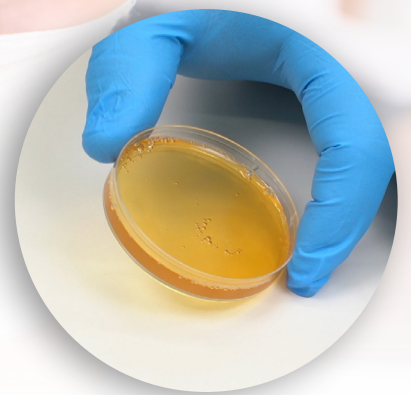




# 2024 Guide for Reimbursement

RegenWound® Gel Coding Guidance for Diabetic Chronic Wounds



RegenLab Patient Access Program in  
collaboration with PRIA Healthcare  
Advancing Health Innovation

Regenkit®-Wound Gel is designed to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel (RegenWound Gel) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the RegenWound Gel is typically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds.

**regenlab**®  **TISSUE  
ENGINEERING  
SPECIALISTS**



RegenLab USA LLC  
Brooklyn Army Terminal, 140 58th St Building A,  
Brooklyn, NY 11220, United States

## RegenWound® Gel

510(k) Number: BK210661 | RegenKit®-Wound Gel-2  
Coding & Reimbursement Guidance for  
Diabetic Chronic Wounds (G0465)

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RegenLab provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. RegenLab makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, compliance department and/or legal counsel for interpretation of coding, coverage, and payment policies. Documentation in the medical record must support the codes reported and made available to the contractor upon request. The responsibility for correct coding lies with the provider of services. This document provides assistance for FDA-approved or cleared indications only. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service. The existence or absence of a HCPCS code does not mean that an item or service is covered or non-covered. As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment. RegenLab expressly disclaims liability for the results or consequences of any actions taken in reliance on information in this guide. Coding guidance is from CMS Transmittal 11171 (January 12, 2022) and CMS Transmittal 11460 (June 17, 2022); NCD 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds, April 13, 2021. CPT® codes and descriptions only are copyright ©2022 American Medical Association. All rights reserved. The American Medical Association assumes no liability for data contained or not contained herein. Refer to the Instructions for Use supplied with the Device for indications, contraindications, side effects, warnings and precautions.

# Autologous RegenPRP™ + ATS Wound Gel

## Definitions and Determinations:

**Definition of a Diabetic Chronic Wound:** A Diabetic Chronic Wound is that which is classified as “difficult to heal” and persists beyond a period of 30 days, comorbid to a diagnosis of Diabetes Mellitus. This includes (but is not completely limited to) Diabetic Ulcer (foot or otherwise located), Venous Stasis Ulcer, Arterial Insufficiency Ulcer, etc.

**Intended Use / Indications for Use:** RegenKit®-Wound Gel-2 is designed to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel (RegenWound® Gel) from a small sample of a patient’s own peripheral blood. Under the supervision of a healthcare professional, RegenWound® Gel is typically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds. It is a Class II Automated Blood Cell Separator commonly known as a peripheral blood processing device for wound management.

**Medicare National Coverage Determination (NCD):** On April 13, 2021, CMS issued an NCD authorizing coverage for autologous PRP for the treatment of chronic non-healing diabetic wounds for a duration of 20 weeks, when the PRP is prepared by devices whose Food and Drug Administration (FDA)–cleared indications include the management of exuding cutaneous wounds, such as diabetic foot ulcers.

## Coding Guidelines:

HCPSC Code*:	<b>G0465:</b> Autologous platelet rich plasma (PRP) for diabetic chronic wounds/ulcers using and FDA-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment). The G-Code is utilized as the CPT code.
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Two ICD-10 Codes Req'd:	<ul style="list-style-type: none"><li>• E Code of Diabetes Mellitus plus Chronic Ulcer (foot / skin)</li><li>• L Code representing Location &amp; Nature of Chronic Ulcer</li></ul>
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PTAN	Personal Transaction Access Number (PTAN) is your unique Medicare Identification number. This will be required along with facility and diagnosis information.
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POS Codes for Provider Fees	<ul style="list-style-type: none"><li>• Outpatient Hospital – off Campus (19)</li><li>• In-Office (11)</li><li>• Clinic (49)</li><li>• Outpatient Hospital – on Campus (22)</li><li>• Ambulatory Surgical Center (24)</li></ul>
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Notes Related to Place(s) of Service:	<ul style="list-style-type: none"><li>• Reimbursement is directly related to the Place of Service as published by the CMS Final Payment Rules for that site of care. The reimbursement amount for CY 2024 for the outpatient department setting (POS 19 &amp; 22) is on national average \$1739.33.</li><li>• Currently private practice offices (POS 11) do not have a national reimbursement amount set by CMS and the reimbursement amount is currently contractor-determined by each MAC for G0465 when used on Chronic Diabetic Wounds</li><li>• In-patient Hospital reimbursement falls under the MS-DRG payment methodology and are reimbursed as bundled rates.</li><li>• Skilled nursing facilities utilize a bundled payment system where unless the patient is beyond their initial 100 days of admittance, Medicare reimbursement is included within the bundled payment.</li></ul>
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\* G0460 is determined on a case by case basis by the regional MACs, based upon a standard of “reasonable and necessary.”

## Treatment Guidelines

Treatment Schedule Guidelines:	Standard treatment schedule currently covered by Medicare is 1 treatment per week, for up to 20 weeks. While the necessity may vary from patient to patient, the guidelines exist via CMS, but determinations may be made to extend care if provider deems necessary. The Diabetes must also be qualified as “managed”.
Suggested Resolutions:	Suggested standard of practice is to “treat to closure”, as there are concerns regarding the ability to obtain reimbursement on a chronic wound which has neared closure and then reopens due to treatment which was discontinued prematurely. As such, if treatment requires continued applications beyond the 20 weeks, <b>proper modifier usage</b> (see below) and supporting documentation will be required.
Modifier (-KX) for Extended Use:	Effective for claims on or after April 13, 2021, local MACs shall have discretion to pay PRP services for chronic non-healing diabetic wounds, G0465, that are performed <u>more than 20 weeks</u> after the date of the first PRP service when the - <u>KX modifier</u> is reported on the claim.
Potential Medicare Reimbursement:	Outpatient Prospective Payment System (OPPS): The Medicare national average allowable rate for CY 2024 G0465 is <b>\$1,739.33</b> . Medicare Physician Fee Schedule (MPFS): Each MAC will establish relative value units and payment amounts for G0465 generally on an individual case-by-case basis following review of documentation (such as a procedure report). Please refer to the “Helpful Links” section for links to information regarding MAC’s.
Contraindications to be aware of:	<ul style="list-style-type: none"> <li>• Congenital and acquired disorders of platelet function and thrombocytopenia</li> <li>• Hemodynamic instability</li> <li>• Severe metabolic or system disorders</li> <li>• Septicemia</li> <li>• Coronary Artery Disease</li> <li>• Congestive Heart Failure</li> <li>• Liver Failure</li> <li>• Renal failure on dialysis</li> <li>• Active gastrointestinal bleeding</li> <li>• Hemoglobin less than 10g/dl</li> <li>• Platelet count less than 100x109/L</li> <li>• Serum albumin level less than 2.5 g/dl</li> <li>• Wounds with active clinically diagnosed infection</li> <li>• Patient unwilling to accept known risks</li> <li>• Hypersensitivity to sodium citrate anticoagulant</li> </ul>

## Treatment Guidelines

**Multiple Procedure Reduction Rule:** If more than one procedure is billed through Medicare for the same patient, on the same day, there is a percentage reduction in reimbursement for each additional treatment, based upon their individual coverage determinations.

**\*Note:** Reimbursement at the maximum of each is not guaranteed, nor is which item is reimbursed at a given tier.

**1st** treatment at a Maximum of: 100%\*

**2nd** treatment at a Maximum of: 75%\*

**3rd** treatment at a maximum of: 50%\*

# Autologous RegenPRP™ + ATS Wound Gel

## Detailed Device Information



### RK-WG-2

The RegenKit®-Wound Gel-2 produces approximately 13 ml of RegenWound® Gel for use in the treatment of wounds, such as diabetic foot ulcers, classified up to 3A according to the University of Texas classification. The material produced will treat an approximate area of 0.62 +/- 0.49 cm<sup>2</sup> with a depth of 15.1 +/- 9.6 mm, or the equivalent. The RegenKit-Wound Gel is designed for the preparation of PRP by simple centrifugation of a small sample of the patient's own blood.

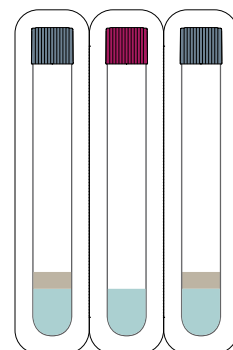
## Device Kit Components

RegenKit-Wound Gel is supplied in one model RegenKit-Wound Gel-2:

**2 x RegenWound® PRP tubes**

**1 x RegenWound® ATS tube**

Required commercially available components, not supplied in the kits: 1 x Safety-Lok™ Butterfly needle, 1 x Collection holder (blue top); 1 x Transfer device (pink top); 2 x 18G 1 1/2 Red transfer needles, 2 x 5 ml Luer-Lok™ syringes. Small sterile container, with a flat bottom, a maximal bottom surface of 30 cm<sup>2</sup> (4.6 in<sup>2</sup>) and a minimal capacity of 15 mL (0.5 oz); Tube holder; Accessories for phlebotomy and wound dressing including, but not limited to, tourniquet, sterile alcohol prep pads, and sterile adhesive.



## Coding Guidelines:

**The following is a list of common ICD-10 diagnosis codes** that may be associated with PRP for chronic, non-healing diabetic wounds. The codes on this list are provided for illustrative purposes only and are not intended to be exhaustive or all-inclusive.

Please note that CMS updates its accepted coding standards regularly, as such it is in good practice to review their quarterly updates as well as the updates to ICD coding which occur periodically.



## E-Codes (Diagnosis of Diabetes Mellitus & A Chronic Wound)

- E08.621** Diabetes mellitus due to underlying condition with foot ulcer
- E08.622** Diabetes mellitus due to underlying condition with other skin ulcer
- E09.621** Drug or chemical induced diabetes mellitus with foot ulcer
- E09.622** Drug or chemical induced diabetes mellitus with other skin ulcer
- E10.621** Type 1 diabetes mellitus with foot ulcer
- E10.622** Type 1 diabetes mellitus with other skin ulcer
- E11.621** Type 2 diabetes mellitus with foot ulcer
- E11.622** Type 2 diabetes mellitus with other skin ulcer
- E13.621** Other specified diabetes mellitus with foot ulcer
- E13.622** Other specified diabetes mellitus with other skin ulcer

## L-Codes (Chronic Ulcer Location & Nature)

- L97.111** Non-pressure chronic ulcer of right thigh limited to breakdown of skin
- L97.112** Non-pressure chronic ulcer of right thigh with fat layer exposed
- L97.113** Non-pressure chronic ulcer of right thigh with necrosis of muscle
- L97.114** Non-pressure chronic ulcer of right thigh with necrosis of bone
- L97.115** Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis
- L97.116** Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
- L97.118** Non-pressure chronic ulcer of right thigh with other specified severity
- L97.121** Non-pressure chronic ulcer of left thigh limited to breakdown of skin
- L97.122** Non-pressure chronic ulcer of left thigh with fat layer exposed
- L97.123** Non-pressure chronic ulcer of left thigh with necrosis of muscle
- L97.124** Non-pressure chronic ulcer of left thigh with necrosis of bone
- L97.125** Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis
- L97.126** Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis
- L97.128** Non-pressure chronic ulcer of left thigh with other specified severity
- L97.211** Non-pressure chronic ulcer of right calf limited to breakdown of skin
- L97.212** Non-pressure chronic ulcer of right calf with fat layer exposed
- L97.213** Non-pressure chronic ulcer of right calf with necrosis of muscle
- L97.214** Non-pressure chronic ulcer of right calf with necrosis of bone
- L97.215** Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
- L97.216** Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
- L97.218** Non-pressure chronic ulcer of right calf with other specified severity
- L97.221** Non-pressure chronic ulcer of left calf limited to breakdown of skin
- L97.222** Non-pressure chronic ulcer of left calf with fat layer exposed
- L97.223** Non-pressure chronic ulcer of left calf with necrosis of muscle

## L-Codes (Chronic Ulcer Location & Nature) - continued

- L97.224** Non-pressure chronic ulcer of left calf with necrosis of bone
- L97.225** Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
- L97.226** Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
- L97.228** Non-pressure chronic ulcer of left calf with other specified severity
- L97.311** Non-pressure chronic ulcer of right ankle limited to breakdown of skin
- L97.312** Non-pressure chronic ulcer of right ankle with fat layer exposed
- L97.313** Non-pressure chronic ulcer of right ankle with necrosis of muscle
- L97.314** Non-pressure chronic ulcer of right ankle with necrosis of bone
- L97.315** Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
- L97.316** Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis
- L97.318** Non-pressure chronic ulcer of right ankle with other specified severity
- L97.321** Non-pressure chronic ulcer of left ankle limited to breakdown of skin
- L97.322** Non-pressure chronic ulcer of left ankle with fat layer exposed
- L97.323** Non-pressure chronic ulcer of left ankle with necrosis of muscle
- L97.324** Non-pressure chronic ulcer of left ankle with necrosis of bone
- L97.325** Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis
- L97.326** Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis
- L97.328** Non-pressure chronic ulcer of left ankle with other specified severity
- L97.411** Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
- L97.412** Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
- L97.413** Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
- L97.414** Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
- L97.415** Non-pressure chronic ulcer of right heel and midfoot with muscle involvement w/o evidence of necrosis
- L97.416** Non-pressure chronic ulcer of right heel and midfoot with bone involvement w/ot evidence of necrosis
- L97.418** Non-pressure chronic ulcer of right heel and midfoot with other specified severity
- L97.421** Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
- L97.422** Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
- L97.423** Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
- L97.424** Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
- L97.425** Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
- L97.426** Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis
- L97.428** Non-pressure chronic ulcer of left heel and midfoot with other specified severity
- L97.511** Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
- L97.512** Non-pressure chronic ulcer of other part of right foot with fat layer exposed
- L97.513** Non-pressure chronic ulcer of other part of right foot with necrosis of muscle
- L97.514** Non-pressure chronic ulcer of other part of right foot with necrosis of bone
- L97.515** Non-pressure chronic ulcer of other part of right foot with muscle involvement
- L97.516** Non-pressure chronic ulcer of other part of right foot with bone involvement w/o evidence of necrosis
- L97.518** Non-pressure chronic ulcer of other part of right foot with other specified severity
- L97.521** Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
- L97.522** Non-pressure chronic ulcer of other part of left foot with fat layer exposed
- L97.523** Non-pressure chronic ulcer of other part of left foot with necrosis of muscle
- L97.524** Non-pressure chronic ulcer of other part of left foot with necrosis of bone

## L-Codes (Chronic Ulcer Location & Nature) - continued

- L97.525** Non-pressure chronic ulcer of other part of left foot with muscle involvement w/o evidence of necrosis
- L97.526** Non-pressure chronic ulcer of other part of left foot with bone involvement w/o evidence of necrosis
- L97.528** Non-pressure chronic ulcer of other part of left foot with other specified severity
- L97.812** Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
- L97.813** Non-pressure chronic ulcer of other part of right lower leg with necrosis of muscle
- L97.814** Non-pressure chronic ulcer of other part of right lower leg with necrosis of bone
- L97.815** Non-pressure chronic ulcer of other part of right lower leg with muscle involvement w/o necrosis
- L97.816** Non-pressure chronic ulcer of other part of right lower leg with bone involvement w/o necrosis
- L97.818** Non-pressure chronic ulcer of other part of right lower leg with other specified severity
- L97.821** Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
- L97.822** Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
- L97.823** Non-pressure chronic ulcer of other part of left lower leg with necrosis of muscle
- L97.824** Non-pressure chronic ulcer of other part of left lower leg with necrosis of bone
- L97.825** Non-pressure chronic ulcer of other part of left lower leg with muscle involvement w/o necrosis
- L97.826** Non-pressure chronic ulcer of other part of left lower leg with bone involvement w/o necrosis
- L97.828** Non-pressure chronic ulcer of other part of left lower leg with other specified severity
- L98.411** Non-pressure chronic ulcer of buttock limited to breakdown of skin
- L98.412** Non-pressure chronic ulcer of buttock with fat layer exposed
- L98.413** Non-pressure chronic ulcer of buttock with necrosis of muscle
- L98.414** Non-pressure chronic ulcer of buttock with necrosis of bone
- L98.415** Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis
- L98.416** Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis
- L98.418** Non-pressure chronic ulcer of buttock with other specified severity
- L98.421** Non-pressure chronic ulcer of back limited to breakdown of skin
- L98.422** Non-pressure chronic ulcer of back with fat layer exposed
- L98.423** Non-pressure chronic ulcer of back with necrosis of muscle
- L98.424** Non-pressure chronic ulcer of back with necrosis of bone
- L98.425** Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis
- L98.426** Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis
- L98.428** Non-pressure chronic ulcer of back with other specified severity
- L98.491** Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin
- L98.492** Non-pressure chronic ulcer of skin of other sites with fat layer exposed
- L98.493** Non-pressure chronic ulcer of skin of other sites with necrosis of muscle
- L98.494** Non-pressure chronic ulcer of skin of other sites with necrosis of bone
- L98.495** Non-pressure chronic ulcer of skin of other sites with muscle involvement w/o evidence of necrosis



# Autologous RegenPRP™ + ATS Wound Gel

## Supplemental Notes for Billing & Coding Personnel

### Types of Bills (TOB) and Payment Method for PRP\*

\*Please refer to your internal billing procedures for any updates or specialized billing practices

- Hospital outpatient TOBs 12X and 13X – Outpatient Prospective Payment System
- Skilled Nursing Facility TOBs 22X and 23X – Medicare Physician Fee Schedule
- TOB 71X – based on the all-inclusive rate
- TOB 75X – Medicare Physician Fee Schedule
- TOB 77X – based on the all-inclusive rate
- TOB 85X – based on reasonable cost
- Critical Access Hospitals TOB 85X and revenue codes 096X, 097X, or 098X

### RegenLab® Patient Access Program Hotline

- Phone: 860-374-2712
- Email: regenlabusa@priahealthcare.com

## Helpful Links:



[CMS MACs by State](#)



[MACs Overview | CMS](#)



[CMS MAC Info Center](#)



[NCD 270.3 Eff. 04.13.2021](#)



[HCPCS Quarterly Update](#)



[2024 ICD-10-CM | CMS](#)



[MLN Matters - MM12403](#)



[SSA - Section 1862\(a\)\(1\)\(A\)](#)



[Pub 100-03 - NCD 270.3](#)



[Pub 100-04 - Claims Processing](#)



Developed & Manufactured in the USA

## Contact Customer Care:

(800) 220-9082 ext. 1 | [customercare@regenlabusa.com](mailto:customercare@regenlabusa.com)

### RegenLab® USA LLC

140A 58th Street, 2nd Floor

Brooklyn Army Terminal

Brooklyn, NY 11220

Phone /Fax: 1 (800) 220-9082

[www.regenlabusa.com](http://www.regenlabusa.com)

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