Medicare Learning Network
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Information for Medicare Fee-For-Service Health Care Professionals

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# Autologous Blood-Derived Products for Chronic, Non-Healing Wounds

Note: This article was updated on April 5, 2013, to reflect current Web addresses. All other information remains unchanged.

## Provider Types Affected

All Medicare providers

## Provider Action Needed

No action is necessary. This article is informational only. The Centers for Medicare & Medicaid Services (CMS) has determined, upon reconsideration of existing policy, that Autologous Blood-Derived Products for Chronic Non-Healing Cutaneous Wounds, both platelet-derived growth factor (PDGF) in platelet-poor plasma and platelet-rich plasma (PRP), will remain non-covered as CMS continues to believe that the clinical effectiveness of these autologous blood-derived products is not adequately proven in scientific literature.

## Background

Patient-donated blood is centrifuged to produce an autologous gel for the treatment of chronic non-healing cutaneous wounds that persist for 30 days or longer and fail to complete the healing process properly. Autologous blood-derived products for chronic non-healing wounds include both PDGF products, such as Procuren and more recent products, and PRP products.

PRP differs from previous products because it contains whole cells, including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibroblasts. PRP is used by physicians in clinical settings. PDGF does not contain cells and was marketed as a product to be used by patients at home.

In 1992 CMS issued a national Medicare non-coverage determination in relation to platelet-derived wound healing formulas containing growth factors in the treatment of non-healing wounds. The determination was based on a lack of sufficient

published data to determine the safety and efficacy of such formulas, and a Public Health Service technology assessment.

Recently, CMS reconsidered that 1992 decision and concluded that the clinical effectiveness of autologous PDGF products continues to be inadequately proven in scientific literature, and it remains non-covered for treatment of chronic, non-healing cutaneous wounds. Additionally, the clinical evidence does not support a benefit in the application of autologous PRP for the treatment of chronic, non-healing wounds, and CMS has determined it is not reasonable and necessary and is nationally non-covered.

It will remain at the local carrier's discretion whether to pay for Becaplermin, a non-autologous growth factor product approved by the FDA for the treatment of chronic non-healing subcutaneous wounds. Also, the routine costs of autologous PRP products for the treatment of chronic non-healing wounds associated with Category B Investigational Device Exemption clinical trials are covered by Medicare in accordance with 42 CFR 405.201 – 405.215, 411.15, and 411.406 or section 310.1 of the National Coverage Determinations Manual.

## Additional Information

The official instruction issued to your carrier/intermediary regarding this change may be found at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R19NCD.pdf on the CMS website.

If you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.