White Paper

Biosimilars in the U.S.: Reimbursement and Impacts to Uptake

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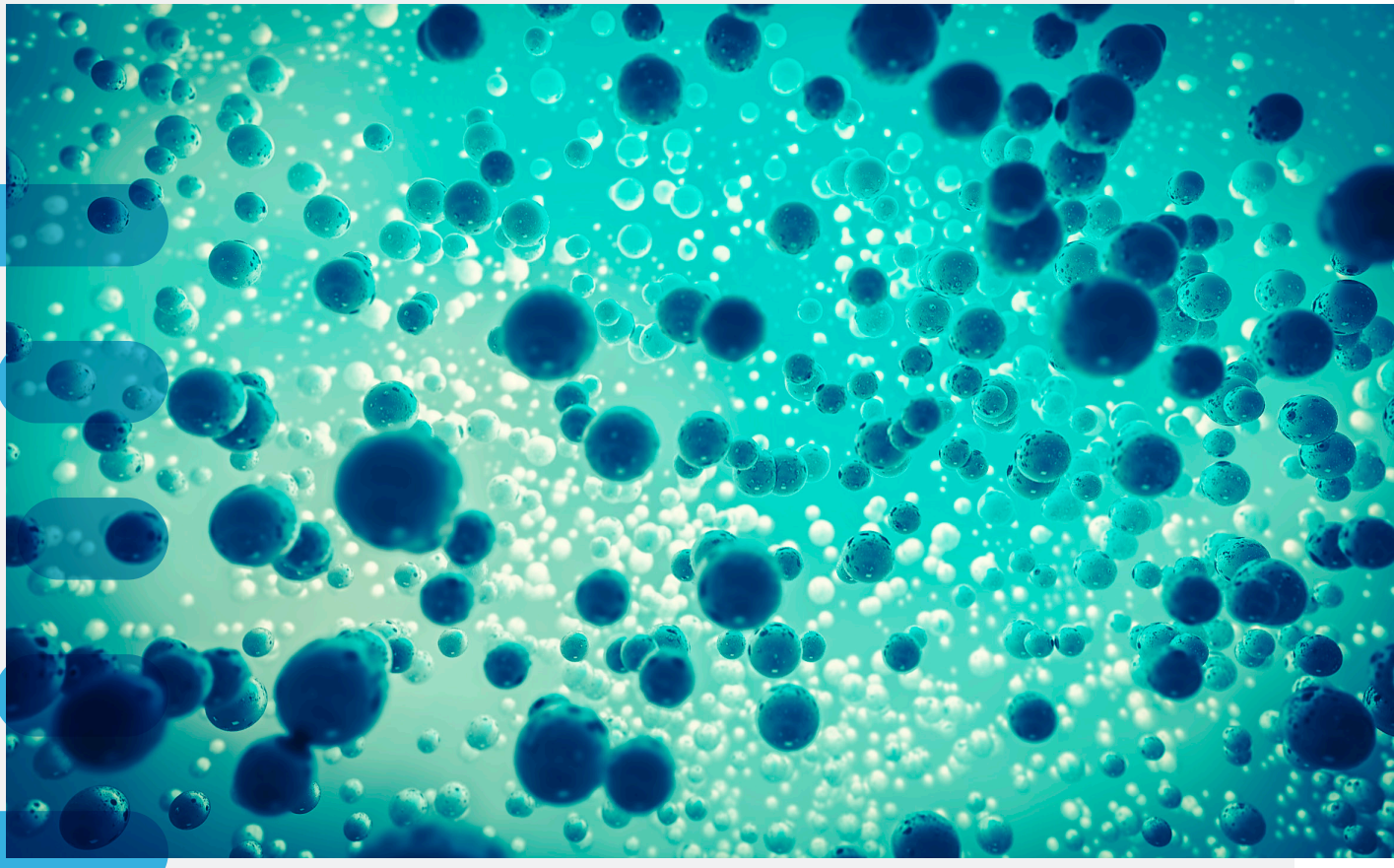


Introduction

Since Zarxio's launch in the U.S. nearly five years ago, 29 biosimilars have been approved by the FDA in therapy areas that include treatment for diabetes, a range of cancers, and autoimmune disorders. Nearly two thirds of these approved biosimilars have already launched. While often described as the "generics" of large molecule biologics, biosimilars have exhibited uptake challenges over the past five years.

Stakeholders have investigated various reasons to explain the slower adoption rates. This paper further explores how practice economics and site of care play a role in biosimilar uptake. Results demonstrate that biosimilar adoption is more favorable where relative reimbursement ratios benefit practice economics. Similarly, factors specific to site of care will influence biosimilar adoption patterns, including payer policies such as "white-bagging" or payment models such as the Oncology Care Model.

In continuing the public conversation on biosimilars, IQVIA is committed to using longitudinal claims data and analytics to better evaluate this growing sector of the biopharmaceutical industry.

Background

A 2020 report from the IQVIA Institute showed that biosimilars average a 30% reduction in Average Sales Price (ASP) compared to reference brands' pre-biosimilar ASP[1]. These savings in invoice prices have amounted to an estimated total of $37 billion since 2010 compared to what spending would have been without biosimilars. These estimated savings reflect the modest uptake biosimilars have experienced. Though adoption has increased over the last few years, in 2020, biosimilars account for only a fifth of accessible molecule volume across all markets.

Even with these challenges around adoption, the IQVIA Institute expects that biosimilar-related savings will range from $69 to $140 billion over the next five years. What portion of these estimated savings will be realized depends, in part, on biosimilar adoption in the years to come.

BIOSIMILAR REIMBURSEMENT DYNAMICS

Though some biosimilars are or will be available at pharmacies — such as insulins and the anticipated TNF-inhibitors — most approved biosimilars are administered by providers and are mostly adjudicated through patients' medical benefits. The analyses in this paper are focused on physician-administered therapies and how financial dynamics are measured within them.

Provider-administered therapies are traditionally covered by the medical benefit in an arrangement known as **"buy-and-bill."** Under this model, providers will purchase a given medicine at a negotiated price and store it until administering the treatment to a patient. The provider then bills that patient's insurer and is reimbursed based on a contracted rate for both the medicine and treatment administration.

Under a buy-and-bill model, the rate of reimbursement can vary across providers as well as insurers. In private, employer-based coverage, reimbursement will depend on existing contracts and payer policies, with the payment amount calculated based on benchmarks such as Average Sales Price (ASP), Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), or the charged amount.

Medicare reimbursement under Part B for established[2] brands is 106% of the drug's ASP ("ASP+6%"). Prior to 2018, payment for biosimilars was benchmarked to a blended code reflecting the volume weighted average of all the biosimilars for a molecule and adjusted by 6% of the brand ASP. Out of concern for limiting biosimilar adoption, The Centers for Medicare & Medicaid Services (CMS) changed the policy in 2018 so that biosimilars would be reimbursed at 100% of the individual biosimilar's ASP + 6% of the reference product's ASP.

[1] IQVIA Institute for Human Data Science, Biosimilars in the United States 2020-2024, October 2020

[2] At launch, biologic treatments do not yet have their own ASP. As such, CMS has codified reimbursement rates for innovator brands and recently launched biologics in addition to when they have an established ASP.

Not all physician-administered treatments are billed to the medical benefit. Physicians who **"white bag"** medicines are only reimbursed for administering the product while the drug acquisition and costs are managed through a pharmacy.

SITE OF CARE DYNAMICS

The setting in which medicine is administered can have differing effects on reimbursement and biosimilar use. While the Medicare add-on payment for biosimilars and their reference biologic is the same across sites of care, acquisition costs as well as commercial reimbursement for drug administration and other services will vary. These differences are especially clear between physician offices and outpatient hospital departments. Outpatient hospitals generally receive higher reimbursement rates for these services than physician offices, meaning total payments (payments for services, plus payments for drug acquisition) are higher. This is due primarily to hospitals' size and the prevalence of charge-based reimbursement. Other factors that vary by site of care and can influence reimbursement include

- **Prevalence of white bagging:** Physician offices that do not operate with a buy-and-bill model do not have the same practice economics influencing the biologics that are stocked.
- **Payer footprint:** Depending on what specific payers/plans may require, providers with a buy-and-bill model may also be compelled to use specialty pharmacies for some patients but not others. Payer mix also affects reimbursement rates under buy-and-bill.
- **Patient Care Model:** Accountable Care Organizations, Oncology Care Models (OCMs), and other organizations change the practice economics and influence treatment protocols.

Relative reimbursement ratio

Biosimilars are competitor products brought to market as an alternative to the reference product. A principal mechanism to gain adoption is through reduced pricing. As such, acquisition costs and, consequently, reimbursement amounts for biosimilars relative to their reference products are typically lower. Depending on the biosimilar, the difference may be small (<2 percentage points averaged across all reimbursed claims) or substantial (nearly half the reference drug's reimbursement).

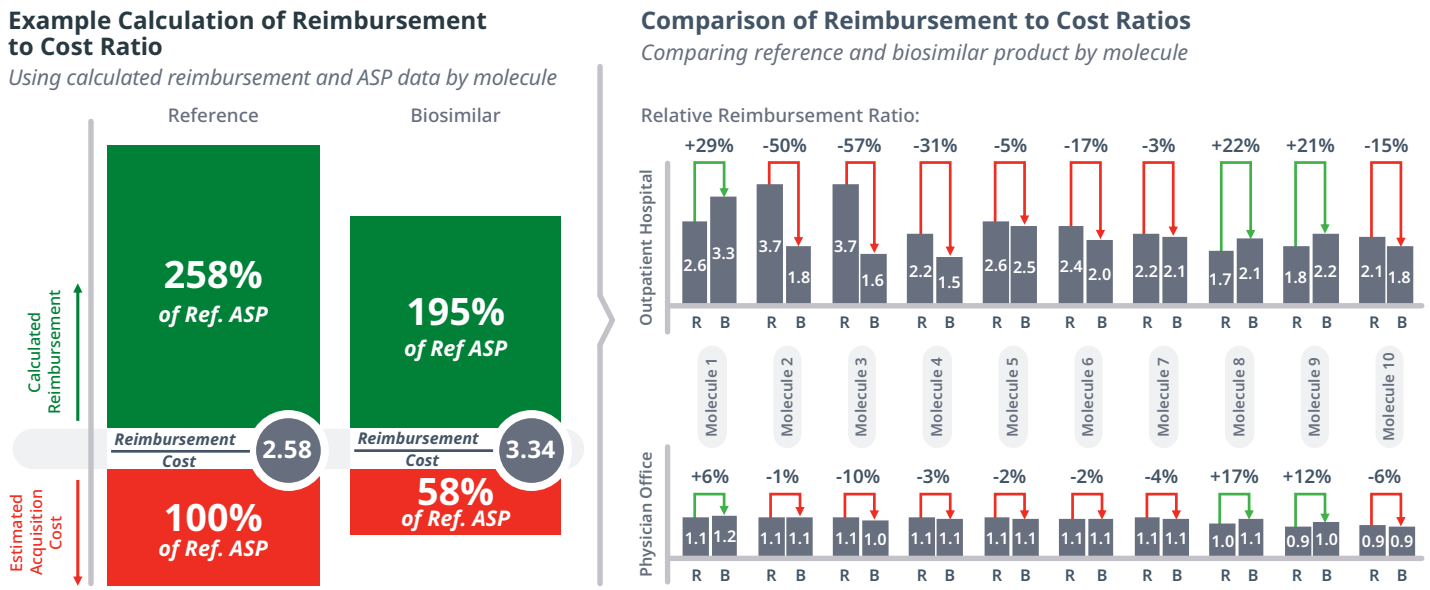
Therefore, it is important to compare the **relative reimbursement ratio**[3] per unit of treatment between the reference product and the corresponding biosimilar. A higher ratio is financially favorable for medical practices looking to balance the

[3] In simple terms, the relative reimbursement ratio is the difference between ASP cost to reimbursement ratios in biosimilars and their reference products. Relative reimbursement ratio can be explained with an example: if a reference product is acquired for $500 and reimbursed at $1,500 (ratio A), the relative reimbursement per unit of treatment is two times (+100%) the reference product acquired for $500 and reimbursed for $750 (ratio B).

"risk" of drug acquisition with reimbursement in a buy-and-bill model. In totality, it is possible for biologics with a higher reimbursement ratio to cost less as both acquisition and reimbursement amounts are lower than the reference. Because reimbursement arrangements and acquisition costs vary between payers and providers, reimbursement ratios can vary not only from payer to payer, but also from practice to practice. Figure 1 shows the calculated average reimbursement ratio in ten biosimilars, using actual claims data. Where the reimbursement to acquisition cost ratio is higher in a biologic compared to the reference, that is considered a favorable relative reimbursement ratio for the biosimilar.

Across the treatments analyzed, three biosimilars have, on average, higher relative reimbursement ratios than their reference products in both outpatient hospitals and physician's offices [Figure 1]. Each of the molecules highlighted in green exhibit *lower* reimbursement rates overall when compared to their reference counterparts, yet because of their lower acquisitions costs, financing and relative reimbursement for these biosimilars may be favorable for physicians in a buy-and-bill setting.

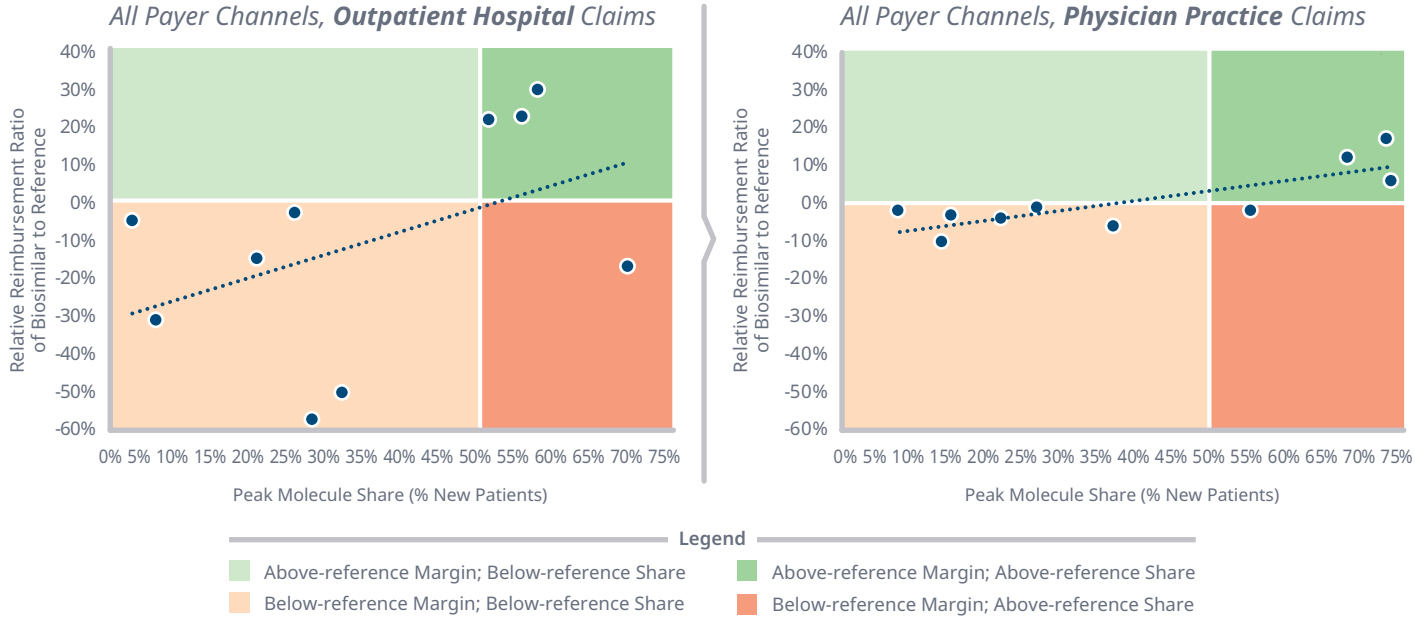
Figure 1: Reimbursement to Cost Ratios in Biosimilars vs. Reference



Source: CMS-reported ASP pricing, IQVIA LAAD Remittance Claims, US Market Access Strategy Consulting analysis

Relative reimbursement ratios and financial realities can affect the decision to stock and administer a particular biologic. Figure 2 compares biosimilar relative reimbursement ratio with peak market share[4] in outpatient hospitals and physician offices. The correlation between the two measures suggests that biosimilars are better positioned to grow market share when relative reimbursement ratios are higher than their reference counterpart. When relative reimbursement ratios are lower for the biosimilar than the reference product, biosimilars have a greater economic barrier. This trend is more apparent in the outpatient hospital sites, where relative reimbursement ratios are more extreme – a likely by-product of hospitals' negotiating leverage and variation in site of care reimbursement.

Figure 2: Relative Reimbursement Ratio and Peak Share by Biosimilar



Note: Relative Reimbursement Ratio is the difference between biosimilars and their references in ASP cost to reimbursement ratios. Peak Market Share is defined as the highest observed new-to-brand (NBRx) share in the observed time following launch.

Source: CMS-reported ASP pricing, IQVIA LAAD Remittance Claims, US Market Access Strategy Consulting analysis

[4] Peak market share reflects the highest observed proportion of new-to-brand claims within a molecule that is attributed to a biosimilar.

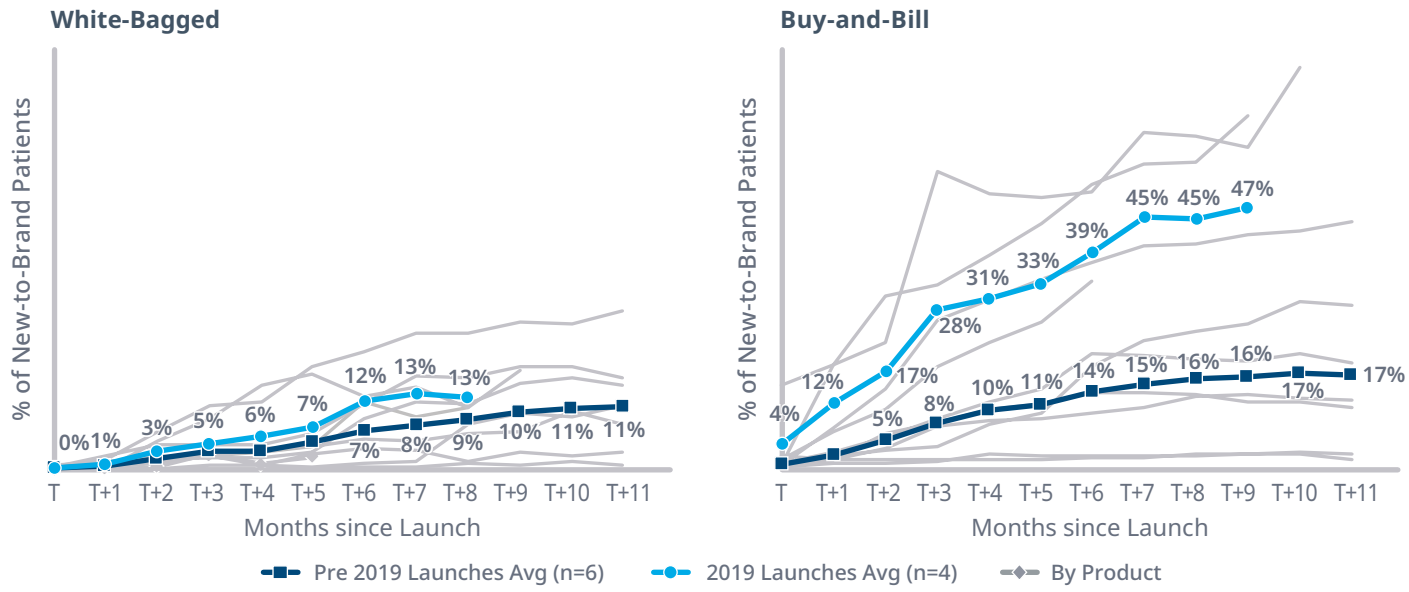
Biosimilar share horizon

The role of relative reimbursement in biosimilar adoption is highlighted by reviewing two settings: white bagging and Oncology Care Models.

WHITE BAGGING

In a site of care with buy-and-bill structure, where practice economics are at play, providers may benefit from the favorable economics of biosimilars with a higher relative reimbursement ratio. When treatment is white bagged and the acquisition-reimbursement processes are owned by pharmacies, providers have less incentive to choose a biosimilar over the reference and may opt for the more familiar legacy product or a preferred formulary product. The difference in biosimilar adoption rates is substantial between the two. Biosimilars that were launched before 2019 achieved peak shares more than 50% higher under buy-and-bill compared to white-bagging (Figure 3). In more recent biosimilar launches, the difference is even more dramatic. Relative reimbursement ratios do not benefit providers operating within a white-bagging model and thus do not facilitate biosimilar adoption in that setting.

Figure 3: Comparison of Biosimilar Market Share Trend by Billing Type



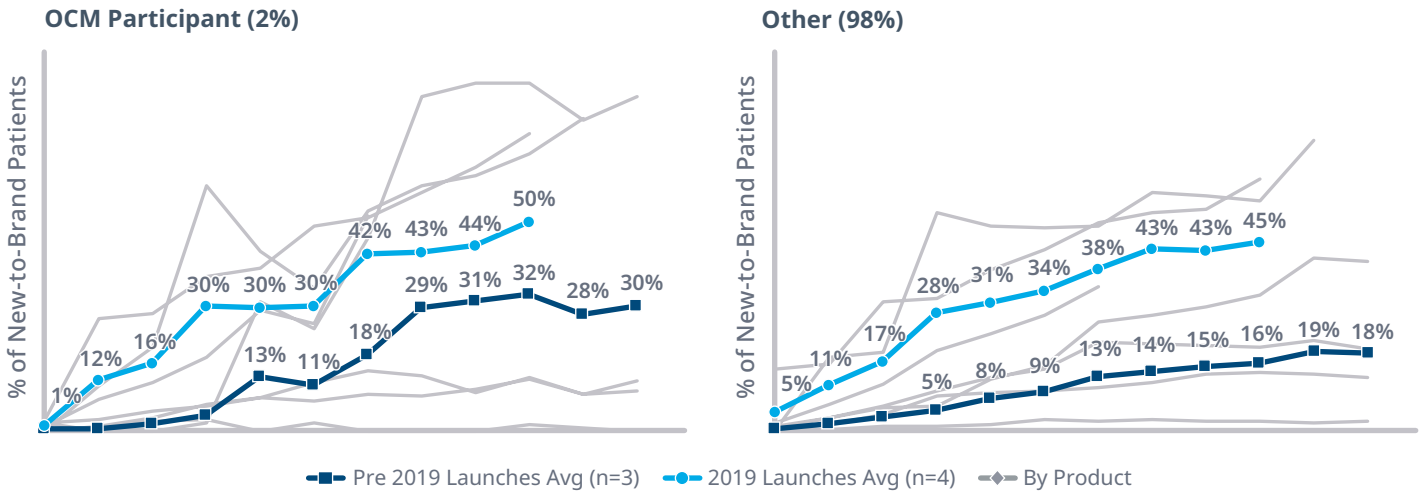
Source: IQVIA LAAD Pharmacy Adjudication and Medical Procedure Claims, US Market Access Strategy Consulting analysis

ONCOLOGY CARE MODELS

To further evaluate the role of reimbursement in provider adoption, CMS Oncology Care Model (OCM) programs were carved out for additional analysis. The OCM was established by CMS' Innovation Center to coordinate care and lower costs by allowing participating practices to opt into a value-based payment arrangement that includes financial and performance accountability. Recently, CMS' Innovation Center also introduced the Oncology Care First (OCF) model that is expected to succeed OCMs in the summer of 2021 and expands to include more approaches to cancer treatment and management. OCM providers have additional incentives to administer biosimilars over reference products; CMS payments to OCM providers are tied to overall performance, rather than cost benchmarks for specific drugs. As such, OCM providers may have greater financial incentive to administer biosimilar products compared to providers not taking part in the OCM[5].

In Figure 4, providers that participate in an OCM show higher biosimilar adoption rates than those in other provider settings. Across molecules, OCM participants are more likely than non-OCM providers to administer a biosimilar (versus a biologic reference product) to new patients starting therapy[6]. The OCM example uniquely demonstrates how much of an impact organizational systems may have on encouraging biosimilar use, proving to be another important factor when considering their uptake.

Figure 4: Comparison of Oncology Biosimilar Share Trend by Provider OCM Status



Source: IQVIA LAAD Medical Procedure Claims, US Market Access Strategy Consulting analysis

[5] Centers for Medicare and Medicaid Services, Evaluation of the Oncology Care Models, May 2020

[6] Figure represents oncology-related products only, from Q3-2019 through Q2-2020. During this time period, biosimilars in OCM-participating facilities maintained 59% NBRx share (compared to 41% NBRx share among non-OCM providers).

Conclusion

As the public discourse on healthcare costs, sustainability, and affordability continue, stakeholders must evaluate how the mechanisms and economics of our current system drive decision making. Biosimilars are one component of this. Unlike small molecule generics, where the incentives for adoption are clear, the choice for biosimilars over reference products is more complex and driven by many factors.

Since the launch of the first biosimilars, it is evident that biosimilar adoption has been partly influenced by practice economics. Where reimbursement and site-of-care incentives favor biosimilars, adoption has increased over time – be it higher relative reimbursement ratios or the practice goals of an oncology care model. Conversely, biosimilar use is muted where these incentives are not applicable (such as white bagging).

Yet there are other influences that drive adoption and require further evaluation as the industry continues to invest in and plan for biosimilars. Manufacturers of reference and biosimilar products alike must consider these influences, including

- **Payer contracts:** Payers in both the pharmacy and medical space may prefer a reference product to a biologic or vice versa. Contracts may impact provider reimbursement, treatment access, and white-bagging prevalence.
- **Contracted rebates:** Rebates in the pharmacy benefit may result in reference products more financially favorable to payers, despite reductions to ASP.
- **Provider negotiations:** Acquisition costs and reimbursement rates will vary across providers, affecting practice finances differently.
- **Physician familiarity/patient continuity:** Current adoption trends suggest that providers have historically preferred more familiar and established reference products regardless of potential savings.
- **Pharmacy substitution:** Unlike with AB-rated small molecule generics, biosimilars cannot be automatically substituted for reference brands, thus putting the burden on prescribers to specify biosimilar distribution.
- **OCF Introduction:** In a departure from the current OCM model, OCF sites could introduce two-sided risk for participants and also expand partnership into commercial and Medicaid payers such that providers face even more incentive to manage costs.

While the current administration's immediate focus will be on countermeasures to combat COVID-19, it is expected that the promotion of biosimilar treatments will certainly continue to be a key initiative for policymakers in the coming years. Specific steps, actions, and plans released by policymakers will be important to monitor in the coming months and years as the biosimilar landscape continues to evolve and grow.

Appendix

Buy-and-Bill Reimbursement in Medicare

For most Part B drugs, CMS reimburses providers at:

- **WAC+3%* at launch** until full quarter of ASP available (can be up to 9 months due to 2-quarter lag)
- **ASP+6%** therafter (however, due to sequestration, the effective amount +4.3%)
- Exception for 340B entities is such that they receive **ASP-22.5%** (litigation still underway to contest this rule**)

Biosimilars are treated differently:

- **WAC+3% at launch** until the biosimilar's ASP is available
- Prior to 2018, **ASP+6% based on all biosimilars that share the same reference product**
- Starting in 2018, each biosimilar uses **its own ASP+6% of the reference product's ASP**

About IQVIA's Market Access Center of Excellence

With a passion for innovation, quality, and customer service, IQVIA's Market Access COE is at the forefront of industry trends in biopharma and therapy access. The COE's portfolio of services includes patient engagement and commercial solutions that continue to advance a long-standing mission to the enhancement of patient access and health outcomes while delivering an unyielding focus on driving client satisfaction. Market Access is committed to driving real change for its clients and patients by way of newly combined offerings, expertise, and talent from the diverse organizations of 1,000+ dedicated individuals within it.

Disclaimer

This report and the analyses used were commissioned by the Biosimilars Council, a division of the Association for Accessible Medicines (AAM). IQVIA maintained editorial control.

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