January 25th, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201


Dear Administrator Verma,

On behalf of the more than eight million Americans living with psoriasis and psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to comment on the 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P).

As the patient advocacy organization for the psoriatic disease community for more than 50 years, the NPF is keenly aware of the improvements in health outcomes that have resulted from advances in treatment innovation. Therefore, the NPF remains committed to ensuring Medicare beneficiaries with psoriasis and psoriatic arthritis have access to the full range of treatments and therapies necessary to successfully manage their disease. Understanding that cost can be one of the biggest barriers to this critical access, we commend the Administration for its focus on reducing the financial burden for our community. Upon review of this proposed rulemaking, we will be highlighting some areas of agreement and some areas that we believe require further detail and explanation as this rulemaking process advances.

In September 2018, the HHS Office of Inspector General released a report, “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials” (OEI-09-16-00410). While the report did not focus specifically on Part D, it did find that inappropriate denials were a widespread and persistent problem in Medicare Advantage (MA) plans. We are especially concerned that, while 75% of beneficiary and provider appeals were successful, only 1% of denials were appealed in the first place. As the OIG report states, “each overturned denial represents a case in which beneficiaries or providers had to file an appeal to receive services or payments that are covered by Medicare.” The low rate of appealed denials further represents care that beneficiaries are not receiving which they are entitled to under the Medicare program. We were encouraged to see that several of the suggestions brought forth in this report, and agreed to by CMS in your response, are included in this proposed rule. NPF does, however, believe there is a need to strengthen aspects of the appeal process based on the report and our patient community’s experience in other markets. Furthermore, we would call to the department’s attention that the OIG is scheduled to release a report, “Denials and Appeals in Medicare Part D” (OEI-09-16-00411) in late July 2019 according to OIG staff. Considering CMS’s proposal to largely mirror the Part D appeal process in Part B, we encourage CMS to pull back this component of the proposed rule until after the OIG report has been issued and thoroughly reviewed. We would also encourage that any

1 https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf
future rulemaking takes into account any recommendations for program improvements included in the report, should doing so be appropriate.

**Transparency and Education**

We commend CMS for proposing to improve the quality and transparency of e-prescribing by updating requirements to include a real time benefit tool (RTBT). NPF appreciates the effort to provide beneficiaries with real time information regarding utilization management tools, formulary alternatives, and patient out-of-pocket costs. We recommend that starting in 2020 CMS require plans to use these tools in order to provide enrollees with the most current and pivotal information, particularly related to out-of-pocket costs. Additionally, NPF supports CMS’s proposal to require that prescription drug plans include drug pricing information in the explanation of benefits (EOB) statements, including specific information regarding drug price increases and alternatives that present an opportunity for the consumer to save money.

While we will comment further regarding utilization management tools and their impact on the psoriatic disease community, we find it relevant in this section to suggest that CMS prohibit mid-year changes to utilization management tools in both Part D and Part B. As beneficiaries seek cost efficient plans that offer coverage tailored to their unique needs, permitting plans to adopt utilization management tools not contained in the plan overview at the time of enrollment places an undue burden on plan members forced to navigate a change mid-year that they were not anticipating.

**Increased use of Biosimilars**

While the NPF has concerns about the long-term impact of utilization management on our patient community and the health care system as a whole, we agree that these tools present opportunities at times to improve access to lower cost medications. Following the release of the “Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs” memo in August of 2018, the NPF has monitored MA shifts in coverage and was pleased to see increased access to biosimilars by at least one carrier. In October, United Health Care announced 2019 step therapy requirements for MA plans in a provider bulletin. This bulletin showed that while new start beneficiaries seeking coverage for Remicade—a drug commonly used to treat psoriasis—would be subject to step therapy, both biosimilars of that originator product—Inflectra and Renflexis—were listed as preferred drugs and did not require step therapy. While this is encouraging, we are seeking further data on the difference in co-insurance for these three products, particularly given recent macro level data showing that in Part D, the differences in co-insurance percentages between a biosimilar and originator product is marginal. For example, a 2017 study which analyzed Part D data showed a difference of only 1.8% between the co-insurance for Inflectra and Remicade, which minimizes the costs savings to the patient. As CMS considers implementing the portion of the proposed rule related to allowing biosimilars for protected classes of drugs, we encourage the agency to pursue strategies that incentivize carriers to lower these out-of-pocket beneficiary costs.

**Prohibition of Pharmacy Gag Clauses**

The NPF commends Congress and the Administration for its support of the “Know the Lowest Price Act of 2018,” (P.L. 115-262) which prohibits the use of pharmacy gag clauses in Part D. In addition to supporting this now-law, the NPF has actively supported the nearly 30 pieces of legislation that have passed at the state level codifying these protections. This bill would allow an enrollee to be informed of all available treatment options and corresponding costs; a reasonable approach to full disclosure which enables patients to treat their disease at the lowest cost. Prohibiting pharmacy gag clauses ensures patients are not paying more than their insurer when purchasing a prescription drug that is essential to maintaining their health. We support CMS’s proposal to include this new requirement in the Part D regulations.

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3 [https://www.healio.com/rheumatology/rheumatoid-arthritis/news/online/%7Bdcf3f185-04df-4a70-86b4-2b2d4fd2ae5-7D/infliximab-biosimilar-only-moderately-less-costly-vs-biologic-under-medicare-part-d](https://www.healio.com/rheumatology/rheumatoid-arthritis/news/online/%7Bdcf3f185-04df-4a70-86b4-2b2d4fd2ae5-7D/infliximab-biosimilar-only-moderately-less-costly-vs-biologic-under-medicare-part-d)
We appreciate CMS seeking comment “concerning the impact that allowing step therapy for Part B drugs would have on MA plans and enrollees.” The individuals NPF represents are intimately familiar with step therapy practices across the country and have a direct understanding of how these policies impact their care, health outcomes, and overall well-being. We recognize the Administration’s efforts to explore methods for controlling healthcare spending. However, we seek to share our significant experience with this topic and put forward some proven solutions to ensure any MA step therapy protocols allow for appropriate utilization management while recognizing the primacy of the patient-physician relationship for beneficiaries.

The NPF commends CMS for proposing to require MA plans to execute the existing organization determination and appeals process for Part B drugs in line with the timeframes applicable for Part D coverage. These timelines – which require a response within 72 hours for standard and 24 hours for expedited appeals – are in sync with reforms that have been passed in numerous states. This congruency across different markets will assist in lessening the administrative burden to providers and carriers. However, we seek more information in regard to the statement by CMS that, “CMS monitors organization determination and appeals activity through the audit process to ensure enrollee requests are appropriately evaluated and processed with applicable timeframes.” We would like to understand further how a MAO, who is identified as a frequent offender, is identifiable by a consumer. In this regard, NPF embraces the suggestion in the previously referenced HHS OIG report that:

“Because audit results no longer impact Star Ratings, CMS should develop another method for informing beneficiaries of serious violations identified by audits, including those that lead to civil money penalties. This information should be clear, meaningful, and easily accessible to beneficiaries in places where beneficiaries typically access information, such as on the Medicare Plan Finder website. CMS already includes information about MAO sanctions on the Medicare Plan Finder website, and could expand this effort to include civil money penalties, as it proposed in the 2019 draft call letter. CMS could also consider including information about audit violations in addition to enforcement actions. CMS could also revisit policy options for adjusting Star Ratings in response to audits and enforcement actions, such as adding a new Star Ratings measure that takes enforcement actions into account, or by directly adjusting an MAO’s overall and summary Star Ratings in response to enforcement actions. This would help to ensure that Star Ratings serve as a “one-stop shop” for beneficiaries to evaluate differences in performance among MAOs.”

Being able to consider serious violations identified by CMS audits is crucial for beneficiaries to make informed decisions when selecting plans. We encourage CMS to explore policy options to provide this information through the Medicare Plan Finder website.

NPF endorses the approach by CMS to require MA plans to use a Pharmacy and Therapeutics (P&T) committee to review and approve step therapy programs to ensure medically appropriate implementation of step therapy for Part B drugs. However, we encourage CMS to strengthen this rule as it relates to both Part B and Part D, as medications used to treat psoriasis and psoriatic arthritis fall under both programs. While the requirements for membership, including lack of conflict, a practicing pharmacist, a physician, and expert in the care of elderly and disabled person is a positive condition, we ask that CMS take this a step further and require membership to contain an expert in the fields of immunology, rheumatology, and mental health.

We also support CMS proposing that step therapy only be applied to new prescriptions of Part B drugs, however we share concerns expressed by others that a 108 day look-back period may not be appropriate across all disease states.

Additionally, NPF agrees with the statement by CMS that:
“Enrollees can request an organization determination if they believe that they need direct access to a Part B drug that would otherwise only be available after trying an alternative drug. MA plans would adjudicate these organization determinations based on medical necessity criteria.”

However, we strongly encourage CMS to take this adjudication criteria a step further. Medical necessity is a comprehensive term as defined but also allows for great flexibility on the part of the carrier. More robust protections and requirements are necessary. As such, we suggest that CMS adopt patient protections that mirror those enacted by twenty states that permit the use of step therapy in individual marketplace plans with appropriate guardrails. Specifically, we suggest that CMS require MA plans to waive the step therapy requirement if any of the following criteria are met:

1) the treatment is contraindicated;
2) the treatment is expected to be ineffective based on the physical or mental characteristics of the patient or the nature of the treatment;
3) the treatment will cause or is likely to cause an adverse reaction to the individual;
4) the treatment is not in the best medical interest of the patient because the provider is already following applicable clinical practice guidelines or because the treatment is expected to decrease the individual’s ability either to perform daily activities, occupational responsibilities, or adhere to the treatment plan; or
5) the individual is stable on another drug to treat his or her condition.

CMS already suggests aspects of these criteria when it states (emphasis added):

“Although not required under our proposal, an MA organization may establish an evaluation process for the appropriateness of enforcing its step therapy protocols on an enrollee when the enrollee’s healthcare provider’s assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug). MA organizations may work with their network providers to develop processes that eliminate the necessity for an enrollee to file a request for an organization determination in such cases. **We are not proposing to require such additional policies or processes but we are similarly not prohibiting them.**”

However, the language bolded needs to be strengthened. We recommend not only that CMS require the above but that they pull back this component of the proposed rule until after the OIG report has been issued and thoroughly reviewed. We would also encourage that any future rulemaking takes into account any recommendations for program improvements included in publication of the “Denials and Appeals in Medicare Part D” (OEI-09-16-00411) report in the summer of 2019.

We appreciate your attention to the comments made by NPF on behalf of the millions of Americans who live with psoriatic disease. Should you wish to reach us to discuss any of our suggestions please contact Patrick Stone at pstone@psoriasis.org.

Sincerely,

Patrick Stone
Vice President, Government Relations & Advocacy