Cost Review Study Process

Board Meeting

March 25, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Timeline

Identify → **Select**

PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
Public Reporting of Drug Affordability Issues Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review	Identifying prescription drug products to consider for cost review- this is a subset from eligibility list Refer prescription drug products to the Stakeholder Council for input	PDASC will review and discuss the referred prescription drug products at an open meeting	Public comment	Board selects prescription drug product(s) for cost review Next Steps: ➔ Collect ➔ Analyze ➔ Results

Cost Review Study Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results

Selection Process

Selecting Drugs Eligible for Cost Review: COMAR 14.01.04.03

ELIGIBLE DRUGS

BOARD MEMBERS PROVIDE CHAIR WITH DRUG(S) FOR AGENDA

CHAIR PROVIDES AGENDA FOR MARCH 25 MEETING

PUBLIC COMMENT

BOARD SELECTS DRUG(S) TO REFER TO STAKEHOLDER COUNCIL

Selection Process

Selecting Drugs Eligible for Cost Review: COMAR 14.01.04.03

WRITTEN PUBLIC COMMENT ON REFERRED DRUGS (30 DAYS)

THERAPEUTIC ALTERNATIVES POSTED

WRITTEN PUBLIC COMMENT ON TA (30 DAYS)

STAKEHOLDER COUNCIL INPUT

BOARD SELECTS DRUG(S) FOR COST REVIEW

Select:
Selecting Drug(s) for Referral to Stakeholder Council

Board may consider:

- **The prescription drug products identified under the statutory metrics and regulatory criteria in COMAR 14.01.04.02**
- **Information provided under COMAR 14.01.04.03B**
- **The average cost share of the prescription drug product, the average patient total out-of-pocket cost, and the average total payor cost**
- **Any written or oral public comment**

Board posts notice of referred drugs on website and public may provide written comments concerning prescription drug products referred to the Stakeholder Council within 30 days

Overview of Eligible Drugs

- Number of Total Eligible NDCs: 2287
- At least one of the NDCs of the following products are on the Eligibility List

Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council

Drug	Drug Name	Dose Strength	Dose Strength Unit of Measure
BIKTARVY	Biktarvy	50-200-25	MG
DUPIXENT	Dupixent	300	MG/2ML
	Dupixent	200	MG/1.14ML
FARXIGA	Farxiga	10	MG
	Farxiga	5	MG
JARDIANCE	Jardiance	25	MG
	Jardiance	10	MG
OZEMPIC	Ozempic (0.25 or 0.5 MG/DOSE)	2	MG/1.5ML
	Ozempic (1 MG/DOSE)	2	MG/1.5ML
	Ozempic (1 MG/DOSE)	4	MG/3ML
	Ozempic (2 MG/DOSE)	8	MG/3ML

Drug	Drug Name	Dose Strength	Dose Strength Unit of Measure
SKYRIZI	Skyrizi	150	MG/ML
	Skyrizi (150 MG Dose)	75	MG/0.83ML
	Skyrizi Pen	150	MG/ML
TRULICITY	Trulicity	0.75	MG/0.5ML
	Trulicity	1.5	MG/0.5ML
	Trulicity	3	MG/0.5ML
	Trulicity	4.5	MG/0.5ML
VYVANSE	Vyvanse	70	MG
	Vyvanse	60	MG
	Vyvanse	50	MG
	Vyvanse	40	MG
	Vyvanse	30	MG
	Vyvanse	20	MG

Biktarvy

Eligibility:

- § 21-2C-08(c)(1)(i)- Launch WAC Greater than $30,000
- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 2/7/2018

Therapeutic Class: Antiretroviral Combination

Active Shortage Status: No

Subject to Drug Negotiation: No

Dupixent

Eligibility:

- § 21-2C-08(c)(1)(i)- Launch WAC Greater than $30,000
- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: March 28, 2017

Therapeutic Class: Interleukin(IL)-4 Receptor Alpha Antagonist

Active Shortage Status: No

Subject to Drug Negotiation: No

Farxiga

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 1/8/2014

Therapeutic Class: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Active Shortage Status: No

Subject to Drug Negotiation: Yes

Jardiance

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 1/8/2014

Therapeutic Class: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Active Shortage Status: No

Subject to Drug Negotiation: Yes

Ozempic

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 12/5/2017

Therapeutic Class: Glucagon-Like Peptide (GLP)-1 Receptor Agonist

Active Shortage Status: Yes

Subject to Drug Negotiation: No

Skyrizi

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 4/23/2019

Therapeutic Class: Interleukin (IL)-23 Antagonist

Active Shortage Status: No

Subject to Drug Negotiation: No

Trulicity

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(1)(g)- Top 100 prescription drug products with the highest percent change increase in total gross spending

FDA Approval: 9/18/2014

Therapeutic Class: Glucagon-Like Peptide (GLP)-1 Receptor Agonist

Active Shortage Status: Yes

Subject to Drug Negotiation: No

Vyvanse

Eligibility:

- 14.01.04.02D(1)(a)- Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year
- 14.01.04.02D(2)(a)- Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year

FDA Approval: 2/23/2007

Therapeutic Class: Central Nervous System Stimulant

Active Shortage Status: Yes

Subject to Drug Negotiation: No

Opportunity for Public Comment and Engagement

- Public Reporting of Drug Affordability Issues (COMAR 14.01.04.01)
- Public Comment in Selection Process
  - Oral and written comments concerning the drugs proposed for referral to the Stakeholder Council (COMAR 14.01.04.03C(4))
  - Written comments concerning the list of prescription drug products referred to the Stakeholder Council (30 days) (COMAR 14.01.04.03F)
  - Written comments concerning list of therapeutic alternatives (30 days) (COMAR 14.01.04.03H)
  - Oral and written comments concerning Board selection of prescription drug product for cost review (COMAR 14.01.04.03I(2))
- Public Facing Information to Understand the Process

Questions/Feedback

- Comments may always be submitted to comments.pdab@maryland.gov

MARYLAND
Prescription Drug Affordability Board

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