Medicare Learning Network
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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.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareAppealsProcess.pdf or to order hard copies, please visit the MLN Product Ordering Page at http://cms.meridianksi.com/kc/pfs/pfs_lnkfrm_fl.asp?lgnfrm=reqprod&function=pfs 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

Note: This article was revised on July 6, 2013 to add a reference to article MM8213 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8213.pdf) to inform you of a new National Coverage Decision for claims with dates of service beginning August 2, 2012. CMS will cover PRP for treatment of chronic, non-healing diabetic, venous, and/or pressure wounds only when provided under a clinical research study. All other information remains the same.

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 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

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.gov/Regulations-and-Guidance/Guidance/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* 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 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

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

You may want to review MM8213 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8213.pdf) which alerts providers that effective for claims with dates of service beginning August 2, 2012, CMS will cover autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds only when provided under an approved clinical research study to assess the health outcomes of PRP for treatment of such wounds.

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.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.