Maryland PDAB Annual Report

Md. Code Ann., Health-General § 21-2C-09(c)

PDAB Meeting

November 25, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Health-General § 12-2C-09(c) - Report Requirement

On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1257 of the State Government Article, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to Board review and the results of the review; and

(3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

Md. Code Ann., Health-General § 21-2C-09(c)

2024 Maryland PDAB Actions

- Cost Review Study Process - Select Updates
  - The Board publish regulations establishing the 5-phase Cost Review Study Process as COMAR 14.01.04 at the end of 2023 and began implementing its first series of cost reviews in early 2024
  - March 2024: The Board referred 8 drugs to the Stakeholder Council for input
  - July 2024: The Board selected 6 of those 8 drugs for the Cost Review Study Process (Farxiga, Jardiance, Ozempic, Trulicity, Dupixent, and Skyrizi; Biktarvy and Vyvanse were not selected)
  - July 2024: The Board issued Requests for Information for Farxiga, Jardiance, Ozempic, and Trulicity
  - The Board will likely issue RFIs for Dupixent and Skyrizi in early 2025
  - Appendix A in the 2024 PDAB Annual Report contains a detailed list of other completed Board actions related to the Cost Review Study Process; the list above is not all-inclusive

2024 Maryland PDAB Actions - Recent

- Upper Payment Limits (UPLs) and the Upper Payment Limit Action Plan
  - September 2024: The Board submitted its Upper Payment Limit Action Plan to the Legislative Policy Committee (LPC)
  - October 2024: The Legislative Policy Committee approved the Action Plan
  - October 2024: The Board published draft regulations for implementing the Upper Payment Limit Action Plan
  - The Board will continue to work towards proposing the adoption of regulations establishing the UPL framework
  - Appendix A in the 2024 PDAB Annual Report contains a detailed list of other completed Board actions related to Upper Payment Limits; the list above is not all-inclusive

Earlier UPL Timeline (for Reference)

Previous Actions:

- Stakeholder Council reviewed UPL draft and provided feedback at 8/26/24 meeting
- Public comments were accepted on the UPL draft from 8/9/2024 to 8/26/24
    - 22 Comment Letters Received, posted on the website and shared with the Board
- Comments were reviewed by staff and changes were made for Board meeting on 9/10/2024
- Board approved UPL Action Plan on 9/10/2024

Prior UPL work:

- Board meeting July 24, 2023
- PDASC meeting August 28, 2023
- Board meeting September 18, 2023
- PDASC meeting October 23, 2023
- Supply Chain Report January 29, 2024
- Board meeting July 22, 2024

2024 Trends in Drug Prices

- Overall U.S. spending growth on biopharmaceuticals decreased in 2023, largely due to declining utilization of COVID-19 vaccines and therapeutics
- Excluding COVID-19 vaccines and therapeutics, spending growth increased to 9.9%, largely due to increased spending for oncology, immunology, diabetes, and obesity drugs
- The average out-of-pocket cost per retail prescription increased in 2023
- Aggregate out-of-pocket costs for all patients increased by 6% in 2023
- List prices increased by 4.9% in 2023 (slower growth than in prior years)
- Companies launched new 2023 U.S. drugs at prices 35% higher than in 2022

Key Themes: Prescription Drug Affordability Boards

- Increasing number of states are establishing prescription drug affordability boards
- April 2024: At least 11 states had enacted some form of a PDAB
- At least 4 states have given their PDABs the authority to establish some form of upper payment limit, but state law varies regarding UPL application
- Many states and the federal government are working on legislation involving prescription drug affordability

Key Themes: Inflation Reduction Act (IRA)

- The 2022 IRA limits how much drugmakers can raise prices for treatments offered under Medicare
- The IRA allows the Medicare program to negotiate with drug companies for the price of a limited number of existing drugs
  - 2023: 10 drugs were selected for the first cycle of Medicare price negotiations
  - 2024: Negotiated prices for the 10 selected drugs were revealed
  - 2026: Negotiated prices will go into effect
- The IRA also limits out-of-pocket spending for Medicare beneficiaries to $2,000/year and out-of-pocket costs for insulin to $35/month

Key Themes: Biosimilars

- The U.S. biosimilars market is continuing to grow, with the industry estimating 2023 savings from the use of biosimilars increasing 30% from 2022 to 2023
- Biosimilars only accounted for a third of the biological product market in 2023
- In June 2024, the FDA issued a draft guidance which reveals the FDA's intention to make the requirements for demonstrating interchangeability less restrictive for manufacturers
- Many challenges to biosimilar uptake remain, and there is unmet potential for biosimilar use to make treatments more affordable for patients

Key Themes: Glucagon-Like Peptide-1 Receptor Agonists

- GLP-1 RA use for diabetes and weight loss has increased significantly
- Between 2019 and 2023, the number of patients without diabetes that started GLP-1 RA treatment in the U.S. increased more than 700%
- Off-label use of GLP-1 RAs has increased, almost doubling from 2019-2023
- Rapid uptake of GLP-1 RAs has caused domestic and international shortages
- Current law prohibits Medicare coverage of drugs used for weight loss
- Maryland Medicaid covers certain GLP-1 RAs for type 2 diabetes treatment
- Maryland will study the impact of requiring Maryland Medicaid to cover GLP-1 RAs for weight loss

Next Steps

- The Board will continue to collect information and data and conduct specified analyses in accordance with COMAR 14.01.04.05 for the Cost Review Study Process
- The Board expects to make a preliminary determination on whether the drugs in the Cost Review Study Process may cause affordability challenges in late 2024 or early 2025
- The Board will continue to work towards proposing the adoption of regulations establishing the Upper Payment Limit framework
- The Board will continue to track the key themes nationally and within the state

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