Plate Gel CMS Coverage

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Original Consideration for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190N)

First reconsideration for Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds (CAG-00190R)

Second reconsideration for Autologous Blood Derived Products for Chronic Non-Healing Wounds (CAG-00190R2)

CMS has determined that the evidence is inadequate to conclude that autologous platelet rich plasma (PRP) for the treatment of chronic non-healing cutaneous wounds, acute surgical wounds when the autologous PRP is applied directly to the closed incision, or dehiscent wounds improves health outcomes in the Medicare population. Therefore, CMS has determined that PRP is not reasonable and necessary for the treatment of these indications.

Consequently, CMS is issuing a non-coverage determination for acute surgical wounds when the autologous PRP is applied directly to the closed incision and for dehiscent wounds. CMS will maintain the current non-coverage for chronic, non-healing cutaneous wounds.

In accordance with section 310.1 of the National Coverage Determinations Manual, Medicare covers the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds.

The new NCD language can be found in Appendix C.

III. History of Medicare Coverage

In 1992, CMS issued a national non-coverage determination for platelet-derived wound healing formulas intended to treat patients with chronic, non-healing wounds.

In December 2003, CMS issued a national non-coverage determination for use of autologous PRP for the treatment of chronic non-healing cutaneous wounds except for routine costs when used in accordance with the clinical trial policy defined in section 310.1 of the National Coverage Determinations Manual.

In April 2005, CMS issued a national coverage determination (NCD) to correct the erroneous potential for local coverage of becaplermin, printed in section 270.3 of the NCD manual, entitled “Blood-Derived Products for Chronic Non-Healing Wounds.” CMS deleted the erroneous sentences and inserted the correct statement that “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered under Part B based on §1861(s)(2)(A) and (B) because this product is usually administered by the patient.”

Current Request

On June 20, 2007, Cytomedix submitted a formal request to CMS to reconsider coverage of autologous blood-derived products when used for the treatment of chronic non-healing wounds.

Autologous PRP is a prevalent blood product used for treating chronic non-healing wounds, open cutaneous wounds, soft tissue, and bone.

Cytomedix submitted new evidence and requested CMS to re-evaluate the coverage of autologous PRP gel for the following open-cutaneous wounds, including chronic wounds:

 Wounds caused by an acute surgical incision or dehiscence.

 Full-thickness chronic wounds that have failed an adequate course of standard wound therapy.

On February 15, 2008, CMS received a letter from the submitter (Cytomedix) requesting that CMS revise the proposed decision memorandum to allow for coverage of autologous PRP “when used as a treatment of chronic diabetic foot ulcers.” The letter also included a discussion about the use of a registry approach that would allow coverage of autologous PRP for treatment of chronic diabetic foot ulcers. The submitter explained that the use of a registry would permit CMS to continue to gather data that will help “develop the evidence base for improved treatment of diabetic foot ulcers.”

V. FDA Status

The AutoloGel™ System has been cleared by the FDA under Section 510(k) in a determination that the device is substantially equivalent (for the following listed indications) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976. The device “is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient’s own blood. Under the supervision of a healthcare professional, the PRP gel produced by the AutoloGel™ System is suitable for exuding wounds, such as leg ulcers, pressure ulcers and for the management of mechanically- or surgically-debrided wounds.”

FDA concluded, “Based on the clinical performance information, it can be concluded that AutoloGel is substantially equivalent to the marketed wound dressing IPM Wound Gel.” (FDA 510(k) summary accessed at http://www.fda.gov/cber/510ksumm/k060007S.pdf accessed November 15, 2007.) The AutoloGel system is one example of systems that produce autologous PRP products.

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

Methodological principles of study design that are used to assess the literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

Effective Date of this Version

3/19/2008

Implementation Date

6/2/2008

A. General

Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin's surface. Wounds are categorized as either acute, in where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, in where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner. Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors.

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products (such as Procuren), and (2) PRP.

The PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibroblasts.

The PRP is used by physicians in clinical settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone. Alternatively, PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

Indications and Limitations of Coverage

B. Nationally Covered Indications

C. Nationally Noncovered Indications

 Effective December 28, 1992, the Centers for Medicare & Medicaid Services (CMS) issued a national non-coverage determination for platelet-derived wound-healing formulas intended to treat patients with chronic, non-healing wounds. This decision was based on a lack of sufficient published data to determine safety and efficacy, and a public health service technology assessment.

 Effective July 23, 2004, upon reconsideration, the clinical effectiveness of autologous PDGF products continues to not be adequately proven in scientific literature. As the evidence is insufficient to conclude that autologous PDGF in a platelet-poor plasma is reasonable and necessary, it remains non-covered for treatment of chronic, non-healing cutaneous wounds. Also, the clinical evidence does not support a benefit in the application of autologous PRP for the treatment of chronic, non-healing, cutaneous wounds. Therefore, CMS determines it is not reasonable and necessary and is nationally non-covered.

 Effective April 27, 2006, coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds, remains nationally non-covered under Part B based on section 1861 (s)(2)(A) and (B) of the Social Security Act because this product is usually administered by the patient.

 Effective March 19, 2008, upon reconsideration, the evidence is not adequate to conclude that autologous PRP is reasonable and necessary and remains non-covered for the treatment of chronic non-healing, cutaneous wounds. Additionally, upon reconsideration, the evidence is not adequate to conclude that autologous PRP is reasonable and necessary for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.

D. Other

In accordance with section 310.1 of the National Coverage Determinations Manual, the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds are covered by Medicare.

(This NCD last reviewed March 2008.)

Third reconsideration for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (this document)

National Coverage Analysis (NCA) for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190R3)

Formal Request Accepted and Review Initiated: 11/09/2011

CMS has defined a chronic wound as one in which the healing process has failed to progress properly and the wound persists for longer than 30 days. Chronic wounds are common in the face of many disease processes, including diabetes and vascular insufficiency as well as in those individuals with mobility impairments.

Platelet rich concentrates, gels and releasates have been used as topical treatments for many years. Platelets contain a large number of growth factors and cytokines, which when released, are thought to stimulate the process of wound healing.

**CMS has made previous pertinent decisions regarding plasma products used for wound healing, the last being in March 2008, in a National Coverage Decision (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3). At that time, we determined that the evidence was not adequate to conclude that autologous platelet-rich plasma (PRP) is reasonable and necessary for the treatment of chronic non-healing, cutaneous wounds. Additionally, we determined the evidence was not adequate to conclude that autologous PRP is reasonable and necessary for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision or for dehiscent wounds.**

However, interested parties have asked for reconsideration of NCD 270.3 in order to examine new evidence surrounding the use of autologous platelet rich gel used to improve the health outcomes in patients with chronic non-healing pressure ulcers, venous ulcers and diabetic foot ulcers. Specifically, they are asking that we cover PRP gel produced by systems that have received clearance or approval by the Food and Drug Administration for the treatment of pressure ulcers, venous ulcers or diabetic foot ulcers may be covered for those indications following a period of at least 30 days during which alternative covered treatments have been unsuccessful in reducing wound area or depth. The request includes a proposal to prospectively collect outcomes data to furnish additional evidence.

CMS is reconsidering NCD 270.3 to complete a thorough review of the evidence to determine if the use of autologous platelet rich gel in patients with chronic non-healing pressure ulcers, venous ulcers and diabetic foot ulcers is reasonable and necessary under the Medicare program.

**As we are considering coverage under Section 1862(a)(1)(A) and Section 1862(a)(1)(E) of the Social Security Act, we also encourage the submission of comments that would pertain to clinical studies falling under the Coverage with Evidence Development (CED) paradigm.**