

Biosimilar Uptake: The Physician Perspective

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Executive Summary:

Biosimilars offer hope for competition in the high-cost specialty drug space where costs continue to skyrocket. However, the lackluster uptake of biosimilars in the US market has ramifications for patients, employers sponsoring coverage, and taxpayers. Conceptually, the ultimate driver of biosimilar use is the prescriber. In this brief, we examine the opportunity, impact, and circumstances of biosimilar uptake from the provider and provider organization perspective.

The FDA approves biosimilars noting that there is no clinical difference when compared to the reference products. The hesitancy to prescribe based on clinical concern is overstated by those with interests in delaying biosimilar uptake. To the degree that clinical concern is an issue, it is present primarily in drugs that are part of an on-going regimen to address chronic conditions. Clinician concern about switching patients from reference products to biosimilars is sometimes compounded by patient angst, causing hesitancy to change prescribing habits. That said, case studies in the US and abroad demonstrate successful switching campaigns.¹

The primary culprit blocking uptake of biosimilars among physicians contracted through Preferred Provider Organizations (PPOs) is a set of misaligned incentives that are difficult to unravel.

Below is a list of the most critical contractual and financial dynamics within and surrounding physician practices that impact biosimilar adoption:

- Providers are dependent on drug revenues to run their practices.
- Provider organizations are prevented from optimizing volume discounts that could be passed on due to health plan deals with manufacturers to which providers are bound through formulary compliance.
- The mix of upfront discounts and after-the-fact rebates makes it difficult for provider-based finance departments to know with certainty what drugs cost.
- Specialists with multiple ACO and health plan contracts may be bound by the formularies of those ACOs with their own rebate-driven rules. This demands administrative rigor to ascertain which rules apply to which patient. Errors in managing this were referenced by multiple practice managers who understand the cost of not getting paid if the wrong brand gets used.
- Physician compensation based on buy-and-bill reimbursement may result in a paycut for selecting lower cost drugs and may be at odds with the accountable care organization's interest in total care management based on value-based contracts.
- Health plans do NOT routinely pass medical channel drug rebates to employers in self-insured plans resulting in misaligned incentives. Some rebate deals involve drug mix bundles from a manufacturer. For example, a health plan's contract might result in use of multiple biosimilars

and a high cost reference product from one manufacturer, cutting out lower cost drugs from another manufacturer. This “bundle” creates barriers for competition and increases costs for all.

- Tactics deployed by employers to address costs have direct impact on provider practice, e.g. “white-bagging” and site-of-care management.

This jumble of conflicting pressures can only be addressed by changing the payment system to reward high-value care with excellent clinical outcomes and superlative patient experience (the triple AIM).

Background

The introduction of biosimilars into the high-cost specialty marketplace, particularly those that are available today, which are largely physician-administered, is impacted by a complicated array of financial, structural, and operational factors. In-depth interviews were conducted with physicians, practice managers, prior authorization staff, and pharmacoeconomists at 10 different physician practices across the country, two infusion suites and two national associations of physician practices.² We observed not only a web of conflicted incentives that work against lowest cost/highest value care but also substantial operational inefficiencies and intra-clinic variation based on line-of-business and payer. We noted universal themes among our interviews. .

Clinical Concerns Diminishing

Clinical concern about the safety or efficacy of biosimilars is often cited as a hinderance to adoption. Among the prescriber physicians interviewed, that concern was acknowledged only in the context of switching a longer duration (chronic) patient doing well on the reference drug to a biosimilar. Indeed, clinicians agree that the variance among batches of the reference drug is the same as the variance between the reference drug and the biosimilar and that patient concern about switching has a greater influence impacting the switch than does legitimate clinical concern. Educational efforts and compelling data regarding the safety and efficacy of biosimilars have been effective at addressing clinical concerns among physicians. There is still work to be done to address concerns about switching both at physician and patient level. Addressing patient concerns and increasing patient/purchaser demand for biosimilars over reference products will increase the rate of switching from reference to biosimilars. Patient incentives can be deployed to engage that important constituency and will be discussed in a separate brief. While there is more to be done in this arena, it is clear that clinical concerns are not the overriding obstacle among prescribing physicians.

Payer and Organizational Structure-a Myriad of Influences

Physicians’ prescribing with regard to medical channel drugs, which is where most biosimilars reside today, varies based on three main variables:

- A. Is the patient covered by Medicare or a commercial plan, i.e. is pre-authorization used to direct compliance with a formulary?
- B. Is physician compensation “buy-and-bill,” or another method?
- C. Is the prescriber accountable for total cost of care, i.e. are value-based contracts in place?

A. Medicare vs. Commercial

Medicare patients generally have no pre-authorization requirement. The prescribing physician makes the decision about which drug to administer, be it reference or biosimilar. It behooves providers to do their own negotiations with manufacturers and distributors for discounts and rebates. Provider groups will typically elect to target a specific drug for which they get best pricing and they will enter that preference into their EMRs for point-of-care decision support. In this way, the physician or practice can leverage volume discounts and rebates from manufacturers and distributors. Assuming an interest in engaging in competitive or value-based contracts, those discounts and rebates can be applied to lower total cost of care. Moreover, providers reported an interest in utilizing lower cost drugs to lower patient cost share.

In contrast, physicians working with patients covered by commercial insurance face a terrible tangle of contract arrangements between manufacturers, health plans, specialty pharmacies, distributors, and other intermediaries. In most commercial fee-for-service (FFS) PPOs, health plan preauthorization of biologic drugs is required, and the allowed drug will be dependent on the formulary selected by the health plan, which is based on rebates flowing through the intermediaries to that particular health plan. Health plans share little or no rebates with employers who ultimately pay for the care. This dynamic exists in both pharmacy and medical drug channels and is largely responsible for high drug list prices. It has been moderated in the PBM-managed pharmacy benefit space (particularly for large employers) more than in the health plan-managed medical channel space, creating high incentive for health plans to prefer high rebate/high cost drugs.

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The variation in preferred drugs among the health plans, from reference product to a specific biosimilar, not only causes administrative and operational burden for providers who must manage multiple inventories, but also impacts providers' capacity to optimize volume-based discounts and rebates, which would enable them to perform better on total cost of care contracts. Compounding this inefficiency is the fact that any one physician or physician group might have contracts with multiple Accountable Care Organizations (ACOs) – some of which have developed their own formulary based on their own set of contracts/rebates for the supply of biologic drugs.

Several medical groups reported concern over infusion of the wrong brand of drug. This is not a patient safety issue, but rather a financial one. They report instances of mistakes being made and the wrong brand being infused resulting in non-payment from the health plan, forcing the provider group to absorb the cost of the drug and forgo payment for administration of the drug to the patient. This could mean a loss of tens of thousands of dollars to physician practices for just one patient. It illustrates the challenges associated with inventory and management of multiple formularies and multiple drug brands.

Provider organizations also shared frustrations with tracking net drug cost because rebates are paid retroactively and are not well mapped to drugs purchased three months prior. Additionally, some rebates get convoluted based on drug combinations (or bundles). Time of purchase discounts are much easier for practice administrators to track and quantify, and are, consequently, preferred.

B. Provider Compensation

Medicare Fee-for-Service (FFS) pays physicians based on a Medicare fee schedule, which is a factor of the medication's Average Sales Price (ASP). However, in an effort to avoid financially penalizing doctors for prescribing lower cost biosimilars, Medicare pays doctors based on the ASP of the reference product, no matter which biologic – reference or biosimilar – is used. Therefore, there is no downside, for physicians when they prescribe/use the biosimilar with Medicare patients³.

In the commercial FFS world, many physicians are compensated for their services by marking up the cost of the drug they administer. The percentage mark-up can vary widely – from as little as ASP+6% to ASP+100% or more. This methodology, known as “buy-and-bill,” is pervasive among non-salaried prescribers. Every administrator, physician and pharmacoeconomist interviewed agreed that the practice of buy-and-bill was an anathema to the goal of driving down the cost of health care to those patients needing biologic drugs because it represents a misaligned incentive. It is worth noting that there is variance of opinion about the degree to which ASP+ based pricing impacts physician decision making, however generally speaking, tying physician reimbursement to drug prices is rife with potential for conflict of interest.^{4 5 6}

Health systems with prescribing physicians on staff and compensated via a fixed salary found it easier to convert from reference products to biosimilars because they were not impacting the income of their admitting physicians. Because physicians on salary do not have their base income increased or decreased based on the price of the drug used, they have no inherent conflict of interest with using a lower cost drug. Kaiser Permanente has shared that they now have 80%-95% adoption of the 6 biosimilars used by the organization, with a savings to the organization of about \$200 million since the inception of their program.⁷ Other large medical systems with salaried physicians also reported a relatively smooth conversion to biosimilars when they engaged prescribing physicians with clinical data and cost of care information. But when asked if they approach physicians in the community currently operating under a buy-and-bill reimbursement methodology that also admit patients to their facilities about moving to biosimilars, the universal reaction was that they do not. The topic is simply too sensitive. No hospital system wants to offend admitting physicians by starting a conversation about whether or not buy-and-bill is in the best interests of the patient and/or the health care delivery system. Hospitals and integrated health systems also enjoy large profits from specialty drug mark-up. In an earlier Brief, we discussed the variance in opinion about the degree to which 340B discounts impact biosimilar adoption but there is no disagreement about the impact on hospital profits resulting from that legislation.

Simply put, basing reimbursement to hospitals or physicians on drug cost is an innate conflict of interest. Value-based contracts that give providers accountability for total cost of care is a step towards more aligned incentives that reward prescribers and intermediaries that identify opportunities for cost savings.

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It is important to note that some value-based contracts negotiated with large health systems do not adjust the misaligned incentive for prescribing doctors. The contract between the plan

and the health system might be aligned, but the contract between the system and the individual providers may or may not be aligned to achieve highest value.

Large health systems with value based contracts and their own specialty pharmacies might also benefit by adopting a “biosimilar first” policy if doing so implies movement of drug procurement to their internal specialty pharmacy. This strategy provides savings through bulk and bundled discounts, 340B pricing, rebates and improved inventory management. Requiring that specialty drugs be procured and managed through a health system specialty pharmacy involves careful analysis to understand savings opportunities for the purchaser. Moreover, it requires purchaser fortitude. Most specialty drugs under the management of a commercial health plan, with the exception of buy-and-bill drugs infused in a doctors’ office, are acquired through the health plan or PBM-owned specialty pharmacy. This is a profit center for intermediaries and they will not readily permit moving drug procurement to hospital specialty pharmacies.

Moving physician-administered drugs to a hospital or other provider-based specialty pharmacy to avoid buy-and-bill profiteering also comes with challenges. The practice of “white bagging, brown bagging, or clear bagging” is discussed by many as a viable mechanism for “taking control” but may not always result in savings and is highly unpopular with treating physicians.

White-bagging, brown bagging, and clear-bagging are terms used to describe a process where the typical physician practice of buying, inventorying, and then billing for the drug they administer is intervened upon. It can be a successful strategy if reimbursement methods with physicians include large buy-and-bill profits and/or it is a method that supports better drug management, e.g. site of care management or a biosimilar first policy. It involves removing drug management from the physician and giving it to an intermediary, usually a PBM, that mandates purchase of the drug through a select pharmacy. The operational aspect of getting the drug to the doctor’s office for administration has coined the “bagging” terms.

1. White bagging implies that the drug is “drop shipped” for a specific patient.
2. Brown bagging implies that the patient brings their drug for administration to the doctor’s office.
3. Clear bagging implies that the drug will be procured by a health system specialty pharmacy and delivered “just in time” for the appropriate patient.

Critics of the practice indicate that chain of command is threatened and impacts patient safety. They also indicate that waste results when patients’ schedules change and drugs pre-delivered can no longer be used.

C. Prescriber’s responsibility for Total Cost of Care

In pure capitation arrangements such as Kaiser Permanente and in many ACO arrangements, where physicians receive bonus payments based on their ability to control the total cost of care (TCOC), practice administrators report a partnership with physicians to prescribe biosimilars. ACO models dominated by value based contracts usually have incentives in place to identify highest value drug options. The degree to which provider organizations can benefit from controlling TCOC will vary by the nature of the contract, which can range from shared savings to two sided risk.

As noted earlier, some ACOs accepting risk have not yet engaged their contracted physicians in payment reform. Employers expecting savings from ACO contracts need to ensure that downstream contracts are in alignment with the self-funded plan’s goals. Health systems balancing various types of reimbursement and managing various types of physician contracts will have to consider the revenue deficit from selecting lower cost drugs compared to the revenue gain from performing well on value-based contracts. It is particularly challenging for a health system to perform well on a value-based contract when a small portion of their patient population is enrolled. Systems have difficulty managing different treatment protocols for different types of contracts and will lose revenues under traditional fee-for-service contracts by performing well on smaller scaled total cost of care contracts.

The following table illustrates the variables described here that impact provider incentives to use biosimilars.

Factors to consider for commercial plans include consideration for how doctors are paid and the formularies of health plans, which are based on rebate arrangements.		Traditional Medicare plans are fundamentally different than commercial plans in that physicians have more control over what and how they prescribe.	
<ul style="list-style-type: none"> • Doctors negotiate with PPO health plans for reimbursement based on a drug ASP. In this model, use of biosimilars will imply a pay cut for doctors without cost-saving incentives in place, i.e. a value-based contract with payment reform at the doctor-level. • Note that some value-based contracts negotiated with medical groups do not adjust misaligned incentive for prescribing doctors. • In most commercial FFS PPOs, the allowed drug will be dependent on the formulary selected by the health plan, which reflects the health plan’s negotiations with manufacturers for rebates. • Doctors that negotiate with multiple accountable care organizations might be bound to the formularies set by the ACOs . • Doctors might be salaried or agree to payment reform principles that align incentives for higher value prescribing, e.g. HMOs or select ACO models. 	<ul style="list-style-type: none"> • Traditional Medicare FFS pays doctors based on a Medicare fee schedule, which is a factor of ASP. However, in an effort to not financially penalize doctors for prescribing biosimilars, Medicare pays doctors based on the ASP of the reference product. Therefore, there is no downside, for Medicare patients, to prescribing biosimilars. 		
Value-Based Contracts			
<p>Commercial Value Based Contracts create the incentive for provider organizations to identify highest value drug options. The degree to which provider organizations can benefit from controlling total cost of care will vary by nature of the contract, which can range from shared savings to two sided risk. Health systems profiting from buy and bill arrangements will have to consider the revenue hit from selecting lower cost drugs compared to the revenue gain from performing well on value-based contracts.</p> <p>Medicare Advantage Plans are a form of value based contract where the health system incentives are aligned to control for total cost of care. Some Medicare Advantage plans may engage doctors in payment reform further partnering with them for accountable total cost of care management. But, not all MA plans do.</p>			
More Risk (incentive to control costs)		→	Less Risk
Commercial	HMO → ACO → PPO		
Medicare	Medicare Advantage → Medicare Fee for Service		
<p>Physician arrangements may not be aligned with the organizational arrangements. For instance, doctors may be paid fee-for-service (including traditional buy and bill) despite organizational value-based contracts. There are structural and political challenges to fully aligning payment between physicians and provider organizations.</p>			

SUMMARY

From the prescribing physicians' point of view there are three main variable affecting the level of biosimilar adoption:

- ◆ Line of business: Medicare or a commercial plan?
- ◆ How is the physician compensated, via “buy-and-bill,” or salary?
- ◆ What incentive is in place for the physician to consider total cost of care in addition to patient outcomes?

By examining these three primary influencers and addressing misaligned incentives, there is tremendous opportunity to increase the adoption of biosimilars. No one disputes the current uptake of biosimilars in the US market has been slow. This slow adoption has resulted in substantial missed cost savings estimated to be \$20.4 billion from 2018 to 2020. Moreover, patients could have saved \$167.5 million in out-of-pocket expenses in 2020.⁸

The implications of the misaligned incentives leading to the slow adoption of biosimilars has serious financial implications for benefit managers trying to control the rising cost of health care coverage and indeed, the sustainability of the employer sponsored insurance market.

¹ Switching Reference Medicines to Biosimilars: A Systemic Literature Review of Clinical Outcomes.

<https://link.springer.com/article/10.1007/s40265-018-0881-y>

² AC3 Health – South Bend IN, Memorial Hermann – Houston TX, Virginai Mason – Seattle WA, Memorial Care Health System and the Memorial Todd Cancer Center – Southern CA, Ponchatrain Cancer Center – Covington LA, Carolina Blood and Cancer Care – Charlotte NC, OSO Home Infusion – Southern CA, Northwest Medical Specialties – Tacoma WA, The Center for Cancer and Blood Disorders – Fort Worth TX, Mercy Saint Louis – St. Louis MO, Hill Physicians – Bay Area CA, National Cancer Treatment Alliance, Community Oncology Alliance

³ <https://www.centerforbiosimilars.com/contributor/sonia-oskouei/2017/10/cms-biosimilar-reimbursement-shift-what-you-need-to-know>

⁴ Levine, S., Barraeta, A., Webster, P.F., “Realigning Incentives To Optimize Generic And Biosimilar Prescribing”. Health Affairs, June 13, 2019 <https://www.healthaffairs.org/doi/10.1377/hblog20190611.58590/full/>

⁵ Mulcahy AW, Hlavka JP, Case SR. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Rand Health Q. 2018;7(4):3. Published 2018 Mar 30. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6075809/>

⁶ <https://communityoncology.org/bad-medicine-oncologists-review-the-evidence-2/>

⁷ Sameer V Awsare, MD, FACP, Associate Executive Director, The Permanente Medical Group, presentation to the PBGH/IBI Biosimilar Forum, August 13, 2020.

⁸ Juliana Reed, MS, Vice President, Global Corporate Affairs Lead at Pfizer, presentation to the PBGH/IBI Biosimilar Forum, August 12, 2020.