MILLIMAN WHITE PAPER

Biosimilar Utilization at 340B and Non-340B Outpatient Hospitals in the Commercial Market

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SUMMARY

Biosimilar products are FDA approved competitors to originator biologic products, known as reference products. Biosimilars reduce overall costs both directly, by offering lower priced alternatives, and indirectly, by causing downward pricing pressures on reference products as they compete for market share. Biosimilars are highly similar to their reference products both in safety and effectiveness, but growth of biosimilars in the US has been modest[1]. Milliman studied biosimilar market share at 340B and non-340B outpatient hospitals for commercially insured patients from 2017 to 2020. Overall, we found:

- On average, biosimilar utilization at 340B outpatient hospitals is lower than at non-340B outpatient hospitals across all four study years.
- Patient out-of-pocket costs are higher for reference products than for biosimilars. Among claims subject to cost sharing at 340B facilities, patient out-of-pocket costs are 16.1% lower on average for biosimilars compared to the reference product.

The lower biosimilar adoption at 340B than non-340B hospitals may be contributing to higher patient out-of-pocket costs than if biosimilar use was more prevalent.

BACKGROUND

BIOSIMILAR DRUGS

Biological products represent a growing source of health care spending, naturally putting pressure on payers and providers to pursue strategies to curb these costs. Shifting utilization from reference to biosimilar products could be one tactic towards containing increasing outpatient drug costs.

The FDA approved the first biosimilar drug in March 2015. As of mid-2022, there are 22 biosimilars available in the US. Biosimilar adoption has been slow despite the potential cost savings. However, the most recently launched biosimilars achieved higher market share during the year of launch, suggesting that the rate of biosimilar adoption is increasing. Most biosimilars currently available are administered in an outpatient facility or physician's office and covered under the medical benefit. This study focuses specifically on biosimilar utilization at outpatient facilities.

340B PROGRAM

The 340B program, administered by the Health Resources and Services Administration (HRSA) within the Department of Health and Human Resources (HHS), allows participating hospitals to obtain certain outpatient medications at discounted rates, which can range from 23.1% (minimum statutory Medicaid rebate rate) to 100%. These hospitals (referred to as 340B hospitals) are eligible for the program based on serving a disproportionate share of low-income Medicare and Medicaid patients and other specified criteria. Since providers keep the difference between the reimbursement amount and the drug's acquisition cost at the 340B price, there may be financial incentives for participating hospitals to prescribe more expensive reference products.

RESULTS

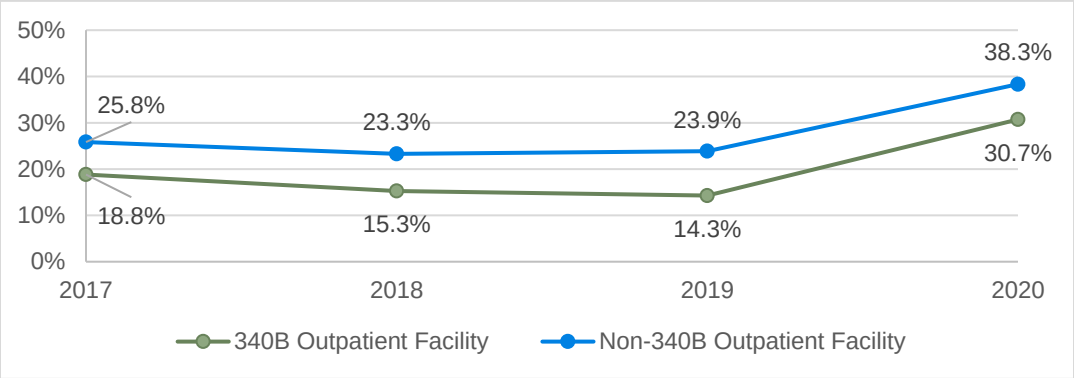
This study found that on average, utilization of biosimilars at 340B hospitals is lower than at non-340B hospitals.

Figure 1 shows biosimilar utilization as a percentage of total combined biosimilar and reference product utilization, limited to molecules with a biosimilar available in each given year. For example, a value of 5% indicates that 5% of utilization was for biosimilars and 95% was for the reference products.

[1] Kvien TK, Patel K, Strand V. The cost savings of biosimilars can help increase patient access and lift the financial burden of health care systems. Semin Arthritis Rheum. Published online December 30, 2021: https://www.ajmc.com/view/us-uptake-of-biosimilars-remains-suboptimal-and-requires-intervention

FIGURE 1: BIOSIMILAR UTILIZATION AS A PERCENTAGE OF TOTAL BIOSIMILAR + REFERENCE PRODUCT CLAIMS

340B VERSUS NON-340B SETTINGS – COMMERCIAL MARKET



For all four years studied, 340B utilization of biosimilar drugs is lower than that of non-340B hospitals. Since 340B providers' compensation is greater due to the larger margin between the acquisition cost and reimbursement for the drug, they may be incentivized to utilize medicines with a higher price. Therefore, 340B hospitals may choose to continue using reference products over the lower list-priced biosimilars.

Figure 1 shows that biosimilar drug utilization decreased in 2018 and 2019 relative to 2017. This is driven by a different mix of products with biosimilars available in each year. As new biosimilars launch, overall biosimilar market share could temporarily drop if biosimilar market share is initially small, which occurred for a new biosimilar introduced in 2018. However, within any given therapy, biosimilar utilization increased from each year to the next.

In 2020, biosimilar utilization for the seven molecules with biosimilars available during the study period (bevacizumab, epoetin alfa, filgrastim, infliximab, pegfilgrastim, rituximab, and trastuzumab), averaged 30.7% at 340B facilities, ranging from 15.6% to 73.1% by product, and 38.3% at non-340B facilities, ranging from 21.7% to 91.8%. At both 340B and non-340B facilities, products with the longest biosimilar availability in the market had the highest share of biosimilar utilization by 2020.

Biosimilar utilization increased across every product from 2017 to 2020. In 2017, filgrastim and infliximab were the only products with biosimilars available. While biosimilar adoption was relatively slow between 2017 and 2018, there was a notable increase in available biosimilar drugs and biosimilar usage in 2019 and 2020. In particular, non-340B hospitals have been quicker than 340B hospitals to adopt biosimilar drugs shortly after their launch.

Biosimilar claim costs are typically about 20% to 40% lower than their reference products. The difference between these prices tends to increase over time. It is typical for outpatient drugs to be subject to a coinsurance benefit—which is often based on a markup from the medicines' average sales price (ASP), not the price the provider or insurer ultimately pays (net of rebates)—such that patient out-of-pocket costs are lower when a lower-cost drug is used.

At 340B hospitals in 2020, the average out-of-pocket patient cost per claim for biosimilars was 16.1% lower than for their reference products, for therapies launched before 2020. The relationship between patient cost is similar to the ratio of allowed costs. Patient out-of-pocket costs would generally be lower if biosimilar utilization was greater.

DISCUSSION

This study indicates that 340B hospitals have a lower rate of adopting and utilizing biosimilar drugs than non-340B hospitals. Since providers' compensation is tied to the price of the drug, and 340B providers receive a larger margin due to lower acquisition costs, they may be incentivized to utilize medicines with a higher price. While biosimilar list prices and reimbursement rates are typically 20% to 40% lower than their reference products, the price at which 340B hospitals acquire drugs does not necessarily follow the same pattern, and there may be cases where biosimilar acquisition costs are actually higher than reference product acquisition costs. However, as patient costs are often tied to the list price, patients do not benefit from these additional discounts.

Our study focuses on understanding biosimilar utilization and the implications for patient cost sharing at 340B outpatient hospitals. While we did not study differences in purchase prices between 340B and non-340B facilities, prior studies[2,3] concluded that the commercial reimbursement margin for outpatient hospital medications is higher at 340B hospitals than at non-340B hospitals, and therefore, 340B hospitals may be incentivized to

[2] U.S. Government Accountability Office. (2015, June). MEDICARE PART B DRUGS: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. (Publication No. GAO-15-442). Retrieved from https://www.gao.gov/assets/680/670676.pdf

[3] Milliman, Inc. (2019, December). Analysis of 340B hospitals' outpatient department acquisition cost and commercial reimbursement for physician-administered brand medications. Retrieved from: *https://assets.milliman.com/ektron/Margin_Analysis_of_HOPD_Rx_at_340B_Hospitals.pdf*

prescribe more medications or more expensive medications. As such, the mix of higher-cost reference products could contribute to higher out-of-pocket costs than if more biosimilars were used.

Commercial insurance plans are subject to a maximum out-of-pocket (MOOP) limit of no more than $8,150 for self-only coverage in 2020, and average MOOPs are closer to about $4,000[4]. Given the cost of biologics, it is possible many patients will reach their MOOP, especially those in high deductible health plans. As such, it is possible a patient may have the same annual out-of-pocket spending, equal to their MOOP, regardless of whether they use a biosimilar or reference product. However, patients not reaching MOOP would generally have savings when using a biosimilar, and even those reaching their MOOP would typically have lower costs per claim and spread their costs more evenly throughout the year.

This study focuses on hospital outpatient pharmacy claims. Some patients also receive the studied products at a physician's office. We did not attempt to evaluate professional biological claims and retail pharmacy outpatient claims at contract pharmacies. These claims would primarily be for self-administered medications and less likely to be reimbursed through the medical benefit (the focus of this study).

Payer formularies are a factor that could influence biosimilar utilization in the future. While drugs covered under the medical benefit have historically not been subject to as many (or sometimes any) formulary controls as drugs covered under the pharmacy benefit, more attention has been given to medical benefit products in recent years. In some cases, payers may require a patient to try the biosimilar before the reference product[5], which could cause a future shift toward more biosimilar utilization even at 340B facilities.

METHODOLOGY

DATA SOURCES

We used Milliman's 2017, 2018, 2019, and 2020 Consolidated *Health Cost Guidelines* Sources Database (CHSD) as the source for all claims data in this study. The CHSD dataset contains over 40 million lives from commercial lines of business and is a consolidation of member experience data contributed by numerous health plans throughout the nation. Prior to using the data, we validated it for consistency and overall reasonability.

We used Health Resources & Services Administration's (HRSA) 340B database to identify 340B hospitals.

IDENTIFYING HOSPITAL TYPES

We use a combination of Medicare IDs and National Provider Identifiers (NPIs) to identify providers in our CHSD database as a 340B or non-340B hospital for each year. We identified 340B participating hospitals using HRSA's Office of Pharmacy Affairs on-line database. We limited the outpatient results to short term care hospitals, as defined by CMS's public use files (PUF), in the 48 contiguous states, Hawaii, Alaska and Washington, D.C.

BIOSIMILAR AND REFERENCE PRODUCTS

To identify biosimilars and their corresponding reference products, we used the Healthcare Common Procedure Coding Systems (HCPCS) Reimbursement Codes Master Datafile (RCMD), which lists all active biological products categorized under each HCPCS reimbursement code. We are only able to identify biosimilars if they were coded with a separately payable HCPCS. Therefore, if a biosimilar was coded with a not-otherwise-classified (NOC) code, it was excluded from this analysis.

COST SHARING

Cost sharing is defined as the out-of-pocket expenses for the patient including deductible, coinsurance, and copay. Premiums are not included as part of cost sharing. We calculated cost sharing on a per patient per claim basis for each molecule. Note there may be some differences in dosing for certain biosimilars, though the dosages in our data generally aligned. Many claims have no patient out-of-pocket costs due to patients hitting the out-of-pocket maximum. To adjust for this, we removed claims with zero patient out-of-pocket cost when calculating averages. However, we also compared results with zero patient cost claims included, and the difference between biosimilar and reference products was even greater.

OTHER EXCLUSIONS

We limited our data to hospital outpatient claims from hospitals providing short-term acute care in the 50 states and Washington, D.C. As such, we omitted:

- Any hospital not providing acute care
- Hospitals outside of the 50 states and Washington, D.C.
- Prospective Payment System (PPS)-exempt hospitals
- Freestanding cancer centers
- Sole community hospitals
- Children's hospitals
- Rural referral centers
- Critical access hospitals

In addition, we excluded the following claims from this analysis:

- Claims occurring at an inpatient setting
- Claims with non-positive units or allowed reimbursement
- Outpatient hospital claims that did not have an identifiable NPI

[4] Kaiser Family Foundation. 2020 Employer Health Benefits Survey. Published October 2020. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf

[5] Joszt, Laura. "Mayo Clinic Saves $23M Through Biosimilar Adoption Program." Retrieved from https://www.ajmc.com/view/mayo-clinic-saves-23m-through-biosimilar-adoption-program

CAVEATS AND LIMITATIONS

This report is designed to assist PhRMA in better understanding the difference in biosimilar outpatient utilization between 340B participating and non-participating hospitals for commercially insured patients. This work is not intended to be used for other purposes or to benefit any other party. PhRMA may share this report to third parties with Milliman's permission. Milliman does not intend to benefit, and assumes no duty or liability to, other parties who receive this work product. Any third party recipient of this report who desires professional guidance should not rely on Milliman's work product, but rather should engage qualified professionals for advice appropriate to its own specific needs. Any releases of this report should be in its entirety.

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to analyze biosimilar utilization at different settings. We have reviewed the models, including their inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP). The models rely on data and information as input to the models. In preparing this analysis, we relied on the 2017, 2018, 2019, and 2020 Consolidated *Health Cost Guidelines* Sources Databases (CHSD), Milliman *Health Cost Guidelines*™ (*HCGs*), and HRSA 340B database. While we reviewed this data for reasonableness, we did not audit or independently verify any of the information furnished. To the extent that the data and information relied upon is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

Katie Holcomb and Peter Chang are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to perform the analysis supporting this report. The material in this report represents the opinion of the authors and is not representative of the views of Milliman.

The terms of the Master Services Agreement between Milliman and PhRMA, signed January 19, 2016 and amended October 26, 2021, apply to this report and its use.

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