NATIONAL PSORIASIS FOUNDATION
50 YEARS

Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

January 16, 2018

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

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-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 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs For Contract Year 2019 (CMS-4182-P)*. As the patient advocacy organization for the psoriatic disease community for more than 50 years, the NPF understands the critical role that prescription drug coverage plays in ensuring our community is able to treat the disease to the level of its severity. Since its creation, the Medicare Part D program has assisted millions of Medicare beneficiaries better manage their complex chronic conditions by enhancing access to vital prescription medications. We are encouraged to see the Centers for Medicare and Medicaid Services' (CMS) commitment to expanding access and reducing costs for beneficiaries and are pleased to have this opportunity to discuss the impact some of these proposed changes could have on our community going forward.

Background on Psoriasis

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 the most prevalent autoimmune disease in the United States, affecting approximately 3 percent of the adult U.S. population.[i] 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.[ii] 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,[iii] diabetes[iv], hypertension[v], and stroke[vi]. A higher prevalence of atherosclerosis[vii], Crohn's disease[viii], cancer[ix], metabolic syndrome[x], obesity[xi] and liver disease[xii] 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.[xiii]

As heterogeneous chronic autoimmune 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.[xiv] Additionally, treatments that work for one person may not work for others, and many patients cycle through numerous accepted treatment options.[xv] As medicine becomes increasingly more personalized, we anticipate the far more patients will encounter such situations. Adding to the burden of the disease are insurance policies and practices that erect barriers for patients in urgent need of treatment. These barriers include narrow provider networks, fail-first or step therapy protocols that prevent or delay access to a clinically recommended therapy, increased patient cost-sharing, and a lack of transparency in benefit design.

Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

We appreciate CMS's recognition of increasingly complex plan benefit packages (PBPs) with more variation in type and level of cost-sharing across formulary tiers. We are pleased that CMS is interested in updating regulations to more accurately reflect current practice and to ensure all enrollees have access to needed drugs at the most favorable cost-sharing terms possible. However, we are troubled that these reforms do not extend to medications listed on specialty tiers.

The psoriatic disease community has greatly benefited from the introduction of biologic products, but the realization of these benefits has been limited for too many persons because access to these therapies is increasingly restricted by their placement on specialty tiers. As was shared by many persons living with psoriatic disease during a Food and Drug Administration (FDA) Patient Focused Drug Development meeting on psoriasis in March 2016, biologic products to treat psoriasis and psoriatic arthritis have led to 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. Unfortunately, insurance policy design, including the higher cost sharing inherent in specialty tier medications, has limited access to these critical therapies. This has contributed to the fact that over 50% of patients with psoriasis remain dissatisfied with their treatment, despite the introduction of new therapies.[xvi] This has broader economic impacts as patients with inadequately treated psoriatic disease have significantly reduced work productivity and recent data suggest the cost of psoriasis to the US economy is approximately $112 billion annually.[xvii] [xviii]

As the proposed rule notes on page 56371, specialty tiers were used by 99.8 percent of tiered Part D plans in 2017. These tiers increasingly include all biologic medications, meaning an entire class of drugs is restricted for use by our community. In fact, a 2015 study of Medicare Part D coverage for high cost specialty drugs for rheumatoid arthritis, a similar autoimmune disease, found that 95 percent of Part D plans placed disease modifying biologic treatments on specialty tiers.[xix] As the threshold for specialty tier inclusion is a fixed dollar amount, higher cost medications will continue to be placed on a tier with limited patient protections.

We suggest CMS reconsider the proposed reforms and expand the more patient-friendly tiering exception process to specialty tier medications. Expanded access to tiering exceptions could be particularly beneficial because a recent study suggests that non-Low Income Subsidy (LIS) beneficiaries have reduced access to biologic treatments. The study, by the Perelman School of Medicine at the University of Pennsylvania, found psoriasis "patients without a Medicare Part D low-income subsidy (LIS) had 70% lower odds of having received biologics than those with LIS."[xx] Published 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."[xxi] An additional study, published this month in the *Journal of the American Academy of Dermatology*, highlights further treatment barriers faced by racial minorities. The study shows that black, Asian, and other non-Hispanic minorities are approximately 40 percent less likely to see a dermatologist for psoriasis than whites.[xxii] Even though studies have shown that psoriatic disease can be more severe in minority populations, these communities are both less likely to see a dermatologist for their condition and,

those who have access to a specialist, see the physician less frequently than non-Hispanic white patients.[xxiii] Continuing to restrict access to patient-friendly tiering exception protocols for these therapies will only exacerbate these existing disparities and lead to worse health outcomes for many in the Medicare population with psoriatic disease.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

We are concerned with the proposed reforms to midyear formulary changes, particularly as they relate to reducing the required notification period such changes. The proposal to allow plans to make immediate formulary changes - even during the first 60 days of a plan year –without specific advanced notice to beneficiaries, coupled with the removal of transition fills in these instances, could diminish access to therapies for the psoriatic disease community. However, we appreciate CMS's clarification that this new policy would not apply to follow-on biologic products, also known as biosimilars, because under current FDA guidance, these therapies have not been classified as interchangeable.

Requiring Part D plans to provide prospective and current enrollees with general notice that certain generic substitutions could occur without additional specific advance notice of formulary changes is inadequate to ensure that beneficiaries continue to receive the clinically recommended care they need. By not giving beneficiaries direct advanced notice of formulary changes, you limit the ability for individuals to proactively seek coverage determinations and exceptions. Additionally, you may also restrict the ability for patients to better prepare for cost sharing changes and copay/coinsurance increases. By only providing general notice in advance, patients could be surprised by medication or cost sharing changes at the pharmacy counter. This could delay needed care for the millions of Americans living with complex chronic conditions, like psoriatic disease.

As stated on page 56413 of the proposed rule, "the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled." Due to the ability for therapies to profoundly change the lives of those living with psoriatic disease, many in our community carefully choose their insurance plans, including selecting offerings with higher premiums and other costs, to ensure coverage of needed medications. Reforms that increase plan flexibility to the point of diminishing patient access to information reduce the confidence patients should have that the plan contact they agreed to will be upheld. We strongly suggest CMS reconsider the proposals to reduce notification requirements for midyear formulary changes.

Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

We are concerned with the proposal to establish limitations for the Part D Special Election Period (SEP) for dually eligible and low-income subsidy (LIS) beneficiaries. As noted in the proposed rule, less than less than 10 percent of the LIS population used the SEP in 2016. However, due to the size of the LIS population, this equates to over one million elections and, of this group, more than a quarter used more than one SEP.[xxiv]

We think this proposed change is especially concerning when coupled with the proposal to expand mid-year formulary changes. Combined, these proposals could vastly limit the ability for particularly vulnerable beneficiaries to access the medications they need to properly manage their care. Going forward, beneficiaries could be faced with multiple surprise mid-year formulary changes. Limiting SEP will mean these individuals do not have the recourse to switch Part D plans that are a better fit for their health care needs. This could lead to reduced medication adherence and worsening health outcomes. As previously highlighted, psoriatic disease patients rely on a variety of therapies to treat their disease to the level of its severity. Expanding the ability for Part D plans to reduce access to medications throughout a plan year while diminishing the ability for LIS beneficiaries to switch to plans that meet their specific health needs could jeopardize the health of thousands of beneficiaries. We urge CMS to continue with current policy, especially while the implications of any proposed midyear formulary reforms are uncertain.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

We appreciate CMS's efforts to lower cost sharing for follow-on biologic treatments for non-LIS catastrophic coverage and LIS cost sharing. The NPF recognizes the role biosimilars could play in expanding beneficiary access to innovative therapies and improving care for a great number of psoriatic disease patients. Similar to the advances in treatment and improved quality of life that have stemmed from the introduction of biologics, we are optimistic of the promise of biosimilars in advancing care for our community. As CMS highlights, lower cost sharing for lower-cost alternatives could improve enrollee incentives to choose follow-on biological products and subsequently reduce costs to both Part D enrollees and the Part D program, and we appreciate CMS's willingness to make these types of reforms that ease patient access.

However, the nature of follow-on biologic therapies calls for a nuanced approach to determining payment structures. At its core, Medicare payment policy should be transparent and clear to patients while enabling access to therapies at the lowest possible rate. While this reform could have positive implications for some biosimilar cost sharing, these therapies are still disadvantaged by Part D policies concerning treatment of biosimilars in the coverage gap. Due to coverage gap policies, psoriasis and psoriatic arthritis patients who choose a biosimilar therapy still face higher out-of-pocket exposure than they would for a reference biologic. In addition, coverage gap policies provide an added disincentive for Part D plans to offer biosimilars, as their financial commitment is larger for the follow-on biologics than the reference biologic. Layering this proposed reform onto the current coverage structure would provide some relief but only to a limited segment of Medicare Part D enrollees and would not address more macro considerations of biosimilar policy.

Over the last two years, five biosimilars have been approved by the FDA to treat psoriatic disease and two of those have entered the market. While the two therapies that are currently available are physician administered and therefore not subject to these cost-sharing reforms, our community is optimistic about the upcoming availability of Part D covered biosimilars to treat psoriasis and psoriatic arthritis. Therefore, we believe now is a critical time for CMS to put forward a comprehensive biosimilar coverage policy. We appreciate CMS's desire to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We believe the psoriatic disease community would be best served by a consistent and cohesive approach to biosimilars coverage that would go further in advancing the shared goal of reducing costs to both Part D enrollees and the Part D program.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

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 *Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value*. Increasingly, psoriatic disease patients face coinsurance instead of copays 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."[xxv] The report demonstrates that rebates and manufacturer discounts are substantial more for psoriasis drugs, however, 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."[xxvi] 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.

Thank you for your attention to our comments. We appreciate your commitment to increasing beneficiary access and hope our comments are helpful in ensuring that psoriatic disease patients are able to fully realize the stated benefits of your reform proposals. 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,

Patrick Stone
Vice President, Government Relations and Advocacy

[i] Helmick CG, Lee-Han H, Hirsch SC, Baird TL, Bartlett CL. Prevalence of Psoriasis Among Adults in the U.S: 2003–2006 and 2009–2010 National Health and Nutrition Examination Surveys. American journal of preventive medicine. 2014;47(1):37-45. doi:10.1016/j.amepre.2014.02.012.

[ii] Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis. 2005;64(suppl 2):ii14–ii17. - See more at: http://www.rheumatologynetwork.com/psoriatic-arthritis/classification-criteria-psoriatic-arthritis-caspar#sthash.Or6zBLgM.dpuf

[iii] Neimann AL, Shin DB, Wang X, Margolis DJ, Troxel AB, Gelfand JM. Prevalence of cardiovascular risk factors in patients with psoriasis. Journal of the American Academy of Dermatology. 2006; 55(5):829-35. **And:** Prodanovich S, Kirsner RS, Kravetz JD, Ma F, Martinez L, Federman DG. Association of psoriasis with coronary artery, cerebrovascular, and peripheral vascular diseases and mortality. Archives of Dermatology. 2009 Jun; 145(6):700-3.

[iv] Armstrong AW, Harskamp CT, Armstrong EJ. Psoriasis and the risk of diabetes mellitus: a systematic review and meta-analysis. JAMA Dermatology. 2013 Jan; 149(1): 84-91.**And:** Neimann AL, Shin DB, Wang X, Margolis DJ, Troxel AB, Gelfand JM. Prevalence of cardiovascular risk factors in patients with psoriasis. Journal of the American Academy of Dermatology. 2006; 55(5):829-35.

[v] Robinson D Jr., Hackett M, Wong J, Kimball AB, Cohen R, Bala M; the IMID Study Group. Co-occurrence and comorbidities in patients with immune-mediated inflammatory disorders: an exploration using US healthcare claims data, 2001-2002. Current medical research and opinion. 2006; 22(5):989-1000. **And:** Armstrong AW, Harskamp CT, Armstrong EJ. The association between psoriasis and hypertension: a systematic review and meta-analysis of observational studies. Journal of Hypertension. 2012 Dec 15. [Epub ahead of print]

[vi] Gelfand JM, Dommasch ED, Shin DB, Azfar RS, Kurd SK, Wang X, Troxel AB. The Risk of Stroke in Patients with Psoriasis. Journal of Investigative Dermatology. 2009; 129, 2411–2418.

[vii] Prodanovich S, Kirsner RS, Kravetz JD, Ma F, Martinez L, Federman DG. Association of psoriasis with coronary artery, cerebrovascular, and peripheral vascular diseases and mortality. Archives of Dermatology. 2009 Jun; 145(6):700-3.

[viii] Najarian DJ, Gottlieb AB. Connections between psoriasis and Crohn's disease. Journal of the American Academy of Dermatology 2003; 48:805-21.

[ix] Gelfand JM, Shin DB, Neimann AL, Wang X, Margolis DJ, Troxel AB. The risk of lymphoma in patients with psoriasis. Journal of Investigative Dermatology. 2006 Oct; 126(10):2194-201.

[x] Azfar RS, Gelfand JM. Psoriasis and metabolic disease: epidemiology and pathophysiology. Current Opinion in Rheumatology. 2008; 20(4)416-22. **And:** Armstrong AW, Harskamp CT, Armstrong EJ. Psoriasis and metabolic syndrome: A systematic review and meta-analysis of observational studies. Journal of the American Academy of Dermatology. 2013 Apr; 68(4):654-62.

[xi] Ogden CL, Fryar CD, Carroll MD, Flegal KM. Mean body weight, height and body mass index, United States 1960-2002. Advance Data 2004; 347:1-17.

[xii] Robinson D Jr., Hackett M, Wong J, Kimball AB, Cohen R, Bala M; the IMID Study Group. Co-occurrence and comorbidities in patients with immune-mediated inflammatory disorders: an exploration using US healthcare claims data, 2001-2002. Current medical research and opinion. 2006; 22(5):989-1000.

[xiii] Kurd SK, Troxel AB, Crits-Christoph P, Gelfand JM. The risk of depression, anxiety and suicidality in patients with psoriasis: A population-based cohort study. Archives of dermatology. 2010;146(8):891-895. doi:10.1001/archdermatol.2010.186.

[xiv] Naik HB, Natarajan B, Stansky E, Ahlman MA, Teague H, Salahuddin T, Ng Q, Joshi AA, Krishnamoorthy P, Dave J, Rose SM, Doveikis J, Playford MP, Prussick RB, Ehrlich A, Kaplan MJ, Lockshin BN, Gelfand JM, Mehta NN. Severity of Psoriasis Associates With Aortic Vascular Inflammation Detected by FDG PET/CT and Neutrophil Activation in a Prospective Observational Study. Arterioscler Thromb Vasc Biol. 2015 Dec;35(12):2667-76. doi: 10.1161/ATVBAHA.115.306460. Epub 2015 Oct 8.

[xv] Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. Journal of Investigative Dermatology Symposium Proceedings. 2004 Mar; 9(2):136-9

[xvi] Armstrong, A.W., Robertson, A.D., Wu, J., Schupp, C., and Lebwohl, M.G. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States: findings from the National Psoriasis Foundation surveys, 2003-2011. JAMA Dermatol. 2013; 149: 1180–1185

[xvii] Armstrong, A.W., Schupp, C., Wu, J., and Bebo, B. Quality of life and work productivity impairment among psoriasis patients: findings from the National Psoriasis Foundation survey data 2003-2011. PLoS One. 2012; 7: e52935

[xviii] Brezinski, E.A., Dhillon, J.S., and Armstrong, A.W. Economic burden of psoriasis in the United States: a systematic review. JAMA Dermatol. 2015; 151: 651–658

[xix] Yazdany, J., Dudley, R. A., Chen, R., Lin, G. A., & Tseng, C.-W. (2015). Coverage For High Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D. Arthritis & Rheumatology (Hoboken, N.J.), 67(6), 1474–1480. http://doi.org/10.1002/art.39079

[xx] 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.

[xxi] Ibid.

[xxii] Fischer, Alexander H. et al. Health care utilization for psoriasis in the United States differs by race: An analysis of the 2001-2013 Medical Expenditure Panel Surveys, Journal of the American Academy of Dermatology , Volume 78 , Issue 1 , 200 - 203

[xxiii] Ibid.

[xxiv] CMS-4182-P page 56375

[xxv] 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.

[xxvi] Ibid.