight hours. There were 2,287 (77%) requests received electronically and 695 (23%) 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 01/1/2014 – 03/31/2014. 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 40.23% 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 10.65% of total claims.

Review of Drug Spend

The committee reviewed a table showing SD Medicaid drug spend from 2011 – 2013. The average cost per script rose from $63.57 in 2011 to $69.24 in 2013. The average recipient script cost rose from $172.51 in 2011 to $187.99 in 2013.

Patent Expirations

The committee reviewed a list of medications with an upcoming anticipated availability of a first-time generic.

Sovaldi and Olysio Second Review

The committee reviewed Olysio and Sovaldi prior authorization forms. The committee heard testimony from Paul Miner (Gilead) and Kathleen Karnik (Janssen). A motion was made by B. Ladwig to approve the Sovaldi and Olysio forms. D. Farver seconded the motion. The motion was approved unanimously. Utilization data will be brought to the September meeting for committee review.

Luzu Second Review
The committee made a motion at the March meeting to place Luzu on prior authorization. The form was brought back for committee approval. There was no public comment. A motion was made by B. Ladwig to approve the Luzu prior authorization form. K. Oehlke seconded the motion. The motion was approved unanimously.

Hetlioz Review
The committee made a motion at the March meeting to place Hetlioz on prior authorization. The form was brought back for committee approval. There was no public comment. A motion was made by D. Farver to approve the Hetlioz prior authorization form. K. Oehlke seconded the motion. The motion was approved unanimously.

Advair Utilization Review
At the March meeting, the committee requested Advair utilization be added to the June agenda. Utilization was reviewed.

Stimulant Use in Adults
At the March meeting, the committee requested stimulant use in adults be added to the June agenda. Utilization was reviewed. The committee requested that a list of the top 10-15 prescribers writing stimulants for adults be brought back to the next meeting.

Oral Allergen Extracts (Ragwitek, Grastek, Oralair)
The committee reviewed oral allergen extracts clinical information. There was no public comment. R. Holm made a motion to place oral allergen extracts on prior authorization for indication. K. Oehlke seconded the motion. The motion was approved unanimously. A prior authorization form will be developed and brought back to the September meeting for committee approval.

Northera Review
The committee reviewed Northera clinical information. There was no public comment. This topic was tabled.

The next meeting is scheduled for September 26, 2014. K. Oehlke made a motion to adjourn the P&T Committee meeting. D. Farver seconded the motion. The motion passed unanimously and the meeting was adjourned.

South Dakota Medicaid
Monthly Prior Authorization Report
August 1, 2014 – August 31, 2014

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
3,026	3,017	9	99.70%	0.30%

By Form Type

Form Type	Description	Approve	Deny
ADP	Antidepressant	102	147
AFX	Amrix and Fexmid	0	4
AMB	Ambien CR	2	6
ANF	Anti-Infectives(anti-biotic)	0	85
ANT	Antihistamines	9	51
APS	Antipsychotic	261	311
ARB	ARBS	3	3
COA	Oral Anticoagulants	6	5
DAW	Dispense As Written	11	0
EME	Antiemetics	0	19
GRH	Growth Hormone	5	16
GSM	Genitourinary SMR	13	18
HLM	Head Lice Medication	2	61
LID	Lidoderm	1	55
MAX	Max Units Override	70	1034
NAR	Name Brand Narcotics	2	3
NUC	Opioids	6	13
ONF	Onfi	3	9
OPH	Ophthalmic Antihistamines	0	37
PPI	Proton Pump Inhibitors	44	138
SMR	Skeletal Muscle Relaxants	0	15
STE	Nasal Steroids	15	98
STI	Stimulants	4	21
SUB	Suboxone/Subutex	3	4
TIM	Targeted Immune Modulators	10	7
TOP	Topical Acne Agents	21	174
TRP	Triptans	7	67
ULT	Ultram ER	0	9
XIF	Xifaxan	1	12
XOI	Xanthine Oxidase Inhibitor	0	2
XOL	Xolair	1	0
Totals		602	2424

South Dakota Medicaid
Monthly Prior Authorization Report
August 1, 2014 – August 31, 2014

By Request Type

08/01/14 - 08/31/14	# of	Electronic Requests		Faxed Requests	
	Requests	#	%	#	%
Prior Authorizations:					
Antidepressant	249	144	58%	105	42%
Amrix and Fexmid	4	3	75%	1	25%
Ambien CR	8	5	63%	3	38%
Anti-Infectives(anti-biotic)	85	83	98%	2	2%
Antihistamines	60	55	92%	5	8%
Antipsychotic	572	330	58%	242	42%
ARBS	6	5	83%	1	17%
Oral Anticoagulants	11	5	45%	6	55%
Dispense As Written	11	0	0%	11	100%
Antiemetics	19	19	100%	0	0%
Growth Hormone	21	14	67%	7	33%
Genitourinary SMR	31	15	48%	16	52%
Head Lice Medication	63	49	78%	14	22%
Lidoderm	56	41	73%	15	27%
Max Units Override	1104	1022	92%	82	8%
Name Brand Narcotics	5	0	0%	5	100%
Opioids	19	16	84%	3	16%
Onfi	12	6	50%	6	50%
Ophthalmic Antihistamines	37	32	86%	5	14%
Proton Pump Inhibitors	182	127	70%	55	30%
Skeletal Muscle Relaxants	15	15	100%	0	0%
Nasal Steroids	113	99	88%	14	12%
Stimulants	25	20	80%	5	20%
Suboxone/Subutex	7	2	29%	5	71%
Targeted Immune Modulators	17	8	47%	9	53%
Topical Acne Agents	195	147	75%	48	25%
Triptans	74	63	85%	11	15%
Ultram ER	9	8	89%	1	11%
Xifaxan	13	9	69%	4	31%
Xanthine Oxidase Inhibitor	2	2	100%	0	0%
Xolair	1	0	0%	1	100%
Prior Authorization Totals	3026	2344	77%	682	23%

South Dakota Medicaid
Monthly Prior Authorization Report
August 1, 2014 – August 31, 2014

Electronic PAs (unique)

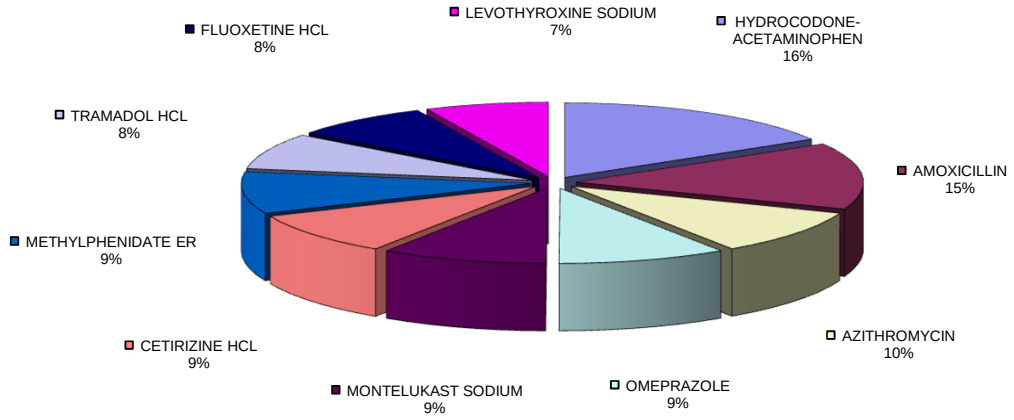
08/01/14 - 08/31/14	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antidepressant	35	109	0	144	24.30%	144
Amrix and Fexmid	0	3	0	3	0.00%	3
Ambien CR	2	3	0	5	40.00%	5
Anti-Infectives(anti-biotic)	0	83	0	83	0.00%	83
Antihistamines	9	45	0	54	16.70%	55
Antipsychotic	92	223	0	315	29.20%	330
ARBS	2	3	0	5	40.00%	5
Oral Anticoagulants	2	3	0	5	40.00%	5
Antiemetics	0	19	0	19	0.00%	19
Growth Hormone	0	14	0	14	0.00%	14
Genitourinary SMR	2	11	0	13	15.40%	15
Head Lice Medication	0	49	0	49	0.00%	49
Lidoderm	0	40	0	40	0.00%	41
Max Units Override	27	951	0	978	2.90%	1022
Opioids	5	11	0	16	31.30%	16
Onfi	0	5	0	5	0.00%	6
Ophthalmic Antihistamines	0	32	0	32	0.00%	32
Proton Pump Inhibitors	12	107	0	119	10.10%	127
Skeletal Muscle Relaxants	0	14	0	14	0.00%	15
Nasal Steroids	7	87	0	94	7.40%	99
Stimulants	0	18	0	18	0.00%	20
Suboxone/Subutex	0	2	0	2	0.00%	2
Targeted Immune Modulators	4	4	0	8	50.00%	8
Topical Acne Agents	4	141	0	145	2.80%	147
Triptans	5	55	0	60	8.30%	63
Ultram ER	0	8	0	8	0.00%	8
Xifaxan	0	9	0	9	0.00%	9
Xanthine Oxidase Inhibitor	0	2	0	2	0.00%	2
TOTALS	208	2051	0	2259	9.20%	2344

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2014 - 06/30/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	6,452	$ 116,352.74	$ 18.03	3.33%
AMOXICILLIN	PENICILLINS	5,671	$ 47,436.15	$ 8.36	2.93%
AZITHROMYCIN	MACROLIDES	3,834	$ 57,387.96	$ 14.97	1.98%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,697	$ 43,028.68	$ 11.64	1.91%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	3,639	$ 76,707.29	$ 21.08	1.88%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	3,585	$ 27,462.65	$ 7.66	1.85%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,555	$ 545,005.55	$ 153.31	1.83%
TRAMADOL HCL	OPIATE AGONISTS	3,077	$ 23,740.70	$ 7.72	1.59%
FLUOXETINE HCL	ANTIDEPRESSANTS	3,039	$ 24,316.61	$ 8.00	1.57%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,716	$ 24,320.59	$ 8.95	1.40%
VYVANSE	AMPHETAMINES	2,680	$ 515,053.40	$ 192.18	1.38%
SERTRALINE HCL	ANTIDEPRESSANTS	2,662	$ 19,936.52	$ 7.49	1.37%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	2,349	$ 44,311.32	$ 18.86	1.21%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,175	$ 13,237.55	$ 6.09	1.12%
DEXTROAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,090	$ 293,629.38	$ 140.49	1.08%
TRAZODONE HCL	ANTIDEPRESSANTS	2,089	$ 12,747.13	$ 6.10	1.08%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	2,066	$ 11,498.93	$ 5.57	1.07%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,954	$ 468,836.04	$ 239.94	1.01%
VENTOLIN HFA	BETA-ADRENERGIC AGONISTS	1,932	$ 91,803.29	$ 47.52	1.00%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,736	$ 29,670.28	$ 17.09	0.90%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,705	$ 11,776.42	$ 6.91	0.88%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	1,685	$ 30,529.66	$ 18.12	0.87%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,683	$ 13,256.47	$ 7.88	0.87%
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	1,670	$ 44,928.46	$ 26.90	0.86%
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	1,668	$ 15,112.90	$ 9.06	0.86%
TOTAL TOP 25		69,409	$ 2,602,086.67	$ 37.49	35.82%

Total Rx Claims From 04/01/2014 - 06/30/2014	193,758

Top 10 Drugs
Based on Number of Claims

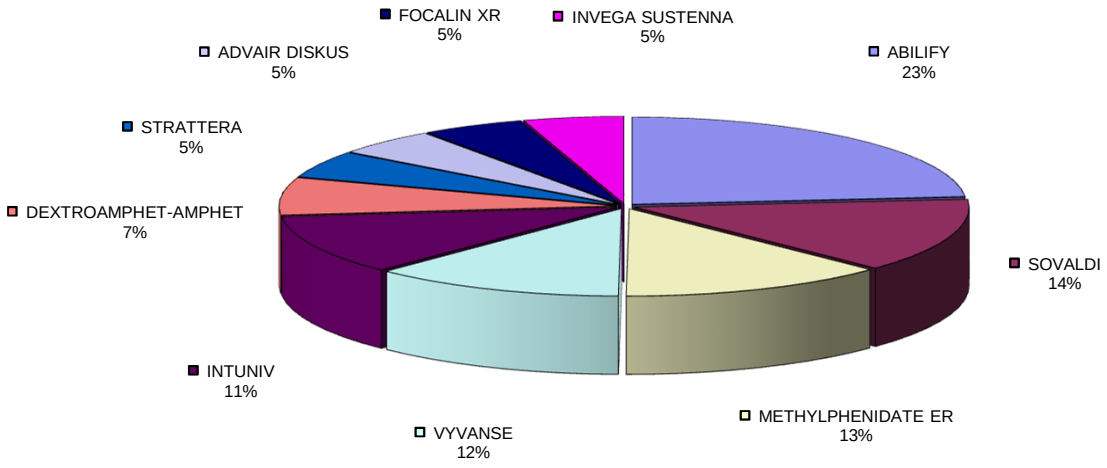


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2014 - 06/30/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,373	$1,000,869.83	$ 728.97	0.71%
SOVALDI	HCV ANTIVIRALS	20	$ 582,847.87	$29,142.39	0.01%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	3,555	$ 545,005.55	$ 153.31	1.83%
VYVANSE	AMPHETAMINES	2,680	$ 515,053.40	$ 192.18	1.38%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,954	$ 468,836.04	$ 239.94	1.01%
DEXTROAMPHET-AMPHET	AMPHETAMINES	2,090	$ 293,629.38	$ 140.49	1.08%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	888	$ 212,607.44	$ 239.42	0.46%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	708	$ 210,614.53	$ 297.48	0.37%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	874	$ 210,256.14	$ 240.57	0.45%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	142	$ 205,138.32	$ 1,444.64	0.07%
LATUDA	ANTIPSYCHOTIC AGENTS	286	$ 195,470.24	$ 683.46	0.15%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	650	$ 184,584.16	$ 283.98	0.34%
PULMOZYME	MUCOLYTIC AGENTS	63	$ 172,810.91	$ 2,743.03	0.03%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	63	$ 164,793.75	$ 2,615.77	0.03%
PREVACID	PROTON-PUMP INHIBITORS	569	$ 163,631.51	$ 287.58	0.29%
DULOXETINE HCL	ANTIDEPRESSANTS	751	$ 151,543.31	$ 201.79	0.39%
LANTUS SOLOSTAR	INSULINS	458	$ 150,535.17	$ 328.68	0.24%
COPAXONE	IMMUNOMODULATORY AGENTS	28	$ 141,783.92	$ 5,063.71	0.01%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	791	$ 139,730.62	$ 176.65	0.41%
OXYCONTIN	OPIATE AGONISTS	427	$ 132,627.56	$ 310.60	0.22%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	49	$ 125,612.10	$ 2,563.51	0.03%
NEXIUM	PROTON-PUMP INHIBITORS	453	$ 121,192.51	$ 267.53	0.23%
NOVOLOG	INSULINS	389	$ 119,475.82	$ 307.14	0.20%
BUDESONIDE	CORTICOSTEROIDS (RESPIRATORY TRACT)	396	$ 118,297.19	$ 298.73	0.20%
HYDROCODONE-ACET	OPIATE AGONISTS	6,452	$ 116,352.74	$ 18.03	3.33%
TOTAL TOP 25		26,109	$6,443,300.01	$ 246.78	13.48%

Total Rx Claims From 04/01/2014 - 06/30/2014	193,758

Top 10 Drugs
Based on Total Claims Cost



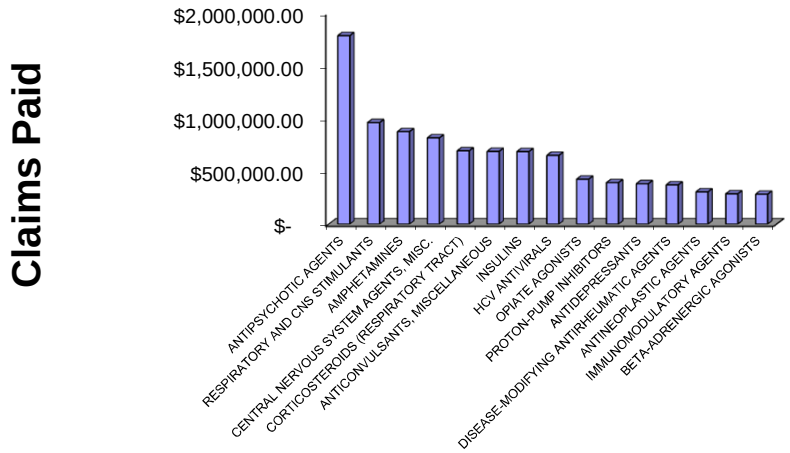
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2014 - 06/30/2014

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	6,494	$ 1,784,545.36	$ 274.80	3.35%
RESPIRATORY AND CNS STIMULANTS	6,255	$ 963,339.55	$ 154.01	3.23%
AMPHETAMINES	5,674	$ 877,495.76	$ 154.65	2.93%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	2,914	$ 818,299.45	$ 280.82	1.50%
CORTICOSTEROIDS (RESPIRATORY TRACT)	2,831	$ 695,597.16	$ 245.71	1.46%
ANTICONVULSANTS, MISCELLANEOUS	8,576	$ 690,087.14	$ 80.47	4.43%
INSULINS	2,196	$ 688,350.26	$ 313.46	1.13%
HCV ANTIVIRALS	23	$ 652,131.01	$ 28,353.52	0.01%
OPIATE AGONISTS	13,955	$ 426,381.59	$ 30.55	7.20%
PROTON-PUMP INHIBITORS	5,931	$ 393,839.28	$ 66.40	3.06%
ANTIDEPRESSANTS	16,391	$ 383,874.99	$ 23.42	8.46%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	171	$ 372,645.99	$ 2,179.22	0.09%
ANTINEOPLASTIC AGENTS	454	$ 306,473.92	$ 675.05	0.23%
IMMUNOMODULATORY AGENTS	57	$ 287,485.52	$ 5,043.61	0.03%
BETA-ADRENERGIC AGONISTS	6,372	$ 283,931.42	$ 44.56	3.29%
TOTAL TOP 15	78,294	$ 9,624,478.40	$ 122.93	40.41%

Total Rx Claims From 04/01/2014 - 06/30/2014	193,758

Top 15 Therapeutic Classes
Based on Total Cost of Claims



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 6 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:	NAME OF SPECIALIST CONSULTED:
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 6 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.
- 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 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.
- Documentation showing that patient is drug and alcohol free for the past 6 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:	NAME OF SPECIALIST CONSULTED:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug: □ **Olysio** Dosage: _____	Presence of Q80K polymorphism? □ YES □ NO	Diagnosis for this request: Genotype:	Patient is drug and alcohol free for past 6 months: □ YES □ NO
	Documented liver fibrosis:	Pegylated interferon dose: Ribavirin dose:	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

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

SD Medicaid Olysio/Sovaldi Utilization			
01/01/14 - 08/27/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
SOVALDI 400 MG TABLET	49	$1,431,786.56	$29,220.13
OLYSIO 150 MG CAPSULE	10	$232,603.92	$23,260.39
21 recipients	59	$1,664,390.48	

16 States Polled			
	Yes	**No**	**Case by Case**
Combination therapy of Sovaldi and Olysio	2	6	8
Lifetime limits	4	4	8

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION
Request for Prior Authorization
Hepatitis C Agents

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

South Dakota Medicaid Treatment Agreement for Hepatitis C Therapy

Please submit the completed treatment agreement with the initial prior authorization forms.

Patient Information	Prescriber Information
Name:	Name:
Medicaid Recipient ID Number:	Medicaid Provider ID Number:
Date of Birth:	Office Contact Name:
Hepatitis C Medication Regimen:	Telephone Number: Fax Number:

Patient instructions: Please read this treatment agreement carefully. Please initial each item to show you have read and understand it. Be sure to ask any questions you have before you sign it.	Patient's Initials
1. I have been told how to take my hepatitis C medicines. I understand how to take them. I am aware of possible side effects. I understand why it is important to finish all of the therapy.	
2. I will take my hepatitis C medicines like my doctor said and I will not miss doses.	
3. I understand that if I miss doses, Medicaid may no longer pay for my hepatitis C medicines.	
4. I will tell my doctor and pharmacist the medicines I take. I understand there may be some medicines I cannot take with my hepatitis C medicines.	
5. I understand that Medicaid may only pay for hepatitis C medicines for a certain number of weeks over my lifetime.	
6. I understand that past use of certain hepatitis C medicines may keep me from using medicines like them again.	
7. I have not used alcohol or IV drugs within the past 6 months and will not use alcohol or IV drugs while on treatment or after completion of therapy.	
8. I am (or my female partner is) not pregnant.	
9. I am (or my female partner is) not planning on getting pregnant while I am on my hepatitis C medicines and for at least 6 months after I finish therapy.	
10. I (or my female partner) will use two forms of non-hormonal birth control while I am taking my hepatitis C medicines and for at least 6 months after I finish taking them.	
11. I (or my female partner) will have monthly pregnancy testing while I am taking my hepatitis C medicines.	
12. I am ready to start treatment on the following date:	

I have read the above statements and understand the agreement.

Patient Signature:_____ Date:_____

Physician Signature:_____ Date:_____

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION
Request for Prior Authorization
Hepatitis C Agents

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

South Dakota Medicaid Informed Consent for Hepatitis C Therapy

This document is to help you understand the drugs being used to treat Hepatitis C.

- You must take these medications for at least 12 weeks. If you stop one, then the other will not work and it will need to be stopped as well.
- One of the commonly used medications is ribavirin. Ribavirin often has side effects. You may have flu-like symptoms throughout the treatment. If severe side effects happen while taking ribavirin, you need to contact the physician's office for direction.
- These drugs are harmful to babies. Females are asked to provide information on two methods to avoid getting pregnant. If you are male, you need to understand that a baby may have serious birth defects if exposed during the pregnancy to these drugs. If a woman's partner is taking this drug, then she must avoid becoming pregnant. The drug may impact the unborn child for up to 6 months after the drug has been stopped.
- Contraceptive measures must be used to prevent severe birth defects or fetal deaths.
- Alcohol must be avoided to prevent further harm to the liver. The use of alcohol during treatment may lead to coverage of medications being cancelled.
- Illegal substances must be avoided. Exposure to another form of Hepatitis C would make it more challenging to treat the viral infection.
- If you fail to strictly follow the drug regimen, it may not be effective.

By signing this document, I acknowledge that I have read the above information that I will abide by all parts of it and that failure may result in termination of my medication for hepatitis C.

PRINTED NAME:_____

SIGNATURE:_____

DATE:_____

Adult (21 and older) Stimulant Utilization 08/28/13 to 08/27/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ADDERALL XR 20 MG CAPSULE	3	$588.10	$196.03
ADDERALL XR 25 MG CAPSULE	11	$4,920.08	$447.28
ADDERALL XR 30 MG CAPSULE	2	$357.36	$178.68
AMPHETAMINE SALTS 10 MG TABLET	309	$19,549.82	$63.27
AMPHETAMINE SALTS 15 MG TABLET	80	$3,816.79	$47.71
AMPHETAMINE SALTS 20 MG TABLET	596	$42,765.50	$71.75
AMPHETAMINE SALTS 30 MG TABLET	274	$15,726.95	$57.40
AMPHETAMINE SALTS 5 MG TABLET	68	$5,059.21	$74.40
AMPHETAMINE SALTS 7.5 MG TAB	2	$134.92	$67.46
DAYTRANA 20 MG/9 HOUR PATCH	11	$1,212.46	$110.22
DEXMETHYLPHENIDATE 10 MG TAB	10	$417.20	$41.72
DEXMETHYLPHENIDATE 5 MG TAB	13	$344.02	$26.46
DEXTROAMP-AMPHET ER 10 MG CAP	140	$23,389.04	$167.06
DEXTROAMP-AMPHET ER 15 MG CAP	128	$29,803.34	$232.84
DEXTROAMP-AMPHET ER 20 MG CAP	592	$99,731.68	$168.47
DEXTROAMP-AMPHET ER 25 MG CAP	117	$14,367.27	$122.80
DEXTROAMP-AMPHET ER 30 MG CAP	505	$79,791.93	$158.00
DEXTROAMP-AMPHET ER 5 MG CAP	13	$1,656.55	$127.43
DEXTROAMPHETAMINE 10 MG TAB	99	$19,023.76	$192.16
DEXTROAMPHETAMINE 5 MG TAB	2	$212.90	$106.45
FOCALIN 5 MG TABLET	1	$19.36	$19.36
FOCALIN XR 10 MG CAPSULE	27	$5,955.17	$220.56
FOCALIN XR 15 MG CAPSULE	7	$980.81	$140.12
FOCALIN XR 20 MG CAPSULE	63	$14,873.38	$236.09
FOCALIN XR 25 MG CAPSULE	13	$3,074.02	$236.46
FOCALIN XR 30 MG CAPSULE	11	$2,288.77	$208.07
FOCALIN XR 40 MG CAPSULE	6	$976.69	$162.78
FOCALIN XR 5 MG CAPSULE	21	$4,551.24	$216.73
INTUNIV ER 1 MG TABLET	5	$1,711.01	$342.20
INTUNIV ER 2 MG TABLET	36	$6,709.82	$186.38
INTUNIV ER 3 MG TABLET	21	$5,447.97	$259.43
INTUNIV ER 4 MG TABLET	60	$12,373.54	$206.23
METADATE ER 20 MG TABLET	1	$14.71	$14.71
METHYLPHENIDATE 10 MG TABLET	223	$12,066.87	$54.11
METHYLPHENIDATE 20 MG TABLET	194	$13,741.70	$70.83
METHYLPHENIDATE 5 MG TABLET	54	$2,338.38	$43.30
METHYLPHENIDATE ER 18 MG TAB	50	$7,182.96	$143.66
METHYLPHENIDATE ER 20 MG TAB	32	$3,190.25	$99.70
METHYLPHENIDATE ER 27 MG TAB	57	$8,765.72	$153.78
METHYLPHENIDATE ER 36 MG TAB	191	$42,619.09	$223.14
METHYLPHENIDATE ER 54 MG TAB	155	$18,258.62	$117.80
METHYLPHENIDATE LA 20 MG CAP	21	$2,950.64	$140.51
METHYLPHENIDATE LA 30 MG CAP	16	$2,382.84	$148.93
METHYLPHENIDATE LA 40 MG CAP	28	$4,224.28	$150.87
METHYLPHENIDATE SR 20 MG TAB	14	$1,049.82	$74.99

Adult (21 and older) Stimulant Utilization 08/28/13 to 08/27/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
MODAFINIL 100 MG TABLET	1	$377.44	$377.44
MODAFINIL 200 MG TABLET	18	$11,388.13	$632.67
RITALIN LA 10 MG CAPSULE	8	$1,478.92	$184.87
RITALIN LA 30 MG CAPSULE	1	$194.47	$194.47
RITALIN LA 40 MG CAPSULE	2	$348.14	$174.07
STRATTERA 10 MG CAPSULE	7	$3,103.98	$443.43
STRATTERA 100 MG CAPSULE	47	$10,457.55	$222.50
STRATTERA 18 MG CAPSULE	2	$481.18	$240.59
STRATTERA 25 MG CAPSULE	14	$2,976.76	$212.63
STRATTERA 40 MG CAPSULE	144	$39,269.87	$272.71
STRATTERA 60 MG CAPSULE	132	$27,396.94	$207.55
STRATTERA 80 MG CAPSULE	65	$17,366.47	$267.18
VYVANSE 20 MG CAPSULE	51	$10,391.15	$203.75
VYVANSE 30 MG CAPSULE	250	$47,190.42	$188.76
VYVANSE 40 MG CAPSULE	245	$47,714.14	$194.75
VYVANSE 50 MG CAPSULE	204	$38,832.30	$190.35
VYVANSE 60 MG CAPSULE	175	$31,486.87	$179.92
VYVANSE 70 MG CAPSULE	309	$59,530.57	$192.66
837 recipients	**5957**	**$890,601.84**	
Approximately 40% of scripts are written by 20 prescribers			
	10	Psychiatrists	
	4	Family Practice	
	6	PA/CNP	

ORAL ALLERGEN EXTRACTS
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 oral allergen extracts must meet the following criteria:

- Patient must have the FDA approved indication for the drug requested.
- Diagnosis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies.
- History of failure, contraindication, or intolerance to two of the following: oral antihistamine, intranasal antihistamine, intranasal corticosteroid, or leukotriene inhibitors.
- History of failure or intolerance to subcutaneous allergen immunotherapy (allergy shots).
- Patient must not have severe, unstable, or uncontrolled asthma.

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:	Diagnosis for this Request:	History of Failure:
□ GRASTEK	□ GRASS POLLEN-INDUCED ALLERGIC RHINITIS	**1.**
□ ORALAIR	□ RAGWEED POLLEN-INDUCED ALLERGIC RHINITIS	**2.**
□ RAGWITEK		**3.**

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 INTUNIV (GUANFACINE)

INDICATIONS AND USE: Intuniv is a central alpha$_{2A}$-adrenergic receptor agonist indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

DOSAGE FORMS: Intuniv is available as 1 mg, 2 mg, 3 mg or 4 mg extended-release tablets.

DOSAGE AND ADMINISTRATION:

- Recommended dose: 1 to 4 mg once daily in the morning or evening.
- Begin at a dose of 1 mg once daily and adjust in increments of no more than 1 mg/week.
- Do not crush, chew, or break tablets before swallowing.
- Do not administer with high-fat meals, because of increased exposure.
- If switching from immediate-release guanfacine, discontinue that treatment and titrate.
- Consider dosing on a mg/kg basis. Improvements observed starting at doses of 0.05 – 0.08 mg/kg once daily. Doses up to 0.12 mg/kg once daily may provide additional benefit.
- When discontinuing, taper the dose in decrements of no more than 1 mg every 3 to 7 days.

SPECIAL POPULATIONS:

- Intuniv is classified as pregnancy category B. There are no adequate and well-controlled studies of Intuniv in pregnant women.
- Exercise caution when Intuniv is administered to a nursing woman.
- The safety and effectiveness of Intuniv in pediatric patients less than 6 years of age have not been established.
- The safety and efficacy of Intuniv in geriatric patients have not been established.

WARNINGS AND PRECAUTIONS:

- Hypotension, bradycardia, and syncope: Use Intuniv with caution. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Advise patients to avoid becoming dehydrated or overheated.
- Sedation and somnolence: Consider the potential for additive sedative effects with CNS depressant drugs. Caution patients against operating heavy equipment or driving until they know how they respond to Intuniv.

ADVERSE REACTIONS: The most common adverse reactions (≥ 5% and at least twice placebo rate) in the monotherapy trials: somnolence, fatigue, nausea, lethargy, and hypotension. Most common adverse reactions (≥ 5% and at least twice placebo rate) in the adjunctive trial: somnolence, fatigue, insomnia, dizziness, and abdominal pain.

DRUG INTERACTIONS:

- Strong CYP3A4 inhibitors (e.g., ketoconazole): Coadministration increases guanfacine exposure. Guanfacine dose should be limited to no more than 2 mg/day. When discontinuing CYP3A4 inhibitors, guanfacine dose should be doubled based on patient tolerability. The maximum dose should not exceed 4 mg/day.
- Strong CYP3A4 inducers (e.g., rifampin): Coadministration decreases guanfacine exposure. Guanfacine dose may be titrated up to 8 mg/day. When discontinuing CYP3A4 inducers, guanfacine dose should be decreased by half in 1-2 weeks based on patient tolerability. The maximum dose should not exceed 4 mg/day.

PATIENT COUNSELING INFORMATION:

- Swallow whole with water, milk, or other liquids. Tablets should not be crushed, chewed, or broken prior to administration because this may increase the rate of release of the active drug.
- Do not stop taking Intuniv without talking to the doctor.
- Intuniv should be taken 1 time a day.
- Do not take Intuniv with a high-fat meal.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how Intuniv affects you.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking Intuniv until you talk with your doctor.

UTILIZATION:

SD Medicaid Intuniv Utilization			
08/28/13 - 08/27/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
INTUNIV ER 1 MG TABLET	1327	$325,322.21	$245.16
INTUNIV ER 2 MG TABLET	2849	$656,982.32	$230.60
INTUNIV ER 3 MG TABLET	2090	$482,646.91	$230.93
INTUNIV ER 4 MG TABLET	1632	$378,092.46	$231.67
1,107 recipients	7898	$1,843,043.90	

Summary by Age			
	Age	**Count**	
	3-10	545	
	11-20	545	
	21-30	12	
	31-40	3	
	41-50	1	
	51-56	1	
Approximately 60% of scripts are written by 20 prescribers			
	13	Psychiatrists	
	4	Pediatricians	
	3	Nurse Practitioners	

References:

1. Intuniv [package insert]. Wayne, PA: Shire US, Inc.; August 2013.

PRODUCT DETAILS OF TRANSDERMAL ANDROGENS

INDICATIONS AND USE: Transdermal androgens are indicated for the management of male hypogonadism. Hypogonadism is a defect of the reproductive system which results in a lack of function of the gonads (testes). It can be categorized by the level of the reproductive system that is defective. Primary hypogonadism results from a defect of the gonads while secondary hypogonadism (hypogonadotropic hypogonadism) results from defects in the hypothalamus or pituitary.

DOSAGE FORMS: Transdermal androgens are available as patches, gels, and solutions.

ADMINISTRATION:

- AndroGel 1% – initial, 50 mg once daily in the morning; maintenance, 50 to 100 mg/day.
- AndroGel 1.62% – initial, 40.5 mg applied topically once daily in the morning; maintenance, 20.25 to 81 mg/day.
- Androderm – initial, 4 mg/day applied nightly for 24 hours; maintenance, 2 to 6 mg/day applied at night.
- Fortesta – initial, 40 mg applied once daily in the morning; maintenance, 10 to 70 mg/day.
- Testim – initial, 5 g once daily; maintenance, 5 to 10 g/day.
- Axiron – initial, 60 mg applied once daily in the morning; maintenance, 30 to 120 mg/day.
- Vogelxo – initial, 50 mg applied topically once daily; maintenance 50 to 100 mg/day.

SPECIAL POPULATIONS:

- Safety and efficacy in patients younger than 18 years have not been established.

WARNINGS AND PRECAUTIONS:

- Black Box Warning – Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Ensure that children avoid contact with unwashed or unclothed application sites in men using transdermal testosterone.
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening signs and symptoms.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products.
- Exogenous administration of androgens may lead to azoospermia.
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease.
- Sleep apnea may occur in those with risk factors.
- Monitor serum testosterone, prostate specific antigen (PSA), hematocrit, hemoglobin, liver function, and lipid concentrations periodically.

ADVERSE REACTIONS: Most common adverse reactions (incidence≥ 5%) are acne, application site reaction, abnormal lab tests, and prostatic disorders.

PATIENT COUNSELING INFORMATION:

- Men with known or suspected carcinoma of the breast or prostrate should not use testosterone gel.
- Know signs and symptoms of secondary exposure in children and women.
- Wash hands with soap and water after application.
- Cover the application site with clothing after the gel has dried.
- Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.
- Testosterone gel is an alcohol-based product and is flammable; therefore avoid fire, flame or smoking until the gel has dried.
- Be aware of the potential adverse reactions with androgens: changes in urinary habits, breathing disturbances, too frequent or persistent erections of the penis, nausea, vomiting, changes in skin color, or ankle swelling.
- Wait 2 hours before swimming or washing following application.

UTILIZATION:

SD Medicaid Testosterone Utilization			
08/28/13 - 08/27-14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ANDRODERM 2 MG/24HR PATCH	7	$1,341.30	$191.61
ANDRODERM 4 MG/24HR PATCH	2	$406.56	$203.28
ANDROGEL 1% GEL PUMP	25	$9,127.05	$365.08
ANDROGEL 1%(5G) GEL PACKET	13	$5,192.99	$399.46
ANDROGEL 1.62% GEL PACKET	1	$396.68	$396.68
ANDROGEL 1.62% GEL PUMP	44	$18,481.15	$420.03
ANDROGEL 1.62%(2.5G) GEL PCKT	5	$2,066.30	$413.26
AXIRON 30 MG/ACTUATION SOLN	16	$6,311.84	$394.49
DEPO-TESTOSTERONE 100 MG/ML	8	$361.67	$45.21
DEPO-TESTOSTERONE 200 MG/ML	22	353.14	$16.05
TESTIM 1% (50MG) GEL	8	$6,188.80	$773.60
TESTOSTERONE 50 MG/5 GRAM GEL	1	$647.75	$647.75
TESTOSTERONE CYP 200 MG/ML	22	$511.36	$23.24
TESTOSTERONE ENAN 1,000 MG/5 ML	7	$188.60	$26.94
TESTOSTERONE CYP 1,000 MG/10 ML	1	$55.82	$55.82
TESTOSTERON CYP 2,000 MG/10 ML	14	$1,224.03	$87.43
52 recipients	**196**	**$52,855.04**	

References:

1. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; June 2014.
2. Axiron [package insert]. Indianapolis, IN: Lilly USA, LLC: June 2014.
3. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; June 2014.
4. Androderm [package insert]. Parsippany, NY: Watson; November 2013.
5. Androgel [package insert]. North Chicago, IL: AbbVie, Inc.; June 2014.
6. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc.; June 2014.

PRODUCT DETAILS OF PHOSPHATE BINDERS

INDICATIONS AND USE: The mainstay of therapy for patients with chronic kidney disease (CKD) unable to excrete phosphate is dietary restriction of phosphate. However, high concentrations of phosphorous are found in many foods including dairy products, nuts, and meat. Consequently, most patients with chronic kidney disease (CKD) will require a phosphate-binding medication. Maintaining serum phosphorus of 2.7 to 4.6 mg/dL in patients who are not receiving dialysis and 3.5 to 5.5 mg/dL in those receiving dialysis is generally considered a clinically acceptable outcome of treatment with phosphate binders.

Drug	Indication
Calcium acetate (Phoslo, Eliphos, others)	To reduce serum phosphorous in patients with end-stage renal disease (ESRD).
Lanthanum carbonate (Fosrenol)	To reduce serum phosphate in patients with end-stage renal disease (ESRD).
Sevelamer hydrochloride (Renagel)	Control of serum phosphorous in patients with CKD on dialysis.
Sevelamer carbonate (Renvela)	Control of serum phosphorous in patients with CKD on dialysis.
Sucroferric oxyhydroxide (Velphoro)	Control of serum phosphorous levels in patients with CKD on dialysis.

DOSAGE FORMS: Phosphate binders are available in capsules, solution, tablets, suspension, and chewable tablets.

ADMINISTRATION:

- Calcium acetate – 1334 mg three times daily with meals
- Lanthanum carbonate – 500 mg three times daily with meals
- Sevelamer hydrochloride – 800 to 1600 mg three times daily with meals
- Sevelamer carbonate – 800 to 1600 mg three times daily with meals
- Sucroferric oxyhydroxide – 500 mg three times daily with meals.

SPECIAL POPULATIONS:

- Safety and efficacy have not been established in pediatric patients.
- Pregnancy category B (sucroferric oxyhydroxide)
- Pregnancy category C (sevelamer, lanthanum, calcium acetate)

WARNINGS AND PRECAUTIONS:

- Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with sucroferric oxyhydroxide. Monitor effect and iron homeostasis.

- Serious cases of dysphagia, bowel obstruction, and perforation have been associated with sevelamer use, some requiring hospitalization and surgery.
- Chew or crush lanthanum carbonate completely to reduce the risk of serious adverse effects.
- Serious cases of gastrointestinal obstruction, ileus, and fecal impaction have been associated with lanthanum use, some requiring surgery or hospitalization. Risk factors include altered gastrointestinal anatomy, hypomotility disorders, and concomitant medications.
- Lanthanum has radio-opaque properties and therefore may give the appearance typical of an imaging agent during abdominal X-ray procedures.
- Patients with end stage renal disease (ESRD) may develop hypercalcemia while treated with calcium. Monitor calcium levels regularly.

ADVERSE REACTIONS: Most common adverse reactions include discolored feces, diarrhea, hypercalcemia (calcium acetate), nausea, vomiting, and abdominal pain.

PATIENT COUNSELING INFORMATION:

- Take with or immediately after meals.
- Chew or crush completely before swallowing. (lanthanum carbonate)
- Report new onset or worsening of existing constipation promptly to a physician.
- Tablets must be chewed and not swallowed whole. (sucroferric oxyhydroxide)

UTILIZATION:

SD Medicaid Phosphate Binder Utilization		
08/28/13 - 08/27/14		
Label Name	**Rx Num**	**Total Reimb Amt**
CALCIUM ACETATE 667 MG CAPSULE	87	$6,513.52
CALCIUM ACETATE 667 MG GELCAP	8	$1,084.64
FOSRENOL 500 MG TABLET CHEW	19	$15,077.15
PHOSLYRA 667 MG/5 ML SOLUTION	5	$522.89
RENAGEL 800 MG TABLET	4	$1,021.67
RENVELA 0.8 GM POWDER PACKET	4	$7,906.03
RENVELA 2.4 GM POWDER PACKET	29	$29,966.52
RENVELA 800 MG TABLET	81	$56,204.14
SEVELAMER CARBONATE 800 MG TAB	4	$1,955.37
46 recipients	**241**	**$120,251.93**

References:

1. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; December 2013.
2. Renagel [package insert]. Cambridge, MA: Genzyme: May 2011.
3. Renvela [package insert]. Cambridge, MA: Genzyme; May 2011.
4. Fosrenol [package insert]. Wayne, PA: Shire US, Inc.; October 2012.

PRODUCT DETAILS OF ZONTIVITY (VORAPAXAR)

INDICATIONS AND USE: Zontivity is a protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Zontivity has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

DOSAGE FORMS: Zontivity is available as 2.08 mg tablets.

ADMINISTRATION: Take one tablet of Zontivity 2.08 mg orally once daily, with or without food. There is no experience with use of Zontivity alone as the only administered antiplatelet agent. Zontivity has been studied only as an addition to aspirin and/or clopidogrel. There is limited clinical experience with other antiplatelet drugs.

SPECIAL POPULATIONS:

- Zontivity is classified as pregnancy category B. There are no adequate and well-controlled studies of Zontivity use in pregnant women.
- It is unknown whether Zontivity or its metabolites are excreted in human milk, but it is actively secreted in milk of rats. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Zontivity, discontinue nursing or discontinue Zontivity.
- The safety and effectiveness of Zontivity in pediatric patients have not been established.
- Because older patients are generally at a higher risk of bleeding, consider patient age before initiating Zontivity.

WARNINGS AND PRECAUTIONS:

- Like other antiplatelet agents, Zontivity increases the risk of bleeding.
- Avoid use with strong CYP3A inhibitors or inducers.

ADVERSE REACTIONS:

- Black Box Warning-Do not use Zontivity in patients with a history of stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH), or active pathological bleeding.
- Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.

PATIENT COUNSELING INFORMATION:

- Take medication exactly as prescribed.
- Do not discontinue Zontivity without discussing with the prescribing physician.
- Report any unanticipated, prolonged or excessive bleeding, or blood in the stool or urine.
- Inform physicians and dentists of Zontivity use before surgery or dental procedures.

- List all prescription medications, over-the-counter medications, or dietary supplements they are taking or plan to take so that the physician knows about other treatments that may affect bleeding risk.

References:

1. Zontivity© [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2014.

PRODUCT DETAILS OF EVZIO (NALOXONE HYDROCHLORIDE INJECTION)

INDICATIONS AND USE: Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present.

DOSAGE FORMS: Evzio is available as a 0.4mg/0.4mL naloxone hydrochloride solution in a pre-filled auto-injector.

ADMINISTRATION: Administer the initial dose of Evzio to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. The requirement for repeat doses of Evzio depends upon the amount, type, and route of administration of the opioid being antagonized.

If the desired response is not obtained after 2 or 3 minutes, another Evzio dose may be administered. If there is still no response and additional doses are available, additional Evzio doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.

SPECIAL POPULATIONS:

- Evzio is classified as pregnancy category B. There are no adequate and well-controlled studies of Evzio in pregnant women.
- Exercise caution when Evzio is administered to a nursing woman.
- The safety and effectiveness of Evzio have been established in pediatric patients for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients.

WARNINGS AND PRECAUTIONS:

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Other supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

- Reversal of respiratory depression by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.

ADVERSE REACTIONS: The following adverse reactions have been identified during use of naloxone hydrochloride in the post-operative setting: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia and have caused agitation.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, hyperactive reflexes.

PATIENT COUNSELING INFORMATION:

- Become familiar with the Evzio instructions for use.
- Practice using the trainer before Evzio is needed.
- Each Evzio can only be used one time; however, the trainer (which is black and white) can be re-used for training purposes and its red safety guard can be removed and replaced.
- Make sure Evzio is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (i.e., opioid emergencies).
- Instruct the patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of Evzio.
- When in doubt, if a patient is unresponsive and an opioid overdose is suspected, administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
- Seek emergency medical assistance after administering the first dose of Evzio.

References:

1. Evzio [package insert]. Richmond, VA: Kaléo , Inc.; April 2014.

PRODUCT DETAILS OF OTEZLO (APREMILAST)

INDICATIONS AND USE: Otezla is an inhibitor of phosphodiesterase 4 (PDE4) and is indicated for the treatment of adult patients with active psoriatic arthritis.

DOSAGE FORMS: Otezla is available as 10 mg, 20 mg, and 30 mg tablets.

DOSAGE AND ADMINISTRATION: To reduce the risk of gastrointestinal symptoms, titrate to a recommended dose of 30 mg twice daily according to the following schedule:

- Day 1: 10 mg in the morning
- Day 2: 10 mg in the morning and 10 mg in the evening
- Day 3: 10 mg in the morning and 20 mg in the evening
- Day 4: 20 mg in the morning and 20 mg in the evening
- Day 5: 20 mg in the morning and 30 mg in the evening
- Day 6 and thereafter: 30 mg twice daily
- Otezla dosage should be reduced to 30 mg once daily in patients with severe renal impairment.

SPECIAL POPULATIONS:

- Otezla is classified as pregnancy category C. There are no adequate and well-controlled studies of Otezla in pregnant women.
- Because many drugs are present in human milk, caution should be exercised when Otezla is administered to a nursing woman.
- The safety and effectiveness of Otezla in pediatric patients less than 18 years of age have not been established.
- No overall differences were observed in the safety profile of elderly patients ≥ 65 years of age and younger adult patients < 65 years of age in the clinical studies.

WARNINGS AND PRECAUTIONS:

- Treatment with Otezla is associated with an increase in adverse reactions of depression. Before using Otezla in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with Otezla in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes.
- During the controlled period of the studies, weight decrease between 5-10% of body weight was reported in 10% of patients compared to 3.3% treated with placebo. Patients treated with Otezla should have their weight monitored regularly.
- Co-administration of strong cytochrome P450 enzyme inducer, rifampin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of Otezla. Therefore, the use of cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with Otezla is not recommended.

ADVERSE REACTIONS: The most common adverse reactions leading to discontinuation for patients taking Otezla were nausea (1.8%), diarrhea (1.8%), and headache (1.2%). The proportion of patients with psoriatic arthritis who discontinued treatment due to any adverse reaction was 4.6% for patients taking Otezla 30 mg twice daily and 1.2% for placebo-treated patients.

PATIENT COUNSELING INFORMATION:

- Before using Otezla in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risk and benefits of treatment.
- Be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and if such changes occur, contact their healthcare provider.
- Patients treated with Otezla should have their weight monitored regularly.
- The use of cytochrome P450 enzyme inducers is not recommended.
- Otezla can be taken with or without food.
- Tablets should not be crushed, split or chewed.

References:

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; March 2014.