The Hilltop Institute

Prescription Drug Affordability Board (PDAB) Legislative Measures Methodology

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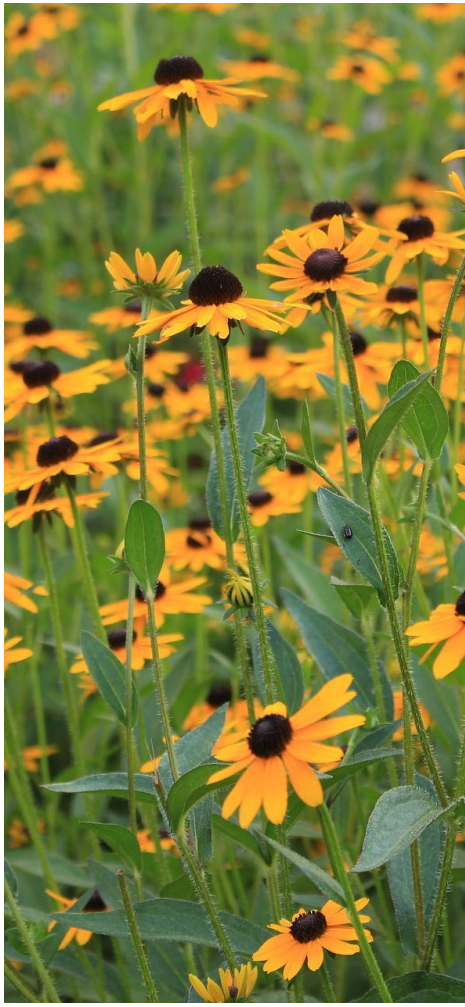

UMBC

Overview

- MD Code Ann., Health-Gen. § 21-2C-08
- Identify:
  - Brand name drugs with a launch Wholesale Acquisition Cost (WAC) of $30,000+ *per year or course of treatment*
  - Brand name drugs with a WAC increase of $3,000+ *per year or course of treatment*
  - Biosimilars with a launch WAC not at least 15% lower than the reference biologic
  - Generic drugs that cost $100+ *for a 30-day supply (or less)* **and** experienced a price increase of at least 200%

Challenges

- WAC pricing data are unit cost
- How to aggregate to yearly utilization?
- Scope of the data forestalls manual review
  - Tens of thousands of National Drug Codes (NDCs)
  - Recommended dosage can vary

Proposed Methodology

- Proposed solution
  - Top-down, data-driven methodology to calculate NDC-specific utilization using claims data
- Then, link this NDC-specific utilization calculation to unit WAC pricing

Hypothetical Example: Distribution of Claims

Table 1. Distribution of Claims of a Hypothetical NDC in CY 2020

NDC	Person ID	Claim Date	# Units
12345878910	1	1/1/2020	1
12345878910	1	4/1/2020	1
12345878910	1	7/1/2020	1
12345878910	1	10/1/2020	1
12345878910	2	5/1/2020	1
12345878910	2	8/1/2020	1
12345878910	2	11/1/2020	1
12345878910	3	11/1/2020	1
12345878910	4	1/1/2020	1
12345878910	4	4/1/2020	1
12345878910	4	7/1/2020	1
12345878910	4	10/1/2020	1
12345878910	5	1/1/2020	1
12345878910	5	2/15/2020	1
12345878910	5	4/1/2020	1
12345878910	5	5/15/2020	1
12345878910	5	7/1/2020	1
12345878910	5	8/1/2020	1

Hypothetical Example: Distribution of Person-Level Annual Utilization

Table 2. Distribution of Annual Utilization among Users of a Hypothetical NDC in CY 2020

NDC	Person ID	Total # Units
12345878910	1	4
12345878910	2	3
12345878910	3	1
12345878910	4	4
12345878910	5	6

Table 3: Ordered Distribution of Annual Utilization among Users of a Hypothetical NDC in CY 2020

NDC	Person ID	Total # Units
12345878910	3	1
12345878910	2	3
12345878910	1	4
12345878910	4	4
12345878910	5	6

Median annual utilization across users: **4 units**

Estimated Utilization Distribution

- In the preceding example, use the observed median quantity (4) in conjunction with WAC prices
- Very similar methodology for generic drugs
  - Typical utilization for a 30-day supply or less

Potential Limitations

- Restricts focus to NDCs for which there is any utilization
  - **Mitigation**: We use three large claims databases to cast as wide a net as possible
    - Maryland Medicaid
    - Maryland All-Payer Claims Database (APCD)
    - Maryland Medicare
- Relies on representativeness of claims experience
  - **Mitigation**: Manual review of a sample of drugs to assess accuracy of utilization estimate

More Potential Limitations

- Utilization estimates may be skewed downward by individuals with partial year coverage
  - **Mitigation**: Restrict focus to individuals with at least 320 days of coverage (Medicaid and APCD).
- This analysis is NDC-level, not drug-level
  - **Mitigation**: It is not *a priori* clear how to aggregate across different dosage forms to the "drug" level. Future work could seek to reprice claims utilization using WAC prices, then aggregate to the drug level.

Additional Assumptions

- First NDC entry in the First Databank WAC database is the launch price
- Consumer Price Index (CPI) Medical for inflation adjustment
- Identifying all generic drugs that were:
  - Ever over $100 for a 30-day supply (or less)

    AND
  - Ever experienced a 200% price increase

Biosimilars Methodology

1. Used the FDA Purple Book, current as of December 2021, to ID:
    a. Generic name, proprietary name, and approval date of all approved biosimilars in the U.S.
    b. Generic name and proprietary name of the corresponding reference biologic
2. Systemic search of manufacturer websites and press releases to ID biosimilar *launch dates*
3. Used the FDA directory to identify all NDC codes for *launched* biosimilars and their originator biologics

Methodology
continued

4. Used NDC codes, launch date data, and the WAC pricing file to:
   a. ID biosimilar *launch WAC*
   b. ID the reference biologic WAC *at the time of biosimilar launch*
   c. Flag biosimilars that launched at a WAC price that was not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched

Sensitivity Check

- Repeated step 4a and 4b above by biosimilar *packaging availability*.
- Example:
  - Drug A available as a 10mg/ml 50 ml vial & a 10 mg/ml 10 ml vial
  - WAC pricing is per ML → theoretically the pricing should be the same for a 10ml vial and a 50ml vial.
  - Check for potential differential pricing:
    - ID launch WAC of Drug A available in a 10ml vial formulation & in a 50ml vial formulation.
    - ID WAC/ml of reference biologic Drug B at the time of Drug A launch for the corresponding 10ml vial formulation and the corresponding 50 ml vial formulation.
    - Flag any differential pricing by packaging → **NONE.**