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Biosimilar Adoption: Challenges and Opportunities

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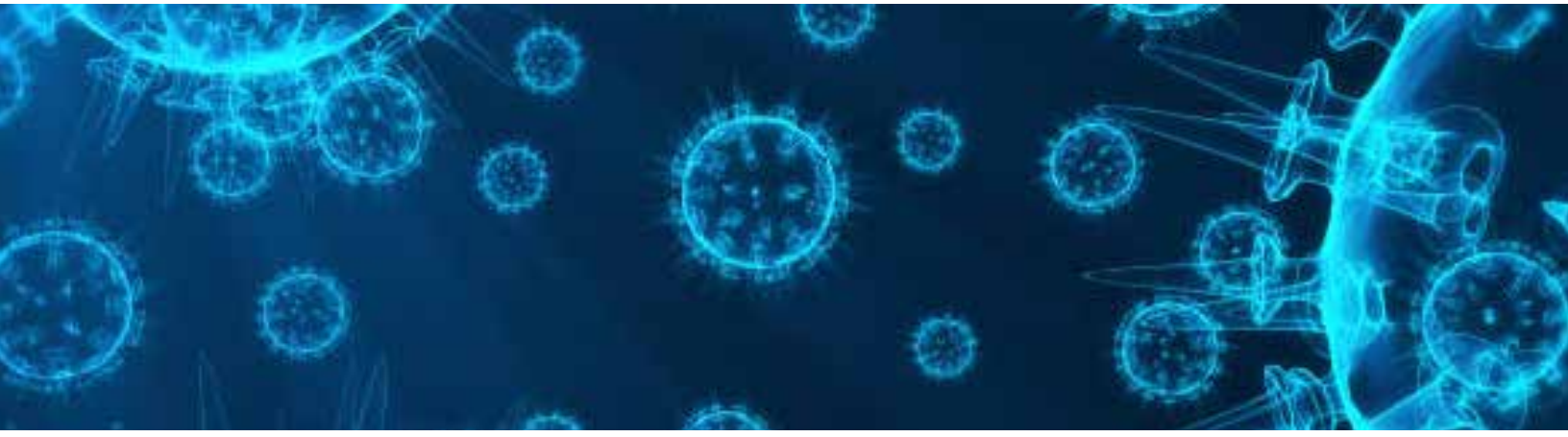
PBGH Purchaser Business Group on Health

Introduction

PBGH undertook a project to identify the market challenges associated with biosimilar adoption. The project included three bodies of work.

1. Qualitative interviews of representatives of health plans, accountable care organizations (ACOs) and oncology practices led to two distinct briefs outlining observations.[1, 2] Key observations outlined in the Briefs emphasize:
   - The challenge of provider organizations to manage the drug inventory operations required due to commercial health plan disparate coverage policies
   - The evolution of health plan drug formularies as new biosimilars launch.
2. Experience was logged from the prior-authorization process of multiple infusion centers to better understand prescription conversions, i.e., distinctions between what was prescribed and what was approved.
3. In partnership with Archimedes, data from three large purchasers were evaluated to identify opportunity for savings with "biosimilar first" policies.[3]



1 Brief one: Observations from interviews with ACOs. Link

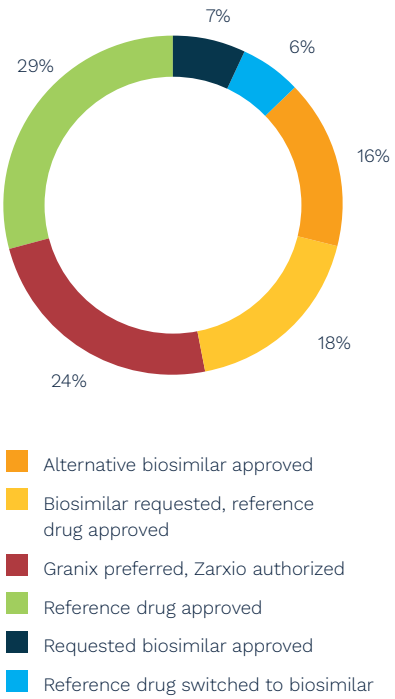
2 Brief two: Physicians' Perspectives. Link

3 Link

Prior-Authorization Observations and Health plan coverage policies

Ninety-three prior-authorization experiences of four oncology-related infusion centers were tracked. The PAs represented the actions of 14 health insurers and various health plan designs covering commercial populations, e.g., PPO, HDHP, HMO. The objective was to identify patterns that might demonstrate health plan preference for brand drugs over biosimilars and put in motion interventions with purchasers to address the barrier.

PA Activity among 14 health plans and 4 infusion sites



Observations

- Health plan coverage policies are known and understood by providers' PA staff. Often, a prescription is converted to the preferred drug prior to the PA process, assuring approval. The majority (36%) of requests in this exercise were approved as requested; 29% reference drugs and 7% biosimilars. Any conversions to accommodate preferred drugs prior to the PA are unknown.
- Health plan coverage policies often allow a select biosimilar "at parity", which means a prescribed reference drug will be allowed. This allows a lag in uptake and resulting opportunity cost in savings as changes are made within the provider setting to motivate biosimilar-prescribing.
- Health plan formularies may prefer one specific biosimilar over another. Although this may reduce costs, it represents negotiations between health plans and biosimilar manufacturers resulting in rebated biosimilars, increased list prices and misaligned incentives; i.e. a perpetuation of the existing ecosystem and related challenges. Competition will reduce prices but the preservation of our existing rebate structure will not optimize the value of a functional marketplace. Moreover, providers report that this practice does not ease operational inefficiencies they incur due to inventorying and managing multiple drugs. This scenario represents 16% of the PA experiences in our observation.
- Nearly a quarter of the instances were Granix requests that were denied in favor of Zarxio. Granix is not technically a biosimilar as it was approved by the FDA prior to the Biologics Price Competition and Innovation Act of 2009, which was the pathway for bioismilar approval. However, in interviews, providers have expressed frustration about their inability to prescribe Granix, citing missed opportunity for equal clinical efficacy and lower costs.

- Eighteen percent of the PAs were for a biosimilar that was not approved in favor of a reference drug.
    - The majority of those observations was with UHC preferring Neulasta and Rituxan over biosimilar options. Both of those preferences has been adjusted in the UHC 1/1/21 formulary release.[4]
    - Four of those observations were from a regional Blues plan preferring Rituxan, Avastin, and Neupogen over the requested Truxima, Mvasi, and Granix alternatives. A large client of the regional Blues plan has been contacted to open a dialogue with their vendor, outcome of which is not yet determined.
- The tracking exercise did not include rheumatologists, despite efforts to engage that specialty due to the prevalence of Remicade prescriptions and the availability of multiple biosimilar options. Health plan coverage policies of the four national carriers serving self-insured employer PPO lines of business reflect that Remicade is preferred over reference drugs for three out of four plans. This is a an opportunity for intervention by purchasers because there are rebates associated with Remicade prescriptions. As discussed elsewhere in this report, health plans usually retain all or most of the rebate for medical channel drugs (as opposed to PBM channel drugs where some or most of the rebates are generally passed through to the purchaser) — creating a large incentive for them to prefer highly rebated drugs. Self-insured employers and public purchasers should require full and auditable accounting of rebates by health plans for medical benefit drugs.

By engaging with the provider organizations treating larger segments of their employed populations, plan sponsors can better understand the pharmaceutical work flow and procurement processes impacting their costs and the value proposition of allowing biosimilar prescriptions.

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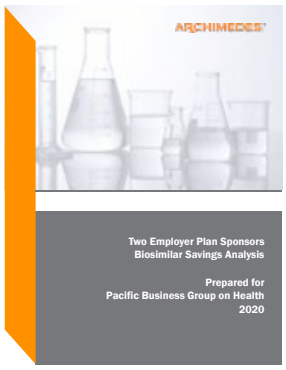


Commentary on the Data Analysis of Three Large Purchasers

The Biosimilar uptake project also included analysis of two distinct purchaser data sets and information regarding savings potential based on a third, less comprehensive data set. See the report for a full explanation of methodology and findings.[5] This introduction references the report findings and adds additional commentary offered by PBGH. This commentary is not a derivative of the report or its findings.

PBGH solicited data sets from three large purchasers and engaged Archimedes to evaluate the savings opportunity if uptake of biosimilar use was optimized. The three "data donors" varied by size and represented different health plan models and funding types. Data donors A and C covered the same geography while data donor B had no geographical overlap. The health plan designs addressed across the three represent a mix of PPO and HMO lines of business as well as self-insured and fully-insured funding.

Purchasers A and B provided actual data however Purchaser C provided summary information only and analysis on that purchaser was therefore limited. Due to data limitations, there is no reference to Purchaser C included in the Archimedes analysis.

Despite the variance in make-up, the maximum savings opportunity was similar across data donors as a percentage of spend for the reference and biosimilar drugs considered. Note that the maximum savings opportunity assumes the purchaser received the largest observed discounts but did not forego any rebates on the reference drugs (a situation which is customary for medical benefit drugs) and 97% biosimilar uptake.

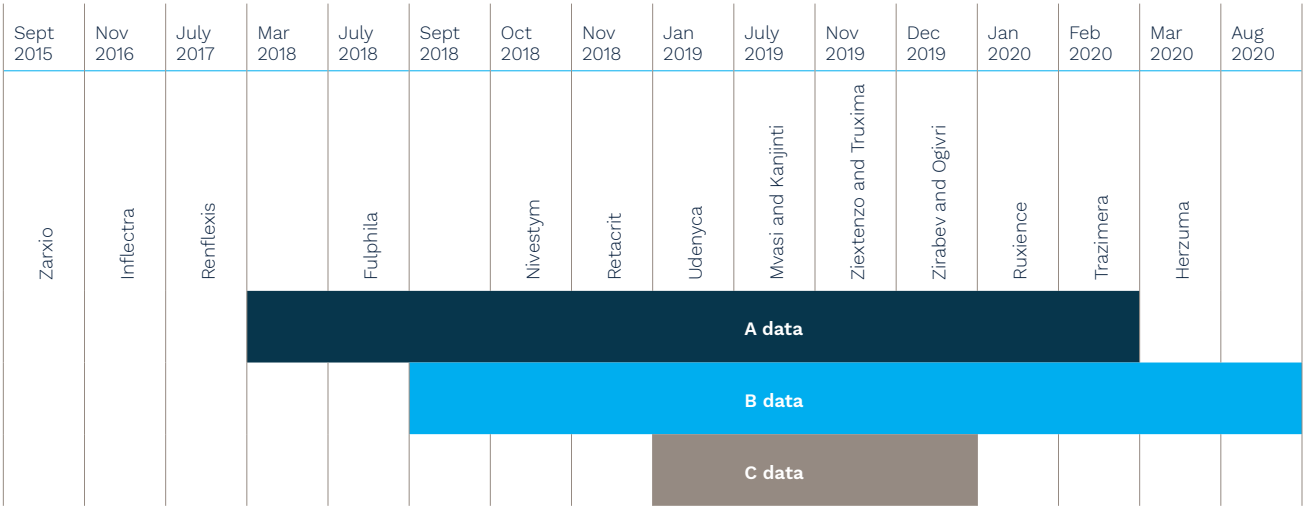
Summary of data donor characteristics

	A data	B data	C data
Data date range	March 2018 to Feb 2020	September 2018 to August 2020	2019
Spend on considered reference drugs	$208.8 million	$11,799,409	$60,285,183
# claims evaluated	Medical 6.2 m Pharmacy 1.5 m 101,429 reference and biosimilar claims considered	Medical 49,000 Pharmacy 575 1,151 reference and biosimilar claims considered	3,430 reference and biosimilar claims considered
Maximum savings potential among reference drugs considered	$48,408,793	$2,430,001	$10,368,347
Maximum savings potential as % of spend on reference drugs considered	23%	21%	17%

5 The Archimedes data report can be accessed here.

Note that some of the biosimilars available on the market today were not available for the complete time span represented by the data considered in the report, accounting for some of the lower uptakes on those specific biosimilars. The calculation of savings opportunity compared to the national average uptake remains relative.

This figure illustrates launch dates of biosimilars considered and time spans of the data from the three purchasers (one of which was not comprehensive data and was not included in the report)



The criteria impacting savings potential include rebates, biosimilar uptake and biosimilar pricing (discounts for biosimilars as compared to reference drug prices). The work also includes observations about cost differentials based on site of care.

Rebates

Any calculation of biosimilar-associated savings must account for rebates. Rebates are discounts offered by the manufacturer in exchange for formulary position driving market share, i.e., volume-based discounts. However, rebates (or the portion thereof) that are not returned to the ultimate purchaser are not discounts, and instead create a misaligned incentive for the health plan or PBM to promote use of the more heavily rebated drug despite a higher cost to the purchaser and patient. This is the crux of one substantial cost driver within the U.S. pharmaceutical distribution system.

The rebate conversation can be further distilled by looking at self-insured plans vs. fully-insured plans. The cost impact for self-insured plans is direct; rebates are either 1) discounts to the self-insured plan or 2) are an undeclared revenue source for intermediaries that leads to the selection or preference of more expensive drugs. However, the same rebate in a fully insured health plan is transparent to the "purchaser," (the health plan), leading one to assume that because fully insured health plans hold risk for medical expense, their decision to utilize biosimilars is directly related to the degree to which biosimilar net costs are less than reference drug net costs, i.e., one would assume that fully insured health plans have the incentive to prefer low-net-cost drugs. The assumption is challenged by the protection offered to health plans through premium underwriting, i.e., premiums are adjusted to account for high costs. Additionally, it has been suggested that the Medical Loss Ratio (MLR) provision of the Patient Protection and Affordable Care Act's (PPACA) might actually incentivize increased medical costs (the denominator) allowing for higher actual administrative costs (the numerator).[6 7] The interests of fully-insured plans are further nuanced by the consideration of patient cost sharing discussed below.

Plan sponsors need to better understand the impact of rebates on their drug spend and should demand comprehensive reporting of drug specific rebate attribution as well as rebate retention by the health plan or PBM.

The Archimedes report provides information assuming varying levels of rebate passed through to the purchaser. The larger the rebate received by the purchaser for reference drugs, the more the potential biosimilar savings are offset (reduced) by those rebates foregone. The report considers 0%, 10% and 20% rebate pass-through scenarios. It should be understood that for medically administered drugs, i.e., those distributed through the medical benefit as opposed to the pharmacy benefit, rebate pass-through is not common. The biosimilars on the market today are predominantly found in the medical benefit.

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A discussion about the impact of rebates on our pharmaceutical supply chain would not be complete without discussing impact on the patient. Patients' cost share is typically calculated based on the "list price" or pre-rebate price of the drug. If/when a rebate is returned to the plan sponsor, that patient is in effect pre-paying the discount that is returned to his or her plan sponsor. It is true that plan sponsors can reduce premiums for all by reinvesting the received rebates in subsequent years, but this defies the purpose of insurance. Using rebates prepaid by drug-taking patients to reduce costs for all patients is corollary to the sick (drug-takers) subsidizing the healthy (premiums for all insured lives). This is the opposite of how insurance is designed to work. Further, pharmaceutical manufacturers, recognizing the impact of high cost share on drug adherence, provide various opportunities to cover the patient cost share, which represents costs added to the drug price borne, but not fully understood, by us all.[8]

The impact on patient cost share is also relevant to the distinction between fully and self-insured health plans. As referenced earlier, fully insured health plans are at risk for the drug cost and may be driven to prefer low net cost drugs. However, if patient cost share includes a portion of the rebate returned to the insurer, low net cost TO THE INSURER might be a highly rebated drug. A pioneering approach to point-of-sale rebates by United Healthcare for its fully insured book of business identified the inequitable and possibly unethical added pre-discount expense charged to patients and implemented a corrective policy.[9]

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Uptake

The study assumes various levels of uptake based on national market share for each biosimilar drug, with a best-case assumption of 97% across biosimilars, to inform plan sponsors of various opportunities. In practice, there might be clinical hesitancy to switch stable chronic care patients from a drug regimen to a new biosimilar despite case studies demonstrating the efficacy of doing so.[10, 11] The interviews undertaken as a part of this project identified other factors impacting clinicians' receptivity to prescribing biosimilars including impact to drug revenue and patient resistance.[12]

Engaging enrolled members in adoption of high value care options such as biosimilar use through shared savings via value-based insurance design will reduce overall plan costs and improve members' experience with their employer sponsored insurance coverage.

Specific strategies to increase uptake can be adopted by plan sponsors.

- Measure uptake by continuously monitoring against national averages and communicate expectations for improvement to health plan and PBM intermediaries.
- Engage with reimbursement models that might impact physician, provider organization and hospital receptivity to biosimilar use. This should include value-based contracting that includes accountability for total cost-of-care. Reimbursement models are varied and complicated but plan sponsor engagement in better understanding these underlying incentives would influence not only system readiness for biosimilar adoption but healthcare system reform overall.
- Engage with employees and other covered lives through benefit design. As the report demonstrates, biosimilar adoption is a valuable lever for health plan cost management. Building incentives into an employee benefit program to encourage partnership for high-value care (and discourage low-value care) is an under-utilized plan sponsor strategy. Value-based insurance design is an evolving science and holds hope for effectively garnering the powerful force of consumerism.[13]

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This table below delineates the uptake of biosimilar alternatives per reference drug for each of the data donors and notes corresponding observations.

Biosimilar Uptake for three large purchasers across all plans (for which data were submitted)

Reference Drug	Biosimilar(s)	National Uptake	A data	B data	C Data
Avastin	Mvasi	25%	3%	0%	0%
Epogen-Procrit	Retacrit	29%	4%	28%	20%
Neupogen	Zarxio/Nivestym	72%	79%	90%	80%
Remicade	Inflectra, Renflexis, or	14%	33%	1%	0%
Neulasta/Neulasta Onpro	f/Fulphila Udenyca	29%	12%	58%	17%
Rituxan/ Other Brand	Truxima	5%	2%	1%	0%
Herceptin	Ogivri/Kanjinti	17%	3%	7%	3%

Observations about uptake:

- The large uptake of biosimilars for Neupogen is driven largely by Zarxio. Granix wasn't evaluated (it is not technically a biosimilar) although lower pricing has been reported.
- Biosimilars for Avastin, Herceptin and Rituxan are new to the market, launching second half of 2019. These data reflect start dates as early as March 2018, which contributes to the lower uptake numbers.
- Data donor B's biosimilar uptake for Neulasta and Neulasta/Onpro is largely driven by Udenyca with uptake of that biosimilar generally evenly spread across all plans.
- Lackluster uptake of biosimilars for Remicade is particularly disappointing because biosimilars have been available since November 2016. This dynamic is reflected in health plan drug coverage policies, where Remicade continues to be the reference product preferred over biosimilar options for multiple plans.[14]
- Data donor A has particularly high uptake for Remicade biosimilars, which is largely driven by one large HMO plan.

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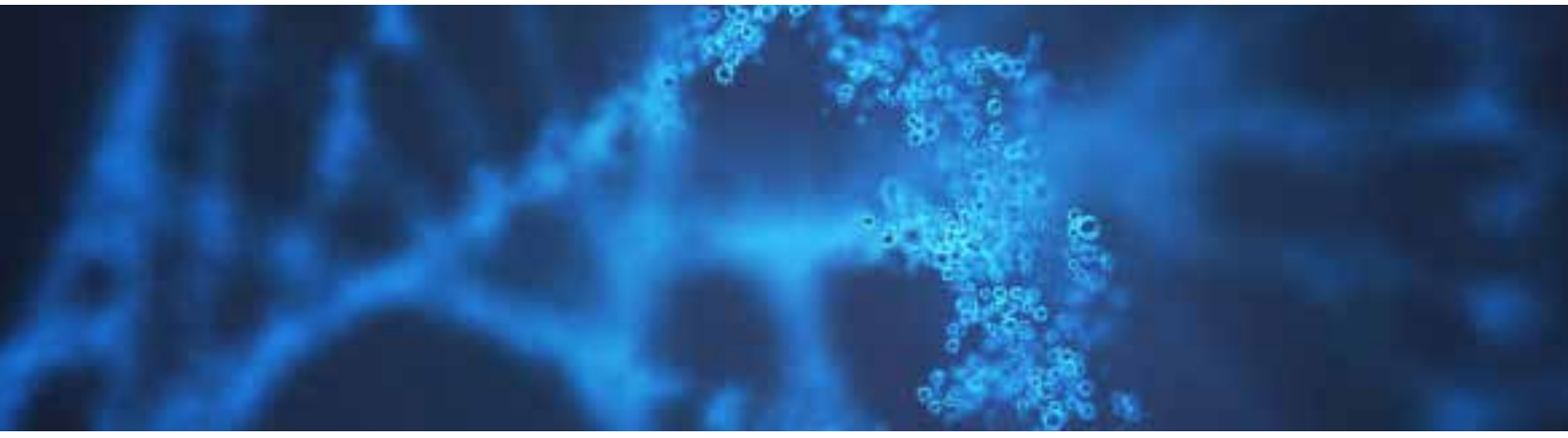
Site of Care

The report illustrates the variation in pricing based on site of care. Although site of care savings is not specific to biosimilars and was not measured in the Archimedes analyses, there is evidence showing that site-of-care management remains a viable opportunity for savings that is not being optimized.[15] [16]

Remicade is often used to demonstrate site of care savings because it is not an oncology drug. Employers report hesitancy to intervene on any aspect of oncology care given the sensitivity associated with the condition, although case studies suggest effective and successful intervention is feasible and productive.[17] The intervention to adjust site of care to a more cost-effective option is an ideal opportunity to also raise the issue of moving to a biosimilar alternative.



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Savings potential of 20% or more is possible when engaged employers insist on health plan adoption of cost-cutting solutions such as biosimilar-first policies. This will reduce healthcare cost for employers and for their employees and families. If biosimilars do not get used, there will be less interest among manufacturers to invest in their development

Saving Opportunity

As the sensitivity analysis tables in the report indicate, savings opportunity is substantial. Given both clinical and real-world evidence pointing to the efficacy and safety of biosimilars, purchasers should engage with their intermediaries to pursue larger uptake of this cost-saving strategy. Low net cost is impossible to determine confidently and accurately due to the existing opaque rebate infrastructure that exists in our pharmaceutical supply chain. Only when purchasers insist on full transparency and responsible administration of their organizations' and beneficiaries' pharmaceutical (and overall health care) resources will we fully optimize the value for our collective spend and related population health.

Acknowledgment

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