January 25, 2019

BY ELECTRONIC DELIVERY

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, CMS-4180-P

Dear Administrator Verma:

The National Osteoporosis Foundation (NOF) is pleased to submit its comments to the above-referenced proposed rule entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses (the Proposed Rule). We previously responded to the Centers for Medicare & Medicaid Services' (CMS') International Pricing Index Model (IPI) proposal for Part B drugs, noting our significant concerns that it could have an unintended consequence of exacerbating real-world deficiencies in osteoporosis care for Medicare beneficiaries. This Proposed Rule raises similar concerns and, when layered onto a potential IPI Model, places CMS' policy initiatives at increasing odds with its "patients first" promise to our nation's elderly and disabled populations.

The NOF is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and related areas.

Our Policy Institute brings together the expertise, resources, and perspective of the full spectrum of bone health stakeholders to advocate for health policy initiatives that promote bone health and reduce both the personal and financial costs of fragility fractures. The breadth

of our mission extends beyond the bone health concerns associated with advancing age. Our comments to this Proposed Rule, however, are focused on ensuring that all Medicare beneficiary have access to the osteoporosis treatment options that they determine, in consultation with their clinicians, are most appropriate.

Included in NOF's core mission are efforts to stimulate education and research toward advancing appropriate use of existing therapies and development of new treatment options. We reiterate our support for CMS' efforts to curb the rising cost of prescription drugs and, most importantly, reduce patient out-of-pocket expenses for medically necessary treatments. Our comments on the Proposed Rule reflect our concern that any savings achieved may be counterbalanced by negative impacts on patients as treatment decisions become increasingly driven by short-term cost considerations rather than the decision-making relationship between a patient and their trusted provider.

Osteoporosis is an emerging health policy crisis – it is both underdiagnosed and undertreated. Because there is no over-utilization of osteoporosis drugs to curb, any increase in utilization management across this set of therapies could deter their appropriate use and significantly undermine NOF's education and outreach efforts to close the care gap. While osteoporosis treatments are not directly impacted by the proposed new exceptions to coverage within the six protected classes, we are concerned that the underlying rationales and justifications create a poor policy precedent, particularly when applied to the most vulnerable subsets of the Medicare population.

Background

In April of 2014, NOF released an update to its prevalence data, revealing that an estimated 10.2 million adults in the U.S. have osteoporosis, and another 43.4 million have low bone mass. This means 54 million U.S. adults, representing 50 percent of the U.S. population over age 50, are at risk of a fragility fracture. Our healthcare system is armed with the tools to detect and diagnosis low bone mass and osteoporosis, and an understanding of the risk factors signaling the need for testing. Individuals in whom osteoporosis is detected have a variety of therapeutic options to effectively address their condition and reduce their risk of a fragility fracture.

Despite our ability to identify and manage osteoporosis, Medicare patients continue to suffer fragility fractures at an alarming rate. For the Medicare program, the annual cost of treating these fractures exceeds $20 billion. Although patients treated for a fragility fracture are at a high risk of future fractures, a significant majority of US hip fracture patients are released from the inpatient setting without any evaluation for osteoporosis and the vast majority are never treated. While we expect the quality of our healthcare to improve with introduction of new diagnostic and treatment options, the care gap in osteoporosis has actually worsened over time. We simply cannot afford to maintain the trajectory of the current status quo. Any formulary flexibility policies through Part D or Medicare Advantage that reduces treatment

options would risk trading modest short-term savings on "preferred" products for the significant long-term costs of untreated bone fragility.

The Medicare program and its beneficiaries diverge substantially from the populations addressed by commercial plans; grafting utilization management tools designed to contain costs associated with treating the general population requires a cautious, considered analysis of the potential benefits and risks. Moreover, the likely high volume of prior authorization and formulary exception requests associated with patient populations where comorbidities, multiple chronic conditions, and complications are the rule rather than the exception could create administrative costs that approach or exceed any savings to Medicare. We urge CMS to reconsider the policies contained in the Proposed Rule in favor of a more targeted initiative through which savings can be obtained without risk of compromising patient access or outcomes.

Utilization management and cost-containment tools for Part B drugs within Medicare Advantage (MA) Plans

NOF's primary concern with MA plan use of utilization management tools, including step therapy, for Part B drugs was clearly articulated by CMS' in preamble to the Proposed Rule. The Agency acknowledged that its longstanding prohibition on MA plan use of step therapy for Part B drugs was more mandate than decision as it "interpreted existing law to prohibit MA plans from using step therapy for Part B drugs because such a utilization management tool would create an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law." [1]

We are concerned that CMS appears to have either summarily dismissed the "unreasonable barrier" step therapy requirements might impose on Medicare beneficiaries or determined that the benefits of providing MA plans with the means to "better manage and negotiate the costs of providing Part B drugs"[2] is a sufficient counterbalance.

NOF echoes the concerns expressed by stakeholders when CMS announced this policy in the form of a program memorandum in August 2018. We note that CMS appears to have addressed some of these objections by proposing a requirement for MA plan use of a pharmacy and therapeutics (P&T) committee and use of the streamlined appeals timeline applicable in Part D so that patients do not experience lengthy treatment delays.

While these refinements may reduce patient access risks, they do not remove the risk that step therapy could deny access to a statutorily-covered Part B drug. NOF urges CMS to reconsider this proposal until it can ensure that MA plans are capable of implementing sufficient patient

[1] Proposed Rule. https://www.regulations.gov/document?D=CMS-2018-0149-0002
[2] Id.

protections to ensure that step therapy requirements do not constrict or deter access to the full set of benefits under Part B. This would include:

- CMS should ensure that any step therapy protocols are subject to a notice and comment process similar to those followed when restrictions are placed on otherwise-covered services in Medicare fee-for-service, and that they follow clinical practice guidelines and best practices that are developed for, or applicable to, an elderly and disabled population.

- The step therapy requirements should not be applied to patients with comorbidities and complications not considered within the evidence base for the step therapy protocol.

- P&T Committee: CMS should require, and not simply encourage, MA plans to select P&T committee members representing various clinical specialties, including geriatricians and bone health experts, so that all conditions are adequately considered in the development of step therapy programs.

- Requiring that step therapy protocols address an identified pattern of over-utilization of products that are more costly than at least one equally-effective alternative.

- Requiring that plans not impose a significant burden on clinicians requesting an exception to a step protocol that would not be clinically appropriate for a particular patient.

- Ensure that patients receiving a Part B osteoporosis treatment can continue to receive that treatment. NOF is concerned that the proposed 108-day lookback, when applied to osteoporosis treatments, could jeopardize a patient's ability to continue receiving their treatment doses. It would be unreasonable an unfair to demand that patients restart the step therapy protocol if their Part B drug is labeled for administration outside the 108-day lookback.

- MA plan costs associated with implementing utilization management tools for Part B drugs should be excluded from the plan's reported costs.

- CMS must conduct sufficient oversight to ensure that step therapy protocols do not impose a barrier to access.

- Medicare beneficiaries should know in advance of enrolling whether an MA plan uses restrictive step therapy protocols for Part B drugs. NOF urges CMS to ensure that the information beneficiaries receive, in advance of enrolling in a particular plan, is sufficiently granular and specific to allow them to understand the potential impact on

their care. A simple statement of the plans intention to utilize step therapy for some Part B drugs should not be sufficient.

NOF believes that the enhanced chronic care management services available to patients enrolled in a high-quality managed care organization could improve diagnosis of osteoporosis and enable appropriate treatment. NOF urges CMS to ensure that step therapy protocols are not implemented for medications addressing osteoporosis and other conditions that are grossly underdiagnosed and undertreated.

The proposed new exceptions to coverage within protected classes create a poor policy precedent, particularly when applied to the most vulnerable subsets of the Medicare population.

As we noted previously, osteoporosis treatments are not directly impacted by the proposed new exceptions to coverage within the six protected classes. Age-related bone fragility, however, cuts across patient populations and can substantially impact quality of life in patients suffering conditions within these areas of clinical concern. Similarly, NOF understands that the protections associated with classes and categories of clinical concern serve two policy objectives that are as important now as they were at the inception of the Part D program. First, the protections increase patient access to needed treatment options by ensuring that clinicians can choose from among the full set of treatment options to address the unique needs of each patient. Second, these protections decrease the likelihood that plans can structure their formularies to discourage enrollment by patients with particularly high-cost conditions.

The Proposed Rule sets forth a set of three new exceptions to the requirement that plans maintain formulary inclusion for all or substantially all products within the protected classes. The exceptions would permit Part D plans to:

- impose utilization management (UM) tools on drugs included in the protected classes, including increased use of prior authorization (PA) and step therapy;
- exclude drugs from formularies for new formulations of existing drugs; and
- exclude products with price increases exceeding CMS' defined threshold.

While NOF acknowledges CMS' statutory authority to devise exceptions to the formulary requirements for the protected classes, the proposed exceptions do not appear to be "based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, [is] consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents)."[3]

[3] SSA 1860D-4(b)(3)(G

We share CMS' interest in containing the cost associated with prescription drugs to both the Medicare program and its beneficiaries. While CMS has stated that "by limiting the ability of Part D sponsors to implement utilization management tools (for example, prior authorization or step therapy requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary," plans currently utilize a range of formulary tools to discourage broad utilization of products within the protected classes. For example, most of these products are subject to tier placement associated with higher cost-sharing through coinsurance rather than copayment mechanisms, and utilization management tools such as prior authorization are commonly applied and sufficiently curb misuse, abuse, and medically inappropriate prescribing. [4]

NOF urges CMS to approach the creation of additional exceptions within the protected classes in a manner that focuses on a particular concern with a product or set of products, and to devise a solution based upon clinical and scientific evidence applicable to this vulnerable Medicare population.

Conclusion

Once again, the NOF appreciates the opportunity to provide feedback as CMS considers implementing the policies outlined in the Proposed Rule. We look forward to working with CMS toward our shared goal of improved patient outcomes at a lower cost to the Medicare program.

If you have any questions or wish to discuss our concerns in greater detail, please contact me at 703-647-3020 or our Chief Mission Officer, Claire Gill, at 703-647-3025.

Very truly yours,

Elizabeth Thompson
Chief Executive Officer
National Osteoporosis Foundation

[4] See: Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements. Updated January 2016.