**MEDICAL POLICY – 2.01.98**

**Orthopedic Applications of Platelet-Rich Plasma**

<table>
<thead>
<tr>
<th>BCBSA Ref. Policy:</th>
<th>2.01.98</th>
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</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>July 1, 2023</td>
</tr>
<tr>
<td>Last Revised:</td>
<td>June 12, 2023</td>
</tr>
<tr>
<td>Replaces:</td>
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**RELATED MEDICAL POLICIES:**

- 2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
- 2.01.26 Prolotherapy
- 2.01.31 Intra-articular Hyaluronan Injections for Osteoarthritis
- 7.01.78 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
- 8.01.52 Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow)

Select a hyperlink below to be directed to that section.

- POLICY CRITERIA
- CODING
- RELATED INFORMATION
- EVIDENCE REVIEW
- REFERENCES
- HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

**Introduction**

Growth factors are some of the proteins that the body makes. Growth factors help wounds heal. Platelets are found in blood and are a rich source of growth factors. Platelets not only help the blood clot when there is a wound, but they also aid in repairing and regenerating tissue. The idea behind platelet rich plasma is to provide a much higher concentration of platelets to an injured area to ease pain and help a wound heal. Platelet rich plasma is made by taking a sample of a person’s own blood and then concentrating the platelets in the lab. The enriched platelets are then injected (given by a shot) into the person. There have been a number of studies looking at whether platelet rich plasma is effective for conditions affecting bones, muscles, ligaments, and other tissues (orthopedics). When these studies are taken as a whole, there is no evidence that platelet rich plasma is effective for orthopedic conditions. Many of the studies are small and were not well designed. Platelet rich plasma is considered unproven (investigational) for orthopedic uses. The health plan does not pay for investigational services.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for
Policy Coverage Criteria

<table>
<thead>
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<tr>
<td>All orthopedic indications</td>
<td>Use of platelet-rich plasma is considered investigational for all orthopedic indications. This includes, but is not limited to, use in the following situations:</td>
</tr>
<tr>
<td></td>
<td>• Primary use (injection) for the following conditions:</td>
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<tr>
<td></td>
<td>o Achilles tendinopathy</td>
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<td></td>
<td>o Lateral epicondylitis</td>
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<td>o Osteochondral lesions</td>
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<td></td>
<td>o Osteoarthritis</td>
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<tr>
<td></td>
<td>o Plantar fasciitis</td>
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<td></td>
<td>• Adjunctive use in the following surgical procedures:</td>
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<tr>
<td></td>
<td>o Anterior cruciate ligament (ACL) reconstruction</td>
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<td></td>
<td>o Hip fracture</td>
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<td></td>
<td>o Long-bone nonunion</td>
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<td></td>
<td>o Patellar tendon repair</td>
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<tr>
<td></td>
<td>o Rotator cuff repair</td>
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<td></td>
<td>o Spinal fusion</td>
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<td></td>
<td>o Subacromial decompression surgery</td>
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<tr>
<td></td>
<td>o Total knee arthroplasty</td>
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Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
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<td>HCPCS</td>
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Description

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.

Background

A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factors (PDGFs), 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. Recombinant platelet-derived growth factor has also been extensively investigated for clinical use in wound healing (see Related Policies).

Autologous platelet concentrate suspended in plasma, also known as 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 a variety of periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a type of transforming growth factor, 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 (discussed in a Related Policy). However, prolotherapy differs in that it involves injection of chemical irritants that are intended to stimulate inflammatory responses and induce 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 VITASEAL™ (Johnson & Johnson Surgical Technologies) are examples of commercially available fibrin sealants. Autologous fibrin sealants can be created from platelet-poor plasma. This policy does not address the use of fibrin sealants.

Summary of Evidence

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-analysis. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life 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 (i.e., pain) or functional outcomes. Findings from a subsequently published RCT failed to find improvement compared with placebo. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.
Primary Treatment for Non–Tendon Soft Tissue Injury or Inflammation

For individuals with non–tendon soft tissue injury or inflammation (e.g., plantar fasciitis) who receive PRP injections, the evidence includes several small RCTs, multiple prospective observational studies, and a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life and treatment-related morbidity. The 2014 systematic review, which identified three RCTs on PRP for plantar fasciitis, did not pool study findings. Results among the remaining RCTs were inconsistent. The largest RCT showed that treatment with PRP compared with corticosteroid injection resulted in statistically significant improvement in pain and disability, but not quality of life. A 2023 systematic review found improved VAS scores with platelet-rich plasma compared to corticosteroid injections out to 6 months duration, but numerical differences between groups were small. Larger RCTs completed over a sufficient duration of time (i.e., 2 years) are still needed to address important uncertainties in efficacy and safety. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, quality of life, and treatment-related morbidity. The quasi-randomized study found a statistically significantly 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 that the technology results in an improvement in the net health outcome.

Primary Treatment for Knee or Hip Osteoarthritis

For individuals with knee or hip osteoarthritis (OA) who receive PRP injections, the evidence includes multiple RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Most trials have compared PRP with hyaluronic acid for knee osteoarthritis. Systematic reviews have generally found that PRP was more effective than placebo or hyaluronic acid in reducing pain and improving function. However, systematic review authors have noted that their findings should be interpreted with caution due to important limitations including significant residual
statistical heterogeneity, questionable clinical significance, and high risk of bias in study conduct. RCTs with follow-up durations of at least 12 months published subsequent to the systematic reviews found statistically significantly greater 12-month reductions in pain and function scores, but these findings were also limited by important study conduct flaws including potential inadequate control for selection bias and unclear blinding. Also, benefits were not maintained at 5 years. Using hyaluronic acid as a comparator is questionable because the evidence demonstrating the benefit of hyaluronic acid treatment for osteoarthritis is not robust. Two systematic reviews evaluating hip osteoarthritis did not report any statistically or clinically significant differences in pain or functional outcomes compared to hyaluronic acid, corticosteroids, or placebo. 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 osteoarthritis. Studies are also needed to determine the optimal protocol for delivering PRP. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Adjunct to Surgery**

For individuals with anterior cruciate ligament reconstruction who receive PRP injections plus orthopedic surgery, the evidence includes several systematic reviews of multiple RCTs and prospective studies and a retrospective matched case-control study. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. In two systematic reviews that conducted a meta-analysis, adjunctive PRP treatment did not result in significant effect on International Knee Documentation Committee (IKDC) scores, a patient-reported, knee-specific outcome measure that assesses pain and functional activity. One systematic review found improvements with PRP compared to controls in outcomes at 6 months, but these differences were determined to be clinically irrelevant with the exception of pain at 6 months which was improved with platelet-rich plasma. Individual trials have shown mixed results. A retrospective matched case-control study found no differences in knee function scores or time to return of activity between PRP and matched-control groups at 2 years; however, the platelet-rich plasma group demonstrated a higher rate of postoperative knee motion loss compared with the control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, quality of life, morbid events, resource utilization, and
treatment-related morbidity. The single open-labeled RCT failed to show any statistically significant reduction in the need for surgical revision with the addition of PRP treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with long bone nonunion who receive PRP injections plus orthopedic surgery, the evidence includes three RCTs. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. One trial with 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 individuals receiving PRP in a modified intention-to-treat analysis, the results did not differ in the intention-to-treat analysis. An RCT that compared PRP with recombinant human bone morphogenetic protein-7 (rhBMP-7), also failed to show any clinical or radiologic benefits of PRP over rhBMP-7. The third RCT reported no difference in the number of unions or time-to-union in individuals receiving PRP injections compared with no treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, quality of life, morbid events, resource utilization, and treatment-related morbidity. Although systematic reviews consistently found significant reductions in pain with PRP at 12 months, important study conduct and relevance weaknesses limit interpretation of these findings. While the systematic reviews and meta-analyses generally failed to show a statistically and/or clinically significant impact on other outcomes, one meta-analysis found a statistically significant reduction in retear rate in a subgroup analysis of four RCTs that were at least 24 months in duration. The findings of a subsequently published 10-year follow-up of a small RCT failed to demonstrate the superiority of PRP over control for clinical and radiologic outcomes. The variability in PRP preparation techniques and PRP administration limits the generalizability of the available evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals undergoing spinal fusion who receive PRP injections plus orthopedic surgery, the evidence includes a single small RCT and a few observational studies. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. Studies have generally failed to show a statistically and/or clinically significant impact on symptoms (i.e., pain). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals with subacromial decompression surgery who receive PRP injections plus orthopedic surgery, the evidence includes a small RCT. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. A single small RCT failed to show 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 that the technology results in an improvement in the net health outcome.

For individuals with total knee arthroplasty who receive PRP injections plus orthopedic surgery, the evidence includes a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. The review showed no significant differences between the PRP and untreated control groups in range of motion functional outcomes, and long-term pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Clinical Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<tr>
<td>NCT05742763</td>
<td>Platelet-Rich Plasma and the Effects of NSAIDs on Pain and Functional Scores in Knee Osteoarthritis</td>
<td>300</td>
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<td>NCT05742061</td>
<td>Intra-articular Platelet Rich Plasma vs Corticosteroid in Treatment of Knee Osteoarthritis</td>
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<td>NCT No.</td>
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<td>NCT03734900</td>
<td>Comparison of Effectiveness Between PL and PRP on Knee Osteoarthritis: a Prospective, Randomized, Placebo-controlled Trial</td>
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<td>NCT04703998</td>
<td>Arthroscopic Rotator Cuff Repair Augmented With Platelet Rich Plasma</td>
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<tr>
<td>NCT03984955</td>
<td>A Prospective, Double Blind, Single Centre, RCT, Comparing the Effectiveness of Physiotherapy in Addition to One of 3 Types of Image Guided Injection of the Common Extensor Tendon, on Pain and Function in Patients With Tennis Elbow</td>
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<td>April 2024 (recruiting)</td>
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<tr>
<td>NCT01843504</td>
<td>Platelet-Rich Plasma (PRP) Injection for the Treatment of Chronic Patellar Tendinopathy</td>
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<td>NCT01668953*</td>
<td>Impact of Platelet Rich Plasma Over Alternative Therapies in Patients With Lateral Epicondylitis (IMPROVE)</td>
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<td>Dec 2022</td>
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<td>Unpublished</td>
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<tr>
<td>NCT04697667</td>
<td>The Combination of Exercise and PRP vs Exercise Alone in Patients With Knee Osteoarthritis: A Randomized Controlled Clinical Trial</td>
<td>84</td>
<td>Feb 2022 (completed)</td>
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</table>

NCT: national clinical trial
* Denotes industry-sponsored or cosponsored trial

**Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.
American Academy of Orthopaedic Surgeons

In 2021, the American Academy of Orthopaedic Surgeons (AAOS) guidelines for the management of OA of the knee made the following recommendation:62

• “Platelet-rich plasma (PRP) may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee. (Strength of Recommendation: Limited)” The variability of study findings was noted to have contributed to the low strength of recommendation rating.

In 2017, the AAOS issued evidence-based guidelines on the management of OA of the hip.63 In the section on intra-articular injectables, the guidelines stated that there is strong evidence supporting the use of intra-articular corticosteroids to improve function and reduce pain in the short term for individuals with OA of the hip. There was also strong evidence that the use of intra-articular hyaluronic acid does not perform better than placebo in improving function, stiffness, and pain in individuals with hip OA. The guidelines also noted that there were no high-quality studies comparing PRP with placebo for the treatment of OA of the hip.

In 2019, the AAOS issued evidence-based guidelines on the management of rotator cuff injuries.64 The guideline noted the following recommendations related to the use of platelet-rich plasma in this setting:

• “There is limited evidence supporting the routine use of platelet-rich plasma for the treatment of cuff tendinopathy or partial tears (Strength of Recommendation: Limited).” The variability of study findings was noted to have contributed to the low strength of recommendation rating.

• “Strong evidence does not support biological augmentation of rotator cuff repair with platelet-derived products on improving patient reported outcomes; however, limited evidence supports the use of liquid platelet rich plasma in the context of decreasing re-tear rates (Strength of Recommendation: Strong)."

• “In the absence of reliable evidence, it is the consensus of the work group that we do not recommend the routine use of platelet rich plasma in the non-operative management of full-thickness rotator cuff tears. (Strength of Recommendation: Consensus)”
National Institute for Health and Clinical Excellence

In 2013, the NICE issued guidance on the use of autologous blood injection for tendinopathy.65 The NICE concluded that the current evidence on the safety and efficacy of autologous blood injection for tendinopathy was “inadequate” in quantity and quality.

In 2013, the NICE also issued guidance on the use of autologous blood injection (with or without techniques for producing PRP) for plantar fasciitis.66 The NICE concluded that the evidence on autologous blood injection for plantar fasciitis raises no major safety concerns but that the evidence on efficacy was “inadequate in quantity and quality.”

In 2019, the NICE issued guidance on the use of PRP for OA of the knee.67 The NICE concluded that current evidence on PRP injections for OA of the knee raised “no major safety concerns”; however, the “evidence on efficacy is inadequate in quality”. Therefore, NICE recommended that "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Blood products such as PRP are included in these regulations. Under these regulations, certain products (including blood products such as PRP) are exempt and therefore do not follow the traditional FDA regulatory pathway. To date, the FDA has not attempted to regulate activated PRP.

A number of PRP preparation systems are available, many of which were cleared for marketing by FDA through the 510(k) process for producing platelet-rich preparations intended to be mixed with bone graft materials to enhance bone grafting properties in orthopedic practices. The use of PRP outside of this setting (e.g., an office injection) would be considered off-label. The Aurix System® (previously called AutoloGel™, Nuo Therapeutics) and SafeBlood® (SafeBlood Technologies) are two related but distinct autologous blood-derived preparations that can be prepared at the bedside for immediate application. Both AutoloGel™ and
SafeBlood® have been specifically marketed for wound healing. Other devices may be used during surgery (e.g., autoLog® Autotransfusion system [Medtronic], the Smart PreP® [Harvest Technologies] device). The Magellan® Autologous Platelet Separator System (Isto Biologics) includes a disposables kit designed for use with the Magellan™ Autologous Platelet Separator portable tabletop centrifuge. GPS® II (BioMet Biologics), a gravitational platelet separation system, was cleared for marketing by FDA through the 510(k) process for use as disposable separation tube for centrifugation and a dual cannula tip to mix the platelets and thrombin at the surgical site (GPS® III [Zimmer Biomet] is now available). Filtration or plasmapheresis may also be used to produce platelet-rich concentrates. The use of different devices and procedures can lead to variable concentrations of activated platelets and associated proteins, increasing variability between studies of clinical efficacy.

References


### History

<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>07/14/15</td>
<td>New Policy. Policy created based on the orthopedic applications of platelet-rich plasma (PRP) that were previously described in Policy No. 2.01.16. PRP is considered investigational for treating orthopedic/musculoskeletal conditions detailed in this policy.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy updated with literature review through February 19, 2016; references 8-9, 14, 16-18, 20, and 27-29 added. Policy statement unchanged.</td>
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<tr>
<td>01/15/19</td>
<td>Minor update, removed 12.04.93 from Related Policies as it was archived.</td>
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<tr>
<td>07/01/21</td>
<td>Annual Review, approved June 1, 2021. Policy updated with literature review through March 5, 2021; references added. Policy statements unchanged.</td>
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<tr>
<td>07/01/23</td>
<td>Annual Review, approved June 12, 2023. Policy updated with literature review through March 1, 2023; references added. Policy statements unchanged. Changed the wording from “patient” to “individual” throughout the policy for standardization.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
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