South Dakota Department of Social Services

Medicaid P&T Committee Meeting

September 14, 2012

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 14, 2012
1:00 – 3:00 PM

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

Pierre
Capitol Building
DDN Room A
500 E Capitol

Rapid City
Dept of Human Services
111A New York St

Call to Order

Approval of Minutes of Previous Meeting

Prior Authorization Update

Review of Top 15 Therapeutic Categories/Top 25 Drugs

Old Business
- **Antipsychotic PA Update**
- **Lidoderm**
- **Early Refill**
- **Onfi**

New Business
- **Inhaled Corticosteroids**
- **Nasal Steroids for Allergic Rhinitis**
- **Ophthalmic Prostaglandin Agonists Review**
- **Antiretrovirals**
- **Genitourinary Smooth Muscle Relaxants**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

Minutes of the June 22, 2012
Pharmacy & Therapeutics (P&T) Committee Meeting
SD Department of Social Services, Medical Services Division

Members present
Debra Farver, PharmD; Dana Darger, RPh; Timothy Soundy, MD; Bill Ladwig, RPh; James Engelbrecht, MD; Michelle Baack, MD; Mikel Holland, MD; Kelly Oehlke, PharmD; Lenny Petrick, PharmD, Rick Holm, MD

DSS staff present
Mike Jockheck, RPh
Ann Schwartz, Dep. Director, Medical Services

HID staff present
Candace Rieth, PharmD

Administrative Business
The P&T meeting was called to order by D. Darger at approximately 1:00pm. The minutes of the June 22, 2012 meeting were presented. D. Farver made a motion to approve. K. Oehlke seconded the motion. The motion was approved unanimously.

Prior Authorization Update and Statistics
C. Rieth presented an overview of the prior authorization (PA) activity for April 2012. There were a total of 2,738 PAs processed in the month of April, with 98.87% of those requests responded to in less than 8 hours. There were 2,247 (82%) requests received electronically and 491 (18%) requests received by fax.

Analysis of the Top 15 Therapeutic Classes
C. Rieth reviewed the Top 15 Therapeutic Classes by total cost of claims from 01/01/2012 – 03/31/2012. The top five classes were antipsychotics, cerebral stimulants, amphetamines, corticosteroids (respiratory tract), and central nervous system agents, misc. The top 15 therapeutic classes make up 38.30% of total claims. C. Rieth also reviewed the top 25 drugs based on total claims cost and number of claims. The top 25 drugs by claims cost make up 16.69% of total claims. Committee members asked that inhaled corticosteroids and antiretrovirals be included on the next agenda.

Antipsychotics Review
C. Rieth reviewed data for antipsychotics. Previous recommendations made by the committee were included with the review along with new recommendations made by Dr. Farver and Dr. Soundy. P. Arends, representing NAMI, spoke to the committee. After review, the committee made the following changes to the proposed PA form:

1. Add intermittent explosive disorder, pervasive developmental disorder, and tourettes to the list of diagnoses.
2. Add developmental pediatrician, child/adolescent psychiatrist and pediatric neurologist to the list of specialists involved in care of recipients <6 years of age.
3. Change FDA approved indication to ‘included indication’.
4. Change two atypical antipsychotics must involve psychiatrist or associated mid-level practitioner consult to ‘two atypical antipsychotics must involve psychiatrist or mid-level practitioner in collaboration with a psychiatrist’.

M. Baack made a motion to approve the amended PA form. B. Ladwig seconded the motion. The motion was approved unanimously.

Lidoderm Review
C. Rieth presented clinical information and utilization for Lidoderm. J. Engelbrecht made a motion to place Lidoderm on prior authorization for FDA approved indication. L. Petrick seconded the motion. The motion was approved unanimously. The PA form will be reviewed at the next meeting.

Brilinta Review
C. Rieth presented clinical information and utilization for Brilinta. There was no public comment. This topic was tabled.

Early Refill Review
M. Jockheck reviewed early refill information with the committee. There was no public comment. The committee requested that more information be provided at the next meeting including a list of the drugs that fall into the 22-24 day early refill range.

Onfi Review
C. Rieth reviewed Onfi clinical information and utilization. There was no public comment. J. Engelbrecht made a motion to place Onfi on prior authorization for FDA approved indication. R. Holm seconded the motion. The motion was approved unanimously. The PA form will be reviewed at the next meeting.

Topical Corticosteroid Review
C. Rieth reviewed topical corticosteroid clinical information and utilization. This topic was tabled.

Actinic Keratoses Review
C. Rieth reviewed actinic keratoses clinical information and utilization. This topic was tabled.

The next meeting date is scheduled for September 14, 2012. A motion was made by M. Baack at 3:00pm to adjourn the SD Medicaid P&T meeting. K. Oehlke seconded the motion. Motion passed unanimously and the meeting was adjourned.

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2012 – July 31, 2012

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
2,056	2,029	27	98.69%	1.31%

By Form Type

Form Type	Description	Approve	Deny
ADP	Antidepressant	82	164
ALT	Altabax	0	3
AMB	Ambien CR	5	9
ANF	Anti-Infectives	1	1
ANT	Antihistamines	10	54
APS	Antipsychotic	14	38
ARB	ARBS	10	15
DAW	Dispense As Written	8	57
EME	Antiemetics	0	6
FUN	Antifungals	0	1
GRH	Growth Hormone	4	9
HLM	Head Lice Medication	13	58
MAX	Max Units Override	43	755
NAR	Name Brand Narcotics	3	16
NUC	Opioids	8	29
OPH	Ophthalmic Antihistamines	2	48
PPI	Proton Pump Inhibitors	44	113
SAN	Sancuso	1	0
SMR	Skeletal Muscle Relaxants	0	2
STI	Stimulants	9	32
SUB	Suboxone/Subutex	4	29
TIM	Targeted Immune Modulators	3	12
TOP	Topical Acne Agents	32	256
TRP	Triptans	5	40
ULT	Ultram ER	3	3
VUS	Vusion	0	1
XOI	Xanthine Oxidase Inhibitor	1	0
Totals		305	1751

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2012 – July 31, 2012

By Request Type

07/01/12 - 07/31/12	# of	Electronic Requests		Faxed Requests	
	Requests	#	%	#	%
Prior Authorizations:					
Antidepressant	246	193	78%	53	22%
Altabax	3	3	100%	0	0%
Ambien CR	14	10	71%	4	29%
Anti-Infectives	2	1	50%	1	50%
Antihistamines	64	51	80%	13	20%
Antipsychotic	52	41	79%	11	21%
ARBS	25	19	76%	6	24%
Dispense As Written	65	39	60%	26	40%
Antiemetics	6	6	100%	0	0%
Antifungals	1	1	100%	0	0%
Growth Hormone	13	8	62%	5	38%
Head Lice Medication	71	39	55%	32	45%
Max Units Override	798	743	93%	55	7%
Name Brand Narcotics	19	13	68%	6	32%
Opioids	37	32	86%	5	14%
Ophthalmic Antihistamines	50	44	88%	6	12%
Proton Pump Inhibitors	157	122	78%	35	22%
Sancuso	1	0	0%	1	100%
Skeletal Muscle Relaxants	2	2	100%	0	0%
Stimulants	41	33	80%	8	20%
Suboxone/Subutex	33	24	73%	9	27%
Targeted Immune Modulators	15	11	73%	4	27%
Topical Acne Agents	288	226	78%	62	22%
Triptans	45	37	82%	8	18%
Ultram ER	6	3	50%	3	50%
Vusion	1	0	0%	1	100%
Xanthine Oxidase Inhibitor	1	0	0%	1	100%
Prior Authorization Totals	2,056	1,701	83%	355	17%

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2012 – July 31, 2012

Electronic PAs (unique)

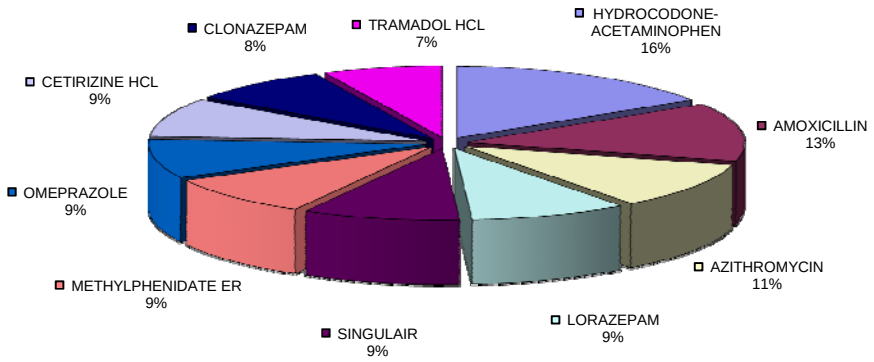
07/01/12 - 07/31/12	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antidepressant	54	131	0	185	29.20%	193
Altabax	0	3	0	3	0.00%	3
Ambien CR	4	6	0	10	40.00%	10
Anti-Infectives	0	1	0	1	0.00%	1
Antihistamines	6	44	0	50	12.00%	51
Antipsychotic	7	33	0	40	17.50%	41
ARBS	6	12	0	18	33.30%	19
Dispense As Written	0	37	0	37	0.00%	39
Antiemetics	0	6	0	6	0.00%	6
Antifungals	0	1	0	1	0.00%	1
Growth Hormone	0	7	0	7	0.00%	8
Head Lice Medication	0	39	0	39	0.00%	39
Max Units Override	13	695	0	708	1.80%	743
Name Brand Narcotics	0	13	0	13	0.00%	13
Opioids	6	26	0	32	18.80%	32
Ophthalmic Antihistamines	1	42	0	43	2.30%	44
Proton Pump Inhibitors	31	76	0	107	29.00%	122
Skeletal Muscle Relaxants	0	2	0	2	0.00%	2
Stimulants	4	28	0	32	12.50%	33
Suboxone/Subutex	0	18	0	18	0.00%	24
Targeted Immune Modulators	0	11	0	11	0.00%	11
Topical Acne Agents	9	208	0	217	4.10%	226
Triptans	5	32	0	37	13.50%	37
Ultram ER	1	2	0	3	33.30%	3
Prior Authorization Totals	147	1473	0	1620	9.10%	1701

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2012 - 06/30/2012

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	7,234	$ 90,771.50	$ 12.55	3.23%
AMOXICILLIN	PENICILLINS	5,951	$ 55,780.90	$ 9.37	2.66%
AZITHROMYCIN	MACROLIDES	4,743	$ 74,128.61	$ 15.63	2.12%
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,150	$ 30,831.14	$ 7.43	1.86%
SINGULAIR	LEUKOTRIENE MODIFIERS	4,146	$ 620,351.96	$ 149.63	1.85%
METHYLPHENIDATE ER	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	4,096	$ 703,147.82	$ 171.67	1.83%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,967	$ 53,258.04	$ 13.43	1.77%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	3,961	$ 69,182.20	$ 17.47	1.77%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,691	$ 28,454.33	$ 7.71	1.65%
TRAMADOL HCL	OPIATE AGONISTS	3,138	$ 38,018.06	$ 12.12	1.40%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,987	$ 25,026.40	$ 8.38	1.34%
VYVANSE	AMPHETAMINES	2,716	$ 406,685.84	$ 149.74	1.21%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,628	$ 22,687.64	$ 8.63	1.17%
SERTRALINE HCL	ANTIDEPRESSANTS	2,567	$ 22,032.61	$ 8.58	1.15%
TRAZODONE HCL	ANTIDEPRESSANTS	2,405	$ 15,836.93	$ 6.59	1.08%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,334	$ 15,002.59	$ 6.43	1.04%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	2,267	$ 39,456.35	$ 17.40	1.01%
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	2,263	$ 19,493.01	$ 8.61	1.01%
DEXTROAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,256	$ 367,508.22	$ 162.90	1.01%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	2,222	$ 13,646.22	$ 6.14	0.99%
CITALOPRAM HBR	ANTIDEPRESSANTS	2,076	$ 13,225.41	$ 6.37	0.93%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	2,076	$ 32,087.76	$ 15.46	0.93%
CEPHALEXIN	CEPHALOSPORINS	2,065	$ 23,390.42	$ 11.33	0.92%
CEFDINIR	CEPHALOSPORINS	1,972	$ 76,770.69	$ 38.93	0.88%
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	1,958	$ 53,448.96	$ 27.30	0.88%
TOTAL TOP 25		79,869	$ 2,910,223.61	$ 36.44	35.71%

Total Rx Claims From 04/01/2012 - 06/30/2012	223,677

Top 10 Drugs
Based on Number of Claims

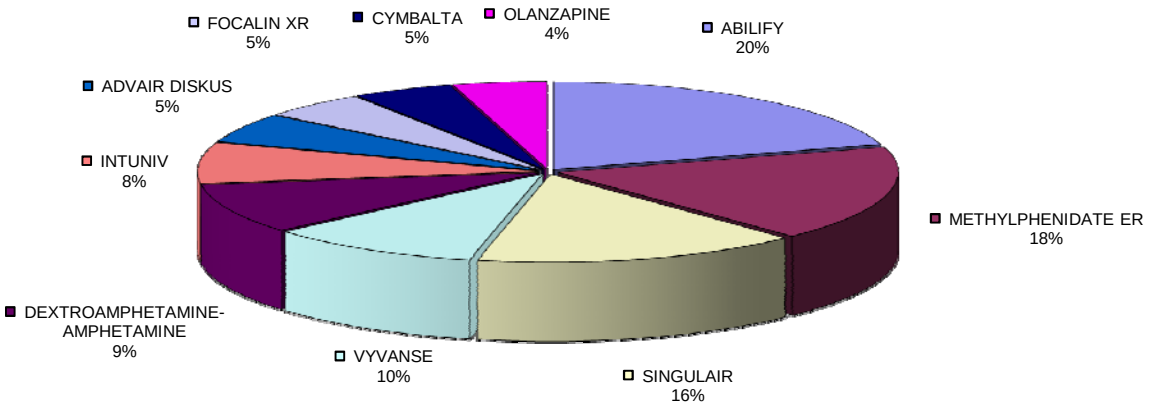


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2012 - 06/30/2012

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,612	$ 815,592.54	$ 505.95	0.72%
METHYLPHENIDATE ER	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	4,096	$ 703,147.82	$ 171.67	1.83%
SINGULAIR	LEUKOTRIENE MODIFIERS	4,146	$ 620,351.96	$ 149.63	1.85%
VYVANSE	AMPHETAMINES	2,716	$ 406,685.84	$ 149.74	1.21%
DEXTROAMPHETAMINE-AMPHETAMINE	AMPHETAMINES	2,256	$ 367,508.22	$ 162.90	1.01%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,853	$ 301,624.11	$ 162.78	0.83%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	943	$ 217,825.94	$ 230.99	0.42%
FOCALIN XR	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,151	$ 200,080.60	$ 173.83	0.51%
CYMBALTA	ANTIDEPRESSANTS	966	$ 191,105.54	$ 197.83	0.43%
OLANZAPINE	ANTIPSYCHOTIC AGENTS	517	$ 178,743.53	$ 345.73	0.23%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	959	$ 174,137.93	$ 181.58	0.43%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	131	$ 163,585.06	$ 1,248.74	0.06%
OXYCONTIN	OPIATE AGONISTS	474	$ 151,428.17	$ 319.47	0.21%
NOVOLOG	INSULINS	672	$ 150,795.83	$ 224.40	0.30%
PULMOZYME	ENZYMES	52	$ 149,279.10	$ 2,870.75	0.02%
PREVACID	PROTON-PUMP INHIBITORS	732	$ 143,447.69	$ 195.97	0.33%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	65	$ 142,602.06	$ 2,193.88	0.03%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	890	$ 127,946.74	$ 143.76	0.40%
GENOTROPIN	PITUITARY	71	$ 125,969.25	$ 1,774.21	0.03%
INCIVEK	HCV PROTEASE INHIBITORS	7	$ 124,130.86	$ 17,732.98	0.00%
ONE TOUCH ULTRA TEST STRIPS	DIABETES MELLITUS	741	$ 120,274.73	$ 162.31	0.33%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,389	$ 119,131.63	$ 85.77	0.62%
NEXIUM	PROTON-PUMP INHIBITORS	556	$ 117,972.70	$ 212.18	0.25%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	580	$ 116,184.29	$ 200.32	0.26%
SEROQUEL XR	ANTIPSYCHOTIC AGENTS	293	$ 114,527.66	$ 390.88	0.13%
TOTAL TOP 25		27,868	$ 6,044,079.80	$ 216.88	12.46%

Total Rx Claims From 04/01/2012 - 06/30/2012	223,677

Top 10 Drugs
Based on Total Claims Cost



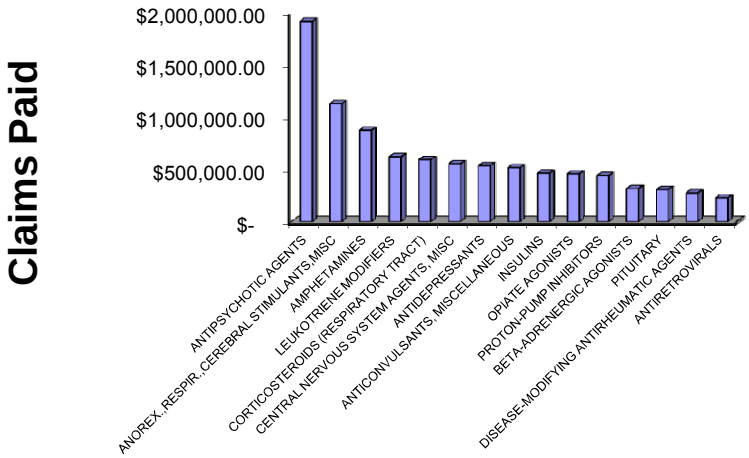
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2012 - 06/30/2012

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	7,810	$ 1,915,768.69	$ 245.30	3.49%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	6,741	$ 1,129,937.32	$ 167.62	3.01%
AMPHETAMINES	6,003	$ 874,598.63	$ 145.69	2.68%
LEUKOTRIENE MODIFIERS	4,152	$ 620,769.84	$ 149.51	1.86%
CORTICOSTEROIDS (RESPIRATORY TRACT)	3,062	$ 594,538.55	$ 194.17	1.37%
CENTRAL NERVOUS SYSTEM AGENTS, MISC	2,864	$ 554,754.24	$ 193.70	1.28%
ANTIDEPRESSANTS	17,336	$ 535,764.61	$ 30.90	7.75%
ANTICONVULSANTS, MISCELLANEOUS	8,357	$ 517,743.39	$ 61.95	3.74%
INSULINS	2,180	$ 465,928.54	$ 213.73	0.97%
OPIATE AGONISTS	15,957	$ 458,801.85	$ 28.75	7.13%
PROTON-PUMP INHIBITORS	6,621	$ 442,248.55	$ 66.79	2.96%
BETA-ADRENERGIC AGONISTS	6,683	$ 318,167.92	$ 47.61	2.99%
PITUITARY	599	$ 307,604.00	$ 513.53	0.27%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	149	$ 274,956.20	$ 1,845.34	0.07%
ANTIRETROVIRALS	251	$ 228,253.02	$ 909.37	0.11%
TOTAL TOP 15	88,765	$ 9,239,835.35	$ 104.09	39.68%

Total Rx Claims From 04/01/2012 - 06/30/2012	223,677

Top 15 Therapeutic Classes
Based on Total Cost of Claims



LIDODERM
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 Lidoderm must meet the following criteria:

- **Patient must have a diagnosis of post-herpetic neuralgia.**

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: □ Lidoderm	Diagnosis for this request:
Dosing Instructions:	
PHYSICIAN SIGNATURE:	DATE:

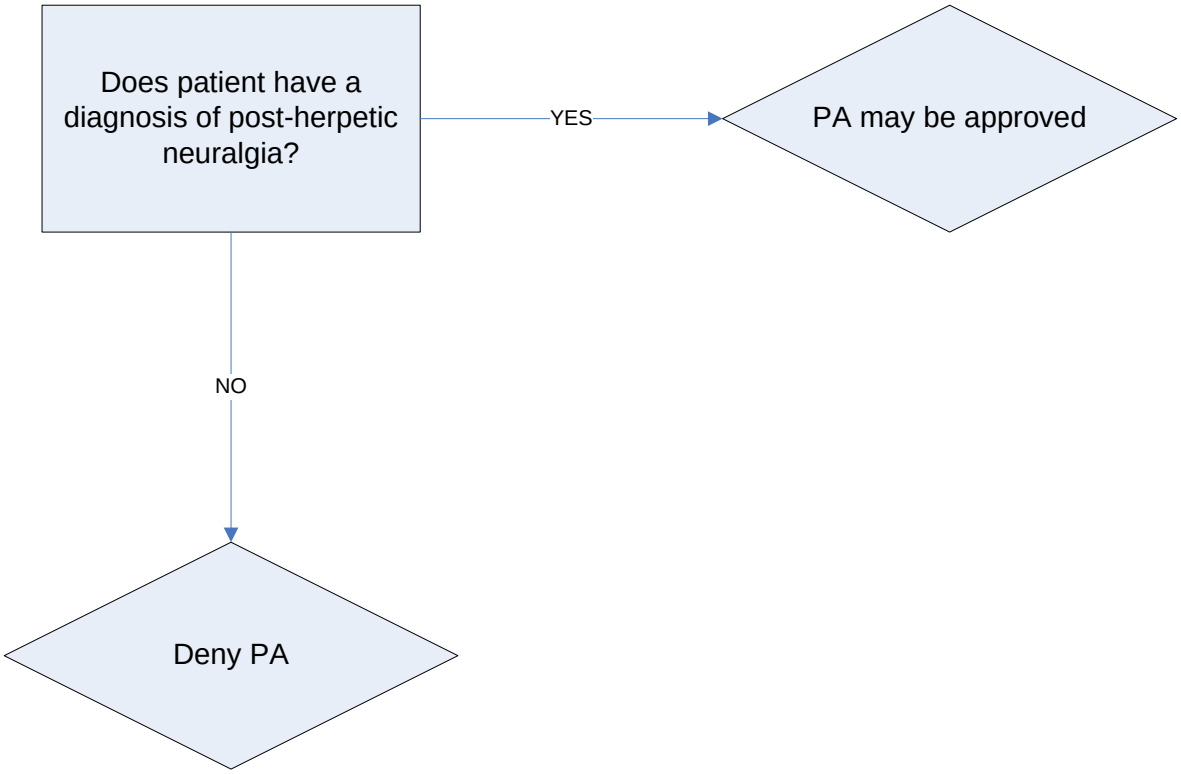
Part IV: PHARMACY INFORMATION

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

Part V: FOR OFFICIAL USE ONLY

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

South Dakota Department of Social Services
Lidoderm Prior Authorization Algorithm



Early Refill Edit

The Point-of-Sale system is currently set to deny for early refill before 70% of the previous prescription has been consumed.

Example: For a 30 day prescription (30 * 0.7=21), the prescription can be refilled on day 22. If a recipient fills the prescription every 22 days for one year they will have filled 17 prescriptions, all for a 30 day supply. This equates to 510 tabs in one year for a quantity 30 prescription.

Adjusting the early refill percentage to 80% would allow the recipient to refill on day 25.

Based on available data for 20 states, five are at 75%; the remaining 15 are between 80%-90%.

Edit %	Fill date
70%	22 days
73.3%	23 days
76.6%	24 days
80%	25 days
83.3%	26 days
86.6%	27 days
90%	28 days
93.3%	29 days

Review Period: 01/01/12 - 03/31/12

Top 50 Drugs by Script Count filled between days 22 to 24

OMEPRAZOLE	105
METHYLPHENIDATE ER	94
CLONAZEPAM	91
FLUOXETINE HCL	76
DEXTROAMPHETAMINE-AMPHETAMINE	75
CITALOPRAM HBR	73
SINGULAIR	73
VYVANSE	73
CETIRIZINE HCL	72
CLONIDINE HCL	71
TRAZODONE HCL	69
GABAPENTIN	68
LORAZEPAM	65
LEVOTHYROXINE SODIUM	59
SERTRALINE HCL	54
LISINOPRIL	54
INTUNIV	53
ABILIFY	51
TRAMADOL HCL	50
ZOLPIDEM TARTRATE	49
HYDROCODONE-ACETAMINOPHEN	48
RISPERIDONE	47
SEROQUEL	41
ALPRAZOLAM	35
METFORMIN HCL	33
FOCALIN XR	31
RANITIDINE HCL	31
AMITRIPTYLINE HCL	30
LORATADINE	27
LEVETIRACETAM	27
LAMOTRIGINE	26
CYCLOBENZAPRINE HCL	25
BUPROPION XL	25
CYMBALTA	25
LANSOPRAZOLE	24
POLYETHYLENE GLYCOL 3350	24
FUROSEMIDE	24
DIVALPROEX SODIUM	23
TOPIRAMATE	22
STRATTERA	22
LYRICA	22
WARFARIN SODIUM	22
MIRTAZAPINE	22
AMLODIPINE BESYLATE	22
DIAZEPAM	21
FOLIC ACID	21
PREVACID	21
LEXAPRO	20
BACLOFEN	20
SIMVASTATIN	20

ONFI
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 Onfi must meet the following criteria:

- **Patient must have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS).**
- **Patient must be 2 years of age or older.**

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: □ Onfi	Diagnosis for this request:
Dosing Instructions:	
PHYSICIAN SIGNATURE:	DATE:

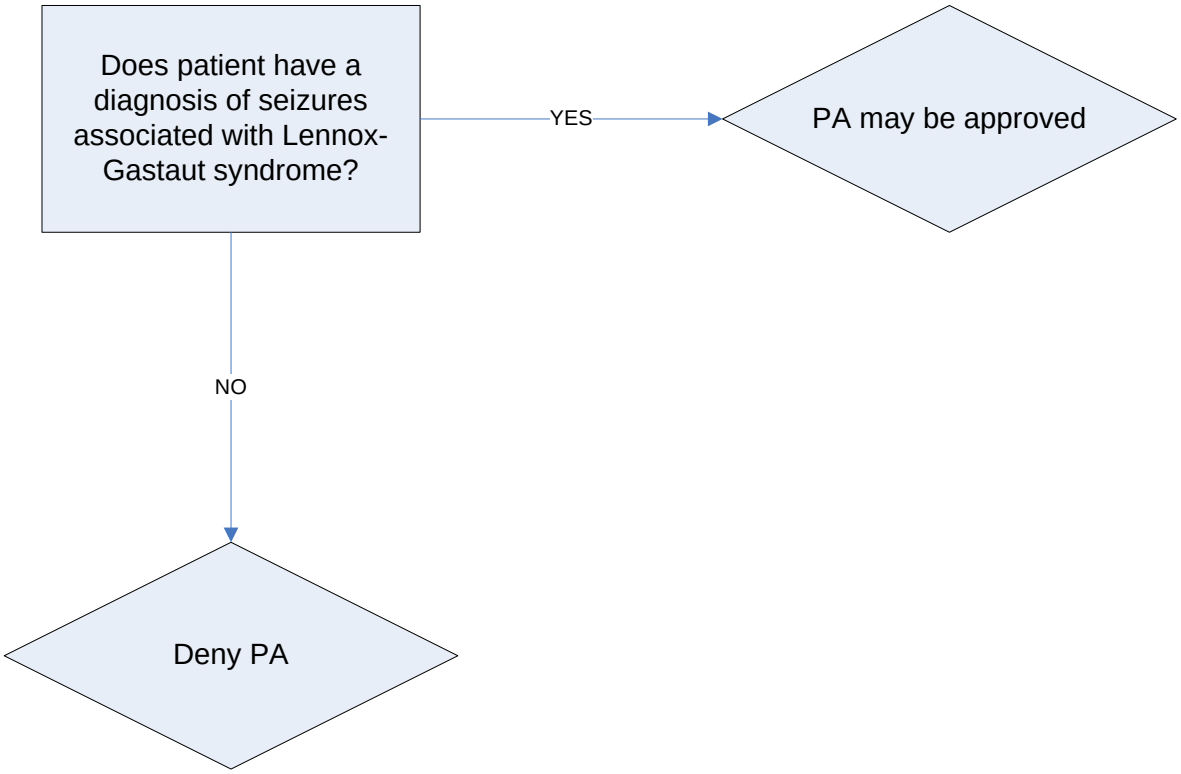
Part IV: PHARMACY INFORMATION

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

Part V: FOR OFFICIAL USE ONLY

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

South Dakota Department of Social Services
Onfi Prior Authorization Algorithm



South Dakota Department of Social Services
P&T Meeting
Corticosteroid Inhalants

I. Overview

Inhaled corticosteroids (ICSs) are the most effective anti-inflammatory medications for the treatment of persistent asthma. Studies have demonstrated their efficacy in reducing asthma symptoms, improving quality of life, improving lung function, decreasing airway hyperresponsiveness, controlling airway inflammation, reducing frequency and severity of exacerbations and reducing asthma mortality.

Inhaled corticosteroids differ in product formulation and delivery. ICSs can be delivered via nebulization, pressurized metered dose inhaler, or dry powder inhaler. There is marked individual variability of responsiveness to ICSs and because of this and recognized poor adherence to treatment, many patients will require higher doses to achieve full therapeutic benefit.

In general, ICSs are favored over oral corticosteroids because their anti-inflammatory effect is directed at the airways, which reduces the risk of unwanted systemic effects. Seven different ICSs currently are available in the United States: beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, and triamcinolone.

Corticosteroid Inhalants Included in this Review

Generic Name	Brand Name	Dosage Form	Generic Availability	Manufacturer
Beclomethasone dipropionate	Qvar®	Aerosol inhaler	No	Ivax
Budesonide	Pulmicort Flexhaler®, Pulmicort Respules®	Powder for oral inhalation, Inhalation suspension	Yes (suspension)	AstraZeneca
Budesonide/formoterol	Symbicort®	Aerosol inhaler	No	AstraZeneca
Ciclesonide	Alvesco®	Aerosol inhaler	No	Sunovion
Fluticasone propionate	Flovent Diskus®, Flovent HFA®	Powder for oral inhalation, Aerosol inhaler	No	GlaxoSmithKline
Fluticasone/salmeterol	Advair Diskus®, Advair HFA®	Powder for oral inhalation, Aerosol inhaler	No	GlaxoSmithKline
Mometasone furoate	Asmanex®	Powder for oral inhalation	No	Schering
Mometasone/formoterol	Dulera®	Aerosol inhaler	No	Schering

II. FDA Approved Indications

FDA-Approved Indications for the Single Entity Corticosteroid Inhalants

Indication	Beclomethasone	Budesonide	Ciclesonide	Fluticasone	Mometasone
Maintenance treatment of asthma as prophylactic therapy in patients 12 months to 8 years of age		✓‡			
Maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older	✓				
Maintenance and treatment of asthma as prophylactic therapy in patients 6 years of age and older		✓†			
Maintenance and treatment of asthma as prophylactic therapy in patients 4 years of age and older				✓	✓
Maintenance and treatment of asthma as prophylactic therapy in patients 12 years of age and older			✓		
Patients requiring systemic corticosteroid administration	✓			✓	

† Powder for inhalation
‡ Inhalation suspension

FDA Approved Indications for the Combination Corticosteroid Inhalants

Indication	Budesonide/ Formoterol	Fluticasone/Salmeterol Diskus	Fluticasone/Salmeterol HFA	Mometasone/ Formoterol
Maintenance treatment of asthma in patients 12 years of age and older.	✓		✓	✓
Treatment of asthma in patients 4 years of age and older.		✓		

Indication	Budesonide/ Formoterol	Fluticasone/Salmeterol Diskus	Fluticasone/Salmeterol HFA	Mometasone/ Formoterol
Maintenance treatment of airflow obstruction in patients with COPD associated with chronic bronchitis and/or emphysema.		✓*		
Reduce exacerbations of COPD in patients with a history of exacerbations.		✓*		

* 250/50mcg is the only strength FDA approved for this indication

III. Pharmacology

Corticosteroids may have direct inhibitory effects on many cells involved in airway inflammation in asthma (e.g., macrophages, T lymphocytes, eosinophils, airway epithelial cells). In vitro, corticosteroids decrease cytokine-mediated survival of eosinophils, reducing the number of eosinophils in the circulation and airways of patients with asthma during corticosteroid therapy. While corticosteroids may not inhibit the release of mast cells in an allergic reaction, they do reduce the number of mast cells within the airway. Corticosteroids may also inhibit plasma exudation and the secretion of mucous in inflamed airways.

Inhaled corticosteroids have anti-inflammatory effects of the bronchial mucosa in asthma patients. Treatment with inhaled corticosteroids for 1 to 3 months results in a reduction in mast cells, macrophages, T lymphocytes, and eosinophils in the epithelium and submucosa in the bronchioles. By reducing airway inflammation, inhaled corticosteroids lessen airway hyperresponsiveness in asthmatic adults and children. Long-term therapy reduces airway responsiveness to histamine cholinergic agonists and allergens. Treatment also lowers responsiveness to exercise, fog, cold air, bradykinin, adenosine, and irritants. Inhaled corticosteroids make the airways less sensitive to these spasmogens and limit the maximal narrowing of the airway. Maximal effects of inhaled corticosteroid treatment may not be seen for several months.

IV. Drug Interactions

Table 6. Significant Drug Interactions with the Corticosteroid Inhalants Included in this Review

Drug	Interaction	Description
Budesonide, ciclesonide, fluticasone, mometasone	Ketoconazole	Potent inhibitor of CYP3A4 and may increase plasma levels during concomitant dosing.
Ciclesonide	Delavirdine, protease inhibitors	Plasma levels of ciclesonide may be increased.

V. Adverse Drug Events

Common Adverse Events (%) Reported with the Single Entity Corticosteroid Inhalants

Adverse Event(s)	Beclomethasone	Budesonide	Ciclesonide	Fluticasone	Mometasone
Cardiovascular					
Chest pain	< 2	1 - 3[‡]	<1	-	-
Tachycardia	< 2	-	-	-	-
CNS					
Headache	12	13 - 14[†]	5-11	17 - 22[#] 9 - 15[†]	22
Insomnia	< 2	1 - 3[†]	-	-	-
Migraine	< 2	1 - 3[†]	-	1 - 3[†]	-
GI					
Abdominal pain	-	1 - 3[†] 2 - 3[‡]	≥ 3	1 – 3[†]	6
Anorexia	-	1 - 3[‡]	-	-	1 to <3
Diarrhea	< 2	2 - 4[‡]	-	1 - 3[#] < 4[†]	-
Dry mouth	-	1 - 3[†]	-	-	-
Dyspepsia	-	1 - 4[†]	-	1 - 3[#]	5
Gastroenteritis	-	1 - 3[†] 5[‡]	-	1 – 3[†]	1 to <3
Nausea	1	1 - 3[†]	<1	1 - 3[#]	3
Oral candidiasis	-	2 - 4[†]	<1	2 - 5[#] 3 - 11[†]	6
Vomiting	-	1 - 3[†] 2 - 4[‡]	≥3	1 - 3[#]	3
Miscellaneous					
Back Pain	1	2 - 6[†]	≥3	-	6
Bronchitis	< 2	-	-	1 - 3[#] 1 – 4[†]	-
Bronchospasm	Rare	-	-	Rare	-
Chest congestion	< 2	-	-	1 - 3[#,†]	-

Adverse Event(s)	Beclomethasone	Budesonide	Ciclesonide	Fluticasone	Mometasone
Conjunctivitis	-	< 1 – 4‡	≥3	1 – 3†	-
Cough	1 - 3	5 - 9‡	<1	-	-
Dysphonia	1 - 3	1 - 3‡	<1	3 - 8# < 1 – 6†	1 to <3
Earache	< 2	1 - 3‡	-	1 – 3†	1 to <3
Ear infection	-	2 - 5‡	-	-	-
Epistaxis	-	2 - 4‡	-	1 – 3†	1 to <3
Fever	< 2	< 4†	-	1 - 3# 2 – 4†	7
Flu Syndrome	-	6 – 14† 1 - 3‡	≥3	3 - 8# 3 - 4†	-
Infection	-	1 - 3†, ‡	-	-	1 to <3
Nasal congestion	-	-	2-6	8 - 16# 4 – 7†	-
Otitis media	-	9 - 12‡	-	1 – 3†	-
Pharyngitis	8	5 - 10†	0	10 - 14# 6 – 13†	8 - 13
Rhinitis	6	7 - 12‡	1	1 - 3# 2 – 9†	-
Sinusitis	3	2 - 11†	3-6	3 - 6# 4 – 6†	6
Sneezing	-	-	-	1 – 3†	-
URTI	9	19 – 24† 34 - 38‡	4-9	15 - 22# 16 - 22†	15
Viral Infection	-	3 - 5‡	-	-	-
Weight changes	-	1 - 3†	1 - 3	-	-

† Powder for inhalation
‡ Inhalation suspension
# Aerosol inhaler

Common Adverse Events (%) Reported with the Combination Corticosteroid Inhalants

Adverse Event(s)	Budesonide/Formoterol	Fluticasone/Salmeterol	Mometasone/Formoterol
CNS			
Headache	6.5 – 11.3	12 – 13	2 – 4.5

Adverse Event (s)	Budesonide/Formoterol	Fluticasone/Salmeterol	Mometasone/Formoterol
GI			
Diarrhea	-	2 – 4	-
GI discomfort and pain	-	1 – 4	-
Nausea	-	4 – 6	-
Oral candidiasis	1.4 – 3.2	1 – 4	-
Stomach discomfort	1.1 – 6.5	-	-
Viral GI infections	-	0 – 3	-
Vomiting	1.4 – 3.2	4 – 6	-
Respiratory			
Bronchitis	-	2 – 8	-
Cough	-	3 – 6	-
Influenza	2.4 – 3.2	-	-
Nasal congestion	2.5 – 3.2	-	-
Nasopharyngitis	9.7 – 10.5	10 – 13	4.7
Pharyngolaryngeal pain	6.1 – 8.9	-	-
Sinusitis	4.8 – 5.8	4 – 5	2 – 3.3
Upper respiratory tract infection	7.6 – 10.5	21 – 27	-
Upper respiratory tract inflammation	-	6 – 7	-
Viral respiratory infections	-	4	-
Miscellaneous			
Back pain	1.6 - 3.2	-	-
Hoarseness/dysphonia	-	2 - 5	-
Musculoskeletal pain	-	2 - 4	-
Nonsite specific candidiasis	-	0 - 3	-

Black Box Warning for Symbicort®

Long-acting beta-2 adrenergic agonists (LABAs) such as formoterol, one of the active ingredients in budesonide/formoterol, increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another LABA

(salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of the LABAs, including formoterol. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABAs. Available data from controlled clinical trials suggest that LABAs increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, only use budesonide/formoterol for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or for patients whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue budesonide/formoterol) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication such as an inhaled corticosteroid. Do not use budesonide/formoterol for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

Black Box Warning for Advair®

Long-acting beta-2 adrenergic agonists such as salmeterol may increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of salmeterol or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol (13 deaths of 13,176 patients treated for 28 weeks on salmeterol vs 3 deaths of 13,179 patients on placebo). Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma-control drugs mitigates the increased risk of asthma-related death from long-acting beta-2 adrenergic agonists. Available data from controlled clinical trials suggest that long-acting beta-2 adrenergic agonists increase the risk of hospitalization in children and adolescents.

Therefore, when treating patients with asthma, only prescribe fluticasone/salmeterol for patients not adequately controlled on a long-term asthma-control medication (e.g., inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and long-acting beta-2 adrenergic agonist. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue fluticasone/salmeterol) if possible without loss of asthma control, and maintain the patient on a long-term asthma-control medication, such as an inhaled corticosteroid. Do not use fluticasone/salmeterol for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

Black Box Warning for Dulera®

Asthma-related death: Long-acting beta$_2$-adrenergic agonists (LABAs), such as formoterol, one of the active ingredients in mometasone/formoterol, increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another LABA (salmeterol) with placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with

salmeterol is considered a class effect of the LABAs, including formoterol. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABAs. Available data from controlled clinical trials suggest that LABAs increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, use mometasone/formoterol only in patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or in patients whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals, step down therapy (e.g., discontinue mometasone/formoterol) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication such as an inhaled corticosteroid. Do not use mometasone/formoterol for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

VI. Dosing and Administration

Generic Name(s)	Usual Adult Dose	Usual Pediatric Dose	Availability
Beclomethasone	Asthma: 40 to 160 mcg twice daily; maximum, 320 mcg twice daily	Asthma: ≥5 years of age: 40 mcg twice daily; maximum, 80 mcg twice daily.	Aerosol inhaler: 40 mcg 80 mcg
Budesonide	Asthma: Dry powder inhaler: 180 to 360 mcg twice daily; maximum, 720 mcg twice daily	Asthma: Dry powder inhaler: ≥6 years of age: 180 mcg twice daily; maximum, 360 mcg twice daily Inhalation suspension: 12 months to 8 years: 0.5mg total daily dose administered once or twice daily; maximum, 1 mg total daily dose	Dry powder inhaler: 90 mcg 180 mcg Inhalation suspension: 0.25 mg/2 ml 0.5 mg/2 ml 1 mg/2 ml
Budesonide and formoterol	Asthma: 2 inhalations (80-4.5 mcg or 160-4.5 mcg) twice daily COPD: 2 inhalations (80-4.5 mcg or 160-4.5 mcg) twice daily	Asthma: ≥12 years of age: 2 inhalations (80-4.5 mcg or 160-4.5 mcg) twice daily	Aerosol inhaler: 80-4.5 mcg 160-4.5 mcg

Generic Name(s)	Usual Adult Dose	Usual Pediatric Dose	Availability
Ciclesonide	Asthma: 80 mcg twice daily; maximum, 320 mcg twice daily	Asthma: ≥12 years of age: 80 mcg twice daily; maximum, 320 mcg twice daily	Aerosol inhaler: 80 mcg 160 mcg
Fluticasone	Asthma: Aerosol inhaler: 88 to 220 mcg twice daily; maximum, 880 mcg twice daily Dry powder inhaler: 100 to 250 mcg twice daily; maximum, 1,000 mcg twice daily	Asthma: Aerosol inhaler: 4-11 years of age: 88 mcg twice daily; maximum, 88 mcg twice daily ≥12 years of age: 88 to 220 mcg twice daily; maximum, 880 mcg twice daily Dry powder inhaler: 4-11 years of age: 50 mcg twice daily; maximum, 100 mcg twice daily ≥12 years of age: 100 to 250 mcg twice daily; maximum, 1,000 mcg twice daily	Aerosol inhaler: 44 mcg 110 mcg 220 mcg Dry powder inhaler: 50 mcg 100 mcg 250 mcg
Fluticasone and salmeterol	Asthma: Aerosol inhaler: 2 inhalations twice daily (based on patient's current asthma therapy); maximum, 2 inhalations (of 230/21 mcg formulation) twice daily Dry powder inhaler: 1 inhalation (100-50 mcg, 250-50 mcg, 500-50 mcg) twice daily	Asthma: Aerosol inhaler: ≥12 years of age: 2 inhalations twice daily (based on prior asthma therapy); maximum, 2 inhalations (230/21 mcg) twice daily Dry powder inhaler: 4-11 years of age: 1 inhalation (100-50 mcg) twice daily ≥12 years of age: 1 inhalation (100-50 mcg, 250-50 mcg, 500-50 mcg) twice daily	Aerosol inhaler: 45-21 mcg 115-21 mcg 230-21 mcg Dry powder inhaler: 100-50 mcg 250-50 mcg 500-50 mcg

Generic Name(s)	Usual Adult Dose	Usual Pediatric Dose	Availability
	COPD: Dry powder inhaler: 1 inhalation (250-50 mcg) twice daily		
Mometasone	Asthma: 220 mcg once daily in the evening; maximum, 880 mcg per day	Asthma: 4-11 years of age: 110 mcg once daily in the evening; maximum, 110 mcg once daily ≥12 years of age: 220 mcg once daily in the evening: maximum, 880 mcg per day	Dry powder inhaler: 110 mcg 220 mcg
Mometasone and formoterol	Asthma: 2 inhalations (100-5 mcg or 200-5 mcg) twice daily based on prior asthma therapy; maximum, 800-20 mcg	Asthma: ≥12 years of age: 2 inhalations (100-5 mcg or 200-5 mcg) twice daily based on prior asthma therapy; maximum, 800-20 mcg.	Aerosol inhaler: 100-5 mcg 200-5 mcg

VII. Utilization

Inhaled Corticosteroid Utilization			
07/26/11 - 07/25/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
BUDESONIDE 0.25 MG/2 ML SUSP	698	$144,921.48	$207.62
BUDESONIDE 0.5 MG/2 ML SUSP	1099	$278,713.95	$253.61
PULMICORT 0.25 MG/2 ML RESPUL	24	$7,522.91	$313.45
PULMICORT 0.5 MG/2 ML RESPULE	13	$5,510.52	$423.89
PULMICORT 1 MG/2 ML RESPULE	69	$37,218.16	$539.39
PULMICORT 180 MCG FLEXHALER	136	$20,652.90	$151.86
PULMICORT 90 MCG FLEXHALER	24	$2,735.49	$113.98
QVAR 40 MCG INHALER	70	$5,946.27	$84.95
QVAR 80 MCG INHALER	106	$12,005.74	$113.26
SYMBICORT 160-4.5 MCG INHALER	547	$109,277.37	$199.78
SYMBICORT 80-4.5 MCG INHALER	178	$30,590.36	$171.86
1,244 recipients	2964	$655,095.15	

References

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisions. St. Louis, MO. 2012.
2. Advair HFA® [package insert] Research Triangle Park, NC: GlaxoSmithKline; January 2011.
3. Advair Diskus® [package insert] Research Triangle Park, NC: GlaxoSmithKline; January 2011.
4. Flovent HFA® [package insert] Research Triangle Park, NC: GlaxoSmithKline; January 2012.
5. Flovent Diskus® [package insert] Research Triangle Park, NC: GlaxoSmithKline; September 2011.
6. Pulmicort Flexhaler® [package insert] Wilmington, DE: AstraZeneca; May 2011.
7. Qvar® [package insert] Horsham, PA: Teva Respiratory, LLC; May 2012.
8. Symbicort [package insert] Wilmington, DE: AstraZeneca; June 2010.
9. Dulera [package insert] Whitehouse Station, NJ: Merck & Co., Inc.; August 2012.
10. Alvesco [package insert] Marlborough, MA: Sunovion Pharmaceuticals, Inc.; September 2011.
11. Asmanex [package insert] Whitehouse Station, NJ: Merck & Co., Inc.; July 2012.

South Dakota Department of Social Services
P&T Meeting
Intranasal Steroid Review

I. Overview

Intranasal corticosteroids are one of the most effective medications used to treat allergic rhinitis. These agents produce direct local anti-inflammatory effects with minimal systemic side effects when used within recommended dosing guidelines. More than 50 million Americans suffer from allergic diseases, and allergic rhinitis (AR) is estimated to affect 10 to 30% of adults and up to 40% of children. The common signs and symptoms of AR include runny/itchy nose, sneezing, tearing eyes, and problems with smell. Symptoms that may develop later include stuffy nose, coughing, clogged ears, sore throat, dark circles under the eyes, puffiness under the eyes, fatigue, irritability and headache. Although generally thought to be a mildly disturbing malady, allergic rhinitis can actually have a significant impact on the quality of life for both adults and children, resulting in school absenteeism and decreased work productivity. Additionally, untreated or poorly controlled allergic rhinitis can lead to increased prevalence of several comorbidities. These include worsening asthma, sinusitis, otitis media, sleep disorders, and nasal polyps. It is estimated that allergies are the 5th most common chronic illness, costing the United States healthcare system about 14.5 billion dollars annually.

Treatment of allergic and non-allergic rhinitis includes trigger avoidance, environmental modification, and pharmacologic therapy. Medication management may target symptom relief or the underlying inflammatory response. Treatment options include oral antihistamines, intranasal corticosteroids, intranasal antihistamines, oral decongestants, oral corticosteroids, intranasal cromolyn sodium, oral anti-leukotriene agents, and intranasal ipratropium bromide. Patients with severe rhinitis may benefit from allergen immunotherapy. As will be discussed, intranasal corticosteroids play a very important role in the management of allergic rhinitis.

Intranasal Corticosteroids Included in this Review

Generic Name	Brand Name
Beclomethasone dipropionate monohydrate	Beconase AQ®, Qnasl®
Budesonide	Rhinocort Aqua®
Ciclesonide	Omnaris®, Zetonna®
Flunisolide	Various generics
Fluticasone propionate	Flonase®**
Fluticasone propionate/azelastine	Dymista®
Fluticasone furoate	Veramyst®
Mometasone furoate monohydrate	Nasonex®
Triamcinolone acetonide	Nasacort AQ®**

**Available generically.

II. FDA Approved Indications

All of the nasal corticosteroids are approved to treat allergic rhinitis. The table below outlines the specific types of rhinitis and the age guidelines as outlined by the FDA.

FDA Approved Indications for the Intranasal Corticosteroids

Generic Name	FDA Approved Indications
Beclomethasone	Beconase: Adults and children 6 years of age and older – Seasonal or perennial and nonallergic rhinitis; Prevention of recurrence of nasal polyps. Qnasl: Adults and adolescents 12 years of age and older – Seasonal and perennial allergic rhinitis.
Budesonide	Rhinocort Aqua: Adults and children 6 years of age and older – Seasonal and perennial allergic rhinitis.
Ciclesonide	Omnaris: Adults and children 6 years of age and older – Seasonal and perennial allergic rhinitis. Zetonna: Adults and children 12 years of age and older – Seasonal and perennial allergic rhinitis.
Flunisolide	Various generics: Seasonal and perennial allergic rhinitis.
Fluticasone propionate	Various generics: Adults and children 4 years of age and older – Seasonal, perennial, and nonallergic rhinitis.
Fluticasone propionate/azelastine hydrochloride	Dymista: Adults and children 12 years of age and older – Seasonal allergic rhinitis.
Fluticasone furoate	Veramyst: Adults and children 2 years of age and older – Seasonal and perennial allergic rhinitis.
Mometasone	Nasonex: Adults and children 2 years of age and older – Seasonal rhinitis, perennial rhinitis and nasal congestion associated with seasonal rhinitis. Adults and children 12 years of age and older – Prophylaxis of allergic rhinitis. Adults 18 years of age and older – Treatment of nasal polyps.
Triamcinolone	Various generics: Adults and children 2 years of age and older – Seasonal and perennial rhinitis.

III. Pharmacology

This class of drugs has potent glucocorticoid activity and weak mineralocorticoid activity. The exact mechanisms of action of these drugs in the nasal mucosa is unknown, however, these drugs have inhibitory actions on many different types of cells (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in allergic and nonallergic/irritant-mediated inflammation. These agents, when administered topically in recommended doses, exert direct local anti-inflammatory effects with minimal systemic effects.

IV. Warnings and Precautions

- Special senses**:** Temporary or permanent loss of the sense of smell and taste has been reported with flunisolide.

- Systemic corticosteroids: The combined administration of alternate-day systemic prednisone with these products may increase the likelihood of HPA suppression.

- Hypercorticism: If recommended doses of intranasal corticosteroids are exceeded or if individuals are sensitive, symptoms of hypercorticism may occur, including menstrual irregularities, acneiform lesions, cataracts, and cushingoid features. If such changes occur, discontinue slowly.

- Nasopharyngeal irritation: If persistent nasopharyngeal irritation occurs, it may be an indication to stop therapy.

- Epistaxis: Observed more frequently in patients with allergic rhinitis treated with beclomethasone or mometasone compared with those who received placebo in clinical studies.

- Ophthalmic effects: Rare instances of cataracts, glaucoma, and increased intraocular pressure have been reported following intranasal application of corticosteroids.

- Infections: Localized *Candida albicans* infections of the nose and pharynx have been reported only rarely in users of intranasal steroids. As expected, patients receiving immunosuppressant therapy may be more susceptible to infections. Corticosteroids should be used with caution in patients with active or quiescent tuberculosis infection; untreated fungal, bacterial, or systemic viral infections; or ocular herpes simplex.

- Nasal septum perforation: Rare instances of nasal septum perforation have been reported following the intranasal application of corticosteroids.

- Wound healing: Because of the inhibitory effect of corticosteroids on wound healing, do not use nasal steroids in patients who have experienced recent nasal septal ulcers, recurrent epistaxis, or nasal surgery or trauma until healing has occurred.

- Effect on growth: Intranasal corticosteroids may cause a reduction in growth velocity when administered to children.

- Vasoconstrictors: In the presence of excessive nasal mucosa secretion or edema of the nasal mucosa, the drug may fail to reach the site of intended action. In such cases, use a nasal vasoconstrictor during the first 2 to 3 days of therapy.

- Respiratory effects: Rare instances of wheezing have been reported following intranasal application of corticosteroids.

- Systemic effects: Although systemic effects are low when used in recommended dosage, HPA suppression and other systemic effects may occur, especially with excessive doses.

- Hypersensitivity reactions: Rare cases of immediate and delayed hypersensitivity reactions, including angioedema, bronchospasm, rash, and urticaria, have been reported after intranasal administration of corticosteroids.

V. Drug Interactions

Concerns regarding drug-drug interactions with the inhaled nasal corticosteroids are limited due to the method of administration and relatively low systemic bioavailability with most of these agents. There is slight potential for absorption into systemic circulation which may occur through absorption in the nasal mucosa as well as through the gastrointestinal tract from swallowing the inhaled drug.

There are no significant drug interactions reported for beclomethasone, flunisolide, mometasone, or triamcinolone. Budesonide, ciclesonide, and fluticasone are metabolized in the liver via the CYP3A system, so there is potential for these drugs to interact with other medications. Drugs which inhibit the CYP3A4 system (e.g., clarithromycin, ketoconazole, itraconazole, erythromycin, cimetidine, ritonavir) inhibit metabolism of the steroid and may increase systemic exposure.

VI. Adverse Effects

The most common side effects of this class of drugs include local effects such as nasal irritation, dryness, and bleeding. Headache, lightheadedness, urticaria, nausea, epistaxis, rebound congestion, bronchial asthma, and insomnia have also

been reported, although not commonly. Nasal septal perforations have been reported rarely and patients should be instructed to direct sprays away from the nasal septum during administration.

VII. Dosing and Administration

Dosing and Administration Guidelines of the Intranasal Corticosteroids

Drug	Dosing and Administration		
	Age	Recommended Daily Dose	Maximum Daily Dose
Beclomethasone	≥12 years old	Beconase: 1 or 2 inhalations in each nostril 2 times a day. Qnasl: 2 sprays in each nostril once daily.	Beconase: 2 inhalations in each nostril 2 times a day. *Discontinue in 3 weeks if no improvement. Qnasl: 4 nasal sprays per day.
	6-12 years old	Beconase: 1 inhalation in each nostril 2 times a day.	
Budesonide	≥6 years old	1 spray in each nostril once daily.	**≥12 years old:** 4 sprays in each nostril once daily. **6-11 years old:** 2 sprays in each nostril once daily.
Ciclesonide	≥12 years old	Zetonna: 1 spray in each nostril once daily.	**Zetonna:** 1 spray in each nostril per day. **Omnaris:** 2 sprays in each nostril per daily.
	≥6 years old	Omnaris: 2 sprays in each nostril once daily.	
Flunisolide	>14 years old	2 sprays in each nostril 2 times a day.	**≥ 15 years old:** 8 sprays in each nostril daily. **6-14 years old:** 4 sprays in each nostril daily. *Discontinue in 3 weeks if no improvement.
	6-14 years old	1 spray in each nostril 3 times a day ***or*** 2 sprays in each nostril 2 times a day.	
Fluticasone furoate	≥12 years old	2 sprays in each nostril once daily	No well-established maximum doses.
	2-11 years old	1 spray in each nostril once daily.	
Fluticasone propionate	≥4 years old	2 sprays in each nostril once daily.	2 sprays in each nostril daily.
Fluticasone prop/azelastine	≥12 years old	1 spray per nostril twice daily.	1 spray per nostril twice daily.
Mometasone	≥12 years old	2 sprays in each nostril once daily.	2 sprays in each nostril once daily.
	2-11 years old	1 spray in each nostril once daily.	

Triamcinolone	≥12 years old	2 sprays in each nostril once daily.	2 sprays in each nostril once daily.
	6-11 years old	1 spray in each nostril once daily.	
	2-5 years old	1 spray in each nostril once daily.	

VIII. Utilization

Intranasal Steroid Utilization			
07/26/11 - 07/25/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
BECONASE AQ 0.042% SPRAY	25	$3,486.75	$139.47
FLONASE 0.05% NASAL SPRAY	5	$148.50	$29.70
FLUNISOLIDE 0.025% SPRAY	19	$817.95	$43.05
FLUTICASONE PROP 50 MCG SPRAY	4926	$133,763.29	$27.15
NASACORT AQ NASAL SPRAY	15	$1,578.02	$105.20
NASONEX 50 MCG NASAL SPRAY	1610	$178,431.40	$110.83
OMNARIS 50 MCG NASAL SPRAY	79	$8,187.84	$103.64
RHINOCORT AQUA NASAL SPRAY	198	$19,754.12	$99.77
TRIAMCINOLONE 55 MCG NASAL SPR	316	$30,465.52	$96.41
VERAMYST 27.5 MCG NASAL SPRAY	577	$55,653.04	$96.45
3,848 recipients	**7,770**	**$432,286.43**	

QNASL $106.98 per script
DYMISTA $138.99 per script
ZETONNA $114.03 per script

References

1. Allergy Facts and Figures. Asthma and Allergy Foundation of America. www.aafa.org. Accessed August 2012.
2. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2012.
3. Veramyst® [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; August 2011.
4. Dymista® [prescribing information]. Somerset, New Jersey. Meda Pharmaceuticals, Inc. April 2012.
5. Beconase® [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; April 2005.
6. Qnasl® [prescribing information]. Horsham, PA. Teva Respiratory, LLC. March 2012.
7. Zetonna® [prescribing information]. Marlborough, MA. Sunovion Pharmaceuticals, Inc. January 2012.

South Dakota Department of Social Services
P&T Meeting
Ophthalmic Prostaglandin Agonists Review

I. Overview

There are currently four ophthalmic prostaglandin agonists approved by the Food and Drug Administration for the treatment of glaucoma; bimatoprost (Lumigan), latanoprost (Xalatan), tafluprost (Zioptan) and travoprost (Travatan Z). These agents are believed to lower the intraocular pressure (IOP) in humans by increasing outflow of aqueous humor through the trabecular meshwork and uveoscleral routes. Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

II. Indication

Lumigan (bimatoprost): reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

Xalatan (latanoprost): reduction of elevated IOP in patients with open-angle glaucoma and ocular hypertension who are intolerant of other IOP lowering medications or insufficiently responsive to another IOP lowering medication.

Zioptan (tafluprost): reduction of IOP in patients with open-angle glaucoma or ocular hypertension.

Travatan Z (travoprost): reduction of elevated IOP in patients with open-angle glaucoma and ocular hypertension who are intolerant of other IOP lowering medications or insufficiently responsive to another IOP lowering medication.

III. Warnings/Precautions

- Ocular pigment changes – may cause changes to pigmented tissues.
- Eye color changes – may gradually increase the pigmentation of the iris.
- Eyelid skin darkening – may be reversible upon discontinuation.
- Hair growth – in areas where solution comes in contact with the skin surface.
- Active intraocular inflammation – use with caution because inflammation may be exacerbated.
- Macular edema

IV. Adverse Reactions

- Lumigan – conjunctival hyperemia, growth of eyelashes, ocular pruritus (15%-45%).

- Xalatan – blurred vision, burning and stinging, conjunctival hyperemia, foreign body sensation, itching, increased pigmentation of the iris, eyelash changes (increased length, thickness, pigmentation, and number of lashes) and punctuate epithelial keratopathy (5%-15%).

- Zioptan – conjunctival hyperemia, ocular stinging/irritation, ocular pruritus including allergic conjunctivitis, cataract/dry eye/ocular pain, eyelash darkening, growth of eyelashes, vision blurred, headache, common cold, cough, and urinary tract infection (2%-20%).

- Travatan Z – Ocular hyperemia, decreased visual acuity, eye discomfort, foreign body sensation, pain, pruritus, and conjunctival hyperemia (5%-50%)

V. Dosage and Administration

- Lumigan – One drop in the affected eye(s) once daily in the evening. Reduction of the IOP starts approximately 4 hours after the first administration, with maximum effect reached within approximately 8 to 12 hours.

- Xalatan – One drop in the affected eye(s) once daily in the evening. Reduction of the IOP starts approximately 3-4 hours after administration, and the maximum effect is reached after 8 to 12 hours.

- Zioptan – One drop in affected eye(s) once daily in the evening. Reduction of the IOP starts approximately 2 to 4 hours after the first administration, reaching the maximum effect after 12 hours.

- Travatan Z – One drop in affected eye(s) once daily in the evening. Reduction of the IOP starts approximately 2 hours after administration, and the maximum effect is reached after 12 hours.

VI. Utilization

Ophthalmic Prostaglandin Agonist Utilization			
07/26/11 - 07/25/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
LATANOPROST 0.005% EYE DROPS	179	$1,990.81	$11.12
LUMIGAN 0.01% EYE DROPS	18	$1,651.51	$91.75
LUMIGAN 0.03% EYE DROPS	65	$7,949.46	$122.30
TRAVATAN Z 0.004% EYE DROP	124	$12,799.88	$103.22
XALATAN 0.005% EYE DROPS	11	$953.36	$86.67
73 recipients	**397**	**$25,345.02**	

ZIOPTAN approximately $96.90

References

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2012.
2. Zioptan® [prescribing information] Whitehouse Station, NJ. Merck & Co., Inc.; July 2012.
3. Travatan Z® [prescribing information] Fort Worth, TX. Alcon Laboratories, Inc.; August 2011.
4. Lumigan® [prescribing information] Irvine, CA. Allergan; March 2012.

South Dakota Medicaid P&T Committee
Antiretroviral Utilization

In the first quarter 2012, antiretrovirals were the 15th top therapeutic class based on total cost of claims. There were 248 prescriptions reported at a cost of $217,360.87. This averages out to approximately $876 per prescription. At the June 2012 meeting, the P&T committee requested a review of antiretroviral utilization.

Antiretroviral Utilization			
07/26/11 - 07/25/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
ABACAVIR 300 MG TABLET	1	$507.64	$507.64
APTIVUS 250 MG CAPSULE	13	$14,411.10	$1,108.55
ATRIPLA TABLET	139	$220,191.87	$1,584.11
COMBIVIR TABLET	19	$16,569.66	$872.09
EMTRIVA 200 MG CAPSULE	6	$2,580.10	$430.02
EPIVIR 10 MG/ML ORAL SOLN	24	$3,755.63	$156.48
EPIVIR 150 MG TABLET	4	$1,623.66	$405.92
EPIVIR HBV 100 MG TABLET	13	$4,849.39	$373.03
EPZICOM TABLET	5	$4,804.65	$960.93
INTELENCE 200 MG TABLET	14	$11,413.81	$815.27
ISENTRESS 400 MG TABLET	45	$45,713.82	$1,015.86
KALETRA 200-50 MG TABLET	37	$21,061.98	$569.24
KALETRA 400-100/5 ML ORAL SOLU	22	$7,077.08	$321.69
LAMIVUDINE-ZIDOVUDINE TABLET	16	$15,475.77	$967.24
NEVIRAPINE 200 MG TABLET	5	$270.01	$54.00
NORVIR 100 MG SOFTGEL CAP	82	$32,693.12	$398.70
NORVIR 100 MG TABLET	58	$19,778.05	$341.00
PREZISTA 400 MG TABLET	9	$9,258.36	$1,028.71
PREZISTA 600 MG TABLET	21	$21,357.47	$1,017.02
REYATAZ 150 MG CAPSULE	12	$11,844.06	$987.01
REYATAZ 200 MG CAPSULE	21	$20,599.94	$980.95
REYATAZ 300 MG CAPSULE	79	$77,067.23	$975.53
SELZENTRY 150 MG TABLET	4	$3,978.82	$994.71
SUSTIVA 200 MG CAPSULE	4	$1,520.00	$380.00
SUSTIVA 600 MG TABLET	44	$24,440.80	$555.47
TRIZIVIR TABLET	13	$18,939.21	$1,456.86
TRUVADA 200 MG-300 MG TABLET	189	$212,913.74	$1,126.53
VIRAMUNE 200 MG TABLET	14	$6,172.69	$440.91
VIRAMUNE 50 MG/5 ML SUSP	4	$878.65	$219.66
VIREAD 300 MG TABLET	28	$19,665.46	$702.34
ZIAGEN 300 MG TABLET	13	$5,355.64	$411.97
ZIDOVUDINE 300 MG TABLET	5	$164.30	$32.86
ZIDOVUDINE 50 MG/5 ML SYRUP	26	$3,311.31	$127.36
72 recipients	**989**	**$860,245.02**	

Summary by Age of the 72 recipients taking antiretrovirals

0-10	6
11-20	4
21-30	11
31-40	24
41-50	13
51-60	10
60 and above	4

South Dakota Department of Social Services
P&T Meeting
Genitourinary Smooth Muscle Relaxants

I. Overview

Normal voiding is dependent on acetylcholine-induced stimulation of muscarinic receptors on bladder smooth muscle. Darifenacin, fesoterodine, solifenacin, tolterodine and trospium act as muscarinic receptor antagonists, inhibiting bladder contraction, decreasing detrusor pressure (decreasing urgency) and increasing bladder capacity. Flavoxate has direct antispasmodic effects on the smooth muscle of the bladder, thereby reducing symptoms associated with bladder spasticity and increasing bladder capacity. Oxybutynin also has a direct antispasmodic effect on smooth muscle, but also inhibits the muscarinic action of acetylcholine.

Muscarinic receptors can also be found in the gastrointestinal tract, salivary glands and tear ducts. Because these agents have varying affinity for the different types of muscarinic receptors, common side effects include dry mouth, blurred vision, abdominal discomfort, drowsiness and nausea. In addition, these agents may cause confusion or cognitive impairment in the elderly.

Genitourinary Smooth Muscle Relaxants Included In This Review

Generic Name	Available Formulation(s)	Brand Name(s)
Darifenacin	Extended-release tablet	Enablex®
Fesoterodine	Extended-release tablet	Toviaz®
Flavoxate	Tablet	N/A
Oxybutynin	Tablet, syrup, extended-release tablet, transdermal gel, transdermal patch	Ditropan®*, Ditropan XL®*, Gelnique®, Oxytrol®
Solifenacin	Tablet	Vesicare®
Tolterodine	Tablet, extended-release tablet	Detrol®*, Detrol LA®
Trospium	Tablet, extended-release tablet	Sanctura®*, Sanctura XR®

*Indicates that a generic product is available.

II. Indications

Darifenacin, fesoterodine, solifenacin, tolterodine and trospium are indicated for the treatment of overactive bladder (OAB) with symptoms of urinary incontinence, urgency and frequency. Flavoxate is indicated for symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence that may occur in cystitis, prostatitis, urethritis, urethrocystitis/urethrotrigonitis. Oxybutynin immediate-release tablets and syrup are indicated for the relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder. Oxybutynin extended-release tablets, transdermal patch and transdermal gel are indicated for the treatment of OAB. Oxybutynin is also indicated in patients ages 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida).

III. Warnings

- These agents should be used with caution in patients with clinically significant bladder outflow obstruction because of the risk of urinary retention.

- Agents for the treatment of OAB should also be used with caution in patients with gastrointestinal obstructive disorders (e.g. ulcerative colitis, severe constipation) because of the risk of gastric retention and decreased gastric motility.

- GU smooth muscle relaxants should be used with caution in patients with controlled narrow-angle glaucoma and myasthenia gravis, due to effects of increased anticholinergic activity.

- Oxybutynin transdermal gel is alcohol-based and therefore flammable. Instruct patients to avoid open fire or smoking until gel has dried.

IV. Precautions

Recommendations For Dosage Adjustments Based On Hepatic and Renal Function

Generic Name	Renal Function Impairment	Hepatic Function Impairment
Darifenacin	*No dosage adjustments	*No dosage adjustments for mild hepatic impairment *Max dose = 7.5mg for patients with moderate hepatic impairment (Child-Pugh class B) *Not recommended for patients with severe hepatic impairment (Child-Pugh class C)
Fesoterodine	*No dosage adjustments for patients with mild/moderate renal insufficiency. *Max dose = 4mg for patients with severe renal insufficiency	*No dosage adjustments for patients with mild/moderate hepatic impairment. *Not recommended for patients with severe hepatic impairment
Flavoxate	*No recommendations	*No recommendations
Oxybutynin	*Use with caution - no recommendations for dosage adjustments	*Use with caution – no recommendations for dosage adjustments
Solifenacin	*Use with caution in patients with reduced renal function *Max dose = 5mg in patients with severe renal impairment (CrCl < 30mL/min)	*Use with caution in patients with reduced hepatic function *Max dose = 5mg in patients with moderate hepatic impairment (Child-Pugh class B) *Not recommended for patients with severe hepatic impairment (Child-Pugh class C)
Tolterodine	*IR – Significantly reduced renal function, recommended dose is 1mg BID	*IR – Significantly reduced hepatic function, recommended dose is 1mg BID

Generic Name	Renal Function Impairment	Hepatic Function Impairment
	*ER – Severe renal impairment (CrCl 10 to 30mL/min), recommended dose is 2mg QD. If CrCl is less than 10mL/min, use is not recommended	*ER – Mild to moderate hepatic impairment (Child-Pugh class A or B), recommended dose is 2mg QD. If patient has severe hepatic impairment (Child-Pugh class C), use is not recommended
Trospium	*IR – Severe renal impairment (CrCl < 30mL/min), recommended dose is 20mg HS. *ER – Not recommended for use in patients with severe renal impairment (CrCl < 30mL/min)	*Use caution when administering to patients with moderate or severe hepatic dysfunction.

V. Drug Interactions

- When genitourinary smooth muscle relaxants (darifenacin, fesoterodine, solifenacin, tolterodine) are used concurrently with agents that inhibit CYP3A4 (imidazoles, macrolides, nefazodone and protease inhibitors), the plasma concentrations and effects of the genitourinary smooth muscle relaxant may be increased.

- When genitourinary smooth muscle relaxants (oxybutynin, trospium) are used with phenothiazines, the antipsychotic effectiveness of the phenothiazines may be decreased.

- Potassium tablet preparations are contraindicated for use in patients using anticholinergic agents like the genitourinary smooth muscle relaxants. Delay in tablet passage through the GI tract may occur, affecting potassium absorption. Administration of the potassium as a liquid preparation is a suitable alternative.

VI. Adverse Reactions

- The most common adverse reactions to the genitourinary smooth muscle relaxants are urinary retention, dry mouth and constipation.

- Other side effects include dry eyes, dizziness/somnolence, abdominal pain, nausea, dyspepsia, urinary tract infection.

- Hypersensitivity reactions, including angioedema with airway obstruction, pruritis, rash and urticaria have occurred.

VII. Dosage and Administration

Adult and Pediatric Dose Recommendations

Generic Name	Adult Dose Recommendations	Pediatric Dose Recommendations	Availability
Darifenacin	7.5 to 15mg daily	Safety and efficacy in children have not been established.	ER Tablet: 7.5mg 15mg
Fesoterodine	4 to 8mg daily	Safety and efficacy in children have not been established.	ER Tablet: 4mg 8mg
Flavoxate	100 to 200mg 3 to 4 times/day	≥12 years of age: 100 to 200mg 3 to 4 times/day	Tablet: 100mg
Oxybutynin	Tablet (IR)/syrup: 5mg 2 to 3 times/day; max dose = 5mg 4 times/day Tablet (ER): 5mg daily; max dose = 30 mg/day Transdermal gel: 10% - one sachet applied daily 3% - apply 3 pumps daily Transdermal patch: one 3.9mg/day system applied twice weekly (every 3 to 4 days)	≥5 years of age: Tablet (IR)/syrup: 5mg 2 times a day; max dose = 5mg 3 times a day ≥6 years of age (detrusor overactivity associated with a neurological condition): Tablet (ER): 5mg once daily; max dose = 20mg/day	Syrup: 5mg/5mL ER Tablet: 5mg 10mg 15mg IR Tablet: 5mg Transdermal gel: 3%, 10% Transdermal patch: 3.9mg/24hr
Solifenacin	5 to 10mg daily	Safety and efficacy in children have not been established.	Tablet: 5mg 10mg
Tolterodine	Tablet (IR): 2mg 2 times/day Capsule (ER): 4mg once daily	Safety and efficacy in children have not been established.	IR Tablet: 1mg 2mg ER Capsule: 2mg 4mg
Trospium	Tablet (IR): 20mg 2 times/day Capsule (ER): 60mg daily	Safety and efficacy in children have not been established.	IR Tablet: 20mg ER Capsule: 60mg

VIII. Utilization

Genitourinary Smooth Muscle Relaxant Utilization 07/26/11 to 07/25/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
Detrol tablet	69	$7,346.27	$106.47
Detrol LA capsule	625	$95,278.12	$152.44
Ditropan XL tablet	13	$1,680.47	$129.27
Enablex tablet	67	$10,784.59	$160.96
Flavoxate tablet	13	$1,048.75	$80.67
Oxybutynin 5mg tablet	693	$6,707.21	$9.68
Oxybutynin 5mg/5mL syrup	119	$1,168.93	$9.82
Oxybutynin ER tablet	674	$35,046.65	$52.00
Oxytrol patch	9	$1,326.96	$147.44
Sanctura XR capsule	51	$8,453.48	$165.75
Tolterodine tablet	2	$176.30	$88.15
Toviaz ER tablet	237	$31,895.92	$134.58
Trospium tablet	10	$1449.42	$144.94
Vesicare tablet	515	$82,389.27	$159.98
Total (488 Recipients)	**3,097**	**$284,752.34**	**$91.94**

References

1. Facts and Comparisons, Wolters Kluwer Health, Inc. 2012.
2. Clinical Pharmacology, 2012 Elsevier/Gold Standard.
3. Micromedex 2.0 DRUGDEX Drug Evaluations, 2012 Thomson Healthcare.
4. Enablex [package insert]. Rockaway, NJ: Warner Chilcott (US) LCC; March 2012.
5. Toviaz [package insert]. New York, NY: Pfizer; August 2012.
6. Ditropan XL [package insert]. Raritan, NJ: Ortho-McNeil-Janssen; March 2012.
7. Gelnique Gel 10% [package insert]. Parsippany, NJ: Watson Pharma, Inc.; March 2012.
8. Gelnique Gel 3% [package insert]. Parsippany, NJ: Watson Pharma, Inc.; December 2011.
9. Oxytrol [package insert]. Parsippany, NJ: Watson Pharma, Inc.; April 2011.
10. Vesicare [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; August 2012.
11. Detrol LA [package insert]. New York, NY: Pfizer; August 2012.
12. Sanctura [package insert]. Irvine, CA: Allergan, Inc.; July 2012.
13. Sanctura XR [package insert]. Irvine, CA: Allergan, Inc.; August 2012.