August 12, 2020

DRC Meeting ZOOM Webinar

Board Members Present

Laurence Miller, M.D. Daniel Pace, M.D. Chadwick Rodgers, M.D. Melissa Max, Pharm. D. Grace Marable, Pharm. 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. Karen Evans, P.D. <u>PASSE Members Present</u> Kristen Pohl, Pharm. D. Christopher Page, Pharm. D. Lauren Jimerson, Pharm. D.

Board Members Absent

(1) Pharmacist Vacancy Tonya Robertson, Pharm.D.

Meeting held virtually by ZOOM Webinar. All committee members, Medicaid staff and Dr. Boudreaux were considered panelists. A quorum was present, and the Chair called the meeting to order at 9:08 a.m.

I. GENERAL ANNOUNCEMENTS

- a. Public meeting was recorded. All visitors/attendees were muted.
- b. Committee members and DHS were able to speak at any time.
- c. Robert's Rules of Order were used to conduct business.
- d. Voting on motions was performed by roll call.

II. SPEAKERS

- 1) Gibby Rodriguez, Pharm.D.—Indivior Perseris[®]
- 2) Tara McKinley, Pharm.D.—Otsuka Abilify Maintena®
- 3) Mandi Champ, Pharm.D.—Amgen Repatha®
- Shannon Sands, Pharm.D.—Janssen Invega Sustenna[®] Invega Trinza[®]
- 5) Courtney L. Walker, Pharm.D., R.Ph—Novo Nordisk Rybelsus[®] Tresiba[®]

DRC members had no questions for any speakers.

III. UNFINISHED/OLD BUSINESS OR GENERAL INFORMATION

- Chair read the Disclosure of Conflicts of Interest Statement. Dr. Marable emailed her signed form prior to the meeting. Chair took verbal confirmation from Drs. Max, Pace, Miller and Rodgers. No conflicts were declared by the committee members or chair.
- 2) Update on meeting location—no decision has been made for the November 2020 meeting.

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- Meeting minutes for the May 2020 DRC meeting were discussed. Motion by Dr. Pace to accept the minutes as written; seconded by Dr. Marable; All members present voted for the motion. Motion passed.
- 4) Update on PDL implementation from May 13, 2020 DRC meeting and July 2020 DUR meeting
 - PDL updates were effective 7/1/2020—short-acting analgesics, ophthalmic agents (allergic conjunctivitis, antibiotics, antibiotics/steroid, anti-inflammatory, and glaucoma), and topical corticosteroids
 - b. DUR PA manual review drugs were effective immediately; no new POS edits. Criteria updated for PCSK9 agents and Acthar[®] gel. Palforzia[®] was tabled for more research.
 - c. Lysteda[®] POS edits from the April 2020 DUR meeting were postponed until August 18, 2020.

IV. NEW BUSINESS

1) ANTIDIABETIC AGENTS

This review is a renewal of the insulin drug class and most antidiabetic drug classes on PDL. Some antidiabetic classes will be new to the PDL. Chair provided current criteria and current PDL list for all products. Dr. Boudreaux presented a PowerPoint with the following information.

- 1. Discussion of diabetes guidelines from ADA
- 2. Information on each specific class of antidiabetics

A. ALPHA-GLUCOSIDASE INHIBITORS

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

Chair made note that this class is currently not on PDL. With low utilization, it would be appropriate to makes agents preferred. Dr. Rodgers commented that the utilization is not high, and there are people who must benefit from these meds. Dr. Rodgers recommended to add this class to the PDL with agents currently not requiring a PA as preferred. Dr. Max agreed. Dr. Boudreaux stated that we would place the agents on the PDL as preferred with no criteria. Dr. Pace agreed with the discussion.

ACTION:

Motion to add this class to the PDL with preferred agents was made by Dr. Rodgers; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

B. INCRETIN MIMETICS (Amylin analogues, DPP-4 enzyme inhibitors and GLP-1 agonists)

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Evidence based medicine summaries
- d) Claims summary from 1/1/2019-12/31/2019

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DISCUSSION of Amylin analogues:

Dr. Boudreaux stated that Symlin is currently nonpreferred and manually reviewed. The chair stated that given the utilization data, this product should remain nonpreferred.

ACTION:

Motion to approve that Symlin remained nonpreferred was made by Dr. Rodgers; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

DISCUSSION of DPP-4 inhibitors:

Dr. Boudreaux stated that the current preferred medication is Janumet (sitagliptin/metformin). The chair stated that based on the ADA guidelines, the DPP-4 inhibitors are recommended after GLP-1 agonists and SGLT2 agents. Dr. Boudreaux stated that GLP-1 agents are used more due to weight loss potential and other benefits as well as ADA recommendations. Dr. Max asked if the recommendation was to make these nonpreferred. Dr. Boudreaux clarified that metformin, alpha glucosidase inhibitors, meglitinides and sulfonylureas currently process without a PA. Other agents like the DPP-4 inhibitors are manual review even if given a preferred status. These products do not process at POS. Compliance on metformin, HbA1c and if a second agent is required will be taken into consideration. Dr. Max stated that linagliptin does not require renal adjustment and beneficial to many older people, but she recognized that information can be presented on manual review.

ACTION:

Motion to approve as current PDL status or alter if cost is beneficial to the state was made by Dr. Max; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

DISCUSSION of GLP-1 agonists:

Chair stated that this class is one of our most utilized classes and products have similar efficacies. Dr. Boudreaux stated that the current preferred list is a good representation, and Victoza was in the cardiovascular study with data that it prevents major cardiovascular events. Dr. Rodgers asked why they should be manual review if used more often. Dr. Boudreaux stated they would be reviewed manually by a pharmacist for documentation of trials with other therapies and any nonpreferred requests would require documentation of medical necessity.

ACTION:

Motion to approve as current PDL status was made by Dr. Marable; seconded by Dr. Max. All voting members present voted for the motion. Motion passed.

C. INSULIN AND RELATED AGENTS

- a) FDA approved indications
- b) Pharmacodynamics
- c) Mechanism of action and overview
- d) Claims summary from 1/1/2019-12/31/2019

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DISCUSSION:

Chair asked the committee if there was a current nonpreferred insulin that they felt should be changed. Dr. Pace stated that the current preferred list is a good selection. In his practice he feels that the insulins in each category are fairly interchangeable. Dr. Pace doesn't have a problem with the current list. Dr. Rodgers stated that he agreed with Dr. Pace, but his only concern was for availability of certain insulins. Dr. Rodgers also mentioned the problem when patients rotate on and off Medicaid with insulin cost being an issue. Dr. Max had concerns about adding Humulin R U-500 pens as a preferred medication for safety (possible dosing errors with vials that would not be seen in pens). Dr. Max commented on the decrease in nocturnal hypoglycemia with Tresiba, but she acknowledged that a PA request could be made. Dr. Boudreaux stated that manual review requests for the U-500 pens could be approved if there was a concern for safety. Dr. Marable asked about procedures for receiving an insulin pump through Medicaid.

ACTION:

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

D. MEGLITINIDES

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

Chair suggested that the current preferred list should remain the same. There were no other comments by the committee.

ACTION:

Motion to approve the current list was made by Dr. Rodgers; seconded by Dr. Marable. All voting members present voted for the motion. Motion passed.

E. METFORMINS

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

Chair stated that the metformin agents currently are not on the PDL, but we are wanting them added to have a complete diabetes list on the PDL. Chair recommended that the current agents that do not require a PA should be preferred. Dr. Miller wanted to notify the committee that our office does see utilization of metformin in the adolescents on antipsychotics due to metabolic syndrome.

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ACTION:

Motion was made by Dr. Max to add the metformin class to the PDL and change agents not requiring a PA to preferred status; seconded by Dr. Miller. All voting members present voted for the motion. Motion passed.

F. SGLT2

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Evidence based medicine summaries
- d) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

Chair stated that the current preferred list has multiple options. Dr. Max stated that canagliflozin is labeled for CKD progression, but dapagliflozin currently is not. She asked that if a request for dapagliflozin was made for CKD progression, would it be approved? Dr. Boudreaux stated that evidence based medicine shows the other agents have this benefit even though not on label. Request would be reviewed on a case-by-case basis. Dr. Marable asked if some new products were missing from the presentation. Dr. Boudreaux said she accidentally left them off, but they are currently nonpreferred.

ACTION:

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

G. SULFONYLUREAS

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

No discussion.

ACTION:

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

H. TZD

- a) FDA approved indications
- b) Mechanism of action and overview
- c) Claims summary from 1/1/2019-12/31/2019

DISCUSSION:

No discussion.

ACTION:

Motion to approve the current list was made by Dr. Max; seconded by Dr. Marable. All voting members present voted for the motion. Motion passed.

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2) ANTIPSYCHOTIC LONG-ACTING INJECTION

This review is a renewal of the long-acting injection antipsychotic class. Chair provided current criteria and current PDL list for all products. Dr. Boudreaux presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Overview of LAI
- c) Administration, means of delivery, dosing and necessity of oral overlap for each product
- d) Claim counts and expenditure for each PASSE from 7/1/2019-6/30/2020
- e) Claims summary for FFS from 1/1/2019-12/31/2019

DISCUSSION:

The Chair stated that she would not be opposed to making all agents preferred. Dr. Rodgers commented that Invega Sustenna had fairly good utilization even in the PASSEs, and he would be ok with moving all agents to preferred. Dr. Miller stated that the LAIs are useful options in our toolbox, and first generation LAIs are having a resurgence. Some patients respond to first generation better and vice versa. Dr. Miller stated that many of these patients deny their illness or are not compliant. But even with a LAI, many patients will not come back to clinic for more injections without prompting and outreach. Dr. Miller would like to see all agents preferred to give patients all options they need. All agents have an indication of schizophrenia, Invega has the indication of schizoaffective disorder and some have indications for bipolar. The Chair reminded the committee that no matter the preferred list, they would remain manually reviewed. Dr. Rodgers asked Dr. Miller if he felt there was a product that stood out to him regarding side effects and safety profile. Dr. Miller commented that first generation agents can cause extrapyramidal symptoms, and second generation agents can cause metabolic syndrome. The Chair raised concern about patients continuing counseling between injections. Dr. Marable asked Dr. Miller about Aristada Initio as a preferred agent.

ACTION:

Motion to approve moving all agents to preferred status was made by Dr. Miller; seconded by Dr. Pace. All voting members present voted for the motion. Motion passed.

3) LIPOTROPICS—PCSK9 INHIBITORS

This review is a new class added to the PDL. Chair provided current criteria and current PDL list for all products. Dr. Boudreaux presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Mechanism of action
- c) Overview of PCSK9 inhibitors advantages
- d) Evidence Based Medicine summaries
- e) Claims summary from 1/1/2019-12/31/2019

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DISCUSSION:

The Chair mentioned results and recommendations from the ICER reports. Data does show a significant decrease in cholesterol levels, but the agents lacked support by ICER based on QALY. The Chair recommended that at least one product be added to the preferred list. Dr. Boudreaux stated that the agents would remain manual review. The Chair stated that she may lean to Repatha as preferred, but the drug cost committee would need to input. Dr. Rodgers agreed that one agent should be added as preferred with the agent chosen being the best option for the state.

ACTION:

Motion to approve the above recommendations was made by Dr. Rodgers; seconded by Dr. Miller. 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.