

Pharmacist Role in Biosimilar Utilization

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Abstract

Biologic drugs are the largest driver of rising drug prices due to the complexity of the manufacturing process. The use of biologic medications continues to increase exponentially, as they are used to treat and cure a variety of chronic disease states. Due to the high costs of biologics, access to medication and utilization is limited. Biosimilars are emerging as an alternative to reference biologic agents. Despite being available in the market, biosimilars remain unfamiliar to the general population. As the pharmacist's role shift from the traditional dispensing towards medication management, pharmacists are in a key position to increase utilization of biosimilars to lower biologic drug expenditure and increase access to care. Pharmacists can educate stakeholders such as physicians and patients on the similarities between reference products and their biosimilars in an effort to impact prescribing patterns, increase access to biologic medications and decrease drug cost.

Keywords: *Biologics; Biosimilar Utilization; Pharmacist; Medication Management*

Abbreviations

FDA: Food and Drug Administration; IQVIA: Intercontinental Medical Statistics Quintiles Via; U.S.: United States

Introduction

Biologics are large, complex molecules that may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell [1]. Biologic drugs are the largest driver of rising drug prices due to the complexity of the manufacturing process. To provide perspective on how biologics are driving drug expenditure, the Intercontinental Medical Statistics Quintiles Via (IQVIA) conducted a report on "Medicine Use and Spending in the U.S." in 2018. Statistics showed that in 2014, biologics represented 93% of all net drug spending growth [2]. By 2017, biologics represented only 2% of all prescriptions in the U.S., but 37% of net drug spending [2]. The use of biologic medications continues to increase exponentially, as they are used to treat and cure a variety of chronic disease states; however, the question remains: how do we increase patient access to these expensive and essential medications?

One solution to help overcome the cost barrier of biologic medications is to convert patients to biosimilar products. A biosimilar product is a biologic drug that is highly similar to and has no clinically meaningful difference compared to its existing Food and Drug Administration (FDA)-approved reference biologic [1]. "Highly similar" is defined as having minor differences in clinically inactive components such as a stabilizer or a buffer; however, clinically meaningful differences in safety, purity and potency are not acceptable [1]. Biosimilars are not generic products, as they demonstrate high similarity but not bioequivalence. In addition, biosimilars are not interchangeable with their reference product unless proven to show equivalent clinical results without increased risks or diminished efficacy [1]. Once a bio-

similar is approved by the FDA to be interchangeable, it may be used in place of the reference product without consulting the prescriber. As of yet, there are no interchangeable biosimilars approved in the U.S [1].

Biosimilars present an opportunity for competition due to their similarities in safety and efficacy, and reduced costs compared to reference products. Reference biologics and their biosimilars compete in price for increased market share. Insurers and providers, being the majority of stakeholders, have the power to drive prescribing. Patients may also benefit from the use of biosimilars due to lower insurance premiums, lower out-of-pocket costs, and as a result, increased access to medications [3]. With biosimilar utilization, there is a potential to reduce direct spending on biologic drugs by \$54 billion by 2026 and increase their access to an additional 1.2 million U.S. patients by 2025 [3,4].

When new medications come to market, they are often accompanied with hesitation for use. This uncertainty is not lessened with biologics. With the rise of biosimilars, some barriers for utilization include prescriber and patient caution, biosimilar interchangeability and payer considerations. Regarding biosimilar interchangeability, currently there are no biosimilars that are approved to be interchangeable by the FDA. In addition, payer considerations are dependent on the insurer's formulary. However, pharmacists have the ability to play a large role in implementing biosimilars and overcoming these barriers. With the pharmacists' role evolving away from traditional medication production and dispensing and more towards direct patient care and medication management, pharmacists are in a key position to assist providers with the implementation of biosimilar utilization.

Pharmacists with expertise in medication management play a large role in the implementation of approaches to increase biosimilar utilization. Pharmacists are trustworthy, accessible, and knowledgeable. These qualities allow pharmacists to collaborate with providers and insurance companies for improved insurance premiums and policies, educate physicians and patients to transition prescribing to biosimilars, and aid in facilitating biosimilar addition to hospital formularies for increased access to medication.

Conclusion

Biologics are driving healthcare costs exponentially and is attributable to nearly all net drug spending growth. Biosimilars, however, are emerging as an alternative to reference biologics and provide significant reductions in healthcare costs. As biosimilars remain in their early phases, there continues to be caution for its use by providers and patients. This is where pharmacists may play a large role in educating physicians and patients and influencing prescribing patterns to increase utilization of biosimilars and lower expenditure on biologics.

Disclosure

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