Blood and Blood Components and Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions Prolotherapy
Corporate Medical Policy

File Name: Blood and Blood Components and Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions Prolotherapy
File Code: UM.BIOPROD.01
Last Review: 05/2017
Next Review: 05/2018
Effective Date: 09/01/2017

Description/Summary

I. Blood and Blood Components

Whole blood and blood components (red cells, plasma, platelets, and leukocytes) are used in the treatment of a wide variety of conditions.

Blood derivatives are factors extracted from whole blood and blood components. Blood derivatives are also used to treat a wide variety of conditions. Some examples of blood derivatives are as follows:

1. Albumin
2. Gamma Globulin
3. Factors VIII and IX (clotting factors)
4. Rho (D) immune globulins (RhoGAM)
5. Prothrombin

Transfusion services are those services necessary to test donor blood and administer transfusions.

Allogenic blood is from another donor; autologous is blood the patient donates for his/her own use.

Policy - Blood and Blood Components

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I
Attachment II
Blood and Blood Components

When a service may be considered medically necessary

BCBSVT will provide coverage for transfusion services of whole blood, blood components, and blood derivatives when ordered by the member’s physician under circumstances where the transfusion of blood or blood products is an accepted medical practice and is therefore considered medically necessary.

BCBSVT will provide coverage for cost that the facility incurs from a community blood bank for the bank’s processing expenses. Must be billed under revenue code 0392, with HCPCS code (P9010 - P9040, P9043-P9044, P9048 - P9072).

BCBSVT will provide coverage for clinical laboratory studies/tests in connection with blood and blood transfusion services related to the patient receiving the blood.

Blood transfusion services are included in the Room and Board charges for members who are observation/inpatient.

Blood transfusion services are separately reimbursed for outpatient transfusion services (CPT codes 36430 -36460).

* BCBSVT may request medical records for retrospective determination of medical necessity.

Policy Guidelines - Blood and Blood Components

Charges for blood derivatives, which are classified as formulary drugs (i.e., hemophilia factors), are eligible for coverage as prescription drugs.

If the autologous blood is not used by the donor and becomes part of the blood bank supply, the cost of testing should be passed on to the ultimate recipient as an allogenic transfusion.

When a service is considered non-covered

- Storage of whole blood, blood components/products at facilities, this is considered inclusive to transfusion services (provider liability)

When a service is considered a benefit exclusion and therefore not covered

- Whole blood, blood components, costs associated with the storage of blood, testing of blood the patient donates for his or her own use (even if the blood is used).
- Transfusion services for blood and blood components the patient donates for his or her own use in the absence of a covered surgical procedure.

II. Recombinant Platelet-Derived Growth Factors
Policy - Recombinant Platelet-Derived Growth Factor (PGDF)

When a service may be considered medically necessary

Recombinant platelet-derived growth factor (PGDF) (ie, becaplermin) may be considered medically necessary when used as an adjunct to standard wound management for the following indications (for further information on patient selection criteria, see Policy Guidelines next.)

- Neuropathic diabetic ulcers extending into the subcutaneous tissue
- Pressure ulcers extending into the subcutaneous tissue

When a service is considered investigational

Other applications of becaplermin are considered investigational, including, but not limited to, ischemic ulcers, ulcers related to venous stasis, and ulcers not extending through the dermis into the subcutaneous tissue.

Use of autologous blood-derived preparations (ie, platelet-rich plasma) is considered investigational. This includes, but is not limited to, use in the following situations:

- Treatment of acute or chronic wounds including nonhealing ulcers
- Adjunctive use in surgical procedures
- Primary use (injection) for other conditions such as epicondylitis (ie, tennis elbow), plantar fasciitis, or Dupuytren contracture

Autologous Blood Derived Preparations Platelet Rich Plasma (PRP)

BCBSVT considers platelet-rich plasma (PRP) injection investigational for all indications including the following (not an all-inclusive list) because its effectiveness has not been established.

This includes, but is not limited to, use in the following situations:

- Treatment of acute or chronic wounds including nonhealing ulcers
- Adjunctive use in surgical procedures
- Primary use (injection) for other conditions such as epicondylitis (ie, tennis elbow), plantar fasciitis, or Dupuytren contracture

Policy Guidelines for Recombinant platelet-derived growth factor (ie, becaplermin)

Appropriate candidates for becaplermin gel for treatment of neuropathic ulcers should meet ALL of the following criteria:

1. Adequate tissue oxygenation, as measured by a transcutaneous partial pressure of oxygen of 30 mm Hg or greater on the foot dorsum or at the margin of the ulcer
2. Full-thickness ulcer (ie, stage III or IV), extending through dermis into subcutaneous tissues
3. Participation in a wound-management program, which includes sharp débridement, pressure relief (ie, non-weight bearing), and infection control
Appropriate candidates for becaplermin gel for the treatment of pressure ulcers should meet ALL of the following criteria:

1. Full-thickness ulcer (ie, Stage III or IV), extending through dermis into subcutaneous tissues
2. Ulcer in an anatomic location that can be off-loaded for the duration of treatment
3. Albumin concentration >2.5 dL
4. Total lymphocyte count >1000
5. Normal values of vitamins A and C

Patients are typically treated once daily for up to 20 weeks or until complete healing. Application of the gel may be performed by the patient in the home.

Becaplermin is available in 2-, 7.5-, and 15-g tubes and is applied in a thin continuous layer, about 1/16 of an inch thick, ie, the thickness of a dime. The amount of the gel used will depend on the size of the ulcer, measured in square centimeters. However, an average-sized ulcer, measuring 3 cm², treated for an average length of time of 85 days, will require a little more than one 15-g tube. If the ulcer is treated for the maximum length of time of 140 days, 1.75 of the 15-g tubes would be required.

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.

**Policy Guidelines for Recombinant Platelet-Derived Growth Factors PRP**

**When a service is considered investigational**

Autologous platelet gel application following total knee arthroplasty is considered **investigational** because its effectiveness has not been established.

Bone marrow plasma injection is considered **investigational** for the treatment of tendonopathies (e.g., elbow, heel, knee, and shoulder) and all other indications because its effectiveness has not been established.

Bone marrow derived mesenchymal stromal cells administration is considered **investigational** for the treatment of Crohn’s disease and osteoarthritis because its effectiveness has not been established.

Adipose-tissue-derived stem cells injection treatment for chondromalacia patellae is considered investigational because its effectiveness has not been established.

**Summary - Recombinant Platelet-Derived Growth Factor**

Results from randomized controlled trials (RCTs) show improved rates of healing with use of recombinant platelet-derived growth factor (PDGF) for diabetic neuropathic ulcers and pressure ulcers. Evidence is insufficient to determine whether becaplermin gel improves health outcomes when used to treat other types of wounds, including
ischemic or chronic venous ulcers or acute traumatic wounds. Recombinant PDGF in combination with an osteoconductive agent is not currently approved for marketing in the U.S.

For platelet-rich plasma (PRP) treatment, there are numerous small controlled trials for a wide variety of conditions. 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 oldest and most established evidence is in the area of dental surgery, which is outside the scope of medical policy. Recent literature indicates an increasing number of RCTs for other conditions, and a search of the clinical trials database (available online at: www.clinicaltrials.gov) reveals that many more RCTs are in progress.

**Rationale/Scientific Background**

American Academy of Orthopaedic Surgeons (AAOS) 2013 guidelines were unable to recommend for or against growth factor injections and/or PRP for patients with symptomatic osteoarthritis of the knee. 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.

In 2009, the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) issued guidance on use of autologous blood injection for tendinopathy. 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 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.

**Regulatory Status for Recombinant platelet-derived growth factor (ie, becaplermin)**

A recombinant PDGF product, becaplermin gel (Regranex®, McNeil Pharmaceutical) has been approved by the U.S. Food and Drug Administration (FDA). The labeled indication is as follows: “Regranex Gel is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. When used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp débridement, pressure relief and infection control, Regranex Gel increases the complete healing of diabetic ulcers. The efficacy of Regranex Gel for the treatment of diabetic neuropathic ulcers...
that do not extend through the dermis into subcutaneous tissue or ischemic diabetic ulcers has not been evaluated.” In 2008, the manufacturer added this black box warning to the labeling for Regranex, “An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of REGRANEX Gel in a post-marketing retrospective cohort study. REGRANEX Gel should only be used when the benefits can be expected to outweigh the risks. REGRANEX Gel should be used with caution in patients with known malignancy.”

Augment Bone Graft (Wright Medical) is composed of recombinant PDGF with a conductive scaffold of beta tricalcium phosphate. In August 2013, FDA rejected Wright Medical’s premarket application for use in ankle/foot arthrodesis, expressing concern that “the population enrolled was predominantly low risk and, therefore, may not have warranted the use of either autograft or Augment Bone Graft.” In October 2013, FDA agreed to hold a dispute resolution panel with Wright Medical. Augment Bone Graft is currently available outside of the U.S.

**Regulatory Status for PRP**

A number of commercially available centrifugation devices are used for the preparation of platelet-rich plasma. For example, AutoloGel™ (Cytomedix) and SafeBlood® (SafeBlood Technologies) are 2 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 Electromedic, 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. 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.

**III. Prolotherapy**

**Policy - Prolotherapy**

When a service is considered investigational

Prolotherapy is considered *investigational* as a treatment of musculoskeletal pain.

Prolotherapy to promote tissue repair or growth by prompting release of growth factors, such as cytokines, or by increasing the effectiveness of an existing circulating growth factor is considered *investigational*, because its effectiveness has not been established.

**Summary - Prolotherapy**
Prolotherapy describes a procedure intended for healing and strengthening ligaments and tendons by injecting an agent that induces inflammation and stimulates endogenous repair mechanisms. Prolotherapy may also be referred to as proliferant injection, prolo, joint sclerotherapy, regenerative injection therapy, growth factor stimulation injection, or nonsurgical tendon, ligament, and joint reconstruction. The literature on prolotherapy consists of small randomized trials on a variety of pain syndromes, with inconsistent results. The body of scientific evidence does not permit conclusions concerning the effect of prolotherapy on health outcomes for chronic neck or back pain, tendinopathies of the upper or lower limbs, osteoarthritic pain, or other musculoskeletal pain conditions. Therefore, prolotherapy is considered investigational.

**Rationale /Scientific Background for Prolotherapy**

Prolotherapy has been investigated as a treatment of various etiologies of musculoskeletal pain, including arthritis, degenerative disc disease, fibromyalgia, tendinitis, and plantar fasciitis. As with any therapy for pain, a placebo effect is anticipated, and thus randomized placebo-controlled trials are necessary to investigate the extent of the placebo effect and to determine whether any improvement with prolotherapy exceeds that associated with a placebo. When this policy was created, there was extensive literature on prolotherapy; however, a literature search revealed only 4 randomized placebo-controlled trials. The literature has since been updated periodically with searches of the MEDLINE database. The most recent review was performed through July 17, 2014.

**Practice Guidelines and Position Statements**

The 2011 American College of Occupational and Environmental Medicine guideline on knee disorders states that prolotherapy is not recommended in the treatment of knee disorders.

**U.S. Preventive Services Task Force Recommendations**

Use of prolotherapy is not a preventive service.

**Reference Resources**

1. Blue Cross and Blue Shield Association Medical Policy; Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions.
2. Blue Cross and Blue Shield Association Medical Policy; Prolotherapy

**Document Precedence**

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT
reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for Recombinant Platelet-Derived Factors as a Treatment of Wound Healing and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP) members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information
Updated language and coding information. Coding additions/deletions or clarifications. Recombinant Platelet-Derived Factors as a Treatment of Wound Healing medical necessity criteria added.

05/2017  Updated Coding table additions/deletions or clarifications. Deleted ICD9 coding table.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors          Date Approved 05/01/2017

Gabrielle Bercy-Roberson, MD, MPH
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH
Chief Medical Officer

Attachment I
Blood and Blood Products

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Brief Description</th>
<th>Policy Instructions</th>
<th>Outpatient</th>
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<td>0391</td>
<td>Blood Admin (transfusion services)</td>
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<td>0392</td>
<td>Blood/Processing/Storage</td>
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<td>CPT® Codes</td>
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<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>
<td>Prior Approval Required Eligible for specific diagnosis codes, See Attachment II</td>
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<td>S0157</td>
<td>Becaplermin gel 0.01%, 0.5 gm</td>
<td>Prior Approval Required Eligible for specific diagnosis codes, See Attachment II</td>
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<td>P9010</td>
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<td>P9019</td>
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<td>P9022</td>
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<td>P9023</td>
<td>Plasma, pooled multiple donor, solvent/detergent treated, frozen each unit</td>
<td>Not Covered, provider responsibility</td>
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Miscellaneous Pathology

Blood (whole) for transfusion, per unit
Blood (split unit) specify amount
Cryoprecipitate, each unit
Red blood cells, leukocytes reduced, each unit
Fresh frozen plasma (single donor), frozen within eight hours of collection, each unit
Platelets, each unit
Red blood cells, each unit
Red blood cells, washed, each unit
Plasma, pooled multiple donor, solvent/detergent treated, frozen each unit
<p>| P9031 - P9037 | Platelets (various type products), each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9038 - P9040 | Red blood cells (various type products), each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9041 | Infusion, albumin (human), 5%, 50 ml. | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9043 | Infusion, plasma protein fraction (human), 5%, 50 ml. | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9044 | Plasma, cryoprecipitate, reduced, each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9045 - P9047 | Infusion, albumin (human), various %, various ml. | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9048 | Infusion, plasma protein fraction (human) 5%, 250 ml. | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9050 | Granulocytes, pheresis, each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9051 | Whole blood or red blood cells, leukocytes reduced | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9052 - P9053 | Platelets, various products, each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9054 | Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit | Not Covered, provider responsibility | Not Covered, provider responsibility |
| P9055 | Platelets, leukocytes | Not Covered, provider | Not Covered, provider |</p>
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<th>Code</th>
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<td>P9072</td>
<td>Platelets, pheresis, pathogen reduced, each unit</td>
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The following codes will be denied as Investigational

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<th>HCPCS Codes</th>
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<th>Prolotherapy</th>
<th>Investigational Not covered</th>
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<tr>
<td>P9020</td>
<td>Platelet Rich Plasma</td>
<td>Investigational Not covered</td>
<td>Investigational Not covered</td>
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**CPT® Codes**

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>0232T</th>
<th>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed.</th>
<th>Investigational Not covered</th>
<th>Investigational Not covered</th>
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</thead>
</table>

**Type of Service**

Outpatient, Inpatient

**Place of Service**

Facility

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**Attachment II**

Eligible Diagnosis Codes for Recombinant and Autologous Platelet Derived Growth Factors as Treatment of Wound Healing

<table>
<thead>
<tr>
<th>ICD - 10 Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E11.40-E11.43</td>
<td>Diabetes with neurological manifestations code range</td>
</tr>
<tr>
<td>E11.49</td>
<td>Diabetes with other diabetic neurological complication</td>
</tr>
<tr>
<td>L89.000-L89.95</td>
<td>Pressure ulcer code range</td>
</tr>
<tr>
<td>L97.121-L97.929</td>
<td>Pressure ulcer lower limbs and foot code range</td>
</tr>
<tr>
<td>L98.491-L98.499</td>
<td>Non pressure chronic ulcer of skin and other sites</td>
</tr>
</tbody>
</table>