Subject: Platelet-rich Plasma (PRP)		Original Effective Date: 10/8/2014
Policy Number: MCP-207	Revision Date(s):	
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members. [1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Platelet-rich plasma (PRP) is a blood product derived from plasma that contains an increased concentration of platelets. PRP is also referred to as autologous platelet concentrate (APC) and autologous platelet gel (APG). The use of PRP is an approach being investigated for the treatment of soft tissue and bone healing, chronic non-healing wounds including burns and diabetic ulcers, osteoarthritis, tendon and ligament injuries and other surgeries. It is proposed that activated platelets initiate repair by releasing potent locally acting growth factors that stimulate a connective tissue response, causing division and migration of fibroblasts and formation of new capillaries to aid in the healing process. Platelet-rich plasma is usually prepared by a clinician or technician where blood is taken from the patient and centrifuged to obtain a concentrated suspension of platelets. PRP is injected or implanted during surgery with the goal of accelerating healing of the damaged tendon or ligament. For wound healing PRP is applied directly to the wound surface to promote growth of skin, soft tissue, and blood vessels.

RECOMMENDATION [2-25]

Platelet rich plasma is considered experimental, investigational and unproven because of insufficient evidence in the peer reviewed medical literature for any of the following conditions:

- ❑ Achilles tendon repair
- ❑ Acute surgical wounds

- ❑ Anterior cruciate ligament repair
- ❑ Burns
- ❑ Chronic non-healing diabetic, venous and/or pressure wounds*
- ❑ Dupuytren's contracture
- ❑ Epicondylitis (e.g., tennis elbow, elbow epicondylar tendinosis)
- ❑ Hamstring tendon injuries
- ❑ Injection of any ligament or tendon injury
- ❑ Osteoarthritis of the hip & knee
- ❑ Periodontal surgery
- ❑ Plantar fasciitis
- ❑ Rotator cuff repair
- ❑ Sinus surgery
- ❑ Spinal fusion or any other surgery using bone grafting
- ❑ Various tendinopathies
- ❑ All other conditions not listed above

Note: See CMS NCD for Medicare members [1]

SUMMARY OF MEDICAL EVIDENCE [3-34]

Results from both randomized controlled trials (RCTs) and nonrandomized controlled studies provide varied and inconclusive evidence regarding the ability of injection of platelet-rich plasma (PRP) to improve outcomes or accelerate healing in patients who have tendon or ligament injuries. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for platelet rich plasma for any indication. Below is a summary of the most relevant evidence based studies.

Chronic Wounds

According to the Cochrane Review (2012) there is currently no evidence to suggest that autologous PRP is of value for treating chronic wounds. The reports analyzed were based on small numbers of randomized controlled studies for the treatment of chronic wounds including 325 patients, most of whom were at either high or unclear risk of bias. [3]

A systematic review and meta-analysis evaluated the use platelet rich plasma (PRP) for the treatment of cutaneous wounds compared to standard wound care. These studies included 3 systematic reviews, 12 randomized controlled trials, 2 prospective cohort studies, 3 prospective comparative studies and 4 retrospective reviews. The results of the meta-analysis suggested that PRP therapy can positively impact wound healing and associated factors such as pain and infection in cutaneous wounds. Limitations of the studies included heterogeneous patient populations, lack of long-term follow-up, and pooling of data on different types of PFG products and regimens. Several of the studies included in the meta-analysis had conflicting results. [4]

Knee Osteoarthritis

A meta-analysis in a systematic review of 6 studies, including 577 patients, compared the outcomes of patients with symptomatic knee osteoarthritis treated by platelet-rich plasma, hyaluronic acid or normal saline (placebo).

There was no difference in the pooled results for visual analog scale score or overall patient satisfaction. Adverse events occurred more frequently in patients treated with PRP than in those treated with HA/placebo. [5] In a RCT of 109 patients with knee degenerative pathology treated by platelet-rich plasma (n=54) or hyaluronic acid injections (n=55), there was no statistically significant differences observed between groups at 12‑month follow-up. [6] Another RCT of 78 patients with bilateral OA were divided randomly into 3 groups. Group A (52 knees) received a single injection of PRP, group B (50 knees) received 2 injections of PRP 3 weeks apart, and group C (46 knees) received a single injection of normal saline. Results reported that a single dose of WBC-filtered PRP in concentrations of 10 times the normal amount is as effective as 2 injections to alleviate symptoms in early knee OA. The results, however, deteriorate after 6 months. [21] RCT's compared the effectiveness of intraarticular (IA) multiple and single platelet-rich plasma (PRP) injections as well as hyaluronic acid (HA) injections in different stages of osteoarthritis (OA) of the knee and found there was no significant difference in the scores of patients injected with one dose of PRP or HA. [24-25]

Tendon and Ligament Injuries

A long-term pilot study intratendinous injection of platelet-rich plasma under US guidance to treat tendinopathy in the upper (medial and lateral epicondylar tendons) and the lower (patellar, Achilles, hamstring and adductor longus, and peroneal tendons) limbs of 408 patients reported that residual US size of lesions were lower after intratendinous injection of PRP under US guidance at 6 weeks and during long-term follow-up (32 weeks) compared with baseline. [7]

There are several RCTs that evaluated PRP for tendon and ligament injuries. All studies found PRP treatment to be reasonably safe. Although many of the RCTs reported double- or single-blinding, all of the studies were relatively small, with treatment and control groups that had 10 to 80 patients and evaluated PRP as an adjunct to surgery for treatment of anterior cruciate ligament (ACL) injuries [8-10] Other RCTs evaluated PRP as an adjunct to arthroscopic or open surgery for the treatment of rotator cuff injuries [11-13] [22] and chronic rotator cuff tendinopathy.[20] Three RCTs evaluated PRP for the treatment of elbow tendon injuries, such as lateral epicondylitis or elbow tendinopathy. [14-16] Several RCTs evaluated PRP for the treatment of Achilles tendinopathy or tendon rupture. [17] [18] [23] One RCT assessed PRP in hamstring injuries. [19] Results from these RCTs provide mixed and inconclusive evidence regarding the ability of injection of platelet-rich plasma (PRP) to improve outcomes or accelerate healing in patients who have tendon or ligament injuries. A Cochrane review (2014) found there is currently insufficient evidence to support the use of PRT for treating musculoskeletal soft tissue injuries. [3]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed

HCPCS	Description
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation,

	and all other preparatory procedures, administration and dressings, per treatment
P9020	Platelet rich plasma, each unit

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any Diagnosis

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Government Agency

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Hayes

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    - Comparative Effectiveness Review: Platelet-Rich Plasma for Rotator Cuff Repairs, Tendinopathies, and Related Conditions: A Review of Reviews. May, 2018.
    - Comparative Effectiveness Review: Platelet-Rich Plasma for Treatment of Lateral Epicondylitis: A Review of Reviews. Dec, 2017. Updated Nov, 2018.
    - Comparative Effectiveness Review: Platelet-Rich Plasma for Knee Osteoarthritis: A Review of Reviews. Nov 2017, updated Nov, 2018.
    - Comparative Effectiveness Review: Platelet-Rich Plasma for Treatment of Ligament Injuries and Tendinopathies of the Knee: Review of Reviews. Dec 2017, updated March 2019.
    - Search & Summary: Platelet-Rich Plasma for Treatment of Thoracic and Lumbar Spinal Pain. Oct 2018.
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Peer Reviewed Literature

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

(CMS) has determined that platelet-rich plasma (PRP) an autologous blood-derived product, will be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds **only** when the patient is enrolled in a randomized clinical trial. [1]

Review/Revision History:
10/8/14: Policy created
12/16/15, 9/15/16, 9/19/17: Policy reviewed, no changes
9/13/18 & 6/19/19: Policy reviewed, current literature indicates that procedure remains experimental, investigational and unproven for all indications. References updated.