

Preliminary Eligible Prescription Drugs For Affordability Review

Results are preliminary and subject to change

Overview



Summary of thresholds for affordability review specified by Chapter 70.405 RCW



Examples



Preliminary number of eligible NDCs

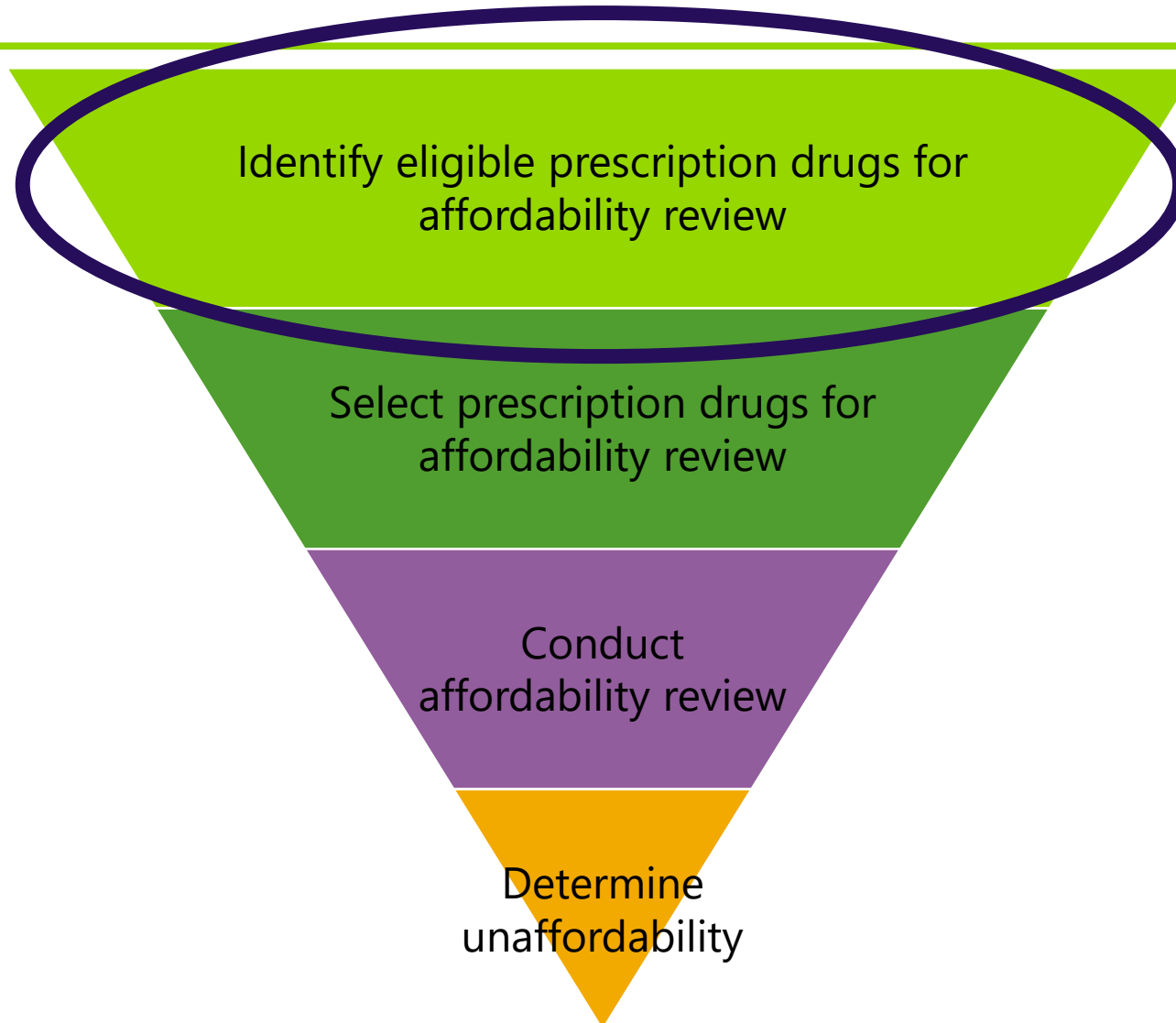


Questions\Discussion



Next steps

Overview



We are here!



RCW 70.405.030

The board must identify prescription drugs on the market for at least seven years, are dispensed at a retail, specialty, or mail-order pharmacy, are not designated by the United States food and drug administration under 21 U.S.C. Sec. 360bb as a drug solely for the treatment of a rare disease or condition, and meet the following thresholds:

- ▶ (1) Brand name prescription drugs and biologic products that:
 - ▶ (a) Have a wholesale acquisition cost (WAC) of \$60,000 or more per year or course of treatment lasting less than one year; or
 - ▶ (b) Have a price increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase over three years;
- ▶ (2) A biosimilar product with an initial wholesale acquisition cost that is not at least 15 percent lower than the reference biological product; and
- ▶ (3) Generic drugs with a wholesale acquisition cost of \$100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months.

(1) Brand name prescription drugs and biologic products that:

(a) Have a wholesale acquisition cost (WAC) of \$60,000 or more per year or course of treatment lasting less than one year

Data Source

- ▶ First Databank (FDB) dosing modules
 - ▶ Sources: manufacturer documentation, clinical literature, regulatory announcements
 - ▶ Dosing data is presented by age category

Definitions

Term	Definition
High dose	High drug dose per day specific to the patient age, reason for use, dose type, and route of administration
High duration of therapy	Recommended amount of time for which a drug should be administered, in days. A high duration of therapy of 0 means the drug can be used for a chronic condition.
Disease duration	Likely duration (acute, chronic, or both) of the diagnosis/disease states/health-related conditions or procedures linked with the NDC
Maintenance dose ⁴	Dose required to achieve steady-state drug concentration
Single dose	Dose taken at one time
Billing unit	The form of the drug (each (tablets, kits, etc.), milliliters (liquids), grams (solids))

Methodology



De-duplication



Obtain number of units used per year by multiplying NDC's high dose per day by high duration of therapy in days



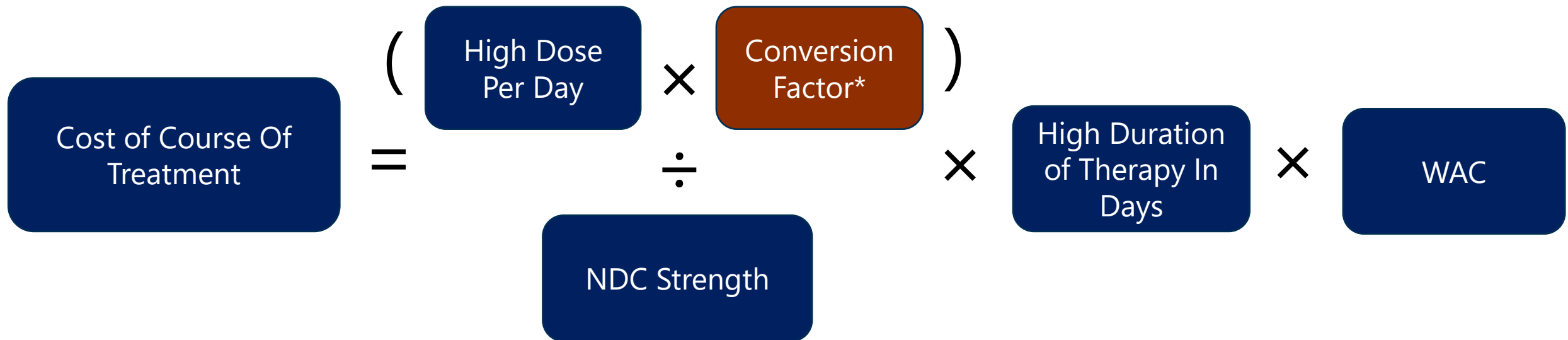
Obtain cost of course of treatment per year by multiplying number of units used per year by WAC unit price as of 1/1/2023

Goal of De-Duplication

Choose one dosing data record per NDC for calculation of course of treatment

- ▶ Choose dosing data for highest age range
- ▶ Choose chronic dosing data if available
- ▶ Choose maintenance dosing data if available

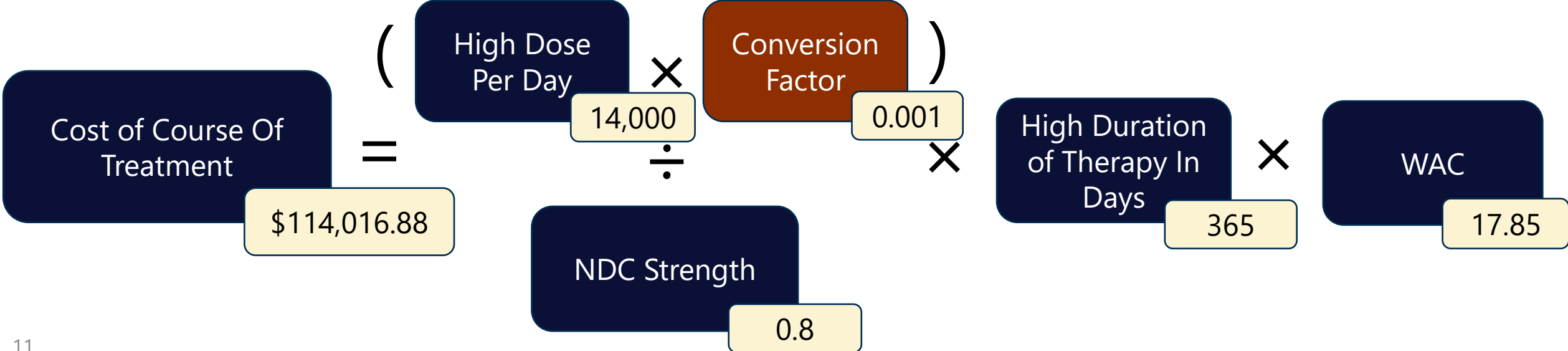
Cost of Course of Treatment



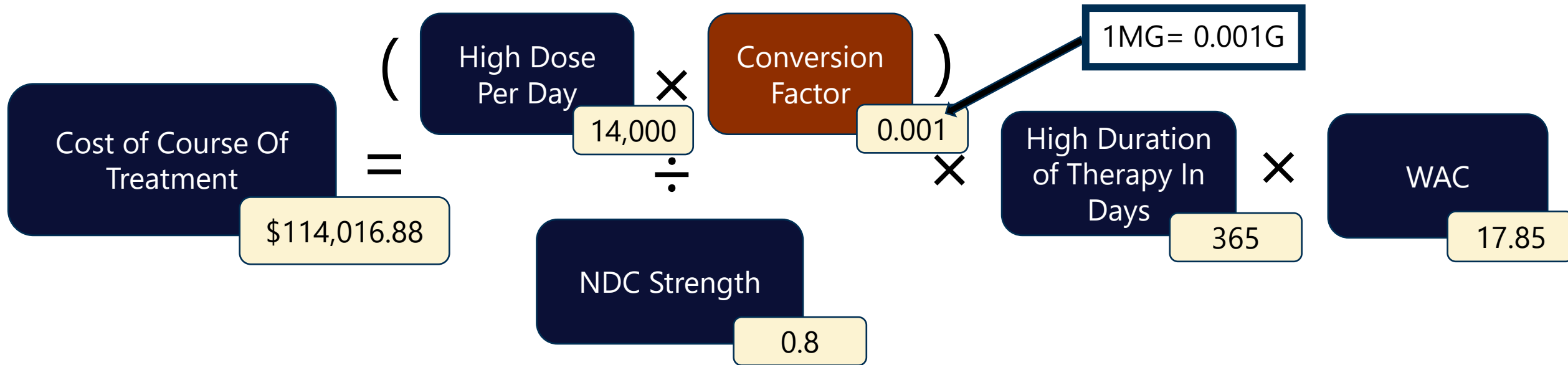
*A conversion factor will be applied if the high dose is not in the same units as the NDC strength

Example: Renvela (sevelamer carbonate) 0.8 GM Powder Packet (NDC: 58468013201)

High dose	High dose unit description	High duration of therapy (in days)	WAC unit price	Billing unit each (tablets, kits, etc.)	NDC strength	NDC strength unit of measure
14,000	MG/DAY	0	\$17.85	each (tablets, kits, etc.)	0.8	G



Renvela 0.8 GM Powder Packet Cost of Course of Treatment



Renvela costs **\$114,016.88** for a course of treatment for one year, which meets the cost threshold of \$60,000 for review.

(1) Brand name prescription drugs and biologic products that:

(b) Have a price increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase over three years

One Year Increase Methodology

- ▶ Current WAC: NDC's WAC unit price from its most recent price increase between 1/1/2022-1/1/2023
- ▶ One year WAC: WAC unit price from NDC's earliest price increase in the immediately preceding 12-month period from the date the current WAC was set.
 - ▶ If there is no increase in the immediately preceding 12-month period, the increase will be calculated from the WAC at the beginning of the period.

One Year Increase Methodology

$$\text{One Year Price Increase} = \frac{(\text{Current WAC} - \text{One Year WAC})}{\text{One Year WAC}}$$

Example: Lovaza (omega-3-acid ethyl esters) 1 GM Capsule (NDC: 69784042012)

Market entry date	One year WAC unit price effective date	One year WAC unit price	Current WAC unit price effective date	Current WAC unit price
12/17/2015	10/1/2021	\$3.30	12/2/2022	\$6.12

$$\text{One Year Price Increase} = \frac{(\text{Current WAC} - \text{One Year WAC})}{\text{One Year WAC}}$$

85.45 = $\frac{(6.12 - 3.30)}{3.30}$

Lovaza 1 GM Capsule One Year Price Increase

$$\begin{array}{c} \text{One Year Price Increase} \\ 85.45 \end{array} = \frac{\left(\begin{array}{c} \text{Current WAC} \\ 6.12 \end{array} - \begin{array}{c} \text{One Year WAC} \\ 3.30 \end{array} \right)}{\begin{array}{c} \text{One Year WAC} \\ 3.30 \end{array}}$$

Lovaza **increased by 85.45%** in a 12-month period, which meets the threshold of an increase of 15% or more for review.

Three Year Increase Methodology

- ▶ Current WAC: NDC's WAC unit price from its most recent price increase between 1/1/2022-1/1/2023
- ▶ One year WAC: WAC unit price from NDC's earliest price increase in the immediately preceding 36-month period from the date the current WAC was set.
 - ▶ If there is no increase in the immediately preceding 36-month period, the increase will be calculated from the WAC at the beginning of the period.

Three Year Increase Methodology

$$\text{Three Year Price Increase} = \frac{(\text{Current WAC} - \text{Three Year WAC})}{\text{Three Year WAC}}$$

Example: Lovaza (omega-3-acid ethyl esters) 1 GM Capsule (NDC: 69784042012)

Market entry date	Three year WAC unit price effective date	Three year WAC unit price	Current WAC unit price effective date	Current WAC unit price
12/17/2015	5/21/2021	\$2.87	12/2/2022	\$6.12

$$\text{Three Year Price Increase} = \frac{(\text{Current WAC} - \text{Three Year WAC})}{\text{Three Year WAC}}$$

113.24 = $\frac{(6.12 - 2.87)}{2.87}$

Lovaza 1 GM Capsule Three Year Price Increase

$$\text{Three Year Price Increase} = \frac{(\text{Current WAC} - \text{Three Year WAC})}{\text{Three Year WAC}}$$

The diagram illustrates the calculation of the three-year price increase for Lovaza 1 GM Capsule. It shows the following values:

- Current WAC: 6.12
- Three Year WAC: 2.87
- Three Year Price Increase: 113.24

Lovaza **increased by 113.24%** in a three-year period, which meets the threshold of an increase of 50% or more for review.

**(2) A biosimilar product with an initial
wholesale acquisition cost that is not
at least 15 percent lower than the
reference biological product**

Biosimilar Increase Methodology

- ▶ Initial biosimilar WAC: the biosimilar's earliest listed WAC unit price
- ▶ Reference biologic WAC: the reference biologic's WAC unit price at the time of the earliest listed biosimilar WAC

Biosimilar Increase Methodology

$$\text{Biosimilar Price Increase} = \frac{(\text{Initial Biosimilar WAC} - \text{Reference Biologic WAC})}{\text{Reference Biologic WAC}}$$

Example: Truxima (rituximab) 100 MG/10 ML VIAL (NDC: 63459010310)

Reference biologic label name	Reference biologic market entry date	WAC unit price of reference biologic as of initial biosimilar WAC	Price effective date of reference biologic WAC unit price	Initial WAC unit price of biosimilar	Price effective date of initial WAC unit price of biosimilar
Rituxuan (rituximab) 100 MG/10 ML VIAL	12/16/1997	\$93.95	7/1/2018	\$84.56	11/9/2019

$$\text{Biosimilar Price Increase} = \left(\frac{\text{Initial Biosimilar WAC} - \text{Reference Biologic WAC}}{\text{Reference Biologic WAC}} \right)$$

-9.99 = $\left(\frac{84.56 - 93.95}{93.95} \right)$

Truxima 100 MG/10 ML VIAL Biosimilar Increase Methodology

$$\text{Biosimilar Price Increase} = \frac{(\text{Initial Biosimilar WAC} - \text{Reference Biologic WAC})}{\text{Reference Biologic WAC}}$$

The diagram illustrates the calculation of the biosimilar price increase. It shows the following values:

- Biosimilar Price Increase: -9.99
- Initial Biosimilar WAC: 84.56
- Reference Biologic WAC: 93.95

Truxima's initial WAC unit price is **9.99% lower** than its reference biologic's price at the time the initial WAC was set, which meets the threshold for review of not being at least 15% lower.

(3) Generic drugs with a wholesale acquisition cost of \$100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months.

Methodology



De-duplication



Calculate the price increase over a 12-month period



Of NDCs with a 200% or more increase, obtain number of NDC units used for a 30-day supply



Obtain cost of a 30-day supply by multiplying the number of NDC units used for a 30-day supply by their WAC unit price

Goal of De-Duplication

Choose one dosing data record per NDC for calculation of course of treatment

- ▶ Choose dosing data for highest age range
- ▶ Choose chronic dosing data if available
- ▶ Choose maintenance dosing data if available

Price Increase Methodology

- ▶ Current WAC: NDC's WAC unit price from its most recent price increase between 1/1/2022-1/1/2023
- ▶ One year WAC: WAC unit price from NDC's earliest price increase in the immediately preceding 12-month period from the date the current WAC was set.
 - ▶ If there is no increase in the immediately preceding 12-month period, the increase will be calculated from the WAC at the beginning of the period.

Price Increase Methodology

$$\text{One Year Price Increase} = \frac{(\text{Current WAC} - \text{One Year WAC})}{\text{One Year WAC}}$$

Methodology: Calculating 30-Day Supply

If high duration of therapy in days ≥ 30 days:

- Multiply amount of NDC used per day by 30

If high duration of therapy in days < 30 days:

- Multiply amount of NDC used per day by exact high duration of therapy in days

If high duration of therapy in days ≥ 30 days:

- Multiply amount of NDC used per day by 30

$$\text{Cost of 30-Day Supply} = \left(\frac{\text{High Dose Per Day} \times \text{Conversion Factor}^*}{\text{NDC Strength}} \right) \times 30 \times \text{WAC}$$

*A conversion factor will be applied if the high dose is not in the same units as the NDC strength

If high duration of therapy in days < 30 days:

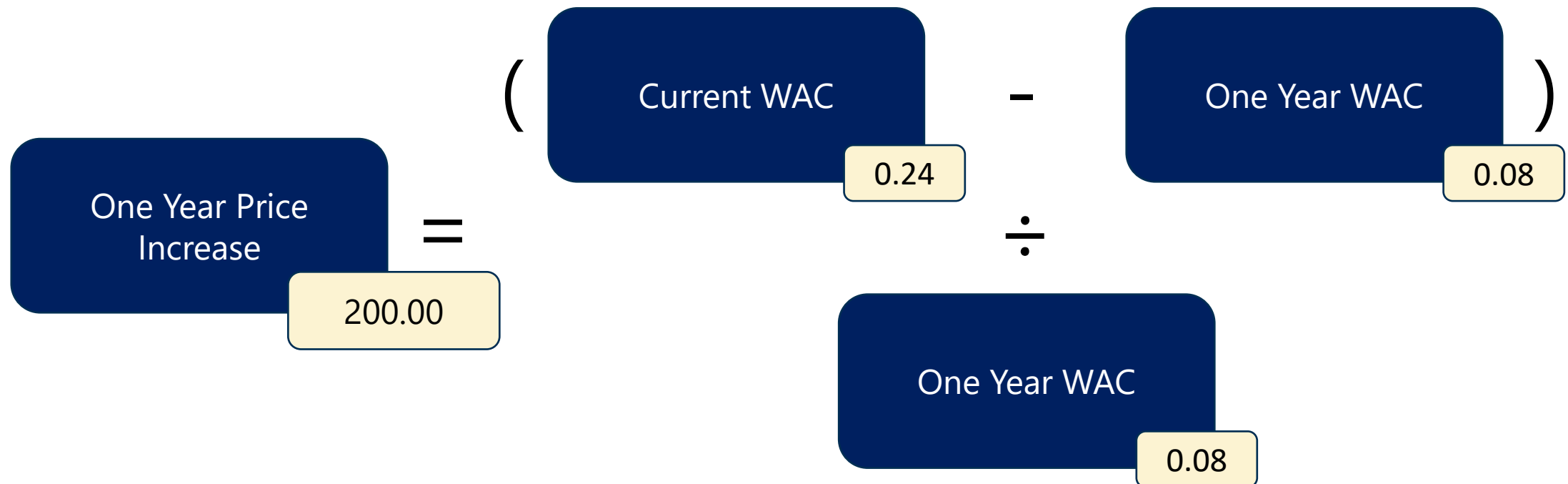
- Multiply amount of NDC used per day by exact high duration of therapy in days

$$\text{Cost of 30-Day Supply} = \left(\frac{\text{High Dose Per Day} \times \text{Conversion Factor}^*}{\text{NDC Strength}} \right) \times \text{High Duration of Therapy In Days} \times \text{WAC}$$

*A conversion factor will be applied if the high dose is not in the same units as the NDC strength

Example: Primidone 50 MG Tablet (NDC: 42291050901)

One year WAC unit price effective date	One year WAC unit price	Current WAC unit price effective date	Current WAC unit price
9/1/2010	\$0.08	3/22/2022	\$0.24



Example: Primidone 50 MG Tablet (NDC: 42291050901)

High dose	High dose unit description	High duration of therapy (in days)	WAC unit price	Billing unit each (tablets, kits, etc.)	NDC strength	NDC strength unit of measure
2000	MG/DAY	0	\$0.24		50	MG

$$\begin{aligned}
 &\text{Cost of 30-Day Supply} = \$288.00 \\
 &= \left(\frac{\text{High Dose Per Day} \times \text{Conversion Factor}}{\text{NDC Strength}} \right) \times 30 \times 0.24 \\
 &= \left(\frac{2000 \times 1}{50} \right) \times 30 \times 0.24
 \end{aligned}$$

Primidone 50 MG Tablet

Price Increase and Cost of 30-Day Supply

One Year Price Increase

200.00

Cost of 30-Day Supply

\$288.00

- Primidone **increased by 200%** over a 12-month period, which meets the threshold of an increase of 200% or more for review.
- Primidone costs **\$288.00** for a 30-day supply, which meets the threshold of the cost of \$100 or more for review.
- Primidone is eligible for affordability review.

Preliminary Number Of Eligible NDCs

Bill Section	Number of Distinct NDCs			
(1) Brand name prescription drugs and biologic products that: (a) Have a wholesale acquisition cost of \$60,000 or more per year or course of treatment lasting less than one year; or	Brand		238	
	Biologic		93	
	Total		331	
(b) Have a price increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase over three years		15% Increase*	50% Increase*	Both
	Brand	105	21	13
	Biologic	1	0	0
	Total	106	21	13
(2) A biosimilar product with an initial wholesale acquisition cost that is not at least 15 percent lower than the reference biological product	9			
(3) Generic drugs with a wholesale acquisition cost of \$100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months.	2			

*Includes NDCs with both 15% and 50% increase

Discussion/Questions

Next Steps

Next Steps

- ▶ Identify and aggregate other eligible NDCs of the same labeler that have the same brand name, active ingredient, and formulation
- ▶ Start work on methodology for selecting eligible drugs for affordability review

Appendix

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
- ▶ The same drug can have multiple NDC codes

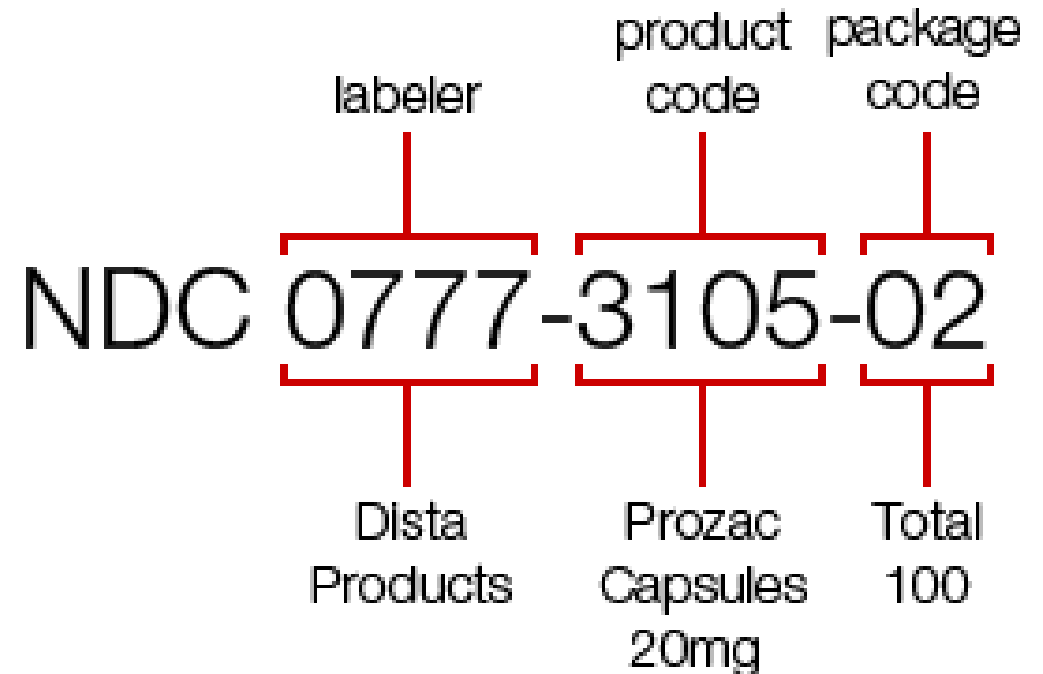


Image source: <https://www.drugs.com/ndc.html>

Drug Types²

▶ Brand

- ▶ A drug under a specific name or trademark and that is protected by a patent

▶ Generic

- ▶ A drug with the same active-ingredient formula as a brand-name drug
- ▶ Generics are certified by the FDA to be as safe and effective as brand-name drugs



Image source: https://medium.com/@Gregory_Silas/should-we-use-generic-drugs-9a8c96e3cef5

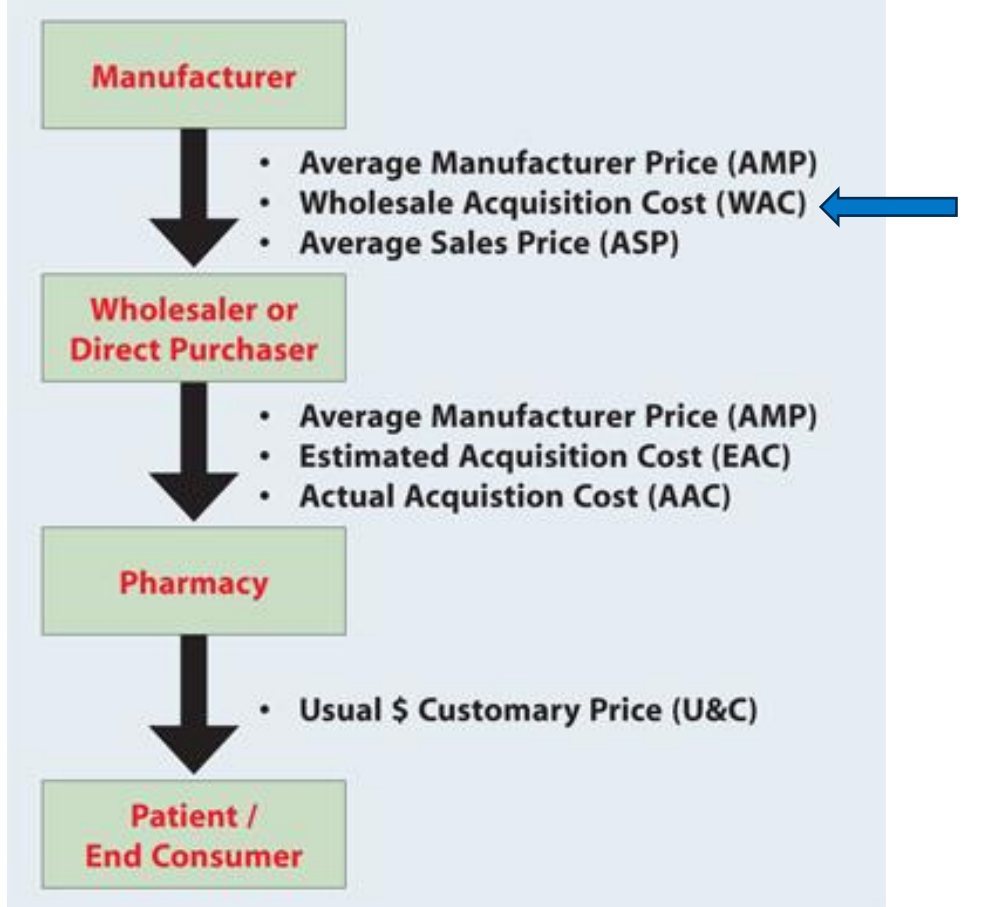
Drug Types³

- ▶ Biologic
 - ▶ Drug product made from natural and living sources such as animal and plant cells, and microorganisms such as bacteria or yeast
- ▶ Biosimilar
 - ▶ Highly similar to an existing biologic (also known as the original or reference biologic)
 - ▶ Must be shown to have the same safety and effectiveness as reference biologic



Image source: <https://insulin.store/blog/semglee-vs-lantus-exploring-the-differences-and-similarities/>

Wholesale Acquisition Cost (WAC)



- ▶ Defined in the US Social Security Act §1847A as "...the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price..."

Image source: <https://www.uspharmacist.com/article/understanding-drug-pricing>

Interpretation of Bill Language

Term	Interpretation
Drug	<p>For purposes of identifying prescription drugs that meet criteria of RCW 70.405.030, each distinct National Drug Code (NDC) is defined as a separate drug.</p> <p>For purposes of affordability review, all NDCs for the drug ingredient will be included in the review</p>
Seven years on the market	The drug ingredient has been on the market as of 7/1/2016

Interpretation of Bill Language

Term	Interpretation
Dispensed at a retail, specialty, or mail-order pharmacy	Using First Databank (FDB) provided indicators, exclude institutional products and products likely to be used by home healthcare providers
Not designated by the United States food and drug administration under 21 U.S.C. Sec. 360bb as a drug solely for the treatment of a rare disease or condition	Drug is in FDA maintained orphan drug database

References

- ▶¹ <https://www.drugs.com/ndc.html>
- ▶² <https://www.healthcare.gov/glossary>
- ▶³ <https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients>
- ▶⁴ <https://www.sciencedirect.com/topics/immunology-and-microbiology/maintenance-drug-dose>