OVERVIEW
This policy documents the coverage determination for autologous platelet-derived growth factors (PDGF) (i.e., platelet-rich plasma [PRP]). Autologous platelet-derived growth factors have been investigated as wound-healing products.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Coverage of autologous platelet-rich plasma (PRP) for BlueCHiP for Medicare members is allowed only as part of a Centers for Medicare and Medicaid (CMS) approved clinical trial. Refer to Related Policy section.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products
Autologous blood-derived preparations (i.e., platelet-rich plasma) are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary among groups. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factor (PDGF), 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, and osteoblasts), and vascular endothelial growth factors.

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma (PRP), can be prepared from samples of centrifuged autologous blood. Exposure to a solution of thrombin and calcium chloride degranulates platelets, releasing various growth factors, and results in the polymerization of fibrin from fibrinogen, creating a platelet gel. The platelet gel can then be applied to wounds or may be used as an adjunct to surgery to promote hemostasis and accelerate 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 factor, 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.

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 International) and Hemaseel® (Haemacure Corp.) are examples of commercially available fibrin sealants. Autologous fibrin sealants can also be created from platelet-poor plasma.

For individuals who have chronic wounds or acute surgical or traumatic wounds who receive platelet-rich plasma (PRP), the evidence includes a number of small controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Current results of trials using PRP are mixed and the studies are limited in both size and quality. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this service is considered not medically necessary for Commercial products.

The Centers for Medicare & Medicaid Services (2012) revised its national coverage decision on autologous blood-derived products for chronic non-healing wounds. This revision replaces prior noncoverage decisions.

The Centers for Medicare & Medicaid Services covers autologous PRP only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds and when all of the following conditions are met:

"The patient is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation…"

"The clinical research study must meet the requirements specified below to assess the effect of PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds. The clinical study must address:

"Prospectively, do Medicare beneficiaries that have chronic non-healing diabetic, venous and/or pressure wounds who receive well-defined optimal usual care, along with PRP therapy, experience clinically significant health outcomes compared to patients who receive well-defined optimal usual care for chronic non-healing diabetic, venous and/or pressure wounds as indicated by addressing at least one of the following:

a. Complete wound healing?

b. Ability to return to previous function and resumption of normal activities?

c. Reduction of wound size or healing trajectory which results in the patient’s ability to return to previous function and resumption of normal activities?"

CODING
The following code is allowed for BlueCHiP for Medicare as part of a CMS approved clinical study and not medically necessary for Commercial products:

G0460 Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment

Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

Modifier Q0 – Investigational clinical service provided in a clinical research study that is in an approved research study (BlueCHiP for Medicare claims filed without the Q0 modifier will deny as not covered)

Note: If you are treating a BlueCHiP for Medicare member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy Clinical Trials BlueCHiP for Medicare
The following code is not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

**0232T** Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

**RELATED POLICIES**
Clinical Trials BlueCHiP for Medicare
BlueCHiP for Medicare National and Local Coverage Determinations

**PUBLISHED**
Provider Update, May 2020
Provider Update, May 2019
Provider Update, January 2019
Provider Update, December 2017
Provider Update, January 2017
Provider Update, Apr 2015
Provider Update, Sep 2014
Provider Update Aug 2013

**REFERENCES:**

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