CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12437	**Date: December 28, 2023**
	Change Request 13217

Transmittal 12252 issued November 02, 2023, is being rescinded and replaced by Transmittal 12437, dated December 28, 2023 to update business requirement 13217.7 - The contractor shall reject claims for services (Q2052) when the place of service is NOT one of the following: 12, 13, 14, 32 or 33, to add the following place of service codes: 04 – Homeless Shelter 54 – Intermediate Care Facility/Mentally Retarded 55 – Residential Substance Abuse Treatment Facility 56 – Psychiatric Residential Treatment Center. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 02, 2023. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Implementation of the New Home Intravenous Immune Globulin (IVIG) Items and Services Payment

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement the new IVIG payment effective January 1, 2024.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	20/Table of Contents
N	20/213/ Billing for Home IVIG Items and Services Payment

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12437	Date: December 28, 2023	Change Request: 13217

Transmittal 12252 issued November 02, 2023, is being rescinded and replaced by Transmittal 12437, dated December 28, 2023 to update business requirement 13217.7 - The contractor shall reject claims for services (Q2052) when the place of service is NOT one of the following: 12, 13, 14, 32 or 33, to add the following place of service codes: 04 – Homeless Shelter 54 – Intermediate Care Facility/Mentally Retarded 55 – Residential Substance Abuse Treatment Facility 56 – Psychiatric Residential Treatment Center. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 02, 2023. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Implementation of the New Home Intravenous Immune Globulin (IVIG) Items and Services Payment

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to specify the payment rate for 2024, for the new Home IVIG Items and Services payment. Division FF, section 4134 of the Consolidated Appropriations Act (CAA), 2023 added coverage and payment of items and services related to administration of IVIG in the home of a patient with a diagnosed primary immune deficiency disease (PIDD) furnished on or after January 1, 2024. Division FF, section 4134(a) of the CAA, 2023 amended the existing IVIG benefit category at section 1861(s)(2)(Z) of the Act by adding coverage for IVIG administration items and services in the home of a patient with a diagnosed primary immune deficiency disease. This benefit covers items and services related to administration of IVIG in the home of a patient with a diagnosed primary immune deficiency disease. In addition, section 4134(b) of Division FF of the CAA, 2023 amended section 1842(o) by adding a new paragraph (8) that established the payment for IVIG administration items and services. Under the new CAA, 2023 provision, payment for these items and services is required to be a bundled payment separate from the payment for the IVIG product, made to a supplier for all items and services related to administration of IVIG furnished in the home of a patient during a calendar day. The CAA, 2023 provision clarifies that a supplier who furnishes these services meet the requirements of a supplier of medical equipment and supplies. This means that suppliers that furnish IVIG administration items and services must meet the existing DMEPOS supplier requirement for payment purposes under this benefit. Suppliers of IVIG administration items and services must enroll as a DMEPOS supplier and comply with the Medicare program's DMEPOS supplier standards (found at 42 CFR § 424.57(c)) and DMEPOS quality standards to become accredited for furnishing medical equipment and supplies. Further, in order to receive payment for home IVIG items and services, the supplier must also meet the requirements under subpart A of Part 424 - Conditions for Medicare Payment. The DMEPOS supplier may subcontract with a provider in order to meet the nursing services. All professionals who furnish services directly, under an individual contract, or under arrangements with a DMEPOS supplier to furnish services related to the administration of IVIG in the home of a patient, must be legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State, and local laws, and must act only within the scope of their State license or State certification, or registration. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs or from any other federal procurement or non-procurement programs.

B. Policy: Contractors shall ensure that the payment rate for Q2052: "Services, Supplies, and Accessories used in the Home for the Administration of Intravenous Immune Globulin" for 2024 is $420.48.

Note: This payment rate shall be applicable for dates of service from January 1, 2024 through December 31, 2024. Also note that this is the same code (with a new descriptor) that DMEPOS suppliers were previously billing for these items and services under the IVIG Demonstration Project. The IVIG Demonstration Project will end on December 31, 2023.

The Q-code could be billed separately from, or on the same claim as, the J-code for the IVIG product and would be processed through the DMEPOS MACs. The Q-code should be billed as a separate claim line on the same claim for the same place of service as the J-code for the IVIG. In cases where the IVIG product is mailed or delivered to the patient prior to administration, the date of service for the administration of the IVIG (the Q-code) may be no more than 30 calendar days after the date of service on the IVIG product claim line. No more than one Q-code should be billed per claim line per date of service.

If a provider is billing for multiple administrations of IVIG on a single claim, then the DMEPOS supplier should bill the Q-code for each date of service on a separate claim line, which would be payable per visit (that is, each time the IVIG is administered). There may be situations in which multiple units of IVIG are shipped to the patient and billed on a single "J" code claim line followed by more than one Q-code administration claim line, each with a separate date of service on which the IVIG was administered. However, only one Q-code shall be paid per infusion date of service. To identify and process claims for the items and services furnished under the home IVIG items and services payment, a Common Working File (CWF) edit has been implemented for the submitted Q-code claims. If an eligible IVIG product J-code is not found on the same claim as the billed items and services (Q-code), the claims processing system will recycle the Q-code claim for the professional services associated with the administration of the IVIG product, until a claim containing the J-code for the IVIG product is received in the CWF. The professional visit claim (Q-code) will recycle three times (with a 30-day look back period) for a total of 15 business days. After 15 business days, if no eligible J-code claim is found in claims history, the Q-code claim will be denied. Suppliers must ensure that the IVIG product J-code associated with the visit is billed with the visit or no more than 30 days prior to the visit. Claims that contain more than one line of the IVIG Q-code with the same line item date of service shall be returned as unprocessable.

Providers should report visit length in 15-minute increments (15 minutes=1 unit). See the attachments to this CR for the Table of rounding of units.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13217.1	Contractors shall ensure that the payment rate for Q2052: "Services, Supplies, and Accessories used in the Home for the Administration of Intravenous Immune Globulin" for 2024 is $420.48. Note: This payment rate shall be applicable for dates of service from January 1, 2024 through December 31, 2024.				X					
13217.1.1	Contractors shall not multiply the rate by the units reported (units reported in 15-minute increments are				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	informational only. Pay only the single rate per line item date of service).									
13217.2	The contractor shall discontinue requirements to check for beneficiary eligibility for the demo as the demo has been discontinued.								X	
13217.3	Contractors shall discontinue any edits that may exist from the IVIG demo that required the drug code and the Q2052 to be on the same claim.				X				X	
13217.4	Contractors shall return claims as unprocessable that contain more than one line of the IVIG Q code (Q2052) with the same line item date of service.				X			X		
13217.5	Contractors shall reject the IVIG visit (Q2052) if one of the drug J codes from the allowable codes on attachment A is not found on the same claim or in the claims history within 30 days prior to the date of service of the Q2052. NOTE: This edit shall be overiddable.								X	
13217.5.1	Contractors shall deny the IVIG visit (Q2052) for beneficiary submitted claims when one of the J codes from the allowable codes on attachment A is not found on the same claim or in the claims history within 30 days prior to the date of service of the Q2052							X		
13217.5.2	Contractors shall use the following Group Code, CARC, RARC and MSN message codes: Group Code: CO CARC: B15 - This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated. RARC: M51 - Missing/incomplete/invalid procedure code(s). MSN: 21.21 - This service was denied because Medicare only covers this service under certain circumstances.				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Note: J codes required are below in the attachment.									
13217.6	When the claim is rejected for no drug code in history, the contractor shall recycle the IVIG Q2052 claim up to 3 times for a total of 15 business days until one of the drug J codes is found in history. Note: J codes required are below in the attachment A.							X		
13217.6.1	The contractor shall deny the CWF rejected for the Q2052 code when the allowable drug code (J codes in attachment A) is not found in history after the claim has been recycled for the third time.							X		
13217.6.2	Contractors shall use the following Group Code, CARC, RARC and MSN message codes: Group Code: CO CARC: B15 - This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated. RARC: M51 - Missing/incomplete/invalid procedure code(s). MSN: 21.21 - This service was denied because Medicare only covers this service under certain circumstances. Note: J codes required are below in the attachment.				X					
13217.7	The contractor shall reject claims for services (Q2052) when the place of service is NOT one of the following: 04, 12, 13, 14, 32, 33, 54, 55 or 56..							X		
13217.8	The contractor shall make any necessary updates to the DME MAC Local Coverage Determination or LCD-related Policy Article in accordance to this change request.				X					
13217.9	For dates of service on 12/31/2023 the contractor shall: • end date the IVIG Demo, and • discontinue the use of Demo value ‘71’							X	X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13217.10	The contractor shall add HCPCS code Q2052 to the list of codes used to enforce existing HH consolidated billing edits, effective for claims with dates of service on or after January 1, 2024.								X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13217.11	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.				X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

ATTACHMENT A

Attachment A: Home IVIG Items and Services Payment

Table 1 shows the time increments providers should report visit length in 15-minute increments (15 minutes=1unit) when billing for IVIG (Q2052). See the table below for the rounding of units.

Table 1: Time increments

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Table 2 shows the J-codes for the IVIG product associated with the items and services payable under the Home IVIG Items and Services payment. (This table is located on L33610 and maintained and updated by the DME MACs)

	Description
J1459	INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1554	INJECTION, IMMUNE GLOBULIN (ASCENIV), 500 MG
J1556	INJECTION, IMMUNE GLOBULIN (BIVIGAM), 500 MG
J1557	INJECTION, IMMUNE GLOBULIN, (GAMMAPLEX), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1561	INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1566	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, LYOPHILIZED (E.G., POWDER), NOT OTHERWISE SPECIFIED, 500 MG
J1568	INJECTION, IMMUNE GLOBULIN, (OCTAGAM), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1569	INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G., LIQUID), 500 MG
J1572	INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1599	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), NOT OTHERWISE SPECIFIED, 500 MG
J1576	INJECTION, IMMUNE GLOBULIN (PANZYGA), INTRAVENOUS, NON-LYOPHILIZED (e.g., liquid), 500 mg

Table 3 shows the ICD-10 CM codes that support medical necessity for home administration of IVIG, associated with the items and services payable under the Home IVIG Items and Services payment. (This table is located on A52509 and maintained and updated by the DME MACs)

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

Medicare Claims Processing Manual
Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Table of Contents
(Rev.: 12437, Issued:12-28-23)

213- Billing for Home IVIG Items and Services
(Rev. 12437, Issued: 12-28-23, Effective: 01-01-24, Implementation: 01-02-24)

Effective January 1, 2024, Medicare makes a separate bundled payment for home intravenous immune globulin (IVIG) items and services to DME suppliers. This payment amount covers the cost of nursing services and supplies including an infusion set and tubing, for the provision of IVIG administration in the home by a DME supplier.

The items and services payment is made per visit for days on which the IVIG is administered by a nurse in the patient's home. The patient must have a diagnosis of Primary Immune Deficiency Disease (PIDD) as indicated in the Intravenous Immune Globulin Policy Article (A5209). Payment for home IVIG items and services is only made when the patient is receiving one of the IVIG products listed on the Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610).

A single payment will be made for the items and services provided on the calendar day when such items and services are furnished in the home. The HCPCS (Q2052) "Services, Supplies, and Accessories used in the Home for the Administration of Intravenous Immune Globulin") will be billed separately from, or on the same claim as, the J-code for the IVIG product. The Q-code should be billed as a separate claim line on the same claim for the same place of service as the J-code for the IVIG. In cases where the IVIG product is mailed or delivered to the patient prior to administration, the date of service for the administration of the IVIG (the Q-code) may be no more than 30 calendar days after the date of service on the IVIG product claim line. No more than one Q-code should be billed per claim line per date of service.

If a provider is billing for multiple administrations of IVIG on a single claim, then the supplier would bill the Q-code for each date of service on a separate claim line, which would be payable per visit (that is, each time the IVIG is administered). There may be situations in which multiple units of IVIG are shipped to the patient and billed on a single "J" code claim line followed by more than one Q-code administration claim line, each with the date of service on which the IVIG was administered. However, only one unit of service (Q-code) shall be paid per infusion date of service.

Providers should report visit length in 15-minute increments (15 minutes=1 unit)) when billing for IVIG (Q2052). See the table below for the rounding of units.

Rounding of Time Units

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

A submitted claim for home IVIG items and services is subject to a Common Working File (CWF) edit in the event that an IVIG J-code is not found on the same claim as the IVIG items and services payment code (Q-code), or in claims history in the previous 30 days. If a J-code is not found on the same claim as the Q-code, the claims processing system will recycle the Q-code claim for the IVIG items and services associated with the administration of the IVIG product (J-code), until a claim containing the J-code for IVIG product is received in the CWF. The home IVIG items and services claim will recycle three times (with a 30-day look back period) for a total of 15 business days. After 15 business days, if

no J-code claim is found in claims history, the Q-code claim will be denied.

Suppliers must ensure that an eligible J-code (as indicated on L33610) associated with the visit is billed with the visit or no more than 30 days prior to the visit. Visits are denied if an eligible J-code for the visit is not billed. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.