DUR Board Meeting
June 3, 2015
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
June 3, 2015
1 pm

1. Administrative items
    - Travel vouchers
    - Introduction of new members

2. Old business
    - Review and approval of minutes of 03/15 meeting
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Second review of Otezla
    - Second review of Xtoro
    - Second review of Hemangeol
    - Second review of Lemtrada
    - Second review of agents used to treat idiopathic pulmonary fibrosis (Ofev, Esbriet)
    - Second review of GLP-1 receptor agonists
    - Second review of topical therapies for onychomycosis

3. New business
    - Plan for implementation/changes to narcotic quantity limits
    - Concurrent use of narcotics and benzodiazepines
    - Review of cholesterol lowing drugs
    - Review of muscle relaxants
    - Review of injectable anticoagulants
    - Review of Akynzeo
    - Review of Nuvessa
    - Review of Cholbam
    - 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 4, 2015

Members Present: John Savageau, Jeffrey Hostetter, Peter Woodrow, Russ Sobotta, Tanya Schmidt, Michael Booth, Carlotta McCleary, Laura Schield, Katie Kram, Wendy Brown, Michael Quast

Members Absent: James Carlson, Leann Ness, Steve Irsfeld

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

J. Savageau called the meeting to order at 1:00 p.m. Chair J. Savageau asked for a motion to approve the minutes from the December meeting. P. Woodrow moved that the minutes be approved, and W. Brown seconded the motion. Chair J. Savageau called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Introduction of new member:
B. Joyce introduced the new board member, Dr. Michael Quast. Dr. Quast was appointed by the North Dakota Medical Association.

Budget update:
Legislative session ongoing and the budget is being reviewed. There is a new bill going through session regarding Medication Therapy Management (MTM). If passed, the MTM program could be used to manage many disease states, including patients with Hepatitis C.

Otezla review
B. Joyce reviewed Otezla with the board. K. Bergstresser, representing Celgene spoke regarding Otezla. A recommendation was made by the board to ask for specialist involved in therapy and diagnosis on the form. A motion was made by J. Hostetter to place Otezla on prior authorization. L. Schield seconded the motion. This topic will be reviewed at the next meeting.

Xtoro review
B. Joyce reviewed Xtoro with the board. A motion was made by M. Booth to place Xtoro on prior authorization. K. Kram seconded the motion. This topic will be reviewed at the next meeting.

Hemangeol review
B. Joyce reviewed Hemangeol with the board. A motion was made by M. Booth to place Hemangeol on prior authorization. W. Brown seconded the motion. This topic will be reviewed at the next meeting.

Lemtrada review
B. Joyce reviewed Lemtrada with the board. A recommendation was made by the board to ask for specialist involved in therapy. A motion was made by M. Booth to place Lemtrada on prior authorization.

Agents used to treat idiopathic pulmonary fibrosis review
B. Joyce reviewed agents used to treat idiopathic pulmonary fibrosis with the board. A recommendation was made by the board to ask for indication and specialist involved in therapy. A motion was made by P. Woodrow to place these agents on prior authorization. The motion was seconded by W. Brown. Rachel Anhorn, representing Boehringer Ingelheim, spoke regarding Ofev. Lee Ding, representing Genentech, spoke regarding Esbriet. This topic will be reviewed at the next meeting.

GLP-1 receptor agonists review
B. Joyce reviewed GLP-1 receptor agonists with the board. Brad Haas, representing AstraZeneca spoke regarding Byetta. M. Booth made a motion to place GLP-1 receptor agonists on prior authorization. K. Kram seconded the motion. This topic will be reviewed at the next meeting.

Topical therapies for onychomycosis review
B. Joyce reviewed topical therapies for onychomycosis. There was no public comment. P. Woodrow made a motion to place these agents on prior authorization. J. Hostetter seconded the motion. 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, new warnings, etc. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. W. Brown moved to approve the new criteria and M. Booth seconded the motion. Chair J. Savageau called for a voice vote. The motion passed with no audible dissent.

The next DUR Board meeting will be held June 3 in Bismarck. J. Hostetter made a motion to adjourn the meeting. W. Brown seconded. The motion passed with no audible dissent. J. Savageau adjourned the meeting.

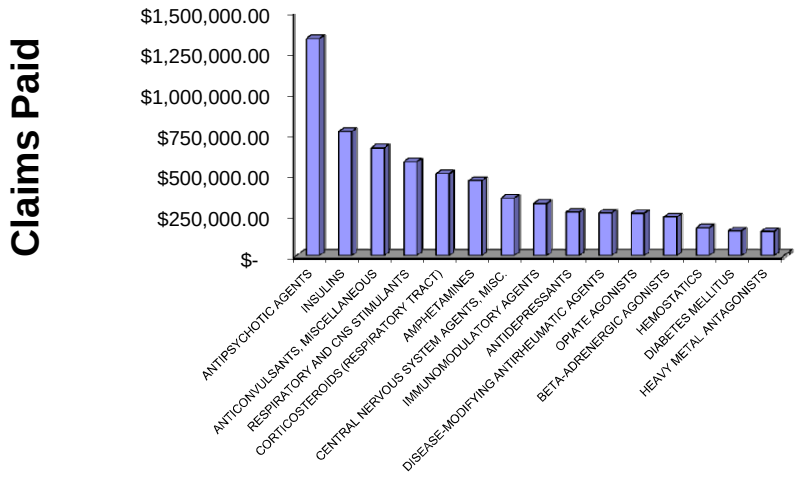
NORTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 10/01/2014 - 12/31/2014

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	6,026	$ 1,334,824.48	$ 221.51	4.15%
INSULINS	1,737	$ 764,215.80	$ 439.96	1.20%
ANTICONVULSANTS, MISCELLANEOUS	8,137	$ 662,899.00	$ 81.47	5.60%
RESPIRATORY AND CNS STIMULANTS	5,172	$ 577,677.55	$ 111.69	3.56%
CORTICOSTEROIDS (RESPIRATORY TRACT)	1,955	$ 504,766.74	$ 258.19	1.35%
AMPHETAMINES	3,923	$ 461,360.60	$ 117.60	2.70%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,561	$ 353,419.66	$ 226.41	1.07%
IMMUNOMODULATORY AGENTS	61	$ 321,384.85	$ 5,268.60	0.04%
ANTIDEPRESSANTS	13,693	$ 267,739.96	$ 19.55	9.43%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	99	$ 262,663.09	$ 2,653.16	0.07%
OPIATE AGONISTS	9,003	$ 259,924.23	$ 28.87	6.20%
BETA-ADRENERGIC AGONISTS	4,103	$ 237,168.28	$ 57.80	2.82%
HEMOSTATICS	10	$ 170,764.01	$ 17,076.40	0.01%
DIABETES MELLITUS	1,043	$ 152,239.90	$ 145.96	0.72%
HEAVY METAL ANTAGONISTS	9	$ 149,011.04	$ 16,556.78	0.01%
Total Top 15	56,532	$ 6,480,059.19	$ 114.63	38.92%

Total Rx Claims From 10/01/2014 - 12/31/2014	145,261

Top 15 Therapeutic Classes
Based on Total Cost of Claims



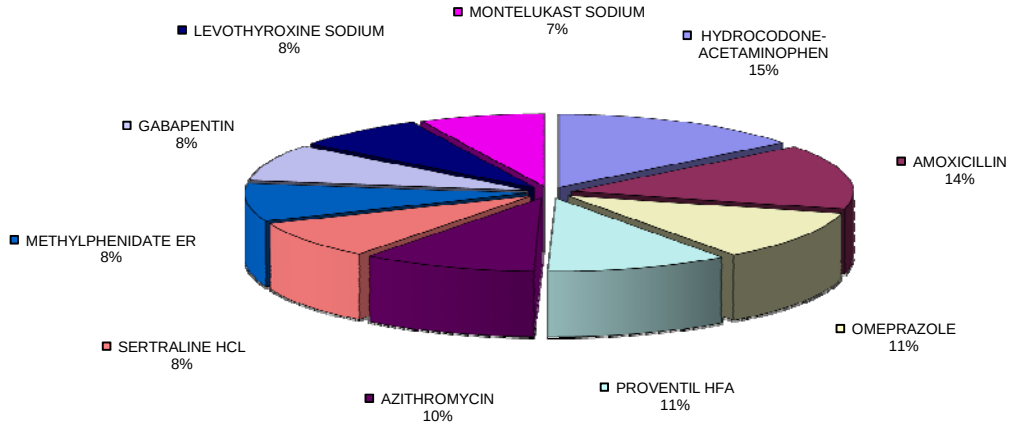
NORTH DAKOTA MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/2014 - 12/31/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	3,645	$ 51,552.75	$ 14.14	2.51%
AMOXICILLIN	PENICILLINS	3,606	$ 36,537.75	$ 10.13	2.48%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,783	$ 31,196.38	$ 11.21	1.92%
PROVENTIL HFA	BETA-ADRENERGIC AGONISTS	2,618	$ 167,924.57	$ 64.14	1.80%
AZITHROMYCIN	MACROLIDES	2,503	$ 47,237.55	$ 18.87	1.72%
SERTRALINE HCL	ANTIDEPRESSANTS	2,105	$ 20,158.99	$ 9.58	1.45%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	2,094	$ 276,127.56	$ 131.87	1.44%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,051	$ 40,392.28	$ 19.69	1.41%
LEVOTHYROXINE SODIUM	THYROID AGENTS	1,880	$ 30,428.62	$ 16.19	1.29%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,799	$ 37,079.41	$ 20.61	1.24%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,778	$ 13,360.84	$ 7.51	1.22%
FLUOXETINE HCL	ANTIDEPRESSANTS	1,749	$ 11,889.44	$ 6.80	1.20%
TRAZODONE HCL	ANTIDEPRESSANTS	1,738	$ 12,402.33	$ 7.14	1.20%
TRAMADOL HCL	OPIATE AGONISTS	1,467	$ 12,616.13	$ 8.60	1.01%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,459	$ 11,773.19	$ 8.07	1.00%
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	1,441	$ 37,151.40	$ 25.78	0.99%
VYVANSE	AMPHETAMINES	1,428	$ 230,503.29	$ 161.42	0.98%
OXYCODONE-ACETAMINOPHEN	OPIATE AGONISTS	1,396	$ 46,309.28	$ 33.17	0.96%
DEXTROAMPHETAMINE-AMPHET ER	AMPHETAMINES	1,380	$ 150,301.00	$ 108.91	0.95%
METHYLPHENIDATE HCL	RESPIRATORY AND CNS STIMULANTS	1,339	$ 62,914.49	$ 46.99	0.92%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,334	$ 17,208.80	$ 12.90	0.92%
METFORMIN HCL	BIGUANIDES	1,291	$ 10,541.68	$ 8.17	0.89%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,230	$ 24,432.08	$ 19.86	0.85%
BUPROPION XL	ANTIDEPRESSANTS	1,226	$ 27,330.47	$ 22.29	0.84%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,215	$ 15,247.19	$ 12.55	0.84%
TOTAL TOP 25		46,555	$ 1,422,617.47	$ 30.56	32.05%

Total Rx Claims From 10/01/2014 - 12/31/2014	145,261

Top 10 Drugs
Based on Number of Claims



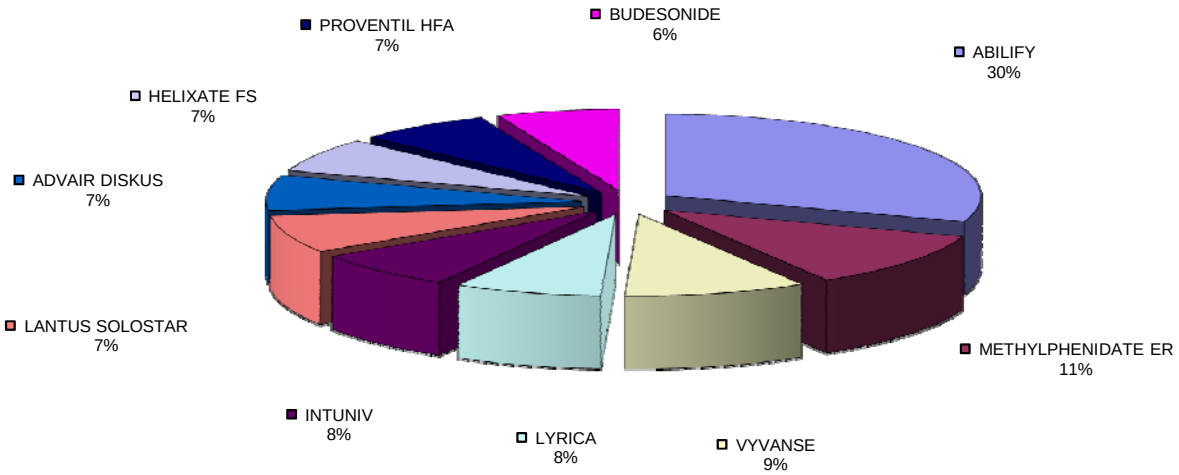
NORTH DAKOTA MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/2014 - 12/31/2014

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ABILIFY	ANTIPSYCHOTIC AGENTS	1,093	$ 747,183.17	$ 683.61	0.75%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	2,094	$ 276,127.56	$ 131.87	1.44%
VYVANSE	AMPHETAMINES	1,428	$ 230,503.29	$ 161.42	0.98%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	605	$ 185,944.27	$ 307.35	0.42%
INTUNIV	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	855	$ 184,893.68	$ 216.25	0.59%
LANTUS SOLOSTAR	INSULINS	455	$ 184,840.73	$ 406.24	0.31%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	593	$ 171,288.44	$ 288.85	0.41%
HELIXATE FS	HEMOSTATICS	6	$ 168,413.72	$ 28,068.95	0.00%
PROVENTIL HFA	BETA-ADRENERGIC AGONISTS	2,618	$ 167,924.57	$ 64.14	1.80%
BUDESONIDE	CORTICOSTEROIDS (RESPIRATORY TRACT)	538	$ 154,726.14	$ 287.60	0.37%
DEXTROAMPHETAMINE-AMPHET ER	AMPHETAMINES	1,380	$ 150,301.00	$ 108.91	0.95%
NOVOLOG FLEXPEN	INSULINS	316	$ 144,762.82	$ 458.11	0.22%
COPAXONE	IMMUNOMODULATORY AGENTS	25	$ 141,829.00	$ 5,673.16	0.02%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	597	$ 140,835.91	$ 235.91	0.41%
FREESTYLE LITE STRIPS	DIABETES MELLITUS	916	$ 132,431.72	$ 144.58	0.63%
SYPRINE	HEAVY METAL ANTAGONISTS	6	$ 127,711.92	$ 21,285.32	0.00%
ENBREL	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	39	$ 126,065.50	$ 3,232.45	0.03%
SEROQUEL XR	ANTIPSYCHOTIC AGENTS	275	$ 125,472.70	$ 456.26	0.19%
LATUDA	ANTIPSYCHOTIC AGENTS	156	$ 116,851.71	$ 749.05	0.11%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	40	$ 113,650.29	$ 2,841.26	0.03%
LEVEMIR FLEXTOUCH	INSULINS	225	$ 106,840.88	$ 474.85	0.15%
HUMALOG	INSULINS	209	$ 95,219.14	$ 455.59	0.14%
TAMIFLU	NEURAMINIDASE INHIBITORS	655	$ 94,774.55	$ 144.69	0.45%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	52	$ 77,766.56	$ 1,495.51	0.04%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	265	$ 75,940.07	$ 286.57	0.18%
TOTAL TOP 25		15,441	$ 4,242,299.34	$ 274.74	10.63%

Total Rx Claims From 10/01/2014 - 12/31/2014	145,261

Top 10 Drugs
Based on Total Claims Cost



OTEZLA
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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 Provider Number		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug: □ OTEZLA	Diagnosis for this Request:	History of Failure:	Is Otezla being used in combination with other biologic therapies?	
□ *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 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)	

XTORO
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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

- **Patient must be 1 year of age or older**
- **Patient must have a diagnosis of acute otitis externa (AOE).**
- **Ciprofloxacin, ciprofloxacin/dexamethasone, ofloxacin, neomycin/polymyxin B/hydrocortisone, and acetic acid solution 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			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug: □ XTORO	History of 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 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)	

HEMANGEOL
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug: □ HEMANGEOL	Diagnosis: Patient's weight:	Does patient have ANY contraindications to Hemangeol?	
□ *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 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:
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Denied: (Reasons)	

LEMTRADA
PA FORM

Fax Completed Form to:
866-254-0761
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 Lemtrada must meet the following criteria:

- **Patient must be 17 years of age or older.**
- **Patient must have a relapsing-remitting form of multiple sclerosis.**
- **Patient must have a specialist involved in therapy.**
- **Patient must have a clinical exacerbation, or evidence of worsening on two or more drugs indicated for the treatment of multiple sclerosis.**
- **Patient must not use Lemtrada in combination with other immunomodulatory therapies used in the treatment of multiple sclerosis.**

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 Number	
Address		City	State	Zip Code
Requested Drug: □ LEMTRADA	Diagnosis for this Request:	History of Failure (2):	Is Lemtrada being used in combination with other biologic therapies?	
□ *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 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

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Denied: (Reasons)	

AGENTS USED TO TREAT IDIOPATHIC PULMONARY FIBROSIS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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 diagnosed of idiopathic pulmonary fibrosis.**
- **Patient must have a specialist involved in therapy.**
- **Patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 days.**

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 Number	
Address	City	State	Zip Code
Requested Drug: □ OFEV □ ESBRIET	Diagnosis: FVC:	Is patient pregnant: □ YES □ NO	
□ *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 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:
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Denied: (Reasons)	

GLP-1 RECEPTOR AGONISTS
PA FORM

Fax Completed Form to:
866-254-0761
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 GLP-1 receptor agonists must meet the following criteria:

- **Patient must have a diagnosis of type 2 diabetes mellitus.**
- **Patient must fail trial of metformin, sulfonylurea, combination of metformin/sulfonylurea, or a combination of metformin and a thiazolidinedione.**

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: □ BYETTA □ TRULICITY □ BYDUREON □ VICTOZA □ TANZEUM	Diagnosis: Current Hgb A1c: Test Date:	Trial: Start Date: End Date:	Trial: 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 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

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Denied: (Reasons)	

TOPICAL THERAPIES FOR ONYCHOMYCOSIS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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

- **Patient must be 18 years of age or older.**
- **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 ciclopirox, itraconazole, or terbinafine.**

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: □ JUBLIA □ KERYDIN	Diagnosis:	Trial: 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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

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Denied: (Reasons)	

North Dakota Medicaid
Trends for Prescription Drug Abuse
Reported by ND Bureau of Criminal Investigation

Bismarck/Mandan:

Hydrocodone

Tramadol

Fentanyl

Percocet

Jamestown/Valley City:

Fentanyl patches

Oxycodone

Grand Forks:

Opiates

Benzo's (such as Xanax)

Amphetamines (such as Adderall)

Fargo:

Suboxone (cash only operations)

Minot:

Alprazolam

Lorazepam

Dextroamphetamine

Williston:

Blue Oxy is what we see here. Most of our pill users have graduated to heroin so we don't see as many as we used to.

Devils Lake:

Seeing a lot of the opiates: oxycodone, hydrocodone. Also morphine, fentanyl, and tramadol.

Dickinson:

Mostly morphine. Occasionally Adderall, Fentanyl, and Roxicodone.

M E M O R A N D U M

TO: Physicians Who Prescribe to Medicaid Patients

FROM: Brendan K. Joyce, PharmD, Administrator Pharmacy Services

SUBJECT: Quantity Limits on Immediate Release Opioids

Under Section 1927 of the Social Security Act and the 2003 Legislative Assembly House Bill 1430, a Drug Utilization Review (DUR) Board was formed that monitors for overutilization, incorrect drug dosage or duration of drug treatment and clinical abuse/misuse and, as necessary, introduces remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

The DUR Board, consisting of six physicians, six pharmacists, one consumer advocate, two non-voting members of the Department and two Pharmaceutical Representatives has reviewed and supports the Department's plan to implement quantity limits on opioids. This notice provides important details on how physicians and patients will continue to access Medicaid pharmaceutical benefits with quantity limits in place. There will be a stepwise implementation beginning April 1st, 2015 with full implementation of the quantity limit set at 6 per day for each medication listed below by November 1st, 2015.

You are receiving this notice because Department records indicate that you have prescribed an opioid listed below to Medicaid beneficiaries during the past 90 days. Included, you will find documentation on how to access the North Dakota NDC Drug Lookup website. This website provides current drug coverage information, including access to quantity limit information.

DIRECTIONS FOR PHYSICIANS

The quantity limit implementation includes:

- Hydrocodone /Acetaminophen 5-325mg and 10-325mg
- Hydromorphone 2mg and 4mg
- Oxycodone 5mg, 15mg, and 30mg
- Oxycodone /Acetaminophen 5-325mg and 10-325mg

Note the implementation dates and quantity limits below.

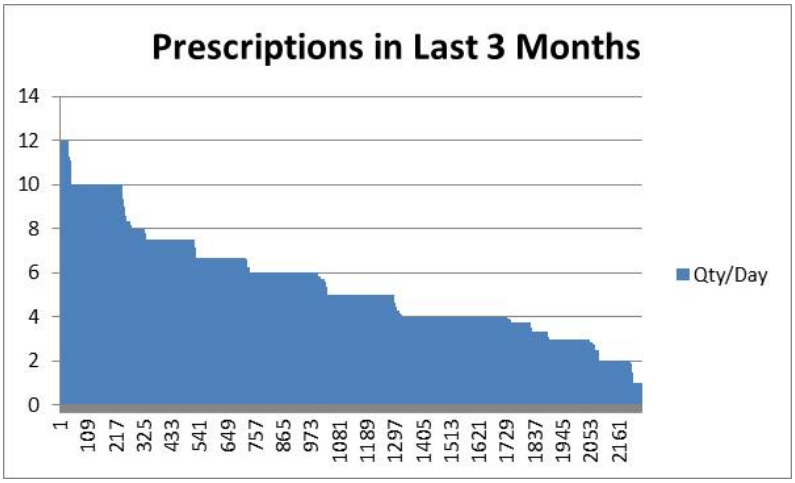
As the prescribing physician, when you prescribe one of the medications listed above for your patient/s, the quantity must not exceed the defined limits or the Department will deny the claim at the pharmacy. Please consider options such as splitting tablets, using higher strengths, and using extended release products as appropriate. Extended release product cost information is included to guide cost effective decisions.

For additional information regarding the implementation of quantity limits, please contact Brendan Joyce, PharmD, DHS Director of Pharmaceutical Services, at (701) 328-4023.

Hydrocodone/Acetaminophen

Hydrocodone/Acetaminophen 5-325mg

Cost: $0.15830 per tablet

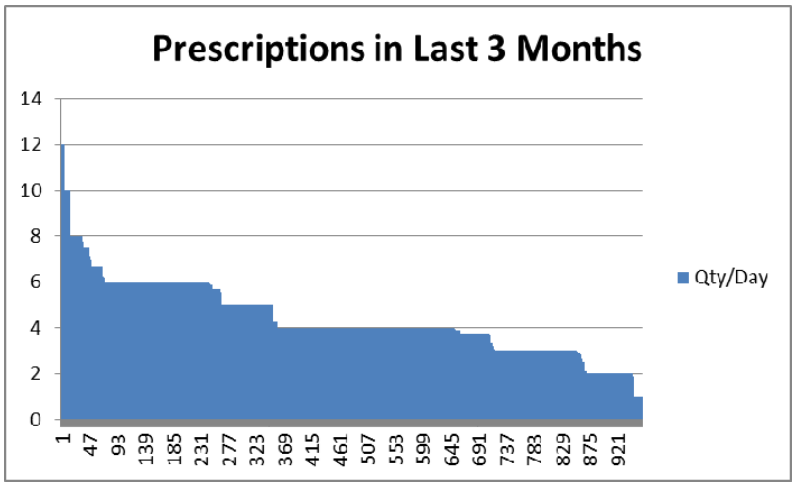


Schedule of Implementation:

April 1st, 2015:	10/day
July 1st, 2015:	8/day
September 1st, 2015:	6/day

Hydrocodone/Acetaminophen 10-325mg

Cost: $0.44210 per tablet



Schedule of Implementation:

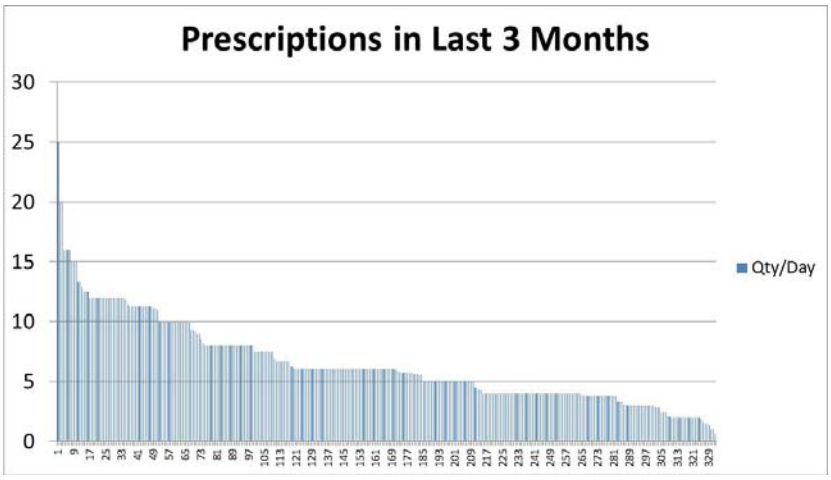
April 1st, 2015:	10/day
July 1st, 2015:	8/day
November 1st, 2015:	6/day

Oxycodone

Oxycodone 5 mg

Cost: $0.20219 per tablet

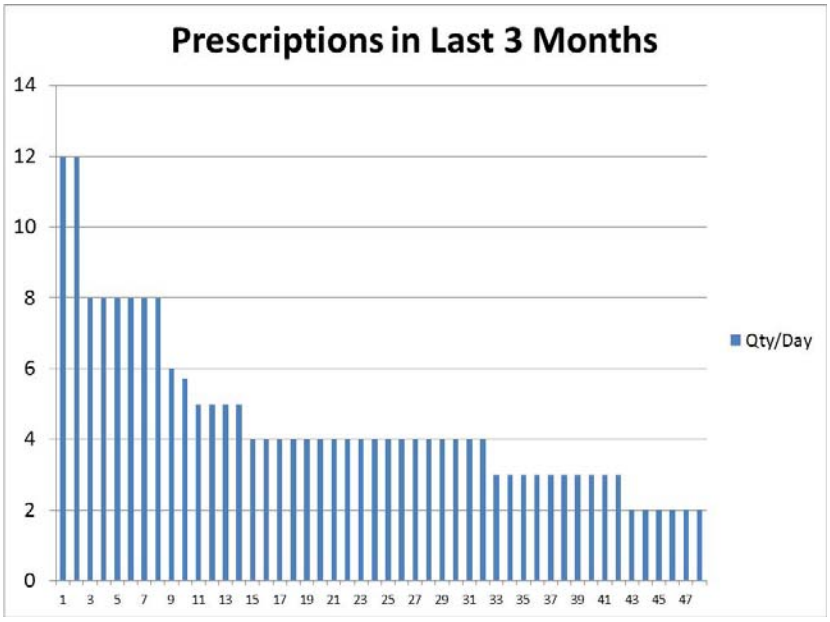
Schedule of Implementation:
April 1st, 2015: 10/day
July 1st, 2015: 8/day
September 1st, 2015: 6/day



Oxycodone 15mg

Cost: $0.25028 per tablet

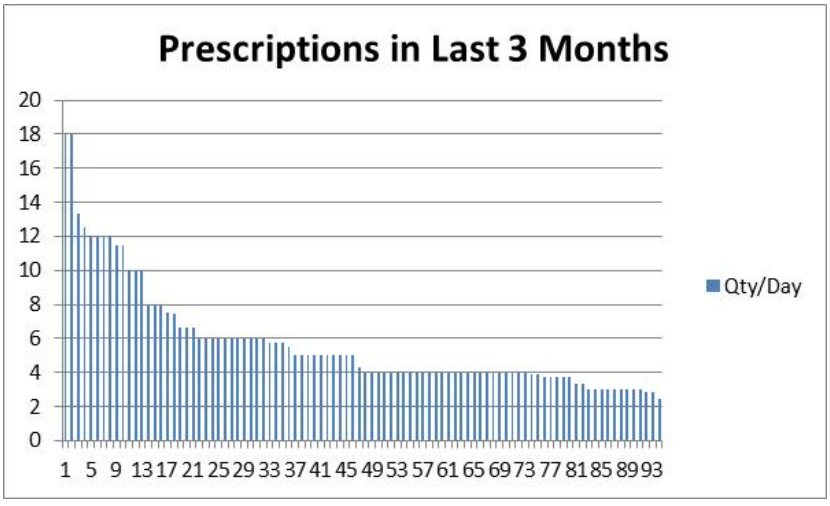
Schedule of Implementation:
April 1st, 2015: 8/day
July 1st, 2015: 6/day



Oxycodone 30 mg

Cost: $0.46800 per tablet

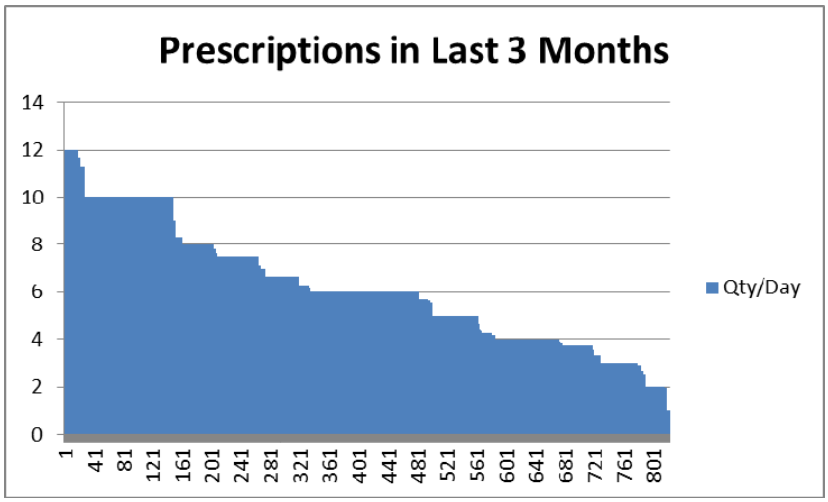
Schedule of Implementation:
April 1st, 2015: 12/day
July 1st, 2015: 10/day
September 1st, 2015: 8/day
November 1st, 2015: 6/day



Oxycodone/Acetaminophen

Oxycodone/Acetaminophen 5/325mg

Cost: $0.235 per tablet

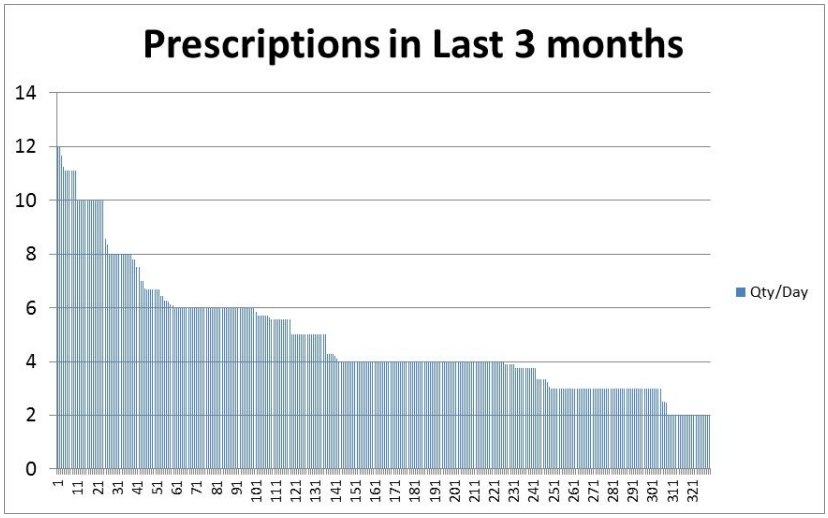


Schedule of Implementation:

April 1st, 2015:	10/day
July 1st, 2015:	8/day
September 1st, 2015:	6/day

Oxycodone/Acetaminophen 10/325mg

Cost: $0.8752 per tablet



Schedule of Implementation:

April 1st, 2015:	10/day
July 1st, 2015:	8/day
September 1st, 2015:	6/day

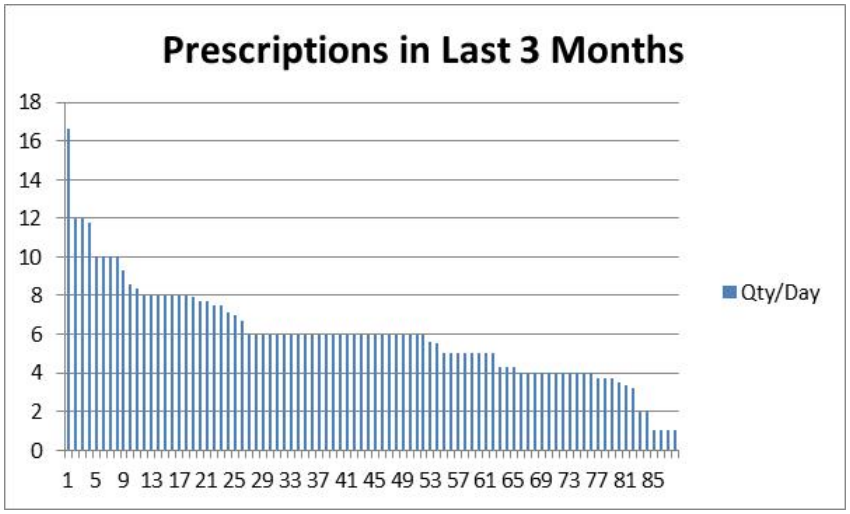
Hydromorphone

Hydromorphone 2mg

Cost: $0.121 per tablet

Schedule of Implementation:

April 1st, 2015:	12/day
July 1st, 2015:	10/day
September 1st, 2015:	8/day
November 1st, 2015:	6/day

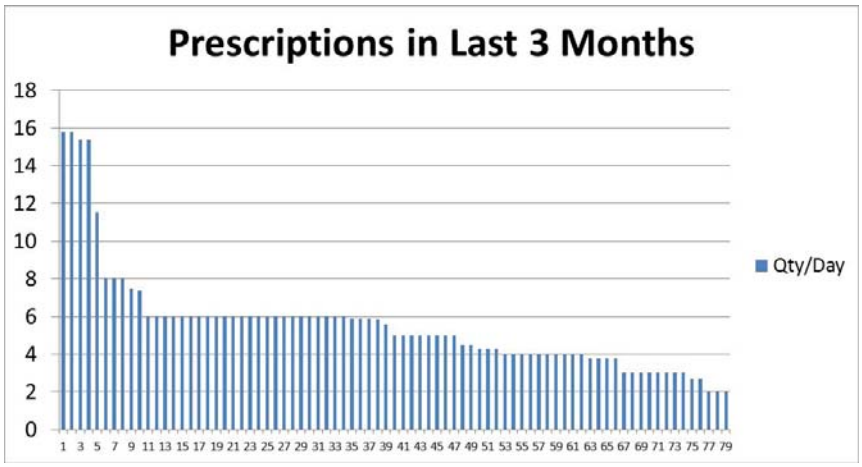


Hydromorphone 4mg

Cost: $0.207 per tablet

Schedule of Implementation:

April 1st, 2015:	8/day
July 1st, 2015:	6/day



Long-Acting Opioid Costs

*Prices are calculated with indicated frequency. Actual cost may vary.

Do NOT Require Prior Authorization

MS Contin (Twice Daily)
MS Contin 15mg: $32.84
MS Contin 30mg: $54.12
MS Contin 60 mg: $100.50
MS Contin 100mg: $174.54
MS Contin 200mg: $327.60

Morphine Sulfate Tablets ER (Twice Daily)
Morphine Sulfate ER 15mg: $32.84
Morphine Sulfate ER 30mg: $54.12
Morphine Sulfate ER 60mg: $100.50
Morphine Sulfate ER 100mg: $174.54
Morphine Sulfate ER 200mg: $327.60

Fentanyl Patch (Every 3 Days)
Fentanyl 12mcg/hr: $143.70
Fentanyl 25mcg/hr: $44.69
Fentanyl 50mcg/hr: $78.54
Fentanyl 75mcg/hr: $100.12
Fentanyl 100mcg/hr: $120.23

Require Prior Authorization

Oxycodone ER (Twice Daily)
Oxycodone 10mg ER $76.09
Oxycodone 20mg ER $145.61
Oxycodone 40mg ER $433.64
Oxycodone 80mg ER $815.45

Avinza (Daily)
Avinza 30mg: $171.89
Avinza 45mg: $254.87
Avinza 60mg: $333.79
Avinza 75mg: $424.77
Avinza 90mg: $501.88
Avinza 120mg: $592.16

Kadian (Daily)
Kadian 10mg: $189.22
Kadian 20mg: $129.90
Kadian 30mg: $141.00
Kadian 40mg: $303.26
Kadian 50mg: $232.50
Kadian 60mg: $277.20
Kadian 70mg: $530.71
Kadian 80mg: $368.10
Kadian 100mg: $460.50
Kadian 130mg: $988.20
Kadian 150mg: $1140.16
Kadian 200mg: $1535.76

Oxycontin (Twice Daily)
Oxycontin 10mg: $174.42
Oxycontin 15mg: $256.79
Oxycontin 20mg: $325.29
Oxycontin 30mg: $452.40
Oxycontin 40mg: $557.10
Oxycontin 60mg: $804.96
Oxycontin 80mg: $972.12

Zyhydro ER (Twice Daily)
Zohydro ER 10mg: $398.03
Zohydro ER 15mg: $425.25
Zohydro ER 20mg: $438.86
Zohydro ER 30mg: $452.47
Zohydro ER 40mg: $466.07
Zohydro ER 50 mg: $486.49

Hysingla ER (Daily)
Hysingla ER 20mg: $212.87
Hysingla ER 30mg: $310.71
Hysingla ER 40 mg: $418.61
Hysingla ER 60 mg: $579.64
Hysingla ER 80 mg: $781.49
Hysingla ER 100mg: $994.36
Hysingla ER 120mg: $1101.92

Morphine Sulfate Capsules ER (Daily)
Morphine Sulfate ER 10mg: $122.66
Morphine Sulfate ER 20mg: $129.90
Morphine Sulfate ER 30mg: $148.50
Morphine Sulfate ER 45mg: $220.20
Morphine Sulfate ER 50mg: $232.50
Morphine Sulfate ER 60mg: $277.20
Morphine Sulfate ER 75mg: $367.00
Morphine Sulfate ER 80mg: $368.10
Morphine Sulfate ER 90mg: $433.62
Morphine Sulfate ER 100mg: $460.50
Morphine Sulfate ER 120mg: $544.63

Fentanyl Patch (Every 3 Days)
Fentanyl 37.5mcg/hr: $587.82
Fentanyl 62.5mcg/hr: $854.15
Fentanyl 87.5mcg/hr: $1162.94

Hydromorphone ER (Daily)
Hydromorphone ER 8mg $365.58
Hydromorphone ER 12mg $548.36
Hydromorphone ER 16mg $731.15
Hydromorphone ER 32mg $1462.30

REVIEW OF BENZODIAZEPINE USE IN COMBINATION WITH OPIOID PAIN RELIEVERS

OVERVIEW:

Benzodiazepines are prescription drugs used to treat anxiety, sleep disorders, and drug/alcohol withdrawal symptoms. Benzodiazepines can enhance the effects of drugs, such as narcotic pain relievers, when used together. Emergency department and substance abuse treatment data show that benzodiazepines and narcotics are commonly used together. Between 2000 and 2010, substance abuse treatment admissions for combined benzodiazepines and narcotic pain reliever abuse jumped almost 570%-from 5,032 in 2000 to 33,701 in 2010. These figures come from the Treatment Episode Data Set (TEDS) Report issued by the Substance Abuse and Mental Health Services Administration (SAMHSA). TEDS describes the people who co-abuse the two drugs as a "high-need, treatment-resistant population." This population reports more severe withdrawal symptoms and higher treatment failure rates than people withdrawing from narcotic pain medications alone.

DEMOGRAPHIC CHARACTERISTICS OF BENZODIAZEPINE AND NARCOTIC COMBINATION ADMISSIONS:

- Non-Hispanic White 91.4%
- Female 49.2%
- Male 50.8%
- Unemployed 46.4%
- Not in labor force 37.0%
- Not insured 58.7%
- Age group 18-34 66.9%

MANAGEMENT:

- Drug-drug edits
- Drug treatment plans
- Prescription drug monitoring reports
- Quantity and duration limits
- Increased awareness between prescribers and patients

References:

1. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (December 13, 2012). *The TEDS Report: Admissions Reporting Benzodiazepine and Narcotic Pain Reliever Abuse at Treatment Entry*. Rockville, MD.
2. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (December 18, 2014). The DAWN Report: Benzodiazepines in Combination with Opioid Pain Relievers or Alcohol: Greater Risk of More Serious ED Visit Outcomes. Rockville, MD.

North Dakota Medicaid
Concomitant Therapy
Narcotics/Benzodiazepines
12/1/14 - 2/1/15

Row Labels	ALPRAZOLAM 0.25 MG	ALPRAZOLAM 0.5 MG	ALPRAZOLAM 1 MG	ALPRAZOLAM 2 MG	ALPRAZOLAM ER 1 MG	ALPRAZOLAM ER 2 MG
ACETAMINOPHEN-COD #3 TABLET		2				
ACETAMINOPHEN-COD #4 TABLET						
ACETAMINOPHEN-CODEINE SOLUTION						
BUTORPHANOL 10 MG/ML SPRAY						
FENTANYL 100 MCG/HR PATCH						
FENTANYL 12 MCG/HR PATCH		1	2			
FENTANYL 25 MCG/HR PATCH		4				
FENTANYL 50 MCG/HR PATCH		6				
FENTANYL 75 MCG/HR PATCH						
HYDROCODON-ACETAMIN 7.5-325/15						
HYDROCODON-ACETAMINOPH 7.5-325						
HYDROCODON-ACETAMINOPHEN 5-325	19	37	33	5		2
HYDROCODON-ACETAMINOPHN 10-325	2	23	31	5		
HYDROCODONE-IBUPROFEN 7.5-200						
HYDROMORPHONE 2 MG TABLET	2	2	3			
HYDROMORPHONE 4 MG TABLET			3			
MEPERIDINE 50 MG TABLET						
METHADONE 5 MG/5 ML SOLUTION						
METHADONE HCL 10 MG TABLET		3	3			
METHADONE HCL 5 MG TABLET		3	1			
MORPHINE SULF 100 MG/5 ML SOLN						
MORPHINE SULF ER 15 MG TABLET	1	3	1			
MORPHINE SULF ER 30 MG TABLET		2				
MORPHINE SULFATE ER 30 MG CAP						
MORPHINE SULFATE IR 15 MG TAB		2				
NUCYNTA 75 MG TABLET						
OXYCODONE HCL 10 MG TABLET	1	1	9			
OXYCODONE HCL 15 MG TABLET			2			
OXYCODONE HCL 30 MG TABLET		2	2			
OXYCODONE HCL 5 MG TABLET	3	15	12	4		
OXYCODONE HCL 5 MG/5 ML SOLN						
OXYCODONE-ACETAMINOPHEN 10-325	1	6	19	2		
OXYCODONE-ACETAMINOPHEN 5-325	3	20	15	2		
OXYCONTIN 20 MG TABLET						
OXYCONTIN 40 MG TABLET		1	1			
OXYMORPHONE HCL 5 MG TABLET						
TRAMADOL ER 300 MG TABLET			2		2	
TRAMADOL HCL 50 MG TABLET	11	23	22	3		
TRAMADOL-ACETAMINOPHN 37.5-325						
ZOHYDRO ER 20 MG CAPSULE		2				
Grand Total	43	158	161	21	2	2

North Dakota Medicaid
Concomitant Therapy
Narcotics/Benzodiazepines
12/1/14 - 2/1/15

Row Labels	ALPRAZOLAM ER 3 MG	ALPRAZOLAM XR 1 MG	ALPRAZOLAM XR 2 MG	CHLORDIAZEPOXIDE 25 MG	CLONAZEPAM 0.25 MG ODT	CLONAZEPAM 0.5 MG
ACETAMINOPHEN-COD #3 TABLET						6
ACETAMINOPHEN-COD #4 TABLET						
ACETAMINOPHEN-CODEINE SOLUTION					1	
BUTORPHANOL 10 MG/ML SPRAY						
FENTANYL 100 MCG/HR PATCH						
FENTANYL 12 MCG/HR PATCH						
FENTANYL 25 MCG/HR PATCH						
FENTANYL 50 MCG/HR PATCH						
FENTANYL 75 MCG/HR PATCH						
HYDROCODON-ACETAMIN 7.5-325/15						
HYDROCODON-ACETAMINOPH 7.5-325						1
HYDROCODON-ACETAMINOPHEN 5-325	2			2		36
HYDROCODON-ACETAMINOPHN 10-325						24
HYDROCODONE-IBUPROFEN 7.5-200						6
HYDROMORPHONE 2 MG TABLET	2					6
HYDROMORPHONE 4 MG TABLET						
MEPERIDINE 50 MG TABLET						
METHADONE 5 MG/5 ML SOLUTION						
METHADONE HCL 10 MG TABLET						
METHADONE HCL 5 MG TABLET						
MORPHINE SULF 100 MG/5 ML SOLN						
MORPHINE SULF ER 15 MG TABLET						2
MORPHINE SULF ER 30 MG TABLET						1
MORPHINE SULFATE ER 30 MG CAP						3
MORPHINE SULFATE IR 15 MG TAB						2
NUCYNTA 75 MG TABLET						
OXYCODONE HCL 10 MG TABLET						
OXYCODONE HCL 15 MG TABLET						
OXYCODONE HCL 30 MG TABLET						
OXYCODONE HCL 5 MG TABLET						4
OXYCODONE HCL 5 MG/5 ML SOLN						
OXYCODONE-ACETAMINOPHEN 10-325						10
OXYCODONE-ACETAMINOPHEN 5-325						11
OXYCONTIN 20 MG TABLET						
OXYCONTIN 40 MG TABLET						
OXYMORPHONE HCL 5 MG TABLET						2
TRAMADOL ER 300 MG TABLET						
TRAMADOL HCL 50 MG TABLET		1	2			23
TRAMADOL-ACETAMINOPHN 37.5-325						
ZOHYDRO ER 20 MG CAPSULE						
Grand Total	4	1	2	2	1	137

North Dakota Medicaid
Concomitant Therapy
Narcotics/Benzodiazepines
12/1/14 - 2/1/15

Row Labels	CLONAZEPAM 1 MG	CLONAZEPAM 2 MG	DIAZEPAM 10 MG	DIAZEPAM 2 MG	DIAZEPAM 5 MG	DIAZEPAM 5 MG/5 ML SOLUTION
ACETAMINOPHEN-COD #3 TABLET	3				2	
ACETAMINOPHEN-COD #4 TABLET			2			
ACETAMINOPHEN-CODEINE SOLUTION			1			
BUTORPHANOL 10 MG/ML SPRAY						
FENTANYL 100 MCG/HR PATCH						
FENTANYL 12 MCG/HR PATCH						
FENTANYL 25 MCG/HR PATCH	2		2			
FENTANYL 50 MCG/HR PATCH	2	2	2			
FENTANYL 75 MCG/HR PATCH	1		1		2	
HYDROCODON-ACETAMIN 7.5-325/15	2				1	1
HYDROCODON-ACETAMINOPH 7.5-325						
HYDROCODON-ACETAMINOPHEN 5-325	30		4	1	30	
HYDROCODON-ACETAMINOPHN 10-325	13	6	9	1	11	
HYDROCODONE-IBUPROFEN 7.5-200	2		2		1	
HYDROMORPHONE 2 MG TABLET	2		1		4	
HYDROMORPHONE 4 MG TABLET	2				2	
MEPERIDINE 50 MG TABLET			1			
METHADONE 5 MG/5 ML SOLUTION						
METHADONE HCL 10 MG TABLET	8				1	
METHADONE HCL 5 MG TABLET						
MORPHINE SULF 100 MG/5 ML SOLN	1					
MORPHINE SULF ER 15 MG TABLET	2					
MORPHINE SULF ER 30 MG TABLET						
MORPHINE SULFATE ER 30 MG CAP						
MORPHINE SULFATE IR 15 MG TAB	5				1	
NUCYNTA 75 MG TABLET					2	
OXYCODONE HCL 10 MG TABLET	5				2	
OXYCODONE HCL 15 MG TABLET	3					
OXYCODONE HCL 30 MG TABLET				1	2	
OXYCODONE HCL 5 MG TABLET	12			1	8	
OXYCODONE HCL 5 MG/5 ML SOLN					2	1
OXYCODONE-ACETAMINOPHEN 10-325	6	8	3		9	
OXYCODONE-ACETAMINOPHEN 5-325	12	6	5	1	6	
OXYCONTIN 20 MG TABLET	3					
OXYCONTIN 40 MG TABLET	1		3			
OXYMORPHONE HCL 5 MG TABLET						
TRAMADOL ER 300 MG TABLET						
TRAMADOL HCL 50 MG TABLET	41	1	1		2	
TRAMADOL-ACETAMINOPHN 37.5-325			3			
ZOHYDRO ER 20 MG CAPSULE						
Grand Total	158	23	40	5	88	2

North Dakota Medicaid
Concomitant Therapy
Narcotics/Benzodiazepines
12/1/14 - 2/1/15

Row Labels	DIAZEPAM 5 MG/ML ORAL CONC	LORAZEPAM 0.5 MG	LORAZEPAM 1 MG	LORAZEPAM 2 MG	LORAZEPAM INTENSOL 2 MG/ML	Grand Total
ACETAMINOPHEN-COD #3 TABLET			9			22
ACETAMINOPHEN-COD #4 TABLET						2
ACETAMINOPHEN-CODEINE SOLUTION		1			1	4
BUTORPHANOL 10 MG/ML SPRAY			5			5
FENTANYL 100 MCG/HR PATCH		3				3
FENTANYL 12 MCG/HR PATCH	1					4
FENTANYL 25 MCG/HR PATCH		2				10
FENTANYL 50 MCG/HR PATCH		1	1			14
FENTANYL 75 MCG/HR PATCH			2	2		8
HYDROCODON-ACETAMIN 7.5-325/15						4
HYDROCODON-ACETAMINOPH 7.5-325						1
HYDROCODON-ACETAMINOPHEN 5-325		36	42	3		282
HYDROCODON-ACETAMINOPHN 10-325		19	31	3		178
HYDROCODONE-IBUPROFEN 7.5-200		1		1		13
HYDROMORPHONE 2 MG TABLET		2	2			26
HYDROMORPHONE 4 MG TABLET		5	5			17
MEPERIDINE 50 MG TABLET						1
METHADONE 5 MG/5 ML SOLUTION					2	2
METHADONE HCL 10 MG TABLET			5			20
METHADONE HCL 5 MG TABLET			1			5
MORPHINE SULF 100 MG/5 ML SOLN		4	1			6
MORPHINE SULF ER 15 MG TABLET			2			11
MORPHINE SULF ER 30 MG TABLET		1				4
MORPHINE SULFATE ER 30 MG CAP						3
MORPHINE SULFATE IR 15 MG TAB		2	7			19
NUCYNTA 75 MG TABLET						2
OXYCODONE HCL 10 MG TABLET		4	3			25
OXYCODONE HCL 15 MG TABLET		1	3			9
OXYCODONE HCL 30 MG TABLET						7
OXYCODONE HCL 5 MG TABLET		8	8		1	76
OXYCODONE HCL 5 MG/5 ML SOLN						3
OXYCODONE-ACETAMINOPHEN 10-325		3	16	2		85
OXYCODONE-ACETAMINOPHEN 5-325		7	21			109
OXYCONTIN 20 MG TABLET		3				6
OXYCONTIN 40 MG TABLET		1				7
OXYMORPHONE HCL 5 MG TABLET						2
TRAMADOL ER 300 MG TABLET						4
TRAMADOL HCL 50 MG TABLET		20	24	1		175
TRAMADOL-ACETAMINOPHN 37.5-325		1	2			6
ZOHYDRO ER 20 MG CAPSULE						2
Grand Total	1	125	190	12	4	1182

North Dakota Medicaid
Concomitant Therapy
Narcotics/Benzodiazepines
12/1/14 – 2/1/15

Plan for edits to decrease concomitant use of narcotics and benzodiazepines

Phase 1

Alprazolam ER = 11

Clonazepam ODT = 1

Chlordiazepoxide = 2

Diazepam 2mg = 5

Phase 2

Lorazepam 2mg = 12

Diazepam 10mg = 40

Alprazolam 2mg = 21

Clonazepam 2mg = 23

Phase 3

Alprazolam 0.25mg = 43

Diazepam 5mg = 88

Phase 4

Clonazepam 0.5mg = 137

Clonazepam 1 mg = 158

Lorazepam 0.5mg = 125

Lorazepam 1mg = 190

Alprazolam 0.5mg = 158

Alprazolam 1mg = 161

PRODUCT DETAILS OF NEW CHOLESTEROL LOWERING DRUGS

OVERVIEW:
PCSK9 inhibitors belong to a new class of cholesterol-lowering drugs currently undergoing FDA review prior to approval. These new agents target and inactivate proprotein convertase subtilisin kexin 9 (PCSK9) to lower LDL-uptake from circulation, and thus reduce hypercholesterolemia and associated atherosclerosis.

In 2013, lipid regulators accounted for 13.6 billion dollars of the annual US prescription drug expenditure; the7th highest category. Statins are the most common class of medications used to treat patients with high cholesterol. Statins include atorvastatin, simvastatin, pravastatin, lovastatin, and rosuvastatin. In addition to being highly effective, they are generally safe and well-tolerated for most people. Due to patent expirations in the statin class, the cost for statins has dropped dramatically, in recent years.

COST:

- Analysts are projecting costs somewhere between $5,000 and $15,000 per year for PCSK9 inhibitors.
- PCSK9 inhibitors could have 5 billion dollars in US sales one year after launch without CV outcomes information, and around 12 billion dollars in US sales by 2019 if CV outcomes trials support their use.
- ND Medicaid spent approximately 218 thousand dollars in 2014 for statins. The average cost per script was 22 dollars.

MANAGEMENT

New biological drugs, like PCSK9 inhibitors, are rapidly entering the market. It is important to monitor this process closely and to have a plan as soon as they appear. While we know that statins reduce cholesterol with long-term effects on cardiovascular disease, the studies required to demonstrate long-term effects with the new agents will take years.

PCSK9 inhibitors can be managed by step therapy/prior authorization. This will ensure that they are used in the patients they are intended for; patients that cannot tolerate the statins or whose cholesterol levels remain uncontrolled.

References:

1. IMS Institute for Healthcare Informatics. Medicine use and shifting costs of healthcare. April 2014. Accessed online May 7, 2015.
2. Medical Marketing and Media. Analyst gives PCSK9 preview. March 2014. Accessed online May 7, 2015.

Statins
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed a name-brand statin must first try a generic statin.
Note:

- ***Generic statins already on the market do not require a prior authorization***

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:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
PHONE 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)	

PRODUCT DETAILS OF SKELETAL MUSCLE RELAXANTS

INDICATIONS:

Drug	Indication
Baclofen	For the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
Carisoprodol, Chlorzoxazone, Cyclobenzaprine, Methocarbamol, Metaxalone, Orphenadrine	As an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.
Dantrolene	Controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders (e.g., spinal cord injury, stroke, cerebral palsy, or multiple sclerosis).
Tizanidine	For the management of spasticity.

UTILIZATION:

ND Medicaid Skeletal Muscle Relaxant Utilization		
01/01/14 - 12/31/14		
CARISOPRODOL 350 MG TABLET	301	$2,590.35
CHLORZOXAZONE 500 MG TABLET	14	$111.07
CYCLOBENZAPRINE 10 MG TABLET	4231	$28,701.84
CYCLOBENZAPRINE 5 MG TABLET	428	$2,753.65
METAXALONE 800 MG TABLET	269	$53,315.26
METHOCARBAMOL 500 MG TABLET	350	$3,736.76
METHOCARBAMOL 750 MG TABLET	197	$2,598.36
TIZANIDINE HCL 2 MG TABLET	85	$910.27
TIZANIDINE HCL 4 MG CAPSULE	1	$183.77
TIZANIDINE HCL 4 MG TABLET	1497	$34,387.76
2,675 recipients	**7373**	**$129,289.09**

MANAGEMENT

- Quantity limits
- Carisoprodol annual limits
- Step therapy

References:

1. Facts & Comparisons eAnswers. 2015 Clinical Drug Information, LLC.

CARISOPRODOL PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients using carisoprodol 350mg longer than two times per year (272 tablets) must receive a prior authorization. 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	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ CARISOPRODOL	**Diagnosis for this request:**		
Qualifications for coverage:			
□ CHRONIC CARISOPRODOL RECIPIENT BEING WEANED (PLEASE INCLUDE WEANING SCHEDULE)	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.*			
Physician 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)	

PRODUCT DETAILS OF INJECTABLE ANTICOAGULANTS

INDICATIONS:

Drug	Indication
Fragmin (dalteparin)	• Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction. • Prophylaxis of deep vein thrombosis (DVT) in abdominal surgery, hip replacement surgery, or medical patients with severely restricted mobility during acute illness. • Extended treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence in patients with cancer. In these patients, the Fragmin therapy begins with the initial VTE treatment and continues for six months.
Lovenox (enoxaparin)	• Prophylaxis of DVT in abdominal surgery, hip replacement surgery, knee replacement surgery, or medical patients with severely restricted mobility during acute illness. • Inpatient treatment of acute DVT with or without pulmonary embolism (PE). • Outpatient treatment of acute DVT without pulmonary embolism. • Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI). • Treatment of acute ST-segment elevation myocardial infarction (STEMI) managed medically or with subsequent percutaneous coronary intervention (PCI).
Arixtra (fondaparinux)	• Prophylaxis of VTE for up to one month post-surgery in patients undergoing orthopedic surgeries of the lower limbs such as hip fracture, knee surgery, or hip replacement surgery. • Prophylaxis of VTE in patients undergoing abdominal surgery who are at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery. • Treatment of acute DVT and treatment of acute PE. • Management of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) for the prevention of death and subsequent myocardial infarction. • Management of STEMI for the prevention of death and myocardial reinfarction in patients who are managed with thrombolytics or who initially are to receive no form of reperfusion therapy.

UTILIZATION:

ND Medicaid Injectable Anticoagulants		
01/01/14 - 12/31/14		
Label Name	**Rx Num**	**Total Reimb Amt**
ENOXAPARIN 100 MG/ML SYRINGE	55	$41,480.37
ENOXAPARIN 120 MG/0.8 ML SYR	40	$39,318.05
ENOXAPARIN 150 MG/ML SYRINGE	7	$2,291.09
ENOXAPARIN 30 MG/0.3 ML SYR	10	$1,865.49
ENOXAPARIN 300 MG/3 ML VIAL	4	$1,163.36
ENOXAPARIN 40 MG/0.4 ML SYR	106	$18,371.68
ENOXAPARIN 60 MG/0.6 ML SYR	50	$14,404.59
ENOXAPARIN 80 MG/0.8 ML SYR	65	$30,717.96
FONDAPARINUX 10 MG/0.8 ML SYR	1	$2,064.80
FRAGMIN 5,000 UNITS/0.2 ML SYR	5	$5,310.55
LOVENOX 30 MG/0.3 ML SYRINGE	1	$90.39
LOVENOX 300 MG/3 ML VIAL	1	$224.81
LOVENOX 40 MG/0.4 ML SYRINGE	2	$1,509.52
LOVENOX 60 MG/0.6 ML SYRINGE	1	$1,506.71
148 recipients	**348**	**$160,319.37**

MANAGEMENT

- Quantity limits
- Step therapy
- Prior Authorization for diagnosis

References:

1. Facts & Comparisons eAnswers. 2015 Clinical Drug Information, LLC.

PRODUCT DETAILS OF AKYNZEO (NETUPITANT/PALONOSETRON)

INDICATIONS AND USE: Akynzeo is a fixed combination of netupitant, a substance P/neurokinin 1 (NK_1) receptor antagonist and palonosetron, a serotonin-3 ($5\text{-}HT_3$) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

DOSAGE FORMS: Capsule: 300 mg netupitant/0.5 mg palonosetron.

ADMINISTRATION:

- One capsule administered approximately 1 hour prior to the start of chemotherapy.

WARNINGS AND PRECAUTIONS:

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron with or without known hypersensitivity to other $5\text{-}HT_3$ receptor antagonists.
- Serotonin syndrome has been reported with $5\text{-}HT_3$ receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

USE IN SPECIFIC POPULATIONS:

- Avoid use in patients with severe hepatic impairment.
- Avoid use in patients with severe renal impairment or end-stage renal disease.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥3%) are headache, asthenia, dyspepsia, fatigue, constipation, and erythema.

DRUG INTERACTIONS:

- Inhibition of CYP3A4 by netupitant can result in increased plasma concentrations of the concomitant drug that can last at least 4 days and may last longer after single dosage administration of Akynzeo; use with caution.
- Inducers of CYP3A4 decreased plasma concentrations of netupitant; avoid use.

PATIENT COUNSELING INFORMATION:

- Take with or without food approximately 1 hour prior to the start of chemotherapy.
- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron. Seek immediate medical attention if any signs or symptoms of hypersensitivity reaction occur.
- Seek immediate medical attention if the following symptoms occur: changes in mental status, autonomic instability, or neuromuscular symptoms.

COST

- Akynzeo costs approximately $540 dollars per capsule.

References:

1. Akynzeo [package insert]. Woodcliff Lake, NJ: Eisai Inc., October 2014.

PRODUCT DETAILS OF NUVESSA (METRONIDAZOLE VAGINAL GEL 1.3%)

INDICATIONS AND USE: Nuvessa is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in non-pregnant women.

DOSAGE FORMS: Vaginal gel – 65 mg of metronidazole in 6 grams of gel (1.3%) in a prefilled applicator.

ADMINISTRATION:

- A single-dose, pre-filled disposable applicator administered once intravaginally at bedtime.

WARNINGS AND PRECAUTIONS:

- Convulsive seizures and peripheral neuropathy have been reported in patients treated with oral or intravenous metronidazole. Discontinue promptly if abnormal neurologic signs develop.
- Metronidazole may interfere with certain serum chemistry lab values.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 1%) were vulvovaginal candidiasis, headache, vulvovaginal pruritus, nausea, diarrhea, and dysmenorrhea.

DRUG INTERACTIONS:

- Prolonged anticoagulant effects of warfarin and other coumarin anticoagulants have been reported with co-administration of oral metronidazole.
- Elevated plasma lithium concentrations have been reported with oral metronidazole.

PATIENT COUNSELING INFORMATION:

- Do not consume alcoholic beverages and preparations containing ethanol or propylene glycol during and for at least 24 hours after treatment.
- Do not use if disulfiram has been used within the last two weeks, and inform the healthcare provider if taking oral anticoagulants or lithium.
- Do not engage in vaginal intercourse, or use other vaginal products, following the single administration.
- Consider discontinuing milk feeding or pump and discard the milk during treatment and for 24 hours after treatment.
- Discontinue use and consult a healthcare provider if vaginal irritation occurs.

COST

- Nuvessa 1.3% costs approximately $165 per treatment.

References:

1. Nuvessa [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2015.

PRODUCT DETAILS OF CHOLBAM (CHOLIC ACID)

INDICATIONS AND USE: Cholbam is a bile acid indicated for treatment of bile acid synthesis disorders due to single enzyme defects as well as adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.
DOSAGE FORMS: Capsules: 50 mg, 250 mg.

ADMINISTRATION:

- Take with food. Do not chew or crush the capsules.
- The recommended dosage is 10 to 15 mg/kg once daily or in two divided doses, in pediatric patients and adults.
- The recommended dosage in patients with concomitant familial hypertriglyceridemia is 11 to 17 mg/kg once daily or in two divided doses and is adjusted based on clinical response.
- Monitor AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next three years and annually thereafter. Administer the lowest dose that effectively maintains liver function.
- Discontinue Cholbam if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; continue to monitor liver function and consider restarting a lower dose when parameters return to baseline.

WARNINGS AND PRECAUTIONS:

- Monitor liver function and discontinue if liver function worsens while on treatment.

ADVERSE REACTIONS: The most common adverse reactions, occurring in ≥ 1%, are diarrhea, reflux esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy.

DRUG INTERACTIONS:

- Bile salt efflux pump (BSEP) inhibitors (e.g., cyclosporine): Avoid concomitant use; if concomitant use is necessary, monitor serum transaminases and bilirubin.
- Bile acid resins and aluminum-based antacids: Take at least one hour before or 4 to 6 hours after a bile acid binding resin or aluminum-based antacids.

PATIENT COUNSELING INFORMATION:

- Undergo laboratory testing periodically while on treatment to assess liver function.
- Cholbam may worsen liver impairment therefore immediately report any symptoms associated with liver impairment (e.g., skin or whites of the eyes turn yellow, urine turns dark or brown, pain on the right side of stomach, bleeding or bruising occurring more easily than normal, or increased lethargy).

COST

- Cholbam 250 mg approximately $890 per capsule.
- Cholbam 50 mg approximately $300 per capsule.

References:

1. Cholbam [package insert]. San Diego, CA: Manchester Pharmaceuticals, Inc.; March 2015.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2015

Criteria Recommendations ***Approved*** ***Rejected***

1. Dabigatran 150 mg / P-gp Inhibitors / CKD Stage 3 _____ _____

Alert Message: In patients with moderate renal impairment (CrCl 30-50 mL/min) consider reducing the dose of Pradaxa (dabigatran) to 75 mg twice daily when administered concomitantly with the P-gp inhibitor dronedarone or ketoconazole. Concurrent use of dabigatran with one of these agents in patients with moderate renal impairment is expected to produce increased dabigatran exposure greater than that seen with either factor (P-gp inhibition or renal impairment) alone.

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

Util A	Util B	Util C **(Include)**
Dabigatran 150mg	Dronedarone	CKD Stage 3
	Ketoconazole	

References:
Clinical Pharmacology, 2015 Elsevier/Gold Standard
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.

2. Dabigatran / P-gp Inhibitors / CKD Stage 4 & 5 _____ _____

Alert Message: Concurrent use of Pradaxa (dabigatran) and a P-gp inhibitor in patients with severe renal impairment (CrCl 15-30 mL/min) should be avoided. P-gp inhibition and impaired renal function are the major independent factors that result in increased dabigatran exposure. Concomitant use of dabigatran with a P-gp inhibitor in patients with severe renal impairment is expected to produce increased dabigatran exposure greater than that seen with either factor alone.

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

Util A	Util B	Util C **(Include)**
Dabigatran	Dronedarone	CKD Stage 4 & 5
	Ketoconazole	
	Itraconazole	
	Verapamil	
	Diltiazem	
	Amiodarone	
	Quinidine	
	Clarithromycin	
	Erythromycin	
	Ticagrelor	
	Ritonavir	
	Cyclosporine	
	Cobicistat	
	Nicardipine	
	Felodipine	
	Tacrolimus	

References:
Clinical Pharmacology, 2015 Elsevier/Gold Standard
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug InteractionaLabeling/ucm093664.htm

3. Namzaric / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Namzaric (memantine ER/donepezil). 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

Util A	Util B	Util C
Memantine ER/Donepezil		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Eng Jrnl Med. 2005;353:487-97.
Arlt S, Lindner R, Rosler A, et al., Adherence to Medication in Patients with Dementia, Predictors and Strategies for Improvement. Drugs Aging 2008;25(12):1033-1047.
Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.

4. Amphetamine Sulfate / Overutilization _____ _____

Alert Message: Evekeo (amphetamine sulfate) may be over-utilized. The usual dosing range for amphetamine sulfate for the treatment of narcolepsy is 5 to 60 mg per day in divided doses (intervals of 4 to 6 hours) depending on individual patient response. Doses exceeding the recommended range may increase the risk of adverse effects.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amphetamine		Narcolepsy

Max Dose: 60 mg/day

References:
Evekeo Prescribing Information, May 2014, Arbor Pharmaceuticals, Inc.

5. Amphetamine Sulfate / Overutilization _____ _____

Alert Message: Evekeo (amphetamine sulfate) may be over-utilized. The usual dosing range for amphetamine sulfate for the treatment of obesity is 5 to 30 mg per day in divided doses, 30 to 60 minutes before meals. Doses exceeding the recommended range may increase the risk of adverse effects.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amphetamine		Obesity

Max Dose: 30 mg/day

References:
Evekeo Prescribing Information, May 2014, Arbor Pharmaceuticals, Inc.

6. Amphetamine Sulfate / Obesity ≤ 11 yoa _____ _____

Alert Message: Evekeo (amphetamine sulfate) is not recommended for use as an anorectic agent in children under 12 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Amphetamine	Obesity	ADHD/ADD
		Narcolepsy

Age Range: 0-11 yoa

References:
Evekeo Prescribing Information, May 2014, Arbor Pharmaceuticals, Inc.

7. Tramadol - All / Certain CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of a tramadol-containing agent with a CYP3A4 inhibitor may result in increased tramadol plasma concentrations and risk of tramadol-related adverse effects (e.g., respiratory depression, sedation or serotonin syndrome) due to inhibition of tramadol CYP3A4-mediated metabolism. Monitor patient for therapeutic and adverse effects and adjust tramadol dose if necessary.

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

Util A	Util B	Util C
Tramadol	Nefazodone	
Tramadol/APAP	Ketoconazole	
	Itraconazole	
	Posaconazole	
	Voriconazole	
	Clarithromycin	
	Telithromycin	
	Erythromycin	
	Boceprevir	
	Telaprevir	

References:
Clinical Pharmacology, 2015 Elsevier/Gold Standard.
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.

8. Tramadol - All / CYP2D6 Inhibitors _____ _____

Alert Message: Concurrent use of a tramadol-containing agent with a CYP2D6 inhibitor may decrease the metabolism of tramadol to its M1 active metabolite leading to decreased analgesic effects and possible increased tramadol (parent drug) plasma concentrations. The patient may be at increased risk of adverse effects (e.g., respiratory depression, sedation or serotonin syndrome) due to elevated parent drug levels. Monitor patient for therapeutic and adverse effects and adjust tramadol dose if necessary.

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

Util A	Util B	Util C
Tramadol	Quinidine	
Tramadol/APAP	Propafenone	

References:
Clinical Pharmacology, 2015 Elsevier/Gold Standard.
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.

9. Tramadol – All / Dual CYP 3A4 & 2D6 Inhibitors _____ _____

Alert Message: Concurrent use of a tramadol-containing agent with a drug that inhibits both CYP3A4 and 2D6 mediated metabolism may result in elevated tramadol plasma concentrations and decreased levels of the tramadol active metabolite (M1). Clinical monitoring for tramadol therapeutic and adverse effects (e.g., serotonin syndrome and seizures) is recommended and tramadol dosage reduction may be required.

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

Util A	Util B	Util C
Tramadol	Ritonavir	
Tramadol/APAP	Delavirdine	
	Ranolazine	
	Imatinib	
	Amiodarone	

References:
Clinical Pharmacology, 2015 Elsevier/Gold Standard.
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.

10. Mitigare / Dual CYP3A4 & P-pg Inhibitors _____ _____

Alert Message: The concurrent use of Mitigare (colchicine capsules) with drugs that inhibit both P-gp and CYP3A4 is contraindicated in patients with renal or hepatic impairment. Combining these dual inhibitors with colchicine in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity.

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

Util A	Util B	Util C
Colchicine	Amiodarone	
	Ranolazine	
	Dronedarone	
	Verapamil	
	Diltiazem	
	Felodipine	
	Cobicistat	
	Nilotinib	
	Erythromycin	
	Clarithromycin	
	Ketoconazole	
	Itraconazole	
	Saquinavir	
	Ritonavir	
	Nelfinavir	
	Boceprevir	
	Telaprevir	

References:
Mitigare Prescribing Information, Sept. 2014, Hikma Americas, Inc.

11. Beclomethasone 40 mcg / Overutilization _____ _____
Alert Message: Children's QNASL (beclomethasone nasal aerosol) may be over-utilized. The manufacturer's recommended dose of beclomethasone nasal aerosol is 80 mcg per day administered as 1 actuation in each nostril once daily (maximum 2 actuations per day).

Drugs/Diseases
Util A Util B Util C
Beclomethasone 40 mcg

Max Dose: 80 mcg/day (1 canister per month – 60 actuations)

References:
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

12. Beclomethasone 40 mcg / Therapeutic Appropriateness 0-3 yoa _____ _____
Alert Message: The safety and effectiveness of Children's QNASL (beclomethasone nasal aerosol) in children less than 4 years of age have not been established.

Drugs/Diseases
Util A Util B Util C
Beclomethasone 40 mcg

Age Range: 0-3 yoa

References:
Facts & Comparisons, 2015 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

13. Umeclidinium / Overutilization _____ _____
Alert Message: The manufacturer's recommended dose of Incruse Ellipta (umeclidinium) is 1 inhalation (62.5 mcg) once daily by orally inhaled route only.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Umeclidinium

Max Dose: umeclidinium 62.5mcg per day

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.

14. Umeclidinium / Therapeutic Appropriateness (Age 0-18 yoa) _____ _____
Alert Message: The safety and efficacy of Incruse Ellipta (umeclidinium) in pediatric patients have not been established.

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

Age Range: 0-18 yoa

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.

15. Umeclidinium / Narrow Angle Glaucoma _____ _____

Alert Message: Incruse Ellipta (umeclidinium) should be used with caution in patients with narrow-angle glaucoma. Umeclidinium is an anticholinergic agent and its use in this patient population can worsen the condition.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Umeclidinium		Narrow Angle Glaucoma

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.

16. Umeclidinium / Urinary Retention _____ _____

Alert Message: Incruse Ellipta (umeclidinium) should be used with caution in patients with urinary retention. Umeclidinium is an anticholinergic agent and its use can worsen urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Umeclidinium	Urinary Retention	
	Bladder Neck Obstruction	
	Prostatic Hyperplasia	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.

17. Umeclidinium / Other Anticholinergics _____ _____

Alert Message: The concurrent use of Incruse Ellipta (umeclidinium) with anticholinergic agents should be avoided. Umeclidinium 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

Util A	Util B	Util C
Umeclidinium	Trihexyphenidyl	
	Benztropine	
	Orphenadrine	
	Darifenacin	
	Fesoterodine	
	Flavoxate	
	Oxybutynin	
	Solifenacin	
	Tolterodine	
	Trospium	
	Hyoscyamine	
	Scopolamine	
	Propantheline	
	Glycopyrrolate	
	Mepenzolate	
	Methscopolamine	
	Dicyclomine	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.

18. Umeclidinium / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Incruse Ellipta (umeclidinium). 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

Util A	Util B	Util C
Umeclidinium		

References:
Incruse Ellipta Prescribing Information, 2014, GlaxoSmithKline.
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. 2014 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.

19. Fluticasone Inhalation / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Arnuity Ellipta (fluticasone inhalation) in pediatric patients younger than 12 years of have not been established.

Conflict Code: TA – Therapeutic Appropriateness

Util A	Util B	Util C
Fluticasone Inhaled Powder		

Age Range: 0 – 11 yoa

References:
Arnuity Ellipta Prescribing Information, August 2014, GlaxoSmithKline.

20. Fluticasone Inhalation / Overutilization _____ _____

Alert Message: Arnuity Ellipta (fluticasone inhalation) may be over-utilized. The manufacturer recommended maximum dose is 200 mcg once daily. If a dosage regimen of fluticasone inhalation fails to provide adequate control of asthma, the therapeutic regimen should be re-evaluated and additional therapeutic options should be considered according to asthma guidelines.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C
Fluticasone Inhaled Powder		

Max Dose: 30 Blister packs/month

References:
Arnuity Ellipta Prescribing Information, August 2014, GlaxoSmithKline.

21. Fluticasone Inhalation / Therapeutic Appropriateness _____ _____

Alert Message: Arnuity Ellipta (fluticasone inhalation) should be used with caution in patients with moderate to severe hepatic impairment. In clinical studies fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment when compared with healthy subjects.

Conflict Code: TA – Therapeutic Appropriateness

Util A	Util B	Util C **(Include)**
Fluticasone Inhaled Powder		Hepatic Impairment

References:

Arnuity Ellipta Prescribing Information, August 2014, GlaxoSmithKline.

22. Fluticasone Inhalation / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Caution should be exercised when co-administering Arnuity Ellipta (fluticasone inhalation) with long-term ketoconazole or other know strong CYP3A4 inhibitors due to risk of increased systemic corticosteroid adverse effects. Fluticasone is a CYP3A4 substrate and inhibition of CYP3A4-mediated metabolism may result in elevated fluticasone exposure.

Conflict Code: DD – Drug/Drug Interactions

Drugs/Diseases

Util A	Util B	Util C
Fluticasone Inhaled Powder	Nefazodone	Ketoconazole
	Clarithromycin	Itraconazole
	Telithromycin	Posaconazole
	Saquinavir	Voriconazole
	Ritonavir	Boceprevir
	Nelfinavir	Telaprevir
	Indinavir	

References:

Arnuity Ellipta Prescribing Information, August 2014, GlaxoSmithKline.
FDA US Food and Drug Administration: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm

23. Empagliflozin/Linagliptin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Glyxambi (empagliflozin/linagliptin). 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
Empagliflozin/Linagliptin		

References:

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.

24. Empagliflozin/Linagliptin / Overutilization _____ _____

Alert Message: Glyxambi (empagliflozin/linagliptin) may be over-utilized. The manufacturer's recommended dose of the combination agent is empagliflozin 10 mg/ linagliptin 5mg once daily in the morning. Patients tolerating this dose may be increased to a maximum of 25 mg/5 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin		

Max Dose: 25mg/5mg per day

References:
Glyxambi Prescribing Information, Jan. 2015, Boehringer Ingelheim Pharmaceuticals, Inc.

25. Empagliflozin/Linagliptin / Mild to Moderate Renal Impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Glyxambi (empagliflozin/linagliptin) and periodically thereafter. No dosage adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m^2. Empagliflozin/linagliptin should not be initiated in patients with an eGFR less than 45 mL/min/1.73m^2 and should be discontinued if eGFR is persistently less than 45 mL/min/1.73m^2.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Empagliflozin/Linagliptin		CKD Stage 1
		CKD Stage 2
		CKD Stage 3

References:
Glyxambi Prescribing Information, Jan. 2015, Boehringer Ingelheim Pharmaceuticals, Inc. .

26. Empagliflozin/Linagliptin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Glyxambi (empagliflozin/linagliptin) use is contraindicated in patients with severe renal impairment, end-stage renal disease, or receiving dialysis. Based on its mechanism of action, inhibition of SGLT2 in the proximal renal tubules, the empagliflozin component of the combination product is not expected to be effective in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Empagliflozin/Linagliptin		ESRD
		CKD Stage 4 & 5
		Dialysis

References:
Glyxambi Prescribing Information, Jan. 2015, Boehringer Ingelheim Pharmaceuticals, Inc.

27. Empagliflozin/Linagliptin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Glyxambi (empagliflozin/linagliptin) in pediatric patients under 18 years of age have not been established

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin		

Age Range: 0-17 yoa

References:
Glyxambi Prescribing Information, Jan. 2015, Boehringer Ingelheim Pharmaceuticals, Inc.

28. Empagliflozin/Linagliptin / Insulin & Sulfonylureas _____ _____

Alert Message: The concurrent use of Glyxambi (empagliflozin/linagliptin) 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/linagliptin.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin	Insulins	
	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolazamide	
	Tolbutamide	

References:
Glyxambi Prescribing Information, Jan. 2015, Boehringer Ingelheim Pharmaceuticals, Inc.

29. Amiodarone / Sofosbuvir / Simeprevir _____ _____

Alert Message: Concurrent use of amiodarone with Sovaldi (sofosbuvir) in combination with another direct acting antiviral (DAA) is not recommended. There have been postmarketing reports of serious and life-threatening cases of symptomatic bradycardia when these antiviral agents are co-administered with amiodarone. Patients taking amiodarone who have no other viable treatment options other than sofosbuvir with a DAA should be counseled about the risk of serious bradycardia and have cardiac monitoring conducted according to manufacturer's recommendations.

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

Util A	Util B	Util C **(Include)**
Amiodarone	Sofosbuvir	Simeprevir

References:
Sovaldi Prescribing Information, March 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015, Elsevier/Gold Standard.

30. Amiodarone / Ledipasvir/Sofosbuvir _____ _____

Alert Message: Concurrent use of amiodarone with Harvoni (ledipasvir/sofosbuvir) is not recommended. There have been postmarketing reports of symptomatic bradycardia, as well as fatal cardiac arrest, when ledipasvir/sofosbuvir is coadministered with amiodarone. Patients taking amiodarone who have no other viable treatment options other than ledipasvir/sofosbuvir should be counseled about the risk of serious bradycardia and have cardiac monitoring conducted according to manufacturer's recommendations.

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

Util A	Util B	Util C
Amiodarone	Ledipasvir/sofosbuvir	

References:
Harvoni Prescribing Information, March 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015, Elsevier/Gold Standard.