Selecting Prescription Drugs for Affordability Review: Aggregated Affordability Review Shortlists



Overview

Brief overview of RCW 70.405.040: Affordability Reviews



Data revisions



Data measures used for affordability review selection



Creating aggregated shortlists for affordability review



Overview

Identify eligible prescription drugs for affordability review

Select prescription drugs for affordability review

Focus of this presentation

Conduct affordability review

> Determine unaffordability

Brief Overview of RCW 70.405.040: Affordability Reviews



Deciding Whether to Conduct a Review

- The Board shall consider:
 - The class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;
 - Input from relevant advisory groups established pursuant to RCW 70.405.020; and
 - The average patient's out-of-pocket cost for the drug.
- Board can choose up to 24 drugs per year





Data Revisions

- Four NDCs were dropped from the list of eligible prescription drugs for affordability review due to being distributed by a repackager
 - Definition of manufacturer from Chapter 70.405 RCW: ""Manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager."
- There are now 290 eligible prescription drugs for affordability review instead of 294

Data Revisions

Four NDCs dropped from eligibility list:

NDC	Label Name	Generic Name	Category
69263082201	BETA 1 KIT	betamethasone acetate/betamethasone sodium phosphate	Course of treatment \$60,000 or more
69263080501	BSP 0820 KIT	betamethasone acetate/betamethasone sodium phosphate	Course of treatment \$60,000 or more
76420076601	DOUBLEDEX KIT	dexamethasone sodium phosphate/PF	Course of treatment \$60,000 or more
82154045104	PEGASYS 180 MCG/0.5 ML SYRINGE	peginterferon alfa-2a	Course of treatment \$60,000 or more

Data Measures for Affordability Review Selection



Affordability Review Selection Criteria

The Board shall consider:



= Criteria proposed by the PDAB

Creating Aggregated Shortlists for Affordability Review



How Will Selection Criteria Be Used?



How Will Selection Criteria Be Used?



Separating Specialty Prescription Drugs

- Specialty: medications that require special storage, handling, administration, or monitoring
- Biologic and biosimilar prescription drugs were flagged as specialty drugs, except those that were reclassified as biologics under the Biologics Price Competition and Innovation (BPCI) Act.
- Brand and generic prescription drugs were considered nonspecialty drugs.

How Will Selection Criteria Be Used?



What is a National Drug Code (NDC)?¹

- A unique 11-digit number for identifying drug products maintained by the US Food and Drug Administration (FDA)
- A NDC contains three segments of identifying code:
 - Labeler
 - Product
 - Package Size



Image source: https://fdalisting.com/page/112/fda-national-drug-code-ndc-labeler-code/



Aggregating by Labeler Code and Generic Name

- Labeler Code: the first 5 digits of the prescription drug's NDC, which uniquely identifies the company who manufactures and/or distributes the prescription drug
- Generic Name: description of the drug ingredient names in the ingredient list

Aggregating by Labeler Code and Generic Name

- Selection criteria for NDCs within the same labeler code and generic name will be combined (for example, the total paid amount for NDCs within the same labeler code and generic name will be summed)
- People who had claims for multiple NDCs within the same labeler code and generic name will only be counted once towards the number of people using the labeler code and generic name

Aggregating by Labeler Code and Generic Name Example

NDC	Label Name	Generic Name	No. of Using	People the Drug	Total OOP Co	ost	Avg OOP Cost	Total Paid Amt
00003218811	ORENCIA 125 MG/ML SYRINGE	abatacept	520		\$560,1	24.71	\$1,077.1	6 \$19,344,439.42
00003218851	ORENCIA CLICKJECT 125 MG/ML	abatacept	1,109		\$1,052,1	05.24	\$948.7	70 \$38,890,351.75
Labeler Code	Generic Name	No People the La Code Ger Na	o. of e Using abeler e and neric ime	Total C	DOP Cost	Æ	Avg OOP Cost	Total Paid Amt
00003	abatacept	1,5	585	\$1,61	2,229.95	\$	51,017.18	\$58,234,791.17

¹⁹ OOP: out-of-pocket

How Will Selection Criteria Be Used?



Data Measure Ranking

Each quantitative data measure is sorted in descending order and assigned rankings

Data Measure Ranking Example

Labeler Code and Generic Name	Average OOP Cost	Average OOP Cost Rank	Total OOP Cost	Total OOP Cost Rank	Total Paid Amount	Total Paid Amount Rank	Total # of People Using the Labeler Code and Generic Name	Total # of People Using the Labeler Code and Generic Name Rank
00001 A	\$427	1	\$5,000	2	\$10,000	5	356	2
00002 B	\$426	2	\$3,000	4	\$15,000	4	123	4
00003 C	\$384	3	\$2,500	5	\$40,000	2	84	5
00004 D	\$200	4	\$7,000	1	\$30,000	3	472	1
00005 E	\$104	5	\$4,500	3	\$60,000	1	210	3
22 OOP: out of pocket								

OOP: out-of-pocket

Breaking Tied Rankings

- For tied rankings, the average ranking is assigned to each tied rank.
- Example:

Labeler Code and	Total Paid Amount	Total Paid Amount
Generic Name		Rank
00001 A	\$4	1.0
00002 B	\$7	2.0
00003 C	\$12	3.5
00004 D	\$12	3.5
00005 E	\$19	5.0

- Labeler code and generic name 00003 C and 00004 D have the same total paid amount and were ranked in positions 3 and 4.
- The tied labeler code and generic names' final total paid amount rank is the average of their rankings: (3+4)/2=3.5

Board Member Points Allocations

Board Member	Average Out-of- Pocket Cost	Total Out-of- Pocket Cost	Total Paid Amount	Total Number of People Using the Drug	Total
1	7	13	0	0	20
2	5	7	5	3	20
3	2	5	8	5	20
4	5	0	10	5	20
5	0	10	10	0	20
Total	19	35	33	13	100
Weight (Total/100)	0.19	0.35	0.33	0.13	



Calculating Weighted Rank



Calculating Weighted Rank





Weighted Rank Example Labeler Code: 00078 Generic Name: fingolimod HCL



How Will Selection Criteria Be Used?



Preliminary Affordability Review Shortlists

Non-Specialty Specialty Labeler Labeler Code Brand Name Rank Generic Name Rank Code Generic Name Brand Name 00469 enzalutamide **XTANDI** 1 58406 ENBREL etanercept 2 42388 CABOMETYX cabozantinib s-malate 2 HUMIRA 00074 adalimumab 3 00069 tofacitinib citrate XELJANZ TALTZ 00002 ixekizumab 3 4 61958 sofosbuvir/velpatasvir EPCLUSA 5 62856 lenvatinib mesylate LENVIMA 00003 ORENCIA 4 abatacept 6 00078 fingolimod HCI GILENYA 5 50474 CIMZIA certolizumab pegol INLYTA 7 00069 axitinib 6 57894 golimumab SIMPONI 8 58468 teriflunomide AUBAGIO 7 50242 tocilizumab ACTEMRA 9 00078 PROMACTA eltrombopag olamine 10 64406 dimethyl fumarate TECFIDERA 8 66658 KINERET anakinra 11 00078 dabrafenib mesylate TAFINLAR 9 64406 peginterferon beta-1a PLEGRIDY 12 tapentadol HCI 24510 NUCYNTA 10 NUCALA 00173 mepolizumab 13 corticotropin 63004 ACTHAR 11 55513 pegfilgrastim NEULASTA ONPRO 14 50242 ERIVEDGE vismodeaib 43386 15 peg 3350/sod sulf/sod bicarb/sod .. GAVILYTE 12 73604 rilonacept ARCALYST ledipasvir/sofosbuvir 16 61958 HARVONI 13 00004 peginterferon alfa-2a PEGASYS 17 49502 SEMGLEE (YFGN) insulin glargine-yfgn 14 00003 abatacept/maltose ORENCIA 18 00078 everolimus AFINITOR 15 EYLEA 61755 aflibercept 19 00078 pazopanib HCI VOTRIENT YERVOY 20 15054 lanreotide acetate SOMATULINE DEPOT 16 00003 ipilimumab sodium polystyrene sulfonate/sor.. SPS 21 46287 TRUXIMA 17 63459 rituximab-abbs 22 **KEVEYIS** 71090 dichlorphenamide 23 TUDORZA PRESSAIR 00310 aclidinium bromide

24

25

63481

00187

oxycodone HCI/acetaminophen

bupropion HBr

PERCOCET

APLENZIN

Reviewing the Preliminary Affordability Review Shortlists



Drugs Selected for Affordability Reviews By Other PDABs

	<u>Colorado</u>	Maryland	Oregon
1	Cosentyx (secukinumab)	Dupixent (dupilumab)	Cosentyx (secukinumab)
2	Enbrel (etanercept)	Farxiga (dapagliflozin)	Entyvio (vedolizumab)
3	Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)	Jardiance (empagliflozin)	Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)
4	Stelara (ustekinumab)	Ozempic (semaglutide)	Inflectra (infliximab-dyyb)
5	Trikafta (elexacaftor/tezacaftor/ivacaftor; ivacaftor)	Skyrizi (risankizumab)	Ocrevus (ocrelizumab)
6		Trulicity (dulaglutide)	Rybelsus/Ozempic (semaglutide)
7			Shingrix Zoster Vaccine Recombinant Adjuvanted
8			Skyrizi/Skyrizi Pen (risankizumab)
9			Tremfya (guselkumab)
10	= On WA PD	AB's	Triumeq/Triumeq PD (abacavir/dolutegravir/lamivudine)
11	affordability	review shortlist	Trulicity (dulaglutide)
12			Vyvanse (lisdexamfetamine dimesylate)

Drugs Selected for Affordability Reviews by Other PDABs (Cont'd)

	<u>Colorado</u>	<u>Maryland</u>	Oregon
13			Tresiba (insulin degludec)
14			Tresiba FlexTouch (insulin degludec)
15			Humulin R U-500 KwikPen (insulin
			regular)



Next Steps





Review specialty and non-specialty shortlists of the top 25 labeler code and generic names eligible for affordability review Select labeler code and generic names for review from shortlists

Discussion and Questions

