

EXCLUSIVE COVERAGE

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From Approval to Practice: Addressing the Hurdles in Biosimilar Integration

By Skylar Jeremias

DESPITE FACING CONSIDERABLE BARRIERS to adoption, biosimilars have significant potential to reshape the health care landscape, as highlighted in recent discussions at an Institute for Value-Based Medicine event cohosted by *The American Journal of Managed Care* and Providence in Seattle, Washington, on August 29, 2024.

Experts emphasized the growing momentum in biosimilar approvals, driven by an anticipated market value of \$10 billion by 2028, as more biologics approach the end of their patent protection. However, restrictive payer policies and physician hesitancy continue to hinder the drugs' integration into standard medical practice. Panelists also offered insights into leveraging artificial intelligence (AI) for enhanced formulary management and the necessity of collaborative efforts among stakeholders to improve biosimilar acceptance. The importance of patient education and the role of health care professionals in navigating these challenges were key themes throughout the presentations.

THE PHARMACOECONOMICS OF BIOSIMILARS

Sophia Humphreys, PharmD, MHA, BCBBS, director of system formulary management and clinical programs at Sutter Health, highlighted the growing momentum in biosimilar approvals and their market potential. In recent years, there has been a notable trend in biosimilar approvals, with an average of 4 to 6 biosimilars receiving approval annually. This surge is linked to the increasing number of biologics nearing the end of their patent protection, creating significant market opportunities. By 2028, the biosimilar market is projected to be valued at \$10 billion, she said, driven by these expirations and the entry of biosimilars as cost-effective alternatives.

Despite the high expectations surrounding biosimilars, their initial market performance has not matched these projections. Adoption rates have been slower than



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anticipated, primarily due to a combination of factors such as restrictive payer policies, a lack of widespread patient education, and physician hesitancy to prescribe biosimilars. Humphreys said that these elements have contributed to a more gradual integration of biosimilars into standard medical practice than initially expected.

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—Sophia Humphreys, PharmD, MHA, BCBS, director of system formulary management and clinical programs, Sutter Health

However, the landscape is rife with both challenges and opportunities for improving biosimilar adoption, she noted. One significant barrier to adoption has been payer policies, which are negotiated through pharmacy benefit managers (PBMs) and often prioritize higher rebates from originator biologics over the lower-cost alternatives that biosimilars offer. Addressing these rebate-driven policies can open doors to wider biosimilar acceptance.

Additionally, enhancing patient education and increasing physician confidence in the efficacy and safety of biosimilars are vital steps to boost their prescription rates. Establishing biosimilar comparability to reference biologic products can further reinforce trust within health care systems. Humphreys also called on health care organizations to foster collaboration among integrated delivery networks (IDNs), payers, manufacturers,

and physicians, which will be key to overcoming these challenges and ensuring the successful integration of biosimilars into the health care landscape.

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AI-ENHANCED FORMULARY MANAGEMENT

Steve Pickette, PharmD, BCPS, chief clinical pharmacist at InpharmD, provided a presentation on the intricacies of the formulary process and the potential role of AI in enhancing its efficiency. He began by outlining the steps involved in the formulary process, which include gathering and summarizing evidence, engaging relevant stakeholders, presenting the information to the pharmacy and therapeutics committee, and ultimately implementing the committee’s decisions. Pickette emphasized that this process is labor-intensive, often requiring 6 to 8 weeks to review a single drug or drug class.

A key focus of his presentation was the role AI can play in streamlining formulary analysis. Using a class review for botulinum toxins as an example, Pickette demonstrated how AI tools can quickly gather and summarize relevant evidence, presenting it in a standardized format. However, he noted that AI-generated content is not final until reviewed and edited by a drug information specialist, underscoring the importance of human oversight in ensuring accuracy and relevance.

Pickette also discussed financial aspects of the formulary process, particularly the need for a thorough financial analysis of new drugs entering the market. He introduced an AI-powered tool developed at InpharmD that can analyze drug utilization, costs, and reimbursement data to provide comprehensive financial reviews. Tools such as this are capable of recommending optimal drug choices based on factors such as cost, annualized spending, and profit margins, revealing significant financial opportunities for health care organizations.

Moreover, Pickette emphasized the broader role of AI in pharmacy practice, noting its potential to assist with clinical decision support and other repetitive, detail-oriented tasks. He was careful to emphasize that AI is not a replacement for clinical pharmacists but a valuable tool to enhance their work. Pharmacists’ expertise and judgment remain critical and irreplaceable in making final decisions, he said.

“You need to monitor [AI] to make sure it works, right? You need to respond to questions, and a lot of education needs to happen, so you need to gear up all your clinical pharmacists to be able to answer questions and provide them with the resources,” he said.

Overall, Pickette’s presentation demonstrated how AI can significantly improve the efficiency of the formulary review process while preserving the essential role of human expertise and oversight, particularly in clinical and financial decision-making.

He concluded: “I don’t think AI is much of a threat. It’s really a help, and it’s new. Anything new is kind of scary, but it’s pretty exciting, really, and can save quite a bit of time in this overall formulary process.”

MULTISPECIALTY UPDATES

The presentation from Steven Stanos, DO, a pain specialist at Providence Swedish Health Services, focused on the evolving understanding of pain and the importance of a comprehensive approach to its management. He traced the history of pain theory from René Descartes’ mechanistic view to the modern biopsychosocial model, emphasizing the complex mechanisms of pain, including peripheral and central sensitization, which influence how individuals experience pain.

Stanos reviewed several classes of pain medications—nonsteroidal anti-inflammatory drugs, opioids, and serotonin and norepinephrine reuptake inhibitors—and explained their mechanisms of action. However, he noted that even the most commonly used pain medications often provide only modest relief, underscoring the need for a broader, multidisciplinary approach. This approach includes not only drugs but also physical and occupational therapy, psychological support, and relaxation techniques, which together address both the physical and psychological dimensions of pain.

He also discussed pain neuroscience education, which helps patients understand the mechanisms of pain and how to control their response to it. Additionally, he introduced graded motor imagery, a technique to retrain the brain for improved pain management. Stanos concluded by stressing the need for individualized treatment plans because patients respond differently to various interventions.

Mike Skafi, RPh, MSQA, system assistant vice president of pharmacy at Providence, provided a comprehensive overview of Alzheimer disease (AD), a progressive neurocognitive disorder marked by memory loss, cognitive decline, and behavioral changes. He emphasized the


escalating prevalence of AD, noting projections that it will affect approximately 14 million individuals in the US by 2060, with significant disparities among different ethnic and racial groups.

Skafi reviewed current treatment options, including cholinesterase inhibitors and N-methyl-D-aspartate receptor antagonists, which primarily offer symptomatic relief. He discussed newer disease-modifying therapies, such as anti-amyloid monoclonal antibodies lecanemab (Leqembi) and donanemab (Kisunla), which target the underlying pathology of AD. Although these therapies show promise, Skafi noted the need for careful monitoring due to potential adverse events such as amyloid-related imaging abnormalities and highlighted the substantial costs associated with these treatments.

Skafi expressed optimism about the development of new therapies aimed at modifying the disease trajectory, which could significantly alleviate the burden of AD on patients, caregivers, and the health care system.

JT Lew, PharmD, BCPS, managed care pharmacist at MultiCare Health System, addressed the multifaceted challenges that patients with multiple sclerosis face in accessing medications. He discussed the complexities of health insurance coverage, noting that high out-of-pocket costs and the intricacies of health plan benefits can be significant barriers to medication access. Lew highlighted that patients often encounter difficulties when transitioning between insurance plans or employers, which could disrupt their therapy. Utilization management tools, such as prior authorizations and step therapy protocols, while intended to control costs, can also delay access to necessary medications.

To navigate these challenges, Lew suggested that value-based agreements between health care providers and payers could be a viable solution to help reduce overall health care expenditures while ensuring patient access to essential treatments. He also underscored the importance of patient assistance programs, including co-pay cards and federal assistance, to support patients in managing medication costs.

Lew concluded by emphasizing the pivotal role of health care professionals, including pharmacists and care navigators, in helping patients overcome access barriers, ensuring continuity of care, and optimizing treatment outcomes. 

Author Information: Ms Jeremias is an employee of MJH Life Sciences, the parent company of the publisher of *Population Health, Equity & Outcomes*.