



Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html> on the CMS website.

MLN Matters Number: MM5123

Related Change Request (CR) #: 5123

Related CR Release Date: June 9, 2006

Effective Date: April 27, 2006

Related CR Transmittal #: R977CP and R59NCD

Implementation Date: July 10, 2006

Note: This article was updated on November 8, 2012, to reflect current Web addresses. All other information remains unchanged.

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

Provider Types Affected

Physicians, providers and suppliers submitting claims to Medicare carriers, fiscal intermediaries (FIs) and/or regional home health intermediaries (RHHs) for chronic non-healing wound related services furnished to Medicare beneficiaries.

Impact on Providers

This article is based on Change Request (CR) 5123 which instructs Medicare contractors (carriers, FIs, and RHHs) that claims submitted for **becaplermin**, a self-administered, non-autologous growth factor for chronic, non-healing, subcutaneous wounds **will remain non-covered**.

Becaplermin, Healthcare Common Procedure Coding System (HCPCS) **S0157**, is nationally non-covered because it is usually self-administered by the patient.

Background

After releasing a national non-coverage determination (NCD) on Autologous Blood-Derived Products for Chronic Non-Healing Wounds in December of 2003, an error was printed in the NCD Manual.

To correct that error, the Centers for Medicare & Medicaid Services (CMS) is revising section 270.3 of the *National Coverage Determinations (NCD) Manual* (Publication 100-03, Chapter 1, Part 3, "Blood-Derived Products for Chronic Non-

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Healing Wounds”) to accurately reflect the payment policy for non-autologous blood derived products for chronic non-healing wounds, effective April 27, 2006.

In this revision, the following sentence is being deleted:

“Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.”

The correct statement should read:

“Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, **will remain nationally non-covered** under Part B based on §1861(s)(2)(A) and §1861(s)(2)(B) because this product is usually self-administered by the patient.”

While CMS makes every effort to provide accurate and complete information, the erroneous coverage statement printed in the NCD Manual regarding non-autologous blood-derived products was not intended, and is not part of the Decision Memorandum (DM) posted on December 15, 2003. Non-autologous blood-derived products are not in the same class as the products referred to in the December 15, 2003, DM.

NCDs are binding on all carriers, FIs, quality improvement organizations, health maintenance organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR 405.1060)(a)(4), effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD (see section 1869(f)(1)(A)(i) of the Social Security Act).

Additional Information

CR5123 is the official instruction issued to your Medicare carrier or FI/RHHI regarding changes mentioned in this article. There are two transmittals for CR5123. Transmittal 59, containing the NCD revision, is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R59NCD.pdf> on the CMS website. Transmittal 977, containing the Medicare claims processing instructions, is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R977CP.pdf> on the CMS website.

If you have questions, please contact your Medicare Carrier/FI/RHHI 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.

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