

The U.S. Generic & Biosimilar Medicines Savings Report

OCTOBER 2021





The U.S. Generic & Biosimilar Medicines Savings Report

OCTOBER 2021

Introduction

- 3 Letter from the President and CEO
- 4 Letter from the Biosimilars Council Executive Director
- 5 Your Generics and Biosimilars Industry

Combined Savings

- 6 Topline Findings
- 7 Savings From Generics and Biosimilars

Generic Savings

- 8 Percent of U.S. Drug Spend
- 9 Annual Savings
- 10 Savings by Product
- 11 Savings by State
- 12 Savings by Payment Type
- 13 Savings by Age
- 14 Savings by Patient Condition
- 15 Average Primary Copay

COVID-19

- 17 Generic Supply Chain Proves Resilient

Biosimilar Savings

- 18 Approvals
- 19 Market Landscape
- 20 Estimated Savings
- 21 Annual Saving by Type
- 22 Accessible Market Opportunity
- 23 Oncology
- 24 Autoimmune
- 25 Brand Exclusivity Expiry
- 26 Biosimilars Adoption

Methodology

Contact Us

Letter from the President and CEO

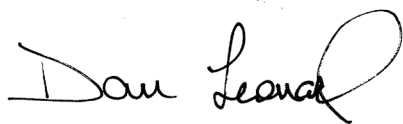
Rising Savings, Expanding Opportunity

Tens of Millions of Americans Entrust Their Health to Generics and Biosimilars

In the United States, 76 million patients took at least one prescription medicine in 2020. The doctors ordering these prescriptions and the pharmacists filling them recognize that FDA-approved generics and biosimilars are just as safe and effective as their brand-name counterparts. As this report demonstrates, savings for individual consumers and the health care system as a whole continue to grow, reaching \$338 billion in 2020.

Throughout the pandemic, U.S. patients and their families have been able to count on their prescription drugs to keep them healthy and productive. Generic and biosimilar manufacturers have worked tirelessly to ensure Americans have access to the medicines they need.

The data in this report tell a public health success story of resilience and innovation. On behalf of all the manufacturers and organizations that belong to AAM, I thank the men and women who have gone the extra mile to make these savings possible.



Dan Leonard

CEO, Association for Accessible Medicines



Letter from the Biosimilars Council Executive Director

Biosimilars Means Savings for Patients with Cancer and Other Illnesses in the U.S.

Over \$12.6 Billion in Savings Since 2011

In the U.S., the safe, effective alternative versions of existing biologic medicines known as biosimilars have been used in more than 121 million days of patient therapy. They have resulted in almost 10 million additional days of care, fulfilling their promise of expanding patient access. As with small-molecule generic drugs, biosimilars depend on a competitive marketplace in order to deliver savings to patients and to the health care system.

I am encouraged by recent progress as shown in this report. Two oncology biosimilars, for example, launched in late 2019 and soon gained market share. Over the next five years, biosimilars are projected to yield \$133 billion in savings.

The promise of biosimilars is coming into view, but it won't be fully realized until more policymakers and physicians understand the value proposition of these FDA-approved treatments for acute and chronic conditions. The Biosimilars Council is dedicated to advocacy, education and collaboration to increase accessibility and, therefore, savings.



Christine Simmon

Executive Director, Biosimilars Council



Your Generics and Biosimilars Industry



**Health is the foundation for everything in life.
Healthy people are better able to reach their full potential.**

- Generics and biosimilars help more people live healthier and longer. The Association for Accessible Medicines (AAM) works to make generic and biosimilar medicines more accessible to more people who need them. AAM improves access to safe, quality and effective medicines.
- Generic pharmaceutical companies manufacture the medicines used in 9 out of every 10 prescriptions dispensed in the United States. Our members form an integral and powerful part of the health care system.
- The Biosimilars Council, a division of AAM, works to ensure a positive regulatory and policy environment for biosimilar products and educates the public, providers and patients about the safety and effectiveness of biosimilar medicine.

Topline Findings

Generic Savings

- The average generic copay: \$6.61
- The average brand-name copay: \$55.82
- 93% of generics have a copay less than \$20, while only 51% of brands have a copay less than \$20



Biosimilar Savings

- Savings increased to \$8 billion in 2020
- Reduced the growth of oncology spending by nearly half
- Projected to save \$133 billion by 2025¹

Health Care System Savings

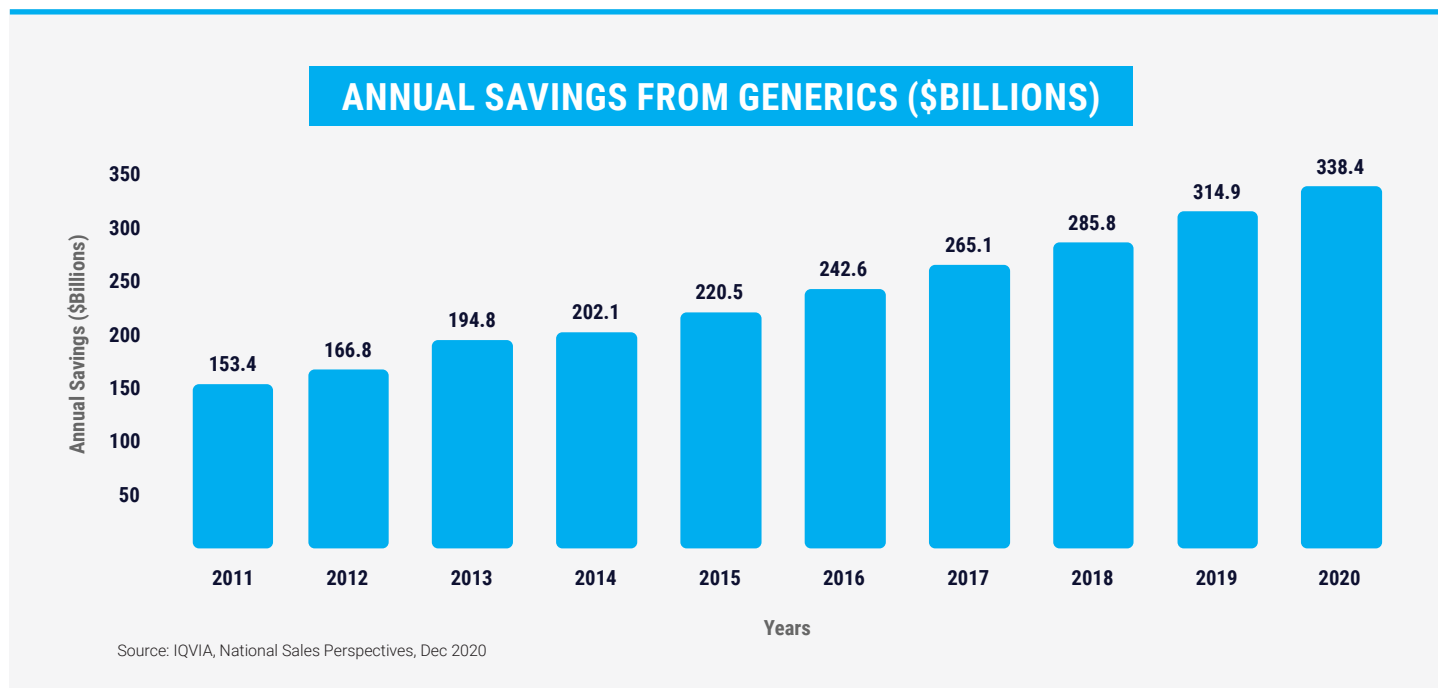
- 2020 generic and biosimilar drug savings: \$338 billion
- Generic 10-year savings: nearly \$2.4 trillion
- 2020 savings to Medicare: \$109.6 billion
- 2020 savings to Medicaid: \$53.8 billion
- Nearly four billion generic and biosimilar prescriptions dispensed
- Generics represent 90% of prescriptions filled, yet account for only 18.1% of prescription drug spending
- Generics represent only 3% of all health care spending²

¹ IQVIA Institute for Human Data Science. (October 2020). "Biosimilars in the United States 2020–2024."

² Peterson-KFF Health System Tracker. "What drives health spending in the US compared to other countries." September 25, 2020. Note: Generic and brand drug share of prescription drug spending was calculated using an analysis of the 2018 Medical Expenditure Panel Survey (MEPS). Total drug spending was segmented into generics and brands. Those percentages were then applied to the Peterson-KFF Health System Tracker analysis of spending by type of expenditure in the U.S. health care system.

Savings from Generics and Biosimilars Totaled \$338 Billion in 2020

GENERIC AND BIOSIMILAR SAVINGS INCREASED BY \$23.5 BILLION FROM 2019 TO 2020

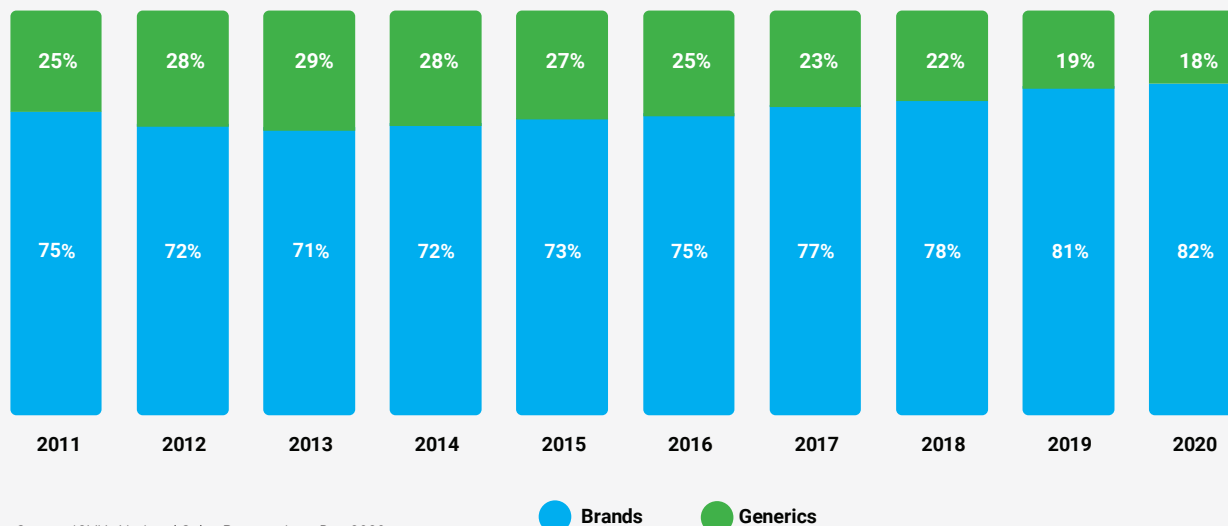


- Generic drugs contain the same active ingredients at the same strength and purity as their brand-name counterparts but come at a fraction of the cost.
- Likewise, biosimilars are lower-cost versions of costly biologic medicines and are approved by FDA as highly similar to and with no clinically meaningful differences from an existing FDA-approved reference product.
- As a result, generics and biosimilars represent 9 out of every 10 prescriptions dispensed in the United States and total generic savings continue to grow.
- Yearly savings from generics and biosimilars exceeded \$338 billion – an increase of more than \$23 billion from 2019 – and yearly savings consistently increase by 7-10%.
- The above figure includes savings from biosimilars, which more than tripled from 2019 to 2020 – from \$2.5 billion in 2019 to nearly \$8 billion in 2020.

Generics Account for 18.1% of Total Medicine Spending

GENERIC MAKE UP 90% OF ALL PRESCRIPTIONS

BRAND AND GENERIC SHARE OF TOTAL MEDICINE SPENDING (%)

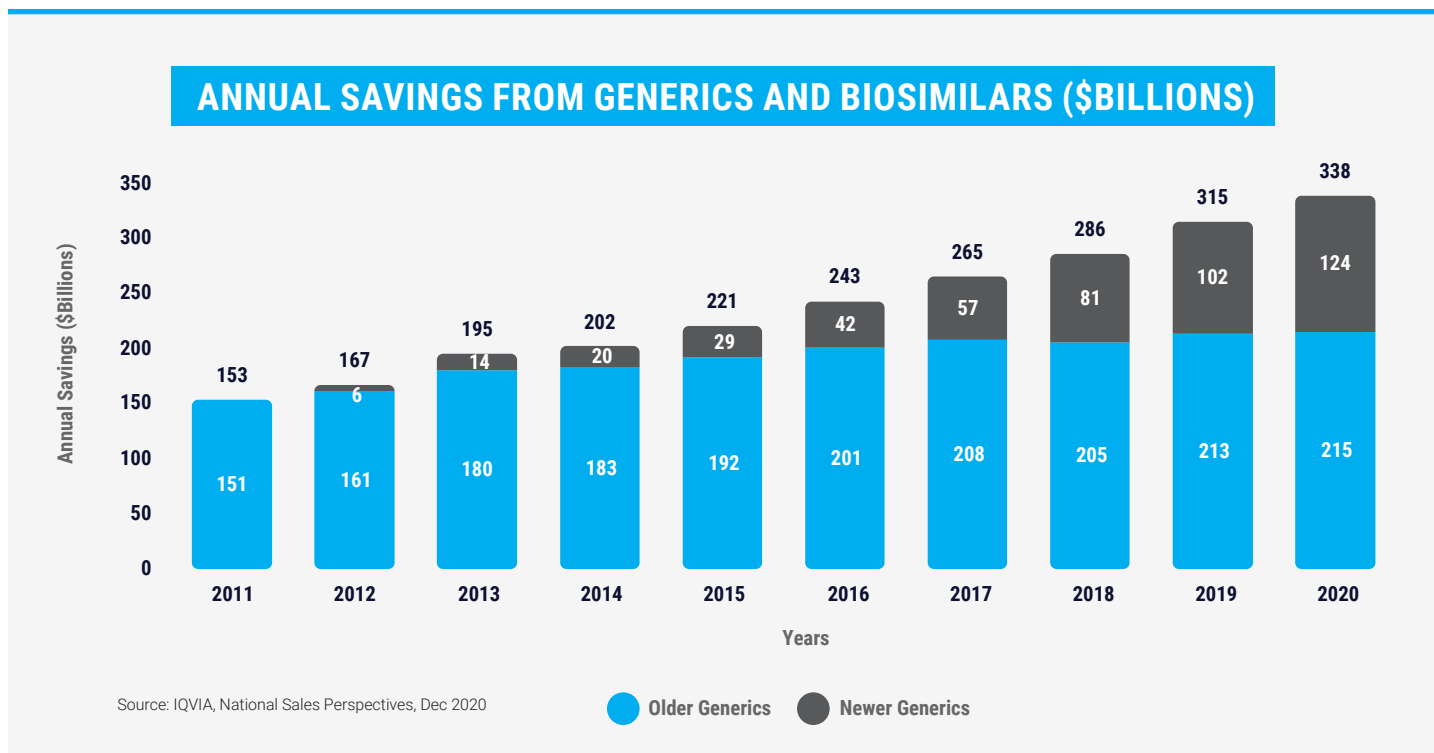


Source: IQVIA, National Sales Perspectives, Dec 2020

- Generics continued to demonstrate their value proposition – representing more than 90% of all prescriptions, but only 18.1% of spending.
- This continues a years-long trend of generic price deflation contrasted with brand price inflation. In fact, the share of spending attributable to brand drugs continues to increase even as the total number of prescriptions filled by brand drugs has declined by half in the past 10 years.
- Generics make up 90% of dispensed prescriptions, up from 78% in 2010, and are dispensed 97% of the time when available.
- While spending on brand drugs continued to increase in 2020, spending on generic drugs declined. This continued a four-year period during which spending on generic drugs declined by more than 10%.
- The U.S. health care system has saved nearly \$2.4 trillion in the last 10 years due to the availability of affordable generics

New Generic Entrants Generated \$124 Billion in Savings in 2020

ANNUAL GROWTH RATE OF SAVINGS FROM NEW GENERICS EXCEEDS 20%



- New generics represent lower costs and greater access to care for patients.
- New generics and biosimilars are increasingly contributing savings – from \$6 billion in 2012 to 20 times that: \$124 billion in 2020.
- Annual growth rate of savings from new generics is 20.5% since 2011 and has remained at about 21% for the past five years.
- These include first generics and new generics with a 180-day exclusivity period that have challenged brand patents to enter the market.
- This includes \$8 billion in savings from biosimilars in 2020, and \$2.5 billion in 2019.
- Many of these biosimilars are complex or specialty products that are used to treat a range of diseases from psychological disorders, infectious diseases, cardiac and respiratory conditions to Alzheimer’s and a broad range of cancers.
- Unfortunately, some policymakers have proposed reducing the incentives for patent challenge and early generic entry. This would harm generic competition and delay patient access to lower-cost medicines.

The Top 10 Medicines of 2020 Saved \$99.1 Billion in 2020

THE TOP 10 PRODUCTS REPRESENT 29% OF THE OVERALL SAVINGS IN THE PAST 10 YEARS

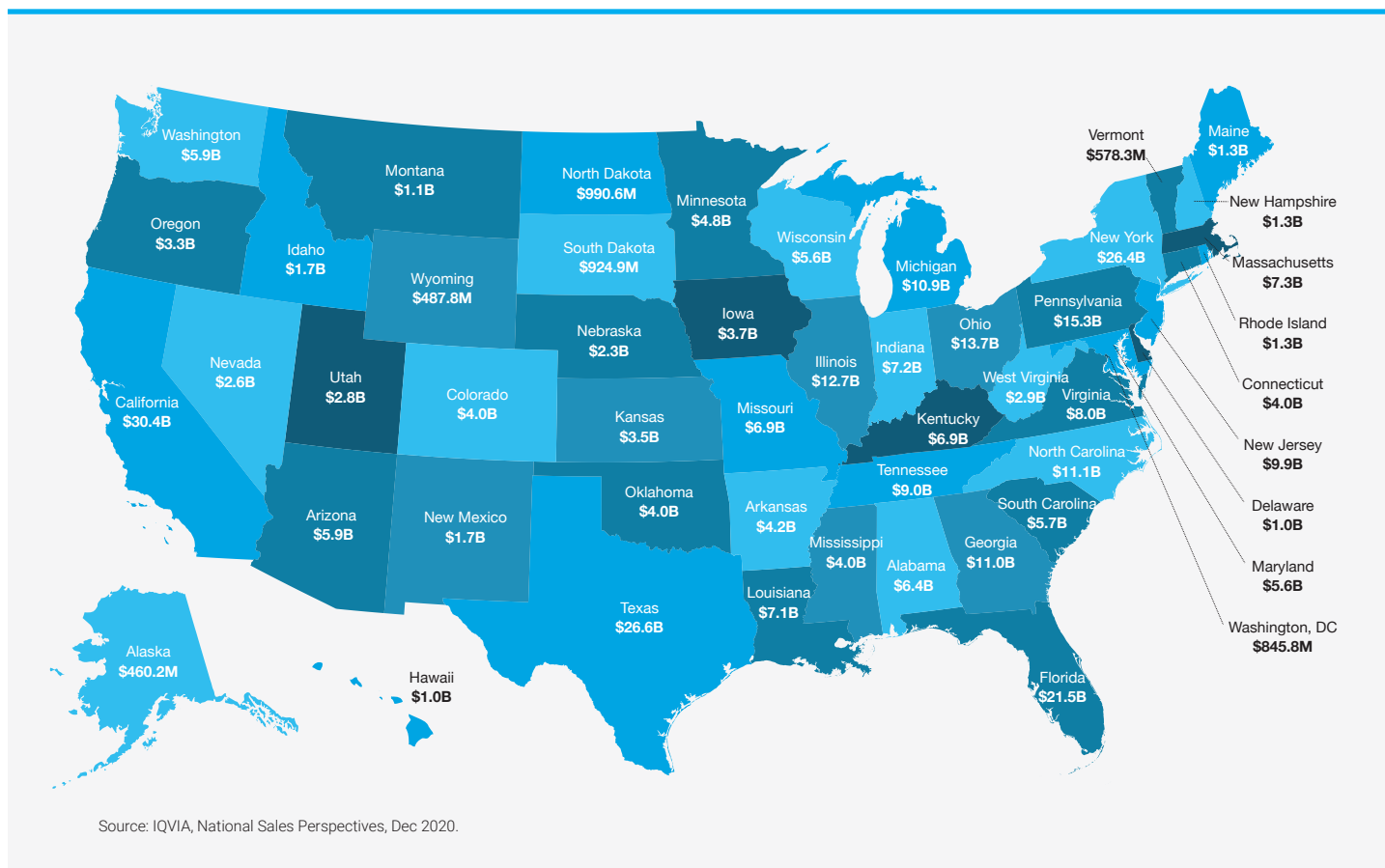
TOP 10 MEDICINES WITH GREATEST SAVINGS IN 2020

Products	Generic Entry Year	Brand Pre-Expiry Price (per unit)	Price of Generic Equivalent 2020 (per unit)	2020 Savings (\$Bn)	Percent Savings	2020 Dispensed Rxs (Mn)
Lipitor	2011	\$3.29	\$0.08	\$19.2	98%	5982
Zofran	2006	\$21.67	\$0.16	\$13.9	99%	745
Prilosec	2002	\$3.31	\$0.06	\$12.0	98%	4116
Crestor	2016	\$5.78	\$0.08	\$10.7	99%	1899
Abilify	2015	\$21.68	\$0.40	\$8.9	99%	423
Neurontin	2004	\$1.02	\$0.07	\$7.5	93%	7864
Norvasc	2007	\$1.54	\$0.02	\$7.4	99%	4799
Singulair	2012	\$3.74	\$0.09	\$6.6	98%	1821
Cymbalta	2012	\$4.61	\$0.21	\$6.5	96%	1462
Protonix	2005	\$3.63	\$0.03	\$6.2	98%	2290

Source: IQVIA, National Sales Perspectives, Dec 2020

- Generic competition continues to generate billions in savings each year for high-priced brand-name drugs, led by generics for medicines such as Crestor and Abilify, to name a few more recent generic launches.
- Savings are also found in high-volume generics. The 10 generics with the highest volume in 2020 represented 18% of all savings, and included generic versions of Glucophage, Lipitor and Neurontin.
- But generics also provide savings each day through thousands of small-volume and low-margin products. Although these are not found on a top 10 list, they are nonetheless essential for patient health and affordability.

Savings by State, 2020



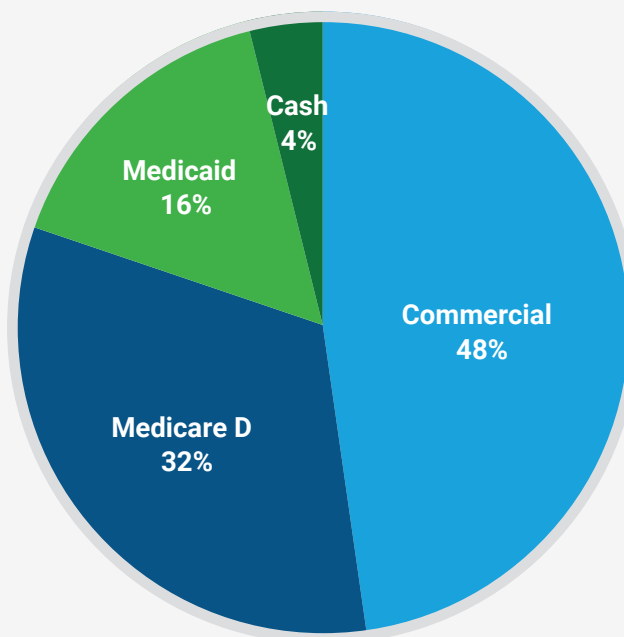
- Encouraging use of lower-cost generic medicines is a critical tool to manage spending within states.
- On average, states saved \$6.6 billion from the use of generics in 2020. This includes \$2.1 billion for Medicare enrollees and \$1.1 billion for Medicaid enrollees, on average.
- Although larger states realized greater overall savings, the states with the highest per capita Medicaid savings were WV, KY, LA, ND and NJ.

A Majority of Prescriptions, and Thus Generic Savings, Are Attributed to Commercially Insured Patients

STATE-LEVEL SAVINGS ESTIMATED BASED ON RETAIL PRESCRIPTIONS

2020 GENERIC SAVINGS

BY PAYMENT TYPE



Source: IQVIA, National Sales Perspectives; PayerTrak, Dec 2020; CMS National Expenditures, March 2021.

- Generics and biosimilars provide critical savings throughout the health care system, and are particularly valuable to Medicare and private health insurance.
- Generics and biosimilars saves Medicare and Medicaid \$109.6 and \$53.8 billion, respectively, in 2020.
- Medicaid enrollees use 7.5 prescriptions per enrollee per year, and use generics more than commercial or Medicare Part D enrollees.
- Total savings due to biosimilar introductions are forecast to be \$133 billion (\$85-\$183 billion range) in aggregate by 2025.³
- Patients without insurance coverage paid \$14 billion for prescriptions, 97% of which was for generic medicines.
- Generics are one of the most effective mechanisms to control drug costs and yet utilization varies considerably across insurance types. Generic utilization among commercial payers is 1% higher than in Medicare, and states that have expanded Medicaid have 1.1% higher generic use than those that have not. Usage under Managed Medicaid is 3% higher than under fee-for-service.

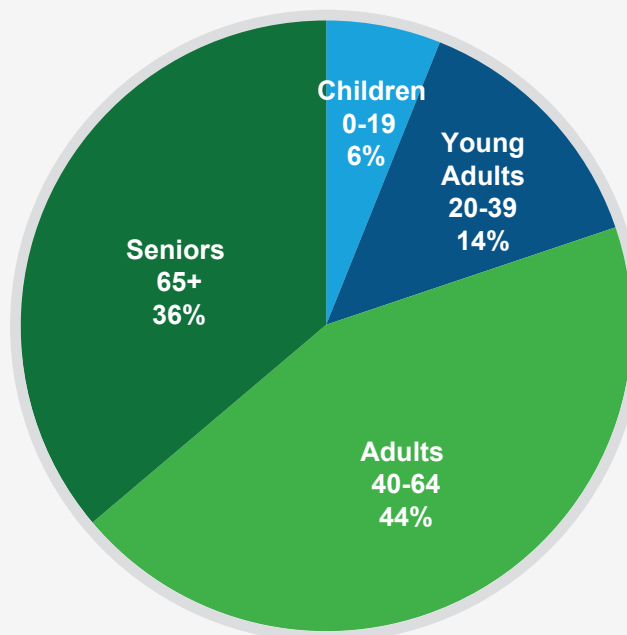
3 IQVIA Institute for Human Data Science. (October 2020). "Biosimilars in the United States 2020–2024.

Generic Medicines Used by Seniors Account for 36% of Savings

GENERICS SAVED BILLIONS FOR PATIENTS WITH COMMON CONDITIONS

2020 GENERIC SAVINGS

BY PATIENT AGE



Source: IQVIA, National Sales Perspectives, Dec 2020.

- Medicines taken by older adults and seniors account for the majority (~80%) of the \$338 billion in savings generated by generics and biosimilars in 2020.
- Generic medicines taken by older adults aged 40-64 accounted for \$147 billion in savings in 2020.
- Generic drugs taken by seniors over age 65 accounted for \$120 billion in savings, 36% of total savings.
- Medicare Part D has remained relatively unchanged in the prescription growth rate at 5%, only slightly above the population growth rate for those 65+ years old.
- Nonetheless, many seniors are paying too much for their generics as a result of increasing copays, even when the generic price has declined.⁴
- In fact, almost half of all seniors in Medicare paid the full cost of their generic at least once in 2017 because they faced copays that were higher than the cost of the drug.⁵

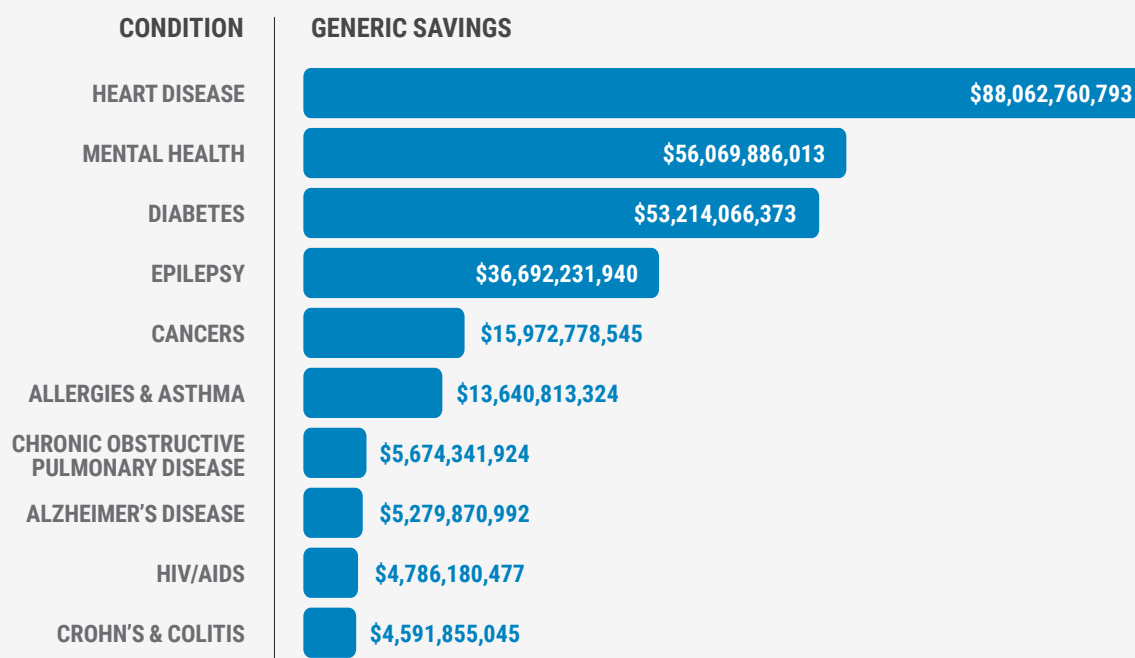
4 Avalere. (May 22, 2018). "Seniors Pay More for Medicare Part D Generics Despite Stable Prices." <https://avalere.com/press-releases/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-stable-prices>.

5 Avalere. (July 20, 2021). "Some Part D Beneficiaries May Pay Full Price for Certain Generic Drugs" <https://avalere.com/insights/some-part-d-beneficiaries-may-pay-full-price-for-certain-generic-drugs>.

Savings by Primary Patient Condition

GENERICS SAVED AMERICANS WITH COMMON CONDITIONS BILLIONS

TOP 10 GENERIC SAVINGS BY CONDITION IN 2020



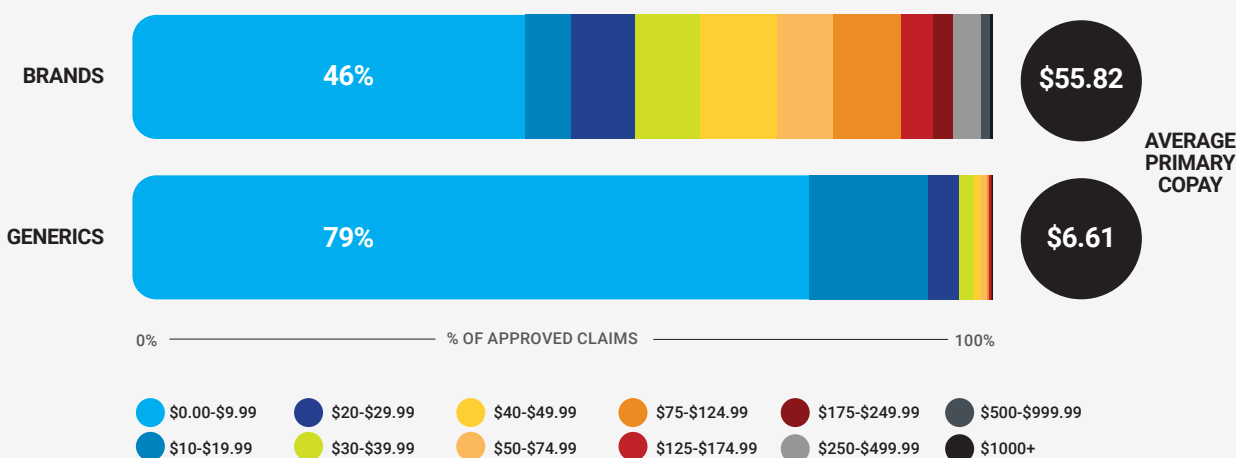
Source: IQVIA, National Sales Perspectives, Dec 2020.

- America's patients can see how much they save by treating their health conditions using generic drugs for common conditions, demonstrating the tremendous value generics bring year over year to the individual patient communities who collectively represent tens of millions of American patients. Each dollar saved represents an American patient with a health condition impeding the ability to lead a full and productive life – or even threatening life.
- Savings by conditions correlate with the top 10 chronic conditions affecting Americans, including hypertension, major depressive disorder, high cholesterol and coronary artery disease.
- Just as generics offer savings over brand-name drugs, biosimilars – safe, effective alternative versions of biologic medicines – have great potential to improve the quality of life for America's patients, while at the same time saving the health system billions of dollars.

Generic Copays Are About 8.5 Times More Affordable Than Brands

93% OF GENERIC COPAYS ARE BELOW \$20, COMPARED TO ONLY 51% OF BRANDS

PRIMARY COPAY DISTRIBUTION FOR BRAND VS. GENERIC CLAIMS



Note: Includes commercial, Medicare Part D and Medicaid channels; Limited to standard market baskets.
 Source: IQVIA LAAD dataset; US Market Access Strategy Consulting analysis.

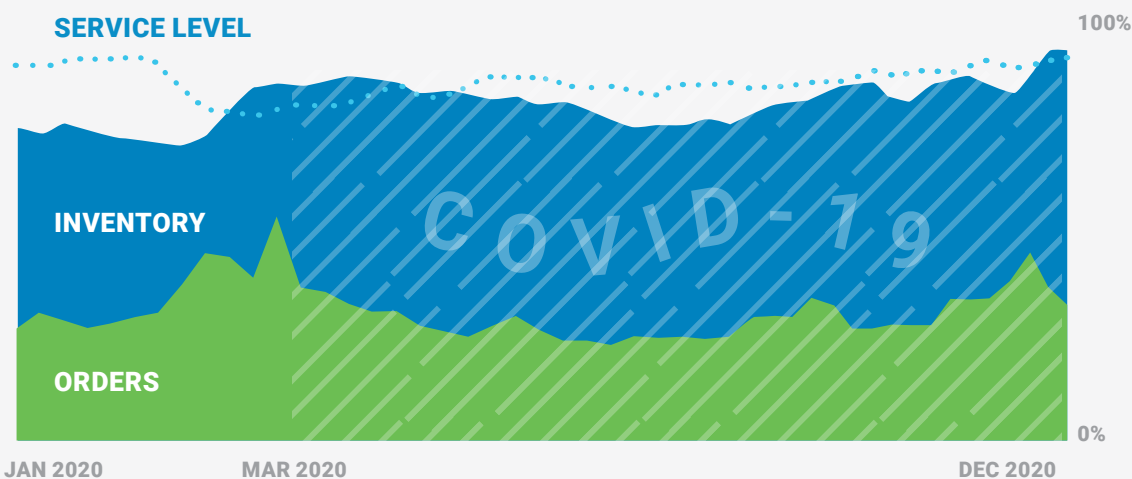
- The value of low-cost generics to patients leads to high levels of generic dispensing.
- The average generic copay declined \$.36 per script since 2019 to \$6.61, down from \$6.97.
- 93% of branded and generic prescriptions have a final out-of-pocket cost below \$20, and only 0.9% have a cost above \$125. Only 51% of brands have a copay less than \$20.
- Nonetheless, there are still instances when patients are forced to pay too much for a generic.
- A recent Avalere analysis found that nearly half of all Medicare patients paid the full cost of their generic because the plan-imposed copay was higher than the cost of the medicine.⁶

6 Avalere. (July 20, 2021). "Some Part D Beneficiaries May Pay Full Price for Certain Generic Drugs." <https://avalere.com/insights/some-part-d-beneficiaries-may-pay-full-price-for-certain-generic-drugs>.

Generic Supply Chain Proves Resilient

AFTER AN INITIAL SPIKE IN DEMAND FOR MEDICINES, INVENTORY AND AVAILABILITY OF PRODUCT RETURNED TO HISTORICAL LEVELS

DURING COVID, THE GENERIC SUPPLY CHAIN HAS BEEN RESILIENT



Source: IQVIA, National Sales Perspectives, Dec 2020.

- The COVID-19 crisis had the potential to upend normal operations. Reviewing the supply chain during the initial outbreak of COVID-19 as well as in the subsequent months of the pandemic provides insight into the resilience of the pharmaceutical supply chain.
- At the request of AAM, IQVIA reviewed the availability of brand and generic drugs. For all prescription drugs, wholesaler sales and inventory levels were relatively steady prior to the crisis but sales began to increase the week of March 2. Demand for medicines spiked following the declaration of a national emergency on March 13. During the ensuing weeks, dispensing locations attempted to place orders with their wholesalers to ensure they did not run out of product. Although service levels dropped as wholesalers allocated product to their customers, inventory quickly increased, allowing service levels to recover to historical norms.
- A similar dynamic emerges when reviewing a broad market basket of generic drugs. Generic product sales and inventory were steady prior to March. During the March COVID-19 crisis period, weekly sales increased 23% over the pre-crisis average, but inventory quickly recovered.
- This dynamic is also observed among products that saw some of the greatest spikes in demand. Specifically, products associated with the inpatient use of respirators experienced significant and unusual spikes in demand. Nonetheless, national inventory of these products quickly recovered and exceeded pre-crisis levels as the supply chain increased supplies in anticipation of future demand.

Biosimilar Access Drives Savings

31
Approvals

Projected Savings
Through 2025
\$133 Billion

20
Launched

Biosimilars have been used in more than **121 million days** of patient therapy and have resulted in almost **10 million incremental days** of therapy.

As of October, 2021.
Source: U.S. FDA.

- To date, the FDA has approved 31 biosimilars across 11 molecules. Twenty biosimilars are on the market, with prices that average 30% less than their reference brand biologic.⁷ At least six more biosimilars are scheduled to come to market in 2023 as biosimilar versions of adalimumab and are allowed to launch as a result of procompetitive patent settlements.
- The biosimilar pipeline remains strong, with 90 biosimilar development programs underway.⁸
- This competition has lowered costs for both the reference product and its biosimilars such that biosimilars provided \$7.9 billion in savings in 2020 and more than \$12.6 billion in savings over the last 10 years.
- In addition to savings, biosimilars increase patient access to care. Since their introduction, biosimilars have been used in more than 121 million days of patient therapy and have supported almost 10 million incremental days of therapy – care that patients would not have received without the availability of lower-cost biosimilars.⁹

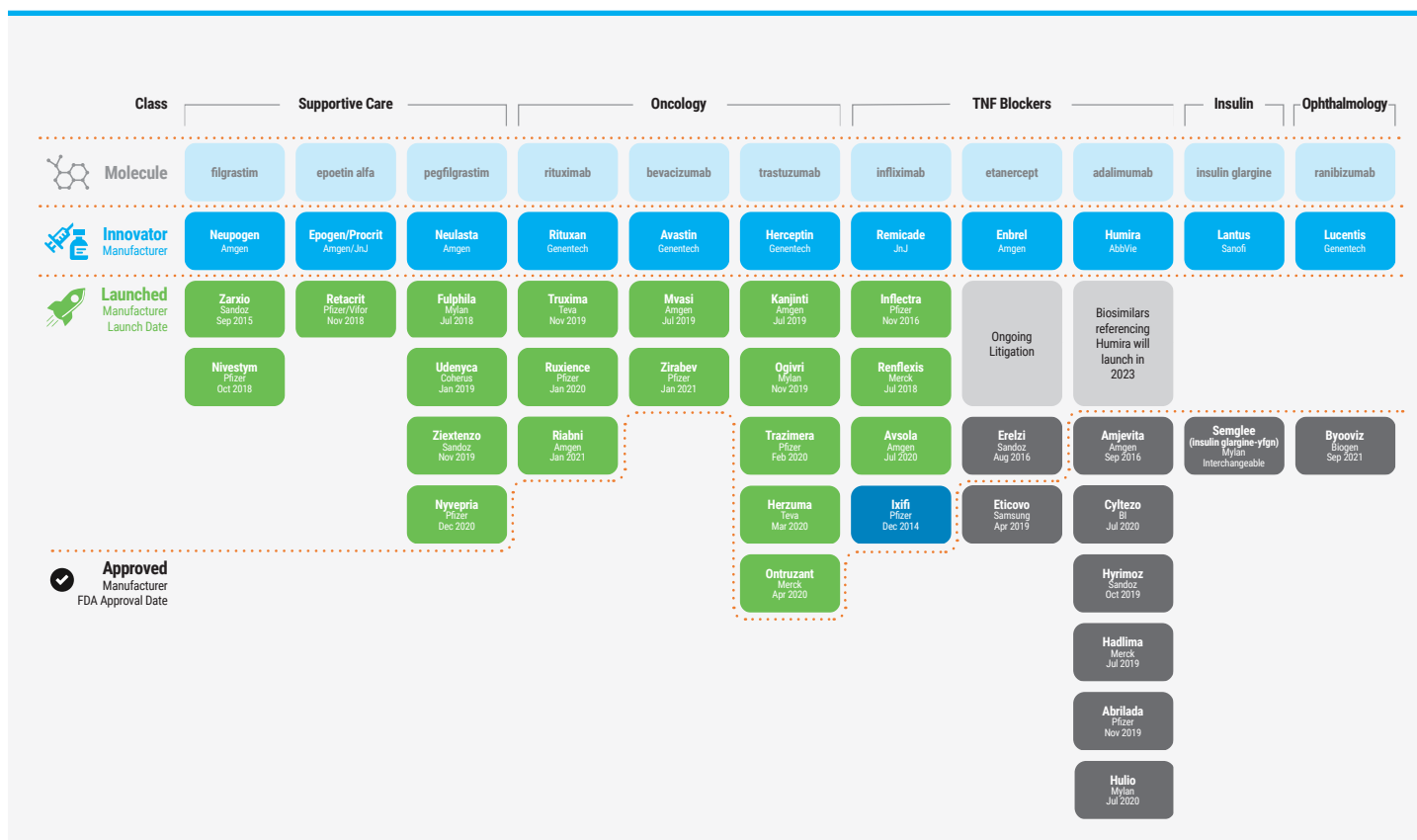
7 IQVIA Institute for Human Data Science. (October 2020). "Biosimilars in the United States 2020–2024."

8 FDA-TRACK: Center for Drug Evaluation & Research. Pre-Approval Safety Review. Biosimilars Dashboard, June 2021.

9 Biosimilars Council. (June 2021). "Biosimilar Medicines Equal More Accessible Care for America's Patients" <https://biosimilarscouncil.org/resource>.

U.S. Biosimilars Market Landscape

AS OF AUGUST 1, 2021

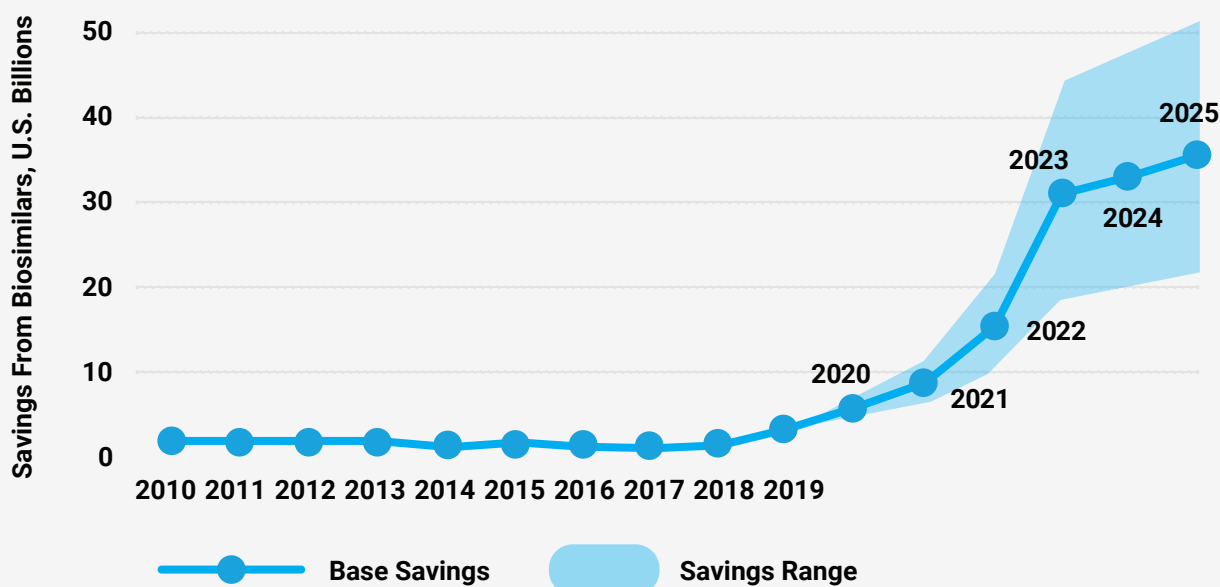


- Of the 31 biosimilars that have been approved, 20 are currently available to patients.
- Six biosimilar adalimumabs (reference biologic Humira) are scheduled to come to market in 2023. These launches are the result of patent settlements allowing the biosimilars to enter before the expiration of more than 100 patents on the reference biologic.
- Similarly, litigation is ongoing between the etanercept reference manufacturer and biosimilar manufacturers, blocking those two biosimilars from coming to market.
- FDA has approved the first interchangeable biological product (Semglee [insulin glargine-yfgn]), although the product has not yet launched.
- And as noted, the biosimilar pathway is strong, with more than 90 development programs underway.

Biosimilars Are Projected to Provide \$133 Billion in Savings by 2025

SAVINGS WILL DEPEND ON APPROPRIATE POLICIES TO SUPPORT ADOPTION

FIVE-YEAR SAVINGS SCENARIOS – \$85 BILLION - \$183 BILLION



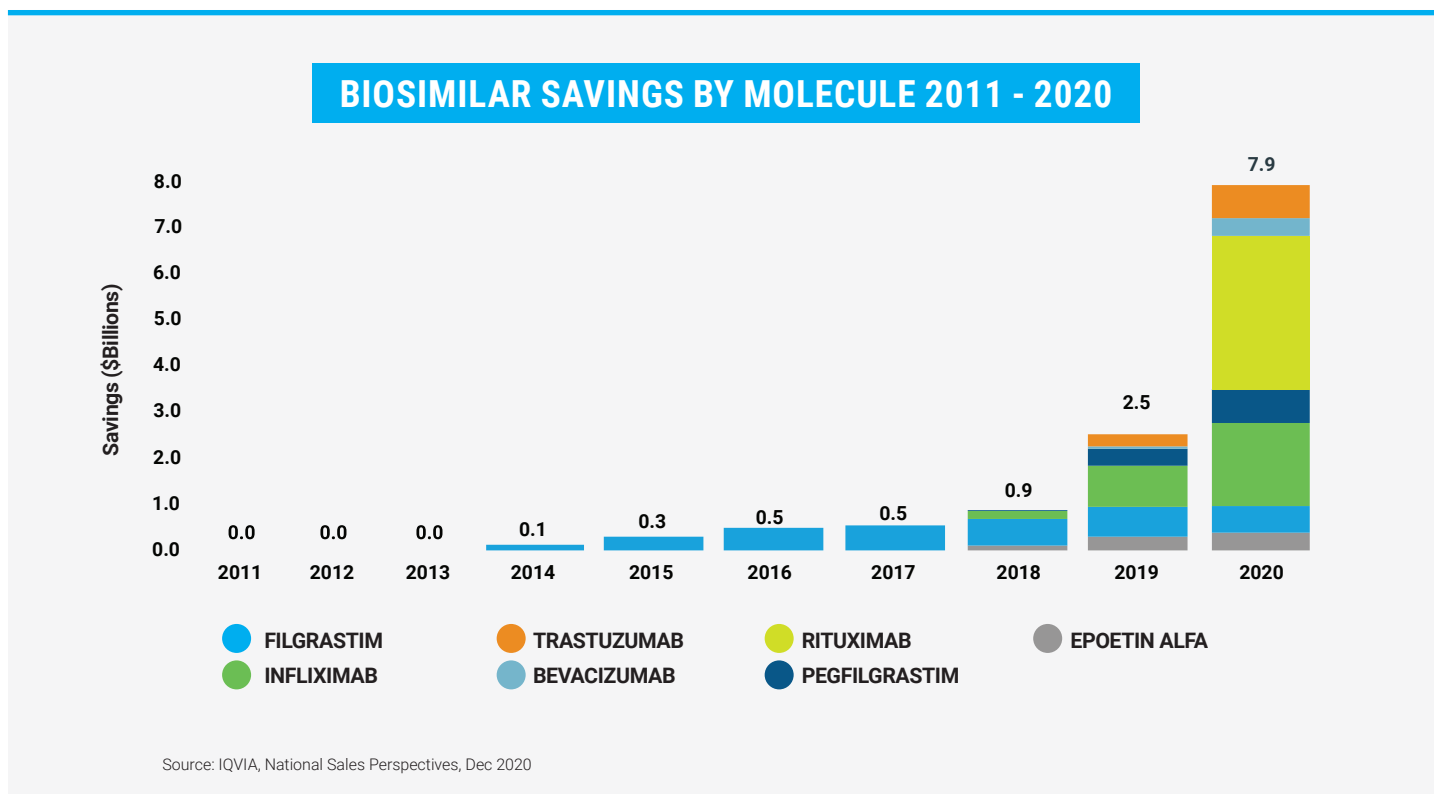
Source: IQVIA, National Sales Perspectives, Dec 2020.

- IQVIA projects savings from biosimilar competition to exceed \$133 billion by 2025, with a low range of \$85 billion and high range of \$183 billion.¹⁰
- Biosimilars compete with high-cost specialty brand biologics that represent only 2% of all prescriptions but more than half of all pharmaceutical spending.
- These savings are therefore a critical component to continued patient access to care.
- Nonetheless, biosimilar adoption has been slower than hoped for to date. Achieving the higher end of potential savings from biosimilar competition will require action by policymakers in Congress and HHS.
- Specifically, it is important to align Medicare policies to encourage biosimilar utilization by providers in Medicare Part B and to ensure that Medicare Part D is updated to encourage biosimilar uptake.

10 IQVIA Institute for Human Data Science. (October 2020). "Biosimilars in the United States 2020–2024."

Biosimilar Savings Totaled \$7.9 Billion in 2020

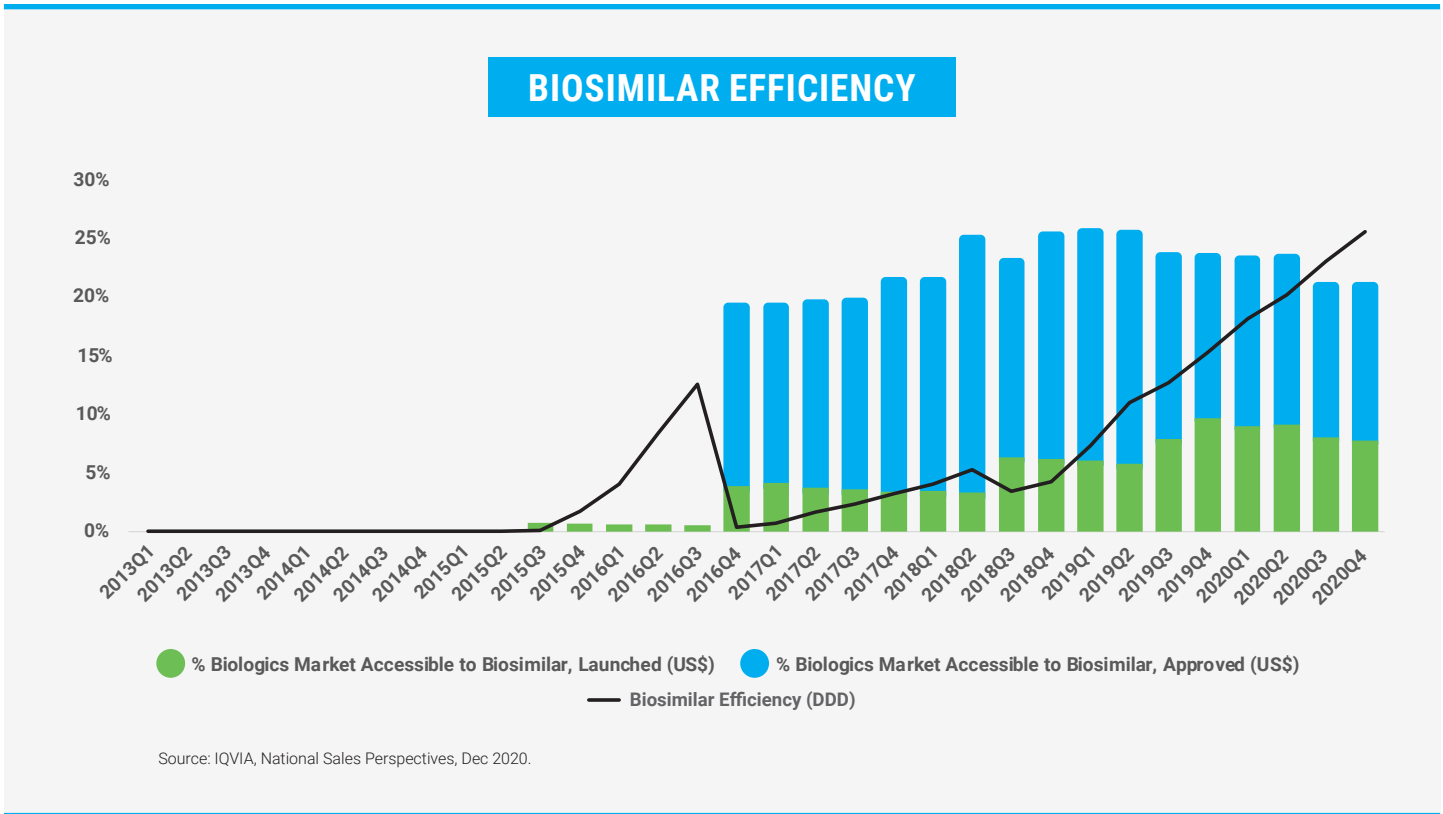
SAVINGS FROM BIOSIMILAR USE MORE THAN TRIPLED FROM 2019



- Use of lower-cost biosimilars has provided \$12.6 billion in savings since 2011. The significant growth in biosimilars savings has primarily been driven by oncology biosimilars – bevacizumab, rituximab and trastuzumab. These therapies were launched in late 2019 and quickly progressed to nearly 60% market share at a significant discount relative to their reference products.
- However, it is too early to declare the biosimilars market a success. Other biosimilars continue to underperform adoption goals. It is critical that policymakers take steps to ensure a vibrant competitive biosimilars marketplace across therapeutic areas, acute and chronic alike.
- Adoption can be affected by three general areas: education and/or misinformation, provider reimbursement and health plan formulary decisions. As such, policies are needed to continue provider and patient education and combat misinformation about biosimilars, while providing appropriate incentives for provider and plan adoption.

Although Improving, Biosimilar Adoption Continues to Underperform

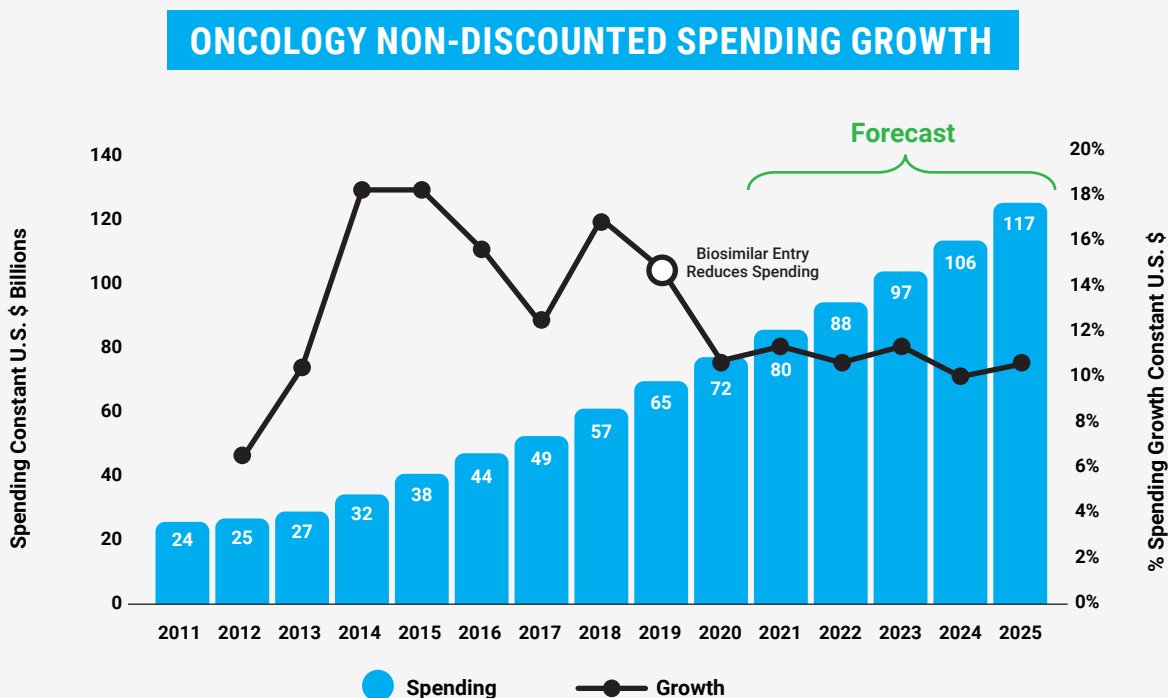
BIOSIMILAR VOLUME SHARE IN ACCESSIBLE MARKETS REMAINS LESS THAN 30%



- Although biosimilar adoption and savings continues to grow, it is too early to declare the market a success. In 2020, the biosimilar efficiency rate improved significantly, but biosimilars nonetheless continue to capture less than 30% of volume in the molecules where they compete.
- This difference reflects strong brand biologic patent litigation and patent thickets that serve to delay biosimilar entry. For example, there are six adalimumab biosimilars that have been approved over the last few years but have not been able to enter the market. But as a result of procompetitive settlements between the biosimilar developers and the brand manufacturer, those products will come to market at various points in 2023.

Biosimilar and Generic Medicines Are Bending the Cost Curve

BIOSIMILARS AND GENERICS REDUCED ONCOLOGY COST GROWTH BY ROUGHLY 50%

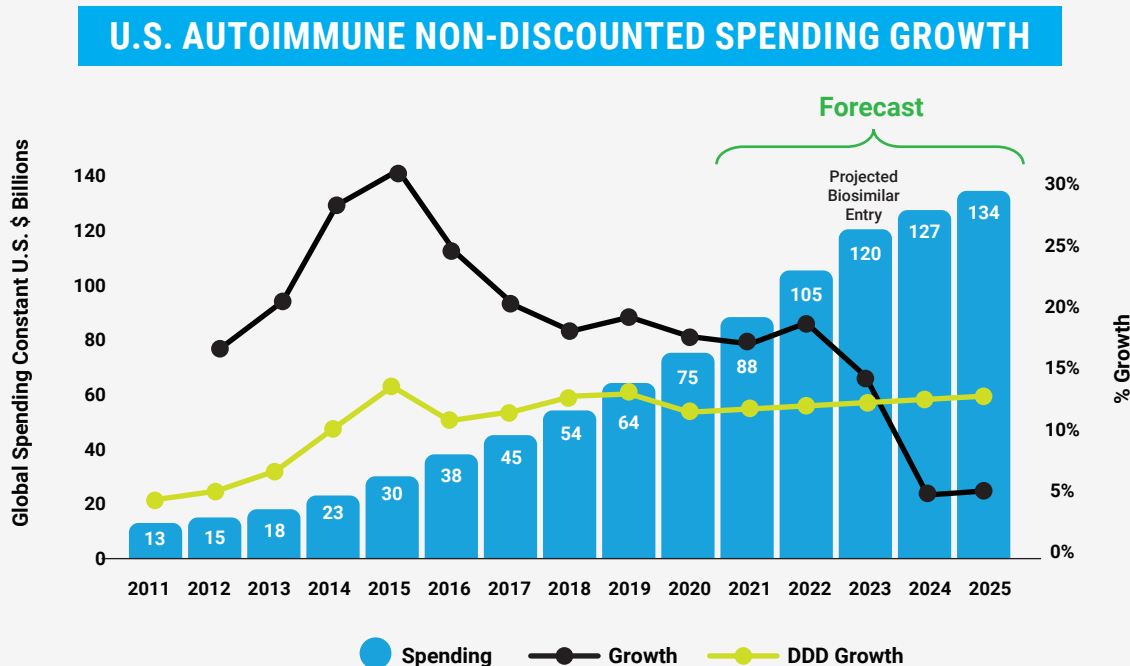


Source: IQVIA Institute for Human Data Science, May 2021. "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025."

- The promise of biosimilars is one of lower costs and greater patient access, and it is now being realized in the oncology market.
- As a direct result of biosimilar competition, oncology spending growth declined from about 16% in 2018 to 10% in 2020, and it is projected to decline further. This is due to robust competition from biosimilars that has bent the cost curve.
- Biosimilars are forecast to continue to play an integral role in controlling oncology spending in the years ahead, even as new higher-priced oncology drugs come to market.

Biosimilars Are Projected to Reduce Growth of Autoimmune Spending

SPENDING GROWTH PROJECTED TO DROP BY TWO-THIRDS BY 2024



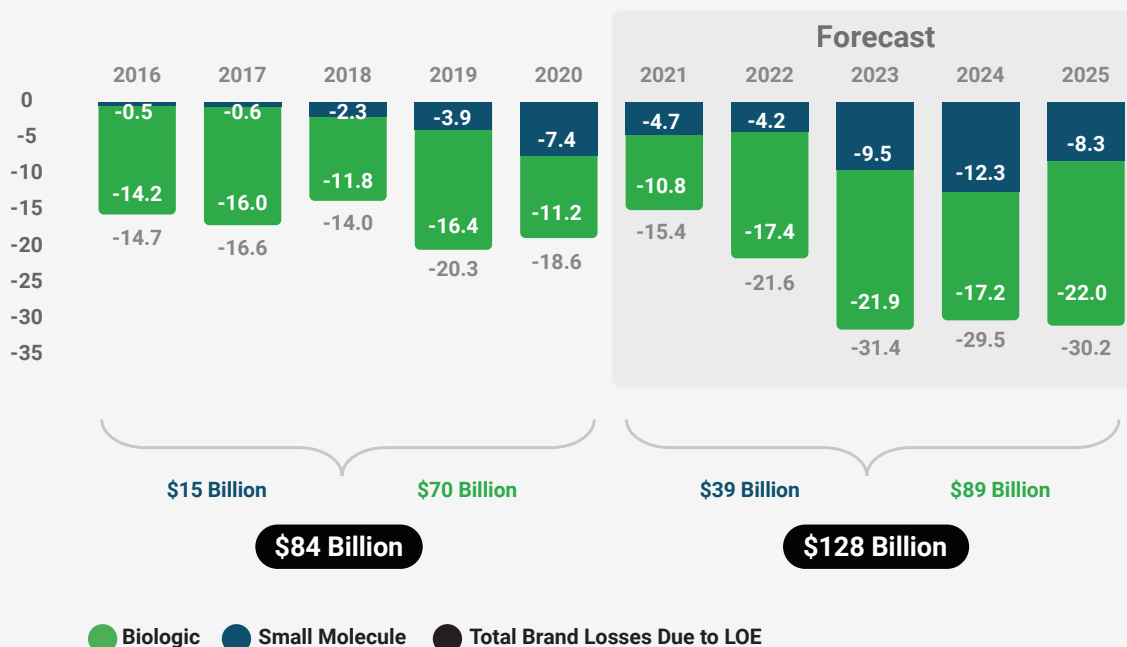
Source: IQVIA Institute for Human Data Science, May 2021. "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025."

- Spending growth among autoimmune medicines has ranged from 17% to 30% since 2012, but is projected to decline to just over 5% by 2024. This is largely a result of the scheduled launch of up to six biosimilar adalimumabs in 2023.
- These biosimilars are coming to market as a result of procompetitive patent settlements, without which they would not be able to launch until at least 2031.
- Over the next five years, the volume in this therapy area is estimated to have double digit growth per year, and strong competition from biosimilars is essential for limiting the corresponding growth in spending.
- Biosimilars' ability to deliver savings and bend the cost curve will be dependent on market dynamics, like rebating and other contracting considerations, effective provider and patient education, and potential changes to Medicare.

Further Savings Are Possible Through Timely Market Entry and Adoption

NEW SAVINGS OPPORTUNITIES WILL GROW BY 50% THROUGH 2025

IMPACT OF BRAND LOSSES OF EXCLUSIVITY 2016-2025 U.S. (BILLIONS)



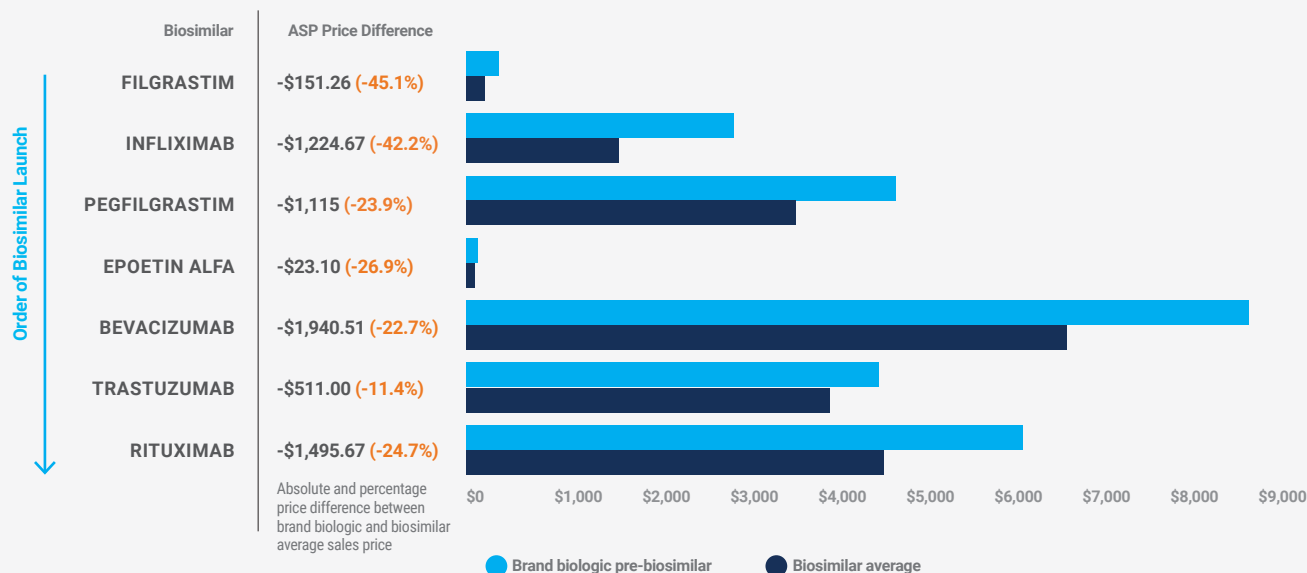
Source: IQVIA Institute. (May 27, 2021). "The Use of Medicines in the U.S. Spending and Usage Trends and Outlook to 2025". <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>.

- As generics and biosimilars continue to deliver value, a forward look at opportunities for new generic or biosimilar competition makes clear that further savings are possible through timely generic or biosimilar market entry and adoption.
- The total value of brands that are forecasted to lose exclusivity in the next five years is \$128 billion – nearly 50% greater than the past five years. This includes both small molecule and biologics, many of which are complex or specialty products.

Biosimilars Are Less Expensive Than Their Reference Brand Biologic

BIOSIMILAR COMPETITION HAS BEEN STABLE AND PROVIDES CONSISTENT SAVINGS

ORIGINATOR AND MEAN BIOSIMILAR AVERAGE SALES PRICE, JULY 2020



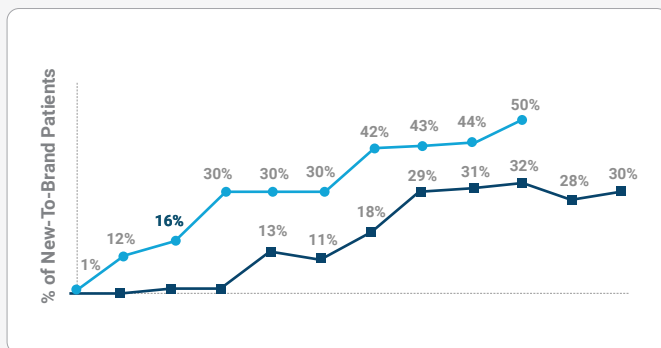
Source: IQVIA Institute (October 2020) "Biosimilars in the United States 2020-2024; Competition Savings and Sustainability."

- Reference products and biosimilars compete on price, and the average price discount of biosimilars within each molecule type ranges from low double-digit savings to almost 50%.
- Overall, biosimilars cost about 30% less than the reference product, demonstrating that enabling products to compete on price provides sustainable and significant savings.
- Biosimilar competition also serves to bring down over time the price of reference products, lowering costs for all patients.
- These lower costs provide savings directly to patients, like Medicare beneficiaries who are responsible for 20% of the cost of these outpatient therapies.
- Biosimilars' lower cost and impact on overall costs together drive savings for patients and payers.
- However, despite their discounted price, biosimilars for certain therapies have had difficulties garnering market share, leaving savings on the table. Policymakers should act to encourage greater adoption of lower-cost biosimilars.

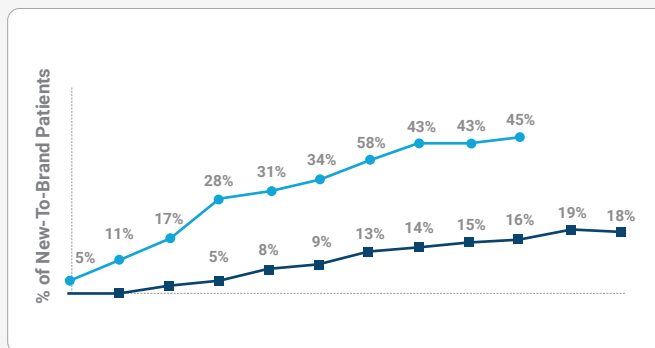
Provider Education Drives Biosimilars Adoption

ONCOLOGY CARE MODEL (OCM) PARTICIPANTS MORE LIKELY TO UTILIZE BIOSIMILARS

OCM PARTICIPANTS



OTHER



● 2019 Launches Avg (n=3)

■ Pre 2019 Launches Avg (n=3)

Source: IQVIA Analysis Highlights Role of Reimbursement Policy.

- As the biosimilar market has grown, so has the understanding of what factors influence provider adoption of biosimilars. For instance, IQVIA reports that provider biosimilar adoption patterns are highly heterogeneous.¹¹
- Although some providers have fully embraced the use of lower-cost biosimilars, too many continue to show reticence toward biosimilars.
- Data on provider biosimilar adoption highlights the role that appropriately aligning incentives through payment policy can play in biosimilar adoption.
- For instance, providers participating in the CMS oncology care model (OCM) are notably more likely to utilize biosimilars than other providers. This appears across all molecules and therapeutic categories and demonstrates that payment policy can positively affect utilization of lower-cost biosimilars.¹² The OCM was established by CMS to coordinate care and lower costs by allowing participating practices to opt into a value-based payment arrangement under which payments are tied to overall performance, rather than cost benchmarks for specific drugs.

¹¹ IQVIA Institute for Human Data Science. (October 2020). "Biosimilars in the United States 2020–2024."

¹² IQVIA. (March 2021). "Biosimilars in the U.S.: Reimbursement and Impacts to Uptake."

Methodology

The value of generics currently on the market was estimated using the pre-expiry prices of the brands they replaced. The current dataset includes pre-expiry brand prices for 1255 generic molecules. The value of each generic molecule was determined by multiplying its pre-expiry brand price by the generic volume sold in each of the last ten years. This value represents what would have been spent on brand name medicines in the absence of generic competition.

The savings attributed to each of the 1255 generic molecules was determined by subtracting historic generic spending from the estimated brand spending in the absence of generic competition. This analysis was refreshed with annual sales and volume data for all medicines sold in the United States between 1992 and 2020, focusing on the 10-year savings for the period 2011 to 2020. Savings from generics launched in the 1993 to 2020 study period are based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 1993 were calculated using brand prices from 1992 which is the oldest archived data period retained by IQVIA.

Generic savings were calculated at the molecule-class level using a single average price for each molecule across all formulations (oral solid, liquid). Molecules that are available in multiple formulations are assumed to have the same pre- and post-expiry utilization patterns. Molecules with injectable formulations were calculated related to specific formulations to appropriately measure the cost differences between brands and equivalent generic forms.

State level generic savings was estimated by apportioning total savings for each molecule by each state's share of the national retail prescription volume. This method embeds two assumptions; first, that prices are uniform across the country, and second, that retail prescription activity mirrors prescription activity in other channels, notably mail order.

Savings generated by children, young adults, older adults, and seniors were estimated based on national prescription trends captured in the IQVIA New to Brand Audit™. These figures represent the portion of the national savings generated by each age group, not the sum of the patients' personal savings.

Savings by pay type were estimated using the share of each molecule dispensed via retail pharmacies to patients paying with cash and those covered by Medicare, Medicaid, and commercial insurance. After calculating savings at the molecule, state, and payer level, results were summed to the state-payer level. This method does not analyze the cost to the patient who may have a co-pay or discount card; rather it divides generic savings equally amongst patients based on prescription use, regardless of insurance plan.

Patients with Medicaid, Medicare, and commercial insurance pay different prices for their medications based on their insurance benefit design. This analysis did not attempt to estimate savings to individual patients based on their method of payment. Instead, total generic savings for each molecule was divided evenly based on the number of prescriptions filled by patients of each pay type.

Methodology

In earlier editions of this study, the IQVIA Institute has employed not previously available historic archives. Prior versions of this study were based on archives and live data covering 2003 to present. The current edition of the study includes archives extending a further 11 years to 1992. The calculation of generic savings depends upon the brand's pre-expiry price or the oldest available brand price if the pre-expiry price is not available. Older generics, particularly those first launched before 1992, and even during 1992-2003, are now more accurately represented in the study. As brand prices change post-expiry, the more complete and accurate representation of their prices has improved the accuracy of the savings estimated in the study.

In the 2015 study release, the 10-year savings 2005-2014 were \$1.68 trillion. Using the new study's current method, the 2005-2014 savings would have been \$1.26 trillion, with the majority of the difference from older generics due to more complete and accurate availability of pre-expiry brand prices. Offsetting these reduced savings modestly was the inclusion of some medicines where brands ceased to be marketed between 1992-2003, leaving only their generics available. These medicines were previously excluded due to the absence of a brand price for calculations of savings, and which can now be included in the study.

Patient Savings: Methodological Overview

Base Savings Estimates: The base savings were calculated by IQVIA. We generated condition-level savings by assigning drugs to a list of common conditions and aggregating savings for all drug that are used to treat these conditions. Product condition assignments were conducted by a Doctor of Pharmacy. Importantly, many products treat multiple conditions. For purposes of this analysis, we ensured that the most common used of the product was the condition into which it was assigned.

Comorbidity Estimates: We used published epidemiological data to determine the 3 most common comorbidities for each of the index conditions. We calculated the base savings for the primary condition in the same manner as described above, and then assigned a weighted savings to each of the 3 selected comorbid conditions based on published prevalence data. Because the IQVIA data provided units rather than patients, we used units as a proxy for the number of patients treated and adjusted the units, and thus savings, in proportion to the published prevalence of each comorbid condition. Importantly, this methodology, due to the differences in units utilized by patients for specific conditions, could occasionally lead to estimates of comorbidity savings that exceed the total savings for that stand alone condition. In these cases, the savings were either capped, when the total numbers were relatively low relative to the main condition or, more commonly, the incidence rate for the comorbidity was applied again, to ensure a lower savings estimate. While this is a methodological choice and likely underestimates the savings from the comorbidity, it effectively assumes that the commorbidity requires more units per patient treated than the main condition.

Get in Touch

Association for Accessible Medicines

601 New Jersey Ave NW
Suite 850
Washington, D.C. 20001
202-249-7100

accessiblemeds.org

AAM All Access Podcast

<https://aamallaccess.podbean.com/>

Follow AAM on social media



Biosimilars Council

A division of the Association for Accessible Medicines

biosimilarscouncil.org

Follow the Council on social media



Download this report at RxAccessReport.us



aam
Association for Accessible Medicines

accessiblemeds.org

 **Biosimilars
Council**

biosimilarscouncil.org