



Biologics Driving Better Outcomes at a Higher Cost

Rising rates of cancer and autoimmune diseases are increasing demand for innovative therapies. Cancer incidence is projected to increase by 47% (2020-2040) to 28.4 million new cases annually, and autoimmune diseases affect 5% of the global population[1]. Innovative medications in precision oncology and targeted immunotherapies have significantly improved survival rates and quality of life, evidenced by a 33% decline in U.S. cancer mortality since 1991[2]. Biologic and biosimilar medicines are improving patient outcomes, significantly enhancing survival and quality of life for cancer patients, and biologics reducing disease activity in immunological conditions with biosimilar availability further improving access to these treatments.

However, the high cost of biologics is a significant challenge for payers, projected to exceed \$200 billion in annual U.S. drug expenditures by 2025[3]. Despite comprising only 2% of prescriptions, biologics account for nearly 40% of net drug spending[4]. Biosimilars, which cost 30% less, offer a crucial opportunity to expand access and deliver high-value care. Adoption varies, with stronger uptake in oncology than immunology due to factors like payer incentives and prescriber hesitancy.

FDA Landscape: A Decade of Growth for Biosimilar Availability

Since 2015, the FDA has approved over 71 biosimilars, with 21 deemed interchangeable. While all biosimilars are highly similar to their reference biologics with no clinically meaningful differences, interchangeable biosimilars meet extra criteria allowing pharmacy-level substitution without prescriber intervention, where state law permits. Interchangeable designation requires strong evidence that the biosimilar produces the same clinical result and that switching between the biosimilar and reference product poses no greater risk than using the reference product alone.

In 2024, the FDA removed the requirement for dedicated switching studies, enabling manufacturers to seek interchangeability status based solely on analytical and clinical data. This change is expected to increase interchangeable biosimilars and improve access, especially in retail and specialty pharmacies.

[1] Cancer Research UK. (2023). Worldwide cancer incidence statistics. Cancer Research UK. https://www.cancerresearchuk.org/health-professional/cancer-statistics/worldwide-cancer/incidence
[2] Michaeli, D. T., Michaeli, J. C., & Michaeli, T. (2023, June 19). Advances in cancer therapy: Clinical benefit of new cancer drugs. Aging (Albany NY), 15(12), 5232–5234. https://doi.org/10.18632/aging.204839
[3] Center for Biosimilars. (2024, June 17). The role of biosimilars: Advancing access, financial health, and system sustainability. https://www.centerforbiosimilars.com/view/the-role-of-biosimilars-advancing-access-financial-health-and-system-sustainability
[4] Raymond, B. (2023, June 15). Biosimilar uptake has been slow, but this is changing. Managed Healthcare Executive. https://www.managedhealthcareexecutive.com/view/biosimilar-uptake-has-been-slow-but-this-is-changing





Are Biosimilars Cost-Saving?

Biosimilars offer significant global and domestic savings. U.S. biosimilars have reduced wholesale acquisition costs by 18% to 67%, with average sales price discounts exceeding 50% for some oncology agents like trastuzumab, bevacizumab, and rituximab[5],[6].

An analysis of claims data was conducted to assess the potential financial impact of transitioning a client from a reference biologic to a biosimilar. Examining 337 claims from an existing ProCare Rx client, a significant opportunity for cost savings was identified. It is projected that this client could realize annual savings of \$1.25 million, an average savings of \$3,700 x claim.

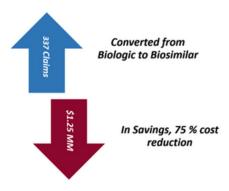
These savings are achieved even after accounting for all applicable rebates, underscoring the substantial financial benefit. This represents an approximate savings rate of 75%, demonstrating the enhanced efficiency of biosimilars. Importantly, these substantial cost reductions can be achieved while ensuring members continue to receive necessary innovative and specialized medications, thereby benefiting both budgetary considerations and patient care.

Biosimilars offer self-insured and commercial health plans a key opportunity to cut pharmacy benefit costs and ensure member access to vital specialty medications. Specialty drugs, despite being only 1-2% of claims, represent 50-55% of total pharmacy spend by 2024[7], highlighting the need for cost control. Biosimilars, clinically identical to existing biologics, introduce market competition, lowering drug prices without compromising safety or efficacy.

This saves money for plans, employers, and members. Beyond immediate savings, biosimilars foster a more competitive market, encouraging innovation and improving access to treatments, making their integration into formulary management crucial for sustainable, accessible healthcare.

Medicare Part D: Adoption Lags despite Growing Coverage

Despite this near-universal coverage, the adoption of biosimilars remains low. A major factor is that almost all Medicare Part D plans place Humira and its biosimilars on the same cost-sharing tier, offering little financial incentive for patients to switch. This strategy, often involving bundled rebate strategies and copay assistance programs (only applicable in commercial plans) from reference biologic manufacturers, aims to protect their market share and significantly delays the adoption of biosimilar alternatives.



[5] Jeremias, S. (2025, January 16). Biosimilars drive cost savings and achieve 53% market share across treatment areas. The Center for Biosimilars.

https://www.centerforbiosimilars.com/view/biosimilars-drive-cost-savings-and-achieve-53-market-share-across-treatment-areas
[6] World Health Organization. (2025, February 13). Biosimilars: expanding access to essential biologic therapies. World Health Organization. https://www.who.int/news/item/13-02-2025-biosimilars--expanding-access-to-essential-biologic-therapies
[7] Intercept Health. (2025, February 17). Understanding specialty drugs and their impact on health plans. Intercept Health. https://intercept.health/insights/blog/understanding-specialty-drugs-and-their-impact-on-health-plans/



The practice of flat-tier placement led to an estimated \$84 million in lost Medicare savings in 2019 due to the underutilization of lower-cost biosimilars. In response, the Centers for Medicare & Medicaid Services (CMS) finalized a 2024 rule, effective in 2025, allowing midyear formulary substitutions of biosimilars, even those without interchangeable status[8]. While this regulatory change aims to boost biosimilar uptake, real-world adoption will ultimately depend on aligning formulary design, patient incentives, and contracting strategies.

PBM Market Trends: 2025 Snapshot

The year 2025 marked a pivotal shift in the biosimilar landscape, largely driven by major Pharmacy Benefit Managers (PBMs) strategically prioritizing private-label biosimilars over their commercially available counterparts. This aggressive tactic saw the rise of PBM-affiliated brands, such as Cordavis, a subsidiary of CVS, and Quallent, part of Cigna, which rapidly came to dominate formularies. A key driver of their swift adoption was the frequent offering of \$0 copays, a powerful incentive that effectively displaced many of the Humira biosimilars launched in 2023[9].

While this approach seemingly delivers immediate affordability for patients and potentially lower costs for health plans, it simultaneously introduces a host of new concerns. The most prominent among these are the significant risks of market consolidation and the potential for diminished long-term competition within the biosimilar sector. This strategy could inadvertently create a less diverse market, where a few dominant players control access and pricing, ultimately limiting future innovation and choice.

As biosimilar launches continue to proliferate across a wide array of therapeutic areas, the success of their adoption remains inextricably linked to formulary design. Crucially, contracting arrangements and rebate strategies employed by PBMs play a determinative role, acting as either facilitators or formidable barriers to uptake. An increasing emphasis is being placed on evaluating the "lowest net cost" of biosimilars, a metric that factors in rebates and other discounts, to ensure their competitive positioning.

Furthermore, PBMs are actively working to establish biosimilar positioning in preferred formulary tiers, often coupled with low copays, to actively promote their adoption. Some PBMs are even pursuing more aggressive strategies, aiming to entirely eliminate access to the biologic reference product in favor of its biosimilar alternative, thereby compelling usage and maximizing market share for their preferred biosimilar options. This complex interplay of pricing, access, and strategic maneuvering by PBMs will continue to shape the future of biosimilar utilization and market dynamics.

Biosimilars Driving Broader Access

Biologics for oncology and immunology continue to drive U.S. drug spending, with therapies for cancer, autoimmune conditions, and chronic inflammation among the most expensive[10]. Biosimilars for drugs like rituximab, trastuzumab, adalimumab, ustekinumab, and denosumab are vital for increasing patient access, enhancing formulary flexibility, and generating system-wide savings.

In 2025, biosimilars referencing ustekinumab, omalizumab, denosumab, and tocilizumab were approved or launched in the U.S., addressing conditions such as Crohn's disease, psoriasis, osteoporosis, and asthma[11].

- [8] Centers for Medicare & Medicaid Services. (2024, April 4). Contract Year 2025 Medicare Advantage and Part D Final Rule (CMS-4205-F). https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-medicare-advantage-and-part-d-final-rule-cms-4205-f
- [9] Fein, A. J. (2025, January 22). The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars. Drug Channels. https://www.drugchannels.net/2025/01/the-big-three-pbms-2025-formulary.html
- [10] GoodRx. (2024, April 1). 10 of the most expensive drugs in the U.S. https://www.goodrx.com/drugs/savings/most-expensive-drugs-in-us
- [11] Jeremias, S. (2025, January 21). A banner year for biosimilars: The 19 FDA approvals from 2024. The Center for Biosimilars. https://www.centerforbiosimilars.com/view/a-banner-year-for-biosimilars-the-18-fda-approvals-from-2024



IQVIA estimates that denosumab biosimilar entry alone could generate €998 million in EU savings by 2030[12], highlighting the financial impact of increased market competition and clinical confidence.

At ProCare Rx, our strategy for biosimilar integration prioritizes clinical appropriateness, regulatory status as well as lowest-net-cost modeling, all in line with evidence-based care and access objectives.

Barriers to Adoption and Possible Solutions

Biosimilar adoption is hindered by payer, provider, and patient barriers, despite clear benefits. Addressing these obstacles is key to wider use and system savings.

Barrier	Key Challenge	Alternative
Market/Contracting	Rebates and contracting incentives favor reference biologics.	Use lowest-net-cost evaluations and biosimilar-first formularies
Provider Hesitancy	Concern about switching stable patients, limited biosimilar knowledge.	Education programs, CME, and pharmacist support with focus on the affordability aspect, critical to increase access while reducing unnecessary costs for payers and patients.
Patient Awareness	Misconceptions and copay assistance reduce switching.	Engage plan members in conversations about how the rising long-term cost of medications may threaten the sustainability of their overall medical coverage, as payers are forced to reconsider what can be covered with limited resources.
Therapeutic-Class Variation	Oncology adoption faster than immunology.	Tailor strategies by therapeutic area, share real-world evidence.
Regulatory/Operational	Flat-tier placement or inconsistent plan design slows uptake.	Apply CMS substitution guidance and standardize plan designs.

[12] IQVIA Institute for Human Data Science. (2025, May). Unlocking biosimilar potential: Learnings from an osteoporosis case study of complex patient pathways. https://www.iqviainstitute.org



As employers, health plans, and Pharmacy Benefit Managers (PBMs), we have a unique opportunity to partner with our members and their healthcare providers to ensure comprehensive medical coverage. By openly discussing the long-term costs of medications, we can work together to strengthen our healthcare offerings. This collaborative approach is essential for thoughtfully managing pharmaceutical expenses, which in turn allows us to maintain robust medical coverage and continue providing valuable benefits.



This shared understanding can lead to innovative solutions, such as:

- **Empowered Member Cost-Sharing:** Collaboratively exploring options that engage members in their healthcare spending, fostering ownership and informed decision-making with provider guidance.
- Optimized Formulary Design: Designing formularies that achieve excellent clinical outcomes while offering accessible and affordable medication choices, simplifying processes for members and providers.
- Enhanced Benefit Structures: Evolving benefit designs to maximize access to a broad range of essential treatments and therapies, ensuring members receive the care they need through seamless provider interactions.
- Streamlined Utilization Management: Developing clear and efficient processes for high-cost drugs, ensuring timely access to necessary treatments while promoting responsible resource allocation in collaboration with providers.
- **Proactive Focus on Value-Based Care:** Embracing models that prioritize both cost-effectiveness and positive patient outcomes, leading to more impactful and sustainable medication choices with active patient and provider participation.

By including members and providers in this conversation, we can cultivate deeper trust and a shared vision for a healthier future. This collaborative spirit empowers members to make informed choices about their treatment options and actively participate in shaping a sustainable healthcare system, supported by their healthcare providers. Together, we can ensure continued access to essential medicines while securing the financial viability of our health plans and employers. This open dialogue will foster a sense of security and partnership, empowering members to navigate their healthcare journey with confidence and clarity alongside their providers.

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