

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-02 Medicare Benefit Policy</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 259</b>	<b>Date: July 12, 2019</b>
	<b>Change Request 11295</b>

**SUBJECT: Update to Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to update the list of ICD-10 codes to be included in the Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home.

**EFFECTIVE DATE: August 13, 2019**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: August 13, 2019**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 259	Date: July 12, 2019	Change Request: 11295
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**EFFECTIVE DATE: August 13, 2019**

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## I. GENERAL INFORMATION

**A. Background:** 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 (PIDD) in the home. 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.

Effective for dates of service on or after January 1, 2004, via CR 3060, the appropriate International Classification of Diseases, Ninth Revision (ICD-9) codes were as follows: 279.04, 279.05, 279.06, 279.12, and 279.2.

Effective for dates of service on or after October 1, 2015, via CR 8605, the appropriate ICD-9 codes were converted to the following ICD-10 codes: D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary.

**B. Policy:** Effective for dates of service on or after the implementation date of this transmittal, the coverage for intravenous immune globulin in home for the treatment of primary immune deficiency diseases is updated to include the following International Classification of Diseases, Tenth Revision, Clinical Modification (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, D81.89, 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.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility										
		A/B MAC			D M E	Shared- System Maintainers				Other		
		A	B	H H H		F M V C	M C M S	V M S S	C W F			
11295.1	All MACs shall be aware of the updated list of ICD-10-CM codes effective for dates of services on or after the implementation date of this transmittal.	X	X	X	X							

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
11295.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X	X	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

**Pre-Implementation Contact(s):** Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov.

**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**

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

*(Rev.259, Issued: 07-12-19, Effective: 08-13-19, Implementation: 08-13-19)*

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-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2 or 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, D81.89, 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. The benefit does not include coverage for items or services related to the administration of the derivative. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment.