The Year of the Biosimilar

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With the advent of biologics decades ago, the practice of oncology was forever changed. Today, the United States has the largest market for biologics in the world, accounting for nearly 50 percent of all prescription drug expenditures. This class of drugs also represents the nation's fastest growing pharmaceutical sector. More than 80 percent of the revenue from biologic therapy is derived from oncology indications, and this percentage is expected to increase in coming years as the use of these essential drugs expands throughout clinical care. These trends are not limited to the United States, however, as the global biologics market is expected to top $100 billion by 2023.[1]

The Biologics Price Competition and Innovation Act of 2009, which created an abbreviated pathway to approval for biosimilar agents, was designed to increase competition with reference biologics to lower prices, increase patient access, and accelerate innovation. Anticipated cost savings with the introduction of biosimilars in the U.S. market was estimated to be from $40 billion to $250 billion over the following 10 years.[2] The added advantages of biosimilar implementation under alternative payment models, such as the Oncology Care Model and Merit-Based Incentive Payment System are still yet to be fully realized.

To date, more than 25 biosimilars have been approved by the U.S. Food and Drug Administration (FDA), including rheumatology therapies, oncology supportive care agents, and therapeutic oncology drugs. The first biosimilar, filgrastim-sndz, was approved in 2015, and as of early 2018 more than 60 biosimilars were enrolled in the FDA's biosimilar development program.[3] Despite this aggressive approval and development landscape, integration of biosimilars into the U.S. market has been slow. Barriers to effective biosimilar implementation vary based on the size and resources of the specific program and can include:

- State and federal legislation
- Reimbursement and coverage challenges
- Electronic health record processes and integration issues
- Insufficient or ineffective education for healthcare team members and patients
- Pharmacy and therapeutics (P&T) integration
- Pharmacovigilance processes and an understanding of biosimilar outcomes, which have been associated with a lack of knowledge of biosimilars
- Uncertainty around therapeutic outcomes.

As we move into this new decade, biosimilars represent terrific innovation and (as yet) unrealized potential for cost savings. Use of these therapies may help cancer programs improve access to care, reduce total healthcare expenditures, and meet alternative payment model goals and requirements. If we are to realize the full potential of these therapies, however, integration of biosimilars is critical and must be achieved through interdisciplinary education of the entire cancer team—from physicians and nurses to pharmacy staff to financial navigators and patients and beyond. We can all play a vital role in the education, advocacy, and safety needs inherent with this new class of anti-cancer therapies. OI

References

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