HealthManagement
Promoting Management and Leadership

Dynamics of the Biosimilar Market: Coverage Strategies & Market Impact

The Biologics Price Competition and Innovation Act (BPCIA) of 2009 marked a significant milestone in the U.S. healthcare landscape by establishing a regulatory pathway for biosimilars. While not exact replicas of their biologic counterparts, these products offer similar safety and efficacy at potentially lower costs. Despite the promising economic and accessibility benefits, the uptake of biosimilars in the U.S. has been slower than expected. An article recently published in HealthAffairs Scholar examines how different coverage strategies—sole preferred and non-sole preferred—employed by originator biologic manufacturers influence biosimilars' market share and pricing.

Sole Preferred Coverage Strategy: A Defensive Market Approach

The sole preferred coverage strategy is a defensive tactic originator biologic manufacturers use to retain their market dominance. This strategy involves offering steep discounts, often exceeding 50% of the product's average sales price (ASP) prior to the introduction of biosimilars, to ensure that the originator product remains the preferred option in payer formularies. For instance, infliximab and pegfilgrastim, two biologics under this strategy, saw substantial price reductions, which allowed them to maintain significant market share even as biosimilars entered the market.

This approach effectively creates a barrier to biosimilar penetration, as payers, enticed by the lower prices, continue to prioritise the originator products over biosimilars. This strategy not only preserves the originator's market share but also limits the growth of biosimilars, which struggle to compete on price despite potentially offering similar therapeutic outcomes.

Non-Sole Preferred Coverage Strategy: Promoting Competition

In contrast, the non-sole preferred coverage strategy allows for a more competitive market environment. Under this strategy, originator manufacturers do not aggressively reduce prices, resulting in both the originator and biosimilar products being covered under comparable terms. This is observed in the cases of trastuzumab and filgrastim, where the price reductions have been less than 50%. Consequently, biosimilars in these categories have gained a more substantial market share as payers adopt a more inclusive approach to formulary management.

This strategy fosters a more competitive landscape by providing biosimilars with a fair opportunity to capture market share. The increased competition drives down prices and encourages broader access to these essential medications. As a result, patients benefit from more choices and potentially lower out-of-pocket costs, while payers can leverage biosimilars to negotiate better prices from all manufacturers involved.

Market Share and Pricing Dynamics: A Complex Interaction

The impact of these strategies on market share and pricing is multifaceted. Products under the sole preferred coverage strategy, such as infliximab and pegfilgrastim, retain higher market shares due to significant discounts and favourable formulary placement. This results in limited uptake of biosimilars, which cannot offer sufficiently attractive pricing to disrupt the established market positions of the originators.

Conversely, in the non-sole preferred category, biosimilars such as those competing with trastuzumab and filgrastim have experienced greater success in gaining market share. This is primarily due to the originators' lack of aggressive pricing, which allows biosimilars to compete more effectively. The overall market-weighted ASP for both originators and biosimilars tends to decline following the introduction of biosimilars, indicating that the presence of biosimilars exerts downward pressure on prices, benefiting the healthcare system.

Despite the potential for cost savings, biosimilar uptake alone does not fully encapsulate the market's competitive dynamics. The strategies

originator manufacturers employ, including rebates and discounts, play a crucial role in shaping the market landscape. This complexity underscores the need for comprehensive policies that consider both pricing and access to ensure a fair and competitive market.

These findings suggest that simply increasing biosimilar availability is insufficient to guarantee cost savings. Policymakers and stakeholders must consider the broader market dynamics, including the potential anti-competitive practices and the role of Pharmacy Benefit Managers (PBMs) in shaping the market. As new biosimilars enter the market and policies such as the Inflation Reduction Act take effect, ongoing monitoring and analysis will be critical to understanding and optimising the impact of biosimilars on the U.S. healthcare system. Future research should focus on the long-term effects of these strategies on market competition, patient access, and overall healthcare costs.

Source: **HealthAffairs Scholar**

Image Credit: **iStock**

Published on : Thu, 1 Aug 2024