



*Dale R. Folwell, CPA*  
STATE TREASURER OF NORTH CAROLINA  
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## Pharmacy & Therapeutics Committee Meeting

*Formulary and Program Updates Effective 7/1/19*

May 15, 2019  
6:30 – 8:00 PM

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*A Division of the Department of State Treasurer*

# Role Call

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## P&T COMMITTEE MEMBERS

- David Konanc, MD
- Matthew K. Flynn, MD
- Jennifer Burch, PharmD
- Peter Robie, MD
- Tony Gurley, RPh, JD
- John B. Anderson, MD, MPH
- John Engemann, MD
- Joseph Shanahan, MD
- Sundhar Ramalingam, MD

## PLAN STAFF & VENDORS

### State Health Plan

- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones

### CVS Caremark

- Renee Jarnigan, RPh
- Stephanie Morrison, PharmD

# Ethics Awareness & Conflict of Interest Reminder

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In accordance with the NC State Health Plan for Teachers and State Employees' ethics policy, it is the duty of every member of the Pharmacy & Therapeutics Committee, whether serving in a vote casting or advisory capacity, to avoid both conflicts of interest and appearances of conflict.

Does any Committee member have any known conflict of interest or the appearance of any conflict with respect to any manufacturers of any medication to be discussed at today's meeting?

Or, if during the course of the evaluation process if you identify a conflict of interest or the appearance of a conflict.

If so, please identify the conflict or appearance of conflict and refrain from any undue participation in the particular matter involved.

# Recent Plan Formulary Decisions

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All approved negative formulary changes from February's meeting went into effect 4/1/2019 and include the following:

## Removed the following products from the formulary:

- ZYTIGA, EPOGEN, & PROCRIT, BUTALBITAL/ACETAMINOPHEN 50-300 MG, & DICLOFENAC GEL 1%.

## Moved the following branded products to non-preferred status:

- ATRALIN GEL 0.05%, COREG CR, ESTRACE VAGINAL CREAM 0.01%, LUZU CREAM 1%, UCERIS, MESTINON TIMESPAN, & TOPICORT..

## Adopted the following new utilization management criteria:

- Butalbital Containing Analgesics (Brand/Generics) Policy,
- Fortamet/Glumetza Policy (Proposed Revisions),
- Onfi Policy,
- Orilissa Policy.

# Minutes from Previous Committee Meeting

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Instead of having the Secretary read the minutes, copies found in the P&T Booklet were distributed prior to the meeting for your review.

- Are there any additions or corrections to the minutes?
- If not, the minutes will stand approved as is.

# Formulary Updates – Effective 7/1/2019

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## CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes
- New Drug Additions
- Utilization Management Criteria

## Presented by:

- Heather Renee Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **EPIVIR® (lamivudine)**

- Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection.
- Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir) and Viread (tenofovir disoproxil fumarate).

### **VEMLIDY® (tenofovir alafenamide fumarate)**

- Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection.
- Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir) and Viread (tenofovir disoproxil fumarate).

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **BARACLUDE® tablets (entecavir)**

- Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection.
- Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir), and Viread (tenofovir disoproxil fumarate).

### **HEPSERA® (adefovir dipivoxil)**

- Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection.
- Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir), and Viread (tenofovir disoproxil fumarate).



# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **ZARXIO® (fligrastim)**

- Availability of another short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.
- The preferred option is Nivestym (filgrastim-aafi).

### **GRANIX® (filgrastim)**

- Availability of another short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.
- The preferred option is Nivestym (filgrastim-aafi).

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **FULPHILA® (pegfilgrastim)**

- Availability of other long-acting colony-stimulating factor options for those who are receiving myelosuppressive anti-cancer therapy.
- Preferred options include Neulasta (pegfilgrastim) and Udenyca (pegfilgrastim-cbqv).

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **ZORTRESS® (everolimus)**

- Availability of a generic option for the prophylaxis of organ rejection in kidney and liver transplant recipients.
- The preferred option is sirolimus.

### **RAPAMUNE® (sirolimus)**

- Availability of a generic option for the prophylaxis of organ rejection in renal transplant recipients and the treatment of lymphangiomyomatosis (LAM).
- The preferred option is sirolimus.

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **CELLCEPT® (mycophenolate)**

- Availability of generic options for the prophylaxis of organ rejection in transplant recipients.
- Preferred options include mycophenolate mofetil and mycophenolate sodium.

### **MYFORTIC® (mycophenolate)**

- Availability of generic options for the prophylaxis of organ rejection in renal transplant recipients.
- Preferred options include mycophenolate mofetil and mycophenolate sodium.

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **ASTAGRAF XL® (tacrolimus)**

- Availability of generic options for the prophylaxis of organ rejection in transplant recipients.
- Preferred options include cyclosporine; cyclosporine, modified; and tacrolimus.

### **ENVARSUS XR® (tacrolimus)**

- Availability of generic options for the prophylaxis of organ rejection in transplant recipients.
- Preferred options include cyclosporine; cyclosporine, modified; and tacrolimus.

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **CHORIONIC GONADOTROPIN**

- Availability of other options for the treatment of induction of ovulation and pregnancy in women.
- The preferred option is Ovidrel (choriogonadotropin alfa).

### **NOVAREL® (chorionic gonadotropin, human)**

- Availability of other options for the treatment of induction of ovulation and pregnancy in women.
- The preferred option is Ovidrel (choriogonadotropin alfa).

# Formulary Updates – Product Exclusions

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## Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

### **PREGNYL® (chorionic gonadotropin, human)**

- Availability of other options for the treatment of induction of ovulation and pregnancy in women.
- The preferred option is Ovidrel (choriogonadotropin alfa).

# Formulary Updates – Product Exclusions

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## Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

## **ZORVOLEX® (diclofenac)**

- Availability of generic nonsteroidal anti-inflammatory agents (NSAIDs) for treating mild to moderate pain, or pain associated with osteoarthritis (OA).
- Preferred options include diclofenac sodium, meloxicam, and naproxen.

## **RHEUMATE® (folate, B12, curcuminoid turmerone complex)**

- Availability of a generic option for folate supplementation during methotrexate therapy.
- The preferred option is folic acid.



# Formulary Updates – Product Exclusions

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## Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

### **FOSTEUM® (genistein, zinc chelazome, cholecalciferol)**

- Availability of generic options for treating osteopenia and osteoporosis.
- Preferred options include alendronate, ibandronate, and risedronate.

### **FOSTEUM PLUS® (calcium compounds phosphate, genistein aglycone, citrated zinc bisglycinate, transmenaquinone-7, cholecalciferol)**

- Availability of a generic option for folate supplementation during methotrexate therapy.
- The preferred option is folic acid.

# Formulary Updates – Product Exclusions

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## Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

## **VASCULERA® (diosmin glycoside, alka4-complex)**

- Availability of other options for dietary supplementation in maintaining the integrity of vein walls and decreasing inflammation to prevent progression to chronic venous disease (CVD).
- Consult doctor for preferred options.

## **FML LIQUIFILM® (fluorometholone)**

- Availability of other options for treating inflammation within the eye.
- Preferred options include dexamethasone, prednisolone acetate 1%, Durezol (difluprednate), Flarex (fluorometholone), FML Forte (fluorometholone), FML S.O.P. (fluorometholone), Maxidex (dexamethasone), and Pred Mild (prednisolone acetate).

# Formulary Updates – Product Exclusions

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## Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

### **LACTULOSE PAK 10 GM® (only NDC: 46600020003010)**

- Availability of other less expensive generic NDC's.
- Preferred options include Lactulose, Enulose, & Generlac solution 10 GM/15 ML.

### **NAPROXEN SUSP 125MG/5ML® (only NDC: 66100060001805)**

- Availability of other less expensive generic NDC's.
- Preferred options include Naproxen suspension 125MG/5 ML by Palmetto Pharmaceuticals, Inc.

# Formulary Updates – Uptiers

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## Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.
- All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

### **SAVELLA® (milnacipran hydrochloride)**

- Availability of another option for the treatment of fibromyalgia.
- The preferred option is Lyrica (pregabalin).

### **RAPAFLO® (silodosin)**

- Availability of generic options for the treatment of benign prostatic hyperplasia (BPH).
- Preferred options include alfuzosin ext-rel, doxazosin, silodosin, tamsulosin, and terazosin.

# Formulary Updates – Uptiers

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## Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.
- All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

### **CANASA® (mesalamine)**

- Availability of other options for the treatment of ulcerative proctitis.
- Preferred options include hydrocortisone enema, mesalamine rectal suspension, and Cortifoam (hydrocortisone acetate foam).

### **CARAFATE® (sucralfate)**

- Availability of a generic option for the treatment of active duodenal ulcers.
- The preferred option is sucralfate.

# Formulary Updates – Uptiers

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## Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.
- All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

### **TENORETIC® (atenolol/chlorthalidone)**

- Availability of other beta-blocker/diuretic combination medications for treating hypertension.
- Preferred options include atenolol/chlorthalidone, bisoprolol/hydrochlorothiazide, metoprolol/hydrochlorothiazide, Lopressor HCT (metoprolol/hydrochlorothiazide), and Ziac (bisoprolol/hydrochlorothiazide).

### **CIALIS® 2.5mg and 5 mg (tadalafil)**

- Availability of generic options for the treatment of benign prostatic hyperplasia (BPH). Cialis (and generics) for use for erectile dysfunction remains a Plan Exclusion.
- Preferred options are sildenafil and tadalafil.

# Formulary Updates – Downtiers

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## Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- Non-specialty drugs will move from tier 3 (non-preferred brand) to tier 2 (preferred brand) while specialty drugs will move from tier 6 (non-preferred specialty) to tier 5 (preferred specialty).

## **NEULASTA® (pegfilgrastim)**

- To provide a long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.
- Specialty medication moving from tier 6 to tier 5

## **EYLEA® (aflibercept)**

- To provide an option for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy in patients with diabetic macular edema.
- Specialty medication moving from tier 6 to tier 5

# Formulary Updates – Downtiers

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## Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- Non-specialty drugs will move from tier 3 (non-preferred brand) to tier 2 (preferred brand) while specialty drugs will move from tier 6 (non-preferred specialty) to tier 5 (preferred specialty).

## LUCENTIS® (ranibizumab)

- To provide an option for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.
- Specialty medication moving from tier 6 to tier 5

## V-GO® (disposable insulin delivery device)

- To provide an option for continuous/basal and on-demand/bolus insulin delivery in insulin-dependent diabetes.
- Non-specialty medication moving from tier 3 to tier 2



# Formulary Updates – New Drug Additions

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## New-to-Market Block Removals

- CVS Health program that initially blocks new drugs from being added to the formulary and evaluates:
  - Drug's place in therapy
  - Potential market share
  - Cost
  - Appropriate utilization management
- CVS adds new drugs to their formulary throughout the year; however the Plan only adds these medications on a quarterly basis

## Add-Backs

- Medications that were previously removed from the formulary but are now being added back
- Only occurs once a year
  - Xeljanz, & Xeljanz XR were added back this year beginning 1/1/2019

## New Molecular Entities

- Are also initially placed on CVS's New-to-Market Block
- These medications are reviewed by the members of the Plan's P&T Committee to determine:
  - Satisfactory tier position
  - Appropriate utilization management

# Formulary Updates – New Drug Additions

## Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Antineoplastic Agents/ Anti-CD123	<b>ELZONRIS</b> (tagraxofusp)	Y	2/13/19	6	Indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older	Y
Anti-Infectives/ Antiretroviral Combinations	<b>CIMDUO</b> (lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.	Y
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	<b>SYMFI</b> (efavirenz 600 mg /lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.	Y
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	<b>SYMFI LO</b> (efavirenz 400 mg /lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.	Y
Central Nervous System/ Anticonvulsants	<b>DIACOMIT</b> (stiripentol)	Y	5/1/19	6	Indicated for treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older.	Y
Hematologic/ Hematopoietic Growth Factors	<b>UDENYCA</b> (pegfilgrastim)	Y	5/1/19	4	To provide a long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	N

# Formulary Updates – New Drug Additions

## Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Hematologic/ Hematopoietic Growth Factors	<b>NIVESTYM</b> (filgrastim)	Y	5/1/19	4	To provide a short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	N
Respiratory Agents/Pulmonary Fibrosis Agents	<b>ESBRIET 267 &amp; 801 MG</b> (pirfenidone)	Y	5/4/2018	5	New tablet formulation available in 2018	N
Cardiovascular Agents/Pulmonary Hypertension	<b>ALYQ 20 MG</b> (tadalafil)	Y	2/6/19	4	Generic (tadalafil) for Adcirca	N
Cardiovascular Agents/Pulmonary Hypertension	<b>TADALAFIL TAB 20MG</b>	Y	3/1/19	4	Generic (tadalafil) for Adcirca	N
Anti-Infectives/ Glycopeptide	<b>VANCOMYCIN INJ 1.5/300</b>	N		3	New SSB	N
Antineoplastic Agents/ Monoclonal Antibodies	<b>TECENTRIQ INJ 840/14</b> (atezolizumab)	Y	3/20/19	6	New strength of product already on formulary	N

# Formulary Updates – New Drug Additions

## Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Immunologic Agents/ Immunosuppressants/ Calcineurin Inhibitors	PROGRAF GRA 0.2 & 1 MG (tacrolimus)	Y	3/20/19	2	New SSB granule packets for suspension formulation; CVS Excludes from ACSF; Historically, NCSHP placed Prograf at tier 2.	N
Endocrine and Metabolic/ Estrogens/ Vaginal	FEMRING 0.05/24H & 0.1MG/24 (estradiol acetate)	N	3/20/19	3	New strength of product already on formulary	N
Endocrine and Metabolic/ Antidiabetics/ Insulins	NOVOLIN INJ FLEXPEN (Insulin regular [human])	N	3/20/19	2	Removal of Flexpen formulation from NTM block.	N
Antineoplastic Agents/ Cytoprotective Agents	LEUCOVORIN INJ 500/50ML	N	4/10/19	1	New generic available in the 500mg/50ml strength	N
Central Nervous System/ Antidepressants/ NMDA Receptor Antagonists	SPRAVATO 56 & 84 MG (esketamine)	Y	4/18/19	6	Esketamine, the S-enantiomer of ketamine, in a nasal sprayform indicated, in conjunction with an oral antidepressant, for the tx of treatment-resistant depression in adults. Has a REMS Program.	N
Topical/ Dermatology/ Antibiotics, Quinolone	XEPI CREAM 1% (ozenoxacin)	N	4/18/19	3	Indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older.	N

# Formulary Updates – New Molecular Entities

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## ELZONRIS (tagraxofusp)

### Indication:

- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

### Mechanism of Action:

- Anti-CD123; Antineoplastic agent

### Drug Facts:

- 12 mcg/kg IV once daily on days 1 to 5 of a 21-day cycle
- Warnings: capillary leak syndrome, hepatotoxicity, and drug-drug interactions

### Place in Therapy:

- The first and only approved treatment for blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- In treatment-naïve patients 72% had a complete response, 90% had an overall response rate with 45% bridging to stem cell transplantation

### Proposed Tier Placement:

- Tier 6 – Non-preferred Specialty

# Formulary Updates – New Molecular Entities

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## ELZONRIS (tagraxofusp)

### Specialty Guideline Management:

#### **Blastic plasmacytoid dendritic cell neoplasm (BPDCN)**

Authorization of 12 months may be granted for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) when the patient's disease is positive for CD123 expression.

# Formulary Updates – New Molecular Entities

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## CIMDUO (lamivudine/tenofovir disoproxil fumarate)

### Indication:

- Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg

### Mechanism of Action:

- Antiretroviral, Reverse Transcriptase Inhibitor, Nucleoside

### Drug Facts:

- One tablet taken orally once daily with or without food.
- Warnings: Lactic acidosis/hepatomegaly, Chronic hepatitis B, Renal toxicity, Interferon alfa, Decreased bone mineral density, Osteomalacia and renal dysfunction, Immune reconstitution syndrome, Fat redistribution, Appropriate use, & Drug-drug interactions.

### Place in Therapy:

- Double combination HIV treatment

### Proposed Tier Placement:

- Tier 2 – Preferred Brand

# Formulary Updates – New Molecular Entities

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## CIMDUO (lamivudine/tenofovir disoproxil fumarate)

### Specialty Quantity Limit:

### **HUMAN IMMUNODEFICIENCY VIRUS (HIV) MEDICATIONS**

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

- A. 30 per 30 days
- B. Based on FDA-recommended dosing of one tablet once daily



# Formulary Updates – New Molecular Entities

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## SYMFI & SYMFI LO (efavirenz/lamivudine/tenofovir disoproxil fumarate)

### Indication:

- Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.

### Mechanism of Action:

- Antiretroviral, Reverse Transcriptase Inhibitor, Non-nucleoside & Nucleoside

### Drug Facts:

- One tablet taken orally once daily on an empty stomach, preferably at bedtime
- Warnings: Lactic acidosis/hepatomegaly, Chronic hepatitis B, Drug-drug interactions, Renal toxicity, Psychiatric effects, CNS effects, Rash, Hepatotoxicity, Interferon alfa, Pancreatitis, Seizure disorder, Hypercholesterolemia, Decreased bone mineral density, Osteomalacia and renal dysfunction, Immune reconstitution syndrome, Fat redistribution, QT prolongation, & HIV-associated dementia.

### Place in Therapy:

- Three-drug single-tablet antiretroviral (ARV) regimen
- Symfi Lo is the first combination regimen in the U.S. with a reduced dose of efavirenz

### Proposed Tier Placement:

- Tier 2 – Preferred Brand

# Formulary Updates – New Molecular Entities

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SYMFI (efavirenz/lamivudine/tenofovir disoproxil fumarate)

Specialty Quantity Limit:

## **HUMAN IMMUNODEFICIENCY VIRUS (HIV) MEDICATIONS**

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

- A. 30 per 30 days
- B. Based on FDA-recommended dosing of one tablet once daily

# Formulary Updates – New Molecular Entities

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## DIACOMIT (stiripentol)

### Indication:

- Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam.

### Mechanism of Action:

- Anticonvulsant, Miscellaneous
- Direct effects mediated through the GABA<sub>A</sub> receptor and indirect effects involving inhibition of cytochrome P450 activity with resulting increase in blood levels of clobazam and its active metabolite

### Drug Facts:

- 50 mg/kg/day in 2 to 3 divided doses daily with a meal and glass of water
- Warnings: Appetite/Weight loss, Blood dyscrasias, Withdrawal, Powder for suspension, Suicidal ideation, Appropriate use, & Drug-drug interactions

### Place in Therapy:

- Provides a new treatment option to young patients with Dravet syndrome

### Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

# Formulary Updates – New Molecular Entities

## DIACOMIT (stiripentol)

### Specialty Quantity Limit:

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for the treatment of seizures associated with Dravet syndrome fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

Medication	Standard Limit	FDA-recommended dosing
<u>Diacomit</u> 250 mg capsule	360 per 30 days	50 mg/kg/day, administered in 2 or 3 divided doses (i.e., 16.67 mg/kg three times daily or 25 mg/kg twice daily). If the exact dosage is not achievable given the available strengths, round to the nearest possible dosage, which is usually within 50 mg to 150 mg of the recommended 50 mg/kg/day. A combination of the two <u>Diacomit</u> strengths can be used to achieve this dosage. The maximum recommended total dosage is 3,000 mg/day.
<u>Diacomit</u> 500 mg capsule	180 per 30 days	
<u>Diacomit</u> 250 mg powder for oral suspension	360 per 30 days	
<u>Diacomit</u> 500 mg powder for oral suspension	180 per 30 days	

# Utilization Management Policy Review

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## XIIDRA Initial Prior Authorization

### Affected Medications:

- XIIDRA (lifitegrast)

### Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for dry eye disease
- AND
- The patient has experienced an inadequate treatment response, intolerance or contraindication to artificial tears products

# New Opioid UM Strategy for Children and Adolescents



## Restricting children and adolescent opioid naïve members<sup>1</sup> to a 3-day supply

### Includes

- Limits new-to-therapy members age 19 years and younger to a 3-day short acting opioid supply<sup>2</sup>
- Applies to immediate release (IR) and immediate release combination opioid products
- A step therapy<sup>3</sup> if ER criteria is not already in place requiring appropriate trial of an IR before an extended release (ER) opioid for acute conditions, reducing patient exposure to ER drugs

### Exceptions and Exclusions

- Prior authorization requests will be evaluated on a case-by-case basis for patients whose clinical diagnosis may require a longer day supply for ongoing therapy
- Members with a diagnosis of cancer or sickle cell disease, or undergoing palliative care are exempt from this edit

- 1. Age 19 years and younger
- 2. For clients adopting the enhanced opioid utilization management strategy, extended release opioid products are not available to opioid-naïve members.
- 3. Step therapy for minors is required for client without ER or step therapy criteria.

# Utilization Management Policy Review

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## Acetaminophen/Aspirin/Ibuprofen Containing Opioid Analgesics Initial Step; Duration Limit and Post Limit Prior Authorization

Prior authorization applies only to patients  $\leq$  19 years of age

### Affected Medications\*:

- (acetaminophen and benzhydrocodone)
- (acetaminophen and codeine)
- (acetaminophen and hydrocodone)
- (acetaminophen and oxycodone)
- (acetaminophen and tramadol)
- (acetaminophen, caffeine and dihydrocodeine)
- (aspirin and oxycodone)
- (asprin, caffeine and dihydrocodeine)
- (ibuprofen and hydrocodone)
- (ibuprofen and oxycodone)

- \*Includes brands and generics; generic name and dosage form listed

# Utilization Management Policy Review

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## Acetaminophen/Aspirin/Ibuprofen Containing Opioid Analgesics Initial Step; Duration Limit and Post Limit Prior Authorization

### Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care

**OR**

- The requested drug is being prescribed for moderate to severe **CHRONIC** pain where use of an opioid analgesic is appropriate. [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

**OR**

- The patient requires extended treatment beyond 3 days for ongoing management of **ACUTE** pain



# Utilization Management Policy Review

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## Immediate-Release Opioid Analgesics Initial Step; Duration Limit; Initial Limit and Post Limit Prior Authorization

Prior authorization applies only to patients  $\leq$  19 years of age

### Affected Medications\*:

- (codeine sulfate oral solution; tablets)
- (hydromorphone hydrochloride oral solution, suppositories, tablets)
- (levorphanol tartrate tablets)
- (meperidine hydrochloride oral solution, tablets)
- (morphine sulfate oral soln, oral soln concentrate, suppositories, tablets)
- (oxycodone hydrochloride capsules, oral soln, oral soln concentrate, tablets)
- (oxymorphone hydrochloride tablets)
- (pentazocine/naloxone tablets)
- (tapentadol oral solution, tablets)
- (tramadol hydrochloride tablets)

- \*Includes brands and generics; generic name and dosage form listed

# Utilization Management Policy Review

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## Immediate-Release Opioid Analgesics Initial Step; Duration Limit; Initial Limit and Post Limit Prior Authorization

### Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care

**OR**

- The patient can safely take the requested dose based on their history of opioid use. [Note: The lowest effective dosage should be prescribed for opioid naïve patients.]

**AND**

# Utilization Management Policy Review

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## Immediate-Release Opioid Analgesics Initial Step; Duration Limit; Initial Limit and Post Limit Prior Authorization

### Coverage Criteria (Continued):

- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder

#### **AND**

- The requested drug is being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate. [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

#### **AND**

- The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety

#### **OR**

- The patient requires extended treatment beyond 3 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

# Summary of Formulary Changes Effective 7/1/19

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## DRUG EXCLUSIONS

- EPIVIR HBV, VEMLIDY, ZARXIO, ZORTRESS, BARACLUDE tablets, HEPSERA, CHORIONIC GONADOTROPIN, NOVAREL, PREGNYL, FULPHILA, GRANIX, CELLCEPT, MYFORTIC, RAPAMUNE, ASTAGRAF XL, ENVARUSUS XR, ZORVOLEX, RHEUMATE, FOSTEUM, FOSTEUM PLUS, VASCULERA, FML LIQUIFILM & LACTULOSE (NDC 46600020003010), NAPROXEN (NDC 66100060001805) & **ALTABAX.**

## UPTIERS

- SAVELLA, RAPAFLO, CANASA, CARAFATE, TENORETIC, & CIALIS (2.5 and 5 mg).

## DOWNTIERS

- NEULASTA, EYLEA, LUCENTIS, & V-GO.

## NEW DRUG ADDITIONS

- ELZONRIS, DIACOMIT, UDENYCA, NIVESTYM, CIMDUO, SYMFI LO, SYMFI, ESBRIET, ALYQ, TADALAFIL, VANCOMYCIN, TECENTRIQ, PROGRAF, FEMRING, NOVOLIN, LEUCOVORIN, & SPRAVATO.

## UTILIZATION MANAGEMENT

- Opioid Policies for Age  $\leq 19$ , Xiidra Policy, Specialty Quantity Limit HIV Meds & Diacomit, & Elzonris SGM.



Next meeting: **August 14, 2019**



*North Carolina*  
**State Health Plan**  
FOR TEACHERS AND STATE EMPLOYEES

*A Division of the Department of State Treasurer*



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