



Related MLN Matters Article #: MM3384

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Related CR #: 3384

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

Key Words

MM3384, CR3384, R19NCD, Blood, PDGF, Cutaneous, Wound, Chronic

Provider Types Affected

All Medicare providers

Key Points

- The effective date of the instruction is July 23, 2004.
- The implementation date is July 23, 2004.
- The Centers for Medicare & Medicaid Services (CMS) reconsidered a 1992 decision and concluded that the clinical effectiveness of autologous platelet-derived growth factor (PDGF) products continues to be inadequately proven in scientific literature, and it remains non-covered for treatment of chronic, non-healing cutaneous wounds.
- Clinical evidence does not support a benefit in the application of autologous platelet-rich plasma (PRP) for the treatment of chronic, non-healing wounds; therefore, CMS has determined it is not reasonable and necessary and is nationally non-covered.
- Whether or not to pay for Becaplermin, a non-autologous growth factor product approved by the Food and Drug Administration for the treatment of chronic non-healing subcutaneous wounds, will remain at the local carrier's discretion.
- 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.
- 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, 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.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3384.pdf> on the CMS website.

The official instruction (CR3384) regarding this change may be viewed at

<http://www.cms.gov/Transmittals/downloads/R19NCD.pdf> on the CMS website.

If providers have any questions, they may contact their carrier/intermediary at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.