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# CMS Manual System

## Pub. 100-04 Medicare Claims Processing

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

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Transmittal 977

Date: JUNE 9, 2006

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CHANGE REQUEST 5123

**SUBJECT: Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds**

**I. SUMMARY OF CHANGES:** CMS is correcting Section 270.3, of the National Coverage Determinations (NCD) Manual, entitled Blood-Derived Products for Chronic Non-Healing Wounds, by proposing to delete the following sentences, "Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion." Becaplermin is approved by the Food and Drug Administration. The correct statement should read, Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered.

**NEW/REVISED MATERIAL:**

**EFFECTIVE DATE\*:** April 27, 2006

**IMPLEMENTATION DATE:** July 10, 2006

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

**III. FUNDING:** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

**IV. ATTACHMENTS:**

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

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

# Attachment – One-Time Notification

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**SUBJECT: Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds**

## I. GENERAL INFORMATION

**A. Background:** After releasing a national non-coverage determination on Autologous Blood-Derived Products for Chronic Non-Healing Wounds in December of 2003, an error was printed in the National Coverage Determinations (NCD) Manual. The error reads, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion.” While the Centers for Medicare & Medicaid Services (CMS) makes every effort to provide accurate and complete information, the erroneous coverage statement printed in the NCD Manual regarding non-autologous blood-derived products was not intended and not part of the Decision Memorandum (DM) posted on December 15, 2003. Non-autologous blood-derived products are not in the same class as the products referred to in the December 15, 2003, DM.

**B. Policy:** CMS is correcting section 270.3 of the NCD Manual, entitled “Blood-Derived Products for Chronic Non-Healing Wounds,” by deleting the following sentences, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.” The correct statement should read “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered under Part B based on §1861(s)(2)(A) and §1861(s)(2)(B) because this product is usually self-administered by the patient.”

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5123.1	Contractors shall be aware that effective April 27, 2006, section 270.3, of the NCD Manual, Pub. 100-03, is being revised to accurately reflect that becaplermin, a self-administered, non-autologous growth factor for chronic, non-healing, subcutaneous wounds, is nationally	X	X	X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
	non-covered.  Therefore, HCPCS S0157 remains non-payable by Medicare and no action is required other than education about this NCD correction.								
5123.2	Contractors shall not search for claims already processed but shall deny any claims for becaplermin brought to their attention with dates of service 12/15/03 forward.	X	X	X					
5123.3	Contractors shall use MSN 16.10: Medicare does not pay for this item or service, along with MSN 15.20: The following policy (Pub. 100-03 NCD Manual, section 270.3) was used when we made this decision.	X	X	X					

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
5123.4	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles">www.cms.hhs.gov/MLNMattersArticles</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. 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 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next	X	X	X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN 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: NA**

X-Ref Requirement #	Instructions

**B. Design Considerations: NA**

X-Ref Requirement #	Recommendation for Medicare System Requirements

**C. Interfaces: NA**

**D. Contractor Financial Reporting /Workload Impact: NA**

**E. Dependencies: NA**

**F. Testing Considerations: NA**

**V. SCHEDULE, CONTACTS, AND FUNDING**

<b>Effective Date*:</b> April 27, 2006 <b>Implementation Date:</b> July 10, 2006 <b>Pre-Implementation Contact(s):</b> Coverage: Beverly Lofton at <a href="mailto:Beverly.Lofton@cms.hhs.gov">Beverly.Lofton@cms.hhs.gov</a> or 410-786-7136 <b>Post-Implementation Contact(s):</b> Regional office	<b>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.</b>
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