

PLATELET RICH PLASMA/PLATELET RICH FIBRIN MATRIX/ AUTOLOGOUS BLOOD-DERIVED PRODUCTS/BMAC

Effective Date: December 1, 2024 Review Dates: 6/08, 6/09, 6/10, 6/11, 6/12, 6/13, 8/14, 8/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 11/21, 11/22,

11/23, 11/24

Date Of Origin: June 2008 Status: Current

Related policies:

 91443 - Autologous Chondrocyte Implant/ Meniscal Allograft/ Osteochondral Replacement

• 91571 - Osteoarthritis of the Knee

Summary of Changes

• Clarification I.A.vi.1. and I.B:

- Specified indications referenced in other medical policies or prior authorized by TurningPoint.
- Deletion: I.C Replaced criteria specific to Medicare members with link to CMS' NCD 270.3

I. POLICY/CRITERIA

- A. Platelet rich plasma (PRP), autologous blood-derived growth factors, bone marrow aspirate concentrate (BMAC), and mesenchymal stem cells are considered investigational and experimental for all indications, including, but not limited to:
 - i. Avascular necrosis of the hip
 - ii. Bone healing and fusion, including as an adjunct to spinal fusion
 - iii. Chronic non-healing wounds
 - iv. Dupuytren's contracture
 - v. Epicondylitis (e.g., tennis elbow, elbow epicondylar tendinosis)
 - vi. Osteoarthritis
 - 1. For the treatment of the knee see the Osteoarthritis of the Knee # 91571 medical policy.
 - vii. Plantar fasciitis
 - viii. Sinus surgery
- B. Applications of platelet rich plasma (PRP), autologous blood-derived growth factors, bone marrow aspirate concentrate (BMAC), and/or mesenchymal stem for orthopedic applications may or may not be medically necessary according to TurningPoint criteria.
- C. For Medicare members: Centers for Medicare & Medicaid Services (CMS) covers autologous blood-derived products/PRP for chronic non-

Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

healing diabetic wounds according to <u>National Coverage Determination</u> (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3).

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **❖** HMO/EPO: This policy applies to insured HMO/EPO plans.
- ❖ POS: This policy applies to insured POS plans.
- * PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- * INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **❖** MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- * MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 42542 42543 42546 42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. DESCRIPTION

Blood-derived biologic therapies:



Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

Platelet rich plasma (PRP) is defined as a platelet-rich concentrate with platelet levels greater than the baseline count in whole blood. It is manufactured using centrifugation of blood, which separates the denser red cells from the plasma.

PRP and fibrin matrix (PRFM), or autologous platelet-derived growth factors, are proposed as an adjunct to standard treatment for several indications including wound care for the treatment of diabetic ulcers and venous stasis ulcers, bone augmentation and fusion, tendonitis, and plantar fasciitis. PRP is a general term describing a therapy with no standardized preparation or administration technique. PRP can be produced in an autologous or homologous manner. Autologous PRP is made of the patient's own blood while homologous PRP is derived from blood from multiple donors. The PRP contains whole cells including white cells, red cells, plasma, platelets, fibrin, stem cells, and fibrocyte precursors. Blood is centrifuged to produce an autologous gel and then used by physicians in clinical settings. PRFM is a second-generation platelet concentrate in does not require any gelifying agent. PRFM attempts to accumulate platelets and released cytokines in a fibrin clot using platelet cytokines, growth factors, and cells to serve as a resorbable membrane. (Naik, 2013).

Administration of PRP is a procedure and is, therefore, not subject to regulation by the Food and Drug Administration (FDA). However, the devices used to prepare PRP are regulated by the FDA premarket approval process. Several centrifuge devices have been approved by the FDA for preparation of PRP.

One example of a commercially available device, the Cascade® Autologous Platelet System produces a completely autologous platelet biologic with a high concentration of viable platelets, extracted from a small amount of the patient's own blood, spun through a centrifugation process and resulting in a dense suturable platelet rich fibrin matrix (PRFM) that can be delivered directly to the tear site and sutured in place to potentially stimulate a reparative healing response for soft tissue and bone repair.

The heterogeneity and the small number of controlled trials make it difficult to assess the efficacy of PRP for tendon and muscle injuries and disorders. A systematic review and meta-analysis of 40 randomized and quasi-randomized controlled trials, including 3035 patients with knee osteoarthritis did not show that PRP improved pain or function compared with hyaluronic acid, intra-articular steroid, or saline (Costa, 2023). PRP has been used in conjunction with different grafting materials in bone augmentation procedures since the day of its introduction; the results from these studies are controversial and no conclusions can be drawn regarding the bone regenerative effect of PRP till date. There is insufficient evidence to support the use of autologous platelet-derived growth factors for any indication at this time.

Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

Cellular therapies:

Bone marrow aspirate concentrate (BMAC) is an injectable product derived from a patient's bone marrow. Bone marrow is harvested from the iliac crest using commercial aspiration kits. The bone marrow aspirate is then processed and injected back into the patient (Chala, 2017). BMAC has been proposed for anti-inflammatory and regenerative treatment for joints and tendons (Ryu, 2020). Several studies have examined outcomes after BMAC injection, but there remains a lack of consensus in terms of the frequency of injection, the amount of BMAC that is injected, and the timing of BMAC injections. Mesenchymal stem or stromal cell (MSC) is a rare, undifferentiated multipotent stem cell. MSCs are multipotent progenitor cells that can be obtained from bone marrow, adipose tissue, synovium, articular cartilage, and skeletal muscles (Koga, 2008; Orozco, 2013). MSCs differentiate into fat, bone, and cartilage.

V. CODING INFORMATION

ICD-10 Codes: Not specified

CPT/HCPCS Codes:

Not Covere	ed for the indications listed in this policy
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance,
	harvesting and preparation when performed
0481T	Injection(s), autologous white blood cell concentrate (autologous protein
	solution), any site, including image guidance, harvesting and preparation,
	when performed
20939	Bone marrow aspiration for bone grafting, spine surgery only, through
	separate skin or fascial incision (List separately in addition to code for
	primary procedure) (Subject to Prior Authorization)
20999	Unlisted procedure, musculoskeletal system, general (Explanatory notes
	must accompany claims)
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation,
	per collection; autologous
38232	Bone marrow harvesting for transplantation; autologous
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
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) (Covered for Medicare only)
P9020	Platelet rich plasma, each unit (facility only)
P9073	Platelets, pheresis, pathogen-reduced, each unit



Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

Revenue Codes:

0383	Blood and Blood Components-Plasma
0384	Blood and Blood Components-Platelets
0390	Administration, Processing and Storage for Blood and Blood Components General
0399	Administration, Processing and Storage for Blood and Blood Components-Other Processing and Storage

VI. REFERENCES

- 1. American Academy of Orthopedic Surgeons (AAOS). <u>Management of osteoarthritis of the knee (nonarthroplasty): Evidence-based clinical practice guideline</u>. Aug 30, 2021.
- 2. Chahla J, Mannava S, Cinque ME, Geeslin AG, Codina D, LaPrade RF. Bone Marrow Aspirate Concentrate Harvesting and Processing Technique. Arthrosc Tech. 2017 Apr 10;6(2):e441-e445. doi: 10.1016/j.eats.2016.10.024. PMID: 28580265; PMCID: PMC5443590.
- 3. Chang KV, Hung CY, Aliwarga F, Wang TG, Han DS, Chen WS. Comparative effectiveness of plateletrich plasma injections for treating knee joint cartilage degenerative pathology: a systematic review and meta-analysis. Arch Phys Med Rehabil. 2014 Mar;95(3):562-75. doi: 10.1016/j.apmr.2013.11.006. Epub 2013 Nov 27.
- 4. Cohn CS, Lockhart E, McCullough JJ. The use of autologous platelet-rich plasma in the orthopedic setting. Transfusion. 2015 Jul;55(7):1812-20.
- Costa LAV, Lenza M, Irrgang JJ, Fu FH, Ferretti M. How Does Platelet-Rich Plasma Compare Clinically to Other Therapies in the Treatment of Knee Osteoarthritis? A Systematic Review and Meta-analysis. Am J Sports Med. 2023 Mar;51(4):1074-1086. doi: 10.1177/03635465211062243. Epub 2022 Mar 22. PMID: 35316112.
- 6. Dai WL, Zhou AG, Zhang H, Zhang J. Efficacy of Platelet-Rich Plasma in the Treatment of Knee Osteoarthritis: A Meta-analysis of Randomized Controlled Trials. Arthroscopy. 2017 Mar;33(3):659-670.e1.
- 7. CMS. National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic Non-Healing Wounds. Available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=217&ncdver=6&&sortBy=type&bc=2 (Accessed October 9, 2024).
- 8. Del Pino-Sedeño T, Trujillo-Martín MM, Andia I, Aragón-Sánchez J, Herrera-Ramos E, Iruzubieta Barragán FJ, Serrano-Aguilar P. Platelet-rich plasma for the treatment of diabetic foot ulcers: A metaanalysis. Wound Repair Regen. 2019 Mar;27(2):170-182. doi: 10.1111/wrr.12690. Epub 2018 Dec 21.



Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

- 9. Dong Y, Zhang B, Yang Q, Zhu J, Sun X. The effects of platelet-rich plasma injection in knee and hip osteoarthritis: a meta-analysis of randomized controlled trials. Clin Rheumatol. 2020 Jun 12. doi: 10.1007/s10067-020-05185-2. Epub ahead of print. PMID: 32533337.
- Eder C, Schmidt-Bleek K, Geissler S, Sass FA, Maleitzke T, Pumberger M, Perka C, Duda GN, Winkler T. Mesenchymal stromal cell and bone marrow concentrate therapies for musculoskeletal indications: a concise review of current literature. Mol Biol Rep. 2020 Jun;47(6):4789-4814. doi: 10.1007/s11033-020-05428-0. Epub 2020 May 25. PMID: 32451926; PMCID: PMC7295724.
- 11. Feiz-Erfan I, Harrigan M, Sonntag VKH, Harrington TR. Effect of autologous platelet gel on early and late graft fusion in anterior cervical spine surgery. J Neurosurg Spine. 2007 Nov;7(5):496-502.
- 12. Hayes, Inc. Hayes Search & Summary. Platelet Injections for Treatment of Plantar Fasciitis. Lansdale, PA: Hayes, Inc.; October 23, 2006
- 13. Hayes, Inc. Hayes Search & Summary. Platelet-Rich Plasma for Bone Healing and Fusion. Lansdale, PA: Hayes, Inc.; January 15, 2007.
- 14. Hayes, Inc. Hayes Technology Brief. Autologous Platelet-Rich Plasma to Aid Bone Fusion Following Ankle Surgery. Lansdale, PA: Hayes, Inc.; July 25, 2007.
- 15. Hayes, Inc. Platelet Rich Plasma for Ligament and Tendon Injuries, Directory Report, February 2011 & December 2012, update December 2013.
- 16. (Retrieved June 11, 2014, January 4, 2017 & December 28, 2018)
- 17. Hayes, Inc. Autologous Stem Cell Therapy for Treatment of Avascular Necrosis of the Hip, December 2015
- 18. Hayes, Inc. Bone Marrow Aspirate Concentration Systems, May 11, 2017
- 19. Hayes, Inc. Platelet-Rich Plasma for Knee Osteoarthritis: A Review of Reviews. November 9, 2017.
- 20. Hohmann E, Tetsworth K, Glatt V. Platelet-Rich Plasma Versus Corticosteroids for the Treatment of Plantar Fasciitis: A Systematic Review and Meta-analysis. Am J Sports Med. 2021 Apr;49(5):1381-1393. doi: 10.1177/0363546520937293. Epub 2020 Aug 21. PMID: 32822236.
- 21. Inchingolo F, Tatullo M, Marrelli M, Inchingolo AM, Scacco S, Inchingolo AD, Dipalma G, Vermesan D, Abbinante A, Cagiano R. Trial with Platelet-Rich Fibrin and Bio-Oss used as grafting materials in the treatment of the severe maxillar bone atrophy: clinical and radiological evaluations. Eur Rev Med Pharmacol Sci. 2010 Dec;14(12):1075-84. PMID: 21375140.
- 22. Keceli HG, Sengun D, Berberoğlu A, Karabulut E. Use of platelet gel with connective tissue grafts for root coverage: a randomized-controlled trial. J Clin Periodontol. 2008 Mar;35(3):255-62.
- 23. Koga H, Shimaya M, Muneta T, Nimura A, Morito T, Hayashi M, Suzuki S, Ju YJ, Mochizuki T, Sekiya I. Local adherent technique for transplanting mesenchymal stem cells as a potential treatment of cartilage defect. Arthritis



Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

- Res Ther. 2008;10(4):R84. doi: 10.1186/ar2460. Epub 2008 Jul 29. PMID: 18664254; PMCID: PMC2575632.
- 24. Martínez-Zapata MJ, Martí-Carvajal A, Solà I, Bolibar I, Angel Expósito J, Rodriguez L, García J. Efficacy and safety of the use of autologous plasma rich in platelets for tissue regeneration: a systematic review. Transfusion. 2009 Jan;49(1):44-56.
- 25. Naik B, Karunakar P, Jayadev M, Marshal VR. Role of Platelet rich fibrin in wound healing: A critical review. J Conserv Dent. 2013 Jul;16(4):284-93. doi: 10.4103/0972-0707.114344. PMID: 23956527; PMCID: PMC3740636.
- 26. Orozco L, Munar A, Soler R, Alberca M, Soler F, Huguet M, Sentís J, Sánchez A, García-Sancho J. Treatment of knee osteoarthritis with autologous mesenchymal stem cells: a pilot study. Transplantation. 2013 Jun 27;95(12):1535-41.
- 27. Peerbooms JC, Sluimer J, Bruijn DJ, Gosens T. Positive effect of an autologous platelet concentrate in lateral epicondylitis in a double-blind randomized controlled trial: platelet-rich plasma versus corticosteroid injection with a 1-year follow-up. Am J Sports Med. 2010 Feb;38(2):255-62.
- 28. Shams A, El-Sayed M, Gamal O, Ewes W. Subacromial injection of autologous platelet-rich plasma versus corticosteroid for the treatment of symptomatic partial rotator cuff tears. Eur J Orthop Surg Traumatol. 2016 Dec;26(8):837-842.
- 29. Ryu DJ, Jeon YS, Park JS, Bae GC, Kim JS, Kim MK. Comparison of Bone Marrow Aspirate Concentrate and Allogenic Human Umbilical Cord Blood Derived Mesenchymal Stem Cell Implantation on Chondral Defect of Knee: Assessment of Clinical and Magnetic Resonance Imaging Outcomes at 2-Year Follow-Up. Cell Transplant. 2020 Jan-Dec;29:963689720943581. doi: 10.1177/0963689720943581. PMID: 32713192; PMCID: PMC7563925.
- 30. Singh P, Madanipour S, Bhamra JS, Gill I. A systematic review and metaanalysis of platelet-rich plasma versus corticosteroid injections for plantar fasciopathy. Int Orthop. 2017 Jun;41(6):1169-1181.
- 31. Torres J, Tamimi F, Martinez PP, Alkhraisat MH, Linares R, Hernández G, Torres-Macho J, LópezCabarcos E. Effect of platelet-rich plasma on sinus lifting: a randomized-controlled clinical trial. J Clin Periodontol. 2009 Aug;36(8):677-87.
- 32. Vannini F, Di Matteo B, Filardo G, Kon E, Marcacci M, Giannini S. Plateletrich plasma for foot and ankle pathologies: a systematic review. Foot Ankle Surg. 2014 Mar;20(1):2-9.
- 33. Ye Y, Zhou X, Mao S, Zhang J, Lin . Platelet rich plasma versus hyaluronic acid in patients with hip osteoarthritis: A meta-analysis of randomized controlled trials. Int J Surg. 2018 May;53:279-287. doi: 10.1016/j.ijsu.2018.03.078. Epub 2018 Apr 5.
- 34. Zhao JG, Zhao L, Jiang YX, Wang ZL, Wang J, Zhang P. Platelet-rich plasma in arthroscopic rotator cuff repair: a meta-analysis of randomized controlled trials. Arthroscopy. 2015 Jan;31(1):125-35.



Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC

AMA CPT Copyright Statement:

All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.