South Dakota
Department of Social Services

Medicaid P&T Committee Meeting

September 7, 2018

DSS

Strong Families - South Dakota's Foundation and Our Future

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Strong Families - South Dakota's Foundation and Our Future

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

September 7, 2018
1:00 – 3:00 PM

DDN Locations:
Sioux Falls
University Center
DDN Room FADM145
4801 North Career Avenue

Pierre
Capitol Building
DDN Room CAP A
500 East Capitol

Rapid City
Black Hills State University
DDN Room UC113
4300 Cheyenne Boulevard

Call to order

Approval of minutes of previous meeting

Committee introduction to new member Deidra Van Gilder

PA update

Review of top 15 therapeutic categories/top 50 drugs

Program update

Old business
- **Review criteria for Lyrica & PCSK9 Inhibitors**
- **Review of Aimovig criteria**

New business
- **PDL/Formulary 101**

Public comment accepted after individual topic discussion

Next meeting date 12/7/18 & adjournment

South Dakota Department of Social Services, Division of Medicaid Services
Pharmacy & Therapeutics (P&T) Committee Meeting Minutes

Friday, June 15, 2018
1:00 – 3:00 pm CT

Members and DSS Staff

Michelle Baack, MD	X	Kelley Oehlke, PharmD	X
Dana Darger, RPh		Lenny Petrik, PharmD	X
James Engelbrecht, MD	X	Timothy Soundy, MD	
Mikal Holland, MD		Mike Jockheck, DSS Staff	X
Richard Holm, MD	X	Sarah Akers, DSS Staff	X
Bill Ladwig, RPh, Chair	X	Bill Synder, DSS Staff	X

Administrative Business
The meeting was called to order by Ladwig at 1:05 PM. The minutes of the March meeting were presented. Baack made a motion to approve. Oehlke seconded the motion. Motion was approved unanimously.

Prior Authorization Update (PA) and Statistics
The committee reviewed the PA activity report for January 1, 2018 through March 31, 2018. There were a total of 1,236 PAs reviewed during this time period. There were 275 requests (22%) received via telephone and 961 requests (73%) received via fax. PA appeals information were also reviewed.

Analysis of the Top 15 Therapeutic Classes and Drug Spend
The committee reviewed the top 15 therapeutic classes by total cost of claims from January 1, 2018 to March 31, 2018. The top five classes were atypical antipsychotics, insulins, respiratory and CNS stimulants, amphetamines, and anticonvulsants. The top 15 therapeutic classes make up 28.39% of total claims. The committee also reviewed the top 50 drugs based on total claims cost and number of claims. The top 50 drugs by claims cost make up 13.26% of total claims. Neuraminidase inhibitors moved to the top 15 therapeutic classes by total cost of claims during this quarter.

Review of PA Forms & Criteria
The committee reviewed requested utilization and PA statistics for an in-depth review of specific PA criteria identified at the previous meeting. The following PA criteria were targeted for an update or selected for deeper review for the next meeting.

- Non-Sedating Antihistamines – PA on levocetirizine 5 mg tab will be removed
- Nasal Steroids – Committee requested in-depth utilization data on mometasone 50 mcg spray
- Proton Pump Inhibitors – Committee requested in-depth utilization data such as patients' age on all packs/chews/liquids

Review of Lyrica PA
Committee requested utilization data for Lyrica.

Review criteria for Genitourinary Smooth Muscle Relaxants PA
Committee reviewed criteria and commented changes were not necessary.

Review of PCSK9 Inhibitors
Committee requested utilization data for PCSK9 inhibitors.

Review of Duzallo & Zurampic
The committee reviewed clinical information on Duzallo and Zurampic and utilization summary of all anti-gout agents. After review and consideration, Committee commented PA was not necessary at this time. Committee will monitor this class.

Review of Ingrezza
The committee reviewed clinical information on Ingrezza and utilization summary of all agents used to treat tardive dyskinesia. After review and consideration, Committee commented PA was not necessary at this time. Committee will monitor this class.

Opioids antitussives for children
Committee reviewed the proposed PA criteria for opioid antitussives for recipients under 18 years old. Committee requested to review it again at the September meeting. Committee requested information on how other State Medicaid programs are covering the opioid antitussives for children.

Review of Aimovig
Committee requested to review it again at the September meeting and review proposed PA criteria for the CGRP antagonist class.

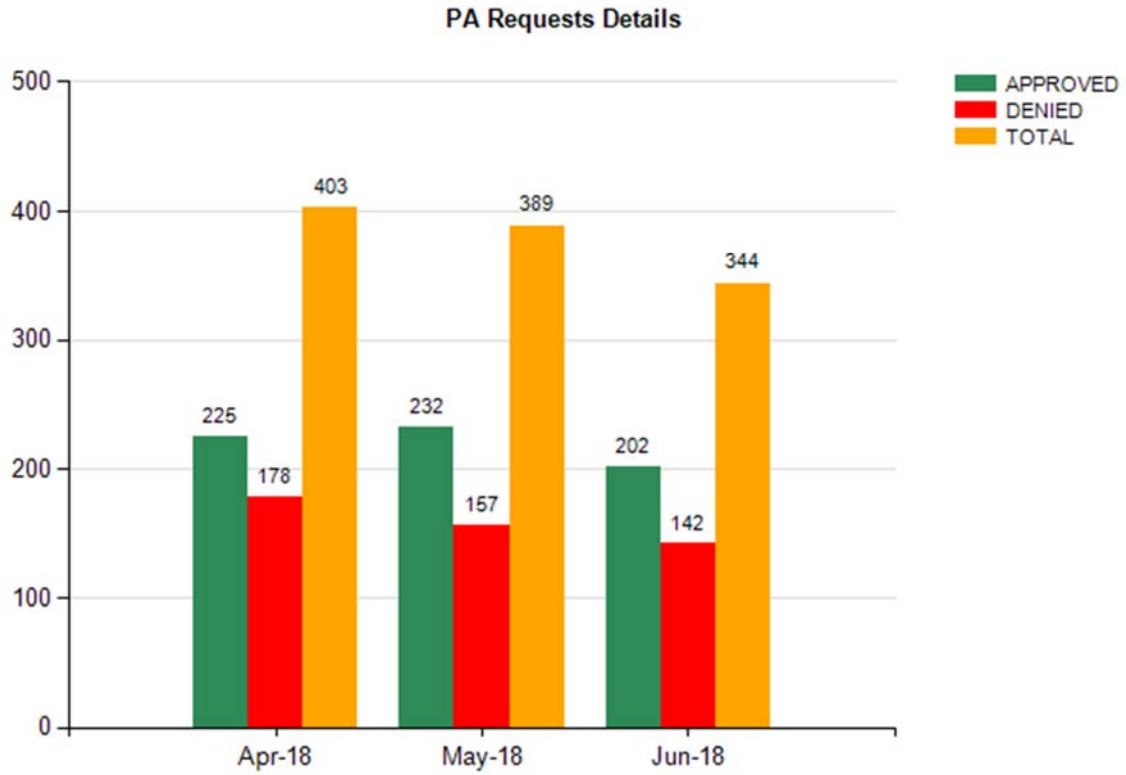
The September meeting is scheduled for 9/7/2018. Baack made a motion to adjourn. Oehlke seconded the motion. The meeting adjourned at 2:35 PM.

South Dakota Medicaid Quarterly Report
4/1/2018 to 6/30/2018

Priority	Total PAs	PAs Compliant(Standard - 72 Hrs Urgent - 24 Hrs)	PAs Not Compliant	% PAs Compliant	% PAs Not Compliant
STANDARD	1099	1099	0	100.00%	0.00%
URGENT	37	37	0	100.00%	0.00%
GRAND TOTAL	**1136**	**1136**	**0**		

Prior Authorization Initial Requests Summary

Month	Approved	Denied	Total
Apr-18	225	178	403
May-18	232	157	389
Jun-18	202	142	344
2Q18	659	477	1136
Percent of Total	58.01%	41.99%	



Top 5 Therapeutic Classes for PA

Drug Class	Approved	Denied	Total	Approval Rate	% of Total Requests	Most Requested Products
72 - Anticonvulsants	85	114	199	42.71%	17.52%	LYRICA, ONFI
58 - Antidepressants	82	33	115	71.30%	10.12%	DULOXETINE HCL, FLUOXETINE HCL
90 - Dermatologicals	43	63	106	40.57%	9.33%	LIDOCAINE, CLINDAMYCIN/BENZOYL PEROXIDE
59 - Antipsychotics/ Antimanic Agents	85	20	105	80.95%	9.24%	LATUDA, RISPERIDONE
49 - Ulcer Drugs	65	31	96	67.71%	8.45%	ESOMEPRAZOLE MAGNESIUM, DEXILANT
Others -	299	216	515	58.06%	45.33%	
2Q18	659	477	1136	58.01%		

PA Drug Class Summary

Drug Class	Approved	Denied	Total	Approval Rate
01 - PENICILLINS*	1	0	1	100.00%
02 - CEPHALOSPORINS*	3	0	3	100.00%
07 - AMINOGLYCOSIDES*	2	1	3	66.67%
11 - ANTIFUNGALS*	2	1	3	66.67%
12 - ANTIVIRALS*	6	12	18	33.33%
16 - ANTI-INFECTIVE AGENTS - MISC.*	5	3	8	62.50%
19 - PASSIVE IMMUNIZING AND TREATMENT AGENTS*	1	0	1	100.00%
21 - ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	9	0	9	100.00%
25 - CONTRACEPTIVES*	2	0	2	100.00%
27 - ANTIDIABETICS*	12	1	13	92.31%
30 - ENDOCRINE AND METABOLIC AGENTS - MISC.*	12	9	21	57.14%
32 - ANTIANGINAL AGENTS*	1	0	1	100.00%
33 - BETA BLOCKERS*	0	3	3	0.00%
34 - CALCIUM CHANNEL BLOCKERS*	0	1	1	0.00%
36 - ANTIHYPERTENSIVES*	2	2	4	50.00%
39 - ANTIHYPERLIPIDEMICS*	3	1	4	75.00%

40 - CARDIOVASCULAR AGENTS - MISC.*	3	1	4	75.00%
41 - ANTIHISTAMINES*	9	4	13	69.23%
42 - NASAL AGENTS - SYSTEMIC AND TOPICAL*	0	1	1	0.00%
44 - ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	7	3	10	70.00%
45 - RESPIRATORY AGENTS - MISC.*	2	0	2	100.00%
49 - ULCER DRUGS*	65	31	96	67.71%
50 - ANTIEMETICS*	14	8	22	63.64%
51 - DIGESTIVE AIDS*	1	1	2	50.00%
52 - GASTROINTESTINAL AGENTS - MISC.*	24	20	44	54.55%
54 - URINARY ANTISPASMODICS*	19	19	38	50.00%
56 - GENITOURINARY AGENTS - MISCELLANEOUS*	0	1	1	0.00%
58 - ANTIDEPRESSANTS	82	33	115	71.30%
59 - ANTIPSYCHOTICS/ANTIMANIC AGENTS*	85	20	105	80.95%
60 - HYPNOTICS/SEDATIVES/SLEEP DISORDER AGENT	4	3	7	57.14%
61 - ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	21	27	48	43.75%
62 - PSYCHOTHERAPEUTIC AND NEUROLOGICAL AGENT	10	3	13	76.92%
65 - ANALGESICS - OPIOID*	49	18	67	73.13%
66 - ANALGESICS - ANTI-INFLAMMATORY*	27	8	35	77.14%
67 - MIGRAINE PRODUCTS*	3	16	19	15.79%
68 - GOUT AGENTS*	3	1	4	75.00%
72 - ANTICONVULSANTS*	85	114	199	42.71%
75 - MUSCULOSKELETAL THERAPY AGENTS*	7	3	10	70.00%
79 - MINERALS & ELECTROLYTES*	0	1	1	0.00%
82 - HEMATOPOIETIC AGENTS*	1	1	2	50.00%
83 - ANTICOAGULANTS*	31	7	38	81.58%
86 - OPHTHALMIC AGENTS*	3	36	39	7.69%
90 - DERMATOLOGICALS*	43	63	106	40.57%
2Q18	659	477	1136	
Percent of Total	58.01%	41.99%		

PA Appeals Summary

Month	Approved	Approved %	Denied	Denied %	Total
Apr-18	2	28.57%	5	71.43%	7
May-18	0	0.00%	1	100.00%	1
Jun-18	8	72.73%	3	27.27%	11
2Q18	10	52.63%	9	47.37%	19

Appeals Detail

Drug Class	Approved	Denied	Total	Approval Rate
AMITIZA	0	3	3	0.00%
AMPHETAMINE/DEXTROAMPHETAMINE	2	0	2	100.00%
ENBREL SURECLICK	1	0	1	100.00%
GRALISE	0	1	1	0.00%
LYRICA	1	1	2	50.00%
MAVYRET	1	1	2	50.00%
MYRBETRIQ	1	1	2	50.00%
NORDITROPIN FLEXPRO	1	1	2	50.00%
NUTROPIN AQ NUSPIN 20	1	0	1	100.00%
RIZATRIPTAN BENZOATE ODT	1	0	1	100.00%
STELARA	0	1	1	0.00%
XARELTO	1	0	1	100.00%
2Q18	10	9	19	

South Dakota Medicaid

Top 15 Therapeutic Class Profile Summary by Total Cost of Claims

AHFS Description	Total Rxs	Pharmacy Due Amount	Paid/ Rx	%Total Claims
ATYPICAL ANTIPSYCHOTICS	7,298	$1,869,353.93	$256.15	3.67%
INSULINS	2,847	$1,328,568.67	$466.66	1.43%
AMPHETAMINES	6,305	$1,223,640.40	$194.07	3.17%
RESPIRATORY AND CNS STIMULANTS	6,463	$1,187,979.12	$183.81	3.25%
MISCELLANEOUS ANTICONVULS	10,532	$1,113,581.05	$105.73	5.29%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	239	$1,098,477.84	$4,596.14	0.12%
ANTINEOPLASTIC AGENTS	360	$760,773.88	$2,113.26	0.18%
SELECTIVE BETA-2-ADRENERGIC AGONISTS	6,998	$710,610.52	$101.54	3.52%
ADRENALS	5,462	$667,130.21	$122.14	2.74%
SKIN AND MUCOUS MEMBRANE	427	$603,775.23	$1,413.99	0.21%
IMMUNOMODULATORY AGENTS	57	$460,698.85	$8,082.44	0.03%
HEMOSTATICS	30	$333,219.87	$11,107.33	0.02%
SOMATOTROPIN AGONISTS	87	$321,254.65	$3,692.58	0.04%
PROTON-PUMP INHIBITORS	5,949	$307,612.97	$51.71	2.99%
BENZODIAZEPINES (ANTICONV	1,965	$293,365.85	$149.30	0.99%
TOTAL TOP 15 THERAPEUTIC CLASSES	55,019	$12,280,043.04	$223.20	27.64%

Top 15 Therapeutic Class Profile Summary by Total Number of Claims

AHFS Description	Total Rxs	Pharmacy Due Amount	Paid/ Rx	%Total Claims
SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	11,271	$113,263.88	$10.05	5.66%
MISCELLANEOUS ANTICONVULS	10,532	$1,113,581.05	$105.73	5.29%
OPIATE AGONISTS	8,289	$277,895.12	$33.53	4.16%
ATYPICAL ANTIPSYCHOTICS	7,298	$1,869,353.93	$256.15	3.67%
SECOND GENERATION ANTIHIS	7,264	$60,375.53	$8.31	3.65%
SELECTIVE BETA-2-ADRENERGIC AGONISTS	6,998	$710,610.52	$101.54	3.52%
AMINOPENICILLIN ANTIBIOTICS	6,526	$90,278.05	$13.83	3.28%
RESPIRATORY AND CNS STIMULANTS	6,463	$1,187,979.12	$183.81	3.25%
AMPHETAMINES	6,305	$1,223,640.40	$194.07	3.17%
PROTON-PUMP INHIBITORS	5,949	$307,612.97	$51.71	2.99%
ADRENALS	5,462	$667,130.21	$122.14	2.74%
THYROID AGENTS	3,654	$62,444.48	$17.09	1.84%
LEUKOTRIENE MODIFIERS	3,459	$43,334.85	$12.53	1.74%
OTHER NONSTEROIDAL ANTI-INFLAM. AGENTS	3,360	$50,715.73	$15.09	1.69%
MISC. ANXIOLYTICS, SEDATI	3,230	$117,221.38	$36.29	1.62%
TOTAL TOP 15 THERAPEUTIC CLASSES	96,060	$7,895,437.22	$82.19	48.25%

Total Rx Claims from 04/01/2018 - 06/30/2018	**199,080**

Top 50 Drugs Based on Amount Paid from 4/1/2018 to 6/30/2018

Drug Brand Name	AHFS Description	Total Rxs	Pharmacy Due Amount	Paid/ Rx	%Total Claims
VYVANSE	AMPHETAMINES	3,220	$921,523.19	$286.19	1.62%
METHYLPHENIDATE HCL ER	RESPIRATORY AND CNS STIMULANTS	3,793	$795,735.99	$209.79	1.91%
LATUDA	ATYPICAL ANTIPSYCHOTICS	428	$514,246.59	$1,201.51	0.21%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	75	$443,698.05	$5,915.97	0.04%
INVEGA SUSTENNA	ATYPICAL ANTIPSYCHOTICS	165	$359,546.33	$2,179.07	0.08%
STELARA	SKIN AND MUCOUS MEMBRANE	16	$300,639.51	$18,789.97	0.01%
ONFI	BENZODIAZEPINES (ANTICONV	216	$281,899.28	$1,305.09	0.11%
KALYDECO	CYSTIC FIBROSIS (CFTR) POTENTIATORS	11	$273,305.46	$24,845.95	0.01%
AMPHETAMINE/DEXTROAMPHETA	AMPHETAMINES	2,922	$273,164.19	$93.49	1.47%
NOVOLOG FLEXPEN	INSULINS	508	$266,068.39	$523.76	0.26%
DEXMETHYLPHENIDATE HCL ER	RESPIRATORY AND CNS STIMULANTS	1,150	$233,871.61	$203.37	0.58%
ENBREL SURECLICK	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	42	$229,084.55	$5,454.39	0.02%
LANTUS SOLOSTAR	INSULINS	626	$228,106.29	$364.39	0.31%
ADVAIR DISKUS	SELECTIVE BETA-2-ADRENERGIC AGONISTS	521	$217,352.55	$417.18	0.26%
LYRICA	MISCELLANEOUS ANTICONVULS	405	$210,690.90	$520.22	0.20%
FLOVENT HFA	ADRENALS	883	$210,678.25	$238.59	0.44%
ARIPIPRAZOLE	ATYPICAL ANTIPSYCHOTICS	1,632	$182,174.77	$111.63	0.82%
PULMOZYME	MUCOLYTIC AGENTS	49	$182,025.37	$3,714.80	0.02%
VIMPAT	MISCELLANEOUS ANTICONVULS	205	$151,361.92	$738.35	0.10%
ARISTADA	ATYPICAL ANTIPSYCHOTICS	65	$142,573.99	$2,193.45	0.03%
BANZEL	MISCELLANEOUS ANTICONVULS	62	$139,955.43	$2,257.35	0.03%
BUDESONIDE	ADRENALS	382	$139,327.00	$364.73	0.19%
NORDITROPIN FLEXPRO	SOMATOTROPIN AGONISTS	43	$138,864.18	$3,229.40	0.02%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	23	$137,397.74	$5,973.81	0.01%
NOVOLOG	INSULINS	272	$134,152.30	$493.21	0.14%
RECOMBINATE	HEMOSTATICS	5	$131,686.77	$26,337.35	0.00%
REVLIMID	ANTINEOPLASTIC AGENTS	8	$130,729.42	$16,341.18	0.00%
JANUVIA	DIPEPTIDYL PEPTIDASE-4(DPP-4) INHIBITORS	306	$128,830.02	$421.01	0.15%
LEVEMIR FLEXTOUCH	INSULINS	269	$124,377.35	$462.37	0.14%
MAVYRET	HCV PROTEASE INHIBITOR ANTIVIRALS	9	$124,060.20	$13,784.47	0.00%
ATOMOXETINE	MISC. CENTRAL NERVOUS SYS	867	$118,206.05	$136.34	0.44%
GATTEX	MISCELLANEOUS GI DRUGS	3	$115,942.14	$38,647.38	0.00%
IMBRUVICA	ANTINEOPLASTIC AGENTS	9	$111,909.12	$12,434.35	0.00%
GENOTROPIN	SOMATOTROPIN AGONISTS	22	$110,474.78	$5,021.58	0.01%
BEXAROTENE	ANTINEOPLASTIC AGENTS	2	$109,492.42	$54,746.21	0.00%
ACTIMMUNE	IMMUNOMODULATORY AGENTS	2	$109,256.72	$54,628.36	0.00%
VENTOLIN HFA	SELECTIVE BETA-2-ADRENERGIC AGONISTS	1,839	$108,919.02	$59.23	0.92%
INVEGA TRINZA	ATYPICAL ANTIPSYCHOTICS	16	$108,425.64	$6,776.60	0.01%
PROAIR HFA	SELECTIVE BETA-2-ADRENERGIC AGONISTS	1,635	$106,063.04	$64.87	0.82%
EPCLUSA	HCV POLYMERASE INHIBITOR ANTIVIRALS	4	$104,076.92	$26,019.23	0.00%
ADVAIR HFA	SELECTIVE BETA-2-ADRENERGIC AGONISTS	264	$102,110.07	$386.78	0.13%
TRESIBA FLEXTOUCH	INSULINS	186	$100,816.56	$542.02	0.09%
TOBRAMYCIN	AMINOGLYCOSIDES	22	$98,530.62	$4,478.66	0.01%
SYMDEKO	CYSTIC FIBROSIS (CFTR) CORRECTORS	4	$93,546.80	$23,386.70	0.00%
VICTOZA	INCRETIN MIMETICS	122	$93,533.81	$766.67	0.06%
ABILIFY MAINTENA	ATYPICAL ANTIPSYCHOTICS	42	$90,801.00	$2,161.93	0.02%
SYMBICORT	ADRENALS	274	$88,664.68	$323.59	0.14%
ADVATE	HEMOSTATICS	6	$87,689.95	$14,614.99	0.00%
ORKAMBI	CYSTIC FIBROSIS (CFTR) CORRECTORS	4	$87,376.32	$21,844.08	0.00%
NOVOLOG PENFILL	INSULINS	194	$84,728.59	$436.75	0.10%
TOTAL TOP 50 DRUGS		23,828	$9,777,691.84	$410.34	11.97%

Top 50 Drugs Based on Number of Claims from 4/1/2018 to 6/30/2018

Drug Brand Name	AHFS Description	Total Rxs	Pharmacy Due Amount	Paid/Rx	%Total Claims
AMOXICILLIN	AMINOPENICILLIN ANTIBIOTICS	5,119	$47,693.74	$9.32	2.57%
CETIRIZINE HCL	SECOND GENERATION ANTIHIS	4,136	$32,155.77	$7.77	2.08%
FLUOXETINE HCL	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	4,100	$40,398.91	$9.85	2.06%
METHYLPHENIDATE HCL ER	RESPIRATORY AND CNS STIMULANTS	3,793	$795,735.99	$209.79	1.91%
SERTRALINE HCL	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	3,603	$25,589.87	$7.10	1.81%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,573	$29,600.27	$8.28	1.79%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	3,446	$41,323.12	$11.99	1.73%
VYVANSE	AMPHETAMINES	3,220	$921,523.19	$286.19	1.62%
LEVOTHYROXINE SODIUM	THYROID AGENTS	3,180	$43,240.45	$13.60	1.60%
GABAPENTIN	MISCELLANEOUS ANTICONVULS	3,169	$51,227.43	$16.17	1.59%
HYDROCODONE/ACETAMINOPHEN	OPIATE AGONISTS	3,015	$31,514.96	$10.45	1.51%
AMPHETAMINE/DEXTROAMPHETA	AMPHETAMINES	2,922	$273,164.19	$93.49	1.47%
TRAZODONE HCL	SEROTONIN MODULATORS	2,706	$16,629.00	$6.15	1.36%
LISINOPRIL	ANGIOTENSIN-CONVERTING EN	2,437	$11,194.99	$4.59	1.22%
GUANFACINE ER	MISC. CENTRAL NERVOUS SYS	2,275	$53,683.21	$23.60	1.14%
AZITHROMYCIN	OTHER MACROLIDE ANTIBIOTICS	2,102	$37,842.70	$18.00	1.06%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	2,082	$16,860.13	$8.10	1.05%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS	1,963	$18,206.34	$9.27	0.99%
LORATADINE	SECOND GENERATION ANTIHIS	1,921	$11,516.88	$6.00	0.96%
TRAMADOL HCL	OPIATE AGONISTS	1,851	$10,441.36	$5.64	0.93%
VENTOLIN HFA	SELECTIVE BETA-2-ADRENERGIC AGONISTS	1,839	$108,919.02	$59.23	0.92%
ESCITALOPRAM OXALATE	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	1,780	$17,058.92	$9.58	0.89%
ALBUTEROL SULFATE	SELECTIVE BETA-2-ADRENERGIC AGONISTS	1,708	$41,292.57	$24.18	0.86%
POLYETHYLENE GLYCOL 3350	CATHARTICS AND LAXATIVES	1,707	$41,383.85	$24.24	0.86%
PROAIR HFA	SELECTIVE BETA-2-ADRENERGIC AGONISTS	1,635	$106,063.04	$64.87	0.82%
ARIPIPRAZOLE	ATYPICAL ANTIPSYCHOTICS	1,632	$182,174.77	$111.63	0.82%
CLONAZEPAM	BENZODIAZEPINES (ANTICONV	1,628	$8,798.57	$5.40	0.82%
COMPOUND	-	1,612	$75,115.01	$46.60	0.81%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBIT	1,602	$13,516.12	$8.44	0.80%
PREDNISONE	ADRENALS	1,559	$10,611.16	$6.81	0.78%
CEPHALEXIN	1ST GENERATION CEPHALOSPORIN ANTIBIOTICS	1,535	$20,144.69	$13.12	0.77%
METFORMIN HCL	BIGUANIDES	1,534	$7,401.90	$4.83	0.77%
RISPERIDONE	ATYPICAL ANTIPSYCHOTICS	1,484	$16,646.33	$11.22	0.75%
QUETIAPINE FUMARATE	ATYPICAL ANTIPSYCHOTICS	1,452	$20,226.75	$13.93	0.73%
LAMOTRIGINE	MISCELLANEOUS ANTICONVULS	1,418	$23,142.82	$16.32	0.71%
AMOXICILLIN/CLAVULANATE P	AMINOPENICILLIN ANTIBIOTICS	1,401	$41,908.74	$29.91	0.70%
TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS (SKIN, MUCOUS MEMBRANE)	1,384	$15,514.25	$11.21	0.70%
DULOXETINE HCL	SEL.SEROTONIN,NOREPI REUPTAKE INHIBITOR	1,348	$22,639.69	$16.80	0.68%
BUPROPION HCL XL	ANTIDEPRESSANTS, MISCELLANEOUS	1,316	$41,775.09	$31.74	0.66%
CEFDINIR	3RD GENERATION CEPHALOSPORIN ANTIBIOTICS	1,303	$58,371.52	$44.80	0.65%
IBUPROFEN	OTHER NONSTEROIDAL ANTI-INFLAM. AGENTS	1,283	$8,499.74	$6.62	0.64%
VITAMIN D	VITAMIN D	1,221	$5,941.44	$4.87	0.61%
MIRTAZAPINE	ANTIDEPRESSANTS, MISCELLANEOUS	1,220	$11,379.54	$9.33	0.61%
LEVETIRACETAM	MISCELLANEOUS ANTICONVULS	1,207	$40,999.87	$33.97	0.61%
TOPIRAMATE	MISCELLANEOUS ANTICONVULS	1,185	$17,499.36	$14.77	0.60%
LORAZEPAM	BENZODIAZEPINES (ANXIOLYT	1,184	$7,206.53	$6.09	0.59%
CYCLOBENZAPRINE HCL	CENTRALLY ACTING SKELETAL MUSCLE RELAXNT	1,170	$5,522.73	$4.72	0.59%
RANITIDINE HCL	HISTAMINE H2-ANTAGONISTS	1,153	$10,756.48	$9.33	0.58%
DEXMETHYLPHENIDATE HCL ER	RESPIRATORY AND CNS STIMULANTS	1,150	$233,871.61	$203.37	0.58%
SULFAMETHOXAZOLE/TRIMETHO	SULFONAMIDES (SYSTEMIC)	1,136	$16,521.92	$14.54	0.57%
TOTAL TOP 50 DRUGS		**103,399**	**$3,740,446.53**	**$36.17**	**51.94%**

Utilization and PA Data for PA Criteria Review

Time frame: 4/1/2018 – 6/30/2018

Nasal Steroids (ST)

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizing Members	Age Range
mometasone 50 mcg spray	76	$14,368.46	$189.06	58	2-78
• 2- 19 years old	53	$9,911.00	$187.00	42	
• 12-78 years old	23	$4,457.85	$193.82	14	
flunisolide 0.025% spray	3	$191.07	$63.69	1	
fluticasone 50 mcg spray	1,963	$18,206.34	$9.27	1,389	
triamcinolone 55 mcg aero	3	$39.83	$13.28	3	
Beconase AQ 0.042%	5	$1,543.45	$308.69	2	
Qnasl Child Spr 40 mcg	2	$446.62	$223.31	1	
Dymista 137-50 spray	0		~$189		
Nasonex 50 mcg	0		~$188		
Omnaris spray	0		~$273		

Proton Pump Inhibitors (ST)

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizing Members	Age Range
Nexium 2.5 mg packet	1	$287.34	$287.34	1	1
Nexium 5 mg packet	5	$1,436.70	$287.34	4	0 - 1
Nexium 10 mg packet	16	$6,062.35	$378.90	8	0 - 11
Nexium 20 mg packet	13	$6,483.28	$498.71	11	3 - 74
Nexium 40 mg packet	17	$6,505.51	$382.68	11	6 - 48
lansoprazole suspension 3mg/ml	54	$4,279.83	$79.29	29	0 - 37
lansoprazole 15 mg tab	76	$34,601.86	$450.82	44	0 - 55
lansoprazole 30 mg tab	22	$7,801.96	$354.63	11	3 - 22
Prevacid 15 mg Solutab	69	$34,064.04	$493.68	33	0 - 76
Prevacid 30 mg Solutab	64	$34,418.38	$569.04	24	5 - 54
omeprazole 2mg/ml suspension	60	$4,918.82	$81.98	40	0 - 7
Prilosec 2.5 mg pack (delayed release granules for suspension)	8	$6,231.53	$778.94	3	0 & 1
Prilosec 10 mg pack (delayed release granules for suspension)	3	$1,176.28	$392.09	3	1 & 9
Protonix Pak	2	$907.52	$453.76	2	37 & 73
Aciphex Sprinkles	0				
Zegerid Oral Packet	0				

Lyrica (PA)

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizing Members	Age Range	Quantity
Lyrica	406	$211,091.96	$519.94	150	10 - 67	#30–120/30 days 6.7% - 1 per day 52.2% - 2 per day 39.9% - 3 per day 1.2% - 4 per day

PCKS9 (PA)

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizing Members
Praluent inj 75mg/ml	3	$3,511.14	$1,170.38	1
Repatha Inj 140mg/ml	8	$9,339.28	$1,167.41	3

DSS
Strong Families - South Dakota's Foundation and Our Future

Please note: All information below is required to process this request.
Fax to 1-800-527-0531
Mon-Sat: 7am to 7pm Central

Lyrica® Prior Authorization Request Form (Page 1 of 2)

DO NOT COPY FOR FUTURE USE. FORMS ARE UPDATED FREQUENTLY AND MAY BE BARCODED

Member Information (required)			Provider Information (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:	Specialty:	
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:

Medication Information (required)

Medication Name:	Strength:	Dosage Form:
❑ Check if requesting **brand**	Directions for Use:	
❑ Check if request is for **continuation of therapy**		

Clinical Information (required)

Select the diagnosis below:
- ❑ Diabetic peripheral neuropathy (DPN)
- ❑ Fibromyalgia
- ❑ Neuropathic pain associated with postherpetic neuralgia (PHN)
- ❑ Neuropathic pain associated with spinal cord injury
- ❑ Partial onset seizure
- ❑ Radiculopathy
- ❑ Trigeminal neuralgia
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Will the patient receive concomitant gabapentin therapy with Lyrica? ❑ **Yes** ❑ **No**

For Lyrica solution requests, also answer the following:

Does the patient have a diagnosis which confirms a difficulty in swallowing? ❑ **Yes** ❑ **No**

Diabetic peripheral neuropathy, fibromyalgia, neuropathic pain associated with postherpetic neuralgia, and trigeminal neuralgia:

Has the patient had a trial and failure, contraindication, or intolerance to a tricyclic antidepressant **OR** an immediate-release gabapentin? ❑ **Yes** ❑ **No**

Partial onset seizure:

Is Lyrica being used as adjunctive therapy? ❑ **Yes** ❑ **No**

Reauthorization:

If this is a reauthorization request, answer the following:

Is there documentation of positive clinical response to Lyrica therapy? ❑ **Yes** ❑ **No**

Will the patient receive concomitant gabapentin therapy with Lyrica? ❑ **Yes** ❑ **No**

For Lyrica solution requests, also answer the following:

Does the patient have a diagnosis which confirms a difficulty in swallowing? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per DAY? _____

What is the reason for exceeding the plan limitations?
- ❑ Titration or loading dose purposes
- ❑ Patient is on a dose-alternating schedule (e.g., one tablet in the morning and two tablets at night, one to two tablets at bedtime)
- ❑ Requested strength/dose is not commercially available
- ❑ Other: _____

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Lyrica® Prior Authorization Request Form (Page 2 of 2)

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Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-855-401-4262.
This form may be used for non-urgent requests and faxed to 1-800-527-0531.

Strong Families - South Dakota's Foundation and Our Future

Please note: All information below is required to process this request.
Fax to 1-800-527-0531
Mon-Sat: 7am to 7pm Central

Praluent® & Repatha® Prior Authorization Request Form

DO NOT COPY FOR FUTURE USE. FORMS ARE UPDATED FREQUENTLY AND MAY BE BARCODED

Member Information (required)			Provider Information (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:	Specialty:	
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:

Medication Information (required)		
Medication Name:	Strength:	Dosage Form:
❑ Check if requesting **brand**	Directions for Use:	
❑ Check if request is for **continuation of therapy**		

Clinical Information (required)

Select the diagnosis below:

- ❑ Heterozygous familial hypercholesterolemia (HeFH)
- ❑ Homozygous familial hypercholesterolemia (HoFH) [**Repatha** only]
- ❑ Hyperlipidemia in a high risk patient with clinical arteriosclerotic cardiovascular disease (ASCVD)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is the patient's baseline LDL-C level greater than or equal to 70 mg/dL? ❑ **Yes** ❑ **No**

Has the patient been receiving high dose statin therapy for at least 3 months (i.e., atorvastatin tab 40 mg, atorvastatin tab 80 mg, rosuvastatin tab 20 mg, rosuvastatin tab 40 mg)? ❑ **Yes** ❑ **No**

Is the patient a non-candidate for high dose statin therapy (e.g., labeled contraindication to all statins, patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with creatine kinase elevations greater than 10 times upper limit of normal [ULN])? ❑ **Yes** ❑ **No**

Is the requested medication prescribed by or in consultation with a cardiologist or endocrinologist? ❑ **Yes** ❑ **No**

Reauthorization:

If this is a reauthorization request, answer the following:

Is there documentation of positive clinical response to therapy with LDL level less than 70 mg/dl or decreased 30% from baseline? ❑ **Yes** ❑ **No**

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-855-401-4262.
This form may be used for non-urgent requests and faxed to 1-800-527-0531.

Custom Criteria Request Form

Date of Request	*After P&T review*

CODING:	
Drug Name	
AIMOVIG (erenumab-aooe)	
fremanezumab	
galcanezumab	

APPROVAL DURATION:

Initial: 6 months
Reauthorization: 12 months

CRITERIA FOR CGRP Inhibitors

Aimovig will be considered for coverage under the pharmacy benefit program when the following criteria are met for the preventive treatment of migraine in adults:

Episodic Migraines

1. Diagnosis of episodic migraines
2. Patient is 18 years of age or older
3. Patient has 4 to 14 migraines per month, but no more than 14 headache days per month
4. Prescribed by or in consultation with one of the following:
- Neurologist
- Pain or headache specialist

5. Trial and failure, defined as at least 2 months of therapy with >80% adherence, or an intolerance/contraindication to at least one medication from each of the THREE prophylactic therapies [documentation required]
6.1 Beta-blockers (atenolol, propranolol, nadolol, timolol, or metoprolol)
6.2 Anti-epleptics (topiramate or divalproex sodium)
6.3 Antidepressants (venlafaxine or tricyclic antidepressant such as amitriptyline or nortryiptyline)
6. Medication will not be used in combination with another CGRP inhibitor

Chronic Migraines

1. Diagnosis of chronic migraines
2. Patient is 18 years of age or older
3. Patient has been evaluated for rebound headaches casued by medication overuse and if diagnosed, treatment will include a plan to taper off the offending medication or does not suffer from rebound headaches (more than 12 doses per month of narcotics, triptans, caffeine, or NSAIDs)
4. Patient has greater than or equal to 15 headaches days per month, of which at least 8 must be migraine days for at least 3 months
5. Prescribed by or in consultation with one of the following specialists:
   - Neurologist

- Pain or headache specialist

6. Trial and failure, defined as at least 2 months of therapy with >80% adherence, or an intolerance/contraindication to at least one medication from each of the THREE prophylactic therapies [documentation required]
   6.1 Beta-blockers (atenolol, propranolol, nadolol, timolol, or metoprolol)
   6.2 Anti-epleptics (topiramate or divalproex sodium)
   6.3 Antidepressants (venlafaxine or tricyclic antidepressant such as amitriptyline or nortryiptyline)
7. Medication will not be used in combination with another GCRP inhibitor
8. Medication will not be used in combination with Botox (onabotulinumtoxinA)

Renewal Criteria for Episodic and Chronic

1. Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
2. Use of acute migraine medications (NSAIDs, triptans, narcotics) has decreased since the start of CGRP therapy
3. Prescribed by or in consultation with one of the following specialist
   - Neurologist
   - Pain or headache specialist

INTRODUCTION

- Migraine is a common, recurrent, incapacitating disorder characterized by moderate to severe headaches and disabling features, including nausea, vomiting, neurologic symptoms, photophobia, and phonophobia (*International Headache Society [IHS] 2013, Starling et al 2015).*
- There are 4 phases of a migraine attack, although not all migraine attacks unfold into all 4 phases. These phases include prodrome, development of aura, the headache phase, and postdrome. Combined, all 4 phases can last anywhere between 3 and 5 days (*Burgos−Vega et al 2015).*
- The pathophysiology of migraines is assumed to involve the activation of trigeminal sensory nerves, which triggers the release of vasoactive neuropeptides including CGRP, neurokinin A, and substance P. CGRP is involved in migraine pathophysiology through nociceptive mechanisms in the trigeminovascular system. CGRP is a vasodilator and is found at higher concentrations during a migraine attack. Vasodilation of dural blood vessels may occur with extravasation of dural plasma, resulting in inflammation *(Goadsby et al 2017, Starling et al 2015, Silberstein et al 2012)*.
- The International Classification of Headache Disorders (ICHD) defines chronic migraine as ≥ 15 headache days per month for > 3 months with the features of migraine headache for at least 8 migraine days per month (MMD). The most common cause of symptoms suggestive of chronic migraine is medication overuse. According to the ICHD, around 50% of patients apparently with chronic migraine revert to an episodic migraine type after drug withdrawal; such patients are in a sense wrongly diagnosed with chronic migraine. In most clinical trials, migraine that is not chronic (ie, with < 15 headache days per month) is considered to be episodic migraine, although the condition is not clearly defined in the ICHD (*IHS 2013, Silberstein et al 2008, Starling et al 2015*).
- Migraines have a global prevalence of 15 to 18% and are a leading cause of disability worldwide. Chronic migraine is estimated to occur in 2 to 8% of patients with migraine, whereas episodic migraine occurs in more than 90% of patients (*Global Burden of Disease Study [GBD] 2016, IHS 2013, Lipton et al 2016, Manack et al 2011*).
- Treatments for migraines are divided into acute and preventive therapies. Evidence and reputable guidelines clearly delineate appropriate therapies for episodic migraine treatment and prophylaxis; options stretch across a wide variety of therapeutic classes and are usually oral therapies. For the prevention of migraines, treatment options include oral prophylactic therapies, injectable prophylactic therapies, and neuromodulator devices. Guidelines discourage the overuse of acute headache therapies, including analgesics, triptans, and ergots, which can precipitate medication overuse headache. Additionally, opioids and barbiturates should not be prescribed as they may contribute to the development of chronic daily headache (*American Migraine Foundation [AMF] 2017, Edvinsson et al 2017, IHS 2013, Silberstein et al 2008, Silberstein et al 2012, Simpson et al 2016, Starling et al 2015)*.
  - Oral prophylactic therapies have modest efficacy (with reduction estimates of 1.5 headaches/month to standard mean differences of −0.57 from baseline [*Jackson et al 2015*]); however, certain oral therapies may not be appropriate for individual patients due to intolerability or eventual lack of efficacy.
  - Onabotulinumtoxin A (Botox), the first injectable drug approved for the prophylaxis of chronic migraine, has been found to be ineffective for the prophylactic treatment of episodic migraines.
  - Other options include devices which leverage electrical, temperature−altering, or magnetic approaches to treatment (ie, Cefaly, SpringTMS, and gammaCore); these devices are considered to have no significant adverse events known or expected.
- Aimovig (erenumab−aooe) is a first−in−class CGRP inhibitor. Other CGRP inhibitors under clinical development include:
  - Fremanezumab (administered subcutaneously [SC] monthly or quarterly) and galcanezumab (administered SC monthly), which are anticipated to be FDA−approved in September 2018 (*BioPharmCatalyst 2018, Eli Lilly press release 2018, House 2018, Teva press release 2018*).
  - Eptinezumab (administered intravenously) and atogepant (the first oral CGRP inhibitor), which are anticipated to pursue the indication for prevention of migraines with potential 2019 FDA−approval dates (*Alder press release 2018, Allergan press release 2018*).
- Medispan class: Migraine products – monoclonal antibodies; Calcitonin gene−related peptide (CGRP) receptor antagonists

Table 1. Medications Included Within Class Review

Drug	Generic Availability
Aimovig (erenumab−aooe)	−

(*Drugs@FDA 2018, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2018*)

INDICATIONS

Table 2. Food and Drug Administration Approved Indications

Indication	Aimovig (erenumab−aooe)
Prevention treatment of migraine in adults	✔

(*Aimovig prescribing information 2018)*

- Information on indications, mechanism of action, pharmacokinetics, dosing, and safety has been obtained from the prescribing information for the individual products, except where noted otherwise.

CLINICAL EFFICACY SUMMARY

- The approval of erenumab−aooe was based on 4 pivotal trials in approximately 2500 patients with episodic or chronic migraine subtypes and 2 incomplete, open−label extension (OLE) trials with data from interim analyses in published and unpublished formats.
  - The episodic migraine program included 3 trials in 1778 episodic migraine patients. All patients had a history of 4 to 14 MMD:
    - The STRIVE trial was a 6−month, double−blind (DB), placebo−controlled (PC), multi−center (MC), Phase 3 trial in which 955 patients with episodic migraine were randomized to placebo (n = 319), erenumab−aooe 70 mg (n = 317), or erenumab−aooe 140 mg (n = 319) once monthly. A total of 2.5 to 3.1% of patients had current use of add−on preventive therapy during the trial. Patients with medication overuse were not permitted. The primary endpoint was the change in mean MMD from baseline to months 4 to 6, which favored treatment with erenumab−aooe 70 mg (mean change vs placebo, −1.4; 95% confidence interval [CI], −1.9 to −0.9; p < 0.001) and erenumab−aooe 140 mg (mean change vs placebo, −1.9; 95% CI, −2.3 to −1.4; p < 0.001). Erenumab−aooe significantly increased the proportion of patients achieving ≥ 50% reduction in MMD (difference for 70 mg vs placebo, 16.7%; odds ratio [OR], 2.13; difference for 140 mg vs placebo, 23.4%; OR, 2.81). Erenumab−aooe was also associated with a significant decrease in the mean monthly acute migraine−specific medication treatment days (difference for 70 mg vs placebo, −0.9; difference for 140 mg vs placebo, −1.4) (*Goadsby et al 2017*).
    - The ARISE trial was a 12−week, DB, PC, MC, Phase 3 trial in which 577 patients with episodic migraine were randomized to placebo (n = 291) or erenumab−aooe 70 mg (n = 286) once monthly. A total of 5.5 to 6.6% of patients had current use of add−on preventive therapy during the trial. Patients with medication overuse were not permitted. The primary endpoint was the change in MMD from baseline to weeks 9 to 12, which favored treatment with erenumab−aooe 70 mg (mean change vs placebo, −1.0; 95% CI, −1.6 to −0.5; p < 0.001). Compared to placebo, erenumab−aooe significantly increased the proportion of patients achieving ≥ 50% reduction in MMD (difference, 10.2%; OR, 1.59). Erenumab−aooe was also associated with a significant decrease in the mean monthly acute migraine−specific medication treatment days (difference, −0.6) (*Dodick et al 2018*).
    - The LIBERTY trial was a currently unpublished, 12−week, DB, PC, MC, Phase 3b trial in which 246 patients with episodic migraine who failed 2 to 4 prior preventive migraine treatments were randomized to placebo (n = 125) or erenumab−aooe 70 mg (n = 121) once monthly. Erenumab−aooe significantly increased the primary endpoint, the proportion of patients with ≥ 50% reduction in MMD from baseline to the last 4 weeks of DB treatment (weeks 9 to 12) over placebo (difference, 16.6%; OR, 2.73; 95% CI, 1.43 to 5.19; p = 0.002). Compared to placebo, a total of 5.9% more patients treated with erenumab−aooe 140 mg reported a 100% reduction in MMD, or migraine cessation. Erenumab 70 mg/month compared with placebo significantly reduced the MMD (difference, −1.61; 95% CI, −2.70 to −0.52; p = 0.004). Erenumab−aooe was also associated with a significant decrease in the mean monthly acute migraine−specific medication treatment days (difference, −1.73) (*Reuter et al 2018*).
  - The chronic migraine program included 1 trial in 667 chronic migraine patients. All patients had a history of ≥ 15 MMD (baseline average, 17.8 to 18.2):
    - *Tepper et al* was a 12−week, DB, PC, MC, Phase 2 trial in which 667 patients with chronic migraine were randomized to placebo (n = 286), erenumab−aooe 70 mg (n = 191), or erenumab−aooe 140 mg (n = 190) once monthly. No patients were allowed current use of add−on preventive therapy during the trial. Patients with medication overuse were permitted to participate. The primary endpoint was the change in MMD from baseline to weeks 9 to 12, which favored treatment with erenumab−aooe 70 mg and erenumab−aooe 140 mg (mean change

for both doses vs placebo, −2.5; 95% CI, −3.5 to −1.4; p < 0.0001). Erenumab−aooe significantly increased the proportion of patients achieving ≥ 50% reduction in MMD (difference for 70 mg vs placebo, 17%; OR, 2.2; difference for 140 mg vs placebo, 18%; OR, 2.3). Of note, these outcomes were not dose−dependent. Both erenumab−aooe 70 mg (difference, −1.9) and erenumab−aooe 140 mg (difference, −2.6) significantly reduced the mean acute migraine−specific medication days; however, the higher 140 mg dose had a greater reduction numerically over placebo and reductions may be dose−dependent (*Tepper et al 2017*).

- Two 5−year OLE trials are currently underway in patients with episodic and chronic migraine:
  - Episodic migraine patients from a 12−week, DB, PC parent study continued within an OLE study and received erenumab−aooe 70 mg monthly up to 5 years, of which an interim analysis of data was published with data at 1 year. Of 472 patients in the parent study, 383 (81.1%) remained in the OLE and 307 (80.2%) completed 1 year of treatment. Patients had 8.8 MMDs at parent study baseline. After 3 months of treatment in the parent study, the number of MMDs was reduced to 6.3 days (mean change, 2.5). After a total of 16 months of treatment, the number of MMDs was reduced to 3.7 days (mean change, 5.1). After 64 weeks, a total of 65% (n = 184) of episodic migraine patients achieved a ≥ 50% reduction in MMD and 26% (n = 73) had achieved a 100% reduction in MMDs or migraine−free status (*Ashina et al 2017*).
  - Caution should be exercised in interpreting results from extension trials. The open−label design may contribute to biased reports. Extension trials may have biased outcomes because those experiencing benefit are included in extension trials; however, results are useful for reporting trends in treatment.

CLINICAL GUIDELINES

- According to the American Academy of Neurology and American Headache Society (AAN/AHS) − Evidence−based guideline update on the pharmacologic treatment for episodic migraine prevention in adults (*Silberstein et al 2012*), the following medications are effective preventive treatment options (see Appendix A for a definition of classifications):
  - Level A (established efficacy and > 2 Class I trials):
    - Antiepileptic drugs: divalproex sodium, sodium valproate, and topiramate
    - Beta blockers: metoprolol, propranolol, and timolol
    - Triptans (for menstrual related migraine [MRM]): for short−term prophylaxis, frovatriptan
  - Level B (probably effective and 1 Class I or 2 Class II trials):
    - Antidepressants: amitriptyline and venlafaxine
    - Beta blockers: atenolol and nadolol
    - Triptans (for MRM): for short−term prophylaxis, naratriptan and zolmitriptan
  - Level C (possibly effective and 1 Class II trial):
    - Angiotensin−converting enzyme (ACE) inhibitors: lisinopril
    - Angiotensin II receptor blockers (ARBs): candesartan
    - Alpha agonists: clonidine and guanfacine
    - Antiepileptic drugs: carbamazepine
    - Beta blockers: nebivolol and pindolol
    - Antihistamines: cyproheptadine
- The AAN recommends onabotulinumtoxin A as an effective treatment option that should be offered for chronic migraine. However, onabotulinumtoxin A is considered ineffective for the treatment of episodic migraines and should not be offered. There is insufficient evidence to compare the effectiveness of botulinum neurotoxin A with that of oral prophylactic topiramate (*Simpson et al 2016*).

SAFETY SUMMARY

- There are no contraindications or warnings and precautions associated with erenumab−aooe.
- The most common adverse reactions (% difference from placebo) observed in erenumab−aooe studies included injection site reactions (erenumab−aooe 70 mg, 3%; erenumab−aooe 140 mg, 2%) and constipation (erenumab−aooe 70 mg, 0%; erenumab−aooe 140 mg, 2%).
  - Across studies, adverse effects were generally mild and/or similar to placebo with 1.3% of patients treated with erenumab−aooe discontinuing treatment due to adverse events during trials.
- CGRP is a vasodilator and is found at higher concentrations during a migraine attack. The long−term implications of prolonged CGRP inhibition are not fully established and safety has not been fully characterized for erenumab−aooe.
  - In the 1−year interim analysis of the OLE study, 2 patients had severe adverse events (an arteriosclerosis event and a myocardial ischemia event), of which 1 was fatal and 1 was confounded by sumatriptan administration (*Ashina et al 2017*).

- There are no adequate data on the risks associated in patients who are pregnant, nursing, or in adolescent or pediatric populations. Caution should be exercised in these populations.

DOSING AND ADMINISTRATION

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Aimovig (erenumab−aooe)	Injection	SC	Once monthly	May be self−administered by patients in the abdomen, thigh, or upper arm. Latex−sensitive patients may have an allergic reaction to the needle shield within the white cap and the gray needle cap of the syringe. There are no data in pregnant women or breastfed infants. A benefit/risk assessment should be taken into consideration prior to administering.

See the current prescribing information for full details

CONCLUSION

- Migraine is a common, recurrent, incapacitating disorder characterized by moderate to severe headaches and disabling features, including nausea, vomiting, neurologic symptoms, photophobia, and phonophobia. Migraines have a spectrum of frequency and severity that can significantly affect the quality of life of patients (*IHS 2013, Silberstein et al 2008, Starling et al 2015*).
- Guidelines have not been updated to include the CGRP inhibitors. Current evidence−based prophylactic treatment options and guidance are limited for chronic migraine, and oral prophylactic medications prescribed for episodic migraine are often used also for the preventive treatment of chronic migraine. Prophylactic migraine treatment options include oral agents (mainly anti−seizure agents, antidepressants, and beta blockers), injectable agents (onabotulinumtoxin A for chronic subtypes only), or neuromodulation devices for migraine or headache attacks (ie, Cefaly, Spring TMS, gammaCore). There is no optimal prophylactic migraine therapy and head−to−head trials are lacking (*AMF 2017, Silberstein et al 2012, Simpson et al 2016*).
- Erenumab−aooe is a first−in−class CGRP inhibitor with limited long−term data. Compared to placebo, erenumab−aooe has consistently demonstrated modest, but statistically significant, reductions in MMDs ranging from 1 to 2.5 days after 3 to 6 months of treatment. Overall, the odds for a 50% reduction in MMDs were approximately 2 times higher with erenumab−aooe than placebo. There are no head−to−head studies with erenumab−aooe and no prophylactic migraine agent is clearly superior to others (*Ashina et al 2017, Dodick et al 2018, Goadsby et al 2017, Reuter et al 2018, Tepper et al 20117*).
- CGRP is a vasodilator and is found at higher concentrations during a migraine attack. The long−term implications of prolonged CGRP inhibition are not fully established and safety has not been fully characterized for erenumab−aooe *(Ashina et al 2017, Goadsby et al 2017, Starling et al 2015).*
- Lack of information during pregnancy and breastfeeding is a consideration as many migraine patients are women of childbearing potential. The unknown risks of monoclonal antibodies and the effects on certain vascular conditions are not fully characterized. Important co−morbid populations which suffer migraines were excluded from trials (eg, patients with anxiety, depression, hypertension, or fibromyalgia), which also limits the generalizability to broader groups. Based on current data, the safety profile of erenumab−aooe is generally mild with the most common adverse effects observed being constipation and injection site reactions.
- Overall, erenumab−aooe represents another therapy option in the prevention of episodic or chronic migraines. Based on currently available evidence and the mild safety profile of erenumab−aooe, this product may have a role in a subset of patients unable to tolerate established oral prophylactic therapies.

APPENDIX

- **Appendix A. AAN levels of evidence classification** *(Gronseth et al 2011)*

Rating of recommendation	
A	Established as effective, ineffective, or harmful for the given condition in the specified population
B	Probably effective, ineffective, or harmful for the given condition in the specified population
C	Possibly effective, ineffective, or harmful for the given condition in the specified population
U	Data inadequate or conflicting; given current knowledge, treatment is unproven.
Rating of therapeutic article	
Class I	RCT in representative population with masked outcome assessment. The following are required: a) concealed allocation; b) primary outcome(s) is/are clearly defined; c) exclusion/inclusion criteria are clearly defined; d) adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; e) certain requirements are needed for noninferiority or equivalence trials claiming to prove efficacy for 1 or both drugs.
Class II	Cohort study that meets a–e (Class I) or RCT that lacks 1 criterion from above (b−e).
Class III	Controlled trials (including well−defined natural history controls or patients serving as own controls), a description of major confounding differences between groups, and where outcome assessment is independent of patient treatment.
Class IV	Does not include patients with the disease, different interventions, undefined/unaccepted interventions or outcomes measures, and/or no measures of effectiveness or statistical precision presented or calculable.

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South Dakota Medicaid

Preferred Drug List/Formulary 101

A formulary is a list of prescription drugs available to members. Formularies are developed based on evaluations of efficacy, safety, and cost-effectiveness of drugs. Tiered copay formularies provide financial incentives for patients to select lower-cost drugs in commercial health plans. Since Medicaid precludes tiering of copays, a preferred drug list (PDL) can be developed instead to incentivize prescribers. A PDL is a list of medications that Medicaid will cover the cost for without the need to request prior authorization (PA).[1] PDLs are comprised of medications that either are generic formulations or are the result of price negotiations between the pharmaceutical companies and Medicaid.[1] PDLs create incentives for a provider to prescribe a drug on the PDL if possible or receive PA to do otherwise.[2] Utilization management tools such as prior authorization, step therapy, and quantity limits can still be utilized with a PDL.

Pros/Cons

Preferred Drug List would allow management of drug classes that are currently not managed, for example allow short acting bronchodilators or insulins to be managed via PDL vs clinical PA thus moving members to the most cost effective, clinically appropriate product.

Supplemental rebate negotiations vs multi-state purchasing pools

- Hiring rebate contractor for supplemental rebate negotiations & ongoing maintenance of contracts
- Using internal resources to negotiate supplemental rebates & ongoing maintenance of contracts
- Joining a multi-state purchasing pool, would require internal resources to manage this program and deciding which purchasing pool to join

P&T sessions to review financials

- 4 extra meetings per year for P&T
- Add independent meetings to existing meetings (could entail a session to discuss clinical component of drug, then another session to review financials, then another session to announce decisions made in the financial review session)

Grandfathering members vs moving members to preferred drugs

- Grandfathering members for therapy classes such as multiple sclerosis drugs and targeted immune modulator therapies; new starts to use preferred drug(s)
- For therapy classes such as short acting bronchodilators or insulins, move members to preferred drugs – member/physician/pharmacy notification sent XX days in advance
- Increased PA rejects for non-preferred drugs causing member disruption and increased calls to prescribers by pharmacies to switch members to preferred drugs
- If all therapy classes are grandfathered, there will be no savings

Member/Physician/Pharmacy impact

- Member disruption and possible gaps in care
- Prescriber burden to prescribe the preferred drug for Medicaid
- Prescriber burden to submit PA requests to prescribe non-preferred drugs

- Increased PA rejects at pharmacy point-of-sale, outbound calls to prescribers to switch to preferred drug or continue to use non-preferred drugs

More administrative work/burden

- Quarterly maintenance of PDL document that will need to be updated and posted along with sending physician/pharmacy communications
- Therapy classes currently not managed will require UM criteria for preferred vs non-preferred status (increase in the number of PA criteria to manage)
- Updating existing UM criteria based on preferred vs non-preferred status
- Implementing and updating all system PA coding for preferred/non-preferred drugs

Closed formulary or closed certain therapeutic classes to have greater leverage to obtain supplemental rebates

- Massachusetts submitted an application to CMS that included a provision to amend its Section 1115 Medicaid demonstration waiver to create a closed formulary[2]
- Potential for greater supplemental rebates for closed therapy classes
- No clinical PA reviews of non-preferred drugs in closed therapy classes

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