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VIA ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1744–IFC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency CMS–1744–IFC

Dear Administrator Verma:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule with comment period (IFC), published in the Federal Register on April 6, 2020.[1]

Amgen is a science-based, patient-driven company committed to using science and innovation to dramatically improve patient lives. Amgen develops innovator medicines and biosimilar biological products, and we are dedicated to improving access to innovative drug and biological therapies and promoting high-quality care for Medicare beneficiaries. Many of Amgen's products are covered under Medicare Part B and, absent the COVID-19 emergency, would be administered by healthcare professionals (HCPs) in a physician's office or a hospital outpatient department. Amgen's comments reflect our strong interest in ensuring continued beneficiary access to therapies, and in particular Part B covered drugs, during the COVID-19 emergency while avoiding exposure to, and risk of, further spread of the virus by minimizing the need for patients to leave their home and travel to the physician's office to receive drug administration services.

We appreciate and support the changes in the IFC that facilitate the ability of beneficiaries to receive their needed drugs and biologicals[2] in the home during the COVID-19 emergency. At the same time,

[1] 85 Fed. Reg. 19,230 (Apr. 6, 2020).
[2] For ease of reference, hereafter, a reference to "drugs" should be considered to include drugs and biologicals.

Amgen urges CMS to pursue additional steps to ensure that beneficiaries can obtain such products in the home. Specifically, CMS should:

A. create even greater flexibility for entities such as home health agencies and qualified home infusion providers to provide and administer Part B covered injectable and infused drugs in the home setting and be paid appropriately under Part B for both the drug and the drug administration service;

B. make clear that under the home health benefit, beneficiaries in need of a drug administration service that is administered less frequently than once every 60 days would be considered to be in need of an intermittent skilled nursing service; and

C. identify the range of osteoporosis drugs that can be covered under the home health benefit.

We have addressed these comments in detail below. Amgen further supports the comments from the Pharmaceutical Research and Manufacturers of America as well as the Biotechnology Innovation Organization.

BACKGROUND

CMS has taken helpful steps to make services more available to Medicare beneficiaries in the home setting during the COVID-19 emergency. For example, CMS has enabled physicians to provide direct supervision of drug administration services furnished by other personnel via interactive telecommunications systems during the COVID-19 emergency.[3] As another example, CMS clarified that a beneficiary may qualify as "homebound" for purposes of receiving home health services where a physician certifies that the beneficiary must stay at home to avoid exposure to COVID-19.[4] In addition, CMS now allows physicians to certify the need for home health services, a condition of accessing those services, via telehealth.[5] Amgen applauds CMS for taking these much needed steps to ensure that more Medicare beneficiaries can access drug administration services in the home during the COVID-19 emergency.

However, as CMS noted in the IFC, it is important to provide additional flexibilities "for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health…"[6] Further, leaving the home may put some patients at greater risk of contracting an infectious disease.[7] While the adopted flexibilities have helped address some of these issues, patients continue to face access issues with respect to physician-administered drugs covered under Medicare Part B, including HCP-administered osteoporosis drugs. For example, a recent, large survey of physicians across a wide range of non-cancer specialties reported that "across neurology, nephrology, dermatology, rheumatology, gastroenterology and primary care, [doctors] project massive disruption on patient and prescribing trends alike . . ." and physicians reported that outpatient visits were "down between 40-68% in the past week."[8] Additionally, multiple patient and provider organizations have

[3] 85 Fed. Reg. at 19,245-46. The term "interactive telecommunications system" means "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." *Id.* at 19,286.

[4] *Id.* at 19,247.

[5] CMS, *COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing* (Apr. 29, 2020), *available at* https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf (page 37).

[6] 85 Fed. Reg. at 19,232.

[7] *Id.* at 19,247.

[8] *See* Spherix Global Insights, COVID-19 Wreaking Havoc in Specialty Practices and the Vast Majority of Physicians Expect It to Get Worse in the Next Two Weeks, According to a New Report by Spherix Global Insights (Mar. 24,

written about or published surveys about experience accessing or providing care during the COVID-19 emergency. These indicate patients are having difficulty accessing in-person care and practitioners report challenges to get patients appropriate treatments across different therapeutic areas.[9] This information points to patients not accessing needed drug administration services. It is precisely because of these ongoing access issues that Amgen urges CMS to take additional steps during the public health emergency to make administration services available in the home for HCP-administered Part B drugs.

HCP-administered osteoporosis drugs are among the Part B drugs that Amgen is concerned patients may have difficulty accessing during the COVID-19 emergency. These drugs are an essential part of the treatment for many patients with osteoporosis, and therefore critical to caring for many Medicare beneficiaries. According to the National Osteoporosis Foundation, "[o]f the estimated 10 million Americans with osteoporosis, about eight million or 80% are women."[10] In addition, "[a]pproximately one in two women over age 50 will break a bone because of osteoporosis."[11] Finally, "[a] woman's risk of breaking a hip is equal to her combined risk of breast, uterine and ovarian cancer."[12]

Research indicates that the hospital burden of fractures from osteoporosis for Medicare beneficiaries is greater than that of heart attacks, stroke or breast cancer for older women. Specifically, over a ten year period, osteoporosis fractures accounted for significantly more hospitalizations (42.7%) than for the next closest of the conditions (26.1% for stroke) in women 55 years old and older.[13] Given the prevalence and significant morbidity and mortality related to this disease, the U.S. Preventive Services Task Force updated its osteoporosis screening recommendations to recommend "screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older" (B recommendation).[14] Treatment with osteoporosis medications, including subcutaneous denosumab (aka Prolia®) for certain patients, is one way to reduce the incidence of fractures.[15]

Amgen manufactures two Part B covered drugs to treat osteoporosis, Prolia (denosumab) injection and EVENITY™ (romosozumab-aqqg) injection. Prolia is an HCP-administered subcutaneous injection used to treat osteoporosis in men and women that are at a high risk for facture and is

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2020), *available at* https://www.spherixglobalinsights.com/covid-19-wreaking-havoc-in-specialty-practices-and-the-vast-majority-of-physicians-expect-it-to-get-worse-in-the-next-two-weeks-according-to-a-new-report-by-spherix-global-insights/.

[9] American Cancer Society Cancer Action Network, *Survey: COVID-19 Affecting Patients' Access to Cancer Care* (Apr. 15, 2020) (citing a survey from *Survivor Views*), *available at* https://www.fightcancer.org/releases/survey-covid-19-affecting-patients%E2%80%99-access-cancer-care. Global Healthy Living Foundation, *COVID-19 Patient Impact & Insights* (Mar. 2020), *available at* https://www.ghlf.org/wp-content/uploads/2020/04/GHLF-COVID-19_Patient_Support_Program_Report_Week_0413_Final.pdf. National Osteoporosis Foundation, *COVID-19 and Osteoporosis Treatment: Webinar for Healthcare Professionals* (Apr. 23, 2020), *available at* https://cdn.nof.org/wp-content/uploads/COVID-HCP-Webinar-4.23.20v1.pdf.

[10] National Osteoporosis Foundation, *What Women Need to Know*, https://www.nof.org/preventing-fractures/general-facts/what-women-need-to-know/ (last visited from Apr. 29, 2020).

[11] *Id*.

[12] *Id.*

[13] Andrea Singer et al., *Burden of Illness for Osteoporotic Fractures Compared With Other Serious Diseases Among Postmenopausal Women in the United States*, 90 Mayo Clin. Proc. 53 (Jan. 2015). The authors also noted that lengths of stay for osteoporosis fractures ranged from about 2.5 days to about 7 days, with hip and femur fractures at the upper end of that range of length of stay.

[14] USPSTF, *Screening for Osteoporosis to Prevent Fractures: USPSTF Recommendation Statement*, 319 JAMA 2,521 (2018). *See also Final Recommendation Statement: Osteoporosis to Prevent Fractures: Screening*, U.S. Preventive Services Task Force, (Jun. 26, 2018),, *available at* https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening1.

[15] Robert B. Conley et. al, *Secondary Fracture Prevention: Consensus Clinical Recommendations from a Multistakeholder Coalition*. 35 J. Bone Miner Res. 36, 45 (Jan. 2020).

administered once every six months.[16] EVENITY is an HCP-administered subcutaneous injection used to treat osteoporosis in post-menopausal women at high risk of fracture and is administered once every month.[17] Amgen is extremely concerned about the consequences for patients of being unable to continue their Prolia or EVENITY regimens during the COVID-19 pandemic due to diminished access to usual settings of care for their injections.

Beginning in March, Amgen observed a negative impact of COVID-19 on Prolia injections.[18] Patients begin to lose bone mineral density if they discontinue Prolia, with bone mineral density returning to pretreatment levels within eighteen months after the last dose of Prolia, leading to an increased risk of fractures.[19] Patients who have discontinued use of Prolia have experienced an increased risk of multiple vertebral fractures as early as seven months after their last dose or one month after they were last due.[20] Patients that experience these fractures may need additional pain management care or may no longer be able to live at home because of these increased risks.

Medicare beneficiaries that require Part B drugs may have limited options for treatment during the COVID-19 emergency. In some cases, their provider may no longer be offering injections. For those whose providers continue to offer in-office injections, beneficiaries are having to choose between going to the hospital or clinic for treatment at a time when they remain at higher risk of exposure to COVID-19, or foregoing those treatments at the risk of suffering complications from preexisting illnesses. For these reasons, Amgen urges CMS to adopt additional flexibilities to support access to Part B covered HCP-administered drugs during the COVID-19 emergency, as discussed below.

DISCUSSION

A. CMS Should Use Its Authorities to Enable Additional Entities, Such as Home Health Agencies and Qualified Home Infusion Therapy Suppliers, to Furnish, Administer, and Bill for Part B Covered Drugs in the Home Setting and Be Paid Appropriately Under Part B for the Drug and the Related Administration Service

Amgen appreciates CMS's efforts to increase the availability of drugs and drug administration services to beneficiaries in the home for the duration of the COVID-19 emergency, including by allowing physicians to provide direct supervision of drug administration services provided in the home via interactive telecommunications systems. Nevertheless, there remain a number of limitations on the ability of patients to access drug administration services from the home due to operational complexities and capacity constraints. For instance, physician practices may not have enough clinical staff available or trained for home visits. As CMS noted in the IFC, a physician could contract with a home health agency or home infusion therapy supplier to provide services in the home, with the physician providing direct supervision remotely, during the COVID-19 emergency.[21] However, contracting for these auxiliary staff needs and managing such contracts can be time consuming, further delaying the ability of physicians to meet the needs of their patients.

To ensure beneficiary access to Part B covered drugs during the COVID-19 emergency, CMS should provide additional flexibilities to allow additional entities, such as home health agencies and qualified home infusion therapy suppliers, to provide, administer, and bill for Part B covered drugs in the home

[16] FDA, Prolia Prescribing Information (Mar. 2020), *available at* https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/prolia/prolia_pi.pdf.

[17] FDA, EVENITY Prescribing Information (Dec. 2019), *available at* https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx.

[18] Amgen Q1 2020 Earnings Call Presentation (April 30, 2020) *available* at http://investors.amgen.com/static-files/5818caaf-5231-426f-a507-50ab5d07a9f.

[19] Prolia Prescribing Information, *supra* note 17, at §5.6.

[20] *Id.*

[21] 85 Fed. Reg. at 19,246.

setting, with a physician's order. Since the treating physician would be prescribing the drug and ordering the home administration, the physician would retain the key role of determining whether the particular drug can be safely administered in the home setting by a qualified non-physician practitioner or supplier. These types of entities already have the capability to provide home-based services, including the administration of drugs. Importantly, entities such as home health agencies and qualified home infusion suppliers are already enrolled in Medicare as providers and suppliers and have the capability to bill the program and directly receive reimbursement for services they provide.

Finally, CMS must ensure that payment rates are sufficient to cover the additional costs of providing drug administration services in the home, both when provided incident to a physician's service or if CMS authorizes additional entities to provide and bill for drug administration services under Part B during the COVID-19 emergency.

1. CMS has authority to allow additional entities to furnish, administer and bill for Part B drugs in the home setting during the COVID-19 emergency

Amgen encourages CMS to use its authority to modify the requirements for the provision of drugs and drug administration services provided incident to physician services so that other entities already able to bill Medicare can purchase, furnish, and administer drugs in the home during the COVID-19 emergency, to the extent permitted within their scope of practice and licensure under existing state law. We appreciate that CMS has been using newly granted authority in light of the declaration of a public health emergency to promote greater beneficiary access to items and services for Medicare beneficiaries. For example, section 1135 of the Social Security Act (SSA) gives CMS authority to waive certain requirements of the Medicare program in the event that the President has declared an emergency or disaster under the National Emergencies Act or Stafford Act and where the Secretary of the Department of Health and Human Services has declared a public health emergency.[22] CMS has already used its authority under section 1135 of the SSA during the current COVID-19 emergency, and Amgen believes that CMS could further use its authority, under section 1135(b)(1)(B) of the SSA, to modify program participation and other requirements so that other entities already able to bill Medicare can temporarily provide drug administration services during the emergency.[23] This would include, for example, home health agencies and home infusion therapy suppliers. Ensuring that beneficiaries have sufficient access to the drugs they need is essential during the COVID-19 emergency. Inadequate access to drug therapies can result in beneficiaries experiencing more complications of their illness, such as the increased risk of fracture for patients missing treatment with osteoporosis drugs discussed previously.

2. CMS should ensure adequate payment for Part B drugs and drug administration services furnished to beneficiaries in the home during the COVID-19 emergency

If CMS adopts additional flexibilities to allow entities already able to bill Medicare to provide home drug administration services during the COVID-19 emergency, it must further ensure that these entities are appropriately paid for these services. The drugs themselves should continue be paid for under the methodologies laid out under section 1847A of the SSA, *e.g.*, at the average sales price plus 6%, consistent with how Medicare pays for most Part B drugs.[24]

For drug administration services, we do not believe using the usual Medicare physician fee schedule rates for such services would be sufficient to cover the costs of these services in the home. For

[22] SSA § 1135(a), (g).
[23] *Id.* at § 1135(b)(1)(B).
[24] *E.g.*, *id*. at § 1847A(a)(1)(B).

example, the current physician fee schedule drug administration rate of $14.44 for Current Procedural Terminology (CPT)[25] code 96372, "[t]herapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular," does not appropriately account for the additional cost to physicians and other entities of having to drive to each beneficiary's home to administer drugs, safely store the drugs in the vehicle, and practice the additional hygiene efforts that are necessary because of the COVID-19 pandemic while moving from one beneficiary's home to the next.

CMS therefore should look to alternate payment mechanisms to determine the appropriate payment for the drug administration services, whether those services are provided incident to a physician's services or as part of any expanded authorization for other entities to provide such services under CMS's waiver authority discussed previously. One option could be to establish add-on codes that would be billed in addition to the usual drug administration code, with the payment for such codes compensating for the added costs of furnishing the drugs in the home (e.g., travel time). Alternatively, CMS could use a different Medicare payment system to set rates.

As an example of an appropriate comparator, CMS could look to the existing codes and payment rates for home infusion therapy services for intravenous drugs (G0068) and subcutaneous drugs (G0069) to determine how to appropriately compensate entities already able to bill Medicare for drug administration services in the home under any additional waivers it adopts.[26] CMS could then establish a G-code, or series of G-codes to be used to bill for drug administration services in the home setting during the COVID-19 emergency. Expanding access to these services is essential to meeting the needs of beneficiaries that would benefit from home drug administration services during the COVID-19 emergency, and Amgen therefore urges CMS to take further action to facilitate beneficiary access to their needed medications and ensure that HCPs and other entities are appropriately compensated for these services.

B. CMS Should Clarify That Beneficiaries Needing Drugs Administered Less Often Than Once Every 60 Days Under the Home Health Benefit During the COVID-19 Emergency Qualify as Needing Intermittent Skilled Nursing Services

To qualify for home health services, Medicare beneficiaries must (1) be homebound, (2) have a physician certified plan of care, (3) be under the care of a physician, and (4) be in need of skilled services, and (5) the services must be provided by an appropriate health agency.[27] As to the need for skilled services, that can be met when there is a need for intermittent skilled nursing services,[28] and CMS has said that drug administration services qualify as "skilled nursing" services under the home health benefit.[29] However, home health agencies and referring physicians may have questions about how drugs that need to be administered less frequently than once every 60 days satisfy the requirement that the skilled nursing services be provided on an "intermittent" basis under CMS's current guidelines. Providing clarification is important to ensuring that beneficiaries at risk are able to access needed therapies, particularly for drugs such as Prolia, which is administered every six months.[30]

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[25] CPT is a registered trademark of the American Medical Association.

[26] CMS, Medicare Part B Home Infusion Therapy Services With the Use of Durable Medical Equipment SE19029 (Dec. 13, 2019), *available at* https://www.cms.gov/files/document/SE19029.pdf.

[27] 42 C.F.R. § 409.42.

[28] *Id*. at § 409.42(c)(1).

[29] *See* Medicare Benefit Policy Manual (MBPM) , ch. 7, § 40.1.2.4(A) ("Intravenous, intramuscular, or subcutaneous injections and infusions . . . require the skills of a licensed nurse to be performed (or taught) safely and effectively. Where these services are reasonable and necessary to treat the illness or injury, they may be covered").

[30] Prolia Prescribing Information, *supra* note 17 at §2.2.

By statute, "'intermittent' means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable)."[31] CMS clarifies through guidance that "[t]o meet the requirement for 'intermittent' skilled nursing care, a patient must have a medically predictable recurring need for skilled nursing services. In most instances, this definition will be met if a patient requires a skilled nursing service at least once every 60 days."[32] CMS further clarifies that services may be provided and paid less frequently than once every 60 days but "only if documentation justifies a recurring need for reasonable, necessary, and medically predictable skilled nursing services."[33] For example, CMS may pay for intermittent skilled nursing facility services for "[t]he patient with an indwelling silicone catheter who generally needs a catheter change only at 90-day intervals" or where "[t]he blind diabetic who self-injects insulin may have a medically predictable recurring need for a skilled nursing visit at least every 90 days. . . .to observe and determine the need for changes in the level and type of care which have been prescribed thus supplementing the physician's contacts with the patient."[34] The need for these less frequent services must be specifically documented in the patient's plan of care.[35]

Where a drug, such as EVENITY, is administered once every month, furnishing that service on a monthly basis qualifies as an intermittent skilled nursing service provided at least once every 60 days. Where a drug, such as Prolia, is administered less than once every 60 days but every 6 months, CMS should issue guidance to clarify that these services also would qualify as intermittent and thus meet the intermittent skilled nursing care requirement for coverage under the home health benefit. The beneficiary's medical record would justify the recurring need for these services in the home and the duration of the need for these services is finite and predictable. Amgen urges CMS to make these clarifications as soon as feasible, such as by adding an example to section 40.1.3 of Chapter 7 of the Medicare Benefit Policy Manual clarifying that administering drugs which are needed less frequently than once every 60 days, such as drugs with product labeling for administration every six months, qualifies as an intermittent skilled nursing service.

C. CMS Should Ensure that Home Health Agencies Are Aware of the Range of Osteoporosis Drugs that Can Be Covered

Amgen encourages CMS to clarify the drugs that qualify as covered osteoporosis drugs for purposes of the home health benefit. By statute, the home health benefit includes covered osteoporosis drugs, specifically injectable drugs "approved for the treatment of post-menopausal osteoporosis" without limitation as to how frequently the drug may be administered.[36] Amgen's drugs Prolia and EVENITY both fit within the scope of covered osteoporosis drugs under the statute. Yet as written, the Medicare Claims Processing Manual (MCPM) implies that there are only two osteoporosis drug Healthcare Common Procedure Coding System (HCPCS) J-codes that would be covered through the home health benefit, namely HCPCS codes J0630 and J3110.[37] The manual notes other osteoporosis drugs that are FDA approved can use a miscellaneous code of J3490 until a specific HCPCS code is approved for use.[38] Because the manual only references two drug-specific codes, it creates a possible access problem for Medicare beneficiaries seeking coverage of osteoporosis drugs, as home health agencies

[31] SSA § 1861(m). *See also* MBPM, ch. 7, § 40.1.3.
[32] *See* MBPM, ch. 7, § 40.1.3.
[33] *Id*.
[34] *Id*.
[35] *Id*.
[36] SSA § 1861(m)(5), (kk). In addition, to be a covered osteoporosis drug, "(1) the individual's attending physician [must] certif[y] that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and (2) the individual [must be] confined to the individual's home [except where that item is provided on an outpatient basis in a facility.]" *Id.* at § 1861(kk).
[37] MCPM, ch. 10, § 90.1.
[38] *Id.*

or possibly the home health and hospice (HH+H) Medicare Administrative Contractors (MACs) may interpret this guidance to say that only drugs reported with those two HCPCS codes can be covered, wrongly blocking access to other drugs such as Prolia and EVENITY.

To avoid this issue, and to ensure consistency across the HH+H MACs in processing claims for these codes, Amgen asks that CMS identify the full range of osteoporosis drug codes that are covered under the home health benefit, including J0897 and J3111, and update the manual accordingly. Doing so will be essential to ensuring timely appropriate coverage during the COVID-19 pandemic as the HH+H MACs may begin to receive an increase in claims for covered osteoporosis drugs and more generally.

CONCLUSION

Given the access issues beneficiaries are facing during the COVID-19 emergency, it is incredibly important to maintain continuity of care for beneficiaries on drug therapies who may be unable to receive them as they have been in the past. As discussed above, while the IFC contains steps in that direction, more steps are needed to ensure that beneficiaries can receive such therapies in the home. As detailed above, we think that CMS has the ability to do so and we recommend that CMS take steps to allow a broad range of entities already able to bill Medicare to furnish drugs in the home and be paid sufficiently for the drug and the related administration services. In addition, we urge CMS to make important clarifications to what constitutes "intermittent skilled nursing care" and the osteoporosis drugs that fall under the home health benefit to ensure access to covered osteoporosis drugs.

We appreciate your consideration of our comments. We look forward to continuing to work with CMS to ensure continued access for Medicare beneficiaries to drug administration services and covered osteoporosis drugs during the COVID-19 emergency. Please contact Jason Spangler, MD, MPH, FACPM at 202.585.9659 or jspangle@amgen.com if you have any questions regarding our comments.

Sincerely,

Victoria Blatter
Senior Vice President
U.S. Government Affairs & Policy