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First Year in Review: Top Ten Things to Know about Biosimilar Reimbursement in the U.S.

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Health Care

It has now been a full year since the Food and Drug Administration ("FDA") approved the first biosimilar product to proceed under the new abbreviated biological pathway. With recent spotlights on the cost of pharmaceutical drug products, the potential of biosimilars to offer patients additional and more affordable choices has been widely discussed. Most recently, the Department of Health and Human Services' 2017 Budget in Brief noted that the first approval under the abbreviated pathway could be the "next step to increasing treatment options for patients." As the U.S. landscape continues to evolve, below are the top ten things to know about the reimbursement developments in the last year.

From FDA Approval to Medicare and Medicaid Payments

1. Biosimilar products have been on the market in Europe since 2006, whereas the U.S. statutory pathway for approval of biosimilars was not established until 2010, when the Affordable Care Act created an abbreviated licensure pathway under § 351(k) of the Public Health Service Act—in a subtitle known as the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). Under this pathway, a follow-on biological product is approved based on a showing that it is "biosimilar" to or "interchangeable" with a biological product already licensed by the FDA, called the "reference product." The BPCIA provides that biosimilar approval is conditioned upon a showing that the follow-on product is highly similar to the reference product, with no clinically meaningful differences in terms of safety, purity and potency from the reference product. Interchangeable approval requires demonstration of biosimilarity and satisfaction of additional standards. An interchangeability approval reflects the agency's determination that the follow-on product may be substituted for the reference product without intervention from the prescriber of the reference product.
2. On March 6, 2015, the FDA approved Zarxio™—manufactured by Sandoz—the first and only biosimilar on the U.S. market to date. The biosimilar is a follow-on to Amgen Inc.'s innovator biological, Neupogen®, and entered the market in September 2015.
3. One year later—on April 5, 2016—the FDA approved Inflectra™, which is manufactured by Celltrion Inc., finding the product to be biosimilar to Janssen Biotech, Inc.'s innovator biological, Remicade®. The product has not yet entered the market in light of ongoing patent litigation.
4. On the heels of the FDA approval of Zarxio, on March 30, 2015, the Centers for Medicare & Medicaid Services ("CMS") released three policy statements on payment policies for biosimilars dispensed to individuals covered under Medicare Part B, D and state Medicaid programs. (Please also see our previous alert on the subject.)

5. Effective July 1, 2015, for biosimilars reimbursed under Medicare Part B, which generally covers services provided in physician offices and clinics (including clinics operated as hospital outpatient departments), CMS set the stage for its coding policy to group all biosimilar products of a single reference product under the same HCPCS code. For Zarxio, CMS established a temporary billing code, HCPCS code Q5101 ("Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram"). Effective January 1, 2016, the billing code for the reference product was revised to expressly exclude biosimilars. HCPCS code J1442 now reads: "Injection, Filgrastim (G-CSF), excludes biosimilars, 1 microgram." CMS left the door open for future coding decisions to separate some or all biosimilars into their own codes.
6. Although CMS established a single HCPCS code methodology for the biosimilar payment calculations, the agency acknowledged a need for a better understanding of products being dispensed or administered. Mandatory modifiers, therefore, which identify the manufacturer of the administered biosimilar, must be appended to a HCPCS code on an individual claim. The modifiers are posted on a dedicated CMS webpage. For example, the modifier for Zarxio is "ZA." In addition, under an FDA draft guidance, for pharmacovigilance and other purposes, the nonproprietary names of biological products would include a unique four letter suffix that is devoid of meaning (e.g. "filgrastim-bflm" instead of the current "filgrastim-sndz" for Zarxio). Inflectra was assigned the nonproprietary name "infliximab-dyyb" upon its licensure.
7. The payment for biosimilars under Medicare Part B is generally based on the products' average sales price ("ASP") of all national drug codes ("NDCs") assigned to the biosimilar biological products included within the same HCPCS code. An additional amount of six percent of the ASP of the reference product would be added. The total payment limit for biosimilars therefore is 100% of the weighted ASP of all the biosimilar products sharing the same HCPCS code plus 6% of the ASP of the reference product. On March 8, 2016, CMS announced a proposal to test new Part B payment models for prescription drugs, including biosimilars. Spurred by the rising expenditures for Part B drugs (from $11 billion in 2007 to an estimated $22 billion in 2015), CMS promulgated a proposed rule that would proceed in two phases. In Phase I, CMS would test moving from the current ASP plus 6% add-on formula to an ASP plus 2.5% add-on, along with a flat fee of $16.80. In Phase II, CMS would use a value-based purchasing strategy, which may include discounting or eliminating patient cost sharing; feedback on prescribing patterns and online decision support tools; indications-based pricing; reference pricing; or risk-sharing agreements based on outcomes.
8. Under Medicare Part D, biosimilars may be added to a plan formulary at any time as a formulary enhancement, but are not considered interchangeable with the reference product. Biosimilars are not subject to the coverage gap discount and, because they are not generics, biosimilars are subject to higher maximum copayments for individuals eligible for low income subsidies or who have entered catastrophic coverage.
9. On February 2, 2016, CMS restated its March 2015 guidance on the classification of biosimilars under the Medicaid program, confirming that biosimilars are "single source drugs" and subject to higher rebates under the Medicaid Drug Rebate Program.

Looking Down the Pipeline…

10. CMS has repeatedly stated in its rules and guidance that the reimbursement policies are developing and that the agency would consider refinements in future policies and guidance. In addition, FDA has not yet released draft guidance on what is needed to obtain approval of an "interchangeable" biosimilar product nor approved any biosimilars as interchangeable with their reference products. Stakeholders should therefore monitor for developments in light of the recent approval of Inflectra, pending biosimilar applications for FDA review and the possibility of future approvals of interchangeable products.

Given the noted attention to biosimilar reimbursement and the political interest in pricing issues in the pharmaceutical space generally, it is certain that 2016 will be just as activity-filled as 2015. We will be monitoring this area closely in the coming months.

If you have any questions concerning the material discussed in this client alert, please contact the following members of Health Care practice:

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