KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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CMS Issues Guidance on Reimbursement for Biosimilars under Medicare and Medicaid

Biosimilars Are Generally Treated as Single Source Drugs

On March 30, 2015, in the wake of the first biosimilar product licensed by the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS) issued several guidance documents addressing the treatment of biosimilar products under Medicare Part B, Medicare Part D and the Medicaid Drug Rebate Program. Generally, because biosimilar products do not meet the definitions of "generic" or "multiple source" drugs under either the Medicare or Medicaid programs, in part, because biosimilars are approved via a biological license application ("BLA"), CMS will treat the products as single source drugs for rebating and reimbursement purposes. This subjects biosimilars to separate coding, higher copayments for beneficiaries, and higher Medicaid rebate obligations for manufacturers than if they had been characterized as noninnovator products. FDA has yet to designate any biosimilar products as "interchangeable," however, and although CMS's position regarding the Medicaid Drug Rebate Program is broadly applicable to all biosimilars, it remains unclear whether CMS will treat all biosimilars equally under the Medicare program. CMS has committed to issuing additional guidance regarding Medicare reimbursement of interchangeable products in the future.

Background

The Patient Protection and Affordable Care Act ("ACA") amended section 351 of the Public Health Service Act ("PHSA") to create a new abbreviated licensure pathway for follow-on biological products that are demonstrated to be "biosimilar" to or "interchangeable" with a "reference" biological product licensed by FDA. A biosimilar product is one that is highly similar to the reference product, and has no clinically meaningful differences in terms of safety, purity and potency from the reference product. If the FDA also designates the biosimilar as "interchangeable" with the reference product, then the biosimilar may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.[1]

On March 6, 2015, Zarxio, manufactured by Sandoz, Inc., a follow-on to Amgen Inc.'s innovator biologic, Neupogen (filgrastim), became the first

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biosimilar to receive FDA licensure for marketing.[2] The FDA did not designate Zarxio to be interchangeable with Neupogen. Sandoz has announced that it will not launch Zarxio until May 11, 2015, or a ruling by the Federal Circuit on Amgen's motion for an injunction pending appeal in patient litigation regarding the biosimilar, whichever is earlier.[3] Given that biosimilars will soon become commercially available in the U.S., CMS issued guidance documents in three key areas to help States, providers, beneficiaries and others understand how CMS plans to implement Medicare and Medicaid rebating and reimbursement for biosimilars.

Medicare Part B Guidance[4]

As with any drug or innovator biologic approved or licensed by the FDA, biosimilars will be eligible for Medicare Part B reimbursement if they are considered "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[5] Consistent with ACA requirements, CMS will utilize the Average Sales Price ("ASP") payment methodology for Medicare Part B reimbursement of biosimilars. Until sales data to calculate an ASP payment limit is available, biosimilars will be reimbursed at 106% of the manufacturer's wholesale acquisition cost ("WAC") of the biosimilar product. Once adequate data is available to calculate ASP (generally two quarters after launch), Medicare Part B reimbursement will be set at an amount equal to the ASP of the biosimilar product plus six percent of the ASP for the *reference product*. Notably, the biosimilar is not reimbursed at 106% of its own ASP. By structuring Medicare Part B reimbursement for biosimilars to include the additional 6% payment based on the putatively higher-priced reference product, Congress sought to create financial incentives to lead providers to prescribe the biosimilar product.

In the case of Zarxio, CMS will create a separate Healthcare Common Procedure Coding System ("HCPCS") code to distinguish the biosimilar product from the innovator Neupogen. CMS anticipates that the new HCPCS code for Zarxio will be included in the quarterly HCPCS release effective July 1, 2015, and may be used for claims with dates of service retroactive to its FDA approval date. CMS is still considering policy options for coding of additional, follow-on biosimilars of the same reference product, including whether it will group all biosimilars under one HCPCS code or provide unique codes for each additional biosimilar. CMS is also considering how an FDA designation of "interchangeability" may affect coding policy.

CMS expects that Zarxio will be covered under Medicare Part B, but acknowledges that the product could be covered under Medicare Part D in certain circumstances (e.g., if it is administered in nursing homes, or in Intermediate Care Facilities for Individuals with Intellectual Disabilities).

Medicare Part D Guidance[6]

CMS also provided guidance regarding the treatment of biosimilars under Medicare Part D formulary review policies, the Medicare Part D Low-Income Subsidy ("LIS"), and the Medicare Part D Coverage Gap Discount Program. CMS noted that this guidance applies only to "biosimilar" products and that additional guidance may be issued for products designated as "interchangeable" at a later date.

As a general matter, CMS will evaluate plan sponsors' formulary change requests involving biosimilars on a case-by-case basis to determine whether they meet Part D formulary review and approval requirements based on information in the products' FDA-approved label and statutory compendia. Biosimilars may be added to formularies at any time as a formulary enhancement. However, replacing a reference product with a biosimilar will be considered a non-maintenance change that requires case-by-case review to ensure that formulary review standards are met. Because not all biosimilars are (or will be) interchangeable, CMS expects that biosimilars will be reviewed by plan sponsors' Pharmacy and Therapeutics Committees in accordance with the Formulary Management Considerations in section 30.1.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. Biosimilars and reference products should also be treated as different products for purposes of Part D transition supply and notice requirements, such that enrollees

taking one product should receive a transition supply when only the other product is available on the sponsor's formulary.

Notably, CMS will *not* treat the reference biological product and biosimilar as different drugs for purposes of satisfying the two distinct drugs requirement for each of the categories and classes on Part D formularies.[7] Therefore, even if both the reference biological product and its biosimilar are included in a particular category or class on a formulary, Part D sponsors are required to include at least one additional product in that category or class.

Under the LIS and the Catastrophic Cost Sharing programs in Medicare Part D, because biosimilars do not meet the statutory and regulatory definitions of "generic" and "multiple source" drugs,[8] CMS will treat biosimilars as single source innovator drugs. Accordingly, biosimilars are subject to higher copayments for LIS eligible individuals and enrollees in catastrophic coverage.

Importantly, consistent with the ACA, biosimilars are not "applicable drugs" under the Medicare Part D Coverage Gap Discount Program and, therefore, are not discounted or otherwise subject to the program's requirements.[9]

Medicaid Drug Rebate Program[10]

For purposes of the Medicaid Drug Rebate Program, CMS classifies biosimilars as "single source drugs," which means that manufacturers must pay States the innovator rebate for Medicaid utilization of biosimilar products. Biosimilars will therefore be subject to Best Price reporting and inflation penalty rebate calculations just like all other innovator products.

CMS encourages States to incorporate biosimilars into their formularies to the extent that they provide cost savings and enhance beneficiary access to expensive therapeutics for chronic conditions, and to adopt drug utilization and cost management tools (such as step therapy, prior authorization, and preferred drug lists) to promote the use of biosimilars. CMS also suggests that States take advantage of supplemental rebate agreements to increase cost savings.

Because biosimilars are not simply generic versions of branded products, they are not subject to State generic substitution rules. As a result, CMS reminds States to advise physicians and pharmacists on the proper prescription and dispensing of biosimilars, which is important to maximize their use. CMS also encourages States to use their drug utilization programs and pharmacy and therapeutics committees to educate physicians and pharmacists about these issues, as well as well as potential designations of interchangeability among biological products. Additional information on biosimilars and interchangeability designations can be found in in the FDA Purple Book.[11]

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As FDA continues to license biosimilars and begins to make designations regarding interchangeability, we expect that CMS will issue additional guidance on how biological products are reimbursed and rebated under Medicare Part B, Medicare Part D and the Medicaid Drug Rebate Program. King & Spalding LLP will monitor these developments. Should you have questions or need additional information, please contact us.

[1] 21 U.S.C. § 262(k)(2), (4).

[2] *FDA Approves First Biosimilar Product Zarxio*, FDA News Release (Mar. 6, 2015) available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm
[3] Brief of Plaintiff-Appellant at 1, Amgen v. Sandoz, No. 3:14-cv-04741-RS (N.D. Cal., Mar. 24, 2015).
[4] *Food and Drug Administration Approval of First Biosimilar Product*, MLN Matters, No. SE1509 (Mar. 30, 2015).
[5] 42 U.S.C. § 1395y(a)(1)(A).
[6] *Part D Requirements for Biosimilar Follow-on Biological Products*, Letter to Part D Sponsors From Amy K. Larrick, Acting Director, Medicare Drug Benefit and C&D Data Group (Mar. 30, 2015).
[7] *See* 42 C.F.R. § 423.120(b)(2).
[8] *See* Definition "generic drug," 42 C.F.R. § 423.4; Definition "multiple source drug," 42 U.S.C. § 1396r-8(k)(7).
[9] Similarly, sales of biosimilars are not included in determination of the Annual Fee on Branded Prescription Drug Manufacturers administered by the Internal Revenue Service, because the ACA defined "branded prescription drug" under the program to include only innovator biologics licensed under the PHSA. *See* ACA § 9008(e); *Branded Prescription Drug Fee, Final Regulations*, 79 Fed. Reg. 43,631, 43,639 (July 28, 2014) (defining "branded prescription drugs" as those approved under Section 505(b) of the Food, Drug, and Cosmetic Act or Section 351(a) of the PHSA, excluding biosimilars, which are approved under Section 351(k) of the PHSA).
[10] Medicaid Drug Rebate Program Notice for State Technical Contacts, No. 169 (Mar. 30, 2015); Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, No. 92 (Mar. 30, 2015).
[11] *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.