

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING

Monday, July 22, 2024

Minutes

AGENDA ITEM 1

Call Meeting to Order

Chair Van Mitchell called the meeting to order at 2:01 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 May 20, 2024 meeting minutes as submitted.

Dr. Anderson made the motion, which Dr. 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 five written comments were received, provided to the Board and posted to the website. No one registered for oral public comment.

AGENDA ITEM 4

Cost Review

a. Amend Prior Board Action to Approve Individual Drugs for Cost Review Study Process

Dr. Levy moved to amend the motion previously adopted at the May Board meeting “to do a cost review for the two GLP-1 drugs and the two SGL-2 inhibitor drugs” as follows: he moved to strike the language “for the two GLP-1 drugs and the two SGL-2 inhibitor drugs” and insert the “study of Ozempic, Trulicity, Farxiga and Jardiance.” This is to clarify that although the Board may organize or order the cost reviews by class or other grouping, each drug is selected for study individually.

Dr. Anderson seconded the motion.

In discussion, Dr. Anderson articulated multiple reasons for studying each of the four drugs. Dr. Onukwugha commented on the data.

The Chair called for a vote on the motion. With no opposition, the Board amended the motion previously adopted at the May Board meeting to do a cost review study of Ozempic, Trulicity, Farxiga and Jardiance.

Action: Prior Board Action AMENDED—Board to conduct a cost review study of Ozempic, Trulicity, Farxiga and Jardiance.

b. Amend Prior Board Action to Approve Skyrizi and Dupixent For Cost Review Study Process Following Study of Diabetes Drugs

Dr. Levy moved to amend the motion previously adopted at the May meeting to “conduct a cost review of Skyrizi at the same priority level as the diabetes drugs, and to conduct a cost review study of Dupixent” as follows. Dr. Levy moved to strike the language “at the same priority level as the diabetes drugs, and to conduct a cost review study of Dupixent” and insert “and Dupixent when staff capacity and resources permit.” This is to clarify the organization and ordering of the cost reviews consistent with Board priorities and staff resources.

Dr. Anderson seconded this motion.

Dr. Anderson noted the limited resources and prioritization of work. The Chair called for a vote on the motion. With no opposition, the Board amended the motion previously adopted at the May Board meeting to conduct a cost review study of Skyrizi and Dupixent when staff capacity and resources permit.

Action: Prior Board Action AMENDED—Board to conduct a cost review study of Skyrizi and Dupixent when staff capacity and resources permit.

c. Amend Prior Board Action to Approve Therapeutic Alternatives and Specified List of Insulins

Dr. Levy moved to amend the motion previously adopted at the May meeting that amended the proposed list of therapeutic alternatives for Ozempic, Trulicity, Farxiga and Jardiance to include Metformin and insulins. Dr. Levy then moved to amend the proposed list of therapeutic alternatives for each drug— Ozempic, Trulicity, Farxiga and Jardiance—to include the list of specific insulins for each drug that have been provided to the Board by staff and to amend the motion to add “approve the proposed lists of therapeutic alternatives for Ozempic, Trulicity, Farxiga and Jardiance as amended.”

Dr. Anderson seconded this motion.

Dr. Onukwughua’s recusal from consideration of therapeutics alternatives for Trulicity, Ozempic, Jardiance, Farxiga, Skyrizi and Dupixent was noted.

Dr. Levy asked about the list of insulins provided in the materials. AAG McDonald explained that the motion made by Dr. Levy incorporated the list of specific insulins into the list of therapeutic alternatives by amendment and adopted the list of therapeutic alternatives as amended. The Chair called for a vote on the motion.

With no opposition, (Dr. Onukwughua recused), the Board amended the list of therapeutic alternatives to include the list of specific insulins and to approve the proposed list of therapeutic alternatives for Ozempic, Trulicity, Farxiga and Jardiance as amended.

Action: Prior Board Action AMENDED–Proposed list of therapeutic alternatives AMENDED to include specific insulins and APPROVED as therapeutic alternatives for Ozempic, Trulicity, Farxiga and Jardiance as amended.

d. Cost Review Study Process Update-Presentation

Executive Director York provided an update on the Cost Review Study Process. He provided detailed information regarding the Request for Information (RFI) timelines and processes. The presentation is posted on the Board page of the PDAB website. Chair Mitchell requested that PDAB staff provide a concrete timeline to the Board for the Cost Review Study process. Staff addressed questions and the Board discussed specific parts of the Cost Review Study Process.

AGENDA ITEM 5

Regulations

a. Approve Final Regulations COMAR 14.01.02 (Prescription Drug Affordability Fund)

Assistant Attorney General Michele McDonald provided a brief overview of the proposed amendments to COMAR 14.01.02, Prescription Drug Affordability Fund. No comments were received and no changes were made to the proposed amendments, which are now ready for final Board action. This presentation and final regulations are posted on the Board page of the PDAB website.

Chair Mitchell requested a motion to approve the regulations COMAR 14.01.02, Prescription Drug Affordability Fund, as submitted. Dr. Rockower made the motion which Dr. Anderson seconded. The motion proceeded to a vote. With no opposition, the Board unanimously approved the amendments to Regulations, COMAR 14.01.02 (Prescription Drug Affordability Fund), as a final action

Action: Final Regulations COMAR 14.01.02 (Prescription Drug Affordability Fund) ADOPTED AS FINAL.

AGENDA ITEM 6

Upper Payment Limit (UPL) Action Plan Update

Executive Director York gave an update on the Upper Payment Limit Action Plan, a draft outline of the plan and potential policies around setting UPLs. The presentation is posted on the Board

page of the PDAB website. The PDASC will have an opportunity to provide input concerning the UPL Action Plan at the August 26, 2024 meeting.

The Board directed PDAB staff to provide a timeline of pertinent dates for consideration and approval of the UPL Action Plan. Additional Board meetings may be scheduled to facilitate approval of the UPL Action Plan.

AGENDA ITEM 7

Annual Report- Policies and Options

Executive Director York discussed the PDAB Annual Report- Policies and Options. The presentation is posted on the Board page of the PDAB website.

The Board encouraged staff to refrain from adding additional policies to the annual report this year and to prioritize the cost reviews and UPL Action Plan.

AGENDA ITEM 8

Administrative Update

- FY25 fee assessment invoices will be transmitted in August.
- PDAB staff anticipates providing a budget closeout update at the September meeting.
- The next PDASC meeting is scheduled for August 26, 2024 at 2:00PM, virtually.
- The new PDAB website is live and pertinent information should be easier to locate on the new site.

AGENDA ITEM 9

Chair's Update

Chair Mitchell stated that the Board will continue to work with staff on timelines and that additional meetings may be scheduled to move important projects forward.

AGENDA ITEM 10

Adjournment

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

Adjourned at 3:30 PM