



## OHIO DEPARTMENT OF MEDICAID

### Pharmacy & Therapeutics Committee

#### Ohio Department of Medicaid

GoToMeeting:

<https://attendee.gotowebinar.com/register/1161608053921347853>

July 8, 2020

**10:00 AM MEETING**

**MINUTES**

#### **Committee Members Present:**

Susan Baker, CNP  
Scott Baran, RPh  
Mary Ann Dzurec, Pharm D  
Suzanne Eastman, RPh, MS, Vice Chair  
Jennifer Gwilym, DO  
Stephen Hersey, MD  
Karen Jacobs, DO Chair  
Melissa Jefferis, MD  
Nathan Samsa, DO, Pharm D.

#### **Ohio Medicaid Staff Present:**

Michelle Barger, PharmD  
Sean Eckard, Pharm D

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

Laureen Biczak, DO  
Jill RK Griffith, BS, PharmD  
Steve Liles, PharmD Gail  
Master, RPh  
Philip Verret, PharmD

Also present were approximately 78 observers, most representing pharmaceutical manufacturers.

#### **I. Call to Order**

Dr. Jacobs called the meeting to order at 10:01 A.M.

#### **II. Introductions**

S. Baran welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. The committee members each introduced themselves.

#### **III. Approval of the January 15, 2020 Meeting Minutes**

The minutes from the prior P&T meeting were reviewed and approved by the Committee.

#### **IV. Administrative Matters**

S. Baran explained the Conflict of Interest Statement. Next, he reviewed changes in the bylaws. A discussion ensued about adding a limit to the number of unscheduled presenters. The Ohio Department of Medicaid (ODM) will discuss this internally and this will be presented at the next P&T meeting. Votes were taken, and the committee approved the bylaws as written.

#### **V. Department of Medicaid Update**

S. Baran announced that in response to the declared state of emergency for COVID-19 in Ohio, ODM along with all Ohio Medicaid Managed Care Plans implemented several emergency changes affecting pharmacy benefits, telehealth services, and service authorization requirements. The goals of these changes were to ease barriers to care, maintain member health, safety & welfare, and reduce burdens on hospitals and providers.

Additionally, ODM has recently implemented system changes to allow pharmacies to submit claims for COVID-19 specimen collection kits.

Next, the Centers for Medicare and Medicaid Services (CMS) has issued the FFY 2019 Annual DUR Report template to the States. Like last year's survey, it will include information on both Fee-For-Service and Managed Care Plan DUR programs. The due date has been pushed back to September 30, 2020.

Also, ODM submitted and received CMS approval on the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act State Plan Amendment, also referred to as the SUPPORT Act SPA.

Next, every two years, ODM conducts a Cost of Dispensing Survey. This survey is administered to ODM enrolled pharmacies and a final report with the findings is generated and posted on the Medicaid Pharmacy website. This survey is slated to occur later this year.

Finally, the ODM Pharmacy Industry Day application form to request a meeting with ODM clinical and policy staff has been added as a hyperlink on their pharmacy website and can be found on the UPDL Tab for those manufacturer representatives interested in this platform.

#### **VI. Interested Party Presentations**

- a.** Abdelhakim Hussein, MD representing Ohio Neurology & Headache Centre of Excellence  
New Acute Migraine Medications
- b.** Karen J. Brown, LSW representing Epilepsy Alliance Ohio  
Valtoco® (diazepam nasal spray)

#### **VII. Unified Preferred Drug List (PDL) Proposal**

##### **a. Analgesic Agents-Gout: Gloperba® (colchicine solution), Avion Pharmaceuticals**

P. Verret reviewed the clinical criteria and next Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed clinical criteria and category as shown below:

## Analgesic Agents: Gout

**LENGTH OF AUTHORIZATIONS:** 365 Days

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

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

**ADDITIONAL INFORMATION**

The requested medication may be approved if the following is true:

- Febuxostat will be approved after 30-day trial of maximum allopurinol dose, or intolerance/contraindication to allopurinol.
- Lesinurad will be approved when target serum uric acid levels (<6mg/dL) are not achieved on appropriate dose of xanthine oxidase inhibitor alone for at least 90 days and the treatment plan includes ongoing use of an appropriate dose of xanthine oxidase inhibitor
  - o Appropriate dose of xanthine oxidase inhibitors:
    - Allopurinol: 300mg daily (200mg daily in patients with eCrCl <60mL/min)
    - Febuxostat: 80mg daily

Use of the combination tablet of lesinurad and allopurinol will be limited to those cases where lesinurad has already demonstrated that the patient has reached their target serum uric acid levels

- Colchicine will be approved if any one of the following is true:
  - o Diagnosis of Familial Mediterranean Fever (FMF) (180-day approval); OR
  - o Trial of one of the following within the last 30 days:
    - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
    - Oral corticosteroid
- Gloperba® will be approved if the member is unable to swallow colchicine tablets or capsules and if all of following are met:
  - o Member is using Gloperba for the prevention of gout flares
  - o Trial of one of the following within the last 30 days:
    - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
    - Oral corticosteroid

**ANALGESIC AGENTS: GOUT – Analgesic Agents\***

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
COLCHICINE tablets (generic of Colcrys®) COLCHICINE capsules (generic of Mitigare®)	GLOPERBA® solution (colchicine)

\* Colchicine quantity limit 6/claim for acute gout, 60/30 days for chronic gout after trial on xanthine oxidase inhibitor, 120/30 days for FMF

\* Gloperba quantity limit is 1.2 mg per day



**b. Blood Formation, coagulation, and Thrombosis: Colony Stimulating Factors: Ziextenzo™ (pegfilgrastim-bmez injection), Sandoz Inc**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a Clinical PA Required “Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

**LENGTH OF AUTHORIZATIONS:** Dependent on diagnosis

**ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:**

Approval based upon diagnosis:

Diagnosis	Approval Length
Acute Myeloid Leukemia (AML)	14 days or duration of chemotherapy regimen
Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation	14 days or duration of chemotherapy regimen
Myeloid Engraftment for bone marrow transplant (BMT)	30 days
Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mm <sup>3</sup> and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers).	30 days
Hematopoietic radiation injury syndrome	30 days

**PDL CRITERIA:**

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 all medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

2. Has the patient failed a therapeutic trial of 14 days with one preferred medication?

**BLOOD AGENTS: HEMATOPOIETIC AGENTS-COLONY STIMULATING FACTORS**

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
GRANIX® (tbo-filgrastim) UDENYCA® (pegfilgrastim-cbqv) ZIE XTE N ZO™ (pegfilgrastim-bmez)	FULPHILA™ (pegfilgrastim-jmdb) LEUKINE® (sargramostim) NEULASTA® (pegfilgrastim) NEUPOGEN® (filgrastim) NIVESTYM™ (filgrastim) ZARXIO® (filgrastim-sndz)

**c. Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors: Esperoct® (antihemophilic factor- recombinant, glycopegylated-exei), Novo Nordisk**

Margaret Fischer, Pharm D, presented clinical information on Esperoct®, on behalf of Novo Nordisk. Dr. Biczak provided an additional clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors

**LENGTH OF AUTHORIZATIONS:** 365 Days

**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 previously, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:**

Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.

**PDL CRITERIA:**

1. Is there any reason the patient cannot use a medication not requiring prior approval?  
Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to all medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient trialed one preferred medication?
3. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.
4. If Rebinyn® is requested, confirmation that it is not being used for routine prophylaxis

**BLOOD AGENTS: FACTOR VIII**

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
ADVATE® (factor VIII recombinant)	ADYNOVATE® (factor VIII recombinant) †
AFSTYLA® (factor VIII recombinant)	ELOCTATE® (factor VIII recombinant, fc fusion protein) †
HEMOFIL M® (factor VIII human)	<b>ESPEROCT® (antihemophilic factor- recombinant, glycopegylated-exe i)†</b>
KOATE® (factor VIII human)	JIVI® (factor VIII recombinant, pegylated-aucl) †
KOGENATE FS® (factor VIII recombinant)	KOVALTRY® (factor VIII recombinant)
MONOCLATE-P® (factor VIII human)	OBIZUR® (factor VIII recombinant, porcine sequence)
NOVOEIGHT® (factor VIII recombinant)	
NUWIQ® (factor VIII recombinant)	
RECOMBINATE® (factor VIII recombinant)	
XYNTHA® (factor VIII recombinant)	

†Denotes long half-life factor

**d. Cardiovascular Agents: Lipotropics, ATP Citrate Lyase (ACL) Inhibitor: Nexletol™ (bempedoic acid tablet), Esperion Therapeutics, Inc. and Nexlizet™ (bempedoic acid and ezetimibe tablet), Esperion Therapeutics, Inc**

Dr. Biczak provided a clinical overview of Nexletol. ODM recommended a PA Required “Non- Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category. Dr. Biczak provided a clinical overview of Nexlizet. A discussion ensued around the clinical criteria. The clinical criteria were amended and following this discussion, votes were taken, and the committee recommended the changes. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed clinical criteria and category as shown below:

## Cardiovascular Agents: Lipotropics

**LENGTH OF AUTHORIZATIONS:** 365 days all Lipotropics except Omega-3 Fatty Acid 60 days for Omega-3 Polyunsaturated Fatty Acid

<b>Trial period</b>	30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia®) , 90 days for Fibrates
<b>Number of non-PA agents</b>	1 medication – The assumption is that the medication must be in the same class of the medication requested, if available, except for HMG-CoA reductase inhibitors- see specific criteria

**GENERAL GUIDELINES:**

- 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-to-drug interaction with medications not requiring prior approval (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system)
  - History of unacceptable/toxic side effects to medications not requiring prior approval
- If there has been a therapeutic failure to no less than two of the HMG-CoA preferred products for a 30-day trial, then a non-preferred HMG-CoA agent will be authorized.

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
  - Presence of tendon xanthomas or 1<sup>st</sup> or 2<sup>nd</sup> degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC >290 mg/dL **OR**
  - Confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
  - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease: must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin and
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
  - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH): must meet all:

1. Total cholesterol and LDL-C >600 mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia®) 10 mg daily with at least 1 other concurrently administered lipid lowering agent
3. Age ≥ 13 years old

## **ADDITIONAL CRITERIA FOR ATP Citrate Lyase (ACL) Inhibitor:**

- All products in this class require clinical prior authorization:
  - Age ≥18 years
  - Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose
    - o Nexlizet™ (bempedoic acid and ezetimibe tablet) approval requires one of the previous statin trials to be in combination with ezetimibe (Zetia®)
    - o Documented adherence to prescribed lipid lowering medications for previous 90 days Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes
    - o Lipid profile required at week 8 for HeFH or ASCVD

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
  - o Presence of tendon xanthomas or 1<sup>st</sup> or 2<sup>nd</sup> degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL **OR**
  - o Confirmation of diagnosis by gene or receptor testing

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin

### **CARDIOVASCULAR AGENTS: LIPOTROPICS - ATP Citrate Lyase (ACL) Inhibitor**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NEXLETOL™ (bempedoic acid) NEXLIZET™ (bempedoic acid and ezetimibe)

**e. Central Nervous System (CNS) Agents: Anti-Migraine Agents Category Reorganization**

S. Baran explained the reorganization of the Anti-Migraine Agents into categories of acute, cluster headache and prophylaxis. No clinical information was changed.

**f. Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute: Nurtec™ ODT (rimegepant orally disintegrating tablet), Biohaven Pharmaceuticals, Inc**

Chelsea Leroue, PhD, presented clinical information on Nurtec ODT™, on behalf of Biohaven Pharmaceuticals. Dr. Biczak provided an additional clinical overview of the medication. A discussion ensued around the clinical criteria and a decision was made to move Nurtec ODT from a PA Required “Non-Preferred” agent to a Step Therapy Required “Preferred” place on the PDL. The clinical criteria were amended and following this discussion, votes were taken, and the committee recommended the changes. Votes were then taken on the step therapy placement on the PDL, and the committee recommended the proposed category as shown below.

**Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute: Reyvow™ (lasmiditan tablet), Eli Lilly and Company**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below.

**Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute: Ubrelvy™ (ubrogepant tablet), Allergan, Inc.**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:



## Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute

**LENGTH OF AUTHORIZATIONS:** 180 Days

**APPROVAL CRITERIA:**

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to preferred medications
  - Contraindication to all preferred medications
  - History of unacceptable/toxic side effects to at least two preferred medications

□ **STEP THERAPY APPROVAL CRITERIA:**

- For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least two medications not requiring prior approval
- For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least one medication requiring step therapy

□ Calcitonin Gene-Related Peptide (CGRP) receptor antagonists must be started by a neurologist

**ADDITIONAL INFORMATION**

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer’s package insert.

**CNS AGENTS: ANTI-MIGRAINE AGENTS – ACUTE MIGRAINE TREATMENT**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
NARATRIPTAN (generic of Amerge®) RIZATRIPTAN tablets (generic of Maxalt®) RIZATRIPTAN ODT (generic of Maxalt-MLT®) SUMATRIPTAN tablets, nasal spray, injection (generic of Imitrex®)	NURTEC™ ODT (rimegepant)*	ALMOTRIPTAN (generic of Axert®) CAFERGOT® (ergotamine w/caffeine) ELETRIPTAN (generic of Relpax®) ERGOMAR® (ergotamine) FROVA® (frovatriptan) MIGERGOT® (ergotamine w/caffeine) MIGRANAL® (dihydroergotamine) ONZETRA™ XSAIL™ (sumatriptan) RE YVOW™ (las mid ita n) SUMAVEL DOSEPRO® (sumatriptan) TOSYMRA® (sumatriptan) TREXIMET® (sumatriptan/naproxen) UBRE LV Y™ (u b ro gep an t)* ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan)

\* Cannot be taken with another CGRP receptor antagonist

## Central Nervous System (CNS) Agents: Anti-Migraine Agents, Cluster Headache

**LENGTH OF AUTHORIZATIONS:** 180 Days

**APPROVAL CRITERIA:**

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

- Allergy to preferred medications
- Contraindication to all preferred medications
- History of unacceptable/toxic side effects to at least one preferred medication

**ADDITIONAL CRITERIA FOR EPISODIC CLUSTER HEADACHE**

1. At least 5 attacks within 30 days
2. Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration
3. Patient must have one or more of the following symptoms:
  - A. At least one of the following ipsilateral to the headache:
    - I. Conjunctival injection and/or lacrimation
    - II. Nasal congestion and/or rhinorrhea
    - III. Eyelid edema
    - IV. Forehead and facial sweating
    - V. Miosis and/or ptosis
  - B. A sense of restlessness or agitation
4. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
5. Not better accounted for by another ICHD-3 diagnosis
6. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more
7. Failure or intolerance to verapamil titrated at least to a dose of 480 mg daily (may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)
8. No concurrent therapy with other CGRP receptor antagonist
9. CGRP receptor antagonists must be started by a neurologist

**ADDITIONAL INFORMATION**

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

**CNS AGENTS: ANTI-MIGRAINE AGENTS – CLUSTER HEADACHE TREATMENT**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VERAPAMIL (Generic of Calan®) VERAPAMIL SR/ER (Generic of Calan SR®, Isoptin SR®, Verelan®)	EMGALITY™ (galcanezumab)

## Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis

**LENGTH OF AUTHORIZATIONS:** Initial Authorization 180 days  
Subsequent Authorizations 365 days

**APPROVAL CRITERIA:**

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to preferred medications
  - Contraindication to three preferred medications
  - History of unacceptable/toxic side effects to at least three preferred medications

**ADDITIONAL CRITERIA FOR EPISODIC MIGRAINE PROPHYLAXIS:**

1. Patient must have a diagnosis of episodic migraine with the following frequencies of migraine:
  - 4-15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
2. Prior Authorization may be approved if the patient has failed a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).
3. CGRP receptor antagonist must be started by a neurologist
4. No concurrent therapy with other CGRP receptor antagonists
5. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control. Re-authorization requests may be managed in consultation with a specialist.

**ADDITIONAL INFORMATION**

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer’s package insert.

**CNS AGENTS: ANTI-MIGRAINE AGENTS – PROPHYLAXIS TREATMENT**

NO PA REQUIRED “PREFERRED” (Trials of at least 3 controller medications)	PA REQUIRED “NON-PREFERRED”
Cardiovascular Agents: Beta-blockers CNS Agents: Anticonvulsants CNS Agents: Serotonin-norepinephrine reuptake inhibitors CNS Agents: Tricyclic antidepressants	AIMOVIG™ (erenumab-aooe) † AJOVY™ (fremanezumab-vfrm) * EMGALITY™ (galcanezumab)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

\* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days.

**g. Central Nervous System (CNS) Agents: Anticonvulsants: Valtoco® (diazepam nasal spray), Neurelis, Inc**  
 Dr. Biczak provided an additional clinical overview of the medication. ODM recommended a No PA Required “Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Central Nervous System (CNS) Agents: Anticonvulsants

**LENGTH OF AUTHORIZATIONS:** 365 Days

**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.

**STEP THERAPY:** all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least one preferred product.

**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 30 days 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 30 days. This provision applies only to the standard tablet/capsule dosage form and does not apply to brand products with available generic alternatives.

**ANTICONVULSANTS: FIRST GENERATION**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
CLONAZEPAM tablet (generic of Klonopin®)	CELONTIN® (methsuximide)
DIAZEPAM rectal gel (generic of Diastat®)	CLONAZEPAM ODT (generic of Klonopin® wafer)
DIVALPROEX (generic of Depakote®)	CLOBAZAM (generic for Onfi®)
DIVALPROEX ER (generic of Depakote® ER)	PEGANONE® (ethotoin)
ETHOSUXAMIDE (generic of Zarontin®)	STAVZOR® (valproic acid delayed release)
NAYZILAM® (midazolam)	SYMPAZAN™ (clobazam film)
PHENOBARBITAL	
PHENYTOIN (generic of Dilantin®)	
PRIMIDONE (generic of Mysoline®)	
VALPROIC ACID (generic of Depakene®)	
VALTOCO® (diazepam)	

**h. Central Nervous System (CNS) Agents: Atypical Antipsychotics, Second Generation, Oral/Transdermal: Caplyta™ (lumateperone capsule), Intra-Cellular Therapies**

Tobie Escher, PhD presented clinical information on Caplyta™ on behalf of Intra-Cellular Therapies. Dr. Biczak provided an additional clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below.

**Central Nervous System (CNS) Agents: Atypical Antipsychotics, Second Generation, Oral/Transdermal: Secuado® (asenapine patch), Noven Therapeutics**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Central Nervous System (CNS) Agents: Atypical Antipsychotics

**GRANDFATHERING:**

Patients who have a claim for a non-preferred drug, or drug requiring step therapy, 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.

**PSYCHIATRIST EXEMPTION:**

Providers (as identified below) are exempt from prior authorization of any non-preferred second-generation antipsychotic, or step therapy of any preferred brand, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the provider.

- **FFS:** Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry
- **MCOs:** Physicians with a specialty in psychiatry, nurse practitioners certified in psychiatric mental health, or clinical nurse specialists certified in psychiatric mental health, who are credentialed via the Medicaid managed care plan

**LENGTH OF AUTHORIZATIONS:**

365 Days

**STEP THERAPY:** all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least one preferred product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products



### OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications
- For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
- The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
- Lurasidone (pregnancy category B) may be approved if a patient is pregnant
- Abilify Mycite® will be restricted to prescribing by a psychiatrist following an aripiprazole serum blood level draw indicating need for further investigation of adherence.

### **NTIPSYCHOTICS, SECOND GENERATION, ORAL/TRANSDERMAL**

<b>NO PA REQUIRED “PREFERRED”</b>	<b>STEP THERAPY REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
ARIPIPRAZOLE tablet (generic of Abilify®) OLANZAPINE (generic of Zyprexa®) CLOZAPINE (generic of Clozaril®) QUETIAPINE (generic of Seroquel®) RISPERIDONE (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	LATUDA® (lurasidone) QUETIAPINE ER (generic of Seroquel XR®) FANAPT® (iloperidone) SAPHRIS® (asenapine)	ABILIFY DISCMELT® (aripiprazole) ABILIFY MYCITE® (aripiprazole with IEM) ARIPIPRAZOLE solution (generic of Abilify®) <b>CAPLY TA™ (lu mat ep ero n e )</b> CLOZAPINE RAPID DIS (generic of Clozaril®) FAZACLO® (clozapine) OLANZAPINE ODT (generic of Zyprexa® Zydys) PALIPERIDONE (generic of INVEGA®) REXULTI® (brexpiprazole) <b>SECUADO® (asenapine)</b> VERSACLOZ® (clozapine oral suspension) VRAYLAR™ (cariprazine capsule)

**i. CNS Agents: Multiple Sclerosis Disease Modifying Agents, Oral: Vumerity™ (diroximel fumarate capsule), Biogen Inc**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Central Nervous System (CNS) Agents: Multiple Sclerosis

### DISEASE MODIFYING AGENTS

**LENGTH OF AUTHORIZATIONS:** 365 Days

**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.

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

2. The requested medication may be approved if there has been a therapeutic failure to no less than a 30-day trial on at least one medication not requiring prior approval.

**CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
GILENYA® (fingolimod)	AUBAGIO® (teriflunomide) MAVENCLAD® (cladribine) MAYZENT® (siponimod)† TECFIDERA® (dimethyl fumarate) <b>VUMERITY™ (diroximel fumarate)</b>

†Must review liver function tests (LFTS) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG) prior to initiation. Must confirm patient is not CYP2C9\*3\*3 genotype. Dose limited to 2mg/day.

**j. Dermatological: Topical Acne Products, Antibiotic Products: Amzeeq™ (minocycline topical foam), Foamix Pharmaceuticals Inc.**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Dermatological: Topical Acne Products

**LENGTH OF AUTHORIZATIONS:** 365 Days

**CLINICAL CRITERIA:**

All topical retinoids require prior authorization for patients age 24 and older:

- Patient diagnosis psoriasis – may approve tazarotene (Tazorac®)
- Patient diagnosis acne vulgaris – may approve retinoid if the patient has a history of at least 30 days of therapy with alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days
- Patient diagnosis skin cancer – may approve retinoid

**PDL CRITERIA:**

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

**ADDITIONAL INFORMATION**

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 30-day trial of at least one medication in the same class not requiring prior approval

**ANTIBIOTIC PRODUCTS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
CLINDAMYCIN gel (generic of Cleocin T®, Clindamax®)	<b>AMZEEQ® foam (minocycline)</b>
CLINDAMYCIN lotion (generic of Cleocin T®, Clindamax®)	CLINDACIN® Pak (clindamycin/skin cleanser kit)
CLINDAMYCIN solution (generic of Cleocin T®)	CLINDAMYCIN foam (generic of Evoclin®)
ERYTHROMYCIN gel	CLINDAMYCIN pledgets (generic of Cleocin T®)
ERYTHROMYCIN solution (generic of A/T/S®, Akne- Mycin®)	ERYTHROMYCIN pads (generic of Ery Pads®)



**k. Dermatological: Topical Acne Products, Retinoid and Combination Products: Akliel® (trifarotene cream), Galderma Laboratories**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

**Dermatological: Topical Acne Products, Retinoid and Combination Products: Arazlo™ (tazarotene lotion), Bausch Health US LLC.**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Dermatological: Topical Acne Products

**LENGTH OF AUTHORIZATIONS:** 365 Days

**CLINICAL CRITERIA:**

All topical retinoids require prior authorization for patients age 24 and older:

- Patient diagnosis psoriasis – may approve tazarotene (Tazorac®)
- Patient diagnosis acne vulgaris – may approve retinoid if the patient has a history of at least 30 days of therapy with alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days
- Patient diagnosis skin cancer – may approve retinoid

**PDL CRITERIA:**

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

**ADDITIONAL INFORMATION**

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 30-day trial of at least one medication in the same class not requiring prior approval

**RETINOID AND COMBINATION PRODUCTS\***

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
DIFFERIN® cream, gel, lotion (adapalene)	ADAPALENE cream, gel (generic of Differin®)
TAZORAC® cream, gel (tazarotene)	ADAPALENE/BENZOYL PEROXIDE gel (generic of EPIDUO®)
TRETINOIN cream, gel (generic of Retin-A®)	<b>AKLIEF® cream (trifarotene)</b>
TRETINOIN micro gel (generic of Retin-A® micro)	ALTRENO™ lotion (tretinoin)
	<b>ARAZLO™ lo tio n (t az ar o ten e)</b>
	ATRALIN® gel (tretinoin)
	CLINDAMYCIN/TRETINOIN (generic of Veltin®)
	FABIOR® foam (adapalene)
	PLIXDA™ pad (adapalene)
	ZIANA® gel (clindamycin/tretinoin)

\*PA required for age 24 and older



**I. Endocrine Agents: Androgens, Oral Agents: Jatenzo® (testosterone undecanoate capsule), Clarus Therapeutics, Inc.**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Endocrine Agents: Androgens

**LENGTH OF AUTHORIZATIONS:** 365 Days

All products within this category require submission of lab work to support the need for testosterone supplementation

The requested medication may be approved if there has been a therapeutic failure to no less than a 90-day trial of all medications not requiring prior approval.

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

Acceptable reasons include:

- Allergy to all medications not requiring prior approval
- Contraindication to or drug interaction with all medications not requiring prior approval
- History of unacceptable/toxic side effects to all medications not requiring prior approval

### ADDITIONAL INFORMATION

Use limited to FDA approved indications in those 18 years and older.

### **ORAL AGENTS: ANDROGENS**

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	ANDROXY® (fluoxymesterone) <b>JATENZO® (testosterone undecanoate)</b> METHYLTESTOSTERONE (generic of Android®, Methitest®, Testred®) STRIANT (testosterone)



**m. Endocrine Agents: Diabetes – Non-Insulin: Trijardy® XR (empagliflozin, linagliptin, metformin hydrochloride tablet), Boehringer Ingelheim Pharmaceuticals, Inc.**

Dr. Biczak provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

## Endocrine Agents: Diabetes – Non-Insulin

**LENGTH OF AUTHORIZATIONS:** 365 Days

**STEP THERAPY:**

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonyleurea/ metformin or TZD/metformin combination), including a trial of no less than 90 days of at least one preferred metformin product
  2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than 90 days of at least one preferred or step therapy product
- Note: Inadequate clinical response is the inability to reach A1C goal after at least 90 days of recommended therapeutic dose with documented adherence to the regimen.

**OTHER APPROVAL CRITERIA:**

Is there any reason the patient cannot be changed to a medication within the same class 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

**DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND COMBINATIONS**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	SYNJARDY® (empagliflozin and metformin)	INVOKAMET® (canagliflozin/metformin) INVOKAMET® XR (canagliflozin/metformin) SEGLUROMET™ (ertugliflozin/metformin) SYNJARDY® XR (empagliflozin/metformin) <b>TRIJARDY® XR (empagliflozin/linagliptin/metformin)</b> XIGDUO XR® (dapagliflozin/metformin)

**VIII. Drug Class Announcement**

There were no new drug class announcements.



**IX. Other Business**

The committee determined that a presentation regarding the use of diabetes drugs for the treatment of cardiovascular disease will be tabled for discussion during the September P&T meeting.

**X. Next Meeting Dates**

The Committee agreed to the following 2021 meeting dates:

January 13<sup>th</sup>, 2021

April 14<sup>th</sup>, 2021

Quarter 3 and 4 meeting dates will be set at the September P&T meeting.

**XI. Adjournment**

Dr. Jacobs adjourned the meeting at 12:56 P.M.