Platelet Rich Plasma (PRP)

Policy Number: 2015M0078A  Effective Date: May 1, 2015

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
MEDICAL POLICY

POLICY DESCRIPTION:

This policy describes the use of platelet rich plasma (PRP), also referred to as platelet concentrate or platelet gel, prepared from blood collected by venipuncture and then separated from the red blood cells by centrifugation. Such a preparation contains a higher concentration of growth factors, and it is hypothesized this quality may promote faster healing. Platelet rich plasma has been used for a variety of indications, including healing chronic wounds and spinal, maxillofacial, cosmetic, and orthopedic surgeries.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Treatment with Platelet Rich Plasma (PRP) is considered EXPERIMENTAL AND/OR INVESTIGATIONAL and is not a Covered Health Service for any other condition including, but not limited to, the following:

- Epicondylitis (e.g., lateral epicondylitis, elbow tendinopathy, or tennis elbow),
- Chronic wounds,
- Bone healing and spinal fusion,
- Tendonitis,
- Anterior cruciate ligament injuries,
- Rotator cuff repair,
- Shoulder surgery,
- Bone fusion after ankle surgery, due to lack of clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature.

Clinical Considerations:

There is insufficient evidence to establish definitive patient selection criteria for treatment of lateral epicondylitis injuries with PRP.

Researchers (Everts et al., 2006b; Vogrin et al., 2010b) have emphasized that candidates for application of PRP should undergo a hematological evaluation for blood disorders or platelet dysfunction. The following conditions are considered relative contraindications for the application of PRP:

- Platelet count < 105 per microliter; hemoglobin level < 10 grams per deciliter,
- Presence of a tumor in the wound bed,
- Metastatic disease,
- Active infections,
- Platelet dysfunction or other blood disorder.
BACKGROUND:

Platelets are small cells in the blood that release a variety of substances called growth factors which help the body repair itself. It is speculated that a concentrated preparation of platelets known as platelet-rich plasma (PRP) with its increased numbers of growth factors may promote faster healing. Such preparations have been investigated for a number of indications including wound healing and orthopedic surgery.

If harvested from a patient’s own blood, PRP, also called “buffy coat”, is termed autologous platelet concentrate (APC) or autologous platelet gel (APG). It is prepared from blood collected by a single, uninterrupted venipuncture with minimal manipulation and damage to the donor's tissue. The plasma is separated from the red blood cells by centrifugation. The resultant PRP is injected or implanted into wounds during surgery with the goal of accelerating healing of the damaged area.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

   Injection of PRP is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

   SubChapter F-Biologics, Part 640 – Additional Standards for Human Blood and Blood Products, Subpart D – Plasma Sec. 640.34 Processing, provides the following information regarding PRP: d) Platelet Rich Plasma. Platelet rich plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after completion of the phlebotomy or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. The time and speed of the centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 deg. C immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 deg. Centrifuge devices have been cleared by the FDA for preparation of PRP from a sample of whole blood. These devices are used in a laboratory setting or at the point of care of the patient. Examples of 4 centrifuge devices approved for autologous platelet separation are listed below:

   K103340: SmartPReP 2 BMAC System (Harvest Technologies Corp.), cleared on December 6, 2010
   K030555: GPS Platelet Separation Kit (Biomet Inc.), cleared on April 11, 2003
   K030340: AutoloGel Process Centrifuge (Cytomedix Inc.), cleared on April 11, 2003

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
Effective August 2, 2012, upon reconsideration, The Centers for Medicare and Medicaid Services (CMS) determined that platelet-rich PLASMA (PRP) – an autologous blood-derived product, would be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds and only when the patient is enrolled in a clinical trial that addresses certain questions and the trial uses validated and reliable methods of evaluation. Any clinical study undertaken pursuant to this NCD needed to be approved no later than August 2, 2014. If there are no approved clinical studies on or before August 2, 2014, this CED would expire. Any clinical study approved must adhere to the timeframe designated in the approved clinical study protocol. Medicare has no other National Coverage Determination (NCD) for PRP. No Local Coverage Determination (LCD) was identified.
3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding platelet rich plasma for the treatment of healing wounds in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

Numerous randomized or nonrandomized, controlled studies and case series were identified that investigated the use of platelet rich plasma for the treatment of repair of injured tendons and ligaments of the legs, rotator cuffs, elbows, and ankles including the Achilles.

SUMMARY:

Results from 19 randomized controlled trials (RCTs) and 3 nonrandomized controlled studies provide mixed and inconclusive evidence regarding the ability of injection of platelet-rich plasma (PRP) to improve outcomes or accelerate healing in patients who have tendon or ligament injuries. Although some studies that evaluated PRP injection as an adjunct to surgical repair of anterior cruciate ligament (ACL) injuries reported improvements in knee stability or tissue healing, most studies reported no improvement. The evaluation of PRP injection as an adjunct to arthroscopic rotator cuff repair or open subacromial decompression surgery for shoulder impingement yielded mixed results. PRP injection was superior to dry needling for treatment of tendinosis or partial tears of the rotator cuff in one study. As a treatment for lateral epicondylitis or elbow tendinopathy, PRP injection was comparable to autologous blood injection (ABI) in two studies, and superior to corticosteroid injection in one study. Two controlled studies reported that PRP injection for the treatment of Achilles tendon injuries did not improve healing or function. No serious complications were reported in any of the studies.

There are only a small number of case series investigating the efficacy of PRP for ankle surgery. Although bone fusion rates of 95% to 100% were observed compared with somewhat lower historical rates in other patient groups (60% to 85%), the evidence is too limited and of insufficient quality to draw any conclusions about the long-term efficacy of this therapy. Prospective randomized trials are required to provide definitive answers.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>0232T</td>
<td>Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed</td>
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<tr>
<td>P9020</td>
<td>Platelet rich plasma, each unit</td>
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<tr>
<td>G0460</td>
<td>Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment</td>
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### ICD-9 Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>726.32</td>
<td>Lateral epicondylitis</td>
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<tr>
<td>726.64</td>
<td>Patellar tendinitis</td>
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<tr>
<td>726.71</td>
<td>Achilles bursitis or tendinitis</td>
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<tr>
<td>727.61</td>
<td>Complete rupture of rotator cuff</td>
</tr>
<tr>
<td>727.65</td>
<td>Nontraumatic rupture of quadriceps tendon</td>
</tr>
<tr>
<td>727.66</td>
<td>Nontraumatic rupture of patellar tendon</td>
</tr>
<tr>
<td>727.67</td>
<td>Nontraumatic rupture of Achilles tendon</td>
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<tr>
<td>727.68</td>
<td>Nontraumatic rupture of other tendons of foot and ankle</td>
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<tr>
<td>728.71</td>
<td>Traumatic plantar fasciitis</td>
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<tr>
<td>844.1</td>
<td>Sprains and strains of the medial collateral ligament of the knee</td>
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<tr>
<td>844.2</td>
<td>Sprains and strains of the cruciate ligament of the knee</td>
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### ICD-10 Codes

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<tr>
<td>M72.2</td>
<td>Plantar fascial fibromatosis</td>
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<tr>
<td>M76.5</td>
<td>Patellar tendinitis</td>
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<tr>
<td>M76.6</td>
<td>Achilles tendinitis</td>
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<tr>
<td>M77.1</td>
<td>Lateral epicondylitis</td>
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<td>S46.0</td>
<td>Injury of tendon of the rotator cuff of shoulder</td>
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<tr>
<td>S76.1</td>
<td>Injury of quadriceps tendon and muscle</td>
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<tr>
<td>S83.4</td>
<td>Sprain and strain involving fibular collateral ligament of knee</td>
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<tr>
<td>S83.5</td>
<td>Sprain and strain involving anterior cruciate ligament of knee</td>
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<tr>
<td>S86.0</td>
<td>Injury of Achilles tendon</td>
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### CPT® Codes

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### REFERENCES:


controlled trial. JAMA. 2010;303(2):144-149.


POLICY HISTORY:

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<td>03-26-2015</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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<td>04/01/2015</td>
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QUESTIONS AND ANSWERS:

Q1: A1:

ATTACHMENTS: