Ohio
Department of Medicaid

Pharmacy & Therapeutics Committee
Ohio Department of Medicaid
50 W. Town Street, Columbus, OH
October 4, 2017
9:00 AM

MINUTES

Committee Members Present:
Susan Baker, CNP
Michelle Barger, PharmD
Mary Ann Dzurec, PharmD
Jennifer Gwilym, DO
Jennifer Hauler, DO
Stephen Hersey, MD
Karen Jacobs, DO, Chair
Melissa Jefferis, MD
Margaret Scott, RPh

Committee Members Not Present:
Suzanne Eastman, PharmD
Sandra Hrometz PhD, RPh

Contract Staff/Change Healthcare Staff Present:
Chad Bissell, PharmD
Jill RK Griffith, BS, PharmD
Jacqueline Hedlund, MD
Ben Link, PharmD
Gail Master, RPh

Also present were approximately 100 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Margaret Scott, RPh, called the meeting to order at 9:22 a.m.

II. Introductions

Ms. Scott welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. Guest were reminded to sign in and advised of where the facility resources are located.

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III. Department of Medicaid Update

Ms. Scott provided information regarding Ohio Department of Medicaid's ongoing collaboration with the five managed care plans to move to a single Preferred Drug List (PDL). Although originally planned to be effective January 1, 2018, it was announced that the implementation of the single PDL would be delayed until July 1, 2018.

IV. Manufacturer Presentations

a. ***Sandoz, Zarxio®***
b. ***CSL Behring, Afstyla®***
c. ***Shire, Adynovate®***
d. ***CSL Behring, Idelvion®***
e. ***AstraZeneca, Brilinta®***
f. ***Novartis, Entresto®***
g. ***Biogen, Tecfidera®***
h. ***Merck, Belsomra®***
i. ***Sunovion Pharmaceuticals, Aptiom®***
j. ***Otsuka America Pharmaceuticals, Rexulti®***
k. ***Novo Nordisk, Tresiba®***
l. ***Janssen, Invokana®***
m. ***Eli Lilly, Trulicity®***
n. ***Pfizer, Xeljanz®,***
o. ***Gilead Sciences, Harvoni®, Epclusa®, Vosevi®***
p. ***ViiV Healthcare, Triumeq®,***
q. ***Sunovion, Utibron®, Seebri®***
r. ***Boehringer Ingelheim, Stiolto™ and Spiriva® Respimat®***
s. ***GlaxoSmithKline, Breo®, Anoro®, Incruse®***
t. ***Pfizer, Eucrisa®***

With no other presenters, the session was adjourned at 11:05 a.m. with a break for lunch.

P & T reconvened at 12:10 p.m. with presentations by interested parties not affiliated with manufacturers.

V. Interested Party Presentation

Ms. Scott repeated the announcement that although originally planned to be effective January 1, 2018, the implementation of the single PDL would be delayed until July 1, 2018.

a. ***Michael Para, MD, drug coverage for HIV antiretroviral drugs***
b. ***Brian Beesley, DO, drug coverage for HIV antiretroviral drugs & Hepatitis C***
c. ***Jonathan Pedrick, MD, drug coverage for Lyrica***
d. ***Aaron Clark, PharmD, HIV drug coverage and Androgens***
e. ***Douglas Van Fossen, MD, Brilinta®***
f. ***Kittie Wyne, MD, Diabetes and Androgens***

g. ***Ms. Lisa France, Hepatitis C***
h. ***Manhomhan Katapadi, MD, Entresto®***
i. ***Bruce Auerbach, MD, Eliquis®***
j. ***Peter Amsterdam, MD, Brilinta, Entresto***
k. ***Aref Amro, MD, Entresto®***
l. ***Frank Morocco, DO, Eucrisa®***
m. ***Mr. Graig Cote, drug coverage for HIV antiretroviral drugs***
n. ***Janet Briggs, CNP, HIV drug coverage***
o. ***Rajaram Karne, MD, Diabetes***
p. ***Mr. Burt Dhira, Medication Assisted Treatment for Opioid Addiction***
q. ***Shawn Ryan, MD, Medication Assisted Treatment for Opioid Addiction***
r. ***Ms. Cindy Costello, Medication Assisted Treatment for Opioid Addiction***
s. ***Mr. Casey Weidner, Hemophilia***
t. ***Ms. Shelia Bilges, Hemophilia***
u. ***Hosain Aghamoosa, PharmD, Hemophilia***
v. ***Ms. Randi Clites, Hemophilia***

Following the interested party presentations, a member of the audience, Jeanette Moleski, DO, requested to address the Committee on the topic of Medication Assisted Treatment for Opioid Addiction. Following a vote, Dr. Moleski was not granted time to present to the P&T Committee.

VI. Approval of July 12th, 2017 Meeting Minutes

The minutes from the prior P&T meeting were reviewed. Dr. Hauler moved to approve the minutes, seconded by Dr. Jefferis.

VII. Preferred Drug List Review

Following the completion of presentations from drug manufacturers and interested parties, it was announced that the recommendation for Brilinta® to be made non-preferred was to be changed to recommend Brilinta® as preferred. The P&T Committee members deliberated on the classes for extraction. The following drug categories were extracted for review and discussion with the remainder of the categories being voted and approved as recommended by Change Healthcare in the draft PDL document with the correction to Brilinta®:

a. ***Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. Votes were taken and the category was approved without any recommended changes.

b. ***Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. Dr. Link announced that Novoeight will be Preferred. There is also a Factor XIII product (Corifact®), inadvertently on the list and it will be removed. The Committee voted unanimously to amend the prior authorization criteria to allow trial of one preferred product

rather than two products, and to approve a product if it had been previously used by the patient. Votes were taken and the category was approved without any additional changes.

*c. **Cardiovascular Agents: Angina, Hypertension, & Heart Failure***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. The Committee voted unanimously to augment Entresto™ and Ranexa® specific criteria. The recommended criteria follow below.

ARB/ NEPRILYSIN INHIBITOR COMBINATION CLINICAL PRIOR AUTHORIZATION CRITERIA:
Valsartan/sacubitril (Entresto™) may be approved if all the following are met:
1. Diagnosis of chronic heart failure (NYHA Class II-IV), and
2. Age greater than or equal to 18 years, and
3. Left ventricular ejection fraction less than or equal to 40%, and
4. No history of angioedema or unacceptable side effects with ACE inhibitor or ARB, and
5. Not concomitantly taking an ACE inhibitor or other ARB, and

CHRONIC STABLE ANGINA STEP THERAPY:
Ranolazine (Ranexa®) may be approved for new patients if there has been a therapeutic failure to no less than a one-month trial of at least a beta blocker, a diltiazem product, AND a nitrate (excluding sublingual nitroglycerin), or contraindications to these agents exist.

*d. **Cardiovascular Agents: Lipotropic***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. Dr. Link announced that in the PCSK 9 Inhibitor category, a trial of statins plus ezetimibe (Zetia®) would no longer be required for patients diagnosed with either homozygous or heterozygous Familial Hypercholesterolemia. The Committee requested that Change Healthcare evaluate rosuvastatin and ezetimibe utilization to revisit at the next meeting. Votes were taken and the category was approved with the above changes.

*e. **Central Nervous System (CNS) Agents: Multiple Sclerosis***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. A brief discussion ensued, and a motion was made for Tecfidera® to be preferred. Votes were taken and the recommendation follows below:

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL *

NO PA REQUIRED "PREFERRED"	PA REQUIRED
GILENYA® (fingolimod) TECFIDERA® (dimethyl fumarate)	AUBAGIO® (teriflunomide)

f. Central Nervous System (CNS) Agents: Neuropathic Pain

Change Healthcare provided an overview of the current drug category and a review of the current criteria. A brief discussion ensued, and a motion was made that Lyrica® be approved for patients when initiated during a hospitalization. Votes were taken and the recommendation unanimously approved.

g. Endocrine Agents: Androgens

Change Healthcare provided an overview of the current drug category and a review of the current criteria. Votes were taken and the category was approved without any recommended changes.

h. Endocrine Agents: Diabetes Adjunctive Therapy

Change Healthcare provided an overview of the current drug category and a review of the current criteria. The Committee requested that patient received approval for a non-preferred mediation after therapeutic failure to one preferred medication in this category rather than two. Votes were taken and the recommendations follow below.

ENDOCRINE AGENTS: DIABETES – GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
BYDUREON® (exenatide) BYETTA® (exenatide) VICTOZA® (liraglutide) TRULICITY® (dulaglutide)	ADLYXIN™ (lixisenatide) BYETTA® (exenatide) TANZEUM™ (albiglutide)

i. Endocrine Agents: Diabetes – Insulin

Change Healthcare provided an overview of the current drug category and a review of the current criteria. Votes were taken and the category was approved without any recommended changes.

j. Endocrine Agents: Diabetes – Oral Hypoglycemics

Change Healthcare provided an overview of the current drug category and a review of the current criteria. The Committee requested that an extended release metformin 1,000 mg strength be covered for once daily dosing. After discussion, the committee agreed that an extended release 750 mg metformin product would satisfy. Discussion around the sodium-glucose cotransporter 2 (SGLT2) inhibitors took place. Votes were taken and the category was approved without any recommended changes.

k. Infectious Disease Agents: Antivirals-Hepatitis C Agents

A brief discussion was undertaken regarding the appropriateness of the prior authorization criteria for these agents. The AASLD guidelines were discussed and the committee voted and recommended that the criteria be modified as follows:

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ADDITIONAL CRITERIA FOR DAAs:

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

Step 1: Patient Readiness Evaluated

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

Step 2: Clinical Assessment of Disease

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

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

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
- HCV RNA testing is required every 4 weeks; treatment beyond the initial 8 weeks of therapy require confirmation of lowered viral load; refills will NOT be granted unless a greater than or equal to a 2 log reduction in the HCV RNA or the HCV RNA is less than 25 IU/mL
- HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications
- Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved. Regimens listed as not recommended will not be approved.

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*l. **Infectious Disease Agents: Antivirals-HIV Integrase Inhibitor& RTI Combination***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. Votes were taken and the recommendation follows below.

HIV INTEGRASE INHIBITOR & RTI COMBINATION

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

*m. **Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. The committee noted a lack of choice in the LABA/LAMA combination category and asked that an additional option be added with a different type of device than Bevespi®. Votes were taken and the recommendation follows below.

RESPIRATORY AGENTS: BETA-ADRENERGIC-STEROID COMBINATIONS (LABA/ICS)

STEP THERAPY REQUIRED PREFERRED	PA REQUIRED
ADVAIR® DISKUS® (salmeterol/fluticasone)† ADVAIR® HFA (salmeterol/fluticasone) BREO® ELLIPTA® (fluticasone/vilanterol)† DULERA® (formoterol/mometasone) SYMBICORT (formoterol/budesonide)	AIRDUO™ Respiclick® (salmeterol/fluticasone) FLUTICASONE-SALMETEROL Respiclick®

*n. **Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction***
Change Healthcare provided an overview of the current drug category and a review of the current criteria. The Committee voted to remove prior authorization on preferred products. The Committee requested penal system utilization be discussed at the next meeting. Ms. Scott will work with her State partners to meet this request. Votes were taken and the recommendation follows below.

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION

"PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUNAVAIL® buccal film (buprenorphine/naloxone) SUBOXONE® SL film (buprenorphine/naloxone) ZUBSOLV® SL tablets (buprenorphine/naloxone)	BUPRENORPHINE SL tablets (generic of Subutex®) BUPRENORPHINE/NALOXONE SL tablets

VIII. Other Business

No new business

IX. Next Meeting Date

Next meeting is at 10 a.m. on Wednesday, January 10th, 2018, at 50 W. Town Street, Room C621-A and C621-B. Attendees were encouraged to check the Medicaid website, http://pharmacy.medicaid.ohio.gov, for information regarding the next meeting date and time.

X. Adjournment

Dr. Jacobs adjourned the meeting at 5:25 p.m.