

DRUG REVIEW COMMITTEE (DRC) MEETING MINUTES

February 12, 2020

DRC Meeting
DEPARTMENT OF HUMAN SERVICES BUILDING
Donaghey Plaza South
700 Main Street
Conference Room A
Little Rock, AR 72201

Board Members Present

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

Medicaid Staff Present

Cindi Pearson, Pharm. D., Chair
Annette Jones
Cynthia Neuhofel, Pharm. D.
Elizabeth Pitman, JD

Magellan Staff Present

Lynn Boudreaux, Pharm. D.

Board Members Absent

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

PASSE Members Present

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

Meeting held in the Department of Human Services Donaghey Plaza South building Conference Room A at 700 Main Street in Little Rock, Arkansas. A quorum was present, and the Chair called the meeting to order at 9:09 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. Kunal Ramani, Pharm. D. from Xeris Pharmaceuticals on Gvoke™ PFS and Gvoke™ Hypopen

Committee members did not have questions for the speaker.

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. 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
- 3) Introduction of the new PASSE representative from Summit—Lauren Jimerson, Pharm. D.

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- 4) Introduction of Division of Medical Services staff
 - a. Cynthia Neuhofel, Pharm. D.—Pharmacy Program Administrator
 - b. Elizabeth Pitman, JD—DMS Deputy Director
- 5) Meeting minutes for the November 2019 DRC meeting were discussed.
Motion by Dr. Rodgers to accept the minutes as written; seconded by Dr. Robertson; All members present voted for the motion. Motion passed.
- 6) Update on PDL implementation from November 13, 2019 DRC meeting and January 2020 DUR
 - a. Antimigraine agents, COPD agents, Inhaled Corticosteroids, MS agents, oral and topical NSAIDs, Substance Use Disorder injection, Pulmonary Arterial Hypertension—1/1/2020
 - b. January 2020 DUR Board voted on point-of-sale edits for Entresto®, Sensipar®, Procrit® and Epogen® along with updates based on latest GINA report—will be effective 4/1/2020

IV. NEW BUSINESS

1) Androgenic Agents (topical and injectable)

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

- a) FDA approved indications
- b) Overview of hypogonadism
- c) Evidence Based Medicine summaries
- d) Summary list of Androgenic Agents
- e) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Rodgers stated that the data shows most patients receive the injections, but it would be nice to have a topical option. Dr. Boudreaux noted that topical preparations (any nonpreferred agent) can be reviewed through the PA process with documentation of medical necessity. Dr. Pace asked about office administration. Dr. Boudreaux commented that this meeting was discussing only pharmacy claims. Most patients are trained to administer their own injection. Based on committee discussion, the Chair noted that all products were basically equal and recommended that overall cost should decide the outcome.

ACTION:

Motion to approve the above recommendation was made by Dr. Rodgers; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

2) Topical Antifungal Agents

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

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- a) FDA approved indications
- b) Overview of common fungal infections
- c) Evidence Based Medicine summaries
- d) Summary list of topical antifungal agents
- e) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Rodgers stated current options are pretty good with creams, ointments, powders and ketoconazole shampoo. Dr. Pace asked if there was an oral medication available for onychomycosis. Dr. Boudreaux stated that terbinafine was available without a PA. Dr. Robertson asked if we could not cover the topical onychomycosis agents since they are not effective. Dr. Boudreaux stated that we do have to cover them, but we can make them nonpreferred and require a PA. Based on committee discussion, the Chair noted that all products were basically equal except those for toenail fungal infections. The Chair recommended that toenail fungal medications should remain nonpreferred requiring a PA and overall cost should decide the outcome for the rest of the medications.

ACTION:

Motion to approve the above recommendations was made by Dr. Pace; seconded by Dr. Rodgers. All voting members present voted for the motion. Motion passed.

3) Bladder Relaxants

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

- a) FDA approved indications
- b) Overview of overactive bladder
- c) Pharmacology of bladder relaxant agents
- d) Evidence Based Medicine summaries
- e) American Urological Association guidelines
- f) Summary list of bladder agents
- g) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Miller asked if these medications were just for adults. Dr. Boudreaux stated that oxybutynin syrup is used in children. Dr. Pace stated we should have at least 2 options. Dr. Boudreaux stated that if someone needed a patch, then medical necessity could be considered. Based on committee discussion, the Chair noted that all products were basically equal in efficacy with some additional side effects for oxybutynin and recommended that overall cost should decide the outcome.

ACTION:

Motion to approve the above recommendations was made by Dr. Robertson; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

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4) Bronchodilators (Long-Acting Beta Agonists and Short-Acting Beta Agonists)

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

- a) Key points on beta₂ agonists
- b) FDA approved indications
- c) Evidence Based Medicine summaries
- d) Summary list of LABAs and SABAs
- e) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

SABA and LABA were considered separately. Dr. Max wanted verification of the current preferred medications for SABAs. Dr. Boudreaux verified that preferred are branded albuterol products (Proventil HFA and ProAir HFA) due to better federal rebates. Dr. Rodgers has no concerns over current SABA list. Dr. Max wanted to know if we should be concerned about expiratory ability with powder preparations like Serevent. Dr. Max wondered if preferred list should include powder and MDI options. Dr. Pace stated that onset of action should not be an issue when used properly. Dr. Boudreaux reiterated that salmeterol has a longer onset of action than formoterol. Magellan is working on edits to allow Symbicort to pay at POS without a PA based on GINA recommendations. Dr. Boudreaux stated that there are no head-to-head trials between these products, but if used properly each product is efficacious. The Chair mentioned that we have had patients with very poor expiratory ability that could not use a powder formulation, and a PA was issued on a MDI formulation. Based on committee discussion, the Chair noted that all products were basically equal in efficacy if used properly and recommended that overall cost should decide the outcome.

ACTION:

Motion to approve the above recommendations for long-acting agents was made by Dr. Rodgers; seconded by Dr. Max. Motion to approve the above recommendations for short-acting agents was made by Dr. Rodgers; seconded by Dr. Robertson. All voting members present voted for the motion. Motion passed.

5) Glucagon/Hypoglycemic Agents

The Chair provided background information on the glucagon/hypoglycemic class and current criteria. This class will be new for the Arkansas Medicaid PDL. Dr. Boudreaux presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Overview of hypoglycemia
- c) Management of hypoglycemia (symptomatic and severe)
- d) Summary list of glucagon/hypoglycemic agents

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- e) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Rodgers stated that in an emergency, glucagon kits are difficult to use. The “EpiPen-like” device would be good especially for children. Dr. Rodgers suggested glucagon kits would be fine, but there should be an option for Gvoke. Dr. Max agreed, but she wondered about the safety issue of taking time to draw up glucagon from a vial. Dr. Max was confused about the current approval criteria for Gvoke and Baqsimi. Type 1 diabetics’ blood sugars could be erratic even with a patient compliant on a meal plan. Dr. Boudreaux voiced that every Type 1 diabetic should have some sort of emergency product. Dr. Rodgers added that there is a great need in newly diagnosed children as they are titrating insulin. Dr. Robertson asked about cost difference and preference of nasal spray versus prefilled syringe. The Chair stated she did not know cost for all products at this time. Dr. Rodgers suggested a relaxed criterion for the newer products especially in children ages 2-4 years. Dr. Max suggested that the approval criteria for Gvoke and Baqsimi should only require a Type 1 diabetes diagnosis. Dr. Robertson stated she is okay with leaving Gvoke and Baqsimi as manual review. After committee discussions, the Chair reiterated the consensus that Glucagon kits remain preferred, but Gvoke and Baqsimi requests by manual review are considerate of the patients age and Type 1 diabetes.

ACTION:

Motion to approve the above recommendations was made by Dr. Robertson; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

6) Intranasal Rhinitis Agents

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

- a) FDA approved indications
- b) Overview of allergic rhinitis
- c) Overview of perennial and vasomotor rhinitis
- d) Evidence Based Medicine summaries
- e) AAAAI 2017 treatment guidelines
- f) Summary list of intranasal rhinitis agents (corticosteroids and antihistamines/anticholinergic)
- g) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Boudreaux stated that Nasacort and Rhinocort are only available OTC and not covered under Medicaid, and Veramyst is off the market. Dr. Pace stated that the data provided does not indicate superiority over any other product and recommends 1-2 options as preferred. Dr. Rodgers stated that compliance is an issue in children with fluticasone due to taste and smell. Dr. Rodgers stated that it would be nice to have another option. Based on committee discussion, the Chair noted that all products were basically equal and recommended that overall cost should decide the outcome.

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ACTION:

Motion to approve the above recommendations was made by Dr. Pace; seconded by Dr. Max. All voting members present voted for the motion. Motion passed.

7) Anti-inflammatory/Immunomodulators Ophthalmic Agents

The Chair provided background information on the anti-inflammatory/immunomodulator ophthalmic agents class and current criteria. This class will be new for the Arkansas Medicaid PDL. Dr. Boudreaux presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Overview of Keratoconjunctivitis
- c) Overview of treatment
- d) Evidence Based Medicine summaries
- e) Summary list of anti-inflammatory/immunomodulator ophthalmic agents
- f) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Pace asked about the official indication of Restasis. Dr. Boudreaux and Dr. Pohl discussed that Restasis is not technically indicated for the treatment of the signs and symptoms of dry eye disease but is used to treat keratoconjunctivitis sicca by increasing tear production. The Chair reiterated that the only real difference in the products is that cyclosporine has a shorter onset of action. Based on committee discussion, the Chair noted that all products were basically equal and recommended that overall cost should decide the outcome.

ACTION:

Motion to approve the above recommendations was made by Dr. Pace; seconded by Rodgers. All voting members present voted for the motion. Motion passed.

8) Long-Acting Opioids

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

- a) FDA approved indications
- b) Overview of pharmacology
- c) Summary including list of abuse-deterrent formulations
- d) Summary list of long-acting opioids
- e) Claims summary from 1/1/2018-12/31/2019

DISCUSSION:

Dr. Boudreaux asked for input on adding another abuse deterrent option as preferred. Dr. Pace asked why Hysingla was removed from the preferred list. Dr. Boudreaux stated that it was removed last

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review based on cost as the manufacturer stopped giving supplemental rebate. The available abuse deterrent options include Morphobond, Hysingla, Oxycontin and Xtampza ER. Dr. Miller asked if any companies made bids. Dr. Boudreaux stated that there were no bids. Dr. Max asked about the status of Butrans brand since it is the same manufacturer as multiple other medications. Dr. Boudreaux stated that Purdue has been paying the rebate on their products. If Purdue discontinues rebate payments, the preferred could be changed to the generic. Dr. Pace asked about utilization of all LAOs as he usually only sees Hysingla in his practice. Dr. Robertson asked if there are clinical criteria on LAOs. Dr. Boudreaux confirmed that all LAOs require a manual review PA unless there is utilization in the last 60 days or a cancer diagnosis. Dr. Pace stated an abuse deterrent formulation doesn't have to be preferred since it would be available through manual review unless required by CMS. Based on committee discussion, the Chair noted that an abuse deterrent is not required and recommended that overall cost should decide the outcome.

ACTION:

Motion to approve the above recommendations was made by Dr. Pace; seconded by Dr. Rodgers. All voting members present voted for the motion. Motion passed.

- V. Chair provided schedule of future DRC meeting dates.
- VI. Meeting adjourned at approximately 10:50 a.m.