Section 21-2c-09(c) 2022 Annual Cost Review Report

Maryland Prescription Drug Affordability Board

December 31, 2022

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The Prescription Drug Affordability Board's website address:

https://pdab.maryland.gov/index.html

Introduction

Section 21-2c-09(c) of the Health-General Article, Annotated Code of Maryland, directs the Maryland Prescription Drug Affordability Board (Board) to submit an annual report on or before December 31 that includes: (1) price trends for prescription drug products; (2) the number of prescription drug products that were subject to Board review and the results of the review; and (3) any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

Background

I.   Price Trends for Prescription Drug Products

A.   National Price Trends 2021-2022

Throughout 2022, prescription drug prices have continued to increase nationwide. Prices like the wholesale acquisition cost (WAC) are set nationally, so the trends outlined in national reports apply to those same drugs in Maryland. For the twelve-month period from July 2021 to July 2022, 1,216 prescription drug products experienced list price increases that exceeded the inflation rate of 8.5 percent.[1] Although the average price increase was 31.6%, some drugs increased by more than $20,000 or 500% during that 12-month period. The majority of these price increases occurred during the months of January and July with most price increases occurring in January. For example, in January 2022, the average price increase was nearly $150 per drug (10%), and in July 2022, it was $250 (7.8%). These dollar increases were larger than for the same months in previous years.[2] Prices for certain drug products increased faster than medical inflation, which may contribute to affordability challenges.

In a recent report, the IQVIA Institute found that spending on medicines in the United States rose 12.1% in 2021 to $407 billion due, primarily, to COVID-19 vaccines and therapies.[3] Although

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[1] Bosworth A, Sheingold S, Finegold K, Lew ND, Sommers BD. *Price Increases for Prescription Drugs, 2016-2022*. United State Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation HHS (ASPE) Office of Health Policy Issue Brief. September 30 2022. https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf

[2] Bosworth A, Sheingold S, Finegold K, Lew ND, Sommers BD. *Price Increases for Prescription Drugs, 2016-2022*. United State Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) Office of Health Policy Issue Brief. September 30 2022. https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf

[3] IQVIA Institute. *The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026*. IQVIA. April 21, 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022

overall spending increased by 12%, spending without COVID-19 vaccines and therapeutics grew by only 4.9 percent. And despite an increase in overall spending, costs per prescription were on average flat or slightly declined. This report also noted large differences between list prices and the amounts spent by payers and patients or received by manufacturers, though these data are proprietary. Real per capita spending at estimated net manufacturer prices grew by 5.8% in 2021 but would have declined by one percent excluding the impact of COVID-19 vaccines and therapeutics. IQVIA notes that based on their data, protected brand list prices increased 4.8% in 2021, while net prices increased by only 1 %—the fifth year at or below the CPI. Finally, an overview of patient out-of-pocket costs shows that while most patients' costs are falling, a small proportion have high costs that impact their use of medicines with implications for their health outcomes. Specialty medicines accounted for 56% of spending, up from 28% in 2011, and largely driven by growth in autoimmune, oncology, and diabetes spending.[4]

Another report analyzed changes in drug spending between 2016 and 2021.[5] The report found that spending growth, not accounting for rebates, was primarily due to increases in price rather than increases in prescriptions. Spending on non-retail drugs rose by 25% compared to the 13 %   for retail drugs. In addition, spending growth has varied by site of service. Mail-order pharmacies, outpatient clinics, and home health services saw the largest growth in spending from 2016 to 2021. The most expensive drugs have an outsized impact on spending: even though the top 10% of drugs make up less than one percent of volume, they accounted for 15% of retail spending and 25% of non-retail spending.

Another report noted that over 800 prescription drug products became more expensive in January 2022 as compared to previous years. Many of those 800 prescription drugs had steadily increased in price over the last three years. Close to 60% of the drugs that increased in price this year also increased in price in January 2020 and January 2021. The vast majority, 98%, of these price increases were for brand drugs. Specialty drugs (199 drugs) and physician-administered drugs (84) made up a notable minority of increases. Overall, the average price increased by 5.1% from 2021.

These reports show that prescription drug spending continues to rise, though increases in overall prescription drug spending may be less than overall medical inflation. For certain prescription drugs, their spending and prices continue to rise significantly, causing important affordability challenges for patients and payers.

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[4] IQVIA Institute. *The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026*. IQVIA. April 21, 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022

[5] Parasrampuria S, Murphy S. *Trends in Prescription Drug Spending, 2016-2021*. United States Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation HHS (ASPE) Office of Health Policy Issue Brief. September 30 2022. https://aspe.hhs.gov/reports/trends-prescription-drug-spending

B. Maryland Drug Price and Spending Trends 2018-2020

Overall, pricing and spending trends in Maryland align with the national trends. All of the national pricing findings above apply to those same drugs sold in Maryland. Current Maryland-specific data have limitations (described below), but generally align with findings at the national level.

Maryland pricing data are based on Board research on wholesale acquisition costs (WAC) and Maryland drug spending trends are based on the Maryland Medical Care Data Base (MCDB), which is the Maryland All Payer Claims Database (APCD). The APCD represents about 60% of insured Marylanders, including Marylanders covered by Medicare and Medicaid, and Marylanders that are covered by non-self-funded commercial plans The most recent data in the APCD are through 2020 for the commercial and Medicaid markets, and there are some dates that do not have Medicare data. Maryland has some more timely data, and the Board will include those sources when possible in future reports.

The total gross prescription drug spend in the APCD increased from $6.43 billion ($5.53 billion on name brand drugs and $1.39 on generic drugs) in 2018 to $6.83 billion ($5.92 billion on brand name drugs and $1.45) in 2019. As seen at the national level, overall spending increases are driven by brand name drugs.

In 2020, the Board identified 17 brand name drugs with a WAC increase of over $3,000 per year or course of treatment, and 2 generic drugs that are more than $100 for a 30 days supply and increase in price over 200 percent.

Below, we provide some trends in pricing data and spending data, and context for these data based on published reports. After providing overall trends, we provide more details of the top 10 products by spending in Maryland.
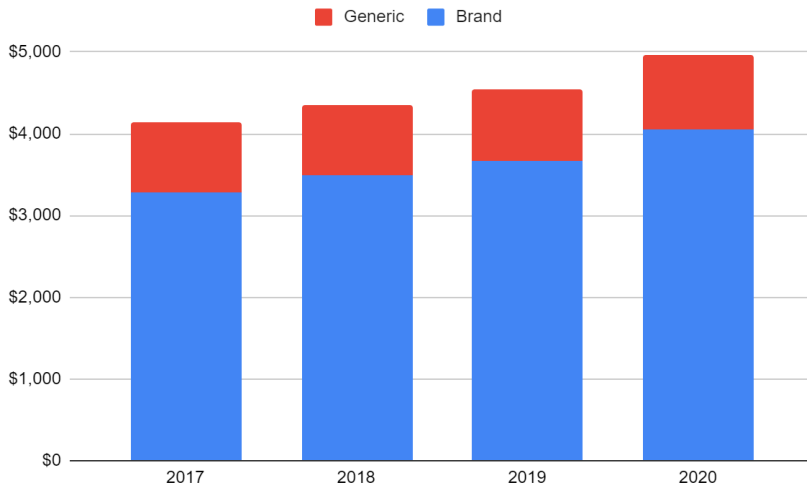
Figure 1: Trends in Maryland Commercial and Medicaid Drug Spend (in millions of dollars)
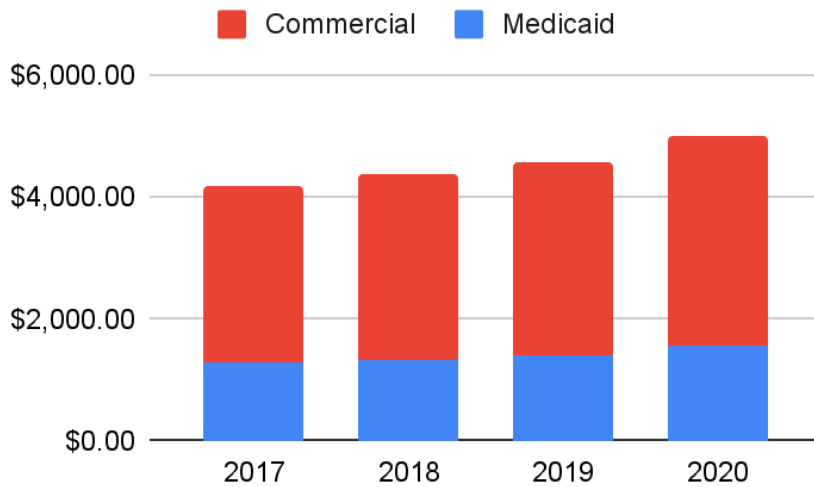
Source: Analysis of Maryland APCD Data

Figure 1 shows the over trend in drug spending in Maryland. Commercial insurance makes up nearly 50%   of the gross spending on drugs in Maryland even when this data does not include self-insured plans and health plans provided by the federal government. With these populations included the percentage would be higher. Gross drug spending by all types of insurance has generally increased over time.

Figure 2: Trends in Maryland Drug Spending by Brand Status in Commercial Insurance and Medicaid (in millions of dollars)

Source: Analysis of Maryland APCD Data

Figure 2 shows Maryland drug spending by brand and generic status of drugs. Across time generic drugs have made up around 20% of drug spending. More detailed analysis by insurance type shows a lower percentage of drug spending is generic in Medicaid (around 15%) than in commercial insurance or Medicare. The analysis also shows spending on generic drugs as a percent of spending as it has been slightly decreasing over time in the commercial market.

Figure 3: Trends in Maryland Drug Spending by Brand Status Medicare (in millions of dollars)
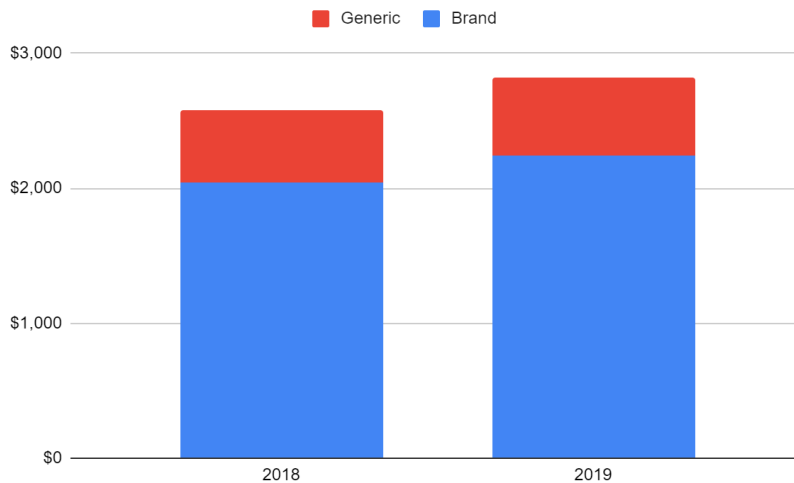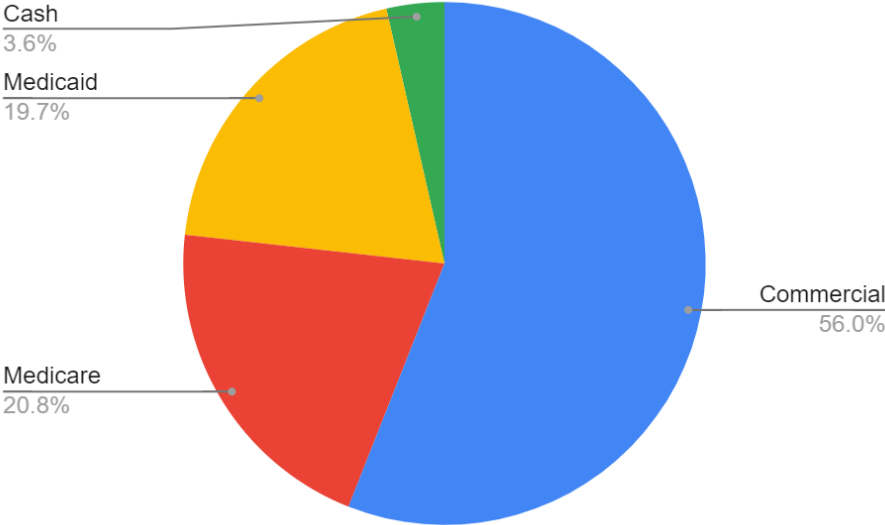

Source: Analysis of Maryland APCD Data

Figure 3 shows the trends for brand and generic spending in Maryland among Medicare Part D enrollees. The time lag in the Medicare data only allowed for the analysis of 2018 and 2019.

The Kaiser Family Foundation (KFF) used data from IQVIA to examine the dispensed prescription and spending on drugs in retail pharmacies and mail order pharmacies in 2019 by state.[6] According to this data across payers, Maryland pharmacies (including mail order pharmacies) dispensed 66.5 million prescriptions and received $9.5 billion in gross payments. This results in an average price of $143 per prescription. On average, Maylanders received 11.1 prescriptions per person in 2019. Figure 4 and Figure 5 break down the distribution of prescriptions and spending by method of payment.

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[6] Kaiser Family Foundation. *Health Costs & Budgets*. The State Health Facts Project. https://www.kff.org/state-category/health-costs-budgets/prescription-drugs/

Figure 4. Maryland Drug Volume by Method of Payment, 2019

Cash
3.6%

Medicaid
19.7%

Medicare
20.8%

Commercial
56.0%

Source: Analysis by the Kaiser Family Foundation of IQVIA Data

Figure 5. Maryland Drug Spending by Method of Payment, 2019

Cash
1.8%

Medicaid
14.2%

Medicare
27.7%

Commercial
56.3%
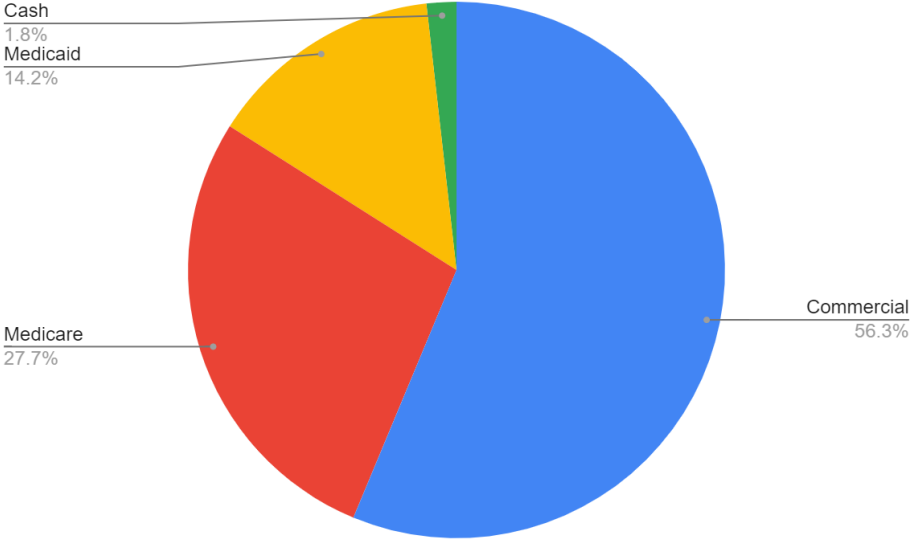
Source: Analysis by the Kaiser Family Foundation of IQVIA Data

Table 1 below shows the top ten drugs in Maryland based on the total claims in the Maryland APCD in 2018 and 2019. Between 2018 and 2019, three drugs dropped out of the top ten list. Also, in 2019, two different formulations of Humira were listed in the top ten drugs in Maryland.

Table 1. Top 10 Drugs by Spend in 2018 and 2019, Spending in Millions of Dollars

	2018			2019	
Rank	Drug	Spending	Rank	Drug	Spending
1	HUMIRA PEN 40 MG/0.8 ML	$ 209.6	1	HUMIRA PEN 40 MG/0.8 ML	$ 148.3
2	GENVOYA TABLET	$ 109.3	2	BIKTARVY 50-200-25 MG TABLET	$ 137.1
3	TRIUMEQ 600-50-300 MG TABLET	$ 95.8	3	ELIQUIS 5 MG TABLET	$ 121.4
4	ELIQUIS 5 MG TABLET	$ 84.0	4	HUMIRA(CF) PEN 40 MG/0.4 ML	$ 93.5
5	TECFIDERA DR 240 MG CAPSULE	$ 71.0	5	GENVOYA TABLET	$ 93.2
6	TRULICITY 1.5 MG/0.5 ML PEN	$ 50.6	6	TRIUMEQ 600-50-300 MG TABLET	$ 90.7
7	HARVONI 90-400 MG TABLET	$ 50.6	7	TECFIDERA DR 240 MG CAPSULE	$ 76.9
8	XARELTO 20 MG TABLET	$ 49.8	8	TRULICITY 1.5 MG/0.5 ML PEN	$ 73.7
9	VICTOZA 3-PAK 18 MG/3 ML PEN	$ 48.9	9	STELARA 90 MG/ML SYRINGE	$ 69.3
10	NOVOLOG 100 UNIT/ML FLEXPEN	$ 48.9	10	NOVOLOG 100 UNIT/ML FLEXPEN	$ 53.6

Table 2 examines how the top ten drugs compare between the three types of health insurance in 2019. Twenty- one different drugs appear in the top ten for at least one type of insurance. Four drugs appeared in both the top ten for commercial insurance and Medicare. Meanwhile, five drugs appeared on both the list for commercial insurance and Medicaid. Three drugs appeared on the top ten lists for both Medicare and Medicaid.

Table 2. Top 10 Drug Spend in 2019 by Insurance Type, in Millions of Dollars

Commercial			Medicare			Medicaid		
Rank	**Drug**	**Spending**	**Rank**	**Drug**	**Spending**	**Rank**	**Drug**	**Spending**
1	HUMIRA PEN 40 MG/0.8 ML	$ 95.7	1	ELIQUIS 5 MG TABLET	$ 79.6	1	BIKTARVY 50-200-25 MG TABLET	$ 55.5
2	HUMIRA(CF) PEN 40 MG/0.4 ML	$ 75.1	2	REVLIMID 10 MG CAPSULE	$ 38.0	2	SUBOXONE 8 MG-2 MG SL FILM	$ 33.5
3	STELARA 90 MG/ML SYRINGE	$ 57.3	3	BIKTARVY 50-200-25 MG TABLET	$ 34.0	3	GENVOYA TABLET	$ 32.3
4	BIKTARVY 50-200-25 MG TABLET	$ 47.6	4	XARELTO 20 MG TABLET	$ 32.7	4	SUBOXONE 12 MG-3 MG SL FILM	$ 32.2
5	TECFIDERA DR 240 MG CAPSULE	$ 44.2	5	HARVONI 90-400 MG TABLET	$ 31.1	5	TRIUMEQ 600-50-300 MG TABLET	$ 29.9
6	GENVOYA TABLET	$ 41.1	6	HUMIRA PEN 40 MG/0.8 ML	$ 28.6	6	MAVYRET 100-40 MG TABLET	$ 25.0
7	TRULICITY 1.5 MG/0.5 ML PEN	$ 39.3	7	ELIQUIS 2.5 MG TABLET	$ 27.6	7	HUMIRA PEN 40 MG/0.8 ML	$ 23.9
8	ELIQUIS 5 MG TABLET	$ 35.4	8	NOVOLOG 100 UNIT/ML FLEXPEN	$ 27.6	8	BASAGLAR 100 UNIT/ML KWIKPEN	$ 22.2
9	TRIUMEQ 600-50-300 MG TABLET	$ 33.5	9	TRIUMEQ 600-50-300 MG TABLET	$ 27.3	9	HUMIRA(CF) PEN 40 MG/0.4 ML	$ 18.5
10	TRUVADA 200 MG-300 MG TABLET	$ 28.2	10	LANTUS SOLOSTAR 100 UNIT/ML	$ 27.2	10	TIVICAY 50 MG TABLET	$ 15.1

Table 3 examines how the top ten drugs compare for commercial insurance and Medicaid combined in 2017 and 2020. Five drugs appeared in the top ten in both years showing the dynamic market in drug utilization and spending.

Table 3. Top 10 Drug Spend in Commercial and Medicaid in 2017 and 2020, in Millions of Dollars

	2017			2020	
Rank	**Drug**	**Spending**	**Rank**	**Drug**	**Spending**
1	HUMIRA PEN 40 MG/0.8 ML	$ 148.9	1	BIKTARVY 50-200-25 MG TABLET	$ 190.1
2	GENVOYA TABLET	$ 68.8	2	HUMIRA(CF) PEN 40 MG/0.4 ML	$ 158.6
3	TRIUMEQ 600-50-300 MG TABLET	$ 58.4	3	STELARA 90 MG/ML SYRINGE	$ 97.9
4	TECFIDERA DR 240 MG CAPSULE	$ 46.7	4	HUMIRA PEN 40 MG/0.8 ML	$ 76.2
5	TRUVADA 200 MG-300 MG TABLET	$ 40.1	5	GENVOYA TABLET	$ 68.2
6	STELARA 90 MG/ML SYRINGE	$ 27.3	6	TRULICITY 1.5 MG/0.5 ML PEN	$ 62.5
7	ODEFSEY TABLET	$ 23.9	7	TRIUMEQ 600-50-300 MG TABLET	$ 61.8
8	VICTOZA 3-PAK 18 MG/3 ML PEN	$ 23.5	8	ELIQUIS 5 MG TABLET	$ 58.75
9	SUBOXONE 8 MG-2 MG SL FILM	$ 21.5	9	TECFIDERA DR 240 MG CAPSULE	$ 47.2
10	TRULICITY 1.5 MG/0.5 ML PEN	$ 21.4	10	TRIKAFTA 100-50-75 MG/150 MG	$ 41.7

Table 4 shows the top ten drugs by spending per patient for both Medicaid and commercial insurance in 2020. These numbers measure annual spending per unique patient. Surprisingly, only one drug (Alprolix) appeared on both lists. Moreover, the spending per patient for this drug is dramatically different between the two types of insurance.

Table 4. Top 10 Drugs in Spending per Patient in Commercial vs Medicaid in 2020, in Dollars

	Commercial			Medicaid	
Rank	Drug	Spending Per Patient	Rank	Drug	Spending Per Patient
1	RAVICTI 1.1 GRAM/ML LIQUID	$1,074,901	1	ZOLGENSMA 3.6-4.0 KG KIT	$2,181,677
2	STRENSIQ 80 MG/0.8 ML VIAL	$606,402	2	ZOLGENSMA 6.1-6.5 KG KIT	$2,125,011
3	NAGLAZYME 5 MG/5 ML VIAL	$581,696	3	ZOLGENSMA 4.1-4.5 KG KIT	$2,041,959
4	HAEGARDA 3,000 UNIT VIAL	$509,518	4	VIMIZIM 5 MG/5 ML VIAL	$1,753,326
5	MYALEPT 11.3 MG (5 MG/ML) VIAL	$505,195	5	ELOCTATE 3,000 UNIT NOMINAL	$951,166
6	SOLIRIS 300 MG/30 ML VIAL	$469,258	6	EXONDYS-51 500 MG/10 ML VIAL	$832,283
7	CINRYZE 500 UNIT VIAL	$440,964	7	ALPROLIX 4,000 UNIT NOMINAL	$830,833
8	CRYSVITA 30 MG/ML VIAL	$440,509	8	ELOCTATE 2,000 UNIT NOMINAL	$815,112
9	JUXTAPID 20 MG CAPSULE	$413,460	9	ADVATE 3,601-4,800 UNIT VIAL	$745,921
10	ALPROLIX 4,000 UNIT NOMINAL	$412,793	10	ACTIMMUNE 100 MCG/0.5 ML VIAL	$744,684

II.   Maryland's Cost Review Experience

A. Overview of Cost Review Process

Section 21–2c–08 of the Health General Article directs the Board to identify prescription drug products that meet certain statutory metrics, and "[o]ther prescription drug products that may create affordability challenges for the State health care system and patients."[7]

With its vendor, the Hilltop Institute, the Board developed a methodology (Appendix A) for identifying drugs that meet these statutory metrics: (a) brand name drugs (and biologics) with a launch Wholesale Acquisition Cost (WAC) of $30,000 or more per year or course of treatment; (b) brand name drugs (and biologics) with a WAC increase of $3,000 or more per year or course of treatment; (c) biosimilars with a launch WAC not at least 15% lower than the reference biologic; and (d) generic drugs that cost $100 or more for a 30-day supply (or less) and experienced a price increase of at least 200 percent.   Initial application of this methodology to the APCD data yielded: (a) 707 brand name NDCs[8] (launch WAC of over $30,000 dollars); (b) 884 brand name NDCs (increase over $3000); (c) 2 NDCs of biosimilars (not at least 15% less than the reference biologic); and (d) 483 NDCs of generic drugs (over $100 for a 30 day supply and have an increase of over 200 percent).[9]

With input from the Stakeholder Council, multiple other metrics—used to ascertain prescription drugs "that may create affordability challenges"—have been identified and discussed. Ultimately, once selected the metrics will be published in regulation.

After identifying qualifying prescription drug products, and with input from the Stakeholder Council, the Board then selects a drug or drugs to undergo the cost review process.[10] Because the metrics yield thousands of qualifying drugs, establishing guidelines for selecting a drug for review is complicated. The Board, in consultation with the Stakeholder Council, is continuing to work through this process, which will be published in regulation.[11]

Once a drug is selected, the Board then undertakes the cost review process. To the extent practicable, the Board considers ten statutory factors, many of which are dependent on obtaining data or information from manufacturers, health plans, and pharmacy benefit managers such as average monetary price concessions, discounts, and rebates.[12] The Board may also consider any

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[7] Md. Code Ann., Health-Gen. § 21-2c-08(c).

[8] The National Drug Code (NDC) is a unique, three-segment number used to identify drugs by the FDA.

[9] These numbers will change with final design decisions in the methodology, such as setting a look back period.

[10] Md. Code Ann., Health-Gen. § 21-2c-09(a)(1).

[11] Various frameworks for screening drugs for selection were presented and discussed at the September 26, 2022 Board meeting, and at the October 24, 2022 Stakeholder Council meeting.

[12] Md. Code Ann., Health-Gen. § 21-2c-09(b). These statutory factors and possible sources for obtaining this information were presented and discussed at the November 28, 2022 Board meeting and the December 19, 2022 Stakeholder Council meeting.

other factor established by the Board in regulation. In conducting this review, the Board "shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients."[13]

Additionally, if the Board is unable to determine whether a prescription drug product will produce or has produced affordability challenges the Board may consider five additional statutory factors.

B. Number of Cost Reviews and Results

Because the cost review process is under development, including the drafting of regulations necessary to implement the process, and further, because additional contracting may be required to fulfill these statutory requirements, no cost reviews were completed in 2022.

III. Recommendations

The Board does not recommend additional legislation at this time, but will continue to explore future legislation that may be effective in making prescription drugs more affordable for Marylanders.

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[13] Md. Code Ann., Health-Gen. § 21-2c-09(b).

Appendix A

Methodology Document for Analyses Requested by the Maryland Prescription Drug Affordability

The Hilltop Institute
UMBC

report

Methodology Document for Analyses Requested by the Maryland Prescription Drug Affordability Board

June 29, 2022

The Hilltop Institute

Acknowledgements

The Hilltop Institute

**Methodology Document for Analyses Requested by the
Maryland Prescription Drug Affordability Board**

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The Hilltop Institute

**Methodology Document for Analyses Requested by the
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Introduction

Health-Gen. § 21-2C-02 of the Maryland Code established the Maryland Prescription Drug Affordability Board (PDAB) to protect state residents, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from the high costs of prescription drug products.[1] Among its legislated requirements, PDAB is tasked with collecting data on brand-name and generic prescription drug products that meet certain pricing and utilization criteria.[2] PDAB contracted with The Hilltop Institute at the University of Maryland, Baltimore County (UMBC) to conduct some aspects of this analytic work. This document describes Hilltop's methodology and presents the results of the requested analyses.

Hilltop performed the following measures outlined in PDAB's statute:

1. Identified all brand name drugs or biologics that either have an inflation-adjusted launch wholesale acquisition cost (WAC) of $30,000 or more for a year or course of treatment, or an increase in the WAC of $3,000 or more in any 12-month period or course of treatment.[3] Hilltop identified **707** and **884** such drugs meeting the first and second criteria, respectively. Using only median annual utilization for each NDC, we identified **489** and **558** drugs, respectively. See Section 1 for details of the methodology used for this analysis.

2. Identified biosimilar drugs that have a launch WAC that is not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched.[4] Hilltop identified two drugs meeting these criteria. See Section 2 for details of the methodology used for this analysis.

3. Identified generic drugs with a WAC of at least $100 for a 30-day supply, and that "increased by 200% or more during the immediately preceding 12–month period."[5] Hilltop identified **483** such drugs. Of these, **447** experienced their maximum increase (of over 200%) in 2011 or later. However, only **29** drugs experienced their maximum increase in 2017 or later. See Section 3 for details of the methodology used for this analysis.

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[1] Md. Code Ann., Health-Gen. § 21-2C-02.
[2] Md. Code Ann., Health-Gen. § 21-2C-08(c)(1).
[3] Md. Code Ann., Health-Gen. § 21-2C-02.
[4] Md. Code Ann., Health-Gen. § 21-2C-08(c)(2).
[5] Md. Code Ann., Health-Gen. § 21-2C-08(c)(3).

The Hilltop Institute

Section 1: Brand Name Drugs

Health-Gen. § 21-2C-08(c) of the Maryland Code requires PDAB to identify brand name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a launch wholesale acquisition cost of $30,000 or more per year (or course of treatment); or a WAC cost increase of $3,000 or more in any 12-month period (or course of treatment if less than 12 months). PDAB requested Hilltop to conduct this analysis.

Estimation of Typical Utilization

PDAB provided Hilltop with a WAC database in late November 2021. The WAC data include *unit cost* data at the national drug code (NDC) level for brand name and generic prescription drugs, with the start and end dates during which each stated cost/price was active. In order to determine the expected cost per *treatment* with an NDC during a given year, Hilltop developed a methodology that aggregates the unit cost to a cost-per-year estimate of treatment expenditures. In general, such aggregation is challenging, as drugs may have more than one treatment indication, and prescribed amounts will vary based on patient characteristics and clinical presentation. Thus, a "bottom-up" approach to estimating annual costs for NDCs based on prescribed usage adjusted for individual patient factors will likely result in a *range* of costs that vary by these factors. Moreover, given the volume of NDCs, it is infeasible for PDAB to perform manual utilization estimates for each drug.

Due to these limitations, Hilltop employed a top-down, data-driven approach to circumvent these issues. Using prescription drug claims and encounters from Maryland Medicaid, pharmacy claims from commercial insurers in the Maryland Medical Care Data Base (MCDB), and Medicare Part D claims, for Maryland residents, Hilltop leveraged the *observed* distribution of NDC utilization among beneficiaries to *estimate* the number of units of an NDC received by a *typical recipient* during a given calendar year (CY). Then, using this derived utilization, Hilltop estimated the NDC's *annual* WAC cost.

The estimation of typical utilization relied on the observed variation among users of a given NDC during a calendar year. Suppose that, during CY 2020, 10 unique individuals had some experience with a given NDC across the respective claims databases. Among these 10 unique individuals, the hypothetical distribution of annual utilization of the drug from claims data is as outlined in Table 1 below.

Table 1. Distribution of Annual Utilization among Users of a Hypothetical NDC in CY 2020

Total Number of Units Received during the Year	Number of Unique Recipients
1	1
2	1
3	7
4	1

The Hilltop Institute

Among the 10 hypothetical individuals, 1 received a total of 1 unit of this drug in CY 2020; 1 individual received 2 units; 7 individuals received 3 units; and 1 individual received 4 units. To derive an estimate of the drug units received by a *typical* individual in a year from the distribution of drug units across users, a summary statistic can be useful to derive a single estimate from the different observations. While several types of summary statistic are available—such as mean, median, and modal utilization—Hilltop provided the mean, median, and 90th percentile. To continue the example, the median claims-based utilization from Table 1 above is 3 units.

Hilltop performed two adjustments (noted in the "Limitations" section) intended to improve the accuracy of this methodology to estimate the typical annual utilization for a given NDC. First, in order to prevent individuals with partial-year coverage from biasing estimates of typical utilization downward, Hilltop included only claims from individuals with at least 320 days of coverage by Medicaid or commercial insurance during the calendar year. Second, in order to account for potential switching between NDCs within a given drug product, Hilltop used claims for only those individuals who had not switched between NDCs in a given drug product over the course of the year.

In order to estimate the NDC-level utilization for a typical user over a calendar year, Hilltop used Maryland Medicaid claims and encounters from January 1 through December 31, 2020; MCDB claims from January 1 through December 31, 2020; and Medicare claims for Maryland residents from January 1 through December 31, 2019 (the latest year available). In total, these data sets include 57.3 million claims by 3.2 million unique individuals, which represents approximately 53% of the total Maryland population.

After estimating the typical annual utilization per NDC, Hilltop calculated the estimated annual expenditure based on drug unit costs obtained from the WAC database in order to calculate the legislative requirements.

WAC Pricing Database Transformations

To complete the analyses requested by PDAB for brand name drugs and biologics, Hilltop performed two additional operations using the WAC pricing database. First, Hilltop calculated the inflation-adjusted launch WAC for brand name and biological drugs. Second, Hilltop calculated 12-month increases in the WAC pricing database.

Inflation-Adjusted Launch WAC

To identify the launch WAC, for each NDC in the WAC pricing database, Hilltop used the *earliest* available WAC by date. Thus, while a given NDC may appear multiple times in the WAC data because of multiple WAC changes over time, Hilltop retained the WAC with the earliest active date. This is predicated on the assumption that the earliest entry in the WAC database accords with the launch date and launch price for a given NDC.

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PDAB's legislation requires inflation adjustment to account for the general increase in nominal prices over time. After consultation with PDAB members, Hilltop used the medical care index (CPI-Medical) for the main analysis (adjusted to 2022 prices). However, Hilltop also replicated its analysis using the Consumer Price Index for All Urban Consumers (CPI-U) as a robustness check.[6]

12-Month WAC Increase

In addition to identifying the launch WAC, Hilltop also identified year-over-year increases in the WAC for each drug. Hilltop used this year-over-year change in WAC in conjunction with the estimates of NDC-level utilization in order to estimate changes in annual WAC.

An NDC's WAC can change multiple times within a calendar year, which argues for a granular approach to calculating WAC increases: For example, simply calculating the increase in *average* WAC from one year to the next might mask large increases in the WAC during a given year.[7] Thus, Hilltop used the daily WAC of an NDC as the unit of analysis to identify inflation-adjusted WAC changes for each brand-name drug or biologic NDC within all 12-month periods in the data. Hilltop then retained the highest increase that occurred within a one-year period per NDC from the calculations.[8]

Hilltop operationalized this measure by first filtering out all non-brand-name and non-biologic NDCs from the WAC database. In order to determine the brand/generic status of each NDC, PDAB provided Hilltop with a file with a generic/brand indicator for each NDC. However, this indicator identified all drugs, and their corresponding NDCs, approved through a Biologics License Application (BLA) as generics. To correct for this miscategorization, Hilltop flagged all NDCs associated with a BLA application as "biological products" and created their own brand/generic indicator for these products using the following methodology:

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[6] Source for CPI-Medical inflation: https://fred.stlouisfed.org/series/CPIMEDSL; source for CPI-Urban inflation: https://fred.stlouisfed.org/series/CPIAUCSL. Using the CPI-U inflation adjustment, we identified 698 drugs meeting the threshold for a launch WAC price of at least $30,000; 931 drugs meeting the threshold for having an annual WAC price increase of at least $3,000; and 480 generic drugs meeting the trigger threshold. There is substantial overlap between these results and those estimated using the CPI-Medical inflation adjustment.

[7] For example, suppose that the WAC for a given NDC is $1 from January 1, 2018, to June 30, 2018; $2 from July 1, 2018, to February 28, 2019; and $4 from March 1, 2019, to December 31, 2019. The average (day-weighted) annual WAC would be $1.50 for 2018 and $3.50 for 2019. Thus, comparing average annual WACs would lead us to conclude that the WAC for this drug increased by $2 from 2018 to 2019. However, from March 1, 2019-June 30, 2019, the WAC technically increased by $3 (that is, from $1 to $4). This motivates our granular, day-level approach to calculating WAC increases.

[8] Hilltop's reasoning for this filter was that, if a drug's greatest WAC increase does not translate to a $3,000 increase in annual treatment cost, then its other (smaller) WAC increases also will not. Conversely, if multiple WAC increases for a given drug led to over $3,000 increase in annual treatment cost, then it is only necessary to identify one such increase.

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1. Hilltop used the Food and Drug Administration (FDA) Purple Book, current as of May 2022, to identify the following the generic name, proprietary name, and approval date of all approved "biosimilars" in the United States

2. Hilltop conducted a systematic search of manufacturer websites and press releases to identify biosimilar launch dates as these often differ from FDA approval dates

3. For biosimilars that have been launched, Hilltop used the FDA directory to identify all NDC codes for launched biosimilars and flagged these NDCs as biosimilars

4. All NDCs associated with a BLA application as "biological products" but not included in the list of NDCs as biosimilars were marked as "branded biologics"

This processing retained 44,693 NDCs of brand name drugs and biologics and included **175,627** pricing spans of these drugs. Hilltop transformed the WAC database—which was provided at the NDC-span level—into a longitudinal daily WAC per NDC structure, adjusted for inflation using the CPI-Medical, and calculated—for each NDC, for each day—the change in inflation-adjusted WAC relative to the price for each day within the previous 365 days. Hilltop then retained the maximum WAC change for each NDC.

Of the resulting maximum WAC changes, the median change in WAC unit price was **$0.0537**, while the mean change was **$22.53**. This indicates that the distribution of maximal WAC increases is significantly right-skewed, with a small number of NDCs experiencing very high WAC increases.

Results

Launch WAC of $30,000 or more

Hilltop multiplied the estimates of typical utilization by the inflation-adjusted launch WAC and retained the NDCs with an estimated WAC per year of treatment of $30,000 or more. This resulted in **707** NDCs meeting the threshold according to either mean, median, or 90th percentile utilization metrics. Using only the median utilization, Hilltop found that **489** drugs meet this threshold.

WAC Increase of $3,000 or more

Hilltop multiplied the estimates of typical NDC utilization by the inflation-adjusted increases in WAC and retained the NDCs with maximal 12-month increases of $3,000 or greater. This resulted in **884** NDCs meeting the threshold according to either mean, median, or 90th percentile utilization metrics. Using only the median utilization, Hilltop found that **558** drugs meet this threshold.

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Limitations

This methodology has several limitations. First, Hilltop estimated typical utilization for an NDC using a single (the most recently available) year of claims data. This underscores the assumptions that the annual utilization of a drug by any included individual occurred completely within the calendar year, and that utilization of the drug during the selected calendar year is representative of utilization during other years. However, it is possible for an individual to have started a course of treatment with a given NDC at any point during the prior calendar year, or for an individual to continue its use into the following calendar year. Additionally, an individual may have begun to use a given drug prior to gaining coverage through a public or commercial insurer included in these analyses. It is also possible that an individual may commence utilization of a high-cost drug shortly after becoming insured. These examples may bias the estimation of typical utilization of a given NDC under Hilltop's approach.

To partially address these concerns, Hilltop's utilization estimates include only claims from individuals with at least 320 days of coverage during the selected calendar year, which minimizes the potential influence of partial-year coverage.[9] Furthermore, the use of *median* utilization may mitigate the impact of outlying or extreme values from partial-year utilization on the reported estimates.

Second, Hilltop is only able to estimate drugs for which there is utilization or experience within the Maryland Medicaid, Medicare, or MCDB populations, and for which pricing is provided in the WAC database. Hilltop is unable to account for drugs that might meet the thresholds but for which there is no claims experience among these populations. Hilltop also did not have access to data on pharmaceutical experience by Marylanders who were uninsured or who were covered by self-insured commercial insurance plans that are exempt from reporting claims data to the state's all-payer database managed by the Maryland Health Care Commission. Hilltop's use of multiple claims data sets from the state's largest insurers for these analyses increases generalizability of the findings, but Hilltop acknowledges that the inferences of its claims-based approach may be limited to the specific drugs and populations present in the data available.

Third, to the extent that individuals may switch between different NDCs within a given drug product, it is possible for the typical utilization of a drug to be understated at the NDC level. For example, suppose a given drug product has two NDCs—one a 5 mg dose, the other a 10 mg dose—and patients sometimes change doses (either due to changing disease state, weight, age, or other conditions). If a patient changes NDCs within the calendar year, then calculating utilization at the NDC level would understate the true drug product utilization; i.e., a patient might have three claims for the first NDC and three claims for the second NDC, and this method would not recognize that these claims are for the same drug product. Hilltop mitigated the potential for this scenario to result in underestimates of NDC-level utilization by excluding

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[9] Hilltop only operationalized this 320-day coverage filter for Medicaid and Commercial claims.

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utilization from our claims database from individuals that exhibited switching between NDCs within a given drug product.

Section 2: Biosimilar Analysis

The statute also requires PDAB to identify biosimilar drugs that have a launch WAC that is not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched.[10] The following sections outline Hilltop's methodology and present the results.

Methodology

This analysis used the following data sources: the WAC data file provided by PDAB already described in Section 1 above,[11] the FDA Purple Book,[12] and the FDA NDC directory.[13] Hilltop identified biosimilars that launched at a WAC price that was not at least 15% lower than the referenced brand biologic at the time the biosimilars were launched using the following logic:

1. Hilltop used the FDA Purple Book, current as of December 2021, to identify the following:
   a. Generic name, proprietary name, and approval date of all approved biosimilars in the United States.
   b. Generic name and proprietary name of the corresponding reference biologic.
2. Hilltop conducted a systematic search of manufacturer websites and press releases to identify biosimilar launch dates as these often differ from FDA approval dates.
3. For biosimilars that have been launched, Hilltop used the FDA directory to identify all NDC codes for launched biosimilars and their originator biologics.
4. Using NDC codes, launch date data, and the WAC pricing file, Hilltop performed the following:
   a. Identified the biosimilar launch WAC.
   b. Identified the reference biologic WAC at the time of biosimilar launch.
   c. As a sensitivity check, Hilltop repeated steps 4a and 4b above by biosimilar packaging availability.
      i. For example, assume a biologic is available as a 10mg/ml 50 ml vial and a 10 mg/ml 10 ml vial. WAC pricing for the biologic is per ml and *theoretically* the pricing should be the same for a 10ml vial and a 50ml vial. To check for any potential differential pricing based on packaging, Hilltop identified the launch WAC per ml of the biologic available in a 10ml vial formulation and in a 50ml vial formulation. Then, Hilltop identified the WAC per ml of the biosimilar's reference biologic *at the time of the biosimilar's launch* for the corresponding 10ml vial formulation and the corresponding 50 ml vial formulation.

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[10] MD Code Ann., Health-Gen. § 21-2C-08.
[11] https://www.fdbhealth.com/solutions/medknowledge-drug-database/medknowledge-drug-pricing
[12] https://purplebooksearch.fda.gov/
[13] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

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d. Flagged and listed biosimilars that launched at a WAC that was not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched.

Results

Hilltop identified 21 biosimilars that had *launched* as of December 2021. Of these, only two launched at a WAC that was not at least 15% lower than the referenced brand biologic at the time of their launch (Table 2).

Table 2. Biosimilars that Meet PDAB Trigger

Biosimilar Name	Launch Date	Reference Product	% Discount
Herzuma (trastuzumab-pkrb)	March 2020	Herceptin (trastuzumab)	10%
Truxima (rituximab-abbs)	November 2019	Rituxan (rituximab)	10%

On July 28, 2021, the FDA approved Semglee (insulin glargine-yfgn) as the first *interchangeable* biosimilar. This approval of Semglee as interchangeable was associated with a WAC increase from $9.87/ml to $26.94/ml. To the extent that one considers interchangeable Semglee a "new" biosimilar approval, it launched at only a 5% discount from the referenced biologic (Lantus) WAC, meeting PDAB's trigger.

Section 3: Generic Drugs Analysis

PDAB is required to identify generic prescription drug products that meet two requirements. First, as adjusted annually for inflation in accordance with the Consumer Price Index, the generic drug must have a WAC of $100 or more for one of the following:

- A 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the FDA

- A supply lasting a patient for fewer than 30 days based on the recommended dosage approved by the FDA

- One unit of the drug if the labeling approved by the FDA does not recommend a finite dosage

Second, the generic drug increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting WAC and the average of the wholesale acquisition cost reported over the immediately preceding twelve months.[14]

This section of the report outlines Hilltop's approach to these measures.

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[14] MD Code Ann., Health-Gen. § 21-2C-08(c)(3).

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Identification of Generic Drugs

As a first step, Hilltop identified the universe of generic drugs from the file provided by PDAB described in Section 1 above.

Order of Operations

Hilltop's interpretation of the legislative requirement described above is that any generic drug identified through this analysis must cost at least $100 for a 30-day supply <u>and</u> have a price increase of greater than 200%. Drugs without **both** conditions will not be identified. However, it is important to note that Hilltop did not interpret the language of the statute to imply temporal ordering: that is, we identified the intersection of the sets of drugs which were (a) <u>ever</u> above $100 for a 30-day supply, and which (b) had <u>ever</u> experienced an annual WAC increase of over 200%. Hilltop did not require these to occur in the *same* calendar year.

Estimation of Typical Utilization

The legislative language indicates that PDAB must calculate the inflation-adjusted WAC for a 30-day supply of a given generic drug based on recommended dosage approved for labeling by the FDA for each generic drug.[15] However, the WAC database available for this analysis contains *unit* cost data at the NDC level. This analysis, then, must estimate the number of units that make up a 30-day supply based on FDA recommended dosage for each generic drug and then multiply that estimate of utilization by the appropriate WAC unit cost.

It is important to note that dosage can vary for 30-day supplies of a given NDC, meaning that— for example—one individual might receive 30 units, another might receive 15 units, and another 60 units. While dosage can vary for several reasons, given the volume of generic drugs currently available, it is infeasible to manually identify the recommended dosage for every drug. Instead, as with the legislative measures described in Section 1 above, Hilltop pursued a data-driven approach to identifying the generic drugs that fulfill these criteria. Hilltop used Medicaid, Medicare, and MCDB data to identify the median NDC-level utilization for all claims with a 30-day supply or less. We then linked these estimates of typical utilization to the WAC pricing database in order to calculate the legislative requirements.

Hilltop notes that, for the purposes of this analysis, it is not necessary to impose the corrections used for the brand-name legislative measures described in Section 1 above. The estimate of utilization for generic drugs occurs at the claim level, not the person-year level, so partial-year coverage should not affect our estimates. Similarly, while NDC-switching may affect utilization estimates for an individual over a year, this should not affect claim-level utilization estimates.

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[15] Hilltop operationalized this by keeping all claims with supply less than or equal to 30 days but refers to these as drugs with a 30-day supply in the text for ease of exposition.

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WAC Pricing Database Transformations

As with the approach to the brand-name drug legislative measure, in order to complete the generic legislative measure, it was necessary to transform the WAC pricing database twice. First, Hilltop calculated the inflation-adjusted WAC for generic drugs. Second, Hilltop calculated relative price increases in the WAC pricing database. Trigger drugs were identified as meeting both conditions. Each of these operations is discussed in turn.

Inflation-Adjusted WAC

While a given NDC's WAC may change multiple times during a calendar year, the legislative language only requires the identification of drugs that ever cross the threshold of $100 or more for a 30-day supply (or less). To that end, Hilltop transformed the WAC database into the *maximum* inflation-adjusted WAC per calendar year for generic drugs (using CPI Medical). This data reduction step allowed Hilltop to identify which generic drugs met this trigger while also significantly reducing the computational load.

200% Increase in WAC

Next, Hilltop performed a second transformation of the WAC pricing database by identifying all generic drugs for which the price had increased by 200% or more relative to average WAC over the previous 12 months. This will identify NDCs for which the WAC sharply rose, relative to trend.

The WAC pricing database contains tens of thousands of generic NDCs, each of which consists of many years of pricing history. Thus, creating an NDC-day panel data set directly from the WAC pricing database would result in hundreds of millions of NDC-day observations; computing the average WAC for each 365-day period (as required by the legislative ask), for each NDC, would require substantial computing resources.

Instead, we used the order of operations cited above to estimate the annual price increases for the subset of NDCs that were identified as meeting the first criteria. That is, for the **7803** NDCs meeting the threshold of a $100 WAC for a 30-day supply or less, we transformed the WAC pricing database into an NDC-day structure, adjusted for inflation using CPI-Medical, and then looped over each 365-day period in which the drug appears in the WAC pricing database to compute the average inflation-adjusted WAC. Then, we calculated the change in WAC for each day, relative to the average price over the previous year.

Hilltop notes that a small number of drugs have a WAC of $0 at certain points. In order to avoid erroneously flagging these drugs as experiencing large proportional price increases, we removed these NDCs from the WAC pricing file prior to conducting this analysis.

Of the **7803** NDCs that meet the $100 or more threshold, Hilltop found that **483** of these also experienced a price increase of 200% or more.

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Limitations

Hilltop estimated the utilization for generic drugs for all claims with supply of 30 days or less. By aggregating all claims with a supply of 30 days or less, it is possible to understate true 30-day utilization: for example, a generic drug may have two claims—one for a 30-day supply with a quantity of 30, and one for a 14-day supply with a quantity of 14—and the median utilization estimate across these claims will be the mid-point of the two, or 21. While this may understate true utilization for 30-day supplies of a given generic drug, we believe that this interpretation is in line with the language of the PDAB enabling legislation. Moreover, to the extent that a preponderance of the utilization of a given drug is for fewer than 30 days, then it is not inappropriate that the utilization estimate reflects both the distribution of days' supply and the distribution of quantity.

It is important to note that this top-down, data-driven method of estimating utilization presumes that, if an individual has incurred a claim and that claim has been processed, adjudicated, and paid, that the quantity supplied accords with recommended dosage approved for labelling by the FDA. Hilltop believes that use of the median utilization of a given NDC should minimize the possibility that any erroneous or inappropriate dosages are used to identify drugs meeting the threshold.

Additionally, Hilltop does not explicitly identify drugs for which the FDA does not recommend a finite dosage; the algorithm will capture these drugs based on claims-based experience, but Hilltop is unaware of a scalable methodology to identify these drugs.

Additionally, as noted above, Hilltop did not require temporal ordering: that is, we identified the NDCs that ever cost $100 or more for a 30-day supply or less, and then, from this pool, identified drugs that ever incurred a price increase of 200% or more. This leaves open the possibility that a drug may incur a large proportional price increase—for example, a WAC increase from $0.01 to $0.04—without hitting the $100 threshold due to that particular price increase but instead hit the $100 threshold (potentially years) later due to gradual price increases. Hilltop believes that this circumstance will be relatively rare.

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