September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: *Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)*

Dear Administrator Verma:

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 proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P). 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. We are encouraged to see CMS recognize in the proposed rule the value of phototherapy in managing various skin diseases, including psoriasis, by proposing an appropriate level of reimbursement for this treatment modality, especially phototherapy with type B ultraviolet light or UVB. We also offer comments, per the request in the rule, on the agency's Medicare Part B biosimilar biological product payment policy. The psoriatic disease community is uniquely positioned on this issue. There are a number of biologic and biosimilar therapies that have already been approved in our space which – in a 2016 Institute for Clinical and Economic Review (ICER) review – were found to be "of good value."[i] However, research has demonstrated that some in our community who receive care through Medicare struggle with accessing advanced therapies due to cost (as evidenced by the lower rates of utilization of biologics when these patients do not have low income subsidies[ii]).

<u>Photochemotherapy (CPT Code 96910)</u>

Phototherapy, or light therapy (PUVB), is used to treat and manage various skin and related disorders, including psoriasis and psoriatic arthritis. In addition, the treatment benefits millions of Americans living with eczema, cutaneous lymphoma, and vitiligo, among other dermatologic disorders. Phototherapy, combined with topical

coal tar (also known as Goeckerman regimen) or petrolatum, is considered medically necessary for individuals with severe psoriasis (defined as psoriasis that affects more than 10 percent of body surface area).

Phototherapy is a well-proven, safe, and effective therapy most commonly administered in a physician's office or hospital outpatient setting. For individuals with severe psoriasis who are unable to receive treatment in an office setting or who need to initiate therapy immediately, home phototherapy is also an essential option. Phototherapy is a particularly necessary treatment option for certain patients, such as persons with suppressed immune systems who might not be a candidate for biologic treatments, pregnant women, and pediatric patients.

The NPF is encouraged to see CMS's recognition of the value of this therapy, reflected in the increased payment rate proposed for CY18. We are, nonetheless, concerned to see that the agency is considering reductions on clinical staff time and lower prices on supply items used for photochemotherapy. CMS should retain the RUC recommended times to prepare and position patient/monitor patient/setup IV (15 minutes), monitor patient during procedure (16 minutes), and clean room/equipment by physician staff (15 minutes) and not adopt the significant reductions to these times under consideration. As the agency knows, the NPF was very concerned about past reductions to phototherapy CPT codes and the impact these cuts have had on beneficiary access. The proposed Relative Value Units for CPT code 96910 in particular will help address these concerns and, we hope, restore and sustain greater Medicare beneficiary access to this treatment option. The body of evidence clearly demonstrates the effectiveness of this therapy, and this proposed increased rate – and no reductions to clinical staff time and supply item prices - will help ensure more providers offer this medically necessary treatment option.

As the nation grapples with the challenges of high-cost medicines, it is worth noting that phototherapy can delay or minimize the need for more expensive biologic and novel medications, helping control federal healthcare costs overall. As such, the NPF enthusiastically supports the clinical and economic benefits of this proposed change and we encourage CMS to move forward with finalizing this increase in the CY18 final rule. Phototherapy is a critical treatment option for psoriasis patients and providers and, therefore, should be appropriately reimbursed to ensure beneficiaries have continued access to this safe and effective option.

Payment for Biosimilar Biological Products

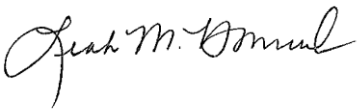
The agency has also requested input on CMS' Medicare Part B biosimilar biological product payment policy, which went into effect January 1, 2016. CMS has specifically requested new or updated information on the marketplace. As the agency is aware, the NPF remains optimistic about the potential use of biosimilars as treatment options for our patient community. As was shared by many living with psoriatic disease during a 2016 Food and Drug Administration Patient Focused Drug Development meeting on psoriasis in March 2016, the introduction of biologic products to treat psoriasis and psoriatic arthritis was a significant advancement in the care for those with psoriatic disease. Biologics opened up a new world of combination therapies with their use alongside systemic treatments, 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.

Regrettably, 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. As such, the NPF recognizes the role biosimilars could play in expanding access to such therapies and improving care for a great number of psoriatic disease patients. As the agency considers future changes to the current policy, we encourage you to keep the patient at the center of these deliberations. As ICER noted in their December 2016 final report following a review of psoriasis therapies, "[h]igher 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."[iii] We would also encourage the agency to review a study by the Perelman School of Medicine at the University of Pennsylvania that found "psoriasis patients who do not have low income subsidy (LIS) – additional coverage provided for prescription drugs, also known as Medicare Extra Help – as part of their

Medicare prescription drug coverage (Part D) plan are less likely to receive biologics than Medicare recipients with full low income subsidy benefit."[iv] Released in the December 2015 issue of the *Journal of Investigative Dermatology*, these findings are the "first to suggest the presence of economic and racial barriers that impact the treatment of moderate to severe psoriasis."[v] Given both of these reviews, the NPF urges the agency to bear in mind any patient impact a pricing policy may have – both intended and unintended. 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 and effective. The nature of these therapies also calls for a nuanced approach to determining pricing structures that encourage innovation and maintain opportunities for additional therapy development. Medicare payment policies should be transparent and clear to patients while enabling access to therapies at the lowest rate possible.

Thank you, again, for recognizing the value of phototherapy for the psoriasis community and adjusting the CY18 rate appropriately. We also appreciate the consideration you are giving to the impact of pricing policies for new therapies on the marketplace and the ultimate consumer of these therapies – the patients. 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,



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[i] Institute for Clinical and Economic Review. Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value . Final Evidence Report, Institute for Clinical and Economic Review. 2016.
[ii] Takeshita, Junko et al. Psoriasis in the US Medicare Population: Prevalence, Treatment, and Factors Associated with Biologic Use Journal of Investigative Dermatology. 2015. Dec; 135(12), 2955 – 2963.
[iii] Institute for Clinical and Economic Review. Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value . Final Evidence Report, Institute for Clinical and Economic Review. 2016.
[iv] Takeshita, Junko et al. Psoriasis in the US Medicare Population: Prevalence, Treatment, and Factors Associated with Biologic Use Journal of Investigative Dermatology. 2015. Dec; 135(12), 2955 – 2963.
[v] Ibid.