

Cost Review Study Process

PDASC Meeting

April 29, 2024

PDAB Staff



Timeline



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



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



Select: Therapeutic Alternatives

- Board staff may develop and post preliminary therapeutic alternatives for each drug referred to Stakeholder Council
- Within 30 days of posting, public may provide written comments to the Board regarding preliminary therapeutic alternatives
- Staff may modify the list of therapeutic alternatives for consideration by Board
- Board shall determine the therapeutic alternatives for each prescription drug product selected for cost review study



Drugs Referred to the Stakeholder Council



Discussion and Feedback: Procedure

- **The Co-Chairs will identify each drug for discussion and recognize council members for the purpose of offering comment**
- **Time will be allocated to receive feedback from the Stakeholder Council for each drug**
 - **If more time is needed the Co-Chairs will decide at the end of this meeting if we will proceed with a second meeting on May 6, 2024.**
- **The Stakeholder Council feedback will be summarized and presented to the Board by Staff**



Discussion and Feedback: Purpose

- The Board seeks the Stakeholder Council's input to obtain valuable stakeholder insight and context about the referred drugs
 - Provide feedback on why a drug should or should not be selected for study



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	Reyataz
darunavir	Prezista
doravirine	Pifeltro
efavirenz	Sustiva

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



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
bexagliflozin	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



Jardiance- Preliminary Therapeutic Alternatives

Jardiance (empagliflozin)

Non- Proprietary Name	Drug Name
dapagliflozin	Farxiga
bexagliflozin	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: Yes

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
bexagliflozin	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

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- 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	

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- Preliminary Therapeutic Alternatives

Trulicity (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	Jentaduetto
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

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



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

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

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