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Implementation Date: June 12, 2006

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

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

Provider Types Affected

Physicians or providers submitting claims to carriers or fiscal intermediaries (FIs) for CAS post approval extension studies.

Impact on Providers

This article 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, the CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare.

Background

CMS issued Change Request (CR) 3489 (Transmittal 314, dated October 15, 2004, <http://www.cms.gov/Regulations-and-Guidance/Guidance/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

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http://www.cms.gov/manuals/downloads/ncd103c1_Part1.pdf on the CMS website).

Approval Process for Extension Studies

To grant approval for post-approval studies, the FDA reviews each study protocol, and once approval is granted, the FDA issues a formal approval letter to the study sponsor.

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.

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.

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.

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).

What Providers Must Do

To receive Medicare coverage for patients participating in post-approval extension studies, providers should follow the process as established in CR3489 for informing Medicare contractors of their participation (Transmittal 314, dated October 15, 2004, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R314CP.pdf>).

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There is also an MLN Matters article related to CR3489 at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM3489.pdf> on the CMS website.

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 Fls.** 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 CR 3489).

Please note that:

- Providers participating in the Capture 2 post-approval extension study must submit copies of two letters to their local contractor, i.e., an FDA acknowledgement letter and a CMS coverage letter.
- After receiving the above letters, the Medicare contractor will issue a letter to the provider assigning an effective date for participation in the extension study.
- Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date.
- Medicare contractors will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors will adjust claims brought to their attention.
- Providers should continue to follow the guidelines for processing post-approval study claims as directed in Change Request 3489, Transmittal 314, issued October 15, 2004.

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Additional Information

For complete details, please see the official instruction issued to your carrier/intermediary regarding this change. That instruction may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R951CP.pdf> on the CMS website.

If you have any questions, please contact your carrier/intermediary 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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