

CREATING A ROBUST REIMBURSEMENT SUPPORT PROGRAM FOR BIOSIMILARS

Solutions to improve access with exceptional patient and provider services

The addition of biosimilars to the drug development space raises many questions about reimbursement. It is unclear how payers will cover these new products, how providers will be reimbursed for them and whether patients will adopt them. Manufacturers also are weighing how much to spend on support services, given that they have already invested millions of dollars in research and development for treatments that will be priced approximately 15% lower than the reference product.

For at least the first wave of biosimilars, reimbursement hubs will play a critical role. Many providers have come to rely on strong customer support programs, and manufacturers will need to provide services at least on par with those of reference products. In fact, these support services may be the only way in which biosimilar developers can differentiate themselves from the competition.

By helping patients and providers navigate reimbursement and financial challenges with new products at launch, biosimilar manufacturers can increase their chances of gaining traction in the market.

Improving Access Throughout the Patient Journey

Hub services should improve access and retention during every step of the process, from ensuring that the patient obtains the drug quickly to offering financial assistance and social support.



Resolving access issues

The goal is to eliminate barriers to access so that patients can start treatment as soon as possible. For example, a patient's insurance company may require prior authorization, which can take a few days. If the patient needs the medication immediately, the manufacturer can offer a free trial or sample through a specialty pharmacy until the insurance kicks in. Programs such as copayment assistance also can reduce the patient's out-of-pocket burden.

Supporting adherence and clinical services

For some drugs, the patient may need to return to the clinic regularly for infusions or lab tests. Manufacturers should assess whether the patient is likely to be adherent and act accordingly. For example, they can offer behavioral coaching to encourage patients to keep their appointments and continue treatment. Case management services could include everything from helping the provider obtain approval from the insurance company to verifying that the patient receives the medication. Clinical education, adverse event triage, administration training and personalized patient interventions also can improve adherence.

The Importance of Market Access Planning

Manufacturers should expect the commercial path for biosimilars to be as challenging as it is for an innovator biologic. Sponsors will need to perform the full spectrum of market access and health economic planning activities to assess the landscape, beginning early in the development process. In particular, biosimilar developers should understand the services currently offered by the reference product. Key questions include:

- ▶ What is the payer mix for the product?
- ▶ Will there be coverage restrictions?
- ▶ How much will the copay or coinsurance be?
- ▶ In which settings of care will the product be used?

Answering these questions will help manufacturers focus their support service efforts.

The Need for Best-in-Class Customer Support

Providers in certain therapeutic areas, such as oncology and rheumatoid arthritis, have high expectations for customer support. As the market has become more competitive, manufacturers have continually raised the bar on these services. Some provider offices now rely entirely on reimbursement support programs to handle insurance issues. At least initially, biosimilar developers will need to provide a comparable level of service, which should include:

1. Reimbursement support

These services remove barriers to successful payment of claims and provide a resource for patients with coverage-related questions. For example, manufacturer-sponsored hubs can perform insurance verifications to reduce denied claims, clarify how providers should submit a claim and communicate with the insurance company to validate billing processes. At the same time, reimbursement support provides an additional channel for building a relationship with customers, strengthening loyalty by delivering prompt service and resolving issues.

2. Financial support

A financial support strategy must account for several categories of patients, ranging from completely uninsured patients to insured patients who cannot afford their out-of-pocket expenses. The following models of financial support are typically offered:

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| “Free product” patient assistance programs | <ul style="list-style-type: none">▶ An option for uninsured patients who meet certain criteria▶ Sometimes an option for under-insured patients (patients whose insurance does not cover the new product) |
| Copay assistance programs | <ul style="list-style-type: none">▶ An option for uninsured patients who meet certain criteria▶ Not an option for patients with public insurance (e.g., Medicare, Medicaid) |
| Copayment foundation | <ul style="list-style-type: none">▶ An option for publicly-insured patients who cannot afford their copay or coinsurance |

3. Provider education

Ongoing provider education is another key element of best-in-class customer support. Many manufacturers take a multi-pronged approach to educational resources, including reimbursement-focused website content; leave-behind materials that explain product coverage, coding and payment; and interactive customer-facing tools, such as coverage databases or specialty pharmacy finders. Provider portals allow physician offices to submit requests regarding insurance or copays online, eliminating the need to call or fax.

4. Field reimbursement teams

These teams educate providers and solve patient-specific issues proactively and reactively. They often function as an extension of the support program to provide personalized interactions with offices. For example, field reimbursement managers can discuss the range of services offered, help with claim submission challenges and deal with denials. They also can:

- ▶ Coordinate with the call center, specialty pharmacies, payers and health care providers
- ▶ Work effectively with all field stakeholders
- ▶ Improve customer service
- ▶ Leverage unique resources to support customers
- ▶ Understand hub services and reimbursement policies

Making Strategic Considerations

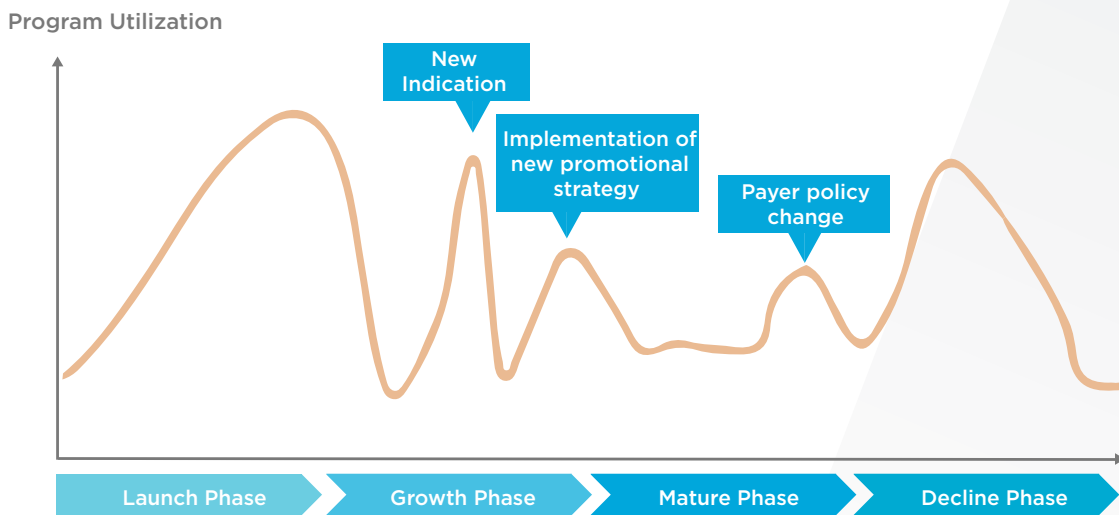
Manufacturers should consider a few other key issues when developing their reimbursement and financial support programs.

1. Type of insurance benefit

The type of insurance benefit will determine how closely the manufacturer works with the physician’s office or specialty pharmacies.

2. Stage of life cycle

The stage of a product's life cycle will influence customer needs, expectations and utilization of hub support services. During launch, therapies often face more payer challenges, which increase the time to complete insurance verifications. For example, if an unlisted, miscellaneous code is used, providers may face denied or underpaid claims. Volume will likely plateau as coding and insurance issues become clearer but could spike if a new indication, promotional strategy or payer policy change emerges. Hotlines also often experience surges at the beginning of the year when providers want to re-verify.



Navigating Uncharted Territory

Biosimilars must provide competitive customer service for several reasons. The coding, coverage and payment for biosimilar products are uncharted territory for providers who have become accustomed to exceptional customer support for biologics. Manufacturers of reference products may enhance their support offerings to maintain brand loyalty.

As additional biosimilars of the same reference product are introduced, superior support services will be one of the few ways that manufacturers can differentiate their treatments. Given these uncertainties and challenges, developing a robust reimbursement program will be critical to launching a successful biosimilar product.

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