

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10660	Date: March 17, 2021
	Change Request 11877

Transmittal 10307, dated August 21, 2020, is being rescinded and replaced by Transmittal 10660, dated, March 17, 2021, to extend the Demonstration end date to December 31, 2023 by revising the title and effective date, updating the background and policy sections, and by removing the note in business requirement 11877.1. All other information remains the same.

SUBJECT: The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2023

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to notify those interested, that the IVIG Demonstration is ending on December 31, 2023.

EFFECTIVE DATE: January 1, 2021 - Demonstration ends on December 31, 2023

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

IMPLEMENTATION DATE: January 4, 2021

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
N/A	

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:

Demonstrations

Attachment - Demonstrations

Pub. 100-19	Transmittal: 10660	Date: March 17, 2021	Change Request: 11877
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I. GENERAL INFORMATION

A. Background: The "Medicare Intravenous Immune Globulin (IVIG) Access and Strengthening Medicare and Repaying Taxpayers Act of 2012" authorized a three-year demonstration under Part B of Title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of Primary Immunodeficiency Disease (PIDD). Title III, section 302 of the Disaster Tax Relief and Airport and Airway Extension Act of 2017 extended the IVIG demonstration through December 31, 2020. Congress again had extended the demonstration on December 21, 2020 for three additional years under the "Consolidated Appropriations Act, 2021," Division CC, Section 104, Extension of Medicare Patient IVIG Access Demonstration Project.

Per previous CMS direction, the Business Requirements for IVIG specified the payment rate for the administration of IVIG under the demonstration. This CR establishes the end date of the demonstration and ends on December 31, 2023.

B. Policy: Contractors shall ensure that no Dates of Service after December 31, 2023 will be paid.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared- System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
11877.1	Contractors shall deny payment for claims with a Date of Service AFTER December 31, 2023.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C
		A	B	H H H	M A C	I
11877.2	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	

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): Debra Gillespie, 410-786-4631 or Debra.Gillespie@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0