Platelet-Derived Growth Factors for Wound Healing

iCare
INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories

NCD	Blood-Derived Products for Chronic Non-Healing Wounds	**270.3**		
LCD	Platelet Rich Plasma	**L38937**	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCA	Billing and Coding: Platelet Rich Plasma	**A58609**	JK - National Government Services, Inc. (Part A/B MAC	CT, NY, ME, MA, NH, RI, VT
LCD	Platelet Rich Plasma	**L39068**	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCA	Billing and Coding: Platelet Rich Plasma	**A58808**	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCD	Platelet Rich Plasma	**L38745**	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCA	Billing and Coding: Platelet Rich Plasma	**A58282**	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD	Platelet Rich Plasma	**L39071**	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCA	Billing and Coding: Platelet Rich Plasma	**A58810**		

Description

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, nonhealing 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.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistenly, iCare may consider the criteria contained in the following:

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, will be considered medically reasonable and necessary. [9]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following services/items will not be considered medically reasonable and necessary:

- 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[9]

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Platelet rich plasma (PRP) injections and/or applications as a means of managing musculoskeletal injuries and/or joint conditions are considered not medically reasonable and necessary.[5-8]

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

PRP is a general term describing a therapy with no gold standard of preparation or administration technique. This heterogeneity and the small number of controlled trials make it difficult to assess the efficacy of PRP for any disorder. There is a lack of standardization of the preparations of PRP amongst the trials, with varying concentration of platelet, frozen vs. fresh preparations, and the filtration of white cells. While the body of evidence of utility for PRP is large, the overall quality of evidence is low. The studies are relatively small, observational studies, often confounded by lack of treatment control, precluding cause-and-effect conclusions. RCTs that compare outcomes in patients whose treatment is standardized are needed to determine definitive patient selection criteria and clinical utility. There is insufficient high-quality evidence to justify the use of PRP for the treatment of any condition except for within the confines of a well-designed clinical trial. Thus, National Government Services considers PRP injection and PRP combined with stem cells for musculoskeletal injuries and/or joint conditions, whether primary or adjunctive use, to be experimental and investigational, because its effectiveness has not been established. [6]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	Description	Comments

	Injection(s), platelet rich plasma, any site, including image	
0232T	guidance, harvesting and preparation when performed	
HCPCS Code(s)	**Description**	**Comments**
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	
G0465	Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an fda-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)	
P9020	Platelet rich plasma, each unit	

References

1.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Article Determination (LCA). Billing and Coding: Platelet Rich Plasma (A58282). https://www.cms.gov. Published February 7, 2021. Updated July 1, 2023. Accessed August 30, 2023.

2.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Article Determination (LCA). Billing and Coding: Platelet Rich Plasma (A58609). https://www.cms.gov. Published August 1, 2021. Updated August 1, 2021. Accessed August 30, 2023.

3.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Article Determination (LCA). Billing and Coding: Platelet Rich Plasma (A58808). https://www.cms.gov. Published December 12, 2021. Updated July 1, 2023. Accessed August 30, 2023.

4.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Article Determination (LCA). Billing and Coding: Platelet Rich Plasma (A58810). https://www.cms.gov. Published December 12, 2021. Updated July 1, 2023. Accessed August 30, 2023.

5.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Platelet rich plasma (L38745). https://www.cms.gov. Published February 7, 2021. Updated March 23, 2023. Accessed August 2, 2023.

6.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Platelet rich plasma (L38937) https://www.cms.gov. Published August 1, 2021. Updated February 10, 2022. Accessed August 2, 2023.

7.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Platelet rich plasma (L39068). https://www.cms.gov. Published December 12, 2021. Accessed August 2, 2023.

8.   Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Platelet rich plasma (L39071). https://www.cms.gov. Published December 12, 2021. Accessed August 2, 2023.

9.   Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Blood-derived products for chronic non-healing wounds (270.3). https://www.cms.gov. Published December 28, 1992. Updated April 13, 2021. Accessed August 2, 2023.

Change Summary

- 01/01/2024 New Policy.
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