South Dakota
Department of Social Services

Medicaid P&T Committee Meeting

June 11, 2021

South Dakota
Department of
Social Services

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South Dakota Department of Social Services

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

June 11, 2021
1:00 – 3:00 PM

Meeting Link:
https://teams.microsoft.com/l/meetup-join/19%3ameeting_NGQxNWNlNmItMzYxYS00ZjllLThiY2QtMGJhZDA1N2I3MGI5%40thread.v2/0?context=%7b%22Tid%22%3a%22db05faca-c82a-4b9d-b9c5-0f64b6755421%22%2c%22Oid%22%3a%22b6efd724-b34e-4a86-b34c-e34f07dd4ceb%22%7d

Join by phone
+1 952-222-7450
Phone Conference ID: 444 826 867#

Call to order

Approval of previous meeting minutes

PA update

Review of top 15 therapeutic categories/top 50 drugs

Old business
- **90-Day Fill update**
- **Atypical Antipsychotic utilization in children**
- **ADHD utilization**
- **Opioid update**

New business
- **Review PA forms & criteria**
- **Gabapentin high-dose utilization review**
- **Opioid-benzodiazepine-stimulant utilization review**
- **Imcivree**
- **Juxtapid**

Public input accepted after individual topic discussion
Next meeting date September 17, 2021 & adjournment

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

Friday, March 5, 2021
1:00 – 3:00 pm CT

Members and DSS Staff

Michelle Baack, MD	X	Heather Preuss, MD	X
Dana Darger, RPh, Chair	X	Matthew Stanley, DO	
Mikal Holland, MD		Deidre Van Gilder, PharmD	X
Bill Ladwig, RPh	X	Mike Jockheck, DSS Staff	X
Kelley Oehlke, PharmD	X	Matthew Ballard	X
Lenny Petrik, PharmD	X	Bill Snyder, DSS Staff	X

Administrative Business

Darger called the meeting to order at 1:03 pm. The minutes of the December meeting were presented. Baack made a motion to approve. Oehlke seconded the motion. The motion was unanimously approved via roll call vote.

Prior Authorization Update (PA) and Statistics

The committee reviewed the PA activity report from October 1, 2020 to December 31, 2020. A total of 1,494 PAs were reviewed of which 142 requests (9.5%) were received via telephone and 872 requests (58.4%) were received via fax, and 480 (32.1%) were reviewed via electronically. There was a 21.4% decrease of PAs received from the previous quarter.

Analysis of the Top 15 Therapeutic Classes and Drug Spend

The committee reviewed the top 15 therapeutic classes by total cost of claims from October 1, 2020 to December 31, 2020. The top five therapeutic classes based on paid amount were atypical antipsychotics, cystic fibrosis correctors, disease-modifying anti-rheumatic agents, amphetamines, and hemostatics. The top 15 therapeutic classes make up 25.39% of total claims. The committee also reviewed the top 50 drugs based on amount paid and number of claims. The top 50 drugs by amount paid make up 9.91% of total claims. New utilization for Evrysdi was noted on the top 50 drugs based on amount paid. Committee requested an asterisk notation if new drugs debut on the list or if a drug moves up the list by at least 10 spots.

Old Business

90-Day Fill

Jockheck provided an update on the 90-day fill which was implemented on 10/1/2020. A 90-day supply of generic maintenance medication is allowed after member establishes three monthly fills. There has been a slight uptick in utilization, about 600 per month. Provider notification was sent out to providers in February. A follow-up notice will be sent out to remind providers again.

Accumulation edit

Jockheck provided an update on the accumulation edit. The edit is not currently configured for the accumulation messaging. The edit would need to be configured before further consideration.

Atypical antipsychotic utilization in children
Committee reviewed atypical antipsychotic utilization in children 17 years old and under. Members currently taking 2 or more antipsychotics were specifically reviewed. Committee reviewed the proposed PA criteria for prescribers wanting to add a 3 or more atypical antipsychotics. Committee requested the criteria to be discussed at next meeting. Darger inquired if there was any public comment. There were none.

ADHD utilization
Committee reviewed ADHD utilization in members 21 years and older. They also reviewed the comparison of PMPM and PUPM of other state Medicaid. Baack and Preuss discussed diversion concerns. Committee requested utilization and PMPM/PUPM figures to be reviewed again at the next meeting.

Evrysdi
Committee reviewed utilization and proposed PA criteria for Evrysdi. Jeremy Whalen from Genentech provided public comment on Evrysdi. Baack requested to review the reauthorization criteria again in 12 months. Baack made a motion to approve the Evrysdi PA criteria with the following addendum – #7 The following exam has been conducted to establish baseline motor ability by a board-certified neurologist. Ladwig seconded the motion. The motion was unanimously approved via roll call vote.

Opioid update
The committee reviewed 4Q20 opioid outcomes compared to previous quarters from the opioid initiatives. There was a decrease in opioid utilization and opioid utilizers during fourth quarter even though there is an increase in eligible members. There was a 20% increase in medication assisted therapy during fourth quarter.

New Business

Antihistamine PA approval review
Committee reviewed the PA approval rate for antihistamines. Based on current trend, no changes were needed as the Committee deemed the reviews appropriate.

Analgesic/Anti-inflammatory PA approval review
Committee reviewed the PA approval rate for analgesics/anti-inflammatories. After review, Ladwig made a motion to remove quantity level limits on meloxicam. Baack seconded the motion Darger inquired if there was any public comment. There were none. The motion was unanimously approved via roll call vote.

Antidepressants PA approval rate
Committee reviewed the PA approval rate for antidepressants. Preuss pinpointed the large number of reviews for duloxetine 60mg. Due to the use of fibromyalgia and chronic pain, it's a better drug choice than opioids. Baack made a motion to increase the quantity level limit for duloxetine 60mg to 2 per day, 30mg, to 3 per day, and 20mg to 3 per day. Ladwig seconded the motion. Darger inquired if there was any public comment. There were none. The motion was unanimously approved via roll call vote. Ladwig suggested updating the quantity level limits to maximum dosage for each drug. Ladwig made a motion and Van Gilder seconded the motion. Darger inquired if there was any public comment. There were none. The motion was unanimously approved via roll call vote.

Relexxi

Relexxi was reviewed. More drugs to treat ADHD were approved recently. Committee requested to bring back new drugs and to continue the discussion to manage these class of drugs at the next meeting.

Adjournment

The next meeting is scheduled for June 11, 2021. The September meeting is tentatively scheduled on September 17, 2021. Ladwig made a motion to adjourn the meeting and Baack seconded the motion. The motion passed unanimously, and the meeting adjourned at 2:50 PM.

PA Report
1/1/2021 – 3/31/2021

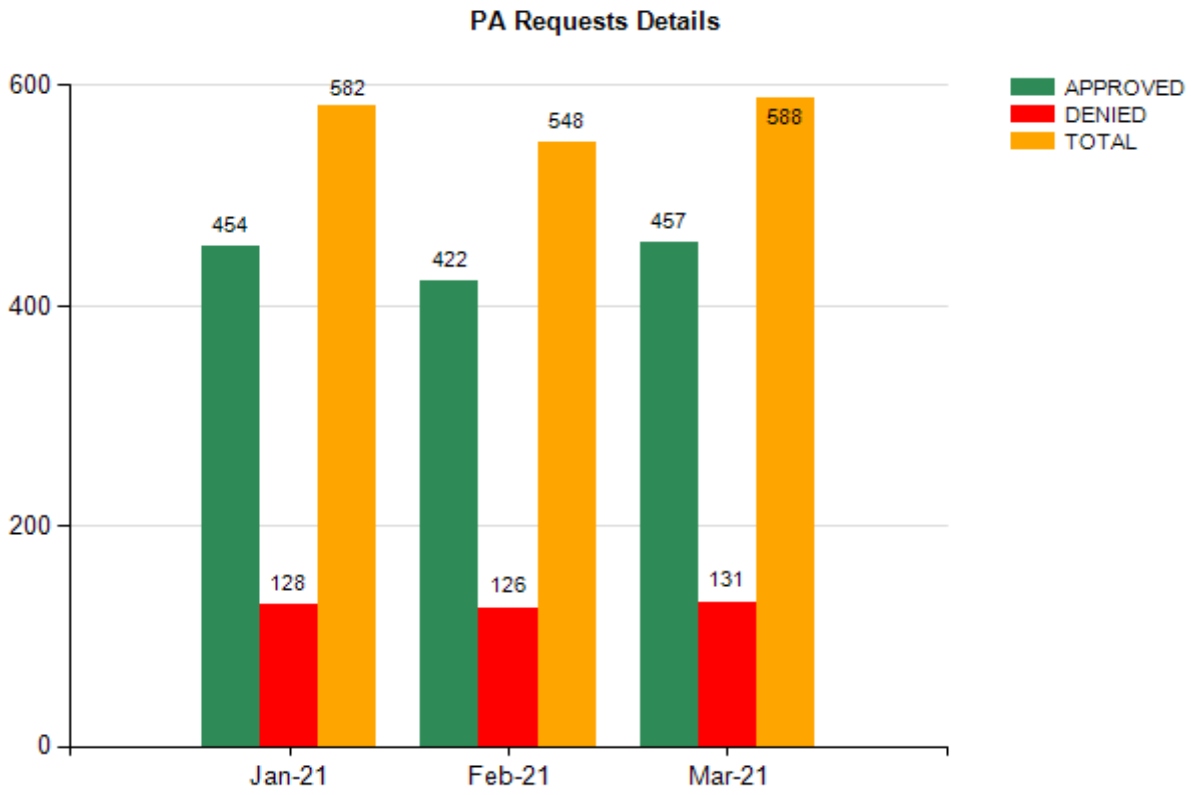
Compliance Summary

Priority	Total PAs	PAs Compliant (Standard - 72 hrs Urgent - 24 hrs)	PAs Not Compliant	% PAs Compliant	% PAs Not Compliant
STANDARD	1,662	1,662	0	100.00%	0.00%
URGENT	56	56	0	100.00%	0.00%
GRAND TOTAL	**1,718**	**1,718**	**0**		

	# of	Phone Requests		Fax Requests		Real-Time PA	
Drug Class	Requests	#	%	#	%	#	%
TOTAL	**1,718**	**168**	**9.8%**	**952**	**55.4%**	**598**	**34.8%**

PA Initial Requests Summary

Month	Approved	Denied	Total
Jan-21	454	128	582
Feb-21	422	126	548
Mar-21	457	131	588
1Q21	**1,333**	**385**	**1,718**
Percent of Total	**77.59%**	**22.41%**	



Top Therapeutic Classes for PA

Drug Class	Approved	Denied	Total	Approval Rate	% of Total Requests	Most Requested Products
59 - ANTIPSYCHOTICS/ANTIMANIC	254	13	267	95.13%	15.54%	, ARIPIPRAZOLE
58 - ANTIDEPRESSANTS*	197	40	237	83.12%	13.80%	, DULOXETINE
65 - ANALGESICS - OPIOID*	138	74	212	65.09%	12.34%	HYDROCODONE/APAP, TRAMADOL
49 - ULCER DRUGS/ ANTISPASMODIC/ANTICHOLINERG	134	24	158	84.81%	9.20%	, ESOMEPRAZOLE MAGNESIUM
90 - DERMATOLOGICALS*	72	78	150	48.00%	8.73%	CLINDAMYCIN/BENZOYL PEROXIDE, METRONIDAZOLE
OTHERS -	538	156	694	77.52%	40.40%	
1Q21	**1,333**	**385**	**1,718**	**77.59%**		

PA Drug Class Summary

Drug Class	Approved	Denied	Total	Approval Rate
59 - ANTIPSYCHOTICS/ANTIMANIC AGENTS*	254	13	267	95.13%
58 - ANTIDEPRESSANTS*	197	40	237	83.12%
65 - ANALGESICS - OPIOID*	138	74	212	65.09%
49 - ULCER DRUGS/ANTISPASMODICS/ANTICHOLINERG	134	24	158	84.81%
27 - ANTIDIABETICS*	122	5	127	96.06%
72 - ANTICONVULSANTS*	91	8	99	91.92%
90 - DERMATOLOGICALS*	72	78	150	48.00%
52 - GASTROINTESTINAL AGENTS - MISC.*	62	15	77	80.52%
66 - ANALGESICS - ANTI-INFLAMMATORY*	42	10	52	80.77%
67 - MIGRAINE PRODUCTS*	39	22	61	63.93%
61 - ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	32	20	52	61.54%
16 - ANTI-INFECTIVE AGENTS - MISC.*	20	3	23	86.96%
75 - MUSCULOSKELETAL THERAPY AGENTS*	19	5	24	79.17%
41 - ANTIHISTAMINES*	12	4	16	75.00%
54 - URINARY ANTISPASMODICS*	12	4	16	75.00%
62 - PSYCHOTHERAPEUTIC AND NEUROLOGICAL AGENT	12	2	14	85.71%
30 - ENDOCRINE AND METABOLIC AGENTS - MISC.*	11	14	25	44.00%
44 - ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	8	1	9	88.89%
50 - ANTIEMETICS*	6	5	11	54.55%
21 - ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	5	3	8	62.50%
33 - BETA BLOCKERS*	5	1	6	83.33%
60 - HYPNOTICS/SEDATIVES/SLEEP DISORDER AGENT	5	4	9	55.56%
83 - ANTICOAGULANTS*	5	2	7	71.43%
36 - ANTIHYPERTENSIVES*	4	0	4	100.00%
39 - ANTIHYPERLIPIDEMICS*	4	2	6	66.67%
12 - ANTIVIRALS*	3	14	17	17.65%
34 - CALCIUM CHANNEL BLOCKERS*	3	0	3	100.00%
40 - CARDIOVASCULAR AGENTS - MISC.*	3	0	3	100.00%
84 - HEMOSTATICS*	3	1	4	75.00%
03 - MACROLIDES*	2	3	5	40.00%
11 - ANTIFUNGALS*	1	0	1	100.00%
20 - ALLERGENIC EXTRACTS/BIOLOGICALS MISC*	1	0	1	100.00%
24 - ESTROGENS*	1	0	1	100.00%
45 - RESPIRATORY AGENTS - MISC.*	1	2	3	33.33%
51 - DIGESTIVE AIDS*	1	0	1	100.00%
74 - NEUROMUSCULAR AGENTS*	1	0	1	100.00%
80 - NUTRIENTS*	1	0	1	100.00%
99 - MISCELLANEOUS THERAPEUTIC CLASSES*	1	1	2	50.00%
01 - PENICILLINS*	0	1	1	0.00%
02 - CEPHALOSPORINS*	0	1	1	0.00%
42 - NASAL AGENTS - SYSTEMIC AND TOPICAL*	0	1	1	0.00%
86 - OPHTHALMIC AGENTS*	0	2	2	0.00%
1Q21	**1,333**	**385**	**1,718**	
Percent of Total	**77.59%**	**22.41%**		

PA Appeals Summary

Month	Approved	Approved %	Denied	Denied %	Total
January-21	15	71.43%	6	28.57%	21
February-21	14	82.35%	3	17.65%	17
March-21	16	59.26%	11	40.74%	27
1Q21	**45**	**69.23%**	**20**	**30.77%**	**65**

Appeals Detail

Drug Class	Approved	Denied	Total	Approval Rate
ACETAMINOPHEN/CODEINE	1	0	1	100.00%
AIMOVIG	2	2	4	50.00%
AMITIZA	7	0	7	100.00%
CLOBAZAM	1	0	1	100.00%
COSENTYX SENSOREADY PEN	1	0	1	100.00%
DESMOPRESSIN ACETATE	0	1	1	0.00%
DEXILANT	1	2	3	33.33%
DIFICID	2	0	2	100.00%
DOXYLAMINE SUCCINATE/PYRIDOXINE HCL	1	0	1	100.00%
DULOXETINE HYDROCHLORIDE	1	0	1	100.00%
EMGALITY	1	1	2	50.00%
EPCLUSA	0	1	1	0.00%
EPIDIOLEX	1	0	1	100.00%
FENTANYL	1	0	1	100.00%
FLUOXETINE HYDROCHLORIDE	1	0	1	100.00%
HUMIRA	1	1	2	50.00%
HYDROCODONE BITARTRATE ER	1	0	1	100.00%
KOSELUGO	1	1	2	50.00%
LINZESS	1	0	1	100.00%
LUBIPROSTONE	2	0	2	100.00%
LYRICA	1	0	1	100.00%
MAVYRET	1	7	8	12.50%
METHYLPHENIDATE HYDROCHLORIDE ER	0	1	1	0.00%
METRONIDAZOLE	3	1	4	75.00%
MODAFINIL	1	0	1	100.00%
MYFORTIC	1	0	1	100.00%
MYRBETRIQ	1	0	1	100.00%
NORDITROPIN FLEXPRO	2	0	2	100.00%
NURTEC	1	0	1	100.00%
ORENCIA	1	0	1	100.00%
OTEZLA	1	1	2	50.00%
OXYCODONE HYDROCHLORIDE	1	0	1	100.00%
PAROXETINE HCL	1	0	1	100.00%
SOFOSBUVIR/VELPATASVIR	0	1	1	0.00%
TETRABENAZINE	1	0	1	100.00%
TRAMADOL HCL	1	0	1	100.00%
TRIPTODUR	1	0	1	100.00%
1Q21	**45**	**20**	**65**	

Top 15 Therapeutic Classes & Top 50 Drugs

TOP 15 THERAPEUTIC CLASSES BASED ON NUMBER OF CLAIMS FROM 1/1/2021 – 3/31/2021					
	AHFS Description	**Total Rxs**	**Pharmacy Due Amount**	**Paid/Rx**	**%Total Claims**
1	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	13,941	$185,861.72	$13.33	6.94%
2	ANTICONVULSANTS, MISCELLANEOUS	11,384	$1,071,788.80	$94.15	5.66%
3	ATYPICAL ANTIPSYCHOTICS	8,995	$2,581,383.03	$286.98	4.48%
4	SECOND GENERATION ANTIHISTAMINES	6,905	$79,557.22	$11.52	3.44%
5	RESPIRATORY AND CNS STIMULANTS	6,869	$529,658.43	$77.11	3.42%
6	AMPHETAMINES	6,738	$1,170,786.21	$173.76	3.35%
7	SELECTIVE BETA-2-ADRENERGIC AGONISTS	6,533	$486,611.16	$74.49	3.25%
8	PROTON-PUMP INHIBITORS	6,257	$198,817.52	$31.78	3.11%
9	OPIATE AGONISTS	5,881	$176,301.37	$29.98	2.93%
10	ADRENALS	4,776	$588,984.49	$123.32	2.38%
11	ANXIOLYTICS, SEDATIVES, & HYPNOTICS, MISC	4,350	$145,271.49	$33.40	2.16%
12	AMINOPENICILLIN ANTIBIOTICS	4,329	$62,058.47	$14.34	2.15%
13	CONTRACEPTIVES	3,855	$117,928.92	$30.59	1.92%
14	SEROTONIN MODULATORS	3,661	$126,789.19	$34.63	1.82%
15	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	3,641	$260,105.73	$71.44	1.81%
Total		**98,115**	**$7,781,903.75**	**$79.31**	**48.81%**

TOP 15 THERAPEUTIC CLASSES BASED ON AMOUNT PAID FROM 1/1/2021 – 3/31/2021					
	AHFS Description	**Total Rxs**	**Pharmacy Due Amount**	**Paid/Rx**	**%Total Claims**
1	ATYPICAL ANTIPSYCHOTICS	8,995	$2,581,383.03	$286.98	4.48%
2	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	247	$1,387,365.46	$5,616.86	0.12%
3	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	556	$1,211,857.11	$2,179.60	0.28%
4	AMPHETAMINES	6,738	$1,170,786.21	$173.76	3.35%
5	CYSTIC FIBROSIS (CFTR) CORRECTORS	60	$1,169,438.56	$19,490.64	0.03%
6	HEMOSTATICS	56	$1,165,254.94	$20,808.12	0.03%
7	ANTICONVULSANTS, MISCELLANEOUS	11,384	$1,071,788.80	$94.15	5.66%
8	LONG-ACTING INSULINS	1,388	$651,977.83	$469.72	0.69%
9	ADRENALS	4,776	$588,984.49	$123.32	2.38%
10	RESPIRATORY AND CNS STIMULANTS	6,869	$529,658.43	$77.11	3.42%
11	INCRETIN MIMETICS	640	$514,118.95	$803.31	0.32%
12	ANTINEOPLASTIC AGENTS	256	$504,699.58	$1,971.48	0.13%
13	SELECTIVE BETA-2-ADRENERGIC AGONISTS	6,533	$486,611.16	$74.49	3.25%
14	RAPID-ACTING INSULINS	1,346	$472,780.06	$351.25	0.67%
15	HIV INTEGRASE INHIBITOR ANTIRETROVIRALS	130	$361,155.69	$2,778.12	0.06%
Total		**49,974**	**$13,867,860.30**	**$277.50**	**24.86%**

Total Rx Claims from 1/1/2021 – 3/31/2021	**201,001**

TOP 50 DRUGS BASED ON NUMBER OF CLAIMS FROM 1/1/2021 – 3/31/2021						
	AHFS Description	**Drug Label Name**	**Total Rxs**	**Pharmacy Due Amount**	**Paid/Rx**	**%Total Claims**
1	RESPIRATORY AND CNS STIMULANTS	METHYLPHENIDATE	4,934	$272,726.77	$55.27	2.45%
2	SECOND GENERATION ANTIHISTAMINES	CETIRIZINE	3,866	$41,603.22	$10.76	1.92%
3	PROTON-PUMP INHIBITORS	OMEPRAZOLE	3,777	$43,969.67	$11.64	1.88%
4	SELECTIVE BETA-2-ADRENERGIC AGONISTS	ALBUTEROL SULFATE HFA	3,606	$154,766.57	$42.92	1.79%
5	AMPHETAMINES	VYVANSE	3,527	$1,051,986.86	$298.27	1.75%
6	SEROTONIN MODULATORS	TRAZODONE	3,372	$34,895.85	$10.35	1.68%
7	ANTICONVULSANTS, MISCELLANEOUS	GABAPENTIN	3,344	$57,607.39	$17.23	1.66%
8	AMINOPENICILLIN ANTIBIOTICS	AMOXICILLIN	3,248	$40,715.88	$12.54	1.62%
9	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	FLUOXETINE	3,138	$40,541.17	$12.92	1.56%
10	LEUKOTRIENE MODIFIERS	MONTELUKAST SODIUM	3,091	$42,905.75	$13.88	1.54%
11	AMPHETAMINES	AMPHETAMINE/DEXTROA	3,040	$92,724.03	$30.50	1.51%
12	THYROID AGENTS	LEVOTHYROXINE SODIUM	2,902	$50,577.51	$17.43	1.44%
13	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	ESCITALOPRAM OXALATE	2,892	$38,126.76	$13.18	1.44%
14	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	SERTRALINE HCL	2,565	$30,716.09	$11.98	1.28%
15	CENTRAL ALPHA-AGONISTS	CLONIDINE	2,406	$23,666.15	$9.84	1.20%
16	ANGIOTENSIN-CONVERTING ENZYME INHIBIT	LISINOPRIL	2,179	$20,367.65	$9.35	1.08%
17	ANTIDEPRESSANTS, MISCELLANEOUS	BUPROPION	2,178	$42,238.61	$19.39	1.08%
18	ATYPICAL ANTIPSYCHOTICS	ARIPIPRAZOLE	2,165	$37,819.70	$17.47	1.08%
19	HMG-COA REDUCTASE INHIBITORS	ATORVASTATIN CALCIUM	1,963	$23,178.57	$11.81	0.98%
20	OPIATE AGONISTS	HYDROCODONE/APAP	1,924	$28,134.27	$14.62	0.96%
21	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	SERTRALINE	1,912	$23,614.07	$12.35	0.95%
22	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	FLUOXETINE HCL	1,909	$23,312.69	$12.21	0.95%
23	SECOND GENERATION ANTIHISTAMINES	LORATADINE	1,770	$19,379.99	$10.95	0.88%
24	COMPOUNDS	-	1,717	$71,280.59	$41.51	0.85%
25	ATYPICAL ANTIPSYCHOTICS	RISPERIDONE	1,703	$21,597.21	$12.68	0.85%
26	ATYPICAL ANTIPSYCHOTICS	QUETIAPINE FUMARATE	1,689	$21,558.93	$12.76	0.84%
27	ANTICONVULSANTS, MISCELLANEOUS	LAMOTRIGINE	1,589	$23,841.16	$15.00	0.79%
28	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	GUANFACINE	1,556	$29,543.61	$18.99	0.77%
29	BIGUANIDES	METFORMIN	1,536	$13,975.94	$9.10	0.76%
30	CORTICOSTEROIDS (EENT)	FLUTICASONE PROPIONAT	1,501	$22,311.36	$14.86	0.75%
31	SEL.SEROTONIN, NOREPI REUPTAKE INHIBITOR	DULOXETINE	1,497	$23,233.24	$15.52	0.74%
32	BENZODIAZEPINES (ANTICONVULSANTS)	CLONAZEPAM	1,484	$16,295.52	$10.98	0.74%
33	5-HT3 RECEPTOR ANTAGONISTS	ONDANSETRON ODT	1,447	$21,398.73	$14.79	0.72%
34	1ST GENERATION CEPHALOSPORIN ANTIBIOTICS	CEPHALEXIN	1,412	$21,777.54	$15.42	0.70%
35	CORTICOSTEROIDS (SKIN, MUCOUS MEMBR)	TRIAMCINOLONE ACETON	1,352	$20,254.05	$14.98	0.67%
36	ANTICONVULSANTS, MISCELLANEOUS	LEVETIRACETAM	1,310	$28,077.87	$21.43	0.65%
37	ADRENALS	PREDNISONE	1,278	$13,279.77	$10.39	0.64%
38	OPIATE AGONISTS	TRAMADOL HCL	1,252	$13,376.37	$10.68	0.62%
39	CENTRALLY ACTING SKELETAL MUSCLE RELAXNT	CYCLOBENZAPRINE	1,247	$12,909.02	$10.35	0.62%
40	ANTICONVULSANTS, MISCELLANEOUS	TOPIRAMATE	1,247	$18,463.69	$14.81	0.62%
41	ANTIDEPRESSANTS, MISCELLANEOUS	MIRTAZAPINE	1,227	$17,842.70	$14.54	0.61%
42	ANXIOLYTICS, SEDATIVES, & HYPNOTICS, MISC	HYDROXYZINE	1,204	$14,576.99	$12.11	0.60%
43	DIHYDROPYRIDINES	AMLODIPINE BESYLATE	1,203	$11,652.22	$9.69	0.60%
44	VITAMIN D	VITAMIN D	1,163	$11,965.30	$10.29	0.58%
45	OTHER NONSTEROIDAL ANTI-INFLAM. AGENTS	IBUPROFEN	1,120	$13,720.95	$12.25	0.56%
46	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	GUANFACINE ER	1,113	$21,406.23	$19.23	0.55%
47	SELECTIVE BETA-2-ADRENERGIC AGONISTS	ALBUTEROL SULFATE	1,110	$21,835.99	$19.67	0.55%
48	OTHER MACROLIDE ANTIBIOTICS	AZITHROMYCIN	1,104	$18,550.36	$16.80	0.55%
49	PROTON-PUMP INHIBITORS	PANTOPRAZOLE SODIUM	1,085	$14,597.70	$13.45	0.54%
50	AMINOPENICILLIN ANTIBIOTICS	AMOXICILLIN/CLAVULANA	1,081	$21,342.59	$19.74	0.54%
	Total Top 50 Drugs		**101,935**	**$2,796,240.85**	**$27.43**	**52.58%**

TOP 50 DRUGS BASED ON AMOUNT PAID FROM 1/1/2021 – 3/31/2021						
	AHFS Description	**Drug Label Name**	**Total Rxs**	**Pharmacy Due Amount**	**Paid/Rx**	**%Total Claims**
1	AMPHETAMINES	VYVANSE	3,527	$1,051,986.86	$298.27	1.75%
2	CYSTIC FIBROSIS (CFTR) CORRECTORS	TRIKAFTA	35	$767,619.34	$21,931.98	0.02%
3	ATYPICAL ANTIPSYCHOTICS	INVEGA SUSTENNA	275	$656,426.04	$2,387.00	0.14%
4	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	HUMIRA PEN	89	$643,102.18	$7,225.87	0.04%
5	ATYPICAL ANTIPSYCHOTICS	LATUDA	433	$553,597.14	$1,278.52	0.22%
6	HEMOSTATICS	ADVATE	13	$551,543.98	$42,426.46	0.01%
7	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	STELARA	25	$507,790.43	$20,311.62	0.01%
8	ATYPICAL ANTIPSYCHOTICS	ARISTADA	165	$411,709.75	$2,495.21	0.08%
9	CYSTIC FIBROSIS (CFTR) CORRECTORS	ORKAMBI	22	$399,732.51	$18,169.66	0.01%
10	MUCOLYTIC AGENTS	PULMOZYME	86	$316,690.14	$3,682.44	0.04%
11	ATYPICAL ANTIPSYCHOTICS	VRAYLAR	258	$297,382.07	$1,152.64	0.13%
12	RESPIRATORY AND CNS STIMULANTS	METHYLPHENIDATE	4,934	$272,726.77	$55.27	2.45%
13	LONG-ACTING INSULINS	LANTUS SOLOSTAR	576	$232,364.27	$403.41	0.29%
14	OTHER MISCELLANEOUS THERAPEUTIC AGENTS	EVRYSDI	10	$223,419.10	$22,341.91	0.00%
15	SOMATOTROPIN AGONISTS	NORDITROPIN FLEXPRO	72	$213,641.60	$2,967.24	0.04%
16	ANTICONVULSANTS, MISCELLANEOUS	VIMPAT	229	$206,129.42	$900.13	0.11%
17	ADRENALS	FLOVENT HFA	851	$204,030.27	$239.75	0.42%
18	VESICULAR MONOAMINE TRANSPORT2 INHIBIT	INGREZZA	32	$194,643.41	$6,082.61	0.02%
19	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	HUMIRA	29	$194,592.15	$6,710.07	0.01%
20	INCRETIN MIMETICS	OZEMPIC	230	$191,382.32	$832.10	0.11%
21	HEMOSTATICS	HEMLIBRA	3	$184,880.28	$61,626.76	0.00%
22	INCRETIN MIMETICS	TRULICITY	229	$179,498.93	$783.84	0.11%
23	ATYPICAL ANTIPSYCHOTICS	REXULTI	167	$178,816.99	$1,070.76	0.08%
24	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	COSENTYX SENSOREADY	31	$178,316.63	$5,752.15	0.02%
25	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	DUPIXENT	55	$172,112.15	$3,129.31	0.03%
26	SELECTIVE BETA-2-ADRENERGIC AGONISTS	ALBUTEROL SULFATE HFA	3,606	$154,766.57	$42.92	1.79%
27	SODIUM-GLUC COTRANSPORT 2 (SGLT2) INHIB	JARDIANCE	291	$152,507.28	$524.08	0.14%
28	LONG-ACTING INSULINS	TRESIBA FLEXTOUCH	267	$152,380.04	$570.71	0.13%
29	HEMOSTATICS	RECOMBINATE	3	$152,236.80	$50,745.60	0.00%
30	HIV INTEGRASE INHIBITOR ANTIRETROVIRALS	BIKTARVY	49	$150,460.84	$3,070.63	0.02%
31	DIGESTANTS	CREON	83	$144,224.96	$1,737.65	0.04%
32	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	XYREM	10	$142,925.40	$14,292.54	0.00%
33	RAPID-ACTING INSULINS	INSULIN ASPART FLEXPEN	396	$141,299.45	$356.82	0.20%
34	HEMOSTATICS	XYNTHA SOLOFUSE	6	$140,083.17	$23,347.20	0.00%
35	ANTICONVULSANTS, MISCELLANEOUS	EPIDIOLEX	59	$138,174.83	$2,341.95	0.03%
36	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	TALTZ	21	$136,719.10	$6,510.43	0.01%
37	RIFAMYCIN ANTIBIOTICS	XIFAXAN	67	$128,673.14	$1,920.49	0.03%
38	LONG-ACTING INSULINS	LEVEMIR FLEXTOUCH	248	$127,857.89	$515.56	0.12%
39	HIV INTEGRASE INHIBITOR ANTIRETROVIRALS	GENVOYA	39	$127,847.20	$3,278.13	0.02%
40	DIPEPTIDYL PEPTIDASE-4(DPP-4) INHIBITORS	JANUVIA	280	$124,172.15	$443.47	0.14%
41	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	ENBREL SURECLICK	22	$124,103.79	$5,641.08	0.01%
42	ATYPICAL ANTIPSYCHOTICS	ABILIFY MAINTENA	57	$120,698.24	$2,117.51	0.03%
43	SELECTIVE BETA-2-ADRENERGIC AGONISTS	ADVAIR HFA	328	$119,830.04	$365.34	0.16%
44	ANTITOXINS AND IMMUNE GLOBULINS	HIZENTRA	29	$119,306.10	$4,114.00	0.01%
45	DIRECT FACTOR XA INHIBITORS	ELIQUIS	247	$113,795.73	$460.71	0.12%
46	ANTICONVULSANTS, MISCELLANEOUS	BANZEL	48	$109,922.56	$2,290.05	0.02%
47	ATYPICAL ANTIPSYCHOTICS	INVEGA TRINZA	14	$109,529.29	$7,823.52	0.01%
48	GI DRUGS, MISCELLANEOUS	CHOLBAM	5	$107,852.50	$21,570.50	0.00%
49	VASODILATING AGENTS (RESPIRATORY TRACT)	UPTRAVI	11	$105,123.33	$9,556.67	0.01%
50	ENZYMES	STRENSIQ	2	$102,974.40	$51,487.20	0.00%
	Total Top 50 Drugs		**18,564**	**$12,231,599.53**	**$658.89**	**9.58%**

Utilization

90 Day Fill update

Atypical Antipsychotic PA Criteria:

1. For continuation of atypical antipsychotic agent **OR**

2. All of the following

2.1 One of the following:

2.1.1 Diagnosis of one of the following:

- Aphagia
- Autistic disorder
- Bipolar depression
- Bipolar disorder
- Bipolar II disorder
- Conduct disorders
- Cyclothymic disorder
- Dementia in other diseases
- Dementia, unspecified
- Dysphagia, unspecified
- Dysthymic disorder
- Intermittent explosive disorder
- Mania
- Mood (affective) disorders, unspecified
- Oppositional defiant disorder
- Persistent mood (affective) disorders
- Schizophrenia
- Schizophreniform disorder
- Tourette's syndrome
- Unspecified psychosis
- Vascular dementia

OR

2.1.2 Both of the following:

2.1.2.1 Patient has a diagnosis of depression **AND**

2.1.2.2 Patient has tried and failed 2 different antidepressants

AND

2.2 Children younger than 6 years of age must have a psychiatrist, developmental pediatrician, child/adolescent psychiatrist or pediatric neurologist involved in care

AND

2.3 For alternative dosage forms (e.g., rapid dissolve tablets, injectables, extended-release), one of the following criteria must be met:

2.3.1 The patient is unable to swallow **OR**

2.3.2 The patient failed a standard dosage form from this drug class in the last 30 days

AND

2.4 For members requesting ***more than 2*** different antipsychotics, the following criteria must be met:

2.4.1 All antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist **AND**

2.4.2 One of the following:

2.4.2.1 History of at least 4 weeks of dual agent therapy at an adequate dose **OR**

2.4.2.2 The medications involved in the therapeutic duplication are being cross-tapered and it is the first request for an authorization due to cross-tapering

ADHD Utilization

History of utilization reviews:

- March 2019 P&T meeting – reviewed utilization of all members on ADD/ADHD medications
- June 2019 P&T meeting – reviewed utilization of members aged 1-20 years old vs 21 years old & older
- September 2019 P&T meeting – reviewed utilization of members aged 26 years old & older
- December 2020 P&T meeting – reviewed utilization of members 21 years & older
- March 2021 P&T meeting – reviewed utilization of members 21 years plus & PMPM & PUPM comparison

Time frame: 1/1/2021 – 3/31/2021

State Comparison of all utilization (IHS excluded) for all members

State Medicaid	# ADHD Claims	Plan Paid	PMPM	PUPM	PA Criteria
State A	131,614	$19,571,451	$4.03	$136.59	PA for ≥ 21 years old
State B	9,848	$1,072,827	$1.93	$97.87	Vyvanse PA for adults & children
State C	32,390	$4,079,793	$4.39	$137.09	PA for < 6 years old, PA for ≥ 21 years old
State D	31,979	$5,851,083	$5.58	$170.42	PA for all NP; PA for ≥ 21 years old
South Dakota	17,472	$1,816,661	$4.33	$109.58	

ADD/ADHD Drugs – 21 years old and older only

	4Q2020				1Q2021			
Class	Total Rx	Paid Amount	Paid/Rx	Utilizers	Total Rx	Paid Amount	Paid/Rx	Utilizers
Amphetamines	1,686	$206,686.60	$131.31	536	1,780	$226,216.32	$127.09	602
Respiratory & CNS Stimulants	420	$32,358.18	$68.27	148	398	$23,333.99	$58.63	142

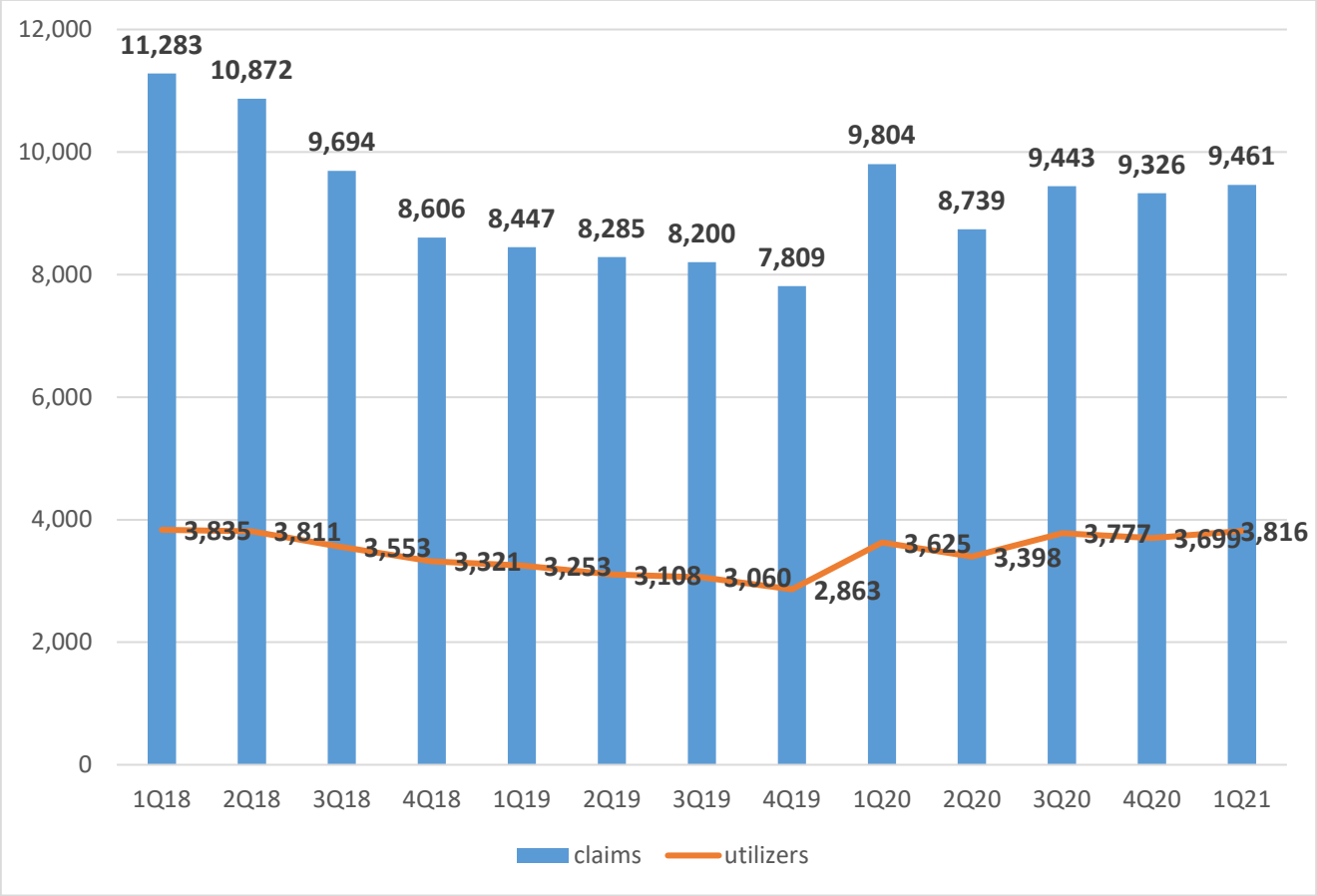
Amphetamine

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizers	Avg Quantity
Amphetamine-dextroamphetamine					
• amphetamine tab	1	$18.08	$18.08	1	#60 per 30 days
• Adderall tab	3	$1,495.74	$498.58	1	#60 per 30 days
• Adderall XR cap	6	$1,250.31	$208.39	2	#45 per 30 days
• amphet/dextroamephtamine cap ER	500	$18,113.43	$36.23	186	#37 per 29.5 days
• amphet/dextroamephtamine tab	599	$16,972.87	$31.46	231	#55per 29 days
• Mydayis	11	$3,307.16	$300.65	4	#30 per 30 days
Dextroamphetamine sulfate					
• dextroamephtamine cap ER	5	$965.68	$193.14	2	#96 per 30 days
• dextroamephtamine tab	21	$1,036.80	$49.37	8	#124.7 per 28 days
Lisdexamfetamine dimesylate					(5 Rxs with 60 per 30 days)
• Vyvanse cap	629	$181,898.99	$289.19	234	#29 per 29 days
• Vyvanse chew	5	$1,157.26	$231.45	2	#21 per 30 days

Respiratory & CNS Stimulants

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizers	Avg Quantity
Dexmethylphenidate					
• dexmethylphenidate tab	10	$255.59	$25.56	4	#60 per 30 days
• dexmethylphenidate cap ER	21	$1,762.43	$83.93	8	#29 per 29 days
Methylphenidate hcl					
• Adhansia XR cap	1	$310.53	$310.53	1	#30 per 30 days
• methylphenidate cap ER	26	$1,860.03	$71.54	10	#29.6 per 28 days
• methylphenidate tab	115	$2,528.52	$21.99	47	#60.5 per 29 days
• methylphenidate tab ER	223	$15,798.13	$70.84	81	#36 per 30 days
• Daytrana DIS	2	$818.76	$409.38	1	#30 per 30 days

Opioid Summary



-1Q2018 to 4Q2019 excludes IHS
-1Q2020 to current includes HIS
-2Q20 pandemic closure

Total Eligibility

Quarter	Avg eligible members	Avg utilizing members of all drugs	% utilizing members of all drugs
1Q2020	123,552	27,893	22.6%
2Q2020	126,777	20,747	16.4%
3Q2020	132,373	23,388	17.7%
4Q2020	136,262	21,785	15.9%
1Q2021	139,922	21,763	15.6%

-March 2021 utilizers 22,845

Opioid Utilization Snapshot

SDM 4Q2020

Sep 20 to Dec 20

Opioid Claims **9,326**

3.2% prescription claims filled for an opioid

0.5% lower than Medicaid FFS benchmark

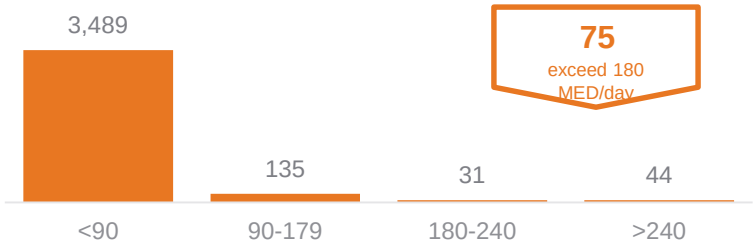
Utilizers **3,699**

31.3% are high utilizers [1]

-19.5% lower than high utilizers Medicaid FFS

Utilizers by Cumulative MED[4]

Current CDC Guidelines[5] urge doses of 90 MME[6] or less in chronic opioid utilizers[5]



Shoppers: Poly Pharmacy

37 opioid utilizing members with 3+ pharmacies

Shoppers: Poly Prescriber

232 Shoppers: Poly Prescriber

opioid utilizing members with 3+ prescribers

1Q2021

Dec 20 to Mar 21

Opioid Claims **9,461**

3.2% prescription claims filled for an opioid

0.3% higher than Medicaid FFS benchmark

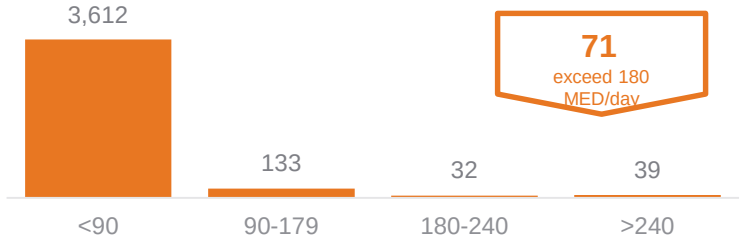
Utilizers **3,816**

31.1% are high utilizers [1]

-4.8% lower than high utilizers Medicaid FFS

Utilizers by Cumulative MED[4]

Current CDC Guidelines[5] urge doses of 90 MME[6] or less in chronic opioid utilizers[5]



Shoppers: Poly Pharmacy

48 opioid utilizing members with 3+ pharmacies

Shoppers: Poly Prescriber

251 Shoppers: Poly Prescriber

opioid utilizing members with 3+ prescribers

OPTUMRx®

[1]Defined as 3+ opioid scripts within 120 days period; [4]**MED** – Morphine Equivalent Dose is a relative potency of an opioid to standard of a morphine; Cumulative MED is daily MED or narcotic load across all active opioid prescriptions in a members profile within a 120 day period; [5]JAMA. 2016 Apr 19;315(15):1624-45. [6]MME – Morphine Milligram Equivalent represents a relative potency of an opioid to a morphine dose.

Opioid Utilization

SDM 1Q2021
Opportunities date range: Dec 2020 - Mar 2021
Benchmark: MEDICAID FEE FOR SERVICE

Utilizers: 3,816

3.2% of all Rx claims are filled for an Opioid

Opioid dependence can start in just a few days, and the risk of chronic opioid use increases with each additional day of opioid supplied, starting with the third day. Our Opioid Risk Management program, which includes point of sale, utilization management and retrospective drug utilization edits, are tightly aligned with CDC opioid prescribing guidelines which can help reduce exposure to excessive doses and prevent more members from transitioning from acute to chronic use.

- Opioid prescriptions account for 3.2% of all prescriptions this period, which is 0.3% higher than the benchmark
- 1,187 high opioid utilizers were identified this period, which is -4.8% lower than the benchmark

Opioid claims

9,461
TOTAL RXS

PERCENT OPIOID CLAIMS
3.2%

Opioid utilizers

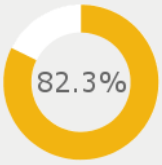
3,816
TOTAL UTILIZERS

HIGH UTILIZERS
31.1%
1,187 high utilizers

-4.8% under benchmark

High utilizers – 3+ opioid scripts within 120 days

Claim breakdown



short acting opioids

82.3% of all opioid Rxs were filled for short acting opioids. **1,075** Rxs were for medication assisted therapy (MAT) and **60** were for rescue therapy. CDC guidelines advise prescribers to manage pain with the lowest effective dose and to avoid or carefully justify doses for chronic users >90mg MME/day.

MAT – Medication Assisted Therapy (buprenorphine, etc)
Overdose rescue therapy – opioid overdose reversal w/ naloxone
MME – relative potency of an opioid to a morphine dose

Utilizers by cumulative MED

71 utilizers exceed 180 MED/day

MED Scores	<90	90-179	180-240	>240
Utilizers	3,612	133	32	39

MED – Morphine Equivalent Dose is a relative potency of an opioid to standard of a morphine; Cumulative MED is daily MED or narcotic load across all active opioid prescriptions in a members profile within a 120 day period

Opioid Opportunity Assessment

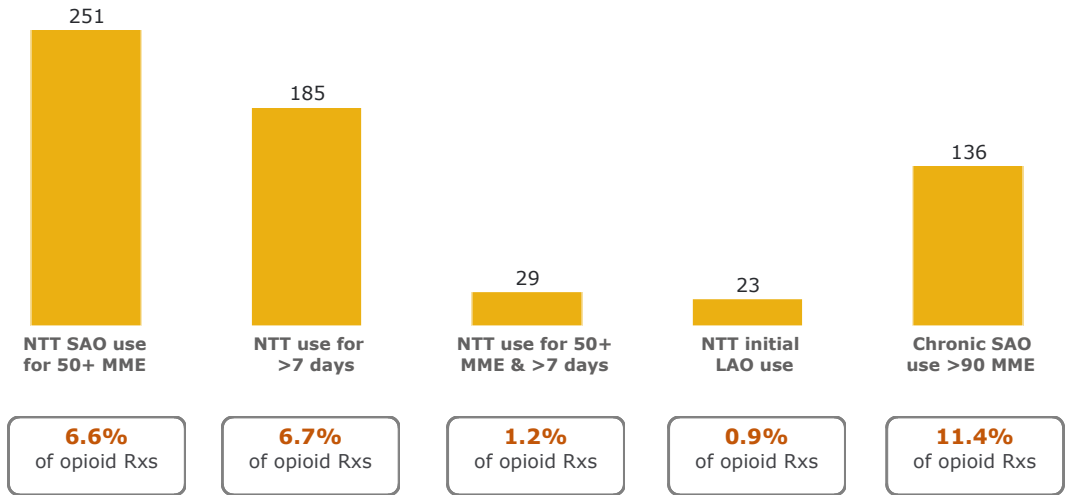
SDM 1Q2021

Opportunities date range: Dec 2020 - Mar 2021

Benchmark: MEDICAID FEE FOR SERVICE

Utilizers

(new to therapy and chronic use)



NTT - view definition | SAO - view definition | LAO - view definition | MME - view definition

48 opioid utilizing members use 3 or more pharmacies and 251 opioid utilizing members use 3 or more prescribers.

NNT - New to Therapy
SAO - Short Acting Opioid
LAO - Long Acting Opioid
MME - Morphine Milligram Equivalent represents a relative potency of an opioid to a morphine dose

Opioid utilizers with potentially contraindicated medication use

SKELETAL MUSCLE RELAXANTS	BENZODIAZEPINES	ANTICONVULSANTS	MEDICATION ASSISTED THERAPY	PRENATAL
687	585	665	N/A	112

Anticonvulsants –view definition

Table of Contents

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Dispense As Written (DAW) 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)

Clinical information:

Has the patient had a trial and failure with the generic product? ❑ **Yes** ❑ **No**

Has the patient had a trial with the generic product and experienced an adverse reaction (a MedWatch form must be completed)? ❑ **Yes** ❑ **No**

Does the patient have a contraindication to the generic product? ❑ **Yes** ❑ **No**

Is the generic product unavailable? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

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Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

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)

What is the patient's diagnosis for the medication being requested?

ICD-10 Code(s): _____

What medication(s) has the patient tried and failed?

Are there any supporting labs or test results? (Please specify)

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
- ❑ Patient requires a greater quantity for the treatment of a larger surface area **[Topical applications only]**
- ❑ Other: _____

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

_____

_____

_____

_____

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Quantity Limit Request Form

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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)

What is the patient's diagnosis for the medication being requested?

ICD-10 Code(s): _____

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
- ❑ Patient requires a greater quantity for the treatment of a larger surface area **[Topical applications only]**
- ❑ Other: _____

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.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

High Dollar/Claim Dollar Amount Override 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)

What is the patient's diagnosis for the medication being requested?

ICD-10 Code(s): _____

What is the requested quantity per day/fill/prescription/ or month? _____
Please indicate the daily dosages and the quantity requested per prescription/fill/ or month and the duration (i.e., 3 capsules per day, 4 capsules per prescription/per 30 days). Use/take as directed is not sufficient information.

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Topical Acne Agents 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:

- ❑ Acne vulgaris
- ❑ Plaque psoriasis **[Tazorac (tazarotene) only]**
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial and failure of a generic topical acne agent (benzoyl peroxide, tretinoin, clindamycin phosphate, erythromycin, sulfacetamide sodium/sulfur, sulfacetamide sodium) in the last 120 days? ❑ **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?

_____

_____

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_____

Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Topical Rosacea Agents 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:

❑ Acne rosacea

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial of a generic topical acne agent (benzoyl peroxide, clindamycin phosphate, erythromycin, sulfacetamide sodium/sulfur, sulfacetamide sodium, tretinoin, metronidazole cream/gel/lotion) in the past 120 days? ❑ **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?

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Please note: This request may be denied unless all required information is received.
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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Grastek®, Oralair®, Ragwitek® 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)

What is the patient's diagnosis for the medication being requested? (Mandatory)

_____

ICD-10 Code(s): _____

Clinical information:

Is the patient's diagnosis confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies? ❑ **Yes** ❑ **No**

Has the patient had a history of failure or intolerance to subcutaneous allergen immunotherapy (allergy shots)? ❑ **Yes** ❑ **No**

Does the patient have severe, unstable or uncontrolled asthma? ❑ **Yes** ❑ **No**

Select the medication categories that the patient has tried and failed:

- ❑ Intranasal antihistamines (e.g., azelastine, olopatadine, azelastine/fluticasone)
- ❑ Intranasal corticosteroids (e.g., beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone)
- ❑ Leukotriene inhibitors (e.g., montelukast, zafirlukast, zileuton)
- ❑ Oral antihistamines (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, or loratadine)

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

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_____

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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Altabax® 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:

❑ Methicillin resistant Staphylococus aureus (MRSA)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient tried and failed generic mupirocin ointment or cream for a minimum of 5 days within the last 90 days? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

What is the reason for exceeding the plan limitations?

❑ Patient requires a larger quantity to cover a larger surface area

❑ Other:

_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Antidepressants 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)

What is the patient's diagnosis for the medication being requested? _____

ICD-10 Code(s): _____

Clinical information:

Is the patient already stabilized on therapy with the requested medication? ❑ **Yes** ❑ **No**

Please list ALL medications the patient has had a trial of within the past 12 months: _____

_____

For Drizalma Sprinkle, Lexapro solution, Paxil suspension, Prozac solution, Remeron SolTab, and Zoloft concentrate 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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Brisdelle™ 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)

Medication history:

Has the patient had a 60 day trial and failure of paroxetine oral tablets within the past 6 months? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Atypical Antipsychotics 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)

Continuation of therapy:
Is this for a continuation of a second generation atypical antipsychotic agent? ❑ **Yes** ❑ **No**

What is the patient's diagnosis for the medication being requested? (Mandatory)

_____

ICD-10 Code(s) [Mandatory]: _____

Clinical information:
For patients with a diagnosis of depression, has the patient tried and failed 2 different antidepressants? ❑ **Yes** ❑ **No**
For patients younger than 6 years of age, is a psychiatrist, developmental pediatrician, child/adolescent psychiatrist or pediatric neurologist involved in care? ❑ **Yes** ❑ **No**

For alternative dosage forms (e.g., rapid dissolve tablets, injectables, extended-release), also answer the following:
Is the patient unable to swallow? ❑ **Yes** ❑ **No**
Has the patient failed a standard dosage form from this drug class in the last 30 days? ❑ **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: _____

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

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Akynzeo® 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:

❑ Prophylaxis of chemotherapy-induced nausea/vomiting

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient received highly emetogenic chemotherapy regimens or regimens including anthracyclines and cyclophosphamide in the past 90 days? ❑ **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?

_____

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_____

Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Diclegis® 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:

❑ Hyperemesis gravidarum

❑ Other diagnosis: _____ ICD-10 Code(s): _____

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

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Sancuso® 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:

❑ Prophylaxis of chemotherapy-induced nausea/vomiting

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial of a generic -Hydroxytryptamine type 3 (5-HT3) receptor antagonist for 14 days in the past 90 days? ❑ **Yes** ❑ **No**

Is the patient receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days? ❑ **Yes** ❑ **No**

Is the patient unable to tolerate oral medications for chemotherapy-induced nausea and vomiting due to a diagnosis of difficulty swallowing? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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

_____

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Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Zuplenz® 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)

Clinical information:

Has the patient had a trial of a generic -Hydroxytryptamine type 3 (5-HT3) receptor antagonist for 14 days in the past 90 days? ❑ **Yes** ❑ **No**

Is the patient receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days? ❑ **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?

_____

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Non-Sedating Antihistamines 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:

- ❑ Chronic idiopathic urticaria
- ❑ Perennial allergic rhinitis
- ❑ Seasonal allergic rhinitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient tried and failed a 14-day trial of one of the following: Cetirizine, cetirizine & pseudoephedrine, fexofenadine, fexofenadine & pseudoephedrine, loratadine, or loratadine & pseudoephedrine? ❑ **Yes** ❑ **No**

Please note: Patient preference does NOT constitute treatment failure.

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Non-Sedating Antihistamines (chewable, liquid, orally disintegrating tablet [ODT] formulations) 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:
- ❑ Chronic idiopathic urticaria
- ❑ Perennial allergic rhinitis
- ❑ Seasonal allergic rhinitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Does the patient have a documented difficulty in swallowing diagnosis? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Edarbi and Edarbyclor 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)

Clinical information:

Has the patient been stable on the requested angiotensin II receptor blocker (ARB) for more than 60 days? ❑ **Yes** ❑ **No**

Has the patient tried an angiotensin-converting enzyme (ACE) inhibitor or a generic ARB within the last 120 days? ❑ **Yes** ❑ **No**

Does the patient have an additional diagnosis of chronic obstructive pulmonary disease (COPD) or acute/chronic renal failure? ❑ **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?

_____

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_____

_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Byvalson™ 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:

❑ Hypertension

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial of concurrent use of nebivolol plus generic valsartan for at least 90 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Amrix® & Fexmid® (cyclobenzaprine) 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:

- ❑ Adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had at least a 60 day trial and failure of cyclobenzaprine 5 mg tablets **OR** cyclobenzaprine 10 mg tablets within the past 120 days? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Cambia®, Zipsor®, Zorvolex® 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)

Medication history:

Has the patient had a documented 30 day trial of a generic diclofenac product within the last 120 days? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Amitiza®, Linzess®, Movantik™ 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:

- ❑ Chronic idiopathic constipation [**Amitiza** and **Linzess** only]
- ❑ Irritable bowel syndrome with constipation (IBS-C) [**Amitiza** and **Linzess** only]
- ❑ Opioid-induced constipation in an adult patient with chronic pain [**Amitiza** and **Movantik** only]
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

For opioid-induced constipation in an adult patient with chronic pain, answer the following:

Is the pain associated with cancer? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Aimovig™, Ajovy™, Emgality™ 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:

❑ Chronic migraines
❑ Episodic migraines
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is the requested medication prescribed by or in consultation with a neurologist or pain/headache specialist? ❑ **Yes** ❑ **No**

Will the requested medication be used in combination with another CGRP inhibitor? ❑ **Yes** ❑ **No**

Select the prophylactic therapies the patient has had a trial and failure, (defined as at least 2 months of therapy with greater than 80% adherence), or an intolerance/contraindication to:

❑ Antidepressants (i.e., venlafaxine or tricyclic antidepressant such as amitriptyline or nortriptyline)
Please specify: _____

❑ Anti-epileptics (i.e., topiramate or divalproex sodium). Please specify: _____

❑ Beta-blockers (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol). Please specify: _____

For chronic migraines, also answer the following:

Has the patient been evaluated for rebound headaches caused by medication overuse (more than 12 doses per month of narcotics, triptans, caffeine, or NSAIDs)? ❑ **Yes** ❑ **No**

If diagnosed, will treatment include a plan to taper off the offending medication? ❑ **Yes** ❑ **No**

Does the patient have greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months? ❑ **Yes** ❑ **No**

For episodic migraines, also answer the following:

Does the patient have 4 to 14 migraines per month (but no more than 14 headache days per month)? ❑ **Yes** ❑ **No**

Reauthorization:

If this is a reauthorization request, answer the following:

Has the patient experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity? ❑ **Yes** ❑ **No**

Has the use of acute migraine medications (e.g., NSAIDs, triptans, narcotics) decreased since the start of CGRP therapy? ❑ **Yes** ❑ **No**

Is the requested medication prescribed by or in consultation with a neurologist or pain/headache specialist? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Desoxyn® (methamphetamine) 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:

❑ Attention Deficit Disorder with Hyperactivity

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial and failure (after a mimimum of a 60 day trial), contraindication, or intolerance to any four medications from any of the following options in the past 90 days? ❑ **Yes** ❑ **No**

- Atomoxetine
- Guanfacine
- Long-acting amphetamine salts product
- Long-acting methylphenidate product

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Dificid® 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:

❑ Clostridium difficile-associated diarrhea (CDAD)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient been treated per the current guidelines? ❑ **Yes** ❑ **No**

Select the following that the patient has failed:

❑ Initial episode (mild to moderate severity) – metronidazole

❑ Initial episode (severe) – vancomycin

❑ Initial episode (severe, complicated) – vancomycin and metronidazole

❑ First recurrence – same regimen as first episode

❑ Second recurrence – oral vancomycin in tapered regimen

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Durlaza™ 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:

- ❑ Chronic coronary artery disease (CAD)
- ❑ Ischemic stroke
- ❑ Transient ischemic attack
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a 90 day trial and failure with immediate release aspirin? ❑ **Yes** ❑ **No**

Please submit clinical rationale explaining why a failure with the extended-release product is not expected:

_____

_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Emflaza™ 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:

❑ Duchenne muscular dystrophy

❑ Other diagnosis: _____ ICD-10 Code(s): _____

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

_____

_____

_____

_____

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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Epidiolex® 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:

❑ Seizures associated with Dravet syndrome

❑ Seizures associated with Lennox-Gastaut syndrome (LGS)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Epidiolex prescribed by or in consultation with a neurologist? ❑ **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.
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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Genitourinary smooth muscle relaxants 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)

What is the patient's diagnosis for the medication being requested? (Mandatory)

_____

ICD-10 Code(s) [Mandatory]: _____

Medication history:

Has the patient had a 30-day trial of oxybutynin or oxybutynin extended-release (ER)? ❑ **Yes** ❑ **No**

For Gelnique and Oxytrol 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 MONTH? _____

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:

_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

GLP-1 Agonists 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:

❑ Type 2 diabetes mellitus

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Gralise® & Horizant® 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:

- ❑ Moderate to severe primary restless leg syndrome (RLS) [**Horizant** only]
- ❑ Neuropathic pain associated with postherpetic neuralgia (PHN)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Moderate to severe primary RLS:

Has the patient had a trial and failure (to a minimum of a 90 day trial), contraindication, or intolerance to ropinirole or pramipexole in the past 180 days? ❑ **Yes** ❑ **No**

Neuropathic pain associated with PHN:

Has the patient had a trial and failure (to a minimum of a 90 day trial), contraindication, or intolerance to an immediate-release gabapentin in the past 180 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Growth Hormones Prior Authorization Request Form (Page 1 of 3)

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 requested medication below:

- ❑ Genotropin
- ❑ Humatrope
- ❑ Norditropin
- ❑ Nutropin AQ
- ❑ Omnitrope
- ❑ Saizen
- ❑ Zomacton

Select the diagnosis below:

For Pediatric Patients (less than 18 years of age):

- ❑ Growth hormone deficiency in children
- ❑ Growth failure due to chronic renal insufficiency
- ❑ Growth failure due to panhypopituitarism
- ❑ Growth failure due to Prader-Willi syndrome
- ❑ Idiopathic short stature in children
- ❑ Noonan syndrome
- ❑ Septo-optic dysplasia sequence
- ❑ Short stature homeobox containing gene (SHOX) deficiency
- ❑ Small for gestational age
- ❑ Turner's syndrome

For Adults (18 years of age or older):

- ❑ Growth hormone deficiency in adults
- ❑ Panhypopituitarism
- ❑ Prader-Willi syndrome
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Contraindications/Exclusions:

Does the patient have acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure? ❑ **Yes** ❑ **No**

Does the patient have active malignancy? ❑ **Yes** ❑ **No**

Does the patient have active proliferative or severe non-proliferative diabetic retinopathy? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Growth Hormones Prior Authorization Request Form (Page 2 of 3)

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

For Pediatric Patients (less than 18 years of age):

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

Are the patient's epiphyses open? ❑ **Yes** ❑ **No**

Has the patient been screened for intracranial malignancy or tumor? ❑ **Yes** ❑ **No**

For growth hormone deficiency in children, also answer the following:

Has growth hormone deficiency been confirmed with provocative test and/or IGF-1 levels? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to two (2) pharmacological growth hormone stimulation tests* with peak level below 10 ng/mL? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to at least one (1) pharmacological growth hormone stimulation test* with peak level below 10 ng/mL for a patient with defined CNS pathology, multiple pituitary hormone deficiencies, history of irradiation, or proven genetic cause? ❑ **Yes** ❑ **No**

**Please note: acceptable tests include: arginine, clonidine, glucagon, insulin, and levodopa*

Is the patient's height more than 3 standard deviations (SDs) below the mean for same age and gender? ❑ **Yes** ❑ **No**

Is the patient's height more than 2 SDs below the mean for same age and gender AND the patient has decreased growth velocity more than 1 SD below the mean for the same age and gender? ❑ **Yes** ❑ **No**

Is the patient's growth velocity measured 2 SDs below the mean over one year or 1.5 SDs below the mean sustained over 2 years for the same age and gender? ❑ **Yes** ❑ **No**

Have other causes of growth failure been ruled out (e.g., hypothyroidism, chronic systemic disease, skeletal disorders, malnutrition)? ❑ **Yes** ❑ **No**

For growth failure due to chronic renal insufficiency, also answer the following:

Has the patient's nutritional status been optimized and metabolic abnormalities been corrected? ❑ **Yes** ❑ **No**

Has the patient had a kidney transplant? ❑ **Yes** ❑ **No**

Is the patient's height less than the 3rd percentile? ❑ **Yes** ❑ **No**

Is the patient's growth velocity measured over 1 year > 2 standard deviations below the mean for same age and gender? ❑ **Yes** ❑ **No**

For growth failure due to panhypopituitarism or Prader-Willi syndrome, also answer the following:

Has the patient's diagnosis of panhypopituitarism or Prader-Willi syndrome been confirmed by appropriate genetic testing? ❑ **Yes** ❑ **No**

Is the diagnosis of panhypopituitarism caused by cranipharyngioma surgery? ❑ **Yes** ❑ **No**

Does the patient have severe obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment? ❑ **Yes** ❑ **No**

Is the patient's height more than 2 standard deviations below the mean for same age and gender? ❑ **Yes** ❑ **No**

For idiopathic short stature, also answer the following:

Is the patient's height more than 2.25 standard deviations below the mean? ❑ **Yes** ❑ **No**

Is the patient's predicted height less than or equal to 65 inches for male or less than or equal to 60 inches for females? ❑ **Yes** ❑ **No**

For short stature homeobox-containing gene (SHOX) deficiency or Noonan syndrome, also answer the following:

Is the patient's height more than 3 standard deviations (SDs) below the mean for same age and gender? ❑ **Yes** ❑ **No**

Is the patient's height more than 2 SDs below the mean for same age and gender AND the patient has decreased growth velocity more than 1 SD below the mean for the same age and gender? ❑ **Yes** ❑ **No**

Is the patient's growth velocity measured 2 SDs below the mean over one year or 1.5 SDs below the mean sustained over 2 years for the same age and gender? ❑ **Yes** ❑ **No**

For small for gestational age (SGA), also answer the following:

Did the patient have post-natal growth failure at one year? ❑ **Yes** ❑ **No**

Is the patient below the 5th percentile for height? ❑ **Yes** ❑ **No**

Was the patient's birth weight or length at least 2 standard deviations below the mean for gestational age? ❑ **Yes** ❑ **No**

For Turner's syndrome, also answer the following:

Has the patient's diagnosis of Turner's syndrome been confirmed by chromosome analysis? ❑ **Yes** ❑ **No**

Is the patient's height less than the 5th percentile for same age and gender? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Growth Hormones Prior Authorization Request Form (Page 3 of 3)

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

For Adult Patients (18 years of age or older):

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

For growth hormone deficiency in adults, also answer the following:

Has growth hormone deficiency been confirmed with two provocative tests and IGF-1 levels? ❑ **Yes** ❑ **No**

Has the patient been screened for intracranial malignancy or tumor? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Serostim® 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:

❑ HIV infection/AIDS wasting

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Serostim prescribed by or in consultation with an infectious disease specialist? ❑ **Yes** ❑ **No**

Has the patient tried and had an inadequate response or intolerance to dronabinol or megestrol? ❑ **Yes** ❑ **No**

Is the patient currently receiving treatment with antiretrovirals? ❑ **Yes** ❑ **No**

Does the patient have acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure? ❑ **Yes** ❑ **No**

Has the patient been screened to verify the absence of any active malignancy? ❑ **Yes** ❑ **No**

Does the patient have active proliferative or severe non-proliferative diabetic retinopathy? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Zorbtive® 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:

❑ Short bowel syndrome

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Zorbtive prescribed by or in consultation with a gastroenterologist? ❑ **Yes** ❑ **No**

Is the patient receiving specialized nutritional support (i.e., parenteral nutrition)? ❑ **Yes** ❑ **No**

Does the patient have acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure? ❑ **Yes** ❑ **No**

Has the patient been screened to verify the absence of any active malignancy? ❑ **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.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

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Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Lindane shampoo, Ovide® (malathion), Natroba™ (spinosad), Sklice®
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)

Medication history:

Has the patient had a trial and failure, contraindication, or intolerance to a permethrin or pyrethrins-piperonyl butoxide product in the past 90 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Hemangeol™ 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:

❑ Proliferating infantile hemangioma requiring systemic therapy

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is the patient's weight 2 kilograms (kg) or greater? ❑ **Yes** ❑ **No**

Does the patient have asthma or a history of bronchospasm? ❑ **Yes** ❑ **No**

Does the patient have bradycardia (less than 80 beats per minute)? ❑ **Yes** ❑ **No**

Does the patient have greater than first-degree heart block, decompensated heart failure? ❑ **Yes** ❑ **No**

Does the patient have blood pressure less than 50/30 mmHg? ❑ **Yes** ❑ **No**

Does the patient have pheochromocytoma? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Hepatitis C Prior Authorization Request Form (Page 1 of 3)

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:

❑ Hepatitis C virus infection

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Document the patient's genotype: _____

Select if the patient has one of the following:

- ❑ Liver biopsy confirming a Metavir score of F3 or F4, unless medically contraindicated
- ❑ Serum aspartate aminotransferase (AST)-to-platelet ratio index (APRI) score of 2 or greater
- ❑ Fibroscan score of 10 or greater

Does the patient have cirrhosis? ❑ **Yes** ❑ **No**

Does the patient have compensated liver disease? ❑ **Yes** ❑ **No**

Is there documentation the patient has severe extrahepatic manifestions of hepatitis C infection? ❑ **Yes** ❑ **No**

Is the requested medication prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist? ❑ **Yes** ❑ **No**

Does the provider attest that the patient is drug and alcohol free for the past 6 months? ❑ **Yes** ❑ **No**

If the patient is female and prescribed ribavirin, does the patient have a negative pregnancy test within 30 days prior to initiation of therapy and will receive a monthly pregnancy test during treatment? ❑ **Yes** ❑ **No**

For Daklinza, also answer the following:

Will Daklinza be used in combination with Sovaldi (sofosbuvir), with or without ribavirin? ❑ **Yes** ❑ **No**

Is the patient taking strong inducers of cytochrome P450 (CYP) 3A (e.g., phenytoin, carbamazepine, rifampin, St. John's wort)? ❑ **Yes** ❑ **No**

For brand Epclusa or generic sofosbuvir/velpatasvir, also answer the following:

Is the patient taking P glycoprotein (P-gp) inducers? ❑ **Yes** ❑ **No**

Is the patient taking moderate to potent CYP inducers (e.g., carbamazepine, rifampin, St. John's wort)? ❑ **Yes** ❑ **No**

For brand Harvoni or generic ledipasvir/sofosbuvir, also answer the following:

Is the patient treatment naïve? ❑ **Yes** ❑ **No**

Does the patient have severe renal impairment (eGFR < 30 mL/min/1.73 m^2)? ❑ **Yes** ❑ **No**

Does the patient have end stage renal disease? ❑ **Yes** ❑ **No**

Select if the patient is taking any of the following medications:

- ❑ Carbamazepine
- ❑ Oxcarbazepine
- ❑ P glycoprotein (P-gp) inducers (e.g., rifampin, St. John's wort)
- ❑ Phenobarbital
- ❑ Phenytoin
- ❑ Rosuvastatin
- ❑ Tenofovir-containing HIV regimens
- ❑ Tipranavir/ritonavir

South Dakota Department of Social Services

Hepatitis C Prior Authorization Request Form (Page 2 of 3)

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For Mavyret, also answer the following:

Is the patient treatment naïve? ❑ **Yes** ❑ **No**

Select if the patient has been previously treated with a regimen containing the following (select all that applies):

- ❑ An HCV NS5A inhibitor
- ❑ An NS3/4A protease inhibitor (PI)
- ❑ Interferon (including pegylated formulations), ribavirin, and/or Sovaldi (sofosbuvir)

For Olysio, also answer the following:

Does the patient have the NS3 Q80K polymorphism? ❑ **Yes** ❑ **No**

Will Olysio be used in combination with Sovaldi? ❑ **Yes** ❑ **No**

Will Olysio be used in combination with pegylated interferon and ribavirin? ❑ **Yes** ❑ **No**

Is the patient taking strong inducers of cytochrome P450 (CYP) 3A (e.g., phenytoin, carbamazepine, rifampin, St. John's wort)? ❑ **Yes** ❑ **No**

For Sovaldi, also answer the following:

Select if the patient will use Sovaldi in combination with the following:

- ❑ Daklinza (daclatasvir)
- ❑ Olysio (simeprevir)
- ❑ Pegylated interferon and ribavirin
- ❑ Ribavirin

Does the patient have severe renal impairment (eGFR < 30 mL/min/1.73 m^2)? ❑ **Yes** ❑ **No**

Does the patient have end stage renal disease? ❑ **Yes** ❑ **No**

Does the patient have hepatocellular carcinoma that meets criteria for liver transplant? ❑ **Yes** ❑ **No**

For Technivie, also answer the following:

Will Technivie be used in combination with ribavirin? ❑ **Yes** ❑ **No**

Is the patient taking moderate to strong inducers of CYP3A or drugs that are highly dependent on CYP3A for clearance? ❑ **Yes** ❑ **No**

Does the patient have moderate to severe hepatic impairment? ❑ **Yes** ❑ **No**

For Viekira, also answer the following:

Does the patient have moderate to severe hepatic impairment (Child-Pugh B and C)? ❑ **Yes** ❑ **No**

Is the patient a liver transplant recipient with normal hepatic function and mild fibrosis? ❑ **Yes** ❑ **No**

Select if the patient is taking Viekira with any of the following medications:

- ❑ Alpha 1-adrenoreceptor antagonist (alfuzosin)
- ❑ Anti-gout (colchicine)
- ❑ Anticonvulsants (carbamazepine, phenytoin, phenobarbital)
- ❑ Antihyperlipidemic agent (gemfibrozil)
- ❑ Antimycobacterial (rifampin)
- ❑ Cisapride
- ❑ Ergot derivatives (ergotamine, dihydroergotamine, methylergonovine)
- ❑ Ethinyl estradiol containing products (e.g., combined oral contraceptives)
- ❑ Herbal products (St. John's wort)
- ❑ HMG-CoA reductase inhibitors (lovastatin, simvastatin)
- ❑ Lurasidone
- ❑ Neuroleptics (pimozide)
- ❑ Non-nucleoside reverse transcriptase inhibitor (efavirenz)
- ❑ Phosphodiesterase-5 inhibitor (sildenafil; when administered for pulmonary arterial hypertension)
- ❑ Ranolazine
- ❑ Sedative/hypnotics (triazolam, orally administered midazolam)

For Vosevi, also answer the following:

Has the patient been previously treated with a regimen containing an NS5A inhibitor? ❑ **Yes** ❑ **No**

Has the patient been previously treated with a regimen containing Sovaldi (sofosbuvir) without an NS5A inhibitor? ❑ **Yes** ❑ **No**

For Zepatier, also answer the following:

Has the patient been tested for the presence of NS5A resistance-associated polymorphisms? ❑ **Yes** ❑ **No**

If yes to the above question, does the patient have baseline NS5A polymorphisms? ❑ **Yes** ❑ **No**

Does the patient have moderate to severe hepatic impairment (Child-Pugh B and C)? ❑ **Yes** ❑ **No**

Has the patient failed the 2-drug regimen of peginterferon alfa and ribavirin? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Hydrocodone-acetaminophen (APAP) Products
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)

Medication history:

Has the patient had a history of a 60 day trial (in the past 90 days) with one of the following generics listed below? ❑ **Yes** ❑ **No**

- Hydrocodone-APAP 5-325
- Hydrocodone-APAP 7.5-325
- Hydrocodone-APAP 10-325

Clinical information:

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation: _____

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation: _____

_____

_____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Brand Name narcotics 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)

Medication history:

Has the patient had a trial and failure (at least a 30 day trial) of a generic narcotic in the past 90 days? ❑ **Yes** ❑ **No**

Clinical information:

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation: _____

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation: _____

_____

_____

Quantity limit requests:

What is the patient's diagnosis for the medication being requested?

_____ ICD-10 Code(s): _____

What is the quantity requested per MONTH? _____

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: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Opioid Naïve 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)

Clinical information:

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, major surgery, etc)? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

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

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Morphine Equivalent Dose (MED) Limit 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)

Clinical information:

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

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.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Long Acting and Short Acting Opioid 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)

Clinical information:

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**
If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation:

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**
If **yes**, please provide documentation:

_____

_____

_____

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.
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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Evzio™ 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)

Clinical information:

Is the patient currently receiving greater than 100 mg of a morphine equivalent dose (MED) per day? ❑ **Yes** ❑ **No**

Select if the patient is currently taking opioids with other interacting medication(s) from one of the following classes:

❑ Benzodiazepines
❑ Central muscle relaxants
❑ Opiods

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

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Esbriet® & Ofev® 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:

❑ Idiopathic pulmonary fibrosis (IPF)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Does the patient have a forced vital capacity (FVC) greater than or equal to 50% of predicted in the last 60 days? ❑ **Yes** ❑ **No**

Is the requested medication prescribed by or in consultation with a pulmonologist? ❑ **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?

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Dupixent® 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:

- ❑ Atopic dermatitis
- ❑ Chronic rhinosinusitis with nasal polyposis (CRSwNP)
- ❑ Moderate to severe asthma
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Atopic dermatitis:

Has the patient had a documented trial of a topical corticosteroid, pimecrolimus cream, or tacrolimus ointment within the last 120 days? ❑ **Yes** ❑ **No**

Was Dupixent prescribed by or in consultation with a dermatologist or allergist/immunologist? ❑ **Yes** ❑ **No**

Chronic rhinosinusitis with nasal polyposis (CRSwNP):

Does the patient have a diagnosis of inadequately controlled CRSwNP? ❑ **Yes** ❑ **No**

Has the patient had a documented trial of an intranasal corticosteroid (INCS) within the last 120 days? ❑ **Yes** ❑ **No**

Was Dupixent prescribed by or in consultation with an allergist/immunologist, pulmonologist, or otolaryngologist (i.e., ENT)? ❑ **Yes** ❑ **No**

Moderate to severe asthma:

Has the patient had a documented trial of an inhaled corticosteroid (ICS) within the last 120 days? ❑ **Yes** ❑ **No**

Select if the patient has had a documented trial of one of the following controller medications within the last 120 days:

- ❑ Long-acting beta 2 agonist (LABA)
- ❑ LABA/ICS combination
- ❑ Long-acting muscarinic antagonists (LAMA)
- ❑ Leukotriene modifiers
- ❑ Theophylline

Was Dupixent prescribed by or in consultation with an allergist/immunologist or pulmonologist? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029.
Mon-Sat: 7am to 7pm Central

Fasenra™ 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:

❑ Severe asthma with an eosinophilic phenotype

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient experienced inadequate control of asthmatic symptoms after a minimum of three months use of a high-dose inhaled corticosteroid (ICS) and controlled medication (long-acting beta2 agonist (LABA) or high-dose LABA/ICS combination product or leukotriene receptor antagonist)? ❑ **Yes** ❑ **No**

Is Fasenra prescribed by or in consultation with a rheumatologist, pulmonologist, allergist, or immunologist? ❑ **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?

_____

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nucala® 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:

- ❑ Eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome)
- ❑ Severe asthma with an eosinophilic phenotype
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Nucala prescribed by or in consultation with a rheumatologist, pulmonologist, allergist, or immunologist? ❑ **Yes** ❑ **No**

For severe asthma with an eosinophilic phenotype, also answer the following:

Has the patient experienced inadequate control of asthmatic symptoms after a minimum of three months use of a high dose corticosteroid and controller medication? ❑ **Yes** ❑ **No**

Has the patient had at least two asthma exacerbations requiring medical intervention within the past 12 months? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xolair® Prior Authorization Request Form

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

Member Information (required)

Member Name:		
Insurance ID#:		
Date of Birth:		
Street Address:		
City:	State:	Zip:
Phone:		

Provider Information (required)

Provider Name:		
NPI#:	Specialty:	
Office Phone:		
Office Fax:		
Office Street Address:		
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:

❑ Asthma
❑ Chronic idiopathic urticaria (CIU)
❑ Other diagnosis: _____ ICD-10 Code(s): _____

For asthma, answer the following:

Does the patient have a positive skin test or in vitro reactivity to a perennial aeroallergen? ❑ **Yes** ❑ **No**
Does the patient have an elevated serum IgE level? ❑ **Yes** ❑ **No**
Are the patient's symptoms inadequately controlled with inhaled corticosteroids? ❑ **Yes** ❑ **No**
Is Xolair prescribed by or in consultation with a pulmonologist, allergist, or immunologist? ❑ **Yes** ❑ **No**

For chronic idiopathic urticaria, answer the following:

Does the patient remain symptomatic despite H1 antihistamine treatment? ❑ **Yes** ❑ **No**
Is Xolair prescribed by or in consultation with a dermatologist, rheumatologist, pulmonologist, allergist, or immunologist? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029.
Mon-Sat: 7am to 7pm Central

Actemra® 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:

- ❑ Active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Active systemic juvenile idiopathic arthritis (sJIA)
- ❑ Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Temporal arteritis or giant cell arteritis (GCA)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if Actemra is prescribed by or in consultation with one of the following specialists:

- ❑ Allergist/immunologist
- ❑ Rheumatologist

Will Actemra be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active polyarticular juvenile idiopathic arthritis (pJIA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For active systemic juvenile idiopathic arthritis (sJIA), also answer the following:

Has the patient had an inadequate response or intolerance to at least one oral systemic agent [i.e., non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid]? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For temporal arteritis or giant cell arteritis (GCA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to oral or parenteral corticosteroid? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Cimzia® 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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ Moderately to severely active Crohn's disease
- ❑ Moderately to severely active rheumatoid arthritis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Gastroenterologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe chronic plaque psoriasis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **Yes** ❑ **No**

For moderately to severely active Crohn's disease, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more immunosuppressive agents (e.g., azathioprine, mercaptopurine, methotrexate)? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

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

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

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Cosentyx® 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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis
- ❑ Moderate to severe plaque psoriasis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

❑ Dermatologist ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis, also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis, also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe plaque psoriasis, also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Enbrel® 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:

- ❑ Active ankylosing spondylitis (AS)
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis (PsO)
- ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis (AS), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe chronic plaque psoriasis (PsO), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **Yes** ❑ **No**

For moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

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

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

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Humira® 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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ Moderate to severe hidradenitis suppurativa (e.g., Hurley Stage II or III)
- ❑ Moderately to severely active Crohn's disease
- ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (JIA)
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Moderately to severely active ulcerative colitis
- ❑ Non-infectious uveitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:
❑ Dermatologist ❑ Gastroenterologist ❑ Ophthalmologist ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis (AS), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe chronic plaque psoriasis (PsO), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **Yes** ❑ **No**

For moderate to severe hidradenitis suppurativa, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more of the following: oral or topical antibiotic therapy OR oral or injectable steroid therapy? ❑ **Yes** ❑ **No**

For moderately to severely active Crohn's disease, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more immunosuppressive agents (e.g., azathioprine, mercaptopurine, methotrexate)? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

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

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For moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For moderately to severely active ulcerative colitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with one or more of the following: corticosteroids (i.e., prednisone, methylprednisolone), 5-ASAs (i.e., mesalamine, sulfasalazine, balsalazide, olsalazine), non-biologic DMARDs (i.e., azathioprine, methotrexate, mercaptopurine)? ❑ **Yes** ❑ **No**

For non-infectious uveitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more of the following: methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, cyclophosphamide? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Ilaris® 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:

- ❑ Active systemic juvenile idiopathic arthritis
- ❑ Cryopyrin-associated periodic syndromes (CAPS) [including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)]
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

For active systemic juvenile idiopathic arthritis, answer the following:

Is Ilaris prescribed by or in consultation with a rheumatologist? ❑ **Yes** ❑ **No**

Will Ilaris be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response or intolerance to at least one oral systemic agent [i.e., non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid]? ❑ **Yes** ❑ **No**

For cryopyrin-associated periodic syndromes (CAPS) [including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)], answer the following:

Will Ilaris be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Is Ilaris diagnosed by, or upon consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist? ❑ **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?

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Ilumya™ 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:

❑ Moderate-to-severe plaque psoriasis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Ilumya prescribed by or in consultation with a dermatologist? ❑ **Yes** ❑ **No**

Will Ilumya be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Kevzara® 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:

❑ Moderately to severely active rheumatoid arthritis (RA)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Kevzara prescribed by or in consultation with a rheumatologist? ❑ **Yes** ❑ **No**

Will Kevzara be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **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?

_____

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Kineret® 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:

❑ Cryopyrin-associated periodic syndromes (CAPS)
❑ Moderately to severely active rheumatoid arthritis (RA)
❑ Other diagnosis: _____ ICD-10 Code(s): _____

For cryopyrin-associated periodic syndromes (CAPS), also answer the following:

Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) with neonatal-onset multisystem inflammatory disease (NOMID)? ❑ **Yes** ❑ **No**

Will Kineret be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Is Kineret diagnosed by, or upon consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Is Kineret prescribed by or in consultation with a rheumatologist? ❑ **Yes** ❑ **No**

Will Kineret be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Olumiant® 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:

❑ Moderately to severely active rheumatoid arthritis (RA)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Olumiant prescribed by or in consultation with a rheumatologist? ❑ **Yes** ❑ **No**

Will Olumiant be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **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?

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Orencia® 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:

- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Otezla® 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:

❑ Active psoriatic arthritis (PsA)
❑ Moderate to severe chronic plaque psoriasis (PsO)
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:
❑ Dermatologist ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe plaque psoriasis (PsO), also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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?

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Rinvoq™ 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:

❑ Moderately to severely active rheumatoid arthritis (RA)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Rinvoq prescribed by or in consultation with a rheumatologist? ❑ **Yes** ❑ **No**

Will Rinvoq be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **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?

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Siliq® 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:

❑ Moderate to severe chronic plaque psoriasis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Siliq prescribed by or in consultation with a dermatologist? ❑ **Yes** ❑ **No**

Will Siliq be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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?

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Simponi® 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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Moderately to severely active ulcerative colitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:
❑ Dermatologist ❑ Gastroenterologist ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis (AS), also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to methotrexate? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis (RA), also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)? ❑ **Yes** ❑ **No**

For moderately to severely active ulcerative colitis, also answer the following:

Has the patient had an inadequate response, contraindication, or intolerance to conventional therapy with one or more of the following: corticosteroids (i.e., prednisone, methylprednisolone), 5-ASAs (i.e., mesalamine, sulfasalazine, balsalazide, olsalazine), non-biologic DMARDs (i.e., azathioprine, methotrexate, mercaptopurine)? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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
- ❑ Patient requires a greater quantity for the treatment of a larger surface area **[Topical applications only]**
- ❑ Other: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Skyrizi™ 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:

❑ Moderate to severe plaque psoriasis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Skyrizi prescribed by or in consultation with a dermatologist? ❑ **Yes** ❑ **No**

Will Skyrizi be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Stelara® 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:

- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ Moderately to severely active Crohn's disease
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Gastroenterologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active psoriatic arthritis (PsA), also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe chronic plaque psoriasis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **Yes** ❑ **No**

For moderately to severely active Crohn's disease, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more immunosuppressive agents (e.g., azathioprine, mercaptopurine, methotrexate)? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per TREATMENT? _____ syringe every _____ weeks

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: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Taltz® 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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis
- ❑ Moderate to severe plaque psoriasis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active ankylosing spondylitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more non-steroidal anti-inflammatory drugs (NSAIDs)? ❑ **Yes** ❑ **No**

For active psoriatic arthritis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderate to severe plaque psoriasis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Tremfya® 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:

❑ Moderate to severe plaque psoriasis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Tremfya prescribed by or in consultation with a dermatologist? ❑ **Yes** ❑ **No**

Will Tremfya be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with at least one of the following: phototherapy or one or more oral systemic treatments (i.e., methotrexate, cyclosporine, acitretin, sulfasalazine)? ❑ **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?

_____

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xeljanz® & Xeljanz XR® 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:

- ❑ Active psoriatic arthritis
- ❑ Moderately to severely active rheumatoid arthritis
- ❑ Moderately to severely active ulcerative colitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:

- ❑ Dermatologist
- ❑ Gastroenterologist
- ❑ Rheumatologist

Will the requested medication be used in combination with another biologic agent? ❑ **Yes** ❑ **No**

For active psoriatic arthritis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderately to severely active rheumatoid arthritis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to methotrexate? ❑ **Yes** ❑ **No**

For moderately to severely active ulcerative colitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with one or more of the following: corticosteroids (i.e., prednisone, methylprednisolone), 5-ASAs (i.e., mesalamine, sulfasalazine, balsalazide, olsalazine), non-biologic DMARDs (i.e., azathioprine, methotrexate, mercaptopurine)? ❑ **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?

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Topical Ketoconazole 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:

❑ Seborrheic dermatitis in immunocompetent patients

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure (a minimum of 60 day trial) of ketoconazole cream or shampoo in the past 120 days? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

What is the reason for exceeding the plan limitations?

❑ Patient requires a larger quantity to cover a larger surface area

❑ Other: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Topical onychomycosis agents 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:

❑ Onychomycosis of the toenails

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure of 90 days of terbinafine tablets and 90 days of topical ciclopirox in the last 12 months? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Luzu® 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)

What is the patient's diagnosis for the medication being requested? (Mandatory)

_____

ICD-10 Code(s) [Mandatory]: _____

Medication history:

Has the patient tried and failed two topical antifungal agents in the last 365 days? ❑ **Yes** ❑ **No**

Has the patient tried and failed two oral antifungal agents in the last 365 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Oravig® 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:

❑ Local treatment of oropharyngeal candidiasis (OPC)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure of clotrimazole troches, fluconazole tablets/suspension, or nystatin suspension within the past 60 days? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Vusion® 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:

❑ Adjunctive treatment of diaper dermatitis complicated by candidiasis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure (a minimum of 14 day trial) to topical nystatin or topical OTC miconazole in the last 30 days? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

What is the reason for exceeding the plan limitations?

❑ Patient requires a larger quantity to cover a larger surface area

❑ Other: _____

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

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
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: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Metozolv® ODT (metoclopramide orally disintegrating tablet [ODT]) 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:

❑ Diabetic gastroparesis (diabetic gastric stasis)
❑ Symptomatic gastroesophageal reflux disease
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a 30-day trial and failure of Brand Reglan or generic metoclopramide tablet or solution within the last 90 days? ❑ **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: _____

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

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Moxatag® (amoxicillin extended-release [ER]) 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)

Has the patient had a 10-day trial and failure of generic amoxicillin within the past 30 days? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Multiple Sclerosis 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 medication being requested:

❑ Ampyra	❑ Copaxone	❑ Glatopa	❑ Mitoxantrone	❑ Tysabri
❑ Aubagio	❑ Dalfampridine ER	❑ Kesimpta	❑ Plegridy	❑ Vumerity
❑ Avonex	❑ Extavia	❑ Lemtrada	❑ Ponvory	❑ Zeposia
❑ Bafiertam	❑ Gilenya	❑ Mavenclad	❑ Rebif	❑ Zinbryta
❑ Betaseron	❑ Glatiramer	❑ Mayzent	❑ Tecfidera	

Select the diagnosis below:

❑ Moderate-to-severe Crohn's disease (Tysabri only)
❑ Multiple sclerosis
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Prescriber's specialty:

Select if the requested medication is prescribed by or in consultation with one of the following specialists:
❑ Gastroenterologist (Tysabri only)
❑ Neurologist
❑ Physiatrist [Ampyra (dalfampridine ER) only]

For Ampyra (dalfampridine ER), also answer the following:

Does the patient have a history of seizures? ❑ **Yes** ❑ **No**

For Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatiramer, Glatopa, Lemtrada, Mayzent, Plegridy, Rebif, Tecfidera, or Vumerity, also answer the following:

Does the patient have a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease? ❑ **Yes** ❑ **No**

For Mavenclad, also answer the following:

Does the patient have a relapsing form of multiple sclerosis, including relapsing-remitting disease or active secondary progressive disease? ❑ **Yes** ❑ **No**

Has the patient already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine? ❑ **Yes** ❑ **No**

Select the disease-modifying therapies for multiple sclerosis the patient has failed after a trial of at least 4 weeks, has a contraindication to, or intolerance to:

❑ Aubagio (teriflunomide)	❑ Gilenya (fingolimod)	❑ Rebif (interferon beta-1a)
❑ Avonex (interferon beta-1a)	❑ Lemtrada (alemtuzumab)	❑ Tecfidera (dimethyl fumarate)
❑ Betaseron (interferon beta-1b)	❑ Mayzent (siponimod)	❑ Tysabri (natalizumab)
❑ Copaxone/Glatopa (glatiramer acetate)	❑ Ocrevus (ocrelizumab)	❑ Zinbryta (daclizumab)

❑ Extavia (interferon beta-1b) ❑ Plegridy (peginterferon beta-1a)

South Dakota Department of Social Services

Multiple Sclerosis Prior Authorization Request Form (Page 2 of 2)

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

For mitoxantrone, also answer the following:

Select the form of multiple sclerosis that applies to the patient:

- ❑ Progressive relapsing multiple sclerosis
- ❑ Secondary progressive multiple sclerosis
- ❑ Worsening relapsing-remitting multiple sclerosis

For Tysabri, also answer the following:

Does the patient have a relapsing form of multiple sclerosis? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nasal Steroids 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:

- ❑ Nasal polyps
- ❑ Nonallergic (vasomotor) rhinitis
- ❑ Perennial allergic rhinitis
- ❑ Seasonal allergic rhinitis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial and failure of a generic nasal steroid in the past 6 months? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nascobal® 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)
Has the patient had a trial and failure of injectable cyanocobalamin within the past 6 months? ❑ **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?

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nuplazid™ 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:

❑ Hallucinations and delusions associated with Parkinson's disease psychosis

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Nuplazid prescribed by or in consultation with a neurologist or psychiatrist? ❑ **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?

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Please note: This request may be denied unless all required information is received.
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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nuvessa™ 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)
Has the patient had a trial and failure of metronidazole vaginal gel 0.75% within the past 30 days? ❑ **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?

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Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Hetlioz® 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:

❑ Non-24-Hour Sleep-Wake Disorder

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient tried and failed a generic sedative-hypnotic (estazolam, eszopiclone, temazepam, triazolam, zaleplon, zolpidem) within the last 120 days? ❑ **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?

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For urgent or expedited requests please call 1-855-401-4262.
This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nuvigil® (armodafinil) and Provigil® (modafinil) 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:

- ❑ Excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome
- ❑ Narcolepsy
- ❑ Shift work sleep disorder
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

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: _____

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

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xyrem® 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:

❑ Narcolepsy with cataplexy
❑ Narcolepsy with excessive daytime sleepiness
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical Information:

Is the patient enrolled in the Xyrem Success Program? ❑ **Yes** ❑ **No**

For narcolepsy with excessive daytime sleepiness, answer the following:

Has the patient had a previous trial of at least one of the following standard stimulant agents: amphetamine/dextroamphetamine, armodafinil, modafinil, dextroamphetamine, methylphenidate? ❑ **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
❑ Patient requires a greater quantity for the treatment of a larger surface area **[Topical applications only]**
❑ Other: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Sunosi™ and Wakix® 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:

- ❑ Narcolepsy with excessive daytime sleepiness
- ❑ Obstructive sleep apnea
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

For narcolepsy with excessive daytime sleepiness, answer the following:

Has the patient had a previous trial of at least one of the following standard stimulant agents: amphetamine/dextroamphetamine, armodafinil, modafinil, dextroamphetamine, methylphenidate? ❑ **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
- ❑ Patient requires a greater quantity for the treatment of a larger surface area **[Topical applications only]**
- ❑ Other: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Onfi® 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:

❑ Intractable treatment-resistant seizure disorder
❑ Seizures associated with Lennox-Gastaut syndrome (LGS)
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Prescriber specialty:

Is Onfi prescribed by or in consultation with a neurologist? ❑ **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?

_____

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_____

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South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Bepreve®, Lastacaft®, Pataday®, Patanol®, Pazeo®
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:
❑ Allergic conjunctivitis
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:
Has the patient had a 5 day trial of azelastine, emedastine, epinastine, generic olopatadine, or ketotifen in the last 120 days? ❑ **Yes** ❑ **No**

Quantity limit requests:
What is the quantity requested per MONTH? _____
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:
_____

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

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Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Oracea®, Seysara®, and Solodyn® 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:

- ❑ Inflammatory lesions of non-nodular moderate to severe acne vulgaris [**Seysara** and **Solodyn** only]
- ❑ Inflammatory lesions (papules and pustules) of rosacea [**Oracea** only]
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure (a minimum of 90 day trial) of doxycycline monohydrate, doxycycline hyclate, minocycline immediate-release, or tetracycline in the last 180 days? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Otrexup® 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:

- ❑ Active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Severe, active rheumatoid arthritis (RA)
- ❑ Severe, recalcitrant, disabling psoriasis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

For active polyarticular juvenile idiopathic arthritis (pJIA) or severe, active rheumatoid arthritis (RA), answer the following:

Is the patient intolerant of or has had an inadequate response to first-line therapy? ❑ **Yes** ❑ **No**

Has the patient tried and failed one month of a standard dosage form of methotrexate (e.g., oral, injectable) within the last 180 days? ❑ **Yes** ❑ **No**

For severe, recalcitrant, disabling psoriasis, answer the following:

Has the patient had inadequate response to other forms of therapy? ❑ **Yes** ❑ **No**

Has the patient tried and failed one month of a standard dosage form of methotrexate (e.g., oral, injectable) within the last 180 days? ❑ **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?

_____

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Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
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?

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Please note: This request may be denied unless all required information is received.
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This form may be used for non-urgent requests and faxed to 1-844-403-1029.

South Dakota Department of Social Services

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Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Proton Pump Inhibitor 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:

❑ Barrett's esophagitis ❑ Erosive esophagitis ❑ Zollinger-Ellison Syndrome

❑ Other diagnosis: _____ ICD-10 Code(s): _____

For Aciphex Sprinkle, Nexium oral packet, Prevacid Solutab (lansoprazole orally disintegrating tablet [ODT]), Prilosec delayed release suspension pack, Protonix packet, and Zegerid oral packet (omeprazole/sodium bicarbonate oral packet) requests, answer the following:

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

For Dexilant, esomeprazole strontium capsule, Nexium capsule (esomeprazole magnesium capsule), Prevpack oral pack (lansoprazole-amoxicillin-clarithromycin oral pack), Protonix tablet, and Zegerid capsule (omeprazole-sodium bicarbonate capsule) requests, answer the following:

Has the patient had a trial and failure (after a minimum of 14 days) in the past year with at least one of the following generics: Lansoprazole, omeprazole, pantoprazole, or rabeprazole? ❑ **Yes** ❑ **No**

Has the patient experienced an adverse reaction (must be documented on a MedWatch form), allergy or contraindication to **ALL** of the following: Lansoprazole, omeprazole, pantoprazole, and rabeprazole? ❑ **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: _____

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

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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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Duexis® & Vimovo® 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:

- ❑ Ankylosing spondylitis [**Vimovo** only]
- ❑ Osteoarthritis
- ❑ Rheumatoid arthritis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Does the patient have a history of peptic ulcer disease/gastrointestinal (GI) bleed? ❑ **Yes** ❑ **No**

Does the patient have one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)? ❑ **Yes** ❑ **No**

Does the patient have a history of asthma or urticaria after taking aspirin or other NSAIDs? ❑ **Yes** ❑ **No**

For Duexis requests, please also answer the following:

Has the patient had a 30 day trial of a preferred generic H2-receptor blocker (e.g., famotidine, cimetidine, ranitidine, nizatidine) AND a generic NSAID within the last 180 days? ❑ **Yes** ❑ **No**

For Vimovo requests, please also answer the following:

Has the patient had a 30 day trial of a preferred generic proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole) AND a generic NSAID within the last 180 days? ❑ **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: _____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Qualaquin® (quinine) 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:

❑ Malaria

❑ Other diagnosis: _____ ICD-10 Code(s): _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Rayos® 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)
Has the patient had a trial and failure of generic prednisone tablets in the past 60 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Relistor® 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:

❑ Opioid-induced constipation in adult patients with advanced illness

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical Information:

Does the patient require palliative care? ❑ **Yes** ❑ **No**

Has the patient had at least a 10 day trial and failure of one other laxative (e.g., stimulant, osmotic, bulk forming, etc.) in the last 30 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Soma® 250 (carisoprodol) 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:

❑ Acute painful musculoskeletal condition

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a 6 month trial of carisoprodol 350 mg within the last 120 days? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Tivorbex™ 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)

Has the patient had a trial and failure (a minimum of a combined 30 day trial) of two generic prescription strength nonsteroidal anti-inflammatory drugs (NSAIDs) in the past 180 days? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Ultram® ER (tramadol extended-release [ER]) 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)

Clinical information:

Is the patient currently stable on tramadol ER tablet or Ultram ER? ❑ **Yes** ❑ **No**

Has the patient failed a 30 day trial of immediate release tramadol in the last 120 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Conzip®, Synapryn®, tramadol extended-release (ER) biphasic capsule, tramadol ER biphasic tablet 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)

Member Name:		
Insurance ID#:		
Date of Birth:		
Street Address:		
City:	State:	Zip:
Phone:		

Provider Information (required)

Provider Name:		
NPI#:	Specialty:	
Office Phone:		
Office Fax:		
Office Street Address:		
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)

Clinical information:

Is the patient currently stable on Conzip, Synapryn (tramadol suspension), tramadol ER biphasic capsule, or tramadol ER biphasic tablet? ❑ **Yes** ❑ **No**

Has the patient failed a 30-day trial of generic immediate-release tramadol in the last 120 days? ❑ **Yes** ❑ **No**

Has the patient had an adverse reaction to generic immediate-release tramadol and the prescriber has documented it on a MedWatch form? ❑ **Yes** ❑ **No**

Has the patient had a drug allergy or contraindication to generic immediate-release tramadol and the prescriber has documented it in the patient's chart notes/medical records? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of cancer in the past 365 days? ❑ **Yes** ❑ **No**

Does the patient have a diagnosis of a terminal illness? ❑ **Yes** ❑ **No**

Does the patient have an illness associated with significant pain (e.g., sickle cell anemia, etc)? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Does the patient have an injury associated with significant pain? ❑ **Yes** ❑ **No**

If **yes**, please list the diagnosis: _____

Have efforts been made to taper the patient to the lowest effective dose? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

Reauthorization:

If this is a reauthorization request, answer the following:

Is the prescriber maintaining the most conservative, effective treatment? ❑ **Yes** ❑ **No**

If **yes**, please provide documentation: _____

_____

_____

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Triptans 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:

❑ Migraine with or without aura

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial and failure of a generic triptan within the last 6 months? ❑ **Yes** ❑ **No**

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Maxalt-MLT® (rizatriptan orally disintegrating tabet [ODT]) & Zomig ZMT® (zolmitriptan ODT) 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:

❑ Migraine with or without aura

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

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

Quantity limit requests:

What is the quantity requested per MONTH? _____

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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Nurtec ODT™, Reyvow®, Ubrelvy™ 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:

❑ Acute treatment of migraine with or without aura

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial and failure of a triptan in the last 120 days? ❑ **Yes** ❑ **No**

Has the patient had an inadequate response, intolerance to, or contraindication to triptans? ❑ **Yes** ❑ **No**

Does the patient have cardiovascular disease? ❑ **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: _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Onzetra™ Xsail™ 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)

Has the patient had a trial and failure to at least six other triptans in the past 36 months? ❑ **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?

_____

_____

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_____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Uloric 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:

❑ Chronic gout

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Has the patient received an adequate trial of at least 1 month of allopurinol? ❑ **Yes** ❑ **No**

Does the patient have renal or hepatic dysfunction? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Viberzi™ 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:

❑ Irritable bowel syndrome with diarrhea (IBS-D)

❑ Other diagnosis: _____ ICD-10 Code(s): _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xenazine® 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)

Clinical information:

Does the patient have a confirmed diagnosis of chorea associated with Huntington's disease? ❑ **Yes** ❑ **No**

Is the requested medication prescribed by or in consultation with a neurologist or psychiatrist? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xepi™ 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:

❑ Impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes*

❑ Other diagnosis: _____-_____ ICD-10 Code(s): _____

Medication history:

Has the patient had a 10 day trial and failure of mupirocin ointment/cream within the past 6 months? ❑ **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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Xifaxan® 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:

- ❑ Hepatic encephalopathy (HE)
- ❑ Irritable bowel syndrome with diarrhea (IBS-D)
- ❑ Travelers' diarrhea
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

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 1-844-403-1029.

South Dakota Department of Social Services

Please note: All information below is required to process this request.
Fax to 1-844-403-1029
Mon-Sat: 7am to 7pm Central

Ambien CR® (zolpidem extended-release [ER]), Edluar™, Intermezzo® (zolpidem sublingual tablet [SL]), Zolpimist™ 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:

❑ Insomnia

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Medication history:

Has the patient had a trial (at least a 14 day trial in the last 365 days) and inadequate response, adverse reaction (prescriber must have documented it on a MedWatch form), or contraindication to generic immediate release oral zolpidem tablets or brand Ambien tablets? ❑ **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: _____

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 1-844-403-1029.

Utilization

Time Frame: 1/1/2021 to 3/31/2021

Gabapentin High-Dose Utilization Review

Dose Per Day	Total Utilizers	Females	Males	Age Range
ALL – 3,343 claims	1,325	941	384	1 – 89
< 1,500 mg	899	647	253	1 – 89
1,500 mg – 1,765 mg	106	70	36	11 – 69
1,800 mg	237	147	90	16 – 64
1,843 mg – 1,971 mg	3	2	1	16 – 52
2,000 mg – 2,956mg • 2,400 mg	160 88	114 63	46 25	19 – 64
3,000 mg – 3,900 mg • 3,200 mg • 3,600 mg	73 46 20	58 38 15	15 8 5	17 – 64
4,800 mg	1	1		61
5,400 mg – 5,419 mg	3	1	2	50 – 60
6,000 mg – 6,400 mg	2	1	1	39 – 40

> 1800 mg Dose per Day	Total Rx	Plan Paid	Paid/Rx	Utilizers	Avg Quantity
Gabapentin 100 mg	2	$49.24	$24.62	1	#480 per 24 days
Gabapentin 250 mg/5ml	18	$1,008.76	$56.04	4	417 ml per 10 days
Gabapentin 300 mg	407	$8,604.61	$21.14	167	#228.5 per 30 days
Gabapentin 400 mg	23	$563.66	$24.51	11	#215 per 30.8 days
Gabapentin 600 mg	544	$11,783.67	$21.66	216	#116 per 30 days
Gabapentin 800 mg	173	$3,881.25	$22.43	68	#102 per 29.6

High Dose management of gabapentin from other states

- State 1 – managed via RetroDUR
- State 2 – QL allow 3600 mg per day for all strengths and dosage forms

Opioid–Benzodiazepine–Stimulant Utilization Review

- 43 members taking opioid and benzodiazepine and stimulant during 1Q2021
- 12 members taking concurrent therapy
    - Prescribers
        - 1 office – 1 member
        - 2 offices – 6 members
        - 3 offices – 1 member
        - 4 offices – 1 member

Opioid–Stimulant–Zolpidem/Belsomra Utilization Review

- 11 members taking opioid and benzodiazepine and zolpidem/Belsomra, etc during 1Q2021
- 5 members taking concurrent therapy
    - Prescribers
        - 1 office – 1 member
        - 2 offices – 4 members

Opioid–Benzodiazepine–Muscle Relaxant Utilization Review

- 84 members taking opioid and benzodiazepine and muscle relaxants during 1Q2021

Proposed Imcivree Criteria

- Verification of appropriate age
- Confirmation of diagnosis of obesity
- Documentation of genetic deficiency (POMC, PCSK1 or LEPR) as stated in labeling
- Confirmation that other causes/types of obesity have been ruled out (e.g., other genetic syndromes, polygenic obesity)
- Approval is for 6 months, at which time achieve weight loss will be evaluated to establish efficacy of therapy consistent with clinical trials

PCSK9 Inhibitor Utilization

Drug Name	Total Rx	Paid Amount	Paid/Rx	Utilizers	Avg Quantity
Praluent 75mg/ml inj	7	$1,937.45	$276.78	3	#2 per 28 days
Praluent 150mg/ml inj					
Repatha 140mg/ml inj	5	$2,763.32	$552.66	4	#2.4 per 37.2 days
Repatha Sure 140mg/ml Inj	28	$12,817.65	$457.77	11	#2 per 30 days
Repatha Push 420/3.5 inj					

INTRODUCTION

- Obesity is a complex, chronic disease resulting from a combination of causes and factors including behavior and genetics. Obesity is associated with a significant increase in morbidity and mortality and can increase the risk of many disorders including metabolic and cardiovascular disease, cancer, physical limitations, decreased quality of life, and mental illness (*Centers for Disease Control [CDC] 2020*, *Perreault 2019*).
- The estimated prevalence of obesity in the United States (US) is about 42% for adults and 18.5% for children and adolescents aged 2 to 19 years (*CDC 2019, CDC 2020*).
- Obesity is commonly defined as weight that is higher than what is considered healthy for a given height. For adults, body mass index (BMI) is the accepted standard measure and screening tool with the following classifications based upon risk of cardiovascular disease (CVD) (*CDC 2020, Perreault 2020*):
  - Underweight: < 18.5 kg/m^2
  - Normal weight: 18.5 to 24.9 kg/m^2
  - Overweight: 25 to 29.9 mg/m^2
  - Obese: ≥ 30 kg/m^2
- In children, weight status is determined using an age and sex specific percentile for BMI rather than the BMI categories used for adults, due to the variability in body composition between boys and girls as they age (*CDC 2018*):
  - Underweight: < 5th percentile
  - Normal weight: 5th to 85th percentile
  - Overweight: 85th to 95th percentile
  - Obese: > 95th percentile
- In addition to BMI, waist circumference is commonly used in overweight and obese individuals to identify adults at increased risk for morbidity and mortality. Patients with abdominal obesity (also called central adiposity, visceral, android, or male-type obesity) are at increased risk for heart disease, type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, nonalcoholic fatty liver disease, and have higher overall morbidity and mortality rates (*Perreault 2020*).
- Studies suggest that heritable factors are responsible for 30 to 70 percent of the variation in adiposity. Some forms of early-onset obesity are due to genetic variants that can disrupt the melanocortin pathways, which is thought to play a key role in bodyweight regulation. (*CDC 2013*, *Clement et al 2020, Perreault 2019*).
  - Leptin gene/leptin receptor gene (LEPR): the gene produces leptin and signals the brain about quantity of fat stored. Obesity may result from the deficiency of leptin or a defect in the receptor.
  - Melanocortin-4 receptor (MC4R): the congenital deficiency of MC4R is associated with early-onset obesity and taller-than-average height. Changes in this gene are found in a small fraction (< 5%) of obese people in various ethnic groups. Affected children feel extremely hungry and become obese because of consistent hyperphagia.
  - Proprotein convertase subtilisin/kexin type 1 gene (PCSK1): congenital deficiency of PCSK1 is associated with early-onset obesity.
  - Proopiomelanocortin (POMC): mutations present with adrenal crisis in neonatal life due to adrenocorticotropin hormone (ACTH) deficiency. Individuals have early-onset obesity due to severe hyperphagia.
  - Bardet-Biedl syndrome: autosomal recessive disorder characterized by obesity and other abnormalities.
  - Other genes that may also have a role in the development of obesity include brain-derived neurotrophic factor (BDNF) and its tyrosine kinase receptor tropomyosin-related kinase B (TrkB).
- Obesity disorders due to POMC, PCSK1 and LEPR deficiencies are considered ultra-rare diseases due to a lack of awareness and need for genetic testing and features that may overlap with other forms of obesity (*Clement et al 2020*). There have only been approximately 150 cases reported in medical literature for all 3 deficiencies combined (*Food and Drug Administration [FDA] press release 2020*).
- The FDA granted orphan disease designation, breakthrough therapy designation and priority review to Imcivree (setmelanotide), a first in class therapy for chronic weight management in patients with obesity due to genetic origin. It is an MC4R agonist shown to reduce bodyweight and hunger in individuals with obesity caused by POMC, PCSK1 or LEPR deficiency (*Clement et al 2020*).

- Prior to this approval, there were no approved therapies for obesity due to these genetic variants, and bariatric surgery is considered ineffective due to persistent hunger post-surgery (*FDA clinical review 2020).*
- Medispan class: anti-obesity agents, MC4R agonists.

INDICATIONS

- Setmelanotide is a MC4R agonist indicated for chronic weight management in adult and pediatric patients ≥ 6 years of age with obesity due to POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
  - Setmelanotide is not indicated for the treatment of patients with the following conditions (*Imcivree prescribing information 2020*):
    - Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign.
    - Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.
- 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 safety and efficacy of setmelanotide was evaluated in 2 identically designed phase 3, single arm, open label, multicenter trials. A total of 21 patients ≥ 6 years of age with severe obesity (defined as bodyweight > 95% for age on growth chart assessment for individuals 6 years to < 18 years or BMI ≥ 30 kg/m^2 for individuals ≥ 18 years) due to POMC or PCSK1 (study 1) or LEPR (study 2) deficiency were evaluated. Patients with recent diet and/or exercise regimen resulting in weight loss or previous gastric bypass surgery resulting in more than 10% weight loss with no evidence of weight regain were excluded from the study. The primary endpoint in both trials was the proportion of patientss who achieved ≥ 10% weight loss compared with baseline at approximately 1 year. Key secondary endpoints were the mean percentage change in bodyweight at approximately 1 year on therapeutic dose, mean percentage change in the most hunger score on an 11-point Likert-type scale in participants ≥ 12 years at approximately 1 year on the therapeutic dose, and proportion of participants who achieved ≥25% reduction in the most hunger score at approximately 1 year on therapeutic dose.
  - Both trials started with a 2 to 12-week open label titration phase with the final 2 weeks at the individualized therapeutic dose. This was followed by a 10-week open label treatment phase. Patients who had at ≥ 5 kg reduction in weight or ≥ 5% weight loss if < 100 kg (from baseline) entered an 8-week double-blind, placebo-controlled withdrawal sequence where patients received 4 weeks of setmelanotide and 4 weeks of placebo. Patients then resumed open-label active treatment for 32 weeks. Total time on therapeutic dose was 48 weeks.
    - In study 1 (N = 10), 8 (80%) patients with obesity due to POMC or PCSK1 deficiency had a ≥ 10% weight loss after 1 year of treatment (95% confidence interval [CI], 44.4% to 97.5%; p< 0.0001 compared with historical data).
      - The mean percentage change in body weight at approximately 1 year was −25.6% (Standard Deviation [SD], 9.9; 90% CI, −28.8 to −22.0; p < 0.0001)
      - The mean percentage change in the most hunger score was −27.1% (SD, 28.1; 90% CI, −40.6 to −15.0; p = 0.0005). Overall, 4 patients experienced a 25% reduction in the most hunger score at 1 year.
    - In study 2 (N = 11), 5 (45%) patients with obesity due to LEPR deficiency had a ≥ 10% weight loss after 1 year of treatment (95% CI, 16.8% to 76.6%; p = 0.0001 compared with historical data).
      - The mean percentage change in body weight at approximately 1 year was −12.5% (SD, 8.9; 90% CI −16.1 to −8.8; p < 0.0001).
      - The mean percentage change in the most hunger score was −43.7% (SD, 23.7; 90% CI, −54.8 to −29.1; p < 0.0001). Overall, 8 patients experienced a 25% reduction in the most hunger score at 1 year.
  - Upon discontinuation of setmelanotide, 16 patients experienced a 5 to 6 kg weight gain over 4 weeks. Re-initiation of setmelanotide resulted in subsequent weight loss.
  - The most common adverse event (AE) occurring in all patients in both studies was injection site reaction.

CLINICAL GUIDELINES

- **An Endocrine Society Clinical Practice Guideline**: Pediatric Obesity—Assessment, Treatment, and Prevention (*Styne et al 2017*)

- For the prevention and treatment of obesity, clinicians should prescribe and support healthy eating habits (ie, avoiding calorie-dense, nutrient-poor foods and encouraging the consumption of whole fruits rather than fruit juices) and physical activity (ie, ≥ 20 minutes [optimally 60 minutes] of vigorous physical activity ≥ 5 days per week).
- Pharmacotherapy for children or adolescents with obesity is suggested only after a formal program of intensive lifestyle modification has failed to limit weight gain or to ameliorate comorbidities. In children and adolescents < 16 years of age who are overweight but not obese pharmacotherapy is only recommended in the context of clinical trials.
- FDA-approved pharmacotherapy for obesity should only be administered with a concomitant high intensity lifestyle modification program and only by clinicians who are experienced in the use of anti-obesity agents and are aware of the potential for adverse reactions. Clinicians should discontinue medication and re-evaluate the patient if they do not have a > 4% BMI or BMI z-score reduction after taking anti-obesity medication for 12 weeks at the full therapeutic dose.
- Bariatric surgery should only be considered in certain cases (eg, the patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of > 40 kg/m^2 or has a BMI of > 35 kg/m^2 and significant, extreme comorbidities; extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy).
- Genetic testing in patients with extreme early onset obesity (ie, before 5 years of age) and that have clinical features of genetic obesity syndromes (in particular extreme hyperphagia) and/or a family history of extreme obesity should be performed. The diagnosis of a genetic obesity syndrome can provide information that helps the family and health care providers appropriately manage the child's or adolescent's health and possibly lessen the social stigma. A genetic diagnosis can inform management, including the possibility of bariatric surgery (many such patients are relatively resistant to weight loss through changes in diet and exercise).

- **An Endocrine Society Clinical Practice Guideline:** Pharmacological Management of Obesity (*Apovian et al 2015*)
  - In the initial clinical encounter, clinicians should identify contributing factors to obesity, including family history, sleep disorders, disordered eating, genetics, and environmental or socioeconomic causes. Clinicians should also identify medications that contribute to weight gain and prescribe drugs that are weight neutral or that promote weight loss when possible.
    - Diet, exercise and behavioral modification should be included in all obesity management approaches for BMI ≥ 25 kg/m^2.
    - Pharmacotherapy (for BMI ≥ 27 kg/m^2 with comorbidity or BMI > 30 kg/m^2) and bariatric surgery (for BMI ≥ 35 kg/m^2 with comorbidity or BMI > 40 kg/m^2) should be used as adjuncts to behavioral modification when possible.
  - Efficacy and safety should be assessed at least monthly for the first 3 months, then at least every 3 months in all patients prescribed weight loss medications. If a patient's response to a weight loss medication is deemed effective (weight loss ≥ 5% of body weight at 3 months) and safe, the medication should be continued. If deemed ineffective (weight loss < 5% at 3 months) or if there are safety or tolerability issues at any time, the medication should be discontinued and alternative medications or referral for alternative treatment approaches should be considered.
- **National Institutes of Health (NIH):** Managing Overweight and Obesity in Adults (*NIH 2013*)
  - Understanding obesity as a complex, chronic disease is essential for providing effective healthcare for overweight and obese patients. Research has shown that for a given environment, body size is predicted largely by genetic factors. However, the topic of genetics in obesity are not covered by the Obesity Expert Panel in this report.
  - In overweight and obese adults at risk for T2DM, average weight losses of 2.5 to 5.5 kg at 2 or more years reduces the risk for developing T2DM by 30 to 60%. In overweight and obese adults with T2DM, weight loss of 5 to 10% is associated with hemoglobin (Hb)A1c reductions of 0.6 to 1.0% and reduced need for diabetes medications. In observational cohort studies, overweight and obese adults with T2DM who intentionally lost 9 to 13 kg had a 25% decrease in mortality rate compared to weight-stable controls. In overweight and obese adults with T2DM, orlistat compared to placebo, both with lifestyle treatment, results in a 2 to 3 kg greater weight loss at 1 and 2 years. The addition of orlistat is associated with greater reductions in fasting blood glucose, averaging 11 and 4 mg/dL at 1 and 2 years, respectively, as well as an average greater reduction in HbA1c of 0.4% at 1 year.
  - Compared to placebo, the addition of orlistat to lifestyle intervention in overweight and obese adults results in an improvement in lipid panels and triglyceride levels.
  - In overweight or obese adults with elevated cardiovascular disease risk, a 5% weight loss produced a weighted mean reduction in systolic and diastolic blood pressure of approximately 3 and 2 mmHg, respectively.
  - To achieve weight loss, an energy deficit is required, and the principal components of an effective high-intensity lifestyle intervention are: a reduced calorie diet (ie, ≥ 500 kcal/day), increased physical activity (ie, ≥ 150 minutes per

week or ≥ 30 minutes per day on most days of the week), and behavioral strategies (eg, self-monitoring of food intake, physical activity, and weight).
  - In obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight. Bariatric surgery also generally results in more favorable impact on obesity-related comorbid conditions (ie, T2DM, dyslipidemia, hypertension, quality of life, and mortality) than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss.
- **US Preventive Services Task Force (USPSTF) 2018:** Behavioral Weight Loss Interventions to Prevent Obesity-related Morbidity and Mortality in Adults (*USPSTF 2018*)
  - Clinicians should offer or refer adults with a BMI ≥ 30 to intensive, multi-component behavioral interventions (eg, problem solving to identify barriers, self-monitoring of weight, peer support, relapse prevention, and use of tools such as pedometers, food scales, and/or exercise videos).
- **Veteran's Affairs/Department of Defense (VA/DoD):** clinical practice guidelines for the management of adult overweight and obesity (*Va/DoD 2020*).
  - A comprehensive lifestyle intervention (CLI) with 3 critical components (behavioral, dietary and physical activity) that aim to produce negative energy balance is central to successful and sustained weight loss and management. A multifaceted approach that combines CLI, pharmacologic and surgical options can enhance weight loss and maintenance.
  - Other key elements of weight loss and weight management addressed by the guideline include shared decision making and elimination of obesogenic drugs and considering the use of agents that are weight neutral or promote weight loss.
    - There are several FDA-approved medications indicated for weight loss. In addition to efficacy and safety, it is important to individualize treatment, taking into consideration the potential for side effects, patient tolerability, and patient preferences, to optimize long-term adherence. Providers and patients must both be aware that weight regain often results after discontinuation; thus long-term maintenance treatment is often needed.
      - Pharmacotherapy is recommended in patients with a BMI ≥ 30 kg/m^2 or a BMI ≥ 27 kg/m^2 and an obesity-related comorbidity (ie, hypertension, T2DM, dyslipidemia, metabolic syndrome, obstructive sleep apnea, cancer , osteoarthritis, GERD, non-alcoholic fatty liver disease).
        - Guidelines recommended pharmacotherapy include phentermine/topiramate, naltrexone/bupropion ER, orlistat and liraglutide.

SAFETY SUMMARY

- Setmelanotide carries the following warnings and precautions:
  - Disturbance in sexual arousal: spontaneous penile erections in males and sexual adverse reactions in females occurred. Inform patients that these events may occur and instruct patients who have an erection lasting longer than 4 hours to seek emergency medical attention.
  - Depression and suicidal ideation: Depression and suicidal ideation have occurred. Monitor patients for new onset or worsening depression. Consider discontinuing if patients experience suicidal thoughts or behaviors.
  - Skin pigmentation and darkening of pre-existing nevi: generalized increased skin pigmentation and darkening of pre-existing nevi. Perform a full body skin examination prior to initiation and periodically during treatment to monitor pre-existing and new pigmentary lesions.
  - Risk of serious adverse reactions due to benzyl alcohol preservative in neonates and low birth weight infants: serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and low birth weight infants.

  The most common AEs of setmalonotide include (incidence ≥ 20%): injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection, and spontaneous penile erection.

DOSING AND ADMINISTRATION

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Imcivree (setmelanotide)	Injection	Subcutaneous (SC)	Once daily	Not recommended in moderate to severe renal impairment or end stage renal disease (estimated glomerular filtration rate [eGFR] < 60 mL/min/1.73m^2). Evaluate weight loss after 12 to 16 weeks of treatment. If a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential, discontinue. Monitor patients for gastrointestinal adverse reactions and reduce dose.

See the current prescribing information for full details

CONCLUSION

- Obesity disorders due to POMC, PCSK1 and LEPR are considered ultra-rare diseases due to a lack of awareness and features that may overlap with other forms of obesity. These genetic variants of early-onset obesity disrupt the melanocortin pathways, which are thought to play a key role in bodyweight regulation. There have only been approximately 150 cases reported in medical literature for all 3 deficiencies combined.
- Setmelanotide is a first-in-class MC4 receptor agonist indicated for chronic weight management in adult and pediatric patients ≥ 6 years of age with obesity due to POMC, PCSK1, or LEPR deficiency.
- Until the approval of setmelanotide, there were no approved treatments for these genetic variants. Obesity caused by these genetic variants increases the risk of metabolic disorders such as T2DM, hypertension, dyslipidemia, CVD, morbidity and mortality. Bariatric surgery is also considered ineffective due to persistent hunger post-surgery.
- Most clinical guidelines do not discuss management of genetic obesity syndromes. They suggest comprehensive lifestyle modifications (ie, behavioral changes, diet, physical activity) with the addition of pharmacological treatment or bariatric surgery.
  - The Endocrine Society clinical practice guideline for pediatric obesity suggests genetic testing in patients with extreme early onset obesity (ie, before 5 years of age) and that have clinical features of genetic obesity syndromes (in particular extreme hyperphagia) and/or a family history of extreme obesity.
- Key AEs (incidence ≥ 20%) include injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection, and spontaneous penile erection.

REFERENCES

- Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-362.
- Centers for Disease Control and Prevention (CDC). Adult overweight and obesity. Updated September 17, 2020. Web site. Available at https://www.cdc.gov/obesity/adult/index.html. Accessed December 14, 2020.
- Centers for Disease Control and Prevention (CDC). Childhood overweight and obesity: childhood obesity and facts. Updated June 24, 2019. Web site. https://www.cdc.gov/obesity/childhood/index.html. Accessed December 14, 2020.
- Centers for Disease Control and Prevention (CDC). Childhood overweight and obesity: defining childhood obesity. Updated July 3, 2018. Web site. https://www.cdc.gov/obesity/childhood/index.html. Accessed December 14, 2020.
- Centers for Disease Control and Prevention (CDC). Genes and obesity. Updated May 17, 2013. Web site. https://www.cdc.gov/genomics/resources/diseases/obesity/obesedit.htm. Accessed January 25, 2021.

- Clement K, van den Akker E, Argente E, et al. Efficacy and safety of setmelanotide, an MC4R agonist, in individuals with severe obesity due to LEPR or POMC deficiency: single-arm, open-label, multicentre, phase 3 trials. *Lancet Diabetes Endocrinol*. 2020;8(12):960-970.
- Drugs@FDA: FDA approved drug products. Food and Drug Administration Web site. https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed December 14, 2020.
- FDA. FDA approves first treatment for weight management for people with certain rare genetic conditions [press release]. 2020. Web site. Available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-first-treatment-weight-management-people-certain-rare-genetic-conditions. Accessed January 11, 2021.
- Food and Drug Administration (FDA). Summary review: Imcivree. 2020. Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213793Orig1s000SumR.pdf. Accessed January 25, 2021.
- Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc.; November 2020.
- National Institutes of Health (NIH). Managing overweight and obesity in adults: systematic evidence review from the obesity expert panel. 2013. Web site. https://www.nhlbi.nih.gov/sites/default/files/media/docs/obesity-evidence-review.pdf. Accessed January 13, 2021.
- Perreault L. Genetic contribution and pathophysiology of obesity. Uptodate Web site. www.uptodate.com. Updated November 22, 2019. Accessed December 14, 2020.
- Perreault L. Obesity in adults: Etiology and risk factors. Uptodate Web site. www.uptodate.com. Updated September 6, 2019. Accessed December 14, 2020.
- Perreault L. Obesity in adults: Prevalence, screening and evaluation. Uptodate Web site. www.uptodate.com. Updated March 20, 2020. Accessed December 14, 2020.
- Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity—Assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.
- US Preventive Services Task Force (USPSTF). Behavioral weight loss interventions to prevent obesity-related morbidity and mortality in adults: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2018;320(11):1163-1171.
- Veteran's Affairs/Department of Defense (VA/DoD) clinical practice guidelines for the management of adult overweight and obesity. Department of Veterans Affairs Web site. July 2020. https://www.healthquality.va.gov/guidelines/CD/obesity/VADoDObesityCPGFinal5087242020.pdf. Accessed January 12, 2021.

Publication Date: January 28, 2021

Therapeutic Class Overview
Familial Hypercholesterolemia Agents

INTRODUCTION

- Cardiovascular disease (CVD) is the leading cause of death worldwide and accounted for 868,662 deaths in the United States (U.S.) in 2017. Key cardiovascular (CV) risk factors include smoking, physical inactivity, obesity, hypercholesterolemia, poor nutrition, hypertension, and diabetes mellitus *(American Heart Association [AHA] 2021)*.
- Serum cholesterol is known to be related to atherosclerotic CVD (ASCVD), with low-density lipoprotein cholesterol (LDL-C) being the dominant form of atherogenic cholesterol. LDL-C is a primary cause of atherosclerosis, but other major contributing risk factors include cigarette smoking, hypertension, dysglycemia, and other lipoprotein abnormalities *(Grundy et al 2019).*
- Almost 40% of American adults have total cholesterol serum levels of ≥ 200 mg/dL, and nearly 30% have elevated levels of LDL-C (≥ 130 mg/dL) *(AHA 2021)*.
- Familial hypercholesterolemia (FH) is a common and serious genetic condition affecting LDL-C metabolism and resulting in severely elevated cholesterol concentrations *(Goldberg et al 2011, Raal et al 2018)*. Elevated LDL-C concentrations are present beginning at birth, which increases the risk of premature atherosclerotic cardiovascular disease (ASCVD).
- Patients can have homozygous FH (HoFH) or heterozygous FH (HeFH). HeFH is estimated to occur in 1 in 200 to 250 adults in the U.S. and is associated with 2 to 3 times higher incidence of elevated LDL-C levels and occurrence of CHD before the age of 55 years *(Goldberg et al 2011, Raal et al 2018)*. HoFH is much rare with an estimated prevalence of 1:300,000 to 1:400,000, but LDL-C elevations are more severe, which leads to extremely premature ASCVD *(Raal et al 2018, Rosenson and Durrington 2020).* Treatment of LDL-C levels should begin at the time of diagnosis and continue for life. Despite treatment with statins, patients with FH typically have a persistent elevated risk for ASCVD, indicating that additional lipid lowering therapy may be indicated.
- Alirocumab and evolocumab are fully human monoclonal antibodies that inhibit proprotein convertase subtilisin/kexin type 9 (PCSK9). PCSK9 is an enzyme that leads to the degradation of hepatocyte LDL receptors (LDLR), which results in increased LDL-C levels; by inhibiting PCSK9, LDLR recycling is preserved, and LDL-C levels are subsequently reduced *(Navarese et al 2015*).
- Additional lipid lowering agents used to treat HoFH include evinacumab and lomitapide. Evinacumab is an intravenous monoclonal antibody that inhibits angiopoietin-like 3 (ANGPTL-3), a hepatic protein that is associated with lipoprotein metabolism and increased levels of triglycerides and LDL-C *(Raal et al 2018)*. Lomitapide is an oral microsomal triglyceride transfer protein (MTP) inhibitor, which targets a lipid transfer protein in the liver responsible for lipoprotein synthesis and secretion.
- Current guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) *(Grundy et al 2019)*, American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) *(Handelsman et al 2020)*, and the National Lipid Association (NLA) *(Jacobson et al 2015, Orringer et al 2017)* all recommend maximally-tolerated statins as first-line therapy for hypercholesterolemia, including FH, or CVD, with ezetimibe and the PCSK9 inhibitors being potential adjunctive agents for patients not achieving adequate LDL-C lowering; however, there is no consensus on goal LDL-C levels. Lomitapide is an additional treatment option for patients with HoFH not responsive to PCSK9 inhibitors. Evinacumab was approved in 2021, and its role in therapy has not been clearly defined (*Drugs@FDA 2021)*.
- Medispan class: Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors, Microsomal Triglyceride Transfer Protein (MTP) Inhibitors, Angiopoietin-like Protein Inhibitors

Table 1. Medications Included Within Class Review

Drug	Generic Availability
PCSK-9 inhibitors	
Praluent (alirocumab)	-
Repatha (evolocumab)	-
Other	
Evkeeza (evinacumab-dgnb)	-
Juxtapid (lomitapide)	-

(Drugs@FDA 2021, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2021, Purple Book: Database of Licensed Biological Products 2021)

INDICATIONS

Table 2. Food and Drug Administration Approved Indications

Indication	Evkeeza (evinacumab-dgnb)	Juxtapid (lomitapide)	Praluent (alirocumab)	Repatha (evolocumab)
To reduce the risk of myocardial infarction (MI), stroke, and unstable angina (UA) requiring hospitalization in adults with established CVD			✔	
As an adjunct to diet, alone or in combination with other lipid lowering therapies (eg, statins, ezetimibe) for treatment of adults with primary hyperlipidemia (including HeFH) to reduce LDL-C			✔	✔
As an adjunct to other LDL-C-lowering therapies in patients with HoFH to reduce LDL-C			✔	✔
To reduce the risk of MI, stroke, and coronary revascularization in adults with established CVD				✔
As an adjunct to low-fat diet and other lipid-lowering treatments to reduce LDL-C, total cholesterol, non-high density lipoprotein cholesterol (HDL-C) in patients with HoFH		✔ *		
As an adjunct to other LDL-C-lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with HoFH	✔ *			

*Limitations of use: safety and efficacy has not been established in patients with hypercholesterolemia who do not have HoFH, including those with HeFH, and the effect on cardiovascular morbidity and mortality has not been determined.

(Prescribing information: Evkeeza 2021, Juxtapid 2020, Praluent 2021, Repatha 2021)

- 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 efficacy of alirocumab was evaluated in the ODYSSEY program, which consists of various Phase 3, multi-center (MC), double-blind (DB), randomized controlled trials (RCTs).
  - Patients with HeFH and/or high or very high CV risk were enrolled in 10 trials, and patients with HoFH were enrolled in 1 trial evaluated HoFH. The majority of trials evaluated alirocumab in patients receiving background statin therapy (typically at maximally-tolerated doses), whereas 2 trials evaluated alirocumab as monotherapy, including in statin-intolerant patients (ie, ODYSSEY ALTERNATIVE and ODYSSEY MONO). Ezetimibe was the comparator in the 5 active-controlled (AC) trials, whereas the other trials were placebo-controlled (PC).
- The efficacy of evolocumab was evaluated in multiple Phase 3, MC, DB, RCTs.
  - In most of the trials, patients with HeFH, HoFH, or primary hyperlipidemia were randomized to receive evolocumab or placebo, and received background statin therapy in both treatment arms, ranging from moderate-intensity statin therapy (eg, atorvastatin 10 mg) to high-intensity statin therapy (eg, atorvastatin 80 mg). In 3 trials, evolocumab was compared to ezetimibe as monotherapy, including in statin-intolerant patients (ie, GAUSS-2 and -3).
- Evinacumab and lomitapide were each evaluated in a single clinical trial including patients with HoFH.

Familial hypercholesterolemia (FH)
Alirocumab

- ODYSSEY FH I-II and HIGH FH compared the efficacy of alirocumab with placebo in patients with HeFH for a 24-week duration. In FH I-II, patients were initiated on alirocumab 75 mg SC every 2 weeks (Q2W) with an up-titration dosing strategy, whereas patients in HIGH FH were initiated on alirocumab 150 mg SC Q2W with no up-titration (*Kastelein et al 2015*).
  - ODYSSEY FH I-II were 2 identical, PC, RCTs evaluating alirocumab in 735 patients with HeFH and LDL-C > 70 mg/dL with a history of CVD or LDL-C > 100 mg/dL without history of CVD. Patients had a mean baseline LDL-C level of 140 mg/dL while receiving statin therapy; 85% of patients received high-intensity statin therapy, and 60% received ezetimibe. After 24 weeks of treatment, alirocumab reduced LDL-C by 58% and 51% in FH I and FH II, respectively, compared to placebo ($p < 0.0001$) *(Kastelein et al 2015*).
  - ODYSSEY HIGH FH evaluated alirocumab in 107 patients with HeFH and LDL-C > 160 mg/dL. Patients had a mean baseline LDL-C of approximately 200 mg/dL while receiving statin therapy; about 70% of patients were receiving high-intensity statins (eg, atorvastatin 40 to 80 mg daily or rosuvastatin 20 to 40 mg daily). Compared to placebo, alirocumab reduced LDL-C by 39% at 24 weeks ($p < 0.0001$) *(Ginsberg et al 2016*).
- ODYSSEY ESCAPE was a DB, PC, RCT that randomized patients with HeFH who were undergoing lipoprotein apheresis to alirocumab 150 mg SC Q2W (n = 41) or placebo (n = 21) for 18 weeks. Patients were treated in combination with their usual apheresis schedule for 6 weeks. At week 6, the mean percent change from baseline in pre-apheresis LDL-C was -53.7% in alirocumab-treated patients vs 1.6% in placebo-treated patients; subsequently, apheresis was discontinued in 63.4% of alirocumab-treated patients, and the rate was at least halved in 92.7% *(Moriarty et al 2016).*
- ODYSSEY HoFH was a DB, PC, Phase 3 RCT that randomized patients with HoFH in a 2:1 fashion to either alirocumab 150 mg every 2 weeks (n = 45) or placebo (n = 24) *(Blom et al 2020)*. Baseline LDL-C levels were 259.6 mg/dL in the placebo group and 295.0 mg/dL in the alirocumab group. Lipid-lowering therapy (LLT) at baseline included statins (97.1%), ezetimibe (72.5%), lomitapide (14.5%), and apheresis (14.5%). Patients in the alirocumab group had a greater reduction in LDL-C at week 12 compared to patients on placebo (-26.9% vs 8.6%; $p<0.0001$).

Evinacumab

- ELIPSE HoFH was a DB, PC, Phase 3, RCT that randomized 65 patients ≥12 years of age with HoFH in a 2:1 fashion to intravenous (IV) evinacumab 15 mg/kg every 4 weeks or placebo *(Raal et al 2020)*. The mean baseline LDL-C level was 255.1 mg/dL. Baseline therapies included statins (94%), PCSK9 inhibitors (77%), ezetimibe (75%), lomitapide (25%), and apheresis (34%). There was a mean reduction of 47.1% in LDL-C levels in the evinacumab group at week 24 compared to baseline, and a 1.9% increase in the placebo group (between group difference, -49.0%; 95% confidence interval (CI), -65.0 to -33.1; $p < 0.0001$).

Evolocumab

- In RUTHERFORD-2, patients with HeFH were randomized to receive evolocumab 140 mg SC Q2W (n = 111), evolocumab 420 mg SC every 4 weeks (Q4W) (n = 110), or placebo (n = 110) for 12 weeks. Patients had a mean baseline LDL-C level of 155 mg/dL while receiving statin therapy; 87% of patients were receiving high-intensity statin therapy, and 62% of patients were receiving ezetimibe. Compared to placebo, evolocumab 140 mg SC Q2W lowered LDL-C by 59% and evolocumab 420 mg SC Q4W by 61% at 12 weeks ($p < 0.0001$) *(Raal et al 2015b).*
- The TESLA Part B trial randomized 50 patients with HoFH on stable LLT to evolocumab 420 mg SC Q4W (n = 33) or placebo (n = 17) for 12 weeks. Patients in the evolocumab group had a mean baseline LDL-C of 356 mg/dL; those in the placebo group had a mean baseline LDL-C of 336 mg/dL. Treatment with evolocumab reduced LDL-C by 23.1%, whereas patients treated with placebo had an increase in LDL-C by 7.9% (treatment difference, -30.9%; $p < 0.0001$); however, the mean on-treatment LDL-C remained significantly elevated at 271 mg/dL *(Raal et al 2015a).*
- In HAUSER-RCT, pediatric patients (10 to 17 years of age) with HeFH who had received stable LLT for at least 4 weeks before screening were randomly assigned to evolocumab 420 mg (n = 104) or placebo (n = 53) SC once monthly (*Santos et al 2020a*). Results revealed a mean percentage change from baseline in LDL-C levels of -44.5% for evolocumab and -6.2% for placebo at week 24 (difference, -38.3%; $p < 0.001$). Results for all secondary lipid variables were also significantly improved with evolocumab therapy. The incidences of adverse effects (AEs) were similar between groups.
- Evolocumab was also shown to have long-term efficacy and safety in 300 patients with either HoFH or severe HeFH over a median of 4.1 years in the final report from the TAUSSIG trial (*Santos et al 2020b*). The most commonly reported

AEs with therapy were nasopharyngitis, influenza, upper respiratory tract infection, and headache; improvements in LDL-C were sustained over time.

Lomitapide

- A single-arm, open-label (OL) Phase 3 study evaluated the safety and efficacy of lomitapide for treatment of patients with HoFH (n = 23) as an adjunct to a low-fat diet and other lipid-lowering treatments *(Cuchel et al 2013)*. Lomitapide was initiated at a dose of 5 mg daily for 2 weeks and escalated at 4-week intervals based on safety and efficacy parameters to a maximum dose of 60 mg daily. Baseline lipid-lowering medications included statins (93%), ezetimibe (76%), nicotinic acid (10%), bile acid sequestrant (3%), fibrate (3%), and apheresis (62%). At 26 weeks, mean LDL-C levels were reduced by 50% from baseline (336 mg/dL vs 166 mg/dL; $p < 0.0001$). At the 56- and 78-week safety follow-up, mean LDL-C levels remained decreased by 44% ($p < 0.0001$) and 38% ($p < 0.0001$) compared to baseline, respectively.

Patients with hypercholesterolemia not adequately controlled on other LLTs

- ODYSSEY COMBO I and II were 2 similarly designed 24-week, DB, RCTs in high CVD risk patients who were inadequately controlled with maximally-tolerated statin therapy. Patients were included if they had a history of CVD with LDL-C ≥ 70 mg/dL, or LDL-C ≥ 100 mg/dL and CHD risk equivalents. In COMBO I, patients were randomized to alirocumab 75 mg SC Q2W (n = 209) or placebo (n = 107), whereas in COMBO II, patients were randomized to alirocumab 75 mg SC Q2W (n = 479) or ezetimibe 10 mg daily (QD) (n = 241). Both studies employed the up-titration protocol *(Cannon et al 2015, Kereiakes et al 2015).*
  - In COMBO I, 78.2% of patients had a history of CHD, 43.0% had CHD risk equivalents, and 43.0% had type 2 diabetes mellitus (T2DM). All patients but 1 received statin therapy, with 62.7% receiving high-dose statin therapy. From a baseline of 100.3 mg/dL for patients with alirocumab and 104.6 mg/dL for patients with placebo, alirocumab reduced LDL-C by 45.9% compared with placebo ($p < 0.0001$) *(Kereiakes et al 2015).*
  - In COMBO II, 75.6% of patients had CHD, 31.0% had CHD risk equivalents, and 30.7% had T2DM. All patients but 1 received statin therapy, with 66.7% receiving high-dose statin therapy. From a mean baseline of 109.0 mg/dL for patients with alirocumab and 105.0 mg/dL for patients with ezetimibe, alirocumab reduced LDL-C by 29.8% compared with ezetimibe ($p < 0.0001$) *(Cannon et al 2015).*
- ODYSSEY OPTIONS I and II were 24-week, DB, RCTs evaluating alirocumab in combination with atorvastatin or rosuvastatin in patients with hypercholesterolemia who were inadequately controlled (very high CV risk and LDL-C ≥ 70 mg/dL or high CV risk and LDL-C ≥ 100 mg/dL). In ODYSSEY OPTIONS I, 355 patients on atorvastatin 20 or 40 mg at baseline were randomized to (1) add alirocumab 75 mg SC Q2W with up-titration per ODYSSEY protocol, (2) add ezetimibe 10 mg QD, (3) double their atorvastatin dose, or (4) switch to rosuvastatin. In ODYSSEY OPTIONS II, 305 patients on rosuvastatin 10 or 20 mg were randomized to (1) add alirocumab 75 mg SC Q2W with up-titration per ODYSSEY protocol, (2) add ezetimibe 10 mg QD, or (3) double their rosuvastatin dose *(Bays et al 2015, Farnier et al 2016, Robinson et al 2014a).*
  - In OPTIONS I, among patients receiving atorvastatin 20 and 40 mg, greater LDL-C reduction was achieved with add-on alirocumab (44.1%, 54.0%), compared with add-on ezetimibe (20.5%, 22.6%), doubling atorvastatin dose (4.8%, 5.0%), or switching to rosuvastatin (21.4%; $p < 0.001$ for all comparisons) *(Robinson et al 2014a, Bays et al 2015).*
  - In OPTIONS II, in patients receiving rosuvastatin 10 mg, greater LDL-C reduction was achieved with add-on alirocumab (50.3%) compared with add-on ezetimibe (14.4%), or doubling the rosuvastatin dose (16.3%) ($p < 0.0001$ for all comparisons). In the rosuvastatin 20 mg group, the addition of alirocumab reduced LDL-C by 36.3%, but the comparisons with the ezetimibe and double rosuvastatin groups did not reach statistical significance *(Farnier et al 2016).*
- LAPLACE-2 was a Phase 3 study evaluating evolocumab in combination with various statin regimens. Patients with different LDL-C levels and different background LLT were first randomized to 1 of 5 OL statin regimens (atorvastatin 80 mg, rosuvastatin 40 mg, atorvastatin 10 mg, rosuvastatin 5 mg, or simvastatin 40 mg) for 4 weeks, and then randomized to evolocumab 140 mg SC Q2W or 420 mg SC Q4W (n = 1117), ezetimibe 10 mg QD (n = 221; patients receiving atorvastatin only), or placebo (n = 558) for 12 weeks. Compared with placebo, evolocumab further reduced LDL-C by at least 60% in all statin groups; compared with ezetimibe, evolocumab further reduced LDL-C by approximately 40% in patients receiving low-dose and high-dose atorvastatin (*Robinson et al 2014b*).
- Alirocumab was evaluated specifically in patients with diabetes in ODYSSEY DM-INSULIN and ODYSSEY DM-DISLIPIDEMIA *(Leiter et al 2017, Ray et al 2018).*

- ODYSSEY DM-INSULIN was a 24-week, DB, PC, RCT in patients with type 1 diabetes mellitus (T1DM) (n = 71) or T2DM (n = 441) treated with insulin and not controlled on maximally-tolerated statin therapy. Patients were randomized to receive alirocumab 75 mg SC Q2W with an up-titration strategy or placebo. Alirocumab reduced LDL-C from baseline to week 24 by 49% and 47.8% vs placebo in patients with T2DM and T1DM, respectively (both p < 0.0001). Glycated hemoglobin (HbA1c) and fasting blood glucose levels remained stable and treatment-emergent AEs were comparable across the groups *(Leiter et al 2017).*
- ODYSSEY DM-DISLIPIDEMIA was a 24-week, OL, RCT in patients with T2DM and mixed dyslipidemia (defined as non-HDL-C ≥ 100 mg/dL and triglycerides ≥ 150 mg/dL but < 500 mg/dL) not adequately controlled despite maximally-tolerated statin therapy. Patients were randomized to receive alirocumab (n = 276) or usual care (n = 137). Alirocumab reduced non-HDL-C by 37.3% vs 4.7% with usual care (p < 0.0001). No clinically meaningful effect was seen on HbA1c or change in number of glucose-lowering agents. The rate of treatment-emergent AEs was similar between the groups *(Ray et al 2018).*

Monotherapy and patients unable to tolerate statin therapy

- ODYSSEY MONO was a 24-week, DB, AC, RCT comparing alirocumab monotherapy with ezetimibe in patients with hypercholesterolemia. Patients were randomized to receive alirocumab 75 mg SC Q2W (n = 52) with the option to titrate to 150 mg Q2W, or ezetimibe 10 mg QD (n = 51). At 24 weeks, alirocumab reduced LDL-C from baseline by 47.2% vs 15.6% for ezetimibe (treatment difference, -31.6%; p < 0.0001). Adverse effects were similar between the groups *(Roth and McKenney 2015).*
- MENDEL-2 was a 12-week, DB, AC, PC, RCT comparing evolocumab monotherapy with ezetimibe or placebo in patients with hypercholesterolemia. Patients were randomized to receive evolocumab 140 mg SC Q2W (n = 153) or 420 mg SC Q4W (n = 153), ezetimibe 10 mg QD (n = 154), or placebo (n = 155). Evolocumab reduced LDL-C from baseline by 55% to 57% more than placebo and 38% to 40% more than ezetimibe (p < 0.001 for all comparisons). Treatment-emergent AEs and muscle-related AEs were comparable across the groups *(Koren et al 2014b).*
- ODYSSEY ALTERNATIVE was a 24-week, DB, AC, RCT comparing alirocumab with ezetimibe and atorvastatin in statin-intolerant patients. Patients were randomized to receive alirocumab 75 mg SC Q2W (n = 126) with the option to titrate to 150 mg, ezetimibe 10 mg QD (n = 125), or atorvastatin 20 mg QD (n = 63) (validation arm). Alirocumab reduced LDL-C by 45% from baseline vs 14.6% for ezetimibe (treatment difference, -30.4%; p < 0.0001). Alirocumab was better-tolerated than atorvastatin in patients in terms of muscle-related treatment-emergent AEs (32.5% vs 46.0%; p = 0.042) *(Moriarty et al 2015).*
- GAUSS-2 and -3 both compared evolocumab with ezetimibe in statin-intolerant patients *(Nissen et al 2016, Stroes et al 2014)*.
  - GAUSS-2 was a 12-week, DB, PC, active-controlled (AC) trial with patients randomized to evolocumab 140 mg SC Q2W + placebo orally QD (n = 103), evolocumab 420 mg SC Q4W + placebo orally daily (n = 102), or ezetimibe 10 mg orally QD + placebo SC Q2W or Q4W (n = 102). Evolocumab reduced LDL-C from baseline by 53% to 56%, corresponding to treatment differences vs ezetimibe of 37% and 39% (p < 0.001). Muscle-related treatment-emergent AEs occurred in 12% of evolocumab-treated patients vs 23% of ezetimibe-treated patients *(Stroes et al 2014).*
  - GAUSS-3 was a 24-week, 2-stage RCT in patients with a history of intolerance to 2 or more statins (N = 511). Phase A used a 24-week crossover protocol with atorvastatin or placebo to identify patients experiencing muscle-related AEs only to atorvastatin. In Phase B, patients experiencing intolerance only to atorvastatin were randomized to ezetimibe 10 mg QD (n = 73) or evolocumab 420 mg SC Q4W (n = 145) for 24 weeks. From baseline, evolocumab reduced LDL-C by 52.8% vs 16.7% for ezetimibe (treatment difference, -36.1%; p < 0.001). Muscle-related AEs were reported in 20.7% of evolocumab-treated patients and 28.8% of ezetimibe-treated patients *(Nissen et al 2016).*
- The EVOPACS trial is the first randomized study to evaluate evolocumab in the acute phase of acute coronary syndrome (ACS) (*Koskinas et al 2019*). In EVOPACS, 308 patients hospitalized for ACS with elevated LDL-C levels were randomly assigned to SC evolocumab 420 mg (n = 155) or matching placebo (n = 153) administered in-hospital and after 4 weeks, in addition to atorvastatin 40 mg. The majority of enrolled patients (78.2%) had not received prior statin therapy. Results revealed that the difference in mean percentage change from baseline in LDL-C between groups was -40.7%, favoring evolocumab (p < 0.001) at week 8. Greater than 95% of evolocumab-treated patients achieved currently recommended target LDL-C levels at week 8 compared to 37.6% of patients administered placebo.
- A meta-analysis of 8 RCTs compared ezetimibe vs PCSK9 inhibitors for LDL-C reduction in patients not on statin therapy (*Benhuri et al 2021*). Results showed that PCSK9 inhibitors were superior to ezetimibe for LDL-C reduction (mean difference [MD], -36.5; 95% CI, -38.3 to -34.7; p < 0.00001).

Longer term efficacy and safety

- ODYSSEY LONG TERM was a 78-week, DB, PC, RCT in which high CVD risk patients who were receiving maximally-tolerated statin therapy and had an LDL-C ≥ 70 mg/dL were randomized to receive alirocumab 150 mg SC Q2W (n = 1553) or placebo (n = 788) (*Robinson et al 2015*).
  - Compared with placebo, alirocumab reduced LDL-C by 61.9% at 24 weeks (p < 0.001); LDL-C reduction was sustained through 78 weeks (56.0% vs placebo; p < 0.001).
  - In a post hoc analysis, patients treated with alirocumab had a lower rate of adjudicated composite CVD events (ie, CHD death, nonfatal MI, ischemic stroke, or unstable angina [UA] requiring hospitalization) compared with placebo (1.7% vs 3.3%, respectively; hazard ratio [HR], 0.52; 95% CI, 0.31 to 0.90; p = 0.02). However, there was no difference when including all positively adjudicated CVD events (ie, congestive heart failure requiring hospitalization, ischemia-driven coronary revascularization) (4.6% vs 5.1%, respectively; p = 0.68).
  - The frequency of AEs was similar in both groups (81.0% vs 82.5%, respectively), as were discontinuation rates (7.2% vs 5.8%, respectively).
- The OSLER studies enrolled 4465 patients who had completed a Phase 2 or Phase 3 trial with evolocumab, and randomly assigned them to OL evolocumab plus standard of care (SOC) or SOC alone. OSLER-1 enrolled patients from Phase 2 trials to receive evolocumab 420 mg SC Q4W, whereas OSLER-2 enrolled patients from Phase 3 trials to receive evolocumab 140 mg SC Q2W or 420 mg SC Q4W depending on patient choice. The parent trials included patients on statin therapy (70.1%), as well as patients who were statin intolerant or were not on other LLTs *(Koren et al 2014a, Sabatine et al 2015).*
  - Compared with SOC alone, evolocumab reduced LDL-C by 58.8% at 24 weeks (p < 0.001); LDL-C reduction was sustained through 48 weeks (58.4% vs SOC; p < 0.001).
  - In a prespecified exploratory analysis, patients treated with evolocumab had a lower rate of CVD events (ie, death, MI, UA requiring hospitalization, coronary revascularization, stroke, transient ischemic attack [TIA], heart failure requiring hospitalization) (0.95% vs 2.18% with SOC; HR, 0.47; 95% CI, 0.28 to 0.78; p = 0.003).
  - The frequency of AEs was similar in both groups (69.2% vs 64.8%, respectively), as were serious AEs (7.5% in each group). Although uncommon overall, neurocognitive AEs were more frequent with evolocumab (0.9% vs 0.3% with SOC).
  - In 5-year results from OSLER-1, evolocumab demonstrated sustained mean LDL-C reductions over time, with patients maintaining a 56% reduction from baseline at year 5. Evolocumab was not associated with an increase in AEs or neutralizing antibodies over time *(Koren et al 2018 [abstract])*.
- DESCARTES was a 52-week RCT comparing evolocumab with placebo in 901 hypercholesterolemic patients with a range of CVD risk. Prior to the treatment phase, patients were assigned to 1 of 4 background LLT groups in a 4- to 12-week OL run-in period: diet alone, diet with atorvastatin 10 mg QD, diet with atorvastatin 80 mg QD, or diet with atorvastatin 80 mg QD and ezetimibe 10 mg QD. Patients were intensified to the next level of background LLT if they did not reach their LDL-C goal per guidelines (Adult Treatment Panel [ATP] III). After the run-in period, patients were then randomized in a 2:1 ratio to evolocumab 420 mg SC Q4W (n = 599) or placebo (n = 302). After 52 weeks, evolocumab reduced LDL-C in all 4 LLT groups compared with placebo (55.7%, 61.6%, 56.8%, 48.5%, respectively; p < 0.001 for all comparisons) *(Blom et al 2014).*

Cardiovascular outcomes

- FOURIER, a DB, PC, RCT, was the first completed CV outcomes trial for the PCSK9 inhibitors. The trial enrolled 27,564 high-risk patients with CVD and LDL-C levels ≥ 70 mg/dL while receiving optimized LLT (99.7% of patients were receiving moderate- or high-intensity statins). Patients were randomized to receive evolocumab (either 140 mg SC Q2W or 420 mg SC Q4W) or placebo, while remaining on their baseline LLT. The primary endpoint was a composite of CV death, MI, stroke, hospitalization for UA, and coronary revascularization *(Sabatine et al 2017)*.
  - At 48 weeks, the least-squares mean (LSM) percentage reduction in LDL-C levels with evolocumab, as compared with placebo, was 59%, from a median baseline value of 92 mg/dL to 30 mg/dL (p < 0.001).
  - The composite endpoint occurred in 9.8% of evolocumab-treated patients vs 11.3% of placebo-treated patients (treatment difference, 1.5%; HR, 0.85; 95% CI, 0.79 to 0.92; p < 0.001) during a median follow-up period of 26 months. The benefit was driven by reduction of MI, stroke, and coronary revascularization; no benefit was identified in CV death or death from any cause.

- ODYSSEY OUTCOMES was a DB, PC, RCT enrolling 18,924 patients who had experienced an ACS between 1 to 12 months prior and had inadequate control of their lipids (eg, LDL-C ≥ 70 mg/dL) despite maximally-tolerated statin therapy. Patients were randomized to receive alirocumab (75 mg or 150 mg SC Q2W) or placebo in addition to their baseline LLT to treat to an LDL-C target of 25 to 50 mg/dL. The primary endpoint was a composite of CHD death, non-fatal MI, ischemic stroke, and UA requiring hospitalization. Median follow-up was 2.8 years *(Schwartz et al 2018).*
  - Compared to placebo, alirocumab reduced the overall risk of the primary composite outcome (alirocumab: 9.5% vs placebo: 11.1%; HR, 0.85; 95% CI, 0.78 to 0.93; p = 0.0003) and was associated with a lower risk of non-fatal MI (alirocumab: 6.6% vs placebo: 7.6%; HR, 0.86; 95% CI, 0.77 to 0.96; p = 0.006), ischemic stroke (alirocumab: 1.2% vs placebo: 1.6%; HR, 0.73; 95% CI, 0.57 to 0.93; p = 0.01), and UA (alirocumab: 0.4% vs placebo: 0.6%; HR, 0.61; 95% CI, 0.41 to 0.92; p = 0.02).
    - For the primary composite endpoint, the absolute benefit of alirocumab was greater among patients with a baseline LDL-C level ≥ 100 mg/dL (HR, 0.76; 95% CI, 0.65 to 0.87) compared to patients with lower baseline levels; however, the analysis on this subgroup was not prespecified.
  - Alirocumab was associated with a lower risk of all-cause mortality (alirocumab: 3.5% vs placebo: 4.1%; HR, 0.85; 95% CI, 0.73 to 0.98; nominal p = 0.026), and there were also numerically fewer CHD deaths (alirocumab: 2.2% vs placebo: 2.3%; HR, 0.92; 95% CI, 0.76 to 1.11; p = 0.38).
  - In a prespecified analysis of 8242 patients eligible for ≥ 3 years follow-up, alirocumab reduced death (HR, 0.78; 95% CI, 0.65 to 0.94; p = 0.01). A post hoc analysis found that patients with baseline LDL-C ≥ 100 mg/dL had a greater absolute risk of death and a larger mortality benefit from alirocumab (HR, 0.71; 95% CI, 0.56 to 0.90; *p*interaction = 0.007). Patients who achieved lower LDL-C values at 4 months (down to ~ 30 mg/dL) appeared to be at lower risk of subsequent death (*Steg et al 2019*).
  - In another pre-specified analysis of ODYSSEY OUTCOMES, alirocumab reduced the risk of any stroke (HR, 0.72; 95% CI, 0.57 to 0.91) and ischemic stroke (HR, 0.73; 95% CI, 0.57 to 0.93) without increasing hemorrhagic stroke (HR, 0.83; 95% CI, 0.42 to 1.65) at a median follow-up of 2.8 years (*Wouter Jukema et al 2019*). Risk of hemorrhagic stroke was not dependent upon achieved LDL-C levels within the alirocumab group, which is significant as concerns have existed that very low LDL-C levels may increase the potential risk of this stroke type.

Additional meta-analyses

- A Cochrane Review of 24 studies (N = 60,997) comparing PCSK9 inhibitors with placebo or active treatment(s) for primary and secondary prevention of CVD was conducted *(Schmidt et al 2020)*. Eighteen trials randomized subjects to alirocumab and 6 to evolocumab. All subjects received background LLT or lifestyle counseling. Six alirocumab studies used an active treatment comparison vs 3 evolocumab studies.
  - Compared with placebo, alirocumab decreased the risk of CVD events, with an absolute risk difference (RD) of -2% (odds ratio [OR], 0.87; 95% CI, 0.80 to 0.94), decreased the risk of mortality (RD -1%; OR, 0.83; 95% CI, 0.72 to 0.96), MI (RD -2%; OR, 0.86; 95% CI, 0.79 to 0.94), and for any stroke (RD 0%; OR, 0.73; 95% CI, 0.58 to 0.91).
  - Compared with placebo, evolocumab decreased the risk of CVD events, with an absolute RD of -2% (OR, 0.84; 95% CI, 0.78 to 0.91), for mortality, the RD was < 1% (OR, 1.04; 95% CI, 0.91 to 1.19), MI (RD - 1%; OR, 0.72; 95% CI, 0.64 to 0.82), and for any stroke (RD < -1%; OR, 0.79; 95% CI, 0.65 to 0.94).
  - The evidence base of PCSK9 inhibitors compared with active treatment was much weaker, and it is unclear whether evolocumab or alirocumab might be effectively used as replacement therapies.
- A meta-analysis was conducted on 35 RCTs comparing treatment with a PCSK9 inhibitor to no PCSK9 inhibitor in adults with hypercholesterolemia (N = 45,539). Compared with no PCSK9 inhibitor use, treatment with a PCSK9 inhibitor was associated with a statistically significant reduction in MI (PCSK9 inhibitor: 2.3% vs control: 3.6%; OR, 0.72; 95% CI, 0.64 to 0.81), stroke (1.0% vs 1.4%; OR, 0.80; 95% CI, 0.67 to 0.96), and coronary revascularization (4.2% vs 5.8%; OR, 0.78; 95% CI, 0.71 to 0.86). Use of a PCSK9 inhibitor was not significantly associated with a decrease in all-cause mortality (1.9% vs 2.2%; OR, 0.71; 95% CI, 0.47 to 1.09) or CV mortality (1.1% vs 1.3%; OR, 1.01; 95% CI, 0.85 to 1.19) *(Karatasakis et al 2017).*
- In an updated meta-analysis involving 62,281 patients from 28 RCTs, the CV outcomes of PCSK9 inhibitor therapy (N = 33,204) vs placebo (N = 29,077) were assessed (*Casula et al 2019*). Results revealed no significant difference in all-cause mortality between the groups (OR, 0.93; 95% CI, 0.85 to 1.03). However, PCSK9 inhibitor therapy was associated with a significant reduction in CV events as compared to placebo (OR, 0.83; 95% CI, 0.78 to 0.87). Additionally, the occurrence of stroke and MI were significantly reduced with the PCSK9 inhibitors. CV mortality was not significantly different between the groups (OR, 0.94; 95% CI, 0.83 to 1.07).

CLINICAL GUIDELINES

- The updated ACC/AHA (2018) treatment guidelines for hypercholesterolemia emphasize reducing the risk of ASCVD through lipid management, including in patients with FH. In patients with clinical ASCVD, LDL-C should be reduced with high-intensity or maximally-tolerated statin therapy. In very high risk ASCVD, an LDL-C threshold of 70 mg/dL should be utilized to consider the addition of non-statins to maximally-tolerated statin therapy. If the addition of ezetimibe does not decrease LDL-C levels < 70 mg/dL, the addition of a PCSK9 inhibitor is reasonable. Similarly, in patients with severe primary hypercholesterolemia (LDL-C ≥ 190 mg/dL), high-intensity statin therapy should be initiated, but if the LDL-C level remains ≥ 100 mg/dL, adding ezetimibe may be reasonable. If the LDL-C level on statin plus ezetimibe remains ≥ 100 mg/dL and the patient has multiple factors that increase subsequent risk of ASCVD events, a PCSK9 inhibitor may be considered. The guideline notes that long-term safety (> 3 years) with the PCSK9 inhibitors is uncertain, and cost-effectiveness for patients with FH without ASCVD on maximally tolerated statin and ezetimibe therapy is uncertain at mid-2018 prices *(Grundy et al 2019)*.
- The NLA guideline (2015) recommends that the central focus of pharmacotherapy in hypercholesterolemia be moderate- or high-intensity statin therapy, and acknowledges that RCT evidence is limited in guiding combination drug therapy in patients receiving maximally-tolerated statin therapy whose atherogenic cholesterol remains elevated above treatment goals *(Jacobson et al 2015).*
  - The NLA Expert Panel evidence-based recommendations on treatment with PCSK9 inhibitors are summarized in Table 3. Patients with ASCVD and/or additional risk factors who have not met their LDL-C goals should be considered for adjunct therapy with a PCSK9 inhibitor; it is emphasized that clinicians should reinforce the importance of statin therapy and attention to lifestyle therapy with each patient visit *(Orringer et al 2017)*.

Table 3. 2017 NLA expert panel PCSK9 inhibitor recommendations

Disorder	LDL-C/Non-HDL-C for threshold for Rx (mg/dL)
ASCVD + additional risk factors	≥ 70/ ≥ 100
Progressive ASCVD	≥ 70/ ≥ 100
LDL-C ≥ 190, age 40 to 79 with no uncontrolled risk factors or key additional risk markers	≥ 100/ ≥ 130
LDL-C ≥ 190, age 40 to 79 with uncontrolled risk factors or key additional risk markers	≥ 70/ ≥ 100
LDL-C ≥ 190, age 18 to 39 with uncontrolled risk factors or key additional risk markers or FH causing mutation	≥ 100/ ≥ 130
HoFH phenotype	≥ 70/ ≥ 100
ASCVD + statin intolerance	Clinical judgment

- The AACE/ACE guidelines recommend LDL-C treatment goals based on ASCVD risk categories. Target LDL-C levels range from < 130 mg/dL for patients at low CV risk with zero ASCVD risk factors, to < 55 mg/dL for patients considered at extreme risk with progressive ASCVD. Statin therapy is recommended as the primary pharmacologic agent to achieve target LDL-C goals on the basis of morbidity and mortality outcome trials. PCSK9 inhibitors should be considered as adjunct therapy in patients who are unable to reach their LDL-C goals with maximally-tolerated statin therapy. Lomitapide may be considered as a treatment option for HoFH in patients not responsive to PCSK9 inhibitors *(Handelsman et al 2020).*
- Recent guidelines on the treatment of HoFH are limited. Most of the guidelines recommend maximally tolerated statins, ezetimibe, PCSK9 inhibitors and if the LDL-C level remains above the target goal of > 50% reduction from baseline, lomitapide and lipid apheresis may be considered (*de Ferranti et al 2019, Gidding et al 2015*). Evinacumab has not been added to any guidelines yet.

SAFETY SUMMARY

- Contraindications
  - Alirocumab, evinacumab, and evolocumab should not be used in patients with a history of serious hypersensitivity reaction to any component of the product.

- Lomitapide is contraindicated in pregnancy, in patients with moderate or severe hepatic impairment or acute liver disease including unexplained persistent abnormal liver function tests, and when used concomitantly with strong or moderate CYP3A4 inhibitors.

- Warnings/precautions
  - Hypersensitivity reactions (eg, pruritus, rash, urticaria), including some serious events (eg, hypersensitivity vasculitis, hypersensitivity reactions requiring hospitalization), have been reported with alirocumab, evinacumab, and evolocumab treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment, treat according to the SOC, and monitor until signs and symptoms resolve.
  - Lomitapide is associated with multiple warnings and should be used cautiously when taken concomitantly with certain medications.
    - Hepatotoxicity, including elevations in transaminases and hepatic steatosis, has been reported with lomitapide, which has prompted restricted distribution through a Risk Evaluation and Mitigation Strategy (REMS) program. In clinical trials, 34% of patients had an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) increase ≥ 3x upper limit of normal (ULN), and 14% has at least 1 elevation ≥ 5x ULN. Hepatic steatosis is a risk factor for steatohepatitis and cirrhosis, and long-term risk has not been rigorously evaluated.
    - Absorption of fat-soluble vitamins and serum fatty acids is reduced in patients taking lomitapide. Patients should take daily supplements containing 400 international units of vitamin E and at least 200 mg linoleic acid, 210 mg alpha-linolenic acid (ALA), 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA).
    - Use of lomitapide with CYP3A4 inhibitors results in an increased exposure to lomitapide. If use of strong and moderate CYP3A4 inhibitors cannot be avoided, lomitapide should be discontinued during treatment. Dose adjustments are warranted when administered with weak CYP344 inhibitors. Lomitapide can increase the drug concentration of simvastatin, lovastatin, and warfarin leading to AEs.

- Adverse effects
  - Alirocumab and evolocumab are generally well-tolerated. The most common AEs include nasopharyngitis, injection site reactions, and influenza.
  - Common AEs reported for evinacumab include nasopharyngitis, influenza-like illness, dizziness, rhinorrhea, and nausea.
  - The most common AEs reported in the Phase 3 lomitapide trial were diarrhea (79%), nausea (65%), vomiting (34%), dyspepsia (38%), and abdominal pain (34%). A total of 27 patients (93%) in the Phase 3 clinical trial reported a gastrointestinal AEs.

- Low LDL-C levels (ie, LDL-C < 25 mg/dL) were frequently encountered with alirocumab and evolocumab in clinical trial experience; however, symptoms associated with abetalipoproteinemia, a familial condition with minimal or nonexistent LDL-C levels (eg, fat malabsorption syndromes, hepatic steatosis, progressive neurologic degenerative disease, retinitis pigmentosa, acanthocytosis), were not observed *(McKenney 2015).* Rates of overall AEs, serious AEs, and neurocognitive AEs among patients achieving very low LDL-C levels were similar to those among the overall group *(Robinson et al 2015, Sabatine et al 2015, Sabatine et al 2017).* The long-term effects of very low LDL-C levels by alirocumab or evolocumab are unknown *(Praluent Prescribing Information 2021, Repatha Prescribing Information 2021).*
- Neurocognitive AEs occurred infrequently, but more often in patients treated with alirocumab (1.2% vs 0.5% with placebo) and evolocumab (0.9% vs 0.3% with placebo) in longer-term safety analyses *(Robinson et al 2015, Sabatine et al 2015).*
  - The EBBINGHAUS trial evaluated cognitive function in 1204 patients enrolled in the FOURIER trial and identified no important cognitive differences between patients treated with evolocumab vs placebo over a median follow-up of 19 months *(Giugliano et al 2017).*
  - A meta-analysis of 14 Phase 2 and 3 alirocumab trials found no significant differences in rates of patient-reported neurocognitive treatment-emergent AEs between alirocumab and controls (placebo or ezetimibe). No association was found between neurocognitive treatment-emergent AEs and LDL-C < 25 mg/dL *(Harvey et al 2018).*
- There are no data available on use of alirocumab or evolocumab in pregnant or lactating women to inform a drug-associated risk. Evinacumab and lomitapide may cause fetal harm, and lomitapide is contraindicated in pregnancy.

DOSING AND ADMINISTRATION

Table 4. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Evkeeza (evinacumab-dgnb)	Single-dose vial: 345 mg/2.3 mL, 1200 mg/8 mL	IV	15 mg/kg every 4 weeks	Safety and efficacy were evaluated in a single 15 year old patient, and drug concentrations were within the range of observed adult concentrations.
Juxtapid (lomitapide)	Oral capsule: 5 mg, 10 mg, 20 mg, and 30 mg	Oral	Starting dose: 5 mg once daily, the dosage may be increased to a maximum dose of 60 mg daily	Safety and efficacy have not been established in the pediatric population. Patients with end-stage renal disease or mild hepatic impairment should not exceed 40 mg daily.
Praluent (alirocumab)	Single-dose pre-filled pen: 75 mg/mL, 150 mg/mL	SC	Starting dose: 75 mg every 2 weeks or 300 mg every 4 weeks If LDL-C response is inadequate, the dosage may be adjusted to the maximum dose of 150 mg every 2 weeks HeFH patients undergoing LDL apheresis or patients with HoFH: 150 mg every 2 weeks; can be administered without regard to timing of apheresis	The safety and efficacy of alirocumab have not been established in the pediatric population.
Repatha (evolocumab)	Single-dose pre-filled syringe: 140 mg/mL Single-dose pre-filled autoinjector: 140 mg/mL Single-dose pre-filled cartridge with on-body infusor: 420 mg/3.5 mL	SC	Established ASCVD or primary hyperlipidemia: 140 mg every 2 weeks or 420 mg once monthly HoFH: 420 mg once monthly If LDL-C response is not achieved in 12 weeks, the dosage may be adjusted to 420 mg every 2 weeks HoFH patients undergoing lipid apheresis: 420 mg every 2 weeks; administer after apheresis session	The safety and efficacy of evolocumab in combination with diet and other LDL-C lowering therapies in adolescents with HoFH were established based on data from a 12-week, PC trial that included 10 adolescents (ages 13 to 17 years old) with HoFH. Safety and effectiveness have not been established in pediatric patients with HoFH who are younger than 13 years old. Safety and effectiveness have not been established in pediatric patients with primary hyperlipidemia or HeFH.

See the current prescribing information for full details

CONCLUSION

- CVD is the leading cause of death worldwide *(AHA 2021)*. Serum cholesterol is known to be related to ASCVD, with LDL-C being the dominant form of atherogenic cholesterol *(Grundy et al 2019).* FH is a genetic disorder that causes elevated LDL-C levels and premature ASCVD *(Raal et al 2018)*. Despite use of statin therapy, patients with FH are at a persistent increased risk for ASCVD.
- Alirocumab and evolocumab are fully human monoclonal antibodies that inhibit PCSK9, leading to substantial LDL-C reduction *(Navarese et al 2015*). The PCSK9 inhibitors are administered SC every 2 weeks or once monthly.
  - Alirocumab is indicated as an adjunct to diet, alone or in combination with other LLTs (eg, statins, ezetimibe) for treatment of adults with primary hyperlipidemia (including HeFH) to reduce LDL-C; to reduce the risk of MI, stroke, and UA requiring hospitalization in adults with established CVD; and as an adjunct to LLTs for the treatment of adults with HoFH.
  - Evolocumab is indicated as an adjunct to diet, alone or in combination with other LLTs (eg, statins, ezetimibe) for treatment of adults with primary hyperlipidemia (including HeFH) to reduce LDL-C; as an adjunct to diet and other LLTs (eg, statins, ezetimibe, LDL apheresis) in patients with HoFH who require additional lowering of LDL-C; and to reduce the risk of MI, stroke, and coronary revascularization in adults with established CVD.
- Evinacumab is an IV monoclonal antibody that inhibits ANGPTL-3 and is indicated as an adjunct to other LLTs in patients ≥12 years of age with HoFH. Evinacumab is dosed every 4 weeks.
- Lomitapide is an oral MTP inhibitor indicated as an adjunct to low-fat diet and other LLT to reduce LDL-C, total cholesterol, and non-HDL-C in patients with HoFH.
- The efficacy and safety of alirocumab and evolocumab have been demonstrated across numerous clinical trials in various patient populations. The PCSK9 inhibitors offer substantial LDL-C lowering, and both have been shown to reduce CV events in high-risk patients, although benefit on mortality is still unclear. The safety and efficacy of evinacumab were evaluated in a Phase 3, PC, clinical trial, and lomitapide was evaluated in a single-arm, OL trial in patients with HoFH. Lomitapide and evinacumab have only shown safety and efficacy for reducing LDL-C levels in patients with HoFH, and the effect of these drugs on CV morbidity and mortality has not been determined.
- Alirocumab, evolocumab, and evinacumab are generally well-tolerated. The most common AEs include nasopharyngitis and influenza, as well as injection site reactions for the PCSK9 inhibitors, and dizziness, rhinorrhea, and nausea for evinacumab. Lomitapide is associated with a risk for hepatotoxicity and frequent gastrointestinal adverse effects.
  - Low LDL-C levels (ie, LDL-C < 25 mg/dL) were frequently encountered with alirocumab and evolocumab in clinical trial experience; however, rates of overall AEs, serious AEs, and neurocognitive AEs among these patients were similar to those among the overall group. The long-term effects of very low LDL-C levels by alirocumab or evolocumab are still unknown.
  - Given lomitapide's risk for hepatotoxicity, distribution is restricted via a REMS program. Additionally, supplementation with vitamin E, linoleic acid, ALA, EPA, and DHA is recommended while taking lomitapide due to reduced gastrointestinal absorption of fatty acids.
- Current guidelines from the ACC/AHA *(Grundy et al 2019)*, AACE/ACE *(Handelsman et al 2020)*, and the NLA *(Jacobson et al 2015, Orringer et al 2017)* all recommend maximally-tolerated statins as first-line therapy, with ezetimibe and the PCSK9 inhibitors as potential second-line agents for patients not achieving adequate LDL-C lowering. Patients with ASCVD or at high risk for ASCVD may benefit from more aggressive LDL-C targets; however, there is no consensus on goal LDL-C levels. Lomitapide may be considered in patients with HoFH not responsive to PSCK9 inhibitors. Evinacumab has not yet been incorporated into practice guidelines, given its recent approval.

REFERENCES

- American Heart Association. 2021 heart disease and stroke statistical update fact sheet: at-a-glance. AHA Web site. 2021. https://www.heart.org/-/media/phd files 2/science news/2/2021 heart and stroke stat-update/2021_heart_disease_and_stroke_statistics_update_fact_sheet_at_a_glance.pdf?la=en. Accessed April 6, 2021.
- Bays H, Gaudet D, Weiss R, et al. Alirocumab as add-on to atorvastatin versus other lipid treatment strategies: ODYSSEY OPTIONS I randomized trial. *J Clin Endocrinol Metab*. 2015;jc20151520.
- Benhuri B, Ueyama H, Takagi H, Briasoulis A, Kuno T. PCSK9 Inhibitors and ezetimibe monotherapy in patients not receiving statins: a meta-analysis of randomized trials. *Curr Vasc Pharmacol*. 2021;19(4):390-397. doi:10.2174/1570161118666200807114559.
- Blom DJ, Hala T, Bolognese M, et al. A 52-week placebo-controlled trial of evolocumab in hyperlipidemia. *N Engl J Med.* 2014;370:1809-1819.
- Blom DJ, Harada-Shiba M, Rubba P, et al. Efficacy and safety of alirocumab in adults with homozygous familial hypercholesterolemia: the ODYSSEY HoFH trial. *J Am Coll Cardiol.* 2020;76(2):131-142. doi: 10.1016/j.jacc.2020.05.027.
- Cannon CP, Cariou B, Blom D, et al. Efficacy and safety of alirocumab in high cardiovascular risk patients with inadequately controlled hypercholesterolaemia on maximally tolerated doses of statins: the ODYSSEY COMBO II randomized controlled trial. *Eur Heart J*. 2015;36:1186-1194.

- Casula M, Olmastroni E, Boccalari MT, Tragni E, Pirillo A, Catapano AL. Cardiovascular events with PCSK9 inhibitors: an updated meta-analysis of randomized controlled trials. *Pharmacol Res*. 2019; May;143:143-150. doi: 10.1016/j.phrs.2019.03.021.
- Cuchel M, Meagher EA, du Toit Theron H, et al; Phase 3 HoFH Lomitapide Study investigators. Efficacy and safety of a microsomal triglyceride transfer protein inhibitor in patients with homozygous familial hypercholesterolemia: a single-arm, open-label, phase 3 study. *Lancet*. 2013;381(9860):40-46. doi: 10.1016/S0140-6736(12)61731-0.
- de Ferranti SD, Steinberger J, Amedura R, et al; on behalf of the American Heart Association Atherosclerosis, Hypertension and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; and Council on Quality of Care and Outcomes Research. Cardiovascular risk reduction in high-risk pediatric patients: a scientific statement from the American Heart Association. *Circulation*. 2019;139:e603-e634. doi: 10.1161/CIR.0000000000000618.
- Drugs@FDA: FDA approved drug products. Food and Drug Administration Web site. https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed April 6, 2021.
- Farnier M, Jones P, Severance R, et al. Efficacy and safety of adding alirocumab to rosuvastatin versus adding ezetimibe or doubling the rosuvastatin dose in high cardiovascular-risk patients: the ODYSSEY OPTIONS II randomized trial. *Atherosclerosis*. 2016;244:138-146.
- Gidding SS, Champagne MA, de Ferranti SD, Defesche J, Ito MK, et al; on behalf of the American Heart Association Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, and Council on Lifestyle and Cardiometabolic Health. The agenda for familial hypercholesterolemia: a scientific statement from the American Heart Association. *Circulation*. 2015;132:2167–2192.
- Ginsberg HN, Radar DJ, Raal FJ, et al. Efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia and LDL-C of 160 mg/dl or higher. *Cardiovasc Drugs Ther*. 2016;30(5):473-483.
- Giugliano RP, Mach F, Zavitz K, et al. Cognitive function in a randomized trial of evolocumab. *N Engl J Med*. 2017;377(7):633-643.
- Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis, and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipidol*. 2011;5(3 Suppl):S1-8. doi: 10.1016/j.jacl.2011.04.003.
- Grundy SM, Stone NJ, Bailey AL, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019;73(24):e285-e350. doi: 10.1016/j.jacc.2018.11.003.
- Handelsman Y, Jellinger PS, Guerin CK, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the management of dyslipidemia and prevention of cardiovascular disease algorithm – 2020 executive summary. *Endocr Pract*. 2020;26(10):1-29. doi: 10.4158/CS-2019-0472.
- Evkeeza [package insert], Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2021.
- Harvey PD, Sabbagh MN, Harrison JE, et al. No evidence of neurocognitive adverse events associated with alirocumab treatment in 3340 patients from 14 randomized phase 2 and 3 controlled trials: a meta-analysis of individual patient data. *Eur Heart J.* 2018;39:374-381.
- Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1—full report. *J Clin Lipidol*. 2015;9(2):129-169.
- Juxtapid [package insert], Dublin, Ireland: Amryt Pharmaceuticals DAC; September 2020.
- Karatasakis A, Danek BA, Karacsonyi J, et al. Effect of PCSK9 inhibitors on clinical outcomes in patients with hypercholesterolemia: a meta-analysis of 35 randomized controlled trials. *J Am Heart Assoc.* 2017;6:e006910.
- Kastelein JJ, Ginsberg HN, Langslet G, et al. ODYSSEY FH I and FH II: 78 week results with alirocumab treatment in 735 patients with heterozygous familial hypercholesterolaemia. *Eur Heart J.* 2015;36(43):2996-3003.
- Kereiakes DJ, Robinson JG, Cannon CP, et al. Efficacy and safety of the proprotein convertase subtilisin/kexin type 9 inhibitor alirocumab among high cardiovascular risk patients on maximally tolerated statin therapy: the ODYSSEY COMBO I study. *Am Heart J.* 2015;169:906-15.e13.
- Koren MJ, Giugliano RP, Raal FJ, et al. Efficacy and safety of longer-term administration of evolocumab (AMG 145) in patients with hypercholesterolemia: 52 week results from the Open-Label Study of Long-Term Evaluation Against LDL-C (OSLER) randomized trial. *Circulation*. 2014a;129:234-243.
- Koren MJ, Lundqvist P, Bolognese M, et al. Anti-PCSK9 monotherapy for hypercholesterolemia: the MENDEL-2 randomized, controlled phase III clinical trial of evolocumab. *J Am Coll Cardiol*. 2014b;63:2531-40.
- Koren MJ, Sabatine MS, Giugliano RP, et al. Final report of the OSLER-1 study: long-term evolocumab for the treatment of hypercholesterolemia. Presented at: American Heart Association Scientific Sessions 2018; November 10-12, 2018; Chicago, IL.
- Koskinas KC, Windecker S, Pedrazzini G, et al. Evolocumab for early reduction of LDL cholesterol levels in patients with acute coronary syndromes (EVOPACS). *J Am Coll Cardiol*. 2019;74(20):2452-2462. doi: 10.1016/j.jacc.2019.08.010.
- Leiter LA, Cariou B, Muller-Wieland D, et al. Efficacy and safety of alirocumab in insulin-treated individuals with type 1 or type 2 diabetes and high cardiovascular risk: the ODYSSEY DM-INSULIN randomized trial. *Diabetes Obes Metab*. 2017;19(12):1781-1792.
- McKenney JM. Understanding PCSK9 and anti-PCSK9 therapies. *J Clin Lipidol.* 2015;9:170-186.
- Moriarty PM, Parhofer KG, Babirak SP, et al. Alirocumab in patients with heterozygous familial hypercholesterolaemia undergoing lipoprotein apheresis: the ODYSSEY ESCAPE trial. *Eur Heart J*. 2016;37(48):3588-3595.
- Moriarty PM, Thompson PD, Cannon CP, et al. Efficacy and safety of alirocumab versus ezetimibe in statin-intolerant patients, with a statin rechallenge arm: the ODYSSEY ALTERNATIVE randomized trial. *J Clin Lipidol.* 2015;9(6):758-769. doi: 10.1016/j.jacl.2015.08.006.
- Navarese EP, Kolodziejczak M, Schulze V, et al. Effects of proprotein convertase subtilisin/kexin type 9 antibodies in adults with hypercholesterolemia: a systematic review and meta-analysis. *Ann Intern Med.* 2015;10.7326/M14-2957.
- Nissen SE, Stroes E, Dent-Acosta RE, et al. Efficacy and tolerability of evolocumab vs ezetimibe in patients with muscle-related statin intolerance: the GAUSS-3 randomized clinical trial. *JAMA*. 2016;315(15):1580-1590.
- Orange Book: Approved drug products with therapeutic equivalence evaluations. Food and Drug Administration Web site. https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Accessed April 6, 2021.
- Orringer CE, Jaconson TA, Saseen JJ, et al. Update on the use of PCSK9 inhibitors in adults: recommendations from an expert panel of the National Lipid Association. *J Clin Lipidol*. 2017;11(4):880-890.

- Praluent [package insert], Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2021.
- Purple Book: Database of licensed biological products. Food and Drug Administration Web site. https://purplebooksearch.fda.gov. Accessed April 6, 2021.
- Raal FJ, Honarpour N, Blom DJ, et al. Inhibition of PCSK9 with evolocumab in homozygous familial hypercholesterolaemia (TESLA Part B): a randomised, double-blind, placebo-controlled trial. *Lancet.* 2015a;385:341-350.
- Raal FJ, Hovingh GK, Catapano AL. Familial hypercholesterolemia treatments: guidelines and new therapies. *Atherosclerosis.* 2018;277:483-492. doi: 10.1016/j.atherosclerosis.2018.06.859
- Raal FJ, Rosenson RS, Reeskamp LF, et al; ELIPSE HoFH Investigators. Evinacumab for homozygous familial hypercholesterolemia. *N Engl J Med.* 2020;383(8):711-720. doi: 10.1056/NEJMoa2004215
- Raal FJ, Stein EA, Dufour R, et al. PCSK9 inhibition with evolocumab (AMG 145) in heterozygous familial hypercholesterolemia (RUTHERFORD-2): a randomised, double-blind, placebo-controlled trial. *Lancet.* 2015b;385:331-340.
- Ray KK, Leiter LA, Muller-Wieland D, et al. Alirocumab vs usual lipid-lowering care as add-on to statin therapy in individuals with type 2 diabetes and mixed dyslipidaemia: the ODYSSEY DM-DYSLIPIDEMIA randomized trial. *Diabetes Obes Metab.* 2018;20(6):1479-1489.
- Repatha [package insert], Thousand Oaks, CA: Amgen Inc.; February 2021.
- Robinson JG, Calhoun HM, Bays HE, et al. Efficacy and safety of alirocumab as add-on therapy in high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg): design and rationale of the ODYSSEY OPTIONS Studies. *Clin Cardiol*. 2014a;37:597-604.
- Robinson JG, Nedergaard BS, Rogers WJ, et al. Effect of evolocumab or ezetimibe added to moderate- or high-intensity statin therapy on LDL-C lowering in patients with hypercholesterolemia: the LAPLACE-2 randomized clinical trial. *JAMA*. 2014b;311:1870-1882.
- Robinson JG, Farnier M, Krempf M, et al, for the ODYSSEY LONG TERM investigators. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. *N Engl J Med*. 2015;372(16):1489-1499. doi: 10.1056/NEJMoa1501031.
- Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: overview. UpToDate Web site. www.uptodate.com. Updated September 21, 2020. Accessed April 6, 2021.
- Roth EM, McKenney JM. ODYSSEY MONO: effect of alirocumab 75 mg subcutaneously every 2 weeks as monotherapy versus ezetimibe over 24 weeks. *Future Cardiol*. 2015;11:27-37.
- Sabatine MS, Giugliano RP, Keech AC et al. Evolocumab and clinical outcomes in patients with cardiovascular disease. *N Engl J Med*. 2017;376(18):1713-1722.
- Sabatine MS, Giugliano RP, Wiviott SD, et al. Efficacy and safety of evolocumab in reducing lipids and cardiovascular events. *N Engl J Med.* 2015;372:1500-1509.
- Santos RD, Ruzza A, Hovingh GK, et al, for the HAUSER-RCT investigators. Evolocumab in pediatric heterozygous familial hypercholesterolemia. *N Engl J Med*. 2020a;383(14):1317-1327. doi: 10.1056/NEJMoa2019910.
- Santos RD, Stein EA, Hovingh GK, et al. Long-term evolocumab in patients with familial hypercholesterolemia. *J Am Coll Cardiol*. 2020b;75(6):565-574. doi: 10.1016/j.jacc.2019.12.020.
- Schmidt AF, Carter JPL, Pearce LS, et al. PCSK9 monoclonal antibodies for the primary and secondary prevention of cardiovascular disease. *Cochrane Database Syst Rev*. 2020;10:CD011748. doi: 10.1002/14651858.CD011748.pub.
- Schwartz GG, Steg PG, Szarek M, ODYSSEY OUTCOMES Committees and Investigators, et al. Alirocumab and cardiovascular outcomes after acute coronary syndrome. *N Engl J Med.* 2018;379(22):2097-2107. doi: 10.1056/NEJMoa1801174.
- Steg PG, Szarek M, Bhatt DL, et al. Effect of alirocumab on mortality after acute coronary syndromes. *Circulation*. 2019;140(2):103-112.
- Stroes E, Colquhoun D, Sullivan D, et al. Anti-PCSK9 antibody effectively lowers cholesterol in patients with statin intolerance: the GAUSS-2 randomized, placebo-controlled phase 3 clinical trial of evolocumab. *J Am Coll Cardiol*. 2014;63:2541-2548.
- Wouter Jukema J, Zijlstra LE, Bhatt DL, et al. Effect of alirocumab on stroke in ODYSSEY OUTCOMES. *Circulation*. 2019;140(25):2054-2062. doi: 10.1161/CIRCULATIONAHA.119.043826.

Publication Date: April 30, 2021