



# Department of Medicaid

## OHIO DEPARTMENT OF MEDICAID

Pharmacy & Therapeutics Committee

Ohio Department of Medicaid

50 W. Town Street, Room C621A and C621B

Columbus, OH

July 10, 2019

10:00 AM

MINUTES

### Committee Members Present:

Scott Baran, RPh

Mary Ann Dzurec, PharmD

Suzanne Eastman, RPh, MS Vice Chair

Jennifer Gwilym, DO

Stephen Hersey, MD

Karen Jacobs, DO Chair

Melissa Jefferis, MD

Nathan Samsa, DO, PharmD

### Committee Members Not Present:

Susan Baker, CNP

### Ohio Medicaid Staff Present:

Tracey Archibald, PharmD

Michelle Barger, PharmD

### Contract Staff/Change Healthcare Staff Present:

Jacquelyn Hedlund, MD

Jill RK Griffith, BS, PharmD

Benjamin Link, PharmD

Gail Master, RPh

Also present were approximately 70 observers, most representing pharmaceutical manufacturers.

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

Dr. Jacobs called the meeting to order at 10:00 a.m.

#### **II. Introductions**

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

#### **III. Administrative Matters**

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Dr. Link reminded the Committee that that the October 2<sup>nd</sup> meeting will be the annual review and may be of longer duration than other quarterly meetings. Dr Jacobs asked the Committee members double check their calendars to assure a quorum would be present for the October meeting.

#### **IV. Department of Medicaid Update**

Mr. Baran announced that ODM continues to move forward with the Single Preferred Drug List (PDL) initiatives with a planned implementation start date of January 1<sup>st</sup>, 2020. Mr. Baran identified that since the announcement at the prior meeting, ODM Pharmacy staff have hosted 6 visitation days and welcomed guests from over 15 different manufacturers. He reminded those present that parties who wish to meet with ODM Pharmacy Staff will be required to complete and return a request form. To request a copy of the form, please email the ODM Pharmacy mailbox (MEDICAID\_PHARMACY@medicaid.ohio.gov). Mr. Baran announced that The Centers for Medicare and Medicaid Services (CMS) Annual Drug Utilization Review (DUR) report was due on July 1<sup>st</sup>, 2019. For the first time the annual DUR report included information on DUR activity for Medicaid Managed Care Plans (MCPs). He concluded by sharing information on ODM's planned future interventions.

#### **V. Approval of the April 10<sup>th</sup>, 2019 Meeting Minutes**

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

#### **VI. Drug Class Announcements**

Dr. Link announced that the Ohio Department of Medicaid expanded coverage to include home phototherapy units available through durable medical equipment suppliers. As a result, the criteria for the drugs covered in the current PDL category of Immunomodulator Agents for Systemic Inflammatory Disease was modified to recognize this treatment option in the July PDL document. Upon review of the criteria by the P&T Committee there were no questions.

Dr. Link announced that a new PDL category for Infectious Disease Agents: Antibiotics – Tetracyclines was proposed for addition to the PDL to support the discussions of Nuzyra® (omadacycline) and Seysara™ (sarecycline) later in the meeting.

#### **VII. Interested Party Presentations**

There were no interested party presentations.

#### **VIII. Preferred Drug List Review**

##### **a. Analgesic Agents: NSAIDs: Qmiiz™ ODT (meloxicam)**

Dr. Hedlund provided a clinical overview of the medication and following a brief discussion the medication was recommended as non-preferred. Votes were taken, and the committee approved the proposed category, shown below:



## Analgesic Agents: NSAIDs

**LENGTH OF AUTHORIZATIONS:** Dependent on medication request

NSAID Type	Approval Criteria	Approval Length
Non-Gastroprotective NSAIDs	no less than a <u>one-month</u> trial of at least <u>two</u> non-gastroprotective NSAID medications	1 year
Gastroprotective	no less than a <u>one-month</u> trial of at least <u>two</u> non-gastroprotective NSAID medications.	1 year
Gastroprotective	patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.	2 months
Gastroprotective	patients is being treated for H. pylori.	30 days
Transdermal/Topical	diclofenac solution: no less than a <u>one-month</u> trial of at least <u>one</u> preferred topical NSAID medications within the past 6 months	3 months

**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-to-drug interaction with medications not requiring prior approval. Acceptable contraindications for GASTROPROTECTIVE NSAIDs include:
  - Concurrent or history of a GI event (perforation, ulcer, bleed)
  - Other risks for treatment with NON-GASTROPROTECTIVE NSAIDs:
    - Coagulation disorders (i.e. hemophilia, chronic liver disease), erosive esophagitis
    - Documented NSAID-induced ulcer
    - Peptic ulcer disease (PUD)
    - Patient on warfarin or heparin
    - Patient on oral corticosteroids
    - Patient on methotrexate
- 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:

1. The medication is prescribed for an approved indication
2. There has been a therapeutic failure as defined as:
  - NON-GASTROPROTECTIVE NSAIDS:
    - no less than a one-month trial of at least two non-gastroprotective NSAID medications
  - GASTROPROTECTIVE NSAIDS:

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- no less than a one-month trial of at least two non-gastroprotective NSAID medications.  
OR
  - patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.  
OR
  - patient is being treated for *H. pylori*.
- TRANSDERMAL/TOPICAL:
- no less than a one-month trial of at least one preferred topical NSAID medications within the past 6 months

### ANALGESIC AGENTS: NON-GASTROPROTECTIVE NSAIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DICLOFENAC SODIUM (generic of Voltaren <sup>®</sup> )	QMIIZ ODT™ (meloxicam)
DICLOFENAC POTASSIUM (generic of Cataflam <sup>®</sup> )	TIVORBEX <sup>®</sup> (indomethacin)
ETODOLAC (generic of Lodine, Lodine XL)	VIVLODEX™ (meloxicam)
FENOPROFEN	ZORVOLEX <sup>®</sup> (diclofenac)
IBUPROFEN (generic of Motrin <sup>®</sup> )	
INDOMETHACIN (generic of Indocin <sup>®</sup> )	
KETOPROFEN	
KETOROLAC	
MECLOFENAMATE SODIUM	
MEFENAMIC ACID (generic of Ponstel <sup>®</sup> )	
MELOXICAM (generic of Mobic <sup>®</sup> )	
NABUMETONE	
NAPROXEN	
OXAPROZIN (generic of Daypro <sup>®</sup> )	
PIROXICAM (generic of Feldene <sup>®</sup> )	
SULINDAC	
TOLMETIN	

### b. Analgesic Agents: Opioids: Apadaz™ (benzhydrocodone & acetaminophen)

Dr. Hedlund provided a clinical overview of this medication and Mr. Baran recommended a non-preferred place on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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## Analgesic Agents: Opioids

### LENGTH OF AUTHORIZATIONS:

For the course of therapy, up to 6 months

- There must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least one preferred product.

### OTHER APPROVAL CRITERIA:

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

- Allergy to at least two unrelated 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
- Patient must have failed the generic product (if covered by the state) before brand is authorized, in addition to the above.

### ADDITIONAL CRITERIA FOR EXCEEDING SHORT-ACTING OPIOID NEW START CRITERIA

- System will define “new start” as having less than a 1-day supply of opioids in the previous 90 days
- Exemptions for certain conditions: active cancer treatment, palliative care, and end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery
- Attestation that patient is not opioid naïve
  - For example, if patient is newly eligible for Medicaid and there is no prior claims data
  - For example, if patient was on a higher dose in the hospital
- Non-pharmacologic treatments and/or non-opioid analgesics ineffective or contraindicated
- Diagnosis code required: should be for somatic type pain
- Benefits and risks of opioid therapy have been discussed with patient (attestation)
- Prescriber has checked OARRS (attestation)
- Length of authorization: UP TO 90 days, depending on the indication (could be more restrictive)

### **ANALGESIC AGENTS: OPIOIDS – SHORT-ACTING ORAL SINGLE-ENTITY CII \***

Note: Effective July 1, 2018, patients with short acting opioid therapy will be limited to 30 MED per prescription and a maximum of 7 days per prescription. Prior authorization will be required to exceed these limits\*

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## ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination and tramadol

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
<b>Codeine Combinations</b>	
ACETAMINOPHEN w/CODEINE TABLETS (generic of Tylenol® #2, #3, #4)	
<b>Dihydrocodeine Combinations</b>	
	DIHYDROCODEINE/ASPIRIN/CAFFEINE (generic of Synalgos-DC®)
<b>Hydrocodone Combinations</b>	
HYDROCODONE/ACETAMINOPHEN tablets containing 325mg acetaminophen (generic of Lorcet, Lortab, Norco)	APADAZ™ (benzhydrocodone & acetaminophen) HYDROCODONE/ IBUPROFEN (generic of Ibudone®, Vicoprofen®) HYDROCODONE/ACETAMINOPHEN tablets containing 300mg acetaminophen (generic of Vicodin®, Xodol®)
<b>Oxycodone Combinations</b>	
OXYCODONE W/ ACETAMINOPHEN tablets (generic of Percocet®)	OXYCODONE W/ IBUPROFEN (generic of Combunox®) PRIMLEV® (oxycodone/ acetaminophen)
<b>Pentazocine Combinations</b>	
<i>Not advocated for use</i>	PENTAZOCINE/NALOXONE (generic of Talwin NX®)
<b>Tramadol</b>	
TRAMADOL (generic of Ultram®) TRAMADOL/ACETAMINOPHEN (generic of Ultracet®)	
<b>Carisoprodol Combinations</b>	
	CARISOPRODOL/ASPIRIN/CODEINE (generic of Soma Compound w/Codeine®)

### c. Central Nervous System (CNS) Agents: Anticonvulsants: Diacomit® (stiripentol)

Kimberly Gittings, PharmD, MS, presented clinical information on Diacomit® on behalf of Biocodex. Following the presentation, Dr. Link reviewed criteria for Epidiolex® and informed the committee that a maximum dose was added to the criteria for authorization Epidiolex®. A question was raised about the efficacy and side effect profile of topiramate. A discussion ensued about the preference of these drugs. Mr. Baran informed the committee that ODM is grandfathering current Diacomit® patients and recommended a clinical prior authorization for the medication. Votes were taken, and the committee approved the proposed category, shown below:

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## Central Nervous System (CNS) Agents: Anticonvulsants

### ADDITIONAL CRITERIA FOR CANNABINOID

**LENGTH OF AUTHORIZATIONS:** Initial Authorization 6 months  
Subsequent Authorizations 1 year

- Patient has a diagnosis of Lennox-Gastaut syndrome or Dravet syndrome
- Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for one month each (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
- Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
- **Maximum daily dose (QL) not to exceed 20 mg/kg/day (titration based on response/tolerability)**

### ANTICONVULSANTS: CANNABINOID

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EPIDIOLEX® (cannabidiol)†	

†Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

### ADDITIONAL CRITERIA FOR STIRIPENTOL

**LENGTH OF AUTHORIZATIONS:** Initial Authorization 6 months  
Subsequent Authorizations 1 year

- Medication is prescribed by a neurologist or in consultation with a neurologist
- Patient has Dravet Syndrome
- Patient has baseline hematologic testing (CBC)
  - Prescribers must include management plans for patients with neutrophil counts <1500 cells/mm3 or platelet count less than 150,000/μL
- Address any co-morbid conditions
  - Patients with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine
- Patient must be concurrently managed with clobazam.
- Dose will be restricted based upon patient weight to 50 mg/kg/day. Requested dose not to exceed 3,000mg/day
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

### ANTICONVULSANTS: STIRIPENTOL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIACOMIT® (stiripentol)	

†Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

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**d. Central Nervous System (CNS) Agents: Multiple Sclerosis (MS): Mayzent® (siponimod)**

Jodi Jensen, PharmD, presented an update on Tecfidera on behalf of Biogen and informed the committee that with the approval of Siponimod (Mayzent) earlier this year the U.S. Food and Drug Administration (FDA) stated “The siponimod labeling will be the first explicitly describing that relapsing forms of MS include Clinically Isolated Syndrome (CIS), Relapsing-Remitting MS (RRMS), and secondary progressive disease, but all sponsors of the drugs approved for the treatment of relapsing forms of MS will be required to update their indication statements to conform with this contemporary nomenclature.” (Summary Review for Regulatory Action; NDA209884-siponimod; March 26, 2019) but no timeline by the FDA has been given for compliance with this labeling update. Following her presentation, Domenic Mantella, Pharm D, MBA, provided clinical information on Mayzent® on behalf of Novartis. A brief discussion around the adverse effects and pre-treatment testing requirements ensued. Mr. Baran recommended a non-preferred place on the PDL. The P&T Committee requested changes to the proposed criteria. Votes were taken, and the committee approved the proposed category, shown below:

DRAFT





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

### DISEASE MODIFYING AGENTS

**LENGTH OF AUTHORIZATIONS:** 1 year

**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.

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 one-month trial on at least one medication not requiring prior approval.

### CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, INJECTABLE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AVONEX <sup>®</sup> (interferon beta-1a) BETASERON <sup>®</sup> (interferon beta-1b) COPAXONE <sup>®</sup> (glatiramer) REBIF <sup>®</sup> (interferon beta-1a)	EXTAVIA <sup>®</sup> (interferon beta-1b) GLATOPA <sup>™</sup> (glatiramer) PLEGRIDY <sup>®</sup> (peginterferon beta-1a)

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GILENYA <sup>®</sup> (fingolimod)	AUBAGIO <sup>®</sup> (teriflunomide) MAYZENT <sup>®</sup> (siponimod) <sup>†</sup> TECFIDERA <sup>®</sup> (dimethyl fumarate)

<sup>†</sup>Must review liver function tests (LFTs) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG) prior to initiation. Must confirm member is not CYP2C8\*3\*3 genotype. Dose limited to 2mg/day.

**e. Central Nervous System (CNS) Agents: Parkinson’s Agents: Inbrija™ (levodopa)**

Dr. Hedlund provided a clinical overview of this medication and Mr. Baran recommended a non-preferred place on the PDL. Following a brief discussion votes were taken, and the committee approved the proposed category, shown below:

## Central Nervous System (CNS) Agents: Parkinson's Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

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 both of the following are true:

1. If there has been a therapeutic failure to no less than a one-month trial of at least one medication not requiring prior approval
2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
3. Neupro® or **Inbrija™** may be approved if the patient is unable to swallow.

### PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, **ORAL**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CARBIDOPA/LEVODOPA (generic of Sinemet®)	AZILECT® (rasagiline)
CARBIDOPA/LEVODOPA CR (generic of Sinemet® CR)	CARBIDOPA/LEVODOPA dispersible tablets (generic of Parcopa®)
SELEGILINE (generic of Eldepryl®)	CARBIDOPA/LEVODOPA/ENTACAPONE (generic of Stalevo®)
	<b>INBRIJA™ (levodopa)</b>
	NEUPRO® patch (rotigotine)
	RYTARY® (carbidopa/levodopa ER)
	XADAGO® (safinamide)
	ZELAPAR® ODT (selegiline)

- f. Gastrointestinal Agents: Irritable Bowel Syndrome (IBS)/ Selected GI: Motegrity™ (prucalopride)**  
 Dr. Hedlund provided a clinical overview of this medication and Mr. Baran recommended a non-preferred place on the PDL. Votes were taken, and the committee approved the proposed category, shown below:



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## Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) / Selected GI

**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
2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least two medications not requiring prior approval

**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 two-week trial of at least two medications not requiring prior approval
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two-week trial of at least two step therapy products

**ADDITIONAL INFORMATION:**

1. Patient must be 18 years or older
2. NUTRESTORE™, ZORBTIVE®, and GATTEX® require a diagnosis of short bowel syndrome (SBS) and evidence of specialize nutritional support
  - a. NUTRESTORE™ requires evidence of concurrent use of recombinant growth hormone
  - b. GATTEX® requires evidence of parenteral nutrition support at least three times per week and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 6 months prior to initiation
  - c. Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)
3. MYTESI™ requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy
  - a. MYTESI™ will be limited to no more than 2 tablets per day

**IBS WITH CONSTIPATION & CHRONIC IDIOPATHIC CONSTIPATION AGENTS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BISACODYL (generic of Dulcolax®) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®) LACTULOSE (generic of Chronulac®) POLYETHYLENE GLYCOL (generic of Miralax®) PSYLLIUM FIBER (e.g. Konsyl®) SENNA (generic of Senokot®)	AMITIZA® capsule (lubiprostone) LINZESS™ capsule (linaclotide)	MOTEGRITY™ (prucalopride) TRULANCE™ (plecanatide)

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**g. Infectious Disease Agents: Antibiotics-Inhaled: Arikayce® (amikacin)**

Dr. Hedlund provided a clinical overview of this medication. Mr. Baran recommended a clinical prior authorization on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

Infectious Disease Agents: Antibiotics – Inhaled	
<b>ADDITIONAL CRITERIA FOR AMIKACIN</b>	
<b>LENGTH OF AUTHORIZATIONS:</b>	Initial authorization 6 months Subsequent authorizations 1 year
1. Clinical criteria for initial authorization:	
<ul style="list-style-type: none"> <li>• Diagnosis of <i>Mycobacterium avium</i> complex (MAC) lung disease; and</li> <li>• Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide, rifampin, &amp; ethambutol)</li> </ul>	
2. Criteria for subsequent authorizations	
<ul style="list-style-type: none"> <li>• Evidence of culture conversion (negative sputum culture)</li> </ul>	
3. Dose will be limited to 1 dose per day	
<b>INFECTIOUS DISEASE AGENTS: ANTIBIOTICS – INHALED AMIKACIN</b>	
CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ARIKAYCE® (amikacin)	

**h. Infectious Disease Agents: Antibiotics – Tetracyclines: Nuzyra® (omadacycline)**

Melanie Lauterio, PhD provided a clinical overview of this medication for Paratek Pharmaceuticals. Mr. Baran recommended a non-preferred place on the PDL. A discussion ensued regarding the appropriate authorization criteria for this medication. The draft criteria was amended, votes were taken, and the committee approved the proposed category, shown below:

## Infectious Disease Agents: Antibiotics – Tetracyclines

### ADDITIONAL CRITERIA FOR OMADACYCLINE

**LENGTH OF AUTHORIZATIONS:** 14 Days

1. Clinical criteria for initial authorization:

- Diagnosis of Community-Acquired Bacterial Pneumonia (CABP) with prior failure of other first line agent OR
- Diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) with prior failure of other first line agent

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) If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.

- Note diagnosis and any culture and sensitivity reports

### ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

### TETRACYCLINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NUZYRA® (omadacycline)

**i. Infectious Disease Agents: Antibiotics – Tetracyclines: Seysara™ (sarecycline)**

Dr. Hedlund provided a clinical overview of this medication. Mr. Baran recommended a non-preferred place on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

## Infectious Disease Agents: Antibiotics – Tetracyclines

**LENGTH OF AUTHORIZATIONS:** for the date of service only; no refills

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. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
  - Note diagnosis and any culture and sensitivity reports
3. If there have been therapeutic failures to no less than a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

### ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

### TETRACYCLINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Doxycycline tablets, capsules 50mg & 100mg	DORYX <sup>®</sup> (doxycycline)
Doxycycline syrup	Doxycycline tablets, capsules 20mg, 40mg, 75mg, & 150mg
Minocycline capsules	Doxycycline DR
Tetracycline capsules	Minocycline ER
	MINOLIRA™ ER (minocycline)
	SEYSARA™ (sarecycline)
	SOLODYN <sup>®</sup> ER (minocycline)
	XIMINO <sup>®</sup> (minocycline)

**j. Ophthalmic Agents: Glaucoma: Rocklatan™ (netarsudil and latanoprost)**

Dr. Hedlund provided a clinical overview of this medication. Mr. Baran recommended a preferred place on the PDL. Votes were taken, and the committee approved the proposed category, shown below:



Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: ACROSS ALL AGENTS

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

OTHER APPROVAL 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
Contraindications to or drug interaction with medications not requiring prior approval
History of unacceptable/toxic side effects to medications not requiring prior approval

GLAUCOMA AGENTS – RHO KINASE AND PROSTAGLANDIN INHIBITORS COMBINATIONS

Table with 3 columns: NO PA REQUIRED 'PREFERRED', STEP THERAPY REQUIRED 'PREFERRED', NON-PREFERRED 'NON-PREFERRED'. Row 1: ROCKLATAN (netarsudil and latanoprost)

IX. Other Business

There was no other business to discuss.

X. Next Meeting Date

The next meeting date is October 2, 2019 at 9:00 A.M. at the Ohio Department of Medicaid, 50 W Town St.

XI. Adjournment

Dr. Jacobs adjourned the meeting at 11:20 A.M.