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What Should Payers Be Doing Now to Prepare for Biosimilars?

***SPECIALTY PHARMACY NEWS* is designed to help health plans, PBMs, providers and employers contain costs and improve outcomes related to high-cost specialty products.**

By Angela Maas, Managing Editor
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The FDA approved the first biosimilar product, Sandoz Inc.'s Zarxio (filgrastim-sndz), earlier this month, and the industry expects more such approvals. So how should payers be preparing for this new class of drugs?

In cases such as Zarxio's in which the FDA grants indication extrapolation for a biosimilar (see story, p. 1), "Payers need to be really thinking through what it means for their commercial opportunities," says Gillian Woollett, M.A., D.Phil., senior vice president and head of the FDA Practice at Avalere Health LLC. The issue of extrapolation has been "very glossed over."

According to Mary Jo Carden, senior director of regulatory affairs, Academy of Managed Care Pharmacy, "Payers are considering ways to manage biosimilars. Some may develop a tiering structure similar to brand and generics, or some may implement value- or outcomes-based arrangements. Payers will also consider the implications for the pharmacy benefit in comparison to the medical benefit."

"Payers have been awaiting Zarxio's approval for the past several months," says David Lassen, Pharm.D., chief clinical officer for Prime Therapeutics LLC. He tells *SPN* that Prime has "been working with our Blue plans to ensure that we're reviewing the drug in our [pharmacy and therapeutics] committee and developing medical utilization management policies, since the majority of coverage will be on the medical benefit."

Rebates, Support Services May Be Factors

Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, says that "it will take health plans and PBMs some time to evaluate Zarxio, and decide where it fits in the drug formulary and with respect to patient cost share *vis-a-vis* Neupogen. It is likely that these decisions will be influenced by Novartis/Sandoz pricing/discounting strategy, and the net resulting cost difference to Neupogen. In addition to a payer's net cost, other factors that may impact payer preference for the biosimilar or the originator include differences in support services, such as patient assistance, differences in drug distribution strategy, and educational support for patients and prescribers *vis-a-vis* comparison of Zarxio to Neupogen."

Joshua P. Cohen, Ph.D., a research associate professor at the Tufts Center for the Study of Drug Development, says that payers "will likely place them in lower cost-sharing tiers on the formulary in order to boost their use and reap cost savings. They may sign rebate deals with biosimilar manufacturers that aim to increase their market share (through formulary management, i.e., tiering). Ultimately, payers will want to have therapeutic interchangeability established, not just biosimilarity. If FDA says that a product is therapeutically interchangeable with another, this will facilitate switching of products for patients already on an originator biologic. Payers will not have as much trouble promoting the use of biosimilars to new patients as they will promoting the use of biosimilars among existing patients."

Helen Sherman, Pharm.D., vice president at Solid Benefit Guidance, and Lynn Nishida, assistant vice president, pharmacy consulting, at SBG, say "payers should be preparing their pharmacy and therapeutics committee for reviewing these types of products," in terms of issues such as "biosimilarity vs interchangeability definitions, considerations in evaluating the clinical studies that may be largely based on intermediate endpoints…to assure consistent review methods and decision-making parameters." They tell *SPN* that because the FDA did not give Zarxio an interchangeable designation, "the ability to substitute for the reference

product from the perspective of the prescriber and the pharmacist will need to be based on an ultimate source that the FDA designates to communicate a product's interchangeability," which could be the drug's package insert, the product's name or the FDA's new *Purple Book (SPN 9/14, p. 12)*. "Whatever the source, this needs to be very clear what the source is and further defined in federal/state laws and [states'] boards of pharmacy rules." In addition, payers should "ideally clarify how biosimilars are to be covered under their health plan contracts (e.g., designation as brands) or minimally in coverage policies."

Asked if she thinks Sandoz may apply for the interchangeability designation, Woollett says the company has "clearly done the switching studies.…I imagine that is the next step." Stacie Ropka, Ph.D., an intellectual property litigator with Axinn, Veltrop & Harkrider LLP, agrees that Sandoz "may go back to FDA to get acceptance as an interchangeable."

And although the FDA has not issued guidance on interchangeability of biosimilars — although the topic is on the agency's list of 2015 planned guidance — "the FDA will make the decision [on interchangeability] when they have a specific decision to make," says Woollett.

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