



**News Flash** - *The Medicare Appeals Process: Five Levels to Protect Providers, Physicians and Other Suppliers* brochure has been updated and is now available to order print copies or as a downloadable PDF file. To view the PDF file, go to <http://www.cms.hhs.gov/MLNProducts/downloads/MedicareAppealsProcess.pdf> or to order hard copies, please visit the MLN Product Ordering Page at [http://cms.meridianksi.com/kc/main/kc\\_frame.asp?kc\\_ident=kc0001&loc=5](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5) on the CMS website.

MLN Matters Number: MM6043

Related Change Request (CR) #: 6043

Related CR Release Date: May 2, 2008

Effective Date: March 19, 2008

Related CR Transmittal #: R83NCD

Implementation Date: June 2, 2008

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

### Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), and/or Part A/B Medicare Administrative Contractors (A/B MACs)) for services provided to Medicare beneficiaries.

### Provider Action Needed



#### STOP – Impact to You

This article is based on Change Request (CR) 6043 which provides the Centers for Medicare & Medicaid Services (CMS) updated policy regarding autologous blood-derived products for chronic, non-healing wounds.



#### CAUTION – What You Need to Know

Effective March 19, 2008, CMS is maintaining its current non-coverage determination for autologous platelet rich plasma (PRP) for the treatment of

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



### GO – What You Need to Do

See the Background and Additional Information Sections of this article for further details.

## Background

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In 1992, the Centers for Medicare & Medicaid Services (CMS) issued a national non-coverage determination for autologous, 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 platelet rich plasma (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 the Medicare National Coverage Determinations (NCD) Manual (Section 310.1; see [http://www.cms.hhs.gov/manuals/downloads/ncd103c1\\_Part4.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf) on the CMS website).

In April 2005, CMS issued an NCD to correct the erroneous potential for local coverage of becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, stating that, because it is usually self-administered, it would remain nationally non-covered under Part B based on the Social Security Act (Section 1861(s)(2)(A) and (B); see [http://www.ssa.gov/OP\\_Home/ssact/title18/1861.htm](http://www.ssa.gov/OP_Home/ssact/title18/1861.htm) on the Internet).

On March 19, 2008, CMS issued a Decision Memorandum following a National Coverage Analysis to evaluate the use of autologous blood-derived products for the treatment of chronic, non-healing cutaneous wounds, specifically the use of autologous PRP for the treatment of acute wounds where PRP is applied directly to the closed incision site, or for dehiscent wounds.

CMS determined that the evidence is inadequate to conclude that autologous 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, effective March 19, 2008, CMS is maintaining its current non-coverage determination for autologous PRP for the treatment of chronic, non-healing cutaneous wounds, and issuing a non-coverage determination for acute surgical

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wounds when the autologous PRP is applied directly to the closed incision and for dehiscent wounds. Effective for claims with dates of service on or after March 19, 2008, the use of autologous PRP for the treatment of acute surgical wounds where the PRP is applied directly to the closed incision, or dehiscent wounds, will be denied by Medicare contractors.

### Additional Information

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The official instruction, CR 6043, issued to your carrier, FI, and A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R83NCD.pdf> on the CMS website.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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