

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

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11/23, 11/24, 11/25

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:TurningPoint reviews platelet rich plasma (PRP), autologous bloodderived growth factors, bone marrow aspirate concentrate (BMAC) only when submitted as an adjunct to a primary orthopedic/MSK procedure.
- Formatting changes

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:
 - 1. Avascular necrosis of the hip
 - 2. Bone healing and fusion, including as an adjunct to spinal fusion
 - 3. Chronic non-healing wounds
 - 4. Dupuytren's contracture
 - 5. Epicondylitis (e.g., tennis elbow, elbow epicondylar tendinosis)
 - 6. Osteoarthritis
 - 1. For the treatment of the knee see the Osteoarthritis of the Knee # 91571 medical policy.
 - 7. Plantar fasciitis
 - 8. Sinus surgery

II. BACKGROUND/DESCRIPTION

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

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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.

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

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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. Practice guidelines and position statements, guidance appears to confer weak support against treatment of knee osteoarthritis (KOA) with bone marrow-derived stem cells (BMSC). American College of Rheumatology/Arthritis Foundation guidelines state, "Stem cell injections are strongly recommended against in patients with knee and/or hip [OA]. There is concern regarding the heterogeneity and lack of standardization in available preparations of stem cell injections, as well as techniques used" (Kolasinski et al., 2020). Osteoarthritis Research Society International states, "[Intraarticular] stem cell therapy and [intraarticular platelet rich plasma], in particular, were strongly recommended against because the evidence in support of these [tx] is of extremely low quality, and the formulations themselves have not yet been standardized. Future investigation is needed to fully evaluate the appropriateness of these [tx] in [knee] OA" (Bannuru,2019).

III. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

National Coverage Determinations (NCDs)		
National Coverage Determinations	Blood-Derived Products for Chronic	
(NCDs)	Non-Healing Wounds (NCD 270.3)	
Local Coverage Determinations (LCDs)		
Local Coverage Determinations	N/A	
(LCDs)		

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Family	Platelet-Rich Plasma vs.
Physicians, Family Practice Inquiries	Corticosteroids for Refractory Plantar
Network	Fasciitis (2021)
American Academy of Orthopedic	Management of Osteoarthritis of the
Surgeons (AAOS)	Knee (Non-Arthroplasty) (2021)
American College of Foot and Ankle	Clinical Consensus Statement:
Surgeons	Diagnosis and Treatment of Adult
	Acquired Infracalcaneal Heel Pain
	(2018)

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American College of	American College of
Rheumatology/Arthritis Foundation	Rheumatology/Arthritis Foundation
	Guideline for the Management of
	Osteoarthritis of the Hand, Hip, and
	<u>Knee</u> (2019)
International Working Group on the	Guidelines on interventions to
Diabetic Foot (IWGDF)	enhance healing of foot ulcers in
	people with diabetes (2023)
Osteoarthritis Research Society	OARSI Guidelines for the Non-
International (OARSI)	surgical Management of Knee, Hip,
	and Polyarticular Osteoarthritis
	(2019)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

Preparation and implantation of bone marrow-derived stem cells (BMSC) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. BMSC treatment meets the FDA's definition under the Code of Federal Regulations (CFR) for human cells, tissues, and cellular and tissue-based products (HCT/Ps) (21 CFR 1271.3[d]) and does not require FDA premarket approval or 510(k) clearance. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of HCT/Ps.

VI. 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.

Applications of platelet rich plasma (PRP), autologous blood-derived growth factors, bone marrow aspirate concentrate (BMAC), and/or mesenchymal stem may be reviewed for medical necessity according to TurningPoint criteria when done in conjunction with an orthopedic procedure.

To access TurningPoint guidelines: Log into <u>Priority Health Prism</u> → Authorizations → Authorization Criteria Lookup.

VII. 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.



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- * 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.

VIII. CODING INFORMATION

ICD-10 Codes: *Not specified*

CPT/HCPCS Codes:

CP I/HC	rcs codes:
Not Cove	red 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 (PRP) or other blood-derived product for
	nondiabetic chronic wounds/ulcers (includes, as applicable: administration,
	dressings, phlebotomy, centrifugation or mixing, and all other preparatory
	procedures, per treatment)
G0465	Autologous platelet rich plasma (PRP) for diabetic chronic wounds/ulcers,
	using an FDA-cleared device (includes administration, dressings,



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	pinicootoniny,	centinugation,	and an our	er preparato	ry proc	caures, per

treatment) (Covered for Medicare only)

P9020 Platelet rich plasma, each unit *(facility only)* P9073 Platelets, pheresis, pathogen-reduced, each unit

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

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PRP

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