PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING
Monday, May 20, 2024
Minutes

AGENDA ITEM 1

Call the Meeting to Order:
Chair Van Mitchell called the meeting to order at 2:00 p.m.

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Joseph Levy, Ph.D., Stephen Rockower, MD, FAAOS

AGENDA ITEM 2

Approval of minutes
Chair Mitchell asked for a motion to approve the March 25, 2024 meeting minutes as submitted. Dr. Stephen Rockower made the motion, which Dr. Joseph Levy seconded, and the Board unanimously approved the minutes.

Action: Minutes APPROVED.

AGENDA ITEM 3

Opportunity for Public Comment
Christina Shaklee, Health Policy Analyst, advised that 19 written comments were received, provided to the Board and posted to the website.
Seven people provided oral comment:

1. Oluyomi Amoye, Public Consumer, Agenda Item V
2. Katherine Klem, PharmD, Gilead, Agenda Item V
3. Suzanne Schlattman, Healthcare for All, Agenda Item V
4. Derek Spencer, Gilead, Agenda Item V
5. Chesahna Kindred, MD, MBA, FAAD, Agenda Item V
6. Shawn G. Kwatra, MD, University of Maryland, Agenda Item V
7. Tiffany Westrich-Robinson, AiArthritis, Agenda Item V

AGENDA ITEM 4

Staff Report:- Presentation on Input From Stakeholder Council

Executive Director Andrew York and Christina Shaklee, Health Policy Analyst, presented input from the Stakeholder Council on each of the eight drugs referred to the Stakeholder Council. The presentation reviewed each of the eight drugs, the statutory and regulatory factors under consideration, and the feedback provided by the members of the Stakeholder Council at its April

29, 2024 meeting. Board members had the opportunity to ask questions. The presentation is posted on the Board page of the website for reference.

AGENDA ITEM 5

Select Drug(s) for Cost Review Study

a. Select Drug(s) for Cost Review Study

Chair Mitchell entertained a motion to select a drug or drug(s) for the study and discussion.

Dr. Levy made a motion to do a cost review for the two GLP-1 drugs and two SGL-2 inhibitor drugs , which Dr. Rockower seconded. Chair Mitchell requested thatDr. Levy identify the drugs in the motion. Dr. Levy identified Ozempic, Trulicity, and Farxiga and Jardiance as the drugs specified in the motion. The Board discussed the identified drugs.
The Chair called for a vote on the motion. With no opposition, the Board unanimously approved GLP-1s, Ozempic andTrulicity, and SGLT-2s Farxiga and Jardiance, for cost review study.

Action: Ozempic, Trulicity, Farxiga and Jardiance APPROVED for Cost Review Study Process.

The Board then discussed the remaining four drugs, including certain animating issues, and the Board's allocation of resources. Dr. Onukwugha commented that prior to the meeting she thought she would make a motion to study the four diabetic drugs, Skyrizi and Dupixent, but not study Vyvanse and Bitarvy.

Dr. Levy made a motion to do a cost review study of Skyrizi, which Dr. Anderson seconded. This study would be conducted after the first four drugs.

Dr. Onukwugha stated that she had moved to study Skyrizi and Dupixent in a tiered fashion. The Chair advised that he did not understand her prior comment to have been a motion.

Dr. Levy then offered to withdraw his motion to do a cost review on Skyrizi.

Following discussion, Dr. Levy amended his motion to conduct a cost review on Skyrizi at the same priority level as the two diabetes drug classes, and then conduct a cost review study at a later time of Dupixent, and not conduct a cost review on which was seconded by Dr. Anderson.

The motion proceeded to a vote. With no opposition, the Board unanimously approved Skyrizi and Dupixent for study through a cost review study.
Action: Skyrizi and Dupixent APPROVED for Cost Review Study Process.

Dr. Anderson then discussed several concerns and questions regarding some feedback and comments received by the Board. Dr. Rochower also provided comment. Dr. Onukwugha raised several process questions concerning the data sets.

b. Approve Therapeutic Alternatives for Drug(s) Advanced for Cost Review Study

Assistant Attorney General Michele McDonald stated for the record that Dr. Onukwugha is recused from consideration of therapeutic alternatives for Trulicity, Ozempic, Jardiance, Farxiga, Skyrizi and Dupixent, and Dr. Rockower is recused from consideration of therapeutic alternatives for Skyrizi.

Dr. Levy made a motion to add Metformin and a variety of insulins to the list of specified therapeutic alternatives for both diabetes classes of drugs (GLP-1 and SGL-2), which Dr. Rockower seconded. The motion proceeded to a vote. With no opposition, the Board approved the addition of Metformin and a variety of insulins to the therapeutic alternatives list for both diabetes classes of drugs (GLP-1 and SGL-2) (Mitchell, Levy, Anderson, Rockower, with Onukwugha recused).

Action: Metformin and Insulins ADDED to the Therapeutic Alternative list for all diabetes drugs.

Dr. Levy made a motion to adopt the therapeutic alternative list for Skyrizi and Dupxient, which Dr. Anderson seconded. The motion proceeded to a vote. With no opposition, the Board approved to adopt the list of therapeutic alternatives for Skyrizi and Dupxient (Mitchell, Levy, Anderson, with Onukwugha and Rockower recused).

Action: Therapeutic Alternative List ADOPTED for Skyrizi and Dupxient.

AGENDA ITEM 6

Discussion of Draft Upper Payment Limit Action Plan

Executive Director York gave an update on the status of the Upper Payment Limit Action Plan. He reiterated that the Stakeholder Council will need to provide feedback on the UPL Action Plan before it can be approved by the Board. There was a short discussion around the UPL Action Plan timeline.

AGENDA ITEM 7

Administrative Update

- Executive Director York stated that the current fiscal year ends on June 30, 2024. PDAB staff are working diligently on the end of year close out including the Fee Assessment. There were questions from the Board regarding staff capacity and data contracts.
- Ms. Shaklee stated that HB1056- State Board of Pharmacy - Prohibition on Discrimination Against 340B Drug Distribution passed during the legislative 2024

session. This bill requires PDAB in consultation with MDH to compile a report by July 1, 2026.

- The next PDASC meeting will take place virtually on Monday, June 24, 2024 at 2:00PM.

AGENDA ITEM 8

Chair's Update

Chair Mitchell stated that the next Board meeting is on July 22, 2024 in the Senate Amoss Hearing room.

AGENDA ITEM 9

Adjournment

Chair Mitchell asked for a motion to adjourn the meeting. Dr. Onukwugha made the motion to adjourn, which was seconded by Dr. Levy.

Adjourned at 3:48 PM