

August 28, 2019

The Honorable Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1711-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**RE: Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements (CMS-1711-P)**

Dear Administrator Verma:

On behalf of the Immune Deficiency Foundation (IDF) and all Americans impacted by primary immunodeficiency diseases (PI), I write to thank you for the opportunity to provide comments on home infusion therapy services for Calendar Year 2021 and subsequent years. IDF has strongly supported efforts over the years to enhance Medicare beneficiary access to home infusion services, particularly for immunoglobulin (Ig) therapies, which are life-sustaining for our population. In these comments, I will speak to this topic with a focus on the proposed home infusion services payment scheduled to take effect in 2021 and specific actions IDF would like to see CMS take to confirm and clarify applicability of this benefit to beneficiaries with PI receiving Ig therapy. The core points IDF will be addressing in this letter are similar to those raised in our August 2018 comment letter and include:

- A desire for clear confirmation from CMS as to the applicability of the permanent home infusion services payment to intravenous immunoglobulin (IVIG);
- Expression of our continued concerns about the impact of the Self-Administered Drug (SAD) list restriction on beneficiary access to Ig therapies; and
- Expression of our continued concerns as to the adequacy of the permanent services payment.

Before I speak to these points, I will provide some brief background on PI to place our concerns in context.

**Background on Primary Immunodeficiency Diseases**

Primary Immunodeficiency diseases (PI) are a group of more than 350 rare, chronic genetic disorders in which part of the body's immune system is missing or functions improperly. Because of their condition, individuals with PI live their entire lives more susceptible to infections--enduring recurrent health problems and, often developing serious and debilitating illnesses. Even a common cold or relatively modest infection can pose significant risk for a person with PI. Fortunately, many people with PI have an effective treatment in immunoglobulin (Ig) replacement therapy that restores the antibodies the body is unable to produce and provides protection from serious infections. Regular, lifelong Ig therapy allows a person with PI to live a full and independent life. Ig is prepared from plasma collected from tens of thousands of carefully screened healthy individuals and undergoes a rigorous purification process. All Ig licensed in the U.S. is made from plasma collected in the U.S.

## Routes of Administration & Coverage Policies

Ig replacement therapy is generally administered either intravenously (abbreviated IVIG), or subcutaneously (abbreviated SCIG). The most recent data from our patient surveys estimates that 70 percent of those diagnosed with PI are receiving Ig treatment, and of those, approximately 60 percent use SCIG and 40 percent use IVIG.<sup>1</sup> Beneficiaries with most PI diagnoses may receive SCIG under Medicare Part B, and others may receive it, albeit with significant co-pays, under the Part D benefit. Medicare beneficiaries may receive IVIG in hospitals, infusion centers or physician offices or may infuse at home through the Medicare IVIG demonstration project. Through a provision included in the Medicare Modernization Act, Medicare has covered the costs of immunoglobulin drugs administered in the home, but services and supplies used to administer the Ig are currently only available via the bundled payment demonstration that is limited to 4,000 beneficiaries and set to expire at the end of 2020.

There are benefits and side effects for each route of administration. For example, a person using SCIG administers multiple times a week but for shorter durations than a person with IVIG, and the more frequent administrations of the medication reduce side effects associated with the larger dosage delivered via IVIG. For others, frequent self-administration of SCIG may be challenging and can cause skin irritation. The determination of route of administration of Ig therapy (IVIG or SCIG) should be a decision resulting from discussions between the patient and provider. The decision is based on a number of factors that are considered including the clinical characteristics of each patient, the patient's lifestyle and preferences for therapy, and appropriate site of care. For these reasons, individuals with PI must have adequate access to both routes of administration.

Unfortunately, as noted previously, Medicare beneficiaries with PI can only access in-home IVIG via the current demonstration that is now in its second and final phase. This places Medicare policy out of line with most commercial policies that routinely cover in-home administration of IVIG because of the benefits to patients and the cost savings associated with care provided in-home as opposed to in a healthcare facility. The PI community is eager for a permanent resolution to this impediment to beneficiary access that we anticipate coming through implementation of the permanent services payment in 2021.

## Confirming Applicability of Permanent Services Payment to IVIG

As required by the 21st Century Cures Act (Pub. L. 114-255), CMS is establishing a permanent home infusion therapy benefit starting in 2021. The statutory reference to the services payment defines a home infusion drug as follows:

*“The term ‘home infusion drug’ means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:*

- (i) Insulin pump systems.*
- (ii) A self-administered drug or biological on a self-administered drug exclusion list.”<sup>2</sup>*

A plain reading of this statutory language indicates that IVIG products would meet the definition of a home infusion drug administered intravenously and thus, would be covered under the permanent services payment. However, our review of the proposed rule has led to some questions and concerns we would like the agency to address in the final rule. Specifically, the proposed rule states that the benefit will apply to intravenous therapies they are administered through use of a pump, as defined by a Local Coverage Determination (LCD) for infusion pumps (L33794). We note that this LCD contains a reference that IVIG products, despite requiring a pump for administration, are not covered by Medicare under this LCD. However, the proposed rule contains additional text that provides examples of Part B durable medical equipment (DME) infusion drugs covered under the benefit to “include, among others, certain IV drugs for

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<sup>1</sup> Immune Deficiency Foundation (2018). IDF 2017 National Patient Survey [PowerPoint slides].

<sup>2</sup> <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf> (p. 167)

heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.” Related to this point, we are concerned that the proposed codes for home infusion therapy service payment categories (Table 28) for the permanent services payment do not clearly reflect how IVIG services will be addressed. Specifically, we would like to understand where IVIG therapies would fall under this table. It is our understanding that category 2 pertains only to products administered subcutaneously while category 1, per the proposed rule, “would include any subsequent intravenous infusion drug additions.”

In response to IDF’s comments to last year’s proposed rule, CMS acknowledged our concerns in the final rule and stated the agency’s intent to “continue to examine the scope of drugs covered under Part B... for full implementation of the home infusion therapy benefit in 2021.” **Given this previous commitment and the concerns we note above, we urge CMS to include in the final rule a clear confirmation as to the applicability of the permanent services payment to IVIG therapies.** This understanding is a priority to our community, particularly those Medicare beneficiaries with PI who need to understand their coverage options going forward.

### **SAD List Exemption**

As CMS recognized in the proposed rule, the permanent services payment will reduce access to certain SCIG products because the statutory definition of home infusion drugs does not include products included on self-administered drug (SAD) lists. IDF is concerned about the impact this SAD list exemption will have on beneficiary access to therapies and reiterates the issues highlighted in our comments submitted on August 23, 2018.<sup>3</sup> We also remain concerned that inclusion of a SCIG product on this list demonstrates a lack of recognition of the process and time involved in administering such products. Specifically, administration of SCIG requires the use of a DME pump, which is primarily administered for periods greater than 15 minutes. This makes SCIG products and their administration very different from a SAD administered through an injection or autoinjector in a matter of seconds.

We recognize that the statutory language limits the actions CMS can take to address this challenge and are hopeful Congress will enact legislation to permanently remove or clarify the SAD list impediment. However, we encourage the agency to consider giving additional guidance to Medicare Administrative Contractors (MACs) as to the process and time involved in administering SCIG therapies. Finally, IDF remains very interested in serving as a resource to CMS and/or MACs so that agency decision makers can further understand these medications and their routes of administration.

### **Adequacy of Home Infusion Services Payment**

IDF continues to have concerns regarding the potential limitations on beneficiary access to care that could result if providers determine that the new home infusion services payment is inadequate to cover their costs. We appreciate that CMS has sought to address some of these concerns in the proposed rule by increasing the bundled payment from four hours to five hours beginning in January 2021. However, this approach still limits payment only to times when a provider is physically present in the beneficiary’s home and does not account for the work home infusion providers do and patient care management and monitoring, when not physically present in the home. IDF remains willing to serve as a resource to the agency to address any questions as to what goes into administration of both SCIG and IVIG therapies, and we are hopeful these concerns will be addressed in the final rule.

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<sup>3</sup> See attachment 1

## Conclusion

Thank you for this opportunity to comment. We have enjoyed working collaboratively with CMS, particularly over the past year, to address policies that were limiting PI beneficiary access to a full array of treatment options. We appreciate the improvements that were made in response to our concerns and are most hopeful that the agency will fully address the issues stated in this letter. 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 [lalbizo@primaryimmune.org](mailto:lalbizo@primaryimmune.org).

Sincerely,



John G. Boyle  
President & CEO