

March 17, 2020

The Honorable Mitch McConnell  
Senate Majority Leader  
317 Russell Senate Office Building  
Washington, DC 20510

The Honorable Charles Schumer  
Senate Minority Leader  
322 Hart Senate Office Building  
Washington, DC 20510

The Honorable Nancy Pelosi  
Speaker of the House  
1236 Longworth H.O.B.  
Washington, DC 20515

The Honorable Kevin McCarthy  
House Minority Leader  
1236 Longworth House Office Building  
Washington, DC 20515

Re: Measures to protect immune deficient community

Dear Majority Leader McConnell, Speaker Pelosi, Minority Leader Schumer, and Minority Leader McCarthy,

As Congress continues to respond to the unprecedented health and economic challenges associated with the Coronavirus 19 (COVID-19), I am writing on behalf of the [Immune Deficiency Foundation \(IDF\)](#), and all Americans impacted by primary immunodeficiency (PI), to urge Congress to ensure the response meets the unique health needs of our community.

PIs include more than 400 types of rare, chronic disorders in which part of the body's immune system is missing or functions improperly. In the United States there are approximately 250,000 people diagnosed with PI and many more that go undiagnosed. Most people with PI can live healthy productive lives if they receive regular lifelong immunoglobulin (Ig) infusion therapy that replaces the antibodies the body is unable to sufficiently produce. Other treatments for some PIs include bone marrow transplants and gene therapy procedures. While there are treatments, the very nature of PI means our community is especially vulnerable to viruses like influenza and COVID-19.

IDF commends Congress for actions taken or being taken to battle this global pandemic. Specifically, we appreciate the actions taken to provide necessary funding into our overwhelmed public health and healthcare delivery systems, to support delivery of food and other services to vulnerable populations and to remove cost-sharing requirements that could hinder access to COVID-19 testing. Given the magnitude of this challenge, we urge you to promptly take additional actions to support our nation, particularly those persons with PI who find themselves most vulnerable. As older Americans with compromised immune systems, the approximately 10,000 Medicare beneficiaries with PI who are dependent of Ig therapy face the greatest risk from the coronavirus and must be properly protected.

To do so, I urge you to take the following actions to ensure access to all life-extending immunoglobulin (Ig) products.

- Ensure all Medicare beneficiaries with PI can continue receiving access to in-home intravenous immunoglobulin (IVIG) by extending the current Medicare IVIG bundled payment demonstration and removing the cap on beneficiaries.
- Ensure all Medicare beneficiaries with PI can continue receiving access to subcutaneous immunoglobulin (SCIG) by permanently addressing a looming challenge posed by the Self-Administered Drug (SAD) list exclusion that threatens to limit access to certain drugs.

### **IVIG Access**

In 2003, Congress added IVIG medications for beneficiaries with PI to the Medicare Part B statute. However, this provision did not include the services or supplies – notably home infusion nursing care – needed to infuse the drugs. Recognizing this gap, in 2012 Congress passed legislation establishing a Medicare demonstration to evaluate the efficacy of an in-home IVIG bundled payment. This program began in 2014 and was extended in 2017. However, absent additional action, this access will end by the end of this year. Additionally, the number of beneficiaries is currently capped at 4,000, and as of the latest count from CMS, more than 3,338 beneficiaries are enrolled.

If access to in-home IVIG is limited, this means Medicare beneficiaries would only be able to receive this necessary treatment by traveling to facility-based treatment sites. Such sites are already in short supply and, when they do exist, are especially challenging for persons with PI given their compromised immune systems. To keep beneficiaries from losing access to in-home IVIG, **I urge you to take action to extend the Medicare IVIG bundled payment demonstration until at least the end of 2022 and to remove the cap of 4,000 beneficiaries.**

### **SCIG Access**

Subcutaneous immunoglobulin, or SCIG, is an increasingly popular route of administration that allows beneficiaries to use a durable medical equipment (DME) pump to self-administer their Ig therapy, typically several times a week. For those beneficiaries with poor veins and other limitations, SCIG can be the only viable treatment alternative. Under current law, Medicare provides a payment to support the services and supplies necessary for beneficiaries to administer SCIG therapies in the home. Unfortunately, if Congress fails to act, starting in 2021 payments for services related to SCIG would be limited if a drug is on a self-administered drug exception list maintained by Medicare Administrative Contractors (MACs). To ensure Medicare beneficiaries with PI who need access to SCIG therapies retain this access, **I urge Congress to continue current law and policy by permanently removing any SAD list exclusions pertaining to SCIG therapies.**

Given the fluidity of the situation and the tremendous uncertainty that exists, there may be additional requests that we will put forward at a later date, particularly if additional measures are necessary to protect the most vulnerable, including those with PI. Given the chronic nature of these diseases and the necessity of Ig therapies to help prevent infections like COVID-19,

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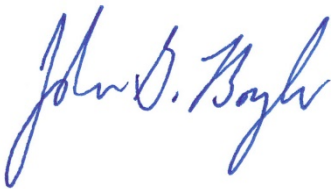
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this may include measures to ensure adequate access to these medications which can already be in short supply. It may also require modification of agency guidances for COVID19 testing that recognize the uniqueness of some individuals with PI who may not spike a fever in response to viral infections.

As you are navigating the myriad issues related to the COVID-19 response and recovery, the Immune Deficiency Foundation offers our fullest level of support, including any clinical expertise or guidance that might be useful to inform policies around protecting people with compromised immune systems from this outbreak. Taking the actions requested in this letter will ensure Medicare beneficiaries with PI are better protected from the COVID-19 outbreak. I urge you to promptly take up and enact legislation to address these concerns, and I thank you in advance for your attention to this most important issue.

If you have any questions, would like to discuss these issues further or would like us to connect you with clinical experts in the field of immunology, please contact Lynn H. Albizo, Associate Vice President of Public Policy, at [labizo@primaryimmune.org](mailto:labizo@primaryimmune.org).

Sincerely,



John G. Boyle  
President & CEO

Cc:

Representative Kevin Brady  
Representative Doris Matsui  
Senator Lamar Alexander  
Senator Ben Cardin