Cost Review Study Process
Input from Stakeholder Council

PDAB Meeting

May 20, 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 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

Drugs Referred to the Stakeholder Council- Input from Stakeholder Council

Select:
Stakeholder Council Input

At an open meeting, the Stakeholder Council:

- **Hears any public comments presented to the SC**
- **Reviews any written comments provided to the SC**
- **Reviews the information provided for each referred prescription drug product**
- **Discusses the referred prescription drug products**

Board staff presents the Stakeholder Council input discussed at the open meeting to the Board

Discussion and Feedback: Purpose

- **PDASC meeting occurred on April 29, 2024**
- **The Board seeks the Stakeholder Council's input to obtain valuable stakeholder insight and context about the referred drugs.**
  - **Provide feedback on whether a drug should or should not be selected for study.**
  - **Identify issues**

Written Comment and Oral Public Comment from PDASC Meeting

Written Comments Received

(posted on the PDASC website)

The following entities provided written comment

- **AbbVie**
- **American Partnership of Eosinophilic Disorders**
- **Community Access National Network (CANN)**
- **Gilead**
- **Global Coalition on Aging**
- **Heart to Hand, Inc.**
- **HIV + Hepatitis Policy Institute**
- **Ian Cook, PharmD, AAHIVP, BCACP, DPLA**
- **NAACP, Maryland State Conference**
- **PhRMA**
- **Sanofi**
- **Takeda Pharmaceuticals**
- **Value of Care Coalition**
- **Boehringer Ingelheim**

The following people provide oral public comment:

1. **Shawn Kwatra, MD, University of Maryland- SOM**
2. **Jen Laws, CANN**
3. **Benjamin Lockshin, Board Certified Dermatologist**
4. **Catherine Kirk Robins, Healthcare for All Coalition**
5. **Derek Spencer, Gilead**
6. **Mary Jo Strobel, APFED**
7. **Dr. Danita Tolson, NAACP Maryland**

Written Comment on Drug List Referred to the Stakeholder Council

Written Comments Received (posted on the Cost Review Study process webpage)

The following entities provided written comment

- Boehringer Ingelheim
- Mark Varner
- Chase Brexton (Letter #1)
- AFSCME Maryland
- Maryland Tech Council
- ICER
- ICER- Final Evidence Report- Moderate to Severe Plaque Psoriasis
- ICER- Final Evidence Report- Atopic Dermatitis
- ICER- Final Evidence Report- Treatment of Asthma associated with Type 2 Inflammation
- Chase Brexton (Letter #2)
- AARP Maryland
- Maryland Legislative Coalition
- Mid-Atlantic Association of Community Health Centers

Written Comments Received (cont'd)

- Gilead
- Community Access National Network
- AbbVie
- Global Coalition on Aging
- National Eczema Association
- Equality Federation
- Chase Brexton (Letter #3)
- HealthHIV
- Richard DeBenedetto, PharmD, MS, AAHIVP
- Sanofi
- Novo Nordisk
- Takeda
- Lilly

Written Comment on Therapeutic Alternatives

Written Comments Received (posted on the Cost Review Study Process webpage)

The following entities provided written comment:

- **AbbVie**
- **AiArthritis**
- **Boehringer Ingelheim**
- **Ensuring Access through Collaborative Health**
- **Dana R. Fasanella, PharmD, CDCES, BCACP**
- **Gilead**
- **Dr. Chesahna Kindred**
- **Lilly**
- **National Eczema Association**
- **PhRMA**
- **Sanofi**

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

Biktarvy- Preliminary Therapeutic Alternatives

Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)

Non- Proprietary Name	Drug Name
abacavir, dolutegravir, lamivudine	Triumeq
elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	Genvoya
elvitegravir, cobicistat emtricitabine, tenofovir disoproxil fumarate	Stibild
dolutegravir, lamivudine	Dovato
emtricitabine, tenofovir alafenamide	Descovy
dolutegravir	Tivicay
raltegravir	Isentress
atazanavir	Reyatz
darunavir	Prezista
doravirine	Pifeltro
efavirenz	Sustiva

Biktarvy Feedback

- Biktarvy has improved adherence to medication and some stakeholders do no want treatment potentially disrupted.
- Comment letters raised various concerns about sending Biktarvy into cost review
- Biktarvy is an all in one treatment for HIV and the therapeutics alternatives presented should mirror the same therapeutic equivalency.
- Stakeholder Council members raised concerns that there is misinformation about what the cost review process really means based on the comment letters.
    - Selecting Biktarvy for further review would mean a recognition of importance that it is a high cost drug and that paying a lower price would not necessarily reduce access.

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

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

Dupixent Feedback

- Dupixent also treats asthma as well as atophic dermatitis which can co-occur.
- Dupixent treats EoE and there are limited treatment options for this diagnosis.
- Value based price has been established (ICER) and that should be considered by the Board, but not necessarily a reason for it to not be on the list.
- Dupixent is driving the increased use of dermatologics within that therapeutic class.
- Some therapeutics on the TA list may not an appropriate alternatives to Dupixent.

Diabetes Drugs Feedback

- Therapeutic equivalency list does not necessarily take into account the indication.
- Payor often wants cheapest drug utilized first, one benefit of cost review could allow for these drugs to be used in a more evidence-based way.
- Consider looking at anti-diabetics as a class.
- Anti-diabetics make up the biggest drug share of State of Maryland prescription drug spend, cost on average $62 per member per month. Net cost increased from end of FY23 to beginning of FY24.
    - Individual premiums are increasing.
    - Important to look at the anti-diabetics.
- Look at the effects of the high cost of these drugs on other aspects of the healthcare system (emergency room visits etc).
- Diabetes drugs are seeing an increase in utilization which in result is seeing a higher spend. These products have improved efficacy (e.g., cardiovascular benefits). Want to look at these additional improvements as part of the cost review process.
- Need action to address issues with patients not being able to access diabetes medications.

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

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

Farxiga Feedback

- **Generic of Farxiga became available early in 2024. Board should consider that in deliberations. Cost could potentially decrease.**

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

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

Jardiance Feedback

- **Important to look at both Farxiga and Jardiance if one of the two were selected. They're similar drugs with slightly different indications. By looking at both and their indications, will be informative to the process of how the drugs play a role in affordability. Down the line, may inform the development of UPLs.**

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

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

Ozempic Feedback

- Ozempic is very effective which makes it important to look at this drug.
- Equity analysis should be included on this drug and it should be in the hands of more people at an affordable price.
- Suggested that the drug is not necessarily unaffordable at $50 per month (OOP cost per patient), based on dashboard information.

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

Trulicity Feedback

- **No comments were provided on Trulicity.**

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
bexagliflozin	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

Skyrizi Feedback

- **Skyrizi is a heavily advertised product. The amount of money spent on direct to consumer advertising is worth considering.**

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	

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: No

Subject to Drug Negotiation: No

Vyvanse- Preliminary Therapeutic Alternatives

Vyvanse (lisdexamfetamine dimesylate)	
Non- Proprietary Name	**Drug Name**
dextroamphetamine,amphetamine- extended release	Adderall XR
dextroamphetamine, amphetamine- extended release	Mydayis
amphetamine- extended release	Dyanavel XR
amphetamine- extended release	Adzenys XR-ODT
dextroamphetamine- sustained release	
dextroamphetamine patch	Xelstrym
methylphenidate- extended release	Metadate ER
methylphenidate- extended release chewable tablets	Quillichew ER
methylphenidate extended release orally disintegrating tablets	Cotempla XR-ODT
methylphenidate extended release osmotic controlled release oral delivery system	Concerta, Relexxii
methylphenidate long acting	Ritalin LA
methylphenidate hydrochloride extended-release capsules	
methylphenidate- extended release	Aptensio XR
methylphenidate extended release oral suspension	Quillivant XR
methylphenidate extended release capsules	Jornay PM
methylphenidate patch	Daytrana
dexmethylphenidate extended release	Focalin XR
Serdexmethylphenidate, dexmethylphenidate	Azstarys
atomoxetine	Strattera
viloxazine	Qelbree
guanfacine extended release	Intuniv
clonidine extended release	Kapvay

Vyvanse Feedback

- There will be less utilization and spend on the brand name due to the presence of generics. Shortages among generics may push utilization to the brand. Argues we should reserve the list of drugs in the cost review study to those without available generics.
- Two drugs on the Therapeutic Alternative list are only used for pediatrics and should not be considered as an alternative. (Intunvi, Kapvay)
- Suggested that it may actually be useful to look at high cost drugs with generic competition.
- Price information may not be available for awhile on the cost impact with generics in the market therefore process should not be delayed.

Cost Review Process Comments

- Health equity should be considered in deliberations.
- Individual patient affordability would be important in the process as the whole.
- Consider Medicare Negotiation timelines when making a decision on these drugs.
- Process may be lacking some information (rebates, patient assistance information, and cost sharing methods).
    - This information may lead to products having absolutely no affordability challenges.
    - Payors cannot get rebate information on a drug by drug basis.
    - Board should try to gather this information if possible.
    - Patient access and discount programs are not always the easiest to access or navigate. Part of this could be just finding out what assistance is available.
    - Skepticism that patient affordability is improved due to patient assistance programs.
- Industry has real concerns about the methodology to send these drugs to the PDASC.
    - There is newer and more up to date data that should be considered.
    - Process questions came up about manufacturers being able to submit further information (Staff addressed this by answering questions around the public comment process).

General Comments

Process

- Public Comments should occur at the end of meetings. Public should have more time to make public comments, greater than 90 seconds.
- Argument that PDASC and public need more time to provide useful information that feeds into Board's decisions.
- UPLs could block access to drugs especially to patients on Medicaid or safety net programs.

Access

- Manufacturers have little control of Out of Pocket Cost and access for certain medications.

Therapeutic Alternatives

- Recommendation to consider looking at indications related to some of the alternatives. Biologics could have multiple indications and the alternatives provided do not necessarily cover all those indications.

Additional Opportunity for Public Comment After SC Meeting

- Public Comment in Selection Process
  - Written comments concerning the list of prescription drug products referred to the Stakeholder Council (30 days from posting) (May 10) (COMAR 14.01.04.03F)
  - Written comments concerning preliminary therapeutic alternatives (30 days from posting) (May 10 and May 13 - please consult website) (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))

Visit the Cost Review Study Process page on the Board's website to learn about how to submit comments to the Board and the deadlines

MARYLAND
Prescription Drug Affordability Board

comments.pdab@maryland.gov
pdab.maryland.gov