Related MLN Matters Article #: MM5088

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Related CR #: 5088

Payment for Carotid Artery Stenting (CAS) Post-Approval Extension Studies

Key Words

MM5088, CR5088, Carotid, Artery, Stent, CAS, R951CP, CR3489, R314CP

Provider Types Affected

Physicians or providers submitting claims to Medicare Carriers or Fiscal Intermediaries (FIs) for CAS post-approval extension studies

Key Points

- The effective date of the instruction is February 28, 2006.
- The implementation date is June 12, 2006.
- MM5088 is based on Change Request (CR) 5088, which informs providers that the Centers for Medicare & Medicaid Services (CMS) has determined that all extension studies must be reviewed by the Food and Drug Administration (FDA).
- The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data.
- Upon receipt of this letter and review of the extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare.
- CMS issued Change Request (CR) 3489 (Transmittal 314, dated October 15, 2004; *http://www.cms.hhs.gov/transmittals/Downloads/R314CP.pdf*) to provide Medicare contractors (carriers and/or FIs) with instructions for processing claims for CAS procedures performed in FDA-approved post-approval studies.
- As the post-approval studies began to end, CMS received requests to extend their coverage.
- CMS reviewed the extension requests and has determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies (*Medicare National Coverage Determinations Manual,* Pub. 100-3, Chapter 1, Part 1, Section 20.7; available at *http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf* on the CMS website).

Post-Market Approval Number

- Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.
- Extensions of post-approval studies are not subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies.
- Therefore, since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study.
- Because an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

FDA Review

- Even though extensions of post-approval studies are not subject to approval by the FDA, CMS has determined that the FDA must review all extension study protocols. If the FDA determines the extension study protocol is scientifically valid, the FDA will:
  - Issue an acknowledgement letter stating that the extension study protocol is scientifically valid and
  - Generate clinically relevant post-market data.
- CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare upon receipt of the FDA's:
  - Acknowledgement letter and
  - Review of the extension study protocol indicating the study protocol is scientifically valid.

Medicare Coverage for Post-Approval Extension Studies

- To receive Medicare coverage for patients participating in post-approval extension studies, providers should follow the process for informing Medicare contractors of their participation, as established in CR3489 (Transmittal 314, dated October 15, 2004, at *http://www.cms.hhs.gov/transmittals/Downloads/R314CP.pdf* on the CMS website).
- There is also an MLN Matters article related to CR3489 at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3489.pdf* on the CMS website.
- To receive reimbursement, providers should submit to their Medicare contractor:
  - The FDA acknowledgement letter;
  - The CMS letter providing coverage for the extension study to their contractor; and
  - Any other materials their Medicare contractor would require for FDA-approved post-approval studies.
- In response, the provider's Medicare contractor will issue a letter assigning an effective date for each facility's participation in the extension study.
- Providers:

- Should follow the billing instructions from CR3489 (Transmittal 314, dated October 15, 2004);
- **May bill** for procedures performed in the extension study for dates of service on and after the assigned effective date; and
- **Must bill** using the most current ICD-9 CM procedure codes when billing FIs. For example, when billing a CAS extension study with dates of service July 1, 2006 through July 15, 2006, the provider should bill the most current ICD-9 CM procedure codes 00.61 and 00.63 (instead of the 39.50 and 39.90 procedure codes published in CR3489).

Note: Medicare contractors will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention

Important Links

http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5088.pdf

http://www.cms.hhs.gov/Transmittals/downloads/R951CP.pdf

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