Medical Coverage Policy

Autologous Platelet-Derived Growth Factors (i.e., Platelet-Rich Plasma)-PREAUTH BLUECHIP FOR MEDICARE

☐ Device/Equipment ☐ Drug ☒ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	7/1/2013	Policy Last Updated:	6/18/2013

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description

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 PDGFs have been investigated as wound-healing products. For example, platelets are a rich source of PDGFs, transforming growth factors (which 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 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. Activated platelets then degranulate, releasing the various growth factors.

There is a number of commercially available centrifugation devices used for the preparation of PRP. 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. 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. In addition, PRP has also been proposed as a primary

treatment of miscellaneous conditions, such as epicondylitis, plantar fasciitis, and Dupuytren's contracture.

Use of autologous PDGF as a primary treatment of soft-tissue injuries in an early stage, peer-review literature is limited to small studies and the evidence is insufficient to permit conclusions concerning the effect of PDGF on health outcomes. It was requested that CMS cover PRP through a National Coverage Determination (NCD) with data collection as a condition of coverage; and requested that this would provide a practical means by which CMS could obtain the necessary data to evaluate the performance of PRP and to confirm the outcomes presented in their request.

CMS determined that PRP is covered for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only when the following conditions are met:

1. The patient is enrolled in a randomized clinical trial that addresses the questions listed below using validated and reliable methods of evaluation. Clinical study applications for coverage pursuant to this National Coverage Determination (NCD) must be approved by August 2, 2014. Any clinical study approved by August 2, 2014, will adhere to the timeframe designated in the approved clinical study protocol.

   If there are no approved clinical studies on or before August 2, 2014, Coverage with Evidence Development (CED) for PRP only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds will expire.

2. The clinical research study must meet the requirements specified below to assess PRP's effect on the treatment of chronic non-healing diabetic, venous and/or pressure wounds.

   The clinical study must address:

   - Prospectively, do Medicare beneficiaries, with 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 only well-defined optimal usual care for such 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?

3. The required PRP clinical trial must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- Its principal purpose is to test whether PRP improves the participants' health outcomes;

- It is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

- It does not unjustifiably duplicate existing studies;

- Its design is appropriate to answer the research question being asked in the study;

- It is sponsored by an organization or individual capable of executing the proposed study successfully;

- It is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46;

- All of its aspects are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (http://www.icmje.org);

- It has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED);

- It is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options;

- It is registered on the ClinicalTrials.gov website (http://www.clinicaltrials.gov/) by the principal sponsor/investigator prior to the enrollment of the first study subject;

- Its study protocol:

    a. Specifies the method and timing of public release of all pre-specified outcomes to be measured, including the release of outcomes that are negative or that the study is terminated early.

The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection;

b. Must explicitly discuss:

1) Subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies;

2) How the inclusion and exclusion criteria effect enrollment of these populations, and

3) A plan for the retention and reporting of said populations on the trial.

If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

c. Must explicitly discusses how the results are, or are not, expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Medical Criteria:
BlueCHiP for Medicare

Autologous PDGF is covered only for members enrolled in a Medicare approved clinical trial for the treatment of chronic non-healing diabetic, venous and/or pressure wounds. Available clinical trials can be found at http://www.clinicaltrials.gov/

Policy:
Effective 07/01/2013- BlueCHiP for Medicare

Preauthorization is required.

Autologous platelet-derived growth factor is covered only for members enrolled in a Medicare approved clinical trial for the treatment of chronic non-healing diabetic, venous and/or pressure wounds. Clinical trials may be found at http://www.clinicaltrials.gov/

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates

consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial Products
Autologous blood-derived preparations (i.e., platelet-rich plasma) are considered **not medically necessary** as the literature is limited to small studies and the evidence is insufficient to permit conclusions concerning the effect on health outcomes**.**

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement, applicable "Services Not Medically Necessary" coverage.

Coding:
For Commercial products, there is no specific CPT code for obtaining the blood, deriving the platelet-rich plasma, and injecting it. This process is considered to be a single service and it should be properly reported with an unlisted musculoskeletal procedure code that is specific to the anatomic site treated. Specifically, this is not obtaining a graft and use of CPT code 20926 is incorrect. Providers who have erroneously used this procedure code should submit amended claims to BCBSRI to correct the error using the Claim Adjustment Request Form.

The following code is considered not medically necessary for all BCBSRI products:
0232T

Effective 07/01/2013
The following HCPCS code is covered for BlueCHiP for Medicare with preauthorization when filed with the QO modifier. It is not medically necessary for all other BCBSRI products:
G0460 Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment.

Modifier
Q0 Investigational clinical service provided in a clinical research study that is in an approved research study

Note: Medicare claims filed without the QO modifier will deny as not medically necessary.

Related Topics:
CPT Category III Codes
https://www.bcbsri.com/sites/default/files/polices/CPT_Category_III_Codes.pdf

Also Known As:

Platelet-Rich Plasma (PRP)

Published:
Provider Update, August 2013
Provider Update, September 2012
Provider Update, September 2011
Provider Update, July 2009
Provider Update, October 2010
Provider Update, May 2009

References:

Medicare National Coverage Determinations Manual. Chapter 1, Part 4 (Sections 200 – 310.1) 270.3 - Blood-Derived Products for Chronic Non-Healing Wounds.

Blue Cross and Blue Shield Association. Medical Policy Reference Manual. 2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions.

National Institutes of Health ClinicalTrials.gov Web Site http://www.clinicaltrials.gov/

Review History:
06/18/2013: Annual review with new information regarding coverage for Medicare members.