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CMS Revises Medicare Part B Biosimilar Coding and Payment Policies

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Health Care

On November 1 and 2, 2017, the Centers for Medicare & Medicaid Services ("CMS") released two final rules addressing changes to Medicare Part B reimbursement policies for biosimilars. These final rules—for the Medicare Physician Fee Schedule ("PFS") and the Hospital Outpatient Prospective Payment System ("OPPS")[1]—announced new directions for both the coding and payment policies initially developed in 2015. Beginning in 2018, instead of classifying biosimilars with the same reference product in the same Healthcare Common Procedural System ("HCPCS") code, CMS will establish a unique code for each biosimilar product; and instead of calculating a single blended payment rate, CMS will calculate a payment rate specific to each biosimilar product. In addition, for qualifying biosimilars, instead of considering only the first biosimilar product for the reference product for OPPS pass-through payment status, each biosimilar will be eligible. Our prior alert on this topic is available here.

In its 2018 final rules, CMS indicated that it was persuaded that the change in policy will encourage innovation and address concerns about a stronger marketplace, access, and provider and patient choices. This client alert provides an overview of both CMS's current and new reimbursement policies. We also provide as background the current Food and Drug Administration ("FDA") biosimilar landscape in the United States.

Current FDA Approvals of Biosimilars

The U.S. biosimilar marketplace is still in its early stages, but the number of biosimilar products is expected to increase. According to FDA, there were 69 biosimilar development programs in FDA's biosimilar biological development program as of June 2017. As of November 8, 2017, FDA has approved seven biosimilar products, and three of these are currently on the market, with a fourth set to launch in 2013.

The current FDA program implements the statutory pathway for approval of biosimilars in the United States, which was established in 2010 through the Biologics Price Competition and

[1] The final rules—Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements and Medicare Diabetes Prevention Program (Nov. 2, 2017); and Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Nov. 1, 2017)—will be published in the Federal Register on November 15 and 13, respectively. The final rules are currently available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23953.pdf and https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf.

Innovation Act ("BPCIA"), which was enacted as part of the Patient Protection and Affordable Care Act ("ACA").[2] A biosimilar product may be approved based on a showing that (1) it is "highly similar" to a biological product already licensed by the FDA, called the "reference product," "notwithstanding minor differences in clinically inactive components," and (2) there are "no clinically meaningful differences" from the reference product in terms of safety, purity, and potency.[3]

An additional showing is required for a biosimilar product to obtain a determination from FDA that it is interchangeable with the reference product, meaning that it "may be substituted for the reference product without the intervention of" the prescriber.[4] In addition to demonstrating biosimilarity, the sponsor must show that the product "can be expected to produce the same clinical result as the reference product in any given patient," and that "for a biological product that is administered more than once to an individual," alternating or switching between the proposed interchangeable product and the reference product does not lead to an increased risk in terms of safety or diminished efficacy compared to using the reference product without such alternation or switch.[5]

Below are the seven biosimilar products that have been approved. No products have received an interchangeability determination.

1. Zarxio® (filgrastim-sndz), manufactured by Sandoz, became the first approved biosimilar on March 6, 2015. Its reference product is Amgen's Neupogen® (filgrastim). Zarxio entered the U.S. market in September 2015.
2. Inflectra® (infliximab-dyyb), manufactured by Celltrion, was approved on April 5, 2016. Its reference product is Janssen Biotech's Remicade® (infliximab). Inflectra entered the U.S. market in November 2016.
3. Erelzi™ (etanercept-szzs), manufactured by Sandoz, was approved on August 30, 2016. Its reference product is Amgen's Enbrel® (etanercept). Enbrel has not yet entered the U.S. market due to ongoing patent litigation.
4. Amjevita™ (adalimumab-atto), manufactured by Amgen, was approved on September 23, 2016. Its reference product is AbbVie's Humira® (adalimumab). Based on a settlement announced on September 28, 2017, Amgen is expected to launch Amjevita in the U.S. market on January 31, 2023.
5. Renflexis™ (infliximab-abda), manufactured by Merck & Co., was approved on March 21, 2017. Its reference product is Janssen's Remicade® (infliximab). The U.S. launch of Renflexis was announced on July 24, 2017.
6. Cyltezo™ (adalimumab-adbm), manufactured by Boehringer Ingelheim, was approved on August 25, 2017. Its reference product is AbbVie's Humira®. Cyltezo has not yet entered the U.S. market due to ongoing patent litigation.
7. Mvasi™ (bevacizumab-awwb), manufactured by Amgen, was approved on September 14, 2017. Its reference product is Genentech's Avastin® (bevacizumab). Amgen has not

[2] Pub. L. No. 111-148, tit. VII, subtit. A.
[3] Public Health Service Act § 351(i)(2) (codified at 42 U.S.C. § 262(i)(2)).
[4] *Id*. § 351(i)(3).
[5] *Id*. § 351(k)(4).

announced when it will launch Mvasi, but it provided Genentech a 180-day notice of commercial marketing on October 6, 2017. Patent litigation is pending.

Current Medicare Part B Reimbursement Policy for Biosimilars

In 2015, after the first biosimilar entered the market, CMS finalized a rule that provided that all biosimilars of the same reference product would share the same HCPCS code and payment rate, separate from the reference product. This rule created a single, blended Medicare reimbursement rate for biosimilars of 100 percent of the weighted ASP of all biosimilars that share the HCPCS code, plus six percent of the ASP for the reference product. To effectuate its policy, CMS also revised the language in the regulation on this topic, which reinforced that all biosimilars included in a single billing code would be paid the same amount. This stated policy went into effect on January 1, 2016 as part of the 2016 PFS final rule.[6]

Because CMS currently relies on the same payment formula for drugs and biologicals that are not packaged under OPPS, the agency's coding and payment policies for hospital outpatient departments track the 2016 PFS final rule. CMS's 2016 OPPS final rule also extended pass-through payment eligibility to biosimilar biological products, but only to the first eligible biosimilar to a reference product.[7]

New Medicare Part B Reimbursement Policy for Biosimilars

To address policy concerns raised by stakeholders, in the 2018 PFS proposed rule, CMS requested comments on the effects of its 2016 policy. The agency specifically "sought data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending." Stakeholders expressed varying opinions about Medicare Part B payments for biosimilars. Those opposed to a single payment amount for all biosimilars of a single reference product argued that the 2016 policy would decrease incentives for biosimilar development, increase costs for biosimilar products, limit prescribers' choices, and impair pharmacovigilance activities. Supporters of the policy, however, express concerns that separate payments for each biosimilar would result in decreased competition among manufacturers, which could lead to higher payment amounts for Medicare and beneficiaries.

In response to these and other comments, and CMS's belief "that a policy that could potentially increase provider and patient choice is superior to existing policy and may lead to additional cost savings," the PFS final rule reverses CMS's prior policies. This is a change in interpretation only; there have been no changes to the statutory or regulatory language. In the 2018 PFS final rule's preamble, CMS states that "[e]ffective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same HCPCS code." Each biosimilar will now receive its own HCPCS code and payment will be based on the sum of 100 percent of the biosimilar's ASP plus 6 percent of the reference biological's ASP. In turn, the 2018 OPPS final rule extends transitional pass-through eligibility to all qualifying biosimilars.

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[6] *See* 80 Fed. Reg. 70886, 71096-71101 (Nov. 16, 2015); 42 C.F.R. § 414.904(j).
[7] 80 Fed. Reg. 70298, 70445-46 (Nov. 13, 2015).

The PFS final rule also states that CMS "will issue detailed guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers." CMS states that it will make the required changes to the claims processing system as soon as possible, but the changes should not be expected to be complete by January 1, 2018. CMS anticipates that the changes will be complete by mid-2018 and will issue instructions using subregulatory means, such as change requests/transmittals to contractors and the ASP website.

With only three biosimilar products currently on the market and no approved interchangeable products, CMS states that it intends "to continue to monitor Part B biosimilar payment and utilization, particularly as they relate to access, including the number of products available to beneficiaries with Part B and cost savings associated with Medicare and beneficiary payments." We will be monitoring this area closely as CMS implements the 2018 and any future changes.

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

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