

## Biosimilars Come to the U.S.

Some thought the day would never come, but the Food and Drug Administration (FDA) has approved the first biosimilar for the U.S. market, Zarxio®. Considered to have the same mechanism of action, route of administration, dosage form, and strength as Amgen's Neupogen®, Zarxio® was approved for the same indications. Despite all the fanfare, many questions are still unanswered, namely, what nonproprietary names will be used for biosimilars.

For this first biosimilar approval, the FDA used a placeholder nonproprietary name, filgrastim-sndz, based on the manufacturer of the drug. While the FDA stated that this name does not reflect the agency's final decision on its naming methodology, which has yet to be revealed, it does lead one to believe that the FDA is leaning towards using the unique international nonproprietary names (INNs). An INN is a unique drug name that is globally recognized and is public property. Most refer to the INN as the generic name. A unique INN would include the INN with a prefix or suffix added. This approach is in stark contrast to the wishes of most generic manufacturers, retail pharmacies, and many pharmacy organizations, since the addition of a suffix or prefix is in opposition to how generic drug products have traditionally been named. In a task group email, an American Society of Health-System Pharmacists (ASHP) member referred to the decision as an "untested, controversial naming scheme". Similar comments are anticipated from many other pharmacy groups.

Regardless of what the FDA decides to do in regards to nonproprietary naming, physicians must prescribe Zarxio® by the product name. Since the drug received biosimilar status and not interchangeability status, substitutions cannot be made in the pharmacy. Furthermore, while Medi-Span has not finalized or updated their drug file, they have published a substitution group spreadsheet showing that filgrastim and filgrastim-sndz will reside in separate GPI numbers, thus signifying that the products are not pharmaceutically equivalent. This is likely due to their lack of interchangeability status. The FDA has yet to issue guidance regarding what level of studies will be necessary for a drug to gain interchangeability status, so placement in the same GPI was unlikely anyway. While not confirmed, we expect First Databank will assign a separate GCN to the biosimilar.

For biosimilars that do not have interchangeability status, such as Zarxio®, manufacturers will likely need to employ a sales team, something previously unheard of in the traditional generic small molecule space. With the extra costs necessary to produce and market biosimilars, discounts on biosimilars will most likely be significantly less than those seen with traditional generics. Many sources have estimated that biosimilars will be priced at 30% below their corresponding brand drugs, but once biosimilars actually launch, this figure could change. In Norway, for example, Merck's Remicade® biosimilar is going for a discount of almost 70% and has captured 50% of the market.

Unlike most small molecule generics, many biosimilars will be reimbursed under a patient's Medical benefit, if the product is administered in a physician's office. This means that PBMs will have less of an impact on cost controls, due to a lack of formulary development and tiering. Because the product will be covered under a medical benefit on many plans, patients will likely not be conscious of the product pricing. While patients may feel the financial burden of high coinsurance costs for other specialty drugs, medical benefit coverage eliminates some of a patients' awareness about a drug's specific price. Without direct PBM and pharmacy pressure on prescribers to switch to biosimilars, uptake could be slow. Thus, the impetus for Zarxio® uptake will likely come from Sandoz's (1) prescriber education initiatives and (2) contracting strategy with the payer community.

The launch of additional biosimilars could produce a shift in the way that health plans view these drugs, and there may be a shift from medical benefit to pharmacy benefit coverage for several of these products. This change would provide more control over medication utilization through the use of formularies and tiering arrangements, which may help health plans to reign in their rising specialty costs. How health plans handle Zarxio® will serve as a model for future biosimilars. PHSI will continue to follow these exciting developments and provide periodic updates.

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## Winners & Losers with Biosimilar Medical Benefit Coverage

With the approval of Sandoz's new filgrastim-sndz product, Zarxio®, we must begin thinking about the winners and losers when biosimilar drug products are covered under patients' medical benefits. Since brand Neupogen® (filgrastim) is currently being covered under the medical benefit on numerous health plans, this scenario is likely to continue for biosimilar products that are approved in the near term. How biosimilars will be affected by medical benefit coverage will be of utmost importance to payers, physicians, and patients.

For payers, covering biosimilars under the medical benefit will make drug spending less transparent. Currently, office-administered specialty drugs are primarily covered under the medical benefit, while self-administered agents are typically covered under pharmacy benefits. Some have noted that the advent of biosimilars may prompt payers to move more specialty products to the pharmacy benefit (including office-administered agents) to better track drug spending and enable implementation of prior authorization protocols and other coverage edits. Overall, biosimilars are expected to provide cost savings for health plans, but the use of managed care utilization tools seen with pharmacy coverage could further improve savings.

In theory, administering biosimilars could lead to decreased revenue for physicians, due to the average sales price (ASP) plus 6% reimbursement on physician-administered drugs under Medicare Part B. However, this reimbursement methodology would have incentivized the use of more expensive brand medications, so CMS has provided new draft reimbursement guidance. Biosimilars will be reimbursed at the ASP for the biosimilar plus 6% of the ASP for the reference listed drug. CMS will create separate HCPCS codes to distinguish biosimilars from reference listed drugs, and identifiers, like "sndz", will not play into the distinction. For physicians administering biosimilars, this should make biosimilars as or more profitable than brands when coverage is provided under the medical benefit.

With more costly generic medications and the advent of biosimilars, many pharmacy payers are creating plans with additional tiering levels. It is not uncommon to see plans with five or more patient copay tiers. For patients, this can mean a copay difference between biosimilars and brand name specialty products for coverage under the pharmacy benefit. However, when biosimilars are covered under the medical benefit, a patient's cost sharing will depend on their plan design. We can assume that some level of cost sharing will be present for most patients. It is likely that biosimilars will be more costly for patients if they are covered under a patient's medical benefits instead of under their pharmacy benefits, due to the prevalence of high deductibles and cost sharing.

Due to the variety of plan designs and coinsurance differences, it is impossible to universally note winners and losers in regards to medical benefit coverage for biosimilars. However, in the majority of cases, PHSI estimates that physicians will be dubbed "winners". Meanwhile, payers and patients will likely be "losers" if biosimilars are covered under a patient's medical benefit where utilization controls are not in place. Nobody likes to be the loser though, and you can be assured that some plans will adjust benefit designs to transition coverage of biosimilars from medical to pharmacy benefits. Only time will tell how quickly this situation plays out!

### PHSI to Attend NCPDP

PHSI President Tim Kosty and Consultant Dave Schuetz will be attending the NCPDP Joint Technical Work Group Meetings and Annual Technology & Business Conference in Scottsdale, Arizona May 3-6, 2015. If you would like to schedule a meeting with Tim or Dave while at the Work Group Meetings or Conference, please contact PHSI at [bmattiko@phsrx.com](mailto:bmattiko@phsrx.com)