

July 13, 2018

The Honorable Alex M. Azar II
Secretary
United States Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Dear Secretary Azar:

On behalf of all persons who are impacted by primary immunodeficiency diseases, the Immune Deficiency Foundation (IDF) appreciates the opportunity to submit comments in response to the US Department of Health and Human Services (HHS) Request for Information (RFI) on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (HHS-OS-2018-0010). IDF would like to focus our comments specifically on the importance of continued access to necessary treatments for patients with primary immunodeficiency diseases with a particular focus on Medicare beneficiaries.

Background on Primary Immunodeficiency Diseases

Primary Immunodeficiency diseases (PI) are a group of more than 350 rare and chronic genetic disorders in which part of the body's immune system is missing or functions improperly. Because of their condition, individuals with PI are far more susceptible to infections from even relatively modest viruses. A common treatment for many forms of PI is immunoglobulin (Ig) replacement therapy which is derived from human plasma collected at plasma donation centers that undergoes a rigorous purification process before being developed into treatments. The most recent patient data from one of IDF's landmark surveys estimates that 70 percent of those diagnosed with PI reported that they are being treated with Ig, and of those, there is a near even split between the use of subcutaneous immunoglobulin (SCIG) and intravenous immunoglobulin (IVIG). Regular, lifelong Ig treatments restore the antibodies the body is unable to produce and allows a person with PI to live a full life. However, when access to these therapies is limited or threatened, many persons with PI will experience frequent, severe and potentially life threatening infections and illnesses.

Background on Medicare Part B Coverage of SCIG and IVIG

As part of the 21st Century Cures Act (Cures Act), Congress created a new Medicare reimbursement for SCIG and other Part B drugs administered via durable medical equipment. This provision included professional services as well as training, education and monitoring services. There was a gap in reimbursement, however, which would have delayed the benefit's implementation until 2021. Recognizing that this was an oversight, Congress included a provision (Sec. 50401) in the Bipartisan Budget Act of 2018 (P.L. No. 115-123) that established a temporary services payment between 2019 and 2020 and would mirror the benefits included in the Cures Act. We are pleased that this, soon to be enacted, legislative fix will ensure that all Medicare beneficiaries with PI will continue to have access to SCIG treatment.

In addition, under current law, Medicare covers the cost of IVIG drugs but not the supplies and services needed to administer it in-home, which most commercial insurance policies cover as a more cost-effective and patient friendly service. To address this, in 2012, Congress enacted the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act (Public Law 112-242) which required the Centers for Medicare and Medicaid Services (CMS) to establish a demonstration program to evaluate the impact of providing a bundled payment for in-home administration of IVIG for Medicare beneficiaries with PI. Prior to the demonstration, Medicare beneficiaries who needed IVIG were only able to receive this treatment in an infusion center, hospital or other community setting, which can be dangerous for persons whose immune systems are compromised. The project was set to end in October 2017, but thankfully, just before it expired, Congress extended it through 2020. It is our understanding that in January 2021, IVIG will be permanently covered via the new home infusion benefit that was included in the Cures Act and we look forward to continuing to work with HHS and CMS toward implementation of this benefit.

Moving Part B Drugs to Part D

As demonstrated above, the Medicare Part B program is of critical importance to beneficiaries with PI and IDF strongly opposes moving Part B infusion drugs to Part D. The PI community is particularly concerned that moving these infusion drugs to Part D would result in even higher out-of-pocket costs to our patient population. In Part B fee-for-service, beneficiaries generally pay 20 percent of all costs for their drugs and medical services. Because of the high cost of life-saving Ig treatments, beneficiaries often rely on Medigap, supplemental insurance to cover the 20 percent coinsurance. Medigap plans, however, cannot be used to supplement Part D plans, so patients are likely to experience a significant increase in their out-of-pocket costs. Even with the closure of the Part D “doughnut hole” or coverage gap in 2019, beneficiaries who meet this threshold are responsible for paying 25 percent of their drug costs if or until they reach catastrophic coverage. For beneficiaries with PI who need life-long Ig treatment, this would amount to a significant financial loss compared to the current cost sharing model.

IDF is also concerned that applying Part D purchasing methods and formulary use to Part B drugs for Ig therapy could have unintended negative consequences for the PI community. Because there are no generic Ig products, developing closed formularies will merely limit patient choice without resulting in significant savings. While the efficacy of all Ig products are equivalent as a whole, individual PI patients respond better to different products. In fact, some patients have serious allergic responses to different formulations. It is therefore essential that PI patients have access to the full range Ig therapy options as is currently available under Part B.

Ensuring that Ig infusion therapy for PI continues to be reimbursed under Medicare Part B is essential to the PI community and was recently reinforced by Congressional action with the passage of (1) the Cures Act, (2) the Bipartisan Budget Act which included the temporary services payment and (3) legislation extending the IVIG demonstration project. These recent actions by Congress, addressing reimbursement for Ig therapy under Part B, indicate that Congress intended for these services to be covered under the Medicare Part B program. For these reasons, we strongly urge HHS to not move forward with any proposal moving Medicare Part B drugs to Part D.

Value-Based Purchasing in Federal Programs

IDF supports the Administration’s exploration of new payment models that encourages competition, rewards value and protects patient access to treatment options. Such models should ensure that any savings are passed on to patients, and that patients are informed of any incentives employed that may drive clinician treatment decisions. It is essential that the patient voice is included when developing value-based care

strategies for treatment of PI and other chronic conditions. Direct and diverse patient experiences are needed to define what treatment options are of value. The definition of value varies among different populations, evolves over time and is highly dependent on individual lifestyles and preferences. It is therefore essential that as the HHS seeks to develop systems that support high value treatment that patients continue to have access to a variety of valuable therapy options to support their health needs, preferences and lifestyle.

Indication Based Payments

IDF is supportive of the Administration's further consideration of the use of indication based pricing to address challenges with the cost of medications. As a patient advocacy organization, IDF's primary concern is the impact on individuals with PI including their access to treatment and the fiscal effect on families. We welcome further investigation on indication based pricing models that would support improved access and consumer pricing for Ig therapy for patients with PI. The medical community has long recognized that, despite its high cost, lifelong Ig therapy is a very high value treatment for those with PI who meet specific criteria. There are other indications for which Ig therapy is now being used that may not be considered high value. It therefore may make sense to provide varying reimbursement rates depending upon the indication. In addition, it should be recognized that PI is a chronic condition and Ig therapy is used long-term rather than in acute situations as it is for other conditions. Rather than endorsing new pricing methods, IDF is cautiously supportive of further review of such methods and when details are revealed would support proposals that prove to be helpful to improving treatment access to individuals with PI.

Site Neutrality for Physician Administered Drugs – Treatments at Skilled Nursing Facilities

With the availability of home IVIG as part of the demonstration project, individuals with PI have not experienced many access challenges related to Part A and Part B payment policies except in cases when a beneficiary is admitted to a skilled nursing facility (SNF). IDF has received reports from beneficiaries who were receiving SCIG or IVIG therapy at home through Medicare Part B and were not able to receive Ig treatments once they were admitted to a SNF for rehabilitation. Instead, they were told that they could only receive treatments if they were transferred to a hospital or outpatient clinic. This included patients who in the community had administered SCIG themselves without nursing assistance. The rationale for this was that the SNFs received a bundled payment under Part A for Medicare patients and Ig therapy would not be separately reimbursed. This policy is risky and disruptive to patients who need to be transported to a new facility, may be exposed to new infections and have multiple health needs justifying admission to a SNF. IDF recommends that a policy is developed that allows reimbursement for Ig therapy provided in a SNF to ensure PI patients on Medicare receiving rehabilitation in SNFs are able to receive their Ig treatment in the facility.

Reducing the Impact of Rebates

As advocates for individuals with PI, IDF is supportive of any system changes that will address the high cost of medications for patients and improves patient access to necessary treatments. Any measures to restrict the use of manufacturer rebates must include guardrails to ensure that patients are protected from potentially higher out-of-pocket costs downstream. The impact of such restrictions will depend on how manufacturers and health insurance plans respond to such a change, which could inadvertently lead to increased costs for patients and poorer health outcomes. IDF recommends that the Administration carefully evaluate the implications of moving away from the current rebate system and implement any changes in small increments, with cautious measurement of effects throughout the process.

Modify Drug Co-pay Assistance Regulations

Many people with PI count on drug discount programs to lower patient cost sharing for Ig therapy which in total may cost as much as \$10,000 per month. IDF's most recent insurance survey of individuals with PI found that a total of 28% received co-pay assistance from multiple sources including foundations, pharmacies and manufactures and 39% of those receiving assistance comes from manufacturers. While there is criticism that co-pay assistance programs drive utilization of higher cost drugs when a generic is available, this is not the case with Ig therapy which has no generic equivalent. Most people with PI who require Ig therapy must take it for a lifetime to remain healthy. Under the current system, PI patients reliant on Ig therapy have very high out-of-pocket costs and therefore rely on manufacturer or charity assistance to afford the medicines they need to improve or maintain their health. While efforts to lower out-of-pocket costs are a top priority for the Administration and Congress, co-pay assistance remains a vital lifeline for patients in the interim. Thus, we urge caution when considering addressing their usage and encourage the Administration to consider nuanced and incremental approaches with significant input from the patient community as HHS attempts to address this issue.

Reduced Out-of-Pocket Costs

IDF appreciated and supports the Administration's goal to lower out-of-pocket costs for patients. As noted above, individuals with PI often require expensive specialty medications in order to live healthy lives. Unfortunately, their only health insurance options contain formularies with high coinsurance for the treatments they need. This financial burden on patients and families increases the likelihood that the most vulnerable among us will forego care. For example, a 2014 IDF Health Insurance Survey found that approximately one-third (1/3) of patients reported that they had skipped Ig treatments, in part, because they could not afford the out-of-pocket costs. Not only can skipped treatment lead to negative outcomes, even death, it can also result in high costs to the health system including inpatient hospital stays and expensive treatments for declining conditions.

Gag Clauses within Part D Contracts

IDF is supportive of the Administration's proposal to eliminate the "gag clauses" in contracts between health plans and pharmacies that prohibit pharmacists from informing patients when drugs could be purchased at a lower price if they did not use their insurance. While this issue does not impact high cost medications with no generic equivalent such as Ig therapy, it does impact PI patients' access to other medications, including antibiotics. IDF's most recent treatment survey revealed that 51% of patients on Ig also received prophylactic antibiotic therapy. In addition, the survey showed that among Ig users, PI patients reported many comorbid health conditions, including asthma (55%), arthritis (50%), autoimmune condition (37%), digestive disease (34%) and malabsorption/diarrhea (29%). As a result, numerous PI patients require many different types of medications which are impacted by these gag clause policies. Health insurance is intended to help patients access healthcare by making it more affordable, including the medicines they need, and "gag clauses" do the contrary by withholding information from patients.

IDF would caution that a potential unintended consequence of allowing pharmacists to inform patients regarding costs is that patients may choose lower-cost options outside of their plan and end up paying more money because such payments would not count toward their total out-of-pocket costs as tallied by the insurer. We fully support the Administration's effort to end "gag clauses" but encourage greater pharmacist education to ensure that they are aware of this unintended consequence and fully educate patients regarding this concern.

Conclusion

IDF appreciates the opportunity to comment on the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs and is committed to educating you and your staff regarding health access issues impacting the PI community. Participation in decision making regarding health system changes is essential to ensuring that the patient perspective is taken into account. As system changes and proposals are further refined, IDF will remain engaged and will continue to advocate to ensure access to affordable, comprehensive health coverage and necessary treatments for individuals with PI and other chronic and rare conditions. We reiterate our caution against moving any infusion drugs from the Medicare Part B program to Part D, as we are concerned that it would only increase out-of-pocket costs for the PI community.

Thank you for considering these comments. If you have any questions or if you would like to discuss this topic directly, please have your staff contact Lynn Albizo, Senior Director of Public Policy, at lalbizo@primaryimmune.org or 443-632-2544.

Sincerely,

A handwritten signature in blue ink that reads "John G. Boyle". The signature is written in a cursive, flowing style.

John G. Boyle
President & CEO