CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 83	**Date: May 2, 2008**
	Change Request 6043

SUBJECT: Blood-Derived Products for Chronic, Non-Healing Wounds

I. SUMMARY OF CHANGES: On March 19, 2008, CMS issued a Decision Memorandum for the use of autologous blood-derived products for the treatment of chronic, non-healing wounds (autologous platelet rich plasma (PRP)) for treatment of acute wounds where PRP is applied directly to the closed incision site, and for dehiscent wounds. CMS issued a non-coverage determination for the use of Autologous PRP for the indications noted above. Current non-coverage for chronic, non-healing cutaneous wounds is maintained. This addition/revision of section 270.3 of Pub.100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD(Section 1869(f)(1)(A)(i) of the Social Security

NEW / REVISED MATERIAL
EFFECTIVE DATE: MARCH 19, 2008
IMPLEMENTATION DATE: June 2, 2008

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/270.3/Blood-Derived Products for Chronic, Non-Healing Wounds (Various Effective Dates Below)

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: 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:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 83	Date: May 2, 2008	Change Request: 6043

SUBJECT: Blood-Derived Products for Chronic, Non-Healing Wounds

Effective Date: March 19, 2008

Implementation Date: June 2, 2008

I.   GENERAL INFORMATION

A.   Background: In 1992, The Centers for Medicare and Medicaid Services (CMS) issued a national non-coverage determination for autologous, platelet-derived wound healing formulas intended to treat patients with chronic, non-healing wounds.

In December 2003, CMS issued a national non-coverage determination for use of autologous PRP for the treatment of chronic non-healing cutaneous wounds except for routine costs when used in accordance with the clinical trial policy defined in section 310.1 of the National Coverage Determinations (NCD) Manual.

In April 2005, CMS issued an NCD to correct the erroneous potential for local coverage of becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, stating that it would remain nationally non-covered under Part B based on section 1861(s)(2)(A) and (B) of the Social Security Act because it is usually self-administered.

B.   Policy: On March 19, 2008, CMS issued a Decision Memorandum following a National Coverage Analysis to evaluate the use of autologous blood-derived products for the treatment of chronic, non-healing cutaneous wounds, specifically the use of autologous platelet rich plasma (PRP) for the treatment of acute wounds where PRP is applied directly to the closed incision site, or for dehiscent wounds.

The CMS has determined that the evidence is inadequate to conclude that autologous PRP for the treatment of chronic non-healing cutaneous wounds, acute surgical wounds when the autologous PRP is applied directly to the closed incision, or dehiscent wounds, improves health outcomes in the Medicare population.

Therefore, effective March 19, 2008, CMS is maintaining its current non-coverage determination for autologous PRP for the treatment of chronic, non-healing cutaneous wounds, and issuing a non-coverage determination for acute surgical wounds when the autologous PRP is applied directly to the closed incision and for dehiscent wounds.

II.   BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6043.1	Effective for claims with dates of service on or after March 19, 2008, the use of autologous PRP for the	X		X	X						

Number	Requirement	A/B MAC	DME MAC	FI	CARRIER	RHHI	FISS	MCS	VMS	CWF	OTHER
	treatment of (1) acute surgical wounds where the PRP is applied directly to the closed incision, or (2) dehiscent wounds, shall be denied.										
6043.2	Contractors shall deny claims for the two additional indications noted in 6043.1 in accordance with section 270.3 of Pub. 100-03 of the NCD Manual based on reasonable and necessary determinations, and shall make local supplemental edits accordingly.	X		X	X						
6043.2.1	Contractors shall use MSN message 15.20, "The following policies [NCD 270.3] were used when we made this decision," and remittance reason code 50, "These are non-covered services because this is not deemed a 'medical necessity' by the payer," when denying claims.	X		X	X						
6043.2.2	Denials are subject to appeal, and contractors shall allow for medical review override of denials for appeal purposes.	X		X	X						
6043.3	A provider may have the beneficiary sign an advance beneficiary notice (ABN), making the beneficiary liable for services not covered by Medicare. Contractors shall assign liability for the denied charges to the provider unless documentation of an ABN is present on the claim.	X		X	X						
6043.4	Contractors need not search their files to retract payment for claims already paid from March 19, 2008 until implementation of this CR. However, contractors shall adjust claims brought to their attention.	X		X	X						

III.   PROVIDER EDUCATION TABLE

Number	Requirement	A/B MAC	DME MAC	FI	CARRIER	RHHI	FISS	MCS	VMS	CWF	OTHER
6043.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ 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 one week of the	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	FISS	MCS	VMS	CWF	OTHER
							Shared-System Maintainers				
	availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. 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

V. CONTACTS

Pre-Implementation Contact(s): Jamie Hermansen, Coverage and Analysis Group, 410-786-2064, Jamie.hermansen@cms.hhs.gov, Pat Brocato-Simons, Coverage and Analysis Group, 410-786-0261, patricia.brocatosimons@cms.hhs.gov

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *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.

Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

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(Rev.83. 05-02-08)

270.3 - Blood-Derived Products for Chronic Non-Healing Wounds - *(Various Effective Dates Below)*
(Rev. 83, Issued: 05-02-08, Effective: 03-19-08, Implementation: 06-02-08)

A. General

Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin's surface. Wounds are categorized as either acute, in where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, in where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner. Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors.

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persists for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products (such as Procuren), and (2) PRP.

The PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibroblasts.

The PRP is used by physicians in clinical *settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue, and bone. Alternatively,* PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

B. Nationally Covered Indications

Not applicable.

C. Nationally Non-Covered Indications

1.   Effective December 28, 1992, the Centers for Medicare & Medicaid Services (CMS) issued a national non-coverage determination for platelet-derived wound-healing formulas intended to treat patients with chronic, non-healing wounds. This decision was based on a lack of sufficient published data to determine safety and efficacy, and a public health service technology assessment.

2. *Effective July 23, 2004,* upon reconsideration, the clinical effectiveness of autologous PDGF products continues to not be adequately proven in scientific literature. As the evidence is insufficient to conclude that autologous PDGF in a platelet-poor plasma is reasonable and necessary, it remains non-covered for treatment of chronic, non-healing cutaneous wounds. *Also, the clinical evidence does not support a benefit in the application of autologous PRP for the treatment of chronic, non-healing, cutaneous wounds. Therefore, CMS determines it is not reasonable and necessary and is nationally non-covered.*

3. *Effective April 27, 2006,* coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds, remains nationally non-covered under Part B based on section 1861(s)(2)(A) and (B) *of the Social Security Act* because this product is usually administered by the patient.

4. *Effective March 19, 2008, upon reconsideration, the evidence is not adequate to conclude that autologous PRP is reasonable and necessary and remains non-covered for the treatment of chronic non-healing, cutaneous wounds. Additionally, upon reconsideration, the evidence is not adequate to conclude that autologous PRP is reasonable and necessary for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.*

D. Other

In accordance with section 310.1 of the National Coverage Determinations Manual, the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds are covered by Medicare.

(This NCD last reviewed *March 2008.)*