July 16, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991–ZA49)

Dear Secretary Azar,

On behalf of the more than 8 million Americans living with psoriasis and psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to comment on the Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991–ZA49). 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. However, high cost and restrictive formulary practices mean that for many in our community, these therapies and their promised health improvements are simply out of reach.

We are particularly appreciative of the Administration’s stated commitment to reducing out-of-pocket costs for Americans. The psoriatic disease community is all too well aware of the impact high cost of treatments can mean for access, outcomes, and overall well-being. A 2018 NPF Advocacy survey of our members found that nearly 50 percent of psoriasis and psoriatic arthritis patients experienced financial strain due to the cost of their therapies. Additionally, across all insurance types, almost one in four patients spend more than $150 per month in out-of-pocket costs to access the treatments they need to manage their conditions. This number increases to one in three for Medicare beneficiaries enrolled in Part D drug plans. These figures demonstrate the stark reality our community faces and the difficult choices many are forced to make when it comes to treating their psoriatic disease, decisions that lead far too many people to undertreat or not treat their disease. Therefore, we welcome the discussion about ways to tackle costs that keep patients at the center of the conversation.

Background on Psoriatic Disease

The National Psoriasis Foundation exists to drive efforts toward a cure for psoriasis and psoriatic arthritis and to dramatically improve the health outcomes of individuals living with psoriatic disease. Psoriasis is an immune-mediated disease that affects approximately 3 percent of the adult U.S. population, totaling more than 8 million individuals in the United States. Up to 30 percent of individuals with psoriasis may also develop psoriatic arthritis, an inflammatory form of arthritis that can lead to irreversible joint damage if left untreated. Beyond the physical pain and discomfort of these diseases, individuals living with psoriatic disease also face higher incidence of comorbid health conditions, including cardiovascular disease, diabetes, hypertension, and stroke. A higher prevalence of atherosclerosis, Crohn’s disease, cancer, metabolic syndrome, obesity and liver disease are also found in people with psoriasis, as compared to the general population. In addition, those living with psoriasis have a 39 percent increased risk of being diagnosed with depression than those without the disease, while the risk of an anxiety diagnosis is 31 percent higher.
As heterogeneous chronic immune-mediated diseases, psoriasis and psoriatic arthritis require sophisticated medical care. Without medical management by dermatologists and rheumatologists as well as the tools to control their symptoms, people with psoriatic disease cycle through periods of intense pain, fatigue, unbearable itch, whole-body inflammation, flaking and bleeding of large swaths of the skin, and joint degradation. Recent research also suggests that the risk for comorbidities such as cardiovascular disease may increase with the severity of psoriatic disease, thereby magnifying the critical need for timely patient access to effective treatment options. Additionally, treatments that work for one person may not work for others, and many patients cycle through numerous accepted treatment options. As medicine becomes increasingly more personalized, we anticipate that far more patients will encounter such situations.

Success and Opportunities for the Psoriatic Disease Community

Included in the Blueprint are several areas that we think could have a positive impact on the psoriatic disease community. In particular, we are pleased to see the Administration’s focus on expanding the market for biosimilars. As the agency is aware, the NPF remains optimistic about the potential application of biosimilars as treatment options for our patient community. Beginning nearly two decades ago, biologics opened up a life-changing treatment category for many persons with psoriatic disease alongside existing treatments that include systemic therapies, phototherapy, and/or topicals. For many individuals, biologics have profoundly and dramatically changed their ability to manage their condition and live more comfortably with psoriatic disease. By helping persons keep their disease in check and well-managed, biologics have led to fuller and more productive lives for countless persons with psoriatic disease and other conditions, and have helped lessen costs associated with more intensive interventions such as hospitalizations. However, restrictive formularies, high patient cost sharing of these treatments, and insurance barriers such as step therapy or fail first policies, have limited access to biologics for a significant portion of our community. The NPF recognizes the role biosimilars could play in expanding access to such therapies and improving care for a greater number of psoriatic disease patients. To date, six of the 11 FDA-approved biosimilars are used to treat psoriasis or psoriatic arthritis, meaning our community is poised to be significantly impacted by the continued development, approval, and launch of these new products. Due to the unique nature of the disease, ensuring patient access to a wide range of therapies will maximize the chances that individual patients can find treatment regimens that are safe, effective, and affordable. We look forward to continued collaboration with HHS, the Centers for Medicare & Medicaid Policy (CMS), and the Food and Drug Administration (FDA) to ensure continued innovation in this area that increases the number of safe and effective treatments for psoriatic disease.

We are also encouraged by the steps the Administration has already taken to protect consumers from excessive charges for prescription medication due to pharmacy gag clauses. These gag clauses, which restrict or penalize pharmacists from disclosing the cost of the prescription and the availability of alternative and less costly payment options, such as paying by not using an insurance plan, can lead to inappropriately inflated prices for consumers. Patients should have access to the full range of information to make informed health care choices. Prohibiting these gag clauses is a reasonable approach to full disclosure that enables patients to treat their disease at the lowest possible cost. We hope insurers respond positively to the Administration’s directive to eliminate these clauses in plan contracts, and we stand ready to work with the Administration to ensure patients are not paying more than their insurer when purchasing a prescription drug that is essential to maintaining their health.

Overall, as the Department assesses ways to implement the policy proposals it has outlined, we urge you to keep the patient experience at the forefront. As potential reforms come together, they should reduce the financial burden on patients and should not limit access as a means to bring down system expenditures. Proposals that simply limit choices are not sustainable and do a disservice to the millions of Americans who rely on prescription drugs to treat their psoriasis and psoriatic arthritis. They also help contribute to overall increases in healthcare spending by limiting patient access to therapies that could help avoid more intensive and expensive procedures. With that principle in mind, below are some comments directed at areas of the Blueprint and RFI that the NPF believes could have a particularly large impact on our community and some areas of consideration for ensuring that any future reform proposals meet the stated aims of reducing out of pocket costs for health care consumers.
5-part plan to modernize the Medicare Part D

While many individuals living with psoriatic disease experience high out-of-pocket costs when accessing care, it is especially acute for Medicare beneficiaries with Part D coverage. In the Part D program, biologics used to treat psoriasis and psoriatic arthritis are routinely placed on specialty tiers of plan formularies, resulting in an average coinsurance rate of more than 30 percent of the drug costs and no access to tiering exceptions that are provided to other formulary tiers. A recent NPF Advocacy survey showed that nearly one in three Medicare beneficiaries who take a biologic report a monthly out-of-pocket cost of more than $200. Due to this burden, a full half of Medicare beneficiaries with psoriatic disease reported financial strain due to the cost of accessing biologics. In fact, a study of Medicare beneficiaries with psoriasis showed that those without access to the Low Income Subsidy (LIS) program (or ExtraHelp) were 70% less likely to receive a biologic as a consequence of the inability to pay.\textsuperscript{xvi}

We are pleased to see that CMS is considering potential policy proposals for applying some manufacturer rebates and pharmacy price concessions to the price of drugs at the point of sale. As CMS examines the best way to operationalize this reform, we encourage the agency to review a 2016 report released by the Institute for Clinical and Economic Review (ICER) on \textit{Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value}. Increasingly, psoriatic disease patients face coinsurance instead of copay rates, particularly for higher-cost biologic treatments. As ICER notes, “higher out-of-pocket costs put patients at high risk of coverage loss, bankruptcy, and inability to access effective treatment necessary to control a chronic disease.”\textsuperscript{xvii} The report demonstrates that even though rebates and manufacturer discounts are substantially more for psoriasis drugs, patient out-of-pocket payments are still based on the list price for these medications. To address this, ICER argues that “co-payment and/or co-insurance for therapies should be based on prices net of discounts and rebates instead of list price.”\textsuperscript{xviii} This would allow patients to share in savings from cost-effective treatment pathways, especially if part of a step therapy protocol. We believe this policy change could lead to improved access, increased medication adherence, and improved health outcomes and we are willing to serve as a resource as CMS evaluates options for implementation.

We are also pleased to see the proposal to eliminate cost sharing for generics for LIS beneficiaries. Reducing barriers to lower cost medications is a win-win for patients and the system as a whole and we appreciate the Administration’s leadership in this area.

The NPF is also encouraged to see the inclusion of proposals to cap out-of-pockets costs for those enrolled in Medicare Part D plans. Since the start of the program, we have seen a rise in specialty tiers and coinsurance rates for therapies that can result in patients paying as much as 33 percent of a drug’s list price for each medication they take. Additionally, patients with psoriatic disease have a high rate of comorbid conditions and, according to a recent study, Medicare beneficiaries with psoriasis take an average of 4.7 medications in addition to the ones used to treat their psoriatic disease.\textsuperscript{xx} The lack of an out-of-pocket cap that protections against catastrophic costs means that patients, many of whom are on a fixed income, can face thousands of dollars in out-of-pocket costs each year. These costs can also be unpredictable as beneficiaries do not usually have access to the drug list price to understand their coinsurance burden. A true cap would provide financial protection against unreasonable out-of-pocket costs, stability for beneficiaries, and make Medicare Part D more reflective of other health insurance programs.

However, we do not believe the implementation of an out-of-pocket cap should be paired with changes to the True Out-of-Pocket (TrOOP) calculation. Removing the manufacturers’ contribution could drastically increase the patient cost burden and ultimately be counterproductive in reaching the stated aim of reducing out-of-pocket costs and increasing access for patients. The NPF is a member of MAPRx, a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications in Medicare Part D and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The coalition commissioned a study on this policy when it was proposed by the Medicare Payment Advisory Commission (MedPAC) in 2016. That analysis showed that removing the manufacturer contribution from TrOOP would increase out-of-pocket costs for those beneficiaries who reach the catastrophic phase of the Part D benefit each year. It found that, on average, 1.1 million Part D enrollees would experience higher OOP costs each year between 2017 and 2021 and that total Part D beneficiary spending would increase by about $5.1 billion over the same period. OOP spending for each affected beneficiary would
increase by an average of almost $1,000 per year throughout the 5-year period. As more biologics and biosimilars are approved to treat psoriatic disease, our patient community is increasingly reliant on specialty medications and therefore particularly vulnerable to the negative implications of this particular reform. We again urge CMS to ensure that any future reforms do not make patients worse off than today’s status quo.

We also would strongly caution against implementing any Medicare Part D policy changes that aim to reduce costs by reducing access, such as allowing for more restrictive formularies. As stated previously, psoriasis and psoriatic arthritis are heterogeneous chronic diseases that require tailored treatment plans. Treatments that work for one person may not be effective for others, and a drug that works well for a person may decrease in efficacy over time. Given this reality, many of our patients cycle through a variety of accepted treatment options before finding the most effective therapies, or combination of therapies, a situation that necessitates access to a wide array of approved treatments. We urge the Administration to ensure continued access to treatments remains at the core of any policy proposals.

**Shifting Medicare Part B Drugs to Part D**

We understand the Administration is also interested in exploring ways to introduce the competition inherent in the Part D model into the Part B drug delivery system. We acknowledge the Administration’s intention to reduce costs to the system by increasing the ability to negotiate drug prices. However, we are concerned that depending on implementation of this policy, the millions of Medicare beneficiaries with psoriatic disease could end up bearing the burden of this change. Moving Part B therapies into Part D could increase both the cost and logistical burden on individuals with chronic and complex conditions. This policy change could means thousands more in out-of-pocket costs each year for already vulnerable populations. This could lead to reduced adherence and worse health outcomes for our community, and many others.

As outlined above, Medicare beneficiaries with psoriatic disease already face cost burdens that limit access. Currently, Medicare beneficiaries with psoriasis and psoriatic arthritis have access to therapies in both Part D and Part B. Some psoriatic disease treatment options can be accessed through only one of the Medicare prescription drug benefit programs but there are also a significant number of therapies that are available in both programs. This gives patients and providers options when assessing the best treatment choices to meet individual circumstances. Removing these options by moving Part B drugs into the Part D system could severely limit the choices that our community needs to find the most appropriate treatment for each individual.

Importantly, the cost sharing implications for accessing therapies across programs is substantially different. For a physician-administered biologic, a patient is responsible for 20 percent of the drug cost. For those that have a Medigap plan or other supplemental plans, that cost sharing can be significantly less or even zero dollars per treatment. However, to access that same biologic treatment in Part D most likely means a far larger cost sharing burden. As noted previously, most biologics used to treat psoriasis and psoriatic arthritis are found on the specialty tier of Part D plan formularies. That means the drugs are subject to an up to 33 percent coinsurance rate, with no access to supplemental coverage or tiering exceptions. This reform could cost an individual thousands of dollars more per year in out-of-pocket spending and, for many, would prohibit access to those that treatment. Patients accessing care through Part D are also subject to delays due to the high burden of prior authorization and step therapy inherent in the Part D model. These delays in treatment can lead to increased disease activity, loss of function, and possible irreversible disease progression.

At a recent NPF-hosted Congressional briefing on Medicare Access Challenges in the Chronic Disease Community, a patient advocate from Pennsylvania highlighted the struggle she faced in accessing the most appropriate therapy in Medicare. Because of the significantly larger cost-sharing burden in Part D, she was unable to afford any of the biologics covered by the program even when recommended as the most clinically appropriate drug by her physician. However, because the out-of-pocket burden is much lower in Part B, she could access physician-administered therapies to treat her psoriatic arthritis. It was only after recently qualifying for the Part D LIS program that she had access to the full range of treatment choices to manage her conditions. Proposals that would merge these programs could severely limit treatment choices for many in our community and effectively eliminate whole classes of drugs for individuals with chronic and complex conditions.
It is also not clear that this proposal would generate significant savings in the Medicare system. A review of the recently released Medicare drug spending dashboard showed that costs in the Part B system are not significantly higher than in Part D. For instance, infliximab (brand name Remicade) is a common psoriatic disease treatment that is available in both programs. In Part D, the average spending per beneficiary in 2016 was $28,282 while it was only $22,924 in the Part B program. Additionally, the dashboard shows that the change in average spending per dose unit was 1.34% in Part B but 6.61% in Part D. We recognize that there are program differences that limit a straight comparison of these figures but we think they are reflective of overall trends that could limit the cost savings of this proposal.

Additionally, we are concerned about the implications of this change on the practical considerations our patients make when managing their treatment regimes. By creating an extra step between Part B therapies and the physicians who administer them, the Administration could inadvertently shift the burden of collecting, transporting, and storing these sensitive medications to the patient. This could have implications for drug safety as well as potentially reduce adherence by making the process overly burdensome.

As the reform proposal develops, we would also appreciate more information on the implications of this policy on Part D premiums. We are concerned that moving a large number of specialty drugs into the Part D system will mean a dramatic rise in premiums. This could make the Part D program prohibitively expensive, especially for those with low incomes or those on multiple medications. We caution the Administration to carefully weigh the secondary effects of this plan and what it could mean for drug access more broadly for the Medicare population.

**Medicaid Formulary Demonstrations**

We are particularly concerned with the proposal included in the President’s FY19 Budget and referenced in the RFI to allow states to test offer closed formulary to Medicaid beneficiaries. As stated previously, treatment flexibility is required to ensure psoriatic disease patients have access to the full range of therapies needed to treat their condition over time. Policy reforms, especially those geared to the vulnerable Medicaid population, should not focus on cutting costs by reducing access to medically necessary treatments.

For instance, one Medicaid program, MassHealth in Massachusetts, covers more than a dozen medications classified as “immunomodulators” that are approved to treat psoriasis and/or psoriatic arthritis. We commend the Administration for recently rejecting the state’s proposal to move to a closed formulary, particularly given the potential precedent such an approval may have set. Reducing the state’s formulary to potentially one therapy per class could have devastating implications for patients trying to access care in these programs. We understand the implications of rising drug costs and appreciate the Medicaid programs long-standing commitment to ensuring that quality and effective therapies are offered through the Medicaid program. However, a 2016 Institute for Clinical and Economic Review (ICER) report found that, at the time of the report publication, all currently approved advanced therapies for psoriasis offer a good value. Ultimately, treatment decisions should be at the discretion of providers and patients and this reform could substantially limit the ability for physicians to prescribe the most appropriate medications for those living with psoriasis.

As many psoriatic disease patients know, the exceptions process to access medications restricted by formularies can be overly burdensome and can lead to worse health outcomes. These processes need to be clinically grounded with patient-centric guardrails if patients are not to experience harmful delays in necessary care. The ICER report referenced above also cautions against barriers to accessing treatments, including these kinds of utilization management protocols, which can prevent patients from accessing the therapy recommended by their doctor.

We appreciate your consideration of our comments. If you or your colleagues have any questions, please feel free to contact the NPF by reaching out to Jessica Nagro, Federal Government Relations & Health Policy Manager at jnagro@psoriasis.org or 503.546.5559.

Sincerely,


