DUR Board Meeting
June 1, 2016
Brynhild Haugland Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
June 1, 2016
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 03/16 meeting minutes
    - Budget update
    - Second review of Glumetza
    - Second review of naloxone rescue medications
    - Second review of naltrexone
    - Second review of Edecrin
    - Second review of interleukin-5 antagonist monoclonal antibodies
    - Second review of acitretin
    - Second review of lice medications
    - Second review of NK_1 receptor antagonists
    - Second review of Tirosint
    - Prior authorization/PDL update

3. New business
    - Review of kits
    - Review of dipeptidyl peptidase-4 (DPP-4) inhibitors
    - Review of immunoglobulins
    - Review of bowel preparation agents
    - Review of agents used to treat plaque psoriasis
    - Review of platelet aggregation inhibitors
    - Review of gout medications
    - Criteria recommendations
    - Upcoming meeting date/agenda

4. Closed session for profile review

5. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
March 2, 2016

Members Present: Tanya Schmidt, Laura Schield, Katie Kram, Wendy Brown, Russ Sobotta, Peter Woodrow, Andrea Honeyman, Jeffrey Hostetter, Carlotta McCleary, Michael Booth, Leneika Roehrich

Members Absent: James Carlson, Michael Quast

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

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. M. Booth moved that the minutes be approved, and P. Woodrow 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 were made at the December meeting to place insulin, steroid inhalers, digestive enzymes, nasal steroids, otic anti-infectives, and ulcer anti-infectives on prior authorization. The topics were brought up for a second review. There was no public comment. The motion to place these medications on prior authorization passed with no audible dissent.

Prior authorization review
A. Murphy gave an update on drugs that have been added to prior authorization. Buphenyl, tetrabenazine, phenoxybenzamine, Miacalcin, Carbaglu, Keveyis, and Strensiq have been added to the >$3,000 PA. Uptravi was added to the PAH PA. Repatha was added to the PCSK9 PA. Crestor, Luzu, Finacea, Kadian (except 200 mg), Nucynta, and Nucynta ER were all removed from PA. A. Murphy also informed the board that there will be generics that require prior authorization when the brand equivalent is preferred and not on prior authorization. Examples include Niaspan, Provigil, Tobradex, and Tindamax.

Glumetza review
B. Joyce reviewed Glumetza with the Board. There was no public comment. T. Schmidt made a motion to place Glumetza on prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting.

Narcan nasal spray review
B. Joyce reviewed Narcan nasal spray with the Board. A motion was made by L. Schield to place Narcan nasal spray on prior authorization. The motion was seconded by K. Kram. There was no public comment. This topic will be reviewed at the next meeting.

Naltrexone review
B. Joyce reviewed naltrexone with the Board. A motion was made by L. Roehrich to place naltrexone on prior authorization. The motion was seconded by J. Hostetter. There was no public comment. This topic will be reviewed at the next meeting.

Edecrin review
B. Joyce reviewed Edecrin with the Board. A motion was made by T. Schmidt to place Edecrin on prior authorization. K. Kram seconded the motion. There was no public comment. This topic will be reviewed at the next meeting.

Nucala review
B. Joyce reviewed Nucala with the Board. Ted Sheedy, representing GSK, spoke. M. Booth made a motion to place Nucala on prior authorization. P. Woodrow seconded the motion. This topic will be reviewed at the next meeting.

Acitretin review
B. Joyce reviewed acitretin with the Board. There was no public comment. M. Booth made a motion to place acitretin on prior authorization. J. Hostetter seconded the motion. This topic will be reviewed at the next meeting.

Lice medications review
B. Joyce reviewed lice medications with the Board. There was no public comment. J. Hostetter made a motion to place lice medications on prior authorization. M. Booth seconded the motion. This topic will be reviewed at the next meeting.

NK1 receptor antagonists review
B. Joyce reviewed NK1 receptor antagonists with the Board. There was no public comment. T. Schmidt made a motion to place NK1 receptor antagonists on prior authorization. K. Kram seconded the motion. This topic will be reviewed at the next meeting.

Tirosint review
B. Joyce reviewed Tirosint with the Board. There was no public comment. T. Schmidt made a motion to place Tirosint on prior authorization. K. Kram 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. J. Hostetter moved to approve the new criteria, and M. Booth 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 1, 2016 in Bismarck. L. Schield made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. W. Brown adjourned the meeting.

Closed session for profile review
Chair W. Brown called the closed session for profile review to order. Topics discussed included recipient with diabetes receiving medications from different prescribers and risperidone underutilization and the role of MTM. After discussion, a motion was made by L. Schield to adjourn the meeting. L. Roehrich seconded the motion. W. Brown adjourned the meeting.

GLUMETZA PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

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 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):			
Prescriber (or Staff) / Pharmacy Signature		Date	

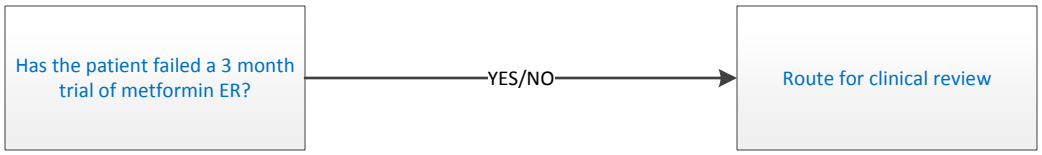
Part II: TO BE COMPLETED BY PHARMACY

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
Glumetza Authorization Algorithm



NALOXONE RESCUE MEDICATIONS
PA FORM

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Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for a naloxone rescue medication 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	
Prescriber Name	Addiction Counseling Provider: Specialty: Phone Number:		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:** **Current Opioid Misuse Measure:** **Reasoning behind patient's inability to take naloxone:**		

Does the patient have a chronic pain issue where benefit outweighs risk of continuing treatment?	**□YES □ NO**
Is the patient receiving addiction counseling?	**□YES □ NO**
Has the patient had a previously covered dose in the past year?	**□YES □ NO**
Has the previous dose of Narcan nasal spray or Evzio expired?	**□YES □ NO**
Can prescriber attest the previously covered dose was taken by the patient?	**□YES □ NO**
Is the patient concurrently taking opioids?	**□YES □ NO**
Does the prescriber attest the patient is taking the opioids as prescribed?	**□YES □ NO**
Has the opioid dose been decreased?	**□YES □ NO**
If no, has the prescriber provided reasoning behind the opioid dose not being decreased?	**□YES □ NO**

List all failed medications (drug name, date of trial, reason for failure):	
Prescriber (or Staff) / Pharmacy Signature	Date

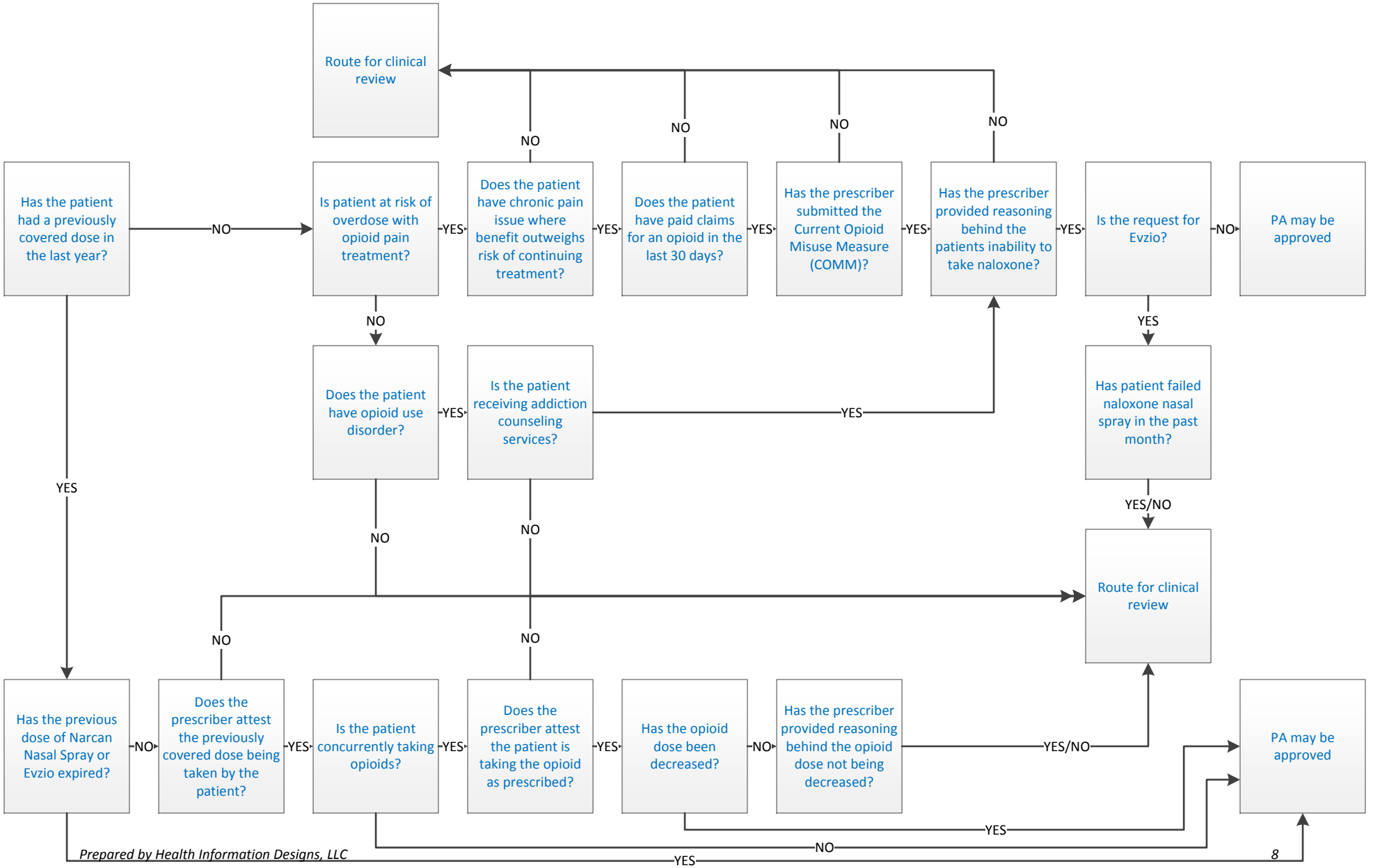
Part II: TO BE COMPLETED BY PHARMACY

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
Naloxone Rescue Medications Authorization Algorithm



NALTREXONE PA FORM

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Prior Authorization Vendor for ND Medicaid

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

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

- **Patient must have a diagnosis of alcohol dependence or opioid use disorder.**

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:**		
Prescriber (or Staff) / Pharmacy Signature		Date	

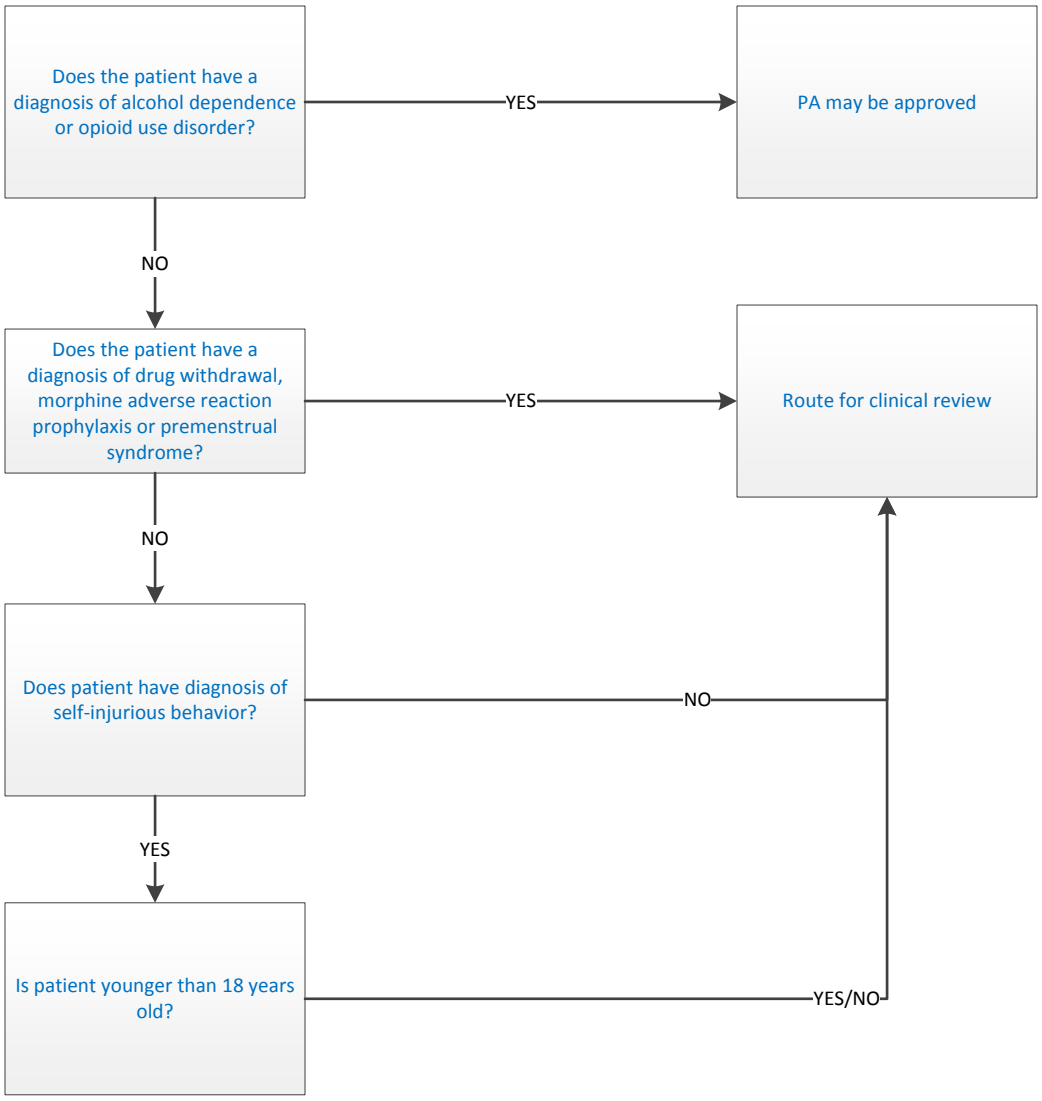
Part II: TO BE COMPLETED BY PHARMACY

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
Naltrexone Authorization Algorithm



EDECRIN PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

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):			
Prescriber (or Staff) / Pharmacy Signature		Date	

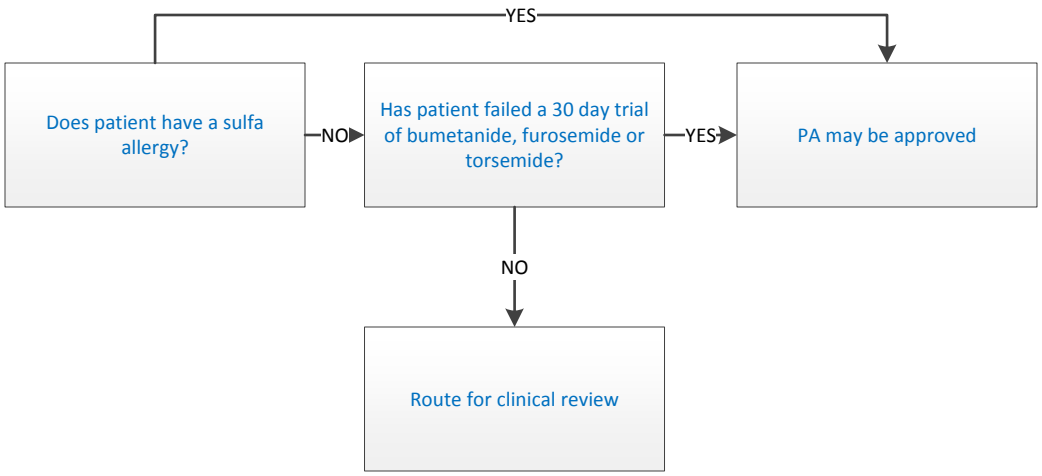
Part II: TO BE COMPLETED BY PHARMACY

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
Edecrin Authorization Algorithm



INTERLEUKIN-5 ANTAGONIST
PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

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.**

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:** **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?**			
Prescriber (or Staff) / Pharmacy Signature		Date	

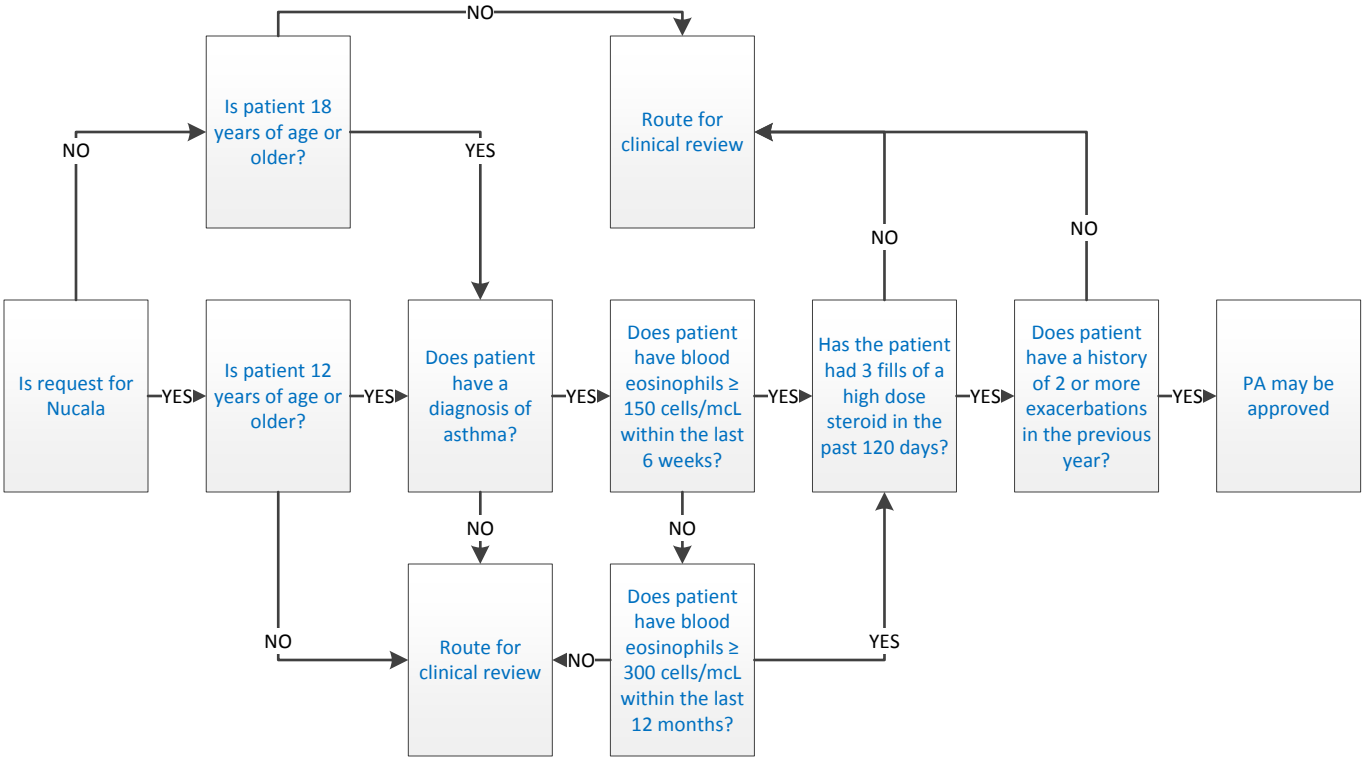
Part II: TO BE COMPLETED BY PHARMACY

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
Interleukin-5 Antagonist Authorization Algorithm



ACITRETIN PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

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 not be pregnant or intend to become pregnant during 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 and Dosage:	**FDA approved indication for this request:** **Is patient permanently unable to bear children? □ YES □ NO**		
Prescriber (or Staff) / Pharmacy Signature		Date	

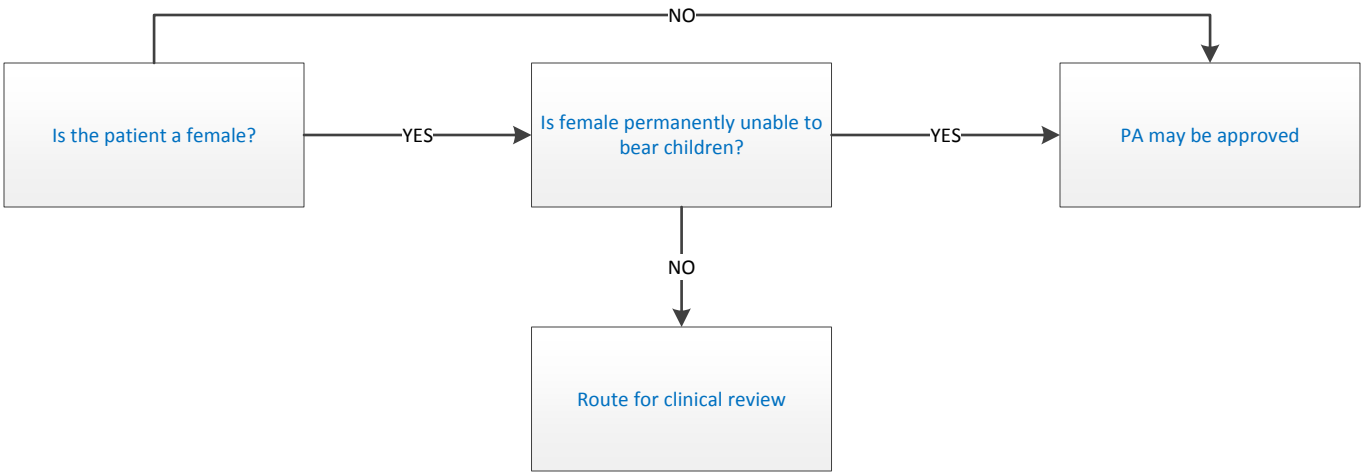
Part II: TO BE COMPLETED BY PHARMACY

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
Acitretin Authorization Algorithm



LICE MEDICATIONS PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for lice medications must meet one of the following criteria:

- **Patient must have failed a 30-day trial 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 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):			
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)	

CRITERIA DETAILS OF LICE MEDICATIONS

LICE		
Category PA Criteria: A thirty (30) day trial of each of the preferred agents will be required before a non-preferred agent will be authorized. This requirement will be waived in the presence of a documented community breakout of a resistant strain that is only susceptible to a non-preferred agent. Non-preferred agents will require an FDA indication.		
LICE SOLUTION (piperonyl butoxide/pyrethrins)	EURAX (crotamiton) CREAM	
lindane lotion	EURAX (crotamiton) LOTION	
lindane shampoo	malathion	
NATROBA (spinosad)	OVIDE (malathion)	
permethrin cream	spinosad	
permethrin liquid		
ULESFIA (benzyl alcohol)		

NK_1 RECEPTOR ANTAGONISTS PA FORM

health information designs

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for NK_1 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 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:** **Chemotherapy being used:** **How many cycles of chemotherapy will need NK_1 receptor antagonist treatment?** **Date of final chemotherapy treatment:**		
List all failed medications (drug name, date of trial, reason for failure):			
Prescriber (or Staff) / Pharmacy Signature		Date	

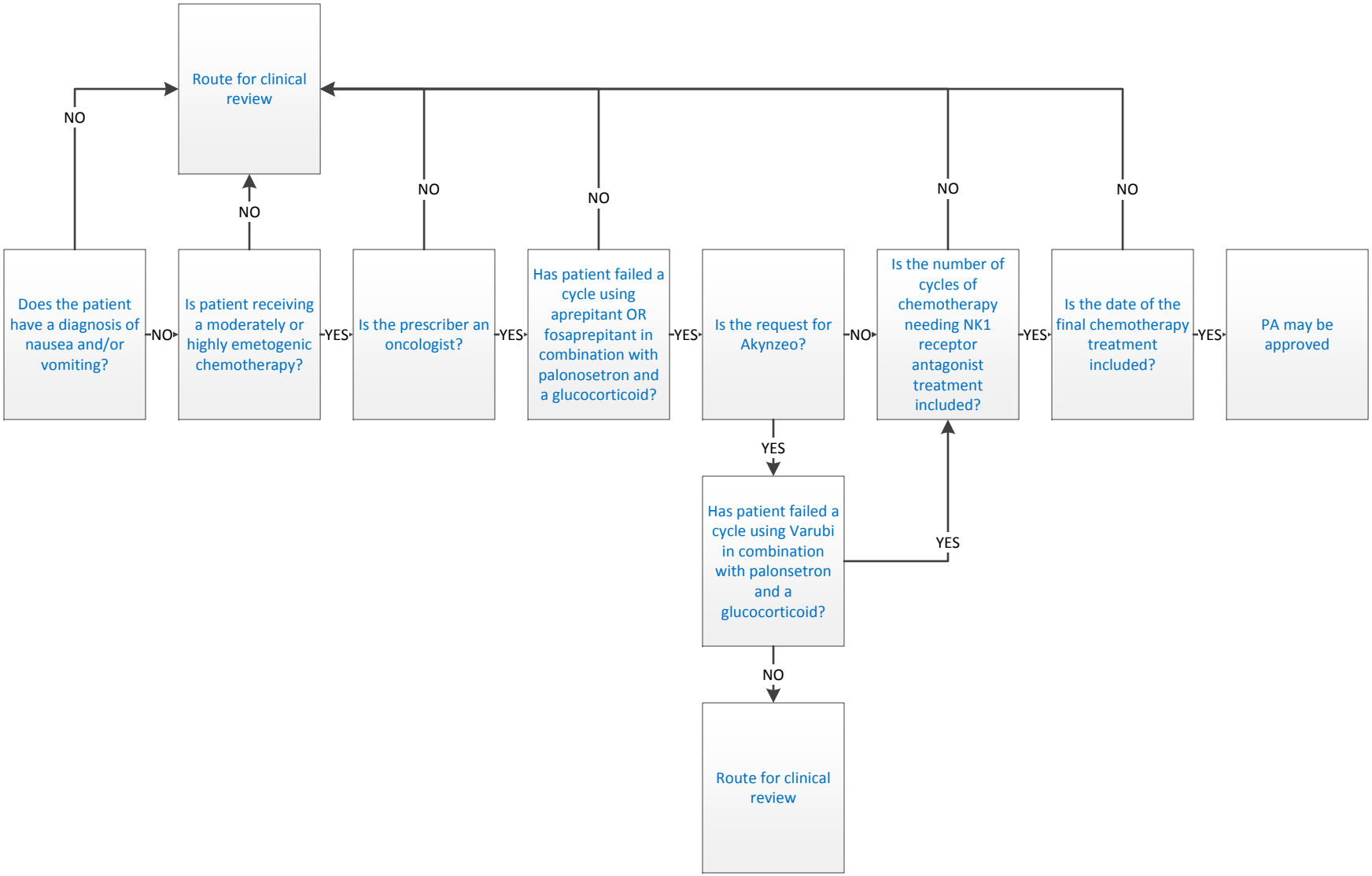
Part II: TO BE COMPLETED BY PHARMACY

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
NK1 Receptor Antagonists Authorization Algorithm



TIROSINT PA FORM

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

health information designs

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			
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):			
Prescriber (or Staff) / Pharmacy Signature		Date	

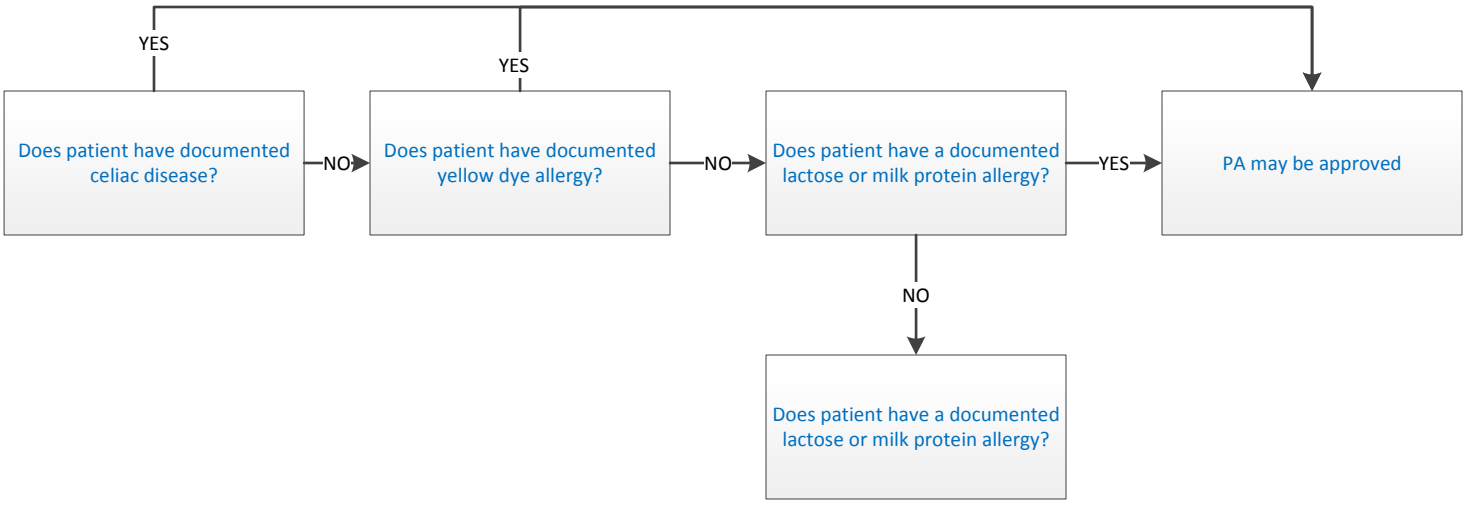
Part II: TO BE COMPLETED BY PHARMACY

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
Tirosint Authorization Algorithm



- Prior authorization for a non-preferred agent in any category will be given only if there has been a trial of the preferred brand/generic equivalent or preferred formulation of the active ingredient, at a therapeutic dose, that resulted in a partial response with a documented intolerance.

- Prior authorization of a non-preferred isomer, pro-drug, or metabolite will be considered with a trial of a preferred parent drug of the same chemical entity, at a therapeutic dose, that resulted in a partial response with documented intolerance or a previous trial and therapy failure, at a therapeutic dose, with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis. (The required trial may be overridden when documented evidence is provided that the use of these preferred agent(s) would be medically contraindicated.)

- 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.

- PA criteria for non-preferred agents apply in addition to 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.

- The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

- Quantity limits may apply. Refer to the Max Units List at: http://www.hidesigns.com/ndmedicaid

- This is not an all-inclusive list of medications that require PA. For more information visit.

- Acronyms
  PA – Indicates Preferred Agents that Require Clinical PA.

- This PDL is subject to change. Preferred positions and criteria will go into effect when a SRA is executed.

This is not an all-inclusive list of available covered drugs requiring 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 prior authorization for medications not found in this list.

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
ADHD		
Category PA Criteria: Branded non-preferred agents: require a fourteen (14) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement. Generic non-preferred agents: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
ADDERALL XR (dextroamphetamine/amphetamine)	ADDERALL (dextroamphetamine/amphetamine)	*** Kapvay will require a 1 month trial of immediate release clonidine.
ADZENYS XR - ODT (amphetamine)	clonidine ER	
clonidine	CONCERTA	
DAYTRANA (methylphenidate)	DEXEDRINE (dextroamphetamine)	
DESOXYN (methamphetamine)	dexmethylphenidate ER	
dexmethylphenidate	dextroamphetamine/amphetamine ER	
dextroamphetamine	FOCALIN (dexmethylphenidate)	
dextroamphetamine 5mg/5ml	INTUNIV (guanfacine ER)	
dextroamphetamine ER	METHYLIN (methylphenidate) chew tablets	
dextroamphetamine/amphetamine	METHYLIN (methylphenidate) solution	
DYANAVEL XR (amphetamine)	methylphenidate CD 30-70	
EVEKEO (amphetamine)	methylphenidate ER capsules 50-50	
FOCALIN XR (dexmethylphenidate)	methylphenidate ER tablet - Mallinckrodt	
guanfacine ER	methylphenidate LA capsules - 50-50	
KAPVAY (clonidine)PA	RITALIN (methylphenidate)	
METADATE CD (methylphenidate CD)		
METADATE ER (methylphenidate)		
methamphetamine		
methylphenidate chew tablet		
methylphenidate ER tablet- Actavis		
methylphenidate solution		
methylphenidate tablet		
PROCENTRA (dextroamphetamine)		

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
QUILLIVANT XR (methylphenidate)		
RITALIN LA (methylphenidate LA capsules - 50-50)		
STRATTERA (atomoxetine)		
VYVANSE (lisdexamfetamine)		
ZENZEDI (dextroamphetamine)		
ALLERGENIC EXTRACTS		
Category PA Criteria: 1. Patient must not have severe, unstable, or uncontrolled asthma 2. Patient must be a FDA approved age 3. Patient must have a FDA approved diagnosis of allergic rhinitis due to a pollen contained in the requested product 4. Patient's diagnosis must be confirmed by positive skin test or in vitro testing for pollen specific IgE antibodies contained in the requested product. Non-preferred agents: 1. Must have failed a trial of 2 of the following: oral antihistamines, intranasal antihistamines, intranasal corticosteroids, or leukotriene inhibitors 2. Must have failed a trial or have intolerance to subcutaneous allergen immunotherapy (allergy shots)		
GRASTEK (GRASS POLLEN-TIMOTHY, STD)PA	ORALAIR (GR POL-ORC/SW VER/RYE/KENT/TIM)	
RAGWITEK (WEED POLLEN-SHORT RAGWEED)PA		
ANTIANGINAL		
RANEXA (ranolazine)		
ANTICOAGULANTS - INJECTABLE		
Category PA Criteria: A thirty (30) day trial of one (1) preferred agent will be required before a non-preferred agent will be authorized. All non-preferred agents will require a FDA indication.		
enoxaparin	ARIXTRA (fondaparinux)	
	fondaparinux	
	FRAGMIN (dalteparin)	
	LOVENOX (enoxaparin)	
ANTICOAGULANTS - ORAL		
Category PA Criteria: A thirty (30) day trial of all preferred agent will be required before a non-preferred agenet will be authorized. All agents will require a FDA indication.		

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
ELIQUIS (Apixaban)PA	SAVAYSA (edoxaban)	
PRADAXA (dabigatran)PA		
XARELTO (rivaroxaban)PA		
ANTICONVULSANTS		
Category PA Criteria: Branded non-preferred agents: require a fourteen (14) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement. Generic non-preferred agents: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
APTIOM (esucarbazepine)	carbamazepine ER capsule	
BANZEL (rufinamide) ORAL SUSPENSION	carbamazepine oral suspension	
BANZEL (rufinamide) TABLET	carbamazepine XR tablet	
carbamazepine chewable tablet	CARBATROL (carbamazepine)	
carbamazepine tablet	DEPAKENE (valproic acid) CAPSULE	
CELONTIN (methsuximide)	DEPAKENE (valproic acid) ORAL SOLUTION	
divalproex ER	DEPAKOTE (divalproex sodium) TABLET	
divalproex sprinkle	DEPAKOTE ER (divalproex sodium)	
divalproex tablet	DEPAKOTE SPRINKLE (divalproex sodium)	
ethosuximide capsule	DILANTIN (phenytoin) CHEWABLE TABLET	
ethosuximide oral solution	DILANTIN (phenytoin) ORAL SUSPENSION	
felbamate oral suspension	DILANTIN ER (phenytoin)	
felbamate tablet	EPITOL (carbamazepine)	
FYCOMPA (perampanel)	FELBATOL (felbamate)	
gabapentin capsule	FELBATOL (felbamate) ORAL SUSPENSION	
gabapentin oral solution	FELBITOL (felbamate) ORAL SUSPENSION	
gabapentin tablet	KEPPRA (levetiracetam)	

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
GABITRIL (tiagabine)	KEPPRA (levetiracetam) ORAL SOLUTION	
LAMICTAL ER (lamotrigine) DOSE PACK	KEPPRA (levetiracetam) ORAL SOLUTION	
LAMICTAL ODT (lamotrigine)	KEPPRA XR (levetiracetam)	
LAMICTAL ODT (lamotrigine) DOSE PACK	LAMICTAL (lamotrigine)	
LAMICTAL XR (lamotrigine)	LAMICTAL (lamotrigine) CHEWABLE TABLET	
lamotrigine chewable tablet	LAMICTAL (lamotrigine) DOSE PACK	
lamotrigine dose pack	MYSOLINE (primidone)	
lamotrigine ER	NEURONTIN (gabapentin) CAPSULE	
lamotrigine ODT	NEURONTIN (gabapentin) ORAL SOLUTION	
lamotrigine tablet	NEURONTIN (gabapentin) TABLET	
levetiracetam ER	QUDEXY XR (topiramate)	
levetiracetam oral solution	TOPAMAX (topiramate)	
levetiracetam tablet	TOPAMAX (topiramate) SPRINKLE CAPSULE	
LYRICA (pregabalin)	TRILEPTAL (oxcarbazepine)	
LYRICA (pregabalin) ORAL SOLUTION	TRILEPTAL (oxcarbazepine) ORAL SUSPENSION	
oxcarbazepine oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION	
oxcarbazepine tablet	ZONEGRAN (zonisamide)	
OXTELLAR XR (oxcarbazepine)	ZARONTIN (ethosuximide)	
PEGANONE (Ethotoin)		
phenobarbital elixir		
phenobarbital tablet		
PHENYTEK (pheytoin)		
phenytoin chewable tablet		
phenytoin ER capsule		
phenytoin suspension		
POTIGA (ezogabine)		
primidone		

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
SABRIL (vigabatrin)		
SABRIL (vigabatrin) POWDER PACK		
TEGRETOL (carbamazepine)		
TEGRETOL XR (carbamazepine)		
TEGRETROL (carbamazepine oral suspension)		
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		
ANTICONVULSANTS - BENZODIAZEPINES - RECTAL		
Category PA Criteria: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
DIASTAT (diazepam) RECTAL KIT	diazepam rectal kit	
ANTIDEMENTIA		
Category PA Criteria: All agents will require a FDA indication for patients less than 30 years old Branded non-preferred agents: require a fourteen (14) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement. Generic non-preferred agents: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
donepezil	ARICEPT (donepezil)	
EXELON (rivastigmine)	donepezil ODT	
EXELON (rivastigmine) PATCH	NAMENDA (memantine)	
galantamine	NAMZARIC (memantine/donepezil)	
galantamine ER	RAZADYNE (galantamine)	

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
galantamine oral solution	RAZADYNE ER (galantamine)	
memantine	rivastigmine patch	
NAMENDA (memantine) ORAL SOLUTION		
NAMENDA XR (memantine)		
rivastigmine		
ANTIDEPRESSANTS - NEW GENERATION		
Category PA Criteria: Branded non-preferred agents: require a fourteen (14) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement. Generic non-preferred agents: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (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	EFFEXOR XR (venlafaxine)	
citalopram oral solutoin	fluoxetine DR	
clomipramine	FORFIVO XL (bupropion)	
desvenlafaxine ER	IRENKA (duloxetine)	
duloxetine	LEXAPRO (escitalopram)	
escitalopram	LEXAPRO (escitalopram) ORAL SOLUTION	
escitalopram oral solution	PAXIL (paroxetine)	
FETZIMA (levomilnacipran)	PAXIL CR (paroxetine)	
fluoxetine capsule	PROZAC (fluoxetine)	
fluoxetine solution	WELLBUTRIN (bupropion)	
fluoxetine tablet	WELLBUTRIN SR (bupropion)	
fluvoxamine	WELLBUTRIN XL (bupropion)	
fluvoxamine ER	ZOLOFT (sertraline)	
KHEDEZLA ER (desvenlafaxine)	ZOLOFT (sertraline) ORAL CONCENTRATE	
nefazodone		
OLEPTRO ER (trazodone)		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
paroxetine		
paroxetine ER		
PAXIL (paroxetine) ORAL SUSPENSION		
PEXEVA (paroxetine)		
PRISTIQ ER (desvenlafaxine)		
PROZAC WEEKLY (fluoxetine)		
sertraline		
sertraline oral concentrate		
trazodone		
TRINTELLIX (vortioxetine)		
venlafaxine capsule		
venlafaxine ER tablets		
venlafaxine tablet		
VIIBRYD (vilazodone)		
ANTIHEMOPHILIC FACTORS		
Category PA Criteria: 1. Patient must visit an accredited Hemophilia Treatment Center for yearly checkups 2. The doctor must provide the date of patient's last appointment at the treatment center 3. The doctor must include the contact information for the treatment center last visited by the patient		
ADVATE[PA]		
ADYNOVATE[PA]		
ALPHANATE[PA]		
ALPHANINE SD[PA]		
ALPROLIX[PA]		
BEBULIN[PA]		
BENEFIX[PA]		
ELOCTATE[PA]		
FEIBA[PA]		
HELIXATE FS[PA]		
HEMOFIL M[PA]		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
HUMATE-P[PA]		
IXINITY[PA]		
KOATE-DVI[PA]		
KOGENATE FS[PA]		
KOGENATE FS BIO-SET[PA]		
MONOCLATE-P[PA]		
MONONINE[PA]		
NOVOEIGHT[PA]		
NOVOSEVEN[PA]		
OBIZURE[PA]		
PROFILNINE SD[PA]		
RECOMBINATE[PA]		
RIXUBIS[PA]		
WILATE[PA]		
XYNTHA[PA]		
ANTIHYPERLIPIDEMICS - CETP INHIBITORS		
VYTORIN (ezetimibe/simvastatin)		
ZETIA (ezetimibe)		
ANTIHYPERLIPIDEMICS - NIACIN		
Category PA Criteria: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
NIASPAN ER (niacin)	niacin ER	
ANTIHYPERTENSIVE - BETA BLOCKERS		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
acebutolol	BETAPACE AF (sotalol)	
atenolol	CORGARD (nadolol)	
betaxolol	INDERAL LA (propranolol)	
bisoprolol	LOPRESSOR (metoprolol)	
BYSTOLIC (nebivolol)	SECTRAL (acebutolol)	

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
INDERAL XL (propranolol)	SORINE (sotalol)	
INNOPRAN XL (propranolol)	TENORMIN (atenolol)	
metoprolol	TOPROL XL (metoprolol)	
metoprolol ER	ZEBETA (bisoprolol)	
nadolol		
pindolol		
propranolol		
propranolol ER		
sotalol		
sotalol AF		
timolol		
ANTIPROTOZOAL AGENTS		
Category PA Criteria: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
ALINIA (nitazoxanide)	tinidazole	
atovaquone		
MEPRON (atovaquone)		
TINDAMAX (tindazole)		
ANTIRETROVIRALS - PROTEASE INHIBITORS		
APTIVUS (tipranavir)		
CRIXIVAN (indinavir)		
EVOTAZ (atazanavir/cobicistat)		
GENVOYA (elvitegravir, cobicistat, emtricitabine and tenofovir)		
INVERASE (saquinavir)		
KALENTRA (lopinavir/ritonavir)		
LEXIVA (fosamprenavir)		
NORVIR (ritonavir)		
PREZCOBIX (darunavir/cobicistat)		
PREZISTA (darunavir)		
RAYATAZ (atazanavir)		
VIRACEPT (nelfinavir)		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
ASTHMA - LONG ACTING ANTICHOLINERGICS		
Category PA Criteria: Patient must be 12 years old or older		
SPIRIVA RESPIMAT 1.25 MG (tiotropium)		
ATYPICAL ANTIPSYCHOTICS		
Category PA Criteria: Branded non-preferred agents: require a fourteen (14) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement. Generic non-preferred agents: A thirty (30) day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
ABILIFY (aripiprazole)	aripiprazole	
ABILIFY (aripiprazole) ORAL SOLUTION	CLOZARIL (clozapine)	
ABILIFY DISCMELT (aripiprazole)	GEODON (ziprasidone)	
clozapine	INVEGA ER (paliperidone)	
clozapine ODT	RISPERDAL (risperidone)	
FANAPT (iloperidone)	RISPERDAL (risperidone) ORAL SOLUTION	
FAZACLO (clozapine) RAPDIS	RISPERDAL M-TAB (risperidone)	
LATUDA (lurasidone)	SEROQUEL (quetiapine)	
olanzapine	ZYPREXA (olanzapine)	
olanzapine ODT	ZYPREXA ZYDIS (olanzapine)	
olanzapine/fluoxetine		
paliperidone ER		
quetiapine		
REXULTI (brexipiprazole)		
risperidone		
risperidone ODT		
risperidone oral solution		
SAPHRIS (asenapine)		
SEROQUEL XR (quetiapine)		
SYMBYAX (olanzapine/fluoxetine)		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
VRAYLAR (cariprazine)		
ziprasidone		
ATYPICAL ANTIPSYCHOTICS - LONG ACTING		
ABILIFY MAINTENA (aripiprazole)		
ARISTADA (aripiprazole lauroxil)		
INVEGA SUSTENNA (paliperidone)		
INVEGA TRINZA (paliperidone)		
RISPERDAL CONSTA (risperidone)		
ZYPREXA RELPREVV (olanzapine)		
COPD		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized. All preferred agents indicated only for COPD will require verification of FDA approved indication for patients who are less than 40 years of age. All non preferred agents will require FDA approved indication regardless of age.		
Long Acting anticholinergics		
SPIRIVA (tiotropium)	INCRUSE ELLIPTA (umeclidium)	
SPIRIVA RESPIMAT 2.5 MG (tiotropium)		
TUDORZA PRESSAIR (aclidinium)		
Long Acting Beta Agonists		
FORADIL (formoterol)	ARCAPTA NEOHALER (indacaterol)	***Brovana/Arcapta Neohaler require a 30 day trail of Striverdi in addition to Category PA Criteria
SEREVENT (salmeterol)	BROVANA (arformoterol)	
PERFOROMIST (formoterol)	STRIVERDI RESPIMAT (olodaterol)	
Short Acting Combination		
albuterol/iptratopium	DUONEB (albuterol/ipratropium)	
COMBIVENT RESPIMAT (albuterol/ipratropium)		
Long Acting Combination		
Group PA Criteria: A thirty (30) day trial of one (1) preferred agent in either the Long Acting Beta Agonist or Long Acting anticholinergic group will be required in addition to category PA criteria before a non-preferred agent will be authorized.		
ANORO ELLIPTA (umeclidium/vilanterol)	STIOLTO RESPIMAT (tiotropium/olodaterol)	
PDE4 - Inhibitor		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
Group PA Criteria: In addition to the Category PA Criteria, patient must have a history of exacerbations treated with corticosteroids within the last year and have had the following thirty (30) day trials: 1. one (1) agent in the Long Acting Anticholinergic group 2. one (1) agent in the Long Acting Beta Agonist group or one (1) agent in the Steroid/Anticholinergic Combination Inhalers category 3. one (1) agent in the Steroid Inhalers category or one (1) agent in the Steroid/Anticholinergic Combination Inhalers category		
	DALIRESP (roflumilast)	
CYSTIC FIBROSIS ANTIINFECTIVES		
Category PA Criteria: A twenty eight (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 a FDA approved age and indication.		
BETHKIS (tobramycin)	CAYSTON (aztreonam)	***Cayston - Patient must have a forced expiratory volume in less than one second (FEV1) less than 25% or greater than 75% predicted. ***Tobramycin/TOBI/TOBI Podhaler - Patient must have a forced expiratory volume in less than one second (FEV1) less than 40% or greater than 80% predicted. Patient must not have been colonized with *Burkholderia Cepacia*.
KITABIS PAK (tobramycin/nebulizer)	TOBI (Tobramycin)	
	TOBI PODHALER (Tobramycin)	
	Tobramycin	
CYTOKINE MODULATORS		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized. All agents will require a FDA approved indication.		
COSENTYX (secukinumab)PA	ACTEMRA (tocilizumab)	***Cosentyx - A 3 month trial of Humira only will be required for plaque psoriasis before Cosyntyx is approved.
ENBREL (etanercept)PA	CIMZIA (certolizumab)	
HUMIRA (adalimumab)PA	KINERET (anakinra)	
HUMIRA PSORIASIS (adalimumab)PA	ORENCIA (abatacept)	
	OTEZLA (apremilast)	
	REMICADE (infliximab)	
	SIMPONI (golimumab)	
	STELARA (ustekinumab)	
	XELJANZ (tofacitanib)	
DIABETES - DPP4 INHIBITORS		
JANUMET (sitagliptan/metformin)		
JANUMET XR (sitagliptan/metformin)		
JANUVIA (sitagliptan)		
JENTADUETO (linagliptin/metformin)		
KAZANO (alogliptin/metformin)		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
KOMBIGLYZE XR (sitagliptan/metformin)		
NESINA (alogliptin)		
ONGLYZA (saxagliptin)		
OSENI (alogliptin/pioglitazone)		
TRADJENTA (linagliptin)		
DIABETES - GLP1 AGONISTS		
Category PA Criteria: Non preferred agents will require: 1. A thirty (30) day trial of two (2) preferred agents 2. A FDA indication 3. Concurrent metformin therapy 4. A 3 month trial of metformin		
BYDUREON (exenatide microspheres)	TANZEUM (albiglutide)	
BYETTA (exenatide)	TRULICITY (dulaglutide)	
VICTOZA (liraglutide)		
DIABETES - INSULIN		
PA Criteria: A thirty (30) day trial of one (1) preferred agent will be required in the past year before a non-preferred agent will be authorized.		
HUMALOG (insulin lispro) VIAL	AFREZZA (insulin regular, human)	
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	APIDRA (insulin glulisine) VIAL	
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	
HUMULIN 70/30 (insulin NPH human/regular insulin human) INSULIN PEN	HUMALOG (insulin lispro) CARTRIDGE	
HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	HUMALOG (insulin lispro) KWIKPEN	
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	
HUMULIN N (insulin NPH human isophane) INSULIN PEN	HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN	
HUMULIN N (insulin NPH human isophane) KWIKPEN	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL	

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
HUMULIN N (insulin NPH human isophane) VIAL	NOVOLIN N (insulin NPH human isophane) VIAL	
HUMULIN N (insulin NPH human isophane) VIAL	NOVOLIN R (insulin regular, human) VIAL	
HUMULIN R (insulin regular, human) VIAL	TOUJEO SOLOSTAR (insulin glargine)	
HUMULIN R U-500 (insulin regular, human) VIAL	TRESIBA (insulin degludec)	
LANTUS (insulin glargine) SOLOSTAR		
LANTUS (insulin glargine) FLEXTOUCH		
LANTUS (insulin glargine) VIAL		
LEVEMIR (insulin detemir) VIAL		
LEVEMIR (insulin glargine) FLEXTOUCH		
NOVOLOG (insulin aspart) CARTRIDGE		
NOVOLOG (insulin aspart) FLEXPEN		
NOVOLOG (insulin aspart) VIAL		
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) INSULIN PEN		
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL		
DIABETES - SGLT2 INHIBITORS		
Category PA Criteria: All agents will require a 3 month trial of metformin. Non-preferred agents will require: 1. A 3 month trial of all preferred agents 2. A FDA indication 3. Concurrent metformin therapy		
FARXIGA (dapagliflozin)PA	JARDIANCE (empagliflozin)	
INVOKANA (canaglifozin)PA		
DIABETES - SGLT2 INHIBITORS COMBINATIONS		
Category PA Criteria: Non preferred agents will require: 1. A 3 month trial of all preferred agents 2. A FDA indication 3. A 3 month trial of metformin		
INVOKAMET (canafliflozin/metformin)	GLYXAMBI (empagliflozin/linagliptan)	

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
	SYNJARDY (empagliflozin/metformin)	
	XIGDUO XR (dapagliflozin/metformin)	
DIGESTIVE ENZYMES		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
CREON (lipase/protease/amylase)	PANCREAZE (lipase/protease/amylase)	
ZENPEP (lipase/protease/amylase)	PANCRELIPASE (lipase/protease/amylase)	
	PERTZYE (lipase/protease/amylase)	
	ULTRESA (lipase/protease/amylase)	
	VIOKACE (lipase/protease/amylase)	
EPINEPHRINE PENS		
Category PA Criteria: A thirty (30) day trial of one (1) preferred agent will be required before a non-preferred agent will be authorized.		
EPIPEN (epinephrine)	ADRENACLICK (epinephrine)	
EPIPEN JR (epinephrine)	epinephrine	
FIBROMYALGIA		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
duloxetine	CYMBALTA (duloxetine)	
gabapentin capsule	NEURONTIN (gabapentin) CAPSULE	
gabapentin oral solution	NEURONTIN (gabapentin) TABLET	
gabapentin tablet	NEURONTIN (gabapentin) ORAL SOLUTION	
LYRICA (pregabalin)		
LYRICA (pregabalin) ORAL SOLUTION		
SAVELLA (milnacapran)		
GROWTH HORMONE		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
Category PA Criteria: 1. Patients new to GH therapy, must meet criteria below and be started on a preferred growth hormone 2. Patients continuing GH therapy and having met criteria listed below must be switched to a preferred growth hormone 3. Patients must not have an active malignancy Additional criteria applies. See for details: http://www.hidesigns.com/assets/files/ndmedicaid/Criteria/2016/growth_hormone_criteria.pdf		
GENOTROPIN (somatropin)PA	HUMATROPE (somatropin)	
GENOTROPIN MINIQUICK (somatropin)PA	NUTROPIN AQ (somatropin)	
NORDITROPIN FLEXPRO (somatropin)PA	SAIZEN (somatropin)	
OMNITROPE (somatropin)PA	ZOMACTON (somatropin)	
HEMATOPOIETIC, GROWTH FACTOR		
ARANESP (darbopoetin alfa)		
EPOGEN (epoetin alfa)		
MIRCERA (methoxy polyethylene glycol-epoetin beta)		
PROCRIT (epoetin alfa)		
HEPATITIS C TREATMENTS		
Category PA Criteria: Non-preferred agents will require a failed trial of all preferred treatment options indicated for the patient's genotype. 1. Patient must have FDA approved diagnosis 2. Patient must be an FDA approved age 3. Patient must attest that they will continue treatment without interruption for the duration of therapy 4. Prescriber must be or consult with a hepatologist, gastroenterologist, or infectious disease specialist 5. Prescriber must provide documentation that the patient has been drug and alcohol free for the past 12 months 6. Patient must have liver biopsy Metavir score of 2 or greater; or Ishak score of 3 or greater 7. HCV RNA level must be taken on week 4 and sent with a renewal request for any duration of treatment 12 weeks or longer 8. Females using ribavirin must have a negative pregnancy test in the last 30 days and receive monthly pregnancy tests during treatment 9. PA approval duration will be based on label recommendation.		
HARVONI (ledipasvir/sofosbuvir)PA	DAKLINZA (Daclatasvir)	***Harvoni: - Patient must have eGFR > 30 mL/min/1.73m2 ***Technivie: - Patients must not have moderate (Child-Pugh B) or severe (Child-Pugh C)
SOVALDI (sofosbuvir)PA	OLYSIO (simeprevir)	
TECHNIVIE (Ombitasvir/Paritaprevir/ Ritonavir)PA		

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)PA		hepatic impairment - Patients must not have cirrhosis -Technivie must be used with Ribavirin in treatment experienced patients ***Olysio: - Olysio must be taken in conjunction with pegylated interferon and ribavirin ***Viekira Pak: - Patients must have hepatic laboratory tests before treatment and 4 weeks after treatment begins - Patients must not have moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment - Viekira Pak must be used with Ribavirin except for genotype 1b without cirrhosis or mild (Child-Pugh A) hepatic impairment. ***Zepatier: - Patients must not have moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment - Genotype 1a: Patient must be tested for baseline NS5A polymorphisms - Zepatier must be used with Ribavirin in patients with baseline NS5A polymorphisms - Zepatier must be used with Ribavirin in patients that have failed HCV NS3/4A protrase inhibitor (PI) + RBV + PegIFN treatment - Patients that have failed HCV NS3/4A protrase inhibitor (PI) + RBV + PegIFN treatment must not have baseline NS5A polymorphisms
ZEPATIER (elbasvir/grazoprevir)PA		
INFLAMMATORY BOWEL AGENTS (ULCERATIVE COLITIS) - NONSTEROIDAL		
Category PA Criteria: A thirty (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	ASACOL HD (mesalamine)	
balsalazide capsule	AZULFIDINE (sulfasalazine)	
DELZICOL (mesalamine) CAPSULE	AZULFIDINE DR (sulfasalazine)	
LIALDA (mesalamine) TABLET	COLAZAL (balsalazide)	
PENTASA (mesalamine) CAPSULE	DIPENTUM (olsalazine)	
sulfasalazine DR tablet	GIAZO (balsalazide)	

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
sulfasalazine tablet	SULFAZINE (sulfasalazine)	
Rectal		
CANASA (mesalamine) RECTAL SUPPOSITORY	mesalamine enema kit	
mesalamine enema	SF ROWASA (mesalamine) ENEMA	
IRRITABLE BOWEL SYNDROME - CONSTIPATION		
Category PA Criteria: Patients must be 18 years old. All medications will require an FDA indication		
AMITIZA (lubiprostone)		*** Linzess - A 30 day trial of Amitiza is required before Linzess will be authorized.
LINZESS (linaclotide)PA		
LICE		
Category PA Criteria: A thirty (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.		
EURAX (crotamiton) CREAM	ELIMITE (permethrin) CREAM	
EURAX (crotamiton) LOTION	OVIDE (malathion)	
LICE SOLUTION (piperonyl butoxide/pyrethrins)	spinosad	
lindane lotion		
lindane shampoo		
malathion		
NATROBA (spinosad)		
permethrin cream		
permethrin liquid		
ULESFIA (benzyl alcohol)		
MIGRAINE PROPHYLAXIS - 5HT(1) AGONISTS		
Category PA Criteria: Patients 18 years old or greater: A thirty (30) day trial of all preferred agents in the past 24 months will be required before a non-preferred agent will be authorized. Patients 6 to 17 years of age: A thirty (30) day trial rizatriptan in the past 24 months will be required before a non-preferred agent will be authorized.		
RELPAX (eletriptan)	almotriptan	***Zomig Nasal Spray - a 30 day trial of zolmitriptan 5mg within the past 24 months

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
rizatriptan	ALSUMA (sumatriptan) PEN INJCTR	will be required in addition to class criteria ***Treximet - For patients 18 years or older, the patient must be stable on the combination product and have had a 30 day trial of naproxen in addition to sumatriptan to be approved. This criteria is in addition to the class criteria. ***Frova - A 30 day trial of naratriptan 2.5 mg within the past 24 months will be required in addition to the class criteria. The patient's migraine headaches must be long in duration and or recur. ***Axert/Sumatriptan Nasal Spray - a 30 day trial of Naratriptan 2.5mg, Zomig Nasal Spray 5 mg, Zomitriptan 5 mg, Treximet, and Frova in the past 24 months will be required in addition to the class criteria. ***Zecuity/Sumavel DosePro - a 30 day trial of Naratriptan 2.5mg, Sumatriptan Nasal Spray 20 mg, Zomig Nasal Spray 5 mg, Zomitriptan 5 mg, Axert 12.5mg, Treximet, and Frova in the past 24 months will be required in addition to the class criteria.
sumatriptan tablet	AMERGE (naratriptan)	
	FROVA (frovatriptan)	
	IMITREX (sumatriptan) CARTRIDGE	
	IMITREX (sumatriptan) PEN INJCTR	
	IMITREX (sumatriptan) SPRAY	
	IMITREX (sumatriptan) TABLET	
	IMITREX (sumatriptan) VIAL	
	MAXALT (rizatriptan)	
	MAXALT MLT (rizatriptan)	
	naratriptan	
	rizatriptan tab rapdis	
	sumatriptan cartridge	
	sumatriptan pen injctr	
	sumatriptan spray	
	sumatriptan syringe	
	sumatriptan vial	
	SUMAVEL DOSEPRO (sumatriptan)	
	TREXIMET (sumatriptan/naproxen)	
	ZECUITY (sumatriptan) PATCH	
	zolmitriptan	
	zolmitriptan ODT	
	ZOMIG (zolmitriptan)	
	ZOMIG (zolmitriptan) SPRAY	
	ZOMIG ODT (zolmitriptan)	
MULTIPLE SCLEROSIS		
Non-Interferons		
Category PA Criteria: A three (3) month long trial of all preferred agents will be required before a non-preferred agent will be authorized. A three (3) month trial of Copaxone is required. If patient has a documented intolerance, hypersensitivity, or labeled contraindication to Copaxone, a 3 month trial of interferon beta-1 is required. A FDA indication is required.		
GILENYA (fingolimod)PA	AUBAGIO (teriflunomide)	***Aubagio - Prescriber must be a neurologist - Transaminase and bilirubin levels must have been obtained within 6 months of
COPAXONE (glatiramer) 20 MG/ML	LEMTRADA (alemtuzumab)	

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
	TECFIDERA (dimethyl fumarate)	request - Patient must not be pregnant and if patient is of childbearing potential, reliable contraception must be used - Must not be coadministered with leflunomide ***Copaxone 40 mg/mL/glatopa (glatiramer) - These agents will require three (3) month trials of Aubagio and Tecfidera in addition to category criteria ***Gilenya - Patient must have had within 6 months of request: 1. CBC with differential 2. Electrocardiogram 3. Transaminase and bilirubin levels - Patient must have an opthalmologic evaluation at baseline - If patient has not been vaccinated or have a history of *Varicella Zoster Virus* (VZV), prescriber must take VZV antibioties - Appointment date for first dose must be supplied ***Lemtrada - Unless patient has early aggressive disease defined as >= 2 relapses in the year and >=1 Cadollmium (Cd)+ lesion, three (3) month trials of Tecfidera, Aubagio, and Tysabri will be required in addition to category criteria. - If patient has not been vaccinated or have a history of Varicella Zoster Virus (VZV), prescriber must take VZV antibioties - Patient must have had a urinalysis with urine cell counts - Patient must have had a thyroid function test - Patient must have had a TB test - Patient must have SCr levels *** Tecfidera - Patient must have had a CBC with lymphocyte count within 6 months of request ***Tysabri - Unless patient has early aggressive disease defined as >= 2 relapses in the year and >=1 Cadollmium (Cd)+ lesion, three (3) month trials of Tecfidera and Aubagio and will be required in addition to category criteria.
	COPAXONE (glatiramer) 40 MG/ML	
	glatopa (glatiramer)	
	TYSABRI (natalizumab)	
Interferons		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
Category PA Criteria: A three (3) month long trial of a preferred agent will be required before a non-preferred agent will be authorized. A FDA indication is required.		
BETASERON (interferon beta-1B)	AVONEX (interferon beta-1A)	
REBIF (interferon beta-1A)	AVONEX (interferon beta-1A) PEN	
REBIF REBIDOSE (interferon beta-1A)	AVONEX (interferon beta-1A) ADMINISTRATION PACK	
	EXTAVIA (interferon beta-1B)	
	PLEGRIDY (peginterferon beta-1A)	
	PLEGRIDY PEN (peginterferon beta-1A)	
OPHTHALMIC ANTIHISTAMINES		
Category PA Criteria: A thirty (30) day trial of three (3) preferred agents will be required before a non-preferred agent will be authorized.		
BEPREVE (bepotastine)	ALOCRIL (nedocromil)	***Patanol, epinastine, and Lastacaft will require a 30 day trail of azelastine and Elestat in addition to the Category PA Criteria
cromolyn	ALOMIDE (lodoxamide)	
EMADINE (emedastine)	azelastine	
PATADAY (olopatadine)	ELESTAT (epinastine)	
PAZEO (olopatadine)	epinastine	
	LASTACAFT (alcaftadine)	
	olopatadine	
	PATANOL (olopatadine)	
OPHTHALMIC ANTIINFECTIVES		
Category PA Criteria: A three (3) day trial of three (3) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
bacitracin ointment	AK-POLY-BAC (bacitracin/polymixin) OINTMENT	
bacitracin/polymixin ointment	AZASITE (arithromycin) DROPS	
ciprofloxacin drops	BESIVANCE (besifloxacin) DROPS	
erythromycin ointment	CILOXAN (ciprofloxacin) DROPS	
gentamicin sulfate drops	CILOXAN (ciprofloxacin) OINTMENT	
gentamicin sulfate ointment	gatifloxacin drops	
MOXEZA (moxifloxacin) DROPS	GENTAK (gentamicin sulfate) OINTMENT	
neomycin SU/bacitracin/polymixin B drops	ILOTYCIN (erythromycin) OINTMENT	
neomycin SU/polymixin B/gramicidin drops	levofloxacin drops	

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
OCUFLOX (ofloxacin) DROPS	NEO-POLYCIN (neomycin SU/bacitracin/polymixin B) DROPS	
ofloxacin drops	NEOSPORIN (neomycin SU/polymixin B/gramicidin) DROPS	
polymixin B/trimethoprim drops	POLYCIN (bacitracin/polymixin) OINTMENT	
tobramycin drops	POLYTRIM (polymixin B/trimethoprim) DROPS	
TOBREX (tobramycin) OINTMENT	TOBREX (tobramycin) DROPS	
VIGAMOX (moxifloxacin) DROPS	ZYMAXID (gatifloxacin) DROPS	
OPHTHALMIC ANTIINFECTIVES/ANTIINFLAMMATORIES		
Category PA Criteria: A seven (7) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
neomycin/polymyxin b/dexamethasone	tobramycin/dexamethasone	
neomycin/bacitracin/polymyxin b/hydrocortisone	MAXITROL (neomycin/polymyxin b/dexamethasone)	
neomycin/polymyxin b/hydrocortisone		
PRED-G (gentamicin/prednisol ac)		
TOBRADEX (tobramycin/dexamethasone)		
TOBRADEX ST (tobramycin/dexamethasone)		
ZYLET (tobramycin/lotepred etab)		
OPHTHALMIC ANTIINFLAMMATORIES		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions is indicated on the form. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
ACULAR LS (ketorolac)	ACULAR (ketorolac)	
ACUVAIL (ketorolac)	FML (fluorometholone)	
ALREX (loteprednol)	OCUFEN (flurbiprofen)	
bromfenac sodium	OMNIPRED (prednisolone acetate)	
dexamethasone sodium phosphate	PRED FORTE (prednisolone acetate)	
diclofenac sodium		
DUREZOL (difluprednate)		
FLAREX (fluorometholone)		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
fluorometholone		
flurbiprofen sodium		
FML FORTE (fluorometholone)		
FML S.O.P. (fluorometholone)		
ILEVRO (nepafenac)		
ILUVIEN (fluocinolone)		
ketorolac tromethamine		
LOTEMAX (loteprednol)		
MAXIDEX (dexamethasone)		
NEVANAC (nepafenac)		
OZURDEX (dexamethasone)		
PRED MILD (prednisolone)		
prednisolone acetate		
prednisolone sodium phosphate		
PROLENSA (bromfenac)		
RETISERT (fluocinolone)		
TRIESENCE (triamcinolone)		
VEXOL (rimexolone)		
OPHTHALMIC GLAUCOMA COMBINATION AGENTS		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions is indicated on the form. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
COMBIGAN (brimonidine/timolol)	COSOPT (dorzolamide/timolol)	
COSOPT PF (dorzolamide/timolol)		
dorzolamide/timolol		
SIMBRINZA (brinzolamide/brimonidine)		
OPHTHALMIC GLAUCOMA PROSTAGLANDINS		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions is indicated on the form. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
bimatoprost	XALATAN (latanoprost)	
latanoprost		
LUMIGAN (bimatoprost)		
TRAVATAN Z (travoprost)		

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
travoprost		
ZIOPTAN (tafluprost)		
OPIOID ANALGESIC - LONG ACTING		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized. For non-preferred agents to be authorized, patient must have required around the clock pain relief for the past 90 days and 3 months of the PDMP report must be reviewed and attached.		
EMBEDA (morphine/naltrexone)	BUTRANS (buprenorphine)	*** Oxycontin, morphine ER capsules, oxymorphone ER, Zohydro ER require a 30 day failed trial of Opana ER in addition to Category PA criteria. *** Hysingla, Fentanyl Patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr, and methadone require a 30 day failed trial of Opana ER, Oxycontin, and Zohydro ER in addition to Category PA criteria. ***Hydromorphone ER and Exalgo - the 90 day around the clock pain relief requirement must be met by an eqaianalgesic dose of 60mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30mg oxycodone daily, 8 mg of oral hydromorphone daily or another opioid daily. A 30 day failed trial of Opana ER, Oxycontin, and Zohydro ER is required in addition to Category PA criteria.
fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr	DURAGESIC (fentanyl)	
KADIAN (morphine) 10 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG, 80 MG, 100 MG	DURAGESIC PATCH (fentanyl)	
morphine ER tablets	EXALGO (hydromorphone)	
NUCYNTA ER (tapentadol)	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr	
	hydromorphine ER tablets	
	HYSINGLA ER (hydrocodone)	
	KADIAN (morphine) 200 mg	
	methadone	
	morphine ER capsules	
	MS CONTIN (morphine)	
	OPANA ER (oxymorphone)	
	oxycodone ER	
	OXYCONTIN (oxycodone)	
	oxymorphone ER tablets	
	tramadol ER	
	ULTRAM ER (tramadol ER)	
	XARTEMIS XR (oxycodone/acetaminophen)	
	ZOHYDRO ER (hydrocodone)	
OPIOID ANTAGONIST - OPIOID AND ALCOHOL DEPENDENCE		
VIVITROL (Naltrexone Microspheres)		
OPIOID PARTIAL ANTAGONIST - OPIOID DEPENDENCE		

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
Category PA Criteria: A thirty (30) day trial of one (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 registred 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 thre prescriber must have developed a treatment plan 5. The prescriber must perform routine drug screens 6. The prescriber must routinely check the PDMP, and attach the last 3 months of PDMP reports that have been reviewed 7. The prescriber must be enrolled with ND Medicaid		
ZUBSOLV (buprenorphine/naloxone)PA	BUNAVAIL FILM (buprenorphine/naloxone)	*** Bunavail/Suboxone Film/buprenorphine - will require a 30 day trial of buphrenorphine/naloxone tablets in addition to the Category PA Criteria
	buprenorphine tablets	
	buprenorphine-naloxone tablets	
	SUBOXONE FILM (buprenorphine/naloxone)	
OTIC ANTINFECTIVES - FLOROQUINOLONES		
Category PA Criteria: A seven (7) day trial of one (1) preferred product in the past three (3) months is required before a non-preferred product will be approved.		
CIPRO HC (ciprofloxacin/hydrocortisone)	OCUFLOX (ofloxacin)	
CIPRODEX (ciprofloxacin/dexamethasone)	ofloxacin	
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 three (3) month trial of three (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	*** Fosrenol Powder Pack - A 3 month trail of Renvela Powder Pack will be required in addition to Category PA Criteria *** Velphoro - A 3 month trail of Aryxia will be required in addition to Category PA Criteria
calcium acetate tablet	FOSRENOL (lanthanum) POWDER PACK	
ELIPHOS (calcium acetate) TABLET	RENVELA (sevelamer) POWDER PACK	
FOSRENOL (lanthanum) CHEWABLE TABLET	VELPHORO (sucroferric oxyhydroxide) CHEWABLE TABLET	
PHOSLO (calcium acetate) CAPSULE		
PHOSLYRA (calcium acetate) ORAL solution		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
RENAGEL (sevelamer) TABLET		
RENVELA (sevelamer) TABLET		
PLATELET AGGREGATION INHIBITORS		
Category PA Criteria: A thirty (30) day trial of two (2) preferred agents will be required before a non-preferred agent will be authorized unless one (1) of the exceptions is indicated on the form. A thirty (30) day trial of two (2) preferred generics of the same medication will satisfy this requirement.		
AGGRENOX (aspirin/dipyridamole)	PLAVIX (clopidogrel)	***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.
aspirin/dipyridamole ER	ZONTIVITY (vorapaxar)	
BRILINTA (ticagrelor)	PERSANTINE (dipyridamole)	
clopidogrel		
dipyridamole		
EFFIENT (prasugrel)		
ticlopidine		
PULMONARY HYPERTENSION		
PDE-5 Inhibitors		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized. All medications require an FDA approved indication.		
ADCIRCA (tadalafil)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 ***sildenafil - A thirty (30) day trial of Adcirca will be required for all patients less than 18 years old
sildenafilPA	REVATIO (sildenafil) TABLET	
Soluble Guanylate Cyclase Stimulators		
Category PA Criteria: Patients of childbearing potential must not be pregnant, be taking a reliable form of birth control, and have a pregnancy test before initiation and monthly during therapy. All medications require an FDA approved indication. Patients must be at least 18 years of age.		
ADEMPAS (riociguat)PA		
Endothelin Receptor Antagonist		
Category PA Criteria: Patients of childbearing potential must not be pregnant, be taking a reliable form of birth control, and have a pregnancy test before initiation and monthly during therapy. All medications require an FDA approved indication. Patients must be at least 18 years of age.		
LETAIRIS (ambrisentan)PA		***Tracleer - LFTs must be measured at baseline and monthly during therapy
OPSUMIT (macitentan)PA		
TRACLEER (bosentan)PA		

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PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
Prostacyclins		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized. Patients must be at least 18 years of age.		
eprosprostenol[PA]	REMODULIN (treprostinil)	***Ventavis 20mcg/mL - A patient must be maintained at a 5 mcg dose and repeatedly experiencing incomplete dosing due to extended treatment time to be approved
FLOLAN (epoprostenol)[PA]	TYVASO (treprostinil)	
ORENITRAM ER (treprostinil)[PA]	UPTRAVI (selexipag)	
VELETRI (epoprostenol)[PA]	VENTAVIS (iloprost) 20 mcg/mL	
VENTAVIS (iloprost) 10 mcg/mL[PA]		
STEROID/LONG ACTING BETA AGONIST (LABA) COMBINATION INHALERS		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents must have FDA approved indication. For COPD diagnosis, the following will be required in addition to the Category PA criteria. 1. A thirty (30) day trial of Tudorza Pressair, Spiriva, Incruse Ellipta, Anoro Ellipta, or Stiolto Respimat will be required. 2. A thirty (30) day trial of Anoro Ellipta, Stiolto Respimat, Foradil, Brovana, Arcapta, or Sevevent will be required. For Asthma diagnosis, patient must have been reviewed for step down therapy for all renewal requests.		
ADVAIR DISKUS (fluticasone/salmeterol)	ADVAIR HFA (fluticasone/salmeterol)	
DULERA (mometasone/formoterol)	BREO ELLIPTA (fluticasone/vilanterol)	
SYMBICORT (budesonide/formoterol)		
STEROID INHALERS		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized		
AEROSPAN (flunisolide)	ASMANEX HFA (mometasone)	
ALVESCO (ciclesonide)	ARNUITY ELLIPTA (fluticasone)	
ASMANEX (mometasone) TWISTHALER		
FLOVENT DISKUS (fluticasone)		
FLOVENT HFA (fluticasone)		
PULMICORT FLEXHALER (budesonide)		
QVAR (beclomethasone)		
STEROID TOPICAL SOLUTIONS		
clobetasol solution		

EFFECTIVE
April 1st, 2016
Version 2016.3

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
ELOCON (mometasone) solution		
fluocinolone solution		
hydrocortisone solution		
mometasone solution		
SYNALAR (fluocinolone) SOLUTION		
TEXACORT (hydrocortisone SOLUTION		
TOPICAL TESTOSTERONE		
Category PA Criteria: A thirty (30) day trial of all preferred agents will be required before a non-preferred agent will be authorized. All medications require a FDA approved indication.		
ANDROGEL (testosterone) PACKET[PA]	ANDRODERM (testosterone)	
ANDROGEL (testosterone) GEL MD PMP[PA]	FORTESTA (testosterone)	
AXIRON (testosterone)[PA]	NATESTO (testosterone)	
	TESTIM (testosterone)	
	TESTOPEL (testosterone)	
	testosterone gel	
	testosterone Gel MD PMP	
	VOGELXO (testosterone) GEL MD PMP	
ULCER ANTI-INFECTIVES		
Category PA Criteria: A ten (10) day trial in the past 3 months of all preferred agents will be required before a non-preferred agent will be authorized		
PYLERA (bismuth/methronidazole/tegracycline)	PREVPAC (lansoprazole/amoxicillin/clarithromycin)	
	lansoprazole/amoxicillin/clarithromycin	
	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)	
URINARY ANTISPASMODICS		
Category PA Criteria: A thirty (30) day trial of four (4) preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents require a FDA approved indication.		
ENABLEX (darifenacin)	DETROL (tolterodine)	***tolterodine ER will require a 1 month trial of Sanctura XR, Myrbetriq, trospium, and tolterodine in addition to the Category PA Criteria. ***trospium ER will require a 1 month trial of Myrbetriq, trospium, and tolterodine in
flavoxate	DETROL LA (tolterodine)	
oxybutynin ER	DITROPAN XL (oxybutynin)	
oxybutynin syrup	GELNIQUE (oxybutynin)	

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
oxybutynin tablet	MYRBETRIQ (mirabegron)	addition to the Category PA Criteria. ***Myrbetriq will require a 1 month trial of trospium and tolterodine in addition to the Category PA Criteria. ***trospium will require a 1 month trial of tolterodine in addition to the Category PA Criteria.
TOVIAZ (fesoterodine)	OXYTROL (oxybutynin) PATCH	
VESICARE (solifenacin)	SANCTURA (trospium)	
	SANCTURA ER (trospium)	
	tolterodine	
	tolterodine ER	
	trospium	
	trospium ER	

EXAMPLES OF KITS

NDC	Brand Name	Strength	Generic Name	Manufacturer	Package Description	Route Description	Price
51021044006	PRO DNA MEDICATED COLLECTION	20 MG/ML	LIDOCAINE HCL/GLYCERIN	SIRCLE LABORATO	KIT	MUCOUS MEM	$691.40700
59088009300	INFLAMMACIN	75MG-.025%	DICLOFENAC/CAPSICUM	PURETEK CORPORA	KIT	MISCELL	$3,249.00000
59088036300	DERMACINRX SILAZONE	0.10%	TRIAMCINOLONE ACETON/SILICONES	PURETEK CORPORA	KIT	TOPICAL	$4,661.59500
59088039200	TICANASE	50MCG-0.9%	FLUTICASONE/SOD CHL/SOD BICARB	PURETEK CORPORA	KIT	NASAL	$3,404.89800
59088039300	SILAZONE-II	0.10%	TRIAMCINOLONE ACETON/SILICONES	PURETEK CORPORA	KIT	TOPICAL	$4,661.59500

DIPEPTIDYL PEPTIDASE-4 INHIBITORS (DPP-4)

INDICATIONS AND USE:
DPP-4 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Not for the treatment of type 1 diabetes or diabetic ketoacidosis.

DOSAGE FORMS:
- Januvia (sitagliptin) – 100 mg, 50 mg, and 25 mg tablets
- Nesina (alogliptin) – 25 mg, 12.5 mg, and 6.25 mg tablets
- Onglyza (saxagliptin) – 5 mg and 2.5 mg tablets
- Tradjenta (linagliptin) – 5 mg tablets

ADMINISTRATION:
- Januvia – The recommended dose of Januvia is 100 mg once daily, with or without food. Dosage adjustment is recommended for patients with moderate or severe renal insufficiency or end-stage renal disease.
- Nesina – The recommended dose in patients with normal renal function or mild renal impairment is 25 mg once daily, with or without food. Adjust dose if moderate or severe renal impairment or end-stage renal disease.
- Onglyza – The recommended dosage is 2.5 mg or 5 mg once daily, with or without food. Patients with moderate or severe renal impairment or end-stage renal disease 2.5 mg once daily with or without food.
- Tradjenta – The recommended dose is 5 mg once daily, with or without food.

WARNINGS AND PRECAUTIONS:
- Pancreatitis – postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue.
- Acute renal failure (sitagliptin) – postmarketing reports of acute renal failure, sometimes requiring dialysis. Dosage adjustment is recommended.
- Hypoglycemia – there is an increased risk of hypoglycemia when added to an insulin secretagogue or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia.
- Serious allergic and hypersensitivity reactions – reactions such as anaphylaxis, angioedema, and exfoliative skin conditions (including Stevens-Johnson) may occur. In such cases, promptly discontinue.
- Severe and disabling arthralgia has been reported. Consider as a possible cause for severe joint pain and discontinue drug if appropriate.
- Hepatic effects (alogliptin) – postmarketing reports of hepatic failure, sometimes fatal. If liver injury is detected, promptly discontinue.

- Heart failure – consider the risks and benefits of therapy prior to initiating treatment in patients at risk of heart failure. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation.

ADVERSE REACTIONS:

- Januvia (sitagliptin) – the most common adverse reactions reported in ≥5% of patients were upper respiratory tract infection, nasopharyngitis, and headache. When added to sulfonylurea and insulin therapy, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo.
- Nesina (alogliptin) – the most common adverse reactions reported in ≥4% of patients were nasopharyngitis, headache, and upper respiratory tract infection.
- Onglyza (saxagliptin) – the most common adverse reactions reported in ≥5% of patients were upper respiratory tract infection, urinary tract infection, and headache.
- Tradjenta (linagliptin) – the most common adverse reactions reported in ≥5% of patients included nasopharyngitis.

UTILIZATION

ND Medicaid DPP-4 Utilization			
09/15/14 - 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
GLYXAMBI 25 MG-5 MG TABLET	2	$1,040.00	$520.00
JANUMET 50-1,000 MG TABLET	296	$73,150.94	$247.13
JANUMET 50-500 MG TABLET	80	$18,719.00	$233.99
JANUMET XR 100-1,000 MG TABLET	28	$6,962.80	$248.67
JANUMET XR 50-1,000 MG TABLET	54	$8,057.69	$149.22
JANUMET XR 50-500 MG TABLET	4	$1,370.50	$342.63
JANUVIA 100 MG TABLET	432	$131,249.45	$303.82
JANUVIA 25 MG TABLET	63	$18,812.77	$298.62
JANUVIA 50 MG TABLET	126	$41,727.79	$331.17
JENTADUETO 2.5 MG-1000 MG TAB	17	$5,937.39	$349.26
KOMBIGLYZE XR 2.5-1,000 MG TAB	19	$6,012.93	$316.47
KOMBIGLYZE XR 5-1,000 MG TAB	15	$2,690.99	$179.40
ONGLYZA 2.5 MG TABLET	2	$673.37	$336.69
ONGLYZA 5 MG TABLET	77	$25,998.29	$337.64
TRADJENTA 5 MG TABLET	116	$40,163.87	$346.24
213 recipients	**1331**	**$382,567.78**	

References:

1. Januvia [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2016.
2. Nesina [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.; April 2016.
3. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2016.
4. Tradjenta [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc., August 2015.

PRODUCT DETAILS OF IMMUNE GLOBULINS (BIVIGAM, CARIMUNE NF, FLEBOGAMMA, GAMMAGARD, GAMMAGARD S/D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, OCTAGAM, PRIVIGEN)

INDICATIONS AND USE:
The immune globulins are FDA-approved for use in one or more of the following conditions:

- Primary immune deficiency disorder (PID).
- Idiopathic and chronic thrombocytopenic purpura (ITP).
- Prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL).
- Prevention of coronary artery aneurysms associated with Kawasaki disease.
- Measles prophylaxis.
- Chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.
- To improve muscle strength and disability in adult patients with multifocal motor neuropathy (MMN).

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic reactions to human immunoglobulin
- IgA deficient patients with antibodies to IgA and a history of hypersensitivity
- Corn or maltose hypersensitivity
- Hereditary fructose intolerance
- Hyperprolinemia

PRECAUTIONS:

- Thrombotic events have occurred in patients receiving IGIV therapy.
- IgA deficient patients with antibodies against IgA are at a greater risk of developing severe hypersensitivity and anaphylactic reactions.
- Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

- Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy.
- Aseptic meningitis syndrome has been reported with IGIV treatments, especially with high doses or rapid infusion.
- Hemolytic anemia can develop subsequent to treatment with IGIV products. Monitor patients for hemolysis and hemolytic anemia.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Risk of transmitting infectious agents.
- Special care should be taken when measuring blood glucose in patients taking a parenteral product that contains maltose.
- Consider patient's fluid status when determining the IVIG dose and product to be used.
- Certain cautions are to be used with patients receiving IVIG who must undergo vaccination.

ADVERSE REACTIONS:
The most common adverse reactions were abdominal pain, anemia, asthenia, back pain, bleeding, bradycardia, bronchospasm, chest pain, chills, conjunctivitis, cough, diarrhea, dizziness, dyspnea, ecchymosis, elevated hepatic enzymes, epistaxis, fatigue, fever, headache, hyperbilirubinemia, hypotension, infection, infusion-related reactions, injection site reaction, musculoskeletal pain, nasal congestion, nausea, otalgia, petechiae, pharyngitis, purpura, rash, rhinitis, rhinorrhea, sinus tachycardia, sinusitis, thrombocytopenia, vomiting, and wheezing.

DRUG INTERACTIONS:
Do not vaccinate patients with most live virus vaccines for at least 3 months after administration of IVIG.

IVIG products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients receiving known nephrotoxic drugs. Administer IGIV products at the minimum concentration available and the minimum rate of infusion practicable and closely monitor renal function.

UTILIZATION:

ND Medicaid IVIG Utilization			
09/15/14 - 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
GAMMAGARD LIQUID 10% VIAL	25	$50,236.67	$2,009.47
HIZENTRA 1 GRAM/5 ML VIAL	22	$20,342.08	$924.64
HIZENTRA 2 GRAM/10 ML VIAL	14	$15,246.43	$1,089.03
HIZENTRA 4 GRAM/20 ML VIAL	12	$27,414.06	$2,284.51
8 recipients	**73**	**$113,239.24**	

References:

1. http://www.clinicalpharmacology.com; Accessed May 9, 2016.
2. http://online.factsandcomparisons.com; Accessed May 9, 2016.

PRODUCT DETAILS OF BOWEL PREP AGENTS (COLYTE, GOLYTELY, NULYTELY, PEG 3350, HALFLYTELY-BISACODYL, MOVIPREP, OSMOPREP, PREPOPIK, SUPREP, SUCLEAR)

INDICATIONS AND USE:
For cleansing of the colon as a preparation for colonoscopy.

CONTRAINDICATIONS:
- Known or suspected bowel obstruction
- Gastric retention
- Bowel perforation
- Toxic colitis
- Toxic megacolon
- Ileus
- Biopsy-proven acute phosphate nephropathy (Osmoprep)
- Gastric bypass or stapling surgery (Osmoprep)
- Severely reduced renal function (CrCl > 30mL/min) (Prepopik)

WARNINGS AND PRECAUTIONS:
- If severe diarrhea occurs, discontinue use.
- Prolonged, frequent, or excessive use may lead to electrolyte imbalance.
- Use with caution in patients with renal impairment.
- Use with caution in patients at increased risk of arrhythmias.
- Use with caution in patients with a history of seizures.
- Use with caution in patients with impaired gag reflex and those prone to regurgitation or aspiration.

ADVERSE REACTIONS:
Most common adverse reactions include nausea, vomiting, abdominal bloating, cramping, flatulence, diarrhea, excessive stool frequency, dizziness, malaise, rigors, sleep disorder, increased thirst, and headache.

DRUG INTERACTIONS:
- Drugs that increase risks due to fluid and electrolyte changes.
- Oral medications taken within 1 hour of start of each dose might not be absorbed properly.
- PEG 3350 may decrease the serum concentration of digoxin.
- Prior or concomitant use of antibiotics may reduce efficacy of Prepopik.

UTILIZATION:

ND Medicaid Bowel Prep Agents Utilization			
09/15/14 - 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
GAVILYTE-C SOLUTION	14	$263.12	$18.79
GAVILYTE-G SOLUTION	88	$1,753.69	$19.93
GAVILYTE-N SOLUTION	8	$637.96	$79.75
GOLYTELY PACKET	124	$1,656.41	$13.36
GOLYTELY SOLUTION	28	$447.36	$15.98
MOVIPREP POWDER PACKET	2	$88.47	$44.24
PEG 3350 ELECTROLYTE SOLN	72	$1,245.98	$17.31
POLYETHYLENE GLYCOL 3350 POWD	3240	$67,386.77	$20.80
SUPREP BOWEL PREP KIT	38	$2,364.13	$62.21
TRILYTE WITH FLAVOR PACKETS	3	$212.48	$70.83
	3617	**$76,056.37**	**$363.18**

References:

1. http://www.clinicalpharmacology.com; Accessed May 9, 2016.
2. http://online.factsandcomparisons.com; Accessed May 9, 2016.

PRODUCT DETAILS OF TOPICAL ANTIPSORIATICS

INDICATIONS AND USE:

- Dovonex cream (calcipotriene) – indicated for the treatment of plaque psoriasis of the body.
- Calcitrene ointment (calcipotriene) – indicated for the treatment of plaque psoriasis of the body.
- Sorilux foam (calcipotriene) – indicated for the treatment of plaque psoriasis of the body or of the scalp.
- Calcipotriene solution (calcipotriene) – indicated for the treatment of plaque psoriasis of the body or of the scalp.
- Taclonex ointment/suspension (calcipotriene/betamethasone) – treatment of plaque psoriasis in patients 12 years and older (ointment); treatment of plaque psoriasis of the scalp in patients 12 years and older and body (adults).
- Enstilar foam (calcipotriene/betamethasone) – treatment of plaque psoriasis in patients 18 years and older.
- Tazorac cream/gel (tazarotene) – topical treatment of plaque psoriasis in patients 18 years and older (cream); topical treatment of stable plaque psoriasis of up to 20% body surface area involvement in patients 12 years and older (gel).
- Vectical ointment (calcitriol) – topical treatment of mild to moderate plaque psoriasis in adults 18 years of age and older.
- Sernivo spray (betamethasone diproprionate) – treatment of mild to moderate plaque psoriasis in patients 18 years of age and older.

ADMINISTRATION:

- Calcipotriene cream – Apply a thin film to the affected skin twice daily.
- Calcipotriene foam – Apply a thin film to the affected skin or scalp twice daily.
- Calcipotriene ointment – Apply a thin film to the affected skin once or twice daily.
- Calcipotriene solution – Apply to the affected scalp twice daily.
- Taclonex – 100 g per week according to the prescribing information (ointment, suspension).
- Enstilar – 60 g every 4 days according to the prescribing information.
- Tazarotene – initiate therapy with 0.05%. Apply once daily to psoriatic lesions using enough to cover only the lesion with a thin film; for gel, apply to no more than 20% of body surface area. May increase strength to 0.1% if tolerated and necessary.
- Vectical – 200 g weekly according to the prescribing information.
- Sernivo – Apply to the affected skin areas twice daily. Rub in gently. Use for up to 4 weeks.

DOSAGE FORM AND STRENGTHS:

- Calcipotriene – 0.005% ointment, cream, foam, and solution.
- Taclonex – 0.064% betamethasone/0.005% calcipotriene suspension and ointment.
- Enstilar – 0.064% betamethasone/0.005% calcipotriene hydrate foam.
- Tazarotene – 0.5% and 0.1% cream and gel.
- Vectical – 3 mcg/gm ointment.
- Sernivo – 0.05% spray

WARNINGS AND PRECAUTIONS:

- For external use only.
- Reduce frequency or discontinue use if skin irritation appears.
- May cause transient increases in serum calcium. If hypercalcemia occurs, discontinue treatment until calcium levels return to normal.
- Foam, solution – flammable.
- Adrenal suppression and systemic effects (corticosteroid containing products).
- Avoid excessive exposure of treated skin to natural or artificial sunlight.

ADVERSE REACTIONS:

The most common adverse reactions include: skin discomfort, pruritus, psoriasis, urine abnormality, hypercalciuria, tingling of the skin, burning sensation, skin irritation, rash, atrophy, erythema, and xeroderma.

UTILIZATION:

ND Medicaid Antipsoriatics (topical) Utilization			
09/15/14 - 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
CALCIPOTRIENE 0.005% SOLUTION	4	$1,075.39	$268.85
CALCIPOTRIENE 0.005% OINTMENT	1	$293.36	$293.36
TACLONEX OINTMENT	1	$865.49	$865.49
DOVONEX 0.005% CREAM	2	$1,117.10	$558.55
CALCIPOTRIENE 0.005% CREAM	27	$11,659.22	$431.82
16 recipients	**35**	**$15,010.56**	

References:

1. Clinical Pharmacology. Available at http://www.clinicalpharmacology.com.; Accessed on May 9, 2016.
2. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com.; Accessed on May 9, 2016.

PRODUCT DETAILS OF PLATELET AGGREGATION INHIBITORS

INDICATIONS AND USE:

- Brilinta (ticagrelor) – $P2Y_{12}$ platelet inhibitor indicated to reduce the rate of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI
- Effient (prasugrel) – $P2Y_{12}$ platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are to be managed with PCI as follows:
  - Patients with unstable angina or non-ST-elevation MI (NSTEMI).
  - Patients with ST-elevation MI (STEMI) when managed with either primary or delayed PCI.
- Plavix (clopidogrel) – P2Y12 platelet inhibitor indicated:
  - Acute coronary syndrome – for patients with non-ST-segment elevation ACS [unstable angina (UA)/non-ST-elevation MI (NSTEMI)], clopidogrel has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI, or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke or refractory ischemia. For patients with ST-elevation MI (STEMI), clopidogrel has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction, or stroke.
  - Recent MI, recent stroke, or established peripheral arterial disease. Clopidogrel has been shown to reduce the combined endpoint of new ischemic stroke, new MI, and other vascular death.
- Zontivity (vorapaxar) – protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Vorapaxar has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

ADMINISTRATION:

- Brilinta – Initiate treatment with 180 mg oral loading dose following an ACS event. Continue treatment with 90 mg twice daily during the first year after an ACS event. After one year, administer 60 mg twice daily. Use Brilinta with a daily maintenance dose of aspirin of 75 mg to 100 mg.

- Effient – Initiate treatment with a single 60 mg oral loading dose. Continue at 10mg once daily. Patient should also take aspirin (75 mg to 325mg) daily.
- Plavix – ACS UA/NSTEMI: 300 mg loading dose followed by 75 mg once daily in combination with aspirin (75-325 mg once daily). STEMI: 75 mg once daily, in combination with aspirin (75-325 mg once daily), with or without a loading dose. Recent MI, stroke, or established peripheral arterial disease: 75 mg once daily.
- Zontivity – One tablet orally once daily. Use with aspirin and/or clopidogrel according to their indications or standard of care. There is limited clinical experience with other antiplatelet drugs and none with vorapaxar as the only antiplatelet agent.

DOSAGE FORM AND STRENGTHS:
Brilinta: 60 mg and 90 mg tablets
Effient: 5 mg and 10 mg tablets
Plavix: 75 mg and 300 mg tablets
Zontivity: 2.08 mg tablets

CONTRAINDICATIONS:
Brilinta: History of intracranial hemorrhage (IH) and active pathological bleeding.
Effient: Active pathological bleeding and prior transient ischemic attack or stroke.
Plavix: Active pathological bleeding, such as peptic ulcer or IH.
Zontivity: History of stroke, TIA, or ICH.

WARNINGS AND PRECAUTIONS:
Brilinta: Dyspnea and severe hepatic impairment.
Effient: CABG-related bleeding, premature discontinuation, thrombotic thrombocytopenic purpura (TTP) and hypersensitivity.
Plavix: Avoid concomitant use with omeprazole and esomeprazole, bleeding, premature discontinuation, recent TIA or stroke, TTP, and cross-reactivity among thienopyridines.
Zontivity: Increased risk of bleeding and avoid use with CYP3A inhibitors or inducers.

ADVERSE REACTIONS:
Brilinta: Most common are bleeding and dyspnea.
Effient: Bleeding, including life-threatening and fatal bleeding.

Plavix: Bleeding, including life-threatening and fatal bleeding.
Zontivity: Bleeding, including life-threatening and fatal bleeding.

DRUG INTERACTIONS:
Brilinta: Avoid use with strong CYP3A inhibitors or CYP3A inducers. Patients receiving more than 40mg per day of simvastatin or lovastatin may be at increased risk of statin-related adverse effects. Monitor digoxin levels.
Effient: Warfarin and non-steroidal anti-inflammatory drugs may increase the risk of bleeding.
Plavix: Non-steroidal anti-inflammatory drugs, warfarin, selective serotonin and serotonin norepinephrine reuptake inhibitors (SSRI/SNRI) may increase the risk of bleeding.
Zontivity: Avoid concomitant use with strong inhibitors of CYP3A and strong inducers of CYP3A.

UTILIZATION:

ND Medicaid Platelet Aggregation Inhibitors Utilization			
09/15/14 – 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
Brilinta 90mg Tablet	18	$4,853.07	$269.62
Clopidogrel 75mg Tablet	1109	$13,573.04	$12.24
Effient 10mg Tablet	74	$23,663.01	$319.77
185 recipients	**1201**	**$42,089.12**	

References:

1. Brilinta [package insert]. Wilmington, DE: AstraZeneca LP; September, 2015.
2. Effient [package insert]. Indianapolis, IN: Eli Lilly and Company; July, 2015.
3. Plavix [package insert]. Bridgewater, NJ: Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; July, 2015.
4. Zontivity [package insert]. Whitehouse Station, NJ. Merck & Co., Inc.; April, 2015.

PRODUCT DETAILS OF ANTIHYPERURICEMICS

INDICATIONS AND USE:

- Allopurinol – management of patients with signs and symptoms of primary or secondary gout.
- Colcrys (colchicine) – prophylaxis and treatment of acute gout flares when taken at the first sign of a flare.
- Mitigare (colchicine) – prophylaxis of gout flares in adults.
- Probenecid – for treatment of hyperuricemia associated with gout and gouty arthritis.
- Uloric (febuxostat) – for the chronic management of hyperuricemia in patients with gout.
- Zurampic (lesinurad) – in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.

ADMINISTRATION:

- Allopurinol – 200 to 300 mg/day for patients with mild gout and 400 to 600 mg/day for those with moderately severe tophaceous gout. The appropriate dosage may be administered in divided doses or as a single equivalent dose with the 300 mg tablet. Dosage requirements in excess of 300 mg should be administered in divided doses.
- Colcrys – 0.6 mg once or twice daily for prophylaxis of gout flares. 1.2 mg at the first sign of a gout flare followed by 0.6mg one hour later.
- Mitigare – 0.6 mg once or twice daily.
- Probenecid – 250 mg (1/2 tablet) twice a day for 1 week followed by 500 mg twice a day thereafter. When acute attacks have been absent for 6 months or more and serum urate levels remain within normal limits, the daily dosage may be decreased by 500 mg every 6 months.
- Uloric – 40 mg or 80 mg once daily.
- Zurampic – 200 mg once daily in combination with a xanthine oxidase inhibitor, including allopurinol or febuxostat.

DOSAGE FORM AND STRENGTHS:

- Allopurinol – tablets, 100 mg and 300 mg
- Colcrys – tablets, 0.6 mg

- Mitigare – capsules, 0.6 mg
- Probenecid – tablets, 500 mg
- Uloric – tablets, 40 mg and 80 mg
- Zurampic – tablets, 200 mg

CONTRAINDICATIONS:

- Allopurinol – patients who have developed a severe reaction to allopurinol should not be restarted on the drug.
- Colcrys – do not give to patients with renal or hepatic impairment in conjunction with P-gp or strong CYP3A4 inhibitors.
- Mitigare – do not give to patients with renal or hepatic impairment in conjunction with drugs that inhibit both P-gp and CYP3A4. Should not be given to patients with both renal and hepatic impairment.
- Uloric – do not give to patients being treated with azathioprine or mercaptopurine.
- Zurampic – severe renal impairment, end stage renal disease, kidney transplant recipients, or patients on dialysis. Tumor lysis syndrome or Lesch-Nyhan syndrome.

WARNINGS AND PRECAUTIONS:

Allopurinol

- Reduce dose in patients receiving mercaptopurine or azathioprine
- Drowsiness
- Acute gout attacks
- Increase fluid intake

Colcrys/Mitigare

- Fatal overdoses have been reported
- Blood dyscrasias
- Monitor for toxicity
- Drug interaction P-gp and/or CYP3A4 inhibitors
- Neuromuscular toxicity

Probenecid

- Exacerbation of gout following therapy with probenecid may occur; in such cases colchicine or other appropriate therapy is advisable.

- Should not be given in conjunction with methotrexate because of reports of increased methotrexate plasma levels with resultant increased methotrexate toxicity.
- Should not be given with salicylates because of antagonism of the uricosuric action of probenecid.
- Liberal fluid intake and alkalization of the urine is recommended.
- Use with caution in patients with a history of peptic ulcer.
- May not be effective in chronic renal insufficiency, particularly when the glomerular filtration rate is 30 mL/min or less.

Uloric

- Increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents. Discontinue if gout flare occurs.
- Higher rate of cardiovascular thromboembolic events was observed. Monitor for signs and symptoms of MI and stroke.
- Postmarketing reports of hepatic failure, sometimes fatal.

Zurampic

- Renal events
- Cardiovascular events

ADVERSE REACTIONS:

- Allopurinol – rash, maculopapular rash, diarrhea, nausea, alkaline phosphatase increase, AST/ALT increase, acute attacks of gout.
- Colcrys/Mitigare – diarrhea and pharyngolaryngeal pain.
- Probenecid – headache, GI symptoms, urinary frequency, hypersensitivity reactions, sore gums, flushing, dizziness, and anemia have occurred. In gouty patients, exacerbation of gout and uric acid stones, with or without hematuria, renal colic, or costovertebral pain, have been observed.
- Uloric – liver function abnormalities, nausea, arthralgia, and rash.
- Zurampic – headache, influenza, blood creatinine increased, and gastroesophageal reflux disease.

UTILIZATION:

ND Medicaid Antihyperuricemics Utilization			
09/15/14 – 09/14/15			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ALLOPURINOL 100MG	222	$2,953.50	$13.30
ALLOPURINOL 300MG	198	$1,558.80	$7.87
COLCHICINE 0.6MG TABLET	15	$3,732.88	$248.86
COLCRYS 0.6MG TABLET	29	$6,268.25	$216.15
PROBENECID 500MG TABLET	1	$6.88	$6.88
ULORIC 40MG TABLET	7	$1,691.86	$241.69
ULORIC 80MG TABLET	6	$1,610.22	$268.37
	478	**$17,822.39**	

References:

1. http://www.clinicalpharmacology.com; Accessed May 9, 2016.
2. http://online.factsandcomparisons.com; Accessed May 9, 2016.
3. Zurampic [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals, LP. December 2015.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2016

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

1. Alirocumab / Overutilization _____ _____

Alert Message: Praluent (alirocumab) may be over-utilized. The recommended starting dose of alirocumab is 75 mg administered subcutaneously once every 2 weeks. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Alirocumab		

Max Dose: 150 mg every 2 weeks

References:
Praluent Prescribing Information, July 2015, Sanofi.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

2. Alirocumab / Statin Therapy (Negating) _____ _____

Alert Message: A review of the patient's drug history does not reveal the concurrent use of a statin with Praluent (alirocumab). Alirocumab is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Alirocumab		Lovastatin
		Fluvastatin
		Pravastatin
		Simvastatin
		Atorvastatin
		Rosuvastatin
		Pitavastatin

References:
Praluent Prescribing Information, July 2015, Sanofi.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

3. Alirocumab / Pediatric Use _____ _____

Alert Message: The safety and efficacy of Praluent (alirocumab) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Alirocumab		

Age Range: 0-18 yoa

References:
Praluent Prescribing Information, July 2015, Sanofi.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

4. Alirocumab / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Praluent (alirocumab). 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
Alirocumab		

References:
Praluent Prescribing Information, July 2015, Sanofi.
Osterberg L, Blaschke T. Adherence to Medication. N Eng Jrnl Med. 2005;353:487-97.
Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.

5. Evolocumab / Overutilization _____ _____

Alert Message: Repatha (evolocumab) may be over-utilized. The recommended dosage of evolocumab in patients with primary hyperlipidemia with established clinical atherosclerotic (CVD) is either 140 mg administered subcutaneously every 2 weeks OR 420 mg once monthly. The recommended dosage of evolocumab in patients with HoFH is 420 mg once monthly.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Evolocumab		

Max Dose: 420 mg per month

References:
Repatha Prescribing Information, August 2015, Amgen Medical Information.

6. Evolocumab / Statin Therapy (Negating) _____ _____

Alert Message: A review of the patient's drug history does not reveal the concurrent use of adjunct lipid lowering therapy with Repatha (evolocumab). Evolocumab is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease, who require additional lowering of low density lipoprotein cholesterol (LDL-C). For the treatment of patients with HoFH who require additional lowering of LDL-C evolocumab is indicated as an adjunct to diet and other LDL-lowering therapies.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**	
Evolocumab		Lovastatin	Atorvastatin
		Fluvastatin	Rosuvastatin
		Pravastatin	Pitavastatin
		Simvastatin	Ezetimibe

References:
Repatha Prescribing Information, August 2015, Amgen Medical Information.

7. Evolocumab / Pediatric Use _____ _____

Alert Message: Repatha (evolocumab) should be used with caution in pediatric patients. The safety and effectiveness of evolocumab have not been established in pediatric patients with HoFH who are younger than 13 years old nor in pediatric patients with primary hyperlipidemia or HeFH.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Evolocumab		

Age Range: 0 - 12 yoa

References:
Repatha Prescribing Information, August 2015, Amgen Medical Information.

8. Evolocumab / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Repatha (evolocumab). 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
Evolocumab		

References:
Repatha Prescribing Information, August 2015, Amgen Medical Information.
Osterberg L, Blaschke T. Adherence to Medication. N Eng Jrnl Med. 2005;353:487-97.
Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.

9. Metformin / Dolutegravir _____ _____

Alert Message: With concomitant use of a metformin-containing agent and a dolutegravir-containing agent, limit the total daily dose to 1000 mg of metformin either when starting metformin or dolutegravir. When stopping dolutegravir, the metformin dose may require an adjustment. Dolutegravir inhibits elimination of metformin via the renal cation transporter OCT2 resulting in increased metformin exposure.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Metformin		Dolutegravir

Max dose metformin: 1000 mg/day

References:
Tivicay Prescribing Information, August 2015, ViiV healthcare.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.
Triumeq Prescribing Information, August 2015, ViiV healthcare.

10. Orlistat / Amiodarone _____ _____

Alert Message: The concurrent use of orlistat (Alli and Xenical) and amiodarone may result in a reduction in exposure to amiodarone and its active metabolite, desethylamiodarone. Monitor patients for altered efficacy of amiodarone when orlistat is added or discontinued from their regimen.

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

Util A	Util B	Util C
Orlistat	Amiodarone	

References:
Xenical Prescribing Information, August 2015, Genentech.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

11. Orlistat / Antiepileptic Agents _____ _____

Alert Message: Convulsions have been reported in patients treated concomitantly with orlistat (Alli and Xenical) and antiepileptic agents. Patients should be monitored for possible changes in frequency and/or severity of convulsions. A mechanism for the potential interaction has not been stated.

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

Util A	Util B				Util C
Orlistat	Clobazam	Lacosamide	Tiagabine	Clonazepam	
	Lamotrigine	Topiramate	Clorazepate	Levetiracetam	
	Valproic Acid	Diazepam	Oxcarbazepine	Vigabatrin	
	Carbamazepine	Perampanel	Eslicarbazepine	Ezogabine	
	Felbamate	Primidone	Gabapentin	Rufinamide	
	Pregabaliln	Ethosuximide	Ethotoin	Methsuximide	
	Phenytoin	Zonisamide			

References:
Xenical Prescribing Information, August 2015, Genentech.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

12. Cariprazine / Overutilization _____ _____

Alert Message: Vraylar (cariprazine) may be over-utilized. The manufacturer's recommended maximum daily dose of cariprazine for patients with schizophrenia or bipolar I with mania or mixed episodes is 6 mg once daily. Dosages above 6 mg daily have not been shown to confer increased effectiveness sufficient to outweigh dose-related adverse reactions (e.g., extrapyramidal symptoms and akathisia).

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Cariprazine		

Max Dose: 6 mg/day

References:
Vraylar Prescribing Information, September 2015, Actavis.

13. Cariprazine / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Cariprazine		

Age Range: 0-17 yoa

References:
Vraylar Prescribing Information, September 2015, Actavis.

14. Cariprazine / Cardio & Cerebrovascular Disease _____ _____

Alert Message: Vraylar (cariprazine) should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose patients to hypotension (e.g., dehydration, hypovolemia, and treatment with antihypertensives). Cariprazine has been shown to cause orthostatic hypotension and these patients may be at increased risk.

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

Util A	Util B	Util C
Cariprazine	Heart Failure	
	Myocardial Infarction	
	Coronary Artery Disease	
	Ischemia	
	Conduction Abnormalities	
	Dehydration	
	Hypovolemia	

References:
Vraylar Prescribing Information, September 2015, Actavis.

15. Cariprazine / Antihypertensive Medications _____ _____

Alert Message: Vraylar (cariprazine) should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose patients to hypotension (e.g., dehydration, hypovolemia, treatment with antihypertensives). Cariprazine has been shown to cause orthostatic hypotension and these patients may be at increased risk.

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

Util A	Util B	Util C
Cariprazine	ACEIs	
	ARBs	
	CCBs	
	B-Blockers	
	α-B Blockers	
	Direct Renin Inhibitors	
	Selective Aldosterone Antagonist	
	Diuretics	
	Centrally-Acting Adrenergic Agents	
	Peripherally-Acting Adrenergic Agents	

References:
Vraylar Prescribing Information, September 2015, Actavis.

16. Cariprazine / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Vraylar (cariprazine) with a strong CYP3A4 inhibitor may result in increased cariprazine exposure due to inhibition of cariprazine CYP3A4-mediated metabolism. If a strong CYP3A4 inhibitor is initiated, reduce the current cariprazine dosage by half. If cariprazine is added onto a regimen already containing a strong CYP3A4 inhibitor the maximum dose should not exceed 3 mg daily. If the strong CYP3A4 inhibitor is discontinued, the cariprazine dosage may need to be increased.

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

Util A	Util B		Util C
Cariprazine	Nefazodone	Cobicistat	
	Clarithromycin	Boceprevir	
	Telithromycin	Ketoconazole	
	Saquinavir	Itraconazole	
	Ritonavir	Posaconazole	
	Indinavir	Voriconazole	
	Nelfinavir		

References:
Vraylar Prescribing Information, September 2015, Actavis.

17. Cariprazine / Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Vraylar (cariprazine) with a strong CYP3A4 inducer has not been evaluated and is not recommended because the net effect on the active drug and metabolites is unclear.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B		Util C
Cariprazine	Phenobarbital	Rifampin	
	Primidone	Rifapentine	
	Phenytoin	Rifabutin	
	Carbamazepine		

References:
Vraylar Prescribing Information, September 2015, Actavis.

18. Cariprazine / Non-Adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vraylar (cariprazine). 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

Util A	Util B	Util C
Cariprazine		

References:
Vraylar Prescribing Information, September 2015, Actavis.
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.
Berger A, Edelsbery J, Sanders KN, et al., Medication Adherence and Utilization in Patients with Schizophrenia or Bipolar Disorder Receiving Aripiprazole, Quetiapine, or Ziprasidone at Hospital Discharge: A Retrospective Cohort Study. BMC Psychiatry 2012,12:99.
Stephenson JJ, Tuncelli O, Gu T, et al., Adherence to Oral Second-Generation Antipsychotic Medications in Patients with Schizophrenia and Bipolar Disorder: Physicians' Perceptions of Adherence vs. Pharmacy Claims. Int J Clin Pract, June 2012, 66, 6, 565-573.
Morken G, Widen JH, Grawe RW. Non-adherence to Antipsychotic Medication, Relapse and Rehospitalisation in Recent-Onset Schizophrenia. BMC Psychiatry. 2008, 8:32.

19. Elbasvir+Grazoprevir / _____ _____

Alert Message: The manufacturer's recommended dose of Zepatier (elbasvir/grazoprevir) is one tablet once daily (total 50 mg elbasvir/100 mg grazoprevir).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Elbasvir/Grazoprevir		

Max Dose: 1 Tablet per day

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

20. Elbasvir+Grazoprevir / Hepatic Impairment _____ _____

Alert Message: Zepatier (elbasvir/grazoprevir) is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations.

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

Util A	Util B	Util C **(Include)**
Elbasvir/Grazoprevir		Hepatic Impairment

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

21. Elbasvir+Grazoprevir / OATP1B1/3 Inhibitors _____ _____

Alert Message: Concurrent use of Zepatier (elbasvir/grazoprevir) with organic anion transporting polypeptide (OATP1B1/3) inhibitors (e.g., atazanavir, saquinavir, and cyclosporine) is contraindicated. The grazoprevir component of the combination antiviral is a OATP1B1/3 substrate and co-administration of these agents my increase grazoprevir plasma concentrations increasing the risk of ALT elevations.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Atazanavir	
	Darunavir	
	Lopinavir	
	Saquinavir	
	Tipranavir	
	Cyclosporine	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

22. Elbasvir+Grazoprevir / Strong 3A4 Inducers & Efavirenz _____ _____

Alert Message: Concurrent use of Zepatier (elbasvir/grazoprevir) with a strong CYP3A inducer (e.g., carbamazepine, phenobarbital, and enzalutamide) or an efavirenz-containing agent is contraindicated. Both components of the combination antiviral are CYP3A substrates and co-administration with CYP3A inducers my lead to loss of virologic response due to significant decreases in the elbasvir/grazoprevir plasma concentrations.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Carbamazepine	
	Phenytoin	
	Primidone	
	Phenobarbital	
	Rifampin	
	Efavirenz	
	Enzalutamide	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

23. Elbasvir+Grazoprevir / Moderate CYP3A Inducers _____ _____

Alert Message: Concurrent use of Zepatier (elbasvir/grazoprevir) with a moderate CYP3A inducer (e.g., etravirine, modafinil, and dexamethasone) is not recommended. Both components of the combination antiviral are CYP3A substrates and co-administration with CYP3A inducers may lead to reduced virologic response due to decreases in the elbasvir/grazoprevir plasma concentrations.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Bosentan	
	Etravirine	
	Nevirapine	
	Modafinil	
	Armodafinil	
	Dexamethasone	
	Bexarotene	
	Dabrafenib	
	Deferasirox	
	Eslicarbazepine	
	Oxcarbazepine	
	Rifapentine	
	Rifabutin	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

24. Elbasvir+Grazoprevir / Certain Strong CYP3A Inhibitors _____ _____

Alert Message: Concurrent use of Zepatier (elbasvir/grazoprevir) with a strong CYP3A inhibitor (e.g., ketoconazole, nefazodone, and clarithromycin) is not recommended. Both components of the combination antiviral are CYP3A substrates and co-administration with strong CYP3A inhibitors may lead to increased plasma concentration of elbasvir/grazoprevir and risk of adverse effects.

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

Util A	Util B	Util C **(Negating)**
Elbasvir/Grazoprevir	Nefazodone	Atazanavir
	Ketoconazole	Darunavir
	Itraconazole	
	Cobicistat	
	Indinavir	
	Nelfinavir	
	Ritonavir	
	Clarithromycin	
	Telithromycin	
	Boceprevir	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

25. Elbasvir+Grazoprevir / Tacrolimus _____ _____

Alert Message: Concurrent use of Zepatier (elbasvir/grazoprevir) with systemic tacrolimus, a narrow therapeutic index drug, may result in increased tacrolimus concentrations due to inhibition, by the grazoprevir component of the antiviral agent, of tacrolimus CYP3A4-mediated metabolism. Frequent monitoring of tacrolimus whole blood concentrations, changes in renal function, and tacrolimus-related adverse events is recommended.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Tacrolimus	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

26. Elbasvir+Grazoprevir / Atorvastatin 40 & 80 mg _____ _____

Alert Message: The dose of an atorvastatin-containing product should not exceed a daily dose of 20 mg when co-administered with Zepatier (elbasvir/grazoprevir). The grazoprevir component of the antiviral agent is a CYP3A4 inhibitor and co-administration with atorvastatin, a CYP3A4 substrate, may result in elevated atorvastatin concentrations and increased risk of statin-related myopathy and rhabdomyolysis.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Atorvastatin 40 & 80mg	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

27. Elbasvir+Grazoprevir / Rosuvastatin 20 & 40 mg _____ _____

Alert Message: The dose of Crestor (rosuvastatin) should not exceed a daily dose of 10 mg when co-administered with Zepatier (elbasvir/grazoprevir). Both elbasvir and grazoprevir are BCRP transport inhibitors and co-administration with rosuvastatin, a BCRP substrate, may result in elevated rosuvastatin concentrations and increased risk of statin-related myopathy and rhabdomyolysis.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Rosuvastatin 20 & 40mg	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

28. Elbasvir+Grazoprevir / Higher Strengths of Fluvastatin, Lovastatin & Simvastatin _____ _____

Alert Message: Caution should be exercised when co-administering Zepatier (elbasvir/grazoprevir) with fluvastatin, lovastatin, or simvastatin. Concomitant use may result in elevated statin concentrations increasing the risk of statin-related myopathy and rhabdomyolysis. The lowest necessary dose of the statin should be used and the patient should be closely monitored for statin-associated adverse effects.

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

Util A	Util B	Util C
Elbasvir/Grazoprevir	Lovastatin Fluvastatin Simvastatin	

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

29. Elbasvir+Grazoprevir / Pediatric Use _____ _____

Alert Message: The safety and efficacy of Zepatier (elbasvir/grazoprevir) in pediatric patients less than 18 years of age have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Elbasvir/Grazoprevir		

Age Range: 0 – 17 yoa

References:
Zepatier Prescribing Information, Jan. 2016, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

30. Mepolizumab / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Nucala (mepolizumab) is 100 mg administered once every 4 weeks by subcutaneous injection.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Mepolizumab		

Max Dose: 1 injection/4 weeks

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

31. Mepolizumab / Overutilization _____ _____

Alert Message: The safety and efficacy of Nucala (mepolizumab) in pediatric patients younger than 12 years of age have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Mepolizumab		

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

32. Mepolizumab / Helminth Infection _____ _____

Alert Message: The patient has a diagnosis of an helminth infection and is receiving Nucala (mepolizumab) which may adversely influence the a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with mepolizumab. If patients become infected while receiving treatment with mepolizumab and do not respond to anti-helminth treatment, discontinue mepolizumab treatment until infection resolves. Mepolizumab is an interleukin-5 antagonist (IL-5) which reduces the production and survival of eosinophils.

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

Util A	Util B	Util C
Mepolizumab	Helminth Infection	

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

33. Genvoya / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Genvoya (EVG/c/FTC/TAF). Non-adherence to the prescribed dosing regimen may result in insufficient plasma levels of the agents in the combination product and therefore only partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Conflict Code: LR - Nonadherence

Drugs/Diseases		
Util A	Util B	Util C
EVG/c/FTC/TAF		

References:

Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Hoffman C, Mulcahy F, Goals and Principles of Therapy - Eradication, Cost, Prevention and Adherence. Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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. April 9, 2015.
Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

34. Genvoya / Overutilization _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) may be over-utilized. The manufacturer's maximum recommended dose of the combination agent in adults and pediatric patients 12 years and older with body weight of at least 35 kg, is one (1) tablet orally once daily with food.

Conflict Code: ER - Overutilization

Drugs/Diseases		
Util A	Util B	Util C
EVG/c/FTC/TAF		

Max Dose: 1 tablet/day

References:

Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

35. Genvoya / Severe Renal Disease _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) use is not recommended in patients with estimated creatinine clearance below 30 ml per minute as the safety of EVG/c/FTC/TAF has not been established in these patients.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF		CKD Stage 4 & 5

Max Dose: 1 tablet per day

References:

Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

36. Genvoya / Severe Hepatic Impairment _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) use is not recommended in patients with severe hepatic impairment as there is not pharmacokinetic or safety data available regarding the use of EVG/c/FTC/TAF in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF		Cirrhosis

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

37. Genvoya / All Other Antiretrovirals _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) is a combination product that is a complete HIV treatment regimen. The use of this other antiretroviral agents with EVG/c/FTC/TAF should be avoided.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Protease Inhibitors	
	CCR5	
	Fusion Inhibitor	
	Integrase Inhibitors	
	NNRTIs	
	NRTIs	
	NARTI	
	ART Boosting Agent	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

38. Genvoya / Drugs Contraindicated with Genvoya _____ _____

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

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

Util A	Util B		Util C
EVG/c/FTC/TAF	Alfuzosin	Pimozide	
	Carbamazepine	Revatio	
	Phenobarbital	Triazolam	
	Phenytoin	Midazolam Oral	
	Rifampin	Ergotamine	
	Lovastatin	Dihydroergotamine	
	Simvastatin	Methylergonovine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

39. Genvoya / Drugs Affecting Renal Function _____ _____

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Genvoya (EVG/c/FTC/TAF) and a drug that affects renal function. The emtricitabine (FTC) and tenofovir (TAF) components of the fixed combination product EVG/c/FTC/TAF are primarily excreted by the kidneys and co-administration with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and TAF increasing the risk of adverse reactions.

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

Util A	Util B			Util C
EVG/c/FTC/TAF	Acyclovir	Everolimus	Methotrexate	
	Valacyclovir	Aspirin	Allopurinol	
	Valganciclovir	Acetaminophen		
	Lithium	ACEIs		
	Cyclosporine	ARBs		
	Tacrolimus	NSAIDS		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

40. Genvoya / 3A4, 2D6, P-gp, BCRP OATP1B1 & OATP1B3 Substrates _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with drugs that are primarily substrates for these isoenzymes and/or transporters may result in elevated substrate plasma concentrations and increased risk of substrate-related adverse effects.

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

Util A	Util B		Util C
EVG/c/FTC/TAF	Amiodarone	Zolpidem	
	Bupropion	Lapatinib	
	Canagliflozin	Pazopanib	
	Digoxin	Imatinib	
	Boceprevir	Topotecan	
	Chlorpromazine	Methotrexate	
	Disopyramide	SSRIs	
	Flecainide	TCAs	
	Propafenone	Methadone	
	Quinidine	Oxycodone	
	Tamoxifen	Hydrocodone	
	Trazodone	Codeine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

41. Genvoya / CYP2C9 Substrates _____ _____

Alert Message: The elvitegravir component of Genvoya (EVG/c/FTC/TAF) is a modest inducer of CYP2C9 and concurrent use of EVG/c/FTC/TAF with drugs that are primarily substrates for CYP2C9 may result in elevated substrate plasma concentrations and increased risk of substrate-related adverse effects.

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

Util A	Util B		Util C
EVG/c/FTC/TAF	Amitriptyline	Mefenamic Acid	
	Carvedilol	Meloxicam	
	Celecoxib	Montelukast	
	Chlorpheniramine	Nateglinide	
	Diclofenac	Piroxicam	
	Dronabinol	Quetiapine	
	Fluoxetine	Rosiglitazone	
	Fluvastatin	Tamoxifen	
	Glipizide	Tolbutamide	
	Ibuprofen	Torsemide	
	Imipramine	Valsartan	
	Indomethacin	Warfarin	
	Irbesartan	Zafirlukast	
	Losartan	Zileuton	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.
Evidence-Based Medicine (EBM) CONSULT Cytochrome P450 (CP450) Drug Reference Table – Medication Substrates
Available at: http://www.ebmconsult.com/content/pages/cytochrome-cyp-p450-enzyme-medication-herbs-substrates

42. Genvoya / Clarithromycin / CKD Stage 2 & 3 _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with clarithromycin may result in increased plasma concentrations of both clarithromycin and the cobicistat component of the combo antiretroviral. While no clarithromycin dosage adjustment is required for patients with CLcr 60 ml/min or greater, patients with CLcr 50 to 60 ml/min should have the clarithromycin dose reduced by 50%. Clarithromycin and cobicistat are CYP3A4 substrates as well as inhibitors and clarithromycin is renally eliminated.

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

Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF	Clarithromycin	CKD Stage 2 & 3

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

43. Genvoya / Telithromycin _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with telithromycin may result in elevated plasma concentrations of telithromycin and/or the cobicistat component of the combo antiretroviral increasing the risk of adverse effects. Telithromycin and cobicistat are CYP3A4 substrates as well as inhibitors. Consider monitoring the patient for adverse effects of both medications.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Telithromycin	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

44. Genvoya / Oxcarbazepine _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with oxcarbazepine may result in decreased plasma concentrations of the elvitegravir (EVG) and cobicistat (c) components of the combo antiretroviral which may result in loss of antiretroviral efficacy and potential development of viral resistance. Elvitegravir and cobicistat are CYP3A4 substrates and oxcarbazepine is a CYP3A4 inducer. Alternative anticonvulsants should be considered for patients prescribed EVG/c/FTC/TAF.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Oxcarbazepine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

45. Genvoya / Ethosuximide _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with ethosuximide may result in elevated plasma concentrations of ethosuximide due to inhibition, by the cobicistat component, of ethosuximide CYP3A4-mediated metabolism. Clinical monitoring is recommended with concomitant use.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Ethosuximide	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

46. Genvoya / Rifabutin & Rifapentine _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with rifabutin or rifapentine is not recommended due to potential for loss of virologic response. Both rifabutin and rifapentine are inducers of CYP3A4-mediated metabolism and co-administration may result in the decreased plasma concentrations of the components which are CYP3A4 substrates (cobicistat, elvitegravir, and tenofovir) in the fixed dosed combination product EVG/c/FTC/TAF.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Rifabutin	
	Rifapentine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

47. Genvoya / Certain Benzodiazepines _____ _____

Alert Message: Concurrent use of Genvoya (EVG/c/FTC/TAF) with benzodiazepines that are metabolized via CYP3A4 may result in elevated benzodiazepine levels increasing the risk of benzodiazepine-related adverse effects. The cobicistat component of EVG/c/FTC/TAF is a potent inhibitor of the CYP3A4 isoenzyme. Clinical monitoring for benzodiazepine-related adverse effects is recommended and a dosage reduction may be necessary.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Alprazolam	
	Chlordiazepoxide	
	Clonazepam	
	Clorazepate	
	Diazepam	
	Estazolam	
	Flurazepam	
	Quazepam	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

48. Genvoya / Beta-Blockers - CYP3A4, CYP2D6 & P-gp Substrates _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with beta-blockers that are primarily substrates for these isoenzymes and/or transporters may result in elevated beta-blocker plasma concentrations. Clinical monitoring is recommended and a dosage decrease of the beta-blocker may be necessary.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Metoprolol - 2D6	
	Timolol - 2D6	
	Bisoprolol - 2D6 & 3A4	
	Nadolol - P-glycoprotein	
	Nebivolol - 2D6	
	Pindolol - 2D6	
	Propranolol - 2D6	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

49. Genvoya / Beta-Blockers - CYP3A4, CYP2D6 & P-gp Substrates _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with beta-blockers that are primarily substrates for these isoenzymes and/or transporters may result in elevated beta-blocker plasma concentrations. Clinical monitoring is recommended and a dosage decrease of the beta-blocker may be necessary.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Metoprolol - 2D6	
	Timolol - 2D6	
	Bisoprolol - 2D6 & 3A4	
	Nadolol - P-glycoprotein	
	Nebivolol - 2D6	
	Pindolol - 2D6	
	Propranolol - 2D6	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

50. Genvoya / CCBs - CYP3A4, CYP2D6 & P-gp Substrates _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with calcium channel blockers (CCBs) that are primarily substrates for these isoenzymes and/or transporters may result in elevated CCB plasma concentrations. Clinical monitoring is recommended upon co-administration of these agents.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Amlodipine - 3A4	
	Diltiazem - 2D6 & 3A4	
	Felodipine - 3A4	
	Isradipine -3A4	
	Nicardipine - 2D6 & 3A4	
	Nifedipine - 2D6 & 3A4	
	Nimodipine - 3A4	
	Nisoldipine - 3A4	
	Verapamil - 2D6 & 3A4 & P-gp	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

21. Genvoya / Dexamethasone _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with dexamethasone may result in decreased plasma concentrations of the elvitegravir and cobicistat components of the combo antiretroviral which may result in loss of antiretroviral efficacy and potential development of viral resistance. Elvitegravir and cobicistat are CYP3A4 substrates and dexamethasone is a CYP3A4 inducer. Alternative corticosteroid therapy should be considered for patients prescribed EVG/c/FTC/TAF.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Dexamethasone	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

52. Genvoya / Fluticasone _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with a fluticasone-containing product may cause increased fluticasone plasma concentrations due to inhibition of fluticasone CYP3A4-mediated metabolism by the cobicistat component of the antiretroviral product. Concomitant therapy may result in adverse systemic corticosteroid effects. Alternative corticosteroids should be considered, particularly for long-term use.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Fluticasone	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

53. Genvoya / Atorvastatin _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with atorvastatin may result in increased plasma concentrations of atorvastatin due to inhibition, by cobicistat component of the antiretroviral, of atorvastatin CYP3A4-mediated metabolism. When prescribing atorvastatin with EVG/c/FTC/TAF initiate atorvastatin at the lowest starting dose and titrate carefully while monitoring for safety.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Atorvastatin	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

54. Genvoya / Norgestimate/Ethinyl Estradiol OCs _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with a norgestimate/estradiol oral contraceptive may result in increased plasma concentrations of norgestimate and decreased concentrations of ethinyl estradiol. The effects of elevated norgestimate concentrations are not fully known and can include increased risk of insulin resistance, dyslipidemia, and venous thrombosis. The potential risks and benefits associated with co-administration of these agents should be considered, particularly in women who have risk factors for these events.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Norgestimate/Ethinyl Estradiol OCs	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

55. Genvoya / Immunosuppressants _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzyme CYP3A4 and a p-glycoprotein (P-gp) inhibitor. Concomitant use of EVG/c/FTC/TAF with an immunosuppressant that is a substrate of CYP3A4 or P-gp may result in elevated immunosuppressant plasma concentrations. Therapeutic monitoring is recommended if these agents are co-administered.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Cyclosporine	
	Tacrolimus	
	Sirolimus	
	Everolimus	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

56. Genvoya / Colchicine / Renal & Hepatic Impairment _____ _____

Alert Message: Concurrent use of Genvoya (EVG/c/FTC/TAF) with colchicine may result in elevated colchicine plasma concentrations. If co-administration is necessary use the following dosage adjustment for gout flares, administer a single 0.6 mg dose of colchicine, followed by 0.3 mg 1 hour later and treatment course repeated repeat no sooner than 3 days. If used for gout prophylaxis and the original regimen was 0.6 mg BID, reduce dose to 0.3 mg QD, if regimen was 0.6 mg QD, reduce to 0.3 mg QOD. If used for familial Mediterranean fever the maximum daily dose is 0.6 mg.

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

Util A	Util B	Util C **(Negate)**
EVG/c/FTC/TAF	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

57. Genvoya / Antipsychotic _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6. Concomitant use of EVG/c/FTC/TAF with antipsychotics that are primarily substrates for these isoenzymes may result in elevated antipsychotic plasma concentrations. A decrease in the dosage of the antipsychotic may be needed when co-administered with EVG/c/FTC/TAF.

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

Util A	Util B		Util C
EVG/c/FTC/TAF	Aripiprazole	Chlorpromazine	
	Asenapine	Fluphenazine	
	Brexpiprazole	Haloperidol	
	Cariprazine	Perphenazine	
	Clozapine	Thioridazine	
	Iloperidone		
	Lurasidone		
	Olanzapine		
	Paliperidone		
	Quetiapine		
	Risperidone		
	Ziprasidone		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

58. Genvoya / Itraconazole & Ketoconazole _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with ketoconazole or itraconazole may result in elevated plasma levels of the antifungal and the cobicistat component of the combination product. The maximum daily dose of ketoconazole or itraconazole should not exceed 200 mg per day when administered with (EVG/c/FTC/TAF). Both antifungals and the cobicistat component of EVG/c/FTC/TAF are CYP3A4 substrates as well as strong CYP3A4 inhibitors.

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

Util A	Util B	Util C **(Include)**
Itraconazole		EVG/c/FTC/TAF
Ketoconazole		

Max Dose: 200 mg/day

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

59. Genvoya / Voriconazole _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with voriconazole may result in elevated plasma levels of voriconazole and the cobicistat component of the combination product. Both voriconazole and the cobicistat component of EVG/c/FTC/TAF are CYP3A4 substrates as well as strong CYP3A4 inhibitors. Co-administration is not recommended unless benefit/risk assessment justifies the use.

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

Util A	Util B	Util C
EVG/c/FTC/TAF	Voriconazole	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.