

Biosimilars

Community Oncology Alliance Position Statement



Summary:

The Community Oncology Alliance (COA) is committed to advancing knowledge and acceptance of biosimilars as an important, promising element in reducing drug costs and overall health care spending, and the financial toxicity of cancer care for patients. COA will work to support biosimilars and innovative biosimilar (biologic) development with all stakeholders, including policymakers, manufacturers, payers and employers, and other advocacy, patient, and policy organizations.

Background:

Since the early 1990s, biologics (monoclonal antibodies and growth factors) have represented one of the fastest growing sectors of the drug industry worldwide, be it for supportive care, autoimmune disorders, or cancer care. Biologics are produced from the cells of living organisms and purified in a complex, multi-step process, including recombinant DNA technology, controlled gene expression, and antibody technologies. Compared with chemically synthesized small molecule drugs, biologics have a much more complex manufacturing process and have required a complicated and innovative research and design process; their physiochemical structure is complex and difficult to characterize. Biologic agents are highly sensitive to changes in manufacturing conditions, and as a result, need a complex manufacturing and production process.

As the current cost of biologics are high, long-term treatment of patients with biologics can be a chronic burden to the health care system. In the United States (U.S.), total spending on cancer care has increased from \$27 billion in 1990 to \$124 billion in 2010, with spending projected to reach around \$174 billion by 2020.ⁱ The total cost of cancer care for the U.S. population is predicted to increase across all phases of care. At the same time, patients are shouldering an increasing share of these rising costs as health plans restructure their benefit designs, including high-deductible health plans that shift costs onto beneficiaries. The financial consequences and toxicity of cancer treatment on patients and their families is a substantial, well-documented burden.

The fastest growing drug classes within oncology are biological agents, accounting for over 40% of U.S oncology spending. Sales figures in 2015 for three of the top 20 global products – bevacizumab, rituximab, and trastuzumab – were \$6.2 billion, \$6.3 billion, and \$5.6 billion, respectively.ⁱⁱ

The increased prevalence of cancer, earlier treatment initiation, and improved patient outcomes all contribute to the growing use of oncology and supportive care biologic agents, as well as the overall high cost of cancer care. These factors, coupled with the high costs of manufacturing biologics, alongside macro- and micro-economic factors have resulted in significantly higher health care costs, a major concern for the sustainability of health care financing and policy.

Biosimilars of reference biologic agents offer an appealing alternative and potential solution to rising cancer care cost trends. The FDA defines a biosimilar as a biologic product that is highly similar to an already licensed reference biologic and that has no clinically meaningful differences in terms of safety, purity, and potency.

By 2020, a range of biosimilars for biologic agents used in oncology treatment are expected to receive FDA approval and become available in the U.S. Their availability will provide increased treatment options and market competition. Congress developed a regulatory framework for biosimilar approvals with the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI). This created an abbreviated licensure pathway, 351 (k), for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed biological product (or “reference product”). Since then, multiple biosimilars for both supportive oncology care and therapeutic care have been approved, including the FDA-approved biosimilars of targeted therapies bevacizumab, rituximab, and trastuzumab.

Biosimilars may offer more affordable alternatives to biologics. The Congressional Budget Office (CBO) estimates that the sales-weighted market average discount on biosimilars would be 20–25% relative to reference agents in the first year. In the fourth year, the CBO estimates this would reach about 40%.ⁱⁱⁱ The Rand Corporation estimates that savings to the U.S. health care system resulting from the use of biosimilars over biologics range from an estimated \$13 billion to \$66 billion over the 10-year period between 2014 and 2024.^{iv} Indeed, the benefits have already been demonstrated for the biosimilar filgrastim, for which the Average Sales Price (ASP) shows a 35% discount over the reference biologic.^v If fully realized, the expanded treatment choices provided by biosimilars will open up new opportunities to improve value, access, and care delivery for patients.

Realization of the projected cost savings, however, will require that biosimilars are embraced and utilized. As more biosimilars become available after receiving regulatory approval, adoption in clinical practice is expected to increase, but this is currently in its infancy and much work remains. The results of a 2015–2016 survey led by the Biosimilars Forum show that major knowledge gaps about biosimilars and their potential use in clinical practice still exist among U.S. specialty physicians, including oncologists.^{vi} Key gaps include defining biologics versus biosimilars in the context of biosimilarity; understanding the approval process and the use of the “totality of evidence” approach by the FDA for biosimilar evaluation; understanding the evidence requirements for demonstration of safety and immunogenicity of a biosimilar versus its reference product; understanding the rationale for indication extrapolation; and defining interchangeability in the context of pharmacy-level substitution.

As additional biosimilars are approved in the U.S. and awareness grows, it is anticipated that biosimilar uptake and utilization will increase subject to acceptance by the prescribers, payers, and patients. There is a need to educate multiple stakeholders, including physicians and other health care providers, about biosimilars, and to raise awareness and increase utilization of these potentially cost-saving therapies. Patient education is also critical to increasing acceptance of biosimilars. Biosimilars will also play a key role in the success of value-based care models, such as the Oncology Care Model and the Medicare Shared Savings Program.

Community Oncology Alliance Position:

COA is committed to working with the relevant public policy bodies (FDA, CMS, etc.), clinical organizations, professional associations, and advocacy groups, to support the acceptance of biosimilars across a range of sectors and bridge the knowledge gap in the key areas mentioned above. COA is also committed to working together with manufacturers of innovative biologics and biosimilars to reduce the cost of care, improve access, and reduce financial toxicities while continuing to provide logistical support for innovation in cancer treatment. With the intent of

providing better access at affordable prices, reducing overall spending in Part B drug prices, and reducing financial toxicities experienced by patients, COA will work with all stakeholders to assimilate biosimilars and provide support to patients, physicians, and payers.

Date:

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References:

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ⁱⁱ Patel KB, Arantes LH, Tang WY, Fung S. The role of biosimilars in value-based oncology care. *Cancer Manag Res.* 2018;10:4591-4602. Published 2018 Oct 17. doi:10.2147/CMAR.S164201.

ⁱⁱⁱ Congressional Budget Office Cost Estimate, “S. 1695 Biologics Price Competition and Innovation Act of 2007.” <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/94xx/doc9496/s1695.pdf>.

^{iv} Rand Corporation, “Biosimilar Cost Savings in the United States Initial Experience and Future Potential” https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf.

^v Center for Biosimilars. “Pfizer Launches Biosimilar Filgrastim, Nivestym, at a Substantial Discount.” <https://www.centerforbiosimilars.com/news/pfizer-launches-biosimilar-filgrastim-nivestym-at-a-substantial-discount>

^{vi} Cohen, H., Beydoun, D., Chien, D. et al. *Adv Ther* (2016) 33: 2160. <https://doi.org/10.1007/s12325-016-0431-5>. <https://link.springer.com/article/10.1007/s12325-016-0431-5>.