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

Last Approval: 4/10/2024
Next Review Due By: April 2025

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 (Hayes 2022; Hayes 2023; Hayes 2024).

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.

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

Hossman et al. (2022) completed a single-center, prospective, randomized controlled study to compare the local application of PRP to standard wound care for non-ischemic diabetic foot ulcers. Eighty patients were enrolled and randomized 1:1, to receive either local injection of PRP to the healing edge and floor of the diabetic foot ulcer (Group A) or receive standard wound care with moist dressing, either with or without collagenase ointment (Group B). Primary outcomes measured included improvement of the diabetic foot ulcer total surface area and rate of complete healing.

Secondary outcomes included rates of wound infection, and major limb amputation. The following inclusion criteria for patient selection was applied: American Society of Anesthesiologists (ASA) type II, with either type 1 or type 2 diabetes, a chronic diabetic foot ulcer of 6 months duration or longer, no signs on infection, intact pedal pulse and an arterial duplex showing a patent arterial tree with a peak systolic velocity of >60 cm/sec. Patients with an ASA of > II were excluded from the study. Group A received prepared PRP to the ulcer every two weeks up to three times. Group B received standard wound care. Participants had follow up sessions every week, for up to 12 weeks. Baseline and weekly photos were taken of the diabetic foot ulcers, and total surface area was measured. Over the first five weeks there was a statistically higher reduction in diabetic foot ulcer in Group A than in Group B. At 2.5 weeks in Group A there was a ≥50% reduction in ulcer total surface area, compared to 4.5 weeks for Group B ($p < 0.001$). Group A had a 90% reduction in ulcer total surface area at 5 weeks, compared to 7 weeks for Group B ($p < 0.001$). At week 6, 95% of Group A had achieved complete would healing, as compared to 77.8% of group B in the ninth week ($p < 0.001$). There were 4 superficial wound infections in Group A (PRP), compared to 18 in Group B (standard care) who developed either superficial or deep wound infection and cellulitis ($p < 0.001$). No major amputations occurred in Group A. There were four major amputations in Group B. The author noted limitations included lack of standardization in the fabrication of the PRP and application method. Additional limitations included small patient population and lack of long term follow up. This meta-analysis showed that at the 3, 6, and 12 month follow ups that intra-articular FR-PRP had better overall outcomes than intra-articular HA injections in patients with knee osteoarthritis in WOMAC and IKDC scores. There was no difference in the VAS scores of the LR-PRP group as compared to the HA group e at 1, 3, 6, and 12 months after injection. Limitations to this study were English only publications, high heterogeneity (gender, age, and severity of knee osteoarthritis). Additional elements include PRP injection frequency, volumes, intervals, as well as injection techniques. Lastly, some of the RCTs reviewed had small patient sample sizes.

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 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** updated guidelines on treatment of diabetic foot ulcers state “The evidence is uncertain for the efficacy of therapy with platelet rich plasma as studies report mixed results regarding the benefits of this therapy”(Lavery et al. 2024).

The International Working Group on the Diabetic Foot (IWGDF) Guidelines on interventions to enhance healing of foot ulcers in people with diabetes state “With the exception of autologous leucocyte, platelet and fibrin patch we suggest not using autologous platelets therapy (including blook bank derived platelets) as an adjunct therapy to standard of care” (Chen et al. 2023).

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 ([1] NICE 2019).

Knee Osteoarthritis

A meta-analysis of 14 RCT studies involving 1485 subjects for treatment of knee osteoarthritis was published by Peng et al. (2022) to evaluate treatment of knee osteoarthritis with intra-articular injections of leukocyte rich platelet-rich plasma (LR-PRP) versus hyaluronic acid (HA). Inclusion criteria included RCTs that compared intra-articular injections of LR-PRP with HA injection in symptomatic adult patients with knee osteoarthritis. Only RCTs that were published in the English language were included. Exclusion criteria were children under the age of 18, RCTs without a control group, studies that were noted to be cohort, case-controlled, cross-sectional, review article and conference abstracts. Cadaveric and animal studies were excluded as well. Outcomes that were measured included Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores, visual analog scale (VAS) scores, International Knee Documentation Committee (IKDC) scores, and adverse events. Quality of the studies: "One study did not report methods of random sequence generation. Eight studies reported allocation concealment. Eight studies reported blinding participants and personnel, and seven studies reported blinding of outcome assessors. In total, five studies were double-blinded." Of the 1485 patients included in the study 815 patients had received LR-PRP injections, and 670 patients received HA injections. LR-PRP treatment protocols varied with dosage ranges from 2-14 mL, intervals between doses ranged between 1 to 4 weeks, and injection times ranging from 1 – 4 times. HA treatment protocols varied with dosages of molecular weight from 500 to >10,000 (kDa [kilodaltons]) with five studies not mentioning the molecular weight. Intervals between doses ranged between 1 to 4 weeks, and injection times ranging from 1 – 4 times. The Western Ontario and McMaster Universities Index (WOMAC) is used to evaluate hip and knee osteoarthritis. This is a self-administered questionnaire with 24 questions that evaluate the categories of pain, stiffness, and physical function. The WOMAC score is usually obtained by adding the scores of the three categories. Scores can range from 0 to 96. The higher the score, the worse the pain, stiffness, or physical function (Collins et al. 2011). The International Knee Documentation Committee (IKDC Questionnaire) is a tool that looks at the following three categories: symptoms, sports and daily activities, and knee function. Within these three categories are subscales that pain, stiffness, swelling, knee giving away, going up and down stairs, standing up from seated, squatting and jumping. There are a total of 18 items queried. The possible score range is 0 -100, with 100 being no limitations and no symptoms (Collins et al. 2011). Delgado et al. (2018) defines the visual analog scale is a validated, subjective measure for acute and chronic pain. Patients record the pain score on a 10cm line that is a continuum between 'no pain' or 0cm on the left and 10 cm worst pain on the right. This meta-analysis showed that at the 3, 6, and 12 month follow ups that intra-articular LR-PRP had better overall outcomes than intra-articular HA injections in patient with knee osteoarthritis in WOMAC and IKDC scores. There was no difference in the VAS scores of the LR-PRP group as compared to the HA group e at 1, 3, 6, and 12 months after injection. No major adverse effects were reported in the LR-PRP or HA groups. Limitations to this study were English only publications, high heterogeneity (gender, age, and severity of knee osteoarthritis). Additional elements include PRP injection frequency, volumes, intervals, as well as injection techniques. Lastly, some of the RCTs reviewed had small patient sample sizes. The authors note "The ideal composition, injection intervals, and injection times of PRP for knee osteoarthritis injection treatment remain controversial".

A systematic review and meta-analysis completed by Sax et al. (2022) included 24 RCTs comparing PRP injections to treatment with a control group (hyaluronic acid, corticosteroid injections, normal saline injections, or exercise therapy). The results showed that PRP could potentially be associated with improvements in pain and functional improvements; however, there was no clinically significant differences or knee-related structural changes between PRP injections and control groups. An 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 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 systematic review and meta-analysis including 5 RCTs with 340 patients concluded there was no statistically significant difference in visual analog and patient-related tennis elbow evaluation scores when comparing PRP injections to surgery (Kim et al. 2022). 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 RTC 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 and meta-analyses evaluated PRP for the treatment of Achilles tendinopathy or tendon rupture (Boksch et al. 2022; Chen et al. 2022; 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.

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 ([2]NICE 2019).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when

	performed

HCPCS (Healthcare Common Procedure Coding System) Codes

Code	Description
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) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
P9020	Platelet rich plasma, each unit

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

04/10/2024 Policy reviewed, no changes to coverage criteria. Summary of Medical Evidence and References updated.
04/13/2023 Policy reviewed, no changes to coverage criteria. Summary of Medical Evidence and References updated.
04/13/2022 Policy reviewed, no changes to coverage criteria. Summary of evidence and references updated. IRO Peer Review on March 18, 2022, by a practicing physician board-certified in Orthopedic Surgery.
04/05/2021 Policy reviewed, no changes.
06/17/2020 Policy reviewed, no changes, references updated.
06/19/2019 Policy reviewed, no changes, references updated.
09/13/2018 Policy reviewed, no changes, references updated.
09/19/2017 Policy reviewed, no changes.
09/15/2016 Policy reviewed, no changes.
12/16/2015 Policy reviewed, no changes.
10/08/2014 New policy.

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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.*

Washington
For Medicaid reviews, consider and apply the following state-specific criteria: Health Technology Assessment (HTA) "Hyaluronic Acid/Viscosupplementation and Platelet Rich Plasma for Knee or Hip Osteoarthritis" Washington State Healthcare Authority, June 26, 2023.