BIOSIMILARS: THE COMMERCIAL CHALLENGE

Biosimilars have emerged as one of the fastest-growing categories in the biopharmaceutical sector. As with innovator drugs, the commercial success of biosimilars will be determined by the three main stakeholders of market access: payers, providers and patients. Although the potential cost savings that biosimilars offer will undoubtedly be attractive to payers, many payers may be reluctant to aggressively steer utilization toward these agents without compelling data showing that their safety and efficacy profiles are truly comparable to that of the innovator product. Similarly, many prescribers and patients may prefer proven treatments for cancer, anemia and other serious illnesses, rather than taking a chance on a somewhat less-expensive product with no track record.

Given these stakeholder concerns, as well as the possibility that biosimilars may be priced at only a slight discount relative to innovator products, the issue of “interchangeability” is expected to play a crucial role in determining market access. Although the FDA’s draft guidance states that the agency can make a determination that a biosimilar is interchangeable with the innovator product, in most cases this determination cannot be made until after a biosimilar has received FDA approval, due to the likelihood that post-marketing studies will be required to demonstrate interchangeability. Therefore, in the initial post-launch period, nearly all biosimilars will face skepticism from payers, providers and patients, which will be difficult for manufacturers to counter without credible claims of interchangeability.

The Payer Perspective

A key question to the successful uptake of biosimilars is how US health insurers will manage them. Will payers steer beneficiaries toward these lower-cost products, as they do with generic drugs, or will they be hesitant to drive utilization toward a new, unproven category?

To better understand payers’ views on biosimilars, Covance recently surveyed its panel of commercial payer decision makers, with survey respondents representing over 100 million covered lives. The survey was designed to explore several factors that may influence how payers manage biosimilars, including therapeutic area, type of FDA approval (abbreviated biosimilar pathway versus full BLA), interchangeability and pricing.

This survey produced several important findings:

▶ The commercial payers on our panel are relatively open to incorporating biosimilars into their formularies and steering utilization away from branded innovator biologics, with cost as a driving factor.

▶ The three factors that payers ranked as most important in coverage decision making for biosimilars were the magnitude of the cost differential between the brand and the biosimilar, FDA interchangeability status and CMS coverage.

▶ The majority of payers surveyed expect biosimilars to be priced at a 20% to 30% discount as compared to the branded product.
Some of the survey findings were particularly eye-opening. For example, although the importance placed on interchangeability is perhaps to be expected, payers were surprisingly broad in their interpretation of what makes a biosimilar interchangeable with a branded product. The majority of payers surveyed would be willing to make this determination based on factors other than a formal FDA designation of interchangeability, such as compendia listings, clinical evidence demonstrating efficacy and safety, clinical guidelines, CMS coverage decisions and key opinion leader input.

In addition, payers were very frank regarding the extent to which their views on biosimilars would be influenced by the provider and patient communities—the levels of support or opposition within these groups were ranked as two of the least important factors in payers’ coverage decision making for biosimilars.

**Differences Across Therapeutic Areas**

When assessing the factors driving biosimilar uptake, it is important to take into account the potential for variation across different therapeutic areas. For example, payers in the US historically have been fairly “hands off” in their management of oncology relative to other disease states, and it is unclear whether this management approach will persist once biosimilar cancer therapies are available.

Covance examined this dynamic in our recent survey by comparing payers’ views on biosimilars in oncology versus rheumatoid arthritis (RA). We found that payers indeed are less likely to steer utilization toward biosimilars in oncology than in RA, but the difference was less pronounced than one might expect; the survey results make clear that payers are willing to create favorable policies for biosimilars if there is a potential for significant cost savings—even in oncology.

**Physician Acceptance**

Of course, payers are just one of the stakeholders that will determine market uptake for biosimilars. Although payers can remove barriers to access for biosimilars and create incentives to encourage their use, ultimately the commercial success of biosimilars will depend on physicians’ willingness to prescribe these products over the branded alternatives.

As with payers, physician attitudes toward biosimilars can be expected to vary by disease state. For example, as compared to other specialists, oncologists tend to be less cost sensitive when making treatment decisions, and are more likely to regard therapies as unique. Both of these factors could cause oncologists to be resistant to biosimilars, and to view with skepticism any claims of interchangeability even if a formal designation has been granted by the FDA. In contrast, rheumatologists may be much more receptive to biosimilars, as RA has long been a field characterized by competition among multiple alternative therapies that—to at least some extent—may be viewed as substitutable.

One similarity between oncologists and rheumatologists is that both specialties rely heavily on “buying and billing.” In other therapeutic areas characterized by different economic models, providers’ views on biosimilars may be very different. In dialysis, for example, the predominance of bundled payment systems has created an urgent need for cost savings among providers. In and of itself, this economic incentive would seem to suggest a willingness to use biosimilars, although the safety concerns resulting from the 2013 recall of Omontys (a highly anticipated erythropoiesis-stimulating agent) may give pause to providers when they are faced with the prospect of switching to a new biosimilar version of an established product.
The seemingly conflicting incentives of dialysis providers (i.e., economics vs. safety) speak to the complexity of the dynamics surrounding biosimilar uptake in different markets. Therefore, when assessing the market landscape for biosimilars, it will be important to look at each therapeutic area individually.

**Market Planning and Support**

To facilitate market access in this challenging environment, biosimilar companies will need to engage in the full spectrum of market access and health economic planning activities, such as conducting landscape assessments, developing and testing value messages, benchmarking the customer support resources currently offered for innovator products, and performing market research with stakeholders. These activities must begin early in clinical development, as market access planning is an iterative, multi-year process that requires the involvement of nearly all major divisions within an organization.

It also will be crucial for biosimilar companies to offer customer support resources that are at least on par with those being offered by the market-leading innovator products. These support resources, which include full-service reimbursement hotlines, patient support programs and provider educational programs, will be especially important in specialty disease areas where providers have very high expectations regarding customer support. It is likely that the market access landscape will become even more competitive when biosimilars enter the market, as marketers of innovator drugs can be expected to ramp up their own customer support resources to further solidify brand loyalty and reduce the attractiveness of the new lower-priced alternatives.

The commercial path for biosimilars in many ways will be as challenging as that for a unique innovator biologic. For more than two decades, Covance has specialized in supporting the successful commercialization of biopharmaceuticals facing market challenges like these.

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