

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11171</b>	<b>Date: January 12, 2022</b>
	<b>Change Request 12403</b>

**Transmittal 11119, dated September 10, 2021, is being rescinded and replaced by Transmittal 11171, dated, January 12, 2022 to add HCPCS code G0465 to the instructions and to include additional information on HCPCS code G0460. This correction modifies the IOM attachment for publication 100-04, it also updates the background section for publication 100-04, and business requirements 12403 - 04.1 through 12403 - 04.2.2 and 12403 - 04.3 through 12403 - 04.6. This correction does not make any revisions to the companion publication 100-03; all revisions are associated with publication 100-04. All other information remains the same.**

**SUBJECT: National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds**

**I. SUMMARY OF CHANGES:** The purpose of this change request is to inform MACs that effective April 13, 2021, CMS will cover autologous Platelet-Rich Plasma (PRP) for the treatment of chronic non-healing diabetic wounds under specific conditions.

**EFFECTIVE DATE: April 13, 2021**

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

**IMPLEMENTATION DATE: February 14, 2022 - for MACs; January 3, 2022 - Shared Systems**

*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-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/270/3/Blood-Derived Products for Chronic, Non-Healing Wounds

**III. FUNDING:**

**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**

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 11171	Date: January 12, 2022	Change Request: 12403
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**SUBJECT: National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds**

**EFFECTIVE DATE: April 13, 2021**

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**IMPLEMENTATION DATE: February 14, 2022 - for MACs; January 3, 2022 - Shared Systems**

## **I. GENERAL INFORMATION**

**A. Background:** 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.

Due to the critical role that platelets and various growth factors play in tissue repair and regeneration, as well as its antibacterial properties in traumatic injuries, a number of platelet-derived products have been developed for medical use. Platelet-rich plasma (PRP) can be created in autologous or homologous forms. Autologous PRP is the fraction of blood plasma from a patient's peripheral blood that contains higher than baseline concentrations of platelets including concentrated growth factors and cytokines. Alternatively, homologous PRP is derived from blood from multiple donors. The PRP preparation contains concentrated platelets, as few red blood cells as possible, and leukocytes at different levels for various indications.

Section 270.3 of the Medicare National Coverage Determinations (NCD) Manual establishes conditions of coverage for blood-derived products for chronic non-healing wounds. In 2003, the Centers for Medicare & Medicaid Services (CMS) first issued an NCD non-covering autologous platelet-derived growth factor (PDGF), and the policy has been expanded over the years. CMS last reconsidered this NCD in 2012, providing coverage of autologous PRP only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds in CMS-approved studies under coverage with evidence development (CED).

**B. Policy:** Effective for claims with dates of service on and after April 13, 2021, CMS will cover autologous PRP for the treatment of chronic non-healing diabetic wounds under section 1862(a)(1)(A) of the Social Security Act (the Act) for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration (FDA)-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by local Medicare Administrative Contractors (MACs).

Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by local MACs under section 1862(a)(1)(A) of the Act.

## II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC		H H H	M A C	D M E	Shared-System Maintainers				Other
		A	B				F I S S	M C S	V M S	C W F	
12403 - 03.1	Effective for claims with dates of service on and after April 13, 2021, contractors shall cover autologous PRP for the treatment of chronic, non-healing diabetic wounds for up to 20 weeks when prepared by devices whose FDA-cleared indications include the management of exuding, cutaneous wounds, such as diabetic ulcers. Services beyond 20 weeks are covered at local MAC discretion. See Publication 100-03, Part 1, section 270.3 for complete coverage criteria.	X	X								

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
12403 - 03.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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**Section B: All other recommendations and supporting information: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Billin) , David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Professional Billing)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

**VI. FUNDING**

**Section A: 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.

**ATTACHMENTS: 0**

## **270.3 – Blood-Derived Products for Chronic, Non-Healing Wounds**

*(Rev. 11171; Issued: 01-12-22; Effective: 04-13-21 Implementation: 02-07-22 MACs, 01-03-22 Shared Systems Contractors)*

### **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, 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, 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 persist 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, and (2) PRP (such as AutoloGel).

The PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrin, stem cells, and fibrocyte precursors.

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**

*Effective for services performed on or after April 13, 2021, the Centers for Medicare & Medicaid Services (CMS) will cover autologous PRP for the treatment of chronic non-healing diabetic wounds under section 1862(a)(1)(A) of the Social Security Act (the Act) for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.*

### **C. Nationally Non-Covered Indications**

Autologous PDGF for the treatment of chronic, non-healing cutaneous wounds, and,

Becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds, and,

Autologous PRP for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.

### **D. Other**

*Effective for services performed on or after April 13, 2021:*

*Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by the local Medicare Administrative Contractors (MACs).*

*Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by the local MACs under section 1862(a)(1)(A) of the Act.*

*(This NCD last reviewed April 2021.)*