

Integrating Biosimilars Within a Community, Academic, or Health-System Setting

Biosimilar agents have been used in Europe for at least 10 years and recently entered the United States market through supportive care therapies (filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmdb, pegfilgrastim-cbqv, and epoetin alfa-epbx). In addition to these supportive care biosimilars, the U.S. Food and Drug Administration (FDA) has approved the following biosimilars for use in oncology practice: bevacizumab-awwb, rituximab-abbs, trastuzumab-dkst, trastuzumab-pkrb, trastuzumab-dttb, and most recently trastuzumab-qyyp. Amidst all these approvals, the number of oncology biosimilar agents is anticipated to increase by 2020 as several oncology products lose their patent protection. The approval process for biosimilars requires that manufacturers demonstrate these agents have no clinically meaningful differences from an existing FDA-approved reference product. As real-world data matures (as it has done within autoimmune diseases), this pre-approval requirement will continue to be scrutinized via practice-based clinical safety and efficacy data. Biosimilars offer the potential for cost savings, for instance, by enhancing competition and reducing patient co-pays and premiums, but many challenges exist which may limit biosimilar development and expected savings in the future. It is incumbent on physician and pharmacy leaders to consider how and where biosimilars can be substituted for reference products to contribute to savings in oncology care; with this in mind, in October 2018, the Association of Community Cancer Centers (ACCC) hosted a pre-conference workshop at its 35th National Oncology Conference to review how oncology pharmacists can best respond to rapid changes in the oncology environment.

Barriers to Incorporating Biosimilars into Pharmacy Practice

Attendee polling revealed that while a majority of participants were aware that biosimilars represent an important topic in the evolving value-based oncology landscape, they also lacked familiarity with biosimilar drugs and the approval process. Panelists Nimer Alkhatib, PharmD, MS, of the Health and Policy Outcome Center for Health Outcomes and PharmacoEconomic Research (HOPE) at the College of Pharmacy, University of Arizona; Ali McBride, PharmD, MS, BCOP, Clinical Coordinator, Hematology/Oncology in the Department of Pharmacy at the University of Arizona Cancer Center; Kashyap B. Patel, MD, Medical Oncologist at Carolina Blood & Cancer Care Associates; and Marc Earl, PharmD, BCOP, Assistant Director of Pharmacy-Oncology, Cleveland Clinic agreed that this lack of familiarity, while unsurprising, poses a significant barrier to the integration

of biosimilars. Other technical and infrastructural factors may also pose barriers to integration, including how financial and patient assistance organizations will react, and the lack of biosimilar inclusion in electronic medical record (EMR) protocols. Clinicians may also have questions about extrapolating use of a biosimilar to all reference product-approved indications, as well as about the role of patients in making decisions about whether or not they agree to treatment with biosimilars. Indeed, a recent *New England Journal of Medicine* article emphasized the confusion and uncertainty among many clinicians about the naming and labeling of biosimilars, coverage and reimbursement issues (such as whether step therapy could

Defining Biosimilars

The FDA defines biosimilar products as large, complex molecules derived from biologic processes that are similar but not identical to the original agent.¹ They are “highly similar” to their reference products in physicochemical characteristics in that they contain a version of the active substance of an already authorized, original biological medicinal product (reference medicinal product). Section 351(i) of the U.S. Public Health Service Act defines a biosimilar as a “product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components,” and “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.” The abbreviated approval process for biosimilars requires stepwise demonstration of comparability in quality, efficacy, and safety between the biosimilar and reference product, and relies on preclinical studies/pharmacologic data versus new clinical trial data (which already exists for the reference product).

mandate biosimilars before using other therapies), and how best to integrate biosimilars into clinical practice.²

The Economics of Biosimilars and Value-Based Care

Strategies to conceptualize and measure value in oncology continue to be at the forefront of discussions about the rising costs of cancer care. A key question about biosimilars is whether and how they might stimulate changes in economic methods for capturing value. Dr. Alkhatib noted that biosimilars could usher in an opportunity to design economic metrics to more accurately quantify value in care, for instance, by shifting from cost benefit to cost minimization as a unit of analysis. In Europe, which has a longer history of using biosimilars, evidence points to reduced costs as measured via the effects of biosimilars on price, volume, and market share, as well as improvements in patient access to therapy. In the U.S., studies have shown significant efficiency savings in direct acquisition and administration costs for biosimilar filgrastim-sndz compared with reference products in the context of chemotherapy-induced neutropenia prophylaxis.³ Moreover, as Dr. Earl noted, it remains difficult to reduce overall costs in alternative payment models such as the Oncology Care Model (OCM), because there are so many variables to consider within large organizations as part of measuring cost, such as hospital admissions, drug costs, and emergency room visits. Biosimilars offer a substantive means to reduce costs and increase value, not only by lowering medication costs, but also by lowering patient out-of-pocket expectations.⁴

Strategies to Support Biosimilar Integration to Clinical Settings

In response to the potential for biosimilars to mitigate healthcare costs, the American Society of Clinical Oncology (ASCO) recently published a statement to address their integration into clinical practice.⁴ The discussion highlighted several strategies that will be

necessary to ensure effective integration of biosimilars into clinical practice. Public awareness about biosimilars, including their approval, clinical challenges, and potential benefits, will need to increase. It will be important to encourage clinical research, collect real-world data on safety and efficacy, and work collaboratively as clinicians, health economists, and policy makers to improve biosimilar uptake in the United States and help realize maximal cost savings. Pharmacoeconomic analysis can also be employed to assess comparative cost barriers and expected savings with biosimilars, with a focus on evaluation of methods for reimbursement and payer policies. In addition, ongoing professional and patient education via professional organizations such as ASCO and ACCC will play a vital role in establishing public and clinical confidence in the efficacy and safety of biosimilars and supporting their integration into clinical settings. ■

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The **ACCC Oncology Pharmacy Education Network** advocates on behalf of hematology-oncology pharmacists as vital members of the cancer care team, and is committed to developing educational resources and multidisciplinary connections that advance the field and elevate oncology pharmacy professionals to top-of-license practice.



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