Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project: Interim Report to Congress

U.S. Department of Health and Human Services
March, 2016

Introduction

Section 101 of H.R. 1845 Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Medicare IVIG Access Act), Public Law 112-242, mandates the establishment, implementation, and evaluation of a three-year Medicare Patient Intravenous Immunoglobulin (IVIG) Access Demonstration Project under Part B of title XVIII of the Social Security Act. The demonstration project will voluntarily enroll up to 4,000 Medicare beneficiaries who have been diagnosed with Primary Immunodeficiency Diseases. Under the demonstration, Medicare will provide to suppliers of IVIG a bundled payment under Part B for items and services necessary to administer IVIG in-home to enrolled beneficiaries who are not otherwise homebound or receiving home health care benefits.

The Act also requires a report to Congress that provides interim evaluation findings on the impact of the demonstration project on Medicare beneficiaries' access to items and services needed for the in-home administration of IVIG. This interim report fulfills the statutory requirement.

Background

Primary Immunodeficiency Diseases (PIDD) are a group of conditions that are triggered by genetic defects which cause a lack of and/or impairment of antibody function, resulting in the body's immune system not being able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD, and it is the treatment of choice for Medicare beneficiaries with this diagnosis. The goal of IG therapy is to use IG obtained from normal donor plasma to keep enough antibodies in the blood of patients with PIDD to fight off bacteria and viruses. There are two forms of IG therapy: intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG).

In 2006, the U.S. Food and Drug Administration (FDA) approved an SCIG product for the treatment of patients with PIDD. Patients may self-administer this product at home using an infusion pump. Traditional fee-for-service (FFS) Medicare covers the SCIG product and the infusion pump needed at home under the Medicare durable medical equipment (DME) benefit. Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, amended section 1861 of the Social Security Act, to require Medicare Part B coverage of IVIG for the treatment of PIDD in the home. The statute only covers IVIG and did not cover any of the items and services needed to administer the drug. The specific items and services are the supplies and in-home nursing services necessary to inject the drug intravenously. These items and services for administering the drug may be covered if the person is homebound or otherwise receiving services under a Medicare home health episode of care. As a result, many beneficiaries receive IVIG at their doctor's office or in an outpatient hospital setting, or they elect to receive the IG therapy subcutaneously because the items needed to administer SCIG in-home are covered by Medicare.

Under the Medicare Patient IVIG Access Demonstration, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the

beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

Implementation of the Medicare Patient IVIG Demonstration Project

The Centers for Medicare & Medicaid Services (CMS) developed, as required by the Medicare IVIG Access Act, a bundled per-visit amount to be paid to any Medicare supplier that is able to provide the IVIG drug and the professional services needed for administration. The supplier is also able to provide the professional services either using their own staff or through a separate contract. All staff administering the drug must meet their licensure requirements.

Eligible suppliers who submit claims for the drug and administration of the drug on a single claim form to a Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) will receive the bundled payment for the supplies and services to administer the drug in addition to the payment for the drug which is currently covered under the Medicare benefit. Home health agencies are not eligible to be paid under the demonstration for the administration of the IVIG although they may contract with suppliers in their area to provide professional services. In such situations, the supplier would receive the demonstration payment and reimburse the home health agency directly in accordance with their contract.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of intravenous immunoglobulin was based on the national per visit low-utilization payment (LUPA) amount under the prospective payment system for home health services established under section 1895 of the Social Security Act. The demonstration bundled payment that covers medically necessary items and services needed for the in-home administration of IVIG is based on the LUPA rate used in the Medicare Home Health Prospective Payment System. The LUPA rate is made for beneficiaries who require four or fewer visits during a 60-day home health episode.

A home health episode with four or fewer visits is paid the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage-adjusted per visit amount for each of the visits rendered instead of the full episode amount. The national per visit amounts by discipline (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) are updated and published annually by the applicable market basket for each visit type.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of IVIG includes infusion services provided by a skilled nurse. Therefore, the bundled payment is based on the LUPA for skilled nursing only because the services of the other LUPA disciplines are not required for this demonstration. A total per-visit bundled payment of $300 in 2014 was initially calculated. This payment rate is based on the full skilled nursing LUPA for the first 90 minutes of the infusion ($120) and 50% of the LUPA for each hour thereafter for an average 4.5 hour infusion [(100% x $120) + (50% x 3 hours x $120)]. The payment rate is to be revised and updated annually based on the LUPA rate. The payment rate is also subject to

sequestration. In 2015, the bundled payment rate was $319.23. This service is subject to coinsurance and deductibles similar to other Part B services provided in the doctor's office.

Prior to finalizing the design of the demonstration, CMS reached out to relevant stakeholders, including beneficiary advocacy groups, suppliers, and professional societies among others. In addition to in-person meetings, CMS hosted several Open Door conference calls and webinars to increase awareness of, and obtain input on, the demonstration project.

CMS contracted with NHIC, Corp., one of the Medicare Administrative Contractors, to perform the demonstration implementation activities. Tasks included outreach and education, enrollment application processing, handling the demonstration hotline, resolving denied demonstration claims, and reporting. Demonstration claims are payable if the demonstration code (Q2052) is billed with the drug (J code) on the same claim. There are also requirements related to dates for each of the line items on the claim. When claims are not submitted in accordance with the specified requirements, claims may be denied. NHIC Corp. reviews all denied claims and if needed, works with the supplier to resolve any problems. Claims that are denied due to submission errors may be resubmitted. NHIC engaged in targeted outreach to physicians who treat PIDD beneficiaries, beneficiary advocacy groups and IG suppliers. NHIC conducted public dissemination activities to increase awareness and facilitate demonstration enrollment.

To be eligible to enroll in the demonstration project, traditional Medicare must be the beneficiaries' primary insurance, thereby excluding beneficiaries (e.g. some working aged beneficiaries) for whom alternative insurance is the primary payer. Beneficiaries must also: a) have current coverage under the Medicare fee-for-service program; b) have coverage under Medicare Part B; c) have a diagnosis of PIDD; d) submit a completed application with physician approval; and e) not be currently receiving Medicare home health services. For the purposes of the demonstration, the following Medicare covered PIDD diagnoses were included: common variable immunodeficiency, selective immunoglobulin M (IgM) deficiency, Wiskott-Aldrich syndrome, congenital hypogammaglobulemia, and immunodeficiency with increased IgM.

NHIC conducted an analysis of Medicare claims to identify all Medicare fee-for-service beneficiaries with a PIDD diagnosis who had been treated with IVIG across the country. Based on this analysis, information about the demonstration and application letters were mailed out to 9,216 potentially eligible beneficiaries with PIDD who had claims for IG treatment in August, 2014 and, again, in January 2015. Letters were also sent to professional societies and providers treating beneficiaries for PIDD.

The Medicare Patient IVIG Demonstration Project was announced via twitter and on the CMS website. CMS sent out the following tweet on August 5, 2014 announcing the demonstration 'Interested in #IVIG? Announced #Medicare Intravenous Immune Globulin Demonstration 8/5, info: http://go.cms.gov/1s838K2 #careinnovation'. CMS also posted information about the demonstration on the CMS website at https://innovation.cms.gov/initiatives/IVIG/.

The beneficiary application mailings began August 8, 2014 with an initial September 15, 2015 deadline. Bundled payment for approved beneficiary IVIG services started on October 1, 2014. Beneficiary applications are now accepted on a rolling basis as long as space is available.

In October 2014, 352 beneficiaries had enrolled in the program. Due to the low initial enrollment in the demonstration project, targeted outreach was done in order to increase enrollment. In January 2015, NHIC mailed out a second letter and application to beneficiaries who had not applied to inform them that there were still openings in the demonstration. This targeted mailing resulted in an increase in the number of inquiries to the designated demonstration hotline number and an increase in enrollment. By August 1, 2015, the demonstration project enrollment had increased to 872 beneficiaries.

As of August 1, 2015, 9.5 percent (n=872) of the 9,216 eligible Medicare beneficiaries had submitted completed application forms and were enrolled in the demonstration project. Monthly growth has averaged around 44 new enrollees per month (range 30-84) reflecting a mix of those new to the Medicare program, beneficiaries newly diagnosed with PIDD, and those just learning about the demonstration or only now interested in possibly switching to in-home administration of the IVIG drug. Among those enrolled, about fifty percent (449 beneficiaries) have used the demonstration benefit based on the claims submitted and paid under the demonstration through August 7, 2015. Additionally, 235 suppliers have submitted demonstration claims.

Evaluation of the Medicare Patient IVIG Demonstration Project

The Medicare IVIG Access Act requires an interim and a final evaluation report due no later than one year after the demonstration project ends, to be submitted to Congress. The interim report is to contain an evaluation of the impact of the demonstration on access for Medicare beneficiaries to items and services needed for the in-home administration of IVIG. The final report will contain a final evaluation of the impact on access to IVIG items and services, as well as an analysis of the appropriateness of implementing a new methodology for payment for IVIG in all care settings, and an update to the 2007 report by the Assistant Secretary for Planning and Evaluation (ASPE) of the Department of Health and Human Services (HHS), entitled *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immunoglobulin Intravenous*.

CMS awarded a contract to Dobson, DaVanzo & Associates, LLC, to conduct the evaluation activities. The assessment of the impact on access to IVIG items and services, as well as the analysis of the appropriateness of implementing a new payment methodology, will include both a qualitative (beneficiary surveys and provider interviews) and a quantitative (Medicare claims) analytic approach. The update of the ASPE report will also include both qualitative and quantitative research activities. These analyses will be described in the final report.

Because the demonstration has operated for less than a year, there is insufficient demonstration claims experience available to date for analysis, thus, analytic findings concerning the demonstration's impact on Medicare beneficiary access to items and services needed for the in-home administration of IVIG are not included in the interim report. However, this report provides information on the implementation experience to date and a descriptive analysis of Medicare claims information for the demonstration baseline in 2014. Medicare Part A and B claims for beneficiaries with a PIDD diagnosis (consistent with the ICD-9 codes eligible for demonstration enrollment) and the receipt of IVIG (drug code and infusion administration) on the same day for the year 2014 were used for the baseline analysis. The demonstration claims for the

three months (October-December, 2014) showed low demonstration enrollment, and with the claims lag time provided insufficient information to draw preliminary conclusions.

The implementation experience findings were based on the review and analysis of NHIC's reports and hotline logs. Beneficiary surveys and supplier interviews were not included in this interim RTC. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled), suppliers, and other stakeholders in the final RTC. These activities are expected to be initiated in 2016.

The purpose of the baseline analysis is to describe the demographics and patterns of IVIG utilization among beneficiaries with PIDD prior to the demonstration project.

Key findings related to implementation experience indicate that:

- Enrollment in the demonstration is lower than anticipated with 872 enrolled as of August 01, 2015;
- Claims submitted for demonstration services by enrolled participants (n=449) are lower than anticipated as of August 01, 2015;
- Some beneficiaries appear to be enrolling in the demonstration just to reserve spots "in case" they want it—concerned about potential future limits;
- It has not been difficult to find suppliers nationwide; and
- Some beneficiaries are confused about the demonstration benefit offered.

Key findings from the baseline analyses illustrated in Tables 1 and 2 below include:

- There was approximately a 60 percent growth rate in Medicare beneficiaries with PIDD receiving IVIG treatment over the past 5 years;
- The average age of Medicare beneficiaries with PIDD who received IVIG was 68 years old in the year 2014, with over half (59 percent) aged 65 to 79 years;
- Twenty-five percent of the Medicare beneficiaries with PIDD in the year 2014 were beneficiaries younger than 65 years old;
- In 2014, the majority of the PIDD population who received IVIG was white (95 percent) and female (68 percent); and
- In 2014, most of the Medicare beneficiaries with PIDD who were treated with IVIG received their IG treatment in an outpatient facility setting including hospitals, outpatient departments, and infusion suites (66 percent). The rest received IVIG services in a doctor's office.

Table 1. Medicare PIDD growth from 2010 through 2014

Year	**2010**	**2011**	**2012**	**2013**	**2014**
Medicare beneficiaries with PIDD	15,473	17,579	20,097	22,755	23,970
Medicare beneficiaries with PIDD receiving IVIG treatment	5,723	6,468	7,496	8,483	9,150

Table 2. Demographics in baseline year 2014.

Variables	Medicare beneficiaries with PIDD on IVIG in 2014	
Age	Beneficiaries	Percent
<65	2,303	25%
65-69	2,046	22%
70-74	2,010	22%
75-79	1,361	15%
80-84	815	9%
85+	615	7%
Total	9,150	100%
Gender	Beneficiaries	Percent
Male	2,953	32%
Female	6,197	68%
Total	9,150	100%
Race	Beneficiaries	Percent
Unknown	104	1%
White	8,684	95%
Black	164	2%
Other	92	1%
Asian	31	0%
Hispanic	53	1%
North American Native	22	0%
Total	9,150	100%
Original reason for Medicare Entitlement - Disability benefit	Beneficiaries	Percent
Age less than 65 years	2,262	24.7%
Age 65 and older	1,329	14.5%
Total	3,591	39.2%

Overall, the baseline data show that the Medicare beneficiaries with PIDD on IVIG are more likely to be younger (66% younger than 74 years of age), female (68%), white (95%) and non-disabled (75%).

Limitations of the Evaluation

This interim report has several limitations. The low initial enrollment of beneficiaries into the demonstration project makes it difficult to present any findings at this time. Additionally, Medicare claims data for the time period covered in the report (the first ten months of the demonstration) are not yet available due to the lag in obtaining claims data, so an analysis based on demonstration Medicare claims could not be included.

Conclusion

In summary, the demonstration enrollment is voluntary. Presently, beneficiaries have the option to receive the IVIG drug and services in an outpatient setting, a physician's office, an infusion center, or an in-home setting. Given the limited 10-month demonstration experience and low enrollment uptake to date, the interim report does not include an assessment of the impact of the demonstration on beneficiaries' access to items and services needed for the in-home administration of IVIG. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled).

Future recommendations on beneficiaries' access to items and services for in home administration of IVIG will be provided in the final evaluation report. In the meantime, CMS will continue its outreach efforts to beneficiaries and suppliers about the demonstration. This will include targeted outreach focused on non-enrolled beneficiaries eligible for the demonstration via mailings (i.e., a personal letter informing them about the demonstration on an annual basis). The final report to Congress will provide findings based on the full three years of the demonstration project.