Orthopedic Applications of Platelet-Rich Plasma

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 providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Indication</th>
<th>Investigational</th>
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</thead>
<tbody>
<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>
</tr>
<tr>
<td></td>
<td>o Achilles tendinopathy</td>
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<td></td>
<td>o Lateral epicondylitis</td>
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<td></td>
<td>o Osteochondral lesions</td>
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<td></td>
<td>o Osteoarthritis</td>
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<td></td>
<td>o Plantar fasciitis</td>
</tr>
<tr>
<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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<tr>
<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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<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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<td></td>
<td>o Total knee arthroplasty</td>
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</tbody>
</table>

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>P9020</td>
<td>Platelet rich plasma, each unit</td>
</tr>
</tbody>
</table>

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Related Information

N/A

Evidence Review

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 PDGF, transforming growth factors that function as a mitogen for fibroblasts, smooth muscle cells, osteoblasts, and vascular endothelial growth factors. Recombinant PDGF has also been extensively investigated for clinical use in wound healing (see Related Policies).

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 a variety of 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 (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 Hemaseel® (Haemacure Corp) 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. 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 (ie, pain) or functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

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 3 small RCTs, multiple prospective observational studies, and a systematic review. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life and treatment-related morbidity. The systematic review, which identified 3 RCTs on PRP for plantar fasciitis, did not pool study findings. Results among the 3 RCTs were inconsistent. The largest RCT showed that treatment with PRP with corticosteroid injection resulted in statistically significant but temporary improvements in American
Orthopaedic Foot and Ankle Society Ankle-Hindfoot 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. Therefore, this treatment is considered investigational for these conditions.

**Primary Treatment for Osteochondral Lesions**

For individuals with osteochondral lesions who receive PRP injections, the evidence includes an open-labeled quasi-randomized study. 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 the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

**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. Relevant outcomes are symptoms, functional outcomes, health status measures, 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 3 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 2 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 to placebo and with alternatives other than hyaluronic acid are needed to determine the efficacy of PRP for knee and hip osteoarthritis. Further 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. Therefore, this treatment is considered investigational for these conditions.
Adjunct to Surgery

For individuals with anterior cruciate ligament reconstruction who receive PRP injections plus orthopedic surgery, the evidence includes 2 systematic reviews of multiple RCTs and prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. Only 1 of the 2 systematic reviews conducted a meta-analysis; it showed that 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. Individual trials have shown mixed results. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

For individuals with hip fracture who receive PRP injections, the evidence includes an open-labeled RCT. 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 the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

For individuals with long bone nonunion who receive PRP injections plus orthopedic surgery, the evidence includes 3 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 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 (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 patients receiving PRP injections compared with no treatment. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

For individuals with rotator cuff repair who receive PRP injections plus orthopedic surgery, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are symptoms,
functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. The systematic reviews and meta-analyses failed to show 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. Therefore, this treatment is considered investigational for these conditions.

For individuals with spinal infusion who receive PRP injections plus orthopedic surgery, the evidence includes 2 controlled prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. The 2 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. Therefore, this treatment is considered investigational for these conditions.

For individuals with subacromial decompression surgery who receive PRP injections plus orthopedic surgery, the evidence includes a small RCT. 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 the effects of the technology on health outcomes. Therefore, this treatment is considered investigational for these conditions.

For individuals with total knee arthroplasty who receive PRP injections plus orthopedic surgery, the evidence includes a small RCT. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid 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. Therefore, this treatment is considered investigational for these conditions.

Ongoing and Unpublished Clinical Trials

Some currently 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>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
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<tr>
<td>NCT02116946</td>
<td>Plasma Injections Plus Exercise for Patellar Tendinopathy</td>
<td>120</td>
<td>Dec 2017 (ongoing)</td>
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<tr>
<td>NCT01843504</td>
<td>Platelet-Rich Plasma (PRP) Injection for the Treatment of Chronic Patellar Tendinopathy</td>
<td>44</td>
<td>Mar 2018 (ongoing)</td>
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<tr>
<td>NCT03138317</td>
<td>Evaluation of Platelet Rich Plasma (PRP) for Knee Osteoarthritis</td>
<td>60</td>
<td>May 2018</td>
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<tr>
<td>NCT01668953a</td>
<td>Impact of Platelet Rich Plasma Over Alternative Therapies in Patients With Lateral Epicondylitis (IMPROVE)</td>
<td>100</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>NCT01923909</td>
<td>Intraarticular Platelet-rich Plasma Injections Versus Intraarticular Corticosteroid Injections in Primary Knee Osteoarthritis</td>
<td>100</td>
<td>Dec 2017 (ongoing)</td>
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<tr>
<td>NCT01945528</td>
<td>Platelet Rich Plasma (PRP) in Chronic Epicondylitis</td>
<td>86</td>
<td>Jun 2018</td>
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<tr>
<td>NCT02920177</td>
<td>Platelet-rich Plasma Versus Corticosteroid Injection for the Treatment of Femoroacetabular Impingement</td>
<td>40</td>
<td>Jul 2018</td>
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<tr>
<td>NCT02694146</td>
<td>Clinical Trial to Evaluate the Use of Platelet Rich Plasma in Front Hyaluronic Acid in Coxarthrosis</td>
<td>74</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>NCT03129971</td>
<td>Platelet-Rich Plasma Combined with Conventional Surgery in the Treatment of Atrophic Nonunion of Femoral Shaft Fractures</td>
<td>92</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT01833598</td>
<td>Percutaneous Needle Tenotomy (PNT) Versus Platelet Rich Plasma (PRP) with PNT in the Treatment of Chronic Tendinosis</td>
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<tr>
<td>NCT02984228</td>
<td>Platelet-rich Plasma vs. Hyaluronic Acid for Glenohumeral Osteoarthritis</td>
<td>70</td>
<td>Aug 2019</td>
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<tr>
<td>NCT02923700</td>
<td>Leukocyte-rich PRP vs Leukocyte-poor PRP for the Treatment of Knee Cartilage Degeneration: a Randomized Controlled Trial</td>
<td>192</td>
<td>Dec 2020</td>
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<tr>
<td>NCT03133416</td>
<td>Platelet-Rich Plasma Injections and Physiotherapy in the Treatment of Chronic Rotator Cuff Tendinopathy</td>
<td>165</td>
<td>Dec 2020</td>
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<tr>
<td>NCT01406821</td>
<td>Treatment of Acute and Chronic Ligament and Tendon Injuries with Platelet Rich Plasma</td>
<td>100</td>
<td>Dec 2020</td>
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<tr>
<td>NCT02872753</td>
<td>Intra-operative PRP Injection Following Partial Meniscectomy</td>
<td>90</td>
<td>Mar 2021</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
<td>NCT03300531</td>
<td>Impact of Autologous Pure Platelet-Rich Plasma in the Treatment of Tendon Disease</td>
<td>540</td>
<td>Dec 2021</td>
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<tr>
<td>NCT03136965</td>
<td>Platelet-Rich Plasma Therapy for Patellar Tendinopathy (PRP)</td>
<td>66</td>
<td>Aug 2022</td>
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**Unpublished**

<table>
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<td>NCT01915979</td>
<td>Effect of Plasma Rich in Growth Factors in Rotator Cuff Tendinopathy</td>
<td>84</td>
<td>May 2015 (unknown)</td>
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<td>NCT02325063</td>
<td>Evaluation of Three Types of Injection for the Treatment of Lateral Epicondylalgia (LET)</td>
<td>13</td>
<td>May 2017 (terminated)</td>
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<tr>
<td>NCT02669303</td>
<td>Platelet-rich Plasma (PRP) Injection for Treating Shoulder Subacromial Impingement Syndrome (ShIP)</td>
<td>19</td>
<td>Jan 2017 (terminated)</td>
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<tr>
<td>NCT02978833</td>
<td>Platelet-rich Plasma vs. Whole Blood for Gluteus Medius Tendinopathy</td>
<td>2</td>
<td>Jun 2017 (terminated)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial

**Practice Guidelines and Position Statements**

*American Academy of Orthopaedic Surgeons (AAOS)*

The AAOS 2013 guidelines did not recommend for or against growth factor injections and/or PRP for patients with symptomatic osteoarthritis of the knee.\(^4^6\) A recommendation of inconclusive is based on a single low-quality study and conflicting findings. The AAOS recommendation is based on 3 studies that were published before May 2012.

AAOS issued evidence-based guidelines (2017) on the management of OA of the hip.\(^4^7\) 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 patients 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 patients 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.
National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) issued guidance (2013) on the use of autologous blood injection for tendinopathy.\(^{48}\) NICE concluded that the current evidence on the safety and efficacy of autologous blood injection for tendinopathy was “inadequate” in quantity and quality.

NICE also issued guidance (2013) on the use of autologous blood injection (with or without techniques for producing PRP) for plantar fasciitis.\(^{49}\) 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.

NICE issued guidance (2014) on the use of PRP for osteoarthritis (OA) of the knee.\(^{50}\) NICE concluded that current evidence on PRP injections for osteoarthritis of the knee raised “no major safety concerns”; however, the evidence on efficacy is inadequate in quality.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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 platelet-rich plasma (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 (eg, an office injection) would be considered off-label. The Aurix System™ (previously called AutoloGel™, Cytomedix) 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 (eg, Medtronic Electromedics, Elmd-500 Autotransfusion system, the Plasma Saver device, the Smart PreP® [Harvest Technologies] device). The Magellan™ Autologous Platelet Separator System (Medtronic Sofamor Danek) 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. 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


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<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>
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<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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</table>

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Email AppealsDepartmentinquines@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Illoko (Ilocano):
Daytoy a pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalim nga adda ket naglaon iti napateg nga impormasion maiyaggepp iti aplikasyono woy coverag babaen iti Premera Blue Cross. Daytoy ket mabalim dagiti importante a petsa iti daytoy a pakdaar. Mabalim nga adda rumbeng nga aramidensyo nga addang sabbay dagiti partikular a naitading nga aldaw tapno maplagataydeo ti coverag ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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