**Title:** Orthopedic Applications of Platelet-Rich Plasma

**Interventions**
- Platelet-rich plasma injections

**Comparators**
- Nonpharmacologic therapy (eg, exercise, physical therapy)
- Analgesics
- Anti-inflammatory agents

**Outcomes**
- Symptoms
- Functional outcomes
- Health status measures
- Quality of life
- Treatment-related morbidity

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| Individuals:  
  - With non–tendon soft tissue injury or inflammation (eg, plantar fasciitis)  
    - Platelet-rich plasma injections |  |  |  |
| Individuals:  
  - With osteochondral lesions  
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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.

OBJECTIVE
The objective of this policy is to assess whether use of platelet-rich plasma in patients with musculoskeletal conditions and those undergoing orthopedic surgical procedures improve net health outcomes.

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.

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 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. 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 for many years 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® 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.

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, FDA has not attempted to regulate activated PRP.

There are numerous PRP preparation systems on the market today with FDA clearance. Many of these systems have 510(k) clearance for producing platelet-rich preparations intended to be used to mix with bone graft materials to enhance bone grafting properties in orthopedic practices. The Aurix System™ (previously called AutoloGel™ from 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 in the operating room setting, such as Medtronic Electromedics, Elmd-500 Autotransfusion system, the Plasma Saver device, or the Smart PreP device. The Magellan Autologous Platelet Separator System (Medtronic) 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 a 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 active platelets and associated proteins, increasing variability between studies of clinical efficacy.
POLICY

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

A. Primary use (injection) for the following conditions:
   1) Achilles tendinopathy
   2) Lateral epicondylitis
   3) Osteochondral lesions
   4) Osteoarthritis
   5) Plantar fasciitis

B. Adjunctive use in the following surgical procedures:
   1) Anterior cruciate ligament reconstruction
   2) Hip fracture
   3) Long-bone nonunion
   4) Patellar tendon repair
   5) Rotator cuff repair
   6) Spinal fusion
   7) Subacromial decompression surgery
   8) Total knee arthroplasty

Policy Guidelines

The American Medical Association’s Department of Coding instructs that placement of platelet-rich plasma into an operative site is an inclusive component of the operative procedure performed and not separately reported.

RATIONALE

This policy was created in 2015 with literature review of the MEDLINE database through February 23, 2017. Following is a summary of key references to date, focusing on systematic reviews and randomized controlled trials (RCTs).

Assessment of the efficacy for a therapeutic intervention involves a determination whether an intervention improves health outcomes compared to available alternatives. The optimal study design for this purpose is a randomized controlled trial (RCT) that compares the therapeutic intervention with existing alternative treatments and includes clinically relevant measures of health outcomes. It is recognized that RCTs are extremely important to assess treatments of pain conditions, due to the expected placebo effect and the subjective nature of pain.

The best evidence on the efficacy of platelet-rich plasma (PRP) consists of several RCTs comparing PRP with conservative therapy (eg, rest, physical therapy) and medication (eg, corticosteroid injection), and systematic reviews of these trials. A number of systematic reviews of RCTs, with or without the addition of observational studies, on PRP have been published; we focus on them in this evidence review. Individual RCTs are reviewed in some instances, eg, if no
systematic review is available or if an individual RCT is likely to influence this evidence review but
was not included in a systematic review.

At present, there are a large number of techniques available for the preparation of PRP or PRP
gel. The amount and mixture of growth factors produced by different cell-separating systems
vary, and it is also uncertain whether platelet activation before injection is necessary.1-6 Following
is a summary of key literature to date.

PRP as a Primary Treatment for Tendinopathy
Several systematic reviews have evaluated PRP for treating mixed tendinopathies. They include
trials on tendinopathies of the Achilles, rotator cuff, patella, and/or lateral epicondyle (tennis
elbow). Recent (ie, 2014 to present) systematic reviews of RCTs and/or nonrandomized studies
are described next.

In 2016, Tsikopoulos et al published a systematic review of RCTs that compared PRP to placebo
or dry needling in patients with tendinopathy lasting at least 6 weeks.7 Minimum length of follow-
up was 6 months. The primary outcome of interest was pain intensity; the secondary outcome
was functional disability. Five RCTs met reviewers' eligibility criteria. Two RCTs addressed lateral
epicondylitis, 2 rotator cuff tendinopathy, and 2 patellar tendinopathy. Three RCT studies had a
saline control group and 2 compared PRP with dry needling. In a pooled analysis of all 5 RCTs,
there was no statistically significant difference in pain intensity at 2 to 3 months between PRP
and placebo/dry needling (standardized mean difference [SMD], -0.29; 95% confidence interval
[CI], -0.60 to 0.02). The between-group difference in pain intensity was statistically significant at
6 months in a pooled analysis of 4 trials (SMD = -0.48; 95% CI, -0.86 to -0.10). While
statistically significant, reviewers noted that the difference between groups in pain intensity at 6
months was not clinically significant. Three trials reported functional disability levels at 3 months
and meta-analysis of these trials found a significantly greater improvement in function disability
in the PRP group (SMD = -0.47; 95% CI, -0.85 to -0.09). Functional disability 6 months
postintervention was not addressed.

A 2015 systematic review by Balasubramaniam et al included RCTs on PRP for tendinopathy.8 In
contrast to the Tsikopoulos (2016) review, these reviewers did not limit inclusion criteria by type
of control intervention or postintervention length of follow-up. They included 4 of the 5 RCTs in
the Tsikopoulos review and 5 other RCTs. Four RCTs evaluated epicondylitis, 2 rotator cuff
tendinopathy, 2 patellar tendinopathy, and 1 Achilles tendinopathy. Comparison interventions
included placebo (n=3), dry needling (n=2), autologous blood (n=2), extracorporeal shock wave
therapy (n=1), and corticosteroid injections (n=2). (One study included both placebo and
corticosteroid control groups.) Reviewers did not pool study findings due to a high level of
heterogeneity among studies. In their qualitative analysis of the literature by anatomic site of
tendonopathy, they concluded that 1 trial on PRP for Achilles tendinopathy was insufficient to
draw conclusions about efficacy. Findings of trials of other anatomic sites were mixed. Some
trials showed statistically significant greater benefits of PRP than controls on outcomes and some
did not, or some found statistically significant better outcomes at some time points but not
others.

In 2014, Andia et al published a systematic review on use of PRP in the treatment of painful
tendinopathies.9 They included 13 prospective controlled trials (12 RCTs, 1 controlled trial that
was not randomized) with data from 636 patients included in the meta-analysis. The trials
assessed various tendinopathies, including 7 on chronic elbow, 2 on rotator cuff, 3 on patellar, and 1 study on Achilles. Control interventions included physical therapy (1 trial), extracorporeal shock wave therapy (1 trial), corticosteroid (3 trials), autologous blood (3 trials), saline (3 trials), and dry needling (2 trials). Risk of bias was considered to be low in 4 studies, unclear in 3, and high in 6. Meta-analysis found that PRP was no better than control interventions in reducing pain at 1 or 2 month follow-up. A small significant effect in pain reduction was found at 3 months (weighted mean difference [WMD], -0.61). At 1 year, the WMD between PRP and control interventions was significant at -1.56. Due to heterogeneity between studies, these findings had low power and precision.

Section Summary: PRP as a Primary Treatment of Tendinopathy
Multiple RCTs and systematic reviews with meta-analyses have evaluated the efficacy of PRP injections in individuals who have tendinopathy. The more recently-published systematic reviews and meta-analyses that only included RCTs failed to show a statistically and/or clinically significant impact on symptoms (ie, pain) or functional outcomes.

PRP as a Primary Treatment of Non‒Tendon Soft Tissue Injury or Inflammation
In 2014, Franceschi et al published a qualitative systematic review of the literature on PRP for chronic plantar fasciitis.10 Eight prospective studies were identified, 3 of which were randomized. The 3 single-blinded RCTs (total N=90 patients) compared treatment with PRP with corticosteroids (n=60) or prolotherapy (n=30). The largest RCT (N=40) by Monto (2014) compared PRP with corticosteroid injection and had follow-up to 24 months.11 There was an apparent difference in age and baseline scores between the PRP and steroid groups. Blinded assessment using American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scores at 3, 6, 12, and 24 months showed temporary improvements in the corticosteroid group, with a return to near-baseline levels (score, 58; scoring range, 0-100, with higher scores indicating less disability) by 12 months. In the PRP group, the AOFAS score increased from 37 at baseline to 95 at 3 months and remained elevated through 24 months, with a final score of 92 (difference of 46 from controls, p=0.001). Confirmation of these results in a larger double-blind RCT would permit greater certainty on the efficacy of PRP in plantar fasciitis.

Section Summary: PRP as a Primary Treatment of Non‒Tendon Soft Tissue Injury or Inflammation
Three small RCTs and multiple prospective observational studies have evaluated the efficacy of PRP injections in individuals with chronic plantar fasciitis. The largest of the 3 RCTs showed that treatment with PRP compared to corticosteroid resulted in statistically significant but temporary improvements in AOFAS ankle-hindfoot scores, indicating improved outcomes. Statistical significance was not reported in the published article. Larger RCTs are required to confirm these findings.

PRP as a Primary Treatment of Osteochondral Lesions
No RCTs on treatment of osteochondral lesions were identified. In 2012, Mei-Dan et al reported a quasi-randomized study of 29 patients with 30 osteochondral lesions of the talus assigned to 3 intra-articular injections of hyaluronic acid or PRP.12 At 28-week follow-up, scores on the AOFAS ankle-hindfoot score improved to a greater extent in the PRP group (from 68 to 92) than in the hyaluronic acid group (from 66 to 78) (p<0.05). Subjective global function also improved to a greater extent in the PRP group (from 58 to 91) than in the hyaluronic acid group (from 56 to 73). Interpretation of the composite measures of visual analog scale (VAS) scores for pain and
function is limited by differences between the groups at baseline. In addition, neither the patients nor the evaluators was blinded to treatment in this small study.

Section Summary: PRP as a Primary Treatment of Osteochondral Lesions
A single quasi-randomized study has evaluated the efficacy of PRP injections in individuals who have osteochondral lesions. It showed that treatment with PRP compared to hyaluronic acid resulted in statistically significant improvements in AOFAS ankle-hindfoot scores and global function, indicating improved outcomes. Adequately powered and blinded RCTs are required to confirm these findings.

PRP as a Primary Treatment of Knee or Hip Osteoarthritis
A number of RCTs and several systematic reviews of RCTs evaluating use of PRP for knee osteoarthritis (OA) have been published.\textsuperscript{13-19} Protocols used in PRP interventions for knee OA varied widely. For example, in the studies identified in the Laudy et al (2015) systematic review, PRP was prepared using single, double, or triple spinning techniques and interventions included between 1 and 3 injections delivered 1 to 3 weeks apart.\textsuperscript{13}

Chang et al (2014) published a systematic review that included 5 RCTs, 3 quasi-randomized controlled studies, and 8 single-arm prospective series (total N=1543 patients) that compared PRP with hyaluronic acid (4 RCTs, 2 quasi-randomized) or saline placebo (1 RCT) for knee OA.\textsuperscript{14} Meta-analysis of functional outcomes found that the effectiveness of PRP was greater than that of hyaluronic acid and improved over 12 months. Fewer than 3 injections, single spinning, and lack of additional activators led to greater uncertainty in the treatment effects. PRP also had lower efficacy in patients with higher degrees of cartilage degeneration. Results were consistent when analyzing only RCTs, but asymmetry in funnel plots suggested significant publication bias.

The systematic review by Chang (2014) identified only 1 placebo-controlled trial, Patel et al (2013).\textsuperscript{20} This RCT included 78 patients with bilateral knee OA. Patients were randomized to a single injection of PRP, 2 injections of PRP, or a single saline placebo injection. There was statistically significant greater improvement in the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores at 1, 3 and 6 months in the active treatment groups combined compared with the placebo group (p<0.01) as well as in VAS scores (p<0.01). The WOMAC scores in the PRP arm decreased by approximately 50\% of their baseline values at 6 months (from 50 to 27 in group that received 1 PRP injection, from 53 to 31 in group that received 2 PRP injections). For WOMAC scores at baseline in this intermediate range (<51.4) and high range (>51.5), the minimal clinically important difference (MCID) is in the range of 10 to 19 point reduction.\textsuperscript{21} For WOMAC scores at baseline in this intermediate range, the MCID is in the range of 12- to 17-point reduction.\textsuperscript{21} Briefly, the WOMAC consists of 24 total items divided among 3 subscales (pain, stiffness, physical function). However, no responder analysis was reported. The difference in WOMAC scores between patients who received 1 or 2 PRP injections did not differ significantly. Multiple limitations of this trial were recognized. While powered to detect a difference of 1.5 points in VAS scores, the primary end point was deemed to be WOMAC scores. More importantly methods to control for type I error for multiple comparisons were not described and possibly not used. Further, the process of randomization and randomized allocation was not described. Lastly, though the trial was described as double-blind, the number of injections between the active arm receiving 2 PRP injections differed from that for placebo and that for PRP patients who received only 1 injection; as such, maintenance of blinding through the trial period is questionable.
A double-blind, placebo-controlled trial in patients with knee osteoarthritis published after the aforementioned systematic review, by Smith et al (2016), showed that treatment with PRP resulted in statistically and clinically significant improvements in WOMAC scores compared to placebo, beginning at week 2 (p=0.016) and continuing through the trial duration at 1 year.22 A similar trend was seen in all 3 domains of the WOMAC (pain, stiffness, physical function). Overall WOMAC mean scores in the PRP- and placebo-treated arms at baseline were 47 and 46, respectively. Post-1 year, the respective overall mean scores were 10 and 43 (p<0.05). Patients answered the questions and then received a cumulative score for each of the 3 areas (pain, 0-20; stiffness, 0-8; physical function, 0-68). Higher scores represent greater pain and stiffness as well as worsened physical capability.

Dallari et al (2016) reported results of an RCT that compared PRP with hyaluronic acid alone or combination PRP plus hyaluronic acid in 111 patients with hip OA.23 Although this well-conducted RCT reported positive results, with statistically significant reductions in VAS scores (lower scores imply less pain) at 6 months in the PRP arm versus the hyaluronic acid arm or the PRP plus hyaluronic acid arm (21; [95% CI, 15 to 28] vs 35 [95% CI, 26 to 45] and 44 [95% CI, 36 to 52], respectively), the impact of treatment on other secondary outcome measures such as Harris Hip Score and WOMAC scores was not observed. Notably, there was no control for type I error for multiple group comparisons at different time points and the trial design did not incorporate a sham-control arm.

Section Summary: PRP as a Primary Treatment of Knee or Hip Osteoarthritis
Multiple RCTs and systematic reviews with meta-analysis have evaluated the efficacy of PRP injections in individuals with knee or hip OA. Two RCTs have compared PRP with placebo while other trials have compared PRP with hyaluronic acid for knee OA. A single RCT has compared PRP with hyaluronic acid alone or combination PRP plus hyaluronic acid in hip OA. Compared to placebo, PRP resulted in statistically significant and clinically meaningful improvements in overall WOMAC scores up to 1 year posttreatment in knee OA. It is difficult to interpret the relative efficacy of PRP over hyaluronic acid because the overall efficacy of hyaluronic acid relative to placebo is limited in knee OA. The single RCT in hip OA reported positive results, with statistically significant reductions in VAS scores, the impact of treatment on other secondary outcome measures such as Harris Hip Score and WOMAC scores was not observed. Additional studies comparing PRP to placebo and alternatives other than hyaluronic acid are needed to determine the efficacy of PRP for knee and hip OA. Further studies are also needed to determine the optimal protocol for delivering PRP.

PRP as an Adjunct to Surgery
Anterior Cruciate Ligament Reconstruction
A 2013 Cochrane review of platelet-rich therapies for musculoskeletal soft tissue injuries identified 2 RCTS and 2 quasi-randomized studies (total N=203 patients) specifically on PRP used in conjunction with anterior cruciate ligament (ACL) reconstruction.24 Pooled data found no significant difference in International Knee Documentation Committee (IKDC) scores between the PRP and control groups. The IKDC is a patient-reported, knee-specific outcome measure that measures pain and functional activity. A 2015 qualitative systematic review by Figueroa et al included 11 RCTs or prospective cohort studies (total N=516 patients).25 Four studies found significantly faster graft maturation while 3 found no significant difference. One study showed faster tunnel healing while 5 showed no benefit. One study showed better clinical outcomes while 5 showed no improvement in clinical outcomes when using PRP. The largest RCT is that by Nin et
al (2009), who randomized 100 patients to arthroscopic ACL reconstruction with or without PRP. The use of PRP on the graft and inside the tibial tunnel in patients treated with bone–patellar tendon–bone allografts had no discernable clinical or biomechanical effect at 2-year follow-up.

**Subsection Summary: PRP as Adjunctive Treatment of Anterior Cruciate Ligament Reconstruction**

Two systematic reviews that included multiple RCTs, quasi-randomized studies, and prospective studies have evaluated the efficacy of PRP injections in individuals undergoing ACL reconstruction. Only 1 of the 2 systematic reviews conducted a meta-analysis; it showed that adjunctive PRP treatment did not result in a significant effect on IKDC score. Individual studies have shown mixed results.

**Hip Fracture**

One RCT was identified for treatment of hip fracture. In 2013, Griffin et al reported on a single-blind randomized trial assessing use of PRP for the treatment of hip fractures in patients aged 65 years and older. Two hundred patients underwent internal fixation of a hip fracture with cannulated screws and were randomized to standard-of-care fixation or standard-of-care fixation with injection of PRP into the fracture site. The primary outcome measure was the failure of fixation within 12 months, defined as any revision surgery. The overall risk of revision by 12 months was 36.88% and the risk of death was 21.5%. There was no significant risk reduction (39.74% control vs 34.15% PRP) or significant difference between groups for most of the secondary outcome measures. For example, mortality was 23% in the control group and 20% in the PRP group. The length of stay was significantly reduced in the PRP-treated group (median difference, 8 days). For this measure, there is a potential for bias from the nonblinded treating physician.

**Subsection Summary: PRP as Adjunctive Treatment for Hip Fracture**

A single open-labeled RCT has evaluated the efficacy of PRP injections in individuals with hip fracture. This trial failed to show any statistical significant reductions in the need for revision surgery with the addition of PRP treatment.

**Long Bone Nonunion**

A 2012 Cochrane review found only 1 small (N=21) RCT evaluating PRP for long bone healing. However, because only studies comparing PRP with no additional treatment or placebo were eligible for inclusion, reviewers did not select a larger RCT by Calori et al (2008) (discussed below). The trial study by Dallari et al (2007), which was included in the systematic review, compared PRP plus allogenic bone graft with allogenic bone graft alone in patients undergoing corrective osteotomy for medial compartment osteoarthrosis of the knee. According to the Cochrane reviewers, the risk of bias in this study was substantial. Results showed no significant differences in patient-reported or clinician-assessed functional outcome scores between groups at 1 year. However, the proportion of bones united at 1 year was statistically significantly higher in the PRP plus allogenic bone graft arm (8/9) compared to the allogenic bone graft alone arm (3/9; RR=2.67; 95% CI, 1.03 to 6.91). This benefit, however, was not statistically significant when assuming poor outcomes for participants who were lost to follow-up (8/11 vs 3/10; RR=2.42; 95% CI, 0.88 to 6.68).
Calori et al (2008) compared application of PRP or recombinant human bone morphogenetic protein-7 (rhBMP-7) for the treatment of long bone nonunions in an RCT involving 120 patients and 10 surgeons. Inclusion criteria were posttraumatic atrophic nonunion for at least 9 months, with no signs of healing over the last 3 months, and considered as treatable only by means of fixation revision. Autologous bone graft had been used in a prior surgery in 23 cases in the rhBMP-7 group and in 21 cases in the PRP group. Computer-generated randomization created 2 homogeneous groups; there were generally similar numbers of tibial, femoral, humeral, ulnar, and radial nonunions in the 2 groups. Following randomization, patients underwent surgery for nonunion, including bone grafts according to the surgeon’s choice (66.6% of rhBMP-7 patients, 80% of PRP patients). Clinical and radiologic evaluations by 1 radiologist and 2 surgeons trained in the study protocol revealed fewer unions in the PRP group (68%) than in the rhBMP-7 group (87%). Clinical and radiographic healing times were also found to be slower by 13% to 14% with PRP.

**Subsection Summary: PRP as Adjunctive Treatment for Long Bone Nonunion**

Two RCTs have evaluated the efficacy of PRP injections in individuals with long bone nonunion. One trial with substantial risk of bias failed to show significant differences in patient-reported or clinician-assessed functional outcome scores between patients who received PRP plus allogenic bone graft versus those who received only allogenic bone graft. While the trial showed statistically significant increases in the proportion of bones that healed in patients receiving PRP in a modified ITT, the results did not differ in the ITT analysis. The second RCT, which compared PRP with rhBMP-7, also failed to show any clinical and radiologic benefits of PRP over rhBMP-7.

**Rotator Cuff Repair**

The literature on PRP for rotator cuff repair consists of RCTs that have evaluated the efficacy of PRP membrane or matrix combined with surgical repair of the rotator cuff. In addition, several systematic reviews of the literature, which pooled analysis of data, generally did not show a statistically or clinically significant benefit of PRP.

Fu et al (2016) reported on the results of a meta-analysis that only included RCTs comparing the efficacy of PRP with platelet-rich fibrin matrix for improving healing of rotator cuff injuries. A total of 11 RCTs were included; they enrolled 320 patients with active treatment and 318 patients as controls. The primary outcome of functional score change from pre- to posttreatment was similar between patients administered PRP plus fibrin matrix and patients in the control group (standard difference in means for functional scores, 0.029; 95% CI, -0.132 to 0.190; p=0.725). The SMD was similar between patients administered PRP and the controls (SMD=0.142; 95% CI, -0.080 to 0.364; p=0.209). Authors concluded that the results of this meta-analysis did not support the use of PRP plus platelet-rich fibrin matrix in patients with rotator cuff injuries.

In 2016, Saltzman et al published a systematic review of meta-analyses on PRP at the time of surgery and clinical outcomes for patients undergoing rotator cuff repair. Reviewers identified 7 meta-analyses, all published after 2012, that performed pooled analyses of trial data. Systematic reviews varied in their outcomes of interest, but all pooled data on the overall retear rate and none found a statistically significant difference in the retear rate among patients who received PRP compared to a control intervention; the relative risks ranged from 0.55 to 0.94 and the odds ratio reported in 1 study was 1.11. However, one of the meta-analyses included in the Saltzman review found a significantly lower risk of retear with PRP use when an outlier study was excluded from the analysis.
A 2013 Cochrane review, which pooled data for long-term function from 6 RCTs of PRP applied with rotator cuff repair, showed no statistically or clinically significant differences between the PRP groups and control groups. Moreover, a 2015 meta-analysis included 8 RCTs with sample sizes ranging from 28 to 88 (total N=464 patients). Meta-analysis showed no significant differences between the PRP groups and control groups in retear rate (RR=0.94; 95% CI, 0.70 to 1.25; p=0.66), Constant score (mean difference, 1.12; 95% CI, -1.38 to 3.61; p=0.38), or University of California at Los Angeles (UCLA) Shoulder Score (mean difference, -0.68; 95% CI, -2.00 to 0.65; p=0.32). The strength of the evidence based on GRADE was considered to be low for retear, moderate for Constant score, and low for UCLA Shoulder Score.

**Subsection Summary: PRP as Adjunctive Treatment for Rotator Cuff Repair**

Multiple RCTs and systematic reviews with meta-analyses have evaluated the efficacy of PRP injections in individuals undergoing rotator cuff repair. The systematic reviews and meta-analyses failed to show a statistically and/or clinically significant impact on symptoms (ie, pain) or functional outcomes.

**Spinal Fusion**

No RCTs on use of PRP for spinal fusion were identified. Two prospective observational studies found no differences in fusion rates with use of a platelet gel or platelet glue compared to a historical control.

**Subacromial Decompression Surgery**

One small RCT used PRP as an adjunct to subacromial decompression surgery. Everts et al (2008) reported on a rigorously conducted, small (N=40) double-blinded RCT of platelet and leukocyte-rich plasma (PLRP) gel following open subacromial decompression surgery in a carefully selected patient population. Neither self-assessed nor physician-assessed instability improved. Both subjective pain and use of pain medication were lower in the PLRP group across the 6 weeks of measurements. For example, at 2 weeks after surgery, VAS scores for pain were lower by about 50% in the PLRP group (close to 4 in the control group, close to 2 in the PLRP group), and only 1 (5%) patient in the PLRP group was taking pain medication compared with 10 (50%) control patients. Objective measures of range of motion showed clinically significant improvements in the PLRP group across the 6-week assessment period, with patients reporting improvements in activities of daily living, such as ability to sleep on the operated shoulder at 4 weeks after surgery and earlier return to work.

**Subsection Summary: PRP as Adjunctive Treatment for Subacromial Decompression Surgery**

A single small RCT has evaluated the efficacy of PRP injections in individuals undergoing subacromial decompression surgery. Compared to controls, PRP treatment did not improve self-assessed or physician-assessed instability. However, subjective pain, use of pain medication, and objective measures of range of motion showed clinically significant improvements with PRP. Larger RCTs are required to confirm these benefits.

**Total Knee Arthroplasty**

Morishita et al (2014) reported on the results of an RCT of 40 patients, scheduled for unilateral total knee arthroplasty, were randomized to intraoperative PRP (n=20) or no additional intraoperative treatment (n=20). There were no significant differences between the PRP and untreated control groups in bleeding, range of motion, swelling around the knee joint, muscle power recovery, pain, Knee Society Scores, or Knee Injury and Osteoarthritis Outcome Score.
Subsection Summary: PRP as Adjunctive Treatment for Total Knee Arthroplasty
A single small RCT has evaluated the efficacy of PRP injections in individuals undergoing total knee arthroplasty. There were no significant differences between the PRP and untreated control groups across several functional and pain outcomes.

SUMMARY OF EVIDENCE
Primary Treatment for Tendinopathies
For individuals with tendinopathy who receive platelet-rich plasma (PRP) injections, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews with meta-analyses. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Findings from meta-analyses of RCTs were mixed and 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 3 small RCTs, multiple prospective observational studies, and 1 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. The largest of the 3 RCTs showed that treatment with PRP compared to 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 is 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. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The quasi-randomized study found a statistically significant greater impact on outcomes in the PRP group than in the group receiving hyaluronic acid. 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 osteoarthritis who receive PRP injections, the evidence includes multiple RCTs and systematic reviews with meta-analyses. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Two RCTs have compared PRP with placebo while other trials have compared PRP with hyaluronic acid for knee OA. A single RCT has compared PRP with hyaluronic acid alone or combination PRP plus hyaluronic acid in hip OA. Compared to placebo, PRP resulted in statistically significant and clinically meaningful improvements in overall Western Ontario and McMaster Universities Arthritis Index scores up to 1 year posttreatment in knee OA. However, it is difficult to interpret the relative efficacy of PRP over hyaluronic acid because the overall efficacy of hyaluronic acid relative to placebo is limited. The single RCT in hip osteoarthritis
reported positive results, with statistically significant reductions in VAS scores, the impact of treatment on other secondary outcome measures such as Harris Hip Score and WOMAC scores was not observed. Additional studies comparing PRP to placebo and to 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.

Adjunct to Surgery
For individuals with anterior cruciate ligament reconstruction who receive PRP injections, 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 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, the evidence includes 1 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.

For individuals with long bone nonunion who receive PRP injections, the evidence includes 2 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 (ITT), the results were not different in the ITT 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 evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with rotator cuff repair who receive PRP injections, the evidence includes multiple RCTs and systematic reviews with meta-analyses. 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.

For individuals with spinal infusion who receive PRP injections, 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.

For individuals with subacromial decompression surgery who receive PRP injections, the evidence includes 1 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 reduced self-assessed or physician-assessed spinal instability 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, the evidence includes 1 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 terms of 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.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Orthopaedic Surgeons
The 2013 American Academy of Orthopaedic Surgeons (AAOS) guidelines were unable to recommend for or against growth factor injections and/or platelet-rich plasma (PRP) for patients with symptomatic osteoarthritis of the knee.39 A recommendation of inconclusive was based on a single low-quality study and conflicting findings that did not permit a recommendation for or against the intervention. The AAOS recommendation as based on 3 studies published before May 2012.

National Institute for Health and Care Excellence
In 2013, the U.K.’s National Institute for Health and Care Excellence (NICE) issued guidance on use of autologous blood injection for tendinopathy.40 NICE concluded that the current evidence on the safety and efficacy of autologous blood injection for tendinopathy is “inadequate” in quantity and quality. NICE recommended “this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”

In 2013, NICE also issued guidance on use of autologous blood injection (with or without techniques for producing PRP) for plantar fasciitis.41 NICE concluded that the evidence on autologous blood injection for plantar fasciitis raised no major safety concerns but that the evidence on efficacy was “inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.” In addition, physicians should ensure that patients “understand the uncertainty about the procedure’s efficacy, [be] aware of alternative treatments” and be provided “with clear written information.”

In 2014, NICE issued guidance on use of PRP for osteoarthritis of the knee.42 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. Therefore, this procedure
should only be used with special arrangements for clinical governance, consent, and audit or research.” In addition, physicians should ensure that patients “understand the uncertainty about the procedure’s efficacy and provide them with clear written information.”

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<th>NCT No.</th>
<th>Trial Name</th>
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<td>NCT01668953a</td>
<td>Impact of Platelet Rich Plasma Over Alternative Therapies in Patients With Lateral Epicondylitis (IMPROVE)</td>
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<td>NCT02669303</td>
<td>Platelet-rich Plasma (PRP) Injection for Treating Shoulder Subacromial Impingement Syndrome (ShIP)</td>
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<td>NCT02325063</td>
<td>Evaluation of Three Types of Injection for the Treatment of Lateral Epicondylalgia (LET)</td>
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<td>NCT02694146</td>
<td>Clinical Trial to Evaluate the Use of Platelet Rich Plasma in Front Hyaluronic Acid in Coxarthrosis</td>
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<td>Intraarticular Platelet-rich Plasma Injections Versus Intraarticular Corticosteroid Injections in Primary Knee Osteoarthritis</td>
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<td>NCT02920177</td>
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<td>Effect of Plasma Rich in Growth Factors in Rotator Cuff Tendinopathy</td>
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<td>NCT02978833</td>
<td>Platelet-rich Plasma vs. Whole Blood for Gluteus Medius Tendinopathy</td>
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<td>NCT02872753</td>
<td>Intra-operative PRP Injection Following Partial Meniscectomy</td>
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<td>NCT02923700</td>
<td>Leukocyte-rich PRP vs Leukocyte-poor PRP for the Treatment of Knee Cartilage Degeneration: a Randomized Controlled Trial</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

CPT/HCPCS

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<td>86999</td>
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<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
</tr>
<tr>
<td>P9020</td>
<td>Platelet rich plasma, each unit</td>
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In July 2010, a new CPT category III code for injections of platelet-rich plasma became effective: 0232T. The instructions with the code state that it is not to be reported with codes 20550, 20551, 20600-20610, 20926, 76942, 77002, 77012, 77021, and 86955. Code 0232T includes the harvesting and preparation of the platelet-rich plasma.

For situations other than injection (when 0232T would be reported), no specific CPT codes describe the preparation of autologous blood-derived products but CPT code 86999 (unlisted transfusion medicine procedure) can be used.

Diagnoses
Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

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REFERENCES


Other References
1. Blue Cross and Blue Shield of Kansas Orthopedic Liaison Committee, June 2016.