CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 6 **Date: JANUARY 23, 2004**

CHANGE REQUEST 3059

I. SUMMARY OF CHANGES: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as of January 1, 2004, covers intravenous immune globulin in the home for the treatment of primary immune deficiency diseases.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004
***IMPLEMENTATION DATE: April 5, 2004**

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.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/Table of Contents
N	15/50.6/Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Business Requirements

Pub. 100-02	Transmittal: 6	Date: January 23, 2004	Change Request 3059

SUBJECT: Intravenous Immune Globulin

I. GENERAL INFORMATION

A. Background: The "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (MMA), effective January 1, 2004, covers intravenous immune globulin for the treatment of primary immune deficiency diseases in the home.

B. Policy: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides for coverage of intravenous immune globulin (IVIG) in the home, and defines IVIG as an approved pooled plasma derivative for the treatment of primary immune deficiency disease. The IVIG is covered under this benefit when the patient has a diagnosed primary immune deficiency disease, it is administered in the patient's home, and the physician determines administration of the derivative in the patient's home is medically appropriate. The benefit does not cover items or services related to the administration of the derivative.

C. Provider Education: Intermediaries and carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site within 2 weeks. Also, intermediaries and carriers shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about submission of Medicare contractors' self-administered drug exclusion lists is available on their Web site.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3059.1	Intravenous immune globulin is defined as an approved pooled plasma derivative for the treatment of primary immune deficiency disease.	DMERCs/RHHIs
3059.2	Medicare provides coverage of intravenous immune globulin when the patient has a diagnosed primary immune deficiency disease.	DMERCs/RHHIs
3059.3	Coverage is provided if the intravenous immune globulin is administered in the patient's home.	DMERCs/RHHIs
3059.4	Coverage is provided if the physician determines that administration of the derivative in the patient's home is medically appropriate.	DMERCs/RHHIs

3059.5	Coverage does not include items or services related to the administration of the derivative.	DMERCs/RHHIs
3059.6	Coverage is for dates of service on or after January 1, 2004.	DMERCs/RHHIs
3059.7	The appropriate HCPCs are J1563 and J1564. Ch. 17, Sec 80.6, Pub. 100-04, Medicare Claims Processing Manual.	DMERCs/RHHIs
3059.8	The appropriate ICD-9 codes are as follows: 279.04, 279.05, 279.06, 279.12, and 279.2, Ch. 17, Sec 80.6, Pub. 100-04, Medicare Claims Processing Manual.	DMERCs/RHHIs
3059.9	Contractors shall inform affected providers by posting either a summary or relevant portions of this document on the Web site within 2 weeks. Also, contractors shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about the submission of Medicare contractors' self-administered drug exclusions lists is available on their Web site.	DMERCs/RHHIs

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: January 1, 2004 **Implementation Date: April 5, 2004** **Pre-Implementation Contact(s): Appropriate regional office** **Post-Implementation Contact(s): Appropriate regional office**	**These instructions should be implemented within your current operating budget.**

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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(Rev.6, 01-23-04)

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

(Rev.6, 01-23-04)

Beginning for dates of service on or after January 1, 2004, 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 (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2) in the home. The corresponding HCPCS codes are J1563 and J1564. 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.