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VIA ELECTRONIC DELIVERY

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1631-P; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for Calendar Year 2016

Dear Acting Administrator Slavitt:

Amgen, Inc. (Amgen) is writing regarding the calendar year (CY) 2016 Medicare Physician Fee Schedule (MPFS) Proposed Rule (Proposed Rule), which the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* on July 15, 2015.[1] Amgen is committed to using science and innovation to dramatically improve people's lives, and we are vitally interested in improving access to innovative drugs and biologicals and promoting high-quality care for all Medicare beneficiaries.

In our comments, we address the following topics:

- The proposal to adopt a Part B reimbursement methodology for biosimilar biological products under which all biosimilars with the same reference product would be assigned to a single Healthcare Common Procedure Coding System (HCPCS) code and would be reimbursed based on the volume-weighted Average Sales Price (ASP) of all the products associated with the code plus 6 percent of the reference product's ASP;

- The proposal to add new quality measures for psoriasis and primary headache disorders to the Physician Quality Reporting System (PQRS), and separately, the proposal to add a new quality measure for statin therapy to the PQRS and the Medicare Shared Savings Program (MSSP); and

- The proposal to review approximately 118 Current Procedural Terminology (CPT) codes as potentially misvalued, based on a screen of codes with Medicare allowable charges in excess of $10 million.

[1] 80 Fed. Reg. 41,686 (July 15, 2015).

Below, we review each topic area in detail and discuss our specific recommendations.

1. **CMS Should Assign a Separate HCPCS Code and Calculate a Separate Payment Rate for Each Manufacturer's Biosimilar Product.**

In the Proposed Rule, CMS proposes to adopt a reimbursement methodology for biosimilar products under Part B that would assign all biosimilars with the same reference product to a single HCPCS code, then reimburse for that code based on the volume-weighted ASP of all products under the code plus 6 percent of the reference product's ASP.[2] CMS describes this approach as being "similar to the ASP calculation for multiple source drugs."[3]

Amgen, as both an innovator biologics company facing biosimilar competition and a future biosimilars manufacturer, urges CMS not to finalize this proposal. Amgen is a member of the Biosimilars Forum, a broad alliance of current and future biosimilar manufacturers, and we concur with its recommendation that CMS establish a unique code and payment rate for each biosimilar product. Separate codes and payment rates are consistent with the statute, which requires payment for a biosimilar biological product to be based on the data for "all National Drug Codes assigned to such product" plus six percent of the ASP of the reference biological product,[4] Congressional intent (see Appendix A),[5] and good public health and economic policy.

As we describe below, because biosimilars are different from multiple source drugs in critical ways, they should not be treated like multiple source drugs for coding and payment purposes. Importantly, a sustainable marketplace for biosimilars requires a science-based policy framework that recognizes the unique aspects of each biosimilar relative to the innovator and to one another, a framework quite different from what exists for generic small molecule drugs. The Food and Drug Administration (FDA) has made great efforts over many years to ensure that this science-based framework is viable and appropriately distinguishable from the generic framework.[6] Grouping multiple biosimilars into one HCPCS code would make it difficult, if not impossible, to track the safety of such biosimilars once they are approved and enter the market. It would create inappropriate incentives for physicians and providers to select therapies based on cost and reimbursement, rather than clinical characteristics, would increase the chances for inappropriate switching, and would increase administrative burdens associated with documenting the patient's treatment. Biosimilars are developed and marketed to compete against the reference product and other biosimilars. CMS's approach would force biosimilar manufacturers to compete solely on price, rather than on clinical characteristics, and thereby risks stifling additional investment and entry into the emerging market for biosimilars. Instead, CMS should assign each biosimilar product to a separate HCPCS code and calculate reimbursement separately for each code, which will allow effective post-market tracking and foster the development of a robust market for biosimilars.

a. Assigning biosimilars to a shared HCPCS code would impede safety monitoring.

It is essential to protecting the safety of the public that the FDA and other agencies be able to effectively monitor the safety of drug products, including biological products, once they have been approved and have entered the market. In recent draft guidance and regulations, the FDA proposes

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[2] *Id.* at 41,801-02.
[3] *Id.* at 41,801.
[4] Social Security Act § 1847A(b)(8).
[5] *See* Letter from Representatives Anna Eshoo and Joe Barton, et al, to Acting Administrator Slavitt, regarding coding and payment for biosimilar biological products, August 4, 2015.
[6] 80 Fed. Reg. 52,224 (August 28, 2015).

different nonproprietary names for non-interchangeable biosimilars from their reference products, noting a need to clearly identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. The FDA states that their approach is intended to minimize inadvertent substitution and switching of products that have not been determined to be interchangeable as immune response may be affected; to minimize the risk of medication errors that could occur when biosimilars have different indications, routes of administration, or delivery systems from the reference product; and to avoid confusion that could arise among health care providers who based on their experience with small molecule drugs may incorrectly assume the same name means the products are interchangeable.[7]

We are deeply concerned that CMS's proposal to assign multiple biosimilar products into a single code will hinder effective monitoring and accountability for adverse events at the manufacturer level, a pharmacoviligence activity that the FDA has stated is "fundamentally important" for all biological products. Further, the possible use of modifier codes to identify particular biosimilar products could lead to pharmacovigilance problems because while HCPCS codes are widely used by private payers, some of those payers do NOT use the modifiers, thus making the identification of exactly what product was given to a patient very difficult, if not impossible, for some of the non-Medicare patients. Similarly, using National Drug Codes (NDCs) on each claim would be difficult for national implementation as some providers do not have claim processing systems capable of using NDCs on each claim. The FDA also has noted that NDCs are not routinely recorded in billing and claims records in many clinical settings.[8]

Biological products, including biosimilar biological products, are different from multiple source drug products in that each biological medicine exhibits unique properties and sensitivity to manufacturing and handling processes. As a result, even when two biosimilar products are approved based on the same reference product, slight differences in the production process between the two products can reduce efficacy or induce different patient immunogenic responses from one product to another.[9] Further, because FDA's Sentinel drug safety tracking system (among others) relies on billing records to associate drug safety information and patient outcomes with specific drug products, CMS's proposal to include multiple biosimilar products in a single billing code would make it difficult or impossible for FDA to track the safety record of a specific biosimilar product.[10]

b. CMS's proposal would create inappropriate incentives for physicians and providers to select therapies based on cost and reimbursement instead of clinical characteristics and would increase providers' administrative burdens.

CMS's proposal also threatens to undermine patient safety by creating a financial incentive for inappropriate choices among biosimilars, even those that are not designated as interchangeable by the FDA. As explained above, biosimilars are unlike generic drugs in that each biosimilar product has unique properties that can significantly affect safety and efficacy. And while generic drugs *are* classified by the FDA as identical and it is appropriate to alternate freely between them, biosimilars are neither expected nor required to be identical to another biological product, and in most cases there is no required evaluation of patient safety when switching from one biosimilar to another. Accordingly, it

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[7] 80 Fed. Reg. 52,226 (August 28, 2015).
[8] 80 Fed. Reg. 52,227 (August 28, 2015).
[9] *See* Ameet Sarpatwari et al., Progress and Hurdles for Follow-On Biologics, 372 *New England Journal of Medicine* 2380, 2381 (June 18, 2015).
[10] *See id.*

is important that physicians and hospitals carefully consider which biological product is medically appropriate for the patient, including which product the patient may have received in the past.

Under CMS's proposal, however, physicians and providers would receive the same reimbursement for any biosimilar associated with the same code, regardless of which biosimilar the provider actually used. This approach risks creating an incentive for physicians and providers to purchase and administer the least expensive therapy regardless of what the patient may have received in the past. This raises clinical concerns as the FDA has noted that the "switching or alternating of biological products not determined by the FDA to be interchangeable may raise unique safety concerns related to immunogenicity."[11] In particular, providers who choose to administer a medically appropriate biosimilar product, or to maintain the patient on the product previously received, may be reimbursed less than the provider paid for the product because reimbursement is based on the ASP of every biosimilar product under the code.

In addition, assigning shared codes to biosimilars would complicate physicians' and providers' efforts to ensure that their patients receive the most appropriate therapy. Because the HCPCS code would not identify the exact therapy administered, physicians and other providers would need to make additional entries to the medical record to identify the therapy. This increased administrative burden could be avoided simply by assigning each biosimilar a unique code.

c. CMS's proposal would impede the development of multiple biosimilars for each reference product and would discourage manufacturers from entering the biosimilars market.

Finally, we believe that reimbursing biosimilars through shared codes will force manufacturers to prioritize price above all other product features and cause manufacturers to continually reduce costs in order to compete, which ultimately will result in fewer and less innovative biosimilar products on the market and may discourage many manufacturers from entering the biosimilars market at all.

As noted above, CMS's proposal will create an incentive for providers – the potential customers in the biosimilars market – to choose among biosimilars that share a code based solely or primarily on price. While in the short-term, CMS may consider that to be a desirable policy outcome, such a policy could negatively impact the quality and availability of biosimilars over time. Manufacturers of biosimilars would need to compete to reduce the price of their biosimilar product relative to the other products under the code, to the detriment of other essential aspects of drug development, such as improving product quality, generating additional clinical data to reduce uncertainty, carrying sufficient inventory to ensure adequate supply, and seeking incremental innovation to compete with the branded biological product.

In addition to reducing biosimilar manufacturers' incentives to produce more and higher quality biosimilar products, shared codes risk discouraging investment in biosimilars as a whole. The cost of developing a biosimilar product has been estimated by the Federal Trade Commission at $100 to $200 million (reflecting significantly greater manufacturing costs as well as more-extensive clinical trial requirements for approval), compared with the $1 to $5 million required for small-molecule generic drugs.[12] As a result, any manufacturer considering the development of a biosimilar would need a certain level of confidence that it could recoup its investment later on through effective competition with the branded biological product as well as any other approved biosimilars. However, as explained

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[11] 80 Fed. Reg. 52,226 (August 28, 2015).
[12] *See* Fed. Trade Comm'n, Emerging Health Care Issues: Follow-on Biologic Drug Competition (2009), available at: http://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report (accessed August 7, 2015).

above, CMS's proposal would induce biosimilar manufacturers to focus almost exclusively on the price and cost of goods, driving the price of all of the biosimilars rapidly downward and eventually forcing most or all of the manufacturers to exit the market. With such a limited window in which to establish a biosimilar product as an effective competitor to the branded biological product, it is reasonable to expect that manufacturers will doubt their ability to generate a favorable return on their investment and will simply decline to make the investment in biosimilars in the first place.

We urge CMS not to finalize its proposal and instead to adopt a reimbursement methodology that assigns each biosimilar product to a separate HCPCS code and calculates reimbursement separately for each biosimilar product. This approach will ensure effective monitoring of the safety of each biosimilar product following approval, encourage providers to prescribe the biosimilar product that is most medically appropriate for each patient, and foster the creation of a robust competitive environment for biosimilars that will help to realize and sustain the potential benefits of biosimilars.

2. CMS Should Implement New Measures for Psoriasis and Primary Headache Disorders within the PQRS in CY 2016.

Amgen supports performance measures that encourage the diagnosis and treatment of psoriasis and psoriatic arthritis, and supports the implementation of the new measure: Clinical Response to Oral Systemic or Biologic Medications. Psoriasis is a systemic inflammatory disease of the skin and is the most common autoimmune disease in the US, affecting nearly 7.5 million people, according to the National Psoriasis Foundation.[13] Up to thirty percent of patients with psoriasis can develop psoriatic arthritis, which causes joint swelling and pain.[13] With very few quality measures in dermatology, this measure addresses a significant measure gap. Both conditions can be debilitating and can lead to permanent disability if left untreated. Fortunately, psoriasis and psoriatic arthritis respond to various treatments, including systemic oral immunosuppressants and injectable biologic immunotherapy. Evaluating clinical response to psoriasis medications can determine if the patient is taking the most effective treatment. Implementation of this measure may enhance appropriate use of psoriasis medication in this population. We fully support this measure that highlights the importance of evaluating treatment among psoriasis patients.

Additionally, Amgen supports performance measures that encourage migraine prevention, diagnosis, and treatment, and supports the implementation of the new measure: Quality of Life Assessment for Patients with Primary Headache Disorders. There are significant unmet needs in the prevention of primary headache disorders, particularly migraines, and diagnosis and treatment rates are low. Although there are current treatment options, the majority of patients discontinue therapy within one year of initiation. Assessing quality of life for those afflicted by primary headache orders is vital for deciding on appropriate therapy, increasing subsequent adherence, and ensuring effective management of this disabling condition. This measure will help improve the quality of care for the many patients that suffer from primary headache disorders, including the more than 36 million people in the US that suffer from migraines, according to the American Migraine Foundation.[14]

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[13] National Psoriasis Foundation, available at https://www.psoriasis.org/cure_known_statistics (accessed August 7, 2015).
[14] American Migraine Foundation, available at http://www.americanmigrainefoundation.org/about-migraine/#who (accessed August 7, 2015).

3. CMS Should Modify the New Measure for Statin Therapy by Describing it as a Cholesterol/ Lipid Lowering Measure, Rather than a Statin Therapy Measure, Before Implementation within the PQRS and the MSSP in CY 2016 and Develop Additional Measures.

CMS proposes to implement a new cholesterol management measure, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, within PQRS and MSSP in CY 2016. Amgen supports comprehensive measures that improve cholesterol management for the prevention and treatment of cardiovascular disease. Current evidence from interventional and large epidemiologic studies and human genetics provide strong evidence for the role of low-density lipoprotein cholesterol (LDL-C) in cardiovascular (CV) risk. This evidence has supported the rationale and strong clinical interest in pursuing clinical programs designed to further lower LDL-C.

With the removal of several lipid screening and lipid control measures from both the PQRS and the MSSP in prior years, this proposed new measure would help fill the current quality measure gap in cholesterol management. Consistent with the new ACC/AHA guidelines for cholesterol management, the measure addresses appropriate first-line lipid-lowering therapy. Additionally, the measure recognizes the need to address both LDL-C levels for identifying specific patient populations outside of secondary prevention (*i.e.*, LDL-C above 190) and LDL-C thresholds in the diabetic population.

We do recommend a few modifications to improve the proposed measure. Specifically, we recommend that the measure description be broadened by replacing the word “statin” in the title and “statin therapy” in the description with “cholesterol/lipid lowering”. Although statins are first-line therapy for managing cholesterol, additional therapies are also effective in lowering LDL-C and CV event rates, as demonstrated most recently from the results of the IMProved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE IT).

Although not a direct modification to this measure, we also recommend the addition or development of a lipid screening measure consistent with the specifications of this measure. Because the proposed new measure lists LDL-C levels as a descriptor in the denominators, an additional quality measure addressing lipid screening would improve its performance.

Both of our recommending modifications – broadening the measure description to “cholesterol/lipid lowering” and developing a lipid screening measure - are consistent with the new guidelines as well as anticipate upcoming new therapies in cholesterol lowering.

4. CMS Should Exercise Caution in Reviewing and Revaluing the 118 Codes Proposed as Potentially Misvalued to Ensure that Physicians Continue to Receive Adequate Reimbursement for Services under the MPFS.

In the Proposed Rule, CMS proposes to review approximately 118 CPT codes as potentially misvalued, identifying these codes as a subset of the new statutory category of “codes that account for the majority of spending under the Physician Fee Schedule.” CMS initially proposed this screen in the MPFS proposed rule for CY 2015,[15] based on the top 20 codes by specialty in terms of Medicare allowed charges, excluding codes that were reviewed in the last five years, had total allowed charges less than $10 million, or described anesthesia or evaluation and management (E/M) codes. CMS proposes to apply the same screen this year, but also to exclude any codes with 10- and 90-day global periods.[16] The agency identified several drug administration codes in this subset of potentially misvalued codes,

[15] *See* 79 Fed. Reg. at 40,337.
[16] *See* 80 Fed. Reg. at 41,706.

including 96372 (therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular); 96374 (therapeutic, prophylactic, or diagnostic injection, intravenous push, single or initial substance/drug); 96375 (therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug); 96401 (chemotherapy administration, subcutaneous or intramuscular, non-hormonal anti-neoplastic); 96402 (chemotherapy administration, subcutaneous or intramuscular, hormonal anti-neoplastic); 96409 (chemotherapy administration; intravenous, push technique, single or initial substance/drug); and 96411 (chemotherapy administration; intravenous, push technique, each additional substance/drug).[17]

Amgen reiterates the concerns that we expressed in response to CMS's initial proposal for CY 2015 and urges CMS to exercise caution in reviewing these codes as potentially misvalued. The agency should ensure that any review of these codes takes full account of the costs that providers incur in performing the services and that Medicare reimbursement remains adequate to allow Medicare beneficiaries to continue to have access to these services.

In particular, we urge CMS to use caution in evaluating the values of codes across specialties in light of the agency's explanation in the CY 2015 proposed rule that it planned to review these codes "to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties."[18] Physician work, equipment, supplies, and other costs of providing physician services can vary widely across specialties and may lead to differences between the relative values of physician services that are entirely appropriate. It is particularly important that CMS's efforts to collect data on the resources associated with these codes include all of the relevant specialties for each procedure.

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Thank you for the opportunity to provide these comments. Amgen looks forward to continuing to work with CMS to ensure that reimbursement methodologies of the Medicare program encourage innovation and provide Medicare beneficiaries access to high quality health care and vital therapies. Please contact Jason Spangler, MD, MPH by phone at (202) 585-9659 or by email at jspangle@amgen.com if you have any questions regarding our comments.

Thank you for your attention to these important matters.

Regards,

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cc: Sean Cavanaugh, Deputy Administrator and Director, Center for Medicare, CMS
Elizabeth Richter, Deputy Center Director, Center for Medicare, CMS

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[17] *See id.*
[18] *See* 79 Fed. Reg. at 40,337.

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