Prescription Drug Affordability Board:

Introduction to the Affordability Review Outline

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Objectives

- To introduce and discuss the outline for the future affordability review
- To collect any additional interests and/or suggestions on the data elements from the Board members

- No voting – This is all work in progress, and changes/updates will be made as we collect various inputs and feedback.

Affordability Review Overall Process

1. Preparation
   - Gathering inputs from the Board members on data/information they'd like to have as part of the affordability review
     - Sharing the outline today
   - Setting up a secure submission portal with the Agency
   - Creating individual stakeholder forms and/or surveys
     - For data/information collection from our stakeholders (manufacturers, patients, carriers/payers, PBMs, wholesalers, subject matter experts)
     - Feedback/inputs will be collected from stakeholders.
2. Information collection and stakeholder surveys
3. Data verification and stakeholder and advisory group meetings
4. Information review with the Board members

Affordability Review Elements

The current outline compiles contents:

- Required by the legislation (Chapter 70.405 RCW)
- Requested by individual board members
- Advised by our external consultants (PORTAL)
- Shared by other states' PDABs and similar programs reviewing drug costs and pricing

Affordability Review Data Sources

- Manufacturers
- Patients
- Carriers/payers
- PBMs
- Wholesalers (TBD)
- Internal data source (FDB, Medi-Span, APCD, DPT data)
- External consultants

Affordability Review Outline

1. Background Information
2. Efficacy and Safety
3. Drug Price Information
4. Manufacturing, delivery, and administration costs
5. Cost to patients
6. Price effect on consumers' access to the drug in WA
7. Manufacturer patient assistance program and coupons
8. Therapeutically equivalent drugs
9. Price and availability of therapeutic alternatives

Affordability Review Outline (cont.)

10. Cost-effectiveness analysis
11. Summary input from the Advisory Groups
12. Summary input from patients
13. Summary input from individuals with medical or scientific expertise
14. Additional information from the manufacturers
15. Impact of PBM policies on the price consumers pay for the drug
16. Off-label usage of the drug

1. Background Info

- Generic name
- Brand name
- Drug class
- National Drug Codes (NDCs)
- Indications and approval dates by the FDA
- Orphan drug status
- Drug shortage status
- Manufacturer contact information

Potential data source: manufacturer, FDA websites

2. Efficacy and Safety

- Efficacy and safety information per indication
  - Brief summaries simply to inform the PDAB and the public

Potential data source: manufacturer, primary literature

3. Drug Price Info

- Wholesale acquisition cost (WAC)
- Average wholesale price (AWP)
- National average drug acquisition cost (NADAC)
- Average manufacture price (AMP)
- Most current WAC for a therapy duration
- Discounts
- Rebates
- Other price concessions
- Manufacturer net price of drug purchases after all discounts, rebates, and other price concessions
- Wholesaler net price after all discounts, rebates, and other price concessions
- PBM net payment after all discounts, rebates, and other price concessions
- Drug price in other developed countries

Potential data source: manufacturer, wholesalers, PBM, FDB/MediSpan

4. Manufacturing, Delivery, and administration Costs

- Research and Development (R&D) cost
- Recurring cost for drug manufacturing
- Marketing, advertising, and lobbying budget and expenditures
- Cost of delivering the drug to patients
- Cost of administering the drug to patients
- Other administrative costs

Potential data source: manufacturer

5. Cost to Patients

- Patient copay
- Patient coinsurance
- Insurance premium, deductible, and patient out-of-pocket maximum
- Average amount responsible by patient per claim

Potential data source: carriers, APCD

6. Price Effect on Consumers' Access to the Drug in WA

- Prevalence and Incidence of Indicated Condition(s) in the State
- Estimated Patient's Drug Cost and Utilization in the Nation vs. the State
- Recent Utilization in the State

Potential data source: manufacturer, APCD, patient advocacy groups, other agencies

7. Manufacturer Patient Assistance Program and Coupons

- Patient Assistance Program (PAP) Availability and Patient Eligibility
- PAP-Approved Product Quantity and Dollar Value
- Coupon Availability
- Coupon Limitations

Potential data source: manufacturer

8. Therapeutically Equivalent Drugs

- Generics
- Biosimilars

Potential data source: manufacturer, FDA websites

9. Price and Availability of Therapeutic Alternatives

- For each indication:
  - Availability of therapeutic alternatives (*drugs within the same therapeutic class, as well as drugs from different therapeutic classes evaluated within guidelines for treating the same disease and the same severity)*
  - Summary tables
    - Place in therapy
    - Guideline recommendations
    - Costs
    - Efficacy/safety profiles
- Considerations for the drug(s) in the same therapeutic class but which is/are not considered therapeutic alternatives

Potential data source: manufacturer, subject matter experts, external consultants

10. Cost-Effectiveness Analysis

- Analysis requested for each approved indication
- Submission of an interactive model also requested

Potential data source: manufacturer, subject matter experts, external consultants

TBD: Stakeholder Surveys

11. Summary input from the Advisory Groups
12. Summary input from patients
13. Summary input from individuals with medical or scientific expertise

Potential data source: respective stakeholder

14. Additional Information from the Drug Manufacturer

- Exclusivity and Patent Expiration Date (if applicable)
- Relevant Information on Exclusivity and the Patent Expiration Date (if applicable)
- Life-Cycle Management
- For each approved indication:
  - Market Competition and Context
  - Past Revenue
  - Projected Revenue
  - Budget Impact Analysis
- Submission of an interactive model for the budget impact analysis will be requested.
- Additional Information for Drug Pricing

Potential data source: manufacturer

15. Impact of Pharmacy Benefit Manager Policies on the Price Consumers Pay for the Drug

- Drug Tier Information
- Prior Authorization (PA) and Step Therapy

Potential data source: PBMs

16. Off-Label Usage of the Drug

- Summary Table for Off-Label Usage
  - Efficacy/safety
  - How common the off-label usage is

Potential data source: manufacturer, clinical database, primary literature

"Excess Costs" Discussion

- Based on RCW 70.405.010, "Excess costs" means:
  - (a) Costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments; or
  - (b) Costs of appropriate utilization of a prescription drug that are not sustainable to public and private health care systems over a 10-year time frame.
- Perspectives to consider whether the drug pricing leads to "excess costs"
  - 1) the drug's cost relative to therapeutic alternatives
  - 2) the drug's out-of-pocket costs to patients and the impact of these costs on access
  - 3) the drug's budgetary impact on the state's public and private payers, as well as Washingtonians
    - E.g. Impact on insurance premiums for Washingtonians

Where We Are and What's Next

- Currently, details on the data to be collected are being developed, along with draft datasheets.
- Once information to be collected from different stakeholders are sorted out, we'll share more specifics and collect feedback and inputs.