CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11364	**Date: April 27, 2022**
	Change Request 12611

Transmittal 11262, dated February 10, 2022, is being rescinded and replaced by Transmittal 11364, dated, April 27, 2022, to include new business requirement 2611.6 for new CWF requirements to FISS. All other information remains the same.

SUBJECT: Common Working File (CWF) Editing - 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 contractors of the CWF frequency editing for the 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: July 5, 2022; October 3, 2022 - CWF - Business Requirement 12611.5

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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

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:

One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 11364	Date: April 27, 2022	Change Request: 12611

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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 four 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 NCD Manual establishes conditions of coverage for blood-derived products for chronic non-healing wounds. In 2003, the 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: The 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 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.

NOTE: The following codes became effective retroactive back to the effective date of this policy, April 13, 2021: Healthcare Common Procedure Coding System (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 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.

NOTE: This Change Request follows-up on CR 12403 to provide CWF editing for autologous PRP claims for diabetes and chronic ulcers, HCPCS G0465, for claims which are performed more than 20 weeks after the Date of Service (DOS) of the first HCPCS G0465. CWF edits will allow payment for such claims when the KX modifier is included on the claim, where the MAC has exercised its discretion to cover such claims.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12611.1	Effective for claims with DOS on or after April 13, 2021, contractors shall have discretion to pay autologous PRP claims for diabetes and chronic ulcers, HCPCS G0465, under the conditions and criteria outlined in NCD Manual Section 270.3, and Pub. 100-04, Chapter 32, section 11 which are performed more than 20 weeks after the DOS of the first HCPCS G0465 when the KX modifier is included on the claim.	X	X							
12611.2	Effective for claims with DOS on or after April 13, 2021, CWF shall create a new edit to reject autologous PRP claims for diabetes and chronic ulcers, HCPCS G0465, when the date of service is more than 20 weeks after the DOS of the first HCPCS G0465 service and the KX modifier is not included on the claim line, i.e., 21 **weeks prior or forward.** Note: This edit shall be overrideable.					X			X	

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12611.2.1	Effective for claims with DOS on or after April 13, 2021, upon receipt of new CWF reject, 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. Claim Adjustment Reason Code (CARC) 119 – Benefit Maximum for this time period or occurrence has been reached. Remittance Advice Remark Codes (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. 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: This new CWF edit	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	shall be overridable.									
12611.3	Effective for claims with DOS on or after April 13, 2021, CWF shall create a new edit to reject autologous PRP claims for diabetes and chronic ulcers, HCPCS G0465, when the date of service is more than 20 weeks after the DOS of the first HCPCS G0465 service and the KX modifier is included on the claim line, i.e., 21 weeks prior or forward. Note: This edit shall be overrideable.					X			X	
12611.3.1	Effective for claims with DOS on or after April 13, 2021, at their discretion, contractors shall approve or 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 when the -KX modifier is included on the claim line; 21 weeks forward. NOTE: The contractors shall accept or override the CWF reject based on whether they choose to approve or deny the claim.	X	X							
12611.3.2	Should contractors decide to deny the above claim in 12611.3.1, they shall return the same messages provided in 12611.2.1 and apply Group Code CO.	X	X							
12611.4	CWF shall create a new Auxiliary File to identify all allowed Outpatient and Part B claims with HCPCS G0465					X	X		X	

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	for CWF to read the Earliest and Latest detail line date to calculate the 20 weeks (140 days). The new Auxiliary file will be carried in HIMR.									
12611.5	Effective October 3, 2022, CWF shall create a new HICR function for the new Auxiliary File.								X	
12611.6	CWF shall send FISS the HUQA transaction data for the DDE Screen Entry.					X			X	
12611.7	Contractors shall not search for claims to adjust for PRP services performed on or after April 13, 2021, but may adjust claims brought to their attention.	X	X						X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12611.8	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:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): David Dorlan, David.Dorlan@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, wanda.belle@cms.hhs.gov (Coverage and Analysis) , Thomas Dorsey, Thomas.Dorsey@cms.hhs.gov (Practitioner Claims) , Wil Gehne, Wil.Gehne@sms.hhs.gov (Institutional Claims) , Patricia Brocato-Simons, Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 1