



HIT Monitoring Report

January 2022

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Executive Summary

Under Fee-for-service (FFS) Medicare, home infusion therapy (HIT) involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. The components needed to perform home infusion include the drug (for example, antivirals, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. Nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

This report summarizes utilization for the HIT service visits (Exhibits 1 through 4), characteristics of HIT recipients (Exhibits 5 through 7), and characteristics of DME/HIT supplier organizations (Exhibits 8 through 10). Data are presented through the end of the first quarter (Q1) of 2021.

Important aspects of this version of the report are (1) utilization during the COVID-19 public health emergency (PHE), and (2) the transition from the temporary transitional payment (TTP) period to the permanent benefit, which began on January 1, 2021. There are two major changes between the TTP and the permanent benefit. First, under the TTP, only DME suppliers can provide HIT service visits. Under the permanent benefit, any qualified HIT supplier who is accredited and enrolled in Medicare can provide HIT service visits. Second, the list of HIT-eligible drugs changed slightly with three low-utilization drugs being removed (Morphine Sulfate, Preservative Free, Ziconotide, and Floxuridine) and one subcutaneous immune globulin drug (XEMBIFY) being added.

From Q1 2019 to Q1 2021, the quarterly average of HIT service visits remains low at about 6,000 visits. Although the two highest quarters over that time period occurred during the PHE (Q1 and Q2 2020), the rate of utilization growth appears to have slowed during the PHE. The number of HIT service visits has since decreased to 5,382 visits during the first quarter of the permanent benefit (Q1 2021).

For the past twelve months, utilization has been concentrated in the Mid-Atlantic and Florida, which is partly reflected by the concentration of Medicare fee-for-service (FFS) enrollment in those locations. Similarly, HIT service visit recipients tend to be white and under 75 years of age.

The HIT market is very concentrated with 5 of the 80 DME/HIT suppliers providing almost half of the HIT service visits in the past twelve months. The quarterly average of DME/HIT supplier organizations declined from 55 during 2019 (the first year of the TTP period), to 53 (the second year of the TTP period), to 40 in Q1 2021 (the first quarter of the permanent benefit).

Overall Methodology

Data for analyses come from the CMS Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC), where 100% of HIT related Medicare Part B claims are extracted quarterly beginning with quarter 1 (Q1) of 2019. For this report we examine the nine quarters of data that exist from Q1 2019 through Q1 2021. Each quarter of data is extracted seven months after the quarter's end to account for claims processing timelines.¹ These data are used to track HIT utilization among Medicare fee-for-service (FFS) beneficiaries with Part B coverage during the temporary transitional payment (TTP) period, spanning January 1, 2019 to December 31, 2020, and the permanent benefit, which began January 1, 2021.

We identify HIT drug fills by identifying DME claim line-items that include the HCPCS code for one of the 37 drugs covered by the TTP for claims in calendar years 2019-2020,² or one of the 34 drugs covered by the permanent benefit for claims on or after January 1, 2021.³ Any beneficiary with a HIT drug fill is considered a "HIT drug recipient". All HIT drug recipients are potentially eligible to receive HIT professional service visits through the TTP and the permanent HIT benefit.

Under both the TTP and the permanent HIT benefit, CMS pays HIT suppliers for professional services furnished for each infusion drug administration calendar day.⁴ Medicare covers the professional services for three payment categories of HIT drugs:

- **Category 1** for certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs,
- **Category 2** for subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions, and
- **Category 3** for chemotherapy drugs or other highly complex infusion drugs or biologicals

Because utilization patterns and beneficiary characteristics can vary by drug category, many of the tables and figures below present findings by drug category.

We identify HIT service visits when a HIT claim line-item includes one of the following payment category-specific HCPCS codes (G-codes) in calendar years 2019 and 2020: G0068 for HIT service visits related to Category 1 drugs, G0069 for HIT service visits related to Category 2 drugs, and G0070 for HIT service visits related to Category 3 drugs.^{5,6} Beginning January 1, 2021, three additional HIT service visit

¹ Providers have up to a year from service date to submit claims (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf>). Table 3 of the CCW White Paper: Medicare Claims Maturity indicates that over 95 percent of claims are final after six months (<https://www2.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf>).

² <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf>

³ <https://www.cms.gov/files/document/mm11880.pdf>

⁴ For more details on Medicare reimbursement of HIT service visits, consult Pub 100-04 Medicare Claims Processing Transmittal 10547 (<https://www.cms.gov/files/document/r10547cp.pdf>).

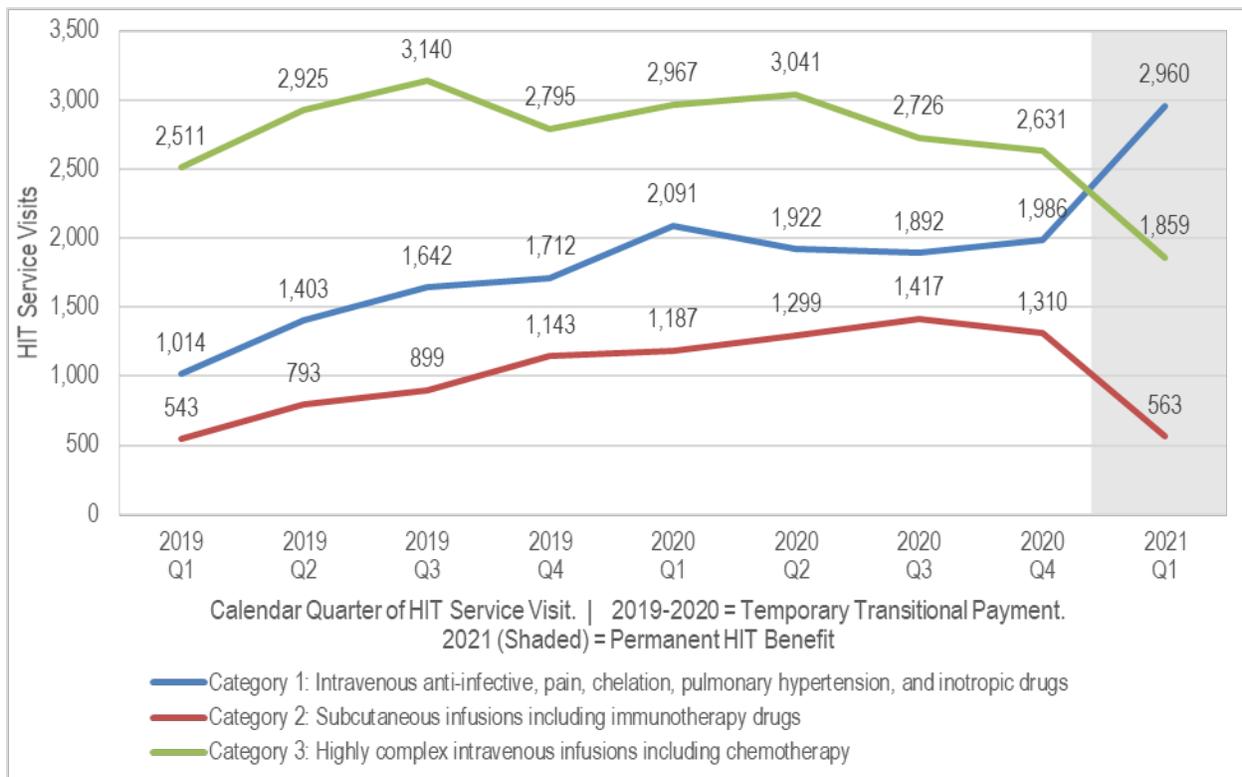
⁵ For the TTP, HIT claims are located on the durable medical equipment (DME) Medicare Part B claims. For the permanent benefit, the HIT claims are located on the carrier Medicare Part B claims.

⁶ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10836.pdf>

G-codes were added to differentiate between initial and subsequent visits. In 2021, the G-codes used during the TTP period are used for subsequent visits, whereas the three additional G-codes (G0088, G0089, and G0090, ordered by payment category) are used for initial visits.⁷ Any beneficiary with a HIT service visit is considered a “HIT service visit recipient.” Additional information on the HIT drug and service visit codes can be found in Appendix A.

⁷ <https://www.cms.gov/files/document/mm11880.pdf>

Exhibit 1. Number of HIT service visits by drug category (Q1 2019 – Q1 2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

The total **number of visits increased by almost 4,000 visits**, despite the ongoing public health emergency (PHE).

2019
20,520 total visits

2020
24,469 total visits

During the TTP period,

CATEGORY 1 increased by **2,120 visits** from 2019 (5,771 visits) to 2020 (7,891 visits),

CATEGORY 2 increased by **1,835 visits** from 2019 (3,378 visits) to 2020 (5,213 visits), and

CATEGORY 3 held steady between 2019 (11,371 visits) and 2020 (11,365 visits).

During the TTP period, **CATEGORY 3** visits accounted for the largest share of visits. With the implementation of the permanent benefit in 2021,

CATEGORY 1 accounts for the largest share of visits.



EXHIBIT 1 METHODOLOGY:

Refer to Overall Methodology for details.

Exhibit 2. Breakdown of HIT service visits by initial/subsequent visit and by drug category under the Temporary Transitional Payment (CY 2019 & 2020) and Permanent HIT Benefit (Q1 2021)

Type of HIT Service Visit	Category 1		Category 2		Category 3		Total	
	N	%	N	%	N	%	N	%
CY 2019 & 2020								
Initial	991	7.3%	1,341	15.6%	2,040	9.0%	4,372	9.7%
Subsequent	12,671	92.7%	7,250	84.4%	20,696	91.0%	40,617	90.3%
Total	13,662	100.0%	8,591	100.0%	22,736	100.0%	44,989	100.0%
2021 (Q1)								
Initial	81	2.7%	31	5.5%	82	4.4%	194	3.6%
Subsequent	2,879	97.3%	532	94.5%	1,777	95.6%	5,188	96.4%
Total	2,960	100.0%	563	100.0%	1,859	100.0%	5,382	100.0%

Category 1: Intravenous anti-infective, pain management, chelation, pulmonary hypertension, and inotropic drugs.

Category 2: Subcutaneous infusions including immunotherapy drugs.

Category 3: Highly complex intravenous infusions including chemotherapy drugs.

Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

The share of initial HIT service visits has decreased

FROM the temporary transitional payment period **TO** the permanent HIT period

CYS 2019 & 2020

CY 2021

Across both periods, **CATEGORY 2** has the highest share of initial HIT service visits, followed by Category 3 and Category 1.



EXHIBIT 2 METHODOLOGY:

For the permanent benefit, refer to Overall Methodology for details. For the TTP period, we identify a HIT service visit as an initial visit if no other HIT service visit occurred in the 60 days prior; otherwise, the visit is considered as subsequent.

Exhibit 3. Utilization of HIT service visits by HIT drug category and linked drug, past twelve months (ending 3/31/2021)

Drug Category	Linked Drug	Frequency of HIT Service Visits	Share of Drug Category	Share of All HIT Service Visits
Category 1	Milrinone lactate (J2260)	5,184	59.2%	22.0%
	Dobutamine HCl (J1250)	621	7.1%	2.6%
	Treprostinil (J3285)	218	2.5%	0.9%
	Other	2,737	31.2%	11.6%
	Category 1 Total	8,760	100.0%	37.1%
Category 2	Hizentra (J1559 JB)	1,905	41.5%	8.1%
	Hyqvia (J1575 JB)	906	19.7%	3.8%
	Cuvitru (J1555 JB)	649	14.1%	2.7%
	Other	1,129	24.6%	4.8%
	Category 2 Total	4,589	100.0%	19.4%
Category 3	Fluorouracil (J9190)	8,659	84.4%	36.7%
	Blinatumomab (J9039)	193	1.9%	0.8%
	Doxorubicin HCl (J9000)	26	0.3%	0.1%
	Other	1,379	13.4%	5.8%
	Category 3 Total	10,257	100.0%	43.5%

Category 1: Intravenous anti-infective, pain management, chelation, pulmonary hypertension, and inotropic drugs.

Category 2: Subcutaneous infusions including immunotherapy drugs.

Category 3: Highly complex intravenous infusions including chemotherapy drugs.

Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

The most linked drug is fluorouracil

CATEGORY 3

followed by milrinone lactate

CATEGORY 1

followed by Hizentra and Hyqvia

CATEGORY 2



These four drugs link to 70.6 percent of all HIT service visits.

One linked drug dominates the share of each drug category, with

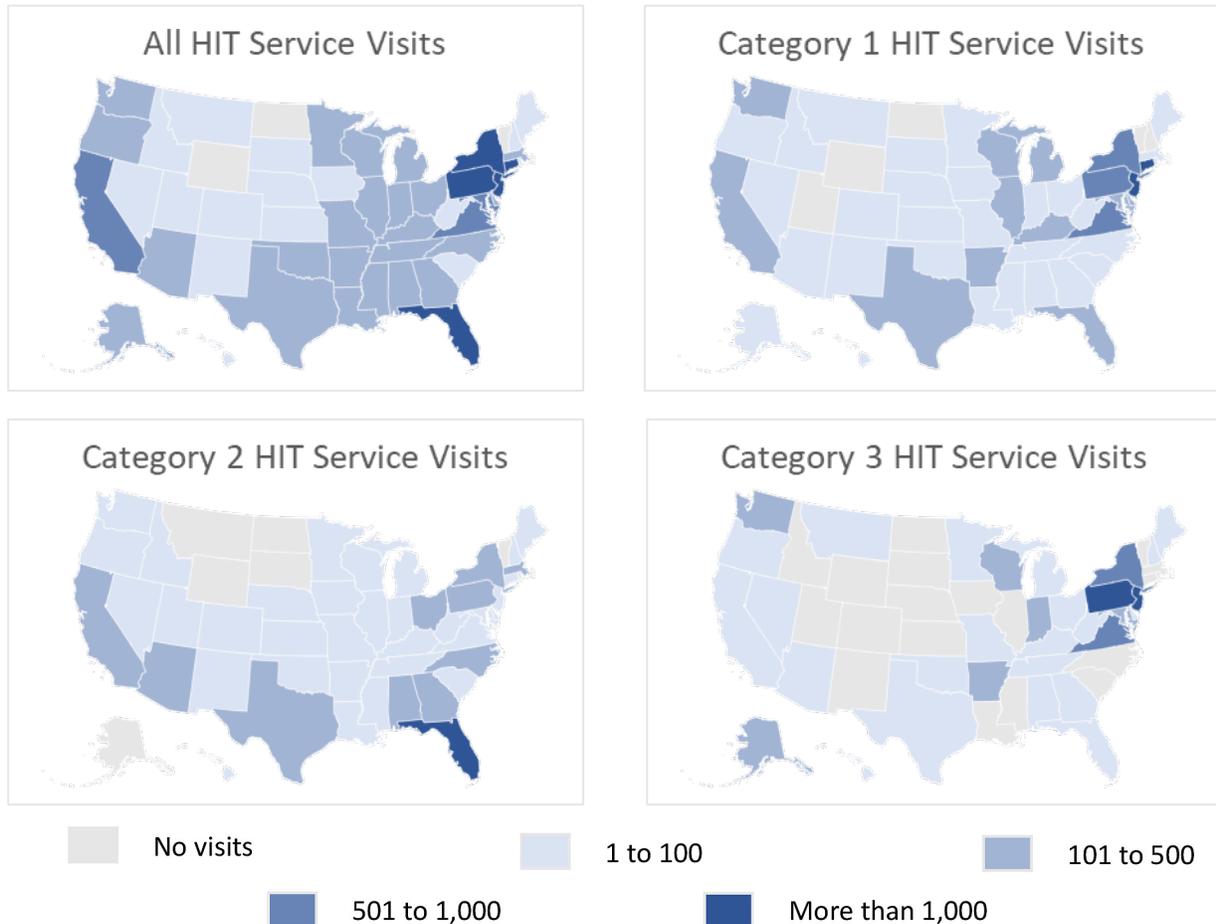
milrinone lactate at 59.2 percent, Hizentra at 41.5 percent, and fluorouracil at 84.4 percent.



EXHIBIT 3 METHODOLOGY:

For reimbursement, all HIT service visits must occur within 30 days of a HIT prescription fill, which can be identified using drug-specific HCPCS codes (J-codes) on the Part B Medicare FFS DME claims data.

Exhibit 4. HIT service visits by state and payment category, past twelve months (ending 3/31/2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)

Category 1: Intravenous anti-infective, pain management, chelation, pulmonary hypertension, and inotropic drugs.
Category 2: Subcutaneous infusions including immunotherapy drugs.
Category 3: Highly complex intravenous infusions including chemotherapy drugs.



KEY TAKEAWAYS:

Without adjusting for Medicare FFS enrollment across states, **HIT service visits are concentrated in the Mid-Atlantic**, especially Pennsylvania and New Jersey. Some southeastern states also exhibit elevated rates of visits. With some exceptions, the West and Midwest have very few visits.

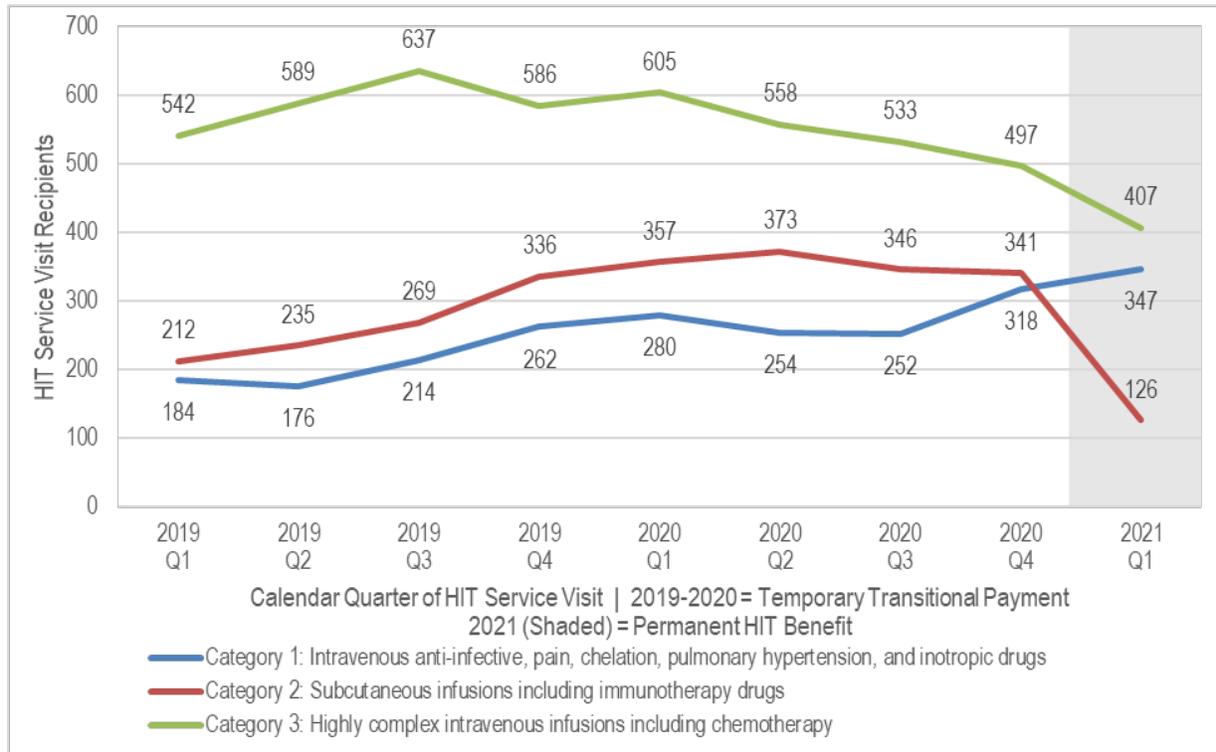
- CATEGORY 3** HIT service visits are heavily concentrated in the Mid-Atlantic.
- CATEGORY 2** visits are concentrated in Florida, and **CATEGORY 1** visits are more geographically dispersed.



EXHIBIT 4 METHODOLOGY:

We identify the state of the HIT service visits using the beneficiary residence state code located on the HIT claim.

Exhibit 5. Number of HIT service visit recipients by drug category (Q1 2019 – Q1 2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)

KEY TAKEAWAYS:

The number of HIT service visit recipients increased by 218 beneficiaries
FROM Q1 2019 TO Q4 2020.

The number of beneficiaries fell or leveled off during the public health emergency.

The number of HIT service visit recipients decreased with the implementation of the permanent benefit,
FROM Q4 2020 TO Q1 2021
1,156 users **880 users**

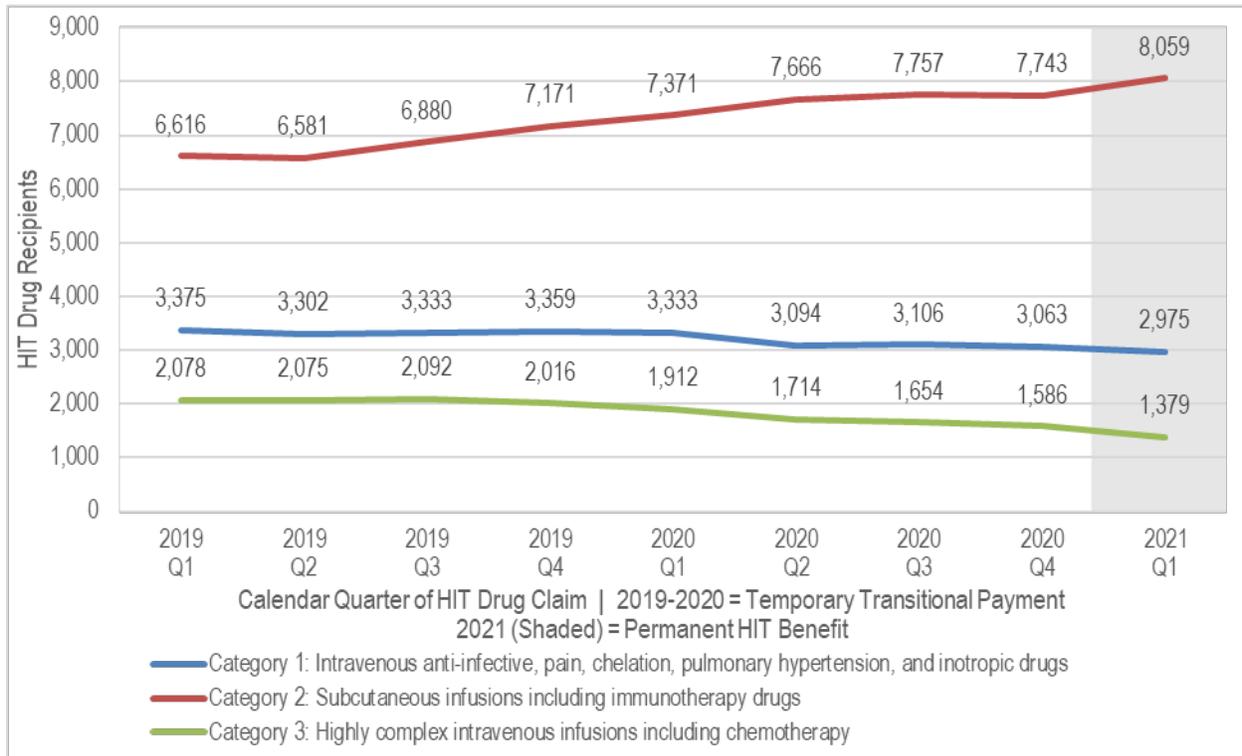
After an initial rise, **CATEGORY 3** beneficiaries have been declining since Q3 2019.

After a steady increase during the TTP period, **CATEGORY 2** beneficiaries decreased in the first quarter of the permanent benefit.

EXHIBIT 5 METHODOLOGY:

Note that recipients who receive service visits in multiple quarters will be included in each quarterly total when the service visit occurred. Refer to Overall Methodology for other details.

Exhibit 6. Number of HIT drug recipients (Q1 2019 – Q1 2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

The number of **CATEGORY 2** HIT drug recipients **continues to increase through the public health emergency**, while the number of Category 1 and 3 HIT drug recipients declined.

On average, **9 percent of HIT drug recipients also receive a HIT service visit** in each quarter during the TTP period, and that share **decreases to 5 percent in Q1 2021** (see also Exhibit 5).



EXHIBIT 6 METHODOLOGY:

Refer to Overall Methodology for details on definitions for HIT drug recipients and payment categories. If a HIT drug recipient receives multiple HIT drug fills within a quarter across payment categories, the highest numbered payment category is assigned to that recipient. Note that recipients who fill HIT prescriptions in multiple quarters will be included in each quarterly total when the HIT prescriptions were filled.

Exhibit 7. Number and percent of HIT service visit recipients by demographic characteristics, past twelve months (ending 3/31/2021)

Demographic	Category 1		Category 2		Category 3		Total HIT		Medicare FFS 2020*
	N	%	N	%	N	%	N	%	%
Race									
White	537	68.9%	634	94.2%	958	83.4%	2,129	81.9%	80.8%
Black	173	22.2%	n/a	n/a	111	9.7%	293	11.3%	9.1%
Other	69	8.9%	39	5.8%	79	6.9%	178	6.8%	10.1%
Total	779	100.0%	673	100.0%	1,148	100.0%	2,600	100.0%	100.0%
Sex									
Female	287	36.8%	533	79.2%	535	46.6%	1,355	52.1%	52.8%
Male	492	63.2%	140	20.8%	613	53.4%	1,245	47.9%	47.2%
Total	779	100.0%	673	100.0%	1,148	100.0%	2,600	100.0%	100.0%
Age									
Age < 65	184	23.6%	111	16.5%	136	11.8%	431	16.6%	13.1%
65 <= Age < 75	290	37.2%	331	49.2%	639	55.7%	1,260	48.5%	51.3%
75 <= Age < 85	235	30.2%	182	27.0%	339	29.5%	756	29.1%	24.5%
85 <= Age	70	9.0%	49	7.3%	34	3.0%	153	5.9%	11.1%
Total	779	100.0%	673	100.0%	1,148	100.0%	2,600	100.0%	100.0%
Eligibility for both Medicare and Medicaid (Dually Eligible)									
Never Dually Eligible	602	77.3%	585	86.9%	1,007	87.7%	2,194	84.4%	86.9%
Any Dually Eligible	177	22.7%	88	13.1%	141	12.3%	406	15.6%	13.1%
Total	779	100.0%	673	100.0%	1,148	100.0%	2,600	100.0%	100.0%

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

Source: Analyses of Medicare FFS Part B DME claims and the MBSF (Accessed from CCW VRDC on October 29, 2021)

Category 1: Intravenous anti-infective, pain management, chelation, pulmonary hypertension, and inotropic drugs.

Category 2: Subcutaneous infusions including immunotherapy drugs.

Category 3: Highly complex intravenous infusions including chemotherapy drugs.



KEY TAKEAWAYS:

HIT service visit recipients are predominately

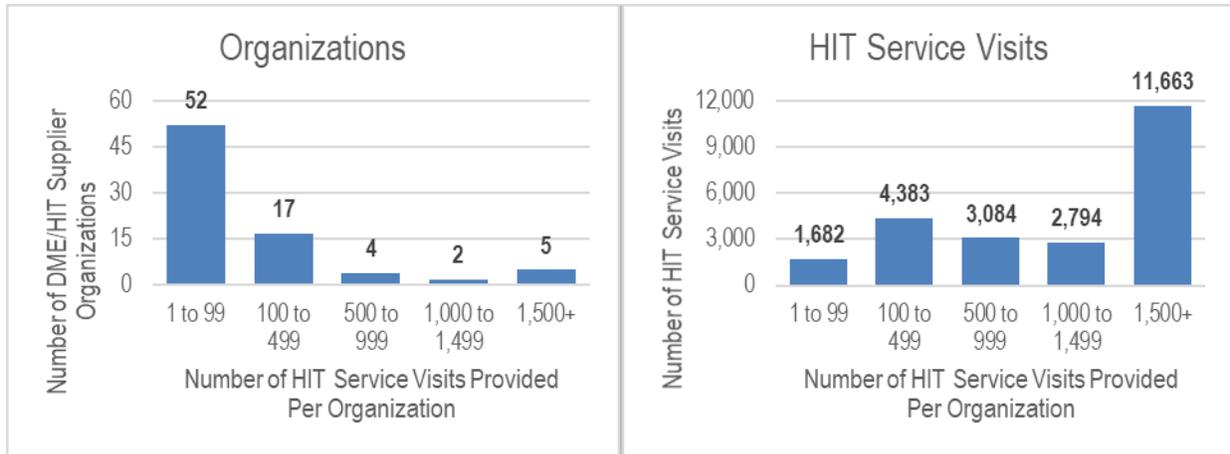
WHITE and **UNDER 75 YEARS OF AGE.**

Relative to the other payment categories, the **CATEGORY 1** HIT service visit recipients were more likely **BLACK**, **UNDER 65 YEARS OF AGE**, and dual eligible for Medicare and Medicaid.

**EXHIBIT 7 METHODOLOGY:**

We obtained demographic characteristics for HIT service visit recipients from the Medicare Beneficiary Summary File (MBSF). We calculate age at the end of the twelve-month period or at the beneficiary's date of death, if applicable. Dual eligibility status for Medicare and Medicaid, which is assigned monthly in the MBSF, is assigned as never eligible versus any eligibility for the 12 months we examined. Because recipients exist over multiple quarters, the sum of recipients in Exhibit 5 will not equal the totals in this exhibit. We combine cell sizes less than 10 with the next smallest cell size and denote the suppressed cell as "n/a."

Exhibit 8. Histogram of DME/HIT supplier organizations and HIT service visits by HIT service visits provided per organization, past twelve months (ending 3/31/2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

Five of 80 DME/HIT supplier organizations supply 49.4 percent of HIT service visits.

52 organizations provide fewer than 100 HIT service visits.



EXHIBIT 8 METHODOLOGY:

During the TTP period, only DME suppliers could provide HIT service visits. After implementation of the permanent HIT benefit, only accredited HIT suppliers, which could include DME suppliers, can provide HIT service visits. Any supplier (based on its National Provider Identifier (NPI)) that provides at least one or more HIT service visit is considered a DME/HIT supplier. After identification, NPIs are consolidated using the NPI's organization name field in the National Plan & Provider Enumeration System (NPPES). NPIs with the same or similar organization names are grouped together as a single organization.

Exhibit 9. Number of DME/HIT supplier organizations providing HIT service visits (Q1 2019 – Q1 2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

By comparing

2019-2020

to

Q1 2021

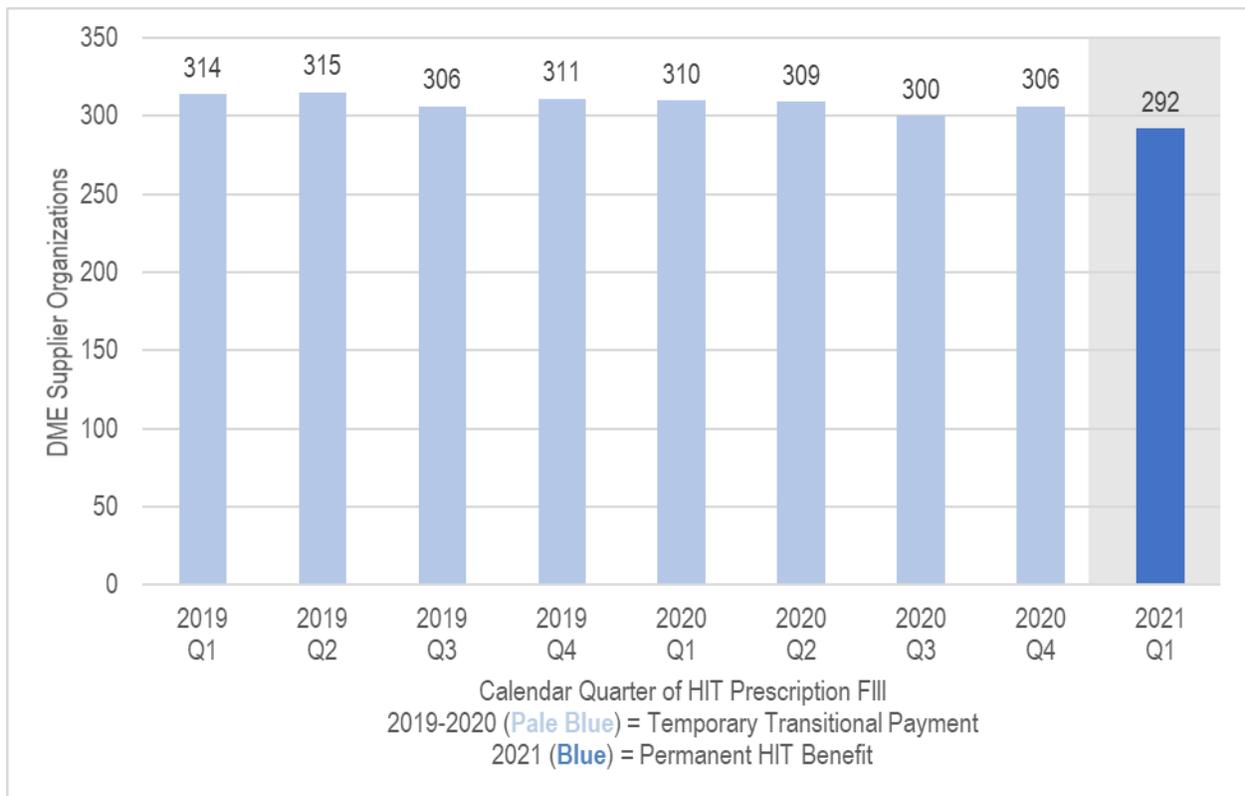
there appears to be a **decrease in the number of DME/HIT supplier organizations providing HIT service visits** after implementation of the permanent HIT benefit.



EXHIBIT 9 METHODOLOGY:

During the TTP period, only DME suppliers could provide HIT service visits. After implementation of the permanent HIT benefit, only accredited HIT suppliers, which could include DME suppliers, can provide HIT service visits. Any supplier (based on its National Provider Identifier (NPI)) that provides at least one or more HIT service visit is considered a DME/HIT supplier. After identification, NPIs are consolidated using the NPI's organization name field in the National Plan & Provider Enumeration System (NPPES). NPIs with the same or similar organization names are grouped together as a single organization.

Exhibit 10. Number of DME supplier organizations providing HIT prescription fills (Q1 2019 – Q1 2021)



Source: Analyses of Medicare FFS Part B DME claims (Accessed from CCW VRDC on October 29, 2021)



KEY TAKEAWAYS:

The number of DME supplier organizations providing HIT drugs has been stable over time, although the number of Q1 2021 DME supplier organizations is slightly lower at 292 than the TTP period average of 309.



EXHIBIT 10 METHODOLOGY:

Only DME suppliers can provide HIT prescription fills. Any supplier (based on its National Provider Identifier (NPI)) that provides at least one or more HIT prescription fill is considered a DME supplier. After identification, NPIs are consolidated using the NPI's organization name field in the National Plan & Provider Enumeration System (NPPES). NPIs with the same or similar organization names are grouped together as a single organization.

Appendix A: HIT HCPCS Codes

Table A1: Transitional Home Infusion Drugs Covered by Medicare Part B, specified by the Bipartisan Budget Act of 2018

HCPCS Code	Therapeutic Class	Drug Name (Listed in Corresponding Order with HCPCS Code)
Category 1: Anti-Infectives, Chelation, Pain Management, and Cardiovascular Drugs		
J0133; J0285; J0287; J0288; J0289; J0895; J1455; J1457; J1570	Anti-Infective, Chelation, and Hypercalcemia	Acyclovir; Amphotericin B; Amphotericin B, Lipid; Amphotericin B, Cholesteryl Sulfate; Amphotericin B, Liposome; Deferoxamine Mesylate; Foscarnet Sodium; Gallium Nitrate; Ganciclovir Sodium
J1170; J2175; J2270; J2274*; J2278*; J3010	Pain Management	Hydromorphone; Meperidine HCl; Morphine Sulfate; Morphine Sulfate, Preservative Free*; Ziconotide*; Fentanyl Citrate
J1250; J1265; J1325; J2260; J3285	Cardiovascular	Dobutamine HCl; Dopamine HCl; Epoprostenol; Milrinone Lactate; Treprostinil
Category 2: Subcutaneous Immune Globulin		
J1555 JB; J1559 JB; J1561 JB; J1562 JB; J1569 JB; J1575 JB	Immune Globulin	CUVITRU; Hizentra; GAMUNEX-C/GAMMAKED; Vivaglobin; GAMMAGARD LIQUID; HYQVIA
Category 3: Chemotherapy Drugs		
J9000; J9039; J9040; J9065; J9100; J9190; J9200*; J9360; J9370	Chemotherapy	Doxorubicin; Blinatumomab; Bleomycin Sulfate; Cladribine; Cytarabine; Fluorouracil; Floxuridine*; Vinblastine Sulfate; Vincristine Sulfate

* HCPCS codes and corresponding drug names with asterisks were eligible drugs during the TTP period but were removed from the permanent HIT benefit (beginning on January 1, 2021). The Category 2 drug XEMBIFY (J1558 JB) was not an eligible drug during the TTP period and became eligible with the implementation of the permanent HIT benefit.

Table A2: HIT Service Visit Codes

HCPCS Code	Description
G0068	Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0069	Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0070	Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0088*	Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0089*	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0090*	Professional services, initial visit, for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes

* The HCPCS codes G0088, G0089, and G0090 signify an initial HIT service visit only and were created as part of the implementation of the permanent HIT benefit. These codes were not in use during the TTP period.