South Dakota
Department of Social Services

Medicaid P&T Committee Meeting

March 21, 2025

South Dakota Department of Social Services

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DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
700 GOVERNORS DRIVE
PIERRE, SD 57501-2291
PHONE: 605-773-3495
FAX: 605-773-5246
WEB: dss.sd.gov

South Dakota Department of Social Services

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA
https://prdgov-rxadmin.optum.com/rxadmin/SDM/welcome.html

March 21, 2025
1:00 – 3:00 PM CT
12:00 – 2:00 PM MT

Meeting Link:
https://teams.microsoft.com/l/meetup-join/19%3ameeting_N2U0YmYxZTgtNmJlYS00NjQxLWJjZmItYjBkMDAwN2VjZjUw%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 with a video conferencing device
teams@optum.onpexip.com
Video Conference ID: 113 268 347 84

Join by phone
+1 952-222-7450
Phone Conference ID: 781 974 697#

Call to order

Approval of previous meeting minutes, December 14, 2024 meeting postponed to March 21, 2025

PA update
Review of top 15 therapeutic categories/top 50 drugs
Old business
- **Opioid update**
- **Review PA forms & criteria**

New business
- **Daybue**
- **Dupixent**
- **Fintepla**
- **Voquezna**

Public input accepted after individual topic discussion
Next meeting date June 2025 (date to be determined) & adjournment

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

Friday, September 20, 2024
1:00 – 3:00 pm CT

Members and DSS Staff

Michelle Baack, MD	-	Matthew Stanley, DO	X
Bill Ladwig, RPh	X	Brandi Tackett, PharmD	X
Mark List, MD	X	Deidra Van Gilder, PharmD, Chair	X
Kelley Oehlke, PharmD	X	Clarissa Barnes, MD, DSS Staff	X
Lenny Petrik, PharmD	X	Mike Jockheck, DSS Staff	X
Heather Preuss, MD	X	Taylor Koerner, DSS Staff	X

Administrative Business

Van Gilder called the meeting to order at 1:02 pm. Jockheck introduced new committee member Mark List, family physician at Avera in Sioux Falls. The minutes of the June meeting were presented. Ladwig made a motion to approve. Stanley seconded the motion. The motion to approve the minutes was approved unanimously.

Prior Authorization Update (PA) and Statistics

The committee reviewed the PA activity report from April 1, 2024, to June 30, 2024. A total of 3,408 PAs were reviewed of which 126 requests (3.7%) were received via telephone, 102 requests (3%) were received via fax, 1,389 (40.7%) were reviewed electronically, and 1,789 requests (52.5%) were received via ePA. There was a 2.5% decrease in PAs received compared to the previous quarter. There was a 38% decrease in number of appeals.

Analysis of the Top 15 Therapeutic Classes and Drug Spend

The committee reviewed the top 15 therapeutic classes by total cost of claims from April 1, 2024, to June 30, 2024. The top five therapeutic classes based on paid amount were atypical antipsychotics, disease-modifying anti-rheumatic agents, skin and mucous membrane agents, incretin mimetics, and antineoplastic agents. These top 15 therapeutic classes comprise 22.02% 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 constitute 8.32% of total claims.

Old Business

CGM review

Committee reviewed CGM utilization and compliance data. Van Gilder commented on the data showing some members had increased utilization of test strips with concurrent use of CGMs. Committee discussed implementing tighter glucose test strip limits for patients concurrently receiving CGMs. Mariham Fahim, Medical Outcomes Liaison from Abbott Diabetes Care, provided public comment. Ladwig stressed the importance of CGM data and asked about using a student to analyze A1C/outcomes data. Jockheck is open to working with Ladwig's or Van Gilder's students to review A1C and outcomes. Van Gilder asked to consider adding quantity limit for members using CGM. Ladwig discussed the appropriate number of strips for members using CGM. Van Gilder stated testing once per day is appropriate. Preuss made a motion to limit blood glucose test strips to #50 strips per month when using a CGM. Stanley second the

motion. The motion was approved unanimously. Jockheck asked for public comment on CGM compliance. Kimbra Brooks, Senior Regional Account Manager with Abbott Diabetes Care, provided input.

Veozah review
Veozah utilization and adherence data were presented for review. Committee will continue to monitor Veozah. Jeenal Choksi, Associate Director from Medical Value and Access at Astellas, provided public comment.

Zurvuvae review
Zurzuvae utilization and PA data were presented for review. Daphne Ni, Medical Liaison with Biogen, provided public comment. Stanley requested to monitor Zuzuvae and repoll other state policies. Ladwig asked to continue monitoring. Lisa Gronneberg, Regional Account Director from Biogen, provided information from other states. Anne Carroll-Palmer, National Account Director with Sage, provided public comment. Crystal McAuley from the Policy Center from Maternal Mental Health provided public comment. The committee took no action.

Opioid Update
The committee reviewed 2Q2024 opioid outcomes compared to the previous quarter from the opioid initiatives. There was an increase in opioid utilization and utilizers during 2Q2024 with corresponding increase in total eligibility and utilizers. The committee also reviewed the average MME/day/utilizer graph.

New Business

GLP-1 review
Glucagon-like peptide-1 receptor (GLP-1) agonist multi-part review was presented to the committee. Committee was asked to consider step therapy on preferred drugs before non-preferred drug. Ladwig made a motion for a trial of one preferred drug for three months before allowing non-preferred product. Stanley seconded the motion. Van Gilder inquired if there was any public comment. There were none. The motion was approved unanimously.

Next the Committee reviewed the indication for major adverse cardiovascular event (MACE). Barnes provided insight on starting to expand access to these mediations starting with MACE. Shawn Hansen, Medical Account Director with Novo Nordisk, provided public comment. The committee discussed PA criteria. Tackett expressed concern with the suggested age range. Stanley made a motion to implement criteria A with coverage expanded to 18 years and older with the caveat to revisit the criteria again. Preuss seconded the motion. Motion passed unanimously.

ADHD review
This agenda item has been tabled until the next meeting.

Daybue
This agenda item has been tabled until the next meeting.

Adjournment
The next meeting is scheduled on December 13, 2024. The March meeting is scheduled for March 21, 2025. Preuss motioned to adjourn the meeting and Oehlke seconded the motion. The motion to adjourn the meeting was unanimous and the meeting adjourned at 3:03 pm CT.

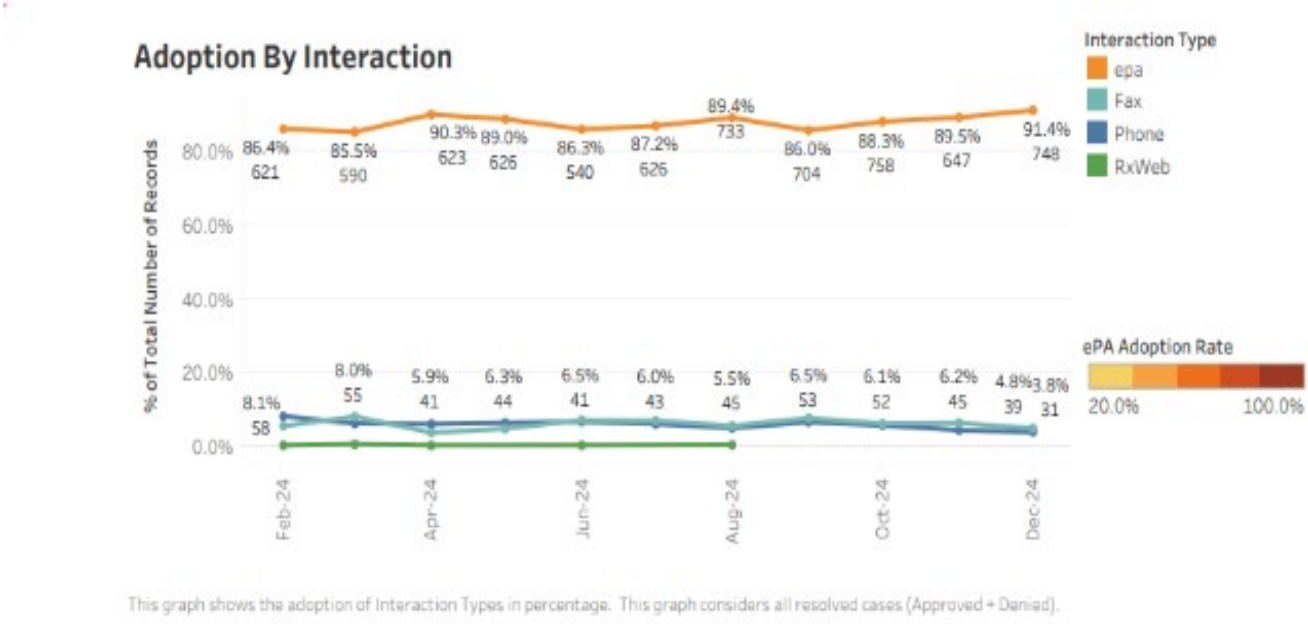
PA Report
10/1/2024 – 12/31/2024

Compliance Summary

Priority	Total PAs	PAs Compliant	PAs Not Compliant	% PAs Compliant	% PAs Not Compliant
Standard	3,441	3,441	0	100.00%	0.00%
Urgent	396	396	0	100.00%	0.00%
Grand Total	**3,837**	**3,837**	**0**		

Priority	Standard	Urgent
ePA	1,783	372
Fax	130	6
Phone	94	18
Real-Time	1,434	0

Request Summary	Total # of Requests	Phone Requests		Fax Requests		Real-Time PA		ePA PA	
		#	%	#	%	#	%	#	%
Total	**3,837**	**112**	**2.9%**	**136**	**3.5%**	**1,434**	**37.4%**	**2,155**	**56.2%**



PA Initial Requests Summary

Month	Approved	Denied	Total
Oct-24	1,140	220	1,360
Nov-24	957	190	1,147
Dec-24	1,141	189	1,330
4Q24	**3,238**	**599**	**3,837**
Percent of Total	**84.39%**	**15.61%**	

Top Therapeutic Classes for PA

Drug Class	Approved	Denied	Total	Approval Rate	% of Total Requests	Most Requested Products
ANTIDIABETICS	579	46	625	92.64%	16.29%	, OZEMPIC
ANTIPSYCHOTICS/ANTIMANIC	555	38	593	93.59%	15.45%	, VRAYLAR
MEDICAL DEVICES & SUPPLIES	353	99	452	78.10%	11.78%	, DEXCOM G7 SENSOR
ANALGESICS - OPIOID	322	44	366	87.98%	9.54%	HYDROCODONE/APAP
DERMATOLOGICALS	267	54	321	83.18%	8.37%	DUPIXENT, MALATHION
OTHERS -	1,162	318	1,480	78.51%	38.57%	
4Q24	**3,238**	**599**	**3,837**	**84.39%**		

PA Appeals Summary

Month	Approved	Approved %	Denied	Denied %	Total
Oct-24	16	72.73%	6	24.27%	22
Nov-24	15	65.22%	8	34.78%	22
Dec-24	25	71.43%	10	28.57%	35
4Q24	**56**	**70%**	**24**	**30%**	**80**

PA Drug Class Summary

Drug Class	Approved	Denied	Total	Approval Rate
27 - ANTIDIABETICS*	579	46	625	92.64%
59 - ANTIPSYCHOTICS/ANTIMANIC AGENTS*	555	38	593	93.59%
97 - MEDICAL DEVICES AND SUPPLIES*	353	99	452	78.10%
65 - ANALGESICS - OPIOID*	322	44	366	87.98%
90 - DERMATOLOGICALS*	267	54	321	83.18%
58 - ANTIDEPRESSANTS*	183	48	231	79.22%
67 - MIGRAINE PRODUCTS*	164	32	196	83.67%
52 - GASTROINTESTINAL AGENTS - MISC.*	136	17	153	88.89%
61 - ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	83	44	127	65.35%
49 - ULCER DRUGS/ANTISPASMODICS/ANTICHOLINERG	107	7	114	93.86%
66 - ANALGESICS - ANTI-INFLAMMATORY*	74	14	88	84.09%
54 - URINARY ANTISPASMODICS*	69	16	85	81.18%
41 - ANTIHISTAMINES*	41	10	51	80.39%
16 - ANTI-INFECTIVE AGENTS - MISC.*	43	5	48	89.58%
12 - ANTIVIRALS*	37	10	47	78.72%
72 - ANTICONVULSANTS*	33	9	42	78.57%
44 - ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	24	10	34	70.59%
62 - PSYCHOTHERAPEUTIC AND NEUROLOGICAL AGENT	27	4	31	87.10%
21 - ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	25	3	28	89.29%
94 - DIAGNOSTIC PRODUCTS*	6	18	24	25.00%
60 - HYPNOTICS/SEDATIVES/SLEEP DISORDER AGENT	6	15	21	28.57%
39 - ANTIHYPERLIPIDEMICS*	11	5	16	68.75%
50 - ANTIEMETICS*	11	5	16	68.75%
28 - THYROID AGENTS*	14	1	15	93.33%
33 - BETA BLOCKERS*	6	9	15	40.00%
30 - ENDOCRINE AND METABOLIC AGENTS - MISC.*	9	5	14	64.29%
75 - MUSCULOSKELETAL THERAPY AGENTS*	8	4	12	66.67%
34 - CALCIUM CHANNEL BLOCKERS*	5	6	11	45.45%
83 - ANTICOAGULANTS*	6	1	7	85.71%
82 - HEMATOPOIETIC AGENTS*	6	0	6	100.00%
03 - MACROLIDES*	4	1	5	80.00%
40 - CARDIOVASCULAR AGENTS - MISC.*	4	1	5	80.00%
99 - MISCELLANEOUS THERAPEUTIC CLASSES*	5	0	5	100.00%
36 - ANTIHYPERTENSIVES*	2	2	4	50.00%
42 - NASAL AGENTS - SYSTEMIC AND TOPICAL*	0	4	4	0.00%
45 - RESPIRATORY AGENTS - MISC.*	3	1	4	75.00%
22 - CORTICOSTEROIDS*	1	2	3	33.33%
51 - DIGESTIVE AIDS*	2	1	3	66.67%
74 - NEUROMUSCULAR AGENTS*	2	1	3	66.67%
79 - MINERALS & ELECTROLYTES*	2	1	3	66.67%
57 - ANTIANXIETY AGENTS*	0	2	2	0.00%
86 - OPHTHALMIC AGENTS*	0	2	2	0.00%
15 - ANTHELMINTICS*	0	1	1	0.00%
19 - PASSIVE IMMUNIZING AND TREATMENT AGENTS*	1	0	1	100.00%
56 - GENITOURINARY AGENTS - MISCELLANEOUS*	1	0	1	100.00%
76 - ANTIMYASTHENIC/CHOLINERGIC AGENTS*	0	1	1	0.00%
78 - MULTIVITAMINS*	1	0	1	100.00%
4Q24	**3,238**	**599**	**3,837**	
Percent of Total	**84.39%**	**15.61%**		

Appeals Detail

Drug Class	Approved	Denied	Total	Approval Rate
VRAYLAR	8	1	9	88.89%
LINZESS	4	3	7	57.14%
AJOVY	5	0	5	100.00%
EMGALITY	3	1	4	75.00%
QELBREE	1	3	4	25.00%
AIMOVIG	3	0	3	100.00%
DEXCOM G7 SENSOR	1	2	3	33.33%
MAVYRET	2	1	3	66.67%
REPATHA SURECLICK	1	2	3	33.33%
RINVOQ	3	0	3	100.00%
AMPHETAMINE/DEXTROAMPHETAMINE	2	0	2	100.00%
DAPSONE	2	0	2	100.00%
FREESTYLE LIBRE 3 PLUS/SENSOR/CGM	1	1	2	50.00%
FREESTYLE LIBRE 3/SENSOR/CGM	2	0	2	100.00%
LUBIPROSTONE	2	0	2	100.00%
LYBALVI	0	2	2	0.00%
ONETOUCH VERIO TEST STRIPS	1	1	2	50.00%
SPINOSAD	2	0	2	100.00%
ABILIFY ASIMTUFII	1	0	1	100.00%
AMBIEN CR	1	0	1	100.00%
AZELASTINE HCL/FLUTICASONE PROPIONATE	1	0	1	100.00%
BELSOMRA	0	1	1	0.00%
CIMZIA STARTER KIT	1	0	1	100.00%
COSENTYX UNOREADY	0	1	1	0.00%
DUPIXENT	1	0	1	100.00%
ESCITALOPRAM OXALATE	0	1	1	0.00%
EVRYSDI	0	1	1	0.00%
GEMTESA	0	1	1	0.00%
GLIMEPIRIDE	1	0	1	100.00%
KISQALI	1	0	1	100.00%
LAMICTAL	1	0	1	100.00%
NUCALA	1	0	1	100.00%
OTEZLA	0	1	1	0.00%
PALIPERIDONE ER	0	1	1	0.00%
QUVIVIQ	1	0	1	100.00%
STELARA	1	0	1	100.00%
VENCLEXTA	1	0	1	100.00%
XOLAIR	1	0	1	100.00%
4Q24	**56**	**24**	**80**	

Top 15 Therapeutic Classes & Top 50 Drugs

TOP 15 THERAPEUTIC CLASSES BASED ON NUMBER OF CLAIMS FROM 10/1/2024 – 12/31/2024					
	AHFS Description	**Total Rxs**	**Plan Paid Amount**	**Paid/Rx**	**% Total Claims**
1	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	18,784	$240,063.60	$12.78	5.98%
2	ATYPICAL ANTIPSYCHOTICS	12,734	$4,532,626.75	$355.95	4.05%
3	SELECTIVE BETA-2-ADRENERGIC AGONISTS	10,589	$528,063.38	$49.87	3.37%
4	RESPIRATORY AND CNS STIMULANTS	10,348	$1,130,617.39	$109.26	3.29%
5	PROTON-PUMP INHIBITORS	9,678	$234,790.57	$24.26	3.08%
6	ADRENALS	9,581	$1,074,164.23	$112.11	3.05%
7	AMINOPENICILLIN ANTIBIOTICS	9,314	$139,279.18	$14.95	2.96%
8	AMPHETAMINES	9,204	$1,083,504.45	$117.72	2.93%
9	SECOND GENERATION ANTIHISTAMINES	8,820	$97,747.61	$11.08	2.81%
10	GABA-MEDIATED ANTICONVULSANTS	8,408	$258,726.94	$30.77	2.68%
11	OPIOID AGONISTS (28:08)	8,002	$233,904.27	$29.23	2.55%
12	ANTICONVULSANTS, MISCELLANEOUS	7,381	$861,242.52	$116.68	2.35%
13	SEROTONIN MODULATORS	7,357	$196,057.02	$26.65	2.34%
14	HMG-COA REDUCTASE INHIBITORS	6,716	$80,713.36	$12.02	2.14%
15	SEL.SEROTONIN,NOREPI REUPTAKE INHIBITOR	6,087	$114,303.86	$18.78	1.94%
Total		**143,003**	**$10,805,805.13**	**$75.56**	**45.52%**

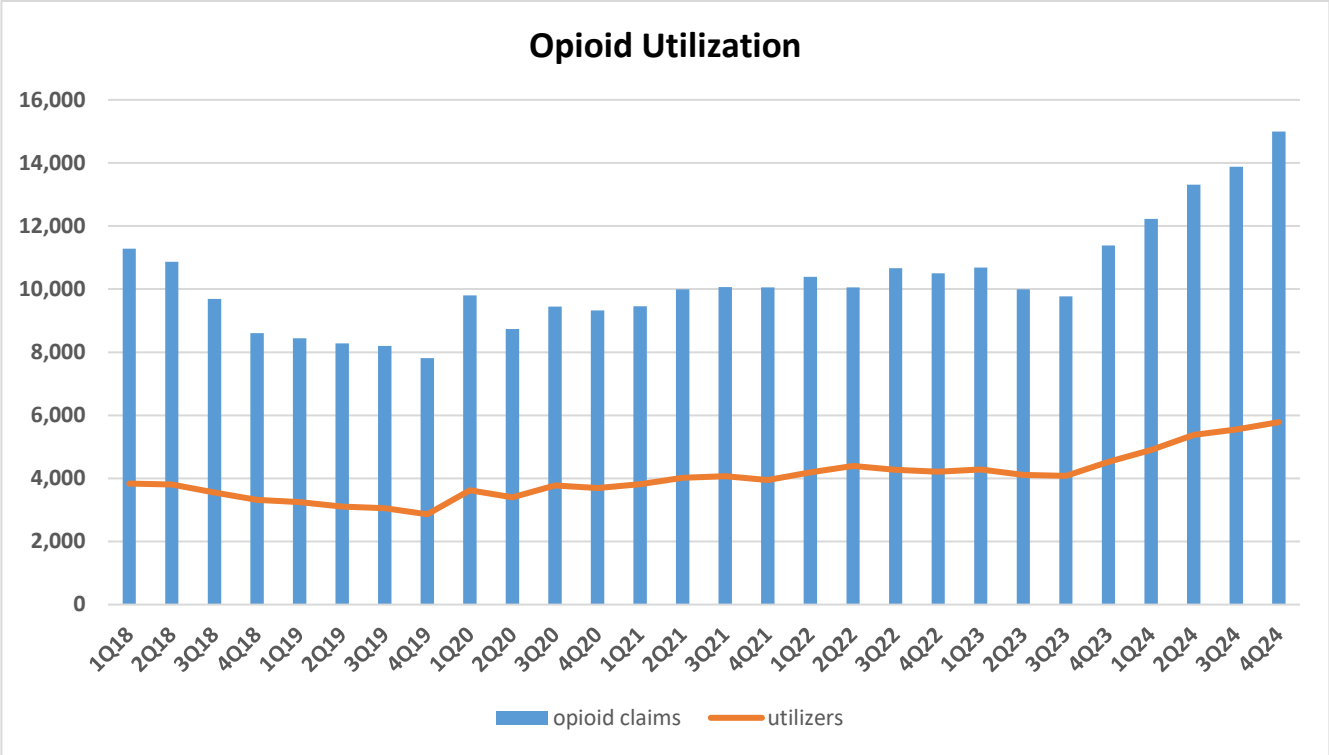
TOP 15 THERAPEUTIC CLASSES BASED ON AMOUNT PAID FROM 10/1/2024 – 12/31/2024					
	AHFS Description	**Total Rxs**	**Plan Paid Amount**	**Paid/Rx**	**% Total Claims**
1	ATYPICAL ANTIPSYCHOTICS	12,734	$4,532,626.75	$355.95	4.05%
2	INCRETIN MIMETICS	3,203	$3,086,105.89	$963.50	1.02%
3	INTERLEUKIN-MEDIATED AGENTS, MISC	233	$2,796,046.11	$12,000.20	0.07%
4	TUMOR NECROSIS FACTOR INHIBITORS, MISC	309	$2,491,698.88	$8,063.75	0.10%
5	ANTINEOPLASTIC AGENTS	440	$2,394,025.29	$5,440.97	0.14%
6	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	501	$1,902,037.50	$3,796.48	0.16%
7	CYSTIC FIBROSIS (CFTR) CORRECTORS	72	$1,746,740.24	$24,260.28	0.02%
8	HEMOSTATICS	62	$1,287,200.50	$20,761.30	0.02%
9	RESPIRATORY AND CNS STIMULANTS	10,348	$1,130,617.39	$109.26	3.29%
10	AMPHETAMINES	9,204	$1,083,504.45	$117.72	2.93%
11	ADRENALS	9,581	$1,074,164.23	$112.11	3.05%
12	HIV INTEGRASE INHIBITOR ANTIRETROVIRALS	287	$1,051,249.34	$3,662.89	0.09%
13	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	3,256	$1,007,751.52	$309.51	1.04%
14	SODIUM-GLUC COTRANSPORT 2 (SGLT2) INHIB	1,810	$985,659.22	$544.56	0.58%
15	IMMUNOMODULATORY AGENTS (84:06)	259	$872,262.79	$3,367.81	0.08%
Total		**52,299**	**$27,441,690.10**	**$524.71**	**16.65%**

Total Rx Claims from 10/1/2024 – 12/31/2024	**314,132**

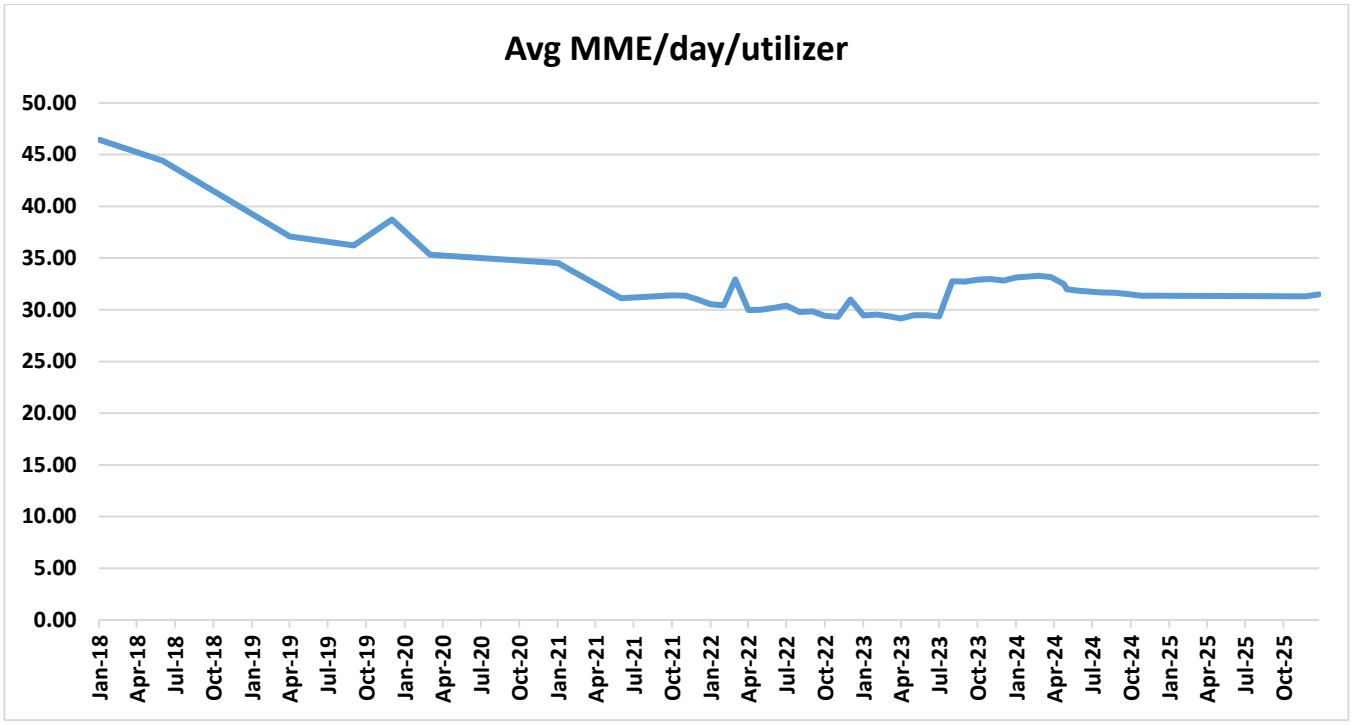
TOP 50 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/1/2024 – 12/31/2024						
	Therapeutic Class Name	**Drug Label Name**	**Total Rxs**	**Plan Paid Amount**	**Paid/Rx**	**% Total Claims**
1	Penicillins	AMOXICILLIN	6,654	$89,382.42	$13.43	2.12%
2	Antidepressants	FLUOXETINE	6,476	$78,196.86	$12.07	2.06%
3	Inhaled Bronchodilator	ALBUTEROL SULFATE HFA	6,153	$203,298.32	$33.04	1.96%
4	Antidepressants	**SERTRALINE**	**5,825**	**$73,326.05**	**$12.59**	**1.85%**
5	Proton Pump Inhibitors	**OMEPRAZOLE**	**5,733**	**$65,111.57**	**$11.36**	**1.83%**
6	Anticonvulsants - 2nd Generation	GABAPENTIN	5,678	$86,619.06	$15.26	1.81%
7	ADHD & Narcolepsy Medications	METHYLPHENIDATE	5,624	$308,476.18	$54.85	1.79%
8	Antidepressants	TRAZODONE	5,036	$56,427.26	$11.20	1.60%
9	ADHD & Narcolepsy Medications	AMPHETAMINE/DEXTROAMP	4,696	$141,251.79	$30.08	1.49%
10	Antihistamines	**CETIRIZINE**	**4,602**	**$48,496.40**	**$10.54**	**1.46%**
11	Antidepressants	ESCITALOPRAM	4,585	$56,570.68	$12.34	1.46%
12	Thyroid Hormones	LEVOTHYROXINE	4,579	$52,079.46	$11.37	1.46%
13	Antidepressants	**BUPROPION**	**4,158**	**$75,675.87**	**$18.20**	**1.32%**
14	Statins & Combos	ATORVASTATIN	3,937	$46,563.46	$11.83	1.25%
15	Biguanides & Combos	METFORMIN	**3,934**	**$47,727.63**	**$12.13**	**1.25%**
16↑	Macrolides	AZITHROMYCIN	3,797	$55,419.68	$14.60	1.21%
17	ACE Inhibitors & Combos	LISINOPRIL	3,667	$36,401.86	$9.93	1.17%
18	Antidepressants	**DULOXETINE**	**3,235**	**$48,842.87**	**$15.10**	**1.03%**
19	Leukotriene Modulators	MONTELUKAST SODIUM	3,232	$40,863.42	$12.64	1.03%
20	ADHD & Narcolepsy Medications	GUANFACINE	3,150	$49,323.13	$15.66	1.00%
21	Antiadrenergic Antihypertensives	CLONIDINE	2,999	$27,558.78	$9.19	0.95%
22	ADHD & Narcolepsy Medications	LISDEXAMFETAMINE	2,989	$462,103.62	$154.60	0.95%
23	Glucocorticosteroids	PREDNISONE	2,956	$28,428.89	$9.62	0.94%
24	Opioid Agonists & Combos	HYDROCODONE BITE/AC	2,926	$50,777.89	$17.35	0.93%
25	Atypical Antipsychotics	ARIPIPRAZOLE	2,721	$37,970.99	$13.95	0.87%
26	Antiemetics	ONDANSETRON ODT	2,706	$37,310.57	$13.79	0.86%
27	Penicillins	AMOXICILLIN/CLAVULANATE	2,656	$49,837.80	$18.76	0.85%
28	Antianxiety Agents	**BUSPIRONE**	**2,654**	**$33,175.39**	**$12.50**	**0.84%**
29	Antianxiety Agents	HYDROXYZINE	2,617	$32,509.73	$12.42	0.83%
30	Angiotensin II Receptor Antagonists & Combo	LOSARTAN	2,559	$29,398.00	$11.49	0.81%
31	Anticonvulsants - 2nd Generation	LAMOTRIGINE	2,435	$32,580.97	$13.38	0.78%
32	Calcium Channel Blockers	AMLODIPINE	2,429	$23,820.60	$9.81	0.77%
33	Atypical Antipsychotics	QUETIAPINE	2,414	$31,763.12	$13.16	0.77%
34	Muscle Relaxants & Combos	CYCLOBENZAPRINE	2,262	$23,702.44	$10.48	0.72%
35↑	Inhaled Bronchodilator	ALBUTEROL	2,185	$43,367.01	$19.85	0.70%
36	Proton Pump Inhibitors	PANTOPRAZOLE	2,168	$27,054.08	$12.48	0.69%
37	Antihistamines	**ALLERGY RELIEF**	**2,108**	**$22,070.28**	**$10.47**	**0.67%**
38↑	Cephalosporins	CEPHALEXIN	2,093	$31,302.74	$14.96	0.67%
39	Beta Blockers & Combos	METOPROLOL ER	2,065	$25,940.79	$12.56	0.66%
40	Atypical Antipsychotics	RISPERIDONE	2,058	$26,877.98	$13.06	0.66%
41	Antidepressants	**VENLAFAXINE**	**2,057**	**$30,121.39**	**$14.64**	**0.65%**
42	Statins & Combos	ROSUVASTATIN C	2,049	$25,041.27	$12.22	0.65%
43	Anticonvulsants - 2nd Generation	TOPIRAMATE	2,005	$24,959.33	$12.45	0.64%
44	Anticonvulsants - 2nd Generation	CLONAZEPAM	1,954	$22,472.08	$11.50	0.62%
45	Nonsteroidal Anti-Inflammatory Agents	MELOXICAM	1,925	$16,551.62	$8.60	0.61%
46	Nasal Steroids	FLUTICASONE PROPIONATE	1,859	$31,491.63	$16.94	0.59%
47	Antidepressants	MIRTAZAPINE	1,766	$23,383.90	$13.24	0.56%
48	Opioid Agonists & Combos	**OXYCODONE**	**1,720**	**$25,314.20**	**$14.72**	**0.55%**
49↑	Cephalosporins	CEFDINIR	1,715	$33,354.69	$19.45	0.55%
50	Anticonvulsants - 2nd Generation	LEVETIRACETAM	1,684	$32,294.97	$19.18	0.54%
	Total Top 50 Drugs		**163,485**	**$3,002,590.72**	**$18.37**	**52.04%**

TOP 50 DRUGS BASED ON AMOUNT PAID FROM 10/1/2024 – 12/31/2024						
	Therapeutic Class Name	**Drug Label Name**	**Total Rxs**	**Plan Paid Amount**	**Paid/Rx**	**% Total Claims**
1	Chronic Inflammatory Disease	DUPIXENT	548	$2,118,659.57	$3,866.17	0.17%
2	Chronic Inflammatory Disease	**HUMIRA**	**205**	**$1,765,743.42**	**$8,613.38**	**0.07%**
3	Cystic Fibrosis	TRIKAFTA	72	$1,746,740.24	$24,260.28	0.02%
4	Atypical Antipsychotics	**INVEGA SUSTENNA/TRINZA/HAFYERA**	**438**	**$1,465,279.64**	**$3,345.39**	**0.14%**
5	GLP-1 Receptor Agonists	MOUNJARO	1,383	$1,412,971.02	$1,021.67	0.44%
6	GLP-1 Receptor Agonists	OZEMPIC	1,479	$1,371,226.44	$927.13	0.47%
7	Chronic Inflammatory Disease	STELARA	50	$1,280,705.03	$25,614.10	0.02%
8	Atypical Antipsychotics	VRAYLAR	779	$1,027,554.84	$1,319.07	0.25%
9	Chronic Inflammatory Disease	**COSENTYX/SENSOREADY/UNOREADY**	**101**	**$921,348.71**	**$9,122.26**	**0.03%**
10	Rett Syndrome Agent	DAYBUE	13	$811,331.67	$62,410.13	0.00%
11	Chronic Inflammatory Disease	**SKYRIZI/PEN**	**38**	**$770,096.35**	**$20,265.69**	**0.01%**
12	HIV-Multiclass Combo	BIKTARVY	187	$724,751.97	$3,875.68	0.06%
13	SGLT-2 Inhibitors & Combos	JARDIANCE	1,156	$664,445.26	$574.78	0.37%
14	Chronic Inflammatory Disease	TALTZ	73	$553,984.83	$7,588.83	0.02%
15	Atypical Antipsychotics	**ARISTADA/INITIO**	**189**	**$541,698.58**	**$2,866.13**	**0.06%**
16	Chronic Inflammatory Disease	**ENBREL/SURECLICK/MINI**	**70**	**$516,450.97**	**$7,377.87**	**0.02%**
17	Diabetes Monitoring and Testing	**DEXCOM**	**1,356**	**$473,625.03**	**$349.28**	**0.43%**
18	Antihemophilic Products	HEMLIBRA	15	$463,625.13	$30,908.34	0.00%
19	ADHD & Narcolepsy Medications	LISDEXAMFETAMINE DIMESYLA	2,989	$462,103.62	$154.60	0.95%
20	Anticonvulsants - 2nd Generation	EPIDIOLEX	164	$437,485.32	$2,667.59	0.05%
21	ADHD & Narcolepsy Medications	VYVANSE	1,237	$436,243.47	$352.66	0.39%
22	Oral Anticoagulants	**ELIQUIS/STARTER PACK**	**783**	**$427,916.17**	**$546.51**	**0.25%**
23↑	Oncology	KISQALI	30	$427,689.63	$14,256.32	0.01%
24	Atypical Antipsychotics	**ABILIFY MAINTENA/ASIMTUFII**	**132**	**$394,616.47**	**$2,989.52**	**0.04%**
25	Atypical Antipsychotics	REXULTI	261	$347,208.07	$1,330.30	0.08%
26	Chronic Inflammatory Disease	RINVOQ	53	$341,799.76	$6,449.05	0.02%
27	Inhaled Asthma/COPD Combo	TRELEGY ELLIPTA	526	$331,740.70	$630.69	0.17%
28	Atypical Antipsychotics	CAPLYTA	213	$324,940.62	$1,525.54	0.07%
29	ADHD & Narcolepsy Medications	METHYLPHENIDATE HYDROCHLO	5,624	$308,476.18	$54.85	1.79%
30	Growth Hormones	NORDITROPIN FLEXPRO	71	$297,294.97	$4,187.25	0.02%
31	Movement Disorder Drug Therapy	INGREZZA	40	$278,179.46	$6,954.49	0.01%
32	Hepatitis C	SOFOSBUVIR/VELPATASVIR	33	$264,348.15	$8,010.55	0.01%
33	Oncology	KOSELUGO	16	$261,974.96	$16,373.44	0.01%
34	PIK3CA-Related Overgrowth	VIJOICE	8	$260,084.40	$32,510.55	0.00%
35	Irritable Bowel Syndrome (IBS) Agts	LINZESS	487	$253,542.04	$520.62	0.16%
36↑	Migraine Products	NURTEC	221	$246,945.69	$1,117.40	0.07%
37	Antihemophilic Products	NOVOSEVEN RT	3	$241,231.65	$80,410.55	0.00%
38	Glucagon-Like Peptide-2 (GLP-2)	GATTEX	5	$227,687.15	$45,537.43	0.00%
39↑	Cystic Fibrosis	PULMOZYME	46	$226,491.22	$4,923.72	0.01%
40	Anti-Infective Agents - Misc.	XIFAXAN	77	$224,276.30	$2,912.68	0.02%
41	Oncology	REVLIMID	14	$212,336.76	$15,166.91	0.00%
42	Inhaled Bronchodilator	ALBUTEROL SULFATE HFA	6,153	$203,298.32	$33.04	1.96%
43	Pulmonary Arterial Hypertension	OPSUMIT	16	$201,728.76	$12,608.05	0.01%
44	Chronic Inflammatory Disease	OTEZLA	45	$197,713.09	$4,393.62	0.01%
45↑	Antihemophilic Products	XYNTHA SOLOFUSE	4	$193,253.40	$48,313.35	0.00%
46↑	Oncology	IBRANCE	12	$191,915.28	$15,992.94	0.00%
47	Chronic Inflammatory Disease	TREMFYA	14	$187,233.42	$13,373.82	0.00%
48↑	ADHD & Narcolepsy Medications	AZSTARYS	473	$181,287.23	$383.27	0.15%
49↓	Spinal Muscular Atrophy (SMA) Agt	EVRYSDI	7	$181,282.57	$25,897.51	0.00%
50↑	ADHD & Narcolepsy Medications	JORNAY PM	410	$175,064.36	$426.99	0.13%
	Total Top 50 Drugs		**28,319**	**$27,577,627.89**	**$973.82**	**9.02%**

Opioid Summary



- 1Q18 to 4Q19 excludes IHS
- 1Q20 to current includes IHS
- March 13, 2020 – Pandemic Closure



Opioid Initiatives:

1. June 1, 2018 – early refill threshold for controlled substance changed from 75% to 85%
2. July 1, 2028 – PA for more than one LAO and one SAO
3. August 1, 2018 – opioid Naïve PA (initial 7-day supply and 60 MED limit)
4. October 1, 2018 to October 1, 2019 – decrease from 300 MED to 90 MED (cancer diagnosis excluded)

Other Initiatives:

- Buprenorphine PA (Bunavail/Suboxone/Zubsolv/Subutex) and ST (Belbuca/Butrans) removed 10/14/2019
- Lidoderm PA removed 8/1/2020

Total Eligibles and Utilizers

Quarter	Avg eligible members	Avg utilizing members of all drugs	% utilizing members of all drugs
1Q2020	123,573	27,090	21.9%
2Q2020	126,777	20,746	16.4%
3Q2020	132,373	23,417	17.7%
4Q2020	136,262	23,489	17.2%
1Q2021	139,748	24,407	17.5%
2Q2021	142,872	26,206	18.3%
3Q2021	146,023	27,933	19.1%
4Q2021	149,034	29,317	19.7%
1Q2022	151,735	29,092	19.2%
2Q2022	154,608	28,370	18.3%
3Q2022	157,627	29,167	18.5%
4Q2022	160,060	32,124	20.1%
1Q2023	162,684	31,612	19.4%
2Q2023	142,001	27,296	19.2%
3Q2023	131,292	26,218	19.9%
4Q2023	134,270	29,320	21.8%
1Q2024	141,162	32,891	23.3%
2Q2024	149,613	32,686	21.8%
3Q2024	159,160	35,263	22.2%
4Q2024	162,163	36,468	22.5%

SDM 4Q2024
Sep 24 to Dec 24

Opioid Utilization Snapshot

3Q2024
Jun 24 to Sep 24

Opioid Claims **14,999**

3.1% prescription claims filled for an opioid

1.3% higher than Medicaid FFS benchmark

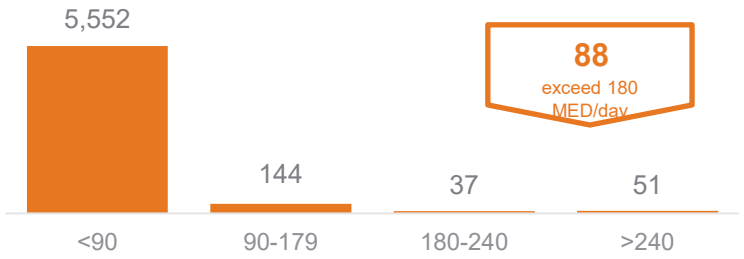
Utilizers **5,784**

31.8% are high utilizers [1]

4.5% higher 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

77 opioid utilizing members with 3+ pharmacies

559 Shoppers: Poly Prescriber

opioid utilizing members with 3+ prescribers

Opioid Claims **13,885**

3.1% prescription claims filled for an opioid

1.2% higher than Medicaid FFS benchmark

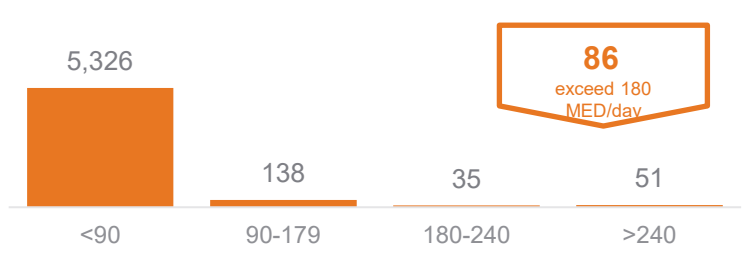
Utilizers **5,550**

31.0% are high utilizers [1]

4.4% higher 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

68 opioid utilizing members with 3+ pharmacies

516 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 4Q2024
Opportunities date range: Sep - Dec 2024
Benchmark: MEDICAID FEE FOR SERVICE

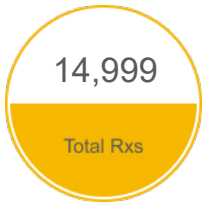
Utilizers: 5,784

3.1% 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.

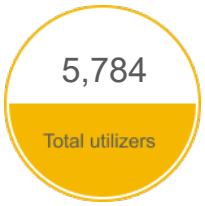
- Opioid prescriptions account for 3.1% of all prescriptions this period, which is 1.3% higher than the benchmark
- 1,841 high opioid utilizers were identified this period, which is 4.5% higher than the benchmark

Opioid claims



PERCENT NON-COMPLIANT
12.2%

Opioid utilizers

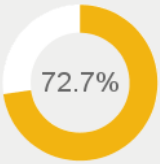


HIGH UTILIZERS
31.8%
1,841 high utilizers

4.5% over benchmark

High utilizers – view definition

Claim breakdown



short acting opioids

72.7% of all opioid Rxs were filled for short acting opioids. **3,177** Rxs were for medication assisted therapy (MAT) and **166** 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 – view definition
Overdose rescue therapy – view definition
MME – view definition

Utilizers by cumulative MED

88 utilizers exceed 180 MED/day

MED Scores	<90	90-179	180-240	>240
Utilizers	5,552	144	37	51

MED – view definition

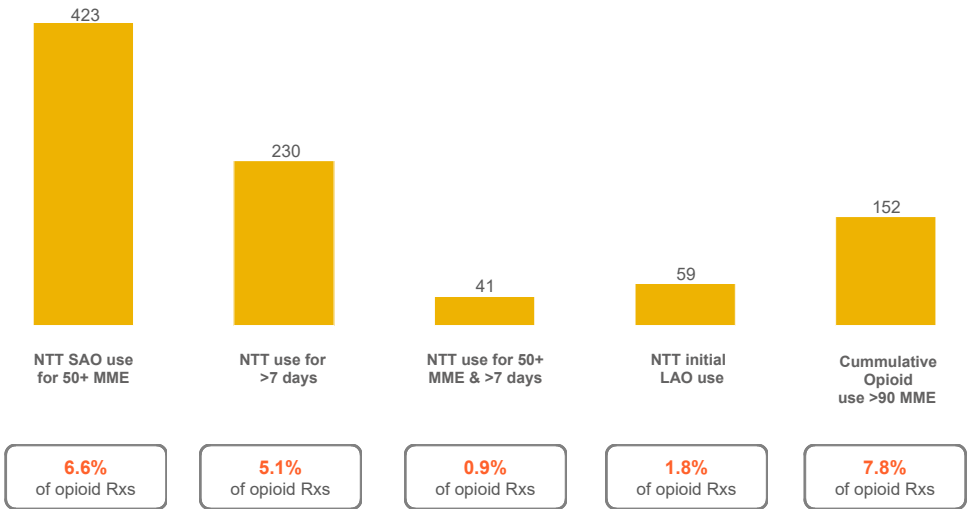
Opioid Opportunity Assessment

SDM 4Q2024
Opportunities date range: Sep - Dec 2024
Benchmark: MEDICAID FEE FOR SERVICE

Percent non-compliant: 12.2%

Utilizers non-compliant to opioid Rx CDC guidelines

(new to therapy and chronic use)



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

DID YOU KNOW?

77 opioid utilizing members use 3 or more pharmacies and 559 opioid utilizing members use 3 or more prescribers.

Identification, management and prevention of fraudulent or potential abuse of opioid medications are monitored and addressed by OptumRx through various means in pharmacy network audit capabilities and high touch clinical programs that include care coordination with opioid prescribers.

Opioid utilizers with potentially contraindicated medication use

SKELETAL MUSCLE RELAXANTS	BENZODIAZEPINES	ANTICONVULSANTS	MEDICATION ASSISTED THERAPY	PRENATAL
1,228	733	1,085	608	153

Anticonvulsants –view definition

Table of Contents

***Red font denotes new PA/Fax Form since last review**

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

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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 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?

_____

_____

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_____

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South Dakota Department of Social Services

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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?

_____

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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

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.
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 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?

_____

_____

_____

_____

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

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?

_____

_____

_____

_____

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

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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.
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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

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.
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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

Auvelity® 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:

❑ Major depressive disorder

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

Clinical information:

1. The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted) List all: _____
2. The physician attests that the requested medication is medically necessary. Document rationale for use: _____
3. Patient has a history of failure, contraindication or intolerance to at least 3 preferred alternatives* in the last 3 years:

❑ bupropion/SR/XL	❑ duloxetine	❑ fluvoxamine	❑ sertraline
❑ citalopram	❑ escitalopram	❑ mirtazapine	❑ trazodone
❑ desvenlafaxine ER	❑ fluoxetine	❑ paroxetine	❑ venlafaxine/ER
			❑ other _____

4. How long has the patient tried the above listed medications? _____

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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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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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

Lybalvi® 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:

- ❑ Schizophrenia
- ❑ Bipolar I disorder: acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
- ❑ Bipolar I disorder: maintenance monotherapy treatment in adults with Bipolar I disorder.
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

1. Patient has a history of failure, contraindication or intolerance to at least 2 preferred alternatives* in the last 3 years:
   - ❑ aripiprazole ❑ olanzapine ❑ risperidone
   - ❑ asenapine ❑ paliperidone ❑ ziprasidone
   - ❑ clozapine ❑ quetiapine/ER ❑ other_____
2. How long has the patient tried the above listed medications? _____

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.
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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

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?

_____

_____

_____

_____

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

Bonjesta® 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): _____

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.
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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

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?

_____

_____

_____

_____

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

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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South Dakota Department of Social Services

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

Varubi Prior Authorization 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)

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?

_____

_____

_____

_____

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**

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?

_____

_____

_____

_____

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

Brexafemme® 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:

❑ Vulvovaginal candidiasis

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

Clinical information:

Has the patient tried and failed 3 trials of fluconazole or clotrimazole in the past 14 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?

_____

_____

_____

_____

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?

_____

_____

_____

_____

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™, Motegrity®, Symproic®, Trulance®
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
- ❑ Irritable bowel syndrome with constipation (IBS-C)
- ❑ Opioid-induced constipation in an adult patient with chronic pain
- ❑ 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

Continuous Glucose Monitors 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 requested medication below:

Preferred Products:

- ❑ Dexcom G6
- ❑ Dexcom G7
- ❑ FreeStyle Libre 14
- ❑ FreeStyle Libre 2
- ❑ FreeStyle Libre 3
- ❑ Guardian 3
- ❑ Guardian 4
- ❑ Guardian Link 3
- ❑ Guardian Connect

Select the requested medication below:

Non-Preferred:

- ❑ List:

Select the diagnosis below:

- ❑ Type 1 diabetes mellitus
- ❑ Gestational diabetes mellitus
- ❑ Type II diabetes mellitus
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

For diagnosis of Type II diabetes mellitus:

Is the patient using rapid or short acting insulin? ❑ **Yes** ❑ **No** If yes, which one? _____

How often does the patient use rapid or short acting insulin? _____

Non-preferred product request:

If a request for a non-preferred agent is medically necessary or required for a particular member, prescriber must provide a brief summary for use of the non-preferred agent over a preferred alternative

_____

_____

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

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?

_____

_____

_____

_____

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

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, list ICD-10 Code(s): _____
- ❑ Seizures associated with Lennox-Gastaut syndrome, list (LGS) ICD-10 Code(s): _____
- ❑ Seizures associated with Tuberous Sclerosis Complex (TSC), list ICD-10 Code(s): _____
- ❑ Refractory epilepsy, list ICD-10 Code(s): _____
- ❑ 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.
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® & Sympazan® 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 the requested medication 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.
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

Eucrisa® 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:

❑ Atopic dermatitis

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

Clinical information:

Has the patient had a documented trial of a topical corticosteroid, pimecrolimus cream, or tacrolimus ointmentointment within the last 120 days? ❑ **Yes** ❑ **No** If yes, which one _____

How long has the patient tried the above listed medication? _____

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

Evrysdi® 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:

❑ Spinal muscular atrophy (SMA): Type _____

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

Clinical information:

1. Select if the requested medication is prescribed by or in consultation with one of the following specialists:
   - ❑ Neurologist with expertise in the diagnosis and treatment of SMA
   - ❑ Other _____
2. How many SMN2 copies? _____
3. Does the mutation or deletion of genes in chromosomes 5q result in the following:
   - ❑ Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) _____
   - ❑ Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) _____
   - ❑ Other _____
4. Is the patient dependent on invasive ventilation or tracheostomy? ❑ **Yes** ❑ **No**
5. Is the patient dependent on use of non-invasive ventilation beyond use for naps and nighttime sleep? ❑ **Yes** ❑ **No**
6. Has one of the other exams listed below (based on patient's age and motor ability) been conducted to establish baseline motor ability by a board-certified neurologist?
   - ❑ Hammersmith Functional Motor Scale Expanded (HFMSE)
   - ❑ Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
   - ❑ Upper Limb Module (ULM) Test (Non ambulatory)
   - ❑ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
   - ❑ Motor Function Measure 32 (MFM-32) Scale
7. Is the patient on concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza)?
   - ❑ **Yes** ❑ **No**
8. Has the patient previously received gene replacement therapy for the treatment of SMN (e.g., Zolgensma)? ❑ **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

Evrysdi™ Prior Authorization Request Form (Page 2 of 3)

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9. If patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma), provider to attests that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months) or worsening in clinical status since receiving gene therapy as demonstrated by a decline of minimally clinical important difference fro highest score achieved on one of the following exams:
   - ❑ HFMSE: decline of at least _____ points on kicking and _____ points on any other milestones (excluding voluntary grasp)
   - ❑ HINE-2: decline of at least _____ points
   - ❑ CHOP INTEND: decline of at least _____ points

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: _____

Reauthorization:
If this is a reauthorization request, answer the following:

1. How many SMN2 copies? _____

2. Provide documentation of positive clinical response to therapy (e.g., chart notes, laboratory values) from pretreatment baseline status as demonstrated by the most recent results (less than 1 month prior to reauthorization request) from one of the following exams:
   - ❑ One of the following HINE-2 milestones _____
     - ❑ Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick
     - ❑ Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
     - ❑ Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
     - ❑ Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)
   - ❑ One of the following HFMSE milestones _____
     - ❑ Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline
     - ❑ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)
   - ❑ One of the following ULM test milestones _____
     - ❑ Improvement or maintenance of a previous improvement of at least a 2-point increase in score from pretreatment baseline
     - ❑ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)
   - ❑ One of the following CHOP-INTEND milestones _____
     - ❑ Improvement or maintenance of a previous improvement of at least a 4-point increase in score from pretreatment baseline
     - ❑ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)
   - ❑ One of the following MFM-32 milestones _____
     - ❑ Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline
     - ❑ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

3. Is the patient dependent on invasive ventilation or tracheostomy? ❑ **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

Evrysdi™ Prior Authorization Request Form (Page 3 of 3)

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

4. Is the patient dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep? ❑ **Yes** ❑ **No**
5. Is the requested medication prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA? ❑ **Yes** ❑ **No**
6. Is the patient is receiving concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza)? ❑ **Yes** ❑ **No**
7. Has the patient previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)? ❑ **Yes** ❑ **No**
8. Was there inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)? If so, submit medical records (e.g., chart notes) documenting the inadequate response to gene therapy.

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

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, oxybutynin ER, darifenacin ER, fesoterodine ER, solifenacin, tolterodine, tolterodine ER, trospium, or trospium ER ? ❑ **Yes** ❑ **No**

List drug(s) tried_____

For Gelnique, Myrbetriq suspension, Oxytrol, or Vesicare LS 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)

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 requested medication below:

Preferred Drugs:

- ❑ Genotropin
- ❑ Norditropin

Select the requested medication below:

Non-Preferred:

- ❑ Humatrope
- ❑ Nutropin AQ
- ❑ Omnitrope
- ❑ Nglena
- ❑ Skytrofa
- ❑ Sogroya
- ❑ 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
- ❑ Short stature homeobox containing gene (SHOX) deficiency
- ❑ Small for gestational age
- ❑ Turner's syndrome

Select the diagnosis below:

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

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 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

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 3 of 3)

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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**

Non-preferred drug request:

If a request for a non-preferred agent is medically necessary or required for a particular member, prescriber must provide a brief summary for use of the non-preferred agent over a preferred alternative

_____

_____

_____

_____

_____

_____

Nutropin and Nutropin AQ are non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency.
Humatrope and Zomacton are non-preferred unless member has a diagnosis of SHOX deficiency

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

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.
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

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 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:

❑ Hepatitis C virus infection

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

Clinical information:

Document the patient's genotype: _____

Document the patient's weight: _____Kg

Does the patient have one of the following (providers may be asked to provide documentation):

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

Does the patient have compensated liver disease (Child-Pugh A)? ❑ **Yes** ❑ **No**

Does the patient have decompensated liver disease (Child-Pugh B or C)? ❑ **Yes** ❑ **No**

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

Select one of the following:

- ❑ Patient is ribavirin intolerant/ineligible
- ❑ Patient is female and prescribed ribavirin, patient has a negative pregnancy test within 30 days prior to initiation of therapy and will receive a monthly pregnancy test during treatment
- ❑ Patient is not prescribed ribavirin
- ❑ Patient is prescribed ribavirin or ribavirin eligible

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

Has the patient had prior treatment failure with sofosbuvir or NS5A-based treatment? ❑ **Yes** ❑ **No**

Is the patient taking P-glycoprotein (P-gp) inducers (e.g., rifampin, St. John's wort)? ❑ **Yes** ❑ **No**

Is the patient taking anticancers (e.g., topotecan)? ❑ **Yes** ❑ **No**

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

Is the patient receiving Epclusa (sofosbuvir/velpatasvir) in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]? ❑ **Yes** ❑ **No**

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

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

- ❑ Anticonvulsants (e.g., carbamazepine, oxcarbazepine, phenobarbital, phenytoin)
- ❑ P-glycoprotein (P-gp) inducers (e.g., rifampin, St. John's wort)
- ❑ HIV antiretrovirals (e.g., tipranavir/ritonavir)
- ❑ Tenofovir-containing HIV regimens
- ❑ Anticaners (e.g., topotecan)

Is the patient receiving Harvoni (ledipasvir/sofosbuvir) in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]? ❑ **Yes** ❑ **No**

South Dakota Department of Social Services

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

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For Mavyret (glecaprevir-pibrentasvir), also answer the following:

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)

Is the patient receiving Mayvret in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]? ❑ **Yes** ❑ **No**

For Sovaldi (sofosbuvir), also answer the following:

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

- ❑ Pegylated interferon and ribavirin
- ❑ Ribavirin

Does the patient have severe renal impairment (eGFR < 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 Vosevi (sofosbuvir-velpatasvir-voxilaprevir), 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** Is the patient receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]? ❑ **Yes** ❑ **No**

For Zepatier (elbasvir-grazoprevir), also answer the following:

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

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

Is the patient receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir)]? ❑ **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

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?

_____

_____

_____

_____

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:

- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Active systemic juvenile idiopathic arthritis (sJIA)
- ❑ Temporal arteritis or giant cell arteritis (GCA)
- ❑ Systemic sclerosis-associated interstitial lung disease
- ❑ 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 ❑ Pulmonologist ❑ Rheumatologist ❑ Other _____

Will Actemra be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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** List _____

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** List _____

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** List _____

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

Tyenne™ 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:

- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Active systemic juvenile idiopathic arthritis (sJIA)
- ❑ Temporal arteritis or giant cell arteritis (GCA)
- ❑ Systemic sclerosis-associated interstitial lung disease
- ❑ 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 ❑ Other _____

Will Tyenne be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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** List _____

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** List _____

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** List _____

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

Adbry® 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:

❑ Atopic dermatitis (describe severity level)_____

❑ 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 ❑ Allergist/Immunologist ❑ Other _____

Medication history:

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

Has the patient have a documented 14-day trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, or Eucrisa (crisaborole)? _____

_____

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

Arcalyst® 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) [including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)]
- ❑ Deficiency of interleukin-1 receptor antagonist (DIRA)
- ❑ Recurrent pericarditis
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is diagnosed by, or upon consultation with or recommendation of the following specialists:
❑ Allergist/Immunologist ❑ Dermatologist ❑ Neurologist ❑ Rheumatologist ❑ Other _____

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

For recurrent pericarditis, answer the following:

Has the patient had an inadequate response or intolerance to, or contraindication to a trial of colchcine or one oral systemic glucocorticoids? ❑ **Yes** ❑ **No** List _____

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: _____

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

Bimzelx® 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
- ❑ Active psoriatic arthritis
- ❑ Active ankylosing spondylitis
- ❑ Active non-radiographic axial spondyloarthritis
- ❑ 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 ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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 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** List _____

For active non-radiographic axial spondyloarthritis, 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** List _____

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

Cibinqo™ 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:

❑ Atopic dermatitis (describe severity level)_____

❑ 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 ❑ Allergist/Immunologist ❑ Other _____

Medication history:

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

Has the patient have a documented 14-day trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, or Eucrisa (crisaborole)? _____

_____

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

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

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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:

- ❑ Moderately to active polyarticular juvenile idiopatic arthritis (pJIA)
- ❑ Active psoriatic arthritis
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ Moderately to severely active rheumatoid arthritis
- ❑ Moderately to severely active Crohn's disease
- ❑ Active ankylosing spondylitis
- ❑ Active non-radiographic axial spondyloarthritis
- ❑ 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 ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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** List _____

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** List _____

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 2 of 2)

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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** List _____

For active non-radiographic axial spondyloarthritis, 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** List _____

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: _____

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

Cosentyx® 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 plaque psoriasis
- ❑ Active Non-radiographic axial spondyloarthritis
- ❑ Active enthesitis-related arthritis
- ❑ Moderate to severe hidradenitis suppurativa (e.g., Hurley Stage II or III)
- ❑ 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 ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

For active non-radiographic axial spondyloarthritis or enthesitis-related arthritis, 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** List _____

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** List _____

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
- ❑ Eosinophilic esophagitis
- ❑ Prurigo nodularis
- ❑ 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:
❑ Allergist/Immunologist ❑ Gastroenterologist ❑ Otolaryngologist ❑ Pulmonologist ❑ Other _____

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

Atopic dermatitis:

Has the patient had a documented trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, Eurisa (crisaborole) ointment within the last 120 days? ❑ **Yes** ❑ **No** List _____

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**

List _____

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

Eosinophilic esophagitis:

Has the patient had a documented trial for at least 8 weeks of a proton pump inhibitor or corticosteriod (e.g., fluticasone, budesonide suspension)? ❑ **Yes** ❑ **No** List _____

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 2 of 2)

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Prurigo nodularis

Has the patient had a documented trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, Eurisa (crisaborole) ointment within the last 120 days? ❑ **Yes** ❑ **No** List _____

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: _____

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

Ebglyss™ 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:

❑ Atopic dermatitis (describe severity level)_____

❑ 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 ❑ Allergist/Immunologist ❑ Other _____

Medication history:

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

Has the patient have a documented 14-day trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, or Eucrisa (crisaborole)? _____

_____

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: _____

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

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

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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:

- ❑ Active ankylosing spondylitis (AS)
- ❑ Active psoriatic arthritis (PsA)/Juvenile psoriatic arthritis (JPsA)
- ❑ Active juvenile idiopathic arthritis (PJIA)
- ❑ 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 ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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

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

For active juvenile idiopathic arthritis (PJIA), 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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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** List _____

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** List _____

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

Enspryng® 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:

❑ Neuromyelitis optical disorder (NMOSD)

❑ 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:

❑ Neurologist ❑ Other _____

Will the requested medication be used in combination with another biologic agent? ❑ **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

Entyvio® 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 Crohn's disease
❑ 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:
❑ Gastroenterologist ❑ Other _____
Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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 conventional therapies: azathioprine, 6-mercaptopurine, methotrexate, corticosteroids (e.g., prednisone, methylprednisolone) ❑ **Yes** ❑ **No** List _____

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** List _____

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: _____

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

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
❑ Eosinophilic granulomatosis with polyangiitis
❑ 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:
❑ Allergist/Immunologist ❑ Pulmonologist ❑ Rheumatologist ❑ Other _____

For severe asthma with eosinophilic phenotype:

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**

For eosinophilic granulomatosis with polyangiitis:

Is the patient continuing to use an inhaled corticosteroid (e.g., fluticasone, budesonide) with or without additional asthma controlled medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist, long-acting muscarinic antagonist) unless there is a contraindication or intolerance to these medications? ❑ **Yes** ❑ **No**

- leukotriene receptor antagonist (e.g., montelukast)
- long-acting beta-2 agonist (e.g., salmeterol)
- long-acting muscarinic antagonist (e.g., tiotropium)

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)

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:

- ❑ 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 ❑ Other _____

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

If requesting a citrate-free product, has the patient tried citrate product first? ❑ **Yes** ❑ **No** **When:** _____

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** List _____

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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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 2 of 2)

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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 conventional therapies: azathioprine, 6-mercaptopurine, methotrexate, corticosteroids (e.g., prednisone, methylprednisolone) ❑ **Yes** ❑ **No** List _____

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** List _____

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** List _____

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** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**

List _____

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: _____

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

Abrilada™ Prior Authorization Request Form (Page 1 of 2)

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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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Abrilada) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

Abrilada™ Prior Authorization Request Form (Page 2 of 2)

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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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Amjevita™ Prior Authorization Request Form (Page 1 of 2)

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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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Amjevita) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

Amjevita™ Prior Authorization Request Form (Page 2 of 2)

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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, corticosteroids)? ❑ **Yes** ❑ **No** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Cyltezo® 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
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Cyltezo) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____ _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Hadlima™ Prior Authorization Request Form (Page 1 of 2)

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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)

Select the diagnosis below:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Hadlima) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

Hadlima™ Prior Authorization Request Form (Page 2 of 2)

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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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

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

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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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Hulio) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**

List _____

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: _____

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

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

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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)

Select the diagnosis below:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Hymiroz) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

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

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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:

- ❑ Active ankylosing spondylitis
- ❑ Active psoriatic arthritis (PsA)
- ❑ Moderate to severe chronic plaque psoriasis
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Idacio) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Simlandi® 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
- ❑ 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
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Simlandi) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Yuflyma® 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
- ❑ 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
- ❑ Moderate to severe hidradenitis suppurativa (e.g., Hurley Stage II or III)
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Yuflyma) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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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** List _____

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** List _____

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** List _____

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** Lisa _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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

Yusimry™ 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
- ❑ 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
- ❑ Moderately to severely active ulcerative colitis
- ❑ Hidradenitis Suppurativa
- ❑ 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 ❑ Other _____

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

Justification for the use of a non-preferred product (Yusimry) over a preferred product (Humira):

If non-preferred agent is medically necessary or required, provide a brief summary for use of the non-preferred agent over a preferred alternative: _____

_____

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** List _____

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, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

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

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

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** List _____

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** List _____

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** List _____

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** List _____

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 retinoid therapy, dapsone, or acitretin? ❑ **Yes** ❑ **No** List _____

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, oral/injectable steroid therapy? ❑ **Yes** ❑ **No**
List _____

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: _____

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)]
- ❑ Tumor necrosis factor receptor associated periodic syndrome or hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) or familial mediterranean fever
- ❑ Still's disease
- ❑ Gout
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Select if the requested medication is diagnosed by, or upon consultation with or recommendation of the following specialists:
❑ Allergist/Immunologist ❑ Dermatologist ❑ Neurologist ❑ Rheumatologist ❑ Other _____

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

For active systemic juvenile idiopathic arthritis or Still's disease, 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** List _____

For gout, answer the following:

Has the patient had an inadequate response, intolerance, or contraindication to BOTH oral systemic agents NSAIDs AND colchicine? ❑ **Yes** ❑ **No** List _____

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

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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: _____

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)
❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
❑ Polymyalgia Rheumatica (PMR)
❑ 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:
❑ Rheumatologist ❑ Other _____

Will Kevzara be used in combination with another biologic agent? ❑ **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** List _____

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** List _____

For polymyalgia rheumatica (PMR), also answer the following:

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

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: _____

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

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)
- ❑ Deficiency of interleukin-1 receptor antagonist (DIRA)
- ❑ 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:

❑ Allergist/ Immunologist ❑ Dermatologist ❑ Gastroenterologist ❑ Neurologist ❑ Rheumatologist

❑ Other _____

Will the requested medication be used in combination with another biologic agent? ❑ **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** List _____

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: _____

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

Nemluvio® 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:

❑ Prurigo Nodularis (describe severity level)_____

❑ 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 ❑ Allergist/Immunologist ❑ Other _____

Medication history:

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

Has the patient have a documented trial of a topical corticosteroid, pimecrolimus cream, or tacrolimus ointment within the last 120 days?

_____

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: _____

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

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:

- ❑ Severe asthma with an eosinophilic phenotype
- ❑ Eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome)
- ❑ Hypereosinophilic syndrome
- ❑ Chronic rhinosinusitis with nasal polyps (CRWsNP)
- ❑ 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:

❑ Allergist/Immunologist ❑ Hematologist ❑ Otolaryngologist ❑ Pulmonologist ❑ Rheumatolgist ❑ Other _____

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**

For chronic rhinosinusitis with nasal polyps (CRWsNP), also answer the following:

Has the patient experienced inadequate response to nasal corticosteroid? ❑ **Yes** ❑ **No**

List intranasal corticosteroid tried by the patient and duration of use: _____

_____

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**

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

Omvoh™ 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 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:

❑ Gastroenterologist ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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: _____

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

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:

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

❑ Dermatologist ❑ Rheumatologist ❑ Other _____

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** List _____

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** List _____

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

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)
❑ Aphthlous Ulcer associated with Behcet's syndrome
❑ 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 ❑ Other _____
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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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

Rinvoq® 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:

- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Moderately to severely active ulcerative colitis
- ❑ Active psoriatic arthritis
- ❑ Active ankylosing spondylitis
- ❑ Active atopic dermatitis
- ❑ Moderately to severely active Crohn's disease
- ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Non-radiographic axial spondyloarthritis
- ❑ 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 ❑ Allergist/Immunologist ❑ Other _____

Will Rinvoq be used in combination with another biologic agent, Janus Kinus inhibitor e.g., Olumiant, Dupixent, Xeljanx/XR), or other potent immunsuppressants (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, etc)? ❑ **Yes** ❑ **No**

For rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, non-radiographic axial spondyloarthritis, and ankylosing spondylitis also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more TNF blockers (e.g., Cimzia, Enbrel, Humira, Simponi, Remicade, etc)? _____

For atopic dermatitis also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more topical corticosteroid, pimecrolimus cream, tacrolimus ointment, or Eucrisa (crisaborole) ointment; or systemic drug product for the treatment of atopic dermatitis (e.g., Adbry, Dupixent, etc)? _____

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

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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: _____

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

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** List _____

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** List _____

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** List _____

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
- ❑ 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
- ❑ Active psoriatic arthritis
- ❑ Moderately to severely active Crohn's disease
- ❑ 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 ❑ Other _____

Will the requested medication 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 (list)_____

_____

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: _____

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

Sotyktu® 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:

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

❑ Dermatologist ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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: _____

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

Spevigo® 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 generalized pustular psoriasis (GPP)

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

Clinical information:

Does the patient have presence of fresh pustules (new appearance or worenign pustules)? ❑ **Yes** ❑ **No**

Is at least 5% of body surface area covered with erythema and presence of pustules? ❑ **Yes** ❑ **No**

What is the Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score? _____

What is the patient's weight? _____

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

❑ Dermatologist ❑ Other _____

Will Spevigo be used in combination with another biologic agent or targeted immunomodulator? ❑ **Yes** ❑ **No**

Medication history:

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

Has the patient have a documented 14-day trial of a topical corticosteroid, pimecrolimus cream, tacrolimus ointment, or Eucrisa (crisaborole)? _____

_____

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: _____

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

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
- ❑ 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 ❑ Other _____

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, calcipotriene, cyclosporine, acitretin, sulfasalazine, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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 conventional therapy (e.g., azathioprine, mercaptopurine, methotrexate, corticosteroids)? ❑ **Yes** ❑ **No** List _____

For moderately to severely active Ulcerative Colitis, also answer the following:

Has the patient had an inadequate response to, intolerance to, or contraindication to one or more conventional therapy (e.g., corticosteroids, mesalamine, balsalazide, olsalazine, azathioprine, mercaptopurine, methotrexate)? ❑ **Yes** ❑ **No**

List _____

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 (Page 1 or 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 plaque psoriasis
- ❑ Non-radiographic axial spondyloarthritis with objective of inflammation
- ❑ 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 ❑ Other _____

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

For active ankylosing spondylitis or non-radiographic axial spondyloarthritis, 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** List _____

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**

List _____

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

Tezspire® 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

❑ 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:

❑ Allergist/Immunologist ❑ Pulmonologist ❑ Other _____

For severe asthma, also answer the following:

Has the patient had two or more asthma exacerbations requiring systemic corticosteroids withn the past 12 months?

□ **Yes** □ **No** If yes, list corticosteroids tried_____

Has the patient had asthma-related hospitalization within the past 12 momths? □ **Yes** □ **No**

Has the patient tried high-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)? □ **Yes** □ **No** If yes, list ICS tried _____

Has the patient tried additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) □ **Yes** □ **No** If yes, list drug tried _____

Has the patient tried one maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/ salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]) □ **Yes** □ **No** If so, list drug tried _____

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: _____

Reauthorization: If this is a reauthorization request, answer the questions in the previous sections and the following below:

Does the patient demonstrates positive clinical response to therapy as evidenced by one of the following:

- A reduction in asthma exacerbations □ **Yes** □ **No**
- Improvement in forced expiratory volume in 1 second (FEV1) from baseline □ **Yes** □ **No**

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

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-855-401-4262.
This form may be used for non-urgent requests and faxed to 1-844-403-1029.

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
- ❑ Moderate to severe psoriatic arthritis
- ❑ Moderate to severe ulcerative colitis
- ❑ 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**

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, calcipotriene, tazarotene, corticosteroid)? ❑ **Yes** ❑ **No** List _____

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 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** List _____

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: _____

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

Velsipity™ 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 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:

❑ Gastroenterologist ❑ Other _____

Will the requested medication be used in combination with another biologic agent or targeted immunomodulator? ❑ **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** List _____

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

Xeljanz® & Xeljanz XR® 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:

- ❑ Active psoriatic arthritis
- ❑ Moderately to severely active rheumatoid arthritis
- ❑ Moderately to severely active ulcerative colitis
- ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
- ❑ Active ankylosing spondylitis
- ❑ 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 ❑ Other _____

Will the requested medication 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 TNF blockers (e.g., Cimzia, Enbrel, Humira, Simponi, Avsola, Inflectra, Renflexis, Remicade)? If so, which one(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

Xolair® 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:
- ❑ Asthma
- ❑ Chronic idiopathic urticaria (CIU)
- ❑ Nasal polyps with inadequate response to nasal steroid
- ❑ IgE Mediated Food Allergy
- ❑ 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:
❑ Allergist ❑ Dermatologist ❑ Immunologist ❑ Pulmonologist ❑ Rheumatologist ❑ Other _____

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

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**

For chronic idiopathic urticaria, answer the following:

Does the patient remain symptomatic despite H1 antihistamine treatment? ❑ **Yes** ❑ **No**

For nasal polyps with inadequate response to nasal steroid, answer the following:

Does the patient remain symptomatic despite nasal steroid? ❑ **Yes** ❑ **No**

For IgE mediated food allergy, answer the following:

Dose the patient have a history of an IgE-mediated (Type I) allergic reaction to one or more food allergens? ❑ **Yes** ❑ **No**
Does the patient have a positive skin prick test (SPT) (≥ 4 mm wheal) to identified foods? ❑ **Yes** ❑ **No**
Does the patient have a positive IgE screening (≥ 6 kUA/L) to identified foods? ❑ **Yes** ❑ **No**
Prescriber attests that member has been counseled to continue food allergen avoidance while utilizing omalizumab: ❑ **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

Zymfentra™ 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 Crohn's disease
❑ Moderately to severely ulcerative colitis
❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is Zymfentra prescribed by or in consultation with a gastroenterologist? ❑ **Yes** ❑ **No**
Will Zymfentra be used in combination with another biologic agent? ❑ **Yes** ❑ **No**
Did the patient have an IV infliximab treatment? ❑ **Yes** ❑ **No** If yes, how long was the IV infliximab treatment? _____
Did the patient achieve a clinical response following IV infliximab? ❑ **Yes** ❑ **No**
List reason(s) continued IV administration is not appropriate for the patient _____

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: _____

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

Juxtapid® 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)

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

Clinical information:

Is the patient's baseline LDL-C level greater than or equal to 190 mg/dL? ❑ **Yes** ❑ **No**

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

Has the patient had trial and failure of Praluent or Repatha? ❑ **Yes** ❑ **No**

If yes, what was the documented failure with Praluent or Repatha _____

_____

What is the medical rationale for use of Juxtapid over Praluent or Repatha? _____

_____

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

Extina, Xolgel™ & Xolegel™ Duo 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.
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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 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?

_____

_____

_____

_____

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

Metozolv® ODT (metoclopramide ODT) and Gimoti® nasal spray 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
- ❑ Postsurgical gastroparesis
- ❑ 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**

What is the medical justification for use of metoclopramide nasal spray over oral metoclopramide? _____

_____

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

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	❑ Briumvi	❑ Gilenya	❑ Mavenclad	❑ Rebif
❑ Aubagio	❑ Copaxone	❑ Glatiramer	❑ Mayzent	❑ Tascenso ODT
❑ Avonex	❑ Dalfampridine ER	❑ Glatopa	❑ Plegridy	❑ Tecfidera
❑ Bafiertam	❑ Extavia	❑ Kesimpta	❑ Ponvory	❑ Vumerity
❑ Betaseron				❑ Zeposia

Select the diagnosis below:

❑ 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:

- ❑ 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, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatiramer, Glatopa, Kesimpta, Lemtrada, Mayzent, Plegridy, Ponvory, 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 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

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 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)
- ❑ Avonex (interferon beta-1a)
- ❑ Bafiertam (monomethyl fumarate)
- ❑ Betaseron (interferon beta-1b)
- ❑ Briumvi (ublituximab-xiiy)
- ❑ Copaxone/Glatopa (glatiramer acetate)
- ❑ Extavia (interferon beta-1b)
- ❑ Gilenya (fingolimod)
- ❑ Kesimpta (ofatumumab)
- ❑ Lemtrada (alemtuzumab)
- ❑ Mayzent (siponimod)
- ❑ Ocrevus (ocrelizumab)
- ❑ Plegridy (peginterferon beta-1a)
- ❑ Rebif (interferon beta-1a)
- ❑ Tecfidera (dimethyl fumarate)
- ❑ Tysabri (natalizumab)
- ❑ Vumerity (diroximel)
- ❑ Zeposia (ozanimod)

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

Tysabri® 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:

❑ Multiple Sclerosis (type) _____ ICD-10 Code(s): _____
❑ Crohn's Disease (severity level) _____ ICD-10 Code(s): _____
❑ Other _____ ICD-10 Code(s): _____

Prescriber's specialty:

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

❑ Neurologist
❑ Gastroenterologist
❑ Other _____

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.
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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

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.
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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

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?

_____

_____

_____

_____

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

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?

_____

_____

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-855-401-4262.
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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

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
- ❑ Nighttime sleep disturbances in Smith-Magenis syndrome
- ❑ 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?

_____

_____

_____

_____

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

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?

_____

_____

_____

_____

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™ & 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

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

Nuzyra® 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:

❑ Community-acquired pneumonia

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

Clinical information:

Has the patient had an inadequate response to, intolerance to, or contraindication to conventional therapy with one or more of the following: tetracyclinc product (e.g., minocycline, doxycycline, etc) in the past 30 days? ❑ **Yes** ❑ **No** Date tried _____

Quantity limit requests:

What is the quantity requested per TREATMENT? _____

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

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?

_____

_____

_____

_____

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

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

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

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.
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

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?

_____

_____

_____

_____

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

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.
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

Opzelura™ 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:

❑ Actopic dermatitis

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

Clinical information:

1. Does the patient have greater than or equal to 3% body surface area involvement? ❑ **Yes** ❑ **No**
2. Does it involve sensitive body areas (e.g., face, hands, feet, scalp, groin)? ❑ **Yes** ❑ **No**
3. Greater than or equal to 90 days of topical drug therapy with **one** of the following: corticosteroids, pimecrolimus and/or tacrolimus, crisaborole? ❑ **Yes** ❑ **No**
4. Is the patient using concurrently with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine? ❑ **Yes** ❑ **No**
5. What is the requested quantity? _____
6. How long will the patient be using Opzelura? _____

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

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?

_____

_____

_____

_____

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

Praluent® & Repatha® Prior Authorization Request Form

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

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

Medication Information (required)

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

Clinical Information (required)

Select the diagnosis below:

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

Clinical information:

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

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

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

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

Reauthorization:

If this is a reauthorization request, answer the following:

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

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

_____

_____

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-855-401-4262.
This form may be used for non-urgent requests and faxed to 1-844-403-1029.

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

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, Konvomep (omeprazole-bicarbonate), Nexium oral packet, Prevacid Solutab (lansoprazole orally disintegrating tablet [ODT]), Prilosec delayed release suspension pack, Protonix PAK, 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, Nexium capsule (esomeprazole magnesium capsule), 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?

_____

_____

_____

_____

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

Qelbree® 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:

❑ Diagnosis _____ ICD-10 Code(s): _____

Clinical information:

Has the patient had a trial of atomoxetine? ❑ Yes ❑ No

If yes, when did the patient have a trial of atomoxetine _____

How long was the trial of atomoxetine _____

Has the patient had a trial of stimulants? ❑ Yes ❑ No

If yes, which stimulant has the patient tried _____

When did patient try the listed stimulant _____

How long did the patient try the stimulant _____

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

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

Rezdiffra™ 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 and list the rating scale and score below:
- ❑ Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH)
- ❑ Other diagnosis: _____ ICD-10 Code(s): _____

Clinical information:
- ❑ Patient has fibrosis stage F2 or F3. **Submit documentation such as medical records or tests confirming fibrosis stage.**
- ❑ Patient does not have decompensated cirrhosis (Child-Pugh Class B or C)
- ❑ Prescribed by or in consultation with a gastroenterologist or hepatologist

Prescriber attests that the patient has been counseled and has agreed to adhere to the following:
- ❑ Prescriber attests patient is participating in a supervised comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity

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

Rukobia® 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:

❑ Diagnosis _____ ICD-10 Code(s): _____

Clinical information:

List optimized antiretroviral regimen

_____

_____

_____

_____

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

Seglentis® 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:

❑ Diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

Is the prescriber aware of generic celecoxib and generic tramadol? ❑ **Yes** ❑ **No**

Prescriber needs to submit a letter of medical necessity.

Quantity limit requests:

What is the quantity requested per TREATMENT? _____

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

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

Tirosint®capsule/levothyroxine capsule 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)

Enter diagnosis below:
Diagnosis: _____ ICD-10 Code(s): _____

New to Tirosint capsule or levothyroxine capsule therapy:
Has the patient tried 2 different levothyroxine tablets in the last 180 days? ❑ Yes ❑ No
Has the patient experienced failure to levothyorixine tablets? ❑ Yes ❑ No If yes, explain_____

_____

Submit documentation of medication failure.
Does the patient have an allergy, contraindication, drug-to-drug interaction, or history of unacceptablet/toxic side effects with levothyroxine tablets? ❑ Yes ❑ No If yes, explain_____

_____

Submit documentation of allergy, contraindication, drug-to-drug interaction, or history of unacceptable/toxic side effects with levothyroxine tablets.

Patient is currently taking Tirosint capsule/levothyroxine capsule therapy:
Has the patient tried 2 different levothyroxine tablets? ❑ Yes ❑ No If yes, explain _____
Submit documentation of trial and failure.

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

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**

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

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?

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™, Qulipta™, 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
- ❑ Preventive treatment of episodic migraine in adults
- ❑ Preventive treatment of chronic migraine in adults
- ❑ 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

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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?

_____

_____

_____

_____

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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

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

Vtama® 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:

❑ Plaque psoriasis

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

Clinical information:

Has the patient had a documented trial of a corticosteroid (e.g., betamethasone, clobesatol), vitamin D analogs (e.g., calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), anthralin, coal tar, or cominbation topical therapy (e.g., vitamin D analog/corticosteroid) within the last 120 days? ❑ **Yes** ❑ **No**

If yes, which one _____

How long has the patient tried the above listed medication? _____

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

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

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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)

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?

_____

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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

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®, 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.

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

Belsomra®, Dayvigo®, Quviviq™ 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 180 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.

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

Zoryve® 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:

❑ Plaque psoriasis
❑ Seborrheic dermatitis
❑ Atopic dermatitis
❑ Diagnosis: _____ ICD-10 Code(s): _____

Clinical information:

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

Has the patient had a documented trial of one or more of the following?:

- Corticosteroid (e.g., betamethasone, clobesatol) ❑ **Yes** ❑ **No** List _____
- Vitamin D analogs (e.g., calcitriol, calcipotriene) ❑ **Yes** ❑ **No** List _____
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) ❑ **Yes** ❑ **No** List _____
- Eucrisa (crisaborole) ointment ❑ **Yes** ❑ **No**
- Tazarotene ❑ **Yes** ❑ **No**
- Anthralin ❑ **Yes** ❑ **No**
- Coal tar ❑ **Yes** ❑ **No**
- Cominbation topical therapy (e.g., vitamin D analog/corticosteroid) ❑ **Yes** ❑ **No** List _____
- Topical antifungals (ketoconazole, ciclopirox, miconazole, clotrimazole) ❑ **Yes** ❑ **No** List _____

How long has the patient tried the above listed medication(s)? _____

When did the patient try the above listed medication(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.
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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

Zurzuvae™ 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 and list the rating scale and score below:

❑ Diagnosis of severe postpartum depression as indicated by DSM-5 criteria and/or an appropriate depression rating scale (e.g., HAM-D, MADRS, PHQ-9, etc.) _____

❑ Diagnosis of mild to moderate postpartum depression as indicated by DSM-5 criteria and/or an appropriate depression rating scale (e.g., HAM-D, MADRS, PHQ-9, etc) _____

- ❑ Trial and failure, contraindication or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine, etc)
  List SSRI or SNRI tried and duration _____
- ❑ If disqualifying agents due to contraindications alone (without history of previous failed therapy), contraindications to both SSRI and SNRI classes is required. Documentation must be submitted indicating reasoning behind each contraindication.
  List the contraindications for SSRI and SNRI _____

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

Clinical information:

When was the onset of symptoms? Provide date: _____

When was the delivery date? Provide date: _____

Has the patient been treated with brexanolone (IV formulation)? ❑ **Yes** ❑ **No** If yes, date: _____

Prescriber attests that the patient has been counseled and has agreed to adhere to the following:

- ❑ Patient will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence, or the degree of driving impairment caused by Zurzuvae
- ❑ Patient has ceased lactating or breastmilk produced will not be used for feedings during treatment and up to 7 days following last dose
- ❑ Females of reproductive potential should be advised to use effective contraception during treatment and for 1 week after the final dose
- ❑ Therapy will not be used in the same pregnancy as brexanolone (Zulresso)

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.

New Business

Daybue (trofinetide) indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

Daybue								
Quarter	**Total Rx**	**Ingredient Cost**	**Paid Amount**	**Paid/Rx**	**Mbr**	**Avg Qty/Days**	**Age Range**	**Gender**
June 2023	1	$37,980	$37,990.55	$37,990.55	1	1,800 ml per 28 days	13	Female
July-Sept '23	11	$541,215	$495,367.15	$45,033.38	5	2,332 per 27.6 days	8 – 30	
Oct-Dec '23	17	$759,600	$666,504.71	$39,206.16	6	2,118 per 27.8 days	5 – 30	
Jan-Mar '24	20	$921,015	$738,081.72	$36,904.09	6	2,182 per 26.5 days	5 – 43	
Apr-June '24	16	$915,838	$770,028.47	$48,126.78	5	2,559 per 28.4 days	6 – 43	
July-Sept '24	14	$924,531	$774,399.70	$55,314.26	7	2,861 per 28.6 days	6 – 43	
Oct-Dec '24	13	$914,143	$811,331.67	$62,410.13	6	3,046 ml per 29 days	9 – 44	

State A

Initial Authorization – 12 months
1. Patient is 2 years of age or older
2. Diagnosis of Rett Syndrome
3. Prescribed by, or in consultation with, a neurologist, clinical geneticist, or developmental pediatrician

Reauthorization – 12 months
1. Documentation of positive clinical response to Daybue (e.g. improvement or stabilization in purposeful hand skills, spoken language, repetitive hand movements, and gait abnormalities)

State B

Initial Authorization – 6 months
1. Prescribed by or in consultation with one of the following:
   a. Geneticist
   b. Neurologist
   c. Developmental pediatrician experienced in the treatment of Rett syndrome
2. Patient is 2 years of age or older
3. Diagnosis of Rett syndrome
4. The member has mutation(s) in the *methyl CpG binding protein 2 (MECP2)* gene confirmed by molecular genetic testing.
5. Member has documentation of one of the following baseline assessment scores (for verification of benefit on renewal request):
   a. Rett Syndrome Behavioral Questionnaire (RSBQ) score
   b. Clinical Global Impression-Severity (CGI-S) score

Reauthorization – 12 months
1. Member has experienced a positive clinical response to therapy as demonstrated by an improvement or stabilization of RSBQ or CGI-S score compared to baseline

State C

Initial Authorization: 6 months
Must meet all of the following:
1. Member is 2 years of age or older
2. Member weighs 9 kg or more [PAS note- add a field for submitter to provide member weight]
3. Diagnosis of Rett syndrome (RTT) with both of the following:
   a. Genetic analysis demonstrating mutation(s) in the methyl-CpG binding protein-2 (MECP2) gene (documentation of genetic confirmation required)
   b. Diagnosis of Typical or Classic Rett syndrome with a period of regression followed by recovery or stabilization, confirmed by ALL of the following:
      - Partial or complete loss of acquired purposeful hand skills
      - Partial or complete loss of acquired spoken language
      - Gait abnormalities: impaired or absence of ability to walk
      - Hand wringing/squeezing/clapping/tapping, mouthing, and/or washing/rubbing that seems habitual or uncontrollable
4. Prescribed by, or in consultation with, a neurologist or specialist with expertise in the management of RTT
5. Prescriber attests that member does not have any of the following:
   - Brain injury secondary to trauma (peri-or postnatally), neurometabolic disease, or severe infection that causes neurological problems
   - Moderate to severe renal impairment (eGFR < 45 mL/minute/1.73 m2)
6. Requested quantity does not exceed 120 mL per day or 8 bottles (450 mL) per 30 days

Reauthorization – 12 months
Must meet all of the following:
1. History of the requested agent for at least 90 days of the past 120 days, as confirmed by claims history or chart documentation (excluding claims with an emergency supply indicator)
2. Prescriber has submitted clinical documentation demonstrating ONE of the following (documentation must be provided):
   - Member has achieved disease stability
   - Member has achieved clinically significant improvement in core symptoms
   - Member has experienced less than expected decline in disease progression
3. Prescriber attests that member does NOT have any of the following:
   - Brain injury secondary to trauma (peri-or postnatally), neurometabolic disease, or severe infection that causes neurological problems
   - Moderate to severe renal impairment (eGFR < 45 mL/minute/1.73 m2)
4. Requested quantity does not exceed 120 mL per day or 8 bottles (450 mL) per 30 days

Commercial

Initial Authorization – 3 months
1. Diagnosis of Rett syndrome [submission of medical records (e.g., chart notes)]
2. Patient is 2 years of age or older
3. One of the following:
   a. Submission of medical records (e.g., chart notes) confirming presence of ALL of the following clinical signs and symptoms:
      - A pattern of development, regression, then recovery or stabilization
      - Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
      - Partial or complete loss of spoken language

- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

b. Submission of medical records (e.g., chart notes) documenting molecular genetic testing confirms mutations in the MECP2 gene

4. Prescribed by or in consultation with one of the following:
   a. Geneticist
   b. Neurologist

Reauthorization – 12 months

1. Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

Dupixent (dupilumab) new indication for the add-on maintenance treatment of inadequately controlled chronic obstructive pulmonary disease (COPD), (e.g., chronic bronchitis or emphysema) in patients with eosinophilic phenotype

State A

Initial Criteria: 6 months

1. Chronic Obstructive Pulmonary Disease (COPD) Initial Criteria
2. Patient is ≥ 18 years of age
3. Diagnosis of COPD AND Eosinophilic phenotype confirmed by peripheral blood eosinophil levels > 300 cells/mcL
4. COPD is inadequately controlled as shown by one of the following:
   a. Two or more exacerbations requiring systemic corticosteroids and/or antibiotics within the past 12 months
   b. COPD-related emergency treatment (e.g., hospitalization in the past 12 months, mechanical ventilation)
5. Patient is currently receiving standard of care COPD treatment, unless contraindicated (i.e., ICS/LAMA/LABA)
6. Post-bronchodilator FEV1/FVC ratio < 79%
7. Medication will be used as maintenance add-on therapy

Renewal Criteria:

1. Positive clinical response to treatment (e.g., improved FEV1 from baseline, reduction in COPD exacerbations)
2. Patient is currently receiving standard of care COPD treatment, unless contraindicated (i.e., ICS/LAMA/LABA)
3. Medication will be used as maintenance add-on therapy

Commercial

Approval Criteria

1. Diagnosis of chronic obstructive pulmonary disease (COPD)
2. Patient demonstrates a positive clinical response to therapy (e.g., improved lung function, a reduction in COPD exacerbations)
3. Patient continues to receive one of the following therapies at an optimized dose:
   a. Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA)
   b. If ICS are contraindicated, a LAMA and a LABA
4. Prescribed by or in consultation with a pulmonologist

Fintepla (fenfluramine)

- Dravet Syndrome Indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.
- Lennox-Gastaut Syndrome Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.

Time Period 7/1/2024 to 12/31/2024

Drug Name	Total Rx	Paid Amount	Paid/Rx	Avg Qty/DS	Utilizers	Age Range
Fintepla sol 2.2mg/ml	10	$177,113.12	$17,711.31	330 ml/30 days	3	10 – 16
Epidiolex sol 100mg/ml	316	$888,581.91	$2,811.97	198 ml/24 days	50	3 – 39
Banzel tab	12	$48,009.42	$4,000.79	195 per 30 days	1	18
Banzel susp	6	$10,133.43	$1,688.91	460 per 17 days	1	11
rufinamide tab	57	$14,929.95	$261.93	194 per 29 days	11	12 – 32
rufinamide susp	72	$24,348.91	$338.18	800 per 23 days	11	8 – 29
Briviact (brivaracetam) tab	96	$145,480.9175	$1,515.43	81 per 28 days	22	10 – 55
Briviact sol	28	$27,070.06	$966.79	303 per 23 days	6	6 – 27
Diacomit (stiripentol) ***-Dravet syndrome***	0					
clobazam tab	365	$11,566.34	$31.69	67 per 29 days	74	12 – 32
clobazam susp	409	$19,767.73	$48.33	238 per 23 days	64	4 – 63
Onfi susp	7	$8,304.11	$1,186.30	67 per 29 days	1	11
Onfi tab	6	$20,702.28	$3,450.38	60 per 30 days	1	20
Sympazan film	40	$71,480.29	$1,787.018	84 per 27 days	7	8 – 31
divalproex Depakote cap/tab ***-Dravet syndrome***	2,305	$65,808.38	$28.55	90 per 28 days	413	1 – 81
felbamate tab	74	$8,068.54	$109.03	160 per 31 days	15	3 – 45
felbamate susp ***-Lennox-Gastaut syndrome***	35	$6,187.79	$176.79	450 per 30 days	8	9 – 32
lamotrigine/Lamictal ***-Lennox-Gastaut syndrome***	5,194	$148,484.38	$28.59	62 per 30 days	1,089	3 – 88
levetiracetam/Keppra/Spritam	2,421	$57,656.63	$23.82	91 per 31 days	544	4 – 69
levetiracetam/Keppra sol	1,139	$52,638.96	$46.22	389 per 27 days	229	0 – 58
topiramate cap/tab	3,897	$48,735.45	$12.51	59 per 31 days	1,029	4 – 75
topiramate cap ER/XR	141	$43,758.81	$310.35	42 per 29 days	41	7 – 55
Eprontia sol ***-Lennox-Gastaut syndrome***	19	$3,994.91	$210.26	110 per 31days	9	4 – 28
valproic acid cap	51	$1,809.39	$35.48	127 per 28 days	23	22 – 64
valproic acid sol ***-Dravet syndrome***	197	$5,752.59	$29.20	589 per 22 days	55	3 – 46
zonisamide cap	320	$6,029.57	$18.84	95 per 32 days	62	7 – 58
Zonisade susp	122	$87,318.13	$715.72	320 per 23 days	21	1 – 38

*Red font denotes drug is on PA

State A

Approval Criteria

1. An FDA approved diagnosis of 1 of the following:
   - Dravet syndrome; OR
   - Lennox-Gastaut syndrome (LGS); AND
2. Member must be 2 years of age or older; AND
3. Initial prescription must be written by, or in consultation with, a neurologist; AND
4. Member must not be taking monoamine oxidase inhibitors (MAOIs) within 14 days of administration of Fintepla®; AND
5. Prescriber must verify the member's blood pressure will be monitored; AND
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; AND
7. For a diagnosis of Dravet syndrome, member must have failed or be inadequately controlled with at least 2 other anticonvulsants; AND
8. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; AND
9. Pharmacy and prescriber must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; AND
10. Member must be enrolled in the Fintepla® REMS program; AND
11. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; AND
12. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; AND
13. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; AND
14. A quantity limit of 360mL per 30 days will apply

State B

Approval Criteria

1. Must meet ONE of the following:
   a. Diagnosis of seizures associated with Dravet syndrome AND one of the following:
      - Previous trial and failure of Epidiolex (cannabidiol) AND Diacomit (stiripentol), confirmed by claims history or chart documentation
      - Prescriber has submitted valid medical justification for the use of Fintepla (fenfluramine) over Epidiolex (cannabidiol) AND Diacomit (stiripentol)
   b. Diagnosis of seizures associated with Lennox-Gastaut syndrome AND one of the following:
      - Previous trial and failure of Epidiolex (cannabidiol), confirmed by claims history or chart documentation
      - Prescriber has submitted valid medical justification for the use of Fintepla (fenfluramine) over Epidiolex (cannabidiol)

Reauthorization

1. History of the requested antiseizure agent for 30 of the past 60 days, as confirmed by claims history or chart documentation

State C

Approval Criteria – 6 months

1. Patient must be 2 years of age or older
2. Diagnosis of ONE of the following:
   - Dravet syndrome (DS)
   - Lennox-Gastaut syndrome (LGS)
3. Prescribed by a neurologist or epileptologist
4. Patient has not received MAOI therapy within 14 days and will not receive during Fintepla therapy
5. Prescriber attests that baseline echocardiogram has been completed and will be monitored throughout treatment, and 3 to 6 months after final
6. Patient has had inadequate response to trials of 2 preferred anticonvulsant agents

Reauthorization – 6 months

1. Patient continues to meet initial criteria
2. Patient is responding to therapy (e.g., reduced seizure frequency and/or duration)
3. Patient has no treatment-limiting adverse effects (e.g., serotonin syndrome, abnormal AST/ALT, CrCl, abnormal echocardiogram)

Commercial

Approval Criteria – Dravet syndrome

1. Diagnosis of seizures associated with Dravet syndrome
2. Patient is 2 years of age or older
3. One of the following:
   a. Both of the following:
      i. Trial and failure, contraindication or intolerance to one of the following:
         - clobazam, valproic acid
      ii. Trial and failure, contraindication or intolerance to one of the following:
         - Diacomit (stiripentol), Epidiolex (cannabidiol), Briviact (brivaracetam)
         - levetiracetam, topiramate, zonisamide
   b. For continuation of prior therapy
4. Prescribed by or in consultation with a neurologist

Reauthorization

1. Patient demonstrates positive clinical response to therapy as evidenced by the reduction in seizure frequency from baseline

Approval Criteria – Lennox-Gastaut syndrome

1. Diagnosis of seizures associated with Lennox-Gastaut syndrome
2. Patient is 2 years of age or older
3. ONE of the following:
   - Trial and inadequate response, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate)
   - For continuation of prior therapy
4. Prescribed by or in consultation with a neurologist

Reauthorization

1. Patient demonstrates positive clinical response to therapy as evidenced by the reduction in seizure frequency from baseline

State D

Approval Criteria

1. Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:
    1.1. Diagnosis of seizures associated with Dravet syndrome
    1.2. History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies)*:
        - divalproex
        - Epidiolex
        - levetiracetam
        - topiramate
        - valproic acid
        - zonisamide
    1.3. ONE of the following:
        1.3.1. BOTH of the following:
            1.3.1.1. Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
            1.3.1.2. Lack of compliance as a reason for treatment failure has been ruled out

        OR

        1.3.2. BOTH of the following:
            1.3.2.1. Documentation of failure of preferred formulary alternatives due to intolerable side effects
            1.3.2.2. Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

2. Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:
    2.1. Diagnosis of seizures associated with Lennox-Gastaut syndrome
    2.2. History of greater than or equal to 8-week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies)*:
        - Banzel (rufinamide)
        - clobazam
        - divalproex
        - Epidiolex
        - felbamate
        - lamotrigine
        - topiramate
        - valproic Acid
    2.3. ONE of the following:
        2.3.1. BOTH of the following:
            2.3.1.1. Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
            2.3.1.2. Lack of compliance as a reason for treatment failure has been ruled out

        OR

        2.3.2 BOTH of the following:
            2.3.2.1 Documentation of failure of preferred formulary alternatives due to intolerable side effects
            2.3.2.2 Lack of compliance as a reason for treatment failure has been ruled out

OR

3. For continuation of prior therapy for a seizure disorder

Voquezna (vonoprazan)

- for Helicobacter pylori (H. pylori) eradiation as part of dual or triple therapy
- for the treatment of erosive esophagitis (EE or erosive GERD) and pyrosis (heartburn) associated with EE
- to maintain healing of all grades of erosive esophagitis (EE) and relief of heartburn associated with EE
- for the treatment of non-erosive gastroesophageal reflux disease (GERD)

Time Period 10/1/2024 to 12/31/2024

Drug Name	Total Rx	Paid Amount	Paid/Rx	Avg Qty/DS	Utilizers	Age Range
Voquezna 10mg	3	$1,903.54	$634.54	30 per 30 days	2	14, 32
Voquezna 20mg	12	$7,065.16	$588.76	28 per 28 days	8	14 – 61
Dexilant cap	7	$2,144.85	$306.41	30 per 30 days	2	47 – 48
dexlansoprazole cap	252	$41,300.14	$163.89	31 per 28 days	95	0 – 102
esomeprazole cap	578	$8,981.86	$15.54	35 per 29 days	249	1 – 70
esomeprazole **granules**	47	$9,770.66	$207.89	34 per 32 days	27	0 – 43
Nexium cap	9	$2,474.54	$274.95	30 per 30 days	2	34, 45
Nexium granules	10	$4,448.07	$444.81	48 per 29 days	2	0, 1
lansoprazole cap	519	$7,418.55	$14.29	41 per 32 days	241	1 – 91
lansoprazole tab	1	$142.33	$142.33	60 per 30 days	1	54
lansoprazole **ODT**	77	$6,958.80	$90.37	40 per 30 days	33	0 – 63
pantoprazole susp **PAK**	3	$489.24	$163.08	22 per 22 days	3	18 – 48
pantoprazole cap	2,165	$26,564.84	$12.27	42 per 33 days	1,049	9 – 96
Prilosec **powder**	9	$6,328.85	$703.21	53 per 30 days	5	0 – 11
omeprazole cap	5,733	$65,111.57	$11.36	38 per 32 days	2,839	0 – 100
Konvomep **supsension** (omeprazole-sodium bicarb)	147	$50,221.65	$341.64	260 per 27 days	66	0 – 47
rabeprazole tab	122	$2,447.86	$20.06	48 per 32 days	58	11 – 64

*Red font denotes drug is on PA/ST

Time Period 10/1/2024 to 12/31/2024

Drug Name	Total Rx	Paid Amount	Paid/Rx	Avg Qty/DS	Utilizers	Age Range
Voquezna Dual Pak amoxicillin/vonoprazan	0					
Voquezna Triple Pak amoxicillin/clarithromycin/ vonoprazan	0					
Helidac Therapy bismuth subsalicylate-metronidazole/tetracycline	0					
bismuth subcitrate/ metronidazole/tetracycline (**Pylera**)	2	$1,085.49	$542.75	144 per 12 days	2	37 – 38
Omeclamox-Pak amoxicillin/clarithromycin/ omeprazole	0					
Talicia amoxicillin/rifabutin/ omeprazole	0					

SDM PPI PA Criteria

1. Diagnosis of one of the following
   - Erosive esophagitis
   - Barrett's esophagitis
   - Zollinger-Ellison Syndrome
2. OR Trial and failure (after a minimum of 14 days) in the past year with at least one of the following generics:
   - omeprazole
   - pantoprazole
   - rabeprazole
   - lansoprazole
   - esomeprazole
3. OR Patient has experienced an adverse reaction (must be documented on a MedWatch form), allergy or contraindication to ALL of the following:
   - omeprazole
   - pantoprazole
   - lansoprazole
   - rabeprazole
   - esomeprazole
4. OR for granules, ODT, PAK, powder, suspension – for children or patients with dysphagia

State A

Approval Criteria – 8 weeks to 6 months based on diagnosis

1. Diagnosis of erosive esophagitis with gastroesophageal reflux disease (GERD) symptoms needing active treatment of maintenance of healing of erosive esophagitis and one of the following:
   - Member has tried and failed two standard dose proton pump inhibitors (PPI) for total of 8 weeks in the past 6 months, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
   - Prescriber has submitted medical justification for use of Voquezna (vonoprazan) over ALL PPIs (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes)
2. Requested dose and duration of therapy will not exceed one of both (as applicable) of the following:
   - Active treatment of erosive esophagitis: 20 mg once daily for 8 weeks
   - Maintenance treatment of healed erosive esophagitis: 10 mg once daily for 6 months
3. Member is 18 years of age or older

Approval Criteria – 4 weeks of therapy every 6 months

1. Diagnosis of symptomatic non-erosive esophagitis with gastroesophageal reflux disease (GERD) requiring heartburn relief and one of the following:
   - Member has tried and failed two standard dose proton pump inhibitors (PPI) for total of 8 weeks in the past 6 months, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
   - Prescriber has submitted medical justification for use of Voquezna (vonoprazan) over ALL PPIs and/or H2Ras (any medical justification regarding intolerance of adverse effects must be supported by documentation within submitted chart notes)
2. Requested dose and duration of therapy will not exceed 10 mg once daily for 4 weeks
3. Member is 18 years of age or older

State B

Approval Criteria – Voquezan Dual, Triple Pak or Voquezna 20mg tablet – one month

1. Diagnosis of Helicobacter pylori infection
2. Trial and failure, contraindication, or intolerance to ONE of the following first line treatment regimens
    - Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]
    - Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

Approval Criteria – Voquezna 20mg tablet – 8 weeks

1. Diagnosis of erosive esophagitis
2. Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis:
    - Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection
    - Used in combination with amoxicillin for the treatment of H. pylori infection
3. Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's)
    - omeprazole
    - esomeprazole
    - pantoprazole
    - lansoprazole
    - rabeprazole
    - dexlansoprazole

Approval Criteria – Voquezna 10mg tablet – 6 months

1. Used to maintain healing and relief of heartburn associated
2. Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's)
    - omeprazole
    - esomeprazole
    - pantoprazole
    - lansoprazole
    - rabeprazole
    - dexlansoprazole

Approval Criteria – Voquezna 10mg tablet – 1 month

1. Diagnosis of non-erosive Gastroesophageal Reflux Disease (GERD)
2. Both of the following:
    - Patient has history of heartburn for at least 6 months
    - Heartburn symptoms are present for at least 4 days during any consecutive 7-day period
3. Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's)
    - omeprazole
    - esomeprazole
    - pantoprazole
    - lansoprazole
    - rabeprazole
    - dexlansoprazole

State C

Approval Criteria – Voquezna 10mg and 20mg – 2 months

1. Patient is 18 years of age or older
2. Request is for active treatment of erosive esophagitis
3. Trial and failure, contraindication, or intolerance to TWO preferred proton pump inhibitors (e.g. Dexilant, esomeprazole, lansoprazole, omeprazole, and pantoprazole)

Approval Criteria – Voquezna 10mg tablet – 6 months

1. Patient is 18 years of age or older
2. Request is for maintenance treatment of healed erosive esophagitis or non-erosive gastroesophageal reflux disease (GERD)
3. Trial and failure, contraindication, or intolerance to TWO preferred proton pump inhibitors (e.g. Dexilant, esomeprazole, lansoprazole, omeprazole, and pantoprazole)

Approval Criteria – Voquezna Dual and Triple Pak – 14 days

1. Documentation of recent positive H. Pylori test
2. Trial and failure, contraindication, or intolerance to one preferred combination agent

Optum Rx®

Therapeutic Class Overview

Insulin- Like Growth Factor-1 agents

Introduction

- Insulin-like growth factor 1 (IGF-1) is a hormone that plays a pivotal role in fetal development, adolescent growth, and adult tissue homeostasis. Imbalance in IGF production is associated with various pathologic conditions such as short stature, insufficient skeletal acquisition, alternations in body composition, metabolic disorders and reduced mental and physical capacity (*Yakar and Adamo 2012*).
- Growth hormone insensitivity (GHI) is a group of rare autosomal recessive disorders in which there is a reduction in or absence of the biologic effects of GH despite normal levels of GH. This is generally caused by loss-of-function mutations in the GH receptor gene or its downstream mediators, namely *IGF-1*, *STAT5b*, or *IGFALS*. In affected children, IGF-1 levels are abnormally low, referred to as primary IGF-1 deficiency, in that, no chronic medical condition can be identified causing the low levels. The most common form is known as Laron's syndrome; where abnormal GH receptor gene makes patients resistant to GH, resulting in low levels of IGF-1. There are less than 500 known cases of Laron Syndrome worldwide; 65% have Middle Eastern ancestry or are of Ecuadorian decent (*Food and Drug Administration [FDA] medical review 2005, National Organization for Rare Diseases [NORD] 2016*, *Richmond and Rogol 2022*).
- Severe primary IGF-1 deficiency is defined as both height and serum IGF-1 levels ≤ -3 standard deviations (SD) despite normal or elevated GH levels. Guidelines indicate basing diagnosis primary IGF deficiency on a combination of factors (eg, abnormally low serum IGF-1, secondary causes excluded, presence of characteristic features [eg, microcephaly, protruding forehead, saddle nose, small chin, high pitched voice]) (*Grimberg et al 2016)*.
- Increlex (mecasermin) is a recombinant IGF-1 recommended for children with severe primary IGF-1 deficiency who are 2 years of age or older with open epiphyses and height and basal IGF-1 SD both ≤-3 due to GH gene deletion or who have developed neutralizing antibodies to GH (*Daybue prescribing information 2023*). Once diagnosed, patients should be treated chronically until epiphyseal plate closure (ie, until no further linear growth is possible) (*FDA Medical Review 2005*). If the cause of GHI has not been established, a trial of GH therapy may be recommended prior to initiating recombinant IGF-1 (*Grimberg et al 2016*).
- Rett syndrome is a neurodevelopmental disorder that affects mainly girls, and most cases result from mutations in the *MECP2* gene, but a small group are caused by mutations in *CDKL5* or *FOXG1* genes. Symptoms typically present between 6 and 18 months of age. Rett syndrome presents as loss of speech and hand use, stereotypic hand movements, and gait abnormalities. Additional features include deceleration of head growth, seizures, autistic features, and breathing abnormalities. There are 2 phenotypic types of Rett syndrome (*NORD 2023, Schultz and Suter 2022[a-b]*):
  - Typical (classic) form: Affected patients initially develop normally and then experience loss of speech and purposeful hand use and onset of stereotypic hand movement and gait abnormalities. Deceleration of head growth can be one of the first signs. Additional manifestations can include seizures, autistic features, intermittent breathing abnormalities, autonomic nervous system dysfunction, cardiac abnormalities, and sleep disturbances.
  - Atypical form: Often presents similarly to the typical form but may not have all of the clinical features of the typical form.
- Rett syndrome is the second most common cause of severe intellectual disability after Down syndrome. The incidence of Rett syndrome in the United States is estimated to be 1 in 10,000 girls by age 12. In a report from a large population-based registry in Texas, the prevalence of classic Rett syndrome was estimated as 1 per 22,800 females ages 2 through 18 years, or 0.44 per 10,000. The prevalence per 10,000 girls was 0.56 in France, 0.65 in Sweden and Scotland, and 0.72 in Australia (*NORD 2023, Schultz and Suter 2023[a-b]*).
- Daybue (Trofinetide) is the first therapy FDA-approved for Rett syndrome. Trofinetide is a synthetic analog of the amino-terminal tripeptide of IGF-1, which occurs naturally in the brain. The mechanism by which trofinetide exerts its therapeutic effect in Rett syndrome is unknown (*Daybue prescribing information 2023*). Currently, the mainstay of treatment includes symptomatic treatment. Specific issues that commonly require attention include growth failure and nutrition, bone quality, epilepsy, breathing dysfunction, cardiac abnormalities, scoliosis, sleep disturbance, and motor dysfunction. Therapy in areas of communication, physical and occupational disciplines may be warranted (*Schultz and Suter 2023[a-b]*).
- The marketing and distribution of mecasermin rinfabate (Iplex) was discontinued in the United States due to legal reasons between manufacturers (*Pollack 2007*).
- Medispan Class: Insulin-Like Growth Factors (Somatomedins)

Table 1. Medications Included Within Class Review

Drug	Alternative Available (same molecular entity)*
Daybue (trofinetide) oral solution	-
Increlex (mecasermin) injection	-

*For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.

(*Drugs@FDA 2024, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2024*)

Indications

Table 2. Food and Drug Administration Approved Indications

Indication	Daybue (trofinetide)	Increlex (mecasermin)
Treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency* or with GH gene deletion who have developed neutralizing antibodies to GH. †		✔
Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older	✔	

*Defined as height SD score and basal IGF-1 SD score ≤ -3 with normal or elevated GH.
†Limitations of use: not a substitute to GH for approved GH indications, and not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids

(*Prescribing information: Daybue 2023, Increlex 2024*)

- 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 FDA-approval of mecasermin was based on pooled efficacy analysis of 5 clinical studies (4 open-label [OL] and 1 double-blind [DB], placebo-controlled [PC] trials) in pediatric patients with severe primary IGF-1 deficiency. Patients were enrolled in the trials based on extreme short stature, slow growth rates, low IGF-1 serum concentrations, and normal GH levels. This study integrated 23 patients from 4 preceding OL clinical studies (treated with mecasermin twice daily for up to 2 years) into a single study named 1419 (N = 48) for a total of 71 patients. The primary endpoint was the increase in height velocity (*FDA medical review 2005, Increlex prescribing information 2024*).
  - Sixty-one patients had at least 1 year of treatment. Fifty-three (87%) had Laron Syndrome; 7 (11%) had GH gene deletion, and 1 (2%) had neutralizing antibodies to GH. Thirty-seven (61%) were male; forty-eight (79%) were Caucasian. Fifty-six (92%) patients were prepubertal at baseline.
  - Annual height results showed a statistically significant improvement in height velocity (cm/year) compared to baseline for years 1 to 6, but not year 7 or 8.
    - Year 1: + 5.2 cm/year, n = 58, p < 0.0001
    - Year 2: + 2.9 cm/year, n = 48, p < 0.0001
    - Year 3: + 2.3 cm/year, n = 38, p < 0.0001
    - Year 4: + 1.5 cm/year, n = 23, p = 0.0045
    - Year 5: + 1.5 cm/year, n = 21, p = 0.0015
    - Year 6: + 1.5 cm/year, n = 20, p = 0.0009
    - Year 7: + 1.0 cm/year, n = 16, p = 0.0897
    - Year 8: + 0.7 cm/year, n = 13, p = 0.3059
  - The major secondary analysis was the assessment of change in height SD score. The mean SD scores increased from -6.7 at baseline to a mean of -5.9 at year 1 and maintained through year 8. Bone maturation rate was also assessed in 49 patients, with bone age increasing 8.1% faster than chronological age (5.3 vs 4.9 years, respectively). Of note, approximately 42% of patients reported at least one hyperglycemic episode during their course of therapy.

- A multicenter, OL study evaluated the long-term efficacy of mecasermin in 76 children (treated for up to 12 years) with IGF-1 deficiency due to GH insensitivity. Inclusion criteria included patients over the age of 2 years old with SD scores for height and circulating IGF-I concentration less than - 2 for age and sex, and evidence of resistance to GH. The primary outcome was the increase in height velocity (*Chernausek et al 2007*).
  - The baseline height velocity (2.8 cm/year on average) increased to 8.0 cm/year during the first year of treatment ($p < 0.0001$). The median increment in first-year height velocity over baseline was 5.3 cm/year (mean 5.2 cm/year; range -2.8 to 10.4).
  - The first-year growth was dose dependent, with those patients receiving 120 ug/kg twice daily growing the fastest ($p < 0.001$). For patients receiving an average dose of at least 100 ug/kg twice daily for 2 years (N = 19), first- and second year mean height velocities were 8.7 ± 1.7 and 6.1 ± 1.6 cm/year, respectively, significantly greater ($p < 0.0001$) than the baseline height velocity (2.8 ± 1.3 cm/year). Treatment effects persisted and remained above baseline up to year 8.
- A 1-year, randomized, OL trial evaluated the safety and efficacy of mecasermin in 136 pediatric patients aged 3 or older with SD scores for height and circulating IGF-I concentration less than - 2 and stimulated GH ≥ 7 ng/mL. Patients were randomized to observation or 1 of 2 doses of mecasermin; Initially, the 2 dose groups were 40 and 80 ug/kg. However, 40 ug/kg was replaced with 120 ug/kg by trial amendment when it was determined that the 40 ug/kg dose did not normalize serum IGF-I. The primary endpoint was the increase in first-year height velocity (centimeters per year, cm/year) (*Midyett et al 2010*).
  - Mean first-year height velocities were significantly increased for the 80 and 120 ug/kg groups vs the untreated group using the intention to treat population (N = 136; 6.9 ± 1.0, 7.7 ± 1.5, and 5.2 ± 1.0 cm/yr, respectively; $p < 0.0001$ vs the untreated group). Results were consistent with those patients who completed the study (N = 124; $p < 0.0001$ vs untreated group), and first-year height velocities were also significantly greater for the 120 vs the 80 g/kg group (1.0 cm/year; $p < 0.0002$).
- The approval of trofinetide was supported by results from the DB, PC, Phase 3, LAVENDER (N = 187) study that tested the efficacy and safety of trofinetide vs placebo in female patients with Rett syndrome, aged 5 to 20 years of age. A total of 93 patients were randomly assigned to trofinetide twice daily and 94 patients received placebo for 12 weeks. After 12 weeks, trofinetide showed a statistically significant improvement from baseline compared with placebo on both the caregiver-assessed Rett Syndrome Behavior Questionnaire (RSBQ; Least square mean difference [LSMD] vs placebo, -3.1; 95% confidence interval [CI], -5.7 to -0.6; p = 0.0175) and 7-point Clinical Global Impression-Improvement (CGI-I; LSMD, -0.3; 95% CI, -0.5 to -0.1; p = 0.003) scale (*Neul et al 2022, Neul et al 2023*).

Clinical Guidelines

- The 2016 Pediatric Endocrine Society guidelines for GH and IGF-1 treatment in children and adolescents: GH deficiency, idiopathic short stature, and primary insulin-like growth factor-1 deficiency recommends the use of IGF-1 therapy to increase height in patients with severe primary IGF-1 deficiency (*Grimberg et al 2016*).
  - Diagnosis of primary IGF-1 deficiency or GHI should be based on a combination of 4 factors including 1) screening (eg, growth parameters and low IGF-1 concentrations, 2) excluding causes of secondary IGF-1 deficiencies (eg, poor nutrition, hepatic disease, and GH deficiency), 3) circulating levels of GH binding protein (low levels suggesting Laron's Syndrome and normal levels considered non-informative), and 4) IGF-1 generation test and mutation analysis (limited usefulness).
  - A trial of GH therapy is recommended in patients with unexplained IGF-1 deficiency.
  - Patients with hormone signaling defects known to be unresponsive to GH treatment can start directly on IGF-1 replacement, including:
    - Very low or undetectable levels of GH binding protein and/or proven GH receptor gene mutations know to be associated with Laron Syndrome/GHI, GH-neutralizing antibodies, *STAT5b* gene mutations, and IGF1 gene deletion or mutation.
  - The guideline recommends a starting dose of 80 to 120 ug/kg 2 times daily, given after a carbohydrate containing meal. Patients and families should be educated on the symptoms and risks of hypoglycemia associated with treatment.
- The International Rett Syndrome Foundation published guidance and best practices to assist health professionals and families in care. The guidelines include a checklist and detailed references for guidance developed by consensus. The International Rett Syndrome Foundation states given the median life expectancy well into the sixth decade, guidance is provided to health professionals to achieve current best possible outcomes for these special-needs individuals.

Treatment is supportive and focuses on gastrointestinal, respiratory, neurological, cardiology, dermatological, orthopedics, urology, development and behavioral, sleep, pain, and physical symptoms and systems (*Fu et al 2020*).

Safety Summary

- Pediatric use: The safety and effectiveness of mecasermin or trofinetide have not been established in children less than 2 years of age.

Daybue (trofinetide)

- Warnings and precautions:
  - Diarrhea: Most patients experience diarrhea during treatment. Counsel to stop laxatives prior to initiating therapy. If diarrhea occurs, patients should start antidiarrheal treatment, increase oral fluids, and notify their healthcare provider. Interrupt, reduce dose, or discontinue trofinetide if severe diarrhea occurs or if dehydration is suspected.
  - Weight loss: may occur in patients treated with trofinetide. Monitor weight and interrupt, reduce dose, or discontinue therapy if significant weight loss occurs.
- Adverse effects
  - Most common in clinical trials: diarrhea and vomiting.

Increlex (mecasermin)

- Contraindications:
  - Hypersensitivity to mecasermin
  - Intravenous (IV) administration
  - Closed epiphyses
  - Malignant neoplasia (current or history of)
- Warnings and precautions:
  - Risk of hypoglycemia: due to insulin-like effects.
  - Hypersensitivity and allergic reactions, including anaphylaxis: Parents and patients should be informed that such reactions are possible and that if a systemic allergic reaction occurs, treatment should be interrupted and prompt medical attention should be taken.
  - Intracranial hypertension: funduscopic examination is recommended at the initiation and periodically during therapy.
  - Lymphoid tissue hypertrophy
  - Slipped capital femoral epiphysis (SCFE): characterized by limp or hip/knee pain.
  - Progression of scoliosis
  - Risk of malignant neoplasms: Several cases of malignant neoplasia have been observed in pediatric patients treated with mecasermin. Therapy should be discontinued if evidence of malignant neoplasia develops, and appropriate expert medical care sought.
  - Risk of serious adverse reactions (including death) in infants due to benzyl alcohol preserved solution: use in infants is not recommended.
- Adverse effects
  - Most common in clinical trials: hypoglycemia, local and systemic hypersensitivity, and tonsillar hypertrophy.

Dosing and Administration

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Daybue (trofinetide)	Solution	Oral	Twice daily in the morning and evening	Dosing is based on patient weight. May be administered with or without food. May be administered orally or via gastrostomy

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
				(G) tube through a G-port.
Increlex (mecasermin)	Injection	SC	Twice daily	Administer shortly before or after a meal or snack due to insulin-like hypoglycemic effect. Pre-prandial glucose monitoring is recommended at treatment initiation and until a well-tolerated dose is established. Injection sites should be rotated to a different site (upper arm, thigh, buttock, or abdomen) with each injection to help prevent lipohypertrophy.

See the current prescribing information for full details.

Conclusion

- IGF-1 is a hormone that manages the effects of GH. Together, they promote the normal linear growth of bones and tissues. GHI occurs when the body is unable to adequately use GH, generally caused by loss-of-function mutations.
- Mecasermin is an injectable recombinant IGF-1, that is FDA-approved for the long-term treatment of growth failure in pediatric patients with severe primary IGF-1 deficiency (defined as both height and serum IGF-1 concentration below –3 SD despite normal or elevated GH levels), or patients with GH gene deletion who developed neutralizing antibodies to GH after a trial of GH therapy. Eligible children must have an open epiphysis.
- In a pooled analysis of 5 clinical trials, mecasermin showed a statistically significant acceleration of linear growth as characterized by height velocity compared to baseline from year 1 through year 6. These results were also consistent in subsequent studies that demonstrated increased in mean first-year height velocities in patients with severe primary IGF-1 deficiency treated with 80 and 120 ug/kg twice daily mecasermin).
  - The safety and effectiveness have not been established in children less than 2 years of age.
  - Use in infants is not recommended due to risk of serious adverse reactions (including death) due to benzyl alcohol preservative content.
- The 2016 guidelines from the Pediatric Endocrine Society recommend starting directly on IGF-1 therapy to increase height in patients with severe primary IGF-1 deficiency and in patients with hormone signaling defects known to be unresponsive to GH treatment.
- Contraindications to the use of mecasermin include hypersensitivity to the drug, IV administration, individuals with closed epiphyses, or with current or history of cancer.
- IGF-1 is associated with insulin-like hypoglycemic effects, so it is recommended to be administered after a carbohydrate containing meal or snack.
- Long-term studies have demonstrated that recombinant IGF-1 (mecasermin) has proven efficacy in stimulating height velocity for a very small patient population that is affected by GHI characterized by a lack of normal growth due to mutations in GH receptor and IGF-1 and continues to be an important treatment option for these patients.
- Rett syndrome is a rare developmental disorder, and the second leading cause of intellectual disability in girls. Treatment is mostly supportive care across a wide range of body systems. In the LAVENDER trial, trofinetide demonstrated a statistically significant improvement from baseline in Rett Syndrome behaviors as assessed by caregiver questionnaire (RSBQ) and CGI-I scales; offering patients and families a potential option to treat a debilitating

range of symptoms. Trofinetide is administered orally twice daily, and most patients will experience diarrhea during treatment.

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Optum Rx®

Therapeutic Class Overview

Respiratory and allergy biologics

Introduction

- The respiratory and allergy biologics (ie, antiasthmatic monoclonal antibodies) include the interleukin-5 (IL-5) antagonists Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab), the immunoglobulin E (IgE) inhibitor Xolair (omalizumab), the interleukin-4 (IL-4) inhibitor Dupixent (dupilumab), and the thymic stromal lymphopoietin (TSLP) blocker Tezspire (tezepelumab-ekko).
  - Respiratory and allergy biologics are a mainstay of treatment for severe asthma; in addition, various agents in this class are also indicated for use in chronic idiopathic urticaria (CIU), eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyposis (CRSwNP), hypereosinophilic syndromes (HES), eosinophilic esophagitis (EoE), IgE-mediated food allergy, and chronic obstructive pulmonary disease (COPD).
- Asthma is a chronic lung disease that inflames and narrows the airways, making it difficult to breathe. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages but most often starts during childhood. In 2021, asthma affected an estimated 20.3 million adults and 4.6 million children in the United States (U.S.). The exact causes of asthma are unknown. A combination of factors such as genetics, certain respiratory infections during childhood, and contact with airborne allergens can contribute to its development. Most patients with asthma also have allergies (*Centers for Disease Control and Prevention Web site 2024, National Heart, Lung, and Blood Institute [NHLBI] Web site 2024*).
- Pharmacologic options for asthma management are categorized as: (1) controller medications to achieve and maintain control of persistent asthma or prevent exacerbations (also referred to as maintenance treatment, as appropriate), and (2) reliever medications for symptom relief and before exercise to prevent exercise-induced asthma symptoms (also referred to as rescue inhalers) (*Cloutier et al 2020, NHLBI 2007, Global Initiative for Asthma [GINA] 2024*).
  - Controller medications include:
    - Corticosteroids (inhaled corticosteroids [ICSs], or oral corticosteroids for severe exacerbations or severely uncontrolled asthma)
    - Long-acting beta$_2$-agonists (LABAs) in combination with ICS (ICS/LABA)
    - Leukotriene receptor antagonists (LTRAs) in select patients
    - Add-on immunomodulators (ie, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko) in patients with severe asthma
    - Add-on tiotropium
    - Add-on azithromycin
  - Reliever medications include:
    - Short-acting beta$_2$-agonists (SABAs)
      - The GINA report no longer recommends treatment of asthma in adults and adolescents with a SABA alone. All adults and adolescents with asthma should receive ICS-containing reliever treatment (referred to by GINA as an anti-inflammatory reliever therapy) to reduce the risk of serious exacerbations and to control symptoms.
    - Anti-inflammatory relievers (AIRs) that contain both a low-dose ICS and a rapid-acting bronchodilator, including ICS (ie, budesonide)/formoterol and ICS/albuterol combinations
    - Short-acting muscarinic antagonists (ie, ipratropium bromide) as an alternative bronchodilator for those not tolerating a SABA (these agents have a slower onset of action vs SABA)
- Approximately 3.7% of asthma patients have severe disease and 17% have difficult-to-treat asthma. Difficult-to-treat asthma is asthma that is uncontrolled despite prescribing of medium- or high-dose ICS with a second controller (usually a LABA) or with maintenance OCS, or that requires high-dose treatment to maintain good symptom control and reduce exacerbations. Severe asthma is a subset of difficult-to-treat asthma; it is defined as asthma that is uncontrolled despite adherence with maximal optimized high-dose ICS/LABA treatment and management of contributory factors, or that worsens when high-dose treatment is decreased (*GINA 2024*).
  - While there are currently no widely accepted definitions of specific asthma phenotypes, several strategies have been proposed to categorize severe asthma phenotypes based on characteristics such as patient age, disease onset, corticosteroid resistance, chronic airflow obstruction, or type of cellular infiltrate in the airway lumen or lung tissue (*Walford et al 2014*). GINA guidelines on severe or difficult-to-treat asthma recommend assessing for Type 2 inflammation through blood and sputum eosinophil levels, exhaled nitric oxide levels, and allergic triggers to asthma (*GINA 2024*).

- CIU, also called chronic spontaneous urticaria (CSU), is defined by the presence of hives on most days of the week for 6 weeks or longer, with or without angioedema. The hives are circumscribed, raised, erythematous plaques, often with central pallor and variable in size. No external allergic cause or contributing disease process can be identified in 80 to 90% of adults and children with CIU (*Khan 2023, Saini 2024*).
  - CIU affects up to 1% of the general population in the U.S., and the prevalence is believed to be similar in other countries. The condition is more common in adults than children and typically begins in the third to fifth decades of life. CIU is a self-limited disorder in most patients although the condition generally has a prolonged duration of 2 to 5 years (*Saini 2024*).
  - Non-sedating H_1-antihistamines are the cornerstone of therapy for CIU. Limited courses of oral glucocorticoids are often used in combination with antihistamines for refractory symptoms. Other pharmacologic options for patients who do not respond to H_1-antihistamines include the use of H_2-antihistamines, leukotriene modifiers, cyclosporine, tacrolimus, mycophenolate, hydroxychloroquine, sulfasalazine, dapsone, and omalizumab (*Khan 2023, Maurer et al 2013, Sabroe et al 2021, Zuberbier et al 2022*).
- EGPA, previously called Churg-Strauss syndrome, is a systemic necrotizing vasculitis that affects small-to-medium-sized vessels. It is typically associated with eosinophilia and severe asthma (*Chung et al 2021, Connelly-Smith et al 2023, Groh et al 2015).*
  - EGPA is a rare condition with a prevalence of approximately 13 cases per 1 million persons and an annual incidence of approximately 7 new cases per 1 million persons. It has a higher incidence in patients with asthma (*Groh et al 2015*).
  - Systemic glucocorticoids are the mainstay of treatment for EGPA. For refractory EGPA, the addition of cyclophosphamide, azathioprine, mepolizumab, methotrexate, rituximab, or intravenous immunoglobulins (IVIG) can be considered *(Chung et al 2021, Groh et al 2015).* In more than 85% of patients with EGPA, remission can be achieved with glucocorticoids with or without an immunosuppressant; however, relapses occur in more than 33% of patients (*Pagnoux and Groh 2016*).
  - Biologic agents in this review that are Food and Drug Administration (FDA)-approved for EGPA include benralizumab and mepolizumab.
- CRSwNP has a prevalence of approximately 2.7% in adults, and peaks in the sixth decade of life. Symptoms include nasal obstruction, reduced sense of smell, and sleep disturbance, all of which can substantially impact the quality of life. The majority of cases are idiopathic but may be due to genetic, metabolic, or immunologic causes, resulting in inflammation characterized by eosinophilia and elevated levels of IL-4, IL-5, and interleukin-13 (IL-13) (*Hopkins 2019*).
  - Common treatment options for CRSwNP include saline irrigation and intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids, surgery, and biologic agents in patients with severe symptoms *(Hopkins 2019)*. Biologic agents in this review that are FDA-approved for CRSwNP include dupilumab, mepolizumab, and omalizumab.
- HES are disorders characterized by the overproduction of eosinophils, which causes organ damage (*Roufosse et al 2022*). Treatment for idiopathic HES may include systemic glucocorticoids, imatinib, hydroxyurea, interferon alfa, alemtuzumab, and Janus kinase inhibitors (eg, tofacitinib and ruxolitinib). Additionally, mepolizumab was FDA-approved for HES in 2020.
- EoE is a chronic allergic inflammatory disease in which eosinophils build up in the lining of the esophagus (*Hirano et al 2020a*). The presence of eosinophils cause inflammation in the esophagus, which may cause the following symptoms: vomiting, stomach or chest pain, failure to thrive (particularly in children), and difficulty swallowing. Front-line treatments for EoE include proton pump inhibitors and topical glucocorticoids. Additionally, dupilumab was FDA-approved for EoE in 2022.
- IgE-mediated food allergy is a leading cause of anaphylaxis (*Fleischer et al 2021, Sampson et al 2014*). Common food allergens include cow's milk, egg, peanut, tree nuts, fish/shellfish, wheat, sesame seed, and soy. Food-related reactions are associated with a broad range of signs and symptoms that can involve the skin, gastrointestinal tract, respiratory tract, and the cardiovascular system. Xolair is approved for IgE-mediated food allergy in adults and children ≥ 1 year of age for the reduction of allergic reactions with accidental exposure (*Xolair Prescribing Information 2024*). Guidelines for food allergies mostly focus on nutritional interventions and have not been updated to include recommendations for omalizumab.
- COPD is a chronic respiratory disease caused by abnormalities of the airways and/or alveoli. In 2021, 14.2 million adults in the U.S. (6.5% of the adult population) were estimated to have COPD (*Liu et al 2023*). Symptoms typically include dyspnea, chest tightness, fatigue, activity limitation, and cough with or without sputum production. Patients with COPD

may also experience exacerbations, which are periods of acute worsening of respiratory symptoms (*Global Initiative for Chronic Obstructive Lung Disease [GOLD] 2024*).
  - Treatment goals in COPD aim to reduce symptoms and the risk of future exacerbations. Choice of therapy depends on a patient's severity of dyspnea and risk of exacerbations, and often includes the use of inhaled bronchodilators (ie, long-acting muscarinic antagonists [LAMAs] or LABAs) and ICSs (*GOLD 2024*).
  - Type 2 inflammation is associated with an increased risk of exacerbations.
    - An estimated 885,000 (0.6% of the U.S. adult population) patients ≥ 40 years of age with COPD in the U.S. are treated with triple therapy; 36% (319,000) of these patients are in a subpopulation who have type 2 inflammation with blood eosinophils ≥ 300/µL and moderate-to-severe uncontrolled COPD (*Dupixent formulary dossier 2024*).
- Descriptions of the respiratory and allergy biologics are as follows:
  - Cinqair, Fasenra, and Nucala are humanized monoclonal antibody IL-5 antagonists. The mechanism of action of Fasenra is slightly different, in that it binds to the IL-5 receptor on immune effector cells, whereas Cinqair and Nucala bind to the IL-5 cytokine. Eosinophils play a key role in the pathobiology of airway disorders by contributing to inflammation through the release of leukotrienes and pro-inflammatory cytokines. Increases in eosinophils are often correlated with greater asthma severity. IL-5, a cytokine critical to eosinophil differentiation and survival, has been isolated as a potential target in eosinophilic asthma.
  - Xolair is a recombinant DNA-derived monoclonal antibody that selectively binds to human anti-IgE. Xolair, which reduces the allergic response mediators, is useful in a subset of patients with allergic asthma. In addition, Xolair is approved for CIU in patients ≥ 12 years of age who remain symptomatic despite antihistamine treatment, as add-on maintenance treatment of CRSwNP in adult patients with inadequate response to nasal corticosteroids, and for IgE mediated food allergy in patients ≥ 1 year of age for the reduction of allergic reactions with accidental exposure.
  - Dupixent is a human monoclonal antibody that inhibits signaling of IL-4 and IL-13. This results in a reduction of the release of inflammatory mediators including cytokines, chemokines, nitric oxide, and IgE. These actions are useful for eosinophilic asthma, EoE, add-on therapy for inadequately controlled COPD (with eosinophilic phenotype), and add-on therapy for inadequately controlled CRSwNP. Dupixent is also approved to treat moderate to severe atopic dermatitis and prurigo nodularis; these indications for dermatologic conditions are not discussed in this review.
  - Tezspire, a human monoclonal antibody, is a TSLP blocker. Tezspire binds to human TSLP, an epithelial cell-derived cytokine, and blocks its interaction with the TSLP receptor to reduce biomarkers and cytokines associated with inflammation (eg, blood and airway submucosal eosinophils, IgE, fractional exhaled nitric oxide [FeNO], IL-5, and IL-13); however, the mechanism of tezepelumab-ekko action in asthma has not been definitively established.
    - TSLP has also been shown to affect non-Type 2 inflammatory processes between airway structural and immune cells, and there are many cell types activated by, or that respond to, TSLP (including mast cells, basophils, natural killer T cells, innate lymphoid cells, and neutrophils) that may play a role in inflammation in asthma beyond Type 2 inflammation (*Corren et al 2017a, Menzies-Gow et al 2021*).
- Medispan class: Antiasthmatic – Monoclonal Antibodies

Table 1. Medications Included Within Class Review

Drug	Alternative Available (same molecular entity)*
Cinqair (reslizumab)	-
Dupixent (dupilumab)	-
Fasenra (benralizumab)	-
Nucala (mepolizumab)	-
Xolair (omalizumab)	-
Tezspire (tezepelumab-ekko)	-

*For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.

(*Drugs@FDA 2024, Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations 2024*)

Indications

Table 2. Food and Drug Administration Approved Indications

Indication	Cinqair† (reslizumab)	Dupixent (dupilumab)	Fasenra† (benralizumab)	Nucala (mepolizumab)	Xolair‡ (omalizumab)	Tezspire (tezepelumab-ekko)
Moderate to severe persistent asthma in patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with ICS					✔	
Add-on maintenance treatment for patients ≥ 6 years of age with severe asthma with an eosinophilic phenotype			✔			
Add-on maintenance treatment for patients ≥ 12 years of age with severe asthma						✔
Add-on maintenance treatment for patients ≥ 6 years of age with severe asthma with an eosinophilic phenotype				✔		
Add-on maintenance treatment for patients ≥ 6 years of age with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma		✔				
Add-on maintenance treatment for patients ≥ 18 years of age with severe asthma with an eosinophilic phenotype	✔					
Treatment of adult patients with EGPA			✔	✔		
Treatment of adults and adolescents ≥ 12 years of age with CIU who remain symptomatic despite					✔	

Indication	Cinqair† (reslizumab)	Dupixent (dupilumab)	Fasenra† (benralizumab)	Nucala (mepolizumab)	Xolair‡ (omalizumab)	Tezspire (tezepelumab-ekko)
H_1-antihistamine treatment.						
Add-on maintenance treatment in adult patients with inadequately controlled CRSwNP				✔	✔	
Add-on maintenance treatment in adult and pediatric patients ≥ 12 years old with inadequately controlled CRSwNP		✔				
Treatment of adult and pediatric patients ≥ 12 years of age with HES for ≥ 6 months without an identifiable non-hematologic secondary cause				✔		
Treatment of adult and pediatric patients ≥ 1 year of age and weighing ≥ 15 kg with EoE		✔				
IgE-mediated food allergy in adults and children ≥ 1 year of age for the reduction of allergic reactions with accidental exposure					✔	
Add-on maintenance treatment of adult patients with inadequately controlled COPD with an eosinophilic phenotype		✔				

* None of the agents are indicated for the relief of acute bronchospasm or status asthmaticus.
† Not indicated for the treatment of other eosinophilic conditions.
‡ Not indicated for other allergic conditions or other forms of urticaria. Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

(*Prescribing information: Cinqair 2020, Dupixent 2024, Fasenra 2024, Nucala 2023, Xolair 2024, Tezspire 2023*)

- 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

Xolair (omalizumab)

Asthma

- The original FDA approval of omalizumab was based on the results of 3 randomized, double-blind, placebo-controlled, multicenter trials conducted in patients ≥ 12 years of age with moderate to severe asthma for ≥ 1 year and a positive skin test reaction to a perennial aeroallergen. All patients were required to have a baseline IgE between 30 and 700 international unit (IU)/mL and body weight not more than 150 kg. Patients were treated according to a dosing table to administer at least 0.016 mg/kg/IU (IgE/mL) of omalizumab or placebo over each 4-week period.
  - Each study was comprised of a run-in period to achieve a stable conversion to a common ICS, followed by randomization to omalizumab or placebo. Patients received omalizumab for 16 weeks with an unchanged ICS dose unless an acute exacerbation necessitated an increase. Patients then entered an ICS reduction phase of 12 (*Busse et al 2001, Solèr et al 2001*) and 16 weeks (*Holgate et al 2004*) during which ICS dose reduction was attempted in a stepwise manner.
  - In the 28-week study by Busse et al (N = 525), during the steroid stable phase, patients treated with omalizumab had fewer mean exacerbations/subject (0.28 vs 0.54; p = 0.006) and decreased mean duration of exacerbations (7.8 vs 12.7 days; p < 0.001) compared with placebo-treated patients. Similarly, during the steroid reduction phase, omalizumab was associated with fewer exacerbations/subject (0.39 vs 0.66; p = 0.003), and a shorter mean duration of exacerbations (9.4 vs 12.6 days; p = 0.021) (*Busse et al 2001*).
  - In the 28-week study by Solèr et al (N = 546), asthma exacerbations/patient, the primary endpoint, decreased more in the omalizumab group compared to placebo during both the stable steroid (0.28 vs 0.66; p < 0.001) and steroid reduction phases (0.36 vs 0.75; p < 0.001) (*Solèr et al 2001*).
  - In the 32-week study by Holgate et al (N = 246), the percentage reduction in ICS dose, the primary endpoint, was greater among patients treated with omalizumab than among patients treated with placebo (median, 60% vs 50%; p = 0.003). The percentages of patients with ≥ 1 asthma exacerbation were similar between omalizumab and placebo groups during both the stable steroid and steroid reduction phases (p-value not reported). The absence of an observed treatment effect may be related to differences in the patient population compared with the first 2 studies, study sample size, or other factors (*Holgate et al 2004*).
- A meta-analysis of 3 of the previously mentioned trials (*Busse et al 2001, Holgate et al 2004, Solèr et al 2001*) and their extension studies assessed the efficacy of omalizumab in a subgroup of 254 patients at high risk of serious asthma-related mortality and morbidity. Patients were defined as high-risk due to asthma histories that included the following: intubation history, emergency room visit within the last year, overnight hospitalization, or intensive care unit treatment. The primary outcome was an annualized rate of acute exacerbation episodes based on data from the initial 16-week stable steroid phase for high-risk patients. Two kinds of acute exacerbation episodes were considered as endpoints: significant acute exacerbation episodes and all acute exacerbation episodes (ie, all episodes recorded by the investigator). Significant acute exacerbation episodes were defined as those requiring a doubling of baseline ICS dose (*Busse et al 2001, Solèr et al 2001*) or use of systemic steroids (all 3 studies). During the stable steroid phase, mean significant acute exacerbation episode rates were 1.56 and 0.69/patient-year, respectively, a reduction of 56% with omalizumab (p = 0.007). Similar reductions in exacerbations in favor of omalizumab were observed for the whole study period and for all acute exacerbation episodes. The authors concluded that 113 significant acute exacerbation episodes were prevented for every 100 patients treated with omalizumab for 1 year (*Holgate et al 2001*).
- A Cochrane Review conducted in 2014 evaluated the efficacy of omalizumab in patients with allergic asthma. Treatment with omalizumab was associated with a significant reduction in the odds of a patient having an asthma exacerbation (odds ratio [OR], 0.55; 95% confidence interval [CI], 0.42 to 0.6; 10 studies; 3261 participants). This represents an absolute reduction from 26% for participants suffering an exacerbation on placebo to 16% on omalizumab, over 16 to 60 weeks. Additionally, in patients with moderate to severe asthma and in those who were receiving background ICS therapy, treatment with omalizumab resulted in a significant reduction in the odds of having an asthma exacerbation (OR, 0.50; 95% CI, 0.42 to 0.6; 7 studies; 1889 participants). A significant benefit was noted for subcutaneous (SC) omalizumab vs placebo with regard to reducing hospitalizations (OR, 0.16, 95% CI, 0.06 to 0.42; 4 studies; 1824 participants), representing an absolute reduction in risk from 3% with placebo to 0.5% with omalizumab over 28 to 60 weeks. The authors concluded that omalizumab was effective in reducing asthma exacerbations and hospitalizations as an adjunctive therapy to ICS and significantly more effective than placebo in increasing the numbers of participants who were able to reduce or withdraw their ICS. Omalizumab was generally well tolerated, although there were more injection

site reactions with omalizumab. However, the clinical value of the reduction in steroid consumption must be considered in light of the high cost of omalizumab (*Normansell et al 2014*).

- A systematic review of 8 randomized, placebo-controlled trials (N = 3429) evaluated the efficacy and safety of SC omalizumab as add-on therapy to corticosteroids in children and adults with moderate to severe allergic asthma. At the end of the steroid reduction phase, patients taking omalizumab were more likely to be able to withdraw corticosteroids completely compared with placebo (relative risk [RR], 1.8; 95% CI, 1.42 to 2.28; p = 0.00001). Omalizumab patients showed a decreased risk for asthma exacerbations at the end of the stable (RR, 0.57; 95% CI, 0.48 to 0.66; p = 0.0001) and adjustable-steroid phases (RR, 0.55; 95% CI, 0.47 to 0.64; p = 0.0001); post-hoc analysis suggests this effect was independent of duration of treatment, age, severity of asthma, and risk of bias. The frequency of serious adverse effects was similar between omalizumab (3.8%) and placebo (5.3%). However, injection site reactions were more frequent in the omalizumab patients (19.9% vs 13.2%). Omalizumab was not associated with an increased risk of hypersensitivity reactions, cardiovascular effects, or malignant neoplasms (*Rodrigo et al 2011*).
- In July 2016, the FDA expanded the indication of omalizumab to patients 6 to 11 years of age with moderate to severe persistent asthma. The approval was based primarily on a 52-week, randomized, double-blind, placebo-controlled, multicenter trial. The study evaluated the safety and efficacy of omalizumab as add-on therapy in 628 pediatric patients 6 to < 12 years of age with moderate to severe asthma inadequately controlled despite the use of an ICS (*Lanier et al 2009*).
  - Over the 24-week fixed-steroid phase, omalizumab reduced the rate of clinically significant asthma exacerbations (worsening symptoms requiring doubling of baseline ICS dose and/or systemic steroids) by 31% vs placebo (0.45 vs 0.64; RR, 0.69; p = 0.007). Over a period of 52 weeks, the exacerbation rate was reduced by 43% (p < 0.001). Other efficacy variables such as nocturnal symptom scores, beta-agonist use, and forced expiratory volume in 1 second (FEV_1) were not significantly different in omalizumab-treated patients compared to placebo.
- A 2017 systematic review of 3 randomized, placebo-controlled trials and 5 observational studies evaluated the safety and efficacy of omalizumab in children and adolescents. Omalizumab reduced exacerbations compared with placebo or baseline in all studies that included this outcome. The randomized controlled trials (RCTs) did not identify significant differences in FEV_1; however, 3 of the 4 observational studies that included this outcome did find significant FEV_1 improvement with omalizumab. Generally, ICS and rescue medication use were reduced with omalizumab in the studies. The authors concluded that the evidence strongly supports omalizumab safety and efficacy in patients 6 to 11 years of age *(Corren et al 2017b)*.
- The EXCELS study was a multicenter, observational cohort study to evaluate the clinical effectiveness and long-term safety of omalizumab in patients with moderate-to-severe allergic asthma. Patients were evaluated as part of 3 groups: non-omalizumab users, those newly starting omalizumab, and those who have established users at study initiation.
  - Interim efficacy results demonstrated that at month 24, the Asthma Control Test (ACT) score increased in all 3 patient groups: from 18.4 to 20 in non-omalizumab users, from 15.2 to 19.4 in those newly starting on omalizumab, and from 18.2 to 19.4 in established omalizumab users. For patients newly starting omalizumab treatment, 54% achieved at least a minimally important difference, defined as a ≥ 3-point increase from baseline in ACT. The study demonstrated that established users of omalizumab maintained asthma control during the study period (*Eisner et al 2012*).
  - To investigate the relationship between omalizumab and malignant neoplasms, safety information from the EXCELS trial was analyzed. Similar rates of primary malignancies in omalizumab- and non-omalizumab-treated patients were found. However, study limitations preclude definitively ruling out a malignancy risk with omalizumab (*Long et al 2014*).
  - A higher incidence of overall cardiovascular and cerebrovascular serious adverse events was observed in omalizumab-treated patients compared to non-omalizumab-treated patients (*Iribarren et al 2017*). To further evaluate the risk, a pooled analysis of 25 RCTs was conducted. An increased risk of cardiovascular and cerebrovascular serious adverse events was not noted, but the low number of events, the young patient population, and the short duration of follow-up prevent a definite conclusion about the absence of a risk (*FDA 2014*).
  - Patients from the EXCELS study were eligible for the XPORT trial, a 52-week, randomized, placebo-controlled trial evaluating the persistence of response to omalizumab in patients who discontinued omalizumab therapy after long-term use. Patients were randomized to continue their omalizumab therapy or to omalizumab discontinuation. More patients who continued omalizumab did not have an exacerbation compared to those who discontinued therapy (67.0% vs 47.7%; absolute difference, 19.3%; 95% CI, 5.0 to 33.6). The authors concluded that continuation of omalizumab after long-term use results in sustained benefit (*Ledford et al 2017*).

CIU

- The safety and efficacy of omalizumab for the treatment of CIU was assessed in 2 placebo-controlled, multiple-dose clinical studies. Patients received omalizumab 75, 150, or 300 mg or placebo by SC injection every 4 weeks in addition to their baseline level of H_1 antihistamine therapy for 24 or 12 weeks, followed by a 16-week washout observation period. In both studies, patients who received omalizumab 150 mg or 300 mg had greater decreases from baseline in weekly itch severity scores and weekly hive count scores than placebo at week 12. The 75 mg dose did not demonstrate consistent evidence of efficacy and is not approved for use (*Kaplan et al 2013, Maurer et al 2013*).
- Another randomized, double-blind, placebo-controlled study evaluated omalizumab as add-on therapy for 24 weeks in patients with CIU who remained symptomatic despite H_1 antihistamine therapy. Similar to previous studies, patients treated with omalizumab had significantly greater reductions in weekly itch severity score from baseline to week 12 compared to placebo ($p \leq 0.001$) (*Saini et al 2015*).
- A meta-analysis of randomized clinical trials evaluating omalizumab for the treatment of CIU was published in 2016. The analysis included 7 randomized, placebo-controlled studies with 1312 patients with CIU. Patients treated with omalizumab (75 to 600 mg every 4 weeks) had significantly reduced weekly itch and weekly wheal scores compared with the placebo group. The effects of omalizumab were dose-dependent, with the strongest reduction in weekly itch and weekly wheal scores observed with 300 mg. Rates of complete response were significantly higher in the omalizumab group ($p < 0.00001$) and dose-dependent, with the highest rates in the 300 mg group. Rates of patients with adverse events were similar in the omalizumab and placebo groups (*Zhao et al 2016*). Similar results were identified in a 2019 meta-analysis of 6 trials and a 2020 meta-analysis of 9 trials, both comparing omalizumab with placebo (*Jia and He 2020, Rubini et al 2019*).
- A Phase 4 randomized clinical trial evaluated the effect of omalizumab in 205 patients with antihistamine-resistant CIU/chronic spontaneous urticaria. After an initial 24-week period of open-label treatment with omalizumab 300 mg every 4 weeks, patients randomized to continue omalizumab for another 24 weeks of double-blind therapy experienced a significantly lower rate of clinical worsening compared with patients randomized to double-blind placebo (21.0% vs 60.4%; $p < 0.0001$). No new safety signals were detected over the 48-week omalizumab treatment period *(Maurer et al 2018)*.

CRSwNP

- The efficacy and safety of omalizumab for the treatment of CRSwNP in adult patients with an inadequate response to intranasal corticosteroids were based on results from 2 randomized, multicenter, double-blind, placebo-controlled, Phase 3 studies, POLYP 1 (n = 138) and POLYP 2 (n = 127) (*Gevaert et al 2020*). Patients were randomly assigned to omalizumab 75 to 600 mg SC every 2 or 4 weeks (based upon pretreatment serum total IgE level and body weight) or placebo for 24 weeks. All patients received background intranasal mometasone therapy. Results from both studies revealed that omalizumab was associated with a significantly greater improvement from baseline at week 24 in Nasal Polyp Score (NPS) and weekly average Nasal Congestion Score (NCS) as compared to placebo. In POLYP 1 and POLYP 2, the mean changes in NPS from baseline to week 24 for omalizumab compared to placebo were -1.08 vs 0.06 ($p < 0.0001$) and -0.9 vs -0.31 ($p = 0.014$), respectively, and mean changes in NCS from baseline were -0.89 vs -0.35 ($p = 0.0004$) and -0.7 vs -0.2 ($p = 0.0017$), respectively. Adverse events were similar between treatment groups.

IgE-mediated food allergy

- Omalizumab was FDA-approved for IgE-mediated food allergy in adults and children ≥ 1 year of age based on the results of a randomized, multicenter, double-blind, placebo-controlled trial in 180 patients with allergies to peanut and at least 2 other foods, including milk, egg, wheat, cashew, hazelnut, or walnut. Patients with a history of severe anaphylaxis (defined as neurological compromise or requiring intubation) were excluded from the study. Results demonstrated a significantly higher response with omalizumab vs placebo (67% vs 7%, respectively; $p < 0.001$) for the primary outcome (ie, the percentage of patients able to tolerate a single dose of ≥ 600 mg of peanut protein without experiencing dose-limiting symptoms [ie, moderate to severe skin, respiratory, or gastrointestinal symptoms]) (*Wood et al 2024*).

Fasenra (benralizumab)

Asthma

- The safety and efficacy of benralizumab were evaluated in a 52-week dose-ranging exacerbation trial, 4 confirmatory trials, and a 12-week lung function trial (*Bleecker et al 2016, Castro et al 2014, Ferguson et al 2017, Fitzgerald et al 2016, Nair et al 2017, Harrison et al 2021*).

- In a randomized, controlled, double-blind, dose-ranging Phase 2b study, 324 adults with uncontrolled eosinophilic asthma were randomly assigned to placebo (n = 80), benralizumab 2 mg (n = 81), benralizumab 20 mg (n = 81), or benralizumab 100 mg (n = 82) and 285 adults with non-eosinophilic asthma were randomized to benralizumab 100 mg (n = 142) or placebo (n = 143) (*Castro et al 2014*). Treatments were given as 2 SC injections every 4 weeks for the first 3 doses, then every 8 weeks, for 1 year. Among adults with eosinophilic asthma, benralizumab 100 mg reduced exacerbation rates as compared to placebo (0.34 vs 0.57; rate reduction, 41%; 80% CI, 11 to 60; p = 0.096). A significant reduction in exacerbation rates was not seen with benralizumab 2 mg or 20 mg as compared to placebo in these patients. In patients with a baseline blood eosinophil count of ≥ 300 cells/µL, exacerbation rates were lower than in the placebo group for the benralizumab 20 mg (0.30 vs 0.68; rate reduction, 57%; 80% CI, 33 to 72; p = 0.015) and 100 mg (0.38 vs 0.68; rate reduction, 43%; 80% CI, 18 to 60; p = 0.049) groups.
- SIROCCO was a randomized, multicenter, double-blind, placebo-controlled, 48-week, Phase 3 trial (N = 1205) involving patients with severe asthma with eosinophilia uncontrolled with high-dose ICS and LABAs (*Bleecker et al 2016*). Enrolled patients were randomly assigned to placebo (n = 407), benralizumab 30 mg every 4 weeks (n = 400), or benralizumab 30 mg every 8 weeks (n = 398). Compared with placebo, benralizumab reduced the annual asthma exacerbation rate over 48 weeks when administered every 4 weeks (RR, 0.55; 95% CI, 0.42 to 0.71; p < 0.0001) or every 8 weeks (RR, 0.49; 95% CI, 0.37 to 0.64; p < 0.0001). Both doses of benralizumab also significantly improved pre-bronchodilator FEV_1 in patients at week 48 vs placebo. Asthma symptoms were improved with benralizumab every 8 weeks, but not every 4 weeks, as compared to placebo.
- CALIMA was a randomized, multicenter, double-blind, placebo-controlled, 56-week, Phase 3 trial that assessed benralizumab as add-on therapy (to high-dose ICS and LABA) for patients with severe, uncontrolled asthma and elevated blood eosinophil counts (*Fitzgerald et al 2016*). A total of 1306 patients were randomly assigned to benralizumab 30 mg every 4 weeks (n = 425), benralizumab 30 mg every 8 weeks (n = 441) or placebo (n = 440). When compared to placebo, significant reductions in annual exacerbation rates were seen with benralizumab every 4 weeks (RR, 0.64; 95% CI, 0.49 to 0.85; p = 0.0018) and every 8 weeks (RR, 0.72; 95% CI, 0.54 to 0.95; p = 0.0188). Benralizumab was also associated with significantly improved pre-bronchodilator FEV_1 and total asthma symptom scores vs placebo.
- Patients enrolled in the SIROCCO and CALIMA trials who completed treatment were eligible for the BORA Phase 3 safety extension trial. This was a randomized, double-blind study that randomized patients to receive benralizumab 30 mg every 4 or 8 weeks. Adult patients received treatment for 52 weeks and adolescents (12 to 17 years of age) were treated for 108 weeks. A total of 1576 patients were included in the full analysis set with safety assessed at 56 weeks. Treatment discontinuation due to any adverse event occurred in approximately 2% of patients in each group. The most common adverse events were viral upper respiratory tract infections and worsening asthma. Serious adverse events included worsening asthma (3% in the every-8-week dosing group and 4% in the every-4-week dosing group), pneumonia (< 1% in both groups) and pneumonia caused by bacterial infection (< 1% in the every-4-week dosing group and 1% in the every-8-week dosing group). New malignancy occurred in 12 (1%) of the 1576 patients. Hypersensitivity related to treatment occurred in 3 patients. For the secondary efficacy outcome, patients with elevated blood eosinophil levels had similar exacerbation rates to that observed during the first year of treatment in the SIROCCO and CALIMA trials (*Busse et al 2019a*).
- BISE was a randomized, multicenter, double-blind, placebo-controlled, 12-week, Phase 3 trial that evaluated benralizumab therapy for patients with mild to moderate persistent asthma (*Ferguson et al 2017*). Patients (N = 211) had been receiving either low- to medium-dose ICS or low-dose ICS plus LABA therapy and were randomized to benralizumab 30 mg every 4 weeks (n = 106) or placebo (n = 105). Benralizumab resulted in an 80 mL (95% CI, 0 to 150; p = 0.04) greater improvement in pre-bronchodilator FEV_1 after 12 weeks as compared to placebo. Despite this improvement, this lung function result does not warrant the use of benralizumab in mild to moderate asthma because it did not reach the minimum clinically important improvement of 10%.
- ZONDA was a randomized, multicenter, double-blind, placebo-controlled, 28-week trial that primarily assessed whether benralizumab was effective as an oral glucocorticoid-sparing therapy in patients on oral steroids to manage severe asthma associated with eosinophilia (*Nair et al 2017*). Of the enrolled patients, 220 were randomly assigned to benralizumab 30 mg every 4 weeks (n = 72), benralizumab 30 mg every 8 weeks (n = 73), or placebo (n = 75). Results revealed that the 2 benralizumab dosing regimens significantly reduced the median final oral glucocorticoid doses from baseline by 75% vs a 25% reduction seen with placebo (p < 0.001 for both comparisons). Additionally, benralizumab administered every 4 weeks resulted in an annual exacerbation rate that was 55% lower than that seen with placebo (marginal rate, 0.83 vs 1.83; p = 0.003) and benralizumab administered every 8 weeks resulted in a 70% lower rate than that seen with placebo (marginal rate, 0.54 to 1.83; p < 0.001).

  - ANDHI was a randomized, multicenter, double-blind, placebo-controlled, Phase 3b study that assessed the effect of benralizumab in adults with severe eosinophilic asthma and at least 2 exacerbations in the previous year despite use of medium- to high-dose ICS plus another asthma controller (*Harrison et al 2021*). Patients were randomized to receive benralizumab 30 mg every 8 weeks (with the first 3 doses given 4 weeks apart; n = 427) or placebo (n = 229). Benralizumab significantly reduced annualized asthma exacerbation rate over the 24-week treatment period compared to placebo (RR, 0.51; 95% CI, 0.39 to 0.65; p < 0.0001).
- The safety of benralizumab in children 6 to 11 years of age with severe eosinophilic asthma was demonstrated in a 48-week, open-label, pharmacokinetic/pharmacodynamic study. A total of 28 children received benralizumab 10 mg (for those weighing < 35 kg) or 30 mg (for those weighing ≥ 35 kg) administered every 4 weeks for the first 3 doses, then every 8 weeks thereafter. Authors concluded that the pharmacokinetics, decrease in blood eosinophil levels, and safety profile in children 6 to 11 years of age were similar to findings in adolescents and adults (*Wedner et al 2024*).
- Fitzgerald et al conducted a study exploring the efficacy of benralizumab for patients with different baseline blood eosinophil thresholds and exacerbation histories. This study was a pooled analysis (N = 2295 patients) of the results from the SIROCCO and CALIMA Phase 3 studies. The annual exacerbation rate among patients with baseline blood eosinophil counts of ≥ 0 cells/μL was 1.16 (95% CI, 1.05 to 1.28) in patients who received placebo vs 0.75 (95% CI, 0.66 to 0.84) in patients who received benralizumab every 8 weeks (RR, 0.64; 95% CI, 0.55 to 0.75; p < 0.0001). In patients who received benralizumab every 4 weeks who had eosinophil counts of ≥ 0 cells/μL, the annual exacerbation rate was 0.73 (95% CI, 0.65 to 0.82); RR vs placebo was 0.63 (95% CI, 0.54 to 0.74; p < 0.0001). The extent to which exacerbation rates were reduced increased with increasing blood eosinophil thresholds and with greater exacerbation history in patients in the every-4-week and every-8-week benralizumab groups. Greater improvements in the annual exacerbation rate were seen with benralizumab compared with placebo for patients with a combination of high blood eosinophil thresholds and a history of more frequent exacerbations *(FitzGerald et al 2018).*
- The Phase 4 SHAMAL trial evaluated the reduction in daily maintenance ICS use with benralizumab in patients with severe eosinophilic asthma. Patients were randomized 3:1 to taper their high-dose ICS to a medium-dose, low-dose, and as-needed dose (collectively referred to as the reduction group; n = 168) or continue their ICS/formoterol therapy (reference group; n = 43) for 32 weeks, with maintenance follow up at 48 weeks. The primary endpoint was the proportion of patients an ICS/formoterol dose reduction by week 32. Results demonstrated that by the end of week 32, 92% of patients were able to reduce their ICS/formoterol dose: 61% to as-needed only, 17% to low-dose, and 15% to medium-dose. Of these patients, 96% of patients were able to maintain the dose that was used at week 32 to week 48. Throughout the entire study period, there were 16 asthma exacerbations in the reduction group and 5 in the refence group (rate ratio, 1.05; 95% CI, 0.41 to 2.68) (*Jackson et al 2024*).
- A 2017 meta-analysis evaluated the therapeutic efficacy and safety of benralizumab in patients with eosinophilic asthma. A total of 7 articles (n = 2321) met the inclusion criteria of the systematic review. The pooled analysis found that benralizumab significantly reduced exacerbations (RR, 0.63; 95% CI, 0.52 to 0.76; p < 0.00001) compared to placebo. There was no statistical trend for improvement in FEV_1 or asthma control indices such as Quality of Life Assessment (AQLQ) and Asthma Control Questionnaire (ACQ) score in benralizumab-treated patients. In addition, safety data indicated that benralizumab administration did not result in an increased incidence of adverse events and was well tolerated (RR, 1.00; 95% CI, 0.95 to 1.05; p = 0.96) *(Tien et al 2017)*.

EPGA

- MANDARA was a Phase 3, multicenter, double-blind, active-controlled noninferiority trial comparing the efficacy of benralizumab vs mepolizumab in 140 adult patients with relapsing or refractory EGPA. For the primary endpoint, the adjusted proportion of patients with remission at weeks 36 and 48 was 59% in patients treated with benralizumab vs 56% with mepolizumab (difference, 3%; 95% CI, -13 to 18; p = 0.73), demonstrating the noninferiority of benralizumab to mepolizumab. For secondary endpoints, the accrued duration of remission and time to first relapse were similar between agents, and complete withdrawal of corticosteroids during weeks 48 to 52 was achieved in 41% of patients taking benralizumab and 26% of patients taking mepolizumab (*Wechsler et al 2024*).

Nucala (mepolizumab)

Asthma

- The safety and efficacy of mepolizumab were evaluated in 3 double-blind, placebo-controlled, multicenter RCTs in adolescent and adult patients with severe refractory asthma and signs of eosinophilic inflammation. Generally, patients were eligible for enrollment in the trials if they had eosinophils ≥ 150 cells/μL in the peripheral blood at screening or ≥

300 cells/μL at some time during the previous year. Patients also were required to be on a high-dose ICS as well as another controller medication (*Bel et al 2014, Ortega et al 2014, Pavord et al 2012*).
  - DREAM was a dose-ranging, 52-week, Phase 2b/3 study (N = 621) that compared annual asthma exacerbation frequency and improvements in clinical symptoms between patients receiving 75 mg, 250 mg, and 750 mg intravenous (IV) mepolizumab and placebo. Mepolizumab decreased clinically significant exacerbation rates across all doses compared to placebo, at a rate of 2.40 per patient per year in the placebo group, 1.24 in the 75 mg mepolizumab group ($p < 0.0001$), 1.46 in the 250 mg mepolizumab group ($p = 0.0005$), and 1.15 in the 750 mg mepolizumab group ($p < 0.0001$). No significant improvements were found for secondary clinical symptom measures, which included change in pre-bronchodilator FEV_1 from baseline, or change in ACQ scores *(Pavord et al 2012)*.
  - MENSA was a 32-week Phase 3 trial (N = 576) that compared annual asthma exacerbation frequency and improvements in clinical symptoms between patients receiving SC and IV mepolizumab vs placebo. Patients were selected on the basis of frequent exacerbations, treatment with high doses of ICS, and a defined blood eosinophil count. Both SC and IV mepolizumab significantly decreased clinically significant exacerbation rates compared to placebo, at a rate of 1.74 per patient per year in the placebo group, 0.93 per patient per year in the IV mepolizumab group ($p < 0.001$), and 0.83 per patient per year in the SC mepolizumab group ($p < 0.001$). In both the SC and IV mepolizumab-treated groups, the ACQ scores met thresholds for minimal clinically important change and were significantly improved compared to placebo ($p < 0.001$) *(Ortega et al 2014)*.
  - SIRIUS was a 24-week Phase 3 trial (N = 135) that compared oral corticosteroid requirements between patients receiving SC mepolizumab and placebo. The likelihood of a reduction in the daily oral glucocorticoid dose was 2.39 times higher in the mepolizumab group (95% CI, 1.25 to 4.56; $p = 0.008$). The median reduction in daily oral corticosteroid dose was 50% (95% CI, 20 to 75) in the mepolizumab-treated group compared to 0% (95% CI, -20 to 33.3) in the placebo group ($p = 0.007$) *(Bel et al 2014)*.
- A post-hoc analysis of data from DREAM and MENSA was conducted to assess the relationship between baseline blood eosinophil counts and efficacy of mepolizumab. Of 1192 patients, 846 received mepolizumab and 346 received placebo. The overall rate of mean exacerbations per person per year was reduced from 1.91 with placebo to 1.01 with mepolizumab (47% reduction; RR, 0.53; 95% CI, 0.44 to 0.62; $p < 0.0001$). The exacerbation rate reduction with mepolizumab vs placebo increased progressively from 52% (RR, 0.48; 95% CI, 0.39 to 0.58) in patients with a baseline blood eosinophil count of ≥ 150 cells/μL to 70% (RR, 0.30; 95% CI, 0.23 to 0.40) in patients with a baseline count of ≥ 500 cells/μL. At a baseline count < 150 cells/μL, predicted efficacy of mepolizumab was reduced. The authors concluded that the use of a baseline blood eosinophil count will help to select patients who are likely to achieve important asthma outcomes with mepolizumab (*Ortega et al 2016*).
- COSMOS was a 52-week, open-label extension study in patients who received mepolizumab or placebo in MENSA or SIRIUS. Patients received SC mepolizumab regardless of prior treatment allocation and continued to receive appropriate standard-of-care asthma therapy throughout. In total, 558 (86%; previous mepolizumab: 358; previous placebo: 200) and 94 (14%; previous mepolizumab: 58; previous placebo: 36) patients experienced on-treatment adverse events and serious adverse events, respectively. No fatal adverse events or instances of mepolizumab-related anaphylaxis were reported. Mepolizumab treatment was shown to exert a durable response, with patients who previously received mepolizumab in MENSA or SIRIUS maintaining reductions in exacerbation rate and oral corticosteroid dosing throughout COSMOS. Patients who previously received placebo in MENSA or SIRIUS demonstrated improvements in these endpoints following treatment with mepolizumab (*Lugogo et al 2016*).
- COLUMBA was an open-label extension study of patients enrolled in the DREAM trial who received mepolizumab 100 mg every 4 weeks plus standard of care until criterion for discontinuation was met (safety profile not positive for patient, patient withdrawn by their physician, patient withdrew consent, or drug became commercially available). There were 347 patients enrolled who received treatment for a mean of 3.5 years. Adverse events most frequently reported were respiratory tract infection (67%), headache (29%), bronchitis (21%), and worsening asthma (27%). Although 6 deaths occurred, none were considered related to study treatment. No anaphylaxis reactions were reported. Malignancy was reported in 2% (n = 6) of patients. The exacerbation rate for patients on treatment for 156 weeks or longer was 0.74 events/year, which was a 56% reduction from the off-treatment period between the 2 studies (*Khatri et al 2018*).
- A pharmacokinetic study of SC mepolizumab 40 and 100 mg (for bodyweight < 40 and ≥ 40 kg, respectively) every 4 weeks in 36 children 6 to 11 years of age with severe eosinophilic asthma and ≥ 2 exacerbations in the prior year demonstrated reductions in blood eosinophil count by 89% at week 12 *(Gupta et al 2019a)*. A 52-week safety extension study of 30 children demonstrated no safety or immunogenicity concerns, as well as improvements in blood eosinophil

counts and asthma control from baseline *(Gupta et al 2019b)*. Findings of these studies supported FDA approval of mepolizumab for the treatment of severe eosinophilic asthma in children (*GlaxoSmithKline 2019*).

- A systematic review and meta-analysis compared hospitalization or hospitalization and/or emergency room visit rates in patients with severe eosinophilic asthma treated with mepolizumab or placebo in addition to standard of care for ≥ 24 weeks. Four studies (N = 1388) were eligible for inclusion. Mepolizumab significantly reduced the rate of exacerbations requiring hospitalization (relative rate, 0.49; 95% CI, 0.30 to 0.80; p = 0.004) and hospitalization/emergency room visit (relative rate, 0.49; 95% CI, 0.33 to 0.73; p < 0.001) vs placebo. Significant reductions of 45% and 38% were also observed for the proportion of patients experiencing 1 or more hospitalization and hospitalization and/or emergency room visit, respectively (*Yancey et al 2017*).

EGPA

- A 52-week, randomized, placebo-controlled, double-blind, parallel-group, multicenter, Phase 3 trial assessed the efficacy and safety of mepolizumab as add-on therapy (to glucocorticoid treatment, with or without immunosuppressive therapy) for patients with relapsing or refractory EGPA (*Wechsler et al 2017*). A total of 136 patients were randomly assigned to mepolizumab 300 mg every 4 weeks (n = 68) or placebo (n = 68). Results demonstrated the following for the mepolizumab and placebo groups, respectively:
  - Percentage of patients with ≥ 24 weeks of accrued remission: 28% vs 3% (OR, 5.91; 95% CI, 2.68 to 13.03; p < 0.001).
  - Percentage of patients in remission at both week 36 and week 48: 32% vs 3% (OR, 16.74; 95% CI, 3.61 to 77.56; p < 0.001).
  - Annualized relapse rate: 1.14 vs 2.27 (RR, 0.50; 95% CI, 0.36 to 0.70; p < 0.001).
  - Percentage of patients able to reduce their daily dose of concomitant prednisone or prednisolone to 4 mg or less (average of weeks 48 to 52): 44% vs 7% (OR, 0.20; 95% CI, 0.09 to 0.41; p < 0.001).

HES

- A 32-week, double-blind, placebo-controlled, multicenter, RCT evaluated the efficacy and safety of mepolizumab in patients ≥ 12 years with HES (without an identifiable nonhematologic secondary cause) for at least 6 months *(Nucala prescribing information 2023, Roufosse et al 2020)*. A total of 108 patients were assigned to mepolizumab 300 mg every 4 weeks (n = 54) or placebo (n = 54). Results demonstrated the following for mepolizumab and placebo groups, respectively:
  - Proportion of patients with ≥ 1 HES flare or withdrew from the trial: 28% vs 56% (OR, 0.28; 95% CI, 0.12 to 0.64; p = 0.002)
  - Adjusted mean rate of HES flares per year: 0.50 vs 1.46 (rate ratio, 0.34; 95% CI, 0.19 to 0.63; p < 0.001)
  - Probability of first HES flare by week 32: 26.3% vs 52.7% (hazard ratio, 0.34; 95% CI, 0.18 to 0.67; p = 0.002)

CRSwNP

- SYNAPSE, a 52-week, double-blind, randomized, placebo-controlled, multicenter trial, evaluated the efficacy and safety of mepolizumab in adult patients with CRSwNP. A total of 407 patients with recurrent, refractory, severe, bilateral nasal polyp symptoms despite standard care treatment were enrolled. Patients were randomly assigned to receive 100 mg mepolizumab (n = 206) or placebo (n = 201) every 4 weeks. The total endoscopic nasal polyp score significantly improved from baseline with mepolizumab vs placebo (adjusted difference in medians, -0.73; 95% CI, -1.11 to -0.34; p < 0.0001). The nasal obstruction visual analogue score (VAS) score during weeks 49 to 52 also significantly improved (adjusted difference in medians, -3.14; 95% CI, -4.09 to -2.18; p < 0.0001). Adverse events related to study treatment occurred in 15% of the mepolizumab group and 9% of the placebo group (*Han et al 2021*).

Cinqair (reslizumab)

Asthma

- The safety and efficacy of reslizumab were evaluated in 4 double-blind, placebo-controlled, multicenter RCTs. In all 4 studies, patients were required to be on at least a medium-dose ICS with or without additional controller medications (*Bjermer et al 2016, Castro et al 2015, Corren et al 2016*).
  - Studies 3082 and 3083 were 52-week studies (N = 953) in patients with asthma who were required to have a blood eosinophil count ≥ 400 cells/μL, and ≥ 1 asthma exacerbation requiring systemic corticosteroid use over the past 12 months. These studies compared the asthma exacerbation rate and improvements in clinical symptoms between patients receiving reslizumab 3 mg/kg IV administered once every 4 weeks and placebo. In both studies, patients receiving reslizumab had a significant reduction in the frequency of asthma exacerbations (Study 3082: RR, 0.50; 95% CI, 0.37 to 0.67; Study 3083: RR, 0.41; 95% CI, 0.28 to 0.59; both p < 0.0001) compared with those receiving

placebo. In both trials, an improvement in FEV_1 was evident for reslizumab vs placebo by the first on-treatment assessment at week 4, which was sustained through week 52. Reslizumab treatment also resulted in significant improvements compared with placebo in AQLQ total score, ACQ-7 score, and Asthma Symptom Utility Index (ASUI) score (*Castro et al 2015*).
  - Study 3081 was a 16-week study (N = 315) in patients who were required to have a blood eosinophil count ≥ 400 cells/μL. The study compared the change from baseline in FEV_1 and improvements in clinical symptoms between reslizumab 3 mg/kg vs placebo. Reslizumab 3 mg/kg significantly improved FEV_1 (difference vs placebo: 160 mL; 95% CI, 60 to 259; p = 0.0018). Reslizumab also statistically significantly improved ACQ and AQLQ; however, the minimally important difference was only reached for AQLQ (*Bjermer et al 2016*).
    - Study 3084 was a 16-week study in 496 patients unselected for baseline blood eosinophil levels (approximately 80% of patients had a screening blood eosinophil count < 400 cells/μL). Patients were not allowed to be on maintenance oral corticosteroids. The study compared the change from baseline in FEV_1 and improvements in clinical symptoms between reslizumab 3 mg/kg vs placebo. In the subgroup of patients with baseline eosinophils < 400 cells/μL, patients treated with reslizumab showed no significant improvement in FEV_1 compared with placebo. In the subgroup with eosinophils ≥ 400 cells/μL, however, treatment with reslizumab was associated with much larger improvements in FEV_1, ACQ, and rescue SABA use compared with placebo (*Corren et al 2016*).
  - An open-label, non-randomized extension study of these placebo-controlled trials continued treatment of patients with eosinophilic asthma with reslizumab 3 mg/kg every 4 weeks for up to 24 months to assess the drug's safety. Patients initially randomized to placebo also received active drug. A total of 1051 patients were included (n = 480 reslizumab-naive and n = 571 reslizumab-treated patients). Of these, 740 patients received treatment for 12 months or longer, and 249 patients received treatment for 24 months or longer. Worsening asthma and nasopharyngitis were the most common adverse events. Serious adverse events occurred in 7% of patients and treatment discontinuation due to an adverse event occurred in 2% of patients. No deaths (n = 3) were related to treatment. Malignancy occurred in 15 (1%) patients. Patients previously on reslizumab maintained asthma control and those naive to treatment demonstrated improvement in asthma control and lung function. The authors concluded that reslizumab maintained asthma control for up to 2 years in patients with moderate-to-severe eosinophilic asthma (*Murphy et al 2017*).
  - A post hoc analysis of pooled data from 2 randomized, placebo-controlled trials in patients with inadequately controlled asthma and elevated blood eosinophil levels compared the efficacy of reslizumab vs placebo among the subgroup of patients with oral corticosteroid-dependent asthma. Reslizumab was associated with a significant improvement in overall asthma exacerbations (RR, 0.32; 95% CI, 0.18 to 0.55) *(Nair et al 2020)*.
- A 2017 meta-analysis of 5 RCTs comparing reslizumab to placebo (N = 1366) revealed improvements in exacerbations, FEV_1, and ACQ score with reslizumab. Asthma exacerbations occurred less frequently in reslizumab-treated patients vs placebo (OR, 0.46; 95% CI, 0.35 to 0.59; p < 0.00001). FEV_1 also improved with reslizumab compared to placebo (mean difference, 0.16; 95% CI, 0.10 to 0.23; p < 0.00001). Finally, ACQ score improved with reslizumab compared to placebo (mean difference, -0.26; 95% CI, -0.36 to -0.16; p < 0.00001). All studies included in the meta-analysis were of limited duration of 15 or 16 weeks (*Li et al 2017*).
- A 2019 meta-analysis of 6 RCTs (5 placebo-controlled trials and 1 open-label extension) evaluated the safety of reslizumab (n = 1028) with placebo (n = 730) in adults with uncontrolled asthma. Compared with placebo, reslizumab was associated with lower proportions of patients with ≥ 1 adverse event (67% vs 81%; RR, 0.83; 95% CI, 0.79 to 0.89) and with ≥ 1 serious adverse event (7% vs 10%; RR, 0.65; 95% CI, 0.48 to 0.89) *(Virchow et al 2020)*.

Dupixent (dupilumab)

Asthma

- A 52-week randomized, double-blind, placebo-controlled study evaluated the efficacy of dupilumab in patients ≥ 12 years of age with moderate-to-severe asthma uncontrolled with a medium-to-high dose ICS plus up to 2 additional controller medications (LABA and/or LTRA). Approximately 1900 patients were randomized to add-on therapy with dupilumab (200 mg or 300 mg every 2 weeks) or matching placebo for 52 weeks. The annual rate of severe exacerbations during the 52-week study period and the absolute change in FEV_1 at week 12 were the primary endpoints. A subgroup analysis of patients with an elevated blood eosinophil count of 300 cells/μL was also planned. Both doses of dupilumab resulted in a reduced rate (46% and 47.7%, respectively) of asthma exacerbation compared to placebo (p < 0.0001). Patients with higher blood eosinophil levels had greater than 65% reduction in the annual exacerbation rate compared to placebo. The change in FEV_1 was also significantly improved with both doses of dupilumab compared to placebo and even more pronounced in patients with elevated blood eosinophil levels. Adverse

events more common with dupilumab compared to placebo included injection-site reactions and eosinophilia (*Castro et al 2018*). In the subgroup of patients with baseline evidence of allergic asthma, dupilumab 200 mg and 300 mg every 2 weeks reduced severe asthma exacerbation rates by 36.9% and 45.5%, respectively (both $p < 0.01$) and improved FEV_1 at week 12 by 0.13 and 0.16 L, respectively (both $p < 0.001$) *(Corren et al 2020)*.

- A total of 210 patients ≥ 12 years of age with oral glucocorticoid-dependent severe asthma were randomized to receive add-on therapy with dupilumab 300 mg or placebo every other week for 24 weeks. Glucocorticoid doses were tapered from week 4 to week 20 and then maintained at a stable dose for 4 weeks. The percentage in glucocorticoid dose reduction at week 24 was the primary outcome. The percentage change in glucocorticoid dose was -70.1% with dupilumab vs -41.9% with placebo ($p < 0.001$). A dose reduction of ≥ 50% was observed in 80% of dupilumab-treated patients compared to 50% of placebo patients. Almost 70% of patients in the dupilumab group achieved a glucocorticoid dose of less than 5 mg compared to 33% in patients who received placebo. The exacerbation rate was 59% lower with dupilumab compared to placebo. Injection site reactions and eosinophilia were more common with dupilumab compared to placebo (*Rabe et al 2018*).
- A meta-analysis and systematic review of 4 RCTs evaluated the safety and efficacy of dupilumab compared to placebo in approximately 3000 patients with uncontrolled asthma. The rate of severe asthma exacerbation was significantly reduced with dupilumab compared to placebo (RR, 0.44; 95% CI, 0.35 to 0.055; $p < 0.01$). FEV_1 was also significantly increased with dupilumab with a mean difference of 0.14 L (95% CI, 0.12 to 0.17; $p < 0.01$). With respect to adverse events, the risk of injection site reactions was higher with dupilumab compared to placebo (RR, 1.91; 95% CI, 1.14 to 2.59; $p < 0.01$) (*Zayed et al 2018*).
- A randomized, double-blind, placebo-controlled trial (Liberty Asthma VOYAGER) evaluated the safety and efficacy of dupilumab in pediatric patients 6 to 11 years of age with moderate-to-severe asthma on a medium- or high-dose ICS and a second controller medication or high-dose ICS alone. In the 52-week trial, patients were randomized to receive dupilumab (n = 273) or placebo (n = 135) every other week. Dosing was dependent on body weight: patients ≤ 30 kg received 100 mg every 2 weeks and those > 30 kg received 200 mg every 2 weeks. The annualized rate of severe asthma exacerbation events (the primary endpoint) during the study period was 0.31 for dupilumab and 0.75 for placebo (RR reduction, 59.5%; $p < 0.001$). Among patients with a baseline eosinophil count of ≥ 300 cells/μL, the annualized rate of asthma exacerbations was 0.24 with dupilumab and 0.67 with placebo (RR reduction, 64.7%; $p < 0.001$). Mean change from baseline in percent predicted FEV_1 was also significantly improved in the dupilumab group compared to placebo (least-squares mean difference vs placebo, 5.32; 95% CI, 1.76 to 8.88). The efficacy of dupilumab 300 mg every 4 weeks in patients 6 to 11 years of age with body weight 15 to < 30 kg was extrapolated from efficacy of a clinical trial of 100 mg every 2 weeks with support from population pharmacokinetic analyses. The risks of any adverse event, serious adverse events, and adverse events leading to treatment discontinuation were not significantly different between dupilumab and placebo with the addition of helminth infections (*Dupixent prescribing information 2024, Bacharier et al 2021*).

COPD

- Two identically designed, 52-week Phase 3, double-blind, placebo-controlled, randomized controlled trials (BOREAS and NOTUS) evaluated the efficacy of dupilumab in adult patients 40 to 80 years of age with inadequately controlled moderate-to-severe COPD. Inclusion criteria were FEV_1/forced vital capacity [FVC] ratio < 0.70 and post-bronchodilator FEV_1 % predicted > 30% and ≤ 70%, an elevated exacerbation risk (defined as ≥ 2 moderate exacerbations or ≥ 1 severe exacerbations within the year before screening) despite the use of standard triple therapy (LAMA/LABA/ICS), and a blood eosinophil count ≥ 300 cells/μL. A total of 98.2% of enrolled patients were receiving background triple therapy; double therapy (LAMA/LABA alone) was allowed if ICS was contraindicated. Patients were randomized 1:1 to receive dupilumab 300 mg via SC injection as add-on maintenance therapy or placebo every 2 weeks (*Bhatt et al 2023, Bhatt et al 2024*).
  - The primary end point, the annualized rate of moderate or severe exacerbations of COPD over the 52-week treatment period, demonstrated significant improvement with dupilumab vs placebo in both studies:
    - BOREAS: 0.78 events/year vs 1.10 events/year (rate ratio, 0.70; 95% CI, 0.58 to 0.86; $p < 0.001$).
    - NOTUS: 0.86 events/year vs 1.30 events/year (rate ratio, 0.66; 95% CI, 0.54 to 0.82; $p < 0.001$).

CRSwNP

- Two randomized, double-blind, placebo-controlled trials evaluated dupilumab added to standard of care in adults with severe bilateral CRSwNP (*Bachert et al 2019*). Patients had experienced symptoms despite receiving intranasal corticosteroids, systemic corticosteroids in the previous 2 years, or sinonasal surgery. In both the 24- and 52-week trials, dupilumab resulted in significant improvement as measured by least-squares mean differences in NPS (-2.06; 95%

CI, -2.43 to -1.69 and -1.80; 95% CI, -2.10 to -1.51, respectively), nasal congestion or obstruction score (-0.89; 95% CI, -1.07 to -0.71 and -0.87; 95% CI, -1.03 to -0.71, respectively), and Lund-Mackay computed tomography score (-7.44; 95% CI, -8.35 to -6.53 and -5.13; 95% CI, -5.80 to -4.46, respectively). The risks of any adverse event, serious adverse events, and adverse events leading to treatment discontinuation were not significantly different between dupilumab and placebo.

EoE

- A 2-part placebo-controlled clinical trial with two 24-week treatment periods evaluated the efficacy of weekly and twice monthly SC injections of dupilumab 300 mg in patients ≥ 12 years of age and weighing ≥ 40 kg with EoE. The coprimary endpoints in parts A and B of the study were 1) the proportion of patients achieving histological remission (defined as peak esophageal intraepithelial eosinophil count of ≤ 6 eosinophils/high-power field [hpf]) and 2) the absolute change in the patient-reported Dysphagia Symptom Questionnaire (DSQ) score (range, 0 to 84). Results for weekly dupilumab administration (FDA-approved dose for EoE in patients ≥ 12 years of age) are as follows (*Dellon et al 2022*):
  - In part A (dupilumab, n = 42; placebo, n = 39), histologic remission was achieved in 60% of patients who received weekly dupilumab vs 5% who received placebo (difference, 55 percentage points; 95% CI, 40 to 71). The absolute reduction from baseline in DSQ score was also significantly higher with dupilumab vs placebo (21.9 vs 9.6; difference, -12.32; 95% CI, -19.11 to -5.54).
  - In part B (dupilumab, n = 80; placebo, n = 79), histologic remission was achieved in 59% of patients who received weekly dupilumab vs 6% who received placebo (difference, 54 percentage points; 95% CI, 41 to 66). The absolute reduction from baseline in DSQ score was also significantly higher with dupilumab vs placebo (23.78 vs 13.86; difference, -9.92; 95% CI, -14.81 to -5.02).
  - The histological, symptomatic, endoscopic, and molecular features of EoE showed sustained or continued improvement up to week 52 with weekly dupilumab treatment (*Rothenberg et al 2023*).
- A 12-week Phase 2 study compared weekly injections of dupilumab 300 mg (n = 23) or placebo (n = 24) in adults with EoE (*Hirano et al 2020b*). The primary endpoint was change from baseline to week 10 in Straumann Dysphagia Instrument (SDI) patient-reported outcome score. At the beginning of the study, the mean SDI score was 6.4. After 10 weeks, SDI scores were reduced by a mean value of 3.0 in the dupilumab group compared with a mean reduction of 1.3 in the placebo group (p = 0.0304).
- A 2-part placebo-controlled clinical trial evaluated the efficacy of dupilumab in children 1 to 11 years of age and weighing ≥ 15 kg with EoE (*Dupixent prescribing information 2024*).
  - Part A evaluated dupilumab 200 mg every 2 weeks (if weight ≥ 15 to < 30 kg) or 300 mg every 2 weeks (if weight ≥ 30 to < 60 kg), or placebo, in 61 children during a 16-week treatment period. The primary outcome of histological remission, defined as a decrease in esophageal eosinophil count to ≤ 6 eosinophils/hpf, was achieved by 65.6% of children who received dupilumab vs. 3.4% of children who received placebo (difference, 62%; 95% CI, 44 to 79.95).
  - In Part B, histological remission was achieved at 52 weeks in 17 of 32 children treated with dupilumab in Parts A and B and 8 of 15 children treated with placebo in Part A and dupilumab in Part B.

Tezspire (tezepelumab-ekko)

Severe asthma

- A 52-week, Phase 3, randomized, double-blind, placebo-controlled study (NAVIGATOR) evaluated the efficacy of tezepelumab-ekko in 1061 patients ≥ 12 years of age with severe asthma uncontrolled with a medium-to-high dose ICS and ≥ 1 controller medication. Patients were randomized 1:1 to receive tezepelumab-ekko (210 mg SC injection every 4 weeks) or matching placebo. The annual rate of severe exacerbations during the 52-week study period was the primary outcome, with a subgroup analysis of patients with a baseline blood eosinophil count of < 300 cells/μL. Secondary endpoints included change in FEV_1 from baseline and changes in quality of life and asthma severity questionnaires (ACQ, AQLQ, and Asthma Symptom Diary [ASD]). Tezepelumab-ekko was associated with an annualized asthma exacerbation rate of 0.93 vs 2.10 with placebo (rate ratio, 0.44; p < 0.001). For a subgroup of patients with baseline eosinophil counts < 300 cells/μL, the annual rate of asthma exacerbations was 1.02 with tezepelumab-ekko vs 1.73 with placebo (rate ratio, 0.59; p < 0.001). Change from baseline in FEV_1 was 0.23 L with tezepelumab-ekko and 0.09 L with placebo (p < 0.001). Changes in AQLQ and asthma severity scores were also significant in favor of tezepelumab-ekko *(Menzies-Gow et al 2021*).
  - In a long-term extension study (DESTINATION), for patent initially enrolled in NAVIGATOR, the annualized asthma exacerbation rate ratio over 104 weeks was 0.42 (95% CI, 0.35 to 0.51) in favor of tezepelumab vs placebo (*Menzies-Gow et al 2023).*

- The PATHWAY trial was a 52-week, Phase 2b, randomized, double-blind, placebo-controlled, dose-ranging trial which evaluated the efficacy of tezepelumab-ekko in patients 18 to 75 years of age with asthma uncontrolled with medium-to-high dose ICS and a controller medication. A total of 550 patients were randomized to treatment with tezepelumab-ekko 70 mg every 4 weeks, tezepelumab-ekko 210 mg every 4 weeks, tezepelumab-ekko 280 mg every 2 weeks, or placebo every 2 weeks, administered via SC injection, for 52 weeks. The primary endpoint was the annualized rate of asthma exacerbations at week 52. Secondary endpoints included change in FEV_1 from baseline and quality of life/asthma severity scores. Outcomes were also assessed by baseline blood eosinophil counts (≥ 250 or ≤ 250 cells/µL) and Th2 lymphocyte status (high: IgE > 100 IU/mL and blood eosinophil ≥ 140 cells/µL; low: IgE ≤ 100 IU/mL and blood eosinophil < 140 cells/µL). At week 52, asthma exacerbation rates were lower with tezepelumab-ekko compared with placebo by 62%, 71%, and 66% for 70 mg, 210 mg, and 280 mg doses of tezepelumab-ekko, respectively ($p < 0.001$ for all comparisons). Asthma exacerbation rates were also lower with tezepelumab-ekko vs placebo, regardless of baseline eosinophil count or Th2 status. Change in FEV_1 was greater with tezepelumab-ekko than with placebo (differences from placebo ranging from 8.30 to 10.44 L). Quality of life and asthma severity scores (ACQ-6, AQLQ, and Asthma Symptom Scores) were also improved significantly with tezepelumab-ekko over placebo *(Corren et al 2017a).*
- In patients with severe uncontrolled asthma, a pooled analysis of 6 placebo-controlled RCTs demonstrated that treatment with tezepelumab improved FEV_1 by 0.15 L (95% CI, 0.12 to 0.17) and reduced the asthma exacerbation rate per year by 0.60 (95% CI, 0.51 to 0.70) when compared with placebo (*Zoumot et al 2022*).

Comparative reviews

Asthma

- In 2017, *Cockle et al* conducted a systematic review and indirect treatment comparison to assess the comparative effectiveness and tolerability of mepolizumab and omalizumab, as add-on therapy to standard of care, in patients with severe asthma. Studies included in the primary analysis were double-blind, RCTs, ≥ 12 weeks' duration enrolling patients with severe asthma with a documented exacerbation history and receiving a high-dose ICS plus ≥ 1 additional controller. Two populations were examined: patients potentially eligible for 1) both treatments (overlap population) and 2) either treatment (trial population) (*Cockle et al 2017*).
  - For the overlap population, no difference was found between mepolizumab and omalizumab. However, trends in favor of mepolizumab were observed, with median estimated RRs of 0.66 (95% CI, 0.37 to 1.19) for the rate of clinically significant exacerbations and 0.19 (95% CI, 0.02 to 2.32) for the rate of exacerbations requiring hospitalization.
  - Results of the trial population analysis showed that mepolizumab was associated with an estimated median RR of 0.63 (95% CI, 0.45 to 0.89) corresponding to a reduction of 37% in the rate of clinically significant exacerbations vs omalizumab. No difference between treatments was observed for the rate of exacerbations resulting in hospitalization; however, the median RR of 0.58 (95% CI, 0.16 to 2.13) demonstrated a trend for mepolizumab over omalizumab.
  - Both treatments had broadly comparable effects on lung function and similar tolerability profiles.
- Another 2017 systematic review was unable to detect differences in efficacy when comparing add-on therapy with mepolizumab or omalizumab in asthma patients who were not well controlled on ICS therapy. The analysis included both RCTs and cohort studies with duration of ≥ 12 weeks. A total of 18 omalizumab studies (N = 4854) and 4 mepolizumab studies (N = 1620) were included. Network meta-analysis did not find a significant difference in FEV_1 between groups (mean difference, 9.3 mL in favor of mepolizumab; 95% CI, -67.7 to 86.3). Both omalizumab and mepolizumab reduced the annualized rates of asthma exacerbations by approximately 50% compared with placebo. Although the authors were unable to identify significant differences in efficacy, there was high heterogeneity among the clinical trials and major differences in study inclusion criteria *(Nachef et al 2018)*.
- A systematic review of the IL-5 antagonists, mepolizumab, reslizumab, and benralizumab, included 16 studies (N = 7600) conducted in patients with asthma poorly controlled by ICS. The majority of patients had severe eosinophilic asthma. All the IL-5 antagonists reduced asthma exacerbations by approximately 50% and improved FEV_1 by 0.08 L to 0.15 L. Overall, there was not an increase in serious adverse events with any IL-5 antagonist; however, more patients discontinued benralizumab (42/2026) than placebo (11/1227) due to adverse events *(Farne et al 2022)*.
- A 2019 network meta-analysis of 11 studies aimed to indirectly compare the efficacy (n = 1855) and safety (n = 3462) of reslizumab with benralizumab in patients with eosinophilic asthma. The efficacy analysis compared a benralizumab subgroup with blood eosinophils ≥ 300 cells/µL (n = 1537) to a reslizumab subgroup in GINA step 4/5 with 2 or more previous exacerbations and blood eosinophils ≥ 400 cells/µL. Reslizumab was found to have significantly greater

improvement in the ACQ and AQLQ scores compared to benralizumab. No significant difference between the groups was observed in clinical asthma exacerbation, but a sensitivity analysis with the overall study population suggested a significantly greater reduction in exacerbations with reslizumab. There were fewer discontinuations due to adverse events with reslizumab; however, the frequency and types of adverse events were not significantly different between treatment groups (*Casale et al 2019).*

- A 2019 network meta-analysis of 11 studies compared efficacy of licensed doses of mepolizumab, benralizumab, and reslizumab in patients with severe eosinophilic asthma based on eosinophil levels. Mepolizumab reduced clinically significant exacerbations compared to benralizumab for patients with blood eosinophils ≥ 150 cells/μL (RR, 0.66; 95% CI, 0.49 to 0.89), ≥ 300 cells/μL (RR, 0.61; 95% CI, 0.37 to 0.99), and ≥ 400 cells/μL (RR, 0.55; 95% CI, 0.35 to 0.87) and with mepolizumab compared to reslizumab for patients with blood eosinophils ≥ 400 cells/μL (RR, 0.55; 95% CI, 0.36 to 0.85). Additionally, change from baseline in ACQ score was greater with mepolizumab compared to benralizumab in patients with baseline blood eosinophils ≥ 150 cells/μL (difference, -0.33; 95% CI, -0.54 to -0.11), ≥ 300 cells/μL (difference, -0.40; 95% CI, -0.76 to -0.03), and ≥ 400 cells/μL (difference, -0.36; 95% CI, -0.66 to -0.05) and compared to reslizumab with blood eosinophils ≥ 400 cells/μL (difference, -0.39; 95% CI, -0.66 to -0.12). There was no difference between reslizumab and benralizumab in clinically significant exacerbations or ACQ scores in patients with blood eosinophils ≥ 400 cells/μL *(Busse et al 2019b)*.
- A 2019 systematic review and network meta-analysis of 30 RCTs compared biologic therapies for treatment of type 2 (ie, eosinophilic) asthma. Mepolizumab, reslizumab, and benralizumab significantly reduced the risk of exacerbations compared with placebo; however, network meta-analysis showed no superiority of any biologic therapy for this outcome among benralizumab, dupilumab, mepolizumab, reslizumab, and other biologics not available in the U.S. (lebrikizumab, tralokinumab) *(Edris et al 2019)*.
- In a 2020 meta-analysis including data from 3 trials (n = 2640), dupilumab and benralizumab were compared in patients with inadequately controlled asthma. While there were no significant differences in the annual exacerbation rates between both drugs in the overall population (RR, 0.83; 95% CI, 0.62 to 1.09) and in the subgroup with the blood eosinophil count < 150 cells/μL (RR, 1.57; 95% CI, 0.73 to 2.82), dupilumab was superior to benralizumab for the subgroup with a blood eosinophil count of ≥ 300 cells/μL (RR, 0.58; 95% CI, 0.39 to 0.84) and ≥ 150 to < 300 cells/μL (RR, 0.51; 95% CI, 0.29 to 0.92). The incidence of adverse events was similar between groups (OR, 1.023; 95% CI, 0.688 to 1.526) (*Ando et al 2020*).
- Additional meta-analyses have not found significant differences in asthma exacerbation rates between mepolizumab and reslizumab or between benralizumab and mepolizumab *(Bourdin et al 2018, Henriksen et al 2018, Yan et al 2019).*
- The magnitude of treatment effect of biologic agents (including benralizumab, reslizumab, dupilumab, mepolizumab, lebrikizumab [investigational], and tralokinumab [investigational]) in patients with eosinophilic asthma was evaluated in a network meta-analysis. The outcomes evaluated were change in FEV_1, ACQ score, and AQLQ score. Event rates for asthma exacerbation and associated RRs were determined for each drug. A total of 26 studies were included in the analysis (n = 7 benralizumab, n = 2 dupilumab, n = 4 lebrikizumab, n = 7 mepolizumab, n = 4 reslizumab, n = 2 tralokinumab) with a total of 8444 patients (n = 4406 on active treatment, n = 4038 in control groups). The duration of treatment ranged from 12 to 56 weeks. An increase in FEV_1, reduction in ACQ score, and increase in AQLQ score were observed with all treatments except tralokinumab. Compared to placebo, the greatest FEV_1 increase was with dupilumab (0.16 L; 95% CI, 0.08 to 0.24), followed by reslizumab (0.13 L; 95% CI, 0.10 to 0.17), and benralizumab (0.12 L; 95% CI, 0.08 to 0.17). Mepolizumab and lebrikizumab both had an increase of 0.09 L (95% CI, 0.03 to 0.15 with mepolizumab, 0.04 to 0.15 with lebrikizumab). Reduction in ACQ score (indicating better asthma control) in order of greatest to least reduction was mepolizumab, dupilumab, benralizumab, and reslizumab. The investigational agents had the least impact on the ACQ score. Quality of life scores were similarly increased with the 4 agents while the investigational agents had the least impact on quality of life. Compared to placebo, the calculated RR for annualized asthma exacerbation was significant only for dupilumab (RR, 0.37; 95% CI, 0.17 to 0.80) and reslizumab (RR, 0.64; 95% CI, 0.53 to 0.78). Comparisons between treatments did not show any significant difference for change in FEV_1, asthma control or quality of life except for superiority of mepolizumab to the 2 investigational agents in ACQ score reduction (*Iftikhar et al 2018*).
- In a 2020 network meta-analysis including 9 studies, treatment rankings estimated that dupilumab was most effective at reducing the risk of asthma exacerbation, followed by mepolizumab, reslizumab, and benralizumab. Similar to other indirect treatment comparisons, there were no within-group differences as related to the risk for asthma exacerbations (*Ramonell et al 2020*).
- A 2022 network meta-analysis of 8 RCTs (N = 6461) compared the safety and efficacy of mepolizumab, benralizumab, and dupilumab in patients with severe eosinophilic asthma. Dupilumab had the highest probability (> 95%) of having the

highest or second-best overall surface under the cumulative ranking curve (SUCRA) score in reducing exacerbation rates and improving lung function. Mepolizumab and benralizumab had a 30% and ~10% chance of being ranked best, respectively (*Akenroye et al 2022*).

- A 2023 network meta-analysis of 10 RCTs (N = 9201) compared the efficacy of tezepelumab compared to mepolizumab, benralizumab, and dupilumab in patients with eosinophilic asthma. Tezepelumab was associated with lower exacerbation rates compared to benralizumab (RR, 0.63; 95% CI, 0.46 to 0.86), but no difference was seen compared to dupilumab or mepolizumab. Improvements in FEV_1 were non-significantly larger with tezepelumab compared to mepolizumab and benralizumab. Tezepelumab had the highest SUCRA score for reducing exacerbation rate (89% probability of having the highest- or second-best rank), followed by dupilumab (38%), mepolizumab (6%), and benralizumab (< 1%) (*Nopsopon et al 2023*).
- A systematic review and network meta-analysis of 64 trials (N = 26,630) compared the efficacy of biologic therapies for asthma in adults with moderate, moderate-to-severe, or severe asthma. Key findings included (*Pitre et al 2023*):
  - Treatment with tezepelumab, dupilumab, benralizumab, mepolizumab, reslizumab, and omalizumab probably reduced exacerbations vs placebo in patients with blood eosinophil levels ≥ 300 cells/μL (moderate to high certainty).
  - Dupilumab, tezepelumab and reslizumab probably improved lung function vs to placebo (moderate to high certainty).
  - Dupilumab and tezepelumab were the most effective for reducing exacerbations in patients with blood eosinophil levels ≥ 300 cells/μL (RR, 0.32 [95% CI, 0.24 to 0.42] and 0.30 [95% CI, 0.22 to 0.43], respectively) and improving lung function compared to other agents (mean difference [MD], 0.25 L [95% CI, 0.21 to 0.29] and MD, 0.24 L [95% CI, 0.16 to 0.32], respectively) (high certainty for both outcomes); neither demonstrated superiority over the other for both endpoints.
  - Moderate-certainty evidence showed that dupilumab, omalizumab, and tezepelumab probably reduced hospitalizations compared to placebo (moderate certainty). The authors also concluded that in patients with low eosinophils, biologics likely do not improve asthma outcomes.

CRSwNP

- In a 2022 network meta-analysis including 9 RCTs, 4 different biologics (dupilumab [n = 3], omalizumab [n = 4], mepolizumab [n = 2]) and placebo were compared in patients with CRSwNP. Dupilumab was found to be the most efficacious in terms of NPS, Sino-Nasal Outcome Test-22 (SNOT-22) score, University of Pennsylvania Smell Identification Test (UPSIT) score, and NCS with SUCRA values of 0.900, 0.916, 1.000, and 0.807, respectively. Omalizumab ranked second in efficacy in SNOT-22, UPSIT, and NCS scores with SUCRA values of 0.606, 0.500, and 0.693, respectively. Mepolizumab had the highest risk of adverse events for SUCRA values of 0.746 (*Wu et al 2022*).

Clinical Guidelines

Asthma

- The National Asthma Education and Prevention Program (NAEPP) guideline from the NHLBI states that the initial treatment of asthma should correspond to the appropriate asthma severity category, and it provides a stepwise approach to asthma management. Long-term control medications such as ICSs, long-acting bronchodilators, leukotriene modifiers, cromolyn, and immunomodulators should be taken daily on a long-term basis to achieve and maintain control of persistent asthma. ICSs are the most potent and consistently effective long-term asthma control medication. Quick-relief medications such as SABAs and anticholinergics are used to provide prompt relief of bronchoconstriction and accompanying acute symptoms such as cough, chest tightness, and wheezing. Systemic corticosteroids are important in the treatment of moderate or severe exacerbations because these medications prevent progression of the exacerbation, speed recovery, and prevent relapses (*NHLBI 2007*).
- The 2024 GINA report also provides a stepwise approach to asthma management (*GINA 2024*).
  - Treatment recommendations are based on patient age, and stepping down should be considered when asthma symptoms have been well-controlled and lung function has been stable for ≥ 3 months.
    - ICS/$beta_2$-agonist combination products are recommended for both controller (ie, maintenance treatment) and reliever use in patients ≥ 6 years of age, while the preferred controller option in patients ≤ 5 years of age consists of low-dose ICS plus as-needed SABA as a reliever.
  - In patients ≥ 6 years of age diagnosed with severe asthma and uncontrolled on Step 4 treatment (eg, with maintenance ICS/LABA therapy), phenotyping for Type 2 inflammation into categories such as severe allergic, aspirin-exacerbated, allergic bronchopulmonary aspergillosis, chronic rhinosinusitis, nasal polyposis, atopic dermatitis, or eosinophilic asthma is recommended. Add-on treatment with a biologic agent should be considered as follows:

  - Severe allergic asthma: Anti-IgE treatment with omalizumab is recommended for patients ≥ 6 years of age.
  - Severe eosinophilic asthma: Add-on anti-IL-5 therapy is recommended for patients ≥ 6 years of age (mepolizumab and benralizumab) or ≥ 18 years of age (reslizumab).
  - Severe eosinophilic/Type 2 asthma: Anti-IL4 therapy (dupilumab) is recommended for patients ≥ 6 years of age.
  - Adults or adolescents requiring oral corticosteroids for maintenance therapy: Anti-IL4 therapy (dupilumab) is recommended.
  - Severe asthma: Anti-TSLP therapy (tezepelumab-ekko) is recommended for patients ≥ 12 years of age.
  - Prior to initiation of a biologic agent, several factors should be considered including cost, insurance eligibility criteria, evaluation of predictors of response, delivery route, dosing frequency, and patient preference.
- The European Respiratory Society/American Thoracic Society guideline on the management of severe asthma suggests the use of anti-IL-5 therapy as an add-on in adults with severe uncontrolled eosinophilic asthma or severe corticosteroid-dependent asthma. A blood eosinophil count of ≥ 150 cells/µL is suggested as a cut-point to guide initiation of anti-IL-5 therapy in adults with severe asthma and prior exacerbations. A blood eosinophil count of ≥ 260 cells/µL or an exhaled nitric oxide level of 19.5 parts per billion or greater may be used to identify adolescents and adults with severe allergic asthma who are likely to benefit from anti-IgE treatment. Dupilumab is suggested for adults with severe eosinophilic asthma, and for those with severe corticosteroid-dependent asthma regardless of eosinophil levels (*Holguin et al 2020*).

CIU

- Guidelines developed by the Joint Council of Allergy, Asthma & Immunology, comprised of members from the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology, recommend a stepwise treatment approach for CIU. Treatment with omalizumab is recommended in patients inadequately controlled with antihistamines and a LTRA (*Bernstein et al 2014*).
- Joint guidelines by the European Academy of Allergy and Clinical Immunology, the Global Allergy and Asthma European Network, the European Dermatology Forum, and the World Allergy Organization recommend treatment with omalizumab in patients with symptoms despite treatment with a 4-fold dose of modern second-generation antihistamines. This is a change from previous guidelines in which use of either omalizumab or cyclosporine after failure of high-dose antihistamines was recommended. However, due to adverse effects and the lack of an approved indication, the new recommendation was that cyclosporine should only be considered if omalizumab does not provide an adequate response (*Zuberbier et al 2022*).
- Guidelines published by the British Association of Dermatologists similarly recommend omalizumab as a potential second-line agent in patients inadequately controlled on first-line second-generation antihistamines (*Sabroe et al 2021*).

EGPA

- In 2021, a joint guideline from the American College of Rheumatology and Vasculitis Foundation published recommendations for the management of EGPA along with other related conditions (*Chung et al 2021*). The following relevant conditional recommendations were provided:
  - Patients with active, severe EGPA should be treated with cyclophosphamide or rituximab over mepolizumab for remission induction.
  - Patients with active, nonsevere EGPA should be treated with mepolizumab and glucocorticoids over methotrexate, azathioprine, or mycophenolate mofetil and glucocorticoids.
  - Patients with severe EGPA whose disease has entered remission should be treated with methotrexate, azathioprine, or mycophenolate mofetil over mepolizumab for remission maintenance.
  - Patients with EGPA who have experienced relapse with nonsevere disease manifestations (ie, asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: mepolizumab should be added over switching to another agent.
  - Patients with EGPA who have experienced relapse with nonsevere disease manifestations (asthma and/or sinonasal disease) while receiving low-dose glucocorticoids and no other therapy: mepolizumab should be added over adding methotrexate, azathioprine, or mycophenolate mofetil.
  - Patients with EGPA and high serum IgE levels who have experienced relapse with nonsevere disease manifestations (asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: mepolizumab should be added over adding omalizumab.
- Both the EGPA (Churg-Strauss) Consensus Task Force recommendations and the American Society for Apheresis guideline recommend glucocorticoids alone for patients without life- and/or organ-threatening EGPA. For patients with

life- and/or organ-threatening EGPA, both glucocorticoids and an immunosuppressant are recommended, as well as maintenance therapy with azathioprine or methotrexate. Guidelines from the American Society for Apheresis recognized mepolizumab as a future treatment option, and the EGPA Consensus Task Force recommendations noted that mepolizumab held promise for this condition based on the pilot studies available at the time of guideline development. IVIG can be considered for refractory EGPA or for treatment during pregnancy (*Connelly-Smith et al 2023, Groh et al 2015*).

CRSwNP

- Treatment of CRSwNP is addressed in guidelines from the American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology; the International Forum of Allergy & Rhinology; the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA); and the International Consensus Statement on Allergy and Rhinology: Rhinosinusitus (ICAR-RS) (*Orlandi et al 2021, Peters et al 2014, Rosenfeld et al 2015, Rank et al 2023*).
- Routine treatment recommendations include saline irrigation and/or intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids and surgery in patients with severe or refractory symptoms (*Orlandi et al 2021, Peters et al 2014, Rosenfeld et al 2015, Rank et al 2023*). Biologics rather than no biologics are recommended for patients with CRSwNP, and dupilumab is specifically recommended by ICAR-RS (*Orlandi et al 2021, Rank et al 2023*).
- In 2023, EUFOREA published an updated expert consensus focused on the use of biologics for CRSwNP. Biologics are indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following criteria: evidence of type 2 inflammation (biological biomarkers); the need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids) or contraindications to systemic corticosteroids, significant quality-of-life impairment, significant loss of smell, and diagnosis of comorbid asthma. Once eligibility according to the EUFOREA 2023 criteria has been determined, a patient's preference for a surgical or non-surgical approach should be considered if funding within the healthcare system allows. In patients who have never had surgery, 4 of the aforementioned criteria need to be met before a biologic is indicated. Patients with previous sinus surgery plus severe asthma may also qualify for treatment in consultation with their pulmonologist. Lastly, biologics should not be initiated in the following situations: CRSwNP and lack of signs of type 2 inflammation, cystic fibrosis, unilateral nasal polyps, mucoceles, general contraindications for biological treatments (eg, immunodeficiencies), and patient-related factors such as noncompliance to therapy (*Fokkens et al 2023*).

HES

- The World Health Organization (WHO) guidance on eosinophilic disorders has stated that identification of rearranged *PDGFRA* or *PDGFRB* is important in the management of eosinophilic disorders as those variants respond to imatinib (*Shomali and Gotlib 2024*). For patients with idiopathic HES (without imatinib-sensitive variants), corticosteroids are first-line therapy; second-line options include hydroxyurea, interferon-alfa, other cytotoxic chemotherapy agents, and hematopoietic stem cell transplantation. The WHO states that mepolizumab is FDA-approved for idiopathic HES, but other biologic agents are considered investigational.

EoE

- In 2020, the American Gastroenterological Association and the Joint Task Force on Allergy Immunology Practice Parameters (AGA/JTF) published a guideline on the management of EoE (*Hirano et al 2020a)*. In patients with symptomatic esophageal eosinophilia, the AGA/JTF suggests using proton pump inhibition over no treatment. Furthermore, for patients with EoE, topical glucocorticoids are recommended over no treatment and topical glucocorticoids are suggested rather than oral glucocorticoids. Authors did not recommend the use of the following therapies outside of a clinical trial setting based on the available data in patients with EoE at the time of guideline publication: anti-IL13, anti-IL4, anti-IL5, and anti-tumor necrosis factor therapies, montelukast, cromolyn sodium, and immunomodulators. The guideline suggested against the use of anti-IgE therapy for EoE. Similar recommendations are provided in an older guideline from the American College of Gastroenterology (*Dellon et al 2013*).

IgE-mediated food allergy

- National guidelines for food allergies focus on nutritional interventions and have not been updated to include recommendations for omalizumab (*Fleischer et al 2021, Sampson et al 2014*).

COPD

- The 2024 GOLD guidelines recommend that the choice of initial COPD maintenance therapy should be based on a patient's level of symptoms and exacerbation history (*GOLD 2024*). Regimens may include monotherapy with LAMA or LABA, double therapy with LAMA + LABA, or triple therapy with LAMA + LABA + ICS. Additional treatments appropriate for some patients include roflumilast, an oral phosphodiesterase (PDE) 4 inhibitor indicated to decrease the risk of COPD exacerbations in patients with chronic bronchitis and a history of exacerbation; azithromycin, an oral macrolide antibiotic; and Ohtuvayre (ensifentrine) inhalation suspension, a combined PDE3 and PDE4 inhibitor indicated for the maintenance treatment of COPD in adult patients (*GOLD 2024, Ohtuvayre prescribing information 2024).* National guidelines for COPD have not been updated to include recommendations for dupilumab or ensifentrine at the time this therapeutic class overview was published.

Safety Summary

- All the antiasthmatic monoclonal antibodies are contraindicated in patients with a history of hypersensitivity to the specific agent or excipients of the formulation.
- Abrupt discontinuation of systemic, topical, or inhaled corticosteroids is not recommended when treatment with any of these agents are initiated. If appropriate, the corticosteroid dosage should be reduced gradually.

Cinqair (reslizumab)

- Boxed warning: Anaphylaxis has been observed with Cinqair infusion in 0.3% of patients in placebo-controlled clinical studies. Anaphylaxis was reported as early as the second dose of Cinqair. Patients should be observed for an appropriate period of time after Cinqair administration by a healthcare professional prepared to manage anaphylaxis.
- Key warnings and precautions:
  - In placebo-controlled clinical studies, 6/1028 (0.6%) patients receiving 3 mg/kg Cinqair had ≥ 1 malignant neoplasm reported compared to 2/730 (0.3%) patients in the placebo group. The observed malignancies in Cinqair-treated patients were diverse in nature and without clustering of any particular tissue type.
  - Pre-existing helminth infections should be treated before therapy with Cinqair. If patients become infected while receiving Cinqair and do not respond to anti-helminth treatment, Cinqair should be discontinued until the parasitic infection resolves.
- The most common adverse reaction (≥ 2%) included oropharyngeal pain.

Dupixent (dupilumab)

- Key warnings and precautions:
  - Hypersensitivity reactions (eg, anaphylaxis, erythema nodosum, erythema multiforme, serum sickness, angioedema, urticaria, and rash) have occurred after administration of Dupixent. Dupixent should be discontinued in the event of a hypersensitivity reaction.
  - For patients with asthma, cases of eosinophilic pneumonia and vasculitis consistent with EGPA have been reported. Occurrence of vasculitic rash, worsening pulmonary symptoms, and/or neuropathy, especially upon reduction of oral corticosteroids should be monitored.
  - New or worsening eye symptoms (conjunctivitis and keratitis) or new or worsening joint symptoms (arthralgias) should be evaluated. Visual disturbances associated with conjunctivitis or keratitis have been reported (except in patients taking dupilumab for EoE) and may require ophthalmological examination. Discontinuation of Dupixent may be necessary in some cases of arthralgia.
  - Dupilumab should not be used to treat acute symptoms or acute exacerbations of asthma or COPD.
  - Pre-existing helminth infections should be treated before therapy with Dupixent. If a patient becomes infected while receiving Dupixent and does not respond to anti-helminth treatment, Dupixent should be discontinued until the parasitic infection resolves.
  - Use of live vaccines should be avoided.
- Adverse reactions:
  - Asthma: the most common adverse reactions included injection site reactions, oropharyngeal pain, and eosinophilia.

- The safety profile in patients 6 to 11 years of age was similar to the safety profile from studies in adults and adolescents with the addition of helminth infections. Adverse reactions of helminth infections were reported in pediatric patients (5 cases of enterobiasis and 1 case of ascariasis) who participated in clinical studies.
- COPD: the most common adverse reactions included viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reactions, rhinitis, eosinophilia, toothache, and gastritis.
- CRSwNP: the most common adverse reactions included injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.
- EOE: the most common adverse reactions included injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

Fasenra (benralizumab)

- Key warnings and precautions:
  - Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration of Fasenra. Fasenra should be discontinued in the event of a hypersensitivity reaction.
  - Pre-existing helminth infections should be treated before therapy with Fasenra. If patients become infected while receiving Fasenra and do not respond to anti-helminth treatment, Fasenra should be discontinued until the parasitic infection resolves.
- The most common adverse reactions (≥ 5%) included headache and pharyngitis.

Nucala (mepolizumab)

- Key warnings and precautions:
  - Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration of Nucala.
  - Herpes zoster infections have occurred in patients receiving Nucala. Vaccination should be considered if clinically appropriate.
  - Pre-existing helminth infections should be treated before therapy with Nucala. If patients become infected while receiving Nucala and do not respond to anti-helminth treatment, Nucala should be discontinued until the parasitic infection resolves.
- The most common adverse reactions (≥ 5%) included headache, injection site reaction, back pain, and fatigue. Mouth/throat pain and joint pain have been reported in patients with CRSwNP.

Xolair (omalizumab)

- Boxed warning: Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported. Initiate Xolair in a healthcare setting and closely observe patients for an appropriate period of time after administration. Health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Selection of patients for self-administration of Xolair should be based on criteria to mitigate risk from anaphylaxis.
  - Patients with a prior history of anaphylactic reactions to foods, medications, or other causes may be at an increased risk for anaphylaxis. The frequency of anaphylaxis is reported to be between 0.1 to 0.2% and may occur immediately or up to a year post-treatment. Approximately 60 to 70% of anaphylaxis cases have been reported to occur within the first 3 doses.
- Key warnings and precautions:
  - Malignant neoplasms were observed at a higher rate in Xolair-treated patients (0.5%) compared to control patients (0.2%) in clinical trials. A subsequent 5-year observational cohort study found similar rates of primary malignancies in Xolair- and non-Xolair-treated patients. However, study limitations preclude definitively ruling out a malignancy risk with Xolair (*Long et al 2014*).
  - Rarely, patients on therapy with Xolair may present with serious systemic eosinophilia, which may present with features of vasculitis consistent with Churg-Strauss syndrome. These events usually have been associated with the reduction of oral corticosteroid therapy.
  - Systemic or inhaled corticosteroids should not be abruptly discontinued upon initiation of Xolair therapy for asthma or nasal polyps.
  - Some patients have reported signs and symptoms similar to serum sickness, including arthritis/arthralgia, rash, fever, and lymphadenopathy; Xolair should be stopped for signs and symptoms of serum sickness.

- Serum IgE levels increase following Xolair therapy and may persist for up to 1 year following discontinuation of therapy.
- Xolair should not be used for emergency treatment of allergic reactions, including anaphylaxis.

- Adverse reactions:
  - Asthma: In patients ≥ 12 years of age, commonly observed adverse reactions in clinical studies (≥ 1% in Xolair-treated patients and more frequently than reported with placebo) were arthralgia, pain (general), leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In clinical studies with pediatric patients 6 to < 12 years of age, the most common adverse reactions were nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
    - Cardiovascular and cerebrovascular events in asthma studies: In a 5-year observational cohort study, a higher incidence of overall cardiovascular and cerebrovascular serious adverse events was observed in Xolair-treated patients compared to non-Xolair-treated patients. To further evaluate the risk, a pooled analysis of 25 randomized, controlled, clinical trials was conducted. An increased risk of cardiovascular and cerebrovascular serious adverse events was not noted, but the low number of events, the young patient population, and the short duration of follow-up prevent a definite conclusion about the absence of a risk (*FDA 2014*).
  - CIU: Adverse reactions from 3 placebo-controlled, multiple-dose CIU studies that occurred in ≥ 2% of patients receiving Xolair and more frequently than in those receiving placebo included arthralgia, cough, headache, nasopharyngitis, nausea, sinusitis, upper respiratory tract infection, and viral upper respiratory tract infection.
  - CRSwNP: The most common adverse reactions (≥ 3% of patients) in clinical studies included headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness.

Tezspire (tezepelumab-ekko)

- Key warnings and precautions:
  - Hypersensitivity reactions (eg, rash, allergic conjunctivitis) have occurred after administration of Tezspire, either within hours after administration or after days.
  - Tezspire should not be used to treat acute asthma symptoms or asthma exacerbations.
  - Systemic or inhaled corticosteroids should not be abruptly discontinued upon initiation of Tezspire therapy for asthma; if appropriate, corticosteroid treatment should be reduced gradually.
  - Pre-existing helminth infections should be treated prior to therapy with Tezspire. If patients become infected while receiving Tezspire and do not respond to anti-helminth treatment, Tezspire should be discontinued until the parasitic infection resolves.
  - Use of live attenuated vaccines should be avoided in patients receiving Tezspire.
- Adverse reactions:
  - In patients ≥ 12 years of age, commonly observed adverse reactions in clinical studies (≥ 3%) were pharyngitis, arthralgia, and back pain.

Dosing and Administration

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Cinqair (reslizumab)	Single-use vials	IV	Every 4 weeks	• Safety and effectiveness in pediatric patients ≤ 17 years of age have not been established. • Cinqair should be administered by a healthcare professional by IV infusion over 20 to 50 minutes.
Dupixent (dupilumab)	Single-dose pre-filled syringe, single-dose pre-filled pen	SC	Asthma: In adults and pediatric patients (6 to 11 years of age) weighing ≥ 30 kg, every other week; in pediatric patients (6 to 11 years	• Safety and efficacy in patients < 6 years of age (asthma), < 1 year of age (EoE), and < 18 years of age (CRSwNP) have not been established. • Dupixent may be administered by a healthcare professional or self-

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
			of age) weighing 15 to < 30 kg, every 4 weeks COPD: Every other week CRSwNP: Every other week EoE: Weight-based dosing in adults and children ≥ 1 year of age: 15 to < 30 kg, 200 mg every other week; 30 to < 40 kg, 300 mg every other week; ≥ 40 kg, 300 mg every week	administered via pre-filled syringe or pen.
Fasenra (benralizumab)	Single-dose pre-filled syringe, single-dose pre-filled pen (autoinjector)	SC	Asthma: Every 4 weeks for first 3 doses, followed by every 8 weeks EGPA: Every 4 weeks	• Safety and efficacy in pediatric patients < 6 years of age have not been established. • Fasenra may be administered by a healthcare professional or self-administered via an autoinjector.
Nucala (mepolizumab)	Single-dose vial for reconstitution, single-dose pre-filled pen (autoinjector), single-dose prefilled syringe	SC	Asthma: Every 4 weeks EGPA: Every 4 weeks HES: Every 4 weeks CRSwNP: Every 4 weeks	• Safety and efficacy in pediatric patients < 6 years (asthma), < 18 years (EGPA), < 12 years (HES) of age, and < 18 years of age (CRSwNP) have not been established. • Nucala may be administered by a healthcare professional or self-administered via an autoinjector or pre-filled syringe. • The 40 mg/0.4 mL prefilled syringe for patients 6 to 11 years of age should be administered by a healthcare professional or a patient caregiver.
Xolair (omalizumab)	Single-dose vial for reconstitution; single-dose prefilled syringe or autoinjector	SC	Allergic asthma: Every 2 or 4 weeks CIU: Every 4 weeks CRSwNP: Every 2 or 4 weeks IgE-mediated food allergy: Every 2 or 4 weeks	• Safety and efficacy in patients < 1 year of age (IgE-mediated food allergy); < 6 years of age (asthma), < 12 years of age (CIU), < 18 years of age (CRSwNP) have not been established. • Xolair should be initiated in a healthcare setting: once therapy has been safely established, Xolair may be administered by a healthcare professional or self-administered via a pre-filled syringe. • For allergic asthma, CRSwNP, and IgE-mediated food allergy, the dose and frequency are determined by serum

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
				total IgE level (measured before the start of treatment) and body weight; dosage determination should be based on the primary diagnosis for which Xolair is being prescribed. • Doses should be adjusted for significant changes in bodyweight. • Dosing in CIU is not dependent on serum IgE level or body weight.
Tezspire (tezepelumab-ekko)	Single-dose glass vial, single-dose prefilled syringe, single-dose prefilled pen	SC	Asthma: Every 4 weeks	• Safety and efficacy in pediatric patients < 12 years of age have not been established. • The Tezspire vial and prefilled syringe are intended for administration by a healthcare professional. The prefilled pen may be self-administered after proper training.

See the current prescribing information for full details.

Conclusion

- The respiratory and allergy biologics include the IgE inhibitor Xolair (omalizumab), the IL-4 inhibitor Dupixent (dupilumab), the IL-5 antagonists Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab), and the TSLP blocker Tezspire (tezepelumab-ekko).
  - These agents are a mainstay of treatment for severe asthma; in addition, various agents in the class are indicated for use in EGPA, CIU, COPD, CRSwNP, HES, EoE, and IgE-mediated food allergy.
- Xolair (omalizumab) is a humanized monoclonal antibody that is FDA-approved for patients ≥ 6 years of age with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with an ICS. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.
  - Although clinical trial results have been mixed and several trials had an open-label design, there is some evidence to indicate that Xolair may decrease asthma-related emergency visits and hospitalizations, as well as decreasing the dose of ICS and rescue medication and increasing symptom-free days (*Buhl et al 2002, Busse et al 2011, Holgate et al 2004, Lanier et al 2003, Solèr et al 2011*).
  - Xolair carries a boxed warning due to the risk of anaphylaxis, and thus must be initiated in a healthcare setting. Once therapy has been safely established, select patients may be able to self-administer Xolair using a pre-filled syringe.
  - Although Xolair therapy is generally safe, analysis of a 5-year, observational cohort, epidemiological study (EXCELS) showed an increased number of cardiovascular and cerebrovascular adverse events in patients receiving Xolair compared to placebo (*Iribarren et al 2017*). However, a pooled analysis of 25 randomized, double-blind, placebo-controlled clinical trials did not find notable imbalances in the rates of cardiovascular and cerebrovascular serious adverse events (*FDA 2014*).
  - Asthma guidelines generally recommend Xolair therapy in patients with severe allergic asthma that is inadequately controlled with a combination of high-dose ICS and LABA (*Cloutier et al 2020, GINA 2024, NHLBI 2007*). Based on a limited place in therapy, Xolair is appropriate for a small percentage of patients with asthma.
- Xolair received FDA approval for the treatment of adults and adolescents (≥ 12 years of age) with CIU who remain symptomatic despite H_1-antihistamine treatment. Two randomized, placebo-controlled trials demonstrated its efficacy in reducing weekly itch severity scores and weekly hive count scores significantly greater than placebo at week 12. Xolair was well-tolerated, with a safety profile similar to that observed in asthma patients.
  - In patients with CIU, Xolair is administered at 150 or 300 mg SC every 4 weeks.
  - Guidelines for the treatment of CIU recommend treatment with Xolair in patients who are inadequately controlled with a 4-fold dose of modern second-generation antihistamines. Although previous guidelines suggested the use of

omalizumab after a LTRA, the most recent guideline from the European Academy of Allergy and Clinical Immunology, the Global Allergy and Asthma European Network, the European Dermatology Forum, and the World Allergy Organization state that a recommendation regarding use of a LTRA cannot be made due to a low level of evidence. Additionally, use of Xolair is recommended before treatment with cyclosporine (*Bernstein et al 2014, Zuberbier et al 2022, Sabroe et al 2021*).

- Xolair was approved as add-on maintenance treatment for CRSwNP in adult patients with an inadequate response to nasal corticosteroids, based on results from 2 identical, randomized, multicenter, double-blind, placebo-controlled, Phase 3 studies [POLYP 1 and POLYP 2] (*Gevaert et al 2020*). Results from both studies revealed that Xolair was associated with a significantly greater improvement from baseline at week 24 in NPS and weekly average NCS as compared to placebo. Adverse events were similar between groups.
- Xolair was approved for IgE-mediated food allergy in patients ≥ 1 year of age based on the results of a randomized, multicenter, double-blind, placebo-controlled trial in patients with allergies to peanut and at least 2 other foods (*Wood et al 2024)*. Results demonstrated a significantly higher response with Xolair vs placebo for the primary outcome (percentage of patients able to tolerate a single dose of ≥ 600 mg of peanut protein without experiencing dose-limiting symptoms). Guidelines for food allergies mostly focus on nutritional interventions and have not been updated to include recommendations for omalizumab (*Fleischer et al 2021, Sampson et al 2014)*.
- Dupixent (dupilumab) is an IL-4/IL-13 antagonist approved for the treatment of patients ≥ 6 years of age with moderate-to-severe asthma of the eosinophilic type or dependent on oral corticosteroids, patients ≥ 1 year of age and weighing ≥ 15 kg with EoE, and as an add-on treatment in adults with inadequately controlled CRSwNP.
  - According to GINA guidelines, the use of Dupixent for severe asthma with an eosinophilic phenotype can be considered for patients with severe eosinophilic/Type 2 asthma or patients taking oral corticosteroids.
- Dupixent was approved for CRSwNP after the publication of several guidelines, although some acknowledged the potential role for biologic therapies (*Orlandi et al 2021, Peters et al 2014, Rank et al 2023).*
  - In a 2023 EUFOREA expert consensus publication focused on the use of biologics for CRSwNP, biologics were indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following criteria: evidence of type 2 inflammation (biological biomarkers), need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids) or contraindications to systemic corticosteroids, significant quality-of-life impairment; significant loss of smell, and diagnosis of comorbid asthma (*Fokkens et al 2023*).
- Dupixent was approved for EoE after the publication of available guidelines (*Dellon et al 2013, Hirano et al 2020a).*
- Dupixent is the first biologic agent approved for COPD, and the first treatment specifically approved for type 2 inflammation in COPD (eosinophil phenotype). 2024 GOLD guidelines do not include recommendations for its use in COPD.
- Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab) are IL-5 antagonists approved as add-on treatment options for patients with severe eosinophilic asthma and have demonstrated effectiveness in reducing asthma exacerbations (*Bel et al 2014, Bjermer et al 2016, Castro et al 2015, Corren et al 2016, Pavord et al 2012, Ortega et al 2014, Bleecker et al 2016, Fitzgerald et al 2016*).
  - The mechanism of action of Fasenra is slightly different, in that it binds to the IL-5 receptor on immune effector cells, whereas Cinqair and Nucala bind to the IL-5 cytokine. All these agents provide a more targeted treatment option for patients with severe asthma and should be considered in patients who are uncontrolled despite a high-dose ICS/LABA, and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroids (*GINA 2024*).
- Nucala and Fasenra are approved for the treatment of adult patients with EGPA. In a head-to-head trial, benralizumab was shown to be non-inferior to mepolizumab in adult patients with relapsing or refractory disease. A joint guideline from the American College of Rheumatology and Vasculitis Foundation provides recommendations for the place in therapy for Nucala in the management of EGPA based on the severity of disease and prior treatments (*Chung et al 2021*). Nucala is also approved as an add-on treatment in adults with inadequately controlled CRSwNP, and in patients ≥ 12 years of age with HES.
- Tezspire (tezepelumab-ekko), a human monoclonal antibody, is a TSLP blocker approved for severe, uncontrolled asthma in patients ≥ 12 years of age. Efficacy of Tezspire was shown in the NAVIGATOR trial, with significant reductions in asthma exacerbations compared to placebo. While approximately one-half of enrolled patients had eosinophil counts of ≥ 300 cells/μL, efficacy was seen in patients with low and high eosinophil counts. *(Menzies-Gow et al 2021).*
- There are no head-to-head trials comparing Cinqair, Fasenra, Dupixent, Nucala, or Tezspire for the treatment of asthma.

- A systematic review of the IL-5 antagonists conducted in patients with asthma poorly controlled by ICS revealed that all of the IL-5 antagonists reduced asthma exacerbations by approximately 50% and improved FEV1 by 0.08 L to 0.15 L. Overall, there was not an increase in serious adverse events with any IL-5 antagonist; however, more patients discontinued benralizumab (42/2026) than placebo (11/1227) due to adverse events (*Farne et al 2022*).
- One network meta-analysis of IL-4, IL-5 and IL-13 antagonists demonstrated that all agents reduced FEV1 and improved ACQ and AQLQ scores, except for the investigational agent, tralokinumab; other analyses found that dupilumab, mepolizumab, reslizumab, and benralizumab significantly reduced the risk of exacerbations compared with placebo (*Ando et al 2020, Edris et al 2019, Iftikhar et al 2018, Ramonell et al 2020*).
- Treatment rankings in a 2020 network meta-analysis estimate that dupilumab is most effective at reducing the risk of asthma exacerbation, followed by mepolizumab, reslizumab, and benralizumab (*Ramonell et al 2020*).
- A systematic review and network meta-analysis of 64 trials in 26,630 patients with moderate, moderate-to-severe, or severe asthma determined that treatment with benralizumab, dupilumab, mepolizumab, reslizumab, omalizumab, and tezepelumab probably reduce exacerbations vs placebo in patients with eosinophilic asthma (blood eosinophil levels ≥ 300 cells/µL; moderate to high certainty). Overall, dupilumab and tezepelumab were the most effective for reducing exacerbations in patients with eosinophilic asthma and improving lung function compared to other agents (both high certainty). Of note, the authors concluded that in patients with low eosinophils, biologics likely do not improve asthma outcomes (*Pitre et al 2023*).

- Compared to Dupixent, Nucala, and Fasenra, Cinqair has various limitations for use in eosinophilic asthma, including an indication for patients ≥ 18 years of age (vs ≥ 6 years with Nucala, Dupixent, and Fasenra), IV administration (SC for Dupixent, Nucala, and Fasenra), and a boxed warning for anaphylaxis.
- SC autoinjector formulations are available for Fasenra, Nucala, and Xolair; single-dose prefilled syringes and/or pens are available for Dupixent, Fasenra, Nucala, Xolair, and Tezspire.

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Therapeutic Class Overview

Anticonvulsants

Introduction

- Epilepsy is a disease of the brain defined by any of the following (*Fisher et al 2014*):
  - At least 2 unprovoked (or reflex) seizures occurring > 24 hours apart;
  - 1 unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after 2 unprovoked seizures, occurring over the next 10 years;
  - Diagnosis of an epilepsy syndrome.
- Types of seizures include generalized seizures (previously called primary generalized), focal seizures (previously called partial), and seizures of unknown onset (*Fisher et al 2017A, Fisher et al 2017B, Nguyen et al 2023*). Seizure classifications from the International League against Epilepsy (ILAE) were updated in 2017.
  - Generalized seizures affect both sides of the brain and are classified by the type of symptoms:
    - Motor seizures: can be further classified by the type of motor symptoms
      - Tonic-clonic (previously called grand mal): begin with stiffening of the limbs, followed by jerking of the limbs and face
      - Myoclonic: characterized by rapid, brief contractions of body muscles, usually on both sides of the body at the same time
      - Atonic: characterized by abrupt loss of muscle tone; they are also called drop attacks or akinetic seizures and can result in injury due to falls
    - Nonmotor (absence) seizures (previously called petit mal): typical symptoms include brief lapses of awareness, sometimes with staring, that begin and end abruptly; they are more common in children than adults and may be accompanied by brief myoclonic jerking of the eyelids or facial muscles, a loss of muscle tone, or automatisms.
  - Focal seizures are located in just 1 area of the brain and are classified by the level of awareness and type of symptoms on onset of the seizure:
    - Focal aware (previously called simple) vs focal impaired awareness (previously called complex): retained awareness relates to ability for patient to remain aware of self and environment during a seizure
    - Motor onset vs nonmotor onset: grouped by earliest most prominent sign, either motor (eg, atonic, clonic, or tonic movements) or nonmotor (eg, autonomic or sensory symptoms)
    - Focal to bilateral tonic-clonic (previously called secondarily generalized seizures): describes pattern of a seizure that propagates to involve both sides of the brain
  - Seizures of unknown onset are classified by the type of symptoms, but onset is unable to be classified.
  - Any seizure type can lead to status epilepticus, which is characterized by prolonged, uninterrupted seizure activity.
- There is variation between the ILAE classifications and many of the Food and Drug Administration (FDA)-approved indications for antiepileptic drugs (AEDs) (*Nguyen et al 2023; Schachter 2024[a]*). For example, a “focal aware” seizure corresponds to the prior term “simple partial seizure,” a “focal impaired awareness” seizure corresponds to the prior term “complex partial seizure,” “generalized” seizure corresponds to the prior term “primary generalized,” “generalized tonic-clonic” seizure corresponds to the prior term “grand mal,” and “absence” seizure corresponds to the prior term “petit mal.”
- A number of epilepsy syndromes have also been described; these are defined by groups of features that tend to occur together such as having a similar seizure type, age of onset, part of the brain involved, and electroencephalogram (EEG) pattern (*Epilepsy Foundation 2013*). An example is a childhood epilepsy syndrome called Lennox-Gastaut syndrome (LGS), which is characterized by several seizure types including tonic (stiffening) and atonic (drop) seizures. In LGS, there is a classic EEG pattern seen and intellectual development is usually impaired (*Epilepsy Foundation 2020*).
- Epilepsy management is focused on the goals of 1) controlling seizures, 2) avoiding treatment-related adverse effects (AEs), and 3) maintaining or restoring quality of life. Management options vary based on the seizure type. It is usually appropriate to refer patients to a neurologist to establish the epilepsy diagnosis and formulate the management strategy (*Schachter 2024[b]*).
  - A correct diagnosis is essential to proper treatment selection. For example, absence seizures are commonly confused with complex partial seizures. However, drugs that reduce absence seizures are generally ineffective for complex partial seizures, and the most effective drugs for complex partial seizures may be ineffective against or even increase the frequency of absence seizures.

- When possible, monotherapy with a single AED is the preferred treatment approach. Use of monotherapy increases the probability of treatment adherence, provides a wider therapeutic index, and is associated with fewer idiosyncratic reactions, teratogenic effects, and potential drug interactions. However, data are conflicting on the benefits of mono- vs polytherapy. When combination therapy is needed, it is recommended to select products with different mechanisms of action and AE profiles. There is little comparative clinical data to support the use of specific combinations (*Schachter 2024[b]*).
- Several broad classes of AEDs are available, including barbiturates, benzodiazepines, hydantoins, and miscellaneous agents (see Table 1).
- Several newer products with different mechanisms of action have been approved in the past several years for use in childhood epilepsy syndromes such as LGS and Dravet syndrome. These include cannabidiol (Epidiolex), stiripentol (Diacomit), and fenfluramine (Fintepla).
- In March 2022, ganaxolone (Ztalmy) was approved by the FDA as an orphan drug for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder. In November 2022, phenobarbital injection (Sezaby) was approved by the FDA as an orphan drug for the treatment of neonatal seizures. Previous formulations of phenobarbital were not FDA-approved.
- Everolimus tablets for oral suspension (Afinitor Disperz) received an expanded indication in April 2018 for use in partial-onset seizures associated with tuberous sclerosis complex (TSC). This product is a kinase inhibitor that also has several oncology indications.
- Intranasal formulations of benzodiazepines have also been recently approved for the acute treatment of seizures, including midazolam nasal spray (Nayzilam) and diazepam nasal spray (Valtoco).
- Several of the AEDs are used for additional indications beyond the management of epilepsy, including (but not limited to) bipolar disorder, migraine prophylaxis, and several types of neuropathic pain. These additional indications are listed in Table 2; however, this review primarily focuses on the use of AEDs for the management of epilepsy. Additionally, brands and formulations that are FDA-approved and marketed only for non-epilepsy indications are not included within this review; these include gabapentin tablets (Gralise), gabapentin enacarbil extended-release tablets (Horizant), pregabalin extended-release tablets (Lyrica CR), and everolimus oral tablets (Afinitor, Zortress).
- Medispan class: Antianxiety agents, benzodiazepines; Anticonvulsants, AMPA glutamate receptor antagonists; Anticonvulsants, anticonvulsants – misc; Anticonvulsants, carbamates; Anticonvulsants, GABA modulators; Anticonvulsants, hydantoins; Anticonvulsants, succinimides; Anticonvulsants, valproic acid; Hypnotics/Sedatives/Sleep Disorder Agents, barbiturate hypnotics

Table 1. Medications Included Within Class Review

Drug	Alternative Available (same molecular entity)*
Barbiturates	
Pentobarbital (Nembutal)	✔
Phenobarbital† (Sezaby)	✔
Primidone (Mysoline)	✔
Benzodiazepines	
Clobazam (Onfi, Sympazan)	✔ ‖
Clonazepam (Klonopin§)	✔
Clorazepate (Tranxene T-Tab§)	✔
Diazepam (Diastat, Diastat AcuDial, Diazepam Intensol, Libervant, Valium§, Valtoco)	✔ ‖
Midazolam (Nayzilam, Seizalam)	-
Hydantoins	
Fosphenytoin (Cerebyx)	✔ ‖
Phenytoin (Dilantin§, Phenytek**)	✔ ‖
Miscellaneous	
Brivaracetam (Briviact)	-
Cannabidiol (Epidiolex)	-
Carbamazepine (Carbatrol, Epitol**, Equetro, Tegretol§, Tegretol-XR)	✔ ‖

Drug	Alternative Available (same molecular entity)*
Cenobamate (Xcopri)	-
Divalproex sodium (Depakote, Depakote ER, Depakote Sprinkle)	✔
Eslicarbazepine (Aptiom)	-
Ethosuximide (Zarontin)	✔
Everolimus (Afinitor Disperz)	✔
Felbamate (Felbatol)	✔
Fenfluramine (Fintepla)	-
Gabapentin (Neurontin)	✔
Ganaxolone (Ztalmy)	-
Lacosamide (Vimpat)	✔
Lacosamide (Motpoly XR)	-
Lamotrigine (Lamictal, Lamictal ODT, Lamictal XR, Subvenite**)	✔
Levetiracetam (Keppra, Keppra XR, Roweepra**, Spritam, Elepsia XR)	✔ ‖
Methsuximide (Celontin)	✔
Oxcarbazepine (Oxtellar XR, Trileptal)	✔ ‖
Perampanel (Fycompa)	-
Pregabalin (Lyrica)	✔
Rufinamide (Banzel)	✔
Stiripentol (Diacomit)	-
Tiagabine (Gabitril)	✔
Topiramate (Topamax, Topamax Sprinkle, Trokendi XR, Qudexy XR, Eprontia)	✔ ‖
Valproic acid/valproate sodium	✔
Vigabatrin (Sabril, Vigadrone**)	✔
Vigabatrin (Vigafyde)	-
Zonisamide (Zonegran§, Zonisade)	✔ ‖

*For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.
† Only Sezaby is FDA-approved; other phenobarbital products are marketed without FDA approval
§ Brand marketing status may vary by strength and/or formulation
‖ Generic availability may vary by strength, brand and/or formulation
** Branded generic

(*Drugs@FDA 2024, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2024*)

Indications

- Tables 2A and 2B provide an overview of the various indications for the anticonvulsant category of medications. Except where noted, only FDA-approved products and indications are included. For items marked with an asterisk, there is additional information about the indication provided in the box following the tables.
  - Acute-care indications that are not related to convulsive disorders (for example, pre-procedural use of benzodiazepines in hospital settings) are not included.

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Table 2A. Indications for anticonvulsants (Part 1 of 2)

Indications	Brivaracetam	Cannabidiol	Carbamazepine	Cenobamate	Clobazam	Clonazepam	Clorazepate	Diazepam	Divalproex Sodium	Eslicarbazepine	Ethosuximide	Everolimus	Felbamate	Fenfluramine	Fosphenytoin	Gabapentin	Ganaxolone	Lacosamide	Lamotrigine	Levetiracetam
Partial seizures (simple partial, complex partial and/or secondarily generalized)	✔, A*		✔*	✔*			A		✔, A*	✔, A*			✔, A*			A*		✔*	✔, A*	✔*
Primary generalized tonic-clonic seizure (grand mal)			✔												✔*			A*	A*	A*
Absence seizure (petit mal)						✔*			✔, A*		✔									
Multiple seizure types that include absence seizures									A											
Seizures of Lennox-Gastaut syndrome (LGS)		✔*			A*	✔, A							A*	✔*					A*	
Seizures of Dravet syndrome		✔*												✔*						
Juvenile myoclonic epilepsy (JME)																				A*
Emergency/acute/short-term use for seizure control (see notes)								✔*							✔*					
Akinetic and myoclonic seizures						✔, A														
Convulsive disorders (see notes)								A*												
Certain mixed seizure patterns or other partial or generalized seizures			✔*																	
Migraine prophylaxis									✔*											
Trigeminal neuralgia			✔*																	
Postherpetic neuralgia																✔*				
Bipolar disorder			✔*						✔*										✔*	
Panic disorder, with or without agoraphobia						✔														
Anxiety disorder; short-term relief of anxiety symptoms							✔	✔												
Symptomatic relief of acute alcohol withdrawal							✔	✔												

Indications	Brivaracetam	Cannabidiol	Carbamazepine	Cenobamate	Clobazam	Clonazepam	Clorazepate	Diazepam	Divalproex Sodium	Eslicarbazepine	Ethosuximide	Everolimus	Felbamate	Fenfluramine	Fosphenytoin	Gabapentin	Ganaxolone	Lacosamide	Lamotrigine	Levetiracetam
Relief of skeletal muscle spasm, spasticity, athetosis, and stiff-man syndrome								A												
Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder																	✔ *			
Seizures associated with tuberous sclerosis complex (TSC)		✔ *										A*								
TSC for the treatment of subependymal giant cell astrocytoma (SEGA)												✔ *								

✓ = monotherapy (or not specified); A = adjunctive therapy

Table 2B. Indications for Anticonvulsants (Part 2 of 2)

Indications	Midazolam	Methsuximide	Oxcarbazepine	Pentobarbital	Perampanel	Phenobarbital†	Phenytoin	Pregabalin	Primidone	Rufinamide	Stiripentol	Tiagabine	Topiramate	Valproic acid	Vigabatrin	Zonisamide
Partial seizures (simple partial, complex partial and/or secondarily generalized)			✔, A*		✔, A*		✔ *	A*	✔, A*			A*	✔, A*	✔, A*	A*	A*
Primary generalized tonic-clonic seizure (grand mal)					A*		✔ *		✔, A*				✔, A*			
Absence seizure (petit mal)		✔ *												✔, A*		
Multiple seizure types which include absence seizures														A*		
Seizures of LGS										A*			A*			
Seizures of Dravet syndrome											A*					
Emergency/acute/ short-term use for seizure control (see notes)	✔ *			✔ *			✔ *									

Indications	Midazolam	Methsuximide	Oxcarbazepine	Pentobarbital	Perampanel	Phenobarbital†	Phenytoin	Pregabalin	Primidone	Rufinamide	Stiripentol	Tiagabine	Topiramate	Valproic acid	Vigabatrin	Zonisamide
Infantile spasms															✔ *	
Convulsive disorders (see notes)						✔ *										
Neonatal seizures						✔ *										
Migraine prophylaxis													✔ *			
Postherpetic neuralgia								✔								
Sedative for anxiety, tension, and apprehension																
Neuropathic pain associated with diabetic peripheral neuropathy								✔								
Neuropathic pain associated with spinal cord injury								✔								
Fibromyalgia								✔								
Short-term treatment of insomnia¥				✔												

✓ = monotherapy (or not specified); A = adjunctive therapy
†Only Sezaby is FDA-approved; other phenobarbital products are marketed without FDA approval
¥Use is not recommended.

Notes: Additional Detail on Selected Indications

- Brivaracetam:
  - Treatment of partial-onset seizures in patients ≥ 1 month of age
- Cannabidiol:
  - Treatment of seizures associated with LGS, Dravet syndrome, or TSC in patients ≥ 1 year of age
- Carbamazepine:
  - Partial seizures with complex symptomatology (psychomotor, temporal lobe); patients with these seizures appear to show greater improvement than those with other types; generalized tonic-clonic seizures (grand mal); mixed seizure patterns which include the above, or other partial or generalized seizures
  - Absence seizures (petit mal) do not appear to be controlled; carbamazepine has been associated with increased frequency of generalized convulsions in these patients
  - Treatment of pain associated with true trigeminal neuralgia; beneficial results also reported in glossopharyngeal neuralgia
  - Bipolar indication is for an extended-release capsule formulation (Equetro) only: treatment of patients with acute manic or mixed episodes associated with bipolar I disorder
- Cenobamate:
  - Treatment of partial-onset seizures in adult patients
- Clobazam:
  - Seizures associated with LGS in patients ≥ 2 years of age
- Clonazepam:
  - In patients with absence seizures who have failed to respond to succinimides, clonazepam may be useful
- Diazepam:
  - Oral diazepam (tablets, solution, concentrate) may be used adjunctively in convulsive disorders; it has not proved useful as sole therapy

- Injectable diazepam is a useful adjunct in status epilepticus and severe recurrent convulsive seizures
- Diazepam nasal spray and rectal gel are indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy ≥ 6 years of age (nasal spray), ≥ 2 years of age (rectal gel), or 2 to 5 years of age (buccal film)

- Divalproex sodium:
  - Monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures (≥ 10 years of age for all formulations)
  - Monotherapy and adjunctive therapy in the treatment of simple and complex absence seizures (≥ 10 years of age for extended-release tablets; age not specified for tablets/sprinkle capsules)
  - Adjunctive therapy for treatment of multiple seizure types that include absence seizures
  - The tablets and extended-release tablets have indications in bipolar disorder and migraine prophylaxis; the sprinkle capsule formulation does not. For bipolar disorder, safety and effectiveness for long-term use (> 3 weeks) has not been demonstrated in controlled clinical trials. Bipolar disorder indications are as follows:
    - Treatment of the manic episodes associated with bipolar disorder (tablets)
    - Treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features (extended-release tablets)
- Eslicarbazepine:
  - Treatment of partial-onset seizures in patients ≥ 4 years of age
- Everolimus:
  - Adjunctive treatment of adult and pediatric patients ≥ 2 years of age with TSC-associated partial-onset seizures
  - Adult and pediatric patients ≥ 1 year of age with TSC for the treatment of SEGA that requires therapeutic intervention but cannot be curatively resected
- Felbamate:
  - Not first-line; recommended only in patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of aplastic anemia and/or liver failure is deemed acceptable
  - Monotherapy or adjunctive therapy in the treatment of partial seizures, with and without generalization, in adults with epilepsy
  - Adjunctive therapy of partial and generalized seizures associated with LGS in children (age not specified in indication; dosage instructions are provided for patients ≥ 2 years of age)
- Fenfluramine:
  - Treatment of seizures associated with Dravet syndrome and LGS in patients ≥ 2 years of age
- Fosphenytoin:
  - Treatment of generalized tonic-clonic status epilepticus
  - Prevention and treatment of seizures occurring during neurosurgery
  - Can be substituted short-term for oral phenytoin when oral phenytoin administration is not possible
- Gabapentin:
  - Adjunctive therapy in the treatment of partial-onset seizures, with and without secondary generalization, in adults and pediatric patients ≥ 3 years of age with epilepsy
  - Management of postherpetic neuralgia in adults
- Ganaxolone:
  - Treatment of seizures associated with CDKL5 deficiency disorder in patients ≥ 2 years of age
- Lacosamide:
  - Treatment of partial-onset seizures in patients ≥ 1 month of age (tablet, oral solution, injection [Vimpat] only) and in adults and pediatric patients weighing ≥ 50 kg (extended-release capsule [Motpoly XR] only)
  - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ≥ 4 years of age [Vimpat] and in adults and pediatric patients weighing ≥ 50 kg [Motpoly XR]
- Lamotrigine immediate-release formulations:
  - Age ≥ 2 years for adjunctive therapy for partial-onset seizures, primary generalized tonic-clonic seizures, and generalized seizures of LGS
  - Age ≥ 16 years for conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single AED

- Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy (treatment of acute manic or mixed episodes is not recommended)

- Lamotrigine extended-release tablets:
  - Age ≥ 13 years for adjunctive therapy for primary generalized tonic-clonic seizures and partial-onset seizures with or without secondary generalization, and age ≥ 13 years for conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with a single AED
  - The extended-release formulation is not FDA-approved for bipolar disorder
- Levetiracetam:
  - Tablets, oral solution, injection, and tablets for oral suspension:
    - Treatment of partial-onset seizures in patients ≥ 1 month of age (tablets, oral solution, and injection [Keppra]); treatment for partial-onset seizures in patients ≥ 4 years of age and weighing > 20 kg (tablets for oral suspension [Spritam])
    - Adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents ≥ 12 years of age with JME
    - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children ≥ 6 years of age with idiopathic generalized epilepsy
  - The extended-release tablets are only indicated for the treatment of partial-onset seizures in patients ≥ 12 years of age
- Methsuximide:
  - Control of absence (petit mal) seizures that are refractory to other drugs
- Midazolam:
  - Nasal spray: Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy ≥ 12 years of age
  - IM injection: Treatment of status epilepticus in adults
- Oxcarbazepine immediate-release formulations:
  - Monotherapy in the treatment of partial seizures in adults and children 4 to 16 years of age
  - Adjunctive therapy in the treatment of partial seizures in adults and children 2 to 16 years of age
- Oxcarbazepine extended-release tablets:
  - Treatment of partial-onset seizures in adults and children ≥ 6 years of age
- Pentobarbital:
  - In anesthetic doses in the emergency control of certain acute convulsive episodes, eg, those associated with status epilepticus, cholera, eclampsia, meningitis, tetanus, and toxic reactions to strychnine or local anesthetics
- Perampanel:
  - Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy ≥ 4 years of age
  - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy ≥ 12 years of age
- Phenobarbital (Sezaby is the only formulation that is FDA-approved):
  - Phenobarbital tablets and elixir are indicated for the treatment of generalized and partial seizures; the generic injection is indicated as an anticonvulsant for the treatment of generalized tonic-clonic and cortical focal seizures, in the emergency control of certain acute convulsive episodes, and in pediatric patients as an anticonvulsant; the brand Sezaby injection is indicated for the treatment of neonatal seizures in term and preterm infants
- Phenytoin oral formulations:
  - Treatment of tonic-clonic (grand mal) and complex partial (psychomotor, temporal lobe) seizures and prevention and treatment of seizures occurring during or following neurosurgery (the oral suspension does not have the neurosurgery indication)
- Phenytoin injection:
  - Treatment of generalized tonic-clonic status epilepticus and prevention and treatment of seizures occurring during neurosurgery
  - Can be substituted as short-term use for oral phenytoin when oral phenytoin administration is not possible
- Pregabalin:
  - Adjunctive therapy for treatment of partial-onset seizures in patients ≥ 1 month of age

- Primidone:
  - Control of grand mal, psychomotor, and focal epileptic seizures; may control grand mal seizures refractory to other anticonvulsant therapy
- Rufinamide:
  - Adjunctive treatment of seizures associated with LGS in adults and pediatric patients ≥ 1 year of age
- Stiripentol:
  - Treatment of seizures associated with Dravet syndrome in patients taking clobazam who are ≥ 6 months of age and weigh ≥ 7 kg; no clinical data to support its use as monotherapy
- Tiagabine:
  - Adjunctive therapy in adults and children ≥ 12 years of age in the treatment of partial seizures
- Topiramate:
  - Initial monotherapy in patients with partial-onset or primary generalized tonic-clonic seizures (age ≥ 2 years for tablets, immediate-release sprinkle capsules, oral solution, and Qudexy XR extended-release capsules; age ≥ 6 years for Trokendi XR extended-release capsules)
  - Adjunctive therapy for adults and pediatric patients with partial-onset seizures or primary generalized tonic-clonic seizures and in patients with seizures associated with LGS (age ≥ 2 years for tablets, immediate-release sprinkle capsules, oral solution, and Qudexy XR extended-release capsules; age ≥ 6 years for Trokendi XR extended-release capsules)
  - Prophylaxis of migraine headache in patients ≥ 12 years of age
- Valproic acid/valproate sodium:
  - Monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures; sole and adjunctive therapy in the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types which include absence seizures
- Vigabatrin:
  - Adjunctive therapy for patients ≥ 2 years of age with refractory complex partial seizures who have responded inadequately to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss (tablets and powder for solution only)
  - Monotherapy for patients with infantile spasms 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss (tablets, powder for solution, and concentrated solution)
- Zonisamide:
  - Zonegran oral capsules: adjunctive therapy in the treatment of partial seizures in adults with epilepsy (safety and effectiveness in children < 16 years of age have not been established)
  - Zonisade oral suspension: adjunctive therapy in the treatment of partial-onset seizures in adults and pediatric patients ≥ 16 years of age

- 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

- Overall, the anticonvulsants have demonstrated efficacy for their FDA-approved uses. Clinical trial data demonstrating efficacy of the anticonvulsants for the treatment of epilepsy is described in the prescribing information for the individual products, particularly for anticonvulsants more recently approved by the FDA. However, the prescribing information for some older, conventional products (eg, benzodiazepines, carbamazepine, ethosuximide, methsuximide, phenytoin, and primidone) and non-FDA approved products (eg, most formulations of phenobarbital) do not contain efficacy data in their prescribing information.
- When possible, monotherapy with a single AED is the preferred treatment approach. This increases the probability of treatment adherence, provides a wider therapeutic index, and is associated with fewer idiosyncratic reactions, teratogenic effects, and potential drug interactions. However, data are conflicting on the benefits of mono- vs polytherapy (*Schachter 2024[b]*). Most patients with epilepsy are treated with anticonvulsant monotherapy (*Nevitt et al 2022*).

- No single AED is clearly the most effective. Comparative efficacy data for the management of epilepsy are limited, and trials have generally not shown significant differences among drugs in terms of efficacy. However, the quality of the data is limited and generally derived from short-term trials (*Karceski 2024*).
- An evidence review summarized AED efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes (*Glauser et al 2013*). This publication provides conclusions based on a review of 64 randomized trials and 11 meta-analyses. Conclusions include the following:
  - As initial monotherapy for adults with newly diagnosed or untreated partial-onset seizures:
    - Carbamazepine, levetiracetam, phenytoin, and zonisamide are established as efficacious/effective.
    - Valproate is probably efficacious/effective.
    - Gabapentin, lamotrigine, oxcarbazepine, phenobarbital, topiramate, and vigabatrin are possibly efficacious/effective.
    - Clonazepam and primidone are potentially efficacious/effective.
  - As initial monotherapy for children with newly diagnosed or untreated partial-onset seizures:
    - Oxcarbazepine is established as efficacious/effective.
    - Carbamazepine, phenobarbital, phenytoin, topiramate, valproate, and vigabatrin are possibly efficacious/effective.
    - Clobazam, carbamazepine, lamotrigine, and zonisamide are potentially efficacious/effective.
  - As initial monotherapy for elderly adults with newly diagnosed or untreated partial-onset seizures:
    - Gabapentin and lamotrigine are established as efficacious/effective.
    - Carbamazepine is possibly efficacious/effective.
    - Topiramate and valproate are potentially efficacious/effective.
  - As initial monotherapy for adults with newly diagnosed or untreated generalized-onset tonic-clonic seizures:
    - Carbamazepine, lamotrigine, oxcarbazepine, phenobarbital, phenytoin, topiramate, and valproate are possibly efficacious/effective.
    - Gabapentin, levetiracetam, and vigabatrin are potentially efficacious/effective.
    - Carbamazepine and phenytoin may precipitate or aggravate generalized-onset tonic-clonic seizures.
  - For children with newly diagnosed or untreated generalized-onset tonic-clonic seizures:
    - Carbamazepine, phenobarbital, phenytoin, topiramate, and valproate are possibly efficacious/effective.
    - Oxcarbazepine is potentially efficacious/effective.
    - Carbamazepine and phenytoin may precipitate or aggravate generalized-onset tonic-clonic seizures.
  - As initial monotherapy for children with newly diagnosed or untreated absence seizures:
    - Ethosuximide and valproate are established as efficacious/effective.
    - Lamotrigine is possibly efficacious/effective.
    - Gabapentin is established as inefficacious/ineffective.
    - Carbamazepine, oxcarbazepine, phenobarbital, phenytoin, tiagabine, and vigabatrin may precipitate or aggravate absence seizures (based on scattered reports).
  - As initial monotherapy for children with benign childhood epilepsy with centrotemporal spikes (BECTS):
    - Carbamazepine and valproate are possibly efficacious/effective.
    - Gabapentin, levetiracetam, oxcarbazepine, and sulthiame (not available in the United States) are potentially efficacious/effective.
  - For patients with newly diagnosed JME:
    - Topiramate and valproate are potentially efficacious/effective.
    - Carbamazepine, gabapentin, oxcarbazepine, phenytoin, tiagabine, and vigabatrin may precipitate or aggravate absence, myoclonic, and in some cases generalized tonic-clonic seizures. There has also been a report that lamotrigine may exacerbate seizures in JME.
  - There is a lack of well-designed randomized trials in epilepsy, particularly for generalized seizures and in the pediatric population.
- A Cochrane systematic review evaluated the efficacy of AED monotherapy for epilepsy (*Nevitt et al 2022*). The review included the use of carbamazepine, phenytoin, valproate, phenobarbital, oxcarbazepine, lamotrigine, gabapentin, topiramate, levetiracetam, zonisamide, eslicarbazepine, and lacosamide for the treatment of partial-onset seizures (simple partial, complex partial or secondarily generalized) or generalized tonic-clonic seizures with or without other generalized seizure types.
  - This network meta-analysis showed that for the primary outcome, the time to withdrawal of allocated treatment:

    - For individuals with partial seizures, lamotrigine performed better than most other treatments. No significant difference was found between lamotrigine and levetiracetam for any outcome related to treatment failure, and both drugs were found to perform better than all other AEDs.
    - For individuals with generalized onset seizures, valproate performed better than carbamazepine, lacosamide, topiramate, and phenobarbital.
  - For the secondary outcome, time to first seizure:
    - For individuals with partial seizures, phenobarbital performed better than both carbamazepine and lamotrigine. No significant differences were found among newer agents (eg, oxcarbazepine, topiramate, gabapentin, levetiracetam, zonisamide, and lacosamide) for partial or generalized onset seizures.
    - For both partial and generalized seizure types, phenytoin and phenobarbital generally performed better than other treatments.
  - Few notable differences were shown for either partial or generalized seizure types for the secondary outcomes of time to 6-month or 12-month remission of seizures.
  - Overall, direct evidence and network meta-analysis estimates were numerically similar, and effect sizes had overlapping confidence intervals.
  - Data for individuals with generalized seizures are still limited and additional randomized trials are needed.
- The relative efficacy among valproate, lamotrigine, phenytoin, carbamazepine, ethosuximide, topiramate, levetiracetam, and phenobarbital as monotherapy for generalized (n = 7 studies) or absence seizures (n = 3 studies) was evaluated in a systematic review and network meta-analysis (*Campos et al 2018*). The outcomes analyzed were seizure freedom and withdrawal due to inefficacy. Compared to valproate, phenytoin had a lower odds of seizure freedom (odds ratio, 0.50; 95% credible Interval [CrI], 0.27 to 0.87) in patients with generalized tonic-clonic seizures. Lamotrigine had the highest probability of seizure freedom and valproate had the highest probability of withdrawal due to inefficacy in these patients. For absence seizures, ethosuximide and valproate were found to have a higher probability of seizure freedom compared to lamotrigine.
- A meta-analysis estimated the comparative efficacy of achieving seizure freedom with 22 antiepileptic drugs and placebo in children and adolescents (*Rosati et al 2018*). For the treatment of newly diagnosed focal epilepsy (n = 4 studies), point estimates suggested superiority of carbamazepine and lamotrigine; however, this was not statistically significant. For refractory focal epilepsy (n = 9 studies), levetiracetam and perampanel were more effective than placebo in mixed comparisons. Ethosuximide and valproic acid were more effective than lamotrigine for absence seizures. The authors concluded that better designed comparative studies with appropriate length of follow-up, well-defined outcomes, and reliable inclusion criteria are needed to validate these results.
- A meta-analysis compared monotherapy with carbamazepine or phenytoin in children and adults with focal onset seizures (simple or complex focal and secondarily generalized), or generalized onset tonic-clonic seizures (with or without other generalized seizure types). Results demonstrated that the time to treatment failure (primary outcome) did not significantly differ between treatment groups. The time to first seizure after randomization and 6-month and 12-month remission were also similar between groups (*Nevitt et al 2019)*.
- A network meta-analysis comparing third-generation AEDs (brivaracetam, cenobamate, eslicarbazepine, lacosamide, and perampanel) for adjunctive treatment of partial-onset seizures in adults found that cenobamate had the greatest likelihood of being the best option to reduce seizure frequency and brivaracetam and lacosamide had the highest probabilities of being the best-tolerated treatments (*Lattanzi et al 2022*).
- As many as 20% to 40% of patients with epilepsy can be considered refractory to drug treatment, referred to as drug-resistant epilepsy. Treatment of drug-resistant epilepsy may include additional anticonvulsant drug trials, epilepsy surgery, vagus nerve stimulation, responsive cortical stimulation, deep brain stimulation, cannabinoids, and dietary changes (the ketogenic diet) (*Sirven 2023*).
  - Combination AED regimens are an option for the treatment of drug-resistant epilepsy. However, robust clinical evidence of suitable combinations of AEDs has been difficult to generate due to the large number of possible combinations of drugs and doses. Examples of combinations for which there is some evidence of efficacy include valproate plus lamotrigine for partial-onset and generalized seizures, valproate plus ethosuximide for absence seizures, and lamotrigine plus topiramate for various seizure types; however, even this evidence is fairly limited. In general, when considering combination therapy, it is recommended to combine medications with different mechanisms of action, and to be mindful of the overall drug load to minimize AEs. Two-drug therapy should be attempted before considering addition of a third drug, and higher numbers of drugs should be avoided as they are associated with a very low likelihood of additional seizure reduction (*Kwan et al 2011*).

- A meta-analysis examined the efficacy of newer AEDs (eslicarbazepine, brivaracetam, perampanel, and lacosamide) vs levetiracetam as adjunctive therapy for uncontrolled partial-onset seizures. Most patients in this meta-analysis were on at least 2 other AEDs at the time of treatment. In this analysis, eslicarbazepine, lacosamide, and brivaracetam were non-inferior to levetiracetam in terms of efficacy, but all newer AEDs except brivaracetam had worse tolerability profiles than levetiracetam at high doses (*Zhu et al 2017*).
- A network meta-analysis examined the efficacy of AEDs (including brivaracetam, eslicarbazepine acetate, gabapentin, lacosamide, levetiracetam, lamotrigine, oxcarbazepine, pregabalin, perampanel, rufinamide, tiagabine, topiramate, vigabatrin, and zonisamide) for adjunctive use in patients with refractory partial-onset seizures while using monotherapy (*Zhao et al 2017*). The efficacy outcomes studied were 50% responder rate and state of seizure freedom. The authors concluded that topiramate, levetiracetam, pregabalin, and oxcarbazepine were preferable for their relatively high efficacy and low risk of AEs. Rufinamide was the least preferable medication due to its low efficacy and high risk of AEs.
- A systematic review and network meta-analysis evaluated the efficacy and safety of 6 AEDs in LGS (*Zhang et al 2022*). A total of 8 RCTs were included in the analysis, which evaluated the use of lamotrigine, rufinamide, cannabidiol, topiramate, clobazam, and felbamate.
  - Based on the proportion of patients achieving at least a 50% reduction in drop seizures (reported for 5 AEDs in 7 RCTs), all active AEDs were considered superior to placebo therapy. Based on the surface under the cumulative ranking curve (SUCRA), rufinamide, cannabidiol, and topiramate were ranked highest, followed by clobazam and lamotrigine; however, there were no significant differences among these AEDs.
  - For the proportion of patients achieving a 75% reduction in drop seizures (reported for 4 AEDs in 5 RCTs), clobazam was ranked highest, followed by cannabidiol therapy; both were superior to placebo. For topiramate and rufinamide, no significant differences were found vs placebo.
  - When evaluating safety, lamotrigine, cannabidiol, and felbamate ranked highest (worst) for serious AEs; however, cannabidiol was the only AED with a significantly higher incidence of serious AEs vs placebo. No substantial difference was observed between the active AEDs.
- A network meta-analysis was conducted to evaluate the efficacy of 17 newer AEDs for treatment of refractory partial-onset epilepsy with or without secondary generalization (*Hu et al 2018*). The primary outcome was seizure freedom, which was defined as a 100% seizure reduction in the maintenance or double-blind treatment period of the trial. Safety was assessed by the withdrawal rate due to treatment-emergent AEs. Based on results of 54 studies that evaluated the efficacy outcome, the most effective agents included tiagabine, brivaracetam, and valproic acid, and the least effective agents included rufinamide, lamotrigine, and zonisamide. Products with favorable safety included levetiracetam, brivaracetam, and perampanel, while those with the least favorable safety included retigabine (not available in the United States), oxcarbazepine, and rufinamide. The authors stated that agents with the best outcomes in terms of efficacy and safety included levetiracetam, vigabatrin, valproic acid, and brivaracetam.
- A network meta-analysis was conducted to evaluate the efficacy of add-on fenfluramine, stiripentol, cannabidiol, or soticlestat (investigational product) for Dravet syndrome (*Xia et al 2024*). A total of 6 trials (N = 633) were included. All drug regimens were superior to placebo at achieving at least 50% and 75% reductions in convulsive seizure frequency, but only stiripentol, fenfluramine 0.4 mg/kg/day, and fenfluramine 0.7 mg/kg/day reduced monthly convulsive seizure frequency. Based on SUCRA, stiripentol ranked highest for reducing monthly convulsive seizure frequency, followed by fenfluramine 0.4 mg/kg/day, fenfluramine 0.7 mg/kg/day, cannabidiol 20 mg/kg/day, and fenfluramine 0.2 mg/kg/day. With regard to achieving at least a 50% reduction in convulsive seizure frequency, based on SUCRA, stiripentol ranked highest, followed by fenfluramine 0.4 mg/kg/day, soticlestat, fenfluramine 0.7 mg/kg/day, fenfluramine 0.2 mg/kg/day, cannabidiol 20 mg/kg/day, and cannabidiol 10 mg/kg/day. With regard to achieving at least a 75% reduction in convulsive seizure frequency, based on SUCRA, fenfluramine 0.7 mg/kg/day ranked highest, followed by fenfluramine 0.4 mg/kg/day, fenfluramine 0.2 mg/kg/day, cannabidiol 10 mg/kg/day, and cannabidiol 20 mg/kg/day.

Recently approved agents

- Cannabidiol (Epidiolex) was approved in June 2018 for use in pediatric patients 2 years of age and older with LGS or Dravet syndrome (*FDA news release 2018*). It is the first FDA-approved drug for the treatment of patients with Dravet syndrome and is the first approved drug that contains a purified substance, cannabidiol, derived from marijuana. Its approval for these 2 indications was based on 3 placebo-controlled trials in patients refractory to other treatments. Cannabidiol, along with use of other agents demonstrated a significant reduction in seizure frequency compared to placebo (*Thiele et al 2018*; *Devinsky et al 2018; Devinsky et al 2017*). A combined analysis of these trials and an

additional randomized dose-ranging trial found that cannabidiol was effective in the overall population as well as in patients using it in conjunction with clobazam (*Gunning et al 2021*). In July 2020, cannabidiol was FDA-approved for a third indication, treatment of seizures associated with TSC, and the age range for all 3 indications was aligned to include pediatric patients 1 year of age and older (*FDA news release 2020)*. In a placebo-controlled trial of 224 patients with TSC and seizures inadequately controlled with ≥ 1 concomitant AED, cannabidiol resulted in a significant reduction in seizure frequency compared to placebo (*Thiele at al 2021*). To date, no comparative trials vs other AEDs have been published.

- Everolimus tablets for oral suspension (Afinitor Disperz) received an expanded indication for adjunctive use in TSC-associated partial-onset seizures in April 2018. Results of a randomized, double-blind, placebo-controlled study of 366 patients with inadequately controlled seizures on 2 or more AEDs demonstrated a significant reduction in seizure frequency compared to placebo (*French et al 2016*).
- In August 2018, the FDA approved a second drug, stiripentol (Diacomit), for use in the treatment of seizures associated with Dravet syndrome. Two multicenter placebo-controlled studies evaluated the addition of stiripentol to clobazam and valproate therapy in patients 3 years to < 18 years of age with Dravet syndrome. Responder rates (seizure frequency reduced by 50%) with respect to generalized tonic-clonic seizures were significantly lower with stiripentol compared to placebo (*Chiron et al 2000, Diacomit prescribing information 2024).* The effectiveness of stiripentol for patients aged 6 months to < 3 years was extrapolated from effectiveness data in patients 3 years to < 18 years of age (*Diacomit prescribing information 2022)*.
- In May 2019, a nasal spray formulation of midazolam (Nayzilam) was approved for the acute treatment of cluster seizures in adults and adolescents. In one randomized controlled trial in patients with seizure clusters while receiving a stable AED regimen, the proportion of patients who experienced treatment success (seizure termination within 10 minutes and no recurrence for the next 6 hours) was significantly higher with midazolam nasal spray compared to placebo (53.7% vs 34.4%; p = 0.0109) with similar tolerability (*Detyniecki et al 2019*).
- Cenobamate was approved in late 2019 and its efficacy has yet to be compared to other AEDs. The approval of this agent was based on 2 multicenter, randomized, double-blind, placebo-controlled studies that enrolled 655 adults with partial-onset seizures with or without generalization who were not adequately controlled with 1 to 3 other AEDs (*Chung et al 2020, Krauss et al 2020*). The results of these trials demonstrated that cenobamate significantly reduced the frequency of seizures occurring in a 28-day period. In the first trial, the median percent change in seizure frequency from baseline was -55.6% with cenobamate and -21.5% with placebo. In the second trial, the median percent change ranged from -36.3% to -55.3% with cenobamate and was -24.3% with placebo.
- In June 2020, the FDA approved a third drug, fenfluramine (Fintepla), for use in the treatment of seizures associated with Dravet syndrome. Two randomized, double-blind, placebo-controlled studies evaluated fenfluramine in patients 2 to 18 years of age with Dravet syndrome who were inadequately controlled with 1 to 4 other AEDs (*Lagae et al 2020, Nabbout et al 2019*). In both trials, fenfluramine significantly reduced the frequency of convulsive seizures occurring in a 28-day period as compared to placebo. In the first trial, in patients not receiving stiripentol, fenfluramine at a dose of 0.7 mg/kg/day demonstrated a 62.3% greater reduction in mean monthly convulsive seizure frequency (MCSF) over 14 weeks compared with placebo. In the second trial, in patients who were receiving a stiripentol-inclusive AED regimen, fenfluramine at a dose of 0.4 mg/kg/day showed a 54% greater reduction in MCSF over 15 weeks compared with placebo.
  - An additional randomized, double-blind, placebo-controlled trial evaluated fenfluramine in patients with Dravet syndrome aged 2 to 18 years with poorly controlled convulsive seizures (≥ 6 seizures during the baseline period); patients were randomized to receive placebo, fenfluramine 0.2 mg/kg/day, or fenfluramine 0.7 mg/kg/day for a total of 14 weeks (*Sullivan et al 2023*). The primary endpoint was the change in mean MCSF from baseline in patients treated with fenfluramine 0.7 mg/kg/day versus placebo. Patients treated with fenfluramine 0.7 mg/kg/day demonstrated a 64.8% greater reduction in MCSF compared to placebo (p < 0.0001).
  - In March 2022, the FDA approved fenfluramine for use in the treatment of seizures associated with LGS based on the results of a randomized, double-blind, placebo-controlled trial (*Knupp et al 2022*). The trial included adults and pediatric patients 2 to 35 years of age with LGS who were inadequately controlled with 1 to 4 other AEDs and found that the change in drop seizure frequency from baseline was -26.5% in patients treated with 0.7 mg/kg/day of fenfluramine, -14.2% in patients who received 0.2 mg/kg/day of fenfluramine, and -7.6% with placebo.
- Ganaxolone was approved by the FDA as an orphan drug in 2022 for the treatment of seizures associated with CDKL5 deficiency disorder. A randomized, double-blind, placebo-controlled trial evaluated ganaxolone in patients 2 to 21 years of age with a molecularly confirmed CDKL5 variant that was pathogenic or likely pathogenic and a history of

uncontrolled early-onset seizures despite treatment with ≥ 2 AEDs (*Knight et al 2022*). Results demonstrated a median percent change in 28-day major motor seizure frequency of -30.7% in patients treated with ganaxolone and -6.9% in patients treated with placebo.

- Although previous formulations of phenobarbital were not FDA-approved, phenobarbital injection (Sezaby) was approved in 2022 for the treatment of neonatal seizures. A randomized, double-blind study compared phenobarbital (n = 42) to levetiracetam (n = 64) in neonates younger than 14 days who were gestational ages between 36 and 44 weeks (< 2 weeks of age) (*Sharpe et al 2020*). The percentage of patients with seizure termination for > 24 hours was higher with phenobarbital (73%) compared to levetiracetam (25%) *(Sezaby prescribing information 2023).*
- In 2023, lacosamide extended-release capsules were approved for the treatment of partial-onset seizures. This approval was supported by efficacy data from studies involving immediate-release lacosamide in patients with partial-onset seizures, as well as by demonstrating the relative bioavailability of extended-release capsules compared to immediate-release lacosamide in healthy adults (*Motpoly XR prescribing information 2024*).
- In 2024, vigabatrin concentrated oral solution was approved for the treatment of infantile spasms based on a comparison of the compositional differences between vigabatrin powder for oral solution and vigabatrin concentrated oral solution (*Vigafyde prescribing information 2024*).
- In 2024, diazepam buccal film was approved for pediatric patients 2 to 5 years of age for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. The safety and effectiveness of this product are supported by evidence from studies of diazepam rectal gel in adult and pediatric patients, adult bioavailability studies comparing diazepam buccal film with diazepam rectal gel, adult and pediatric diazepam buccal film pharmacokinetic data, and an open-label safety study of diazepam buccal film (*Libervant prescribing information 2024*).
  - In the open-label safety study, 118 patients 2 to 65 years of age received at least 1 dose of diazepam buccal film. Eleven treatment-related AEs (10 being mild or moderate in severity) occurred in 9 patients over a mean of 243 days of follow-up; no patient discontinued participation because of AEs. The film was successfully administered on a first or second attempt on 96.6% of use occasions. A second dose was required within 24 hours after the first dose on 8.5% of use occasions (*Seinfeld et al 2020*).

Status epilepticus

- A 2019 randomized controlled trial of children and adults with benzodiazepine-refractory convulsive status epilepticus compared the efficacy of intravenous (IV) levetiracetam (n = 145 patients), fosphenytoin (n = 118), or valproate (n = 121) in this setting. Results demonstrated that each agent led to seizure cessation and improved alertness by 1 hour in approximately 50% of patients, with no significant differences between groups (*Kapur et al 2019*).
- A meta-analysis of 9 randomized controlled trials evaluated the efficacy and safety of levetiracetam vs phenytoin as second-line treatment for benzodiazepine-resistant status epilepticus in children and adults. The efficacy outcomes included seizure cessation and seizure recurrence within 24 hours. The authors did not find a significant difference in efficacy between levetiracetam and phenytoin in the overall population or in the subgroup analysis of pediatric patients. AEs were similar across both groups except for a higher incidence of cardiac instability, reported mainly as hypotension, in the phenytoin group (*DeMott et al 2020).*

Clinical Guidelines

- **Efficacy and tolerability of the new antiepileptic drugs I: treatment of new-onset epilepsy**. American Academy of Neurology and American Epilepsy Society (*French et al 2004A [retired], Kanner et al, 2018A [reaffirmed in 2021]*).
  - A 2018 update to the 2004 guideline focuses on treatment of new-onset epilepsy with second and third generation AEDs. The 2004 publication summarizes the efficacy, tolerability, and safety of gabapentin, lamotrigine, topiramate, tiagabine, oxcarbazepine, levetiracetam, and zonisamide for the treatment of children and adults with newly diagnosed partial and generalized epilepsies.
  - The recommendations from the 2004 guideline include the following:
    - Patients with newly diagnosed epilepsy who require treatment can be initially treated with standard AEDs such as carbamazepine, phenytoin, valproic acid, or phenobarbital, or with the newer AEDs lamotrigine, gabapentin, oxcarbazepine, or topiramate. Choice will depend on individual patient characteristics.
    - Lamotrigine can be included in the options for children with newly diagnosed absence seizures.
  - The 2018 recommendations include the following:

- As monotherapy in adult patients with new-onset focal epilepsy or unclassified generalized tonic-clonic seizures:
  - Lamotrigine use should be considered to decrease seizure frequency.
  - Lamotrigine use should be considered and gabapentin use may be considered to decrease seizure frequency in patients aged ≥ 60 years.
  - Levetiracetam and zonisamide use may be considered to decrease seizure frequency.
  - Vigabatrin appears to be less efficacious than carbamazepine immediate-release and may not be offered; furthermore, the toxicity profile precludes vigabatrin use as first-line therapy.
  - Pregabalin 150 mg per day is possibly less efficacious than lamotrigine 100 mg per day.
  - There is insufficient evidence to consider use of gabapentin, oxcarbazepine, or topiramate over carbamazepine.
  - There is insufficient evidence to consider use of topiramate instead of phenytoin in urgent treatment of new-onset or recurrent focal epilepsy, unclassified generalized tonic-clonic seizures, or generalized epilepsy presenting with generalized tonic-clonic seizures.
  - Data are lacking to support or refute use of third-generation AEDs (eslicarbazepine, ezogabine [no longer marketed], lacosamide, perampanel, pregabalin, and rufinamide), clobazam, felbamate, or vigabatrin for new-onset epilepsy.
  - Data are lacking to support or refute use of newer AEDs in treating unclassified generalized tonic-clonic seizures.
- Ethosuximide or valproic acid should be considered before lamotrigine to decrease seizure frequency in children with absence epilepsy. An exception would be if there are compelling AE-related concerns with use of ethosuximide or valproic acid.
- The guideline does not address newly approved agents including cannabidiol, everolimus, stiripentol, cenobamate, fenfluramine, or ganaxolone.

- **Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy**. American Academy of Neurology and American Epilepsy Society (*Kanner et al 2018B [reaffirmed in 2021]*, *French et al 2004B [retired]*).
  - A 2018 update to the 2004 guideline focuses on management of treatment-resistant epilepsy with second and third generation AEDs. The 2004 publication summarizes the efficacy, tolerability, and safety of gabapentin, lamotrigine, topiramate, tiagabine, oxcarbazepine, levetiracetam, and zonisamide for the treatment of children and adults with refractory partial and generalized epilepsies.
  - Recommendations from the 2004 guideline include the following:
    - It is appropriate to use gabapentin, lamotrigine, tiagabine, topiramate, oxcarbazepine, levetiracetam, and zonisamide as add-on therapy in patients with refractory epilepsy.
    - Oxcarbazepine, topiramate, and lamotrigine can be used as monotherapy in patients with refractory partial epilepsy.
    - Topiramate may be used for the treatment of refractory generalized tonic-clonic seizures in adults and children.
    - Gabapentin, lamotrigine, oxcarbazepine, and topiramate may be used as adjunctive treatment of children with refractory partial seizures.
    - Topiramate and lamotrigine may be used to treat drop attacks associated with LGS in adults and children.
  - Recommendations from the 2018 guideline include the following:
    - As adjunctive therapy in patients with treatment-resistant adult focal epilepsy (TRAFE):
      - Immediate-release pregabalin and perampanel are established as effective to reduce seizure frequency.
      - Lacosamide, eslicarbazepine, and extended-release topiramate should be considered to decrease seizure frequency.
      - Vigabatrin and rufinamide are effective for decreasing seizure frequency, but are not first-line agents.
      - Ezogabine (no longer marketed) use should be considered to reduce seizure frequency, but carries a serious risk of skin and retinal discoloration.
      - Clobazam and extended-release oxcarbazepine may be considered to decrease seizure frequency.
    - As monotherapy in patients with TRAFE:
      - Eslicarbazepine use may be considered to decrease seizure frequency.
      - Data are insufficient to recommend use of second- and the other third-generation AEDs.
    - For add-on therapy for generalized epilepsy, immediate-release and extended-release lamotrigine should be considered as add-on therapy to decrease seizure frequency in adults with treatment-resistant generalized tonic-clonic seizures secondary to generalized epilepsy. Levetiracetam use should be considered to decrease seizure

frequency as add-on therapy for treatment-resistant generalized tonic-clonic seizures and for treatment-resistant JME.
  - Rufinamide is effective to reduce seizure frequency as add-on therapy for LGS. Clobazam use should be considered as add-on therapy for LGS.
  - For add-on therapy in pediatric patients with treatment-resistant focal epilepsy:
    - Levetiracetam use should be considered to decrease seizure frequency (age 1 month to 16 years).
    - Zonisamide use should be considered to decrease seizure frequency (age 6 to 17 years).
    - Oxcarbazepine use should be considered to decrease seizure frequency (age 1 month to 4 years).
    - Data are unavailable on the efficacy of clobazam, eslicarbazepine, lacosamide, perampanel, rufinamide, tiagabine, or vigabatrin.
  - The guideline does not address newly approved agents including cannabidiol, everolimus, stiripentol, cenobamate, fenfluramine, or ganaxolone.

- **Evidence-based guideline: management of an unprovoked first seizure in adults.** Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society (*Krumholz et al 2015*; reaffirmed in 2018, 2021, and 2024).
  - This practice guideline makes recommendations based on a consideration of the evidence for prognosis and treatment of adults with an unprovoked first seizure.
  - Recommendations include the following:
    - Adults presenting with an unprovoked first seizure should be informed that the chance for a recurrent seizure is greatest within the first 2 years after a first seizure (21% to 45%).
    - Clinicians should also advise such patients that clinical factors associated with an increased risk of seizure recurrence include a prior brain insult such as a stroke or trauma, an EEG with epileptiform abnormalities, a significant brain-imaging abnormality, or a nocturnal seizure.
    - Clinicians should advise patients that, although immediate AED therapy, as compared with delay of treatment pending a second seizure, is likely to reduce the risk of a seizure recurrence in the 2 years subsequent to a first seizure, it may not improve quality of life.
    - Clinicians should advise patients that over the longer term (> 3 years), immediate AED treatment is unlikely to improve the prognosis for sustained seizure remission.
    - Patients should be advised that their risk for AED AEs ranges from 7% to 31% and that these AEs are predominantly mild and reversible.
  - Immediate AED therapy after an unprovoked first seizure is likely to reduce seizure recurrence risk. A reduction in risk may be important, particularly for adults, for whom seizure recurrences may cause serious psychological and social consequences such as loss of driving privileges and limitations on employment. However, immediate AED treatment is not well accepted and is debated. Decisions should be based on weighing the risk of recurrence against the AEs of AED therapy and should take patient preferences into account.
  - It is accepted that when a patient has a second or additional seizures, an AED should be initiated because the risk of subsequent seizures is very high.

- **Evidence-based guideline: treatment of convulsive status epilepticus in children and adults.** Guideline Committee of the American Epilepsy Society (*Glauser et al 2016*).
  - This publication provides conclusions and a treatment algorithm based on a structured literature review of randomized trials of anticonvulsant treatments for seizures lasting longer than 5 minutes. A total of 38 trials were included.
  - For treatment in the adult population, conclusions included the following:
    - Intramuscular (IM) midazolam, IV lorazepam, IV diazepam (with or without phenytoin), and IV phenobarbital are established as efficacious at stopping seizures lasting at least 5 minutes.
    - IV lorazepam is more effective than IV phenytoin in stopping seizures lasting at least 10 minutes.
    - There is no difference in efficacy between IV lorazepam followed by IV phenytoin, IV diazepam plus phenytoin followed by IV lorazepam, and IV phenobarbital followed by IV phenytoin.
    - IV valproic acid has similar efficacy to IV phenytoin or continuous IV diazepam as second therapy after failure of a benzodiazepine.
    - Insufficient data exist in adults about the efficacy of levetiracetam as either initial or second therapy.

    - In adults with status epilepticus without established IV access, IM midazolam is established as more effective compared with IV lorazepam.
    - No significant difference in effectiveness has been demonstrated between lorazepam and diazepam in adults with status epilepticus.
  - For treatment in the pediatric population, conclusions included the following:
    - IV lorazepam and IV diazepam are established as efficacious at stopping seizures lasting at least 5 minutes.
    - Rectal diazepam, IM midazolam, intranasal midazolam, and buccal midazolam are probably effective at stopping seizures lasting at least 5 minutes.
    - Insufficient data exist in children about the efficacy of intranasal lorazepam, sublingual lorazepam, rectal lorazepam, valproic acid, levetiracetam, phenobarbital, and phenytoin as initial therapy.
    - IV valproic acid has similar efficacy but better tolerability than IV phenobarbital as second therapy after failure of a benzodiazepine.
    - Insufficient data exist in children regarding the efficacy of phenytoin or levetiracetam as second therapy after failure of a benzodiazepine.
    - In children with status epilepticus, no significant difference in effectiveness has been established between IV lorazepam and IV diazepam.
    - In children with status epilepticus, non-IV midazolam (IM/intranasal/buccal) is probably more effective than diazepam (IV/rectal).
  - Conclusions included the following (age not specified):
    - Insufficient data exist about the comparative efficacy of phenytoin and fosphenytoin. Fosphenytoin is better tolerated compared with phenytoin. When both are available, fosphenytoin is preferred based on tolerability, but phenytoin is an acceptable alternative.
  - The overall treatment algorithm directs that:
    - A benzodiazepine (IM midazolam, IV lorazepam, or IV diazepam) is recommended as the initial therapy of choice in the first phase of treatment (5 to 20 minutes after the beginning of the seizure). Although IV phenobarbital is established as efficacious and well tolerated as initial therapy, its slower rate of administration positions it as an alternative initial therapy. For prehospital settings or where first-line benzodiazepine options are not available, rectal diazepam, intranasal midazolam, and buccal midazolam are reasonable initial therapy alternatives.
    - In the second phase of treatment (from 20 to 40 minutes after the beginning of the seizure), reasonable options include fosphenytoin, valproic acid, and levetiracetam. There is no clear evidence that any of these options is better than the others. Because of AEs, IV phenobarbital is a reasonable second-therapy alternative if none of the 3 recommended therapies are available.
    - There is no clear evidence to guide therapy in the third phase of therapy (≥ 40 minutes after the beginning of the seizure).

- **Practice parameter: treatment of the child with a first unprovoked seizure.** Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society (*Hirtz et al 2003*; reaffirmed in 2018, 2021, and 2024)
  - This parameter reviews published literature relevant to the decision to begin treatment after a child or adolescent experiences a first unprovoked seizure and presents evidence-based practice recommendations. Treatment during the neonatal period is not addressed.
  - Recommendations include the following:
    - Treatment with AEDs is not indicated for the prevention of the development of epilepsy.
    - Treatment with AEDs may be considered in circumstances where the benefits of reducing the risk of a second seizure outweigh the risks of pharmacologic and psychosocial AEs.
  - The majority of children who experience a first unprovoked seizure will have few or no recurrences. Treatment with AEDs after a first seizure as opposed to after a second seizure has not been shown to improve prognosis for long-term seizure remission.
  - Treatment has been shown in several studies combining both children and adults to reduce the risk of seizure recurrence; however, there is a relative paucity of data from studies involving only children after a first seizure.

- **Summary of recommendations for the management of infantile seizures**. Task force report for the ILAE Commission of Pediatrics (*Wilmshurst et al 2015*).

- This publication recommends an approach to the standard and optimal management of infants with seizures. When possible, recommendations are evidence-based; however, when no evidence was available, recommendations are based on expert opinion and standard practice.
- Recommendations/findings include the following:
  - There is no indication for initiation of chronic AEDs for simple febrile seizures. However, in the acute treatment of febrile seizures, it is important to treat seizures lasting 10 minutes or longer.
  - In an otherwise healthy infant, a policy of "wait and see" is reasonable after the first afebrile seizure. However, this is a rare event and close monitoring is essential.
  - Treatment options with established or probable efficacy include the following:
    - Focal seizures: levetiracetam
    - Epileptic spasms: High-dose or low-dose ACTH
    - Dravet syndrome: stiripentol
  - Treatment options with possible efficacy include the following:
    - Generalized seizures: levetiracetam, valproate, lamotrigine, topiramate, clobazam
    - Epileptic spasms: prednisone, vigabatrin
    - Benign infantile convulsions: carbamazepine, phenobarbital, valproate
    - Dravet syndrome: topiramate, zonisamide, valproate
    - Benign myoclonic epilepsy of infancy: valproate, topiramate, lamotrigine, clonazepam
    - Provoked or situational seizures: carbamazepine
  - There is no clear evidence supporting an optimal duration of treatment; this is dependent on seizure type.

- **Treatment of seizures in the neonate.** International League Against Epilepsy (ILAE) *(Pressler et al 2023).*
  - This document was prepared based on a systematic review of the literature and included the following 6 core recommendations:
    - The first-line AED should be phenobarbital, regardless of etiology, unless channelopathy is the likely cause for seizures (eg, due to family history), in which case phenytoin or carbamazepine should be used.
    - Second-line AEDs include phenytoin, levetiracetam, midazolam, or lidocaine. Levetiracetam may be preferred in neonates with cardiac disorders.
    - Following cessation of acute provoked seizures without evidence for neonatal-onset epilepsy, AEDs should be discontinued before discharge home, regardless of magnetic resonance imaging or electroencephalographic findings.
    - Therapeutic hypothermia may reduce seizure burden in neonates with hypoxic-ischemic encephalopathy.
    - Treating neonatal seizures (including electrographic-only seizures) to achieve a lower seizure burden may be associated with improved outcomes.
    - A trial of pyridoxine may be attempted in neonates with clinical features of vitamin B6-dependent epilepsy and seizures unresponsive to second-line AEDs.

- **Teratogenesis, Perinatal, and Neurodevelopmental Outcomes After In Utero Exposure to Antiseizure Medication: Practice Guideline From the American Academy of Neurology, American Epilepsy Society, and Society for Maternal-Fetal Medicine** (*Pack et al 2023*).
  - This publication summarizes evidence for selected issues regarding the clinical management of people with epilepsy of childbearing potential (PWECP).
  - Recommendations include the following:
    - Clinicians must consider using lamotrigine, levetiracetam, or oxcarbazepine in PWECP when appropriate based on the patient's epilepsy syndrome, likelihood of achieving seizure control, and comorbidities, to minimize the risk of major congenital malformations (MCMs).
    - Clinicians must avoid the use of valproic acid in PWECP to minimize the risk of MCMs, neural tube defects, urogenital and renal malformations, and poor neurodevelopmental outcomes, if clinically feasible.
    - To reduce the risk of cardiac malformations, clinicians must avoid the use of phenobarbital in PWECP, if clinically feasible.
    - To reduce the risk of oral clefts, clinicians should avoid the use of phenobarbital and topiramate in PWECP, if clinically feasible.

- Clinicians should avoid the use of valproic acid or topiramate in PWECP to minimize the risk of offspring being born small for gestational age.

- **Practice parameter: management of epilepsy in pregnancy: a report from the International League Against Epilepsy Task Force on Women and Pregnancy** (*Tomson et al 2019*)
  - This publication provides recommendations on the clinical management of WWE who are of childbearing potential.
  - Recommendations include the following:
    - Valproate is associated with the highest risk of inducing MCMs, phenobarbital and topiramate are associated with intermediate risk of MCM to specific organs, and lamotrigine and levetiracetam have the lowest associated risks.
    - The risk of MCMs is dose-dependent for valproate and may also be dose-dependent for other AEDs (ie, carbamazepine, phenobarbital, lamotrigine).
    - Exposure to valproate in the womb is associated with a significant risk of cognitive and neurodevelopmental disorders.
    - Carbamazepine does not appear to cause major neurobehavioral teratogenicity.
    - Current data suggest a reduced risk of neurodevelopmental effects from lamotrigine.
    - Limited data suggest a low risk for neurodevelopmental effects from levetiracetam and topiramate, but further research is needed.

- **Practice parameter update: management issues for women with epilepsy – focus on pregnancy (an evidence-based review): vitamin K, folic acid, blood levels, and breastfeeding.** Quality Standards Subcommittee and Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and American Epilepsy Society (*Harden et al 2009*; reaffirmed in 2022; update in progress)
  - This publication summarizes evidence for selected issues regarding the clinical management of WWE who are pregnant or planning to be pregnant.
  - Recommendations include the following:
    - The fact that phenobarbital, primidone, phenytoin, carbamazepine, levetiracetam, valproate, gabapentin, lamotrigine, oxcarbazepine, and topiramate cross the placenta may be factored into the clinical decision regarding the necessity of AED treatment for a WWE.
    - Monitoring of lamotrigine, carbamazepine, and phenytoin levels during pregnancy should be considered.
    - Monitoring of levetiracetam and oxcarbazepine (as monohydroxy derivative) levels during pregnancy may be considered.
    - There is insufficient evidence to support or refute a change in phenobarbital, valproate, primidone, or ethosuximide levels related to pregnancy, but this lack of evidence should not discourage monitoring levels of these AEDs during pregnancy.
    - Valproate, phenobarbital, phenytoin, and carbamazepine may not transfer into breast milk to as great an extent as primidone, levetiracetam, gabapentin, lamotrigine, and topiramate.
  - Although many of the AEDs were shown to cross the placenta or enter breast milk, studies were limited in duration and did not systematically evaluate neonatal symptoms.

- **Practice advisory update summary: Antiseizure medication withdrawal in seizure-free patients.** Report of the American Academy of Neurology Guideline Subcommittee (*Gloss et at 2021,* an update to the 1996 practice parameter)
  - This publication addresses the available evidence on the risk of seizure development in adult and pediatric patients who have been seizure-free and may be considering discontinuing AED treatment. Clinicians should provide counseling noting that recurrent seizures increase the risk of status epilepticus or death, although existing data do not suggest an increased risk of status epilepticus or death after AED withdrawal. Clinicians must explore contributors to patients' quality of life as part of shared decision-making. Additional recommendations include:
    - In adult patients:
      - In adults who are seizure-free for at least 2 years, there should be a discussion between the clinician and the patient or caregiver about the risks and benefits of AED withdrawal, noting that there is possibly higher seizure recurrence in patients after AED withdrawal, and if seizures recur, there is a small chance they will no longer respond to medications.
      - It is unknown if EEG or imaging studies inform the decision to withdraw AEDs.
      - The risk of seizure recurrence in patients who have had epilepsy surgery is uncertain.

- In pediatric patients:
  - In children who are seizure-free for 18 to 24 months who do not have an electroclinical syndrome suggesting otherwise, a discussion of the risks and benefits of discontinuing AEDs should take place. This discussion should include acknowledgement that if seizures recur after discontinuing AEDs, there is a small chance they will no longer respond to treatment.
  - Clinicians should discuss with children and their families that AED discontinuation can be considered since discontinuation does not clearly increase the risk of seizure.
  - In children seizure-free for 18 to 24 months in whom AED withdrawal is being considered, an EEG should be ordered. If no epileptiform activity is shown, AED discontinuation can be offered, and tapering should occur no faster than 25% every 10 to 14 days.
  - Clinicians must consider the history of the patient's electroclinical syndrome when counseling about discontinuation of AEDs.

- Guidelines also support the use of AEDs for several common non-epilepsy indications:
  - The American Academy of Neurology and American Headache Society state that AEDs with established efficacy for migraine prevention include valproate, divalproex sodium, and topiramate; carbamazepine is noted to be possibly effective (*Silberstein et al 2012;* reaffirmed in 2022; update in progress). An American Academy of Neurology guideline for pediatric migraine prevention noted that children and adolescents with migraine receiving topiramate are probably more likely than those receiving placebo to have a reduction in migraine or headache day frequency, whereas there was insufficient evidence to support the efficacy of extended-release divalproex sodium for reducing frequency (*Oskoui et al 2019 [reaffirmed in 2022]*).
  - The American Academy of Neurology states that oral drugs from any of the following drug classes are probably more likely than placebo to improve pain due to diabetic neuropathy: gabapentinoids, sodium channel blockers, serotonin norepinephrine reuptake inhibitors (SNRIs), and SNRI-opioid dual mechanism agents (eg, tramadol); tricyclic antidepressants (TCAs) are possibly more likely than placebo to improve pain (*Price et al 2022*). The guideline recommends that gabapentinoids, sodium channel blockers, SNRIs, or TCAs be offered by clinicians to treat pain in patients with painful diabetic neuropathy.
  - The American Diabetes Association (ADA) recommends gabapentinoids, SNRIs, TCAs, and sodium channel blockers as initial pharmacologic treatments for neuropathic pain in diabetes (*ADA 2024*).
  - A retired guideline from The American Academy of Neurology states that gabapentin and pregabalin are of benefit in reducing pain from postherpetic neuralgia (*Dubinsky et al 2004; retired February 27, 2018*).
  - American Psychiatric Association guidelines describe the key role of AEDs in the management of bipolar disorder, including the following (*Hirschfeld et al 2002*):
    - First-line pharmacological treatment for more severe manic or mixed episodes is either lithium plus an antipsychotic or valproate plus an antipsychotic; for less ill patients, monotherapy with lithium, valproate, or an antipsychotic may be sufficient. For mixed episodes, valproate may be preferred over lithium. Carbamazepine and oxcarbazepine are alternatives.
    - First-line pharmacological treatment for bipolar depression is either lithium or lamotrigine. When an acute depressive episode of bipolar disorder does not respond to first-line medication treatment, the next steps include adding lamotrigine, bupropion, or paroxetine.
    - The initial treatment for patients who experience rapid cycling should include lithium or valproate; an alternative is lamotrigine.
    - The medications with the best empirical evidence to support their use in maintenance treatment include lithium and valproate; possible alternatives include lamotrigine, carbamazepine, or oxcarbazepine.
    - Note: This guideline was published in 2002 and cannot be assumed to be current; however, AEDs continue to be recommended for both acute (mania or hypomania) and maintenance phases of bipolar disorder *(Post 2023, Stovall 2024).*

Safety Summary

- Tolerability and safety are as important as efficacy in determining the overall effectiveness of epilepsy treatment (*Schachter 2024[b]*).
- Common AEs among AEDs include the following (*Schachter 2024[b], individual package inserts*):
  - Systemic AEs:

        - Nausea, vomiting, constipation, diarrhea, anorexia
        - Rash
        - Hyponatremia (carbamazepine, eslicarbazepine, oxcarbazepine)
        - Weight gain (pregabalin, perampanel, valproate, vigabatrin), weight loss (felbamate, topiramate, stiripentol, fenfluramine)
    - Neurologic AEs:
        - Headache
        - Somnolence, sedation, drowsiness, lethargy, fatigue
        - Dizziness, vertigo
        - Tremor, anxiety, nervousness, insomnia
        - Aggression, irritability, hyperactivity
        - Depression, mood alteration
        - Confusion
        - Ataxia
        - Blurred or double vision
- Examples of rare but serious AEs include the following (*Schachter 2024[b], individual package inserts*):
    - Suicidal ideation and behavior (AEDs as a class, except everolimus)
    - Psychosis (brivaracetam, levetiracetam)
    - Neutropenia, leukopenia, pancytopenia, agranulocytosis, thrombocytopenia, and/or aplastic anemia (brivaracetam, carbamazepine, divalproex, ethosuximide, felbamate, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, primidone, stiripentol, valproate, vigabatrin, zonisamide)
    - Anaphylaxis or angioedema (brivaracetam, fosphenytoin, gabapentin, levetiracetam, phenytoin, pregabalin)
    - Acute toxic reaction (sedation, dizziness, ataxia, nausea, and vomiting) (primidone)
    - Severe skin rashes, Stevens-Johnson syndrome (SJS), and/or toxic epidermal necrolysis (TEN) (carbamazepine, cenobamate, clobazam, divalproex, eslicarbazepine, ethosuximide, fosphenytoin, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, primidone, rufinamide, tiagabine, topiramate, valproate, zonisamide)
    - Drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity (clobazam, levetiracetam)
    - Hypersensitivity reactions (including angioedema, erythema, and pruritus) (cannabidiol)
    - Aseptic meningitis (lamotrigine)
    - Hepatic failure (carbamazepine, divalproex, ethosuximide, felbamate, phenytoin, phenobarbital, primidone, valproate)
    - Hepatocellular injury (cannabidiol)
    - Elevated liver transaminases and ammonia levels (hyperammonemia) (cannabidiol [especially with concomitant use of valproate, clobazam, or both], zonisamide)
    - Encephalopathy (zonisamide)
    - Pancreatitis (carbamazepine, valproate)
    - Lupus syndrome (carbamazepine, phenytoin)
    - Hirsutism (phenytoin)
    - Hypogammaglobulinemia (carbamazepine, lamotrigine, levetiracetam, valproate)
    - Prolonged PR interval, atrioventricular block, changes in QT interval, and/or cardiac rhythm or conduction abnormalities (cenobamate, eslicarbazepine, lacosamide, lamotrigine, rufinamide)
    - Serum sickness (carbamazepine, ethosuximide, phenytoin, phenobarbital, primidone, valproate)
    - Multiorgan hypersensitivity (carbamazepine, cenobamate, ethosuximide, gabapentin, lacosamide, lamotrigine, oxcarbazepine, perampanel, phenytoin, rufinamide, valproate, zonisamide)
    - Severe neuropsychiatric effects/hostility/aggression (brivaracetam, clonazepam, levetiracetam, perampanel)
    - Hemophagocytic lymphohistiocytosis (HLH) (lamotrigine)
    - Cardiac AEs, including bradycardia and cardiac arrest (phenytoin)
    - Abnormal magnetic resonance imaging signals in infants (vigabatrin)
    - Intramyelinic edema (vigabatrin)
    - Serotonin syndrome (fenfluramine)
    - Significant elevation in blood pressure including hypertensive crisis (fenfluramine)
    - Respiratory depression, especially in the setting of underlying respiratory impairment or concurrent use of opioids (gabapentin, pregabalin)

- Hyperammonemia and hyperammonemic encephalopathy (divalproex)
- Hypothermia (divalproex)
- Increased rates of pneumonia (when cannabidiol is given concomitantly with clobazam)
- Neonatal sedation and withdrawal syndrome (clobazam, clonazepam, clorazepate, diazepam, midazolam)
- Increased intraocular pressure in patients with glaucoma (diazepam)
- Embryofetal toxicity (topiramate)
- Connective tissue contractures (phenobarbital, primidone)
- Complex regional pain syndrome (phenobarbital)
- Adenopathy, pseudolymphoma, neuropathy, ataxia (phenytoin)
- Rhabdomyolysis (pregabalin)
- Nonconvulsive status epilepticus (tiagabine)
- Polycystic ovary syndrome (valproate)
- Nephrolithiasis (topiramate, zonisamide)
- Acute myopia and secondary angle closure glaucoma (zonisamide)
- Oligohidrosis and hyperthermia (topiramate)
- Fever and hyperhidrosis (zonisamide)

- A number of AEDs carry boxed warnings related to potentially serious AEs; these include the following:
  - Carbamazepine:
    - Serious and sometimes fatal dermatologic reactions, including TEN and SJS, have been reported. Studies in patients of Chinese ancestry have found a strong association between the risk of developing SJS/TEN and the presence of HLA-B*1502, an inherited allelic variant of the HLA-B gene. Patients with ancestry in genetically at-risk populations (across broad areas of Asia) should be screened for the presence of HLA-B*1502 prior to initiating treatment with carbamazepine.
    - Aplastic anemia and agranulocytosis have been reported. If a patient exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely, and discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.
  - Clobazam, clonazepam, clorazepate, diazepam, and midazolam:
    - Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Concomitant prescribing should be reserved for use in patients for whom alternative treatment options are inadequate, and patients should be followed for signs and symptoms of respiratory depression and sedation.
  - Clobazam, diazepam, and midazolam:
    - Use of benzodiazepines may expose users to risks of abuse, misuse, and addiction, which may result in overdose or death; continued use of benzodiazepines may lead to physical dependence, especially with high doses and longer treatment duration. Abrupt discontinuation may result in acute, potentially life-threatening, withdrawal reactions. In some cases, protracted withdrawal symptoms can occur, which can last weeks to more than 12 months. Before prescribing and throughout treatment, each patient should be assessed for abuse, misuse, and addiction. For patients using benzodiazepines more frequently than recommended, the agents should be gradually tapered when discontinuing to minimize withdrawal reactions.
  - Felbamate
    - Use is associated with a marked increase in the incidence of aplastic anemia. Felbamate should only be used in patients whose epilepsy is so severe that the risk of aplastic anemia is deemed acceptable. Routine blood testing cannot be reliably used to reduce the incidence of aplastic anemia, but it will in some cases allow detection of hematologic changes before the syndrome declares itself clinically. Felbamate should be discontinued if any evidence of bone marrow depression occurs.
    - Cases of acute liver failure have been reported. Felbamate should not be prescribed for anyone with a history of hepatic dysfunction. Treatment should be initiated only in individuals without active liver disease and with normal baseline serum transaminases. It has not been proven that periodic serum transaminase testing will prevent serious injury, but it is generally believed that early detection of drug-induced hepatic injury along with immediate withdrawal of the suspect drug enhances the likelihood for recovery. Serum transaminases should be monitored at baseline and periodically thereafter. Felbamate should be discontinued if either aspartate aminotransferase (AST) or alanine aminotransferase (ALT) become increased to ≥ 2 times the upper limit of normal, or if clinical signs and symptoms suggest liver failure, and should not be considered for retreatment.
  - Fenfluramine:

- Use of serotonergic drugs with 5-HT2B receptor agonist activity (eg, fenfluramine) is associated with valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment with fenfluramine, and the benefits vs risks of initiating or continuing treatment with this product must be considered based on echocardiogram findings.
- Due to the risks of valvular heart disease and pulmonary arterial hypertension, fenfluramine is available only through a risk evaluation and mitigation strategy (REMS) program (*FDA REMS 2024*). Healthcare providers who prescribe fenfluramine and pharmacies that dispense the product must be certified. Each patient must be enrolled in the REMS program. Prescribers must ensure that periodic cardiovascular monitoring is performed and report any AE suggestive of valvular heart disease and/or pulmonary hypertension to the fenfluramine REMS program.

- Fosphenytoin and phenytoin:
  - There is a cardiovascular risk associated with rapid IV infusion rates. The rate of administration should not exceed recommendations, and careful cardiac monitoring is required.
- Lamotrigine:
  - Cases of life-threatening serious skin rashes, including SJS and TEN, and/or rash-related death have been caused by lamotrigine. Benign rashes are also caused by lamotrigine; however, it is not possible to predict which rashes will prove to be serious. Lamotrigine should be discontinued at the first sign of a rash, unless the rash is clearly not drug related.
- Perampanel:
  - Serious or life-threatening psychiatric and behavioral AEs including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported. Patients should be monitored for these reactions and for changes in mood, behavior, or personality. The dose should be reduced if these symptoms occur, and it should be discontinued if symptoms are severe or worsening.
- Valproic acid and divalproex sodium:
  - Hepatotoxicity, including fatalities, has been reported, usually during the first 6 months of treatment. Serum liver tests are required and patients should be monitored closely. There is an increased risk of valproate-induced acute liver failure and resultant deaths in patients with mitochondrial disease. Valproic acid and divalproex sodium are contraindicated in patients known to have mitochondrial disorders caused by polymerase gamma (POLG) gene mutations, and in children < 2 years of age who are suspected of having a mitochondrial disorder.
  - There is a risk to fetuses exposed in utero, particularly neural tube defects, other major malformations, and decreased intelligence quotient (IQ). Valproate should not be given to a woman of childbearing potential unless the drug is essential to the management of her medical condition, and women should use effective contraception while using valproate.
  - Pancreatitis, including fatal hemorrhagic cases, has occurred. Patients and guardians should be warned that abdominal pain, nausea, vomiting, and/or anorexia can be symptoms of pancreatitis that require prompt medical evaluation.
- Vigabatrin:
  - Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, vigabatrin may also damage the central retina and may decrease visual acuity. Baseline and periodic vision assessment are recommended. However, this assessment cannot always prevent vision damage, and once detected, vision loss due to vigabatrin is not reversible. Vigabatrin should be withdrawn from patients who fail to show substantial clinical benefit.
  - Due to the risks of vision loss, vigabatrin is available only through a REMS program (*FDA REMS 2024*). Healthcare providers who prescribe vigabatrin and pharmacies that dispense the product must be specially certified. Each patient must be enrolled in the REMS program. Prescribers must ensure that periodic visual monitoring is performed and report any AE suggestive of vision loss to the vigabatrin REMS program.

- Everolimus is an antineoplastic, immunosuppressant agent associated with several AEs.
  - The most common AE that occurred in trials for TSC-associated partial-onset seizures was stomatitis.
  - More serious AEs include:
    - Non-infectious pneumonitis
    - Infections
    - Hypersensitivity reactions
    - Angioedema (when taken with an angiotensin-converting enzyme inhibitor)
    - Renal failure
    - Impaired wound healing

- Myelosuppression
- Reduced immune response with vaccination
- Hyperglycemia
- Hyperlipidemia
- Embryo-fetal toxicity

- Topiramate:
  - Topiramate can decrease lumbar bone mineral density, which has been correlated with decreased serum bicarbonate in some patients, reflective of metabolic acidosis. Topiramate monotherapy has demonstrated negative effects on patient growth (both height and weight gain) when used over long periods. Increases in urinary calcium and decreases in urinary citrate have also been observed, increasing the risk of kidney stones and/or nephrocalcinosis.
    - Although decreases in bone mineral density have been observed in pediatric patients of all ages, patients 6 to 9 years of age are most commonly affected.
- The most common AEs associated with ganaxolone include somnolence, pyrexia, salivary hypersecretion, and seasonal allergy. More serious AEs include somnolence and sedation, suicidal behavior and ideation, and a potential for increased seizure frequency and status epilepticus associated with rapid withdrawal of therapy.

Dosing and Administration

- General dosing information is provided in Table 3. Dosing may vary based on the specific indication, interacting medications, and the patient's age and renal and hepatic function. Additionally, some medications are recommended to be titrated during initial treatment. Please refer to the prescribing information of the individual products for more detailed information.

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Barbiturates				
Pentobarbital (Nembutal)	injection	IV, IM	Single dose	Acute use only. If needed, additional small increments may be given after the initial dose.
Phenobarbital* (Sezaby)	tablets, elixir, injection	oral, IV, IM	2 to 3 times per day	IV/IM single dose may also be used for acute convulsions. May be repeated in 6 hours (generic). For Sezaby, the single dose may be repeated in 15 minutes, then every 8 to 12 hours for up to 5 days.
Primidone (Mysoline)	tablets	oral	3 to 4 times per day	
Benzodiazepines				
Clobazam (Onfi, Sympazan)	tablets, oral suspension, oral film	oral	1 or 2 times per day	Daily doses > 5 mg should be given in divided doses 2 times per day. Sympazan should be applied on top of the tongue where it adheres and dissolves.
Clonazepam (Klonopin)	tablets, orally disintegrating tablets (wafers)	oral	3 times per day	

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Clorazepate (Tranxene T-Tab)	tablets	oral	2 to 3 times per day	
Diazepam (Diastat, Libervant, Valium, Valtoco)	tablets, oral solution, oral concentrate, buccal film, rectal gel, injection, nasal spray	oral, buccal, rectal, IV, IM, intranasal	2 to 4 times per day (oral tablets, solution, concentrate) Acute treatment: single dose followed by a second dose 4 to 12 hours after the first dose (rectal gel) or 4 hours after the first dose (nasal spray, buccal film) as needed Acute treatment (IV/IM): single dose; may be repeated every 10 to 15 minutes up to maximum dose of 30 mg	The buccal film, nasal spray, and rectal gel should be used to treat no more than 1 episode every 5 days and no more than 5 episodes per month.
Midazolam (Nayzilam, Seizalam)	nasal spray, injection	Intranasal, IM	Intranasal: Single dose followed by a second dose given at least 10 minutes after the first dose if needed IM: Single dose	Intranasal: Should be used to treat no more than 1 episode every 3 days and no more than 5 episodes per month. IM: Should be administered by a healthcare professional. After administration, monitoring of respiratory and cardiac function is recommended until the patient is stabilized.
Hydantoins				
Fosphenytoin (Cerebyx)	injection	IV, IM	2 times per day or other divided doses based on drug levels	Generally used in acute situations as a loading dose; may be given in divided doses when substituted for oral phenytoin.
Phenytoin (Dilantin, Phenytek)	extended-release capsules, chewable tablets, oral suspension, injection	oral, IV, IM	2 to 4 times per day	Capsules are extended-release and may be suitable for once-daily dosing in some adults.
Miscellaneous				
Brivaracetam (Briviact)	tablets, oral solution, injection	oral, IV	2 times per day	The injection may be used when oral administration is temporarily not feasible.
Cannabidiol (Epidiolex)	oral solution	oral	2 times per day	The provided oral syringe should be used to measure an accurate dose.
Carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Tegretol-XR)	tablets, chewable tablets, oral suspension, extended-release	oral	2 to 4 times per day	Immediate-release tablets are given 2 to 3 times per day and the suspension is given 4 times per day. Carbatrol and Equetro are twice-daily

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
	tablets, extended-release capsules			extended-release capsule formulations; these capsules may be opened and sprinkled on soft food. Tegretol-XR is a twice-daily extended-release tablet formulation; these tablets must be swallowed whole.
Cenobamate (Xcopri)	Tablets	oral	once daily	The recommended titration schedule should not be exceeded. Tablets may be administered whole or crushed; the crushed tablet can be mixed with water and either administered by mouth as an oral suspension or administered via a nasogastric tube.
Divalproex sodium (Depakote, Depakote ER, Depakote Sprinkle)	delayed-release tablets, delayed-release sprinkle capsules, extended-release tablets	oral	2 to 3 times per day (once daily for extended-release tablets)	Delayed-release tablets and extended-release tablets should be swallowed whole. Sprinkle capsules may be opened and sprinkled on soft food. Delayed-release tablet and capsule doses > 250 mg per day should be given in divided doses.
Eslicarbazepine (Aptiom)	tablets	oral	once daily	Tablets may be crushed.
Ethosuximide (Zarontin)	capsules, oral solution/syrup	oral	once daily or in divided doses	
Everolimus (Afinitor Disperz)	tablets for oral suspension	oral	once daily	Should be taken at the same time each day with or without food. Suspension should be prepared using water only and administered immediately after preparation. The suspension should be discarded if not taken within 60 minutes of preparation. Dose adjustments are made based on trough drug concentration.
Felbamate (Felbatol)	tablets, oral suspension	oral	3 or 4 times per day	

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Fenfluramine (Fintepla)	oral solution	oral	2 times per day	The provided oral syringe should be used to measure an accurate dose.
Gabapentin (Neurontin)	tablets, capsules, oral solution	oral	3 times per day	Capsules should be swallowed whole.
Ganaxolone (Ztalmy)	oral suspension	oral	3 times per day	The provided oral syringe should be used to measure an accurate dose.
Lacosamide (Vimpat)	tablets, oral solution, injection	oral, IV	2 times per day (oral route) 2 or 3 times per day IV	An alternate initial dosing regimen including a loading dose and/or higher initial dosage may be used in patients for whom achieving the recommended maintenance dosage in a shorter timeframe is clinically indicated.
Lacosamide (Motpoly XR)	extended-release capsule	Oral	once daily	Extended-release capsules should not be opened, chewed, or crushed.
Lamotrigine (Lamictal, Lamictal ODT, Lamictal XR, Subvenite)	tablets, chewable dispersible tablets, orally disintegrating tablets, extended-release tablets	oral	2 times per day (once daily for extended-release tablets)	Only whole tablets should be administered. Extended-release tablets must not be chewed or crushed.
Levetiracetam (Keppra, Keppra XR, Roweepra, Spritam, Elepsia XR)	tablets, tablets for oral suspension, oral solution, extended-release tablets, injection	oral, IV	2 times per day (once daily for extended-release tablets)	Tablets and extended-release tablets should not be chewed or crushed. Tablets for oral suspension (Spritam) can be dissolved in liquid and swallowed or allowed to disintegrate in the mouth.
Methsuximide (Celontin)	capsules	oral	2 to 4 times per day (*Lexicomp 2024*)	
Oxcarbazepine (Oxtellar XR, Trileptal)	tablets, oral suspension, extended-release tablets	oral	2 times per day (once daily for extended-release tablets)	In conversion of oxcarbazepine immediate-release to Oxtellar XR, higher doses of Oxtellar XR may be necessary. Extended-release tablets must not be chewed or crushed.
Perampanel (Fycompa)	tablets, oral suspension	oral	once daily at bedtime	The provided oral syringe should be used to measure an accurate dose.
Pregabalin (Lyrica)	capsules, oral solution	oral	2 to 3 times per day	
Rufinamide (Banzel)	tablets, oral suspension	oral	2 times per day	Tablets can be administered whole, as half tablets, or crushed.

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Stiripentol (Diacomit)	capsules, powder for oral suspension	oral	2 to 3 times per day	Capsules must be swallowed whole with a glass of water during a meal. Powder should be mixed with water and taken immediately after mixing during a meal.
Tiagabine (Gabitril)	tablets	oral	2 to 4 times per day	
Topiramate (Topamax, Topamax Sprinkle, Trokendi XR, Qudexy XR, Eprontia)	tablets, sprinkle capsules, extended-release capsules, extended-release sprinkle capsules, oral solution	oral	2 times per day (once daily for extended-release capsule formulations)	Sprinkle capsules may be opened and sprinkled on soft food. Extended-release capsules (Trokendi XR) must not be chewed or crushed, but extended-release sprinkle capsules (Qudexy XR) may be sprinkled on soft food.
Valproic acid/ valproate sodium	capsules, oral solution/ syrup, injection	oral, IV	1 to 4 times per day (*Lexicomp 2024*)	Capsules should be swallowed whole without chewing to avoid local irritation of the mouth and throat. If the total dose exceeds 250 mg, it should be given in divided doses.
Vigabatrin (Sabril, Vigadrone, Vigafyde)	tablets, powder for oral solution, concentrated oral solution	oral	2 times per day	Powder for oral solution is supplied in individual dose packets to be mixed with water before administration. Vigafyde is a concentrated formulation as compared to other vigabatrin products.
Zonisamide (Zonegran, Zonisade)	capsules, oral suspension	oral	1 or 2 times per day	Capsules must be swallowed whole. The provided oral syringe should be used to measure an accurate dose of the oral suspension.

* Only Sezaby is FDA-approved; other phenobarbital products are marketed without FDA approval
See the current prescribing information for full details.

Conclusion

- Several classes of AEDs are available, including barbiturates, benzodiazepines, hydantoins, and miscellaneous agents. These products vary in terms of their indications for specific seizure types and indications other than epilepsy.
- Overall, the anticonvulsants have demonstrated efficacy for their FDA-approved uses. When possible, monotherapy with a single AED is the preferred treatment approach; however, data are conflicting on the benefits of mono- vs polytherapy.
- Patients who are refractory to monotherapy may be treated with combination therapy. When considering combination therapy, it is recommended to combine medications with different mechanisms of action and AE profiles.
- Comparative efficacy data for the management of epilepsy are limited.

- Tolerability and safety are as important as efficacy in determining the overall effectiveness of epilepsy treatment. Both systemic AEs and neurologic AEs commonly occur. Some AEDs are associated with rare but serious AEs, and careful patient selection and monitoring are required.
- Epilepsy management can be complex and is often performed by neurologists. Availability of a variety of AEDs supports the ability of clinicians to select the most clinically appropriate agent for individual patients.
- Anticonvulsants are also established as effective for several non-epilepsy indications, including (but not limited to) bipolar disorder, migraine prophylaxis, and neuropathic pain.

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Optum Rx®

Therapeutic Class Overview

H. pylori combinations

Introduction

- *Helicobacter pylori* (*H. pylori*), a common gastric gram-negative spiral bacterium, is associated with dyspepsia, chronic gastritis, peptic ulcer disease, gastric adenocarcinoma, and gastric mucosa-associated lymphoid tissue (MALT) lymphoma (*Hu et al 2021, Lamont 2022*). *H. pylori* acts by disrupting the mucous layer, liberating enzymes and toxins, and adhering to the gastric epithelium (*Lamont 2022*).
  - Approximately one-half of the world's population is infected with *H. pylori*, and worldwide, nearly 90% of non-cardia gastric cancer has been attributed to *H. pylori* infection (*Hu et al 2021*). Prevalence estimates can vary greatly, depending on the location of the study group and the characteristics of the population studied (*Lamont 2022*).
- Eradication of *H. pylori* is part of the effective treatment and/or prevention of gastric and/or duodenal disorders. The most common method for the eradication of *H. pylori* infection consists of the administration of a proton pump inhibitor (PPI) in combination with 1 or more antimicrobial agent(s) (*Crowe 2019, Lamont 2023*).
  - Successful *H. pylori* eradication may decrease levels of gastric inflammation, relieve dyspepsia, prevent the progression of gastric mucosa, and reduce the incidence of peptic ulcer and gastric cancer; recent studies have demonstrated that *H. pylori* treatment was associated with a lower risk of gastric cancer even in older patients (*Hu et al 2021*).
- Six Food and Drug Administration (FDA)-approved *H. pylori* eradication packaged combination products are available in the United States (U.S.) (*Drugs@FDA 2024, prescribing information: Helidac Therapy 2024, lansoprazole, amoxicillin, and clarithromycin kit 2024, Omeclamox-Pak 2023, Pylera 2024, Talicia 2024, Voquezna Dual Pak and Triple Pak 2024*).
  - Helidac Therapy is a co-packaged kit containing bismuth subsalicylate tablets, metronidazole tablets, and tetracycline capsules; it requires the concomitant administration of an H2-antagonist (H2A).
  - Pylera (bismuth subcitrate potassium, metronidazole, and tetracycline) fixed-dose combination capsule is approved for use in combination with omeprazole.
  - A co-packaged product, previously known by the brand name Prevpac, is a triple-therapy eradication regimen kit that includes lansoprazole capsules, amoxicillin capsules, and clarithromycin tablets; a generic remains available.
  - Omeclamox-Pak is a triple-therapy co-packaged kit that includes omeprazole capsules, clarithromycin tablets, and amoxicillin capsules.
  - Talicia (omeprazole, amoxicillin and rifabutin), a triple-therapy, fixed-dose combination capsule, was FDA-approved in 2019 and developed to address *H. pylori* treatment challenges due to increasing antibiotic resistance. Due to the differences in the pharmacokinetics of the components of Talicia, substitution of the individual components is not possible using commercially available individual products.
  - Voquezna is available in a co-packaged Dual Pak consisting of vonoprazan tablets with amoxicillin capsules, or a Triple Pak consisting of vonoprazan tablets, amoxicillin capsules, and clarithromycin tablets.
    - Vonoprazan is a first-in-class potassium-competitive acid blocker (PCAB). Unlike PPIs, vonoprazan does not require acid activation and has a more potent and longer duration of acid suppression including during the night (*Scott et al 2015, Shin et al 2011).*
- Comparative studies of worldwide and regional efficacy of *H. pylori* regimens are lacking (*Rokkas et al 2021*). There are also limited data on *H. pylori* antibiotic resistance rates to guide therapy. The choice of initial antibiotic regimen to treat *H. pylori* should be guided by the presence of risk factors for macrolide resistance and local antibiotic resistance patterns (if known), penicillin allergy, adverse events, and ease of administration. In patients with ≥ 1 risk factor for macrolide resistance, clarithromycin-based therapy should be avoided (*Crowe 2019, Lamont 2023*).
  - Risk factors for macrolide resistance include prior exposure to macrolide therapy and high local clarithromycin resistance rates ≥ 15% or eradication rates with clarithromycin triple therapy ≤ 85%.
  - In the U.S., given the limited information on antimicrobial resistance rates, it is generally assumed that clarithromycin resistance rates are > 15% unless local data indicate otherwise. Data suggest that *H. pylori* antibiotic resistance rates are high worldwide, and clarithromycin-resistant *H. pylori* has been included in the World Health Organization (WHO) priority list of antibiotic-resistant bacteria (*Hu et al 2021, Savoldi et al 2018*).
  - Additional *H. pylori* eradication regimens under investigation also include hybrid and reverse hybrid therapies (ie, a PPI and amoxicillin for 10 to 14 days with the addition of clarithromycin and metronidazole for the final or first 7 days, respectively), with eradication rates of > 85% reported (*Hu et al 2021*).
- Approximately 20% of patients fail an initial attempt at *H. pylori* eradication and require salvage therapy (*Lamont 2023*).

- In patients with persistent *H. pylori* infection, the choice of antibiotic therapy should be guided by the patient's initial treatment regimen, the use of other antibiotics, and the presence of relevant antibiotic allergies. Antibiotics included in the initial regimen should generally be avoided. However, amoxicillin can be reused as resistance rarely develops. Patients with a reported history of penicillin allergy should be referred to an allergist to determine if they have a true penicillin allergy.
- Salvage regimens include bismuth quadruple therapy, levofloxacin triple therapy, high-dose dual therapy (with amoxicillin and a PPI), clarithromycin-based concomitant therapy, and rifabutin triple therapy.

- Medispan class: Ulcer therapy combinations

Table 1. Medications Included Within Class Review

Drug	Alternative Available (same molecular entity)*
amoxicillin, clarithromycin, lansoprazole	-
Helidac Therapy (bismuth subsalicylate, metronidazole, tetracycline)	-
Omeclamox-Pak (amoxicillin, clarithromycin, omeprazole)	-
Pylera (bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride)	✔
Talicia (omeprazole magnesium, amoxicillin, rifabutin)	-
Voquezna Dual Pak (vonoprazan and amoxicillin)	-
Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin)	-

*For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.

(*Drugs@FDA 2024, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2024*)

Indications

Table 2. Food and Drug Administration Approved Indications

Indication	amoxicillin; clarithromycin; lansoprazole	Helidac Therapy (bismuth subsalicylate, metronidazole, tetracycline)	Omeclamox-Pak (amoxicillin; clarithromycin; omeprazole)	Pylera (bismuth subcitrate potassium, metronidazole, tetracycline)	Talicia (omeprazole magnesium, amoxicillin rifabutin)	Voquezna Dual Pak (vonoprazan amoxicillin); Triple Pak (vonoprazan, amoxicillin, clarithromycin)
In combination with omeprazole, for the treatment *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*				✔		
In combination with an H2A, for the treatment of *H. pylori* infection and duodenal ulcer disease (active or history of duodenal		✔ *				

Indication	amoxicillin; clarithromycin; lansoprazole	Helidac Therapy (bismuth subsalicylate, metronidazole, tetracycline)	Omeclamox-Pak (amoxicillin; clarithromycin; omeprazole)	Pylera (bismuth subcitrate potassium, metronidazole, tetracycline)	Talicia (omeprazole magnesium, amoxicillin rifabutin)	Voquezna Dual Pak (vonoprazan amoxicillin); Triple Pak (vonoprazan, amoxicillin, clarithromycin)
ulcer) to eradicate *H. pylori*						
Treatment of *H. pylori* infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) to eradicate *H. pylori*	✔		✔			
Treatment of *H. pylori* infection in adults					✔	✔

*The eradication of *H. pylori* has been demonstrated to reduce the risk of duodenal ulcer recurrence in patients with active duodenal ulcer disease.

(*Prescribing information: Helidac Therapy 2024; lansoprazole, amoxicillin, and clarithromycin kit 2024; Omeclamox-Pak 2023; Pylera 2024; Talicia 2024; Voquezna Dual Pak and Triple Pak 2024*)

- 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

- Older clinical trials comparing triple therapy (lansoprazole, amoxicillin, and clarithromycin) to dual therapy (lansoprazole with amoxicillin or clarithromycin), lansoprazole monotherapy, or placebo found that triple therapy provided significantly greater eradication rates of *H. pylori*. In some instances, it was not reported or unclear whether the medications were prescribed as daily administration packs or as individual products (*Bazzoli et al 1998, Laine et al 2003, Lamouliatte et al 1998, Nagahara et al 2007, Schwartz et al 1998, Veldhuyzen van Zanten et al 2003*).
- A meta-analysis of 14 randomized controlled trials reported that high-dose dual therapy (a PPI given 4 times daily plus high-dose amoxicillin for 14 days) was as effective for *H. pylori* eradication when compared to bismuth-based quadruple therapy (*Zhou et al 2023*). In the high-dose dual therapy group, adverse effects were significantly lower when compared to bismuth-based quadruple therapy (relative risk, 0.42; 95% confidence interval [CI], 0.34 to 0.50, low quality evidence).
- Head-to-head trials and meta-analyses have reported that bismuth-based quadruple therapy was at least as effective as standard triple therapy for the eradication of *H. pylori*, and a few studies reported higher eradication rates with quadruple therapy when compared to 7 to 14-day standard triple therapy (*Chey et al 2017, Katelaris et al 2002, Laine et al 2003, Liou et al 2016, Luther et al 2010, Macías-Gracía et al 2019*, *Magaret et al 2001, Malfertheiner et al 2011, O'Morain et al 2003, Uygun et al 2007, Uygun et al 2008, Venerito et al 2013*). Bismuth-based quadruple therapy was also reported to be effective in patients who had received or failed previous *H. pylori* treatment regimens (*Miehlk et al 2003, Uygun et al 2008*).
  - Laine et al 2003 reported that a 10-day course of omeprazole plus a triple antibiotic capsule (bismuth, metronidazole, and tetracycline) was at least as efficacious as standard therapy with omeprazole, amoxicillin, and clarithromycin for the eradication of *H. pylori*. The bismuth-based regimen demonstrated effectiveness even in the presence of metronidazole and clarithromycin-resistant strains of *H. pylori* with eradication rates of 80% and 77%, respectively, in the intention-to-treat (ITT) analysis.
  - Liou et al 2016 reported *H. pylori* eradication frequencies of 90.4% in their ITT population with bismuth quadruple 10-day therapy (bismuth, lansoprazole, tetracycline, metronidazole), 85.9% with 10-day non-bismuth-based quadruple

therapy (lansoprazole, amoxicillin, clarithromycin, metronidazole) and 83.7% with 14-day triple therapy (lansoprazole, amoxicillin, clarithromycin). Superiority was achieved with bismuth 10-day quadruple therapy vs 14-day triple therapy (difference, 6.7%; 95% CI, 2.7 to 10.7), although rates of adverse events were highest in the bismuth 10-day quadruple therapy group (67% vs 47%).
  - A Phase 3 non-inferiority trial reported that a 10-day course of omeprazole plus a triple antibiotic capsule (bismuth, metronidazole, and tetracycline) was at least as efficacious as standard therapy with omeprazole, amoxicillin, and clarithromycin for 7 days in the eradication of *H. pylori* (*Malfertheiner et al 2011*). The bismuth-based regimen demonstrated eradication rates that were significantly higher than the 7-day standard triple therapy. Compliance rates in both groups exceeded 95%.
  - In a 2013 meta-analysis of 12 studies by Venerito et al, a bismuth-based quadruple regimen (bismuth, metronidazole, tetracycline, and PPI) for a treatment duration of 10 days was found to be more effective for *H. pylori* eradication when compared to a 7-day triple therapy regimen containing a PPI, amoxicillin, and clarithromycin. Eradication was achieved in 77.6% of patients receiving the 10-day bismuth-based quadruple regimen vs 68.9% of patients receiving 7-day triple therapy (risk difference, 0.06; 95% CI, -0.01 to 0.13). When triple therapy was extended to 10 days of treatment, however, eradication rates between triple therapy and 7-day quadruple therapy were considered similar. Compliance and rates of side effects were also similar between treatment groups.
  - A meta-analysis of 30 studies reported that the first-line *H. pylori* eradication rate of Pylera plus a PPI was 90% (95% CI, 87% to 92%; 21 trials; I^2 = 88%). In the second-line setting, the eradication rate of Pylera plus a PPI against *H. pylori* was 89% (95% CI, 86% to 93%; 12 studies; I^2 = 78%). For the second-line treatment following previous treatment with clarithromycin, the eradication rate of Pylera plus a PPI was 90% (95% CI, 87% to 93%; 11 studies; I^2 = 78%) (*Nyssen et al 2019*).
  - The efficacy and safety of Helidac (bismuth subsalicylate, metronidazole, tetracycline) were established in eradicating *H. pylori* infection in patients with an active duodenal ulcer. Eradication rates for Helidac therapy of 14 days were 77% and 82% in 2 clinical trials. The rates of duodenal ulcer recurrence at 12 months after treatment with Helidac plus ranitidine or ranitidine alone were 13% and 100% in the patients with a negative *H. pylori* test after treatment (*Helidac prescribing information 2020*).
- A prospective multicenter study and 1 meta-analysis have reported that non-bismuth-based quadruple therapy containing a nitroimidazole as a component of the regimen is safe and achieves higher eradication rates than standard non-bismuth-based triple therapy (*Gisbert and Calvet 2012*, *Molina-Infante et al 2015)*.
  - Gisbert and Calvet reported in their meta-analysis that *H. pylori* eradication was improved with non-bismuth-based quadruple therapy (PPI, amoxicillin, metronidazole, and clarithromycin) vs non-bismuth-based triple therapy (PPI, amoxicillin, clarithromycin). In their analysis of 7 randomized controlled trials, 90% of patients achieved *H. pylori* eradication in the ITT analysis in the quadruple group vs 78% in the triple therapy group (odds ratio [OR], 2.36; 95% CI, 1.67 to 3.34). The duration of the quadruple regimens differed across the studies included in the analysis and ranged from 3- to 5-day treatment durations, vs regimens of 5 to 7 days duration with triple therapy. Overall, quadruple and triple therapy regimens were found to have similar safety profiles.
  - A prospective, multicenter study found that empiric non-bismuth-based quadruple therapy (esomeprazole, amoxicillin, clarithromycin, metronidazole) for 14 days vs non-bismuth-based triple therapy (esomeprazole, amoxicillin, clarithromycin) for 14 days achieved significantly higher rates of *H. pylori* eradication (90.4 % vs 81.3% in ITT analysis; $p < 0.001$). While adverse events occurred at higher rates in the quadruple therapy group, the rate was not significantly increased compared to triple therapy and did not result in significant differences in treatment compliance between the 2 regimens (*Molina-Infante et al 2015*).
- The efficacy and safety of Talicia (equivalent to omeprazole 120 mg, amoxicillin 3 g, rifabutin 150 mg daily) were demonstrated in 2 double-blind, randomized controlled studies in treatment-naïve patients regardless of peptic or duodenal ulcer status. The ERADICATE Hp2 trial evaluated Talicia vs amoxicillin 3 g + omeprazole 120 mg daily in 455 patients with confirmed *H. pylori* infection. The eradication rate was significantly higher in the Talicia group compared to the active control group (83.8% vs 57.7%; $p < 0.0001$) (*Graham et al 2020*). The placebo-controlled ERADICATE Hp study that enrolled 118 patients found the eradication rate success for Talicia was significantly higher than the historical control using the standard of care (89.4% vs 2.7%; $p < 0.001$) (*Talicia Formulary Dossier 2020*).
- The efficacy and safety of Voquezna were demonstrated in a randomized, noninferiority study which assigned 1046 treatment-naïve patients with *H. pylori* infection to receive open-label Voquezna dual therapy (vonoprazan 20 mg twice daily plus amoxicillin 1 g three times daily) or double-blind triple therapy with either Voquezna twice daily (vonoprazan 20 mg, amoxicillin 1 g, clarithromycin 500 mg) or lansoprazole (lansoprazole 30 mg, amoxicillin 1 g, clarithromycin 500 mg) twice daily for 14 days. The eradication rates of *H. pylori* strains not resistant to clarithromycin or amoxicillin were

78.5% with Voquezna dual therapy, 84.7% with Voquezna triple therapy, and 78.8% with lansoprazole triple therapy. Both analyses were considered noninferior to lansoprazole triple therapy (difference, 5.9%; 95% CI, -0.8 to 12.6; p < 0.001; difference -0.3%; 95% CI, -7.4 to 6.8; p = 0.007) *(Chey et al 2022).*

- A systematic review and meta-analysis of 15 studies (N = 4568) comparing Voquezna dual therapy to other recommended regimens for *H. pylori* eradication (eg, Voquezna triple therapy, Voquezna quadruple therapy [Voquezna triple therapy plus bismuth], and PPI-based therapies [dual, triple, or bismuth-containing quadruple]) found that the pooled eradication rate of Voquezna dual therapy per ITT analysis was 85.0%. Voquezna dual therapy showed a higher cure rate vs PPI-based triple therapy (82.0% vs 71.4%, p < 0.01) but a lower rate vs Voquezna-based quadruple therapy (83.1% vs 93.3%, p = 0.02). There was no significant difference in efficacy between Voquezna dual therapy vs Voquezna triple therapy, PPI-based dual therapy, or PPI-based quadruple therapy (*Du et al 2023*).

Clinical Guidelines

- The 2017 American College of Gastroenterology (ACG) guideline recommends a 14-day therapy of a triple-drug regimen containing a PPI, clarithromycin, and either amoxicillin or metronidazole as the preferred treatment in regions where *H. pylori* has < 15% resistance to clarithromycin and in patients with no previous history of macrolide exposure. The triple-drug regimen should be given for 14 days as meta-analyses have shown better outcomes with 14-day treatment compared to 7-day and 10-day treatments. Other first-line options include bismuth quadruple therapy (PPI + bismuth + a nitroimidazole [metronidazole or tinidazole] + tetracycline) for 10 to 14 days and “concomitant therapy” consisting of a PPI, clarithromycin, amoxicillin, and a nitroimidazole for 10 to 14 days (*Chey et al 2017*).
  - Bismuth quadruple therapy or levofloxacin triple therapy (PPI + amoxicillin + levofloxacin) for 14 days are the preferred options for patients who have failed a first-line clarithromycin-containing regimen. Clarithromycin or levofloxacin-containing salvage regimens are the preferred treatment options for patients who have received first-line bismuth quadruple therapy.
  - Rifabutin triple regimen of a PPI, amoxicillin, and rifabutin for 10 days is one of several suggested salvage regimens; however, this is not the same dosing regimen as in the FDA-approved Talicia labeling.
- The 2020 American Gastroenterological Association (AGA) guidelines on the management of gastric intestinal metaplasia recommend that patients with gastric intestinal metaplasia undergo testing for *H. pylori* followed by eradication (strong recommendation; moderate quality of evidence) (*Gupta et al 2020*).
- The 2021 AGA expert review on the management of refractory *H. pylori* infection states that treatment will depend on the previous regimen used. If macrolides or fluoroquinolones were previously used, then clarithromycin- or levofloxacin-based regimens, respectively, should be avoided. If bismuth quadruple therapy failed, then either a levofloxacin- or rifabutin-based triple therapy plus high dose PPI and amoxicillin, or an alternative bismuth-containing quadruple therapy should be chosen. Additional recommendations include ensuring appropriate metronidazole dosing, adequate acid suppression, and longer treatment duration (14 days instead of 7 days) *(Shah et al 2021).*
- The updated 2021 World Gastroenterology Organization (WGO) global guidelines for *H. pylori* indicate 2 core choices for first-line eradiation therapy that have widespread use around the world. These include triple therapy with PPI plus amoxicillin and clarithromycin (where clarithromycin resistance is low) or bismuth-based quadruple therapy (PPI + bismuth + metronidazole + tetracycline or amoxicillin [amoxicillin may be useful when high primary clarithromycin resistance)]. Optimal duration may vary from country to country depending on resource availability (*Katelaris et al 2021*).

Safety Summary

Clarithromycin-containing combinations (Omeclamox-Pak and amoxicillin/clarithromycin/lansoprazole)

- All products are contraindicated in patients with hypersensitivity to any component of the formulation. Due to the clarithromycin component, Omeclamox-Pak and amoxicillin/clarithromycin/lansoprazole are contraindicated in patients taking drugs reported to result in cardiac arrhythmias when administered concomitantly (eg, ergotamine, dihydroergotamine, and pimozide), in patients with history of QT prolongation or ventricular cardiac arrhythmia, in patients taking concomitant lurasidone, and in those with a history of jaundice/hepatic dysfunction associated with prior clarithromycin use. PPIs are contraindicated with rilpivirine-containing products.
- Warnings and precautions for amoxicillin/clarithromycin/lansoprazole and Omeclamox-Pak associated with the clarithromycin component include fetal risk, colchicine toxicity, hepatotoxicity, QT prolongation, and myasthenia gravis. Other warnings include *Clostridioides difficile*-associated diarrhea, risk of gastric malignancy, development of bacterial superinfections, acute interstitial nephritis, cutaneous and systemic lupus erythematosus, acute interstitial nephritis, and the risk of severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal

necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP).
- They should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and there is no appropriate alternative therapy.
- A decision should be made whether to discontinue nursing or to discontinue amoxicillin/clarithromycin/lansoprazole, considering the importance of the therapy to the mother. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Omeclamox-Pak and any potential adverse effects on the breast-fed child from clarithromycin or from the underlying maternal condition.
- Omeclamox-Pak should not be used in Asian patients or in patients with hepatic impairment.
- Numerous drug-drug interactions exist with the components of Omeclamox-Pak, amoxicillin/clarithromycin/lansoprazole, and Pylera; some interactions, including colchicine, have led to fatal toxicity (refer to the prescribing information for more details).
- The most common adverse effects reported in clinical trials when all 3 components of either Omeclamox-Pak or amoxicillin/clarithromycin/lansoprazole were administered included diarrhea, headache, and taste perversion.

Metronidazole- and tetracycline-containing combinations (Helidac Therapy and Pylera)
- Boxed warning: Pylera and Helidac both have a boxed warning for potential carcinogenicity associated with metronidazole. Metronidazole has been shown to be carcinogenic in mice and rats, but it is unknown whether the drug is associated with carcinogenicity in humans.
- Contraindications for use of Pylera and Helidac include hypersensitivity reactions, severe renal impairment, concurrent use of methoxyflurane, patients with Cockayne syndrome, use of disulfiram in the past 2 weeks, and consumption of alcoholic beverages for 3 days during or after therapy. Pylera is additionally contraindicated in pregnancy.
- Warnings and precautions for Pylera and Helidac include potential for carcinogenicity, fetal toxicity, maternal hepatotoxicity, tooth enamel discoloration and hypoplasia, photosensitivity, increased plasma concentrations in patients with hepatic impairment, central nervous system effects, severe cutaneous reactions, darkening of the tongue and/or black stool, and caution in patients with a history of blood dyscrasias.
  - A woman should pump and discard human milk for the duration of Pylera therapy and for 2 days after therapy ends. Nursing women should avoid breastfeeding their infant during Helidac therapy and for 24 hours after the last dose.
  - Helidac and Pylera should not be used in children up to 8 years of age since tetracycline use in children may cause permanent discoloration of the teeth.
- Helidac, due to the salicylate component, has a warning- for the risk of Reye's syndrome in children and adolescents who have or who are recovering from varicella or influenza.
- The most frequently reported adverse effects (≥ 5%) with Pylera included abnormal feces, diarrhea, nausea, and headache. For Helidac, the most frequently reported adverse effects (≥ 5%) were nausea, diarrhea, and abdominal pain.
- There are numerous drug interactions with Helidac and Pylera, including those with methoxyflurane, disulfiram, alcohol, oral contraceptives, anticoagulants, lithium, antacids, multivitamins, dairy products, cytochrome P450 (CYP) inducers and CYP inhibitors. QT prolongation has also been reported with metronidazole, particularly when administered with drugs with the potential for prolonging the QT interval. See the current prescribing information for full details.

Talicia (omeprazole magnesium, amoxicillin, rifabutin)
- Contraindications for use of Talicia include hypersensitivity to any of the components and use of rilpivirine-containing products, delaviridine, or voriconazole.
- Warnings and precautions for Talicia include *Clostridioides difficile*-associated diarrhea, reduction in the efficacy of hormonal contraceptives, drug-induced enterocolitis syndrome (DIES), rash in patients with mononucleosis, acute interstitial nephritis, cutaneous and systemic lupus erythematosus, and acute tubulointerstitial nephritis.
- Talicia carries an additional warning and precaution for the risk of SCARs including SJS, TEN, DRESS, and AGEP.
- Use of Talicia should be avoided during pregnancy.
- The most commonly reported adverse effects (≥ 1%) with Talicia included diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.
- Talicia should be avoided in patients with renal or hepatic impairment.
- Components of Talicia have the potential for numerous clinically important drug interactions with CYP2C19 and CYP3A4 substrates, inducers, and inhibitors. See the current prescribing information for full details.

Pharmacogenomics

- CYP2C19, a polymorphic enzyme, is involved in the metabolism of omeprazole. Approximately 15 to 20% of Asians are poor metabolizers, which can lead to increased concentrations of omeprazole. Risk vs benefit should be considered when prescribing Omeclamox-Pak or Talicia in this population.

Voquezna Dual Pak (vonoprazan, amoxicillin) and Triple Pak (vonoprazan, amoxicillin, and clarithromycin)

- Contraindications for use of Voquezna include hypersensitivity to vonoprazan, amoxicillin or other beta-lactams, clarithromycin or other macrolide antibiotics and concomitant use of rilpivirine-containing products. Contraindications to Voquezna Triple Pak due to the clarithromycin component include concomitant drugs reported to result in cardiac arrhythmias when administered concomitantly (eg, ergotamine, dihydroergotamine, and pimozide), concurrent lipid-lowering agents (lomitapide, simvastatin, and lovastatin) and colchicine in patients with renal or hepatic impairment, concomitant lurasidone, and in those with a history of jaundice/hepatic dysfunction associated with prior clarithromycin use.
- Warnings and precautions include risk of SCARs (SJS, TEN, DRESS, and AGEP), *Clostridioides difficile*-associated diarrhea, DIES, rash in patients with mononucleosis, interactions with diagnostic investigations for neuroendocrine tumors, and development of drug-resistant bacteria. Warnings and precautions due to the clarithromycin component include QT prolongation, hepatotoxicity, embryo-fetal toxicity, and exacerbation of myasthenia gravis.
- Voquezna Triple Pak is not recommended in pregnancy unless there are no available alternative therapies. Voquezna Dual Pak has not been adequately assessed in pregnancy.
- Components of Voquezna have the potential for numerous clinically important drug interactions, including with CYP3A4 substrates, inducers, and inhibitors. See the current prescribing information for full details.
- The most common adverse events with Voquezna Triple Pak (≥ 2%) included dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension. The most common adverse events with Voquezna Dual Pak (≥ 2%) included diarrhea, abdominal pain, vulvovaginal candidiasis, and nasopharyngitis.

Dosing and Administration

Table 3. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
amoxicillin, clarithromycin, lansoprazole	Capsules (amoxicillin, lansoprazole), tablets (clarithromycin)	oral	Lansoprazole 30 mg, amoxicillin 1000 mg, and clarithromycin 500 mg each given twice daily for 10 or 14 days	
Helidac Therapy (bismuth subsalicylate, metronidazole, tetracycline)	Chewable tablets (bismuth subsalicylate), tablets (metronidazole), capsules (tetracycline)	oral	Bismuth subsalicylate 525 mg, metronidazole 250 mg, and tetracycline 500 mg taken 4 times daily for 14 days	Should be administered after meals and at bedtime. Bismuth subsalicylate tablets should be chewed and swallowed. An H2A should be administered as directed.
Omeclamox-Pak (amoxicillin, clarithromycin, omeprazole)	Capsules (amoxicillin, omeprazole), tablets (clarithromycin)	oral	Omeprazole 20 mg, clarithromycin 500 mg, and amoxicillin 1000 mg, each given twice daily for 10 days	Should be administered in the morning and evening before eating a meal. All tablets and capsules should be swallowed whole.

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
				In patients with an ulcer at initiation of therapy, an additional 18 days of omeprazole 20 mg once daily is recommended.
Pylera (bismuth subcitrate potassium, metronidazole, tetracycline)	Capsules	oral	3 capsules (bismuth subcitrate 140 mg, metronidazole 125 mg, and tetracycline 125 mg) 4 times daily for 10 days	Should be administered after meals and at bedtime. Omeprazole 20 mg should be taken twice a day with Pylera after the morning and evening meal.
Talicia (omeprazole magnesium, amoxicillin, rifabutin)	Capsules	oral	4 capsules (omeprazole 10 mg, amoxicillin 250 mg, and rifabutin 12.5 mg) 3 times daily (at least 4 hours apart) for 14 days	Should be administered with food and a full glass of water. Capsules should be swallowed whole. Should not be administered with alcohol.
Voquezna Dual Pak (vonoprazan, amoxicillin)	Tablets (vonoprazan) Capsules (amoxicillin)	oral	Vonoprazan 20 mg twice daily plus amoxicillin 1000 mg 3 times daily for 14 days	Can be administered with or without food.
Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)	Tablets (vonoprazan, clarithromycin) Capsules (amoxicillin)	oral	Vonoprazan 20 mg, amoxicillin 1000 mg, and clarithromycin 500 mg each given twice daily for 14 days	

See the current prescribing information for full details.

Conclusion

- *H. pylori* eradication rates have been steadily diminishing in the U.S. as clarithromycin resistance has been increasing worldwide. Eradication rates with commonly prescribed triple therapy regimens have fallen below 80%.
- Although treatment of *H. pylori* was studied in many randomized controlled trials conducted in North America during the first decade of this century, the number of treatment trials assessing modern regimens is modest to non-existent. As such, the clinical guideline recommendations rely upon clinical trial data generated in other parts of the world when considering a number of regimens. The treatment regimen that is selected must consider local antibiotic resistance patterns (if known), previous exposure and allergies to specific antibiotics, adverse effects, and ease of administration (*Chey et al 2017*).
  - The ACG 2017 guideline recommends a 14-day therapy of a triple-drug regimen containing a PPI, clarithromycin, and either amoxicillin or metronidazole as a preferred treatment in regions where *H. pylori* has < 15% resistance to clarithromycin. Other first-line options include bismuth quadruple therapy (PPI + bismuth + a nitroimidazole [metronidazole or tinidazole] + tetracycline) for 10 to 14 days and “concomitant therapy” consisting of a PPI, clarithromycin, amoxicillin, and a nitroimidazole for 10 to 14 days. Preferred salvage regimens include bismuth quadruple therapy and levofloxacin triple therapy for patients who received a first-line treatment containing clarithromycin. For patients who had bismuth quadruple therapy as first-line, clarithromycin or levofloxacin-containing salvage regimens are preferred second-line treatment options. Suggested salvage treatment comprises many options including a rifabutin-containing regimen.

- There are no major differences in the adverse event profile of bismuth-related regimens and standard clarithromycin-based triple therapy. Bismuth-based therapy is commonly associated with darkening of the tongue and stool, nausea, and gastrointestinal adverse effects. Clarithromycin-based triple therapies are commonly associated with gastrointestinal adverse effects, headache, and diarrhea. Talicia regimen is associated with diarrhea, headache, rash, and dyspepsia. The most common adverse effects reported with the Voquezna regimens were diarrhea, dysgeusia, vulvovaginal candidiasis, abdominal pain, and headache.
- The combination products in this class include individual drugs co-packaged together in either kits or fixed-dose combination capsules in an effort to improve compliance while maintaining high eradication rates. Data demonstrating improved compliance or improved outcomes vs administration of the individual components are lacking. Antibiotic resistance is highly variable in different geographic areas and must be carefully considered when choosing among the various *H. pylori* treatment regimens. The newest co-packed product, Voquezna Dual and Voquezna Triple Therapy Pak, has demonstrated non-inferiority to lansoprazole triple therapy in patients without a clarithromycin- or amoxicillin-resistant strain at baseline. Data comparing vonoprazan regimens with bismuth quadruple therapy are limited.

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