Ohio
Department of Medicaid
John R. Kasich, Governor
Barbara R. Sears, Director

OHIO DEPARTMENT OF MEDICAID (ODM)
Pharmacy & Therapeutics Committee
Ohio Department of Medicaid, 50 W. Town Street, Room B406 Columbus, OH
January 11th, 2017
10:00 AM

MINUTES

Committee Members Present:
Susan Baker, CNP
Mary Ann Dzurec, PharmD
Suzanne Eastman, RPh
Jennifer Gwilym, DO
Jennifer Hauler, DO
Michael Howcroft, RPh
Karen Jacobs, DO, Chair
Melissa Jefferis, MD
Margaret Scott, RPh

Committee Members Not Present:
Sandra Hrometz PhD, RPh

Contract Staff/Change Healthcare Staff Present:
Jacqueline Hedlund, MD
Laureen Biczak, DO
Ben Link, PharmD

Also present were approximately 29 observers, most representing pharmaceutical manufacturers. Representatives of Change Healthcare in the audience were Chad Bissel, PharmD, MBA, Jill RK Griffith, BS, PharmD, Steve Liles, PharmD, and Gail Master, RPh

I. Call to Order
Karen Jacobs, DO, called the meeting to order at 10:13 a.m.

II. Introductions
Dr. Jacobs welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

III. Administrative Matters
Ms. Scott noted that the recommendations for changes to the clinical criteria for the Hepatitis C Agents from the prior P&T meeting was under review by ODM and would be discussed at a future meeting. Dr. Jacobs thanked participants who bring information to the P&T committee.

IV. Department of Medicaid Update

Ms. Scott announced the departure of Ohio Medicaid Director John McCarthy and the newly appointed Director Barbara Sears.
Ms. Scott provided information regarding the upcoming legislative changes related to opioid prescription management in chronic pain. These will be discussed with the Ohio Medicaid Drug Utilization Review (DUR) Board.
Ms. Scott also provided information related to upcoming reimbursement changes that are being made as part of the Affordable Care Act (ACA). These changes will be implemented on April 1, 2017 and include payment based upon actual acquisition costs (AAC) of medications plus a professional dispensing fee.

V. Approval of October 5th, 2016 Meeting Minutes

The minutes from the prior P&T meeting were approved. Dr. Gwilym moved to approve the minutes, seconded by Ms. Baker.

VI. Drug Class Announcements

Dr. Link announced that there were no drug class updates. Information on the prescriber specialties of agents under the Anti-Parkinson PDL Category was shared. This information was requested at the prior P&T meeting. The data showed that the most common prescriber specialties were Internal Medicine and General Practice. No changes to the current neurologist prior authorization criteria were recommended.

VII. Interested Party Presentation

Dr. Brian Beesley, drug coverage for HIV antiretroviral drugs

Dr. Beesley requested clarification on the PDL changes recommended by the P&T Committee for HIV agents at the October meeting. Ms. Scott clarified that no drugs were changed from preferred status to non-preferred status.

VIII. Preferred Drug List (PDL) Proposal

Pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from committee members.

a) New PDL Category: *Ophthalmic Agents: Dry Eye Treatments*

Sharad Rastogi, MD, MBA, presented on behalf of Shire US Manufacturing Inc. Change Healthcare provided a review of the prevalence of Dry Eye disease and a review of the current treatment guidelines. After review Change Healthcare recommended Restasis® as preferred following a trial of OTC eye drops and Xiidra™ as non-preferred. Votes were taken and the committee approved the proposed category, shown below.

Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS: 1 year

All drugs in this class require step therapy: Patient must have a claim for an artificial tear or OTC dry eye drop in the previous 120 days.

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
   - Contraindications to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to at least one of the preferred agents.

OPHTHALMIC AGENTS: Dry Eye Treatments

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
RESTASIS® trays (cyclosporine)	RESTASIS® multi-dose (cyclosporine) XIIDRA™ (lifitegrast)

b) Analgesic Agents: Gout. Zurampic® (lesinurad)

Change Healthcare recommended Zurampic® be made non-preferred after a trial of preferred agent and to ensure through the PA process that the medication would be used in combination with a xanthine oxidase inhibitor regimen per the drugs labeling. Votes were taken and the committee approved the proposed criteria and PDL.

- 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
  - Appropriate dose of xanthine oxidase inhibitors:
    - Allopurinol: 300mg daily (200mg daily in patients with eCrCl <60mL/min)
    - Febuxostat: 80mg daily

ANALGESIC AGENTS: GOUT – Agents to Reduce Hyperuricemia

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALLOPURINOL (generic of Zyloprim®) PROBENECID (generic for Benemid®) PROBENECID-COLCHICINE	ULORIC® (febuxostat) ZURAMPIC® (lesinurad)

c) Analgesics: Opioids-Long Acting, Oral. Xtampza® ER (oxycodone, extended release)

Change Healthcare recommended Xtampza® as non-preferred on the PDL. Votes were taken and the committee approved the proposed criteria and PDL.

ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral

NO PA REQUIRED	STEP THERAPY REQUIRED	NON-PREFERRED
Extended Release Buprenorphine Products		
		BELBUCA™ (Buprenorphine buccal film)
Extended Release Hydrocodone Products		
		ZOHYDRO ER® (hydrocodone)
Extended Release Morphine Products		
MORPHINE SULFATE ER tablet (generic of MS Contin®)		EMBEDA® (morphine sulfate/ naltrexone) MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®)
Extended Release Oxycodone Products		
		HYSINGLA ER® (hydrocodone) OXYCODONE ER (generic of Oxycontin®) OXYCONTIN® (oxycodone) XARTEMIS XR® (oxycodone/ acetaminophen) XTAMPZA® ER (oxycodone)

d) Cardiovascular Agents: Angina, Hypertension & Heart Failure. Byvalson™ (nebivolol and valsartan)

Change Healthcare recommended Byvalson™ as non-preferred on the PDL. Votes were taken and the committee approved the proposed criteria and PDL.

4. For ARB/beta blocker combinations, the preferred drug trial may be a preferred beta blocker or ARB

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ BETA BLOCKERS COMBINATION

NO PA REQUIRED	STEP THERAPY REQUIRED	NON-PREFERRED
		BYVALSON™ (nebivolol/valsartan)

e) Cardiovascular Agents: Angina, Hypertension & Heart Failure. Qbrelis™ (lisinopril)

Bruce Wallace, RPh, presented on behalf of Silvergate Pharmaceuticals, Inc. Change Healthcare recommended Qbrelis™ as non-preferred. Clinical discussion ensued regarding use of compounded ACE inhibitors in the Ohio Medicaid program. After discussion, a motion was made to remove lisinopril and enalapril powder from coverage and to add Qbrelis™ as non-preferred. Votes were taken and the committee approved the proposed criteria and PDL.

ACE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BENAZEPRIL (generic of Lotensin®) CAPTOPRIL (generic of Capoten®) ENALAPRIL (generic of Vasotec®) EPANED® (enalapril oral solution) FOSINOPRIL (generic of Monopril®) LISINOPRIL (generic of Zestril®, Prinivil®) MOEXIPRIL (generic of Univasc®) PERINDOPRIL ERBUMINE (generic of Aceon®) QUINAPRIL (generic of Accupril®) RAMIPRIL (generic of Altace®) TRANDOLAPRIL (generic of Mavik®)	QBRELIS™ (lisinopril oral solution)

f) Central Nervous System (CNS) Agents: Anti-Migraine Agents. Onzetra™ Xsail™ (sumatriptan)

Change Healthcare recommended Onzetra™ Xsail™ as non-preferred. After brief clinical discussion votes were taken and the committee approved the proposed criteria and PDL.

CNS AGENTS: ANTI-MIGRAINE AGENTS – SEROTONIN 5-HT1 RECEPTOR AGONISTS – "Fast" Onset

NO PA REQUIRED "PREFERRED"	PA REQUIRED
RIZATRIPTAN tablets (generic of Maxalt®) RIZATRIPTAN ODT (generic of Maxalt-MLT®) SUMATRIPTAN tablets, nasal spray, injection (generic of Imitrex®)	ALMOTRIPTAN (generic of Axert®) ONZETRA™ XSAIL™ (sumatriptan) RELPAX® (eletriptan) SUMAVEL DOSEPRO® (sumatriptan) ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan) ZECUITY® (sumatriptan)

g) Central Nervous System (CNS) Agents: Anticonvulsants. Spritam® (levetiracetam)

Change Healthcare recommended Spritam® as non-preferred. Votes were taken and the committee approved the proposed criteria and PDL.

ANTICONVULSANTS: SECOND GENERATION

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

h) Central Nervous System (CNS) Agents: Antipsychotics, Second Generation. Nuplazid™ (pimavanserin)

Sherry Andes, PharmD, presented on behalf of Acadia Pharmaceuticals, Inc.

Change Healthcare recommended the medication be made non-preferred with additional criteria added to ensure it was used as indicated. A clinical discussion around whether a neurologist would be exempt from the prior authorization process ensued. Votes were taken and the committee approved the proposal recommending that Nuplazid™ be non-preferred with an exemption to the criteria granted to a prescriber with a neurology specialty on a member with a history of an agent to treat Parkinson's Disease.

Additional Criteria for AGENTS FOR PARKINSON'S DISEASE PSYCHOSIS (Nuplazid™):

Pimavanserin (Nuplazid™) may be approved if all of the following are met:

1. Patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis
2. These psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic AND are not related to dementia or delirium
3. The patient's other medications for Parkinson's Disease have been reduce or adjusted and psychotic symptoms remain OR patient is unable to tolerate adjustment of these other medications
4. There has been inadequate clinical response to a trial of no less than fourteen days of either quetiapine or clozapine OR these therapies cannot be utilized
5. An exemption to the criteria will be granted for prescribing doctors with a neurology specialty to a patient with a history of an anti-Parkinson's agent

ANTIPSYCHOTICS, SECOND GENERATION, AGENTS FOR PARKISON'S PSYCHOSIS*

NO PA REQUIRED	STEP THERAPY REQUIRED	NON-PREFERRED
		NUPLAZID™ (pimavanserin)

*Patients on current regimens will be grandfathered.

i) Central Nervous System (CNS) Agents: Multiple Sclerosis: Zinbryta™ (daclizumab)

Gina McKnight-Smith, PharmD, presented on behalf of AbbVie Inc. Change Healthcare recommended Zinbryta™ as non-preferred with a new subclass added to the PDL to address the specific criteria for the medication. Votes were taken and the committee approved the proposed criteria and PDL.

INTERLEUKIN RECEPTOR BLOCKERS

LENGTH OF AUTHORIZATIONS: 1 year

1. Clinical criteria authorization:
    - Diagnosis of multiple sclerosis
    - Patient does not have pre-existing hepatic disease or impairment (AST or ALT is not above 2 times the upper limit of normal; confirmed prior to initiation of treatment)
    - Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver
    - Patient does not have an existing infection and has demonstrated a negative tuberculin test
    - The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial on at least two medications in the Multiple Sclerosis drug category

CNS AGENTS: MULTIPLE SCLEROSIS INTERLEUKIN RECEPTOR BLOCKERS

NO PA REQUIRED "PREFERRED"	CLINICAL PA REQUIRED
	ZINBRYTA® (daclizumab)

j) Endocrine Agents: Diabetes-Oral Hypoglycemics. Invokamet® XR (canagliflozin and metformin)

Change Healthcare recommend Invokamet® be added as non-preferred to the PDL. Votes were taken and the committee approved the proposed criteria and PDL.

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

NO PA REQUIRED	STEP THERAPY REQUIRED	PA REQUIRED
		FARXIGA® (dapagliflozin) GLYXAMBI® (empagliflozin/ linagliptin) INVOKAMET® (canagliflozin/ metformin) INVOKAMET® XR (canagliflozin/ metformin) INVOKANA® (canagliflozin) JARDIANCE® (empagliflozin) SYNJARDY® (empagliflozin and metformin) XIGDUO XR® (dapagliflozin/ metformin)

k) Endocrine Agents: Diabetes-Oral Hypoglycemics. Jentadueto® XR (linagliptin and metformin)

Change Healthcare recommend Jentadueto® XR be added as non-preferred to the PDL. Votes were taken and the committee approved the proposed criteria and PDL.

DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR COMBINATIONS

NO PA REQUIRED	STEP THERAPY REQUIRED	PA REQUIRED
	JANUMET™ (sitagliptin/metformin) JANUMET XR™ (sitagliptin/ metformin) JENTADUETO™ (linagliptin/ metformin)	JENTADUETO® XR (linagliptin/ metformin) KAZANO® (alogliptin/ metformin) KOMBIGLYZE XR® (saxagliptin/metformin)

l) Gastrointestinal Agents: Opioid-Induced Constipation. Relistor® tablets (methylnaltrexone)

Change Healthcare recommend Relistor® tablets be added as non-preferred to the PDL. Votes were taken and the committee approved the proposed criteria and PDL.

GASTROINTESTINAL AGENTS: OPIOID-INDUCED CONSTIPATION AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BISACODYL(generic of Dulcolax®) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®) POLYETHYLENE GLYCOL (generic of Miralax®) SENNA (generic of Senokot®)	AMITIZA® capsules (lubiprostone) MOVANTIK® tablets (naloxegol) RELISTOR® tablets and subcutaneous injection (methylnaltrexone bromide)

m) Infectious Disease Agents: Antivirals-Hepatitis C Agents. Viekira™ XR (ombitasvir/paritaprevir and ritonavir/dasaubvir)

Gina McKnight-Smith, PharmD, presented on behalf of AbbVie Inc. Change Healthcare reviewed the clinical information for Viekira™ XR and recommended it be made a preferred medication. It was noted that changes to the clinical criteria for the PDL category were under review by ODM. Votes were taken and the committee approved the proposed positioning of Viekira™ XR.

INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
EPCLUSA® (sofosbuvir/velpatasvir) HARVONI® (ledipasvir/sofosbuvir) tablets TECHNIVIE™ (ombitasvir/paritaprevir and ritonavir) VIEKIRA PAK™ (ombitasvir/paritaprevir and ritonavir tablets/dasabuvir tablets) VIEKIRA XR™ (ombitasvir/paritaprevir and ritonavir tablets/dasabuvir tablets) ZEPATIER™ (elbasvir and grazoprevir tablet)	DAKLINZA™ (daclatasvir) SOVALDI® (sofosbuvir)

n) Bromsite™ (bromfenac)

Change Healthcare recommend Bromsite™ be added as non-preferred to the PDL. Following a brief clinical discussion votes were taken and the committee approved the proposed criteria and PDL.

OPHTHALMIC NSAIDs

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DICLOFENAC (generic of Voltaren®) FLURBIPROFEN (generic of Ocufen®) KETOROLAC (generic of Acular®, Acular LS®)	ACUVAIL® (ketorolac) BROMFENAC (generic of Bromday®, Xibrom®) BROMSITE™ (bromfenac) ILEVRO® (nepafenac) NEVANAC® (nepafenac) PROLENSA® (bromfenac)

o) Otovel® (ciprofloxacin and fluocinolone)

Change Healthcare recommend Otovel® be added as non-preferred to the PDL. Following a brief clinical discussion votes were taken and the committee approved the proposed criteria and PDL.

OTIC AGENTS: ANTIBACTERIAL – STERIOD COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CIPRODEX® suspension (ciprofloxacin with dexamethasone) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin® solution) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin® suspension)	CIPRO HC® suspension (ciprofloxacin with hydrocortisone) COLY-MYCIN-S® suspension (neomycin and colistin with hydrocortisone) CORTISPORIN-TC® suspension (neomycin and colistin with hydrocortisone) OTOVEL® (ciprofloxacin with fluocinolone)

p) Bevespi Aerosphere™ (glycopyrrolate and formoterol)

Change Healthcare recommended Bevespi Aerosphere™ as non-preferred. It was noted that there is no long-acting muscarinic antagonist and long-acting β_2-agonist (LAMA/LABA) product in a

preferred position. The committee had no recommendations for a preferred product but proposed that ODM evaluate the cost and clinical information and make a LAMA/LABA product a preferred medication. Votes were taken and the motion passed.

IX. Other Business:

Ms. Scott reminded the P&T Committee that annually they sign a conflict of interest. Dr. Link will circulate the statement prior to the April 12th meeting. A question was raised on how committee members can discuss new clinical information on existing drugs. Ms. Scott indicated drug information can be emailed to her and Dr. Link.

X. Next Meeting Dates:

The next P & T meeting is scheduled for April 12th, 2017 at Ohio Department of Medicaid, 50 W Town Street, Room C621. The two remaining 2017 meetings need to be scheduled.

XI. Adjournment

Dr. Jacobs adjourned the meeting at 11:49 a.m.

1/26/2017: Following the meeting, ODM accepted the Committee's recommendations. ODM has chosen Stiolto™ Respimat® (tiotropium/olodaterol) as the preferred LAMA/LABA product as requested by the Committee.

Methylin® ER, Methylin® Chew, Nexium® 24HR, Prilosec OTC®, Zegerid OTC® are no longer covered under the federal Medicaid Drug Rebate Program so will be removed from coverage.

Prior authorization criteria for the Medication Assisted Treatment of Opioid Addiction class has been re-worded to be clearer in its intent. The criteria have not changed.