OHIO DEPARTMENT OF MEDICAID

Pharmacy & Therapeutics Committee
Ohio Department of Medicaid
50 W. Town Street, Room C621A and C621B
Columbus, OH
October 2, 2019
9:00 A.M.
MEETING MINUTES

Committee Members Present:
Susan Baker, APN
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

Ohio Medicaid Staff Present:
Tracey Archibald, PharmD
Michelle Barger, PharmD

Contract Staff/Change Healthcare Staff Present:
Laureen Biczak, DO
Jill RK Griffith, BS, PharmD
Steve Liles, PharmD
Gail Master, RPh

Also present were approximately 126 observers, most representing pharmaceutical manufacturers.

I. Call to Order
Dr. Jacobs called the meeting to order at 9:02 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
Dr. Archibald reminded the Committee that the entirety of the Unified Preferred Drug List (UPDL) would be reviewed today and implemented on January 1st, 2020. This UPDL applies to both FFS and MCP members.

Ohio | Department of Medicaid

IV. Department of Medicaid Update

S. Baran announced that the Ohio Department of Medicaid is implementing a UPDL on January 1st, 2020 that will encompass the entire Medicaid population regardless of enrollment in Managed Care or Fee for Service (FFS). ODM pharmacy staff and leaders from the Managed Care Plans collaborated together in clinical, technical, and communications-based workgroups to help ensure a smooth transition. The draft UPDL marks the culmination of many months of cooperative effort aimed at: 1) reducing the administrative burden for providers by simplifying the prescribing and prior authorization process; 2) allowing for a standard prior authorization process across FFS and managed care; 3) clinical coordination of care for approximately 3 million covered Medicaid lives; and 4) minimizing member movement between the Ohio Medicaid Managed Care Plans.

There were several pharmacy-related initiatives included in the most recent State Budget. Some examples include: 1) adopting rules to provide a supplemental dispensing fee under the care management system to retail pharmacies; and 2) selecting a single, Pharmacy Benefit Manager (PBM) to be used by all Ohio Medicaid Managed Care Plans. ODM is tasked with selecting a provisional Single-PBM no later than July 1, 2020. Both of these initiatives are in the early stages of development. Expect more details to be shared in the coming months.

ODM recently concluded the pilot phase of the Pharmacy Third Party Resource Day (3PRD) program. This program was an opportunity for drug manufacturer representatives to present new clinical information to ODM about their products. Over the past six months, ODM has met with nearly 50 companies and over 100 guests on a wide-variety of products & disease states. ODM plans to review the design, schedule, and format of this program. Additional details will be forthcoming.

Last month, the Centers for Medicare & Medicaid Services (CMS) issued their guidance to the States concerning implementation of new Medicaid Drug Utilization Review provisions that were included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also referred to as the SUPPORT Act. This guidance addressed the following requirements: 1) opioid prescription claims review at the pharmacy point of sale and in retrospective reviews; 2) monitoring and management of antipsychotic medication in children; 3) identification of processes to detect fraud and abuse; and 4) mandatory DUR report updates. Each State must submit a State Plan Amendment by the end of 2019, which ODM is currently working on.

The annual Drug Utilization Review Report has been submitted to CMS. This report will be posted to the Medicaid.gov website later this year. This was the first year that the Medicaid Managed Care Plans were required to submit reports in addition to FFS reports.

V. Approval of the July 10th, 2019 Meeting Minutes

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

VI. Presentations by Drug Manufacturers

a. Epidiolex®, Greenwich Biosciences

b. Kevzara®, Sanofi Genzyme

c. Cimzia®, UCB
d. Abilify MyCite®, Otsuka
e. Rebinyn®, Novo Nordisk
f. Emgality®, Eli Lilly
g. Ajovy®, Teva
h. Aubagio®, Sanofi Genzyme
i. Invokana®, Janssen
j. Tresiba®, NovoNordisk
k. Ozempic®, NovoNordisk
l. Symtuza™, Janssen
m. sofosbuvir/velpatasvir (Epclusa® authorized generic), Gilead

VII. Interested Party Presentations

a. Jim Herbst, PharmD, representing Nationwide Children's Hospital, Partners For Kids
  i. Epidiolex Clinical Criteria and Coverage
b. Matthew C. Jacques, representing the public and Medication Assisted Treatment Facilities
  i. Prior Authorizations and Brand Limitations for Buprenorphine/Naloxone Medications
c. Dr. Brett Toward, CMO, representing Third Street Family Health Services
  i. Medication Assisted Treatment, Withdrawal Management Options/ Detoxification
d. Daniel Hurley, representing the Ohio Bleeding Disorders Council
  i. Hemophilia Factors, Specifically Long Half-Life Factors
e. Roger Garcia, DO representing an Addictionologist who owns Addiction Angels of America
  i. Experiences with addiction patients
f. Brian J. Beesley, DO, AAHIVS representing: The Ohio State University College of Medicine, Ohio University Heritage College of Osteopathic Medicine, and Mount Carmel Medical Group, Victorian Village
  i. HIV Treatment and Open Access to Medications

VIII. Preferred Drug List Annual Review

Following the completion of presentations from drug manufacturers and interested parties, the P&T Committee members deliberated on the classes for extraction. The following drug categories were extracted for discussion and review. The remainder of the categories were approved as recommended in the draft PDL document.

Cardiovascular Agents: Lipotropics
Central Nervous System (CNS) Agents: Anti-Migraine Agents
Central Nervous System (CNS) Agents: Anticonvulsants
Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction
Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting
Respiratory Agents: Chronic Obstructive Pulmonary Disease
Endocrine Agents: Diabetes – Non-Insulin
Infectious Disease Agents: Antivirals-HIV

a. **Cardiovascular Agents: Lipotropics**

Change Healthcare provided a clinical overview of the category. Discussion ensued regarding the required use of Over-the-Counter (OTC) fish oil products before obtaining access to omega 3-acid ethyl esters (generic Lovaza®) or Vascepa®. The Committee recommended that ODM remove the required use of OTC fish oil before obtaining access to omega 3-acid ethyl esters.

The Committee recommended amending the Additional Criteria For Omega-3 Polyunsaturated Fatty Acid And Icosapent Ethyl (Lovaza®, Vascepa®) criteria to read as follows: "Prescription-only omega-3 polyunsaturated fatty acid and icosapent ethyl are approvable only for adult patients with triglyceride levels equal to or greater than 500 mg/dL who have been unable to lower triglyceride levels with fibrates, niacin, or lifestyle changes including diet and exercise."

CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OMEGA 3-ACID ETHYL ESTERS (generic of Lovaza®)	VASCEPA® (icosapent ethyl)

b. **Central Nervous System (CNS) Agents: Anti-Migraine Agents**

Change Healthcare provided a clinical overview of the category. Discussion ensued regarding the Clinical Considerations for Migraine Prophylaxis with Calcitonin Gene-Related Peptide Receptor Antagonist (CGRP) Medications. The Committee voted to amend the Prior Authorization (PA) criteria to read: "Prior Authorization may be approved if the patient has failed a trial of at least 30 days ~~within the last 120 days~~ each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, neuroleptics, tricyclic antidepressants, and/or serotonin-norepinephrine).

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

Change Healthcare provided a clinical overview of the category. Discussion ensued regarding Fycompa® positioning. The Committee recommended that Fycompa® be moved from "Step Therapy Required-Preferred" to "No PA Required Preferred". Epidiolex PA criteria was reviewed and discussed. No changes to the current criteria were recommended.

ANTICONVULSANTS: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FYCOMPA® (perampanel) 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®)	PREGABALIN (generic for Lyrica®)	BANZEL® (rufinamide) BRIVIACT® (brivaracetam) FELBAMATE (generic of Felbatol®) LAMICTAL® ODT (lamotrigine) LAMOTRIGINE ER tablet (generic of Lamictal® XR) LEVETIRACETAM ER tablet (generic of Keppra® XR) QUDEXY XR® (topiramate ER) SABRIL® powder (PA required for age > 2) SABRIL® tablet (vigabatrin) SPRITAM® (levetiracetam tablet for suspension) SUBVENITE (lamotrigine) TIAGABINE (generic of Gabitril®) TOPIRAMATE ER TOPIRAMATE sprinkle cap (generic of Topamax® sprinkle cap) TROKENDI XR® (topiramate)

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

The Committee recommended the State consider adding Lucemyra™ (lofexidine) to the PDL. The topic was tabled and will be brought back for discussion in January 2020.

e. **Respiratory Agents**

The Committee recommended the State consider reorganizing the Respiratory Agents to reflect drug mechanism of action rather than disease state indications. The topic was tabled and will be brought back for discussion in January 2020. No other changes to the category were recommended.

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

Change Healthcare provided a clinical overview of the category. After a discussion of emerging cardiovascular data in the category, the Committee recommended that the PA criteria be revisited in January 2020. No other changes to the category were recommended.

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

Change Healthcare provided a clinical overview of the category. The Committee recommended moving Symtuza™(darunavir, cobicistat, emtricitabine, tenofovir alafenamide), Dovato (dolutegravir/lamivudine), Triumeq®(dolutegravir/abacavir/lamivudine) and Juluca (dolutegravir/rilpivirine) from "PA Required Non-Preferred" to "No PA Required Preferred" status.

HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS

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

HIV INTEGRASE INHIBITOR & RTI COMBINATION

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

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

HIV INTEGRASE INHIBITOR & NON-NUCLEOSIDE COMBINATION

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

IX. Other Business

No other business was discussed.

X. Next Meeting Dates

The next meeting dates were set as follows to be held at 50 W. Town Street.

a. January 15th, 2020
b. April 8th, 2020
c. July 8th, 2020
d. September 30th, 2020

XI. Adjournment

Dr. Jacobs adjourned the meeting at 1:47 P.M.