

Methodology For Identifying Drugs For Affordability Review

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Overview



Summary of thresholds for affordability review specified by Chapter 70.405 RCW



Summary of methodologies for identifying drugs subject to affordability review



Questions\Discussion



Next steps

Summary of thresholds For affordability review



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 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.

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

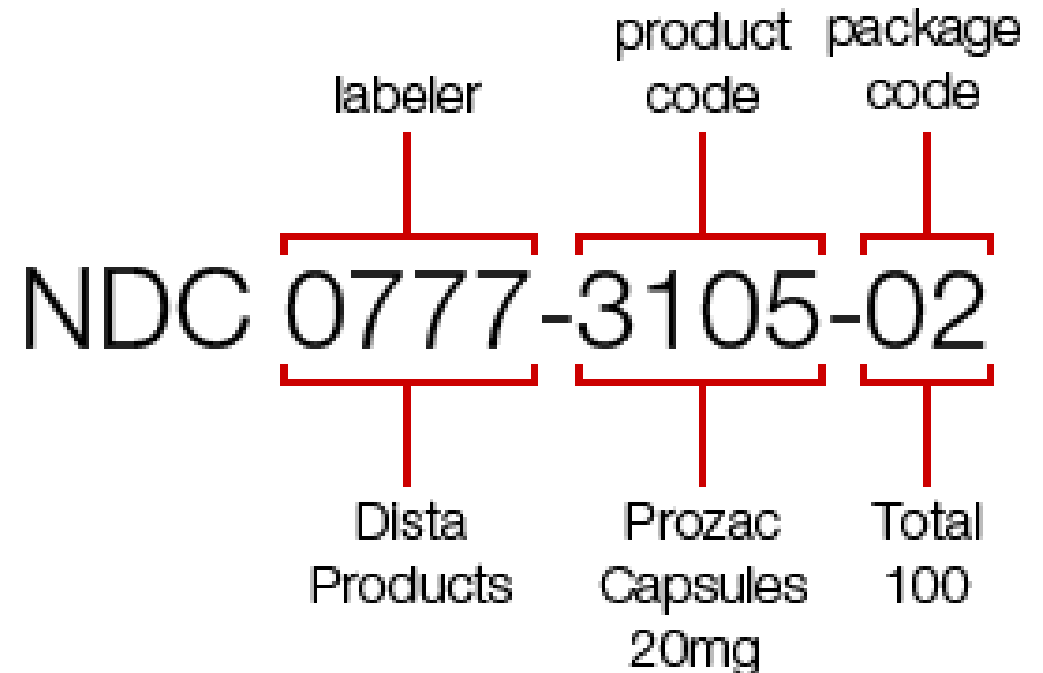


Image source: <https://www.drugs.com/ndc.html>

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

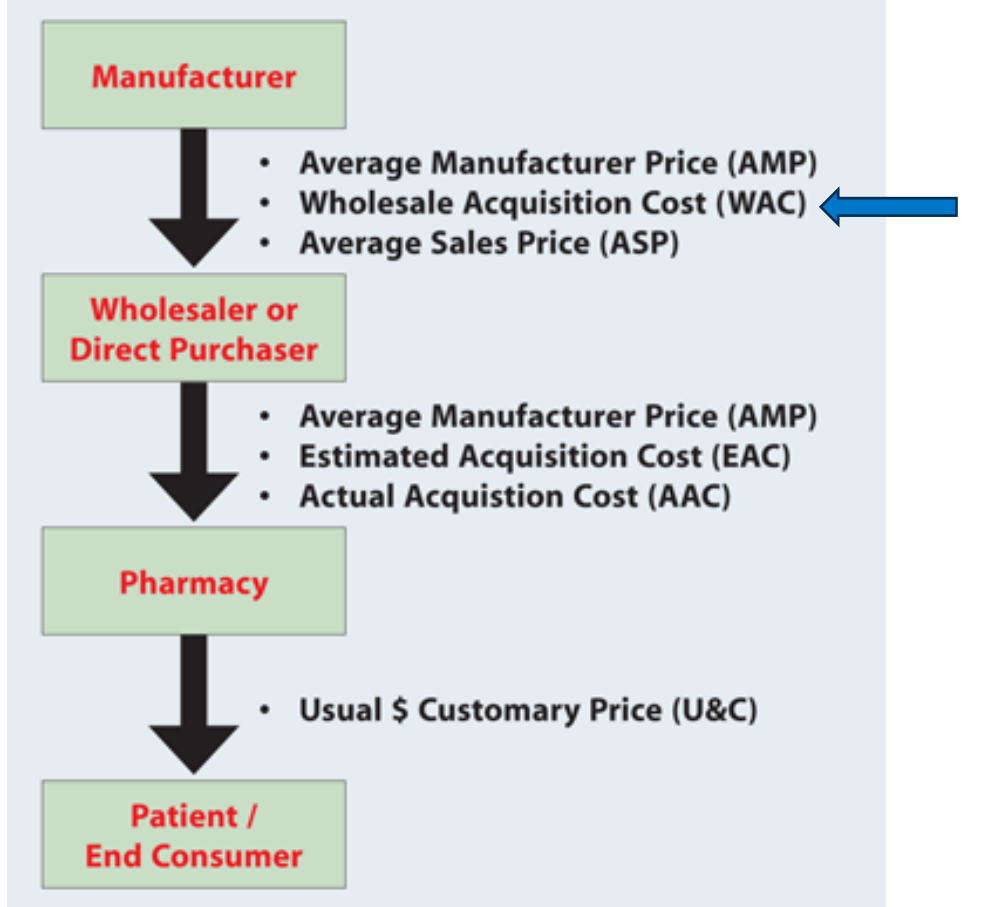
Drug Types³

- ▶ 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 from a single labeler or branded products, with the same 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

Summary of methodologies for identifying drugs subject to affordability review

Methodologies presented are preliminary and subject to change

Data Sources

Commercial databases of drug pricing and clinical information for drugs approved by the US Food and Drug Administration (FDA), over-the-counter drugs, and medical devices:

- ▶ First Databank (FDB)
- ▶ Medi-Span

Other Exclusions From Affordability Review

- ▶ Non-prescription drugs or medical devices as defined in the Federal Food, Drug, and Cosmetic Act (FDCA)
- ▶ Products that are neither drugs nor devices as defined in the FDCA
- ▶ Medical devices, bulk products and healthcare supplies
- ▶ NDCs obsolete as of 7/1/2023
- ▶ NDCs expired or withdrawn (with the exception of reference biologics, who can be expired or withdrawn as long as their biosimilar is not) as of 7/1/2023

Drugs Eligible For Review

Drug Type	Distinct NDC Count*
Brand	6,316
Generic	28,902
Biologic	1,262

*Orphan drugs have not been excluded from NDC count

(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

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
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

Exclusions

- ▶ Vaccines
- ▶ Non-drug products

Methodology

- ▶ Identify brand NDCs using FDB provided Generic Name Indicator (GNI) data field
 - ▶ GNI identifies the NDC as brand, generic, or medical devices, bulk products and healthcare supplies based on the product's name
- ▶ Identify biologics using FDA Purple Book, current as of January 2023

Methodology

1. De-duplication
2. Multiply NDC's high dose by high duration of therapy to get number of units used in a year, performing any NDC unit conversions if necessary
3. Multiply number of units used in a year by WAC unit price as of 1/1/2023 to obtain cost of a course of treatment for one year

Methodology: De-Duplication

Example: Bactrim DS (sulfamethoxazole and trimethoprim)

Lowest patient age	Highest patient age	Dose type	Disease Duration	High dose	High dose unit description	Billing unit	NDC strength	NDC strength unit of measure
28 days	59 days	SINGLE DOSE	Both	0.063	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
28 days	59 days	MAINTENANCE	Both	0.125	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
60 days	6569 days	SINGLE DOSE	Both	0.063	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
60 days	6569 days	MAINTENANCE	Both	0.125	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	MAINTENANCE	Both	4	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	LOADING	Both	2	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	SINGLE DOSE	Both	2	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG

Methodology: De-Duplication

- ▶ NDCs can have dosing data for multiple age categories, disease duration, dose type, etc.
- ▶ De-duplication algorithm:
 - ▶ 1. Use maintenance dosing data, if not available, use single dose
 - ▶ 2. Use chronic dosing data if NDC has both chronic and acute dosing data
 - ▶ 3. Use the dosing data for the highest age range
 - ▶ Ex: After executing steps 1) and 2), NDC still has dosing data for ages 18-65 years and 18-110 years old. In this case, we will use the data for ages 18-110 years old.

Methodology: De-Duplication

Example: Bactrim DS (sulfamethoxazole and trimethoprim)

Lowest patient age	Highest patient age	Dose type	Disease Duration	High dose	High dose unit description	Billing unit	NDC strength	NDC strength unit of measure
28 days	59 days	SINGLE DOSE	Both	0.063	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
28 days	59 days	MAINTENANCE	Both	0.125	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
60 days	6569 days	SINGLE DOSE	Both	0.063	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
60 days	6569 days	MAINTENANCE	Both	0.125	TAB-CAP/KG/D	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	MAINTENANCE	Both	4	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	LOADING	Both	2	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG
6570 days (18 years)	40150 days (110 years)	SINGLE DOSE	Both	2	TAB-CAP/DAY	each (tablets, kits, etc.)	160	MG

Methodology: Cost of Course of Treatment

$$\text{Cost of course of treatment for one year} = \frac{\text{high dose}}{\text{NDC strength}} * \text{high duration of therapy} * \text{WAC unit price}$$

- ▶ High dose: the high drug dose per day specific to the patient age, reason for use, dose type, and route of administration
- ▶ NDC strength: the NDC's ingredient strength. Unit conversions of high dose units may be required
- ▶ High duration of therapy: recommended amount of time for which a drug should be administered, in days
- ▶ WAC unit price: WAC price per each unit (tablet, capsule, lozenge, suppository, etc.), gram, or milliliter, as defined by the package size unit of measure

Example: Juxtapid (lomitapide) 30 MG capsule (NDC: 76431013001)

- ▶ Dosing information applies for patients 18-110 years old
- ▶ Dosing information contains maintenance dose is for both acute and chronic disease durations
- ▶ High duration of therapy = 0 means that the high duration is either not applicable (e.g., chronic medication) or not specified

Example: Juxtapid (lomitapide) 30 MG capsule (NDC: 76431013001)

High dose	High dose unit description	High duration of therapy (in days)	WAC unit price	Billing unit	NDC strength	NDC strength unit of measure
60	MG/DAY	0	\$1710.61	each (tablets, kits, etc.)	30	MG

$$\begin{aligned}
 \text{Cost of course of treatment for one year} &= \frac{\text{high dose}}{\text{NDC strength}} * \text{high duration of therapy} * \text{WAC unit price} \\
 &= \frac{60}{30} * 365 * 1710.61 \\
 &= \$1,248,745.30 \text{ for a course of treatment}
 \end{aligned}$$

This NDC costs \$1,248,745.30 for a course of treatment for one year, which meets our 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

Methodology

- ▶ Have a price increase of 15 percent or more in any 12-month period
 - ▶ 12-month period: 12-month period prior to most recent unit price as of 1/1/2023
 - ▶ One year price increase:
 - ▶ Current unit price: NDC's most recent unit price as of 1/1/2023
 - ▶ One year unit price: NDC's price as of 12 months prior to date of current unit price

$$\text{One-Year Price Increase} = \frac{\text{Current Unit Price} - \text{One-Year Unit Price}}{\text{One-Year Unit Price}}$$

Example: Nalocet (oxycodone/acetaminophen) 2.5-300 MG Tablet (NDC: 72245019303)

Market entry date	One-year unit price effective date	One-year unit price	Current unit price effective date	Current unit price
7/25/2006	7/1/2020	\$24.04	1/1/2022	\$31.73

- Current unit price: NDC's most recent unit price as of 1/1/2023
- One year unit price: NDC's price as of 12 months prior to date of current unit price
 - In this example, the one-year unit price would be the price of the NDC as of 1/1/2021

Example: Nalocet (oxycodone/acetaminophen) 2.5-300 MG Tablet (NDC: 72245019303)

Market entry date	One-year unit price effective date	One-year unit price	Current unit price effective date	Current unit price
7/25/2006	7/1/2020	\$24.04	1/1/2022	\$31.73

$$\begin{aligned}\text{One-Year Price Increase} &= \frac{\text{Current Unit Price} - \text{One-Year Unit Price}}{\text{One-Year Unit Price}} \\ &= \frac{31.73 - 24.04}{24.04} = 31.99\% \text{ increase}\end{aligned}$$

This WAC unit price of this NDC increased by 31.99% over a one-year period, which meets our review threshold of an increase of 15% or more.

Methodology

- ▶ Have a 50 percent cumulative increase over three years
 - ▶ Three-year price increase:
 - ▶ Current unit price: NDC's most recent unit price as of 1/1/2023
 - ▶ Three-year unit price: NDC's price as of three years prior to date of current unit price

$$\text{Three-Year Price Increase} = \frac{\text{Current Unit Price} - \text{Three-Year Unit Price}}{\text{Three-Year Unit Price}}$$

Example: Mytesi (crofelemer) 125 MG DR Tablet (NDC: 70564080260)

Market entry date	Three-year unit price effective date	Three-year unit price	Current unit price effective date	Current unit price
5/24/2013	1/1/2019	\$11.14	12/1/2022	\$39.58

- Current unit price: NDC's most recent unit price as of 1/1/2023
- Three-year unit price: NDC's price as of three years prior to date of current unit price
 - In this example, the three-year unit price would be the price of the NDC as of 12/1/2019

Example: Mytesi (crofelemer) 125 MG DR Tablet (NDC: 70564080260)

Market entry date	Three-year unit price effective date	Three-year unit price	Current unit price effective date	Current unit price
5/24/2013	1/1/2019	\$11.14	12/1/2022	\$39.58

$$\begin{aligned}
 \text{Three-Year Price Increase} &= \frac{\text{Current Unit Price} - \text{Three-Year Unit Price}}{\text{Three-Year Unit Price}} \\
 &= \frac{39.58 - 11.14}{11.14} = 255.30\% \text{ increase}
 \end{aligned}$$

This WAC unit price of this NDC increased by 255.30% over a three-year period, which meets our review threshold of an increase of 50% or more.

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

Methodology

- ▶ Identify reference biologic NDCs and their biosimilar NDCs using the First Databank's (FDB) "Identify a Reference Biologic's Biosimilar NDCs" documentation

$$\text{Biosimilar Price Increase} = \frac{\text{Initial Unit Price Of Biosimilar} - \text{Unit Price Of Reference Biologic As Of Initial Biosimilar Price}}{\text{Unit Price of Reference Biologic As Of Initial Biosimilar Price}}$$

- ▶ Initial unit price of biosimilar: earliest listed biosimilar WAC unit price
- ▶ Unit price of reference biologic as of initial biosimilar price: most current reference biologic WAC at the time of biosimilar launch

Example: Semglee (insulin glargine-yfgn) 100 UNIT/ML Pen (NDC: 49502025175)

Reference biologic label name	Reference biologic market entry date	Unit price of reference biologic as of initial biosimilar price	Date of unit price of reference biologic as of initial biosimilar price	Initial unit price of biosimilar	Date of initial unit price of biosimilar
Lantus Solostar (insulin glargine injection) 100 UNITS/ML	7/9/2007	\$28.35	1/4/2019	\$26.94	10/20/2021

- Initial unit price of biosimilar: earliest listed biosimilar WAC unit price
- Unit price of reference biologic as of initial biosimilar price: most current reference biologic WAC at the time of biosimilar launch

Example: Semglee (insulin glargine-yfgn) 100 UNIT/ML Pen (NDC: 49502025175)

Reference biologic label name	Reference biologic market entry date	Unit price of reference biologic as of initial biosimilar price	Date of unit price of reference biologic as of initial biosimilar price	Initial unit price of biosimilar	Date of initial unit price of biosimilar
Lantus Solostar (insulin glargine injection) 100 UNITS/ML	7/9/2007	\$28.35	1/4/2019	\$26.94	10/20/2021

$$\begin{aligned}
 \text{Biosimilar Price Increase} &= \frac{\text{Initial Unit Price Of Biosimilar} - \text{Unit Price Of Reference Biologic As Of Initial Biosimilar Price}}{\text{Unit Price of Reference Biologic As Of Initial Biosimilar Price}} \\
 &= \frac{26.94 - 28.35}{28.35} = -4.97\%
 \end{aligned}$$

The initial WAC unit price of the biosimilar is 4.97% lower than the unit price of its reference biologic as of the biosimilar's initial WAC unit price, which meets our threshold for review because it is not at least 15% lower

Discussion/Questions

Limitations

- ▶ No adjustments made for price inflation
- ▶ Data sources may not contain complete price history for NDC
- ▶ Cost of course of treatment based on the high dose of NDCs may not always reflect the amount most people are prescribed

Next Steps

Next Steps

- ▶ Finalize methodology for calculating amount of NDC units used for a 30-day supply
- ▶ Finalize methodology for identifying orphan NDCs
- ▶ Produce preliminary lists of NDCs eligible for review

Appendix

Additional examples of drug price calculations

Example: Dipentum (olsalazine sodium) 250 MG capsule (NDC: 00037686010)

- ▶ Dosing information applies for patients 13-110 years old
- ▶ Dosing information contains maintenance dose is for both acute and chronic disease durations
- ▶ High duration of therapy = 0 means that the high duration is either not applicable (e.g., chronic medication) or not specified

Example: Dipentum (olsalazine sodium) 250 MG capsule (NDC: 00037686010)

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
1	G/DAY	0	\$14.22		250	MG

- The high dose unit is different from NDC strength unit, so need to convert G to MG, using the conversion 1G=1000MG

$$\begin{aligned}
 \text{Cost of course of treatment for one year} &= \frac{\text{high dose} * 1000}{\text{NDC strength}} * \text{high duration of therapy} * \text{WAC unit price} \\
 &= \frac{1 * 1000}{250} * 365 * 14.22 \\
 &= \$20,761.20 \text{ for a course of treatment}
 \end{aligned}$$

This NDC costs \$20,761.20 for a course of treatment for one year, which does not meet our cost threshold of \$60,000 for review.

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>