

Cost Review Study Process Update

PDAB Meeting

September 10, 2024

PDAB Staff



Drugs Selected for Cost Review Study

- 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.



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 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 directly about RFI and the notification also went out through the listserv.
- RFI's were due Monday, August 26, 2024. (30 day extension, September 23, 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>



Collection Process Continued

Request for Information for Cost Review: COMAR 14.01.04.04

Information Received:

- A person submitting information requested through the RFI, including data and records, shall comply with the procedures for designating confidential, trade-secret, and proprietary information set forth in COMAR 14.01.01.04.
- The information and data obtained by the Board under COMAR 14.01. and Health-General Article, Title 21, Subtitle 2C, Annotated Code of Maryland, that is not otherwise publicly available, is:
 - (a) Considered to be a trade secret and confidential and proprietary information; and
 - (b) Is not subject to inspection or disclosure under the Public Information Act.



Cost Review Study Process

Next Steps

Next Steps

- Staff is currently drafting the “dossiers” for the drugs in the Cost Review Study process
- Staff will post public versions of the drafts before an upcoming Board meeting





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Prescription Drug Affordability Board

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