Transmittal 10981, dated September 8, 2021, is being rescinded and replaced by Transmittal 11119, dated, November 10, 2021 to: (1) change Business Requirements (BRs) 12403 - 04.2, BR 12403 - 04.2.1 and BR 12403 - 04.2.2 to deny, (2) revise BR 12403 - 04.4.2.2 messaging, (3) add BR 12403 - 04.2.2.1, (4) remove Part A from BR 12403 - 04.3 and BR 12403 - 04.3.1, (5) revise verbiage in BR 12403 - 04.5, and extends the implementation date. 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: November 23, 2021 - for MACs; January 3, 2022 - Shared Systems

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>1/270/3/Blood-Derived Products for Chronic, Non-Healing Wounds</td>
</tr>
</tbody>
</table>

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:
Transmittal 10981, dated September 8, 2021, is being rescinded and replaced by Transmittal 11119, dated, November 10, 2021 to: (1) change Business Requirements (BRs) 12403 - 04.2, BR 12403 - 04.2.1 and BR 12403 - 04.2.2 to deny, (2) revise BR 12403 - 04.4.2.2 messaging, (3) add BR 12403 - 04.2.2.1, (4) remove Part A from BR 12403 - 04.3 and BR 12403 - 04.3.1, (5) revise verbiage in BR 12403 - 04.5, and extends the implementation date. 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

EFFECTIVE DATE: April 13, 2021
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: November 23, 2021 - for MACs; January 3, 2022 - Shared Systems

I. GENERAL INFORMATION

A. Background: Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin’s surface. Wounds are categorized as either acute, in where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, in where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

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

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

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

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

II. BUSINESS REQUIREMENTS TABLE
"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/B MAC</td>
<td>DME</td>
<td>MAC</td>
</tr>
<tr>
<td>A</td>
<td>B</td>
<td>HHH</td>
</tr>
<tr>
<td>12403 - 03.1</td>
<td>Effective for claims with dates of service on and after April 13, 2021, contractors shall cover autologous PRP for the treatment of chronic, non-healing diabetic wounds for up to 20 weeks when prepared by devices whose FDA-cleared indications include the management of exuding, cutaneous wounds, such as diabetic ulcers. Services beyond 20 weeks are covered at local MAC discretion. See Publication 100-03, Part 1, section 270.3 for complete coverage criteria.</td>
<td>X</td>
</tr>
</tbody>
</table>

### III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/B MAC</td>
<td>DME</td>
<td>MAC</td>
</tr>
<tr>
<td>A</td>
<td>B</td>
<td>HHH</td>
</tr>
<tr>
<td>12403 - 03.2</td>
<td>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.</td>
<td>X</td>
</tr>
</tbody>
</table>

### IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

<table>
<thead>
<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

V. CONTACTS

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

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0
A. General

Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin's surface. Wounds are categorized as either acute, where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner. Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors.

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products, and (2) PRP (such as AutoloGel).

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

The PRP is used by physicians in clinical settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone. Alternatively, PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

B. Nationally Covered Indications

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

C. Nationally Non-Covered Indications

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

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

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

D. Other

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

Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by the local Medicare Administrative Contractors (MACs).
Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by the local MACs under section 1862(a)(1)(A) of the Act.

(This NCD last reviewed April 2021.)
Diabetes mellitus due to underlying condition with other skin ulcer
Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
Non-pressure chronic ulcer of right ankle with other specified severity
Non-pressure chronic ulcer of left heel and midfoot with other specified severity
Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of right thigh with fat layer exposed
Non-pressure chronic ulcer of buttock with necrosis of muscle
Non-pressure chronic ulcer of left thigh with other specified severity
Non-pressure chronic ulcer of left calf limited to breakdown of skin
Non-pressure chronic ulcer of left thigh with necrosis of muscle
Non-pressure chronic ulcer of left ankle with necrosis of bone
Non-pressure chronic ulcer of left thigh limited to breakdown of skin
Non-pressure chronic ulcer of right calf with fat layer exposed
Drug or chemical induced diabetes mellitus with foot ulcer
Non-pressure chronic ulcer of right thigh with necrosis of bone
Non-pressure chronic ulcer of right thigh with necrosis of muscle
Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin
Non-pressure chronic ulcer of right calf with other specified severity
Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of left ankle limited to breakdown of skin
Non-pressure chronic ulcer of right thigh with necrosis of bone
Non-pressure chronic ulcer of right thigh with necrosis of muscle
Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of right thigh with necrosis of muscle
Non-pressure chronic ulcer of back with necrosis of muscle
Non-pressure chronic ulcer of right calf with necrosis of bone
Non-pressure chronic ulcer of skin of other sites with fat layer exposed
Non-pressure chronic ulcer of right calf with other specified severity
Non-pressure chronic ulcer of buttock limited to breakdown of skin
Non-pressure chronic ulcer of back limited to breakdown of skin
Type 1 diabetes mellitus with foot ulcer
Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
Non-pressure chronic ulcer of back with necrosis of bone
Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
Diabetes mellitus due to underlying condition with foot ulcer
Type 1 diabetes mellitus with other skin ulcer
Non-pressure chronic ulcer of left calf with other specified severity
Non-pressure chronic ulcer of right calf with necrosis of muscle
Non-pressure chronic ulcer of buttock with necrosis of bone
Non-pressure chronic ulcer of left calf with necrosis of muscle
Non-pressure chronic ulcer of left thigh with necrosis of bone
Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
Drug or chemical induced diabetes mellitus with other skin ulcer
Non-pressure chronic ulcer of left thigh with fat layer exposed
Non-pressure chronic ulcer of right calf with fat layer exposed
Non-pressure chronic ulcer of buttock limited to breakdown of skin
Non-pressure chronic ulcer of back limited to breakdown of skin
Diabetes mellitus due to underlying condition with foot ulcer
Type 1 diabetes mellitus with other skin ulcer
Non-pressure chronic ulcer of left calf with other specified severity
Non-pressure chronic ulcer of right calf with necrosis of muscle
Non-pressure chronic ulcer of buttock with necrosis of bone
Non-pressure chronic ulcer of left calf with necrosis of muscle
Non-pressure chronic ulcer of left thigh with necrosis of bone
Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
Drug or chemical induced diabetes mellitus with other skin ulcer
Non-pressure chronic ulcer of left thigh with fat layer exposed
Non-pressure chronic ulcer of right calf with fat layer exposed
Non-pressure chronic ulcer of buttock limited to breakdown of skin
Non-pressure chronic ulcer of back limited to breakdown of skin
Type 1 diabetes mellitus with foot ulcer
Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
Non-pressure chronic ulcer of back with necrosis of muscle
Non-pressure chronic ulcer of right calf with necrosis of bone
By 3M for CMS
DRAFT  Translation for Review
<table>
<thead>
<tr>
<th>NCD</th>
<th>270.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCD Title</td>
<td>Blood Derived Products for Chronic Non-healing Wounds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 PCS</th>
<th>ICD-10 PCS Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
**Rule Description**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A/MACs:</td>
<td>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 - by 8/12/14.</td>
<td>G0460</td>
<td>n/a</td>
<td>12x</td>
<td>22X</td>
<td>23X</td>
<td>71X</td>
<td>75X</td>
<td>77X</td>
<td>85X</td>
</tr>
<tr>
<td>A/MACs:</td>
<td>Effective for DOS on or after 04/13/2021, CMS covers 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 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 as R&amp;N. These claims require the -KX modifier. <strong>NOTE:</strong> Coverage of autologous PRP for tx of all other chronic non-healing wounds are determined by local MACs. See NCD 270.3 for complete coverage criteria.</td>
<td>G0460</td>
<td>n/a</td>
<td>n/a</td>
<td>Q0</td>
<td>n/a</td>
<td>21.25</td>
<td>-</td>
<td>119</td>
<td>20.5</td>
</tr>
<tr>
<td>A/MACs:</td>
<td>Two ICD-10 diagnosis codes are required- Diabetic Mellitus plus Chronic Ulcer see diagnosis tab.</td>
<td>G0460</td>
<td>n/a</td>
<td>12x</td>
<td>13X</td>
<td>22X</td>
<td>23X</td>
<td>71X</td>
<td>75X</td>
<td>77X</td>
</tr>
</tbody>
</table>

**By 3M for CMS**
### Rule Description

**NCD**: 270.3  
**NCD Title**: Blood Derived Products for Chronic Non-healing Wounds (TR63, CR3384, CR5123, CR6043, CR8213, CR10318, CR10859, CR11392, CR12403)  
**IOM**: [Link](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&ncdver=4&DocID=270.3&SearchType=Advanced&bc=IAAAAAgAAAAA&n=270.3)  

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Part B</td>
<td><strong>B/MAC, MCS:</strong> 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 - by 8/2/14.</td>
<td>G0460</td>
<td>n/a</td>
<td>11</td>
<td>19</td>
<td>Q0</td>
<td>n/a</td>
<td>21.25</td>
<td>58</td>
</tr>
</tbody>
</table>
| Part B | **B/MACS** Effective for DOS on or after 04/13/2021. CMS covers autologous platelet-rich plasma (PRP) for tx of chronic non-healing diabetic wounds 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 diabetic wounds beyond 20 weeks will be determined by local MACs as R&N. These claims require the -KX modifier.  
- **NOTE:** Coverage of autologous PRP for tx of all other chronic non-healing wounds are determined by local MACs. See NCD 270.3 for complete coverage criteria. | G0460 | n/a | 11 | 19 | 20.5 | - | 119 | N386 | ---- | 16 | M76 | N428 |
| Part B | **B/MACS:** Two ICD-10 diagnosis codes are required - Diabetic Mellitus plus Chronic Ulcer see diagnosis tab. | G0460 | n/a | 11 | 19 | 22 | n/a | 21.25 | 58 | N428 |

#### Revision History

Remove CARC 16, RARC MA130, M16 from lines 7, 8, 9 to align with CORE  
**CR10859**: To correct the record, ICD-10 dx I83.219 deleted 10/1/17 was an error, correct code is I83.219.  
**CR11392**: Add ICD-10 dx effective 10/1/19: L89.016, L89.026, L89.116, L89.126, L89.136, L89.146, L89.156, L89.216, L89.226, L89.316, L89.326, L89.46, L89.516, L89.526, L89.566, L89.626, L89.816, L89.896  
**CR12403**: Effective with NCD 270.3 reconsideration dated 4/13/21, remove CED.  
**CR12404**: Change national coverage to 20 weeks.  
**CR12405**: Add -KX modifier for MAC coverage beyond 20 weeks.  
**CR12406**: Add POS 19 effective 4/13/21.  
**CR12407**: End-date MCS edit 032L, FISS RCs 31820, 31821 effective 4/13/21 to allow MAC discretion beyond 20 weeks and for all other chronic, non-healing wounds.

DRAFT Translation for Review  
By 3M for CMS