

Molina Clinical Policy

Platelet-Rich Plasma (PRP): Policy No. 207

Last Approval: 4/13/2022

Next Review Due By: April 2023



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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 drawing blood from the patient and processing the sample in a centrifuge to obtain a concentrated suspension of platelets. PRP is injected or implanted during surgery with the goal of accelerating healing. For wound healing, PRP is applied directly to the wound surface to promote growth of skin, soft tissue, and blood vessels.

COVERAGE POLICY

For **Medicare** coverage determinations, refer to the Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) prior to applying this policy.

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:

1. Achilles tendon repair; **OR**
2. Acute surgical wounds; **OR**
3. Anterior cruciate ligament repair; **OR**
4. Burns; **OR**
5. Chronic non-healing diabetic, venous and/or pressure wounds; **OR**
6. Dupuytren's contracture; **OR**
7. Epicondylitis (e.g., tennis elbow, elbow epicondylar tendinosis); **OR**
8. Hamstring tendon injuries; **OR**
9. Injection of any ligament or tendon injury; **OR**
10. Osteoarthritis of the hip and knee; **OR**
11. Periodontal surgery; **OR**
12. Plantar fasciitis; **OR**
13. Rotator cuff repair; **OR**
14. Sinus surgery; **OR**
15. Spinal fusion or any other surgery using bone grafting; **OR**
16. Various tendinopathies; **OR**
17. All other conditions not listed above.

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DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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 for any indication. Below is a summary of the most relevant evidence-based studies.

Chronic Wounds

Qu et al. (2020) conducted a systematic review and meta-analysis to evaluate the effectiveness of PRP in healing lower extremity diabetic ulcers, lower extremity venous ulcers, and pressure ulcers. The study included 22 randomized controlled trials (RCTs) and 5 observational studies with a total of 1,796 subjects. Follow up ranged from no follow up to 11 months. PRP therapy increased complete wound closure or healing (moderate strength of evidence) and shortened healing time and reduced wound size (low strength of evidence) in lower extremity diabetic ulcers compared to therapy without PRP. No significant changes were found regarding wound infection, amputation, wound recurrence, or hospitalization. The evidence was insufficient to estimate the effect of PRP on lower extremity venous ulcers or pressure ulcers. Limitations of the study include inadequate description of wound care procedures, wound characteristics, PRP formulation techniques, concentration, and volume; inadequate length of follow up; and lack of stratification by comorbidities and other patient characteristics.

Following a systematic review of 10 RCTs, Martinez-Zapata et al. (2016) concluded that PRP may improve the healing in diabetic foot ulcers, but the quality of evidence for this conclusion is low and based on two small RCTs. It is unclear whether or not autologous PRP is of value for treating other chronic wounds. Reports analyzed were based on small numbers of randomized controlled studies for the treatment of chronic wounds including 442 patients, most of whom were at either high or unclear risk of bias.

Another 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 RCTs, 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 (Carter, 2011).

The **Wound Healing Society** guidelines on treatment of diabetic foot ulcers state that platelet rich plasma has not demonstrated an increase in the healing rate or proportion of wounds that heal (Lavery et al., 2016).

The **National Institute of Health (NICE) Guideline** [NG19] on diabetic foot problems recommends against using platelet-rich plasma gel to treat diabetic foot ulcers unless as part of a clinical trial (NICE, 2019a).

Knee Osteoarthritis

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 (Filardo et al., 2012). 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 (Patel et al., 2013). Two RCTs 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 (Gormeli et al., 2017; Montanez-Heredia et al., 2016). A double-blind RCT

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conducted by Bennell et al. (2021) compared injection with PRP versus placebo (saline) in a group of 288 participants with symptomatic medial knee OA and found no significant difference in symptoms or joint structure at 12 months between the two treatment groups.

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 (Khoshbin et al, 2013). Dai et al. (2017) conducted a meta-analysis of 10 RCTs including 1069 patients to evaluate the efficacy and safety of PRP injections vs. control treatments for the treatment of knee OA. The study concluded that intra-articular PRP injection may have more benefit in pain relief compared with hyaluronic acid and saline injections, however there were limitations to the study including variations in the preparations of PRP, variations in injection frequencies and volumes, and substantial heterogeneity.

Tendon and Ligament Injuries

Results from RCTs evaluating use of PRP for tendon and ligament injuries provide mixed and inconclusive evidence regarding the ability of injection of PRP to improve outcomes or accelerate healing. A Cochrane review by Moraes et al. (2014) analyzed 19 studies with a total of 1088 patients and concluded there is currently insufficient evidence to support the use of PRP for treating musculoskeletal soft tissue injuries. Topics of the studies analyzed included rotator cuff tear repair, shoulder impingement syndrome surgery, elbow epicondylitis, anterior cruciate ligament reconstruction, patellar tendinopathy, and Achilles tendinopathy and rupture repair.

A Cochrane review including 32 RCTs and quasi-RCTs with 2337 participants concluded that evidence does not support the use of autologous blood or PRP injection for treatment of lateral elbow pain, or epicondylitis (Karjalainen et al., 2021). A RCT conducted by Kesikburun et al. (2013) compared treatment with PRP vs. saline injection in a group of 40 patients with chronic rotator cuff tendinopathy. At 1-year follow up, PRP injection was not found to be more effective in improving quality of life, pain, disability, and shoulder range of motion than placebo. Kwong et al. (2021) compared PRP with corticosteroid injection in patients with rotator cuff tendinopathy and partial-thickness rotator cuff tears in a double-blind RCT and found that although subjects treated with PRP obtained superior improvement in pain and function at 3-month follow up, there was no sustained benefit of PRP over corticosteroid at the 12-month follow up. Zhao et al. (2015) conducted a meta-analysis of level I and II RCTs and found that evidence does not support the use of PRP in arthroscopic rotator cuff repair due to similar clinical outcomes and retear rates compared to placebo. Several RCTs evaluated PRP for the treatment of Achilles tendinopathy or tendon rupture (de Vos et al., 2010; de Jonge et al., 2011; Krogh et al., 2016; Keene et al., 2019; Kearney et al., 2021), with none showing long-term benefit of treatment with PRP. Scott et al. (2019) conducted a RCT comparing injections of leukocyte-rich PRP, leukocyte-poor PRP, or normal saline for the treatment of patellar tendinopathy in a group of 57 subjects and concluded that a single injection of either PRP formulation was no more effective than saline for the improvement of patellar tendinopathy symptoms.

For articles reviewed in the development of this policy, please see the Reference section.

National and Specialty Organizations

The **American College of Rheumatology/Arthritis Foundation** *Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee* (Kolansinski et al., 2019) gives a strong recommendation against PRP for management of osteoarthritis of the knee or hip. Strong recommendations for management include exercise, weight loss, Tai Chi, oral and topical nonsteroidal anti-inflammatory drugs (NSAIDs), and intraarticular steroids.

A *Clinical Practice Guideline on Management of Osteoarthritis of the Knee (3rd Edition)* published by the **American Academy of Orthopaedic Surgeons** indicates PRP may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee, however the strength of the recommendation is limited, and the recommendation was downgraded two levels because of inconsistent evidence (AAOS, 2021).

A guideline published by **Veteran Affairs/Department of Defense** (VA/DoD, 2020) states there is insufficient evidence to recommend for or against PRP injections for the treatment of OA of the hip or knee.

The **National Institute of Health (NICE)** published interventional procedures guidance [IPG637] for platelet-rich plasma injections for knee osteoarthritis which notes that evidence on efficacy is limited in quality. As such, the procedure should only be used with special arrangements and data should be collected either by audit or research (NICE, 2019b).

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SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

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

HCPCS Codes

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 Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2022	Policy reviewed, no changes to coverage criteria. Summary of evidence and references updated.
4/5/2021	Policy reviewed, no changes.
6/17/2020	Policy reviewed, no changes, references updated.
6/19/2019	Policy reviewed, no changes, references updated.
9/13/2018	Policy reviewed, no changes, references updated.
9/19/2017	Policy reviewed, no changes.
9/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
10/08/2014	New policy.

REFERENCES

Government Agency

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National coverage determination (NCD) for blood-derived products for chronic non-healing wounds (270.3). Available from [CMS](https://www.cms.gov). Effective Date April 13, 2021. Implementation Date November 19, 2021. Accessed February 18, 2022.

Evidence Based Reviews and Publications

- Cook J, Young M. Biologic therapies for tendon and muscle injury. <http://www.uptodate.com>. Updated August 27, 2020. Accessed February 23, 2022. Registration and login required.
- Dane Street Peer Review. Policy reviewed in March 2022 by a Dane Street practicing, board-certified physician in the area of Orthopaedic Surgery.
- Hayes. <https://evidence.hayesinc.com>. Registration and login required.
 - Comparative effectiveness review of platelet-rich plasma for treatment of conditions of the Achilles tendon and plantar fascia. Published March 1, 2018. Updated March 14, 2019. Accessed February 22, 2022.
 - Comparative effectiveness review of platelet-rich plasma for rotator cuff repairs, tendinopathies, and related conditions. Published May 31, 2018. Accessed February 22, 2022.
 - Comparative effectiveness review of platelet-rich plasma for treatment of lateral epicondylitis. Published December 8, 2017. Accessed February 22, 2022.

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- Comparative effectiveness review of platelet-rich plasma for knee osteoarthritis. Published November 9, 2017. Accessed February 22, 2022.
 - Comparative effectiveness review of platelet-rich plasma for tendinopathies or ligament injuries of the knee. Published December 29, 2017. Accessed February 22, 2022.
 - Platelet-rich plasma for hip osteoarthritis. Published June 14, 2019. Accessed February 22, 2022.
 - Platelet-rich plasma for wound treatment in diabetic foot ulcers. Published February 10, 2022.
 - Platelet-rich plasma for wound treatment in venous leg ulcers. Published October 26, 2021.
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Peer Reviewed Publications

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.