



## AUTOLOGOUS PLATELET DERIVED GROWTH FACTOR (ALSO KNOWN AS PLATELET RICH PLASMA)

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### Overview

A skin wound, whether created by scalpel or trauma, undergoes a similar and predictable healing process. A wound is described as partial thickness where the wound involves the outer two layers of the skin (the epidermis and dermis). A wound is described as full-thickness where it involves all three layers of the skin (the epidermis, dermis and subcutaneous tissue). The normal wound healing process has three progressive phases: the inflammatory phase, the proliferative phase, and the maturational phase. The typical normal wound healing duration is about four weeks. A wound is labeled acute when it has yet to proceed through the three stages of normal wound healing. The presumption is that an acute wound will heal in an orderly and timely process. By contrast, a chronic wound is of sufficient age that it should have progressed through the three stages, but has failed to do so. Normal wound healing involves many variables that interact in a dynamic and interactive manner, and the reasons for abnormal wound healing are multifactorial. The presence of co-morbid conditions, such as diabetes, increases this variability. A dehiscent wound is typically an incision site that was closed at the end of surgery that has subsequently split open along the suture line. Wound dehiscence is a potential complication that occurs as a result of poor wound healing.

During the inflammatory stage, platelets migrate to the area releasing proteins which stabilize the wound and begin the healing process. Recognizing the role of platelets in tissue repair, platelet derivatives have been investigated as wound healing products. Topically applied recombinant platelet derived growth factor (PDGF) has been most extensively investigated, and a recombinant PDGF product, becaplermin gel (Regranex®, McNeil Pharmaceutical) has been approved by the U.S. Food and Drug Administration for the treatment of neuropathic diabetic ulcers of the lower extremities extending into the subcutaneous tissue and certain pressure ulcers.<sup>1</sup>

Autologous PDGF, also known as platelet rich plasma (PRP) has also been investigated. The first autologous platelet derived product, Procuren®, was developed in the 1990s. Procuren® was available as part of a wound care management program at the Wound Care Centers. A sample of blood was collected from the patient and shipped to a specialized laboratory for processing. It was then returned to the patient to be applied topically to a wound. Wound Care Centers, owned by Curative Technologies, Inc., was

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<sup>1</sup> Regranex® is a prescription medication. Regranex® requires prior authorization. The prescribing physician should submit an authorization request for Regranex® to FCHP Pharmacy Services.



a network of about 130 hospital-based wound care centers located in 33 states. Procuren® did not receive FDA-approval and is no longer available.<sup>2</sup> Currently, autologous platelet concentrate is prepared from a sample of the patient's blood at the point of care. A centrifuge spins the blood to separate the platelets. The platelet concentrate is then treated with a reagent to create a gel-like substance which is applied directly to the wound. A number of commercially available FDA-approved devices are available for the preparation of autologous platelet derived products, including, Autogel™ (Cytomedix, Inc.), SafeBlood® (SafeBlood Technologies), and Cascade® Autologous Platelet System (Cascade Medical Enterprises, LLC). Autologous platelet derived products have also been used to treat a variety of acute surgical wounds and dehiscent wounds, and as a treatment for tendon injuries, such as epicondylitis, and plantar fasciitis.

There is insufficient evidence in the peer-reviewed published literature to permit conclusions regarding the effectiveness of autologous platelet derived products, including autologous platelet derived growth factor, for the treatment of chronic non-healing wounds or for the treatment of other conditions including but not limited to acute surgical wounds, dehiscent wounds, lateral epicondylitis, plantar fasciitis, and Dupuytren's contracture.

### Policy

FCHP considers autologous platelet derived growth factor experimental/investigational for any indication.

### Codes

There is no specific CPT or HCPCS code for autologous platelet derived products. CPT code 20926 (Tissue grafts, other) should not be used to bill for autologous platelet derived products. HCPCS codes P9020 and S9055 are not reimbursed and if billed will be denied provider liable.

Codes	Number	Description
HCPCS	P9020	Platelet rich plasma, each unit
	S9055	Procuren® or other growth factor preparation to promote wound healing (Procuren® is no longer available)

### References

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<sup>2</sup> On January 2, 2001, Cytomedix, Inc. acquired the assets of Curative Technologies, Inc., including the intellectual property rights to the development and production of platelet-derived growth factors. In May 2001, Cytomedix shut down the entire Procuren operation, citing the inability to receive FDA-approval for Procuren® and resulting financial loss.

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14. Mazzucco L, Medici D, Serra M, Panizza R, Rivara G, Orecchia S, Libener R, Cattana E, Levis A, Betta PG, Borzini P. The use of autologous platelet gel to treat difficult-to-heal wounds: a pilot study. *Transfusion.* 2004 Jul;44(7):1013-8.
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16. Stacey MC, Mata SD, Trengove NJ, Mather CA. Randomised double-blind placebo controlled trial of topical autologous platelet lysate in venous ulcer healing. *Eur J Vasc Endovasc Surg.* 2000 Sep;20(3):296-301.

## Products to Which This Policy Applies

*Autologous Platelet Derived Growth Factor (also known as Platelet Rich Plasma)*



- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

**Committee review dates:**

Technology Assessment Subcommittee: 04/22/08, 06/24/08, 06/23/09

Technology Assessment Committee: 10/14/08, 09/30/09

**IMPORTANT NOTE**

**Not all services are covered for all products or employer groups.** This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.