

December 17, 2019

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1711-FC, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: CY 2020 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; Quality Reporting Requirements CMS-1711-P**

To Whom it May Concern:

On behalf of the Immune Deficiency Foundation (IDF), which advocates on behalf of people living with primary immunodeficiency (PI), I am writing to offer the following comments on the Calendar Year (CY) 2020 Home Health Prospective Payment System Final Rule. These comments build upon those submitted on August 28, 2019 on the Proposed 2020 rule as well as comments submitted on August 23, 2018 on the Proposed 2019 rule.

In summary, IDF maintains the position that the home infusion services payment should apply to the administration of in-home intravenous immunoglobulin (IVIG). We were disappointed to read that the home infusion services permanent benefit, scheduled to take effect January 2021, will not be applicable to IVIG. As we have noted in our previous comments, IVIG is one of two therapeutic options – the other being subcutaneous immunoglobulin – that is effective for approximately 70% of individuals living with some form of PI. This includes an estimated 40,000 Medicare beneficiaries who require immunoglobulin replacement therapy to replenish the antibodies their bodies are unable to produce.

**Use of a Pump at Durable Medical Equipment (DME)**

In our comments, we noted that the statutory definition of home infusion drug contained in the 21st Century Cures Act (*below*) would appear to cover IVIG

*“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>1</sup>*

Rather than relying on the clear statutory language, the agency’s comments in the final rule connects drug coverage to a specific Durable Medical Equipment (DME) Local Coverage Determination (LCD) – L33794 resulting in a far narrower definition of home infusion drugs than that which is included in the statute. This interpretation is not consistent with the statutory language, which on its reading, would indicate that IVIG should be covered under the benefit.

<sup>1</sup> <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf> (p. 167)

While CMS also noted in the final rule that an infusion pump is not covered within the current bundled payment for the IVIG demonstration, the agency recognized that decisions on the infusion process are ultimately left to the supplier and that this administration “may or may not include the use of a pump.” IDF’s consulting medical directors have shared that DME pumps are currently a general recommendation for use in the administration of IVIG. Use of a motorized pump for IVIG to control the infusion flow rate helps to mitigate rate-related side effects including headaches, nausea, fever, and vomiting. Additionally, many of the electronic pumps provide added safety for patients by including alarms to alert the administering nurse about possible problems, such as occlusions and air in the line. In fact, many specialty pharmacies require the use of a pump to administer IVIG in the home.

Given that the standard of care for IVIG is evolving toward the administration of IVIG via a DME pump, there is a need for CMS to ensure coverage policies keep pace with clinical practice. With this in mind, IDF appreciates the opportunity to respond to CMS’s solicitation of comments in the final rule as to criteria the agency could consider in making decisions to cover additional drugs under this important benefit. In this case, we urge CMS to expand its coverage of Immunoglobulin Replacement Therapy to include IVIG as well as SCIG as part of the DME home infusion benefit. We recommend a full review of clinical care guidelines and standards, journal publications, commercial coverage policies, and other evidence. We are confident that such a review will demonstrate the need for Medicare coverage for IVIG with utilization of a pump. These sources align with the changes to the LCD development process that took effect earlier this year and encourage maintaining an open and transparent process.

### **Concerns Regarding Covered Services**

IDF recognizes that the determination by CMS on the final services payment included limitations on how it will pay for home infusion services and does not cover the full costs associated with such care beyond the in-home nursing costs. We remain concerned that failure to remedy this inadequacy may result in limiting access to in-home infusion care for our beneficiary population – elderly persons with impaired immune systems - who may have to forgo treatment or receive it in a less than ideal community setting. While we do not advocate on behalf of providers, IDF does support remedying this coverage limitation in order to ensure that patients in need of these services are able to access home infusion providers who are willing and able to provide the necessary treatments and services at the benefit rate and reimbursement level offered by Medicare.

### **Comments on Criteria for Covering Additional Drugs as Part of the DME benefit**

IDF strongly supports CMS revisiting the criteria used for considering additional drugs under the home infusion services payment. It is our view that Medicare coverage of home infusion drugs should be more reflective of the totality of Medicare-covered drugs administered in the home including IVIG. Aside from the current IVIG demonstration that is limited in both time and total beneficiary numbers, the lack of coverage of IVIG in the home makes Medicare an outlier compared to commercial payers. Commercial payers have overwhelmingly covered home-based IVIG because it provides a better, safer option for many patients and because the home is a lower-cost site of care compared to a physician’s office or outpatient alternatives. This lack of Medicare coverage is increasingly more challenging for patients who are aging into Medicare. Many of these patients have been receiving IVIG for years at home through their private insurance and now may not have access to this site of care.

Further, as we approach the last year of the IVIG demonstration, with over 3,180 people enrolled, and with enrollment capped at 4,000, it is essential to have a path for Medicare recipients with PI to receive home infusions. As the law stands now, CMS will have one year to draft its report on the outcome of the demonstration, and then Congress would have to pass a

new law creating a permanent benefit. This leaves patients who have been receiving IVIG in home, through the demonstration, left with having to seek treatment at a facility. This could be particularly challenging for patients living in remote areas or who do not have access to transportation. Home infusion therapy allows patients to receive treatment without disrupting their lives and are, therefore, more able to consistently maintain their treatment regimen. In addition, many patients with PI do not want to receive treatment in facilities where they are more likely to be exposed to infections.

In addition, with the recent shortages of Ig in hospitals and hospital-affiliated centers, there may be unique challenges for more individuals having to utilize facilities that have limited contracting for Ig products within a hospital system. Allowing patients the option to receive home IVIG, provides more choice to patients who are able to use a variety of providers and products putting less strain on the limited Ig product offered by one hospital system.

In terms of specific considerations used to make updates to the DME benefit, IDF encourages CMS to consider alignment of Medicare benefits with commercial and Advantage Plan coverage policies to ensure consistency and to reduce negative impacts on patient access to various modes of treatment. Further, we know that private insurer decisions are often driven by the bottom line and we believe that payers have chosen to include home IVIG as a benefit because it is cost-efficient. Based upon estimates gleaned from IDF's 2016 National Health Insurance Survey, there are an estimated 40,000 individuals with PI on Medicare receiving Ig therapy and an estimated 15,000 individuals receiving IVIG, including those enrolled in a Medicare Advantage plan. According to CMS, there are currently approximately 1,150 individuals receiving IVIG in the home through the Medicare IVIG Demonstration. If there were a permanent benefit available, more individuals with PI would have the option of receiving IVIG at home. As noted above, this option is cost-efficient and preferred by many people who may have challenges traveling to facilities or who do not want to be exposed to infections unnecessarily by receiving treatment around other people in a hospital or infusion center.

### **Conclusion**

IDF recommends that CMS consider adding the home IVIG benefit to the DME benefit that currently covers SCIG, but not IVIG. This will streamline the benefit for providers, and as discussed above, will improve access and a continuum of care for many beneficiaries with PI who need IVIG treatment. Since most people receive IVIG using a pump, it is appropriate to review the criteria to consider adding IVIG for coverage under the DME benefit.

Thank you for this opportunity to comment. 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