CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12352	**Date: November 8, 2023**
	Change Request 13414

SUBJECT: Manual Updates for Coverage of Intravenous Immune Globulin (IVIG) For Treatment of Primary Immune Deficiency Diseases in the Home

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Pub. 100-02 Medicare Benefit Policy Manual to edit Chapter 15, Section 50.6 Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home to reflect changes from the Consolidated Appropriations Act of 2023 (CAA, 2023).

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	15/50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

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. 100-02	Transmittal: 12352	Date: November 8, 2023	Change Request: 13414

SUBJECT: Manual Updates for Coverage of Intravenous Immune Globulin (IVIG) For Treatment of Primary Immune Deficiency Diseases in the Home

EFFECTIVE DATE: January 1, 2024
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I. GENERAL INFORMATION

A. Background: Division FF, section 4134 of the CAA, 2023 added coverage and payment of items and services related to administration of IVIG in a patient's 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 a patient's 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 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 during a calendar day. In the Calendar Year (CY) 2024 Home Health Prospective Payment System (HH PPS) final rule we finalized changes to implement the CAA, 2023 provisions. Please refer to CR 13217 for information on the CY 2024 payment rate for IVIG Items and Services.

B. Policy: Effective January 1, 2024, items and services related to the administration of IVIG are added to the benefit category defined under section 1861(s)(2)(Z) of the Act (the Social Security Act provision requiring coverage of the IVIG product in the home). The same beneficiary eligibility requirements for the IVIG product would apply for the IVIG administration of items and services.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13414.1	The Contractors shall be aware of the revisions to Pub. 100-02, Chapter 15 related to the policies discussed in this CR.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13414.2	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: 0

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

(Rev. 12352; Issued:11-08-23)

50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

(Rev. 12352, Issued: 11-08-23, Effective:01-01-24, Implementation:01-02-24)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases in the home (ICD-10-CM codes G11.3, D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.82, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, or D83.9 if only
an unspecified diagnosis is necessary). The Act defines "intravenous immune globulin" as an approved pooled plasma derivative for the treatment of primary immune deficiency disease. It is covered under this benefit when the patient has a diagnosed primary immune deficiency disease, it is administered in the home of a patient with a diagnosed primary immune deficiency disease, and the physician determines that administration of the derivative in the patient's home is medically appropriate. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment. *Division FF, section 4134 of the Consolidated Appropriation Act, 2023 mandated that CMS establish a permanent, bundled payment for items and services related to administration of IVIG in a patient's home. The permanent, bundled home IVIG items and services payment is effective for home IVIG infusions furnished on or after January 1, 2024. Payment for these items and services is required to be a separate bundled payment made to a durable medical equipment supplier for all items and services furnished in the home during a calendar day. It is up to the provider to determine the services and supplies that are appropriate and necessary to administer the IVIG for each individual. This may or may not include the use of a pump; however, a pump is not covered under the home IVIG items and services payment.*