



HOPA Biosimilars Issue Brief: Improving Access and Decreasing Costs for Cancer Patients

History of Biosimilars

Medications can generally be categorized as small molecule drugs (traditional medication) or biologic drugs (biologics). Small molecule drugs have a simple chemical structure, whereas biologic drugs are larger, structurally more complex, and are derived from living sources. The FDA defines a biosimilar as “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.”¹ Biosimilar drugs have the same mechanism of action and cost less than the reference product; however there have been a number of barriers in the United States which have prevented utilization of biosimilars*. Per the FDA, “All biosimilar (...) products meet FDA’s rigorous standards for approval for the indications (medical conditions) described in product labeling. Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.”²

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 a frequent barrier to patients receiving promising cancer therapies.

- Four of the top 5 cancer medications currently used in the US are biologics, as are most of the 1,100 new medications and vaccines in the cancer development pipeline.^{3,4}
- The biologic oncology products expected to lose patent protection by 2020 account for more than \$20 billion in global annual spending.⁵ Biosimilars are expected to reduce direct spending on biologic drugs by \$54 billion from 2017 to 2026.⁶
- Biosimilars lower costs, thus enabling more patients to receive the biologic therapy they need.

Patient and Provider Information and Education

With patient and provider education, understanding the challenges 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. As with any biologic, the following is critical

- 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 financial value and potential risks and clinical benefits associated with biosimilars.

Recommendations: Ensure Access, Safety, and Affordability

HOPA feels strongly that individuals with cancer should have 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. HOPA makes the following recommendations to ensure appropriate access to, and safe use of, biosimilars.

- Support elimination of manufacturer rebate incentives with payers and PBM's that restrict access to biosimilars. This restricted access inhibits provider decision making regarding patient access to lower cost treatments for patients and increases patient financial toxicity.
- Support parity access to all biosimilars with third-party payers which would eliminate a preferred product preference of one particular biosimilar product within a class. The result of which would eliminate undo administrative, financial, and legal liabilities due to increased inventory management complexity.
- Promote education regarding the scientific, regulatory, pharmacovigilance, and practice implications regarding biosimilars. This information should be provided to all healthcare stakeholders, but especially providers, payers, and patients.
- Infrastructure should be improved to facilitate provider reporting and monitoring of any unique toxicities of all biological drugs observed after approval.
- Future biosimilar substitution legislation should be developed with input from State Boards of Pharmacy, local pharmacy organizations, and healthcare providers. Key parameters within current law regarding generic substitution should be a basis for the legislative discussion.

*This continues to impede biosimilar adoption in the US. Many institutions will struggle to identify at what time point to switch patients from reference product to biosimilars. This practice can slow integration of biosimilars and cause confusion within health systems when some patients receive reference biologic agents and others receive biosimilars. Many biosimilars are not approved for all the indications that the reference product carries, due to patent litigation issues. It is unclear how these will be adopted into practice. Will the institution carry both biosimilar and reference product or will they be comfortable with extrapolating indications outside the label, including indications where off label use was heavy for the reference product. Patients and providers do not have a clear understanding of financial implications of adopting biosimilars because payors are covering reference products and some are even denying coverage for biosimilars (due to heavy rebating from reference product manufacturers and some going to the extent of requiring patients to fail reference product to receive a biosimilar. There needs to be more education on the financial benefits for patients and providers and better government oversight on anticompetitive practices from manufacturers.

References

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²FDA: Prescribing Biosimilar and Interchangeable Products.

<https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm580430.htm>. Accessed 4.23.19

³Top 10 Best Selling Oncology Drugs in 2018: <https://www.igeahub.com/2018/05/28/10-best-selling-drugs-2018-oncology/>. Accessed 3.18.19

⁴Medicines in Development For Cancer:

http://phrma-docs.phrma.org/files/dmfile/2018_MID_Cancer.pdf. Accessed 3.18.19

⁵IMS Health. The impact of biosimilar competition. London: QuintilesIMS, June 2016:

<https://www.scribd.com/document/349757084/IMS-Impact-of-Biosimilar-Competition-2016>. Accessed 3.18.19

⁶Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case, Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017.

<https://www.rand.org/pubs/perspectives/PE264.html>.