BIOSIMILARS: WHEN LOWER-COST MEDICATIONS MEAN LOWER PROVIDER PROFITS

by John Reddan, MBA, Jason Moore, MBA, Eric Snyder, Ph.D., and Zi Yang, Ph.D., Navigant

ABSTRACT

Background: The availability of biosimilars in the United States has the potential to reduce the cost of treatment with expensive biologic medications. However, to date the uptake of the first biosimilars has been modest. One critical factor limiting provider use of biosimilars appears to be the “buy-and-bill” reimbursement model for infused therapies. While the Centers for Medicare & Medicaid Services (CMS) incentivizes biosimilar use through differential reimbursement, private payers generally do not. As a result, adoption of lower-cost biosimilars in today’s reimbursement model leads to a reduction in practice profits for most providers.

Review and Results: We examine dynamics across provider types and determine the impact of provider setting and payer mix on biosimilar adoption. For a hypothetical infused innovator product that costs $1,000 per unit dose, and a biosimilar priced at a 15 percent discount, adoption of the biosimilar could lead the average physician office to lose $9 in gross profit per dose. Outpatient hospitals could lose $43 per dose and 340B or disproportionate share hospitals could lose as much as $79 per dose. Individual providers with 50 patients on therapy could stand to lose as much as $50,000 per year – a loss that would grow with multiple biosimilars coming to market. Considering a single innovator brand such as Remicade which was used to treat over 130,000 Americans in 2016, broad adoption of a biosimilar could decrease profits by as much as $100 million across providers. In this environment, private payers will need to meaningfully change their reimbursement scheme, or preferentially incentivize the use of biosimilars, in order to spur adoption. Following the lead of CMS, commercial payers could offer favorable and differential reimbursement of an additional 4 percentage points for physician practices, 8 percentage points for hospitals, or 16 percentage points for 340B hospitals as a means to neutralize the profit loss for providers that adopt biosimilars. With this type of differential reimbursement, payers can minimize an important barrier to biosimilar usage and seek a middle ground where both payers and providers see cost savings and increased profits.
BIOSIMILARS AND PROVIDER MARGINS

With the first approval of Zarxio (filgrastim-sndz, Neupogen) in 2015, followed by Inflectra (infliximab-dyyb, Remicade), Erelzi (etanercept-szss, Enbrel), and Amjevita (adalimumab-atto, Humira) in 2016 and now Renflexis (infliximab-abda, Remicade) biosimilars of market-leading therapeutics are a reality in the United States, with more on the horizon. These alternative biologic agents are anticipated to spur competition by offering bioequivalence to high-cost, branded, innovator molecules at lower prices. While the road to biosimilar launches has been a long one in the U.S., the Food and Drug Administration (FDA) has made recent strides in issuing long-awaited final guidance on naming and biosimilar requirements, and draft guidance on interchangeability has been largely well-received by stakeholders. Additionally, the U.S. Supreme Court recently ruled that biosimilar products can be marketed as soon as they are FDA-approved, as long as there are no injunctions against the biosimilar company from any pending patent litigation brought by the reference product manufacturer. However, the future markets for biosimilars remain uncertain, and longer-term commercial pricing and contracting will likely be the key drivers of uptake in the U.S.

At launch, Sandoz and Pfizer announced wholesaler price discounts of 15 percent for Zarxio and Inflectra, respectively. Payers publicly expressed disappointment and expected larger opening discounts in line with European markets (30-40 percent range.) With only one recent case of multiple biosimilars approved for the U.S. market (Samsung’s Bioepis, Merck’s Renflexis, and Pfizer’s Inflectra), single biosimilar agents are not yet available for each brand, and these discount figures are not expected to drop across the board as biosimilars manufacturers find it necessary to aggressively compete for uptake. A recent study of European discounting practices documented the absence of correlation between biosimilar G-CSF (filgrastim) market share and higher levels of discounting, further muddying the relationship in the minds of all stakeholders.

The biosimilars that have launched in the U.S. are infused or injected products and, as such, are reimbursed to providers as “buy-and-bill” therapeutics. Under this structure, providers are reimbursed for biologics with an additional percentage of the product price added to cover acquisition, storage, and dispensing costs associated with delivering care. Reimbursement typically ranges from a CMS-mandated 6 percent of the drug’s average sales price (ASP) under Medicare coverage (approximately 4.3 percent under the current 2011 Budget Control Act sequestration) to a more robust 9 to 10 percent reimbursement from typical commercial plans. This environment creates a disincentive for providers to favor lower-cost biosimilar products.

In designing this coverage model, CMS recognized this challenge and mandated that physicians who dispense biosimilars will be reimbursed at ASP plus 6 percent of the innovator’s price. While this mandate was enacted to remove a disincentive for prescribing biosimilars for patients on Medicare, it does not address considerations for patients covered by commercial insurers. Indeed, patients with commercial insurance represent the majority of billings for most U.S. providers.

Analysis

To better understand the impact of the buy-and-bill reimbursement of biosimilars on providers, we modeled the financial cost-recovery and gross margin (reimbursement less acquisition cost) providers may receive with a theoretical branded biologic (the branded “innovator”) and a biosimilar. We also explored how changes to reimbursement structure may impact provider gross margin.

To do so, we considered three potential sites of care for an infused or injected biologic agent: a physician’s office, a hospital outpatient infusion suite, and a 340B hospital outpatient infusion suite.

We made several assumptions to simplify this analysis, including that the typical provider will stock and prescribe either the branded agent or the biosimilar, but not both. Other key assumptions include:

• Drug pricing is based on wholesale acquisition cost (WAC), defined as a manufacturer’s list price to wholesalers or direct purchasers for branded or biosimilar products (i.e., “buy and bill” providers,) not including discounts (e.g., prompt pay discounts, purchase-based discounts, rebates, or other reductions to WAC).
• WAC for a biosimilar is assumed to be 15 percent below the branded agent. Our model is therefore based on theoretical branded innovator drugs and biosimilars priced at $1,000 and $850, respectively.
Branded drug and biosimilar manufacturers are assumed to offer provider segments similar purchase discounts off wholesaler list prices: 10 percent to hospital outpatient clinics and specialty pharmacies, 30 percent to physician offices, and 34 percent to 340B programs. See Table 1 below.

**TABLE 1: ACQUISITION COST BY SITE OF SERVICE**

<table>
<thead>
<tr>
<th></th>
<th>Hospital Outpatient</th>
<th>340B Programs</th>
<th>Physician Office</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquisition Cost</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Wholesaler Acquisition Cost (WAC)</td>
<td>$1,000</td>
<td>$850</td>
<td>-$150</td>
</tr>
<tr>
<td>Discount</td>
<td>10%</td>
<td>10%</td>
<td>34%</td>
</tr>
<tr>
<td>Realized Cost per Unit</td>
<td>$900</td>
<td>$765</td>
<td>-$135</td>
</tr>
</tbody>
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ASP for both branded agents and biosimilars was calculated as the mean product price paid by ASP-eligible sites of care. Discounted sales to 340B programs were excluded from the ASP calculation, as were prompt-pay discounts, distribution service agreements offered to distributors, and group purchasing organization administrative fees. The ASP in effect for a given quarter was that calculated two quarters prior.

Hospital outpatient and 340B settings were assumed to receive 25 percent of their reimbursement under an ASP-based model and 75 percent under a “percentage of billed charges” model. Physician offices were assumed to receive 100 percent of their reimbursement under an ASP-based model.

Commercial payer reimbursement to hospital outpatient and 340B settings was assumed to be at ASP plus 10 percent. Physician offices were assumed to be reimbursed by commercial payers at ASP plus 9 percent.

Reimbursement as a percentage of billed charges was assumed to be slightly more than twice ASP-based reimbursement (175% of WAC). For example, the hospital receives $1,750 when reimbursed as a percent of billed charges and $837.76 when reimbursed at ASP plus 10 percent, for the $1,000 WAC innovator drug.

Medicare reimbursement was assumed to be ASP plus 4.3 percent for the branded agent, and ASP plus 6.0 percent of the innovator ASP for the biosimilar. Medicaid reimbursement was assumed at ASP plus 6.0 percent.

Providers were assumed to have a mix of payer business that reflects the national average of 62 percent commercial, 16 percent Medicare, and 22 percent Medicaid. We recognize that individual providers may have a significantly different mix of business, and modeled the sensitivity of this factor in our analysis.

**Results**

Under these conditions and reimbursement structure, all sites of care see a reduced weighted average gross margin when adopting biosimilars (Table 2). More specifically, all sites of care receive lower margin in their commercial business when using biosimilars vs. branded agents and, in almost all cases, providers’ Medicare and/or Medicaid businesses are individually more profitable using biosimilars (340B programs are a slight standout). The mix of government-payer business at these sites of care is not high enough to displace the innovator as the higher-margin product.

The weighted average gross margin loss ranges from $9 per unit vial in a physician office setting, to $43 in an outpatient hospital, and $79 in a 340B hospital. While this impact may seem minimal, it could add up – a hospital treating 50 patients using two vials of drug per month stands to lose over $50,000 per year. Considering a single brand such as Remicade, which was used to treat over 130,000 Americans in 2016, broad adoption of a biosimilar could decrease profit by as much as $100 million across providers. The loss stands to grow as multiple biosimilars come to market and decrease profit across additional brands.
We explored the impact of a lower acquisition cost of the biosimilar WAC, simulating biosimilar manufacturers’ strategies to spur provider adoption, with the assumption that at some point the decreasing acquisition cost of the biosimilar would yield an improved margin. However, in both “ASP plus” and “percentage of billed charges” commercial reimbursement models, the provider’s gross margin is tied to the drug’s acquisition cost and reducing the acquisition cost only serves to further decrease the gross margin realized by the provider (and the manufacturer).

We also modeled for each site of care the impact of a changing payer mix by increasing the percentage of Medicare business with a corresponding offset in the percentage of commercial business (the percentage of Medicaid business was assumed constant.)

As shown in Figure 1, the biosimilar becomes more attractive as the percentage of Medicare patients increases. This is due to the CMS mandate to reimburse biosimilars at ASP plus 6 percent of the innovator price, while the branded agent is currently reimbursed at ASP plus 4.3 percent. But the very high percentage of Medicare business required to make the biosimilar the more profitable, preferred choice is unrealistic. Physician offices and hospitals need to have greater than 50 percent of their business coming from Medicare to realize a net margin improvement by adopting the biosimilar (vs. the 22 percent average cited above). 340B hospitals, given their significant discounts off the innovator price, do not see a benefit by switching to a biosimilar until the percentage of Medicare business is greater than 75 percent.

**FIGURE 1: IMPACT OF MEDICARE BUSINESS ON RELATIVE VALUE OF BIOSIMILAR VERSUS INNOVATOR**

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<tr>
<td>Realized Cost per Unit</td>
<td>$900</td>
<td>$765</td>
<td>-$135</td>
</tr>
<tr>
<td><strong>Average Reimbursement</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
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<td>$1,294</td>
<td>-$228</td>
</tr>
<tr>
<td>Medicaid</td>
<td>$807</td>
<td>$719</td>
<td>-$88</td>
</tr>
<tr>
<td><strong>Gross Margin</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>$622</td>
<td>$529</td>
<td>-$93</td>
</tr>
<tr>
<td>Medicare</td>
<td>-$106</td>
<td>-$72</td>
<td>$34</td>
</tr>
<tr>
<td>Medicaid</td>
<td>-$93</td>
<td>-$46</td>
<td>$47</td>
</tr>
<tr>
<td><strong>Weighted Average Gross Margin</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted Average Gross Margin</td>
<td>$348</td>
<td>$306</td>
<td>-$42</td>
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TABLE 2: WEIGHTED AVERAGE GROSS MARGIN LOSS BY PROVIDER

**NOTE:** Rounding may create mathematical variances of $1 in Table 2.
The analysis presented so far helps explain the challenges faced by payers in gaining adoption of biosimilars. In integrated delivery networks, e.g., Kaiser Permanentte, and accountable care organizations where providers receive a fixed case-rate for care regardless of therapy choice, we can likely expect a continued shift toward the adoption of biosimilars. A Kaiser executive recently stated that aggressive (but undisclosed) levels of discounting by Sandoz helped the biosimilar Zarxio capture up to 95 percent of Kaiser’s filgrastim volume in their pediatric units.

In more typical provider settings, adoption of biosimilars will be limited by the reimbursement environment, as well as by potential concerns regarding therapeutic equivalence, product safety, and risks of switching stable patients away from well-performing branded drugs. While pharmacy benefit managers and payers are taking high-profile stances on high-cost biologics, payers are to-date unwilling to go so far as to fully exclude branded agents from formularies, or otherwise force providers to switch current patients to biosimilars. Likewise, providers and patients are increasingly vocal stakeholders when faced with high levels of payer control over clinical choices.

OPTIONS TO OVERCOME LOSSES

There are two noteworthy scenarios in which the use of biosimilars in lieu of the innovator biologic is more financially beneficial for both payers and providers: the fixed and differential reimbursement models.

Fixed Reimbursement

With a fixed reimbursement model the payer “capitates” the cost of the drug by paying a fixed amount regardless of whether the innovator or biosimilar was administered, thereby eliminating the financial incentive for providers to use the more expensive innovator drugs. Under this type of reimbursement model, providers realize the value of lowering their acquisition cost, while payers, which reimburse less than they are currently paying for the innovator, and more than they are paying for the biosimilar, reduce their drug spend.

Differential Reimbursement

Alternatively, payers could use an approach similar to CMS’ and establish a differential reimbursement model with more favorable reimbursement rates for biosimilars. About 3 percent of commercial payers currently report using differential reimbursement as a management tool to incentivize medical benefit product choice by providers.

Our analysis shows if payers increase the incentive for a biosimilar by about 4 percentage points (e.g., from ASP plus 10 percent to ASP plus 14 percent) it would alter the relative margin for physician offices and remove the financial disincentive of using a biosimilar. Hospitals would require more significant incentives, upwards of 16 percentage points. This sensitivity is reflected in Figure 2.

FIGURE 2: IMPACT OF DIFFERENTIAL REIMBURSEMENT ON BIOSIMILAR VALUE

![Relative Provider Gross Margin (biosimilar – innovator)](image)

- Hospital Outpatient
- 340B Eligible
- Physician Office
For differential reimbursement to be a viable option, incentives must exist for both payers and providers. In our analysis we found this “middle ground” possible — payers can realize cost savings with a differential reimbursement model that provides financial incentives for providers to adopt biosimilars. See Figure 3 below.

**FIGURE 3: PAYER SAVINGS BY INCENTING BIOSIMILAR UPTAKE WITH DIFFERENTIAL REIMBURSEMENT**

![Graph showing payer savings](image)

**CONCLUSION**

Biosimilars have the potential to reduce overall treatment costs, but the current reimbursement models for these therapies present a significant obstacle to broader adoption. While U.S. regulation that enables substitution and interchangeability of biosimilars may be key to lower prices, increased competition, and market access for patients, the near-term adoption of biosimilars is likely going to be driven by those responsible for the drug spend — most notably, commercial payers and pharmacy benefit managers. Though it may be possible for insurers to influence biosimilar uptake through restrictive formularies and benefit design, getting providers on board will require longer-term commercial reimbursement models that align hospital and physician incentives with those of the payer.
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