DUR Board Meeting March 1, 2017 Heritage Center Lecture Rooms A & B



North Dakota Medicaid DUR Board Meeting Agenda Heritage Center Lecture Rooms A & B State Capitol 612 East Boulevard Avenue Bismarck, ND March 1, 2017 1pm

- 1. Administrative items
 - Travel vouchers
- 2. Old business
 - Review and approval of 12/16 meeting minutes
 - Budget update
 - Review top 15 therapeutic categories/top 25 drugs
 - Second review of prednisolone ODT, Millepred, Veripred
 - Second review of metformin OSM
 - Second review of testosterone oral
 - Review of 2016 DUR projects
 - Prior authorization/PDL update
- 3. New business
 - Criteria recommendations
 - Upcoming meeting date/agenda
- 4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

December 7, 2016

Members Present: Tanya Schmidt, Laura Schield, Russ Sobotta, Peter Woodrow, Andrea Honeyman, Michael Booth, LeNeika Roehrich

Members Absent: Katie Kram, Wendy Brown, Jeffrey Hostetter, Carlotta McCleary, Gaylord Kavlie, Zach Marty, James Carlson, Michael Quast

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy, Gary Betting

Old Business

P. Woodrow served as Chair in the absence of W. Brown, and called the meeting to order at 1:00 p.m. Chair P. Woodrow asked for a motion to approve the minutes of the September meeting. L. Roehrich moved that the minutes be approved and G. Betting seconded the motion. Chair P. Woodrow called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Second Reviews

A motion and second was made at the September meeting to place Namenda XR, Dihydroergotamine, Tetracycline, Spiriva Respimat 2.5 mcg, ophthalmic corticosteroids, and erythropoiesis-stimulating agents on prior authorization. The topics were brought up for a second review. The motion to place Namenda XR, Dihydroergotamine, Tetracycline, Spiriva Respimat 2.5 mcg, ophthalmic corticosteroids, and erythropoiesis-stimulating agents on prior authorization passed with no audible dissent.

PDL Update

B. Joyce shared with the Board all of the recommended PDL changes since the last 2016 version of the PDL posted. R. Troxell, representing Novartis, inquired about the criteria used to determine PDL status. R. Troxell also inquired about timeframe to address/discuss changes with DUR Board members before implementation in January. B. Joyce responded to questions.

Annual Prior Authorization Review of Forms and Criteria

The Board reviewed all forms and criteria that have previously been placed on prior authorization. Kelly Spielman, representing Merck, presented product information regarding Belsomra. B. Joyce spoke regarding an email from K. Kram asking if the narcotic/APAP form was still needed. B. Joyce said that the request would be reviewed. No changes were recommended during the review of the forms and criteria.

New Business

Synagis

B. Joyce shared with the Board the decision to move the handling of Synagis prior authorizations and claims over to the Medical management, therefore Synagis will not be covered under Pharmacy management.

Narcan Nasal Spray

B. Joyce shared with the Board the decision to not require Prior Authorization for the first (initial) fill of Narcan Nasal Sprays. Subsequent fills will require a prior authorization, but not initial.

Hepatitis C Update

A. Murphy reviewed changes in Hepatitis C criteria and updated Board members on utilization of treatments Medicaid covered this year.

Prednisolone non-solid oral dosage forms

B. Joyce reviewed prednisolone non-solid oral dosage forms (i.e., solution/ODT) with the Board. A motion was made by L. Roehrich to manage the class through prior authorization. The motion was seconded by P. Woodrow. This topic will be reviewed at the next meeting.

Metformin OSM

B. Joyce reviewed metformin OSM with the Board. A motion was made by T. Schmidt to manage the class through prior authorization. The motion was seconded by M. Booth. This topic will be reviewed at the next meeting.

Oral Testosterone

B. Joyce reviewed oral testosterone with the Board. A motion was made by L. Schield to manage the class through prior authorization. The motion was seconded by L. Roehrich. This topic will be reviewed at the next meeting.

Criteria Recommendations

The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. M. Booth moved to approve the new criteria and A. Honeyman seconded the motion. P. Woodrow called for a voice vote. The motion passed with no audible dissent.

The next DUR Board meeting will be held March 1, 2017 at the Heritage Center in Bismarck. P. Woodrow made a motion to adjourn the meeting. M. Booth seconded. The motion passed with no audible dissent. P. Woodrow adjourned the meeting.

	Top 25 Drugs Based on Numb	per of Clai	ms		
	10/01/2016 - 12/31/2	2016			
Drug	Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
METHYLPHENIDATE HCL	ADHD	3,542	\$383,270.94	\$108.21	2.74%
ALBUTEROL SULFATE	Beta Agonists	3,004	\$158,586.55	\$52.79	2.32%
AMOXICILLIN	Antiinfectives	2,972	\$42,588.64	\$14.33	2.30%
OMEPRAZOLE	Proton Pump Inhibitors	2,622	\$38,207.47	\$14.57	2.03%
HYDROCODONE/ACETAMINOPHEN	Narcotics	2,220	\$43,249.57	\$19.48	1.72%
SERTRALINE HCL	Antidepressants	2,152	\$26,256.82	\$12.20	1.66%
GABAPENTIN	Anticonvulsants	2,115	\$37,049.44	\$17.52	1.64%
DEXTROAMPHETAMINE/AMPHETAMINE	ADHD	2,106	\$253,183.38	\$120.22	1.63%
LEVOTHYROXINE SODIUM	Other	2,021	\$38,829.78	\$19.21	1.56%
FLUOXETINE HCL	Antidepressants	1,927	\$23,646.09	\$12.27	1.49%
MONTELUKAST SODIUM	Leukotriene Inhibitors	1,875	\$36,091.35	\$19.25	1.45%
AZITHROMYCIN	Antiinfectives	1,732	\$33,747.80	\$19.48	1.34%
TRAZODONE HCL	Other	1,724	\$22,707.70	\$13.17	1.33%
METFORMIN HCL	NonInsulin Diabetes Me	1,701	\$22,544.44	\$13.25	1.32%
LISINOPRIL	Hypertension	1,697	\$19,691.45	\$11.60	1.31%
ATORVASTATIN CALCIUM	Cholesterol	1,631	\$23,604.76	\$14.47	1.26%
BUPROPION HCL	Antidepressants	1,463	\$33,790.86	\$23.10	1.13%
LISDEXAMFETAMINE DIMESYLATE	ADHD	1,459	\$283,360.08	\$194.22	1.13%
QUETIAPINE FUMARATE	Antipsychotics	1,435	\$89,542.21	\$62.40	1.11%
CLONIDINE HCL	Other	1,429	\$17,323.60	\$12.12	1.10%
ESCITALOPRAM OXALATE	Antidepressants	1,411	\$20,685.68	\$14.66	1.09%
ASPIRIN	Other	1,304	\$7,816.03	\$5.99	1.01%
AMOXICILLIN/POTASSIUM CLAV	Antiinfectives	1,295	\$30,387.65	\$23.47	1.00%
RISPERIDONE	Antipsychotics	1,205	\$17,244.43	\$14.31	0.93%
LAMOTRIGINE	Anticonvulsants	1,166	\$29,075.15	\$24.94	0.90%
Total Top 25		47,208	\$1,732,481.87	\$36.70	36.50%
Total Claims 10/01/2016 - 12/31/2016	129,335				



	Top 25 Drugs Based o	n Claims (Cost		
	10/01/2016 - 12/	/31/2016			
Drug	Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
METHYLPHENIDATE HCL	ADHD	3,542	\$383,270.94	\$108.21	2.74%
SOFOSBUVIR/VELPATASVIR	Hepatitis	14	\$347,625.92	\$24,830.42	0.01%
INSULIN ASPART	Insulins	585	\$298,602.49	\$510.43	0.45%
LISDEXAMFETAMINE DIMESYLATE	ADHD	1,459	\$283,360.08	\$194.22	1.13%
DEXTROAMPHETAMINE/AMPHETAMINE	ADHD	2,106	\$253,183.38	\$120.22	1.63%
ADALIMUMAB	Immunomodulators	52	\$227,818.19	\$4,381.12	0.04%
INSULIN GLARGINE, HUM. REC. ANLOG	Insulins	536	\$219,009.72	\$408.60	0.41%
VIGABATRIN	Anticonvulsants	13	\$203,061.47	\$15,620.11	0.01%
PREGABALIN	Anticonvulsants	554	\$200,204.93	\$361.38	0.43%
LURASIDONE HCL	Antipsychotics	201	\$192,568.18	\$958.05	0.16%
ALBUTEROL SULFATE	Beta Agonists	3,004	\$158,586.55	\$52.79	2.32%
FLUTICASONE/SALMETEROL	Steroid/LABA Combo	486	\$153,003.38	\$314.82	0.38%
BUDESONIDE	Steroid Inhalers	404	\$141,023.35	\$349.07	0.31%
PALIPERIDONE PALMITATE	Antipsychotics	63	\$139,424.05	\$2,213.08	0.05%
BLOOD SUGAR DIAGNOSTIC	Other	982	\$139,243.81	\$141.80	0.76%
ETANERCEPT	Immunomodulators	40	\$138,923.16	\$3,473.08	0.03%
GLATIRAMER ACETATE	Multiple Sclerosis	22	\$134,605.69	\$6,118.44	0.02%
ARIPIPRAZOLE	Antipsychotics	1,094	\$125,203.98	\$114.45	0.85%
LEDIPASVIR/SOFOSBUVIR	Hepatitis	4	\$121,902.22	\$30,475.56	0.00%
INSULIN DETEMIR	Insulins	245	\$107,012.78	\$436.79	0.19%
DEXMETHYLPHENIDATE HCL	ADHD	599	\$105,548.81	\$176.21	0.46%
QUETIAPINE FUMARATE	Antipsychotics	1,435	\$89,542.21	\$62.40	1.11%
TIOTROPIUM BROMIDE	Other	311	\$88,081.42	\$283.22	0.24%
SOMATROPIN	Growth Hormone	32	\$79,813.36	\$2,494.17	0.02%
USTEKINUMAB	Immunomodulators	6	\$77,087.57	\$12,847.93	0.00%
Total Top 25		17,789	\$4,407,707.64	\$247.78	13.75%
Total Claims 10/01/2016 - 12/31/2016	129,335				



Top 15 Therapeutic Classes Based on Number of Claims						
10/01/2016 - 12/31/2016						
Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims		
Antidepressants	11,862	\$273,907.36	\$23.09	9.17%		
Antiinfectives	11,738	\$576,074.10	\$49.08	9.08%		
Anticonvulsants	9,143	\$780,780.17	\$85.40	7.07%		
ADHD	8,879	\$1,073,620.15	\$120.92	6.87%		
Hypertension	6,359	\$118,784.25	\$18.68	4.92%		
Narcotics	5,748	\$153,298.08	\$26.67	4.44%		
Antipsychotics	5,428	\$777,562.55	\$143.25	4.20%		
Proton Pump Inhibitors	3,622	\$64,718.80	\$17.87	2.80%		
Allergy	3,527	\$50,119.89	\$14.21	2.73%		
Sedative/Hypnotics	3,457	\$53,605.47	\$15.51	2.67%		
Cholesterol	3,220	\$77,272.90	\$24.00	2.49%		
Beta Agonists	3,140	\$168,823.24	\$53.77	2.43%		
Steroid Inhalers	2,908	\$254,999.41	\$87.69	2.25%		
NonInsulin Diabetes Med	2,709	\$238,879.66	\$88.18	2.09%		
NSAIDS/COXII	2,399	\$38,514.34	\$16.05	1.85%		
Total Top 25	84139	\$4,700,960.37	\$52.29	65.06%		
Total Claims 10/01/2016 - 12/31/2016	129,335					



Top 15 Th	nerapeutic Classes	Based on Claims Cost				
10/01/2016 - 12/31/2016						
Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims		
ADHD	8879	\$1,073,620.15	\$120.92	6.87%		
Anticonvulsants	9143	\$780,780.17	\$85.40	7.07%		
Antipsychotics	5428	\$777,562.55	\$143.25	4.20%		
Insulins	1522	\$726,623.21	\$477.41	1.18%		
Antiinfectives	11738	\$576,074.10	\$49.08	9.08%		
Immunomodulators	107	\$487,620.33	\$4,557.20	0.08%		
Hepatitis	18	\$469,528.14	\$26,084.90	0.01%		
Multiple Sclerosis	56	\$336,917.23	\$6,016.38	0.04%		
Antidepressants	11862	\$273,907.36	\$23.09	9.17%		
Steroid/LABA Combo	933	\$271,485.72	\$290.98	0.72%		
Steroid Inhalers	2908	\$254,999.41	\$87.69	2.25%		
NonInsulin Diabetes Med	2709	\$238,879.66	\$88.18	2.09%		
Beta Agonists	3140	\$168,823.24	\$53.77	2.43%		
Narcotics	5748	\$153,298.08	\$26.67	4.44%		
Hypertension	6359	\$118,784.25	\$18.68	4.92%		
Total Top 25	70550	\$6,708,903.60	\$2,541.57	54.55%		
Total Claims 10/01/2016 - 12/31/2016	129,335					

Top 15 Therapeutic Classes Based on Total Cost of Claims



PREDNISOLONE NON-SOLID ORAL DOSAGE FORMS

PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for brand prednisolone non-solid oral dosage forms must meet the following criteria:

• Patient must first try generic prednisolone.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Please list all medications patie	nt has tried:	
	Please give reason why patient generic prednisolone:	cannot take	
Prescriber (or Staff) / Pharmacy Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received:					Initials:	
		–		,		
Approved - Effective dates of PA: From: /	/	To:	/	/	Approved by:	
Denied: (Reasons)						

North Dakota Department of Human Services Prednisolone Non-Solid Oral Dosage Forms Authorization Algorithm



GLUMETZA PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Glumetza must meet the following criteria:

• Patient must first try 3 months of metformin ER.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Med	dicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Please list all medications patien		
Prescriber (or Staff) / Pharmacy Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:		
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received:					Initials:
Dale Necelleu.					initials.
	,	-	1	,	A 11
Approved - Effective dates of PA: From: /	/	To:	/	/	Approved by:
Denied: (Reasons)					
Defiled. (Reasons)					





ORAL TESTOSTERONE PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for oral testosterone must meet the following criteria: • Patient must first try a topical testosterone product.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Med	dicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Please list all medications patien	t has tried:	
	Please include reason why patier testosterone product:	nt cannot use a	a topical
Prescriber (or Staff) / Pharmacy Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services Oral Testosterone Authorization Algorithm









Age edit May-16









DUR & Edit put in April 2016



Patients taking Long Acting Narcotics - Fentanyl, Morphine, Oxycodone









1st set of quantity limits	Nov-15
IR oxycodone put on PA	Jan-16
IR + IR Combos drug-drug edits	Jan-16
2nd set of quantity limits	May-16
Another step added to Oxycontin	May-16
1st set of First Fill edits - narcotics	Sep-16
2nd set of First Fill edits - narcotics	Nov-16









DUR sentJun-16Quantity limit to < 1800 mg</td>Aug-16



DUR sent16-AugEdit put in16-Oct



Drug - drug edit with benzos for sleep and other sleeping medications	Sep-16
All benzos for sleep put on PA	Sep-16



QTR 1 QTR 2 QTR 3

2013

2013

2013

QTR 4

2013

QTR 1 QTR 2

2014

2014

QTR 3

2014

QTR 4

2014

QTR 1 QTR 2

2015

2015

QTR 3

2015

QTR 4

2015

QTR 1

2016

QTR 2

2016

QTR 3

2016

QTR 4

2016














































































Non-Stimulant ADHD











Insulins



Narcotics



Not included in narcotics graph								
Row Labels	QTR 1 2013	QTR 2 2013	QTR 3 2013	QTR 4 2013	QTR 1 2014	QTR 2 2014	QTR 3 2014	QTR 4 2014
AVINZA	0.15%	0.13%	0.00%	0.00%	0.16%	0.04%	0.00%	0.00%
BELLADONNA-OPIUM	0.00%	0.01%	0.00%	0.00%	0.04%	0.00%	0.00%	0.01%
BUTORPHANOL 10 MG/ML SPRAY	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%
CODEINE SULFATE 30 MG TABLE	0.05%	0.04%	0.05%	0.04%	0.02%	0.00%	0.03%	0.04%
DEMEROL SYRINGE	0.03%	0.13%	0.09%	0.00%	0.07%	0.10%	0.04%	0.00%
HYDROMORPHONE INJECTION	0.15%	0.00%	0.11%	0.20%	0.06%	0.02%	0.01%	0.28%
MEPERIDINE ORAL	0.15%	0.12%	0.07%	0.07%	0.13%	0.14%	0.09%	0.04%
MORPHINE INJECTION	0.18%	0.08%	0.26%	0.37%	0.10%	0.17%	0.05%	0.14%
NALBUPHINE 20 MG/ML AMPUL	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
PENTAZOCINE-NALOXONE TABLET	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%
Row Labels	QTR 1 2015	QTR 2 2015	QTR 3 2015	QTR 4 2015	QTR 1 2016	QTR 2 2016	QTR 3 2016	QTR 4 2016
AVINZA	0.14%	0.00%	0.00%	0.00%	0.15%	0.00%	0.00%	0.00%
BELLADONNA-OPIUM	0.01%	0.02%	0.01%	0.00%	0.03%	0.02%	0.00%	0.03%
BUTORPHANOL 10 MG/ML SPRAY	0.04%	0.05%	0.05%	0.04%	0.04%	0.04%	0.04%	0.03%
CODEINE SULFATE 30 MG TABLE	0.04%	0.03%	0.04%	0.02%	0.05%	0.04%	0.01%	0.03%
DEMEROL SYRINGE	0.07%	0.10%	0.00%	0.01%	0.12%	0.06%	0.00%	0.00%
HYDROMORPHONE INJECTION	0.06%	0.01%	0.02%	0.20%	0.04%	0.01%	0.07%	0.00%
MEPERIDINE ORAL	0.15%	0.09%	0.11%	0.09%	0.09%	0.07%	0.09%	0.03%
MORPHINE INJECTION	0.17%	0.15%	0.04%	0.23%	0.09%	0.05%	0.33%	0.18%
NALBUPHINE 20 MG/ML AMPUL	0.01%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
PENTAZOCINE-NALOXONE TABLET	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%









Prior Authorization/PDL Update

Added to PA
ADLYXIN (lixisenatide)
BASAGLAR KWIKPEN U-100 (insulin glargine,hum.rec.anlog)
BENLYSTA (belimumab)
DALVANCE (dalbavancin)
FABRAZYME (agalsidase beta)
FOSRENOL (lanthanum carbonate)
HUMULIN 70/30 KWIKPEN (insulin nph hum/reg insulin hm)
HUMULIN N KWIKPEN (insulin nph human isophane)
HUMULIN R U-500 KWIKPEN (insulin regular, human)
JENTADUETO XR (linagliptin/metformin hcl)
KANUMA (sebelipase alfa)
KEPIVANCE (palifermin)
ORBACTIV (oritavancin)
PANHEMATIN (hemin)
OTOVEL (ciprofloxacin hcl/fluocinolone)
PRESTALIA (perindopril arg/amlodipine bes)
SOLIQUA 100-33 (insulin glargine/lixisenatide)
SPINRAZA (nusinersen/preservative free)
TOBRADEX ST (tobramycin/dexamethasone)

Prior Authorization/PDL Update

Removed from PA
ALOCRIL (nedocromil sodium)
ALOMIDE (lodoxamide tromethamine)
ALVESCO (ciclesonide)
AZASITE (azithromycin)
AZELASTINE HCL (azelastine hcl)
BECONASE AQ (beclomethasone dipropionate)
BESIVANCE (besifloxacin hcl)
BROVANA (arformoterol tartrate)
CILOXAN (ciprofloxacin hcl)
DEXILANT (dexlansoprazole)
DIPENTUM (olsalazine sodium)
EPINEPHRINE (epinephrine)
EURAX (crotamiton)
FLOXIN (ofloxacin)
GELNIQUE (oxybutynin chloride)
PREVACID (lansoprazole)
LASTACAFT (alcaftadine)
MAXITROL (neo/polymyx b sulf/dexameth)
OMECLAMOX-PAK (omeprazole/clarith/amoxicillin)
OMNARIS (ciclesonide)
OXYTROL (oxybutynin)
PREVPAC (lansoprazole/amoxiciln/clarith)
QNASL (beclomethasone dipropionate)
RENVELA (sevelamer carbonate)
ZETONNA (ciclesonide)

NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS 1ST QUARTER 2017

Criteria Recommendations

Approved Rejected

1. Lixisenatide / Over-utilization

Alert Message: The manufacturer's recommended maximum daily dose of Adlyxin (lixisenatide) is 20 mcg per day.

Conflict Code: ER – Overuse Drug/Disease <u>Util A Util B Util C</u> Lixisenatide

Max Dose: 1, 2 pen pack per month

References: Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

2. Lixisenatide / Pancreatitis

Alert Message: In clinical trials, there were more cases of pancreatitis-related adverse reactions among patients treated with Adlyxin (lixisenatide) than placebo-treated. If pancreatitis is suspected, promptly discontinue lixisenatide and, if confirmed, lixisenatide should not be restarted.

References: Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

3. Lixisenatide / Basal Insulin & Insulin Secretagogues

Alert Message: The risk of hypoglycemia is increased when Adlyxin (lixisenatide) is used in combination with insulin secretagogues (i.e., sulfonylureas) or basal insulin. Therefore, patients may require a lower dose of sulfonylurea or basal insulin to reduce the risk of hypoglycemia in this setting.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases: Util A Util B Util C Lixisenatide Insulin Glargine, Detemir & Degludec Chlorpropamide Glimepiride Glipizide Glyburide Tolazamide Tolbutamide

References: Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S.

4. Lixisenatide / Renal Impairment

Alert Message: Use caution when initiating or escalating doses of Adlyxin (lixisenatide) in patients with renal impairment. Lixisenatide is a glucagon-like peptide-1 receptor (GLP-1) agonist and there have been postmarketing reports of acute renal failure and worsening of chronic renal failure in patients treated with GLP-1 agonists. No dosage adjustment is recommended in renal impairment but monitoring renal function is recommended in patients reporting severe adverse gastrointestinal reactions.

 Conflict Code:
 MC – Drug Disease Warning/Contraindication

 Drugs/Diseases:
 Util A

 Util A
 Util B

 Lixisenatide
 Renal Impairment

References:

Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

5. Lixisenatide / Severe Gastrointestinal Disorders

Alert Message: Adlyxin (lixisenatide), a glucagon-like peptide-1 (GLP-1) receptor agonist, has not been studied and it use is not recommended in patients with pre-existing severe gastrointestinal disease, including severe gastroparesis. GLP-1 receptor agonists slow gastric emptying and can exacerbate gastrointestinal disorders.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

<u>Util A</u><u>Util B</u> Lixisenatide Util C (Include) Gastroparesis Irritable Bowel Syndrome Diverticular Disease Crohn's Disease Ulcerative Colitis

References:

Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

6. Lixisenatide / Therapeutic Appropriateness < 18 years of age

Alert Message: Safety and effectiveness of Adlyxin (lixisenatide) have not been established in pediatric patients younger than 18 years of age.

 Conflict Code:
 TA – Therapeutic Appropriateness

 Drugs/Diseases
 Util A

 Util A
 Util B

 Lixisenatide
 Util C

Age Range: 0-17 yoa

References: Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

7. Lixisenatide / Pregnancy / Delivery, Miscarriage & Abortion

Alert Message: There are no adequate and well-controlled studies of Adlyxin (lixisenatide) use in pregnant women. Lixisenatide should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning/Contraindication Drugs/Diseases

Util A Util B

Albiglutide Pregnancy

<u>Util C (Negating)</u> Delivery Miscarriage Abortion

Age Range: 11-55 yoa Gender: Female

References: Adlyxin Prescribing Information, July 2016, Sanofi-Aventis U.S. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

8. Lixisenatide / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Adlyxin (lixisenatide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Non-adherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Lixisenatide

References:

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Butler RJ, Davis TK, Johnson WL, et al. Effects of Non adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

9. Methylnaltrexone Tabs / Overutilization

Alert Message: Relistor (methylnaltrexone) may be over-utilized. The manufacturer's recommended dosage of oral methylnaltrexone, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain, is 450 mg once daily in the morning.

Conflict Code: ER - OverutilizationDrugs/DiseasesUtil AUtil BMethylnaltrexone tabs

<u>Util C (Negating)</u> Hepatic Impairment CKD Stage 4 & 5

Max Dose: 450mg/day

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

10. Methylnaltrexone Tabs / Overutilization Renal Impairment

Alert Message: Relistor (methylnaltrexone) may be over-utilized. The manufacturer's recommended dosage of oral methylnaltrexone, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain with moderate to severe renal impairment (e.g., CrCl < 60 mL/min as estimated by Cockcroft-Gault), is 150 mg once daily in the morning.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A

 Wethylnaltrexone tabs

Util C (Include) CKD Stage 4 & 5

Max Dose: 150mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

11. Methylnaltrexone Tabs / Overutilization Hepatic Impairment

Alert Message: Relistor (methylnaltrexone) may be over-utilized. The manufacturer's recommended dosage of oral methylnaltrexone, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain with moderate to severe hepatic impairment (Child-Pugh Class B or C), is 150 mg daily in the morning.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Methylnaltrexone tabs

Util C (Include) Hepatic Impairment

Max Dose: 150mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

12. Methylnaltrexone / Overutilization

Alert Message: Relistor (methylnaltrexone) may be over-utilized. The manufacturer's recommended dosage of methylnaltrexone injection, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain, is 12 mg subcutaneously once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Methylnaltrexone injection

<u>Util C (Negating)</u> Hepatic Impairment CKD Stage 4 & 5

Max Dose: 12mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

13. Methylnaltrexone / Overutilization Mod to Severe Renal Impairment

Alert Message: Relistor (methylnaltrexone) may be over-utilized. The manufacturer's recommended dosage of methylnaltrexone injection, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain, is 6 mg subcutaneously once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Methylnaltrexone injection

Util C (Include) CKD Stage 4 & 5

Max Dose: 6mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

14. Methylnaltrexone / Overutilization Severe Hepatic Impairment

Alert Message: Relistor (methylnaltrexone) has not been studied in patients with severe hepatic impairment. Patients with severe hepatic impairment receiving methylnaltrexone should be monitored for methylnaltrexone-related adverse reactions. If considering dosage adjustment for patients with severe hepatic impairment follow the official product labeling weight-based daily dosing recommendation: < 38 kg give 0.075 mg/kg subQ, 38 to < 62 kg give 4 mg subQ, 62 to 114 kg give 6 mg, more than 114 kg give 0.075 mg/kg subQ.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Methylnaltrexone Injection

Util C (Include) Severe Hepatic Impairment

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

15. Methylnaltrexone / Opioid Agonists (Negating)

Alert Message: The review of the patient's drug history did not reveal current use of opioid medication. Relistor (methylnaltrexone) is approved for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain and OIC in patients with advanced illness who are receiving palliative care with insufficient response to laxative therapy. Methylnaltrexone should be discontinued if treatment with the opioid pain medication is discontinued.

 Conflict Code: TA – Therapeutic Appropriateness

 Drugs/Diseases

 Util A
 Util B

 Methylnaltrexone
 Opioid Agonists

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

16. Methylnaltrexone / Gastrointestinal Obstruction

Alert Message: Relistor (methylnaltrexone) use is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation. Monitor patients for development of severe, persistent, or worsening abdominal pain and discontinue methylnaltrexone in patients who develop these symptom.

 Conflict Code: TA – Therapeutic Appropriateness (Contraindication)

 Drugs/Diseases

 Util A
 Util B

 Methylnaltrexone
 Util C (Include)

 Gastrointestinal Obstruction

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

17. Methylnaltrexone / Reduction in GI Wall Integrity

Alert Message: Cases of gastrointestinal perforation have been reported in patients receiving Relistor (methylnaltrexone) who had conditions associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Monitor patients for the development of severe, persistent, or worsening abdominal pain and discontinue methylnaltrexone in patients who develop this symptoms.

 Conflict Code: TA – Therapeutic Appropriateness (Warning)

 Drugs/Diseases

 Util A
 Util B

 Methylnaltrexone
 Crohn's Disease

 Peptic, Gastric, Duodenal & Gastrojejunal Ulcer Disease

 Perforation of Intestine

 Diverticular Disease of Intestine

Malignant Neoplasm of Intestine Malignant Neoplasm of Stomach

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

18. Methylnaltrexone / Therapeutic Appropriateness

Alert Message: Safety and effectiveness of Relistor (methylnaltrexone) tablets and injection have not been established in pediatric patients.

 Conflict Code: TA – Therapeutic Appropriateness

 Drugs/Diseases

 Util A

 Util B

 Methylnaltrexone

Age Range: 0-17 yoa

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Relistor Prescribing Information, July 2016, Valeant Pharmaceuticals North America.

19. Vandetanib / Overutilization

Alert Message: Caprelsa (vandetanib) may be over-utilized. The manufacturer's recommended maximum daily dose is 300 mg once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Vandetanib

Max Dose: 300mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

20. Vandetanib / QT Prolongation

Alert Message: Caprelsa (vandetanib) is contraindicated in patients with congenital long QT syndrome. Vandetanib can prolong the QT interval in a concentration-dependent manner. Do not start vandetanib in patients whose QTcF interval is greater than 450 ms or in patients with a history of torsades de pointes, bradyarrhythmias, or uncompensated heart failure.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Vandetanib
 Long QT Syndrome

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

21. Vandetanib / Strong CYP3A4 Inducers

Alert Message: The concurrent use of Caprelsa (vandetanib) with known strong CYP3A4 inducers should be avoided. Vandetanib is a CYP3A4 substrate and concomitant use with a strong CYP3A4 inducer may result in decreased vandetanib plasma concentrations.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Vandetanib Carbamazepine Phenytoin Phenobarbital Primidone Rifampin Rifapentine Rifabutin

References: Caprelsa Prescribing Information, July 2016, AstraZeneca. Facts & Comparisons, 2016 Wolters Kluwer Health.

22. Vandetanib / Digoxin

Alert Message: Caution should be exercised when co-administering Caprelsa (vandetanib) with digoxin. Concurrent use of vandetanib with digoxin has been shown to increase digoxin plasma concentrations and exposure. Closely monitor patients for digoxin toxicities.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BUtil BDigoxin

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

23. Vandetanib / Interstitial Lung Disease

Alert Message: Interstitial lung disease (ILD) or pneumonitis, including fatalities, has occurred in patients treated with Caprelsa (vandetanib). Consider a diagnosis of ILD if the patient presents with new or worsening of breathlessness, persistent cough, or fever. Interrupt vandetanib treatment for acute or worsening pulmonary symptoms. Discontinue vandetanib if ILD is confirmed.

Conflict Code: MC - Drug (Actual) Disease Precaution/Warning

<u>Util B</u>	Util C
Interstitial Lung Disease	
Breathlessness	
Cough	
Fever	
	Interstitial Lung Disease Breathlessness Cough

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

24. Vandetanib / Pregnancy / Pregnancy Negating

Alert Message: Based on its mechanism of action, Caprelsa (vandetanib) can cause fetal harm when administered to a pregnant women. Vandetanib is embryotoxic, fetotoxic, and teratogenic in rats at exposures less than or equal to those expected at the recommended human dose of 300 mg/day. If vandetanib is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Vandetanib	Pregnancy	Miscarriage
		Delivery
		Abortion

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

25. Vandetanib / Ischemic Cerebrovascular Event

Alert Message: Ischemic cerebrovascular events, including fatalities, occurred in patients treated with Caprelsa (vandetanib). In the randomized medullary thyroid cancer (MTC) study, ischemic cerebrovascular events occurred more frequently with vandetanib compared to placebo (1.3% compared to 0%). The safety of resumption of vandetanib therapy after resolution of an ischemic cerebrovascular event has not been studied. Discontinue vandetanib in patients who experience a severe ischemic cerebrovascular event.

Conflict Code: MC – Drug (Actual) Disease Precaution/WarningDrugs/DiseasesUtil AUtil BUtil CVandetanibCerebral infarction

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

26. Vandetanib / Hemorrhage

Alert Message: Serious hemorrhagic events, including fatalities, occurred in patients treated with Caprelsa (vandetanib). Discontinue vandetanib in patients with severe hemorrhage. Do not administer vandetanib to patients with a recent history of hemoptysis of greater than or equal to 1/2 teaspoon of red blood.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Vandetanib
 Cerebrovascular Hemorrhage

Cerebrovascular Hemorrhage Gastrointestinal Hemorrhage References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

27. Vandetanib / Heart Failure

Alert Message: Heart failure, including fatalities, occurred in patients treated with Caprelsa (vandetanib). Monitor for signs and symptoms of heart failure. Consider discontinuation of vandetanib in patients with heart failure. Heart failure may not be reversible upon stopping vandetanib.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Vandetanib
 Heart Failure

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Caprelsa Prescribing Information, July 2016, AstraZeneca.

28. Lesinurad / Overutilization

Alert Message: Zurampic (lesinurad) may be over-utilized. The manufacturer's recommended maximum dose is 200 mg daily in combination with a xanthine oxidase inhibitor.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Lesinurad

Max Dose: 200 mg/day

References: Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

29. Lesinurad / Nonadherence

Alert Message: Based on refill history, your patient may be underutilizing Zurampic (lesinurad). Non-adherence to the prescribed regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A Util B Util C</u> Lesinurad

References: Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.

30. Lesinurad / Xanthine Oxidase Inhibitor

Alert Message: A review of the patient medication history did not reveal concurrent use of a xanthine oxidase inhibitor (e.g., allopurinol or febuxostat). Lesinurad should not be used as monotherapy. Failure to take lesinurad with a xanthine oxidase inhibitor may increase the risk of renal adverse reactions, including acute renal failure.

Febuxostat

 Conflict Code: TA – Therapeutic Appropriateness (Black Box)

 Drugs/Diseases

 Util A
 Util B

 Lesinurad
 Allopurinol

References: Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

31. Lesinurad / Severe Renal Impairment

Alert Message: The use of Zurampic (lesinurad) is contraindicated in patients with severe renal impairment (eCLcr < 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis. Lesinurad is not expected to be effective in these patient populations.

 Conflict Code: TA – Therapeutic Appropriateness (Black Box)

 Drugs/Diseases

 Util A
 Util B

 Lesinurad
 CKD Stage 4 & 5

 ESRD

Dependence on Renal Dialysis Kidney Replace by Transplant

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

32. Lesinurad / Mild to Moderate Renal Impairment

Alert Message: Patients with moderate renal impairment receiving Zurampic (lesinurad) have been shown to have a higher occurrence of renal related adverse reactions compared to patients with mild renal impairment or normal renal function. No dosage adjustment is recommended in patients with an eCLcr 45 to 60 mL/min, however frequent renal function monitoring is recommended in these patients. Lesinurad treatment should not be initiated in patients with an eCLcr less than 45 mL/min.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseas	es	
<u>Util A</u>	Util B	Util C (Include)
Lesinurad		CKD 2 & 3

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

33. Allopurinol / Lesinurad

Alert Message: Use of Zurampic (lesinurad) is not recommended for patients taking daily doses of allopurinol less than 300 mg (or less than 200 mg in patients with eCLcr < 60 mL/min).

 Conflict Code: LR – Low Dose

 Drugs/Diseases

 Util A
 Util B

 Allopurinol
 Lesinurad

Minimum Dose: 300 mg/day

References: Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.
34. Lesinurad / Tumor Lysis Syndrome & Lesch-Nyhan Syndrome

Alert Message: The use of Zurampic (lesinurad) is contraindicated in patients with tumor lysis syndrome or Lesch-Nyhan Syndrome, where the rate of uric acid formation is greatly increased. Studies have not been conducted in patients with secondary hyperuricemia.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Lesinurad
 Tumor Lysis Syndrome

Lesch-Nyhan Syndrome

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

35. Lesinurad / Severe Hepatic Impairment

Alert Message: The use of Zurampic (lesinurad) is not recommended in patients with severe hepatic impairment as it has not been studied in this patient population. No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh class A and B).

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Lesinurad
 Cirrhosis

 Hepatic Fibrosis

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

36. Lesinurad / Moderate CYP2C9 Inhibitors

Alert Message: Concurrent use of Zurampic (lesinurad), a CYP2C9 substrate, with moderate CYP2C9 inhibitors (e.g., fluconazole, amiodarone, and oxandrolone) should be done with caution. Concomitant use of these agents may result in increased lesinurad exposure and risk of lesinurad-related adverse effects.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Lesinurad Fluconazole Amiodarone Abiraterone

Sorafenib

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

37. Lesinurad / CYP2C9 Inducers

Alert Message: Concurrent use of Zurampic (lesinurad), a CYP2C9 substrate, with CYP2C9 inducers (e.g., carbamazepine, rifampin, and enzalutamide) should be done with caution. Concomitant use of these agents may result in decreased lesinurad exposure and therapeutic effect. Monitor patients for reduction in lesinurad efficacy or consider therapy modification.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A Util B Util C</u>

Lesinurad	Carbamazepine
	Rifampin
	Enzalutamide

References: Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

38. Lesinurad / Epoxide Hydrolase Inhibitors

Alert Message: Zurampic (lesinurad) should not be administered with an epoxide hydrolase inhibitor (i.e., valproic acid). Concurrent use of these agents may interfere with metabolism of lesinurad.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
Util A	<u>Util B</u>	<u>Util C</u>
Lesinurad	Valproic Acid	

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

39. Lesinurad / Hormonal Contraceptives

Alert Message: Hormonal contraceptives including oral, injectable, transdermal, and implantable forms may not be reliable when co-administered with Zurampic (lesinurad). Females should use additional methods of contraception and not rely on hormonal contraception alone when taking lesinurad.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Util A	Util B	Util C
Lesinurad	Oral Contraceptives	
	Injectable Contraceptives	
	Transdermal Contraceptiv	es
	Implantable Contraceptive	S

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

40. Lesinurad / CYP3A Substrates

Alert Message: Concurrent use of Zurampic (lesinurad), a weak CYP3A4 inducer, with a CYP3A4 substrates (e.g., aprepitant, buspirone, and simvastatin) may result in a decrease in systemic exposure and therapeutic efficacy of the CYP3A4 substrate. Monitor the patient for potential reduction in CYP3A4 substrate efficacy.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Util A Util B Util C Quinidine Lesinurad Budesonide Amiodarone Eplerenone Ivabradine Tolvaptan Eletriptan Ifosfamide Sildenafil Vinblastine Tadalafil Vincristine Vardenafil Vinorelbine Etoposide Avanafil Docetaxel Isradipine Felodipine Abiraterone Amlodipine Imatinib Disulfiram Bortezomib Eszopiclone Erlotinib Flurazepam Sunitinib Alprazolam Dasatinib Triazolam Lapatinib Midazolam Nilotinib Pazopanib Buspirone Quazepam Vandetanib Vilazodone Crizotinib Hydrocodone Axitinib Oxycodone Bosutinib Buprenorphine Cabozantinib Ethosuximide Ibrutinib Clonazepam Ceritinib Tiagabine Irinotecan Aprepitant Olaparib Quetiapine Palbociclib Lurasidone Dapsone Solifenacin Atazanavir Bedaquiline Alfuzosin Tacrolimus Silodosin Tofacitinib Simvastatin Lovastatin Cilostazol Ticagrelor Apixaban

References:

Zurampic Prescribing Information, Jan. 2016, AstraZeneca. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

41. Sofosbuvir/Velpatasvir / Overutilization

Alert Message: Epclusa (sofosbuvir/velpatasvir) may be over-utilized. The manufacturer's recommended daily dose is one tablet (400mg/sofosbuvir/100 mg velpatasvir) once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Sofosbuvir/Velpatasvir

Max Dose: 1 tablet per day

References: Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

42. Sofosbuvir/Velpatasvir / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Epclusa (sofosbuvir/velpatasvir) have not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Sofosbuvir/Velpatasvir

Age Range: 0-17 yoa

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

43. Sofosbuvir/Velpatasvir / Amiodarone

Alert Message: Concurrent use of Epclusa (sofosbuvir/velpatasvir) with amiodarone is not recommended. Serious symptomatic bradycardia may occur in patients taking amiodarone, particularly in patients also receiving beta-blockers, or those with underlying cardiac comorbidities, and/or advanced liver disease. In patients without alternative viable treatment options, cardiac monitoring is recommended.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Sofosbuvir/Velpatasvir Amiodarone</u>

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

44. Sofosbuvir/Velpatasvir / P-gp Inducers, Mod to Potent CYP2B6, 2C8 & **3A4 Inducers**

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with inducers of P-gp and/or moderate to potent inducers of CYP2B6, CYP2C8, or CYP3A4 is not recommended. Co-administration of these agents may significantly decrease plasma concentrations of sofosbuvir/velpatasvir, leading to potentially reduced therapeutic effects.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases

Brage, Broodooo			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Sofosbuvir/Velpatasvir	Carbamazepine	Enzalutamide	
	Phenobarbital	Bosentan	
	Primidone	Efavirenz	
	Phenytoin	Etravirine	
	Rifampin	Nevirapine	
	Rifapentine	Modafinil	
	Rifabutin	Oxcarbazepine	
Defenses		•	

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc.

Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug\InteractionaLabeling/ucm0936 64.htm

45. Sofosbuvir/Velpatasvir / Antacids

Alert Message: It is recommended to separate the administration of an antacid and Epclusa (sofosbuvir/velpatasvir) by 4 hours. The velpatasvir component of the antiviral combo product is pH depended and drugs that increase gastric pH are expected to decreased velpatasvir solubility, and therefore its bioavailability.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sofosbuvir/Velpatasvir	Aluminum hydroxide	
	Magnesium hydroxide	
	Calcium Carbonate	
	Sodium Bicarbonate	
References:		

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

46. Ledipasvir + Sofosbuvir / H2 Blockers

Alert Message: Caution should be exercised when using Epclusa (sofosbuvir/velpatasvir) with an H-2 receptor antagonist. These agents may be administered simultaneously or separated by 12 hours. The H-2 antagonist dose should not exceed a dose that is comparable to famotidine 40 mg twice daily. The velpatasvir component of the antiviral combo product is pH dependent and drugs that increase gastric pH are expected to decrease velpatasvir solubility, and therefore its bioavailability.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases Util A Util C (Include) Util B Cimetidine > 1600mg/day Sofosbuvir/Velpatasvir Famotidine > 80mg/day Ranitidine > 600mg/day Nizatidine > 600mg/day

References: Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

47. Sofosbuvir/Velpatasvir / Proton Pump Inhibitors

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with proton pump inhibitors is not recommended. The solubility of the velpatasvir component of the antiviral combo product is pH dependent and drugs that increase the gastric pH are expected to decrease velpatasvir solubility, and therefore it bioavailability. If concomitant use is considered medically necessary, sofosbuvir/velpatasvir should be administered with food and taken 4 hours before omeprazole 20 mg. Use with other PPIs has not been studied.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
Util A	<u>Util B</u>	<u>Util C</u>
Sofosbuvir/velpatasvir	Omeprazole	
	Esomeprazole	
	Lansoprazole	
	Dexlansoprazole	
	Rabeprazole	
	Pantoprazole	
References	-	

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

48. Sofosbuvir/Velpatasvir / Digoxin

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with digoxin, a P-gp substrate, may result in an increase in the plasma concentration of digoxin due to inhibition, by the velpatasvir component, of the P-gp efflux transporter system. Refer to digoxin prescribing information for monitoring and dose modification recommendations.

Conflict Code: DD – Drug/Drug Interaction

Diugs/Diseases		
<u>Util A</u>	Util B	Util C
Sofosbuvir/Velpatasvir	Digoxin	

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

49. Sofosbuvir/Velpatasvir / Topotecan

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with topotecan, a P-gp and BCRP substrate, is not recommended. Co-administration of these agents may result in an increase in the concentration of topotecan due to inhibition, by the velpatasvir component, of both P-gp efflux transport and BCRP transport.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Sofosbuvir/Velpatasvir
 Topotecan

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

50. Sofosbuvir/Velpatasvir / Tenofovir-containing Agents

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with a tenofovir-containing agent may result in elevated tenofovir concentrations and increased risk of tenofovir-associated adverse reactions. The velpatasvir component of the antiviral is an inhibitor of drugs transporters P-gp, BCRP, OATP1B1, OATP1B3, and OATP2B1. Both tenofovir prodrugs, tenofovir disoproxil fumarate (DF) and tenofovir alafenamide (TAF) are P-gp and BCRP substrates and TAF is also a substrate of OATP1B1 and OATP1B3.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A

 Sofosbuvir/Velpatasvir

 Tenofovir

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

51. Sofosbuvir/Velpatasvir / Tipranavir / Ritonavir

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with ritonavir-boosted tipranavir is not recommended. Tipranavir is a P-gp inducer and co-administration with the P-gp substrates velpatasvir and sofosbuvir may result in decreased velpatasvir and sofosbuvir plasma concentrations, leading to reduced antiviral efficacy.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	Util B	Util C (Include)
Sofosbuvir/Velpatasvir	Tipranavir	Ritonavir

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

52. Sofosbuvir/Velpatasvir / Rosuvastatin

Alert Message: The dose of rosuvastatin should not exceed 10 mg per day when co-administered with Epclusa (sofosbuvir/velpatasvir). The velpatasvir component of the antiviral agent is an inhibitor of BCRP and OATP1B1 transporters and concurrent use with rosuvastatin (both a BCRP and OATP1B1 substrate) may result in a significant increase in the concentration of rosuvastatin which is associated with increased risk of myopathy, including rhabdomyolysis.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Sofosbuvir/Velpatasvir

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

53. Sofosbuvir/Velpatasvir / Atorvastatin

Alert Message: The concurrent use of Epclusa (sofosbuvir/velpatasvir) with an atorvastatin-containing agent is expected to increase the concentrations of atorvastatin. The velpatasvir component of the antiviral agent is an inhibitor of BCRP and OATP1B1 transporters and concurrent use with atorvastatin (both a BCRP and OATP1B1 substrate) may result in an increase in atorvastatin plasma concentrations which is associated with increased risk of myopathy, including rhabdomyolysis.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Sofosbuvir/Velpatasvir
 Atorvastatin

References:

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

54. Sofosbuvir-containing Agents / Pregnancy / Pregnancy Negating

Alert Message: No adequate human data are available to establish whether sofosbuvir-containing agents (Sovaldi, Harvoni, & Epclusa) pose a risk to pregnancy outcomes. Sofosbuvir-containing agents should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. If a sofosbuvir-containing agent is used with ribavirin, the combination therapy is contraindicated.

Conflict Code: MC – Drug (Actual) Disease/Diagnosis Warning

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Sofosbuvir/Velpatasvir	Pregnancy	Delivery
Sofosbuvir/Ledipasvir		Abortion
Sofosbuvir		Miscarriage

Gender: Female Range: 11 - 55 yoa

References:

During /Discos

Epclusa Prescribing Information, June.2016, Gilead Sciences, Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

55. Codeine / Therapeutic Appropriateness

Alert Message: Codeine-containing products, used either as an analgesic or an antitussive, should be prescribed with extreme caution in pediatric patients. Codeine is metabolized to morphine and ultra-rapid metabolizers can have excessive morphine formation and toxicity even after normal therapeutic doses. The use of codeine for post-operative pain management in pediatric patients after a tonsillectomy and/or adenoidectomy is contraindicated due to risk of serious respiratory depression. Codeine/promethazine products are contraindicated in patients less than 6 years of age.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Codeine - All

Age Range: 0 - 17 yoa

References:

Tobias JD, Green TP and Cote CJ. Codeine: Time to Say "No". Pediatrics. 2016 Oct;138(4):e20162396. Clinical Pharmacology, 2016 Elsevier/Gold Standard. Facts & Comparisons, 2016 Wolters Kluwer Health. Racoosin JA, Roberson DW, Pacanowski MA, et al. New Evidence About an Old Drug – Risk with Codeine After Adenotonsillectomy. N Engl J Med 2013;368:2155–7.

56. Nebivolol/Valsartan / Overutilization

Alert Message: Byvalson (nebivolol/valsartan) may be over-utilized. The manufacturer's recommended daily dose is one 5mg/80mg (nebivolol/valsartan) tablet orally once daily. Increasing the dose of nebivolol/valsartan dose not result in any meaningful further blood pressure reduction.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Nebivolol/Valsartan

Max Dose: 5mg/80mg

References: Byvalson Prescribing Information, June 2016, Actavis. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

57. Nebivolol/Valsartan / Contraindications

Alert Message: Byvalson (nebivolol/valsartan) is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (no permanent pacemaker in place), hypersensitivity to the product, or severe hepatic impairment (Child-Pugh >B).

Conflict Code: MC – Drug Disease Contraindication

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C
Nebivolol/Valsartan	2 nd degree Heart Block	
	3 rd degree Heart Block	
	Cardiogenic Shock	
	Cardiac failure	
	Sick Sinus Syndrome	
	Cirrhosis/Hepatic Failure	
References:	·	

Byvalson Prescribing Information, June 2016, Actavis. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

58. Nebivolol/Valsartan / Hepatic Impairment

Alert Message: There are no studies of Byvalson (nebivolol/valsartan) in patients with hepatic insufficiency. No initial dosage adjustment is required for patients with mild hepatic impairment. Nebivolol/valsartan is not recommended as initial antihypertensive treatment in patients with moderate hepatic impairment, because the recommended starting dose of nebivolol, 2.5 mg daily, is not available. Nebivolol/valsartan is contraindicated in patients with severe hepatic impairment (Child-Pugh >B).

 Conflict Code:
 DC – Drug Disease Warning/Contraindication

 Drugs/Diseases
 Util A

 Util A
 Util B

 Nebivolol/Valsartan
 Hepatic Impairment

References: Byvalson Prescribing Information, June 2016, Actavis. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

59. Nebivolol/Valsartan / Renal Impairment

Alert Message: Safety and effectiveness of Byvalson (nebivolol/valsartan) in patients with moderate to severe renal impairment (CrCl </= 60 mL/min) have not been studied. No dosage adjustment is required for patients with mild to moderate renal impairment. Nebivolol/valsartan is not recommended as initial antihypertensive treatment in patients with severe renal impairment, because the recommended starting dose of nebivolol in this population, 2.5 mg once daily, is not available in the fixed dose combination product.

Conflict Code: DC - Drug Disease Precaution/Warning

Drugs/Diseases		
<u>Util A</u>	Util B	<u>Util C (Require)</u>
Nebivolol/Valsartan		Renal Impairment
		Lanthanum
		Sevelamer
		Doxercalciferol
		Paricalcitol
		Calcitriol

References:

Byvalson Prescribing Information, June 2016, Actavis. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

60. Nebivolol/Valsartan / CYP2D6 Inhibitors

Alert Message: Concurrent use of Byvalson (nebivolol/valsartan) and a CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, quinidine, and bupropion) should be avoided. The nebivolol component of the fixed dose antihypertensive agent is a CYP2D6 substrate and use with a CYP2D6 inhibitor may result in elevated nebivolol plasma concentrations. If concurrent therapy is warranted the patient should be monitored closely for nebivolol adverse effects.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u> Nebivolol/ValsartanBupropion Fluoxetine Paroxetine Duloxetine

<u>Util C</u>

References:

Byvalson Prescribing Information, June 2016, Actavis. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

61. Obeticholic Acid / Overutilization / Hepatic Impairment

Quinidine Propafenone Amiodarone

Alert Message: Ocaliva (obeticholic acid) may be over-utilized. The manufacturer's recommended maximum daily dose is 10 mg once daily. Exceeding the maximum daily dose may increase the risk of liver-related adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Obeticholic Acid

Util C (Negating) Hepatic Impairment

Max Dose: 10 mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

62. Obeticholic Acid / Overutilization - Hepatic Impairment

Alert Message: The manufacturer's recommended maximum dose of Ocaliva (obeticholic acid) in patients with moderate to severe hepatic impairment is 10 mg twice weekly (at least three days apart). Exceeding the maximum daily dose may increase the risk of liver-related adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare. No dosage adjustment is needed in patients with mild hepatic impairment.

Conflict Code: ER - Overutilization Drugs/Diseases Util A Util B **Obeticholic Acid**

Util C (Include) Hepatic Impairment

Max Dose: 2 tabs/week

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

63. Obeticholic Acid / Biliary Obstruction

Alert Message: The use of Ocaliva (obeticholic acid) is contraindicated in patients with complete biliary obstruction. Obeticholic acid is a famesoid X receptor (FXR) agonist which increase transport of bile acids out of the hepatocytes in addition to limiting the overall size of the circulating bile pool.

Conflict Code: MC - Drug (Actual) Disease Precaution/Warning Drugs/Diseases

Brage, Broodooo		
Util A	<u>Util B</u>	Util C
Obeticholic Acid	Obstruction of Bile Duct	

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

64. Obeticholic Acid / Bile Acid Binding Resin / Pruritis

Util B

Alert Message: Concurrent use of Ocaliva (obeticholic acid) with a bile acid binding resin may reduce the absorption, systemic exposure, and efficacy obeticholic acid. If concomitant use is warranted, take obeticholic acid at least 4 hours before or 4 hours after the bile acid binding resin, or at as great an interval as possible.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases Util A **Obeticholic Acid**

Util C (Negating) Cholestyramine Pruritus Colesevelam Colestipol

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

65. Obeticholic Acid / Warfarin

Alert Message: Concurrent use of Ocaliva (obeticholic acid) with warfarin may result in a decrease in the INR. If concomitant use is warranted, monitor the INR and adjust the dosage of warfarin, as needed, to maintain the target INR range when co-administering these agents.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Obeticholic Acid
 Warfarin

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

66. Obeticholic Acid / CYP1A2 Substrates w/ NTI

Alert Message: Concurrent use of Ocaliva (obeticholic acid) with a CYP1A2 substrate with a narrow therapeutic index may result in the increased exposure to the CYP1A2 substrate. Therapeutic monitoring of the CYP1A2 substrate is recommended.

Conflict Code: DD – Drug/Drug Interaction

Diugs/Diseases		
Util A	<u>Util B</u>	Util C
Obeticholic Acid	Theophylline	
	Tizanidine	

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

67. Obeticholic Acid / Pruritus / Antihistamines & Bile Acid Binding Resin

Alert Message: Ocaliva (obeticholic acid) can cause severe pruritis. For patients with intolerable pruritis management strategies include the addition of a bile acid resin or antihistamine, obeticholic acid dose reduction or temporary interruption of obeticholic acid dosing.

Colestipol

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Obeticholic Acid 10mg
 Pruritus

 Antihistamines

cholic Acid 10mg	Pruritus	Antihistamines
		Cholestyramine
		Colesevelam

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

68. Obeticholic Acid / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Ocaliva (obeticholic acid) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Obeticholic Acid

Age Range: 0 – 17 yoa

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Ocaliva Prescribing Information, May 2016, Intercept Pharmaceuticals.

69. Glycopyrrolate/Formoterol / Overutilization

Alert Message: The manufacturer's recommended maximum daily dose of Bevespi Aerosphere (glycopyrrolate/formoterol) is two inhalations twice daily. Excessive use of an formoterol-containing agent or use in conjunction with other medications containing a beta-2-agonist can result in clinically significant cardiovascular effects and may be fatal.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Glycopyrrolate/Formoterol

Max Dose: 4 inhalations/day

References: Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

70. Glycopyrrolate/Formoterol / Therapeutic Appropriateness

Alert Message: Bevespi Aerosphere (glycopyrrolate/formoterol) contains a long-acting beta-2-adrenergic agonist (LABA) and all LABAs increase the risk of asthma-related death. The safety and efficacy of the formoterol component in patients with asthma have not been established. Glycopyrrolate/formoterol is not indicated for the treatment of asthma.

 Conflict Code:
 TA - Therapeutic Appropriateness (Black Box Warning)

 Drugs/Diseases
 Util A

 Util A
 Util B

 Glycopyrrolate/Formoterol
 Asthma

References: Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

71. Glycopyrrolate/Formoterol / Therapeutic Appropriateness

Alert Message: Bevespi Aerosphere (glycopyrrolate/formoterol) is not indicated for use in children. The safety and effectiveness of glycopyrrolate/formoterol have not been established in children.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Glycopyrrolate /Formoterol

Age Range: 0 – 17 yoa

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

72. Glycopyrrolate/Formoterol / Cardiovascular, Convulsive Disorders, Thyrotoxicosis & Diabetes

Alert Message: Bevespi Aerosphere (glycopyrrolate/formoterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis or sensitivity to sympathomimetic drugs. The formoterol component is a sympathomimetic amine and can exacerbate these conditions.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Glycopyrrolate/formoterol

Util C (Include) Hypertension Arrhythmias Heart Failure Diabetes Seizures Epilepsy

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

73. Glycopyrrolate/Formoterol / Adrenergic Drugs

Alert Message: Caution should be exercised when Bevespi Aerosphere (glycopyrrolate/formoterol) is prescribed concurrently with other adrenergic sympathomimetic agents, administered by any route, because the sympathetic effects of the formoterol component of the combination product may be potentiated.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases Util A Util C Util B Indacaterol/Glycopyrrolate Ephedrine Metaproterenol Lisdexamfetamine Oxymetazoline Epinephrine Terbutaline Diethylpropion Tetrahydrozoline Pseudoephedrine Methamphetamine Benzphetamine Phenylephrine Methylphenidate Phentermine Albuterol Amphetamine Phendimetrazine Pirbuterol Dextroamphetamine Naphazoline

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

74. Glycopyrrolate/Formoterol / Xanthine Derivatives & Steroids

Alert Message: Caution should be exercised when Bevespi Aerosphere (glycopyrrolate/formoterol) is prescribed concurrently with xanthine derivatives or steroids because concomitant administration may potentiate the hypokalemic effect of the formoterol component of the combination agent.

Conflict Code: DD - Drug/Drug Interaction

Diugs/Diseases			
<u>Util A</u>	<u>Util B</u>		Util C
Glycopyrrolate/Formoterol	Theophylline	Hydrocortisone	
	Aminophylline	Methylprednisolone	
	Dyphylline	Prednisone	
	Betamethasone	Prednisolone	
	Budesonide Cortisone	Dexamethasone	

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

75. Glycopyrrolate/Formoterol / Non-Potassium Sparing Diuretics

Alert Message: Caution should be exercised when Bevespi Aerosphere (glycopyrrolate/formoterol), a beta2-agonist containing combo agent, is prescribed concurrently with non-potassium sparing diuretics because concomitant administration may potentiate the ECG changes or hypokalemia that may result from the administration of the diuretic.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> Glycopyrrolate/Formoterol Furosemide Bumetanide Methyclothiazide Torsemide Metolazone

<u>Util C</u>

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

Chlorthalidone HCTZ

76. Glycopyrrolate/Formoterol / Nonselective β-Blockers / Sel. β-Blockers

Alert Message: Concurrent use of a beta-adrenergic blocker with Bevespi Aerosphere (glycopyrrolate/formoterol), a beta₂-agonist containing combo agent, may diminish the pulmonary effect of the beta-agonist component, formoterol. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with COPD. If concomitant therapy cannot be avoided consider a cardioselective beta-blocker, but administer with caution.

Conflict Code: DD - Drug/Drug Interaction

Diuys/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Glycopyrrolate/formoterol	Carvedilol	Acebutolol
	Nadolol	Atenolol
	Labetalol	Betaxolol
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	
Deferences		

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

77. Glycopyrrolate/Formoterol / Anticholinergics

Alert Message: The concurrent use of Bevespi Aerosphere (glycopyrrolate/formoterol) with anticholinergic agents should be avoided. The glycopyrrolate component of the combo product is an anticholinergic agent and concomitant use with other anticholinergics may lead to an increase in anticholinergic adverse effects.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases

<u>Util Ă</u>	<u>Util B</u>		<u>Util C</u>
Glycopyrrolate/formoterol		Trospium	
	Benztropine	Hyoscyamine	
	Orphenadrine	Scopolamine	
	Darifenacin	Propantheline	
	Fesoterodine	Mepenzolate	
	Flavoxate	Methscopolamine	
	Oxybutynin	Dicyclomine	
	Solifenacin	Tolterodine	

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

78. Glycopyrrolate/Formoterol / MAOIs, TCA & Other QT Prolong Meds

Alert Message: Bevespi Aerosphere (glycopyrrolate/formoterol) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or other drugs known to prolong the QTc interval because the action of the adrenergic agonist, formoterol, on the cardiovascular system may be potentiated by these agents.

Conflict Code: DD – Drug/Drug Interactions

Diugs/Diseases					
<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Glycopyrrolate/Formoterol	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ
	Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil
	Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Isocarboxazid
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Phenelzine
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	Tranylcypromine
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	Linezolid
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	Rasagiline
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Telithromycin	
	Diphenhydramine	lloperidone	Paroxetine	Terbutaline	

References:

Bevespi Aerosphere Prescribing Information, April 2016, AstraZeneca.

79. Glycopyrrolate/Formoterol / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Bevespi Aerosphere (glycopyrrolate/formoterol). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Glycopyrrolate/Formoterol

References:

van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2015 Jan;108(1):103-113.

Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.

Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am Jrnl Geriatr Pharmacother. 2012 Jun;10(3):201-210.

Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.

80. Olaparib / Overutilization

Alert Message: The manufacturer's recommended daily dose of Lynparza (olaparib) is 400 mg (eight 50 mg capsules) taken twice daily for a total daily dose of 800 mg.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Util C

 Olaparib

Max Dose: 800 mg/day

References: Lynparza Prescribing Information, Dec. 2017, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

81. Olaparib / Moderate to Strong CYP3A4 Inhibitors

Alert Message: Concurrent use of Lynparza (olaparib), a CYP3A substrate, with strong and moderate CYP3A inhibitors should be avoided due to risk of increased olaparib concentrations. Alternative agents with less CYP3A4 inhibition should be considered. If the inhibitor cannot be avoided, reduce the olaparib dose to 150 mg taken twice daily for a strong CYP3A inhibitor or 200 mg take twice daily for a moderate inhibitor.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases					
<u>Util A</u>	<u>Util B</u>				Util C
Olaparib	Nefazodone	Indinavir	Fluconazole	Verapamil	
	Ketoconazole	Nelfinavir	Fosamprenavir	Crizotinib	
	Itraconazole	Saquinavir	Imatinib	Delavirdine	
	Posaconazole	Ritonavir	Idelalisib		
	Voriconazole	Tipranavir	Aprepitant		
	Clarithromycin	Darunavir	Ciprofloxacin		
	Telithromycin	Atazanavir	Diltiazem		
	Boceprevir	Cobicistat	Erythromycin		

References:

Lynparza Prescribing Information, Dec. 2017, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

82. Olaparib / Moderate to Strong CYP3A4 Inducers

Alert Message: Concurrent use of Lynparza (olaparib), a CYP3A substrate, with strong and moderate CYP3A inducers should be avoided due to potential for decreased olaparib efficacy. Alternative agents with less CYP3A induction potential should be considered.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
Util A	<u>Util B</u>		<u>Util C</u>
Olaparib	Carbamazepine	Rifapentine	
-	Phenytoin	Bosentan	
	Phenobarbital	Efavirenz	
	Primidone	Modafinil	
	Rifampin	Oxcarbazepine	
	Rifabutin	Etravirine	
References:			

Lynparza Prescribing Information, Dec. 2017, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

83. Olaparib / Monitoring

Alert Message: Myelosdysplastic Syndrome/Acute Myeloid Leukemia (MDS/ALS) has occurred in patients exposed to Lynparza (olaparib) and some were fatal. Monitor complete blood count testing at baseline and monthly thereafter and discontinue olaparib if MSD/AML is confirmed.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

<u>Util A</u>	Util B	Util C
Olaparib		

References:

Lynparza Prescribing Information, Dec. 2014, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

84. Olaparib / Pneumonitis Symptoms

Alert Message: Pneumonitis, including fatal cases, have occurred in patients treated with Lynparza (olaparib). If patients present with new or worsening respiratory symptoms such as dyspnea, fever, cough, wheezing, or a radiological abnormality occurs, interrupt treatment with olaparib and initiate prompt investigation. If pneumonitis is confirmed, discontinue olaparib.

Conflict Code: MC – Drug (Actual) Disease Warning/Precaution

Diago, Diobabbo		
Util A	<u>Util B</u>	<u>Util C</u>
Olaparib	Dyspnea	
	Fever	
	Cough	

References: Lynparza Prescribing Information, Dec. 2017, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

85. Olaparib / Pregnancy / Pregnancy Negating

Alert Message: Lynparza (olaparib) can cause fetal harm in a pregnant woman based on its mechanism of action and findings in animals. Females of reproductive potential should avoid becoming pregnant while taking olaparib. If contraceptive methods are being considered, use highly effective contraceptive methods during treatment and for at least 6 months after receiving the last olaparib dose. If the patient becomes pregnant while taking olaparib, apprise them of the potential hazard to the fetus.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease	S	
Util A	<u>Util B</u>	Util C (Negating)
Olaparib	Pregnancy	Miscarriage
		Delivery
		Abortion

Age Range 11-50

References:

Lynparza Prescribing Information, Dec. 2017, AstraZeneca.

86. Olaparib / Overutilization

Alert Message: The manufacturer's recommended daily dose of Lynparza (olaparib) in patients with moderate renal impairment (CLcr 31 - 50 mL/min) is 300 mg (six 50 mg capsules) taken twice daily, for a total daily dose of 600 mg. No dosage adjustment is recommended in mild renal impairment (CLcr 51 - 80 mL/min). The pharmacokinetics of olaparib have not been evaluated in patients with severe renal impairment or end-stage renal disease (CLcr </= 30ml/min).

ESRD

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C (Include)</u> Olaparib CKD 3, 4 & 5

Max Dose: 600 mg/day

References: Lynparza Prescribing Information, Dec. 2017, AstraZeneca. DUR Board Meeting June 7, 2017 Brynhild Haugland Room State Capitol



North Dakota Medicaid DUR Board Meeting Agenda Brynhild Haugland Room State Capitol 600 East Boulevard Avenue Bismarck, ND June 7, 2017 1:00 pm

- 1. Administrative items
 - Travel vouchers
- 2. Old business
 - Review and approval of 03/17 meeting minutes
 - Budget update
 - Review top 15 therapeutic categories/top 25 drugs
 - Prior authorization/PDL update
- 3. New business
 - Review of Proglycem
 - Review of Biltricide
 - Review of physician prescribing patterns for select therapeutic categories
 - Review of anti-depressant non-compliance
 - Criteria recommendations
 - Upcoming meeting date/agenda
- 4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

March 1, 2017

Members Present: Wendy Brown, Katie Kram, Tanya Schmidt, Laura Schield, Andrea Honeyman, Michael Booth, Gaylord Kavlie, Zach Marty, Jeffrey Hostetter, Carlotta McCleary

Members Absent: James Carlson, Michael Quast, Russ Sobotta, Peter Woodrow, LeNeika Roehrich

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy

Old Business

Chair W. Brown called the meeting to order at 1:00 p.m. Chair W. Brown asked for a motion to approve the minutes of the December meeting. T. Schmidt moved that the minutes be approved and M. Booth seconded the motion. Chair W. Brown called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Second Reviews

A motion and second was made at the December meeting to place prednisolone ODT, Millepred, Veripred, metformin OSM, and testosterone oral on prior authorization. The topics were brought up for a second review. The motion to place prednisolone ODT, Millepred, Veripred, metformin OSM, and testosterone oral on prior authorization passed with no audible dissent.

Review of 2016 DUR Projects

A. Murphy presented a review of DUR projects from the year of 2016. Topics included the utilization of acne medications, utilization of long and short acting narcotics with a high prevalence of abuse, appropriate use of maintenance and rescue inhalers for chronic respiratory conditions, prevalence of benzodiazepine therapy for sleep disorders, and the utilization of duplicate anti-ulcer therapy. Also reviewed was trends in utilization of anticonvulsants, antidepressants, antipsychotics, ADHD stimulants and non-stimulants, and select high-cost or high utilization products.

Prior Authorization and PDL Update

A. Murphy gave an update on drugs that have been added to prior authorization. Adlyxin was added to the GLP-1 Receptor agonist PA. Basaglar Kwikpen U-100, Humulin 70/30 Kwikpen, Humulin N Kwikpen, Humulin R U-500 Kwikpen, and Soliqua 100-33 were added to the Insulin PA. Fosrenol 1000 mg chewable tablet was added to the phosphate binders PA. Otovel was added to the otic anti-infectives PA. Jentadueto XR was added to the DPP4 inhibitors PA. Prestalia was added to the ACEI/ARB/Renin inhibtors PA. Tobradex ST was added to the ophthalmic antiinfectives/anti-inflammatories PA. Benlysta, Spinraza, Dalvance, Fabrazyme, Kanuma, Kepivance, Orbactiv, and Panhematin were added to the Medical Billing Only list of medications. Alocril, Alomide, Alvesco, Azasite, azelastine HCl, Beconase AQ, Besivance, Brovana, Ciloxan, Dexilant, Dipentum, epinephrine, Eurax, Floxin, Gelnique, Prevacid, Lastacaft, Maxitrol, Omeclamox-Pak, Omnaris, Oxytrol, Prevpac, Qnasl, Renvela, and Zetonna were all removed from PA.

New Business

Criteria Recommendations

The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. M. Booth moved to approve the new criteria and A. Honeyman seconded the motion. Chair W. Brown called for a voice vote. The motion passed with no audible dissent.

The next DUR Board meeting will be held June 7, 2017 at the Brynhild Haugland in Bismarck. J. Hostetter made a motion to adjourn the meeting. K. Kram seconded. The motion passed with no audible dissent. Chair W. Brown adjourned the meeting.

NORTH DAKOTA MEDICAID Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 01/01/2017 - 03/31/2017

				% Total
AHFS Therapeutic Class	Rx	Paid	Paid/Rx	Claims
ANTICONVULSANTS, MISCELLANEOUS	8,432	\$ 812,942.27	\$ 96.41	5.72%
ANTIPSYCHOTIC AGENTS	5,856	\$ 807,919.35	\$ 137.96	3.97%
INSULINS	1,830	\$ 798,122.86	\$ 436.13	1.24%
AMPHETAMINES	3,839	\$ 609,938.07	\$ 158.88	2.60%
CORTICOSTEROIDS (RESPIRATORY TRACT)	1,887	\$ 527,897.44	\$ 279.75	1.28%
RESPIRATORY AND CNS STIMULANTS	4,348	\$ 510,534.01	\$ 117.42	2.95%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	117	\$ 422,677.51	\$ 3,612.63	0.08%
ANTIDEPRESSANTS	14,716	\$ 365,976.92	\$ 24.87	9.98%
IMMUNOMODULATORY AGENTS	50	\$ 302,764.27	\$ 6,055.29	0.03%
BETA-ADRENERGIC AGONISTS	3,838	\$ 252,842.04	\$ 65.88	2.60%
PENICILLINS	6,342	\$ 234,495.05	\$ 36.97	4.30%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,695	\$ 232,760.20	\$ 137.32	1.15%
SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	252	\$ 218,669.81	\$ 867.74	0.17%
OPIATE AGONISTS	6,121	\$ 204,500.73	\$ 33.41	4.15%
NEURAMINIDASE INHIBITORS	1,285	\$ 199,702.72	\$ 155.41	0.87%
Total Top 15	60,608	\$ 6,501,743.25	\$ 107.28	41.09%

Total Rx Claims	147,494
From 01/01/2017 - 03/31/2017	

Top 15 Therapeutic Classes Based on Total Cost of Claims



Health Information Designs, Inc.

NORTH DAKOTA MEDICAID Cost Management Analysis

05/04/2017

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 01/01/2017 - 03/31/2017

					% Total
Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	Claims
AMOXICILLIN	PENICILLINS	4,316	\$ 149,107.06	\$ 34.55	2.93%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,811	\$ 52,049.31	\$ 18.52	1.91%
SERTRALINE HCL	ANTIDEPRESSANTS	2,398	\$ 40,486.25	\$ 16.88	1.63%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,353	\$ 66,920.84	\$ 28.44	1.60%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,291	\$ 70,934.78	\$ 30.96	1.55%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,131	\$ 35,464.65	\$ 16.64	1.44%
AZITHROMYCIN	MACROLIDES	2,118	\$ 53,388.53	\$ 25.21	1.44%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,063	\$ 41,467.28	\$ 20.10	1.40%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,996	\$ 288,454.12	\$ 144.52	1.35%
TRAZODONE HCL	ANTIDEPRESSANTS	1,929	\$ 31,442.45	\$ 16.30	1.31%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,892	\$ 42,711.51	\$ 22.57	1.28%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,851	\$ 36,741.13	\$ 19.85	1.25%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	1,756	\$ 46,683.69	\$ 26.59	1.19%
AMOXICILLIN-CLAVULANATE POTASS	PENICILLINS	1,708	\$ 67,168.23	\$ 39.33	1.16%
VYVANSE	AMPHETAMINES	1,576	\$ 326,933.29	\$ 207.44	1.07%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,555	\$ 21,048.17	\$ 13.54	1.05%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,519	\$ 58,589.20	\$ 38.57	1.03%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,473	\$ 28,487.50	\$ 19.34	1.00%
METFORMIN HCL	BIGUANIDES	1,468	\$ 21,328.24	\$ 14.53	1.00%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,359	\$ 21,817.05	\$ 16.05	0.92%
BUPROPION XL	ANTIDEPRESSANTS	1,254	\$ 30,063.98	\$ 23.97	0.85%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,243	\$ 25,094.41	\$ 20.19	0.84%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,242	\$ 20,836.28	\$ 16.78	0.84%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,239	\$ 19,539.96	\$ 15.77	0.84%
ADDERALL XR	AMPHETAMINES	1,238	\$ 239,282.92	\$ 193.28	0.84%
TOTAL TOP 25		46,779	\$ 1,836,040.83	\$ 39.25	31.72%
Total Rx Claims From 01/01/2017 - 03/31/2017	147,494]			



Top 10 Drugs Based on Number of Claims

NORTH DAKOTA MEDICAID Cost Management Analysis

05/04/2017

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 01/01/2017 - 03/31/2017

						% Total
Drug	AHFS Therapeutic Class	Rx		Paid	Paid/Rx	Claims
VYVANSE	AMPHETAMINES	1,576	\$	326,933.29	\$ 207.44	1.07%
NOVOLOG FLEXPEN	INSULINS	590	\$	288,689.43	\$ 489.30	0.40%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,996	\$	288,454.12	\$ 144.52	1.35%
ADDERALL XR	AMPHETAMINES	1,238	\$	239,282.92	\$ 193.28	0.84%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	644	\$	238,949.29	\$ 371.04	0.44%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	615	\$	205,898.71	\$ 334.79	0.42%
LATUDA	ANTIPSYCHOTIC AGENTS	227	\$	191,362.68	\$ 843.01	0.15%
LANTUS SOLOSTAR	INSULINS	457	\$		\$ 395.67	0.31%
PULMICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	399	\$	157,304.62	\$ 394.25	0.27%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	10	\$	152,172.51	\$15,217.25	0.01%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	466		149,539.82	\$ 320.90	0.32%
AMOXICILLIN	PENICILLINS	4,316	\$	149,107.06	\$ 34.55	2.93%
TAMIFLU	NEURAMINIDASE INHIBITORS	757	\$	143,327.31	\$ 189.34	0.51%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	40	\$	141,800.06	\$ 3,545.00	0.03%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	34	\$	139,787.02	\$ 4,111.38	0.02%
FREESTYLE LITE STRIPS	DIABETES MELLITUS	867	\$		\$ 141.76	0.59%
EPCLUSA	HCV ANTIVIRALS	5	\$	122,249.16	\$24,449.83	0.00%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	60	\$	111,876.00	\$ 1,864.60	0.04%
MAPAP	ANALGESICS AND ANTIPYRETICS, MISC.	638	\$	107,005.06	\$ 167.72	0.43%
PROVENTIL HFA	BETA-ADRENERGIC AGONISTS	1,123	\$	105,993.20	\$ 94.38	0.76%
COPAXONE	IMMUNOMODULATORY AGENTS	16		101,077.08	\$ 6,317.32	0.01%
LEVEMIR FLEXTOUCH	INSULINS	331	\$	95,474.23	\$ 288.44	0.22%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	332	\$	92,595.55	\$ 278.90	0.23%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	305	\$	88,999.54	\$ 291.80	0.21%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	158	\$	83,854.57	\$ 530.73	0.11%
TOTAL TOP 25		17,200	\$4	,025,458.05	\$ 234.04	11.66%
Total Rx Claims	147,494					

From 01/01/2017 - 03/31/2017



Top 10 Drugs Based on Total Claims Cost

Added to PA	Category
ADENOVATE 3000 UNIT	Antihemophilia
	Steroid Beta2
AIRDUO RESPICLICK	Agonist
ARYMO ER	Narcotics
AUSTEDO	>\$3,000
DUPIXENT	>\$3,000
EMFLAZA	>\$3,000
ESBRIET	>\$3,000
	Steroid Beta2
FLUTICASONE/SALMETEROL	Agonist
INGREZZA	>\$3,000
IXINITY	Antihemophilia
MIGERGOT	DHE
OCALIVA	>\$3,000
	Cytokine
SILIQ	Modulators
SYNJARDY XR	SGLT2 Inhibitors
TRULANCE	IBS/Constipation
XULTOPHY	GLP-1

Prior Authorization/PDL Update

Bill Medical Side VIA 837I AND 837P				
TRANSACTIONS				
DEFITELIO				
LEMTRADA				
LUCENTIS				
OCREVUS				
QUADRAMET				
TYSABRI				

No Longer Covered
XENICAL

PRODUCT DETAILS OF BILTRICIDE (praziquantel)

INDICATIONS AND USE:

Treatment of infections caused by the following: all species of Schistosoma and the liver flukes (Clonorchis sinensis/Opisthorchis viverrini)

DOSAGE AND ADMINISTRATION:

- Adult and Pediatric: 4 years and older
 - Clonorchiasis and Opisthorchiasis
 - Usual dose is 25 mg/kg 3 times daily, given 4 to 6 hours apart, for 1 day
 - Off-label
 - 25 mg/kg 3 times daily for 2 days
 - o Schistosomiasis
 - 20 mg/kg 3 times daily, given 4 to 6 hours apart, for 1 day
 - o Cysticercosis (off-label)
 - 50 mg/kg/day divided into 3 doses, given every 8 hours for 14 days
 - Tapeworms (off-label)
 - 5 to 10 mg/kg as a single dose (25 mg/kg for Hymenolepis nana)

DOSAGE FORM AND STRENGTHS:

• Biltricide is available as 600 mg tablet

CONTRAINDICATIONS:

- Patients with ocular cysticercosis
- Concomitant administration with strong cytochrome P450 (CYP-450) inducers
- Hypersensitivity to praziquantel or any component of the formulation;

WARNINGS AND PRECAUTIONS:

- Use with caution in patients with cardiac abnormalities due to the risk of unspecified arrhythmias occurring with Biltricide use.
- Biltricide may not be effective against migrating schistosomulae and may be associated with clinical deterioration such as paradoxical reactions or serum sickness.
- Use is not recommended in patients with a history of seizures or signs of central nervous system involvement as use of Biltricide may exacerbate the condition.
 - Patients with cerebral cysticercosis should be hospitalized for the duration of treatment.
- Potentially significant interactions exist, requiring dose or frequency adjustment, additional monitoring, and/or alternative therapy selection.
 - Medications that affect cytochrome 3A4
- Use with caution in patients with moderate to severe hepatic impairment.
- Patients should not drive or operate heavy machinery on the day of, and the day after treatment

ADVERSE REACTIONS:

The most common adverse reactions to therapy with Biltricide are dizziness, headache, fatigue, urticaria, abdominal distress, nausea, and vomiting. Increase serum liver enzymes labs have also been noted.

CURRENT UTILIZATION

ND Medicaid Biltricide Utilization				
Label Name	Rx Num	Total Reimb Amt		
BILTRICIDE 600 MG TABLET	1	\$92.50		

REFERENCES:

- 1. Facts & Comparisons eAnswers. Available at <u>http://online.factsandcomparisons.com.</u> Accessed on April 14, 2017.
- 2. Biltricide (praziquantel) [prescribing information]. Wayne, NJ: Schering; March 2014.

PRODUCT DETAILS OF PROGLYCEM (diazoxide)

INDICATIONS AND USE:

Proglycem is used for the management of hypoglycemia due to hyperinsulinism resulting from specific conditions in adults (inoperable islet cell adenoma or carcinoma, or extrapancreatic malignancy) and in children (leucine sensitivity, islet cell hyperplasia, nesidioblastosis, extrapancreatic malignancy, islet cell adenoma, or adenomatosis). Proglycem should be considered only when other medical or surgical management for hypocalcemia is unsuccessful or not feasible

DOSAGE AND ADMINISTRATION:

- Patients 1 year of age and older
 - The recommended starting dose of Proglycem is 3 mg/kg/day
 - Divided into 3 equal doses every 8 hours
 - Proglycem should be dosed to effect. Usual doses range from 3 to 8 mg/kg/day,
 - Divided into 2 or 3 equal doses every 8 or 12 hours
- Patients less than 12 months of age
 - The recommended starting dose of Proglycem is 10 mg/kg/day
 - Divided into 3 equal doses every 8 hours
 - Proglycem should be dosed to effect, Usual doses range from 8 to 15 mg/kg/day,
 - Divided into 2 or 3 equal doses every 8 or 12 hours
- Therapy should be discontinued if no effect is reached after 2-3 weeks.

DOSAGE FORM AND STRENGTHS:

• Proglycem is available as an oral suspension at a strength of 50 mg/mL.

CONTRAINDICATIONS:

- Patients with functional hypoglycemia
- Hypersensitivity to diazoxide, thiazides, or any component of the formulation;

WARNINGS AND PRECAUTIONS:

- Use may lead to increased fluid retention, and may precipitate heart failure in patients with compromised cardiac reserve.
- Ketoacidosis and non-ketotic hyperosmolar coma may occur during treatment, usually in patients with concomitant illness.
- Use with caution in patients with hyperuricemia or a history of gout.
- Development of abnormal facial features was reported in children treated more than 4 years for hypoglycemia hyperinsulinism.
- Some dosage forms may contain propylene glycol and/or benzoate/benzoic acid

ADVERSE REACTIONS:

The following is a list of the most frequent adverse reactions to therapy with Proglycem (specific frequency not defined)

- CV: Sodium and fluid retention, tachycardia, palpitations
- Endocrine: Hirusism (lanugo-type), hyperglycemia and glycosuria
- GI: anorexia, nausea, vomiting, abdominal pain, ileus, diarrhea, transient loss of taste
- Hematologic: Thrombocytopenia, transient neutropenia
- **Misc**: Increase serum uric acid, skin rash, headache, weakness and malaise.

ND Medicaid Proglycem Utilization					
Label Name	Rx Num	Total Reimb Amt	Avg Cost per Script		
PROGLYCEM 50 MG/ML ORAL SUSP	8	\$6,327.34	\$790.92		

REFERENCES:

- 1. Facts & Comparisons eAnswers. Available at <u>http://online.factsandcomparisons.com.</u> Accessed on April 14, 2017.
- 2. Proglycem (diazoxide) [prescribing information]. North Wales, PA: Teva; September 2015.
- 3. Proglycem (diazoxide) suspension [prescribing information]. Horsham, PA: Teva Select Brands; February 2012
































































Prepared by Health Information Designs, LLC



NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS 2ND QUARTER 2017

Criteria Recommendations

Approved Rejected

1. Benzodiazepines / Opioids

Alert Message: Co-administration of opioids and benzodiazepines should be done with extreme caution as the combination may result in respiratory depression, hypotension, profound sedation, coma, and death. If concurrent administration is clinically warranted consider dosage reduction of one or both agents. Re-evaluate the patient's treatment plan on a regular basis to determine the necessity for continued concomitant use of these agents.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Alprazolam	Codeine	
Chlordiazepoxide	Fentanyl	
Clonazepam	Hydrocodone	
Clorazepate	Hydromorphone	
Diazepam	Levorphanol	
Lorazepam	Meperidine	
Oxazepam	Methadone	
Estazolam	Morphine	
Flurazepam	Oxycodone	
Quazepam	Oxymorphone	
Temazepam	Tapentadol	
Triazolam	Tramadol	
Clobazam	Buprenorphine	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

Sun EC, Dixit A, Humphreys K, et al., Association Between Concurrent Use of Prescription Opioids and Benzodiazepines and Overdose: Retrospective Analysis. BMJ 2017;356:j760

Manchikanti L, Abdi S, Atluri S, et.al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1 – Evidence Assement. Pain Physician 2012;15:S67-S116.

Manchikanti L, Abdi S, Atluri S, et.al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance. Pain Physician 2012;15:S67-S116. VA/DoD Evidence Based Practice Clinical Practice Guideline Management of Opioid Therapy for Chronic Pain, May 2010. Department of Veterans Affairs, Department of Defense.

Available art: http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf

APS – AAPM Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain Evidence Review. The American Pain Society in Conjunction with the American Academy of Pain Medicine. 2009.

Available at: http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf

2. Codeine - All / Obesity & Severe Breathing Problems

Alert Message: The use of codeine-containing agents are not recommended in adolescent patients between 12 and 18 years of age who are obese or have conditions such as sleep apnea, or other severe lung disease due to risk of opioid-induced respiratory depression. Codeine is metabolized via CYP2D6 to morphine and ultra-rapid metabolizers of CYP2D6 can have excessive morphine formation and toxicity even after normal therapeutic doses.

Conflict Code: TA - Therapeutic Appropriateness (Warning)

Drugs/Diseases		
<u>Util A</u>	Util B	Util C (Include)
Codeine – All		Obesity
		Sleep Apnea
		Asthma
		Cystic Fibrosis
		•

Age Range: 12 -18 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm. Accessed April 21, 2017. European Medicines Agency (EMA): Codeine-containing Medicinal Products for the Treatment of Cough or Cold in Paediatric Patients. Retrieved July 1, 2015. Available on the World Wide Web http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Codeine_containing_medicinal_pro_ducts_for_the_treatment_of_cough_and_cold_in_paediatric_patients/human_referral_prac_000039.jsp&mid=WC0b0 1ac05805c516f

3. Codeine - All / Lactation

Alert Message: The use of codeine-containing agents is not recommended in nursing mothers. Codeine is metabolized to morphine which is excreted in breastmilk and may cause sedation and respiratory depression in breast-fed infants. Codeine is metabolized via CYP2D6 and if the nursing mother is a CYP2D6 ultra-rapid metabolizer excessive morphine formation can occur increasing the risk for excessive sedation and respiratory depression.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drugs/Diseases <u>Util A</u> Codeine - All Other Disorder of Lactation

<u>Util C</u>

Age Range: 11 -55 yoa Gender: Female

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women. Available at: https://www.fda.gov/Drugs/Drugs/Drugs49679.htm. Accessed April 21, 2017.

4. Tramadol - All / Therapeutic Appropriateness

Alert Message: Due to the risk of respiratory depression, the use of tramadol-containing agents is contraindicated for the treatment of pain in pediatric patients younger than 12 years of age and in post-operative pain management after tonsillectomy and/or adenoidectomy in pediatric patients younger than 18 years of age. Children who are ultra-rapid metabolizers of CYP2D6, an enzyme responsible for tramadol metabolism, are at increased risk for severe respiratory depression.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Tramadol – All

Age Range: < 18 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm. Accessed April 21, 2017.

5. Tramadol - All / Obesity & Severe Breathing Problems

Alert Message: The use of tramadol-containing agents are not recommended in adolescent patients between 12 and 18 years of age who are obese or have conditions such as sleep apnea, or other severe lung disease. Children who are ultra-rapid metabolizers of CYP2D6, an enzyme responsible for tramadol metabolism, are at increased risk for severe respiratory depression.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C (Include)
Tramadol – All		Obesity
		Sleep Apnea
		Asthma
		Cystic Fibrosis

Age Range: 12 -18 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women. Available at: https://www.fda.gov/Drugs/Drugs/Drugs49679.htm. Accessed April 21, 2017.

6. Tramadol - All / Lactation

Alert Message: The use of tramadol-containing agents is not recommended in nursing mothers. The parent drug tramadol and its active metabolite (M1) are excreted in breastmilk and may cause excessive sedation and respiratory depression, which could result in death in breast-fed infants. Tramadol is a CYP2D6 metabolized drug and if the nursing mother is a CYP2D6 ultra-rapid metabolizer M1 concentrations will be even higher with increased risk for adverse effects.

 Conflict Code: MC – Drug (Actual) Disease Precaution

 Drugs/Diseases

 Util A

 Util B

 Tramadol – All

 Lactation

 Other Disorder of Lactation

Age Range: 11 - 55 yoa Gender: Female

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women. Available at: <u>https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm</u>. Accessed April 21, 2017.

7. Soliqua / Overutilization

Alert Message: The manufacturers' recommended maximum daily dose of Soliqua (insulin glargine/lixisenatide) is 60 units per day. Administration of more than 60 units of insulin glargine/lixisenatide can result in overdose of the lixisenatide (> 20 mcg lixisenatide) component.

Conflict Code: ER - Overutilization ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Insulin Glargine/Lixisenatide</u>

Max Dose: 60 units per day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

8. Soliqua / GLP-1 Receptor Agonists

Alert Message: Soliqua (insulin glargine/lixisenatide) is not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist. Concurrent use of these agents represents an unnecessary duplication of therapy.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases Util A Util B Util C Insulin Glargine/Lixisenatide Lixisenatide Albiglutide Dulaglutide Exenatide Liraglutide

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

9. Soliqua / Gastroparesis

Alert Message: Soliqua (insulin glargine/lixisenatide) has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis. The lixisenatide component of the combination product slows gastric emptying, therefore, use of the product is not recommended in patients with severe gastroparesis.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B
 Util C

 Insulin Glargine/Lixisenatide
 Gastroparesis

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

10. Soliqua / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Soliqua (insulin glargine/lixisenatide) have not been established in pediatric patients below 18 years of age.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Insulin Glargine/Lixisenatide

Age Range: 0 - 17 yoa

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

11. Soliqua / Pancreatitis

Alert Message: Soliqua (insulin glargine/lixisenatide) has not been studied in patients with a history of pancreatitis. The lixisenatide component of the combination product is a GLP-1 receptor agonists and these agents have been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Consider alternative antidiabetic therapy in patients with a history of pancreatitis. If pancreatitis is suspected, promptly discontinue use. If pancreatitis is confirmed, restarting insulin glargine/lixisenatide is not recommended.

 Conflict Code: TA - Therapeutic Appropriateness

 Drugs/Diseases

 Util A

 Insulin Glargine/Lixisenatide

<u>Util C (Include)</u> Pancreatitis

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

12. Soliqua / Renal Impairment

Alert Message: Soliqua (insulin glargine/lixisenatide) should be used with caution in patients with renal impairment. The lixisenatide component is a GLP-1 receptor agonist and these agents have been associated with acute kidney injury and worsening of chronic renal failure. Monitor renal function in patients with renal impairment and in those with severe GI adverse reactions (majority of reported renal events occurred in patients who experienced nausea, vomiting, diarrhea, or dehydration). Insulin glargine/lixisenatide use is not recommended in patients with ESRD.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u> Insulin Glargine/Lixisenatide

<u>Util C **(Include)**</u> Renal Impairment

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

13. Soliqua / Hypokalemia

Alert Message: All insulin-containing products, including Soliqua (insulin glargine/lixisenatide), cause a shift in potassium from extracellular to intracellular space, possibly leading to hypokalemia. Monitor potassium levels in patients at risk for hypokalemia if indicated.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Insulin Glargine/Lixisenatide
 Hypokalemia

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

14. Soliqua / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate and well-controlled studies of Soliqua (insulin glargine/lixisenatide) in pregnant women. Lixisenatide-containing agents should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Abortion

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning

 Drugs/Diseases

 Util A

 Insulin Glargine/Lixisenatide

 Pregnancy

 Delivery

 Miscarriage

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

15. Soliqua / Nonadherence

Alert Message: Non-adherence to Soliqua (insulin glargine/lixisenatide) therapy may result in loss of glycemic control and an increased risk of developing diabetic-related complications.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u> Insulin Glargine/Lixisenatide

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487-497.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People with Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Util C

Butler RJ, Davis TK, Johnson WL, et al. Effects of Non Adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

16. Soliqua / Drugs That Increase Risk of Hypoglycemia

Alert Message: Caution should be exercised when Soliqua (insulin glargine/lixisenatide) is co-administered with drugs that can enhance the hypoglycemic effect of the antidiabetic agent. The patient may be at an increased risk for hypoglycemia. Dose reduction of insulin glargine/lixisenatide and increased frequency of glucose monitoring may be required when co-administering these drugs.

Conflict Code: DD - Drug Interaction

Drugs/Diseases			
Util A	<u>Util B</u>		<u>Util C</u>
Insulin Glargine/Lixisenatide	ACEIs	Pentoxifylline	
C C	ARBs	Pramlintide	
	Disopyramide	Salicylates	
	Fibrates	Sulfamethoxazole	
	MOAIs	Sulfasalazine	
	Fluoxetine	Sulfadiazine	
		Sulfisoxazole	
D (

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

17. Soliqua / Drugs That Decrease blood Glucose Lowering Effect

Alert Message: Caution should be exercised when Soliqua (insulin glargine/lixisenatide) is co-administered with drugs that can decrease the blood glucose lowering effect of insulin glargine/lixisenatide. The patient may be at risk for decreased therapeutic effect of antidiabetic agent. Dosage increase of insulin glargine/lixisenatide and increased frequency of glucose monitoring may be required when co-administering these drugs.

Conflict Code: DD – Drug Interaction Drugs/Diseases	on	
Util A	Util B	Util C
Insulin Glargine/Lixisenatide	Atypical Antipsychotics	
	Danazol	
	Isoniazid	
	Niacin	
	Oral Contraceptives	
	Estrogens	
	Protease Inhibitors	
	Somatropin	
Deferences	Thyroid Hormones	

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Soliqua 100/33 Prescribing Information, Nov. 2016, Sanofi-Aventis.

18. Xultophy / Overutilization

Alert Message: The manufacturer's recommended maximum daily dose of Xultophy (insulin degludec/liraglutide) is 50 units once daily. Administration of more than 50 units of insulin degludec/liraglutide can result in overdose of the liraglutide (> 1.8 mg liraglutide).

Util C

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Insulin degludec/Liraglutide

Max Dose: 50 units per day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

19. Xultophy / GLP-1 Receptor Agonists

Alert Message: Xultophy (insulin degludec/liraglutide) is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist. Concurrent use of these agents represents an unnecessary duplication of therapy.

Conflict Code: DD – Drug/Drug Drugs/Diseases	Interaction		
Util A	til Ă Util B Util (
Insulin degludec/Liraglutide	Liraglutide Lixisenatide Albiglutide Dulaglutide Exenatide		
References:			

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

20. Xultophy / Gastroparesis

Alert Message: Xultophy (insulin degludec/liraglutide) has not been studied in patients with gastroparesis and should be used with caution in this patients population. The liraglutide component of the combination product slows gastric emptying and may exacerbate existing gastroparesis.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Insulin degludec/Liraglutide
 Gastroparesis

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

21. Xultophy / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Xultophy (insulin degludec/liraglutide) have not been established in pediatric patients.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases Util A Util B Insulin degludec/Liraglutide

Util C

Age Range: 0 - 17 yoa

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

22. Xultophy / Pancreatitis

Alert Message: Xultophy (insulin degludec/liraglutide) has not been studied in patients with a history of pancreatitis. The liraglutide component of the combination product is a GLP-1 receptor agonist and these agents have been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Consider alternative antidiabetic therapy in patient with a history of pancreatitis. If pancreatitis is suspected, promptly discontinue use. If pancreatitis is confirmed, restarting insulin degludec/liraglutide is not recommended.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases Util A Util B Insulin degludec/Liraglutide

Util C (Include) Pancreatitis

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

23. Xultophy / Renal Impairment

Alert Message: Xultophy (insulin degludec/liraglutide) should be used with caution in patients with renal impairment as the liraglutide component of the combination product is a GLP-1 receptor agonist and these agents have been associated with acute kidney injury and worsening of chronic renal failure. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Advise patients of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases Util A Util B Util C (Include) Insulin degludec/Liraglutide **Renal Impairment**

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

24. Xultophy / Hypokalemia

Alert Message: All insulin-containing products, including Xultophy (insulin degludec/liraglutide), cause a shift in potassium from extracellular to intracellular space, possibly leading to hypokalemia. Monitor potassium levels in patients at risk for hypokalemia if indicated.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B
 Util C

 Insulin degludec/Liraglutide
 Hypokalemia

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

25. Xultophy / Pregnancy / Pregnancy Negating

Alert Message: There are not adequate and well-controlled studies of Xultophy (insulin degludec/liraglutide) in pregnant women. Liraglutide-containing agents should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning

 Drugs/Diseases

 Util A

 Insulin degludec/Liraglutide

 Pregnancy

 Delivery

 Miscarriage

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

26. Xultophy / Medullary Thyroid Carcinoma

Alert Message: The use of Xultophy (insulin degludec/liraglutide) is contraindicated in patients with a personal or family history of Medullary Thyroid Carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia Syndrome Type 2. Cases of MTC have been reported in patients treated with liraglutide a component of the combination product. In clinical trials, there were 7 reported cases of papillary thyroid carcinomas in liraglutide-treated patients.

Abortion

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u> Insulin degludec/Liraglutide

<u>Util C (Include)</u> Medullary Thyroid Carcinoma Multiple Endocrine Neoplasia Syndrome Type 2

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

27. Xultophy / Nonadherence

Alert Message: Non-adherence to Xultophy (insulin degludec/liraglutide) therapy may result in loss of glycemic control and an increased risk of developing diabetic-related complications.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u> Insulin degludec/Liraglutide

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487-497.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People with Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Util C

Butler RJ, Davis TK, Johnson WL, et al. Effects of Non Adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

28. Xultophy / Drugs That Increase Risk of Hypoglycemia

Alert Message: Caution should be exercised when Xultophy (insulin degludec/liraglutide) is co-administered with drugs that can enhance the hypoglycemic effect of the antidiabetic agent. The patient may be at an increased risk for hypoglycemia. Dose reduction of insulin degludec/liraglutide and increased frequency of glucose monitoring may be required when co-administering these drugs.

Conflict Code: DD - Drug Interaction Drugs/Diseases Util A Util B Util C Insulin degludec/Liraglutide ACEIs ARBs Disopyramide Fibrates MOAIs Fluoxetine Pentoxifylline Pramlintide Salicylates Sulfamethoxazole Sulfasalazine Sulfadiazine Sulfisoxazole

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

29. Xultophy / Drugs That Decrease blood Glucose Lowering Effect

Alert Message: Caution should be exercised when Xultophy (insulin degludec/liraglutide) is co-administered with drugs that can decrease the blood glucose lowering effect of insulin degludec/liraglutide. The patient may at risk for decreased therapeutic effect of the antidiabetic agent. Dosage increase of insulin degludec/liraglutide and increased frequency of glucose monitoring may be required when co-administering these drugs.

Conflict Code: DD – Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u>

<u>Util A</u>	<u>Util B</u>	Util C
Insulin degludec/Liraglutide	Atypical Antipsychotics Danazol	
	Isoniazid Niacin	
	Oral Contraceptives	
	Estrogens	
	Protease Inhibitors	
	Somatropin	
	Thyroid Hormones	

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Xultophy 100/3.6 Prescribing Information, Nov. 2016, Novo Nordisk Inc.

30. Daclizumab / Overutilization

Alert Message: The recommended dosage of Zinbryta (daclizumab) is 150 mg injected subcutaneously once monthly.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Daclizumab

Max Dose: 1 injection/month

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zinbryta Prescribing Information, May 2016, Biogen.

31. Daclizumab / Hepatic Impairment

Alert Message: The use of Zinbryta (daclizumab) is contraindicated in patients with pre-existing hepatic disease, hepatic impairment, including ALT and AST at least 2 times the ULN, history of autoimmune hepatitis or other autoimmune conditions involving the liver. Daclizumab can cause severe liver injury including life-threatening events, liver failure, and autoimmune hepatitis. Liver injury can occur at any time during treatment with daclizumab, with cases reported up to 4 months after the last dose of daclizumab.

 Conflict Code: TA – Therapeutic Appropriateness (Black Box Warning)

 Drugs/Diseases

 Util A
 Util B

 Daclizumab
 Util C (Include)

 Hepatic Impairment

 Autoimmune Hepatitis

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zinbryta Prescribing Information, May 2016, Biogen.

32. Daclizumab / Depression & Suicidal Ideation

Alert Message: The use of Zinbryta (daclizumab) has been associated with depression-related events, including suicidal ideation or suicide attempt. Daclizumab should be used with caution in patients with previous or current depressive disorders. Advise patients and/or caregivers to immediately report any symptoms of new or worsening depression and/or suicidal ideation to their healthcare provider.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

<u>Util A</u>	Util B	<u>Util C (Include)</u>
Daclizumab		Depression
		Suicidal Ideation

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zinbryta Prescribing Information, May 2016, Biogen.

33. Daclizumab / Therapeutic Appropriateness

Alert Message: Safety and effectiveness of Zinbryta (daclizumab) in patients less than 17 years of age have not been established. Use of daclizumab is not recommended in pediatric patients due to the risk of hepatic injury and immune-mediated disorders.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Daclizumab

Age Range: 0 - 16 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zinbryta Prescribing Information, May 2016, Biogen.

34. Daclizumab / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate studies on the developmental risk associated with the use of Zinbryta (daclizumab) in pregnant women. Daclizumab is a monoclonal antibody and these agents are known to cross the placenta. Administration of daclizumab in monkeys during gestation resulted in embryofetal death and reduced fetal growth at maternal exposures greater than 30 times that expected clinically.

Conflict Code: MC – Drug (Actual) Disease Warning Drugs/Diseases Util A Util B Util C (Negating)

Daclizumab	Pregnancy	Miscarriage
		Delivery
		Abortion

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zinbryta Prescribing Information, May 2016, Biogen.

35. Daclizumab / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Zinbryta (daclizumab). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR -	Nonadherence	
Drugs/Diseases		
Util A	Util B	Util C
Daclizumab		

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497. Remington G, Rodriguez Y, Logan D, et al., Facilitating Medication Adherence in Patients with Multiple Sclerosis. Int J MS Care. 2013;15:36-45. McKay KA, Tremlett H, Patten SB, et al., Determinants of Non-adherence to Diseases-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler Jrnl. 2016 June 29;1-9.

36. Daclizumab / Hepatotoxic Drugs

Alert Message: Caution should be exercised when administering Zinbryta (daclizumab) with drugs that can cause hepatotoxicity. Daclizumab can cause severe liver injury, including life-threatening events, and the use with other agents that cause liver injury may increase the risk of the adverse effect.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Daclizumab	Allopurinol	Nevirapine	
	Amiodarone	Nitrofurantoin	
	Amoxicillin-clavulanate	Phenytoin	
	Atorvastatin	Propylthiouracil	
	Azathioprine	Quinidine	
	Busulfan	Pyrazinamide	
	Carbamazepine	Rifampin	
	Chlorpromazine	Simvastatin	
	Dantrolene	TMP-SMZ	
	Diclofenac	Sulfasalazine	
	Didanosine	Sulindac	
	Disulfiram	Telithromycin	
	Efavirenz	Ticlopidine	
	Erythromycin	Valproate	
	Flutamide	Alectinib	
	Ibuprofen	Sunitinib	
	Infliximab	Idelalisib	
	Interferon	Ixazomib	
	Isoniazid	Erlotinib	
	Itraconazole	Lenvatinib	
	Ketoconazole	Nefazodone	
	Methotrexate	Maraviroc	
	Methyldopa		
	Minocycline		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Zinbryta Prescribing Information, May 2016, Biogen.

Bjornsson, ES. Hepatotoxicity by Drugs: The Most Common Implicated Agents. Int Jrnl Mol Sci. 2016 Feb; 17(2);244.

37. Panobinostat / Diarrhea

Alert Message: Farydak (panobinostat) can cause severe diarrhea. Monitor patient for symptoms and ensure the patient has adequate hydration prior to and during therapy. Initiate anti-diarrheal treatment medication at the onset of diarrhea. Interrupt panobinostat therapy at the onset of moderate diarrhea (4 to 6 stools/day) or severe diarrhea (>/= 7 stools/day).

 Conflict Code: MC – Drug (Actual) Disease Warning (Black Box Warning)

 Drugs/Diseases

 <u>Util A</u>

 <u>Util B</u>

 Diarrhea

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

38. Panobinostat / Cardiovascular Events

Alert Message: Severe and fatal cardiac ischemic events, including arrhythmias and ECG changes, have occurred in patients receiving Farydak (panobinostat). Panobinostat may prolong the QT interval. Obtain ECG and electrolytes at baseline and periodically during treatment as clinically indicated. Panobinostat should not be initiated in patients with a QTcF > 450 msec or clinically significant baseline ST-segment or T-wave abnormalities.

 Conflict Code: MC – Drug (Actual) Disease Warning (Black Box Warning)

 Drugs/Diseases

 Util A
 Util B

 Panobinostat
 Util C (Include)

 Myocardial Infarction

 Angina

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

QT Prolongation

*QTcF is the Fridericia corrected QT interval and was formula was used to calculate the QT interval in the clinical trials for Farydak (panobinostat). More than 30 correction formulae have been proposed, of which Bazett's (QTcB) and Fridericiaís (QTcF) corrections are the most widely used. Fridericiaís formula generates a more accurate correction in this circumstance.

39. Panobinostat / Hepatic Impairment

Alert Message: Farydak (panobinostat) can cause hepatic dysfunction. Liver function should be monitored prior to treatment and regularly during treatment. If abnormal liver function tests are observed dose adjustment may be considered. The starting dose of panobinostat should be reduced in patients with mild or moderate hepatic impairment (15 mg and 10 mg, respectively). Avoid use in patients with severe hepatic impairment.

Conflict Code: MC – Drug (Actual) Disease WarningDrugs/DiseasesUtil AUtil BPanobinostatUtil C (Include)Hepatic Impairment

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

40. Panobinostat / Hemorrhage

Alert Message: Fatal and serious hemorrhage has been reported during treatment with Farydak (panobinostat). Obtain a baseline platelet count prior to therapy and monitor the CBC weekly during therapy. Interruption of panobinostat therapy, dose adjustment or drug discontinuation may be necessary if severe toxicity occurs.

Conflict Code: M Drugs/Diseases	C – Drug (Actual) Disease Warning	
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Panobinostat	Gastrointestinal Bleed	
	Subarachnoid Hemorrhage	
	Intracerebral Hemorrhage	
References:	· ·	
Clinical Pharmac	ology 2017 Elsevier/Gold Standard	

Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

41. Panobinostat 15 mg & 20 mg / Strong CYP3A4 Inhibitors

Alert Message: The dose of Farydak (panobinostat) should be reduced to 10 mg when co-administered with strong CYP3A4 inhibitors. Panobinostat is a CYP3A4 substrate and inhibition of its CYP3A4-medicated metabolism may result in significantly increased panobinostat exposure and risk of adverse effects.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Panobinostat 15 & 20mg	Nefazodone Clarithromycin Telithromycin Saquinavir Ritonavir Nelfinavir Indinavir	Ketoconazole Itraconazole Voriconazole Posaconazole Cobicistat	
Max Daga: 10 mg			

Max Dose: 10 mg

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

42. Panobinostat / Strong CYP3A4 Inducers

Alert Message: Concurrent use of Farydak (panobinostat), a CYP3A4 substrate, with strong CYP3A4 inducers should be avoided. While drug interaction studies have not been conducted simulation studies using mechanistic models suggest an approximate 70% decrease in the systemic exposure of panobinostat in the presence of strong inducers of CYP3A4.

Conflict Code: DD – Drug/Drug Interaction

<u>Util B</u>		Util C
Phenytoin	Rifampin	
Phenobarbital	Rifabutin	
Primidone	Rifapentine	
Carbamazepine		
	Phenytoin Phenobarbital Primidone	Phenytoin Rifampin Phenobarbital Rifabutin Primidone Rifapentine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

43. Panobinostat / Sensitive CYP2D6 Substrates

Alert Message: Concurrent use of Farydak (panobinostat), a CYP2D6 inhibitor, with sensitive CYP2D6 substrates (e.g., atomoxetine, metoprolol, and venlafaxine) should be avoided due to risk of elevated CYP2D6 substrate concentrations. If concomitant use with the CYP2D6 substrate is unavoidable monitor patient frequently for adverse reactions.

Conflict Code: DD – Drug/Drug Interaction

Diugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Panobinostat	Atomoxetine	Nebivolol	
	Desipramine	Perphenazine	
	Dextromethorphan	Tolterodine	
	Metoprolol	Venlafaxine	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

44. Panobinostat / QT Prolongation Drugs

Alert Message: Farydak (panobinostat) has been shown to increase the QTc interval and therefore use with drugs that are known to prolong the QT interval is not recommended.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases					
<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Panobinostat	Albuterol	Disopyramide	Imipramine	Pazopanib	Tolterodine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Trazodone
	Amantadine	Dolasetron	Isradipine	Posaconazole	TMP/SMZ
	Amiodarone	Doxepin	Itraconazole	Procainamide	Trimipramine
	Amitriptyline	Dronedarone	Ketoconazole	Propafenone	Vandetanib
	Amphetamine	Droperidol	Lapatinib	Protriptyline	Vardenafil
	Arsenic Trioxide	Ephedrine	Levalbuterol	Quetiapine	Atazanavir
	Asenapine	Epinephrine	Levofloxacin	Quinidine	Ziprasidone
	Erythromycin	Lithium	Ranolazine	Venlafaxine	Zolmitriptan
	Atomoxetine	Escitalopram	Metaproterenol	Risperidone	Ezogabine
	Azithromycin	Felbamate	Methadone	Tizanidine	Rasagiline
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Phenelzine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Tranylcypromine
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Linezolid
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Isocarboxazid	Paliperidone	Telithromycin	
	Diphenhydramine	lloperidone	Paroxetine	Terbutaline	
	· •	-			

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

45. Panobinostat / Therapeutic Appropriateness

Alert Message: Farydak (panobinostat) can cause fetal harm. Advise females of reproductive potential to avoid becoming pregnant while taking panobinostat and to use effective contraception while taking panobinostat and for at least 1 month after the last dose. Because of the potential risk of male-medicated teratogenicity, advise sexually active men to use condoms while on treatment and for 3 months after their last dose of panobinostat.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Panobinostat

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Farydak Prescribing Information, Feb. 2015, Novartis Pharmaceuticals Corporation.

46. Saxagliptin - All / Pancreatitis

Alert Message: There have been post-marketing reports of acute pancreatitis in patients taking saxagliptin-containing products (Onglyza, Kombiglyze XR, and Qtern). After initiation of a saxagliptin-containing agent, the patient should be observed for signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue the saxagliptin-containing agent and initiate appropriate management.

 Conflict Code: MC – Drug (Actual) Disease Precaution/ Warning

 Drugs/Diseases

 Util A
 Util B

 Saxagliptin
 Pancreatitis

 Saxagliptin/Metformin

 Saxagliptin/ Dapagliflozin

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health.

47. Saxagliptin – All / Heart Failure

Alert Message: Consider the risks and benefits of saxagliptin-containing therapy (Onglyza, Kombiglyze XR, and Qtern) in patients who have a history of or who have increased risk factors for heart failure. An increased risk of hospitalization for heart failure has been reported in patients receiving saxagliptin in a cardiovascular outcomes trial. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuing the saxagliptin-containing agents.

Conflict Code: MC – Drug (Actual) Disease Precaution/ Warning Drugs/Diseases Util A Util B Util C (Include)

<u>Util Á</u> Saxagliptin Saxagliptin/Metformin Saxagliptin/ Dapagliflozin Util C (Include) Heart Failure Dyspnea Fatigue Edema Tachycardia Arrhythmia

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health.

48. Venetoclax / Overutilization

Alert Message: Venclexta (venetoclax) may be over-utilized. The manufacturer's recommended maximum daily dose is 400 mg.

Conflict Code: ER – Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Venetoclax

Max Dose: 400 mg/day

References: Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

49. Venetoclax / Strong CYP3A4 Inhibitors

Alert Message: Avoid concomitant use of strong CYP3A4 inhibitors with the CYP3A4 substrate Venclexta (venetoclax) in patients who have completed the ramp-up phase and are on a steady daily dose of venetoclax. If a strong CYP3A4 inhibitor must be used, reduce the venetoclax dose by 75%. Resume the venetoclax dose that was used prior to initiating the CYP3A4 inhibitor 2 to 3 days after discontinuation of the inhibitor. Concurrent use of a strong CYP3A4 inhibitor with venetoclax is contraindicated at initiation and during ramp-up phase of venetoclax therapy.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>	Util C (Include)	
Venetoclax		Clarithromybin	Ketoconazole
		Cobicistat	Itraconazole
		Saquinavir	Voriconazole
		Ritonavir	Posaconazole
		Indinavir	Telithromycin
		Nelfinavir	
		Idelalisib	
Max Dose: > 100) mg/day		

Max Dose: > 100 mg/day Day Supply: > 35 days

References:

Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

50. Venetoclax / Moderate & Strong CYP3A4 Inducers

Alert Message: Avoid concomitant use of Venclexta (venetoclax), a CYP3A4 substrate, with moderate to strong CYP3A4 inducers. Consider alternative treatments with less CYP3A4 induction.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases					
<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Venetoclax	Carbamazepine Phenytoin	Rifabutin	Rifapentine Bosentan	Efavirenz Etravirine	
	Phenobarbital	Rifampin	Modafinil		

References:

Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

51. Venetoclax / Moderate CYP3A4 Inhibitors & P-gp Inhibitors

Alert Message: Avoid concomitant use of moderate CYP3A4 inhibitors or P-gp inhibitors with the CYP3A4 substrate Venclexta (venetoclax). Consider alternative treatment options. If a moderate CYP3A4 or P-gp inhibitor must be used, reduce the venetoclax dose by 50% and monitor the patient closely for signs of venetoclax toxicities. Resume the venetoclax dose that was used prior to initiating the CYP3A4 inhibitor 2 to 3 days after discontinuation of the inhibitor.

Conflict Code: DD – Drug/Drug Interaction

Diuys/Diseases			
<u>Util A</u>	<u>Util B</u>		Util C
<u>Venetoclax</u>	Erythromycin Ciprofloxacin Diltiazem Dronedarone Fluconazole Verapamil Diltiazem Aprepitant Cimetidine Crizotinib Imatinib	Cyclosporine Felodipine Quinidine Ranolazine Ticagrelor Amiodarone Azithromycin Captopril Carvedilol	
Deferences			

References:

Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

52. Venetoclax / P-gp Substrates w/ Narrow Therapeutic Indexes

Alert Message: Avoid concomitant use of a drug that is a P-gp substrate that has a narrow therapeutic index with the P-gp inhibitor Venclexta (venetoclax). If the concurrent use is warranted, the P-gp substrate should be taken at least 6 hours before venetoclax.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Venetoclax Digoxin

Digoxin
Everolimus
Sirolimus
Tacrolimus

References:

Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2016 Elsevier/Gold Standard.

53. Venetoclax / Therapeutic Appropriateness – Pediatric Patients

Alert Message: Safety and effectiveness of Venclexta (venetoclax) have not been established in pediatric patients.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Venetoclax

Age Range: 0 – 17 yoa

References: Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

54. Venetoclax / Therapeutic Appropriateness

Alert Message: Based on its mechanism of action and findings in animals, Venclexta (venetoclax) may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should undergo pregnancy testing before initiation of venetoclax and should be advised to use effective contraception during treatment with venetoclax and for at least 30 days after the last dose.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases Util A Util B Util C (Negating)

Oral Contraceptives Injectable Contraceptives Transdermal Contraceptives Implantable Contraceptives

Gender: Female Age Range: 11 – 50 yoa

Venetoclax

References: Venclexta Prescribing Information, April 2016, AbbVie Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

55. Idelalisib / Overutilization

Alert Message: The manufacturer's recommended maximum daily dose of Zydelig (idelalisib) is 150 mg twice daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Idelalisib

Max Dose: 300 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

56. Idelalisib / Hepatic Impairment

Alert Message: Fatal and/or serious hepatotoxicity occurred in 18% of patients treated with Zydelig (idelalisib) monotherapy and 11% of patients treated with idelalisib in combination trials. Monitor ALT and AST in all patients receiving idelalisib every 2 weeks for the first 3 months of treatment, every 4 weeks for the next 3 months, then every 1 to 3 months thereafter. Withhold idelalisib if the ALT and AST is greater than 5 times the upper limit of normal, and continue to monitor AST, ALT, and total bilirubin weekly until the abnormality it resolved.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning (Black Box Warning)

 Drugs/Diseases

 Util A
 Util B

 Idelalisib
 Hepatic Impairment

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

57. Idelalisib / Diarrhea & Colitis

Alert Message: Fatal and/or severe diarrhea or colitis occurred in 14% of patients treated with Zydelig (idelalisib) monotherapy and 19% of patients treated with idelalisib in combination trials. Diarrhea can occur at any time during idelalisib treatment. In case of severe diarrhea or colitis interrupt idelalisib therapy until problem is resolved then reinitiate therapy at a reduced dose of 100 mg twice a day. Discontinue idelalisib permanently in patients with life-threatening diarrhea.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning (Black Box Warning) Drugs/Diseases Util A Util B Util C

Diamica	
Colitis	
	Diarrhea Colitis

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

58. Idelalisib / Pneumonitis

Alert Message: Fatal and/or serious pneumonitis occurred in 4% of patients treated with Zydelig (idelalisib) in clinical trials. Monitor patient for pulmonary symptoms and bilateral interstitial infiltrates. If pneumonitis is suspected, interrupt idelalisib until etiology of pulmonary symptoms has been determined. Patients with pneumonitis thought to be caused by idelalisib have been treated with discontinuation of idelalisib and administration of corticosteroids.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning (Black Box Warning) Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Idelalisib	Pneumonitis	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

59. Idelalisib / GI Perforation

Alert Message: Fatal and/or serious intestinal perforation can occur in patients receiving Zydelig (idelalisib). At the time of perforation, some patients had moderate to severe diarrhea. Advise patients to promptly report any new or worsening abdominal pain, chills, fever, nausea, or vomiting. Discontinue idelalisib permanently in patients who experience intestinal perforation.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning (Black Box Warning)

 Drugs/Diseases

 Util A
 Util B

 Idelalisib
 GI Perforation

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

60. Idelalisib / Neutropenia

Alert Message: Treatment-emergent Grade 3 or 4 neutropenia occurred in 25% of patients treated with Zydelig (idelalisib) monotherapy and 46% of patients treated with idelalisib in combination trials. Monitor blood counts at least every 2 weeks for the first 6 months of therapy, and at least weekly in patients while neutrophil counts are less than 1.0 Gi/L.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Idelalisib
 Neutropenia

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

61. Idelalisib / Therapeutic Appropriateness

Alert Message: Based on findings in animals, Zydelig (idelalisib) may cause fetal harm when administered to a pregnant woman. If the drug is used during pregnancy, or if the patient becomes pregnant while taking the drugs, apprise the patient of the potential hazard to the fetus. Advise females of reproductive potential to avoid becoming pregnant while taking idelalisib and for 1 month after the last dose of idelalisib.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Idelalisib

Gender: Female Age Range: 11 – 50 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

62. Idelalisib / Strong CYP3A4 Inducers

Alert Message: The concurrent use of Zydelig (idelalisib) with a strong CYP3A4 inducer should be avoided. Idelalisib is a CYP3A4 substrate and co-administration with a strong CYP3A4 inducer may result in a significant decrease in idelalisib exposure and loss of therapeutic effect.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C
Idelalisib	Phenytoin	
	Phenobarbital	
	Primidone	
	Carbamazepine	
	Rifampin	
	Rifapentine	
	Rifabutin	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

63. Idelalisib / Strong CYP3A4 Inhibitors

Alert Message: The concurrent use of Zydelig (idelalisib), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in increased idelalisib exposure and should be avoided. If concomitant use is warranted, monitor the patient for signs of idelalisib toxicity. Follow manufacturer recommended dose modifications for adverse reactions.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
Util A	Util B		Util C
Idelalisib	Ketoconazole	Clarithromycin	
	Itraconazole	Atazanavir	
	Nefazodone	Saquinavir	
	Telithromycin	Ritonavir	
	Indinavir	Nelfinavir	
	Voriconazole	Cobicistat	
	Posaconazole		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Zydelig Prescribing Information, September 2016. Gilead Sciences.

64. Cobicistat / Irinotecan / Atazanavir

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Tybost (cobicistat) and a drug that is contraindicated. Co-administration of cobicistat and the identified agent may result in serious and/or life-threatening events.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Include)
Cobicistat	Irinotecan	Atazanavir

References:

Tybost Prescribing Information, June 2016, Gilead Sciences, Inc. Clinical Pharmacology, 2017, Elsevier/Gold Standard.

65. Cobicistat / Nevirapine / Atazanavir

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Tybost (cobicistat) and a drug that is contraindicated. Co-administration of cobicistat and the identified agent may result in serious and/or life-threatening events.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Include)
Cobicistat	Nevirapine	Atazanavir

References:

Tybost Prescribing Information, June 2016, Gilead Sciences, Inc. Clinical Pharmacology, 2017, Elsevier/Gold Standard.
66. Cobicistat / Indinavir / Atazanavir

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Tybost (cobicistat) and a drug that is contraindicated. Co-administration of cobicistat and the identified agent may result in serious and/or life-threatening events.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Diago Discuses		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Cobicistat	Indinavir	Atazanavir

References:

Tybost Prescribing Information, June 2016, Gilead Sciences, Inc. Clinical Pharmacology, 2017, Elsevier/Gold Standard.

67. Elvitegravir / Other Antiretrovirals

Alert Message: The patient appears to be receiving an INSTI-based ART regimen that is not recommended in treatment-naive patients. The recommended INSTI-based regimens for non-pregnant, adolescent and adults involving elvitegravir include: elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine or elvitegravir/cobicistat/tenofovir disoproxil/emtricitabine.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Elvitegravir	Maraviroc	Atazanavir	
	Enfuvirtide	Darunavir	
	Delavirdine	Fosamprenavir	
	Efavirenz	Indinavir	
	Nevirapine	Nelfinavir	
	Rilpivirine	Ritonavir	
	Abacavir	Saquinavir	
	Didanosine	Tipranavir	
	Lamivudine	•	
	Stavudine		
	Zidovudine		

Age Range: ≥ 12 yoa

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. July 14, 2016. Available at: http://www.aidsinfo.nih.gov/contentfiles/adultand-adolescentgl.pdf.

Panel on Treatment of HIV-infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal\HIV Transmission in the United States. March 28, 2014. Available at: http://aidsinfor.nih.gov/contentfiels/PerinatalGL.pdf

Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. March 1, 2016.

Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

68. Dabigatran / Lovastatin & Simvastatin

Alert Message: Concurrent use of Pradaxa (dabigatran), a P-gp substrate, with simvastatin or lovastatin, strong P-gp inhibitors, may result in increased dabigatran systemic exposure and risk of hemorrhage. Separating the timing of administration of the agents by at least 2 hours may mitigate this interaction. Another consideration is switching the patient to a statin that is not a strong P-gp inhibitor (e.g., atorvastatin, pravastatin, and rosuvastatin) to avoid the increased risk of hemorrhage.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases Util A Util B Util C

		Ull
Dabigatran	Lovastatin	
	Simvastatin	

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Antoniou T, Macdonald EM, Yao Z, et al. Association Between Statin Use and Ischemic Stroke or Major Hemorrhage in Patients Taking Dabigatran for Atrial Fibrillation. *CMAJ* 2016; DOI:10.1503/cmaj.160303 Pradaxa Prescribing Information, Nov. 2015, Boehringer Ingelheim Pharmaceuticals, Inc.

69. ADHD Stimulants / Overutilization

Alert Message: Caution is advised when stimulants are co-administered with serotonergic agents (e.g., SSRIs, SNRIs, and triptans). Concurrent use of these agents may result in potentially life-threatening serotonin syndrome (e.g., agitation, hallucinations, tachycardia, hyperthermia, hyperreflexia, nausea, and vomiting). If concomitant therapy is warranted, monitor the patient for signs and symptoms, particularly during initiation of therapy and dose increases.

Conflict Code: DD – Drug/Drug Interaction

Diago, Discuses			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Methylphenidate	SSRIs	Nefazodone	
Dexmethylphenidate	SNRIs	Mirtazapine	
Amphetamine	TCAs	Trazodone	
Dextroamphetamine	Triptans	Lithium	
Methamphetamine	Ergot Alkaloids	Meperidine	
Lisdexamfetamine	Buspirone	Fentanyl	
	Tramadol		
References:			

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

70. Cabozantinib / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Cabometyx (cabozantinib) have not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Cabozantinib Tabs

Age Range: 0 – 17 yoa

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

71. Cabozantinib / Therapeutic Appropriateness

Alert Message: Based on it mechanism of action, Cabometyx (cabozantinib) can cause fetal harm when administered to a pregnant woman. If used during pregnancy or if the patient becomes pregnancy while taking this drug, she should be apprised of the potential hazard to the fetus. Advise females of reproductive potential to use effective contraception during treatment with cabozantinib and for 4 months after the last dose.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Cabozantinib Tabs

Gender: Female Age Range 11 – 50

References: Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

72. Cabozantinib / Overuse

Alert Message: Cabometyx (cabozantinib) may be over-utilized. The manufacturer's maximum recommended dose for a patient with renal cell carcinoma is 60 mg once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Cabozantinib Tabs

Max Dose: 60 mg/day

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

73. Cabozantinib / Hepatic Impairment

Alert Message: Increased exposure to Cabometyx (cabozantinib) has been observed in patients with mild to moderate hepatic impairment. Reduce the cabozantinib dose in patients with mild (Child-Pugh score (C-P) A) or moderate (C-P B) hepatic impairment. Cabozantinib is not recommended for use in patients with severe hepatic impairment.

 Conflict Code:
 TA – Therapeutic Appropriateness

 Drugs/Diseases
 Util A

 Util A
 Util B

 Cabozantinib Tabs
 Hepatic Impairment

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

74. Cabozantinib / GI Perforations / Fistulas

Alert Message: Cabometyx (cabozantinib) has been shown to cause gastrointestinal (GI) perforations and fistulas in patients with renal cell carcinoma. Patients should be monitored for symptoms of fistulas and perforations. Cabozantinib therapy should be permanently discontinued in patients who experience a fistula which cannot be appropriately managed or a GI perforation.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases Util A Util B Util C

Cabozantinib Tabs	GI Perforation	
	Fistulas	

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

75. Cabozantinib / Hemorrhage

Alert Message: Serious and sometimes fatal hemorrhage has occurred with Cabometyx (cabozantinib) therapy. Do no administer cabozantinib to patients who have or are at risk for severe hemorrhage.

 Conflict Code:
 TA – Therapeutic Appropriateness

 Drugs/Diseases
 Util A

 Util A
 Util B

 Cabozantinib Tabs
 GI Hemorrhage

GI Hemorrhage Subarachnoid Hemorrhage Intracerebral Hemorrhage Hemorrhage, unspecified

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

76. Cabozantinib / Thrombotic Events

Alert Message: Cabometyx (cabozantinib) treatment results in an increased incidence of thrombotic events. Cabozantinib should be discontinued in patients who experience an acute myocardial infarction or other clinically significant arterial thromboembolic complication.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

Diuga/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C
Cabozantinib Tabs	Cerebral Thrombosis	
	Arterial Thrombosis	
	Venous Thrombosis	
Deferences		

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

77. Cabozantinib / CYP3A4 Inhibitors

Alert Message: Concomitant use of Cabometyx (cabozantinib) with strong CYP3A4 inhibitors (e.g., ketoconazole and clarithromycin) may result in increased exposure of cabozantinib and may increase the risk of exposure-related toxicity. If concurrent use cannot be avoided, the dose of cabozantinib should be reduced by 20 mg. Resume the dose that was used prior to initiating the CYP3A4 inhibitor 2 to 3 days after discontinuation of the strong inhibitor.

Conflict Code: DD – Drug-Drug Interaction Drugs/Diseases

Diago, Diobabbo			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Cabozantinib Tabs	Ketoconazole Itraconazole Nefazodone Telithromycin Indinavir	Clarithromycin Atazanavir Saquinavir Ritonavir Nelfinavir	
	Voriconazole	Cobicistat	
	Posaconazole		
Defenses			

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

78. Cabozantinib / CYP3A4 Inducers

Alert Message: Concomitant use of Cabometyx (cabozantinib) with strong CYP3A4 inducers (e.g., phenytoin and carbamazepine) may result in decreased exposure of cabozantinib leading to reduced efficacy. If concurrent use cannot be avoided, the dose of cabozantinib should be increased by 20 mg (i.e., 60 mg to 80 mg daily or 40 mg to 60 mg daily) as tolerated but should not exceed 80 mg daily. Resume the cabozantinib dose that was used prior to initiating the inducer 2 to 3 days after inducer discontinuation.

Util C

Conflict Code: DD – Drug-Drug Interaction

Drugs/Diseases			
Util A	Util B		
Cabozantinib Tabs	Phenytoin	Carbamazepine	
	Rifampin	Rifabutin	
	Rifapentine	Phenobarbital	

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

79. Cabozantinib / Hypertension

Alert Message: Patients taking Cabometyx (cabozantinib) show increased incidence of treatment-emergent hypertension. In a randomized trial, hypertension was reported in 37% of cabozantinib-treated patients as compared to 3.1 % of everolimus-treated patients. Blood pressure should be monitored prior to and throughout therapy. Cabozantinib should be discontinued if there is evidence of hypertensive crisis or severe hypertension that cannot be controlled with anti-hypertensive therapy.

 Conflict Code:
 DB – Drug-Drug Marker and/or Diagnosis

 Drugs/Diseases
 Util B

 Util A
 Util B

 Cabozantinib Tabs
 Hypertension

 Anti-Hypertensive Drugs

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

80. Cabozantinib / Palmar-Plantar Erythrodysesthesia Syndrome

Alert Message: Palmar-plantar erythrodysesthesia syndrome (PPES) has been reported in patients treated with Cabometyx (cabozantinib). Cabozantinib should be withheld in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1, at which time cabozantinib therapy can resume at a reduced dose.

 Conflict Code:
 MC – Drug/Diagnosis Precaution/Warning/Contraindication

 Drugs/Diseases
 Util A

 Util A
 Util B

 Cabozantinib Tabs
 Palmar-Plantar Erythrodysesthesia Syndrome

<u>Util C</u>

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

81. Cabozantinib / Proteinuria

Alert Message: In clinical trials, proteinuria was observed in 2% of patients receiving Cabometyx (cabozantinib) as compared to < 1 % of patient receiving everolimus. Cabozantinib should be discontinued in patients who develop nephrotic syndrome.

 Conflict Code:
 MC – Drug/Diagnosis Precaution/Warning/Contraindication

 Drugs/Diseases
 Util A

 Util A
 Util B

 Cabozantinib Tabs
 Proteinuria

 Nephrotic Syndrome
 Nephrotic Syndrome

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

82. Cabozantinib / Reversible Posterior Leukoencephalopathy Syndrome

Alert Message: Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been reported with Cabometyx (cabozantinib) treatment. An evaluation for RPLS should be performed in any patient presenting with seizures, headaches, visual disturbances, confusion or altered mental function. Cabozantinib should be discontinued if RPLS develops.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication

<u>Util B</u>	<u>Util C</u>
Seizures	
Headache	
Visual Distur	bances
Confusion	
Altered Ment	al Function
	Seizures Headache Visual Distur Confusion

References:

Cabometyx Prescribing Information, April 2016, Exelixis, Inc. Clinical Pharmacology, 2017 Elsevier / Gold Standard.

83. Ivacaftor / Overutilization (\geq 6 yoa)

Alert Message: The recommended daily dose of Kalydeco (ivacaftor) for patients 6 years of age and older is 150 mg taken every 12 hours (300 mg total daily dose).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util</u> Ivacaftor He

Util C (Negating) Hepatic Impairment

Age Range: ≥ 6 yoa Max Dose: 300 mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

84. Ivacaftor / Overutilization- (2 - 5 yoa)

Alert Message: The recommended daily dose of Kalydeco (ivacaftor) for patients ages 2 to less than 6 years of age is weight-based. Patients weighing less than 14 kg should receive one 50 mg ivacaftor packet every 12 hours (100 mg total daily dose). Patients weighing 14 kg or more should receive one 75 mg ivacaftor packet every 12 hours (150 mg total daily dose).

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Ivacaftor
 Hepatic Impairment

Age Range: 2 - 5 yoa Max Dose: 150 mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

85. Ivacaftor / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Kalydeco (ivacaftor) in patients with cystic fibrosis younger than 2 years of age have not been studied and use is not recommended in this patient population.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Ivacaftor

Age Range: 0 - 1 yoa

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

86. Ivacaftor / Overutilization – Hepatic Impairment (≥ 6 yoa)

Alert Message: Kalydeco (ivacaftor) may be over-utilized. The daily dose of ivacaftor should be reduced to one tablet or one packet once daily for patients with moderate hepatic impairment. Ivacaftor should be used with caution in patients with severe hepatic impairment at a dose of one tablet or one packet once daily or less frequently. No dose adjustment is necessary in mild hepatic impairment.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Ivacaftor
 Hepatic Impairment

Age Range: ≥ 6 yoa Max Dose: 150 mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

87. Ivacaftor / Overutilization – Hepatic Impairment (2 - 5 yoa)

Alert Message: Kalydeco (ivacaftor) may be over-utilized. The daily dose of ivacaftor for patients 2 to less than 6 years of age with moderate hepatic impairment is as follows: one 50 mg packet once daily for patients weighing less than 14 kg or one 75 mg packet once daily for patients weighing 14 kg or more. For patients with severe hepatic impairment use the same dose reduction according to weight once daily or less frequently than once daily. No dose adjustment is necessary in mild hepatic impairment.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Ivacaftor
 Hepatic Impairment

Age Range: 2 - 5 yoa Max Dose: 75 mg/day

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

88. Ivacaftor / Strong CYP3A4 Inducers

Alert Message: Concurrent use of Kalydeco (ivacaftor) with strong CYP3A4 inducers is not recommended. Ivacaftor is a sensitive CYP3A4 substrate and concomitant administration with a strong inducer may substantially decrease ivacaftor exposure, reducing its therapeutic effectiveness.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Ivacaftor	Phenytoin	Rifabutin	
	Phenobarbital	Rifapentine	
	Primidone	Rifampin	
	Carbamazepine		

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

89. Ivacaftor / Strong CYP3A4 Inhibitors (≥ 6 yoa)

Alert Message: Concurrent use of Kalydeco (ivacaftor), a sensitive CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in significantly elevated ivacaftor exposure. In patients 6 years and older it is recommended that the dose of ivacaftor be reduced to one 150 mg tablet twice a week during concomitant therapy with a strong CYP3A4 inhibitor.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Util A	<u>Util B</u>	Util C (Include)	
Ivacaftor		Nefazodone	Saquinavir
		Clarithromycin	Ritonavir
		Telithromycin	Nelfinavir
		Ketoconazole	Indinavir
		Itraconazole	Cobicistat
		Voriconazole	Idelalisib
		Posaconazole	
Age Range: 6	– 999 voa		

Age Range: 6 – 999 yoa Max Dose: 300 mg/week

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

90. Ivacaftor / Strong CYP3A4 Inhibitors (2 - 5 yoa)

Alert Message: Concurrent use of Kalydeco (ivacaftor), a sensitive CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in significantly elevated ivacaftor exposure. In patients 2 to less than 6 years of age it is recommended that the daily dose of ivacaftor be reduced as follows: 2 to 6 years of age weighing < 14 kg reduce the dose to one 50 mg packet twice a week and for patients 2 to less than 6 years of age weighing 14 kg or more, reduce the dose to one 75 mg packet twice a week.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Util A	Util B	Util C (Include)	
Ivacaftor		Nefazodone	Saquinavir
		Clarithromycin	Ritonavir
		Telithromycin	Nelfinavir
		Ketoconazole	Indinavir
		Itraconazole	Cobicistat
		Voriconazole	Idelalisib
		Posaconazole	
Age Dengel 2 F			

Age Range: 2 - 5 yoa Max Dose: 150 mg/week References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

91. Ivacaftor / Moderate CYP3A4 Inhibitors (2 - 5 yoa)

Alert Message: Concurrent use of Kalydeco (ivacaftor), a sensitive CYP3A4 substrate, with a moderate CYP3A4 inhibitor may result in significantly elevated ivacaftor exposure. In patients 2 to less than 6 years of age it is recommended that the dose of ivacaftor be reduced as follows: one 50 mg packet once daily in patients weighing less than 14 kg and for patients weighing 14 kg or more, reduce dose to one 75 mg packet once daily.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>	
Ivacaftor		Aprepitant	Erythromycin
		Cimetidine	Fluconazole
		Ciprofloxacin	Fluvoxamine
		Crizotinib	Imatinib
		Cyclosporine	Verapamil
		Diltiazem	Dronedarone
Ago Pango: 2	5 100		

Age Range: 2 - 5 yoa Max Dose: 300 mg/week

References: Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

92. Ivacaftor / Sensitive CYP3A4 or P-gp Substrate

Alert Message: Concurrent use of Kalydeco (ivacaftor), a CYP3A4 and P-gp inhibitor, with a sensitive CYP3A4 and/or P-gp substrate may result in increased substrate exposure which may potentiate or prolong the therapeutic effect and adverse events. Appropriate monitoring is recommended when co-administering these agents.

Conflict Code: DD – Drug/Drug Interaction

<u>Util B</u>	<u>Util C</u>
Cyclosporine	
Digoxin	
Tacrolimus	
	Cyclosporine Digoxin

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Kalydeco Prescribing Information, Feb. 2017, Vertex Pharmaceuticals Inc.

93. Ivacaftor / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Kalydeco (ivacaftor). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Util C

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u> Ivacaftor

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487-497.

Eakin MN, Bilderback A, Boyle MP, Mogayzel PJ, Riekert KA. Longitudinal Association Between Medication Adherence and Lung Health in People with Cystic Fibrosis. Jrnl Cyst Fib. 2011;10(4):258-264.

Bishay LC, Sawicki. Strategies to Optimize Treatment Adherence in Adolescent Patients with Cystic Fibrosis. Adolesc Health, Med & Ther. 2016 Oct 21;7:117-124.

Bishay LC, Sawicki GS., Strategies to Optimize Adherence in Adolescent Patients with Cystic Fibrosis. Adolesc Health, Med & Ther. 2016 Oct 21;7:117-124.

94. Lisdexamfetamine / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Vyvanse (lisdexamfetamine) for the treatment of moderate to severe Binge Eating Disorder (BED) in patients less than 18 years of age have not been established.

Conflict Code: TA – therapeutic AppropriatenessDrugs/DiseasesUtil AUtil BLisdexamfetamineBinge Eating Disorder

Disorder ADHD

Age Range: < 18 years of age

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

95. Evotaz / Overutilization

Alert Message: Evotaz (atazanavir/cobicistat) is not recommended for use in treatmentexperienced patients with end-stage renal disease managed with hemodialysis.

Conflict Code: TA - therapeutic Appropriateness

<u>Util B</u>	<u>Util C</u>
CKD Stage 4 & 5	5
ESRD	
Hemodialysis	
	CKD Stage 4 & 5 ESRD

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Evotaz Prescribing Information, Jan 2017, Bristol-Myers Squibb.

96. Olaparib / Overutilization

Alert Message: The manufacturer's recommended daily dose of Lynparza (olaparib) in patients with moderate renal impairment (CLcr 31 - 50 mL/min) is 300 mg (six 50 mg capsules) taken twice daily, for a total daily dose of 600 mg. No dosage adjustment is recommended in mild renal impairment (CLcr 51 - 80 mL/min). The pharmacokinetics of olaparib have not been evaluated in patients with severe renal impairment or end-stage renal disease (CLcr </= 30 mL/min).

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Olaparib
 CKD 3, 4 & 5

 ESRD

Max Dose: 600 mg/day

References: Lynparza Prescribing Information, Dec. 2017, AstraZeneca. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

97. Terbinafine / Hepatic Impairment

Alert Message: Oral terbinafine is contraindicated in patients with chronic or active hepatic disease. Cases of liver failure, some leading to liver transplant or death, have occurred with the use of terbinafine in individuals with and without preexisting liver disease. Perform liver function test prior to initiation of therapy and periodically thereafter. Discontinue terbinafine if liver injury develops.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Terbinafine		Hepatic Impairment

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

98. Lurasidone / Overutilization Bipolar Depression

Alert Message: Latuda (lurasidone) may be over-utilized. The manufacturer's recommended maximum dose, for the treatment of bipolar depression in adults, is 120 mg once daily. Exceeding the recommended dose may increase the risk of adverse effects (e.g., akathisia, somnolence, and dystonia).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Lurasidone

Util C (Negating) CKD 3, 4 & 5 Hepatic Impairment Mod CYP3A4 Inhibitors Schizophrenia

Age Range: ≥ 18 years of age Max Dose: 120 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health. Latuda Prescribing Information, Feb. 2017, Sunovion Pharma, Inc.

99. Lurasidone / Overutilization (13 – 17 yoa)

Alert Message: Latuda (lurasidone) may be over-utilized. The manufacturer's recommended maximum dose, for the treatment of schizophrenia in adolescents 13 to 17 years of age, is 80 mg once daily. Exceeding the recommended dose may increase the risk of adverse effects (e.g., akathisia, somnolence, and dystonia).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B Util C</u> Lurasidone

Age Range: 13 - 17 years of age Max Dose: 80 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health. Latuda Prescribing Information, Feb. 2017, Sunovion Pharma, Inc.

100. Hydroxychloroquine / Digoxin

Alert Message: Concurrent use of hydroxychloroquine with digoxin may result in increased serum digoxin levels. Serum digoxin levels should be closely monitored in patients receiving combination therapy.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Hydroxychloroquine
 Digoxin

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Plaquenil Prescribing Information, Jan. 2017, Concordia Pharmaceuticals Inc.

101. Hydroxychloroquine / Antidiabetic Medications

Alert Message: Hydroxychloroquine can cause hypoglycemia and concurrent use with insulin or antidiabetic agents may enhance the effects of the hypoglycemic therapy. A decrease in the doses of insulin or antidiabetic agent may be required.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BHydroxychloroquineAntidiabetic Agents

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Plaquenil Prescribing Information, Jan. 2017, Concordia Pharmaceuticals Inc.

102. Metronidazole / Disulfiram

Alert Message: The use of disulfiram with or within 2 weeks of metronidazole-containing agent is contraindicated due to the risk of CNS toxicity (e.g., acute psychosis and confusion).

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BUtil CMetronidazoleDisulfiram

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

103. Pylera / Severe Renal Disease

Alert Message: The use of Pylera (bismuth/metronidazole/tetracycline) is contraindicated In patients with severe renal impairment. The antianabolic action of the tetracycline component of the combination product may cause an increase in blood urea nitrogen (BUN). In patients with significant impaired renal function, higher serum concentrations of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pylera		CKD Stage 4 & 5

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Pylera Prescribing Information, Jan. 2017, Apralis Pharm US, Inc.

104. Repaglinide / Cyclosporine

Alert Message: Concurrent use of repaglinide with cyclosporine may significantly increase repaglinide exposure. The repaglinide total daily dose should not exceed 6 mg if these agents are co-administered. Repaglinide is a substrate of enzyme CYP3A4 and OATP1B1 transport protein and cyclosporine inhibits CYP3A4 and OATP1B1.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Repaglinide
 Util C (Include)

Max Dose: 6 mg

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Prandin Prescribing Information, Feb. 2017, Novo Nordisk.

105. Repaglinide / Clopidogrel

Alert Message: Concurrent use of repaglinide with clopidogrel may significantly increase repaglinide exposure and should be avoided. If co-administration cannot be avoided the total daily dose of repaglinide should not exceed 4 mg. Repaglinide is a substrate of enzyme CYP2C8 and clopidogrel is a strong CYP2C8 inhibitor.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Repaglinide
 Util C (Include)

Max Dose: 4mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Prandin Prescribing Information, Feb. 2017, Novo Nordisk. Micromedex Solutions, DrugDex Drug Evaluations, 2017 Truven Health Analytics.

106. Repaglinide - All / CYP3A4 & CYP2C8 Inhibitors

Alert Message: Concurrent use of a repaglinide-containing agent with a CYP3A4 or CYP2C8 inhibitor may significantly increase repaglinide exposure. Repaglinide is a substrate of CYP3A4 and CYP2C8. Dosage reduction of the repaglinide-containing agent may be required as well as increased frequency of glucose monitoring.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases					
<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Repaglinide - all	Montelukast	Voriconazole	Atazanavir	Fluconazole	
	Phenelzine	Posaconazole	Aprepitant	Fluvoxamine	
	Nefazodone	Saquinavir	Crizotinib	Imatinib	
	Clarithromycin	Ritonavir	Cyclosporine	Verapamil	
	Telithromycin	Indinavir	Diltiazem		
	Ketoconazole	Nelfinavir	Dronedarone		
	Itraconazole	Cobicistat	Erythromycin		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

107. Osimertinib / BCRP Substrates

Alert Message: Concurrent use of the BCRP inhibitor, Tagrisso (osimertinib), with a BCRP substrate may result in increased exposure to the BCRP substrate and risk of exposure-related toxicity. Monitor patient for adverse reactions associated with the BCRP substrate.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

 Util A
 Util B
 Util C

 Osimertinib
 Rosuvastatin

 Sulfasalazine

 Topotecan

 Tenofovir

 Prazosin

 Dantrolene

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Tagrisso Prescribing Information, Sept. 2016, AstraZeneca.

108. Tiotropium / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Spiriva Handihaler (tiotropium inhalation powder) have not been established in children.

 Conflict Code:
 TA - Therapeutic Appropriateness

 Drugs/Diseases
 Util A

 Util A
 Util B

 Tiotropium
 Util C

Age Range: 0-17 yoa

References:

Spiriva Prescribing Information, Dec. 2015, Boehringer Ingelheim Pharmaceuticals, Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

109. Tiotropium / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Spiriva Respimat (tiotropium inhalation spray) for the treatment of asthma in children less than 6 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Tiotropium

Age Range: 0-5 yoa

References:

Spiriva Respimat Prescribing Information, Feb. 2017, Boehringer Ingelheim Pharmaceuticals, Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

DUR Board Meeting September 6, 2017 Brynhild Haugland Room State Capitol



North Dakota Medicaid DUR Board Meeting Agenda Brynhild Haugland Room State Capitol 600 East Boulevard Avenue Bismarck, ND September 6, 2017 1:00 pm

- 1. Administrative items
 - Travel vouchers
- 2. Old business
 - Review and approval of 06/2017 meeting minutes
 - Budget update
 - Sanford Update
 - Review top 15 therapeutic categories/top 25 drugs
 - Second review of Proglycem
 - Second review of Biltricide
 - Prior authorization/PDL update
- 3. New business
 - Review of Juxtapid and Kynamro
 - Review of Procysbi
 - Review of Miacalcin
 - Review of Tymlos
 - Review of Tardive Dyskinesia: Ingrezza, Austedo
 - Review of Jadenu
 - Review of opioid analgesic and benzodiazepine utilization
 - Review of physician prescribing patterns for select therapeutic categories
 - Review of historic stimulant utilization patterns
 - Criteria recommendations
 - Upcoming meeting date/agenda
- 4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

June 7, 2017

Members Present: Tanya Schmidt, Laura Schield, Jeffrey Hostetter, Michael Quast, Gaylord Kavlie, Katie Kram, Wendy Brown, Zach Marty, LeNeika Roehrich, Andrea Honeyman, Carlotta McCleary,

Members Absent: Michael Booth, Peter Woodrow

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy, Gary Betting

Old Business

Chair W. Brown called the meeting to order at 1:00 p.m. Chair W. Brown asked for a motion to approve the minutes of the March meeting. G. Kavlie moved that the minutes be approved and K. Kram seconded the motion. Chair W. Brown called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 15 Therapeutic Categories/Top 25 Drugs

B. Joyce presented the quarterly review of the top 15 therapeutic classes by total cost of claims, top 25 drugs based on number of claims, and top 25 drugs based on claims cost for the 1st quarter of 2017.

PDL Update

A. Murphy gave an update on drugs that have been added to prior authorization. Adenovate 3000 unit and Ixinity were added to the antihemophelia criteria. Airduo Respiclick and fluticasone/salmeterol were added to the steroid Beta2 agonist criteria. Xultophy was added to the GLP-1 criteria. Trulance was added to the IBS/Constipation criteria. Synjardy was added to the SGTL2 Inhibitors criteria. Siliq was added to the cytokine modulators criteria. Migergot was added to the DHE criteria. Arymo ER was added to the narcotics criteria. Austedo, Dupixent, Emflaza, Esbriet, Ingrexxa, and Ocaliva were added to the medications >\$3,000 criteria. Defitelio, Lemtrada, Lucentis, Ocrevus, Quadramet, and Tysarbi were added to the Medical Billing Only list of medications. Xenical was removed from the list of covered medications by North Dakota Medicaid.

New Business

Proglycem

T. DeRuiter and B. Joyce reviewed Proglycem with the Board. A motion was made by J. Hostetter to manage the class through prior authorization. The motion was seconded by G. Kavlie. This topic will be reviewed at the next meeting.

Biltricide

T. DeRuiter and B. Joyce reviewed Biltricide with the Board. A motion was made by J. Hostetter to manage the class through prior authorization. The motion was seconded by G. Kavlie. This topic will be reviewed at the next meeting.

Physician Prescribing Patterns for Select Therapeutic Categories

B. Joyce presented data showing the top prescriber utilization of select medications in therapeutic drug classes as well as the top prescribers with patients on multiple medications within the selected classes of medications, in order to evaluate utilization trends and potential outliers. Therapeutic classes evaluated included antidepressants, antipsychotics, and stimulants for ADHD. Prescriber utilization was presented both in terms of number of prescriptions for and/or patients on select medications in the first quarter and in terms of percent utilization of selected medications within their therapeutic class in the first quarter. The board discussed the value and limitations of the data, as well as potential drug classes and topics to present at future DUR board meetings.

Review of Antidepressant Non-compliance

B. Joyce presented data demonstrating antidepressant underutilization before and after an educational RDUR intervention letter was sent to prescribers, which showed a significant reduction in underutilization after letters were sent. This topic will continue to be evaluated eith interventions sent in future RDUR review cycles.

Criteria Recommendations

The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. G. Kavlie moved to approve the new criteria and Z. Marty seconded the motion. W. Brown called for a voice vote. The motion passed with no audible dissent.

The next DUR Board meeting will be held September 6, 2017 at the Capitol in the Brynhild Haugland room in Bismarck. W. Brown adjourned the meeting.

Medicaid Expansion



Top Line Performance Metrics

• Generic Fill Rate (GFR) increased 0.2 percentage points to 85.9%

	Medica	id Expansion		
Description	2016	2015	Change	
Avg Members per Month	19,506	18,536	5.2%	
Number of Unique Patients	19,936	18,403	8.3%	
Pct Members Utilizing Benefit	102.2%	99.3%	2.9	Medicaid - A
Total Days	10,232,075	8,924,000	14.7%	Weulcalu - F
Total Adjusted Rxs	416,988	369,276	12.9%	2016
Average Member Age	38.9	38.7	0.5%	4
Nbr Adjusted Rxs PMPM	1.78	1.66	7.3%	3
Generic Fill Rate	85.9%	85.7%	0.2	86.
Home Delivery Utilization	0.0%	0.0%	0.0	0.
Member Cost %	0.3%	0.3%	0.0	0.
Specialty Percent of Plan Cost	26.5%	33.3%	-6.9	38
Formulary Compliance Rate	98.8%	98.1%	0.6	98.

Medicaid - Ages 35-65						
2016	Change					
49.2	-0.2%					
3.05	0.5%					
86.0%	0.2					
0.4%	0.0					
0.8%	-0.1					
38.4%	0.9					
98.8%	0.1					



Key Statistics: Specialty Detailed

- Plan Cost PMPM trend on specialty drugs is -19.9%, compared to a 11.2% Plan Cost PMPM trend on non-specialty drugs
- There are 484 unique specialty patients, an increase of 61 specialty patients over the previous period

	Medicaid Expansion							
	Non	-Specialty	Specialty					
Description	2016	2015	Change	2016	2015	Change		
Avg Members per Month	19,506	18,536	5.2%	19,506	18,536	5.2%		
Number of Unique Patients	19,918	18,381	8.4%	484	423	14.4%		
Pct Members Utilizing Benefit	102.1%	99.2%	2.9	2.5%	2.3%	0.2		
Total Days	10,168,021	8,869,438	14.6%	64,054	54,562	17.4%		
Total Adjusted Rxs	414,627	367,255	12.9%	2,361	2,021	16.8%		
Percent of Total Adjusted Rxs	99.43%	99.45%	0.0	0.57%	0.55%	0.0		
Nbr Adjusted Rxs PMPM	1.77	1.65	7.3%	0.01	0.009	11.0%		
Generic Fill Rate	86.2%	86.0%	0.2	34.3%	36.2%	-1.9		
Member Cost %	0.4%	0.4%	0.0	0.0%	0.0%	0.0		

Medicaid - Ages 35-65						
2016 Change						
0.03	-4.2%					
21.4%	-0.4					
0.1%	0.0					



Top 10 Indications

 The largest trend is in Inflammatory Conditions at 71.5%

REPRESENT					
70.4%					
OF YOUR TOTAL					
PLAN COST					

	Top Indications by Plan Cost									
2016 2015										
	Peer		Adjusted		Generic	Peer Generic		Adjusted		Generic
Rank	Rank	Indication	Rxs	Patients	Fill Rate	Fill Rate	Rank	Rxs	Patients	Fill Rate
1	1	DIABETES	30,563	2,501	37.1%	42.8%	2	25,720	2,222	38.3%
2	2	HEPATITIS C	224	47	34.8%	19.3%	1	412	89	38.8%
3	4	PAIN/INFLAMMATION	66,972	10,524	94.1%	97.0%	3	62,124	9,858	93.5%
4	6	INFLAMMATORY CONDITIONS	982	213	30.7%	24.9%	5	654	140	30.7%
5	8	MENTAL/NEURO DISORDERS	9,523	1,658	88.5%	91.3%	4	7,839	1,463	80.8%
6	7	ASTHMA	15,420	3,323	24.2%	26.2%	6	13,276	3,102	22.1%
7	9	MULTIPLE SCLEROSIS	208	29	7.2%	2.6%	8	181	27	0.6%
8	17	DEPRESSION	42,130	6,787	97.0%	98.1%	7	36,651	6,152	96.5%
9	21	ATTENTION DISORDERS	6,717	1,029	71.8%	68.2%	9	6,084	961	73.7%
10	3	HIV	520	67	1.3%	4.8%	11	375	53	3.7%
	•	Total Top 10:	173,259		76.6%			153,316		76.6%
		Differences Between Periods:	19,943		0.0%	,				

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment



Top 25 Drugs

- Represent 42.1% of your total Plan Cost and comprise 12 indications
- 8 of your top 25 are specialty drugs

			Top Drugs by Plan Co	st				
				2016			2015	
Rank	Peer Rank	Brand Name	Indication	Adj. Rxs	Pts.	Prev Rank	Adj. Rxs	Pts.
1	34	NOVOLOG FLEXPEN	DIABETES	3,003	650	4	2,409	551
2	6	SOVALDI*	HEPATITIS C	45	13	1	103	29
3	3	HUMIRA PEN*	INFLAMMATORY CONDITIONS	256	60	7	186	34
4	11	VIEKIRA PAK*	HEPATITIS C	35	15	2	75	30
5	12	LYRICA	PAIN/INFLAMMATION	2,479	511	6	2,186	441
6	36	LEVEMIR FLEXTOUCH	DIABETES	2,118	457	5	1,868	379
7	2	LANTUS SOLOSTAR	DIABETES	1,839	402	8	1,780	395
8	10	ARIPIPRAZOLE	MENTAL/NEURO DISORDERS	1,902	408	9	1,008	271
9	28	DAKLINZA*	HEPATITIS C	25	6	15	14	5
10	4	ADVAIR DISKUS	ASTHMA	1,519	420	10	1,557	435
11	7	ENBREL*	INFLAMMATORY CONDITIONS	111	25	42	47	14
12	23	LATUDA	MENTAL/NEURO DISORDERS	470	114	17	313	87
13	14	SYMBICORT	ASTHMA	1,408	374	16	1,147	335
14	31	VICTOZA 3-PAK	DIABETES	556	114	25	356	81
15	19	ZEPATIER*	HEPATITIS C	20	9			
16	17	ONETOUCH ULTRA TEST STRIPS	DIAGNOSTIC AIDS	3,199	812	14	2,940	799
17	33	EPCLUSA*	HEPATITIS C	13	7			
18	123	VYVANSE	ATTENTION DISORDERS	1,342	251	19	1,182	230
19	55	XIFAXAN	GI DISORDERS	180	59	39	109	47
20	8	JANUVIA	DIABETES	859	158	27	666	138
21	5	SUBOXONE	CHEMICAL DEPENDENCE	947	120	35	526	68
22	130	NOVOLOG	DIABETES	782	158	24	624	138
23	22	SPIRIVA	COPD	941	201	20	914	218
24	16	COPAXONE*	MULTIPLE SCLEROSIS	48	11	18	55	9
25	45	GABAPENTIN	PAIN/INFLAMMATION	12,303	2,352	12	9,880	1,981
			Total Top 25:	36,400			29,945	
			Differences Between Periods:	6,455				

*Specialty Drugs

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment

Top 25 Specialty Drugs

• Represent 23.4% of your total Plan Cost and comprise 9 indications

		Top S	Specialty Drugs by Plan	n Cost				
				201	.6		2015	
Overall Rank	Overall Peer Rank	Brand Name	Indication	Adj. Rxs	Pts.	Overall Rank	Adj. Rxs	Pts.
2	6	SOVALDI	HEPATITIS C	45	13	1	103	29
3	3	HUMIRA PEN	INFLAMMATORY CONDITIONS	256	60	7	186	34
4	11	VIEKIRA PAK	HEPATITIS C	35	15	2	75	30
9	28	DAKLINZA	HEPATITIS C	25	6	15	14	5
11	7	ENBREL	INFLAMMATORY CONDITIONS	111	25	42	47	14
15	19	ZEPATIER	HEPATITIS C	20	9			
17	33	EPCLUSA	HEPATITIS C	13	7			
24	16	COPAXONE	MULTIPLE SCLEROSIS	48	11	18	55	9
26	1	HARVONI	HEPATITIS C	8	3	3	55	29
34	51	GILENYA	MULTIPLE SCLEROSIS	31	5	45	22	4
35	100	AUBAGIO	MULTIPLE SCLEROSIS	35	6	55	21	2
36	35	STRIBILD	HIV	77	10	82	34	5
39	44	STELARA	INFLAMMATORY CONDITIONS	23	8	64	15	3
41	185	REBIF REBIDOSE	MULTIPLE SCLEROSIS	30	4	37	29	5
42	13	TRUVADA	HIV	124	21	54	82	16
44	48	ENOXAPARIN SODIUM	ANTICOAGULANT	266	128	46	210	112
50	20	ATRIPLA	HIV	67	13	28	89	15
52	111	REBIF	MULTIPLE SCLEROSIS	24	4	23	38	4
58	75	VIVITROL	CHEMICAL DEPENDENCE	98	33	181	19	14
76	211	HUMIRA PEN CROHN-UC-HS STAR	TE INFLAMMATORY CONDITIONS	8	8	107	6	6
78	99	LETAIRIS	PULMONARY HYPERTENSION	11	1	76	11	1
87	149	CIMZIA	INFLAMMATORY CONDITIONS	24	3	77	25	4
89	312	ACTEMRA	INFLAMMATORY CONDITIONS	26	6	169	10	1
91	168	XYREM	SLEEP DISORDERS	7	1	96	6	1
95	232	FORTEO	OSTEOPOROSIS	29	4	101	30	5
			Total Top 25:	1,441			1,182	
			Differences Between Periods:	259				

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment



NORTH DAKOTA MEDICAID Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2017 - 06/30/2017

				% Total
AHFS Therapeutic Class	Rx	Paid	Paid/Rx	Claims
ANTICONVULSANTS, MISCELLANEOUS	8,759	\$ 803,700.48	\$ 91.76	6.03%
INSULINS	1,858	\$ 800,903.67	\$ 431.06	1.28%
ANTIPSYCHOTIC AGENTS	6,099	\$ 787,057.99	\$ 129.05	4.20%
AMPHETAMINES	3,719	\$ 594,792.87	\$ 159.93	2.56%
CORTICOSTEROIDS (RESPIRATORY TRACT)	1,970	\$ 565,491.23	\$ 287.05	1.36%
RESPIRATORY AND CNS STIMULANTS	4,064	\$ 525,740.73	\$ 129.37	2.80%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	136	\$ 487,400.69	\$ 3,583.83	0.09%
ANTIDEPRESSANTS	15,131	\$ 361,709.47	\$ 23.91	10.41%
IMMUNOMODULATORY AGENTS	50	\$ 294,686.66	\$ 5,893.73	0.03%
BETA-ADRENERGIC AGONISTS	3,450	\$ 250,772.86	\$ 72.69	2.37%
ANTINEOPLASTIC AGENTS	331	\$ 228,015.98	\$ 688.87	0.23%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,649	\$ 201,861.58	\$ 122.41	1.13%
OPIATE AGONISTS	5,950	\$ 195,779.44	\$ 32.90	4.10%
ANTIRETROVIRALS	158	\$ 174,547.62	\$ 1,104.73	0.11%
PENICILLINS	4,634	\$ 171,717.56	\$ 37.06	3.19%
Total Top 15	57,958	\$ 6,444,178.83	\$ 111.19	39.89%

Total Rx Claims	145,287
From 04/01/2017 - 06/30/2017	

Top 15 Therapeutic Classes Based on Total Cost of Claims



Health Information Designs, Inc.

NORTH DAKOTA MEDICAID Cost Management Analysis

08/08/2017

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2017 - 06/30/2017

						% Total
Drug	AHFS Therapeutic Class	Rx	Paid	Pa	aid/Rx	Claims
AMOXICILLIN	PENICILLINS	3,144	\$ 115,105.44	\$	36.61	2.16%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,805	\$ 56,555.15	\$	20.16	1.93%
SERTRALINE HCL	ANTIDEPRESSANTS	2,575	\$ 52,266.42	\$	20.30	1.77%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,488	\$ 75,643.08	\$	30.40	1.71%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,334	\$ 71,715.27	\$	30.73	1.61%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,157	\$ 37,271.91	\$	17.28	1.48%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,113	\$ 41,127.70	\$	19.46	1.45%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,010	\$ 38,513.21	\$	19.16	1.38%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,985	\$ 43,851.08	\$	22.09	1.37%
TRAZODONE HCL	ANTIDEPRESSANTS	1,932	\$ 31,679.60	\$	16.40	1.33%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	1,871	\$ 44,754.61	\$	23.92	1.29%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,845	\$ 308,180.61	\$	167.04	1.27%
METFORMIN HCL	BIGUANIDES	1,568	\$ 21,426.93	\$	13.67	1.08%
VYVANSE	AMPHETAMINES	1,530	\$ 318,732.07	\$ 2	208.32	1.05%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,525	\$ 22,260.70	\$	14.60	1.05%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,517	\$ 25,191.22	\$	16.61	1.04%
AZITHROMYCIN	MACROLIDES	1,477	\$ 32,840.84	\$	22.23	1.02%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,338	\$ 23,478.79	\$	17.55	0.92%
BUPROPION XL	ANTIDEPRESSANTS	1,334	\$ 31,387.12	\$	23.53	0.92%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,326	\$ 19,314.57	\$	14.57	0.91%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,304	\$ 21,793.38	\$	16.71	0.90%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	1,278	\$ 44,904.79	\$	35.14	0.88%
AMOXICILLIN-CLAVULANATE POTASS	PENICILLINS	1,268	\$ 46,177.12	\$	36.42	0.87%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,255	\$ 27,770.17	\$	22.13	0.86%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,237	\$ 60,318.77	\$	48.76	0.85%
TOTAL TOP 25		45,216	\$ 1,612,260.55	\$	35.66	31.12%
Total Rx Claims From 04/01/2017 - 06/30/2017	145,287					



Top 10 Drugs Based on Number of Claims

Health Information Designs, Inc.

NORTH DAKOTA MEDICAID Cost Management Analysis

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2017 - 06/30/2017

						% Total
Drug	AHFS Therapeutic Class	Rx		Paid	Paid/Rx	Claims
VYVANSE	AMPHETAMINES	1,530	\$	318,732.07	\$ 208.32	1.05%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,845	\$	308,180.61	\$ 167.04	1.27%
NOVOLOG FLEXPEN	INSULINS	565	\$	286,645.24	\$ 507.34	0.39%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	634	\$	241,040.69	\$ 380.19	0.44%
ADDERALL XR	AMPHETAMINES	1,152	\$	234,952.36	\$ 203.95	0.79%
LATUDA	ANTIPSYCHOTIC AGENTS	245	\$	190,913.74	\$ 779.24	0.17%
LANTUS SOLOSTAR	INSULINS	476	\$	185,684.56	\$ 390.09	0.33%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	42	\$	172,727.60	\$ 4,112.56	0.03%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	539	\$	169,713.86	\$ 314.87	0.37%
PULMICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	390	\$	166,294.69	\$ 426.40	0.27%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	492	\$	160,309.87	\$ 325.83	0.34%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	38	\$	132,525.08	\$ 3,487.50	0.03%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	9	\$	125,542.17	\$ 13,949.13	0.01%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	68	\$	123,728.68	\$ 1,819.54	0.05%
FREESTYLE LITE STRIPS	DIABETES MELLITUS	855	\$	119,340.57	\$ 139.58	0.59%
AMOXICILLIN	PENICILLINS	3,144	\$	115,105.44	\$ 36.61	2.16%
LEVEMIR FLEXTOUCH	INSULINS	366	\$	107,339.63	\$ 293.28	0.25%
COPAXONE	IMMUNOMODULATORY AGENTS	16	\$	102,043.91	\$ 6,377.74	0.01%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	22	\$	101,585.13	\$ 4,617.51	0.02%
PROVENTIL HFA	BETA-ADRENERGIC AGONISTS	1,041	\$	99,985.28	\$ 96.05	0.72%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	167	\$	94,875.08	\$ 568.11	0.11%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	319	\$	92,150.32	\$ 288.87	0.22%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	320	\$	92,070.67	\$ 287.72	0.22%
MAPAP	ANALGESICS AND ANTIPYRETICS, MISC.	654	\$	91,870.05	\$ 140.47	0.45%
ONFI	BENZODIAZEPINES (ANTICONVULSANTS)	100	\$	86,713.49	\$ 867.13	0.07%
TOTAL TOP 25		15,029	\$:	3,920,070.79	\$ 260.83	10.34%
Total Rx Claims	145.287	1				
	143,207					

From 04/01/2017 - 06/30/2017



Top 10 Drugs Based on Total Claims Cost

08/08/2017

PROGLYCEM PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Proglycem must meet the following criteria:

- Patient must have a diagnosis of hypoglycemia associated with one of the following conditions (based on age).
 - , ≥18 Years of age
 - Inoperable islet cell adenoma or carcinoma
 - Extrapancreatic malignancy
 - <18 Years of age
 - Extrapancreatic malignancy
 - Islet cell hyperplasia
 - Islet cell adenoma
 - Leucine sensitivity
 - Adenomatosis
 - Nesidioblastosis

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipient N	Medicaid ID Number			
Physician Name		Specialist involved in therapy	Specialist involved in therapy (if not treating physician)				
Physician Medicaid Provider N	umber	Telephone Number	Fax Numbe	er			
Address		City	State	Zip Code			
Requested Drug and Dosage	:	FDA approved indication	for this request:				
		□ Hypoglycemia					
Condition associated with pa	atient's hypogly	cemia:					
Inoperable islet cell adenoma	a or carcinoma	Extrapancreatic malignancy	Islet cell hyp	perplasia			
Islet cell adenoma		Leucine sensitivity	Adenomatos	sis			
Nesidioblastosis		Other (please state)					
Prescriber (or Staff) / Pharmac	y Signature**		Date				
medically necessary, does not	exceed the medi and that any mis	the above request is true, accurate ical needs of the member, and is c representations or concealment of nd recoupment.	inically supported i	n the patient's			
Part II: TO BE COMPLETED	BY PHARMACY	·					
PHARMACY NAME:			ND MEDICAID PF	ROVIDER NUMBER:			
TELEPHONE NUMBER	FAX	DRUG	NDC #				

NUMBER

Patients younger than 18 years of age:

- Patient must have a diagnosis of hypoglycemia associated with one of the following conditions:
 - o Extrapancreatic malignancy
 - o Islet cell hyperplasia
 - o Islet cell adenoma
 - o Leucine sensitivity
 - o Adenomatosis
 - o Nesidioblastosis

Patients 18 years of age and older:

- Patient must have a diagnosis of hypoglycemia associated with one of the following conditions:
 - o Inoperable islet cell adenoma or carcinoma
 - Extrapancreatic malignancy

BILTRICIDE PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Biltricide must meet the following criteria:

- Patient must have one of the following diagnoses:
 - Infection by Opisthorchis viverrini
 - Clonorchiasis
 - o Schistosomiasis
- Patient must not currently be taking any of the following medications as evidenced by paid pharmacy claims.
 - o Rifampin

•

- Phenytoin
- Fosphenytoin
- Carbamazepine
- o dexamethasone

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	ecipient Date of Birth Recipient Medicaid ID Nur					
Dhusioing Name	Specialist involved in thereasy	nvolved in therapy (if not treating physician)					
Physician Name	Specialist involved in therapy	(ii not treating physi	iciari)				
Physician Medicaid Provider Number	Telephone Number	Fax Number	Fax Number				
Address	City	State	Zip Code				
Requested Drug and Dosage:	FDA approved indication f	or this request:					
	Infection by Opisthorchis viverrini						
	Clonorchiasis						
	Schistosomiasis						
	Other (please state below)						
Other diagnosis/indication (if not listed above):							
Prescriber (or Staff) / Pharmacy Signature**		Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is							
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior							
authorization request may subject me to audit and recoupment.							
Part II: TO BE COMPLETED BY PHARMACY							
PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:						

TELEPHONE NUMBER	FAX	DRUG	NDC #
	NUMBER		

Biltricide

- Patient must have one of the following diagnoses:
 - Infection by Opisthorchis viverrini
 - o Clonorchiasis
 - o Schistosomiasis
- Patient is not currently taking any of the following medications as evidenced by paid pharmacy claims.
 - o Rifampin
 - o Phenytoin
 - o Fosphenytoin
 - o Carbamazepine
 - o dexamethasone



JUXTAPID AND KYNAMRO PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Juxtapid or Kynamro must meet the following criteria:

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Patient must be 18 years of age or older
- Patient's LDL is >130 mg/dL after a 90-day trial of combined therapy with either Crestor ≥20 mg or atorvastatin ≥ 40 mg plus another lipid lowering agent
- One of the following:
 - Patient has genetic confirmation of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
 - Patient has an untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
 - o Patient has an untreated LDL level consistent with HeFH in both parents

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number				
Prescriber Name						
Prescriber NPI	Telephone Number	Fax Number				
Address	City	State	Zip Code			
Requested Drug and Dosage:	FDA approved indication for	or this request:				
□ JUXTAPID □ KYNAMRO						
Patient's Current LDL:						
Does the patient have genetic confirmation of 2 mut \square YES \square NO	ant alleles at the LDLR, APOB	, PCSK9, or LDLRAP1 g	ene locus?			
Untreated LDL and total cholesterol level of > 500 m years of age? □ YES □ NO	ng/dl or >300 mg/dl with cutane	eous or tendon xanthoma	a before 10			
Does the patient have an untreated LDL level consis $\hfill\square$ YES $\hfill\square$ NO		s?				
List all failed medications (drug name, date of tri						
 I confirm that I have considered a generic or other successful medical management of the recipient. 	r alternative and that the reque	sted drug is expected to	result in the			
Prescriber (or Staff) / Pharmacy Signature** Date						
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						
Part II: TO BE COMPLETED BY PHARMACY						
PHARMACY NAME:		ND MEDICAID PROVIDE	R NUMBER:			

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #	
Prepared by Health Informa	tion Designs, LLC			18

Prior Authorization/PDL Update

Added to PA	Category			
KEVZARA	Cytokine Modulators			
MORPHABOND ER	Narcotics			
ELLZIA PAK	Kit			
ILARIS	> 3000			
FABIOR	Acne			
BROVANA	COPD			
LIALDA	Inflammatory Bowel Agents			
APRISO	Inflammatory Bowel Agents			
PREDNISOLONE SODIUM PHOSPHATE 10 MG/5 ML	Prednisolone Non-Solid Oral Dosage Forms			
PREDNISOLONE SODIUM PHOSPHATE 20 MG/5 ML	Prednisolone Non-Solid Oral Dosage Forms			
METHYLTESTOSTERONE	Oral Testosterone			
METHYLTEST	Oral Testosterone			
TYMLOS	>3000			

Removed from PA	Category	
XIFAXAN 550MG	Diarrhea IBS	
AVONEX	Multiple Sclerosis Interferons	
AVONEX PEN	Multiple Sclerosis Interferons	

Bill Medical Side VIA 837I AND 837P TRANSACTIONS			
XOLAIR			
BRINEURA			
KETAMINE			

Juxtapid:

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Patient must be 18 years of age or older
- Patient must have LDL levels of >130 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy print-outs:
 - A lipid lowering agent other than a statin combined with either Crestor (rosuvasatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
- One of the following:
 - 1. Patient has had genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
 - 2. Patient has an untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
 - 3. Patient has an untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents

Kynamro:

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Patient must be 18 years of age or older
- Patient must have LDL levels of >130 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy print-outs:
 - A lipid lowering agent other than a statin combined with either Crestor (rosuvasatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
- One of the following:
 - 1. Patient has had genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
 - 2. Patient has an untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
 - 3. Patient has an untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents



PROCYSBI PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Procysbi must meet the following criteria:

- Patient must have a diagnosis of nephropathic cystinosis
- Patient must have failed a 30-day trial of Cystagon, as evidenced by paid claims or pharmacy print-outs.
- Patient must be 2 years of age or older

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number			
Prescriber Name					
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	FDA approved indication for this request:				
List all failed medications (drug name, date of trial, reason for failure):					
I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #
Procysbi:

- Patient must have a diagnosis of nephropathic cystinosis
- Patient must have failed a 30-day trial of Cystagon, as evidenced by paid claims or pharmacy printouts.
- Patient must be 2 years of age or older

MIACALCIN AND TYMLOS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Miacalcin or Tymlos must meet the following criteria:

- Miacalcin: Patient must have one of the below diagnoses and meet the criteria for their diagnosis (if present)
 - o Paget's Disease of the bone: Patient must have failed a 6-month trial of a bisphosphonate
 - **Postmenopausal Osteoporosis:** Patient must be postmenopausal for ≥ 5 years and have failed a 6-month trial of a bisphosphonate
 - o Hypercalcemia
- Tymlos:
 - o Patient must have a history of osteoporotic fractures and have multiple risk factors for fracture
 - Patient has not been taking Tymlos for \geq 2 years

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient	Date of Birth	Recipient Medicaid ID Number	
Prescriber Name				
Freschber Name				
Prescriber NPI	Telephon	e Number	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:	EDA ani	proved indication for this	roquest:	
	FDA approved indication for this request:		request.	
List all failed medications (drug name, date of tri	ial,	Has the patient been post	menopausal for	r ≥ 5 years?
reason for failure):		□ YES □ NO		
		Does the patient have multiple risk factors for fracture?		
□ I confirm that I have considered a generic or other	r alternativ	re and that the requested dr	rug is expected	to result in the
successful medical management of the recipient.				
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the	ahaya raa	waat in true, and a	amplata That t	the request is
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior				
authorization request may subject me to audit and recoupment.				
	•			

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUI	MBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #	
Prepared by Health Informa	tion Designs, LLC			23

Miacalcin:

- For patients with a diagnosis of Paget's Disease of the bone:
 - Patient must have a diagnosis of Paget's Disease of the Bone
 - Patient must have failed a 6-month trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
 - Fosamax (alendronate)
 - Boniva (ibandronate)
 - Aredia (pamidronate)
 - Actonel (risedronate)

• For patients with a diagnosis of Postmenopausal Osteoporosis:

- o Patient must have a diagnosis of Osteoporosis
- o Patient must be postmenopausal for greater than or equal to 5 years
- Patient must have failed a 6-month trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
 - Fosamax (alendronate)
 - Boniva (ibandronate)
 - Aredia (pamidronate)
 - Actonel (risedronate)

• For patients with a diagnosis of Hypercalcemia:

o Patient must have a diagnosis of Hypercalcemia

Tymlos:

- Patient must have a history of osteoporotic fractures
- Patient must have multiple risk factors for fracture
- Patient has not been taking Tymlos for greater than a total of 2 years

TARDIVE DYSKINESIA AGENTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Austedo, Ingrezza, or tetrabenazine must meet the following criteria:

• Austedo and tetrabenazine:

- o Patient must have one of the following diagnoses:
 - Tardive dyskinesia (tetrabenazine only)
 - Chorea associated with Huntinton's disease
 - Patient must not be taking reserpine or a monoamine oxidase inhibitor (MAOI)
- o Patient must not have hepatic impairment
- Ingrezza:

0

- o Patient must have a diagnosis of tardive dyskinesia
- Patient must have failed a 30-day trial of tetrabenazine, as evidenced by paid claims or pharmacy print-outs.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaio	d ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zin Codo	
Address	City	State	Zip Code	
Requested Drug and Dessays	FDA engraved indication to			
Requested Drug and Dosage:	FDA approved indication fo	r this request:		
□ AUSTEDO □ INGREZZA				
	Does the patient have hepatic	: impairment? DYE	ES 🗆 NO	
List all failed medications (drug name, date of trial, reason for failure):				
I confirm that I have considered a generic or other successful medical management of the recipient.	r alternative and that the reques	sted drug is expected to	result in the	
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				
· · ·				
Part II: TO BE COMPLETED BY PHARMACY PHARMACY NAME:		ND MEDICAID PROVIDE	R NUMBER:	
TELEPHONE NUMBER FAX NUMBER DR	UG	NDC #		

Austedo:

- Patient must have a diagnosis of chorea associated with Huntinton's disease
- Patient must not be taking reserpine or a monoamine oxidase inhibitor (MAOI)
- Patient must not have hepatic impairment

Ingrezza:

- Patient must have a diagnosis of tardive dyskinesia
- Patient must have failed a 30-day trial of tetrabenazine, as evidenced by paid claims or pharmacy print-outs.

Tetrabenazine:

- Patient must have one of the following diagnoses:
 - o Tardive dyskinesia
 - o Chorea associated with Huntinton's disease
- Patient must not be taking reserpine or a monoamine oxidase inhibitor (MAOI)
- Patient must not have hepatic impairment



JADENU PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Jadenu must meet the following criteria:

• The prescriber must provide medical justification explaining why the patient cannot use Exjade

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth	Recipient Mec	licaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	FDA approved indication for	or this request:		
List all failed medications (drug name, date of trial, reason for failure): Medical justification for use over Exjade:				
I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.				
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				
Part II: TO BE COMPLETED BY PHARMACY				
PHARMACY NAME:		ND MEDICAID PROV	IDER NUMBER:	

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Jadenu:

• The prescriber must provide medical justification explaining why the patient cannot use Exjade















































































NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS 3RD QUARTER 2017

Criteria Recommendations

Approved Rejected

1. Synjardy XR / Overutilization

Alert Message: Synjardy XR (empagliflozin/metformin extended-release) may be over-utilized. The manufacturer's maximum recommended dose of empagliflozin/metformin XR is 25/2000 mg once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Empagliflozin/metformin XR

Max Dose: 25/2000 mg/day

References: Synjardy XR Prescribing Information, Dec. 2016, Boehringer Ingelheim Pharmaceuticals.

2. Synjardy XR / Mod to Sev Renal Impairment, ESRD & Dialysis

Alert Message: Synjardy XR (empagliflozin/metformin extended-release) use is contraindicated in patients with moderate to severe renal impairment (eGFR below 45 mL/min/1.73m2), end-stage renal disease, or dialysis. Based on its mechanism of action, inhibition of SGLT2 in the proximal renal tubules, the empagliflozin component is not expected to be effective in these patients.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C (In</u> Empagliflozin/metformin XR

<u>Util C (Include)</u> CKD Stage 3, 4 & 5 ESRD Dialysis

References:

Synjardy XR Prescribing Information, Dec. 2016, Boehringer Ingelheim Pharmaceuticals.

3. Synjardy XR / Therapeutic Appropriateness (Age 0-17 yoa)

Alert Message: The safety and effectiveness of Synjardy XR (empagliflozin/metformin extended-release) in pediatric patients under 18 years of age have not been established.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Empagliflozin/metformin XR

Age Range 0 - 17 yoa

References:

Synjardy XR Prescribing Information, Dec. 2016, Boehringer Ingelheim Pharmaceuticals.

4. Synjardy XR / Insulin & Sulfonylureas

Alert Message: The concurrent use of Synjardy XR (empagliflozin/metformin extended-release) with insulin or an insulin secretagogue can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with empagliflozin/metformin XR.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> Empagliflozin/metformin XR Glimepiride Glipizide Glyburide Tolazamide Tolbutamide

References:

Synjardy XR Prescribing Information, Dec. 2016, Boehringer Ingelheim Pharmaceuticals.

5. Synjardy XR / Nonadherence

Alert Message: Based on refill history, our patient may be under-utilizing Synjardy XR (empagliflozin extended-release). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Empagliflozin/metformin XR

References:

Synjardy XR Prescribing Information, Dec. 2016, Boehringer Ingelheim Pharmaceuticals. Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97. Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007. Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012. Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with\Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

6. Calcifediol ER / Overutilization

Alert Message: Rayaldee (calcifediol extended-release) may be over-utilized. The manufacturer's recommended maximum daily dose is 60 mcg once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Calcifediol ER

Max Dose: 60 mcg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rayaldee Prescribing Information, March 2016, OPKO Pharmaceuticals, LLC.

7. Calcifediol ER / Strong CYP3A Inhibitors

Alert Message: The concurrent use of Rayaldee (calcifediol extended-release) with a CYP3A4 inhibitor may inhibit enzymes involved in vitamin D metabolism (CYP24A1 and CYP27B1) and may alter serum levels of calcifediol. Dose adjustment of calcifediol may be required, and serum 25-hydroxyvitamin D, intact PTH and calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
Util A	Util B		Util C
Calcifediol ER	Nefazodone	Saquinavir	
	Ketoconazole	Ritonavir	
	Itraconazole	Indinavir	
	Voriconazole	Nelfinavir	
	Posaconazole	Atazanavir	
	Clarithromycin	Conivaptan	
	Telithromycin	Idelalisib	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Rayaldee Prescribing Information, March 2016, OPKO Pharmaceuticals, LLC.

Wang Z, Schuetz EG, Xu Y, Thummel KE. Interplay between Vitamin D and the Drug Metabolizing Enzyme CYP3A4. The Journal of Steroid Biochemistry and Molecular Biology. 2013;136;54-58. doi:10.1016/j.jsbmb.2012.09.012.

8. Calcifediol ER / Cholestyramine

Alert Message: The concurrent use of Rayaldee (calcifediol extended-release) with cholestyramine may result in reduced intestinal absorption of calcifediol. Dose adjustment of calcifediol may be required, and serum total 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with cholestyramine.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Calcifediol ER
 Cholestyramine

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rayaldee Prescribing Information, March 2016, OPKO Pharmaceuticals, LLC.

9. Calcifediol ER / Thiazide or Thiazide-like Diuretics

Alert Message: The concurrent use of Rayaldee (calcifediol extended-release) with a thiazide or thiazide-like diuretic may cause hypercalcemia. These diuretics are known to induce hypercalcemia by reducing excretion of calcium in the urine. Patients may require more frequent serum calcium monitoring in this setting.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Calcifediol ER
 Hydrochlorothiazide

 Chlorthalidone

 Chlorothiazide

 Methyclothiazide

 Bendroflumethiazide

 Indapamide

 Metolazone

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rayaldee Prescribing Information, March 2016, OPKO Pharmaceuticals, LLC.

10. Calcifediol ER / Agents that Stimulate Hydroxylation of Vitamin D

Alert Message: The concurrent use of Rayaldee (calcifediol extended-release) with agents that stimulate microsomal hydroxylation may reduce the half-life of calcifediol. Dose adjustment of calcifediol may be required, and serum 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with the stimulating agent.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Calcifediol ER

 Anticonvulsants

Rifampin

References:

Micromedex 2.0 (Electronic version) Truven Health Analytics.

Rayaldee Prescribing Information, March 2016, OPKO Pharmaceuticals, LLC. Gupta RP, Hollis BW, Patel SB, Patrick KS, Bell NH. CYP3A4 is a Human Microsomal Vitamin D 25-Hydroxylase. J Bone Miner. Rees 2004;19:680-688.

Wang Z, Schuetz EG, Xu Y, Thummel KE. Interplay between Vitamin D and the Drug Metabolizing Enzyme CYP3A4. The Journal Steroid Biochemistry and Molecular biology. 2013;136:54-58. doi:10.1016/j.jsbmb.2012.09.012.

11. Brodalumab / Therapeutic Appropriateness

Alert Message: Suicidal ideation and behavior, including 4 completed suicides, occurred in subjects treated with Siliq (brodalumab) in the psoriasis clinical trials. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation and behavior, new onset or worsening depression, anxiety, or other mood changes. Reevaluate the risks and benefits of continuing treatment with brodalumab if such events occur.

Conflict Code: TA - Therapeutic Appropriateness (Black Box Warning)

Drugs/Disease	S	
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Brodalumab		Suicidal Ideation
		Depression
		Anxiety

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Siliq Prescribing Information, Feb. 2017, Valeant Pharmaceuticals North America, LLC.

12. Brodalumab / Crohn's Disease

Alert Message: Siliq (brodalumab) is contraindicated in patients with Crohn's disease because brodalumab may cause worsening of the disease state. In clinical trials, which excluded subjects with active Crohn's disease, Crohn's occurred in one subject during treatment and lead to discontinuation of therapy. In other trials, exacerbation of Crohn's disease was observed with brodalumab use.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Brodalumab		Crohn's Disease

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Siliq Prescribing Information, Feb. 2017, Valeant Pharmaceuticals North America, LLC.

13. Brodalumab / Therapeutic Appropriateness (Pediatric)

Alert Message: The safety and effectiveness of Siliq (brodalumab) have not been evaluated in pediatric patients.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Brodalumab

Age Range: 0 - 17 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Siliq Prescribing Information, Feb. 2017, Valeant Pharmaceuticals North America, LLC.

14. Brodalumab / Pregnancy / Pregnancy Negating

Alert Message: There is no human data on Siliq (brodalumab) use in pregnant women to inform a drug associated risk. Human IgG antibodies are known to cross the placental barrier; therefore, brodalumab may be transmitted from the mother to the developing fetus. Advise pregnant females of that the drug may cross placental barrier.

Conflict Code: MC - Drug (Actual) Disease Precaution/Warning

Drugs/Diseases	5	
<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Brodalumab	Pregnancy	Delivery
		Miscarriage

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Siliq Prescribing Information, Feb. 2017, Valeant Pharmaceuticals North America, LLC.

Delivery

15. Brodalumab / Lactation & Disorders of Lactation

Alert Message: There are no data on the presence of Siliq (brodalumab) in human milk, the effects on the breastfed infant, or the effects on milk production. Brodalumab was detected in the milk of lactating cynomolgus monkeys. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for brodalumab and any potential adverse effects on the breastfed infant from brodalumab or from the underlying maternal condition.

 Conflict Code: MC - Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Brodalumab
 Lactation

 Disorder of Lactation

Gender: Female Age Range: 11 – 55 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Silig Prescribing Information, Feb. 2017, Valeant Pharmaceuticals North America, LLC.

16. Telotristat / Overutilization

Alert Message: Xermelo (telotristat ethyl) may be over-utilized. The manufacturer's recommended maximum daily dose of telotristat ethyl is 250 mg three times daily (total 750 mg per day). Exceeding the recommended daily dose may increase the incidence of adverse reactions without increasing benefit, and is not recommended.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Telotristat

Max Dose: 750 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xermelo Prescribing Information, Feb. 2017, Lexicon Pharmaceuticals, Inc.

17. Telotristat / CYP3A4 Substrates

Alert Message: Concurrent use of Xermelo (telotristat) with a CYP3A4 substrate may result in decreased substrate systemic exposure and reduced efficacy. Monitor patient for suboptimal efficacy and consider dosage adjustment for the CYP3A4 substrate.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases				
Util A	Util B			<u>Util C</u>
Telotristat	Ull D Midazolam Triazolam Alprazolam Diazepam Ketoconazole Itraconazole Posaconazole Voriconazole Fluconazole Fluconazole Refazodone Aripiprazole Trazodone Pimozide Clarithromycin Erythromycin Telithromycin Cyclosporine Tacrolimus Sirolimus Amlodipine Diltiazem Felodipine Nifedipine Nifedipine Nifedipine Verapamil Propranolol Aliskiren Eplerenone	Hydrocodone Methadone Oxycodone Tramadol Saquinavir Ritonavir Indinavir Quetiapine Buspirone Lurasidone Haloperidol Vilazodone Ticagrelor Rivaroxaban Fentanyl Imatinib Salmeterol Carbamazepine Sildenafil Tadalafil Avanafil Vardenafil Zolpidem Atorvastatin Cerivastatin Lovastatin Simvastatin Estradiol	Amitriptyline Trimipramine Dexamethasone Aprepitant Alfuzosin Ondansetron Cariprazine Brexpiprazole Pimavanserin Darifenacin Darunavir Everolimus Naloxegol Maraviroc Eletriptan Amiodarone	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xermelo Prescribing Information, Feb. 2017, Lexicon Pharmaceuticals, Inc. FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: <u>http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm09</u> <u>3664.htm</u>

18. Telotristat / Constipation

Alert Message: Xermelo (telotristat ethyl) reduces bowel movement frequency. Patients receiving telotristat ethyl should be monitored for the development of constipation and/or severe, persistent, or worsening abdominal pain. Discontinue telotristat ethyl if severe constipation or severe persistent or worsening abdominal pain develops.

Conflict Code: MC - Drug (Actual) Disease Precaution/Warning

Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Telotristat Constipation

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xermelo Prescribing Information, Feb. 2017, Lexicon Pharmaceuticals, Inc.

19. Codeine / CYP2D6 Inhibitors

Alert Message: Concurrent use of a codeine-containing agent with a CYP2D6 inhibitor may result in a decrease in the effects of codeine. Codeine must be bioactivated via CYP2D6 to morphine to exert an analgesic effect. Consider the use of an alternative analgesic for patients requiring therapy with an agent that is a CYP2D6 inhibitor.

Conflict Code: DD - Drug/Drug Interaction

<u>Util B</u>		<u>Util C</u>
Fluoxetine	Propafenone	
Paroxetine	Quinidine	
Bupropion	Terbinafine	
	Fluoxetine Paroxetine	Fluoxetine Propafenone Paroxetine Quinidine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

20. Bupropion / Digoxin

Alert Message: Concurrent use of bupropion with digoxin may result in decreased digoxin plasma levels. Patients treated concomitantly with bupropion and digoxin should have digoxin levels monitored during concurrent therapy. While the mechanism of interaction is not fully understood the induction, by bupropion, of digoxin OATPAC1-mediated transport in the kidney may play a role.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BUtil CBupropionDigoxin

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Facts & Comparisons, 2017 Wolters Kluwer Health.

He J, Yu Y, Prasad B, et al. Mechanism of Unusual, But Clinically Significant, Digoxin-Bupropion Drug Interaction. Biopharm Drug Dispos. 2014 Jul;35(5):253-63. doi:10.1002/bdd.1890. Epub 2014 Mar3.

Kirby BJ, Collier AC, Kharasch ER, et al. Complex Drug Interactions of the HIV Protease Inhibitors 3: Effect of Simultaneous or Staggered Dosing of Digoxin and Ritonavir, Nelfinavir, Rifampin, or Bupropion. Drug, Metab Dispos. 2012; Vol. 40:610-616. doi: 10.1224/dmd.111042705. Epub 2011 Dec. 21.

21. Dapagliflozin / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate and well-controlled studies of Farxiga (dapagliflozin) in pregnant women. Based on results or reproductive and developmental toxicity studies in animals, dapagliflozin may affect renal development and maturation. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

Conflict Code: MC – Drug (Actual) Disease Precaution Drugs/Diseases

Util A	Util B	Util C (Negating)
Dapagliflozin	Pregnancy	Delivery
		Abortion
		Miscarriage

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.

American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

22. Dapagliflozin-Metformin ER / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate and well-controlled studies of Xigduo XR (dapagliflozin/metformin extendedrelease) in pregnant women. Based on results of reproductive and developmental toxicity studies in animals, dapagliflozin may affect renal development and maturation. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

Conflict Code: MC – Drug (Actual) Disease Precaution

Diuga/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Dapagliflozin/Metformin	Pregnancy	Delivery
		Abortion
		Miscarriage

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.

American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

23. Empagliflozin / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data showing adverse renal effects, Jardiance (empagliflozin) is not recommended during the second and third trimesters of pregnancy. Limited data available with empagliflozin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects and miscarriage. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drugs/Diseases		
Util A	Util B	Util C (Negating)
Empagliflozin	Pregnancy	Delivery
		Abortion
		Miscarriage
Gender: Female		C

Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.

American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

24. Empagliflozin-Metformin / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data showing adverse renal effects, Synjardy (empagliflozin/metformin) is not recommended during the second and third trimesters of pregnancy. Limited available data with empagliflozin/metformin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects and miscarriage. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

Conflict Code: MC – Drug (Actual) Disease Precaution\ Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Empagliflozin/Metformin	Pregnancy	Delivery
		Abortion
		Miscarriage

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.

American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

25. Empagliflozin-Metformin XR / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data showing adverse renal effects, Synjardy XR (empagliflozin/metformin extended-release) is not recommended during the second and third trimesters of pregnancy. Limited available data with empagliflozin/metformin XR in pregnant women are not sufficient to determine a drug-associated risk for major birth defects and miscarriage. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimester.

Conflict Code: MC – Drug (Actual) Disease Precaution Drugs/Diseases Util A Util B Util C (Negating)

Empagliflozin/Metformin XR

Pregnancy Delivery Abortion Miscarriage

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249. American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

26. Plecanatide / Overutilization

Alert Message: Trulance (plecanatide) may be over-utilized. The manufacturer's recommended maximum adult dosage is 3 mg once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Plecanatide

Max Dose: 3 mg per day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Trulance Prescribing Information, Jan. 2017, Synergy Pharmaceuticals.

27. Plecanatide / Therapeutic Appropriateness (Age 0 – 5 yoa)

Alert Message: Trulance (plecanatide) is contraindicated in patients less than 6 years of age. Due to increased intestinal expression of guanylate cyclase (GC-C), patients less than 6 years of age may be more likely than patients 6 years and older to develop severe diarrhea and its potentially serious consequences. In nonclinical studies, the use of plecanatide in young juvenile mice resulted in mortality in some mice within the first 24 hours of therapy, apparently due to dehydration.

Conflict Code: TA - Therapeutic Appropriateness (Black Box Warning) Drugs/Diseases <u>Util A Util B Util C</u> Plecanatide

Age Range: 0 - 5 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Trulance Prescribing Information, Jan. 2017, Synergy Pharmaceuticals.

28. Plecanatide / Therapeutic Appropriateness – Age 6 – 17 yoa

Alert Message: The safety and effectiveness of Trulance (plecanatide) in patients 6 years of age to less than 18 years of age have not been established and its use should be avoided in this patient population.

Conflict Code: TA - Therapeutic Appropriateness (Black Box Warning) Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Plecanatide

Age Range: 6 – 17 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Trulance Prescribing Information, Jan. 2017, Synergy Pharmaceuticals.

29. Plecanatide / Gastrointestinal Obstruction

Alert Message: Trulance (plecanatide) is contraindicated in patients with known or suggested gastrointestinal obstruction. Plecanatide is a guanylate cyclase-C (GC-C) agonist which increases intestinal fluid and accelerates transit.

 Conflict Code: MC – Drug (Actual) Disease Precaution/Warning Drugs/Diseases

 Util A
 Util B

 Plecanatide
 Intestinal Obstruction Paralytic ileus

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Trulance Prescribing Information, Jan. 2017, Synergy Pharmaceuticals.

30. Plecanatide / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Trulance (plecanatide). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Plecanatide

References: Trulance Prescribing Information, Jan. 2017, Synergy Pharmaceuticals. Martin LR, Williams SL, Haskard KB, DiMatteo MR. The Challenge of Patient Adherence. Ther Clin Risk Manag. 2005;1(3):189-199. Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.

31. AirDuo Respiclick / Nonadherence

Alert Message: Non-adherence with prescribed asthma therapy may significantly increase the risk of asthma exacerbations, emergency room visits, hospitalization, and asthma-related deaths. Always verify at each office visit that the patient understands their condition, the treatment plan, and the importance of adherence.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Fluticasone/Salmeterol Inhalation Powder

References:

Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97. Williams LK, Pladevall M, XI Hy, et al., Relationship between Adherence to Inhaled Corticosteroids and Poor Outcomes Among Adults with Asthma. J Allerg Clin Immunol. December 2004;114(6):1288-1293. Tan H, Sarawate C, Singer J et al., Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes. Mayo Clinic Proc. August 2009;84(8):675-684.

32. Tenofovir Alafenamide / Overutilization

Alert Message: Vemlidy (tenofovir alafenamide) maybe over-utilized. The manufacturer's recommended maximum dose is 25 mg once daily.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Tenofovir ala.
 CKD Stage 5

Max Dose: 25 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Nov. 2016, Gilead Sciences, Inc.

33. Tenofovir Alafenamide / Chronic Kidney Disease Stage 5

Alert Message: Vemlidy (tenofovir alafenamide) use is not recommended in patients with end-stage renal disease (estimated creatinine clearance below 15 mL/minute). No dosage adjustment of tenofovir alafenamide is required in patients with mild, moderate, or severe renal impairment.

Conflict Code: TA – Therapeutic AppropriatenessDrugs/DiseasesUtil AUtil BTenofovir ala.Util C (Include)CKD Stage 5

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Nov. 2016, Gilead Sciences, Inc.

34. Tenofovir Alafenamide / Hepatic Impairment

Alert Message: Vemlidy (tenofovir alafenamide) use is not recommended in patients with decompensated hepatic impairment (Child-Pugh B or C). Tenofovir alafenamide use has been associated with lactic acidosis and severe hepatomegaly with steatosis, including fatal cases. No dosage adjustment is tenofovir alafenamide is required in patients with mild hepatic impairment (Child-Pugh A).

Conflict Code: TA – Therapeutic Appropriateness

Diugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Tenofovir ala.		Fibrosis and Cirrhosis of the Liver
		Chronic Hepatic Failure
		Hepatic Failure, Unspecified
		Toxic Liver Disease
		Alcoholic Liver Disease

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Nov 2016, Gilead Sciences, Inc.

35. Tenofovir Alafenamide / Carbamazepine

Alert Message: Concurrent use of Vemlidy (tenofovir alafenamide), a P-gp substrate, with carbamazepine may result in decreased tenofovir alafenamide absorption, which may lead to the loss of tenofovir alafenamide's therapeutic effect, due to induction by carbamazepine of tenofovir alafenamide P-gp mediated transport. When these agents are co-administered the dose of tenofovir alafenamide should be increased to two tablets once daily.

Conflict Code: LR – Inappropriate Dosing.Drugs/DiseasesUtil AUtil BTenofovir ala.Carbamazepine

Minimum Dose: 50 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Nov. 2016, Gilead Sciences, Inc.

36. Tenofovir Alafenamide / Other P-gp Inducers

Alert Message: Concurrent use of Vemīldy (tenofovir alafenamide) with P-gp inducers (e.g., phenytoin, oxcarbazepine, rifampin, and phenobarbital) is not recommended. Tenofovir alafenamide is a P-gp substrate and use with a P-gp inducer may result in decreased tenofovir alafenamide absorption, which may lead to loss of therapeutic effect.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

Util A Util B Tenofovir ala. Phenytoin Oxcarbazepine Phenobarbital Rifampin Rifabutin Rifapentine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Dec. 2016, Gilead Sciences, Inc.

Util C

37. Tenofovir Alafenamide / P-GP & BCRP Inhibitors

Alert Message: Vemlidy (tenofovir alafenamide) is a substrate of both P-gp and BCRP transport. Concurrent use of tenofovir alafenamide with a P-gp and/or BCRP transport inhibitor may result in increased tenofovir alafenamide absorption and plasma concentrations and risk of tenofovir alafenamide-related adverse effects.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Tenofovir ala.	Alectinib	Rolapitant	
	Cobicistat	Tedizolid	
	Daclatasvir	Vemurafenib	
	Olaparib	Cyclosporine	
	Osimertinib	Sorafenib	
	Regorafenib		
	-		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Dec. 2016, Gilead Sciences, Inc.

38. Tenofovir Alafenamide / Drugs Effecting Renal Function

Alert Message: Vemlidy (tenofovir alafenamide) is primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, therefore co-administration of tenofovir alafenamide with drugs that reduce renal function or compete for active tubular secretion may increase tenofovir alafenamide concentrations and increase the risk of tenofovir-related adverse reactions.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
Util A	Util B		Util C
Tenofovir ala.	Salicylates	Bacitracin	
	Acyclovir	Metformin	
	Cidofovir	Dofetilide	
	Ganciclovir	Cyclosporine	
	Valacyclovir	Pamidronate	
	Valganciclovir	Probenecid	
	NSĂIDS	Tacrolimus	
	Adefovir	Tobramycin	
	Zoledronic Acid	-	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Dec. 2016, Gilead Sciences, Inc. Prepared by Health Information Designs, LLC
39. Tenofovir Alafenamide / HIV

Alert Message: The safety and efficacy of Vemlidy (tenofovir alafenamide) have not been established in patients co-infected with hepatitis B (HBV) and HIV-1. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with tenofovir alafenamide, and, if positive, an appropriate antiretroviral combination regimen that is recommended for patients coinfected with HIV-1 should be used.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	<u>Util C (Include)</u>
Tenofovir ala.		HIV-1

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Vemlidy Prescribing Information, Dec. 2016, Gilead Sciences, Inc.

40. Tenofovir Alafenamide / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Vemlidy (tenofovir alafenamide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs. Discontinuation of anti-hepatitis B therapy, including tenofovir alafenamide, may result in severe acute exacerbation of hepatitis B. Advise patients to not discontinue tenofovir alafenamide without first informing their healthcare provider.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Tenofovir ala.

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97. Lieveld FI, van Vlerken LG, Siersema PD, van Erpecum KJ. Patient Adherence to Antiviral Treatment for Chronic Hepatitis B and C: A Systemic Review, Ann Hepatol. 2013 May-Jun;12(3):380-391. Vemlidy Prescribing Information, Dec. 2016, Gilead Sciences, Inc.

41. Lumacaftor/ivacaftor / Overutilization (≥ 12 yoa)

Alert Message: The recommended daily dose of Orkambi (lumacaftor/ivacaftor) for patients age 12 years and older is two lumacaftor 200mg/ivacaftor 125 mg tablets every 12 hours with fat-containing food (total daily dose lumacaftor 800 mg/ivacaftor 500 mg).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Lumacaftor/ivacaftor

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Util C (Negating) Hepatic Impairment

Max Dose: 800mg/500mg (4 tabs) Age Range: ≥ 12 yoa

42. Lumacaftor/ivacaftor / Overutilization (6 - 11 yoa)

Alert Message: The recommended daily dose of Orkambi (lumacaftor/ivacaftor) for patients age 6 to 11 years of age is two lumacaftor 100 mg/ivacaftor 125 mg tablets every 12 hours with fat-containing food (total daily dose lumacaftor 400 mg/ivacaftor 500 mg).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Lumacaftor/ivacaftor

Util C (Negating) Hepatic Impairment

Max Dose: 400mg/500mg (4 tabs) Age Range: 6 – 11 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

43. Lumacaftor/ivacaftor / Overutilization – Hepatic Imp. (≥ 12 yoa)

Alert Message: The recommended daily dose of Orkambi (lumacaftor/ivacaftor) for patients 12 years of age and older with moderate hepatic impairment, is two lumacaftor 200 mg/ivacaftor 125 mg tablets in the morning and one 200 mg/125 mg tablet in the evening (total of 3 tablets per day). Patients 12 years and older with severe hepatic impairment should receive one 200 mg/125 mg tablet in the morning and one 200 mg/ 125 mg tablet in the evening.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Lumacaftor/ivacaftor

Util C (Include) Hepatic Impairment

Max Dose: 600mg/375mg (3 tabs) Age Range: ≥ 12 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

44. Lumacaftor/ivacaftor / Overutilization – Hepatic Imp. (6 – 11 yoa)

Alert Message: The recommended daily dose of Orkambi (lumacaftor/ivacaftor) for patients age 6 to 11 years of age with moderate hepatic impairment, is two lumacaftor 100 mg/ivacaftor 125 mg tablets in the morning and one 100 mg/125 mg tablet in the evening (total of 3 tablets per day). Patients 6 to 11 years of age with severe hepatic impairment should receive one 100 mg/125 mg tablet in the evening.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Lumacaftor/ivacaftor

<u>Util C **(Include)**</u> Hepatic Impairment

Max Dose: 300mg/375mg (3 tabs) Age Range: 6 – 11 yoa

45. Lumacaftor/ivacaftor / Strong CYP3A4 Inducers

Alert Message: Concurrent use of Orkambi (lumacaftor/ivacaftor) with strong CYP3A4 inducers is not recommended. The ivacaftor component of the combination agent is a sensitive CYP3A4 substrate and concomitant administration with a strong CYP3A4 inducer may substantially decrease exposure of ivacaftor reducing the therapeutic effectiveness of ivacaftor.

Conflict Code: DD – Drug/Drug Interaction

Diugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Lumacaftor/ivacaftor	Phenytoin	Rifampin	
	Phenobarbital	Rifabutin	
	Primidone	Rifapentine	
	Carbamazepine		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

46. Lumacaftor/ivacaftor / Hormonal Contraceptives

Alert Message: Orkambi (lumacaftor/ivacaftor) may substantially decrease hormonal contraceptive exposure, reducing their effectiveness and increasing the incidence of menstruation-associated adverse reactions (e.g., amenorrhea, dysmenorrhea, and menorrhagia). Hormonal contraceptives, including oral, injectable, transdermal, and implantable, should not be relied upon as an effective method of contraception when co-administered with lumacaftor/ivacaftor.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lumacaftor/ivacaftor	Oral Contraceptives	
	Injectable Contraceptive	s
	Transdermal Contracep	tives
	Implantable Contracepti	ves
Age Range: 11 – 55 yoa		

Age Range: 11 – 55 yoa Gender: Female

47. Lumacaftor/ivacaftor / Sensitive 3A4 Substrates & 3A4 Substrates w/ NTI

Alert Message: Co-administration of Orkambi (lumacaftor/ivacaftor) is not recommend with sensitive CYP3A4 substrates or CYP3A4 substrates with a narrow therapeutic index (NTI). Lumacaftor is a strong CYP3A4 inducer and co-administration with a CYP3A4 substrate with these substrates may decreased systemic exposure of the CYP3A4 substrate, decreasing the therapeutic effect.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases

<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Lumacaftor/ivacaftor	Tacrolimus	Ibrutinib	Dronedarone	
	Sirolimus	Lomitapide	Eletriptan	
	Everolimus	Lovastatin	Eplerenone	
	Cyclosporine	Naloxegol	Felodipine	
	Midazolam	Nisoldipine	Indinavir	
	Triazolam	Saquinavir	Lurasidone	
	Avanafil	Simvastatin	Maraviroc	
	Buspirone	Tipranavir	Quetiapine	
	Conivaptan	Vardenafil	Sildenafil	
	Darifenacin	Budesonide	Ticagrelor	
	Darunavir	Dasatinib	Tolvaptan	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors\and Inducers. Available at: <u>http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug</u> InteractionaLabeling/ucm093664.htm

48. Lumacaftor/ivacaftor / Certain Antifungals

Alert Message: Concurrent use of Orkambi (lumacaftor/ivacaftor) with the antifungal agent ketoconazole, itraconazole, voriconazole or posaconazole may result in decreased antifungal exposure and therefore co-administration is not recommended. The antifungal agents are CYP3A4 substrates and the lumacaftor component of the combination product is a strong CYP3A4 inducer. If concomitant use is necessary, monitor for antifungal efficacy and adjust dose according to official manufacturer labeling. Consider alternative antifungal such as fluconazole.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	Util B	Util C
Lumacaftor/ivacaftor	Ketoconazole	
	Itraconazole	
	Voriconazole	
	Posaconazole	

References:

49. Lumacaftor/ivacaftor / Digoxin

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with digoxin, a P-gp substrate, may result in altered digoxin exposure. Lumacaftor is both an inhibitor and inducer of P-gp efflux pumps and ivacaftor is a weak P-gp inhibitor. Monitor the serum concentration of digoxin ant titrate the digoxin dose to obtain the desired clinical effect.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases Util A Util B Util C

Lumacaftor/ivacaftor Digoxin

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

50. Lumacaftor/ivacaftor / Sulfonylureas CYP2C9 Substrates

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with a sulfonylurea that is a CYP2C9 substrate may alter the substrate exposure. In vitro data suggest that the lumacaftor component of the combo agent may induce and/or inhibit CYP2C9-mediated metabolism. Dose adjustment of the sulfonylurea may be required to obtain the desired clinical effect.

Conflict Code: DD – Drug/Drug Interaction

Diugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lumacaftor/ivacaftor	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolbutamide	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

51. Lumacaftor/ivacaftor / Repaglinide

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with the CYP3A4 substrate repaglinide may result in reduced repaglinide exposure and effectiveness. The lumacaftor component of the combo product is a strong CYP3A4 inducer. Dose adjustment of the repaglinide may be required to obtain the desired clinical effect.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil ALumacaftor/ivacaftorRepaglinide

52. Lumacaftor/ivacaftor / Warfarin

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with warfarin, a CYP2C9 substrate, may result in altered warfarin exposure. In vitro data suggest that lumacaftor/ivacaftor can induce and/or inhibit CYP2C9. Monitor the international normalized ratio (INR) when warfarin is co-administered with lumacaftor/ivacaftor.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Lumacaftor/ivacaftor Warfarin

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

53. Lumacaftor/ivacaftor / CYP3A4 Substrate Steroids

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with a systemic corticosteroid that is a CYP3A4 substrate (e.g., prednisone, methylprednisolone, and dexamethasone) may result in reduced corticosteroid exposure and effectiveness. The lumacaftor component of the combo product is a strong CYP3A4 inducer. A higher dose of the systemic corticosteroid may be required to obtain the desired clinical effects.

Conflict Code: DD – Drug/Drug Interaction

Diaga/Discases		
<u>Util A</u>	<u>Util B</u>	Util C
Lumacaftor/ivacaftor	Prednisone	
	Dexamethasone	

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

Methylprednisolone

54. Lumacaftor/ivacaftor / CYP3A4 Substrate Antibiotics

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with a macrolide that is a CYP3A4 substrate (e.g., clarithromycin, erythromycin, and telithromycin) may result in reduced antibiotic exposure and effectiveness. The lumacaftor component of the combo product is a strong CYP3A4 inducer. Consider an alternative to these antibiotics, such as ciprofloxacin or azithromycin.

Conflict Code: DD – Dru	g/Drug Interaction	
Drugs/Diseases		
<u>Util A</u>	Util B	Util C
Lumacaftor/ivacaftor	Clarithromycin	
	Erythromycin	
	Telithromycin	

References:

55. Lumacaftor/ivacaftor / Montelukast

Alert Message: The concurrent use of Orkambi (lumacaftor/ivacaftor) with montelukast may result in decreased montelukast exposure and efficacy. Montelukast is a substrate of CYP3A4, CYP2C8, and CYP2C9. The lumacaftor component of the combo product is a strong CYP3A4 inducer as well as an inducer of CYP2C8 and CYP2C9. Increased monitoring is recommended if these agents are administered concurrently.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Lumacaftor/ivacaftor Montelukast</u>

References:

Clinical Pharmacology, 2016 Elsevier/Gold Standard. Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc.

56. Lumacaftor/ivacaftor / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Orkambi (lumacaftor/ivacaftor). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Lumacaftor/ivacaftor

References:

Orkambi Prescribing Information, Sept. 2016, Vertex Pharmaceuticals Inc. Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497. Eakin MN, Bilderback A, Boyle MP, Mogayzel PJ, Riekert KA. Longitudinal Association Between Medication Adherence and Lung Health in People with Cystic Fibrosis. Jrnl Cyst Fib. 2011;10(4):258-264. Bishay LC, Sawicki. Strategies to Optimize Tre

57. Dulera / Nonadherence

Alert Message: Non-adherence with prescribed asthma therapy may significantly increase the risk of asthma exacerbations, emergency room visits, hospitalization, and asthma-related deaths. Always verify at each office visit that the patient understands their condition, the treatment plan, and the importance of adherence.

Conflict Code: LR - Nonadherence		
Drugs/Diseases		
Util A	<u>Util B</u>	<u>Util C</u>
Mometasone/Formoterol Inhalation		

References:

Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97. Williams LK, Pladevall M, XI Hy, et al., Relationship between Adherence to Inhaled Corticosteroids and Poor Outcomes Among Adults with Asthma. J Allerg Clin Immunol. December 2004;114(6):1288-1293. Tan H, Sarawate C, Singer J et al., Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes. Mayo Clinic Proc. August 2009;84(8):675-684.

58. Dapagliflozin-Saxagliptin / Overutilization

Alert Message: Qtern (dapagliflozin-saxagliptin) may be over-utilized. The manufacturer's recommended maximum daily dose of dapagliflozin/saxagliptin is 10 mg dapagliflozin/5 mg saxagliptin once daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Dapagliflozin/Saxagliptin

Util C (Negate) CKD Stage 3, 4 & 5 ESRD

Max Dose: 10 mg/5 mg per day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

59. Dapagliflozin-Saxagliptin / CKD Stage 3, 4 & 5 & ESRD

Alert Message: Qtern (dapagliflozin/saxagliptin) use is contraindicated in patients with moderate to severe renal impairment, end-stage renal disease or on dialysis. The dapagliflozin component of the combo product causes intravascular volume contraction and can cause renal impairment.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C (Include)</u> Dapagliflozin/Saxagliptin CKD Stage 3, 4 & 5 ESRD

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

60. Dapagliflozin-Saxagliptin / Therapeutic Appropriateness

Alert Message: Assessment of renal function is recommended prior to initiation of Qtern (dapagliflozin/saxagliptin) therapy and periodically thereafter. Discontinue dapagliflozin/saxagliptin if estimated glomerular filtration rate (eGFR) falls persistently below 60 mL/min/1.73 m2. Do not initiate dapagliflozin/saxagliptin in patients with an eGFR below 60 mL/min/1.73 m2.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Dapagliflozin/Saxagliptin

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

61. Dapagliflozin-Saxagliptin / Strong CYP3A4/5 Inhibitors

Alert Message: Do not co-administer Qtern (dapagliflozin/saxagliptin) with strong CYP3A4/5 inhibitors (e.g., ketoconazole, atazanavir, nefazodone, ritonavir, and clarithromycin). The saxagliptin component of the combo product is a CYP3A4/5 substrate and use with a strong CYP3A4/5 inhibitor is expected to significantly increase saxagliptin plasma concentrations.

Conflict Code: DD – Drug/ Drugs/Diseases	Drug Interaction		
Util A	Util B		Util C
Dapagliflozin/Saxagliptin	Itraconazole Ketoconazole Atazanavir Clarithromycin Saquinavir Ritonavir	Indinavir Nelfinavir Telithromycin Nefazodone Cobicistat	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

62. Dapagliflozin-Saxagliptin / Insulin & Insulin Secretagogues

Alert Message: The concurrent use of Qtern (dapagliflozin/saxagliptin) with insulin or an insulin secretagogue can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with dapagliflozin/saxagliptin.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases Util A Util B Util C Dapagliflozin/Saxagliptin Insulin Chlorpropamide Tolbutamide Tolazamide Glvburide Glipizide Glimepiride

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

63. Dapagliflozin-Saxagliptin / Bladder Cancer

Alert Message: In clinical trials an increased occurrence of bladder cancer was observed in subjects receiving dapagliflozin (0.17%) as compared to placebo (0.03%). Qtern (dapagliflozin/saxagliptin) should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases Util A Util C (Include) Util B Dapagliflozin/Saxagliptin Neoplasm of Bladder History of Malignant Neoplasm of Bladder

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

64. Dapagliflozin-Saxagliptin / Hypotension (Loop Diuretics)

Alert Message: The dapagliflozin component of Qtern (dapagliflozin/saxagliptin) can cause osmotic diuresis which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Before initiating a dapagliflozin-containing agent in patient with one or more of these characteristics, volume status should be assessed and corrected. Patients should be monitored for signs and symptoms during therapy.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Dapagliflozin/Saxagliptin Torsemide Ethacrynate Bumetanide

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

65. Dapagliflozin-Saxagliptin / Therapeutic Appropriateness (Pediatric)

Alert Message: Safety and effectiveness of Qtern (dapagliflozin/saxagliptin) in patients under 18 years of age have not been established.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Dapagliflozin/Saxagliptin

Age Range: 0 - 17 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

66. Dapagliflozin-Saxagliptin / Therapeutic Appropriateness

Alert Message: The use of Qtern (dapagliflozin/saxagliptin) can cause an increase in LDL-C levels. Patients treated with dapagliflozin/saxagliptin demonstrated a mean percent increase from baseline LDL-cholesterol ranging from 2.1% to 6.9%. Patients receiving dapagliflozin/saxagliptin should have their LDL-C monitored and treated per standard of care.

 Conflict Code: TA – Therapeutic Appropriateness

 Drugs/Diseases

 Util A
 Util B

 Dapagliflozin/Saxagliptin
 Util C (Include)

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca.

67. Dapagliflozin-Saxagliptin / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Qtern (dapagliflozin/saxagliptin). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Util C

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A</u><u>Util B</u> Dapagliflozin/Saxagliptin

References: Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497. Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007. Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012. Qtern Prescribing Information, February 2017, AstraZeneca.

68. Dapagliflozin-Saxagliptin / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data showing renal effects, from dapagliflozin, Qtern (dapagliflozin/saxagliptin) is not recommended during the second and third trimesters of pregnancy. The limited available data with dapagliflozin and saxagliptin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. During pregnancy, consider appropriate alternative therapies.

Miscarriage

 Conflict Code: MC – Drug (Actual) Disease Precaution

 Util A
 Util B

 Dapagliflozin/Saxagliptin
 Pregnancy

 Delivery

 Abortion

Gender: Female Age Range: 11 – 55 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Qtern Prescribing Information, February 2017, AstraZeneca. American College of Obstetricians and Gynecologists (ACOG), Committee on Practice Bulletins - Obstetrics. Practice Bulletin No. 137: Gestational Diabetes Mellitus. Obstet Gynecol. 2013:122(2 Pt 1):406-416. Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):406-416.

69. Rivaroxaban / SSRIs & SNRIs

Alert Message: Concomitant use of Xarelto (rivaroxaban) with SSRIs or SNRIs may enhance the anticoagulant effect of rivaroxaban and increases the risk of bleeding. SSRIs and SNRIs can inhibit serotonin uptake by platelets, thus causing platelet dysfunction and risk of bleeding. Promptly evaluate any signs or symptoms of blood loss if the patient is treated concurrently with these agents.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
Util A	<u>Util B</u>		<u>Util C</u>
Rivaroxaban	Fluoxetine	Venlafaxine	
	Fluvoxamine	Desvenlafaxine	
	Paroxetine	Milnacipran	
	Citalopram	Levomilnacipran	
	Escitalopram	Duloxetine	
	Sertraline		
	Vilazodone		
	Vortioxetine		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health. Xarelto Prescribing Information, Aug. 2016, Janssen Pharmaceuticals.

70. Dabrafenib / Overutilization

Alert Message: Tafinlar (dabrafenib) may be over-utilized. The manufacturer's recommended maximum daily dose is 300 mg (150 mg orally twice daily).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u> Util C Util B Dabrafenib

Max Dose: 30 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health.

71. Dabrafenib / Strong CYP3A4 & CYP2C8 Inhibitors

Alert Message: Concurrent use of Tafinlar (dabrafenib) with a strong CYP3A4 or CYP2C8 inhibitor should be avoided. Dabrafenib is a substrate of CYP3A4 and CYP2C8 and concomitant use with a strong inhibitor of either enzyme may result in increased dabrafenib concentrations and risk of adverse reactions. If co-administration is unavoidable monitor patient closely for adverse events.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Dabrafenib	Gemfibrozil	Indinavir	
	Clopidogrel	Cobicistat	
	Clarithromycin	Ketoconazole	
	Telithromycin	Itraconazole	
	Saquinavir	Voriconazole	
	Ritonavir	Posaconazole	
	Nelfinavir	Nefazodone	
References:			

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health.

72. Dabrafenib / Strong CYP3A4 & CYP2C8 Inducers

Alert Message: Concurrent use of Tafinlar (dabrafenib) with a strong CYP3A4 or CYP2C8 inducer should be avoided. Dabrafenib is a substrate of CYP3A4 and CYP2C8 and concomitant use with a strong inducer of either enzyme may result in decreased dabrafenib concentrations. If co-administration is unavoidable monitor patient closely for loss of dabrafenib efficacy.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases			
Util A	Util B		Util C
Dabrafenib	Carbamazepine	Rifapentine	
	Phenobarbital	Rifampin	
	Phenytoin	Rifabutin	
	Primidone		
References:			

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017, Wolters Kluwer Health.

73. Dabrafenib / Sensitive CYP3A4, 2C8, 2C9, 2C19 & 2B6 Substrates

Alert Message: Concurrent use of Tafinlar (dabrafenib) with agents that are sensitive substrates of CYP3A4, CYP2C8, CYP2C9, CYP2C19 or CYP2B6 may result in loss of efficacy of the substrate. Dabrafenib is an inducer of these enzymes and concomitant use may result in decreased concentrations of the substrates. If co-administration is unavoidable monitor patient closely for loss of substrate efficacy.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dabrafenib	Midazolam	
	Triazolam	
	Warfarin	
	Dexamethasone	
	Desipramine	
	Dextromethorpha	an
	Nebivolol	
	Repaglinide	
	Lansoprazole	
	Omeprazole	
	Hormonal Contra	ceptives
Defenses		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Facts & Comparisons, 2017, Wolters Kluwer Health. FDA Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at: https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664. htm [Accessed 4/2017].

DUR Board Meeting December 6, 2017 Heritage Center Lecture Rooms A & B



North Dakota Medicaid DUR Board Meeting Agenda Brynhild Haugland Room State Capitol 600 East Boulevard Avenue Bismarck, ND December 6, 2017 1:00 pm

- 1. Administrative items
 - Travel vouchers
- 2. Old business
 - Review and approval of 09/06/2017 meeting minutes
 - Budget update
 - Review top 15 therapeutic categories/top 25 drugs
 - Prior authorization/PDL update
 - Annual prior authorization review of forms and criteria
- 3. New business
 - Input regarding opioid and benzodiazepine abuse and overdose diagnoses
 - Review of Eucrisa
 - Review of Skelaxin
 - Criteria recommendations
 - Upcoming meeting date/agenda
- 4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

September 6, 2017

Members Present: Tanya Schmidt, Laura Schield, Jeffrey Hostetter, Michael Quast, Zach Marty, LeNeika Roehrich, Andrea Honeyman, Carlotta McCleary,

Members Absent: Michael Booth, Peter Woodrow, Gaylord Kavlie, Katie Kram, Wendy Brown,

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy

Old Business

L. Roehrich served as Chair in the absence of W. Brown, and called the meeting to order at 1:00 p.m. Chair L. Roehrich asked for a motion to approve the minutes of the September meeting. L. Schield moved that the minutes be approved and Z. Marty seconded the motion. Chair L. Roehrich called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 15 Therapeutic Categories/Top 25 Drugs

B. Joyce presented the quarterly review of the top 15 therapeutic classes by total cost of claims, top 25 drugs based on number of claims, and top 25 drugs based on claims cost for the 2nd quarter of 2017.

Sanford Update

Danny Weiss, representing Sanford Health Plan, spoke regarding ND Medicaid Expansion. In 2016, there were 19,506 average members per month with 102.2% of members utilizing benefits. The generic fill rate was 85.9%. The top 25 drugs represent 42.1% of total plan cost and 8 of the top 25 drugs are specialty drugs. The top 10 indications by cost represent 70.4% of total plan costs with the largest trend being in inflammatory conditions with a 71.5% increase from 2015.

Second Reviews

A motion and second was made at the June meeting to place Biltricide and Procysbi on prior authorization. The topics were brought up for a second review. There was no public comment. The motion to place Biltricide and Procysbi on prior authorization passed with no audible dissent.

PDL Update

A. Murphy shared with the Board all of the recommended PDL changes since the last 2017 version of the PDL was posted. Added to PA required were Kevzara to the Cytokine Modulators criteria, Morphabond ER to the Narcotics criteria, Ellzia Pak to the Kit criteria, Fabior to the Acne criteria, Brovana to the COPD criteria, Lialda and Apriso to the Inflammatory Bowel Agents criteria, Prednisolone sodium phosphate 10 mg/5 mL and 20 mg/5 mL to the Prednisolone Non-Solid Oral Dosage Forms criteria, Methyltest and methyltestosterone to the Oral Testosterone criteria, and Ilaris and Tymlos to the medications >\$3,000 criteria. Xolair, Brineuria, and Ketamine were added to the Medical Billing Only list of medications, and Xifaxan 550 mg, Avonex, and Avonex pen will no longer require PA.

<u>New Business</u>

Juxtapid and Kynamro

B. Joyce presented updated criteria and a drug specific form for Juxtapid and Kynamro for the Board to review. There was no public comment. The motion to approve the updated criteria and form passed with no audible dissent.

Procysbi

B. Joyce presented updated criteria and a drug specific form for Procysbi for the Board to review. There was no public comment. The motion to approve the updated criteria and form passed with no audible dissent.

Tymlos and Miacalcin

B. Joyce presented updated criteria and a drug specific form for Tymlos and Miacalcin for the Board to review. There was no public comment. The motion to approve the updated criteria and form passed with no audible dissent.

Tardive Dyskinesia Agents

B. Joyce and A. Murphy presented updated criteria and a drug specific form for agents used to treat of tardive dyskinesia including Austedo, Ingrezza, and tetrabenazine. Maggie Murphy, representing Teva Pharmaceuticals, offered the opportunity to ask any questions regarding Austedo. Samantha Cicero, representing Neurocrine Biosciences, presented product information regarding Ingrezza. Z. Marty and L. Schield proposed amending the criteria for Ingrezza to require a trial of Austedo as opposed to a trial of tetrabenazine. The motion to approve the amended updated criteria and form passed with no audible dissent.

Jadenu

B. Joyce and A. Murphy presented updated criteria and a drug specific form for Jadenu for the Board to review. There was no public comment. The motion to approve the updated criteria and form passed with no audible dissent.

Review of Opioid Analgesic and Benzodiazepine Utilization

B. Joyce presented data showing current utilization of benzodiazepines, including use with and without opioid analgesics, rate of appropriate utilization for a diagnosis of anxiety, and utilization of multiple benzodiazepines. B. Joyce presented data showing utilization of opioid analgesics, including historic and current utilization of each individual agent by prescription count and average dose. The Board discussed potential provider education and drug edit opportunities.

Physician Prescribing Patterns for Select Therapeutic Categories

B. Joyce presented data showing the top prescriber utilization of select medications in therapeutic drug classes in order to evaluate utilization trends and potential outliers. Therapeutic classes evaluated included opioid analgesics, benzodiazepines, and gabapentin. Prescriber utilization was presented as number of prescriptions for, and patients currently on, selected medications, percent utilization of selected medications within their therapeutic class, and those with the highest number of patients on a high dose of select mediations.

Review of Stimulant Utilization Trends

B. Joyce presented stimulant utilization data trends over time, from 2001 to 2017. The data tracked the average daily dose per patient of each individual medication by age group. The data trends predominantly revealed increase in average daily dose overall with some exceptions in some age groups trending towards a dose decrease.

Criteria Recommendations

The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. J. Hostetter moved to approve the new criteria and Z. Marty seconded the motion. The motion passed with no audible dissent. The next DUR Board meeting will be held December 6, 2017 at the Capitol in the Brynhild Haugland room in Bismarck. L. Roehrich adjourned the meeting.

NORTH DAKOTA MEDICAID Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 07/01/2017 - 09/30/2017

				% Total
AHFS Therapeutic Class	Rx	Paid	Paid/Rx	Claims
INSULINS	1,863	\$ 831,863.50	\$ 446.52	1.35%
ANTICONVULSANTS, MISCELLANEOUS	8,445	\$ 809,726.20	\$ 95.88	6.10%
ANTIPSYCHOTIC AGENTS	5,899	\$ 751,014.15	\$ 127.31	4.26%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	159	\$ 602,010.53	\$ 3,786.23	0.11%
RESPIRATORY AND CNS STIMULANTS	3,619	\$ 498,088.18	\$ 137.63	2.61%
CORTICOSTEROIDS (RESPIRATORY TRACT)	1,974	\$ 478,880.05	\$ 242.59	1.43%
AMPHETAMINES	3,349	\$ 471,604.96	\$ 140.82	2.42%
IMMUNOMODULATORY AGENTS	59	\$ 361,574.73	\$ 6,128.39	0.04%
ANTIDEPRESSANTS	14,568	\$ 341,037.59	\$ 23.41	10.53%
BETA-ADRENERGIC AGONISTS	3,426	\$ 254,195.62	\$ 74.20	2.48%
SCABICIDES AND PEDICULICIDES	781	\$ 198,681.88	\$ 254.39	0.56%
OPIATE AGONISTS	5,550	\$ 193,180.55	\$ 34.81	4.01%
ANTINEOPLASTIC AGENTS	237	\$ 188,027.54	\$ 793.37	0.17%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,584	\$ 176,965.92	\$ 111.72	1.14%
ANTIRETROVIRALS	176	\$ 175,458.24	\$ 996.92	0.13%
Total Top 15	51,689	\$ 6,332,309.64	\$ 122.51	37.35%

Total Rx Claims	138,397
From 07/01/2017 - 09/30/2017	

Top 15 Therapeutic Classes Based on Total Cost of Claims



Health Information Designs, Inc.

NORTH DAKOTA MEDICAID Cost Management Analysis

11/09/2017

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 07/01/2017 - 09/30/2017

							% Total
Drug	AHFS Therapeutic Class	Rx		Paid	Pa	id/Rx	Claims
OMEPRAZOLE	PROTON-PUMP INHIBITORS	49,257.58	\$	18.44	1.93%		
SERTRALINE HCL	ANTIDEPRESSANTS	2,510	\$	44,802.97	\$	17.85	1.81%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,433	\$	78,781.18	\$	32.38	1.76%
AMOXICILLIN	PENICILLINS	2,242	\$	93,546.06	\$	41.72	1.62%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,172	\$	74,809.13	\$	34.44	1.57%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,067	\$	42,246.09	\$	20.44	1.49%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,043	\$	33,334.49	\$	16.32	1.48%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,922	\$	32,045.07	\$	16.67	1.39%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,913	\$	41,629.87	\$	21.76	1.38%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	1,910	\$	45,939.44	\$	24.05	1.38%
TRAZODONE HCL	ANTIDEPRESSANTS	1,846	\$	26,941.66	\$	14.59	1.33%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,656	\$	316,725.42	\$ 1	91.26	1.20%
METFORMIN HCL	BIGUANIDES	1,452	\$	23,481.82	\$	16.17	1.05%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,447	\$	20,893.72	\$	14.44	1.05%
BUPROPION XL	ANTIDEPRESSANTS	1,389	\$	34,188.45	\$	24.61	1.00%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,388	\$	22,682.68	\$	16.34	1.00%
VYVANSE	AMPHETAMINES	1,353	\$	280,973.81	\$ 2	07.67	0.98%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,311	\$	22,307.76	\$	17.02	0.95%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,287	\$	18,803.20	\$	14.61	0.93%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	1,231	\$	42,322.64	\$	34.38	0.89%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,187	\$	21,656.60	\$	18.24	0.86%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,176	\$	80,090.02	\$	68.10	0.85%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,171	\$	22,291.35	\$	19.04	0.85%
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	1,161	\$	51,897.46	\$	44.70	0.84%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,160	\$	26,731.46	\$	23.04	0.84%
TOTAL TOP 25		42,098	\$ [,]	1,548,379.93	\$	36.78	30.42%
Total Rx Claims From 07/01/2017 - 09/30/2017	138,397]					

Total Rx Claims	138,39
From 07/01/2017 - 09/30/2017	



Top 10 Drugs Based on Number of Claims

NORTH DAKOTA MEDICAID Cost Management Analysis

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 07/01/2017 - 09/30/2017

						% Total
Drug	AHFS Therapeutic Class	Rx		Paid	Paid/Rx	Claims
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,656	\$	316,725.42	\$ 191.26	1.20%
NOVOLOG FLEXPEN	INSULINS	571	\$	289,827.47	\$ 507.58	0.41%
VYVANSE	AMPHETAMINES	1,353	\$	280,973.81	\$ 207.67	0.98%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	582	\$	248,176.36	\$ 426.42	0.42%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	54	\$	220,026.35	\$ 4,074.56	0.04%
LANTUS SOLOSTAR	INSULINS	502	\$	195,418.02	\$ 389.28	0.36%
LATUDA	ANTIPSYCHOTIC AGENTS	213	\$	173,357.04	\$ 813.88	0.15%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	502	\$	163,415.01	\$ 325.53	0.36%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	81	\$	150,399.84	\$ 1,856.79	0.06%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	42	\$	145,568.25	\$ 3,465.91	0.03%
FREESTYLE LITE STRIPS	DIABETES MELLITUS	909	\$	130,569.01	\$ 143.64	0.66%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	9	\$	129,026.33	\$14,336.26	0.01%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	363	\$	128,790.88	\$ 354.80	0.26%
COPAXONE	IMMUNOMODULATORY AGENTS	18	\$	117,938.72	\$ 6,552.15	0.01%
LEVEMIR FLEXTOUCH	INSULINS	351	\$	107,950.13	\$ 307.55	0.25%
ADDERALL XR	AMPHETAMINES	548	\$	107,005.88	\$ 195.27	0.40%
GILENYA	IMMUNOMODULATORY AGENTS	15	\$	105,537.66	\$ 7,035.84	0.01%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	180	\$	101,320.48	\$ 562.89	0.13%
PROVENTIL HFA	BETA-ADRENERGIC AGONISTS	1,055	\$	98,659.50	\$ 93.52	0.76%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	24		96,868.72	\$ 4,036.20	0.02%
NIX	SCABICIDES AND PEDICULICIDES	282	\$	96,771.24	\$ 343.16	0.20%
AMOXICILLIN	PENICILLINS	2,242	\$	93,546.06	\$ 41.72	1.62%
ONFI	BENZODIAZEPINES (ANTICONVULSANTS)	97	\$	91,824.90	\$ 946.65	0.07%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	289	\$	85,741.78	\$ 296.68	0.21%
NORDITROPIN FLEXPRO	PITUITARY	24	\$	84,724.14	\$ 3,530.17	0.02%
TOTAL TOP 25		11,962	\$3	3,760,163.00	\$ 314.34	8.64%
Total Rx Claims	138,397	-				
	100,007	1				

From 07/01/2017 - 09/30/2017



Top 10 Drugs Based on Total Claims Cost

11/09/2017

Prior Authorization/PDL Update

Added to PA	Category		
ARMONAIR RESPICLICK	Steroid Inhalers		
BENLYSTA	> 3000		
BILTRICIDE	Biltricide		
CLOBETASOL EMOLLIENT FOAM	Topical Psoriatic Arthritis		
CLOBETASOL PROPIONATE FOAM	Topical Psoriatic Arthritis		
FIASP	Insulins		
FIASP FLEXTOUCH	Insulins		
HAEGARDA	Hereditary Angioedema		
HUMALOG JUNIOR KWIKPEN	Insulins		
HYDROCODONE-IBUPROFEN	Narcotics		
INGREZZA	Tardive Dyskinesia		
LOTEMAX GEL DROPS	OPHTHALMIC ANTIINFLAMMATORIES		
MAVYRET	Нер С		
ORENITRAM ER	Pulmonary Arterial Hypertension		
PROGLYCEM	Proglycem		
QVAR REDIHALER	Inhaled Steroids		
SYMPROIC	IBS/OIC		
SYNDROS	Marinol		
TRELEGY ELLIPTA	COPD		
TREMFYA	Cytokine Modulators		
VOSEVI	Hep C		

Removed from PA	Category
MOVIPREP	Bowel Prep Agents

Bill Medical Side VIA 8371 AND 837P TRANSACTIONS
BRINEURA
KETAMINE
KYMRIAH
PARSABIV
RENFLEXIS
XIAFLEX

ACTINIC KERATOSIS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Solaraze, Zyclara, or Picato must first try imiquimod. • Imiquimod does not require prior authorization

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number			
Physician Name		· · · ·				
Physician Medicaid Provider Number	Telephone Number	Fax Number				
Address	City	State	Zip Code			
Requested Drug and Dosage:	Diagnosis for this Request:					
Physician Signature		Date				
**: By completing this form, I hereby certi						
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical						
records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization						
request may subject me to audit and reco	pupment.		request may subject me to audit and recoupment.			

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

ALTEPLASE PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Alteplase must meet the following criteria:

- Patient must have an FDA approved indication.
- Alteplase is indicated for restoration of function to central venous access devices as assessed by the ability to withdraw blood.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name				
Physician Medicaid Provider Number	Telepho	one Number	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:	D	iagnosis for this Request:		
I confirm that I have considered a generic or other successful medical management of the recipient.	r alterna	tive and that the requested di	rug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of resentati	f the member, and is clinically ions or concealment of any inf	supported in t	he patient's

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:
DRUG	NDC #	
TELEPHONE NUMBER	FAX NUMBER	





Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Amrix must try and fail generic cyclobenzaprine.

- Cyclobenzaprine does not require PA
- Patient must fail therapy on generic cyclobenzaprine before a PA will be considered for Amrix.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipient	Medicaid ID Number	
Physician Name					
Physician Medicaid Provider Numbe	er	Telephone Number	Fax Numb	Fax Number	
Address		City	State	Zip Code	
Requested Drug and Dosage:		Diagnosis for this request		·	
□ AMRIX					
Qualifications for coverage:					
Failed Cyclobenzaprine Therapy? YES □ NO	Start Date	End Date	Dose	Frequency	
 I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient. 					
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ANTIHEMOPHILIC FACTORS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for antihemophilic factors must provide the following information:

- Visit once per year with an accredited Hemophilia Treatment Center
- Date of last appointment with treatment center
- Contact information for treatment center

Recipient Name		Recipient Date of Birth		Recipient Me	Recipient Medicaid ID Number	
Physician Name						
Physician Medicaid Provider Numb	per	Tele	phone Number	Fax Number		
Address		City		State	Zip Code	
Requested Drug and Dosage	:		Diagnosis for this Re	quest:		
TREATMENT CENTER CONTACT INFORMATION: DATE OF LAST APPOINTMENT WITH TREA CENTER:					REATMENT	
Patient visits an accredited Hemophilia Treatment Center for yearly checkups: YES INO						
I confirm that I have consider successful medical manageme			rnative and that the requ	lested drug is expect	ed to result in the	
Prescriber (or Staff) / Pharmacy Signature**						
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						
Part II: TO BE COMPLETED BY	PHARMACY					
PHARMACY NAME: TELEPHONE NUMBER	FAX NUMBER			ND MEDICAID PRC	VIDER NUMBER:	



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving antihistamines must use loratadine (Claritin generic) and cetirizine (Zyrtec generic) as step therapy.

*Note:

- Loratadine OTC and cetirizine OTC (or prescription) may be prescribed WITHOUT prior authorization.
- Patient must have failed a 14 day trial of Xyzal OTC, as evidenced by paid pharmacy claims or pharmacy print-outs.
- Patient must have failed a 14 day trial of one of the following, as evidenced by paid pharmacy claims or pharmacy print-outs:
 - Loratadine OTC
 - Cetirizine OTC

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:		RECIPIENT MEDICAID ID NU	MBER:	
Recipient				
Date of birth: /	/			
PRESCRIBER NAME:		PRESCRIBER MEDICAID ID NU	MBER:	
Address:		Phone: ()		
City:		FAX: ()		
State:	Zip:			
REQUESTED DRUG:		Requested Dos	age:	
		Diagnosis for t	his request:	
Qualifications for coverage:		U	•	
Failed Ioratadine	Start Date:		End Date:	
Failed cetirizine				
□ Failed Xyzal OTC				
I confirm that I have consider successful medical managem		e and that the reque	ested drug is expected to result in the	
Prescriber (or Staff) / Pharma			Date	
medically necessary, does no medical records. I also unders	t exceed the medical needs of th	ne member, and is o s or concealment of	e and complete. That the request is linically supported in the patient's f any information requested in the pric	or

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Short-Acting HFA Beta₂ Agonist PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for ProAir RespiClick, Ventolin HFA, or Xopenex HFA must use Proventil HFA as first line therapy.

*Note: Proventil HFA does not require a prior authorization.

- Ventolin HFA trial of Proventil HFA.
- Xopenex HFA trial of Proventil HFA and Ventolin HFA.
- ProAir RespiClick trial of Proventil HFA, Ventolin HFA, and Xopenex HFA.

Recipient Name		Recipient Date of Birth	Recipient N	Recipient Medicaid ID Number	
Physician Name					
Physician Medicaid Provider Number	er	Telephone Number	Fax Numb	er	
Address		City	State	Zip Code	
Requested Drug and Dosage:		Diagnosis for this request:			
□ XOPENEX HFA					
VENTOLIN HFA					
D PROAIR RESPICLICK					
Qualifications for coverage:					
Failed therapy 1. 2. 3.	Start Date	End Date	Dose	Frequency	
 I confirm that I have considered successful medical managem 		alternative and that the request	ed drug is expecte	ed to result in the	
Prescriber (or Staff) / Pharmacy	Signature**		Date		
**: By completing this form, I her medically necessary, does not e records. I also understand that a request may subject me to audit	xceed the medical ne	eds of the member, and is clini	cally supported in	the patient's medical	

Part II: TO BE COMPLETED BY PHARMACY						
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:			
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #			



Brisdelle PA Form

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Brisdelle must meet the following criteria:

- Patient must have had a 30-day trial of generic paroxetine.
- Patient must have a diagnosis of moderate to severe vasomotor symptoms associated with menopause

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth		Recipient Medicaid ID Number		
Prescriber Name						
Prescriber NPI		Telephone Number		Fax Number		
Address		City		State	Zip Code	
Requested Drug and Dosage:		Diagnosi	s for Request:		•	·
		 Moderate to severe vasomotor symptoms associated with menopause 				
		Other:				
Qualifications for Coverage:						
Medications patient has tried:	Start Da	te:	End Date:	Dos	e:	Frequency:
Other medical justification for use:						
Prescriber (or Staff) / Pharmacy Signature** Date						
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:



LONG ACTING OPIOID ANALGESICS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a short-acting opioid analgesic must meet the following criteria:

- Failure of a 30-day trial of two preferred agents will be required before a non-preferred will be authorized. Oxycodone IR
- The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient.

Physician Name Telephone Number Fax Number Physician Medicaid Provider Number Telephone Number Fax Number Address City State Zip Code Requested Drug and Dosage: Diagnosis for this Request: Cancer Pain Other: Has patient required daily use of opioids for at least 90 days? YES NO Does the prescriber routinely check the PDMP system? YES NO FAILED THERAPY START DATE END DATE DOSE & FREQUENCY	Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number		
Address City State Zip Code Requested Drug and Dosage: Diagnosis for this Request: 	Physician Name			I		
Requested Drug and Dosage: Diagnosis for this Request: □ Cancer Pain □ Other: Has patient required daily use of opioids for at least 90 days? Does the prescriber routinely check the PDMP system?	Physician Medicaid Provider Number	Telephone Nu	umber	Fax Number		
Image: Second state of the preservice of the preservi	Address	City		State	Zip Code	
Does the prescriber routinely check the PDMP system? □ YES □ NO						
FAILED THERAPY START DATE END DATE DOSE & FREQUENCY						
I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.		er alternative a	and that the requested dr	ug is expected	to result in the	
Prescriber (or Staff) / Pharmacy Signature** Date	Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.	medically necessary, does not exceed the medical medical records. I also understand that any misrep	l needs of the l presentations o	member, and is clinically	supported in th	he patient's	
Part II: TO BE COMPLETED BY PHARMACY PHARMACY NAME: ND MEDICAID PROVIDER NUMBER:						

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

ORAL ANTICOAGULANTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Pradaxa, Xarelto, Eliquis, or Savaysa must meet the following criteria:

- Patient must have an FDA approved indication.
- A 30 day trial of all preferred agents will be required before a non-preferred agent will be authorized.

Recipient Name	Rec	ipient Date of Birth	Recipient Me	dicaid ID Number
Physician Name				
Physician Medicaid Provider Number	Tele	ephone Number	Fax Number	
Address	City	,	State	Zip Code
Requested Drug and Dosage: □ PRADAXA □ XARELTO □ ELIQUIS □ SAVAYS/	٨	Diagnosis for this Request:		
I confirm that I have considered a generic or other successful medical management of the recipient.	r altei	rnative and that the requested a	lrug is expecte	ed to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the				
medically necessary, does not exceed the medical medical records. I also understand that any misrepr				
authorization request may subject me to audit and r				
Part II: TO BE COMPLETED BY PHARMACY				
			EDIONID DDO	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



SHORT ACTING OPIOID ANALGESICS PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a short-acting opioid analgesic must meet the following criteria:

• Subsys, Fentora, Lazanda, Actiq and Abstral

- o Patient must be at least 18 years of age for Subsys, Fentora, or Lazanda, and 16 years for Actiq or Abstral.
- The patient must have cancer pain.
- The patient must currently be on around the clock opioid therapy and have been on round the clock opioid therapy for at least 1 week, as evidenced by paid claims or pharmacy print-outs.

Oxycodone IR

- The patient must have chronic pain.
- The patient must currently be on a long-acting narcotic, as evidenced by paid claims or pharmacy print-outs.
- The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient.
- The patient's current total daily Morphine Equivalent Dose (MED), must be greater than the minimum per tablet strength requested (below), as evidenced by paid claims or pharmacy print-outs.
 - For 15 mg tablet ≥300 MED/day, for 20 mg tablet ≥300 MEDs/day, for 30 mg tablet ≥300 MEDs/day.

Oxaydo

- The patient must have failed 3 separate trials of generic, immediate-release narcotics, as evidenced by paid claims or pharmacy print-outs.
- o The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient.

Recipient Name		Recipient Date of Birth			Recipient Medicaid ID Number		
Physician Name							
Physician Medicaid Provider Number		Teleph	one Numbe	r		Fax Number	
ddress		City	City			State	Zip Code
Requested Drug and Dosage:			Diagnos	is for this R	equest:		
			Chror	nic Pain	🗆 Ca	ncer Pain	□ Other:
Is patient on a long-acting narcotic			□ YES	□ NO			
Does the prescriber routinely chec FAILED THERAPY	k the PDMP sys			DOSE & FI		101/	
			ative and t				I to recult in the
I confirm that I have considered successful medical management of successful medical medical management of successful medical medi		er alterna	ative and t	nat the reque	estea art	ig is expected	to result in the
Prescriber (or Staff) / Pharmacy S	ignature**					Date	
**: By completing this form, I herei medically necessary, does not exc medical records. I also understand authorization request may subject	ceed the medical d that any misrep	l needs o presentai	of the men tions or co	ber, and is c	linically :	supported in t	he patient's
Part II: TO BE COMPLETED BY PH	ARMACY						
PHARMACY NAME:					ND ME	EDICAID PROV	/IDER NUMBER:
TELEPHONE NUMBER FA	X NUMBER DI	RUG			NDC #		



ACE-Inhibitors (ACE-I), Angiotensin II Receptor Blockers (ARB) and Renin Inhibitor PA Form

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for an ACE-I, ARB, Renin Inhibitor, or any combination not listed below must meet the following criteria:

- ACE-I: Captopril, enalapril, ramipril, lisinopril, trandolapril, quinapril, benazepril, and fosinopril and their hydrochlorothiazide containing combinations do not require a prior authorization. Epaned does not require a PA for patients less than 7 years of age.
- Angiotensin II receptor antagonists: Losartan and valsartan do not require a prior authorization.
- Renin Inhibitor: Aliskiren and combination products require a prior authorization.
- Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth Recipient Medica		ledicaid ID Number
Prescriber Name			I	
Prescriber NPI		Telephone Number	Fax Numbe	9r
Address		City	State	Zip Code
Requested Drug and Dosage:		Diagnosis for this request: Does patient have symptoma class II-IV)?		t failure (NYHA
Failed therapy (list all that apply)	Start Date	E	Ind Date	
Is the patient unable to ingest solid do	osage form	s (provide documentation)?	YES 🗆 NO	
Prescriber (or Staff) / Pharmacy Signatur	re**		Date	
**: By completing this form, I hereby cert medically necessary, does not exceed th medical records. I also understand that a authorization request may subject me to	ne medical r any misrepre	needs of the member, and is clini esentations or concealment of ar	ically supported in	n the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

ACITRETIN PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Acitretin must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must be male or female permanently unable to bear children.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient N	ledicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Numbe	er
Address	City	State	Zip Code
Requested Drug and Dosage:	FDA approved indication for th	is request:	
	Is patient permanently unable t	o bear childre	n? 🗆 YES 🗆 NO
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medica medical records. I also understand that any misrep	I needs of the member, and is clinica	lly supported in	n the patient's

authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

ACNE AGENTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for an acne agent must meet the following criteria:

- Patients between the ages of 12-35 are eligible for acne treatment.
- Requires step therapy. See acne criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medio	caid ID Number	
Prescriber Name	Dermatologist Involved in therapy:			
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this Request:			
LIST ALL FAILED MEDICATIONS AND REASON:				
I confirm that I have considered a generic or other successful medical management of the recipient.	r alternative and that the requested d	rug is expected	to result in the	
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical I medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is clinically esentations or concealment of any in	v supported in th	he patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

AMPYRA PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Ampyra must meet the following criteria:

- Patient must be 18 years or older.
- Patient must have a specialist (neurologist or physiatrist) involved in therapy.
- Patient must have a confirmed diagnosis of multiple sclerosis.
- Patient must not have a history of seizures
- Patient's CrCl (creatinine clearance) must be greater than 50mL/min
- Renewal PA requests must include patient's current T25FW.

Recipient Name	Recipient Date of Birth	Recipient Me	edicaid ID Number
Physician Name	Specialist involved in therap	y (if not treating physi	ician)
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	FDA approved indication	for this request:	
Has patient experienced any acute exacerbation	s within the last 60 days?		□ NO
Does the patient have a CrCL greater than 50mL	/min?		□ NO
Does the patient have a history of seizures?			□ NO
What is the patient's baseline Timed 25-foot Walk (T25FW)?	If this is a renewal PA re T25FW:	quest, please includ	le patient's current
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical r medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is o esentations or concealment o	clinically supported in	the patient's
Part II: TO BE COMPLETED BY PHARMACY			
PHARMACY NAME:		ND MEDICAID PRO	OVIDER NUMBER:

TELEPHONE NUMBER	FAX	DRUG	NDC #
	NUMBER		


ANTIHYPERURICEMICS PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for antihyperuricemics must meet the following criteria: • Colchicine: Patient must have failed a 30-day trial of Mitigare.

- <u>All Others</u>: Patient must have failed a 30-day trial of allopurinol 300 mg or greater.
- <u>Zuramic</u>: Patient must have failed a 30-day trial of Uloric and be using Zuramic in combination with allopurinol or Uloric.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		K	Recipient Date of Birth			Recipient Medicaid ID Number		
Prescriber Name								
Prescriber NPI			elephon	e Number		Fax Number		
Address	3S					State	Zip Code	
Requested Drug and Dosage:			Diagnosis for Request:					
Qualifications for Coverage:								
Medications patient has tried:	S	tart Date:	:	End Date:	Dos	e:	Frequency:	
Other medical justification for use (e.g. renal or hepatic impairment):								
Prescriber (or Staff) / Pharmacy	Signature**				Date			
**: By completing this form, I he medically necessary, does not e medical records. I also understa authorization request may subje	exceed the me and that any m ect me to audit	edical nee hisreprese and reco	eds of the	e member, and s or concealmen	is clinically	v supported	in the patient's	
Part II: TO BE COMPLETED B	BY PHARMAC	Ϋ́						
PHARMACY NAME:				ND MEDICAID PROVIDER NUMBER:				
TELEPHONE NUMBER	FAX NUMBE	R	DRUG		NDC	#		





Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for antimalarial agents must meet the following criteria:

- For all agents:
 - Patient must have tried a generic quinine in the last 30 days.
 - Provider must submit an appropriate MedWatch form documenting the trial.
- For Malarone with NDC 00173067601:
 - o Patient must meet above criteria
 - Patient must be less than 18 years of age.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth			Recipient Medicaid ID Number		
Prescriber Name							
Prescriber NPI		Telephone Number			Fax Number		
Address		City			State	Zip Code	
Requested Drug and Dosage:		Diagnosis for Request:					
Qualifications for Coverage:							
Medications patient has tried:	Start Date:		End Date:	Dos	e:	Frequency:	
Other medical justification for use (e.g. renal or hepatic impairment):							
Prescriber (or Staff) / Pharmacy Signature				Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. Lalso understand that any misrepresentations or concealment of any information requested in the prior							

authorization request may subject me to audit and recoupment.

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires a 30-day trial of all preferred products before non-preferred agent will be authorized. *Note:

- An FDA approved indication of treatment of flares in patients with moderately active ulcerative colitis is required.
- See list of preferred products at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Da	ate of Birth	Recipient N	Recipient Medicaid ID Number	
Prescriber Name	<u> </u>				
Prescriber NPI	Telephone N	Number	Fax Numb	er	
Address	City		State	Zip Code	
Requested Drug and Dosage:	Diagnosis	for this request:			
List all failed medications:		Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that medically necessary, does not exceed the medi records. I also understand that any misrepreser authorization request may subject me to audit a	lical needs of the ntations or conce	member, and is cli	inically supported	in the patient's medical	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



CYSTIC FIBROSIS ANTI-INFECTIVES PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for TOBI, TOBI Podhaler, tobramycin inhalation or Cayston must meet the following criteria:

- Patient must have had a 28 day trial of Bethkis or Kitabis Pak, as evidenced by paid claims or pharmacy print-outs.
- Patient must have an FDA approved indication.
- Patient must be 6 years of age or older (TOBI) and 7 years of age or older (Cayston).
- The patient has not been colonized with Burkholderia cepacia.
- For Cayston:

•

• Patient must have a FEV1 of less than 25% or greater than 75% predicted

For or TOBI, TOBI Podhaler, or tobramycin inhalation

• Patient must have a FEV1 of less than 40% or greater than 80% predicted.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth			Recipient Medicaid ID Number		
Prescriber Name							
Prescriber NPI		Telepho	ne	Number	Fax Number		
Address		City				State	Zip Code
Requested Drug and Dos	sage:		Di	iagnosis for this	reque	st:	
List all failed medication	IS:			Start Date:	E	nd Date:	
FEV1:				as the patient bee YES □ NO	n color	nized with Burk	holderia cepacia?
I confirm that I have con successful medical man	agement of the recipi		ive a	and that the reque	ested d	rug is expected	l to result in the
Prescriber (or Staff) / Pharmacy Signature**					Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.							
Part II: TO BE COMPLET	ED BY PHARMACY						
PHARMACY NAME:						VIDER NUMBER:	
TELEPHONE NUMBER	FAX NUMBER	DRUG			NDC 7	#	

BOWEL PREP AGENTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for a bowel prep agent must meet the following criteria: • Patient must first try Golytely.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth			Recipient Medicaid ID Number		
Prescriber Name							
Prescriber NPI		Telephone Number			Fax Numb	er	
Address		City			State	Zip Code	
Requested Drug and Dosage:		Diagnosis for Request:					
Qualifications for Coverage:							
Medications patient has tried:	Start Date:		End Date:	Dos	:e:	Frequency:	
Other medical justification for use (reason Golytely cannot be used):							
Prescriber (or Staff) / Pharmacy Signatur				Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.							

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:



CARISOPRODOL PA Form

Prior Authorization Vendor for ND

*Cyclobenzaprine, chlorzoxazone, methocarbamol and orphenadrine do not require a prior authorization.

*Note:

• PA will be approved if recipient is currently taking carisoprodol on a chronic basis and provider is weaning patient.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number		Fax Numb	er
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:			
Qualifications for coverage:				
CHRONIC CARISOPRODOL RECIPIENT BEING INCLUDE WEANING SCHEDULE)	G WEANED (PLEASE	Dose:	F	requency:
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		ested dru	ug is expec	cted to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is cl esentations or concealment of	linically s	supported i	in the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



CIALIS FOR BENIGN PROSTATIC HYPERPLASIA PA Form

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Cialis used to treat benign prostatic hyperplasia (BPH) must meet the following criteria:

- Patient must have diagnosis of BPH
- Patient must try and fail all alpha blockers and 5-alpha reductase inhibitors and combinations, unless contraindicated.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID		dicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
Qualifications for coverage: (please attach any ac	dditional notes listed all products f	ailed)	
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		ed drug is expected	d to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is clinic resentations or concealment of an	cally supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



COMBINATION PRODUCTS PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for a combination product that is more expensive than the individual components must meet the following criteria:

• Patient must be currently stable on the combination product.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Number					
Dressriker Nome						
Prescriber Name						
	Talasha a Nicasha a					
Prescriber NPI	Telephone Number	Fax Number				
Address	City	State	Zip Code			
Requested Drug and Dosage:	Diagnosis for this request:					
Qualifications for coverage:	·					
I confirm that I have considered a generic or other	ar alternative and that the requested	drug is expected	to result in the			
successful medical management of the recipient.						
Prescriber (or Staff) / Pharmacy Signature**		Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is						
medically necessary, does not exceed the medical						
medical records. I also understand that any misrepr			•			

authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Copaxone 40m/mL must meet the following criteria:

- Patient must have a confirmed diagnosis of multiple sclerosis.
- Prescriber must be a neurologist.
- Patient must have failed a 3 month trial of copaxone 20 mg/mL, Aubagio, Tecfidera, and Gilenya.
- The prescriber must provide medical justification indicating why the patient cannot use copaxone 20 mg/mL

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient M	Recipient Medicaid ID Number	
Prescriber Name	Specialist ir	Specialist involved in therapy (if not treating physician)			
Prescriber NPI	Telephone I	Number	Fax Numbe). J	
Address	City		State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this request:				
COPAXONE 40MG					
List all failed medications:		Start Date:	End Date:		
Qualifications for coverage:					
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		and that the requeste	d drug is expec	ted to result in the	
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr	needs of the r	member, and is clinic	ally supported ir	n the patient's	

authorization request may subject me to audit and recoupment.

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:		
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Agents Used to Treat COPD PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred agents to treat COPD must have a diagnosis of COPD and meet the criteria for the specific agent listed in the North Dakota Medicaid Preferred Drug List (link below):

http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PHYSICIAN						
Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number			
Prescriber Name	Specialist involved in therapy (if not t			treating physi	cian)	
Prescriber NPI	Telepho	ne Number		Fax Number		
Address	City			State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this requ			uest:		
				THER:		
List all failed medications:		Start Date	: E	ind Date:		
Additional Qualifications for Coverage (if applications exacerbations treated with corticosteroids)						
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		ve and that the	requested o	Irug is expecte	ed to result in the	
Prescriber (or Staff) / Pharmacy Signature**				Date		
**: By completing this form, I hereby certify that the a medically necessary, does not exceed the medical r medical records. I also understand that any misrepre- authorization request may subject me to audit and r	needs of the sentation	he member, and is or concealme	d is clinically	v supported in	the patient's	

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:		
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



•

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred inhaled corticosteroid/long-acting beta-2 agonist agents must meet the following criteria:

- Patient must have had a 30-day trial with all preferred agents, as evidenced by paid claims or pharmacy print-outs.
 - For COPD diagnosis, a 30-day trial of one drug from each group below will also be required:
 - o Tudorza Pressair, Spiriva, Spiriva Respimat, Incruse Ellipta, Anoro Ellipta, or Stiolto Respimat.
 - Anoro Ellipta, Stiolto Respimat, Foradil, Brovana, Arcapta Neohaler, Striverdi Respimat, Perforomist, or Serevent.
- For asthma diagnosis, patient must have been reviewed for step down therapy for all renewal requests.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipier	Recipient Date of Birth			Recipient Medicaid ID Number	
Prescriber Name							
Prescriber NPI		Telepho	ne l	Number		Fax Number	
Address		City				State	Zip Code
Requested Drug and Dosag	ge:		Di	agnosis for this	reques	st:	
				COPD 🛛 ASTH	MA	OTHER:	
List all failed medications:	-			Start Date:	E	nd Date:	
Additional Qualifications for For renewal requests & an as		s the patient	mu	st have been rev	iewed fo	or step down th	nerapy? □ YES □ NO
 I confirm that I have consider successful medical manage 			ve a	and that the requ	ested d	rug is expected	d to result in the
Prescriber (or Staff) / Pharma	acy Signature**					Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.							
Part II: TO BE COMPLETED BY PHARMACY							
PHARMACY NAME:					ND M	EDICAID PRO	VIDER NUMBER:
TELEPHONE NUMBER F	AX NUMBER	DRUG			NDC #	4	



DISPENSE AS WRITTEN PA FORM

Prior Authorization Vendor for ND Medicaid

North Dakota Medicaid requires that patients receiving a brand name drug, when there is a generic equivalent available, must first try and fail the generic product for one of the following reasons.

- The generic product(s) are not effective (attach MedWatch form for two different generic manufacturers)
- There was an adverse reaction with the generic product(s) (attach MedWatch form for two different generic manufacturers)
- DAW not allowed for drugs with an authorized generic available.
- Primary insurance requires a ND Medicaid non-preferred brand product.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth		Recipient	Recipient Medicaid ID Number				
Prescriber Name	Prescriber Name								
Prescriber NPI Telephone Number Fax Number									
Address		City		State		Zip Code			
Requested Drug:	DOSAGE:	Diagnosis for this request:							
QUALIFICATIONS FOR		Start Date E		End Date	Dose	Frequency			
ADVERSE REACTION T	O GENERIC EQUIVALENT: D FDA N	MEDWATC	CH FORM ATT	CHED FOR E	ACH GEN	VERIC FAILED			
PRIMARY INSURANCE	REQUIRES: D BRAND NAME PRODUC	СТ							
Primary insurance carrier	::								
I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.									
Prescriber (or Staff) / Pharmacy Signature** Date									
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.									

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



DEXPAK/ZEMAPAK PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for DexPak or Zema-Pak must meet the following criteria:

• Patient must first try and fail with dexamethasone.

Recipient Name	Recipient D	ate of Birth	Recipient	Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating physician)			
Prescriber NPI	Telephone Number Fax Number			er
Address	City		State	Zip Code
Requested Drug and Dosage:		Diagnosis for th	nis request:	
□ ZEMA-PAK				
List all failed medications:		Start Date:	End Date:	
Additional Qualifications for Coverage:				
 I confirm that I have considered a generic or oth successful medical management of the recipien 		and that the reque	sted drug is expe	cted to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep	I needs of the I	member, and is cli	nically supported	in the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred diabetic testing supplies must provide medical justification for use. Please see a list fo the preferred diabetic testing supplies at http://www.hidesigns.com/assets/files/ndmedicaid/2017/PDSL/North_Dakota_Medicaid Preferred_Diabetic Supply_2017-2.pdf

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient N	Recipient Medicaid ID Number		
Prescriber Name	Specialist involved in therapy (if not treating physician)					
Prescriber NPI	Telephone Number		Fax Numbe	er		
Address	City		State	Zip Code		
Requested Drug and Dosage:		Diagnosis for this rec	uest:			
	DOTHER:					
List all failed medications:						
□ PATIENT HAS AN INSULIN PUMP NOT COMPA	TIBLE WI	TH THE PREFERRED	TEST STRIPS			
What pump does patient use?						
I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.						
Prescriber (or Staff) / Pharmacy Signature**		Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Diclegis PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Diclegis must meet the following criteria:

- Patient must have diagnosis of nausea and vomiting of pregnancy
- Patient must first try ondansetron, meclizine, and metoclopramide.

Part I: TO BE COMPLETED BY PHYSICIAN					
Recipient Name	Recipient Date of Birth		Recipient I	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating physician)			vsician)	
Prescriber NPI	Telephone Number Fax Number		er		
Address	City		State	Zip Code	
Requested Drug and Dosage:		Diagnosis for th	nis request:		
	□ NAUSEA AND VOMITING OF PREGNANC			PREGNANCY	
List all failed medications:		Start Date:	End Date:		
Additional Qualifications for Coverage:					
 I confirm that I have considered a generic or oth successful medical management of the recipier 		and that the reque	sted drug is exped	cted to result in the	
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misre authorization request may subject me to audit and	al needs of the presentations of	member, and is cli	nically supported i	in the patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



DPP-4 INHIBITORS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for a DPP-4 inhibitor:

- Diagnosis of Diabetes Type II required
- Onglyza: must fail a 3-month trial of metformin and continue taking metformin
- For all other agents, patient must fail a 3-month trial of metformin AND continue taking metformin concurrently AND fail a 30-day trial of both a sitagliptin product (Janumet, Janumet XR, or Januvia) and a linagliptin product (Jentadueto or Tradjenta).

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Has patient taken metformin for Will patient continue therapy wit medication? Please list all medications patier	h metformin ar □	YES □ NO nd the requested □ YES □ NO
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		drug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is clinicall esentations or concealment of any ir	y supported in th	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



EDECRIN PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Edecrin must meet one of the following criteria:

- Patient must have a documented sulfa allergy.
- Patient must have failed a 30-day trial of bumetanide, furosemide, or torsemide.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number			
Prescriber Name					
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage: FDA approved indication for this request:					
List all failed medications (drug name, date of trial, reason for failure):					
Additional Qualifications for Coverage:					
I confirm that I have considered a generic or othe successful medical management of the recipient.	r alternative and that the requested o	lrug is expected	to result in the		
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ELAPRASE PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Elaprase must meet the following criteria: • Patient must have Hunter Syndrome.

Part I: TO BE COMPLETED BY PHYSICIAN Recipient Name **Recipient Date of Birth** Recipient Medicaid ID Number Physician Name Physician Medicaid Provider Number Telephone Number Fax Number Address City State Zip Code **Requested Drug and Dosage:** Diagnosis for this Request: □ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient. Prescriber (or Staff) / Pharmacy Signature** Date **: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

ERYTHROPOIESIS-STIMULATING AGENTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for erythropoiesis-stimulating agents must meet the following criteria:

- Patient must have an FDA approved indication.
- Requires step therapy. Please review criteria for coverage.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Please list all medications patient has tried:		•
Diagnosis:			
Prescriber (or Staff) / Pharmacy Signature** Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.			

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Fulyzaq must meet the following criteria: *Note:

- Patient must be 18 years of age or older.
- Patient must have non-infectious diarrhea.
- Patient must have HIV/AIDS and be taking anti-retroviral therapy.
- Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Numbe	
Physician Name:			
Physician Medicaid Provider Number	Telephone Number	Fax Num	ber
Address	City	State	Zip Code
QUALIFICATIONS FOR COVERAGE:			
Requested Drug and Dosage:	Diagnosis for this request:		
□ Fulyzaq			
	Anti-retroviral therapy		
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medic			

medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



GLP-1 RECEPTOR AGONISTS PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for a non-preferred GLP-1 receptor agonist must meet the following criteria:

- Patient must have a diagnosis of type 2 diabetes mellitus.
- Patient must fail a 3-month trial of metformin and currently be taking metformin.
- Patient must have failed a 30-day trial of 2 preferred products (Trulicity and Adlyxin).

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient D	ate of Birth	Recipient I	Medicaid ID Number
Prescriber Name	Specialist ir	nvolved in therapy (if	not treating phy	vsician)
Prescriber NPI	Telephone I	Number	Fax Numb	er
Address	City		State	Zip Code
Requested Drug and Dosage:		Diagnosis for this	request:	
	Y	□ TYPE 2 DIABETES MELLITUS		
List all failed medications:		Start Date:	End Date:	
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		and that the requeste	d drug is expec	cted to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the				
medically necessary, does not exceed the medical medical records. I also understand that any misrepr				
authorization request may subject me to audit and				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



GLUMETZA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Glumetza must meet the following criteria:

• Patient must fail a 3-month trial of metformin ER.

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth	Recipient I	Medicaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Numb	er	
Address	City	State	Zip Code	
Requested Drug and Dosage:	FDA approved indication for	this request:		
List all failed medications (drug name, date of t	rial, reason for failure):			
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alternative and that the reques	sted drug is expec	ted to result in the	
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



GRALISE PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Gralise must meet the following criteria:

- Patient must have a diagnosis of postherpetic neuralgia
- Patient must first try gabapentin

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medio	caid ID Number	
Physician Name		1		
Physician Medicaid Provider Number	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this Request:	1	I	
Failed Therapy (dose and frequency):	Start Date:			
	End Date:			
□ I confirm that I have considered a generic or other	alternative and that the requested dr	ug is expected to	o result in the	
successful medical management of the recipient.				
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is				
medically necessary, does not exceed the medical n	eeds of the member, and is clinically	supported in the	patient's medical	

medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving Growth Hormone meet one of the criteria below:

- Growth Hormone Deficiency in children and adults with a history of hypothalamic pituitary disease
- Short stature associated with chronic renal insufficiency before renal transplantation
- Short stature in patients with Turners Syndrome (TS), Prader-Willi Syndrome (PWS), or Noonan, SHOX Syndrome
- Human Immunodeficiency Virus (HIV) associated wasting in adults
- See growth hormone criteria for additional information.
- http://www.hidesigns.com/assets/files/ndmedicaid/2017/Criteria/growth_hormone_criteria_1.pdf Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth	า	Recipient Me	edicaid ID Number
Prescriber Name		Specialist involved in t	therapy (if not	treating physi	cian)
Prescriber NPI		Telephone Number		Fax Number	
Address		City		State	Zip Code
REQUESTED DRUG:	Requeste	d Dosage: (must be co	ompleted)		
Qualifications for coverage:					
Diagnosis:	Previous The	erapy:	Dose:	Freq	uency:
Height:	Has patient a	attained epiphyseal clos	sure? 🗆 `	Yes □ N	0
Prescriber (or Staff) / Pharmac	y Signature**			Date	
**: By completing this form, I he medically necessary, does not medical records. I also underst authorization request may subj	exceed the medical ne and that any misrepres	eeds of the member, and sentations or concealme	d is clinically s	upported in th	e patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Genitourinary Smooth Muscle Relaxants (GSMR) Prior Authorization

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires a 30-day trial of all preferred products before a non-preferred agent will be authorized. ***Note:**

• See list of preferred products at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	t Date of Birth Recipient Medicaid ID Numbe	
Prescriber Name:			
Prescriber NPI:	Telephone Number	Fax Numbe	er
Address	City	State	Zip Code
Qualifications for coverage:			
Requested Drug and Dosage:	Diagnosis for this request:		
	Failed therapy-List all (Drug and Dose)		
	Start Date:	End Date:	
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		sted drug is expec	ted to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is cli resentations or concealment of	inically supported i	n the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



HEREDITARY ANGIOEDEMA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for an agent used to treat hereditary angioedema must meet the following criteria:

• Patient must have diagnosis of hereditary angioedema confirmed by a specialist

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipi	ient Medicaid ID Number
Physician Name		Specialist Involved in	n therapy:	
			1	
Physician Medicaid Provider Number		Telephone Number	Fax N	umber
		-		
Address		City	State	Zip Code
Requested Drug and Dosage:	Diagnosis	for this Request:		
I confirm that I have considered a gen successful medical management of the		alternative and that the requ	ested drug is ex	xpected to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is				
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's				
medical records. I also understand that a			f any informatio	on requested in the prior
authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Hemangeol must meet the following criteria:

- Patient must be between 5 weeks and 1 year of age.
- Patient must weigh 2 kg or greater.
- Patient must not have contraindications as listed below: asthma or a history of bronchospasm, bradycardia (<80 beats per minute), greater than first-degree heart block, decompensated heart failure, blood pressure <50/30 mmHg, or pheochromocytoma.
- Patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number			
Prescriber Name					
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug:	Diagnosis:	Does patient have ANY contraindications to Hemangeol?			
	Patient's weight:				
□ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the a medically necessary, does not exceed the medical r medical records. I also understand that any misrepre authorization request may subject me to audit and re	needs of the member, and is clinically esentations or concealment of any in	/ supported in ti	he patient's		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



HEPATITIS C TREATMENTS PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for hepatitis C treatments must meet the following criteria (for further specified criteria, please see the PDL at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf:

- Patient must have an FDA-approved diagnosis and genotype and be of an FDA-approved age for use
- Patient must attest that they will continue treatment without interruption for the duration of therapy and established compliant behavior
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Prescriber must attach documentation that the patient has been drug and alcohol free for the past 12 months.
- Patient must be tested for hepatitis B and must either be treated or closely monitored if the test is positive.
- HCV RNA level must be taken on week 4 and sent with a renewal request for any duration of treatment 12 weeks or longer.
- Females using ribavirin must have a negative pregnancy test in the last 30 days and receive monthly pregnancy tests during treatment
- Patient must not have life expectancy of less than 12 months due to non-liver related comorbid conditions.
- For non-preferred agents: Patient must have failed a trial of all preferred treatment options indicated for the patient's genotype.

Part I: TO BE COMPLETED BY PHYSICIAN

TELEPHONE NUMBER

FAX NUMBER

DRUG

Recipient Name		Recipient Date of Birth		Recipient Medicai	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy					
Prescriber NPI		Telephone Number		Fax Number		
Address		City		State	Zip Code	
Requested Drug and Dose:	Duration re	quested:	Patient is drug and al	Icohol free for past	12 months:	
Diagnosis:	Genotype:		Patient's Child-Pugh	class: □A □	B □ C □ N/A	
Please list any previous treatments the patient has	failed for chro	nic HCV: □ N/A	Regimen:	Dates of treatment:	Response:	
Will the requested medication be given with ribavirin to a patient of child bearing potential? If yes, has the patient had a negative pregnancy test in the last 30 days? Will the receive pregnancy tests monthly during treatment?			□ YES □ YES □ YES Other Agent(s	□ NO □ NO □ N/A □ NO □ N/A		
Is the patient taking the requested medication in combination with another HCV treatment? YES NO						
Does the patient have Hepatitis B?			□ YES	□ NO		
If the patient has Hepatitis B, has it been treated or will it be closely monitored during treatment?			□ YES	□ NO		
Is the patient post-liver transplant?			□ YES	□ NO		
Does the patient's life expectancy greater than one year?			□ YES	□ NO		
Does patient attended scheduled visits with no mo	re than 1 no-sl	how and fill maintenar	nce medications on time	? 🛛 YES	□ NO	
Does patient have any contraindications to therapy	/ with the requ	ested agent?		□ YES	□ NO	
Please confirm that all of the following is attached to the request, along with any other documentation required, as stated in the PDL: □ Baseline HCV RNA □ HCV RNA 4 weeks after starting therapy (for renewal) □ ≥ 2 drug and alcohol tests dated at least 3 months apart □ Chart notes addressing patient's alcohol and drug free status over the past year □ Patient attestation form □ Chart notes addressing patient's alcohol and drug free status over the past year						
Prescriber (or Staff) / Pharmacy Signature**			Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						
Part II: TO BE COMPLETED BY PHARMACY						
PHARMACY NAME: ND MEDICAID PROVIDER N			VIDER NUMBER:			

NDC #

Hepatitis C Patient Consent Form

I, ______, have been counseled by my healthcare provider on the following:

- □ I agree to complete the entire course of treatment and have laboratory tests before starting, during, and after completing treatment as ordered by my healthcare provider.
- □ I understand that for the medication to work, it is important that I take my medication each day for the entire course of treatment.
- □ I understand the importance to not drink alcohol or use illicit drugs during and after my treatment for Hepatitis C.
- □ I understand how to avoid being re-infected with Hepatitis C during and after my treatment.
- □ (Females) I understand that these drugs are harmful to babies. I will use two methods to avoid getting pregnant. I understand that this medication may cause serious birth defects to an unborn child for up to 6 months after I have completed my treatment.
- □ (Males) I understand that while I am taking the medication, I must avoid getting my partner pregnant. If my partner becomes pregnant, the baby may have serious birth defects. My partner and I will prevent pregnancy using two forms of birth control for up to 6 months after my treatment is complete. If I have a committed partner, I have discussed these risks with her.

Patient Signature _____ Date _/_/___

Pharmacy or Prescriber Representative:

Signature _____ Date _/_/___

By signature, the pharmacy or prescriber representative confirms the contract has been reviewed with the patient.



Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Horizant must follow the following guidelines:

- Patient must have a diagnosis of Restless Leg Syndrome.
- Patient must have had a trial of gabapentin, pramipexole, or ropinirole.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number			
Physician Name					
Physician Medicaid Provider Number	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	Diagnosis for this request:				
Horizant					
Qualifications for coverage:					
FAILED THERAPY					
START DATE:	DOSE:				
END DATE:	FREQUENCY:				
□ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is					
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical					
records. I also understand that any misrepresentations or concealment of any information requested in the prior					
authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Medications used to treat IBS/OIC PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for medications used to treat IBS/OIC must meet the following criteria:

- Patient must have diagnosis of chronic constipation, IBS with constipation, or opioid-induced constipation.
- Requires step therapy. See IBS/OIC criteria for more details.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name:				
Prescriber NPI	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:		Diagnosis for this request: Is the patient unable to tolerate oral		
		medicat	:ions ?	
Failed therapy:		Start Da	ate:	
		End Date:		
 I confirm that I have considered a generic or othe successful medical management of the recipient. 	er alternative and that the rec	quested d	rug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



IMMUNE GLOBULINS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for an immune globulin must meet the following criteria:

- If patient's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- For Gammagard S/D patient must be intolerant to IgA.
- For Hizentra, Cuvitru, or Hyqvia patient must be unable to tolerate IV administration and fail a trial of two of the following: Gamunex-C, Gammaked, or Gammagard.
- For all other agents, patient must try and fail two of the following: Gamunex-C, Privigen, or Gammagard.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number		
Prescriber Name				
Fleschber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Is patient BMI over 30?	NO		
	If yes, provide adjusted body wei	ght and calculat	ted dose:	
Indication for this request:	Is patient intolerant to IgA (i.e., treatment of an autoimmune process in a patient with undetectable levels of IgA)? □YES □NO			
	Is patient unable to tolerate IV ad	ministration?		
	Please list all medications patient has tried and failed:			
I confirm that I have considered a generic or other	er alternative and that the requested o	Irug is expected to	to result in the	
successful medical management of the recipient.				
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

INJECTABLE ANTICOAGULANTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for injectable anticoagulants must meet the following criteria: • Patient must have an FDA approved indication.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Med	Recipient Medicaid ID Number		
Prescriber Name	1				
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	FDA approved indication for this rec	quest:			
	Does the patient have an indication that cannot be treated with Lovenox? Does the patient need Extended Treatment for Symptomatic Venous Thromboembolism in Patients with Cancer? Q YES Q NO				
History of preferred agents (drug name			-		
Prescriber (or Staff) / Pharmacy Signature	Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					
Part II: TO BE COMPLETED BY PHARM	IACY				
PHARMACY NAME:		ND MEDICAID PRO	VIDER NUMBER:		

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Insulins Prior Authorization

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for a non-preferred insulin must first try a 30-day trial of one preferred agent in the past year.

- For all non-preferred long-acting insulins:
 - o Patient must have failed patient failed a 3 month trial of both Lantus and Levemir with good compliance.
 - Must have required at least 100 units/day for Tresiba U-200 and Toujeo.
- For pens/syringes when vials are available:
 - Patient must have failed at least a 30-day trial using the vial product OR have valid medical justification explaining why the patient cannot use the vial.
- For Fiasp:
 - Patient must have failed a 30-day trial with at least 3 preferred agents in the past year.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number		
Prescriber Name:	I				
			<u> </u>		
Prescriber NPI	Telephone Number		Fax Number		
Address	City		State	Zip Code	
QUALIFICATIONS FOR COVERAGE:					
Requested Drug and Dosage:		Diagnosis for this request:			
Failed Therapy:		Start Da	Date:		
			End Date:		
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



INTERFERONS – MULTIPLE SCLEROSIS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for interferon must meet the following criteria:

- Patient must have a confirmed diagnosis of multiple sclerosis.
- A three month trial of a preferred agent will be required before a non-preferred agent will be authorized.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	FDA approved indication for thi	is request:	
Prior therapy:			
Start date:	End date:		
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is clinicall esentations or concealment of any in	y supported in th	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



INTERLEUKIN-5 ANTAGONIST PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for an interleukin-5 antagonist must meet the following criteria:

- Patient must have a diagnosis of asthma.
- Patient must have blood eosinophils of ≥ 150 cells/microliter within the last 6 weeks.
- Patient must have had 3 fills of a high dose steroid and a controller medication in the past 120 days.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Birth Recipient Medicaid ID Number		
Prescriber Name	1			
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	FDA approved indication for	this request:		
	Blood eosinophil count:			
	Date of eosinophil count:			
List all failed medications (drug name, date of trial, reason for failure): Does patient have a history of 2 or more exacerbations in the previous year?				
Has patient had a decreased frequency of exace or treatment with systemic corticosteroids)?	and the sening of astim			
Has patient's predicted FEV1 increased from pre	etreatment baseline?	□ YES □ NO		
Has patient had 3 fills of high dose steroids in the	he past 120 days?			
Has patient had 3 fills of a controller medication	in the last 120 days?			
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above necessary, does not exceed the medical needs of the me understand that any misrepresentations or concealment to audit and recoupment.	mber, and is clinically supported in	the patient's medical r	records. I also	
Part II: TO BE COMPLETED BY PHARMACY				
PHARMACY NAME.				

FHARMACT NAME.			ND MEDICAID PROVIDER NOMBER.
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #


AGENTS USED TO TREAT IDIOPATHIC PULMONARY FIBROSIS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for agents used to treat idiopathic pulmonary fibrosis must meet the following criteria:

- Patient must be 18 years of age or older.
- Patient must have documented diagnosis of idiopathic pulmonary fibrosis.
- Patient must have a specialist involved in therapy.
- Patient must have forced vital capacity (FVC) \ge 50% of predicted within prior 60 days.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number		
Prescriber Name	Specialist Involved in Therapy			
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State		Zip Code
Requested Drug:	Diagnosis:	Is patient pregnant?		
	FVC:	Is patient of child-bearing potential?		
	-	Have LFTs been measured?		
		Does patient have moderate to sev	vere liver impair	ment?
		Does patient currently smoke?		□ YES □ NO
 I confirm that I have considered a gene successful medical management of the re 		e and that the requested drug	is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certing medically necessary, does not exceed the medical records. I also understand that and authorization request may subject me to a	e medical needs of the	e member, and is clinically su s or concealment of any inform	pported in th	ne patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Kalydeco must meet the following criteria:

• Patient must be 2 years of age and older and have one of the following mutations in the cystic fibrosis conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this Request:		
I confirm that I have considered a generic or other successful medical management of the recipient.	alternative and that the requested d	rug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the a medically necessary, does not exceed the medical r medical records. I also understand that any misrepre authorization request may subject me to audit and re	needs of the member, and is clinically esentations or concealment of any in	supported in tl	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Kapvay must meet the following criteria: • Patient must first try immediate release clonidine

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth	Recipient Med	icaid ID Number	
Physician Name				
Physician Medicaid Provider Number	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Democrated Draw and Decemen	Diamagia (an this Damagat			
Requested Drug and Dosage:	Diagnosis for this Request:			
Failed Therapy (dose and frequency):	Start Date:			
	End Date:			
- Learnfirm that I have acreated a concrist or othe	l	d day of in a supranta d	to requilt in the	
I confirm that I have considered a generic or othe successful medical management of the recipient.	allemative and that the requested	a drug is expected		
Prescriber (or Staff) / Pharmacy Signature**		Date		
Frescriber (or Starr) / Friannacy Signature		Dale		
**: By completing this form, I hereby certify that the	above request is true, accurate an	d complete. That i	the request is	
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical				
records. I also understand that any misrepresentations or concealment of any information requested in the prior				
authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Ketek must meet the following criteria:

- ND Medicaid will cover Ketek with a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae for patients 18 years and older.
- ND Medicaid will cover Ketek for patients with an allergy to fluoroquinolones or tetracyclines.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Med	dicaid ID Number
Prescriber Name	Specialist involved in therapy (if not	(if not treating physician)	
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
REQUESTED DRUG: Rev • KETEK	quested Dosage: (must be completed	 d)	<u> </u>
Qualifications for coverage:			
 Community acquired pneumonia (of mild to mod resistant isolates, Haemophilus influenzae, Moraxe pneumoniae) for patients 18 years and older. Does the patient have myasthenia gravis? 			
Does the patient have any other antibiotic use in th	e last 3 months?		
Please list fluoroquinolone or tetracycline that particular par	tient is allergic to:		
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alternative and that the requested d	rug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and	needs of the member, and is clinically resentations or concealment of any in	v supported in tl	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for a kit must:

• Use the covered product included in the kit as an individual product

Part I: TO BE COMPLETED BY PHYSICIAN			
Recipient Name	Recipient Date of Birth	Recipient	Medicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Numb	er
Address	City	State	Zip Code
Requested Drug and Dosage:	Is the covered medication included in the kit available commercially as an individual product?		
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alternative and that the reque	sted drug is expe	cted to result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and	needs of the member, and is cli resentations or concealment of a	nically supported	in the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



KUVAN PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Kuvan must meet the following criteria: • Patient must have hyperphenalaninemia.

Part I: TO BE COMPLETE	D BY PHYSICIAN			
Recipient Name		Recipient Date of Birth	Recipient Medi	caid ID Number
Prescriber Name				
Prescriber NPI		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug and Dosage: □ KUVAN	PHE level:	Diagnosis for this Request:	Patient's weig	ght:
Has the patient been kn Are baseline PHE levels Is patient of child-bearin Is this a renewal reques	ng potential?	utations in TRANS?	S D NO S D NO	
	onsidered a generic or othe	er alternative and that the requested o		d to result in the
Prescriber (or Staff) / Pha	armacy Signature**		Date	
medically necessary, doe medical records. I also un	es not exceed the medical	above request is true, accurate and on needs of the member, and is clinically resentations or concealment of any in recoupment.	y supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



LEMTRADA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Lemtrada must meet the following criteria:

- Patient must have a confirmed diagnosis of multiple sclerosis.
- Requires step therapy. See Lemtrada criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Me	edicaid ID Number
Prescriber Name	Specialist involved in therapy (if	not treating physi	cian)
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ LEMTRADA	FDA approved indication for	•	
 Has patient experienced a reduction in relapse Is the patient experiencing early aggressive of year and >= 1 Cadolinium (Cd)+ lesion)? Does the patient have VZV antibodies/vaccing Does the patient have appropriate SCr levels Does the patient have appropriate urinalysis Has the patient had thyroid function tests? Has the patient had a TB test? List all failed medications: 	disease? (>=2 relapses in the nation or history of varicella? ? with urine cell counts? Start Date:	 YES YES YES YES YES YES End Date: 	□ NO □ NO □ NO □ NO □ NO □ NO □ NO □ NO
successful medical management of the recipient. Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the a medically necessary, does not exceed the medical r medical records. I also understand that any misrepre authorization request may subject me to audit and re	needs of the member, and is clinic esentations or concealment of an	cally supported in	the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



LICE MEDICATIONS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for lice medications must meet one of the following criteria:

- Patient must have failed a 28-day trial (2 applications) of each of the preferred agents.
- Non-preferred agents will require an FDA approved indication.
- See list of preferred products at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number		
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Numbe	r	
Address	City State Zip Co			
Requested Drug and Dosage: FDA approved indication for this request:				
List all failed medications (drug name, date of tr	ial, reason for failure):			
 I confirm that I have considered a generic or othe successful medical management of the recipient. 	er alternative and that the requeste	ed drug is expect	ed to result in the	
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



LORZONE PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Lorzone must meet the following criteria: • Patient must first try chlorzoxazone

Part I: TO BE COMPLETED BY PHYSICIAN			
Recipient Name	Recipient Date of Birth	Recipient M	edicaid ID Number
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this Request:		
Failed Therapy (dose and frequency):	Start Date:		
	End Date:		
I confirm that I have considered a generic or othe	l r alternative and that the requeste	ed drug is expect	ed to result in the
successful medical management of the recipient.			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the	above request is true, accurate a	nd complete. The	at the request is
medically necessary, does not exceed the medical			
records. I also understand that any misrepresentation		ation requested i	n the prior
authorization request may subject me to audit and r	ecoupment.		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Luzu must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must be 18 years of age or older.
- Patient must have documented history of failure of two topical antifungal agents (clotrimazole, econazole) and two oral antifungal agents (terbinafine, fluconazole, itraconazole).

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient M	ledicaid ID Number	
Physician Name					
Physician Medicaid Provider Number	Telepho	one Nu	Imber	Fax Numbe	r
Address	City			State	Zip Code
Requested Drug and Dosage:	Di	iagno	sis for this Reques	t:	
List all failed medications:			Start Date:	End Date:	
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alternat	tive a	nd that the requested	l drug is expec	ted to result in the
Prescriber (or Staff) / Pharmacy Signature**				Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical records. I also understand that any misrepresentati authorization request may subject me to audit and	needs of ions or co	the n	nember, and is clinica	ally supported	in the patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Marinol PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Marinol must meet the following criteria:

- Patient must have diagnosis of anorexia associated with weight loss in patients with AIDS; or
- Diagnosis of nausea and vomiting associated with cancer chemotherapy

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipient Me	dicaid ID Number
Prescriber Name:				
Prescriber NPI		Telephone Number	Fax Number	
Address		City	State	Zip Code
QUALIFICATIONS FOR COVE	ERAGE:			
Requested Drug and Dosage: Marinol	 Diagnosis of anorexia associated with weight loss in patients with AIDS Diagnosis of nausea and vomiting associated with cancer chemotherapy 			
	Diagnosis for this re	equest:		
 I confirm that I have conside successful medical manageme 	5	er alternative and that the requested	drug is expected	d to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
medically necessary, does not	exceed the medical i and that any misrepr	above request is true, accurate and needs of the member, and is clinical esentations or concealment of any i ecoupment.	ly supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



MEDICATIONS > \$3,000 PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for medications that cost >\$3,000 must meet the following criteria:

- Patient must have an FDA approved indication for the medication requested.
- May be subject to additional criteria. See PA criteria for complete details.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name			Recipient Date of Birth	Recipient M	ledicaid ID Number
Prescriber Name					
Prescriber NPI			Telephone Number	Fax Numbe	er
Address			City	State	Zip Code
Requested Drug a	ind Dosage:		FDA approved	l indication for	or this request:
		PHENOXYBENZAMINE			
	□ MIACALCIN □ NATPARA	SOMAVERT STRENSIQ			
🗆 I confirm that I h	ave considered a ge	eneric or other alternative and the	at the requested dr	ug is expected	d to result in the
	management of the		,	0 /	
Prescriber (or Staff) / Pharmacy Signat	ure**		Date	
, , , , , , , , , , , , , , , , , , ,	, , , ,				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is					
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's					
		t any misrepresentations or conc	ealment of any info	ormation reque	ested in the prior
authorization reque	est may subject me t	o audit and recoupment.			

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



METOZOLV ODT PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Metozolv must meet the following criteria:

Patient must try metoclopramide.

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Dat	e of Birth	Recipient N	ledicaid ID Number
Physician Name	i			
Physician Medicaid Provider Number	er Telephone Num		Fax Numbe	9r
Address	City		State	Zip Code
Requested Drug and Dosage:		Diagnosis for	this request:	
□ FAILED METOCLOPRAMIDE THERAPY	START DATE	END DATE	DOSE	
I confirm that I have considered a gene in the successful medical management o		tive and that the re	quested drug	is expected to result
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify the medically necessary, does not exceed the me records. I also understand that any misrepres authorization request may subject me to aud	edical needs of the m sentations or conceal	nember, and is clinic	ally supported i	in the patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



MIFEPREX PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Mifeprex must meet the following criteria:

- Patient must have an FDA approved indication for the medication requested.
- Prescriber must provide signed written statement. See criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN					
Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number		
Physician Name					
Physician Medicaid Provider Number	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	Requested Drug and Dosage: FDA approved indication for this request:				
 Is the patient terminating a pregnancy before 49 days of pregnancy? YES NO Is the pregnancy resulting from an act of rape or incest? YES NO If yes, fill out section 1. If no, fill out section 2: Section 1: Has the appropriate law enforcement agency been notified, or agency authorized to receive child abuse and neglect reports? YES NO If yes, has the provider provided a signed written statement indicating that the rape or act of incest has been reported and to whom the report was made? If no, has the provider provided signed written verification that in the provider's professional judgment, the woman's pregnancy resulted from rape or incest? YES NO Has the provider provided a written statement signed by the recipient that her current pregnancy resulted from an act of rape or incest? YES NO Has the provider provided a written statement signed by the recipient that her current pregnancy resulted from an act of rape or incest? YES NO Has the woman suffer from a physical disorder that would place the woman in danger of death unless abortion is performed? YES NO Has the treating provider provided a signed written statement that, in the provider's professional judgment, the life of a woman would be endangered if the 					
 fetus were carried to term? □ YES □ NO Does the statement contain the reasons why the physician be 	lieves the life of the woman would be in dange	_	ed to term? 🗆 YES 🗆 NO		
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and	l needs of the member, and is clinic presentations or concealment of any	ally supported in t	he patient's		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



MOXATAG PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Moxatag must submit documentation of allergies or show a history of intolerable side effects to the inactive ingredients in regular-release amoxicillin.

• Regular-release amoxicillin does not require a prior authorization.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name	<u>I</u>		<u> </u>	
Physician Medicaid Provider Number	Telephon	e Number	Fax Number	
Address	City		State	Zip Code
REQUESTED DRUG :		Dosage		
D MOXATAG				
Qualifications for coverage:				
 Allergic/intolerable side effects to inactive ingrec regular-release amoxicillin. 	lients of	Diagnosis for this request:		
Name of inactive ingredient:				
 I confirm that I have considered a generic or oth successful medical management of the recipient 		tive and that the requested o	drug is expected	d to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and	l needs of presentatic	the member, and is clinically ons or concealment of any in	y supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



NALTREXONE – ORAL PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for naltrexone must meet the following criteria:

• FDA approved indication is alcohol dependence or opioid use disorder.

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Indication for this request:			
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the abornecessary, does not exceed the medical needs of the munderstand that any misrepresentations or concealment to audit and recoupment.	nember, and is clinically supported in the p	oatient's medical re	ecords. I also	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #





ND Medicaid requires that patients receiving proton pump inhibitors must meet the following criteria: **Note:*

- Omeprazole, lansoprazole, pantoprazole, Dexilant, Protonix packet, and Nexium packet do not require prior authorization.
- Requires step therapy. See PPI criteria for more information. <u>www.hidesigns.com/ndmedicaid</u>

Part I: TO BE COMPLETED BY PRESCRIBER				
Recipient Name	Recipient Date of Birth		Recipient Me	dicaid ID Number
Physician Name	I			
Physician Medicaid Provider Number	Telephone N	umber	Fax Number	
Address	City		State	Zip Code
REQUESTED DRUG: Rabeprazole Prevacid Solutab Zenerid Replact Prevacid Solutab	Requested Dosage: (must be completed) Diagnosis for this request:			
 Zegerid Packet Protonix Packet Nexium Dexilant Aciphex Sprinkle 				
List all failed medications:	I	Start Date:	End Date:	
Pregnancy – Due Date		I		
 Inability to take or tolerate oral tablets (must check a book of tube Other tube Requires soft food or liquid administration Other (provide description)))			
Adverse reaction (attach FDA Medwatch form) to omep	orazole/pantopr	azole.		
I confirm that I have considered a generic or other alter medical management of the recipient.	native and that	the requested drug	is expected to result in	n the successful
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the above necessary, does not exceed the medical needs of the me understand that any misrepresentations or concealment of	ember, and is cl	inically supported in	the patient's medical	records. I also

Part II- TO BE COMPLETED BY PHARMACY

to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:			
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #			



Nuedexta PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Nuedexta must have a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) and exhibit signs of pseudobulbar affect.

- Nuedexta is indicated for the treatment of pseudobulbar affect (PBA).
- Nuedexta has not been shown to be safe or effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias.
- Nuedexta is contraindicated in patients with a prolonged QT interval, heart failure, or complete atrioventricular (AV) block.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Me		Recipient Me	dicaid ID Number
Prescriber Name	Specialist ir	nvolved in therapy (if i	not treating physic	cian)
Prescriber NPI	Telephone	Number	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis for	r this request (must	check at least 2):
	PBA: Include baseline PBA episode count			
	If request is a renewal, include current PBA episode count			
		□ MS		
List all failed medications:		Start Date:	End Date:	
Is the Center for Neurological Studies liability bas		(CNS-LS)	•	□ YES □ NO
If request is a renewal, is the CNS-LS current atta			<i></i>	□ YES □ NO
Does the patient have a prolonged QT interval, he	eart failure, or c	omplete atrioventricul	ar (AV) block?	
What is the neurologic condition causing PBA?				
· · · · · · · · · · · · · · · · · · ·				⊓ YES ⊓ NO
Has the neurologic condition been stable for at least 3 months?				
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior				

authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Nitroglycerin Lingual Spray PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Nitrolingual Spray must meet the following criteria: • Patient must first try sublingual tablets

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient D	ate of Birth		Recipient Medicaid ID Number		
Physician Name:						
Physician Medicaid Provider Number	Telephone I	Number		Fax Numbe	er	
Address	City			State	Zip Code	
QUALIFICATIONS FOR COVERAGE:						
Requested Drug and Dosage:			Diagn	Diagnosis for this request:		
Nitroglycerin Lingual Spray						
List all failed medications:		Start Date:		End Date:		
Failed Therapy:			Start I	Date:		
			End D	ate:		
Prescriber (or Staff) / Pharmacy Signature**		Date				
				_		
**: By completing this form, I hereby certify that the above necessary, does not exceed the medical needs of the me understand that any misrepresentations or concealment to audit and recoupment.	ember, and is cl	inically supported	d in the p	oatient's medical	records. I also	
Part II: TO BE COMPLETED BY PHARMACY						
PHARMACY NAME:			ND	MEDICAID PR	OVIDER NUMBER:	

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

NK1 RECEPTOR ANTAGONISTS PA FORM



Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for NK₁ receptor antagonists must meet the following criteria:

- Patient must have a diagnosis of nausea and/or vomiting.
- Patient must be receiving a moderately or highly emetogenic chemotherapy.
- Prescriber must be an oncologist.
- Patient must have failed a cycle using aprepitant or fosaprepitant in combination with palonosetron and a glucocorticoid.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Date of Birth Recipient Medicaid ID Numbe				
Decessible a Nome						
Prescriber Name						
Prescriber NPI	Telephone Number	Fax Number				
Address	City	State	Zip Code			
Requested Drug and Dosage:	FDA approved indication	for this request:				
	Chemotherapy being use	ed:				
	How many cycles of cher antagonist treatment?	How many cycles of chemotherapy will need NK1 receptor antagonist treatment?				
	Date of final chemothera	py treatment:				
List all failed medications (drug name, da	te of trial, reason for failure):					
		Data				
Prescriber (or Staff) / Pharmacy Signature**		Date				
**: By completing this form, I hereby certify th						
medically necessary, does not exceed the m medical records. I also understand that any r						
authorization request may subject me to audit and recoupment.						
Part II: TO BE COMPLETED BY PHARMACY						
PHARMACY NAME:		ND MEDICAID PRO	VIDER NUMBER:			
TELEPHONE NUMBER FAX NUMBER	DRUG	NDC #				



ND Medicaid requires that patients receiving a new prescription for Northera must meet the following criteria: • Patient must have an FDA approved indication.

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name				
Physician Medicaid Provider Number	Tele	ephone Number	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:		Diagnosis for this Request:		
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alte	rnative and that the requested a	lrug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and	need resen	s of the member, and is clinicall tations or concealment of any in	y supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Noxafil must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must have documented history of failure of two agents (itraconazole, fluconazole) to receive Noxafil suspension for oropharyngeal candidiasis.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birt	h	Recipient Medicaid ID Number		
Physician Name	1	I			
Physician Medicaid Provider Number	Telephone Number		Fax Number		
Address	City		State	Zip Code	
Requested Drug and Dosage:		Diagnosis for t	his Request:	-	
NOXAFIL TABLET NOXAFIL SUSPENSION					
Failed Therapy for Oropharyngeal Candidiasis (suspension only): 1.		Start Date: 1.	End Da	ate:	
2.		2.			
□ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



NSAID/COX-II PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients using NSAIDs or COX-II drugs must use a generic NSAID first line. *Note: The PA will be approved if one of the following criteria is met:

- Failed two trials of prescribed oral NSAIDs to receive brand name oral NSAIDs
- Failed trial of Voltaren gel to receive brand name topical NSAIDs for inflammation
- Recipient is on warfarin or corticosteroid therapy
- Recipient has history of gastric or duodenal ulcer or has comorbidities of GI bleed, perforation or obstruction
- Recipient has history of endoscopically documented NSAID induced gastritis with GI bleed
- Solaraze will be covered for patients with a diagnosis of actinic keratoses

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Number				
Prescriber Name	Specialist	t involved in thera	apy (if not treating	physician)	
Prescriber NPI	Telephon	e Number	Fax Number		
Address	City		State	Zip Code	
Requested Drug and Dosage: CELECOXIB OTHER:	 Warfa therap GI ble 	ed, perforation o	t □ Gas □ End r gast	tric or duodenal ulcer oscopically documented ritis with GI Bleed	
obstruction Actinic keratoses (Solaraze) List all failed medications: Start Date:					<u>})</u>
Qualifications for coverage: Does patient have arthritis requiring long-term high dosage of NSAIDS? YES DNO Is patient at high risk for mucosal injury? YES DNO Is the patient taking aspirin at any dose? YES DNO Is patient at risk of cardiovascular disease? YES DNO Will prescriber continue to weigh GI benefits against CV risks and discontinue COX-II as soon as possible? YES DNO Is confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					
Part II: TO BE COMPLETED BY PHARMACY PHARMACY NAME: ND MEDICAID PROVIDER NUMBER:					

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



NUVESSA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Nuvessa must meet the following criteria:

- Patient must have an FDA approved indication.
- Requires step therapy.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	of Birth Recipient Medicaid ID Number			
Prescriber Name		<u> </u>			
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	FDA approved indication for this request:				
	Is the patient pregnant?				
History of preferred agents (drug name, dates of trial, reason for failure):					
Prescriber (or Staff) / Pharmacy Signature**		Date			
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients who are prescribed an orally disintegrating tablet must first try a more cost-effective dosage form.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Num		licaid ID Number	
Physician Name	•	·		
Physician Medicaid Provider Number	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this request:	4	I	
Qualifications for acvarage				
Qualifications for coverage:				
Unable to Swallow				
Medication Failed	Start Date:	Dose:		
	End Date:	Frequency:		
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is				
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's				
medical records. I also understand that any misrepresentations or concealment of any information requested in the prior				

authorization request may subject me to audit and recoupment.

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:	
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Onmel must meet the following criteria:

• Patient must receive two medically necessary courses of therapy with itraconazole (Sporanox) and terbinafine (Lamisil)

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name:			<u> </u>	
Physician Medicaid Provider Number	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:		Diagnosis for this request:		
□ Onmel				
PRESCRIBER (OR STAFF) / PHARMACY SIGNATURE**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:	
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ONYCHOMYCOSIS AGENTS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for onychomycosis treatment must meet the following criteria:

- Patient must have a confirmed diagnosis of onychomycosis by one of the following: KOH prep test, fungal culture, or nail biopsy.
- Patient must have a history of failure to itraconazole and/or terbinafine.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medio	caid ID Number			
Physician Name						
Physician Medicaid Provider Number	Telephone Number	Fax Number				
Address	City	State	Zip Code			
Requested Drug:	Diagnosis:	First Trial:				
D JUBLIA	Confirmed diagnosis by (provide documentation):	Start Date:				
	□ KOH PREP TEST □ FUNGAL CULTURE	End Date:				
SPORANOX (ITRACONAZOLE)		Second Trial:				
ONMEL (ITRACONAZOLE)	Is treatment for fingernails only?	Start Date:				
		End Date:				
□ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.						
Prescriber (or Staff) / Pharmacy Signature** Date						
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



OPHTHALMIC ANTI-INFECTIVES / ANTI-INFLAMMATORIES PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed a non-preferred ophthalmic corticosteroids/anti-infectives must meet the following criteria:

 Requires step therapy. Please see criteria for coverage in the Preferred Drug List at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth		Recipient N	ledicaid ID Number
Prescriber Name				
Prescriber NPI	Telephone Nu	mber	Fax Numbe	r
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:			
List all failed medications:		Start Date:	End Date:	
 I confirm that I have considered a generic or successful medical management of the recip. 		and that the reque	sted drug is expe	cted to result in the
Prescriber (or Staff) / Pharmacy Signature**	ient.		Date	
**: By completing this form, I hereby certify that medically necessary, does not exceed the medi records. I also understand that any misrepreser authorization request may subject me to audit a	ical needs of the ntations or conce	member, and is cli	nically supported	in the patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for ophthalmic antihistamines must meet the following criteria:

 Requires step therapy. Please see criteria for coverage in the Preferred Drug List at <u>http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf</u>

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Da	te of Birth	Recipient M	edicaid ID Number	
Physician Name					
Physician Medicaid Provider Number	Telephone N	umber	Fax Numbe	r	
Address	City		State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this request:			L	
List all failed medications:		Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is					
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior					
authorization request may subject me to audit and					

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:	
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



OPIOID DEPENDENCE PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for buprenorphine and buprenorphine/naloxone combinations must meet the following criteria:

- Patient must be 16 years or older.
- Indicated for use in treatment of documented opioid dependence.
- Must not be taking other opioids, tramadol, or carisoprodol concurrently.
- Prescriber must be registered to prescribe buprenorphine and buprenorphine/naloxone combinations under the Substance Abuse and Mental Health Services Administration (SAMHSA).

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Number		
Prescriber Name	(SAMHSA ID-X DEA Number)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	FDA Approved Indication for	r this request:	
□ BUPRENORPHINE/NALOXONE □ZUBSOLV			
SUBUTEX SUBOXONE FILM BUNAVAIL			
Patient is not taking other opioids, tramadol, or ca	arisoprodol concurrently with requ	ested medication	
Has a contract between the prescriber and patie	nt been signed?		□ NO
Does the prescriber perform routine drug screen	s?	□ YES	□ NO
Does the prescriber routinely check the PDMP s	ystem?		□ NO
□ I confirm that I have considered a generic or oth	er alternative and that the reques	ted drug is expe	cted to result in the
successful medical management of the recipient.			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the	e above request is true. accurate	and complete. T	hat the request is
medically necessary, does not exceed the medica			•
medical records. I also understand that any misre		any information re	equested in the
prior authorization request may subject me to aud	it and recoupment.		
Part II: TO BE COMPLETED BY PHARMACY			
PHARMACY NAME:		ND MEDICAID P	ROVIDER NUMBER:

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ORAL ALLERGEN EXTRACTS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for oral allergen extracts must meet the following criteria:

- Patient must have the FDA approved indication for the drug requested.
- Diagnosis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies.
- History of failure, contraindication, or intolerance to two of the following: oral antihistamine, intranasal antihistamine, intranasal corticosteroid, or leukotriene inhibitors.
- History of failure or intolerance to subcutaneous allergen immunotherapy (allergy shots).
- Patient must not have severe, unstable, or uncontrolled asthma.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name			I		
Prescriber NPI		Telephone Number		Fax Number	
Address		City		State	Zip Code
Requested Drug:	Diagnosis for this Request:		History	of Failure:	
	GRASS POLLEN-INDUCED	ALLERGIC RHINITIS	1.		
		ED ALLERGIC RHINITIS	2.		
□ RAGWITEK	Is the diagnosis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies?		3.		
	ve considered a generic or other management of the recipient.	alternative and that the requ	lested dr	ug is expected	to result in the
Prescriber (or Staff) / Pharmacy Signature**				Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the price authorization request may subject me to audit and recoupment.				ne patient's	
	LETED BY PHARMACY				
PHARMACY NAME:			ND ME	DICAID PROVI	DER NUMBER:

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires patients receiving a prescription for Oravig to try fluconazole, clotrimazole, nystatin or itraconazole. ***Note:**

• Fluconazole, clotrimazole, nystatin, or itraconazole do not require PA

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient N	Recipient Medicaid ID Number	
Physician Name					
Physician Medicaid Provider Number	Telephone N	lumber	Fax Numbe	r	
Address	City		State	Zip Code	
Requested Drug and Dosage:	Diagnosis	for this request:			
□ Oravig					
Qualifications for coverage:					
List all failed medications:		Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



OTEZLA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Otezla must meet the following criteria:

- Patient must be 18 years of age or older.
- Patient must have active psoriatic arthritis or moderate to severe plaque psoriasis.
- Patient must have a specialist involved in therapy.
- Patient must not use Otezla in combination with other biologic therapies.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name		Specialist Involved in Therapy			
Physician Medicaid Pr	ovider Number	Telephone Number		Fax Number	
Address		City		State	Zip Code
Requested Drug:	Diagnosis for this Request:	History of Failure: Is Otezla bein biologic thera		eing used in combination with other rapies?	
Prescriber (or Staff)	/ Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the privation request may subject me to audit and recoupment.				he patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for an otic anti-infective must first try a 7-day trial of a preferred agent in the past 3 months.

• Requires a trial and failure of a preferred agent

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name:	<u> </u>			
Prescriber NPI	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:		Diagnos	sis for this requ	est:
Failed Therapy:		Start Da	ate:	
		End Da	te:	
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is resentations or concealment	s clinically	v supported in tl	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



OUT OF STATE PHARMACY FORM

Prior Authorization Vendor for ND Medicaid

Part I							
Recipient Name	Recipient Date of Birth	1	Recipient Medicaid ID Number				
Requested Drug and Dosage:							
Qualifications for coverage:							
Start Date	End Date	Dose		Frequency			
Passan for out of state pharmaou request							
Reason for out of state pharmacy request:							
Province the residue out of state $2 = VES = NO$							
Recipient is residing out of state? VES NO	-in anday						
If yes, please provide recipient residence, city, state,	zip code.						
Descuented drug is an lu susilable et sut ef state a homeosies?							
Requested drug is only available at out of state pharmacies? □ YES □ NO							
This least way in a staff state share and for a surgery 0 and VEQ. NO							
Third party requires out of state pharmacy for coverage? □ YES □ NO							
If yes, contact State Provider Relations at 1-800-755	-2604.						

Part II

PHARMACY NAME (REQUIRED)				ND MEDICAID PROVIDER NUMBER (REQUIRED)
TELEPHONE NUMBER	FAX NUMBER	DRUG		NDC # (REQUIRED)
Pharmacy Signature:		I	Date:	



PULMONARY ARTERIAL HYPERTENSION AGENTS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for an agent used to treat pulmonary arterial hypertension (PAH) must meet the following criteria:

Patient must have diagnosis of PAH confirmed by a specialist

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Da	ate of Birth	Recipient Me	dicaid ID Number
Prescriber Name	S	Specialist Involved in the	erapy:	
Prescriber NPI	Telephone N	umber	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis	for this Request:	1	
		nt pregnant?		□ Yes □ No
		take monthly pregnar		
		been measured for b		□ Yes □ No □ Yes □ No
		e measured monthly' atient have Class 2 P/		\Box Yes \Box No
		nt taking nitrates of ar		\Box Yes \Box No
		st is for Tyvaso, is the		
		dcirca, Letairis, boser		
		st is for Ventavis 20m		
		experiencing incomple		
	treatment tir		_	
List all failed medications:		Start Date:	End Date:	
I confirm that I have considered a generic or oth successful medical management of the recipient.	ner alternative	and that the requeste	d drug is expecte	ed to result in the
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that th				

medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #


PCSK9 INHIBITORS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for PCSK9 inhibitors must meet the following criteria:

- Patient must have a confirmed diagnosis of heterozygous familial hypercholesterolemia (Praluent only), clinical atherosclerotic cardiovascular disease, or homozygous familial hypercholesterolemia (Repatha only).
- Requires step therapy.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient N	Recipient Medicaid ID Number	
Prescriber Name					
Prescriber NPI	Telephone	Number	Fax Numbe	Pr	
Address	City		State	Zip Code	
Requested Drug and Dosage:	FDA appro	oved indication fo	r this request:		
	LDL level:				
List all failed medications:		Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that medically necessary, does not exceed the med medical records. I also understand that any mis authorization request may subject me to audit a	lical needs of the srepresentations of the section	member, and is cli	nically supported in	n the patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



PHOSPHATE BINDERS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for phosphate binders must meet the following criteria: • Patient must have an FDA approved indication.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	1	Recipient Medi	caid ID Number
Prescriber Name					
Prescriber NPI		Telephone Number		Fax Number	
Address		City		State	Zip Code
Requested Drug and Dosage:	Diagnosis:		Does patient have chronic kidney disease? PYES DNO If so, what stage?		dney disease?
	Lab: Phosphate Level:		List failed med	dications and te	Il reason:
□ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.					
Prescriber (or Staff) / Pharmacy Signature**				Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



PLATELET AGGREGATION INHIBITORS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for platelet aggregation inhibitors must meet the following criteria:

• Patient must first try at least two of the following: Brilinta, Effient, clopidogrel, ticlopidine, dipyridamole, dipyridamole/aspirin, or aspirin.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Nun		dicaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Please list all medications patier	nt has tried:		
Please list reason that immediate release aspirin is not an option:				
If request is for Zontivity, will patient take with aspirin and/or clopidogrel?				
Does the patient have a history of stroke, transi	ent ischemic attack, or intracrania	I hemorrhage?		
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients who are prescribed Promacta must follow these guidelines:

• Patient must have a confirmed diagnosis of chronic immune (idiopathic) thrombocytopenia, Severe Aplastic Anemia, or Hepatitis C.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID Num		dicaid ID Number
Prescriber Name		1	
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
Promacta			
 Failed corticosteroid or immunoglobulin therapy DRUG: Start Date: End Date: Dose: Frequency: Has patient had a splenectomy? YES INO Does patient have Hepatitis C infection currently being treated or to be treated with interferon-based therapy? YES INO 	thrombocytopenia and clinical condition? YES NO Does degree of thrombocytopenia prevent initiation of or ability to maintain interferon-based therapy? YES NO Does patient have a diagnosis of Severe Aplastic Anemia? YES NO		
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the abo medically necessary, does not exceed the medical nee medical records. I also understand that any misreprese authorization request may subject me to audit and reco	ds of the member, and is clinically intations or concealment of any in	/ supported in t	he patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Provigil/Nuvigil Prior Authorization

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Provigil or Nuvigil must suffer from excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, or shift work disorder.

Provigil must be used before Nuvigil will be approved.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
🛛 Nuvigil 🔹 Provigil	EXCESSIVE SLEEPINESS ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME		
	NARCOLEPSY		
	□ SHIFT WORK SLEEP DISORDE	R	
FAILED PROVIGIL (Nuvigil Requests)	START DATE:	DOS	C .
	START DATE.	003	L .
	END DATE:	FREG	QUENCY:
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is			
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior			

authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Pulmozyme Prior Authorization

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Pulmozyme must meet the following criteria: • Patient must have a confirmed diagnosis of cystic fibrosis

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name:				
Physician Medicaid Provider Number	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:		Diagnos	sis for this requ	est:
Pulmozyme				
PRESCRIBER (OR STAFF) / PHARMACY SIGNATURE**		Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



RASUVO AND OTREXUP PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Rasuvo or Otrexup must meet the following criteria:

- Patient must have an FDA approved indication for the medication requested.
- Patient must have tried and failed methotrexate.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient M	edicaid ID Number
Physician Name			I	
Physician Medicaid Provider Number	Telephone	Number	Fax Numbe	r
Address	City		State	Zip Code
Requested Drug and Dosage:	FDA approved indication for this request:			
List all failed medications:		Start Date:	End Date:	
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep authorization request may subject me to audit and i	needs of the resentations of	member, and is cli	nically supported in	the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Rayos must meet the following criteria: • Patient must first try generic prednisone.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Physician Name:				
Physician Medicaid Provider Number	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:	1			
Requested Drug and Dosage:		Diagnos	sis for this requ	est:
□ Rayos				
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



RIBAPAK PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for RibaPak must meet the following criteria: • Patient must first try Ribavirin or Ribasphere.

Part I: TO BE COMPLETED BY PHYSICIAN					
Recipient Name	Recipient Date of Birt	Recipient Date of Birth		/ledicaid ID Number	
Physician Name					
Physician Medicaid Provider Number	Telephone Number		Fax Numbe	PL	
Address	City	City State			
Requested Drug and Dosage:	FDA Approved Indication for this request:				
	_				
Failed therapy with Ribavirin or	Start Date	End Date		Dose	
Ribasphere					
Attach MedWatch form WHAT IS THE HCV GENOTYPE? (I-IV)					
*TREATMENT WILL BE COVERED FOR 24 TO	9 48 WEEKS BASED UP	ON GENOTYP	E AND DIAC	GNOSIS.	
□ Treatment regimen for Hepatitis C will include	pegylated or non-pegylate	ed interferon in	combinatior	n with oral ribavirin.	
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that t medically necessary, does not exceed the medic medical records. I also understand that any misr authorization request may subject me to audit ar	al needs of the member, epresentations or concea	and is clinically	v supported i	in the patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Note: ND Medicaid will not pay for Solodyn, Soolantra, or Oracea without documented failure of a first line tetracycline agent.
First line agents include minocycline and tetracycline.

• Requires step therapy. See Oracea criteria for more information.

Part I:	TO BE	COMPL	ETED.	BY P	RESCRIBER

Recipient Name	Recipient Date of Birth		Recipient I	Medicaid ID Number
Physician Name				
Physician Medicaid Provider Number	Telephone I	Number	Fax Numb	er
Address	City		State	Zip Code
REQUESTED DRUG:	Requested Dosage: (must be completed)			
 Patient has failed a 90 day trial of which firs Moderate to severe acne Severe acne 	st line agent			
List all failed medications:		Start Date:	End Date:	
Prescriber (or Staff) / Pharmacy Signature**		<u> </u>	Date	
**: By completing this form, I hereby certify the medically necessary, does not exceed the me records. I also understand that any misrepres authorization request may subject me to audit	edical needs of the entations or conce	member, and is cli	inically supported	in the patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Sancuso must be unable to take oral medications. **Note:*

- Dolasetron, oral granisetron, and ondansetron do not require PA.
- Patients must be unable to take oral medications or
- Patients must fail therapy on ondansetron or oral granisetron before a PA may be granted.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient D	Recipient Date of Birth		Medicaid ID Number
Prescriber Name				
Prescriber NPI	Telephone I	Number	Fax Numb	er
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request: Does the patient have breast, head/neck, gastrointestinal, or gynecological cancer? Is the patient taking chemotherapy? If so, please list date of last chemotherapy treatment:			
□ Sancuso				
List all failed medications:		Start Date:	End Date:	
PATIENT UNABLE TO TAKE ORAL MEDICA	TIONS			
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that a medically necessary, does not exceed the medic records. I also understand that any misrepresen authorization request may subject me to audit a	cal needs of the tations or conce	member, and is cl	inically supported	in the patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for a name brand Sedative/Hypnotic must use Ambien[®] (zolpidem) as first line therapy.

*Note:

• Requires step therapy. See Sedative/Hypnotic PA criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Med	licaid ID Number
Prescriber Name	I			
Prescriber NPI	Telephone N	umber	Fax Number	
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis	for this request:		
Qualifications for coverage:				
List all failed medications:		Start Date:	End Date:	
Does the patient require dose tapering? □ YES □ N Is the patient's insomnia characterized by difficulty with sleep maintenance? □ YES □ N Is the patient's insomnia characterized by difficulty with sleep initiation? □ YES □ N				□ YES □ NO □ YES □ NO □ YES □ NO □ YES □ NO □ YES □ NO I medical management
Prescriber (or Staff) / Pharmacy Signature** **: By completing this form, I hereby certify that the	above reques	t is true accurate and	Date	the request is
	, anove ieques	ה ום נועם, מטטעומנס מווע	i compicie. Indi	

**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



SGLT2 Inhibitors PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for SGLT2 inhibitors must meet the following criteria:

- Patient must have diagnosis of Type II Diabetes.
- Requires step therapy. Please see criteria for coverage in the Preferred Drug List at <u>http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf</u>

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth		Recipient M	edicaid ID Number
Prescriber Name:		I			
Prescriber NPI		Telephone Number		Fax Numbe	r
Address		City	ity		Zip Code
Requested Drug and Dosage:			Diagnos	sis for this rec	quest:
Failed therapy:	Start Date	2:	End	Date:	
Prescriber (or Staff) / Pharmacy Signatu				Date	
**: By completing this form, I hereby cen medically necessary, does not exceed th medical records. I also understand that a authorization request may subject me to	he medical l any misrepr	needs of the member, and is resentations or concealment	s clinically	v supported in	the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a prescription for Spinraza must meet the following criteria:

• For a diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2 or 3:

- Patient must be less than 2 years of age
- Patient must not have respiratory insufficiency
- i.e. Need for invasive or noninvasive ventiliation for more than 6 hours per 24 hour period.
- o Patient must not require gastric feeding tubes for the majority of feeds
- Patient must not have severe contractures or severe scoliosis
- Patient must not have wasting or cachexia
- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 3:
 - The patient must be experiencing issues with ambulating
 - e.g. falls, trouble climbing stairs, unable to walk independently

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Mec	licaid ID Number
Prescriber Name			I	
Prescriber NPI	Telephone Number		Fax Number	
Address	City		State	Zip Code
Requested Drug and Dose:				
Diagnosis for this request: SMA Type 1	SMA Type 2 🛛 SMA Ty	/pe 3		
Does the patient have respiratory insufficiency?			□ NO	
Does the patient require gastric feeding tubes for			□ NO	
Does the patient have severe contractures or se	vere scoliosis?		□ NO	
Does the patient have wasting or cachexia?				
Does the patient experience issues with ambula	ting (SMA Type 3 only)?			
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is esentations or concealment	s clinically	supported in th	ne patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Spiriva Respimat 1.25 mcg must meet the following criteria:

- Patient must have a diagnosis of asthma.
- Requires step therapy. Please see criteria for coverage.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number		
Prescriber Name					
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage: Please list all medications patient has tried:					
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical r medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the member, and is clinically esentations or concealment of any in	/ supported in t	he patient's		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Statins PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that who are prescribed a name-brand statin must first try a generic statin. *Requires step therapy. See statin criteria for more information.*

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name:				
Prescriber NPI	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:			s for this requ	est:
Medication Failed and Dose (list all)				
Is the statin intensity treatment goal low, moderate,	or high?			
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for a steroid inhaler must first try a 30-day trial of all preferred agents in the past year.

• Requires a trial and failure of all preferred agents in the past year

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number	
Prescriber Name:				
Prescriber NPI	Telephone Number		Fax Number	
Address	City		State	Zip Code
QUALIFICATIONS FOR COVERAGE:				
Requested Drug and Dosage:		Diagnos	is for this requ	iest:
Failed Therapy (list all):		Start Da	ite:	End Date:
Prescriber (or Staff) / Pharmacy Signature**			Date	
			Dato	
**. By completing this form I hereby cortify that the	above request is true, ecour	oto and a	omploto That	the request is
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's				
medical records. I also understand that any misrepr	esentations or concealment			
authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Note:

- Synagis season will be October 19th through April 21st
- Providers will choose when to start dosing Synagis based on prevalence of RSV in the community
- Clinicians may administer up to a maximum of 5 monthly doses during the RSV season.
- Qualifying infants born during the RSV season may require fewer doses.

TO BE COMPLETED BY PRESCRIBER

Recipient Medicaid ID Number	Recipient Date of Birth	Prescriber NPI	Prescriber Fax Number			
Billing Facility NPI	Billing Facility Name		ICD-10 code			
Diagnosis (qualification for Synagi	s)					
Prematurity						
<29 weeks, 0 days gesta	tional age – Synagis allowed if your	nger than 12 months of age at start of	of RSV season (max of 5 doses)			
Gestational Age (e.g. 28	3 weeks, 4 days)					
Weeks	Days					
	ematurity (CLD) – Child ≤12 month or at least the first 28 days after birth	ns old with gestational age <32 weel h.	ks, 0 days and requires			
		ns old with gestational age <32 weel h and continues to receive medical s				
Supplemental Oxyg	en					
Diuretic						
Chronic corticostero	id therapy					
Congenital Heart Disease (C	CHD)					
Child ≤12 months old with	h hemodynamically significant cyan	otic or acyanotic CHD				
Medical Therapy Require	ed					
*children less than 24 months who undergo cardiac transplantation during RSV season may be considered for prophylaxis.						
Neuromuscular disease (may be considered for prophylaxis during the first year of life)						
Pulmonary abnormalities (may be considered for prophylaxis during the first year of life)						
Profoundly Immunocompromised children (children <24 months of age may be considered for prophylaxis during the RSV season)						





ND Medicaid requires that patients who are prescribed Tecfidera must follow these guidelines: *Note:

- Must have relapsing forms of multiple sclerosis.
- Must have a recent CBC (within 6 months).
- Requires step therapy. See Tecfidera criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID			ledicaid ID Number
Prescriber Name	Specialist Ir	volved in Therapy	,	
Prescriber NPI	Telephone I	Number	Fax Numbe	er
Address	City		State	Zip Code
Requested Drug and Dosage:	Diagnosis	for this request:		
□ Tecfidera	Current C	BC (date):		
List all failed medications:		Start Date:	End Date:	
Prescriber (or Staff) / Pharmacy Signature**			Date	
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepresent authorization request may subject me to audit and least the subject me to audit audit and least the subject me to audit and least the subject me to audit and least the subject me to audit a	needs of the r resentations o	member, and is cli	nically supported in	n the patient's

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



TOPICAL TESTOSTERONE PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for a topical testosterone must meet the following criteria: • Patient must have an FDA approved indication.

Part I: TO BE COMPLETED BY PHYSICIAN Recipient Name	Recipient D	ate of Birth	Recipient N	Recipient Medicaid ID Number		
Physician Name						
Physician Medicaid Provider Number	Telephone I	Number	Fax Numbe	er		
Address	City		State	Zip Code		
Requested Drug and Dosage:	Diagr	osis for this Requ	est:			
□ ANDRODERM □ ANDROGEL						
□ FORTESTA □ TESTIM		sterone Level:		Date:		
AXIRON VOGELXO	_					
I confirm that I have considered a generic or othe successful medical management of the recipient.	er alternative	and that the reques	ted drug is expe	cted to result in the		
List all failed medications:		Start Date:	End Date:			
Prescriber (or Staff) / Pharmacy Signature**			Date			
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrep	needs of the	member, and is clin	nically supported	in the patient's		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for a tetracycline must meet the following criteria: • Requires step therapy. Please see criteria for coverage.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number		
Prescriber Name		1		
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Please list all medications patient has tried:			
Diagnosis:				
Prescriber (or Staff) / Pharmacy Signature** Date				
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



CYTOKINE MODULATORS PA FORM

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Actemra, Cimzia, Cosentyx, Enbrel, Humira, Kevzara, Kineret, Orencia, Otezla, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz, and Xeljanz XR and must meet the following criteria:

- All agents will require an FDA-approved indication.
- For non-preferred agents, the patient must have had a 3-month trial with at least 2 preferred agents, as evidenced by paid claims or pharmacy print-outs.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipier	nt Date of Birth		Recipi	ent Med	licaid II	D Number
Prescriber Name							
Prescriber NPI	Telepho	ne Number		Fax Nu	umber		
Address	City			State		Zip C	ode
Diagnosis for this request:			·				
Requested Drug and Dosage:		List all failed med	lication	s:	Start I	Date:	End Date:
ACTEMRA CIMZIA COSENTYX ENBREL HUMIRA HUMIRA							
🗆 KEVZARA 🗆 KINERET 🗆 ORENCIA	313						
□ OTEZLA □ SILIQ □ SIMPONI □ STELARA □ TALTZ □ TREMFYA							
XELJANZ							
 I confirm that I have considered a generic or othe successful medical management of the recipient. 		ve and that the reque	ested dr	rug is e	xpectea	to resi	ult in the
Prescriber (or Staff) / Pharmacy Signature**		Date		Date			
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical I medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of ti esentatior	he member, and is cl ns or concealment of	linically	suppor	ted in th	ie patie	ent's
Part II: TO BE COMPLETED BY PHARMACY							
PHARMACY NAME:			ND ME	EDICAI	D PRO'	VIDER	NUMBER:
TELEPHONE NUMBER FAX NUMBER DF	RUG		NDC #	£			



TIROSINT PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Tirosint must meet one of the following criteria:

• Patient must have documented celiac disease, yellow dye allergy, or lactose/milk protein allergy.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number			
Prescriber Name		1			
Prescriber NPI	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	FDA approved indication for this	s request:			
List all failed medications (drug name, date of trial, reason for failure):					
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



LOCAL ANESTHETICS (TOPICAL) PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for topical local anesthetic must meet the following criteria:

- These medications will only be covered when prescribed for use prior to certain procedures (e.g., placement of a peripheral or central line or injections through an implanted port). Medical procedure must be listed on PA form.
- PA not required for patients 12 years of age and younger.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid ID		dicaid ID Number		
Prescriber Name					
Prescriber NPI	Telephone Number Fax Number				
Address	City	State Zip Code			
Requested Drug and Dosage:	FDA approved indication for this request:				
Lidocaine-prilocaine topical	Placement of a peripheral or cent	ral line			
Lidocaine-tetracaine topical	 Injections through an implanted port Other: 				
Prescriber (or Staff) / Pharmacy Signature**			Date		
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.					

PHARMACY NAME:	PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



TOPICAL ANTIPSORIATICS PA FORM

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for topical antipsoriatics must meet the following criteria:

- Calcipotriene cream and foam Patient must have a 30-day trial of calcipotriene ointment or solution.
- Calcipotriene/betamethasone foam Patient must have a 30-day trial of calcipotriene/betamethasone ointment or solution.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth			Recipient Medicaid ID Number	
Prescriber Name		1				
Prescriber NPI		Telephon	e Number		Fax Number	
Address		City		;	State	Zip Code
Requested Drug and Dosage: Diagnosis for Request:						
Qualifications for Coverage:						
Medications patient has tried:	Start Da	Date: End Date: Dose				Frequency:
Other medical justification for use (why patient is unable to use ointment or solution of the requested product):						
Prescriber (or Staff) / Pharmacy Signature** Date						
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.						

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:



ND Medicaid requires that patients who are prescribed Extina, Xolegel, and Ketocon Plus must first try a covered ketoconazole medication.

*Note:

• Ketoconazole creams and ketoconazole shampoos do not require a prior authorization.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth Recipient Medicaid		dicaid ID Number		
Physician Name					
Physician Medicaid Provider Number	Telephone Number	Fax Number			
Address	City	State	Zip Code		
Requested Drug and Dosage:	Diagnosis for this request:				
Extina Xolegel Ketocon Plus					
Qualifications for coverage:					
Medication Failed	Start Date:	Dose:			
	End Date:	Frequency:			
Prescriber (or Staff) / Pharmacy Signature** Date					
**: By completing this form, I hereby certify that th medically necessary, does not exceed the medica medical records. I also understand that any misre authorization request may subject me to audit and	al needs of the member, and is clinica presentations or concealment of any	lly supported in t	he patient's		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Serotonin (5-HT1) Receptor Agonists -Triptan PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for a triptan must meet the following criteria:

- Patients 6-17 must have a 30 day trial of rizatriptan in the past 24 months.
- Patients 18 years and older must have a 30 day trial of all preferred agents in the past 24 months.
- Sumatriptan tablets, Relpax, rizatriptan tablets, and rizatriptan ODT do not require a PA

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Dat	e of Birth	F	Recipient Me	dicaid ID Number
Prescriber Name		_1		I		
Prescriber NPI		Telephone Nu	umber	F	Fax Number	
Address		City			State	Zip Code
Requested Drug and Dosage:		Does patier	ior this request: nt have menstru migraine long in	ıal migraiı		s it recur?
Failed therapy	Start Date	End Date		Dose	F	requency
List all failed medications:			Start Date:	En	nd Date:	
Prescriber (or Staff) / Pharma	, ,				Date	
**: By completing this form, I medically necessary, does no records. I also understand that	ot exceed the medica	al needs of the	member, and is	clinically s	supported in	n the patient's medical

authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



TYSABRI PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Tysabri must meet the following criteria:

- Patient must have a confirmed diagnosis of multiple sclerosis or Crohn's disease.
- Requires step therapy. See Tysabri criteria for more information.

Part I: TO BE COMPLETED BY PHYSICIAN				
Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number		
Prescriber Name	Specialist involved in therapy (if	not treating physi	cian)	
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	FDA approved indication for	this request:	·	
. Here notions experienced a reduction in relan	as rate? (renowed requests)	□ YES		
Has patient experienced a reduction in relap				
 Has the patient had persistent positive anti-r (2 consecutive positive tests 4 weeks or mo 		□ YES		
 Has patient had anti-JCV antibodies taken? 	re apart) (renewal requests)	□ YES	⊓ NO	
 Has patient had a MRI scan? 				
 Is the patient experiencing early aggressive 	discase $2 (>-2$ relanses in the			
year and >= 1 Gadolinium (Gd)+ lesion)?				
List all failed medications:	Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature**		Date		
**: By completing this form, I hereby certify that the	above request is true, easurate a	nd complete That	the request is	
medically necessary, does not exceed the medical i				
medical records. I also understand that any misrepr				
authorization request may subject me to audit and r		y miornadon lequ		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



VANOS PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Vanos must meet the following criteria:

- Patient must be 12 years of age and older.
- Patient must have documented 3-month trial and failure with generic topical clobetasol or halobetasol.
- Part I: TO BE COMPLETED BY PHYSICIAN **Recipient Name** Recipient Date of Birth Recipient Medicaid ID Number Physician Name Physician Medicaid Provider Number **Telephone Number** Fax Number City Address State Zip Code Requested Drug and Dosage: Diagnosis for this Request: Failed Therapy (dose and frequency): Start Date: End Date: □ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient. Prescriber (or Staff) / Pharmacy Signature** Date **: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Vecamyl must meet the following criteria:

- Patient must have an FDA approved indication.
- Patient must have documented history of failure to achieve blood pressure goals (using maximum tolerated doses of all first and second line agents) as defined by the most recent JNC report.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth		Recipient Medicaid ID Number		
Physician Name	Specialist Involved in Therapy				
Physician Medicaid Provider Number	Telephone Number		Fax Numbe	r	
Address	City		State	Zip Code	
Requested Drug and Dosage: □ VECAMYL	Diag	nosis for this Requ	Jest:		
List all failed medications:	I	Start Date:	End Date:		
Prescriber (or Staff) / Pharmacy Signature**		•	Date		
**: By completing this form, I hereby certify that the medically necessary, does not exceed the medical medical records. I also understand that any misrepr authorization request may subject me to audit and r	needs of the resentations	e member, and is cli or concealment of a	nically supported	in the patient's	

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



Xenical PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Xenical must be seen by a dietician. *Note:

- Patient must have dietician evaluation attached to PA form including height and weight.
- BMI must be equal to or greater than 40.
- 5% weight loss must be realized for continued approval (every 6 months).

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth		F	Recipient Mec	licaid ID Number
Physician Name						
Physician Medicaid Provider	Number	Telepho	ne Number	F	ax Number	
Address		City		S	State Zip Code	
Requested Drug and Dosage:		Diagno	osis for this request	t:		
 Dietician evaluation attached 	Height: Weight:		Weight:		BMI:	
Prescriber (or Staff) / Pharm	acy Signature**				Date	
**: By completing this form, I medically necessary, does n records. I also understand th authorization request may si	ot exceed the medica nat any misrepresenta	l needs of tions or co	the member, and is oncealment of any inf	clinically s	upported in ti	he patient's medical

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving a new prescription for Xifaxan must meet the following guidelines:

- Patient must be 12 years of age or older and have a diagnosis of traveler's diarrhea caused by noninvasive strains of E. coli. Patient must try ciprofloxacin, levofloxacin, OR norfloxacin before PA for Xifaxan will be approved.
- Patient must be 18 years of age or older and have a risk of recurrence of overt hepatic encephalopathy.
- Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than E. coli.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Mec	dicaid ID Number
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
T XIFAXAN	TRAVELER'S DIARRHEA: 200 mg three times a day for 3 days		day for 3 days
		g anoo anoo a	
	□ HEPATIC ENCEPHALOPATHY: 5	550 mg two time	es a day
I confirm that I have considered a generic or oth	er alternative and that the requested	drug is expected	d to result in the
successful medical management of the recipient.			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the			
medically necessary, does not exceed the medical			
medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.			
autionzation request may subject me to audit and	recoupriient.		

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients who are prescribed Xyrem must meet these guidelines: *Note:

- Must be 18 years or older.
- Must have a diagnosis of excessive daytime sleepiness and cataplexy in patients with narcolepsy.
- Must be enrolled in the Xyrem REMS Program

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Mec	licaid ID Number	
Prescriber Name				
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug and Dosage:	Diagnosis for this request:	List failed me	dication:	
□ Xyrem				
Qualifications for coverage:				
Enrolled in Xyrem REMS Program	Enrolled Date:	Dose:		
Is patient taking any sedative/hypnotics, opioids, or muscle relaxants?				
I confirm that I have considered a generic or oth successful medical management of the recipient.	er alternative and that the requested	drug is expected	d to result in the	
Prescriber (or Staff) / Pharmacy Signature** Date				
rescriber (or otar) / r harmacy orgnature		Date		
**: By completing this form, I hereby certify that the				
medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's				
medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.				

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ND Medicaid requires that patients receiving Zanaflex capsules must use tizanidine tablets first line. **Note:*

- Tizanidine tablets do not require a PA.
- Patient must fail therapy on tizanidine tablets before a PA may be granted.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Med	dicaid ID Number
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
Additional Qualifications for Coverage:			
Failed generic drug	Start Date:	Dose:	
	End Date:	Frequency:	
 I confirm that I have considered a generic or other successful medical management of the recipient. 	r alternative and that the requested d	rug is expected t	o result in the
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.			

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #



ZINBRYTA PA FORM

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Zinbryta must meet the following criteria:

- Patient must have a confirmed diagnosis of multiple sclerosis.
- Requires step therapy. See Zinbryta criteria for more details.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Me	dicaid ID Number
Prescriber Name	Specialist involved in therapy (if not	treating physic	ian)
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	FDA approved indication for this	s request:	
Have transaminase and bilirubin levels been	obtained in the last 6 months?	□ YES	□ NO
• Does patient have Hepatitis B or C?			□ NO
Has patient been screened for TB and treated for TB if positive?			
 Is the patient experiencing early aggressive and >= 1 Gadolinium (Gd)+ lesion)? 	disease? (>=2 relapses in the year	□ YES	□ NO
Has the patient had a reduction in relapse ra	te? (renewal requests)		□ NO
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.			

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Since the beginning of the year (2017), 67 people have overdosed on opioids, benzos, heroin, or an unspecified psychotropic drug.

Last 2 months of 2016 (Before Overdose) 13 were gets benzos or narcs paid by Medicaid

6 were getting benzos:

FDB Brand Name	Diagnosis
CLONAZEPAM 1 MG TABLET	T401X1A Poisoning by heroin, accidental, initial encounter
LORAZEPAM 1 MG TABLET	T402X2A Poisoning by other opioids, intentional self-harm, initial encounter
CLONAZEPAM 0.5 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
LORAZEPAM 1 MG TABLET	T401X1A Poisoning by heroin, accidental, initial encounter
CLONAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
ALPRAZOLAM 0.5 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter

4 were getting narcotics: blue is same person

FDB Brand Name	Diagnosis
HYDROCODON-ACETAMINOPHEN 5-	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
OXYCODONE HCL 10 MG TABLET	T40604A Poisoning by unspecified narcotics, undetermined, initial encounter
TRAMADOL HCL 50 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
ACETAMINOPHEN-COD #3 TABLET	T402X1A Poisoning by other opioids, accidental, initial encounter
HYDROCODON-ACETAMINOPHEN 5-	T402X1A Poisoning by other opioids, accidental, initial encounter

3 were getting both:

ID	FDB Brand Name	Diagnosis
1	OXYCODONE-ACETAMINOPHEN 5-3	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
1	CLONAZEPAM 0.5 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
1	HYDROCODON-ACETAMINOPHEN 5-	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
2	HYDROCODON-ACETAMINOPHEN 5-	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
2	LORAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
2	CLONAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
3	OXYCODONE HCL 10 MG TABLET	T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter
3	FENTANYL 75 MCG/HR PATCH	T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter
3	CLONAZEPAM 0.5 MG TABLET	T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter
Last 2 months Aug-Sept 2017 (After Overdose *with 1 exception noted below)

8 were getting benzos

FDB Brand Name	Diagnosis
ALPRAZOLAM 0.5 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
CLONAZEPAM 1 MG TABLET	T401X1A Poisoning by heroin, accidental, initial encounter
CLONAZEPAM 0.125 MG DIS TAB	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
LORAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
ALPRAZOLAM 0.5 MG TABLET	T401X1A Poisoning by heroin, accidental, initial encounter
DIAZEPAM 5 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
LORAZEPAM 1 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter *This overdose was after lorazepam was dispensed
CLONAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter

3 were getting narcotics

FDB Brand Name	Diagnosis
TRAMADOL HCL 50 MG TABLET	T40604A Poisoning by unspecified narcotics, undetermined, initial encounter
TRAMADOL HCL 50 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
OXYCODONE HCL 5 MG TABLET	T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter

1 was getting both

MMIS ID	FDB Brand Name	Diagnosis
1	TRAMADOL HCL 50 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
1	ALPRAZOLAM 2 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
1	LORAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter

Before and After overdose: 7 members on both lists

MMIS ID	Prior to overdose	After Overdose	Diagnosis
1	TRAMADOL HCL 50 MG TABLET	TRAMADOL HCL 50 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
2	CLONAZEPAM 0.5 MG TABLET	DIAZEPAM 5 MG TABLET	T424X2A Poisoning by benzodiazepines, intentional self-harm, initial encounter
3	CLONAZEPAM 1 MG TABLET	CLONAZEPAM 1 MG TABLET	T401X1A Poisoning by heroin, accidental, initial encounter
4	OXYCODONE HCL 10 MG TABLET	TRAMADOL HCL 50 MG TABLET	T40604A Poisoning by unspecified narcotics, undetermined, initial encounter
5	CLONAZEPAM 1 MG TABLET	CLONAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
6	HYDROCODON- ACETAMINOPHEN 5-	TRAMADOL HCL 50 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
6	LORAZEPAM 1 MG TABLET	ALPRAZOLAM 2 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
6	CLONAZEPAM 1 MG TABLET	LORAZEPAM 1 MG TABLET	T424X1A Poisoning by benzodiazepines, accidental, initial encounter
7	OXYCODONE HCL 10 MG TABLET	OXYCODONE HCL 5 MG TABLET	T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter
7	FENTANYL 75 MCG/HR PATCH		T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter
7	CLONAZEPAM 0.5 MG TABLET		T404X4A Poisoning by other synthetic narcotics, undetermined, initial encounter

Plan for Benzo + Narcotic Edit

All Benzos = Solid forms of Alprazolam, diazepam, clonazepam, lorazepam

Step 1: 6/9 66% oxycodone ER, liquid Tylenol/Codeine, tramadol ER, Tylenol #2 & #4; Codeine; Nucynta IR,ER

Step 2: 17/23 people all different prescribers 74% All benzos with: Oxycodone 10-325mg

Step 3: 20/29 people all different prescribers 69% All benzos with Oxycodone 5-325mg

Step 4: 50/69 people all different prescribers 72% Hydrocodone 5-325mg

- a. 20/27 Alprazolam 1mg, 2mg; clonazepam 2mg; diazepam 5mg, 10mg
- b. 20/27 alprazolam 0.25mg, 0.5mg; clonazepam 1mg; lorazepam 1mg
- c. 10/15 the rest

Step 5: 28/45 people all different prescribers 62% Hydrocodone 10-325mg

- a. 8/16 diazepam 5mg, 10mg; alprazolam 1mg; lorazepam 2mg; clonazepam 2mg
- b. 20/29 the rest

Step 6: 11/18 people different prescribers 61% All benzos with: Hydromorphone 2mg and over Oxycodone 10mg and over

Step 7: 11/16 people all different prescribers 69% All benzos with Tylenol #3

Step 9: 12/25 people all different prescribers 48% All benzos with Oxycodone 5mg

Step 8: 40/84 people different prescribers 48% Tramadol 50mg & Tramadol-acetaminophen

a. 18/28 Diazepam 5mg, 10mg; alprazolam 1mg, 2mg; lorazepam 2mg; clonazepam 2mg

- b. 12/27 alprazolam 0.5mg; lorazepam 1mg
- c. 10/23 lorazepam 0.5mg; clonazepam 1mg
- d. 2/7 clonazepam 0.5mg, alprazolam XR, alprazolam 0.25mg

Step 10: 11/16 69% All benzos with Fentanyl patch

Step 11: 12/24 50% All benzos with Morphine IR + ER

PRODUCT DETAILS OF EUCRISA (crisaborole)

INDICATIONS AND USE:

• Treatment of topical treatment of mild to moderate atopic dermatitis in patients 2 years and older.

DOSAGE AND ADMINISTRATION:

• Apply thin film to affected area(s) twice daily.

DOSAGE FORM AND STRENGTHS:

• 2% External ointment in 60 gram tubes

CONTRAINDICATIONS:

• Hypersensitivity to crisaborole or any component of the formulation

WARNINGS AND PRECAUTIONS:

• Hypersensitivity to crisaborole or any component of the formulation

ADVERSE REACTIONS:

- Application site pain (4%).
- Hypersensitivity reaction, urticaria (<1%)

COST

• WAC Package Price: \$580.00

CURRENT UTILIZATION

ND Medicaid Eucrisa Utilization (08/2017-09/2017)			
Label Name	Rx Num		Total Reimb Amt
EUCRISA	9		\$ 4,249.51

REFERENCES:

- 1. Facts & Comparisons eAnswers. Available at <u>http://online.factsandcomparisons.com.</u> Accessed on October 31, 2017.
- Eucrisa (crisaborole) [prescribing information]. Palo Alto, CA: Anacor Pharmaceuticals Inc; October 2017

PRODUCT DETAILS OF SKELAXIN (metaxalone)

INDICATIONS AND USE:

• Relief of discomforts associated with acute, painful musculoskeletal conditions.

DOSAGE AND ADMINISTRATION:

- 13 years of age and older:
 - o 800 mg 3-4 times daily
 - <12 years of age
 - o Safety and efficacy have not been stablished

DOSAGE FORM AND STRENGTHS:

• 400 mg and 800 mg oral tablets

CONTRAINDICATIONS:

- Hypersensitivity to metaxalone or any component of the formulation
- Significantly impaired hepatic or renal function
- Tendency for drug-induced, hemolytic, or other anemias

WARNINGS AND PRECAUTIONS:

- Serotonin Syndrome: Potentially life-threatening serotonin syndrome has been reported; generally occurs when used concomitantly with serotonergic drugs or when exceeding recommended doses
- **Renal Impairment**: Use with caution in patients with renal impairment; contraindicated in patients with significant impairment
- **Hepatic Impairment**: Use with caution in patients with hepatic impairment; contraindicated in patients with significant hepatic impairment. Routine monitoring of transaminases is recommended
- Drug/Drug Interactions: Potentially significant interactions may occur when used with other CNS depressants

ADVERSE REACTIONS:

- The most common adverse effects noted during clinical trials were Dizziness, drowsiness, headache, irritability, nervousness, Gastrointestinal upset, nausea, and vomiting.
- Rare, but serious adverse reactions include anaphylactoid reaction, hypersensitivity reactions, hemolytic anemia, leukopenia, and Jaundice.

COST

• WAC unit price for 800 mg tablets: \$9.29

CURRENT UTILIZATION

ND Medicaid Skelaxin Utilization (08/2017-09/2017)		
Label Name	Rx Num	Total Reimb Amt
SKELAXIN	34	\$ 4,513.87

REFERENCES:

- 1. Facts & Comparisons eAnswers. Available at <u>http://online.factsandcomparisons.com.</u> Accessed on October 31, 2017.
- 2. Skelaxin (metaxalone) [prescribing information]. New York, NY: Pfizer; April 2017.

NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS 4TH QUARTER 2017

Criteria Recommendations

Approved Rejected

1. Safinamide / Overutilization

Alert Message: Xadago (safinamide) may be over-utilized. The manufacturer's recommended maximum dose of safinamide is 100 mg once daily. Daily dosages of safinamide above 100 mg have not been shown to provide additional benefit, and higher dosages increase the risk for adverse reactions. Selectivity for MAO-B inhibition decreased in a dose-related manner above the highest recommended daily dosage.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Safinamide
 Util C (Negate)

Max Dose: 100 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

2. Safinamide / Hepatic Impairment

Alert Message: The recommended maximum daily dose of Xadago (safinamide) in patients with moderate hepatic impairment (Child-Pugh B score 7-9), is 50 mg once daily. Safinamide use is contraindicated in patients with severe hepatic impairment (Child-Pugh C score 10-15). As a patient taking 50 mg safinamide progresses from moderate to severe hepatic impairment, discontinue safinamide.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Safinamide
 Hepatic Impairment

Max Dose: 50 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

3. Safinamide / Severe Hepatic Impairment

Alert Message: Xadago (safinamide) use is contraindicated in patients with severe hepatic impairment (Child-Pugh C score 10-15). In clinical studies subjects with moderate hepatic impairment (Child-Pugh B) receiving safinamide had an approximate 80% increase in safinamide exposure.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	<u>Util B</u>	<u>Util C (Include)</u>
Safinamide		Severe Hepatic Impairment

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

4. Safinamide / Levodopa/Carbidopa

Alert Message: A review of the patient's drug history does not show a concurrent prescription for levodopa/carbidopa. Xadago (safinamide) is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. Safinamide has not been shown to be effective as monotherapy for the treatment of PD.

 Conflict Code: TA – Therapeutic Appropriateness

 Drugs/Diseases

 Util A
 Util B

 Util C (Negate)

Safinamide	Levodopa/Carbidopa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

5. Safinamide / MAO Inhibitors

Alert Message: Xadago (safinamide) is contraindicated for use with other drugs in the MAO inhibitor class or other drugs that are potent inhibitors of monoamine oxidase. Co-administration increases the risk of nonselective MAO inhibition, which may lead to hypertensive crisis. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment of other MAOIs.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
Util A	<u>Util B</u>	<u>Util C</u>
Safinamide	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	
	Linezolid	
	Rasagiline	
	-	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

6. Safinamide / Opioids

Alert Message: Concurrent use of Xadago (safinamide), a MAO-B inhibitor, with opioid drugs is contraindicated. Serious, sometimes fatal reactions have been precipitated with concomitant use of MAOIs and opioids. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment with an opioids.

Conflict Code: DD – Drug/Drug Interaction

<u>Util B</u>		<u>Util C</u>
Meperidine	Fentanyl	
Methadone	Dihydrocodeine	
Morphine	Tapentadol	
Codeine	Tramadol	
Hydrocodone	Oxymorphone	
Hydromorphone	Oxycodone	
Levorphanol		
	Meperidine Methadone Morphine Codeine Hydrocodone Hydromorphone	MeperidineFentanylMethadoneDihydrocodeineMorphineTapentadolCodeineTramadolHydrocodoneOxymorphoneHydromorphoneOxycodone

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

7. Safinamide / Dextromethorphan

Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a dextromethorphan-containing agent is contraindicated. The co-administration of dextromethorphan and MAOIs has been shown to cause episodes of psychosis or bizarre behavior.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BSafinamideDextromethorphan

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

8. Safinamide / Serotonergic Agents

Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a serotonergic drug is contraindicated. The co-administration of MAOIs and a serotonergic agent may result in potentially life-threatening serotonin syndrome. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment with these drugs.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Safinamide SNRIs TCAs Tetracyclic Antidepressants Trazodone Cyclobenzaprine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

9. Safinamide / Sympathomimetic Agents

Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a sympathomimetic agent is contraindicated. Hypertensive crisis has been reported in patients taking the recommended doses of selective MAO-B inhibitors and sympathomimetic medications.

Util C

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> Safinamide Methylphenidate Dexmethylphenidate Amphetamine Dextroamphetamine Methamphetamine Lisdexamfetamine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

10. Safinamide / SSRIS

Alert Message: Caution should be exercised when Xadago (safinamide), a MAO-B inhibitor, is co-administered with selective serotonin re-uptake inhibitors (SSRIs). In clinical trials, serotonin syndrome was reported in a patient treated with safinamide and an SSRI. In a patient treated with concomitant safinamide and an SSRI, use the lowest effective dose of the SSRI and monitor the patient for symptoms of serotonin syndrome.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		Util C
Safinamide	Fluoxetine	Escitalopram	
	Paroxetine	Sertraline	
	Fluvoxamine	Vortioxetine	
	Citalopram	Vilazodone	
References:			

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

11. Safinamide / BCRP Substrates

Alert Message: Concurrent use of Xadago (safinamide) with a drug that is a BCRP substrate may result in increased plasma concentrations of the BCRP substrate. Safinamide and its major metabolite inhibit BCRP transport. If co-administration with safinamide and the BCRP substrate is warranted monitor the patient for increased pharmacologic or adverse effect of the BCRP substrate.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Safinamide	Methotrexate	
	Imatinib	
	Irinotecan	
	Lapatinib	
	Rosuvastatin	
	Sulfasalazine	
	Topotecan	
	Dantrolene	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

12. Safinamide / Dopamine Antagonists

Alert Message: Concomitant use of Xadago (safinamide) with a dopamine antagonist may decrease the effectiveness of safinamide and exacerbate the symptoms of Parkinson's disease.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A
 Util B

 Safinamide
 Antipsychotics

 Metoclopramide

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Xadago Prescribing Information, June 2017, US WorldMeds LLC.

13. Safinamide / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Xadago (safinamide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence Drugs/Diseases <u>Util A Util B</u><u>Util C</u> Safinamide

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487-497.

Xadago Prescribing Information, June 2017, US WorldMeds LLC.

Richy FF, Pietri G, Morna KA et al. Compliance with Pharmacotherapy and Direct Healthcare Costs in Patients with Parkinson's Disease: A Retrospective Claims Database Analysis. Appl Health Ecom Health Policy (2013) 11:395-406.

Fleisher JE, Stern MB. Medication Non-Adherence in Parkinson's Disease. Curr Neuro Neurosci Rep. 2013 October;13(10).

14. Deutetrabenazine / Depression & Suicidality

Alert Message: Austedo (deutetrabenazine) is contraindicated in patients who are actively suicidal, or who have depression which is untreated or undertreated.

Conflict Code: MC – Drug (Actual) Disease Warning Drugs/Diseases Util A Util B Util C Deutetrabenazine Depression – in partial or unspecified remission Suicidal Ideation References: Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

15. Deutetrabenazine / Depression

Alert Message: Caution should be exercised when prescribing Austedo (deutetrabenazine) to patients with a history of depression or prior suicide attempts or ideation. Patients with Huntington's disease are at increased risk for depression, suicidal ideation or behavior. Deutetrabenazine use is associated with risk of or worsening of depression and suicidality.

 Conflict Code:
 MC – Drug (Actual)
 Disease Warning

 Drugs/Diseases
 Util A
 Util B
 Util C (Include)

 Deutetrabenazine
 Depression in Remission

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

16. Deutetrabenazine / Hepatic Impairment

Alert Message: Austedo (deutetrabenazine) use is contraindicated in patients with impaired hepatic function due to the potential for increased deutetrabenazine exposure and greater risk for serious adverse reactions. The effect of hepatic impairment on the pharmacokinetics of deutetrabenazine has not been studied; however in a clinical study conducted with tetrabenazine, a closely related VMAT2 inhibitor, there was a large increase in exposure to tetrabenazine and its active metabolites in patients with hepatic impairment.

Conflict Code: MC - Drug (Actual) Disease Warning Drugs/Diseases

Brage, Broodooo		
<u>Util A</u>	<u>Util B</u>	Util C
Deutetrabenazine	Hepatic Impairment	

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

17. Deutetrabenazine / MAOIs

Alert Message: Austedo (deutetrabenazine) is contraindicated in patients taking MAOIs. Deutetrabenazine should not be used in combination with or within a minimum of 14 days of discontinuing therapy with an MAOI. Concurrent use may result in hypertensive crisis due to depletion of monoamines (dopamine, serotonin, norepinephrine, and histamine) from nerve terminals.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Deutetrabenazine	Isocarboxazio	k
	Phenelzine	
	Tranylcyprom	line
	Linezolid	
	Selegiline	
	Rasagiline	
References:	5	

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

18. Deutetrabenazine / Reserpine

Alert Message: Concurrent use of Austedo (deutetrabenazine) with reserpine is contraindicated due to the potential for significant depletion of serotonin and norepinephrine in the CNS. At least 20 days should elapse after stopping reserpine before starting deutetrabenazine.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases Util A Util B Util C Deutetrabenazine Reserpine

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

19. Deutetrabenazine / Tetrabenazine

Alert Message: Concurrent use of Austedo (deutetrabenazine) with tetrabenazine is contraindicated. Deutetrabenazine therapy may be initiated the day following discontinuation of tetrabenazine. Both deutetrabenazine and tetrabenazine are VMAT2 inhibitors and concomitant use may cause synergistic or additive toxicity.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Deutetrabenazine

References: Facts & Comparisons, 2017 U

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

20. Deutetrabenazine / Strong CYP2D6 Inhibitor

Alert Message: The concurrent use of Austedo (deutetrabenazine) with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine, and quinidine) may markedly increase the exposure to the active metabolites of deutetrabenazine (approximately 3-fold). The total dose of deutetrabenazine should not exceed 36 mg per day in these patients. The maximum single dose should not exceed 18 mg.

Conflict Code: HD – High Dose Drugs/Diseases <u>Util A</u><u>Util B</u> Deutetrabenazine

Util C (Include) Paroxetine Fluoxetine Quinidine Bupropion

Max Dose: 36 mg/day

References: Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

21. Deutetrabenazine / CNS Depressants

Alert Message: The concurrent use of Austedo (deutetrabenazine) with CNS depressants including alcohol may have additive effects and worsen sedation and somnolence.

 Conflict Code: DD – Drug/Drug Interaction

 Drugs/Diseases

 Util A

 Deutetrabenazine

 Sedatives/Hypnotics

 Benzodiazepines

 Narcotics

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

22. Deutetrabenazine / Dopamine Antagonists

Alert Message: The concurrent use of Austedo (deutetrabenazine), a dopamine depleting agent, with dopamine antagonists may result in increased risk for parkinsonism, NMS, and akathisia.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Deutetrabenazine Antipsychotics Metoclopramide Amoxapine

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

23. Deutetrabenazine / QTc Prolongation, Arrhythmias, Bradycardia Hypokalemia & Hypomagnesemia

Alert Message: Austedo (deutetrabenazine) use should be avoided in patients with congenital long QT syndrome, cardiac arrhythmias, or history of hypokalemia or hypomagnesemia. At 24 mg, deutetrabenazine has been shown to cause an approximate 4.5 msec mean increase in the QTc.

Conflict Code: MC - Drug (Actual) Disease Warning

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Deutetrabenazine	Long QT Syndrome	
	Arrhythmias	
	Bradycardia	
	Hypokalemia	
	Hypomagnesemia	

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

24. Deutetrabenazine / Overutilization

Alert Message: The manufacturer's recommended maximum total daily dose of Austedo (deutetrabenazine) is 48 mg (24 mg twice daily). The maximum daily dose in patients who are poor CYP2D6 metabolizers is 36 mg (18 mg twice daily). Administer total daily dosages of 12 mg or above in two divided doses.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Negate)
Deutetrabenazine		Paroxetine
		Fluoxetine
		Quinidine
		Bupropion
Mary Danas 40 mar/d		• •

Max Dose: 48 mg/day

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

25. Deutetrabenazine / Medications Causing QT Prolongation

Alert Message: The concurrent use of Austedo (deutetrabenazine) with medications that are known to prolong QTc should be avoided. At 24 mg, deutetrabenazine has been shown to cause an approximate 4.5 msec mean increase in the QTc.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases					
<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Deutetrabenazin	e Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ
	Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil
	Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroguine	Fluconazole	Mozifloxacin	Salmeterol	LZOYADINE
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	
	Ciprofloxacin		Nilotinib	Sertraline	
		Foscarnet			
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Terbutaline	
	Diphenhydramine	lloperidone	Paroxetine	Apomorphine	

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

26. Valbenazine / Overutilization

Alert Message: Ingrezza (valbenazine) may be over-utilized. The manufacturer's recommended maximum daily dose of valbenazine is 80 mg once daily.

Conflict Code: EF Drugs/Diseases	R - Overutilization		
<u>Util A</u>	<u>Util B</u>	Util C (Negating)	
Valbenazine		Hepatic Impairment	Saquinavir
		Nefazodone	Ritonavir
		Clarithromycin	Indinavir
		Quinidine	Nelfinavir
		Ketoconazole	Cobicistat
		Itraconazole	Bupropion
		Voriconazole	Fluoxetine
		Posaconazole	Paroxetine

Max Dose: 80 mg/day

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

27. Valbenazine / Overutilization – Hepatic Impairment

Alert Message: Ingrezza (valbenazine) may be over-utilized. The manufacturer's recommended maximum daily dose of valbenazine in patients with moderate to severe hepatic impairment (Child Pugh score 7 to 15) is 40 mg once daily.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Valbenazine
 Hepatic Impairment

Max Dose: 40 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

28. Valbenazine / Severe Renal Impairment

Alert Message: Ingrezza (valbenazine) use is not recommended in patients with severe renal impairment (CrCl < 30 mL/min). Dosage adjustment is not necessary for patients with mild to moderate renal impairment (CrCl 30 to 90 mL/min).

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases

Util AUtil BUtil C (Include)ValbenazineCKD Stage 4, 5, & ESRD

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

29. Valbenazine / CYP3A4 Inducers

Alert Message: Concurrent use of Ingrezza (valbenazine) with strong CYP3A4 inducers is not recommended. Valbenazine is a CYP3A4 substrate and co-administration with a strong CYP3A4 inducer may result in decreased exposure to valbenazine and its active metabolite reducing efficacy.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Valbenazine	Carbamazepine	Rifampin	
	Phenytoin	Rifabutin	
	Phenobarbital	Rifapentine	
	Primidone	Enzalutamide	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

30. Valbenazine / MAO Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a VMAT2 inhibitor, with a MAO inhibitor should be avoided. Co-administration of these agents may result in increased concentrations of monoamine neurotransmitters in synapses, potentially leading to increased risk of adverse reactions such as serotonin syndrome or attenuated treatment effect of valbenazine.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases Util A Util B Util C Valbenazine Isocarboxazid Phenelzine Tranylcypromine Selegiline Linezolid Rasagiline

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

31. Valbenazine / Strong CYP3A4 Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in increased exposure to valbenazine and its active metabolite. Concomitant use may put the patient at risk for valbenazine exposure-related adverse reactions. The manufacturer recommends reducing the dose of valbenazine to 40 mg once daily when valbenazine is co-administered with a strong CYP3A4 inhibitor.

Conflict Code: ER - Overutilization

Util A	Util B	Util C (Include)	
Valbenazine	<u>••••</u>	Nefazodone	Saquinavir
		Clarithromycin	Ritonavir
		Ketoconazole	Indinavir
		Itraconazole	Nelfinavir
		Voriconazole	Cobicistat
		Posaconazole	
May Dose: 40 mg	veb/r		

Max Dose: 40 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

32. Valbenazine / Strong CYP2D6 Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a CYP2D6 substrate, with a strong CYP2D6 inhibitor may result in increased exposure to valbenazine and its active metabolite. Concomitant use may put the patient at risk for valbenazine exposure-related adverse reactions. Consider reducing the valbenazine dose based on tolerability when valbenazine is co-administered with a strong CYP2D6 inhibitor.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Valbenazine	Bupropion	
	Paroxetine	
	Fluoxetine	
	Quinidine	

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

33. Valbenazine / Digoxin

Alert Message: Concurrent use of Ingrezza (valbenazine) with digoxin, a P-gp substrate, may result in increased digoxin levels due to inhibition, by valbenazine, of digoxin P-gp mediated transport. Digoxin concentrations should be monitored when co-administering these agents. Dosage adjustment of digoxin may be necessary.

Conflict Code: DD – Drug/Drug InteractionDrugs/DiseasesUtil AUtil BUtil CValbenazineDigoxin

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

34. Valbenazine / QT Prolongation, Arrhythmias, Bradycardia Alert Message: Ingrezza (valbenazine) use should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases Util A Util B Util C (Include)

Valbenazine	Long QT Syndrome
	Arrhythmias

References:

Facts & Comparisons, 2017 Updates, Wolters Kluwer Health. Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

35. Valbenazine / Pregnancy / Pregnancy Negating

Alert Message: The limited available data on Ingrezza (valbenazine) use in pregnant women is insufficient to inform a drug-associated risk. In animal studies no malformations were observed when valbenazine was administered to rats and rabbits during the period of organogenesis at doses up to 24 times the maximum recommended human dose. However, administration of valbenazine to pregnant rats during organogenesis through lactation produced an increase in the number of stillborn pups and postnatal pup mortalities. Advise pregnant females of potential risk to fetus.

Conflict Code: MC – Drug (Actual) Disease Warning Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	Util C (Negating)
Valbenazine	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female Age Range: 11 – 55 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

36. Valbenazine / Medications Causing QT Prolongation

Alert Message: The concurrent use of Ingrezza (valbenazine) with medications that are known to prolong QTc should be avoided. Valbenazine may cause an increase in the QT interval and use with other agents that also prolong the interval may have an additive effect.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases					
Util A	Util B				<u>Util C</u>
Valbenazine	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ
	Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil
	Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Apomorphine
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Telotristat
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Terbutaline	
	Diphenhydramine	lloperidone	Paroxetine	Deutetrabenazine	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

37. Valbenazine / Lactation & Disorders of Lactation

Alert Message: There is no information regarding the presence of Ingrezza (valbenazine) or its active metabolites in human milk. Valbenazine and its metabolites have been detected in rat milk. Based on animal findings of increased perinatal mortality in exposed fetuses and pups, advise a woman to not breastfeed during treatment with valbenazine and for 5 days after the final dose.

 Conflict Code: MC – Drug (Actual) Disease Warning

 Drugs/Diseases

 Util A
 Util B

 Valbenazine
 Lactation

 Disorder of Lactation

Gender: Female Age Range: 11 – 55 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

38. Itraconazole Caps / Avanafil

Alert Message: Stendra (avanafil) is contraindicated for use during and for 2 weeks after itraconazole therapy. Co-administration of avanafil with itraconazole can result in elevated avanafil plasma concentrations and may increase or prolong the pharmacologic effects and adverse reactions to avanafil.

Util C

Conflict Code: DD – Drug/Drug Interactions Drugs/Diseases <u>Util A</u><u>Util B</u> Itraconazole CapsAvanafil

References:

Sporanox Prescribing Information, October 2017, Janssen Pharmaceutical Companies. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

39. Cobimetinib / Overutilization

Alert Message: The manufacturer's recommended dose of Cotellic (cobimetinib) is 60 mg orally once daily for the first 21 days of each 28-day cycle.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Cobimetinib

Max Dose: 60 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotellic Prescribing Information, May 2016, Genentech.

40. Cobimetinib / Therapeutic Appropriateness

Alert Message: Cotellic (cobimetinib) can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with cobimetinib and for 2 weeks following the final dose of cobimetinib.

 Conflict Code: TA - Therapeutic Appropriateness

 Drugs/Diseases

 <u>Util A</u>

 <u>Util B</u>

 Cobimetinib

Gender: Female Age Range: 11 - 50 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotellic Prescribing Information, May 2016, Genentech.

41. Cobimetinib / Overutilization

Alert Message: The safety and effectiveness of Cotellic (cobimetinib) have not been established in pediatric patients.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Cobimetinib

Age Range: ≥ 18 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotellic Prescribing Information, May 2016, Genentech.

42. Cobimetinib / Moderate to Strong CYP3A Inhibitors

Alert Message: Concurrent use of Cotellic (cobimetinib) with strong or moderate CYP3A inhibitors should be avoided. If concurrent short term (14 days or less) use of moderate CYP3A inhibitors including certain antibiotics is unavoidable for patients who are taking cobimetinib 60 mg, reduce cobimetinib dose to 20 mg. After discontinuation of a moderate CYP3A inhibitor, resume cobimetinib at the previous dose. Use an alternative to a strong or moderate CYP3A inhibitor in patients who are taking a reduced dose of cobimetinib.

Conflict Code: DD - Drug/Drug interaction

Drugs/Diseases				
<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Cobimetinib	Nefazodone	Atazanavir	Fluconazole	
	Clarithromycin	Darunavir	Cimetidine	
	Saquinavir	Tipranavir	Cyclosporine	
	Ritonavir	Ciprofloxacin	Erythromycin	
	Nelfinavir	Aprepitant	Idelalisib	
	Indinavir	Diltiazem	Fosamprenavir	
	Cobicistat	Verapamil	Clotrimazole	
	Ketoconazole	Imatinib		
	Itraconazole	Crizotinib		
	Voriconazole	Fluvoxamine		
	Posaconazole	Dronedarone		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotellic Prescribing Information, May 2016, Genentech.

43. Cobimetinib / Moderate to Strong CYP3A Inducers

Alert Message: Concurrent use of Cotellic (cobimetinib) with strong or moderate CYP3A inducers should be avoided. Co-administration of cobimetinib with a strong CYP3A inducer may decrease cobimetinib systemic exposure by more than 80% and reduce its efficacy.

Conflict Code: DD – Drug/Drug interaction			
Drugs/Diseases			
Util A	Util B		
Cobimetinib	Carbamazepine	Modafinil	
	Phenytoin	Bosentan	
	Phenobarbital	Efavirenz	
	Primidone	Etravirine	
	Rifabutin	Mitotane	
	Rifampin	Bexarotene	
	Rifapentine	Dabrafenib	
	Enzalutamide		
Poforoncos:			

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotellic Prescribing Information, May 2016, Genentech. Util C

44. Rucaparib / Overutilization

Alert Message: The manufacturer's recommended dose of Rubraca (rucaparib) is 600 mg taken orally twice daily.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A Util B</u> <u>Util C</u> Rucaparib

Max Dose: 1200 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rubraca Prescribing Information, Feb. 2017, Clovis Oncology, Inc.

45. Rucaparib / Therapeutic Appropriateness

Alert Message: Rubraca (rucaparib) can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the final dose of rucaparib. Pregnancy testing is recommended for females of reproductive potential prior to initiating rucaparib.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Rucaparib

Age Range: 11 - 50 yoa Gender: Female

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rubraca Prescribing Information, Feb. 2017, Clovis Oncology, Inc.

46. Rucaparib / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Rubraca (rucaparib) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Rubraca

Age Range: ≥ 18 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Rubraca Prescribing Information, Feb. 2017, Clovis Oncology, Inc.

47. Deflazacort / Therapeutic Appropriateness 0 – 4 yoa

Alert Message: The safety and effectiveness of Emflaza (deflazacort) for the treatment of Duchenne Muscular Dystrophy (DMD) in patients less than 5 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A Util B Util C</u> Deflazacort

Age Range: 0 – 4 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Emflaza Prescribing Information, Feb. 2017, Marathon Pharmaceuticals, LLC.

48. Deflazacort / Moderate to Strong CYP3A4 Inhibitors

Alert Message: Concurrent use of Emflaza (deflazacort), a CYP3A4 substrate, with a moderate or strong CYP3A4 inhibitor may result in increased total exposure to the active metabolite of deflazacort, 21-desDFZ. Therefore, give one third the recommended dosage of deflazacort when deflazacort is co-administered with moderate or strong CYP3A4 inhibitors.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases				
Util A	Util B			Util C
Deflazacort	Nefazodone	Atazanavir	Fluconazole	
	Clarithromycin	Darunavir	Cimetidine	
	Saquinavir	Tipranavir	Cyclosporine	
	Ritonavir	Ciprofloxacin	Erythromycin	
	Nelfinavir	Aprepitant	Idelalisib	
	Indinavir	Diltiazem	Fosamprenavir	
	Cobicistat	Verapamil	Clotrimazole	
	Ketoconazole	Imatinib		
	Itraconazole	Crizotinib		
	Voriconazole	Fluvoxamine		
	Posaconazole	Dronedarone		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Emflaza Prescribing Information, Feb. 2017, Marathon Pharmaceuticals, LLC.

49. Deflazacort / Moderate to Strong CYP3A4 Inducers

Alert Message: Concurrent use of Emflaza (deflazacort) with a moderate to strong CYP3A4 inducer should be avoided. Deflazacort is a CYP3A4 substrate and concurrent use with a CYP3A4 inducer may significantly decrease the exposure of the active metabolite 21-desDFZ and reduce deflazacort efficacy.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Deflazacort	Carbamazepine	Modafinil	
	Phenytoin	Bosentan	
	Phenobarbital	Efavirenz	
	Primidone	Etravirine	
	Rifabutin	Mitotane	
	Rifampin	Bexarotene	
	Rifapentine	Dabrafenib	
	Enzalutamide		

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Emflaza Prescribing Information, Feb. 2017, Marathon Pharmaceuticals, LLC.

50. Deflazacort / Behavioral & Mood Disturbances

Alert Message: Potentially severe psychiatric adverse reactions may occur with systemic corticosteroids, including Emflaza (deflazacort). Symptoms typically emerge within a few days or weeks of starting treatment and may be dose-related. These reactions may improve after either dose reduction or withdrawal, although pharmacologic treatment may be necessary. Inform patient or caregivers of the potential for behavioral and mood changes and encourage them to seek medical attention if psychiatric symptoms develop, especially if depressed mood or suicidal ideation is suspected.

Conflict Code: MC - Drug (Actual) Disease Precaution/Warning

<u>Util B</u>	<u>Util C</u>
Insomnia	
Unspecified Mood Disorder	
Depression	
Mania	
Irritability	
Anxiety	
Suicidal Ideation	
Amnesia	
Hallucinations	
	Insomnia Unspecified Mood Disorder Depression Mania Irritability Anxiety Suicidal Ideation Amnesia

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Emflaza Prescribing Information, Feb. 2017, Marathon Pharmaceuticals, LLC.

51. Diphenoxylate/Atropine / Therapeutic Appropriateness

Alert Message: Diphenoxylate/atropine is contraindicated in pediatric patients less than 6 years of age due to the risk of respiratory and central nervous system (CNS) depression. Cases of severe respiratory depression and coma, leading to permanent brain damage or death have been reported in patients less than 6 years of age who have received diphenoxylate/atropine.

 Conflict Code: TA - Therapeutic Appropriateness

 Drugs/Diseases

 Util A

 Util B

 Diphenoxylate/Atropine

Age Range: < 6 yoa

References: Lomotil Prescribing Information, October 2017, Pfizer.

52. Diphenoxylate/Atropine / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of diphenoxylate/atropine have not been established in patients less than 13 years of age.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Diphenoxylate/Atropine

Age Range: 6 - 12 yoa

References: Lomotil Prescribing Information, October 2017, Pfizer. Facts & Comparisons, 2017 Wolters Kluwer Health.

53. Diphenoxylate/Atropine / Obstructive Jaundice

Alert Message: Diphenoxylate/atropine is contraindicated in patients with obstructive jaundice.

 Conflict Code: MC – Drug (Actual) Disease Warning/Contraindication

 Drugs/Diseases

 Util A

 Diphenoxylate/Atropine

 Util B

 Util C

 Diphenoxylate/Atropine

References:

Lomotil Prescribing Information, October 2017, Pfizer. Facts & Comparisons, 2017 Wolters Kluwer Health.

54. Dexlansoprazole / Hepatic Impairment

Alert Message: The maximum recommended dosage of Dexilant (dexlansoprazole) in patients with moderate hepatic impairment (Child-Pugh Class B) is 30 mg per day. In a study patients with moderate hepatic impairment who received a single dose of dexlansoprazole, exhibited approximately two times greater systemic exposure (AUC) compared to healthy subjects with normal hepatic function. Dexlansoprazole use is not recommended in patients with severe hepatic impairment. No dosage adjustment is necessary for mild hepatic impairment.

Conflict Code: ER – Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Dexlansoprazole

<u>Util C **(Include**)</u> Hepatic Impairment

Max Dose: 30 mg/day

References:

Dexliant Prescribing Information, October 2017, Takeda Pharmaceuticals America, Inc. Clinical Pharmacology, 2017 Elsevier/Gold Standard.

55. Clindamycin / Strong CYP3A4 & CYP3A5 Inhibitors

Alert Message: Concurrent use of clindamycin a CYP3A4/5 substrate, with a strong CYP3A4 or CYP3A5 inhibitor may result in increased clindamycin plasma concentrations. Monitor patient for clindamycin-related adverse events when co-administering clindamycin with strong 3A4/5 inhibitors.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Clindamycin	Nefazodone	Saquinavir	
	Clarithromycin	Ritonavir	
	Posaconazole	Indinavir	
	Ketoconazole	Nelfinavir	
	Itraconazole	Idelalisib	
	Voriconazole	Cobicistat	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cleocin Prescribing Information, May 2017, Pfizer US.

56. Clindamycin / Strong CYP3A4 & CYP3A5 Inducers

Alert Message: Concurrent use of clindamycin, a CYP3A4/5 substrate, with a strong CYP3A4 or CYP3A5 inducer may result in decreased clindamycin plasma concentrations. Monitor patient for loss of clindamycin efficacy.

Conflict Code: DD - Drug/Drug Interaction Drugs/Diseases Util A Util B Phenytoin Clindamycin Rifampin Phenobarbital Rifapentine

Util C

Primidone Rifabutin Carbamazepine Enzalutamide

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cleocin Prescribing Information, May 2017, Pfizer US.

57. Codeine / CYP2D6 Inhibitors

Alert Message: Concurrent use of a codeine-containing agent with a CYP2D6 inhibitor may result in a decrease in the effects of codeine. Codeine must be bioactivated via CYP2D6 to morphine to exert an analgesic effect. Consider the use of an alternative analgesic for patients requiring therapy with an agent that is a CYP2D6 inhibitor.

Conflict Code: DD - Drug/Drug Interaction

<u>Util B</u>		<u>Util C</u>
Fluoxetine Paroxetine	Propafenone Quinidine	
Bupropion	Terbinafine	
	Fluoxetine Paroxetine	Fluoxetine Propafenone Paroxetine Quinidine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

58. NNRTIs & Enfuvirtide / HIV-2

Alert Message: A review of the patient's records reveals that the patient has a diagnosis of HIV-2 and is receiving an NNRTI. HIV-2 is intrinsically resistant to non-nucleoside reverse transcriptase inhibitors (NNRITs) and to enfuvirtide thus these drugs should not be included in an antiretroviral regimen for an HIV-2 infected patient.

Conflict Code: TA – Therapeutic Appropriateness Druge/Dispasos

Diugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Include)
Delavirdine		HIV-2
Efavirenz		
Etravirine		
Nevirapine		
Rilpivirine		

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. July 14, 2016. Available at: http://www.aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf.

Panel on Treatment of HIV-infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. October 26, 2016. Available at:

http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf

59. NNRTIs & Enfuvirtide / HIV-2

Alert Message: A review of the patient's records reveals that the patient has a diagnosis of HIV-2 and is receiving enfuvirtide. HIV-2 is intrinsically resistant to enfuvirtide and to non-nucleoside reverse transcriptase inhibitors (NNRTIs) thus these drugs should not be included in an antiretroviral regimen for an HIV-2 infected patient.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Include)
Enfuvirtide		HIV-2

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. July 14, 2016. Available at: http://www.aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf.

Panel on Treatment of HIV-infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. October 26, 2016. Available at: http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf

60. Voriconazole / Ergot Alkaloids

Alert Message: Concurrent use of Vfend (voriconazole) with ergot alkaloids is contraindicated due to the risk of ergotism. Voriconazole is a strong CYP3A4 inhibitor and co-administration with an ergot alkaloid which is a CYP3A4 substrate can result in elevated substrate concentrations.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Voriconazole	Ergotamine	
	Dihydroergotamine	
	Methylergonovine	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

61. Voriconazole / Vinca Alkaloids

Alert Message: Concurrent use of Vfend (voriconazole) with vinca alkaloids should be avoided due to the risk if increased vinca alkaloid plasm concentrations which may lead to vinca alkaloid-related neurotoxicity. Voriconazole is a strong CYP3A4 inhibitor and co-administration with a vinca alkaloid which is a CYP3A4 substrate can result in elevated substrate concentrations.

Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases <u>Util A</u> <u>Util B</u> <u>Util C</u> Voriconazole Vincristine Vinblastine Vinorelbine

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

62. Voriconazole / Atazanavir / Ritonavir

Alert Message: The use of Vfend (voriconazole) in patients receiving atazanavir/rtv is not recommended unless an assessment of the benefit/risk to the patient justified the use of voriconazole. If concomitant therapy cannot be avoided patients should be carefully monitored for voriconazole associated adverse reactions and loss of either voriconazole or atazanavir efficacy. Co-administration of voriconazole with atazanavir (without ritonavir) may affect atazanavir concentrations; however, do data are available.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	Util C (Include)
Voriconazole	Atazanavir	Ritonavir

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health.

63. Selexipag / CYP2C8 Inhibitors

Alert Message: Concurrent use of Uptravi (selexipag), a CYP2C8 substrate, with a moderate CYP2C8 inhibitor can be expected to increase exposure to the active metabolite of selexipag. Consider a less frequent dosing regimen, e.g., once daily, when initiating selexipag in patients on a CYP2C8 inhibitor. Reduce selexipag dose when a moderate CYP2C8 inhibitor is initiated.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Selexipag	Teriflunomide	
	Deferasirox	
	Lapatinib	
	Nilotinib	

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Facts & Comparisons, 2017 Wolters Kluwer Health. Uptravi Prescribing Information, July 2017, Actelion Pharmaceuticals US, Inc.

64. Methylphenidate XR-ODT / Overutilization

Alert Message: The manufacturer's recommended maximum total daily dose of Cotempla XR-ODT (methylphenidate extended-release orally disintegrating) is 51.8 mg. Daily doses above 51.8 mg are not recommended.

 Conflict Code: ER - Overutilization

 Drugs/Diseases

 Util A
 Util B

 Methylphenidate XR-ODT

Max Dose: 51.8 mg/day

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Cotempla XR-ODT Prescribing Information, June 2017, Neos Therapeutics, Inc.

65. Dextroamphetamine/amphetamine ER Caps / Overutilization

Alert Message: The manufacturer's recommended maximum total daily dose of Mydayis (dextroamphetamine/amphetamine), in adult patients, is 50 mg.

Util B

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u> Dextroamphetamine/amphetamine ER caps

<u>Util C (Negate)</u> CKD Stage 4 & 5

Max Dose: 50 mg/day Age Range: ≥ 18 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

66. Dextroamphetamine/amphetamine ER Caps /Severe Renal Impairment

Alert Message: The manufacturer's recommended maximum total daily dose of Mydayis (dextroamphetamine/amphetamine), in adult patients with severe renal impairment (GFR 15 to < 30 ml/min/1.73m2), is 25 mg. Dextroamphetamine/amphetamine extended-release is not recommended for use in patients with end stage renal disease (ESRD < 15 ml/min/1.73m2).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u> <u>Util B</u> Dextroamphetamine/amphetamine ER caps

Util C (Include) CKD Stage 4 & 5

Max Dose: 25 mg/day Age Range: ≥ 18 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

67. Dextroamphetamine/amphetamine ER Caps / ESRD

Alert Message: Mydayis (dextroamphetamine/amphetamine) is not recommended for use in patients with end stage renal disease (ESRD < 15 ml/min/1.73m2).

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases Util A Util B

Dextroamphetamine/amphetamine ER caps

Util C (Include) ESRD

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

68. Dextroamphetamine/amphetamine ER Caps / Overutilization

Alert Message: The manufacturer's recommended maximum total daily dose of Mydayis (dextroamphetamine/amphetamine), in pediatric patients 13 to 17 years of age, is 25 mg.

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u><u>Util B</u> Dextroamphetamine/amphetamine ER caps

Util C (Negate) CKD Stage 4 & 5

Max Dose: 25 mg/day Age Range: 13 - 17 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

69. Dextroamphetamine/amphetamine ER Caps / Severe Renal Impairment

Alert Message: The manufacturer's recommended maximum total daily dose of Mydayis (dextroamphetamine/amphetamine), in pediatric patients 13 to 17 years of age with severe renal impairment (GFR 15 to < 30 ml/min/1.73m2), is 12.5mg. Dextroamphetamine/amphetamine extended-release is not recommended for use in patients with end stage renal disease (ESRD < 15 ml/min/1.73m2).

Conflict Code: ER - Overutilization Drugs/Diseases <u>Util A</u> <u>Util B</u> Dextroamphetamine/amphetamine ER caps

<u>Util C (Include)</u> CKD Stage 4 & 5

Util C

Max Dose: 12.5 mg/day Age Range: 13 - 17 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

70. Dextroamphetamine/amphetamine ER Caps / Severe Renal Impairment Alert Message: The safety and effectiveness of Mydayis (dextroamphetamine/amphetamine) have not been established in pediatric patients 12 years of age and younger.

Conflict Code: TA – Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u> Dextroamphetamine/amphetamine ER caps

Age Range: 0 -12 yoa

References: Clinical Pharmacology, 2017 Elsevier/Gold Standard. Mydayis Prescribing Information, June 2017, Shire US, Inc.

71. AirDuo Respiclick / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of AirDuo Respiclick (fluticasone) in pediatric patients below the age of 12 years have not been established.

Conflict Code: TA - Therapeutic Appropriateness Drugs/Diseases <u>Util A</u><u>Util B</u><u>Util C</u> Fluticasone Inhalation Powder

References: AirDuo Prescribing Information, Jan. 2017, Teva Respiratory, LLC. Clinical Pharmacology, 2017 Elsevier Gold Standard.

NORTH DAKOTA DEPARTMENT OF HUMAN SERVICES NORTH DAKOTA MEDICAID PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

EFFECTIVE 01/01/2018 Version 2018.1

This is NOT an all-inclusive list of covered medications or medications that require prior authorization. Only PDL managed categories are included. Refer to cover page for complete list of rules governing this PDL. Visit http://www.hidesigns.com/ndmedicaid for more information on medications not found in this list.

- Prior authorization for a non-preferred agent with a preferred brand/generic equivalent in any category will be given only if DAW criteria is met in addition to clinical criteria and step therapy specific to that category.
- Prior authorization criteria applies in addition to the general Drug Utilization Review policy that is in effect for the entire pharmacy program, including, but not limited to, appropriate dosing, duplication of therapy, etc. Refer to <u>http://www.hidesigns.com/ndmedicaid</u> for applicable quantity limits and therapeutic duplication edits.
- Unless otherwise specified, the listing of a particular brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.
- The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
- This is NOT an all-inclusive list of medications covered by ND Medicaid. Please use the NDC Drug Lookup tool at
 http://nddruglookup.hidinc.com/ to view coverage status, quantity limits, copay, and prior authorization information for
 all medications.
- This is NOT an all-inclusive list of medications that require prior authorization. Please visit <u>http://www.hidesigns.com/ndmedicaid/pa-criteria.html</u> for PA criteria for medications not found on the PDL.
- This PDL is subject to change. Preferred positions and criteria will go into effect when an SRA is executed.
- Acronyms

PA – Indicates preferred agents that require clinical prior authorization.

*** - Indicates that additional PA criteria applies as indicated in the sidebar

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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CHANGES SINCE LAST VERSION		
Category	Product Status Changes	Criteria Changes
ADHD AGENTS	Dextroamphetamine 5 mg/5 ml moved to non-preferred	
ALLERGENIC EXTRACTS		removed as a PDL category
ANALGESICS - NSAIDS - TOPICAL		New PDL Category
TESTOSTERONE TOPICAL	ANDRODERM (testosterone) moved to preferred	Category name changed to ANDROGENS
ANTIHEMOPHILIC FACTORS		removed as a PDL category
COPD - Long Acting Anticholinergics		Spiriva Respimat criteria added
COPD		Category PA Criteria changes
COPD -Combination Anticholinergics/Long Acting Beta Agonists	BEVESPI AEROSPHERE (glycopyrrolate/formoterol) moved to preferred	
COPD -Combination Anticholinergics/Long Acting Beta Agonists	COMBIVENT RESPIMAT (albuterol/ipratropium) moved to non- preferred	Short and Long acting agents combined into one group. Group PA criteria updated
COPD -Combination Anticholinergics/Long Acting Beta Agonists	STIOLTO RESPIMAT (tiotropium/olodaterol moved to non- preferred	
CYSTIC FIBROSIS ANTIINFECTIVES		Category name changed to CYSTIC FIBROSIS INHALED ANTIBIOTICS
DIABETES - DPP4 INHIBITORS		ONGLYZA (saxagliptan) criteria removed
DIABETES - GLP1 AGONISTS	TANZEUM (albiglutide) moved to non- preferred	
DIABETES - GLP1 AGONISTS		Victoza Criteria removed, Category PA Criteria Updated
DIABETES - INSULIN		Category added to PDL
DIABETES - INSULIN	/	Individual insulin criteria updated
DIABETES - INSULIN/GLP1 AGONISTS		New PDL Category

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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CHANGES SINCE LAST VERSION		
Category	Product Status Changes	Criteria Changes
DIABETES - SGLT2 INHIBITORS	INVOKAMET XR (canagliflozin/metformin) moved to non-preferred	
DIABETES - SGLT2 INHIBITORS	SYNJARDY XR (empagliflozin/metformin) moved to preferred	
DIARRHEA - IRRITABLE BOWEL SYNDROME	LOTRONEX (alosetron) moved to preferred	
FIBROMYALGIA		removed as a PDL category
GOUT - COLCHICINE		removed as a PDL category
HEMATOPOIETIC, COLONY STIMULATING FACTORS		New PDL Category
HEMATOPOIETIC, GROWTH FACTOR		Category name changed to HEMATOPOIETIC, ERYTHROPOIESIS STIMULATING AGENTS
LICE	permethrin liquid removed from preferred	
MULTIPLE SCLEROSIS	REBIF (interferon beta-1A) moved to non-preferred	
MULTIPLE SCLEROSIS	REBIF REBIDOSE (interferon beta- 1A) moved to non-preferred	
GLAUCOMA - SYMPATHOMIMETICS		Category name changed to OPHTHALMIC ALPHA ADRENERGICS - GLAUCOMA
OPHTHALMIC ANTIHISTAMINES	EMADINE (emedastine) moved to non-preferred	
OPHTHALMIC ANTIHISTAMINES	Epinastine moved to preferred	
OPHTHALMIC ANTIHISTAMINES	PATADAY 0.2% (olopatadine) moved to preferred	
OPHTHALMIC ANTIINFECTIVES	Bacitracin ointment moved to non- preferred	

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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CHANGES SINCE LAST VERSION			
Category	Product Status Changes	Criteria Changes	
OPHTHALMIC ANTIINFECTIVES	Sulfacetamide ointment moved to non-preferred		
OPHTHALMIC ANTIINFECTIVES	VIGAMOX (moxifloxacin) DROPS moved to non-preferred		
OPHTHALMIC ANTIINFECTIVES/ANTIINFLAMMATORIES	BLEPHAMIDE (sulfacetamide/prednisolone) DROPS moved to preferred		
OPHTHALMIC ANTIINFECTIVES/ANTIINFLAMMATORIES	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS moved to non-preferred		
OPHTHALMIC ANTIINFLAMMATORIES	Bromfenac sodium & BROMSITE (bromfenac sodium) moved to non- preferred		
OPHTHALMIC ANTIINFLAMMATORIES	DUREZOL (difluprednate) moved to non-preferred		
OPHTHALMIC ANTIINFLAMMATORIES	ketorolac tromethamine 0.4% moved to preferred		
OPHTHALMIC ANTIINFLAMMATORIES	Ketorolac tromethamine 0.5% moved to preferred		
OPHTHALMIC ANTIINFLAMMATORIES	LOTEMAX (loteprednol) DROPS moved to preferred		
OPHTHALMIC ANTIINFLAMMATORIES	LOTEMAX (loteprednol) OINTMENT moved to non-preferred		
OPHTHALMIC ANTIINFLAMMATORIES	NEVANAC (nepafenac) moved to non-preferred		
OPHTHALMIC ANTIINFLAMMATORIES	Prednisolone acetate 1% moved to non-preferred		
OPHTHALMIC ANTIINFLAMMATORIES	Prednisolone sodium phosphate 1% moved to preferred		
OPHTHALMIC ANTIINFLAMMATORIES	PROLENSA (bromfenac) moved to non-preferred		

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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CHANGES SINCE LAST VERSION		
Category	Product Status Changes	Criteria Changes
OPHTHALMIC IMMUNOMODULATORS - DRY EYE SYNDROME		New PDL Category
OPIOID ANALGESIC - LONG ACTING	Tramadol ER moved to non-preferred	Category and PA criteria updated
OTIC ANTI-INFECTIVES - FLUOROQUINOLONES	ofloxacin drops - labeler 24208 moved to preferred	Category PA criteria updated
OTIC ANTI-INFECTIVES - FLUOROQUINOLONES	OTOVEL (ciprofloxacin/fluocinolone) moved to preferred	
PHOSPHATE BINDERS	ELIPHOS (calcium acetate) moved to non-preferred	Velphoro criteria removed
PLATELET AGGREGATION INHIBITORS	AGGRENOX (aspirin/dipyridamole) moved to preferred	
PLATELET AGGREGATION INHIBITORS	Aspirin/dipyridamole ER moved to non-preferred	
PLATELET AGGREGATION INHIBITORS	EFFIENT (prasugrel) moved to non- preferred	
PLATELET AGGREGATION INHIBITORS	Prasugrel added to non-preferred	
PULMONARY HYPERTENSION- Prostacyclins	REMODULIN (treprostinil) moved to preferred	
PULMONARY HYPERTENSION-Soluble Guanylate Cyclase Stimulators		Criteria Changes
STEROID/LONG ACTING BETA AGONIST (LABA) COMBINATION INHALERS		AIRDUO RESPICLICK (fluticasone/salmeterol) criteria added
STEROID/LONG ACTING BETA AGONIST (LABA) COMBINATION INHALERS		Category Criteria updated
STEROID INHALERS	AEROSPAN (flunisolide) moved to non-preferred	Category name changed to STEROIDs - INHALED
STEROID INHALERS	budesonide suspension 0.25 mg/2mL added to preferred	
STEROID INHALERS	budesonide suspension 0.5 mg/2mL added to preferred	

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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CHANGES SINCE LAST VERSION			
Category	Product Status Changes	Criteria Changes	
STEROID INHALERS	FLOVENT DISKUS (fluticasone) moved to non-preferred		
STEROID INHALERS	PULMICORT RESPULES (budesonide) 1 mg/2 mL added to preferred		
INFLAMMATORY BOWEL AGENTS (ULCERATIVE COLITIS) - NONSTEROIDAL		Category name changed to ULCERATIVE COLITIS AGENTS - NONSTEROIDAL	
URINARY ANTISPASMODICS		Myrbetriq criteria updated	
PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	ADHD AGENTS	
1 of the exceptions on the PA form is present. Generic non-preferred agents: A 10-day trial of a p of the exceptions on the PA form is present.		uired before a non-preferred agent will be authorized unless ired before a non-preferred agent will be authorized unless 1
ADDERALL XR (dextroamphetamine/amphetamine)	ADDERALL (dextroamphetamine/amphetamine)	*** Kapvay will require a 1-month trial of immediate release clonidine.
ADZENYS XR - ODT (amphetamine)	Clonidine ER	
APTENSIO XR (methylphenidate)	CONCERTA (methylphenidate)	
Atomoxetine	DEXEDRINE (dextroamphetamine)	
Clonidine	Dexmethylphenidate ER	
COTEMPLA XR - ODT (methylphenidate)	Dextroamphetamine 5 mg/5 ml	
DAYTRANA (methylphenidate)	Dextroamphetamine/amphetamine ER - Labelers 00115, 00228, 00555, 66993	
DESOXYN (methamphetamine)	FOCALIN (dexmethylphenidate)	
Dexmethylphenidate	INTUNIV (guanfacine ER)	
Dextroamphetamine	METADATE ER (methylphenidate)	
Dextroamphetamine ER	METHYLIN (methylphenidate) chew tablets	
Dextroamphetamine/amphetamine	METHYLIN (methylphenidate) solution	
Dextroamphetamine/amphetamine ER - Labeler 00781	RITALIN (methylphenidate)	
DYANAVEL XR (amphetamine)	RITALIN LA (methylphenidate LA capsules - 50-50)	
EVEKEO (amphetamine)	STRATTERA (atomoxetine)	
FOCALIN XR (dexmethylphenidate)	ZENZEDI (dextroamphetamine)	
Guanfacine ER		
KAPVAY (clonidine) ^{PA***}		1
Methamphetamine		-

PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
Methylphenidate CD 30-70		
Methylphenidate chew tablet		
Methylphenidate ER capsules 50-50		
Methylphenidate ER tablet		
Methylphenidate LA capsules - 50-50		
Methylphenidate solution		
Methylphenidate tablet		
MYDAYIS (amphetamine/dextroamphetamine)		
PROCENTRA (dextroamphetamine)		
QUILLICHEW ER (methylphenidate)		-
QUILLIVANT XR (methylphenidate)		
VYVANSE (lisdexamfetamine)		
VYVANSE (lisdexamfetamine) CHEW TABLET		
	ANGINA	
RANEXA (ranolazine)		
	ANALGESICS - NSAIDS - TOPICAL	
Category PA Criteria: A 30-day trial of all prefer preferred agents do not work.	red agents will be required before a non-preferred agent v	will be authorized. A medical reason must be provided why
FLECTOR (diclofenac) PATCH	DERMACINRX LEXITRAL (diclofenac/capsicum)	
PENNSAID (diclofenac)	XRYLIX (diclofenac)	
VOLTAREN (diclofenac) GEL	VOPAC MDS (diclofenac)	
	ANDROGENS	
Category PA Criteria: A 30-day trial of all prefermindication.	red agents will be required before a non-preferred agent v	will be authorized. All medications require an FDA-approved
ANDROGEL (testosterone) PACKET 1%PA	AXIRON (testosterone) TOPICAL SOLUTION	
ANDROGEL (testosterone) PACKET 1.62%PA	FORTESTA (testosterone)	
ANDRODERM (testosterone)	NATESTO (testosterone)	
	TESTIM (testosterone)	
	TESTOPEL (testosterone)	
	Testosterone gel	
	Testosterone Gel MD PMP	
	Testosterone topical solution	

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	VOGELXO (testosterone) GEL MD PMP	
	ANTICOAGULANTS - ORAL	
Category PA Criteria: A 30-day trial of all prefe	erred agents will be required before a non-preferred agent	will be authorized. All agents will require an FDA indication.
ELIQUIS (Apixaban) ^{PA}	SAVAYSA (edoxaban)	
PRADAXA (dabigatran) ^{PA}		
XARELTO (rivaroxaban) ^{PA}		
	ANTICONVULSANTS	
1 of the exceptions on the PA form is present. Generic non-preferred agents: A 30-day trial of of the exceptions on the PA form is present.	a pharmaceutically equivalent preferred agent will be requ	ired before a non-preferred agent will be authorized unless 1
APTIOM (eslicarbazepine)	CARBATROL (carbamazepine)	
BANZEL (rufinamide) ORAL SUSPENSION	DEPAKENE (valproic acid) CAPSULE	
BANZEL (rufinamide) TABLET	DEPAKENE (valproic acid) ORAL SOLUTION	
BRIVIACT (brivaracetam)	DEPAKOTE (divalproex sodium) TABLET	
Carbamazepine chewable tablet	DEPAKOTE ER (divalproex sodium)	
Carbamazepine ER capsule	DEPAKOTE SPRINKLE (divalproex sodium)	
Carbamazepine oral suspension	DILANTIN (phenytoin) CHEWABLE TABLET	
Carbamazepine tablet	DILANTIN (phenytoin) ORAL SUSPENSION	
Carbamazepine XR tablet	DILANTIN ER (phenytoin)	
CELONTIN (methsuximide)	EPITOL (carbamazepine)	
Divalproex ER	FELBATOL (felbamate)	
Divalproex sprinkle	FELBATOL (felbamate) ORAL SUSPENSION	
Divalproex tablet	KEPPRA (levetiracetam)	
Ethosuximide capsule	KEPPRA (levetiracetam) ORAL SOLUTION	
Ethosuximide oral solution	KEPPRA XR (levetiracetam)	
Felbamate oral suspension	LAMICTAL (lamotrigine)	
Felbamate tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET	

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
FYCOMPA (perampanel)	LAMICTAL (lamotrigine) DOSE PACK	
FYCOMPA (perampanel) ORAL SUSPENSION	MYSOLINE (primidone)	
Gabapentin capsule	NEURONTIN (gabapentin) CAPSULE	
Gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION	
Gabapentin tablet	NEURONTIN (gabapentin) TABLET	
GABITRIL (tiagabine)	QUDEXY XR (topiramate)	
LAMICTAL ER (lamotrigine) DOSE PACK	TEGRETOL XR (carbamazepine)	
LAMICTAL ODT (lamotrigine)	TEGRETROL (carbamazepine oral suspension)	
LAMICTAL ODT (lamotrigine) DOSE PACK	TOPAMAX (topiramate)	
LAMICTAL XR (lamotrigine)	TOPAMAX (topiramate) SPRINKLE CAPSULE	
Lamotrigine chewable tablet	TRILEPTAL (oxcarbazepine)	
Lamotrigine dose pack	TRILEPTAL (oxcarbazepine) ORAL SUSPENSION	
Lamotrigine ER	ZARONTIN (ethosuximide)	
Lamotrigine ODT	ZARONTIN (ethosuximide) ORAL SOLUTION	
Lamotrigine tablet	ZONEGRAN (zonisamide)	
Levetiracetam ER		
Levetiracetam oral solution		
Levetiracetam tablet		
LYRICA (pregabalin)		
LYRICA (pregabalin) ORAL SOLUTION		
Oxcarbazepine oral solution		
Oxcarbazepine tablet		
OXTELLAR XR (oxcarbazepine)		
PEGANONE (Ethotoin)		
Phenobarbital elixir		
Phenobarbital tablet		
PHENYTEK (phenytoin)		
Phenytoin chewable tablet		
Phenytoin ER capsule		
Phenytoin suspension		
POTIGA (ezogabine)]
Primidone		

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
SABRIL (vigabatrin)		
SABRIL (vigabatrin) POWDER PACK		
SPRITAM (levetiracetam)		
TEGRETOL (carbamazepine)		
Tiagabine		
Topiramate ER		
Topiramate sprinkle capsule		
Topiramate tablet		
TROKENDI XR (topiramate)		
Valproic acid capsule		
Valproic acid oral solution		
VIMPAT (lacosamide)		
VIMPAT (lacosamide) ORAL SOLUTION		
Zonisamide		
ANTIDEMENTIA		

Category PA Criteria: All agents will require an FDA indication for patients younger than 30 years old.

Branded non-preferred agents: A 30-day trial of 2 pharmaceutically preferred agents will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present. A 30-day trial of 2 preferred generics of the same medication will satisfy this requirement.

Generic non-preferred agents: A 30-day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present.

Donepezil	ARICEPT (donepezil)	***Namenda XR – A 30-day trial of memantine IR will be
EXELON (rivastigmine)	Donepezil ODT	required before Namenda XR will be authorized.
EXELON (rivastigmine) PATCH	NAMENDA (memantine)	
Galantamine	NAMZARIC (memantine/donepezil)	
Galantamine ER	RAZADYNE (galantamine)	
Galantamine oral solution	RAZADYNE ER (galantamine)	
Memantine	Rivastigmine patch	
NAMENDA (memantine) ORAL SOLUTION		
NAMENDA XR (memantine)***		
Rivastigmine		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	ANTIDEPRESSANTS - NEW GENERATION	
Category PA Criteria: Branded non-preferred agents: A 30-day trial of 2 pharmaceutically equivalent preferred agents will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present. Generic non-preferred agents: A 30-day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present.		
Bupropion SR tablet	APLENZIN ER (bupropion)	
Bupropion tablet	CELEXA (citalopram)	
Bupropion XL tablet	CYMBALTA (duloxetine)	
Citalopram	Desvenlafaxine ER	
Citalopram oral solution	Desvenlafaxine fumarate ER	
Clomipramine	Desvenlafaxine succinate ER - labelers 00591, 51991, 68180	
Desvenlafaxine succinate ER - labeler 59762	EFFEXOR XR (venlafaxine)	
Duloxetine	FORFIVO XL (bupropion)	
Escitalopram	IRENKA (duloxetine)	
Escitalopram oral solution	KHEDEZLA ER (desvenlafaxine)	
FETZIMA (levomilnacipran)	LEXAPRO (escitalopram)	
Fluoxetine capsule	LEXAPRO (escitalopram) ORAL SOLUTION	
Fluoxetine DR	PAXIL (paroxetine)	
Fluoxetine solution	PAXIL CR (paroxetine)	
Fluoxetine tablet	PRISTIQ ER (desvenlafaxine)	
Fluvoxamine	PROZAC (fluoxetine)	
Fluvoxamine ER	venlafaxine ER tablets	
Nefazodone	WELLBUTRIN (bupropion)	
OLEPTRO ER (trazodone)	WELLBUTRIN SR (bupropion)	
Paroxetine	WELLBUTRIN XL (bupropion)	
Paroxetine ER	ZOLOFT (sertraline)	
PAXIL (paroxetine) ORAL SUSPENSION	ZOLOFT (sertraline) ORAL CONCENTRATE	
PEXEVA (paroxetine)		
Sertraline		

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
Sertraline oral concentrate		
Trazodone		
TRINTELLIX (vortioxetine)		
Venlafaxine ER capsules		
Venlafaxine tablet		
VIIBRYD (vilazodone)		1
ANTIRE	TROVIRALS - NUCLEOSIDE REVERSE TRANSCRIPT	ASE INHIBITORS
Abacavir	EPIVIR (lamivudine)	
Abacavir/lamivudine	EPZICOM (abacavir)	
Abacavir/lamivudine/zidovudine	TRIZIVIR (abacavir/lamivudine)	
ATRIPLA (efavirenz/emtricitabine/tenofovir)	VIDEX EC (didanosine)	
COMBIVIR (lamivudine/zidovudine)	VIREAD (tenofovir)	
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ZERIT (stavudine)	
DESCOVY (emtricitabine/tenofovir)	ZIAGEN (abacavir)	
Didanosine		
EMTRIVA (emtricitabine)		
GENVOYA		
(elvitegravir/cobicistat/emtricitabine/tenofovir)		
Lamivudine		
Lamivudine/zidovudine		
ODEFSEY (emtricitabine/rilpivirine/tenofovir)		
RETROVIR (zidovudine)		
Stavudine		
STRIBILD		
(elvitegravir/cobicistat/emtricitabine/tenofovir)		
Tenofovir		
TRIUMEQ (abacavir/dolutegravir/lamivudine)		
TRUVADA (emtricitabine/tenofovir)		1
VIDEX (didanosine)]
Zidovudine]
	ANTIRETROVIRALS - PROTEASE INHIBITOR	S
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir)	

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
CRIXIVAN (indinavir)		
EVOTAZ (atazanavir/cobicistat)		
GENVOYA (elvitegravir, cobicistat, emtricitabine and tenofovir)		
INVERASE (saquinavir)		
LEXIVA (fosamprenavir)		
lopinavir/ritonavir		
NORVIR (ritonavir)		
PREZCOBIX (darunavir/cobicistat)		
PREZISTA (darunavir)		
RAYATAZ (atazanavir)		
VIRACEPT (nelfinavir)		
ATYPICAL ANTIPSYCHOTICS		

Category PA Criteria:

Branded non-preferred agents: A 30-day trial of 2 pharmaceutically equivalent preferred agents will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present.

Generic non-preferred agents: A 30-day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless 1 of the exceptions on the PA form is present.

ABILIFY (aripiprazole)	
CLOZARIL (clozapine)	
GEODON (ziprasidone)	
INVEGA ER (paliperidone)	
quetiapine ER - labelers 00406, 16729, 49884, 52817	
RISPERDAL (risperidone)	
RISPERDAL (risperidone) ORAL SOLUTION	
RISPERDAL M-TAB (risperidone)	
SEROQUEL (quetiapine)	
SEROQUEL XR (quetiapine)	
ZYPREXA (olanzapine)	
	CLOZARIL (clozapine)GEODON (ziprasidone)INVEGA ER (paliperidone)quetiapine ER - labelers 00406, 16729, 49884, 52817RISPERDAL (risperidone)RISPERDAL (risperidone)RISPERDAL (risperidone) ORAL SOLUTIONRISPERDAL M-TAB (risperidone)SEROQUEL (quetiapine)SEROQUEL XR (quetiapine)

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
Paliperidone ER	ZYPREXA ZYDIS (olanzapine)	
Quetiapine		
quetiapine ER - labeler 00310		
REXULTI (brexpiprazole)		
Risperidone		
Risperidone ODT		
Risperidone oral solution		
SAPHRIS (asenapine)		
SEROQUEL XR (quetiapine) 400mg		
SYMBYAX (olanzapine/fluoxetine)		
VRAYLAR (cariprazine)		
Ziprasidone		
·	ATYPICAL ANTIPSYCHOTICS - LONG AG	CTING
ABILIFY MAINTENA (aripiprazole)		
ARISTADA (aripiprazole lauroxil)		
NVEGA SUSTENNA (paliperidone)		
NVEGA TRINZA (paliperidone)		
RISPERDAL CONSTA (risperidone)		
ZYPREXA RELPREVV (olanzapine)		
	CONSTIPATION - IRRITABLE BOWEL SYNDROME/	OPIOID INDUCED
	mitiza will be required before a non-preferred oral agent v	For opioid-induced constipation, a paid claim for an opioid must will be authorized. For idiopathic constipation, a 30 day trial of al
AMITIZA (lubiprostone)	MOVANTIK (naloxegol)	***Linzess – A 30-day trial of Amitiza is required before
_INZESS (linaclotide) ^{PA***}	RELISTOR (methylnaltrexone) SYRINGE***	Linzess will be authorized.
	RELISTOR (methylnaltrexone) TABLET***	***Relistor Syringe/Vial – Documentation must be
	RELISTOR (methylnaltrexone) VIAL***	submitted to show inability to swallow a solid dosage
	SYMPROIC (naldemedine)	form
	TRULANCE (plecanatide)	—

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
		***Relistor tablets - A 30 day trial of Movantik is required before Relistor tablets will be authorized
	COPD	
Category PA Criteria: All preferred agents indi age. All non-preferred agents will require an FE		oved indication for patients who are younger than 40 years of
Long Acting Anticholinergics		
Group PA Criteria: A 30-day trial of all preferre	d agents will be required before a non-preferred agent wi	II be authorized.
SPIRIVA (tiotropium)	INCRUSE ELLIPTA (umeclidinium)	***SPIRIVA RESPIMAT 2.5 MG (tiotropium) will require a
	SPIRIVA RESPIMAT 2.5 MG (tiotropium)***	30 day trial of Incruse Ellipta and Tudorza Pressair in
	TUDORZA PRESSAIR (aclidinium)	addition to Category PA Criteria
Long Acting Beta Agonists		
PERFOROMIST (formoterol)	ARCAPTA NEOHALER (indacaterol)***	***Arcapta Neohaler/Striverdi Respimat will require a 30
SEREVENT (salmeterol)	BROVANA (arformoterol)***	day trial of Serevent in addition to Category PA Criteria
	STRIVERDI RESPIMAT (olodaterol)***	***Brovana will require a 30 day trial of Perforomist in
		addition to Category PA Criteria
Combination Anticholinergics/Long Acting E	-	
	ed only for COPD will require verification of FDA-approve oducts will be required before a non-preferred agent (shor	d indication for patients who are younger than 40 years of t or long acting) will be authorized.
Albuterol/ipratropium	COMBIVENT RESPIMAT (albuterol/ipratropium)	
ANORO ELLIPTA (umeclidinium/vilanterol)	DUONEB (albuterol/ipratropium)	
BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	STIOLTO RESPIMAT (tiotropium/olodaterol)	
	UTIBRON NEOHALER (glycopyrrolate/indacaterol)	
Combination Steroid/Anticholinergics/Long	Acting Beta Agonists	
	PA criteria, patient must a 30 day trial of all preferred age mbination Inhalers + Long Acting Anticholinergics ta Agonist + Inhaled Steriod	nts in the following combinations:
	TRELEGY ELLIPTA (Fluticasone Furoate/Umeclidinium/Vilanterol)	

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THERAPEUTIC DRUG CLASS PREFERRED AGENTS **NON-PREFERRED AGENTS PA CRITERIA PDE4** - Inhibitor Group PA Criteria: In addition to the category PA criteria, patient must have a history of exacerbations treated with corticosteroids within the last year for initial requests and must have had a decreased number of exacerbations treated with corticosteroids with Daliresp treatment with renewals. Patient must also have had a 30 day trial with a medication in each of the following therapeutic classes from either single ingredient or combination products: Long acting anticholinergic 1. 2. Long acting beta agonist 3. Inhaled Steroid DALIRESP (roflumilast) **CYSTIC FIBROSIS INHALED ANTIBIOTICS** Category PA Criteria: A 28-day trial of 1 preferred agent will be required before a non-preferred agent will be authorized. Non-preferred agents will require that the patient not have been colonized with Burkholderia cepacia and an FDA-approved age and indication. **BETHKIS** (tobramycin) CAYSTON (aztreonam)*** ***Cayston – Patient must have a forced expiratory volume in less than 1 second (FEV1) of less than 25% or KITABIS PAK (tobramvcin/nebulizer) TOBI PODHALER (Tobramvcin)*** greater than 75% predicted. Tobramvcin*** TOBI (Tobramycin)*** ***Tobramycin/TOBI Podhaler – Patient must have a forced expiratory volume in less than 1 second (FEV1) of less than 40% or greater than 80% predicted. Patient must not have been colonized with Burkholderia cepacia. CYTOKINE MODULATORS Category PA Criteria: A 3-month trial of 2 preferred agents will be required before a non-preferred agent will be authorized. All agents will require an FDA-approved indication. COSENTYX (secukinumab)PA ACTEMRA (tocilizumab) ENBREL (etanercept)PA CIMZIA (certolizumab) HUMIRA (adalimumab)PA **KEVZARA** (sarilumab) HUMIRA PSORIASIS (adalimumab)PA KINERET (anakinra) **ORENCIA** (abatacept) **OTEZLA** (apremilast) SILIQ (brodalumab) SIMPONI (golimumab)

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PREFERRED AGENTS	THERAPEUTIC DRUG CLASS NON-PREFERRED AGENTS	PA CRITERIA
	STELARA (ustekinumab)	
	TALTZ (ixekizumab)	
	TREMFYA (guselkumab)	
	XELJANZ (tofacitinib)	
	XELJANZ XR (tofacitinib)	
	DIABETES - DPP4 INHIBITORS	
 An FDA approved indication. Concurrent metformin therapy. A 3-month trial of metformin 		
JANUMET (sitagliptin/metformin)	alogliptan/pioglitzone	***Onglyza - will require an FDA indication, a 3 month trial of metformin and concurrent metformin therapy
ANUMET XR (sitagliptin/metformin)	alogliptin/metformin	and of medomin and concurrent medomin therapy
IANUVIA (sitagliptin)	JENTADUETO XR (linagliptin/metformin)	
JENTADUETO (linagliptin/metformin)	KAZANO (alogliptin/metformin)	
<pre>KOMBIGLYZE XR (saxagliptin/metformin) DNGLYZA (saxagliptin)^{PA***}</pre>	NESINA (alogliptin) OSENI (alogliptin/pioglitazone)	
TRADJENTA (linagliptin)		
	alogliptin DIABETES - GLP1 AGONISTS	
	DIABETES - GEFT AGONISTS	
Category PA Criteria: Preferred agents will require: 1. A 3-month trial of metformin. Non preferred agents will require: 1. A 30-day trial of 2 preferred agents. 2. An FDA indication. 3. Concurrent metformin therapy. 4. A 3-month trial of metformin		
BYDUREON (exenatide microspheres)	ADLYXIN (lixisenatide)	
BYETTA (exenatide)	TRULICITY (dulaglutide)	
STETTA (Exenalice)		

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	DIABETES - INSULIN/GLP1 AGONISTS	
 Category PA Criteria: 1. A 30-day trial of exenatide and liraglutide GLP-1 2. An FDA indication. 3. Concurrent metformin therapy. 4. A 3-month trial of metformin 	agonists in combination with each of insulin glargine a	and insulin detemir insulins
	SOLIQUA (Insulin glargine/lixisenatide)	
	XULTOPHY (insulin degludec/liraglutide)	
	DIABETES - INSULIN	
	red insulin: Humalog, Humalox Mix 50/50, Humalog Mix ovolog Mix 70/30, as evidenced by paid claims or pharn	x 75/25, Humulin 70/30, Humulin N, Humulin R, Humulin R nacy print outs.
APIDRA (insulin glulisine) VIAL	AFREZZA (insulin regular, human)	***Fiasp
APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	BASAGLAR KWIKPEN U-100 (insulin glargine)***	 Patient must have had 30 day trial with Novolog, Humalog, and Apidra
HUMALOG (insulin lispro) VIAL	FIASP (insulin aspart) FLEXTOUCH***	
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	FIASP (insulin aspart) VIAL***	***Tresiba U-1 00 & Basaglar:Patient must fail a 3 month trial of both Lantus and
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	HUMALOG (insulin lispro) CARTRIDGE	Levemir with good compliance, as evidenced by paid claims or pharmacy print outs.
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL HUMALOG (insulin lispro) KWIKPEN		***Toujeo/Tresiba U-200:
HUMULIN N (insulin NPH human isophane) VIAL	HUMALOG JUNIOR KWIKPEN (insulin lispro)	•Patient must require a minimum of 100 units/day of Lantus or Levemir for a minimum of 3 months with good
HUMULIN R (insulin regular, human) VIAL	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	compliance, as evidenced by paid claims or pharmacy print outs.
HUMULIN R U-500 (insulin regular, human) VIAL	HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN	

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
LANTUS (insulin glargine) SOLOSTAR	HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	
LANTUS (insulin glargine) VIAL	HUMULIN N (insulin NPH human isophane) KWIKPEN	
LEVEMIR (insulin detemir) VIAL	HUMULIN R (Insulin regular, human) U-500 KWIKPEN	
LEVEMIR (insulin detemir) FLEXTOUCH	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL	
NOVOLIN R (insulin regular, human) VIAL	NOVOLIN N (insulin NPH human isophane) VIAL]
NOVOLOG (insulin aspart) CARTRIDGE	TOUJEO SOLOSTAR (insulin glargine)***	
NOVOLOG (insulin aspart) FLEXPEN	TRESIBA (insulin degludec) FLEXTOUCH U-100***	
NOVOLOG (insulin aspart) VIAL	TRESIBA (insulin degludec) FLEXTOUCH U-200***	
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN		
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL		
	DIABETES - SGLT2 INHIBITORS	
 Category PA Criteria: Non-preferred agents with 1. An FDA indication. 2. A 3-month trial of a metformin 3. A 3-month trial of a canagliflozin and a 3-mont 4. Concurrent metformin therapy – this condition 		n combination agent.
INVOKAMET (canagliflozin)	FARXIGA (dapagliflozin)	
INVOKANA (canagliflozin)	GLYXAMBI (empagliflozin/linagliptin)	1
JARDIANCE (empagliflozin)	INVOKAMET XR (canagliflozin/metformin)	1
SYNJARDY (empagliflozin/metformin)	XIGDUO XR (dapagliflozin/metformin)	1
SYNJARDY XR (empagliflozin/metformin)		1
	DIARRHEA - IRRITABLE BOWEL SYNDROM	E
Category PA Criteria: Patient must be 18 years approved.	s of age or older. A 30-day trial of all preferred agents will b	be required before a non-preferred medication will be
loperimide	alosetron***	***Alosetron-Patient must be a female.
LOTRONEX (alosetron)***		

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
/IBERZI (eluxadoline)		
(IFAXIN (rifaximin) 550 mg tablet		
	DIGESTIVE ENZYMES	
Category PA Criteria: A 30-day trial of all prefe s present.	erred agents will be required before a non-preferred agent will be	e authorized unless 1 of the exceptions on the PA form
CREON (lipase/protease/amylase)	PANCREAZE (lipase/protease/amylase)	
ENPEP (lipase/protease/amylase)	PANCRELIPASE (lipase/protease/amylase)	
	PERTZYE (lipase/protease/amylase)	
	ULTRESA (lipase/protease/amylase)	
	VIOKACE (lipase/protease/amylase)	
	EPINEPHRINE AUTOINJECTORS	
Category PA Criteria: Medical justification mus	st be provided for why the preferred product will not work.	
pinephrine - labeler 49502	ADRENACLICK (epinephrine)	
	epinephrine - labelers 00115, 54505	
	EPIPEN (epinephrine)	
	EPIPEN JR (epinephrine)	
	GROWTH HORMONE	
2. Patients continuing GH therapy and having m	iteria below and be started on a preferred growth hormone. net the criteria listed below must be switched to a preferred grow /hidesigns.com/assets/files/ndmedicaid/2017/Criteria/growth_hc	
GENOTROPIN (somatropin)PA	HUMATROPE (somatropin)	
GENOTROPIN MINIQUICK (somatropin)PA	NUTROPIN AQ (somatropin)	
NORDITROPIN FLEXPRO (somatropin)PA	OMNITROPE (somatropin)	
	SAIZEN (somatropin)	
	ZOMACTON (somatropin)	
HEART	FAILURE - NEPRILYSIN INHIBITOR/ANGIOTENSIN RECEPT	TOR BLOCKER
Category PA Criteria: 1. Patient must have symptomatic chronic hear 2. Patient must have systolic dysfunction (left ve		

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
ENTRESTO (sacubitril/valsartan)		
	HEMATOPOIETIC, COLONY STIMULATING FACT	ORS
GRANIX (TBO-Filgrastim)		
LEUKINE (Sargramostim)		
NEULASTA (Pegfilgrastim)		
NEUPOGEN (Filgrastim)		
ZARXIO (Filgrastim-SNDZ)		
	HEMATOPOIETIC, ERYTHROPOIESIS STIMULATING	
Category PA Criteria: All agents will require an F authorized.	DA indication. A 4-week trial of all preferred products will	be required before non-preferred agents will be
ARANESP (darbepoetin alfa) ^{PA}	EPOGEN (epoetin alfa)	
PROCRIT (epoetin alfa) ^{PA}	MIRCERA (methoxy polyethylene glycol-epoetin beta)	
	HEPATITIS C TREATMENTS	
 previous treatment. Patient must have an FDA-approved diagnosis. Patient must be an FDA-approved age. Patient must attest that they will continue treatm Prescriber must be, or consult with, a hepatolog Prescriber must provide documentation that the tests dated at least 3 months apart and chart notes HCV RNA level must be taken on week 4 and so Females using ribavirin must have a negative pr Patient must have established compliant behavion time as shown in the prescription medication his Patient must not have life expectancy of less the solution of the patient will be based on label red 	ent without interruption for the duration of therapy. ist, gastroenterologist, or infectious disease specialist. patient has been drug and alcohol free for the past 12 m s addressing patient's alcohol and drug free status throug ent with a renewal request for any duration of treatment regnancy test in the last 30 days and receive monthly pre or including attending scheduled provider visits (defined story for the past 12 months. test is positive, hepatitis B must either be treated or clos nan 12 months due to non-liver related comorbid condition	2 weeks or longer. egnancy tests during treatment. as 1 or less no-shows) and filling maintenance medications ely monitored if patient does not need treatment. ns.
EPCLUSA (sofosbuvir/velpatasvir)PA***	DAKLINZA (Daclatasvir)	***Epclusa:
MAVYRET (glecaprevir/pibrentasvir)PA***	HARVONI (ledipasvir/sofosbuvir)	Must be used with ribavirin for patients with decompensated cirrhosis (Child-Pugh B or Child-Pugh
	OLYSIO (simeprevir)	accompensated cirritosis (Crillid-Fugit D of Crillid-Fugit

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	SOVALDI (sofosbuvir)	C).
	TECHNIVIE (ombitasvir/paritaprevir/ritonavir)	 ***Mavyret/Vosevi: Patient must not have decompensated cirrhosis (Child Pugh B or Child-Pugh C)
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)	
	VIEKIRA PAK XR (dasabuvir/ombitasvir/paritaprevir/ritonavir)	
	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	
	ZEPATIER (elbasvir/grazoprevir)	
	LICE	
walved in the presence of a documented commun	ity breakout of a resistant strain that is only susceptible	to a non-preferred agent.
waived in the presence of a documented commun	ity breakout of a resistant strain that is only susceptible	to a non-preferred agent.
	ELIMITE (permethrin) CREAM	to a non-preferred agent.
EURAX (crotamiton) CREAM	· · ·	to a non-preferred agent.
EURAX (crotamiton) CREAM	ELIMITE (permethrin) CREAM	to a non-preferred agent.
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion)	to a non-preferred agent.
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin)	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion	to a non-preferred agent.
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin)	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion) Spinosad	
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin) ULESFIA (benzyl alcohol)	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion)	
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin) ULESFIA (benzyl alcohol) Category PA Criteria: Patients 18 years old or older: A 30-day trial of all	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion) Spinosad	TS before a non-preferred agent will be authorized.
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin) ULESFIA (benzyl alcohol) Category PA Criteria: Patients 18 years old or older: A 30-day trial of all Patients 6 to 17 years of age: A 30-day trial of riza	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion) Spinosad MIGRAINE PROPHYLAXIS - 5HT(1) AGONIST	TS before a non-preferred agent will be authorized. on-preferred agent will be authorized.
EURAX (crotamiton) CREAM LICE SOLUTION (piperonyl butoxide/pyrethrins) NATROBA (spinosad) Permethrin cream SKLICE (ivermectin) ULESFIA (benzyl alcohol) Category PA Criteria: Patients 18 years old or older: A 30-day trial of all	ELIMITE (permethrin) CREAM EURAX (crotamiton) LOTION Malathion OVIDE (malathion) Spinosad MIGRAINE PROPHYLAXIS - 5HT(1) AGONIST preferred agents in the past 24 months will be required triptan in the past 24 months will be required before a not spinosed	TS before a non-preferred agent will be authorized. on-preferred agent will be authorized.

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
Sumatriptan tablet	Eletriptan	
	FROVA (frovatriptan)***	 ***Frovatriptan – A 30-day trial of naratriptan 2.5 mg within the past 24 months will be required in addition to
	Frovatriptan	the class criteria. The patient's migraine headaches must
	IMITREX (sumatriptan) CARTRIDGE***	either menstrual, long in duration, and/or recurring.
	IMITREX (sumatriptan) PEN INJCTR***	***Almotriptan – A 30-day trial of Zolmitriptan 5 mg in the past 24 months will be required in addition to the class
	IMITREX (sumatriptan) SPRAY	criteria.
	IMITREX (sumatriptan) TABLET	**Zembrance Symtouch/Sumatriptan Injection – A 30-day
	IMITREX (sumatriptan) VIAL***	trial of Naratriptan 2.5 mg, Sumatriptan Nasal Spray 20 mg, Zomig Nasal Spray 5 mg, Zolmitriptan 5 mg, Axert
	MAXALT (rizatriptan)	12.5 mg, Treximet, and Frova in the past 24 months will
	MAXALT MLT (rizatriptan)	be required in addition to the class criteria.
	Naratriptan	-
	ONSETRA XSAIL (sumatriptan)***	
	Sumatriptan cartridge***	
	Sumatriptan pen injctr***	
	Sumatriptan spray	
	Sumatriptan syringe***	
	Sumatriptan vial***	
	SUMAVEL DOSEPRO (sumatriptan)	
	TREXIMET (sumatriptan/naproxen)***	
	Zolmitriptan	
	Zolmitriptan ODT	
	ZOMIG (zolmitriptan)	
	ZOMIG (zolmitriptan) SPRAY	
	ZOMIG ODT (zolmitriptan)	
	MULTIPLE SCLEROSIS	
Interferons		
	eferred agent will be required before a non-preferred ag	gent will be authorized. An FDA indication is required.
AVONEX (interferon beta-1A) PEN	EXTAVIA (interferon beta-1B)	
AVONEX (interferon beta-1A) SYRINGE	PLEGRIDY (peginterferon beta-1A) PEN	

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) SYRINGE	
BETASERON (interferon beta-1B)	REBIF (interferon beta-1A)	
	REBIF REBIDOSE (interferon beta-1A)	
Injectable Non-Interferons		
will be	e, hypersensitivity, or labeled contraindication to Copaxo	and Gilenya will be required before a non-preferred agent ne, a 3-month trial of interferon beta-1 is required. An FDA
COPAXONE (glatiramer) 20 MG/ML	COPAXONE (glatiramer) 40 MG/ML***	***Zinbryta:
	Glatopa (glatiramer)***	 Transaminase and bilirubin levels must have been obtained within 6 months of request.
	ZINBRYTA (daclizumab)***	Patient must not have hepatitis B or C.
		Patient must be screened for TB and have been treated
		if TB positive.
		 If patient has early aggressive disease defined as ≥ 2 relapses in the year and ≥ 1 Gadolinium (Gd)+ lesion, th trials of oral non-interferons will not be required. Patient must have Anti-JC virus antibodies taken. ***Copaxone/Glatopa: A reason must be indicated why Copaxone 20 mg/mL will not work.
Oral Non-Interferons		
Category PA Criteria: A 3-month long trial of all p	referred agents and Copaxone will be required before a red contraindication to Copaxone, a 3-month trial of interfeogist.	
AUBAGIO (teriflunomide)	TECFIDERA (dimethyl fumarate)***	*** Tecfidera: Patient must have had a CBC with
GILENYA (fingolimod)		lymphocyte count within 6 months of request.
	OPHTHALMIC ALPHA ADRENERGICS - GLAUCO	MA

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	erred agents will be required before a non-preferred agent cs of the same medication will satisfy this requirement.	will be authorized unless 1 of the exceptions on the PA form
ALPHAGAN P 0.1% (brimonidine)	Apraclonidine	
ALPHAGAN P 0.15% (brimonidine)	brimonidine 0.15%	
Apraclonidine	IOPIDINE (apraclonidine)	
brimonidine 0.2%		
COMBIGAN (brimonidine/timolol)		
SIMBRINZA (brinzolamide/brimonidine)		
	OPHTHALMIC ANTIHISTAMINES	
Category PA Criteria: A 30-day trial of 3 pref	erred agents will be required before a non-preferred agent	will be authorized.
ALOCRIL (nedocromil)	ELESTAT (epinastine)	
ALOMIDE (lodoxamide)	EMADINE (emedastine)	
Azelastine	Olopatadine 0.2%	
BEPREVE (bepotastine)	PATANOL 0.1% (olopatadine)	
Cromolyn		
Epinastine		
LASTACAFT (alcaftadine)		
Olopatadine 0.1%		
PATADAY 0.2% (olopatadine)		
PAZEO (olopatadine)		
	OPHTHALMIC ANTIINFECTIVES	
present.		will be authorized unless 1 of the exceptions on the PA form is
AZASITE (azithromycin) DROPS	Bacitracin ointment	
Bacitracin/polymyxin ointment	BLEPH-10 (sulfacetamide) DROPS	
BESIVANCE (besifloxacin) DROPS	CILOXAN (ciprofloxacin) DROPS	
CILOXAN (ciprofloxacin) OINTMENT	Gatifloxacin drops	
Ciprofloxacin drops	GENTAK (gentamicin sulfate) OINTMENT	
Erythromycin ointment	Levofloxacin drops	
Gentamicin sulfate drops	moxifloxacin drops	

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
Gentamicin sulfate ointment	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT	
MOXEZA (moxifloxacin) DROPS	NEOSPORIN (neomycin SU/polymyxin B/gramicidin) DROPS	
Neomycin SU/bacitracin/polymyxin B ointment	OCUFLOX (ofloxacin) DROPS	
Neomycin SU/polymyxin B/gramicidin drops	POLYCIN (bacitracin/polymyxin) OINTMENT	
Ofloxacin drops	POLYTRIM (polymyxin B/trimethoprim) DROPS	
Polymyxin B/trimethoprim drops	Sulfacetamide ointment	
Sulfacetamide drops	TOBREX (tobramycin) DROPS	
Tobramycin drops	VIGAMOX (moxifloxacin) DROPS	
TOBREX (tobramycin) OINTMENT	ZYMAXID (gatifloxacin) DROPS	
	OPHTHALMIC ANTIINFECTIVES/ANTIINFLAMMAT	ORIES
present.	agents will be required before a non-preferred agent will	be authorized unless 1 of the exceptions on t
Neomycin/bacitracin/polymyxin b/hydrocortisone ointment	BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	
BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	BLEPHAMIDE S.O.P. (sulfacetamide/prednisolone) ointment	
Neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS	
Neomycin/polymyxin b/dexamethasone ointment	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT	
PRED-G (gentamicin/prednisol ac) DROPS	Neomycin/polymyxin b/hydrocortisone drops	
PRED-G (gentamicin/prednisol ac) OINTMENT	NEO-POLYCIN HC (neomycin SU/bacitracin/polymyxin B/hydrocortisone) OINTMENT	
Sulfacetamide/prednisolone drops	TOBRADEX ST (tobramycin/dexamethasone) DROPS	
TOBRADEX (tobramycin/dexamethasone) DROPS	Tobramycin/dexamethasone	
TOBRADEX (tobramycin/dexamethasone) OINTMENT		
ZYLET (tobramycin/lotepred etab) DROPS		

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	OPHTHALMIC ANTIINFLAMMATORIE	S
	ed agents will be required before a non-preferred agent	will be authorized unless 1 of the exceptions on the PA form is
present.		
ACUVAIL (ketorolac)	ACULAR (ketorolac)	
ALREX (loteprednol) Diclofenac sodium	ACULAR LS (ketorolac) Bromfenac sodium	
FLAREX (fluorometholone)	BROMSITE (bromfenac sodium)	
Fluorometholone	Dexamethasone sodium phosphate	_
Flurbiprofen sodium	DUREZOL (difluprednate)	
FML FORTE (fluorometholone)	FML (fluorometholone)	
FML S.O.P. (fluorometholone)	LOTEMAX (loteprednol) GEL DROPS	
ILEVRO (nepafenac)	LOTEMAX (loteprednol) OINTMENT	
ketorolac tromethamine 0.4%	NEVANAC (nepafenac)	
Ketorolac tromethamine 0.5%	OCUFEN (flurbiprofen)	
LOTEMAX (loteprednol) DROPS	OMNIPRED 1% (prednisolone acetate)	
MAXIDEX (dexamethasone)	PRED FORTE 1% (prednisolone acetate)	
PRED MILD 0.12% (prednisolone acetate)	Prednisolone acetate 1%	
Prednisolone sodium phosphate 1%	PROLENSA (bromfenac)	
	OPHTHALMIC IMMUNOMODULATORS - DRY EYE	SYNDROME
Restasis (cyclosporine)		
Restasis multidose (cyclosporine)		
Xiidra (lifitegrast)		
	OPIOID ANALGESIC - LONG ACTING	i i i i i i i i i i i i i i i i i i i
Category PA Criteria: For non-preferred ager 1. Patient must have required around-the-clock 2. The past 3 months of North Dakota PDMP re		
butorphanol	ARYMO ER (oxycodone)***	*** Hysingla ER, oxymorphone ER, Zohydro ER require
BUTRANS (buprenorphine) PATCHES	BELBUCA (buprenorphine)***	30-day trials of fentanyl, morphine, and oxycodone
EMBEDA (morphine/naltrexone)	buprenorphine patches	products in addition to Category PA Criteria
Fentanyl 12 mcg/hr ^{PA***}	DURAGESIC (fentanyl)	***Belbuca- Patient must have failed 30-day trials of
Fentanyl 25 mcg/hr, 50 mcg/hr, 75 mcg/hr	EXALGO (hydromorphone)***	Butrans, Nucynta ER, and tramadol ER in additional to

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PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
levorphanol	Fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr***	Category PA Criteria
Morphine ER tablets	Hydromorphone ER tablets***	***Hydromorphone ER and Exalgo – The 90-day around- the-clock pain relief requirement must be met by an
NUCYNTA ER (tapentadol)	HYSINGLA ER (hydrocodone)***	equianalgesic dose of 60 mg oral morphine daily, 25 mcg
pentazocine-naloxone	KADIAN (morphine)***	transdermal fentanyl/hour, 30 mg oxycodone daily, 8 mg
	Methadone***	of oral hydromorphone daily, or another opioid daily.
	MORPHABOND ER (morphine)***	Patient must have failed 30-day trials of fentanyl,
	Morphine ER capsules***	morphine, and oxycodone products in addition to Category PA Criteria
	MS CONTIN (morphine)	
	Oxycodone ER***	***Methadone, Fentanyl Patch 37.5 mcg/hr, 62.5 mcg/hr,
	OXYCONTIN (oxycodone)***	87.5 mcg/hr, morphine ER capsules, Arymo ER,
	Oxymorphone ER tablets***	Morphabond ER, and Oxycontin - Clinical justification must be given for why another product will not work in
	Tramadol ER	additional to Category PA Criteria.
	ULTRAM ER (tramadol ER)	
	XTAMPZA ER (oxycodone)***	*** Fentanyl 12 mcg/hr – The total daily opioid dose must
	ZOHYDRO ER (hydrocodone)***	be less than 60 Morphine Equivalent Dose (MED) in additional to Category PA Criteria
		***Tramadol ER Patient must have failed two 30-day trials of preferred medications in additional to Category PA Criteria
		***Xtampza ER - Patient must have failed 30-day trials of fentanyl and morphine products in addition to Category PA Criteria
	OPIOID ANTAGONIST - OPIOID AND ALCOHOL DE	EPENDENCE
VIVITROL (Naltrexone Microspheres)		
	OPIOID PARTIAL ANTAGONIST - OPIOID DEPE	NDENCE

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THERAPEUTIC DRUG CLASS PREFERRED AGENTS NON-PREFERRED AGENTS **PA CRITERIA** Category PA Criteria: A 30-day trial of 1 preferred agent will be required before a non-preferred agent will be authorized. 1. Patient must be 16 years of age or older. 2. Patient must not be taking other opioids, tramadol, or carisoprodol concurrently. 3. The prescriber must be registered to prescribe under the Substance Abuse and Mental Health Services Administration (SAMHSA) and provide his/her DEA number. 4. The prescriber and patient must have a contract or the prescriber must have developed a treatment plan. 5. The prescriber must perform routine drug screens. 6. The prescriber must routinely check the PDMP and the last 3 months of North Dakota PDMP reports must have been reviewed by the prescriber. 7. The prescriber must be enrolled with ND Medicaid. ZUBSOLV (buprenorphine/naloxone)PA BUNAVAIL FILM (buprenorphine/naloxone)*** *** Bunavail/Suboxone Film will require a 30-day trial of buprenorphine/naloxone tablets in addition to the Buprenorphine tablets*** category PA criteria. Buprenorphine-naloxone tablets SUBOXONE FILM (buprenorphine/naloxone)*** ***Buprenorphine tablets will be allowed during a period that a patient is pregnant or breastfeeding. **OTIC ANTI-INFECTIVES - FLUOROQUINOLONES** Category PA Criteria: A 7-day trial of 2 preferred agents will be required before a non-preferred agent will be authorized. A 7-day trial of 2 preferred generics of the same medication will satisfy this requirement. CIPRO HC (ciprofloxacin/hydrocortisone) FLOXIN (ofloxacin) CIPRODEX (ciprofloxacin/dexamethasone) Ofloxacin drops - labelers 50383, 60505 OTOVEL (ciprofloxacin/fluocinolone) ofloxacin drops - labeler 24208 PHOSPHATE BINDERS Category PA Criteria: The following criteria will be required before a non-preferred agent will be authorized: 1. Patient must have had a 3-month trial of 3 preferred different chemical entities. 2. Patient must have end stage renal disease or chronic kidney disease. 3. Patients with chronic kidney disease stage 5 must have a phosphate level greater than 5.5 mg/dL. 4. All other patients must have a phosphate level greater than 4.6 mg/dL. Calcium acetate capsule AURYXIA (ferric citrate) TABLET Calcium acetate tablet ELIPHOS (calcium acetate) TABLET FOSRENOL (lanthanum) 1000 MG CHEWABLE FOSRENOL (lanthanum) 500 MG AND 750 MG CHEWABLE TABLET TABLET PHOSLYRA (calcium acetate) ORAL solution FOSRENOL (lanthanum) POWDER PACK

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THERAPEUTIC DRUG CLASS				
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA		
RENAGEL (sevelamer) TABLET	Lanthanum			
RENVELA (sevelamer carbonate) TABLET	sevelamer powder pack			
RENVELA (sevelamer) POWDER PACK	VELPHORO (sucroferric oxyhydroxide)			
PLATELET AGGREGATION INHIBITORS				
Category PA Criteria: A 30 day trial of 2 preferred the form.	l agents will be required before a non-preferred agent wi	Il be authorized unless 1 of the exceptions is indicated on		
AGGRENOX (aspirin/dipyridamole)	Aspirin/dipyridamole ER	***Zontivity – Patient must be 18 years of age or older. Zontivity must be taken with aspirin and/or clopidogrel. Patient must not have a history of stroke, transient ischemic attack, or intracranial hemorrhage. ***Durlaza/Yosprala DR – Patient must have a reason that immediate release aspirin is not an option.		
BRILINTA (ticagrelor)	Clopidogrel 300mg			
Clopidogrel 75 mg	DURLAZA (aspirin ER)***			
Dipyridamole	EFFIENT (prasugrel)			
Ticlopidine	PERSANTINE (dipyridamole)			
	PLAVIX (clopidogrel)			
	prasugrel			
	YOSPRALA DR (aspirin/omeprazole)***			
	ZONTIVITY (vorapaxar)***			
	PULMONARY HYPERTENSION			
PDE-5 Inhibitors				
Category PA Criteria: A 30-day trial of all preferre indication. Patient cannot be taking nitrates of any		vill be authorized. All medications require an FDA-approved		
Sildenafil ^{PA}	REVATIO (sildenafil) SUSPENSION***	***Revatio Suspension – Patients 7 years and older will be required to submit documentation of their inability to ingest a solid dosage form.		
ADCIRCA (tadalafil)	REVATIO (sildenafil) TABLET			
Soluble Guanylate Cyclase Stimulators				
control, and have a pregnancy test before initiation		ial must not be pregnant, be taking a reliable form of birth FDA-approved indication. Patient may not be taking with nhibitors.		
ADEMPAS (riociguat) ^{PA}				
Endothelin Receptor Antagonist				
	tential must not be pregnant, be taking a reliable form of e an FDA-approved indication. Non-preferred agents will	birth control, and have a pregnancy test before initiation require a 30-day trial of all preferred medications.		

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PREFERRED AGENTS	THERAPEUTIC DRUG CLASS NON-PREFERRED AGENTS	PA CRITERIA		
TRACLEER (bosentan) ^{PA***}	LETAIRIS (ambrisentan)*** OPSUMIT (macitentan)***	***Tracleer – LFTs must be measured at baseline and monthly during therapy. ***Opsumit - A 30 day trial of Letairis will be required in		
Prostacyclins		addition to category PA criteria		
	FDA-approved indication. A 30-day trial of all preferred	agents will be required before a non-preferred agent will be		
ORENITRAM ER (treprostinil) ^{PA}	TYVASO (treprostinil)	***Ventavis 20 mcg/mL – A patient must be maintained at		
REMODULIN (treprostinil)	UPTRAVI (selexipag)	a 5 mcg dose and repeatedly experiencing incomplete dosing due to extended treatment time to be approved.		
VENTAVIS (iloprost) 10 mcg/mLPA	VENTAVIS (iloprost) 20 mcg/mL***	dosing due to extended treatment time to be approved.		
STERO	ID/LONG ACTING BETA AGONIST (LABA) COMBINA	TION INHALERS		
Category PA Criteria: A 30-day trial of all preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents must have an FDA- approved indication. For COPD diagnosis: EITHER both of the following will be required in addition to the category PA criteria: 1. A 30-day trial of Tudorza Pressair, Spiriva, Spiriva Respimat, Incruse Ellipta, or Seebri Neohaler 2. A 30-day trial of Brovana, Arcapta Neohaler, Striverdi Respimat, Perforomist, or Serevent. OR A 30-day trial of Anoro Ellipta, Stiolto Respimat, Utibron NeoHaler, Bevespi Aerosphere, or Trelegy Ellipta For asthma diagnosis, patient must have been reviewed for step down therapy for all renewal requests.				
ADVAIR DISKUS (fluticasone/salmeterol)	ADVAIR HFA (fluticasone/salmeterol)	***Airduo Respiclick - Clinical justification must be provided as to why Advair Diskus or Advair HFA will not work		
DULERA (mometasone/formoterol)	AIRDUO RESPICLICK (fluticasone/salmeterol)***			
SYMBICORT (budesonide/formoterol)	BREO ELLIPTA (fluticasone/vilanterol)			
	fluticasone/salmeterol			
STEROIDs - INHALED				

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THERAPEUTIC DRUG CLASS PREFERRED AGENTS **NON-PREFERRED AGENTS PA CRITERIA** Category PA Criteria: Inhalers: A 30-day trial of all preferred inhalers will be required before a non-preferred agent will be authorized. Inhaled suspensions (nebulizers): Non-preferred Brand medication: A 30-day trial of 2 pharmaceutically equivalent preferred agents will be required before a non-preferred agent will be authorized. Non-preferred Generic medication: A 30-day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized. ALVESCO (ciclesonide) **AEROSPAN** (flunisolide) ASMANEX (mometasone) TWISTHALER ARMONAIR RESPICLICK (fluticasone) budesonide suspension 0.25 ma/2 mL ARNUITY ELLIPTA (fluticasone) budesonide suspension 0.5 mg/2 mL ASMANEX HFA (mometasone) FLOVENT HFA (fluticasone) budesonide suspension 1 mg/2 mL PULMICORT FLEXHALER (budesonide) FLOVENT DISKUS (fluticasone) PULMICORT RESPULES (budesonide) 1 MG/2 PULMICORT RESPULES (budesonide) 0.25 mg/2 ML mL QVAR (beclomethasone) PULMICORT RESPULES (budesonide) 0.5 mg/2 mL **ULCERATIVE COLITIS AGENTS - NONSTEROIDAL** Category PA Criteria: A 30-day trial of each of the preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents will require an FDA indication. Oral APRISO (mesalamine) CAPSULE ***Giazo - Patient must be a male. ASACOL HD (mesalamine) **AZULFIDINE** (sulfasalazine) Balsalazide capsule **DELZICOL** (mesalamine) CAPSULE AZULFIDINE DR (sulfasalazine) **DIPENTUM** (olsalazine) COLAZAL (balsalazide) GIAZO (balsalazide)*** LIALDA (mesalamine) TABLET PENTASA (mesalamine) Mesalamine DR Sulfasalazine DR tablet SULFAZINE (sulfasalazine) Sulfasalazine tablet Rectal

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	THERAPEUTIC DRUG CLASS	
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
CANASA (mesalamine) RECTAL SUPPOSITORY	Mesalamine enema kit	
Mesalamine enema	ROWASA (mesalamine) ENEMA KIT	
SF ROWASA (mesalamine) ENEMA		
	URINARY ANTISPASMODICS	
Category PA Criteria: A 30-day trial of 3 approved indication.	preferred agents will be required before a non-preferred ag	ent will be authorized. Non-preferred agents require an FDA-
ENABLEX (darifenacin)	Darifenacin ER	***SANCTURA ER/Trospium ER and Myrbetriq will
Flavoxate	DETROL (tolterodine)	require a 1-month trial of trospium and
GELNIQUE (oxybutynin)	DETROL LA (tolterodine)	tolterodine/tolterodine ER in addition to the category PA criteria.
Oxybutynin ER	DITROPAN XL (oxybutynin)	ontona.
Oxybutynin syrup	MYRBETRIQ (mirabegron)***	
Oxybutynin tablet	SANCTURA (trospium)	
OXYTROL (oxybutynin) PATCH	SANCTURA ER (trospium)***	
TOVIAZ (fesoterodine)	Tolterodine	
VESICARE (solifenacin)	Tolterodine ER	
	Trospium	
	Trospium ER***	