DRUG REVIEW COMMITTEE (DRC) MEETING MINUTES

November 13, 2019

DRC Meeting
Magellan Medicaid Administration Office
#1 Allied Drive, Suite 1120 Building #1
Little Rock, Arkansas 72202

Board Members Present
Laurence Miller, M.D.
Grace Marable, Pharm. D.
Chadwick Rodgers, M.D.
Melissa Max, Pharm. D.
Daniel Pace, M.D.

Medicaid Staff Present
Cindi Pearson, Pharm. D., Chair
Annette Jones

Magellan Staff Present
Lynn Boudreaux, Pharm. D.

Board Members Absent
(1) Pharmacist Vacancy
Tonya Robertson, Pharm. D.

PASSE Members Present
Kristen Pohl, Pharm. D.
Christopher Page, Pharm. D.
Vanessa Motwani, Pharm. D.

Meeting held in the Magellan Health Boardroom located at #1 Allied Drive, Suite 1120 in Little Rock, Arkansas. A quorum was present, and the Chair called the meeting to order at 9:03 a.m.

I. GENERAL ANNOUNCEMENTS

a. Silence cellphones
b. Bathroom locations
c. Visitor sign-in reminder
d. Speakers will no longer sign-in to speak on the day of the meeting, and visitors may only speak when asked.

II. SPEAKERS

Chair reminded the speaker(s) that they are allotted 2 minutes per drug and all public comments must have been submitted to the chair at least 2 weeks prior to this meeting.

a. Jodi Howard, clinical supervisor from Arkansas Community Correction—Vivitrol®
b. Valerie Ng, Pharm. D., from Indivior—Sublocade®
c. Amy Heidenreich, BSN, BA, RN from United Therapeutics Corp—Orenitram®
d. Evie Knisely, Pharm. D. from Novartis Pharmaceuticals—Mayzent®
e. Robert Greely, Pharm. D. from Biogen—Tecfidera®

Committee members did not have questions for the speakers.

III. UNFINISHED/OLD BUSINESS OR GENERAL INFORMATION

1) Chair read the Disclosure of Conflicts of Interest Statement and asked the committee members to sign the attendance sheet and Disclosure of Conflicts of Interest form. No conflicts were declared by the committee members or chair.
2) Introduction of new committee member, Daniel Pace M.D. The committee introduced themselves individually.
3) Update on meeting location
    a. Meetings will no longer be held in the Magellan Boardroom.

b. All 2020 meetings will be held in conference room A/B in the DHS Donaghey South Building at 700 Main Street in Little Rock

4) Meeting minutes for the August 2019 DRC meeting were discussed.
Motion by Dr. Rodgers to accept the minutes as written; seconded by Dr. Max; All members present voted for the motion. Motion passed.

5) Update on PDL implementation from August 14, 2019 DRC meeting
   a. Inhaled antibiotics, CGRP Antagonist, osteoporosis medications, growth hormones, otic anti-infective agents, pancreatic enzymes and lice treatment—10/1/2019
   b. Oral antipsychotics—10/1/19

IV. NEW BUSINESS

Chair notified the committee that the procedures would change to follow the current bylaws. Clinical information would be given on all medications in the class, and the committee should have clinical discussions to suggest preferred and nonpreferred agents based on clinical evidence. The Drug Cost Committee shall meet following the DRC meeting. Confidential and proprietary information, such as State supplemental rebate contract offers, CMS rebate amount, and the final net cost to the state, shall be reviewed in closed sessions. The DCC shall make a recommendation to the Medicaid Pharmacy Program Director for the most cost-effective selections for preferred status on the PDL.

1) Antimigraine Agents (Triptans only)

The Chair provided background information on triptans and current criteria. This review is a renewal of the triptans drug class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications
b) Migraine etiology
c) Migraine treatment
d) Pharmacology of Triptans
e) Evidence based medicine summaries
f) Summary list of Triptans

DISCUSSION:

Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the triptan class. Preferred, preferred with criteria, and nonpreferred statuses were discussed between the committee members for oral preparations, nasal sprays and injections. Dr. Boudreaux verified that there are no age edits for the triptan MLT products. Chair verified that the quantity edits for oral preparations are 9 tablets per 28 days. The committee held a discussion on the look-back timeframe needed before the use of preferred with criteria agents. Dr. Boudreaux asked the committee if the nasal spray(s) with the best cost for the state could be preferred. Dr. Miller asked if we had utilization reports available. The committee suggested the following:

<u>Preferred</u>

Sumatriptan (Imitrex®) tablet
Rizatriptan (Maxalt®) tablet and MLT

1-2 nasal formulations depending on cost (other agents would be nonpreferred)

Preferred WITH criteria
Eletriptan (Relpax®) tablet
Sumatriptan (Imitrex®) injection

Nonpreferred
Almotriptan (Axert®) tablet
Frovatriptan (Frova®) tablet
Naratriptan (Amerge®) tablet
Sumatriptan/naproxen (Treximet®) tablet
Sumatriptan (Sumavel® DosePro®) injection
Sumatriptan (Zembrace® SymTouch®) injection

ACTION:
Motion was made by Dr. Max to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Pace. All members present voted for the motion. Motion passed.

2) COPD Agents

The chair provided background information on COPD and current criteria. This review is a renewal of the COPD agents drug class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) List of COPD agents divided into mechanism of action with FDA approved indications
b) COPD etiology
c) 2019 GOLD assessment tool
d) Initial pharmacological treatment
e) 2019 GOLD guidelines (key points)
f) Evidence based medicine summaries
g) Summary list of COPD agents

DISCUSSION:
Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the COPD class. Dr. Miller suggested we review by class and suggested that 1-2 agents from each class have preferred status. Dr. Boudreaux confirmed that previous point-of-sale criteria would remain. Dr. Rodgers suggested that since there is no significant difference in efficacy with these agents, that the cost to the state should be the deciding factor. The committee suggested the following:

Preferred WITH criteria:
Short-acting muscarinic agents (SAMA)
Ipratropium nebulization solution (Atrovent®)
Ipratropium (Atrovent® HFA) inhaler

Long-acting muscarinic agents (LAMA)
1-2 in this class based on best product(s) for the state

Short-acting combination product (SABA/SAMA)
Same medication so best product for the state

Long-acting combination products (LABA/LAMA)
1-2 in this class based on best product(s) for the state

All other products would be classified as non-preferred.

ACTION:
Motion was made by Dr. Rodgers to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Pace. All members present voted for the motion. Motion passed.

3) Inhaled corticosteroids

The chair provided background information on inhaled corticosteroid agents and current criteria. This review is a renewal of the Inhaled Corticosteroid drug class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications divided into ICS only and ICS/LABA combination
b) Asthma etiology
c) Diagnosing asthma
d) New 2019 GINA guidelines with key points
e) Evidence based medicine summaries
f) 2019 GINA guidelines for equipotent dosages of inhaled corticosteroids

DISCUSSION:
Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the Inhaled Glucocorticoid class. Dr. Rodgers stated Flovent has always worked well for his treatment population, and it would be nice to have a powder option and respules for children. Dr. Pace stated that the combination products are fairly interchangeable in adults. Dr. Rodgers will typically refer children to allergist/immunologist especially if need combination product. The committee suggested the following:

Single Agents
Preferred
Flovent HFA
Pulmicort Respules
Possibly an inhaled powder formulation

Combination Agents
Interchangeable—decision based on cost benefit to State

ACTION:
Motion was made by Dr. Marable to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Max. All members present voted for the motion. Motion passed.

4) Multiple Sclerosis

The chair provided background information on Multiple Sclerosis agents and current criteria. This review is a renewal of the Multiple Sclerosis class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications
b) Multiple Sclerosis etiology
c) Clinical course of Multiple Sclerosis
d) Disease Modifying Therapy Recommendations
e) Side effect profiles
f) Evidence based medicine summaries
g) Summary list of Multiple Sclerosis agents

DISCUSSION:
Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the Multiple Sclerosis class. Dr. Marable suggested that all first line agents should be available. Dr. Pace suggested that at least one oral should be preferred. Dr. Marable added that at least one injection should be preferred. Dr. Max recommended that Mayzent should be considered. Chair suggested to leave Ampyra nonpreferred and remain manually reviewed. Chair asked the manufacturer rep if there are any head-to-head trials for oral preparations. Chair stated that first line therapy for oral treatment would include Tecfidera, Gilenya, Mayzent and Aubagio. Dr. Miller stated we should make general recommendations. The committee suggested the following:

<u>Preferred</u>
At least one oral agent
At least one injection

<u>Nonpreferred</u>
All other disease-modifying agents would be nonpreferred
Ampyra
Mavenclad

ACTION:
Motion was made by Dr. Marable to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Pace. All members present voted for the motion. Motion passed.

5) Nonsteroidal Anti-Inflammatory Agents

The chair provided background information on NSAID agents and current criteria. This review is a renewal of the NSAID agents class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications for each product
b) NSAIDS key points

DISCUSSION:

Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the NSAIDs class. Dr. Pace asked the previous rationale for preferring Diclofenac ER over the IR formulation as he prefers the IR formulation in his treatment population. Chair suggested that the committee recommend adding celecoxib to the preferred list. Dr. Boudreaux verified that currently all topical preparations require a PA. Dr. Pace uses diclofenac gel in his treatment population, but topical gel is even difficult to get for his patients with private insurance. Dr. Motwani stated that many other states have removed criteria on diclofenac gel. The committee suggested the following:

Preferred
All currently preferred medications except diclofenac ER
Add celecoxib
Add diclofenac IR
Add diclofenac gel

Nonpreferred
All others nonpreferred

ACTION:
Motion was made by Dr. Pace to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Rodgers. All members present voted for the motion. Motion passed.

6) Injectable Medication Assisted Treatment Formulations

The chair provided background information on MAT agents (oral and injection) and current criteria. Injectable MAT agents would be a new PDL class. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications for each product

DISCUSSION:
Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the injectable MAT formulations. Chair stated that one focus in treating Opioid Use Disorder is to prevent barriers to receiving medication. MAT providers are reluctant to keep these expensive injections on hand in their offices. Dr. Boudreaux stated that the Arkansas prison system has a Vivitrol program. Chair suggested to make both medications preferred. Dr. Miller agreed, but we need to continue to monitor appropriate use by the State office. The committee suggested that both medications be added to the preferred drug list.

ACTION:
Motion was made by Dr. Miller to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Max. All members present voted for the motion. Motion passed.

7) Pulmonary Arterial Hypertension

The chair provided background information on Pulmonary Arterial Hypertension agents and current criteria. This review is a renewal of the PAH class on PDL. Dr. Boudreaux presented a PowerPoint with the following information.

a) FDA approved indications for each product
b) Pulmonary Hypertension overview
c) Pulmonary Hypertension classification
d) PAH WHO functional classes
e) PAH agent pharmacology
f) 2018 Updated CHEST guidelines
g) Evidence based medicine summaries
h) Summary list of PAH medications by class

DISCUSSION:
Committee members, Dr. Boudreaux and the Chair discussed multiple options concerning the Pulmonary Arterial Hypertension class. Dr. Boudreaux stated that injectables are not currently on the PDL. Dr. Pace asked if there have been head-to-head studies on oral and inhaled treprostinil. Manufacturer representative stated there has not been head-to-head studies. Dr. Marable stated that Opsumit has a long half-life. Dr. Boudreaux stated that both PDE-5 inhibitors have generic products and are preferred on the PDL. Chair stated that currently the preferred medications include brand name Letairis and Tracleer. Chair reminded the committee that there is data to support dual therapy with ambrisentan and tadalafil. Dr. Boudreaux suggested that both PDE-5 inhibitors remain preferred. The committee discussed triple therapy. The committee suggested the following:

Preferred
Sildenafil
Tadalafil
Letairis

Nonpreferred
Adempas
Uptravi
All not listed on preferred list

ACTION:
Motion was made by Dr. Marable to submit the above recommendations for review along with DCC recommendations to the State; seconded by Dr. Pace. All members present voted for the motion. Motion passed.

V. Chair provided schedule of future DRC meeting dates.

VI. Meeting adjourned at approximately 12:03 p.m.