Eligible Prescription Drugs Policy

1. Purpose

The Prescription Drug Affordability Board (PDAB) establishes this policy pursuant to 70.405.030 RCW, which requires that the Board annually identify prescription drugs that have been 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. [2022 c 153 § 3.]

This policy sets forth the interpretations employed by the Board in identifying drugs eligible for affordability review and provides additional information regarding what types of data the Board will use.

2. Identifying Eligible Prescription Drugs for Affordability Reviews

Staff will prepare and present to the Board a list of eligible prescription drugs that meet the criteria set forth in section 70.405.030 RCW, and "Chapter" to be considered by the Board for an affordability review.

Staff will utilize methodologies, including the following where practicable, to identify prescription drugs eligible for affordability reviews:

1. For all prescription drugs:

a. Data from First Databank (FDB) and Medi-Span, which are commercial databases containing drug pricing and clinical information for drugs approved by the US Food and Drug Administration (FDA), will be utilized to identify prescription drugs eligible for review.

b. The initial Wholesale Acquisition Cost (WAC) means the earliest listed WAC for a prescription drug in FDB or Medi-Span.

c. Each National Drug Code (NDC) is interpreted as a distinct drug product; eligible NDCs will be consolidated with other NDCs of the same labeler, brand name, active ingredient, and

formulation for affordability review. This is because all NDCs from the same labeler with the same drug ingredient are the same prescription drug.

d. A prescription drug on the market for at least seven years means the drug ingredient has been on the market for at least seven years. This means a biosimilar that launches with an initial drug price can be considered for review if the drug ingredient has been on the market for at least seven years.

e. Current WAC means the most recent WAC listed in First Databank (FDB) and/or Medi-Span for NDCs that increased in price in the calendar year immediately preceding January 1st of the year for which the affordability review is being conducted. NDCs with no price increase in this period will not be eligible for price increase calculations and review.

f. High dose per day means high drug dose per day specific to the patient age, reason for use, dose type, and route of administration[1].

g. High duration of therapy in days means the usual recommended amount of time for which a drug should be administered[1].

h. Maintenance dose means the dose of the prescription drug required to achieve and maintain steady-state drug concentration.

i. Single dose means the dose of the prescription drug taken at one time.

j. Obsolete, expired, or withdrawn prescription drugs will not be reviewed. Biosimilar products may be eligible for review if the reference biologic product is obsolete, expired, or withdrawn.

k. Drugs with an orphan indication approval will be identified utilizing the FDA Orphan Drug Product designation database. Drugs approved solely for orphan indications will not be considered for the affordability review, but orphan drugs having non-orphan indication approvals will remain eligible for the affordability review.

l. Prescription drugs dispensed at a retail, specialty, or mail-order pharmacy will be identified by review from a licensed pharmacist and with indicators in FDB. Drugs considered as institutional products or products likely to be used by home healthcare providers will be excluded from the drug price review.

2. For a brand name drug or biological product:

a. Brand name drugs and biological products will be identified utilizing their product name and the FDA purple book.

b. The 12-month period will be defined as the 12 months immediately preceding the date the current WAC was set.

c. Three years will be defined as the 36 months immediately preceding the date the current WAC was set.

d Course of treatment cost will be determined by multiplying the NDC's WAC unit price as of January 1st of the year for which the affordability review is being conducted by the high dose per

day and by the high duration of therapy in days utilizing dosing modules from FDB clinical screening data.

e. Brand name drugs and biologic products identified as costing $60,000 or more per year will be manually reviewed by a licensed pharmacist to ensure the daily high dose and high duration of therapy used for the calculations are clinically sound. Further brand name drugs and biologic products may be excluded from the list after review.

f. For each prescription drug with dosing data for multiple age ranges, dosing types, or disease durations:

i. The dosing data for the highest age range will be utilized for course of treatment cost.

ii. For prescription drugs with dosing data for both maintenance and single doses: in this case, the maintenance high dose will be utilized for course of treatment cost.

iii. For prescription drugs with dosing data for both acute and chronic disease durations: in this case, the high dose per day for chronic or both acute and chronic disease durations will be utilized for course of treatment cost.

g. For adult high doses per day that require body weight or body surface area, the standard adult body weight of 70 kg and standard adult body surface area of 1.73 m^2 will be applied.

h. For child and adolescent high doses per day that require body weight or body surface area, CDC growth charts will be utilized to identify the average of the male and female 50^{th} percentiles for weight or body surface area for the median age of the age range the high dose per day is for.

i. The increase will be calculated from the prescription drug's current WAC unit price and its earliest price increase in the immediately preceding 12-month or 36-month period. If the prescription drug's WAC did not increase in the immediately preceding 12-month or 36-month period, the increase will be calculated from the prescription drug's price at the beginning of the 12-month or 36-month period.

3. For a biosimilar product:

a. NDCs for biosimilar products and corresponding reference biological products will be identified utilizing FDB's NDC attribute indicators for linking reference biologic and biosimilar NDCs.

b. Initial WAC unit price for biosimilars will be compared to the corresponding reference biological product's listed WAC on the date when the initial biosimilar WAC was listed.

4. For a generic drug:

a. Generic drugs will be identified utilizing their product name.

b. Generics of brand name drugs that have been on the market for at least seven years will be identified using their clinical formulation identifier (GCN sequence number), which indicates that the generic drug has the same active ingredient list, route of administration, dosage form, and drug strength as its brand name.

c. For each generic drug for which the WAC unit price increased by 200% or more during the immediately preceding twelve months from the current WAC, the high duration of therapy in days utilizing dosing modules from FDB clinical screening data will be used to determine calculation of the cost of a 30-day supply or less:

i. High duration of therapy is less than thirty days: calculate the WAC for a 30-day supply or less by multiplying the NDC's WAC unit price as of January 1st of the year for which the affordability review is being conducted by the high dose per day and by the exact high duration of therapy in days.

ii. High duration of therapy is thirty days or more: define the high duration of therapy as thirty days and calculate the WAC for a 30-day supply by multiplying the NDC's WAC unit price as of January 1st of the year for which the affordability review is being conducted by the high dose per day and by thirty in lieu of the exact high duration of therapy in days.

5. Note on the methodology:

a. The methodology was selected using the "high dose and duration of therapy" to identify drugs that meet the cost thresholds for certain patients. Patients who need to take higher doses of medications should be treated the same as those who take average or lower doses. By selecting a lower dose or duration of treatment, we would not capture the affordability challenges faced with Washingtonians who need to use high doses of these medications. Additionally, pharmacy claims data may not fully represent how these medications are intended to be used. Reports from the CDC (link: Products - Data Briefs - Number 470 - June 2023 (cdc.gov)) shows that many Americans are not taking medications as prescribed because of high costs and that would lower the amount of drug used by Washingtonians in our claims data. To correct for this survivorship bias, where we only look at data for people who are able to fill their medications, we elected to use a standardized approach to measure drug costs without these potential issues.

b. In keeping with HCA practice and consistent with RCW and WAC, the Board defines a "prescription drug" as a "drug ingredient." Conversely, drugs with individual 11-digit NDCs (derived from NDAs or BLAs) are defined as "drug products."

For example, RCW 70.405.010(9) defines "prescription drug" as a drug regulated under Chapter 69.41 or 69.50 RCW. RCW 69.41.010(10) further defines drugs as "substances recognized as drugs in the official United States pharmacopoeia," among other criteria. The US pharmacopoeia lists drugs by ingredient, not by NDA or BLA. RCW 69.50 uses nearly identical language, defining a drug as "a controlled substance recognized as a drug in the official United States pharmacopoeia," among other criteria.