CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 59	Date: JUNE 9, 2006
	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.

(This revision to 270.3, of Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges may not review an NCD. (See section 1869 (f)(1)(A)(i) of the Social Security Act.)

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 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:
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 (Effective April 27, 2006)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006

IV. ATTACHMENTS:

Manual Instruction

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

Medicare National Coverage Determinations Manual

Chapter 1, Part 3 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev.59, 06-09-06)

270.3 - Blood-Derived Products for Chronic Non-Healing Wounds - *(Effective April 27, 2006)*

(Rev.59, Issued: 06-09-06, Effective: 04-27-06, Implementation: 07-10-06)

A. General

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 more recent products, (2) platelet-rich plasma (PRP). 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. PRP is used by physicians in clinical settings. PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

In latter 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.

B. Nationally Covered Indications

Not applicable.

C. Nationally Non-Covered Indications

1. 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 noncovered for treatment of chronic, non-healing cutaneous wounds.

2. Additionally, the clinical evidence does not support a benefit in the application of autologous PRP for the treatment of chronic, non-healing cutaneous wounds. In light of the absence of data on the health outcomes of this treatment, CMS determines it is not reasonable and necessary and is therefore nationally noncovered.

3. *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 (B) because this product is usually administered by the patient.*

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 *April 2006.*)