CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 513 **Date: MARCH 30, 2005**

CHANGE REQUEST 3705

NOTE: Transmittal 471, dated February 4, 2005 is rescinded and replaced with Transmittal 513, dated March 30, 2005. There was a change on business requirement 3705.1. All other information remains the same.

SUBJECT: Infusion Pumps: C-Peptide Levels as A Criterion for Use

I. SUMMARY OF CHANGES: On August 26, 1999, HCFA (now CMS) issued the first decision memorandum (DM) for "Continuous Subcutaneous Insulin Infusion Pumps" that utilized a C-peptide testing requirement for Medicare coverage of CSII pump therapy. On May 11, 2001, CMS issued a second DM for "Insulin Pump: C-Peptide Levels as a Criterion for Use," and on January 1, 2002, revised the laboratory value for the C-peptide testing requirement for Medicare coverage of CSII pump therapy.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: December 17, 2004
IMPLEMENTATION DATE: February 18, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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 not updated.*)
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

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

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 513	Date: March 30, 2005	Change Request 3705

NOTE: Transmittal 471, dated February 4, 2005 is rescinded and replaced with Transmittal 513, dated March 30, 2005. There were changes on business requirement 3705.1 and 3705.2. All other information remains the same.

SUBJECT: Infusion Pumps: C-Peptide Levels as a Criterion for Use

I. GENERAL INFORMATION

A. Background: On August 26, 1999, HCFA (now CMS) issued the first decision memorandum (DM) for "Continuous Subcutaneous Insulin Infusion Pumps" that utilized a C-peptide testing requirement for Medicare coverage of CSII pump therapy. On May 11, 2001, CMS issued a second DM for "Insulin Pump: C-Peptide Levels as a Criterion for Use," and on January 1, 2002, revised the laboratory value for the C-peptide testing requirement for Medicare coverage of CSII pump therapy.

B. Policy: CMS determines that effective for services performed on or after December 17, 2004, a positive beta cell autoantibody test is added as an adequate diagnostic criterion as an alternative to the updated C-peptide level testing requirement. Fasting C-peptide levels will only be considered valid when a concurrently obtained fasting glucose is $\leq$ 225 mg/dL. Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Alternatively, for patients with renal insufficiency and a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) $\leq$ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method. Levels only need to be documented once in the medical records. CMS will also continue to allow coverage of all other uses of CSII in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1

II. BUSINESS REQUIREMENTS

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

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3705.1	Contractors shall accept CPT 84681(C-peptide) when diagnosis codes 250.00-250.93 are reported.	X		X		X				
3705.2	Contractors shall accept CPT code 86337 (insulin antibodies) when diagnosis codes 250.00-250.93 are reported.	X		X		X				
3705.3	Contractors shall be advised that effective December 17, 2004, continuous subcutaneous insulin infusion pumps and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who: (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and (2) satisfy the remaining criteria for insulin pump therapy as described in Pub. 100-03, section 280.14, of the Medicare National Coverage Determinations Manual.	X		X		X				

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn Matters" listserv.	X		X		X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into your outreach activities, as appropriate. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV. 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

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: December 17, 2004 **Implementation Date: February 18, 2005** **Pre-Implementation Contact(s):** Betty Shaw, 410-786-4165 (coverage) **Post-Implementation Contact(s):**	**Medicare contractors shall implement these instructions within their current operating budgets.**

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