



Pharmacists Optimizing Cancer Care®

Biosimilars Issue Brief: An Important Category of Medications for Cancer Patients

Medications can generally be categorized as chemical molecules (traditional medication) or biologic molecules that are derived from cellular or genetic sources (biologics). Over the last several decades, generic medications—copies of chemical molecules—have decreased medication costs and improved access to care. However, traditional standards used for equivalence between “brand” and “generic” medications do not apply to copies of biologics. When two different companies make the same biologic medication, they turn out similar, not identical, hence the term “biosimilar.” While biosimilars are attractive because they present opportunities for cost-savings, it is important to ensure that biosimilars are equally as safe and effective as their branded counterparts.

History of Biosimilars

Biologic medications have been available for years using plant, animal, and human sources. Federal law allows other companies to manufacture a biosimilar copy of a biologic when it goes off patent, similar to how generic medications are allowed. With the FDA’s biosimilar pathway, manufacturers of biosimilars are required to compare their product to the original branded biologic and submit an abbreviated data package. The biosimilar manufacturer must still conduct tests to ensure that there are no clinically meaningful differences between the biosimilar and the original brand medication in terms of the safety, purity, and potency of the product.

Impact of Biosimilars on Individuals with Cancer

Biologics present new options for cancer treatment, and have the potential to transform cancer care. The high cost of cancer medications is frequently a barrier to patients receiving the latest and most promising cancer therapies. When cancer patients do not receive the treatment they need due to cost, a less-desirable treatment option with increased toxicities may be used.

- The top cancer medication currently used in the US is a biologic, with a large number of additional biologics in the drug development pipeline
- Overall, biologics comprise over 80 percent of the cost of medications worldwide.
- The impact of using biosimilars can reduce direct healthcare costs by \$54 billion by 2026.
- Biosimilars can lower costs and improve medication access, thus enabling more patients to receive the biologic therapy they need.

Biosimilars Safety

Biologics used to treat and manage cancer are complex, which raises concern that side effects may occur. While biologic medications generally have fewer side effects than traditional cancer chemotherapy, providers, such as oncology pharmacists, still need to monitor all medications for unique side effects.

- While biosimilars are not chemically identical to the innovator medication, the primary structure is expected to be highly similar.
- Pre-market testing is required to ensure that the side effects of biosimilars are the same or less than the innovator medication and to identify any new side effects with the biosimilar product.

Patient and Provider Information and Education

Understanding the issues surrounding biosimilars will help healthcare providers and institutions make better patient care decisions. Several questions related to the use, control, and monitoring of biosimilars remain, and providing education to patients and providers about these issues is crucial to patient safety.

- Transparent exchange of information regarding safety and effectiveness between all healthcare stakeholders is necessary to ensure the safe and effective use of biosimilars.
- Providers must understand the appropriate considerations for using, dispensing, administering, and monitoring biosimilars.
- Patients must understand both the value and potential risks associated with biosimilars.

Recommendations: Standards to Ensure Access, Safety, and Affordability

HOPA feels strongly that individuals with cancer should have increased access to biologic medications that offer significant advances in the treatment and cure of cancer. Biosimilars have the potential to increase access to life-saving therapy by reducing the financial barriers that exist for many of the current high-cost cancer therapies. Once available, biosimilars also have the potential to reduce the nation's healthcare costs for patients with cancer and other diseases that are treatable by biologic medications. HOPA makes the following recommendations to ensure appropriate access to, and safe use of biosimilars.

- More education regarding the scientific, regulatory, pharmacovigilance, and practice implications of biosimilars should be provided to healthcare providers, payers, and patients.
 - Implementation of a robust system to assess patient insurance benefits before administration of biosimilars
 - Patient education regarding biosimilar options, clinical outcomes, and out-of-pocket expenses
 - Provider education regarding biosimilar studies that demonstrate similarity or ability to seamlessly interchange applicable agents based on parameters required for FDA approval
- FDA should continue to develop guidance to facilitate the approval of biosimilars that includes the following:
 - The framework for determining when biosimilar indications may be extrapolated;
 - Criteria and clinical use standards for the automatic interchangeability of the biosimilar for the innovator medication
- Infrastructure should be improved to facilitate provider reporting and monitoring of any unique toxicities of biosimilars
- Healthcare IT system design should have incorporate processes for biosimilar designation to ensure accuracy for ordering, dispensing and administration functions in the outpatient and inpatient settings.
- For biosimilar products where the reference product contains a FDA Risk Evaluation and Mitigation Strategy (REMS) program, processes should be centralized to the extent possible to minimize disruptions to healthcare provider workload.
- Reimbursement policies set by third-party payers should take into consideration that preference for one particular biosimilar product within a class may lead to practices having increased administrative, financial, supply chain, and legal liabilities.
- Due to the lack of data around safety and efficacy for switching between biologics and biosimilars within the same treatment course, HOPA supports policies and practices allowing patients to continue with their original therapy.
- Ongoing research into clinical trials examining the patient outcomes and safety risks of switching is required to fully understand the risks, if any, for switching between reference biologics and biosimilars.