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CMS Releases New Reimbursement Guidance for Biosimilars

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Health Care

On March 30, 2015, in the wake of the Food and Drug Administration's ("FDA's") first approval of a biosimilar product, the Centers for Medicare & Medicaid Services ("CMS") released three policy statements on national payment policies for covered biosimilars dispensed to individuals enrolled in Medicare and Medicaid. These CMS guidance documents, which relate to payments under Medicare Parts B and D and state Medicaid programs, are summarized in this Alert.

Background

The enactment of the Affordable Care Act marked the establishment of an abbreviated licensure pathway for biosimilar products under section 351(k) of the Public Health Service Act ("PHSA").[1] (Please see our previous alert on the subject.) 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 licensed by FDA under section 351(a) of the PHSA, called the "reference product." A biosimilar product is a biological product that is approved based on a showing that it is highly similar to the reference product, with no clinically meaningful differences in terms of safety, purity, and potency from the reference product. An interchangeable biological product is biosimilar to the reference product and meets additional standards for interchangeability. An interchangeability determination reflects FDA's judgment that 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. The FDA lists licensed biosimilar products in its new "Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations."

The Affordable Care Act also addressed Medicare payment formulas for biosimilar products. The Act accounts for both the similarities and differences in the way biosimilar biologics and generic pharmaceuticals may be dispensed and administered. For example, whereas the average sales price -- the basis for the payment methodology for most physician-administered drugs and biologics -- is calculated using a weighted average for generic pharmaceuticals, for biosimilars the calculation is made separately, such that each biosimilar will have its own average sales price.

Nearly five years after the enactment of the Affordable Care Act, the FDA approved Zarxio (filgrastim-sndz) on March 6, 2015, which triggered the issuance of CMS's payment guidance.

[1] Pub. L. No. 111-148, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, Pub. L. No. 111-152.

Medicare Part B[2]

The guidance on Part B reimbursement applies to biosimilars administered by a physician in a recognized outpatient setting, generally in the physician office or clinic. According to CMS's recently-released article, Medicare Part B payment will be available for the covered biosimilar product upon its approval by FDA. CMS stated in its article that biosimilars will be assigned their own billing codes. This will allow for a separate payment amount for each biological product. CMS indicated that it "is considering policy options for coding of additional biosimilars, and will release further guidance in the future."

For newly-approved biosimilars, the payment will be 106 percent of the manufacturer's wholesale acquisition cost, or WAC, for the product. Once the manufacturer's average sales price, or ASP, is available, the payment will be 100 percent of the biosimilar's ASP plus six percent of the ASP of the reference product. In other words, the six percent add-on, generally recognized as the payment for the physician's resource costs and overhead, would be the same for the biosimilar product and the reference product. The formula, mandated by the Affordable Care Act, was designed to reduce or eliminate the financial incentive to prescribe the biologic with the higher ASP, typically the reference product.

The agency did not address payment for biosimilars in the hospital outpatient setting. For 2015, however, the formula for eligible biologics administered in this site of service is ASP plus six percent. Therefore, it is likely that CMS will adopt the formula outlined in its article for a biosimilar administered in a hospital outpatient department.

Medicare Part D[3]

CMS announced in a memorandum to Part D sponsors that the agency will evaluate formulary change requests involving non-interchangeable biosimilars on an individual basis. The agency will determine if the biosimilar product meets its formulary review and approval process requirements, based on information in the product's FDA-approved labeling and statutory compendia. A biosimilar may be added to a plan formulary at any time as a formulary enhancement, but the product will not be considered interchangeable with the reference product.

CMS also stated that the reference and biosimilar products will not be considered to be different products for the purpose of satisfying the existing requirement that each of the submitted categories and classes contain two distinct drugs.[4] Thus, the agency would permit plans to select the biosimilar in lieu of the reference product but would not permit the category or class to be populated by just the biosimilar and its reference product. In addition, when only a biosimilar product is offered on the plan's formulary, enrollees who have been taking the reference product may receive a transition supply, and vice versa.

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[2] *See* 42 U.S.C. § 1395w-3a(b)(8).
[3] *See* 42 U.S.C. § 1395w-102, *et seq.*
[4] Although CMS identified a possible exception to this requirement (*see* 42 C.F.R. § 423.120(b)(2)(ii)), which applies where the Part D plan demonstrates only two drugs are available in the category or class and one is clinically superior, it would appear this exception would not be applicable for biosimilars given the FDA's determination that there are no clinical meaningful differences between the biosimilar and reference products.

Consistent with the Affordable Care Act's language on the Part D discount program, biosimilars are not subject to the coverage gap discount. In addition, because they are not generics, biosimilars are subject to higher maximum copayments than generics for individuals eligible for low income subsidies and individuals who have entered catastrophic coverage.

CMS noted in its published guidance memorandum that it may issue additional guidance for interchangeable biological products at a later date.

Medicaid[5]

In a release for the Medicaid Drug Rebate Program, CMS provided guidance to states on the classification of biosimilar biological products for Medicaid rebates and on strategies to reduce costs. The agency instructed state Medicaid programs to view the launch of biosimilar products as "a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions." State programs are also encouraged to enter into supplemental rebate agreements with manufacturers, which would allow for additional savings. (A reduction in state Medicaid expenditures for biological products will also reduce the federal share dollars, for which CMS is responsible.)

CMS noted that biosimilar products fall within the definition of "single source drugs" under the rebate program, reminding stakeholders of the distinctions between the follow-on process for biologics and generic pharmaceuticals. This means that manufacturers of biosimilars must pay rebates on state Medicaid utilization based on the rebate formula for branded drug products, not based on the rebate formula for generics. CMS urged states to educate physicians and pharmacies about prescribing biosimilars by their proprietary names, and also to "encourage and maximize their use." Suggested education vehicles include newsletters to prescribers, electronic prescribing messaging, and point-of-sale edits to pharmacists.

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[5] *See* 42 U.S.C. § 1396r-8.