

**VIA ELECTRONIC DELIVERY**

May 8, 2020

The Honorable Seema Verma  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1744-IFC  
P.O. Box 8016  
Baltimore, MD 21244-8016



**Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (Docket No. CMS-2020-0032)**

Dear Administrator Verma:

On behalf of the Lupus Foundation of America (LFA), I am writing to offer comments on the interim final rule (IFR) entitled *Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*. We applaud the agency for taking swift action to ensure providers have the necessary flexibilities to care for patients during the ongoing Public Health Emergency.

**About Lupus and LFA**

The Lupus Foundation of America is the largest publicly-supported lupus organization devoted to solving the mystery of lupus, one of the world's most cruel, unpredictable and devastating diseases, while giving caring support to those who suffer from its brutal impact. 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 many parts of the body including organs, 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. At least 1.5 million Americans have lupus although there is limited research available on the prevalence of the disease and the actual number may be much higher. The majority of people diagnosed with lupus are women, with 80% of new diagnoses made during childbearing years,<sup>i</sup> although the disease also impacts men and children. Lupus also disproportionately affects women of color, who are twice as likely to develop the disease than are Caucasian women.<sup>ii</sup>

To date, only four treatments for lupus have been approved by FDA and only one of those treatments was specifically developed to treat lupus. Individuals with lupus also use a variety of over-the-counter medications, supplements, and non-pharmacologic treatments. Antimalarials, non-steroidal anti-inflammatory drugs, and corticosteroids are often among the first treatments prescribed to those with lupus. Immunosuppressant drugs also are frequently prescribed.

### **COVID-19 and People with Lupus**

According to the [Centers for Disease Control and Prevention](#), people with lupus are at higher risk of severe illness from COVID-19. Lupus is a chronic autoimmune disease in which the immune system becomes dysfunctional and attacks healthy tissue, making it less effective at fighting infections. In response, people with lupus often take immunosuppressant medications that further limit the body's ability to respond to infections and fight off bacteria and viruses, like COVID-19. Additionally, people with lupus may have other conditions that put them at higher risk for serious illness from coronavirus such as diabetes and cardiovascular or kidney disease.

Importantly, people with lupus across the country have had significant issues accessing hydroxychloroquine as the drug has garnered national media attention while it is being studied as a possible treatment for COVID-19. Hydroxychloroquine is considered a cornerstone medication for people with lupus and while studies vary, it has been reported that up to 70% of people with lupus take hydroxychloroquine. Benefits of the medication for people with lupus include decreased organ and cumulative damage over time, as well as a decrease in the frequency of flares, cardiovascular complications, and the need for steroids in a patient's course of treatment. Hydroxychloroquine is currently reported as being in shortage by the Food and Drug Administration, and many people with lupus have been forced to ration their hydroxychloroquine, or worse, go without it altogether.

In light of these added challenges for people with lupus, we are especially appreciative of CMS for looking to make it easier for patients to receive their infusions at home, allowing them to continue critically important treatments without increasing their potential exposure to the virus.

### **Comments on the Interim Final Rule**

Researchers across the globe have noted that COVID-19 presents severe health risks to those with underlying chronic conditions, such as lupus, and CDC recommends these patients avoid unnecessary exposure to healthcare facilities during the Public Health Emergency. Therefore, we appreciate CMS's commitment to supporting providers and patients by issuing the IFR.

We commend CMS for taking quick action to protect Medicare beneficiaries from unnecessary risks and to ensure the continuity of care by expanding coverage to allow for the use of the home setting for drug infusions. Currently, the only FDA-approved drug designed to specifically treat lupus is often required to be administered by a medical professional through an intravenous infusion. Access to a home infusion option will help keep high-risk lupus patients out of institutional settings without interruption in these essential treatments. This helps keep lupus

patients more safe and enables institutional healthcare resources to be dedicated to addressing the needs of COVID-19 patients.

The following comments serve to further refine the issues around payment and access that are not yet addressed in the IFR to ensure that lupus patients who are Medicare beneficiaries receive physician-administered Part B-covered infused and injectable medicines in the home setting during the Public Health Emergency.

### **Revised Definition of “Homebound” for Eligibility Purposes**

We appreciate that the proposed IFR revises the definition of “homebound” to include patients who would not typically be classified as such, especially those who would be at greater risk of contracting COVID-19 by leaving the home. Allowing a physician to contract with home health agencies to administer drugs in a patient’s home while under the virtual supervision of the physician protects the health of vulnerable populations, like those living with lupus. These actions to increase access to Medicare home health coverage will prevent people with lupus from making the difficult choice between continuing their effective course of treatment and avoiding potential exposures to the virus.

### **Administrative Burdens for Participating Physicians**

While it is beneficial for patients with chronic conditions to allow physicians to treat patients in their own homes, administrative burdens remain that we believe may decrease the availability of these services for people with lupus. For example, the IFR contains provisions to allow physicians to enter into contractual agreements with third-party entities necessary to provide home infusion services (e.g. home health agencies and homes infusion providers). However, physicians would still be required to purchase the drug, contract with a third-party entity to conduct the infusion in the patient’s home, provide supervision via telehealth modalities, bill for the services and drug reimbursement, and provide payment to the third-party entity based on the contractual agreement.

These administrative processes are burdensome to providers and may prevent lupus patients from receiving timely care, particularly outside of large healthcare networks and in rural and community settings where resources are more scarce. We encourage CMS to consider steps to enable administrative simplicity for participating physicians who move patients from the clinic to home infusion under the IFR authority.

### **Limiting Cost-Sharing Burden on Patients**

We also appreciate the draft IFR enables new flexibility to impact how Part B covered drugs are delivered during the public health emergency and allow providers additional opportunities to decide when drug administration can be performed in a patient’s home. We commend CMS for an approach that allows patients living with autoimmune diseases, serious illness, and other

chronic conditions to have access to critical Medicare Part B injection and infusion medicines in home settings.

However, we urge CMS to ensure that the IFR allows for appropriate payment for these treatments without the unintended consequence of raising out-of-pocket costs for Medicare beneficiaries. Many patients with chronic illnesses, such as lupus, have a supplemental plan that limits their Part B out-of-pocket costs, whereas expenses in Part D are not currently capped. At a time when millions of Americans are unable to work, CMS must ensure that the process of enabling therapies to be administered via home infusion does not increase the cost-sharing burden on patients.

Again, LFA appreciates the opportunity to comment on the interim final rule. We appreciate the agency's commitment to protecting the health and safety of Americans during these unprecedented times. If you have any questions, please do not hesitate to contact Travis Smith, Director of Government Relations, at [SmithT@lupus.org](mailto:SmithT@lupus.org).

Sincerely,



Patrick Wildman  
Vice President, Advocacy & Government Relations

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<sup>i</sup> 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.

<sup>ii</sup> 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.