PBGH
PACIFIC BUSINESS GROUP ON HEALTH

Issue Brief:

Value Based Accountable Care Organizations and Biosimilar Uptake

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Executive Summary:
Misaligned financial incentives and opaque drug purchasing arrangments appear to be the primary culprits preventing the robust adoption of biosimilars in the U.S. market. Even when employers align financial interests with their privider partners via double-sided ACO risk based contacts, the rebates that accrue to intermediaries, buy-and-bill markups, 340B program misuse/abuse and other purposefully murky financial arrangments between the myriad of players in the supply and delivery chain confound efforts to make the biologic drug market operate in a truly competitive fashion.

However, we find that all things being equal, armed with information about clinical efficacy, patient preference, and treatment costs, providers are best positioned to make value-based decisions when incentives are aligned via value-based contracts. Purchasers and payers should consider opportunities to delegate both accountability and authority for manging biologic drug expense to provider systems via risk-bearing contracts.

Background

Health care economists and employer benefit managers had high expectations that with the introduction of biosimilar drugs into the US market, drug spending on biologic drugs in this country would decrease. Those hopes have not been realized as expediently as they would have hoped for a number of complex reasons. This brief examines the obstacles faced by Accountable Care Organizations (ACOs) as they work to increase their usage of biosimilars.

ACOs were chosen for examination because several large employers have direct contracts with these risk-bearing organizations. Under the terms of these, and additional health plan ACO contracts, the ACOs have accountability for the cost and quality of patient care. In that regard, their incentives are aligned with patients, employers and other healthcare purchasers.

In-depth interviews were conducted at four different ACOs: one in Washington State, one in Southern California, one in Missouri and one in Texas. The following challenges to biosimilar adoption and uptake were shared by all.

1) PARITY – is it real?

A survey of coverage policies from the four national health plans (Aetna, Anthem, Cigna and United) revealed that on paper, at least, the majority of biosimilar drugs approved by the FDA and available in the US market are covered at parity with the innovator or reference drug.[1]

However, ACOs found that when they requested prior authorization (PA) for the use of a biosimilar, health plans often increased the hassle factor compared to a PA request for the reference drug. Staff members requesting PA for biologic drugs reported a relatively smooth and quick process when requesting use of

the reference drug, but reported being asked for additional documentation and other delays when seeking PA for biosimilars.

Medical channel rebates appear to be the main driver of this phenomenon. Health plans get and keep a larger rebate when reference drugs are used. In this respect, the incentives of the organization administering the self-insured employer plans are not in alignment with the purchasers' interests. Health plan management might argue that the employer also benefits from the larger rebates tied to reference drugs because they get a lower net cost. However, we have yet to see clear evidence that much, if any, medical channel drug rebate dollars are being returned to the employer. In fact, on one specific occurrence, a large PBGH Member was told by a health plan, "we just don't pass rebates to you, it's not what we do". They might argue that they credit ASO fees, which seems unlikely given that it had never been discussed. Keeping in mind that PBGH Members represent the largest and biggest name employers in the country, one can only imagine the degree to which rebates from smaller and less influential self-insured employers add revenue to health plans' bottom line. In this manner, "rebates" from the manufacturer intended for the self-insured employer become a kickback to the health plan – providing large financial rewards for continuing to block adoption and use of biosimilars.

Interestingly, PBMs do tend to share a larger proportion of rebate dollars with employers. This suggests that PBM management of select medical channel drugs and the introduction of biosimilars to the outpatient pharmacy benefit managed by the PBM could make reference product rebates more meaningful to the self-insured plan. That said, today most biosimilars are distributed through the medical channel managed by health plans, and the rebates given to plans are not passed on to the ultimate employer and patient purchasers.

ACOs report that the lack of parity in PA processes could be addressed by allowing providers to seek PA for the "ingredient," regardless of manufacturer. Once it is agreed that the patient is clinically appropriate for the active ingredient, the ACO determines what brand, i.e. reference or biosimilar. The FDA has determined that both are safe and there is no clinical difference between them. ACOs indicate that not only could they then better work with physicians to promote biosimilar prescribing in a more streamlined way, but they would benefit from inventory and purchasing economies themselves, allowing them to share more savings in accordance with their value-based contracts. Indeed, another proposed solution is delegating PA to ACOs and other providers with risk-based arrangements that include responsibility for total cost of care. Both of these approaches only work with value-based contracts. In other words, if the health system does not have accountability for total cost of care along with best clinical outcomes, there could be unintended consequences as they too will identify incentives to maximize rebates resulting in higher overall costs. Incentives must be aligned and most ideally, placed with the entity best positioned to optimize both clinical and financial value; that is, the provider of care.

2) <u>The problem with ASP+ ("Buy and Bill") Reimbursement: Incentives Matter!</u>

ACOs typically engage with physicians in two ways: employment agreements and contractual arrangements. Employed physicians receive a salary whereas contracted physicians are paid Fee-For-Service (FFS), with hefty profits made available through a "buy and bill" system of biologic drug reimbursement. ACO staff reported encountering very little resistance from employed physicians when approached about using a biosimilar. However, the risks of approaching contracted physicians is akin to asking them to take a pay cut. ACOs are sensitive to losing referrals and admissions from those specialists

and are leery of pushing for biosimilar adoption among this group of prescribers. Note that the health system itself loses revenues if reimbursement is not a function of drug price, again reinforcing the need to assure overarching value-based contracts so that their interest is in both clinical excellence and controlled total cost of care. Possibly counteracting that revenue hit, the aforementioned solution to transfer management of select biologics from health plan management to PBM management might have an added benefit for health systems if it includes moving business to their owned specialty pharmacies.[2]

The challenge regarding contracted physicians and buy-and-bill reimbursement requires a systemic multi-payer fix. CMS addresses this misaligned incentive as part of the CY2018 Medicare Physician Fee Schedule (PFS) policy. For Medicare patients, reimbursement for biosimilars is based on the average sales price (ASP) of the reference product, equalizing physician earnings regardless of which drug is prescribed.[3] Commercial payers have not followed suit and the mark-up on biologic drugs can be multiple times the ASP or thousands of dollars per dose. When asked why the CMS approach has not been adopted for commercially insured patients, one health plan specifically stated that "doing so would definitely impact rebates" implying that reference drug manufacturers recognize the importance to their business model of maintaining this profitable reimbursement scheme for their prescribers. Simply put, because the ASP of biosimilars is less than the ASP of the reference drug, physicians do not make as much money stocking and selling a biosimilar as they do a reference drug with buy-and-bill reimbursement processes in place.

Again, this is a case of the financial interests of the physician in conflict with the financial interests of the patient and the self-insured employer paying for the patient's treatment as well as a conflict that might exist between the physician and an ACO with which that physician participates.

3) <u>The impact of 340B on biosimilar uptake</u>

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs, including biologics, at discounted prices to certain health care organizations that care for significant numbers of uninsured and low-income patients.[4] The intent of what is commonly known as the "340B program" is to enable these facilities, called "covered entities," to stretch scarce federal resources as far as possible.

The issue is that while under the 340B program, pharmaceutical manufacturers provide steep discounts on outpatient prescription drugs to covered entities, the covered entities do not always extend those discounts to the patient or third party paying on behalf of the patient.[5]

A Milliman study commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA) found that hospitals participating the in the 340B program are reimbursed for physician-administered medicines at a rate that is on average three times what they paid to acquire the medicine. Using actual claims data, Milliman estimated the difference between a hospital's acquisition cost for physician-administered medicines purchased at the 340B discount and the reimbursement received from commercial insurers for those medicines. The analysis found 340B hospitals pay, on average, $1,591 per claim for a brand medicine, then submit a claim to a commercial insurer and receive $4,673 as reimbursement. That's a difference of $3,082 between what they paid and what they are reimbursed that the 340B hospital retains – twice what the hospital pays to purchase the medicine.[6]

The 340B program has grown from $6.9 billion in discounted sales in 2012 to $24.3 billion in discounted sales in 2017—an increase of over 250 percent[7]. Growing evidence has found that despite the exponential

growth of the 340B program, hospitals are not reinvesting the savings into increased care for vulnerable patient populations. In fact, the average amount of charity care provided by 340B hospitals has declined since 2011, with nearly two out of three 340B hospitals consistently providing below average rates of charity care.[8]

With regard to biosimilars and biosimilar uptake, 340B pricing and reimbursement has been a mixed bag. Some ACOs indicated that the discounts reference drug manufacturers offered outweighed the savings from biosimilars (some 340B rebates on the reference products approach 100%!).[9] Others indicated that the "pass through status" given biosimilars means they are reimbursed at the rate of average sales price (ASP) plus 6%, while reference products are reimbursed at the rate of ASP minus 22.5% - making biosimilars more profitable for that time span. The savings of the biosimilar versus the deeply discounted reference drug was totally dependent on individual contracts, on both the purchasing side and the payer side. Based on our study, no broad conclusions about the impact of 340B pricing and the uptake of biosimilars could be reached.

Conclusion

Working with ACOs to better understand obstacles of biosimilar adoption validates the opportunity for better value. It is clear that systemic misaligned incentives result when physician reimbursement is tied to drug prices. Making adjustment for Medicare patients by CMS is a step in the right direction, but, as is always the case, payer distinctions in policy and practice are a management burden for physician offices and commercial reimbursement will drive behavior given the profitability of that sector. It is also clear that when providers are responsible for both cost of care and clinical outcomes, that interest will drive practice patterns. All things being equal, armed with information about clinical efficacy, patient preference, and treatment costs, providers are best positioned to make value-based decisions when incentives are aligned via value-based contracts. Purchasers and payers should consider opportunities to delegate both accountability and authority to provider systems via risk-bearing contracts.

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[1] https://pbgh.box.com/s/qm6el4pn89zqj9k2ltwwi91yfwjem4cu

[2] The process of "white bagging" or "brown bagging" deployed when medical channel (part b) drugs are moved to management under the pharmacy benefit (part d) is loaded with pros and cons that will be discussed in greater detail in a brief later in this series.

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

[4] https://www.hrsa.gov/opa/eligibility-and-registration/index.html accessed 5/3/2020

[5] See 42 U.S.C. § 256b

[6] Bunger, A., Hunter, M.T., Kim, C. for Milliman "Analysis of 340B hospitals' outpatient department acquisition cost and commercial reimbursement for physician administered brand medicines". December 2019

[7] AIR340B "Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program" November, 2019

[8] Ibid

[9] Hagen, T. "CMS Payment Policy Plays Role in Biosimilar Uptake," January 30, 2020 The American Journal if Managed Care, https://www.centerforbiosimilars.com/conferences/specialty-therapies-and-biosimilars-conference/cms-payment-policy-plays-role-in-biosimilar-uptake