Cost Review Study Dossier- Sections 1 to 3 Overview

PDAB Meeting

March 24, 2025

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Board May Determine

(1) Whether use of the prescription drug product has led or will lead to:

(a) Affordability challenges to the State health care system; or

(b) High out-of-pocket costs for patients;

(2) Whether the use that has led to affordability challenges or high out-of-pocket costs is consistent with:

(a) The labeling approved by the FDA; or

(b) Standard medical practice.

(3) Identify the circumstances under which the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients under §A(1) of this regulation.

Cost Review Dossier

- The regulations provide that the Board may consider several different factors in making an affordability determination
- Board staff has assembled a dossier containing information related to the various factors
- The first 3 sections of the dossier are presented today
- These sections cover three areas:
  - Background information (information to identify the drug under review)
  - Clinical Information
  - Regulatory Approval and Market Context

Section 1- Background Information

- The background information section identifies the drug under review
- This section includes two elements:
  - Proprietary Name and Non-Proprietary Name for Drug Product Under Review
  - NDCs for the Drug Product Under Review
    - All of the previously identified NDCs[1]
    - Some NDCs are no longer active and some do not have data associated with them

1 These NDCs were identified by staff using RXNorm. The Board previously approved the list of NDCs.

Section 2 - Clinical Information

- This section includes clinical information regarding the diseases and conditions treated by the drug product under review
- It includes the following two elements:
  - COMAR 14.01.04.05.C(1)(g)(i)—Clinical information, including FDA indications and doses and information concerning standard medical practice
  - COMAR 14.01.04.05.C(1)(g)(ii)—The disease burden of the condition that is treated by the prescription drug product

COMAR 14.01.04.05.C(1)(g)(i)—Clinical information, including FDA indications and doses and information concerning standard medical practice

- This section focuses on the indications of use for the drug and the dosing used for this drug
- PDAB staff reviewed the most recent FDA label and published clinical guidelines

COMAR 14.01.04.05.C(1)(g)(ii)—The disease burden of the condition that is treated by the prescription drug product

- This section focuses on information related to the impact of the condition(s) for which the drug product is used on human health and wellbeing
- Board staff reviewed published literature on the impact of the disease(s)

Section 3 - Regulatory Approval and Market Context

- The regulatory approval and market context section provide information about how the approved uses of the drug has evolved over time and information about the strategy behind such changes
- It includes the following three elements:
  - Element 3.1: COMAR 14.01.04.05.C(1)(g)(ix)- Analysis of the prescription drug product's approval process
  - Element 3.2: COMAR 14.01.04.05.C(1)(g)(x)- Analysis of the prescription drug product's shortage status
  - Element 3.3: COMAR 14.01.04.05.C(1)(g)(xi)- Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping

COMAR 14.01.04.05.C(1)(g)(ix)- Analysis of the prescription drug product's approval process

- PDAB staff reviewed publicly available information from the FDA and the manufacturer
- This information includes:
  - FDA labels from various dates
  - FDA public review documents
  - FDA post-market commitment database
  - FDA Advisory Committee Materials
  - Press releases by the the manufacturer regarding priority review, breakthrough, and fast track status
  - Press releases by the manufacturer regarding complete response letters

COMAR 14.01.04.05.C(1)(g)(x)- Analysis of the prescription drug product's shortage status

- PDAB Staff reviewed the FDA Drug Shortage Database

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