

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11214</b>	<b>Date: January 20, 2022</b>
	<b>Change Request 12403</b>

**Transmittal 11171, dated January 12, 2022, is being rescinded and replaced by Transmittal 11214, dated, January 20, 2022 to provide clarification to the note in the Claims Processing business instructions, Pub.100-04, business requirement 12403.04-01 and to update the title for the NCD 270.3 Blood Derived Products for Chronic Non-healing Wounds attachment. 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: January 3, 2022 - Shared Systems; February 14, 2022 - for MACs**

***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	32/11/3/Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds
R	32/11/3/1/ Policy
R	32/11/3//2/Healthcare Common Procedure Coding System (HCPCS) Codes, Diagnosis Coding and Frequency Requirements
R	32/11/3/3/Types of Bill (TOB)
R	32/11/3/4/Payment Method
R	32/11/3/5/Place of Service (POS) for Professional Claims
R	32/11/3/6/Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs) and Group Codes

### **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. 100-04	Transmittal: 11214	Date: January 20, 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**

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

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

## **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 a 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 platelet-rich plasma (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:** The Centers for Medicare & Medicaid Services (CMS) will cover autologous platelet-rich plasma (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 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 Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act.

NOTE: The following codes became effective retroactive back to the effective date of this policy, April 13, 2021: HCPCS G0460 , Autologous platelet rich plasma for non-diabetic chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment; and, HCPCS G0465, Autologous platelet rich plasma (PRP) for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (Includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment). These codes appear in the January 2022 updates of the Medicare Physician Fee Schedule Database (MPFSDB) and HCPCS file. CMS will not be reprocessing claims with DOS prior to the implementation date of this correction. Please follow the claims processing instructions provided below.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12403 - 04.1	<p>Effective for claims with dates of services (DOS) on or after April 13, 2021, contractors shall be aware that CMS covers Autologous PRP under the conditions and criteria outlined in NCD Manual Section 270.3, and Pub. 100-04, Chapter 32, section 11. NOTE: 20 weeks of coverage for autologous PRP for diabetes and chronic ulcers (use new HCPCS G0465 for diabetic wounds), beyond 20 weeks of coverage for autologous PRP for diabetes and chronic ulcers is at MAC discretion. Coverage of autologous PRP for all other chronic, non-healing wounds are at MAC discretion (use revised HCPCS G0460 for non-diabetic wounds).</p> <p>NOTE: MACs shall manually add HCPCS G0465 to the 2021 MPFS file in their systems effective April 13, 2021, with the same indicators/values as the January 2021 MPFS file for G0460.</p>	X	X							
12403 - 04.2	Effective for claims with DOS on or after April 13, 2021, contractors shall accept and pay for 20 weeks of autologous PRP claims for diabetes and	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	chronic ulcers, HCPCS G0465, when both an ICD-10 diagnosis code for Diabetes Mellitus and an ICD-10 diagnosis code for Chronic Ulcer from the attached list is appended to the claim.									
12403 - 04.2.1	Effective for claims with DOS on or after April 13, 2021, contractors shall deny/reject autologous PRP claims for diabetes and chronic ulcers, HCPCS G0465, that do not have both an ICD-10 diagnosis code for Diabetes Mellitus and an ICD-10 diagnosis code for Chronic Ulcer from the attached list present on the claim.	X	X							
12403 - 04.2.2	<p>Contractors shall use the following messages when denying/rejecting claims without the appropriate diagnosis codes noted in 04.2.1 above:</p> <p>Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.</p> <p>Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at:  <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>.  If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Medicare Summary Notice (MSN) 15.19 - "We used a</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at <a href="http://www.cms.gov/medicare-coverage-database">www.cms.gov/medicare-coverage-database</a> (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor."</p> <p>Spanish Version -Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en <a href="http://www.cms.gov/medicare-coverage-database">www.cms.gov/medicare-coverage-database</a> (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.</p>									
12403 - 04.2.2.1	<p>(Continued)</p> <p>MSN 15.20 - "The following polices were used when we made this decision: NCD 270.3."</p> <p>Spanish Version – "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 270.3."</p> <p>NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.</p> <p>Group Code – Contractual Obligation (CO) or PR (Patient Responsibility) dependent on liability.</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Group Code – Contractual Obligation (CO)									
12403 - 04.3	Effective for claims with DOS on or after April 13, 2021, contractors shall deny claims for PRP services, HCPCS G0465, for diabetes and chronic ulcers that are performed more than 20 weeks after the date of the first PRP service when the -KX modifier is not included on the claim line; i.e., 21 weeks forward NOTE: The new edit shall be overridable.		X							
12403 - 04.3.1	Effective for claims with DOS on or after April 13, 2021, contractors shall deny PRP services for diabetes and chronic ulcers, HCPCS G0465, that are performed more than 20 weeks after the date of the first PRP service when the -KX modifier is not included on the claim using the following messages: CARC 119 – Benefit Maximum for this time period or occurrence has been reached. RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a> . If you do not have web access, you may contact the contractor to request a copy of the NCD. Medicare Summary Notice (MSN) 20.5 – These services cannot be paid because your benefits are exhausted at this time. Group Code – Contractual Obligation (CO) NOTE: Coverage of PRP for		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	PRP services that are performed more than 20 weeks after the date of the first PRP service shall be determined by the local Medicare contractor.									
12403 - 04.4	Effective for PRP claims with DOS on and after April 13, 2021, contractors shall add POS 19 to existing POS codes 11, 22, and 49.		X							
12403 - 04.5	Contractors shall end-date all PRP shared systems edits April 12, 2021. These are MCS edit 032L and FISS edits 31820 and 31821.  NOTE: To avoid duplicate editing, A/B MACs shall turn off the specific reason codes and edits retroactive to April 13, 2021, until FISS and MCS are able to update their systems in the January 2022 quarterly release.	X	X			X	X			
12403 - 04.6	Contractors shall not search for claims to adjust for PRP services performed on or after April 13, 2021, until the implementation date of this correction CR, but may adjust claims brought to their attention.  NOTE: A subsequent, July 2022 CR is forthcoming that will install shared edits regarding frequency of PRP claims, HCPCS G0465.	X	X							

### III. PROVIDER EDUCATION TABLE



12403 - 04.7	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.*

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

**V. CONTACTS**

**Pre-Implementation Contact(s):** 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) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Billing) , 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: 1**

## **11.3 – Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds** *(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

### **11.3.1 – Policy**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

*Effective for claims with dates of service on or after April 13, 2021, contractors shall accept and pay for autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds 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, in accordance with the coverage criteria outlined in Publication 100-03, chapter 1, section 270.3, of the National Coverage Determinations (NCD) Manual.*

*NOTE: Coverage of PRP services for the treatment of chronic non-healing diabetic wounds that are performed more than 20 weeks after the date of the first PRP service shall be determined by the local Medicare Administrative Contractor (MAC).*

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

### **11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes, Diagnosis Coding and Frequency Requirements**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

#### ***Healthcare Common Procedure Coding System (HCPCS) Code***

*Effective for claims with dates of service on or after April 13, 2021, Medicare providers shall report HCPCS code G0460 for PRP services for the treatment of chronic non-healing non-diabetic wounds.*

*Effective for claims with dates of service on or after April 13, 2021, Medicare providers shall report HCPCS code G0465 for PRP services for the treatment of chronic non-healing diabetic wounds under the conditions and criteria outlined in NCD Manual Section 270.3.*

#### ***If ICD-10 Diagnosis coding is applicable***

*For claims with dates of service on or after April 13, 2021, PRP, for the treatment of chronic non-healing diabetic wounds must be billed reporting both an ICD-10 diagnosis code for diabetes mellitus and an ICD-10 diagnosis code for chronic ulcers.*

*- Two diagnosis codes are required- Diabetic Mellitus plus Chronic Ulcer*

#### ***Diabetes Mellitus***

<i>E08.621</i>	<i>Diabetes mellitus due to underlying condition with foot ulcer</i>
<i>E08.622</i>	<i>Diabetes mellitus due to underlying condition with other skin ulcer</i>
<i>E09.621</i>	<i>Drug or chemical induced diabetes mellitus with foot ulcer</i>
<i>E09.622</i>	<i>Drug or chemical induced diabetes mellitus with other skin ulcer</i>
<i>E10.621</i>	<i>Type 1 diabetes mellitus with foot ulcer</i>
<i>E10.622</i>	<i>Type 1 diabetes mellitus with other skin ulcer</i>
<i>E11.621</i>	<i>Type 2 diabetes mellitus with foot ulcer</i>

- 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*

### **Chronic Ulcer**

- 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*
- L97.115 *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*
- L97.114 *Non-pressure chronic ulcer of right thigh with necrosis of bone*
- 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*
- 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*
- L97.315 *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	<i>Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed</i>
L97.413	<i>Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle</i>
L97.414	<i>Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone</i>
L97.415	<i>Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis</i>
L97.416	<i>Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis</i>
L97.418	<i>Non-pressure chronic ulcer of right heel and midfoot with other specified severity</i>
L97.421	<i>Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin</i>
L97.422	<i>Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed</i>
L97.423	<i>Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle</i>
L97.424	<i>Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone</i>
L97.425	<i>Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis</i>
L97.426	<i>Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis</i>
L97.428	<i>Non-pressure chronic ulcer of left heel and midfoot with other specified severity</i>
L98.411	<i>Non-pressure chronic ulcer of buttock limited to breakdown of skin</i>
L98.412	<i>Non-pressure chronic ulcer of buttock with fat layer exposed</i>
L98.413	<i>Non-pressure chronic ulcer of buttock with necrosis of muscle</i>
L98.414	<i>Non-pressure chronic ulcer of buttock with necrosis of bone</i>
L98.415	<i>Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis</i>
L98.416	<i>Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis</i>
L98.418	<i>Non-pressure chronic ulcer of buttock with other specified severity</i>
L98.421	<i>Non-pressure chronic ulcer of back limited to breakdown of skin</i>
L98.422	<i>Non-pressure chronic ulcer of back with fat layer exposed</i>
L98.423	<i>Non-pressure chronic ulcer of back with necrosis of muscle</i>
L98.424	<i>Non-pressure chronic ulcer of back with necrosis of bone</i>
L98.425	<i>Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis</i>
L98.426	<i>Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis</i>
L98.428	<i>Non-pressure chronic ulcer of back with other specified severity</i>
L98.491	<i>Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin</i>
L98.492	<i>Non-pressure chronic ulcer of skin of other sites with fat layer exposed</i>
L98.493	<i>Non-pressure chronic ulcer of skin of other sites with necrosis of muscle</i>
L98.494	<i>Non-pressure chronic ulcer of skin of other sites with necrosis of bone</i>

**Frequency Requirements:**

*Effective for claims with dates of service on and after April 13, 2021, contractors shall cover PRP services for chronic non-healing diabetic wounds, G0465, for a maximum of 20 weeks beginning with the first week of treatment.*

*Effective for claims with dates of services on or after April 13, 2021, the local MACs shall have discretion to pay PRP services for chronic non-healing diabetic wounds, G0465, that are performed more than 20 weeks after the date of the first PRP service when the -KX modifier is reported on the claim.*

*Effective for claims with dates of service on and after April 13, 2021, contractors shall have discretion to cover, and determine frequency for, PRP services for chronic non-healing non-diabetic wounds, G0460.*

### **11.3.3 – Types of Bill (TOB)**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

The applicable *Types of Bill (TOBs)* for PRP services are: 12X, 13X, 22X, 23X, 71X, 75X, 77X, and 85X.

### **11.3.4 – Payment Method**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

Payment for PRP services is as follows:

- Hospital outpatient departments TOBs 12X and 13X – based on *the Outpatient Prospective Payment System*
- Skilled Nursing Facility TOBs 22X and 23X – based on *the Medicare Physician Fee Schedule (MPFS)*
- TOB 71X – based on *the all-inclusive rate*
- TOB 75X – based on *the MPFS*
- 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 – based on *the MPFS*

*Local MACs* shall pay for PRP services for hospitals in Maryland under the jurisdiction of the Health Services Cost Review Commission on an outpatient basis, TOB 13X, in accordance with the terms of the Maryland waiver.

### **11.3.5 - Place of Service (POS) for Professional Claims**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

Effective for claims with dates of service on or after August 2, 2012, place of service (POS) codes 11, 22, and 49 shall be used for PRP services.

*Effective for claims with dates of service on or after April 13, 2021, POS codes 11, 19, 22, and 49 shall be used for PRP services.*

### **11.3.6 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs) and Group Codes**

*(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)*

Contractors shall deny claims for *PRP* services when provided on other than TOBs 12X, 13X, 22X, 23X, 71X, 75X, 77X, and 85X using:

MSN 21.25 - “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version - “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

CARC 58 - “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. **NOTE:** Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

RARC N428 - “Service/procedure not covered when performed in this place of service.”

*Group Code - CO (Contractual Obligation)*

*Contractors shall reject claims for PRP services for the treatment of chronic non-healing diabetic wounds, G0465, that are performed more than 20 weeks after the date of the first PRP service when the --KX modifier is NOT included on the claim using the following messages:*

*CARC 119 – Benefit Maximum for this time period or occurrence has been reached.*

*RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available [www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp). If you do not have web access, you may contact the contractor to request a copy of the NCD.*

*Medicare Summary Notice (MSN) 20.5 – These services cannot be paid because your benefits are exhausted at this time.*

*Spanish Version: “Estos servicios no pueden ser pagados porque sus beneficios se han agotado.”*

*Group Code – CO (Contractual Obligation)*

*Contractors shall deny/reject claims for PRP services for the treatment of chronic non-healing diabetic wounds, G0465, that don't contain the appropriate diagnosis codes as noted above and use the following messages:*

*Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.*

*Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at: [www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp). If you do not have web access, you may contact the contractor to request a copy of the NCD.*

*Medicare Summary Notice (MSN) 15.19 - “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at [www.cms.gov/medicare-coverage-database](http://www.cms.gov/medicare-coverage-database) (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”*

*Spanish Version -Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en [www.cms.gov/medicare-coverage-database](http://www.cms.gov/medicare-coverage-database) (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.*

*MSN 15.20 - “The following polices were used when we made this decision: NCD 270.3.”*

*Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 270.3.”*

*NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.*

*Group Code – Contractual Obligation (CO).*

<b>NCD:</b> 270.3	
<b>NCD Title:</b> Blood Derived Products for Chronic Non-healing Wounds	
<b>IOM:</b> <a href="http://www.cms.gov/medicare-coverage-database/details/ncd-">http://www.cms.gov/medicare-coverage-database/details/ncd-</a>	
<b>MCD:</b> <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf">http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf</a>	
<b>ICD-10 CM</b>	<b>ICD-10 DX Description</b>
<b>CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.</b>	
<b>Two diagnosis are required- Diabetic Mellitus plus Chronic Ulcer</b>	
<b>Diabetes Mellitus</b>	
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
<b>Chronic Ulcer</b>	
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
L97.115	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
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone
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



	ICD-10 CM	ICD-10 DX Description
	L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone
	L97.215	Non-ressure 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 seerity
	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
	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
	L97.315	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 without evidence of necrosis
	L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without 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
	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





<b>NCD:</b>	270.3		
<b>NCD Title:</b>	Blood Derived Products for Chronic Non-healing Wounds		
<b>IOM:</b>	<a href="http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAaAAAA&amp;">http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAaAAAA&amp;</a>		
<b>MCD:</b>	<a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf">http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf</a>		
		<b>ICD-10 PCS</b>	<b>ICD-10 PCS Description</b>
		N/A	N/A

NCD: 270.3										
NCD Title: Blood Derived Products for Chronic Non-healing Wounds (TR63, CR3384, CR5123, CR6043, CR8213, CR10318, CR10859, CR11392, CR12403)										
IOM: <a href="http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAqAAAA&amp;">http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAqAAAA&amp;</a>										
MCD: <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf">http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf</a>										
Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
Part A	A/MACs: Effective 8/2/12, Coverage is through Coverage with Evidence Development (CED) for all 3 major wound categories: diabetic, venous, and pressure. Inpatient CED Claims: Institutional provider billing must report ICD-10 dx Z00.6, condition code 30, clinical trial modifier -Q0, and value code D4 with an 8-digit clinical trial number. CED sunsets if no trials in 2 years effective 8/12/14. These edits deleted w/DOS 4/13/21.	G0460	n/a	12x 13X 22X 23X 71X 75X 77X 85X	n/a	Q0	n/a	21.25	16	58 M76 N428
Part A	autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds G0465 for a duration of 20 weeks, when prepared by devices whose 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 G0465 beyond 20 weeks will be determined by local MACs as R&N. These claims require the -KX modifier. <b>NOTE:</b> Coverage of autologous PRP for tx of all other chronic non-healing wounds (non-diabetic) G0460 are determined by local MACs. See NCD 270.3 for complete coverage criteria.	G0465 diabetic G0460 non-diabetic	n/a	12x 13X 22X 23X 71X 75X 77X 85X	n/a		n/a	20.5	119	N386
Part A	A/MACs: Two ICD-10 dx are required for diabetic wounds- Diabetic Mellitus plus Chronic Ulcer see dx tab.	G0465 diabetic	n/a	12x 13X 22X 23X 71X 75X 77X 85X	n/a		n/a	15.19 15.20	50	N386

<b>NCD:</b> 270.3										
<b>NCD Title:</b> Blood Derived Products for Chronic Non-healing Wounds (TR63, CR3384, CR5123, CR6043, CR8213, CR10318, CR10859, CR11392, <b>CR12403</b> )										
<b>IOM:</b> <a href="http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAqAAAA&amp;">http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&amp;ncdver=4&amp;DocID=270.3&amp;SearchType=Advanced&amp;bc=IAAAAqAAAA&amp;</a>										
<b>MCD:</b> <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf">http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2710CP.pdf</a>										
Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
Part B	<b>B/MAC, MCS:</b> Effective 8/2/12, Coverage is through CED for all 3 major wound categories: diabetic, venous, and pressure. Outpatient CED Claims: Physician/Supplier claims are only payable when they include ICD-10 dx Z00.6 and HCPCS modifier - Q0. CED sunsets if no trials in 2 years effective 8/2/14. These edits are deleted w/ DOS 4/13/21.	G0460	n/a	11 19 22 49	n/a	Q0	n/a	21.25	16 58	M76 N428
Part B	<b>B/MACS</b> Effective for DOS on or after 04/13/21, CMS covers autologous platelet-rich plasma (PRP) for tx of chronic non-healing <u>diabetic</u> wounds G0465 for a duration of 20 weeks, when prepared by devices whose FDA-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. -Coverage of autologous PRP for the tx of chronic non-healing <u>diabetic</u> wounds G0465 beyond 20 weeks will be determined by local MACs as R&N. These claims require the -KX modifier. - <b>NOTE:</b> Coverage of autologous PRP for tx of all other chronic non-healing wounds (non-diabetic) G0460 are determined by local MACs. See NCD 270.3 for complete coverage criteria.	G0465 diabetic G0460 non-diabetic	n/a	11 19 22 49	n/a		n/a	20.5	119	N386
Part B	<b>B/MACs:</b> Two ICD-10 dx are required for diabetic wounds - Diabetic Mellitus plus Chronic Ulcer see dx tab.	G0465	n/a	11 19 22 49	n/a		n/a	15.19 15.20	50	N386