



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

Medications can generally be categorized as chemical molecules (traditional medication) or biologic molecules that are derived from living 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. Recent federal law now allows other companies to manufacture a biologic when it goes off patent, similar to how generic medications are allowed. With the FDA’s new biosimilar pathway, manufacturers of biosimilars are required to compare their product to the original branded medication 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 three cancer medications currently used in the US are biologics, as are most of the 900 new medications in the cancer development pipeline.
- Overall, biologics comprise 55 percent of the cost of the top 20 cancer medications sold in the US.
- The impact of a 25-percent savings by using biosimilars can be more than \$6 billion per year.
- Biosimilars can lower costs, 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 the same.
- 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.

Importance of Biosimilar Naming

Because biosimilars are not exactly the same, debate and discussion that biosimilars cannot have the same generic name as the original branded medication is ongoing. Health care providers, patients, manufacturers, and regulatory agencies must be able to identify that a product is biosimilar to the original branded medication, and they must be able to associate the medication with the appropriate therapeutic class to assure appropriate prescribing. Naming is important to avoid prescribing and dispensing errors. Further, biosimilars must be able to be easily tracked to monitor safety and quality. Pharmacists are uniquely positioned to understand the important role that naming will have in ensuring appropriate medication substitutions take place when biosimilars are used.

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.
- FDA should rapidly develop guidance to facilitate the approval of biosimilars that includes the following:
 - The conceptual 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;
 - Naming standards to ensure appropriate prescribing and safe dispensing—while the preferred naming convention would include using the current nonproprietary name associated with the reference product and modifying it with a prefix, HOPA supports the use of a meaningful four-letter suffix for FDA-designated non-interchangeable biosimilars; and
 - Publishing a reference manual similar to that of *the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* but unique to biological medications; this reference should compare the quality attributes of a biosimilar product to the reference biologic and rate the comparability of the two products.
- Infrastructure should be improved to facilitate provider reporting and monitoring of any unique toxicities of biosimilars, including the development of separate HCPCS Level II billing codes for each biosimilar product.
- Healthcare IT system design should have efficient process 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 REMS element to assure safe use (ETASU), processes should be centralized to the extent possible to minimize disruptions to healthcare provider workload.
- Legislation defining the parameters by which pharmacists may substitute a biosimilar for the reference product is currently premature because issues such as naming and interchangeability have yet to be resolved. Future biosimilar substitution legislation should be developed with input from the State's Board of Pharmacy, local pharmacy organizations, and from other healthcare providers, taking into consideration parameters within their current law regarding generic substitution as a starting point for discussion.
- 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, and legal liabilities due to increasing their inventory management complexity.