Medical Policy
Orthopedic Applications of Platelet-Rich Plasma

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Policy Number: 737
BCBSA Reference Number: 2.01.98
NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Related Policies
- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions, #111
- Bone Morphogenetic Protein #097
- Orthopedic Applications of Stem Cell Therapy #254
- Prolotherapy, #183

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Use of platelet-rich plasma is considered INVESTIGATIONAL for all orthopedic indications. This includes, but is not limited to, use in the following situations:

- Primary use (injection) for the following conditions:
  - Achilles tendinopathy
  - Lateral epicondylitis
  - Osteochondral lesions
  - Osteoarthritis
  - Plantar fasciitis.

- Adjunctive use in the following surgical procedures:
  - ACL reconstruction
  - Hip fracture
  - Long-bone nonunion
  - Patellar tendon repair
  - Rotator cuff repair
  - Spinal fusion
  - Subacromial decompression surgery
  - Total knee arthroplasty.

Medicare HMO BlueSM and Medicare PPO BlueSM Members
This is not a covered service.

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient
• For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
• For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

| Commercial Managed Care (HMO and POS) | This is not a covered service. |
| Commercial PPO and Indemnity | This is not a covered service. |
| Medicare HMO Blue® | This is not a covered service. |
| Medicare PPO Blue® | This is not a covered service. |

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
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<th>CPT codes:</th>
<th>Code Description</th>
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<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
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Description
A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factors, epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like growth factors. Autologous platelets are a rich source of platelet-derived growth factor, transforming
growth factors that function as a mitogen for fibroblasts, smooth muscle cells, osteoblasts, and vascular endothelial growth factors.

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma (PRP), can be prepared from samples of centrifuged autologous blood. Exposure to a solution of thrombin and calcium chloride degranulates platelets, releasing the various growth factors. The polymerization of fibrin from fibrinogen creates a platelet gel, which can then be used as an adjunct to surgery with the intent of promoting hemostasis and accelerating healing. In the operating room setting, PRP has been investigated as an adjunct to various periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a type of transforming growth factors, and thus PRP has been used in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries. Alternatively, PRP may be injected directly into various tissues. PRP injections have been proposed as a primary treatment of miscellaneous conditions, such as epicondylitis, plantar fasciitis, and Dupuytren contracture.

Injection of PRP for tendon and ligament pain is theoretically related to prolotherapy (see policy #183). However, prolotherapy differs in that it involves the injection of chemical irritants intended to stimulate inflammatory responses and induce the release of endogenous growth factors.

PRP is distinguished from fibrin glues or sealants, which have been used as a surgical adjunct to promote local hemostasis at incision sites. Fibrin glue is created from platelet-poor plasma and consists primarily of fibrinogen. Commercial fibrin glues are created from pooled homologous human donors; Tisseel® (Baxter) and Hemaseel® (Haemacure Corp) are examples of commercially available fibrin sealants. Autologous fibrin sealants can be created from platelet-poor plasma. This evidence review does not address the use of fibrin sealants.

Summary
The use of platelet-rich plasma (PRP) has been proposed as a treatment for various musculoskeletal conditions and as an adjunctive procedure in orthopedic surgeries. The potential benefit of PRP has received considerable interest due to the appeal of a simple, safe, low-cost, and minimally invasive method of applying growth factors.

Primary Treatment for Tendinopathies
For individuals with tendinopathy who receive PRP injections, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews with meta-analyses. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life (QOL), and treatment-related morbidity. Findings from meta-analyses of RCTs have been mixed and have generally found that PRP did not have a statistically and/or clinically significant impact on symptoms (ie, pain) or functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Primary Treatment for Non-Tendon Soft Tissue Injury or Inflammation
For individuals with non-tendon soft tissue injury or inflammation (eg, plantar fasciitis) who receive PRP injections, the evidence includes three small RCTs, multiple prospective observational studies, and a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, and treatment-related morbidity. The systematic review, which identified three RCTs on PRP for plantar fasciitis, did not pool study findings. Results among the three RCTs were inconsistent. The largest RCT showed that treatment using PRP compared with corticosteroid injection resulted in statistically significant but temporary improvements in American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale scores, indicating improved outcomes. Confirmation of these results in larger double-blind RCTs would be needed to permit greater certainty on the efficacy of PRP in plantar fasciitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

Primary Treatment for Osteochondral Lesions
For individuals with osteochondral lesions who receive PRP injections, the evidence includes an open-labeled quasi-randomized study. The relevant outcomes are symptoms, functional outcomes, health
status measures, QOL, and treatment-related morbidity. The quasi-randomized study found a statistically significant greater impact on outcomes in the PRP group than in the hyaluronic acid group. Limitations of the evidence base include lack of adequately randomized studies, lack of blinding, lack of sham controls, and comparison only to an intervention of uncertain efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Primary Treatment for Knee or Hip Osteoarthritis**

For individuals with knee or hip OA who receive PRP injections, the evidence includes multiple RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL quality of life, and treatment-related morbidity. Three RCTs have compared PRP with placebo while most trials have compared PRP with hyaluronic acid for knee OA. A meta-analysis of three trials comparing PRP with placebo showed a significant improvement in functional scores. However, only one of the trials was considered at low-risk of bias. Comparisons between PRP and hyaluronic acid have shown inconsistent results. A meta-analysis including only low-risk of bias trials showed no difference between the two treatments in functional scores. Also, using hyaluronic acid as a comparator is questionable, because the evidence demonstrating the benefit of hyaluronic acid treatment for OA is not robust. The single RCT evaluating hip OA reported statistically significant reductions in visual analog scale scores for pain, with no difference in functional scores. Additional studies comparing PRP with placebo and with alternatives other than hyaluronic acid are needed to determine the efficacy of PRP for knee and hip OA. Studies are also needed to determine the optimal protocol for delivering PRP. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Adjunct to Surgery**

For individuals with anterior cruciate ligament reconstruction who receive PRP injections plus orthopedic surgery, the evidence includes two systematic reviews of multiple RCTs and prospective studies. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity related morbidity. Only one of the two systematic reviews conducted a meta-analysis; it showed that adjunctive PRP treatment did not result in a significant effect on International Knee Documentation Committee scores, a patient-reported, knee-specific outcome measure that assesses pain and functional activity. Individual trials have shown mixed results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with hip fracture who receive PRP injections plus orthopedic surgery, the evidence includes an open-labeled RCT. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related morbidity. The single open-labeled RCT failed to show a statistically significant reduction in the need for surgical revision with the addition of PRP treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with long bone nonunion who receive PRP injections plus orthopedic surgery, the evidence includes three RCTs. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related morbidity. One trial with a substantial risk of bias failed to show significant differences in patient-reported or clinician-assessed functional outcome scores between those who received PRP plus allogenic bone graft and those who received only allogenic bone graft. While the trial showed a statistically significant increase in the proportion of bones that healed in patients receiving PRP in a modified intention-to-treat analysis, the results did not differ in the intention-to-treat analysis. The second RCT, which compared PRP with recombinant human bone morphogenetic protein-7, also failed to show any clinical or radiologic benefits of PRP over morphogenetic protein. The third RCT reported no difference in the number of unions or time to union in patients receiving PRP injections vs no treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with rotator cuff repair who receive PRP injections plus orthopedic surgery, the evidence includes multiple RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related
morbidity. The systematic reviews and meta-analyses failed to show a statistically and/or clinically significant impact on symptoms (ie, pain) or functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with spinal fusion who receive PRP injections plus orthopedic surgery, the evidence includes two controlled prospective studies. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related morbidity. The two studies failed to show any statistically significant differences in fusion rates between the PRP arm and the control arm. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with subacromial decompression surgery who receive PRP injections plus orthopedic surgery, the evidence includes two controlled prospective studies. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related morbidity. A single small RCT failed to show a reduction in self-assessed or physician-assessed spinal instability scores with PRP injections. However, subjective pain, use of pain medications, and objective measures of range of motion showed clinically significant improvements with PRP. Larger trials are required to confirm these benefits. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with total knee arthroplasty who receive PRP injections plus orthopedic surgery, the evidence includes a small RCT. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, morbidity events, resource utilization, and treatment-related morbidity. The RCT showed no significant differences between the PRP and untreated control groups in bleeding, range of motion, swelling around the knee joint, muscle power recovery, pain, or Knee Society Score and Knee Injury and Osteoarthritis Outcome Score. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Policy History

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<th>Date</th>
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<tr>
<td>5/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

### References


