July 20, 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

Re: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements [CMS-2482-P]

Dear Administrator Verma:

On behalf of the more than eight million individuals in the US living with psoriasis including many that also have psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) proposed rule to facilitate the adoption of value-based purchasing (VBP) arrangements, update definitions affecting Medicaid drug rebates, and amend reporting requirements for Medicaid best price.

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, provider and patient education, patient support and research funding. Earlier this month, the NPF announced $3.28 million in research grant and fellowship awards to help drive discoveries that may lead to more and better treatments, better clinical care and eventually a cure.

Psoriasis is a chronic immune-mediated disease often manifesting on the skin but characterized by systemic inflammation. About 30 percent of people affected by psoriasis also develop psoriatic arthritis, a disease in which the same underlying inflammation affects the joints.\(^1\) Psoriatic disease is also associated with several comorbidities including but not limited to cardiovascular disease, metabolic syndrome and depression.\(^2\) Biologic medications have provided those living with chronic and inflammatory conditions more targeted and ultimately


more efficacious treatment options. However, these treatments are often costly and can lead to high out-of-pocket costs for patients.

NPF appreciates the Administration’s continued focus on ways to reduce the financial burdens that pharmaceutical costs place on our community, and we appreciate this proposal promoting value-based payment arrangements. While NPF supports the overall aim of the proposed rule to remove regulatory barriers for value-based payment contracts, our letter also expresses concerns regarding other provisions that could negatively affect patient access to potentially life-changing treatments. Our comments and concerns are further outlined in the letter below.

**Value-Based Purchasing Arrangement (VBPs) Definition**

We appreciate CMS’ effort to address regulatory hurdles that are often cited by a diverse set of stakeholders as barriers to participating in VBPs in the Medicaid program. These unique arrangements offer a possibility to increase patient access to these often expensive, life-changing treatments while providing states the opportunity to better predict and manage prescription drug spending in Medicaid. As CMS examines what evidence and outcomes-based measures should be used in VBPs, it’s important to understand that a one-size-fits-all approach does not account for the challenging nature of managing many heterogeneous chronic diseases, including psoriatic disease.

In the proposed rule, CMS seeks to define VBP’s as “an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population,” including evidence and outcomes-based measures which link the cost of a treatment to its effectiveness and performance in a patient population. CMS is soliciting “suggestions for other measures and a rationale for the suggested measures that could be used to reflect value from a drug therapy.”

The patient perspective should be a leading voice in defining “value” in the health care system. In 2016, the Institute for Clinical and Economic Review (ICER) conducted a review of eight psoriasis therapies to determine their effectiveness and value to patients. NPF provided extensive feedback to ICER throughout that process in order to share the expertise of our patients, clinicians and researchers on the real-world challenges and realities of treating psoriatic disease. We highlighted the importance of accounting for the heterogeneity of chronic diseases such as psoriasis and psoriatic arthritis as well as patient preferences in determining the value of a treatment. The report found that all eight treatments were “of good value” and recommended that insurers expand access to these treatments. Unfortunately, despite such findings, there has been little improvement in access to the reviewed therapies in the four years since the report was published.

On May 28, 2020, NPF convened our fifth annual payer advisory panel. These discussions engage payers, pharmacy benefit managers, employer stakeholders and others to better

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understand challenges impeding patient access to therapies to psoriatic disease. This year’s event included a session on value-based payment models where payers shared their experiences with these models and explored potential opportunities for developing such models for psoriatic disease treatments. During the conversation, multiple stakeholders expressed how the heterogeneity of psoriatic disease, both as a chronic disease and in individual patients, makes these models difficult for psoriatic disease treatments. Disease presentation varies across our patient population from different locations on the body, different systemic symptoms, different severity, and varied response to different treatments. These varying levels of the disease impact a patient’s quality of life. The underlying systemic nature of the disease, personalized outcomes associated with treatments along with the lack of definitive response biomarkers and appropriate clinical outcomes measures were cited as challenges for creating value-based arrangements for psoriatic disease treatments. There is currently no value-based payment arrangement which has fully incorporated some of the newer, more efficacious biologics so it is difficult to assume what factors would increase manufacturer and pharmacy benefit managers (PBM) interest in pursuing such arrangements.

For the psoriatic disease community, criteria that should be included for an evidence or outcomes-based measure in VBPs to determine value include percentage of skin clearance, body surface area coverage, and location of the disease. Measures should also extend beyond disease-specific measures to include symptom improvement, treatment-related adverse events, health-related quality of life, treatment durability and systemic manifestations, as well as data for evidence about the comparative effectiveness of targeted immunomodulatory treatments in affecting domains such as itch, scaling, pain, quality of life, work productivity, and patient satisfaction with treatment.

We urge CMS to ensure that these evidence and outcome-based measure definitions rely on documented evidence that supports the outcomes that matter most to patients and the measures being used to judge success or failure are robust. We also ask that CMS ensure the definition is not too prescriptive to inhibit the evolution of innovative contracting arrangements in the future that can have significant benefit to patients.

**Definition of Best-Price**

Medicaid best price requirements have consistently been cited by manufacturers as a barrier for stakeholders to enter value-based payment contracts. We appreciate CMS’ attempt to provide flexibilities by creating both a best price in the traditional sense and a set of “best prices” for treatments under VBPs. However, we have concerns about the implementation of such a change on the current system and the potential for patients in disease communities not utilizing a VBP. As stated earlier in our comments, stakeholders have expressed the difficulties of entering into such arrangements for psoriatic disease treatments due to the heterogeneity and complexity of the disease and the related comorbidities. We ask that CMS provide further detail regarding the implementation of this program and the overall impact multiple best prices will have on the marketplace and coverage of treatments in Medicaid programs.
Definition of Line Extension

In the proposed rule, CMS is proposing to broaden the definition of “line extension” and “new formulation” for treatments. Specifically of interest to NPF, CMS is requesting comments about “whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation.” Biologic treatments are often used to treat chronic disease patients who have multiple comorbidities that may not be explicitly indicated by the Food and Drug Administration (FDA). Therefore, we ask that CMS not consider new or expanded indications to treat chronic conditions such as psoriatic disease as a new formulation under the proposed “line extension” definition. We believe the exception to this rationale is in the case there is an adjustment to a patient’s treatment regimen or mode of administration. Switching from a subcutaneous injection to an intramuscular injection would directly affect the formulation’s interaction in the body therefore potentially qualifying as a “new formulation.”

NPF is concerned about the effects of patient access to treatments that will now qualify as “line extensions” under this broader definition. Given the limited 30-day comment period, it is difficult to fully respond to which aspects of the redefinition will have negative and positive impacts on our patient community. We request that CMS narrow the redefinition of line extension in future rulemaking with adequate time for stakeholder to consider the impact and comment.

Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs from Determination of Best Price

We agree with CMS that the full amount of patient assistance programs should be passed directly onto the patient and not be used as a benefit to a health plan. NPF has previously submitted comments to CMS in response to the 2021 Notice of Benefit and Payment Parameters final rule expressing our disappointment with CMS’ decision to finalize its proposal that permits health insurers to not count copay assistance from drug manufacturers toward a patient’s annual out-of-pocket obligations and continue to advocate that CMS reverse this policy.

In the proposed rule, CMS states that “manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient,” but does not provide further guidance on how they do so. We are concerned about the impact this change will have on patient access to these critical patient assistance programs and ask that CMS outline specific patient guardrails to ensure the provision on cost-sharing assistance has the intended effect of eliminating inappropriate use of manufacturer assistance while protecting people who rely on assistance to afford their medications.

Patients with serious and chronic conditions such as psoriatic disease often rely on specialized treatments (some of which may be high cost) to adequately treat their conditions and rely on patient assistance programs to access those treatments. In a 2019 NPF survey of people with psoriasis.

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psoriatic disease, 55 percent of individuals with commercial insurance reported using a manufacturer assistance program.⁶ Studies have demonstrated that when facing high out-of-pocket costs, many patients do not use their medications appropriately. For example, patients report skipping doses in order to afford some level of treatment or, in the worst situations, abandoning treatment altogether. According to several studies, prescription abandonment rates increase significantly when cost-sharing exceeds $100.⁷

Many patients find themselves saddled with surprise high out-of-pocket costs by plans that are frequently not transparent about their use of these copay accumulator or maximizer programs.⁸ This lack of transparency and prevalence of copay accumulators could make it more difficult for manufacturers to ensure the patient is receiving the full value of their patient assistance. In order to comply with CMS’ rulemaking, manufacturers may decide to limit or no longer offer patient financial assistance for some products, given the implications of noncompliance with AMP and Medicaid best price. We are concerned that immediate implementation of such a sweeping proposal would create chaos and confusion with patient assistance programs, something patients living with chronic disease cannot afford. Therefore, we ask CMS to provide more insight into consider potential incremental approaches of finalizing this proposal so as not to have a negative effect on patient access.

**Conclusion**

NPF thanks CMS and the Administration for efforts to address high prescription drug spending and out-of-pocket costs for patients. We appreciate your attention to the comments made by NPF on behalf of the millions of individuals in the US who live with psoriatic disease. Should you wish to reach us to discuss any of our suggestions please contact Hannah Lynch, Associate Director of Federal Government Relations and Health Policy at hlynch@psoriasis.org.

Sincerely,

Dr. April Armstrong, M.D  
Chair, National Psoriasis Foundation Medical Board  

Patrick Stone  
Vice President, Government Relations & Advocacy  
National Psoriasis Foundation

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⁶ 2019 NPF Advocacy Survey  