April 6, 2020

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 Contract Year 2021 and 2022 Medicare Advantage (MA) and Part D Proposed Rule (CMS-4190-P).

For more than 50 years, the NPF has been the leading advocacy voice in the effort to cure psoriatic disease and improve the lives of those affected. The NPF supports the psoriatic disease community through advocacy efforts at both the federal and state level, education, patient support and research funding. In the past fiscal year alone the NPF dedicated nearly $2.8 million in research grants and fellowships that help drive discoveries that may lead to more and better treatments and a cure. The NPF works closely with federal funding institutions to ensure our research portfolio and funding strategy compliments their work and supports the development of a robust community of researchers.

Psoriasis and psoriatic arthritis are chronic immune-mediated disorders. While the effects of psoriasis often appear on all areas of the body, about 30 percent of people affected by psoriasis also develop psoriatic arthritis, a disease in which the same underlying inflammation affects the joints. Additionally, psoriatic disease is also associated with several comorbidities including cardiovascular disease, metabolic syndrome and depression. There is currently no known cure for psoriasis and psoriatic arthritis. However, the advent of biologic medications over the past two decades and the continued innovation in this class of medicines is leading to new, more targeted and ultimately more efficacious treatments that are helping people with moderate-to-severe forms of psoriasis achieve longstanding remission of their disease.
Access to these varying treatment options is particularly important for the psoriatic disease community since the heterogeneous nature of this disease means that a drug that may work well for one person may have little to no effect on another. It is also not uncommon for the efficacy of therapies to wane, requiring patients to switch their medications and making access to multiple treatments critically important. Unfortunately, one of the single greatest barriers for Americans living with psoriatic disease is the challenge of affording their prescription medications, particularly these newer and more targeted biologic products. These issues are even more significant for our members who are Medicare beneficiaries because many of them live on fixed incomes and are not permitted to access the benefits associated with manufacturer assistance programs.

NPF applauds the efforts of CMS and the Department of Health and Human Services to address the high cost of prescription medications and remains committed to working with the Administration and Congress to identify and advance policies to lower health care costs, while recognizing the critical need for continuing research and innovation of new therapies for psoriatic disease and ultimately a cure. While we appreciate the attention to the issue of high costs and recognize the potential benefits associated with the ideas put forward, we have a number of concerns regarding the proposals to permit a second “preferred” specialty tier in Part D and to require implementation of a Real-Time Benefit Tool (RTBT). These points must be addressed fully before moving forward given the number of ramifications for beneficiaries, particularly those with chronic conditions like psoriatic disease. Our concerns are further outlined in the letter below.


NPF is intrigued by the proposal to create a second preferred, specialty tier within the Part D program and encourages CMS to continue to more fully research both the potential beneficiary benefits and challenges that could come through such a model. We see value in creating a new specialty tier as long as doing so would result in more affordable and accessible therapies for psoriatic disease patients. However, we have concerns about the consequences that may result if multiple or all therapies for our patient community were placed on a non-preferred tier. If this were to occur, beneficiaries with psoriatic disease would face additional cost and access hurdles to accessing the medications prescribed by their doctors. Further, such a formulary design would violate the requirements under 42 CFR §422.100(f)(2) that mandate CMS oversight to ensure that “MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services.” It is our hope that given these longstanding prohibitions, such concerns would not be triggered. We are also concerned about the potential consequences of a two-tiered specialty category on overall premium and beneficiary costs. For these reasons, we are pleased to offer the following comments for your consideration:
1. Tiering Exceptions & Two Specialty Tiers

We are apprehensive about the potential increase of premiums and cost-sharing requirements for non-specialty tiers that could result from such a proposed change to achieve actuarial equivalence. We applaud CMS for proposing to permit exceptions from the more expensive specialty tier to the preferred tier if an exceptions requirement is met. We seek additional information about the potential consequences associated with not requiring sponsors to permit exceptions between a drug on a specialty tier to a non-specialty tier.

Additionally, NPF has serious reservations about potentially permitting Part D sponsors to exempt drugs on a specialty tier from the tiering process altogether. As noted in our introductory comments, it is not uncommon for people with psoriasis or psoriatic arthritis to have to try multiple therapies or to cycle through several medications during their lifetime. For people who are stable on a product, any gates or barriers to continued affordable access to a medication that is enabling them to manage their disease could pose significant risks to their overall health. For these and other reasons, we oppose any proposals that could lead to exemption of one or multiple drugs on a specialty tier from any exceptions process. We strongly believe that if the appropriate clinical justifications are made that beneficiaries must have timely access to a specific treatment – particularly in cases where they may already be on drug, such as in the case of a beneficiary who is new to Medicare or who is switching Part D plans – that they should be entitled to an exception.

We support the agency’s view that the proposal would not change current regulations that require Part D sponsors to cover drugs for which a tiering exception was approved at the cost-sharing level that applies to the preferred alternative(s). We also support requiring Part D sponsors to permit tiering exceptions for Part D drugs from the higher cost-sharing, specialty tier to the preferred specialty tier if tiering exceptions requirements are met. Examples would include instances in which a therapy on the preferred specialty tier is contraindicated or has already been tried and found to be non-efficacious.

2. Maximum Allowable Cost Sharing and Two Specialty Tiers

We value the significant care and consideration CMS has put into understanding the impact any such proposal might have on beneficiary cost-sharing, particularly the risks that may fall on those beneficiaries who need to take drugs that fall on the higher cost-sharing tier. We specifically appreciate the concerns raised about potential discriminatory plan design that could emerge for these beneficiaries, which could well include beneficiaries impacted by psoriasis and psoriatic arthritis. We support in principal the proposal that the maximum allowable costs for the preferred specialty tier be less than the maximum allowable of the non-preferred tier. However, we have reservations about the proposal to not establish minimum difference between the two which could result in an outcome where the differences between the two options is de minimis in terms of meaningful impact on beneficiary costs.
To prevent this, we encourage CMS to consider additional structure on this aspect of its proposal so there would be a meaningful difference in beneficiary costs between the tiers while still providing flexibility to plans for negotiations. Additionally, we request specific consideration to ensure beneficiaries with psoriasis or psoriatic arthritis not find themselves in situations where they are subject to greater cost-sharing than under the current policies and request further detail and definition, including safeguards to protect beneficiaries from these threats.

3. Tier Composition and Two Specialty Tiers

Regarding the question of restricting the lower cost-sharing or preferred specialty tier for only generic drugs and biosimilars, including interchangeable products if and when available, NPF does not support such a limitation. Specifically, we are concerned that such a policy would preclude the newest innovative products – such as interleukin 17 and interleukin 23 inhibitors – from receiving preferred status. This means that if plans were to establish two specialty tiers, beneficiaries with psoriatic disease enrolled in such plans would always face the highest permitted maximum allowable cost sharing to access the latest treatment options. While beneficiaries would hopefully be able to obtain an exemption to a drug on the lower tier, NPF opposes any plan that would reserve the preferred tier for only generic or biosimilar options.

Implementation of a Real-Time Benefit Tool (RTBT) (42 C.F.R. §423.128)

In addition to the above comments on permitting the establishment of a second specialty tier, NPF wishes to offer comments on the proposed requirement that Part D sponsors implement a real-time benefit tool (RTBT) that plan enrollees can use to obtain up-to-date patient-specific formulary, cost and related information to inform their choice of medication. NPF supports policies that provide beneficiaries with accurate and meaningful information to inform their prescription medication choices while recognizing that clinical efficacy, evidence-based care standards or guidelines and provider recommendations must inform access.

In terms of information provided through RTBTs, we support the proposed inclusion of formulary data as well as plan utilization management requirements, including step or fail first measures, for every formulary drug. NPF has long led efforts at the state and federal levels to ensure that any step therapy measures be used appropriately and that plans maintain clear and transparent exemption processes and timelines for responses, along with some required exemptions – such as when a patient already unsuccessfully tried a drug required as a step. We propose that any RTBT include not only step requirements but also plan contact information, response timelines and any other pertinent information to further inform and empower beneficiary appeals.

We urge that the final proposal require, rather than simply encourage, plans to include the negotiated price of a drug along with the beneficiary cost-share amounts so beneficiaries will
understand a more complete cost picture. Additionally, we urge that RTBT regulations limit a
plan’s abilities to omit inclusion of certain drug from the data presented to the beneficiary and
that any such permitted exclusions be clearly defined and justified. Finally, we urge CMS to
proactively monitor the accuracy of all RTBTs, including that data be regularly updated and
reflect the latest pricing and other information as well as any potential abuse of the plan’s
discretion to choose which medication options should be presented in the RTBT. This oversight
could be done via secret shopping and incorporating reviews into CMS program audits. We also
recommend CMS confirm in the final rule a process for beneficiaries to files grievances with
plans if they believe the RTBT inappropriately excludes medication options.

**Conclusion**

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, VP of Government Relations and Advocacy at
pstone@psoriasis.org.

Sincerely,

Randy Beranek
President and CEO
National Psoriasis Foundation