

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11067	Date: October 21, 2021
	Change Request 12352

SUBJECT: Intravenous Immune Globulin (IVIG) Demonstration Update for a New Drug Code J1554 - ASCENIV

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to add a new J codes (J1554 - ASCENIV). The long description as listed in the Local Coverage Determination (LCD) is INJECTION, IMMUNE GLOBULIN (ASCENIV), 500 MG. and is to be included in the list of approved J codes for the treatment of Primary Immune Deficiency Diseases (PIDD) in the home for the IVIG Demonstration.

EFFECTIVE DATE: April 1, 2021

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

IMPLEMENTATION DATE: April 4, 2022

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

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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 PIDD. It is covered under this benefit and administered in the home when the patient has a diagnosed primary immune deficiency disease, and the physician determines that administration of the derivative in the patient’s home is medically appropriate.

B. Policy: Effective for dates of service on or after April 1, 2021, the coverage for intravenous immune globulin (IVIG) in home for the treatment of primary immune deficiency diseases is updated to include the following IVIG drug J1554 – ASCENIV, that is administered intravenously. The long description as listed in the Local Coverage Determination (LCD) is INJECTION, IMMUNE GLOBULIN (ASCENIV), 500 MG.

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 I S S	M C S	V M S	C W F	
12352.1	The Medicare contractor shall update existing CWF editing to allow HCPCS code Q2052 to be processed when HCPCS code J1554 is on the same claim.								X	
12352.2	The Medicare contractor shall discontinue bypassing the CWF edit when HCPCS codes Q2052 and J1554 are on the same claim.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility
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		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
	None					

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