

March 17, 2020

The Honorable Mark Warner  
United States Senate  
703 Hart Senate Office Building  
Washington, DC 20510

The Honorable Tim Scott  
United States Senate  
104 Hart Senate Office Building  
Washington, DC 20510

Re: Preserving Patient Access to Home Infusion Act – SAD list

Dear Senators Warner and Scott,

On behalf of the [Immune Deficiency Foundation \(IDF\)](#), and all Americans impacted by primary immunodeficiency (PI), thank you for your leadership in introducing S.3457, the Preserving Patient Access to Home Infusion Act. This legislation supports the objectives that you and your colleagues established in enacting a permanent home infusion services benefit, through the 21<sup>st</sup> Century Cures Act of 2016, and the provision of a transitional bridge to that permanent benefit enacted via the Bipartisan Budget Act of 2018. Among other things, S.3457 will fix legislative language prohibiting Medicare reimbursement for all therapies included on self-administered drug (SAD) lists for the permanent services benefit to be implemented January 1, 2021.

IDF is dedicated to improving the diagnosis, treatment, and quality of life of people affected by PI through fostering a community empowered by advocacy, education, and research. PIs include more than 400 types of rare, chronic disorders in which part of the body's immune system is missing or functions improperly. Fortunately, most people with PI can live healthy productive lives if they receive regular lifelong immunoglobulin (Ig) infusion therapy. With approximately 250,000 people diagnosed with PI in the United States, there are an estimated 10,000 Medicare beneficiaries with PI dependent on Ig therapy.

It is critical that Medicare beneficiaries with PI retain access to Ig therapy administered intravenously (IVIG) or subcutaneously (SCIG), as determined by their physician. When Congress established the permanent home infusion services payment, it defined home infusion drugs as “drugs administered intravenously or subcutaneously for 15 minutes or more and using a durable medical equipment (DME) pump.” However, this definition also included a prohibition against drugs on self-administered drug (SAD) lists maintained by Medicare Administrative Contractors (MACs). Ig therapies easily meet the core of the definition and most SCIG treatments are not found on SAD lists. However, some SCIG products frequently prescribed for the treatment of PI have been included on these lists, limiting beneficiary access to them.

Recognizing the negative impact the SAD list exclusion would have on beneficiary access to care, Congress wisely removed the provision in 2018 from the temporary services payment in effect through the end of this year. Unfortunately, the statutory change for the temporary payment did not extend to the permanent benefit that will take effect January 1, 2021. I am very concerned about the impact the restoration of the SAD list exemption would have on beneficiary access to some SCIG products.

While Ig products share the same biological base, they are not interchangeable and one individual may not be able to tolerate a different product. In addition, with a tight market for Ig products, limitations on access to one Ig product can negatively impact the system as a whole.

***To address this challenge for the PI community, IDF supports this legislation ensuring coverage for all drugs covered in the transitional benefit and urges Congress to exempt all immunoglobulin (Ig) therapies used for the treatment of PI from the SAD list exclusion as applied to the implementation of the permanent home infusion services payment that takes effect January 1, 2021.***

Thank you for your time and consideration of this request. If you have any questions, or would like to discuss these issues further, please contact Lynn H. Albizo, Associate Vice President of Public Policy, at [labizo@primaryimmune.org](mailto:labizo@primaryimmune.org).

Sincerely,

A handwritten signature in blue ink that reads "John G. Boyle". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

John G. Boyle  
President & CEO