Cost Review Study Process
Next Steps

PDASC Meeting

June 24, 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

Timeline

Collect → **Results**

Drug(s) in Cost Review	Data Collection	Analyze	PDAB Preliminary Determination of Affordability	Cost Review Study Report
Drug(s) selected for Cost Review Study will be posted on the Board's Website. - 60 day written comment period begins with posting	PDAB may request information from, and post request: 1. Manufacturers 2. Carrier, HMO and MCO 3. Pharmacy Benefits Managers 4. Wholesale Distributor	Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.	Board may determine whether the prescription drug has led or will lead to: - Affordability challenges to the State health care system or - High out of pocket costs for patients	Board creates and adopts a report of the cost review study that summarizes the information considered by the Board in conducting the cost review study, and the Board's preliminary determination.

Cost Review Study Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results

MARYLAND
Prescription Drug Affordability Board

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

In selecting a prescription drug product for study, the Board considers:

- **Item 1: The eight drugs referred to the Stakeholder Council and the information provided concerning the drugs under the regulations;**
- **Item 2: The average cost share, average patient total out-of-pocket cost, average total payor cost (per patient), and publicly available data on direct-to-consumer advertising spending;**
- **Item 3: Stakeholder Council input presented by Staff, including the oral and written comments identified in this presentation; and**
- **Item 4: Public input including the comments made during this meeting and the written comments identified in the presentation and posted on the Board's website.**

Board Selected Drugs for Cost Review Study Process

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

Publicly available data on direct-to-consumer advertising spending for the prescription drug product:
Searches failed to locate 2023 data

Dupixent- NDC 11s Associated with BLA

- 00024-5918-20
- 00024-5915-00
- 00024-5915-01
- 00024-5915-02
- 00024-5915-20
- 00024-5919-00
- 00024-5919-01
- 00024-5919-02
- 00024-5919-20
- 00024-5911-00
- 00024-5911-01
- 00024-5911-02
- 00024-5911-20

Dupixent- Preliminary Therapeutic Alternatives

Dupixent (dupilumab)	
Non- Proprietary Name	**Drug Name**
ralokinumab-ldrm	Adbry
abrocitinib	Cibinqo
upadacitinib	Rinvoq
tacrolimus ointment	Protopic
omalizumab	Xolair
mepolizumab	Nucala
benralizumab	Fasenra

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

Publicly available data on direct-to-consumer advertising spending for the prescription drug product: Searches failed to locate 2023 data

Farxiga- NDC 11s Associated with NDA

- 00003-1428-11
- 00003-1428-12
- 00003-1428-13
- 00003-1428-14
- 00003-1428-91
- 00310-6210-30
- 00310-6210-39
- 00310-6210-90
- 00310-6210-95
- 50090-3481-00
- 55154-6933-08
- 00003-1427-11
- 00003-1427-12
- 00003-1427-13
- 00003-1427-14
- 00003-1427-91
- 00310-6205-30
- 00310-6205-90
- 00310-6205-95
- 50090-3482-00
- 55154-6932-08
- 50090-7057-00
- 63629-3253-01
- 66993-0457-30
- 50090-7056-00
- 66993-0456-30

Farxiga- Preliminary Therapeutic Alternatives

Farxiga (dapagliflozin)	
Non- Proprietary Name	**Drug Name**
empagliflozin	Jardiance
bexaglifloxin	Brenzavvy
canagliflozin	Invokana
ertugliflozin	Steglatro
metformin and dapagliflozin	Xigduo XR
metformin and canagliflozin	Invokamet
linagliptin and empagliflozin	Glyxambi
metformin and empagliflozin	Synjardy
saxagliptin and dapagliflozin	Qtern
metformin and ertugliflozin	Segluromet
sitagliptin and ertugliflozin	Steglujan
metformin, saxagliptin and dapagliflozin	Qternment XR
metformin, linagliptin and empagliflozin	Trijardy XR
semaglutide	Ozempic
dulaglutide	Trulicity

Farxiga- Preliminary Therapeutic Alternatives- Continued

Non- Proprietary Name	Drug Name
liraglutide	Victoza
exenatide	Byetta
lixisenatide	Adlyxin
exenatide- extended release	Bydureon
semaglutide tablets	Rybelsus
tirzepatide	Mounjaro
sitagliptin	Januvia
saxagliptin	Onglyza
linagliptin	Tradjenta
alogliptin	Nesina
metformin and sitagliptin	Janumet
pioglitazone and alogliptin	Oseni
metformin and saxagliptin	Kombiglyze XR
metformin and linagliptin	Jentadueto
metformin and alogliptin	Kazano

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

Publicly available data on direct-to-consumer advertising spending for the prescription drug product: Searches failed to locate 2023 data

Jardiance- NDC 11s Associated with NDA

- 00597-0153-30
- 00597-0153-37
- 00597-0153-70
- 00597-0153-90
- 50090-4384-00
- 50090-4384-01
- 50090-6457-00
- 55154-0412-08
- 70518-2447-00
- 71610-0177-09
- 71610-0177-15
- 71610-0177-30
- 71610-0177-42
- 71610-0177-45

Jardiance- Preliminary Therapeutic Alternatives

Jardiance (empagliflozin)

Non- Proprietary Name	Drug Name
dapagliflozin	Farxiga
bexaglifloxin	Brenzavvy
canagliflozin	Invokana
ertugliflozin	Steglatro
metformin and dapagliflozin	Xigduo XR
metformin and canagliflozin	Invokamet
linagliptin and empagliflozin	Glyxambi
metformin and empagliflozin	Synjardy
saxagliptin and dapagliflozin	Qtern
metformin and ertugliflozin	Segluromet
sitagliptin and ertugliflozin	Steglujan
metformin, saxagliptin and dapagliflozin	Qternment XR
metformin, linagliptin and empagliflozin	Trijardy XR
semaglutide	Ozempic

Jardiance- Preliminary Therapeutic Alternatives- Continued

Non- Proprietary Name	Drug Name
dulaglutide	Trulicity
liraglutide	Victoza
exenatide	Byetta
lixisenatide	Adlyxin
exenatide- extended release	Bydureon
semaglutide tablets	Rybelsus
tirzepatide	Mounjaro
sitagliptin	Januvia
saxagliptin	Onglyza
linagliptin	Tradjenta
alogliptin	Nesina
metformin and sitagliptin	Janumet
pioglitazone and alogliptin	Oseni
metformin and saxagliptin	Kombiglyze XR
metformin and linagliptin	Jentadueto
metformin and alogliptin	Kazano

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: No

Subject to Drug Negotiation: No

Publicly available data on direct-to-consumer advertising spending for the prescription drug product: Searches failed to locate 2023 data

Ozempic- NDC 11s Associated with NDA

- 00169-4132-11
- 00169-4132-12
- 00169-4132-90
- 00169-4132-97
- 50090-5138-00
- 70518-2143-00
- 00169-4136-02
- 00169-4136-11
- 50090-5139-00
- 00169-4130-01
- 00169-4130-13
- 50090-5949-00
- 00169-4772-11
- 00169-4772-12
- 00169-4772-90
- 00169-4772-97
- 50090-6051-00
- 00169-4181-03
- 00169-4181-13
- 00169-4181-90
- 00169-4181-97

Ozempic- Preliminary Therapeutic Alternatives

Ozempic (semaglutide)	
Non- Proprietary Name	**Drug Name**
dulaglutide	Trulicity
liraglutide	Victoza
exenatide	Byetta
lixisenatide	Adlyxin
exenatide- extended release	Bydureon
semaglutide tablets	Rybelsus
tirzepatide	Mounjaro
sitagliptin	Januvia
saxagliptin	Onglyza
linagliptin	Tradjenta
alogliptin	Nesina
dapagliflozin	Farxiga
empagliflozin	Jardiance
bexaglifloxin	Brenzavvy
canagliflozin	Invokana
ertugliflozin	Steglatro

Ozempic- Preliminary Therapeutic Alternatives- Continued

Non- Proprietary Name	Drug Name
metformin and sitagliptin	Janumet
pioglitazone and alogliptin	Oseni
metformin and saxagliptin	Kombiglyze XR
metformin and linagliptin	Jentadueto
metformin and alogliptin	Kazano
metformin and dapagliflozin	Xigduo XR
metformin and canagliflozin	Invokamet
linagliptin and empagliflozin	Glyxambi
metformin and empagliflozin	Synjardy
saxagliptin and dapagliflozin	Qtern
metformin and ertugliflozin	Segluromet
sitagliptin and ertugliflozin	Steglujan
metformin, saxagliptin and dapagliflozin	Qternment XR
metformin, linagliptin and empagliflozin	Trijardy XR

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

Publicly available data on direct-to-consumer advertising spending for the prescription drug product: Searches failed to locate 2023 data

Trulicity- NDC 11s Associated with NDA

- 00002-1434-01
- 00002-1434-61
- 00002-1434-80
- 50090-3483-00
- 50090-6456-00
- 54568-0434-63
- 54568-0434-71
- 00002-2236-01
- 00002-2236-61
- 00002-2236-80
- 50090-5467-00
- 50090-6571-00
- 00002-3182-01
- 00002-3182-61
- 00002-3182-80

Trulicity- Preliminary Therapeutic Alternatives

Trulicy (dulaglutide)	
Non- Proprietary Name	**Drug Name**
semaglutide	Ozempic
liraglutide	Victoza
exenatide	Byetta
lixisenatide	Adlyxin
exenatide- extended release	Bydureon
semaglutide tablets	Rybelsus
tirzepatide	Mounjaro
sitagliptin	Januvia
saxagliptin	Onglyza
linagliptin	Tradjenta
alogliptin	Nesina
dapagliflozin	Farxiga
empagliflozin	Jardiance
bexaglifloxin	Brenzavvy

Trulicity- Preliminary Therapeutic Alternatives- Continued

Non- Proprietary Name	Drug Name
canagliflozin	Invokana
ertugliflozin	Steglatro
metformin and sitagliptin	Janumet
pioglitazone and alogliptin	Oseni
metformin and saxagliptin	Kombiglyze XR
metformin and linagliptin	Jentadueto
metformin and alogliptin	Kazano
metformin and dapagliflozin	Xigduo XR
metformin and canagliflozin	Invokamet
linagliptin and empagliflozin	Glyxambi
metformin and empagliflozin	Synjardy
saxagliptin and dapagliflozin	Qtern
metformin and ertugliflozin	Segluromet
sitagliptin and ertugliflozin	Steglujan
metformin, saxagliptin and dapagliflozin	Qternment XR
metformin, linagliptin and empagliflozin	Trijardy XR

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

Publicly available data on direct-to-consumer advertising spending for the prescription drug product: Searches failed to locate 2023 data

Skyrizi- NDC 11s Associated with NDA

- 00074-2100-01
- 00074-2100-70
- 00074-1050-01
- 00074-1050-70
- 00074-1069-01
- 00074-1069-02
- 00074-1070-01
- 00074-1070-02
- 00074-1065-01
- 00074-1065-02
- 00074-1066-01
- 00074-1066-02
- 00074-7034-02
- 00074-7036-04

Skyrizi- Preliminary Therapeutic Alternatives

Skyrizi (risankizumab)

Non- Proprietary Name	Drug Name
ustekinumab	Stelara
secukinumab	Cosentyx
brodalumab	Siliq
ixekizumab	Taltz
guselkumab	Tremfya
tildrakizumab	Ilumya
bimekizumab	Bimzelx
etanercept	Enbrel
infliximab	Remicade
adalimumab	Humira
golimumab	Simponi
certolizumab pegol	Cimzia
abatacept	Orencia
deucravacitinib	Sotyku
tofacitinib	Xeljanz
upadacitinib	Rinvoq
vedolizumab	Entyvio
natalizumab	Tysabri
apremilast	Otezla
acitretin	Soriatane
methotrexate	
cyclosporine	

Comment Period

“Board Selected Drugs” Comment Period:

- **Written public comments are due for Board Selected Drugs by close of business, Monday, July 22, 2024. (60 days)**
- **Comments can be sent to comments.pdab@maryland.gov with the subject line: Board Selected Drugs (Drug Name).**
- **Comments are shared publicly and will be posted as they are received.**
- **Public reminded comments with proprietary information must be submitted in compliance with COMAR 14.01.01.05B(5) (redact, submit redacted and unredacted versions separately, etc)**

Comment Period

- **Further information is located on the Cost Review Study Process Page on the Board's website**

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

Debrief from April 29th Meeting

- **Feedback from April 29th Meeting:**
  - **What worked well?**
  - **What could be improved?**
  - **Do you have any feedback on the Stakeholder Council discussion and the processes?**
  - **Any suggestions for enhancing the role of the Stakeholder Council in the Cost Review Study Process moving forward?**

MARYLAND
Prescription Drug Affordability Board

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