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Implementation Date: October 2, 2006

Note: This article was revised on August 30, 2007, to add a reference to Change Request (CR) 5667 (<http://www.cms.hhs.gov/Transmittals/downloads/R1315CP.pdf>). CR5667 adds ICD-9-CM diagnosis code 433.11, occlusion of the carotid artery with infarct, to the list of payable claims for PTA to ensure all eligible Medicare beneficiaries are covered. The related MLN Matters article (MM5667) may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5667.pdf> on the CMS website. MM5667 also provides links to other related PTA articles.

Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent with the Placement of an FDA-approved Carotid Stent

Provider Types Affected

Providers, physicians, and suppliers that bill Medicare contractors (fiscal intermediaries (FIs) and carriers) for their services

Key Points

- This article is based on CR5022, which contains instructions (summarized below) that must be implemented to correctly process carotid stenting claims.
- The Centers for Medicare & Medicaid Services (CMS) has additionally updated the carotid artery stenting (CAS) facilities "approved facilities" web site link in Publication 100-03, *The National Coverage Determinations Manual*. The list is now available at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp> on the CMS website.
- Claims that are being billed for Category B IDE studies and post-approval studies, per CR1660 (effective July 1, 2001) and CR3489 (effective October 12, 2004), respectively, are not subject to the same billing requirements as indicated in CR3811 (Effective March 17, 2005).

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The links to CR1660 and the Medicare Learning Network (MLN) articles relating to CR3489 and CR3811 can be found in the *Related Links* section below.

- CMS created a new section in the *Medicare Claims Processing Manual* specific to carotid stents. Please refer to this new section in the manual attachment to CR5022, (Publication 100-04, *The Medicare Claims Processing Manual*, Chapter 32, Sections 160.1-160.3) for more information about PTA for implanting the carotid stent. (This includes information on CR660, CR 3489 and CR3811.)

Background

Percutaneous Transluminal Angioplasty (PTA) involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of PTA is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

Please refer to the manual attachment to CR5022, Transmittal 53, (Publication 100-03, *The Medicare National Coverage Determinations Manual*, Chapter 1, Part 1, Section 20.7) for more information about the nationally covered indications for PTA concurrent with carotid stent placement, and for facilities accepted for services related to CAS with embolic protection. This is available at <http://www.cms.hhs.gov/Transmittals/downloads/R53NCD.pdf> on the CMS website.

Category B IDE Study Claims and Post-approval Study Claims

Effective for dates of service on or after March 17, 2005, the following claims are not subject to the approved facility list. These are CAS claims:

- Billed under a Category B IDE study (identified by a six-digit IDE number preceded by a "G," i.e., G123456); or a
- Billed under an FDA-approved post-approval study (identified by a six-digit PMA number preceded by a "P," i.e., P123456)
- Previously denied due to the unintended application of the "approved" facility edit created per CR 3811 that are brought to your FI's or carrier's attention will be adjusted (per CR1660 for Category B IDE Study Claims, and CR3489 for Post-approval Study Claims).

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CAS with Embolic Protection Claims

- Effective for dates of service on or after March 17, 2005, CAS with embolic protection claims will be paid only if they are from facilities listed on the approved list (see <http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp>). CAS with embolic protection claims from non-approved facilities will be rejected rather than denied. (CR 3811)
- Effective for dates of service on or after March 17, 2005, CAS with embolic protection claims that contain **procedure code 37216** (transcatheter placement of intravascular stent(s) without distal embolic protection) will **not** be paid. CMS has deemed procedure code 37216 a non-covered service for Medicare purposes.

Related Links

CR1660, *Claims Processing Instructions for Clinical Trials on Carotid Stenting With Category B Investigational Device Exemptions (IDEs)* can be found at <http://www.cms.hhs.gov/Transmittals/Downloads/AB0174.pdf> on the CMS website.

MM3489, *Percutaneous Transluminal Angioplasty (PTA)* can be found at the following link <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3489.pdf> on the CMS website.

MM3811, *Expansion of Coverage for Percutaneous Transluminal Angioplasty (PTA)* is located at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf> on the CMS website.

CR5022 is the official instruction issued to your FI or carrier regarding changes mentioned in this article, MM5022. CR5022 may be found by going to Transmittal 911CP at <http://www.cms.hhs.gov/Transmittals/downloads/R1042CP.pdf> for the claims processing instructions and to Transmittal 53NCD for the NCD Manual section, which is at <http://www.cms.hhs.gov/Transmittals/downloads/R53NCD.pdf> on the CMS website.

Please refer to your local FI or carrier if you have questions about this issue. To find their toll-free phone number, go to <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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