South Dakota

Department of Social Services

Medicaid P&T Committee Meeting

December 12, 2008

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

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

Friday, December 12, 2008
1:00 – 3:00 PM

DDN Locations

Sioux Falls	Rapid City	Pierre
University Center	SD School of Mines	Capitol Building
Room 282	Classroom Building	Room B12
	Room 109	

Call to Order

Approval of Minutes of Previous Meeting

Prior Authorization Update

Review of Top 15 Therapeutic Categories/Top 25 Drugs

Old Business

- **Utilization Trends**
  - **Duplicate Antipsychotic Therapy**
  - **Invega®**
  - **Antidepressants**
  - **Quantity Limits**
  - **Singulair®**
- **Drug Product and Utilization Review**
  - **Xopenex®**
  - **Vusion®**
  - **Altabax®**
  - **Lyrica®**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date

Adjournment

Minutes of the September 5, 2008
Pharmacy & Therapeutics (P&T) Committee Meeting
SD Department of Social Services, Medical Services Division

Members present
Verdayne Brandenburg, MD; Dana Darger, RPh; William Ladwig, RPh; Dennis Hedge, PharmD; Willis Sutliff, MD; Rick Holm, MD; Galen Goeden, RPh; Debra Farver, PharmD; Timothy Soundy, MD

Members absent
James Engelbrecht, M.D.

DSS staff present
Mike Jockheck, R.Ph.; Larry Iversen

HID staff present
Candace Rieth, Pharm.D.

Administrative Business
The P&T meeting was called to order by chair, D. Darger, at approximately 1pm. The minutes of the June 20, 2008 meeting were presented. V. Brandenburg made a motion to approve as written, with a second by W. Sutliff. The motion was approved unanimously. L. Iversen introduced Debra Farver, PharmD, and Timothy Soundy, MD, who have both recently been appointed by the governor to serve on the P&T committee.

L. Iversen spoke regarding future meeting venues. P&T Committee meetings are typically held on a quarterly basis and several committee members as well as State employees fly to Sioux Falls to attend. In an effort to contain costs, the State anticipates that at least two meetings a year will be held in a location equipped with teleconferencing capabilities. The teleconferencing equipment will be available in Sioux Falls, Pierre, and Rapid City. Information regarding the location of future meetings will be posted on the HID SD Medicaid website. The next P&T meeting date will be December 12, 2008.

Prior Authorization Statistics
C. Rieth presented an overview of the prior authorization (PA) activity for April, May and June, 2008. There were a total of 1,337 PAs processed in the month of April, with 99.10% of those requests responded to in less than 8 hours. There were a total of 1,644 PAs processed in the month of May, with 98.48% of those requests responded to in less than 8 hours. There were a total of 1.655 PAs processed in the month of June, with 99.21% of those requests responded to in less than 8 hours. In April, there were 1,134 (85%) requests received electronically and 203 (15%) received by fax. In May, there were 1,478 (90%) requests received electronically and 166 (10%) received by fax. In June, there were 1,466 (89%) requests received electronically and 189 (11%) received by fax. In response to a request from the committee, C. Rieth presented the number of approvals and denials, by form type, for the faxed (manual) PA requests.

Analysis of the Top 15 Therapeutic Classes

C. Rieth reviewed the Top 15 Therapeutic Classes by total cost of claims from 01/01/2008 – 03/31/2008. The top five classes were antipsychotics, anticonvulsants, cerebral stimulants, monoclonal antibodies, and antidepressants.

Committee members requested additional information on the antipsychotics, anticonvulsants, cephalosporins, and antidepressants. C. Rieth presented the analysis of these classes including cost per script, number of prescriptions, and age of patients. Committee members asked for percentage spends of antipsychotics, anticonvulsants, and antidepressants in other State Medicaid programs. This information was presented.

Committee members asked for information regarding duplicate antipsychotic utilization. This information will be presented at the next meeting. M. Jockheck suggested the committee implement quantity limits based on the FDA guidelines for maximum dosing. Suggested quantity limits will be presented at the next P&T meeting.

Invega Review

C. Rieth presented the drug review and utilization for Invega, an antipsychotic indicated for the acute and maintenance treatment of schizophrenia. D. Mantella, representing Ortho McNeil Janssen, spoke about Invega. He suggested that patients who are rapid metabolizers of Risperdal as well as patients with hepatic dysfunction are good candidates for Invega therapy, since this medication is renally excreted. P. Arends, representing NAMI, spoke against prior authorization of all medications. K. Oehlke, PA-C, spoke against prior authorizing antipsychotics and antidepressants. Committee members asked that reports comparing Risperdal utilization and Invega utilization be brought to the next meeting. Members also requested the specialty of providers prescribing these agents, the number of patients that have taken Risperdal prior to Invega and the diagnoses of patients. This information will be presented at the next P&T meeting.

Antidepressant Review

C. Rieth presented information regarding the Wyoming Medicaid antidepressant step therapy initiative. Wyoming sent two provider letters asking for guidance in the development of the step therapy process. The step therapy program was implemented August 1, 2008. W. Sutliff made a motion to develop a tier system for antidepressants. V. Brandenburg seconded the motion. A provider letter will be developed for the next meeting.

Singulair Review

In response to a previous request from the committee, C. Rieth presented information regarding diagnosis codes submitted on patients utilizing Singulair. Committee members requested further analysis of the 1,442 patients that had none of the diagnosis codes related to asthma, allergic rhinitis, exercise induced bronchospasm, laryngotracheobronchitis, or reactive airway disease. Committee members suggested that the data include diagnosis codes for the past 2-3 years. This information will be presented at the next P&T meeting.

Medications for Head Lice

C. Rieth presented the drug class review and utilization for medications used to treat head lice. There was no public comment. A motion was made by B. Ladwig to place lindane and malathion on prior authorization. G. Goeden seconded the motion. The prior authorization of lindane and malathion will begin as soon as providers are notified.

New Business

C. Rieth reviewed Opioid utilization with committee members. This topic will be discussed at future meetings.

Because of time restraints, it was requested that the meeting be adjourned. All topics that were not discussed will be tabled until the December meeting. The next meeting date is December 12, 2008. The location will be sent to members and interested parties as soon as possible. The SD Medicaid P&T meeting was adjourned at 3:10pm.

South Dakota Medicaid
Monthly Prior Authorization Report
September 2008

Response Time

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
1,887	1,880	7	99.63%	0.37%

By Form Type

Form Type	Description	Approve	Deny
ANT	Antihistamines	66	239
ARB	ARBS	26	31
DAW	Dispense As Written	10	380
GRH	Growth Hormone	3	4
MAX	Max Units Override	64	723
PPI	Proton Pump Inhibitors	81	260
Totals		250	1637

By Request Type

09/01/08 - 09/30/08	# of	Electronic Requests		Faxed Requests		Mailed Requests		Phone Requests	
	Requests	#	%	#	%	#	%	#	%
Prior Authorizations:									
Ambien CR	0	0	0%	0	0%	0	0%	0	0%
Antihistamines	305	256	84%	49	16%	0	0%	0	0%
ARBS	57	48	84%	9	16%	0	0%	0	0%
Dispense As Written	390	377	97%	13	3%	0	0%	0	0%
Growth Hormone	7	4	57%	3	43%	0	0%	0	0%
Max Units Override	787	718	91%	69	9%	0	0%	0	0%
Proton Pump Inhibitors	341	273	80%	68	20%	0	0%	0	0%
Prior Authorization Totals	1,887	1,676	89%	211	11%	0	0%	0	0%

South Dakota Medicaid
Monthly Prior Authorization Report
September 2008

Electronic PAs

09/01/08 - 09/30/08	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Antihistamines	27	213	0	240	11.30%	256
ARBS	17	31	0	48	35.40%	48
Dispense As Written	0	374	0	374	0.00%	377
Growth Hormone	0	4	0	4	0.00%	4
Max Units Override	11	689	0	700	1.60%	718
Proton Pump Inhibitors	30	241	0	271	11.10%	273
Prior Authorization Totals:	85	1,552	0	1,637	5.20%	1,676

Manual Approvals and Denials

09/01/08 - 09/30/08	# Requests	# Approved	# Denied
Prior Authorizations:			
Ambien CR	0	0	0
Antihistamines	49	39	10
ARBS	9	9	0
Dispense As Written	13	10	3
Growth Hormone	3	3	0
Max Units Override	69	53	16
Proton Pump Inhibitors	68	51	17
Prior Authorization Totals	211	165	46

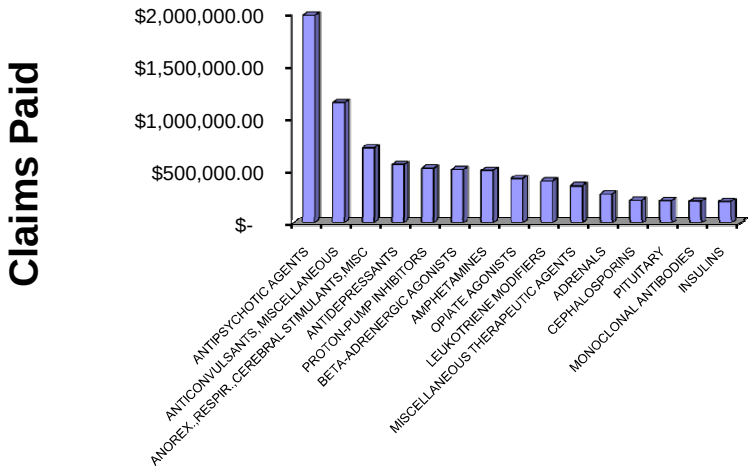
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2008 - 06/30/2008

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	7,232	$ 1,971,519.95	$ 272.61	3.99%
ANTICONVULSANTS, MISCELLANEOUS	6,500	$ 1,142,817.09	$ 175.82	3.59%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	5,349	$ 714,772.29	$ 133.63	2.95%
ANTIDEPRESSANTS	12,516	$ 555,806.73	$ 44.41	6.91%
PROTON-PUMP INHIBITORS	5,494	$ 521,011.93	$ 94.83	3.03%
BETA-ADRENERGIC AGONISTS	7,378	$ 507,958.88	$ 68.85	4.07%
AMPHETAMINES	3,745	$ 498,769.22	$ 133.18	2.07%
OPIATE AGONISTS	12,178	$ 423,077.05	$ 34.74	6.72%
LEUKOTRIENE MODIFIERS	3,799	$ 399,670.82	$ 105.20	2.10%
MISCELLANEOUS THERAPEUTIC AGENTS	1,407	$ 353,199.28	$ 251.03	0.78%
ADRENALS	4,195	$ 275,600.62	$ 65.70	2.31%
CEPHALOSPORINS	5,435	$ 216,736.52	$ 39.88	3.00%
PITUITARY	538	$ 212,232.69	$ 394.48	0.30%
MONOCLONAL ANTIBODIES	155	$ 207,308.97	$ 1,337.48	0.09%
INSULINS	1,609	$ 204,300.03	$ 126.97	0.89%
TOTAL TOP 15	77,530	$ 8,204,782.07	$ 105.83	42.78%

Total Rx Claims From 04/01/2008 - 06/30/2008	181,222

Top 15 Therapeutic Classes
Based on Total Cost of Claims

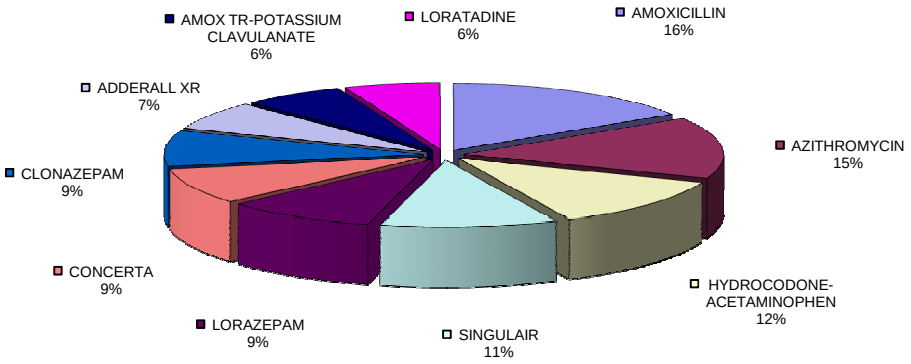


TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2008 - 06/30/2008

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	5,473	$ 54,039.00	$ 9.87	3.02%
AZITHROMYCIN	MACROLIDES	5,071	$ 121,320.67	$ 23.92	2.80%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	4,179	$ 49,360.46	$ 11.81	2.31%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,783	$ 398,172.06	$ 105.25	2.09%
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	3,238	$ 36,884.52	$ 11.39	1.79%
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	2,957	$ 413,734.59	$ 139.92	1.63%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	2,945	$ 34,706.75	$ 11.78	1.63%
ADDERALL XR	AMPHETAMINES	2,366	$ 369,683.89	$ 156.25	1.31%
AMOX TR-POTASSIUM CLAVULANA	PENICILLINS	2,197	$ 78,181.65	$ 35.59	1.21%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,032	$ 27,548.77	$ 13.56	1.12%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	2,012	$ 42,762.97	$ 21.25	1.11%
FLUOXETINE HCL	ANTIDEPRESSANTS	1,955	$ 19,641.96	$ 10.05	1.08%
CEPHALEXIN	CEPHALOSPORINS	1,954	$ 26,422.05	$ 13.52	1.08%
SERTRALINE HCL	ANTIDEPRESSANTS	1,893	$ 24,410.78	$ 12.90	1.04%
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,887	$ 433,194.22	$ 229.57	1.04%
RISPERDAL	ANTIPSYCHOTIC AGENTS	1,881	$ 374,004.97	$ 198.83	1.04%
PREVACID	PROTON-PUMP INHIBITORS	1,765	$ 257,167.01	$ 145.70	0.97%
LEVOTHYROXINE SODIUM	THYROID AGENTS	1,754	$ 19,485.23	$ 11.11	0.97%
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	1,754	$ 13,065.88	$ 7.45	0.97%
ALBUTEROL	BETA-ADRENERGIC AGONISTS	1,672	$ 44,216.48	$ 26.45	0.92%
TRAZODONE HCL	ANTIDEPRESSANTS	1,610	$ 12,351.51	$ 7.67	0.89%
CEFDINIR	CEPHALOSPORINS	1,587	$ 102,582.20	$ 64.64	0.88%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	1,572	$ 45,348.38	$ 28.85	0.87%
ACETAMINOPHEN-CODEINE	OPIATE AGONISTS	1,510	$ 12,217.72	$ 8.09	0.83%
ABILIFY	ANTIPSYCHOTIC AGENTS	1,481	$ 545,521.13	$ 368.35	0.82%
TOTAL TOP 25		60,528	$ 3,556,024.85	$ 58.75	33.40%

Total Rx Claims From 04/01/2008 - 06/30/2008	181,222

Top 10 Drugs
Based on Number of Claims

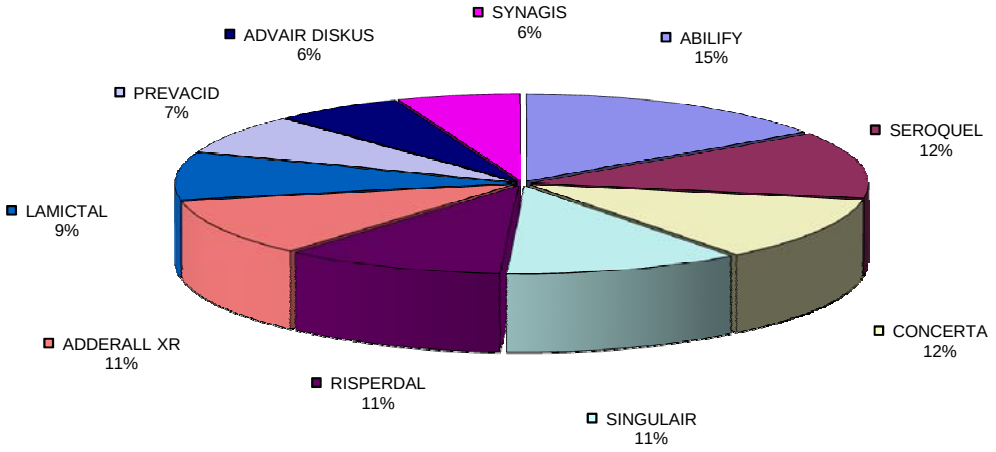


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2008 - 06/30/2008

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,481	$ 545,521.13	$ 368.35	0.82%
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,887	$ 433,194.22	$ 229.57	1.04%
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,957	$ 413,734.59	$ 139.92	1.63%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,783	$ 398,172.06	$ 105.25	2.09%
RISPERDAL	ANTIPSYCHOTIC AGENTS	1,881	$ 374,004.97	$ 198.83	1.04%
ADDERALL XR	AMPHETAMINES	2,366	$ 369,683.89	$ 156.25	1.31%
LAMICTAL	ANTICONVULSANTS, MISCELLANEOUS	1,009	$ 306,555.05	$ 303.82	0.56%
PREVACID	PROTON-PUMP INHIBITORS	1,765	$ 257,167.01	$ 145.70	0.97%
ADVAIR DISKUS	BETA-ADRENERGIC AGONISTS	1,199	$ 216,233.89	$ 180.35	0.66%
SYNAGIS	MONOCLONAL ANTIBODIES	155	$ 207,308.97	$ 1,337.48	0.09%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,323	$ 191,121.34	$ 144.46	0.73%
ZYPREXA	ANTIPSYCHOTIC AGENTS	401	$ 190,102.23	$ 474.07	0.22%
TOPAMAX	ANTICONVULSANTS, MISCELLANEOUS	608	$ 178,013.96	$ 292.79	0.34%
FOCALIN XR	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,028	$ 141,312.60	$ 137.46	0.57%
AZITHROMYCIN	MACROLIDES	5,071	$ 121,320.67	$ 23.92	2.80%
EFFEXOR XR	ANTIDEPRESSANTS	832	$ 119,076.89	$ 143.12	0.46%
KEPPRA	ANTICONVULSANTS, MISCELLANEOUS	448	$ 118,963.00	$ 265.54	0.25%
RISPERDAL CONSTA	ANTIPSYCHOTIC AGENTS	167	$ 115,203.37	$ 689.84	0.09%
PULMICORT	ADRENALS	513	$ 113,140.96	$ 220.55	0.28%
NEXIUM	PROTON-PUMP INHIBITORS	623	$ 112,369.35	$ 180.37	0.34%
GEODON	ANTIPSYCHOTIC AGENTS	310	$ 111,893.38	$ 360.95	0.17%
VYVANSE	AMPHETAMINES	870	$ 110,050.06	$ 126.49	0.48%
OXYCONTIN	OPIATE AGONISTS	373	$ 105,437.20	$ 282.67	0.21%
LEXAPRO	ANTIDEPRESSANTS	1,194	$ 104,424.59	$ 87.46	0.66%
CYMBALTA	ANTIDEPRESSANTS	756	$ 102,803.57	$ 135.98	0.42%
TOTAL TOP 25		33,000	$ 5,456,808.95	$ 165.36	18.21%

Total Rx Claims From 04/01/2008 - 06/30/2008	181,222

Top 10 Drugs
Based on Total Claims Cost



South Dakota Medicaid
Analysis of AHFS Class 281608 - Antipsychotic Agents
10/01/2007 - 12/31/2007

Label Name	Rx Num	Total Paid Amt	Cost Per Script
ABILIFY 1 MG/ML SOLUTION	6	$1,459.82	$243.30
ABILIFY 10 MG TABLET	298	$97,686.96	$327.81
ABILIFY 15 MG TABLET	226	$65,393.81	$289.35
ABILIFY 2 MG TABLET	41	$16,606.72	$405.04
ABILIFY 20 MG TABLET	125	$58,676.76	$469.41
ABILIFY 30 MG TABLET	124	$60,308.02	$486.36
ABILIFY 5 MG TABLET	460	$138,173.94	$300.38
ABILIFY 9.7 MG/1.3 ML VIAL	1	$16.97	$16.97
ABILIFY DISCMELT 10 MG TABLET	3	$1,337.02	$445.67
ABILIFY DISCMELT 15 MG TABLET	3	$1,918.45	$639.48
	1287	$441,578.47	$343.11
CHLORPROMAZINE 10 MG TABLET	2	$43.84	$21.92
CHLORPROMAZINE 100 MG TABLET	5	$120.16	$24.03
CHLORPROMAZINE 25 MG TABLET	7	$186.31	$26.62
CHLORPROMAZINE 25 MG/ML AMP	1	$16.00	$16.00
CHLORPROMAZINE 50 MG TABLET	8	$141.23	$17.65
	23	$507.54	$22.07
CLOZAPINE 100 MG TABLET	297	$27,778.52	$93.53
CLOZAPINE 200 MG TABLET	41	$8,664.27	$211.32
CLOZAPINE 25 MG TABLET	105	$3,051.35	$29.06
	443	$39,494.14	$89.15
CLOZARIL 100 MG TABLET	48	$17,552.69	$365.68
CLOZARIL 25 MG TABLET	5	$502.29	$100.46
	53	$18,054.98	$340.66
FAZACLO 25 MG TABLET	5	$195.62	$39.12
	5	$195.62	$39.12
FLUPHENAZINE 10 MG TABLET	6	$91.50	$15.25
FLUPHENAZINE 5 MG TABLET	10	$165.68	$16.57
FLUPHENAZINE DEC 25 MG/ML VL	2	$47.90	$23.95
	18	$305.08	$16.95
GEODON 20 MG CAPSULE	34	$7,978.64	$234.67
GEODON 20 MG VIAL	1	$114.39	$114.39
GEODON 40 MG CAPSULE	79	$17,593.63	$222.70
GEODON 60 MG CAPSULE	55	$18,640.25	$338.91
GEODON 80 MG CAPSULE	144	$56,438.86	$391.94
	313	$100,765.77	$321.94
HALOPERIDOL 0.5 MG TABLET	6	$59.70	$9.95
HALOPERIDOL 1 MG TABLET	13	$198.75	$15.29
HALOPERIDOL 10 MG TABLET	14	$936.31	$66.88
HALOPERIDOL 2 MG TABLET	19	$271.75	$14.30
HALOPERIDOL 5 MG TABLET	18	$391.72	$21.76
HALOPERIDOL DEC 100 MG/ML VIAL	13	$701.65	$53.97
HALOPERIDOL DEC 50 MG/ML VL	1	$33.28	$33.28
HALOPERIDOL LAC 5 MG/ML VIAL	3	$114.68	$38.23
	87	$2,707.84	$31.12
INVEGA 3 MG ER TABLET	41	$12,777.71	$311.65
INVEGA 6 MG ER TABLET	67	$24,720.90	$368.97

Label Name	Rx Num	Total Paid Amt	Cost per script
INVEGA 9 MG ER TABLET	30	$12,929.51	$430.98
	138	$50,428.12	$365.42
LOXAPINE SUCCINATE 10 MG CAP	8	$439.94	$54.99
LOXAPINE SUCCINATE 25 MG CAP	5	$298.02	$59.60
LOXAPINE SUCCINATE 5 MG CAP	1	$111.39	$111.39
	14	$849.35	$60.67
ORAP 2 MG TABLET	1	$41.31	$41.31
	1	$41.31	$41.31
PERPHENAZINE 16 MG TABLET	1	$38.42	$38.42
PERPHENAZINE 4 MG TABLET	2	$43.70	$21.85
PERPHENAZINE 8 MG TABLET	1	$101.10	$101.10
	4	$183.22	$45.81
RISPERDAL 0.25 MG TABLET	304	$41,799.57	$137.50
RISPERDAL 0.5 MG TABLET	553	$86,680.88	$156.75
RISPERDAL 0.5 M-TAB	35	$4,324.80	$123.57
RISPERDAL 1 MG M-TAB	13	$2,217.41	$170.57
RISPERDAL 1 MG TABLET	517	$77,289.54	$149.50
RISPERDAL 1 MG/ML SOLUTION	56	$6,819.45	$121.78
RISPERDAL 2 MG M-TAB	9	$3,404.58	$378.29
RISPERDAL 2 MG TABLET	216	$58,298.21	$269.90
RISPERDAL 3 MG M-TAB	4	$1,708.44	$427.11
RISPERDAL 3 MG TABLET	135	$40,214.15	$297.88
RISPERDAL 4 MG M-TAB	2	$1,611.04	$805.52
RISPERDAL 4 MG TABLET	87	$35,275.07	$405.46
RISPERDAL CONSTA 25 MG SYR	29	$12,402.68	$427.68
RISPERDAL CONSTA 37.5 MG SYR	49	$25,106.18	$512.37
RISPERDAL CONSTA 50 MG SYR	71	$68,268.34	$961.53
	2080	$465,420.34	$223.76
SEROQUEL 100 MG TABLET	513	$73,409.49	$143.10
SEROQUEL 200 MG TABLET	374	$110,225.48	$294.72
SEROQUEL 25 MG TABLET	371	$41,362.09	$111.49
SEROQUEL 300 MG TABLET	272	$122,589.94	$450.70
SEROQUEL 400 MG TABLET	74	$29,317.44	$396.18
SEROQUEL 50 MG TABLET	320	$45,039.35	$140.75
SEROQUEL XR 200 MG TABLET	31	$6,217.14	$200.55
SEROQUEL XR 300 MG TABLET	39	$11,489.51	$294.60
SEROQUEL XR 400 MG TABLET	19	$6,057.57	$318.82
	2013	$445,708.01	$221.41
THIORIDAZINE 10 MG TABLET	1	$32.29	$32.29
THIORIDAZINE 25 MG TABLET	3	$89.46	$29.82
THIORIDAZINE 50 MG TABLET	3	$61.29	$20.43
	7	$183.04	$26.15
THIOTHIXENE 10 MG CAPSULE	1	$24.55	$24.55
	1	$24.55	$24.55
TRIFLUOPERAZINE 10 MG TABLET	6	$198.30	$33.05
TRIFLUOPERAZINE 2 MG TABLET	10	$201.29	$20.13
TRIFLUOPERAZINE 5 MG TABLET	3	$104.25	$34.75
	19	$503.84	$26.52
ZYPREXA 10 MG TABLET	105	$37,408.51	$356.27
ZYPREXA 10 MG VIAL	8	$521.94	$65.24

Label Name	Rx Num	Total Paid Amt	Cost per script
ZYPREXA 15 MG TABLET	70	$52,354.56	$747.92
ZYPREXA 2.5 MG TABLET	35	$7,223.14	$206.38
ZYPREXA 20 MG TABLET	79	$49,726.12	$629.44
ZYPREXA 5 MG TABLET	99	$27,241.94	$275.17
ZYPREXA 7.5 MG TABLET	18	$5,818.62	$323.26
ZYPREXA ZYDIS 10 MG TABLET	35	$12,158.05	$347.37
ZYPREXA ZYDIS 15 MG TAB	6	$3,297.00	$549.50
ZYPREXA ZYDIS 20 MG TAB	7	$4,657.34	$665.33
ZYPREXA ZYDIS 5 MG TABLET	20	$3,962.73	$198.14
	482	$204,369.95	$424.00
Totals	**6988**	**$1,771,321.17**	

Total spent on Atypical Antipsychotics	$1,766,015.40
Total spent on Traditional Antipsychotics	$5,305.77

Consecutive Duplication for Atypical Antipsychotics > 3 Date: 07/01/07 – 06/30/08
Drug Name (each row represents unique recipient)
ABILIFY 10MG, RISPERDAL 4MG, RISPERDAL CONSTA 25MG
CLOZAPINE 100MG , RISPERDAL CONSTA 25MG, ZYPREXA ZYDIS 5MG
ABILIFY , CLOZARIL 25MG, GEODON , INVEGA
ABILIFY , RISPERDAL CONSTA , SEROQUEL
RISPERDAL , RISPERDAL CONSTA , SEROQUEL , SEROQUEL XR
ABILIFY , GEODON , SEROQUEL , SEROQUEL XR
ABILIFY , RISPERDAL , SEROQUEL
ABILIFY , SEROQUEL , SEROQUEL XR
RISPERDAL , RISPERDAL CONSTA , SEROQUEL , ZYPREXA
ABILIFY , RISPERDAL , SEROQUEL , ZYPREXA ZYDIS
ABILIFY , GEODON , RISPERDAL
GEODON , SEROQUEL , SEROQUEL XR
CLOZAPINE , RISPERDAL CONSTA , SEROQUEL , ZYPREXA ZYDIS
ABILIFY , RISPERDAL , SEROQUEL
GEODON , RISPERDAL , SEROQUEL
RISPERDAL , RISPERDAL CONSTA , SEROQUEL
ABILIFY , INVEGA , ZYPREXA
ABILIFY , RISPERDAL , ZYPREXA
CLOZARIL , RISPERDAL , RISPERDAL CONSTA
ABILIFY , SEROQUEL , ZYPREXA
ABILIFY , INVEGA , SEROQUEL
ABILIFY , FAZACLO , RISPERDAL , RISPERDAL CONSTA
RISPERDAL , SEROQUEL , ZYPREXA
CLOZAPINE , RISPERDAL , RISPERDAL CONSTA , SEROQUEL
ABILIFY , SEROQUEL , ZYPREXA
GEODON , INVEGA , RISPERDAL , RISPERDAL CONSTA , SEROQUEL XR , ZYPREXA , ZYPREXA ZYDIS
ABILIFY , GEODON , RISPERDAL , RISPERDAL CONSTA , SEROQUEL , ZYPREXA , ZYPREXA ZYDIS
GEODON , INVEGA , RISPERDAL , RISPERDAL CONSTA , SEROQUEL , SEROQUEL XR
28 unique patients
36 unique providers

Summary by Age of Patients Taking Multiple Atypical Antipsychotic Therapies

Age	Recip Count
4	1
15	2
16	1
17	1
18	2
20	1
21	1
24	1
26	1
27	2
28	1
35	1
36	1
44	1
45	2
47	1
48	1
50	1
52	2
58	1
59	1
60	1
63	1

Prescribers of greater than 3 Atypical Antipsychotics per patient 07/01/07 - 06/30/08

Specialty	State
Psychiatrist	CO
Pediatrics	SD
-	SD
-	SD
Psychiatrist	WI
Psychiatrist	SD
-	SD
Psychiatrist	CO
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Psychiatrist	SD
Family Practice	SD
Family Practice	WI
-	SD
Psychiatrist	SD
Psychiatrist	SD
Emergency Medicine	SD
Pediatrics	SD
PA	SD
NP	SD
NP	SD
NP	SD
NP	SD
NP	SD
PA	SD
NP	SD
NP	SD
PA	SD
PA	SD
NP	SD

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South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Invega®

I. Overview

Invega (paliperidone) is the major active metabolite of risperidone. The exact mechanism of action is unknown, but it is thought that paliperidone works through a combination of dopamine type 2 and serotonin type 2 receptor antagonisms. Invega is indicated for the acute and maintenance treatment of schizophrenia in patients greater than 18 years of age.

II. Pharmacology

Although the exact mechanism is unknown, paliperidone is a centrally active dopamine type 2 antagonist with serotonin type 2 activities. Paliperidone is also active as an antagonist at α adrenergic receptors and H_1 histaminergic receptors. It has no affinity for cholinergic, muscarinic, or β-adrenergic receptors.

III. Pharmacokinetics

Drug	Serum Half-Life (hours)	C_{max} (hours)	Time to Steady-State Concentration (Days)	Renal Excretion (%)	Active Metabolites
Paliperidone	23	24	4-5	59	Yes

IV. Warnings/Precautions

Increased Mortality in Elderly Patients with Dementia-Related Psychosis (Boxed Warning)-These patients, when treated with atypical antipsychotic drugs, are at an increased risk of death compared to placebo. Analysis of 17 placebo-controlled trials in these subjects revealed a risk of death in the drug-treated subjects of between 1.6 to 1.7 times that seen in placebo-treated subjects. Over the course of a typical 10-week trial, the rate of death in drug-treated subjects was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g. pneumonia) in nature. Invega is not approved for the treatment of patients with Dementia-Related Psychosis.

Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients With Dementia-Related Psychosis-In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly subjects with dementia, there was a higher incidence of cerebrovascular adverse reactions (CVA and TIA) including fatalities compared to placebo-treated subjects. Paliperidone was not marketed at the time these studies were performed; however, it is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS)-This symptom complex has been reported in association with antipsychotic drugs, including paliperidone. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Additional signs may include elevated creatine phosphokinase, myogloinuria, and acute renal failure.

QT Prolongation-Paliperidone causes a modest increase in the corrected QT interval. The use of paliperidone should be avoided in combination with other drugs that are known to prolong QT interval, including Class 1A or Class III antiarrhythmic agents, antipsychotic agents, and certain antibiotics. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Tardive Dyskinesia-This syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs.

***Hyperglycemia and Diabetes Mellitus*-**Hyperglycemia, and in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with all atypical antipsychotics.

***Hyperprolactinemia*-**Paliperidone elevates prolactin levels and the elevation persists during chronic administration. This may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This may inhibit reproductive function and cause a variety of symptoms, including galactorrhea, amenorrhea, gynecomastia, and impotence.

***Potential for Gastrointestinal Obstructions*-**The Invega tablet is non-deformable and does not appreciably change shape in the GI tract. It should ordinarily not be administered to patients with pre-existing severe GI narrowing (pathologic or iatrogenic, for example: esophageal motility disorders, small bowel inflammatory disease, "short guy" syndrome due to adhesions or decreased transit time, past history of peritonitis, cystic fibrosis, chronic intestinal pseudoobstruction, or Meckel's diverticulum).

A decrease in transit time (e.g. diarrhea) would be expected to decrease bioavailability and an increase in transit time (e.g. GI neuropathy or diabetic gastroparesis) would be expected to increase bioavailability.

***Orthostatic Hypotension and Syncope*-**Paliperidone can induce orthostatic hypotension and syncope in some patients because of its alpha-blocking activity.

***Potential for Cognitive and Motor Impairment*-**Somnolence and sedation were reported in subjects treated with paliperidone. Antipsychotics have the potential to impair judgment, thinking, or motor skills.

***Seizures*-**Paliperidone should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

***Dysphagia*-**Esophageal dysmotility and aspiration have been associated with antipsychotic drug use.

***Suicide*-**The possibility of suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy.

***Priapism*-**Drugs with alpha-adrenergic blocking effects have been reported to induce priapism, although no cases have been reported in clinical trials with paliperidone.

***Thrombotic Thrombocytopenic Purpura (TTP)*-**Cases of TTP have been reported in association with risperidone, but no cases have been observed during clinical studies with paliperidone.

***Body Temperature Regulation*-**Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents.

***Antiemetic Effect*-**An antiemetic effect was observed in preclinical studies with paliperidone.

***Use in Patients with Concomitant Illness*-**Clinical experience with paliperidone in patients with certain concomitant illnesses is limited. Patients with Parkinson's disease or Dementia with Lewy Bodies are reported to have an increased sensitivity to antipsychotic medications.

V. Drug Interactions

Drug	Interaction	Description
Paliperidone	Alcohol, CNS depressants	Coadministration may lead to enhanced CNS depression.

Drug	Interaction	Description
Paliperidone	Antihypertensive agents	Paliperidone may enhance the effects of the antihypertensive agent. Because of its alpha blocking activity, paliperidone may cause orthostatic hypotension and/or syncope may occur when given in combination with an antihypertensive medications.
Paliperidone	Levodopa and dopamine agonists	Coadministration may antagonize the effects of levodopa or dopamine agonists.

VI. Adverse Drug Events

Adverse Event ≥ 2% (given in %)	Placebo (n=355)	Paliperidone 3mg (n=127)	Paliperidone 6mg (n=235)	Paliperidone 9mg (n=246)	Paliperidone 12mg (n=242)
Total Adverse Events	66	72	66	70	76
Cardiovascular					
AV block, 1st degree	1	2	0	2	1
BP increased	1	2	<1	<1	1
Bundle branch block	2	3	1	3	<1
QT prolongation	3	3	4	3	5
Abnormal T wave	1	2	1	2	1
Orthostatic hypotension	1	2	1	2	4
Sinus arrhythmia	0	2	1	1	<1
Tachycardia	7	14	12	12	14
CNS					
Akathesia	4	4	3	8	10
Anxiety	8	9	7	6	5
Asthenia	1	2	<1	2	2
Dizziness	4	6	5	4	5
Dystonia	1	1	1	5	4
EPS	2	5	2	7	7
Fatigue	1	2	1	2	2
Headache	12	11	12	14	14
Hypertonia	1	2	1	4	3
Parkinsonism	0	0	<1	2	1
Somnolence	7	6	9	10	11
Tremor	3	3	3	4	3
GI					
Upper abdominal pain	1	1	3	2	2
Dry mouth	1	2	3	1	3
Dyspepsia	4	2	3	2	5
Nausea	5	6	4	4	4
Salivary hypersecretion	<1	0	<1	1	4
Miscellaneous					
Back pain	1	2	3	1	3
Increased blood insulin	1	2	1	1	<1
Cough	1	3	2	3	2
Pain in extremity	1	0	1	0	2
Pyrexia	1	1	<1	2	2
Blurred vision	1	1	<1	0	2

Paliperidone Treatment-Emergent EPS (%)					
EPS Group	**Placebo**	**Paliperidone 3mg**	**Paliperidone 6mg**	**Paliperidone 9mg**	**Paliperidone 12mg**
Parkinsonism	9	11	3	15	14
Akathesia	6	6	4	7	9
Use of anticholinergic medications	10	10	9	22	22
Overall EPS-related adverse event	11	12.6	10.2	25.2	26
Dyskinesia	3.4	4.7	2.6	7.7	8.7
Dystonia	1.1	0.8	1.3	5.3	4.5
Hyperkinesia	3.9	3.9	3	8.1	9.9
Tremor	3.4	3.1	2.6	4.5	3.3

VII. Dosing and Administration

Drug	Adult Dosing	Pediatric Dosing	Availability
Paliperidone	Schizophrenia: Initial dose is 6mg daily, given in the morning. Initial dose titration is not required. Some patients may require up to 12mg/day, while others can be maintained on 3mg/day. Dose increases above 6mg/day should occur at intervals > 5 days and be made in 3mg/day increments.	Safety and efficacy of paliperidone in patients under the age of 18 have not been established.	Paliperidone extended-release tablets are available in 3mg, 6mg, and 9mg.

VIII. Utilization

Invega Utilization 05/01/2007 - 04/30/2008

Label Name	Rx Num	Total Reimb Amt	Average cost per script
INVEGA 9 MG ER TABLET	112	$49,592.93	$442.79
INVEGA 3 MG ER TABLET	157	$49,795.37	$317.17
INVEGA 6 MG ER TABLET	238	$81,804.84	$343.72
Total 97 Recipients	**507**	**$181,193.14**	**$357.38**

Risperdal Utilization 05/01/2007 - 04/30/2008

Label Name	Rx Num	Total Reimb Amt	Average cost per script
RISPERDAL 0.25 MG TABLET	1166	$161,496.12	$138.50
RISPERDAL 0.5 MG TABLET	2092	$328,659.21	$157.10
RISPERDAL 0.5 M-TAB	138	$17,487.75	$126.72
RISPERDAL 1 MG M-TAB	63	$10,311.05	$163.67

Label Name	Rx Num	Total Reimb Amt	Average cost per script
RISPERDAL 1 MG TABLET	2042	$311,025.62	$152.31
RISPERDAL 1 MG/ML SOLN	237	$31,597.61	$133.32
RISPERDAL 2 MG M-TAB	42	$13,561.83	$322.90
RISPERDAL 2 MG TABLET	903	$233,359.70	$258.43
RISPERDAL 3 MG M-TAB	6	$2,270.44	$378.41
RISPERDAL 3 MG TABLET	501	$147,033.26	$293.48
RISPERDAL 4 MG M-TAB	14	$8,077.26	$576.95
RISPERDAL 4 MG TABLET	332	$125,459.78	$377.89
RISPERDAL CONSTA 25 MG	129	$53,969.79	$418.37
RISPERDAL CONSTA 37.5 MG	168	$86,565.51	$515.27
RISPERDAL CONSTA 50 MG	271	$258,113.02	$952.45
Total 1,015 Recipients	**8104**	**$1,788,987.95**	**$220.75**

IX. Ages of Patients

Invega Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
6	3	8
7	1	8
8	2	8
9	3	25
10	3	29
11	1	10
12	3	17
13	10	38
14	4	19
15	2	8
16	4	26
17	5	29
18	3	10
19	5	41
20	4	8
21	2	21
23	1	10
25	2	23
26	3	12
27	2	11
28	1	5
29	1	13

Age	Recip Count	Rx Count
31	1	5
33	2	4
34	1	3
35	2	2
36	1	2
37	1	1
38	1	1
40	4	11
41	2	4
42	2	11
44	1	5
46	1	1
47	1	2
48	1	3
49	2	13
50	1	3
51	1	2
52	1	12
57	1	6
58	1	7
61	1	2
62	3	28

Risperdal Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
1	1	1
2	1	1
3	4	24
4	11	49
5	16	92
6	37	304
7	49	299
8	40	269
9	55	495
10	59	417
11	52	363
12	62	433
13	53	422
14	59	489
15	37	330
16	50	323
17	27	190
18	28	219
19	24	193
20	13	76
21	9	107
22	7	61
23	6	46
24	10	87
25	8	82
26	13	125
27	9	118
28	7	66
29	9	77
30	10	101
31	9	87
32	7	73
33	2	3
34	9	61
35	9	46
36	10	55

Age	Recip Count	Rx Count
37	8	65
38	9	110
39	4	76
40	4	21
41	6	54
42	12	95
43	4	15
44	5	44
45	5	86
46	12	135
47	7	88
48	9	61
49	8	50
50	8	84
51	6	47
52	6	42
53	10	90
54	11	94
55	14	131
56	1	15
57	6	69
58	10	104
59	8	79
60	4	65
61	7	57
62	4	33
63	3	39
64	3	19
65	3	29
66	1	5
82	1	5
83	2	5
87	1	2
94	1	6

X. Conclusion

Paliperidone is the active metabolite of risperidone. There are no head to head comparisons with paliperidone and risperidone. One study compared Invega to one other antipsychotic, Olanzapine, and it showed Invega appeared similar in efficacy. It appears that paliperidone and risperidone have similar efficacy and side effect profiles, differing only in dosing, cost, and drug interaction profiles. No specific advantages of the new formulation have been demonstrated other than being dosed once a day.

HID Recommendation: It is recommended that a prior authorization be placed on paliperidone in consideration of the fact that paliperidone adds significant cost and provides no clinically proven benefit over risperidone. It is further recommended that if a patient fails a course of risperidone, the provider may request a prior authorization for paliperidone.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2008.
2. Invega® [package insert]. Titusville, NJ: Janssen, L.P.; February 2008.
3. New drug: Invega (paliperidone extended-release tablets). Pharmacist's Letter/Prescriber's Letter 2007;23(5):230512.
4. Owen RT. Extended-release paliperidone: efficacy, safety and tolerability profile of a new atypical antipsychotic. Drugs Today. 2007 Apr;43(4):249-58.
5. Yang LP, Plosker GL. Paliperidone extended release. CNS Drugs. 2007;21(5):417-25.

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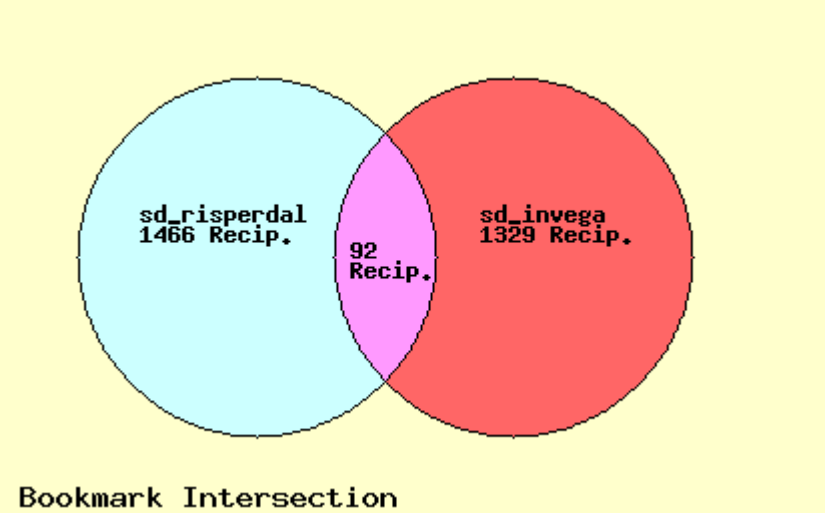
Patients taking Risperdal prior to Invega

January 2006 – April 2008



INVEGA 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 Invega must first try Risperidone.

- **Risperidone (Risperdal) does not require a prior authorization.**

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

RECIPIENT NAME:	RECIPIENT 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 Dosage: (must be completed) **Diagnosis for this request:**
Qualifications for coverage:
☐ Failed / intolerant to Risperidone (Risperdal)
Adverse Reaction (attach FDA MedWatch form) or contraindication to risperidone: (provide description below):
Medical Justification for use of paliperidone without trial of risperidone:
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)	

Dear Doctor:

The South Dakota Medicaid P&T Committee works with the Department of Social Services in developing guidelines to help assure that beneficiaries receive appropriate medication in the most cost-effective manner, while ensuring their needs are being met. As a part of this process, the Committee is asking you to participate in an effort to enlist the expertise of practitioners affected by the following criteria.

On September 5, 2008, the South Dakota Medicaid P&T Committee reviewed antidepressant utilization. Because there is limited evidence in adults showing one antidepressant is more effective or has a better safety profile* than another, the P&T Committee along with the Department of Social Services, would like to develop a two-tiered process for antidepressants.

The P&T Committee requested that as many drugs as possible be made available, if cost differences are within reason. Based on this recommendation, the Department of Social Services has chosen fluoxetine, citalopram, fluvoxamine, sertraline, paroxetine, venlafaxine, mirtazapine, bupropion, bupropion SR, and bupropion XL as first tier antidepressants. (Tricyclic antidepressants will NOT be affected by this policy.) In addition, those currently on therapy will be grandfathered and will not be required to meet the proposed criteria to continue on their current medication. The P&T Committee has proposed the criteria listed below for this class of medications.

Proposed Criteria for Antidepressants
SD P&T Committee
December 12, 2008

Claims for a non-preferred agent will be approved if:

1. A 30 day trial of a preferred agent has been completed within the last 365 days.
2. Cymbalta will be approved with a diagnosis of diabetic neuropathy or fibromyalgia within the last 365 days.

We are sending these draft criteria for comment by practitioners who prescribe these medications. Please provide comments on the listed criteria by March 1, 2009, at the address provided below. Your participation and guidance to the SD P&T Committee are invaluable and I would like to thank you for taking the time to review this information.

Sincerely,

Candace Rieth, PharmD
SD P&T Coordinator

*Nefazodone should not generally be used first-line due to the increased risk of hepatotoxicity

South Dakota Quantity Limit Suggestions

Drug Name	Strength	Limit / Day	Max Supply	Max Days
ABILIFY	2	1.00	34	34
ABILIFY DISCMELT	10	1.00	34	34
ABILIFY DISCMELT	15	1.00	34	34
ACTONEL	75	0.07	2	28
ADVICOR	20 - 1000MG	2.00	68	34
ADVICOR	20 - 500MG	1.00	34	34
ADVICOR	20 - 750MG	2.00	68	34
ADVICOR	40 - 1000MG	2.00	68	34
ALLEGRA ODT	30MG	2.00	68	34
ALLEGRA SUSP	30MG/5ml	10.00	340	34
ALTABAX	1%	0.33	5	15
ALTABAX	1%	0.33	10	30
ALTABAX	1%	0.50	15	30
ALVESCO	160MCG	0.20	6.1	30
ALVESCO	80MCG	0.20	6.1	30
AMBIEN CR	6.25MG	1.00	34	34
AMBIEN CR	12.5MG	1.00	34	34
ARICEPT ODT	5MG	1.00	34	34
ARICEPT ODT	10MG	1.00	34	34
BROVANA	15MCG/2ML	4.00	120	30
BYETTA	5MCG/0.02	0.04	1.2	30
BYETTA	10MCG/0.04	0.08	2.4	30
CADUET	10-10MG	1.00	34	34
CADUET	10-20MG	1.00	34	34
CADUET	10-40MG	1.00	34	34
CADUET	10-80MG	1.00	34	34
CADUET	2.5-10MG	1.00	34	34
CADUET	2.5-20MG	1.00	34	34
CADUET	2.5-40MG	1.00	34	34
CADUET	5-10MG	1.00	34	34
CADUET	5-20MG	1.00	34	34
CADUET	5-40MG	1.00	34	34
CADUET	5-80MG	1.00	34	34
CARDURA XL	4mg	1	34	34
CARDURA XL	8mg	1	34	34
CELEXA	20	2.00	68	34
COREG CR	10	1.00	34	34
COREG CR	20	1.00	34	34
COREG CR	40	1.00	34	34
COREG CR	80	1.00	34	34
CUBICIN	500MG	2.00	68	34
DAYTRANA	10MG/9HR	1	30	30
DAYTRANA	15MG/9HR	1	30	30
DAYTRANA	20MG/9HR	1	30	30
DAYTRANA	30MG/9HR	1	30	30
DURAGESIC	12MCG/HR	0.33	10	30
EFFEXOR	25MG	3.00	102	34
EFFEXOR	37.5MG	3.00	102	34
EFFEXOR	50MG	3.00	102	34
EFFEXOR	75MG	3.00	102	34
EFFEXOR	100MG	2.00	68	34
EXFORGE	5-160	1.00	34	34
EXFORGE	5-320	1.00	34	34

South Dakota Quantity Limit Suggestions

Drug Name	Strength	Limit / Day	Max Supply	Max Days
EXFORGE	10-160	1.00	34	34
EXFORGE	10-320	1.00	34	34
FEXMID	7.5	3.00	63	21
FLECTOR	1.3	2	68	34
FLEXERIL	5	2	68	34
FLUOXETINE	40	1.00	34	34
FLUOXETINE TABLET	10	2.00	68	34
FOCALIN XR	5	1.00	34	34
FOCALIN XR	10	1.00	34	34
FOCALIN XR	20	1.00	34	34
FOSAMAX PLUS D	70/2800	0.14	4	28
FOSAMAX PLUS D	70/5600	0.14	4	28
HUMIRA	40MG	0.07	2	28
HUMIRA	40MG	0.21	6	28
IBUDONE	10 - 200MG	5	170	34
IBUDONE	5 - 200MG	5	170	34
INVEGA	3	1.00	34	34
INVEGA	6	2.00	68	34
INVEGA	9	1.00	34	34
JANUMET	50-500	2.00	68	34
JANUMET	50-1000	2.00	68	34
KADIAN	100MG	2.00	68	34
KADIAN	20MG	2.00	68	34
KADIAN	30MG	2.00	68	34
KADIAN	50MG	2.00	68	34
KADIAN	60MG	2.00	68	34
KADIAN	10	1.00	34	34
KADIAN	200	1.00	68	34
KEROL	42%	1.00	30	30
KEPPRA XR	500mg	6.00	204	34
KEROL EMUL	50%	8.34	283.5	34
KEROL SUSP	50%	8.35	284	34
KEROL ZX	50%	0.35	12	34
LETAIRIS	10	1.00	34	34
LETAIRIS	5	1.00	34	34
LUNESTA	1	1.00	34	34
LUNESTA	2	1.00	34	34
LUNESTA	3	1.00	34	34
LUVOX	50MG	2.00	68	34
LUVOX	100MG	3.00	102	34
LUVOX CR	100MG	1.00	34	34
LUVOX CR	150MG	1.00	34	34
LYRICA	25MG	3.00	102	34
LYRICA	50MG	3.00	102	34
LYRICA	75MG	3.00	102	34
LYRICA	100MG	3.00	102	34
LYRICA	150MG	3.00	102	34
LYRICA	200MG	3.00	102	34
LYRICA	225MG	2.00	68	34
LYRICA	300MG	2.00	68	34
METADATE CD	10MG	1.00	34	34
METADATE CD	20MG	1.00	34	34
METADATE CD	30MG	1.00	34	34

South Dakota Quantity Limit Suggestions

Drug Name	Strength	Limit / Day	Max Supply	Max Days
METADATE CD	40MG	1.00	34	34
METADATE CD	50MG	1.00	34	34
METADATE CD	60MG	1.00	34	34
METADATE ER	10MG	2.00	68	34
METADATE ER	20MG	3.00	102	34
METHYLIN ER	10	2.00	68	34
METHYLIN ER	20	3.00	102	34
NEXIUM PACKET	10	1.00	30	30
NEXIUM PACKET	20	1.00	30	30
NEXIUM PACKET	40	1.00	30	30
NPLATE	250MCG	0.29	8	28
NPLATE	500MCG	0.29	8	28
OPANA ER	15MG	2.00	68	34
OPANA ER	30MG	2.00	68	34
OPANA ER	7.5MG	2.00	68	34
OXYCONTIN	15MG	2.00	68	34
OXYCONTIN	30MG	2.00	68	34
OXYCONTIN	60MG	2.00	68	34
PRISTIQ	100MG	1.00	34	34
PRISTIQ	50MG	1.00	34	34
PROAIR	HFA	0.75	25.5	34
PROVENTIL	HFA	0.59	20.1	34
PULMICORT FLEX	180	0.03	1	30
PULMICORT FLEX	90	0.03	1	30
REQUIP XL	2mg	1.00	30	30
REQUIP XL	4mg	1.00	30	30
REQUIP XL	8mg	3.00	90	30
RISPERDAL CONSTA	25	0.07	2	28
RISPERDAL CONSTA	37.5	0.07	2	28
RISPERDAL CONSTA	50	0.07	2	28
RISPERDAL CONSTA	12.5	0.07	2	28
RISPERDAL M	3	2.00	68	34
RISPERDAL M	4	2.00	68	34
RITALIN SR	20	3.00	102	34
SANCUSO	3.1mg/24h	0.12	4	34
SANCTURA	20MG	2.00	60	30
SANCTURA XR	60MG	1.00	34	34
SEROQUEL	100	3.00	102	34
SEROQUEL	200	4.00	136	34
SEROQUEL	300	5.00	170	34
SEROQUEL	25	3.00	102	34
SEROQUEL	50	3.00	102	34
SEROQUEL	400	3.00	102	34
SEROQUEL XR	200	1.00	34	34
SEROQUEL XR	300	2.00	68	34
SEROQUEL XR	400	2.00	68	34
SIMCOR	20 - 1000MG	2.00	68	34
SIMCOR	20 - 500MG	2.00	68	34
SIMCOR	20 - 750MG	2.00	68	34
SINGULAIR PACK	4MG	1.00	30	30
STRATTERA	10MG	2.00	68	34
STRATTERA	18MG	2.00	68	34
STRATTERA	25MG	2.00	68	34

South Dakota Quantity Limit Suggestions

Drug Name	Strength	Limit / Day	Max Supply	Max Days
SYMBICORT	80	0.34	10.2	30
SYMBICORT	160	0.34	10.2	30
TEKTURNA	300	1.00	34	34
TEKTURNA	150-12.5	1.00	34	34
TEKTURNA	150-25	1.00	34	34
TEKTURNA	300-12.5	1.00	34	34
TEKTURNA	300-25	1.00	34	34
TEKTURNA	150	1.00	34	34
VENTOLIN	HFA	1.06	54	34
VERAMYST	27.5	0.29	10	34
VUSION	0.25	1.00	30	30
VYVANSE	30MG	1.00	34	34
VYVANSE	60MG	1.00	34	34
VYVANSE	20MG	1.00	34	34
VYVANSE	40MG	1.00	34	34
VYVANSE	30MG	1.00	34	34
VYVANSE	50MG	1.00	34	34
VYVANSE	70MG	1.00	34	34
XOPENEX	HFA	1.5	45	30
ZANAFLEX	2MG	2.50	85	34
ZYFLO CR	600	4.00	136	34

South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Singulair® Utilization

The chart below illustrates the findings of Singulair® utilization based on diagnosis during a specified time frame (07/01/07 to 06/30/08).

Diagnosis (ICD-9)	Number of Unique Patients	Percentage of Total Patients receiving a prescription for Singulair®
ALL	3,902	100%
Patients < 18 years	3,389	87%
FDA-Approved Indications:		
Asthma (493)	2,398	61%
Allergic Rhinitis (477)	2,123	54%
Both Asthma and Allergic Rhinitis	1,352	35%
Laryngotracheobronchitis (490)	1,247	32%
Croup (466)	2,033	53%
Patients with NONE of the above diagnoses on file.	399	10%
Unlabeled Uses:		
Urticaria (708)	317	8%
Atopic dermatitis (691.8)	689	18%

*Note: there may be some overlap since patients can have more than one diagnosis on file.

South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Singulair® Utilization

Results for period 05/08/07 – 05/07/08:

Number of unique patients taking Singulair®: 3900
Number of unique patients taking Singulair® ≥ 10 times in one year: 455
Number of unique patients taking Singulair® ≥ 10 times in one year that did not take albuterol or corticosteroids: 142
Number of unique patients taking Singulair® 1 or more times per year that did not take albuterol or corticosteroids: 1523

Singulair Patient's Diagnoses and Occurences 2002 - present			
ACUTE UPPER RESP INFECTIONS UNS	1001	VIRAL WARTS UNSPECIFIED	143
COUGH	851	CROUP	139
ACUTE PHARYNGITIS	832	IMPACTED CERUMEN	139
UNSPECIFIED OTITIS MEDIA	791	UNS INFECTIVE OTITIS EXTERNA	139
ROUTINE INFANT/CHILD HEALTH CHECK	784	SHORTNESS BREATH	138
FEVER	660	UNS ALLERGY	135
VACCINE FOR INFLUENZA	620	REGULAR ASTIGMATISM	133
ALLERGIC RHINITIS CAUSE UNS	588	HYPERTROPHY TONSILS W ADENOIDS	129
ASTHMA UNSPECIFIED	585	OTH FOLLOW-UP EXAMINATION	128
ACUTE BRONCHITIS	432	VACCINE FOR OT DISEASE COMBINATION	125
ACUTE SINUSITIS UNSPECIFIED	431	NAUSEA WITH VOMITING	124
UNSPECIFIED VIRAL INFECTION	381	ROUTINE MEDICAL EXAM HEALTH FACIL	124
PNEUMONIA ORGANISM UNS	366	DEPRESSIVE DISORDER OTHER	122
STREPTOCOCCAL SORE THROAT	364	ROUTINE/RITUAL CIRCUMCISION	122
ABDOMINAL PAIN UNS SITE	354	OTALGIA UNSPECIFIED	121
VACCINATION FOR VIRAL HEPATITIS	350	CONTUSION FACE/SCALP/NCK	120
CONTACT DERMATITIS UNS CAUSE	344	UNS ACUTE CONJUNCTIVITIS	119
VACCINE FOR DTP COMBINED	334	OTH/UNS INJURY KNEE LEG ANKLE/FOOT	118
BRONCHITIS UNSPECIFIED	328	ENCOUNTER LONG TERM USE OTH DRUGS	114
VACCINE FOR MEASLE MUMPS RUBELLA	320	DYSFUNCTION EUSTACHIAN TUBE	113
OTH NONINFECTIOUS GASTROENTERITIS	312	UNSPEC CHEST PAIN	109
HYPERMETROPIA	308	CHRONIC TONSILLITIS	107
VACCINE OTHER VIRAL DISEASES	304	FETAL/NEONATAL JAUNDICE UNSPEC	107
RESPIRATORY ABNORMALITY OT	301	IMPETIGO	107
UNS CONJUNCTIVITIS	300	OTHER PRE OPERATIVE EXAMINATION	105
UNS SINUSITIS (CHRONIC)	289	VOLUME DEPLETION	105
DIARRHEA	286	DIAPER OR NAPKIN RASH	104
OTH DISEASES NASAL CAVITY/SINUSES	284	EXTRINSIC ASTHMA UNSPECIFIED	104
RASH/OTH NONSPEC SKIN ERUPTION	280	EXAMIN EYES/VISION	101
MYOPIA	279	UNSPEC DENTAL CARIES	101
VOMITING ALONE	277	ACUTE NASOPHARYNGITIS	98
VACCINE FOR POLIOMYELITIS	273	DISLOCATION THORACIC VERT CLOSED	96
ACUTE TONSILLITIS	267	ASTIGMATISM UNSPECIFIED	95
VACCINE FOR VARICELLA	249	OTH ATOPIC DERMATITIS/RELATED COND	95
CHRONIC RHINITIS	247	OTH CHRONIC NONSUPPUR OTITIS MEDIA	95
VACCINE STREP PNEUMONIAE	247	URINARY FREQUENCY	94
SGL LIVEBORN NO C-SECTION	222	SIMPLE CHRONIC SEROUS OTITIS MEDIA	90
WHEEZING	218	ANEMIA UNSPECIFIED	87
INFLUENZA W OTH RESPIRATORY MANIF	215	ACUTE SEROUS OTITIS MEDIA	86
UNSPEC CONSTIPATION	215	HYPERTROPHY TONSILS ALONE	86
VACCINE H INFLUENZA B	214	BACKACHE UNSPECIFIED	85
HEADACHE	207	UNSPEC URTICARIA	85
PAIN IN LIMB	189	DISLOCATION CERV VERT UNS CLOSED	84
URINARY TRACT INFECTION UNSPEC	178	CANDIDIASIS MOUTH	83
ESOPHAGEAL REFLUX	177	DISLOCATION LUMBAR VERT CLOSED	82

Singulair Patient's Diagnoses and Occurences 2002 - present			
OTH MEDICAL EXAM FOR ADMIN PURPOSES	175	PAIN IN JOINT LOWER LEG	82
OTHER MALAISE AND FATIGUE	174	NONSUPPURATIVE OTITIS MEDIA	81
ACUTE BRONCHIOLITIS OT INFECT ORG	171	OTH/UNS INJURY ELBOW FOREARM/WRIST	80
ATTENTION DEFICIT DIS W HYPERACT	170	SCREENING FOR DEVELOPMENT PROB	79
ASTHMA UNSPEC W EXACERBATION	162	LABORATORY EXAMINATION	75
DYSURIA	151	UNDIAGNOSED CARDIAC MURMURS	75
SCREENING FOR PULMONARY TB	147	ANXIETY STATE UNSPECIFIED	74
AC SUPPURAT OTITIS MEDIA WO RUPT	144	LUMBAGO	74
SPRAIN/STRAIN OF ANKLE UNSPEC	74	ABDOMINAL PAIN OTHER SITE	48
TEETHING SYNDROME	74	ABNORMAL FINDINGS LUNG FIELD	48
UNS DISTURBANCE CONDUCT	74	OTH DISEASES RESPIRATORY SYSTEM	48
ENTERITIS OTHER VIRAL ORGANISM	73	OTHER DISEASE HAIR/FOLLICLES	48
UNS HEAD INJURY	73	UNSPEC DISORDER SKIN/SUBQ TISSUE	48
ATTENTION DEFICIT DIS WO HYPERACTV	71	ABDOMINAL PAIN EPIGASTRIC	47
RESPIRATORY SYNCYTIAL VIRUS	71	OTH POSTSURGICAL STATUS	47
CERVICALGIA	70	SWELLING LIMB	47
OPPOSITIONAL DEFIANT DISORDER	70	UNSPECIFIED SLEEP APNEA	47
UNSPECIFIED FALL	70	ABRASION HEAD	46
DEHYDRATION	69	ALLERGIC RHINITIS POLLEN	46
ENLARGEMENT OF LYMPH NODES	68	EXAMIN EARS/HEARING	46
SGL LIVEBORN W C-SECTION	68	INJURY FACE/NECK	46
VACCINE FOR OTHER SPEC DISEASE	68	ATTENTION TO DRESSINGS/SUTURES	45
HEALTH EXAMINATION DEFINED SUBPOP	67	OTHER SPECIFIED VIRAL WARTS	45
STRUCK BY OBJ/PERSON OT	66	UNS DISORDER REFRACTION/ACCOM	45
PAIN IN JOINT ANKLE/FOOT	65	VACCINE FOR TETANUS DIPHTHERIA	45
ADJUST DIS EMOT/CONDUCT DISTUR	64	INSOMNIA UNSPECIFIED	44
OBESITY UNSPECIFIED	64	OBSERV FOR OTHER SUSPECT CONDITION	44
OTH PHYSICAL THERAPY	63	SYNCOPE AND COLLAPSE	44
OPEN WOUND OF FOREHEAD	62	UNS ADJUST REAC	44
OTHER CONVULSIONS	62	ABNORMAL WEIGHT GAIN	43
UNS ACUTE NONSUPPUR OTITIS MEDIA	62	ADJUSTMENT DISORDER MIXED	43
OTH DISEASES TRACHEA/BRONCHUS	61	PAIN IN JOINT SHOULDER	43
UNS ACCIDENT	61	APNEA	42
URINARY INCONTINENCE UNSPECIFIED	61	HEMATURIA	42
UNS LOCAL SKIN/SUBQ TISSUE INFECT	60	INGROWING NAIL	42
OPEN WOUND OF FINGER	59	FEEDING DIFFICULTIES/MISMANAGEMENT	41
ACUTE BRONCHIOLITIS RSV	58	LOSS OF WEIGHT	41
NAUSEA ALONE	56	OT RESPIRATORY PROBLEM AFTER BIRTH	41
OTHER ACNE	56	OTH DISEASES LUNG OTHER	41
OPEN WOUND OF SCALP	55	ADJUSTMENT DISORDER DEPRESSED	40
OTH/UNS INJURY FINGER	55	ROUTINE GYNECOLOGICAL EXAM	40
LACK NORM PHYSIOLOG DEVELOP UNSPEC	54	VACCINE FOR DTP W POLIO	40
PAIN IN JOINT FOREARM	54	CHRONIC AIRWAY OBSTRUCTION OTHER	39
UNS MYALGIA/MYOSITIS	54	CONTUSION OF FINGER	39
VIRAL EXANTHEM UNSPEC	54	PAIN IN JOINT PELVIS/THIGH	39

Singulair Patient's Diagnoses and Occurences 2002 - present			
CHRONIC TONSILLITIS/ADENOIDITIS	53	PULMONARY CONGESTION/HYPOSTASIS	39
OTHER INTESTINAL MALABSORPTION	53	UNS CHRONIC SUPPUR OTITIS MEDIA	39
UNS GASTRITIS GASTRODUODENITIS	53	UNS HYPOTHYROIDISM	39
UNS PRE OPERATIVE EXAMINATION	53	ABDOM PAIN R LOWER QUAD	38
PERSON W FEARED COMPLAINT NO DX	51	SPRAIN/STRAIN OF WRIST UNSPEC	38
VACCINE FOR OT VIRAL DISEASE	51	ASPHYXIA AND HYPOXEMIA	37
EPISTAXIS	50	CHRONIC MAXILLARY SINUSITIS	37
FUSSY INFANT (BABY)	50	SPRAIN/STRAIN OF NECK	37
UNSPECIFIED ESSENTIAL HYPERTENSION	50	ACCIDENTAL FALL OTHER TRIP STUMBLE	36
ACUTE MAXILLARY SINUSITIS	49	DISLOCATION SACRUM CLOSED	36
DIZZINESS AND GIDDINESS	49	FAILURE TO THRIVE	36
HYPERTROPHY ADENOIDS ALONE	49	INSECT BITE OT	36
PLACE OCCURRENCE HOME	49	OTH DEVELOPMENTAL SPEECH DISORDER	36
SCREENING MAL NEO CERVIX	49	OTHER DISEASE WHITE BLOOD CELLS	36
UNS VAGINITIS/VULVOVAGINITIS	49	PAIN IN JOINT UPPER ARM	36
UNSPEC CELLULITIS/ABSCESS	49	UNS MIGRAINE NOT INTRACTABLE	36
EDEMA	35	CONTUSION OF KNEE	27
OTHER CHEST PAIN	35	OBSTRUCTIVE SLEEP APNEA	27
OTHER GENERAL SYMPTOMS	35	PULMONARY COLLAPSE	27
TOBACCO USE DISORDER	35	UNS CONDUCTIVE HEARING LOSS	27
UNS HEARING LOSS	35	DERMATITIS FOOD TAKEN INTERNALLY	26
VACCINE FOR UNSPEC DIS COMBINATION	35	DISTURBANCE SKIN SENSATION	26
OTH UNKNOWN/UNS MORBIDITY/MORTALITY	34	HYPOPOTASSEMIA	26
SPRAIN/STRAIN OF HAND UNSPEC	34	NOCTURNAL ENURESIS	26
UNS SYMPTOM FEMALE GENITAL ORGANS	34	OTH ACQUIRED DEFORMITIES ANKLE/FOOT	26
ABNORMALITY OF GAIT	33	OTH/UNS INJURY SHOULDER/UPPER ARM	26
DELIVER SINGLE LIVEBORN	33	OTHER SYMPTOMS INVOLVING HEAD/NECK	26
NEWBORN FEEDING PROBLEMS	33	PNEUMONIA RESPIRATORY SYNCY VIRUS	26
OPEN WOUND OF LIP	33	PRESBYOPIA	26
OTH ABNORMAL BLOOD CHEMISTRY	33	ABDOM PAIN R UPPER QUAD	25
OTH/UNS HYPERLIPIDEMIA	33	AMBLYOPIA UNSPECIFIED	25
PAIN IN JOINT SITE UNS	33	ANOREXIA	25
ALLERGIC RHINITIS OTH ALLERGEN	32	HYPERSOMNIA W SLEEP APNEA UNSPEC	25
DERMATOPHYTOSIS THE BODY	32	NONALLOPATHIC LESION THORACIC	25
DISLOCATION MULT CERV VERT CLOSED	32	SCABIES	25
HAND FOOT/MOUTH DISEASE	32	UNS LYMPHADENITIS EX MESENTERIC	25
MOLLUSCUM CONTAGIOSUM	32	VACCINE UNSPEC SINGLE DISEASE	25
OTORRHEA UNSPECIFIED	32	ADJUST DIS CONDUCT DISTURB	24
PULMONARY EOSINOPHILIA	32	ANTENATAL SCREENING FOR OT	24
STOMATITIS AND MUCOSITIS	32	BIPOLAR DISORDER UNSPECIFIED	24
CAUGHT BETWEEN OBJECTS	31	CONTUSION OF ELBOW	24
FOREIGN BODY IN EAR	31	INCONTINENCE OF FECES	24
UNS DISEASE RESPIRATORY SYSTEM	31	OTH COUNSEL/ADVICE FOR CONTRACEPT	24
ACCID OTH CUT PIERCE INSTRUMENTS	30	OTHER FUNCTIONAL STOMACH DISORDERS	24
ADJUSTMENT DISORDER ANXIETY	30	PAIN IN JOINT HAND	24

Singulair Patient's Diagnoses and Occurences 2002 - present			
DIABETES UNCOMPL TYPE II	30	POSTTRAUMATIC STRESS DISORDER	24
HYPOXEMIA	30	REFLUX ESOPHAGITIS	24
NONALLOPATHIC LESION CERVICAL	30	ROUTINE POSTPARTUM FOLLOW UP	24
OPEN WOUND OF FOOT	30	SIMPLE CHRONIC MUCOID OTITIS MEDIA	24
ORAL APHTHAE	30	TACHYCARDIA UNSPECIFIED	24
OVEREXERTION/STRENUOUS MOVEMENTS	30	UNS PRURITIC DISORDER	24
POLYDIPSIA	30	UNS SUPPURATIVE OTITIS MEDIA	24
SEBACEOUS CYST	30	ACCIDENTAL FALL ONE LEVEL TO ANOTHR	23
SPEECH THERAPY	30	CANDIDIASIS VULVA/VAGINA	23
SUPERVISION OTHER NORMAL PREGNANCY	30	EX ASTHMA W EXACERBATION	23
UNSPECIFIED SLEEP DISTURBANCE	30	FRACTURE DISTAL RADIUS OT CLOSED	23
ABDOMINAL PAIN GENERALIZED	29	GYNECOLOGICAL EXAMINATION	23
CELLULITIS/ABSCESS LEG EX FOOT	29	NONINFECT VAG LEUKORRHEA	23
ENCOUNTER FOR OCCUPATIONAL THERAPY	29	OPEN WOUND OF FACE UNSPEC	23
ENCTR THERAP DRUG MONITORING	29	RESPIRATORY DISTRESS SYNDROME NB	23
OTH CHRONIC ALLERGIC CONJUNCTIVITIS	29	SCREENING FOR CONDITION UNSP	23
OTH/UNS INJURY HAND EX FINGER	29	SPASM OF MUSCLE	23
ABNORMAL INVOLUNTARY MOVEMENTS	28	SWELLING/MASS/LUMP IN HEAD/NECK	23
CONTUSION OF FOOT	28	DYSTHYMIC DISORDER	22
DYSPHAGIA	28	FALL AGAINST OTHER OBJECT	22
OTH MUCOPURULENT CONJUNCTIVITIS	28	INFANT OBSERVATION INFECTOUS	22
OTH PULMONARY INSUFFICIENCY OTHER	28	IRREGULAR MENSTRUAL CYCLE	22
UNS FOLLOW-UP EXAMINATION	28	OTHER ABNORMAL GLUCOSE	22
CONTUSION OF HAND(S)	27	OTHER RESPIRATORY SYMPTOMS	22

South Dakota Department of Social Services
Pharmacy and Therapeutics Committee Meeting
Xopenex®

I. Overview

Xopenex (levalbuterol) is a beta$_2$-agonist. Beta$_2$-agonists relax airway smooth muscle by stimulating beta$_2$-receptors. Xopenex HFA is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease. Xopenex inhalation solution is indicated for the treatment of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

II. Pharmacology

Activation of beta$_2$-adrenergic receptors on airway smooth muscles leads to the activation of adenylcyclase and to an increase in the intracellular concentration of cyclic AMP. This increase leads to the activation of protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in relaxation. Levalbuterol relaxes the smooth muscles of all airways, from the trachea to the terminal bronchioles.

III. Pharmacokinetics

Drug	Serum Half-Life (hours)	Onset (minutes)	Duration (hours)	Renal Excretion (%)	Active Metabolites
Levalbuterol	3.3-4	5-17	3-6	80-100	Yes

IV. Warnings/Precautions

Paradoxical Bronchospasm-Like other inhaled beta-adrenergic agonists, Xopenex can produce paradoxical bronchospasm, which may be life threatening.

Deterioration of Asthma-Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses than usual of beta agonist, this may be a marker of destabilization of asthma.

Use of Anti-Inflammatory Agents-The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids, to the therapeutic regimen.

Cardiovascular Effects-Beta-adrenergic agonists can produce clinically significant cardiovascular effects in some patients, as measured by heart rate, blood pressure, and/or symptoms. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. Levalbuterol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Do Not Exceed Recommended Dose-Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma.

Immediate Hypersensitivity Reactions-Immediate hypersensitivity reactions may occur after administration of racemic albuterol, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema.

Diabetes Mellitus and Ketoacidosis-Large doses of intravenous racemic albuterol have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

V. Drug Interactions

Drug	Interaction	Description
Levalbuterol	Monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, or drugs known to prolong the QTc interval	Beta2 Agonists should be administered very cautiously in patients taking MAOIs, tricyclic antidepressants, or drugs known to prolong the QTc interval or who have taken them within 2 weeks prior to the start of therapy with beta2 agonists.
Levalbuterol	Nonselective beta-adrenergic blocking agents	By blocking the same receptor that the adrenergic agonists target, the nonselective blocking agents may lead to an antagonistic effect.
Levalbuterol	Diuretics	The ECG changes and hypokalemia that may result from the administration of non-potassium-sparing diuretics can be acutely worsened by beta-agonists. Caution is advised in the coadministration of beta-agonists with non-potassium sparing diuretics.
Levalbuterol	Digoxin	Serum digoxin levels in patients who are currently receiving digoxin and Xopenex or albuterol should be monitored.

VI. Adverse Drug Events

Adverse Event	Levalbuterol inhalation solution	Levalbuterol HFA inhalation
Cardiovascular		
Chest pain	< 2	-
ECG change	< 2	-
Hypertension	< 2	< 2
Hypotension	< 2	-
Syncope	< 2	-
Tachycardia	2.7 – 2.8	-
CNS		
Anxiety	< 2.7	-
Asthenia	3	-
Dizziness	1.4 – 2.7	2.7
Somnolence	< 2	-
Tremor	< 6.8	-
GI		
Abdominal pain	< 1.5	-
Constipation	-	< 2
Diarrhea	1.5 – 6	-
Dry mouth	< 2	-
Dyspepsia	1.4 – 2.7	-
Gastroenteritis	< 2	< 2
Nausea	< 2	-

Adverse Event	Levalbuterol inhalation solution	Levalbuterol HFA inhalation
Vomiting	-	10.5
Miscellaneous		
Accidental injury	< 2.7	9.2
Acne	-	< 2
Articular rheumatism	4.5 – 6.1	-
Asthma	9 – 9.1	9.4
Bronchitis	-	2.6
Conjunctivitis	-	< 2
Cough	1.4 – 4.1	-
Cyst	-	< 2
Dysmenorrhea	-	< 2
Ear pain	-	< 2
Edema	1.4 – 2.8	-
Epistaxis	-	< 2
Fever	3 – 9.1	-
Flu syndrome	1.4 – 4.2	< 2
Leg cramps	< 2.7	-
Lymphadenopathy	< 3	-
Myalgia	< 1.5	< 2
Pain (nonspecific)	1.5 – 3	4
Pharyngitis	3 – 10.4	6.6 – 7.9
Rash	< 7.5	-
Rhinitis	2.7 – 11.1	7.4
Sinusitis	1.4 – 4.2	-
Urticaria	< 3	-
Vaginal Moniliasis	-	< 2
Viral infection	7.6 – 9	< 2

VII. Dosing and Administration

Drug	Adult Dosing	Pediatric Dosing	Availability
Levalbuterol	Asthma, nocturnal asthma, and reversible bronchospasm: Inhalation solution: 0.63 mg 3 times daily every 6-8 hours; maximum 1.25 mg 3 times daily. Aerosol inhaler (HFA): 1-2 inhalations (59-118 mcg) every 4-6 hours; maximum 12 inhalations daily.	Inhalation solution: 6-11 years of age: 0.31 mg 3 times daily; maximum 0.63 mg 3 times daily. Aerosol inhaler (HFA): Children 4 years of age and older are approved to use adult dose.	Inhalation solution: 0.31 mg, 0.63 mg, and 1.25 mg unit dose vials. Aerosol inhaler (HFA): 15 g (200 inhalations)

VIII. Clinical Efficacy

References	Study Type and Size	Methods/Results/Conclusions
Lam	Randomized N=20 ICU patients (10 with baseline tachycardia and 10 without baseline tachycardia)	**Method:** Patients were randomized to receive at least 2 consecutive doses of albuterol 2.5mg or levalbuterol 1.25mg via nebulizer 4 hours apart. **Results:** Patients with baseline tachycardia, the mean largest heartrate (HR) increase was 1.4 beats/min (1.3%) with albuterol and 2.0 beats/min (2.1%) with levalbuterol. In patients without baseline tachycardia, there was an increase of 4.4 beats/min (6.7%) with albuterol and 3.6 beats/min with levalbuterol (5.0%). **Conclusions:** This study shows that short-term use of albuterol and levalbuterol results in similar changes in heartrate.
Hardasmalani	Prospective, double-blind, randomized. N=70 (children ages 5-21 with a history of asthma presenting to the ED in acute exacerbation)	**Method:** Patients received either 1.25mg of levalbuterol or albuterol 2.5mg via nebulizer along with ipratropium. Patients received 3 back-to-back treatments as needed every 20 minutes to a maximum of 3 doses; 2mg/kg of oral prednisone was administered after the second treatment. **Results:** All patients in both groups showed improvement in oxygen saturations, respiratory rates, and peak flow rates. No statistically significant difference was observed between the 2 groups. **Conclusions:** This study shows that levalbuterol and albuterol are similarly efficacious.
Qureshi	Prospective, double-blind, randomized, controlled. N=129 (children ages 2-14 presenting to the ED with an acute moderate or severe asthma exacerbation)	**Method:** 64 children were given albuterol and 65 were given levalbuterol – they were treated using a standard ED asthma pathway. Primary outcomes were changes from baseline in clinical asthma score and the percentage of predicted FEV1 after the first, third, and fifth treatment. Secondary outcomes included number of treatments, length of ED care, rate of hospitalization, and changes in pulse rate, respiratory rate, and oxygen saturation. **Results:** There were no differences between groups in primary or secondary outcomes or in the rate of adverse events. **Conclusions:** This study shows that levalbuterol and albuterol are similarly efficacious.
Nelson	Randomized, double-blind, parallel-group. N=362 (patients > 12)	**Method:** Patients were treated with levalbuterol and albuterol via nebulizer three times a day for 28 days. Primary endpoint was peak change in FEV1 after 4 weeks. **Results:** The change in peak FEV1 was nonsignificant after 4 weeks, 0.84L (levalbuterol) and 0.74L (albuterol). All active treatments were well tolerated. At week 4, the predose FEV1 value was greater in patients who received levalbuterol or placebo when compared with albuterol. **Conclusions:** This study shows that levalbuterol and albuterol are similarly efficacious.
Carl	Randomized, double-blind, controlled. N=482 (children age 1-18 years)	**Method:** Patients received albuterol 2.5mg or levalbuterol 1.25mg via nebulizer every 20 minutes (max=6 doses). Primary outcome was hospitalization rate. **Results:** Hospitalization rate was significantly lower in the levalbuterol group (36%) compared to the albuterol group (45%). Length of stay was not significantly shorter in the

References	Study Type and Size	Methods/Results/Conclusions
		levalbuterol group (44.9 hours) compared to the albuterol group (50.3 hours). No significant adverse events occurred in either group. **Conclusions:** This study shows that levalbuterol reduced the rate of hospitalization.
Nowak	Multicenter, randomized, double-blind. N=627 (adults with acute asthma exacerbations)	**Method:** Patients received prednisone and either levalbuterol 1.25mg or albuterol 2.5mg via nebulizer. Treatments were given every 20 minutes in the first hour, then every 40 minutes for 3 additional doses, then as necessary for up to 24 hours. Primary endpoint was time to discharge. Secondary endpoint included changes in lung function and hospitalization rate. A subset of 160 patients had plasma S-albuterol concentrations at study entry. **Results:** Time to discharge did not differ between the 2 treatments. FEV1 improvement was greater following levalbuterol compared to albuterol (0.50 +/- 0.43L and 0.43 +/- 0.37L, respectively). 7.0% of levalbuterol patients and 9.3% of albuterol patients required hospitalization. **Conclusions:** This study shows that levalbuterol and albuterol are effective at improving airway function and are well tolerated.
Berger	Multicenter, randomized, double-blind. N=173 (children aged 4-11)	**Method:** Patients were given levalbuterol 90mcg, albuterol 180mcg, and placebo via MDI QID. Primary endpoint was the double-blind average peak percent change in FEV1 from visit predose. Secondary endpoints included the area under the FEV1 percent change from predose curve and peak percent predicted FEV1. **Results:** Levalbuterol significantly improved the least square mean peak percent change in FEV1 compared with placebo. The incidence of adverse events was 43.4% for levalbuterol, 56.4% for albuterol, and 51.4% for placebo. The rate of discontinuation was 1.3% for levalbuterol, 2.6% for albuterol, and 8.6% for placebo. **Conclusions:** This study shows that levalbuterol and albuterol are similarly efficacious and that levalbuterol offers a significant advantage over placebo.

IX. Summary of Evidence

Short Acting Beta2 Agonists (albuterol vs levalbuterol)

- Among adults with asthma, 1 trial found less rescue medication use with levalbuterol with no apparent difference in symptoms.
- No significant difference between drugs for symptoms, and use of rescue medications, among children with asthma using these medications daily.
- Heart rate increases with both drugs. No significant difference between drugs for blood pressure, palpitations, tachycardia, increased blood glucose, or dizziness/nervousness/anxiety/tremor in adults.
- No significant differences between drugs in heart rate, light-headedness, tremor, dizziness and nervousness in children. Blood glucose increased with both drugs, more with albuterol in children.

X. Conclusion

The National Asthma Education and Prevention Program guidelines state that levalbuterol, at half the dose of albuterol, produces similar bronchodilation and side effects as albuterol. Clinical studies do not support routine use of levalbuterol over albuterol. Albuterol will be safe and well-tolerated for most patients. Certain subsets of patients, including patients requiring high doses of albuterol, might achieve greater bronchodilation from levalbuterol. More prospective studies in these subsets of patients are needed.

HID recommendation: It is recommended that a prior authorization be placed on levalbuterol in consideration of the fact that levalbuterol offers no clinical advantage over the use of albuterol and has a similar side effect profile. It is recommended that providers request prior authorization for patients who fail a trial of albuterol.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2007.
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11. National Asthma Education and Prevention Program. Guidelines for the Diagnosis and Management of Asthma: Expert Panel Report 3 (EPR3). Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute, 2007; Available from http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. Accessed January 11th, 2008.
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14. Hardasmalani MD, DeBari V, Bithoney WG, et al. Levalbuterol versus racemic albuterol in the treatment of acute exacerbation of asthma in children. Pediatr Emerg Care. 2005 Jul;21(7):415-9.
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South Dakota Medicaid
Levalbuterol and Albuterol Utilization
05/01/2007 – 04/30/2008

Total Xopenex Utilization 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
XOPENEX HFA 45 MCG INHALER	612	$30,285.84	$49.49
XOPENEX 0.31 MG/3 ML SOLUTION	239	$24,107.47	$100.87
XOPENEX 0.63 MG/3 ML SOLUTION	1499	$177,247.69	$118.24
XOPENEX 1.25 MG/3 ML SOLUTION	1135	$136,595.61	$120.35
TOTAL	3485	$368,236.61	

There were 1696 unique patients

Total Albuterol Utilization 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
ACCUNEB 0.63 MG/3 ML INH SOLN	292	$18,003.88	$61.66
ACCUNEB 1.25 MG/3 ML INH SOLN	121	$7,473.46	$61.76
ALBUTEROL 0.83 MG/ML SOLN	8240	$140,973.46	$17.11
ALBUTEROL 5 MG/ML SOLUTION	786	$7,738.89	$9.85
ALBUTEROL 90 MCG INHALER	7160	$181,470.03	$25.34
ALBUTEROL SUL 0.63 MG/3 ML SOL	452	$21,083.84	$46.65
ALBUTEROL SUL 1.25 MG/3 ML SOL	678	$37,154.54	$54.80
PROAIR HFA 90 MCG INHALER	2847	$104,914.99	$36.85
PROVENTIL HFA 90 MCG INHALER	432	$18,494.36	$42.81
PROVENTIL 90 MCG INHALER	7	$324.87	$46.41
VENTOLIN HFA 90 MCG INHALER	867	$31,209.10	$36.00
TOTAL	21882	$568,841.42	

There were 10,450 unique patients

Xopenex Utilization - Patients under 18 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
XOPENEX HFA 45 MCG INHALER	315	$16,206.31	$51.45
XOPENEX 0.31 MG/3 ML SOLUTION	237	$23,944.59	$101.03
XOPENEX 0.63 MG/3 ML SOLUTION	1401	$163,571.17	$116.75
XOPENEX 1.25 MG/3 ML SOLUTION	790	$92,474.19	$117.06
TOTAL	2743	$296,196.26	

There were 1460 unique patients < 18

Albuterol Utilization - Patients under 18 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
ACCUNEB 0.63 MG/3 ML INH SOLN	292	$18,003.88	$61.66
ACCUNEB 1.25 MG/3 ML INH SOLN	120	$7,384.45	$61.54
ALBUTEROL 0.83 MG/ML SOLN	7050	$115,412.11	$16.37
ALBUTEROL 5 MG/ML SOLUTION	682	$6,574.52	$9.64
ALBUTEROL 90 MCG INHALER	3474	$89,168.71	$25.67
ALBUTEROL SUL 0.63 MG/3 ML SOL	452	$21,083.84	$46.65
ALBUTEROL SUL 1.25 MG/3 ML SOL	652	$35,552.20	$54.53
PROAIR HFA 90 MCG INHALER	1517	$58,228.55	$38.38
PROVENTIL 90 MCG INHALER	2	$37.36	$18.68
PROVENTIL HFA 90 MCG INHALER	202	$8,760.68	$43.37
VENTOLIN HFA 90 MCG INHALER	489	$17,720.58	$36.24
TOTAL	14,932	$377,926.88	

There were 8096 unique patients < 18

Xopenex Utilization - Patients 18 to 65 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
XOPENEX HFA 45 MCG INHALER	296	$14,025.84	$47.38
XOPENEX 0.31 MG/3 ML SOLUTION	2	$162.88	$81.44
XOPENEX 0.63 MG/3 ML SOLUTION	98	$13,676.52	$139.56
XOPENEX 1.25 MG/3 ML SOLUTION	340	$43,299.25	$127.35
TOTAL	736	$71,164.49	

There were 232 unique patients 18 - 65

Albuterol Utilization - Patients 18 to 65 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
ACCUNEB 1.25 MG/3 ML INH SOLN	1	$89.01	$89.01
ALBUTEROL 0.83 MG/ML SOLN	1158	$24,827.44	$21.44
ALBUTEROL 5 MG/ML SOLUTION	93	$1,057.12	$11.37
ALBUTEROL 90 MCG INHALER	3641	$91,180.01	$25.04
ALBUTEROL SUL 1.25 MG/3 ML SOL	26	$1,602.34	$61.63
PROAIR HFA 90 MCG INHALER	1316	$46,210.73	$35.11
PROVENTIL 90 MCG INHALER	3	$129.87	$43.29
PROVENTIL HFA 90 MCG INHALER	228	$9,651.50	$42.33
VENTOLIN HFA 90 MCG INHALER	362	$12,930.24	$35.72
TOTAL	6828	$187,678.26	

There were 2329 unique patients 18 - 65

Xopenex Utilization - Patients over 65 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
XOPENEX 1.25 MG/3 ML SOLUTION	6	$875.86	$145.98
TOTAL	6	$875.86	

There were 4 unique patients > 65

Albuterol Utilization - Patients over 65 05/01/2007 to 04/30/2008

Drug Name	Number of Prescriptions	Total Paid Amount	Cost per script
ALBUTEROL 0.83 MG/ML SOLN	32	$733.91	$22.93
ALBUTEROL 5 MG/ML SOLUTION	11	$107.25	$9.75
ALBUTEROL 90 MCG INHALER	45	$1,121.31	$24.92
PROAIR HFA 90 MCG INHALER	14	$475.71	$33.98
PROVENTIL 90 MCG INHALER	2	$157.64	$78.82
PROVENTIL HFA 90 MCG INHALER	2	$82.18	$41.09
VENTOLIN HFA 90 MCG INHALER	16	$558.28	$34.89
TOTAL	122	$3,236.28	

There were 25 unique patients > 65

At the June P&T meeting, committee members asked how many patients taking Xopenex or Xopenex HFA were treated acutely. Claims were scanned for patients that had 1 Rx for Xopenex/Xopenex HFA in 12 months (050107 – 043008) and then patients that had 6 or more Rx's for Xopenex/Xopenex HFA in 12 months. Claims were also scanned to find out how many patients had a prescription for albuterol prior to using Xopenex/Xopenex HFA.

Results are:
Number of unique patients taking Xopenex once during the year (acute): 1071
Number of unique patients taking Xopenex 6 or more times in 1year (chronic): 73
Number of unique patients taking Albuterol prior to taking Xopenex: 481

XOPENEX HFA 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 prescription for Xopenex HFA must first try and fail Proventil HFA, ProAir HFA, or Ventolin HFA.

- **Patients must use albuterol HFA products for a minimum of 5 days for the trial to be considered a failure.**
- **Proventil HFA, ProAir HFA, and Ventolin HFA do not require a prior authorization.**

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

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

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

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of albuterol HFA in the last 90 days	Was albuterol HFA trial for at least 5 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication to albuterol HFA: (provide description below):	
Medical Justification for use of Xopenex HFA without trial of albuterol HFA:	
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
Pharmacy and Therapeutics Committee Meeting
Vusion®

I. Overview

Vusion ointment is a combination of miconazole, zinc oxide, and petrolatum. It is indicated as adjunctive treatment of diaper dermatitis when complicated by candidiasis in immunocompetent pediatric patients 4 weeks and older.

II. Pharmacology

Vusion ointment contains miconazole 0.25%, which acts topically as an antifungal agent against candidiasis. There are many over-the-counter (OTC) agents that contain a higher concentration of miconazole, but the thought is that a lower concentration reduces the risk of systemic exposure. Zinc oxide and petrolatum are added to the formulation and act as skin protectants.

III. Warnings/Precautions

General-If irritation occurs or if the rash worsens, use of the medication should be discontinued. This product is for topical use only, not for ophthalmic, oral, or intravaginal use. The safety of miconazole/zinc oxide when used for longer than 7 days is not known.

Immunocompromised patients-The safety and efficacy of miconazole/zinc oxide has not been demonstrated in immunocompromised patients.

Incontinent patients-The safety and efficacy of miconazole/zinc oxide have not been evaluated in incontinent adult patients.

Drug resistance-Do not use miconazole/zinc oxide to prevent the occurrence of diaper dermatitis, such as in an adult institutional setting, because preventative use may result in the development of drug resistance.

Children-Efficacy was not demonstrated in infants younger than 4 weeks of age. Safety and efficacy have not been established in very-low-birthweight infants.

Elderly-Clinical studies of miconazole/zinc oxide did not include any subjects 64 years of age or older. Safety and efficacy in this population have not been evaluated.

IV. Drug Interactions

Drug-drug interaction studies were not conducted. Women who take a warfarin anticoagulant and use a miconazole intravaginal cream or suppository may be at risk for developing an increased prothrombin time, INR, and bleeding, the potential for this interaction to occur between warfarin and Vusion ointment is unknown.

V. Adverse Drug Events

A total of 835 infants and young children were evaluated. Of the 418 subjects in the Vusion ointment group, 58 (14%) reported one or more adverse events. Of the 417 subjects in the zinc oxide/petrolatum control group, 85 (20%) reported one or more adverse events.

Another study was conducted in healthy adult volunteers. The study results indicated that Vusion ointment did not induce a contact dermal phototoxic response, contact dermal photoallergic response, contact dermal sensitization, or show evidence of cumulative irritation potential.

VI. Dosing and Administration

Drug	Dosing	Availability
Miconazole/ zinc oxide/ petrolatum ointment	Prior to application, the skin should be cleansed and dried. The ointment should be applied to the affected area at each diaper change for 7 days.	50 gm tube

VII. Cost Comparisons

Vusion ointment is available as a 50 gram tube. Average wholesale price (AWP) is $240.55.

South Dakota Utilization of Vusion ointment 02/28/06 to 08/06/08 (35 recipients)

Drug Name	Number of Prescriptions	Total Paid Amount	Average Cost/RX
Vusion	64	$8,752.37	$136.75

VIII. Conclusion

Vusion ointment is the first antifungal agent specifically indicated for diaper dermatitis complicated by candidiasis. The concentration of miconazole, 0.25%, is lower than the concentration of miconazole found in over-the-counter antifungal products (usually 2-4%). This may be important since the diaper can serve as an occlusive dressing, thereby increasing the systemic absorption of miconazole.

The efficacy of Vusion ointment has not been directly compared to the individual components (zinc oxide, white petrolatum, and miconazole), however, there is no reason to believe it would be more or less effective than the separate components applied together.

HID Recommendation: While the ease of administration of a single product rather than three separate products is important, Vusion ointment offers no other significant clinical advantage and therefore should be considered for prior authorization.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2008.
2. Vusion® [package insert]. Princeton, NJ: Barrier Therapeutics, Inc.; April 2007.
3. Vusion (miconazole 0.25%) – A new option for treating diaper rash. Pharmacist's Letter/Prescriber's Letter 2006;22(6):220609.

VUSION 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 prescription for Vusion must use nystatin or OTC miconazole first line.

- **Nystatin or miconazole OTC may be prescribed WITHOUT a prior authorization**
- **Patients must use nystatin or OTC miconazole for a minimum of 14 days for the trial to be considered a failure.**

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

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

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

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of nystatin or miconazole in the last 30 days	Was trial for at least 14 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication: (provide description below):	
Medical Justification for use of Vusion without trial of miconazole or nystatin:	
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
Pharmacy and Therapeutics Committee Meeting
Altabax®

I. Overview

Altabax (retapamulin) is a topical antibacterial indicated for the treatment of impetigo. It is FDA-approved for use in infections caused by methicillin-susceptible *S. aureus* or *S. pyogenes*. Retapamulin can be used topically in adults and children down to 9 months of age. Retapamulin was given final FDA approval in April 2007.

Impetigo is a highly contagious skin infection that most often affects children ages two to five, although it can occur in any age group. It is most commonly spread through direct contact. The goals of treatment are to relieve discomfort, prevent further spread of the infection, and prevent recurrence. Currently topical mupirocin ointment is the preferred treatment. Alternative treatments include oral antibiotics, such as amoxicillin/clavulanate, cephalexin, and cefuroxime.

II. Pharmacology

Retapamulin selectively inhibits bacterial protein synthesis by interacting at a site on the 50S subunit of the bacterial ribosome. It is the first topical antibiotic in the pleuromutilin class.

III. Pharmacokinetics

Drug	C_{max} (plasma) Intact skin	C_{max} (plasma) Abraded skin	Excretion	Metabolism
Retapamulin	3.5ng/mL on day 7	9ng/mL on day 7	Not studied due to low systemic exposure	Through CYP450 system

IV. Warnings/Precautions

Local Irritation-In the event that severe local irritation occurs, wipe off ointment, discontinue treatment, and substitute an appropriate alternative medication.

Superinfection-Prescribing retapamulin in the absence of strongly suspected bacterial infection is unlikely to benefit the patient and may promote development of drug-resistant bacteria.

Pregnancy-Category B. Animal studies showed no treatment related effect on embryo fetal development; however, retapamulin should be used with caution in pregnancy as animal models are not always predictive of effects on human patients.

Lactation-It is not known if retapamulin is excreted in breast milk.

V. Drug Interactions

Drug	Interaction	Description
Retapamulin	Oral ketoconazole	Coadministration of oral ketoconazole raised the mean AUC and C_{max} of retapamulin by 81% after topical application on abraded skin of healthy adult males. Dosage adjustment of retapamulin is not necessary due to low systemic exposure.

VI. Adverse Drug Events (> 1% incidence)

Adverse Event	Adults	Children (9 months – 17 years)
CNS		
Headache	2%	1.2%
GI		
Diarrhea	1.4%	1.7%
Nausea	1.2%	-
Local		
Application site irritation	1.6%	-
Application site pruritus	-	1.9%
Pruritis	-	1.5%
Miscellaneous		
Nasopharyngitis	1.2%	1.5%
Pyrexia	-	1.2%

VII. Dosing and Administration

Drug	Adult Dosing	Pediatric Dosing	Availability
Retapamulin	Apply a thin layer to the affected area (up to 100cm^2 in total area) twice daily for 5 days. The area may be covered with a sterile bandage or gauze if desired.	Apply a thin layer to the affected area (up to 2% of total body surface area) twice daily for 5 days. The area may be covered with a sterile bandage or gauze if desired.	Topical ointment 10mg/g. Available in 5, 10, and 15g tubes.

VIII. Cost Comparisons

Retapamulin is available as an ointment for topical application. Average wholesale price (AWP) for retapamulin is $41.14 for a 5g tube, $69.71 for a 10g tube, and $85.22 for a 15g tube. This can be compared to mupirocin ointment (a multisource product) which has an AWP of about $43.00 for a 22g tube.

South Dakota Utilization of Altabax compared to Mupirocin ointment 05/01/07 - 04/30/08

Drug Name	Number of Prescriptions	Total Paid Amount	Average Cost/RX
Altabax ointment-5g	85	$3,481.10	$40.95
Altabax ointment-10g	89	$5,807.13	$65.25
Altabax ointment-15g	364	$28,741.19	$78.96
TOTAL 477 Recipients	**538**	**$38,029.42**	**$70.69**
Mupirocin 1579 Recipients	**1,880**	**$76,211.56**	**$40.54**

IX. Patient Diagnoses

Recipient Count	Diagnosis
0	**IMPETIGO**
51	**STAPH INFECTION**
240	**UNSPECIFIED SKIN CONDITIONS**
252	**DERMATITIS**

X. Ages of Patients Receiving Altabax

Age	Recip Count	Rx Count
0	19	21
1	65	73
2	55	59
3	43	44
4	49	60
5	29	31
6	32	34
7	21	26
8	24	29
9	19	20
10	17	20
11	18	21
12	5	5
13	5	6
14	10	11
15	7	7
16	9	14
17	10	12
18	8	8
19	1	1
20	2	2
21	1	1

Age	Recip Count	Rx Count
22	1	1
23	2	2
24	1	1
27	1	1
28	2	2
29	2	2
30	1	1
32	3	3
35	2	2
36	1	1
37	1	1
41	1	1
43	1	1
44	1	1
45	1	1
47	1	4
50	1	1
55	1	1
56	1	1
57	1	2
60	1	1
63	1	1

XI. Clinical Efficacy

References	Study Type and Size	Methods/Results/Conclusions
Koning	Randomized, double-blind, multi-center, placebo-controlled. N=213 139 received retapamulin 71 received placebo	**Method:** Primary endpoint was clinical response after 7 days. **Results:** Retapamulin was superior to placebo (success rate 85.6% vs. 52.1%). The most common adverse effect, pruritus at the application site, was reported by 6% in retapamulin group and 1% in placebo group. **Conclusions:** This study shows that topical retapamulin is safe and effective in the treatment of primary impetigo.
Oranje	Randomized, observer-blinded, noninferiority, phase III study. N=519	**Method:** Adults and children randomized to retapamulin vs. sodium fusidate (not FDA approved in US, but commonly used for treatment of impetigo in England). **Results:** Retapamulin and sodium fusidate had comparable clinical efficacies (per-protocol population: 99.1 and 94.0%, respectively; intent-to-treat population: 94.8 and 90.1%). Bacteriological efficacies were similar and both drugs were well tolerated. **Conclusions:** This study shows that topical retapamulin is safe and effective in the treatment of primary impetigo.
Parish	Randomized, controlled.	**Method:** Patients with secondarily infected dermatitis (SID) were randomly assigned to retapamulin ointment BID for 5 days or oral cephalexin 500mg BID for 10 days. Primary endpoint was clinical response at follow-up. Secondary outcomes included microbiologic response at follow-up, safety and compliance. **Results:** Retapamulin and oral cephalexin were equally effective (clinical success rates at follow-up: 85.9% and 89.7%,

References	Study Type and Size	Methods/Results/Conclusions
		respectively). Microbiologic success rates at follow-up were 87.2% for retapamulin and 91.8% for oral cephalexin. **Conclusions:** This study shows that topical retapamulin is as effective as cephalexin in treatment of patients with SID.
Free	Randomized, double-blind, double-dummy, multicenter study. N=1904	**Method:** Patients with secondarily infected traumatic lesions were randomly assigned to retapamulin ointment BID for 5 days or oral cephalexin 500mg BID for 10 days. **Results:** Clinical success rates were 89.5% in protocol-adherent patients receiving retapamulin and 91.9% for cephalexin. In patients with *S. aureus* or *S. pyogenes* at baseline, clinical success was 89.2% for retapamulin and 92.6% for cephalexin. **Conclusions:** This study shows that topical retapamulin is as effective as cephalexin in treatment of patients with secondarily infected traumatic lesions.

XII. Summary of Evidence

Antibacterial agents for the treatment of impetigo

- Mupirocin ointment is currently the preferred treatment for impetigo. There are no studies that directly compare mupirocin and retapamulin. Therefore, it is not known if retapamulin is more or less effective than mupirocin.
- Retapamulin is FDA-approved for use in *S. aureus* or *S. pyogenes*, but early data suggests that retapamulin may be effective against methicillin- and mupirocin-resistant strains of S. aureus.
- No significant difference between retapamulin and oral cephalexin when used for the treatment of SID or secondarily infected traumatic lesions.
- All drugs for the treatment of impetigo are well-tolerated.

XIII. Conclusion

The American Academy of Family Physicians (AAFP) recommends the use of mupirocin as first-line therapy for impetigo involving limited body surface area. It also states that oral antibiotics (such as amoxicillin/clavulanate or cephalosporins) are effective for the treatment of impetigo and should be considered for use in patients with impetigo who have more extensive disease. Oral penicillin VK, amoxicillin, topical bacitracin, neomycin, and hydrogen peroxide are not recommended for use in the treatment of impetigo.

Retapamulin is a new antibacterial agent for use in the treatment of impetigo. There is limited information available to suggest that this agent should be used first-line.

HID recommendation: It is recommended that a prior authorization be placed on retapamulin in consideration of the fact that retapamulin adds significant cost and provides no additional benefit over mupirocin. It is further recommended that if a patient fails a course of mupirocin, the provider may request a prior authorization for retapamulin.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2007.
2. Altabax® [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007.
3. Koning S, van der Wouden JC, Chosidow O, et al. Efficacy and safety of retapamulin ointment as treatment of impetigo: randomized double-blind multicentre placebo-controlled trial. Br J Dermatol. 2008 May;158(5):1077-82.
4. Oranje AP, Chosidow O, Sacchidanand S, et al. Topical retapamulin ointment, 1%, versus sodium fusidate ointment, 2%, for impetigo: a randomized, observer-blinded, noninferiority study. Dermatology. 2007;215(4):331-40.
5. Parish LC, Jorizzo JL, Breton JJ, et al. Topical retapamulin ointment (1%, wt/wt) twice daily for 5 days versus oral cephalexin twice daily for 10 days in the treatment of secondarily infected dermatitis: results of a randomized controlled trial. J Am Acad Dermatol. 2006 Dec;55(6):1003-13.
6. Free A, Roth E, Dalessandro M, et al. Retapamulin ointment twice daily for 5 days vs. oral cephalexin twice daily for 10 days for empiric treatment of secondarily infected traumatic lesions of the skin. Skinmed. 2006 Sep-Oct;5(5):224-32.
7. Cole C, Gazewood J. Diagnosis and Treatment of Impetigo. Am Fam Physician 2007;75:859-64,868.
8. New Drug: Altabax (retapamulin 1% ointment) for impetigo. Pharmacist's Letter/Prescriber's Letter 2007;23(6):230605.

ALTABAX 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 prescription for Altabax must first try and fail MUPIROCIN.

- **Patients must use generic mupirocin for a minimum of 5 days for the trial to be considered a failure.**
- **Patients diagnosed with MRSA may be approved to use Altabax first-line.**

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

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

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

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of mupirocin in the last 90 days	Was mupirocin trial for at least 5 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication to mupirocin: (provide description below):	
Medical Justification for use of Altabax without trial of mupirocin:	
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
Pharmacy and Therapeutics Committee Meeting
Lyrica®

I. Overview

Lyrica® (pregabalin) is indicated for use in patients with fibromyalgia, neuropathic pain associated with diabetic peripheral neuropathy, adjunctive therapy for adult patients with partial-onset seizures, and postherpetic neuralgia. It was approved by the FDA in December 2004.

Treatment of neuropathic pain is one of pregabalin's leading uses. Neuropathic pain is chronic pain that arises from damage to sensory nerves and includes pain arising from trapped or compressed nerves, drug-induced nerve damage, diabetic neuropathy, post-herpetic pain, phantom limb syndrome following limb amputation, peripheral neuropathy and fibromyalgia.

II. Pharmacology

Although the mechanism of action of pregabalin is unknown, results with genetically modified mice and with compounds structurally related to pregabalin (such as gabapentin) suggest that binding to the alpha$_2$-delta subunit may be involved in pregabalin's antinociceptive and antiseizure effects in animal models. In vitro, pregabalin reduces the calcium-dependent release of several neurotransmitters, possibly by modulation of calcium channel function.

While pregabalin is a structural derivative of the inhibitory neurotransmitter GABA, it does not bind directly to $GABA_A$, $GABA_B$, or benzodiazepine receptors, does not augment $GABA_A$ responses in cultured neurons, does not alter rat brain GABA concentration, or have acute effects on GABA uptake or degradation. In cultured neurons, however, prolonged application of pregabalin increases the density of GABA transporter protein and increases the rate of functional GABA transport. Pregabalin does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake.

III. Pharmacokinetics

Drug	T_{max} hours	Metabolism	$T_{1/2}$ hours
Pregabalin	1.5	Not appreciably metabolized; approximately 90% excreted in urine unchanged.	6.3

IV. Drug Interactions

Precipitant drug	Object drug	Description
Pregabalin	Ethanol Lorazepam Oxycodone	Additive effects on cognitive and gross motor functioning were seen when pregabalin was coadministered with these drugs. No clinically important effects on respiration were seen.
Pregabalin	Thiazolidinediones	Because the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, take care when coadministering these agents.

V. Warnings and Precautions

- Angioedema (e.g., swelling of the throat, head, and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment.
- Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur.
- Increased seizure frequency may occur in patients with seizure disorders if pregabalin is rapidly discontinued. Withdraw pregabalin gradually over a minimum of one week.
- Pregabalin may cause peripheral edema. Exercise caution when co-administering pregabalin and thiazolidinedione antidiabetic agents.
- Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.

VI. Adverse Effects

In controlled trials of all patient populations combined, dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, and "thinking abnormally" (primarily difficulty with concentration/attention) were more commonly reported by subjects treated with pregabalin than by subjects treated with placebo (five percent or more and twice the rate of that seen in placebo).

There have been post marketing reports of angioedema in patients. Specific symptoms include swelling of the face, mouth, and neck. Some of these reported incidents were life-threatening with respiratory compromise requiring emergency treatment. Caution should be exercised when prescribing pregabalin in patients who have had previous episodes of angioedema or are currently taking other drugs associated with angioedema (e.g. angiotensin converting enzyme inhibitors).

There have been reports of hypersensitivity reactions after initiation of therapy, weight gain, ophthalmic effects, creatine kinase elevation, decreased platelet count, and prolonged PR intervals.

VII. Dosing and Administration

Drug	Adult Dosing	Pediatric Dosing	Availability
Pregabalin	*Neuropathic pain associated with diabetic peripheral neuropathy* – Start 50mg three times a day (150mg/day). Titrate to 300mg/day within one week based on efficacy and tolerability. Maximum recommended dose of pregabalin is 300mg/day in patients with creatinine clearance (CLcr) of at least 60mL/min. Dose should be adjusted for patients with reduced renal function. Doses of 600mg/day have not been shown to confer additional significant benefit and are less well tolerated. *Epilepsy* – Doses of 150 to 600mg/day have been shown to be effective as adjunctive therapy in the treatment of partial-onset seizures in adults.	The safety and efficacy of pregabalin in pediatric patients have not been established.	Capsules: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg.

Drug	Adult Dosing	Pediatric Dosing	Availability
	The total daily dose should be divided and given two or three times daily. The efficacy and adverse reaction profiles of pregabalin have been shown to be dose related. In general, it is recommended that patients be started on a total daily dose no greater than 150mg/day (75 mg two times a day, or 50mg three times a day). Based on individual patient response and tolerability, the dose may be increased to a maximum dose of 600mg/day. *Postherpetic neuralgia* – Recommended dose is150 to 300mg/day in patients with CLcr of at least 60mL/min. Start 75mg two times a day, or 50mg three times a day (150mg/day). Increase to 300mg/day within one week based on efficacy and tolerability. Because pregabalin is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function. Patients who do not experience sufficient pain relief following two to four weeks of treatment with 300mg/day and who are able to tolerate pregabalin may be treated with up to 300mg two times a day or 200mg three times a day (600mg/day). In view of the dose-dependent adverse effects and the higher rate of treatment discontinuation caused by adverse reactions, dosing above 300mg/day should be reserved only for those patients who have ongoing pain and are tolerating 300mg daily. *Fibromyalgia* – Recommended dose is 300 – 450mg/day (for patients with a CLcr greater than 60mL/min). Dosing should begin at 75mg BID (150mg/day) and may be increased to 150mg BID (300mg/day) within one week based on efficacy and		

Drug	Adult Dosing	Pediatric Dosing	Availability
	tolerability. Patients who do not experience sufficient benefit may increase to 225mg BID (450mg/day). There is no evidence that doses above 450mg/day confers additional benefit and is not recommended.		

VIII. Clinical Efficacy

Drug	Condition	Duration	Methods/Results/Conclusions
Pregabalin versus placebo	Fibromyalgia	8 weeks	529 patients with fibromyalgia were followed to primary endpoint of comparison of end point mean pain scores. Pregabalin at 450mg/day significantly reduced the average severity of pain compared with placebo. Significantly more patients in the pregabalin group had ≥ 50% improvement in pain at the end point. Pregabalin at 300 – 450mg/day was associated with significant improvements in sleep quality, fatigue, and global measures of change. Dizziness and somnolence were the most frequent adverse events.
Pregabalin versus placebo	Fibromyalgia	6 weeks (open label) 26 weeks (double blind)	633 patients (279 pregabalin and 287 placebo) were followed to determine the time to loss of therapeutic response (LTR). Time to LTR was significantly longer for patients treated with pregabalin. 61% of placebo patients (vs. 32% of pregabalin patients) had lost therapeutic response. Most adverse effects were mild or moderate in intensity.
Pregabalin versus placebo	Fibromyalgia	14 weeks	745 patients were randomized and had a baseline mean pain score=6.7. Differences from placebo in mean change from baseline to endpoint in pain score were: 300 mg/d, -0.71 (*P*=.0009); 450 mg/d, -0.98, 600 mg/d, -1.00 (each *P*<.0001). On the PGIC, 68% of 300-mg/d, 78% of 450-mg/d, and 66% of 600-mg/d patients reported at least minimal improvement *vs* 48% of placebo patients, representing a statistically significant superiority. Pregabalin 450 and 600 mg/d were associated with statistically significant improvements in total FIQ score: mean differences from placebo at endpoint were: 450 mg/d, -5.24 (*P*=.0041); 600 mg/d, -5.34 (*P*=.0034). Incidence of AEs increased with dosage.

Drug	Condition	Duration	Methods/Results/Conclusions
			The most common AEs were dizziness (pregabalin, 35.8%; placebo, 7.6%) and somnolence (pregabalin, 18.0%; placebo, 3.8%).

IX. Conclusion

Choosing therapy for neuropathic pain can be challenging because of the large number of medications available to treat this condition. Based on a review of evidence comparing pregabalin and gabapentin to placebo, both agents were consistently more effective than placebo for pain relief and/or improvement in function. Further head to head trials are needed to provide evidence supporting the use of pregabalin over gabapentin in the treatment of neuropathic pain.

HID recommendation: It is recommended that a prior authorization be placed on pregabalin based on the lack of clinical evidence comparing pregabalin to gabapentin for patients with neuropathic pain. It is further recommended that if a patient fails a course of gabapentin, the provider may request a prior authorization for pregabalin.

References:

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2008.
2. Lyrica® [package insert]. New York, NY; Pfizer Pharmaceuticals; 2007.
3. Crofford LJ, Rowbotham MC, et al. Pregabalin for the treatment of fibromyalgia syndrome: results of a randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2005 Apr;52(4):1264-73.
4. Crofford LJ, Simpson S, et al. A Six-month, Double-blind, Placebo-controlled, Durability of Effect Study of Pregabalin for Pain Associated With Fibromyalgia. Presentation Number L44, American College of Rheumatology Annual Scientific Meeting, November 10-15, 2006, Washington, DC.
5. Arnold LM, Russell IJ, et al. Pregabalin for Management of Fibromyalgia Syndrome (FMS): A 14-Week, Randomized, Double-Blind, Placebo-Controlled, Monotherapy Trial. [poster] Presented at the 59th Annual American Academy of Neurology, May 1-3, 2007; Boston, MA.

South Dakota Medicaid
Lyrica Utilization 05/01/07 to 04/30/08

Label Name	Rx Num	Total Reimb Amt	Average Cost per script
LYRICA 225 MG CAPSULE	1	$64.56	$64.56
LYRICA 300 MG CAPSULE	12	$1,454.46	$121.21
LYRICA 200 MG CAPSULE	24	$3,699.26	$154.14
LYRICA 25 MG CAPSULE	50	$6,192.01	$123.84
LYRICA 150 MG CAPSULE	139	$20,320.01	$146.19
LYRICA 100 MG CAPSULE	255	$39,212.22	$153.77
LYRICA 50 MG CAPSULE	463	$71,757.62	$154.98
LYRICA 75 MG CAPSULE	565	$78,069.49	$138.18
Total 394 Recipients	**1509**	**$220,769.63**	**$146.30**

Lyrica Utilization Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
14	1	3
15	2	12
17	2	2
18	2	13
19	4	17
20	2	15
21	1	5
22	4	14
23	2	17
24	3	12
25	7	18
26	6	20
27	9	39
28	6	18
29	8	22
30	8	33
31	6	12
32	8	17
33	9	16
34	10	22
35	7	23
36	9	33

Age	Recip Count	Rx Count
37	8	37
38	13	21
39	14	62
40	12	48
41	6	33
42	8	24
43	17	50
44	16	49
45	14	54
46	12	53
47	14	33
48	12	47
49	7	47
50	15	58
51	16	71
52	14	82
53	4	16
54	10	51
55	9	41
56	10	35
57	9	49
58	5	35

Age	Recip Count	Rx Count
59	7	21
60	7	29
61	6	24
62	1	9
63	7	31
64	4	10
65	1	6

South Dakota Medicaid
Gabapentin Utilization 05/01/07 to 04/30/08

Label Name	Rx Num	Total Reimb Amt	Average Cost per script
GABAPENTIN 100 MG CAPSULE	428	$7,271.70	$16.99
GABAPENTIN 300 MG CAPSULE	1202	$33,566.78	$27.93
GABAPENTIN 400 MG CAPSULE	162	$5,373.77	$33.17
GABAPENTIN 600 MG TABLET	460	$29,848.33	$64.89
GABAPENTIN 800 MG TABLET	171	$12,880.39	$75.32
NEURONTIN 100 MG CAPSULE	13	$1,078.53	$82.96
NEURONTIN 250 MG/5 ML SOLN	33	$3,762.07	$114.00
NEURONTIN 800 MG TABLET	10	$3,865.25	$386.53
Total 504 Recipients	2479	$97,646.82	$39.39

Gabapentin Utilization Summary by Age
05/01/2007 – 04/30/2008

Age	Recip Count	Rx Count
1	1	1
3	3	25
4	1	4
6	1	1
7	2	12
8	2	15
10	2	6
11	2	10
13	2	12
14	3	7
15	2	2
16	5	18
17	9	33
18	5	17
19	7	65
20	4	21
21	3	9
22	10	55
23	6	33
24	4	4
25	8	35
26	11	61
27	3	17
28	8	30

Age	Recip Count	Rx Count
29	9	37
30	8	54
31	10	22
32	9	21
33	8	22
34	11	70
35	10	51
36	9	31
37	13	58
38	11	39
39	9	25
40	7	22
41	8	22
42	13	35
43	7	27
44	15	58
45	14	88
46	17	78
47	13	66
48	11	58
49	13	66
50	16	83
51	11	80
52	17	95

Age	Recip Count	Rx Count
53	13	65
54	9	81
55	15	88
56	7	36
57	14	79
58	10	65
59	10	51
60	11	62
61	14	76
62	9	49
63	8	44
64	6	49
65	3	25
69	1	2
76	1	6

Lyrica Recipient Count and Diagnosis
05/01/2007 - 04/30/2008

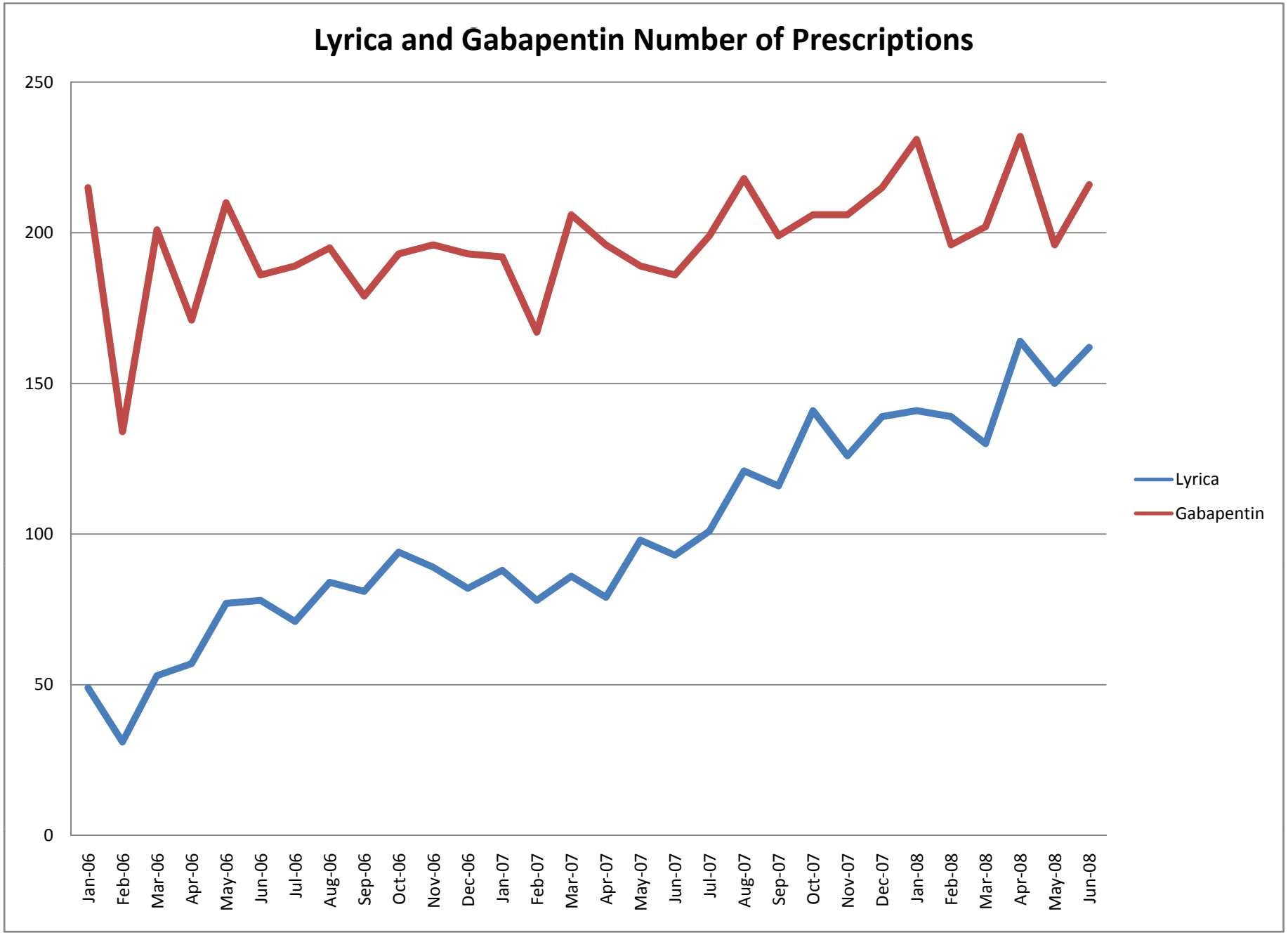
Recipient Count	Diagnosis
20	Seizure
10	Post-herpetic neuralgia
84	Neuropathic Pain
209	Myalgia/Myositis

Gabapentin Recipient Count and Diagnosis
05/01/2007 - 04/30/2008

Recipient Count	Diagnosis
57	Seizure
13	Post-herpetic neuralgia
104	Neuropathic Pain
159	Myalgia/Myositis

At the June P&T meeting, committee members asked how many patients had a prescription for gabapentin prior to using Lyrica.

05/01/07 - 04/30/08
Number of unique patients that took Lyrica: 394
Number of unique patients that took Lyrica 6 or more times during time period: 92
Number of unique patients taking gabapentin (up to 2 years) prior to taking Lyrica: 77


Lyrica and Gabapentin Number of Prescriptions
250
200
150
100
50
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
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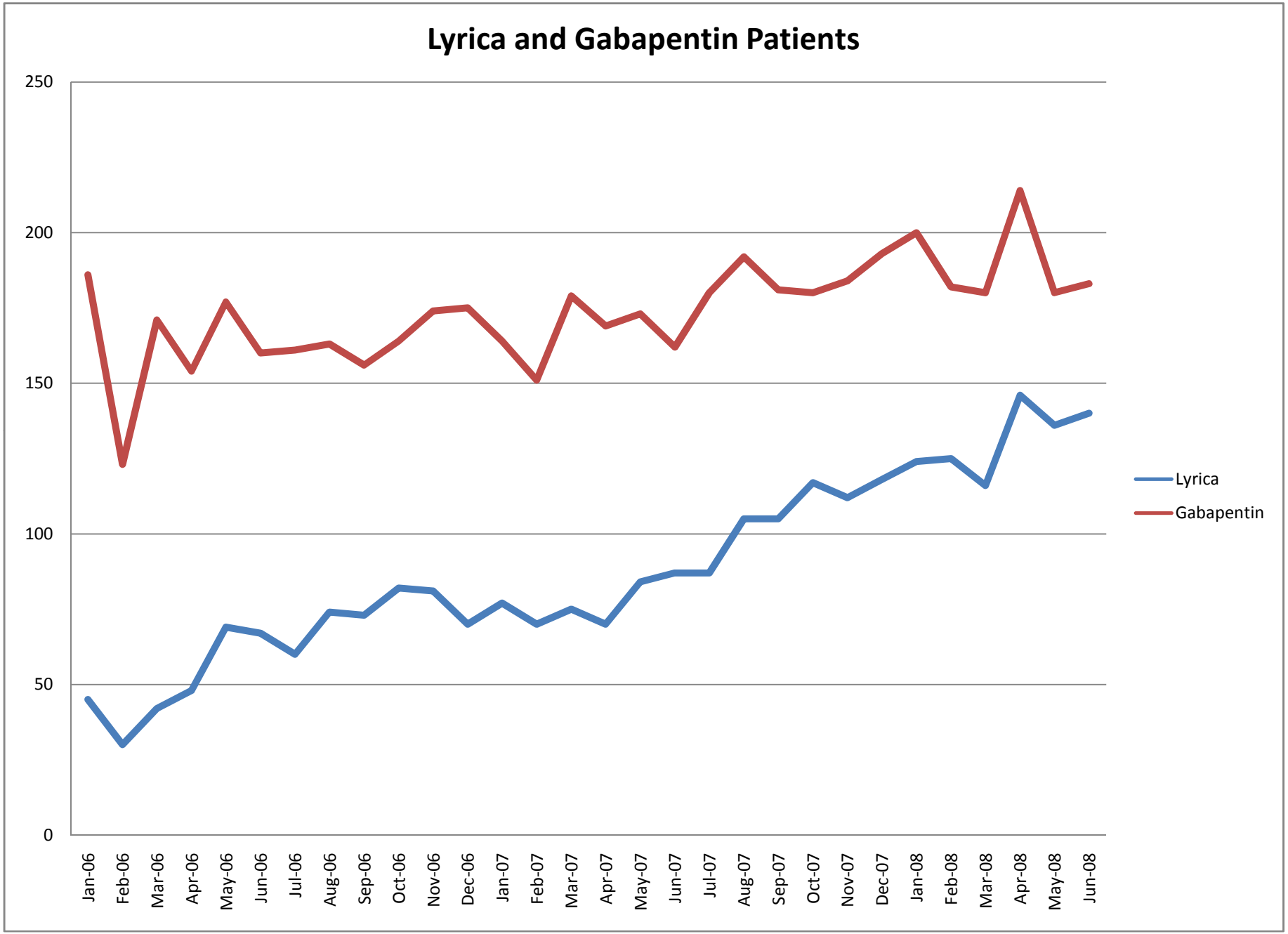
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin


Lyrica and Gabapentin Patients
250
200
150
100
50
0
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
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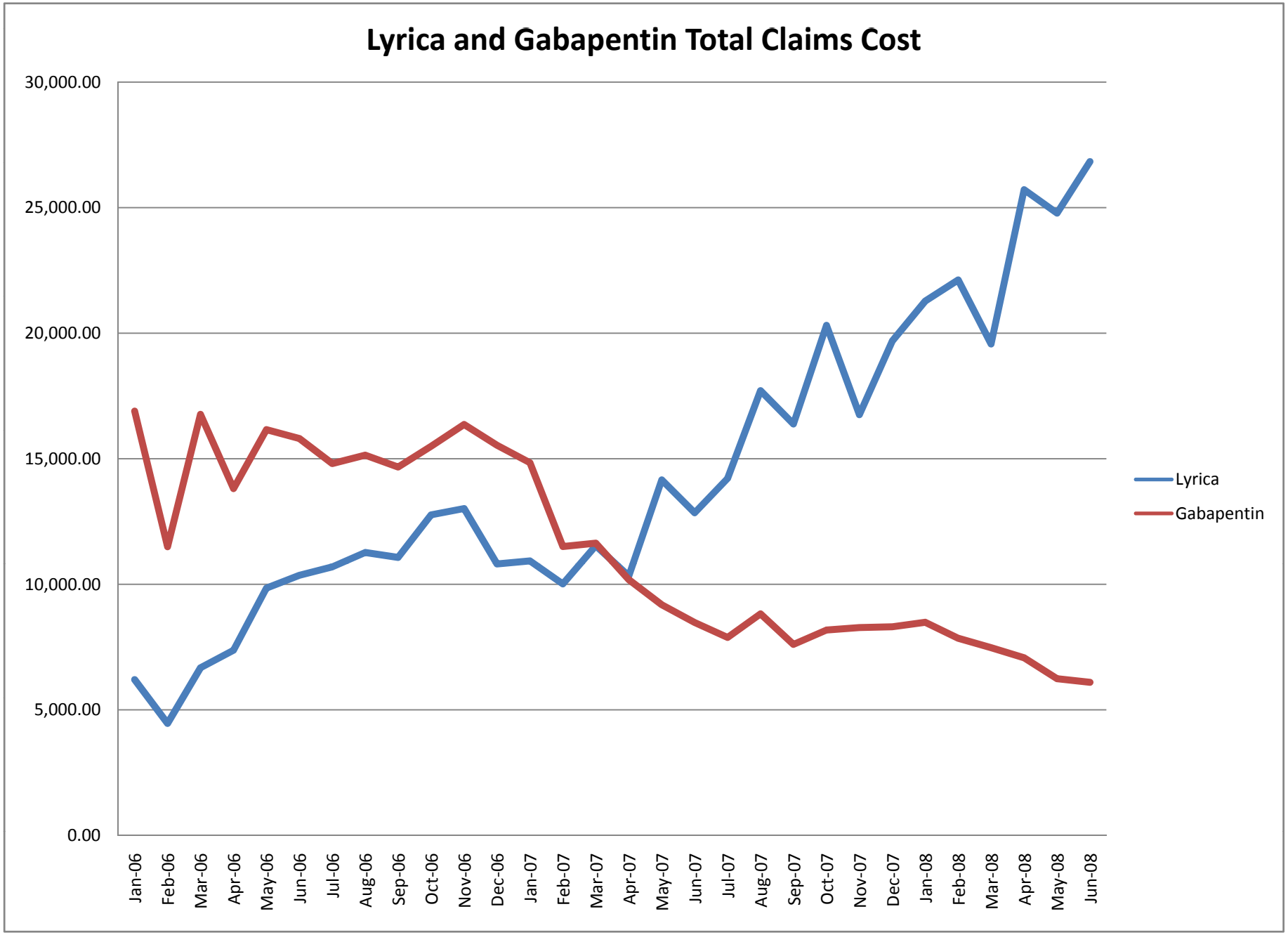
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin


Lyrica and Gabapentin Total Claims Cost
30,000.00
25,000.00
20,000.00
15,000.00
10,000.00
5,000.00
0.00
Jan-06
Feb-06
Mar-06
Apr-06
May-06
Jun-06
Jul-06
Aug-06
Sep-06
Oct-06
Nov-06
Dec-06
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
Sep-07
Oct-07
Nov-07
Dec-07
Jan-08
Feb-08
Mar-08
Apr-08
May-08
Jun-08
Lyrica
Gabapentin

LYRICA 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 Lyrica (pregabalin) must first try Gabapentin.

- **Gabapentin does not require a prior authorization.**

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

RECIPIENT NAME:	RECIPIENT 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 Dosage: (must be completed)

Diagnosis for this request:

Qualifications for coverage:

☐ Failed / intolerant to gabapentin

Adverse Reaction (attach FDA MedWatch form) or contraindication to gabapentin: (provide description below):

Medical Justification for use of pregabalin without trial of gabapentin:

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)	