

Blood-Derived Products for Chronic Non-Healing Wounds (NCD 270.3)

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[↪ Terms and Conditions](#)

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Related Medicare Advantage Coverage Summary
• Wound Treatments

Policy Summary

[↪ See Purpose](#)

Overview

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 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 (such as Procuren), 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, 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.

Guidelines

Nationally Covered Indications

The Centers for Medicare and Medicaid Services (CMS) has determined that platelet-rich plasma (PRP) – an autologous blood-derived product, will be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds and only when the following conditions are met:

The patient is enrolled in a clinical trial that addresses the following questions using validated and reliable methods of evaluation. Clinical study applications for coverage pursuant to this National coverage Determination (NCD) must be received by August 2, 2014.

The clinical research study must meet the requirements specified below to assess the effect of PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds. The clinical study must address:

- Prospectively, do members that have chronic non-healing diabetic, venous and/or pressure wounds who receive well-defined optimal usual care along with PRP therapy, experience clinically significant health outcomes compared to patients who receive well-defined optimal usual care for chronic non-healing diabetic, venous and/or pressure wounds as indicated by addressing at least one of the following:
 - Complete wound healing?
 - Ability to return to previous function and resumption of normal activities?
 - Reduction of wound size or healing trajectory which results in the patient's ability to return to previous function and resumption of normal activities?
- The required clinical trial of PRP must adhere to the following standards of scientific integrity and relevance to the Medicare population:
 - The principal purpose of the clinical study is to test whether PRP improves the participants' health outcomes.
 - The clinical study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - The clinical study does not unjustifiably duplicate existing studies.
 - The clinical study design is appropriate to answer the research question being asked in the study.
 - The clinical study is sponsored by an organization or individual capable of executing the proposed study successfully.
 - The clinical study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
 - All aspects of the clinical study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (<http://www.icmje.org>).
 - The clinical study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED).
 - The clinical study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
 - The clinical study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
 - The clinical study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
 - The clinical study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
 - The clinical study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with §1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Any clinical study undertaken pursuant to this NCD must be approved no later than August 2, 2014. If there are no approved clinical studies on or before August 2, 2014, this CED will expire. Any clinical study approved will adhere to the timeframe designated in the approved clinical study protocol.

Nationally Noncovered Indications

- The Centers for Medicare & Medicaid Services (CMS) has 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.
- 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.
- 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.
- 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.

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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment

Modifier	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Condition Code	Description
30	Qualified clinical trial

Place of Service Code	Description
11	Office
19	Off campus-outpatient hospital
22	On campus-outpatient hospital
49	Independent clinic

References

CMS National Coverage Determinations (NCDs)

[NCD 270.3 Blood-Derived Products for Chronic Non-Healing Wounds](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A58307 Billing and Coding: Platelet Rich Plasma	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A58351 Billing and Coding: Platelet Rich Plasma	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

CMS Claims Processing Manual

[Chapter 32; § 11.3 Autologous Platelet-Rich Plasma \(PRP\) for Chronic Non-Healing Wounds](#)

CMS Transmittal(s)

[Transmittal 154, Change Request 8213, Dated 06/10/2013 \(Autologous Platelet-Rich Plasma \(PRP\) for Chronic Non-Healing Wounds\)](#)

[Transmittal 2362, Change Request 11392, Dated 09/19/2019 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–January 2020 Update](#)

MLN Matters

[Article MM8401, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

[Article MM11392, International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\) – January 2020 Update](#)

UnitedHealthcare Commercial Policy

[Prolotherapy and Platelet Rich Plasma Therapies](#)

Other(s)

[Medicare Managed Care Manual Chapter 4; § 10.7 Clinical Trials, CMS Website](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
02/10/2021	Policy Summary <i>Nationally Covered Indications</i> <ul style="list-style-type: none">Revised list of conditions that must be met for treatment of chronic non-healing diabetic, venous and/or pressure wounds with platelet-rich plasma (PRP); replaced criterion requiring “the patient is enrolled in a <i>randomized</i> clinical trial that addresses the [listed] questions using validated and reliable methods of evaluation” with “the patient is enrolled in a clinical trial that addresses the [listed] questions using validated and reliable methods of evaluation” Applicable Codes

Date	Summary of Changes
	<ul style="list-style-type: none"> Removed HCPCS codes S0157 and S9055 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information Archived previous policy version MPG032.06

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).