



The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

August 23, 2018

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1689-P
PO Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations

Dear Administrator Verma,

On behalf of all people impacted by primary immunodeficiency diseases (PI), the Immune Deficiency Foundation (IDF) appreciates the opportunity to submit comments on the proposed payment for Medicare home infusion therapy services. For more than a decade, IDF has worked with legislators and with the Centers for Medicare and Medicaid Services (CMS) to address home infusion coverage issues to ensure that all Medicare beneficiaries diagnosed with PI have affordable access to the therapy and site of care recommended by their physicians so they can live healthy and productive lives.

IDF applauds Congress for including in the 21st Century Cures Act, PL 114-255 (Cures) a provision to establish a payment for the services needed to provide home infusion to Medicare beneficiaries. This provision included professional services as well as training, education and monitoring services. However, because a second provision changed how CMS reimburses for Part B drugs infused via durable medical equipment (DME) effective January 2017, the law created a four-year gap in reimbursement that would have limited provider participation in the program 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 for 2019 and 2020 to fill this gap while CMS engages in the rulemaking to establish the permanent payment authorized in Cures. We are pleased that this legislative fix, if properly enacted, will ensure that all Medicare beneficiaries with PI will continue to have access to subcutaneous immunoglobulin replacement therapy (SCIG).

We also thank CMS for moving forward to enact regulations to implement this services payment, including the temporary services payment that will take effect in January 2019. This stop-gap measure should help prevent a potentially catastrophic loss of services for beneficiaries with PI had the original Cures timeline remained in effect. Included below are IDF's comments on key elements of the proposed rule and recommended modifications to ensure the payment for home infusion therapy services meets the needs of the PI community. Our comments focus on three core areas:

1. Applicability of the payment for home infusion therapy services to provision of intravenous immunoglobulin replacement therapy (IVIG) for Medicare beneficiaries.
2. The need for a permanent solution regarding the self-administered drug (SAD) list impediment pertaining to SCIG.
3. The overall adequacy of the proposed payment to meet the needs of Medicare beneficiaries with PI.

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. 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 SCIG and 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 people with PI will experience frequent, severe and potentially life threatening infections and illnesses.

IVIG Therapy

Patients receiving IVIG typically receive an infusion every 3-4 weeks, and each infusion generally takes about 3-4 hours to complete. Infusions of Ig are administered intravenously in the arm in various settings including an inpatient or outpatient infusion suite, physician office or in the home. IVIG is administered by a medical professional, and the procedure is scheduled in advance. Many commercial insurance plans provide coverage for patients to receive IVIG therapy at home. This offers the patient convenience and may help limit a person's exposure to a community setting – such as a physician office or infusion center – where he or she would face a heightened risk of contracting infections.

SCIG Therapy

Patients receiving SCIG are usually infused under the skin of the abdomen, thighs or outer buttocks at one or multiple sites, and they have flexibility in dosing and administration. The total monthly dose is calculated by the physician, then divided according to the interval between infusions. SCIG can be given daily, weekly, every 2 weeks, or multiple times per week. The length of each infusion can range from less than an hour to up to 2 hours depending on the dosage and frequency. With professional training and periodic monitoring, patients may administer SCIG independently in their homes using a durable medical equipment (DME) pump. Facilitated SCIG can be given every 3-4 weeks, to deliver the total monthly dose at once, into the subcutaneous space. This is "facilitated" by the use of hyaluronidase, an enzyme which is injected to allow more medication into each site.

Ultimately, the route of administration is determined by a number of factors including the Ig therapy needed to meet the patient's need, the patient's medical condition, his or her ability to tolerate one or both routes, and the recommendation of the patient's physicians.

Medicare IVIG Demonstration

Under current law, Medicare covers the cost of IVIG drugs but not the supplies and services needed to administer it in-home. This stands in contrast to most commercial insurance plans that cover in-home IVIG 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) that 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, unless they paid out-of-pocket for the administration of the drug, Medicare beneficiaries who needed IVIG were only able to receive this treatment in an infusion center, hospital or other community setting—a scenario that can be dangerous for people 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.

Applicability to IVIG

As noted above, beneficiaries with PI are only able to access IVIG via the Medicare IVIG Demonstration, which has a limited enrollment and is set to expire by the end of 2020. To correct this problem, we support a permanent policy change to Medicare to cover the services and supplies necessary for in-home administration of IVIG. **It is our understanding that because Sec. 5012 of the 21st Century Cures Act applies to home infusion drugs that are administered both subcutaneously or intravenously that the services payment would encompass IVIG for beneficiaries with PI.**

Further, we are particularly concerned regarding the interplay between the current demonstration (set to run through the end of 2020) and the start of the services payment in 2021, and the impact that would have on beneficiaries who receive IVIG. Under current law, the final report on the demonstration will not be delivered until one year after its completion. In order to ensure that patients who currently receive IVIG at home under the demonstration are not required to stop home treatment, we urge that the permanent services payment be implemented without delay, and that CMS either complete the report in an expedited manner or implement the benefit prior to the completion of the full report.

In response to the comments and future efforts to develop the payment that will be effective January 2021, we request CMS:

- Affirm our understanding that the services payment would cover IVIG as well as SCIG;
- Comment on specific actions that will need to be taken to ensure this implementation;
- Share timeline for implementation of services benefit as it relates to beneficiaries receiving IVIG, particularly the transition plan for beneficiaries now covered under the demonstration; and
- Clarify how this benefit will impact the plans and current timeframe for the final report of the IVIG demonstration.

Additionally, we wish to ensure that in designing the services payment, CMS take into account the needs of the beneficiary population with PI who will be affected to ensure the scope of the services meets the needs of this population.

SAD List Impediments to SCIG

IDF is concerned about the potentially limited nature of the permanent services payment given the application of a clause referring to drugs contained on self-administered drug (SAD) lists. While this concern was addressed by Congress in establishing the temporary services payment that will apply in 2019 and 2020, it remains a component of the statutory language creating the permanent services payment that takes effect in 2021. As such, **IDF is very concerned that Medicare beneficiaries with PI receiving SCIG will have access to this care for 2 years under the temporary payment but will subsequently lose coverage effective January 2021 because of the application of the SAD list provision. To prevent this from occurring, we are requesting that CMS address this impediment through the rulemaking process pertaining to the permanent services payment.**

Our understanding is that the reference to the self-administered drug exclusion list in Cures was intended to exclude *Part D drugs* from the new professional services benefit, which will apply to Part B DME infusion drugs beginning in 2021. Applying SAD list prohibitions to SCIG therapies represents a failure to fully understand how these medications are administered. While SCIG is self-administered in the home once a patient is appropriately trained, these infusions require the use of DME pumps and take a significant amount of time in their preparation and administration, far beyond a self-administered drug such as a biologic that is pre-loaded in a syringe and given through a simple injection. However, this SAD language, if interpreted out of context, could have the unintended consequence of blocking the new benefit from applying to SCIGs because all regional based Medicare Administrative Contractors (MACS) have placed one or more medications used in SCIG on their respective SAD lists. Currently, patients with PI are not affected by the SAD list because SCIG for individuals with PI is covered under the DME benefit. Since the initial purpose of the services payment legislation was aimed at supporting patients who use DME pumps for home infusions, it is inconceivable that Congress intended to exclude such treatments from coverage.

We urge CMS to speak to this issue and address how the agency plans to ensure Medicare beneficiaries in need of SCIG will continue to have access to these lifesaving medications. IDF would be pleased to work with CMS officials to strengthen agency understanding of SCIG if/as needed, particularly to help in understanding how patients typically go about administering their treatments.

Nursing Services

As a patient organization, our focus is on how the proposed reimbursement policies may impact patient services and, ultimately, patient access to care. We have concerns regarding the agency's comments on page 412 of the proposed rule indicating that the professional services covered under the law are not intended to include ongoing nurse supervision during each treatment. Depending upon the individual, there may be a need for nursing support to ensure beneficiaries on SCIG are properly trained in how to safely and properly administer the therapy using the provided durable medical equipment (DME). Further, access to remote nursing or other health professional services are essential for patients to have the support they need.

When the legislation was developed to provide for a services payment for home infusions, it was Congress's intent to cover professional services including clinical care planning, coordination and monitoring that may be done remotely in addition to on-site. If providers are not able to bill for such services, they may not be willing to provide the help that patients need, resulting in compromised care or reduced access to infused therapy. In addition, for IVIG, the presence of a nurse throughout an IVIG session is standard given the nature of intravenous administration including the risk of infection if not handled properly. We urge CMS to address these deficiencies in the definition contained in the proposed rule to ensure that the scope of nursing services covered under the final rule aligns with the intent of Congress and meets the needs of Medicare beneficiaries.

Scope of the Services Payment

Finally, IDF wishes to offer information to assist you in determining the scope of the services to be covered under the permanent payment. Because of the inherent differences between IVIG and SCIG therapy, it is important for the benefit to address the need of Medicare beneficiaries with PI being treated with either therapy. IDF has produced a publication entitled, *Immune Deficiency Foundation Guide to Immunoglobulin Replacement Therapy for People Living with Primary Immunodeficiency Diseases*. This guide, authored by Kristin Epland, FNP-C and Elena E. Perez, MD, PhD and edited by Mark Ballow, MD, was developed for patients and caregivers to help increase understanding of Ig replacement therapy. We have included in our comment submission the full guide for the agency's review. The below chart (1.1), found on page 9 of the guide, describes the differences in IVIG, SCIG and fSCIG. Please note that while the chart indicates that SCIG is self-administered, it does require extensive initial training and ongoing availability of health professionals able to ensure patient safety via proper administration. If staff have any questions regarding information contained in the publication, IDF can connect you with Dr. Ballow and/or other immunology experts who can answer your questions.

Chart 1.1: Immunoglobulin Treatment Options (*Immune Deficiency Foundation Guide to Immunoglobulin Replacement Therapy for People Living with Primary Immunodeficiency Diseases*)

	Intravenous Immunoglobulin (IVIG)	Subcutaneous Immunoglobulin (SCIG)	Hyaluronidase Facilitated Immunoglobulin (fSCIG)
Who?	Indicated for adult and pediatric patients with PI.	Indicated for adult and pediatric patients with PI.	Indicated for adult patients with PI.
How?	Usually administered by a nurse.	Self-administered.	Either self-administered or given by a nurse.
Where does it go?	Infused directly into the bloodstream through a vein.	Infused or injected under the skin into the subcutaneous tissues of the arms, belly, outer buttock or the thighs.	Infused under the skin into the subcutaneous tissues of the belly, outer buttock or the thighs.
When?	Usually given every 3-4 weeks.	Can be given on a flexible schedule from daily to every 2 weeks.	Can be given every 3-4 weeks.
How long?	Can take 2-6 hours to infuse.	Can take 5 minutes to 2 hours to infuse or inject.	Can take 1-2 hours to infuse.
Where is it given?	Can be infused at home, in a hospital or an outpatient infusion center depending on insurance and patient preference.	Usually administered in a home setting after the patient is trained to be independent.	Can be infused at home or in an outpatient infusion center depending on insurance and patient preference.
Side effects?	Patients can have side effects that are often related to the rate of infusion and can be treated and prevented with other medications, given before or after the treatment.	Skin can be red and irritated at the site of injections. This often improves with each injection.	Skin can be red and irritated at the site of injections. This often improves with each injection. The volume per injection is larger than standard subcutaneous (under the skin) injection, so the volume is more visible under the skin, and may take 48-72 hours to totally absorb.

Conclusion

IDF looks forward to working with the agency regarding appropriate treatment for patients with PI and would be pleased to visit with agency staff to serve as a patient focused community resource. If you have any questions, please have your staff contact my colleague Lynn Albizo, Senior Director of Public Policy, at lalbizo@primaryimmune.org or 443-632-2544.

Sincerely,



John G. Boyle
President & CEO