DRUG REVIEW COMMITTEE (DRC) MEETING MINUTES

August 14, 2019

Board Members Present

Laurence Miller, M.D.
Tonya Robertson, Pharm. D.
Chadwick Rodgers, M.D.
Melissa Max, Pharm. D.

Medicaid Staff Present

Cindi Pearson, Pharm. D., Chair
Mike Munnerlyn, MBA
Annette Jones

Magellan Staff Present

Lynn Hailey, Pharm. D.

Board Members Absent

(1) Physician Vacancy
Grace Marable, Pharm. D.

PASSE Members Present

Kristen Pohl, Pharm. D.
Christopher Page, Pharm. D.
Vanessa Motwani, Pharm. D.

The Chair called the meeting to order at 9:01 a.m.

I. GENERAL ANNOUNCEMENTS

a. Silence cellphones
b. Bathroom locations
c. Visitor sign-in reminder
d. Speaker sign-in reminder

II. SPEAKERS

Chair reminded the speaker(s) that they are allotted 2 minutes per drug.

a. Robert Martin from Insmed spoke on Arikayce®
b. Dave Miley from Teva spoke on Ajovy®
c. Andrew Houch from Chiesi spoke on Pertzye®
d. Joseph Dye from Amgen spoke on Aimovig®
e. Alice Kelly Morgan from Pfizer spoke on Genotropin®

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) Update on meeting location
    a. November 2019 meeting will be held again in the Magellan Health Boardroom at #1 Allied Drive Suite 1120 in Little Rock

   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

3) Meeting minutes for the May 2019 DRC meeting were discussed.
   Motion by Dr. Max to accept the minutes as written; seconded by Dr. Rodgers; All members present voted for the motion. Motion passed.
4) Update on PDL implementation from May 8, 2019 DRC meeting
   a. PPIs—7/1/19
   b. Oral antipsychotics—10/1/19
5) DRC bylaws were last reviewed in entirety in 2016. As per the bylaws, documentation of proposed changes was provided to the committee members during the May 2019 DRC meeting for review during the August DRC meeting.

   Chair discussed the proposed changes with the committee. Motion to approve the DRC bylaws as presented by Dr. Miller; seconded by Dr. Rodgers; All members present voted for the motion. Motion passed.
6) Guidance on non-preferred oral antipsychotics usage
   Chair asked the committee for guidance in length of trial required and number of preferred medications to try prior to moving to a non-preferred medication. Some of the manufacturers requested guidance to assist the PASSEs in following the PDL.

   DISCUSSION:
   Dr. Robertson asked what would be considered a trial. Chair asked Dr. Miller to speak about proposed recommendations. Dr. Miller suggested trying 2 preferred medications prior to moving to a non-preferred product. But he did note that treating this population is not black and white and should be considered on a case-by-case basis. Dr. Miller offered his assistance with any questions when requests are reviewed. Dr. Miller also spoke about allowing a month's supply when recipients are discharged from a facility even if the information sent is deficient. This would apply even if labs are pending. Chair asked the PASSE for their thoughts. Dr. Pohl stated their criteria typically requires 2 preferred medications for a minimum of one month before moving to a non-preferred medication. Dr. Page and Dr. Motwani agreed and asked to have this in writing. Dr. Motwani said a contraindication or adverse reaction would be taken into considered. Dr. Max approved of Dr. Motwani's verbiage. Dr. Motwani asked about procedures for patients who cannot swallow pills. Dr. Miller said each should be reviewed on a case-by-case basis and gave an example of an autistic child which may be an exception to the NPO rule.

   ACTION:
   Motion by Dr. Rodgers to require 2 preferred medications prior to moving to a non-preferred medication; seconded by Dr. Max. All members present voted for the motion. Motion passed. No vote was taken on what constitutes an adequate trial of a medication.

7) Update on proton pump inhibitors
   Chair provided an update on the PPIs. The DRC previously requested that the DUR Board re-review the class taking into consideration the long-term effects of PPI use. Chair gave an overview of PPI utilization and the limitations of the Magellan system regarding the infeasibility

of monitoring lifestyle modifications. Chair noted that no criteria changes were made by the DUR Board, but that RDUR criteria would be established to assess utilization retrospectively.

IV. NEW BUSINESS

1) INHALED ANTIBIOTICS

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

a) FDA approved indications
b) Objectives for treating Cystic Fibrosis
c) Cystic Fibrosis Foundation recommendations for *P. aeruginosa* infection
d) Guidelines for treating *Mycobacterium avium* complex
e) Clinical trial information for Arikayce®
f) CFF guidelines for Cayston® vs Tobramycin

SUGGESTED PREFERRED
Tobramycin (AG and Generic)

SUGGESTED NON-PREFERRED
Kitabis®
Bethkis™
TOBI®
TOBI Podhaler®
Cayston®
Arikayce®

DISCUSSION:
Dr. Rodgers asked for verification if previously preferred products would be non-preferred. Dr. Hailey verified that the only suggested preferred product was the generic Tobramycin.
ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Robertson; motion seconded by Dr. Rodgers. All members present voted for the motion. Motion passed.

2) ANTIMIGRAINE AGENTS (CGRP ANTAGONISTS)

The chair provided background information on CGRP Antagonists and current criteria. CGRP Antagonists are a new PDL class. Dr. Hailey presented a PowerPoint with the following information.

a) FDA approved indications for all 3 medications in the class
b) Overview of migraines
c) Treatment options of active migraine
d) Prophylactic medications
e) Pharmacology of CGRP Antagonists
f) American Headache Society recommendations

SUGGESTED PREFERRED WITH CRITERIA
Emgality® 120mg syringe and pen

SUGGESTED NON-PREFERRED
Emgality® 100mg syringe
Aimovig® Autoinjector (all strengths)
Ajovy® 225mg syringe

DISCUSSION:
Dr. Max asked if the Emgality® would be preferred with criteria. Dr. Hailey verified that medical necessity would be required, and the manual review criteria would need to be met. Dr. Max asked who reviews these requests. The chair stated that the state pharmacists review these medications. Dr. Max asked if the criteria for 15 migraine days per month was absolute even when the patient has tried everything required. The chair and Dr. Hailey both stated that we are flexible and use our clinical judgement. Dr. Hailey did mention that the Emgality® 100mg syringe for episodic migraines was non-preferred. Dr. Rodgers asked about requests for the patients less than 18 years old. Dr. Hailey stated we don't see requests for this age. The chair stated we use the package insert and MicroMedex for verifying the safety and efficacy in pediatrics and follow those recommendations. Dr. Hailey asked the industry reps if there are any trials currently on pediatrics.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Rodgers; motion seconded by Dr. Robertson. All members present voted for the motion. Motion passed.

3) OSTEOPOROSIS MEDICATIONS

The chair provided background information on osteoporosis agents and current criteria. Osteoporosis agents are a new PDL class. Dr. Hailey presented a PowerPoint with the following information.

a) FDA approved indications for Bisphosphonates
b) FDA approved indications for calcitonin-salmon and raloxifene
c) FDA approved indications for the injectable products
d) Osteoporosis overview
e) Osteoporosis AACE and ACE guidelines

SUGGESTED PREFERRED
Alendronate tablet (all strengths)

SUGGESTED NON-PREFERRED WITH CRITERIA
Raloxifene (Evista®) tablet
Prolia® injection

SUGGESTED NON-PREFERRED WITHOUT CRITERIA
Atelvia® (risedronate) tablet
Ibandronate (Boniva®) tablet and injection
Risedronate (Actonel®) tablet

Binosto® (alendronate effervescent) tablet
Tymlos® injection
Evenity® injection (requires manual review)
Etidronate tablet
Forteo® injection
Calcitonin-salmon (Fortical® and Miacalcin®) nasal spray (requires manual review)

DISCUSSION:
Dr. Motwani asked about Forteo®. Dr. Hailey stated that we typically approve if there is medical necessity over Prolia® such as osteonecrosis of the jaw. All injectables require manual review and have no point-of-sale criteria on initial requests. PAs are typically put in for a year.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Max; motion seconded by Dr. Miller. All members present voted for the motion. Motion passed.

4) GROWTH HORMONES

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

a) FDA approved indications for each product

SUGGESTED PREFERRED WITH CRITERIA
Genotropin®

SUGGESTED NON-PREFERRED
Humatrope®
Norditropin®
Nutropin AQ® NuSpin®
Omnitrope®
Zomacton™
Saizen®
Zorbtive

DISCUSSION:
Dr. Rodgers asked if we limit requests to specialists. Dr. Hailey stated we usually see requests from ACH endocrinology or LeBonheur. Dr. Robertson asked about the increase in use. Concern was noted regarding the overuse of growth hormones. Dr. Robertson asked if the criteria should be stricter. Dr. Hailey stated that we are already pretty strict on growth hormone deficiency. Adults with Turner's etc. would be an exception to the growth hormone deficiency requests.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Rodgers; motion seconded by Dr. Robertson. All members present voted for the motion. Motion passed.

5) OTIC ANTI-INFECTIVE AGENTS

The chair provided background information on otic anti-infective agents and current criteria. This review is a renewal of the otic anti-infective agents class on PDL. Dr. Hailey presented a PowerPoint with the following information.

a) FDA approved indications for each product
b) Otitis Media and Otitis Externa overview

SUGGESTED PREFERRED
Acetic acid otic
Ofloxacin otic
Ciprodex® (ciprofloxacin and dexamethasone suspension)
Neomycin/Polymyxin/HC otic solution

SUGGESTED NON-PREFERRED
Cipro® HC Otic
Coly-Mycin® S otic
Ciprofloxacin otic
Otovel® otic (ciprofloxacin and fluocinolone acetonide)
Cortisporin® TC
Otiprio® otic (ciprofloxacin)

DISCUSSION:
Dr. Rodgers feels this is a good preferred list. At one point there was availability issues with ofloxacin and higher costs. Dr. Hailey stated those issues seem to be resolved.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Rodgers; motion seconded by Dr. Robertson. All members present voted for the motion. Motion passed.

6) PANCREATIC ENZYMES

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

a) FDA approved indications for each product
b) List of all products with strengths available

SUGGESTED PREFERRED
Zenpep®
Creon®

SUGGESTED NON-PREFERRED
Viokace®
Pancreaze®
Pertzye®

DISCUSSION:
No comments or suggestions.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Max; motion seconded by Dr. Miller. All members present voted for the motion. Motion passed.

7) HEAD LICE TREATMENTS

The chair provide background information on head lice treatments and current criteria. This review is a renewal of the topical antiparasitic class on PDL. This class was brought for review early due to lice resistance to the preferred agents. Dr. Hailey presented a PowerPoint with the following information.

a) FDA approved indications for each product
b) Head lice overview
c) 2015 AAP and 2018 Red Book recommendations for treatment

SUGGESTED PREFERRED
Permethrin 1% OTC
Permethrin 5% (Elimite™)
Piperonyl butoxide 4%/pyrethrum extract 0.33% OTC
Natroba™ (Spinosad) **BRAND NAME ONLY**

SUGGESTED NON-PREFERRED
Ulesfia® (benzyl alcohol 5%)
Sklice® (ivermectin 0.05%)
Eurax cream and lotion (crotamiton 10%)
Ovide® (malathion 0.05%)
Spinosad 0.9% **GENERIC**

DISCUSSION:
Dr. Rodgers asked if Natroba™ required other trials first. Dr. Hailey confirmed there is no criteria on Natroba™ and treated like the other preferred products. Dr. Hailey reiterated that you only have to treat once with Natroba™ versus retreatment on other preferred products.

ACTION:
Motion to approve the suggested preferred and non-preferred list was made by Dr. Rodgers; motion seconded by Dr. Robertson. All members present voted for the motion. Motion passed.

V. Chair provided schedule of future DRC meeting dates.

VI. Meeting adjourned at approximately 10:45 a.m.