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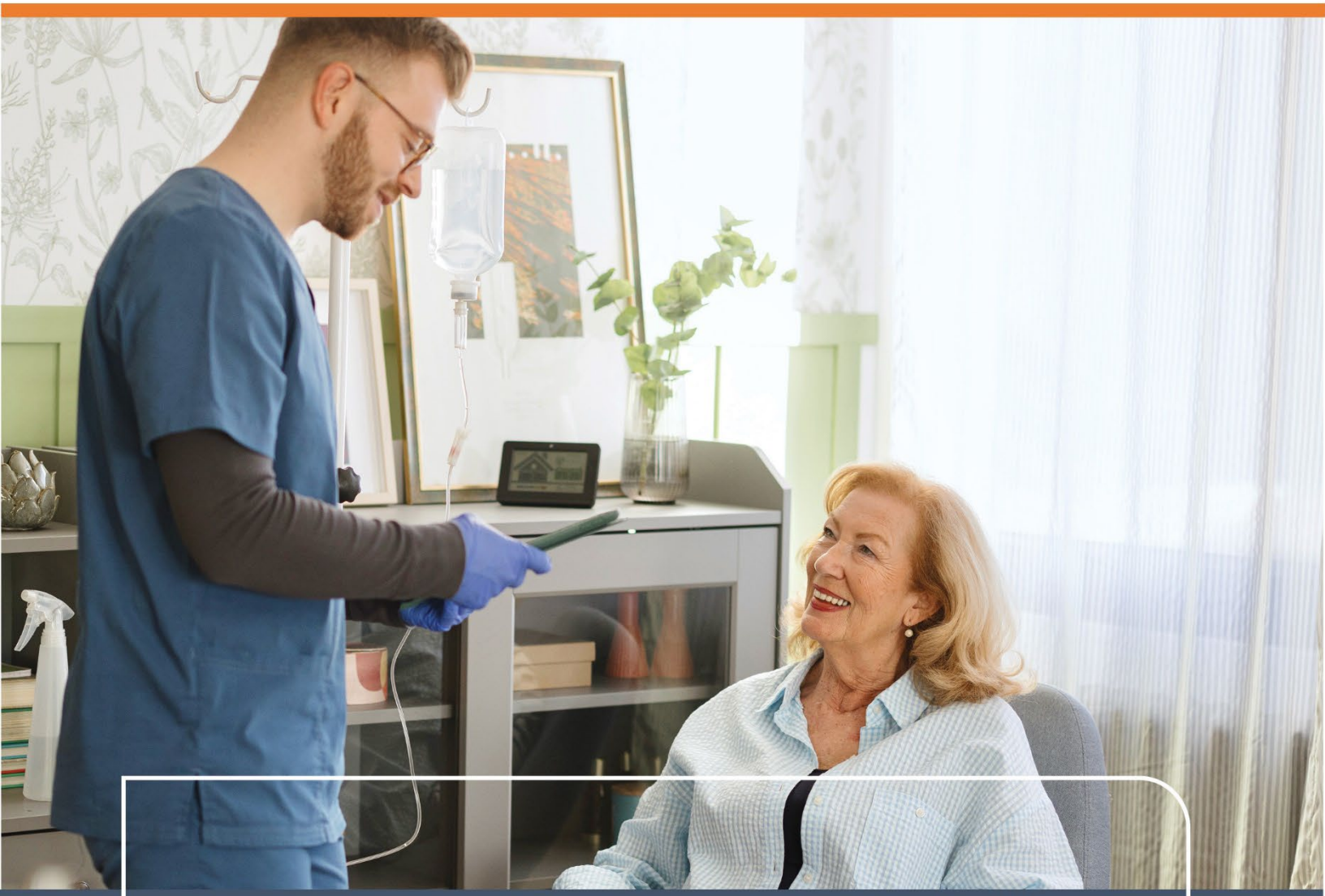

Home IVIG Monitoring Report

February 2025

Analyses and findings within this report were calculated by Abt Global under the contract "Home Health Prospective Payment System (HH PPS) Hospice, Home Infusion Therapy (HIT), Home Intravenous Immune Globulin (IVIG) Items and Services and Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS): Analysis Support and Monitoring" (GS-00F-252CA), funded by the Centers for Medicare & Medicaid Services, Department of Health and Human Services

Abt

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Executive Summary

Coverage of items and services related to the in-home administration of intravenous immune globulin (IVIG) for the treatment of primary immunodeficiency disease (PIDD) became a permanent benefit of Medicare Part B on January 1, 2024, pursuant to Division FF, section 4134 of the Consolidated Appropriations Act, 2023. "Items and services" include infusion equipment and nursing services provided during a visit to the patient's home.[1] Under the benefit, Medicare pays durable medical equipment (DME) suppliers a single payment per visit which is separate from the payment for the IVIG product.[2] Prior to January 1, 2024, the items and services for home IVIG visits were covered for beneficiaries who participated in the Medicare IVIG Demonstration, which began in October 2014.

This report provides information on the number of beneficiaries with claims that included a PIDD diagnosis (Exhibit 1), utilization of home IVIG drugs and visits (Exhibits 2 through 5), characteristics of home IVIG visit recipients (Exhibits 6 and 7), and characteristics of DME/IVIG supplier organizations (Exhibits 8 through 10). Data are presented for the first quarter (Q1) of 2022 through the second quarter (Q2) of 2024. The data for the first eight quarters in this report are from the Medicare IVIG Demonstration and the data for the final two quarters are from the permanent benefit.

From Q1 2022 through Q4 2023, home IVIG visits gradually increased from 4,845 in Q1 2022 to 5,745 in Q4 2023, with an increase in every quarter except Q1 2023. The average quarter-over-quarter increase from Q1 2022 to Q4 2023 was 2.6 percent. Visits increased substantially in 2024 when the permanent benefit began and beneficiaries receiving home IVIG visits were no longer required to be enrolled in the Medicare IVIG Demonstration. Visits increased by 1,077 (18.7 percent) from Q4 2023 to Q1 2024 and increased by 849 (12.4 percent) from Q1 2024 to Q2 2024.

Along with the increase in home IVIG visits, there was a significant increase in the number of visit supplier organizations in 2024. The number of DME suppliers providing home IVIG visits increased from 90 in Q4 2023 to 130 in Q1 2024 (a 44.4 percent increase) after remaining between 86 and 91 organizations in each quarter from Q1 2022 through Q4 2023.

[1] See the discussion in the CY 2024 Home Health final rule: https://www.govinfo.gov/content/pkg/FR-2023-11-13/pdf/2023-24455.pdf.

[2] For more details on payment for home IVIG visits, see the IVIG Policy Article (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52509).

Methodology

Data are from the CMS Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC) and include 100% of Medicare Part B DME claims with a Healthcare Common Procedure Coding System (HCPCS) code indicating either utilization of an IVIG drug or a home IVIG visit. Data also include counts of beneficiaries with an ICD-10-CM diagnosis code indicating PIDD on any Carrier or DME claim by quarter. For this report, we examine the 10 quarters of data from Q1 2022 through Q2 2024. The data for CY 2022 were extracted in April 2024, the data for CY 2023 were extracted in July 2024, and the data for the first two quarters of CY 2024 were extracted in January 2025. The data for each quarter were extracted at least six months after the end of the quarter, which allows sufficient time for claims to process.[3]

To be eligible for the home IVIG benefit a beneficiary must be diagnosed with PIDD, must be using one of 11 drugs covered by the benefit, and the treating practitioner has determined that administration of the IVIG in the patient's home is medically appropriate. To present information on the number of beneficiaries with claims that included a PIDD diagnosis over time, we counted all beneficiaries in each quarter with a DME or Carrier claim that included one of 25 ICD-10-CM codes that indicate a PIDD diagnosis.[4] We identified home IVIG drug prescription fills by searching for DME claim lines that included a HCPCS code for one of the 11 drugs covered by the benefit.[5] We identified home IVIG visits by searching for DME claim lines that included the HCPCS code for items and services related to the in-home administration of IVIG (Q2052). For both prescription fills and visits, we only included claim lines with a positive payment amount.

For this report, DME suppliers were identified using the National Provider Identifier (NPI), and any NPI with at least one home IVIG visit was considered a home IVIG visit supplier. Likewise, any NPI with at least one home IVIG drug fill was considered a home IVIG drug supplier. After identification, NPIs were consolidated using the NPI's organization name field on the National Plan & Provider Enumeration System (NPPES). NPIs with the same or similar organization names were grouped together into a single supplier organization.

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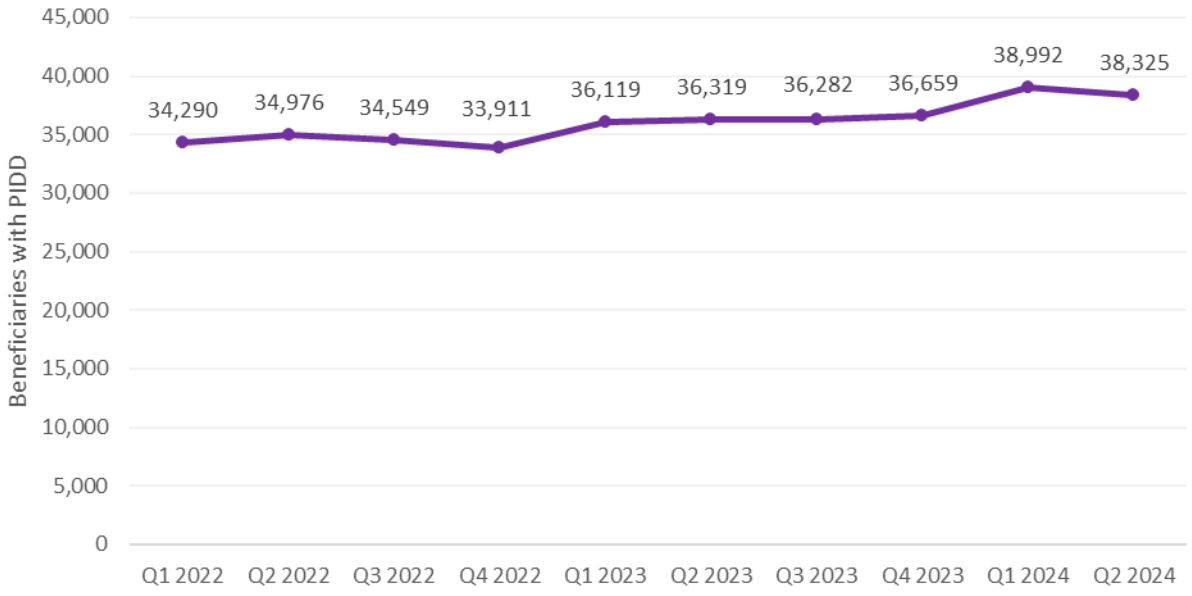
[3] The CCW White Paper: Medicare Claims Maturity reports that 95.45 percent of DME claims for services supplied in July 2010 were final and available in the CCW database within six months of the service date (https://www2.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf).

[4] Table 3 in Pub 100-04 Medicare Claims Processing Transmittal 12437 includes the ICD-10-CM codes indicating a PIDD diagnosis. (https://www.cms.gov/files/document/r12437cp.pdf). Table A1 in Appendix A of this report presents the ICD-10 codes.

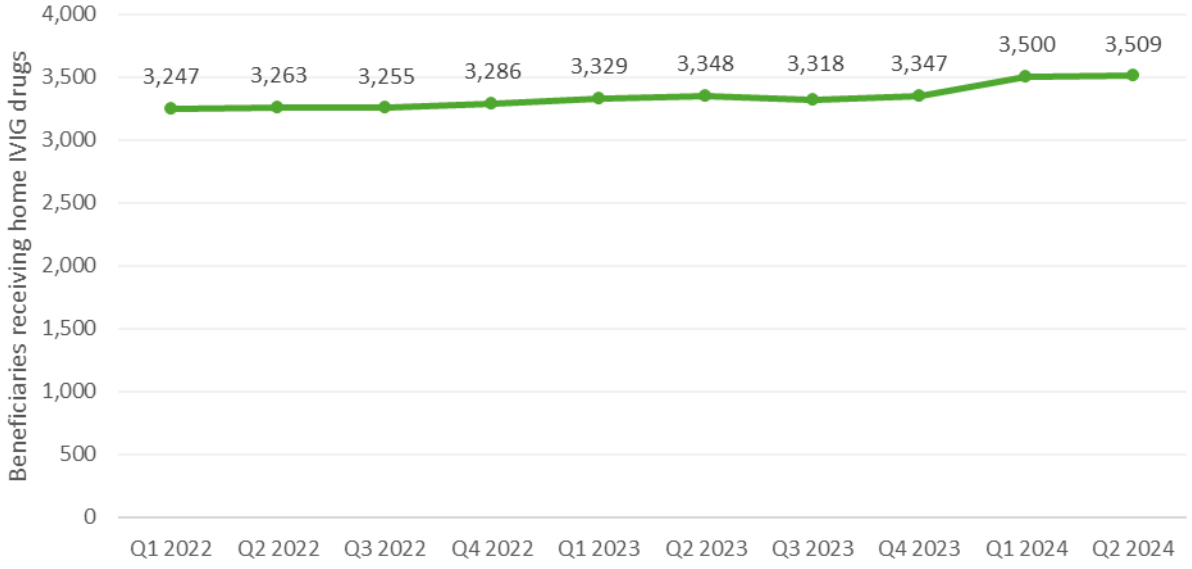
[5] Table 2 in Pub 100-04 Medicare Claims Processing Transmittal 12437 includes the HCPCS codes for home IVIG drugs (https://www.cms.gov/files/document/r12437cp.pdf). Table A2 in Appendix A of this report presents the HCPCS codes.

Exhibit 1. Beneficiaries with a claim that included a diagnosis code for a primary immunodeficiency disease (PIDD) (Q1 2022 – Q2 2024)



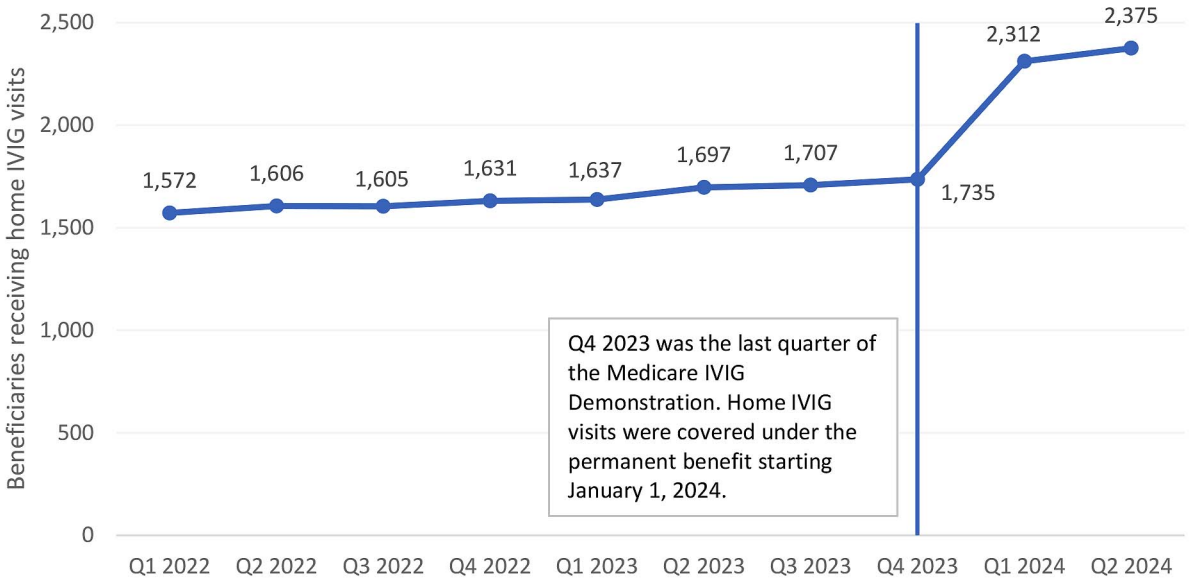
Source: Analyses of Medicare FFS Carrier and DME claims (Accessed from CCW VRDC on January 24, 2025)

Exhibit 2. Beneficiaries receiving home IVIG drugs (Q1 2022 – Q2 2024)



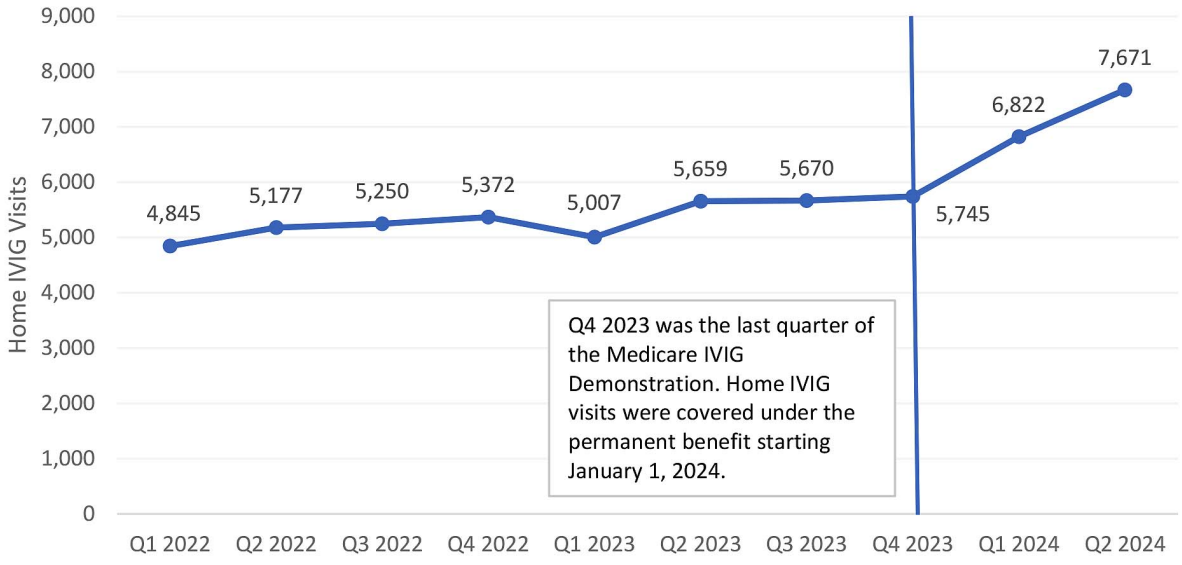
Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

Exhibit 3. Beneficiaries receiving home IVIG visits (Q1 2022 – Q2 2024)



Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

Exhibit 4. Number of home IVIG visits (Q1 2022 – Q2 2024)



Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

KEY TAKEAWAYS:

The **number of beneficiaries with a claim** that included a **diagnosis code for a PIDD** (and so were potentially eligible for home IVIG visits) was **11.8% higher in Q2 2024** than in **Q1 2022**.

The **number of beneficiaries** receiving **home IVIG drugs increased** by **8.1%** over the same period.

The **number of beneficiaries** receiving **home IVIG visits** and the **total number of service visits increased by 51.1%** and **58.3%, respectively**, over the same period. **Most of the increase in home IVIG visits** occurred in **2024**.

EXHIBIT 1-4 METHODOLOGY:

Exhibit 1 shows the number of unique beneficiaries in each quarter that had a Part B DME or Carrier claim with one of 25 ICD-10-CM codes for PIDD.
Exhibit 2 shows the number of unique beneficiaries in each quarter that had a Part B DME claim line with a positive payment amount and a HCPCS code for one of the 11 IVIG drugs that qualify a beneficiary for the home IVIG benefit.
Exhibit 3 shows the number of unique beneficiaries that had a Part B DME claim line with a positive payment amount and the HCPCS code for items and services related to the in-home administration of IVIG (Q2052).
Exhibit 4 shows the number of Part B DME claim lines with a positive payment amount and the HCPCS code for items and services related to the in-home administration of IVIG (Q2052).

Exhibit 5. Utilization of home IVIG visits by linked IVIG drug (Q3 2023 - Q2 2024)

Linked Drug	Number of visits	Share of visits
Gammagard liquid (J1569)	6,609	25.5%
Gamunex (J1561)	6,123	23.6%
Privigen (J1459)	3,188	12.3%
Panzyga (J1576)	2,828	10.9%
Gammaplex (J1557)	2,628	10.1%
Bivigam (J1556)	1,806	7.0%
IVIG, NOS lyophilized (J1566)	1,001	3.9%
Octagam (J1568)	862	3.3%
Asceniv (J1554)	691	2.7%
IVIG, NOS non-lyophilized (J1599)	153	0.6%
Unmatched	21	0.0%
Flebogamma (J1572)	0	0.0%
Total	**25,910**	**100.0%**

Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

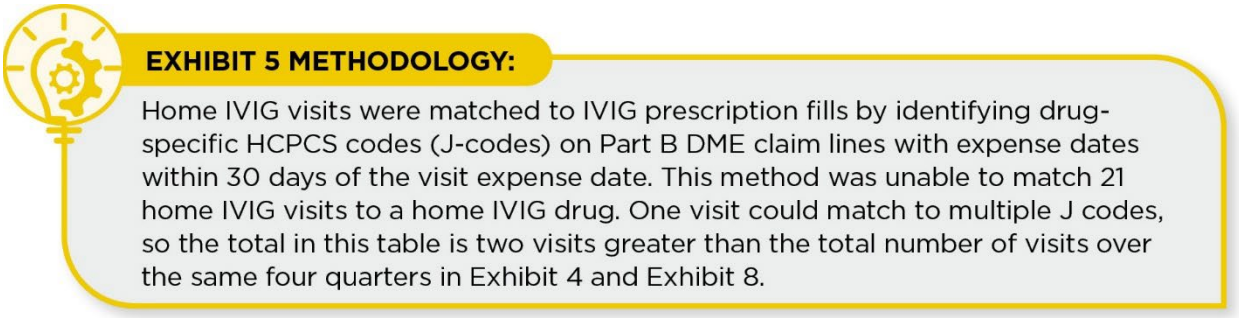
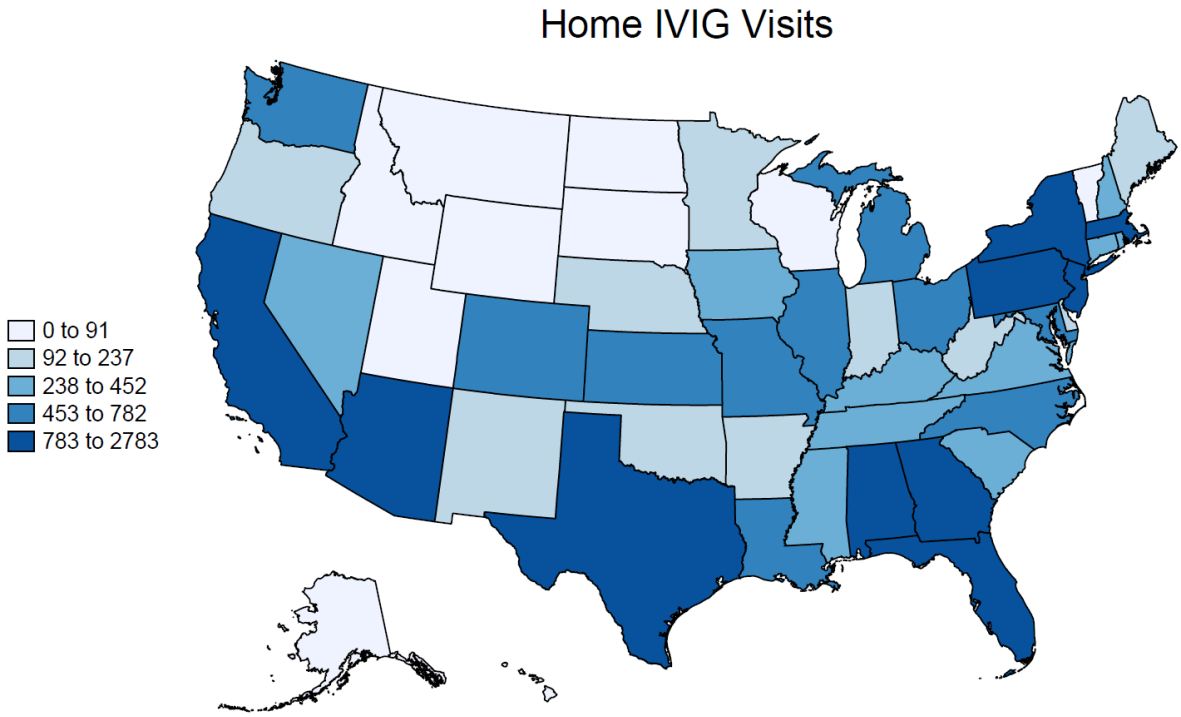
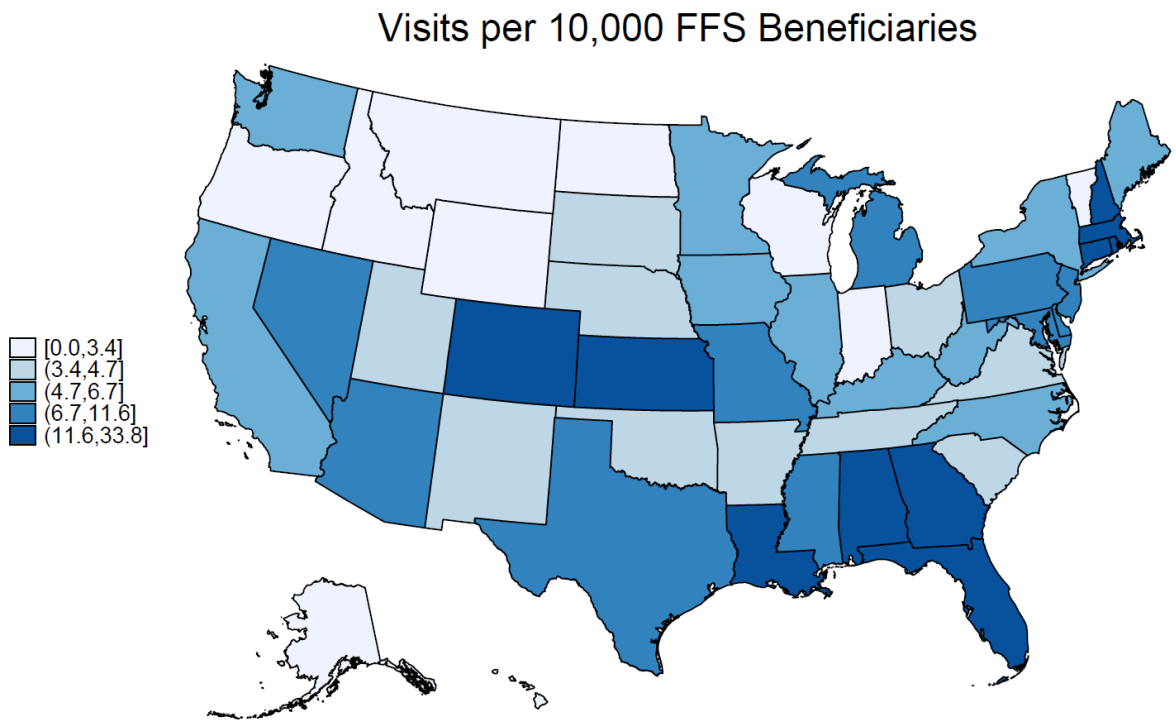


Exhibit 6. Home IVIG visits by state (Q3 2023 - Q2 2024)





Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

KEY TAKEAWAYS:

Without adjusting for differences in Medicare FFS enrollment across states, **IVIG visits were highest** in **Alabama, California, Florida, Georgia, Massachusetts, New York, New Jersey, Pennsylvania**, and **Texas**.

The **number** of **IVIG visits per 10,000 FFS Medicare beneficiaries** was **highest** in **Alabama** and **Rhode Island** at **33.8** and **26.0 visits per 10,000 beneficiaries**, respectively. After Rhode Island, **Massachusetts** had the **next highest number** of **IVIG visits per 10,000 FFS Medicare beneficiaries at 15.4.**

EXHIBIT 6 METHODOLOGY:

The state of a home IVIG visit was identified using the beneficiary residence state code on the DME claim. The number of FFS Medicare beneficiaries for each state was determined using the monthly enrollment for December 2023 reported on the CMS website: https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/monthly-enrollment-state. The categories for the two maps are based on quintiles for the number of visits and for the number of visits per 10,000 FFS beneficiaries, respectively.

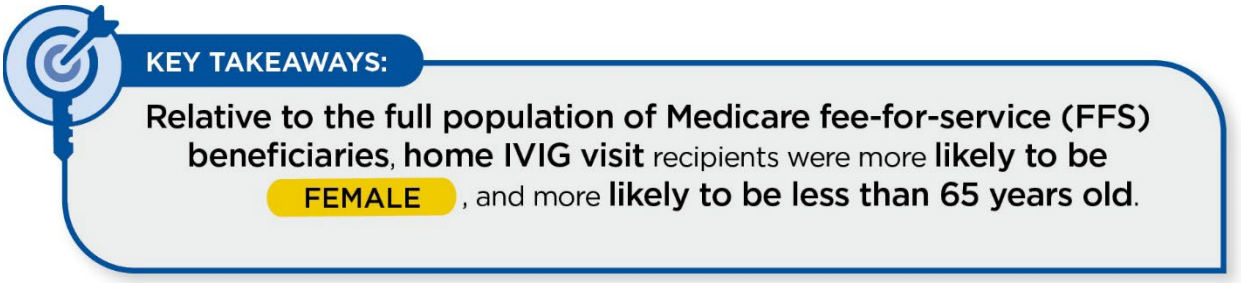
Exhibit 7. Number and percent of beneficiaries with home IVIG visits by demographic characteristics (Q3 2023 - Q2 2024)

	Home IVIG Beneficiaries		Medicare FFS 2023*
	N	%	%
Sex			
Female	2,124	77.8%	52.7%
Male	607	22.2%	47.3%
Total	2,731	100%	100%
Age			
Age < 65	502	18.4%	10.0%
65 <= Age < 75	1,281	46.9%	51.3%
75 <= Age < 85	770	28.2%	27.8%
85 <= Age	178	6.5%	10.9%
Total	2,731	100%	100%
Dual Eligibility**			
Never Dually Eligible	2,401	87.9%	89.0%
Any Dual Eligibility	330	12.1%	11.0%
Total	2,731	100%	100%

* Contains all Medicare FFS beneficiaries from the Medicare Beneficiary Summary File (MBSF) with both Part A and Part B enrollment.

** Eligibility for both Medicare and Medicaid.

Source: Analyses of Medicare FFS Part B DME claims and the MBSF (Accessed from CCW VRDC on January 24, 2024)



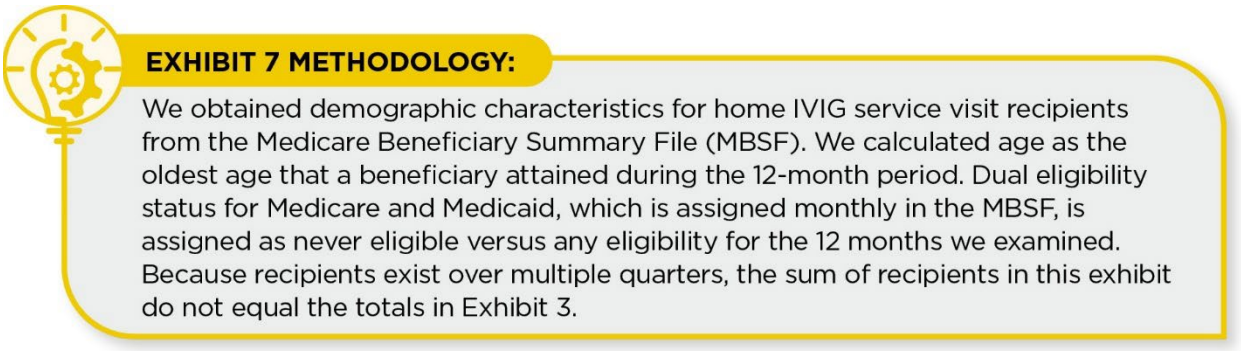
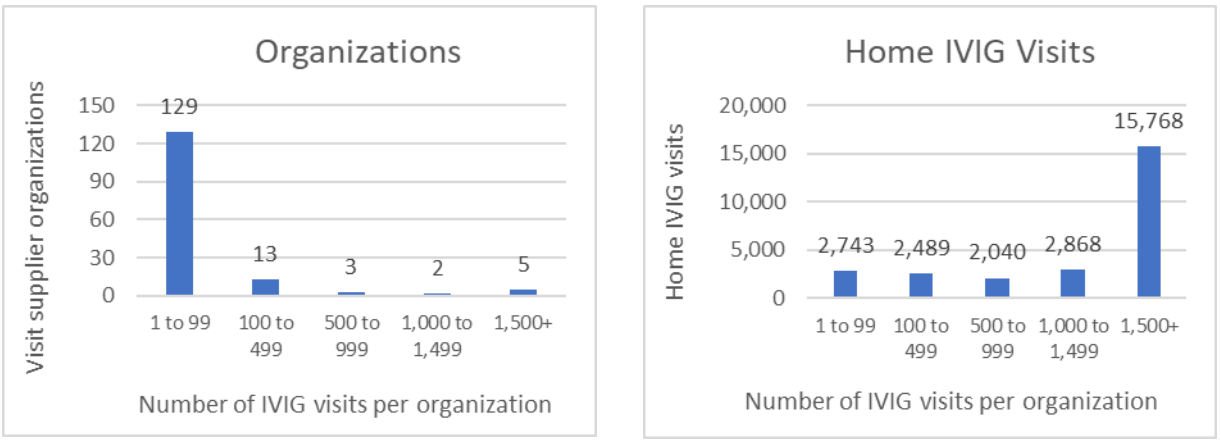
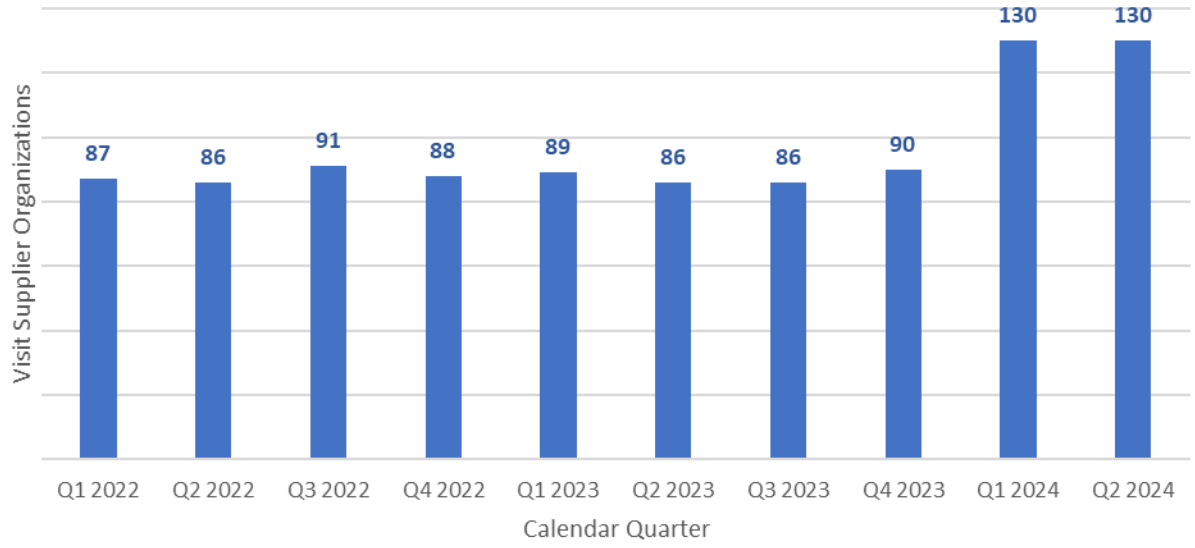


Exhibit 8. Number of home IVIG visit supplier organizations and total number of visits by size of supplier organization (Q3 2023 - Q2 2024)



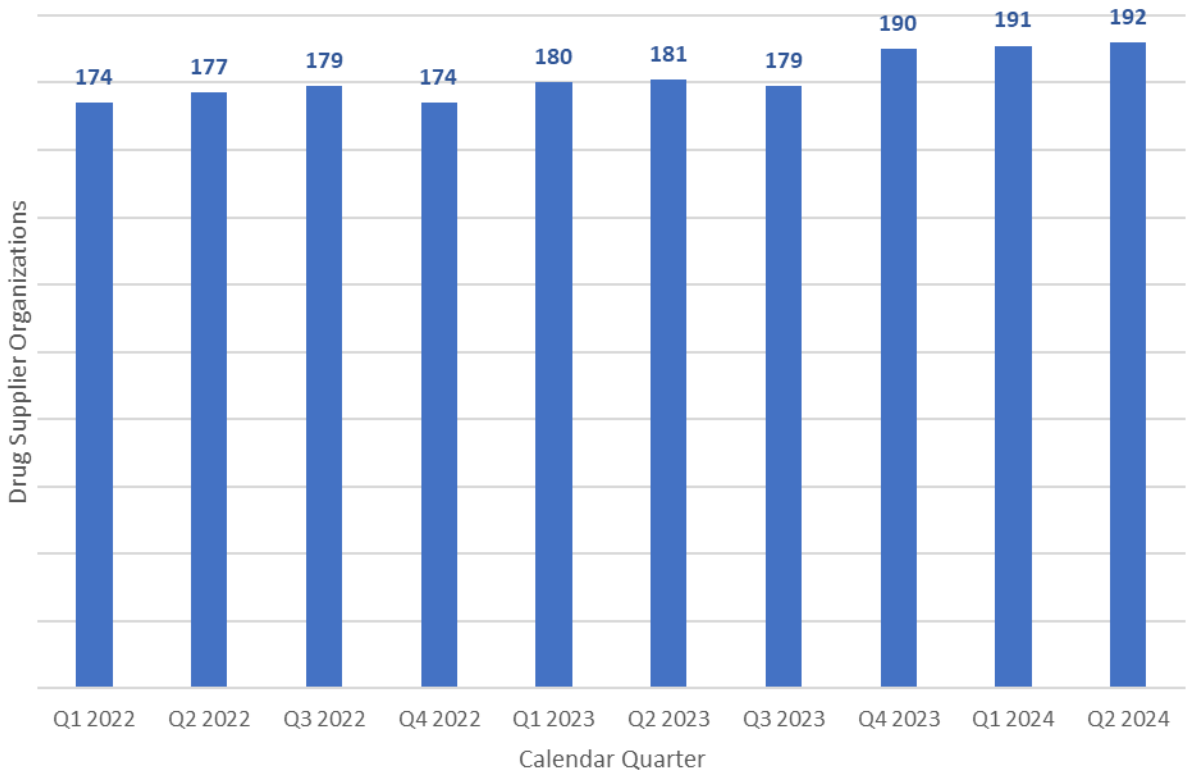
Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

Exhibit 9. Number of home IVIG visit supplier organizations (Q1 2022 - Q2 2024)



Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

Exhibit 10. Number of home IVIG drug supplier organizations (Q1 2022 - Q2 2024)



Source: Analyses of Medicare FFS DME claims (Accessed from CCW VRDC on January 24, 2025)

KEY TAKEAWAYS:

Five DME supplier organizations **supplied 60.9% of home IVIG visits during the 12 months ending June 30, 2024.**
Ten supplier organizations **supplied 79.8% of visits in that 12-month period.**

Of the **152 organizations** that supplied visits during the **12 months ending June 30, 2024**, **129 supplied fewer than 100 visits.**

The number of **DME suppliers** providing **home IVIG visits increased**

FROM Q4 2023 **90 visits** **TO** Q1 2024 **130 visits**

after remaining between 86 and 91 organizations for each quarter from Q1 2022 through Q4 2023

The **number** of **organizations** providing **home IVIG drugs increased**

FROM Q3 2023 **179** **TO** Q4 2023 **190**

EXHIBIT 8-10 METHODOLOGY:

DME suppliers were identified using the National Provider Identifier (NPI), and any NPI with at least one home IVIG visit was considered a home IVIG visit supplier. Likewise, any NPI with at least one home IVIG drug fill was considered a home IVIG drug supplier. After identification, NPIs were consolidated using the NPI's organization name field on the National Plan & Provider Enumeration System (NPPES). NPIs with the same or similar organization names were grouped together into a single supplier organization. For Exhibit 8, we identified 331 NPIs that provided home IVIG visits in the 12 months ending June 30, 2024, and we combined these NPIs into 152 different organizations. For Exhibit 9, we identified 370 NPIs that provided home IVIG visits in the 30-month period from Q1 2022 through Q2 2024, and we combined these NPIs into 163 different organizations. For Exhibit 10, we identified 519 NPIs that provided home IVIG drugs in the 30-month period from Q1 2022 through Q2 2024, and we combined these NPIs into 252 different organizations.

Appendix A: PIDD ICD-10 Codes and IVIG HCPCS Codes

Table A1: PIDD ICD-10-CM Codes (as of February 2025)

Code	Description
D80.0	Hereditary hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G11.3	Cerebellar ataxia with defective DNA repair

Table A1: HCPCS Codes for Home IVIG Drugs (for Calendar Year 2024)

Code	Description
J1459	Privigen, Non-Lyophilized (E.G., Liquid), 500 Mg
J1554	Asceniv, 500 Mg
J1556	Bivigam, 500 Mg
J1557	Gammaplex, Non-Lyophilized (E.G., Liquid), 500 Mg
J1561	Gamunex-C/Gammaked, Non-Lyophilized (E.G., Liquid), 500 Mg
J1566	Lyophilized (E.G., Powder), Not Otherwise Specified, 500 Mg
J1568	Octagam, Non-Lyophilized (E.G., Liquid), 500 Mg
J1569	Gammagard Liquid, Non-Lyophilized, (E.G., Liquid), 500 Mg
J1572	Flebogamma/Flebogamma Dif, Non-Lyophilized (E.G., Liquid), 500 Mg
J1576*	Panzyga, Non-Lyophilized (E.G., Liquid), 500 Mg
J1599	Non-Lyophilized (E.G., Liquid), Not Otherwise Specified, 500 Mg

* Claims for Panzyga for dates of service from January 1, 2021 to June 30, 2023 were submitted using the HCPCS code J1599. Beginning July 1, 2023, claims for Panzyga used the HCPCS code J1576.