

**Updated Interim Report to Congress**

**Evaluation of the Medicare Patient Intravenous  
Immunoglobulin Demonstration Project**

**Centers for Medicare & Medicaid Services**

**August 2022**

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## **LIST OF ACRONYMS**

**CMS:** Centers for Medicare & Medicaid Services

**DME:** Durable Medical Equipment

**ER:** Emergency Room

**FDA:** Food and Drug Administration

**FFS:** Fee-for-Service

**IDF:** Immune Deficiency Foundation

**Ig:** Immune globulin

**IVIG:** Intravenous Immune Globulin

**LUPA:** Low-Utilization Payment Adjustment

**PIDD:** Primary Immunodeficiency Disorders

**SCIG:** Subcutaneous Immune Globulin

## 1. Legislative Summary

Section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Medicare IVIG Access Act), Public Law 112-242, initially mandated the establishment, implementation, and evaluation of the 3-year Medicare Intravenous Immune Globulin (IVIG) Demonstration Project (the Demonstration) under Part B of title XVIII of the Social Security Act, an Interim Report (completed in 2016), and a Final Report to Congress in 2018.

The Medicare IVIG Access Act established the Demonstration, which provided for a bundled payment for items and services involved with administering IVIG in the home for up to 4,000 Fee-for-Service (FFS) Medicare beneficiaries diagnosed with specific Primary Immunodeficiency Disorders (PIDD). Under the Demonstration, the IVIG product continues to be paid for separately under Medicare Part B. The Demonstration began in October of 2014.

Section 302 of the Disaster Tax Relief and Airport and Airway Extension Act of 2017 (Pub. L. 115-63) extended the initial 3-year Demonstration for another three years, to end in December 2020, subject to the availability of funds.

Section 104, Division CC, of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), further extended the Demonstration for another three years through December 2023, increased the enrollment limit from 4,000 to 6,500 FFS Medicare beneficiaries with specific PIDD, and added a requirement for an Updated Interim Report to Congress due no later than two years after enactment (December 27, 2022). A Final Report to Congress is to be issued no later than one year after the completion of the Demonstration (December 2024). The Demonstration legislative timeline is summarized in Figure 1.

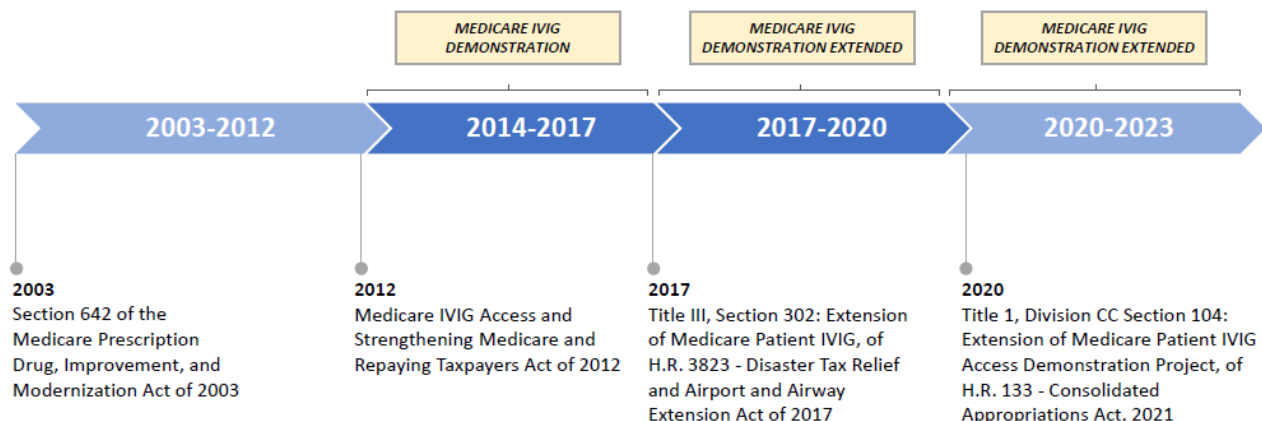
### **Findings in Brief**

*As of December 28, 2020, CMS had paid approximately \$21M for items and services involved with the in-home administration of IVIG under the Demonstration. A total of 2,682 beneficiaries had utilized the Demonstration benefit at least once.*

*The Demonstration provided greater opportunity for non-homebound beneficiaries with select PIDD to receive in-home IVIG. Conversely, administration of IVIG in physician offices and the outpatient setting as well as the use of SCIG declined for Demonstration participants.*

*While surveyed Demonstration participants reported fewer infections and active participants used fewer hospital outpatient and physician services, Medicare payments for Demonstration participants increased by \$8,082 per beneficiary per year.*

**Figure 1: The Medicare IVIG Demonstration Legislative Timeline**



Section 104, Division CC of the Consolidated Appropriations Act, 2021 mandated an updated evaluation and report, herein named the Updated Interim Report to Congress, which focuses on the Demonstration years 2014-2020. This Updated Interim Report to Congress presents the following evaluation findings using quantitative and qualitative analyses:

- (A) The total number of beneficiaries enrolled in the Demonstration project during the updated report period.
- (B) The total number of claims submitted for services during the updated report period, disaggregated by month.
- (C) An analysis of the impact of the Demonstration on beneficiary access to the in-home administration of intravenous immune globulin<sup>1</sup>, including the impact on beneficiary health.
- (D) An analysis of the impact of in-home administration of intravenous immune globulin on overall costs to Medicare, including the cost differential between in-home administration of intravenous immune globulin and administration of intravenous immune globulin in a healthcare facility.
- (E) To the extent practicable, a survey of providers and enrolled beneficiaries that participated in the Demonstration project that identifies barriers to accessing services, including reimbursement for items and services.
- (F) Recommendations to Congress on the appropriateness of establishing a permanent bundled services payment for the in-home administration of intravenous immune globulin for Medicare beneficiaries.

<sup>1</sup> The legislation referred to the Ig product as immune globin. Throughout this report, we refer to it as immune globulin because this is the standard practice.

## 2. Background

Primary Immunodeficiency Disorders (PIDD) are conditions triggered by genetic defects that cause a lack of and/or impairment in antibody function, resulting in the body's immune system not being able to function in a normal way. Immune globulin (Ig) therapy is used to temporarily replace some of the antibodies (i.e., immunoglobulins) that are missing or not functioning properly in people with PIDD.<sup>2</sup> The goal of IVIG therapy is to use Ig obtained from normal donor plasma to maintain a sufficient level of antibodies in the blood of individuals with PIDD to fight off bacteria and viruses. Ig is formulated for both intravenous and subcutaneous administration. Clinicians can prescribe either product to the beneficiary with PIDD according to clinical need and preference, and beneficiaries can switch between intravenous and subcutaneous administration of Ig.

Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), amended section 1861 of the Social Security Act (the Act) to add a new subparagraph (Z) under subsection (s)(2) and a new subsection (zz), which allowed for Medicare Part B to cover the IVIG product for the treatment of PIDD in the home, but not the items and services involved with administering the IVIG product in the home.

In 2006, the Federal Drug Administration (FDA) approved the subcutaneous immune globulin (SCIG) formulation for in-home self-administration. Medicare covers the SCIG product and the items (e.g., an infusion pump and supplies) involved with in-home use under the durable medical equipment (DME) benefit. After 2006, some beneficiaries elected to self-administer the Ig subcutaneously primarily because the pump used to administer SCIG in-home was covered under the Medicare DME benefit.<sup>3</sup>

In 2012, the Medicare IVIG Access Act mandated that the Centers for Medicare & Medicaid Services (CMS) conduct a three-year Demonstration in which Medicare would make a bundled payment for the items and services involved with in-home administration of the IVIG therapy for beneficiaries with specific PIDD diagnoses. Under typical Medicare FFS payment rules, the IVIG product for the treatment of PIDD is paid for in accordance with section 1847A of the Social Security Act (the Act). Items involved with administering the SCIG product in home, such as infusion pumps, are paid for under the Medicare DME benefit, but not for IVIG therapy in the home. Under the Demonstration, Medicare continues to pay for the IVIG product under Part B in accordance with 1847A of the Act. However, a bundled payment for the items and services involved with the administration of IVIG in the home (infusion) is covered under the Demonstration – items may include infusion set and tubing, and services include nursing services to complete an infusion of IVIG lasting on average three to five hours.

Prior to the Demonstration, when Medicare Part B covered only the IVIG product for the treatment of PIDD in the home, approximately 200 Medicare beneficiaries with PIDD received their IVIG infusions in the home per year.<sup>4</sup> With the Demonstration's bundled payment that provided coverage for the items and services involved with IVIG administration in the home, approximately 1,300 beneficiaries with PIDD received in-home IVIG therapy per year.<sup>5</sup> While beneficiaries

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<sup>2</sup> Perez EE, Orange JS, Bonilla F, et al. (2017) *Update on the use of immunoglobulin in human disease: A review of evidence*; Journal Allergy Clin Immunol. 139(3S): S1 – S46.

<sup>3</sup> Immune Deficiency Foundation. (2013). *IDF Patient and Family Handbook for Primary Immunodeficiency Diseases Fifth Edition*. Retrieved June 2015, from <http://primaryimmune.org/idf-publications/patient-family-handbook/>.

<sup>4</sup> Medicare claims data from a 100 percent sample of Medicare beneficiaries with PIDD for 2010-2014

<sup>5</sup> Medicare claims data from a 100 percent sample of Medicare beneficiaries with PIDD for 2015-2020.



enrolled in the Demonstration are able to receive their IVIG therapy in the home, these beneficiaries may also choose to receive their infusions in other care settings.

### 3. Demonstration Overview

Pursuant to the legislation, CMS implemented a bundled per visit payment amount under the Demonstration (see Table 1), based on the national per visit low-utilization payment adjustment (LUPA) for skilled nursing services used under the Medicare Home Health Prospective Payment System established under Section 1895 of the Act. This payment amount is subject to coinsurance and deductibles, as are other Part B services.

**Table 1: Bundled Per Visit Payment Amount for Items and Services Involved With In-home Administration of IVIG throughout the Demonstration Period (2014-2020)**

Demonstration Year	2014	2015	2016	2017	2018	2019	2020
Bundled Payment	\$300.00	\$319.23	\$336.05	\$354.60	\$358.50	\$366.25	\$374.20

Eligible suppliers who submit claims to CMS for the IVIG product and its administration on a single claim form will receive the bundled payment for the services and items involved with the administration in the home under the Demonstration, in addition to a separate payment for the covered IVIG product.

CMS contracted a durable medical equipment (DME) Medicare administrative contractor (MAC) (the “Demonstration implementation contractor”) to perform outreach to eligible beneficiaries with PIDD and enroll them into the Demonstration, as well as to educate suppliers concerning claims submission and the overall Demonstration. Suppliers submit the claims for Demonstration services to the DME MAC for billing and processing.

The Medicare IVIG Demonstration provides coverage under Part B for items and services involved with in-home administration of IVIG to Medicare beneficiaries who are not homebound and receiving services under the Medicare home health benefit. The Demonstration benefit only applies to beneficiaries who choose to receive IVIG for the treatment of PIDD in the home.

Medicare FFS beneficiaries are eligible to voluntarily enroll in the Demonstration if they are:

- enrolled in Medicare Part B;
- have a select PIDD diagnosis<sup>6</sup> and are receiving either IVIG<sup>7</sup> or SCIG treatment (and are interested in switching to in-home IVIG); and
- are not currently receiving home health care services.

<sup>6</sup> List of PIDD diagnoses: Congenital hypogammaglobulinemia (Bruton’s agammaglobulinemia); Selective deficiency of immunoglobulin A; Selective deficiency of immunoglobulin G; Selective deficiency of immunoglobulin M; Immune deficiency with increased IgM Antibody deficiency w/ near-normal immunoglobulin or w/ hyperimmunoglobulin; Transient hypogammaglobulinemia of infancy; Severe combined immune deficiencies; Purine nucleoside phosphorylase [PNP] deficiency; Major histocompatibility complex class I deficiency; Histocompatibility complex class II deficiency; Other combined immunodeficiencies; and Combined immunodeficiency, unspecified; Wiskott-Aldrich syndrome; Di George’s syndrome; Hyperimmunoglobulin E [IgE] syndrome; Common variable immune deficiencies; Cerebellar ataxia with defective DNA repair.

<sup>7</sup> For example, Privigen, Bivigam, Gammaplex, Gamunex-C/Gammaked), Octagam, Gammagard, Flebogamma/Flebogamma.

#### 4. Evaluation Overview and Key Findings

In order to evaluate the impact of the Demonstration, we used a mixed-methods evaluation approach, which included a survey of Medicare FFS beneficiaries with PIDD, healthcare provider interviews, and an analysis of Medicare enrollment and claims data for beneficiaries who were eligible for the Demonstration. Table 2 below provides a description of the populations of interest for each type of impact analysis, as well as the reference groups used throughout this report. The evaluation also included an examination of all beneficiaries receiving IVIG within the total Medicare FFS population, a comparison of the payment methodologies currently used by CMS for administering IVIG in different care settings, and an analysis of the Ig market and other issues associated with IVIG products.

**Table 2: Populations of Interest by Impact Analysis**

<b>Impact Analysis Method</b>	<b>Population of Interest</b>	<b>Description</b>
Beneficiary Survey	Active Demonstration Enrollees	Beneficiaries who self-reported that they were enrolled in the Demonstration and used the Demonstration's benefit at least once
	Non-enrollees with PIDD	Beneficiaries who were eligible for the Demonstration and self-reported that they did not enroll in the Demonstration
	Non-active Demonstration Enrollees	Beneficiaries who self-reported that they were enrolled in the Demonstration but had not received in-home IVIG under the Demonstration by the time the survey was fielded
Medicare Claims Analyses	Active Demonstration Participants	Beneficiaries enrolled in the Demonstration who had at least one Demonstration claim code (i.e., Q2052), indicating that they had received items and services involved with the administration of IVIG in the home under the Demonstration
	Non-participants	Beneficiaries who were eligible for the Demonstration but had no Demonstration claim code
Reference Groups	Beneficiaries with PIDD who ever used IVIG or SCIG	This includes all Demonstration enrollees and participants, those eligible for the Demonstration who did not enroll, and beneficiaries with PIDD who received both SCIG and IVIG
	All Medicare beneficiaries	The overall population of Medicare FFS beneficiaries including all groups listed above

## Summary of Key Evaluation Findings

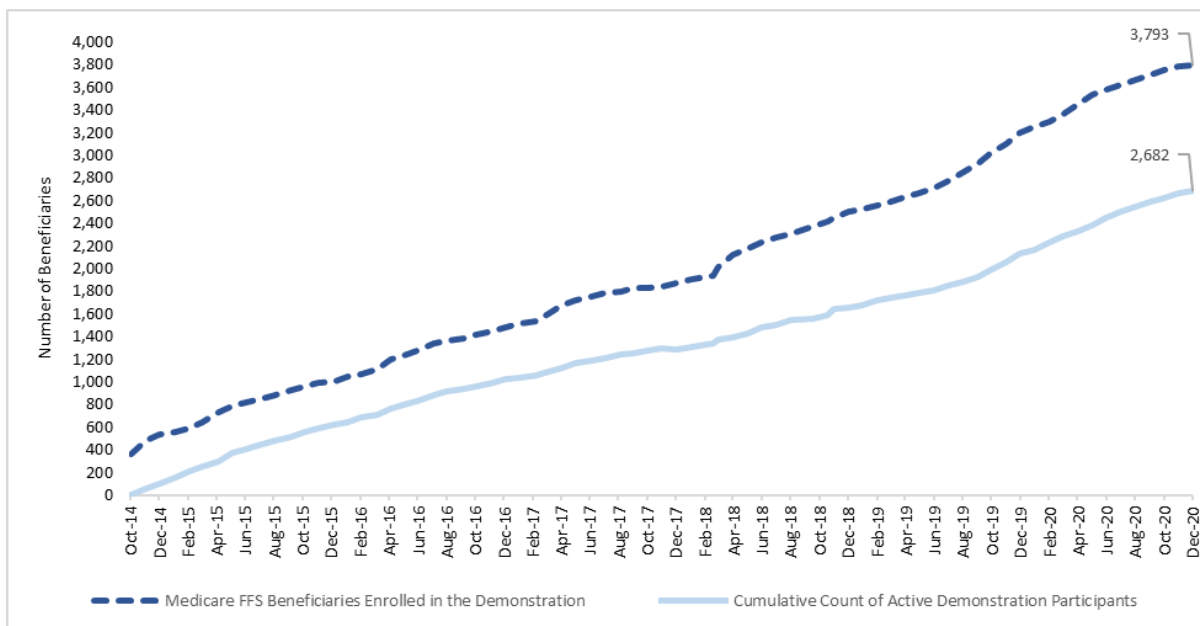
(A) *The total number of beneficiaries enrolled in the Demonstration project during the updated report period.*

There were 12,208 eligible Medicare FFS beneficiaries with PIDD who received IVIG therapy only in 2020, based on Medicare claims data. This may also include beneficiaries who received SCIG treatment who were interested in switching to in-home IVIG. This increased from 2014, where 9,483 eligible beneficiaries with PIDD received IVIG therapy only in that year.

A total of 3,793 eligible Medicare FFS beneficiaries enrolled in the Demonstration between October 1, 2014, and December 28, 2020. Of these, 70.7 percent (2,682) were active Demonstration participants, i.e., Medicare beneficiaries who received in-home IVIG therapy under the Demonstration at least once, as shown in Figure 2.

The count of total FFS beneficiaries who enrolled in the Demonstration and those who actively participated in the Demonstration (i.e., received IVIG in the home at least once) continued to increase between 2014-2020.

**Figure 2: Cumulative Monthly Count of Medicare FFS beneficiaries enrolled in the Demonstration and Active Demonstration Participants during the Demonstration Period (2014 – 2020)**



Source: Dobson | DaVanzo analysis of the IVIG Weekly Report December 28, 2020 - January 1, 2021 prepared by the Demonstration Implementation Contractor as of 12/2020.

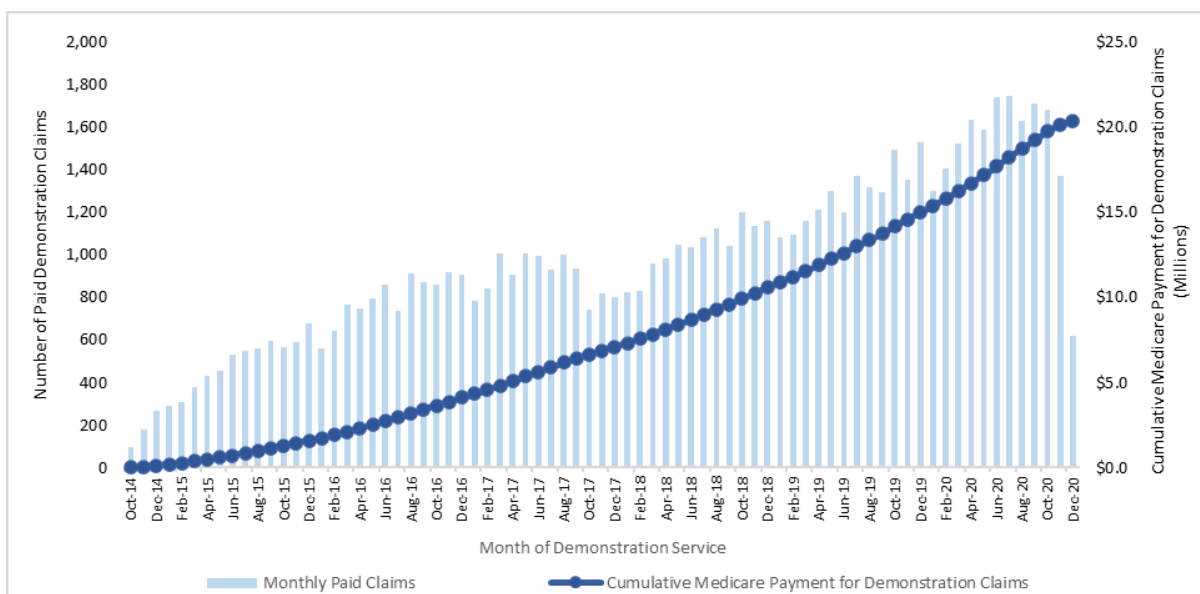
(B) *The total number of claims submitted for services during the updated report period, disaggregated by month.*

CMS processed and paid a total of 72,508 claims for items and services involved with the administration of IVIG in home under the Demonstration from October 1, 2014, through

December 28, 2020.<sup>8</sup> Figure 3 presents the number of claims paid monthly and cumulatively for items and services involved with administering in-home IVIG therapy.

Between October and December 2014, 540 claims were submitted for items and services under the Demonstration. The number of Demonstration claims continued to steadily increase from early 2015 until May 2017 (1,005 claims paid). The number of claims then decreased to 739 by October 2017, when the Demonstration had initially been scheduled to end. Following the Demonstration’s extension through 2020 as a result of the Disaster Tax Relief and Airport and Airway Extension Act of 2017, the trend of monthly Demonstration claims paid started to rise again. CMS paid 1,156 claims in December 2018 and 1,528 claims in December 2019. Over 1,200 claims were paid for each month throughout 2020, concluding with 1,830 claims paid in December 2020.<sup>9</sup>

**Figure 3: Monthly and Cumulative Number of Claims Paid for IVIG Services and Supplies during the Demonstration Period (2014 – 2020)<sup>+</sup>**



Source: Dobson | DaVanzo analysis of the IVIG Weekly Report December 28, 2020-January 1, 2021 prepared by the Demonstration Implementation Contractor as of 12/2020.

<sup>+</sup> This figure shows that 616 paid claims were identified in December 2020, using the IVIG Weekly Report December 28, 2020-January 1, 2021. The IVIG Weekly Report March 22-April 2, 2021 identified 1,830 paid Demonstration claims for December 2020, as this weekly report accounts for the 3-month claims data lag.

*(C) An analysis of the impact of the Demonstration on beneficiary access to in-home administration of intravenous immune globulin, including the impact on beneficiary health.*

The evaluation used both Medicare claims and information from the Beneficiary Survey to determine the impact of the Demonstration on beneficiary access to in-home administration of IVIG and beneficiary health. We analyzed the number of IVIG infusions from the claims and

<sup>8</sup> The paid claims for services under the Demonstration were identified using the Demonstration code Q2052, which is the indicator for the bundled payment for items and services involved with the in-home administration of IVIG.

<sup>9</sup> In the IVIG Weekly Report December 28, 2020-January 1, 2021 prepared by the Demonstration Implementation Contractor, 616 paid claims were identified in December 2020 (as shown in Figure 3). We used the IVIG Weekly Report March 22-April 2 to determine that there were 1,830 total paid Demonstration claims for December 2020, as this report accounts for the 3-month claims data lag.

beneficiary responses to the survey related to Ig therapies to attempt to understand the impact of the Demonstration. We used the percent of beneficiaries who had a physician visit for infection-related services and survey responses to questions concerning respondent health status as indicators of beneficiary health. The impact analysis used Medicare claims data from 2010-2020 for active Demonstration participants who received in-home IVIG services under the Demonstration (n=2,313)<sup>10</sup> and non-participants, i.e., beneficiaries who were eligible for the Demonstration but had no Demonstration claim code, as the comparison group (n=2,081). Survey data were collected from active Demonstration enrollees (n=1,203) and non-enrollees (n=1,399). Separately, interviews were conducted with healthcare providers (e.g., physicians, nurses, and pharmacists) who treated patients with PIDD, and patient advocates from organizations supporting individuals with PIDD who were receiving IVIG or SCIG (n=84).

### Beneficiary Access

- Findings using claims data suggest that active Demonstration participants received an average of 2.26 additional IVIG infusions per year compared to non-participants after adjusting for demographic factors, geographic location, and chronic illnesses.
- Findings using survey data suggest that 71 percent of Demonstration enrollees reported better access to IVIG therapy and less trouble obtaining their Ig treatments than non-enrollees. Non-enrollees with PIDD were 2.7 times more likely to have reported “more trouble overall” getting Ig treatments than Demonstration enrollees.
- Healthcare providers and beneficiaries both reported advantages of in-home IVIG therapy, including reduced transportation barriers, reduced risk of infection, increased treatment compliance, and improved monitoring of the infusion due to one-on-one nursing care.

### Beneficiary Health

- Compared to non-enrollees, surveyed Demonstration enrollees reported being in better health after enrolling in the Demonstration. For example, active Demonstration participants reported a significant drop (about 31 percent) in self-reported serious health issues (pneumonia, bronchitis, hospitalizations, etc.) after enrolling in the Demonstration. They also reported they were less likely to be admitted to a hospital or need antibiotics than non-enrollees.
- In most cases, individuals with PIDD are susceptible to acute, unusual, or recurrent infections, and face greater risks of complications.<sup>11</sup> Findings using claims data suggest that active Demonstration participants were 12.5 percent less likely to receive services (i.e., physician visits) for an infection relative to the comparison group of non-participants, after adjusting for confounding factors such as demographic factors and chronic illnesses. This confirms the qualitative finding from the Beneficiary Survey, which found that non-

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<sup>10</sup> From the 2,682 active Demonstration participants, a total of 2,313 participants met the criteria to be considered for the cost and utilization claims analyses, which required a “run-out” time period. These beneficiaries were required to have paid claims in both their pre- and post-Demonstration periods and to have been entitled to Medicare FFS for a year by the end of 2020.

<sup>11</sup> American Academy of Allergy, Asthma and Immunology (AAAAI). (2011). Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency. <https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf>.

enrollees were 5.9 times more likely to report suffering from infections than active Demonstration enrollees.<sup>12</sup>

- Consistent with results from a 2017 study<sup>13</sup>, findings using 2010-2020 claims data suggest that active Demonstration participants were 18.9 percent less likely to receive services (i.e., physician visits) for an upper respiratory infection when compared to the comparison group of non-participants after adjusting for confounding factors.<sup>14</sup>
- Similarly, findings using 2010-2020 claims analysis suggest that active Demonstration participants were 12.6 percent less likely to receive services (i.e., physician visits) for pneumonia when compared to the comparison group of non-participants after adjusting for confounding factors.<sup>15</sup>

*(D) An analysis of the impact of in-home administration of intravenous immune globulin on overall costs to Medicare, including the cost differential between in-home administration of intravenous immune globulin and administration of intravenous immune globulin in a healthcare facility.*

#### Medicare Payments:

- Overall annual **Medicare payments increased** on average by \$8,082\*\*\*<sup>16</sup> per beneficiary among active Demonstration participants, relative to the comparison group. The beneficiary's total cost of care includes all Medicare A/B expenses, encompassing Part B drug administration and all inpatient and outpatient utilization. Medicare spending for IVIG product in all care settings increased by \$3,647\*\*\* per beneficiary per year among active Demonstration participants.

#### Cost Differential between In-home IVIG Administration and IVIG Administration in a Healthcare Facility

Computing a cost differential for the administration of IVIG infusion between in-home and in a health care facility is not a meaningful comparison, as payment methodologies differ across care settings.

- Payment methodologies for the administration of IVIG differ between in-home and in a healthcare facility, such as a physician's office or a hospital outpatient facility.
- Under the Demonstration, Medicare costs for the items and services involved with the in-home administration of IVIG are bundled into a single fixed payment, whereas services for administering IVIG in a physician's office and a hospital outpatient facility are paid separately or on a per unit basis (e.g., hours).

<sup>12</sup> For reference, the 12.5 percent reduction is equal to 1.66 percentage points divided by the 13.30 percent of Medicare beneficiaries with PIDD who received IVIG therapy in 2014 that had physician visits for an infection.

<sup>13</sup> Wasserman, R., Ito, D., Xiong, Y., Ye, X., & Bonnet, P. (2017). Impact of Site of Care on Infection Rates Among Patients with Primary Immunodeficiency Diseases Receiving Intravenous Immunoglobulin Therapy. *Jour of Clinical Immunology*, 37, 180-186.

<sup>14</sup> For reference, the 18.9 percent reduction is equal to 1.02 percentage points divided by the 5.40 percent of Medicare beneficiaries with PIDD who received IVIG therapy in 2014 that had physician visits to treat an upper respiratory infection.

<sup>15</sup> For context, the 12.6 percent reduction is equal to 0.57 percentage points divided by the 4.50 percent of Medicare beneficiaries with PIDD who received IVIG therapy in 2014 that had physician visits to receive treatment for pneumonia.

<sup>16</sup> \*\*\* = P<0.001.

- In 2020, the average payment for the administration of IVIG was \$94 in physicians' offices for an average of 3.14 hours infusion time, and \$214 in hospital outpatient facilities for an average of 3.09 hours infusion time. For in-home administration of IVIG infusions, the average Medicare bundled payment under the Demonstration was \$297 in 2020.

*(E) To the extent practicable, a survey of providers and enrolled beneficiaries that participated in the Demonstration project that identifies barriers to accessing services, including reimbursement for items and services.*

To identify barriers to accessing services, we gathered information from the survey of Medicare beneficiaries eligible for the Demonstration and a series of semi-structured interviews with healthcare providers. Survey data were collected from active Demonstration enrollees (n=1,203) and non-enrollees (n=1,399). Interviews were conducted with healthcare providers (e.g., physicians, nurses, and pharmacists) who treated patients with PIDD, and patient advocates from organizations supporting individuals with PIDD who were receiving IVIG or SCIG (n=84).

Surveyed beneficiaries who actively used the Demonstration's benefit (i.e., active Demonstration enrollees) identified the following barriers as reasons for applying to the IVIG Demonstration: transportation, risk of infection, out-of-pocket cost, and scheduling in-home IVIG therapy. In addition, the interviewed healthcare providers also indicated the following as barriers to accessing IVIG services: transportation, risk of infection, scheduling in-home IVIG therapy, and staffing and supply issues.

- **Transportation:** Problems with transportation were identified by approximately half of the beneficiaries as a reason for wanting to participate in the Demonstration and receive services in-home. Respondent healthcare providers also identified transportation barriers for beneficiaries who receive IVIG therapy in healthcare settings.
- **Risk of infection:** Over half of beneficiaries identified their exposure to sick patients in healthcare settings as a barrier to accessing their IVIG services. Healthcare providers similarly described the increased risk of infection as an access barrier during their interviews, as a patient's fear of being exposed to infection can affect and/or delay their access to IVIG therapy in a healthcare setting.
- **Cost:** Some beneficiaries identified specific problems with affording their in-home IVIG infusion out-of-pocket costs without the Demonstration.
- **Scheduling in-home IVIG therapy:** Some beneficiaries reported specific difficulties with finding and/or scheduling an in-home IVIG therapy provider, and maintaining consistent in-home IVIG therapy services. Some healthcare providers also reported that patients who live in rural locations are at a higher risk of not receiving their in-home IVIG therapy, as there may be limited availability of trained nurses who can travel long distances to administer their Ig.
- **Staffing and supply issues:** Healthcare providers described barriers to accessing IVIG therapy as limited availability of trained and experienced nurses to administer in-home

IVIG therapy, supply issues with certain concentrations or brands of IVIG, and potential unreliability of commercial shipping companies that deliver Ig products.

*(F) Recommendations to Congress on the appropriateness of establishing a permanent bundled services payment for the in-home administration of IVIG for Medicare beneficiaries.*

Given the voluntary nature of the model, the ability of patients to switch from SCIG to IVIG and vice versa, and the ability for Medicare beneficiaries enrolled in the Demonstration to still receive IVIG infusions in multiple settings (physician's offices; hospital outpatient departments; and at home), patient preferences and selection bias limits our ability to make recommendations on establishing a permanent bundled services payment for in-home administration of IVIG. We will continue to explore ways to ensure that patients have access to the care they need, including in their homes when appropriate and feasible, and any recommendations for legislative action would be included in the President's Budget request for HHS.

## **5. Discussion and Summary**

The Demonstration led to a relative increase of \$8,082 per beneficiary per year in Medicare payments. Subcomponents of Medicare payments looked at included hospital outpatient services, physician services, SCIG products, and in-home IVIG therapy. The Demonstration resulted in decreased Medicare expenditures for hospital outpatient services, physician services, SCIG products, and services for infections among active Demonstration participants, but there was an increase in the frequency and Medicare expenditures associated with in-home IVIG therapy.

To put this finding into context, average annual baseline Medicare spending was \$50,833 per Medicare beneficiary with PIDD who received IVIG therapy in 2019. However, average annual baseline spending for the entire Medicare FFS population was \$10,536 per Medicare beneficiary in 2019. In other words, expenditures for health care among patients with PIDD who receive IVIG therapy can be substantial.<sup>17</sup>

Prior to the start of the Demonstration, FFS Medicare did not cover the items and services involved with administering IVIG therapy at home for patients that were not homebound and able to receive services under the Medicare home health benefit, and less than 3 percent of FFS Medicare IVIG recipients (n=1,442) received IVIG therapy at home between 2010 and 2014. Nearly all beneficiaries received IVIG therapy in a hospital outpatient department or a physician's office. The few who received IVIG therapy at home were younger than the overall group of Medicare beneficiaries with PIDD who received IVIG therapy elsewhere and were predominantly female. Similarly, we found that active Demonstration participants – those who received IVIG therapy with a claim under the Demonstration – were younger and mostly female when compared to non-participants.

Medicare spending for IVIG products prior to and during the Demonstration was significantly higher for Demonstration participants. The annual Medicare spending increase across all settings of \$3,647 for IVIG products during the Demonstration period 2014-2020 may be due in part to beneficiaries switching from SCIG to IVIG therapy in order to meet the Demonstration's eligibility

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<sup>17</sup> Menzin, J., Sussman, M., Munsell, M., & Zbrozek, A. (2014). Economic Impact of Infections Among Patients with Primary Immunodeficiency Disease Receiving IVIG Therapy. *ClinicoEconomics and Outcomes Research*, 2014(6), 297-302.



requirements, as demonstrated by a decrease of \$562 in annual SCIG product payments. However, it is also likely due in part to the fact that Demonstration participants received approximately two additional IVIG therapies relative to recommended amounts per year.

IVIG therapy is typically administered every three to four weeks.<sup>18</sup> Given that active Demonstration participants received on average fewer than 10 in-home IVIG infusions per year, it does not appear that active Demonstration participants are receiving extra therapies beyond recommended amounts.

Healthcare providers stated that they were concerned about the temporary nature of the Demonstration. Some providers expressed concern about recommending their patients to enroll in the Demonstration due to a Demonstration's limited timeframe. Some beneficiaries also noted challenges with finding at home service providers.

Given that the 2014-2020 Demonstration period overlapped with the COVID-19 public health emergency (PHE), we assessed any potential impact of the PHE on our analysis and found that the COVID-19 PHE did not significantly change our evaluation findings.

In summary, during the initial six years of the Demonstration, there was an increase in the number of annual therapies received, the reduced likelihood of Demonstration enrollees missing or having to postpone their IVIG therapies, and there was a decrease in receipt of infection-related services (i.e., physician visits). This report provides evaluation findings of the Demonstration, including the impact on beneficiary access to in-home administration of IVIG, for the Demonstration period October 2014 through December 2020.

The Final Report to Congress, due in 2025, will provide an updated impact analysis of the Demonstration project on IVIG access based on the full nine years of the Demonstration period as well as relevant updates as required by the statute.

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<sup>18</sup> American Academy of Allergy, Asthma and Immunology (AAAAI). (2011). Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency. <https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf>.