



EFFECTIVE DATE: 01|20|2015
POLICY LAST UPDATED: 01|20|2015

OVERVIEW

This policy documents the coverage determination for Autologous Platelet-Derived Growth Factors (PDGF) (i.e., Platelet-Rich Plasma). Autologous Platelet-Derived Growth Factors have been investigated as wound-healing products.

PRIOR AUTHORIZATION

Prior Authorization is required for BlueCHiP for Medicare

POLICY STATEMENT

BlueCHiP for Medicare

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.

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/>.

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 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 are 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 blood-derived preparations (ie, platelet-rich plasma) is considered not medically necessary for Commercial members. 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

Effective in 2012, The Centers for Medicare and Medicaid Services (CMS) has determined that platelet-rich plasma (PRP) – an autologous blood-derived product, will be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds and only when the following conditions are met:

The patient is enrolled in a clinical trial that addresses the following questions using validated and reliable methods of evaluation. Clinical study applications for coverage pursuant to this National Coverage Determination (NCD) must be received by August 2, 2014.

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?

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

- a. The principal purpose of the Clinical Study is to test whether PRP improves the participants' health outcomes.
- b. The Clinical Study 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.
- c. The Clinical Study does not unjustifiably duplicate existing studies.

- d. The Clinical Study design is appropriate to answer the research question being asked in the study.
- e. The Clinical Study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The Clinical Study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
- g. All aspects of the Clinical Study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (<http://www.icmje.org>).
- h. The Clinical Study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED).
- i. The Clinical Study 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.
- j. The Clinical Study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The Clinical study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or 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.
- l. The Clinical Study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and 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 under represented populations, the protocol must discuss why these criteria are necessary.
- m. The Clinical Study protocol 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.

Qualification Process for Clinical Trials:

Using the authority found in §1142 of the Social Security Act (the Act) (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed in the NCD. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel

to be highly likely to have the seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b) (1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

The CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable services not medically necessary coverage/benefits.

CODING

Blue CHiP for Medicare

The following HCPCS code is covered for BlueCHiP for Medicare with preauthorization when filed with the Q0 modifier. It is not medically necessary for Commercial Products.

G0460

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

Note: Medicare claims filed without the Q0 modifier will deny as not medically necessary.

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 codes are considered not medically necessary:

0232T

P9020

RELATED POLICIES

None

PUBLISHED

| | |
|-----------------|-----------|
| Provider Update | Apr 2015 |
| Provider Update | Sep 2014 |
| Provider Update | Aug 2013 |
| Provider Update | Sep 2012 |
| Provider Update | Sep 2011 |
| Provider Update | July 2009 |
| Provider Update | Oct 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.

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

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1):
<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>

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