Recent Regulatory Developments in US Biosimilars Market

While the Biologics Price Competition and Innovation Act (BPCI) was originally enacted under the Obama Administration as part of the Affordable Care Act, it appears that the Trump Administration will continue to take steps to promote and foster the development of biosimilars as part of a larger policy effort to make drugs and biological products more affordable for patients. In particular, the Centers for Medicare & Medicaid Services (CMS) has established new payment and coding policies for biosimilars reimbursed by Medicare. More recently, the Bipartisan Budget Act of 2018 includes a provision to reduce patient cost sharing for biosimilars under the Medicare Part D Prescription Drug Benefit.

At the same time, the Food and Drug Administration (FDA) Commissioner Scott Gottlieb has also made approval of biosimilars under the BPCI a priority for FDA, noting that the "cost of prescription drugs is an ongoing concern, however, a growing market for potentially lower-cost biological products called biosimilars can offer more competition and options for patients." To that end, FDA plans to release a Biosimilar Innovation Plan to streamline the regulatory process for the abbreviated licensure pathway for biosimilars established by BPCI, and improve incentives for biosimilar adoption this year. These points were underscored by a recent White House report by the Council of Economic Advisors (CEA) advocating for the accelerated release of guidelines for demonstrating biosimilar interchangeability as a way to increase competition in the biological product space and lower drug prices.

New Medicare Reimbursement Policy Developments

Medicare to Establish Unique Codes for Each Biosimilars

There have been several significant developments for biosimilars reimbursement in the first year of the Trump Administration. For several years the manufacturers of innovator and biosimilar products have advocated for unique billing codes for each product approved by the FDA. Under the previous policy of the Obama Administration, newly approved biosimilars with a common reference product were grouped under the same billing code for payment purposes. For example, Inflectra and Renflexis, both of which are biosimilars of infliximab, had been assigned the billing code Q5102. As a result, the payment rates for these products were set based on a volume weighted average of the sale prices of each product.

In a rulemaking finalized in November 2017, CMS reversed course, finalizing a policy to assign Part B biosimilars individual billing codes. Agreeing with commenters, CMS reasoned that "this policy change will address concerns about a stronger marketplace, access to these drugs in the United States marketplace, provider and patient choice and competition." Effective January 1, 2018, newly approved biosimilars with a common reference product will be assigned individual codes. This will allow for an individual payment rate for each biosimilar, which will enable biosimilar manufacturers to develop their Medicare reimbursement strategy without concern that their product's rate will be affected by other biosimilars with the same reference product. Effective April 1, 2018, Q5102 will be replaced with two new codes, Q5103 for Inflectra and Q5104 for Renflexis.

Biosimilars Granted Pass-Through Status

Another payment policy established by CMS in November 2017 is also likely to benefit biosimilars, while potentially creating an unbalanced playing field for innovator biologicals. Under the Obama Administration, CMS allowed the first biosimilar for a particular reference biological to receive "pass-through" status in Medicare Part B. Pass-through status is a temporary payment status that manufacturers can apply for quarterly and which allows drugs to receive a temporary payment code and be paid separately at Average Sales Price (ASP) plus 6% in the hospital outpatient setting for up to three years. The goal of pass-through payment status is to help facilitate reimbursement and utilization of new innovative technologies. In November 2017, CMS under the Trump Administration expanded this policy to make pass-through status available to all biosimilars, not only the first one.

However, in the same rulemaking, CMS also finalized major changes to its hospital outpatient payment policies for drugs purchased through the 340B Drug Pricing Program (a program which requires drug manufacturers to sell outpatient drugs to covered entities at significantly reduced prices). The 340B program affects drug pricing for most major hospitals. Under the new 340B policy, CMS significantly reduced the payment for Medicare Part B separately payable, *non-pass through* drugs and biologicals purchased by hospitals through the 340B Program, from ASP plus 6% to ASP minus 22.5%, effective January 1, 2018. This represents a significant loss in revenue for those hospitals that qualify as cover entities under 340B.

CMS clarified that under this new policy, biosimilars with pass-through status would continue to be paid at ASP+6% in the 340B program. This policy could be a significant advantage to biosimilars, especially now that pass-through status will be available to all biosimilars instead of only the first one. However, stakeholders are concerned because it creates an unbalanced playing field between biosimilars and reference products for the two to three years the biosimilar has pass-through status, during which the biosimilar would be paid at ASP+6% while the reference product is paid at ASP minus 22.5%. Given this concern, the House of Representatives included a legislative provision in the Bipartisan Budget Act (BBA) continuing resolution in February 2018 to bar biosimilars from pass-through status. This provision was not ultimately included in the budget agreement signed into law by President Trump.

Biosimilars Added to Part D Coverage Gap Discount Program

Most recently President Trump signed into law on February 9, 2018 the Bipartisan Budget Act, which includes a provision to correct a longstanding gap in how patient cost sharing is calculated for Medicare beneficiaries using biosimilars. Section 53113 of BBA amended the Medicare Coverage Gap Discount Program, which makes manufacturer discounts available to eligible Medicare Part D beneficiaries receiving applicable, covered drugs while they are in the "coverage gap" (commonly known as the "donut hole") between the initial coverage phase and the catastrophic coverage phase of their plan. Biosimilars are currently excluded from the Medicare Coverage Gap Discount Program. Section 53113 of the BBA, however, will end this exclusion effective for plan year 2019.

FDA Developments on the Horizon in 2018?

U.S. regulatory policy was equally active over the past year at the FDA where the agency approved five biosimilars, with four approvals in the past six months. This is a record high for FDA, which only approved the first biosimilar product in 2015, and to date has only approved nine biosimilar products since the new pathway was created in 2010.

Expectations are that Commissioner Gottlieb will take additional action in 2018 to promote the development of biosimilars. For example, in October of 2017, Commissioner Gottlieb announced an agency wide campaign to ensure health care providers "understand what these drugs are, and how they can help patients." As part of these efforts, FDA conducted extensive research and planning to develop materials for provider education and outreach on the regulatory approval process for biosimilars, a new biosimilars agency website, and resources on the type of data and information FDA reviews as part of the biosimilar determination. FDA plans to continue to embark on additional research with health professionals to learn more about the type of information needed to properly communicate about biosimilars with patients. Commissioner Gottlieb noted that educating prescribers and patients about biosimilars was needed, because "[a]n increase in market competition, offered by a growing complement of biosimilars, may lead to meaningfully reduced costs for both patients and our healthcare system[,] . . . thereby potentially improving access and promoting better public health outcomes."

Further, on January 11, 2018, FDA released its 2018 Strategic Policy Roadmap. In the roadmap, the FDA stated that in 2018 it would advance a "Biosimilar Innovation Plan." This would include both steps to improve the efficiency of the regulatory process for development and approval of biosimilars, and improved incentives for the adoption of biosimilars. FDA Commissioner Scott Gottlieb has also indicated that the Biosimilar Innovation Plan will "facilitate claims of interchangeability." On a related topic, in February of 2018, the White House released a report by the CEA on "Reforming Biopharmaceutical Pricing at Home and Abroad," which proposed policy developments for biosimilars to spur the level of price competition seen with small molecule generic drugs. The February CEA report urged the acceleration of the timeline for developing interchangeability guidelines, stating that "[s]peeding up the issuance of final could add certainty and attract additional biosimilar applicants." The report also argues for simplicity in these guidelines, stating that "[i]f these guidelines are relatively easy and inexpensive to adhere to, it could spur interchangeable applications and approvals, which could result in more effective competition . . . and lower prices."

Whether these efforts and other policy innovations continue to promote biosimilars competition as part of the FDA's larger policy strategy to address the affordability of drug pricing will be a critical issue in 2018 and beyond.

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