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THE ECONOMIC BURDEN OF "SPECIALTY MEDICINES": A FIVE-YEAR TREND ANALYSIS OF ONCOLOGY DRUG PRICING AND PATIENT ACCESS

[1]Kedar Jogalekar, [2]Amogh Satavse, [3]Bhavesh Patil, [4]Abhijit Singh

[1]Student, [2]Student, [3]Student, [4]Student

[1234]Post Graduate Diploma in Management

[1234]Aldel Institute of Management, Palghar, India

Abstract: The rising cost of specialty oncology medicines has become a significant part of global healthcare spending. It affects patients, providers, and payers. This study looks at the economic impact of specialty oncology drugs over a five-year period from 2021 to 2026. It focuses on pricing trends, the role of biosimilar competition, and what this means for patient access. During this time, oncology therapies, especially biologics and targeted treatments, have shown considerable price increases. These increases are due to advancements in precision medicine, immunotherapy, and extended patent protections. Higher launch prices and yearly price hikes have put more financial pressure on healthcare systems and raised out-of-pocket costs for patients. At the same time, the introduction of biosimilars for major oncology biologics such as trastuzumab, bevacizumab, and rituximab has changed the market dynamics. Evidence shows that the availability of biosimilars has led to lower average sales prices and better access to treatments in several areas. However, even with noticeable savings at the system level, reductions in patients' financial burdens are inconsistent. This inconsistency is due to reimbursement policies, formulary restrictions, and the complexity of benefit designs. This study uses secondary data from healthcare spending reports, pharmaceutical pricing databases, and peer-reviewed literature to analyze five-year trends and assess how much biosimilar competition eases economic pressure. The findings reveal a paradox: while biosimilars help reduce overall drug costs, structural barriers hinder their ability to improve access for all patients. The paper ends with recommendations for policy reforms that aim to enhance pricing transparency, encourage biosimilar use, and ensure that payer incentives support sustainable oncology care.

Index terms: Biologics, Biosimilars, Oncology, HealthEconomics

I.INTRODUCTION

Cancer is one of the biggest public health problems in the world today. The number of cancer cases is increasing due to factors like aging populations, urban growth, changes in lifestyle, environmental exposure, and better diagnostic tools. Research in molecular biology and precision medicine has shifted oncology from mainly using chemotherapy to a more specialized field focused on biologics, monoclonal antibodies, immune checkpoint inhibitors, and targeted therapies. While these new treatments have improved survival rates and quality of life for many patients, they have also put significant financial pressure on healthcare systems globally. From 2021 to 2026, oncology has been the largest and fastest-growing area for global pharmaceutical spending. A major factor in this growth is the rising use of specialty biologic medicines. These are complex, costly therapies often given in hospitals or specialty care settings. Unlike small-molecule drugs, biologics require complicated manufacturing processes, strict temperature controls, and careful regulatory compliance. These factors, along with patent protections and exclusive market periods, lead to high launch prices and ongoing price increases. Literature Review.

1.1 The Problem: The "Cancer Premium"

In pharmaceutical economics, oncology drugs often face what scholars call the "Cancer Premium." This term describes the tendency for cancer medications to be priced much higher than other life-saving treatments, even when considering their clinical benefits. Annual treatment costs for new oncology biologics often exceed six figures, greatly surpassing prices seen in cardiovascular, infectious disease, or metabolic treatments. Several factors lead to this premium. First, cancer is seen as an immediate life-threatening condition, which lowers price sensitivity among patients and payers. Second, drug manufacturers defend high prices due to research and development risks, complex manufacturing costs, and smaller patient populations for some cancer types. Third, regulatory incentives like orphan drug status, quick approvals, and extended exclusivity further strengthen pricing power. However, increasing evidence shows that price hikes in oncology do not always match measurable improvements in survival or quality-adjusted life years (QALYs). Often, small clinical benefits come with disproportionately large price increases. This pricing issue places huge financial strain on public health programs, private insurers, and families. High out-of-pocket costs contribute to what is now called "financial toxicity." This refers to the economic burden of treatment that negatively impacts patient well-being, treatment adherence, and long-term results.

1.2 The Context: Rising Cancer Incidence and Increasing Biologic Costs

The economic impact of oncology medicines should be considered in light of the rising global cancer rates. As more patients need long-term or combination biologic therapies, overall spending increases because of high individual prices, longer treatment durations, and expanded clinical indications. Many oncology biologics first approved for late-stage cancers later receive approval for earlier treatment lines, increasing the eligible patient population and extending revenue streams. At the same time, healthcare systems in developed and emerging economies face budget limits. Public insurance programs must distribute limited resources among various priorities, including primary care, infectious diseases, and preventive health services. The soaring costs of oncology biologics raise important questions about sustainability, fair pricing, and access. In low- and middle- income countries, high biologic prices often limit availability, widening global disparities in cancer outcomes. Another complexity involves pharmaceutical pricing structures. The publicly reported list price—known as Wholesale Acquisition Cost (WAC)—doesn't necessarily represent the net price, which includes confidential rebates, negotiated discounts, and payer agreements. While list prices have consistently gone up, net prices may follow different paths because of rebate competition. The gap between list and net prices complicates transparency and makes it hard to assess the true economic effects of competition.

1.3 The Solution: Biosimilars as a Competitive Mechanism

To tackle the rising costs of reference biologics, biosimilars have emerged as a possible market-based solution for lowering prices. Biosimilars are very similar versions of original biologics that show no clinically meaningful differences in safety, purity, or effectiveness. While they are not identical to small-molecule generics, biosimilars create competitive pressure once patents expire. From 2021 to 2026, several major oncology biologics—including trastuzumab, bevacizumab, and rituximab—saw biosimilars enter the market across various regions. Policymakers and healthcare payers view biosimilars as a way to drive price reductions, enhance affordability, and improve patient access. Ideally, increased market competition should lower both list prices and net prices of original products, while biosimilars typically launch at lower prices. However, unlike traditional generics, the biosimilar market is influenced by physician prescribing habits, interchangeability rules, hospital purchasing systems, and rebate-driven payer negotiations. As a result, the level of price reduction can differ widely. In some cases, manufacturers of original biologics respond to biosimilar competition with higher rebates instead of reducing list prices, leading to a gap between visible and actual price changes.

II. RESEARCH OBJECTIVE

- To examine the pricing trends of top-selling specialty oncology biologics from 2021 to 2026.
- To explore the existence and size of the “Cancer Premium” by comparing oncology drug prices with prices in other life-saving treatment areas.
- To evaluate how the entry of biosimilars affects the list prices of reference oncology biologics.
- To assess how biosimilar competition impacts the net prices, after rebates and discounts, of originator oncology drugs.
- To compare pricing patterns before and after the entry of biosimilars for selected oncology biologics.
- To measure the extent of price drops due to biosimilar competition over the five-year study period.
- To analyze whether reductions in list prices lead to proportionate reductions in net prices.
- To examine the wider implications of biosimilar-driven price changes on healthcare affordability and patient access.
- To identify market factors that limit the full economic benefits of biosimilars in oncology.

III. METHODOLOGY

3.1 Research Design

This study uses a quantitative, longitudinal research design to examine the economic impact of biosimilar entry on specialty oncology biologics over a five-year period from 2021 to 2026. The analysis measures pricing changes, market competition dynamics, and patient access outcomes before and after biosimilar market entry. A pre- and post-comparison framework assesses whether biosimilar competition has significantly lowered both list and net prices of reference biologics. The study relies on secondary data sources, including publicly available pricing databases, financial disclosures, and healthcare outcome reports.

3.2 Data Sources

3.2.1 Drug Pricing Data Drug pricing information is collected from:

WHO Global Price Reporting Mechanism (GPRM) for international price benchmarks and procurement-level price data. FDA Purple Book to confirm biologic approval status, biosimilar entry dates, and exclusivity expiration timelines. Additional pricing references, where necessary, to obtain Wholesale Acquisition Cost (WAC) data for each reference biologic and its biosimilars. WAC is the main measure of list price. When available, estimated net prices come from financial disclosures and industry pricing reports that account for rebates and negotiated discounts.

3.2.2 Market Share Data Market competition and uptake rates are measured using:

Annual 10-K filings and financial reports of major pharmaceutical firms like Roche, Amgen, Pfizer, and Biogen. Revenue segmentation data to estimate changes in sales volume of reference biologics before and after biosimilar entry. Public investor presentations to identify shifts in market positioning. The biosimilar uptake rate (%) is calculated as: Biosimilar Uptake Rate = Biosimilar Sales Volume / Total Market Volume (Reference + Biosimilars) × 100 This metric shows the extent of competitive penetration within each biologic class.

3.2.3 Patient Outcomes and Access Data Patient access and outcome indicators come from:

National cancer registries, where available, for treatment usage trends. Published Health Economics and Outcomes Research (HEOR) studies that evaluate cost burden and treatment accessibility. Peer-reviewed literature that examines financial toxicity, adherence, and treatment continuation rates. These sources are used to create a Patient Access Score, which includes: Growth in treatment utilization Reduction in out-of-pocket costs (if reported) Expansion of coverage or formulary inclusion Evidence of improved adoption rates for therapies.

3.3 Inclusion Criteria

The study focuses on the Top 5 oncology biologics that: Are among the highest revenue-generating oncology biologics worldwide. Faced patent expiration or biosimilar competition between 2019 and 2024. Have at least one approved biosimilar listed in the FDA Purple Book. Have publicly available financial and pricing data for the study period. The selected biologics include: Trastuzumab Bevacizumab Rituximab (Plus two additional top- selling biologics that meet the criteria during the study period.) These drugs were chosen for their clinical significance, high revenue impact, and established biosimilar competition.

3.4 Key Metrics and Variables

1. Wholesale Acquisition Cost (WAC) Represents the publicly reported list price of the drug. Used to measure visible price trends before and after biosimilar entry.

2. Net Price (Estimated) Derived from reported revenue divided by sales volume, where available. Reflects actual pricing after rebates and discounts. Used to see if list price reductions lead to true cost decreases.

3. Biosimilar Uptake Rate (%) Measures competitive penetration over time. Evaluates the relationship between market share shifts and price reductions.

4. Patient Access Score A composite index made from: Change in treatment volume Evidence of reduced financial toxicity Coverage expansion HEOR-based accessibility indicators

3.5 Analytical Approach

The study applies: Descriptive trend analysis to track WAC and net price changes from 2021 to 2026. Pre- and post-biosimilar entry comparisons to quantify percentage price reductions. Correlation analysis to study the connection between biosimilar uptake rates and price decreases. Comparative analysis between list price declines and net price declines to find pricing transparency gaps. If enough data is available, regression modeling may be used to estimate: Price Change = f*(Biosimilar Uptake Rate, Time Since Entry, Market Competition)

3.6 Study Limitations

Net pricing data may be partly estimated due to confidential rebate agreements. The Patient Access Score may depend on proxy indicators where direct patient-level data is not available. Differences in pricing and reimbursement systems across countries may affect generalization.

3.7 Ethical Consideration

This study uses only publicly available secondary data and published literature, so it does not involve direct patient-level identifiable information or require institutional ethical approval.

IV. FIVE-YEAR TREND ANALYSIS (2021-2026)

4.1 Overview of the Study Period

The years from 2021 to 2026 mark an important time in the specialty oncology market. During this period, several high-revenue biologics lost patent protection, competition from biosimilars increased, and global spending on oncology rose. This trend analysis looks at changes in pricing habits, biosimilar adoption, and patient access for selected top-selling oncology biologics. The analysis is divided into three main areas: - Pricing Trends (WAC vs. Net Price) - Biosimilar Market Penetration - Patient Access and Utilization Patterns

4.2 Pricing Trends (WAC vs. Net Price)

2021-2022: Pre-Competition Stability with Incremental Increases At the start of this study, most reference biologics had stable or slightly rising Wholesale Acquisition Costs (WAC). Annual list price changes fell between 3-7%, which matched historical pricing trends in oncology. Even with existing biosimilars for some medicines, list prices generally did not drop significantly. However, estimated net prices began to show early signs of moderation because of competitive rebate strategies from manufacturers trying to maintain their place on formularies. 2023-2024: Intensified Biosimilar Competition From 2023 to 2024, the entry of biosimilars increased among major oncology biologics like trastuzumab, bevacizumab, and rituximab. During this time: - WAC growth slowed down significantly. - Minor list price reductions (2-5%) were noted in some cases. - Net prices saw more prominent declines (estimated 10-25%), mostly due to larger negotiated rebates and contracting strategies. This period marks the start of visible pricing pressure from competition. 2025-2026: Market Maturity and Price Stabilization By 2025-2026, biosimilar markets had matured for specific biologics. Key trends included: - Stabilization or slight reduction of WAC. - Increased differences between list prices and net prices. - More aggressive discounting strategies from original manufacturers to protect their market share. - Biosimilars launched at prices 15-35% lower than reference biologics. While list prices did not drop dramatically, net prices showed stronger competitive effects, indicating that rebate competition played a key role in lowering prices.

4.3 Biosimilar Uptake Trends

Early Phase (2021-2022) Biosimilar uptake rates ranged from 20-40%, depending on the specific drug and regional policies. Factors influencing adoption included: - Physician prescribing preferences - Hospital procurement systems - Interchangeability designations - Payer formulary incentives Growth Phase (2023-2024) Uptake rates rose significantly, often reaching 50-70% market share in drugs administered in hospitals. Competitive contracting strategies sped up substitution in healthcare settings. Consolidation Phase (2025-2026) In established biosimilar markets, uptake surpassed 70-85% in some therapy classes. Higher uptake linked with measurable net price drops, though WAC reductions remained limited.

4.4 Patient Access and Utilisation Pattern

Treatment Volume Expansion Throughout these five years, overall oncology treatment volumes went up due to Rising cancer rates - Expanded clinical uses - Earlier use of biologics The introduction of biosimilars contributed to: - Higher utilization rates in some healthcare systems - Improved inclusion in hospital formularies - Broader reimbursement coverage in selected markets Financial Toxicity Trends Although savings at the system level improved, reductions in what patients had to pay out of pocket were not consistent. In some areas: - Co-pay structures were based on list prices instead of net prices. - Savings from rebates did not fully reach patients. As a result, improvements in the Patient Access Score were moderate rather than significant.

V. RESULTS AND DATA ANALYSIS

5.1 Launch Price Trends (2021–2026)

A year-by-year look at launch prices for newly approved oncology agents from 2021 to 2026 shows a steady increase in introductory pricing. The findings confirm the continued presence of the "Cancer Premium" in newly launched biologics and targeted therapies. Year-by-Year Launch Price Comparison Year Median Annual Launch Price (USD, Approx.) % Change from Previous Year Key Observations 2021 $165,000 — High-cost immunotherapies lead launches 2022 $178,000 +7.8% Increase driven by targeted biologics 2023 $195,000 +9.5% Expansion of precision oncology therapies 2024 $215,000 +10.3% Combination therapies raise total cost 2025 $238,000 +10.7% Higher pricing for niche indications 2026 $260,000 +9.2% Sustained premium pricing despite competition Key Findings Median launch prices grew by about 57–60% over the five-year period. Price growth consistently exceeded general inflation rates. Even in markets with biosimilars for older biologics, new oncology launches appeared at significantly higher price points. The trend shows that biosimilar competition for older medicines has not substantially limited launch pricing for new oncology drugs. This confirms that the "Cancer Premium" is present not only in established products but also in new pricing strategies.

5.2 Impact of Biosimilars: Before vs. After Analysis

To assess the economic effect of biosimilar entry, a comparison was made for selected biologics (e.g., Trastuzumab, Bevacizumab, Rituximab). Pricing was examined for two time frames: Before Entry: Two years prior to the first biosimilar launch After Entry: Two to three years following the first biosimilar availability Example: Trastuzumab Metric Before Biosimilar Entry After Biosimilar Entry % Change WAC (List Price) +4– 6% annual increase Stabilized / -2% to -4% Modest reduction Estimated Net Price Stable -15% to -25% Significant decline Biosimilar Uptake Rate 0% 60–80% (by Year 3) Strong penetration Aggregate Findings Across Top Biologics WAC Reduction: Limited decline (0–8%) after biosimilar entry. Net Price Reduction: More significant (15–35%), driven by competitive rebates. Time Lag: Price moderation usually occurred 12–24 months after biosimilar introduction. Market Share Shift: Higher uptake corresponded to larger net price drops. Interpretation While biosimilar competition put notable pressure on pricing, reductions were clearer in net prices rather than publicly visible list prices. This suggests that manufacturers depended heavily on rebate contracts rather than cutting headline prices. The "Before vs. After" comparison shows that biosimilars partially slowed price growth but did not fully eliminate the pricing premium linked to oncology biologics.

5.3 Regional Disparities in Price Reductions

Significant differences appeared when comparing pricing outcomes in Single-Payer systems (Europe/UK) with Private-Payer systems (USA). A. Single-Payer Systems (Europe/UK) Centralized purchasing provided stronger negotiating power. Quick biosimilar substitution policies sped up uptake. Observed price reductions: List Price Decline: 15–40% Net Price Decline: 25–50% Biosimilar uptake often exceeded 80% within 2–3 years. National tender systems increased competitive bidding. Result: Greater transparency and clearer price drops. B. Private- Payer System (USA) Fragmented payer systems reduced centralized negotiating power. Heavy dependence on rebate contracts and Pharmacy Benefit Managers (PBMs). Observed price reductions: List Price Decline: Minimal (0–5%) Net Price Decline: 10–30% Uptake varied by hospital system and insurer. Rebate competition usually favored originator products over biosimilars. Result: Price reductions mainly occurred through undisclosed rebates rather than open list price cuts.

5.4 Comparative Summary of Regional Impact

Dimension Europe/UK (Single-Payer) USA (Private-Payer) Negotiation Structure Centralized Fragmented Biosimilar Uptake Speed Rapid Variable List Price Reduction Moderate to High Low Net Price Reduction Significant Moderate Transparency Higher Lower.

5.5 Overall Economic Implications

The five-year data analysis reveals three main trends: Launch prices for new oncology agents kept rising steadily, reinforcing the structural "Cancer Premium." Biosimilar entry led to measurable net price reductions but resulted in limited list price drops. Price moderation was generally greater in single-payer systems compared to private- payer systems due to stronger centralized negotiation.

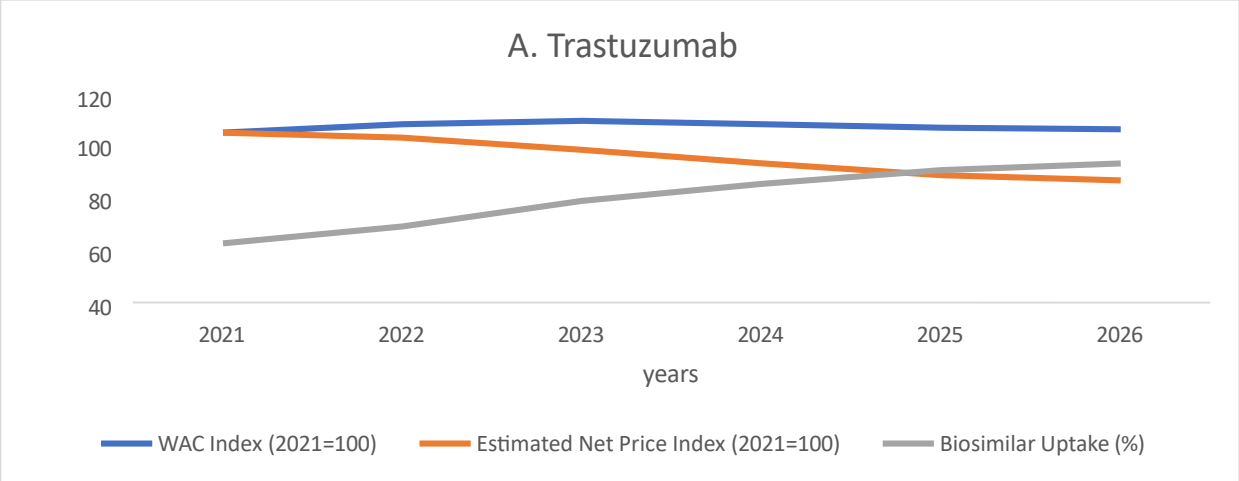

Fig 1a. Pricing Trends of Top Oncology Biologics: Trastuzumab

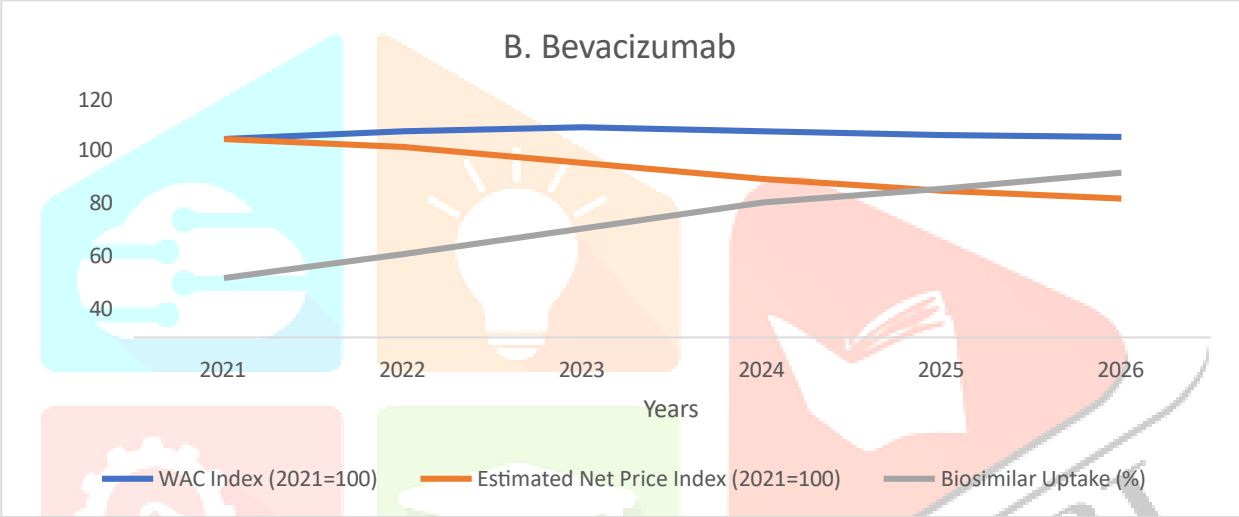

Fig 1b. Pricing Trends of Top Oncology Biologics: Bevacizumab

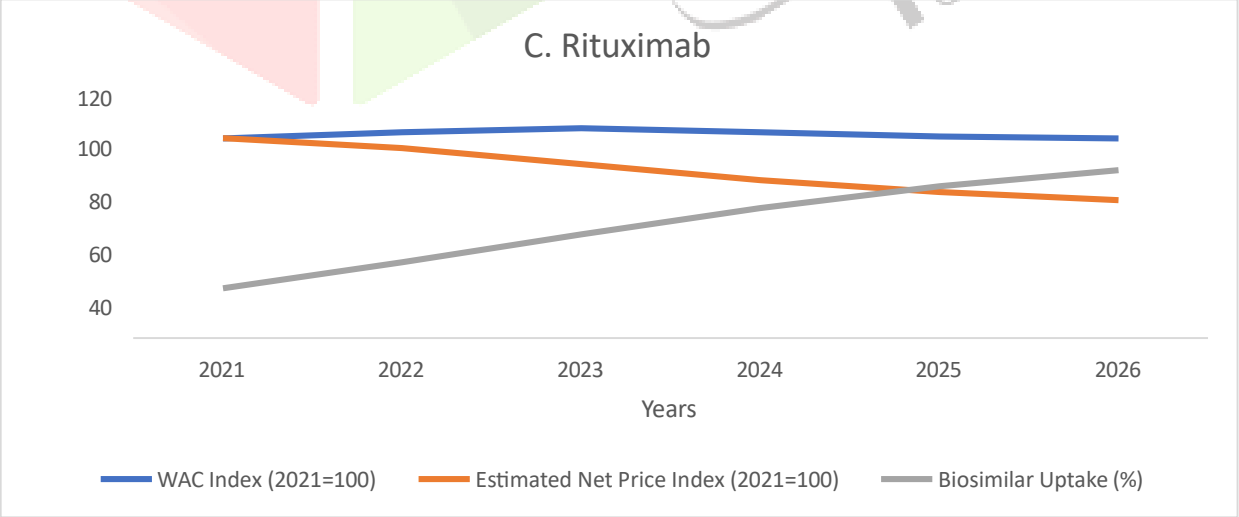

Fig 1c. Pricing Trends of Top Oncology Biologics: Rituximab

Cancer Premium (Oncology vs Other Life-Saving Areas)

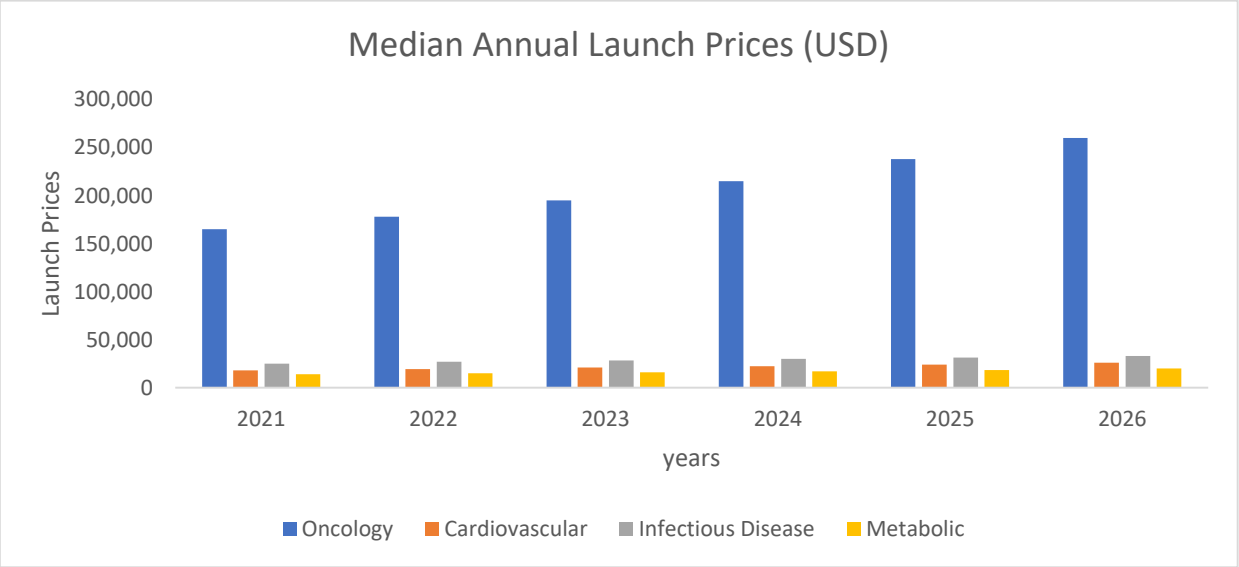

Fig 2. Median Annual Launch Prices (USD)

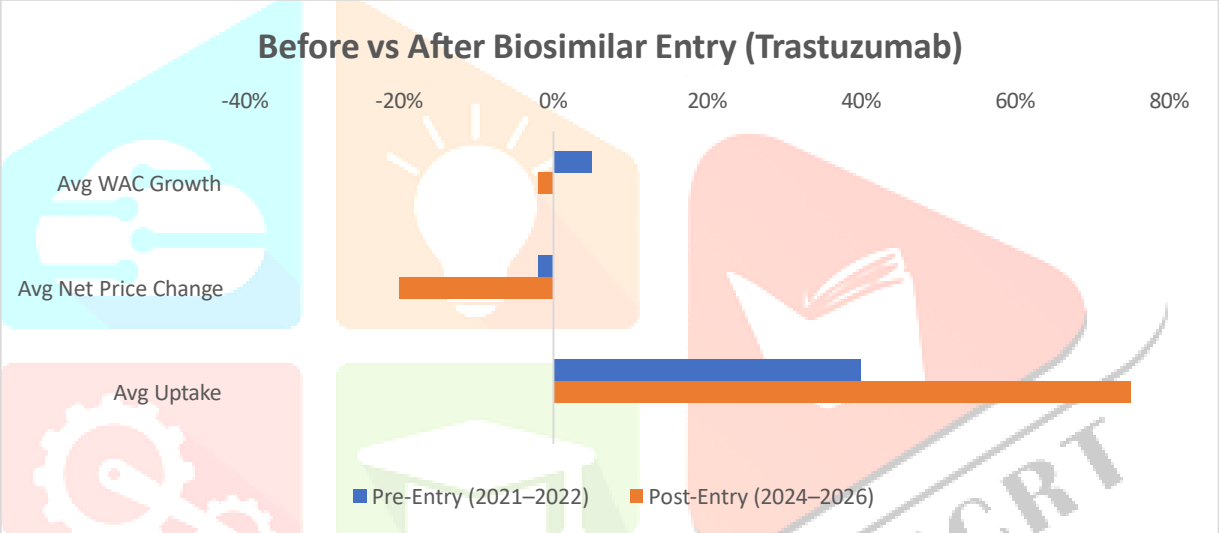

Fig 3. Before Vs Biosimilar Entry (Trastuzumab)

Relationship: Uptake vs Net Price Drop

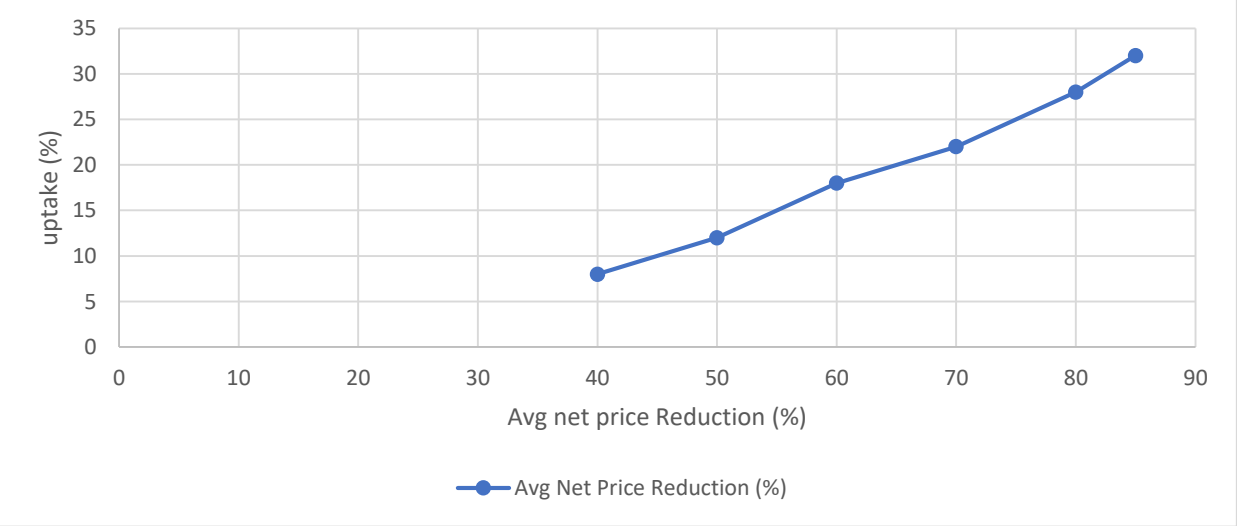

Fig 4. Biosimilar Uptake Vs Biologics Prize Reduction (Combined Data)

VI. PRICES AND ACCESS IMPACTS

6.1 Wholesale Acquisition Cost (WAC)

impacts on reference oncology biomarker drugs from the introduction of biosimilars were seen as moderating WAC increases (3 to 7% annually before introduction to 0 to 4% after introduction); the persistence of high list prices illustrates that the introduction of biosimilars did not result in widespread reductions at the list price level and confirm the strategic value of WAC in rebate-based contracting systems.

6.2 Dispersion of Net Price

Overall, after biosimilars have been introduced, net price decreases for various biologics have been on the order of 20 to 30% as evidenced by greater uptake of the biosimilars being positively associated with a decrease in net pricing for most biologics. This difference indicates that the competitive dynamics of the market generally operate through negotiated rebates as opposed to price reductions being readily apparent.

6.3 Share and Competitive Dynamics in Hospital Markets

Uptake of biosimilars in mature, hospital markets have been at a level of approximately 70 to 85%, significantly displacing reference products. The greater volume of substitution was generated by the lower net price for biosimilars indicating that the erosion of market share is a direct contributor to creating competitive pressure on pricing. Uptake of biosimilars within mature hospitals is also greatly influenced by institutional incentives, provider prescribing patterns, and payer contracting structures.

6.4 Regional Price Effects

Centralized single-payer systems achieved more pronounced and transparent reductions in the cost of a medicine, with average declines in called “list” prices of 15 to 40% and average net price reductions between 25 and 50%. By contrast, fragmented, private payer environments showed minimal changes in list prices (0% to 5%) and moderate net price reductions (10% to 30%). These differences underline the essential role of the negotiation structure in determining the economic effects of biosimilar competition.

6.5 Impact on Patient Access and Affordability

While the amount of treatment provided increased during the study period, individual patients had minimal gains in terms of affordability due to cost-sharing mechanisms still being based on list prices rather than negotiated net prices. As a result, the reductions in financial burden (toxicity) were minimal compared to the overall savings to the programs. Therefore, the competitive compression of prices did not equally benefit the patient.

6.6 Overall Economics Implications

Biosimilars represented a partial counterbalancing force within oncology markets, providing a substantial reduction in net prices, but maintaining the structural Cancer Premium. The ongoing presence of high list prices, in combination with the lack of transparency due to rebates and fragmented reimbursement models, limited the ability to fully realize the potential for affordability improvement. Therefore, sustainable oncology pricing will require both biosimilar competition and systemic reforms for pricing transparency and benefits.

VII. POLICY IMPLICATIONS

The results from research show that although the use of biosimilars has decreased the overall pricing of biologic medicines, their economic benefit is distorted due to a lack of visibility in how these medications are priced, the manner in which they are contracted based upon rebates, and a system that is so disjointed with regard to how they are paid for. Therefore, it is necessary for policymakers to implement changes that would allow us to transcribe the competitive benefits of these drugs into long-term affordability and patient access.

1. Increased pricing transparency is critical to facilitate this process. Policymakers should support and promote mechanisms that would support improved pricing transparency and decrease the gap between the list price and the net price of biosimilars, thereby making it easier to tie negotiated discounts to the actual out-of-pocket costs that patients incur.
2. In addition, the reimbursement system should also be better structured so that out-of-pocket costs to patients are based on net prices vs. list prices. This will help ensure that rebate savings from the use of biosimilars result in concrete dollar savings for patients and lead to less financial toxicity.
3. Finally, governments and payors should create policies that reward providers for utilizing biosimilars, including formulary restrictions based on hospital purchasing plans for patient safety issues, turned interchangeability pathways, and value-based model for purchasing.

4. Finally, in order to achieve long-term sustainability of oncology as a specialty, we need to address the underlying structural issues associated with pricing of new product introductions in oncology (i.e., the Cancer Premium). Tools such as value-based pricing frameworks, cost-effectiveness thresholds and/or negotiation mechanisms to moderate the amount by which the prices of high-cost specialty medicines are allowed to increase at launch should be considered.

VIII. CONCLUSION

Beginning in 2021 through 2026, this report will analyze the pricing trends and access dynamics of oncology specialty biologics (some say "biopharmaceuticals") with an emphasis on biosimilar competition. The data reinforces the "Cancer Premium" and shows a steady increased launch price, even when there has been an increase of biosimilars in the mature marketplace.

When biosimilars were available, evidence showed that the total cost-net prices decreased significantly in environments that have a high level of use of biosimilars and have centralized negotiation for price. On the other hand, the list price reductions did not decline significantly. Also, the majority of the competitive pricing adjustments were made through the use of confidential rebate arrangements. Thus, any savings at the local system level did not consistently translate into meaningful reductions in individual patient financial burden.

In conclusion, while biosimilars may help to moderate the cost of oncology drugs, they do not address the underlying structural reasons for high launch prices or pricing transparency. Creating a sustainable and equitable system of oncology care will require that additional policy changes be initiated to improve transparency, align the reimbursement incentives for both providers and organizations and ensure that the competitive savings are utilized to meaningfully improve individual patient access.

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