

Methodology For Identifying Drugs For Affordability Review Part 2

Overview



Summary of thresholds for affordability review specified by Chapter 70.405 RCW



Methodologies for RCW sections 1) and 3) for identifying drugs subject to affordability review



Questions\Discussion



Next steps



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.

(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

Exclusions

- ▶ Vaccines
- ▶ Non-drug products

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

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

Goal of De-Duplication

- ▶ Choose one dose 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

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.

NDC Utilization Calculation

- ▶ Automated calculation
 - ▶ High dose is in same units as NDC strength
 - ▶ High dose can be converted to same units of NDC strength
- ▶ Manual calculation
 - ▶ High dose conversion to NDC strength requires research

Automated Calculations

- ▶ Cost of course of treatment formula can be applied to NDCs whose strength matches the high dose
- ▶ Units of high dose can be converted to NDC units with a known unit conversion (ex: MG to G)

Manual Calculations

- ▶ NDC label information needs to be researched to determine how much of the NDC is in a high dose

Manual Calculations

- ▶ Examples of high dose units that require manual research:
 - ▶ High dose given in applications per day
 - ▶ High dose given in drops per day
- ▶ Examples of NDC strength unit of measures that require manual research:
 - ▶ NDC strength unit of measure is in % (this is the case for many liquids)
 - ▶ NDC strength unit of measure is in units

(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.

Data Source

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

Exclusions

- ▶ Vaccines
- ▶ Non-drug products

Methodology

- ▶ Identify generic 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
- ▶ Generics whose brand has been on the market for at least seven years also included

Methodology

1. De-duplication
2. Calculate the price increase over a 12-month period for generic NDCs
3. Of NDCs with a 200% or more increase, obtain number of NDC units used for a 30-day supply
4. Multiply number of NDC units used for a 30-day supply by NDC's WAC unit price to obtain cost of 30-day supply

Goal of De-Duplication

Choose the highest amount of NDC a person can use

- ▶ Choose one dose 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

Methodology: 200% or more increase

- ▶ Increased in price by 200% or more in preceding 12 months
 - ▶ 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

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

Methodology: Calculating 30-Day Supply

- ▶ If high duration of therapy in days ≥ 30 days:
 - ▶ Multiply high dose amount of NDC used per day by 30
- ▶ If high duration of therapy in days < 30 days:
 - ▶ Multiply high dose amount of NDC used per day by high duration of therapy

Methodology: Calculating 30-Day Supply

- ▶ If high duration of therapy in days ≥ 30 days:
 - ▶ Multiply high dose amount of NDC used per day by 30

$$\text{Cost of 30-day supply} = \frac{\text{high dose}}{\text{NDC strength}} * 30 * \text{WAC unit price}$$

Methodology: Calculating 30-Day Supply

- ▶ If high duration of therapy in days < 30 days:
 - ▶ Multiply high dose amount of NDC used per day by high duration of therapy

$$\text{Cost of 30-day supply} = \frac{\text{high dose}}{\text{NDC strength}} * \text{high duration of therapy} * \text{WAC unit price}$$

Discussion/Questions

Next Steps

Next Steps

- ▶ Finalize methodology for identifying orphan NDCs
- ▶ Produce preliminary lists of NDCs eligible for 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

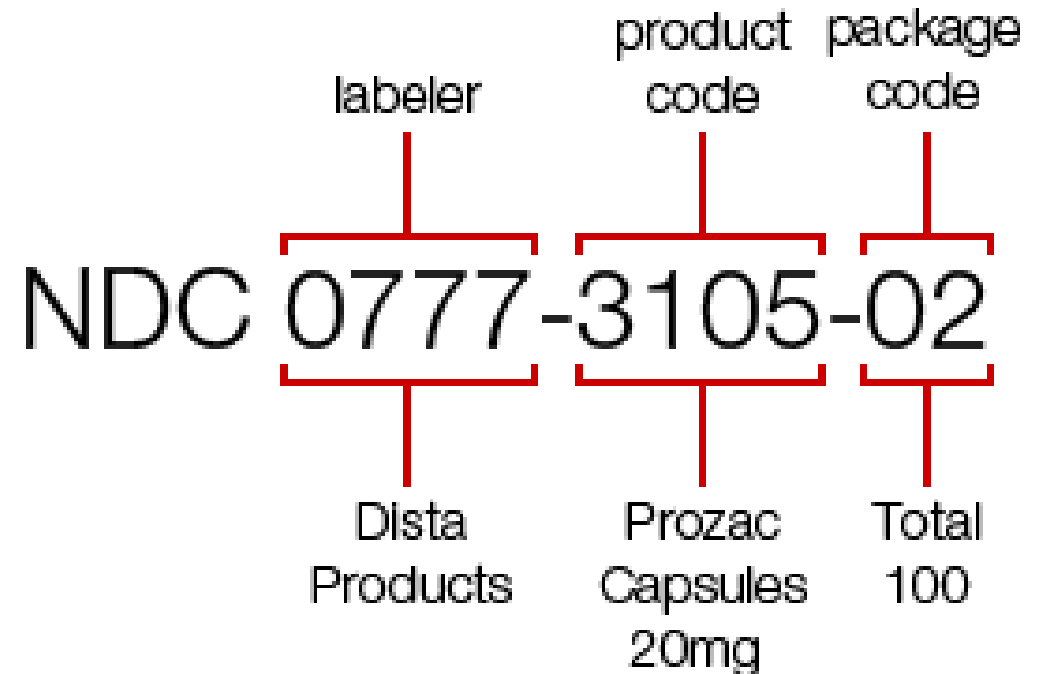


Image source: <https://www.drugs.com/ndc.html>

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

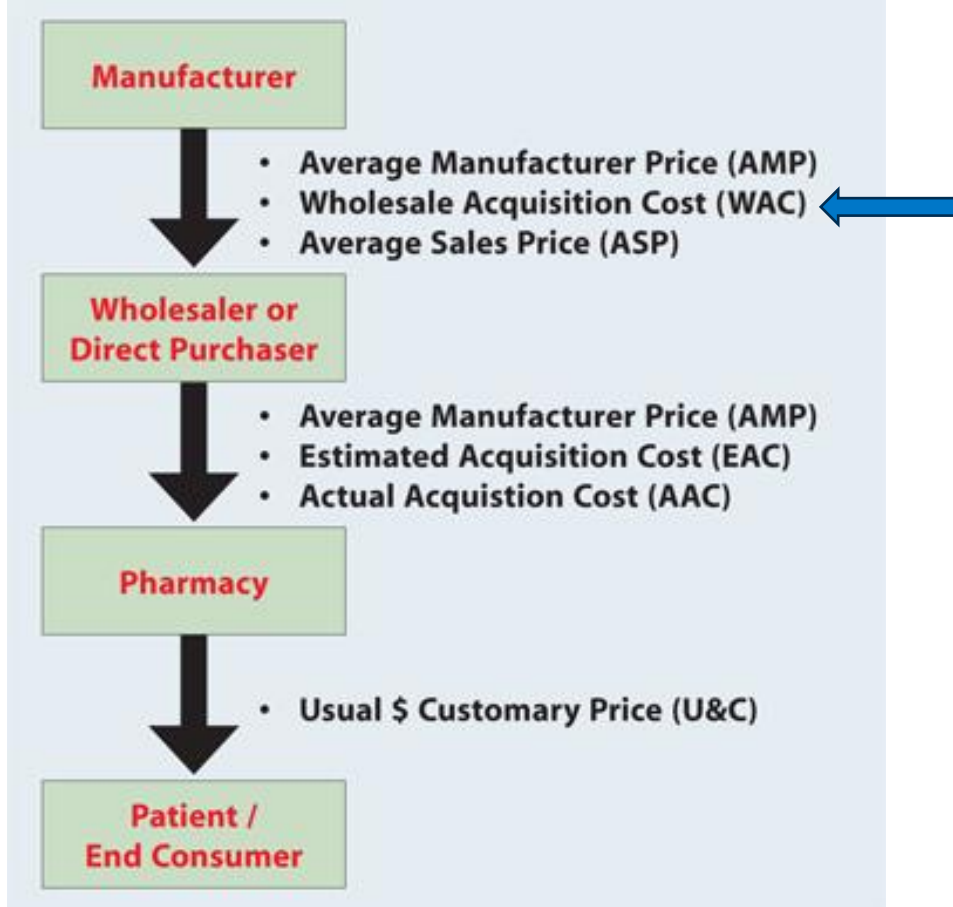
Drug Types³

- ▶ 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>