



**OHIO DEPARTMENT OF MEDICAID**  
**Pharmacy & Therapeutics Committee**  
**Ohio Department of Medicaid**  
**50 W. Town Street, Room C621-A and C621-B**  
**Columbus, OH**  
**October 3, 2018**  
**9:00 AM**  
**MINUTES**

**Committee Members Present:**

Tracey Archibald, PharmD  
Michelle Barger, PharmD  
Susan Baker, CNP  
Mary Ann Dzurec, PharmD  
Suzanne Eastman, RPh  
Jennifer Gwilym, DO  
Stephen Hersey, MD  
Karen Jacobs, DO, Chair  
Melissa Jefferis, MD

**Committee Members Not Present:**

Sandra Hrometz PhD, RPh

**Contract Staff/Change Healthcare Staff Present:**

Jeffrey Barkin, MD  
Chad Bissell, PharmD  
Jill RK Griffith, BS, PharmD  
Steven Liles, MD  
Benjamin Link, PharmD  
Gail Master, RPh  
Payal Patel, PharmD

Also present were approximately 96 observers, most representing pharmaceutical manufacturers.

**I. Call to Order**

Dr. Jacobs called the meeting to order at 9:05 a.m.

**II. Introductions**

Dr. Jacobs welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. The committee introduced themselves.

**III. Department of Medicaid Update**

Dr. Barger provided information about the Ohio Department of Medicaid (ODM) Pharmacy & Therapeutics Committee By-Laws changes. Discussion ensued, and the By-Laws were amended as drafted

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and would be made available on the website for review by interested parties. Dr. Archibald provided updates on the Department's Unified Preferred Drug (PDL) initiative. Beginning January 1, 2019, the Ohio Department of Medicaid (ODM) will require all managed care plans (MCPs) and fee-for-service (FFS) in Ohio to use the ODM preferred drug list (PDL) and prior authorization criteria for selected drug categories as identified in the draft PDL. Dr. Archibald outlined changes to the MCP provider agreements for January 1, 2019 that would include the requirement for transparency with pharmacy claims payment and requirements that the plans move to a pass-through model for their pharmacy services. Dr. Archibald provided an update on the Drug Utilization Review (DUR) Board and Committee for ODM. She identified that new members would be joining the Committee and Board and provided an overview of the recent retrospective DUR interventions conducted. Dr. Archibald also identified the ongoing project with ODM pharmacy students to identify members receiving concurrent opioids and medication assisted treatment (MAT) for opioid use disorder (OUD). Dr. Archibald provided a copy of the report prepared by ODM to the Committee that discusses the benefits of Medicaid expansion in Ohio. The report was published in August of 2018 and is available on ODM's website. The report concludes that Medicaid reduced the rate of uninsured in Ohio, benefited the health of enrollees, and reduced costly Emergency Department visits among other benefits. Dr. Archibald advised the Committee that ODM is developing a new process for interested parties and drug manufacturers to meet with the Department. The Department will announce these changes as more information becomes available and stakeholders are encouraged to check the website for updates. Dr. Archibald identified that ODM is conducting its cost of dispensing survey as required every two years. There were no questions from the Committee related to these updates.

#### IV. **Manufacturer Presentations**

- a. Novo Nordisk, Rebinyn<sup>®</sup>**
- b. Eisai, Fycompa<sup>®</sup>**
- c. Sunovion, Aptiom<sup>®</sup>**
- d. Tris Pharma, Dynavel XR<sup>®</sup>**
- e. Sanofi, Aubagio<sup>®</sup>**
- f. AstraZeneca, Belsomra<sup>®</sup>**
- g. Novo Nordisk, Tresiba<sup>®</sup>**
- h. Astra Zeneca, Qtern<sup>®</sup>/Xigduo<sup>®</sup>**
- i. Janssen, Invokana<sup>®</sup>**
- j. Eli Lilly, Trulicity<sup>®</sup>**
- k. Merck, Steglatro<sup>®</sup>/ Stegluromet<sup>®</sup>/ Steglujan<sup>®</sup>**
- l. Novo Nordisk, Ozempic<sup>®</sup>**
- m. Sanofi, Admelog<sup>®</sup>**
- n. Pfizer, Xeljanz<sup>®</sup>**
- o. Sanofi, Kevzara<sup>®</sup>**
- p. UCB, Cimzia<sup>®</sup>**
- q. Merck, Noxafil<sup>®</sup>**
- r. Janssen, Symtuza<sup>™</sup>**
- s. Sunovion, Utibron<sup>®</sup>Neohaler<sup>®</sup>**
- t. Merck, Asmanex<sup>®</sup> Twisthaler, Asmanex<sup>®</sup> HFA**
- u. Pfizer, Eucrisa<sup>®</sup>**

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The session was adjourned at 11:25 a.m. with a break for lunch.

P & T reconvened at 12:40 p.m. with presentations by interested parties.

**V. Interested Party Presentation**

**a. Dr. Brian Beesley, drug coverage for HIV antiretroviral drugs & Hepatitis C**

Dr. Beesley provided information on the treatment of HIV and requested the removal of prior authorization for the HIV antiretroviral class. Dr. Beesley also provided information on the treatment of hepatitis C and requested access to coverage for Ohio Medicaid members regardless of fibrosis score.

**b. Dr. Antonio Phillips, Eucrisa<sup>®</sup>**

Dr. Phillips provided testimony on his practice's experience with the drug Eucrisa<sup>®</sup>, including benefits of non-steroid option. Dr. Phillips requested a removal of the prior authorization for Eucrisa<sup>®</sup>.

**c. Novartis, Entresto<sup>®</sup>**

Novartis requested the P&T consider the removal of the final two bulleted PA requirements for Entresto<sup>®</sup>.

**VI. Approval of July 12<sup>th</sup>, 2018 Meeting Minutes**

The minutes from the prior P&T meeting were reviewed. Dr. Gwilym moved to approve the minutes, seconded by Dr. Hersey. Votes were taken, and the minutes were approved.

**VII. Preferred Drug List Review**

Following the completion of presentations from drug manufacturers and interested parties, the P&T Committee members deliberated on the classes for extraction. It was announced that the recommendation for Adzenys<sup>®</sup> XR-ODT to be made preferred was to be changed to recommend it remain non-preferred and Vyvanse<sup>®</sup> Chewable remain preferred. The following drug categories were extracted for review and discussion with the remainder of the categories being voted and approved as recommended in the draft PDL document with the correction to Adzenys<sup>®</sup> XR-ODT and Vyvanse<sup>®</sup> Chewable.

Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction

Endocrine Agents: Diabetes – Insulin

Endocrine Agents: Diabetes – Non-Insulin

Infectious Disease Agents: Antivirals – Hepatitis C Agents

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting

Respiratory Agents: Chronic Obstructive Pulmonary Disease

Respiratory Agents: Glucocorticoid Agents – Inhaled

Central Nervous System (CNS) Agents: Anticonvulsants

Immunomodulator Agents for Systemic Inflammatory Disease

Infectious Disease Agents: Antivirals-HIV

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**a. Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction**

Change Healthcare provided a clinical overview of the category and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued regarding the potential coverage of generic buprenorphine tablets without restrictions and ODM identified that outside of the PDL proposal, safety edits would be put in place to ensure appropriate utilization of these products consistent with Ohio Administrative Code Rules for outpatient treatment of opioid addiction. This would include a restriction of buprenorphine-only to females of child bearing age as well as dose limits. Votes were taken, and the category was approved as listed on the draft PDL.

**b. Endocrine Agents: Diabetes – Insulin**

Change Healthcare provided a clinical overview of the management of diabetes and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued around the potential clinical benefits of select insulin products. Votes were taken, and the category was approved as listed on the draft PDL.

**c. Endocrine Agents: Diabetes – Non-Insulin**

Change Healthcare provided a clinical overview of the management of diabetes and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued around the potential clinical benefits of select glucagon-like peptide-1 receptor agonists (GLP-1) and sodium-glucose transporter 2 (SGLT2) inhibitor products. Votes were taken, and the category was approved as listed on the draft PDL.

**d. Infectious Disease Agents: Antivirals – Hepatitis C Agents**

Change Healthcare provided a clinical overview on the management of chronic hepatitis C and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued around proposed fibrosis and specialist restrictions. Votes were taken, and the committee's recommendation is shown below:

## Infectious Disease Agents: Antivirals – Hepatitis C Agents

**LENGTH OF AUTHORIZATIONS:** 1 year except simeprevir and direct acting antivirals (DAAs), see below

Is there any reason the patient cannot be changed to a medication within the same class that does not require prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Member established on current therapy with prior payer (i.e. Commercial, Fee-for-Service, Managed Care Plan, etc).

### **ADDITIONAL CRITERIA FOR DAAs:**

All HCV DAAs require clinical prior authorization. Only regimens recommended by the American Association for the Study of Liver Diseases (AASLD) will be approved. Patients must meet all criteria below.

#### **Step 1: Patient Readiness Evaluated**

- Patient must meet labeled age requirements for product.
- Patient must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy.
- Patient must meet kidney function as indicated in package labeling for product.
- Patient must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information for each agent.
- Patient must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the patient attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria).

**Step 2: Clinical Assessment of Disease**

- Confirmation of chronic hepatitis C (CHC):
  - Hepatitis C Virus (HCV) antibody test reactive
  - Provide HCV RNA load measured within 90 days prior to starting DAA therapy
  - Specify the Genotype
- Document progression of disease:
  - Document the degree of liver fibrosis:
    - ~~Must have a Metavir score of F2 or greater confirmed by:~~
      - Liver biopsy; or
      - ~~Both one radiological and one serological test confirming F2 or greater~~
    - If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score.
    - ~~Document any HCV-related extra hepatic manifestations (e.g., lymphoma, symptomatic cryoglobulinemia, membranoproliferative glomerulonephritis). Manifestations will be considered evidence of degree of liver fibrosis.~~
    - ~~Document any co-infection with HIV. Coinfection with HIV will be considered evidence of degree of liver fibrosis.~~
      - Patients with decompensated cirrhosis (CTP score 7 or higher) will be approved for therapy only after consultation with a physician in a liver transplant center.
  - Document that patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions
  - Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (patient will not be approved if any other HCV treatments have been used in the last 6 months)

**Step 3: Direct Acting Antivirals (DAA) conditions for coverage**

- Must be prescribed by, ~~or in consultation with~~, a hepatologist, gastroenterologist, or infectious disease specialist
- HCV RNA testing is required every 4 weeks
- ~~Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other~~ antiretroviral medications (e.g. DAAs)
- Only regimens listed as recommended or alternative in the current AASLD guidance (<http://hcvguidelines.org>) will be approved ~~with duration of approval based upon guidelines~~. Regimens listed as not recommended will not be approved.

**ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

- Pegylated Interferons have a Black Box Warning which indicates that a patient should be monitored closely with periodic clinical and laboratory evaluations.
- Ribavirins are contraindicated in women who are pregnant and in their male partner(s). At least two reliable forms of contraception must be used during therapy.

**ADDITIONAL CRITERIA FOR PROTEASE INHIBITORS:**

- Patient is receiving prior/concurrent interferon and ribavirin as recommended in the FDA-approved package labeling
- Simeprevir: Patient has genotype 1 disease, and if genotype 1a does not have the Q80k polymorphism. Initial approval for 4 weeks, then must report viral load and follow response-guided therapy outlined in the prescribing information. Simeprevir should not be used in patients who have previously failed therapy with boceprevir or telepravir.

**INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL**

CLINICAL PA REQUIRED "PREFERRED" †	PA REQUIRED "NON-PREFERRED"
EPCLUSA <sup>®</sup> (sofosbuvir/velpatasvir) MAVYRET <sup>®</sup> (glecaprevir and pibrentasvir) ZEPATIER <sup>™</sup> (elbasvir and grazoprevir tablet)	DAKLINZA <sup>™</sup> (daclatasvir) HARVONI <sup>®</sup> (ledipasvir/sofosbuvir) tablets SOVALDI <sup>®</sup> (sofosbuvir) VOSEVI <sup>™</sup> (sofosbuvir, velpatasvir, voxilaprevir)

† Selection of regimen will be based upon guidelines; refer to PA form for guidance.

**INFECTIOUS DISEASE AGENTS: HEPATITIS C - PEGYLATED INTERFERONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PEGASYS <sup>®</sup> (peginterferon alfa-2a) PEG-INTRON <sup>®</sup> (peginterferon alfa-2b)	

**INFECTIOUS DISEASE AGENTS: HEPATITIS C - RIBAVIRINS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
RIBAVIRIN (generic of Rebetol <sup>®</sup> )	COPEGUS <sup>®</sup> (ribavirin) MODERIBA PAK <sup>®</sup> (ribavirin) REBETOL <sup>®</sup> (ribavirin) RIBAPAK <sup>®</sup> (ribavirin) RIBASPHERE <sup>®</sup> (ribavirin) 400mg, 600mg

**INFECTIOUS DISEASE AGENTS: HEPATITIS C – PROTEASE INHIBITORS**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	OLYSIO <sup>®</sup> (simeprevir)

**e. Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting**

Change Healthcare provided a clinical overview on the management of asthma and chronic obstructive pulmonary disease (COPD) and ODM provided an overview of the proposed criteria and drug coverage changes. Votes were taken, and the category was approved as listed on the draft PDL.

**f. Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting**

Change Healthcare provided a clinical overview on the management of asthma and chronic obstructive pulmonary disease (COPD) and ODM provided an overview of the proposed criteria and drug coverage changes. Votes were taken, and the category was approved as listed on the draft PDL.

**g. Respiratory Agents: Chronic Obstructive Pulmonary Disease**

Change Healthcare provided a clinical overview on the management of asthma and chronic obstructive pulmonary disease (COPD) and ODM provided an overview of the proposed criteria and drug coverage changes. Votes were taken, and the category was approved as listed on the draft PDL.

**h. Respiratory Agents: Glucocorticoid Agents – Inhaled**

Change Healthcare provided a clinical overview on the management of asthma and chronic obstructive pulmonary disease (COPD) and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion arose around the 4<sup>th</sup> bullet of the 1<sup>st</sup> step of the proposed criteria for coverage. The recommendation was to change the requirement from a patient's condition being defined as unstable based upon emergency room visits to more closely align with the guidelines for asthma management. Votes were taken, and the committee's recommendation is shown below:

**Respiratory Agents: Glucocorticoid Agents – Inhaled**

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
  - Patient’s condition is clinically unstable—as defined in current guidelines in terms of oral steroid use or patient’s current symptomatology--changing to a medication not requiring prior approval might cause deterioration of the patient’s condition.
2. If there have been therapeutic failures to no less than one-month trials of at least two medications not requiring prior approval, then may approve the requested medication.

**ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

If the patient is a child under 13 years old or a patient with a significant disability, and unable to use an inhaler which does not require prior approval, or is non-compliant on an inhaler not requiring prior approval because of taste, dry mouth, infection; then may approve the requested medication.

**RESPIRATORY AGENTS: GLUCOCORTICIDS – INHALED**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
FLOVENT DISKUS <sup>®</sup> and HFA (fluticasone) PULMICORT FLEXHALER <sup>®</sup> (budesonide) <sup>†</sup>	AEROSPAN <sup>®</sup> HFA (flunisolide) ALVESCO <sup>®</sup> (ciclesonide) ARMONAIR <sup>™</sup> RESPICLICK <sup>®</sup> (fluticasone) + ARNUITY ELLIPTA <sup>®</sup> (fluticasone <u>furoate</u> ) <sup>†</sup> ASMANEX <sup>®</sup> HFA, Twisthaler (mometasone) QVAR <sup>®</sup> (beclomethasone)

<sup>†</sup>Denotes breath actuated inhaler

**RESPIRATORY AGENTS: GLUCOCORTICIDS – NEBULIZERS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
BUDESONIDE nebulizer solution (generic of Pulmicort <sup>®</sup> ) (no PA required for age 4 or under)	BUDESONIDE nebulizer solution (generic of Pulmicort <sup>®</sup> ) (PA required for over age 4)

**i. Central Nervous System (CNS) Agents: Anticonvulsants**

Change Healthcare provided a clinical overview on the management of seizure disorders and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued regarding potential clinical merits of select agents over existing products. Votes were taken, and the committee’s recommendation is shown below:

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**Central Nervous System (CNS) Agents: Anticonvulsants**

**LENGTH OF AUTHORIZATIONS:** 1 year

**GRANDFATHERING:**

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**OTHER APPROVAL CRITERIA:**

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
  - Allergy to two preferred medications
  - Contraindication to or drug interaction with two preferred medications
  - History of unacceptable/toxic side effects to two preferred medications
  - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
2. If there has been a therapeutic failure to no less than two preferred products for a one-month trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid, for products that are used only for seizures, require a trial of one preferred product for one month. This provision applies only to the standard tablet/capsule dosage form, and does not apply to brand products with available generic alternatives.

**ANTICONVULSANTS: CARBAMAZEPINE DERIVATIVES**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CARBAMAZEPINE IR tablet, chewable, oral suspension (generic of Tegretol®)	CARBAMAZEPINE SUSP (generic of Tegretol® Susp)
CARBAMAZEPINE 12-hour ER capsule, tablet (generic of Carbatrol®, Tegretol XR®)	OXTELLAR® XR (oxcarbazepine)
OXCARBAZEPINE tablet, suspension (generic of Trileptal®)	
TEGRETOL® SUSP (carbamazepine)	
TRILEPTAL® suspension (oxcarbazepine)	

**ANTICONVULSANTS: FIRST GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLONAZEPAM tablet (generic of Klonopin®)	CELONTIN® (methsuximide)
DIASTAT® rectal gel (diazepam)	CLONAZEPAM ODT (generic of Klonopin® wafer)
DIVALPROEX (generic of Depakote®)	DIAZEPAM rectal gel (generic of Diastat®)
DIVALPROEX ER (generic of Depakote® ER)	ONFI® (clobazam)
ETHOSUXAMIDE (generic of Zarontin®)	PEGANONE® (ethotoin)
PHENOBARBITAL	STAVZOR® (valproic acid delayed-release)
PHENYTOIN (generic of Dilantin®)	
PRIMIDONE (generic of Mysoline®)	
VALPROIC ACID (generic of Depakene®)	

**ANTICONVULSANTS: SECOND GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FYCOMPA <sup>®</sup> (perampanel)	BANZEL <sup>®</sup> (rufinamide)
GABAPENTIN (generic of Neurontin <sup>®</sup> )	BRIVIACT <sup>®</sup> (brivaracetam)
LAMOTRIGINE IR tablet, chewable tablet (generic of Lamictal <sup>®</sup> )	FELBAMATE (generic of Felbatol <sup>®</sup> )
LEVETIRACETAM IR tablet, solution (generic of Keppra <sup>®</sup> )	LAMICTAL <sup>®</sup> ODT (lamotrigine)
LYRICA <sup>®</sup> (pregabalin)	LAMOTRIGINE ER tablet (generic of Lamictal <sup>®</sup> XR)
SABRIL <sup>®</sup> powder (no PA for age < 2)	LEVETIRACETAM ER tablet (generic of Keppra <sup>®</sup> XR)
TOPIRAMATE tablet (generic of Topamax <sup>®</sup> )	QUDEXY XR <sup>®</sup> (topiramate ER)
ZONISAMIDE (generic of Zonegran <sup>®</sup> )	SABRIL <sup>®</sup> powder (PA required for age > 2)
	SABRIL <sup>®</sup> tablet (vigabatrin)
	SPRITAM <sup>®</sup> (levetiracetam tablet for suspension)
	SUBVENITE (lamotrigine)
	TIAGABINE (generic of Gabitril <sup>®</sup> )
	TOPIRAMATE ER
	TOPIRAMATE sprinkle cap (generic of Topamax <sup>®</sup> sprinkle cap)
	TROKENDI XR <sup>®</sup> (topiramate)

**ANTICONVULSANTS: THIRD GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIMPAT <sup>®</sup> (lacosamide)	APTIOM <sup>®</sup> (eslicarbazepine acetate)

**j. Immunomodulator Agents for Systemic Inflammatory Disease**

Change Healthcare provided a clinical overview on the management of systemic inflammatory disease with cytokine and cell adhesion molecules modifiers and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued around potential benefits of having a first line oral agent as well as the potential benefits of select products in women of child bearing age. The Committee deliberated the merits of enacting changes now or waiting for more clinical information to be available. Votes were taken, and the category was approved as listed on the draft PDL.

**k. Infectious Disease Agents: Antivirals-HIV**

Change Healthcare provided a clinical overview on the management of HIV with a focus on treating treatment naïve patients and ODM provided an overview of the proposed criteria and drug coverage changes. Discussion ensued around the benefits of single tablet regimens on adherence as well as the use of select regimens in women of child bearing age. ODM identified retrospective DUR efforts undertaken to evaluate and address adherence to HIV-regimens. The Committee requested additional information around regimens ODM identified in non-adherent patients. Votes were taken, and the committee's recommendation is shown below:

## Infectious Disease Agents: Antivirals – HIV

**LENGTH OF AUTHORIZATIONS:** 1 year

**GRANDFATHERING:**

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**NIH RECOMMENDED REGIMENS – TREATMENT NAIVE PATIENTS**

**Integrase Strand Transfer Inhibitor-Based Regimens:**

ODM Preferred:

- Dolutegravir (Tivicay<sup>®</sup>) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada<sup>®</sup>)
- Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (AI) (Genvoya<sup>®</sup>)
- Raltegravir (Isentress<sup>®</sup>) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada<sup>®</sup>)
- Dolutegravir (Tivicay<sup>®</sup>) plus tenofovir alafenamide/emtricitabine (AII) (Descovy<sup>®</sup>)
- Raltegravir (Isentress<sup>®</sup>) plus tenofovir alafenamide/emtricitabine (AII) (Descovy<sup>®</sup>)
- **Bictegravir/emtricitabine/tenofovir (Biktarvy<sup>®</sup>)†**

†Recommended Initial Regimen based upon March 27, 2018 NIH News Release

ODM Non-Preferred/PA Required

- Dolutegravir/abacavir/lamivudine (only for patients who are HLA-B\*5701 negative) (AI) (Triumeq<sup>®</sup>)
- Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine (AI) (Stribild<sup>®</sup>)

**OTHER APPROVAL CRITERIA:**

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least one month with at least one medication not requiring prior approval? **If applicable, the request must address the inability to use the individual components.**

**HIV PROTEASE INHIBITORS AND COMBINATIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EVOTAZ <sup>®</sup> (atazanavir/cobicistat) KALETRA <sup>®</sup> (lopinavir/ritonavir) REYATAZ <sup>®</sup> capsules, oral powder (atazanavir sulfate)	CRIXIVAN <sup>®</sup> (indinavir sulfate) INVIRASE <sup>®</sup> (saquinavir mesylate) LEXIVA <sup>®</sup> (fosamprenavir calcium) VIRACEPT <sup>®</sup> (nelfinavir mesylate)

**HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PREZCOBIX <sup>®</sup> (darunavir/cobicistat) PREZISTA <sup>®</sup> (darunavir ethanolate) SYMTUZA <sup>™</sup> (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)	APTIVUS <sup>®</sup> (tipranavir; tipranavir/vitamin E)

**HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOSIDE ANALOGS AND COMBINATIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ABACAVIR SULFATE tablet (generic of Ziagen <sup>®</sup> ) ABACAVIR/LAMIVUDINE (generic of Epzicom <sup>®</sup> ) EMTRIVA <sup>®</sup> (emtricitabine) TRIZIVIR <sup>®</sup> (abacavir/lamivudine/zidovudine) ZIAGEN <sup>®</sup> solution (abacavir sulfate) ZIDOVUDINE (generic of Retrovir <sup>®</sup> )	DIDANOSINE capsule (generic of Videx <sup>®</sup> ) LAMIVUDINE solution, tablet (generic of Epivir <sup>®</sup> ) LAMIVUDINE/ZIDOVUDINE (generic of Combivir <sup>®</sup> ) STAVUDINE (generic of Zerit <sup>®</sup> ) VIDEX <sup>®</sup> solution (didanosine)

**HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOTIDE ANALOGS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIREAD <sup>®</sup> (tenofovir disoproxil fumarate)	

**HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUSTIVA <sup>®</sup> (efavirenz)	EDURANT <sup>®</sup> (rilpivirine) INTELENCE <sup>®</sup> (etravirine) NEVIRAPINE ER (generic of Viramune <sup>®</sup> XR) NEVIRAPINE IR (generic of Viramune <sup>®</sup> ) RESCRIPTOR <sup>®</sup> (delavirdine mesylate)

**HIV INTEGRASE STRAND TRANSFER INHIBITORS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ISENTRESS <sup>®</sup> tablets, chewable tablet, powder packets (raltegravir potassium) TIVICAY <sup>®</sup> (dolutegravir sodium)	

**HIV CCR5 CO-RECEPTOR ANTAGONISTS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SELZENTRY <sup>®</sup> (maraviroc)

**HIV FUSION INHIBITORS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	FUZEON® (enfuvirtide)

**HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DESCOVY® (emtricitabine/ tenofovir alafenamide) CIMDUO™ (lamivudine/tenofovir) TRUVADA® (emtricitabine/tenofovir)	

**HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SYMFI & SYMFI LO™ (efavirenz/lamivudine/tenofovir)	

**HIV RTI, NUCLEOSIDE, NUCLEOTIDE, & NON-NUCLEOSIDE ANALOGS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATRIPLA® (emtricitabine/efavirenz/tenofovir) COMPLERA® (emtricitabine/rilpivirine/tenofovir) ODEFSEY® (emtricitabine/rilpivirine/tenofovir alafenamide)	

**HIV INTEGRASE INHIBITOR & RTI COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GENVOYA® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)	STRIBILD® (elvitegravir/cobicistat/emtricitabine/tenofovir) TRIUMEQ® (dolutegravir/abacavir/lamivudine)†

† Request must address use of the individual components TIVICAY and EPZICOM.

**HIV INTEGRASE INHIBITOR & NUCLEOSIDE ANALOG COMBINATIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BIKTARVY® (bictegravir/emtricitabine/tenofovir)	

**HIV INTEGRASE INHIBITOR & NON-NUCLEOSIDE COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	JULUCA (dolutegravir/rilpivirine)

**HIV PHARMACOKINETIC ENHANCERS (CYP3A INHIBITORS)**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NORVIR® (ritonavir)	TYBOST® (cobicistat)

- VIII. Other Business  
No new business

- IX. Next Meeting Dates  
Next meeting date were set as follows:
- January 16th, 2019 at 50W Town Street
  - April 10th, 2019 at 50W Town Street
  - July 10th, 2019 at 50W Town Street
  - October 2nd, 2019 at 50W Town Street

- X. Adjournment  
Dr. Jacobs adjourned the meeting at 3:10 p.m.

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