Help Us Solve
The Cruel Mystery
LUPUS™
FOUNDATION OF AMERICA

VIA ELECTRONIC DELIVERY

December 31, 2018

The Honorable Seema Verma
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8013

RE: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (Docket No. CMS-5528-ANPRM)

Dear Administrator Verma,

On behalf of the Lupus Foundation of America (LFA), I am writing to provide comments to the Centers for Medicare & Medicaid Services' (CMS) Advance Notice of Proposed Rulemaking entitled *International Pricing Index Model for Medicare Part B Drugs*. LFA appreciates the opportunity to provide feedback to this proposal in order to ensure the needs of people living with lupus and other chronic conditions and illnesses continue to be well-served by Medicare Part B.

The Lupus Foundation of America is the largest publicly-supported lupus organization devoted to solving the mystery of lupus, one of the world's cruelest, most unpredictable and devastating diseases. Through a comprehensive program of research, education, and advocacy, we lead the fight to improve the quality of life for all people affected by lupus. LFA has a strong commitment to advancing lupus research for both adult and pediatric populations and does this through a variety of methods including funding research, building collaborative research partnerships, and advocating for increased federal research funding.

Lupus is a chronic autoimmune disease that can impact any part of the body including the heart, lungs, kidneys, joints, and skin. Symptoms are heterogeneous both across the overall population with the disease and across individual patients' lifetimes. Common symptoms include extreme fatigue, joint and muscle pain, rashes, photosensitivity, organ inflammation, and, in many advanced stages of the disease, kidney damage or failure. Estimates suggest that at least 1.5 million Americans are living with lupus, although research into lupus prevalence is limited – the actual number may be much higher. Although the disease also impacts men and children, the majority of people diagnosed with lupus are women, with 80% of new diagnoses made during childbearing years[i]. Lupus also disproportionately impacts women of color, who are twice as likely to develop the disease as Caucasian women.[ii]

To date, only four treatments for lupus have been approved by the FDA, and only one of those treatments was specifically developed to treat lupus. Antimalarials, immunosuppressants, non-steroidal anti-inflammatory drugs, and corticosteroids are often among the first treatments prescribed to those with lupus. Individuals with lupus also use a variety of over-the-counter medications, supplements, and non-pharmacologic treatments. Unfortunately, many of these therapies can have severe side effects and the disease is often poorly managed. A survey of over 2,000 lupus patients conducted by LFA and partner organizations in 2017 found that over 80% of respondents' symptoms have a moderate impact on their daily lives on their best days, and nearly 68% of respondents said their symptoms have a very high impact on their lives on their worst days.[iii] There is still much to be done to improve therapies for lupus as well as the research processes that will yield these therapies.

Implementing the International Pricing Index Model for Medicare Part B Drugs

The Lupus Foundation of America believes strongly in continuously monitoring and revising the United States' healthcare system to ensure it provides high-value, high-quality care for patients, reimburses physicians and other providers properly, and allows for the significant research and development necessary to continue leading the world in the development of new therapies, devices, and care delivery systems.

While we have appreciated and supported many of CMS' efforts in the past to experiment with new payment models to curb rising healthcare costs, we have deep concerns with this proposal to implement the IPI model and the effects, both intended and unintended, that it may have on people living with lupus. As with everything we do, our number one concern lies with the ability of people living with lupus to work with their doctors to access the medications to effectively manage their condition without confusion or delay.

LFA recognizes that the ANPRM lacks sufficient detail to fully evaluate every consequence of implementing this proposal, and that the details and provisions most affecting patients' access will not be revealed until the proposed rule is released.

Access to Needed Medications

Despite CMS' assertion that patient access will not be harmed by the implementation of the IPI model, we are extremely concerned that using foreign price controls to influence Part B reimbursement rates will result in limited and reduced access to lifesaving medications for people living with lupus and other serious chronic health conditions.

The countries referenced in the ANPRM generally operate under single-payer healthcare systems with tight, closed prescription drug formularies - much different than the US healthcare system. The threat of formulary exclusion artificially drives down drug prices in many of these countries, and many other drugs are unable to secure placement on the national formulary, resulting in limited access to potentially lifesaving medications in these countries.

To manage the implementation of the IPI model, CMS notes that drug vendors will serve as middlemen between patients and physicians, interjecting another layer of outside control into decisions that should be made between the patient and their chosen physician. As we have seen in the private insurance market and other segments of Medicare, these new middlemen may protect their margins by implementing strict utilization management protocols, such as prior authorization and step therapy.

The relationship between a lupus patient and their network of physicians is incredibly important – people living with lupus, faced with ever-changing symptoms and disease manifestations, cannot afford to have their healthcare decisions impacted by a non-medical professional not privy to their unique circumstances. Any delay in accessing treatment can have severe consequences, and we urge CMS to fully evaluate the proposed rule for provisions that may negatively impact patient access.

Increased Costs for Beneficiaries

The LFA is concerned that the fixed add-on fee proposed by CMS will actually increase beneficiary copayments for some patients receiving some Part B drugs. Without built-in protections for beneficiaries, the proposed model and its use of averages would leave some patients paying less and some paying more than they would pay absent the model. Further, the proposal does not specify whether vendor fees created by this model would be considered in the provider add-on payment and could potentially be passed on to patients through increased copayment. We believe that beneficiaries should share in savings projected or accrued in Center for Medicare & Medicaid Innovation models and should not have an increased out-of-pocket cost. One way of moving toward achieving this would be to omit the provider add-on fee from beneficiary copayment calculations.

Model Scope and Evaluation

As previously mentioned, LFA supports CMS' commitment to testing reforms to continuously improve and strengthen the Medicare program for its beneficiaries. However, we believe that the scope of this proposal goes far beyond the types of patient-centered, small-scale reforms that CMS has tested in the past.

This ANPRM lays out a wide-scale demonstration that will affect 50% of physicians and hospitals serving Part B beneficiaries. With limited information from CMS beyond the assertion that access to Part B drugs will not be negatively affected, we are concerned that CMS is risking disrupting the entire Part B system, even for providers outside of the 50% impacted by the model, to the ultimate detriment of the patients relying on these medications. The mandatory nature of the model removes the ability of patients to select providers operating outside of the model, forcing them into situations where they are unable to access needed medications through no fault of their own, with little or no recourse.

A central part of previous CMS demonstrations has been a carefully planned evaluation and analysis process. We see no significant discussion in the ANPRM about this evaluation process, and with such a large percentage of physicians being tagged to participate and so many beneficiaries impacted, the evaluation process should be more important than ever for CMS to decide on next steps. Additionally, systems should be developed to allow patient advocacy organizations to track and provide data detailing the impact of the demonstration on their populations.

Research and Development of New Therapies

LFA is concerned that the IPI model as laid out in the ANPRM would diminish the ability of pharmaceutical companies to invest in the biopharmaceutical research and development that makes the US the global leader in developing groundbreaking therapies. For conditions like lupus with limited treatment options, research and development is incredibly important and we fear that this proposal will result in cuts to drug development programs as pharmaceutical companies struggle to recoup their investment on previously-developed therapies.

Again, we appreciate the opportunity to provide input as CMS looks to implement reforms to the Medicare system. If you have any questions, please do not hesitate to contact me at wildman@lupus.org. Thank you for your consideration.

Sincerely,

Patrick Wildman
Vice President, Advocacy & Government Relations

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[i] Costner MI, Sontheimer RD. “Lupus erythematosus” In: Wolff K, Goldsmith LA, et al. Fitzpatrick’s Dermatology in General Medicine (seventh edition). McGraw Hill Medical, New York, 2008:1515-35.

[ii] Dall'Era M, Cisternas MG, Snipes K, Herrinton LJ, Gordon C, Helmick CG. The Incidence and Prevalence of Systemic Lupus Erythematosus in San Francisco County, California: The California Lupus Surveillance Project. Arthritis Rheumatol. 2017.

[iii] Lupus and Allied Diseases Association, Lupus Foundation of America, Lupus Research Alliance. Lupus: Patient Voices. 2017. http://lupuspfdd.org/LupusPatientVoicesFINAL.pdf