CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

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

Transmittal 19 **Date: JULY 30, 2004**

CHANGE REQUEST 3384

I. SUMMARY OF CHANGES: Upon reconsideration of existing policy, CMS determines that Autologous Blood-Derived Products for Chronic Non-Healing Cutaneous Wounds, both platelet-derived growth factor in a platelet-poor plasma, and platelet-rich plasma (PRP), shall remain noncovered. Coverage for becaplermin, a non-autologous growth factor for the treatment of chronic non-healing subcutaneous wounds, will remain at contractor discretion. Exceptions exist to cover the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic non-healing cutaneous wounds. (See NCD Manual 310.1.)

(This revision to §270.3 of Pub. 100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 23, 2004
***IMPLEMENTATION DATE: July 23, 2004**

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 07/16/04)

***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**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 19	Date: July 30, 2004	Change Request 3384

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

I. GENERAL INFORMATION

A. Background: The CMS issued a national Medicare noncoverage determination in 1992 related to platelet-derived wound healing formulas containing growth factors to treat non-healing wounds based on a lack of sufficient published data to determine its efficacy and safety. Upon reconsideration, CMS continues to believe that the clinical effectiveness of autologous blood-derived products, both platelet-derived growth factor (PDGF) in a platelet-poor plasma, and platelet-rich plasma (PRP), are not adequately proven in scientific literature. Therefore, autologous blood-derived products remain nationally noncovered for chronic, non-healing cutaneous wounds as not reasonable and necessary under section 1861(a) of the Social Security Act.

B. Policy: (1) Autologous blood-derived products, both PDGF in a platelet-poor plasma and PRP, are nationally noncovered to treat chronic, non-healing cutaneous wounds; (2) Coverage for treatments utilizing becaplermin for chronic non-healing subcutaneous wounds remain at local carrier discretion; (3) 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.

C. Provider Education: A provider education article related to this instruction will be available at http://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. 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 must be included in your next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

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

Requirement #	Requirements	Responsibility
3384.1	Autologous platelet-derived growth factor (PDGF) products in a platelet-poor plasma for the treatment of chronic non-healing cutaneous wounds are not considered reasonable and necessary and is not nationally covered by the Medicare program.	FIs and local Part B carriers

3384.2	Autologous platelet-rich plasma (PRP) products for the treatment of chronic non-healing cutaneous wounds are not considered reasonable and necessary and are not nationally covered by the Medicare program.	FIs and local Part B carriers
3384.3	Coverage of becaplermin, a non-autologous growth factor product approved by the FDA for the treatment of chronic non-healing subcutaneous wounds, remains at local carrier discretion.	FIs and local Part B carriers
3384.4	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 the Medicare program.	FIs and local Part B carriers

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: July 23, 2004 **Implementation Date:** July 23, 2004 **Pre-Implementation Contact(s)**: Niccole Corbin, 410-786-2273, Pat Brocato-Simons, 410-786-0261 **Post-Implementation Contact(s):** Niccole Corbin, 410-786-2273, Pat Brocato-Simons, 410-786-0261	**These instructions shall be implemented within your current operating budget.**

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

Table of Contents

(Rev. 19, 07-30-04)

270.3 - Blood-Derived Products for Chronic Non-Healing Wounds - (Effective 07-23-04)

(Rev. 19, Issued, 07-30-04, Effective: 07-23-04, Implementation: 07-23-04)

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, CMS issued a national noncoverage determination for platelet-derived wound healing formulas intended to treat patients with chronic, nonhealing 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 Noncovered 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.

D. Other

1. 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.

2. 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 July 2004.)