MEDICAL POLICY – 2.01.98
Orthopedic Applications of Platelet-Rich Plasma

BCBSA Ref. Policy: 2.01.98
Effective Date: July 1, 2017
Last Revised: June 22, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions
2.01.26 Prolotherapy
8.01.52 Orthopedic Applications of Stem-Cell Therapy
12.04.93 Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing

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 wound healing. 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, and are not paid for by the health plan.

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>
</tr>
</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>
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<tr>
<td></td>
<td>• Primary use (injection) for the following conditions:</td>
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<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>o Osteoarthritis</td>
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<td></td>
<td>o Plantar fasciitis</td>
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<td>• Adjunctive use in the following surgical procedures:</td>
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<td>o 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>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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<tr>
<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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</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
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<tr>
<td>86999</td>
<td>Unlisted transfusion medicine procedure</td>
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<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>P9020</td>
<td>Platelet rich plasma, each unit</td>
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Description
This policy addresses the use of platelet-rich plasma (PRP) as a treatment of musculoskeletal conditions, including but not limited to primary treatment of plantar fasciitis, tendinopathies such as lateral epicondylitis (ie, tennis elbow) and adjunctive use in orthopedic surgical procedures. 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 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 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® (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

This policy addresses the use of platelet-rich plasma (PRP) as a treatment for a variety of musculoskeletal conditions and as an adjunctive procedure in orthopedic surgical procedures. 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.

The evidence for platelet-rich plasma (PRP) injections in individuals who have tendinopathy includes randomized controlled trials (RCTs) and systematic reviews. 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. Therefore this treatment is considered investigational for these conditions.

The evidence for platelet-rich plasma injections in individuals who have non-tendon soft tissue injury or inflammation (eg, plantar fasciitis) 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 compared treatment with PRP to corticosteroid injection and showed statistically significant but temporary improvements in American Orthopaedic Foot and Ankle Society ankle-hindfoot scores with the PRP injections, 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. Therefore, this treatment is considered investigational for these conditions.

The evidence for platelet-rich plasma injections in individuals who have osteochondral lesions 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 group receiving hyaluronic acid injections. 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.

The evidence for platelet-rich plasma injections in individuals who have knee or hip osteoarthritis 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 a combination of 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 post-treatment 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. Therefore this treatment is considered investigational for these conditions.

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, which is 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 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. Therefore this treatment is considered investigational for these conditions.

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. 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. Therefore this treatment is considered investigational for these conditions.

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. Therefore this treatment is considered investigational for these conditions.

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. Therefore this treatment is considered investigational for these conditions.

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. Therefore this treatment is considered investigational for these conditions.

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. 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>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT01668953</td>
<td>Impact of Platelet Rich Plasma Over Alternative Therapies in Patients With Lateral Epicondylitis (IMPROVE)</td>
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<td>Jan 2017 (ongoing)</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>Jun 2017 (terminated)</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>
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<td>Dec 2017</td>
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<td>NCT01923909</td>
<td>Intraarticular Platelet-rich Plasma Injections Versus Intraarticular Corticosteroid Injections in Primary Knee</td>
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<tr>
<td>NCT No.</td>
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<td></td>
<td>Osteoarthritis</td>
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<tr>
<td>NCT02325063</td>
<td>Evaluation of Three Types of Injection for the Treatment of Lateral Epicondylalgia (LET)</td>
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<td>NCT02920177</td>
<td>Platelet-rich Plasma Versus Corticosteroid Injection for the Treatment of Femoroacetabular Impingement</td>
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<td>NCT02984228</td>
<td>Platelet-rich Plasma vs. Hyaluronic Acid for Glenohumeral Osteoarthritis</td>
<td>70</td>
<td>Aug 2018</td>
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<tr>
<td>NCT01945528</td>
<td>Platelet Rich Plasma (PRP) in Chronic Epicondylitis</td>
<td>80</td>
<td>Apr 2019</td>
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<tr>
<td>NCT01915979</td>
<td>Effect of Plasma Rich in Growth Factors in Rotator Cuff Tendinopathy</td>
<td>84</td>
<td>NR</td>
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<tr>
<td>NCT02978833</td>
<td>Platelet-rich Plasma vs. Whole Blood for Gluteus Medius Tendinopathy</td>
<td>72</td>
<td>May 2019</td>
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<tr>
<td>NCT02872753</td>
<td>Intra-operative PRP Injection Following Partial Meniscectomy</td>
<td>90</td>
<td>Dec 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>
</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 were unable to voice an opinion either for or against growth factor injections and/or PRP for patients with symptomatic osteoarthritis of the knee.\(^{39}\) A recommendation of inconclusive is based on a single low-quality study and conflicting findings that do not allow a recommendation for or against the intervention. The AAOS recommendation is based on 3 studies that were published before May 2012.

**National Institute for Health and Clinical Excellence (NICE)**

In 2009, the U.K.’s NICE issued guidance on the 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 recommends this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

In 2013, NICE issued guidance on the use of autologous blood injection (with or without techniques for producing PRP) for plantar fasciitis. NICE concluded that the evidence on autologous blood injection for plantar fasciitis raises no major safety concerns but that the evidence on efficacy is 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 the use of PRP for osteoarthritis of the knee. 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.”

**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. 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 Magella™n Autologous Platelet Separator System (Medtronic) includes a disposables kit designed for use with the Magellan Autologous Platelet Separator portable tabletop centrifuge. BioMet Biologics received marketing clearance through FDA’s 510(k) process for a gravitational platelet separation system (GPS®II), which uses 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.

References


### History

<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>
</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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</table>
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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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**ارabic (Arabic):**


**中文 (Chinese):**

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**Français (French):**


**Italiano (Italian):**

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Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Límite al 800-722-1471 (TTY: 800-842-5357).


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