Cost Review Study Process Update

PDASC Meeting

August 26, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Board Selected Drugs for Cost Review Study Process

- **Farxiga (dapagliflozin)**
- **Jardiance (empagliflozin)**
- **Ozempic (semaglutide)**
- **Trulicity (dulaglutide)**
- **Dupixent (dupilumab)**
- **Skyrizi (risankizumab)**

Please visit the Cost Review Study Page on the Board website to see the list of NDCs and Approved Therapeutic Alternatives.

Cost Review Study Process Updates

July 22, 2024 Amendments of May 26, 2024 Adopted Board Motions:

- **The Board amended the previously adopted motion by striking "for the two GLP-1 drugs and the two SGL-2 inhibitor drugs" and inserting "study of Ozempic, Trulicity, Farxiga and Jardiance" to read "to do a cost review study of Ozempic, Trulicity, Farxiga and Jardiance."**
- **The Board amended the previously adopted motion by striking "at the same priority level as the diabetes drugs, and to conduct a cost review study of Dupixent" and inserting "and Dupixent when staff capacity and resources permit" to read "conduct a cost review of Skyrizi and Dupixent when staff capacity and resources permit."**
- **The Board amended the previously adopted motion to read "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 approve the proposed lists of therapeutic alternatives for Ozempic, Trulicity, Farxiga and Jardiance as amended."**

Collection and Analysis

COMAR 14.01.04.04 and COMAR 14.01.04.05

60 DAY COMMENT PERIOD ON SELECTED DRUGS

REQUEST FOR INFORMATION FROM ENTITIES

DOSSIER OF DATA AND ANALYSIS

60 Day Comment Period

“Board Selected Drugs” Comment Period:

- **Written public comments were due for Board Selected Drugs by close of business, Monday, July 22, 2024. (60 days)**

Collection Process

Request for Information for Cost Review: COMAR 14.01.04.04

- **The Board may request information to conduct a cost review study under Health-General Article, 21-2C-09(a)(2) and COMAR 14.01.04**
- **For each prescription drug product under review, the Board may request information from:**
    - **Manufacturer**
    - **Health Insurance Carrier, HMO, and MCO**
    - **Pharmacy Benefits Managers**
    - **Wholesale Distributors**

Collection Process Continued

Request for Information for Cost Review: COMAR 14.01.04.04

How are entities notified?

- The Board may request information by sending an email or postal mail to the manufacturer, PBMs, health insurance carriers, wholesale distributors, HMOs or MCOs
- The Board will post notice of the request for information on its website
- An entity that has not received a request for information from the Board may submit relevant information in accordance with the regulations

Timeline for notification:

- The entity has 30 days from when the request for information is posted to the website or transmitted to the entity to submit the information requested or any other relevant information
- An entity may request one 30-day extension of time, in writing to the Board, on or before the expiration of the initial submission period

Collection Process Continued

Request for Information for Cost Review: COMAR 14.01.04.04

Request for Information (RFI)

- Request for Information information was posted on the website on July 25, 2024. Optional templates are also posted on the RFI webpage.
- Certain entities were notified about RFI and the notification also went out through the listserv.
- RFI's are due Monday, August 26, 2024.
- Technical Assistance call was held on July 31, 2024.
- More information can be found here: https://pdab.maryland.gov/Pages/Request-for-Information.aspx
- Please email rfi.pdab@maryland.gov for specific RFI questions.

MARYLAND
Prescription Drug Affordability Board

pdab.maryland.gov